Guest Editorial
Introduction to the Focused Section on Surgical and Interventional Medical Devices

I. Introduction

ADVANCED mechatronic medical devices are able to assist physicians deliver less invasive and less disruptive diagnoses and therapies, while enabling novel medical procedures. The adoption of new mechatronics technologies by the medical device sector has historically lagged behind nonmedical fields, such as automotive, aerospace, and consumer products. This is partly due to regulatory constraints, but while these constraints still exist, there is great opportunity to accelerate the translation of the latest advances for medical applications under development by numerous academic and industrial centers around the world.

This "Focused Section on Surgical and Interventional Medical Devices" of the IEEE/ASME Transactions on Mechatronics highlights several important medical technology achievements enabled by mechatronics. Cross-disciplinary topics target both the engineering audience and the clinical community. It strives to encourage collaboration between innovative engineers and clinicians, and includes contributions by clinical authors and coauthors.

The next steps are likely to address technologies that will make the medicine less expensive and more accessible to the population at large, and provide a more uniform standard of care and quality control across physicians, hospitals, and geographic regions.

II. Highlights of the Focused Section and Other Mechatronic Devices Presented in the Transactions

The main applications of the new mechatronics devices presented in this section are related to cancer diagnosis, cure, and management as this remains a clinical need of paramount importance across the world. Even though cancer incidence rates decreased in the most recent time period in both men (1.3% per year from 2000 to 2006) and women (0.5% per year from 1998 to 2006), a total of 1 529 560 new cancer cases and 569 490 deaths from cancer are projected to occur in U.S. in 2010 [1].

Several novel mechatronic devices have been reported in this respect that relate to the following topics of clinical relevance.

A. Intraprocedural Tumor Localization

Papers related to cancer localization during surgery or image-guided interventions include new devices, such as a noncontact tumor imager for video-assisted thoracic surgery, a tactile force feedback system, and a laser-scanner sensor for intraprocedural registration. Previous issues of the Transactions included other interesting developments in this respect, such as a leader–follower system for remote control of ultrasound probes [2].

Design of Noncontact Tumor Imager for Video-Assisted Thoracic Surgery: T. Kawahara, Y. Miyata, K. Akayama, M. Okajima, and M. Kaneko; from the Hiroshima University, Higashi-Hiroshima Medical Center, Osaka University, Japan.

The paper presents a very interesting method of detecting the presence and location of tumors in lungs during minimally invasive thoracic surgery. Even though lung tumors are typically visible with medical imaging, such as computed tomography (CT); during the operation, the lungs are usually collapsed making it difficult for the surgeon to find their location based on preoperative images. Finding the stiffer nodules by palpation is limited due to the restricted port access. Moreover, ultrasound is the most common interventional and intraoperative imaging device, but is notoriously problematic due to the presence of air in the lungs, and is difficult when the lungs are collapsed. X-ray fluoroscopy and anchor needles used as markers are now used for locating the tumors. Researchers have developed several types of sensors and proposed various modes of displaying tactile information, including one that simultaneously displays tactile and kinesthetic mode presented in this Focused Section of the Transactions by a Canadian research group.

A novel sensor built in the form of a 10-mm laparoscopic instrument for detecting the location of tumors by scanning the surface of the lung from a distance of approximately 10 mm is presented. When a relatively stiffer region is detected, the instrument indicates its presence with visual and audio signals alerting the surgeon of a possible tumor.

The instrument uses a noncontact sensor implemented with an air nozzle directed toward the surface of the lung that causes the surface to deform and an optical displacement sensor used to quantify the magnitude of this indentation. The key novelty of the approach is that rather than using the magnitude of the displacement in a typical strain–stress arrangement, the authors use a phase-shift approach. As such, the air supply is pulsed to create a wave excitation and relative tissue properties are estimated based on the phase shift of the resulting displacement. The paper presents how this phase difference varies according to the change in material parameters. It is also very instructive to see in this paper another example of how the use of Lissajous curves can help interpret complex harmonic motion.

