ABSTRACT PER SESSIONS

SESSION 03 – ACTUATORS AND MECHANISMS FOR NOVEL MEDICAL TOOLS

O48: A lockable steerable needle for the TIPS procedure

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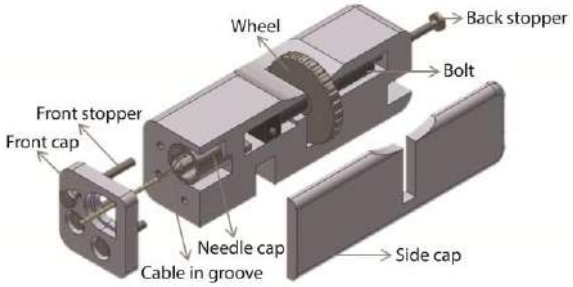

Figure 2: Exploded view of the needle handle

1. Introduction

The Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure is a radiologic intervention in which a portosystemic tract is created between a branch of the hepatic vein and the portal vein (Fig. 1). It is one of the treatment methods to decrease portal venous hypertension caused by liver cirrhosis. During this procedure, access is obtained via the jugular vein in the neck. An instrument set, consisting of a needle, catheter, and guidewire, is used to create the shunt.

The TIPS procedure is considered to be one of the most challenging radiologic interventions, because: 1) the needle deflects upon insertion through the stiff, cirrhotic liver parenchyma, 2) the needle angle required to reach the portal vein cannot sufficiently be achieved. The aim of this present research is to design and validate a lockable steerable needle for the TIPS procedure, to overcome the aforementioned problems.

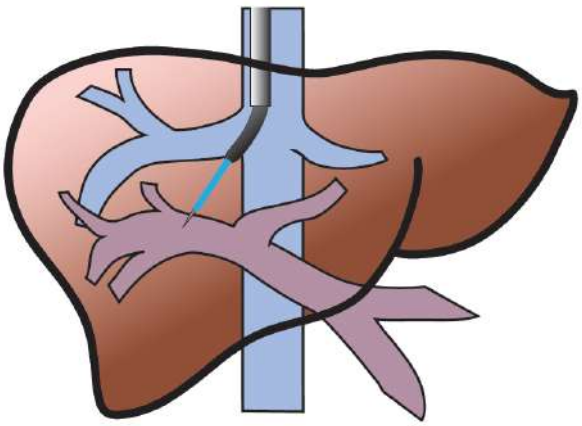

Figure 1: During the TIPS procedure, a stent is placed between the hepatic vein (blue) and portal vein (purple), by means of the transjugular access set.

2. Methods

A steerable needle prototype, intended for single use, was designed and fabricated at TU Delft. The prototype was made by modifying the existing Rosh-Uchida TIPS needle set (Cook Medical). An exploded view of the handle design can be seen in Fig. 2. The threading in the original needle cap was preserved to guarantee its compatibility with the catheter.

A groove was made along the length of the needle, in which a cable was placed and secured with a shrink tube. The interventional radiologist holds the handle in one hand and turns the internally threaded wheel with his thumb. By rotating the wheel, the bolt translates, pulling the cable and therefore bending the needle tip in one direction. The steerable angle automatically locks in the selected position due to high friction in the threading.

The repeatability of needle steering was tested by puncturing (n=12) into porcine gelatin (5 and 15 m% to water) at 5mm/s for an insertion depth of 50mm. Repeatability error was

defined as the distance in millimeters between the mean of all insertions and an individual insertion.

3. Results

The maximal steering angle that can be achieved with the prototype is 14.5°, as shown in Fig. 3. This range was maintained when puncturing in the gelatin phantoms. No significant differences in repeatability were found for the insertions into the different gelatin concentrations. The maximal repeatability error was found to be 1.6mm.

Figure 3: Maximal needle steering angle of the prototype is 14.5°

4. Discussion & Conclusion

In this study, a lockable steerable needle prototype for the TIPS procedure is developed and tested. With this needle, the ultimate goal is to decrease the number of punctures needed to create the tract between the hepatic and portal vein, and thus improving needle placement during the TIPS procedure.

O117:

Ultra-thin steerable needle: an experimental prototype

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1. Introduction

In percutaneous interventions, needles are used, among other tasks, for taking biopsies or delivering drugs. Recently, there is a growing interest in developing steerable needles, which allow the surgeon to follow curved trajectories so that sensitive structures, such as blood vessels, are avoided. Steerability is achieved by giving the needle a pre-defined shape (e.g., bevel-tip) or by actuation means (e.g., cables) [1]. Needles with a pre-defined shape have a simple design that allows miniaturization (e.g., diameter $d < 1$ mm). However, in order to steer in multiple directions, these needles have to be rotated along their axis, which makes their control difficult. Needles that steer by means of actuation are able to steer in multiple directions, but they usually have large diameters ($d > 2$ mm) and complex design.

The goal of this work was to design and experimentally evaluate a steerable needle prototype with a diameter smaller than 0.5 mm which is able to steer in multiple directions without the need of rotation around its longitudinal axis.

2. Methods

A prototype of a hand-held needle device has been developed. To design the needle, we took inspiration from the ovipositor of parasitic wasps (for other similar prototypes, see [2-3]). The ovipositor consists of three parts (so-called valves) and is used by the wasp to deposit eggs into larvae. The wasp can penetrate solid substrates and steers the ovipositor by simultaneously pushing and pulling the valves [4]. Similarly, the bioinspired prototypes consist of multiple longitudinal segments that slide independently along each other and steer by creating an asymmetry at the tip.

The needle presented here consists of three Nitinol wires (d = 0.125 mm), each of which is surrounded by a Nitinol tube to increase the needle stiffness without compromising its bendability. The wires are pre-curved and fixed at the tip by a stainless steel tube (inner d = 0.3 mm, outer d = 0.47 mm, length 10 mm). By pushing and pulling the wires, the tip can bend. A shrinking tube is used to keep the tubes together. The diameter of the needle body is 0.5 mm. The total length is 200 mm, of which 20 mm is the length of the actuated tip (Fig. 1). Each wire is clamped to a block that can move back and forth along a leadscrew. The motion is controlled by wheels, the rotation of which is translated into linear motion of the block. The needle has been tested in gelatine phantoms (10% w/v) at a speed of 2 mm/s using a motorized linear stage.

Figure 1: Needle prototype tip (left) and actuation control unit (right)

3. Results

The needle steered in the direction of the wire that was pulled, covering a total of six directions. Steering curvature increased with the pulling of the wires.

4. Discussion & Conclusion

We have developed an ultra-thin needle (d = 0.5 mm), which steers in multiple directions without the need of axial rotation. In the future, we will add a more intuitive actuation unit and customized the tip design for specific medical applications.

This research is supported by the Netherlands Organization for Scientific Research (NWO), domain Applied and Engineering Sciences (TTW) (project number 12712, STW Perspectief Programme iMIT-Instruments for Minimally Invasive Techniques).

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O46: Minimally invasive prenatal closure of spina bifida

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Introduction

In spina bifida there is a failure of closure of the neural tube causing a defect through which the spinal cord, nerves and meninges can protrude. The current prenatal treatment method is an invasive method and therefore research is performed to operate spina bifida in a minimally invasive manner during the pregnancy. Instead of suturing the defect at the foetus, the ultimate goal is to 3D print a protective cap over the defect.

The progression of the first prototype, which is able to close the defect via one port, was presented at the previous SMIT congress. Here, the follow-up prototype and results of the user evaluation tests are presented.

Methods

The injector is a minimally invasive instrument to apply material over the defect (Figure 1). The control of the instrument is manual; including a joystick to steer the movable tip and a transmission mechanism to inject the material through the instrument. In addition to the ultrasound, a telescope can be connected to the instrument to have visual feedback of the application.

Figure 1: The Injector

A user observation is performed to measure the control and performance of the injector. The test setup includes a stripped boxtrainer, with a 3D printed defect on which a pathway is indicated. By using an Electromagnetic tracking system (Aurora, NDI, Canada), the shaft and tip position can be assessed over time to measure: 1) The tip control, the deviation from a constant speed [mm/s]. Assuming that a larger variability in speed suggests difficulties in controlling the instrument. 2) The test performance, expressed in the average deviation [mm] between the travelled pathway and indicated pathway. 3) The movements of the shaft itself in average deviation [mm] measured at the end of the shaft, relative to the origin in the 2D plane. Ideally, the location of the shaft is at the origin of the XY plane. 4) The duration of the test[s].

Two experimental conditions are defined, without (condition 1) and with injection of the material (condition 2), to determine the effect of manual control of injecting the material. A

paired t-test is performed on each of the above performance measures (SPSS, IBM, United States).

Results

On average, the standard deviation of the speed [mm/s] with which the tip of the instrument is moved, is significantly larger in condition 1 (M=4.7, SE=.2) than in condition 2 (M=3.9, SE=.3), $t(19)=2.4$, $p<.05$, $r=.5$. When looking at the mean deviation [mm] between the ideal and travelled pathway, it is on average significantly larger in condition 2 (M=6.2, SE=.3) compared to condition 1 (M=5.1, SE=.3), $t(19)=-3.1$, $p<.05$, $r=.6$. The average deviation of the shaft relative to the origin in the XY plane has no significant difference between condition 1 (M=3.6, SE=0.1) and condition 2 (M=3.8, SE=0.2). The duration of the task [s] is on average significantly longer in condition 2 (M=23.9, SE=.8) than in condition 1 (M=17.6, SE=.4), $t(19)=-9.0$, $p<.05$, $r=.9$.

Discussion & Conclusion

The user test shows that the test person is able to hold the instrument in place, limiting the amount of movements of the shaft. In both conditions the test can be performed in a short period of time.

However, the results show that the instrument tip positioning is affected by the manual injection of the material. In both conditions the tip positioning is not sufficient. Whether the tip positioning is the right parameter to determine the performance of the instrument is not clear.

It is striking that in condition 2 the speed of movement is more constant, showing more control. This can be a result of the direct feedback of the application of the material to the user.

It can be concluded, that minimally invasive coverage of fetal deficits by using a single instrument is feasible, within limited time and with limited shaft movements. Considering the complexity of concurrently controlling the injection of the material and the positioning the tip, it would be interesting to look into alternative methods of controlling the injection of the material.

O150: Low Melting Point Alloy Based Stiffening of a Soft Robot

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INTRODUCTION

Although soft robots promise to provide unsurpassed dexterity, their usage is limited due to their lack of stiffness. This statement may seem paradoxical, however as discussed by [1], softness comes at a price of load bearing capacity. Soft materials cannot transfer or sustain forces effectively. Thus manipulation and interaction with the environment becomes challenging. This has made means of varying stiffness an active field of research [2]. This work presents the integration of a soft surgical robot (Stiff-Flop [3]) with stiffening fibers made by Low Melting Point Alloy (LMPA). A preliminary analysis shows a marked increase in the stiffness of the module.

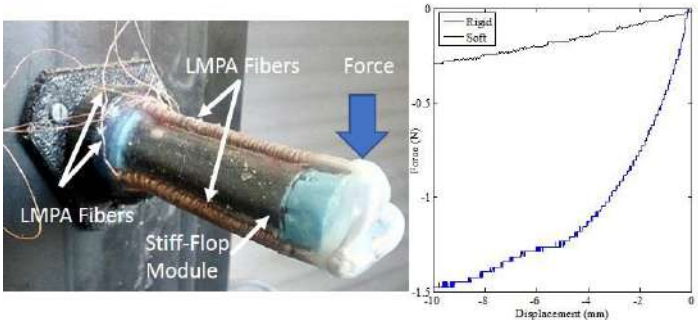

Figure 1: a) Stiff flop with the LMPA fibers. b) A comparison of the force deflection curve in the soft and rigid state

METHODS

The Stiff-Flop modules are made from a soft elastomeric material. The robot operates though pneumatic pressure. The intrinsic softness of the robot grants it unmatched dexterity in the constrained environment of minimally invasive surgery. However its functionalities may be increased if a means of stiffening can be implemented. Respecting the dimensional constraints, a (LMPA) based approach has been considered [4].

The LMPA fibers are made by pumping molten Field's metal alloy into pre-stretched silicone tubes. On solidifying, a conductive wire is wound around the fibers. When current is run through this wire, the resulting heat causes the LMPA to melt, making the fibers soft. Upon cooling the LMPA solidifies, regaining its rigidity. The pre-stretching applied to the silicone tubes ensures that no discontinuities are created during solidification.

The fibers are bonded to the Stiff-Flop module using silicone glue. Once integrated the stiff and soft state of the module may be alternated by heating and cooling the fibers. The fibers can be softened within 20 seconds, at a temperature of about 60 degrees. During operation, higher temperatures can be reached, hence a controller needs to be implemented to avoid excessive heating. They regain rigidity within a minute at room temperature.

RESULTS

To measure the effect of the LMPA fibers, a force deflection curve of the integrated module was made. The tip of the robot was loaded while the LMPA was in molten and solidified state. The corresponding defections shows a significant increase (more than three times) in the load carrying ability of the robot (Figure 1). In the soft state the fibers do not give much resistance hence the intrinsic softness is unaffected.

Discussion and Conclusion

The integration shows a proof of concept of using LMPA fibers for stiffening soft robots. The module cannot be moved while the fibers are in solid state. Hence the fibers may be used in applications where shape locking is needed or when the robot is expected to bear large loads while in static condition. Overall the prototype shows a novel means of achieving rigidity of soft robots. Such a technology may also be used on base structures of soft deployable robots for structural stability.

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Session 05 – image guided surgery

07: 3D TONGUE MODEL CONSTRUCTION AND THE MOTION REGENERATION

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1. Introduction

Computer generated tongue model is necessary to analyze the movement especially for lateral articulation (LA). Fasel et al. extracted tongue contours from ultrasound (US) images based on Deep Belief Networks (DBFs) [1], and Xu et al. visualized tongue motion by using modal warping [2]. However, US images are so noisy that some researchers use Magnetic Resonance Imaging (MRI) instead of US [3,4]. US is yet easily treated and safe for humans. Then, we propose a method how to construct 3D tongue model from US images and regenerate the motion.

2. Methods

The target is a set of images, which is constructed of 19 frontal US images. Fig.1 shows the process that extracts control points, which approximates the tongue surface. First, from the US image (Fig.1(a)), the region of interest (ROI) is extracted (Fig.1(b)). Then, the image is binarized (Fig.1(c)), and thinning processes is performed (Fig.1(d)). For the remained points, N spline curve is applied (Fig.1(e)), which represents the tongue surface of a frontal image in US images. Then, 19 control points are specified for the N spline (Fig.1(f)), and 19 x 19 points construct the tongue surface mesh model for 19 US images. In addition, the thickness is added to the surface model, a tongue image is mapped onto the model, and a mandible model is attached. Finally, the tongue model is constructed as shown in Fig.2. By changing the positions of the control points according to an articulation, the tongue motion is regenerated.

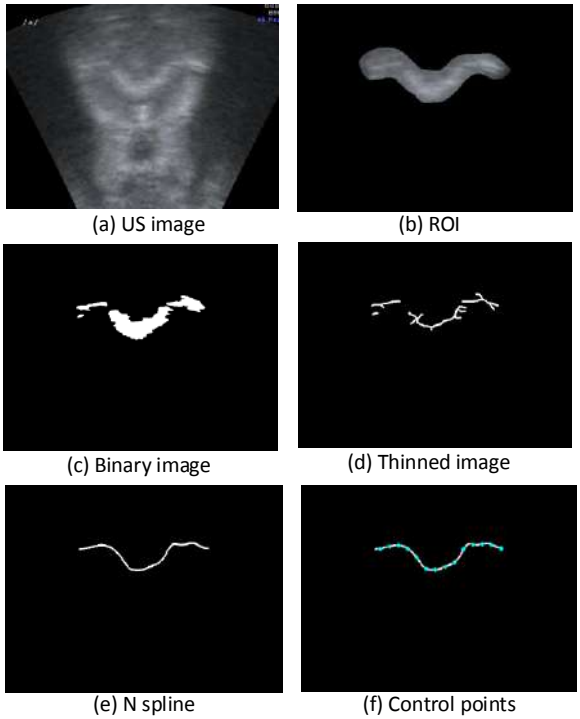

Figure 1: Frontal view image.

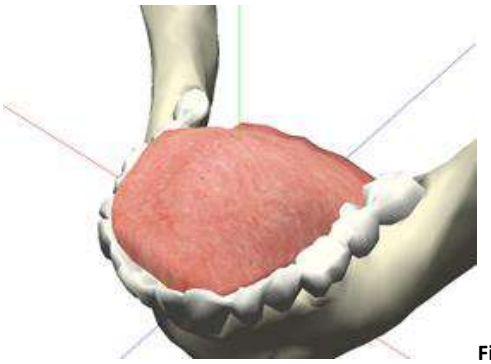

Figure 2: Tongue model.

3. Results

We have constructed a 3D tongue model from US images. The model construction process is almost automatic except for the ROI extraction, where the region is specified by manual. US images are so noisy that it is very difficult to extract the tongue surface. However, once the model is constructed, control points, which are difficult to be picked up in unclear images, can be estimated from the points in the model. A tongue motion, where articulation changes from Japanese vowel /a/ to /i/, is regenerated by changing the control points of the model.

4. Discussion & Conclusion

US images have many noises and it is difficult to obtain the tongue part from the images. However, once a 3D tongue model is generated, the motion can be regenerated by changing the control points according to articulations. By applying the tongue model to the images of LA, the tongue motion is also regenerated and we can use the data for the speech rehabilitation by analyzing the regenerated tongue motion.

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035: ADDITIVE MANUFACTURING FOR GYNAECOLOGICAL BRACHYTHERAPHY: CUSTOM-FIT APPLICATORS BASED ON MRI DATA

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Introduction

The image guided treatment of tumours by means of locally placed, radioactive sources, makes gynaecological brachytherapy a contemporary example of personalized care. The treatment quality largely depends on the ability to place sources at a series of dwell positions. For most patients, an optimal dose distribution is achieved using an intracavitary applicator, occasionally supplemented by interstitial catheters. However, in case of distal parametrial tumour extension or lower (para)vaginal involvement, current instruments may not suffice. The one-size-fits-all designs pose limitations in freedom for individualized treatment planning in these cases.

This study aims to employ additive manufacturing for the optimization of the applicator design. The approach includes a custom-fit device shape, potentially increasing the applicator position stability. This custom approach also allows for (nearly) limitless combinations of catheter channels. Practical path constraints, imposed by the catheter and obturator stiffness, are expected and have therefore been studied.

Methods

The constructed applicator designs were based on MRI-scans of two patients with vaginal cancer. Ultrasound gel was used to augment the visibility of the vaginal cavity. Conventional treatment planning software (Oncentra, Elekta, SE) was used to segment the vaginal cavity and the tumour, and to manually indicate the paths of the desired internal channels. These channels were made compatible with 6F catheters (Proguide, Nucletron BV, NL). The contours were saved in DICOM RT-struct files, and converted (MiVisLab, Fraunhofer MEVIS, DE) to coordinate sets, which allowed for processing in a CAD program (SolidWorks, Dassault Systèmes, US). The personalized applicators were printed from PLA (Ultimaker 2 Extended+, Ultimaker, NL).

Channel curvature constraints were studied with a separate print. This print consisted of an array of channels with path radii ranging from 20-75 mm, bridging an instrument wall thickness of 5 mm. The print was suspended in a 10 m% gelatin phantom. Catheters (with obturators) were inserted at 5 mm/s, using a linear stage (PRO-115, Aerotech, US), and insertion forces were collected (LSB200, Futek, US). The data were compared to subjective evaluations of manual insertions performed by a clinician.

Results

Two personalized applicator designs are shown in Fig. 1. Interstitial catheters enter through the lower cylindrical section, and exit through the holes visible at the top of the product, as shown by the red lines in the left column images.

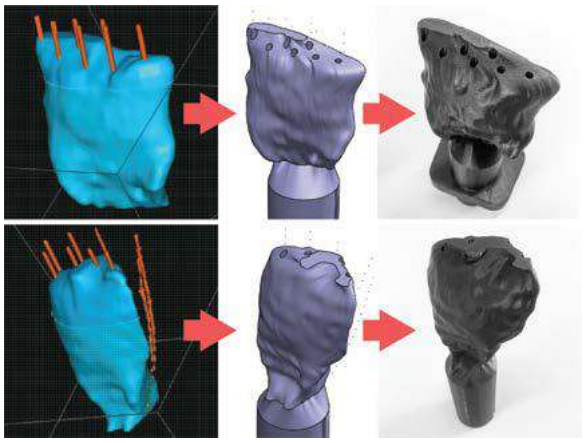

Figure 1: Shown are two customized applicator designs for brachytherapy. Left to right: the vaginal cavity contours in Oncentra, the SolidWorks model, and the resulting prints.

A lower radius limit for internal channels (for the 6F Proguide catheter + obturator), in this setup, was found at approximately 35 mm. With forces building up to 14 N, this radius resulted in subjective discomfort with the insertion process, as well as an increased catheter buckling response in the automated insertion series.

Discussion & Conclusion

MRI-scans from patients with vaginal cancer were successfully translated to custom-fit applicators for intracavitary and interstitial brachytherapy. The recommended lower radius limit of catheter paths, for similar applicator designs, is 35 mm. Follow-up work should improve the procedure of acquiring the MRI scans of the vaginal cavity, optimizing the catheter paths, and transforming this data into a solid model for printing. Moreover, the beneficial effects of custom-fit applicators on the brachytherapy treatment quality should be further evaluated.

0103: Mechanical catheter navigation with electromagnetic tracking to peripheral airway targets

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Introduction

Lung cancer remains the single most deadly cancer in men and women due to low rates of early detection and treatment. Since non-small cell lung cancer usually starts in the outer airways, targeted minimally invasive biopsy which limits radiation exposure and avoids surgery is highly desirable. Current commercial solutions such as the superDimension (Medtronic Inc., Dublin, Ireland), and SpIN (Veran Medical, St. Louis, USA) systems rely on electromagnetic tracking for virtual navigation. However, clinical outcomes have been unconvincing due to poor accuracy, limitations in instrumentation and the lack of tracked catheters. This work proposes a novel mechanical catheter design with embedded electromagnetic tracking to facilitate tip-tracked navigation without the need for proprietary instruments or probe exchange. The catheter was used to reach peripheral airway targets by multiple users in pre-clinical studies.

Methods

The catheter used for this work (Figure 1) consisted in seven lumens within a 3mm diameter package; four lumens for stainless steel tendons used to deflect the distal tip, two lumens each containing one 5-degree-of-freedom EM tracking sensor (Northern Digital, Inc); and the final lumen is a 1.5mm working channel for instruments such as biopsy forceps or therapy probe.

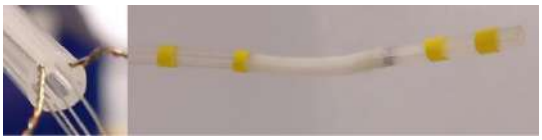
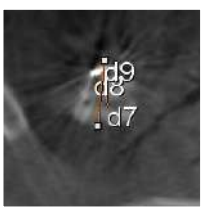


Figure 1: Proximal end (left) and distal articulating section (right) of the catheter

A testing apparatus was constructed with stepper motors and leadscrews for catheter characterisation. Pre-clinical testing was achieved in two live porcine model with independent expert users (MPK, HL) navigating to a total of 8 peripheral airway targets using virtual bronchoscopic navigation. Following virtual navigation to each tumour model, a Tornado® embolization coil (Cook Medical Inc., USA) was deployed at each for post procedure targeting verification using 3D CT.

Results

System characterisation of tendon deflection versus force and tendon extension identified significant non-linearities and hysteresis in the mechanical catheter characteristics. Rudimentary steering was achieved by rotation of the bronchoscopy with the catheter in the working channel. **Notwithstanding catheter steering limitations, expert users successfully navigated to 8 peripheral targets (Figure 2) and deployed 8 marker coils using virtual navigation (see Table 1).**



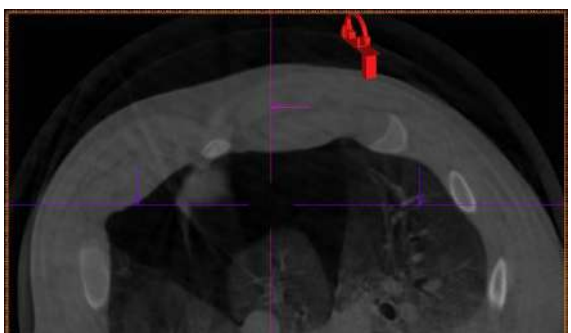


Figure 2: *DynaCT image.*

Table 1: *Closest distance from target to marker coil from CT*

Lung Position	Study 1	Study 2
Upper right	2.48 mm	5.54 mm
Centre left	6.95 mm	12.04 mm
Centre right	3.79 mm	1.97 mm
Lower right	8.07 mm	1.39 mm

Discussion & Conclusion

Tracked catheter navigation is feasible for targeting within 10mm of peripheral airway targets for endoscopic diagnosis and therapy. The results outlined here may serve as a platform for endoscopic catheter navigation in gastroenterology and urology.

O125: Rectal Cancer Segmentation with Fully Convolutional Neural Network

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1. Introduction

The predictive accuracy of the pathologic T-categorization of rectal cancer using MRI is reported to be approximately 71–91% [1]. Since the location of rectal cancer with respect to that of rectum is crucial in deciding the T-staging of rectal cancer, automated segmentation of both rectum and tumor from magnetic resonance (MR) images can greatly improve or at least ease the diagnostic procedure.

2. Methods

We retrospectively analyzed T2-weighted MR images of 133 patients comprising 70 cases of T2 stage and 63 cases of T3 stage patients. T2 stage and T3 stage subjects were chosen since determining tumors of those stages are especially crucial in deciding treatment method [2]. The images have been obtained from National Cancer Center (NCC2017-0031) in Republic of Korea, from September 2004 to June 2016.

Fully convolutional neural network structure called 'U-NET' with batch normalization was exploited and modified [3]. In addition, transposed convolution filters were initialized as bilinear filters, and updated with all the other parameters using Adam optimizer algorithm. In addition, due to the limited dataset, 10-fold cross-validation was implemented to better assess the performance of the network.

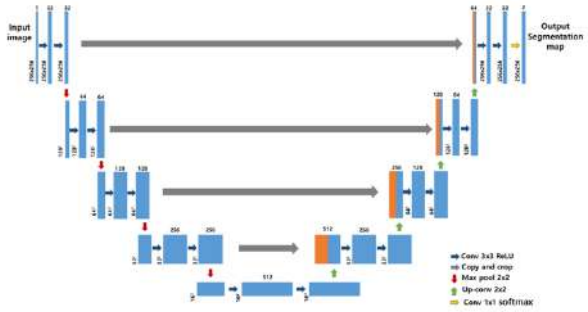

Figure 2: Structure of segmentation network called 'U-NET'

Segmentation for rectum and tumor has not only been carried out with separate networks, but also with single network with additional last softmax layer grafted on the last ReLU layer. Furthermore, a dice loss function was devised inspired from Dice Coefficient. The definitions of this function is described below.

$$\frac{-2\times\sum_{x\in True\ Positive} P(x\in positive)}{\sum_{x\in Predicted\ Positive} P(x\in positive)+|Actual\ positive|}$$

3. Results

Integrated network seems to outperform single network in tumor segmentation whereas the single network surpasses in rectum segmentation. All the metrics were weighed by averaging the outcome from 10-fold cross validation followed by standard deviation.

Separate Network	Dice Score	Sensitivity
Tumor	0.66±0.10	0.69±0.10
Rectum	0.89±0.03	0.88±0.05

Table 1: Segmentation performances using separate segmentation network

Integrated Network	Dice Score	Sensitivity
Tumor	0.69±0.12	0.72±0.11
Rectum	0.88±0.03	0.89±0.05

Table 2: Segmentation performances using integrated segmentation network for tumor and rectum

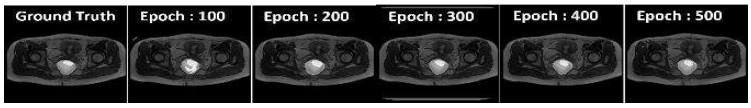

Figure 3: Learning progression for integrated network

4. Discussion & Conclusion

Tumor segmentation turned out to be more challenging than rectum segmentation, owing to the possible confusion between tumor, excrement, and air. Several advantages can be addressed for integrated network such as time consumption, and better tumor segmentation performance.

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Acknowledgement

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SESSION 14 – CAPSULE ENDOSCOPY

O116: Wireless Endoscopic Capsule for Early Screening of Colorectal Cancer Contributions by the WiBEC project

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1. Introduction

Colorectal Cancer (CRC) accounts for a large number of deaths every year. Wireless Capsule Endoscopy (WCE) has emerged as a promising technique for painless, non-invasive and time efficient colonoscopy. Conventional colonoscopy, although still considered the gold standard for diagnosis of colonic diseases comes with inherent issues that pose obstacles in making conventional colonoscopy a mass screening diagnostic technique [1].
The WiBEC (Wireless in Body Environment) project is part of the Horizon 2020 Innovative Training Network initiative funded by the European Union under Marie Skłodowska Curie Action. The project aims to develop wireless technologies for novel implantable devices that will contribute to the improvement in quality and efficacy of healthcare. Two devices are being focused as a use case: leadless pacemaker and wireless endoscopic capsule for CRC screening.

2. Challenges addressed

Magnetic Assisted Capsule Endoscopy (MACE) is a promising technique for controlling endoscopic capsules. The technique involves embedding a permanent magnet inside the capsule and uses external magnetic fields to steer the capsule inside the patient's body. Techniques such as hand held magnetic manipulator, MRI style magnetic control and external robot mounted magnetic manipulators have been investigated by researchers. These solutions are either very expensive, very slow, low performance or are complicated to operate in which case the success of the procedure depends on the skill of the operator [2] [3] [4].
Currently, the gold standard for CRC screening is flexible endoscope that provides a high resolution video. For MACE to compete with flexible endoscopy, a high speed datalink for seamless video transmission is crucial [1]. This is in contrast to the small bowel capsule endoscopy where the preferred method is WCE. In this niche application, it does not have to compete with the flexible endoscope and therefore a comparatively low image quality and low frame rate is acceptable.
Intuitive control of the capsule is also dependent on a high speed datalink. Delays in video result in misalignment of the capsule and the magnetic actuation field, increasing the chance of skipping visualization of polyps and lesions, leading to misdiagnosis and difficulties in real-time control of the capsule.
WiBEC focuses on developing a MACE system using a robot mounted magnetic manipulator and employing a high speed datalink for capsule communication. The project is divided into multiple parts. Key focus areas are antenna design, low power signal processing, image processing, system integration, testing, encapsulation and channel modeling.

3. Conclusion

All existing WCE solutions use low speed communication channels. WiBEC aims to develop a low cost, easy to use WCE system with high communication data rate to solve the problems faced by existing MACE Systems targeting the lower GI tract for early screening of CRC.

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O106: Detection of acute upper gastrointestinal bleeding with the HemoPill acute - a prospective study

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1. Introduction

The ESGE guideline [1] recommends risk stratification into high and low risk groups on patients with suspected acute upper gastrointestinal bleeding (UGIB) to aid clinical decision making regarding timing of esophagogastroduodenoscopy (EGD). There is a need to improve risk stratification tools/methods on patients with suspected acute UGIB. Novel tools which are able to determine the presence or absence of a severe bleeding in a timely and atraumatic manner may provide a clear indication or non-indication for timely endoscopy. Prospective studies showed the potential of video capsule endoscopy in real-time detection of UGIB in emergency departments [2]. The HemoPill acute is a non-imaging capsule equipped with a sensor for direct detection of liquid blood and hematin in the lumen of the upper gastrointestinal tract [3]. The capsule is battery-operated and is administered by swallowing. The sensor signals from the HemoPill acute are transmitted wirelessly to the HemoPill Receiver, which allows real-time detection of blood in the upper gastrointestinal tract [4]. The HemoPill acute is 7.0x26.3mm in size and considerably smaller than a video capsule. The HemoPill acute capsule is intended to support the physician in risk stratification of patients with suspected acute UGIB. The HemoPill acute is a novel diagnostic device with no predicate device in clinical use. The results of an explorative clinical trial on n=30 patients are presented here. The aim of the study was to evaluate the safety and feasibility of the HemoPill acute as well as the performance of the capsule regarding the detection of blood in the upper gastrointestinal tract.

2. Material and methods

A prospective, non-randomized, monocentric clinical trial without predicate device was performed. Patients suspected of having acute UGIB based on clinical symptoms such as hematemesis, tarry stools/melena swallowed a HemoPill acute capsule after signing the informed consent. The capsule sent sensor data to the receiver. Each patient received EGD within 12 hours after capsule ingestion. The endoscopists categorized the bleedings according to the amount of blood: <5ml, 5ml-20ml, and >20ml. The sensor data from the HemoPill acute was compared to the results of EGD. The values measured and transmitted by the HemoPill acute were used to analyze the performance of the HemoPill acute regarding the detection of blood. The thresholds of the sensor signal were defined in order to determine whether the results were positive or negative. Capsule excretion was monitored for up to 4 days. If excretion was not recorded during that time, a follow-up examination of the patient was conducted after 10 days.

3. Results

In the period of 04/2015 to 02/2016, n=30 patients with suspected acute UGIB were included in the trial. Data analysis was performed on n=28 patients, due to the fact that a patient dropped out of the study (EGD was performed >12 hours after capsule ingestion, protocol violation) and data was lost in another case. Capsule ingestion was tolerated well by every patient. According to EGD reports after capsule ingestion, n=10 patients had stigmata of bleeding (n=4 with <5ml; n=4 with 5-20ml; n=2 with >20ml), and n=18 patients had no

bleeding. The HemoPill acute capsule correctly detected 2 of 4 patients (50%) with <5ml of blood, 2 of 4 patients (50%) with 5-20ml of blood, and 2 of 2 patients (100%) with >20ml of blood. The HemoPill acute capsule correctly identified 18 of 18 patients (100%) without bleeding as non-bleeders as per the endoscopy report. No complications related to the use of the HemoPill acute occurred during the trial.

4. Conclusions

Safety and feasibility of the HemoPill acute were positively evaluated in this clinical trial. With regards to clinical relevance and risk stratification, minor bleedings with less than 20ml of blood may not require urgent intervention (low risk group), while severe bleeding does (high risk group). Here, the presence of 20 ml or more liquid blood or hematin in the upper GI tract would indicate severe bleeding with the urgent need for endoscopic evaluation. HemoPill acute capsule detected all severe bleedings (n=2) in the defined patient population (n=28). If an active bleeding (indicated by the presence of liquid blood or hematin) of a certain amount (indicated by the presence of more than 20ml of blood in the upper GI tract) identifies a patient who would benefit from a timely endoscopy, the sensitivity and specificity assessment of the HemoPill acute in detecting such a patient reveals the following results: sensitivity=100% (95%-CI=54-100%); specificity=83% (95%-CI=60-95%). However, a relatively wide confidence interval (95%) must be considered, due to the low number of patients included. Based on the present analysis, the device and procedure proved to be feasible and safe and showed the potential to be a valuable diagnostic tool for risk stratification of patients with acute suspected UGIB.

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O118: **Wireless HD Imaging for Minimal Invasive Surgery**

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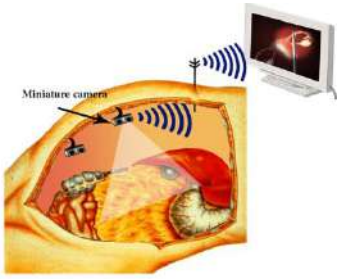
Introduction: In laparoscopic surgery any entry to the abdomen creates a pivot point on the abdominal wall which limits the movements of the instrument or laparoscope. As such, the visual field is confined to the angles allowed by the pivot point, limiting the visual field and forcing the surgeon to compromise on view of the surgical field. In addition current "state of the art" laparoscopes are encumbered by cabling for power, video and a light source inside a semi flexible or rigid mechanical rod. While these laparoscopes provide good image quality, they are cumbersome and require a point of access into the patient through a dedicated separate incision.

Wirelessly transmitting uncompressed high definition video streaming through the body is unrealistic. As the body absorbs most of the transmitted radio waves, the huge data load from the camera leaves very small amount of energy per bit. Therefore, a reliable communication requires high power transmission which is not feasible with a battery and most regulators will not permit this.



Aim: To provide a simple solution to enable high bandwidth wireless transmission from a miniature camera inside the abdominal cavity to the OR monitor. Methods: a simple thin (2mm) antenna was inserted through the abdominal wall of live animal models which connected the inside abdominal cavity to the outside operating room space. Transmission signals were measured within the abdomen and outside as well as high definition video transmission.

Results: There was no significant transmission loss within the inflated cavity in the abdomen and high definition wireless video streaming was demonstrated using an antenna.

Discussion and conclusions: A miniature camera that can be inserted into the abdominal wall and positioned to achieve the best field of vision regardless its entry point is dependent on wireless transmission capability. We demonstrated this ability by using a 2 mm antenna which bypasses the body absorption of transmission waves. A full camera system and wireless transmission is now developed for this purpose.

O61: Post-lymphangiographic multidetector CT for preclinical lymphatic interventions in rabbits

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1. Introduction

Loss of chyle into thoracic/peritoneal cavity can lead to serious life-threatening consequences because of the significant loss of fluid, plasma protein, fats and immunoregulatory lymphocytes, which exhibits clinical features of severe malnutrition, hyponatraemia, acidosis, hypocalcaemia and susceptibility to infection. Reports on lymphatic interventions including lymphangiography for detecting or treating lymphatic leaks (1) and thoracic duct embolization (TDE) for postoperative chylothorax has been increasing. However, postoperative lymphatic leakage remains a challenging clinical problem with high mortality in post esophageal surgery. Despite this clinical problem, an animal model for lymphatic interventions has not been developed so far. For lymphatic interventions and future imaging, detailed lymphatic anatomical features in rabbits should be elucidated. The objective of our present study is to describe the visibility of the lymphatic system on post-lymphangiographic multidetector CT (MDCT) for preclinical lymphatic interventions in rabbits.

2. Methods

Lymphangiography via the popliteal lymph node or vessel was performed, using six healthy female Japanese White rabbits. Post-lymphangiographic MDCT examinations were performed in all rabbits. The dataset images underwent image processing analysis by three-dimensional maximum intensity projection (3-D MIP) technique. Three reviewers evaluated degree of depiction of the lymphatic system using a four-point scale (1 = poor, 4 = excellent). The distance between the body surface and cisterna chyli was measured.

3. Results

The popliteal lymph node was detectable in 90%. The visualization of lymphatic system via the popliteal node was found in 89%. More than 3.0 mean visual scores were the right femoral lymph vessel, left femoral lymph vessel, left iliac lymph vessel, left lumbar lymphatic trunks and cisterna chyli; whereas, less than 3.0 mean visual scores were the right iliac lymph vessel, right lumbar lymphatic trunks and cisterna chyli. The distance between the body surface and cisterna chyli was 4.33 ± 0.14 cm.

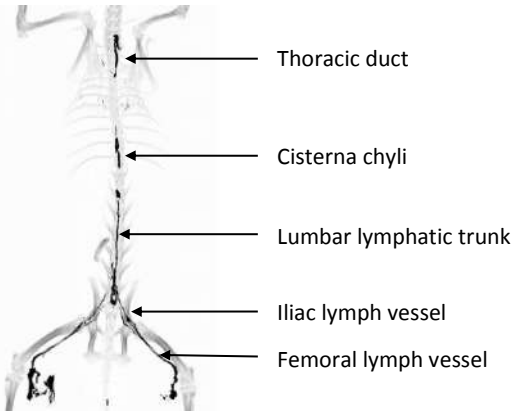

Figure 1: Three-dimensional maximum intensity projection (3-D MIP) image on post-lymphangiographic multidetector CT (MDCT) in anteroposterior view shows the lymphatic system in a rabbit.

4. Discussion & Conclusion

For TDE, the opacified cisterna chyli or retroperitoneal lymphatic duct is usually accessed through a transabdominal approach under fluoroscopic guidance. Rabbits may be suitable for TDE following lymphangiography. The visibility of the lymphatic system on post-lymphangiographic MDCT in rabbits provides enough information for interventional radiologists to perform preclinical lymphatic interventions and future imaging techniques.

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O27: AN INTUITIVE DISPOSABLE ENDOSCOPE WITH INTRINSIC PNEUMATIC ACTUATION

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1. Introduction

Upper Endoscopy is the preferred method for gastric cancer (GC) screening. However, it requires trained operators and comes with high costs [1]. Novel, intuitive, and low-cost endoscopes can hence enable screening programs in low middle-income countries where GC is prevalent. Our team has developed a Disposable Endoscope with Intrinsic Pneumatic Actuation (DEIPA). DEIPA successfully visualized key landmarks in ex-vivo and in-vivo trials [2]. In this abstract, the mechanical design of DEIPA is presented.

2. Methods

DEIPA is made out of 3D printed, extruded, and off-the-shelf components. It does not require a bulky endoscopic tower, nor power supply. The device is battery operated (> 2h of operation between recharges), and the endoscopic images can be visualized in real time on a common smart phone or tablet via Wi-Fi. The DEIPA consists of:

[A] A 14mm Ø steerable tip embeds HD camera and low power Light Emitting Diodes (LEDs) with a parallel bellow actuator as bending section. The bellows dictate the tip diameter. This can be reduced by adopting custom bellows.

[B] A soft tether composed of a multi-lumen catheter (7mm Ø, 130 cm long – Nusil MED-4880 silicone) and electrical wiring provides data transmission, lens cleaning, irrigation, and insufflation. In the current prototype, a tool channel is not included as DEIPA is intended as a first-level screening tool.

[C] A 3D printed case with an intuitive continuum user interface (CUI). The CUI is composed of super elastic Ni-Ti wires, springs, and plastic discs. It is designed to replace the double-knob mechanism of traditional endoscopes with a more intuitive and joystick-like control interface. The case embeds battery, Wi-Fi video transmission module, and the actuation module. The latter consists of three syringes connected through the soft tether to the three bellows at the tip. The syringes are pressurized-depressurized by moving the pistons, which are coupled to the NiTi wires in the CUI.

Both [A] and the user interface in [C] can be considered as continuum manipulator with three degrees of freedom (extension, pan and tilt). As the user manipulates the CUI, the free end of the NiTi wires coupled via a screw mechanism to the syringes' pistons, move up and down resulting in a direct mechanical actuation of the tip. Different syringe sizes and fluid mediums can be used to modulate the mechanical transfer function.

3. Results

DEIPA was assembled with associated prototyping costs <100 USD. The most expensive components are the camera and the Wi-Fi transmission module (15 USD and 30 USD, respectively).

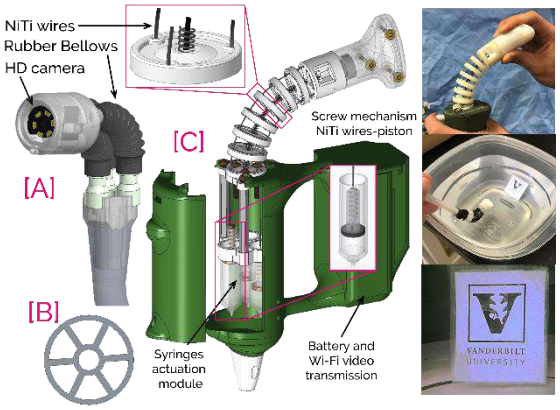

Figure 1: Left: DEIPA's main components. Right: assembled version performing underwater visualization.

4. Discussion & Conclusion

DEIPA is designed to be intuitive to use thanks to direct mechanical coupling between the proximal and the distal end. It can be either fully disposed or redesigned to reuse the camera module. Moving forward DEIPA usability in cadaver will be tested and custom bellow will be adopted to reduce the tip size.

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O131

Sensorized capsule endoscope for closed-loop magnetic navigation and safe tissue interaction

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1. Introduction

Magnetically-driven capsules stand on the edge of a new frontier in the field of active capsule endoscopy. Beyond this frontier, there is a new generation of endoscopic devices aimed at reducing the invasiveness and the discomfort of traditional endoscopes [1]. The authors present an endoscopic capsule equipped with MEMS tactile sensors [2], here preliminarily used as a force sensor module for enhancing closed-loop capsule navigation; this system can also avoid exceeding target forces with the colonic tissue for safety purposes [3].

2. Methods

The system is composed of: *i)* a capsule of 33 mm (l), 26 mm (w) and 17 mm (h), with a soft circular dome of 7 mm diameter made of Dragon Skin® 10, covering a 2x2 array of MEMS tactile sensors and a permanent magnet (Figure 1a); *ii)* a 6-DOFs anthropomorphic manipulator (Comau Racer 5-0.80), with a permanent magnet mounted on its end-effector; and *iii)* a control unit, which receives the tactile sensors output and updates the robot trajectory accordingly.

The capsule is moved into a rigid plastic tube (55 mm diameter, 370 mm length) at four different tilt angles, performing a forward/backward path three times per configuration. The experiment starts with the magnetic end-effector distant from the capsule. The robotic arm is moved towards the capsule (varying z) to establish the magnetic link. The capsule is considered in contact when at least one sensor of the array overcomes 0.25 N contact force. Once the capsule is in contact with the tube it starts moving at a constant speed of 25 mm/s. The trajectory of the robot is adjusted by a proportional control (with K_p 0.25) based on the norm of the used four channels of the array, with a desired target force of 1.1 N.

3. Results

The norm of the force sensors is well maintained at the target force in all the configurations tested, with variations in the range of ±0.09 N. The robustness of the system, following the path, has been validated comparing the actual tilt angle with the angle trajectory computed starting from the manipulator's Cartesian coordinates. The computed angle mean value lays always with in a ±2.1 degrees interval around the actual tilt angle, demonstrating that the manipulator accurately follows the expected path, maintaining a constant distance with the capsule and keeping the contact force within a safety range.

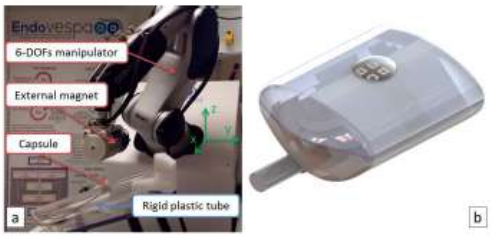

Figure 1 *a)* Robotic test bench, and *b)* capsule rendering

4. Discussion & Conclusion

A novel device with MEMS tactile sensors has been tested for improving closed-loop maneuverability and implementing safety measures in a simplified endoscopic scenario. The system will be tested in a more realistic environment resembling compliance and obstacles of a real intestinal tract. Furthermore, the device has the potentiality to work as a tactile probe for remote palpation, providing the physician with a new tool for diagnosis, beside the established vision-based techniques.

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SESSION 24 – NEW TECH FOR ADVANCED THERAPIES

O97: Pre-clinical validation of open-source airway navigation using Anser EMT and CUSTUSx

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Introduction

Electromagnetic tracking (EMT) is a common navigation technology used in image guided applications. EMT is particularly useful in procedures where line-of-sight of the operating field is not feasible. We present a major update of the open source electromagnetic tracking platform Anser EMT [1] and present its results when performing bronchoscopy in a pre-clinical setting using the open-source CustusX navigation suite [2]. The updated system design is open source and free to use and modify under the Berkeley Standard Distribution (BSD) license.

Methods

The original design of the Anser system [3] was consolidated onto single printed circuit board (PCB). EM-guided virtual bronchoscopy navigation was performed using the CustusX navigation suite. In two pre-clinical validation experiments, 4 calcium-alginate tumour models were percutaneously injected into the right (3) and left (1) lungs. Following CT imaging (Siemens syngo 64-slice), airway segmentation was performed on the post-placement CT scan using an OpenCL accelerated algorithm. Image to patient registration was performed using the iterative closest point (ICP) method in CloudCompare. A custom tip-tracked bronchial catheter was used for tracked airway navigation through a 3.2mm working channel of therapeutic bronchoscope (EB-1970TK, Pentax Europe GmbH). Following virtual navigation to each tumour model, a Tornado® embolization coil (Cook Medical Inc., USA) was deployed at each for post procedure targeting verification.

Results

The system was calibrated using 81 pre-defined test points in a single plane at a height of 85mm above the field generator with an RMS registration error of 1.52mm. Airway segmentation was performed using CustusX in 18 seconds. ICP image-to-patient registration yielded a single rigid registration matrix. Successful navigation and to each tumour target was achieved using EM guided catheter navigation. Targeting errors were measured as the Euclidean distance between the centres of each tumour site and their respective embolization coils, using the post procedure Zeego DynaCT scan of the pig model. Absolute targeting errors in the range of 1.39-12.04mm were recorded in 8 tumour model sites across multiple users in two independent live cases.

Discussion & Conclusion

We have shown successful airway navigation and tumour targeting using a combination of open source hardware and software navigation technologies. Overall tumour targeting accuracy is comparable with previously reported procedures for electromagnetic navigation bronchoscopy.

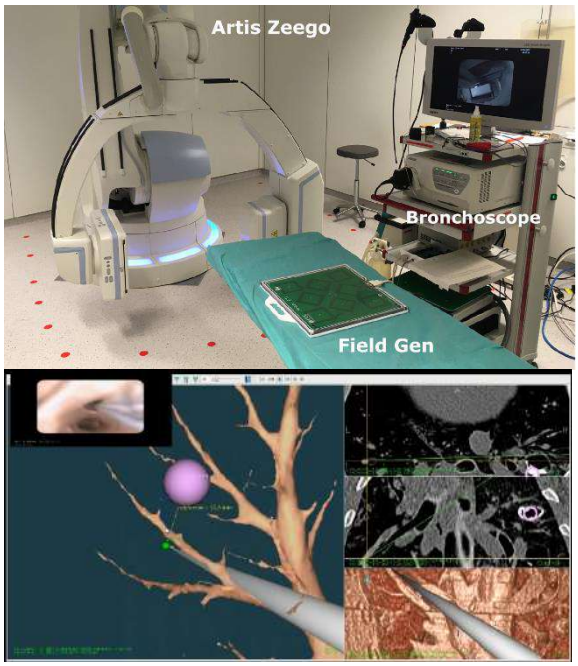

Figure 4. Virtual bronchoscopy using the Anser EMT system (top) and CUSTUSx imaging platform (bottom).

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O87: EXPERIMENTAL CHITOSAN MEMBRANES APPLIED ON THE PERI-PROSTATIC NEUROVASCULAR BUNDLES AFTER NERVE-SPARING ROBOT-ASSISTED RADICAL PROSTATECTOMY: PRELIMINARY RESULTS OF A PHASE II STUDY

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Introduction

The primary aim of the study was the evaluation of the feasibility and the safety of the application of chitosan membranes (ChiMe) on the neurovascular bundles (NVBs) after nerve-sparing robot-assisted radical prostatectomy (NS-RARP).
The secondary aim of the study was to report preliminary data and in particular potency recovery data of patients who underwent NS-RARP and received ChiMe.

Methods
This was a single-centre, single-arm prospective study, enrolling all patients with localised prostate cancer scheduled for RARP with five-item version of the International Index of Erectile Function scores of >17, from July 2015 to September 2016. All patients underwent NS-RARP with application of ChiMe on the NVBs. The demographics, perioperative, postoperative and complications data were evaluated. Potency recovery data were evaluated in particular and any sign/symptom of local allergy/intolerance to the ChiMe was recorded and evaluated.

Results
In all, a hundred-forty patients underwent NS-RARP with application of ChiMe on the NVBs. Applying the ChiMe was easy in almost all the cases, and did not compromise the safety of the procedure.
None of the patients reported signs of intolerance/allergy attributable to the ChiMe and potency recovery data were encouraging.

Discussion & Conclusions
In our experience, ChiMe applied on the NVBs after NSRARP was feasible and safe, without compromising the duration, difficulty or complication rate of the 'standard' procedure. No patients had signs of intolerance/allergy attributable to the ChiMe and potency recovery data were encouraging. A comparative cohort would have added value to the study. The present paper was performed before Conformit_e Europ_eene (CE)-mark achievement.

