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Abstracts appear in alphabetical order according to the last name of first author.

Non-invasive CyberKnife Ablation

John Adler, Stanford University, CA, USA

Background

Although radiosurgery has revolutionized treatment of brain tumours, frame-based targeting is impractical for fractionating brain treatments or treating extracranial lesions. The CyberKnife, was developed in response to these limitations

Material & Methods

The CyberKnife is the first radiosurgical device to incorporate real-time image-guidance, which is based on a concept termed x-ray image-to-image correlation & is accurate to within 1mm. Since 1994 the Stanford CyberKnife has treated more than 2200 patients with a spectrum of conditions involving the brain, spine, chest and abdomen.

Results

Studies show that CK radiosurgery provides better outcomes in acoustic neuroma patients with useful hearing & a range of tumors that are immediately adjacent to the optic nerves and chiasm, and in more than 200 cases, it proved an effective substitute for standard open surgical resection. In addition to neurosurgical disorders, Cyberkife radiosurgical ablation can and is being applied to lesions within the incorporating sensors of chest wall excursion, the CyberKnife system precisely and automatically directs the robot to retarget the radiation beam on lesions affected by diaphragmatic movement such as tumors of the lung, liver and pancreas.

Conclusion

The spatial fidelity afforded by image-guided guided radiosurgery is redefining the clinical management of many benign and malignant lesions & is likely to replace many common cancer and other operations in the future.

Keywords

Radiosurgery, CyberKnife

Endoluminal Fundoplicatio for GERD Past, Present and Future

Alberto Arezzo, Ospedale Evangelico Internazionale, Italy

Background

In recent years first attempts to realize an endoluminal device for GERD treatment were done. Different techniques have been tried including suturing devices, injecting materials, radiofrequency, all with disappointing results

Material & Methods

A novel procedure has been conceived that recreates the anti-reflux barrier by forming a one-way gastroesophageal valve. The EsophyX device rides over a standard endoscope and is inserted through the throat to access the stomach. Through a clear window in the shaft of the device, the z-line is visualized. A suction technique is engaged that allows advancing the z-line to the level of the diaphragm to reduce hiatal hernia. A helical retractor is used to catch the esophago gastric junction, and pull a 3 cm long flap, then held in place with polypropylene fastners on a 240-270° circumference. All is performed under endoscopic vision

Results

The endoluminal fundoplication has been evaluated in a Phase 1 feasibility study and additional studies are ongoing

Conclusion

This new endoluminal fundoplication technique offers significant potential to reduce hiatal hernia, restore the angle of His, create a GE valve and possibly be a non-invasive method for long-term treatment of GERD. Although additional studies and long-term follow-up are needed to demonstrate the long-term safety and efficacy, this technique is an interesting and potentially promising approach to avoid long term PPI therapy

Keywords

Endoluminal GERD Fundoplication

New tools for Endoluminal Resection of Flat GI Lesions

Alberto Arezzo, Ospedale Evangelico Internazionale, Italy

Background

Since the beginning of operative flexible endoscopy the treatment of large flat polyps of the digestive tract, defined as a flat lesion >3 cm in diameter has been controversial.

Material & Methods

In 2001 a new EMR technique was described using an IT knife from Olympus, which should allow a better handling of the lesion to resect. This technique is today widely used in Japan to treat large flat lesions of the upper GI tract. In Western countries we experience more often the finding of large colonic lesions and therefore the new tool is currently tested on the removal of lower GI tract lesions.

Results

In a non randomized trial we have matched 24 patients treated by conventional EMR by lift and cut technique (group A) and 24 patients treated with the aid of the IT knife (group B). In both cases flat lesions were larger than 3 cm in diameter, with an average of 4.5 cm. In group A we collected an average of 4.2 - 1.1 specimens while in group B 4.1 - 1.1 with 10/24 (41%) specimens collected in a single stage. A single case of perforation treated by clip application has been reported in both groups. Two patients in group B were indicated for surgery after endoscopic removal attempt, failed for difficult positioning.

Conclusion

EMR with IT knife is an interesting new chance for flexible Endoscopy. Its employment anyway is skill demanding, operator dependent, difficult to reproduce.

Keywords

Large colonic lesion flexible endoscopy

Measuring RF Heating of Implants

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Background

A metallic implant in the body may cause excessive heating if they are exposed to a electromagnetic field. Because of this reason, patients with implant are not allowed in an MRI scanner. Knowing the exact amount of heating is critical in determining the risks associated. Unfortunately, the heating values reported in the literature uses conflicting methods and therefore producing unreliable results. In this presentation, heating measurement methods will be discussed.

Material & Methods

In the proposed method, a gel phantom is prepared with thermal and electrical properties that are similar to human tissue properties. The implant was embedded into this gel. The RF power is applied for a duration equal to the average perfusion time constant of the body. The peak temperature obtained from the phantom is measured and normalized with respect to the SAR value measured from the a remote location on the same phantom. Normalized temperature is reported for the safety index.

Results

Predicted was compared with measured temperature increase on three rabbits at various tissue types. Results will be discussed in the presentation.

Conclusion

We propose a method to predict in vivo temperature rise when RF heating is applied. This method was used on animal to test the accuracy of prediction technique. We believe that a measurement technique similar to proposed in this presentation needs to be developed as the standard RF safety measurement technique.

Keywords: MRI Safety, Implants, Implant Compatibility

Potential of Sensor Data Processing in the Wireless Biomedical Sensor Nodes

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Complex clinical diagnostics and treatments require use of different biomedical sensors. The sensors are typically used for monitoring a number of parameters such as blood gas, invasive blood pressures, pulse rate, temperature, electrocardiogram, etc. Another example of using biomedical sensors is for the detection of ischemia. However, with a few exceptions, the biomedical sensors are a single device with a single output. This means there will be an array of biomedical sensors needed for measuring multiple physiological parameters to facilitate effective treatment. The individual sensors are often connected to the monitoring devices with wires. This may become a huge problem; the wires can tend to cause adverse events and can restrict the mobility of the patient in the recovery period. Wireless connections produce digital data, which along with other digital data may enable novel clinical as well as logistics applications.

Advanced biomedical sensor network may consist of several sensor nodes connected to each other in a complex manner. It is therefore desired to have some kind of intelligent signal processing of the sensor data locally before transmitting them to a gateway. A gateway in a patient near communication scenario can be a mobile phone. The local processing of data can be seen as data reduction, facilitating reduced number of samples to be sent to a gateway using a wireless communication protocol. This means that the life time of the batteries can be extended significantly as approximately 50% of the power from the batteries is used for data transmission. In an experimental setup we have used wireless sensor nodes from Crossbow Inc, San Jose, CA. Each sensor node contains a few sensors, connectors from external sensors, microcontroller, random access memory, and ZigBee wireless radio unit. We installed the Tiny OS, a custom made operating system for sensor nodes, by the University of California at Berkeley in the microcontroller. The Tiny OS enables easy high level programming interface on microcontroller. A simple experiment was conducted using three sensor nodes in a network. One sensor node contains Electrocardiogram (ECG) data, whereas the second contains invasive Arterial Blood Pressure (ABP). The third sensor node functions as a master node synchronizing and receiving data from ECG and ABT sensor nodes. A fourth node is used as a gateway node, which is connected to a laptop. The data is transferred via the gateway node to the laptop. We use a visualization software by Crossbow Inc to render data from ECG and ABT sensor nodes on the laptop. Measures are taken to reduce the number of bits sent from the wireless sensor node. Signal forms such as ECG and ABT are highly correlated and redundant. This property enables compression in the form of a predictive coding scheme. We also want to monitor changes in a patient's condition. If there are no changes, a minimal amount of data to keep the connection alive would suffice. The signal processing done between sensor sampling and transmission has two goals. Detect changes in the sensed data and vary the data rates based on the significance of the sampled information. The results will be presented at the conference.

MRI Induced Heating of Selected Thin Wire Metallic Implants Laboratory and Computational Studies Findings and New Questions Raised

Howard Bassen, Wolfgang Kainz, Gonzalo Mendoza, U.S. Food and Drug Administration

Background

We performed experiments and computer modelling of the RF heating of a stent and a straight, thin wire at 64 MHz. We explored heating versus many variables.

Material & Methods

We used fibre optic thermometers in a rectangular, saline-gel filled phantom per ASTM F2182-02a for a coiled, double stent (11 cm long) and straight 24.1 cm wire (both had insulation and bare ends). We used a full-size RF body coil at 64 MHz. Computations used FDTD software with a thermodynamics solver. We developed improved computational sources (optimized RF coils and quasi-MRI fields).

Results

The measured temperature rise normalized to 4 W/kg whole body average was 8.6 deg C (local SAR = 5680 W/kg) for the wire and 0.5 deg C (local SAR = 320 W/kg) for the stent. Heating was within 1 mm of the ends and positioning of the temperature probe was critical. The computed plane wave local SAR was 200 W/kg at the ends of a bare stent model with 0.05 deg C at the tips.

Conclusion

Local (point) SAR (initial linear temperature rise) is the most reliable indicator of the heating of an implant and depends greatly on implant length, insulation, shape, location and orientation in the MRI coil. Accurate heating must be determined with millimetre resolution (not available with many temperature probes or software)

Keywords

MRI Implant Heating SAR Computational

Innovative use of Nitinol in Laparoscopic Surgery

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Nitinol having the unique property of returning to a preformed shape once a deformation has been released, or the deformation can be controlled by changing the temperature of the metal. These properties are used to great effect in laparoscopy where access to the peritoneal cavity is limited by narrow straight rigid port placed across the abdominal wall. As result, Nitinol becomes an appealing technology that has a significant future in minimal access surgery. Her are a few examples of how it is being used.

The current retrieval bags used for removing specimens from the abdominal cavity have Nitinol in the necks of the bags to open them once deployed into the peritoneal cavity. This happens automatically and permits the easy placement of specimens into the bags. Nitinol has been used in retractors which are introduced straight and once in the peritoneal cavity form a curve that is them used to retract intra-abdominal organs. Most instruments are straight but Nitinol is used in graspers and dissectors to deflect them once into the peritoneal cavity. They are held straight by a sheath which when pulled back causes the tip to bend. The deflection and therefore the angle and positioning of the tips of the instrument can be controlled by the degree to which the rigid sheath of the instrument is pulled back.

A new and very important use of Nitinol is effect a bowel anastomosis. This can be performed as an end to end or side to side manner using a Nitinol compression ring. Cooling the Nitinol ring opens it so that it can be placed across two ends of tissue. As the ring is warmed up to body temperature it closes compressing the bowel together, holding it together so that it can heal. The bowel that is compressed by the ring becomes necrotic, thus freeing the ring to that it can fall free into the lumen of the bowel to be passed with the feces. When performing a laparoscopic hernia it is often difficult to unroll the mesh that is being placed for the repair. Nitinol has been placed in the edge of the mesh so that as it is unfolded it automatically opens up.

There are many other potential in the practice of minimal access surgery that the unique properties of Nitinol can be used to improve instrumentation.

Poster

Process and Application of Specialized Training Phantoms for MRT / CT / US / Endoscopy on interventional and Laparo-Endoscopic techniques for engineers

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Background

The Department of Physical Engineering at University of Applied Science Gelsenkirchen educates Health Technology to students in an interdisciplinary way.

Material & Methods

For simulating laparoendoscopic surgery we offer training courses for the students using custom-made and modified phantoms for the use of freshly excised porcine organs from the slaughter house. The material of the phantom boxes is synthetic material with a surface of flexible material for simulating abdominal wall non magnetic and radiation transparent for use under CT and MRI. During procedure the animal organs are placed in different levels and are fixed with the gelatine or agar for optimal echo and MR signal behaviour. Another training phantom is a vessel phantom, which was modified to the different demands. The human vasculature is simulated by reproduced glass tubes with several connections.

Results

We have developed a method for conservation of tissue, which allows a longer utilization of the organs. Thus the implementation of the organs in our phantom and the connection with the glass tubes simulating the perfusion is possible.

Conclusion

The different applications of the phantoms during our training courses offer an excellent platform for testing new methods, materials and instruments for development and research.

Keywords

Phantom- MRT / CT / US / Endoscopy on interventional

Interdisciplinary Training Courses in Applied Biomedical Engineering: Endoscopic Surgical and Interventional Techniques for Engineers: 8 years Experience

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Background

The University of Applied Sciences Gelsenkirchen was founded in 1994 and established a speciality study course Health Technology

Material & Methods

The main part of the training is based on anatomical physiological and pathology lectures seminars and hands on training including animal organ preparation in the second year guided by a surgeon and a radiologist. In the last year, students learn in an interdisciplinary way, how to handle the variety of equipments and specific systems of orthopaedic, interventional, Endoscopic and laparoscopic techniques for laparoscopic surgery.

Conclusion

The applied medical technology courses at FH Gelsenkirchen have proven that it is possible to bridge the gap between technology specialists and the physician. Based on this experience, we offer a new certified postgraduate course in close cooperation with the German association of electrical Engineering VDE.

Keywords

Interdisciplinary Training, Biomedical Engineering, Endoscopic surgery, Interventional Techniques

Oral Poster

Membrane Disruption by Optically Controlled Microbubble Cavitation

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Background

Ultrasound mediated approaches to therapy are attractive as they may eventually circumvent the need for invasive surgical interventions. A focal area for current research activity involves ultrasound exposure (insonation) in the presence of contrast agent microbubbles, which is known to lead to enhanced membrane permeability and molecular uptake from the locale. Under strong conditions, this process (sonoporation) can elicit a number of clinically relevant bio effects such as direct lysis and induction of programmed cell death (apoptosis). Under milder conditions, the approach also facilitates introduction of genetic molecules into cells enabling downstream transfection. Sonoporation thus offers significant therapeutic potential. However, the fundamental mechanism responsible for membrane permeabilisation has remained elusive. Here we present direct observational evidence illustrating that energetic micrometer scale interactions between individual cells and cavitating microbubbles can occur. We suggest that less intrusive interactions involving cell compression introduce areal strains that are sufficient to rupture the membrane temporarily and might lead to molecular uptake. We also demonstrate that a more penetrative event can occur involving microjets and that these introduce a more persistent membrane disruption that can lead to cell lysis.

