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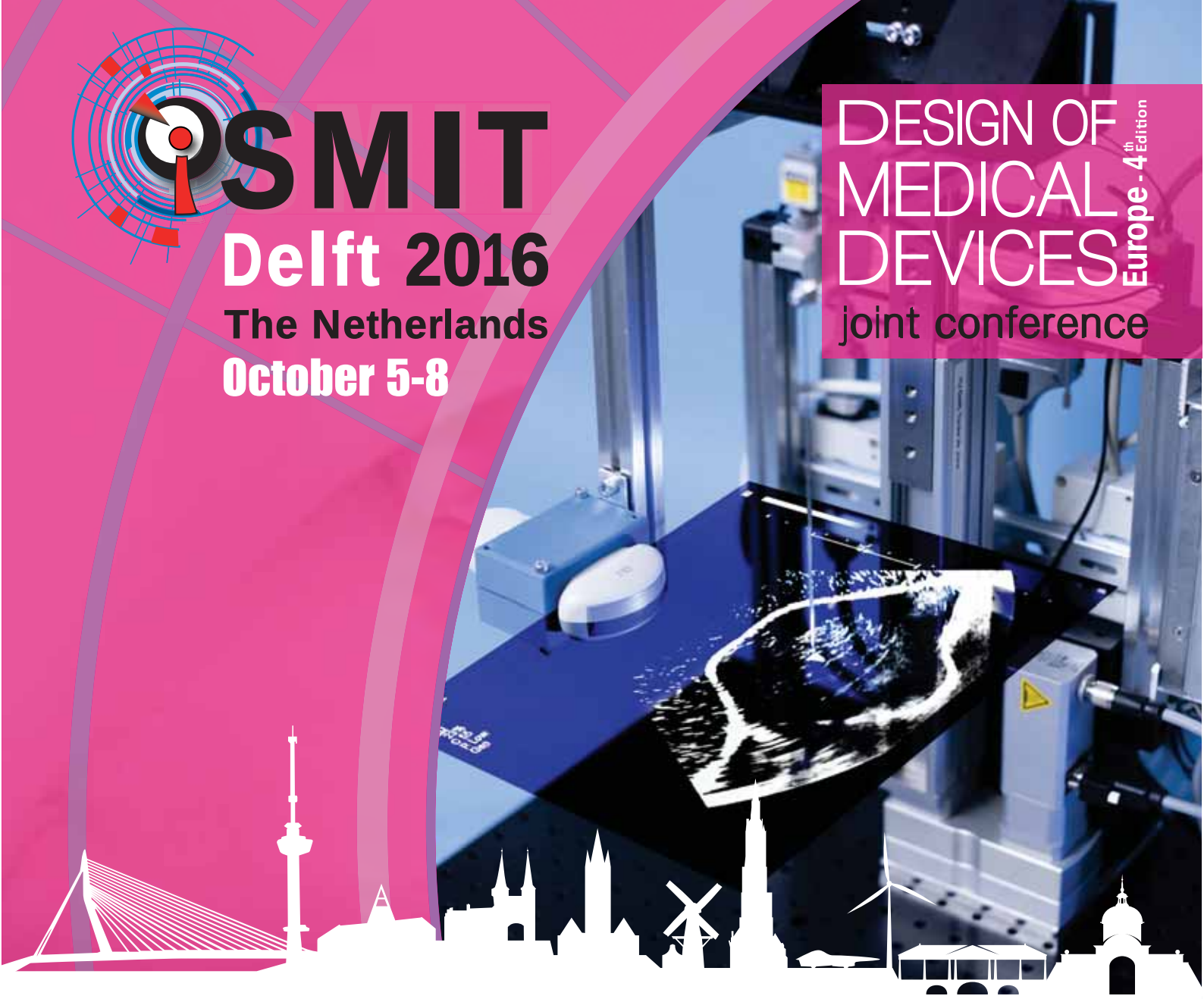

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Context-aware medical assistance systems in integrated surgical environments

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1. Introduction

In modern integrated ORs, the medical devices and systems provide shared interfaces and remote control [1]–[3]. However, they show only very limited cooperative behavior, especially in terms of cooperation with the surgical team. To implement intelligent system's behavior, the devices need to be aware of their actual application context. In this work, we present a set of context-aware assistance systems for ENT surgery. These applications combine concepts of OR device integration, surgical workflow tracking and modeling, as well as behavioral rule sets to establish a surgical working environment that actively cooperates with the surgical team.

2. Methods

The intelligent assistance was implemented in an integrated surgical environment based on the new set of IEEE 11073 standards for device interoperability developed in the OR.Net project [3].

For intelligent applications, surgical processes must be mathematically modelled in multiple perspectives. We implemented a network of process models covering a large variety of perspectives, proposed in [4]. The processing of the network is triggered by workflow recognition data gathered from device states as well as a modified instrument table suggested in [5]. These data were aggregated and consolidated to derive the actual low-level work step with a rule-based approach. Based upon that, the process model network continuously generated hierarchically structured contextual information. Medical devices and systems may consume the contextual information to adapt their parameterization and behavior based on sets of rules [6].

3. Results

A set of intelligent assistance functionalities was implemented for Functional Endoscopic Sinus Surgery. These included the automated switching of the primary video source between preoperative data, navigation, and endoscopic image. At the beginning and the end of the actual endoscopy, the OR light conditions are automatically adapted. Additionally, configuration profiles and device parameter adjustments are proposed depending on the surgical situation. To support patient status tracking and postoperative documentation, automated screenshots are generated and provided in a patient status documentation tool (FessBoard). The phantom demonstration setup is depicted in figure 1.

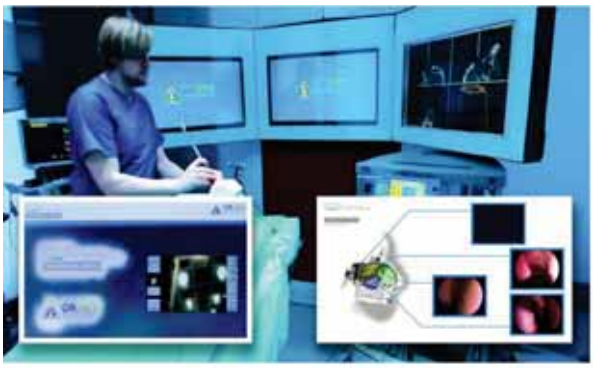

Figure 1: The demonstration setup with screenshots of the video switching tool (left) and the FessBoard (right).

4. Discussion & Conclusion

The presented applications for ENT surgery are designed to optimally support the OR team during the intervention. The amount of manual interaction is significantly reduced by (semi-) automatic adaptations and context-aware information provision. The setup demonstrates the feasibility of the approach for intelligent assistance in integrated surgical environments.

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Situation-Based Extraction of Medical Device Activity for Adaptive OR Task Management

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1. Introduction

Advancing technology inside the integrated operating room (OR) is faced with an increasing amount of heterogeneous data from the patient, medical devices (MD) and the clinical environment [1]. Research approaches focus on extending medical systems to facilitate knowledge management, context information and learning strategies to achieve situational awareness [2]. Traditionally, a surgical situation is examined from different perspectives, e.g. patient, procedure and resources, to include all possible features and relations in a process model [3, 4]. Yet, the perspective of MD activity is only sparsely considered. This is mainly due to limited recognition capabilities and extractable real-time information. With the extension of IEEE 11073 standards over the course of large-scale projects like OR.Net this gap could potentially be closed as manufacturers are encouraged to formalize their MD specifications [5]. In this paper we propose a terminology for MD activity extraction from surgical procedures to calculate MD-specific processes and improve inter-device communication and functionality transfer.

2. Methods

We defined MDs as hard- and software systems with at least two distinct system components interconnected with each other, e.g. a bipolar having an actuator and current control component. We then defined a terminology with main concepts adopted and abstracted from the surgical activity definition approach of [6]. Adopted concepts were *action* and *time*, abstracted concepts were *medical device* (*actor*), *device component* (*instrument*) and *task* (*anatomical region*). Additionally, two abstract activity concepts were introduced to support the investigation of OR self-awareness and autonomy, and system task characteristics within the medical device process. The concept *task_functionality* is inspired by the MAPE-K control loop architecture and contains the entities “monitor”, “analyze”, “plan” and “execute” [7]. The *medical_purpose* concept relates to the domain-specific function a MD is enacting, e.g. patient monitoring.

3. Results

We applied our terminology on surgical activities from brain tumor resection procedures and succesfully extracted and characterized MD activities. One example beeing: tracking system (MD), optical sensor (MD component), register (action), 150 (time), localization (task), analyze (task functionality), navigation (medical purpose).

4. Discussion & Conclusion

To our knowledge this is the first proposal of a medical device-focused work step definition in the OR. Although extracted from surgically-focused procedures the overall concept shows great potential for the investigation of device-specific procedure-dependent processes. A series of individual MD processes may provide “building block”-like functionality for intelligent MD combinations in the OR. However, the activity extraction study needs to be extended and used to calculate device-specific processes and should ultimately be replaced by actual device-specific procedure recordings. Furthermore, the terminology needs to be evaluated and should be connected to standard terminologies. Nonetheless, the shared *action* and *time* concepts possibly allow a mapping of a surgeon`s activity to the respective device-specific activity.

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Implementation of Intel RealSense on PACS; contribution of gesture based interface for intraoperative surgical decision making

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1. Introduction

Information guided surgery has been performed in any field of surgery aiming effective surgical therapy. Operating surgeons refer surgical information intraoperatively when they must make significant decision during procedure. However, operating surgeons cannot manipulate medical equipment and systems by themselves in operating filed because they wear sterilized groves. This fact brings stress to the operating surgeons and they feel dilemma by asking circulating staff to manipulate the information data. The goal of this research is implementing gesture based interface on commercially available picture archiving and communication system (PACS) for enabling operating surgeons to manipulate medical image data intraoperatively by themselves.

2. Methods

Intel RealSense (SR300, Intel Corporation) was installed into commercialized general PACS application (ShadeQuest, Yokogawa Medical Solutions Corporation). The RealSense has a built-in infrared depth camera which is capable to capture operator's hands. Our experiences utilizing Kinect for Windows (Microsoft Corporation) for OPECT system [1] and Kinect driven previous version of PACS [2] allowed operating surgeons to quick-check of key medical images by themselves in operating field. Thus, the gesture based interface resulted promising possibility for appropriate and optimized decision making during procedure. While Kinect forced surgeons to leave approximately 2m for gesture control, RealSense's ideal detecting range is 1 ~ 1.5m and surgeons are able to manipulate medical images close to the PACS monitor.

3. Results

Operator's hand motions were assigned to the keyboard shortcut in PACS application. Surgeons swipe their right hand left/right to scroll CT/MR slices and swipe up to switch the controllable series of DICOM (Fig. 1). Hand's green silhouette was displayed in distinguished area on the right-bottom of the screen to notify the operator that their hand is successfully under detection. Three volunteers completed 5-item questionnaire to evaluate system usability after usage. The mean score was 4.26 +/- 0.52 (from 1 (bad) to 5 (excellent)). They additionally left feedback comments that graphical notifications for operators were cheap, especially graphical actions after motion detections. They also hoped to have more types of motion such as drag and drop to select series of DICOM for dealing the application intuitively.

Figure 1: Full screen of PACS application during RealSense driven manipulation. Operator's hand is silhouetted green under detection.

4. Discussion & Conclusion

Intel RealSense was installed into PACS as a gesture based interface aiming operating surgeons to manipulate DICOM data without using any devices. From the results of the user experience, though the system still had graphical issues for improvement, the proposed work showed promising results and potential for being adapted as part of information guided surgery.

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Intraoperative process model generation using XMS and ISO/IEEE 11073

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1. Introduction

Nowadays, process models (PMs) can be utilized in a variety of possible applications, e.g. workflow analysis, optimization, prediction and management [1-2]. To generate a PM, workflows (WFs) of individual treatments (e.g. surgeries of the same type) are merged into a single PM [1]. Such a generic model represents the whole treatment process with all its possible activities and their corresponding probabilities of succeeding each other. A fundamental prerequisite for PM generation and further processing is the accessibility to WFs. The XMS architecture, which is based on the IHE XDS integration profile, constitutes a web service based solution to distribute WFs and PMs between devices, departments and institutions [3]. However, besides distributing WFs and PMs a method to generate case-specific PMs from a repository is required.

2. Methods

To provide a solution to remedy this lack of functionality, the XMS infrastructure was supplemented with a method to pass required information to the repository and generate a case specific PM from a set of WFs. Besides WFs, the treatment type, the case id as well as the patient id of the treatment, the PM will be used for, are required. In order to ensure simplicity and interoperability of this method, a common, well established standard from the clinical field was mandatory. Since interoperability of medical devices from different manufacturers was implemented and demonstrated in the German OR.NET project by using the ISO/IEEE 11073 standard family [4], the 11073 standard family seemed well suited for the given use case. During the OR.NET project, additional standards were developed to amend the existing ones. These newly developed standards were officially accepted as work items by IEEE in fall 2014 and were identified as well suited to supplement the XMS infrastructure.

3. Results

The order object of the 11073 contains fields and objects which enable the creation of a complete mapping to all required information entities for PM generation. Subsequently, two new message types could be derived to initiate PM generation from other devices and pass the results back to the initiator. The supplemented infrastructure allows the generation and distribution of PMs and integrates clinical repositories for PMs and WF management components in the OR. To ensure system and device interoperability IEEE standards were utilized.

4. Discussion & Conclusion

The proposed infrastructure supports among others context-aware information systems and workflow-driven documentation applications [5]. Many of these applications rely on information about the performed surgical procedure, for instance possible ways of enactment, resource and information requirements, or essential participants, which are encoded in PMs (see Fig. 1). Thus, the infrastructure represents an important standard conform tool for any application generating or using process models.

