Engineering and Urology Society

35th Annual Meeting

Sunday Sep 15, 2022

New Orleans, LA

https://engineering-urology.org/
The Engineering and Urology Society holds its 35th Annual Meeting: “Future or Fantasy: Autonomous Surgical Robots” on Sunday, May 15th in New Orleans, Louisiana. The mission of the Engineering and Urology Society, a subsection of the Endourological Society, is to promote the development and application of new technology in urology through facilitating collaboration between engineers, physicists, and urologists.

Lee Richstone, M.D. (meeting program chair) Chairman of Urology at Lenox Hill Hospital/Northwell Health, has organized a unique opportunity to consider a future in which autonomous surgical robots perform surgery with limited human oversight.

An exciting faculty composed of world class urologists, engineers, as well as biotechnology industry leaders will consider numerous aspects of such technology and its implications. Lectures will explore theoretical benefits as well as risks. Ethics and legal considerations will be explored. The current state of the art will be highlighted for various technical components of autonomous surgery - from artificial intelligence, tracking and navigation, planning and skill modeling, to imaging and registration. Achievements in surgical and industrial robots will be reviewed.

Two poster sessions in the afternoon provide researchers with the opportunity to present their work and update the attendees on the progress on the field and latest innovations. This year we include posters from the cancelled 2021 meeting as well as current ones. Overall, the review of the abstracts for the poster sessions was performed by a group of 69 reviewers from around the world. We would like to thank the reviewers, listed at the end of this program book, for their essential contribution to the quality of the meeting and their constructive comments that they made for the research.

Based on the review scores, the Society presents Awards to two abstracts from each year. These are listed at the end of this program book, together with the Top 10 abstracts, and Best Reviewer Awards. The authors of all awarded abstracts are invited to submit full length articles to the Journal of Endourology on the respective topics. We gratefully thank all reviewers for their hard work, objective scoring, and contribution to the success of the meeting. We thank Dr. George Nagamatsu the founder and first president of the society, and Dr. Jack Vitenson the first Society Treasurer for setting up the foundations based upon which we meet.

Please visit the website https://engineering-urology.org/ for a complete version of this program including the abstracts presented.

We welcome all urologists, engineers, scientists from industry and academia to join us for this cross-disciplinary experience.

Lee Richstone, M.D.
President, Engineering and Urology Society

Dan Stoianovici, Ph.D.
Executive Director, Engineering and Urology Society
Through collaboration and innovation, Boston Scientific is the preferred urology clinical and business partner that offers comprehensive breadth and depth of knowledge and products. We apply our experience to help you to proficiently treat your patients and navigate the complexities of healthcare. We present a robust portfolio of relevant innovations, as well as tailored training and solutions – designed and delivered with our unique collaborative approach.

A patient-first philosophy and innovative spirit have helped Cook become a leader in urology. With a focus on stone management and biopsy, we pride ourselves on providing quality solutions without compromise. By uniting with healthcare professionals around the world, we’re committed to advancing treatment and making a difference, together.

At our core, we believe industry-physician collaboration is vital to providing better healthcare. Our Vista® Education and Training programs encourage sharing best practices and learning new techniques using Cook’s latest product innovations.

Our Purpose: We aspire to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Our purpose is resolute and fueled by the opportunity to improve the lives of millions of women and men, many impacted by diseases during their most productive years of life. Despite the significant burden of common diseases like uterine fibroids, endometriosis, and prostate cancer, many women and men do not have the options they deserve and need.
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Vascular Technology Inc. (VTI) is a diversified medical equipment firm specializing in the development, manufacture, and sale of surgical devices, such as disposable Intraoperative Doppler Systems and Remotely Operated Suction Irrigation (ROSI) devices for robotic surgery.

VTI continues to develop superior products and to be a leader in the industry and we are proud to say that all of our products are made completely on our premises in Nashua, NH. The basic foundation of VTI is to serve the medical community by bringing innovative technology and superior quality to their customers, which in-turn enhances your patient’s health care. We are continuously researching for ways to enhance our existing products, and develop new products. Our goal is to build the highest quality equipment at an affordable price. We understand the need for innovation, quality, and service in the healthcare community.
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ABSTRACT 1

3D PRINTED KIDNEY TUMOR MODELS TO IMPROVE UROLOGIC ROBOTIC SURGICAL TRAINING FOR RESIDENTS AND STAFF PHYSICIANS

Joel Rosenberg*1, Resha Tejpaul*3, Aaron Tucker2, Bethany Juhnke2, Nick Heller3, Geoff Dybcz2, Jenae Putman2, Evan Hochstein2, Paul Rothweiler2, Arthur Erdman2, Subodh Regmi1, Nikolaos Papanikolopoulos3, Christopher Weight1

1 University of Minnesota Medical School, 2 University of Minnesota Earl E. Bakken Medical Devices Center, 3 University of Minnesota Computer Science & Engineering

Introduction: 3D-printed models have revolutionized the surgical planning and education field by providing models with anatomical accuracy, patient specificity, high fidelity, and tactile similarity that surgeons can use to increase surgical skills, reduce operative time, and decrease complications. We developed a 3D-printed kidney tumor model to be used by residents and staff physicians in a one-day robotic partial nephrectomy simulation course; their feedback on the course and models was collected.

Methods: After IRB approval, a 50-year-old female patient’s kidney data were captured on a Siemens SOMATOM Definition Flash CT Scanner, and the DICOM data were extracted and segmented. The 3D-kidney models were printed on the Stratasys J750 printer (Stratasys, Eden Prairie, MN, USA) with assistance from the Earl E. Bakken Medical Devices Center at the University of Minnesota. Four iterations of the model (Figure 1) were created to improve the material characteristics to visually represent human anatomy and mimic the real procedure. We conducted a one-day surgical simulation course for both experts and trainees using the kidney models. Participants completed a survey to assess the fidelity and the educational usefulness of the model.

Results: The first model was anatomically correct but exceeded the firmness of human tissue. The second model was softer, but its stickier tumor-kidney interface failed intraoperatively. The third model contained air pockets between the tumor and kidney, increased stiffness of the artery, vein, ureter, and tumor models, decreased stiffness of the renal medulla, calyx, cortex, and added duplicate tumors for more training opportunities in a single printed model. The fourth model had hollowed artery and vein to mirror clamping, more tumors for training opportunities, and realistic anatomical structure, size, and location of the tumors compared to the CT image of the kidney. However, it had poor fidelity to in vivo surgery as three of the ten models used during suturing techniques broke the needles. In contrast to the body, the artery and vein of the model were pliable and realistic to the anatomical features of a human kidney which was agreed upon by nine out of ten participants.

Conclusion: In summary, most participants found the models to be anatomically realistic. They also were inclined to use 3D models which they believe are valuable for surgical planning and education. Furthermore, with the continuous development of the correct hardness parameters, intercalated air-pockets, and variation in printing material available, we can create a model that is anatomically accurate, has high fidelity to actual surgery, be tactilely similar, and be patient-specific.

Figure 1: The four iterations (A-D) of the 3D-kidney models

* Both authors contributed equally
ASSESSING INTRAOPERATIVE EVENTS AND RISK DURING UROLOGIC SURGERY: OUR OPERATING ROOM BLACK BOX EXPERIENCE

Rai, A; Beland, L; Aro, T; Palter, V; Townsend, SA; De La Cruz, D; Rios, A; Montes, JH; Jarrett, M; Kavoussi, L

Smith Institute of Urology, Northwell Health

Introduction: Intra-operative adverse events (IAEs) negatively contribute to patient outcomes. To mitigate such events, thereby improving patient safety, it is important to understand the context in which these errors occur. To date, however, this area remains under-investigated. The purpose of this study is to characterize the IAEs and potential distractions that occur in minimally invasive urologic procedures.

Methods: We conducted a prospective cohort study in patients undergoing laparoscopic urologic surgery at a tertiary academic health centre. The OR Black Box, a unique technology system which captures video and audio recordings of the operating room as well as the operative field, was used to collect data relating to both the conduct of the operation as well as the operating room environment. Expert analysis of these data was conducted to identify procedure type, critical step, IAEs, and distractions.

Results: 80 sequential cases were analyzed. The majority of these cases were partial nephrectomy (n=36; 45%), radical nephrectomy (n=20; 25%) and adrenalectomy (n=4; 5%). Across all cases there were a total of 138 clinically significant IAEs, 10 of which (14%) were of the highest severity (5 on the SEVerity of intraopeartive Events and REctification Tool (SEVERE) matrix). The most common IAE overall was bleeding (n=63), followed by mechanical injury (n=39); thermal injury (n=33); and spillage (n=3). Of these, 70 (51%) occurred during an a priori defined critical step of the operation (for instance, organ dissection, vascular control, or anastomosis). The median IAE per critical step was 1 event (IQR 1-2) versus 2 (IQR 1-3) for the overall case. Distractions were common across all cases. The median rate of external communication per case was 16 events (IQR 11-22); and per critical step was 4 (IQR 2.75-8). In addition, median room traffic per case was 58 entries/exits (IQR 42-76); and per critical step was 17 (IQR 10-65).

Conclusions: Our data demonstrate that IAEs occur frequently during all phases of the operation at hand. Environmental distractions are common in the operating room, and future work will seek to establish a causal link between distraction and the frequency and severity of IAEs. Such an analysis would form the basis for establishing OR protocols to minimize distraction and room traffic, thereby minimizing IAEs.
ABSTRACT 3

EVALUATION OF INTER-ProvidER VARIABILITY IN GONIOMETRIC AND VOLUMETRIC ASSESSMENT OF PENILE DEFORMITIES USING STANDARD 3D-PRINTED PHANTOMS

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Introduction: Characterization of Peyronie’s disease (PD) deformities involves manual goniometry and measurement of penile length. These techniques neglect volume loss or hourglass, a source of bother. Inter-provider variability complicates accuracy. Using standardized 3D-printed models, we aimed to evaluate accuracy and variability in measurement and establish a workflow for computational assessment including volumetrics.

Methods: Five 3D phantoms were created digitally (Fig. 1A): 13.0 cm cylinder, 13.0 cm hourglass cylinder, 15.0 cm cylinder with 40º angulation, 12.0 cm straight penis, and 12.9 cm PD penis with 68º angulation and hourglass. Lengths, volumes, and curvature angles were determined computationally to serve as standards. Each phantom was printed using a Makerbot Replicator+. Ten urology providers determined length, angle, and volume of phantoms using measuring tape, goniometer, and volume calculator. Means ± SD were calculated. To determine accuracy, depending on data distribution, a t-test or Wilcoxon rank sum test was used to compare provider-determined vs. computationally acquired measurements.

Results: Data are in Fig. 1B. Lengths for cylinder, hourglass cylinder, angled cylinder, straight penis, and PD penis were 12.9 ± 0.9 cm (p=0.0003), 12.9 ± 1.61 cm (p=0.058), 15.0 ± 4.3 cm (p=0.52), 12.0 ± 2.3 (p=0.68), and 12.7 ± 10.8 (p=0.36), respectively. Volumes were 174 ± 22 cc (p=0.003), 150 ± 24 cc (p=0.0008), 186 ± 33 cc (p=0.004), 101 ± 23 cc (p=0.16), and 87 ± 11 cc (p=0.23), respectively. Curvature angles from bent cylinder and PD phantoms were 38.3º ± 3.9º (p=0.25) and 57.5º ± 7.2º (p=0.006), respectively. Discrepancy between goniometry and computationally determined angle ranged 3º to 13º.

Conclusion: Our results suggest urology providers’ measurements suffer from inaccuracy and variability, particularly in volume estimation and PD goniometry. A computational workflow may be useful for the clinical and research armamentarium when greater accuracy or volume assessment is needed. Further work using 3D image-capture techniques may allow translation to patient evaluation.
FEASIBILITY OF A TELEMENTORING APPROACH AS A PRACTICAL TRAINING FOR TRANSURETHRAL ENucleATION OF THE BENIGN PROSTATIC HYPERPLASIA USING BIPOLAR ENERGY

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\textbf{Introduction:} Telementoring is one of the applications of telemedicine. It is capable of bringing highly experienced surgeons to areas lacking expertise. In the current study we aimed to assess a simple and low-cost telementoring application during the learning curve of transurethral enucleation of the prostate using bipolar energy (TUEB).

\textbf{Material & methods:} A simple and low-cost telementoring application was developed by our engineering department. The application consists of a computer, Bluetooth headset, video convertor device, and a workstation for the mentor and it allows video and audio communication with telestrating. This system was used to mentor ten prospective cases of TUEB performed by an expert endourologist (novice to the TUEB). A questionnaire was filled by the operating surgeon and the mentor to provide subjective evaluation of the telementoring system.

\textbf{Results:} Ten consecutive TUEB were performed under guidance of an expert remote mentor using this telementoring application. Delayed and interrupted connection were experienced in two and one patients, respectively; however, their effect was minor and they did not compromise the safety of the procedure. None of the patients required conversion to conventional transurethral resection of the prostate. Only one patient in our series experienced grade IIIb complication.

\textbf{Conclusion:} Telementoring (using the developed application) during TUEB is safe and effective. It could be a feasible option to ensure patients’ safety during the initial phase of the learning curve without time and locations constraints for both the mentor and the trainee.
FIRST EXPERIENCE WITH THE NEW SINGLE-USE PUSEN FLEXIBLE URETEROSCOPE 7.5 FR

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Introduction: Single-use flexible ureteroscopes (SU-fURS) seems now to overcome the main limitations of conventional reusable ureteroscopes in terms of acquisition and maintenance costs and breakages. In the majority of cases the size of the tip is between 8 and 9 Fr. Our aim was to analyze the efficiency and safety of the thinner flexible scope known as Uscope Pusen, PU 3033A (tip = 7.5 Fr.).

Material and methods: We analyzed data from 65 patients with pyelocaliceal stones between January and May 2021. There were unique stones, 49 pyelic, 13 in inferior calyx and 3 in superior calyx. The average stone size (larger diameter) was 18 mm (12-26 mm). The mean age of the patients was 49 years (range 27 to 71 years). We used Uscope Pusen 7.5 Fr. (PU 3033A) and Dornier Medilas H Solvo laser. In all cases we applied no touch technique (NTT). We didn’t use a C-Arm for progression control of the ureteroscope. Gravitational pressure system for irrigation was applied in all cases. We evaluated the patients for stone-free rate (SFR), mean operation time, and complication rate.

Results: The average operative time was 32 ± 21 minutes. For all patients, we didn’t use wires or a ureteral access sheath (NTT). Concerning the laser settings for dusting, we used either low energy: 0.5J, high frequency 50 Hz; for pop-corning we used high energy: >1 J, medium frequency: 10-50 Hz; and for fragmenting we used high energy: >1 J, low frequency: <10 Hz. The SFR status (fragments > 1 mm. being considered residual) was evaluated using CT scans. After one month, the SFR was 92% (4/49 pyelic stones), 77% (3/13 inferior calyx) and 100% (0/3 superior calyx). So, in 7 cases (10.8% - 7/65), we applied a second session with completely dusting of the residual stones. All patients get home in the same day. The visibility and maneuverability of the UScope were optimal and we didn’t describe any mucosal lesions of the ureter when we retired the scope. The intrarenal maneuverability was very good. Clavien I and II occurred in 7 patients. We described 3 cases with urinary tract infections (without sepsis).

Conclusions: This new SU-fURS (7.5 Fr.) seems to be very effective and safe offering us an easy NTT. No ureteral damage and one day surgery are the main real minimally invasive characteristics of this ureteroscope.
SINGLE USE VS REUSABLE URETEROSCOPES 
IN HORSESHOE KIDNEY STONES

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Introduction: Horseshoe kidney (HSK) is one of the most frequent renal malformation which appears to present an increased risk of stone formation caused by the abnormal urine drainage. The special anatomical aspects represent a challenge for the urologist to obtain the stone free status. This study aims to compare the results of single-use flexible ureteroscopy (SUfURS) vs. reusable devices (RfURS) with holmium laser in treating stones in HSK cases.

Material and method: Between February 2017 and November 2020, 29 patients diagnosed with renal stone disease and horseshoe kidney were retrospectively analyzed. Our patients were divided into 2 groups: Group 1 (14 patients) which undergone SUfURS and Group 2 (15 patients) operated with RfURS devices. We analyzed the mean stone burden, operation time, stone free rate and complications. The surgical equipment was represented by the SUfURS PU3022 (Zhuhai Pusen Medical Technology) and RfURS URF-V2 (Olympus).

Results: The mean age was 45.6 years old in Group 1 and 47.3 in Group 2 and the overall male to female ratio was 2.22:1. Mean stone burden was similar: 22 ± 6 mm (range 15-31 mm) for Group 1 and 24 ± 7 mm (range 16-30 mm) for Group 2. Mean stone surface area (SA) was similar: 287 ± 42 mm² (range 146-340 mm²) for Group 1 and 298 ± 49 mm² (range 151-374 mm²) for Group 2. The average operative time was better for Group 1 (86 ± 17 min.) vs. Group 2 (89 ± 20 min.). The stone-free status after first session was similar for both groups: 57.14% for Group 1 vs. 53.33% for Group 2. After second session slightly in favor of Group 1: 85.71% for Group 1 vs. 73.33% for Group 2. After third session the percentages maintained favorable for single use devices (92.25% vs 86.66%). The overall complication rate (Grade I, II and III) was almost similar with a slightly prevalence for Group 1. There were no major complications (Grade IV and V).

Conclusions: Flexible ureteroscopy represents an effective alternative treatment technique for large stones even in kidney abnormalities such as HSK which associates high stone free rates. SUfURS can be successfully used to treat patients with genetically renal malformations and may present slightly better results than RfURS devices.
ABSTRACTS

ABSTRACT 7

A GRAPHICAL INSTRUMENT TO DESCRIBE AND COMMUNICATE EROGENOUS REGIONS OF THE BODY

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Introduction: Erogenous regions of the body are those sensitive to stimulation during sexual activity. Previous studies have attempted to graphically map erogenous anatomy but have been limited by poor resolution [PMID:27091187], exclusive focus on the genitals [PMID:15329118, PMID:19245445] and failure to depict the internal anatomy of the vagina and rectum. Within surgical fields, better delineation of erogenous zones could reveal underappreciated body regions that could affect preoperative counseling and surgical decision-making. An instrument to share erogenous regions could facilitate communication between current or potential partners and between patient and surgeon before and after surgery. In this study we present an instrument to map and quantify erogenous anatomy of the body.

Methods: Illustrations of ten regions of the body (body overview, head and neck, female chest, female external and internal genitals, male dorsal and ventral external genitals, male perineum and female and male rectum) were incorporated into an online survey. Anonymous paid participants gave demographic and health data, designated areas as pleasurable in partnered sexual activity and rated them on a 1-10 scale from “not important” to “extremely important”. Chi-square tests with the Benjamini-Hochberg procedure (FDR=5%) to control for multiple comparisons were used to compare 31 analogous regions between male and female respondents.

Results: The survey was completed by 872 participants (451 self-identified female, avg age 49.0 ± 15.7 years; 421 male, avg age 47.8 ± 17.0 years). The three most erogenous regions for female subjects were the breasts (56.9% selected pleasurable, avg score 7.9/10 ± 2.0), the vaginal introitus (49.6%, 8.71/10 ± 1.5) and the superficial anterior vagina (46.9%, 8.4/10 ± 1.6). The dorsal glans was the most frequently identified erogenous region for both circumcised (74% pleasurable, avg 8.6/10 ± 1.6) and uncircumcised men (72.0%, 8.8/10 ± 1.4) followed by the ventral mid-shaft in circumcised men (63%, 8.1 ± 1.6) and the dorsal coronal margin in uncircumcised men (56%, 8.1 ± 1.8). Of analogous regions, male respondents rated the perineum (22.5% M, 12.0% W) and anus (19.9% M, 12.0% W) as pleasurable significantly more often than women. Women rated the back of the neck as pleasurable significantly more often than men (29.9% M, 40.2% W). No other differences were statistically significant after correction.

Conclusion: We successfully applied our graphical survey to define and compare erogenous regions for 872 survey respondents. This method has broad potential applications including pre- and post-surgical counseling, sexual health research, enabling communication between individuals and in product development (apps, dating platforms, medical records).

Figure 1: Complete body map for one male survey respondent. Green regions indicate those scored as pleasurable. Deeper shades of green correlate to higher 1-10 ratings.
HYDROGEL SPACER (SPACEORA™) IN IMAGE GUIDED INTENSITY MODULATED RADIATION THERAPY (IMRT) FOR PROSTATE CANCER: AN UPDATED COMMUNITY EXPERIENCE

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INTRODUCTION: Intensity modulated radiation therapy (IMRT) is an effective treatment for prostate cancer. Incidental rectal irradiation is associated with significant morbidity. We have shown that absorbable perirectal hydrogel spacers (SpaceOAR™ System, Boston Scientific Inc., Marlborough, MA) reliably reduce rectal exposure in the community setting. We report an updated community-based experience with a perirectal hydrogel spacer injection prior to IMRT.

METHODS: Between 2015 – 2019, 506 men with clinical stage T1c-T2c prostate cancer received SpaceOAR™ prior to IMRT monotherapy (81 Gy, 45 fractions). Dose volume histograms were calculated and analyzed. Results were compared to the experimental (149 men) and control (73 men) groups of a Phase III clinical trial of SpaceOAR™ [http://dx.doi.org/10.1016/j.ijrobp.2015.04.030] and the Quantitative Analyses of Normal Tissue Effects in the Clinic (QUANTEC) guidelines.

RESULTS: The average rectal V70 (rV70) was 0.70% (standard deviation ±1.47%, range 0-13.85%). Average mean penile bulb dose was 10.6 Gy (±7.6 Gy, 0.02–5.77 Gy). Our rV70 was significantly lower than published control (12.4%) and experimental groups (3.3%), representing a 94.4% decrease compared to controls. Our average mean penile bulb was 53.6% lower than the control group (22.8 Gy). All treatment plans satisfied rectal dose constraints and QUANTEC rV70 and penile bulb guidelines (<20% and <50 Gy, respectively).