A well devised set of *in vitro*, *ex vivo*, and even clinical experiments performed in seven patients is presented. The results appear to be a very promising starting point for this prototype

Digital Object Identifier 10.1109/TMECH.2010.2085010

to become an effective clinical instrument, subsequent to verification and validation trials that the group is preparing. One current limitation of the sensor is related to the presence of bronchial tubes and blood vessels in the human lung that appear to cause detection errors. These could be reduced with additional depth information and tissue/system modeling that the group is planning to include. The angle of approach of the air nozzle with respect to the normal surface of the lung is also a factor in the current design and may be a limitation for the minimally invasive approach. Readers will find it interesting to follow the research of this group and observe their new ingenious approaches. Overall, this is a very interesting and instructive paper that could stimulate other research and clinical applications, and future reports of their work are expected with great optimism.

Initial Evaluation of a Tactile/Kinesthetic Force Feedback System for Minimally Invasive Tumor Localization: M. T. Perri, A. L. Trejos, M. D. Naish, R. V. Patel, R. A. Malthaner; from Lawson Health Research Institute and University of Western Ontario, London, ON, Canada.

One of the most important limitations of minimally invasive surgery techniques is the lack of direct contact to the operative site making tumor location difficult for the surgeon. In open surgery, tumors are typically found by direct manual palpation, since tumors are commonly stiffer than neighboring healthy structures of the same organ. Several ingenious remote force feedback and palpation devices have been proposed, yet no technology is available on a large commercial scale till now. Research continues for the development of tactile sensors using piezoelectric [3]–[5], capacitance-based [6], [7], polymer-based [8], and other types of sensors. In this Short Paper included at the end of this Focused Section of the TRANSACTIONS, a research group from Japan presents a new way of using pulsating air jets to detect tumor location. Tactile displays that represent the information of the remote sensors at the fingertips have been proposed [9] but the problem is very difficult due to the need for miniaturization of a high number of display elements. There is also difficulty in representing haptic interactions with surfaces, especially with their texture.

Alternative approaches include other ways of displaying the information of tactile sensors, including audio and visual feedback, in which kinesthetic learning is employed to gradually convey tactile feedback to the surgeon. This paper presents a new visual kinesthetic method for displaying information from a commercial tactile sensor TactArray (Pressure Profile Systems, Los Angeles, CA). This is a capacitance-based sensor with sixty 2-mm square elements arranged in a 4×15 grid. A visual display provides a real-time color contour map of the contact region as measured by the sensors together with an analog display of force magnitude. A comprehensive calibration methodology of the array sensor is presented and performed with specially developed instrumentation. Tests on ex vivo bovine liver were performed by human subjects controlling the instrument with and without visual force feedback, revealing that the kinesthetic visual feedback is instrumental to successful palpation. Statistical significance has not been fully documented in this study mainly due to the reduced number of subjects.

The gold standard for the study was taken from X-ray fluoroscopy images, which can very accurately to detect the locations of simulated tumors embedded in a mockup. Manual palpation, which is the most common way of surgical localization, would probably be less competitive for the instrument.

This is a very interesting and instructive paper including a well written introduction to the field. New reports from this group are expected with improved calibration, higher power studies, and perhaps instrument versus manual investigations.

Intraprocedural Registration for Image-Guided Kidney Surgery: R. E. Ong, C. Glisson, H. Altamar, D. Viprakasit, P. Clark, S. D. Herrell, R. L. Galloway; from the Vanderbilt University, Nashville, TN.

Intraprocedural tumor localization may be a difficult task for the surgeon even if the operation is performed in a classic open fashion. The two previously discussed papers presented novel sensors and ways to display tactile information for minimally invasive surgery. Here, researchers describe a way to locate the tumors based on preoperative images, which complements palpation and is especially useful when the tumors are embedded deep within the organ, making it more difficult to localize. This method applies to both open and laparoscopic surgical approaches and is being implemented for kidney procedures.

Partial nephrectomy is becoming more popular for kidney tumors that are relatively small and well localized within a lobe of the kidney and is the procedure of choice for patients with a solitary kidney. The group from Vanderbilt presents a novel method of tumor localization that uses an intraoperative laser range scanner to determine the surface geometry of the exposed or partially exposed kidney and a registration method to previously segmented images of the kidney (from CT or MRI) to intraoperatively localize the tumor based on the images. An optical tracker is used to determine the location of the laser scanner probe [10]. Based on the image-to-scanner and scanner-tracker mapping, surgical tools instrumented with tracking markers can be guided with respect to the image space providing intraoperative surgical navigation. As such, lesions and critical structures identified in the image can be used to guide the procedure, with the goal to better control the margins of dissection for resecting cancer suspicious lesions while sparing as much as possible of the other nephrons and vascular system of the kidney.