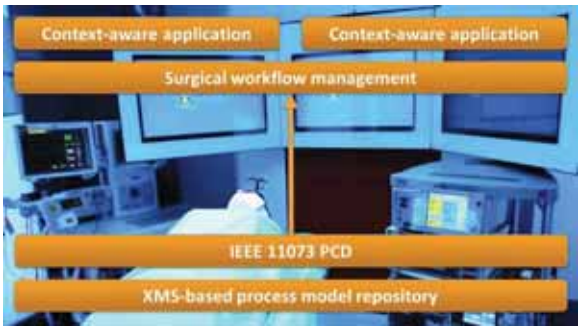

Figure 1: Schematic representation of the proposed approach for the distribution of process models in an integrated operating room.

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Ontology-based instrument classification for workflow-driven surgical assistance in the intelligent operating room

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1. Introduction

Workflow management is a prerequisite for computer-aided surgical assistance, situation-awareness and autonomous adaptation of medical devices in intelligent operating rooms (OR). The integration of ontologies in surgical workflow management allows the enhancement of assistance functionalities by formal knowledge representation and decision support. In literature, various applications for ontology-based surgical workflow support can be found, e.g. instrument detection [1], phase recognition [2], knowledge representation and workflow prediction [3]. For this purpose, surgical processes have to be described through an ontological approach [4], encompassing the *surgical action*, which is performed on an *anatomical structure* using a *surgical instrument* [5]. For the formal representation of these process elements medical ontologies, like SNOMED CT or Foundational Model of Anatomy (FMA) can be used. Especially surgical instruments could be described by SNOMED adequately. However, there is currently no description of the instrument functions provided by the ontology. Thus, a functional classification concept will be presented for the example of surgical instruments. The classification could enable further applications for ontologies in surgical workflow management in intelligent ORs.

2. Methods

The standardized medical ontology SNOMED CT (Int. Edition, Jan. 2016) has been used as a basis for the classification of surgical instruments. The applied concepts were extracted from the "Surgical instrument (device)" hierarchy, which currently consists of 185 child concepts, including specific sub concepts. The upper level concepts were categorized according to the commonly used functional instrument classification, which can be found e.g. in [6]: *Accessory*, *Clamping and Occluding*, *Cutting and Dissecting*, *Grasping and Holding*, *Probing and Dilating*, *Retracting and Exposing*, *Suctioning and Aspirating*, *Suturing and Stapling*, *Viewing* as well as (Instrument) *Set*. The resulting classification was consequently mapped to SNOMED "Action (qualifier value)" concepts and integrated in our ontology-based concept for surgical process modeling [4].

3. Results

All surgical instrument entities and sub concepts have been categorized into one or more of the 10 instrument classes. The sub classes were consistent to their upper level hierarchy regarding the functionality class. Subsequently, the instrument concepts with corresponding functionality classes and action concepts were integrated in the surgical process ontology [4].

4. Discussion & Conclusion

The proposed classification enables a variety of workflow- and knowledge driven assistance functionalities in the digital OR. For example, during surgical navigation the identification of risk structures could be enhanced by context-sensitive warnings, e.g. if cutting or dissecting instruments are used near a risk structure, while grasping instruments do not require any alert. In the field of context-aware controlling of medical devices, the automated adaption of OR light conditions could be implemented if a viewing instrument (e.g. endoscope) is used. For surgical workflow and phase recognition as well as instrument detection, the classification could be used for rule-based preselection of the instruments depending on the current surgical situation in the OR (e.g. stapling instruments could only be used in surgical closure phase). In future work the example classification of surgical instruments will be extended for different surgical entities, like medical devices, activities and anatomical structures.

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A self-adjusting monitor mount for minimally invasive surgery

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1. Introduction

During minimally invasive surgeries the surgeon has no direct view on the situs and relies therefore entirely on the laparoscopic image. While the quality of the camera system and the rendering screen are most crucial for the surgeon's vision, also his viewing angle plays an important role. Non-orthogonal viewing angles can affect the contrast ratio and impose distracting reflections. This problem will become even more pressing with the increasing use of 3D laparoscopic systems, due to the very limited viewing angle of stereoscopic displays [1]. We developed a self-adjusting monitor mount (SAM) for an automatic optimization of the surgeon's viewing angle in relation to the screen.

2. Methods

Requirements specification

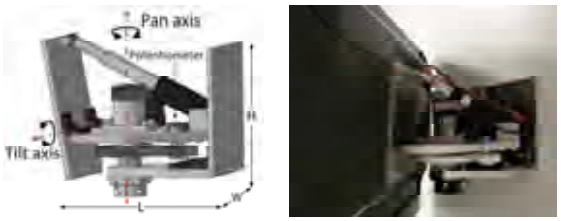
Requirements for the SAM were specified by analyzing the OR infrastructure and by consulting its medical staff. In order to achieve a seamless integration of the proposed system into the installed units of the OR, a compact, lightweight and modular design is required. Modularity is attained by implementing the VESA Mounting Interface Standard on both sides of the SAM. Considering technical requirements, the system must be able to provide sufficient torque in pan and tilt axes in order to adjust the installed screens with various screen sizes (17"-24" diagonal) and weights (up to 7.5kg) with adequate speed and accuracy. The required angular range was defined through analysis of surgeons' positions during typical surgeries and should at least cover a range of ±15° for tilting and ± 45° for panning in order to allow the surgeon to switch sides of the OR-table.

Calculation and correction of angular displacement

The field camera of the head-mounted eye-tracking system Dikablis Essential (Ergoneers, Geretsried, Germany) captures roughly the surgeon's field of view. We apply the POSIT algorithm [2] to estimate the 3D pose of a known object, i.e. the screen, based on the 2D images of the field camera's stream. In order to facilitate referencing points of the 3D object in the 2D image, markers where attached to the corners of the screen. Based on the estimated pose of the monitor the angular displacement between the actual and the ideal, orthogonal viewing angle can be calculated. The corresponding target values are sent wirelessly via UDP to the motor controller of the SAM, which actuates its pan and tilt axes towards the optimal orientation. Communication, data processing and motor control are implemented on an Arduino platform.

3. Results

The prototype of the SAM was designed and manufactured (Fig 1.). Panning is achieved by rotation of a stepper-motor and a connected gear. Tilting within a range of ±15° is controlled via a linear servo-motor attached between two hinge joints on both mounting plates. The range for panning of ±85° is reachable with an angular speed of maximum 25°/s. Speed ramps in the control design ensure jerk-free movements. The integrated potentiometer provides position data without an initial reference drive. The synergy of the POSIT algorithm and the implemented motor control results in an overall angular accuracy of ±5°.



a) b)

Figure 1:.a) CAD-Drawing (LxWxH = 140x125x145 mm) and b) the assembled SAM with open housing. All electronics are placed inside housing.

4. Discussion & Conclusion

The proposed SAM fulfills the defined requirements. Although a version of POSIT, optimized for flat objects was used, the estimation shows some weaknesses for small displacement angles. Future work will focus on optimization of the pose-estimation and the usability of screen mounted sensors (e.g. Microsoft Kinect) instead of intrusive head-mounted ones.

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Endovascular Devices

10.01 **Design of a novel vascular plug delivery device for minimally invasive surgical closure of aortic paravalvular leak.** *M. Borg, D. Sladden, P. Farrugia.*

10.02 **The radial artery access site after coronary angiography or percutanous intervention imaged with very high resolution ultrasound: A puncture's footprint.** *J.M.R.Ligthart, K.Th. Witberg, F. Costa, M. Valgimigli, N. van Mieghem.*

10.03 **3D optical coherence tomography: from offline to online.** *K. Witberg.*

10.04 **Bio-inspired shooting mechanism for crossing chronic total occlusions.** *A. Sakes, D. Dodou, and P. Breedveld.*

10.05 **3D imaging with a single-element forward-looking steerable IVUS catheter.** *J. Janjic, M. Leistikow, A. Sakes, F. Mastik, R.H.S.H. Beurskens, G. Springeling, N. de Jong, J.G. Bosch, A.F.W. van der Steen, G van Soest.*

10.06 **TRISKELE: expanding the horizons of transcatheter heart valve replacement.** *S. Bozkurt, G.L. Preston-Maher, B. Rahmani, R. Torii, G. Burriesci.*

10.07 **Design of a multi-steerable catheter for complex cardiac interventions.** *A. Ali, A.Sakes, E.A. Arkenbout, D.H. Plettenburg, P. Breedveld.*

10.08 **Granular jamming as controllable stiffness mechanism for endoscopic and catheter applications.** *L. Blanc, B. François, P. Lambert.*

10.09 **Time varying spectral analysis of blood flow sounds acquired with a portable digital stethoscope connected to a smart phone.** *A. Illanes, A. Boese, M. Friebe.*

Design of a Novel Vascular Plug Delivery Device for Minimally Invasive Surgical Closure of Aortic Paravalvular Leaks

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1. Introduction

Post-operative paravalvular leaks are a serious complication which may result in mortality [1]. The newer sutureless valves and transcatheter valves (TAVI) are more susceptible to this complication [2]. The gold-standard treatment is a percutaneous one, especially in cases of stable valves with a moderately sized defect between annulus and valve ring. However this method may prove impossible due to the stent of the valve or acute angle of the catheter needing to cross the defect. In such cases the only option is re-operation, which carries significant risk to the patient.

In this paper a delivery device is proposed, which allows surgeons to deploy a vascular plug, identical to that used percutaneously, however with the full control of an open heart surgical operation.

The incision required is an upper mini-sternotomy, where the manubrium and upper part of sternum are divided in the midline using an oscillating saw down to the forth intercostal space. Using a small retractor the superior mediastinum is exposed. The thymic fat and pericardium are dissected away to expose the ascending aorta. A small purstring suture (see Figure 1) is prepared at the site of entry of the trocar. The entire procedure is done on a beating heart and therefore eliminating the risks of cardiopulmonary bypass and cardioplegia.

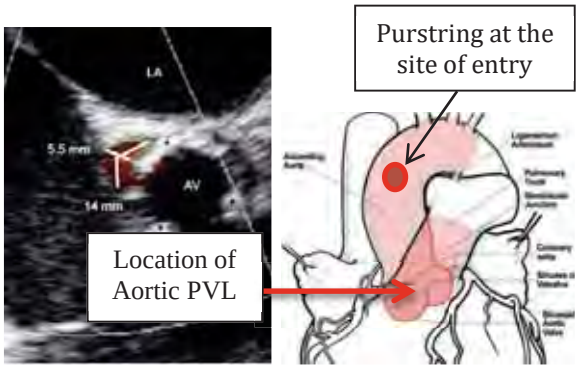

Figure 1: Left; Circled in red, indicating the size of the aortic PVL **[7]**. LA – left atrium, AV – aortoc valve. Right; indicating the purstring suture at the entry site of the acsending aorta **[8]**.

2. Methods

The basic design cycle described in [3] was employed. A problem analysis was initially carried out by conducting a survey with surgeons (n = 4) at the Department of Cardiothoracic surgery, Mater Dei Hospital (MDH), Malta. The customer requirements were then translated into engineering requirements via a Quality Function Deployment (QFD). Ease of operation, set up time, the use of standard components (off-the-shelf components), number of degree of freedom and an overall ergonomic design scored the highest priority number. Using this data, a Product Design Specification (PDS) was generated. By making use of synthesis tools including a Function Means Analysis (FMA) and a Morphological Chart, six functional working principles were chosen, of which two were considered as the best combinations. Meetings with technical personnel at the Department of Industrial and Manufacturing Engineering, University of Malta, indicated machining and stability issues in one of the two working principles and was thus eliminated. Synectics was then used to further improve and finalise the design based on the feedback received medical Cardiothoracic Surgeons. Implementation of various design tools was required to transform the working principle, into a realistic full scale prototype. A set of Design For 'X' (DFX) studies were initially conducted and focus was given on cleanliness, sterilisation, ergonomics, assembly and manufacturability. These were carried out simultaneously with 3D Computer-Aided Design (CAD) modelling and simulations for better visualisation aid and communication purposes.

An extensive material selection exercise was carried out, primarily focusing on Austenitic Stainless Steels AISI 303, AISI 304 and AISI 316. These materials are characterised by good corrosion resistance and are also commonly used for similar surgical devices [4], [5], categorised as Class I according to FDA [6] medical equipment classifications. Based on this knowledge, AISI 304 was the material of choice for the delivery device.

A Failure mode and Effect Analyses (FMEA), indicated no severe Risk Priority Number (RPN) and so a final 3D CAD model (see Figure 2) and engineering drawings were generated and used for building a full scale physical prototype.

The radial artery access site after coronary angiography or percutanous intervention imaged with very high resolution ultrasound: A puncture's footprint.

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1. Introduction

This study aims to visualize morphologic changes in the wall of the accessed radial artery 3 hours and 30 days after trans radial catheterization by means of very-high resolution Ultrasound. Such changes may explain complications like spasm of the radial artery, late total occlusion and decrease in pulsation.

2. Methods

Of 100 patients, who gave written informed consent and who underwent trans radial coronary angiography and/or PCI , the radial artery was visualized using a 40 MHz linear external ultrasound probe. The target radial artery was visualized prior to the procedure, 3 hours post procedure (when the compression bandage was removed) and 30 days post procedure by two experienced operators. The artery was visualized with a long view projection and a cross-section run moving the probe from distal to proximal. All images were recorded in DICOM format. In 17 patients the same acquisitions were made with a conventional low frequency ultrasound system (6,2 MHz). Besides an indication on the wrist where the ultrasound operators felt the strongest pulse, the physician was blinded for the ultrasound images and performed the radial access procedure according to local standards.

3. Results

The very-high resolution 40 MHz Ultrasound allowed for detailed assessment of the radial vessel wall including intima and media layers. The structural changes that were observed 3 hours and 30 days post procedure were among others dissections (scored when an endoluminal flap was visible), hematoma (blood visible between vessel layers), pseudo-aneurysm (hematoma outside the arterial wall, communicating with the artery), thrombus, spasm (radial artery constriction) and spontaneous echo contrast (distinct white noise artifacts due to slow- or turbulent blood flow). Three patients showed an occluded radial artery and one patient showed a fistula or shunt of the radial artery and vein after the puncture. Due to retrograde filling from the ulnar artery, not all closures resulted in loss of pulsation. The structural changes were observed from the images derived with the 40 MHz linear probe and were not visible on the images from the conventional low frequency ultrasound system. There were no complications related to the 40 MHz ultrasound acquisition.