CONCLUSIONS: Perirectal hydrogel spacers are safe, well tolerated, and can be easily applied in the community office setting. We demonstrate that SpaceOAR™ consistently and dramatically reduces rectal irradiation and exposure to the penile bulb during the treatment of prostate cancer.
APPLICATION OF HYDROGEL SPACER (SPACEOAR™) IN HYPOFRACTIONATED RADIOTHERAPY FOR PROSTATE CANCER

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INTRODUCTION: Hypofractionation intensity-modulated radiotherapy (IMRT) is increasingly utilized in the treatment of prostate cancer. Absorbable perirectal hydrogel spacers (SpaceOAR™ System, Boston Scientific, Marlborough, MA) significantly reduce rectal irradiation during conventional IMRT. We report our experience with perirectal spacer in patients receiving hypofractionated radiotherapy (RT).

METHODS: We identified men with stage T1c-T2c prostate cancer scheduled to undergo IMRT hypofractionation (70 Gy, 28 fractions) and who received SpaceOAR™ from August 2017 through December 2019. Dose volume histograms (DVHs) were analyzed and compared against (1) the experimental (149 men) and control (73 men) arms of a Phase III clinical trial of SpaceOAR™ in men receiving conventional IMRT [http://dx.doi.org/10.1016/j.ijrobp.2015.04.030], (2) patients treated at our institution who received SpaceOAR™ prior to conventional IMRT (81 Gy, 45 fractions), and (3) to the Quantitative Analyses of Normal Tissue Effects in the Clinic (QUANTEC) guidelines.

RESULTS: 440 men received SpaceOAR prior to RT, 85 of whom underwent hypofractionated RT. In the hypofractionation cohort, mean rectal V70 (rV70) was 0.074% (standard deviation ±0.40%, range 0-3.20%); average mean penile bulb dose was 10.76 Gy (range 2.11–57.20). Our rV70 in the hypofractionation cohort was significantly lower than the published control (12.4%) and intervention (3.3%) arms. Compared to conventional IMRT, our hypofractionation cohort demonstrated lower rV70 (0.074% vs 0.64%) and mean penile doses (10.76 Gy vs 10.97 Gy).

CONCLUSIONS: Perirectal hydrogels have demonstrated efficacy in conventional IMRT. We demonstrate that when applied in dose-escalation protocols in a community-based practice, hydrogel spacer also consistently offers similarly significant protection to the rectum from irradiation.
ABSTRACT

DENERA: DETRUSOR NERVE TRANSVAGINAL RADIOFREQUENCY ABLATION: PRE-CLINICAL STUDY ON ABLATION SAFETY AND EFFICACY

Rongwei Mao¹, David Alexander Csuka², Yang Zhang¹, G.P. Li¹, Gamal Ghoniem²

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Introduction: Overactive bladder (OAB) is a chronic condition that affects 35 million people in the US and 200 million people worldwide. Typically, once a patient fails behavioral modification and medications, they resort to an interventive approach (3rd line therapies, AUA/SUFU guidelines). Currently there are a few therapies available, such as sacral neuromodulation [nau22544] which requires surgery, cryptoscopic botulinum toxin injection into the bladder muscle [EU2011] which has side effects, and percutaneous tibial nerve stimulation (PTNS) [nau.10036] which requires repeated clinic visits.

Radiofrequency denervation targeting the bladder nerve is a relatively new promising option for OAB [PMC7379657]. However, using a transurethral approach (under investigation) requires anesthesia since a very high temperature of over 90 °C is used. Adverse events such as pain, bladder scarring, and occasional severe adverse events have been reported.

In this article, we report a novel device, DENERA, which transvaginally treats OAB using radiofrequency energy (RFE) with a controlled temperature of 45 °C for minimum thermal damage. It will become a safer OAB treatment by being quick, minimally invasive, and not requiring anesthesia, i.e., a clinic procedure.

Methods: The device includes an elongated shaft with a longitudinal axis, a handle at one end of the shaft, an active header at the other end. The header has three rows of micro needle electrodes (0.4 mm) extending through the flat surface. The RF power used for denervation is moderated by a control unit for the targeted temperature with the T-sensor integrated with the micro needle array. Once inserted into the vagina, the header is aligned with the bladder trigone area where the bladder nerves are most concentrated.

In order to minimize the potential damage to the vaginal/bladder wall, the needle must be perpendicular to the tissue surface during the deployment of the needles. Swinging or bending of needle may cause unnecessary physical damages to the tissue. A special sliding structure was designed with the 6 mm length of needles extruded from top flat surface. This length was chosen to reach the nerves of the bladder wall from the vaginal side.

Temperature control is critical for the safety of the denervation process. Pulsed RF energy was utilized with a target temperature of 45 °C. An ultra-small thermocouple with a diameter of 0.3 mm was integrated with the needle array. The thermocouple was strengthened to penetrate the tissue. In order to verify the design, an ex vivo animal study (adult female sheep) along with two in-vivo studies were carried out.

Results: Both in-vivo and ex-vivo pathology analysis shows the needles penetrated deep into the bladder wall to reach the trigone area. In the two in-vivo studies, post-operative monitoring was performed closely for 48 hours after ablation. Mobility, eating, drinking, pain signs, voiding and serial weights were monitored. The animals recovered immediately with no signs of pain. They urinated without any residual urine. No complications were observed. Preliminary histopathology shows that the device is effective to denervate the bladder subtrigone nerves.

Conclusion: The study proves that the DENERA device is capable of effective subtrigonal denervation. The whole procedure is easy to operate. It has promising potential as a treatment option for OAB.
A NOVEL PLATFORM TO PRODUCE ONSITE SURGICAL SALINE FROM MARGINAL WATER SOURCES

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Introduction: Saline is the lifeblood of healthcare delivery in the world. In endourologic procedures, it is the medium that allows for effective visualization, energy delivery, and tissue evacuation in treating patients with urologic diseases. Despite the importance of saline, healthcare facilities are increasingly threatened by production monopolies and manufacturing shortages. As such, the medical saline market needs novel solutions for onsite production. We have developed a new forward osmosis (FO)-based process for generating saline from local water sources for point-of-care use by medical personnel.

Methods: A bench-scale FO system equipped with electrodes on either side of the cellulose triacetate membrane was used to produce medical-grade saline (0.15 M). Draw solution comprised of 1.5 M sodium chlorides was used to extract water from a model low-quality water. The model water contaminants included alginate and bovine serum album (BSA) to simulate wastewater constituents. Low powered oscillating electric fields were used to prevent FO membrane fouling while maintaining high water recovery (percent water flux) over time.

Results: When compared to control (no electric field), a significantly higher water flux (or saline production rate) was observed in the presence of electric fields (Figure 1). Furthermore, when compared with continuous electric field, water recovery was the highest and can be sustained for entire duration of operation in the presence of pulsed electric field. This remarkable FO performance was attributed to the ability of electric fields to mitigate FO fouling, a process where wastewater constituents (e.g., BSA and alginate) adhere and block the water channels.

Conclusion: This electrically-assisted FO separation process demonstrates a novel antifouling property that allows for improved water flux (saline production) despite contaminants in the draw solution. We postulate that the oscillating electric field causes foulants in water to oscillate and thereby prevents them from sticking to membrane surface. Thus, the FO system generates enhanced water flux and potentially a higher saline production rate than existing manufacturing processes. This technology has significant commercial opportunity for onsite saline generation for a variety of use cases such as disaster relief, defense and aerospace applications as well as back-up saline generation for hospitals. We are currently conducting additional studies to further evaluate our proof of concept.

Figure 1: The effect of electric field parameters and mode on 200 mg/L alginate (left) and 1 g/L bovine serum albumin (BSA) (right) in 5 mM CaCl₂ during forward osmosis. 1.5 M NaCl is used as the draw solution (hypertonic saline).
VISUALIZED PROSTATE BIOPSY: AN INTUITIVE 3D USER INTERFACE FOR SYSTEMATIC AND TARGETED BIOLOGY

Samsun Lampotang, PhD, FSSH, FAIMBE\textsuperscript{1}, Thomas Stringer, MD, FACS\textsuperscript{1}, David E. Lizdas, BS\textsuperscript{1}

\textsuperscript{1}University of Florida

\textbf{Introduction:} Prostate biopsy false negative (PBxFN) percentages are 21\%–47\% [\textit{PMC4104074}] and 16\% [\textit{PMID: 31144593}] for systematic and fused biopsy, respectively. Traditional two-dimensional (2D) transrectal ultrasound (TRUS) guidance may be challenging for users with low spatial ability because it requires mentally reconstructing the complex interactions among the TRUS insonation plane, biopsy device, and prostate to guide the core to the intended biopsy location. Furthermore, there is no explicit, automated feedback in real time regarding sampled cores. An intuitive, three-dimensional (3D), visualized user interface may help reduce PBxFN percentages by providing real-time guidance and feedback during transrectal or transperineal biopsy.

\textbf{Methods:} The visualized prostate biopsy (vPBx) system is a retrofit kit that creates an overlay of graphical data on a replicated 2D TRUS image transferred in real time via an HDMI cable from an unmodified TRUS or microultrasound machine. It also creates a perspective 3D visualization that can be used in addition to, or instead of, the augmented or unmodified 2D TRUS. Removable, cleanable clips contain magnetic sensors (NDI Model 800, Waterloo, ON) and attach onto the TRUS probe and biopsy device to track their positions in 6 degrees of freedom (6DoF; x, y, z, yaw, pitch, roll) relative to the prostate with 0.2-mm accuracy. The prostate is tracked in 6DoF by an NDI Model 180 magnetic sensor embedded in a urinary catheter placed prior to the PBx procedure. The prostate and, if visible in TRUS, regions of interest (ROI) are segmented in situ (in the procedure room). In situ segmentation allows targeted biopsy of TRUS-visible ROIs without a prior MRI scan. Real-time tracking of the moving prostate (including template locations and TRUS-visible regions of interest), TRUS probe, and biopsy device is used to construct a perspective 3D visualization that is different from 3D TRUS imaging. The perspective 3D visualization depicts the prostate (including template locations and regions of interest), TRUS probe, and biopsy needle rendered in a 3D projection, including depth cues such as realistic shading, occlusion, specular highlights and shadows, from any viewpoint chosen by the user. Users visualize, aim, sample, and receive feedback in real time in both the augmented 2D TRUS and the perspective 3D visualization. Using a simulator with simulated TRUS [\textit{PMID: 33961325}], 48 participants performed freehand systematic prostate biopsy (sPBx) with traditional TRUS guidance and afterward with vPBx. Deviation is the shortest distance between the center of a core and its intended sPBx template location. Template deviation is the average of the deviations for all template locations in a template. PBxFN percentage is the number of core sets where an existing lesion was missed divided by the total number of core sets.

\textbf{Results:} During simulated systematic freehand biopsy, there was a significant decrease in mean template deviation (11.8 to 2.5 mm; paired t test, p < 0.001) and the percentage of PBxFNs (52\% to 2\%, p < 0.0001) when using the vPBx compared to traditional TRUS-guided sPBx.

\textbf{Conclusion:} Preliminary results during simulated systematic biopsy warrant retrofitting the vPBx to actual TRUS equipment as a step toward clinical trials with patients. We plan to evaluate the vPBx integrated with actual PBx equipment with simulated physical prostates, then cadavers, followed by a clinical trial on patients.
A METHODICAL PITCH-NEUTRAL TECHNIQUE FOR SIDE-FIRE SYSTEMATIC PROSTATE BIOPSY

Zhou Zhang, MD1, Thomas Stringer, MD, FACS2, Yichao Yu, PhD2, Gulsen Tasdelen-Teker, PhD3, Jonathan Wakim, BS4, Patrick Shenot, MD5, Jason Lee, MD6, Nathan Perlis, MD6, Louis Moy, MD2, William T. Johnson, BS2, Andre Bigos, BS2, Anthony DeStephens, MSE2, David E. Lizdas, BS2, Samsun Lampotang*, PhD, FSSH2

1Chongqing General Hospital, 2University of Florida, 3Hacettepe University, Ankara, Turkey, 4UPenn Medicine, 5Thomas Jefferson University, 6University of Toronto

Introduction: Although freehand systematic prostate biopsy (sPBx) template deviation (average of the shortest distance in mm from a biopsy core center to its intended sPBx template location) for experienced urologists is as high as 9.0 mm [PMC3876458], no methodical technique to reduce deviation has been published. Smaller deviations mean more evenly distributed cores, reducing the risk of not sampling regions that contain lesions and producing prostate biopsy false negatives (PBxFN; 21-47% proportion in patients [PMC4104074]). We developed and evaluated a teachable/learnable technique to decrease deviation to address a training and technique gap, for the long-term goal of reducing PBxFN during freehand sPBx.

Methods: Using a new PBx simulator, we devised a freehand, pitch-neutral (0°, horizontal plane), side-fire, transrectal ultrasound (TRUS) sPBx technique. The simulator recorded deviation and TRUS probe pitch at time of sampling; 34 trainees at 4 Canadian and US programs learned the technique and used it to attain competency (template deviation (TD) ≤ 5 mm). We used a paired-samples t-test on the complete data sets.[PMID: 33961325]

Results: All results are reported as mean ± SD. The mean absolute pitch and TD before learning the technique (baseline) were 8.2 ± 4.1° and 8.0 ± 2.7 mm, respectively, and after mastering the technique decreased to 4.5 ± 2.7° (P = 0.001) and 4.5 ± 0.6 mm (P < 0.001). TD was related to mean absolute pitch (P < 0.001) and increased by 0.5 mm on average with each 1° increase in mean absolute pitch. Participants achieved mastery after practicing 3.9 ± 2.9 double-sextant sets. There was no difference in time to perform a double-sextant set at baseline (277 ± 102 s) and mastery (283 ± 101 s; P = 0.39). Four academic health centers have adopted the technique.

Conclusion: Addressing a lack of a learnable technique, a pitch-neutral, side-fire, freehand technique reduced TD during simulated TRUS side-fire sPBx suggesting it may also reduce false negatives in patients. We have applied for research funding to determine if the pitch-neutral side-fire sPBx technique also reduces false negatives in patients.

Figure 1. Probe pitch correlates to TD. Figure 2. Reduction of TD using pitch neutral technique
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COMPUTER VISION APPROACH FOR QUANTITATIVE ANALYSIS OF STONE COMMINUTION

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Introduction: An important metric characterizing various techniques to treat urinary stones is the rate of stone disintegration, as well as the number and size of stone fragments. The growing concern about residual stone fragments favors “dusting” techniques aimed at producing microscopic-size dust, which can be difficult to characterize (e.g., capture and weigh). The development of computer-vision techniques can mitigate some of these difficulties and provide valuable feedback on stone treatment. Here we develop a method for quantitative analysis of stone fragmentation using a computer-vision approach.

Methods: The approach was implemented in Python (python.org) with OpenCV—an Open-source library of Computer Vision algorithms (opencv.org). Video images of stone comminution were collected with a high-speed camera Shimadzu HPV-X2, as previously described [PMC7241592, PMC6660306]. Here, synthetic stones were pulsed with a holmium:YAG laser in air via a 550-µm fiber (Figure, top left). Stone fragments produced by laser pulses were identified by detecting the difference between the images and tracked with identification numbers (middle) considering the velocities (top right) and size of fragments.

Results: A quantitative assessment of stone comminution is illustrated in plots showing the number and cross-section area of stone fragments (Figure). Shown are the results for all fragments (blue) and for those present in the field of view (red). The measurement uncertainty (light blue, bottom left) shows the number of fragments detected intermittently frame-to-frame. The mean ± standard deviation (bottom right) shows the sum of the means of cross-section areas for all stone fragments as a function of time (frame number).

Conclusion: This work demonstrates a computer-vision approach for a quantitative analysis of stone comminution in laser lithotripsy. With a caveat of characterizing 3D objects based on 2D video images, the approach provides an assessment of number and size of stone fragments produced versus time.

Disclosures: Dr. Stoller is a cofounder of Applaud Medical. This research was supported by the National Institute of Diabetes and Digestive and Kidney Diseases under Award Number R43DK129104. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Figure: Illustration of the proposed approach. Top left panel shows one frame from input sequence of images. Stone fragments produced by the laser pulse were detected and tracked: Magenta numbers show tracking IDs (middle) and velocities (top right) of identified fragments (green). Bottom plots show quantitative assessment of stone fragmentation vs time indicated by frame number. In this frame, 10 stone fragments with cross-section area of 0.24 mm² (middle) were present in the field of view (FoV). This laser pulse produced 27 ± 10 stone fragments (blue, left) with the total cross-section area of 0.44 ± 0.08 mm² (right).
Abstract 15

Competency-Based Simulator Training in Systematic PBx

Samsun Lampotang1, Jonathan Wakim2, Zhou Zhang3, William Johnson1, David Lizdas1, Amy Gunnett1, Louis Moy1, Patrick Shenot4, Thomas Stringer1
1University of Florida, 2UPenn Medicine, 3Chongqing General Hospital, 4Thomas Jefferson University

Introduction: Deviation of biopsy core centers from intended template locations during transrectal ultrasound (TRUS) systematic prostate biopsy (sPBx) is not measurable in patients in real time. We built a simulator to first measure and then via training, improve evenness of actual sPBx core distribution.

Methods: With residents in urology programs A (13) and B (12), we measured deviation of cores during side-fire TRUS sPBx (left lateral decubitus “patient”). We placed the 12 dots on a double sextant schema on a plane ~7 mm anterior and parallel to the rectal surface of the simulated prostate. Template deviation is the average of the shortest distance in mm from each core center to its intended template location. Using a new simulator, we first measured baseline (pre-training) deviation, then trained to competency (template deviation ≤ 5 mm) using a methodical pitch-neutral technique we recently developed on the simulator. The methodical pitch-neutral technique was taught to Center B residents only. Trainees returned for practice sessions (often over multiple days) until they achieved a template deviation ≤ 5 mm.

Results: Only one of 25 residents had a baseline template deviation ≤ 5 mm (Table). All 12 Center B residents adopted the methodical technique we taught, using it to reach competency. The number of 12-core practice sets before reaching competency at Center B ranged from 1 to 10. Unsolicited, some residents shared that they did not previously have a methodical TRUS PBx technique.

Conclusion: Template deviation quantifies how closely the actual core distribution matches a given sPBx template and thus how evenly cores are distributed. More evenly distributed cores decrease the risk of not sampling regions where lesions occur like the apex. Non-sampled regions that contain lesions create false negatives that range from 21-47% in patients [PMC4104074]. The baseline template deviation on simulated side-fire sPBx at both urology programs indicated a performance gap, previously difficult to document, that is likely representative of the state of side-fire sPBx accuracy of US urology residents. The ability of all Center B residents to reach competency indicates that (a) training on the simulator is efficacious in reducing sPBx template deviation and (b) that the ≤ 5 mm competency threshold we set is not overly stringent and is attainable if a methodical approach like the pitch-neutral technique is used during side-fire TRUS sPBx.

Table: Baseline template deviations of study participants

<table>
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<th>Trainee</th>
<th>Year</th>
<th>Baseline Template Deviation (12-core) Mean±SD (mm)</th>
<th>Range (mm)</th>
<th>12-core Practice Sets Taken</th>
<th>Best/Competency Template Deviation (12-core) Mean±SD (mm)</th>
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<td>8.7±1.9</td>
<td>5.7-11.3</td>
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Table: Baseline template deviations of study participants

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<tr>
<td>A12</td>
<td>PGY3</td>
<td>7.1±3.1</td>
<td>3.2-14.2</td>
<td>6</td>
<td>7.1±2.9</td>
<td>2.5-12.5</td>
</tr>
<tr>
<td>A6</td>
<td>PGY4</td>
<td>6.5±2.9</td>
<td>2.2-10.9</td>
<td>6</td>
<td>6±2</td>
<td>0.8-11.4</td>
</tr>
<tr>
<td>A11</td>
<td>PGY4</td>
<td>20.1±6.3</td>
<td>12.1-30.7</td>
<td>3</td>
<td>20.1±6.3</td>
<td>12.1-30.7</td>
</tr>
<tr>
<td>A13</td>
<td>PGY4</td>
<td>7.7±4.8</td>
<td>2.18.2</td>
<td>6</td>
<td>6±2.4</td>
<td>1.3-10.1</td>
</tr>
<tr>
<td>A1</td>
<td>PGY5</td>
<td>9±4.7</td>
<td>3.5-16.7</td>
<td>6</td>
<td>8.5±3.7</td>
<td>1.9-15</td>
</tr>
<tr>
<td>A2</td>
<td>PGY5</td>
<td>11.7±6.7</td>
<td>3.9-25.3</td>
<td>3</td>
<td>7.7±2.4</td>
<td>2.2-27.8</td>
</tr>
<tr>
<td>A4</td>
<td>PGY5</td>
<td>24.5±8.1</td>
<td>11.40.9</td>
<td>6</td>
<td>8.4±5.8</td>
<td>3.2-15.3</td>
</tr>
</tbody>
</table>

35th EUS Annual Meeting, May 15, 2022, New Orleans, LA
IMPACT OF URETERAL STENTS ON FACTORS CONTRIBUTING TO STRICTURE PATHOGENESIS

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Introduction: Ureteral stenting is common for the management of obstructive uropathy. While much research into complications associated with stents has been completed, none has focused on understanding the molecular response of the ureter to stents, which may drive pain and discomfort. Recent preliminary work suggests that stents trigger pre-fibrotic changes in ureteral tissues. To investigate this concept further, the objective of this work was to evaluate the impact of ureteral stents on pro-fibrogenic signaling associated with stricture pathogenesis.

Methods: Pigs (n=3) were stented unilaterally for 14 days with the unstented side serving as the control. Additional pig ureters (n=3) were stented for 14 days and then allowed to recover for 7 days (recovered group). Ureters were analyzed by RNAseq and proteomic analysis to evaluate the presents of pro-fibrotic factors.