Keywords

sonoporation, cancer, microbubbles, ultrasound

Functional Vascular Imaging

How Medical Imaging Can Play A Role on SFA Stent Design

Christopher P. Cheng, Stanford, Palo Alto & Nitinol Devices and Components, Fremont, CA, USA

Angioplasty and stenting have been increasingly employed to treat superficial femoral artery (SFA) occlusive disease. Recently, there have been many reports of the high incidence of stent fracture in the SFA, hypothesized to be largely due to the harsh biomechanical forces present in the artery. Furthermore, these fractures are correlated with poor clinical outcomes. Medical imaging technologies are helpful for understanding stent fracture mechanisms, elucidating the biomechanical forces to which the stents are being subjected, and defining design criteria for more durable stents. Specifically, Xray and CT can be used to detect the location and nature of stent fractures, as well as image stent deformations *in vivo*. MRI and ultrasound can be used to study the natural deformations of the SFA due to pulsatile and musculoskeletal motion. We have found that SFA stents tend to fracture in preferential locations and that the SFA experiences significant axial, twisting, and buckling deformations.

Oral Poster

IGSTK: An Open Source Toolkit for Image-Guided Surgery Applications

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Background

Open source software has tremendous potential for improving the productivity of research labs and enabling the development of new medical applications. The Image-Guided Surgery Toolkit (IGSTK) is an open source, cross platform, software toolkit. IGSTK integrates the basic components needed in surgical guidance applications and provides a common platform for fast prototyping and development of robust image-guided applications. This presentation will give an overview of the IGSTK framework and current status of development followed by an example needle biopsy application to demonstrate how to develop an image-guided application using this toolkit. This project has been a collaborative effort between Georgetown University, Kitware Inc., Atamai Inc., and Arizona State University. The work is supported by the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health.

Keywords

open source, image-guided surgery, surgical guidance, tracking, state machine, needle biopsy, application prototyping

Oral Poster

Fabrication of Multimodality Vascular Imaging Phantoms with Fiducial Markers and Pathological 3D Geometries obtained in CT-Scan

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Multimodality vascular flow phantoms are ideal tools as they provide a way of testing the geometric accuracy, with easy reproducibility of the experimental conditions, when different imaging methods are considered. They can also be used to compare the blood flow velocity patterns obtained by ultrasound and magnetic resonance imaging. With the recent developments in the manufacturing process of vascular phantoms, stereolithography combined with lost-material techniques, rapidly became the most interesting approach to create the casting of realistic vessels. However, even though the Cerrolow metallic alloy seems the better choice because of its superior strength and its ease of removal, metal residues are frequently left in the lumen after casting, especially in complex irregular lumen geometries. This could cause potentially imaging or flow artefacts, specifically with MR imaging. The objective of this study was to develop a new fabrication process that allows enough flexibility to build realistic vessels, that presents a good geometric accuracy without metal residues, and that could be used with x-ray as well as MR and ultrasound. The geometrical accuracy of the new melting material used is discussed and different realistic geometries mimicking pathological vessels are also presented. In-stent restenosis models can also be considered. In conclusion, this new fabrication process, combined with the technology that we had already developed for multimodality vascular imaging phantoms provides fiducial markers visible in DSA, CTA, MRA and ultrasound, and the fabrication of realistic and accurate replicas of any pathological vessels.

Oral Poster

**NEW METHODS OF IMAGING PROSTATE CANCER BASED ON
ULTRASONIC SPECTRUM ANALYSIS AND NEURAL-NETWORK
CLASSIFICATION**

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No reliable method of imaging prostate cancer currently exists. Our prostate tissue-typing studies aim to develop better methods of imaging cancerous prostate tissue and as a result, to improve the effectiveness of biopsy guidance and treatment monitoring. Success will reduce the false-negative rate of biopsies and treatment side-effects. Ultrasonic (US) radio-frequency (RF) echo-signal data, and clinical variables e.g. prostate-specific antigen (PSA), were acquired during biopsy examinations. Spectral data computed from RF signals using biopsy results as the gold standard were used to train a neural-network classifier. The trained classifier then was used to create a lookup table that returned cancer-likelihood scores from computed spectral parameters and the PSA was used to generate tissue-type images (TTIs). Neural-network-based classifier performance gave an improved ROC-curve area of 0.844 ± 0.018 compared to 0.638 ± 0.031 for B-mode based classification. The sensitivity of neural-network based classification was superior to that of B-mode-guided biopsies. TTIs generated from examinations of patients scheduled for prostatectomies showed tumors entirely unrecognized in conventional US images and undetected during surgery. Our classification methods are being extended to include magnetic-resonance spectral (MRS) techniques that use the choline to citrate ratio to distinguish cancerous from non-cancerous prostate tissue. 3-D renderings of prostatectomy histology, US images, and MR images show encouraging correlations, and combining MRS parameters with US spectral parameters appears to have potential to further improve prostate-cancer imaging. TTIs based on neural-network classification of US and clinical parameters continue to show promise for improving the detection and management of prostate cancer.

This research is supported in part by NIH/NCI grant CA053561.

Virtual Reality and Training Centre: Teaching and Development

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Background

In 2003 it was born the idea about a centre of virtual reality for teaching and learning in Naples. AFIM (Alta Formazione In Medicina- high teaching and learning in medicine) in Città della scienza, centre of research and development in Naples, had the idea for showing the development of human with Virtual Reality.

Material & Methods

The project of AFIM was named CORPOREA. Four applications of this project were the goals. The first is about the co-operation between FAD , national MMG and pharmaceutical industries. In this goal it is really important the observation of the projects and the development of these. The second application is SEL, Simulator Emergency Lab. In this project AFIM wants to teach the principal bases for emergency using human model. The third is the observation of new technologies in surgery and the development of these with projects of research and counselling. The fourth application is a co-operation with other laboratories of Virtual Reality in the world for developing virtual operating room for teaching and learning. For these projects we used to have close co-operation with industry and scientific society.

Results

At the moment the first two projects start and the second two are starting.

Conclusion

We have had the first good results from the land and from the University. This project supplies in the order in special field, where conventional teaching is not so satisfactory.

Keywords

VR, training centre

Dynamic imaging of the spine with an open upright MRI

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Background

Imaging of the spine during axial loading and during kinetic maneuvers is now possible with a top-front open MRI unit. The first imaging studies obtained at the fmri center in Zurich confirms the positive statements made by the pioneers, as published by Jinkins

Material & Methods

Patients with a history of recurrent positional or motion-dependent pain and/or neurological dysfunction of the cervical and lumbar spine were investigated in the upright-seated or standing position, including flexion-extension and/or rotation imaging.

Results

A position-dependent appearance or increase of posterior disc protrusions, a varying degree of central canal and foraminal stenosis, and of mobile spinal instability was demonstrated in cases with preceding less remarkable or even negative recumbent MRI examinations. Illustrative cases include, cervical and lumbar unilateral and bilateral spinal instability, lateral, rotational instability, dynamic spinal cervical and lumbar stenosis and position-dependent disc herniations.

Conclusion

By visualizing position-related alterations in the bony structures and the underlying soft tissues in the upright weight-bearing position, fmri enables the physician to make more accurate decisions regarding treatment options and alternatives, as compared to recumbent MRI. In the near future it could become the imaging modality required before performing complex spinal surgery.

Keywords

MRI, UprightMRI, Instability, FBSS

Oral Poster

MR-Safety: Investigation on a worst case implant heating protocol – a simple solution for radio frequency induced heating sequences

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Background

Body implants are in numerous cases a contraindication in a MRI environment, unless shown to be safe. In this study we compared the resulting temperature rise due to rf power induced heating using different pulses and a set of typical clinical MRI protocols.

Material & Methods

Shaped and rectangular pulses were applied over 5 min. global on- and off resonant, with slice selection gradient in different positions. Additionally a set of clinical relevant protocols with various slice positions was investigated. Flip angle of each sequence and timing of the clinical protocols were adjusted to match equal time averaged power and SAR value. According to system monitor the applied power was 88 W and the displayed SAR value was 2.1 W/kg.

Results

Maximum heating was measured using the global on resonant pulses and with a slice position on the implant. Minimum heating was found for configurations with slice positions outside the phantom. The results for slice positions inside the phantom and most clinical protocols range in between.

Conclusion

The findings suggest that a pulse train of on resonant rectangular shaped pulses leads to maximum heating based on the applied time averaged power and the SAR value. Using a comparable worst case heating sequence is therefore considered a great advantage for multi center MRI safety studies.

Keywords

MR-Safety, RF Heating, Phantom

Platelet-Adhesion on Amorphous Carbon (a-C) Films

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Amorphous carbon (a-C) films have attracted much attention for biomedical and biofunctional applications. For example a-C-coatings on implants are been proposed for blood ambiented medical devices. However, the blood coagulation mechanism on a-C surfaces is not well understood. Platelet activation and adhesion are crucial events within the interactions between blood and the materials as they influence the formation of thrombosis. In this work, the behavior of platelets adhered onto amorphous carbon films (a-C) is investigated. Amorphous carbon films with varied deposition parameters are deposited by magnetron sputtering onto FeCr-stainless steel. The wettability of the films was investigated by contact angle measurement as well as the calculation of surface energy. Experiments on Platelet adhesion were carried out to examine the interaction of blood with the films in vitro and the activation of the adhered platelets.

Keywords

amorphous carbon, biocompatibility, biomaterial, wettability, platelet adhesion

The Development and in Vivo Testing of a Thermally Activated Surgical Clip

Tim Frank, University of Dundee, UK

Background

Superelastic and thermal shape recovery properties of shape memory alloy can be usefully exploited in surgical fixators. This could lead to the partial replacement of some existing tissue closure methods by systems that are both quicker and easier to apply. This study concerns the development of staple-like clips for wound closure, activated by thermal shape recovery.

Material & Methods

The clips are processed to allow deployment across a surgical wound in an open shape. Electric current heating is applied to close the clip, which retains an effective closing force at body temperature. Development required material property analysis, stress modelling and thermal modelling. This was followed by clip force measurements, thermographic verification of behaviour in vitro and in vivo studies to assess viability.

Results

An effective clip was developed. Thermographic studies verified that the temperature rise in surrounding tissue was below the damage threshold. Histological examination from the in vivo study verified that these clips could be applied without causing residual tissue damage.

Conclusion

The study demonstrated that a small thermally activated tissue fixator could be applied without collateral thermal damage and with good biocompatibility. No contraindications were observed within the scope of this study.

Keywords

shape memory alloy, surgical clips, thermally activated SMA, minimally invasive surgery, wound closure

HYBRID IMAGING - Emerging New Imaging Systems

Michael Friebe, TomoSystems & Biophan Europe, Castrop Rauxel, Germany

Background

Hybrid imaging is not only PET/CT + SPECT/CT. HYBRID is something of mixed origin or something having two kinds of components that products the same or similar results. Hybrid systems could include combinations of many different imaging systems. This presentation summarizes current techniques with a future outlook.

Material & Methods

Not every combination makes sense. To combine PET or SPECT (molecular imaging) with CT is currently the most widely used Hybrid system. Assumption is that the fusion of molecular imaging and CT data acquired sequentially on one device is clinically superior to side-by-side evaluation of separately performed images. To combine MRI+X-ray also would make a lot of sense. X-ray reveals hard materials (bones+surgical tools). However, it cannot image soft tissues like internal organs and blood vessels can only be seen with injected contrast media. MRI reveals intricate details of soft tissues and vessels but still does not show tool movement accurately. X-Ray + MRI complement each other, but the effects of magnetism on moving electrons needs to be overcome.

Results

Hybrid Systems are mainly used for oncology imaging today. Future systems will also be used for minimally invasive procedures. These procedures reduce trauma, blood loss, and recovery time for patients. Their success hinges on novel imaging systems revealing soft and hard tissues.

Conclusion

Expect to see many more Hybrid Systems in the near future.

Keywords

Hybrid Imaging, PET/CT, MR/PET, XMR

Mobile Linear Accelerator for Intraoperative Application (IORT) Combined with Advanced Diagnostic Systems

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Ernesto Lanzotti, TOMOVATION, Italy

Background

Intraoperative external beam radiation can provide higher effective therapeutic doses of irradiation to regions of malignant areas while dose limiting structures are surgically displaced. Diagnostic imaging control could be advantageous to this therapeutic application.

Material & Methods

Up to 12MeV self-shielded mobile intraoperative linear accelerator (Mobetron, Intraopmedical, Inc.) with up to 10Gy per minute radiation in 3cm to 10cm radiation areas with depths of 1cm to 4cm. Applications in the surgical suite to gastric cancers and sarcomas, early stage breast and pancreas, advanced and recurrent colorectal cancers, mesothelioma and lung cancers, as well as other cancers. The device can be moved to the surgical area so the patient can be stationary.

Results

Intraoperative beam radiation in combination with surgical procedures significantly increase the 5 year survival rates. Combination with diagnostic procedures is difficult due to the weight and size of the equipment and limited to X-ray fluoroscopy at the moment.

Conclusion

IORT has proven to be an effective method for therapeutic radiation treatment in the operating room. The method requires intense collaboration of surgeons, radiation therapists, and radiation oncologists. Further R&D to combine with CT or other advanced diagnostic system could be beneficial.

Keywords

IORT, intraoperative radiation treatment, external beam radiation

Toward Biodegradable Stents

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Background

StemCapture is a medical device firm developing stents that assist stem cells to find and engraft at a target site. The cell capture mechanism uses lectins and is the subject of another talk at this conference, by Prof. Mike King from the University of Rochester. One of the major challenges in developing these adhesion-based, implantable stents is retaining function in vivo in the presence of fouling responses. We are developing biodegradable materials with embedded lectins in collaboration with MI, that slough in the presence of fouling, to continuously expose functional surfaces. These biodegradable materials can be functionalized post-fabrication, with immobilize secondary molecules. We will present data on stem cell capture characteristics of these materials and on biocompatibility issues.

Keywords

stem cells; lectins; implantable stents; fouling responses; biodegradable

Manipulation of Volumetric Models for Maxillofacial Surgery Planning

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Background

In the field of craniofacial surgery the planning of the operation is an expensive and time consuming operation that may limit the quality of the results. Advancements in the planning would be able to improve the results and reduce the planning times.

Material & Methods

We propose a solution based on a simulation of the surgical correction based on 3D virtual models obtained by x-rays (CT scan). In this simulation the surgeon is able to perform the planning by directly manipulating the bone elements through an haptic interface. The force feedback provided by the haptic interface has the objective of replacing the direct manipulation of the expensive plaster casts. More over the virtual system provide visualization and force hints that are not available during the planning with the plaster cast.

Results

We have obtained this result through the development of a new collision detection and response algorithm for volumetric object that allows the haptic manipulation of two bone parts with haptic rates. Finally the haptic feedback and the 3D graphical representation are enhanced with visual and haptic cues aimed to improve the quality of the planning.