The methods and results presented in this paper represent enabling technologies for the development of novel medical mechatronics devices and image-guided robots [11] and may also enable image-fusion methods [12]. Target coordinates such as those provided by the laser sensor and registration method are required for advanced instrument and robotic navigation. The study also presents an alternative to the laser scanner that makes use of a daVinci (Intuitive Surgical Inc., Sunnyvale, CA) laparoscopy robot for generating the exposed surface of the kidney, scanning it with the tip of the probe. A practical way of dealing with organ shape changes by using a set of markers is also presented for the collapsed kidney on which blood vessels have been clamped.

Work continues for the development of other noncontact sensors and following reports from this group are expected. This is an informative paper that describes original sensing methods and includes a well-written introduction to the field of intraoperative registration.

B. Novel Laparoscopy Instruments

New instruments have also been reported for laparoscopy procedures. These include developments for the novel single-port laparoscopy (SPL) and natural orifice transluminal endoscopic surgery, as shown in the following. An advanced system with bilateral leader-follower configuration and a compact size for neurosurgery applications was reported in a previous issue of the TRANSACTIONS [13].

Toward the Development of a Hand-Held Surgical Robot for Laparoscopy: A. H. Zahraee, J. K. Paik, J. Szewczyk, and G. Morel; from the Université Pierre et Marie Curie, Paris, France.

Minimally invasive surgery has been perhaps the most active field of clinical innovation in the past decade and stimulated the development of the most notable applications of mechatronics in medicine. Clearance of the daVinci surgical system (Intuitive Surgical, Inc., Sunnyvale, CA) by the Food and Drug Administration (FDA) has marked a milestone for commercial distribution of medical robotics and substantially contributed to their widespread use and acceptance by the medical community and patient population. Considerable research efforts around the world are now dedicated to developing technologies that will enable novel procedures and improving upon the way that current operations and interventions are being performed. This paper is an example of such novel technologies reported from the Institut des Systems Intelligents et de Robotique in Paris, which is one of the leading medical research groups in Europe.

Laparoscopic surgery now has a large variety of clinical applications and is used on a very wide scale worldwide. The large majority of procedures are typically performed with manual direct-operated instruments. Yet the limited maneuverability of these “keyhole” instruments confines the dexterity of the surgeon and requires substantial training and surgical skill. The daVinci surgical system provides remote leader-follower operation with multiple degrees of freedom (DOF) that reverts the intrinsic inverted operation typical of keyhole instruments and substantially increases surgical dexterity. This paper presents an alternative to this fully robotic approach with laparoscopic instruments that are still controlled directly by the surgeon but provide additional degrees of intrabody motion for controlling wrist yaw and roll at the instrument tip.

First, the paper presents an instructive motivation for laparoscopy and needs for improved instrumentation in the field. Even though a comparison with fully robotic leader-follower instruments is omitted, the paper gives a well-balanced presentation of the commercial systems built for improving laparoscopic wrist dexterity. Original work presented includes an analysis of the motions encountered in laparoscopic surgery derived experimentally with an optical-tracking-based simulation system that they developed. Two modes of controlling tip DOF are investigated. Based on the analysis, a finger operated handle is selected and a Wii game console (Nintendo Corp., Kyoto, Japan) is used to control a dexterous 6 mm prototype instrument constructed by the team that shows an interesting snake-like design. Experimental testing of the prototype is presently limited and future work is expected with interest. This paper contains instructive elements for those entering the field of laparoscopic device developments, presents innovative ideas for current medical device research, and reports the development of a novel instrument.

Assemblable Three-Fingered Nine-Degrees of Freedom Hand for Laparoscopic Surgery: R. Oshima, T. Takayama, T. Omata, K. Kojima, K. Takase, N. Tanaka; from the Tokyo Institute of Technology and Tokyo Medical and Dental University, Japan.