Results: RNAseq demonstrated that the stented ureter had increased transforming growth factor (TGF)-β2, and TGF-β-receptor(R)-2 compared with the unstented ureter. Stenting altered Collagen (Col) RNA levels, with increases in Col 8A1, 4A2, 6A5, 1A2, and 3A1, among others, compared to the unstented group. Compared to the stented group, the recovered group had reductions in TGF-β2 and Col 4A2, 6A5, 1A2, and 3A1 RNA expression. Compared to the unstented group, the recovered group had increased expression of Col 12A1, 17A1 and 8A1 RNA and decreased Col 53A and 8A2. Proteomic analysis demonstrated that compared to the unstented group, the recovered group had increased Col 6A2, 6A3, and 7A1 and decreased Col6A6 and 5A3. The recovered group had few differences in protein expression and no changes in Col levels compared to the stented group.

Conclusion: Indwelling stents result in alterations in signaling pathways associated with stricture formation, an effect that has not been reported previously and may contribute to stent-associated ureteral dysfunction, pain, and discomfort. Some of these alterations revert to patterns similar to unstented ureters, while others remain aberrant 7 days after a stent has been removed. Studies investigating whether these changes revert to normal following stent removal or result in longer-lasting decreased ureteral function are warranted.
**VECTO® PROSTATE BIOPSY:**
A NOVEL ELECTRO-MAGNETIC (EM) BIOPSY TECHNIQUE FOR MPMRI/US FUSION PROSTATE BIOPSIES UNDER LOCAL ANESTHESIA

Christof Kastner1, 2, Peter Fletcher2, Marta De Santis3, Lucy Chinnery4, Ilias Skalkidis5, Georgios Sakas6  
1GenesisCare Cambridge, 2Cambridge University Hospitals, 3Intern Medical School University of Rome ‘Tor Vergata’, 4University of Cambridge School of Clinical Medicine, 5MedCom GmbH, 6Technische Universität Darmstadt

**Introduction:** The importance of mpMRI/US fusion prostate biopsies is well accepted [1]. The classic transperineal prostate biopsy (TPB) is performed with a stepper and template under anesthesia. The template grid ensures the visibility of the needle and the fixed stepper unit allows stability of the probe to avoid deformations of the prostate. Established local anaesthetic (LA) techniques, via two punctures, use free-moving probes (such as PrecisionPoint or transrectal biopsies) which distort the prostate. This makes cognitive or fusion targeting inaccurate. This study introduces a novel method to perform TPB under LA, allowing application of stable fusion by ensuring the minimal deformation of the prostate whilst displaying the trajectory of the biopsy needle from only 2 perineal access points.

**Methods:** Using the BiopSee® fusion system for TPB and the VirtuTRAXTM (CIVCO) technology, 28 patients with indication for mpMRI fusion prostate biopsy were biopsied using the novel technique called Vecto®. The rectal US probe was mounted on a stepper to provide fusion stability and the US images were fused with the MRI. A needle sheath with a vTrax sensor is inserted into the perineum and the trajectory of the needle is tracked and displayed using the electromagnetic field, thereby providing EM aided tracking of the needle rather than visual. Using the displayed circle on the software the biopsy needle is directed precisely to the pre-contoured lesion to be biopsied. Following the Ginsburg protocol, both targeted and systematic biopsies have been taken.

**Results:** From the 28 patients, 21 reported no or minimal discomfort and no episodes of retention have been reported. Only one patient requested antibiotics for a minor UTI. Detection rates of targets are 95% with the highest ISUP grading or core length in the targets. The procedure is extremely well tolerated.

**Conclusion:** The novel Vecto® technique shows to provide a feasible and tolerable procedure for MRI/US fusion TPB under LA. It is planned that more patients are recruited in order to prove the efficiency, the accuracy and the convenience of this method.
DOES THE POSITION AND SIZE OF THE URETERAL ACCESS SHEATH AFFECT RENAL PRESSURES DURING URETEROSCOPY? INTRARENAL PRESSURE MEASUREMENT USING A SINGLE-USE DIGITAL FLEXIBLE URETEROSCOPE

Ben H. Chew\textsuperscript{1}, Nabil Shalabi\textsuperscript{1}, K.F. Victor Wong\textsuperscript{1}, Roman Herout\textsuperscript{1}, Alina Reicherz\textsuperscript{1}, Naeem Bhojani\textsuperscript{2} \\
\textsuperscript{1} University of British Columbia, Vancouver, BC, Canada, \textsuperscript{2} Université de Montréal, Montréal, QC, Canada

Introduction: Ureteral access sheaths (UAS) facilitate ureteroscopy and allow repeated insertions and removal of the ureteroscope into the kidney and ureter. One reported benefit is the reduced intrarenal pressure by allowing efflux of the irrigation thus preventing pressure buildup in the renal pelvis. We sought to determine if the position of the UAS made a difference in renal pressure utilizing a concept pressure-sensing ureteroscope. We also sought to determine if different UAS sizes could impact renal pressure, and this was evaluated using 4 different methods of irrigation.

Methods: A concept single use digital flexible ureteroscope with pressure monitoring technology (Boston Scientific, USA, concept device/technology, not available for sale) was utilized in this study. Utilizing a live-anesthetized porcine model, pressure was verified by measuring pressure through a 5Fr ureteral catheter (via monitor HP78354A as a reference) compared to readings from the concept ureteroscope. Next, an anesthetized porcine model was tested with different sized ureteral access sheaths (UASs) (11/13, 12/14, and 13/15 Fr) in 3 different locations within the urinary system: 1. in the renal pelvis, 2. below the ureteropelvic junction and 3. in the distal ureter. A pressurized bag at 150mmHg was used to deliver irrigation. Pressure measurements were taken with each parameter using the concept ureteroscope after the renal collecting system had reached a steady state.

Results: Intra-renal pressure readings from the concept ureteroscope strongly correlated with the reference device (p=0.972). The lowest pressures occurred with the UAS within the renal pelvis for the 2 largest UAS sizes (11/13, 12/14). If the UAS is below the UPJ, pressure significantly increased for the 11/13 and 12/14 UASs. Only the 13/15 reduced pressure when below the UPJ. None of the UASs in the distal ureter reduced pressure significantly from control. The 12/14 UAS in the renal pelvis had statistically lower pressure than control (p=0.001) and the 11/13 (p<0.0001) but was not as low as the 13/15 (p=0.033).

Table 1. Intrarenal pressures (mmHg) with various UAS sizes and positions at 150mmHg irrigation.

<table>
<thead>
<tr>
<th>UAS Size</th>
<th>UAS in renal Pelvis</th>
<th>UAS below UPJ</th>
<th>UAS in distal ureter</th>
</tr>
</thead>
<tbody>
<tr>
<td>No sheath (control)</td>
<td>52.0±3.1 mmHg</td>
<td>52.0±3.1 mmHg</td>
<td>52.0±3.1 mmHg</td>
</tr>
<tr>
<td>11/13Fr</td>
<td>35.3±0.4 (33-37)</td>
<td>68.4±8.6* (40-143)</td>
<td>50.6±3.2 (35-73)</td>
</tr>
<tr>
<td>12/14Fr</td>
<td>24.8±2.2* (15-40)</td>
<td>76.3±4.7* (31-106)</td>
<td>35.3±4.4 (21-53)</td>
</tr>
<tr>
<td>13/15Fr</td>
<td>9.5±0.5* (9-10)</td>
<td>17.8±0.3* (17-18)</td>
<td>52.0±3.1 (33-69)</td>
</tr>
</tbody>
</table>

Conclusion: Overall, the largest UAS (13/15Fr) offered the lowest pressure in most positions. Placing the UAS below the UPJ actually increased pressure from control in the 11/13 and 12/14 UASs. Only the 13/15 reduced pressure when below the UPJ. None of the UASs in the distal ureter reduced pressure significantly from control. The 12/14 UAS in the renal pelvis had statistically lower pressure than control (p=0.001) and the 11/13 (p<0.0001) but was not as low as the 13/15 (p=0.033).

Acknowledgement: This work was supported by Boston Scientific Inc.
CAMERA-EQUIPPED PATIENT-OPERATED NEOVAGINAL DILATOR FOR GENDER-AFFIRMING VAGINOPLASTY

Calvin C. Zhao¹, Nabeel A. Shakir¹, Gaines Blasdel¹, Rachel Bluebond-Langner¹, Lee C. Zhao¹
¹ Department of Urology, New York University Grossman School of Medicine, New York, NY

**Introduction:** Following gender-affirming vaginoplasty, post-operative neovaginal dilation is essential in preventing complications, strictures, and loss of depth. [1, Pg. 134] However, dilation can be a laborious and unintuitive process, with existing self-dilation products requiring blind operation with poor ergonomics. We sought to develop a camera-equipped patient-operated neovaginal dilator to improve ease of use in patients undergoing gender-affirming vaginoplasty. This device can additionally be used to image the neovaginal canal, enabling remote follow-up and facilitating care for patients far from gender-affirming specialists.

**Methods:** The dilator housing was designed using Solidworks (Dassault Systems, Waltham, MA) and 3D printed using a Form 3 printer (Formlabs, Sommerville, MA) with a biocompatible resin. We mounted a clear acrylic dome with a wide-angle, fixed focus camera (B006605, Arducam) surrounded by white LEDs at the tip of the dilator. The device was powered using a lithium-ion battery cell and designed with a micro-USB charging port at the base. A Linux-based software package was developed to allow users to wirelessly connect to the dilator over a locally hosted encrypted Wi-Fi network. Users can interact with the device through a web-based interface without the need for custom installations. The interface provides a live video feed as well as a gallery to view, download and delete captured images. The software is hosted on a Raspberry Pi Zero W (Raspberry Pi Foundation, Cambridge, UK). Device ergonomics and image quality were tested in a female pelvic training model as well as a soft silicone vaginal-imitation sleeve. Blood and mucus were simulated using ketchup and lubricating gel.

**Results:** The dilator provides a high-resolution, low latency (<20ms) video feed with excellent illumination of up to 3 inches from the device tip. The wide field of view provides circumferential visualization of surrounding structures with excellent clarity even in the presence of fluid. Battery life is over 6 hours. Total cost of materials in non-bulk quantities was $42.

**Conclusion:** We present a low-cost, easy to use, neovaginal dilator that offers patients direct visualization of the dilation process as well as the ability to take high-resolution images of the neo-vaginal canal. This facilitates dilation by enabling better localization and promotes compliance by empowering patients to directly visualize anatomy and appreciate changes over time. Sharing of images with providers may also enable telemedicine care and save patients from costly in-office.

Figure: A) 3D model and prototype device B) Camera interface showing fine detail in a 10-dollar bill C) Gallery view where users can browse, download, and delete images
IN VITRO VALIDATION OF A REAL-TIME 3D MRI URODYNAMICS PROTOCOL

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1 University of Wisconsin – Madison: Department of Mechanical Engineering, 2 University of Wisconsin – Madison: Department of Medical Physics, 3 University of Wisconsin – Madison: Department of Radiology

Introduction: Lower urinary track symptoms (LUTS) and changes in bladder function occur frequently as individuals age1. Patients with LUTS are commonly evaluated through multi-channel urodynamic studies that determine bladder pressure and flow during voiding. However, these tests are invasive and indirect, providing little insight into the changes in bladder anatomy or visualization of the bladder as it contracts during voiding. Non-invasive methods of imaging the bladder are useful, but their use has been limited2. Motion and chemical shift artifacts may interfere with image acquisition in current bladder imaging techniques3. While MRI driven computational fluid dynamics (CFD) has been used to analyze bladder motion during voiding, 3D MRI acquisition has not been performed4. This study utilizes a 3D MRI acquisition protocol of an in vitro bladder model to assess voiding performance and is validated with high-speed optical imaging.

Methods: In this IRB-approved and HIPPA-compliant study, a healthy, 37-year-old subject was recruited to void in the scanner during 3D MRI acquisition. Using this data, an anatomically realistic in vitro bladder model was fabricated. The bladder was segmented from MRI data of the subject and a STL model was exported (Mimics, Materialize, Leuven, Belgium). The STL was 3D-printed using poly-vinyl alcohol (PVA) and coated in silicone and latex. The PVA core was then dissolved out, leaving the latex mold as the in vitro bladder model. A ¼” diameter tube was attached to represent the urethra and used to fill the model with H2O until full (300 mL). The void time of the bladder model was calibrated to 35 seconds. 3D sagittal Differential Subsampling with Cartesian Ordering (DISCO) Flex MRI images were used to analyze model deformation over the voiding cycle. In vitro MRI data were compared to in vitro deformation images obtained from Phantom high-speed cameras (Vision Research, NJ, USA) during identical voiding conditions. Deformation data were analyzed frame-by-frame using ImageJ (NIH, Maryland, USA) and percent deformation rate using line segments was calculated.

Results: Figure 1 shows deformation images obtained from both the MRI sagittal 3D volumes and high-speed camera footage of the in vitro bladder model with the approximate line segments used to calculate percent deformation. Figure 2 shows the deformation rate of both the MRI and phantom camera imaging modalities. The calculated rate of deformation was 6.2 and 5.3% deformation per second for the 3D MRI and optical cases, respectively. There was a 15% difference in the two deformation rates relative to the phantom camera deformation rate. Qualitative analysis of both methods suggests similar patterns of deformation.

Conclusion: 3D MRI urodynamics was able to quantitatively capture real-time displacement of an in vitro model of the bladder during the voiding process. Deformation during voiding was validated using optical imaging. This will help uncover novel MRI-based methods to image the bladder voiding process in vivo.
DEVELOPMENT OF TOUGH HYDROGELS TO MIMIC FIBROUS PROSTATE TISSUE

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\textsuperscript{1}University of Washington, Seattle, USA, \textsuperscript{2}Virginia Polytechnic Institute and State University, Blacksburg, USA

\textbf{Introduction:} Tissue-mimicking gels provide a cost-effective medium to optimize histotripsy treatment parameters with immediate feedback. Agarose and polyacrylamide gels are often used to evaluate treatment outcomes, but have mechanical properties aligned with very soft tissues. We aimed to produce optically transparent hydrogels with high toughness to mimic pathologic connective tissue found in benign prostate hyperplasia (BPH) and other urological diseases that are potentially treatable with histotripsy.

\textbf{Methods:} Polyacrylamide-alginate hybrid gels at 3 weight ratios (85:15, 90:10, 95:5 thickness ~20mm) were prepared to target different stiffness ranges and their acoustic properties (density, sound speed, and attenuation) were acquired. Ex-vivo human prostate tissue (N=17) was acquired from simple prostatectomies. A 3-dimensional stiffness map of each sample was generated using shear wave elastography (SWE). A 700 kHz histotripsy transducer was used to create volumetric lesions in 3 gels of each type in degassed water and tissue. Different pulse doses were administered at a pulse repetition frequency of 10 Hz, and the dose response was compared against 1.5\% agarose hydrogel. Post treatment, lesions in gels were analyzed under SWE, B-mode ultrasound and phase contrast microscopy.

\textbf{Results:} Pre-treatment hybrid gel stiffness ranged from 42.3±6.0–93.7±16.6 kPa, similar to prostate samples (61.4±29.8kPa). Post-histotripsy, SWE showed a significant reduction in stiffness at lesion sites of every gel type (minimum mean difference= -19.7±1.7 \(P<0.0001\)) and in tissue (-49.4±38.6 \(P<0.0001\)). The required dose to achieve liquefaction in the hybrid gel was more than 10 times greater than agarose of comparable stiffness. Phase-contrast analysis showed optical variation in a region consistent with target lesion dimensions which presented partially treated areas as hyperechoic zones and fully liquified areas as hypoechoic zones on B-mode ultrasound.

\textbf{Conclusion:} These results demonstrate that the tough hydrogels formulated, simulate BPH tissue for histotripsy research. The elasticities measured were comparable to pathologic prostate tissue and treated samples show reduced stiffness and liquefaction reflecting histotripsy.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{fig1.png}
\caption{A. Stiffness in hybrid gels - pre vs. post treatment, exposure time:1000s, B. A sample 85-15 hybrid gel. C. B-mode image and SWE map of lesion in 85-15 hybrid gel showing hyperechoic (red) and liquified hypoechoic region (yellow) exposure time-1000s, D. B-mode image and SWE of lesion in prostate sample showing liquified hypoechoic region (yellow), exposure time - 500s E. Phase contrast microscopy of 85-15 hybrid gel showing liquified region circled in red at varying pulse count followed by a processed image using Sobel edge detection reflecting the same. F. Phase contrast microscopy of 1.5\% agarose gel showing liquified region as pointed by the red arrow at varying pulse count, followed by a processed image using Sobel edge detection reflecting the same.}
\end{figure}

\textbf{Source of Funding:} Work supported by R01-DK119310 and L30-DK122509.
ABSTRACT 22

ANALYSIS OF EX VIVO HUMAN BPH TISSUE TREATED BY HISTOTRIPSY: DOSE AND PARAMETER EFFECTS

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2Center for Industrial and Medical Ultrasound, Applied Physics Laboratory, University of Washington
3Department of Biomedical Engineering and Mechanics, Virginia Polytechnic Institute and University
4Department of Pathology, University of Washington

Introduction: Histotripsy is a promising alternative to more invasive procedures for the treatment of benign prostatic hyperplasia (BPH). However, in a phase 1 clinical trial, histotripsy failed to provide objective improvements in urinary function. One explanation may be that the clinical trial pulse parameters, optimized in a canine model, do not translate to more fibrotic human prostates. We aimed to evaluate the efficacy of different pulse parameters to identify a more efficacious exposure in ex-vivo human BPH tissue (EVHP).

Methods: Deidentified EVHP tissue specimens (n=17) were treated using an 18 element 700kHz histotripsy transducer approximating the device used in the prior clinical trial. Pulse parameters reported for the previous clinical system (3 cycle pulses, 500 Hz pulse repetition frequency (PRF)) were compared to a test parameter set (20 cycle pulses, 10 Hz PRF) at varying doses (t = 14s, 28s, 86.6s, 144s for both). Treatment effectiveness was evaluated by measuring pre vs. post treatment Young’s modulus through shear wave elastography (SWE) and histologic analysis (H&E, Masson’s Trichome) of the targeted area. Efficacy of collagen ablation was evaluated by measuring the collagen intensity signal in untreated vs treated areas with second harmonic generation (SHG) optical microscopy.

Results: Test parameters were more effective, per unit time, at causing significant reductions in SWE Young’s modulus compared to clinical parameters (P < .001) (Fig 1A). On histology, clinical trial parameter settings (Fig 1B.) resulted in less complete ablation within the intended target area (white outline) relative to test parameter settings (Fig 1C.). Within treatment zones (Fig 1B/C. red outline), the average collagen intensity signal (Fig 1D.) decreased significantly for both clinical and test parameters settings (P-value <.001 for both exposures).

Conclusion: Histotripsy treatment parameters applied in a prior clinical trial do not produce consistent ablation of EVHP possibly explaining trial results. Conversely, an alternative test parameter set produced more complete ablation, suggesting histotripsy parameters optimized for the treatment of human BPH can improve clinical efficacy.

Figure 1 A. Tissue stiffness change for clinical and test parameters vs. treatment time. B. Masson’s trichome of clinical parameters at 50K pulses C. Masson’s trichome of test parameters at 5000 pulses. D. Collagen intensity signal in untreated and treatment zones for clinical parameters at 50,000 pulses and test parameters at 5000 pulses.
INNOVATION AND MARKET ENTRY DRIVERS FOR SURGICAL DEVICES

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1 UCLA Dept of Urology, 2 SUNY Downstate, 3 UCLA Dept of Bioengineering

Introduction: Introducing innovation into a well-established medical market such as urology requires the support of multiple stakeholders. Regardless of these challenges, there has been an increase in the use of robotic and other novel technology in urology in recent years. Academic researchers and corporate device developers can translate their innovations from concept to industry standards by successfully addressing the needs and concerns of key market stakeholders to generate high demand products. With this in mind, the aim of this study was to outline the current landscape of robotic and other novel surgical device development and to understand the factors that drive or block market entry.

Methods: Over 300 individuals were identified by LinkedIn, social media, recommendations/reputation, and publications. Inclusion criteria were past or current experience with (1) the use or purchase of surgical devices, (2) the use or purchase of a surgical robot, or (3) reimbursement. Interviews were conducted virtually and evaluated by a bioengineer, business professional, and urologist via a modified framework method [10,1186]. Interviews included both specific questions and unprompted discussion. An initial review of interview notes identified main themes, followed by additional reviews for code mapping specific to this secondary analysis of National Science Foundation Innovation Corps interviews performed by the Bio-Zipper team. Codes and references were charted and matched to illustrative quotations. The analytic process involved meetings with the research team to identify all themes and subthemes, concept characterization, generation of typologies, and exploring connections between the different sets of data.