O65: VIDEO-ASSISTED ARTERIOVENOUS FISTULA IN DYALISIS PATIENTS: OUR PRELIMINARY EXPERIENCE WITH VITOM® HD SYSTEM

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1. Introduction

Arteriovenous fistulae (AVF) constructed using native vessels, vascular grafts and central venous catheters are the best permanent access, owing to a lower incidence of stenosis, thrombosis and infection. [1] The radiocephalic AVF of Cimino-Brescia remains the first choice for vascular access. [2,3] Mininvasivally access with a packaging of anastomoses is difficult in a restricted surgical field and traditional micro-dissection requires using the oculars of a stereo or surgical microscope for visualization. [4] Loupes with 2.5–4.5 magnification are most frequently used, but also the operating microscope may be used. [5] Although these magnifying instruments are essential to the optimal care of patients, they often come at a detriment to the operating surgeon in the form of neck or back pain and fatigue. VITOM® HD System can be a valid alternative to the others magnifying instruments (Fig. 1).

Figure 1: First experience of using VITOM® HD 3D System in an experimental model.

2. Methods

We performed a video-assisted radio-cephalic arteriovenous fistula in latero-lateral using prolene 7-0 without loupes (Fig. 2). The patient was a 72 years old man with history of Diabetes Mellitus type II from 15 years, ischaemic cardiomyopathy from 5 years and renal failure from 2 months. He needed a vascular access to start the substitutive haemodialysis treatment 30 days later. The VITOM® HD 3D System used is a KARL STORZ optical instrument coupled with a 1080p full high definition camera system.

3. Results

The average time for packing anastomoses was 46 ± 15 minutes; No complications were noted after decay, anastomoses showed a perfect holding. The consensus opinion of the entire group was that image quality was excellent and the system is ergonomic. The surgeons agreed that neck strain

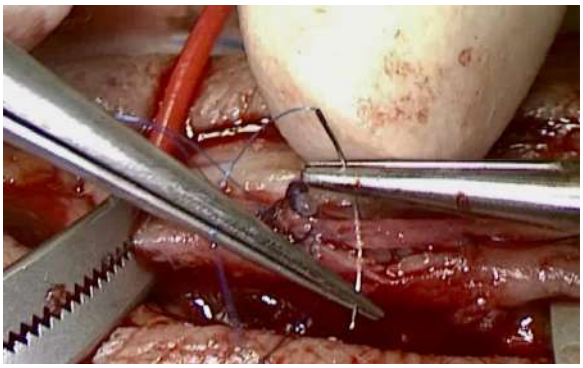
and fatigue were reduced. 

Figure 2: Arteriovenous video-assisted fistula creation using prolene 7-0 and microscopically instruments.

4. Discussion & Conclusion

The arteriovenous fistula creation is a safe and easy-to-realize technique but provides a long training for surgeons who have no experience in microscopically surgery. This technique is particularly suitable for the formation of young surgeons as the images of the operating field are magnificent, enlarged and high-definite on-screen visible to everyone. Thanks to its own features loupes are not necessary

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O84: Design of an Innovative Implant for Rib Fracture Stabilization

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Introduction

Rib fractures are the most common injury that is sustained in the chest area. These occur in the elderly, adults and youths due to blunt chest trauma. Ribs are responsible for healthy respiration, and protect vital organs such as the heart, lungs and arteries. Treating rib fractures comes down to an adequate stabilization of the fracture site until the bones heal [1].

In this paper, an innovative approach to rib fracture stabilization is proposed. The designed implant focuses on an effective and efficient surgery by adopting the approach of Video-Assisted Thoracic Surgery (VATS). Moreover, the implant's design ensures that the surgery is simple, safe and results in less pain to the patients.

Methods

The basic design cycle [2] was employed to systematically develop the implant. An analysis of the anatomy of the thoracic (chest) area was carried out. This went hand in hand with a study of the current state-of-the-art products related to rib fracture stabilization. This was followed by understanding the customer requirements which was used to develop a Quality Function Deployment (QFD) and a detailed Product Design Specification (PDS) that outlined the targets that must be met. Such targets included the surgery time, ease of installation and ease of customization for different patients. In the synthesis stage, several concepts were generated based on these criteria. Once a concept was chosen and refined, it was developed into a real-world implant, building upon a previous design developed by Calleja [3]. Calculations were compiled to ensure that the new design would withstand the forces exerted by the human body. A detailed Computer-Aided Design (CAD) model was generated. A physical prototype was then fabricated on a Ti-6Al-4V sheet using water-jet cutting. The final stage consisted of evaluating the implant in order to identify its strengths and weaknesses.

Results

The final result consists of an implant that is installed by having two elastic clips (one at each end of the implant) applying pressure from the sides of the ribs as a method of fixation. The surgeon is only required to push the implant into location from the top of the rib. Two screws can be installed at the same location. The biggest priority was to develop an implant that can facilitate the installation during the surgery. Hence, to test the implant, the decision was taken that the best strategy was to allow a number of surgeons (N = 2) to install the implant on a plastic skeleton (Figure 1a) and a human cadaver (Figure 1b). These two procedures were accompanied with a discussion between the stakeholders, with regard to the strengths and limitations of the implant.

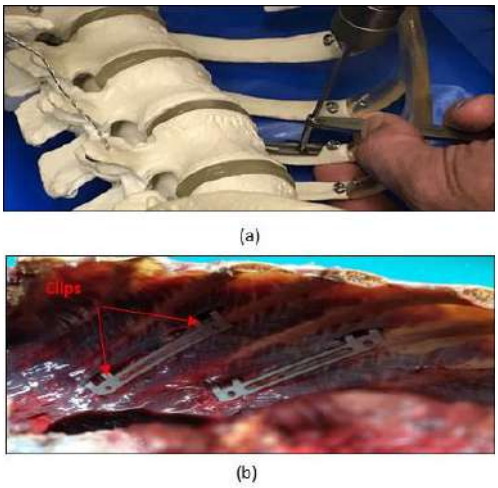

Figure 1: Installation of implant on (a) plastic skeleton (b) human cadaver

Discussion & Conclusion

The procedures showed that the implant satisfied stabilization issues, whilst the surgeons confirmed that the installation of the implant was relatively simple. The only issue with the installation was that specific tools may be required to install the device through VATS. Despite this, other strengths were highlighted, such as the way it contours along the ribs, resulting in a compact implant and the ease with which the implant is sterilised due to the shape and material (Ti-6Al-4V).

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O5: Fibrina Arricchita di Leucociti e Piastrine (L-PRF) nel trattamento delle lesioni cutanee

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RIASSUNTO.

Introduzione. Nell'ultima decade si è affermata in campo odontoiatrico la Fibrina Arricchita di Leucociti e Piastrine (L-PRF) in grado di rigenerare tessuto osseo e gengivale. Le piastrine e i leucociti racchiusi in questo coagulo riescono a liberare fattori di crescita in maggior quantità e durata rispetto ai tradizionali concentrati piastrinici. Intendiamo evidenziare i possibili benefici derivanti dall'utilizzo di L-PRF anche nel trattamento delle lesioni cutanee.

Metodi. 18 pazienti , 6 maschi e 12 femmine , età media 78.8 aa (range 32-99), con 23 lesioni di diversa natura (10 traumatiche, 6 diabetiche, 2 flebostatiche, 1 mista, 2 da pressione, 1 peristomale, 1 reumatoide), con una superficie complessiva di cute ferita di 405.1 cmq (range 1- 98) , alcuni già trattati senza successo con medicazioni avanzate, sono stati sottoposti ad applicazione di L-PRF. Tramite prelievo ematico con provette certificate da 10 ml (Intra-Lock®) immediatamente centrifugate (Intraspin Medical Device Intra-Lock® System Europa SPA) per 12 minuti a 2700 giri/min, sono stati separati i globuli rossi dal materiale plasmatico coagulato. Quest'ultimo è stato applicato con cadenza settimanale su lesioni già granuleggianti. Sono stati ricercati la risoluzione delle lesioni , la comparsa di neovascolarizzazione, gli eventi avversi, la riduzione della sintomatologia algica, il tempo di guarigione.

Risultati. Dei 18 pazienti studiati : 14 hanno raggiunto la guarigione completa con sviluppo di tessuto neoformato ipervascolarizzato; 1 solo paziente con allergia cutanea e polimorbilità ha interrotto il trattamento per recrudescenza dell'ulcera nonostante un iniziale miglioramento, rappresentando questo l'unico evento avverso ; 2 sono deceduti per polimorbilità; 1 ha sospeso la terapia per trasferimento di domicilio . In un caso di piede diabetico con esposizione ossea dell'alluce si è ottenuta la guarigione evitandone l'amputazione . Le ferite traumatiche sono guarite con precoce rivestimento epidermico. In tutti i 18 pazienti (100%) si è verificata la risoluzione del dolore alla prima applicazione. Il tempo medio di guarigione su 19 lesioni è risultato di 8.89 settimane (range 1 – 21).

Conclusioni. L-PRF presidio autologo fresco , facile da ottenere, usato topicamente nelle lesioni cutanee ha dimostrato , nella nostra pur limitata esperienza, ottima tollerabilità, efficacia antalgica, capacità di risolvere rapidamente lesioni traumatiche, riduzione dei tempi di guarigione anche in lesioni inveterate non responders alle medicazioni avanzate, nel piede diabetico potrebbe risevare notevoli ripercussioni sulla qualità di vita.

SESSION 06 – NOVEL DESIGN OF MEDICAL DEVICES: FROM IP TO MARKET ANALYSIS

O100: TISSUEGRAFT: FROM THE IDEA UP TO THE MARKET

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1. Introduction and methods

In 2012, the Commission published two regulation proposals to revise existing legislation on medical devices and *in vitro* diagnostics. The revision affects all medical devices, from home-use items like pregnancy tests and contact lenses, to X-ray machines, pacemakers and breast implants. After nearly four years of negotiation between the EU institutions, industry and Member States, the end of the legislative procedure is finish on 2017.

Manufacturers of medical devices will be confronted with major changes in the European Union's regulatory framework which governs market access to the EU for medical devices.

That's where TissueGraft srl comes in. We operate in Europe, coordinating among multinational owners interested to create new medical devices, financial office and R&D department.

TissueGraft can collaborate with industries in order to develop medical devices following the partners in all the project phases bringing to market. Our goal is developing new products in collaboration with companies interested in regenerative medicine market.

We offer our lab for characterize the products, sharing also innovative ideas, where required. The skills and the instrumentations of TissueGraft company are available for both research institutions and companies.

Our expertise are focalized on biocompatibility and the mechanical characterization.

– Assessing biocompatibility, haemocompatibility and mechanical properties of materials for tissue engineering and regenerative medicine.

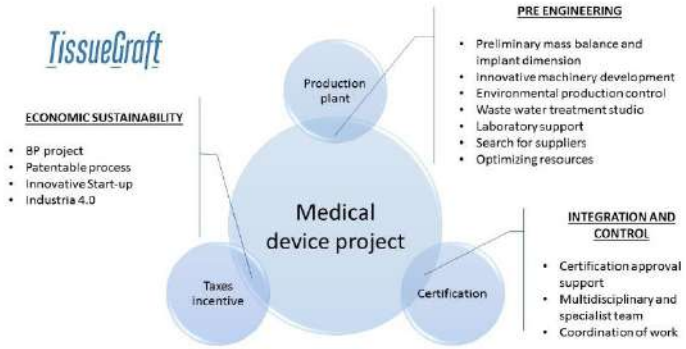
– Improving an existing product of a company involved in regenerative medicine with sueGraft process.

Finally, Tissuegraft can project the industrialization process, optimizing the transfer technology solutions.

2. Results

In Italy, we've been helping several companies get new products approved on the market on the last three years.

In brief, here it is what we offer:



3. Discussion and conclusion

The strength of our team is the multidisciplinary approach. We can collaborate with the industries partners from the certification process to the industrialization of their own products. From the first idea and approval to debut and product maturity, we provide guidance that considers the complex considerations where business and compliance meet.

Many of our collaborators have worked for multinational companies and in the most advanced research centers, and have backgrounds in regenerative medicine, biomedical and chemical engineering and material science, among other disciplines.

O63: An active device for high fidelity simulation in newborn intubation

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1. Introduction

Endotracheal Intubation (EI) procedure is highly complex and it requires wide-ranging competences and experience for avoiding unexpected complications: the force generated by the laryngoscope on the human tissues can easily cause traumas [1]. Airway management and EI are even more delicate for newborns and infants because of limited availability of instrumentation and challenging anatomical and physiological features [2]. Given the complexity of the neonatal domain, a specific education program is required [3] and specific intubation skill trainers are mandatory.

2. Methods

Active intubation skill trainers should not only be high-fidelity simulators of the analogous anatomical structures, but also active instruments able to provide feedback about the trainee's performances. There are several commercial neonatal intubation manikin models. However, to the best of our knowledge, no sensorized skill trainer devices for neonatal intubation have been previously described. Based on these, and starting from our previous experiences [6], we worked on the development of an active, robust and reliable neonatal skill trainer able to provide clinicians with real-time information about the intubation procedure in terms of force peak value, force distribution and timing. In particular, different force sensing elements were integrated into a commercial neonatal intubation mannequin (Figure 1), in well defined points that were recognized as the anatomical areas mainly subjected to injuries during EI.

3. Results

An active prototype was realized by including force and pressure sensors into tongue, epiglottis, superior and inferior gingival arches, neck and trachea. Punctual force sensors (i.e. FSR®400 short - Interlink Electronics, CA, US) were recognised as the most promising sensorization strategy of gingival arches and epiglottis. On the other hand, a custom-made multilayer pressure sensor was used for tongue sensorization in order to guarantee a pressure distribution map (Figure 5). A custom Graphic User Interface (GUI) was implemented for feeding back the data from all the integrated sensors. Validation tests were carried out with 9 users that took part in two intubation sessions held 24 hours apart.

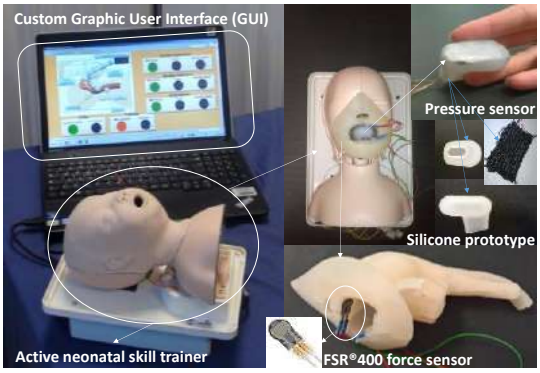

***Figure 5**: Overall view of the sensorized skill trainer with details about the sensorization strategies.*

Each session consisted of 5 intubation attempts: time of procedure and pressure on critical points were anonymously collected. The first test was accomplished with a mean time of 40.34±26.28s, which rapidly decreases in the second session until to reach 16.77±13.59s. Regarding the applied forces, epiglottis forces decreased from 3.01±1.98N down to 1.12±0.62N from the first to the second training session; on the contrary, forces on superior and inferior gingival arches were quite constant (from 0.49±0.68N to 0.34±0.06N for the superior arch and from 0.38±0.15N to 0.27±0.05N for the inferior arch). Finally, with respect to the pressures applied on the tongue, a maximum force of 11.96N was measured and a maximum involved area of 400 mm^2 was revealed. A promising decrease of the maximum applied force between the first and the last attempt was observed.

4. Discussion and Conclusion

We proposed here a skill trainer equipped with force sensors for the training of medical professionals in neonatal EI procedures.

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SESSION 15 – CARDIO@SMIT2017: WHAT'S NEW IN CARDIAC SURGERY

O6: The Development of the Hydraulic Pressure Wave Catheter

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1. Introduction

Crossing Chronic Total Occlusions (CTOs) is challenging, resulting in undesirably low success rates of 50–90% depending on the operator's experience and CTO characteristics. The most common failure mode in the treatment is the inability to apply sufficient force to cross the CTO due to buckling of the guidewire. The inability to cross the CTO often leads to procedural failure and the subsequent referral to the invasive open-heart bypass surgery. Additionally, buckling can cause damage to the blood vessel wall due to bifurcations of the guidewire's shaft and tip motions.

In order to improve the buckling resistance of the guidewire (or other crossing tools alike) and improve the procedural success rate, we propose to apply a mechanical impulse onto the CTO during the crossing procedure. Using an impulse to dynamically load the crossing tool and CTO can prevent buckling in two main ways: 1) the critical force the crossing tool can withstand increases with a decrease in force duration and 2) using an impulse to cross the CTO can lower the penetration load.

In order to transfer the impulse from the incision point towards the CTO with high efficiency, we propose to use a hydraulic pressure wave; a fast-moving longitudinal pressure surge in a fluidic medium (Fig. 1). The proposed tool consists of a saline-filled cardiac catheter-shaft with two free-moving plungers at the proximal and distal end, respectively (Fig. 1). To generate the pressure wave, an input impulse is exerted on the proximal plunger using a spring-loaded hammer (Fig. 1). This pressure wave is, subsequently converted into an impulse during the collision of the output plunger with the CTO.

2. Methods

In order to valorize the proposed hydraulic pressure wave catheter, a proof-of-principle experiment has been performed in which the effectiveness and efficiency of this concept have been tested. In this feasibility experiment, a standard cardiac catheter (Ø2 mm) was used. The input impulse was delivered by a preloaded mass-spring system. Both the input and output impulse were measured using load cells, from which the impulse efficiency and impact peak forces were derived. To test the influence of the shape and flexibility of the catheter on the efficiency, different braided cardiac catheters were guided through several curves and loops.

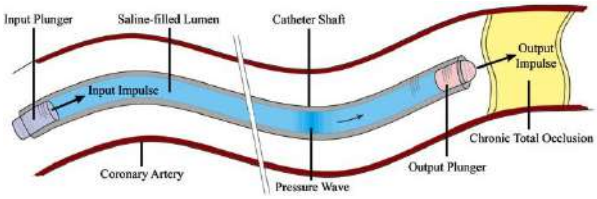

Figure 1: The proposed hydraulic wave catheter concept.

3. Results

From the experiment, a high impulse efficiency of over 80% was found. Furthermore, impact peak forces of up to 43 N were measured, which is approximately 25x higher than what is required [1]. No significant difference was found between the impulse efficiency for the looped catheter (3 loops) compared to the straight catheter. Furthermore, only a minor difference in efficiency of ~13% was found between the different braided catheter types.

4. Discussion & Conclusion

The hydraulic pressure wave catheter is a simple and versatile tool that allows for the delivering high-force impulses through a very tortuous path and under any angle. The catheter can deliver a large variety of output characteristics on the target tissue, from a single pulse to a pulsating motion, making it applicable to several medical fields. Based on the output characteristic and tip shape, it is also able to target a specific tissue type. We, therefore, feel that this tool can be the solution to overcoming current challenges in the treatment of CTOs in future.

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O16: POLYLYSINE-ENRICHED DECELLULARIZED MATRICES: A PROMISING APPROACH FOR VASCULAR SUBSTITUTIONS

Boccafoschi Francesca, Fusaro Luca, Calvo Catoira Marta, Ramella Martina- Deaprtment of Health Sciences/Tissuegraft srl, University of Piemonte Orientale, Novara, Italy

1. Introduction

Cardiovascular diseases are a leading cause of death worldwide. Current clinical approaches show poor efficiency in the replacement of small-caliber arteries (<6 mm). The use of autologous saphenous vein or mammary artery is currently the best surgical option; however, since most of the vessels are affected by widespread atherosclerotic abnormalities, this approach is not always feasible.

The use of synthetic grafts, used with good results in large caliber vessels substitution, due to thrombosis or intimal hyperplasia, leads to implant failure for small-caliber systems. In fact, the different compliance between the native vessel and the synthetic graft influences the mechanical behavior of the vessel wall causing lumen occlusion. In addition, the difference in mechanical properties could generate turbulent blood flow which enhances the formation of thrombi or aneurysms.

The use of decellularized scaffolds is a technique that has shown good perspectives in various applications for regenerative medicine both in preclinical and clinical. Through the decellularization process, it is possible to completely remove the cellular elements, retaining the native extracellular matrix (ECM). The scaffold obtained is an excellent substrate for cell adhesion, growth and proliferation. However, the decellularization process may weak the structure of the vessel. The purpose of this work is to obtain a scaffold chemically enriched with polylysine. Showing improved mechanical properties, without altering biocompatibility and hemocompatibility.

2. Methods

The matrices were obtained by decellularization and enrichment with polylysine (sueGraft®) of porcine arteries (femoral and carotid). In order to verify the effectiveness of the decellularization process, DAPI and hematoxylin/eosin staining were performed, together with the quantification of residual DNA. In order to verify the efficiency of the enrichment procedure, XPS analyses were performed. Endothelial cells were used to test the biocompatibility. In order to measure elasticity and burst pressure, as well as degradation test in working condition, mechanical tests were performed. Finally, several parameters related to hemocompatibility were measured.

3. Results

DAPI and hematoxylin/eosin staining confirmed the effectiveness of the decellularization method. The quantification of the DNA test showed that the amount of residual DNA was significantly and adequately reduced compared to untreated control. Values obtained were lower than the threshold values reported in literature.

Polylysine-enriched matrices showed excellent biocompatibility.

The analysis of the Young moduli showed that stiffness value of the enriched matrix is not significantly different to native vessel. Burst pressure test showed strengthening of the polylysine-enriched matrix, which can withstand higher pressures compared to native vessel. Matrix degradation test showed that the polylysine-enriched vessel has almost no weight loss, which indicates an absent degradation.

Concerning hemocompatibility, the evaluated parameters suggest that polylysine-enriched matrices increase clotting time.

Figure 1. Polylysine-enriched vascular substitute (prototype).

4. Discussion and Conclusion

The matrices obtained by decellularization of blood vessels and enriched with polylysine show a very good biocompatibility, excellent mechanical properties, thanks to the cross-link action of polylysine, and improved hemocompatibility properties for the intended use as vascular substitutes. Based on these results, matrices enriched with polylysine indicates a promising approach for vascular applications.

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O51: DEVELOPMENT OF A MODULAR SUTURING CATHETER FOR MINIMALLY INVASIVE SURGERY: THE POTENTIAL FOR IN VIVO – ASSEMBLY

Murai Estevan Hideki, Homer-Vanniasinkam Shervanthi, Silveira P.G., Dai Jian S, Martins Daniel, Wurdemann Helge- Federal University of Santa Catarina, Mechanical Engineering Department, Florianópolis, Brazil

1. Introduction

Endovascular aneurysm repair (EVAR) is a minimally invasive approach for abdominal aortic aneurysm (AAA) treatment. Compared to open surgery, the benefits of EVAR include faster recovery and shorter time in hospital as well as no general anaesthesia (in most cases). Though EVAR has become a preferred way to treat AAA with an increasing number of procedures, there are persisting complications, e.g. stent-graft migration. One approach to reduce the risk of migration is graft oversizing, using barbed stent-grafts and adding staples [1, 2]. Suturing the stent-graft to the aorta increases the displacement force (DF) necessary to move the implant. However, currently this is not possible within a conventional EVAR procedure.

This paper describes the design of an *in vivo* suturing catheter for EVAR. Due to size requirements, the suturing device is modular: each module can be inserted through the femoral arteries and assembled within the abdominal aorta.

2. Methods

The suturing device consists of two parts each of which is mounted onto a catheter tip. During EVAR procedures, each catheter module is advanced through a femoral artery into the abdominal aorta where they can be assembled using an electromagnetic mechanism. The positioning catheter module provides a stable anchoring and positioning means for the suturing catheter module (see Fig. 1).

The suturing module performs the suturing through the synchronized motion of a needle and looper. After each stitch, the positioning module relocates the suturing catheter to the next stitch location. This procedure is repeated until the entire circumference is sutured. The device is actuated using cables passing through the inside of each catheter module. The CAD model of the proof-of-concept prototype is illustrated in Fig.1. A scaled prototype and an aortic phantom are currently being manufactured.

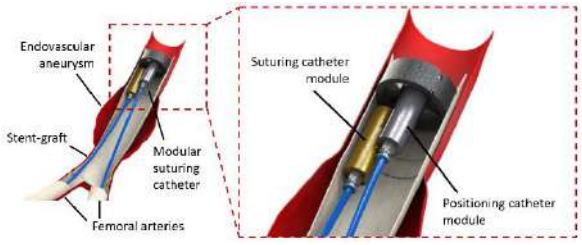

Figure 1: 3D CAD model of the modular suturing system composed of a positioning and suturing catheter module. Each module can be inserted through the femoral arteries into the abdominal aorta where the device assembles.

3. Future work

Experimental testing of the suturing and graft pull-out force is ‘work in progress’. An initial larger-scale prototype of the suturing catheter will be tested in a phantom environment. The prototype will be used to suture a graft to a phantom aorta. Then, DF will be quantified using a pull-out force experiment [1-3].

4. Discussion & Conclusion

An estimation of the DF for the sutured graft can be made using the scaled phantom model. The DF can be then compared with other graft-to-phantom fixation approaches found in the literature [2-3]. We strongly believe that our preliminary study will demonstrate the feasibility for suturing in EVAR using *in vivo* assembled catheters.

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O67: Development of a robotic platform for minimally invasive aortic heart valve surgery

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5. Introduction

Aortic stenosis (AS) is one the most common and serious cardiac valve diseases. It mainly occurs due to aging and has an average survival of only 2 - 3 years after symptoms onset [1]. Among the treatments for AS, surgical aortic valve replacement (SAVR) is widely accepted, as gold standard for lower-risk patients. SAVR is becoming common, with 300,000 estimated interventions carried out annually worldwide [2]. SAVR requires a 25cm incision in the patient's chest, hence requiring a long recovery time. Minimally invasive cardiac surgery combined with robotic approach is gradually becoming an alternative to the traditional sternotomy. It reduces recovery time, but correct valve positioning at the intervention site is still one of the major limitations [3].

The Valvetech project [4] aims to develop a robotic manipulator capable of safely delivering an innovative artificial polymeric valve in its accurate position under endoscopic vision.

6. Methods

A flexible/controllable robotic system is designed to deliver the artificial heart valve in its correct location. The system is composed of a macro placement arm, a micro positioner flexible manipulator (Figure 6) and a control unit. The macro placement system is a commercial surgical arm for attaching to the patient's bed (i.e. Martin's arm, Marina Medical). It is used to help surgeons to plan the best introducing route for valve positioning. The micro positioning manipulator, fixed to the macro arm, is inserted into the patient's body to reach the delivery site. The controllability feature of the flexible micro manipulator makes it suitable for exploring the intervention site. Miniaturized HD cameras on the head of the manipulator facilitate the delivery. The flexible manipulator also utilizes opening/closing flaps for stabilizing the manipulator in the aorta and widening the view of HD endoscopic cameras. Finally, the valve introducer is placed in the free-lumen of the flexible micro-positioner. The introducer is designed for assuring precise rotations and translational movements of the crimped valve to the surgical site in the most accurate way. The controlling commands are given by surgeons through a control unit with the help of cameras. The control unit includes joysticks for system's manoeuvring and an LCD for monitoring the process.

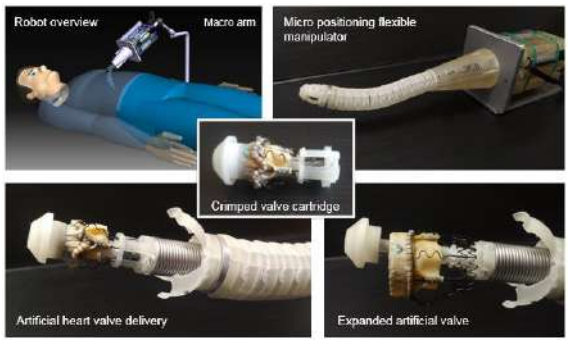

***Figure 6**: General overview of the robotic manipulator for robotic artificial valve replacement.*

7. Results

Prototypes of each robotic element were designed and assembled in the first Valvetech robotic platform. Preliminary assessments of the individual components and the complete integrated platform were carried out. A preliminary control architecture was also implemented, even if further tuning of the parameters is still required.

8. Discussion and Conclusion

A robotic system for robotic minimally invasive replacement of the aortic valve is proposed. Future activities will be devoted to extensively test the manipulator both in *ex-vivo* and *in-vivo* conditions.

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O104: EVALUATION OF A MULTI-STEERABLE CATHETER FOR CARDIAC INTERVENTIONS

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1. Introduction

To overcome the challenges presented by complex 3-dimensional shapes and tortuous vasculature in the cardiovascular environment, we previously developed a prototype of a multi-steerable catheter having 4 DOFs controlled by two joysticks [1]. However, it remains unknown whether the added steering possibilities are beneficial in the cardiovascular anatomy. With this research we aimed to investigate the effect of 0-DOF, 2-DOF, and 4-DOF catheter systems on surgical performance in a cardiovascular model.

2. Methods

Catheter Prototype – The catheter prototype was modified to compare 0-DOF (no steering), 2-DOF (multi-directional steering with a single segment), and 4-DOF steering (multi-directional steering with two segments).

Heart Model & Pathways – A transparent, rigid 3D-printed heart model was fabricated by Materialise (Leuven, Belgium) based on patient CT-data. Three pathways were defined for the experiment, differing in level of complexity:

1. Endo-myocardial biopsy route: starting in the jugular vein to reach a specified location on the intraventricular wall of the right ventricle.
2. Aortic valve implantation route: starting from the femoral artery to reach a specified location past the aortic valve.
3. Trans-septal mitral valve route: starting from the inferior vena cava to reach a specified location past the mitral valve.

Test Setup – The three identified pathways were visibly marked on the heart model and an electrode was placed at the start and end points of each pathway. The electrodes were connected to a National Instruments LabVIEW box to record the elapsed time between the start and end of each test.

Test Procedure – 18 novices (all students and employees at Delft University of Technology) between 18 and 30 years old, participated in the experiment. Each participant conducted three experimental sessions. In each session, one catheter type was used to manoeuvre along each of the three pathways. This resulted in nine tests per participant. Catheter order and pathway order were randomized.

Performance measures – Performance was assessed using the following objective measures: 1) completion time of each of the nine tests, and 2) number and locations of errors (wrong branch or chamber, retraction of the catheter, catheter blocking). Moreover, the following self-reported measured were used: 1) task performance, 2) usability, 3) workload, and 4) catheter preference.

3. Results

General Observations – General observations gave insight in the methods the users applied to overcome difficulties in steering. These methods included rotation of the shaft, fast push-pull movements of the catheter as a whole, shaking movements to direct the catheter in a specific region, and making use of the cardiac wall.

Preliminary Results – Four participants have been tested so far, yielding a total of 36 tests (4 x 9). For both the 0-DOF and the 2-DOF catheters, 4 out of 12 tests succeeded within 5 minutes. With the 4-DOF catheter, the task was completed within 5 minutes in 8 out of 12 tests. From the tasks that were completed within 5

minutes, the average completion time was measured as 102 s for 0-DOF, 126 s for 2-DOF, and 118 s for 4-DOF. Additionally, all four users reported that they preferred the 4-DOF catheter over the other two.

4. Discussion & Conclusion

The preliminary results indicated that the 4-DOF catheter is able to overcome the challenges of the cardiac pathways better than the 0-DOF and 2-DOF catheters. The remaining 14 participants must be tested before any clear conclusions can be drawn from the results.

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O114:

A Beating Heart Simulator for Open and Thoracoscopic Surgery

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1. Introduction

Heart diseases have become a global health problem, and normally surgery is the main method to treat various types of cardiac diseases. Performing surgery on the beating heart brings many advantages to patients, such as avoiding heart-lung machine and removing physiological complications. But it could be a challenge for young surgeons as they need more training to reach the level of qualified cardiac surgeon. It will be very useful to develop a beating heat simulator (BHS) for training and teaching purpose. The BHS system will help surgeons to improve their skills and proficiency in surgical procedures, thereby increasing the success rate of cardiac surgery [1-3]. Here we report a BHS system which could simulate coronary artery bypass grafting (CABG) surgery with continuous heart-beating; it also can simulate cardiac valves replacement in a stopped-jumping environment.

2. Methods

The beating heart simulator training system is showed in Figure 1, the system (Figure 1A) includes a heart model, beating mechanical device, supporting platform, controller (regulation of heart beat frequency and brightness of the LED lamp), operating port, dynamic camera, eyepiece amplifier. Figure 1B shows detailed structure of the beating heart device, the heart model can be a pig heart or 3D print heart model. The beating device is motorized to squeeze the heart model, the frequency and amplitude can be adjusted to simulate different beating motion.

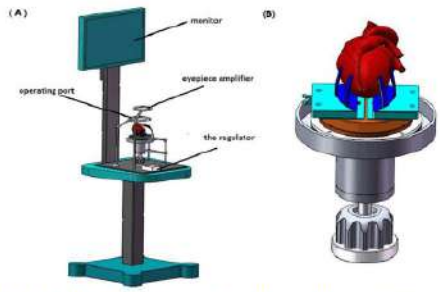

Figure 1: The structure of the cardiac surgery training system.

3. Results

The BHS system can simulate the training of beating heart surgery, such as coronary artery bypass surgery (Figure 2), valve replacement. It also can simulate off-pump surgery. The heart beating frequency can be controlled to imitate different operation environments. A beating heart device can achieve a beating rate of 0 to 100 beats per minute. The usefulness of the BHS system can be evaluated using the Object Structured Assessment of Technical Skill (OASTS) to assess the quality of surgical training.

Figure 2: Training of coronary artery bypass grafting (CABG) with beating heart simulator.

4. Discussion & Conclusions

We have developed a beating heart simulator system with controlled frequency and amplitude for open and thoracoscopic surgery. It could be used to simulate different cardiac surgeries, such as coronary artery bypass grafting and valve replacement.

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SESSION 25 – IMAGE GUIDED SURGERY 2

O8: ELECTROMAGNETIC TRACKING CAN BE USED TO ACCURATELY MESURE LEFT VENTRICULAR DIAMETER IN REAL TIME: A VALIDATION STUDY

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1. Introduction

Left bundle branch block (LBBB) results in a delayed electrical activation of the left ventricular (LV) lateral wall. This causes an inefficient, uncoordinated contraction, manifested as an abnormal shortening and lengthening pattern of the septum-to-lateral wall diameter during the heart cycle (Fig. 1) [1]. LBBB is treated using cardiac resynchronization therapy (CRT), where 2 pacemaker leads are placed on the septum and lateral wall. The LV is paced on both sides to restore synchronous electrical activation and contraction, restoring the normal LV diameter trace. However, successful resynchronization depends on correct placement of the pacing leads. Monitoring the LV diameter trace during implantation could therefore be beneficial.

Electromagnetic tracking (EMT) can be used to measure the movement of instruments in space, and could theoretically be incorporated into a pace lead, and hence measure the position and distance between the pace leads. We therefore validated how accurately EMT could measure LV diameter through the heart cycle as a first feasibility test of a combined EMT and CRT system.

2. Methods

In 6 anesthetized canines we placed EMT sensors at the pacing sites in the septum and LV lateral wall. As reference, sonomicrometry (SM) sensors were placed beside the EMT sensors. LBBB was induced and data was collected during baseline, LBBB, and CRT.

The length between the EMT sensors was calculated as the difference in position over time, and compared to the length measured by SM. The accuracy of the EMT method was calculated as root mean square deviation (RMSD) of the absolute difference between the SM and EMT length traces.

3. Results

The average peak to peak amplitude of measured LV diameter using SM was 4.3±1.5 mm. The LV diameter measured by EMT showed very good agreement with the reference, with an average RMSD of 0.4±0.1 mm. Representative traces are shown in Fig. 1.

4. Discussion & Conclusion

The EMT- and SM sensors could not be placed in the exact same location in our setup, which may in part explain the small error between the methods. Despite this limitation, there was very good agreement between EMT and SM in measuring LV diameter.

The results show that EMT can measure LV diameter continuously with high accuracy, indicating that EMT can be used to aid CRT implantation.

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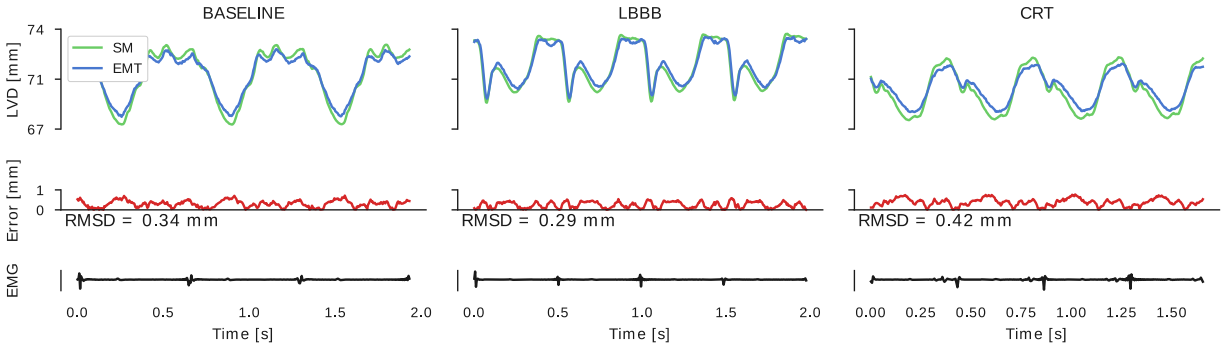

Fig. 1: The top row shows LV diameter (LVD) over time measured using EMT and SM. Middle row shows the absolute deviation between EMT and SM. Bottom row shows EMG measurement of septal activation.

O18: PREDICTION OF GUIDEWIRE TRAJECTORY INSIDE THE VASCULAR SYSTEM: 3D COMPUTER BASED MODEL

Sharei Hoda, van den Dobbelsteen John J, Dankelman Jenny- Delft university of technology, Biomechanical Engineering, Delft, Netherlands

5. Introduction

Guidewires are the basic tools used during interventions to access the place of interest [1]. Since the range of vascular geometries are extensive from one organ to another and from one patient to another, there is a variety of guidewires available. Therefore, the interventionalist needs to select an appropriate guidewire in each procedure. Despite the importance of this selection in the success rate of the procedure, it is mainly subjective and based on experience.

Knowledge of the guidewire's trajectory and applied forces prior to the procedure can support the interventionalist in selecting a guidewire with suitable mechanical properties for successful navigation. Therefore, we developed a 3D model, based on rigid multibody dynamics, to simulate the motion of the guidewire in vascular system. The force transmission between the instrument and the vascular wall was also determined.

Methods

In our model, the guidewire is considered as a discrete body: a number of interconnected rigid segments, each of which may translate and rotate. To account for the bending stiffness of the guidewire, joints with torsional springs and dampers are located at each interconnection [2]. A 3-point bending test is performed to obtain real data regarding the stiffness of guidewire. The left anterior descending (LAD) coronary artery is chosen as vascular geometry. Therefore, based on consultation with specialists, Pilot50 and Pilot200 are used as guidewires.

6. The developed model is based on the forward dynamic method, i.e. given initial conditions and applied forces and/or applied moments, over a given time interval to predict the motion. By applying a defined force to the proximal side of the guidewire, the guidewire moves by a constant speed of 2 mm/s. The model is developed in MATLAB/Simulink (The Math Works, Inc.) environment. To validate the accuracy of our method, a series of experiments on a phantom model were performed.

Results & Discussion

In this study, we have developed a 3D guidewire model and have endeavored to investigate its behavior in a specific vascular geometry and the importance of guidewire's stiffness on the motion. Although we used LAD as the vascular geometry and Pilot50 and Pilot200 as guidewires, the model is generic and it is possible to adopt to any other geometry or guidewire.

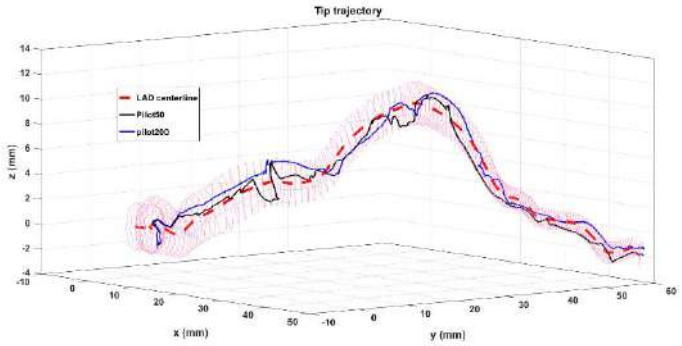

Figure 7: Tip trajectory of two guidewires inside LAD

The results show that the flexibility of a guidewire impacts its behavior during advancement: a higher flexibility, more fluctuation (see Figure 1). This can be explained by the fact that under the applied loads, the flexible tip deflects easier than the stiff one. Moreover, the stiff one (here, Pilot200) causes more applied forces to the vascular wall (see Figure 2).

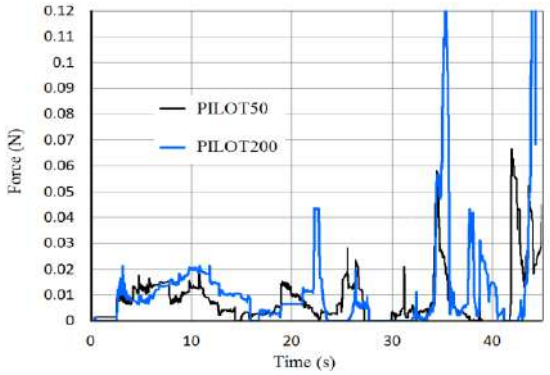

Figure 8: Applied force at the tip of guidewires

Use of such simulations enables the user to assess the possible motions, and even to predict the success rate of the procedure. Moreover, this information might help instrument designers to predict the performance of a new guidewire before manufacturing.

ACKNOWLEDGMENT

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O47: THE SIMULATION OF CATHETER INTERVENTIONAL SURGERY BASED ON VIRTUAL REALITY

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1. Introduction

The haptic-based virtual reality simulation which can create a visual and tactile fusion in virtual environment for operators is an important application in surgical training. The catheter's deformation and force feedback are key techniques in the catheter interventional simulator. The modelling of deformable catheter and the collision detection of the deformable objects are introduced.

2. Methods

The simulation of catheter interventional surgery is developed with the aid of some open–source software, such as OpenGL and CHAI3D, and the force feedback instrument Omega.6 (Force Dimension, Switzerland). CHAI3D is a platform framework for visualization, computer haptic and interactive real-time simulation. To realize the deformation and the haptic effect in virtual system, the skeleton ball-spring model based on classic mass-spring model (MSM) [1] is applied to the catheter 3d model, and the improved GEL dynamics engine is proposed.

According to the skeleton ball-spring model, a set of 6-DOF balls are arranged within the 3d model (shown in Fig.1). By defining the parameters of those balls and springs, such as mass, radius, elasticity, damping and external force, the real characteristic of the catheter can be simulated vividly. The improved model is more accurate than MSM but still computationally efficient.

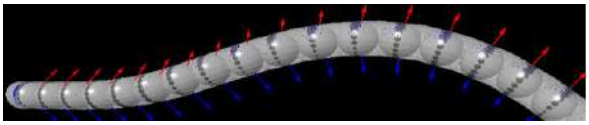

Figure 1: the skeleton ball-spring model of the catheter

The GEL objects created by existing GEL dynamics engine cannot detect collision. The improved GEL dynamics engine, incorporating with the Axis Aligned Bounding Box (AABB) algorithm, enables GEL objects to deform and skeleton balls to detect the collision with the objects in the virtual world.

3. Results

Based on virtual reality, a simulator for catheter interventional surgery is obtainable (shown in Fig.2). The simulator is applied to catheterization (shown in Fig.3). The catheter model and the human body model are imported to the simulator. Operators can insert the virtual deformable catheter in the urethra of the human body model and get force feedback by operating the handle of Omega.6.

Figure 2: the simulator for catheter interventional surgery

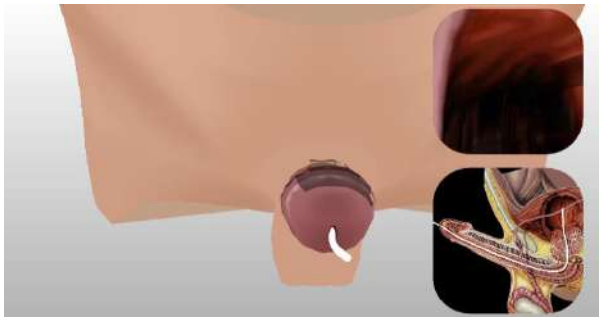

Figure 3: the simulation of catheterization

4. Discussion & Conclusion

The simulator provides an effective surgical training method to help operators practice the catheter interventional surgery and get more skillful in a safe and easy way rather than traditional surgeries. Meanwhile, the deformable and collision-detective catheter model in the simulator provide operators with a more realistic feeling in surgical trainings. The methods can also be applied to other surgical fields.

Acknowledgement:

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O19: GENERATIVELY MANUFACTURED FLEXIBLE INSTRUMENT GUIDANCE DEVICE AND HOLDING ARM FOR MRI-GUIDED INTERVENTIONS

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Introduction

MRI-interventions, e.g. biopsy- or RFA-needle placements, usually are executed by the clinician inside the scanner and under real-time guidance with an in-room monitor next to it. For access to the interventional site the clinician must lean with his hand deeply into the center of the scanner-tunnel (60 cm - 80 cm), while observing the monitor, to adjust the right needle-trajectory by hand. During the complete intervention, he must remain multiple times in that uncomfortable and exhausting position.

MRI-compatible assistance devices, which facilitate such procedures are topic of many robotic-oriented research projects. But still there are no affordable and certified products commercially available. We propose a fully MRI-compatible and easy to handle assistance platform that is based on an universally applicable and flexible instrument guidance device (flexible guide) and a holding arm.

Methods

Our design of the flexible guide provides a 6-DOF (DOF = degree of freedom) flexibility in a range of max. 20 mm and features a universal interface (hub diameter = 9 mm) for holding different types of instrument-adapters. The instrument is aligned manually with the movable hub. Once it matches with the desired trajectory all DOF´s can be fixed simultaneously with one locking element. Mounted on the MRI-compatible holding arm the flexible guide can be positioned in every desired location inside the MRI-tunnel.

We evaluated the setup in our MRI-system (3T, Skyra, Siemens, Germany), using a liver biopsy phantom (Abdominal Phantom 057A, CIRS, USA). The holding arm was attached to the table rail and the flexible guide was mounted on its distal end. For the simulation of the biopsy procedure a needle (21G) was placed with an adapter into the hub of the flexible guide, see Figure 1. The coarse positioning of the flexible guide was made with the holding arm around the estimated interventional location. For the registration of that initial needle position a localizer MR-dataset was acquired with the scanner. Specifically designed and printed fiducial markers [1], which are integrated inside of the flexible guide, provided reliable device visibility and conclusion about the instrument alignment. Following the needle orientation was adapted manually with the flexible guide while an in room monitor provided control of that procedure during real-time MRI-guidance. After the right trajectory was determined, the biopsy needle was locked in its position and pushed through the needle guide into the phantom until the target structure was reached.

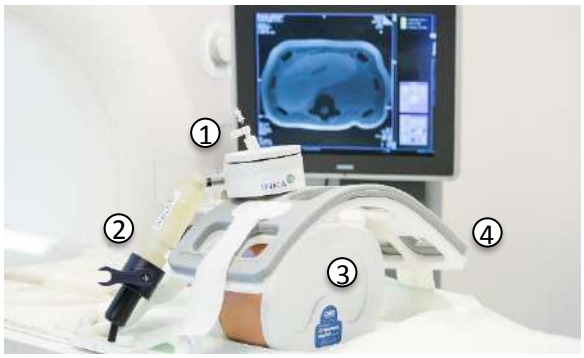

Figure 1: Demonstration of the platform with the flexible guide (1) installed on the holding arm (2) above the liver biopsy phantom (3) and the measuring coil (4).

Results

In combination with the integrated fiducial marker structures the flexible guide allows precise manual instrument-alignment. Along the trajectory the needle was driven precisely to the target structures (standard deviation < 1 mm). The complete setup did not cause any imaging artefacts.

Discussion & Conclusion

We showed that the flexible guide concept allows minimal invasive interventions under MRI-guidance using an affordable and manually controlled platform without any electronic components. Its application offers a significant improvement for the assistance comfort for the surgeon and the precision of instrument guidance. In the future the design will feature a lock-out-function and the flexible guide will be evaluated in the clinical workflow.

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Funding: This work was funded by German BMBF, 03IPT7100X

O62:A robotic approach for FUS in moving organs

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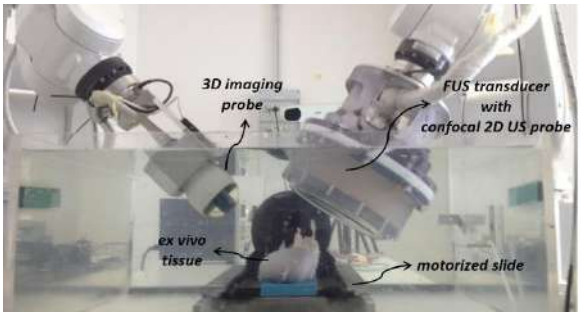
1. Introduction

Focused Ultrasound Surgery (FUS) is a non-invasive therapeutic technology that was demonstrated to be effective for the treatment of various pathologies, even if a wider clinical diffusion would require to compensate physiological movements of abdominal moving organs [1].
We present here an innovative robotic platform intended for FUS (http://www.futuraproject.eu/). A new motion compensation strategy suitable for clinical FUS procedures for moving organs has been introduced and evaluated through *ex vivo* tests. A robotic-assisted approach improves accuracy and flexibility of the overall procedure and enables a fast compensation of target organs' motion, such as for kidney, liver and pancreas.

2. Methods

The FUTURA (Focused Ultrasound Therapy Using Robotic Approaches,) platform is composed by two 6 DoFs manipulators (ABB IRB 120): one holding a custom 16 channels annular array FUS transducer, provided with a confocal 2D ultrasound (US) probe (PA7-4/12, Analogic Ultrasound), and the other one holding a 3D imaging US probe (4DC7-3/40, Analogic Ultrasound). Both US probes are connected with proper US acquisition machines (SonixTablet, Analogic Ultrasound). A dedicated Human Machine Interface developed in ROS (Robot Operating System) controls all system components and manages the entire procedure.
Figure 1. Experimental setup of the FUTURA platform.

Based on the design architecture, the FUTURA platform can treat moving targets by using machine learning and computer vision techniques. The pipeline is mainly composed by: i) a tracking module that detects and tracks a region of interest (ROI) on one of the two B-mode US images, ii) a learning module trained on target trajectory provided by the tracking module. By exploiting the axial steering capabilities



of the annular focused transducer, we implemented an innovative method for compensating the target point motion based on an angular movement of the transducer combined with a fast adjusting of the focal depth. This strategy minimizes the modification of the acoustic window during the breathing phases, which could hamper the correct identification and treatment of the target (e.g. presence of reflective ribs in in vivo applications). The feasibility of the compensation strategy was demonstrated in a simulated respiratory-induced organ motion environment, consisting in an *ex-vivo* porcine kidney placed on a 1 DoF motorized slide moving with an amplitude of 20 mm and a frequency of 0.2 Hz (Figure 1).
The procedure was repeated 10 times in different regions of the *ex vivo* target in order to evaluate the tracking error between the target and transducer focus positions. In addition, a sonication was performed in a chicken breast in static conditions in order to qualitatively demonstrate the accuracy of

the compensation method.

3. Results

The motion compensation error is always lower than 1 mm for all the performed tests (Figure 2-a). The lesion in dynamic conditions appears similar in size and shape to the lesion performed in static conditions, thus qualitatively demonstrating the accuracy of the proposed strategy (Figure 2-b).

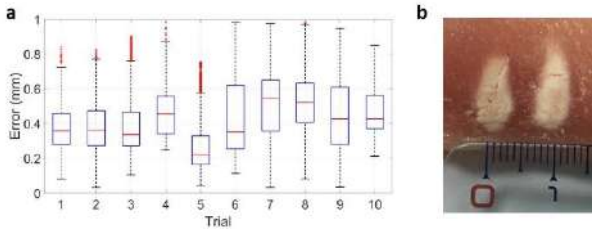


Figure 2. a) Boxplot of the error between the target area and the focal spot. b) lesions on chicken breast performed in static (0 mm) and dynamic conditions (10 mm).

4. Discussion & Conclusion

This work demonstrated the ability of an innovative robotic platform to compensate breathing organ motion and to perform precise focused ultrasound therapy on moving targets. The proposed method has the potential to provide continuous sonication for moving targets in a 3D *in vivo* scenario.