Conclusion

This work presented a haptic system for the planning of craniofacial surgical operations aimed to improve the current methodology through the haptic manipulation and alignment of volumetric representation of the bone parts.

Keywords:

haptics, voxel, collision detection, craniofacial surgery, planning

Microsensors and Microactuators for Minimally Invasive Diagnosis and Therapy

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Background

Endoscopes and catheters are already widely used and new more precise examinations and diagnoses are required. Small medical devices with several functions for use in the human body can be realized installing microsensors and microactuators in the medical devices.

Material & Methods

We have developed microsensors and microactuators for minimally invasive examinations and therapies using MEMS and related microfabrication technologies.

Results

A fibre-optic pressure sensor of 125 μm in diameter has been developed for monitoring local pressure in a very narrow space in the human body. A forward-looking ultrasound imaging probe has been developed for intravascular surgery. A focused ultrasonic therapeutic device has been developed for sonodynamic therapy and sonoporation in the human body. An active bending catheter using a shape memory alloy actuator has been developed for precise manipulation. A laser scanning micro tool has been developed for precise surgical treatment in the human body. Maskless photolithography system on cylindrical substrates has been developed for realization of high-performance and multi-functional tube-shaped micro medical devices.

Conclusion

There is a demand for technology which can enable improved diagnosis and treatment. MEMS and related microfabrication technologies make conventional procedures easier and more precise.

Keywords

minimally invasive treatment, micromachining, MEMS, catheter, endoscope

Next-Generation Ventricular Assist Device

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Background

The acceptance within the medical community that ventricular assist devices (VADs) provide many benefits for heart failure patients has created substantial interest in this new course of treatment for heart disease. We report on a new, minimally invasive VAD for treating many types of heart failure. The MYO-VAD consists of a flexible polymer cup that is installed around the heart, a drive unit, performance monitoring system, and operating algorithms that support the use of the MYO-VAD as a critical life-supporting system. Incorporating a pneumatically activated liner, the MYO-VAD operates by compressing and expanding bi-directionally, providing the energy that allows the heart to restore the input and output of blood to life sustaining levels. The exhausted heart's structure is the pump; the MYO-VAD simply supplies the energy to allow it to beat again. Since only the patient's own heart tissue contacts their blood, the MYO-VAD eliminates the many bleeding, stroke, and infection complications that plague current VADs. Unlike existing VADs, the MYO-VAD provides complete pumping support (both filling and emptying of the heart) to both ventricles. Additionally, the healing environment created by the MYO-VAD promises to rehabilitate many sick hearts, allowing the device to be removed and the heart to function properly again without assistance.

Keywords

ventricular assist devices

Motordriven MRI Localization Device for Needle Biopsies and other Interventional Applications

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Background

To perform a biopsy inside a MRI system it is essential to mark the injection point as well as the injection angle. The Motordriven MRI Biospy Device (MoMBiD) will provide this information automatically based on a previous MRI image evaluation and subsequent planning using this image

Material & Methods

The MoMBiD consists of two guiding rails that are fixed inside the magnet bore. These allow a laser head to be moved in x- (left-right) and in z-direction (front-back). The movement of the laser head is performed by non-magnetic piezzo motors that are part of the guiding rail system. To be able to not only mark the position of the puncture but to also mark the angle of the injection path, the laser head can be tilted in the x-direction. The movement of the positioning system is controlled by a computer system that receives the image data from the MRI system. A graphical interface allows the user to mark the location of the puncture together with the angle of the needle. With this data the software calculates the required movement of the positioning system to place the laser head exactly.

Conclusion

The Motordriven MRI Biospy Device provides the visual information to perform a needle biopsy inside a MRI system without need to move the patient. This will decrease the time required for the procedure and will improve the accuracy of the positioning of the biopsy device

Keywords

MRI, Biopsy, Interventional MRI, Laser Guided Positioning

Safety Assessment of SMA Artificial Anal Sphincters

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Background

As prosthesis to assist the bowel movement control of patients with severe fecal incontinence, an artificial anal sphincter is considered an eventual choice. A novel artificial anal sphincter using shape memory alloys (SMA) was developed by the authors and its functionality has been confirmed. Safety assessment of the device is required to make it closer to clinical trials.

Material & Methods

The SMA artificial sphincter consists of two SMA ribbons connected by hinges and can be fitted around intestinal canal, forming a sandwiching occlusion to maintain the continence. Thermally controlled deformations of the SMA ribbons play a role for the opening and closing functions in this device. The power for the thermal change is provided by a transcutaneous energy transmission system. A mechanical locking mechanism was integrated into the system to shorten the heating time and therefore to eliminate the risk of heat burns which has been a main concern in such a thermally driven device. The safety of the device has been examined by in vivo experiments.

Results

The safety of the device has been confirmed in a series of animal experiments. At autopsy of implantation experiments lasted up to 3 months neither postoperative infection nor heat burns were found around the artificial sphincter and the secondary coil inside body, implying the long-term safety of the system for practical use.

Conclusion

Improvement of the device completely eliminated the risk of heat burns. The new design has fewer parts and makes the device much easier to be implanted and less invasive. Findings from the long-term implantation in animal models suggested the safety of developed SMA artificial sphincters.

Keywords

shape memory alloy, artificial sphincter, long-term implantation, safety

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Experimental Setup of Smart Colonoscopy Phantom – Future Design Implications

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Introduction

Colonoscopy is an effective method for diagnosis and treatment of lower GI diseases but it can cause pain and discomfort for the patient due to mechanical forces which are exerted on the colon and on the mesentery. We have developed an experimental setup and conducted a study to investigate, quantify and locate the forces applied on the mesentery of the bowel during colonoscopy.

Material and Method

A porcine colon was fixated within a body form phantom in the shape of human colon. 5 sensors were positioned according to the mesenterical suspension; Sensor 1 (S1): Recto-sigmoid junction; S2: Promotorium, S3 and S4: Sigma; S5: Transition zone to colon descendens. 80 colonoscopies were performed.

Results

The mean examination time was 222 sec. The highest peak of force as well as the largest area under the curve was measured at S1 (3-4N; 122,67 Ns), followed by S2 (2-3.5N; 54,84 Ns) and S5 (1-2.3N; 51,76 Ns). The measured forces on S3 (<1N; 20,15 Ns) and S4 (<1N; 22,54 Ns;) were small in comparison.

Discussion and Conclusion

The force profiles were characterized by peak forces that occur during propulsion of the endoscope, increasing with the insertion length of the endoscope due to the flexible endoscope become stiffer and increased friction. The maximal forces were identified at the rectosigmoidal transition and left colonic flexure.

The measurement setup was reliable and robust. However, some drawbacks of the setup that were revealed through the described study need further development steps to be overcome. Additional sensors to measure colon distension were endorsed to further improve the significance of the method. Also the need for dummy organs to provide for a more realistic anatomy was identified. As a key requirement for usability an improved attachment of the existing strain sensors was identified.

We have identified requirements for further development firstly to improve the usability by enhanced sensor attachment method at the colon and secondly to make future measurement more accurate by adding sensors such as for insufflation pressure and distension, as well as dummies of organs such as liver, kidney and etc., which simulate the abdominal condition.

Further in the next steps a new sensor fixation method at the porcine colon could improve the usability and additional sensors such as for insufflation pressure and distension, as well as dummies of organs such as liver, kidney and etc., which simulate the abdominal condition, could enhance the phantom and make future measurement more accurate.

Oral Poster

Nocturnal Electroimpedance Volumetric Assessment (NEVA) for examination of erectile dysfunction (ED) after Laparoscopic Radical Prostatectomy (LRP)

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Background

ED is common after LRP. Different therapeutic options to start rehabilitation soon after surgery are available, but there is no standard procedure to objectivate early postoperative ED. We study if NEVA is useful in early postoperative recording of ED when standardized ED questionnaires normally used are not feasible yet.

Material & Methods

The NEVATM-Device utilizing electro bio impedance to study erectile dysfunction, developed in 1997, was never used in this context. A group of 15 patients after LRP underwent non-invasive nocturnal penile tumescence measurement with NEVA in the first night after postoperative removal of the transurethral catheter. Three glue electrodes were put on basis and tip of the penis and on the hip, penile length, cross-sectional area and volume change were recorded continuously.

Results

In 9 patients (60 %), erections were recorded, average number of erections per night was 2.4 (1-5). The average increase of penile volume was 159 % (117-248 %; in healthy persons, it is > 200 %). The mean time of recording was 487 minutes per night (117-663).

Conclusion

First studies proof that erections are demonstrable in an early postoperative stage after LRP, NEVA was feasible. Further studies will show if our goal to use NEVA to divide up patients to the different therapeutic pathways can be reached.

Keywords

Laparoscopy, Nocturnal Penile Tumescence

A Hospital-Based MR Compatibility Testing Policy

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A hospital-based MR compatibility testing policy that enabled utilization of devices not marketed as MR compatible will be discussed. The testing policy covered both active and passive devices. The test policy, combined with elementary designs for switching non-compatible electronic devices and tethering ballistic hazards to fixed structures enabled a more complete array of patient support equipment to be utilized within the intraoperative MR suite.

A Multi-Room OR/Diagnostic MR Suite

Stephen G. Hushek, IMRIS Inc. Milwaukee WI, USA

A multi-room OR/diagnostic MR suite has been developed utilizing an MR scanner that has been designed to ride on an overhead rail. The suite features a standard 1.5T MR scanner with an attached patient handling system for diagnostic scanning and a fully functional, cantilevered operating room table for intraoperative scanning. The MR system can transition between a diagnostic room and an OR at either end of the rails with a magnet holding room in the center. Sliding doors which separate the rooms serve as airtight RF and acoustic barriers. The overhead rails are attached directly to the building structure, eliminating the need for reinforced flooring. The OR can serve as a standard OR when the magnet is being used for diagnostic scanning, maximizing use of all clinical space as well as optimizing use of the MR capital equipment asset. The MR scanner can move from the holding room to the imaging position in the operating room within 90 seconds and is immediately available for imaging.

Poster

Improvement of the MR visualisation of Prosthetic Heart Valves

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Background

The purpose was to improve visualization of a percutaneously implantable heart valves under MRI. Through the use of a resonant circuit on the stent the visualization of intraluminal substrates should be improved.

Material & Methods

A resonant circuit comprising of a helical coil with a non-magnetic capacitor was attached to a Nitinol stent (Memotherm, Bard Angiomed) and tuned to the Larmor frequency of the 1T (42.58MHz) and 1.5T (64MHz) MRT (Philips). The coil was made from copper or gold wire. The resonant structure was insulated with silicon or parylene. Pulmonal and aortic heart valve were excised from a fresh pig heart and sutured in the Nitinol stent with 4-0 Prolene. The MR-tests were made in 0.9% NaCl solution at 21° Celsius in a Tupper ware box in the standard head coil. As MRI sequences Fast-Field-Echo, TR=200ms, TE=6ms with low flip angles (15°-25°) have been applied.

Results

The newly developed valve comprises of a fresh porcine heart valve that was sewed in to a Nitinol stent. The heart valve could be visualized in the MRI by low flip angle (15°). The signal difference of substrate and test liquid was significant. The shielding of the Nitinol stent could be over come.

Conclusion

The results demonstrate that the use of resonant structure on the stents could minimize or avoid the negative shielding effects of the stent based heart valve. This enables direct and improved MRI examination of the valve function with MRI.

Keywords

heart valve, resonant circuit

Oral Poster

Inductively Coupled MR Visualization of the Stent Lumen

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Background

The purpose was to minimize the RF artifacts and to improve the visibility of the stent lumen significantly by integration of the resonant circuits tuned to the Larmor frequency of the MRI.

Material & Methods

The resonant circuits were designed comprising of a helical coil and a non-magnetic capacitor. A Nitinol stent were used for the tests. The coil was made both from gold-alloy and copper wire and attached to the stent. The circuits were tuned to the Larmor frequency of the 1.0 and 1.5 T (42.5 and 64MHz) MRT. Fast-Field-Echo, TR=100ms, TE=6ms, with low FA (10°-20°) were used for the MR imaging. A fresh blood coagulum and freshly excised porcine aortic wall were placed in the stents to simulate a thrombus and intimal hyperplasia. All tests were performed in 0.9% NaCl-solution at 21° Celsius in a test container (Tupper ware) in the standard head coil.

Results

The coagulum and the vessel wall could be visualized in the MRI. The shielding of the Nitinol stent could be overcome by using low angle gradient echo sequences, which allowed the tissues to be visualized with increased signal. Valid depiction of instent tissues in a non-resonant reference Nitinol stent was not possible.

Conclusion

The results demonstrate that the use of a resonant structure on the stent can minimize or avoid the negative shielding effects of the structure of a Nitinol stent. This technology enables direct MRI examination of the stent patency with MRI.

Keywords

MRI, active stent, resonant circuit.

The Impact of Haptic-Visual versus Visual-Only passive Learning in Telem manipulator-assisted Surgery

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Abstract:

Background: The use of a telem manipulator requires special training and surgical performance is associated with a learning curve. The aim of this study was to demonstrate the potential value of Haptic-Visual over Visual-Only passive Training in Telem manipulator-assisted surgery.

Materials & Methods

Two daVinci Telem manipulator consoles were linked through an Application Interface (API) allowing the applicant at the training console to passively follow the motions of the instructor at the master console (Haptic-Visual Learning group, hv).

The trainee and the instructor shared the same 3D vision. Alternatively, subjects received only standard visual training (Visual-Only Learning group, v). Participants (n=20 without previous experience with telem manipulation) performed a set of various tasks in a randomized order.

Results

The first task, with moving items to appropriate locations showed mean time: 2.43min [hv] vs. 4.04min [v]. Accuracy of performance (the number of mistakes and the number of trials before the task could be accomplished) was significantly increased with 1.3 [hv] mistakes vs. 15.2 [v]. With more challenging tasks (cut off a round figure [cut]) the number of mistakes decreased significantly with 7.2 (hv) [cut] vs. 16.4 (v) [cut]. In the third task the applicants were asked to perform double dot suture lines [sti]. We observed significantly less numbers of mistakes with 10.0 (hv) [sti] vs. 23.5 (v) [sti].

Conclusion

This study demonstrated the impact of haptic-visual passive learning in computer-assisted surgery. The clinical benefit of this finding needs to be determined.

Keyword: Surgical Training

The Minimally Invasive Manipulator; an Instrument Improving the Performance in Standardized Tasks for Endoscopic Surgery

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Background

To evaluate the feasibility and efficacy of a mechanical minimally invasive manipulator (MIM) for endoscopic surgery. The MIM consists of two mechanical, hand-controlled endoscopic arms with joints, which allow 7 degrees of freedom (DOFs).