Results: 102 individuals participated in the study and were interviewed, including 29 urologists, 25 device representatives, 22 administrators, 10 patients, 10 researchers, and 6 referring physicians. The attached table outlines a portion of the major themes and subthemes discussed by the interviewees.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Subthemes</th>
</tr>
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<tbody>
<tr>
<td>Adoption curves and trends</td>
<td>• Future predictions, potential for advancement</td>
</tr>
<tr>
<td></td>
<td>• Robotic or ancillary device adoption</td>
</tr>
<tr>
<td></td>
<td>• Impact of COVID</td>
</tr>
<tr>
<td>Drivers / barriers to technology adoption</td>
<td>• Current and historic factors</td>
</tr>
<tr>
<td>Training and education</td>
<td>• Access via residency programs</td>
</tr>
<tr>
<td>Surgical considerations</td>
<td>• Technical aspects of procedure</td>
</tr>
<tr>
<td>Added and perceived value</td>
<td>• Stakeholder appraisal</td>
</tr>
<tr>
<td>Path to market</td>
<td>• Device companies and developers</td>
</tr>
<tr>
<td></td>
<td>• Academic partnerships</td>
</tr>
<tr>
<td></td>
<td>• In-hospital purchasing processes</td>
</tr>
<tr>
<td></td>
<td>• Group Purchasing Organizations (GPOs)</td>
</tr>
<tr>
<td></td>
<td>• Contracts with healthcare entities</td>
</tr>
<tr>
<td></td>
<td>• Major decision makers</td>
</tr>
<tr>
<td>Target market</td>
<td>• Centralization</td>
</tr>
<tr>
<td>Approval and regulatory</td>
<td>• Food and Drug Administration</td>
</tr>
<tr>
<td></td>
<td>• Intellectual Property</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>• Centers for Medicare and Medicaid Services</td>
</tr>
<tr>
<td></td>
<td>• Private insurers and payors</td>
</tr>
</tbody>
</table>

Conclusion: The common themes discussed included the role of value in driving adoption of novel technology, elucidation of system-wide decision makers and their reasons for device adoption, and drivers/barriers to robotic market entry. One unifying point across stakeholders was the need for improved post-operative patient outcomes. Entry into the urologic device market is extremely complex, varies by institution, and requires considerable planning and analysis early in product development. Defining value for each stakeholder will allow inventors to decrease obstacles to market entry and accelerate the adoption of translational technologies. (All interviews were conducted as part of 2020 NSF Innovation Corps: grant #2045366.)
ABSTRACT 24

BRAZILIAN SIGN LANGUAGE APP IN THE MANAGEMENT OF DEAF UROLOGICAL PATIENTS AS SOCIAL INCLUSION TOOL

Gustavo Alarcon, Arthur Araújo, Gabriel Rosa, Bruno Barbão, Nicholas Hermann, Cassio Faria, Caio Andrade, Júlia Alarcon, Soraia Damião, Enrico Andrade

1 USCS Universidade Municipal de São Caetano do Sul - São Paulo – Brazil, 2 HSV Santa Virginia Hospital Urology Institute - São Paulo – Brazil, 3 HAOC Oswaldo Cruz Hospital - São Paulo – Brazil, 4 LAUCRIT Urology Academic League - São Paulo – Brazil

Introduction: The Brazilian Sign Language (Libras) is the sign language used by deaf people in Brazilian urban centers. However, it is present in only a minority consisting of deaf people and around the environment in which they live, in order to demonstrate their capacity and social development. This fact interferes with the lack of trained professionals to receive people who use it, making it difficult for these patients to be included in the public health system. Thus, social inclusion practices were adopted to improve this deficiency, guaranteeing everyone's rights and accessibility.

Methods: Experience report with medical students attending the outpatient clinic of the teaching hospital at the Municipal University of São Caetano do Sul in Brazil. Demonstrate the use of an inexpensive, fast, and effective method of communication and social inclusion during outpatient urological consultation in a teaching hospital. We used the VLIBRAS® application provided by the Ministry of Social Inclusion.

Results: The Application allows to demonstrate clearly and quickly how to express phrases and symptoms during consultation in sign language. In this way, it allows the patient to be fully embraced, with special attention from students in training, and allowing the right to autonomy, without the need for family members to assist in their communication, demonstrating satisfaction with the innovative way they are cared for in the public health system. The student, who is not fluent in language, values mutual understanding and adds such action to their individual learning.

Conclusion: It is expected to advance in this methodology in order to improve and promote improvements in the teaching-learning process in medical schools, since it is a tool that is easy to apply and access, as it uses a cell phone or tablet.
SAFETY, FEASIBILITY, AND ACCURACY OF THE UROMONITOR: A CATHETER-FREE, WIRELESS AMBULATORY CYSTOMETRY DEVICE

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Introduction: We have developed a wireless, catheter-free intravesical pressure sensor, the UroMonitor (UM), to perform telemetric, catheter-free ambulatory bladder monitoring. Our objectives were to evaluate accuracy of UM pressure data and assess safety and feasibility of use in humans.

Methods: Ambulatory adult female patients undergoing evaluation for overactive bladder (OAB) symptoms with urodynamics (UDS) were recruited. After baseline UDS, the UM was transurethrally inserted into the bladder, and a second UDS was performed. UDS catheters were then removed and bladder pressure data from the UM was collected wirelessly and catheter-free while the subject ambulated and voided in privacy. The UM was manually extracted transurethrally via a pre-attached suture. Visual-analog pain scales (0-5) were used to assess patient discomfort in each study phase. Data is provided as mean [range] resulting from this pilot study.

Results:

The UM was tested with 11 patients. Mean UM insertion time was 24.5 s [7-66 s]. The UM did not significantly alter bladder capacity (mean UDS capacity: 365 cc [150-640 cc] vs. mean UDS + UM capacity: 322 cc [50-650 cc], p = 0.146) or maximum flow (mean UDS Qₘₐₓ: 24.7 cc/s [4.8-41.7 cc/s] vs. mean UDS +UM Qₘₐₓ: 22.9 cc/s [8.9-30.0 cc/s], p = 0.792) during UDS. UM accurately reproduced vesical pressure waveforms, capturing 98% (85/87) of voiding and non-voiding urodynamic events. Mean differences between UM-measured and UDS-measured pressures were within +/- 5 cmH₂O for 6 of 9 subjects included in this sub-analysis. UM pressure data correlated to that of UDS (r² of 0.51 [0.11-0.94]) and improved significantly over the course of the study as device modifications and data acquisition methods improved, with a mean r² of 0.87 [0.72-0.94] for the final 6 subjects. All subjects were able to void with only the UM in place and had low post-void residual volumes (mean 11cc [0-50cc]). The median catheter-free pain score with only the UM in place was rated 0 [0-2]. Mean time for UM removal was 2.1 s [1.5 – 3 s]. There were no post-procedural urinary tract infections and no changes to voiding behaviors 48 hours post-procedure.

Conclusion: The UM is the first device to enable catheter-free telemetric ambulatory bladder pressure monitoring in humans. The UM appears safe, is well tolerated by patients, and does not impede LUT function. Data from this pilot study suggests the UM can reliably identify bladder events.
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A FLEXIBLE ROBOT SYSTEM ‘EASYURETEO’ FOR KIDNEY STONE TREATMENT WITH RETROGRADE INTRARENAL SURGERY

Joonhwan Kim¹*, Byungsik Cheon¹,²*, Jungmin Han¹,², Joo Yong Lee³, Sung Yong Cho⁴, Hyung Keun Park⁵, Dong-Soo Kwon¹²

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Introduction: Retrograde Intrarenal Surgery (RIRS) is becoming popular for kidney stone treatment due to its higher stone free rate and lower complication rate that compensates the limitation of Extracorporeal Shock Wave Lithotripsy (ESWL) and Percutaneous Nephrolithotomy (PCNL). However, there are difficulties such as fatigue in ureteroscope manipulation, additional assistant for basket, risk of ureteral injury, and radiation exposure, which limit effectiveness and safety in RIRS. A new flexible robot system easyUretero providing solutions to above difficulties has been developed. We present its features and an initial animal test to validate the feasibility.

Methods: easyUretero is a master-slave robot system that enables teleoperation of flexible ureteroscope as well as basket and laser (Figure 1). The slave robot can mount a commercial flexible ureteroscope. The master console featuring a novel controller interface provides ergonomics and intuitiveness so that a surgeon can easily and comfortably manipulate the ureteroscope, basket, and laser with his/her one hand in a sitting posture. The robot system has automation capability that can record and play the ureteroscope motion which can be effectively utilized in a repetitive task such as multiple stone retrieval. The robot system also provides a safety function that detects the grasping and retrieval of an oversized stone to avoid the ureteral injury. The radiation exposure to the surgeon can be minimized because the surgeon operates the robot behind a radiation shield barrier.

Results: An initial animal test was performed with a pig to verify the feasibility of easyUretero. We confirmed that ureteroscope manipulation, dusting and fragmenting using a laser, stone retrieval using a stone basket worked well. The kidney stones inserted through an access sheath or percutaneously could be successfully removed without conversion (Figure 2). Overall, the surgeons expressed the intuitiveness of ureteroscope manipulation and less fatigue especially in shoulder, wrist, and thumb.

Conclusion: A new robot system easyUretero that enables teleoperation of flexible ureteroscope, basket, and laser was proposed. The initial animal experiment demonstrated that the robot works well in in-vivo and improves surgical ergonomics. After an additional animal test with various evaluation indices and surgeons with different RIRS proficiency, a clinical trial to validate effectiveness and safety was completed favorably.
Purpose: The native urethra has remarkable elasticity, a key finding that supports long-term voiding and tumescence. This property has not been consistently reproduced by either current autografts or engineered scaffolds. The goal of this study was to engineer a biomimetic and biocompatible scaffold that mimics the mechanical properties of healthy urethral tissue. Our hybrid scaffold is composed of two naturally-derived polymers, elastin-like polypeptide (ELP) and gelatin methacryloyl (GelMA). Incorporated ELP improves stretchability and controls degradation and swelling of the scaffold, while the natural arginine-glycine-aspartic acid sequences in GelMA promotes cell adhesion and proliferation. Electrospinning facilitates control of scaffold nanotopography and contributes to its elasticity.

Materials and Methods: A custom-made electrospinning system was used to form the nanofibrous GelMA/ELP scaffolds. GelMA and ELP with different concentrations (3, 5, 7, and 10% (w/v)) were dissolved in 1,1,1,3,3,3-hexafluoroisopropanol, and the solution was pumped from an 18G needle at a rate of 1ml/hr. A high voltage power source charged the needle and a stainless steel collecting plate with a 13 cm working distance. The resultant electrospin sheet was soaked in 1% (w/v) Irgacure 2959 in ethanol for 2 hours and photocrosslinked using UV light for 10 minutes. Mechanical properties were measured using an Instron 5943 mechanical tester. To evaluate native tissue, anterior urethras from 18–20 weeks male New Zealand white rabbits were dissected and opened longitudinally along the dorsal surface. For this study, tensile testing conducted on native tissues was compared with mechanical properties of the engineered scaffolds. A one-way ANOVA statistical test was used to evaluate between-group differences.

Results: The electrospinning process was optimized to fabricate GelMA/ELP scaffolds. Our results showed that ultimate strain (extensibility) significantly increased from 153.33±18.37 kPa to 410.91±113 kPa by substituting 5% (w/v) ELP for GelMA. Moreover, the ultimate tensile strength, Young’s modulus, and extensibility of GelMA 5% (w/v)/ELP 5% (w/v) were not found to be significantly different from anterior urethral tissue (Fig. 1), achieving target mechanical parameters as delineated for scaffold development.

Conclusions: Our preliminary mechanical data suggests that engineered GelMA/ELP hybrid scaffolds are suitable candidates for a substrate that mimics the mechanical properties of native tissue. We plan to fabricate a tubular GelMA/ELP nanofibrous scaffold and evaluate the effects of mechanical properties on in vitro extracellular matrix production and in vivo function following urethroplasty. In the future, such scaffolds may provide an alternative strategy for the engineering of urethral replacement tissue needed for hypospadias and complex stricture repairs.
BIOMECHANICAL CHARACTERIZATION OF SUTURE-URETERAL TEARING THROUGH SUTURE PULLOUT FORCE MEASUREMENTS ON HUMAN CADAVERIC TISSUE

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1 University of Washington, 2 Madigan Army Medical Center, 3 US Army CCDC STTC

Introduction: The most common causes of complication in ureteral trauma reconstruction are inadequate debridement of damaged ureteral tissue, excessive tension on the ureter, and urinary leakage through the site of anastomosis [1]. These complications can lead to urinoma, ureteral strictures or the potential loss of a kidney [1]. Anatomically and biomechanically accurate training simulators may provide the adequate realism needed to teach clinicians proper technique. This study aims to characterize the forces required to tear a suture through the ureter in order to improve tissue-model fidelity to meet reconstructive training requirements.

Methods: Seven ureters from fresh, unfixed cadavers were obtained and tested within 72 hours of death and stored in 1X Phosphate Buffered Saline (pH 7.4) at refrigerator temperatures (1-1.6 C). Excess fat and connective tissue were removed. The suture pullout force (SPOF) was characterized using a lab developed test setup, Fig. 1a. A 4-0 Sofsilk® (Medtronic, Fridley, MN) was placed on one side of the ureter. The suture bite size was measured between the end of the ureter and the suture site. The tissue was then constrained while the suture was secured to a load cell (REB7, Loadstar Sensors, Fremont, CA) and pulled at a constant velocity of 1.58 mm/sec, bringing tension to the suture until tissue failure. The maximum tension force is then recorded at failure.

Results: The results are shown in Fig. 1b. 75 suture pullout tests were performed on 4 female and 3 male donors. Mean donor age and BMI were 47 ± 16 and 23.8 ± 3.51, respectively. Mean tensile load at tissue failure is 3.30 ± 1.97 N. To remove the dependency on the bite size, the force was normalized by the bite size. The average normalized force was 0.96 ± 0.3 N/mm.

Conclusion: Developing more accurate simulators to meet reconstructive training requirements for surgeons can lead to improved patient outcomes and reduce complications [2]. As trainers become more complex, biomechanical characterization of human tissue will be pivotal in developing higher tissue-fidelity models. Benchmarking developed tissue analogs to human tissue biomechanical properties further substantiates the simulation [3]. By utilizing the SPOF reported here in developing these models, proper suturing technique can be trained which may reduce complications in ureteral trauma and ureteral trauma repair cases.

Figure 1: a) Schematic showing the developed test setup. b) Boxplot showing the normalized suture pullout force of the ureter.
A NOVEL “TOUCH & GO” METHOD FOR RETRIEVING TISSUE SPECIMENS FROM PROSTATE BIOPSY NEEDLES THAT PREVENTS CORE FRAGMENTATION AND PRESERVES CORE INTEGRITY

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Introduction and Background: Tissue fragmentation while retrieving specimens from prostate biopsy needles can adversely affect histologic analysis. Degree of fragmentation is a function of the retrieval method and the skill of the assistant. Retrieval by swiping the needle laterally against a foam pad is reported to result in less core fragmentation than dragging the needle proximally on the pad. Vigorous washing of needle tip dislodges the specimen without fragmentation but causes the tissue to warp and curl up. We describe a new method for specimen retrieval utilizing a biocompatible material currently in clinical use. Touching the needle against it lifts the specimen from the needle due to surface tension without shearing movement or direct pressure that can fragment the sample. We report results of comparing the “Touch & Go” method with the three conventional methods to assess differences in specimen quality and integrity for histologic analysis.

Methods: Bovine prostate tissue cores were collected using an 18-gauge prostate biopsy needle. The specimens were retrieved by swiping, dragging, washing or “Touch & Go” method. Histologic analysis was performed following standard protocol to assess tissue artifact, fragmentation, and sample integrity.

Results: Histologic analysis demonstrated consistently less fragmentation and improved integrity of the cores with “Touch & Go” compared with the other methods with the exception of the "side swipe" method which was deemed to be equal in performance. The following are representative slides of specimens retrieved:

No deleterious effects on tissue collected with the “Touch & Go” method were detected in its use in other assays.

Conclusion: The novel “Touch & Go” method of tissue specimen retrieval has the potential to simplify tissue collection while preserving tissue integrity, reducing tissue artifact, and improving diagnostic performance. The results obtained by the side swipe method may be subject to more variability due to the differences in pressure used to remove the tissue with each core, while the "Touch and Go" method uses only surface tension to remove the tissue from the biopsy needle. Further studies, which have been initiated, will help determine if “Touch & Go” consistently preserves core integrity over the “side swipe” and other methods.
SINGLE PORT ROBOTIC VERSUS OPEN KIDNEY TRANSPANTATION: A COMPARISON OF OUTCOMES
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Introduction: We performed the first single-port (SP) robot-assisted kidney transplantation (KTP) using the da Vinci SP platform in 2019. We compare here the perioperative and follow-up outcomes of the initial series of patients who underwent SP KTP with the standard open KTP.

Methods: We compared a prospective cohort of 12 patients who underwent SP robotic KTP from Oct 2019 to Oct 2021 with a retrospective cohort of 12 matched patients who had open KTP at our institute. Patients were matched for donor type, the kidney donor profile index (KDPI) in deceased donors, recipient age, and history of diabetes. Perioperative data were retrieved from our institutional review board (IRB) approved database. Normality of data was tested with the Kolmogorov-Smirnov test when indicated. The comparison of normal data was performed using a T-test. Comparison of percentages was performed using the “N-1” Chi-squared test.

Results: Baseline characteristics and perioperative data of these patients are presented in table 1. No patients in SP arm were converted to open surgery. Mean (SD) revascularization time in SP and open arms were 72.75 (11.93) and 36.25 (9.39) minutes respectively (P < 0.0001). There were no intra or postoperative complications greater than Clavien grade 2 in either group. The morphine milligram equivalents (MME) score during admission was 44.91 (40.15) in SP and 149.16 (119.70) in open groups (P = 0.0091). 6-, and 12-month graft and patient survival were 100% in both arms. There was no significant difference in mean creatinine level at 1, 6, and 12 months between SP vs. open group. There were no vascular or surgical complications during follow-up in either arm.

Conclusion: Single port robotic kidney transplantation offers a minimally invasive approach with similar safety and allograft function compared to open kidney transplantation.

**Table 1 - Baseline characteristics, and perioperative data**

<table>
<thead>
<tr>
<th></th>
<th>SP KTP, N=12</th>
<th>Open KTP, N=12</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Transplantation, Years, Mean (SD)</td>
<td>55.64 (7.09)</td>
<td>55.60 (5.82)</td>
<td>0.60</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, N(%)</td>
<td>6 (50)</td>
<td>5 (41.66)</td>
<td>0.68</td>
</tr>
<tr>
<td>Male, N(%)</td>
<td>6 (50)</td>
<td>7 (58.30)</td>
<td>0.08</td>
</tr>
<tr>
<td>BMI (kg/m2), Mean (SD)</td>
<td>20.95 (7.17)</td>
<td>20.38 (8.24)</td>
<td>0.87</td>
</tr>
<tr>
<td>Dialysis Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preservative, N(%)</td>
<td>5 (41.6%)</td>
<td>3 (25%)</td>
<td>0.30</td>
</tr>
<tr>
<td>IHD, N(%)</td>
<td>4 (33.3%)</td>
<td>7 (58.35)</td>
<td>0.22</td>
</tr>
<tr>
<td>PD, N(%)</td>
<td>1 (8.33)</td>
<td>2 (16.66)</td>
<td>0.62</td>
</tr>
<tr>
<td>Donor Data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living, N(%)</td>
<td>9 (75)</td>
<td>9 (75)</td>
<td>1.00</td>
</tr>
<tr>
<td>Deceased Brain Dead, N(%)</td>
<td>3 (25)</td>
<td>3 (25)</td>
<td>1.00</td>
</tr>
<tr>
<td>Left Kidney, N(%)</td>
<td>11 (91.7%)</td>
<td>11 (91.7)</td>
<td>1.00</td>
</tr>
<tr>
<td>Right Kidney, N(%)</td>
<td>1 (8.33)</td>
<td>1 (8.33)</td>
<td>1.00</td>
</tr>
<tr>
<td>Operative Data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extraperitoneal Approach, N(%)</td>
<td>9 (75)</td>
<td>12 (100)</td>
<td>0.06</td>
</tr>
<tr>
<td>Transperitoneal Approach, N(%)</td>
<td>3 (25)</td>
<td>0 (0.00)</td>
<td>0.06</td>
</tr>
<tr>
<td>Total Operative Time (Minutes), Mean (SD)</td>
<td>339.44 (51.02)</td>
<td>240.77 (65.32)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Revascularization Time (Minutes), Mean (SD)</td>
<td>72.75 (11.93)</td>
<td>36.25 (9.39)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Estimated Blood Loss (mL), Mean (SD)</td>
<td>103.75 (284.50)</td>
<td>170.16 (123.32)</td>
<td>0.87</td>
</tr>
<tr>
<td>Inpatient Data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative Complications ≥ Grade 2, N (%)</td>
<td>0 (0.09)</td>
<td>0 (0.00)</td>
<td></td>
</tr>
<tr>
<td>Postoperative Complications ≥ Grade 2, N (%)</td>
<td>2 (16.66)</td>
<td>0 (0.00)</td>
<td>0.34</td>
</tr>
<tr>
<td>Delayed Graft Function, N (%)</td>
<td>0 (0.09)</td>
<td>1 (8.3%)</td>
<td>0.31</td>
</tr>
<tr>
<td>Inpatient Hospital Stay (days), Mean (SD)</td>
<td>2.79 (1.13)</td>
<td>2.79 (0.60)</td>
<td>1.00</td>
</tr>
<tr>
<td>MGME score in Hospital, Mean (SD)</td>
<td>44.91 (40.15)</td>
<td>40.16 (119.70)</td>
<td>0.0004</td>
</tr>
<tr>
<td>Postoperative Creatinine (mg/dL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month, Mean (SD)</td>
<td>1.31 (0.23)</td>
<td>1.50 (0.50)</td>
<td>0.24</td>
</tr>
<tr>
<td>6 months, Mean (SD)</td>
<td>1.31 (0.24)</td>
<td>1.40 (0.50)</td>
<td>0.63</td>
</tr>
<tr>
<td>12 months, Mean (SD)</td>
<td>1.30 (0.15)</td>
<td>1.33 (0.41)</td>
<td>0.06</td>
</tr>
<tr>
<td>BMI (body mass index), SD (standard deviation), LDF (diameter of femoral artery), PD (pseudocapillary density), MGME (morphine milligram equivalents)</td>
<td></td>
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</tbody>
</table>
EX VIVO WORKBENCH EVALUATION OF NOVEL WIRELESS ENDOCOSCOPIC CAMERA SYSTEM

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Introduction: Wireless technology has yet to make a breakthrough in endoscopic surgery. There are less than a dozen published articles on its design and application to endoscopic minimally-invasive surgeries despite recent advances in wireless and camera technology¹. We evaluated the specifications of a new wireless camera system (Endoluxe Endoscopic Visualization System [EVS], Dunwoody, GA) and its application to laparoscopic surgery in a workbench setting.