Classic laparoscopic instruments present a rigid shaft and a one DOF end instrument at the tip, such as a grasper, needleholder, scissors, or forceps. More advanced instruments such as the Intuitive Surgical EndoWrist provide additional dexterity by adding a multi DOF wrist in close proximity of the end instrument. Similarly, the work presented in this Focused Section of the TRANSACTIONS from the Université Pierre et Marie Curie in Paris, France, shows a novel design of a manually controlled wrist joint.

The research group in this paper takes the end-instrument design to a new level of complexity and potential surgical performance with a design that includes a three finger hand, each finger exhibiting 3 DOF, an “endo-hand.” Their design and construction of the prototype reveals a marvel of miniaturization. Even though these three fingers are highly articulated and long (relative to human fingers) it is extremely impressive how these can be used through an available clinical size port (12 mm). Due to their dexterity and length compared to current laparoscopic instruments this new design may facilitate grasping, retracting, and manipulating large internal organs in a more natural way relative to common instruments. The conceptual role of this endo-hand is for the nondominant hand of the surgeon, to assist the use of laparoscopic instruments in his/her other hand.

The paper presents a very well devised design of the high-DOF mechanisms actuated through gears, cables, and belts. The three fingers present a detachable construction that can be easily attached to the main shaft, so that these can be assembled after passing the laparoscopic port. The paper also presents the construction of the prototype and shows the results of a set of bench experiments that among other show a force capability in excess of 4 N per finger. Two animal experiments are also reported already, which despite a few problems that the group is likely to revise showed that the device can be assembled within the abdomen. Future development of the haptic interface needed for its leader-follower control will likely make the manipulation easier which, in turn, may help with the assembly.

This is a novel design and development with great clinical potential. The paper has numerous educational aspects with respect to laparoscopy instrumentation and is also a great source of inspiration for future research presenting cutting-edge mechatronic technologies. Future developments of this novel instrument are expected.

Design of a Novel Bimanual Robotic System for Single-Port Laparoscopy: M. Piccigallo, U. Scarfogliero, C. Quaglia, G. Petroni, P. Valdastri, A. Menciassi, P. Dario; from Scuola Superiore Sant'Anna, Pisa, Italy.

Going along the other two laparoscopy instrumentation papers in this section, the research group from Pisa presents a truly novel robotic instrument for single-port laproscopy (SPL). This type of minimally invasive operation and the Natural Orifice Transluminal Endoscopic Surgery (NOTES) are the latest of minimally invasive surgical techniques to further reduce invasiveness and excess trauma. The problem, however, is that these procedures are so recent that instrumentation is not yet available, and the limited access constraints of these operations requires special, highly dexterous, miniaturized tools that push the limits of current medical mechatronics developments. This paper describes a novel system purposely designed for SPL, and is most likely the first such system being developed.

The instrument includes two 23 mm diameter and 142 mm long arms with anthropomorphic shoulder, elbow, and wrist joints, each totaling 6 DOF. The kinematics and designs of the transmission components for driving these slender high-maneuverability links is highly remarkable. Several of the motors used are located within the arms in a very interesting miniaturized arrangement. A sophisticated gear arrangement that forms a differential mechanism is presented for actuating the wrist joint. Most of the components appear to be built and preliminary tests are included. Next steps will include further miniaturization, finalizing some of the proximal joints, and control components of the leader-follower robot architecture. Comprehensive validation is expected especially validation that kinematic precision falls within clinical requirements since the complexity of miniaturization and design with several serialized gears may cause joints backlash.

This paper presents the design and ongoing construction of a pioneering robot of substantial clinical significance. Even though its contents are highly technical, this paper will also be of interest to surgeons because of and their level of interest in the novel SPL, and NOTES. Trainees will find a very instructive introduction to the field, and senior researchers will be delighted to see another marvel of engineering design from Prof. Dario's group.

ViKY Robotic Scope Holder: Initial Clinical Experience and Preliminary Results using Instrument Tracking: S. Voros, G. P. Haber, J.-F. Menudet, J. A. Long, P. Cinquin; collaboration between the University of Grenoble, Endocontrol, France and Cleveland Clinic, OH.