Material & Methods

30 medical students performed 4 different tasks in a pelvic trainer box. with two conventional endoscopic needle holders or with a set of MIMs: repositioning coins, rope-passing, passing a suture through rings and tying a surgical knot. All experiments were recorded on videotape (S-VHS) and data was analysed afterwards by an independent observer using a quantitative time action analysis.

Results

A significant difference between numbers of total actions (including failures) was shown in most exercises in favour of the MIM-group. A significant difference in failures per task was shown in favour of the MIM-group as well. There was no significant difference shown in time per exercise.

Conclusion

These tasks clearly demonstrated the efficacy of the MIM, even though some technical flaws emerged during the experiments. Considering the fact that a first prototype of the MIM was tested, modifications are to be expected in a next model. These experiments show the potential of the MIM and it is expected to be a competitive and economical instrument for endoscopic surgery in the near future.

Keywords

Minimally invasive manipulator, Robotics, Performance study.

The Advantages of Video Technique in Anesthesia

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Background

One of the most important features of Minimally Invasive Surgery, (MIS), was the incorporation of video technology. Anesthesiologists have been rather slow in accepting this fact. We used a standard Macintosh laryngoscope blade which has a 3 mm built in image light transmitter. We inserted a small TV camera into the handle creating a panoramic enlarged view of the larynx replacing the limited naked eye keyhole view. The magnified image provides anatomic detail and facilitates tracheal intubation. The miniature TV camera can also be attached to a flexible intubating scope. Television display is the method of choice in teaching endoscopic procedures. We've successfully employed video technique in more than 600 cases. If assistance is required, (i.e. cricoid pressure), the movements are well coordinated because both parties can observe the image simultaneously. It is of importance in the difficult airway situation, (morbid obesity, emergency, etc). Approximately 90% of intubations are performed with a rigid laryngoscope and 10% with a flexible scope which requires more skill and experience. Video technology opened a new chapter in the management of difficult airways and teaching intubation.

Results

Successfully employed video technique in 600 cases.

Conclusion

Video Technology is the method of choice in teaching.

Keywords

Video Technique in Difficult Airways

Roboter-Assisted Biopsy vs. Free-Hand-Technique using Ultrasound Guidance: first in-vitro Results

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Background

To validate feasibility and accuracy of robot-assisted biopsy in-vitro compared to a free-hand technique.

Material & Methods

Peas (diameter 9.9 ± 1.6 mm) embedded within a gel-phantom were randomly selected for either robot-assisted biopsy (n=20) or for biopsy using a free-hand technique (n=20). For robot-assisted biopsy positional data of an US transducer was recorded by an optical tracking system. For hand-held biopsy, a biopsy guidance tool was attached to the US transducer. Only one needle pass was performed and the length of the biopsy specimen was measured to proof efficacy. Abbreviations of the actual needle tract were evaluated using ultrasonography.

Results

A successful biopsy was performed in 19/20 biopsies (95%) using the freehand technique and in 17/20 roboter-assisted biopsies (85%). The length of the harvested specimens (mean 4.7 ± 2.6 mm) was not significant different ($p=0.07$). The deviation of the needle tip from target along the z- axis was not significant ($p=.953$). The median intervention time using the free-hand technique (115.6 sec) was significant shorter ($p<.001$) than with the robot.

Conclusion

Robot-assisted biopsy was feasible and the length of the biopsy specimens were equivalent to the free-hand technique.

Keywords

roboter-assisted, ultrasound, biopsy

Selectin the Target Cell: Flow-Based Capture of Stem Cells and Cancer Cells via Immune Systemic Adhesive Proteins.

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Background

The last several years my lab used a combination of in vitro experiments, complex simulations, and simulated animal models to understand how white blood cells adhesively capture to the blood vessel wall during inflammation. These cell-cell interactions are mediated by a family of carb.-binding proteins called selectins, which are capable of quickly and selectively arresting flowing cells in the blood stream. Selectins cause certain cells such as white blood cells, stem & tumour cells to roll across the blood vessel wall, or synthetic surfaces coated w/purified selectin protein. We have dev. tech. to use this natural. mechanism to rapidly & gently purify haematopoietic stem cells (HSCs) from samples of adult bone marrow, or to capture rare cancerous cells from a mixture of flowing blood. Have also explored strategies to selectively deliver apoptosis (death) signal to cancerous cells as they slowly roll across an implantable device contacting the peripheral blood. Selectin-based cell manipulation opens up a new approach to cancer and stem cell therapies, such as the harvesting of stem cells from donated bone marrow, whole blood, redirecting stem cells within the body, or by capturing and neutralizing circulating cancer cells in an adjuvant clinical setting.

Keywords

in vitro; adhesively captured; selection protein; hematopoietic stem cells (HSC); apoptosis; implantable device; cell manipulation

**MRI AND PET FOR EVALAUTION OF SPINAL DISC DISEASE. THE
“DISEASE OF THE HUMAN RACE”.**

Panos Kondoyannis, Vera Fountoulaki, Athens, Greece

It is an undisputed fact that 80 – 85% of the adult population on this planet will suffer from Low Back Pain at least once in their life span. Another fact is that 90% of these back-aching conditions is due to the intervertebral disc – the “disc disease” or “discopathy”. The main pathological processes affecting the disc are 1.degeneration and 2. trauma. The components of the disc are the annulus fibrosus and nucleus pulposus. These structures mini-fracture and tear, and particularly where they are attached to the bones of the vertebrae. Sites of damage at the interface between discs and bone act as foci through which blood vessels grow into the discs, accompanied sometimes by macrophages and giant cells. This is the beginning of the degeneration process leading to discopathy.

To investigate and consequently help treat disc disease we mainly use the latest medical technologies for evaluation of spinal disorders i.e. Magnetic Resonance Tomography and Positron Emission Tomography.

Poster

Inductive coupled vena cava filter (VCF) to improvement of the MRI visualization and intervention

Sentürk Konak, Stephan Michitsch, Klaas Tohnack, Bastian Urban, Andreas Melzer, INSITE med. & Dept of Physical engineering University of Applied Sciences, Gelsenkirchen and Biophan Europe, Castrop Rauxel, Germany

Background

For the execution of MRI controlled implantation and later course of diagnostic control the VCF must be visible in MRI without artifacts. Aim was the development of an implantable and removable filter for the vena cava inferior, by integration of a resonance circuit (RLC) which improved the MRI lead intervention and the diagnostics.

Material & Methods

For the evaluation of the functional principle prototypes were constructed of copper and phosphorus bronze wire. Filters and SMD condenser were connected to form a RLC, these were tuned on the Larmor frequency of approx 42 and approx 64MHz. Customary filters were tested and equipped with RLC. The prototypes were tested in distilled water and 0,9 % NaCL water, endowed with fresh thrombus as well as implanted and removed into a vessel model under MRI. Imaging was performed in 1.0T/1.5T Philips scanner. GRE sequences (TR/TE =50/5ms, FA = 5-60 °, FOV= 150, ST =2mm) were used.

Results

Filter of titanium and Nitinol with supplement RLC are suitable for MRI. By using of Flip Angle smaller than 10° signal amplification more than 400% was achieved. These filters show only minimal artifacts.

Conclusion

By the integration of RLC in Vena Cava filter good signal amplification can be achieved. This technology can be integrated into conventional filter designs to improve visualization and placement under MRI control.

Keywords

MRT active vena cava filter, MRT intervention, Vena cava filter

Oral Poster

Impact of Ferromagnetic Detection on MRI Safety

Keith Kopp, Kopp Development Inc.

Background

Recent information has indicated that ferromagnetic projectiles are a significant if not the most significant cause of serious injuries. A number of factors including the MR magnet design and operational procedures have caused these risks to increase. A new technology involving a special type of ferromagnetic detection system for MR may help ameliorate the dangers associated with ferromagnetic projectiles.

Material & Methods

A review of current and future magnet design and the effect on projectile risk was undertaken. Particular attention was paid to the role of the static magnetic field spatial gradient. An analysis of the inherent risks associated with typical operational MRI facility layouts and procedures used in the MR environment was carried out. Results of previous MR safety studies were explored with regard to the impact of ferromagnetic detection systems. The types of ferromagnetic detection systems currently available were evaluated for functionality and applicability.

Results

The reduction of safety issues associated with ferromagnetic projectiles is dependent upon the type and method of use of each of the ferromagnetic devices reviewed.

Conclusion

Ferromagnetic projectile risk factors for MR are increasing. Ferromagnetic detection systems when used to supplement a comprehensive screening procedure have the potential of significantly reducing the risk of a projectile incident.

Keywords

MRI safety ferromagnetic detection projectile injury magnet

Fractures and Metastases - 150 patients with CT-guided percutaneous vertebroplasty

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Background

Since the early 90's CT-guided vertebroplasty has proved to be a valuable treatment modality regarding pain relief and functional status. Retrospectively we tried to determine the feasibility of CT-fluoroscopic vertebroplasty emphasizing on outcome, complications as well as short-term results.

Material & Methods

150 patients with more than 220 vertebral bodies treated (mainly osteoporotic compression fractures) over a 5-year period (2000 to 2005) were included in this study. All CT-guided percutaneous interventions were performed with a Siemens Volume Zoom CT (Siemens Medical Solutions; Erlangen, Germany) using a CT-fluoroscopy device and local anaesthesia only. State-of-the-art imaging (MRI) was performed in advance.

Results

CT-fluoroscopic percutaneous and transpedicular treatment was successful in all cases. No significant complications such as venous bone cement leakage were noted. All patients were almost immediately relieved of pain. No neurological deficits occurred during or after the procedure.

Conclusion

Percutaneous vertebroplasty is an efficient technique with low complication rates and a significant reduction in pain. It helps improve mobility and quality of life of patients with posttraumatic, osteoporotic and metastatic compression fractures. Long-term results showing a significant better outcome than other treatments are still missing.

Keywords

Image guided surgery - Computed Tomography - Minimal invasive therapy - Vertebroplasty

Experimental studies with a novel workflow oriented navigation system based on electromagnetic tracking.

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Background

We tried to evaluate a novel electromagnetic navigation system for image guided minimal invasive radiological interventions. Two different phantom studies were designed regarding the system's accuracy.

Material & Methods

The navigation system (CAS innovations AG, Germany) consists of an electromagnetic tracking system Aurora (NDI, Canada), adequate navigation software and newly designed needles with integrated coils in the tip. The navigation system can be fully integrated in the clinical workflow and allows planning of trajectories and navigation of needles with virtual control of the needle in the data set. To test the accuracy two different CT-based phantoms studies were performed.

Results

The handling with the system proved to be comfortable and valuable in the targeting process. Both phantom studies showed accuracy adequate for both, different biopsies and minimal invasive interventions such as CT-guided periradicular therapies. In other navigation based setups the deviation of the needle from the axis (bending) in the puncturing process is a critical point. In this setup the bending of the needle can be visualized / detected by the system.

Conclusion

The navigation system is especially qualified for interventions with necessary double oblique access to reach a lesion and also for interventions that require the use of a thin and instable needle.

Keywords

MITIGS Electromagnetic Tracking CT

Robotic Platform B-RobII: In vitro Tests and Results

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Joachim Kettenbach, University Hospital of Vienna, Austria

Background

A modular automated targeting device for percutaneous interventions under US and CT guidance has been developed. For evaluation of the system concept and accuracy of needle positioning a series of in-vitro tests has been performed. Both robotic system and test results are described in this presentation.

Material & Methods

The developed targeting device consists of one or two 2DOF positioning modules in different configurations. Depending on the chosen configuration the targeting device allows 2DOF needle angulation ($\pm 30^\circ$) and 2DOF positioning (± 20 mm) with high accuracy. For system evaluation different phantom tests have been developed. Planning of the intervention is on basis of imaging data sets - after graphical selection of the target and manual pre-positioning of the device, correct angulation is being set by the robot. Finally the needle is being inserted manually and the deviation between target position and needle tip is measured. Different ways of registration of the robot into the coordinate system of the imaging data have been evaluated.

Results

The developed system is easy-to-use and does not interfere to the clinical work-flow. System accuracy and overall performance is being tested successfully.

Conclusion

The realized prototype of a modular automated needle guide allows positioning of a biopsy needle based on an intra-operatively planning with high accuracy.

Keywords

Interventional Radiology; Medical Robotics; Image Guided Therapy; Needle Placement

Commercialization of Medical Microsystems

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Microtechnology has evolved to the point where it is having an impact on existing medical products, and enabling new ones. Significant advances in microtechnology made for the automotive industry and during the telecom boom have been adapted to medical applications. We use the term Medical Microsystems to refer to medical devices incorporating components engineered at the micron-scale for detection (sensors), motion (actuators), or structural support, either in vivo or in vitro. These components can be micro-electromechanical systems (MEMS), or structures with microfabricated features. Materials are not limited to silicon, but include polymers, ceramics, and metals, and can integrate biological elements such as proteins and cells. In this paper, we review a number of Medical Microsystems that have been commercialized successfully, as well as some applications that are on the horizon. Medical Microsystems can be divided into three categories: diagnostic, therapeutic, and surgical, and examples will be given of each type. Nanotechnology, the field relating to structures with nano-scale (10⁻⁹ m) functional elements, arguably is already playing a pivotal role in the evolution of medical devices (for example, drug eluting coatings, improved materials for implantable batteries, and particles for targeted therapy) but is not the focus of the present paper.

The features and benefits of Medical Microsystems are summarized in Table I. Often times the use of microtechnology is driven by a requirement for miniaturization. This is the case, for example, with catheter based sensors, hand-held and swallowable diagnostic systems, and smart surgical tools. Another attractive feature of Medical Microsystems such as wireless implantable neurostimulators is the ability to make devices that are micro-invasive, limiting trauma and reducing complications during deployment and operation. Other advantages include the ability to treat and measure locally, multiplicity afforded by lithographic processing, and low cost in large quantities.

Table I: Features and benefits of Medical Microsystems.