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O99: CYBERSECURITY: IT RISK PERCEPTION IN THE HEALTHCARE. MARCHE REGION CASE STUDY

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1. Introduction

The use of healthcare technologies, from medical devices to the Internet of Things, has increased the exposure of healthcare companies to hacking [1]. The value of health data transmitted through cyberattacks is even greater than that one of payment card data [2]. Therefore, computer health networks are particularly appealing to computer hackers. The last damage is caused, however, not to the healthcare company or NHS, but to the patient; the subjects of the infringement are the patient' sensitive data [3]. The aim of this study is to understand whether the health care staff is aware of the problem.

2. Methods

The study was conducted through the analysis of survey data provided to the staff of some public and private healthcare facilities in the Marche Region. After the examination of the emerging data in the most current research on the topic, find out through keyword research on PubMed (Medline), Kinahl and Proquest; there was the creation of questions to be included in the survey; the distribution of the survey in nine structures in the Marche Region (Ars – Agenzia Regionale Sanitaria-; Azienda Ospedaliero Universitaria Hospitals of Ancona, at Umberto I Hospital and Pediatric Hospital G. Salesi; Clinitest, in Ascoli and San Benedetto del Tronto; INRCA; Institute of Rehabilitation Santo Stefano , in the headquarters of Ascoli, Porto Potenza Picena and San Benedetto del Tronto; Provincial Hospital of Macerata), finally there was a statistical analysis of the data divided into classes. On the statistic sample, which was considered significant, was considered a distortion factor (e = 1.17) during the processing of the results.

3. Results

On a sample basis n=251, considered an average quadratic error of 1,177; it is noted that despite the almost unanimous belief in the impact of any computer attack, there are still a few initiatives taken to raise awareness about IT security. Staff largely do not know about the ICT security plan, even if this is defined by the structure, a similar scenario can be identified about the formalization of the procedure to be followed in case of computer attack. From this it emerges that there is no synergy between computer and clinical engineers and healthcare staff. Considering the imminent obligation to implement the Minimum ICT Security Measures, it would also be desirable to have a learning pathway for those who daily handle sensitive data.

4. Discussion & Conclusion

Although the health sector is most exposed to computer attacks, the theme is still far from the common interest. In the medical field, the alarm was launched in the last months of 2016 when some research by Deloitte and Trapax estimated that 94% of the 5600 US hospitals were victims of hacking. The focus increased in May 2017 when Wannacry ransomware hit 99 countries and forced the British National Cyber Security Center to work with the National Health Service [4] to contain the consequences of the attack that paralyzed some health facilities for a whole weekend in Britain. It emerges that the digitization of healthcare companies should correspond to an adequate investment in computer security. This study demonstrates the lack of awareness of individual users of risk exposure and highlights that educational campaigns should be directed to the staff involved. Only in this way will be a cooperation between clinical

and computer engineers and the healthcare staff, with the aim to find and implement appropriate solutions. Through this study it is possible to have an indication of the categories on which it is necessary to work most, making them aware and sensitive to the problem.
Correct information would help in addressing the problem in healthcare facilities, would allow for a better collaborative spirit with professional and technical figures that work specifically on cybersecurity, and would make the operators, not only in their role of healthcare staff, but as citizens, more careful, allowing the spread of the rules to be followed to limit the risks also outside the healthcare field, in everyday life.

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SESSION 7 – I HAVE AN IDEA! FROM THE CONCEPT TO THE CLINICAL VALIDATION

O145:

NOVEL DESIGN OF MEDICAL DEVICES: FROM IP TO MARKET ANALYSIS

How patents can foster innovation in the medical device field

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1. Introduction

The rapid progress in the medical device industry over the last decades has led to an increasing number of patent filings all around the world, making medical device companies, as well as universities, rely more and more on Intellectual Property (IP) protection as an essential element to be competitive in the today's market.

Medical technology has indeed become the strongest sector for European patent filings. In 2016 the medical technology field overcame 12.200 patent applications, and, despite a slight drop compared to the previous year, it was once again the sector where the most applications were filed.

Figure 1. Trends in medical technology European patent applications

2. Methods

A patent is a legal right that excludes others from practicing, manufacturing, and selling the claimed technology for a limited period of time, generally 20 years from the filing date of the application.

Only inventions that represent a new and inventive solution to a technical problem can be patentable, i.e. those meeting the requirements of: 1) Novelty; 2) Inventive step; and 3) Industrial applicability.

Drafting a patent application is quite complex and medical companies should be supported by skilled patent attorneys. The decisions made in the application and prosecution stage could limit the commercial value of a patent. For instance, a limited scope of the patent would leave much opportunity for competitors to provide the same functionality without infringing the patent.

A patent is valid in the jurisdiction in which it is granted. If a medical device company wants worldwide protection, it must file a patent application in individual countries worldwide. This could be prohibitively expensive. A mechanism to control costs is filing an international patent application (PCT - Patent Cooperation Treaty) or a regional patent application, such as for instance a European Patent (EP) application.

3. Results

Without patent protection, low-cost competitors may easily copy the costly product development process. However, if the medical device is patentable, the company will be able to (1) create legal barriers to entry by preventing others from copying, selling, or manufacturing the patented device; (2) sell or license the patented device to generate additional revenues (inventive loop); (3) enhance the value of the company by building equity and creating assets that may attract other investments.

If in the past IP was mainly considered a legal tool in order to obtain a competitive barrier, or monopoly, today it represents an important asset for corporate growth and development. Licensing is in particular a major route through which medical device companies can generate income from their innovation. Through licensing, revenues from royalties for the use of a patented technology can be re-invested in the company. This creates a self-sustaining cycle in which the fruits of previous innovation can fund new research, thereby generating an "inventive loop" in which the intangible assets acquire a real economic value.

4. Discussion & Conclusions

Patents are indeed proven to be fundamental for corporate growth and competitiveness. It is indeed vitally important that medical companies invest in patent strategy obtaining expert advice from a reputable patent attorney. It is also vitally important that the advice is commercially focused, and that IP is used in a smart way to protect and exploit a company's competitive edge. Through licensing a strong and well-written patent could become a constant source of revenue, obtain a return on R&D investment and finance new product development.

References

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[2] European Patent Convention (EPC)
[3] Patent Cooperation Treaty (PCT)

O140: Asymmetric – a novel vessel sealing technology, using low energy, and a flexible laser Fiber

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Objective: Vessel sealing during minimally invasive surgery is still a challenge, especially when applying through articulating or flexible devices. Additional disadvantages of current system include low precision and collateral tissue heating.

Technology: The core technology is an asymmetric laser fiber that enables controlled lateral energy emission. This allowed the design and production of several vessel sealing and tissue cutting devices including an articulating grasper, a hook and a loop snare for endoscopy. The devices can be articulated or flexible, fit into a flexible endoscopes' working channels and can be made in diameters even lower than 3 mm. This superior adaptability means the technology is a perfect fit with a variety of surgical robotic platforms.

Preliminary results: The devices were tested in an animal model with successful sealing of arteries up to 5 mm diameter, using low energy and with a durable seal.

Future perspectives: We are currently finalizing the first product design for minimally invasive surgery.

O36: Design requirements for surgical equipment for low-and-middle income countries

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7. Introduction

There is a significant disparity between surgical procedures performed in high-income countries (HICs) and low-and-middle income countries (LMICs), only 3.5 % of the surgeries performed in the world are received by the poorest one third of the world's population(1). Multiple surgical capacity studies have shown that hospitals in LMICs, such as Sierra Leone, Malawi and Nigeria, do not have a 100% coverage of basic surgical equipment such as, theatre lights, anesthesia machines and electro surgical units (ESUs). Equipment that is implemented successfully in HICs (e.g. oxygen concentrators) had a very short life span when implemented in hospitals in Gambia(2). Perry & Malkin et al. (2011) estimated that 40% of the equipment available in hospitals in LMICs is not working(3).

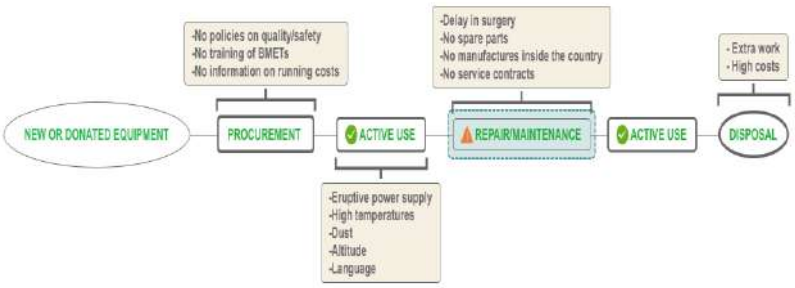

Figure 9: Surgical equipment journey and perceived barriers by stakeholders in Kenya.

Within the department of Biomechanical Engineering of the Delft University of Technology we aim to develop surgical equipment that can be successfully implemented in operating theatres in LMICs. The aim of this study is to develop the design requirements for *context appropriate* surgical devices by identifying the surgical equipment journey in Kenya and the barriers perceived by important stakeholders.

8. Methods

1)To determine the surgical equipment journey in Kenya, semi-structured interviews and participatory mapping exercises were conducted in Kenya in December 2016 with 8 biomedical engineering technicians (BMETs), 1 local distributor of medical equipment, 2 NGO's and 2 surgeons all working in Kenya. 2)Based on the surgical equipment journey and perceived barriers design requirements were developed.

9. Results

The surgical equipment journey in Kenya is displayed in Figure 1. Lack of spare parts, lack of BMET training, lack of service contracts and environmental factors such as electricity, temperature, and humidity were identified as barriers (Fig. 1).

The design requirements should, therefore, take into account both the local context and the different maintenance and repair structure in Kenya:

1. Design should account for repair instructions, spare parts and easy accessible replacement parts
2.Design should withstand a harsh dusty, humid climate with high temperatures
3. Design should be reusable with limited running costs

4.Discussion & Conclusion

We believe that these design requirements will eventually lead to a different set of surgical equipment than used in HIC, without essentially compromising the quality, safety and functionality. The aim is to increase the life span and thereby the longer use of surgical equipment in LMICs. A cryo device, ESU, video laryngoscope and laparoscope for LMICs are currently being designed at Delft University based on these requirements. Further research will focus on determining the order of reparability that is required for successful and safe implementation in LMICs.

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O142: Extending Human Xtensions from device to system: remote controlled articulating tool for MIS surgery

Szold Amir, Sholev Mordechai - Assia Medical Group, Assuta Medical Center, Tel Aviv, Israel

Objective: Human Extensions has developed a hand-held, software driven mechatronic device for MIS. To extend the scope of usability of these platform technologies and broaden the possible configurations for their use a novel table mounted system was developed.

Technology: Using the same core technologies (novel articulation, user interface and control system) a table-mounted software driven electro-mechanical system that can support several end effectors was designed and built The system is composed of a sophisticated user interface that enables unrestricted hand movement at or away from the table, and a novel, motor driven articulating tool that is controlled by the interface and enables all degrees of freedom. The system is lightweight and with a small footprint, requires minimal set up time, can be easily moved between laparoscopic trocars and perform complex motions in the surgical field.

Preliminary results: Following an extensive validation in the lab we have performed an animal trial using a pig model. We have demonstrated excellent manipulation with the device and seamless integration with our hand-held device.

Future perspectives: We are currently testing the system in order to personalize a technology solution to the different needs of surgeons and institutions,

O53:

Design of a fully implantable closed loop artificial pancreas

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10.Introduction

Conventional type 1 diabetes (T1D) therapy implies daily fingerpricks and multiple insulin injections. This approach fails in satisfactorily controlling blood glucose levels and strongly affects patients' life quality. Artificial Pancreas (APs) represent technological solutions combining a sensor for continuous glucose monitoring and an insulin pump. These two elements are connected by a closed-loop control algorithm. Despite recent advancements, current APs (mainly portable ones) still have some limitations since they significantly affect lifestyle and imply delays in the insulin adsorption kinetics. The development of fully implantable AP is hampered, at present, by the need of periodic surgical operations to refill the insulin reservoir and to replace the implanted battery.
In this framework the authors proposed a fully implantable long-term autonomous AP based on a non-invasive insulin refilling [1] and non-invasive battery recharging strategy. The device exploits the intraperitoneal supply route to enable a more physiological insulin profile [2].

11.Methods

The proposed device is conceived to be implanted in close proximity of an intestine loop. This enables to implement a non-invasive refilling procedure based on sensorized ingestible insulin capsules.

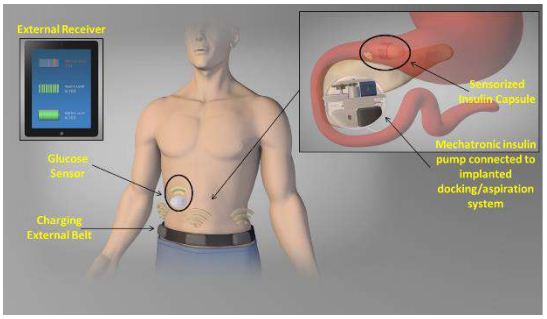

Figure 10 System overview with details showing the implant site, the wireless energy transfer and the communication systems.

Such capsules are expected to go through the gastrointestinal tract, until they are revealed and reversibly captured by the implanted AP. The insulin can be thus transferred to the internal device reservoir. A commercial glucose sensor and a wireless communication module enable to close the control loop and to provide the patient with warning and monitoring information (Figure 1). The AP prototype developed was based on mechatronic components enabling capsule docking, insulin transfer to the reservoir and intraperitoneal insulin microinjection. A Nylon reservoir featured by a variable volume was fabricated to guarantee insulin stability. Long-term system powering can be guaranteed by embedded batteries, rechargeable in a wireless fashion, through non-radiative energy transfer.

12. Results

A docking mechanism based on a magnetic switchable device (MSD) was designed, developed and tested. Two under-actuated mechanisms, each including a stepper motor and a train of gears, were embedded in the system for the activation of the MSD/capsule punching and the suction/injection system, respectively (Figure 11). The Nylon-based reservoir limited insulin aggregation for at least two weeks. A 4 coils-based wireless recharging system was designed, fabricated and preliminarily tested.

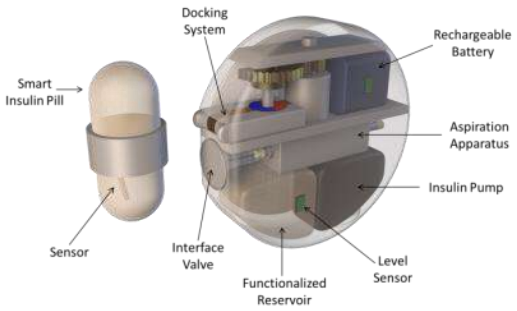

Figure 11 Fully implantable AP mechatronic system.

13. Discussion & Conclusion

The authors demonstrated the overall feasibility of a fully implantable autonomous AP, guaranteeing an intraperitoneal insulin supply. Results are encouraging in view of an in vivo translation of this technology.

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O56: A novel microwaves tool for robotic resection of the liver

Frosini Francesco, Staderini Fabio, Brancadoro Margherita, Dimitri Mattia, Regolini Jacopo, Miniati Roberto, Boushaki Mohamed Nassim, Paternò Linda, Guerra Francesco, Coratti Andrea, Cianchi Fabio, Corvi Andrea, Menciassi Arianna, Biffi Gentili Guido - University of Florence, Department of Information Engineering, Florence, Italy

1. Introduction

Hepatectomy using coagulative necrosis (HCN) has been recently developed in order to avoid bleeding related problems, one of the major concern for the hepatic surgeon [1]. The basic principle of liver pre-coagulation consists of creating a non-perfused zone using very high temperature hyperthermia along the resection line, in order to prevent bleeding during resection maneuvers. Microwave (MW) energy, despite its several advantages when compared to bipolar or monopolar radiofrequency [2], has still never been used as an effective coagulative energy.

2. Methods

The Integrated Medical-Robotics Solution Research Group, a research group funded by Tuscany Region, developed a new tool able to decrease the bleeding during hepatectomy. This tool uses 2.45 GHz MW energy with the aim to create a coagulative necrosis during the robotic resection of the liver. A MW needle [2], consisting on a radiating monopole has been integrated into a robotic arm of the da Vinci Research Kit (dVRK, Intuitive Surgical Inc.) surgical platform. The needle is able to transfer high impulsive energy to the liver parenchyma allowing to establish a transection line and enabling a very precise dissection and safe parenchyma division.

The needle was integrated into the dVRK designing a novel mechanical joint (Figure 1) able to encapsulate the coaxial cable, the rods and the pulleys to control the needle. The tool exploits the motion capability of the dVRK arm and allows one degrees of freedom (*i.e.,* pitch). This joint was developed following 4 important requirements: flexibility, integrability, stability and reliability. Before the liver resection, different applications of sequential ablation were performed along the resection line: particularly a needle of 14 G applied sequential energy pulses of 30 seconds at the power level of 89 W and 100 W.

3. Results

Computer simulations and experimental measures using ex-vivo and in-vivo tissues were performed: both confirmed that the target region reaches 100 °C in 7-10 s, arriving at 150 °C at the end of the 30 s pulse. This allows the instantaneous coagulation of big vessel in contact with the needle. In-vivo procedures demonstrates that this application is capable of coagulating vessels with diameters up to 4-5mm. The coagulation effect seems guaranteed by an internal MW-induced vessels' thrombosis.

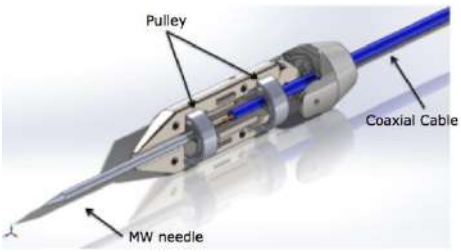

Figure 1: Mechanical joint built for the integration of the MW needle into the dVRK robotic system.

4. Discussion & Conclusion

One of the main reason of the slow spreading of Robotic hepatic surgery probably is the consequence of the absence of effective hepatic coagulative devices. Although the improvement of surgical techniques and instruments, bleeding from parenchyma transection remains the most critical point which can affect post-operative recovery. This novel device joins the advantages of MW energy as a coagulative energy source with the advantages of robotic platform and minimally invasive surgery. Our preliminary tests suggest that this combination could be useful to surgeons that perform robotic hepatic resection. The robotic device seems highly effective in coagulating vessels of small and medium diameter. The only main disadvantage is that the procedure it could be slower because the pre-coagulation phase is time consuming. Eventually, by decreasing the pulse duration and optimizing the MW energy transfer to the liver parenchyma the surgery could be faster; the evaluation of the efficiency is still in progress. In conclusion, MW integrated into the dVRK robotic platform can be useful to decrease the bleeding related problem during a robotic liver resection thus expanding the indications of minimally invasive hepatic surgery.

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O74:

From concept to design: A new flexible robotic uterine elevator

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1.Introduction

Robot-assisted gynaecology and urology surgery is the fastest growing field of robotic surgery. Surgical robots such as the da Vinci robot is now the most popular robot for minimally invasive pelvic surgery [1], [2], [3]. However, some disadvantages of the da Vinci system and other surgical robotic systems are their large size, the high initial and running costs, rigid laparoscopic instruments, limited degrees of freedom and restricted haptic feedback with the consequence that the surgeon has a limited 'feeling' of the surgery performed.

Uterine elevators are widely used for laparoscopic and robotic hysterectomy and other trans-vaginal procedures. In the trans-vaginal manipulation of the uterus, there is no need for an additional laparoscopic port which might be dedicated to manipulating the uterus from above. Hence, manipulation through the vaginal route is highly advantageous as the vagina serves as a single "natural orifice" port. The trans-vaginal uterine elevators are widely used by gynecologists for both laparoscopic and robotic hysterectomy, oophrectomy, myomectomy, lymph node biopsy, and treatment of fibroids, abnormal periods, endometriosis, ovarian cancer and pelvic prolapse [1], [4].

An ideal uterine manipulator must allow manipulation in all directions i.e. pushing, anteversion, retroversion, lateralization, and flexing of the uterus whilst holding on to the cervix. Further, the uterine elevator should be able to maintain the pneumoperitoneum following colpotomy and assist the identification of vaginal cuff, the adnexae and the posterior cul-de-sac. However, the current hand-held and voice controlled trans-vaginal uterine elevators are rigid tools that are often manually positioned by an assistant in response to the surgeon's command. Inefficient response to these commands, lack of experience, lack of coordination between the surgeon and his assistant, poor commands by the surgeon or fatigue and tiredness are some of the issues arising with the current manipulation technique. Furthermore, the manipulation of a rigid and stiff uterine elevator could potentially damage the uterine wall due to slippage.

Literature survey reveals that the commercially available uterine elevators do not offer flexibility for pose control, force sensing, intelligence, autonomy or ease of adaptability [5]-[12].

A flexible uterine manipulator which can be fixed in place relative to the patient and controlled remotely whilst the surgeon is sitting at the operating console would be a big step forward in advancing the state-of-the-art of robotic gynaecological surgery. These issues motivate the research on the development of an innovative flexible robotic uterine elevator.

This paper presents the proof-of-concept of a novel pneumatically controlled, octopus-inspired robotic flexible uterine manipulator - GENTLER (Gynaecological ENdoscopic uTerine eLEvatoR), based on a stiffness controllable and soft continuum mechanism with integrated force and pose sensors.

2. Methods

The key features of the new flexible robotic uterine elevator – GENTLER is listed in Table 1. The first concept of GENTLER is shown in Figure 1 and the current design of the functional prototype is shown in Figure 2.

The flexible manipulator has an outer diameter of 20mm. A ceramic/plastic hard cup with an embedded metallic probe of variable sizes is mounted to the front end of the flexible module. The soft module can be positioned in the vagina, so that the cup is placed over the cervix holding it. The tip of the probe will then enter into the narrow uterine cavity and a balloon (not shown in Figure 2) will be inflated to hold the uterus for manipulation.

The core actuation mechanism of GENTLER is the soft silicone manipulator itself. This silicone-based manipulator is soft and is capable of elongating and bending in the sagittal and lateral planes. Furthermore, it can gently squeeze into narrow openings, such as the uterine cavity, and offers controllable stiffness.

Selective and controllable stiffness is expected to offer increased maneuverability and disturbance rejection capabilities for accurate positioning of the uterus. This would allow tuning its compliance in response to the force exerted onto its surroundings, hence avoiding damage to the tissue wall.

In addition to supporting its own weight, including the weight of the rod and cups that are mounted at the distal end of the manipulator, this lightweight manipulator must be capable of manipulating the uterus effectively. The inbuilt controllable stiffness, using the granular jamming mechanism, also ensures adaptability and better load handling of various sizes and weights of the uterus.

Table 1: Design features of GENTLER

Design Feature	Function
Back cup - available in multiple sizes	Maintaining pneumoperitoneum
Pneumatically driven flexible tube with controlled stiffening	1) Soft structure does not damage tissue walls during manipulation 2) Maximum movement range (170 degrees in anterior/posterior sagittal plane; 170 degrees lateral movement in transverse plane) 3) Stiffening control and soft organ interface ensures no tissue damage
Front cup - comes in varying sizes	Provide delineation of vaginal fornices
Remote controlled	1) Ease of manipulation 2) Able to lock device at certain position to stabilize uterus position 3) Avoid fatigue and tiredness
Angled Shaft	Prevent slip during twisting motion
Partially sterilization and partially reusable	Multiple usage and reducing running costs

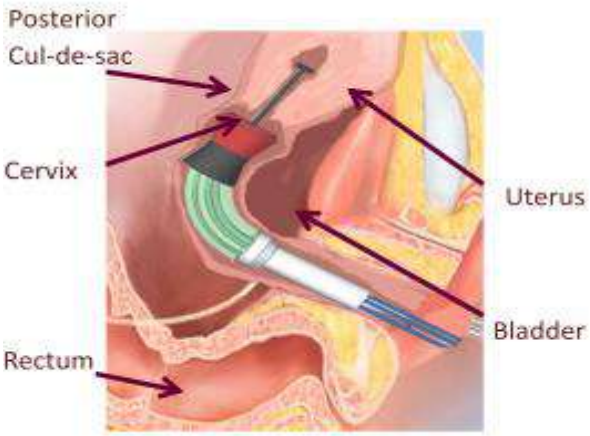

Figure 1: GENTLER Concept

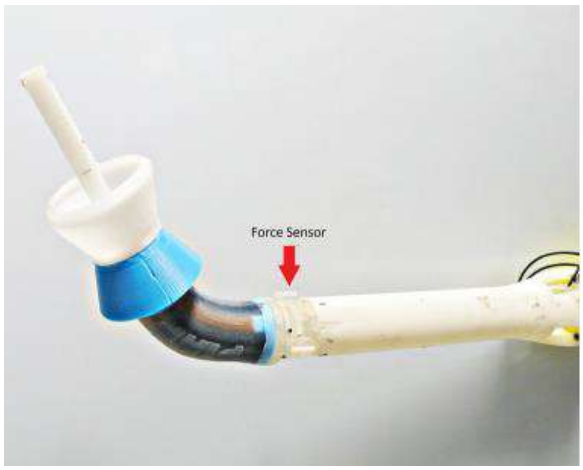

Figure 2: Current functional prototype of GENTLER

3. Results

Experimental results that validate the functionality of the current prototype is presented here. GENTLER was subjected to both anterior and lateral testing. Anterior movement is a movement of flexion and extension of the uterus in the sagittal plane. For anterior testing, the manipulator is actuated to lift the load attached at the tip upward as shown in Figure 3.

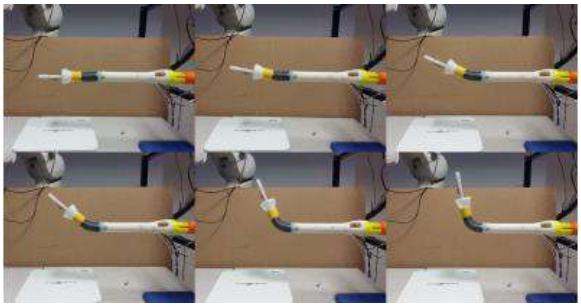

Figure 3: Anterior testing of GENTLER

Table 2: Bending angle with 2 chamber actuation for anterior testing

Weight	Bending angle for 2 chamber actuation without stiffness control	Bending angle for 2 chamber actuation with stiffness control
0 g	>90°	>90°
10 g	>90°	>90°
15 g	>90°	88.3 °
25 g	79.8 °	73.1 °
30 g	64.5 °	59.8 °

Tests were conducted to assess the capability of GENTLER to move in the anterior-posterior plane by actuating two of its chambers with stiffness control and without stiffness control. For both tests, the pressure was initialized to bring the manipulator to a horizontal position so that the tip of the manipulator in aligned with the central line of the manipulator. Then, the pressure within the actuation

chamber was increased incrementally until 90° or until the actuation pressure has reached a maximum of 1.8 bar, whichever occurs first.
A comparison of the bending angle achieved for weight up to 30 g, with and without stiffness control, is shown in Table 2. The manipulator is capable of lifting the 10 g load to reach 90° bending angle before the maximum pressure limit is reached and is able to lift 15 g load to bend 90° at approximately 1.8 bar, which is the maximum limit. However, GENTLER is still unable to bring the 25 g and 30 g load to reach 90°.

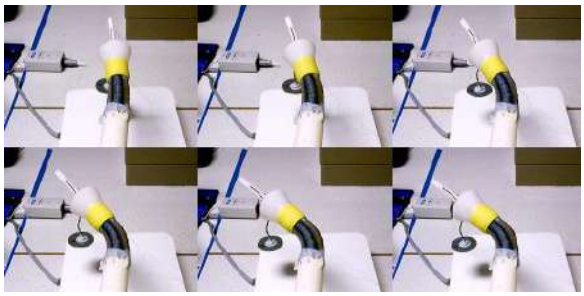

Figure 4: Lateral testing of GENTLER

GENTLER was further subjected to lateral testing in which it is expected to move the uterus to left and right side. This was conducted by actuating the manipulator to left and right of the centerline of the manipulator as shown in Figure 4. Similar to the anterior movement test, the pressure within the chambers was first initialized to bring the manipulator to a horizontal position. The value of chamber pressure is then incrementally increased to move the manipulator that is carrying the load. Here again, the lateral movements were tested with and without activation of the stiffness control.

Table 3: Bending angle with 2 chamber actuation for lateral testing

Weight	Bending angle for 2 chamber actuation without stiffness control	Bending angle for 2 chamber actuation with stiffness control
0 g	>90°	90°
10 g	90°	83.4°
15 g	84.5°	78.1°
25 g	77.9°	72.5°
30 g	59.1°	51.3°

The results for lateral movement test are analogous to the anterior movement tests. The achievable bending angle reduced as the weight at the tip of the manipulator is increased. The highest bending angle the manipulator achieved was 90° (to the left and right of the centerline of the manipulator), when the manipulator is not carrying any load and when 10g is placed at the tip. The maximum bending angle the manipulator can achieve reduced to 85.4° and 78.1° for a system without and with the stiffness mechanism, respectively, when 15 g load is placed at the tip and reduced further with an increase in load. These results are shown in Table 3.

4. Discussion & Conclusion

Commercially available uterine manipulators either require human assistance to hold the manipulator in position or rely on limited capabilities of the motorised, voice controlled holder like the ViKY® UP, which was originally designed for an endoscopy aid. This paper presents the proof-of-concept of a novel flexible robotic uterine elevator for trans-vaginal procedures. This pneumatically actuated uterine elevator is integrated with a precise tip position controller and force feedback controller. It is capable of achieving 180° range of motion in any direction in the absence of load at its tip. However, this range

becomes narrower as more load is placed at the tip. Future research is needed to improve the load carrying capacity of the uterine elevator without losing its flexibility and to incorporate haptic feedback.

Acknowledgement

The authors wish to acknowledge the members of the EU FP7 STIFF-FLOP consortium, in particular, King's College London (UK) for providing their force sensor and Przemysłowy Instytut Automatyki i Pomiarów (Poland) for providing the design of the soft manipulator module.

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O98:

Autonomous Balloon Management for Endovascular Occlusion

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1) University College Cork, Ireland 2) IHU Strasbourg, Strasbourg, France 3) University of Rhode Island, USA 4) Vascular and Endovascular Surgery, University of Stanford School of Medicine, USA.

Introduction

Non-compressible torso hemorrhage is a major cause of preventable death from trauma in civilian and military populations [1]. Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a minimally invasive procedure to increase blood pressure to the brain in such cases. A balloon catheter is inserted through the femoral artery, often percutaneously, and inflated within a patient's aorta. However, prolonged aortic occlusion during transport and in-hospital resuscitation may result in deleterious effects. One possible solution is partial REBOA, where the balloon catheter is inflated to a diameter slightly less than that of the aorta, allowing some distal flow to perfuse the visceral organs. The Autonomus Balloon Management System presented in this work allows automatic pREBOA to be performed while preventing over inflation which could damage the aorta.

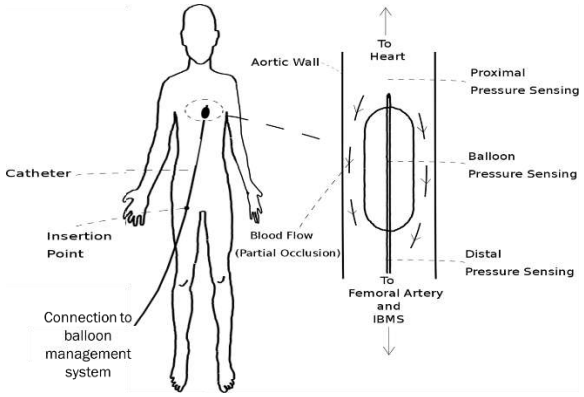

Figure 12- Intelligent balloon management for endovascular occlusion enables a partially occluded aorta allowing distal flow.

Methods

Proximal (above the balloon) and distal (below the balloon) blood pressures, as well as internal balloon pressure (saline) are monitored continuously by the balloon management system. The user may control desired minimum proximal mean arterial pressure (pMAP) via a simple user interface. This user-selected proximal mean arterial pressure is maintained by dynamic inflation and deflation of the balloon catheter within the aorta, which is achieved by controlling a stepper-motor-powered syringe driver to inflate the balloon to the required set point. An Arduino microcontroller is employed to generate a faux PID controller, which uses the three pressure readings in a feedback loop to achieve the required setpoint.

Results

Ex vivo testing was performed on a vascular simulator allowing device characterisation and controller tuning to be performed (Figure 2).

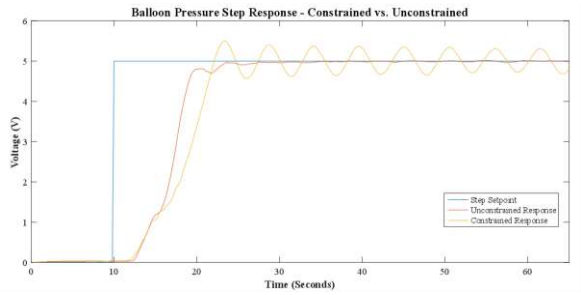

Figure 2 - Step responses for constrained and unconstrained catheter balloon under intelligent control. The damped nature of the control system is visible with roughly 15 second settling time.

Pre-clinical live animal validation was confirmed in three pigs, using a controlled hemorrage protocol and 60 minutes of controlled pREBOA, with user defined blood pressures being successfully maintained throughout the procedure.

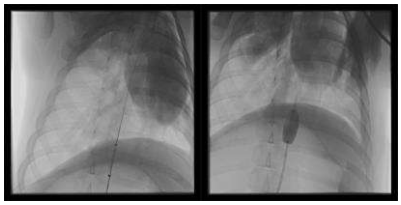

Figure 13 - Fluoroscopy images showing the initial placement of the deflated balloon. Right hand image shows partially inflated balloon, with automoous balloon set-point tracking, which allows distal flow to perfuse through the body.

Discussion & Conclusion

The concept of autonomous pREBOA system has been successfully proven in pre-clinical validation. IBMS maintains a user defined arterial pressure for a partial REBOA situation, can recognise a fully occuluded aorta and prevents over inflation of the balloon.

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O33:

Touchless control of a prototype light system

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1. Introduction

This abstract presents a prototype light system, currently in clinical use in an angiography operation room (OR). The OR is primarily used for minimally invasive procedures such as TEVAR (thoracic endovascular aortic repair). There was a need for an alternative lighting solution because of the likelihood of collisions with specialized equipment (e.g. a robotic CT arm) and the laminar airflow ceiling. An idea mentioned by Hartmann et al. [1] is: "to replace the arm-mounted light [with] remote-controlled lights embedded in the ceiling."

This system comprises 7 controllable (pan, tilt, rotate) ceiling mounted lights. The prototype system is controlled in 2 manners: touchless with midair gestures detected by a Kinect (Microsoft depth camera motion sensor), or using a simple touchscreen interface. The hand tracking is activated by the Kinect through a horizontal **wave** gesture (with an LED tracking status light), and the tracking and lights are turned on/off using a foot pedal.

2. Methods

In order to find out how best to improve the system and assess its usability (including limitations and ideas for improvement), a user survey was administered. The 15 participants (surgeons, radiographers, and nurses) in the survey currently perform or assist in operations in the angiography OR, or have done so recently.

Additionally, the position and usage of the lights was logged. The logging data was compared to the list of performed procedures, so as to understand when and in what procedures the lights are used.

3. Results

Generally, the survey showed the light system meets the basic clinical requirements. The users expressed that the main limitations of the system are not being able to place the lights at specific angles (that non-ceiling mounted lights can achieve) and that the focus of the lights needs to be adjustable. Survey participants with higher self-rated light system skill also rated themselves as more comfortable positioning the lights.

Out of 6 recorded FEVARs the Kinect was used to move the lights on average 2.33 times per procedure (range: 0-5), and the tablet was also used to move the lights on average 1.83 times per procedure (range: 0-5). The lights were turned on average 4 times (range: 2-6) times during each FEVAR. The lights are turned on for periods of a few minutes up to around 30 minutes. One example of the Kinect being used to position the lights, from the data logging, is seen in [fig 1].

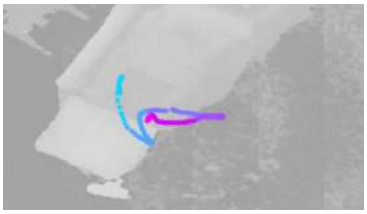

Figure 1: Movement trace of the Kinect hand tracking during a TEVAR procedure, with the depth image shown. The color of the trace indicates where the movement is over time (as it changes from turquoise to pink).

4. Discussion & Conclusion

The gesture recognition reliability needs to be improved (in a realistic setting with many other people / hands in view), and it would be useful to have more gestures to be able to map to more functionality. For instance, a gesture could be used to start and stop the hand tracking instead of using the pedal (which some users expressed can be awkward to access). Feedback is essential to be able to understand if the system is successfully tracking the hand or still searching for a hand. Due to varying

reliability of gesture detection and if more gestures are introduced, it is important for users to understand if an action has resulted in a successful state change.

This prototype allows the clinicians to control the ceiling mounted lights while remaining sterile. This is important because the surgeons are most often those repositioning the lights [2], because they are the ones that know their lighting needs. It is a successful first version of the system, and should be further developed to increase usability and better meet the clinical needs.

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O21: Clear orthodontic aligners biomechanics optimization through finite element analysis

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1. Introduction

Clear aligners treatment (CAT) is spreading in orthodontic world and it is cited to be safe and efficient, but only few papers investigated the predictability and the possible negative periodontal effects of orthodontic movement with clear aligners [1, 2]. The Finite Element Method (FEM) have been proved to be an important instrument in orthodontic research, highlighting forces, moments, displacement and stress distribution areas generated by tested orthodontic appliances. [3]This paper reports two simulations results in which clinical protocols were tested and optimized.

2. Methods

A CAD geometry of upper dental arch, periodontal ligament (PDL), bone, clear plastic aligner and composite attachments was built and imported to a FE software (Fig. 1). Appliance activation was simulated by creating a geometrical gap between aligner and tooth surface, adopting settings similar to interference fit connections. Fixed supports were applied on bone surfaces far away from

tooth and PDL models. Frictional contact settings were applied between aligners and both teeth and attachments. Bonded contact regions were identified between: PDL and Bone, PDL and Teeth, Teeth and attachments, Single tooth aligners (MPC). Frictional connection with a coefficient of μ=0.2 was applied between tooth and aligner.

Material properties for each component was derived from scientific literature. Mesh elements were set of tetrahedral shape, 4 mm size for bone and 0.25 mm for the other components.

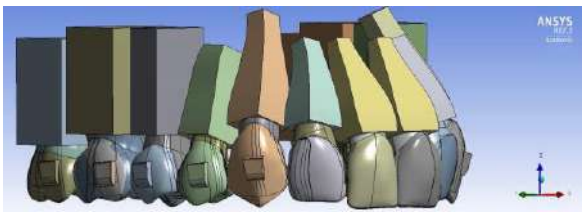

Figure 1: CAD geometry adopted for simulations.

3. Results

From two simulated environments, incisor's root torque movement and first molars rotation optimized biomechanics were obtained (Fig. 2).

Attachments from canines to molars, together with a buccal pressure area on incisors' crown and a crown-rotation activation pattern of 1° released

0.23 N on root PDL with a 0.08 mm root displacement.

Rotation with rectangular attachment only on upper first molars produced a moment of 20 N*mm with a 6 N pressure on mesial surface of the attachment. No collateral forces on molars were reported with this setting.

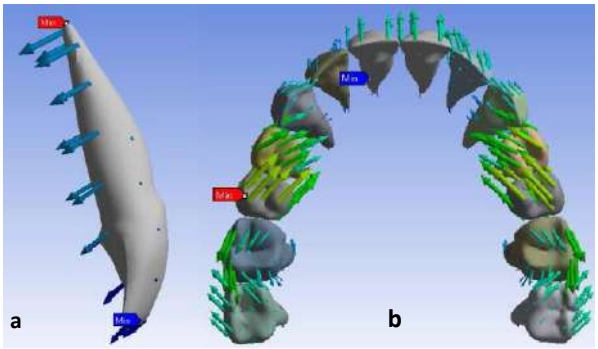

Figure 2: a. Efficient root control with attachments and single pressure area. b. Displacement patterns for the optimized rotational configuration.

4. Discussion & Conclusion

FEM is a reliable technique to study and improve CAT biomechanics, minimizing undesired side effects.

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SESSION 26 – NEW TOOLS FOR LAPAROSCOPY & INTERVENTIONAL RADIOLOGY

O139: A Randomized Controlled Trial of the Fundamentals of Robotic Surgery: Validation of a proficiency-based progression robotic skills course in a multi-specialty, multi-institutional trial.

Satava Richard - University of Washington Medical Center

Objective: To validate the Fundamentals of Robotic Surgery (FRS) skills course in a randomized control trial using multiple simulation platforms.

Methods and Procedures: A randomized clinical trial with a control group and 3 experimental groups: physical "dome" using the robot, virtual reality hybrid simulation using the computer 'backpack' on the surgical console, and stand-alone virtual reality simulator. Training was to proficiency and were set by 80 experts. The multi-institutional trial was conducted 12 international simulation centers and included the multiple specialties that perform robotic surgery.

Results: Face and content validity was verified by 80 experts; concurrent validity was demonstrated by experimental groups performing in less time and with less errors than the control group. The construct validity was demonstrated because the mean time and mean number of errors to perform the various tasks by experts were statistically less the novices. The inter-rater reliability for task specific checklists was $\geq$ 0.80, however the Global Evaluative Assessment of Robotic Skills (GEARS) inter-rater reliability was $\leq$0.80

Conclusion: The Fundamentals of Robotic Surgery is a validated course to teach novices the simplest robotic surgery skills across the many specialties that are currently performing robotic surgery. All the four validities were confirmed on a physical dome model, or any of the computer/virtual reality simulators. The FRS is a robust and validated course (curriculum) to train the basic skills in robotic surgery.

O136:

Safety of single incision robotic cholecystectomy for benign gallbladder disease: a systematic review

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1. Introduction

Multi-port Laparoscopic Cholecystectomy (MLC) is the gold standard technique for cholecystectomy. In order to reduce postoperative pain and improve cosmetic results, the application of the Single-Incision Laparoscopic Cholecystectomy (SILC) technique was introduced, leading surgeons to face important challenges like reduced range of motion and collisions between instruments, loss of classical triangulation, poor ergonomic positions of the surgeon. Robotic technology has been proposed to overcome some of these limitations. The purpose of this review is to assess the safety of Single Incision Robotic Cholecystectomy (SIRC) for benign disease.

2. Methods

An Embase and Pubmed literature search was performed in February 2017. Randomized Controlled Trial and Prospective observational studies regarding SIRC were selected and assessed using PRISMA (Preferred Reporting Items for Systematic review and Meta-Analyses) recommendations. Primary outcome was overall postoperative complication rate. Secondary outcomes were postoperative bile leak rate, total conversion rate, operative time, wound complication rate, postoperative hospital stay and port site hernia rate. The outcomes were analyzed in Forest plots based on fixed and random effects model. Heterogeneity was assessed using the I^2 statistic.

3. Results

A total of 13 studies provided data about 1010 patients who underwent to SIRC for benign disease of gallbladder. About 20% were affected by acute cholecystitis. Overall postoperative complications rate was 11.6% but only 4/1010 (0.4%) patients required further surgery. Postoperative bile leak rate was reported in 3/950 patients (0.3%). Total conversion rate occurred in 4.2% of patients (2.2% to laparoscopy, 2% to open surgery). Operative time consisted of an average of 86.7 minutes to which an average of 42 minutes should be added as for robotic console time. Wound complication rate was reported as 3.7%. Postoperative hospital stay was about 1 day. Port site hernia at the latest follow-up available occurred in 5.2% of patients.

4. Discussion & Conclusion

The use of robotics while performing single port technology seems to obtain similar results in terms of complications and grade of complications compared to standard laparoscopy, while it seems affected by the same limitations of single port surgery consisting of an increased operative time and incidence of port site hernia. No data about pain and cost could be analyzed.

O94: Improving fundamental laparoscopic skills by pre-course tactile exploration

Hardon Sem F., Postema Roelf R., Horeman Tim, Smeets Jeroen B.J., Bonjer H. Jaap - VU University Medical Center, Departmetn of Surgery, Amsterdam, Netherlands

Introduction

Minimally invasive techniques in operation rooms have reduced the tactile and visual feedback compared to open surgery. There is increasing evidence in the neuropsychological literature that visual and haptic information combine or converge to form a mental representation of an object. Because of the combination of these inputs, this mental representation is better, more refined and robust than the image formed by only one of these sensory inputs. We investigated whether haptic exploration of a 3D object before executing a laparoscopic action improves performance.

Methods&Materials

A randomized prospective cohort study was conducted using a case-crossover design. Third year medical students (*N=18*) with no prior laparoscopic experience were included.

Based on well-known FLS tasks, three more complex task platforms were designed and produced for this course using a 3D-printing system. In a box trainer, the participants executed a *peg transfer task* as a baseline test, followed by three repetitions of each 3D task.

The box trainer was equipped with state-of-the-art Forcesense system (Medishield, Delft, The Netherlands) for adequate assessment of skill based on force, motion and time parameters. P Penalty points for errors (e.g. dropping a peg, rope or ring) were scored through analysis and evaluation of captured videos of each performance.

Results

A total of 324 performances were recorded and analyzed. Differences in parameter outcomes and errors were compared between groups. Less errors (i.e. dropping a peg or ring) were detected in video analysis of the pre-course tactile exploration group (*p<0,001*). Additionally, in the same group, lower maximum exerted tissue manipulation forces were detected in the second performed task (*p=0,002*).

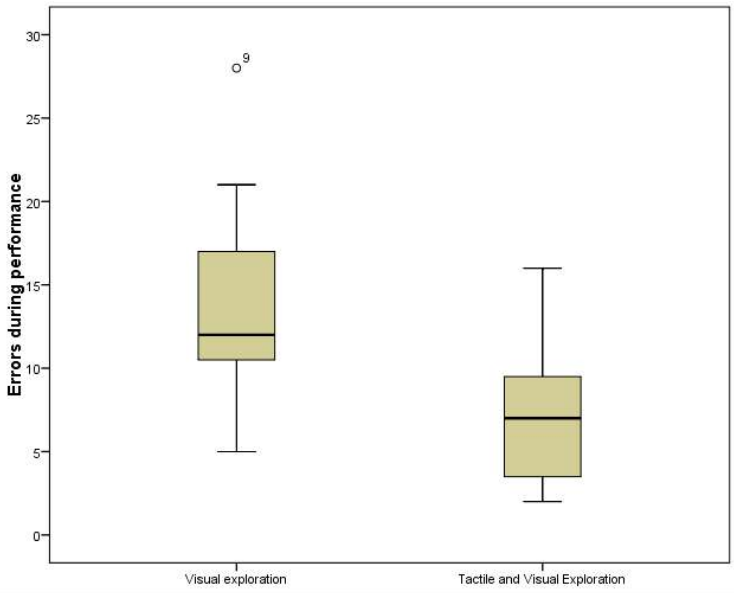

Figure 1 Boxplots showing significant decrease in errors after tactile pre-course exploration, in addition to visual exploration

Discussion & Conclusion

This study shows that pre-course tactile exploration (in addition to visual exploration) results in less errors during performance of fundamental laparoscopic skills tasks. This finding can be of importance in laparoscopic training as it can result in more efficient and accelerated learning curves.

O81: Sentinel node navigation surgery and ICG fluorescence-guided surgery for gastric cancer

Inaki Noriyuki, Tsuji Toshikatsu, Minami Teruya - Ishikawa Prefectural Central Hospital, Gastroenterological Surgery, Kanazawa, Japan

Introduction: We have performed sentinel node navigation surgery (SNNS) for treatment of early gastric cancer through a prospective multicenter trial in Japan using dual tracer endoscopic injection technique. On the other hand, ICG fluorescence-guided surgery has recently used for various digestive surgery in which blood supply or lymphatic basin can be confirmed. We applied the ICG fluorescence-guided technique to complete radical lymphadenectomy for gastric cancer surgery. Both concepts of ICG-using procedure are different each other. In this paper, we demonstrate each procedure and evaluate the feasibility and validity.

Methods: A dual-tracer method using radioactive tin-colloids and ICG is considered reliable method for the detection in patients of early gastric cancer. For early gastric cancer, the establishment of individualized, minimally invasive treatments based on SN concept can retain the patients' quality of life. The laparoscopic and endoscopic cooperative surgery (LECS) has also realized minimally partial resection for gastric tumor, and the closed-LECS, which doesn't require direct opening of the stomach wall and can avoid tumor spreading. Indication of closed-LECS is early gastric cancer, whose tumor size is within 4 cm in diameter. The stomach are laparoscopically conducted and a local injection of 0.5ml ICG 0.5% (5mg/ml) is endoscopically performed. SN is detected and the lymphatic basin (LB) including SN is dissected. Following removal of the whole SN, the LB is checked by intraoperative pathology diagnosis. The closed-LECS is started when all examinations confirm negative SN (Video 1). ICG fluorescence-guided surgery is routinely used laparoscopic gastric cancer surgery. Single tracer of ICG is used for radical lymphadenectomy.(Video 2).

Results: Two cases for early gastric cancer underwent closed-LECS using double tracer. Eighteen cases for gastric cancer underwent ICG fluorescence-guided gastrectomy with radical lymphadenectomy. In both procedures, there was no intra- and post-operative complication.

Conclusion: Sentinel node navigation surgery and ICG fluorescence-guided surgery for gastric cancer is expected to be established as the individualized effective surgical procedure for gastric cancer treatment.

O85: Indocyanine green guided sentinel lymph node identification – a prospective study evaluating the distribution of lymph nodes respectively lymph node metastasis in rectal cancer patients

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1. Introduction

Lymphatic metastasis in rectal cancer is a prognostic parameter and has a strong influence on survival of the patient [1]. It is therefore important to ensure complete lymphadenectomy during the operation in rectal cancer patients. To enable the surgeon to identify the lymph nodes (LN) intraoperatively, we conducted a prospective study. We used Indocyanine green (ICG) to visualize the lymph nodes (sentinel lymph node (SLN)). The aims of our study were to localize the SLN, respectively the metastatic lymph nodes in rectal cancer patients.

2. Methods

We conducted a prospective study on rectal carcinoma patients, regardless of the prior treatment [2]. The statistical calculation determined a group size of thirty patients to identify at least one sentinel lymph node. Two ml of ICG was injected endoscopically in the submucosa near the tumour lesion in the rectum. After anterior or abdominoperineal resection of the rectum including total mesorectal excision, the specimen was illuminated with a near infrared light (NIRL) camera unit to visualize the lymph nodes. They were identified and marked. This was followed by illuminating the operation site with the NIRL camera unit, to detect any missed lymphatic tissue. The examination of the specimen in the pathology department included search for lymph node metastasis (LNM) by immunohistochemistry. Depending on the presence of metastatic disease all lymph nodes were classified as node positive or node negative. LNM was mapped, according to the tumour site, to above or below the tumour.

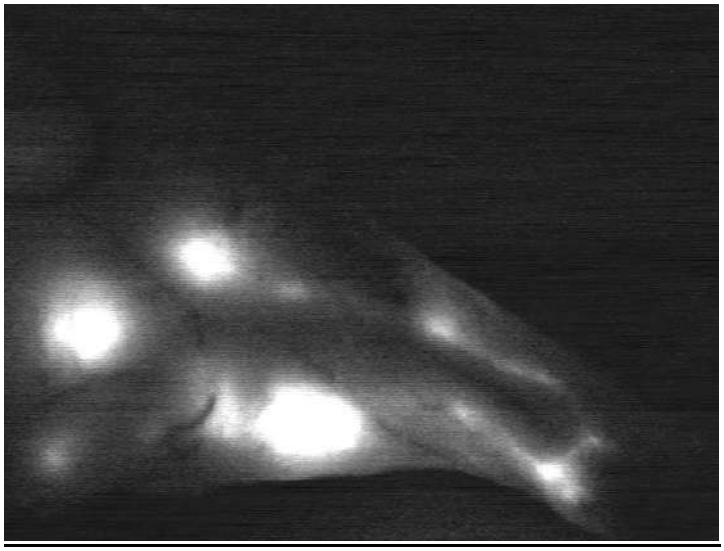
3. Results

Thirty patients with rectal cancer were included in the study. Eleven patients had a rectal cancer in the lower third, nineteen in the middle rectum. Fourteen patients received prior to surgery chemoradiotherapy (CRT). In fifteen patients the tumour was classified T3 (Table 1). We could identify at least one SLN in all operated patients (n=30). In total a 122 SLN were identified in thirty patients. In three patients the SLN were false negative. Two of these patients received chemoradiotherapy (CRT) before operation. The lymph node yield was in minimum 16 and in average 33.5 lymph nodes. In total we excised 1004 lymph nodes. Considering preoperative treatment, the CRT group (n=14) of patients had a mean lymph node yield of 27.7 LN. In the NoCRT group (n=16) the LN yield was 38.5 (in mean). Lymph node metastasis (LNM) was present in 11 patients. In only one patient the LNM was exclusively found above the tumour. And in three patients the LNM was found below the tumour. Seven patients had above and below the tumour LNM. Interestingly the patients with false negative SLN had only above or below the tumour LNM.