Methods: The EVS incorporates a wireless orb with built-in LED display, integrated LED light source, and a wireless camera module that can connect wirelessly with any HDMI adapter. The system also includes a receiver module for the HDMI monitor as well as a charging station. We assessed the transmission latency, resolution (1951 USAF resolution test chart), as well as time to completion of benchmark laparoscopic skills compared to an existing wired camera system (Storz IMAGE1 SPIES H3-Z HD Camera). Two endourologists assessed the quality of the camera system subjectively.

Results: Average latency from CMOS to built-in display was 53 ms (range 30-90 ms) and from CMOS to HDMI display (wireless transmission) was 97 ms (70-170 ms); see chart below. Spatial resolution of imaging system was tested with the 1951 USAF resolution test chart (MIL-STD-150A standard) in comparison with the Storz camera (SPIES). All 54 target elements from the chart were adequately visualized between both EVS and SPIES. See figures below. Performing a simple laparoscopic peg transfer exercise showed no difference in time to completion using either camera systems for both surgeons (EVS 63 +/- 5 sec vs SPIES 67 +/- 8 sec).

Conclusion: The EVS demonstrated accepted mean total transmission latency of 97 ms. Several studies have shown significantly decreased surgeon effectiveness and increased risk of harm to patients at total latencies above 160 ms; while some have shown adequate telesurgical applicability at any latency below 250 ms². EVS has also demonstrated optimal spatial resolution (using 1951 USAF resolution testing) vs traditional endoscopic camera as well as ease-of-use in performing basic laparoscopic exercises in a benchwork setting. Its application to in vivo clinical operations should be investigated further.

Citations:
ABSTRACT 33

A PILOT STUDY TO EVALUATE THE EFFICACY OF PULSED ELECTROMAGNETIC FIELD (PEMF) THERAPY FOR PELVIC PAIN REDUCTION AND SYMPTOM IMPROVEMENT IN INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME

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2 Wake Forest Institute for Regenerative Medicine

Introduction: PEMF therapy has been found to be a safe and effective modality for pain reduction in certain chronic pain disorders, likely due to modulation of cellular inflammatory processes and decreased pain sensitivity. The present study evaluated the efficacy of PEMF therapy for pain/symptom management in women with interstitial cystitis/bladder pain syndrome (IC/BPS) with a non-bladder centric phenotype.

Methods: Women (ages 18-80 y/o) with a confirmed diagnosis of IC/BPS, an anesthetic bladder capacity (BC) > 400ml (non-bladder centric phenotype), and a numeric rating scale (NRS) score for pelvic pain ≥ 6 underwent twice daily, 8-minute full body PEMF sessions for 4 weeks. The primary outcome measure was a reduction in NRS score ≥ 2. Secondary outcomes were assessed with a 7-day voiding diary collected at baseline and conclusion of therapy, as well as the O’Leary Sant Interstitial Cystitis Symptom and Problem Indices (ICSI/ICPI), Pain and Urgency/Frequency (PUF) patient symptom scale, Female Genitourinary Pain Index (F-GUPI), and the Short Form-36 (SF-36) Quality of Life questionnaires, completed at baseline, 4 weeks (conclusion), and 12 weeks (8-week follow-up). Group means are reported, and treatment effects were assessed via Wilcoxon signed-rank test with a p<0.05 being considered significant.

Results: Of 10 women recruited, 8 completed the 4-week treatment, and 7/8 (87.5%) had a significant (≥ 2 point) reduction in pelvic pain (mean 6.9 to 4.2, p=0.011) after 4 weeks (primary outcome measure). There was also a significant decrease (improvement) in daily number of voids (13.8 to 11.5; p=0.046), as well as mean ICSI (13.9 to 8.0; p=0.011), ICPI (13.0 to 9.1; p=0.046), PUF (25.5 to 18.25; p=0.02), and F-GUPI symptom scores (35.3 to 23.4; p=0.012). Patients also experienced significant increases (improvement) in the SF-36 quality of life energy/fatigue (34.4 to 60.2; p=0.018), social function (45.3 to 73.4; p=0.042), and pain (38.4 to 63.1; p=0.042). After 8-weeks post-therapy, the positive effects were somewhat attenuated, yet 4/8 patients (50%) continued to have significant (≥ 2 point) pain reduction (mean 6.9 to 5.4; p=0.027). Mean ICSI (13.9 to 10.0; p=0.017) and PUF (25.5 to 22.1; p=0.028) scores remained significantly lower and the SF-36 energy/fatigue (34.5 to 51.6; p=0.029) and pain (38.4 to 55.3; p=0.04) remained significantly elevated while emotional well-being (62.5 to 78.8; p=0.018) and general health scores (45.0 to 54.5; p=0.017), which were not significantly different at 4 weeks, had increased significantly from baseline. No adverse events were reported.

Conclusion: This proof-of-concept interventional trial found significant pain reduction, decreases in subjective symptom scores, and increases in quality-of-life scores for nearly all patients via the use of PEMF full body treatments, twice daily, for 4 weeks. Many benefits persisted for 8 weeks post-therapy. Randomized, sham-controlled trials are planned to validate these findings.
ABSTRACT 34

QUANTIFICATION OF OUTFLOW RESISTANCE FOR URETERAL DRAINAGE DEVICES USED DURING URETEROSCOPY

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University of Michigan, Ann Arbor, MI, USA

Introduction: It is important to properly manage renal pelvis pressure during ureteroscopy. Renal pelvis pressure is directly related to outflow resistance and irrigation flowrate. Knowledge of the outflow resistance associated with commonly used drainage devices could help guide selection of type and size of ureteral access sheath or catheter for individual ureteroscopic cases. The aim of this study is to experimentally quantify outflow resistance for different drainage devices utilized during ureteroscopy.

Methods: Renal pelvis pressure ($P_{RP}$) is dependent on irrigation flowrate ($Q$) and outflow resistance ($R_{OUT}$).

$$P_{RP} = Q \times R_{OUT}$$

In this study, $P_{RP}$ and $Q$ were measured, allowing calculation of $R_{OUT}$. After placement of a drainage device into a silicone kidney-ureter model, a disposable ureteroscope was inserted with its tip positioned at the renal pelvis. Deionized water irrigation was delivered through the ureteroscope from varying heights above the renal pelvis. Renal pelvis pressure was measured directly from the port of the kidney model using an Opsens pressure sensor. Outflow resistance was determined by plotting flowrate (mass of fluid drained through the drainage devices tip in 60 seconds) versus renal pelvis pressure. All trials were performed in triplicate for each drainage device inserted: 13/15 Fr, 11/13 Fr ureteral access sheath, and 6 Fr, 4.8 Fr, and 4 Fr ureteral access catheters.

Results: Flowrate was linearly dependent on renal pelvis pressure for all drainage devices tested. Outflow resistance values were 0.2, 1.1, 1.4, 3.9, and 6.5 cmH$_2$O/[ml/min] for UAS 13/15 Fr, UAS 11/13 Fr, UAC 6 Fr, UAC 4.8 Fr, and UAC 4.0 Fr, respectively across the range of commonly used irrigation flowrates.

Conclusion: In this study, the outflow resistance of different ureteral drainage devices used during ureteroscopy was determined. This knowledge can be useful when selecting which type and size of drainage device to insert to maintain safe renal pelvis pressure during ureteroscopy.

Figure 1: Irrigation flowrate plotted against renal pelvis pressure for different drainage devices (with a 200 μm D/F/L laser fiber in the working channel of a LithoVue single use ureteroscope) The slope of the line represents the outflow resistance.

Funding: Research grant from Boston Scientific
ABSTRACTS

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ULTRASOUND TOMOGRAPHY FOR PROSTATE CANCER IMAGING: AN EX VIVO PRELIMINARY STUDY

Jacob J. Enders¹, Cheyenne Williams¹, Michael B. Rothberg¹, Zoe Blake¹, Jibriel Noun¹, Yixuan Wu², James Wiskin³, Michael Daneshvar¹, Reza Seifabadi¹, Ayele Negussie¹, Peter Choyke¹, Emad Boctor², John Klock³, Antoun Toubaji¹, Maria Merino¹, Baris Turkbey¹, Bradford J. Wood¹, Peter A. Pinto¹

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Introduction: While multiparametric MRI (mpMRI) and targeted biopsy have improved the detection of high-risk prostate cancer (PCa) over traditional B-mode ultrasound, the use of mpMRI in the diagnostic pathway for PCa remains limited due to variability in image acquisition and interpretation, accessibility, and cost. Ultrasound tomography (UT), previously shown to have high sensitivity for the diagnosis of breast cancer [PMC4641199], provides 360-degree submillimeter-resolution imaging for tissue characterization and cancer detection, even in the presence of bone and air, or with limited view tomographic data. The purpose of this study was to validate UT for the detection of PCa by imaging ex vivo whole prostate specimens after radical prostatectomy, comparing lesion detection and visualization on UT with mpMRI, and correlating imaging findings with wholemount histopathology.

Methods: Following mpMRI and targeted prostate biopsy, patients with biopsy-proven PCa underwent robotic-assisted radical prostatectomy (RARP) and had their prostates subsequently scanned ex vivo in the UT device (QT Imaging Inc, Novato, CA) within 30 minutes of surgery. Tumor boundaries on mpMRI and UT were segmented by an expert genitourinary radiologist, and wholemount pathology slides created with patient-specific molds were annotated by two expert genitourinary pathologists. Correlations between pathology and imaging were done using an 18-sector approach dividing the prostate into anatomical regions (Figure). Sensitivity was defined as the probability of correctly detecting and identifying tumor-positive regions on a given modality (UT or mpMRI) compared with ground truth histopathology. Specificity was defined as the probability of correctly identifying tumor-negative regions.

Results: Thirteen of 53 prostate specimens from patients undergoing RARP from February 2021 to February 2022 had annotated histopathology slides and were evaluated; three cases were excluded due to patient history of androgen deprivation therapy or radiation. Of the remaining 10, the median age at surgery was 60 years [IQR 58.3-67.5] and median PSA was 6.85 ng/mL [IQR 5.78-8.73]. Six patients had Gleason Grade Group (GG) 2 cancer on RARP, one had GG 3, two had GG 4, and 1 had GG 5. On blinded sector-based analysis, UT had a sensitivity of 85.7% and specificity of 93.9%, while mpMRI had a sensitivity of 65.3% and specificity of 96.6%.

Conclusion: In an initial series of 10 patients, blinded UT interpretation demonstrated equal or better sensitivity for detection of cancer compared with mpMRI, while mpMRI had slightly better specificity. Future work will assess these findings in a larger cohort, followed by in vivo studies with limited angle UT.

Figure: Axial correlation between A: mpMRI T2W, B: mpMRI DWI, C: UT, and D: Wholemount pathology in the same prostate. E: Sector-based approach for correlation analysis.
PROSTATE BIOPSY PLAN PERSONALIZATION

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Introduction: Prostate cancer (PCa) diagnosis is made based on pathology results from core needle biopsy acquired under transrectal ultrasound guidance. Classic biopsy methods use a systematic biopsy (SB) approach with a 12-core template plan. More recent biopsy methods incorporated the fusion of ultrasound with MRI to target the biopsy (TB) based on MRI findings [EUS2019, Abs.13]. In addition to TB, we have developed technology that personalizes the SB plan for the patient and executes the TB+SB plan digitally with a robot that handles the transrectal ultrasound (TRUS) probe. A Phase I clinical trial has commenced to 1) gain early evidence on the effectiveness of the TRUS-Robot in detecting PCa and 2) further optimize [EUS2018 Abs.43] the biopsy plans based on the clinical data from the trial.

Methods: The robot is a hands-free TRUS probe manipulator, TRUS-Robot, that moves the probe with the same 4 degrees-of-freedom that are used manually [EUS2017 Abs.34, PMC30624210]. However, it provides uniform 3D ultrasound scanning and accurate needle targeting based on the 3D ultrasound and fused MRI. The needle is guided on target by the robot and biopsy is performed manually, as usual. After the biopsy procedure, we perform offline SB simulations with various plans on data acquired from the robot cases. A SB optimization method and algorithm described in [PMC27760001] is used. In short, a “Capsule” (cylindrical shape with semispherical ends) is the prostatic volume-unit that a biopsy core samples the smallest clinically significant (csPCa) lesion (5cm3). To increase the probability of csPCa detection, the algorithm attempts to distribute the SB capsules so that together with the TB capsules they optimally fill the gland (like in a sphere packing algorithm), thus generating an optimized SB plan.

Results: Two biopsy plans optimized for the same patient are shown in Figure 1. Figure 1a shows the real TB+SB biopsy plan for this patient with 12 SB (blue) cores and 3 TB cores (red), for a total of 15 cores. Figure 1b shows a simulated plan with 16 SB cores, without TB. This includes the original 12 SB cores (blue) plus 4 additional (red) SB cores. The figures show that in this patient SB alone capsules could overlap TB locations by using just one additional core. In this example, however, the prostate volume was relatively small (35cm3).

Conclusion: Personalizing the SB plan for individual patients is feasible. It may also be feasible to make recommendations on the type of plan to be used. Once data from the trial accumulates, the results could be compiled in nomograms to make recommendations for the type of biopsy and number of biopsy cores in individual patients. We will also investigate how often optimized SB cores overlap TB locations and determine the lowest number of simulated personalized SB cores to yield noninferiority to the real TB+SB cores as a function of the prostate volume. If that number is less than or equal to the number of real SB+TB cores, personalized SB alone may be recommended. We plan to study whether SB alone could be offered more confidently to select patients, reducing the need for MRI, healthcare burden and expenses. Results would apply to transrectal as well as transperineal biopsy.

Disclosure: Authors DS, DP, MH and Johns Hopkins have a financial or other interest in this study. The results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins’ policies.

Acknowledgment: Research reported in this publication is supported by the National Cancer Institute of the National Institutes of Health under award number R01CA247959, PI Stoianovici.
IN VIVO PORCINE EVALUATION OF THE MULTIPHZE™ DEVICE: A SELF-CONTAINED BLADDER IRRIGATION SYSTEM

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1 Department of Urology – University of California, Irvine

Introduction: Current standard bladder irrigation methods for clot evacuation are cumbersome, inefficient, and hazardous due to the risk of blood and urine contamination of the patient, environment, and provider. The latest iteration of the Multiphze™ enclosed irrigation system (Multiphze LLC) is a novel self-contained system designed to eliminate spillage while improving the efficiency of clot evacuation (figure 1).

Methods: Two female, juvenile Yorkshire pigs were anesthetized, following which 100 ml of blood was drawn via a femoral vein and mixed with 44.4 ml of Glow-Bright Concentrate. The bladders were drained with a 24 Fr 6 eye hematuria urinary catheter; 100 ml of blood and Glow-Bright Concentrate mixture was instilled into the bladder using a Bard Irrigation Kit (BIK). After 5 minutes, 4 individuals (a urology intern, an endourology fellow, a senior faculty endourologist, and a foreign-trained urologist-researcher) with prior experience using a BIK performed bladder irrigation with 3L of sterile water utilizing both the BIK technique and the Multiphze™ system in two separate trials. The time of each irrigation cycle and clarity of drainage fluid were recorded after each liter of irrigation. Total areas of spillage on the procedural fields were identified with a Wood’s lamp and quantified.

Results: The mean clarity measurements at the end of 2 liters of irrigant for the Multiphze™ and BIK trials were similar to the clarity obtained after 3 liters; however, the mean time to achieve this level of clarity with the Multiphze™ was 50% less than with the BIK (6.98 min. vs. 14.07 min.) (p < 0.001) (Table 1). Wood’s lamp illumination revealed a 100% reduction of spillage with Multiphze™ compared to BIK (208.95 cm² vs. 0) (p = 0.036), as there was no spillage with Multiphze™.

Conclusions: In a porcine model, the Multiphze™ irrigation system significantly halved the time to successfully clear a clot-filled bladder while eliminating spillage and contamination.

<table>
<thead>
<tr>
<th></th>
<th>Standard</th>
<th>Multiphze</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>Time to irrigate 1 L</td>
<td>7.59 [7.17-7.93]</td>
<td>4.33 [3.43-5.0]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>(min.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to irrigate 2 L</td>
<td>14.07 [12.6-15.3]</td>
<td>6.98 [6.37-7.93]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>(min.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to irrigate 3 L</td>
<td>20.05 [17.8-21.8]</td>
<td>9.32 [8.05-10.4]</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>(min.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid clarity at 1 L (%</td>
<td>53.9 [32.5-74.1]</td>
<td>39.6 [35.3-64.7]</td>
<td>0.433</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid clarity at 2 L (%</td>
<td>72.6 [71.4-74.1]</td>
<td>72.3 [68.6-76.1]</td>
<td>0.884</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid clarity at 3 L (%</td>
<td>74 [73.3-74.5]</td>
<td>73.2 [71.0-75.3]</td>
<td>0.431</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spillage area (cm²)</td>
<td>208.95 [88.0-492.7]</td>
<td>0 [0-0]</td>
<td>0.036</td>
</tr>
</tbody>
</table>

Table 1. Mean irrigation time, fluid clarity, and spillage area among all operators

Figure 1. The new Multiphze™ enclosed irrigation system
ABSTRACTS

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3D INTRA-OPERATIVE SCENE RECONSTRUCTION FRAMEWORK IN ROBOT-ASSISTED MINIMALLY INVASIVE SURGERY

Ziyang Chen¹, Davide Alberti¹, Aldo Marzullo¹,², Elena Lievore³, Matteo Fontana³, Ottavio De Cobelli³,⁴, Gennaro Musi³,⁴, Giancarlo Ferrigno¹, Elena De Momi¹

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Introduction: The introduction of robotics in minimally invasive surgery overcomes many obstacles compared with traditional open surgery. It also opens the way for the integration of artificial intelligence in surgery. Image guidance, registering pre-operative model photoed through computed tomography or magnetic resonance imaging into intra-operative soft tissue, has been reported to improve the safety of surgery. The performance of intra-operative scene reconstruction directly affects the reliability of this image guidance technology. Therefore, we propose to design a computer vision-based architecture to reconstruct the 3D appearance of the surgical scene using stereo image pairs from an endoscope.

Methods: A computer vision-driven framework was developed to reconstruct the intra-operative scene, and it was integrated into the da Vinci surgical system (Intuitive Surgical Inc., CA, USA). This framework was designed based on ROS correspondence which is popular in robotic platforms. Furthermore, a computer vision approach, combining the U-net based encoder and Residual block-based decoder, was designed to search for the horizontal disparity of stereo images, and then OpenCV was adopted to perform the re-projection to recover the 3D information of soft tissue surface using generated disparity values. A video of radical prostatectomy with lymphadenectomy procedure was collected through a 3D HD video recorder (HVO-3300MT, SONY, Tokyo) at European Institute of Oncology (IEO, Milan, Italy) in Feb 2022 to verify the performance of the proposed framework.

Results: The overall surgical scene reconstruction architecture took 32.08±1.94 (ms) for one frame, and it performed faster compared with other two state-of-the-art approaches (47.98±2.35 (ms) and 224.86±4.41 (ms), respectively) using an RTX 3080 GPU. It demonstrates that our approach can reconstruct 3D surgical scenes in real time. Furthermore, qualitative evaluation also shows that our framework can achieve satisfactory reconstruction performance, as shown in Figure 1.

Conclusion: We constructed a ROS based framework for real-time reconstruction of soft tissue at the surgical site. The preliminary results show promising reconstruction performance, and the validation through a radical prostatectomy with lymphadenectomy procedure also shows its potential in future robotic surgery.

FIG. 1. Demonstration of the 3D reconstruction result. Two scenes are shown from different viewpoints.
DEVELOPMENT OF FREEHAND TRANSPERINEAL ULTRASOUND-MRI FUSION PROSTATE BIOPSY WITH ELECTROMAGNETIC TRACKING AND NEEDLE AND ULTRASOUND FULLY OUTSIDE THE RECTUM

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2 Philips Research North America, Cambridge, MA
3 Urologic Oncology Branch, National Cancer Institute, National Institute of Health, Bethesda, MD
4 Molecular Imaging Program, National Cancer Institute, National Institutes of Health Bethesda, MD
5 Department of Radiology and Imaging Sciences, National Institutes of Health, Bethesda, MD
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Introduction: Infection, discomfort, and non-compliance complicate prostate biopsy via a transrectal approach. Conventional transperineal (TP) biopsy is guided by TR ultrasound probes (TRUS) and may be performed with multimodality fusion imaging, either via a grid (template) or a clip-on needle guide, with detection rates similar to a fully TRUS approach. We propose a freehand, targeted fusion TP biopsy platform with all instrumentation entirely outside of the rectum. Ergonomics, software, and workflow are described in commercial and a custom software, with presumptive goals of decreasing risk, discomfort, and non-compliance.

Methods: An anthropomorphic prostate US interventional phantom (CIRS) was used to test prostate fusion biopsy platforms and ultrasound probes. Two commercial fusion platforms (UroNav-iU22, and Percunav-EPIQ, Philips) and one custom platform (NIH) were assessed. In commercial platforms, an US sweep or anatomic landmark 3-point registration technique was used and sagittal plane rotation was cognitively estimated and adjusted from supine MRI to lithotomy TP position. In the custom fusion software, a 2D ultrasound sweep across the para-sagittal plane was used for rigid registration to preoperative 3D MR images. Commercially available needle guides (Civco) were used to secure the biopsy needle at a fixed angle relative to the US transducer for the custom software.

Results: The commercial software UroNav was able to segment, register, and display fusion targets using the C9-5 TRUS “end-fire” probe placed on the perineum. However, an inherent rotation inaccuracy in the sagittal plane required manual cognitive correction to customize variable sagittal rotations going from the MRI axis to the pelvic axis in lithotomy position on ultrasound. Use of PercuNav required pre-processing the MR images to correctly align their orientation with that of the TPUS transducer. The C9-5 transducer was challenging to ergonomically maneuver, and the 3D X41 probe required additional programming for image registration. The C5-2 offered the benefit of a wide-field view, but the broad face of the probe crowded the TP space and prohibited or restricted the use of a needle guide. Custom fusion software using the mC7-2 transducer with integrated EM sensor readily allowed for image registration as well as spatial ergonomics for an adjacent needle.