Features	Benefits	Examples
miniaturization	new products	catheter-based sensors, swallowable camera
micro-invasive	fewer complications	wireless implantable neurostimulators
localized treatment or measurement	enhanced effectiveness	AAA pressure sensor
multiplicity (arrays)	greater dynamic range, redundancy	gene chips
low cost in large quantities	reduced cost of treatment	disposable blood pressure sensors

Efficient Medical Device Design Workshop

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Background

The Workshop: Good medical device design is a marriage of good ideas from clinical practitioners and the specialized skills of the medical device designer. What are some of the practical tools that the R+D engineer and physician device researcher and entrepreneur can use to develop and refine a medical device? This workshop will outline some of the ways to develop and prototype a medical device, and familiarize the attendee with some of the resources readily available to them, including rapid prototyping, medical device materials and processes, and many other important topics. About the speaker: Ted Kucklick is a medical device R+D designer and entrepreneur with several years experience in the field, including work for RITA Medical, Somnus, Curon, Starion Instruments, Sleep Solutions, AfX and many others. He is a member of the IEEE/EMBS, AMI, and IDSA professional societies, and is co-founder of Cannuflow, Incorporated, a company dedicated to improved devices for arthroscopy. Ted is inventor on a number of issued and pending patents, and author of The Medical Device R&D Handbook recently published by CRC Press/Taylor and Francis.

Keywords

medical device design, prototype, innovation, invention

Oral Poster

3D Navigation in Laparoscopic Surgery

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Background

In laparoscopic surgery the surgeon has to rely on endoscopic camera visualization without haptic feedback. This might limit the usefulness of laparoscopy.

Material & Methods

To counteract this we have developed a navigation system based on 3D preoperatively acquired magnetic resonance (MR) images or x-ray computed tomography (CT) data sets. This provides the surgeon with an overview of structures beneath the surface of organs not visible with conventional endoscope visualization.

Results

We have attached a tracking device on the video-laparoscope that allows the surgeon to have interactive visualization of preoperative data based on the position and orientation of the video-laparoscope during the procedure. Fiducials were attached to the patients prior to MR/CT imaging. The patients were registered on the operating table and the images were displayed using our own visualization and navigation software.

Conclusion

We believe abdominal 3D image navigation using the video-laparoscope as an interactive navigation pointer is feasible and beneficial in laparoscopic surgery. In particular, this system is useful where vessels and anatomical relations might be difficult to identify using the video-laparoscope only.

Keywords

Navigation, 3D visualization, laparoscopy

Monitoring and comparison of bipolar and monopolar radiofrequency ablation

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Background

Local treatment methods, such as radio frequency ablation (RFA) have shown promising results in minimally invasive treatment of liver tumours. These methods are based on the introduction of an ablation device into the tumour, with the purpose of a homogenous and complete tissue destruction of the entire tumour as well as an approximate one-centimetre surrounding zone of apparently healthy liver tissue.

Material & Methods

We have compared a monopolar system to a bipolar system in ex- and in-vivo experimental models. We measured physiological parameters, monitored temperature development close to the RF probes, determined tissue effects from samples post mortem, and evaluated the effect of RFA with and without Pringle's manoeuvre. In addition, we evaluated a method for monitoring temperature using raw ultrasound echo signals.

Results

The lesion sizes increased with increasing power setting and increasing ablation time. The lesion sizes also seemed to vary due to inhomogeneities in the liver tissue. The temperature measurements from ultrasound data showed that a high frame rate gave clear and noise-free temperature images when using the bipolar system.

Conclusion

The simpler geometry of the bipolar single probe system seems to be more suitable for temperature monitoring using ultrasound signal processing.

Keywords

radio frequency ablation, ultrasound, temperature

Improving working conditions in laparoscopic surgery

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Background

Laparoscopic surgery has many ergonomic disadvantages often not considered in the design of instruments and clothing. Laparoscopic surgeons sometimes experiences heat related discomfort even though the temperature situation is moderate.

Material & Methods

Ergonomic handle: We investigated how laparoscopic handle design can be improved by combining classical ergonomic guidelines with tactile feedback related to handle design.

Cooling vest: We designed a cooling vest using a phase change material to increase thermal comfort for the surgeon. Four physiological tests of one surgeon's skin temperatures and heart rate were conducted during laparoscopic procedures.

Results

Ergonomic handle: An ergonomic handle for laparoscopic grasping, with a built-in tactile sensation display, is presented. **Cooling vest:** The subjective user evaluations demonstrated increased comfort with the final cooling vest prototype, whereas a commercially available cooling vest (made for firemen) only increased MST and discomfort. Furthermore, it was found that whole trunk cooling was more effective than only upper trunk cooling. A final design was proposed based on these findings.

Conclusion

Both the cooling vest and ergonomic handle seem to improve the ergonomic situation for laparoscopic surgeons. Further studies are needed to demonstrate clinical benefits.

Keywords

cooling vest, laparoscopy, ergonomics, handle, tactile feedback

Oral Poster

Development of Minimally Invasive Ambulatory Pressure Monitoring System

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Background

Majority of medical practices focus on localized symptoms rather than systemic observations and snap shots rather than continuous monitoring. The ultimate goal is to enable patients' experiencing peace regarding wellbeing; and the immediate goal is to investigate the physiological change per different lifestyles.

Material & Methods

Our first step is to develop a minimally invasive implantable pressure sensing system that monitors long-term physiological changes in real-time, specifically, the pressure changes in the upper urinary tract per degree of obstruction. Our system integrates three components: 1) miniaturized sensor module; 2) implantable sensor node contains a processing IC, multi-channel ADC, conditioning circuit and the battery; and 3) PDA interfaces and commands these nodes.

Results

Our tether-free system can measure pressure continuously during natural movements for 48 hours and communicate among the implanted sensor nodes and the remote PDA 20 feet away. The challenges encountered—1) biocompatible packaging, 2) transducer drift, 3) power management, and 4) in vivo signal transmission—and the solutions formulated will be presented.

Conclusion

Designed for urological monitoring, this ambulatory sensor network has applications in other pressures (e.g. intracranial). Most importantly, this step brings us closer to having a systemic monitor that improves understanding of human physiology and compliance management.

Keywords

Sensor Network, Implantable Sensors, Urological Monitoring

Novel Nanomaterials for Next Generation Drug Delivery

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Background

Improved methods, drug delivery have received increasing levels of interest, driven by both the growth of combination products such as drug eluting stents, and the desire of pharmaceutical companies to provide novel dosage forms to enhance safety and biocompatibility. Biophan Technologies, thru its Nanolution division, is developing technology, including nanomagnetic particles. These particles show promise for selectively turning on drug delivery from device surfaces and targeting drugs to desired areas of the body. Controlled activation of drugs, in which they are needed, can enable the delivery of higher dosages of material with reduced systemic toxicity. In addition to nanomagnetic particles, Nanolution is working with NaturalNano on the development of naturally occurring nanomaterials to provide controlled drug elution. Halloysite, is an interesting material that is capable of entrapping a range of bioactive agents. Halloysite morphology is found to consist of predominately ultramicroscopic hollow cylinders. The lengths range from 1-20 microns and diameters from 15 nm to 0.3 microns. The small scale of this clay lends itself to use as a release media in tablet applications, inclusion in polymeric structures as part of implantable medical devices or for dermal applications.

Oral Poster

THE DIT.- AN ENDOSCOPIC FINGER

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Background

During endoscopic operations, surgical instruments manipulation through a sheath inserted in the abdominal wall reduces surgeon's manoeuvrability as he cannot manipulate using all upper extremity articulations. Trying to improve the 3 degrees of freedom using endoscopic instruments, many companies have developed some articulated instruments deflecting its tip, principally when a robot is used. As a hand replica to be inserted into the abdominal cavity using a trocar can be utopian, the use of a finger like instrument could be possible and useful for a lot of dissecting manoeuvres.

Conclusion

This device is a handling instrument for endoscopic surgery to facilitate the lax spaces dissection like the pre- or retroperitoneal to be used as a deflecting probe into the abdomen as well, easy to be used with precision by the surgeon. This device is a probe with a double articulation at the tip actuated pressing a finger pusher at the handle. In fact, surgeon's finger movement is reproduced by the tip of the instrument making its use very intuitive. In addition, it can be rotated 360° to facilitate the right position of the tip. Complementary facilities can be incorporated: two holes at the most end of the tip, connected to a vacuum system, facilitates aspiration if needed, as well as a terminal for monopolar electro coagulation for haemostasis.

Keywords

Surgical instrument - Endoscopic surgery

Toward clipless lapchole? 6-year results of cholecystectomy by ultrasonic dissection

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Introduction

Misidentification of anatomy, HF related injuries, frequent instrument changes, potential clip migration are drawbacks of LC. Temperature elevation in tissue after US dissection is $> 40^{\circ}\text{C}$ only within 1 mm from US blade, whereas at a distance of 2 mm the elevation does not exceed 6°C .

Materials and Methods

1075 LC by US dissection (USLC) performed within a prospective nonrandomized trial from 1999 to 2005. Primary endpoint: reduction of BDI. Secondary endpoint: improvement of surgical technique. 2 arms: USLC with no need of cystic duct (CD) ligation 744 (69.2%), and USLC with CD secured by clip 331 (30.8%). 2 subgroups each arm: expert and trainee. Morbidity, mortality, op time, conversion rate, length of po stay analyzed. Complications classified as major (MC) and minor (mC) according to Clavien.

Results

MC = 4.0% and mC = 7.2%. Mortality rate .46%: emergent .28%, elective .18%. BDI related mortality = 0. BDI = .37%, bile leak 1.30% (conservative .65%, surgical .65%). No significant difference between arms. MC, BDI and bile leaks significantly different in expert and trainee subgroups ($p = .026, .03, .049$).

Conclusion

USLC with CD secured by clip and dome-down dissection performed in severe cholecystitis or in CD >3 mm: anatomy well recognized, and no need of io cholangiography. BDI and BDI related mortality lower compared to those in major published cumulative series. US devices requires a learning curve.

Key Words

Lapchole, US dissection

THE OR LOGBOOK

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Background

The ability to record and store information during surgery, should yield to an increase in the safety rates in the health environment for both users and professionals. The OR logbook is a piece of software designed specifically for this purpose

Material & Methods

The application is a specific implementation of a technological platform (Monsurin). As a whole the system is built out of three basic components: a-data grabbing: vital signals, state of devices and multiplexed video and audio; b-data processing: UMDD, video compression (H.264) and audio, vital signals, metadata and other parameters, integration through HL7, and security; c-storage and transmission of data: client-server architecture and web services. HL7 and DICOM

Results

On a computer screen you can see all of the data and activity information that occurred in the OR. The interface is straightforward and intuitive. Monitoring data is displayed synchronous with video recorded during the operation

Conclusion

The scientific value of this platform will come from the analysis of the information recorded in an integrated way. It cannot be underestimated the value of having access to a huge and unified database that will be built over time. Many technology areas are involved but the IT engineering is required to design the architecture of the high performance hardware and software systems needed to support such a high demanding solution both in processing speed and storage terms

Keywords

OR safety-data monitoring and transmission

Initial Experiences using Prototype HD Camera in Endoscopy

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Background

In the time since the advent of color broadcast TV, medicine has experienced a massive growth in the application of closed circuit TV, particularly influencing surgery, where minimally invasive techniques could not have become accepted without it. However, digital broadcast TV now brings High Definition (HD) video as a practical reality in medicine.

Material & Methods

It may be found that HD does not change practice, but its potential to improve the precision of surgery and protect against errors may necessitate hospitals to replace current equipment. Nevertheless, scientific studies must be carried out to reveal the potential clinical benefits, both with regard to patient outcome and surgical performance.

Results

In the future operating room at St. Olav's Hospital in Trondheim, we are currently conducting such a study based on early prototype HD video-laparoscopes (Olympus). Surgeons and scientists (SINTEF) are working closely with industry partners (Olympus, SONY, Siemens) to investigate how technologies such as HD will influence surgical practice.

Conclusion

It is important for the companies that today supply medical and surgical video optic systems, to collaborate closely with hospitals and clinicians. Only in this way can we make sure that a transition from standard definition to HD video is clinically evidence based rather than a strictly commercially driven transition.

Keywords

HD, laparoscopy, surgery

Hospital Information-System of the future

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Background

The health care sector needs a new generation of IT-solution. Up to billing, controlling and workflow functions the IT-solution must also completed integrated and interoperable. Perfectly tailored to full fill needs of health care providers and insurance companies management, patients/clients and their appendixes. Also, the IT-solution must be innovative in functional diversity and technology. A future-oriented and cost optimizing (business processes) solution.

Material & Methods

TPO-Concept: Telematics-cooperative communication, Process support/controlling, Orderly documentation

Results

The IT-solution must supporting the core business (Customers satisfaction and relationship management; high responsibility for a very good treatment/outcome in quality, time and budget; prepare for integrated care; content helpdesk for patient/client/appendixes reintegrating in their social networks;...).

Conclusion

To full fill the needs the IT-solution must be service orientated and integrated / interoperable. The best case is the IT-solution in a „Full Service IT Package“. So they can much more focus on their core business (no installing, maintaining and operating - just using and saving resources for necessary investments).

Keywords

Service, orientated, integrated, interoperable, management, patients, clients, content, helpdesk, appendixes, controlling, business, process, care, core, IT, Package, customer, satisfaction, responsibility, quality, time, budget, relationship

From Image Guided Therapy to Therapeutic Imaging

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Image-guided therapy has become a substantially growing area of minimally invasive procedures. The gold standard of x ray guided percutaneous interventions such as biopsies or catheter based procedures interventions done in a cathlab is evolving to more sophisticated image control of devices for delivery of ablative energy, drugs, genes to diseased tissues. Advanced therapeutic imaging will be a core topic of future medical device development and clinical research. Thereby non-ionising radiation based imaging techniques (US Ultrasound and MRI magnetic resonance imaging) are key technologies for guiding and control of medical devices during interventions and surgery.

Ultrasound can not only been used for diagnostic imaging but also to influence cell membrane interactions, to release drugs or to destroy tissue. The applications of MRI guided therapy using focused ultrasound and other ablation techniques is unravelled to navigate to the target lesion and to monitor temperature responses and tissue destruction. The links between clinical diagnosing and treating cancers through technological innovations ranging from Sonography to Sonoporation with US and from nanoparticle based contrast enhanced molecular MR imaging to molecular oncology carry a great potential. Novel targeted drug delivery using nanospheres or lysosomes utilizing heat or electromagnetically activated drug release in the target volume of a tumour opens new opportunities for medical device design.

MR and CT-Compatible Robotic Instrument Guiding System INNOMOTION

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Background

MR-guided percutaneous interventions have been clinically established with open low field MR systems. As imaging quality of closed bore scanners is superior but the access to the patient limited a fully MR-compatible assistance system.