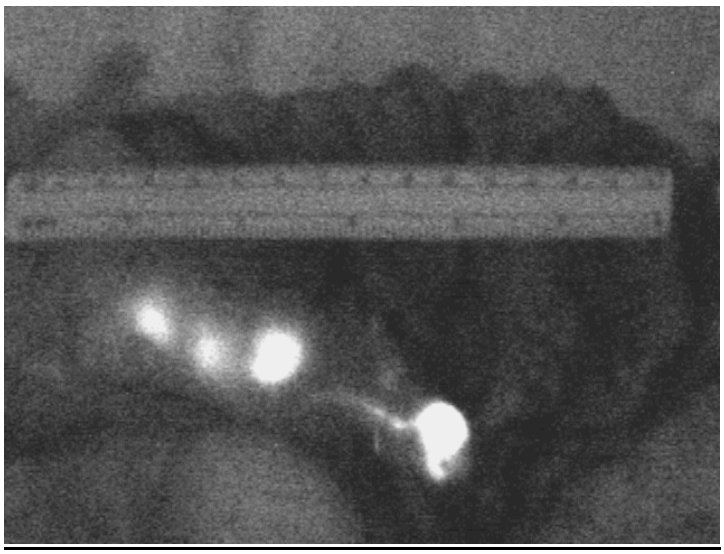
4. Discussion and Conclusion

ICG was successful in detecting SLN in rectal cancer patients. The sensitivity to detect SLN was high, especially in the group of patients without CRT. Our findings suggest that CRT can impair SLN detection, although in this study the number of retrieved lymph nodes of patients with neoadjuvant CRT met the recommendations. The location of lymph node metastasis was found to be not only above, but also below the tumour site. For comprehensive lymphadenectomy the ICG application can be helpful. Through intraoperative visualization of the sentinel lymph nodes the surgeon is enabled to visualize lymph nodes respectively lymphatic vessels and therefore can adjust resection margins to improve the quality. The application of ICG was simple and feasible, without affecting the operating time. However, further studies are required to adopt this concept for routine use in the operation of rectal cancer patients.

Picture 1: SLN visualisation in situ mesorectum



Picture 2: SLN visualisation ex situ specimen



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O59: Instruments and situation awareness: main risk-factors for surgery

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Introduction

Although in (Dutch) hospitals, rates of healthcare related avoidable harm decreased during the last decennium [1], still errors occur in the operating room (OR) due to the complex non-standardized OR environment, inadequate situation awareness, bad teamwork and communication and the large variety of (non-ergonomic) instruments and equipment [2, 3]. To prevent errors from occurring, we designed and implemented a Time Out Procedure *plus* debriefing (TOP*plus*)[4]. The aim of this study was to establish risk-factors for avoidable patient's harm and adapt TOP*plus* accordingly to prevent future errors.

Methods

OR team members were asked to self-report 'details' (remarks and incidents) about the surgery before introduction of TOP*plus* (T_0 baseline measurement) and six months after introduction (T_1). Hospitals were not pre-selected, but joined the TOP*plus* study voluntarily over time. Details were registered via paper registration forms. Data were digitalised and were categorized into remarks and incidents (defined as [5]). Both remarks and incidents where subdivided in subcategories relating to: anaesthesia, surgery, communication, instruments and equipment, leadership, situation awareness, teamwork, perfusion, and TOP*plus.*

Results

In total 8 out of 15 hospitals completed T_0 and T_1: 3 academic, 2 teaching and 3 general hospitals.

Figure 1: Number of self-reported remarks and incidents.

The number of registration forms received included: T_0, n=2,724; T_1, n=22,764 (see Figure 1). In T_0, 18.5% of registrations included an incident and in T_1, 4.6% of registrations included an incident. Figure 2 shows that most self-reported incidents in both T_0 and T_1 were related to situation awareness (T_0: 44.4% - T_1: 26.8%) and to the instruments and equipment (T_0: 29.6% - T_1: 41.8%). The main reasons for the instrument-incidents were linked to incomplete and defect instruments or equipment.

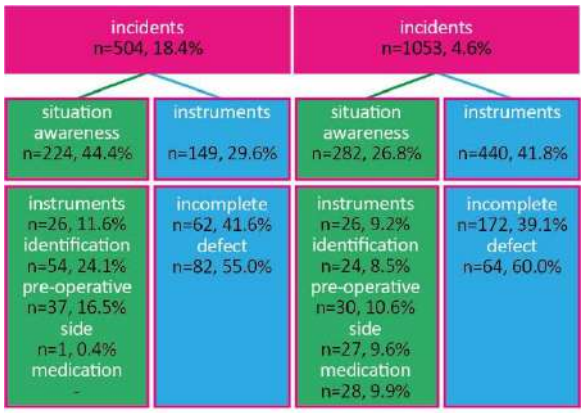

Figure 2: Situation awareness and instruments; main self-reported incidents.

Discussion & Conclusion

Defect and incomplete instruments and equipment and inadequate situation awareness are the main causes of incidents in the OR and therefore the main risk-factors for patient harm. The number of incidents will probably be higher due to (self) underreporting. Although incidents relating to a lack of situation awareness can be addressed and prevented by TOP*plus*, the 'defect' instrument and equipment need redesign to further improve patient safety.

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O147:

Morphological and hemodynamic characterization of post endovascular AAA repair: comparison between two different commercial devices

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1. Introduction

Abdominal aortic aneurysm (AAA) is a vascular disease characterized by a localized expansion of the abdominal aorta. In the last years the minimally invasive endovascular aortic repair (EVAR) approach for AAA treatment has been widely applied as alternative to classical open-chest surgery. EVAR results in (1) redirection of blood through the deployed endograft, and in (2) iliac bifurcation reshaping, thus altering local hemodynamics [1]. In this study the impact that two different commercial endovascular graft (EG) devices, have on vascular geometry and hemodynamics is investigated. In detail, geometric features are pre- and post-operatively evaluated. Computational Fluid Dynamics (CFD) is applied to explore if the vascular territory post interventional reshaping supports the re-establishment of physiological hemodynamics.

2. Methods

Subjects suffering from AAA were treated with two EG systems, N=5 with the Endurant® (Medtronic, CA, USA), N=5 with the Excluder® (Gore Medical, AZ, USA) (fig. 1). Also N=5 healthy subjects underwent CT angiography. CT scans were obtained before and one month after EVAR [1]. 3D models were reconstructed from CT images[1].

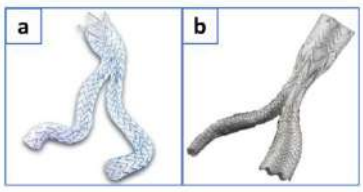

Figure 1: (a) Endurant device, (b) Excluder device.

Centerline-based geometry analysis was carried out on reconstructed models, in terms of curvature, torsion, normalized cross-sectional area and cross-sectional area variation rate [2]. The reconstructed 3D geometries were meshed with tetrahedral elements [1]. The governing equations of blood flow were solved by using the finite volume method. Boundary conditions at inflow and outflow sections were based on flow and pressure measurements [1]. Near-wall hemodynamics and intravascular flow structures were described in terms of time-average wall shear stress (TAWSS), and in terms of helical flow, blood recirculation volume (RV), respectively.

3. Results

Geometric features are similar between treated groups but present higher and more scattered values than healthy subjects, as an average. In terms of hemodynamics, subjects treated with the Excluder present lower percentages of surface area exposed to low WSS and lower RV (fig. 2).

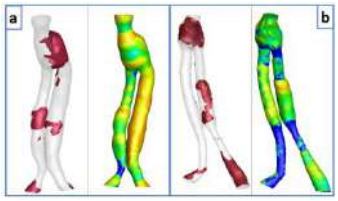

Figure 2: Explanary RV and TAWSS maps: (a) Endurant; (b) Excluder. In TAWSS maps low values are colored with red.

Overall, the Excluder group presents the highest TAWSS and helicity intensity values.

4. Discussion

From the geometrical point of view there are no-marked differences between the two devices. From the hemodynamic point of Excluder models present a higher mean value of TAWSS and helicity that could confirm that the helical flow plays a beneficial role in suppressing low velocity/stagnation regions that could lead to thrombus formation.

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O105: Assessing non-technical skills in the delivery room through multisensory-based simulation

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1. Introduction

High-fidelity simulation (HFS) has proven to be an effective methodology for medical training and for reducing adverse events in the delivery room [1]. The debriefing is the crucial learning moment of the whole method, since it boosts proper metacognition on the actions taken during the simulation [2]. However, the focus is often directed to technical aspects (e.g., drug administration, specific procedures, etc.) while the so-called non-technical skills (NTS, i.e., situation awareness, decision making, communication, leadership, teamwork, workload management) are overlooked or only superficially tackled [3]. Unfortunately, literature on risk management demonstrated that the main contribution to adverse events is due to non-technical issues. HFS has the potential to be one of the most effective methods to train NTS, but it should be based on a sound method to observe and assess them [4].

2. Methods

We are currently developing a method to assess NTS during delivery room emergency simulation, which is based on the integration of multiple sources of information. We developed a comprehensive set of checklists of NTS behavioral markers for each professional and for team performance. These tools will be associated to other behavioral cues representative of NTS, which will be recorded by means of both remote sensors (e.g. 360-degree cameras) and wearable sensors. The data are based on: (i) physiological recordings (e.g., heartbeat, skin conductance, etc.); (ii) body movements (e.g., posture, kinesics, proxemics, gaze direction, etc.); (iii) linguistic and paralinguistic features (e.g., presuppositions, voice pitch, hesitations, emotional contents, etc.); (iv) facial expressions (e.g., muscular patterns related to emotion expressions).

3. Results

The NTS behavioral markers checklists have already been validated and participants to simulation sessions positively rated them for usefulness and usability [5]. We are currently performing pilot tests in simulated scenarios with the addition of wearable and remote sensors and the participants' feedback is positive.

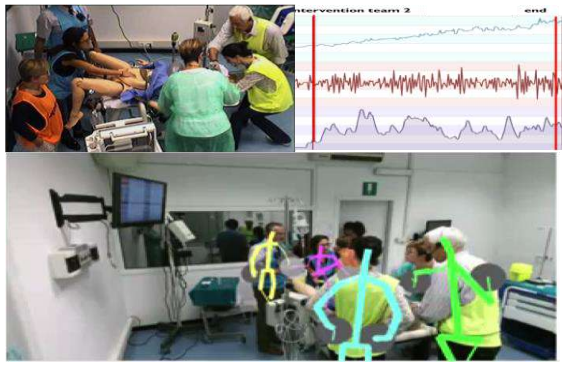

Figure 1: Top-left: the team during the simulation. Top-right: physiological parameters recorded during the simulation. Bottom: a remote-capture of bodily postures.

4. Discussion & Conclusion

Putting together all these cues, we will be able to enrich the debriefing session and the discussion about NTS, since abstract constructs such as leadership or communication will be operationalized in concrete data and observable behavioral patterns. Learning will be improved because it will be based on a multifaceted analysis of aspects that, until now, have only been generically defined as "the contrary of technical skills".

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O128:

Instrumentation of an external fixator for bone healing process monitoring: preliminary results

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1. Introduction

Following a compound fracture, one of the most common surgical treatments is based on the use of external or internal fixators. The success of fracture repair depends on the restoration of the bone biomechanical functions and properties. In order to evaluate the status of a compound fracture different imaging techniques are currently used (*e.g.*, computer tomography, radiography). These techniques present some drawbacks to patients and doctors, such as a frequent exposure to radiations. Recently other methods, based on the measure of static stiffness for evaluating the status of the bone healing process stabilised by means of an external fixator, have been proposed [1], [2].

The aim of this study is to present the preliminary results of an instrumented external fixator to quantitatively assess the bone healing process in terms of frequency resonance and amplitude by means of vibration response.

2. Methods

Figure 1 shows the setup used in this study: the sawbone model of a humerus was integrated with two strain gauges (one for each side), an electrical motor and an Arduino electronic board. The fixated saw-bone humerus was subjected to a through-cut to simulate a fracture.

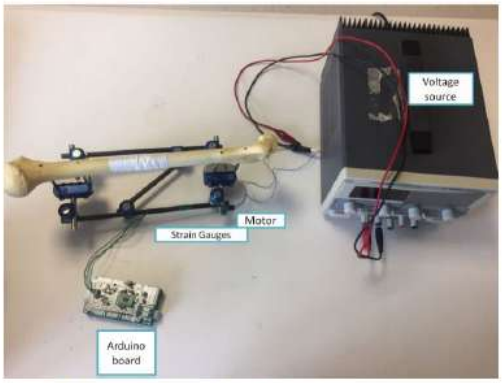

Figure 1. Setup used in this study.

In order to test the system, a different range of voltages (from 1.0 V to 3.0 V, each step represented by 0.1 V) was applied. At each voltage the frequency and the amplitude were measured, by determining the highest amplitude and the resonance frequency of the whole system composed by the external fixator and sawbone model.

3. Results

The vibration amplitudes of the fractured sawbone model are reported in Figure 2. The resonance frequency is 184.9 Hz, corresponding to a motor voltage of 2.3 V.

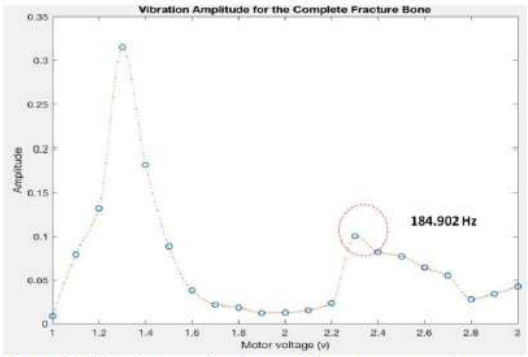

Figure 2. Vibration amplitudes at different motor voltages.

4. Discussion & Conclusion

The first amplitude peak observed at 1.3 V corresponds to the intrinsic resonance frequency of the whole system. The second amplitude peak observed at 2.3 V (corresponding to 184.9 Hz) represents the typical mechanical characteristic of the fractured sawbone model.

The application of vibrations to the whole system is able to provide useful information on the mechanical characteristics of the bone which can be used by the orthopaedic surgeons and rehabilitation staff to monitor, even remotely, the bone healing process.

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SESSION 18 – INNOVATION IN COLORECTAL ENDOSCOPY & SURGERY

0111:

LESS IS MORE: NUOVO APPROCCIO ALL'ADDOME APERTO

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INTRODUZIONE:
L'UTILIZZO DELLA TECNICA DELL'ADDOME APERTO NELLA GESTIONE DEL PAZIENTE CRITICO PRESENTA DIFFUSIONE SEMPRE MAGGIORE. LE PRINCIPALI INDICAZIONI SONO: SINDROME COMPARTIMENTALE, GESTIONE DELLO SHOCK EMORRAGICO DA CAUSA INTRAADDOMINALE NON IMMEDIATAMENTE CONTROLLABILE, TRATTAMENTO DELLE SEPSI DA PERITONITE SEVERA. MENTRE SONO SOSTANZIALMENTE ABBANDONATI L'UTILIZZO DELLA "BOGOTA-BAG" E DELLE PROTESI SINTETICHE "A PONTE", L'UTILIZZO DEI SISTEMI A PRESSIONE NEGATIVA (BARKER'S VACUUM PACK TECHNIQUE □, ABTHERA OA NPT □) TROVA SEMPRE MAGGIORE CONSENSO. ESSO È, TUTTAVIA, GRAVATO DA IMPORTANTI CONTROINDICAZIONI, IN PARTICOLARE L'IMPOSSIBILITÀ DI UTILIZZARLO IN CASO DI SANGUINAMENTO ATTIVO E L'ELEVATO RISCHIO DI FISTOLA ENTEROATMOSFERICA; LA STRUMENTAZIONE NECESSARIA NON È INOLTRE SEMPRE DISPONIBILE IN URGENZA.

METODI:
Abbiamo brevettato un divaricatore/protettore di parete anulare modificato al fine di renderlo adatto alla creazione di una laparostomia temporanea sicura e agevolmente frubile. Esso è configurato come un normale retrattore di parete a doppio anello ma include un cappuccio trasparente di materiale polimerico ed è dotato di apposite asole che consentono l'ancoraggio alla cute mediante sutura (FIG.)

RISULTATI:
IL NOSTRO DISPOSITIVO SI PUÒ UTILIZZARE NEL PAZIENTE EMORRAGICO SENZA CHE VENGA APPLICATA PRESSIONE NEGATIVA, NELL'ADDOME SETTICO IN ASSENZA DI ALTRI PRESIDI, IN PRESENZA DI ESTREMA FRAGILITÀ TISSUTALE CHE CONTROINDICHI L'ASPIRAZIONE E IN PREVISIONE DI REVISIONI IN TEMPI BREVI. LA POSSIBILITÀ DI POSIZIONARE DRENAGGI CONSENTE L'EVACUAZIONE DEI FLUIDI QUANDO È NECESSARIO.

DISCUSSIONE:
Il re-accesso al cavo addominale è immediato e il cappuccio trasparente consente un controllo delle condizioni dello stesso in tempo reale; non viene inoltre a crearsi alcun danno alla parete che rimane anzi continuativamente protetta. Il dispositivo è poco costoso e facilmente utilizzabile anche da centri che non abbiano a disposizione attrezzature per sistemi a pressione negativa.

O14:

RED – Robot for Endoscopic Dissection: preliminary study

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2) Department of Surgical Sciences, University of Torino, Turin, Italy.

Introduction

Endoscopic Submucosal Dissection (ESD) is a flexible endoscopic technique that allows for an en bloc removal of lesions of the gastrointestinal (GI) tract. However, it is associated with high risks of complications and the procedures are long, often requiring around 95min for lesions of even only 3-4cm in diameter. The risk of haemorrhage ranges from 3.5% to 15.5% and the possibility of intestinal perforation is also high (up to 18%) [1]. A flexible robotic endoscope may offer a solution to overcome these limitations, by improving the degrees of freedom (DoF) and operational efficiency [2].

Methods

RED is a novel miniature robotic platform for ESD, designed to effectively remove tumours of the entire GI tract. It has been designed to be coupled to the tip of traditional flexible endoscopes of about 14.5 mm in diameter. The robot exploits the flexibility of the endoscope for navigation through the intestine and integrates 2-actived robotic arms (*i.e.,* cautery and gripper) extending the degrees of freedom (DoF), and thus enhancing the efficiency during complex tasks such as manipulation and surgical tissue dissection. The RED system is supported by an external platform, a personal computer and two Geomagic Touch phantoms (3D System, Inc) (Fig. 1).
During the operation, the surgeon (referred to as *surgeon A*, Fig.1) stands close to the patient to manoeuvre the endoscope for exploring the GI tract and reaching the target area. Another surgeon (referred to as *surgeon B,* Fig.1) operates the RED arms through the computer console, carrying out the surgical procedure.

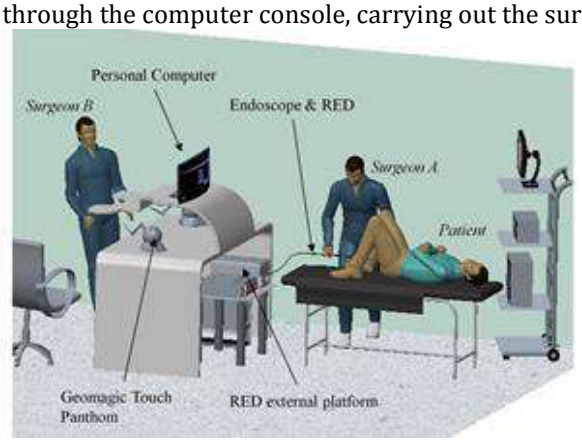

Fig. 1: An overview of the surgery scenario

Results

RED consists of a cap body with two robotic arms (Fig.2). The right arm is equipped with a surgical gripper to grasp and lift the tissue; it is featured by 3 DoFs (*i.e.,* slide, pitch and open/close of the gripper). The left arm is a mono-polar cautery with 3 DoFs (*i.e.,* slide, roll and pitch) employed to cut the lesion. While navigating through the intestine, the RED arms are enclosed in the cap body; when the target area is reached, the arms are deployed and they can start to operate. The external shape of the cap body is approx 27mm in diameter (including the endoscope tip) and has a total length of 50mm; these sizes have been defined considering anatomical constraints (*i.e.,* dimension and shape of the intestine).

Fig. 2: RED design.

Discussion & Conclusion

RED has been designed thanks to a deep collaboration between engineers and medical doctors. It will help the surgeon to accurately excise target tissue through precise dissection. The gripper arm is expected to generate around 3N of lifting force and 10-14N of gripping force. Around 1.5N are availble at the cauthery tip. There are various advantages of using this robotic device. A traditional endoscopic room is enough to carry out a complete surgical operation and the patient does not need to undergo surgery under general anaesthesia. The hospitalization times, and hence the general hospital costs, could be significantly reduced. For the future, we will validate the functionality of the RED, by conducting in-vivo experiments to prove the clinical advantages of the proposed system.

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O112:

ENDOSCOPIC FULL THICKNESS RESECTION: PRELIMINARY INDICATIONS AND RESULTS

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Introduction

Endoscopic full thickness resection (EFTR) is a new procedure to remove difficult lesions, such as epithelial or sub-epithelial tumours unsuitable for conventional resection even with endoscopic mucosal resection (EMR) nor with endoscopic sub-mucosal dissection (ESD). Recently, a new over the scope clip (OTSC) device named full- thickness resection device (FTRD) has been used to perform a full thickness resection in one-step procedure. It consists of a modified OVESCO clip with a longer cap and an integrated snare.

Aims & Methods

Our aim was to evaluate the efficacy and the safety of OTSC assisted EFTR for recurrent adenomas and for evaluation of the muscular layer in neuromuscular suspected diseases. Patients who underwent OTSC assisted EFTR between December 2015 and December 2016 at San Giovanni Bosco Hospital, Torino, were included. The procedure consisted of a) lesion or wall suction into the cap of the OTSC, b) clip deployment and c) en-bloc resection of the lesion above the clip using an electrosurgical snare. Procedure was performed under monitored anaesthesia assistance. Demographic, clinical data, histopathologic diagnosis and adverse events were registered.

Results

Six patients (1 male, median age of 62 years) were included. Four patients underwent EFTR for recurrent adenomas, 2 in the rectum (10 and 12 mm) and 2 in the cecum (9 and 24 mm). In case of proximal adenomas a demo OTSC was used before the procedure to ascertain the possibility to reach the lesion. Moreover 2 patients with chronic severe constipation underwent EFTR to obtain a full thickness sample of the rectum for muscular layer examination. Histopathology confirmed a full-thickness R0 resection (negative margins) in all cases with adenomatous lesions and diagnosis of intestinal neuronal dysplasia in the 2 cases of intestinal chronic constipation. The mean procedure time was 60 minutes (range: 40-75 min). No adverse events occurred. No immediate or delayed perforations were observed, all patients were discharged after 24 hours.

Conclusion

These preliminary data show that OTSC assisted EFTR was effective and safe to remove difficult and recurrent adenomas and to obtain full thickness rectum sample for the diagnosis of neuronal dysplasia. The technique was quite easy in the rectum but it may be challenging in more proximal tracts and a demo OTSC device was used to confirm the possibility to reach lesions located at the cecum.

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O90: QUALITY OF MESORECTAL EXCISION AFTER OPEN, LAPAROSCOPIC, ROBOTIC AND TRANSANAL TME

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1. Introduction

Colorectal cancer is the third most common cancer in the World. Neoadjuvant chemoradiotherapy followed by radical surgery is considered the standard treatment for locally advanced middle and low rectal cancer. Removing all of the mesorectum containing the lymph nodes and tumour is paramount for a good outcome and minimal recurrence within the pelvis. Involvement of the circumferential resection margin (CRM) and the quality of total mesorectal excision (TME) are related to local recurrence and long-term survival 1-3.

The aim of the present prospective study is to evaluate the safety and efficacy of laparoscopic resection vs open vs robotic versus transanal TME. A successful resection was defined when meeting all the following criteria: complete total resection margin, a clear CRM (>1mm) and a clear distal resection margin (>1mm).

2. Methods

Specimen from a series of 101 consecutive patients undergoing TME for histological proven rectal cancer at the Dpt of Oncologic Surgery of San Giovanni Hospital, Rome from July 2015 to July 2017, were collected and pathology exam data recorded prospectically. Evidence of distant metastases was not an exclusion criterion. Patients were divided according to surgical technique in four groups: open (OP), laparoscopic (VLS), robotic (ROB) and TaTME (Ta). Patients who were converted from mini-invasive to open procedure were considered in a different group (VLSconv). Localization of the tumour was categorized as: upper rectum (10-15 cm from the anal verge), middle rectum (5 to 10 cm from the anal verge), low rectum (<5 cm from the anl verge). Demographic data and histopathologic characteristics of the tumour such as lesion size, distance from the anal verge, regression grade after neoadjuvant reatment according to Mandard scale and number of lymph nodes retrieved were analysed. CRM was defined involved when tumor cells were present within 1 mm from the lateral surface of the mesorectum. Completeness of mesorectal excision was defined according to Quirke classification as complete, nearly complete or incomplete.

3. Results

Twenty-eight (27.7%) patients underwent open rectal resection, 35 (34.7%) laparoscopic rectal resection, 18 (17.8%) robotic rectal resection and 13 (12.9%) were treated by trans-anal TME. Seven patients (6.9%) were converted from mini-invasive to open rectal resection. 39 patients (38.6%) with cancer in the upper part of the rectum underwent partial mesorectal excision (PME); 37 patients (36.6%) with cancer in the middle rectum and 39 patients (38.6%) with cancer in the lower rectum underwent total mesorectal excision (61.4%). There were no statistically significant differences between group with respect to sex, age, body mass index, ASA grading, tumour stage and tumour location. CRM resulted positive in 5 patients (4.9%), 2 in the VSL group, 1 in the ROB group and 1 in the VSLconv. Overall, mesorectal excision resulted complete in 68 patients (67.3%), nearly complete in 13 patients (12.9%) and incomplete in 20 patients (19.8%). There were no statistically significant differences between groups (p=0.3). In the sub-group analysis, considering patients with middle and low rectal cancer who

underwent TME, there were no positive margins in the OP g and TaTME g. versus 1 in the VSL g, 1 in the ROB g. and 2 in the VSLconv (p=0.001). According to Quirke classification, complete TME was found in 78% patients in OP g., 66.7% in VSL g., 84.6% in TaTME g. and 50% in ROB group. Nearly complete TME was found in 7.1% in the OP g., 5.6% in the VSL g., 16.4% in the TaTME g. and 21.4% in the ROB group. Incomplete TME was found in 14.3% in the OP g, 27.8% in the VSL g. and 28.6% in the ROB g. None of the patients who underwent TaTME resulted with incomplete TME (p=0.02). Multivariate regression analysis showed that surgical technique was associated with the completeness of mesorectal excision (p=0.02). No differences were found in term of lymph-nodes retrieval (p=0.8) and distal resection margin (p=0.2).

4. Discussion and Conclusions

This prospective single center study investigates hysto-pathologic assessment of the resected protectomy specimen focusing on clear distal and radial margins and completeness of total mesorectal excision, the combination of which defines optimal surgery, and has been shown in other trials to be associated with better long term oncologic outcomes4. We demonstrates that TaTME is not only a feasible and safe technique but improves oncological resection principles in middle and low rectal cancer resulting in better mesorectal excision and circumferential resection margin. Further prospective comparative study are needed to clarify which is the gold standard technique for middle and low rectal cancer .

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O123: Pre-clinical in vivo validation of the CYCLOPS surgical system for ESD-TJC

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1. Introduction

There have been more than 41,000 new cases of colorectal cancer (CRC) in 2014 in the UK, and 16,000 deaths from it. Worldwide, 700,000 people died from CRC in 2012 [1]. Endoscopic Submucosal Dissection (ESD) is an advanced therapeutic endoscopy technique developed as an alternative to conventional open or laparoscopic surgery for *en bloc* resection of gastrointestinal neoplasms. Despite its proven effectiveness, in the Western world ESD is seldom carried out, especially for the removal of colorectal cancers, due to its complex and challenging nature, longer procedure times and high perforation (up to 11.8%) and bleeding rates (up to 3%) [2].

The CYCLOPS is a cable-driven parallel surgical robot, which can be attached at the front of **any** available endoscope. Key advantages include high force exertion and bimanual dexterity, accuracy, mechanical simplicity and low cost [3]. These features make the CYCLOPS an enabling technology for ESD. This abstract provides a brief update on ongoing pre-clinical trials with the system.

2. Methods

The current prototype shown in Figure 1 comprises a deployable scaffold attachment and a pair of robotic inserts used to accommodate and control off-the-shelve flexible endoscopic instruments. The system is currently undergoing extensive *ex vivo* trials on porcine and bovine tissue, and *in vivo* animal trials on pigs, with a focus on ESD surgery.

3. Results

Figure 2 shows the setup and the endoscopic view from one of the *in vivo* pig trials. As shown, the CYCLOPS can successfully be introduced transanally while undeployed and advanced into the pig colon while pneumorectum is successfully maintained. The scaffold is then deployed and the instruments can be manipulated to perform ESD or any other required tasks. Current evidence shows superior task performance, which includes considerable reduction in ESD task execution time.

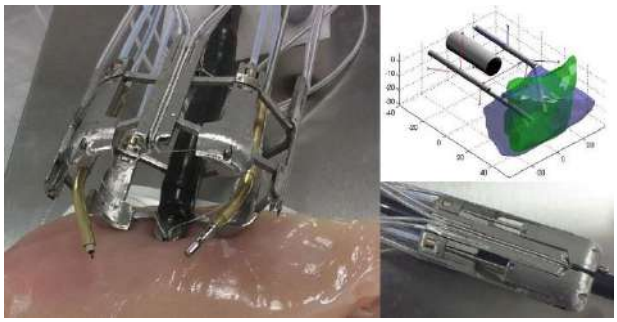

Figure 14 – Scaffold design used for the *in vivo* trials. *Left:* Deployed scaffold without silicone sleeve. *Top-right*: instrument workspace, which can be easily modified according to clinical task requirements [3]. *Bottom-right*: Undeployed scaffold (18x30mm cross-sectional area).

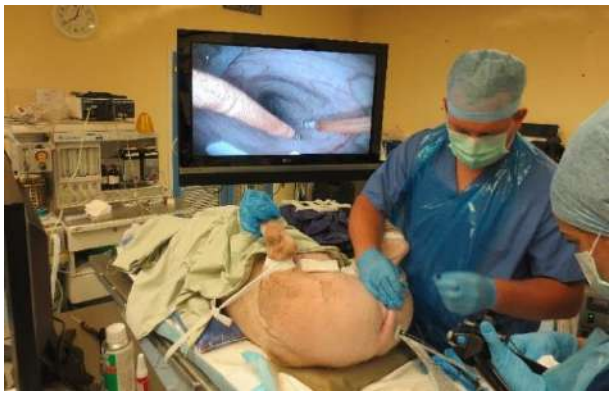

Figure 15 – Setup and endoscopic view inside the pig colon, with two end-effectors visible.

4. Discussion and Conclusion

Based on the initial pre-clinical evidence, a second generation of the system has been developed and currently undergoing further *in vivo* animal validation. Extensive updates will be made public in the near future.

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O119:

Efficacy of the Over-The-Scope Clip (OTSC) for treatment of colorectal postsurgical leaks and fistulas

Verra M, Lo Secco G, Di Benedetto G, Bono L, Morino M, Arezzo A

Introduction

Colorectal postsurgical leaks are complications that occur in about 1 to 10% of the cases and that increase morbidity and mortality. Aim of this study was to evaluate, by reviewing our personal series, the impact of the over-the-scope clip (OTSC) on clinical outcome in sealing acute and chronic leaks and fistulas.

Methods

We reviewed our prospective series of acute and chronic colorectal postsurgical leaks and fistulas observed between April 2008 and February 2017 and treated by OTSC. We reserved this treatment to all the dehiscences with an orifice < 15 mm in maximum diameter, with no extraluminal abscess, luminal stenosis and no signs of generalized peritonitis or sepsis. 26 consecutive patients treated with OTSC were included.

Results

The mean defect size was 8.7 mm. In 10 cases there were acute and in 16 cases chronic leaks (fistula). 4 cases were complicated by recto-vaginal, 3 by recto-vesical and 7 by colo-cutaneous fistula. In 3 cases OTSC was used to complete earlier vacuum sponge therapy. The overall success rate was 77% (20/26), 90% in acute (9/19) and 69% (11/16) in chronic cases. There were no OTSC-related complications, additional surgery was needed in 2 cases.

Conclusion

Anastomotic leakage si a relatively common complication in colorectal surgery and leads to increased morbidity and mortality. Clinically relevant leaks are commonly seen in 3-6% of the cases. OTSC can be considered a safe technique with a high success rate in the closure of colorectal post-surgical leaks and fistula.

O10: A novel method for intraoperative tactile examination in colorectal surgery

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1. Background

Intraoperative localization of small lesions is often challenging, especially in laparoscopies. Localization rate can be increased by preoperative tattooing, clipping or by intraoperative colonoscopy or ultrasound examination [1], but 100% localization rate still remains unachieved. We tested whether utilization of Medical Tactile Endosurgical Complex (MTEC) – a novel system for instrumental palpation – provides further increase of localization rate.

2. Methods

MTEC tactile mechanoreceptor (Fig. 1A) performs measurements by an array of pressure sensors and wirelessly transmits results to a computer. Computer performs processing and visualization with simultaneous reproduction on a specialized tactile display (Fig. 1C) which allows data perception simply via a finger. Processing includes automated artifact correction [2] and detection of heterogeneities in tactile images [3] thus simplifying localization of tumor sites.

Utilization of MTEC in colorectal surgery was tested in 2013-2016 in Moscow Clinical Hospital 31 (Russia) in the course of 29 randomly selected surgeries. Patients' ages were from 42 to 84. A strategy of margin detection and localization was similar to the one used in the study [4].

3. Results

MTEC was first tested on visually identifiable tumors during 9 open surgeries with 20 mm tactile mechanoreceptor which contains 19 pressure sensors (Fig. 1B right). In all cases results of instrumental palpation were consistent with lesion margins. Then MTEC was utilized in 20 laparoscopies to precisely detect and localize tumor site using 10 mm mechanoreceptor with 7 sensors (Fig. 1B left). Successful detection and margin localization was achieved in all cases even for small adenomas and adenocarcinomas of colorectal zone, including small tumors that could not be detected visually in spite of tattooing.

Figure 1: Medical Tactile Endosurgical Complex: **A.** A tactile mechanoreceptor (general view). **B**. Operating heads of a tactile mechanoreceptor with 7 (left) and 19 (right) pressure sensors. **C**. A tactile display.

4. Conclusion

Utilization of MTEC provides a tactile feedback in laparoscopies of colorectal cancer thus increasing its capabilities of correct identification of tumor site in case of visually undetectable tumors.

Acknowledgments

The research was supported by the Russian Science Foundation (project 16-11-00058 "The development of methods and algorithms for automated analysis of medical tactile information and classification of tactile images").

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O95: Hands-on colorectal laparoscopic skills courses: lessons learned after 10 editions

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1. Introduction

The main objective of this study was to report the experience after ten editions of the Advanced Laparoscopic Colorectal Course, organised by our centre and endorsed by the European Association of Endoscopic Surgeons (EAES). We present our experience. We also introduce future models for the practice of Tamis/Tatme procedures and contribute to its standardization.

2. Methods

We organized a 2.5 days theoretical and practical courses. A total number of 146 participants completed these courses (Fig. 1). A previous Elearning web platform is used to prepare the hands-on box trainer tasks. The learning objectives include the acquisition of operative techniques and appreciation of surgical strategies to allow the candidate to progress porcine sigmoidectomy and ileocecal resection. Objective Assessment of laparoscopic intracorporeal suturing (LIS) is emphasized by means of initial level test and acquired learning curve (time, errors). Also, at the end of the course, trainees subjectively rank various educational and organizational topics of the training program by means of a questionnaire.

Fig. 1. Attendant´s mentorship by expert faculty.

3. Results

Average participants´ opinions regarding the "theoretical and audiovisual contents", "hands-on animal model" and overall course rating exceeded 9 points in a 0-10 range. 85% of participants considered the Elearning web platform as useful. With regard to the learning curve, there was a significant improvement of the (LIS) average completion time (minutes): 1st test (inorganic model) = 4.02±1.84 vs 2nd test (organic model) =3.02±1.33 vs 3rd test (porcine model) = 1.82±0.90 (Fig. 2).

4. Discussion & Conclusion

The proposed training program for advanced colorectal laparoscopy showed a very high evaluation and demonstrated participant´s LIS skills evolution. Laparoscopic surgical skills acquisition is imperative for patient safety. Finally, check and evaluation on colorectal surgeons should be placed with great emphasis, and regarded as a prerequisite of engaging colorectal surgery.

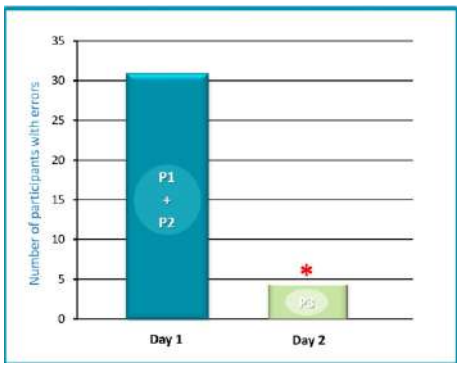

Fig. 2. Evolution in the average quality of the learning curve between the first and last training day

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O92: Trans-anal Total Mesorectal Excision: Pneumodissection of Retroperitoneal Structures Eases Laparosocpic Rectal Resection

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1. Introduction

Laparoscopic total mesorectal excision is effective and safe but often technically challenging because of inadequate exposure. Transanal total mesorectal excision was introduced to mitigate this limitation and improve the quality of mesorectal dissection in even the most challenging cases. Currently, the technique for transanal total mesorectal excision dissection is not standardized.

2. Technique

There are 3 possible sequences for the operative steps: 1) transanal approach followed by laparoscopy, 2) abdominal approach followed by transanal dissection, or 3) a concurrent, dual-team abdominal and transanal approach (the Cecil approach by Lacy et al5). In the transanal-first approach, a down-to-up TME is carried out until the peritoneal reflection is opened. Carbon dioxide (CO2) insufflation in the pelvic space opens the dissection planes by creating a retro-pneumoperitoneum, facilitating the TME. However, if CO2 insufflation time is prolonged, it may produce both pneumomediastinum and subcutaneous emphysema. The risk of peritoneal contamination is present throughout the surgery, performed using this approach. The abdominal-first approach may decrease the risk of peritoneal contamination and avoid severe retroperitoneal pneumatosis, but it does not have the advantage of the opening of fusion planes between embryonic fascias provided by pneumodissection. The main advantage of the simultaneous Cecil approach is that, while carrying out the dissection, traction and countertraction maneuvers performed at the same time from above and below speed the entire procedure and can facilitate mesorectal excision along the proper plane. The main pitfalls of the simultaneous approach are significantly increate personnel costs associated with doubling the surgical team and loss of staff energy.

3. Sequential approach

We performed and evaluated the surgical techniques mentioned above. After considering their pros and cons, we developed and adopted a modified approach to TaTME, the sequential approach, whichThe sequential approach to transanal total mesorectal excision mirrors the principles of the transanal abdominal transanal procedure. It begins with the transanal step, followed by the laparoscopic step, and then the transanal total mesorectal excision. The perirectal space is entered via a full-thickness dissection of the anterior rectal wall. Carbon dioxide is left flowing, widening the embryonic planes between the mesorectal and pelvic fascias, then moving upward through the retroperitoneal space. The surgeon switches to the abdominal field and begins laparoscopic dissection, consisting of inferior mesenteric artery dissection and division, inferior mesenteric vein dissection and division, and possible splenic

flexure dissection. Pneumodissection facilitates this procedure by distancing the inferior mesenteric artery from the hypogastric nerves and opening the embryonic fusion plane between the Toldt and Gerota fascias to allow faster division of the left colon lateral attachments. The operation continues with a switch to the perineal field and mesorectal excision.

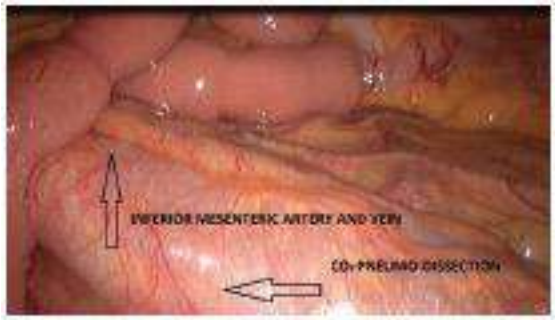

FIGURE 1. Retro-pneumoperitoneum enhances visualization of the dissection planes along the space where the embryonic fascia fuse. Arrow points the inferior mesenteric artery surrounded by carbon dioxide (CO_2) bubbles created by the pneumodissection. Vessels are easily detected as soon as the overlying peritoneum is opened.

3. Discussion and Conclusions

Transanal total mesorectal excision may benefit from pneumodissection, expedites the laparoscopic step, and the sequential approach facilitates the visualization of the correct dissection planes. The safety and cost-effectiveness of the procedure still warrant consideration

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SESSION 27 – WHAT'S COOL IN NAVIGATION

O93: Implementation of natural user interface for medical image navigation and remote control during surgery : Efficiency and face validity

Sánchez-Margallo Francisco Miguel, Sánchez Margallo Juan Alberto, Moyano Cuevas José Luis

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Introduction

Surgical environments require special aseptic conditions for direct interaction with the preoperative images and surgical equipment, which hampers the use of traditional input devices. In a previous study, we presented the feasibility of using a set of gesture control sensors combined with voice control to directly interact in a more intuitive and sterile manner with the preoperative images and the integrated operating room (OR) functionalities during laparoscopic surgery [1]. Results showed that the combination between the MYO armband (Thalmic Labs Inc.) and voice commands provided the most intuitive and accurate natural user interface (NUI). The main objective of this work is to assess the efficiency and face validity of this NUI in an OR for medical image navigation and remote control during the performance of a set of basic tasks.

Methods

Figure 1: Screens displaying the different source of information. TEDCUBE system with the different gesture control sensors (bottom right).

Twenty experienced laparoscopic surgeons participated in this study. They performed 25 basic tasks focused on the interaction with a medical image viewer (Osirix; Pixmeo) and with the functionalities of an integrated OR (OR1; Karl Storz). The tasks were carried out by traditional manual interaction, using a computer keyboard and mouse and a touching screen, and using a gesture control sensor (MYO armband) in combination with voice commands. This NUI is controlled by the TEDCUBE system (TEDCAS Medical Systems) (Fig. 1). Time required to complete the tasks using each interaction method was

recorded. At the end of the tasks, participants completed a questionnaire for face validation and usability assessment of the NUI.

Results

The use of the NUI required significantly less time than conventional manual control to show preoperative studies and information for surgical support. However, the interaction with the medical image viewer was significantly faster using the traditional input devices (Figure 2).

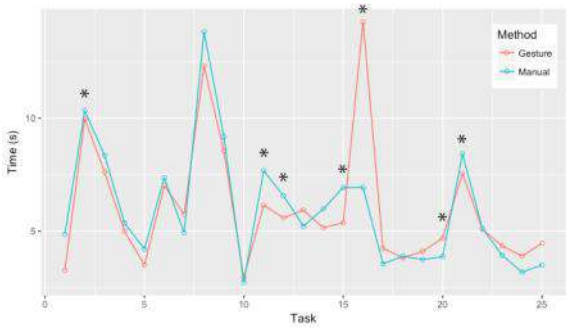

Figure 2: Execution times for the tasks performed.

Participants evaluated the NUI as an intuitive, simple and versatile tool that improves sterility during surgical activity. 75% of the participants would choose the gesture control system as a method of interaction with the patient's preoperative information during surgery.

Discussion & Conclusion

The presented gesture control system allows surgeons to directly interact with preoperative imaging studies and the functionalities of an integrated OR during surgery maintaining the aseptic conditions. For the traditional manual interaction, it is necessary to take into account the possible reaction and displacement time of the technician in order to execute the surgeon's request. A more personalized medical image viewer is required and with higher integration with the capabilities of the presented gesture control system.

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O4:

In vivo identification of liver tumors during liver surgery using electromagnetic navigation: a pilot study

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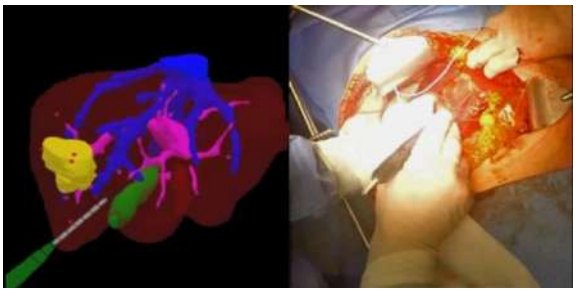
1. Introduction

Surgical resection remains the best curable option for liver malignancies [1]. Using various diagnostic imaging modalities, surgeons can carefully prepare a detailed surgical resection plan, keeping the tumour and the important anatomical liver structures in mind. However, surgical execution of this plan strongly depends on actual real-time localization of the lesions and patient-specific vascular and biliary anatomy during the procedure. Peroperative insight is generally obtained with 2D intraoperative ultrasound imaging which is subsequently linked to the equivalent 3D model of the organ in surgeon's head. Sadly, in 2-23% of the cases, this process results in irradical resections [2] or postoperative morbidity [3]. Intraoperative navigation could provide realtime perioperative feedback on liver anatomy and the peritumoral area and, as a result, improve radical resections rates [4].



2. Methods

Here, we introduce and evaluate an in-house-developed electromagnetic navigation (EM) system for visualization and EM-tool guidance during open liver surgery. To enable real-time tracking of the tumor, a single 6 degrees of freedom (DOF) EM-sensor (Northern Digital Inc.) and 4 surgical clips were attached to the liver surface in close proximity to the tumor. Next, an intraoperative XperCT scan with iv contrast, visualizing the sensor and the clips, was performed and rigidly registered to a preoperative scan containing 3D models of the liver. Sensor orientation was determined by means of point registration on the clips while reading out the sensor's position. At last, EM-pointer tracking within the 3D model was achieved assuming locally rigid anatomy within the area of resection. The accuracy of the navigation was evaluated

by comparing navigation-based to pathology results for the shortest distance between measurement points in the resection plane and the tumor. In this pilot study with the METC approval, a total of 17 navigated surgical resections were performed.

3. Results

Navigated surgical resections were performed with a median surgical overhead time of 43 minutes. This included placement of EM-sensor on the liver surface (9 min), sterile intraoperative contrast-enhanced XperCT scan (13 min), registration of the surgical plan with a real-time situation and all navigation-related measuements (21 min). The navigation technology resulted in an acuurate realtime tracking of liver tumors and had an average accuracy of 7.3 mm, compared to the pathology, and this value is expected to improve in the future.

Figure 1: Sample screen shot from the navigation software during open liver surgery and the corresponding surgical view.

4. Discussion &Conclusions

We successfully developed and implemented EM navigation for open liver surgery. This was done by combining a 3D liver model, intraoperative XperCT and EM tracking of the liver and a sterile EM-pointer. Achieved accuracy shows that the assumption of locally rigid organ registration allows for accurate detection of critical anatomical structures within the resection area.

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O79:Mixed Reality 3D Visualization and Interaction for Surgery using HoloLens

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Introduction

Visualization of patient specific 3D anatomy is gaining importance in healthcare, especially for surgery applications. Visualizing 3D anatomical structures on a flat screen may only partially improve spatial understanding. Thus mixed reality 3D visualization, which is the merging of real and virtual worlds where physical and digital objects co-exist and interact in real time, could provide better 3D information to the surgeons. Microsoft HoloLens can map the users' real environment to place virtual 3D models in relation to reality. This provides the user with a near-real experience, which is essential for it's use in medical applications. The laparoscopic surgeons and the cardiologists at the Oslo University Hospital (OUS), who viewed their corresponding models in HoloLens, were very enthusiastic about its future applications in their respective fields of medicine.

Methods

Planning is an integral part of laparoscopic resection workflow, where the surgeons decide beforehand on the resection plan for the surgery. Also, in complex congenital cardiac anomalies like Pulmonary Atresia With Ventricular Septal Defect and Major Aortopulmonary Collateral Arteries (PA/VSD/MAPCAS) and complex Double-outlet right ventricle (DORV) in paediatric heart, it is essential to understand the exact 3D anatomy before surgery.

With the development of our novel platform for planning liver resections on a computer using segmented and then 3D generated models [1]–[3], the surgeons can plan better and safer resections. This is now taken further with the use of mixed reality by visualizing the 3D segmented models of liver and heart in the HoloLens, thereby giving the surgeons a better spatial and depth information. We have also integrated our resection planning software [1] into the HoloLens application, along with implementing a cutting tool for heart.

Results

We have developed an optimal mixed reality experience for the surgeons to better plan their surgical procedure, with possibility of interaction with the planned models during surgery.

Figure 1: The above pictures show the visualization of liver and heart in mixed reality through HoloLens.

Discussion & Conclusion

Earlier, surgeons had to mentally plan the surgery by looking at the CT/MR images, thus making it difficult to discuss their plans with other surgeons. With our HoloLens application, the surgeons get a better spatial and depth information, along with the possibility to share and discuss with other surgeons with multiple HoloLens devices. Also, having a cutting tool for heart helps the surgeons to cut as many times and places as they require, compared to the 3D printed models that have to be reprinted if cut wrong.

Acknowledgements

The research leading to these results has received funding from the Helse Sør-Øst innovation funding. The authors thank SopraSteria developers for helping us develop the application.

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O86: Intra-operative estimation of surgical progress by tracking instruments use

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Introduction

Driven by rising health care costs due to factors including advancing technology and an aging population, cost-effectiveness has become an increasingly important aspect of care delivery, with the operating room (OR) being a specific area of interest. By means of a surgical process model (SPM), OR systems can gain an understanding of clinical context and surgical workflow, hereby generating ample opportunities to improve OR logistics and surgical care. Applications of SPM's include intra-operative end-time predictions, improved surgical training and assessment, computer-aided surgery and increased autonomy in robotic surgery. The aim of this study is twofold; to predict surgical phases intra-operatively based on data of instrument use and to evaluate the surgical phase recognition model on simulated clinical tasks.

Methods

This study evaluates the use of SPM's for intra-operative recognition of surgical phases in 40 laparoscopic hysterectomy cases. Based on manually annotated instrument usage data, the procedures were split up in 10 phases. Random Forest and Hidden Markov Model were compared and evaluated on two tasks related to clinical practice in the OR: the automatic prediction of surgical end-times and the automatic generation of training material by clipping endoscopic video based on the predictions of phase.

Results

With an out-of-sample accuracy of 77%, phases were best recognized by a Random Forest model. The computation time of the RF model is sufficiently low for intra-operative clinical applications and the model poses several other advantages, including noise resistance and suitability for parallel processing. Simulating surgical end-time predictions based on the RF model was shown to be

promising, with a mean absolute error of 16 minutes. The model is also found suitable for phase extraction for the generation of training material.

Discussion

We conclude that the performance of the Random Forest surgical phase recognition model based on intra-operative data of instrument use, has promising performance. Our further research is aimed at replicating the simulated findings using sensor-based data in an in-vivo clinical setting.