The ViKY robot originated from the Light Endoscope Robot (LER) developed at the "Techniques de l'Ingénierie Médicale et de la Complexité-Informatique, Mathématiques et Applications de Grenoble" Laboratory, Grenoble, France [14]–[16]. The revised ViKY version is now produced by an affiliated company also located in Grenoble (EndoControl Inc.). This paper presents a revised version of this robot, ViKY LX, which is adapted for the novel method of SPL.

From the very beginning, the LER robot presented a very distinctive feature among other medical robots; it was made sufficiently light so that it can rest on the skin of the patient with a ring construction around the laparoscopic port. Later, however, a support arm was also added to augment stability, but the light-ring construction is still maintained in the commercial version. The LER/ViKY is a relatively simple, but effective 3 DOF robot that supports, pivots, and inserts a laparoscopic camera. Another remarkable feature of these robots is that they are entirely sterilizable even with autoclave methods.

The ViKY robot has been used for numerous clinical cases in Europe. Results included in this paper show that the robot can safely and effectively provide a "third hand" to the surgeon during laparoscopy. The paper also presents a visual tracking method for orienting the laparoscope (so that it automatically follows other laparoscopic instruments) and tests of feasibility and safety in preclinical experiments. Finally, the robot has already been used in five SPL cases for radical nephrectomy. Refinements of the robot based on the conclusions of the experiments and trials are currently in progress and updates on the progress of this research group are expected.

This is a very interesting paper for engineers as well as clinical personnel. The paper includes tutorial as well as research components.

C. Ablations for Radiofrequency Ablation

A new robotic system helps correlate the regions of ablation with preoperative plans and a laparoscope is instrumented with an infrared laser for coagulation as shown in the following.

A Robotic System for Overlapping Radiofrequency Ablation in Large Tumor Treatment: L. Yang, R. Wen, J. Qin, C. K. Chui, K. B. Lim, S. Chang; from the National University of Singapore, Singapore.

RF ablation is a viable image-guided percutaneous therapy alternative to invasive surgery in specific cases of cancer treatment including liver, lung, kidney, and spine tumors, and is continuously gaining popularity for its relatively reduced complexity and affordability for a larger scale of patient population. However, image-guided needle interventions require substantial training and skill and are commonly performed by specialized interventional radiologists, whereas the field of radiation therapy benefits from and has largely embraced sophisticated means of image-based treatment planning, common RF ablation technology, methods, and techniques remain limited to the assessment of the physician placing the ablation probes. Significant challenges are related to properly defining and delineating the margins of ablation for complete tumor coverage yet preserving critical neighboring structures, in certain cases making it a very difficult intervention even in most experienced hands. Moreover, intrainterventional means of quality control are typically limited, so that clinical result validation is based on disease recurrence. RF ablations are even more difficult for larger tumors, when the size of ablation produced by one electrode is insufficiently large to cover its volume. In such cases, overlapping ablations are used for the treatment.

The paper presents a novel robotic device for handling a RF ablation needle and software that defines the centers of overlapping ablations based on CT images of the organ. The volumetric images are acquired before the intervention. A treatment plan based on an interesting voxel growing algorithm defines the centers of each overlapping ablation. An optical tracking method is used to track a set of skin markers providing the registration of the robot-image spaces. The needle is then successively placed automatically by the robot according to the digital therapy plan. The robot was designed with three passive and five active DOF. A prototype was then constructed and tested in animal experiments. Targeting accuracy results are on the order of 1 mm, which is likely acceptable for most clinical applications.

One of the possible limitations of the new device is the fact that the robot can only handle one needle at that time, since RF may require collective rather than successive ablations. Systems capable of handling multiple needles have been reported [17], [18], but only for brachy therapy interventions. Moreover, the kinematic design of the new robot includes numerous considerations related to the constraints of the percutaneous procedure (maneuvering the needle constrained at the incision port and creating a Remote Center of Motion (RCM) [19], [20]). Planning the sites of ablation based on interference constrains created by the previously deployed needles would be a great plus in following work. Similarly, using the robotic device within the imaging scanner in a Direct Image-Guided Intervention (DIGI) mode [21] has the potential to reduce registration errors and could be a new way of future developments.

Overall, this is a very interesting medical technology mechatronic development paper for its novel robotic development and intervention planning software. The paper is likely to be of interest for medical device researchers and informative for interventional radiologists and physicians attentive of image-guided procedures. Future development and clinical trial results will be expected with great interest.