Materials and Methods

A CT and MR-compatible assistance system Innomotion has been developed by using polymers and ceramic materials, piezzo electric and pneumatic drives and optoelectronic sensors. The robot arm is attached to an orbital mounted to the MR table and provides adjustment of a cannula guide in 6 degrees of freedom within the MRI scanner. MRI cross-platform compatibility has been achieved for 1.5 T MR scanner, Magnetom Symphony, Siemens, Erlangen and 1.0 T Gyroscan NT and 1.5 T Intera Philips. Precision of insertion site and angulations within the transverse plane have been evaluated for sciatic pain injections at lumbar ganglia of spinal nerve roots and neurolysis of the sympathetic chain ganglia and plexus coeliacus. MR guided insertions with 22-18 G MR compatible titanium cannulae (MRI devices DAUM, Germany) have been conducted. Cannula insertion was visualized with fast gradient and spin echo sequences.

Results

Position and orientation of all cannula insertions were appropriately visualised on axial MRI images. Precision of insertion site in axial plane was +/- 1mm (min of 0.5 mm and max of 3 mm). Angular deviation in the transverse plane of the cannulae shows +/- 1° with min of 0.5 and max of 3°.

Conclusion

CT and MRI guided cannula insertion by using a MR-compatible robotic assist system demonstrates adequate precision of insertion site and orientation of the cannula. Cross platform MRI compatibility can be achieved by using polymer, ceramics, pneumatic drives and optoelectronic sensors

Key words:

Image guided Robotics, MRI compatible Robotic, Interventional MRI

Poster

MR Inductively Coupled Active Septal Occluder for Cardiac Septal Defects

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Background

Generally the percutaneous closure of an ASD (PFO, ASD II) is carried out under X-Ray with the known disadvantages of ionizing radiation, Iodinated Contrast agents and the lack of the soft issues contrast. The closure of the ASD is hampered by the artifacts of commercial Occluders that haven been tested. A new Occluder was developed, which works like a resonant circuit to increase the MRI signal.

Material & Methods

The Occluder consists of 2 connected coils (umbrellas) made of phosphorus bronze wire. The coils which represent the inductance and the connected commercial SMD (surface-mounted device) capacitor build a resonant circuit tuned to 64MHz, for 1.5T. Principle of the resonator is to reach a local signal enhancement by higher FA. The Occluder was fixed in an acryl measurement container and was positioned above a surface coil. The exam was performed in a 1,5T (Philips) with a FE-EPI imaging (TR/TE=19/7, EPI-Factor=3, FOV=235, FA=5-15°). Exams were carried out in long axis and 4-chamber view. Used solution was NaCl doped with 0,5 mmol/l Gd.

Results

By using of FA=5-15° local signal enhancements bigger than 400% were reached. The Occluder was successfully implanted and MR visualized in a fresh porcine heart.

Conclusion

The signal enhancement between both coils of the occluder is sufficiently homogenous. MRI guided implantation and the following diagnoses can be improved.

Keywords

Septal Occluder, MR Occluder, ASD Occluder

Oral Poster

MR compatible Cardiovascular Simulator for Training and Medical Device Testing

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Background

Testing of medical devices under simulation of cardiovascular procedures without using living animals requires in combination with MR imaging appropriate lacks of blood flow, pulsation and heart beating like in real. We have developed a system you are able to perform device testing and simulations of interventional procedures under life-like conditions.

Material & Methods

Physiological pulsatile blood flow and heart beating has been simulated as well as the flow through arteries. To generate this flow we use a type of pump, two magnetic valves and a computer interface. The second part of the system is a model of the body in which for example a freshly excised porcine heart that is pneumatically compressed with a silicon cuff or vessels can be integrated. Breathing movements of organs such as liver can be achieved via hydraulic drive.

Results

The existing System has been tested in 1,0 and 1.5 Tesla MR. The result of this test is that it is possible with our simulator to get adequate signal characteristics under MR imaging.

Conclusion

The aim for the future is to integrate an ECG triggered heart pressure sleeve which can be equip with a real heart to get close to natural physiological conditions as far as possible. If the system provides simulate the periodical pumping of a heart and the inspiration and expiration thereby the number of animal experiments can be reduced.

Keywords

MR imaging, MR- capable cardiovascular simulator

Shape Memory Devices for Compression Anastomosis in the Digestive System

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Background

Anastomosis is an essential component of the reconstructive phase in digestive system surgery. Mechanical suturing enables to create a uniform anastomosis leaving foreign bodies often leading to stricture formation. Sutureless anastomosis eliminates this principal disadvantages. This paper presents NiTi Medical Technologies' products, which are based on a shape memory sutureless anastomosis ring.

Material & Methods

Compression clips and rings made of Ni44.2%Ti alloy were used. Experiments were performed on pigs. Mechanical strength, biological permeability, burst pressure; anastomotic index and tissue histology were tested 1 to 8 weeks after operations.

Results

The use of the shape memory compression device creates near optimal anastomosis: biological connection completely replaces the mechanical connection within 4-5 days; resulting in an early epithelisation of mucosa, full adaptation of the wall layers, no scarring on the anastomotic line, naturally elastic anastomosis with an anastomotic index of nearly 1. Clinical study shows a reduction in the time until the start of passing gas, bowel peristalsis, and the discontinuance of catheterization and antibiotic treatment.

Conclusion

Using shape memory alloy properties it is possible to design a simple and effective implant, capable of creating anastomosis in the digestive system, and of resolving most problems of existing anastomosis methods.

Keywords

Surgery, compression anastomosis, shape memory implant

Results of a Clinical Study with a Computer-Assisted Needle Positioning System

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Background

In order to evaluate a computer-assisted needle positioning system (CAS innovations, Germany) phantom tests and a clinical study were performed.

Material & Methods

The system consists of an optical tracking system (Polaris, NDI, Canada), a needle holder, a reference frame used for patient-to-image-registration, a vacuum patient fixation device (BodyFix, Medical Intelligence, Germany) to reduce patient motion and a PC with touch screen as user interface and navigation software. We performed different punctures (n=10) within the scope of a clinical study approved by an ethics commission.

Results

The phantom studies show a mean technical error of less than 1.0 mm. Within the scope of the clinical study we performed biopsies in bone and soft tissue including punctures with double oblique access. All planned targets were met and in 70% only one control scan was necessary. With the patient fixation it was possible to prevent involuntary patient motion and in that way the system was used with local anaesthesia only. Also a pain-free positioning of the patient in almost any oblique position on the CT table was possible using the fixation device.

Conclusion

The computer-assisted needle positioning system fulfilled all technical specifications and was particularly valuable for biopsies with double oblique access and for deeply located lesions. Disadvantages are the higher complexity of the equipment and the time needed for fixation.

Keywords

navigation

Oral Poster

Navigated Neurosurgery based on Multimodal 3D Display of Intraoperative 3D Ultrasound and Brain Shift Corrected Preoperative MRI

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Background

Intraoperative imaging is important for correction of shifts that occur during neurosurgery.

Material & Methods

We have developed algorithms for updating important preoperative information based on intraoperative ultrasound volumes. Data were imported into an ultrasound navigation system, registered to the patient and used for planning of surgery. Intraoperative 3D ultrasound tissue and angiography data were acquired and used for guidance during surgery. A method based on volume-to-volume registration for detection and correction of mismatch between preoperative MR-angiography and intraoperative ultrasound 3D angiography was developed.

Results

All essential preoperative MR information could be corrected. The display reflected the true location of functional areas after surgery had proceeded. Both preoperative MR data and intraoperative 3D ultrasound data could be displayed simultaneously in the same multimodal 3D scene for guidance. We experienced that display of preoperative fMRI and DTI-based tractograms in the navigation system is feasible and useful for optimal interpretation.

Conclusion

In conclusion, our volume-to-volume registration and correction algorithm can update essential and needed preoperative image information. New multimodal display will make it easier to interpret available information.

Keywords

neurosurgery, navigation, 3D ultrasound, brain shift, multimodal visualization

Nitinol Biocompatibility: Effects of Oxidation

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Equiatomic Titanium-Nickel (TiNi or Nitinol) is an intermetallic compound characterized by a unique combination of properties, including shape memory, superelasticity, corrosion resistance, and biocompatibility. These properties make it very attractive for biomedical applications, such as orthodontic archwires, minimally-invasive instrumentation, and self-expanding stents. It is well known that after appropriate passivation, the Nitinol surface consists mainly of a titanium-oxide (TiO₂) layer similar to that found on Ti alloys with comparable in vivo biocompatibility. However, recent studies concluded that thermal oxidation of Nitinol can lead to surprisingly poor corrosion resistance. As such, this paper reports on a systematic investigation of the oxidation of medical-grade Nitinol with high spatial and angular analytical techniques such as SEM, FIB, and synchrotron microdiffraction and grazing incidence x-ray diffraction.

Corrosion behavior of these oxidized wires was investigated with respect to the breakdown potential (E_{bd}) by potentiodynamic polarization tests. The E_{bd} dramatically decreases from 1000mV to below -100mV vs SCE as the oxide thickness increases from less than 0.01μm to 10μm. The observations from this study are consistent with a model of oxygen absorption on an initially amorphous Ti-O electropolished Nitinol surface that provides a passive barrier and good biocompatibility. During the early stages of thermal oxidation, the primary effect is to convert the amorphous Ti-O to TiO₂. However, the preferential oxidation of Ti creates a Ni-rich zone at the TiNi/TiO₂ interface as well as nanocrystalline islands of pure Ni. Ultimately, these processes lead to the formation of an oxide scale, which easily cracks, exposes Ni to the environment, and leads to poor corrosion and biocompatibility. These results will be discussed in terms of processing parameters for medical devices.

Keywords: oxidation, TiNi, TiO₂, Ni, Ni₃Ti

Oral Poster

Biocompatibility of Smart Magnetic Materials for Medical Micro-Devices

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Background

The minimally invasive surgery is a new paradigm for medical operations and offers opportunities to develop new medical micro-devices. Smart magnetic materials can change their shape in a magnetic field. Hence it seems possible to use it to develop devices which can be activated with external coil. This paper introduces a discussion about the biocompatibility of two smart magnetic materials: single crystal Ni-Mn-Ga, a magnetic shape memory alloy which has a huge deformation (6%), and Terfenol-D, known for its high magnetostriction at room temperature.

Material & Methods

A MTT test is a cell viability test. The cells are in contact with extracts from the materials.

Results

The test shows that the degradation products of the Terfenol-D are not cytotoxic. The problem with the use of this alloy is its poor mechanical properties and its degradation in the medium. A test on Terfenol-D powder confirms that this material is not toxic. The test on single crystal Ni-Mn-Ga powder introduces the cytotoxicity of this alloy after 24hr of incubation. A test on a single crystal bulk sample will allow us to conclude about the Ni-Mn-Ga alloy biocompatibility.

Conclusion

The Terfenol-D is a good candidate to develop medical device but inside a composite. A single N-Mn-Ga alloy has a great potential for medical device but it requires probably a surface treatment.

Keywords

biocompatibility, smart magnetic materials, medical micro-devices, Ni-Mn-Ga alloys, Terfenol-D

SeptRx: A new PFO closure solution

S. Kleshinski, C. Rice and S. Russell (listed in the program)

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Background

The market for devices to close the heart defect *patent foramen ovale* (PFO) is heating up based on recent information linking the presence of a PFO to severe migraine headaches. The presence of a PFO has also been identified as a contributing cause of cryptogenic stroke. A PFO contributes to these conditions by providing a pathway for emboli in the venous system to directly reach the arterial system by passing from the right atrium to the left atrium.

Device Description

Currently marketed percutaneous devices for closing PFOs are based on so-called “double umbrella” designs adapted from similar devices used to close atrial and ventricular septal defects. In contrast, the SeptRx PFO closure device has been designed from the beginning to address the unique anatomical and physiological challenges of the PFO. The unique design characteristics of the SeptRx device are as follows:

- SeptRx directly treats the pocket of the PFO while minimizing the impact to the atrial spaces, especially minimizing the residual material in the left atrium. SeptRx call this *IntraPocket Occlusion* or *IPO*TM.
- The internal mesh of the SeptRx device provides an immediate, reliable barrier to the conduction of emboli.
- The frame of SeptRx laterally stretches the pocket of the PFO to bring the septal tissues into contact and trigger the body’s natural adhesion response.
- SeptRx is delivered via a low profile (9 Fr), over-the-wire delivery system for increased safety and ease-of-use.
- SeptRx is highly radiopaque and fully recapturable.

Poster

Minimal Access Hysterectomy, Without Laparoscopy

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Fifty patients underwent minimal access hysterectomy without laparoscopy through a mean of 4.8cms transverse supra-pubic incision. There were no intra-operative complications, two patients had post-op Urinary tract infection, and one had two units of blood transfusion. Theses patients were compared with 50 comparable patients who underwent routine hysterectomies by the same surgeon; the mean uterine size was 11 weeks versus 14.7 wks; the mean hospital stay was 3.7days versus 5.7; the length of the procedure was 1.11 hrs versus 1.07 hrs and blood loss was 173mls versus 327mls respectively.

The new technique presented is associated with a small scar, reduced post operative hospital stay and low complication rate and does not require expensive laparoscopic equipment. In addition, a small transverse incision of around 4.7cms could be cosmetically more appealing than multiple port incisions dotted around the abdomen which are more visible.

In this technique: The abdomen is opened through small transverse incision, the broad ligament is opened and the ovarian pedicles ligated, the bladder is dissected off the cervix, then both uterine arteries are cut, the uterus is then split in the anterior wall and further on the sides to allow its delivery through a limited opening by pulling on suspensor sutures. The body of uterus is removed first; then the cervix could then be pulled up and two Le Forte clamps applied below the cervix on both sides and the cervical stump is then removed. The vaginal vault is then closed. The post-operative care is similar to that of regular abdominal hysterectomy.

Poster

Artifact Examination of Oxidized Nitinol Wire in MRI at 0.3; 1.0 and 1.5 T

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Alan Pelton, Christine Trepanier, J&J ND&C, Fremont, CA, USA
Andreas Melzer, INSITE med. & Dept of Physical engineering University of Applied Sciences, Gelsenkirchen, Germany

Background

MRI examination of susceptibility artifacts related to the oxide of Ti49.8Ni50.2 medical grade wire.

Material & Methods

3mm diameter Nitinol wire was annealed at 1000°C for 30 minutes, centerless grounded and electro-polished. 30mm sections (d=1mm) were oxidized in air at 400-1.000°C for 10 minutes. Oxide thickness was measured by FIB/SEM. Microscopic photos were taken. The response on a magnet was tested. Sections were examined in a 0.3T Hitachi and in 1.0/1.5T Philips. Samples were placed in a water filled test container, parallel and perpendicular to the main field. A Plexiglas bar with drill holes was used to fix samples. Spin (TR/TE=300/30ms) and gradient (TR/TE=100/6ms, FA=40°) echo images were obtained using the head coil.