Conclusion: Commercial fusion devices and algorithms engineered for TRUS or body ultrasound have inherent shortcomings or assumptions and may not be accurate when applied to the TP approach. The development of custom tools and methodology described here has shown that a TP approach is feasible and should be further studied and tested in the clinical setting. Future studies may support fusion biopsy completely out of the rectum to reduce the risk for infection and improve compliance and comfort.

Figure: Top: TP biopsy fully outside of the rectum and sweep. Bottom. US-MR fusion images
DEVELOPMENT OF URINARY TRACT REMOTE PRESSURE MONITOR

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Introduction: For patients dependent on long-term ureteral stents, there is considerable heterogeneity in the length of time a stent will safely function without failing from encrustation or extrinsic compression. As a result, stents are generally replaced on a fixed schedule to avoid potentially serious sequelae, including progressive pain, renal dysfunction, and infection. We hypothesize that the ability to monitor pressures within the urinary tract with a stent will allow for detection of impending stent failure. Additionally, such measurements may help elucidate the symptomatology of stent colic. We are working on a device that uses pressure sensing electronics to wirelessly monitor pressures within the urinary tract. Relative to other research in the field [1], we aim to enable upper and lower urinary tract measurements.

Methods: A prototype pressure monitoring device was constructed using LPS22H pressure sensors (ST Microelectronics, Switzerland). A microcontroller and radio wirelessly transmit pressure data to an external receiver for recording and analysis. A small battery powers the device. The current version of the device was built on a larger size as a development prototype. However, all major components used in this prototype were selected to be sufficiently small to permit future miniaturization and integration. The device was evaluated in a pressure vessel built to simulate various pressure levels in the urinary tract. (Fig. 1). The vessel is pressurized with a hand pump and the pressure is measured with a U-tube manometer filled with water. Accuracy and hysteresis of pressure measurements were evaluated by placing the prototype in the pressure vessel. Pressure data inside the vessel was read wirelessly from the outside. Pressure in the vessel was increased from 0–60 cm H₂O and then decreased back to zero. Manometer and pressure sensor value pairs were recorded.

Results: Recorded data pairs are shown in Fig. 2, with blue dots on the increasing pressure cycle and red decreasing. Data shows that the response of the pressure sensor is nearly linear (Pearson’s product-moment correlation coefficient $r = 0.9996$). There is slight hysteresis in the response of the sensor with an average difference of 0.387 cm H₂O. Sensor calibration was not required.

Conclusion: A device to remotely measure pressure values of clinical significance within the urinary tract is under development. Preliminary results are promising, showing that accurate remote pressure measurements in the urinary tract range are feasible with the device. Future research includes integration with urinary stents, biocompatibility assurance, miniaturization, and further testing.

Figure 1: Experimental setup

Figure 2: Sensor vs manometer pressure tests: Blue = increasing pressure; Red = decreasing
A VISUAL GUIDE IMPROVES POINTING ACCURACY IN IMAGE-GUIDED ROBOTIC SURGERY

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Introduction: Partial nephrectomy is challenged by the inability to visualize subsurface features, requiring the surgeon to mentally register pre-operative imaging to the operative field. To assist with this, we have previously presented a novel image-guided surgery (IGS) system that integrates with Intuitive’s da Vinci Surgical System [1]. The IGS system helps the surgeon localize subsurface kidney anatomy by displaying segmented pre-operative CT images registered with the operative field. Determining how accurate a surgeon can be with such a system is challenging, and in our in vivo studies, we often ask the surgeon to point at various anatomical features with the da Vinci tool. To improve the fidelity with which the surgeon can point at a desired target, we propose a virtual pointing tool that extends from the surgeon’s tool tip in the IGS display, and evaluate its accuracy in ex vivo phantoms.

Methods: A rigid, plastic phantom was created containing two different targets: a 2mm diameter pin head, and a 40mm diameter ping pong ball. The phantom model was registered using point-based registration to enable the IGS display. Surgeons were then asked to point to both targets (pin head and center of the sphere) using a large needle driver from a variety of distances and angles, while kinematic data was collected. We compared the acquired pointing data to the known target locations to evaluate localization accuracy. The experiments were repeated in three configurations: 1) with only the endoscope video; 2) with the IGS system displayed in the da Vinci surgeon console, but with no pointer; 3) with both the IGS system and pointer displayed in the console. Figure 2 shows the IGS display with the pointer enabled.

Results: The pointer significantly increased the pointing accuracy to the 2mm target. Pointing data was separated into two groups, based on the distance from the target: near (~1cm), and far (~3cm). The results are shown in figure 3. There was no statistical change in accuracy when pointing to the center of the spherical target, but improvements similar to the pin head target were observed when a small visual indicator was added to the IGS display to designate the sphere’s center point.

Conclusion: We find that the accuracy with which a surgeon can point to an intended target with a robot is increased with a virtual pointer. We also find that pointing at an unseen subsurface target (i.e. the center of a sphere) is challenging, but can be aided significantly with a pointer and a visual representation of the target in the virtual display.

<table>
<thead>
<tr>
<th>2mm Target Pointing</th>
<th>Mean distance</th>
<th>Mean error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Far, endoscope only</td>
<td>29.2mm</td>
<td>5.3mm</td>
</tr>
<tr>
<td>Far, IGS only</td>
<td>27.2mm</td>
<td>4.7mm</td>
</tr>
<tr>
<td>Far, IGS w/ pointer</td>
<td>29.5mm</td>
<td>2.9mm</td>
</tr>
<tr>
<td>Near, endoscope only</td>
<td>10.2mm</td>
<td>2.3mm</td>
</tr>
<tr>
<td>Near, IGS only</td>
<td>11.5mm</td>
<td>2.6mm</td>
</tr>
<tr>
<td>Near, IGS w/ pointer</td>
<td>10.7mm</td>
<td>1.1mm</td>
</tr>
</tbody>
</table>

Figure 1: Experimental setup with da Vinci Surgical System and the pointing phantom.

Figure 2: IGS display showing the phantom, da Vinci instruments, and pointing tool extending from the right tooltip.

Figure 3: Mean pointing distances and errors.
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TRANSPERINEAL ROBOTIC PROSTATE BIOPSY WITH PROST

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Introduction: The PROST robotic system (Figure 1) is an integrated platform to enable effective robot-assisted prostate biopsies. It offers MRI/US fusion, needle alignment and cognitive support for target selection and entry point planning. PROST prototype has been already validated in laboratory. The objective of this study was to assess PROST’s positioning accuracy in a realistic anatomical environment.

Methods: To carry out the experimentation, 10 cadaver specimens were used for prostate biopsy. 12 sterile seeds were placed into the prostate of each cadaver, 6 target seeds and 6 reference seeds. The targets marked the position to be reached by the PROST system. The reference seeds were released when the physician performed needle insertion through a guide oriented by PROST. After the procedure, the prostate was removed and the distance between target seeds and reference seeds was assessed using CT scan images and histological examination (Figure 2).

Results: The distance between target seeds and reference seeds was approximately 2.25 ± 0.75 mm, with an estimated error due to needle deflection of 0.38 ± 0.12 mm (with a range of 0.29-0.59 mm).

Conclusion: PROST’s accuracy is compatible with clinical requirements. Further studies need to be conducted for use in clinical practice.

Fig. 1. Artist rendering of the PROST system. Left: the positioning robot (head) used for biopsy procedures. Right: the head as a component of a larger robotic system, used for more advanced procedures. For the experiments described in this paper, the robotic head was mounted on a wheeled cart.

Fig. 2 a. Specimen’s prostate after removal. b. Macro-slices with arrows pointing to seeds. c. 3D volume rendering of a CT scan, prior to prostatectomy. All 12 seeds are visible. The identity of matching seeds can be inferred and distance computed, but without certainty of correct pairing, since the seeds are identical in the image. d. CT scan slice.
SEGMENTATION OF THE UROTHELIUM IN OPTICAL COHERENCE TOMOGRAPHY IMAGES WITH INTRACELLULAR MOTION

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Introduction: Urothelial cancerous cells are initially confined in the urothelium may gradually invade the lamina propria (LP) and musculus propria (MP) underneath the urothelium. Therefore, tracking the invasion depth of urothelial cancerous cells is the cornerstone of stratifying patients into different stages for treatment planning. In normal optical coherence tomography (OCT) images, normal bladder tissue with sufficient distention shows a clear boundary between the urothelium and the LP, due to different scattering coefficients. The boundary fades or disappears when urothelial cancerous cells invade the underlying LP. In clinics, the fading or disappearance of the boundary in normal OCT images is employed as the most important criterion to differentiate muscle-invasive and muscle-noninvasive bladder tumors. However, the invasion depth and the distribution patterns of the urothelial cancerous cells have been correlated with the prognosis of bladder cancer through pathohistological analysis, but cannot be identified in normal OCT images for muscle-invasive bladder tumors.1,2 If OCT can exclusively track urothelial cancerous cells instead of only relying on the boundary feature, physicians may employ the information to predict the recurrence and progression of bladder cancer and avoid over- and under-treatment. Here, we show that intracellular motion (IM) can be used as dynamic contrast to segment the urothelium. Conventionally, the urothelium is considered an impermeable barrier to separate the urine and the blood.

Methods: OCT images acquired ex vivo with fresh porcine bladder tissue. IM was analyzed by tracking speckle variation using autocorrelation function, then quantified with constrained regularization method for inverting data (CONTIN method) to identify the decorrelation time (DT) of the speckle variations. Variance analysis was also conducted to show IM amplitude and distribution in the urothelium. The segmentation of the urothelium was demonstrated with OCT images with a visible urothelial layer and OCT images with an invisible urothelial layer.

Results: Significant speckle variation induced by IM was observed in the urothelium. In Figure 1, we demonstrated the feasibility of using IM as a dynamic contrast to segment the urothelium with only two sequentially acquired images. With the IM as a dynamic contrast, the urothelium can be accurately and exclusively segmented, even the urothelial layer is invisible in OCT images.

Conclusion: IM can be used as a dynamic contrast to exclusively track urothelial cell distribution. This contrast may provide a new mechanism for OCT to image the invasion depth and pattern of urothelial cancerous cells for accurately substaging of bladder cancer.3

References

THREE-DIMENSIONAL SURFACE RECONSTRUCTION USING BIO-INSPIRED THRESHOLD APPLIED TO ENDOSCOPIC AND LAPAROSCOPIC MEDICAL IMAGES

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ⁱCentro Universitário FEI, ²Hospital Universitário USP, ³Faculdade de Medicina de Botucatu UNESP

Introduction: With the new technologies of virtual and augmented reality, applications of three-dimensional reconstruction in the medical field gained new possibilities. These new technologies may benefit minimally invasive surgeries (MIS), such as urologic endoscopy, and laparoscopic and robotic-assisted surgeries. The use of virtual and augmented realities in these surgeries may allow surgeons to, in an immersive environment, view reconstructed organs or project them holographically over the patient. Also, 3D reconstruction may aid the development of robotic surgeries by estimating the depth of the patient's internal environment and enhancing the robot navigation inside the patient. This project presents a method for 3D reconstruction of video images for MIS surgeries.

Methods: The method starts with a pair of images. The first step applies image segmentation, based on the bio-inspired algorithm Firefly, to optimize the thresholds that minimize the total entropy of the scene. Next, the Connected Components Algorithm is applied to obtain regions of interest (ROI) and eliminate the smaller ones. After that, the algorithm SIFT detects and extracts key points on each ROI obtained in the previous step. The points extracted are matched by comparing their descriptors and filtered to eliminate the incorrect matches. Then, the depth of the bi-dimensional points is estimated based on calibration camera equations. Finally, with the three-dimensional points, the Delaunay Triangulation constructs the 3D mesh of the surface.

Results: The objective of this project was to reconstruct the surface of pairs of images from endoscopic and laparoscopic surgeries, using manual texturing on the reconstructed mesh. Our preliminary results demonstrated that the depth of the 3D surface was feasible to obtain using this technique.

Conclusion: The 3D reconstructed surfaces generated by this technique may aid surgeons to understand how to navigate inside the patient, through virtual or augmented reality equipment. In the future, this technique may be used to the development of a totally robot-performed minimally invasive surgery, such as ureteroscopy, percutaneous nephrolithotripsy and laparoscopy. This may require further studies using datasets with ground-truth values of depth-map and camera parameters to assure the accuracy of the depth estimated by the reconstruction.

Figure: Left: 3D reconstructed surface of an organ captured from endoscopic video surgery. Input extracted from [1]. Right: 3D reconstructed surface of an organ captured from laparoscopic video surgery. Input extracted from [2].

ABSTRACT 45

INTERPRETATION AND SPATIAL INFORMATION WITH 3D SYSTEMATIC PROSTATE BIOPSY TEMPLATES

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**Introduction:** Despite advances in graphical rendering tools, systematic prostate biopsy (sPBx) templates for transrectal and transperineal [PMID: 30446447, 26995327] approaches continue to be represented as 2D drawings. 2D sections can be challenging to interpret as they represent a single plane in a 3D organ. As an example, the classic double sextant template for transrectal sPBx represents 12 dots in a coronal plane. While devoid of depth, it is assumed that the 12 dots represent the center of each core. In practice, cores are seldom perpendicular to the prostate capsule, or 2D plane, but rather fan out under the influence of ultrasound probe rotation, needle guide type, and peripheral zone anatomy. While intuited by most urologists, the absence of an explicit third dimension becomes crucial with the introduction of less familiar transperineal templates. From the pathologist standpoint, a 3D representation of the template may contribute to clinicopathologic correlation, including number and length of cores for quality assurance of pathology processing. A 3D template also optimizes the spatial location of the sampled tissue within the zonal anatomy of the prostate gland, and helps better correlate pathology with imaging.

**Methods:** Graphical tools such as Rhino 3D, SolidWorks, Google Sketchup, AutoDesk, Tinkercad, and Unity are now widely available, and can readily produce graphics that are truly 3D. We used Unity.

**Results:** We provide a 3D rendition of the MUSIC transperineal template to illustrate ease of interpretation and additional spatial information (e.g., core orientation) provided by 3D templates.

**Conclusion:** Using a 3D template facilitates creating and providing different perspective views (such as sagittal, axial), representing the prostate and cores as 3D volumes as well as readily appreciating how close the core extremities are to the prostate capsule with the attendant risk of sampling non-prostatic tissue and determining if two back to back cores are needed for larger prostates. A template should ideally have a recommended accompanying technique, preferably validated [PMID: 33961325], to place the core centers as close to the template locations as possible. In a 3D template, the orientation of the cores can suggest the recommended technique, e.g., the lateral and anterior cores in Figure 1 fan in the axial perspective suggesting a needle orientation that optimizes peripheral gland sampling. 3D sPBx templates may assist with the ongoing transition from qualitative to quantitative prostate biopsy. We suggest transitioning from 2D sPBx templates to 3D templates. We believe that providing sPBx templates as 3D representations will help with interpretation and optimization of biopsy templates.

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**Figure 1:** An example of a 3D sPBx template for the MUSIC14-core transperineal biopsy template.
**IN VIVO APPLICATION OF A NOVEL CATHETER FOR ELECTROMOTIVE DRUG ADMINISTRATION (EMDA) IN THE PORCINE URETER**

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**Introduction:** Electromotive Drug Administration (EMDA) is a technique used to enhance drug delivery to targeted tissues, such as the bladder. The application of intra-luminal low-power electrical current induces directional movement of charged molecules into the surrounding tissues. Here we used methylene blue to evaluate the feasibility and safety of EMDA for driving a positively charged, small molecule across the various tissue layers of the ureter.

**Methods:** Two castrate juvenile male Yorkshire pigs were placed under general anesthesia. After creating a perineal urethrostomy, cystoscopy was used to place an 0.035 in. Amplatz super-stiff guidewire into each ureter. A prefabricated 10F ureteral catheter with equidistant (5mm) fenestrations in three rows was advanced into each ureter. A silver wire was then passed into each ureteral catheter; the circumference of the silver wire was larger than the terminal opening in the catheter such that its passage stopped at the catheter’s tip, thereby preventing any flow of instilled fluid from the tip of the catheter. Methylene blue, a heterocyclic aromatic dye with a net positive charge, was infused through each catheter at a rate of 5 ml/min. In the experimental ureter, a positive pulsed electrical current of 10mA was applied using a Physionizer® EDMA device. After 20 mins, both ureters were harvested and flash-frozen for histopathological analysis.

**Results:** Both animals tolerated the procedure well. Macroscopically, the difference in color density between the experimental and control ureter was apparent (Fig. 1A). Microscopically, in the experimental ureters, there was diffuse penetration of methylene blue into the urothelium, lamina propria, muscularis propria, and periureteral tissue (Fig. 1B). In the control ureter, patchy methylene blue staining was seen only on the urothelium without any deeper penetration (black arrows) (Fig. 1C). The experimental ureter showed mild urothelial cell denudation that did not extend to the basal layer of the urothelium; the deeper tissues revealed no injury (Fig. 1D).

**Conclusions:** EMDA at a current of 10mA resulted in safe and successful penetration of methylene blue into all layers of the ureter and out to the periureteral soft tissue.

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**Figure 1.** Macroscopic and histologic sections of the ureters. A. Interior surface of ureters, intense blue staining of the experimental ureter (left side of the image). B&C. dispersion of methylene blue in experimental and control ureters, respectively. (The two arrows in C point to patchy infiltration of the methylene blue only along the urothelium) D. Normal architecture of experimental ureter with mild denudation of urothelium and normal-appearing basement membrane.
PROSTATE BIOPSY FALSE NEGATIVE PERCENTAGE AS A FUNCTION OF SIMULATED LESION SIZE AND LOCATION DURING SYSTEMATIC TRANSRECTAL PROSTATE BIOPSY

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Introduction: Prostate biopsy false negative percentages (PBxFN%) are 21%–47% [PMC4104074] and 16% [PMID: 31144593] for systematic and fused biopsy, respectively. Towards the goal of reducing PBxFN%, it might be helpful to be able to estimate the effect of lesion size and lesion location on PBxFN%, for example, when developing algorithms or models for improving prostate biopsy accuracy. A prostate biopsy simulator can provide a platform for conducting such an estimate.

Methods: Using a mixed reality prostate biopsy simulator [PMID: 33961325], 45 participants at 3 institutions performed 389 sets of 12-core (double sextant schema), side-fire, systematic prostate biopsies with transrectal ultrasound (TRUS) guidance on the simulated prostate included 4 spherical lesions (left/right apex, and left/right anterior zones). Lesion volume and location within a 25 ml prostate were known but not visible in the simulated TRUS image. The location (x, y, z) and orientation (yaw, pitch, roll) of the cylindrical biopsy cores (18 mm long and 0.92 mm diameter) placed by the study participants were tracked to 0.2 mm accuracy and recorded. Any intersection, however small, between a spherical lesion and a placed core was considered a positive biopsy. PBxFN% for a given lesion was defined as the number of 12-core biopsy sets where the given lesion was not intersected by a core divided the total number of attempted 12-core sets. The volume of the virtual lesions was altered to have the same size with the center of the spherical lesions remaining at the same location for each run. The different lesion volumes in ml were 0.125, 0.25, 0.50, 0.75, 1.00, 1.25. For each lesion volume, the repository of 389 core sets was replayed in the simulator to determine the new PBxFN%. PBxFN% was plotted as a function of lesion volume and location. Best fit curves were generated using Excel and statistical analysis with SPSS.

Results: PBxFN% decreased with increased lesion volume according to these equations: Apex (linear: R² = 0.79; PBxFN% = -17.58*Volume + 28.34; logarithmic: R² = 0.90; PBxFN% =30.106e^-1.037*Volume, p<0.01) and anterior (linear: R² = 0.81; PBxFN% = -38.97*Volume + 96.46; logarithmic: R² = 0.76; PBxFN% = 100.6e^-0.584*Volume, p<0.01) (Figure). PBxFN% was significantly higher (p<0.001, Mann-Whitney U test) for the anterior zone compared to the apex location.

Conclusion: We provided a means to use a simulator to estimate PBxFN% as a function of lesion volume and location. Limitations are: only one prostate size and shape was used, lesions were placed at only four locations, the lesions were spheres, only side-fire transrectal biopsy was used. These limitations can be addressed in future studies that extend this proof-of-concept.
DEVELOPMENT AND VALIDATION OF THE METRIC-BASED ASSESSMENT OF A ROBOTIC DISSECTION TASK ON AN AVIAN MODEL

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Introduction: The scientific community is continually seeking to develop training methodologies that allow surgical activity in the operating room only after demonstrating a defined performance level in the use of the robot (basic device training) and in the acquisition of surgical skills (basic surgical skills). To develop and validate (face, content, and construct) the performance metrics for a robotic dissection task using a chicken model.

Methods: In a procedure characterization, we developed the performance metrics (i.e., procedure steps, errors and critical errors) for a robotic dissection task, using a chicken model (Figure 1). In a modified Delphi panel 14 experts from four EU countries agreed on the steps, errors critical errors (CE) of the task. Six experienced surgeons and 8 novice urology surgeons performed the robotic dissection task twice on the chicken model. In the Delphi meeting 100% consensus was reached on 5 procedure Steps, 15 Errors and 2 Critical Errors (CE

Results: Novice surgeons took 20 min to complete the task on trial 1 and 14 minutes during trial 2 whilst experts took 8.2 min and 6.5 min. On average the Expert Group completed the task 56% faster than the Novice Group and made 46% fewer performance Errors. Sensitivity and specificity for procedure Errors and Time were excellent to good (i.e., 1.0 – 0.91) but poor (i.e., 0.5) for Step metrics. The mean inter-rater reliability for the assessments by two robotic surgeons was 0.91 (Expert Group IRR = 0.92 and Novice Group = 0.9).