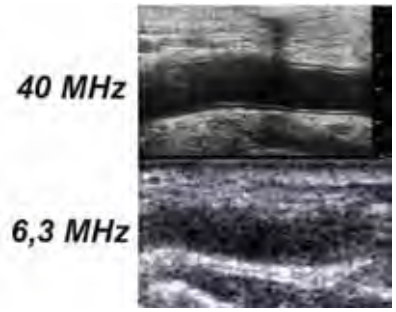

Figure 1: The picture above shows a longitudinal view of a radial artery acquired with a 40MHz probe. The three layered aspect of the vessel is clearly visible. The lower picture shows the same vessel, acquired with a conventional 6,3 MHz ultrasound probe.

4. Conclusion

Ultrasound acquisition of the radial artery pre- and post-procedure with a 40MHz linear external probe is safe and feasible. Structural changes were observed 3 hours post-procedure and at 30 days follow up. The 40 MHz linear probe was superior in visualizing these changes compared to a conventional low frequency ultrasound probe.

3D Optical Coherence Tomography: from offline to online

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1. Introduction

2D angiography has known limitations, that can be overcome by invasive imaging for instance OCT. 2D OCT does not always show a clear insight in the vessel architecture. 3D OCT may give better insight in this architecture and stent placement and therefore may contribute to good patient care.

2. Methods

OCT is increasingly used for intracoronary imaging. Due to its fast pullback speed (up to 36 mm/sec), cardiac motion artefacts are decreased and therefore it is possible to create 3D reconstructions from OCT pullbacks. Before the availability of the 3D module integrated in a OCT console, OCT pullbacks were analysed with offline rendering software. Stent struts were accentuated by a white dot prior to rendering; a work intensive and time consuming process, created when the PCI procedure was already finished.

New faster offline rendering software made it possible to create 3D OCT reconstructions in the catheterization laboratory, however this demanded a delay in the PCI procedure: especially with stented vessels. The quality was comparable with a raw version of the offline result.

Online 3D reconstructions created in the OCT console only take a few mouse clicks. With online 3D reconstruction the offline method seems redundant. However the offline 3D creation is as yet still more sophisticated than an online 3D OCT: among others better visualization of stents and the possibility of a controlled fly-through.

3. Results

The investigators visualized offline stent malapposition, side branch jailing, stent crush, stent deformation, bifurcation stenting in 3D.

3D OCT can be valuable for better understanding of the outcome. This technique was online helpful during PCI with among others guidewire placement during difficult morphology of the vessel and with jailed side branches. 3D OCT may provide accurate information needed for optimal treatment.

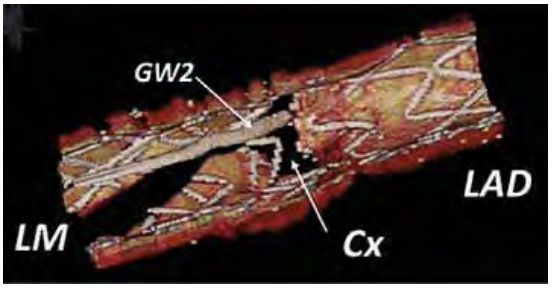

Figure 1: 3D reconstruction of OCT image, showing a guidewire (GW2) through a stented side branch.

4. Discussion & Conclusion

3D OCT reconstruction can clarify the architecture of coronary vessels, providing information for the operator to decide his procedure strategy, however fast online software with good stent detection algorithms is crucial.

With the availability of online 3D OCT rendering in the OCT console it seems only aphoristic that nurses and technicians, who work in interventional cardiology, are familiar with 3D OCT and how this feature can be implemented in the workflow

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Bio-inspired Shooting Mechanism for Crossing Chronic Total Occlusions

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1. Introduction

In nature, shooting mechanisms are used for catching prey, improving spore and seed survival, locomotion, and predator defense. Chameleons, salamanders, and frogs, for example, are able to shoot their tongue with accelerations of up to 500*g* to catch fast-moving prey. To achieve these accelerations, the energy for shooting is gradually stored in elastic structures, such as the elastic filaments surrounding a cylindrical bone in the chameleon tongue (Fig. 1).

We investigated whether a bio-inspired shooting mechanism could potentially improve the success rate of Percutaneous Coronary Interventions (PCIs) of Chronic Total Occlusions (CTOs; heavily calcified complete occlusions of over 3 months old). In PCI, a guidewire (Ø0.36 mm) is guided through the vasculature towards and through the CTO, after which a balloon is used to reopen the artery. The main challenge during PCI is to successfully pass through the hardened CTO, which is complicated by guidewire buckling. A shooting mechanism could potentially improve the crossing procedure. First, by exerting an impulse onto the CTO rather than the currently applied static load, the critical load that the guidewire can sustain increases dramatically. Secondly, by exerting an impulse onto the CTO, the inertia of the CTO and damping of its environment act as a reaction force to the exerted force of the guidewire, preventing energy dissipation.

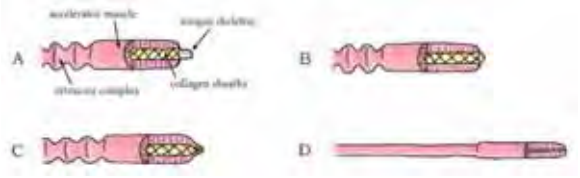

Figure 1: Shooting mechanism of the chameleon tongue A: Chameleon tongue in rest. B: Contraction of the tongue muscles elongates the muscle and stretches the elastic filaments. C–D: The tongue muscle and elastic filaments slide off the bone; releasing the stored elastic energy and propelling the tongue forward.

2. Methods

By studying the working principles of nature's shooting mechanisms and taking inspiration from these, we developed an innovative prototype for crossing CTOs. The mechanical (velocity and impact peak force, n = 5) and puncture performance (number of strikes until puncture) of the prototype was evaluated using a load cell, high-speed camera, and CTO models made of gelatin and calcium. Furthermore, to determine the energy dissipation to the environment, the CTO model displacement along the axis of shooting was evaluated.

3. Results

The developed prototype (Ø2mm) uses a compression spring in combination with a compliant loading mechanism that allows for multiple impacts onto the tissue (Fig. 2). A mean velocity of 3.6 m/s and a mean impact peak force of 19.2 N–more than 10 times higher than what is required to pass through the CTO [1]–were measured. The prototype required on average 2.7 strikes to puncture through the CTO model. A maximum of 1.4 mm displacement of the CTO model was measured, which is significantly less than the displacements reported in the literature for real CTOs [1].

Figure 2: Bio-inspired shooting prototype.

4. Discussion & Conclusion

The shooting prototype exhibited promising mechanical and puncture performance, characterized by high speed, high impact peak force, and a low number of strikes for puncture. Currently, the rigid design of the prototype is translated into a flexible clinical instrument, suitable for in vivo investigation.

This research is supported by the Dutch Technology Foundation STW.

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3D Imaging with a Single-element Forward-looking steerable IVUS catheter

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1. Introduction

In the field of vascular interventions, visualization of complex lesions, such as chronic total occlusions (CTOs), requires forward-looking intravascular ultrasound (FL-IVUS) catheters. Several ultrasound transducer arrays were proposed to achieve 2D and 3D FL-IVUS [1, 2]. Integration of these arrays into catheters compatible with intravascular applications remains a major challenge. In this work, we investigate an alternative strategy for 3D imaging, using a single element transducer and an optical shape sensing fiber (OSS, Philips) in a steerable catheter tip (TU Delft). The device and its functionality were characterized by imaging of a wire phantom in water.

2. Methods

The steerable catheter is shown in Fig. 1. The catheter has an outer diameter of 2 mm and an inner lumen with a diameter of 1 mm. The steerable region is 30 mm long, consisting of four segments, each connected to four pulling wires. A single element transducer (square, 1.4 mm side) is mounted at the tip of the catheter and the coaxial cable is guided through the inner lumen together with the optical fiber. The OSS fiber is 200 µm in diameter and has 4 inner cores that are used to reconstruct the shape through optical frequency-domain reflectometry at 60 Hz. The transducer is excited with a 2 cycle sinusoidal pulse at 14 MHz and 300 Hz pulse repetition frequency. The OSS data and the ultrasound data are acquired continuously, while the catheter is steered across six parallel tungsten wires positioned at different depths (Fig. 1). The ultrasound A-lines provide information about the distance of the wire to the catheter tip, while the OSS data are used to reconstruct the tip position and direction. The ultrasound signal is then combined with the OSS data to locate the wires in the 3D space.

3. Results

The scanning pattern of the steerable catheter enabled to cross all the wires twice, thus for each wire two points are identified Fig 1(c). The distance between the wires is estimated with a mean relative error of 22 %.

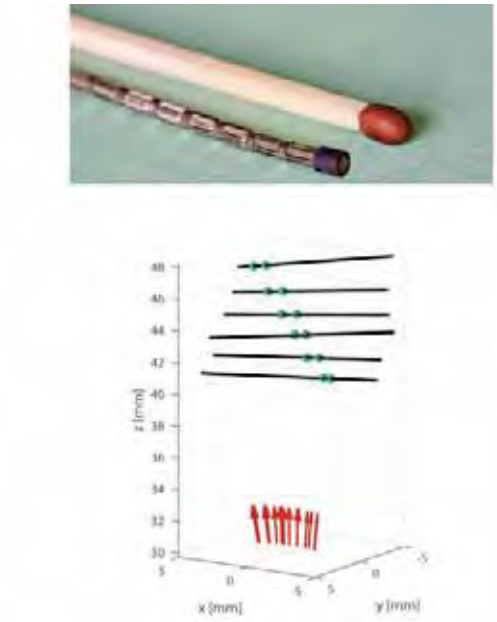

Figure 1: (top) Transducer mounted on the tip of the steerable catheter, (bottom) The reconstructed wires based on the ultrasound signal and the OSS data. The light green dots show the location in the 3D space of the wires ultrasound signals. The red arrows show the scanning pattern of the catheter tip and its direction.

4. Discussion & Conclusion

The six wires are successfully reconstructed in the 3D space.

The estimation and image reconstruction can be further improved by optimizing the set-up. This initial successful attempt of integration will be used to investigate further forward-looking imaging of more complex structures.

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Design, Analysis and Hydrodynamic Assessment of a Novel Transcatheter Mitral Valve

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1. Introduction

Mitral regurgitation is a common mitral valve dysfunction which may lead to heart failure. Because of the rapid ageing of the population, conventional surgical repair and replacement of the pathological valve are not suitable for about half of symptomatic patients [1]. Transcatheter valve replacement could represent a solution, but available solutions are unsuitable for the mitral position [2]. This abstract presents a novel transcatheter mitral valve recently developed at UCL, and describes its preliminary preclinical assessment.

2. Methods

The valve consists of a self-expanding wireframe structure made from superelastic NiTi alloy, supporting two leaflets and a sealing component made from xenograft pericardium. The frame was designed to provide adequate matching to the D-shape mitral valve anatomy, and optimised numerically (MSC.Marc) to minimise the stresses during crimping into a 24 French delivery system (Fig. 1.a,b). Prototypes of the optimised geometry were manufactured and used to validate the numerical analyses (Fig. 1). A similar optimisation procedure was adopted for the valve leaflets (using the package LS-Dyna). These were designed to minimise the stress during systole and provide sufficient length to guarantee proper coaptation at different geometries of the host anatomy (Fig. 2a). The leaflets were obtained from glutaraldehyde fixed porcine pericardium, and sutured to the stent. Additional tissue was included to create a sealing cuff, reducing paravalvular leakage. A skirt made from a PET mesh was included to gently distribute the anchoring force over the annulus (Fig. 2b). The hydrodynamic performance of the prototypes was assessed on a cardiac pulse duplicator, after implanting the devices into mock mitral valves of inter-trigonal sizes ranging from 20 to 26 mm, in compliance with the international standard ISO5840:2015-3.

3. Results

The maximum stress on the optimised stent geometry was 835 MPa, which is below the yield stress for the martensitic phase. The crimped stent geometry (Fig.1d) was in a good agreement with the simulation results (Fig.1.b). *In vitro* tests confirmed a good anchoring of the valve, and compliance with the hydrodynamic requirements in the international standard ISO5840:2015-3. The effective orifice areas and the regurgitant fractions determined at the different implantation sizes are summarised in Fig. 3.

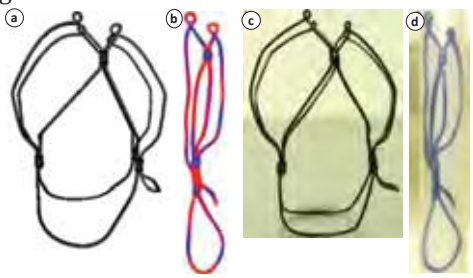

Figure 1: Numerical model of the unloaded (a) and crimped (b) optimised frame; and unloaded (c) and crimped (c) configurations of the physical prototype.

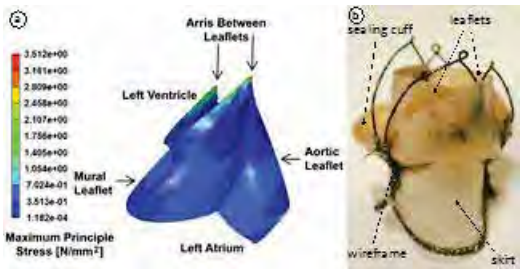

Figure 2: Numerical model of the closed leaflets (a) and the full prototype of the novel valve (b).