Results

Oxide layers of 0.0338µm at 400°C up to 21.9µm at 1000°C were produced. Initial oxide thickness was 11nm. Thicker oxide layers are brittle and tend to flake. Up to 700°C samples showed no magnetic attraction, 1000°C strongest attraction. Parallel orientation does not cause artifacts in contrast to perpendicular. No artifact differentiation for up to 700°C, 1000°C strongest artifacts. From 0.3T to 1.5T the artifact size changes from 25x to 47x the original size for 1000°C.

Conclusion

Increased oxide thickness causes stronger artifacts and samples become magnetisable. Samples up to 700°C need to be better investigated for further comparison. Investigations should also be done at 3.0T.

Keywords

Nitinol, Nitinol oxide

Poster

Examination of Signal Behaviour of Different Nanoparticles in MRI

Daniel Sachtler, Andreas Melzer, INSITE Med, University of Applied Sciences, Gelsenkirchen, Germany
&
Christian Mayer, University of Duisburg, Germany
Andreas Langer, University of Duisburg; Germany

Background

Examination of signal behaviour of nanoparticle dilutions in preparation to visualize cells and medical devices in MRI.

Material & Methods

Iron-cobalt (7 vol%; d=10nm - Liquids Research), iron-platinum and iron-oxide particles (1-4 mass%) were investigated. Dispersions were diluted with distilled water and placed into test container. Imaging was done in a Philips at 1.0 and 1.5T. Spin (TR/TE=555/15ms) and gradient (TR/TE/FA=100/6ms/50°) echo was obtained using the head coil. Signal enhancement was analyzed using OSIRIS DICOM viewer and own written software. Contrast to water was plotted against particles per μl .

Results

Iron-cobalt particles achieved contrast of up to 200% at optimum concentration ($2.8\text{E}+8/\mu\text{l}$). Signal enhancement from $2\text{E}+7$ to $2\text{E}+9$ part/ μl . Iron-oxide particles produced signal enhancement from $5\text{E}+10$ to $3.7\text{E}+12$ part/ μl ; contrast to water up to 320% (510% if stabilized with citric acid). Optimum concentration at $5\text{E}+11$ p/ μl . Iron-platinum particles began to enhance signal at $1.8\text{E}+13$ p/ μl . Maximum concentration examined was $3.6\text{E}+14$ p/ μl (260% contrast to water). No artefacts, so that optimum might be at even more p/ μl .

Conclusion

Iron-oxides produced best contrast. Data to be reproduced; larger amounts of particle dispersion are needed for further investigations. Tests should also be done at 3.0T. Examination of cyto-toxicity and bio-compatibility is necessary.

Keywords

nanoparticles, contrast enhanced imaging, positive contrast, USPIO, SPIO

Oral Poster

Testing methods and standards for MR safety and compatibility of medical devices

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Background

MR safety and image compatibility are important issues for medical devices. ASTM International F2503-05 provides marking requirements and asks for testing results.

Material & Methods

Magnetically induced displacement forces can be measured via a deflection angle test. Magnetically induced torque aligns a device to the magnetic field and is measured at the magnet isocenter. ASTM F2052 and F2213 provide standard testing methods. Radio frequency (RF) induced heating is a multi-parameter dependent MR safety issue. ASTM F2182 provides a basic test method. Computer simulation of electromagnetic fields, SAR and temperature distribution assist in heating testing.

RF pulses and switched gradients can induce voltages in conductive structures. So far, no appropriate standardized test method is available.

The safe functioning is a concern for the MR system and the device respectively. A device must undergo an individual test procedure.

MR imaging artifacts can lead to significant lack of information and thus shall be included in device labelling with results from ASTM F2119 standard test method.

Results

Comprehensive investigation of all interactions and worst-case scenarios is necessary. MR test methods for magnetic force, torque, RF heating and MR artifacts are established. Continuous redefining is required. Further issues have to be examined for standardization. Multi-parameter dependent issues need implementation of computer simulation.

Conclusion

Standardized MR testing of medical devices and items is compulsory for minimizing patient risk, providing the MR user with a safety labelling and guide manufacturers in device development.

Keywords

magnetic resonance imaging, MRI safety, MRI compatibility, MR testing, magnetically induced force, torque, RF heating, induced voltages, MR image artifacts, computer simulation, electromagnetic fields, SAR

Latest imaging performance tests in CT and MR scanners to detect In-Stent Restenosis

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Background

The latest developments in imaging technologies like computer tomography (CT) and magnetic resonance imaging (MRI) increased their application for diagnostics in coronary diseases.

Material & Methods

To explore the impact of different stent material and design properties on CT and MR imaging new in-vitro test methods were developed. For CT in-vitro testing a polymeric stick containing a stenosis inlay was used as a vessel phantom. Expanded coronary stents were stripped over sticks with different diameters between 2.5 and 4 mm. The inlays were manufactured to achieve restenosis levels between 30 - 80%. For MR imaging expanded peripheral stents with 8 mm diameter were embedded in a phantom. The in-stent restenosis was achieved by a waisted tube in the stent lumen filled with a contrast media. Scanned data was correlated with fluoroscopy results.

Results

Both in-vitro test methods produce results helping to understand artifact causes. Additionally they give guidance for future stent development and help cardiologists to interpret their in-vivo results.

Conclusion

Stent material appeared to influence vessel and stenosis visibility to a greater degree than Stent design or strut thickness. MRI phantom study, the results indicate clearly the metallic artifact induced by the stent observers to localize the stent.

Keywords

CT, MRI imaging, stent phantom, In-Stent Restenosis

Micro Machining of Nitinol

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Background

The authors review the current state of micro machining and joining techniques of nitinol materials for medical device applications such as laser cutting, EDM, photochemical etching, laser welding, subsequent surface finishing and inspection methods.

Material & Methods

The paper discusses the status of the above processes applied to nitinol tube and sheet material under practical engineering aspects and their potential for dimensional accuracy, further miniaturization, and multifunctionality of medical components. A focus is on laser technologies due to their key role for micro cutting and joining nitinol materials both with itself and with other metals.

Results

Special emphasise has been placed on the effect of processing techniques on shape memory and superelasticity, corrosion behaviour, biocompatibility as well as on the fatigue behaviour of Nitinol components.

Conclusion

Metallographical, electron optical, surface analytical methods as well as accelerated corrosion and fatigue tests are used to assess the quality of fabrication processes. Finally actual applications of above techniques in todays and future medical devices are discussed.

Keywords

Micro machining, nitinol, medical components,

BIOCOMPATIBILITY AND CORROSION BEHAVIOR OF NITINOL IMPLANTS IN DEPENDENCE ON SURFACE CONDITION

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Background

Due to its superelasticity and biocompatibility, NiTi is the material of choice for medical implants. In-vitro studies report a strong correlation between surface condition, biocompatibility, and corrosion performance.

Material & Methods

Fundamentals of corrosion and biocompatibility for various metal surfaces within biological environments will be reviewed. We will discuss individual potentiodynamic polarization curves and characteristics for NiTi in comparison with other advanced stent materials. The electro-chemical behaviour of Nitinol with Platinum Iridium, Gold and Tantalum will be presented, too.

Results

Surface finishing by electropolishing of Nitinol is state-of-the-art for achieving a highly biocompatible implant surface. The impact of various surface-finishing technologies such as electropolishing vs. mechanical polishing and/or advanced surface treatments (e.g. passivation) on the corrosion behaviour will be discussed in detail.

Conclusion

Surface roughness and topography have been analysed by SEM (scanning electron microscopy) and AFM (atomic force microscopy). In addition, the exact surface condition was further investigated by Auger analyses to characterize and quantify the impacts on biocompatibility.

Keywords

Biocompatibility, corrosion, NiTi implant, surface

Comparison of Whole-body FDG-PET/CT and Whole Body MRI at 3 T for Tumour Staging in Oncology

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Background

To compare the accuracy of PET/CT with whole-body MRI (WBMR) in staging different malignant diseases.

Material & Methods

60 consecutive patients with known primary tumours underwent FDG PET/CT for tumour staging (GE Discovery ST 16). Imaging evaluation was performed for CT alone, PET + CT viewed side by side, and fused PET/CT data. WBMR examinations were performed with a 3T system (Philips Achieva). A coronal STIR-sequence was used before and after administration of 20 ml of GD-DTPA at 2ml/sec. Histopathology or clinical follow-up of 6 (+/- 2) month served as standards of reference.

Results

Fused PET/CT proved significantly more accurate in assessing the overall TNM stage compared to CT alone ($p<0.05$), side-by-side CT + PET ($p<0.05$) and WBMR. Of all 60 patients 54 (90 %) were correctly staged with PET/CT, 42 (70 %) with side-by-side CT + PET, 38 (63 %) with CT alone and 36 (60%) with WBMR. No statistically significant difference could be detected between PET/CT and CT + PET in assessing M-staging. Combined PET/CT had an impact on the treatment plan in 3 patients compared to other PET modalities and with 2 patients compared with WBMR.

Conclusion

Dual-modality is significantly more accurate than CT alone and side-by-side CT + PET when staging different malignant diseases. WBMR is an effective and fast method for staging cancer patients but cannot reach accuracy of FDG-PET/CT.

Keywords

Tumor staging, FDG-PET/CT, whole-body MRI (WBMR)

Poster

Conservation system for organs

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Background

We offer training courses for the medical doctor, engineer or students using animal organs to simulating the reality. The problem with explanted organs is that they develop rigor mortis and rapidly decay. The conservation system VivoCell is based on a computerized hyperbaric oxygenation conservation that preserves the physical characteristics and texture of the organs.

Material & Methods

The conservation system consists of a pressure container. Organs are placed in a cylinder. Vasculature is connected and perfused with a solution (2.5 l NaCl 0.9% with 1 l Custodiol). This cylinder will be cool down all the time by the conservation process. The pressure (max 800 kPa), temperature (280 K) and the volume flow from the pump are controlled over a computer and special hardware components. The software can be individually adapted for the organs.

Results

First test series with muscle tissue in the pressure container were successful. The specimen showed up 14 days a normal texture. Further tests have been performed with a fresh porcine heart with perfusion. The out gassing of the heart is observed after the loss of pressure at 0 Pascal. To avoid this out gassing we are now searching for a special decompression time for the organs as well as an increased level of oxygen.

Conclusion

Vital organs can be conserved with oxygenation process and can be longer used completely applicable for tests of new methods, materials and instruments for development and research.

Keywords

Organ conservation

Nitinol in Medicine

From scientific curiosity to material of choice for medical devices

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Hardly any other material has had such an impact on the way interventions are done. The superelasticity and shape memory of Nitinol, an intermetallic compound of Nickel and Titanium, allows implants and/or instruments to be entered into the body through small entryways (incisions or body openings) and deployed to functional configurations at the treatment site. The deformation behaviour of Nitinol resembles that of natural materials like bone and tendon, making Nitinol implants more biomechanically compatible. Self-expanding stents made from Nitinol, for example, have transformed endovascular intervention. They have become the mainstay of most peripheral vascular interventions, exhibiting optimal wall apposition, gentle chronic outward force, high radial resistive force and crush recoverability. The unusual material characteristics of Nitinol will be explained and their relevance for the functionality of medical devices discussed.

Oral Poster

MRI-GUIDED ROBOT FOR PROSTATE INTERVENTIONS

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Louis Kavoussi, Johns Hopkins Medicine, Baltimore, USA

Background

MRI provides the best visualization of the prostate and its surrounding anatomy. The principal limitations to routine image guided intervention (IGI) use are the challenging MRI environment and scanner ergonomics.

Material & Methods

An MRI compatible robot (MrBot) was developed. The robot is designed for transperineal percutaneous prostate interventions, and customized for fully automated MRI-guided brachytherapy. With different end-effectors, the robot applies to other prostate IGI. The robot is constructed of non-magnetic and dielectric materials and is electricity free using pneumatic actuation and optic sensing. A new actuator (PneuStep) was developed to provide easily-controlled, safe, and precise motion by using a stepping principle.

Results

The robot fits standard, closed-bore MRI scanners along the patient. It is able to stay fully operational during MR imaging without deteriorating the quality of the scan. Tests in tissue mock-ups have shown 0.7 mm (SD 0.36 mm) seed placement errors. The robot tested without any interference up to 7T.

Conclusion

The robot presents uncompromised MRI compatibility by using the first fully MRI compatible motor. It is capable of automated, highly accurate needle placement. Prior to any clinical use, more extensive testing will be performed. We believe that the robot may become a useful IGI instrument. The PneuStep motor may also allow for other IGI robots to be developed.

Keywords

MRI, robot, pneumatic, motor, brachytherapy

High Manoeuvrability Superelastic Guide Wire with Functionally Graded Properties

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Background

The Shape memory alloy (SMA) with superelasticity (SE) is attracting considerable attention as materials for medical devices such as guide wires for catheters etc. The tip portion of the guide wire must be flexible to pass through the blood vessels, while in the body portion of the guide wire, high strength against bending is also required to overcome the high resistance to bending in a blood vessel. Stainless steel and Nitinol guide wires have been widely used. The Nitinol SE wire shows excellent flexibility, but the strength and the responsibility for rotation are insufficient because of low stiffness. On the other hand, the strength of the stainless steel wire is high, although the responsibility for rotation is poor.

Material & Methods

The Cu-Al-Mn and Ni-free Ti-based alloys were used for developing new classes of guide wire with functionally graded properties.

Results

The present authors have developed Cu-Al-Mn-based alloys with excellent ductility and large SE strain. Moreover, it was found that the stiffness significantly increases by ageing. Based on these findings, we have attempted to control the mechanical properties of the tip and end parts individually by employing thermo mechanical treatments.

Conclusion

A new class of guide wire possessing mechanical properties graded from the tip to the end is reported. And, new type of catheter using Ni-free Ti-Mo-Sn SMA are presented.

Keywords

Cu-Al-Mn alloy, Ti-Mo-Sn alloy, superelastic guide wire

How to not forget the duodenum after eso/gastro-jejunal anastomosis? An ultrasound solution

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Background

After total gastrectomies or Bilroth II resections-, the duodenum remains excluded from the digestive circuit. Neither radiology nor endoscopy are of any use. Based on his own experience and also on the scientific literature concerning the ultrasound diagnosis of duodenal pathology, the author makes a simple proposal, proving the value of transcutaneous ultrasonography (TCUS) in the identification of the restant duodenum.

Material and Methods

First 2400 patients are included in screening ultrasound examinations. There are checked the normal values of the wall thickness, the structure, the mucosal folds, the containment, the relationship with neighbour organs.