Conclusion: We report evidence which supports the demonstration of face, content, and construct validity for a standard and replicable basic robotic dissection task on the chicken model.

Figure 1. Different phases of the chicken dissection task execution: a): step 1 and step 2, skin incision and development of the skin incision. b): step 3, dissection of the upper leg, fat removing. c): Step 3: identification of the suture. d): Step 4: dissection of the lower leg)
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HOW TO EVALUATE A FLEXIBLE URETEROSCOPE

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Introduction: Ureteroscopes are constantly evolving to better address clinical needs and improve surgical outcomes. The evolution of ureteroscopes has seen improvements in image quality, maneuverability, and overall functionality. Accordingly, it is critical to identify the most important ureteroscope qualities to urologists and then develop new methodologies for evaluating them.

Methods: Crowdsourcing was used to survey 147 urologists and rank the importance allocated to ureteroscope image quality, maneuverability, physical characteristics, and ergonomics (survey conducted by Medallia Research Service). Based on these findings, we demonstrate standardized bench methodologies with a single-use ureteroscope to measure camera resolution using a 1951 USAF 3x3 inch Resolution Target at various distances, field-of-view using object imaging and trigonometry, latency using custom signal processing, colour authenticity using a color checker and image analysis, tip deflection using a goniometer, and irrigation capacity by directly measuring saline outflow. We also show methods to score the maneuverability and ergonomics in a human cadaver on a scale of 1 to 5 with 5 being the best.

Results: Crowdsourcing showed that 54% of urologists view image quality as the most important, followed by maneuverability (31%), physical characteristics (8%), and ergonomics (7%) (Fig 1 shows a breakdown of these findings). Motivated by these results, the single use ureteroscope showed an image resolution of 10.1 [line pair/mm] in saline at a 10 mm distance (Fig 2A). Moreover, our specific method showed a camera field of view of 89°. The image latency was 58 ms. The colour accuracy was quantified with Delta E, an image analysis variable which showed that the measured colours were more similar than opposite of the true colors (Fig 2B). As for maneuverability and ergonomics, the ureteroscope had an overall score >4 out of 5 (Fig 2C and 2D). Finally, the tip deflection was >283° with an empty channel, and the irrigation rate was >40 ml/min with gravity irrigation at 80 cm (Fig 2E and 2F).

Conclusion: New ureteroscope technologies require new evaluation methodologies. This work tailors bench and in vivo testing of ureteroscopes to the most important clinical needs identified by urologists. Ultimately, our findings can help guide future development of flexible ureteroscopes.

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ABSTRACT 50

A NOVEL AI-DERIVED METRIC IDENTIFIES FAVORABLE CANDIDATES FOR FOCAL THERAPY OF PROSTATE CANCER AND ACCURATELY PREDICTS TREATMENT MARGIN EFFICACY

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Introduction: A machine learning algorithm was developed to estimate voxel-level risk of clinically significant prostate cancer (csPCa), resulting in a 3D lesion heat map (LHM). A novel metric, the Marks Confidence Score (MCS), was developed using whole mount (WM) prostatectomy data to correlate LHMs to the probability of encapsulating all csPCa. This metric can be used to identify favorable candidates for focal therapy (FT) of prostate cancer, and to estimate the efficacy of proposed treatment margins.

Methods: A machine learning model was developed using multi-institutional data from 875 patients. Input data consisted of T2-weighted MRI, surface models of the prostate and PI-RADS region(s) of interest, and tracked biopsy cores. The model combined a convolutional neural network with a gradient-boosted decision tree, and was trained using 5-fold cross validation. LHMs were then generated for WM cases (N = 50) with localized GG2-3 csPCa, wherein ground-truth csPCa-bearing voxels were precisely defined. The LHMs were iteratively thresholded and compared to ground-truth. Finally, the MCS was defined as the proportion of cases with complete csPCa encapsulation at each LHM threshold.

A second set of comparable WM data from an external institution (N = 50, Stanford University) was used to validate the MCS. LHMs were generated, iteratively thresholded, and the observed csPCa encapsulation rate was compared to MCS predictions. Furthermore, for each case the area under the Marks Confidence curve (mAUC) was computed after plotting MCS versus margin volume (Fig 1A). It was hypothesized that patients with a high mAUC (≥ 0.6, N = 24/50) would be more favorable FT candidates.

Results: There were no significant differences (Kolmogorov-Smirnov, p = 0.99) between the observed and MCS-predicted csPCa encapsulation rate (Fig 1B), with a median error of 2% (IQR 0%-6%). Using mAUC to identify FT-favorable candidates (Fig 1C), the mean margin volume for csPCa encapsulation was lower for FT-favorable (31%) versus unfavorable (52%) cases (p = 0.001, Mann-Whitney).

Conclusion: The Marks Confidence Score accurately predicted csPCa encapsulation probability and, when used for FT candidate selection, dramatically reduced the margin size required for complete treatment. This metric could be a valuable tool during focal treatment patient selection and planning.

Figure: (A) Example LHMs and MCS Curves. One LHM predicted a large tumor, giving the case a low “FT-unfavorable” mAUC; (B) csPCa encapsulation rate versus LHM threshold, with negligible deviation from MCS predictions; (C) csPCa encapsulation versus mean margin volume, with greater efficacy and reduced volume for FT-favorable (e.g. high mAUC) cases.
THE BIO-ZIPPER: A NOVEL ADHESIVE POLY(GLYCEROL SEBACATE) PATCH TO SUPPORT AND REINFORCE LOWER URINARY TRACT SUTURE LINES

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1 UCLA Dept of Urology 2 UCLA Dept of Bioengineering 3 Terasaki Institute for Biomedical Innovation

Introduction: Lower urinary tract reconstructions (LUTR) are high risk procedures performed in medically complex patients. Over 150,000 of these procedures are performed in the U.S. annually, with complication rates of 30-68%2-4. These complications (e.g., stricture formation, diverticulum, or dehiscence) are due in part to excessive tension at sites of tissue closure leading to poor wound healing and/or urine leak. A method is needed to facilitate the completion of consistent, low-risk surgical suture lines, and in response the Bio-Zipper was developed. Poly(glycerol sebacate) (PGS) was selected as the flexible backbone material due to its biocompatibility and tunable mechanical properties. Chemical modifications of the pre-polymer resulted in a strongly adherent bio-adhesive.

Methods: PGS synthesis was completed through a polycondensation reaction utilizing equimolar quantities of glycerol and sebacic acid (SA).5 The pre-polymer is then cured at 140ºC to form an elastomer. Adhesive PGS integrated 400mw polyethylene glycol (PEG) into the SA,6 using L-3,4dihydroxyphenylalanine (L-DOPA) as the catechol group. The molar ratio of glycerol, SA, L-DOPA, and PEG was 1:4/3:10:1/3 respectively. The resultant viscous pre-polymer was cured into an elastomer at 140ºC. PGS and PGS-PEG-L-DOPA prepolymer were evaluated with NMR. Both prepolymer were cured, and their elastomer tensile and adhesive properties were evaluated. Adhesion trials were completed using the lap shear method with PGS-PEG-L-DOPA used between two collagen sheets. Burst pressure trials compared a 2-layered bladder repair with and without the application of an adhesive patch (a supportive backbone of PGS cured to a secondary tissue adjacent adhesive layer of PGS-PEG-L-DOPA).

Results: NMR confirmed PGS and PGS-PEG-L-Dopa synthesis. The curing time and temperature determined the mechanical properties of the final elastomers. Tensile tests indicated that PGS was successfully tuned to the physiological ranges of tissue utilized in LUTR (Figure 1c). Adhesive shear strength testing indicated that PGS-Peg-L-Dopa cured for 14 hours had an adhesive strength of ~5kPa which exceeded that of the commercially available fibrin sealant Tissel (~3kPa) 7. The Bio-Zipper team has successfully synthesized a patch with a PGS backbone and a layer of adhesive PGS-PEG-L-Dopa that increased the burst pressure capacity of a sutured porcine bladder incision by ~73% compared to an incision closed with only standard suturing techniques.

Conclusion: PGS and PGS-PEG-L-DOPA are ideal candidates for lower urinary tract suture line reinforcement. Future work will tune the material properties of the PGS backbone and optimize the adhesive properties of PGS-PEG-L-DOPA across target tissues.

ELECTROMAGNETIC TARGETING OF SMALL RENAL MASSES DURING ULTRASOUND-GUIDED LAPAROSCOPIC MICROWAVE ABLATION: A NOVEL TECHNIQUE

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Introduction: Thermal ablation is a therapeutic option for small renal masses (< 4cm) in select patients. Laparoscopic ultrasound (US)-guidance can be used in the radiographically challenging abdomen. This approach is technically difficult with a steep learning curve that requires the surgeon to simultaneously coordinate the spatial relationship between the ablation antenna, pathology, laparoscope, and US probe. The EmprintSX electromagnetic (EM)-targeted ablation system (Medtronic, Minneapolis, MN) greatly reduces this disconnect by coordinating the US probe, pathology, and ablation antenna under a single EM localization field. We introduce the first known use of laparoscopic microwave ablation with EM targeting for renal disease and describe the surgical technique.

Methods: An EM field emitter coil is placed below the mattress of the operating table to allow for tracking of the intraabdominal US probe and ablation antenna. The patient is positioned in a posterior oblique position. Two 5mm trocars and one 12mm trocar are placed in the umbilicus, epigastrium, and lateral abdomen, respectively. The visera are mobilized to expose the anterior surface of Gerota’s fascia. The laparoscopic US transducer is then fitted to a disposable clip containing an EM sensor coil. The tracking system uses the sensor’s locations and orientation within the generated EM field to localize the instruments in a real-time graphic display. The US probe is positioned over the tumor. The skin is punctured with the antenna, and using the EmprintSX localization system, the antenna is placed directly into the tumor. Appropriate wattage and ablation time are determined by the manufacturer based on tumor size and tissue type. A red circle on the display shows the calculated ablation zone, which is adjusted to encompass the mass. The ablation cycle is initiated and monitored via real-time laparoscopic and US imaging. This is repeated as required. Once complete, the antenna is removed, and its tract is ablated to ensure hemostasis. The abdomen is closed in the routine fashion.

Results: This technique was performed on 8 patients with a mean tumor size of 2.54cm. Average procedure time was 1:48 to perform a mean of 2.4 ablation cycles per patient. The associated table summarizes the 8 cases.

Conclusion: This technique provides real time 3D visualization of probe position, orientation, and a calculated zone of ablation with respect to the tumor. This ensures complete ablation of the tumor with appropriate margins.

<table>
<thead>
<tr>
<th>Location</th>
<th>Tumor size (cm)</th>
<th>Biopsy Result</th>
<th>Operative Time</th>
<th>Ablation Cycles</th>
<th>EBL (mL)</th>
<th>LOS (days)</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Upper Pole</td>
<td>3.5</td>
<td>RCC-CC</td>
<td>1:43</td>
<td>2</td>
<td>10</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Left Upper Pole</td>
<td>3.2</td>
<td>OEN</td>
<td>1:28</td>
<td>3</td>
<td>&lt; 5</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Left Upper Pole</td>
<td>2.5</td>
<td>RCC-CC</td>
<td>1:44</td>
<td>1</td>
<td>20</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Right Anterior Mid-Pole</td>
<td>1.3</td>
<td>Benign Renal Parenchyma</td>
<td>1:25</td>
<td>5</td>
<td>30</td>
<td>3</td>
<td>Arterial hemorrhage from ablation tracts. Postoperative nausea. Postoperative pneumonia.</td>
</tr>
<tr>
<td>Right Central</td>
<td>4.6</td>
<td>RCC - CC</td>
<td>2:36</td>
<td>2</td>
<td>20</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Right Upper Pole</td>
<td>1.7</td>
<td>OEN</td>
<td>1:32</td>
<td>1</td>
<td>25</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Right Hilal</td>
<td>2.5</td>
<td>RCC - CC</td>
<td>2:33</td>
<td>2</td>
<td>150</td>
<td>25</td>
<td>Intraoperative lysis of adhesions. Sepsis from cecal perforation requiring bowel resection &amp; diverting ileostomy on POD 2. Prolonged intubation and ICU requirements.</td>
</tr>
<tr>
<td>Left Lower Pole</td>
<td>1.0</td>
<td>RCC - CC</td>
<td>1:26</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>Power surge during ablation (1 minute outage).</td>
</tr>
</tbody>
</table>

RCC-CC = renal cell carcinoma-clear cell; OEN = oncocytic epithelial neoplasm; EBL = estimated blood loss; LOS = length of stay
SAFETY AND EFFICACY ANALYSIS OF VASCULAR TARGETED PHOTODYNAMIC TREATMENT IN A HEALTHY PIG BLADDER

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Introduction: Non muscle invasive bladder cancer is heterogeneous, with significant risk of recurrence and progression. Vascular targeted Photodynamic (VTP) therapy could potentially offer a minimally invasive, bladder-sparing, treatment option for patients with recurrent disease and/or failure of intravesical therapy. In this study we performed a safety and efficacy analysis of VTP treatment of different light dosage.

Methods: After Institutional Animal Care and Use Committee (IACUC) approval, 8 swine underwent VTP treatment. For each swine, 3 ablations were performed (bilateral and posterior bladder walls), resulting in 24 ablations. After a 10-min Padeliporfin (WST11) infusion, frontal Laser fibers (focus adjustable by distance only, λ = 753-nm) were positioned 1.5 cm in distance to the mucosa resulting in a 1 cm beam-diameter. Three dosages were used: 191 J/cm² (n=6); 267 J/cm² (n=12); 535 J/cm² (n=6). Visible effects (VE) on treated areas were scored from 0 (no effect) to 4 (blanched). Animals were divided into two groups based on their euthanasia time point, 4 swine at 24 hours after treatment (Group I) and 4 swine after 28 days (Group II). Necropsy was performed to examine effects on adjacent organs. Histopathological examination was performed on treated areas. Tissue sections were analyzed and scored based on histopathological finding, 0 (none) to 4 (severe), in 3 distinct categories: Tissue damage score (TDS), Vascular Necrosis Score (VNS), (Table 1), and Granulation Fibrosis Score (GFS). To analyze organ penetration each score was again characterized by pathology depth (PD).

Results: Tissue and vascular damage were only detected in group I while granulation fibrosis was only detected in group II, showing a complete recovery, regardless of dose, over 28 days. In group I VNS and VNS/PD showed a positive correlation to dose, at minimum dose the mean VNS was 1.33 with a mean VNS/PD of 1.67 and at maximum dose the mean VNS was 3.00 with a mean VNS/PD of 3.67 (Fig. 1a). TDS and TDS/PD showed a positive correlation to dose. At the minimum dose the mean TDS was 1.33 with a mean TDS/PD of 1.67, and at maximum dose the mean TDS was 3.33 with a mean TDS/PD of 5.00 (Fig. 1b). In group I only 2 (16.67 %) showed a PD of <2 (lamina propria). The GFS showed the highest scores with the maximum dose. [mean GFS: 2.00; mean GFS/PD: 2.67]. There were no perioperative complications, and effects on adjacent organs were seen in two swine, a necro hemorrhagic metritis and a lymph node sinus erythrocytosis. Neither bladder perforation nor ureteral occlusion was detected.

Conclusion: Tissue penetration and treatment effects of VTP in the bladder can be modified by dose (optimum dose <535 J/cm²). VTP can safely reach adequate tissue depth in most cases, with complete healing after 4 weeks, representing a promising treatment modality for bladder cancer.
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NOVEL URETERAL ACCESS SHEATH DESIGN TO IMPROVE IRRIGATION OUTFLOW

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Introduction: Intrapelvic pressure (IPP) during flexible ureteroscopy (fURS) is a predictor of postoperative complications and therefore, decreasing IPP has been a pursuit for technological improvement within endourology. We have previously described that for any given irrigation pressure, the lowest IPP and highest outflow was seen with an offset circular ureteroscope under conditions of laminar flow using finite element analysis [PMC7857755]. The present study aimed to provide a prototype for a ureteral access sheath (UAS) to improve outflow and therefore lower IPP during ureteroscopy by inducing an offset to the ureteroscope.

Methods: A 12 Fr outer sheath of a 10/12 Fr UAS (Olympus, Center Valley, PA, USA) was attached horizontally to a 1 L bag of normal saline (NS) by vinyl tubing at a height of 155 cm. The UAS was occupied by a Boston Scientific (Marlborough, MA, USA) LithoVue® single use flexible ureteroscope (9.5 Fr) and NS was allowed to flow through the tubing for one-minute repeatedly with outflow volume recorded 17 times. The same procedure was repeated with the prototype UAS, which was modified by securing a taut 3-0 Proline® suture (J&J Medical Devices, New Brunswick, NJ, USA) at the inferior aspect of the 12 Fr outer UAS to offset the ureteroscope. Mean flow volumes were compared with 2-tailed Student’s t-tests with significance set to p = 0.05.

Results: The control UAS, which does not offset the ureteroscope, allowed for an average volume of 30.0 mL in one minute (SD +/- 0.35) compared to a volume of 33.76 in one minute (SD +/- 0.90) for the Prolene® model UAS, which does offset the ureteroscope (P<0.05).

Conclusion: Our model for a novel UAS, which offsets the ureteroscope, demonstrated evidence of improved outflow and may therefore provide lower IPP during fURS without affecting inflow or the working channel. Modification of a ureteroscope is more technically challenging but could allow for an off-set to be produced without reducing the cross section of the UAS.

Photo A: empty ureteral access sheath. Photo B: control UAS occupied by a Boston Scientific LithoVue® flexible ureteroscope. Photo C: depicts prototype UAS, which was modified by securing a taut 3-0 Proline® suture.
TRANPERINEAL ROBOTIC PROSTATE BIOPSY WITH PROST: A PILOT STUDY

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Introduction: Transperineal prostate biopsy is commonly performed under ultrasound guidance. This 2D image has the real-time advantage but a limited discrimination of the suspect lesion. We introduce a novel biopsy robotic system PROST for precise targeting of the prostate under ultrasound (US) guidance. PROST is designed for transperineal biopsy procedure with or without fusion. We prove that the system allows inexperienced users to reach the same level of accuracy as expert users. PROST allows the coverage of the whole prostate gland with just two punctures which act as pivot points, giving a biconical configuration of core positions, thus reducing the trauma to the patient but with the same accuracy as a template biopsy.

Methods: A 3DOF parallel robot and 1DOF motorized US probe calibrated with the robot was designed (see figure). The robot allows the needle orientation, while the insertion is done manually. The robot enables 3D US imaging from sagittal 2D tracked images through 3D reconstruction. A dedicated user interface (see figure) and image processing software based on 3D Slicer and developed in python was designed in the lab. In the first test, a 3D phantom with 9 targets and US compatible is employed. The phantom is 3D printed and the position and the dimensions of the target are known. Each user chooses the target in the US image and insert the needle after the robot directs it. In the second test, we use an anatomical phantom of the prostate designed for prostate biopsy (CIRS 053L) compatible with MRI and US and including 3 lesions. First, the user chooses the lesion in the US image, then, after MRI-US fusion, the user chooses the lesion from the MRI image. The orientation of the needle is made by the robot, while the insertion is performed manually by the user.

Results: A cohort of 5 experienced and 5 non-experienced urologists tested the system. The mean error for the experienced user was 2.06±0.75, while for the non-experienced was 2.36±0.95 for the first test. We noticed that the results depended only on the calibration of the robot regardless of the experience of the user. In the second test we obtained an average error of 5.25±0.83 over all users and each of the target lesion was reached.

Conclusion: Using PROST system may have several clinical advantages: precise targeting comparable with in-bore or targeted biopsy, repeatability of the biopsy in active surveillance, standardization of the biopsy procedure regardless of the experience of the user, less trauma for the patient, possibility to combine therapeutic devices. The next steps toward the clinical implementation are tests on cadavers and a new design of the system based on the objective (accuracy, precision, workspace of the robot, movements of the mechanism, compatibility with the clinical standards and requirements on both hardware and software) and subjective evaluations (e.g., ergonomics, usability, improved user interface).

Figure 2. Left to right: test on an anatomic phantom; PROST user interface, PROST with needle holder and US probe.
FOCAL THERAPY ABLATION IN INTERMEDIATE RISK PROSTATE CANCER:
PATIENT SELECTION USING MAGNETIC RESONANCE-ULTRASOUND FUSION BIOPSY

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Introduction: There is increasing interest in focal gland ablation for the treatment of intermediate risk prostate cancer (PCa). Historically, focal ablation has been limited to patients with low risk PCa with patient eligibility primarily defined by expert consensus panels (PMID 28349978). We evaluated a prospective cohort of men undergoing transrectal Magnetic Resonance-Ultrasound (MRI/US) fusion-guided biopsy for detection of prostate cancer to define the eligibility criteria for focal therapy in men with intermediate risk PCa.

Methods: Patients who underwent MRI/US image fusion biopsy between 10/2014-2/2020 were identified within a prospectively maintained database. For the purposes of this study, we defined “Eligibility” for focal therapy as Grade Group (GG) 2 or 3 within an MRI defined region of interest (ROI). Patients remained eligible if systematic random biopsies at time of targeted biopsy were benign or contained <4mm GG1. Exclusion criteria included GG4 or 5 disease in any core, or GG1 only disease. Patient demographics and clinicopathologic features are reported along with percent eligible using descriptive statistics.

Results: Out of 1,513 total patients captured, 1,351 contained a biopsy of GG1-3. Of these, 222/1351 (16.4%) were considered eligible for focal therapy based on the proposed criteria. Eligibility group mean age and PSA at time of biopsy was 66.0 years (SD 7.8) and 8.55 ng/mL; (SD 7.6), respectively. Fusion biopsy was performed for elevated PSA in 175/222 (78.8%), monitoring on active surveillance in 112/222 (50.5%), and prior negative biopsy in 51/222 (30.0%). ROI biopsy pathology revealed that 167/222 (75.2%) had single ROI GG2 disease, and 55/222 (24.8%) had single ROI GG3. 62/222 (27.9%) had GG1 disease detected elsewhere, with 4/62 (6.4%) found in a separate ROI and 59/62 (95.2%) in a systematic core.