O78 : Magnetic resonance imaging compatible liver phantom with 3D printed vessels for pre-clinical assessment

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1. Introduction

Metastatic colorectal cancer is most common in the liver and, despite advances in treatment, resection of metastasis remains the only curative option. Parenchyma-sparing laparoscopic liver resection is associated with significantly less postoperative complications for patients compared to open [1]. In some cases, this approach can be challenging, due to limited field of view and curved resection planes.

All patients undergo pre-operative MR imaging for staging and surgery planning. These volumetric images can already be segmented and reconstructed in 3D to be viewed by surgeons. A 3D view helps the surgeon better understand patient specific anatomy, determine if the patient can undergo surgery, plan the surgery and visualize liver anatomy during the surgery itself.

High Performance Soft-tissue Navigation (HiPerNav) is a Marie Sklodowska-Curie Actions – Innovative training network project. The consortium will address specific bottlenecks in soft tissue navigation for improved treatment of cancer. The technological advancements in soft-tissue navigation would support easier orientation and potentially improve surgical outcomes.

For development and pre-clinical testing of soft-tissue navigation systems, phantoms are needed and commercially available ones can be very expensive [2]. The biggest limitation of phantoms is their degradability and the need to be replaced if cut into. A simple liver phantom has been done before although not anatomically correct [3]. The development of an anatomically correct and inexpensively replaceable liver phantom is required.

2. Methods

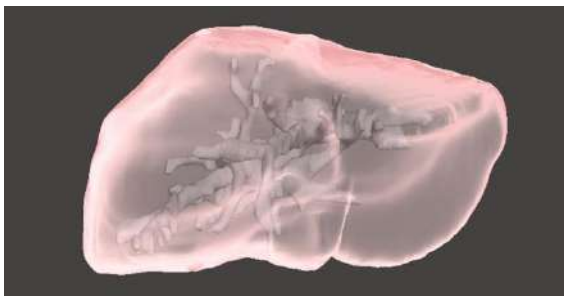
Fully anonymized MR images are used for semi-automatic liver segmentation using tools within “3DSlicer” and ones developed through the NorMit project [3] and the HiPerNav project. Segmentations are then verified by a medical doctor for medical accuracy and optimized for 3D printing. A unidirectional object is added to both the liver and liver vessel model to ensure correct vessel position in the phantom.

In the phantom, material for liver parenchyma is a combination of agar-agar and a mixture of powdered minerals, which gives similar values during imaging to a human liver. Liver vessels are 3D printed for high accuracy, model complexity and duplication ability. A unidirectional object on the vessel model fits in the negative space in the silicon mold and assures correct placement in the phantom. After initial mold creation, this liver phantom can relatively easily and inexpensively be reproduced as many times as needed.

The phantom is MR and CT compatible. Volumetric images of the phantom are used to improve segmentation algorithms and those segmentations are used as ground for development of model-to-patient registration algorithms. This relatively simple liver phantom will be used for validation and assessment of the navigation system, before moving to in-vivo testing.

3. Discussion & Conclusion

This phantom can be quickly and inexpensively replaced, which allows for phantom damaging tests. It can also be designed for patient-specific planning and visualization for the surgeon, and



optimization of the navigation system.

Image 1: 3D liver and liver vessel reconstruction from segmented MR images.

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O66 : Evaluation of a 3D planning tool for irreversible electroporation treatment in pancreatic cancer

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1. Introduction

Local ablation is a treatment alternative for patients with unresectable cancer. Irreversible-electroporation (IRE) is a non-thermal ablation technique that spares vessels and thus is predisposed for appropriate treatment of locally advanced pancreatic cancer [1]. Correct needle positioning and parallel placement is a prerequisite for an efficient and complication-free IRE treatment. Therefore, we propose a 2D/3D planning and visualization solution to support the surgeon during this crucial procedure.

2. Methods

Based on conventional CT image data, and 3D reconstructions of essential anatomical structures (duodenum, pancreas with tumour, aorta with local branches, vena cava, superior/inferior mesenteric-, splenic-, and portal vein), our software provides the surgeon with a structured planning interface. The surgeon can define needle trajectories under consideration of different constraints such as number of needles used, spacing, and parallelism of the IRE needles. As a result, the software displays anatomical structures together with planned IRE trajectories (Figure 1). To explore the current potential of the planning software, the solution was presented to potential users which were subsequently asked to complete a questionnaire. Furthermore, it was investigated if additional navigation support during open, as well as minimally invasive surgeries would be beneficial.

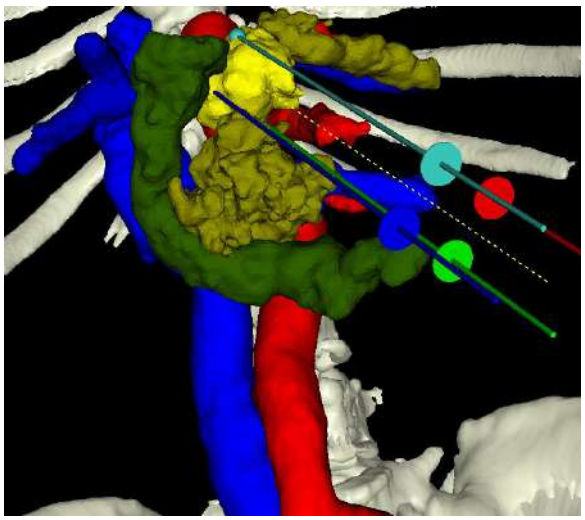

Figure 16: Planning display containing bones structures in white and coloured 3D reconstructions of vessels, pancreas, duodenum, and tumour. The planned IRE needles (n=4) are displayed as coloured lines.

3. Results

The study population consists of 8 medical doctors (MD's) with speciality in HPB surgery (7) and surgical oncology (1) active in USA (1), India(1) Turkey(1), Germany(1), Austria(1), and Switzerland(3). The MD's perform between 30 and 120 pancreatic surgeries annually (average value of 70 surgeries per year). The yearly number of IRE's was situated between 0 and 20 treatments with an average number of 4.5. Figure 2 shows the results of the questionnaire. All the MD's agreed that there is a need for a dedicated planning software and a majority is in favour of 3D planning (against conventional 2D planning). Seven (87.5%) of the MD's would use

a planning software in clinical routine. The majority of the pancreas specialists see a need for minimally invasive pancreas IRE (87.5%) as well as for intra-operative needle navigation (100%).

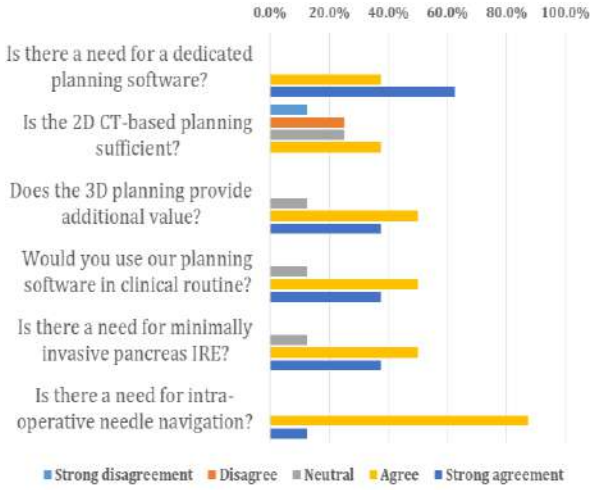

Figure 17: Evaluation of the questionnaire about our dedicated planning software.

4. Discussion & Conclusion

The results in Figure 2 indicate that the pancreas IRE planning solution strongly requires 3D visualization support. The results motivate further developments in the direction of dedicated planning and navigation tools as most surgeons would evaluate it for their daily clinical routine.

We envisage to combine the present planning solution for IRE treatments with a navigation platform providing real time needle guidance to facilitate intraoperative positioning of IRE needles.

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O28 :

Assessment of target registration error for hybrid instrument tracking for image guided surgery applications

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1. Introduction

Instrument tracking for medical applications has mainly been restricted to optical tracking. However, optical instrument tracking presents the disadvantage of losing tracking if line of sight to the cameras is occluded. This limits its use for surgical applications. Electromagnetic tracking (EMT) does not need line of sight track and is therefore starting to attract interest. However, EMT is still limited by its small measurement volume and difficulty in handling ferromagnetic interferences.

Similarly to EMT, inertial sensing is also not interrupted by occlusions. Nevertheless, it is currently not in use for surgical instrument tracking because of its drift issues [1]. A combination of these systems could compensate for the disadvantages of each tracking technology and even improve overall tracking accuracy. This abstract describes some advantages of hybrid tracking techniques and proposes a method to test their accuracy and reliability to track instrument tips for image guided surgery applications.

2. Methods

The first hybrid tracking system makes use of a NDI Polaris Spectra optical tracking cameras and a NDI Aurora electromagnetic tracking system. This combination of tracking systems will be achieved tracking optical passive markers on the instrument's handle and placing an EMT sensor on the tip of the tracked instrument. This will allow handle loss of tracking in case of occlusions. Furthermore, it will reduce the impact of error magnification inherent to optical tracking when tracking the tip of an instrument. The EMT sensor can also be used to localize flexible instrument tips, advantageous for applications such as laparoscopic ultrasonography.

The second hybrid tracking system proposed is a combination of a NDI Polaris Spectra's optical tracking with inertial tracking using a INVENSENSE MTU9250 inertial sensor. This sensor is significantly larger that the EMT sensor (~2cm vs 1,3mm diameter), which makes it impossible to place the inertial sensor at the tip of the tracked instrument. Thus, a solution where the sensor is rigidly connected to the optical tracking markers is proposed. This combination will maintain tracking temporarily in case of occlusions, but also increase the tracking's speed based on the higher update frequency of the inertial sensor.

The two hybrid tracking systems will be assessed and compared based on: **accuracy** and **reliability**. To evaluate tracking accuracy, two measures are commonly used [2]: fiducial localization error (FLE) and target registration error (TRE). FLE is the distance between the position of a fiducial and its measured position. TRE is the error that the tracking system commits in localizing a specific position on the tracked instrument. Tracking the tip of the tool is more relevant to image guided surgery, so the latter is chosen. TRE is calculated either mathematically based on a reported FLE, or via direct measurement [2]. This study proposes a method of direct measurement TRE using a custom made optical verification phantom according to the ASTM F2554-10 standard [3].

The verification phantom is also used to perform a reliability test. The phantom evaluates tracking within a measurement volume similar to that of abdominal surgery (approximately 20x30x15cm). The surgeon will be required to target, with different tracked instruments, 28 positions on the phantom at 9 different orientation planes. The orientation planes reflect the directions tools are held during abdominal surgery. Based on a count of occurrence of loss of tracking data throughout the experiments, reliability of the tracking systems will be assessed.

3. Discussion and Conclusion

The combination between tracking systems can allow for improvement of both accuracy and stability for tracking surgical instruments. The efficacy of the two types of hybrid systems will be compared with a standardized approach in a setup, which will assess the accuracy for an application of surgical instrument tip tracking for image guided surgery applications.

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O96 : An interactive approach for the semi-authomatic segmentation of liver an lesions

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1. Introduction

According to Global Cancer Statistics, liver cancer is reported as the fifth most commonly diagnosed and one among the top three deadly cancers in the modern world [1]. Early detection and accurate staging of liver cancer is an important concern in practical radiology. Computer assisted methods aims at facilitating the extraction of organ shapes from medical images that plays a vital role in the development of 3D surgical tools that can help and guide the surgeon. Segmentation of liver and its lesions plays an important role in the choice of therapeutic strategies for liver disease and treatment monitoring [2]. In this study we propose a semi-automatic segmentation method with minimal user intervention that is expected to obtain good results in both Computed Tomography (CT) and Magnetic Resonance (MR) images.

2. Methods

The user is allowed to select the target organ by defining the region of interest (ROI) by drawing a rough mask on the target structure. This mask is used as the reference for obtaining the mean and standard deviation of the pixels belonging to the target organ. The 2D filtering process along with morphological operations followed by 3D filtering ensures an optimal segmentation result. The cross-remove filter used for the 2D filtering removes the weakly connected regions and small outgrowths. The border noise of the target organ region is reduced using a connectivity-reduction filter. A simple thresholding operation is performed prior to the 3D filtering. The 2D segmentation result is given as input for 3D filtering. The system makes use of three different 3D filtering functions which evaluate the correlation between the neighborhood pixels in consecutive slices. During the final stage of segmentation, the user has an option to use a correction tool if needed.

3. Results

The proposed method has been applied on 10 different CT datasets and percent volume error is measured as 1.02% (obtained by comparing the volume difference after manual segmentation done with the help of an expert by adjusting the final results). The method will be subjected for validation in a large number of datasets. The datasets from Oslo University Hospital, Norway were used in this research.

4. Discussion and Conclusion

The article presents a new method for semi-automatic segmentation of liver from CT images with better results and works as well in MR images. In order to fully confirm the suitability of the described method, it will be tested in large number of datasets. This is a subject of on-going research work related with the EU-project HiPerNav. This system will be used further for the development of ground truth database for the future work related with the implementation of fully automatic segmentation of liver and lesions.

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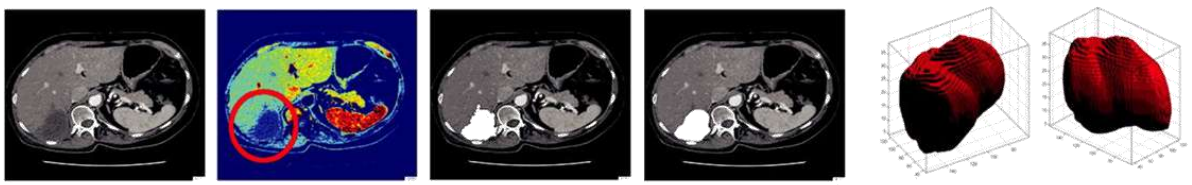

Figure 1: Same slice in the dataset with the presence of tumor undergone 2D filtering followed with 3D filtering technique and volume rendering represented in different views.

O144: Using video-tracking algorithms of the MST robotic camera manipulator for teaching and testing surgical skills

Amir Szold; Assia Medical Group, Assuta Medical Center, Tel Aviv, Israel

Background: MST had commercialized a camera-positioning robotic arm (Autolap), with motion control based on artificial vision and video analysis of generic surgical tools.

Objective: To test the use of the instrument-tracking software for performance analysis and training in minimally invasive surgery

Technology: We have designed a training and assessment mode that can asses surgeon's efficiency by motion analysis of surgical tools, and give feedback on motion efficiency and performance both in the lab and during surgery.

Preliminary results: The prototype was able to track instruments and analyze motion efficiency in different settings.

Future perspectives: We are currently testing the system to differentiate between novice and experienced surgeons and aid in teaching complex maneuvers in a minimally invasive surgery setting.

SESSION 19 – MATERIALS FOR MEDICAL DEVICES : BIOCOMPATIBILITY, FUNCIONAL SURFACES

O41: Low Melting Point Materials as controllable stiffness mechanism for endoscopic and catheter applications

Blanc Loïc - Université Libre de Bruxelles, TIPs, Brussels, Belgium

1. Introduction

During Minimally Invasive Surgery, the endoscopic devices need to be sufficiently flexible to avoid damaging patient tissues or causing pain, but they also have to be stiff enough to transmit force during punctures and grasping tasks or for supporting other tools. Several controllable stiffness solutions have been highlighted in the literature [1]. This work focuses on Low Melting Point Materials that show an important change in mechanical properties when they are heated around their transition temperature. This study is focused on the scaling laws of such solutions for catheter applications (with diameters below 3mm), on the mechanical rules of design and on the optimization based on the stiffness performances.

2. Methods

Several materials with a low melting point are compared in this study (Low Melting Point Metal such as gallium and Low Melting Point Polymer such as polycaprolactone). The stiffness gain between the rigid and the flexible states ranges from two to four orders of magnitude. First, the mechanical characterization of these materials is performed on simplified shapes to observe the influence of the manufacturing process, the dimensions and the working conditions. Bending tests are performed to quantify the flexural stiffness EI characterized by material (Young's modulus E) and geometrical (second moment of area I) properties. The tests are performed at room temperature (rigid state) and at higher temperature (flexible state) in order to characterize the samples thermo-mechanically. For the flexible-state tests, hot air is blown on the samples to change their mechanical properties due to a change of temperature. Other heat transmission solutions are studied to find the most suitable and efficient method for medical devices applications.

3. Results

The characterization tests and different heat transmission solutions are still under study. The current selected heat transmission methods are hot air or hot water flow, Joule losses heating and magnetic heating. The first proof of concept based on these materials shows encouraging performances with a strong change in stiffness around the transition temperature as seen in Figure 1. The initial calibration of polycaprolactone samples (shaped in rectangular parallelepipeds) leads to results very close to the literature for cantilever beam bending tests. The gallium-based solution presents a very large change in stiffness around a lower temperature.

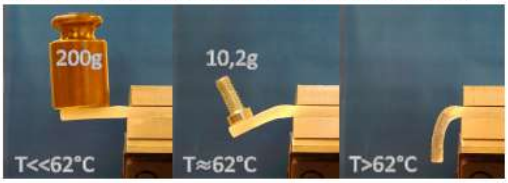

Figure 1: Stiffness transition between rigid (left) and flexible (right) states for a polycaprolactone sample.

4. Discussion & Conclusion

As the targeted application corresponds to endoscopic and catheter tools, a tubular shape design is required. The fabrication of such devices is still under study. The manufacturing of small structures (diameters < 3mm) is challenging. First, a large scale design is implemented as proof of concept and its thermo-mechanical response is studied. The best design has to be chosen based on its ease of manufacturing and its production reproducibility. Furthermore, the thermal efficiency, the safety aspects and the stiffness performances have to be taken into account for the validation step. The current tests have showed promising results. Further characterization and study of the design have to be performed to reach the goals targeted by the application. Several other materials with different mechanical properties may be used in a similar approach. A simplified thermo-mechanical model is under construction to simplify the design.

This work was supported by the F.N.R.S. through an F.R.I.A. grant and by the PREDICTION A.R.C. project.

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O45: Towards a new patient-specific, modular aortic vascular phantom with clinically relevant mechanical properties

Gallarello Antonio, Palombi Andrea, De Momi Elena, Burriesci Gaetano, Homer-Vanniasinkam Shervanthi, Wurdemann Helge - University College London, Department of Mechanical Engineering, London, United Kingdom

1. Introduction

According to [1], the cardiovascular devices market was valued at over US$33 billion worldwide in 2015 with a projected growth of a CAGR (Compound Annual Growth Rate) of 6.6% until 2024.

For early-stage validation of emerging tools, *in vitro* tests are usually preferred to *in vivo* tests as animal experiments and clinical trials are costly, time-consuming and can pose ethical issues [2].

Simulators able to mimic physiological pulsatile flow and pressure are commercially available (e.g., Endovascular simulator by Vivitro Labs). Researchers have further created both rigid and flexible phantoms based on simplified geometries [3] or patient-specific 3D reconstructions [4]. However, the challenge remains to develop hard-wearing vascular testbeds with clinically relevant mechanical properties reproducing the physiological environment.

This paper presents a step-by-step development process of a vascular phantom which will be able to mimic human-like distensibility and thus allow haemodynamic analysis and device testing.

2. Methods

The presented phantom environment should

- comprise the aortic arch, the descending and abdominal aorta as well as the common iliac arteries including the branches
- be modular, using patient-specific data
- be able to mimic human-like distensibility
- be cost-effective
- be MR-compatible

3. Results

A threshold-based image segmentation has been carried out on selected regions of interest of a CT angiogram, using the open-source (OS) software 3D Slicer (Fig.1a). The 3D reconstruction has been manually refined and edited with OS CAD software (Fig.1b). A number of soft materials suitable for moulding (silicone material) and 3D printing (TangoPlus Full Cure 930®) have been characterised by uniaxial tensile testing. The results of the tensile tests followed by a finite element analysis permitted the fabrication of a modular phantom environment made of Eco-Flex 00-30 silicone with a thickness of

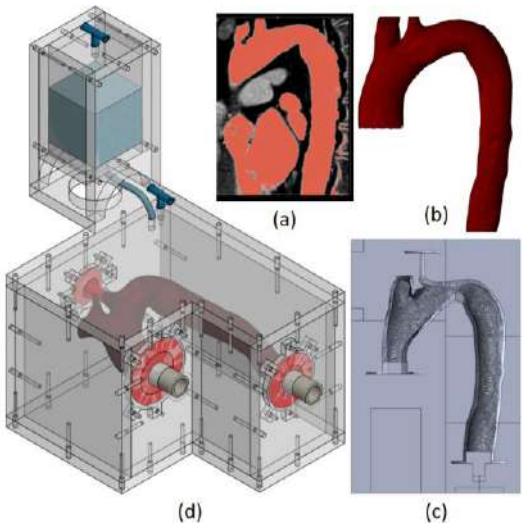

Figure 18. Example of the manufacturing process for a cadiovascular module (here: the aortic arch): (a) Segmentation of angio-CT images; (b) refining and 3D reconstruction of the vessels; (c) post-processing for mould design; (d) final module design with Windkessel chamber.

2.2mm. The external mould is designed as shown in Fig.1c. Furthermore, a Windkessel chamber connected to the water-filled bucket containing the phantom allows variation in the distensibility (Fig.1d).

4. Discussion & Future work

To the best of our knowledge, this is the first description of the development of a patient-specific, modular aortic vascular phantom with clinically relevant mechanical properties. We envisage this phantom environment to be of paramount importance for early-stage validation procedures of medical devices for cardiovascular applications include diagnostic and monitoring devices as well as surgical tools. Ongoing efforts will be dedicated to the fabrication of each module as well as the assembly of the entire phantom environment. Validation results will be carried out and presented at the conference.

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O32: Improving functional recovery after radical prostatectomy: in vitro evidences on a chitosan-based medical device

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1. Introduction

Chitosan (CS) based nerve grafts are employed to promote neural repair after injury raising more and more interest among basic and clinical research. *In vitro* and *in vivo* studies have shown that this biomaterial has biocompatible and biomimetic properties to improve the regeneration process of the peripheral nervous system [1].

It is well known that Prostate cancer (PCa) is the most common cancer among men. The surgical treatment for PCa is represented by the radical prostatectomy, which is the gold standard in the treatment of localized disease. Unfortunately, in patients who underwent a radical prostatectomy, frequently iatrogenic damage to the peri-prostatic nerve bundles occurs, leading to erectile dysfunction (ED).

The aim of this in vitro study is to assess the simultaneous anti-proliferative and pro-regenerative properties of a CS film, which has already achieved a clinical use for the peri-prostatic nerve plexus protection and a patent (Application reference: 102016000070911).

2. Methods

CS-anti-proliferative properties were tested on different human prostate cancer cell lines (PC-3, DU145, LNCap) seeded on two different experimental condition: dissolution products of CS and CS coating. Since the prostatic plexus is innervated by sympathetic, parasympathetic and somatic fibers, the regenerative potential of CS films was assessed through primary neuronal cultures and ex vivo explants derived from autonomic and DRG ganglia.

3. Results

The dissolution products of CS on proliferation assay performed after 1, 3, 6 days determined a significant lower proliferation of cancer cells, accordingly the same cells in direct contact with CS coating showed a substantial change in morphology, but also a significant decrease in proliferation.

Regarding the regenerative potential, CS film were tested and they demonstrated to represent a permissive substrate for neurite regeneration and axonal elongation.

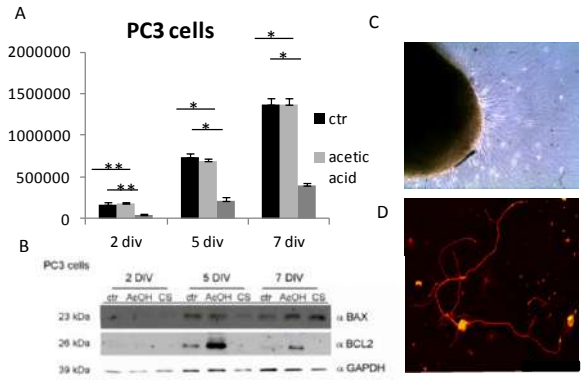

Figure 1: A) PC3 cancer cell line on CS coating, effect on cell proliferation and on Bcl2/Bax expression (B). (C) Pro-regenerative effect of CS on Autonomic ganglia explants and on dissociated autonomic neuron cultures (D)

4. Discussion & Conclusion.

An increasing number of young men have an early prostate cancer diagnosis, and ED caused by radical prostatectomy is associated with distress and impaired quality of life. The clinical application of new techniques and new materials in the field of peripheral nerve regeneration would result in minor inconvenience for patients and allow to extend the treatment also for applications in oncology.

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A novel bactericidal surface to reduce nosocomial infections improving an Italian Patent

O70:

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3) *School of Medicine Dept. of Surgery Molinette Hospital, University of Torino, Torino, Italy.*

1. Introduction

This work would like to improve a 3D Ultra Sound full console machine able by using the SynDiag patented software to output a quantitative triangular mesh in PLY format, a mathematical object that can be printed and studied while the fetus is at its 5th month of pregnancy.

As antibiotic resistance continues to threaten the treatment of various infections, the aim of this work concerns the design of a new coating film for inanimate surfaces containing light activated antimicrobial chemicals and nanoparticles to avoid microbes spread across hospitals.

It is well known that methicillin-resistant *Staphylococcus aureus* (MRSA) is a substantial public health problem not restricted to any geographic area, but worldwide. The same is true for the opportunistic pathogen *Pseudomonas aeruginosa*.

2. Methods

This work involves developing research areas that did not exist previously, such as the light activated polymers which have been studied at Chemistry Department UCL and in some cases commercialized [1].

Micro-organisms selected for this study were Epidemic MRSA 4742 representative of a Gram-positive epidemic bacteria isolated at UCL Hospital and *Pseudomonas aeruginosa* PAO1 as well as the clinical strand isolated at UCL representative of Gram-negative bacteria resistant to the majority of currently used antibiotics. Concerning this one a complementary study of its biofilm-mediated resistance to antibiotics has been followed.

To satisfy the target the dye selected was crystal violet or gentian violet because it has been demonstrated that in vitro it can disrupt *Pseudomonas aeruginosa* biofilms and it can kill MRSA. The nanoparticles (NPs) used for this study were silver ions because the antimicrobial activity of Ag+ ions is well documented and reviewed. The antimicrobial polyurethane coating films produced were tested against these micro-organisms to demonstrate their efficacy [2]. It has been also studied the critical importance of the presence of silver nanoparticles (Image 1) to improve the functional property of the inanimate surface.

3. Results

Antimicrobial activity of control and treated polyurethane samples on 4742 MRSA and PAO1 after 5 hours of incubation at 500 lux. There is no MRSA growth with crystal violet (CV) solution and CV + Silver NPs solution in 5 hours. The situation changes in the case of PAO1 where the growth is reduced only by the solution containing silver NPs in 5 hours. However, after an incubation time of 24 hours in the dark a significant antimicrobial activity was observed.

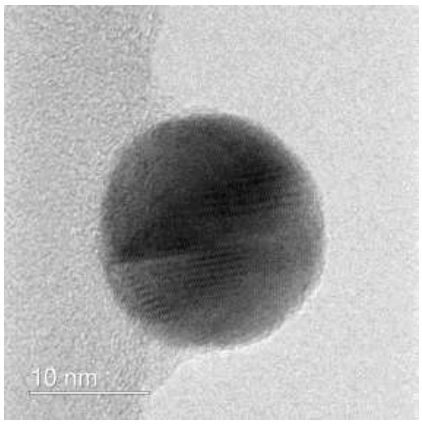

Figure 1: Silver nanoparticle – TEM Image

4. Discussion & Conclusion

Silver NPs used for this work remain inside of the polyurethane matrix – they stay into the bulk and not on the surface and exhibit potent antimicrobial activity. In addiction to this, the combination of silver NPs and a light activated agent (CV) can provide a dual kill mechanism also under dark conditions.

These surfaces are promising candidates for use in healthcare environments to reduce the incidence of hospital-acquired infections.

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SESSION 28 – NEW TOOLS FOR LAPAROSCOPY 2

O141: Artack: a mesh fixation tacking device with potential robotic interface

Szold Amir - Assia Medical Group, Assuta Medical Center, Tel Aviv, Israel

Objective: Vessel sealing during minimally invasive surgery is still a challenge, especially when applying through articulating or flexible devices. Additional disadvantages of current system include low precision and collateral tissue heating.

Technology: The core technology is an asymmetric laser fiber that enables controlled lateral energy emission. This allowed the design and production of several vessel sealing and tissue cutting devices including an articulating grasper, a hook and a loop snare for endoscopy. The devices can be articulated or flexible, fit into a flexible endoscopes' working channels and can be made in diameters even lower than 3 mm. This superior adaptability means the technology is a perfect fit with a variety of surgical robotic platforms.

Preliminary results: The devices were tested in an animal model with successful sealing of arteries up to 5 mm diameter, using low energy and with a durable seal.

Future perspectives: We are currently finalizing the first product design for minimally invasive surgery.

O143: Performance assessment and training using MST core software : Instrument-tracking using video analysis software

Szold Amir - Assia Medical Group, Assuta Medical Center, Tel Aviv, Israel

Background: MST had commercialized a camera-positioning robotic arm (Autolap), with motion control based on artificial vision and video analysis of generic surgical tools.

Objective: To test the use of the instrument-tracking software for performance analysis and training in minimally invasive surgery

Technology: We have designed a training and assessment mode that can asses surgeon's efficiency by motion analysis of surgical tools, and give feedback on motion efficiency and performance both in the lab and during surgery.

Preliminary results: The prototype was able to track instruments and analyze motion efficiency in different settings.

Future perspectives: We are currently testing the system to differentiate between novice and experienced surgeons and aid in teaching complex maneuvers in a minimally invasive surgery setting.

O2:

Is Reduced port laparoscopic cholecystectomy any better than the gold standard?

To assess surgeon stress and workload: a randomized controlled trial

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Introduction

Single incision laparoscopic surgery (SILS) has been attracting attention in the field of minimally invasive surgery. However, it is technical difficulty has delayed its adoption for every surgeons. Reduced port laparoscopic surgery (RPS) may lead to be easier than SILS for surgeon. The aim of this prospective study was to compare surgeon stress and workload during a randomized controlled study for reduced port laparoscopic cholecystectomy (RPLC) and conventional laparoscopic cholecystectomy (CLC) in the operating room.

Methods

16 patients were prospectively randomly assigned to either RPLC or CLC from July 2016 to September 2016. To evaluate differences in surgeon workload and stress between RPLC and CLC procedures, objective and subjective workload data were collected randomized controlled trial (RCT) comparing patient outcomes between RPLC and CLC.

Results

Patient factors and operative outcomes were no significantly difference between RPLC and CLC. In the surgeon reported Surg-TLX, subscale of Task demand was significantly more demanding for RPLC than CLC ($p<0.05$). The other factors were no significantly difference between RPLC and CLC.

Salivary amylase level was no significantly difference during RPLC than CLC.

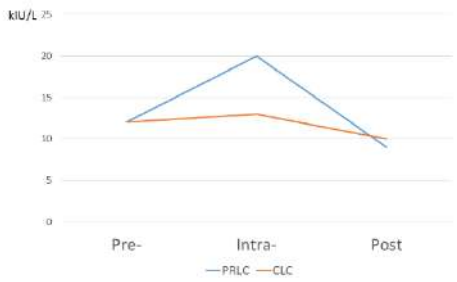

Figure : Salivary amylase levels at the three time points

Discussion & Conclusion

In conclusion, it can be thought that RPLC is as similar as CLC for the surgeons stress. In workload, task demanding was higher in CLC than in RPLC. In other words, we assumed that RPLC might be an acceptable alternatives to CLC in benign gallbladder diseases.

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O52:

Changes in abdominal wall thickness during laparoscopy: Implications for the use of magnetic assisted surgery

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ABSTRACT

INTRODUCTION: In the last two decades efforts are done to minimize surgical invasiveness. Recently, magnetic solutions were proposed such as the Magnetic Anchoring and Guidance System (MAGS). This system and similar technologies includes deployable instruments that are inserted into the abdominal cavity through a single access point. The internal components contain magnets and are manipulated by external magnets, which are held on the abdominal wall's surface. This technology relies on the magnetic force between magnets which is inversely related to the abdominal wall thickness (AWT). The change of AWT before and during laparoscopy was never studied.

OBJECTIVE: To establish the expected change in AWT in obese and non-obese patients after initiation of pneumoperitoneum, to determine preselection of patients appropriate for magnetic guided surgery.

METHODS: AWT prior to and during surgery were measured at the supra-umbilical midline and at the left upper and left lower quadrants, and the change of abdominal wall thickness during laparoscopy was calculated.

RESULTS: Thirty-two patients undergoing various laparoscopic procedures were included. Twenty patients were male (62.5%) and 10 were morbid obese (31%). Mean age was 51 years (range 18-76) and average BMI was 28.1 kg/m^2 (range 19.0-41.0). Mean preoperative AWT was 3.72 centimeters for obese patients and 2.38 centimeters

for non-obese patients ($p<0.001$). AWT decreased on average by 15.6% once pneumoperitoneum was initiated in both obese and non-obese patients ($p=0.01$).

CONCLUSION: Abdominal wall thickness decreases on average by 15 per cent with initiation of pneumoperitoneum as compared to pre-laparoscopy measurements, regardless of age, gender or BMI. Our data suggest that following preoperative assessment of AWT with abdominal wall ultrasound, more patients than expected might be candidates for the use of trans-abdominal magnetic devices.

O83-91:

ANALYSIS OF LOCALIZED MUSCLE FATIGUE IN SINGLE INCISION ENDOSCOPIC SURGERY

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Introduction

The main objective of this study was to evaluate and to compare the effects of single incision endoscopic surgery (SIES) and conventional laparoscopic surgery in the onset of localized trapezius muscle fatigue (high, medium and low portions) and in the paraspinal muscles of the middle cervical portion.

Methods

Eight experienced surgeons in laparoscopic and SIES (> 100 laparoscopic procedures; >20 single incision procedures) participated in this study, all of them with the right hand as the dominant one. The participants performed a dissection of the serosa layer of a porcine stomach, attempting to separate the serosa layer from the muscular layers. This task was carried out for 10 min in a physical laparoscopic training simulator using laparoscopic and single port approaches. For both approaches a laparoscopic camera of 5 mm and 30 degrees was used (Karl Storz, Tuttlingen, Germany). During laparoscopic dissection, participants used a laparoscopic scissors in the right hand (EndoShears®, Covidien, Mansfield, USA) and a dissector (EndoDissect®, Covidien) in the left hand. In the case of SIES dissection, participants used an articulating tip instrument (SILS Shears®, Covidien) in the right hand and a dissector of the same characteristics (SILS Dissector®, Covidien) in the left hand.

For the single port approach a SILS port (Covidien) was used. The muscular activity of the trapezius muscle (high, medium and low portions) and the paraspinal muscles of the middle cervical portion were recorded using the Trigno™ wireless electromyography (EMG) system (Delsys Inc., Natick, MA, USA) (Fig 1). After placing the electrodes on the skin, the area was cleaned with alcohol. Each EMG signal was amplified and filtered to eliminate potential interference. As an indicator of localized muscle fatigue, the temporal change of the mean frequency (fMEDIAN) of the EMG signal, calculated at intervals of 10 seconds, was used. This temporal change was analyzed by linear regression. The RMS value of the EMG signal, normalized to the maximum value of each muscle and subject, was used as an indicator of muscular activity. The muscular activity between both approaches was compared by a repeated measures ANOVA ($\alpha < 0.05$).

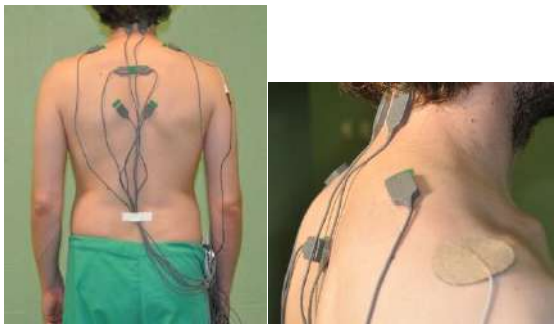

Figure 1: Experiment setup. Wireless electromyography system.

Results

The single port approach led to significantly greater muscle activity in the paraespinal muscles of the right middle cervical portion and the upper right trapezius than the conventional laparoscopic approach. In both approaches, surgeons showed muscle fatigue in at least one of the muscles analyzed. During dissection using a conventional laparoscopic approach, seven of the surgeons reported muscle fatigue in the upper left trapezius. In the case of the single port approach, seven of the surgeons showed muscle fatigue in the right middle trapezius.

Discussion & Conclusion

Surgeons showed increased muscle activity in the paraespinal muscles of the right middle cervical portion and the right upper trapezius during the single port approach. All the surgeons showed muscle fatigue in at least one of the muscles analyzed during both approaches.

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O135: Single-incision laparoscopic cholecystectomy is responsible for increased adverse events: results of a meta-analysisof randomized controlled trials

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Introduction

Over the last decade SLC has gained popularity, although it is not evident if benefits of this procedure overcome the potential increased risk. Aim of this study is to compare the outcome of single-Incision laparoscopic cholecystectomy (SLC) with conventional multi-incision laparoscopic cholecystectomy (MLC) in a meta-analysis of randomised controlled trials only.

Method

A systematic Medline, Embase, and Cochrane Central Register of Controlled Trials literature search of articles on SLC and MLC for any indication was performed. The main outcomes measured were overall adverse events, visual analogue scale for pain score (VAS), Cosmetic results, quality of life and incisions hernias. Linear regression was used to model the effect of each procedure on the different outcomes.

Results

Forty-six trials were included and data from 5141 participants were analysed; 2444 underwent SLC and 2697 MLC respectively. Mortality reported was nil in both treatment groups. Overall adverse events were higher in the SLC group (RR 1.41; $p<0.01$) compared to MLC group, as well severe adverse events (RR 2.06; $p<0.01$) and even mild adverse events (RR 1.23; $p=0.04$). A sensitivity analysis showed that the raw incidence of global adverse events was in favour of MPC also when only trials including 4 ports techniques (RR 1.37, $p=0.004$) or 3 ports techniques were considered (RR 1.89, $p=0.020$). The visual analogue scale pain score by time point showed a standardised mean difference (SMD) of -0.36 ($p<0.001$) in favour of SLC. Cosmetic outcome by time point scored a SMD of 1.49 ($p<0.001$) in favour of SLC. Incisional hernias occurred more frequently (RR 2.97, $p=0.005$) in the SLC group.

Conclusion

Despite SLC offers a better cosmetic outcome and reduction of pain, the consistent higher rate of adverse events, both sever and mild, together with the higher rate of incisional hernias, should suggest to reconsider the application of single incision techniques when performing cholecystectomy with the existing technology.

O121:

Calore Secure Port Closure

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[1]*Department of Surgery, Hadassah-Hebrew University Medical Center*

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Introduction: The effects heat on collagenous tissue is well described. Heat is known to cause both scarring and shrinkage following denaturing of collagen. Alterations of tissue healing in this manner can have beneficial clinical effects. Although increased scarring is cosmetically deleterious in the skin it may be advantageous in the healing of the abdominal wall fascia. Our aim was to develop a laparoscopic heating device for the purpose of port closure.

Methods: The Secure Port Closure device is a laparoscopic device for heating the tissue surrounding a port incision in order to shrink and strengthen the perimeter of the incision. The device is shaped like most laparoscopic devices. At the distal end of the shaft is a heated surface that maintains a constant regulated temperature when activated. The handle includes a trigger, which is used to activate the heater. Connected to the handle via a long flexible wire is the control box that contains the battery and control electronics. We conducted animal model studies in three live pigs. Four 12mm dilating tip trocars were inserted into the abdomen of each pig. Two were closed with our device and two were left open. The camera port was suture closed. Laparoscopic visualization of port closure was done at 14 and 28 days post-op. All trocar sites were sent to pathology after the pigs were sacrificed 28 days after the index operation. We evaluated all port sites (12 overall) for hernia, infection and time to closure.

Results: There were no incisional hernias in the study. Minor wound infections were noticed in two control port sites as well as two experimental port sites. Macroscopically it appeared that control port sites healed more quickly than those treated with our device with the majority closed by 14 days as opposed to 28 days. Microscopically in the pathological specimens there was only one defect that

crossed the entire abdominal wall in a control port site. Experimental port sites showed a more robust scarring pattern.

Conclusions: The Secure Port Closure device is safe for use and did not show any increase in adverse effects. The strength of the closure is still not known. The ports in this study were purposely placed at locations that were less likely to present hernias, to allow for initial evaluation of the device. A possible follow-up study may be to place ports lower in the abdomen– at a location that is known to be more susceptible to hernias. The results indicate that further study and development may lead to a device that could be beneficial for both patients and doctors.

O89: Laparoscopic cutting using Radius r2 DRIVE Instruments : Surgeon's performance and muscular intervention

Sanchez-Margallo Francisco M., Sánchez Margallo Juan Alberto, Skiadopoulos Andreas, Gianikellis Kostantinos- Minimally Invasive Surgery Centre Jesús Usón, Scientific Direction, Cáceres, Spain

Introduction

Laparoscopic surgery entails certain technical limitations for surgeons such as the restriction of movements mainly due to the fixed position of the surgical ports. Several solutions have been developed to address these limitations and ergonomic issues in laparoscopic surgery, mainly new designs for instrument handles and support systems for surgeons such as surgical chairs and armrests [1]. The aim of this study is to analyze the surgeon's performance and muscular intervention using Radius r2 DRIVE laparoscopic instruments (Tubingen Scientific Medical, Germany) during a cutting task.

Methods

Three experienced laparoscopic surgeons performed three intracorporeal cutting tasks on a box trainer using a conventional laparoscopic Maryland dissector and a pair of scissors and their equivalent r2 DRIVE instruments. Execution time and the percentage of the area of deviation from the cutting pattern (circle) were assessed. Surgeon's ergonomics was evaluated through analysis of the surface electromyography (trapezius, deltoid and paravertebral muscles) and the NASA-TLX index.

Results

Execution time was significantly higher using the novel laparoscopic instruments (Conv: 119±31 s vs. r2 DRIVE: 133±35 s; $p<.05$). The use of both instruments had a similar percentage of deviation from the exterior part of the cutting pattern. However, the deviation from the inner part was significantly higher using the r2 DRIVE instruments (Conv: 7.946±1.269% vs r2 DRIVE: 10.783±2.090%; $p<.05$).

Surgeons' muscle activity was significantly higher for the left deltoid muscle and the trapezius muscle bilaterally using the novel instruments (Fig. 1). Surgeons considered the use of these instruments leads to a higher mental and physical workload when compared to traditional laparoscopic instruments during laparoscopic cutting.

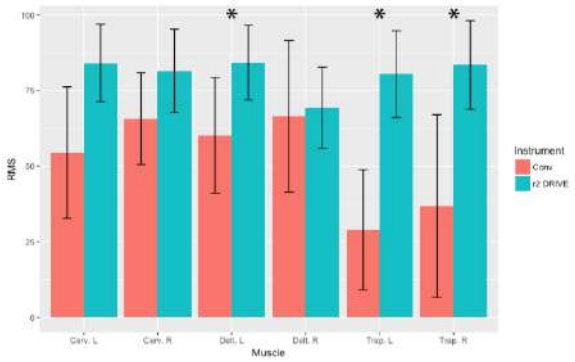

Figure 1: Muscle activity (RMS) of the paravertebral, deltoid and trapezius muscles during the use of the conventional and r2 DRIVE laparoscopic instruments.

Discussion & Conclusion

Despite the novel and ergonomic design of the r2 DRIVE laparoscopic instruments, the results suggest that an improvement in surgical performance and physical workload is required prior their use in a real surgical setting. Further studies should be done to analyze the use of these instruments during other laparoscopic tasks and procedures. We believe that surgeons need a longer training period with these laparoscopic instruments to reach their full potential in laparoscopic surgery.

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O39:

Finite element analysis in colorectal surgery: preliminary results on the interaction between tissue and surgical tool

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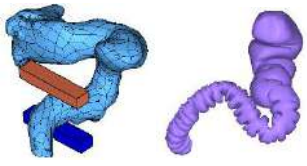
Introduction

The organs and soft tissues analysis through finite element (FEA), is a useful technique to understand some phenomena present in surgeries, to help in the preoperative plans of minimalising invasive surgeries. To achieve an effective evaluation with FEA, it is important to determine the mechanical behaviour of soft tissue such as the colon (non-linear visco-elastic behaviour). Some mechanical behaviour approximations from elastic-linear to hyperelastic material models have been done [1]. Hyperelastic models are necessary when major accuracy is required in the stress-strain evaluation like in preoperative planning, to reproduce and understand phenomena. Although several works have been introduced considering small displacements, there are not many FEA, yet, focused on understanding phenomena presented while working with large deformations. In [2], we have introduced the effects of the material model in complex geometries considering large displacements and deformations. Therefore, the aim of this work is to perform a sensitivity study on two geometric models that approximate the real colon geometry, considering different ways of interaction with a laparoscopic surgical instrument.

Methods

The case study investigated by the FEA is the interaction between a surgical instrument and part of the colorectal tissue. Two geometric models are analysed: a) a simplified geometry (MRIS) where colon rings are not considered, and b) one considering the influence of the rings (CTS), providing a better representation of a real colorectal tissue (Fig 1a and 1b). Simulations have been performed using a Hyper-Elastic mechanical model with a Mooney-Rivlin material model (HE-MR), the pressure is set at roughly 0.08 N/mm^2
(8g$_f$/mm^2) [3]. Several analyses have been applied, using a simplified model of surgical grasper, varying the amount of tissue fixed by the clamp, and the angle at which the grasper acts on the tissue, using each geometric model. Our target is to find forces acting on the clamp during interaction. The kinetic chain of the instrument has been analysed, to obtain the force that must be exercised by the surgeon on the grasper to achieve adequate tissue fixation.



a) b)

Figure 1: Geometrical model. a) MRIS; b) CTS.

Results

The FEAs have been carried out through Hyperworks software, using Radioss as FEA solver, which has been chosen to follow kinematic evolution. Fig. 2 show some results on MRIS with HE-MR. The FEA output has been analysed in terms of: a) Stress-strain distribution around the tissue near the surgical tool; b) Global displacement along the organ; c) Force at the interface between soft tissue and clamp.

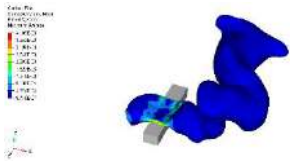


Figure 2: Stress contour-map in the MRIS geometric model.

Discussion & Conclusion

FEA of colorectal surgery can be useful for many medical purposes. FEA accuracy and set-up with specific focus on the tissue-instrument interaction has still to be defined. We want to obtain a sensitivity analysis on different positions of the surgical instrument on the organ during clampling. We are going to correlate the FEA output on soft tissue with the input force applied on the surgical tool. The FEA model used is a non-linear model suitable to capture large displacement.

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SESSION 20 – NANOMEDICINE TOOLS SUPPORTING/REPLACING SURGERY

O20: Ion-doped mesoporous bioactive glass nanoparticles as antibacterial agents in tissue regeneration

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1. Introduction

Bioactive glasses (BGs) have been extensively studied for bone repair and, only recently, for wound healing applications. Among BGs, mesoporous bioactive glasses (MBGs), in which the texture parameters of ordered mesoporous matrices are combined with the properties of bioactive glasses, have received increasing attention as tissue-regeneration systems. Their high surface area and tunable pore dimensions give the possibility of incorporating and releasing therapeutic ions to impart antibacterial functionalities (copper [1], cerium [2], silver [3]).

2. Methods

MBGs doped with three different ions (Ce3+, Cu2+, Ag+) were synthesized following two different routes: a base-catalyzed sol-gel method [4] and an aerosol-assisted spray-drying procedure [5]. Ion-containing MBGs were characterized by FESEM coupled to EDS, XRD and N2 adsorption-desorption analysis. To study the release profiles of the therapeutic ions, nanoparticles were immersed in Tris-HCl and maintained at 37°C in an orbital shaker up to 14 days and then ion contents in the supernatants were measured by ICP-AES.

The antimicrobial properties of the salts used for the nanoparticles synthesis were investigated by assessing the MIC and through viable count analysis. The antibacterial potential of the nanoparticles and their extracts were studied by viable count method using three different bacterial strains.

3. Results

The prepared samples are characterized by different size-between 0.5 and 5 m for spray-dryer and around 100 nm for sol-gel particles. Their high surface area and homogeneous pore size distribution allowed for the incorporation of specific amount of ions, which were released in a sustained way throughout 14 days. Ions-doped BGs showed good antibacterial properties ascribable to the presence of ions, with a bacteria viability reduction of 100% for what concern the silver-containing nanoparticles.

4. Discussion & Conclusion

In this study, novel antibacterial ion-doped mesoporous glasses were successfully obtained by two different routes.

References

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O23: Magneto-Plasmonic nanoparticles for photodynamic therapy

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1. Introduction

Nanoparticles (NPs) have been widely studied for their ability to be used in cancer treatment [1]. Particularly, magneto-plasmonic nanoplatforms (MPNPs), composed by superparamagnetic iron oxide nanoparticles (SPIONs) and gold nanoparticles (GNPs), are of great interest because they possess both magnetic and plasmonic properties. MPNPs represent an innovative approach in magneto-photothermal therapy of cancer [2].

2. Methods

A reproducible synthesis method [3] is used to obtain MPNPs made of a magnetic core and an external gold decoration (figure 1). Superparamagnetic iron-oxide nanoparticles (SPIONs) are prepared by co-precipitation and capped with citric acid (CA) to enhance their stabilization in aqueous solution; CA capped SPIONs are grafted with APTES to covalently attach the gold metals. GNPs are synthetized from soluble gold salts by reduction and added to the suspension of APTES-grafted SPIONs, in order to promote the growth of GNPs on the SPIONs surface. The correct formations of MPNPs is then detected by different physical characterization methods that gives information about size and morphology, while the magneto-plasmonic properties are noticed with hysteresis loop and UV-VIS analysis.
A cytotoxicity study is also performed, comparing the effect of healthy and cancer cells exposed to MPNPs at different concentrations (figure 2). To detect the efficacy of GNPs decoration, a green laser source is used in order to evaluate the ability of GNPs to convert absorbed light into thermal energy.

3. Results

The formation of MPNPs and their composition are proved by the physical characterization, in particular the size range of NPs, detected by FESEM and TEM, results to be around 20-30nm. The superparamagnetic behavior of SPIONs and the plasmonic properties of GNPs are also verified thanks to magnetic and optical characterization respectively.
Cell tests confirm that a concentration of 50μg/ml, causes an important damage of cancer cells, if exposed to 530nm laser light; while is not resulting dangerous in normal cells.
This indicate that the MPNPs allows to convert the light received into heating which can destroy cancer cells, due to their high heat sensitivity.

4. Discussion & Conclusion

The purpose of the study is to combine magnetic and plasmonic properties of SPIONs and GNPs. Thanks to the described synthesis method, we are able to create new nanoplatforms that represents a promising tool to overcome most of the limitations of NPs, enhancing tumor selectivity and bioavailability.
Using these MPNPs is possible to have a new approach to cancer therapy that consents to drive MPNPs directly in tumor site, to use them as contrast agent for magnetic resonance, as drug delivery system and bioimaging platform. Contemporaneously is possible to use MPNPs as photosensitizer for photodynamic therapy [4].