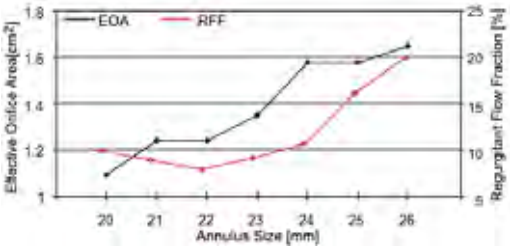

Figure 3: Effective orifice areas and regurgitant fractions determined at different implantation sizes.

4. Discussion & Conclusion

A novel transcatheter mitral valve device was developed and tested. Preliminary tests showed the feasibility of this new device to become an option for transcatheter valve treatment.

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Design of a Multi-Steerable Catheter for Complex Cardiac Interventions

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1. Introduction

Catheters are the most versatile and essential instruments used in interventional cardiology. However, due to the heart's continuous motion and the lack of vessel wall support inside the heart, steering and stabilizing the catheter tip inside the cardiac atria and ventricles remains cumbersome. As a result, the ability to place the instrument tip at the required location inside the heart is often restricted, in turn complicating procedures such as atrial fibrillation ablation and endo-myocardial biopsy that depend on precise positioning and effective instrument-tissue contact. In an effort to overcome these challenges, we are developing a multi-steerable catheter that allows accurate positioning and steering inside the heart by providing snake-like motions and an intuitive, manual control.

2. Methods

Essential clinical needs in interventional cardiology were identified in cooperation with multiple cardiologists, electrophysiologists, and cardiac surgeons from the Erasmus Medical Centre and the Leiden University Medical Centre (Netherlands). The results were further analysed with respect to catheter steering properties and the lack thereof in conventionally available instruments. Challenges related to the limited steering properties were tackled in order to develop a multi-steerable catheter having a flexible shaft with an insertion port (Ø 1.5 mm) and outer diameter of 3 mm. Two steerable tip segments, each consisting of multiple relatively movable elements, were designed for the purpose of multi-steerability and improved controllability in the complex cardiac environment. Finally, the prototype was designed having a novel handle piece that allows the intuitive control and locking of both tip segments. A feasibility test was performed to test the final prototype.

3. Results

The catheter design comprises 2 steerable tip segments, each consisting of multiple relatively movable elements, and a mechanical actuation with cable-ring mechanism. Allowing the tip to be steered over multiple planes and in multiple directions, including S-shaped and multi-planed curves, the steerable catheter allows 4 degrees of freedom. Additionally, the prototype is equipped with a novel handle piece having two joysticks placed at ergonomically convenient locations to allow the intuitive control of both segments. Finally, an intuitive locking mechanism is included that allows the interventionist to lock the position and the curve of the catheter tip upon releasing the joystick.

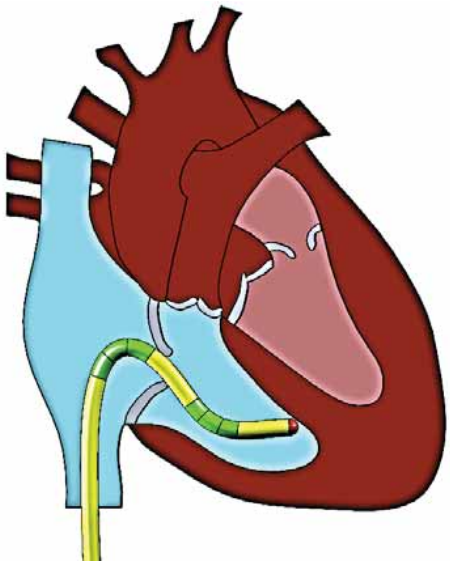

Figure 1: Schematic representation of using a multi-steerable catheter in cardiac applications.

4. Discussion & Conclusion

This study presents an innovative design of a multi-steerable catheter meant for use during complex cardiac interventions. The approach presents a prototype providing two steerable tip segments and a novel handle design for the intuitive control of the segments. Additionally, an intuitive locking mechanism is included that allows the interventionist to lock the position and the curve of the catheter tip upon releasing the joystick. The ability to steer inside the heart and perform complex, S-shaped, or circular curves may potentially improve cumbersome procedures and change conventional approaches in interventional cardiology. The use of such dedicated, steerable, instrumentation may further optimize conventional procedures towards patient-specific needs. Future directions are headed towards application-specific use.

Granular jamming as controllable stiffness mechanism for endoscopic and catheter applications

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1. Introduction

In the medical field, several devices (as endoscopes, catheters, etc.) need to be sufficiently flexible to avoid damaging patient tissues or causing pain, but have to be stiff enough to transmit force for support or e.g. puncture. A promising solution to control the stiffness is based on the jamming of granular media [1]. Grains packed in a membrane behave as a fluid when atmospheric pressure is present and as a solid when vacuum is applied. The study is focused on the scaling laws of such solutions for small applications (with diameters below 3mm), the mechanical rules of design and the optimization based on the stiffness performances.

2. Methods

In targeted applications as vascular occlusions or transbronchial biopsies, the performance of granular jamming solutions may be evaluated by the flexural rigidity EI (with E: Young's modulus and I: inertia of the structure) and the change of stiffness from flexible to rigid configuration. The performances depend on several factors as the membrane [2] and the grains [1]. In this work, the influence of the grains (shape, size and material) is studied using both triaxial compression test and bending test. On the one hand, the triaxial test is a classical tool used in geomechanics to characterize soils and granular media [3]. It can be used to deliver information about elastic modulus of the soil, shear strength and friction angle. On the other hand, the bending test is used to characterize the tunable stiffness solution in its final shape. The scaling law can be studied thanks to this test in which the beam cross-section can be tuned. Such a bending test gives direct information about the flexural rigidity EI by measuring the force-deflection couple. The actuation method to control the stiffness is for now based on applying vacuum in the membrane. Nevertheless, higher pressure differences can be achieved in triaxial tests and are used in order to generalise the results.

3. Results

In Figure 1, the results of the triaxial compression test of dry sand ($D_{50} = 260\mu m$) are presented. First, the stress-strain curves give information about the equivalent compressive Young's modulus, yield and ultimate strengths. The study in Mohr's circles allows to observe the Mohr-Coulomb failure criterion: $\tau_{max} = c + \sigma_N \tan\phi$, with τ_{max} the shear stress at failure, c the cohesion of the material, σ_N the normal stress at failure and ϕ the friction angle of the material. The first results confirm the use of such method for dry granular material as they show a very good repeatability and are in good accordance with the friction coefficient for dry sand. Such results give intrinsic properties of granular material and are used to build a design law for tunable stiffness endoscopes or catheters.

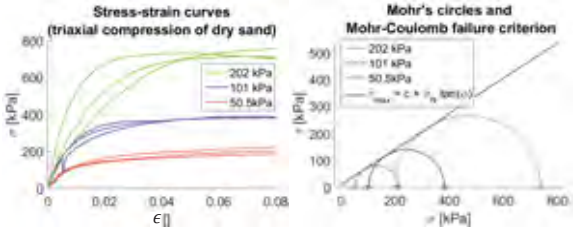

Figure 1: Left: stress-strain curves of dry sand for confinement pressures of 50.5kPa, 101kPa and 202kPa; right: the analysis of Mohr's circles highlights the Mohr-Coulomb failure criterion.

4. Discussion & Conclusion

The future steps will include the comparison of triaxial test results with the measures of the flexural rigidities obtained with the bending test. The use of various granular media with different grain sizes, shapes and materials will give additional information for the design laws and the optimization of the stiffness that can be obtained. The scaling law will be evaluated based on the bending test.

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Time varying spectral analysis of blood flow sounds acquired with a portable digital stethoscope connected to a smart phone

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1. Introduction

Auscultation consists on listening to the internal sounds of the body, using a stethoscope and it is performed for examination of the sounds of the circulatory and respiratory systems. Experienced clinicians can hear the flow of blood e.g. in the carotid arteries. We assume that the sound of blood flow will change over life time due to changes inside the vessels. The deposition of plaque and calcification or a restenosis of an implant causes turbulences in the vessels that will change the sound. Since it is possible to hear the blood flow, it should also be possible to measure changes in the sound of blood flow. This technique could be used for long time monitoring of patients or sportsman.

2. Methods

A prototype stethoscope with a microphone was combined with a smartphone for the acquisition of audio signals from the carotid of five volunteer subjects (see Fig. 1a). For each subject four recordings (one every two weeks) of 45 [s] each were acquired. In order to characterize dynamical changes of the blood flow that could be characteristic of each subject, a time-varying spectral analysis through an autoregressive (AR) parametrical model has been performed over the acquired signals [1]. From the AR model, indicators related to the time varying spectrum and pole representation [2] have been computed for extracting a trace or signature in the audio signal that can characterize patterns from a given subject.

In a first step the audio signal is decimated in order to use an AR model of lower orders. Then a band-pass filtering using Discrete Wavelet Transformation [3] is applied to the decimated signal for attenuation of respiration and other sound artefacts. Then the AR coefficient and poles are computed through a sliding window of 0.5 [s] and 90% overlapping using an AR model of order 30. Finally different indicators are computed based mainly on spectral energy dispersion and tracking of the maximal energy pole.

3. Results

Fig. 1b shows 13 [s] of the recordings from two subjects and the respective AR time varying spectrums, where it is possible to observe different dynamics associated to the inter-cycle intervals and also to the intervals between valves sounds. Both spectrums show that dynamics can be very different from one subject to another one, but that for the same subject the spectral properties are more or less invariant from beat to beat.

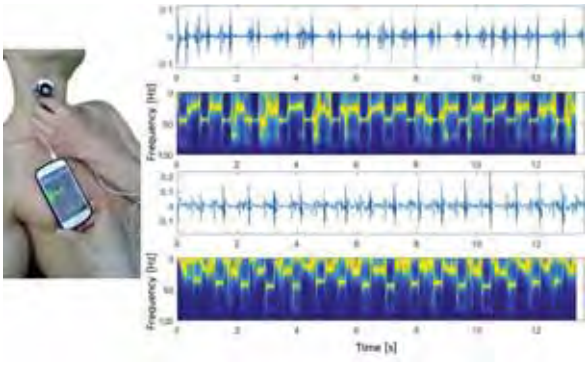

Figure 1: a) Stethoscope connected to a smartphone for measuring blood flow audio recordings from the carotid. b) Two obtained preprocessed audio signals and their corresponding time-varying AR spectrums.

4. Discussion & Conclusion

Preliminary results show that from the time-varying analysis of the audio signal at each cardiac cycle it is possible to extract pole-based and spectrum-based features. Those are associated to a given recording since the same features are obtained consistently over the cardiac cycles. Moreover these features can be different from subject to subject, which is a promising result for further patient specific long term monitoring. With this information we expect to further track long term changes (e.g. monthly changes) which should be extracted from the subject's signal trace.

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MR-Guided Interventions

11.01 **The tip is the key - RFA needle modification using PEEK for reduced susceptibility artifact in MRI.** *M. Al-Maatoq, J.W. Krug, M.H. Friebe.*

11.02 **Evaluation of novel inside-out approach for single slice US/MRI fusion procedure in MRI suite.** *Y. Nagaraj, B. Menze, M. Friebe.*

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11.06 **Performing ISO/TS 10974 'Sequence of Sequences' (SoS) for Combined Field Testing (CFT) for active implantable medical devices (AIMD) on a clinical scanner.** *J.S. van den Brink, N. Fülle, J. Kreutner, P.Sanders, G. Schaefers.*

11.07 **Should 'cheap' and 'easy to use' be primary attributes for MedTec product developments? MRI Injector example.** *M.H. Friebe, A. Boese, J. Traub, S. Hellwig.*

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The tip is the key - RFA needle modification using PEEK for reduced susceptibility artifact in MRI

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1. Introduction

Magnetic resonance imaging (MRI) can be used as a guiding modality in minimally invasive procedures. Due to its superior soft tissue contrast and its ability to obtain information about the temperature, MRI would also be the ideal guiding and monitoring system for radiofrequency ablation (RFA) procedures [1,2]. One of the main challenges in these procedures are the susceptibility artifacts of therapy devices that can significantly affect image quality and distort the MR images [3]. The artifacts are caused by the material composition of the RFA needle. Due to the artifacts, the needle's shaft and tip are not visible because they are covered in an exaggerated appearance of the needle shaft. That obviously does not allow precise placement of the device inside the tumor or the area of interest. It is impossible to determine where the centerline or the tip of the needle are within the artefact image that can have a 5-fold or more diameter to the original diameter.

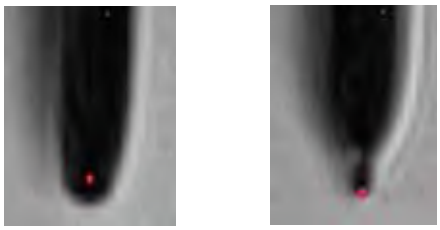
The aim of this study was to reduce or avoid the artifacts particularly on the tip entering the body by replacing the end of a MR-compatible RFA needle with a tip made from polyetheretherketone (PEEK). If the tip location is clearly depictable the increased artefact diameter that follows is of lesser concern.

2. Materials and Methods

The first 7mm of the original tip of a MR-compatible RFA needle (StarBurst MRI RFA Device, Angiodynamics, outer diameter of 2.2mm) were replaced by a PEEK tube with diameter of 3.2mm. For assessing the susceptibility artefacts, the original and reworked needles were placed in a water copper sulfate solution [4]. A FLASH sequence (TR=4.9ms, TE=2.5ms, Flip angle=10°) on a 3T MRI (Sykra, Siemens, Erlangen, Germany) was used to acquire the MR images.

3. Results

Figure 1 shows the MR images of the original and of the modified RFA needle. Prior to the modification, the artifact caused by the RFA needle had a diameter of 13.8mm. Due to the susceptibility artifact, the tip of the RFA needle appeared 3mm away from the real position (Fig. 1(a)). The modified PEEK needle tip appeared with an outer diameter of 3.2mm in the MR images. The location of the PEEK needle tip was in high agreement with the real tip location (Fig. 1(b)).