On a 51 patients lot with excluded duodenum after surgery for gastric cancer or non tumor pathology, was applied an ultrasound protocol of investigation using Color Doppler and Power Doppler devices with 2,6 MHz, 3,5 MHz and 5 MHz, 6 MHz, 7 MHz frequency probes.

Results

As a first point of interest, we obtain concluding details about duodenal stump with a normal healing process of about 6-8 weeks, but also about pathological evolutive signs: leaks, local abscess and pneumoperitoneum. On the same time we obtained relevant data concerning the relation with Common Biliary Duct, Wirsung Duct, Pancreas.

An enlarged duodenal wall with hypo echogeneity of submucosal layers was correlated in two cases with histopathological aspect of chronic duodenitis.

A diameter less than 50 mm, accompanied by alimentary fragments can be considered normal findings in long term evolution of excluded duodenum. A larger duodenum up to 90 mm with an higher intraluminal echogeneity conduce to the suspicion of aferent loop syndrome

Discussions

The screening showed a 2.6 mm average thickness of duodenum wall. For any preoperative ultrasound examination of the duodenum, to identify the pilor is mandatory. In post surgical patients the landmarks for duodenal location are: the Portal Vein, the Common Duct, the Gall Bladder and the Head of Pancreas. In these patients ultrasonography earns importance because of the particular missing of efficiency of the endoscopy and XRay.

Conclusions

TCUS (performed by surgeons) could be of a real benefit after eso or gastro-jejunal anastomosis, remaining the only one real-time imaging method suitable to following-up of the duodenum.

Penelope Surgical Instrument Server

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The PenelopeTM Surgical Instrument Server is a partly autonomous, machine-vision guided, robotic surgical assistant. Penelope uses voice recognition to respond to the surgeon's verbal request for an instrument and hands the instrument to the surgeon with a robotic arm. Using a visual capability, the robot locates the instruments that the surgeon has finished using and returns them to the instrument tray.

Overall behavior of Penelope is controlled by a software "cognitive architecture". The cognitive architecture contains a rule-based inference engine and a set of rules. These rules are essentially IF-THEN statements. Inputs to the cognitive architecture come from the robot's sensory systems such as the visual and speech recognition systems. Inputs also come from sensors which monitor the internal state of the robot, such as position sensors in the joints of the arm. When the conditions of an IF clause of a rule are met, the rule "fires", producing some sort of output of the robot. Outputs may be motor actions, speech utterances or internal "assertions" that are presented back to the inference engine for further consideration. With a fairly large number of rules, very complex behavior can be produced, potentially giving the robot great flexibility to respond to varying conditions including off-nominal ones.

The robot's software also includes a "prediction engine". The prediction engine keeps a simple database about a surgeon's individual preferences. With this database, statistical techniques are used to anticipate the surgeon's requests for instruments. The more experience the software has with a particular surgeon, the better its predictions become.

The machine-vision system is another feature of this robot. Machine-vision identifies and counts surgical instruments. Machine-vision is an excellent way to count all of the items used in surgery including small things such as surgical sutures and orthopedic screws.

Penelope is the first of a new type of autonomous robotic surgical assistant. These robotic co-workers will improve the quality, consistency and safety of surgical care for civilians, soldiers and space travelers. The National Science Foundation, the US Army's Telemedicine and Advanced Technology Research Center, the Defense Advanced Research Projects Agency, the New York-Presbyterian Hospital, and the Department of Surgery of Columbia University deserve the credit for making this innovation happen.

New Nano-Scale Oncotherapy approaches inspired by Computational Biophysics

Jack Tuszynski, University of Alberta, Canada

Background

My group has been involved in computational cell biophysics research over the past decade. In this talk I will give an overview of our quantitative understanding of the key cellular protein, tubulin, & its cylindrical polymers called microtubules. Since 1998 when the Berkeley group of Ken Downing was able to crystallize tubulin, our focus shifted to the application of molecular & Brownian dynamics of tubulin in the quest to understand the relationship between atomic resolution structure & biological function. We have now concentrated our efforts entirely on one key issue, i.e. a rational drug design targeting tubulin with molecules that would interfere with the formation of mitotic spindles during cell division. In collaboration with biochemists & oncologists from the Univ. of Texas our group is using computational methods applied to rational drug design of anti-mitotic compounds with specific preferences for tubulin isotypes. I'll describe our results in the early stages of this exciting research project. New promising compounds will be presented that represent a class of taxane derivatives with better targeting and binding properties. In addition, our better understanding of mechanical properties of microtubules has led to the design of new treatment modalities based on the use of ultrasound, laser action & magnetic fields.

Keywords

cell biophysics; key cellular protein; tubulin; cylindrical polymers

Noninvasive Cancer Therapy: The need for better therapy of cancer is still unmet

Alexander L. Weis, Ph.D., OncoVista, Inc. San Antonio, Texas, USA

Background

The need for better therapy of cancer is still unmet. Advances in treatment (surgery, radio-and chemo therapy) have made only a modest overall impact on mortality. The majority of solid tumors, especially in metastatic form, are difficult to treat. The patient's quality of life is an ongoing concern. This presentation will address new approaches to treatment and ultimately, eradication of cancer based on our improved understanding of the genomic and molecular pathology of cancers. OncoVista's approach to novel, nontoxic and highly efficacious drugs will be discussed along with a critical assessment of current innovative efforts to combat the disease.

Keywords

solid tumor; metastatic; eradication of cancer; genomic and molecular pathology

Innovations in Innovations

Mike Wiener, Biophan Inc. West Henrietta (Rochester) NY, USA

Innovation is often moving along amid the rocks and shoals of institutional and financial constraints and barriers, and not always progressing in the way we might wish for. Successful innovations, those which finally make it through the gauntlet, are proven effective, and get to market and widespread utilization, and which, ideally, bring their inventors and their champions and organizations fame, fortune, and recognition, are few and far between. Society would be much better off if innovation occurred at a more rapid pace, and if there were fewer crashes and failures along the way, particularly with meritorious innovations in the life sciences and in medical devices. Not all of the meritorious ones survive the journey. Were there a higher probability, less risky, less irksome and aggravating, and a means for innovators to cut a swatch through the thickets of problems, obstacles and naysayers, and to get their innovations to market, this would be an innovation of great merit and import. A few selected alternative paths to innovation and progress are reported in this presentation, including several that are the topics of scientific paper at SMIT2006.

Standards for Safety of Medical Devices in MRI

Terry Woods, FDA Center for Devices & Radiological Health

Background

The use of MRI continues to expand, both as a diagnostic tool and in an increasing array of interventional MRI procedures. At the same time, the number of patients with permanent implants increases by the hundreds of thousands each year. These two situations have combined to create an ever-increasing demand for both implants and a rapidly expanding array of interventional devices that are safe in the MR environment.

Material & Methods

Five standards have been developed in ASTM International that address the principal safety issues for passive implants. Some also address active devices, and work is continuing to expand and augment the test methods to cover active implants and other devices.

Results

This talk will describe the major issues that can impact the safety of implants and other devices in the MR environment, present the current ASTM International MR test methods, outline the ongoing process to develop additional test methods, and present the new MR safety icons and the terms MR Safe, MR Conditional, and MR Unsafe.

Conclusion

Finally, it will discuss future standards development work that must be undertaken to continue to assure that medical devices are safe in the MR environment.

Keywords

MRI safety, standards, test methods

Medical Stents using Ti-Ni-base Superelastic Alloys

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Background

Recently, the shape memory alloy (SMA) with superelasticity (SE) such as Ti-Ni alloy is attracting considerable attention as materials for medical devices such as guide wires for catheters, stents and so on. In recent years, two types of metallic stents have been utilized: balloon-expandable (BX) and self-expandable (SX) types. The main materials of BX and SX stents are stainless steel and Ti-Ni SE alloy, respectively. BX stents are superior in mountability and radical force due to their high Young's modulus. However, they may fracture due to the accumulation of plastic strain. On the other hand, Ti-Ni SE stents are more flexible in native vessels and rarely injure the arteries, so when employed in carotid arteries near the surface of the body, they are able to sustain deformation by external pressure. Therefore, SX stents are used for carotid artery and so on.

Material & Methods

The Ti-Ni superelastic alloys and the Ti-Ni-Nb shape memory alloys were used for development of new type of stents.

Results

The Ti-Ni SX-covered stent for aneurysm and the balloon expandable superelastic Ti-Ni-Nb stent were developed.

Conclusion

In this presentation, recent progress in SX bare stent and covered stent using Ti-Ni SE alloys is reported. And, new type of balloon expandable SX stent using Ti-Ni-Nb SE alloy which would show excellent deliverability and mountability is introduced.

Keywords

Stent, shape memory alloy, Ti-Ni-based superelastic alloy

Are cold light sources really cold?

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Background

A fibre optic light source is the central part of endoscopic surgery. However, the light generation process causes heat transmission from a source to tip of a scope. In this study, we measured the amount of heating and pathological effects of direct contact with the tip of scopes on the small bowel in an experimental set-up.

Material & Methods

Temperature measurements were performed at the tip of four different scopes, which were connected to either of three different xenon light sources. Tissue samples from the small bowel of a pig were obtained after exposing them to direct contact with the tip of the scopes or the fibre optic cable.

Results

The temperature measurements at the tip of the scopes varied between 60 to 100 °C. The temperatures showed a wide variation according to the type of light source and fibre optic cable the scopes were connected to. The average temperature at the outlet of the light sources and the tip of fibre optic cables was 750 and 250 °C, respectively. The microscopic scores of the small bowel injury induced by exposition to the heat at the tip of the scopes were significantly high after 5 seconds of contact. Direct contact of the tip of the fibre optic cable caused total carbonization in the wall of the small bowel.

Conclusion

Direct contact of the tip of the scope with small bowel may cause functional and cytological injury even after short durations of exposure.

Keywords

laparoscopy, endoscopy, temperature, xenon light source, small bowel

A Method for the Theoretical Evaluation of Wire Heating in MRI

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Background

We present initial electromagnetic field simulations of MRI experiments to quantify the relative effects of several variables on RF-induced wire tip heating: total wire length, inserted length, wire position in the body, and body position in the scanner.

Material & Methods

Using a commercially available Method-of-Moments (MoM) EM field solver, simulations were performed for the simplified case of a straight conductive wire partially inserted in a finite homogeneous lossy dielectric (simulating the body) excited by a finite birdcage coil at 63.9 MHz (1.5T). Resulting local SAR was averaged with a physiologic weighting function based on the Green's function of the tissue bio heat equation.

Results

Simulation results conform well to data in the published literature. Heating increased as the body was moved further off-center towards the bore wall and as the wire was moved off-center towards the body surface. Maximum heating was found when the inserted length was a half wavelength (~20 cm in the body) and the exposed length of the wire was a quarter wavelength (~1.2 m in air). This implies that a ~1.4 m guide wire may be the worst possible length in terms of RF heating.

Conclusion

This initial work demonstrates the utility of MoM field solvers coupled with physiologic SAR averaging for evaluating RF heating due to conductive wires in MRI.

Keywords

MRI, interventional MRI, RF heating, safety, specific absorption rate, SAR, guidewires, wire tip heating

Oral Poster

Future operating room in Trondheim

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Background

With the challenges that the health sector now faces in accordance to readjustments and demands for increased efficiency, resource utilization and innovation, we have initiated a project to develop the future operating rooms for advanced laparoscopic surgery and endovascular treatment.

Material & Methods

To share experiences and avoid re-conducting the same mistakes as others, we find it suitable to build operation theatres for research and development where we can try out and study new equipment, logistics and communications, operation forms and new technology which both benefit the establishment of the hospital and the establishment of other hospitals and laparoscopic operating rooms nationally and internationally.

Results

The main goals in the project are, through research and development to reveal information and develop technology and methods to establish a more efficient and prospective patient treatment, focused on quality. Furthermore, the new ORs are focused on education and training through an interactive integrated surgical auditorium. The project is deeply rooted in the established research environment in Trondheim.

Conclusion

The goal is also that this will result in the establishment of new industry. Examples from ongoing research activities and projects related to the OR for laparoscopic surgery will be shown in the presentation.

Keywords

future operating room, minimally invasive surgery, laparoscopy, endovascular therapy

How do we construct operating rooms for treatment of vascular disease?

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Hans Olav Myhre, Dept of Surgery, Trondheim, Norway

Background

Traditionally, operating rooms are expensive to build and to run. There is usually lack of flexibility when new surgical methods are introduced into the clinical setting. At St. Olavs Hospital, University of Trondheim, where we are building a completely new hospital, we wanted to focus on research and development to solve some of these problems.

Material & Methods

The unit consists of two operating rooms; one for laparoscopic surgery and one for endovascular therapy. A lecture room in the upper floor allows medical students and specialist candidates to follow procedures on HD-screens on a PC.

Results

A part of this project has been to evaluate what is necessary regarding separate rooms in the neighbouring areas of the operating room itself. A preliminary conclusion is that only the operating room is absolutely necessary while other areas including offices etc. can be replaced. By performing these architectural changes, we think that it is possible to save about 20% of the construction costs for operating rooms compared to traditional construction.

Conclusion

In the operating room for endovascular therapy we have integrated an angiography laboratory with facilities for open surgery. We feel this is important because vascular surgeons and interventional radiologists are to a greater extent working together in the treatment of vascular diseases

Keywords

Vascular surgery - Operating rooms

The Effect of Navigational Aids (virtual fixtures) on the Performance of a Computer Generated Navigational Task; Implications for Virtual Endoscopic Training Systems.

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Virtual fixtures have been shown to improve performance in virtual navigational tasks. Graphic and haptic virtual fixtures were added to a computer generated navigation task consisting of manipulating a virtual object through a maze; the input device was a Phantom stylus and the maze was a two story graphical structure designed in the Virtual Hand Lab. at Simon Fraser University.

32 subjects underwent 15 training trials under four conditions; a green graphic tunnel showing the direct path; or force fields guiding the most direct path; or both haptic force fields and the graphic tunnel; or no virtual fixtures. After 15 training trials, all subjects were transferred to five trials of the same navigation task with no navigational aids.

The results showed significantly improved performance in the initial trials by the haptics and haptics plus graphic groups when compared to the graphic only and no virtual fixtures groups. In contrast, in the transfer trials, the haptic and haptic plus graphic groups showed the greatest deterioration; the best transfer performance was by the group that initially learned to navigate the maze with no virtual fixtures.

These results have implications for the design of virtual endoscopic navigation training systems; for example in angiography, catheter insertion and teleoperation.