An Endoscope with 2DOFs Steering of Coaxial Nd:YAG Laser Beam for Fetal Surgery: N. Yamanaka, H Yamashita, K. Masamune, T. Chiba, and T. Dohi; from the University of Tokyo and the National Center for Child Health and Development, Tokyo, Japan.

This paper presents a very interesting device, which modifies a rigid endoscope so that it can transmit an infrared laser beam coaxially through the shaft of the scope without deteriorating the quality of the video image.

The instrument is equipped with finely controlled mirrors that can precisely steer the direction of the laser ray at the distal end of the scope. The ray can be steered with a large angle of approximately 23°, which is very impressive because it emerges from a slender long tube that would normally narrow the angle. A very well thought, precisely calculated, and made system of lenses is presented in the paper for achieving this scope. This is not a simple task, especially when the video image should not be deteriorated.

Integrated controls are responsible for automatically pointing the beam to locations specified in the video image, so that the surgeon can easily target a region of interest. This includes a modified visual serving calibration method [22]–[23]. In-vitro tests show highly promising results, with laser pointing accuracy on the order of 1 mm.

The main application of this novel mechatronic medical device is related to fetal surgery. Potential applications include laparoscopic laser surgery for tumor ablation. Steering mechanisms and controls coupled with the sophisticated lens architecture make the system reported in this paper very impressive. This is an instructive and very interesting paper.

D. Needle Deflection Sensors

A truly novel sensor is presented in this section. A previous very interesting related paper presenting a contact sensor for measuring biological motion of soft tissue was presented in a previous issue [24].

Real-Time Estimation of Three-Dimensional Needle Shape and Deflection for MRI-Guided Interventions: Y. L. Park, S. Elayaperumal, B. Daniel, S. C. Ryu, M. Shin, J. Savall, R. J. Black, B. Moslehi, M. R. Cutkosky; collaboration between Harvard University, Cambridge, MA, Stanford University, Stanford, CA, and Intelligent Fiber Optic Systems Corporation, Santa Clara, CA.

Needle interventions for biopsy or percutaneous therapy commonly use image-guided techniques and/or technologies to precisely orient the procedure needle so that it points to a target defined in the image. However, when the needle is inserted its trajectory relative to the target does not normally follow a straight line. Arguably, deflections are the hardest controllable source of errors in reaching a "deep" target with the point of the needle. These are soft-tissue deflections and needle bending, and are related to each other. Thin needles cause less tissue deflections but bend more, whereas thicker needles do not bend as much, but push the tissues. Apparently, there is no satisfactory compromise solely based on the gauge of the needle. It is unfortunately true that when a needle is advanced, manually or with the use of a device, there is a significant level of uncertainty as to its path. Depending on the intervention and its proximity to critical structures, this can be a disconcerting thought. Special mechanisms and techniques such as needle spinning [25], pulsing, and or steering [26] have been proposed to cope with this inaccurate targeting problem.

Presently, no real-time medical imaging equipment can fully describe the deflection of a needle during insertion. The technology presented in this paper fills a technology gap for image-guided interventions, reporting a sensor device that can describe needle bending. A well-conceived miniaturized design of Bragg gratings optic fibers is placed along the common 18 Ga size needle for providing measurements. The fibers are strategically placed on the stylet of the needle so that this can be removed after the insertion making room for other instruments and wires to access the site. Moreover, due to the type of optic sensors used, the needle sensor is also compatible with MRI. Since MRI imposes most stringent requirements for device compatibility, the new needle will most likely qualify as multiimager compatible [27]. If successfully developed and translated current to clinical use, this technology will also be applicable to a large variety of clinical applications guided by CT, ultrasound, and other methods. Providing real-time measurements of needle deflections during insertion will enable the development of needle steering methods and image-guided robots for interventions. Current limitations or the technology and errors reported in the paper are likely to be overcome by the research group and new reports on this technology are expected.

In addition to imaging advances, new mechatronic technologies, such as the one presented in this paper will become instrumental in improving the level of confidence in needle targeting for the increasing number of more and more demanding image-guided interventions. This is a very interesting paper reporting original science and is also a well-written informative presentation in the field of image-guided interventions that is likely to educe and inspire future research. Clinical and research significance of the technologies presented is substantial and timely.