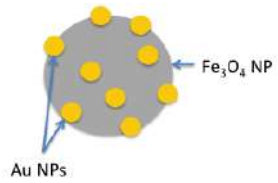

Figure1: MPNPs composition

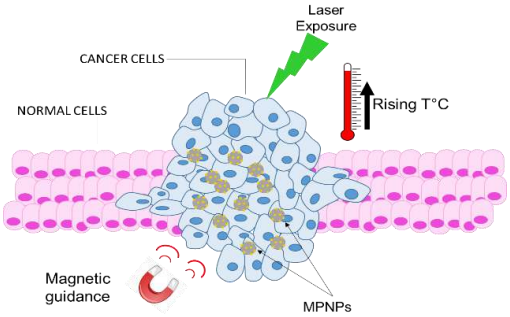

Figure2: Cancer cells exposed to MPNPs

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O55: Antithrombogenic nano-coatings by doping into amorphous carbon films for blood contacting medical devices

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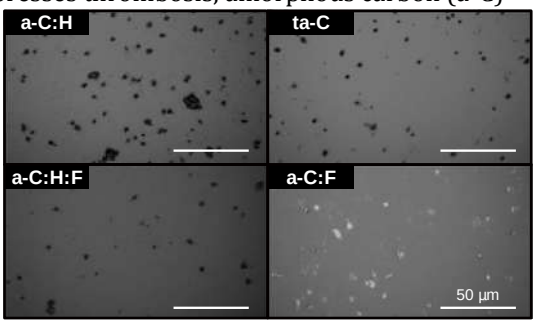
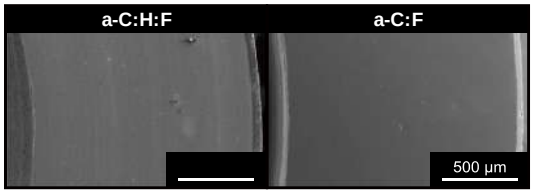
1. Introduction

The medical treatment by implantation or catheter intervention has gained widespread use in modern medical care. However, thrombus formation on the materials after contact with blood remain matters of especially serious concern on implantable medical devices such as stents, heart valves, and artificial hearts. As a coating for blood-contacting devices which suppresses thrombosis, amorphous carbon (a-C) film has received much attention according to its excellent properties. Our group previously reported that fluorine doped hydrogenated a-C (a-C:H:F) contributed to reduce blood cell (platelet) adhesion and activation compared with hydrogenated a-C (a-C:H) films (1). On the other hands, mechanical strength of coating is needed for implantable devices, because their surfaces were worn by friction with other parts or human organs. Therefore, recently, we have developed new antithrombogenic a-C coatings for application to various implantable devices.



In the latest study, we newly synthesized fluorine doped hydrogen free a-C (a-C:F) focused on both blood compatibility of a-C:H:F and mechanical properties of hydrogen free tetrahedral amorphous carbon (ta-C). We evaluated the effects of fluorine doping on antithrombogenicity and simultaneously wear resistant property of a-C:F and a-C:H:F films for application of them on blood contacting implants.



2. Methods

In this study, we synthesized a-C:H, a-C:H:F, ta-C and a-C:F films. The a-C:H and a-C:H:F films were deposited by chemical vapor deposition method from C_2H_2 and C_3F_8 gases. The ta-C and a-C:F films were deposited with arc deposition method using a graphite target and introducing C_3F_8 gas into the chamber. Antithrombogenicity of a-C films were evaluated by platelet adhesion test. Furthermore, mechanical strength of a-C:H:F and a-C:F were evaluated by sliding test.

3. Results

As shown in **Fig. 1**, platelet adhesion was apparently suppressed on fluorine doped a-C surface compared with a-C:H and ta-C surface. Furthermore, newly developed a-C:F films showed as good antityrombogenicity as a-C:H:F films. These results showed that doping fluorine to a-C films affected the enhancement of their antithrombogenic property without regard of their structure.

Figure 1: Images of platelet adhesion on a-C films.

The a-C:F films showed excellent mechanical characteristics compared with a-C:H:F films (**Fig. 2**). This result suggested that a-C:F films is more suitable for mechanical parts of blood contacting devices than a-C:H:F films which have good blood compatibility and proper flexibility for expandable stents.

Figure 2: Images of wear damages on fluorine doped a-C films after sliding test.

4. Discussion & Conclusion

We investigated the blood compatibility and mechanical property of a-C films and showed that fluorine appears to be effective dopant in suppressing blood cell adhesion on a-C films. We can use the films properly as antithrombogenic coatings for blood contacting implants in accordance to the goal of each device.

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SESSION 29 – DIAGNOSTIC SYSTEMS

O107

Detection of acute upper gastrointestinal bleeding with the HemoPill acute – a set of volunteer experiments

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1. Introduction

Acute upper gastrointestinal bleeding (UGIB) is an emergency situation which requires immediate endoscopic assessment and treatment [1]. A new telemetric sensor capsule (HemoPill acute, Ovesco Endoscopy AG, Tuebingen, Germany), can support the physician in the assessment of patients with suspected acute UGIB and contribute to a faster decision making on the indication for esophagogastroduodenoscopy (EGD) [2]. The HemoPill acute is a non-imaging disposable device equipped with a sensor for direct detection of free blood in the upper gastrointestinal tract [3]. The capsule is battery operated and is administered by swallowing. The sensor signals are transmitted wirelessly to the HemoPill Receiver, which allows for real-time detection of blood. The device measures 7.0x26.3mm. A set of experiments in a volunteer provided first information on capsule ingestion, continuous data transmission from the ingested capsule to the receiver, blood detection with or without stomach artefacts (food intake etc.) and the influence of bile on the sensor measurement.

2. Material and methods

A male volunteer ingested defined meals (or no meal) followed by defined amounts of his own blood and the oral intake of one HemoPill acute capsule each (n=8). Breakfast consisted of cereals with milk, while dinner included meat, potatoes with herbal butter, salad, and red wine. Blood concentration in the stomach was calculated by weighing the food and measuring the liquids that the subject ingested. The collected spectrometric receiver data were recorded and analyzed to assess whether the sensor capsule was capable of detecting blood and to evaluate the effect of stomach artefacts.

3. Results

The subject could easily swallow the HemoPill acute in all tests. The data from the ingested capsule was received consistently. The capsule reliably detected the ingested blood concentrations with or without stomach artefacts. The analysis of diverse blood concentrations and the respective sensor signals revealed an exponential relationship of these variables. With this relationship, thresholds for categories indicating the likelihood of blood presence in the gastrointestinal tract were defined.

4. Conclusions

Based on the described set of experiments, all predefined parameters were analyzed. An exponential behavior (up to a blood concentration of 33%) of the diverse ingested blood concentrations in combination with different meals was revealed: the higher the blood concentration, the higher the sensor signal. Furthermore, based on this set of experiments, stomach content (filled or empty) needed to be considered when sensor data values are interpreted. Analysis of the sensor capsule data obtained from an empty stomach showed that bile alters the sensor values to a certain threshold. Highly concentrated bile yields similar values to those which indicate the presence of blood. This observation has been considered in the defined thresholds and categories for indicating the presence of blood. Blood detection seems feasible regardless of stomach content. In the assessment of these observations, the limited number of experiments and the inclusion of a single subject must be considered.

In summary, this first human test shows that the HemoPill acute capsule can reliably detect blood in the upper gastrointestinal tract; moreover, it has the potential to contribute to the risk stratification of patients with suspected acute UGIB [4]. Further clinical data collection is necessary to confirm the analyzed data.

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O130

Colonoscopic Tactile Instrument to improve cancer detection sensitivity

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1. Introduction

Colorectal cancer (CRC) is the fourth leading cause of cancer death in the world and the second and third most common cancer for European women men, respectively [1]. Early detection of CRC is a key factor for survival and the five-year survival rate decreases with the advancement of the pathological stage. Tactile diagnostic methods may have the capability to improve detection sensitivity of tumour tissue, currently attested around 70% [2]. In this paper, we introduce an innovative instrument with three optical fibers each one having a fiber Bragg grating (FBG) sensor. The instrument is aimed at assisting the physician with the remote palpation of the colonic inner wall by its insertion into a standard colonoscope operating channel.

2. Methods

In general, normal tissue is less rigid than cancerous tissue. Kawano *et al.* [3] measured the elastic modulus (EM) of colorectal tissue in *ex-vivo* conditions. The results showed that the EM of colorectal tumor tissue is significantly higher than normal colorectal tissue (*i.e.*, 0.936 kPa for normal tissue and 7.51 kPa for tumor tissue) and progressively increases in accordance with the pathological stage of cancer. Starting from these evidences, a dedicated tactile instrument has been designed in order to measure the elasticity of the inner colonic tissue.
At the center of a lightened part, as close as possible to the tip of the instrument, three FBG sensors were placed at intervals of 120° longitudinally along the body of the instrument, that will be made in Alluminium 7075 (Figure 1). The position of the FBG sensors in the lightened part guarantees the maximization of the stress in a preferential direction and the identification of the magnitude and direction of the orthogonal components of the force.

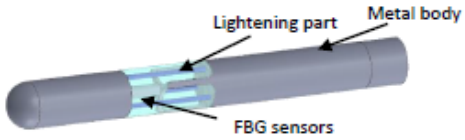

Figure 1. CAD model of the 3-DOFs force sensing.

The mechanical response of the tool and the outputs of the fibres has been analyzed through FEM simulation in different conditions.

3. Results

Figure 2 summarizes the results of the simulations. The strain measured by each fibre is a linear function of the shift in Bragg wavelength and depends by the variation of the angles of pitch and roll. The first one is referred to the contact angle between tissue plane and normal of it, while the second one represents the angle of the fibre with respect to the axis of the tool. However, it can be noted that the mean of normal strain detected by each fibre is constant and independent on the roll and pitch angles.

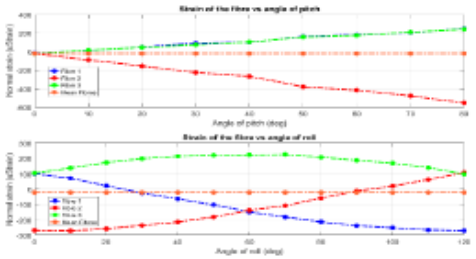

Figure 2. Comparison between the normal strain detected by each fibre and the mean strain under 70mN axial force load.

4. Discussion & Conclusion

A colonoscopic tactile instrument, based on the FBG sensors for remote of the inner colonic wall, has been presented. Results derived by the simulations preliminary show the capabilities of the instrument to measure the contact force. In future steps, the instrument will be manufactured and tested in extensive *in-vitro* and *ex-vivo* test using a dedicated experimental test bench.

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O146

Automation in quantitative medical imaging and its role as an enabling technology

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1. Introduction

Quantitative imaging is becoming an increasingly important tool in modern medicine and automation of techniques is fundamental to standardize measurements and as the amount of data to analyze increases. Completely automatic quantitative methods have been developed for numerous applications at all scales. Here we present a fully automated, generalized approach for quantitative medical imaging and demonstrate its versatility in processing images at scales going from sub-cellular to vascular.

2. Methods

An automatic analysis of cardiospheres in cardiac cell therapy [1], [2] has been done, by first segmenting the membrane and nuclei using an adaptive thresholding algorithm. The functionality of the cardiosphere was then studied analyzing the concentration of various proteins (YAP, GATA4) and their spatial distribution within the nuclei and outside the nuclei ($YAP_{INT/EXT}$ and $GATA4_{INT/EXT}$).

Moreover, on a larger-scale basis, an automatic algorithm for the quantitative analysis of the vascular network based on skeletonization has been developed and tested both on 3D contrast-enhanced ultrasound images (US) and 3D photoacoustic (PA) images [3], [4].

3. Results

The cardiosphere analysis demonstrated quantitatively how YAP is an index of citoskeletal tension, with a higher $YAP_{INT/EXT}$ ratio on the outside layer. GATA4 didn't show any statistically significant differences within all three layers.

YAP's sensitivity to substrate stiffness was also studied, and it was found that YAP was more internalized by the cell as the stiffness grew.

The analysis of the vascular network in both ultrasound and photoacoustic images showed how the skeletonization algorithm is capable of quantitatively describing and differentiating the vascular complexity both in a tumor lesion (US) and burn wound (PA) in preclinical murine studies.

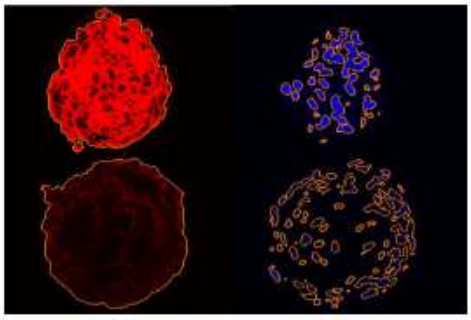

Figure 1: Example of automatic cardiosphere membrane (left column) and nuclei (right column) segmentation.

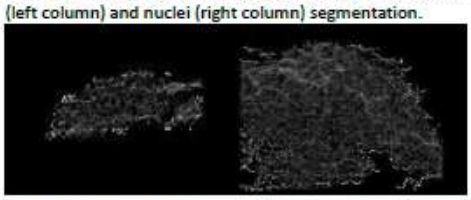

Figure 2: Automatic skeletons at two time points obtained from 3D contrast-enhanced ultrasound images.

4. Discussion & Conclusion

The results show how automatic imaging can provide quantitative results in research fields that have up to now mostly been based on qualitative results, serving as a real enabling technology.

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SESSION 11 – ADVANCES IN RECTAL CANCER SURGERY

O138: **Retroperitoneoscopic left adrenalectomy**

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Retroperineoscopic access represents a minimally invasive technique that radically modified adrenalectomy. Retroperitoneoscopic adrenalectomy is currently adopted in about 20% of referral centers. It provides more direct access to the adrenals, thus avoiding post-operative adhesions and the need for patient repositioning in bilateral adrenalectomy. We would like to present a short video showing the technique, which focuses on surgical landmarks when left adrenal gland is approached during a posterior retroperitoneoscopic adrenalectomy The patient is a 45 years old woman with a drug resistant arterial hypertension due to a left adrenal mass producing aldosterone (Conn disease).

SESSION 21 – ORGAN REPAIR & TISSUE ENGINEERING

O3: Human Liver Stem Cells-derived Extracellular Vesicles reduce hepatic injury in a murine model of ex vivo hypoxic normothermic liver perfusion

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1. Introduction

The gold standard for organ storage during liver transplantation is hypothermia induced by icy preservation solutions [1]. However, static cold storage is unable to protect completely the graft from ischemia - reperfusion injury [2]. An emerging alternative is normothermic machine perfusion (NMP) that provides basis for pharmaceutical interventions during the preservation phase [3]. HLSC, a population of liver-resident pluripotent stem cells-like and its derived extracellular vesicles (EV) have demonstrated to carry regenerative and hepatoprotective properties in injured tissue [4]. In this study, we aimed to explore the feasibility and efficacy of an organ-reconditioning strategy by using a combination of NMP and HLSC-derived extracellular vesicles (HLSC-EV)

2. Methods

A murine model of NMP capable to maintain liver function of hypoxic-injured rat livers was established. Livers were perfused *ex vivo* with a low haematocrit (<10%) during 4 hours in the NMP system without (control group, n=10) or with HLSC-EV (treated group, n=9).

The uptake of HLSC-EV was analysed by immunofluorescence, while tissue injury was analysed by haematoxylin-eosin staining. Then, apoptosis was assessed by TUNEL assay. Total bile production was quantified and perfusate samples were collected hourly to assess metabolic (pH, pO_2, pCO_2) and cytolysis (AST, ALT, LDH) parameters.

3. Results

During the hypoxic NMP perfusion, livers were able to maintain homeostasis and produce bile. The HLSC-EV were randomly distributed into the hepatic parenchyma (Fig.1, A-D). EV-treatment significantly reduced necrosis (Fig. 1, E) (Suzuki score 3.9±0.4, p=0.030), apoptosis (Fig. 1, G) (apoptosis index 0.06±0.01, p=0.049), AST (47±7 U/L/g, p=0.018) and LDH (340±47 U/L/g, p=0.032) at 3 hours of perfusion. The lower levels of AST in the treated group was maintained at 4 hours (80±14 U/L/g, p=0.003).

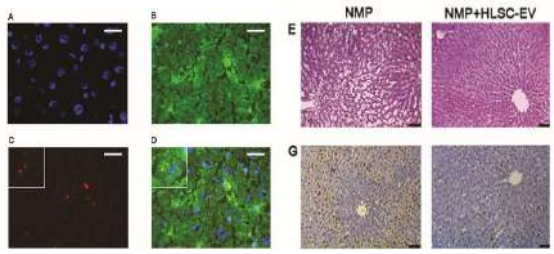

Figure 1: Micrographs of fluorescence microscopy showing rat hepatocytes (A-blue nuclei; B- green P450-4A) and uptaken HLSC-EV (C-red HLSC EV-DIL stained; D-merged) (original magnification 630×, scale bar = 20 µm). Micrographs of H&E staining (E) or of TUNEL assay (G) showing the grade of tissue injury or apoptotic cells (original magnification 200×, scale bar = 50 µm).

4. Discussion & Conclusion

The association of NMP-HLSC-EV reduced injury in a model of *ex vivo* hypoxic livers. This promising strategy for graft reconditioning before transplant surgery warrants further investigations.

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O58: Design of a socket with variable stiffness for lower limb prosthesis

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1. Introduction

Despite the various advances in the prosthetic field, a lot of amputees reject their prostheses or have a low level of satisfaction [1]. To obtain functional and comfortable prostheses, major attention has to be focused on the socket design, and on the interface between the residual limb and the prosthetic leg. High stresses applied on the skin can lead to pressure ulcers, dermatitis and vascular diseases. Moreover, the stress distribution can alter the blood perfusion in the underlying tissues, thus causing a temperature increase. For adapting the stiffness of the socket and its profile to the physiological variations of the stump, the layer jamming principle appears as a promising solution. It is based on an elastic membrane, filled with layers of different materials which compact each other and become stiff by applying vacuum [2]. This innovative technology is proposed to optimize the stress distribution and the socket profile, thus accommodating limb shape and volume fluctuations.

2. Methods

To increase the patient comfort, a preliminary prototype of a variable stiffness socket was realized. It was designed with an open structure, able to reduce the socket barrier to thermal transfer mechanisms. The structure is made of anterior, lateral and posterior 3D printed struts, which guarantee the socket stability, and a medial one, exploiting the layer jamming principle. Indeed, the medial areas of transfemoral stumps are subjected to high pressures, which should be modulated by variable stiffness mechanisms. These struts are inserted into a 3D printed distal cup, designed starting from the scan of a patient limb positive mold (Figure 1a).

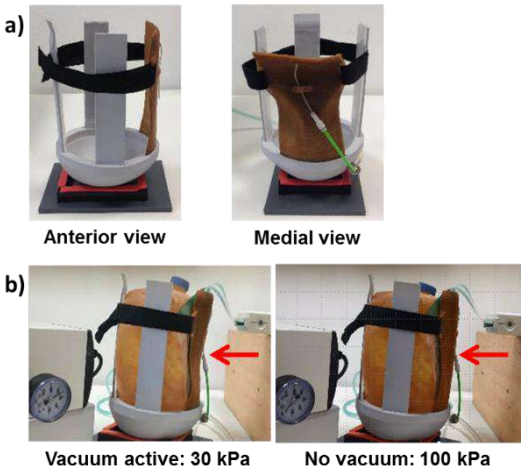

Figure 1: (a) Anterior and medial socket view. (b) Experimental set-up for pressure distribution measures. The arrows indicate a change of the layer jamming profile and the area of contact pressure measurement.

3. Results

A transfemoral amputee was recruited to measure the pressures at the stump/ socket interface and define the location of high pressures. The piezoresistive pressure sensor 5101 (Tekscan, Inc., USA) was placed in the internal surface of the socket, measuring pressure during sitting, standing and single step tasks. Results showed critical areas at the medial site (~45 kPa, ~60 kPa, ~100 kPa during sitting, standing and single step respectively). For this reason, the layer jamming strut was designed for the medial area. Three different types of layers, made of sandpaper P1000, P180 and woven P180, were tested with samples of 45 mm width, 90 mm height and 3 mm thickness, each one including five layers. The bending torque was measured to be 13 N*mm for P1000, 17 N*mm for P180 and 40 N*mm for woven P180, decreasing the pressure of 70 kPa compared to the atmospheric pressure. Since the highest bending stiffness was reached with the woven P180, it was used to realize the medial strut (90 mm width, 190 mm height and 5 mm thickness). Bending tests were repeated showing a maximum value of 140 N*mm at 30 kPa. To validate the socket prototype, the stiffness of the layer jamming strut was changed measuring the related pressure distribution at the medial interface (Figure 1b). A latex bag was realized using the patient limb positive mold and located inside the socket to simulate the stump. The tests showed a mean pressure reduction from ~2 kPa to 1.2 kPa, with a simultaneous change of the socket profile.

4. Discussion & Conclusion

The main objective of this work is to present a new design of a prosthetic socket based on the layer jamming technology. Contrarily to multi-material socket, this design allows for a dynamic variable stiffness (*e.g.* according to patient tasks), able to change the pressure distribution and to accommodate shape and volume variations of the residual limb.

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O73: Nanotechnology-Based Strategies To Treat Chronic Wounds

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1. Introduction

Skin lesions are a global healthcare problem since they can compromise the integrity and the functionality of significant skin areas. More than 40 million people suffer from chronic wounds worldwide (8 million in Europe and 6.5 million in US in 2009), most commonly caused by poor blood supply to the lower limbs. Chronic wound is a frequent and very severe problem in patients with diabetes mellitus, a pathological condition involving around 285 million people globally. In this work, different approaches to treat chronic wounds are presented based on antibacterial gelatin nanofibres or innovative polyurethane-based hydrogels loaded with multifunctional mesoporous nanoparticles.

2. Materials and Methods

Silver nanoparticles (AgNPs) and gentamicin sulphate (GS) loaded gelatin nanofibres were obtained by electrospinning starting from aqueous solution to avoid protein denaturation [1].

Thermosensitive amphiphilic polyurethanes (APU) were synthesized according to a patented procedure [2]. Moreover, novel injectable hydrogels for the targeted release of anti-inflammatory drugs and/or ions with antibacterial properties was designed and characterized.

3. Results

The antibacterial properties of AgNPs and GS loaded nanofibres were tested against four pathogenic bacteria isolated from infected wounds (Staphylococcus aureus, Escherichia coli, Staphylococcus Epidermidis, Pseudomonas aeruginosa) and high efficiency against tested strains was observed. Furthermore, the biocompatibility of the developed nanofibers was confirmed using Neonatal Normal Human Dermal Fibroblasts (NHDF-Neo).

APU were successfully synthetized showing: (1) biocompatibility; (2) long-term stability in biological environment and degradation rate compatible with tissue regeneration rate; (3) solubility in aqueous media; (4) low viscosity at 20°C; (5) gelation at 37°C; (8) ability to encapsulate biomolecules and drugs to achieve a therapeutic effect [3]. Moreover, hydrogel chemistry was tuned to exploit the variation in pH value that characterizes chronic wounds as a smart stimulus to tune the release kinetics of previously encapsulated biomolecules. These pH-sensitive innovative hydrogels were characterized and proposed to treat infected wounds within an innovative approach based on the pH-driven release of

antibacterial ions and drugs loaded into mesoporous nanoparticles coated using a pH-sensitive and self-immolative polymer [4].

4. Discussion & Conclusion

The treatment of chronic wounds requires a multifunctional approach based on nanotechnology to combine long-term antibacterial properties with tissue regeneration strategies. In this work, recent findings using gelatin based nanofibres are reported and novel concepts and future targets are presented exploiting the properties of smart polyurethane-based hydrogels combined with mesoporous and multifunctional nanoparticles.

Acknowledgements

This work was financially supported by the Horizon 2020 European Union funding for Research & Innovation (H2020-NMP6-2015) project “Mozart” (MesopOrous matrices for localiZed pH-triggered releAse of theRapeuTic ions and drugs).

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O88: Injectable polyurethane-based hydrogels for smart drug release in the treatment of chronic skin wounds

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1. Introduction

Chronic skin wounds affect more than 40 million patients worldwide. Their treatment represents a growing burden for healthcare systems due to the increasing health care costs, the population aging and the rise in diabetes and obesity incidence. The ideal wound dressing should (i) provide a moist wound environment, (ii) protect from external agents, (iii) remove exudate from the wound, and (iv) enhance tissue regeneration. However, no existing treatment fulfils all these demands [1]. Hence, the design of innovative, smart and effective wound dressings represents a current and important challenge. In this work, we developed a thermo-responsive polyurethane-based hydrogel able to transfer pH changes from the biological milieu (pH in the range 7.4-8.5) to its core, triggering the release of anti-inflammatory drugs.

2. Methods

An amphiphilic polyurethane (PU) (CHP407) was synthesized starting from Poloxamer P407, 1,6-hexamethylene diisocyanate and 1,4-cycloexane dimethanol [2]. CHP407 powder was plasma treated with Acrylic Acid vapours to introduce carboxylic groups along the polymer chains (PCHP407), thus enhancing hydrogel sensitivity to basic pH. PUs were characterized by Size Exclusion Chromatography, Attenuated Total Reflectance Fourier transform Infrared spectroscopy (ATR-FTIR), Proton Nuclear Magnetic Resonance (^{1}H-NMR) and Toluidine Blue O assay (TBO). CHP407 and PCHP407 hydrogels were characterized in terms of sensitivity to temperature (tube inverting and gelation time tests, rheology) and external pH (swelling tests in the presence of basic or acid buffers). pH-triggered release of hydrophilic and hydrophobic anti-inflammatory drugs was studied. Cytotoxicity was assessed according to ISO10993.

3. Results

Chemical characterization assessed the successful synthesis of CHP407 with a final number average molecular weight of 50 kDa and a polydispersity index of 1.3. TBO assay, ^{1}H-NMR and ATR-FTIR demonstrated the introduction of carboxylic groups along the polymer chains and evidenced a high intra- and inter-synthesis repeatability of plasma treatment. Tube inverting, gelation time and rheological tests showed the ability of 15%w/v concentrated PU solutions to undergo a sol-to-gel transition at about 27°C within few minutes. No differences in gelation kinetics of CHP407- and PCHP407-based hydrogels were reported and both systems were in a complete gel state at 37°C, demonstrating that plasma treatment does not affect hydrogel thermo-sensitivity. Concerning sensitivity to basic pH, PCHP407-based hydrogels transferred basic pH of the surrounding environment to the gel core with a significantly faster kinetics and a significantly higher swelling if compared to CHP407 gels. On the other hand, CHP407- and PCHP407-based hydrogels showed a similar behaviour in the presence of acid buffers. Hence, the introduction of -COOH groups along CHP407 chains increased hydrogel sensitivity to basic pH. These data were also confirmed by studying the pH-triggered release of hydrophobic and hydrophilic drugs. Cytotoxicity tests performed on hydrogel extracts with NIH-3T3 murine fibroblasts showed no cytotoxicity.

4. Discussion and Conclusion

PU-based hydrogels are promising candidates in chronic skin wound treatment as they are characterized by (i) easy injectability, (ii) a sol-to-gel transition within few minutes at 37°C, (iii) a moist environment and (iv) capability to fill cavities without causing pressure. Furthermore, COOH-modified PU-based (i.e. PCHP407) hydrogels showed faster inner pH variations and higher swelling with respect to native ones (i.e. based on CHP407), resulting in pH-triggered and accelerated release kinetics of encapsulated drugs.

5. Acknowledgements

This work was supported by the Horizon 2020 European Union funding for Research & Innovation project "MOZART" (MesopOrous matrices for localiZed pH-triggered releAse of theRapeuTic ions and drugs) (H2020-NMP6-2015).

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O149: Collagen-based biomimetic smart scaffold for bone tissue engineering

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1. Introduction

The ERC BOOST project aims to develop a smart scaffold able to mimic the natural bone chemistry, structure and topography, in order to restore the physiological osteoblast and osteoclast cooperation, responsible for the dynamic process called bone remodelling [1]. The bone microstructure will be reproduced with CAD/CAM models of healthy bone, using STL files obtained from nanoCT of human bone, which will be processed with a dedicated biofabrication platform. To mimic bone composition, type I collagen will be combined with an inorganic phase (hydroxyapatite nanoparticles or mesoporous bioactive glasses).
Type I collagen represents the main component in the extracellular matrix (ECM) of several tissues and organs and it is one of the most used proteins in the field of biomaterials. However, the poor mechanical properties and the fast degradation of collagen matrices request the combination with other materials as well as crosslinking processes in order to increase the final mechanical strength and stability [2].

2. Methods

In this preliminary phase, different concentrations of type I collagen have been studied in order to define the time of physical crosslinking and the rheological properties, with and without the addition of mesoporous bioactive glasses (MBG) nanoparticles in order to define their contribution to the material final properties. The use of 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide hydrochloride (EDC) and *N*-hydroxysuccinimide (NHS) has been evaluated for the chemical crosslink of collagen.
Material stability has been investigated at 37°C for 21 days on both chemical and physical crosslinked samples. The microstructure has been analysed by FE-SEM to observe the MBG embedding amongst reconstituted collagen fibres. Preliminary extrusion tests have been conducted by using 30 G and 32 G needles.

3. Results

Homogeneous suspensions of MBG nanoparticles in solution have been obtained defining a collagen concentration of 1.5%wt. as the minimal starting concentration. The addition of MBG particles has led to increased viscosity values and to a slight delay in gelation time while collagen/MBG solutions have been successfully extruded by 32 G (200 µm) needles. FESEM images have shown proper embedding of MBG particles in the fibrous collagen network (figure 1).
Preliminary data on chemical crosslinking by EDC/NHS have demonstrated a sharp reduction in sample dimensions as well as water uptake ability.

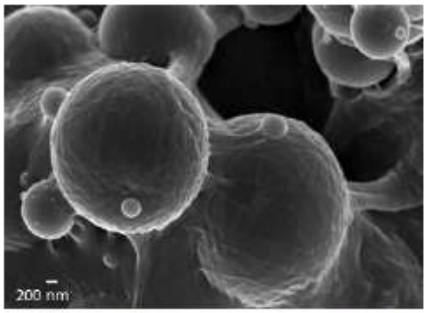

Figure 1: FESEM image of mesoporous bioactive glasses embedded in collagen fibres.

4. Discussion & Conclusion

The incorporation of the inorganic phase into the collagen matrices occurred successfully and led to the material stabilisation without preventing proper extrusion.
The remarkable reduction of initial sample dimension after chemical crosslinking is a critical point for the entire process and for this reason other methods are current under investigation.

5. Acknowledgment

The authors acknowledge the UE financial funding (ERC-CoG-2015, Grant number 681798, BOOST, (www.ercprojectboost.eu)).

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O24: Plant derived natural molecules: a promising way for surface functionalization of biomaterials in bone contact applications

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1. Introduction

Mixtures of molecules derived from plant natural extracts (egg. polyphenols, essential oils) have interesting properties as antibacterial, antitumoral, antinflammatory and osteoinductive activity[1,2]. It is possible to combine the properties of these molecules with those of bioactive materials used in bone contact application by mean of surface functionalization. As an alternative polyphenols are also reductive agents useful for the *in situ* reduction of silver nanoparticles in order to confer to the materials inorganic antibacterial activities.

2. Methods

The substrates used for the surface functionalization were a silica based bioactive glass [3] and a Ti6Al4V alloy made bioactive by means of a patented chemical treatment[4].

The surfaces were functionalized with different molecules reported in figure 1 (gallic acid as model molecules, polyphenols from red grape skins, green tea leaves and *Mentha piperita* essential oil of Pancalieri). The functionalization protocols were tailored using different solvents and different time of functionalization suitable for each kind of biomolecules and for the two different substrates. The presence and the activity of the molecules and ions on the surfaces were analyzed by means of XPS, FTIR, gas chromatograpyc and spectroscopic analyses. The effect of these molecules on cells and bacteria was also investigated with biological tests. The silver ions release was investigated in different media.

3. Results

The presence and the activity of the polyphenols on the surfaces were proved by means of XPS, FTIR and spectroscopic measurements with the Folin&Ciocalteu methods. Cell cultures also prove the ability of polyphenols to promote osteointegration with healthy osteoblast and induce differentiation in mesenchymal stem cells and promote apoptosis of cancer cells.

The presence of the molecules of *Mentha* oil and silver nanoparticles was checked with GC, FTIR and XPS; they have effect against bacteria, but they show also toxicity against cells.

For the samples with silver nanoparticles a well dispersion of the nanoparticles on the substrate and a release at 14 days were observed.

4. Discussion & Conclusion

Regarding polyphenols, the surface functionalization seems to be a promising way for *in loco* use of these molecules rich of beneficial effects on human health. For those concern the samples with the *Mentha* oil and the silver nanoparticles, the protocol of functionalization needs to be improved in order to tailor the amount of *Mentha* oil molecules and silver nanoparticles to avoid cytotoxic effects maintaining the great antibacterial activity. The biomaterial surface functionalization is a promising interest field in order to combine the properties of biomolecules with those of biomaterials. It's possible to confer them new properties using natural molecules with high value but low price that could be also used as additives during different process like nanoparticles reduction.

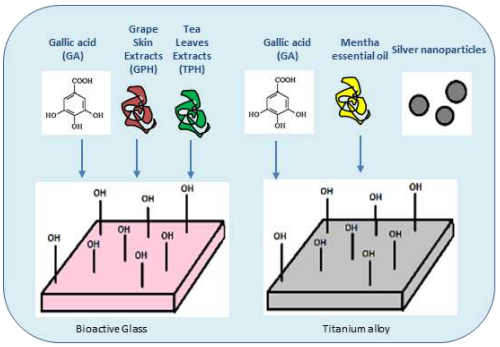

Figure1: Material and chemicals used for the work.

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O12: In-vitro detection of small isolated Cartilage Defects: Intra-Vascular Ultrasound vs. Optical Coherence Tomography

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1. Introduction

Ankle sprains and cartilage fractures are commonly seen in orthopaedics. In up to 50% of all ankle sprains and fractures, isolated cartilage defects occur [1]. These defects affect the articular cartilage and subchondral bone, which can result in deep ankle pain, stiffness of the joint, impaired movement and if left untreated posttraumatic osteoarthritis [2]. This experimental work focuses on a critical aspect in the development of a minimally invasive needle based intervention to treat small cartilage defects in joints: the sensor that identifies the location of the defect in the joint (Figure 1).

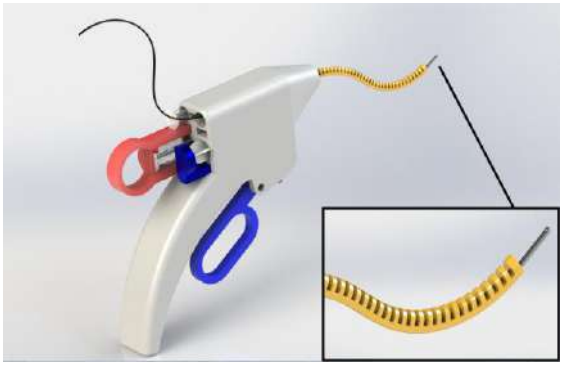

Figure 1: an artist impression of a multifunctional steerable needle device currently in development for detection and treatment of articular cartilage defects in the ankle.

The goal of this study is to identify the most accurate imaging method (Intra-Vascular ultrasound imaging (IVUS) vs. optical coherent tomography (OCT)) that is suitable for integration in a needle compared to a golden standard (µCT).

2. Methods

An in-vitro study was conducted on human Talar bone specimens that were dissected and placed submerged. To simulate natural appearance of cartilage defects 4 types of defects were created according to a standardized protocol: chondral defects, osteochondral defects, bruises and cartilage surface fibrillation, all sized between 0.1-3 mm diameter. A test setup was built to fixate the talus inside a tank and a catheter holding system was developed to scan the bone with different catheters (Figure 2).

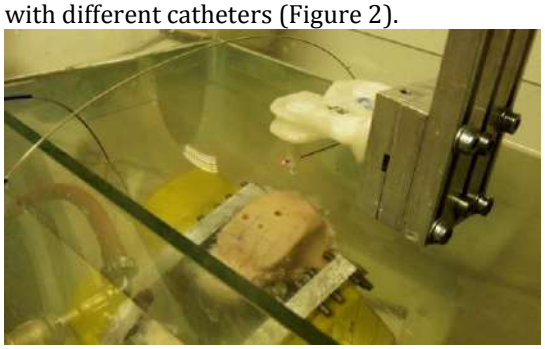

Figure 2: , A picture of the part of the experimental setup that holds the catheters in a constant position and orientation above measurement location on the bone (Talus) surface.

3. Results

The bruises could not be visualised with any of the imaging techniques. The detection rate of the osteochondral defects was 100% by both observers for µCT, 80% for IVUS and 92% for OCT. The detection rate of chondral defects was 97% by both observers for µCT, 60% for IVUS and 83% for OCT. The detection rate of cartilage surface fibrillation was 24% by both observers for µCT, 0% for IVUS and 29% for OCT. The diameter accuracy for OCD and CD showed a significant difference between the golden standard µCT and OCT ($p=0.003$ osteochondral, $p<0.001$ chondral) and the depth accuracy ($p=0.01$ osteochondral, $p=0.03$ chondral). This was as well the case for OCD between µCT and IVUS ($p<0.001$).

4. Discussion & Conclusion

Both imaging methods can detect the presence of OCD and CD accurately if sized larger than 2 mm, and OCT can detect fibrillated cartilage surface as well if at least larger than 3 mm in size. Thus, a slight preference exists to continue with OCT as is more sensitive to various types and sizes of defects.

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SESSION 31 – NEURO@SMIT2017: NEW TECHNIQUES AND DEVICES IN NEUROSEURGERY II

0151: Anatomic model for artery injury simulation in management of vascular complications in endoscopic endonasal surgery

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Introduction: Intraoperative injury of the internal carotid artery (ICA) is the most dreaded complication in endoscopic endonasal surgery (EES) of skull base (1). Training for ICA injury is practically impossible in live operative settings (2)In this study, we evaluate a pulsatile perfusion-based live cadaveric model for ICA injury simulation in a laboratory setting. The major emphasis of the study was to evaluate various means of controlling acute bleeding and evaluating the practical utility of this model for training purposes

Methods: Five embalmed uninjected cadaveric heads were prepared for study by connecting to a pulsatile perfusion pump system filled with artificial blood solution. EES approaches were used to evaluate different types of ICA injuries similar to operative scenarios (3). Various methods of managing ICA injuries such as packing, clipping, trapping, were evaluated. The educational advantages of the live cadaver model were assessed using questionnaires given to participants in a hands-on dissection course

Results: The trainee was faced with several scenarios similar to those encountered during an actual intraoperative ICA injury. Packing, clipping and trapping of the ICA injury was successfully achieved in all segments of the ICA (4). Clipbased reconstruction techniques were successfully developed. All trainees reported gaining new knowledge, learning new techniques (5). The responses to the questionnaire confirmed the significant educational value of this model.

Conclusions: The live cadaver model presented here provides real life experience with major vessel injury during EES in a laboratory setting. This model could significantly improve current training for management of intraoperative vascular injuries during EES

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O102

Clinical Use of Intraoperative Decision-making Supporting System

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1. Introduction

In neurosurgery, an operating surgeon makes a decision based on various intraoperative information such as intraoperative MRI and biological information. Information sharing among a clinical team, including clinical staff inside of operating room (OR), a pathologist and an expert surgeon outside of OR, is essential for optimal intraoperative decision-making. For a smooth communication inside and outside OR, we have proposed an intraoperative decision-making supporting system.

2. Methods

In our proposed system, a software Splashtop Business (Splashtop Inc.) is installed in a tablet which is connecting to a monitor in OR, as shown in Figure 1. By using this software, the pathology diagnosis image which a pathologist is observing with a microscope away from OR can be displayed on the monitor remotely. Furthermore, with a calling function, the sound of OR can be shared with an expert surgeon in other building.

3. Results & Discussion

In conventional glioma surgery in our hospital, the pathologist diagnoses a grade and type of tumor from the pathology image, and tells the result to an operating surgeon in OR using in-hospital PHS. On the other hand, by introducing our system, the pathology image which the pathologist is observing through a microscope could be shared with all clinical staff in OR in real-time, and small nuances, which it is difficult to express in only verbal communication, could be conveyed by the pathologist and operating surgeon talking while looking the same pathology image. As for the calling function, the expert surgeon could check the surgical situation from the sound of OR, and gave instructions to clinical staff in OR as needed. In our laboratory, we have ever developed a strategy desk [1], in which an expert surgeon monitors intraoperative streaming videos such as a surgical microscopic image and overview of inside OR, and the expert surgeon could also gain an understanding of the surgical situation sensuously by adding a sound information.

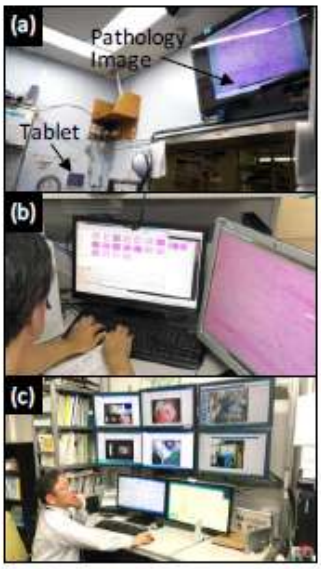

Figure 1: Intraoperative Decision-making Supporting System (a) pathology image displayed on a tablet and a monitor, (b) pathologist desk, and (c) strategy desk.

4. Conclusion

We have proposed an intraoperative decision-making supporting system, in which, pathology diagnosis images which the pathologist is observing through a microscope could be displayed on a monitor in OR, and an expert surgeon could hear the sound of OR and have a conversation with operating surgeons remotely. From the result of introducing our system to neurosurgery, the operative information was shared smoothly among the clinical team and we confirmed that our system could be a useful communication tool for optimal intraoperative decision-making.

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O115

Hyper-spectral imaging of the human brain reveals slow sinusoidal, hemodynamic oscillations at distinct frequencies

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1. Introduction

Slow sinusoidal, hemodynamic oscillations (SSHOs) around 0.1 Hz are frequently seen in mammalian and human brains. Four patients undergoing functional surgery for epilepsy, offered a unique opportunity to determine which SSHOs are present on the human brain.

2. Methods

Hyper-spectral recordings of 4 to 7 wavelengths were made with a two systems: 1) consisting of liquid crystal tunable filter and a monochrome camera mounted to the surgical microscope, 2) consisting of a flat panel light source with 600 LEDs with 17 peak-wavelengths with a monochrome camera mounted in the middle. Concentrations of oxy- and deoxy-hemoglobin were calculated for each set of wavelengths and image pixel. A Fourier transform was applied along the time axis to determine the oscillating amplitude at each frequency. Oscillating regions were determined by manually delineating bright areas.

3. Results

For all 4 patients multiple SSHOs were constantly visible during the entire 4 to 10 minute acquisition time. The observed SSHOs were localized to specific cortical regions with a very distinct frequencies and showed a fixed but sometimes large phase difference within that region. SSHOs of deoxygenated hemoglobin appeared to have an opposite phase with respect to the oxygenated hemoglobin SSHOs. Deoxyhemoglobin SSHOs' amplitude was 90% of the oxygenated hemoglobin SSHOs' amplitude.

4. Discussion & Conclusion

Despite the fact that SSHOs have been known for many decades, their function is still unknown. This study shows that SSHOs have very specific characteristics like frequency, phase and location. More research is needed to study their dependence on pathology, anesthetics and electrical or visual stimuli. Hyper-spectral imaging of the human brain offers a new way to study the origin and function of SSHOs on the human brain.

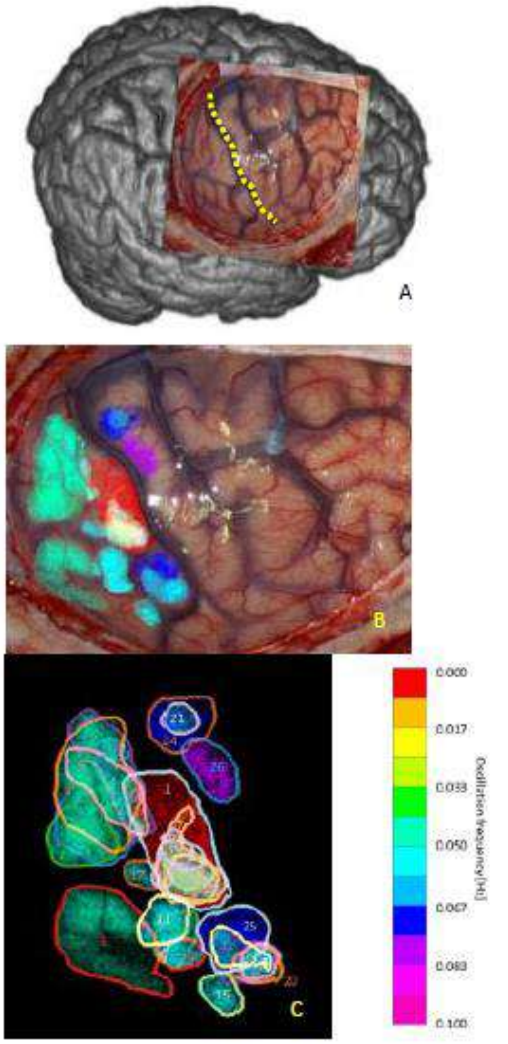

Figure 1: Hyper-spectral imaging the brain of patient with epilepsy showed 26, often overlapping regions with a steady oscillating change in oxy- and deoxyhemoglobin ranging from 0.03 to 0.1 Hz.

O122:

The ReCIVA breath sampler for colorectal cancer screening.

Preliminary evaluation and results

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1. Introduction

Colorectal cancer is a major health concern but it suitable for early diagnosis by mass screening. Current screening tools suffer from unsatisfactory specificity and patients' compliance or high costs and risk. The analysis of the volatile organic compounds (VOCs) in the breath (*breathomic*) has recently been applied to cancer screening with growing interest in the scientific community. Nevertheless, the few studies dealing with VOCs and colorectal cancer (CRC), have identified different number and types of metabolites [1-4], generating confusion on the true reliability of this breath test.

One of the possible reasons may linked to the breath sampling phase, where different environmental condition and instruments can affect the composition of the breath. In this study the reliability of a new breath sampler methodology for possible screening in CRC was evaluated.

2. Methods

From January to July 2017, 29 subjects (15 with CRC, 77% males, 14 controls, 71% males), were blinded enrolled after giving written informed consent. All the controls were disease free and negative to the colonoscopy. Breath sampling was performed, always in the same room, using the ReCIVA Breath Sampler©, a portable device that allows a selection of different volumes and exhaled breath fraction (alveolar, bronchial) using an infra-red CO_2 sensor when respiratory rates (RR) is between 15-25 rpm, while the patient breath a medical air in a mask attached to the device. This makes the lungs free from the main environmental polluting agents.

For each subject, an alveolar air volume of 500mL was gathered on stainless steel biomonitoring sorbent tubes containing a mix of Tenax © and Carbograph © phases that can retain C4-C30 compounds. The VOCs were thermally desorbed and analyzed in a gas chromatography-mass spectrometer (GC-MS) which provides the separation and the identification of VOCs. All the patients completed the test efficiently within 5 min showing a good compliance. Statistical analysis: Analytical data were processed by principal components analysis (PCS), by using Minitab software package.

3. Results

PCs analysis was performed on matrix of 7 chemical parameters – Undecane 4,7-dimethyl; Dodecane; Sulfurous acid cyclohexylmethyl octadecyl ester; Caprolactam; Tetradecane; Phenol, 2-(1,1-dimethylethyl)-6-methyl; Ethanone 1-[4-(1-methylethenyl)phenyl]- and revealed a defined clustering of studied samples. Two clusters, which correspond, except two samples, to the different groups of patients, have been identified by the PCs analysis explaining 94% of the total variance (**Figure 1**).

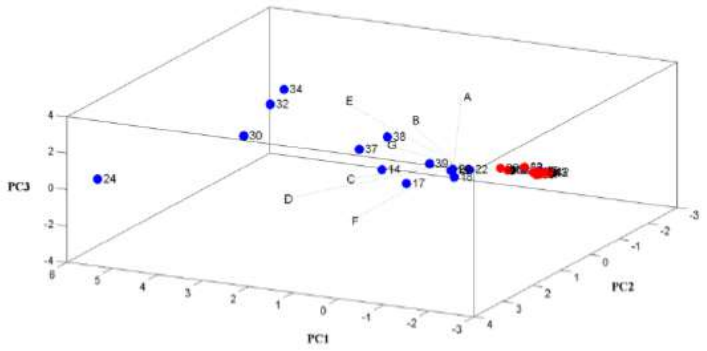

Figure 1

4. Discussion & Conclusion

The new breath sampler has proved to be technically reliable, free from environmental pollutions, and with optimal patient compliance. Furthermore, it allows the identification of a pattern of VOCs with a high discriminatory power between the groups. An extended application of this methodology on larger group of subject is ongoing.

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POSTERS PER SESSIONS

DENTAL SURGERY

44: Focus on soft tissue cell response elicited by anodized titanium

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Introduction

The aim of this work was to investigate how anodization and silicon-based amorphous coatings may enhance the adhesion of soft tissue cells to the Ti surfaces. Therefore, the purpose of this study was to determine in vitro the early cell response of human epithelial cells and fibroblasts on the aforementioned surface modifications.

1. Methods

Ti-Al-V titanium samples were prepared and shaped as 12 × 12 × 4 mm cylinders (l × l × h). Four types of specimens were attained: pristine titanium (Ti, unmodified control), anodized titanium (AnoTi) and two different thin film coatings based on amorphous silicon (a-Si_90 and a-Si_350). Microstructure was studied by means of a Scanning Electron Microscope (Zeiss EVO 50, Carl Zeiss AG, Oberkochen, Germany). The wetting properties were investigated by optical contact angle (OCA) measurements with the sessile drop technique, using an OCAH 200 (DataPhysic Instruments GmbH). To characterize the biological response in vitro, the epithelial cell line HACAT and the fibroblast cell line NHDF (ECACC, Salisbury, UK) were used. Cells were maintained in DMEM supplemented with 10% fetal bovine serum (Life Technologies, Milan, Italy), 100 U/ml penicillin, 100 U/ml streptomycin, were passaged at subconfluency to prevent contact inhibition and were kept under a humidified atmosphere of 5% CO2 in air, at 37°C. Cell adhesion was evaluated by counting cell nuclei. The proliferation rate was assessed by Cell Titer GLO (Promega, Milan, Italy) according to the manufacturer's protocol at 2 days. Data were analysed by GraphPad Prism6 (GraphPad Software, Inc., La Jolla, CA, USA). Each experiment was repeated at least three times. Statistical analysis was performed by using the Student t-test. A p value of <0.05 was considered significant.

2. Results

The non-treated Ti cylinders show a quite hydrophilic behaviour, with an average contact angle (CA) value for water and diiodomethane (CH2I2) of 35° and 40° respectively. After the anodization process, a transition toward the hydrophobic regime was found. The a-Si coating is able to impart two opposite behaviours to the surface, according to the difference in the growth temperature of the film. The surface of the cylinders coated with a-Si grown at low temperature (sample a-Si_90) showed nearly the same hydrophobic behaviour with respect to the anodized sample (Ano-Ti), with an average CA of 80° and 49° for H2O and CH2I2, respectively. On the other hand, the wetting behaviour of the high temperature grown a-Si coating (sample a-Si_350) is comparable with the one observed for the untreated Ti samples. HaCaT cells display an increased proliferation level on AnoTi samples whereas NHDF shown a similar proliferation level on AnoTi and non-treated Ti samples, showing a reduced

viability on a-Si_90 and a-Si_350. HaCaT shown a high level of adhesion on AnoTi and as-Si_90 samples at both 2 and 24 hours. Furthermore, NHDF cells display a significantly higher adhesion level only on AnoTi sample at both 2 and 24 h (Fig.1).

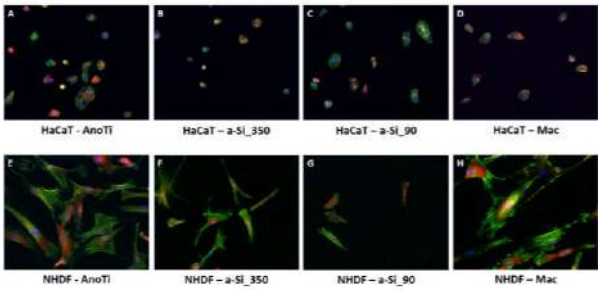

Figure 1: Representative pictures of cell morphology. Fluorescence photomicrographs of HaCaT (A-D) and NHDF (E-H) seeded on different samples for 24 h. The cells were stained for the nucleus (DAPI, blue), the actin (rhodamine-phalloidin, green) and the focal adhesions (paxillin, red).

3. Discussion & Conclusion

In conclusion, this work supports the use of titanium anodization as a strategy to enhance the adhesion of soft tissue cells to the Ti surfaces.