(a) Original needle (b) Needle with PEEK tip

Figure 1: MR images of the original RFA needle (a) with PEEK tip (b). The red dots mark the real positions of the needle tip.

4. Discussion & Conclusion

The tip of an RFA needle was replaced by a PEEK needle resulting in a suppression of the existing susceptibility artifacts at the important tip of the needle, which is used to guide the device and ensure a proper positioning within the target area. The results show that a more precise RFA needle placement could be achieved under MRI guidance by replacing the needle's original tip.

Future works will focus on ensuring a reliable connection between the RFA needle and the PEEK tip, will analyze the mechanical properties of the PEEK needle tip and will also consider other suitable materials such as carbon fibers. The proposed technology can also be used to modify other medical devices used in MRI such as biopsy needles.

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Evaluation of Novel Inside-Out approach for single slice US/ MRI fusion procedure in MRI suite

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1. Introduction

In computer-assisted interventions, object tracking is a key enabling technology which allows continuous localization of therapy tools and patient anatomy. Real-time tracking without the line-of-sight issue can be carried out using electromagnetic (EM) tracking but difficult to use with a close bore MRI system. To combine MRI imaging with an immediate further Ultrasound examination in the MRI suite could provide significant advantages over fusion of US with preoperative image data with that increasing the lesion detectability [1].

In our approach, we suggest Inside-Out approach to detect the position of the US probe using 2D marker based algorithm and corresponding 2D single slices of US and MRI are displayed in real-time.

2. Methods

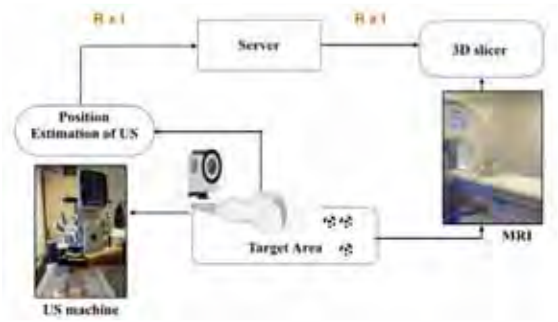

Figure 1: Systematic workflow of the Inside-out approach for the corresponding US and MRI slices.

The proof-of-principle study was conducted using a portable US Machine (Venue 50, GE Healthcare) combined with Inside-Out tracking technique (camera attached to US-probe), as the spatial tracker is illustrated in fig. 1. In this approach, the US-probe tracks its own position with respect to the world coordinates which is different from conventional optical tracking.

We used the direct linear transformation (DLT) tracking framework to obtain location and orientation of camera center in three-dimensional space with respect to the markers (combined optical marker and Vitamin-E capsule placed one below the other). For each good position of US slice with respect to marker-based tracking, corresponding MRI slice is achieved. The MRI transformation with respect to the markers using isocenter of the preoperative MRI volume. The tracking was carried out using a purpose build phantom and corresponding rotation and translation vectors were transferred into the 3D slicer which contained the preoperative MRI data through a server connection, which allows the visualization of the corresponding 2D slices of both modalities.

3. Results

The evaluation of tracking functionality was done using the standard optical tracking system. Once we gained comparable results, the quantification of the 2D US in the 3D MRI volume was necessary. We tested our new approach on a phantom with predefined small circular structure of 2.4cm placed inside. These circular structures had well defined shape and produced no artifacts in the US and MRI images. This strategy helped us determine the optimal similarity measure between both the modalities. For the similarity measure of two modalities we used the already proposed LC2 metric [2]. We used 180 slices in the MRI volume and calculated the similarity measure between MRI and US obtained by inside-out approach and markers which are visible in the MRI data sets, also on the phantom.

US- MRI (Similarity measure using LC2)	Slice1	Slice2	Slice3
Patch size = 10	0.6589	0.7890	0.6290
Patch size = 5	0.7066	0.65543	0.7467

Figure 2: The table illustrates the similarity measure for single 2D slice of MRI and US.

4. Discussion & Conclusion

Our method had comparable translational accuracy to conventional optical tracking system with average mean error of around 2.04 in all direction. We also observed that problematic area found is the one between camera and markers. The presented Inside-Out combined marker approach allows clinicians to do MRI-US image guided Interventions inside the MRI suite, but will benefit further from automated fusion and correction of patient motion.

For future work completely automated fusion systems could correct any patient motion and non rigid deformations for improved outcome of an image guided therapy procedure.

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Development and clinical validation of the Quantitative MR Angiography (QMRA): NOVA®

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1. Introduction

Atherosclerotic occlusive disease is a significant etiology of stroke, with regional hypoperfusion recognized as an important potential contributor to stroke risk. QMRA- NOVA was developed in order to quantify vascular hemodynamics and lately utilized in the Veritas Study to test the hypothesis that among patients with symptomatic VB stenosis or occlusion, those with distal blood flow compromise as measured by large vessel quantitative magnetic resonance angiography (QMRA-NOVA®) are at higher risk of subsequent posterior circulation stroke than those with normal distal flow status.

2. Methods

QMRA- NOVA was developed in order to quantify vascular hemodynamics and lately utilized in the Veritas Study to test the hypothesis that among patients with symptomatic VB stenosis or occlusion, those with distal blood flow compromise as measured by large vessel quantitative magnetic resonance angiography (QMRA-NOVA®) are at higher risk of subsequent posterior circulation stroke than those with normal distal flow status.

3. Results

The Veritas Study, an NIH-sponsored, prospective blinded longitudinal cohort study, was recently concluded and it established that flow status, determined using a noninvasive and practical imaging tool (QMRA-NOVA®), is a robust predictor of subsequent stroke risk in patients with symptomatic atherosclerotic VB occlusive disease.

4. Discussion & Conclusion

The steps in translating this technology from bench, to product and ultimately to clinical validation, will be highlighted. As a result, currently, identification of high risk patients can now guide the implementations of more aggressive interventional or medical therapies.

Tele-operated MR-compatible robot for prostate interventions

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1. Introduction

The most common method to diagnose prostate cancer is the transrectal ultrasound (TRUS)-guided biopsy. However, TRUS-guided biopsies have a limited detection rate and accuracy [1]. Magnetic resonance images (MRI) have higher tissue contrast and larger spatial resolution than ultrasound; this entails visibility of the tumor. Therefore, an MR-compatible robot for prostate interventions was developed as part of the MIRIAM (Minimally Invasive Robotics In An MRI environment) project [2]. The MIRIAM robot can perform an MR-guided prostate biopsy autonomously or with minimal input from the clinician. The aim of the current research is to develop a tele-operated system to provide the clinician more control during the procedure. The clinician controls the needle insertion depth while receiving haptic feedback (Figure 1).

2. Methods

The existing MIRIAM control architecture, including its graphical user interface, is modified to include haptic feedback. The feedback is given to the user through the Phantom Omni device (Sensable, Wilmington, USA). A force model is used to provide the haptic feedback (F_h) to the user. The interaction between the needle and the tissue is modeled as an extended Coulomb-viscous friction model plus a cutting force and is defined as follows:

$$F_h = \begin{cases} k_1 sgn(\dot{x}) + k_2\, x\, \dot{x}, & \dot{x} < 0 \\ 0, & \dot{x} = 0 \\ k_3 sgn(\dot{x}) + k_4\, x\, \dot{x} + k_5 xE + k_6 d, & \dot{x} > 0 \end{cases}$$

where x, $\dot{x}$ and d are the needle's insertion depth, velocity and needle deflection, respectively. E is the phantom's Young's modulus. The model parameters k_1, k_2, k_3, k_4 and k_5 are tissue-dependent, which can be estimated online or preoperatively. In this model, the haptic feedback is computed online based on the haptic device position and velocity. The deflection (d) is estimated based on the needle tip position ($\mathbf{p}_{tip}$) provided by the needle tip tracking algorithm. Due to the lack of real-time MRI, needle tracking is done using a needle integrated with fiber Bragg grating (FBG) sensors. Different control architectures are implemented and will be tested using human subjects.

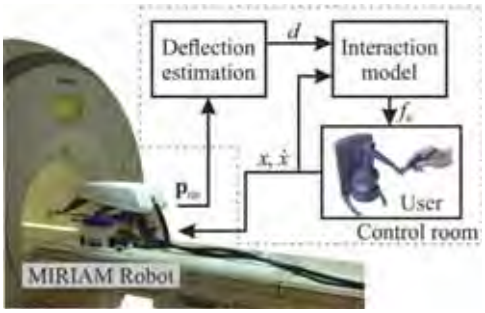

Figure 1: Proposed tele-operation structure for MR-guided prostate biopsies using the MIRIAM robot. The user controls the position (x) and velocity ($\dot{x}$) of the needle. The position of the tip ($\boldsymbol{p}_{tip}$) is tracked and the needle deflection (d) is determined. x, $\dot{x}$ and d provide haptic feedback (f_h) to the user.

3. Preliminary results

A Nano17 force sensor (ATI Industrial Automation, Apex, USA) is attached to the needle base. Experiments inserting the needle into different gelatin phantoms are performed to determine the coefficients of the extended Coulomb-viscous model. The estimated coefficients k_1, k_2, k_3, k_4, k_5, k_6 are $-0.53\,N$, $-0.13\times10^{-2}\,Ns/mm^2$, $-0.70\,N$, $-0.5\times10^{-3}\,Ns/mm^2$, $-0.4\times10^{-4}N/(kPa\,mm)$ and $55.81Nmm$, respectively. The tele-operation setup is first tested in the lab environment. The needle moves corresponding to the input from the user.

4. Discussion

This study presents the design and control of a tele-operated needle steering robot with the goal to include the human in the control loop. A shared control architecture where the clinician controls the insertion depth and the robot controls the needle rotation will increase the acceptance of the presented system by the medical community. Next steps in this research include the validation of the tele-operation control architecture, experiments with users and experiments in the MR scanner.

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A review of labeling information of commercially available MRI accessories related to IEC 62570 standardized ‚MR Safe' and 'MR Conditional' labelling requirements

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1. Introduction

Commercially medical accessories such as Furniture, wheel chairs, instruments and other products can be ferromagnetic or electrically conductive. They are not designed, thus contraindicated to be used in the magnetic resonance environment. Several health injuries have been reported by use of incorrectly or unlabelled MR devices. ASTM F2503 [1], IEC 62570 [2] standards address 'MR Safe'/'MR Conditional' marking and identification of testing requirements for all items with intended use inside the MR.

2. Methods

About 96 conventional available MRI products have been selected randomly and from throughout the daily use of MR clinical application:

- MRI audio and video systems
- MRI gurneys
- MRI goggles
- MRI earmuffs
- MRI injection systems
- MRI suction pumps
- MRI pulseoxymeters
- MRI monitoring system
- MRI positioning
- MRI wheel chairs
- MRI anesthesia machines

The product documentation has been investigated for the ASTM/ IEC required MR marking/labelling information and the completeness of MR labelling information

3. Results

96 Products have been analyzed.
35 of these products are completely designed and made from non-conductive and non-magnetic materials, e.g. plastics and foam materials such as cushions, positioning aids. Therefore statements can be based on a scientific rationale for MR safety.
From these 61 Products only 1 product has an MR test report at the time of investigation.
26 guaranteed compatibility, but there is no certificate because these products are only tested in a clinic with no standardized test procedure.
34 products did not have any verification. There is just a verbal statement from the manufacturers that these products are 'MRI safe/conditional'/compatible.
The result is that more than half of the investigated products have never been properly tested and assessed for safety in the MR environment. There could be fatal consequences if one of these 34 products contain metallic materials, be magnetic, burn the patient or have its function affected as well as interfere the MR system by any MR interaction known, but because not fully analyzed in MR testing, appearing intermittently.

4. Discussion & Conclusion

ASTM F2503-13 and IEC 62570:2014 require that all devices entering the MRE have to be tested and marked comprehensively. Individual statements of manufacturers lead to initial cautions, but cannot be considered as being sufficient for use in the daily clinical MR routine due to many factors of interpretation possibilities or resulting in unclear situations.
Therefore, having proper standardized MR labelling assists to prevent potential projectile injuries, burns and other hazards inside the MRE.

Note: An increasing number of accessories meanwhile receives the attention of ASTM F2503 and IEC 62570 consideration and testing planning. At the date of publication of this investigation the number of products being MR labeled has increased to 3 having an MR test report and up to 20 products are under investigation for getting investigated to receive an MR Safe or MR Conditional labeling.

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[2] IEC 62570:2014 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

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Performing ISO/TS 10974 'Sequence of Sequences' (SoS) for Combined Field Testing (CFT) for active implantable medical devices (AIMD) on a clinical scanner

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1. Introduction

AIMDs have to maintain functionality during or at least after MRI scans. Functionality can be compromised by gradient-induced field interactions as well as RF field-induced interactions. A test procedure for separate fields testing of AIMDs is described in ISO/TS 10974 [1]. Version 1 provides a 'Sequence of Sequences' (SoS) approach to test compliance, not intended to be executed on clinical scanners. We perform an initial investigation in order to establish CFT using the SoS using proprietary technical control software on a clinical MR scanner. Our goal was to implement the required test signals on a standard clinical scanner, in order to allow the use of one identical system for testing which is also closest to a clinical use.

2. Methods

We implemented SoS using the standard, proprietary technical test sequence Toolbox at Philips Ingenia 1.5T MRI scanners. This Toolbox is available for manufacturing and customer service testing, and allows to drive the system to the maximum technical specifications. Exposures and timings (SoS) are implemented using proprietary scripting. A standard body ASTM-phantom was filled with tissue simulating medium and placed inside a clinical 1.5 T MR Scanner. E- and B-field probes were used in order to assure that the required RF amplitudes and time varying gradients are met. Amplitude of the RF coil exposure was set to 5 µT. The RF test was performed for the following combinations of pulse width/period: 0.2/2, 1/5, 2/10, 10/50 ms. For gradient testing gradient rise time t_{slew} = 1 ms and dwell time t_{dwell} = 1 ms were used resulting in a cycle duration of 4ms. A burst of 128 cycles was applied followed by a pause of 5 ms. All three gradients were applied simultaneously with an amplitude of 22.5 mT/m (y-axis) and 11.3 mT/m (x- and z-axis). The time rate change of the magnetic field dB/dt was monitored using a 3-axes search coil.