E. Novel Implantable Instruments

A novel implantable mechatronics device is presented next.

Development of a Novel Artificial Urinary Sphincter: a Versatile Automated Device: H. Lamraoui, A. Bonvilain, G. Robain, H. Combrisson, S. Basrour, A. Moreau-Gaudry, P. Cinquin, P. Mozer; collaboration between the University of Grenoble, Pierre & Marie Curie University Paris, and the Groupe Hospitalier Pitié-Salpétrière, Paris, France.

A paper describing a novel implantable mechatronic instrument is also included in this Focused Section, with this urinary sphincter device designed to exert a circumferential force around the urethra. Current artificial sphincters typically use a constant level of pressure. Since this level should always suffice to occlude the flow, its pressure has to be set at higher values. This constant and relatively high pressure may cause discomfort and even tissue damage [28]. Alternatively, these engineering and clinical researchers have devised a device that maintains a lower level of pressure, but immediately boosts it as needed.

A very clever way of detecting the need for increasing the pressure is used. Instead of taking direct measurements of intravesical pressure, which is difficult to detect due to additional implantable sensors, researchers devised a way to correlate the circumstances in which intravesical pressure may increase with an accelerometer, which is not implanted. Such circumstances include physical activities, such as walking, jumping, climbing stairs, lifting weights, bending, lying down, and getting up. Human experiments were involved to correlate these activities with accelerometer readings.

A miniature circuit board has been designed and built. This includes a microcontroller, the accelerometer, a pressure sensor for closed-loop pressure control, a wireless communication unit, a motor controlling the pressure through a diaphragm, and the circuit is powered by a lithium-polymer battery. The pressure is regulated by the motor under pressure feedback and controls the force exerted by an occlusive cuff of the artificial sphincter. The wireless communication provides bidirectional communication with the board, so that the medical personnel can easily reprogram/configure the implant as needed with pressure values, accelerometer threshold levels, and other data as this may become available.

Results on animal models show promising results. Clinical experiments will have to reveal if occlusion is maintained when the accelerometer remains inactive, in situations such as natural bladder filling, contractions, and other muscular spasms when the body is at rest. Overall this is a clinically significant medical application of mechatronics, the paper will be of interest to clinicians as well as engineers, and gives a fresh breath of clever ideas.

III. Future Trends

Medical robotics is one of the most important fields of medical mechatronics, which has already produced and is expected to provide new devices of high-clinical significance. In addition to current systems that are controlled directly by the surgeon in a leader-follower mode, advances that are currently in development for using intraoperative images for guiding interventions and operations are soon expected to mature to commercial products and become available to a larger patient population base [29]. Image guidance and navigation has been traditionally performed free handed on preacquired images and using spatial localizers, such as optical [30] and magnetic trackers [31]. The current trend is for embedded systems that allow for reimaging during the intervention for relocalization, treatment planning updates, and quality control. We term these Direct Image Guide Interventions (DIGI) [21].

Image-guided robots not only augment physician's manipulation capabilities but establish a digital platform for integrating medical imaging data. This gives robots abilities unattainable to humans, because unlike humans, robots and imagers are digital devices. Especially promising are MRI-guided robots [32]–[34] that can take advantage of the high resolution anatomic and special functional imaging, and operate alongside the man in the MRI scanner to remotely access the prostate with special needles for biopsy and therapy interventions. Several outstanding research reports regarding mechatronics for the MRI have been previously reported in the TRANSACTIONS, and apparently, this type of research is currently a major medical robotics research trust around the world [35]–[37], including developments of new compatible actuation methods [33], [36], [38].

Overall, novel mechatronics systems such as those presented in this section have a substantial potential to create novel instruments for medical applications with a high potential of clinical impact, and the time is now ripe for such developments.

Acknowledgment

The Guest Editors would like to thank all the authors who submitted their manuscripts for publication in this Focused Section. They would also like to acknowledge the efforts of the reviewers who provided their professional and constructive comments in a timely manner. Finally, they would like to thank the Editor-in-Chief, Prof. K.-M. Lee and M. Raine for their support and guidance throughout the production of this focused section.

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