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49:

OCT for oral measurement: a preliminary study.

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1. Introduction

We use optical coherence tomography (OCT) to perform a comprehensive program of *in vivo* and *in vitro* structural imaging of hard and soft tissues within the oral cavity. We have imaged the different types of healthy oral mucosa. The aim of this work was to determine whether OCT is a good technique to: image lip, inner cheek, gum, and the top and bottom of the tongue.

2. Methods

The handheld probe was used for all measurements. An air spacer was used to keep the probe at a fixed distance to the tissue (1300 nm). The 900nm handheld probe was only available with a prototype immersion spacer, hence the surface in the images is always in the shape of the spacer. The TEL220 system with OCTH-LK20 objective gets 1300 nm center wavelength, a scan rate up to 76 kHz, an image depth by 3,5 mm in air, an axial resolution 3 µm in air and a lateral resolution of 9 µm. Measurements were performed with the lightweight handheld OCT scanner (OCTH). The OCTH should be used with a spacer that keeps the sample at a fixed distance (in focus).

3. Results

The comparison between the scans of the two probes shows similar images for both groups examined in oral structures: cheek, gum, lip, tongue top, tongue bottom. Both 900 nm and 1300 nm can be used for oral OCT imaging. The probe by 900 nm show a higher axial and lateral resolution, the images show more details. The probe by 1300 nm show a higher penetration depth, data can be acquired from deeper lying tissue (Fig.1). Since ,the choice of the ideal wavelength depends on the exact application. The small OCTH design allows to image in the mouth. Both spacers work, since the immersion spacer is just a prototype we would recommend the air spacer.

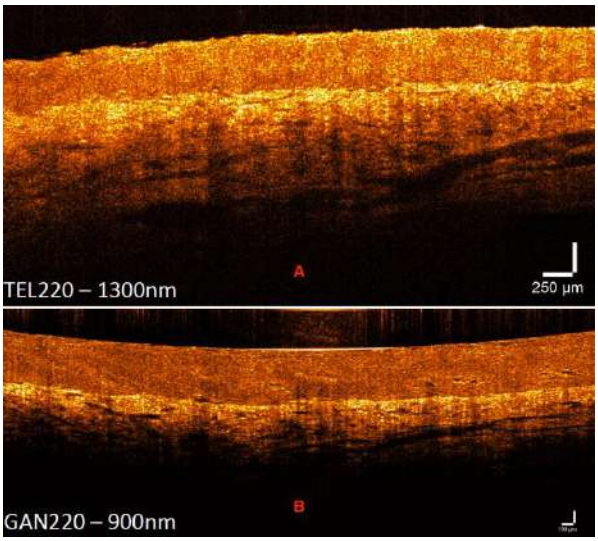

Figure 1: Representative pictures of tissue morphology by cheeck. The difference between image A where sharper surface images and image B are displayed where we have more depth data.

4. Discussion & Conclusion

OCT imaging was rapid, unproblematic and well received by all patients, with the imaging protocol adding only a few minutes to visit duration. Thus, the introduction of OCT imaging techniques to routine patient visits should be well received by patients and clinicians alike. In fact, OCT accurately depicts dental tissue structure and is able to detect small anomalies in that structure. These results suggest that OCT is a potentially useful modality for dental clinical and research applications.

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50:

Effects of fiber-glass-reinforced composite restorations on fracture resistance, failure mode and marginal integrity of endodontically treated molars

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1. Introduction

To evaluate marginal integrity, fracture resistance and fracture pattern of endodontically treated upper premolar, restored with different glass-fiber reinforced materials.

2. Methods

36 extracted intact premolars were endodontically treated; an MOD cavity were prepared and specimens were then divided in 6 groups: sound teeth (G1); no restoration (G2); direct composite restoration with fiber reinforced composite (Ever-x Posterior, GC) (G3), direct ormocer restoration (Admira Fusion, Voco) (G4); G3 reinforced with buccal-oral glass-fibers (G5); G4 reinforced with buccal-oral glass-fibers (G6). Specimens were scanned with micro-CT (SkyScan 1172: Bruker- microCT, Kontich, Belgium), before and after fatigue artificial treatment with Ball Mill Machine, to evaluate marginal integrity. Specimens were then loaded until fracture using a universal testing machine (Instron, Canton, MA, USA). The maximum breaking loads were recorded in Newton (N) and data were analysed with one-way ANOVA and *post-hoc* Bonferroni test ($p<0,05$). Fractured specimens were also analysed with SEM and fractography analysis was performed.

Figure 1: The two images show fracture test with Instrom Machine

3. Results

ANOVA test showed that horizontal glass-fiber insertion did not significantly improved marginal integrity of restorations. However, fracture resistance of G5 and G6 was significantly higher than G3 and G4 ($p=0.001$). All specimens fractured in a catastrophic way. In G5 and G6 glass-fibers inducted a partial deflection of the fracture, even if they were not able to stop the crack propagation.

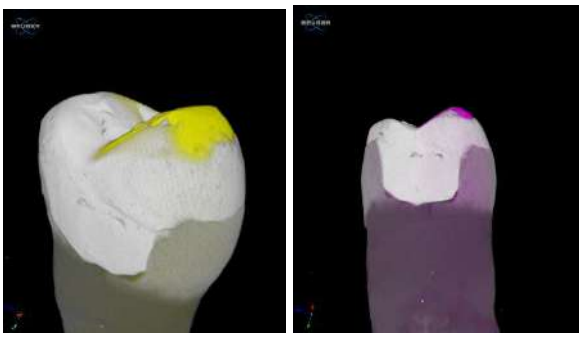

Figure 2: The two images show micro CT scanning and matching.

Discussion & Conclusion

For the direct restoration of endodontically treated premolars, the reinforcement of composite resins with glass-fibers or fiber-post could enhance the fracture resistance. The SEM analysis showed a low ability of glass-fibers in deviating the fracture, but this effect was not sufficient to lead more favorable fracture patterns, over the CEJ.

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76:

Argon-based treatments for titanium dental implants to introduce organic functionalities

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1. Introduction

Plasma polymers deposition and plasma surface activation are technologies capable to enhance biologically relevant surface features of biomaterials. The aim of this study was to evaluate the biological effects of two different surface modifications, i.e. amine (NH2-Ti) and carboxylic/esteric (COOH/R-Ti) functionalities.These modifications were obtained from aminopropyltriethoxysilane (APTES) and methylmethacrylate (MMA) precursors, respectively, through an atmospheric plasma jet RF-APPJ portable equipment.

2. Methods

Three types of specimens were used: pristine titanium (Ti, unmodified control), titanium with carboxylic/ carboxylate functionalization (COOH/R-Ti) and titanium with amine functionalization (NH2-Ti). Methylmethacrylate (MMA, Sigma Aldrich, ≥ 99%) has been used for carboxylic/carboxylate groups while amine functional groups have been obtained using aminopropyltriethoxysilane (APTES, Sigma Aldrich, ≥ 98%) as precursor. All sample coatings were characterized by Scanning Electron Microscopy, XPS, FT-IR spectroscopy and surface energy calculations. Stability after UV sterilisation and in water was also verified.

Total protein amount was evaluated using SERVA
BCA Protein Assay Micro Kit (SERVA
Electrophoresis GmbH, Heidelberg, Germany). To perform the in vitro tests, the pre-osteoblastic murine cell line MC3T3-E1 was used. Cell adhesion was evaluated on titanium samples by counting cell nuclei. Cell proliferation was evaluated using Cell Titer GLO (Promega, Milan, Italy) according to the manufacturer's protocol at 1 and 2 days. To assess the osteogenic differentiation Osteocalcin (OCN) was quantified in cell conditioned media by the use of Mouse Osteocalcin ELISA Kit (MyBioSource, Inc, San Diego, USA) following manufacturer's instructions.

3. Results

Both treated samples showed a higher quantity of adsorbed proteins and they also improved osteoblast cells adhesion on the surfaces compared to the pristine titanium. In particular the COOH/R-Ti led to a nearly two-fold improvement of cell adhesion. Cell proliferation at 24 h on coated samples was initially lower than on titanium control, while, at 48 h, COOH/R-Ti reached the same proliferation rate as pristine titanium. Cells grown on NH2-Ti were more elongated and tapered in shape with smaller areas than on COOH/R-Ti enriched surfaces. Furthermore, NH2-Ti significantly enhanced osteocalcin production, starting from 14 days, whereas COOH/R-Ti had this effect only from 21 days. Notably, NH2-Ti was more efficient than COOH/R-Ti at 21 days. The NH2-Ti surface elicited the most relevant

osteogenic effect in terms of osteocalcin expression: this establishes an interesting correlation between early cell morphology and later differentiation stages.

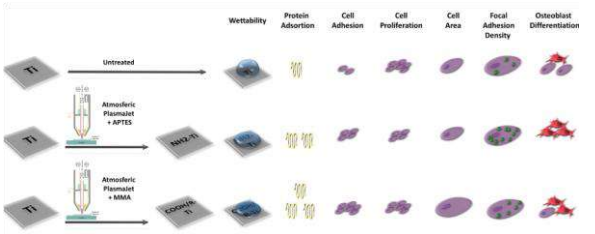

Figure 1: Representative figure of wettability, protein adsorption, cell adhesion, cell proliferation, cell area, focal adhesion density and osteoblast differentiation in untreated sample, in titanium with amine functionalization (NH2-Ti) sample and in titanium with carboxylic/carboxylate functionalization (COOH/R-Ti) sample.

4.Discussion & Conclusion

The flexibility of the presented surface functionalization process, by virtue of a wide range of potential monomers in aerosol or vapour phase, offers the researchers a new tool that can be used to investigate how to regulate cell fate modulating surface chemistry. It also allows the functionalization of complex 3D shaped materials and devices, such as dental implants, and it can be done in less than 1 minute.

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ENGINEERING

9:

TJBOT: a Robot to prevent the cognitive decline

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1. Introduction

The idea of "TjBot: a robot to prevent the cognitive decline" was born during an hackathon aimed to conceive a technological solution for the aged people. The event was organized by IBM, FONDAZIONE MARCHE and ISSNAF.
With the proposed solution, the objective is to counteract cognitive decline approaching the people with the first signs of dementia or Alzheimer's dementia in the last few years of the work career with that Robot. In the workplace, Tjbot, through its Visual Recognition function, is able to recognize eye fatigue, recommending breaks when needed, offering the possibility of ordering a healthy and balanced meal from the Eat&Out-BIOMEDFOOD (spin-off of the Marche Polytechnic University) and remembering, through the resolution of training-brain games, username and password. For older people, Tjbot, connected to home Wi-Fi, allows to challenge the users nearby with the brain training games, communicate with them and meet them in order to fight not only the cognitive decline but also isolation. It can be connected to home automation sensors to allow elderly people monitoring.

2. Methods

The current research being carried out in the field of engineering and medicine, so using a medical approach mainly, but with an economic analysis. In particular, medical theories have been combined with the Internet Of Things (IOT) solution, integrated in the 'TjBot' Robot that uses the IBM Bluemix platform [1] and is managed by its internal Raspberry PI3 CPU.

3. Results

Identifying two target users (pre-retired workers, elderly people with already manifested pathologies), the expected results are distinguished for the companies that will provide the Robots to its employees and for the elderly users. Expected results for the companies: contrast the decline in productivity of people in last years of work, due to aging; decreasing the rate of absenteeism due to the onset of poor metabolic syndrome [2]; encourage compliance with the Laws concerning the safety at work. Expected results for people with disease like cognitive decline or Alzheimer's dementia: monitoring cognitive decline for patients with recognized dementia; stimulation of cognitive and motor functions; contrast to social isolation; increase the awareness to a nutritionally balanced diet[3].

4. Discussion & Conclusion

The International Monetary Fund published a study in 2016 that highlights: the increase of the share of workers in the age range of 55 to 64 years; an increase of about one third, from 15 to 20% of the total, a phenomenon that would result in a loss of between 2 and 4% in terms of productivity. The study underscores how the peak of productivity is between 40 and 50 years, then goes down quickly as it approaches retirement.
Furthermore, according to Alzhaimer's Disease International, dementia patients will reach 75,62 million in 2030, 135,45 million in 2050.
The remarkable amount of epidemiological data presented by Professor Martin Prince, Institute of Psychiatry, King's College, London, highlights some critical data. Prince cites, among other sources, the World Health Organization: 1 ill

every 4 seconds, 7.7 million new cases every year in the world. Critics are highlighted in Asia, Sub-Saharan Africa, Colombia, where obesity and diabetes are widespread and promote cognitive decline and dementia [4].
The main objective is help to shift the ex-ante National Health System optics (prevention) rather than ex-post (disease cure) in order to reduce national health spending.
The project's specific objectives consist of: contrasting the natural cognitive decline (physical and mental); keeping the socially active user, in touch with other users by creating an online community; increasing awareness of the individual to respect a balanced and personalized diet, with the ability to order a ready, healthy and balanced meal.
Currently there is not any integrated solution (Software Program + TJBOT + App + Sensors + Monitoring Devices) in response to the problem being analysed.

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17:

Automatic determination of the two largest axes from the largest slice of thyroid in a 2D Ultrasound Dataset

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1. Introduction

In this work, we propose a method to segment the thyroid images in a set of 2D Ultrasound (US) images and then extract the two largest axes from the largest thyroid in the dataset. In the first step, segmentation is carried out in each of the image in the dataset. A largest thyroid image is computed from the stack of the segmented images which is used to compute the largest axes (i.e. length and breadth). These information can be used to compute the volume of thyroid in order to distinguish whether the thyroid is healthy or pathogenic as most of the thyroid diseases [1] involve change in the shape and size of the thyroid.

2. Methods

A total of 5 Electromagnetically (EM) tracked datasets with more than 1000 2D US images were acquired. For the segmentation process, an active contour algorithm developed by Chan Vese [2] along with an algorithm as mentioned in [3] were used to segment all the 2D images in the dataset. All the segmented images are computed as binary images. After segmentation; a largest thyroid is computed by counting the number of white pixels inside the contour. This thyroid image is then used to compute the largest axes. This is achieved by computing the largest vertical and horizontal line that pass through the thyroid in each image. For that, the image is rotated by 1 degree in each iteration until a full rotation is completed. Out of all these, the image with the largest vertical and horizontal lines will be considered as the largest axes of the thyroid which can be used to compute the thyroid volume by applying an ellipsoidal formula or by volumetric ultrasonography [4].

3. Results

The results of the estimation of largest axes in the four datasets are shown in figure 1 and similarly the quantitive results are shown in table 1.

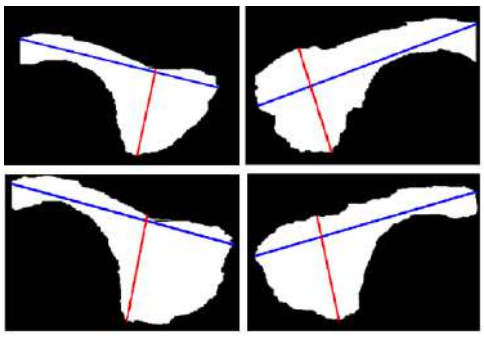

Figure 1: Largest thyroids with largest axis in 4 datasets.

Datasets	Axis length 1 (pixels)	Axis length 2 (pixels)
1	513	210
2	534	233
3	532	212
4	423	243

5	504	244

Table 1: 2 maximum axis lengths in 5 US image datasets

4. Discussion & Conclusion

The presented approach computes the two largest axes in a thyroid image after segmenting it. The obtained results in all the datasets match to each other except for 4th dataset because the acquired images in this dataset did not contain the full thyroid. As a next step we will try to compute the thyroid volume by modelling the thyroid as an ellipsoid and using the largest axes computed here.

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32:

Improving functional recovery after radical prostatectomy: in vitro evidences on a chitosan-based medical device

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1. Introduction

Chitosan (CS) based nerve grafts are employed to promote neural repair after injury raising more and more interest among basic and clinical research. *In vitro* and *in vivo* studies have shown that this biomaterial has biocompatible and biomimetic properties to improve the regeneration process of the peripheral nervous system [1].

It is well known that Prostate cancer (PCa) is the most common cancer among men. The surgical treatment for PCa is represented by the radical prostatectomy, which is the gold standard in the treatment of localized disease. Unfortunately, in patients who underwent a radical prostatectomy, frequently iatrogenic damage to the peri-prostatic nerve bundles occurs, leading to erectile dysfunction (ED).

The aim of this in vitro study is to assess the simultaneous anti-proliferative and pro-regenerative properties of a CS film, which has already achieved a clinical use for the peri-prostatic nerve plexus protection and a patent (Application reference: 102016000070911).

2. Methods

CS-anti-proliferative properties were tested on different human prostate cancer cell lines (PC-3, DU145, LNCap) seeded on two different experimental condition: dissolution products of CS and CS coating. Since the prostatic plexus is innervated by sympathetic, parasympathetic and somatic fibers, the regenerative potential of CS films was assessed through primary neuronal cultures and ex vivo explants derived from autonomic and DRG ganglia.

3. Results

The dissolution products of CS on proliferation assay performed after 1, 3, 6 days determined a significant lower proliferation of cancer cells, accordingly the same cells in direct contact with CS coating showed a substantial change in morphology, but also a significant decrease in proliferation.

Regarding the regenerative potential, CS film were tested and they demonstrated to represent a permissive substrate for neurite regeneration and axonal elongation.

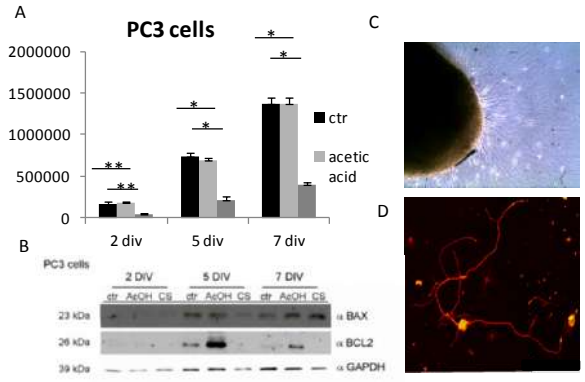

Figure 1: A) PC3 cancer cell line on CS coating, effect on cell proliferation and on Bcl2/Bax expression (B). (C) Pro-regenerative effect of CS on Autonomic ganglia explants and on dissociated autonomic neuron cultures (D)

4. Discussion & Conclusion.

An increasing number of young men have an early prostate cancer diagnosis, and ED caused by radical prostatectomy is associated with distress and impaired quality of life. The clinical application of new techniques and new materials in the field of peripheral nerve regeneration would result in minor inconvenience for patients and allow to extend the treatment also for applications in oncology.

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34:

Joint enhancement of stereo endoscopic images based on vector lifting scheme

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Introduction

The recent medical and technological progress, including the innovation of stereo laparoscopes, has made minimally invasive surgery a popular diagnosis and treatment tool. Due to the dynamic illumination conditions of the endoscopic domain, stereo endoscopic images may present unbalanced brightness and wide dark regions reaching up to 40% of the image resolution. To enhance the quality of the perceived images and improve the output of eventual surgery planning tasks such as feature extraction and 3D organ reconstruction/registration, we propose in this work to design a novel contrast enhancement method for stereo endoscopic images.

Methods

A straightforward method for contrast enhancement of stereo endoscopic images consists in separately applying conventional 2D image enhancement techniques to the left and right views of the stereo data. Among them, wavelet-based image enhancement method can be used [1]. The generated wavelet coefficients are adjusted using a mapping function. Finally, the enhanced images are obtained by applying the inverse wavelet transform. However, the use of such 2D conventional technique is not so efficient since it does not take into account the inter-view dependencies of these three-dimensional (3D) images. For this reason, we propose in this work to resort to a joint wavelet decomposition, based on the concept of Vector Lifting Scheme (VLS) [2], to exploit the correlation between the left and right views. To this end, the stereo matching pixels should be identified by using a given disparity estimation method. Once the wavelet representations of both views are generated, the adjustment technique, used in [1], is performed to enhance the stereo data.

Results

The enhancement methods are evaluated on stereo endoscopic images (pig liver) captured from The Intervention Center at Oslo University Hospital. The standard method, which uses independent wavelet transform, will be denoted by "LS-approach" since classical Lifting Scheme (LS) is separately applied to both views. The proposed method will be designated by "VLS-approach". A quantitative comparison between these two approaches is given in Table 1 in terms of Absolute Measure of Enhancement (AME), Second Derivative like Measure of Enhancement (SDME), Region Contrast (RC) and Edge Content (EC). Note that lower values of AME and SDME, and higher values of RC and EC, show better performance. Our proposed enhanced right view is illustrated in Fig.1.

Methods/Metrics	AME	SDME	RC	EC
VLS-approach	**52.23**	**107.37**	**12.28**	**91.63**
LS-approach	61.37	113.96	7.93	84.92

Table 1: Average quality scores

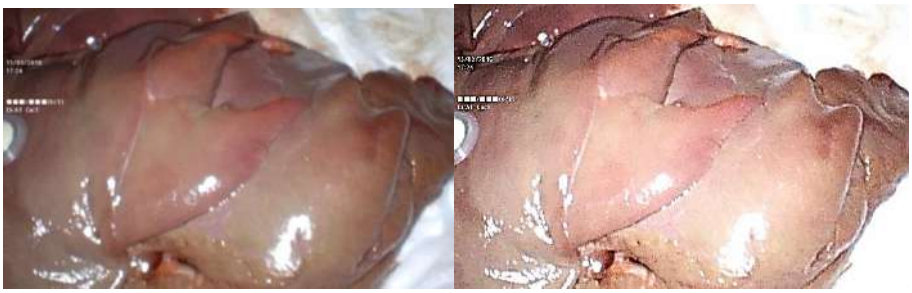

Figure 1: Original right image (upper side) and the enhanced one with the proposed method (bottom side).

Discussion & Conclusion

In this work, we have proposed a new method for contrast enhancement of stereo endoscopic images. While an intra processing of wavelet coefficients has been used as developed in [1], the future work aims at developing joint processing techniques to adjust the wavelet coefficients of both views.

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40:

Mimicking the inorganic component of bone through mesoporous hydroxyapatite and mesoporous bioactive glasses

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1. Introduction

This work represents the initial phase of the ERC Boost Project whose aim is the fabrication of a smart scaffold that mimics the natural bone chemistry, structure and topography for the treatment of osteoporotic fractures. Since human bone is composed of an organic matrix (mainly type I collagen) and an inorganic phase made up by nanometric crystals of hydroxyapatite [1], the starting material chosen for the project is a composite material made by collagen, mesoporous hydroxyapatite (MHA) and/or mesoporous bioactive glasses (MBG). Mesoporous materials have exceptional textural properties (high surface area, high pore volume and ordered mesoporosity) that lead to an improved reactivity in body fluids [2], making them particularly suitable for bone tissue regeneration.

2. Methods

MBG has been synthesised through an aerosol-assisted spray-drying process. We used a basic composition 85%SiO2/15%CaO (mol %), enriched with therapeutic ions to further increase their regenerative potential. In particular strontium has been chosen for its osteogenic and bone antiresorptive properties (Sr_MBG_SD), whereas copper for its antibacterial and angiogenetic behaviour (Cu_MBG_SD, figure 1)[3].

MHA have been prepared through two different routes: the above-mentioned aerosol-assisted spray-drying process and a precipitation method with reflux.

Both MBG and MHA have been characterized through FESEM coupled with EDXS and through adsorption and desorption of nitrogen to evaluate their mesoporosity. In addition, bioactivity and ion release tests have been carried out on MBGs to investigate their behaviour in a physiological-like fluid. XRD technique has been adopted to monitor the bioactivity of MBGs and to investigate the crystalline structure and the size of nanocrystals of MHA.

3. Results

Aerosol-assisted spray-drying process led to the synthesis of spherical microparticles, both for MBG and MHA. The precipitation method instead allowed obtaining nanoHA with rod-like shape. After 1 day of soaking in SBF, MBGs were already covered by HA deposits.

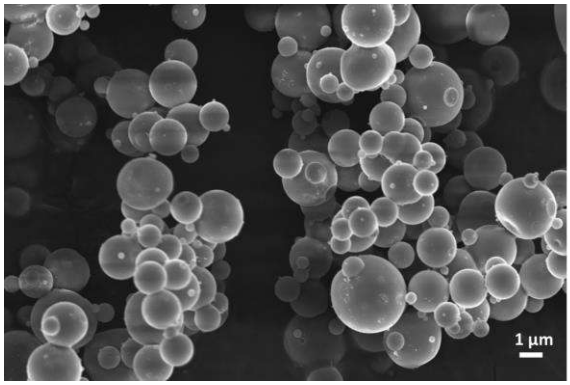

Figure 1: FESEM image of Cu_MBG_SD.

4. Discussion & Conclusion

MBGs and MHA possess high surface area and consequently high reactivity. Furthermore, MBGs show a very fast bioactive behaviour. MHA obtained through precipitation method showed shape and dimensions similar to bone hydroxyapatite nanocrystals.

5. Acknowledgment

The authors acknowledge the UE financial funding (ERC-CoG-2015, Grant number 681798, BOOST, (www.ercprojectboost.eu)).

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42:

PROPOSAL OF AN INSTRUMENT FOR THE TRACEABILITY AND THE MANAGEMENT OF THE CENTRAL VENOUS ACCESSES

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ABSTRACT

Background and aim: Nowadays the central venous accesses (CVC) are widely used devices and they allow a safe delivery of diagnostic and therapeutic services. An inconsistency in CVC management and a lack of data about implanted devices history emerged by the observation in hospital realities.
The aim is to create a valid instrument in order to offer a better healthcare to patients and to provide a guide for nurses for their profession.

Materials and method: The instrument was realized following scientific evidences obtained by consultations of guidelines, articles on PubMed and publications on web sites (GAVaCeLT). A validation procedure is carried out: the instrument was shown to nurses, modified after focus group and applied to test the efficacy.

Results: Completed trial booklets were withdrawn by checking compilation mode and constancy. Approval and validity levels were enquired by analysis of compiled questionnaires after the final focus group.

Analysis and discussion: During the project an increase of positive feedbacks was noticed. The instrument promotes: management standardization, implanted device history knowledge and data availability for possible studies. The CVC consciousness does not increase in all patients because of time limitation that interferes on their education negatively.

Conclusion: The instrument results valid, useful to improve patients' healthcare and efficacy to standardize CVC management delivered by nurses. It is hoped booklets will be use unofficially. Studies and future development are suggested.

57:

The effect of Handle Shape, Size and Coloration of Tightening of Spinal Fusion Drivers

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1. Introduction

The final step of the PPS (percutaneous pedicle screw fixation for degenerative spinal disorders) is plug fixation, which requires high (up to 10 Nm) torque to fixate screws and rods inside patient's spine by a driver. From the point of ergonomics, applied forces greatly depend on our postures and shape of objects to manipulate [1]. Our previous study revealed that putting thumbs on the driver handle increases the torque by 24% [2].

We have designed a new driver handle that the surgeons can easily put their thumbs on and turn. This paper focuses on the effect of shape, size and coloration of the handle. We compare maximum torque with handles in ex vivo environment. We also evaluate whether the holders put their thumbs on the handles with or without coloration.

2. Methods

We have prepared four types of handles (Figure 1).

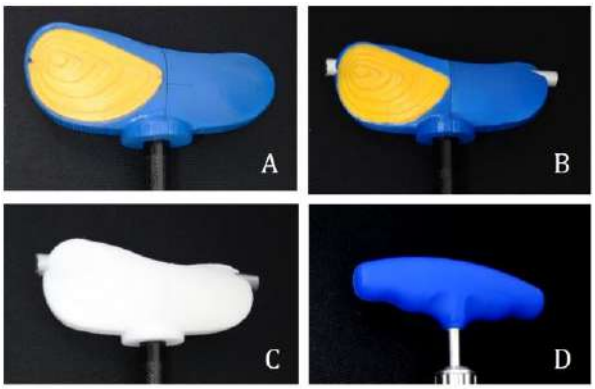

Figure 1: Driver handles. A,B and C are the same shape.
A: Newly designed, colored, big (131mm in width)
B: Newly designed, colored, small (125mm in width)
C: Newly designed, colorless, small (125mm in width)
D: Conventional (115mm in width)

Exp. 1: To measure maximum torque, we used a 6-DOF force sensor (Figure 2). As a real PPS, the tip of the driver is inserted in the head of the screw. The posture of subjects is same as the case of real PPS fixation task.

16 subjects are asked to turn the handles A, B and D (in randomized order) during three seconds as hard as they can. Maximum torques are evaluated.

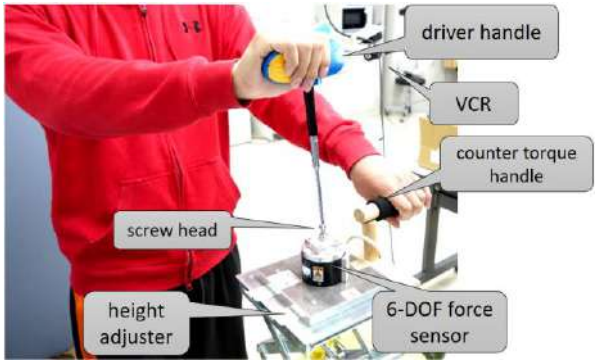

Figure 2: Ex-vivo evaluation of fixation torque.

Exp. 2: 19 subjects without prior knowledge of grasping PPS handle are asked to 'naturally' grasp the handles A, B, C and D. Then their grasping postures are categorized as i)putting thumbs on the handle, ii)not putting thumbs and iii)undefined.

3. Results

The maximum torques of each handles showed statistically significant difference (one-way ANOVA, $p<0.05$). Compared with conventional handle (D), newly designed small handle (B) increased torque by 8%, and newly designed big handle (A) increased torque by 14%.

Whereas ten of 19 subjects put thumbs on the colorless handle (C), 15 subjects put thumbs on the colored handle (B).

4. Discussion & Conclusion

We reconfirmed that the shape affects fixation torque. The conventional handle we compared was relatively small and was inferior as compared with big ones. Our result also suggested that the coloration of the handle could affect grasping postures. Thus the yellow areas of our colored handles are intended to 'attract' thumbs.

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60:

Design to Care through Co-design

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Introduction

Next to fundamental research, applied research is important for the scientific process [1]. Furthermore, there is a demand for new user-centred, context specific design solutions by frontline users, i.e., healthcare professionals and patients. By combining applied research with user-centred design (i.e. design-based research) we can study user's everyday problems, needs and wishes and together co-design solutions. The aim was to study users' problems/challenges and to co-design solutions to improve users' safety and satisfaction using the CaTe approach (Figure 1).

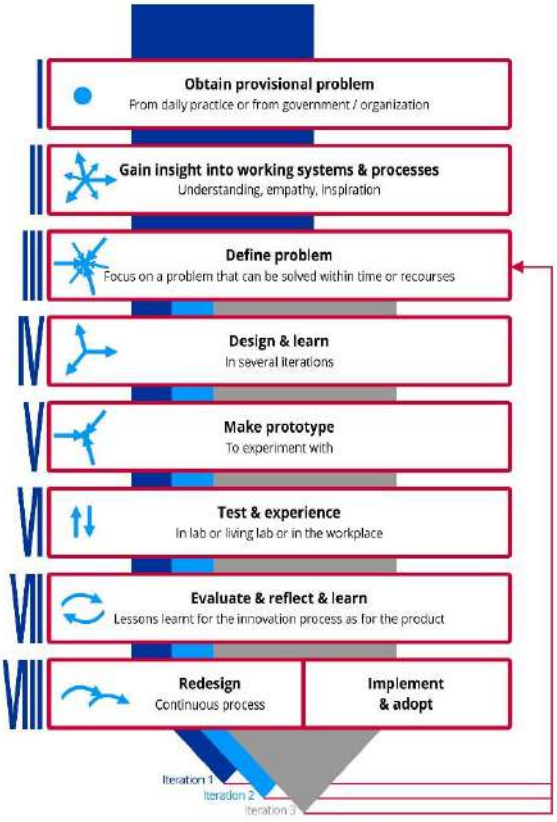

Figure 1: CaTe: CAre TEchnology approach to study and co-design solutions to improve safety and satisfaction.

Methods

Healthcare, Design, Engineering and Communication, Media & Information Technology Bachelor students worked closely together in interprofessional teams with healthcare professionals and/or patients in the Minor course 'Healthcare Technology' (6 months) and during their graduation projects (6 months) and to co-design solutions to improve safety and satisfaction.

Results

1. ID.alistic: Patient identification method (via fingerprints) for the Dialysis Center of the Albert Schweitzer Hospital (=concept).

For the Erasmus MC: Sophia Children's Hospital:

2. ANI: Application to calculate the Neonatal Intake (=concept).
3. Happyfeed: Redesign for holding Feeding Tubes besides the Incubator (=produced & implemented).
4. Baby's length: length-measuring device via light beams (=ready to produce).

Figure 2: Design solution

Discussion & Conclusion

The CaTe approach provided a good structure for students to design user-centred solutions healthcare professionals and patients want to use. The concepts will be developed further and produced.

Acknowledgement

We would like to thanks the students: Maarten Zijlmans, Stijn Kievit, Robin van Everdingen, Sjoerd Keuzenkamp, Mark Rood, Vaashna Beni and Koen van der Beek.

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68:

Technology Innovations in Therapy and Imaging (T^2I^2): International Graduate School for Biodesign and Entrepreneurship

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1. Introduction

The potential for innovation generation and subsequent translation in start-up companies at German universities has not been a focus yet and the process is generally not part of the scientific education. The engineering courses are designed to impart knowledge from the natural sciences in the technical context. Innovation, creation and implementation are rarely part of the engineering curriculum, nor are interdisciplinary approaches. Modern Medicine is evolving at rapid rates. Technology has become a vital part of the diagnostic and therapeutic processes and requires constant attention. There is a growing need for professionals who specialize and are able to bridge the gap between medicine and technology combined with the ability to manage tasks given to them effectively and efficiently witin an economic context. The International Graduate School of Technology Innovations in Therapy and Imaging (T^2I^2) aims to do exactly that. The Ph.D. students are expected to work in a doctoral depth on topics and simultaneously taught to create a successful medical device or service by identifying the "unmet clinical needs" and develop their projects based on the Stanford BIODESIGN [1, - 3].

2. Methods

The T^2I^2 intends to foster the coming generation of health engineers to efficiently develop medical technology and ensure that this technology is a marketable resource. This is not only concentrated on Germany or the USA, but should also be employed in a more global approach including specific needs of healthcare or medical technology needs in developing and emerging countries.
A structured education program with an interdisciplinary approach in the disciplines of Medicine, Technology and Economics is provided. The graduate school participants have to successfully attend at least 300 hours of lecture or lecture equivalent study over a 36-month period.

Students from various disciplines work on topics and projects in the main area of medical imaging, minimally invasive therapy, image guided surgeries, catheter technologies, innovation generation, technical translation. Soft skill development is a core challenge and objective. Close contact and direct involvement to industry- and application oriented research projects, an international exchange and regular further training are core components. The graduate school, while engineering oriented, is located and placed within the medical faculty of the Otto-von-Guericke-University. The students are supervised jointly by a clinical and a technical professor.

3. Results

The central contact point for the Ph.D. program of the Graduate School T^2I^2 is a new Innovation Laboratory with Simulation-OR and Prototyping- Lab located at the University Hospital in Magdeburg. Currently 13 international Ph.D. students (from Egypt, Mexico, Nepal, India, Iran, Taiwan and Germany) are in that structured doctoral program for innovation generation, technology transfer and business implementation of medical technologies.

A strong education focus is on the 21-century skills- to approach complex challenges teaching competencies like critical thinking, creativity, communication and collaboration. Furthermore, for individual and subject-specific education, an external stay of at least 6 weeks is required at a partner university with a similar research focus.

4. Discussion & Conclusion

The aim of our graduate school is to bridge the gap between medicine and technology for products and services that have a future and have a clearly identified need. Students need to work more intimately with the medical personnel to gain a better understanding of their needs. This would hopefully result in identifying much more useful equipment for the healthcare professionals. The school will also focus on the innovative and entrepreneurial aspect of healthcare and teach and urge students to develop more innovative ideas and means to make those innovations marketable.

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75:

Initial results of optical and inertial sensor fusion as a tracking alternative for interventional procedures

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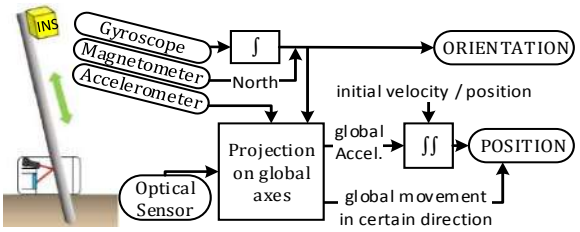
1. Introduction

A significant initial step for an effective image guided interventional treatment is to find the right position and angle to align the used instrument to the target. Additionally, a high navigation accuracy is required to



reach the therapy target precisely. Currently used tracking systems based on optical or electromagnetic (EM) principles come with drawbacks. Optical tracking requires a direct line of sight between the camera and the tracked object and EM systems are very sensitive to environmental changes.

We propose a fusion of optical and inertial sensors that has a potential to achieve a comparable accuracy than EM tracking, which is in the order of 1mm [1], and at the same time avoid the disadvantages of optical tracking systems.

2. Methods

An inertial navigation system (INS) is typically used to track position, orientation and velocity of an object relative to a known reference point by processing accelerometer and gyroscope signals. With recent advances in micromachined electro-mechanical systems (MEMS) the development of small, low cost and lightweight INS for medical applications such as orientation tracking of surgical tools became possible [2].

The gyroscope error propagation caused by the calculation of orientation and position in the strapdown navigation algorithm requires an error compensation for the emerging and critical drift. The integration of information from additional sensors such as magnetometer [3], as well as domain specific constraints and assumptions are common methods to compensate these errors.

We combined a simple optical sensor unit, consisting of a LED and a photodetector with an INS of ≈ 25×20×10 mm size for accurate angle and depth calculation of an interventional instrument. For tracking the orientation and position of a needle tip, the INS was attached to the opposite end. The static optical system was located on the body surface at the position of needle insertion and used to acquire drift free movement data, by recognizing the distance the needle moves alongside the optical sensor during insertion into the body. This information is used as a boundary condition to correct the drift-prone estimation of position. Figure 1 shows the integration of the sensor information into the general strapdown navigation algorithm, as well as the position of the sensors at the needle.

Figure 1: Position of optical and inertial sensor for example on a needle and the integration in the navigation algorithm.

3. Results

Preliminary experiments showed the ability of the optical signal to help reduce the inaccuracy in the position calculation of INS that is caused by the propagation of gyroscope errors. With the knowledge of

the extent of needle (and therefor INS) movement in one particular direction, it is now possible to considerably limit the drift of the navigation system.

4. Discussion & Conclusion

Since the calculated orientation is used to project the optically acquired information to the global axes, the propagation of the gyroscope error through the correction path has to be evaluated as well as the accuracy of the optical measurement setup. In addition, an incorporation of the proposed method into a viable calibration process for further improvement of accuracy has to be considered. Assuming an adequate precision, the navigation system could be used for example in connection with ultrasound as small, capable low-cost solution for guidance of interventional instruments.

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77:

Objective Measurement of Hip Implant Parameters by Automatic Feature Extraction from Planar Femoral X-Rays

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1. Introduction

The total number of arthroplasties, the replacement of a damaged or diseased musculoskeletal joint by implants, is predicted to increase by up to 50% within the next 10-15 years in the UK [1]. Therefore, it is important to provide advanced and easy to use diagnostic support systems for the surgeons to deal with the growing number of patients and to provide a possibility for personalized solutions in the future.

Templating, the process of anticipating the size and position of the implant, is crucial for the success of the surgery by minimizing perioperative complications, reduce future pain and total procedure cost. While several currently available commercial systems deal with the procedure planning, the decision of which implant type will be used is mainly done exclusively by the physician based on more or less objective parameters calculated by the used software. The development of a system that would provide additional information based on the preoperative planar x-ray images and lead to a more objective decision for the critical implant selection process would be very helpful.

Based on image processing of appropriate anteroposterior femoral radiographs, the proposed system could provide important additional and validated parameters that are typically used by the surgeon such as dimensions of certain segments of femur or femoral-acetabular rotation center and offset, but are not provided by the current software solutions. Such a decision system would be image based, complemented with patient specific data, and use an implant database with relevant parameters.

2. Methods

For preliminary testing, we extracted the dimensions (diameter) of significant segments automatically out of 5 planar x-ray images of healthy femur, by processing the images using MATLAB. Initially the x-ray images were obtained and converted into binary images using the gray scale to black and white code and thresholding method. A dataset of the binary images was then created. Segments were obtained in the binary image (anteroposterior view of the femur) using the developed code. The surgeon is provided with fact-based information containing length, angle, width and curvature for the final decision of which possible implants can be placed.

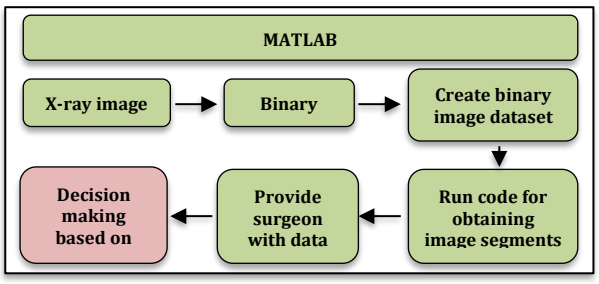

Figure 1: System workflow for objective measurement of hip implant parameters using femoral X-rays.

3. Results

The results obtained from our preliminary developments manifest in the form of segments drawn above and below the Lesser Trochanter in the anteroposterior view of the femoral X-ray. There is also a segment drawn lower than the inferior Lesser Trochanter that is adjustable depending on the curvature of the implant and the angle at which it is required to be implanted. These segments are used as basis on which the surgeon can decide how and where to fit the implant.

4. Discussion & Conclusion

The pre-operative planning procedure for hip implantation is crucial and needs attention. Mere assumptions and being subjective is a risk and could relatively easily be avoided. The proposed system provides standard objective information automatically extracted from planar X-ray images. This has the

potential to reduce surgery risk and making to make the entire process more objective and factual in nature personalised to the patient.

This system could be the basis for a Clinical Decision Support system that would aid the surgeon in the entire planning process, particularly the implant selection and fixation through Machine Learning Algorithms.

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80:

A VR-based surgical simulation system using patient – specific physical computing model

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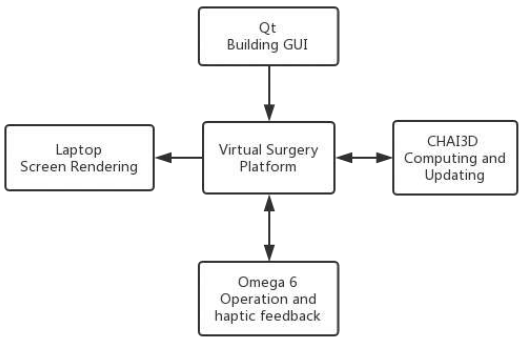
1. Introduction

Apart from the applications in surgical navigations, virtual surgery has become a new feasible method for training young surgeons. Since 2006 virtual simulation has been performed in selected patient cases affected by complex craniomaxillofacial disorders (n = 8) in addition to standard surgical planning based on patient specific 3d-models. [1] Although for training, standard models are enough for young surgeons to practice, we still need to build an accurate and personalized model to simulate a surgery better.

Patients' CT images are considered appropriate references for this procedure. CT images are taken along the axis of the body, and each of them represents the structure of a plane that is perpendicular to the body axis. Information like the gray scale levels of each pixel, which can be used in building a volume model, are also contained. During an operation, the model should be able to give some haptic feedback as well as to update



the changes on the models in real time.

Figure 1: Construction of the surgical simulation program

In this project, we realize these functions with CHAI3D library. Omega 6 is the device we use for applying forces and receiving feedbacks.

2. Hardware and Software Implement

Designed as a platform agnostic framework for computer haptics, visualization, and interactive real-time simulation, CHAI3D is an open source framework that supports a variety of commercially-available three-, six- and seven-degree-of-freedom haptic devices, and makes it simple to support new custom force feedback devices. [2]

The omega.6 is the most advanced pen-shaped force-feedback device available. The combination of full gravity compensation and driftless calibration contributes to greater accuracy. [3]

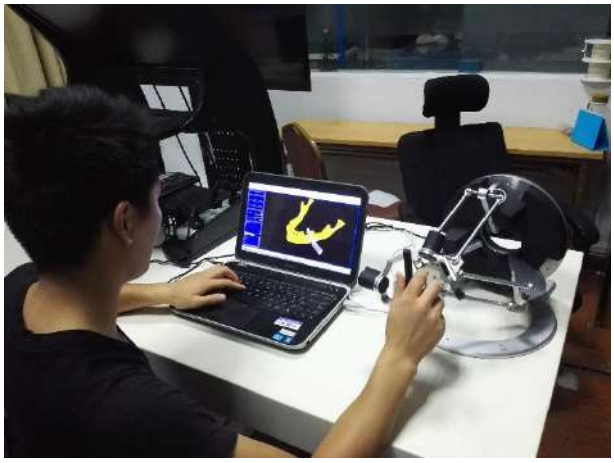
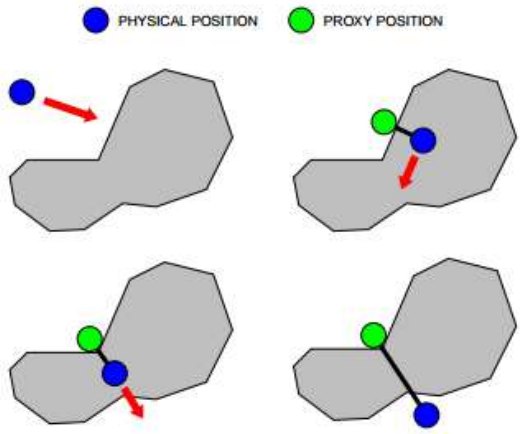


Figure 2: Program interface and Omega 6

3. Methods

In particular, we use the voxel data to determine the shape of the model and then create it in the CHAI3D world. CHAI3D allows users to load a stack of CT images into a multi-image pointer and analyze them. After creating a CHAI3D world and allocating the voxel data for them, we set an isosurface level to the object, and those voxels which gray level values exceed the isosurface level will represent unit points and form the model.

Collision detections and haptic feedback are also added to the model. CHAI3D uses a virtual "finger-proxy" algorithm to compute forces. When a tool object hit the surface of a model, the tool we can see will stop moving directly into its goal. However, the proxy of the tool is actually able to stick into the object, which is shown in the figure below. In this case, forces are computed between the actual tool and its proxy, assuming a string in the middle trying to drag them back together. Users can define the stiffness of the model according to



the materials.

Figure 3: Motion of the virtual proxy in Finger-proxy algorithm

When users click on the switch on Omega 6 while the virtual tool hit the object, the drilling operation is started. CHAI3D will read the collision event, and the determine the point which is contact with the tool. Then, the property of the point is changed, and it is no longer visible and able to give any haptic feedback. Graphic rendering will occur at the same time, and users can know about the result of their operation immediately.

4. Results and Conclusion

At present, some core functions such as loading image files, creating volume objects, and modify objects are completed. Right now, users can drill on models at random directions, and models can update its data and graphics in real time. Simple textures and haptic feedback are also applied on the models. Furthermore, for better simulations, we will calibrate the haptic feedback, restrict the drilling directions, and improve rendering through using colormap in the model. We expect this virtual surgery program can simulate cutting, grinding and even more complicated operations. Therefore, surgical training can be feasible and thus save time and cost in surgery practicing.

Acknowledgement

This work was supported by Natural Science Foundation of China (Grant No.: 81511130089), Foundation of Science and Technology Commission of Shanghai Municipality (Grant No.: 14441901002, 15510722200, and 16441908400).

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101:

MURAB: MRI and ultrasound robotic assisted biopsy

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1. Introduction

The MURAB project aims to design a new image guided robotic approach to improve the precision of diagnostic biopsies and effectiveness of the workflow in breast cancer and muscle diseases, reducing the usage of expensive Magnetic Resonance Imaging (MRI) to a minimum and at the same time yielding an improved precision during the biopsy procedure due to a novel MRI-Ultrasound (US) registration.

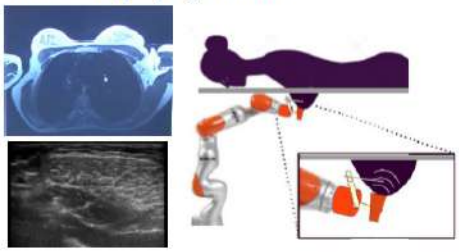

Figure 1: Technical workflow: lesion localization using combined MRI and US imaging (left) and robotic assisted biopsy (right)

2. Methods

Small lesions in breast and other organs cannot be always properly biopsied using, therefore a more accurate MR-guided biopsy is required. Biopsy under MRI guidance is complicated and does not provide real-time feedback. MURAB has the ambition to combine the benefits of real-time US biopsy with the precision of MRI by using state of the art technology. A robotically steered US transducer with additional acoustically transparent force sensing will be autonomously moved to optimally acquire volumetric data (Figure 1). Through new techniques, the system will optimally register the acquired volume to the MR image. Once that is performed, the radiologist can select the target on the MR image and the robot will steer the instrument to the desired location of the lesion by adapting the insertion angle based on real time US measurements.

3. Results

We have computed the elastic properties of a breast phantom through different acquisitions in MRI under the load of the gravity force, then we have tested the model through software simulations (Figure 2). The accuracy obtained during the preliminary tests is around 5mm and will be improved by using markers to track the rigid movement for a better calibration of the elastic properties.

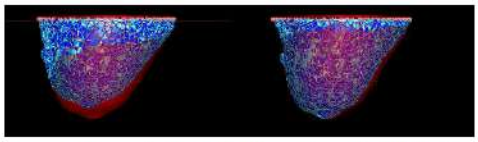

Figure 2: Breast phantom alignment through deformable models. Blue: reference model. Red: target model. Left: before the deformation. Right: after the deformation.

The elastic properties are computed by using the finite element method and the initialization is performed by using rigid and thin-plate-spline registration of the external surface of the model.

We have designed new robotic heads to support the US probe for the scanning of the breast and the biopsy needle (Figure 3).

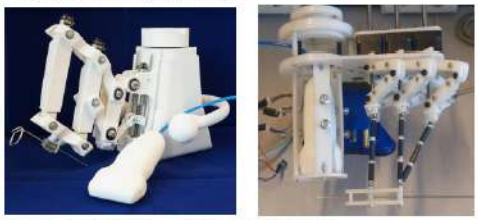

Figure 3: Prototypes of the robotic head

4. Discussion and Conclusion

Until now, most of the technical objectives of the MURAB project were accomplished and tested in-vitro. The next steps of the project will consist of integration and improvement of the technical components and the achievement of the clinical objectives: enabling US-guided robotic biopsies of lesions with higher accuracy than the current manual procedure, reduction of the patient discomfort and increase of the efficiency by preventing repeated procedure.

110:

Development and Face Validation of the Virtual Reality Epley Manoeuvre System (VREMS) for Home Epley Treatment

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1. Introduction

Benign paroxysmal positional vertigo (BPPV) is the most common positional vertigo affecting 2.4% of the general population [1]. The main symptom is perceived sensation of movement, which is associated with, falls, depression, and decreased quality of life [1]. Pathophysiology of BPPV involves calcium carbonate crystals in the utricle sac migrating to the semicircular canals [2]. The Epley manoeuvre is commonly used to move canaliths to prevent symptoms. It can be done in the office by a physician or at home. Office treatments are associated with a 90% success rate while home treatments have a much lower success rate and often require patients to return to the physician [3]. We present the creation and face validation of a high fidelity, low cost, Virtual Reality Epley Manoeuvre System (VREMS) that allows patients to carry out the Epley manoeuvre at home with greater accuracy.