3. Results

Gradient testing revealed an absolute value peak in dB/dt as high as 14.4 T/s and 12.9 T/s on a single axis. Based on a very moderate gradient rise time of 1 ms these values are as expected and can be further increased by a shorter rise time.

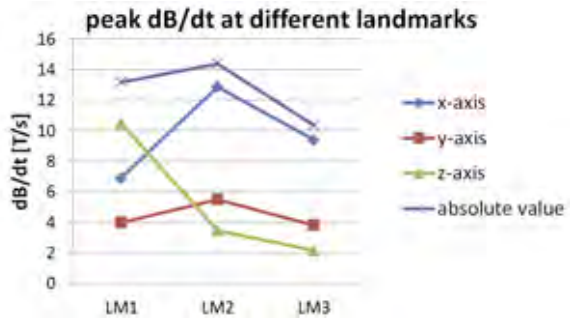

Figure 1: dB/dt values at different positions (LM1, LM2, LM3)

4. Discussion & Conclusion

For the RF sequence the identical RMS E-field values for combinations of pulse width and period with identical duty cycle demonstrate a high reproducibility and stability of the system for various test conditions, which allows for the performance of reliable testing. For pulse width of 0.2 ms and period of 2 ms lower RMS values appear due to a lower duty cycle. Both SoS are capable to produce higher and better controlled values of exposition of RF amplitude and dB/dt assuring a higher safety margin for testing compared with clinical sequences for combined field testing. This allows functionality testing of AIMDs with well-defined worst-case RF and gradient exposure conditions compared to the application of a set of clinical protocols which do not represent a worst-case.

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Should 'cheap' and 'easy to use' be primary attributes for MedTec product developments? MRI Injector Example.

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1. Introduction

Investing money into simplifying complex problems, could develop truly innovative technologies that will benefit most patients [1]. This unfortunately is not considered scientifically 'desirable and cool' at the moment and therefore not in the focus of available public funding.

We wanted to show that by looking at existing technologies and focussing exclusively on reducing complexity and cost would allow us to come up with new product innovations that create additional value for the inventor, the user, and the healthcare system.

For that we analysed MRI Contrast Media Injector (CMI) systems with the plan to develop a system that can handle a majority (>90%) of the required procedures, with greatly reduced error potential (close to '0'), very cheap manufacturing cost (<5% of original cost), and very easy handling.

2. Materials and Methods

MRI CMI systems, injection protocols for the different MRI imaging procedures, and the application notes of the majority of contrast media solutions were carefully analysed. All CMI systems come with electromechanical or hydraulic drive systems, independent injection volumes for contrast media and saline solution, computer controlled injection protocols, flow adjustment in 0.1ml/s steps all the way up to 10ml/s, are quite heavy and bulky (10kg-35kg), and consist of two or three independent hardware components.

This causes handling problems, does not make the CMI fully MRI compatible, and requires extensive training to ensure safe operation [2].

MRI contrast media needs to be injected as a bolus, but in all evaluated cases and as recommended in the application notes exclusively using a flow rate of 2ml/s, and with a patient weight dependent volume (0.2ml/kg), followed by the same volume saline solution.

3. Results

Based on the summary of CMI features that are considered essential (MUST HAVE) versus the ones that are optional and create incremental value, but obviously increase complexity and cost (fig. 1), we build a fully functional and completely mechanical prototype (fig. 2) with manufacturing cost of <€ 200 in only 4 month. This compares very favorably to the current CMI systems end customer pricing of > € 20.000.

Figure 1: CMI features and their cost. Some are absolutely necessary and others are only optional, but add complexity and cost — and are detrimental to patient safety.

Figure 2: Prototype of a fully mechanical MRI CMI with an air storage system, 2bar pressure is sufficient to drive a 30ml contrast media volume at constant 2ml/s followed by 30ml saline solution.

4. Discussion & Conclusion

Basic and fundamental research should not be governed by development attributes like ease of use, affordability, and others.

However, applied medical technology development should very strongly consider complexity and cost reduction as major attributes. New disruptive ideas could develop using that approach.

These type of developments are - despite common believe - technologically quite challenging and risky and should therefore also be positively considered in the future for public research funding proposals.

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New MR marker system for interventional MRI devices

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1. Introduction

The clinical feasibility of interventional MRI has been shown for a number of procedures [1]. However, MRI-guided interventions have not yet reached clinical routine. This is not due to the lack of real-time MR sequences, as most MR scanner manufacturers now offer real-time MR sequences adequate to guide MRI catheterization [2], but to the lack of MR safe/conditional and MR visible devices [3, 4].

2. Methods

In-vitro experiments were performed under real-time MR image guidance to evaluate the MRI visualization of several commercial catheters and sheaths. For navigation tasks, the instruments were used together with an MR visible and MR safe guidewire (MaRVis Medical). For each tool, several sequences were tested so that the lack of proper instrument visualization had to be due to the lack of proper MRI visualization markers on the instruments and not to the MR sequence. The tools that presented a large image artifact were excluded from the study. Should a catheter or sheath not be visualized under MRI-guidance, passive MR markers were added to the instrument. For passive visualization, the state-of-the-art technique is to place a series of discrete MR markers on the instrument. In this study, this approach was compared to a new type of continuous MR maker, designed to enable MRI visualization of the whole length of the tools.

3. Results

All the commercial catheters and sheaths included in the studies were not visible on the MR images. With added MR markers, the tools offered some degree of visualization. The series of discrete MR markers appear on the images similar to a pearl-necklace: a series of ball-shaped dots placed next to each other (fig1). This type of MR marker has been repeatedly used in the field of MR intervention as it is easy to implement and flexible in terms of MR visualization: the diameter and position of each dot can be optimized. However, identification of the position of the tip is difficult with such "pearl-necklace" markers, especially if not all dots appear in the visualized slice. Usually, such dot-type markers are placed only at the distal end of the tool (as in our study), so that there is no shaft visualization. The continuous and MR safe MR maker system, however, offered whole-length shaft visualization on real-time MR images. In addition, one or two tip markers were applied for identification of the tip position. The continuous shaft marker did not prevent visualization of the MR safe guidewire position, via its own tip marker, inside the catheter or sheath lumen (fig2).

Figure 1: MR image of a 7Fr sheath with "pearl-necklace" MR markers system (dots about 5-8 mm diameter).

Figure 2: MR image of a 5Fr SOS Omni catheter with the new continuous MR maker and two MR tip markers. Artifact shaft width: 3.9mm.

4. Discussion & Conclusion

Clinicians desire to visualize both the shaft and the tip of a device. To fulfill this demand, a new type of MR shaft marker has been proposed for catheters and sheaths. This novel marker system offered good MRI visualization of shaft and tip of the device, as well as the possibility to identify the tip of the guidewire inside the catheter or sheath lumen. Based on these in-vitro experiments, interventionalists considered the new marker system superior to the "pearl-necklace" markers for MRI-guided endovascular navigation.

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Ergonomics & Training

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12.02 **3D kinematics of surgeons' upper-arm rotation in laparoscopy.** *J. A. Sánchez-Margallo, F. M. Sánchez-Margallo, K. Gianikellis, A. Skiadopoulos, J. Hermoso.*

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12.09 **The need for multi-infusion training.** *R.A. Snijder, P. Lucas, A. van den Hoogen, A.D. Timmerman.*

12.10 **Mobile health in surgical training.** *C. Tiu, S. Kotzsch, E. Fenyöhöá, L.E. Bernal Vera, A. Negoita, F.M. Sánchez Margallo, L.F. Sánchez Peralta, J. Sándor, G. Wéber.*

3D-printed temporal bone model for ear surgery

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1. Introduction

This project is the result of a research collaboration of Füzy Works, the Erasmus Medical Center of Rotterdam and the Technical University of Delft, Faculty of Industrial Design Engineering. It aims to develop and test a 3-D printed version of a human temporal bone to provide otorhinolaryngology (ORL) residents with additional opportunities to practice drilling skills. The project is based on the master thesis of András Füzy (2014) *"Radical re-thinking of the approach to present patient characteristics in order to support the learning process and medical procedure"*. The artificial temporal bone model contains all anatomical landmarks, necessary to get accustomed to drilling out the mastoid, such as the facial nerve, the semicircular canals, the sigmoid sinus and the tegmen tympani. These structures were coloured by hand with surface paint.

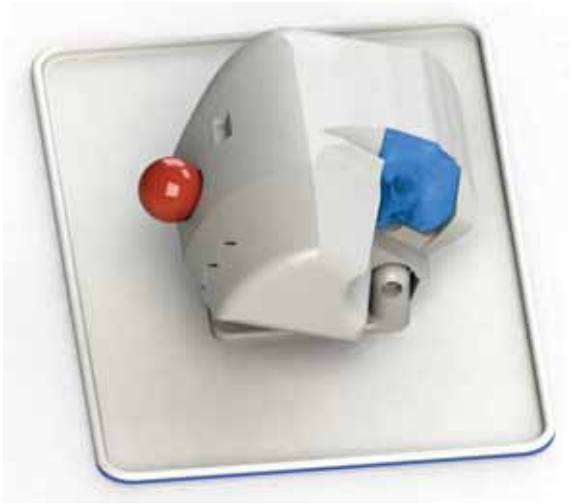

Figure 1: The complete setup of the temporal bone model (blue) that fits in a model of the head (white). The angle of the head can be varied and is fixed by the nose (red).

2. Methods

A field experiment (pilot test) was organized at the Erasmus MC Skills Lab for five ORL residents with diverging levels of surgical experience and one experienced otologic surgeon from a peripheral hospital. All participants practised on the same model and had to perform the same surgical procedure as an exercise.

Content and face validity were discussed with the participants after the test.

Figure 2: Pilot test at Erasmus MC Skills Lab in Rotterdam on 21st of June 2016.

3. Results

The 3D-printed material felt much like bone and reacted similar while drilling. It is slightly transparent, which helped when coloured structures were closely approached. Limitations were the absence of slight colour differences in the printed material, that are present in the human temporal bone and the mastoid air cells being filled with printed support material instead of air.

Residents were able to complete their drilling assignment within approximately 4 hours. The individual amount of time corresponded with the level of experience.

4. Discussion & Conclusion

The 3D-printed temporal bone model is helpful in learning the anatomy of the mastoid and to gain drilling skills for residents, necessary for ear surgery. The model can be used as a replacement for real human bone, at the beginning of the curriculum.

Various models can be designed to mimic different levels of anatomical difficulty and special abnormalities of individual patients. Hence a stepwise curriculum can be made to further improve patient safety.

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3D kinematics of surgeons' upper-arm rotation in laparoscopy

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1. Introduction

In order to foster safer workplaces and to cope with Work-Related Musculoskeletal Disorders (WRMSDs), an ergonomic intervention is required for managing the biomechanical risk factors that appear during laparoscopic surgery tasks. In this sense, surgeons who perform laparoscopy are concerned as a high-risk occupational group for developing WRMSDs as a direct consequence of the postures that they sometimes have to adopt during operation. There are many tracking systems able to track surgeons' motion during laparoscopic activities. Advances in the use of the inertial measurements units (IMUs) for motion capturing make IMUs systems more suitable than 3D photogrammetry for tracking surgeons motion in the operation theaters, as there is no markers occlusion problem [1].

2. Methods

The XSens MVN BIOMECH system (Enschede, The Netherlands) was utilized during laparoscopic surgery to obtain body segment's pose information from inertial units (Figure 1). The pose data were stored as .MVNX files and were post – processed with the Visual3D software (C-motion, Inc., Germantown, MD, USA). The defined segments' local reference systems (LRS) axes X – Y – Z corresponding to mediolateral – anteroposterior – longitudinal directions, respectively. The Z – X – Z Euler sequence of rotation was used allowing the analysis of the upper arm – to – thorax posture adopted by subjects in terms of clinically interpreted position and orientation. Thus, the posture of the upper arms was defined with respect to the trunk, considering posture as the position and orientation of body segments. For every segment of the mechanical model defined, where LRS are fixed, the well-known Euler's sequence of rotation is used to obtain the posture of the upper arm with respect to the trunk:

- 1st rotation with respect to Z axis, where upper-arm rotation takes place (azimuth angle). The 'azimuth angle' defines the plane of elevation.
- 2nd rotation with respect to X axis, where upper-arm elevation takes place (elevation angle).
- 3rd rotation with respect to Z axis, where upper-arm external/internal rotation.

"Data smoothing" was carried out by generalised cross-validation using quintic splines. The R statistical software was utilized to obtain descriptive statistics and to compare the upper arm posture between the conventional axial-handled laparoscopic needle holder (Group L) (Karl Storz) and a robotic handheld laparoscopic needle holder (Group R) with ergonomic handle (DEXTM, Dextérité Surgical).

3. Results

The pair movement of the surgeons' upper arm with respect to the trunk during the laparoscopic operation was analysed and the differences between the two operation tasks were compared. Results revealed that surgeon's upper-arm posture is different between the two tasks.

Figure 1: Experimental set up showing a subject at the operation theater.

4. Discussion & Conclusion

In real operation conditions the use of reflective markers is not an option. IMUs can be an alternative option.

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Ergonomics posture analysis of the surgeons during a total hip replacement surgery: A preliminary study

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1. Introduction

The orthopaedic surgery requires a high physical demand for surgeons. Static positions for long periods of time, repetitive movements, handling heavy instruments and high vibration, high forces for placement of patients, it all contributes to increased loads on the muscles and bones. Back, neck and upper limb injuries are the most common work-related musculoskeletal disorders that suffer these surgeons [1]. 44-66.7% of orthopaedic surgeons reported a work-related musculoskeletal disorder [1,2]. While in other surgical disciplines such as laparoscopy, the posture analysis of surgeons and the causes of the ergonomics problems have been described in many studies, in orthopaedic discipline they are very limited. In particular, the analysis of the posture during total hip replacement surgery has not been described. Therefore, the aim of this work is to perform a preliminary analysis of the positions taken by the surgeon during the intervention for total hip replacement, through the use of objective assessment methods.

2. Methods

This study was conducted at the iQtra Medicina Avanzada (Madrid, Spain). The posture of the surgeon (with more than 12 year of experience) was analysed during the total hip replacement surgery. The ergonomic position and musculoskeletal discomfort during the surgery were also measured. The position of the arm, neck and trunk were scored using the rapid upper-limb assessment (RULA) at various points throughout the surgery. Two video recordings of the surgery were carried out within ergonomic analyses (Figure1). The first camera was placed on a stand, and the second camera was led in hand by an operator which filmed the manual activity of surgeons to avoid occlusions. For registering the musculoskeletal discomfort, a questionnaire was completed by the surgeon. A 5-point Likert scale was used in the questionnaire (discomfort from 1-minimum to 5-maximum).

3. Results

The surgeon experimented musculoskeletal discomfort during the intervention. RULA method showed low scores in the postures of the neck, back and upper limb during the total hip replacement.

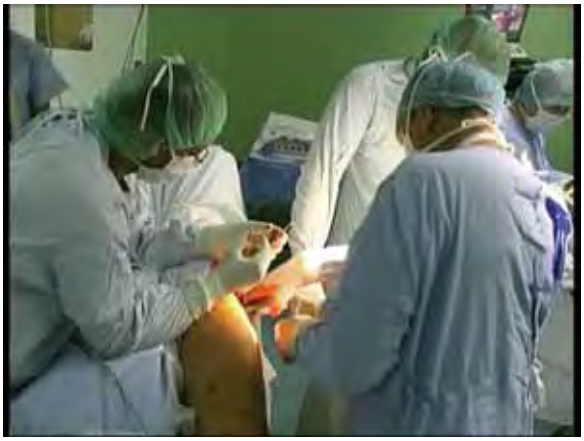

Figure 1: Image recording of the surgeon during the total hip replacement intervention

4. Discussion & Conclusion

The total hip replacement causes discomfort in the orthopaedic surgeons. Besides and in the light of the results obtained by the RULA method, the posture is not ergonomic during the intervention, which could cause musculoskeletal problems in the surgeons. However, this work reports a series of pilot observations only on one subject and therefore, further studies in with larger sample size is needed to validate the conclusions.

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Ergonomics in the Operating Room

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1. Introduction

Since the introduction of minimal invasive surgery, surgeons appear to be experiencing more occupational musculoskeletal injuries [1-4]. The aim of this study is to investigate the current frequency and effects of occupational musculoskeletal injuries on work absence.

2. Methods

An online questionnaire was conducted among all surgeons affiliated to the Dutch Society for Endoscopic Surgery (NVEC) [5], Gastrointestinal Surgery (NVGIC) [6], and Surgical Oncology (NVCO) [7]. In addition, this survey was conducted among surgeons, gynaecologists, and urologists of one cluster of training hospitals in the Netherlands.

3. Results

There were 127 respondents. Fifty-six surgeons currently suffer from musculoskeletal complaints and 30 have previously suffered from musculoskeletal complaints with no current complaints. Frequently reported localizations were the neck (39.5%), the erector spinae muscle (34.9%), and the right deltoid muscle (18.6%). Most of the musculoskeletal complaints were present while operating (41.8%). Currently, 37.5% uses medication and/or therapy to reduce complaints. Of surgeons with past complaints, 26.7% required work leave, and 40.0% made intraoperative adjustments. More surgeons with a medical history of musculoskeletal complaints have current complaints (OR 6.1, 95% CI 1.9-19.6). There were no significant differences between surgeons of different operating techniques in localizations and frequency of complaints, or work leave.

4. Discussion & Conclusion

Despite previous various ergonomic recommendations in the operating room, the current study demonstrated that musculoskeletal complaints and subsequent work absence are still present among surgeons. Especially among surgeons with a positive medical history for musculoskeletal complaints. Even sick leave was necessary to fully recover. There were no significant differences in reported complaints between surgeons of different operating techniques. Almost half of the respondents with complaints made intraoperative ergonomic adjustments to prevent future complaints. The latter would be interesting for future research.

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Surgical performance and ergonomics of the surgeon's hand using a robotic handheld needle holder

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1. Introduction

Laparoscopic surgery offers numerous benefits for the patients. However, this surgical technique entails some technical limitations for surgeons namely two-dimensional visualization, loss of tactile feedback and limited range of movements. This loss of freedom during the surgical maneuvers leads to an increased incidence of adoption and maintenance of forced and static postures for long periods of time. The combination of these factors with inadequate ergonomic design of surgical instruments may result in decreasing the surgeons' performance and accuracy, as well as the incidence of musculoskeletal disorders [1]. In order to address these technical and ergonomics difficulties in laparoscopy, new surgical instruments are currently being developed [2]. The main objective of this study was to analyze the surgical performance and ergonomics of the surgeon's hand during the use of a robotic needle holder in laparoscopic practice.

2. Methods

Five experienced surgeons in laparoscopic surgery performed an urethrovesical anastomosis on an experimental porcine model. They used both a conventional axial-handled laparoscopic needle holder (Group L) (Karl Storz) and a robotic handheld laparoscopic needle holder (Group R) with ergonomic handle (DEX™, Dextérité Surgical). Three of the surgeons had previous experience with the robotic instrument. The robotic instrument is a motor-driven device that provides a flexible tip and unlimited rotation with seven degrees of freedom, and ergonomic handle. During each task, the pressure exerted on the instrument's handle by the surgeon's fingers (thumb, index and middle) and palm of the hand was measured by the Finger Tactile Pressure Sensing System (FingerTPS; Pressure Profile Systems). The FingerTPS system comprises of a series of sensors connected by Bluetooth to the computer where the capture and analysis software is running. Records were taken every 5 minutes. The execution time was recorded and the patency of the anastomosis was tested by a leakage test.

3. Results

The execution time was significantly lower using the conventional needle holder (L: 34.19±3.24 min; R: 57.53±9.29 min). Surgeons exerted higher pressure on the conventional laparoscopic axial handle. The force exerted by the distal phalange of the index finger was significantly higher on the conventional handle than on the robotic instrument's handle. The palm of the hand was the area that received the highest pressure in both instruments, but for longer periods of time using the robotic instrument (Figure 1). Experienced surgeons with the robotic instrument exerted more pressure with the palm of the hand. All anastomoses passed the leakage tests, except one performed using the robotic instrument.

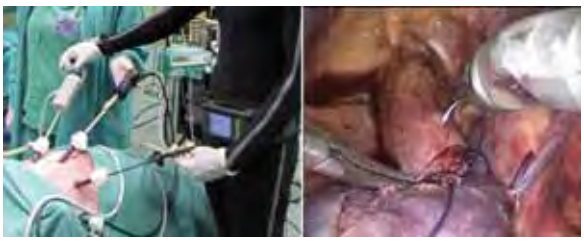

Figure 1: Use of the robotic handled needle holder during the urethrovesical anastomosis: (left) Instrument handling and (right) intracorporeal view during the suture maneuver.

4. Discussion & Conclusion

The distribution of the pressure exerted on the instrument's handle is affected by the design of the handle and the surgical experience. The robotic needle holder requires applying less pressure on the handle than the conventional laparoscopic instrument. A training period is needed to improve the performance and ergonomic use of the robotic instrument.

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Preliminary usability validation of an e-learning laparoscopic course for nursing with an eye tracking device

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1. Introduction

Eye tracking is an emerging technology to perform validation of websites to know how users interact with them and to detect usability problems. However, nowadays there are few studies conducted on the use of eye trackers for usability assessment of health technologies [1]. This study is aimed to objectively validate an e-learning laparoscopic training course for nurses using eye tracking technology.

2. Methods

To perform the validation test, SMI eye tracking glasses 2w and its SMI BeGaze™ analysis software were used. According to previous studies [2], five nurses were recruited to perform the following tasks with a limited time available, using single-blind method and without external support:

1. Visualize lessons (T_{max} = 3')
2. Answer an assessment test (T_{max} = 2' 30")
3. Looking for complementary resources, 3D pdf file (T_{max} = 2' 40")
4. Use the forum, add comments in a discussion (T_{max} = 1' 20")
5. Ask for technical support, send a message to the webmaster (T_{max} = 1' 20")

To analyse results, some Areas of Interest (AOI) where participants are expected to put their attention were defined. Some metrics were selected to analyse the participants' behaviour: 1) AOI *fixations' number*; 2) AOI *gaze duration*; 3) *Spatial density* of fixations; 4) *Elapsed time to first AOI fixation*. In addition, patterns of visual exploration of participants were recorded using the heat maps and scan path tools.

3. Results

Metrics and visual patterns of participants show that the left menu has both the highest *number* and *spatial density* of *fixations*. *Elapsed time to first AOI fixation* on the complementary resources is lower than expected, and on the forum (Figure 1) and the technical support is higher. Participants rapidly access to lessons and assessment tests of sections, however they hardly have *fixations* on buttons to navigate between lessons. Hence, they have difficulty to navigate sequentially in sections. Assessment test has the highest *gaze duration*.

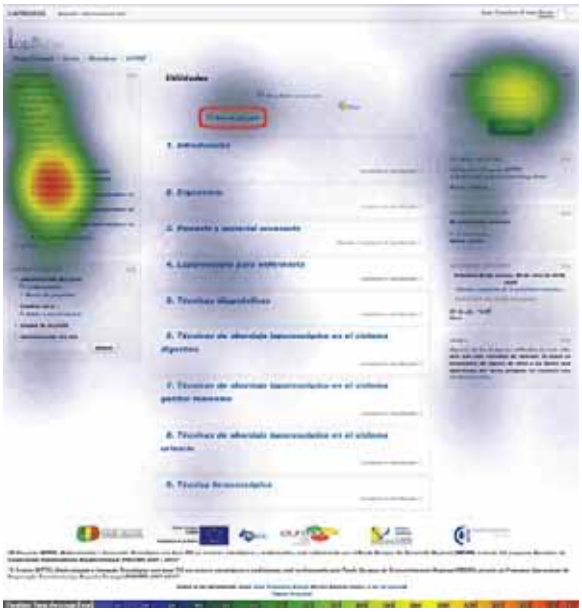

Figure 1: Heat map of participants searching the forum (red box), with highest values on left menu.

4. Discussion & Conclusion

Eye tracking technology is a useful tool to detect strengths and weaknesses of the e-learning environment design and its usability. Left menu is the most important for participants, so all relevant sections must be included on such menu. Buttons apparently more visible and easy to reach (forum, technical support) present more difficulties than buttons more hidden (complementary resources). Improve the visibility of these options, as well as the means for the navigation between lessons, is a priority. Assessment tests present more difficulty to interpret their content for participants, so they must be readapted.

As future works, same nurses will perform additional tests to improve the validation, such as "retrospective think aloud" method, and tasks with the same difficulty to evaluate their progression in learning the use of the platform.

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A light-dependent training tool for flexible cystoscopy

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1. Introduction

Flexible cystoscopy is a non-invasive procedure that examines the bladder and lower urinary system for abnormalities. To supplement cystoscopy training on live patients, many hospitals use different simulation tools. Virtual reality models are useful for repetitive training and can include feedback systems that remove the need for a supervising clinician, but they often lack haptic feedback, are not easily transported, and can be prohibitively expensive, especially for smaller training hospitals [1]. The goal of this work was to design and construct a simple, portable and low-cost cystoscopy training platform for training non-expert clinicians and nurse specialists in bladder endoscopy.

2. Methods

In order to minimise costs, a 3D-printed ABS mechanical prototype was assembled with reverse-mould silicone insert to replicate the urethral passage. Male and female bladders differ slightly in shape and size [1], but both can be approximated as a sphere, 10cm in diameter, as implemented in the dome design of the device (Figure 1a). The silicone insert was designed for ease of assembly of the device. It was created in two halves using a 3D printed ABS mould. The entire device is encased in clear polycarbonate casing and mounted on a metal baseplate (Figure 1b).

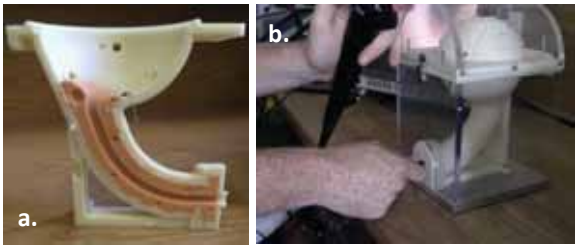

Figure 1: a. Cross-section of training device, showing the lower right half of 3D printed ABS part prior to electronics insertion, as well as the silicone insert. **b.** The trainee inserting the flexible cystoscope into the finished demonstration prototype.

In order to measure competence of the trainee, the interior dome of the bladder was fitted with 14 light-emitting diodes (LEDs) and 14 light-dependent resistors. A simple potential divider design allowed for light thresholding-based detection of the cystoscope's light source when it came into proximity of a light-dependent resistor. The LEDs were included for land-marking and trajectory response timing. The tuneable threshold was controlled by a microcontroller (Arduino Microcontroller Mega 2560) to facilitate calibration to the light source intensity.

3. Results

The final prototype size has a base of 16cm^2 and the height is 25cm, making it very portable. Three investigation modes were implemented; training (to facilitate user comfort with the system), full inspection (to test time and trajectory response for full bladder investigation) and J-manoeuvre (to test circumflexion of the cystoscope upon entry to the simulated bladder dome. A basic user-interface has been created using Matlab which captures user performance metrics including time and trajectory pathway. The device has been tested by for usability and suggested changes in performance metrics and user interface is currently underway.