2. Methods

Our system consisted of an Apple iPhone 6 (Apple Inc, Cupertino, California), placed within a three-dimensional (3D) virtual reality (VR) headset (HooToo, Fremont, California). Unity 3D (Unity Technologies SF, San Francisco, California), a game development platform, was used to create a VR environment which was packaged into an iPhone application, allowing participants to be guided step-by-step through the Epley manoeuvre in a 3D environment (Figure 1). In each step, visual instructions appeared on screen and an audio cue was played, directing the participant to carry out a specific task. Visual targets appeared at pre-set locations and an onscreen gaze pointer allowed the program to confirm the participant's gaze was directed correctly. We carried out a prospective, evaluator-blinded, randomized controlled trial to validate the VREMS system. Twenty healthy participants were recruited and randomized to undergo either a self-administered Epley manoeuvre with an instructional handout (IH) or to be guided using VREMS. Participants were video recorded and two expert, fellowship-trained, otologists evaluated the videos and each participant was assigned a grade (out of 10) for each step of the Epley as well as a total grade on the correctness of their performance.

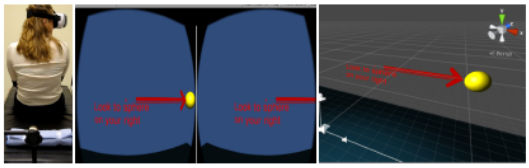

Figure 1: Demonstrating Epley manoeuvre using VREMS. Left: user wearing VREMS headset. Middle: VREMS stereoscopic headset view. Right: VR environment view.

3. Results

The average age was 26.4±7.12 years old in the VREMS group and 26.1±7.72 in the IH group. Overall, the VREMS group achieved an average score of 7.78±0.99 compared to 6.65±1.72 in the IH group ($p<0.0001$). For right-sided Epley, the VREMS group achieved a score of 7.94±0.96 vs. IH's 6.72±1.61($p<0.0001$) while for left sided Epley, the VREMS group achieved a score of 7.62±1.03 compared to IH's 6.58±1.83 ($p=0.01$).

4. Discussion and Conclusion

BPPV is a prevalent disease with important quality of life and health care resource implications [3]. The Epley manoeuvre is an effective treatment for BPPV, when performed correctly. Repeated office Epleys are not practical and home Epley treatments have shown to be far less effective [4]. We have developed and demonstrated face validity for our VREMS platform. VREMS is promising technology, which may help patients improve accuracy of home Epley treatments, achieve symptomatic relief, prevent future bouts, and reduce health care resource usage.

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124:

Phantom study of photoacoustic based analysis of Protoporphyrin IX saturation using a cheap CW laser

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1. Introduction

Protoporphyrin IX (PPIX) is a photosensitizer widely used in Photodynamic Therapy and Diagnostics. As a porphyrin it appears as an intermediate of the Heme-Synthesis and can also be generated in tumors [1].

It readily absorbs light of 405 nm and shows relaxation via non-radiative pathways. This leads to a localized thermo-elastic expansion and to an acoustic signal. If excited with light, PPIX shows a strong photoacoustic signal and a long thermal relaxation time of 15.6 ms [2]. This acoustic signal can be recorded power doppler ultrasound and the resulting data can be correlated with the position of the needle tip. This can be used to map local photosensitizer concentration changes for determining the optimum time to begin photodynamic therapy.

Due to the short wavelength used to excite PPIX, the penetration depth into the tissue is limited. This disadvantage can be overcome by using an optical fibre placed inside a biopsy needle.

The position of the needle can be tracked using external commercially available tracking systems.

The functional (photoacoustic) information is acquired using a Power Doppler-US superimposed on the top of the anatomical US-images. Mapping of local intensity changes in the concentration of the photosensitizer is then possible [3].

2. Methods

A gelatine phantom (FreAlagin™ R gelatine, Sigma-Aldrich Germany) measuring 15x15x10 cm was prepared. A tube was placed in the centre to form a 10x1,6 cm column. After removal of the tube, the column was filled with small gelatine pieces containing different concentrations of PPIX mixed with the gelatine at different concentrations and starting with the highest concentration, stepwise. PPIX (PPIX disodium salt, Sigma-Aldrich Germany), at different concentrations of 300, 150, 75 and 37 µMol/l respectively, and adjusted to a pH of 7,4.

The photoacoustic device consisted of a continuous wave laser with a wavelength of 405 nm (PPM 110, Powertechnology Incorporated, USA) and a mechanical chopper that was adjusted to 3 kHz (360C Ultra Miniature, Scitec, UK).

The beam of the laser was coupled directly into a multimode optical fibre with an inner diameter of 273 µm and an outer diameter of 420 µm. The fibre was placed inside a biopsy needle to probe inside the phantom (see Fig. 1).

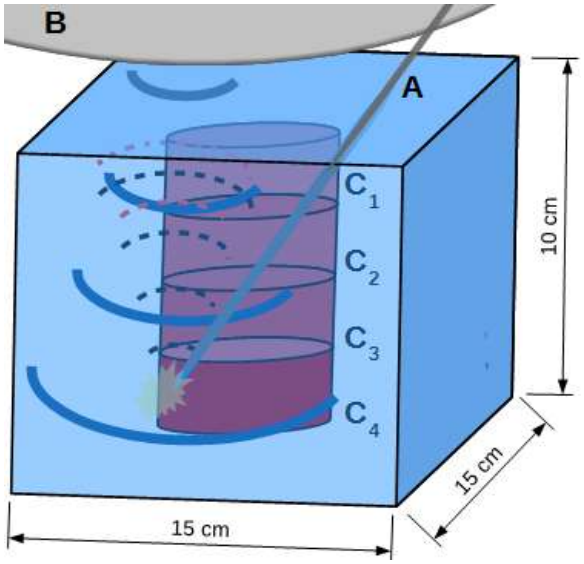

Figure 1 A: Biopsy Needle with fibre, B: Transducer, C_{1-4}: volumes with different concentrations of PPIX - US-Signal: thick continuous line, Echo: thin dotted line, added PA-Signal: thin dotted red line

Tracking of the biopsy needle was achieved using the Logiq E medical Ultrasound system (Logiq E, GE, USA).

3. Results & Discussion

When the fibre probe gets closer to the PPIX samples an increase in amplitude of the frequency spectrum is detectable. Testing the columns with different concentrations of PPIX showed a linear correlation between amplitude and concentration of the PPIX solutions.

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129:

Tumor Identification in Colorectal Histology Image Using Convolutional Neural Network

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1. Introduction

Colorectal cancer (CRC) has been a major health concern throughout the globe. Although the recent mortality rate of CRC has been stabilized or declined, it is still the third most common type of cancer in Korea [1]. Early diagnosis is extremely important as it determines treatment options and has a strong influence on the length of survival. This is typically done by analyzing colon biopsy images. This study proposes to use Deep Neural Network (DNN) to predict whether colon histology images contain tumor as there have been many other proposals that suggest using Convolutional Neural Network (CNN), i.e. DNN specifically adapted to image data, is effectively in classifying or locating tumor for many types of cancer. ImageNet Large Scale Visual Recognition Competition (ILSVRC) is a competition for research teams to compete on several visual recognition tasks to achieve higher accuracy [2]. Winner of 2014 ILSVRC was Visual Geometry Group (VGG). They proposed more layer of the CNN structure it gets, higher the accuracy it will be for visual classification and localization [3].

2. Methods

Data

The colorectal histology image was obtained from National Cancer Center Research Institute, Innovative Medical Engineering & Technology Branch (IRB number: NCC2016-0048). Total of 30 patients who were diagnosed with CRC were participated with the age range from 20 to 80. Among those patients, 30 normal and tumor images were obtained and because some of the images were damaged and were no longer able to use, they were eliminated from this research. Hence, 28 normal and 29 tumor images were obtained. Most of these images exceeded the size of the maximum capability average of 10000 pixel by 10000 pixel that the GPU can process, the raw images were cropped into a fixed size of 256 pixel by 256 pixel. When the images were cropped, 6806 normal images and 3474 tumor images were obtained.

Model

VGG presented 6 different models with different number of layers. Each of them consists of Rectified Linear Unit (ReLU) activation function, convolution, max-pooling, fully-connected layers [3]. Because some of these parts are outdated and the second model has no difference with the first model when applying the adjustment, we omitted the second structure, consequently five model structures.

Methodology

Each model were train and validated using a 10-fold validation data set. In this process, only well distinguished 100 normal and 100 tumor data set were used. After best performing model was selected based on the training and validation, the whole data set was used for the training and validation.

3. Results

Using the 5 different modified VGG models and the 200 selected histology image data set, accuracies for VGG A, B, C, D, and E models were obtained as follows: 82.5%, 87.5%, 87.5%, 91.4%, and 94.3%. As we use the most accurate model out of these 5 models, which is VGG E model, accuracy, loss, sensitivity, specificity was marked as follows: 93.5%, 0.439, 95.1%, 92.8%.

4. Discussion & Conclusion

As Visual Geometry Group stated, the deepest model out of 5 modified model, E model was the most accurate model. Also, by training and validating the colorectal histology image, it shows that we have implemented a practical tumor classification method.

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Acknowledgement

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132:

The MUSHA hand: a New Three Fingered Underactuated Hand for Minimally Invasive Robotic Surgery

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1. Introduction

Minimally invasive robotic surgery (MIRS) needs suitably designed tools able to enter the patient's body and replace the hands of the surgeon by equaling her/his motion dexterity and sensory ability. The use of articulated robots in MIRS endows surgeons with advanced manipulation capabilities. In this work, the design solutions of a novel three fingered robotic hand for MIRS are presented. The design of new instruments could broaden the use of MIRS leveraging the next generation robotic surgical interventions.

2. Methods

To comply with the performance of multiple tasks, the tool should have a high number of degrees of freedom (DoFs) to allow complex and human-like manipulation. The introduced complexity can be reduced by resorting to under-actuation and synergy paradigms. The design requirements have been identified based on both hardly accomplishable surgical tasks and physical constraints. The need of a unified instrument that would allow simultaneous tissue traction and manipulation, that could act as a retractor to gently manipulate organs (such as the bowel) has been considered. In addition, the instrument should provide the ability to perform both fine (needle and thread grasp) and power grasp (even for considerably large anatomical parts). Sensing modules must enrich the surgeon's visual diagnosis capabilities by providing quantitative force data which, eventually, can be fed back to the user. The capability to perform dexterous movements while in contact with the tissue (e.g. torsion or rolling) would contribute to the diagnosis phase as well. On the other hand, physical constraints must be carefully considered during the design phase. These constraints are due to the actuation interface of the widely used da Vinci Research Kit. Based on the considered requirements we develop a conceptual CAD design solution for the MUSHA hand. It has n = 11 DoFs and is actuated by four motors s = 4. In Fig. 1 some significant hand configurations are shown. The hand reconfiguration is possible through rotational joints at the base of index and middle fingers. We consider two possible tendon driven actuations and compare their performances.

Figure 1: Left: some significant hand configurations. Right: Mechanical synergies matrices.

2. Results

The evaluation has been performed using SynGrasp [1]. Tripod and fine grasp have been tested. For each configuration, SGV and principal direction in the object space have been evaluated. Figure 2 shows the results for the hand having S1 kinematic coupling. Similar trends can be found for the hand with S2 kinematic coupling solution.

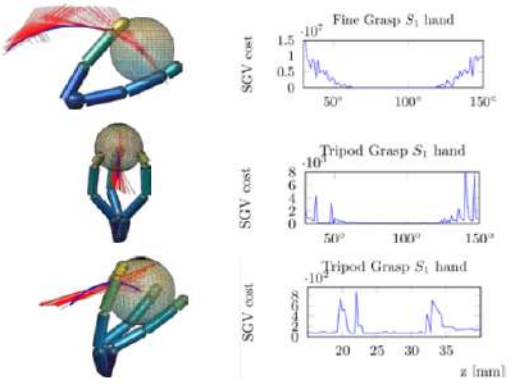

Figure 2: Force-closure cost function (SGV) to be minimized to select the best grasp.

4. Discussion & Conclusion

The hand with S2 kinematic coupling makes possible to command the thumb independently from other fingers (thumb retraction) at the cost of higher motion constraints among the fingers.

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NEUROSURGERY

120:

Brain Fibers Classification: A Shape Similarity Metric

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Introduction

From Diffusion Imaging (DI) data, the white matter fiber tract can be reconstructed using a class of techniques called tractography.

To simplify the visualization and analysis of white matter fiber tracts obtained from DI data, it is often necessary to group them into larger clusters or bundles. In order to perform clustering, first a mathematical definition of fiber similarity [1] (or, more commonly, fiber distance) must be specified. We propose a new method to classify fibers with respect to a novel shape criterion. The proposed method considers the concept of fiber correlation as a similarity indicator.

Methods

As dataset we have considered a Fornix bundle. We show the steps for Shape Similarity Metric:

1. We considered the first fiber as a fiber of reference. Each streamlines in the bundle is compared with streamline of reference, black line in Figure 2.
2. For each point of the streamlines we have calculated the Frenet Frame. Through the Frenet Frame we have information describing the geometry of the fibers.
3. To analyze the shape of fibers, we introduce two parameters that describe a geometric similarity, computed for each pair of fibers and for each points:
   - we denote with symbol *D* (**Difference**), the Euclidean distance between points. This is the Real component of our method
   - we denote with symbol *AS* (**Angular Shape**), the value obtained by comparing the angle between tangents. This is the Imaginary component of our method
4. We represented the fibers as complex form *De^iAS*, as a result of the previous point, and we computed correlation function between pair of fibers
5. We considered the maximum value of the correlation function and we estimated the correlation index for fibers extraction

Results

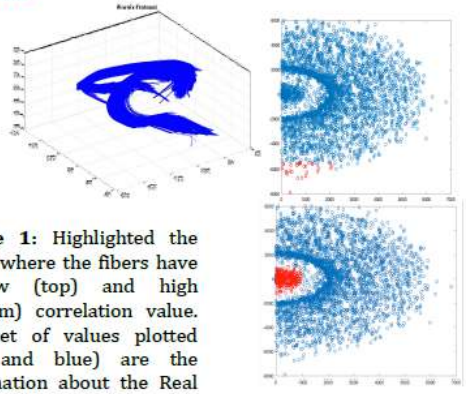

Figure 1: Highlighted the range where the fibers have a low (top) and high (bottom) correlation value. The set of values plotted (red and blue) are the information about the Real and Imaginary part.

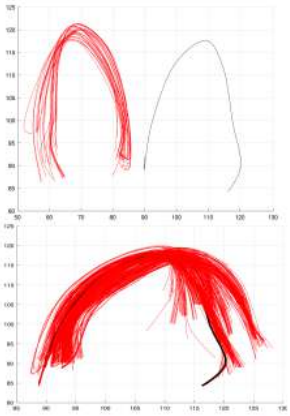

Figure 2: Selected fibers respect to low (top) and high (bottom) correlation index (values in red color Figure 1). In black color, we have the reference fiber used for comparison with other fibers.

Discussion and Conclusion

In this paper we presented a new criterion for classifying fibers. We introduce a new concept of similarity between fibers, computed for each pair of fibers and for each point. Using this new shape similarity metric, we have information on how two fibers are oriented with respect to each other; indeed, calculating the angle for each pair of points of two different fibers, we can estimate how much the fibers are comparable in shape. The results confirm a good fiber classification. In future we want to validate the clustering results by means of a ground-truth.

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SURGERY & ENDOSCOPY

1:

EFFECTS OF WARMED, HUMIDIFIED CO2 INSUFFLATION ON BODY CORE TEMPERATURE AND CYTOKINE RESPONSE: RANDOMIZED COMPARISON VERSUS STANDARD INSUFFLATION DURING ROBOT-ASSISTED RADICAL PROSTATECTOMY

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1. Introduction

Cool and dry gas insufflation in laparoscopy induces hypothermia and cytokine increase, with significant perioperative morbidity [1]. Few studies have suggested that warmed and humidified insufflation leads to an improved body core temperature (BCT) maintenance, a reduction of the inflammatory response and an improved quality of postoperative course, compared with standard insufflation [2-3]. Aim of this study was to assess if warmed and humidified CO_2 insufflation with HumiGard™ device can achieve significant benefits over standard insufflation in terms of risk of hypothermia and cytokine response, in the setting of robot-assisted radical prostatectomy (RARP).

2. Methods

Design, setting, and participants: patients undergoing RARP were randomized into **group H+WB** (32 patients receiving warmed, humidified CO_2 insufflation with HumiGard™ device, plus hot air warming blanket) and **group WB** (32 patients receiving standard CO_2 insufflation, plus hot air warming blanket.

Outcome measurements and statistical analysis: BCT, plasma levels of cytokines IL-6 and TNF-α, pain scores, and intraoperative parameters. The data were analyzed according to the Bayesian paradigm.

3. Results

Intraoperative BCT increased in both groups during surgery, with a statistically significant difference favoring group H+WB, ending at 0.2°C higher on average than group WB. The overall BCT increase was 0.088 degree per hour in the WB group, with an additionnal 0.064 degree per hour in the H+WB group. No difference across groups, at none of the time points, could be shown as far as the mean serum cytokine and the TNF-α levels, were concerned. No statistical differences were noted for pain scores and the other intraoperative parameters. Limitations of study were the low baseline BCT of our patients (mean 35.7°C) and the heating power of our HumiGard™ device, which was less than expected.

4. Discussion & Conclusion

During RARP, warm and humidified CO_2 insufflation with the HumiGard™ device is more effective than the standard CO_2 insufflation in maintaining the patient's heat homeostasis.

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13:

Ultra Structural Changes of Collagen in RadioFrequency (RF)-induced Colorectal anastomoses

Mao Lin, Chen Li, Tu Liangyong, Zhou Yu, Song Chengli- University of Shanghai for Science and Technology, School of Medical Instrument and Food Engineering, Shanghai, -

1. Introduction

The technology exploits the RadioFrequency (RF) energy induced fusion of native colorectum in order to achieve high-quality rapid tissue sealing without introducing any foreign materials, and thus, is expected to greatly reduce morbidity, mortality and cost [1]. Changes in collagen bonds within the fused tissue are thought to be pivotal to the strength of the resulting fusion. Herein, we investigate the ultra structural changes of thermal denaturing collagen in RF-induced colorectal anastomoses (CRA) by Raman spectroscopy, which provides biomolecular insights into the restructuring which occurs during tissue fusion.

2. Methods

The custom-made compression prototype used for creating end-to-end serosa-to-serosa CRA is showed in Figure 1. The electrodes were mounted on insulated and heat resistant ring carriers and then were pressed by a pressure device (ALX-S, Yiding Instrument Corporation) to provide the designated initially force for anastomoses. Each experimental condition was repeated at least five times.

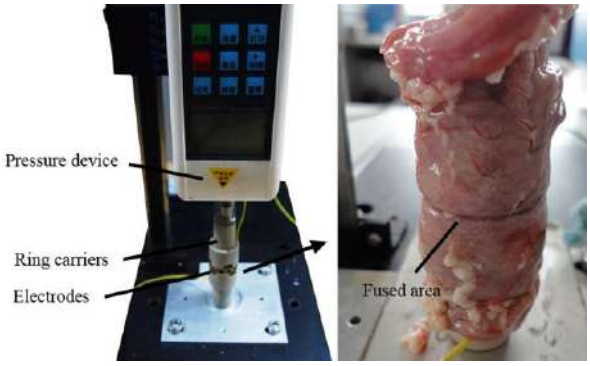

Figure 1: Compression prototype and experimental process. A pair of electrodes is fixed on two ring carriers. Bowel segments were mounted on ring carriers compressed by pressure device.

The collagen-rich regions of fused areas and normal colon were made 15 μm paraffin slices by the cross section and scanned by Raman micro-spectroscope (LabRam-1B, HORIBA Scientific., France) equipped with a microscope and a CCD camera. Raman spectra in the fingerprint regions that 800 ~ 1800 cm^{-1} were acquired. The whole procedure including samples scanning, data acquiring and peak analyzing, were carried out by a senior technician.

3. Results

Raman spectra of a healthy colon and fused colon subjected distinct duration and electric power is showed in Figure 2. Despite electric power, the signals at 875 cm^{-1} (C-C stretching of hydroxyproline ring), 1002 cm^{-1} (phenylalanine C=C symmetric stretching), 1061 cm^{-1} (C-N vibration of proline), 1127 cm^{-1} (C-N stretching group), 1296 cm^{-1} (deformation vibration of CH_2) and 1669 cm^{-1} (Amide I band) shifted consistently to lower wavenumber when compression pressure and duration were 277 kPa and 5 seconds, respectively. Generally, the intramolecular bonding strength was weakened by RF heating. The

signal at 1655 cm^{-1} representing α helix of collagen disappeared after fusion, which implied the disruption of α helix.

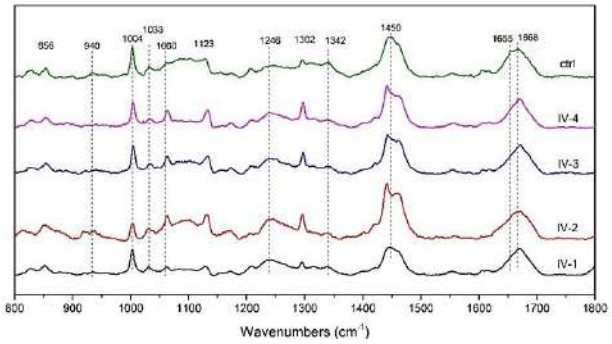

Figure 2: Raman spectra of the healthy colon (control) and fused colon subjected four combinations of electric power and duration (group IV-1 to IV-4).

4. Discussion & Conclusions

Despite the combinations of fusion parameters, collagen denaturation featuring by unfolding triple α helix is confirmed subjected RF by identifying weak C=O bonds and N-H bonds. Tissue fusion may mostly attribute to deformation vibration of CH_2, which subsequently leads to collagen crosslinking and peptides random coil.

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15:

New surgical tools for minimally invasive middle ear surgery

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1. Introduction

A series of new surgical instruments for implantation of latest cochlear electrodes for implantable hearing aids has been developed, in order to support insertion of these highly flexible structures into the human cochlear by minimally invasive surgical interventions.

The extreme flexibility of the electrode structure paired with the limited space for surgical tools and the necessity to orientate the electrode tip directly towards a tiny hole in the fenestra cochleae impede the usage of traditional instruments like tweezers and forceps.

We have developed different types of designs and working samples that aim to overcome these limitations. [1], [2]

2. Methods

To offer the required functionality to the surgeon, we thoroughly analyzed the variation of geometries of the human ear, used this information for the design of tools based on different mechanical mechanisms, manufactured these designs by both conventional machining and metal rapid prototyping technologies such as titanium laser sintering [3], and finally tested them with real human petrous bone samples.

3. Results

We recognized two main functions required for such instruments: Firstly, the electrode tip needs to be stabilized in a way that permits the introduction into the cochlea. Secondly, to advance the electrode further, mechanisms like direction sensitive stick/slip structures or elastic deformation effects had to be implemented.

In a series of prototype tests, we verified our different tool designs. It showed that the performance of some designs was superior to others in terms of functionality and ease of use. We realized that fluids present inside the ear act as a lubricant and can change efficiency of friction based approaches significantly.

Figure 1: 3D rendered tool tip designs based on clamping mechanisms combined with friction-based insertion functionality.

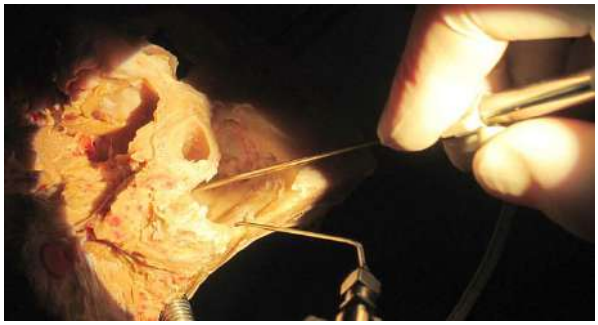

Figure 2: Instrument testing with a human petrous bone sample.

4. Discussion & Conclusion

A series of novel insertion tools for the implantation of flexible electrodes has been developed and evaluated. Future activities will investigate different aspects of functionality in more details in order to further optimize the tool and prepare for a first clinical evaluation.

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This work was supported by NÖ Forschungs- und Bildungsges.m.b.H. (NFB), St. Pölten, Austria

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43:

Use of biological mesh in trans-anal treatment for recurrent recto-urethral fistula

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PURPOSE:
To report the author's experience on a mini-invasive technique using bioprosthetic plug and a rectal wall flap advancement in the treatment of recurrent recto-urethral fistula.

MATERIALS AND METHODS:
Between 2013 and 2015, seven patients with recurrent recto-urethral fistula were referred to the Pederzoli Hospital, Peschiera del Garda, Verona, Italy. Intraoperatively all patients were found to have a rectal wall lesion and were treated with urinary and fecal diversion. For the persistence of the fistula, all the patients underwent a mini-invasive treatment consisting on placement of a bioprosthetic plug in the fistula covered by an endorectal advancement flap through a trans-anal and trans-urethral combined technique.

RESULTS:
Median operative time was 48 min with a median blood loss of 30 ml. Median hospital stay was 3 days (IQR 1-3). No case of fistula recurrence or plug migration was described. None of the patients experienced fecal or urinary incontinence. All patients obtained complete fistula healing.

CONCLUSIONS:
Recurrent recto-urethral fistula is a challenging postsurgical complication for surgeons and urologists, and its best treatment is still unknown. Our method seems to be feasible and effective for the treatment of complex recto-urethral fistula.

4: *In vivo* identification of liver tumors during liver surgery using electromagnetic navigation: a pilot study

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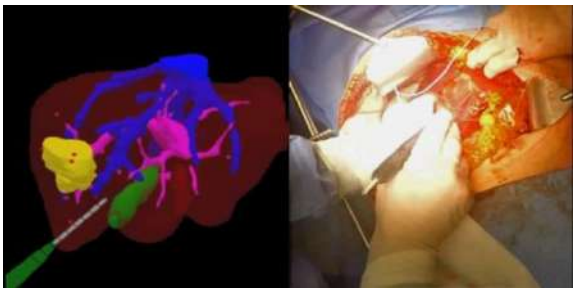
1. Introduction

Surgical resection remains the best curable option for liver malignancies [1]. Using various diagnostic imaging modalities, surgeons can carefully prepare a detailed surgical resection plan, keeping the tumour and the important anatomical liver structures in mind. However, surgical execution of this plan strongly depends on actual real-time localization of the lesions and patient-specific vascular and biliary anatomy during the procedure. Peroperative insight is generally obtained with 2D intraoperative ultrasound imaging which is subsequently linked to the equivalent 3D model of the organ in surgeon's head. Sadly, in 2-23% of the cases, this process results in irradical resections [2] or postoperative morbidity [3]. Intraoperative navigation could provide realtime perioperative feedback on liver anatomy and the peritumoral area and, as a result, improve radical resections rates [4].

2. Methods



Here, we introduce and evaluate an in-house-developed electromagnetic navigation (EM) system for visualization and EM-tool guidance during open liver surgery. To enable real-time tracking of the tumor, a single 6 degrees of freedom (DOF) EM-sensor (Northern Digital Inc.) and 4 surgical clips were attached to the liver surface in close proximity to the tumor. Next, an intraoperative XperCT scan with iv contrast, visualizing the sensor and the clips, was performed and rigidly registered to a preoperative scan containing 3D models of the liver. Sensor orientation was determined by means of point registration on the clips while reading out the sensor's position. At last, EM-pointer tracking within the 3D model was achieved assuming locally rigid anatomy within the area of resection. The accuracy of the navigation was evaluated by comparing navigation-based to pathology results for the shortest distance between measurement points in the resection plane and the tumor. In this pilot study with the METC approval, a total of 17 navigated surgical resections were performed.

3. Results

Navigated surgical resections were performed with a median surgical overhead time of 43 minutes. This included placement of EM-sensor on the liver surface (9 min), sterile intraoperative contrast-enhanced XperCT scan (13 min), registration of the surgical plan with a real-time situation and all navigation-related measuements (21 min). The navigation technology resulted in an acuurate realtime tracking of liver tumors and had an average accuracy of 7.3 mm, compared to the pathology, and this value is expected to improve in the future.

Figure 1: Sample screen shot from the navigation software during open liver surgery and the corresponding surgical view.

4. Discussion &Conclusions

We successfully developed and implemented EM navigation for open liver surgery. This was done by combining a 3D liver model, intraoperative XperCT and EM tracking of the liver and a sterile EM-pointer. Achieved accuracy shows that the assumption of locally rigid organ registration allows for accurate detection of critical anatomical structures within the resection area.

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69:

MIXED TRAINING IN SURGICAL ROBOTIC COMBINING SIMULATION AND TEST ON REAL ROBOT : PRELIMINARY RESULTS

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1. Introduction

The adoption of surgical robotic systems constantly increased in the last two decades, extending the possibility of using the robot in new surgical specialties. This translates into many benefits for the patient but also requires the trainees learning new surgical techniques in addition to other surgical procedures already established in the clinical practice [1]. A lot of interest from the research community and corporations has been put in the development of virtual training simulator able to support the acquisition of basic surgical skills in surgical robotics. Even if many simulation systems are already on the market, no clear indication on how to use such systems neither a standardized curriculum have been defined yet. It is not clear how to mix exercises based on virtual simulator and exercises on the real robot to obtain the most effective training outcome [2]. Therefore, we present preliminary results obtained from a short course to medical students who performed the same pick-and-place tasks on the real robot and on a virtual simulator.

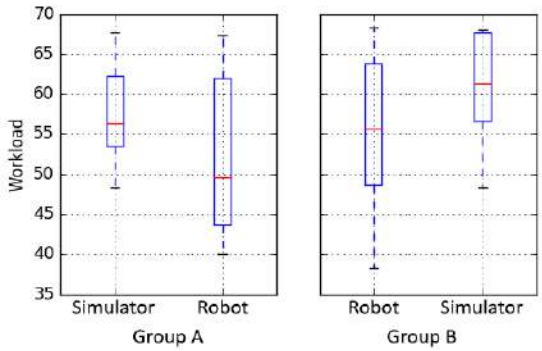

Figure 1: Comparison of TLX Workload on the robot and simulator for the two students' groups.

2. Methods

We involved a group of 24 medical students taking an elective course in robotic surgery and after theoretical classes describing fundamentals technologies used in this surgical technique, we set up an experiment where each student repeated the same pick-and-place exercise on a virtual simulator and on a real robot. The simulator used is Acteon training simulator developed by BBZ srl and the real robot used in the experiment was a dismissed first generation da Vinci Research Kit (DVRK) available in authors' laboratory [3]. We divided students into two groups: group A started with the simulator and then used the DVRK while group B did the inverse. The same test consisted of positioning a set of letters in their correct template holes, during two one-hour sessions.

3. Results

The mean number of task repetitions for each student was 5.8 ± 2.2. The tests with the virtual and real surgical simulators showed the correlation between the experience with the two setups.

In Figure 1, we show the comparison of the workload for the two setups evaluated using the Nasa-TLX protocol [4]. We obtain comparable results even though the perceived workload in the simulated setup is higher than with the real robot. Group A, which performed the first test with the simulator and then with the DVRK, shows a lower workload as compared to Group B when using the real robot. This fact suggests that an initial training in simulation before moving to the real robot would ease the learning process, as confirmed also by other data collected (i.e. exercise completion time, range of motions).

4. Discussion & Conclusion

We have described preliminary results addressing the problem of mixed training in virtual and realistic environments. We are currently comparing our results with other works in literature related to standard laparoscopic training. This work could enable designing personalized curricula with remedial exercises to improve specific surgical skills.

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71:

Evaluation of a small and low cost camera system and a light source for endoscopy

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1. Introduction

Commercial endoscopic systems for medical applications include advanced camera systems and light sources. These systems are mostly integrated into a bulky cart with a large footprint. Transporting the entire cart is tedious. For some applications a small and portable system that provides similar performance would be beneficiary. Therefore a small and portable SMARTSCOPE was designed [1]. A Sony Z5 smart phone (23 Mpx, 4K resolution) was equipped with a snap mount for endoscopic eyepieces and combined with a Fenix LD02 led lamp (100 Lumen max.) for illumination. We evaluated the imaging performance of the SMARTSCOPE compared to a commercial endoscopic imaging system.

2. Methods and Materials

For evaluation a rigid endoscope (70° x 4 mm, Olympus, Germany) was used as standard optic. Two phantoms were developed as described in [2]. Phantom 1 includes a line pattern at the end and an enlarging line pattern on the side wall [3]. The second phantom includes a colour pattern on the side wall and a colour field at the end wall. The patterns were rolled into the lumen of two syringes that mimic a tubular structure like throat or colon.

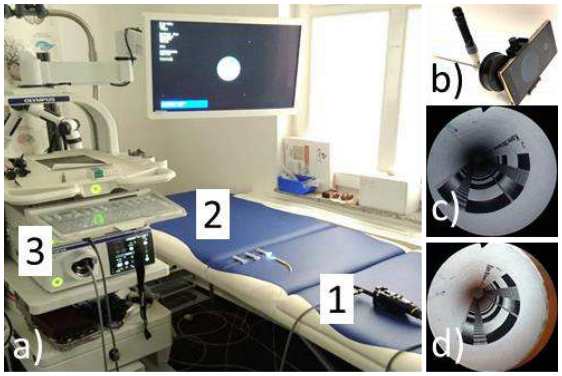

Figure 1. a) Olympus camera (1), cart (3) phantoms (2); b) SMARTSCOPE; c), d) Images of line patterns

As a standard endoscopic system the Evis Exera III, Olympus, Germany with a CH-S190-XZ camera module and CLV-190 light unit was used. The test setup is shown in **Figure** 1 a.

Images were acquired with standard system, with standard camera and Fenix light source and with SMARTSCOPE and Fenix light source. The comparison of the resulting images was based on resolution, brightness and color reproducibility using ImageJ software.

3. Results

The obtained results are shown in **Table 1.**

Table 1: Comparison of Pixel Number, Brightness and Colour reproducibility

Camera System	Pixel Number	Brightness mean	Colour repro. RGB [%]
CH-S190-XZ +CLV-190	646.858	108	83 / 68 / 98

Camera System	Pixel Number	Brightness mean	Colour repro. RGB [%]
CH-S190-XZ +Fenix	653.824	108	70 / 65 / 93
Sony Z5+Fenix	9.315.739	165	81 / 70 / 92

4. Discussion+ Conclusion

Compared to the HD standard endoscopic imaging, the SMARTSCOPE even offers a higher number of pixels. The brightness of the resulting image is also higher and covers a wider spectrum of grey tones even with the Fenix light source. Colour reproducibility is comparable to the Olympus system.

The SMARTSCOPE can deliver comparable image quality in a small, handy and portable system. This is beneficiary for applications like in office examinations or intra surgical imaging [4].

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72:

Improved patient safety during TURBT through catheter based air bubble removal

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1. Introduction

TURBT (transurethral resection of bladder tumor) is a standard treatment for bladder cancer. Air bubble formation caused by the heating of the resectoscope blade causes visual impairments and can also lead to explosive gas formation. The pyrolysis (thermolytic decomposition) of human tissue and electrolysis of inter cellular water can release volatile gases mainly comprised of hydrogen and other hydrocarbons. The bubbles and gases can lead to explosion when combined with oxygen at high temperature (increases carbonization) during cutting and coagulation of tissues. The oxygen that is present inside the bladder is normally insufficient to start igniting the gases, but atmospheric oxygen that enters due to the frequent removal of working element increases the danger. Removing the formed bubbles and gases could also reduce the frequent removal of resectoscope from the bladder currently done to improve visualization.
We propose a bubble trap catheter with an integrated micro air filter which can be inserted into the bladder through the inner shaft of the resectoscope. The mechanism helps to remove suspended bubbles from the suprapubic area of the bladder. A continuous controlled irrigation and simultaneous suction unit are also incorporated with the entire system that could resolve the issues related to opening the irrigation channel.

2. Materials and Methods

The bubble trapping device is a flexible catheter tip with a hydrophobic PTFE filter. The vacuum mechanism pulls the bubbles that are formed inside the bladder to the catheter whenever the gas sensor that is also placed along with the filter at the catheter tip gives an alarm indicating the presence of toxic gas formation. This system can be attached to the resectoscope working element by making an extra channel along with the electrode loop and optic channel. No significant structural changes to the existing system are required but one extra functionality is added that can be operated manually.
The secondary part of the system is a continuous controlled flow and simultaneous suction mechanism that is implemented via a feedback loop to balance the inflow rate and outflow rate. The feedback loop consist of a flow meter, controller and a water pump. A suction apparatus is connected to the outflow channel of the resectoscope for removing the blood stained irrigation fluids and resected tissue samples

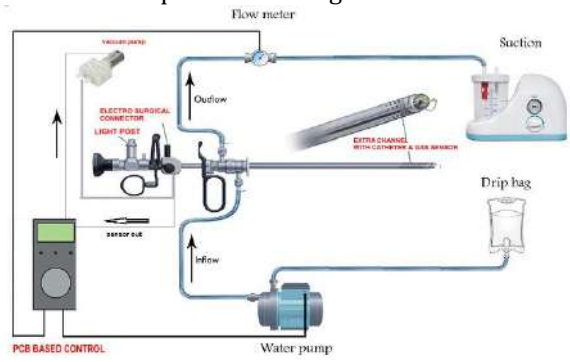

Figure 1. Working mechanism of the entire system

3. Results

The bubble trap device and continuous irrigation system has successfully implemented. The resected tissues are removed by suction at a flow rate of 500 ml/min with an average suction pressure of 30mmHg. The flow rate is monitored by a flow sensor and triggers the pump when the value crosses the threshold preset rate (we used 200ml/min) via a controller. The irrigation liquid is pumped at a rate of 200 ml/min that fills the bladder whenever it is emptied by the suction pressure thereby keeps the bladder filled throughout the procedure. Around 90% of bubbles are trapped using the catheter manually by the surgeon when necessary.

4. Conclusion

The air bubble removal using catheter could resolve the issues such as interrupted vision and toxic gas formation by removing the bubbles that are formed during electro-resection. On the other side continuous controlled irrigation and simultaneous suction helps the surgeons keep away from frequent removal of resectoscope during the surgery. It additionally saves time, effort and reduces the chances of explosion by preventing atmospheric oxygen into the bladder during a transurethral resection.

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108:

Robotic device for insertion of a biopsy gun for targeted biopsies

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1. Introduction

   Biopsies require great precision regarding needle placement in order to achieve a reliable, targeted biopsy. This kind of procedures can be performed by robotic systems in the field of robotic assisted needle placement. Biopsy guns are reliable medical tools which can be successfully used in tissue sampling.
2. Methods

   These guns are one of the ways to obtain an accurate biopsy, by guiding a specialized instrument, with the help of a robotic system, towards the targeted area and then inserting the needle and firing the biopsy gun. The instrument, with a modular mounting frame, can be mounted on and guided by various robotic systems such as PARA-BRAHIROB for liver, breast, thyroid biopsies or BIO-PROS 1 for prostate biopsies.
3. Results

   This procedure offers increased accuracy and minimizes the risk as it has a linear, redundant motion that is independent of the robot's motions, for insertion and retraction of the needle, since the insertion is not influenced by robot control anomalies because the singularities are avoided.
4. Discussion & Conclusion

   Such automated instrument's development shows reliable, feasible, practical applications towards medical placement tasks.

109:

Robotic system for RFA needle insertion

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[2]*Technical University Cluj-Napoca*

1. Introduction

   Liver tumors are one of the most challenging conditions nowadays and a great deal of them cannot be surgically removed. Therefore, radio frequency ablation (RFA) is used to treat them by delivering a certain dose of electromagnetic radiation until necrosis is achieved. During this procedure, which can be performed either intraoperatively or percutaneously, special needles are used. These needles contain a set of electrodes inside a cannula and can create a variable necrosis area, depending on their retraction mark.
2. Methods

   The needle insertion requires increased accuracy therefore robotic assisted needle placement may offer better precision, since a robot has better dexterity. These tasks can be performed by PARA-BRACHYROB, a medical robotic system that can insert both the needle and the electrode within the tumor with great precision. This robotic system has the RFA needle mounted on a device which guides it towards the point of insertion, then inserts it and the electrode on a linear path.
3. Results

   This device has two degrees of freedom, redundant with the output motion of the robotic system.
4. Discussion & Conclusion

   This offers greater precision in the needle placement procedure as well as reducing the risks, since a sequential approach, that requires validation for each step, is used, making the robot control failure impossible.

113:

Systematic Review of Intraoperative Navigation in Otolaryngology

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1. Introduction

Intraoperative navigation systems allow surgeons to identify and localize anatomical landmarks and instruments by locating an instrument tip intraoperatively in relation to the patient and projecting it onto a preoperative image dataset. The surgeon can use this tool for intraoperative navigation or virtual surgical planning preoperatively [1]. Navigation was first introduced in 1970s under the term "framed sterotaxy", which involved fixation of the head in a calibrated frame allowing instruments to be advanced to a pre-set location during neurosurgical operations [2]. Subsequently, navigation systems were introduced into other disciplines and currently their use is well established in neurosurgery and endoscopic sinus surgery. There are increasing reports of navigation use in Otolaryngology with few systematic reviews on this topic. Our study aims to systematically review the literature on the current state and novel uses of navigation systems in Otolaryngology.

2. Methods

A systematic review of literature was conducted using MEDLINE, PubMed, and EMBASE by two independent reviewers. Search terms used included: "image guided surgery", "computer assisted surgery", "intraoperative navigation", "head and neck surgery", and "otolaryngology" and identified a broad list of articles. Inclusion criteria included human based clinical studies, studies within the past 10 years, and articles in English. Dental or neurosurgical applications, robotics application, custom cutting guides, and Functional Endoscopic Sinus Surgery (FESS) were excluded. The search yielded 2125 articles, 2090 articles were removed as they did not satisfy criteria and six articles were duplicates. Twenty-nine articles were included in the study.

3. Results

A total of 933 cases were identified with mean patient age 41.4 years old (10 days to 83 years old) and mean follow up 14.8 months (2 months to 3 years). Indication for navigation was oncological in 34%, non-oncological in 52%, and mixed in 14% of cases. The most common imaging modality was computed tomography (CT) (79.31%) with mean slice thickness of 0.9mm (0.6-1.5 mm). Combination of CT and magnetic resonance imaging (MRI) was used in 13.79%. The main three manufacturers were: BrainLab (27.5%), Medtronic (27.5%), and Stryker (13.7%). The most common navigation modality was optical navigation (93.1%). Electromagnetic navigation was reported in just 3.2%. Sixteen (55.1%) articles reported registration methods, with 31% reporting invasive registration, 63% reporting superficial registration, and 6% reporting a combination. Seven (43.5%) articles reported registration error, all within 2mm; with four within 1mm. Most common adjuvant technologies were preoperative surgical planning, virtual osteotomy and contouring, mirroring for asymmetric correction, custom cutting guides, sound proximity warnings, and patient-specific stereolithographic models. Fourteen (48%) articles reported time factors with 64% reporting increased time and 36% reporting decreased time requirement with navigation use. Eleven articles provided average accuracy of anatomical localization, which ranged from within 0.5mm to 4mm with most reporting accuracy 1-2mm. Qualitative outcomes reported included increased surgeon confidence, easier identification of anatomical landmarks, and more informed resection margins.

4. Discussion and Conclusion

Surgical navigation technology in Otolaryngology began in skull-base and sinus surgery but has expanded to include craniofacial, orbital, ear, parotid, oral cavity procedures amongst others. Navigation systems are safe, accurate and provide improved surgeon confidence. They have shown to be an outstanding adjunct tool for complex as well as routine Otolaryngology cases and the indications for navigations continue to grow.

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126:

Self-assessment and online evaluation tools integrated within a mixed-reality surgical simulator

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1. Introduction

The use of simulation in MIS and laparoscopic surgery training is effective if supported by a suitable evaluation system [1]. The eLaparo4D simulator [2] [3] is a mixed-reality low-cost laparoscopic training platform based on a physical robotic assembly of an operational scenario, with haptic feedback on instruments and endoscopic camera. Acquisition and storage of sensors and actuators data during eLaparo4D sessions allow to monitor the performances in real-time and deferred modes. The paper shows the integration of novel functionalities devoted to improve self-assessment and formal evaluation: remote playback, online annotation of each surgical act, and other allow a better debriefing and evaluation of exercises and exams by teachers and students.

2. Methods

The use of simulation in MIS and laparoscopic surgery training can benefit from the use of immersive realistic simulators as well as elearning facilities. The use of Virtual/Augmented/Mixed Reality allows the improvement of interaction practices among the actors involved in it with the aim of increasing the quality of training and shortening the learning curve of students and practitioners. The integration of these technologies with robotic assemblies capable of haptic feedback has been recently reviewed by Escobar-Castillejos et al. [1]

In the development of the eLaparo4D project, a low cost training simulator designed for MIS training exercises for medicine students in realistic scenarios of videolaparoscopic surgeries, all these aspects have always been considered with the aim of researching, innovating and creating tools that could help the acquisition of work practices and problems with them connected.

The self-assessment of medical students as well as teachers' evaluations of a surgical act is often an issue. Standard pedagogical methods based on checklist and ex-post debriefing could benefit of deferred playbacks and elearning facilities to allow a continuous monitoring of performances while executing tasks.

The idea of this paper is that recording video sessions could be substituted by recording immersive VR/AR/MR experiences. Instead of storing videos, we collect and store all the data coming from sensors and actuators into the rendering VR platform (Unity3D), in order to reproduce, annotate and analyse the data streams into the elearning platform.

So far, students have the opportunity to review their own work and tutorials so that they can analyze their own maneuvers, annotating corer events and understand, with the support of experienced staff, how to change movements in order to have better performances.

Based on these reflections, we have come to the creation of an application concept that allows the acquisition and recording of the data of the positions of the maneuvered instruments by the exercises and their subsequent reuse.

Through the interface, users create a newer interaction stream, allowing re-analysis of the recorded with the ability to pause, annotate or highlight what might be the things to do or not.

3. Results

The novel interface has been implemented on Unity and Node.Js components of eLaparo4D, The elearning facility is now able to collect session raw data storing as JSON structured files, semantically annotated with timestamps, session achievements and user profile.

Some preliminary tests have been conducted in the SimAv simulation center of the University of Genoa by a group of 8 students and 2 teachers. Users have been asked to use the old and the new interface, asking them to fill a questionnaire during the debriefing. The analysis of the annotations and debriefing sessions are in progress at the moment of writing.

4. Discussion & Conclusion

The paper shows the integration of novel functionalities in a low-cost mixed-reality surgical simulator devoted to improve self-assessment and formal evaluation both in presence et at distance. Remote data streaming, online annotation of each surgical act, and other functionality inserted into the elearning facility of the University of Genoa is in progress.

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133:

A novel bioresorbable stent consisting of zinc alloy – properties and first results from an animal model

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Introduction

In the search for an improved coronary and peripheral interventional therapy introducing more optimal bioresorbable stent- or scaffold platforms, a novel Zn-3Ag alloy characterized by an excellent mechanical strength and elongation profile may offer specific advantages over the existing and approved bioresorbable stent platforms consisting of magnesium or PLLA.

Methods

We investigated the mechanical properties and biocompatibility of a novel stent made of zinc alloy in comparison to Mg-(WE43), PLLA, CoCr and Nitinol. The stent design is adapted to the specific material properties of Zn-3Ag alloy.

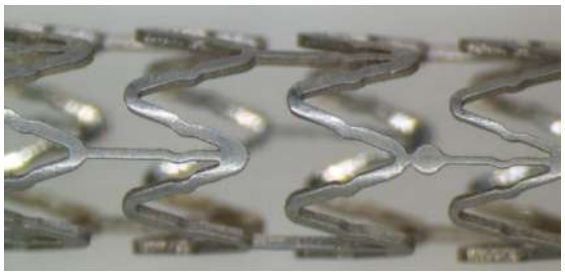

Figure 1: Peripheral Zn-3Ag stent 6x20mm

The stent was also examined in a porcine model. It was implanted in 20 pigs with comparison stents made of Nitinol or PLLA in the iliac (20 stents 6x20mm) and coronary (6 stents 3x20mm) arteries, with follow-ups at 4, 12, and 26 weeks. These studies are work in progress.

Results

Material specifications:

Material	Yield strength [Mpa]	Tensile strength [Mpa]	Elongation at fracture [%]
Magnesium WE43	162	220	2
Zinc alloy	114	192	94
Pure zinc	47	80	8
316L	331	586	35

Zinc alloy has a much better tensile strength than pure zinc, but not as good as 316L. The elongation at fracture is excellent, this was used for an adapted design, which leads to an elevated radial force in conjunction with a very low strut thickness of 85 µm for the coronary stent. The competitor stents made of PLLA (Absorb) and Mg (Dreams) have a strut thickness of 150 µm.

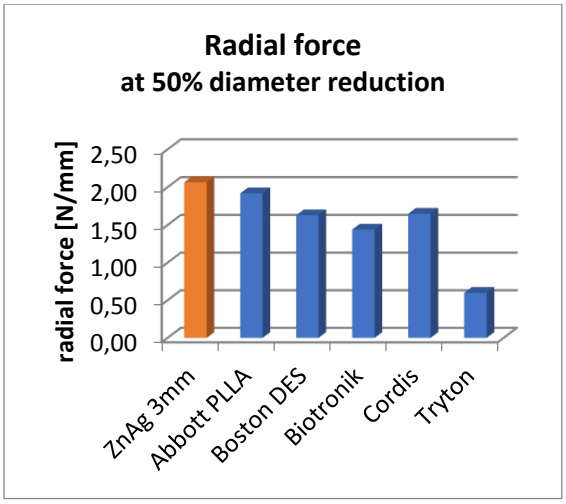

Figure 2: Radial force of coronary stents

Degeneration behavior in the porcine model: After 4 weeks the stents were completely covered with neointima. Decrease of the strut thickness was about 50% after 6 months. Radiopacity of the Zn-3Ag stent is very good; therefore special radiopaque markers are not necessary.

Figure 3: Peripheral Zn-3Ag stent 6x20mm (26 weeks)

Discussion & Conclusion

Zinc alloy has a better tensile strength than pure zinc, but not as good as stainless steel or CoCr. It has an extraordinary elongation at fracture, with an adapted design the radial force of the stent is on the same level with comparable stents, while the strut thickness is very low. First results from the animal study are very promising.

Acknowledgements

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138:

Retroperitoneoscopic left adrenalectomy

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Retroperineoscopic access represents a minimally invasive technique that radically modified adrenalectomy. Retroperitoneoscopic adrenalectomy is currently adopted in about 20% of referral centers. It provides more direct access to the adrenals, thus avoiding post-operative adhesions and the need for patient repositioning in bilateral adrenalectomy. We would like to present a short video showing the technique, which focuses on surgical landmarks when left adrenal gland is approached during a posterior retroperitoneoscopic adrenalectomy The patient is a 45 years old woman with a drug resistant arterial hypertension due to a left adrenal mass producing aldosterone (Conn disease).

139:

A Randomized Controlled Trial of the Fundamentals of Robotic Surgery: Validation of a proficiency-based progression robotic skills course in a multi-specialty, multi-institutional trial.

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ABSTRACT

A Randomized Controlled Trial of the Fundamentals of Robotic Surgery: Validation of a proficiency-based progression robotic skills course in a multi-specialty, multi-institutional trial.

Objective: To validate the Fundamentals of Robotic Surgery (FRS) skills course in a randomized control trial using multiple simulation platforms.

Methods and Procedures: A randomized clinical trial with a control group and 3 experimental groups: physical "dome" using the robot, virtual reality hybrid simulation using the computer 'backpack' on the surgical console, and stand-alone virtual reality simulator. Training was to proficiency and were set by 80 experts. The multi-institutional trial was conducted 12 international simulation centers and included the multiple specialties that perform robotic surgery.

Results: Face and content validity was verified by 80 experts; concurrent validity was demonstrated by experimental groups performing in less time and with less errors than the control group. The construct validity was demonstrated because the mean time and mean number of errors to perform the various tasks by experts were statistically less the novices. The inter-rater reliability for task specific checklists was $\geq$ 0.80, however the Global Evaluative Assessment of Robotic Skills (GEARS) inter-rater reliability was $\leq$0.80

Conclusion: The Fundamentals of Robotic Surgery is a validated course to teach novices the simplest robotic surgery skills across the many specialties that are currently performing robotic surgery. All the four validities were confirmed on a physical dome model, or any of the computer/virtual reality simulators. The FRS is a robust and validated course (curriculum) to train the basic skills in robotic surgery.