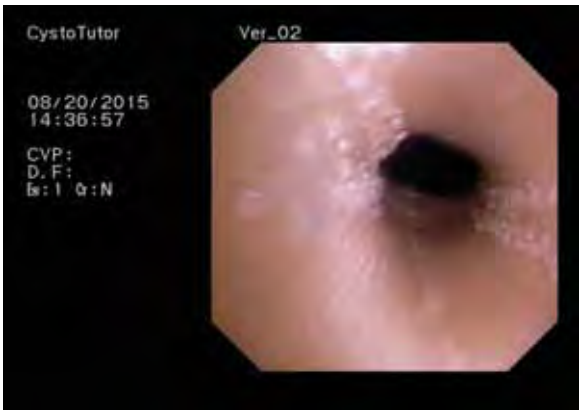

Figure 2: Endoscopic view from the cystoscope during insertion through the silicone urethral model.

4. Discussion & Conclusion

The work presented here represents a low-cost, potrable alternative to available urology trainers such as the Simbionix URO mentor. Further development will seek to improve usability and user performance capture.

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Preliminary validation of a serious game for psychomotor skills training in minimally invasive surgery: Kheiron Training System

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1. Introduction

The Kheiron Training System (KTS) is a serious game for psychomotor skills training in minimally invasive surgery (MIS) [1]. It has been developed to provide medical students and surgical residents with a new approach for the acquisition of the specific skills required in MIS, such as hand-eye coordination or deph perception.

The objetive of this work is to prelimiary validate the KTS serios game with pedagogical experts and end users.

2. Methods

Validation was divided into two approaches. On one side, the possibility of achieving the defined learning objectives for each task included in the KTS serious game was rated in a 5-point Likert scale by pedagogical experts. On the other hand, expert surgeons and medical students and residents tested the serious game and afterwards completed a questionnaire.

Tests were conducted in Spain, Germany, Hungary and Romania. The set-up for playing the KTS serious game allows for different configuration, requesting a PC and monitor (or laptop), a physical box-trainer and two regular, non-modified surgical tools (Figure 1).

Figure 1: Set-up for the KTS serious game validation. It only requires a laptop (left) although it can also be connected to a laparoscopic tower (right).

3. Results

Within the pedagogical validation, experts assessed with 3.44±0.50 out of 5 points the possibility of achievement of the learning objectives with the tested version of the KTS serious game.

10 experts participated in the first stage of the validation process. 7 experts though that the game can increase the performance of medical students and residents and 6 agreed that it could be included in the surgical curriculum but not as a mandatory part.

142 end users tested the serious game. 94.96% (132) users thought that the serious game can potentially train their performance in MIS.

4. Discussion & Conclusion

The KTS serious game is accepted by end users to be a training tool for the acquisition of psychomotor skills in MIS. As opposed to other initiatives [2], the KTS systems is based on a traditional physical box-trainer and regular laparoscopic tools and does not require the additional use of commercial controllers.

Further works are necessary to improve overall technical performance of the KTS serious game, weakest point of the tested prototype. Similarly, further validation trials are requested to determine its effectiveness as training tool and achievement of the learning objectives.

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The need for multi-infusion training

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1. Introduction

One of the highest technology associated risks in critical care is infusion technology [1]. There are many reasons why infusion therapy is challenging. For example, limited vascular access and a high risk of systemic infections typically requires clinicians to connect multiple infusion pumps to one infusion set and catheter. This technique is called multi-infusion. However, in the past years, ample evidence has been gathered that multi-infusion is associated with dosing errors due to ambiguous physical effects, caused by the complex nature of multi-infusion systems [2], [3]. Despite the fact that many of these dosing errors are due to physical effects they can be mitigated or even prevented if multi-infusion users, i.e. physicians and nurses, are given the proper training. Our objective is therefore to investigate the need for specific multi-infusion training.

2. Methods

Within the Metrology for Drug Delivery (MeDD) project [4], we have conducted both quantitative/technical and qualitative research in order to establish the causes of dosing errors in multi-infusion. A "survey of best practices", in which healthcare professionals were surveyed, was used to list the current practices in multi-infusion therapy and identify the potential niche where education is required. Next, we conducted a systematic literature review, aimed to identify the most common physical causes of dosing errors [3]. In addition, experiments were performed to further investigate these dosing errors [2]. Subsequently, we developed a simulation model which is able to provide insights in numerous hypothetical situations. Input parameters consisted of the infusion hardware used in clinical practice, which were analysed as well [5].

3. Results

It was found that despite the fact that syringe pumps are accurate [5], the mechanical properties of infusion hardware combined with flow dynamics may cause dosing errors in many clinical situations [2]. This is especially the case with critical fast-acting medication, often used in critical care. In the "survey of best practices" on the use of infusion, more than 80% of those who answered held that the drug delivery in multi-infusion therapy was more prone to errors, however, the nature of these errors remained elusive to them. Moreover, many answered that extra education and training was desirable. It was therefore decided to start a successor of the MeDD-project. The goal of this new project is to develop a training program for clinical users of infusion technology. The training program will include graphical representations and on site lectures in order to provide an intuitive understanding of the physical effects that complicate drug delivery in multi-infusion systems.

4. Discussion & Conclusion

Although there has been an increase in evidence-based studies investigating the clinical relevance of multi-infusion errors, these studies remain scarce. However, expert opinion holds that a sizeable amount of adverse events are due these errors. Moreover, we have substantiated these claims by investigating a case of a serious norepinephrine overdose in our own hospital. In this case, insights in the physical effects involved, might have mitigated the outcome. The results underline the importance of providing clinicians with additional training in multi-infusion.

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Mobile Health in Surgical Training

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1. Introduction

The priority aim of SurgTTT project is to improve the specialty training in surgical specialties and to ameliorate lacking standardization on the pan-European level. Thus, the main objective of the project is to define the professional profile of surgical trainers by designing and testing the most suitable curricula. Another objective is broadening the scope of application of this professional profile to a European level through the development of an open multilingual online learning platform for consultants.

2. Methods

The project started with a transnational survey of the national frameworks for specialty training and a needs assessment for designing a TTT program. On this basis the professional profile for a surgical trainer will be designed in order to afterwards develop a curriculum and teaching materials. The next step is the testing and validation of the curriculum in TTT courses with our target group. The revision of the program will close this process.

3. Results

The professional profile of surgical trainer was elaborated in concordance with the roles of Teacher defined By Scottish Doctors. The Resource Developer Role has to face the fast development of technics and technologies. In this regard, trainers have to be qualified in new domains like Simulation, Distance Learning or Mobile Health

4. Discussion & Conclusion

The huge potential of surgical applications for iPhones has to be well understood by trainers. They have to influence the behavior of students in this field of learning and to be flexible in adoption of incoming applications in their daily practice

Endoscopic Painting

13.01 **The Fun, Innovative, Nice and Enthusiastic (FINE) way of learning laparoscopic skills through endoscopic painting as laparoscopic box training exercise.** *M.D.I. dela Paz, M.C. Mendoza.*

"The Fun, Innovative, Nice and Enthusiastic (FINE) Way of Learning Laparoscopic Skills through Endoscopic Painting as Laparoscopic Box Training Exercise"

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1. Introduction

It is proven that the use of simulators in laparoscopy such as that of laparoscopic trainer box exercise have significant advantage to skills development as supplement to the standard laparoscopic preceptorship program.[1] Various tasks such as bead transfer, grape peeling, shape cutting and rope running develops hand eye coordination, depth perception, spatial coordination instrumental tactile feedback, tissue handling skills and improvement of skills of non-dominant hand. The strength of these exercises is that it lessen the steep learning curve in laparoscopic surgery. The weakness of these exercises is that the sequence of being repetitive and the absences of aim of achievement makes it boring that most of the trainee surgeon in a basic surgical workshop would just spend just few minutes to the exercise.[2] Hence, creative modification was done by the innovator to introduce a fun, innovative, nice and enthusiastic way of skill exercise in laparoscopic box trainer through endoscopic painting.

2. Methods

The innovator supplements his training in laparoscopy by combining the art of painting and the science of laparoscopy. Endoscopic painting is the practice of applying medium of color or pigment to a miniature canvas. It is an art that unleased unlimited creative forms and expressions to the trainee making the skill exercise fun, relaxing and enthusiastic.[3] It requires a modified laparoscopic box trainer equipped with a rotating circular pallete used as a container for the color paint medium and diluting solution, and an upper horizontal bar used for the application of miniature canvas. It uses a modified laparoscopic brush for the dominant hand of the trainee to apply the color and a laparoscopic grasper for the non-dominant hand to control and manipulate the canvas and the rotating circular palette (Figure 1).

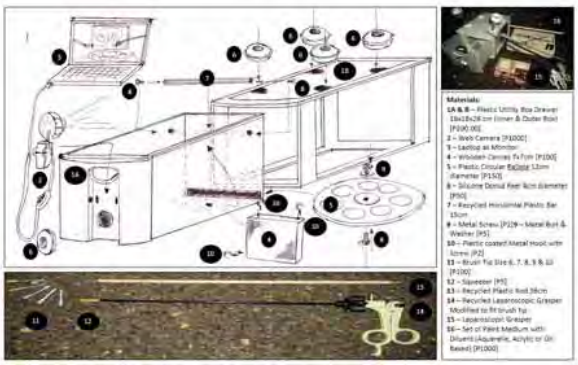

Figure 1: Laparoscopic Painting Box Trainer, Peripherals and Materials Set-up

Any perspective or form of art were done. Choice of color medium in small appropriate amount were placed on each cup of the rotating circular pallete. Miniature canvas was placed inside the box hanging at the center of the horizontal bar. A laparoscopic grasper held by the left non-dominant hand was usedon the left trocar to grasp the left side hook of the canvas to control and stabilize the canvas as if the trainee is exercising the skill of the non-dominant hand of retracting the hartmann's pouch of the gallbladder generously. The laparoscopic brush was held by the right dominant hand on the right trocar. It is used to apply the medium of color paint on the canvas in numerous style like fine sketching, broad circular painting or freestyle as if the trainee is exercising sketching the line of dissection in the peritoneum lining of the gallbladder, gentle dissection of the gallbladder from the cystic plate and controlled cauterization of bleeders in the hepatic bed using maryland dissector or hook dissector.

Figure 2: Endoscopic Painting Exercise

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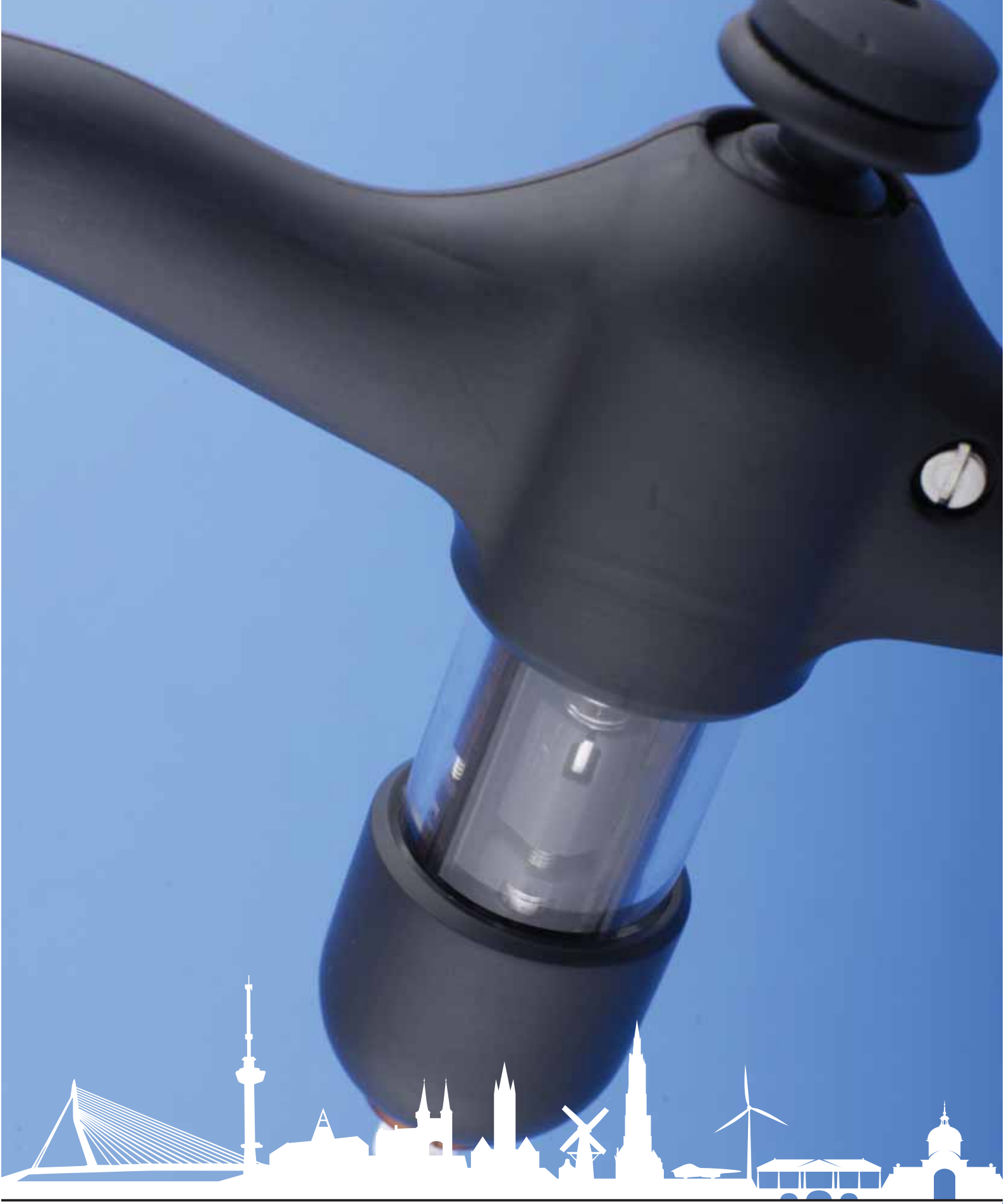

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