Conclusion: A small but specific group of men in this cohort (16.4%) who underwent MRI/US fusion prostate biopsy harbored intermediate risk prostate cancer that were eligible for focal therapy ablation based on our definition. Further post-prostatectomy mapping studies are needed to best define ablation templates in this intermediate risk population.
SAFETY AND FEASIBILITY OF INTRAOPERATIVE REAL-TIME DIGITAL STONE FRAGMENT MEASUREMENT DURING URETEROSCOPY

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¹Brady Urological Institute, Johns Hopkins University, Baltimore, MD
²Mayo Clinic, Rochester, MN
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Introduction: Estimating the size of stone fragments during ureteroscopy is critical for determining the adequacy of stone fragmentation, likelihood of spontaneous fragment passage, and ability to safely extract fragments through the ureter or ureteral access sheath. We previously developed and validated an image processing software that enables digital measurements of stone fragment size during ureteroscopy. This study assesses the safety and feasibility of performing real-time in vivo stone fragment measurement and integrating its use into live operating room workflow.

Methods: Adult patients >18 years old undergoing ureteroscopic stone procedures for renal or proximal ureteral calculi by 2 surgeons at a single center were enrolled prospectively. The software was used to perform a representative series of real-time intraoperative stone fragment measurements. The time required to perform each measurement or series of measurements was recorded, including snaring the fragment with a stone retrieval basket, initiation of the digital measurement by the surgeon, and confirmation of size calculation. Software-related failures, clinical complications, and delays were also recorded. Ethics approval of the feasibility study protocol required that the measurements have no impact on clinical decision-making; thus, surgeons were blinded to the results.

Results: Nine patients undergoing ureteroscopic stone treatment were enrolled. Median age was 50 years (range 25-75). Six (67%) patients were female. Five (56%) procedures were right-sided. Intraoperative real-time measurement of stone fragments was successfully completed in all patients. The median number of measurements performed was 5 (range 3-10). The mean time for each measurement, from snaring the fragment until size calculation, was 9.9 seconds (s) (range 7.1-14.9 s). The median total time spent performing digital measurement per procedure was 50 s (range 25-99 s). There were no technical failures of the software or ureteroscope. No measurement-related delays or clinical complications were observed peri-operatively.

Conclusions: Intraoperative digital stone measurement can be safely performed during ureteroscopy and integrated into operating room workflow, with minimal additional time and no observed complications. These data support a prospective trial of digital stone measurement to guide intraoperative decision-making.
FIRST EXPERIENCE WITH THE NEW SUPERPULSED LASER (SOLTIVE)

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1Sanador Hospital, 2Saint John Emergency Clinical Hospital, Department of Urology, Bucharest, Romania

Introduction: Holmium:YAG laser is considered the current gold standard for laser lithotripsy of urinary stones. High-frequency generators with Moses technology demonstrated faster stone fragmentation. Low-pulse energy settings has proved efficient lithotripsy. The next-generation laser lithotripsy is recently arrived: the Thulium fiber laser (TFL). We analyzed the new Soltive TFL in renal stones fragmentation and dusting.

Material and methods: We used the Soltive Laser System in 59 cases with stone disease: 45 kidney, 9 ureteral, and 5 bladder. The average stone size was 13.1 mm (range, 11-29) for kidney, 8 mm (range, 6-12) for ureteral, and 3.1 mm (27 and 34 mm) for bladder. The average stone density was 1026 HU (range, 870-1752), 980 HU (range, 810-1700), and 1240 HU (970-1510), respectively. We treated only unique stones. We used 150 μm core-diameters fibers (CDF). We applied for fine dusting (0.15 J/100 Hz), for dusting (0.5 J/30 Hz) and for fragmentation (1 J/15 Hz). For renal stones we used disposable ureteroscopes (PU3022A, Pusen, Zhuhai, China) and access sheath 10/12 Fr. in all cases), for ureteral and bladder stones Storz rigid scopes. We analyzed operative time and complications.

Results: Regarding the operative time to complete stone disintegration (especially dust), the average time was 34 minutes for renal stones, 21 minutes for ureteral stones, and 39 minutes for bladder stones. We found that the retropulsion was insignificant in all cases with energy level less than 0.5 J. The visibility and maneuverability were optimal in all cases. The stone-free rate at 1 month posttreatment (CT evaluation) was: 95% for renal stones and 100% for ureteral and bladder stones. We consider fragments over 1 mm. being residual. We observed, especially in fine dusting mode (0.15 J/100 Hz), a very fine dust, stone fragments less than 1 mm in size that pass spontaneously through the access sheath, near the scope. Also, the size of the stone fragments permits aspiration through the working channel of the ureteroscope. Complication rate was very low: for renal stone 1 case Clavien I and 1 case Calvien II. We didn’t describe any cases with Clavien III, IV and IV. 2 cases with urinary tract infections were observed.

Conclusions: This new TFL (Soltive) is very promising because it is going to change the way we treat stones. With a completely different way of delivering the laser energy to the stone, we are now able to fragment stones more quickly and into much smaller pieces.
THE COST OF CONVENIENCE: ESTIMATING THE ENVIRONMENTAL IMPACT OF SINGLE-USE AND REUSABLE FLEXIBLE CYSTOSCOPES

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Introduction: Flexible cystoscopy is one of the most common outpatient procedures performed in urology practices. Single-use flexible cystoscopes may confer cost savings associated with reduced device reprocessing and repair. However, the environmental impact of disposable devices is not well-characterized. This study aimed to compare the carbon footprint of single-use and reusable flexible cystoscopes in urological practice.

Methods: We analyzed the expected life cycle of single-use (Ambu aScope 4 Cysto) and reusable (Olympus CYF-V2) flexible cystoscopes. Performance data on cumulative procedures between repairs and before decommissioning were derived from a high-volume multispecialty practice; to simulate practices with lower and higher volumes, we also estimated life cycle costs at 50% and 200% of case volumes. We estimated carbon expenditures per case using published data on endoscope manufacturing, energy consumption during reprocessing, and solid waste disposal.

Results: Our fleet of 16 reusable cystoscopes in service for up to 135 months averaged 207 cases between repairs and 3920 cases per life cycle. Based on a manufacturing carbon footprint of 11.5 kg CO\(_2\)/kg device for flexible endoscopes, the per-case manufacturing cost was 1.84 kg CO\(_2\) for single-use devices and 0.0001 kg CO\(_2\) for reusable devices (Table). The solid mass of single-use and reusable devices was 0.16 and 0.57 kg, respectively. The energy consumption of device reprocessing using an automated endoscope reprocessor was 0.45 kg CO\(_2\). Per-case costs of device repackaging and repair were 0.005 and 0.02 kg CO\(_2\). The total estimated per-case carbon footprint of single-use and reusable devices was 2.30 and 0.48 kg CO\(_2\), respectively. The estimated footprint of reusable devices at 50%–200% of case volume assumptions was not meaningfully different (0.47–0.51 kg CO\(_2\)).

Conclusion: The environmental impact of reusable flexible cystoscopes is markedly less than single-use cystoscopes over the life cycle of the devices, regardless of case volumes. The primary contributor to the per-case carbon cost of reusable devices is energy consumption of reprocessing, which may be offset with renewable energy sources.

<table>
<thead>
<tr>
<th></th>
<th>Single-use flexible cystoscope</th>
<th>Reusable flexible cystoscope</th>
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<tr>
<td>Life cycle component</td>
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<td>Manufacturing cost (kg CO(_2))</td>
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<td>Mass of solid waste (kg CO(_2))</td>
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<td>Repackaging</td>
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<tr>
<td>Repair cost (kg CO(_2))</td>
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</tr>
<tr>
<td>Mass of solid waste (kg CO(_2))</td>
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<td></td>
</tr>
<tr>
<td>Total</td>
<td>2.30</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Table. Carbon footprint per case for single-use and reusable flexible cystoscopes.
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DEVELOPMENT OF PEDIATRIC CIRCUMCISION SIMULATOR MODEL UTILIZING PROPERTIES OF HUMAN FORESKIN TISSUE

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Introduction: Circumcision is a commonly performed procedure in pediatric patients and is performed globally. Training procedural skills required for circumcision in the simulation environment allows for a learner-centered approach to technical skill acquisition. Accurate representation of mechanical properties of human tissues in synthetic materials used in physical simulator models is important to prevent negative skill transfer. Our objectives were to characterize the mechanical properties of pediatric foreskin tissue donated following pediatric surgical circumcision and develop a simulator model with materials that more closely represented these mechanical properties.

Methods: IRB approval was obtained through the University of Washington and Seattle Children’s Hospital for evaluation of mechanical properties of pediatric foreskin tissue. Pediatric foreskin tissue was collected at the time of surgical circumcision and subsequently underwent tensile tests. Synthetic materials were tested for comparison of mechanical properties. A 3D printed mold was created based on the size of an approximately six-month-old male pelvis and was used to create the physical circumcision simulator model. Synthetic materials with various additives and material ratios were used to adjust the mechanical properties of the simulator model.

Results: There were 23 donors with age range of 5 months to 4 years old and average age of 12.8 months. The foreskin samples demonstrated a “toe” and “linear” region on stress strain curve whereas the synthetic materials demonstrate a linear relationship between stress and strain. The novel features of the circumcision model include materials based on properties of human foreskin tissue as well as anatomical accuracy using 3D printed molds.

Conclusion: The increased fidelity of this model has the potential to decrease the likelihood of negative skill transfer in the simulation environment and has the potential to be integrated into curricula modules for multiple specialties.

Figure 1. 3D printed molding process for circumcision model.
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AUTOMATED METHOD OF TRACKING AND SEGMENTING KIDNEY STONES DURING URETEROSCOPY USING COMPUTER VISION TECHNIQUES

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Introduction: Despite being one of the most commonly performed urologic procedures, ureteroscopy is associated with several challenges. First, image quality can be impacted by blood as well as other debris intraoperatively. Furthermore, larger stone pieces can be difficult to track during fragmentation, which can lead to increased operative time and a decrease in stone free rate. Novel machine learning techniques could help identify and track stones during surgery, mitigating some of these challenges. We sought to develop a computer vision method to automatically segment and track kidney stones endoscopically during ureteroscopy.

Methods: Twenty separate videos of ureteroscopy were collected at the start of stone treatment. All videos were collected with digital ureteroscopes (Karl Storz Flex X²). Frames from each video were extracted at 20 frames per second (fps). The training data was manually annotated to identify the stone in each frame. Three state-of-the-art image segmentation architectures, U-Net, U-Net++, and DenseNet, were implemented (via PyTorch) to accept the raw frames and the annotated frames as input. The Dice coefficient and binary cross entropy (BCE) were computed from the model output to measure accuracy and loss, respectively. We subjected each model to a hyperparameter tuning (i.e. number of epochs, batch size, and learning rate) and compared the performance of the models to discover the best configuration.

Results: Eighty percent of the data was used to train the models with 10% being used as validation and 10% being used as testing (Fig. 1a). The average video time was 22secs (SD+ 13) with 578 of frames extracted for analysis. The number of steps \( \text{total steps} \approx \frac{\text{dataset length}}{\text{batch size}} \times \text{epochs} \) ranged from approximately 800-1600 (20-40 epochs); however, most models converged before 20 epochs. In comparison of the models, U-Net++ achieved highest Dice coefficient (0.91), followed by U-Net (0.89) and DenseNet (0.7) (Fig. 1b). Similarly, U-Net++ had the lowest loss among models whereas DenseNet had the highest. Additionally, the model was able annotate new videos at 30 fps and maintain accuracy.

Conclusion: These preliminary results suggest that computer vision models can be sufficiently trained to accurately segment and automatically track stones during ureteroscopy. The success of the models annotating new videos at 30 frames per second demonstrates the feasibility of their application real-time in the operating room. Further analysis of our models, as well as steps toward an automated, navigational system is ongoing.

Fig 1: (a) Endoscopic video segmentation of a kidney stone during ureteroscopy.
Left: original video;
Middle: predicted segmentation;
Right: heat map showing raw probability output per pixel.

(b) A comparison of our best models’ Dice score (left) and BCE loss (right) from training. The scores were computed at each step where \( \text{total steps} \approx \frac{\text{dataset length}}{\text{batch size}} \times \text{epochs} \). Y-axis is scaled to the range of values.
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SINGLE-PORT ROBOTIC TRANSVESICAL VS EXTRAPERITONEAL RADICAL PROSTATECTOMY: A MATCHED-PAIR COMPARISON

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Introduction: Transvesical robot-assisted radical prostatectomy (RARP) is an alternative approach for transperitoneal and extraperitoneal techniques in the treatment of localized low-intermediate risk prostate cancer. We present the perioperative and postoperative outcomes of our initial 50 patients who underwent transvesical RARP using the single port robot platform, da Vinci SP.

Methods: Fifty patients underwent SP radical prostatectomy through a transvesical approach by a single surgeon. Patients with intermediate-risk, Gleason 6 with a significant family history of prostate cancer, or Gleason 4+3 with extensive previous abdominal surgeries were selected. Through a 3 cm suprapubic midline incision, the bladder was incised, and the prostate was removed.

Results: All cases were completed successfully without any conversion or intraoperative. Median operative time was 214 minutes. Most of the patients (68%) were discharged few hours after the surgery with a median postoperative hospital stay of 4.6 hours. None of the patients required opioids medications. The Median Foley catheter stay was 4 days. Upon follow-up, 64% of the patients had immediate continence after Foley catheter removal, 73% and 81% were continent within 7 days and 6 weeks after the surgery, respectively.

Conclusion: We demonstrated the feasibility of single-port robotic transvesical radical prostatectomy using the novel SP robotic platform. In our early experience, this approach allows for promising results regarding the use of a single incision, no additional ports, minimal opioid use, same-day discharge, and immediate urine control.

Figure 1. Transvesical Approach. Table 1. Baseline characteristics. Table 2: Peri- and Post-operative variables.
TRANSVESICAL SINGLE-PORT RADICAL PROSTATECTOMY: OUR FIRST CLINICAL EXPERIENCE

Jihad Kaouk\textsuperscript{1}, Mahmoud Abou Zeinab\textsuperscript{1}, Alp T. beksac\textsuperscript{1}, Zeyad Schwen\textsuperscript{1}
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Introduction: Transvesical robot-assisted radical prostatectomy (RARP) is an alternative approach for transperitoneal and extraperitoneal techniques in the treatment of localized low-intermediate risk prostate cancer. We present the perioperative and postoperative outcomes of our initial 50 patients who underwent transvesical RARP using the single port robot platform, da Vinci SP.

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Figure 3: Transvesical Approach. Table 1: baseline characteristics. Table 2: Perioperative and postoperative variables.
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A SINGLE BLIND PROSPECTIVE STUDY OF 210 PATIENTS: PORTABLE ELECTROMAGNETIC DIAGNOSTIC DEVICE AGREEMENT WITH PROSTATIC BIOPSY

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Introduction: Prostate cancer (PCa) is the most frequent malignancy in men aged more than 50 years. The definite diagnosis of cancer relies on histopathological analysis of biopsy cores; prostate biopsy is recommended in case of abnormal PSA and/or digital rectal examination. We propose a novel device for the non-invasive detection of prostate cancer, consisting of a scanner that records electromagnetic interactions between a transmitting probe and tissues, retrieved from a dedicated receiver apparatus. The power used is less than 50 mW and electromagnetic emission levels are consistent with the exposure limits set by European regulations, making the device safe. We aim to test the predictive accuracy for PCa of this novel electromagnetic scanner.

Methods: This is a prospective single center study on male adults with clinical indication to prostate biopsy for abnormal PSA and/or positive mpMRI (PIRADS >=3 lesion). Inclusion criteria were age > 18 years and eligibility to prostate biopsy. Immediately before the procedure, patients underwent a non-invasive diagnostic assessment with an electromagnetic probe located in the lower abdomen directed to the pelvis below the pubic bone. The scanner detects physiological and pathological differences in electromagnetic behavior between tissues. Signs were recorded in a dichotomic fashion (normal/abnormal electromagnetic signs). All examinations were performed by a single operator. We tested the level of agreement between the output of the electromagnetic scanner and histopathology at prostate biopsy (presence vs absence of PCa). The diagnostic ability was assessed by estimating sensitivity, specificity, positive and negative predictive values, and the area under the receiver operating characteristic curve (AUC).

Results: A total of 210 consecutive patients fulfilled inclusion criteria and entered the study. Mean age was 72; mean PSA level was 8.2. Eighty-eight patients had a negative mpMRI whereas the remaining had a PIRADS >=3 lesion. In case of mpMRI positivity a target sampling was performed together with the systematic one. The examination with the electromagnetic scanner was fully completed before prostate biopsy in all cases. Overall, 107 out of 210 patients had PCa at final histopathology. The electromagnetic examination was positive in 116/210 patients; the scanner identified PCa with 96.3% sensitivity, 90% specificity, 93.3% diagnostic accuracy. The positive predictive value was 91.3%, the negative predictive value was 95.7%. False negative patients (negative electromagnetic examination but a PCa finding, n=4) had a non clinically significant Pca (GS 3+3). No side effects were recorded.

Conclusion: The electromagnetic scanner we propose represents a non-invasive tool likely to detect the presence of cancer in patients at risk of PCa; its accurate diagnostic performance makes the device suitable for outpatients to aid the diagnostic pathway of PCa.
NEURAL NETWORK PREDICTION OF CORE DEVIATION FROM INTENDED SPBX TEMPLATE LOCATION

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¹University of Florida

Introduction: The current gold standard for prostate biopsy is freehand, systematic (aka “random”) prostate biopsy (sPBx) using transrectal ultrasound (TRUS) imaging. The biopsy cores are half-cylinders about 17-22 mm long and about 1 mm diameter. During sPBx, the biopsy core centers are, in theory, placed at or close to template locations that are evenly distributed in the prostate such as the 12-core double sextant template or schema. The template locations are not prostate cancer (PCa) lesions or regions of interest. If the actual core centers are closer to template locations, the actual cores will be more evenly distributed reducing the risk that one region of the prostate is not sampled. If a non-sampled prostate region contains a clinically significant PCa (csPCa) lesion but only healthy prostate regions are sampled, then upon pathology exam of the cores that only contain normal prostate tissue, a prostate biopsy false negative (PBxFN) undesirably occurs. A PBxFN delays eventual PCa diagnosis, allowing more time for PCa to progress, which may reduce treatment and cure options and thus survival and quality of life (QoL). Thus, although usually performed in an office setting, sPBx is a high-stakes procedure. The overall, long-term goal of our project is within the context of translational simulation in healthcare: to eventually reduce PBxFN proportion in patients (ranging from 21% to 47%; [PMC4104074]) thereby improving PCa survival and QoL of PCa survivors via simulation-based training to competency in sPBx.

Methods: We implemented in Keras running on TensorFlow (Google Brain, Mountain View, California) using Python 3.7.4 (Python Software Foundation, Wilmington, DE), pandas 1.0.1 (NumFOCUS, Austin, TX) and scikit-learn 0.22.1 (Pedregosa et al) deep learning neural networks NNA1 and NNA2 (both feedforward multiple-layer perceptrons, MLP) using data collected from a PBx simulator. NNA1 is a binary classification model that predicts if a simulated biopsy core that is about to be sampled will be within (good) or outside (bad) an acceptable deviation of 5 mm. We used 3,216 simulated biopsy core records that contain core deviation, intended template location, the tracked TRUS probe’s pitch, yaw, roll, and insertion depth, and the tracked prostate position. We used a train/test split of 0.2 and a validation split of 0.2. In other words, the NNs were trained with 80% of the data and the remaining 20% of the data was used to test the accuracy of the NN predictions. The records were imported into pandas dataframes and scaled using scikit-learn preprocessing libraries. We used template deviation as the target variable. The training data was balanced with 47% of deviations below 5 mm (good) and 53% bad.

Results: Given only TRUS probe position, the tracked prostate position, and the intended template location, NNA1 predicted in real time with no noticeable delay if the biopsy core will be good or bad within 81.5% accuracy. We generated a confusion matrix and a Receiver operating characteristic (ROC) curve to illustrate the diagnostic ability of the binary classification system. Using the same inputs as NNA1, NNA2 is a regression model that predicted core deviation to within 3.46 mm.

Conclusion: The accuracy of both NNs can be improved with more training data, additional inputs, and optimization. We anticipate that in the future NNs can be used for coaching on the simulator as well as during clinical use when biopsying actual patients.
ABSTRACTS

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INTRALUMENAL PRESSURE MONITORING ACCURACY OF A CONCEPT SINGLE-USE DIGITAL FLEXIBLE URETEROSCOPE

O’Shaughnessy S.¹, Steele P.¹, Budrewicz J², Sluti A¹, Olceroglu E.¹, Walter T.¹
¹Boston Scientific, Inc. ²CBSET, Inc.

Introduction: Elevated pressure in the upper urinary tract during endourological procedures is hypothesized to play a role in the development of post-operative infection and other complications [PMC29915945]. Specialized devices that routinely measure intraluminal pressure during endourological procedures are not currently commercially available. Herein we present a preclinical study of the accuracy of a concept single-use digital flexible ureteroscope with pressure monitoring technology (Boston Scientific, USA, concept device and technology, not available for sale).

Methods: Ureteroscopy was performed in 4 anesthetized female Yorkshire swine in a total of 8 kidneys. A reference pressure transducer was connected to the working channel of the concept ureteroscope. Upper urinary tract pressurization was achieved via irrigation fluid infusion. Target intraluminal pressure was increased from baseline up to 150 mmHg maximum. Pressure measurements were simultaneously recorded by the reference transducer and a pressure sensor on the distal tip of the concept ureteroscope. Measurements were obtained in multiple locations within the upper urinary tract. The accuracy of the concept ureteroscope pressure was evaluated, and measurement error was calculated by subtracting the corresponding concept ureteroscope measurement values from reference transducer measurements and taking the absolute value of the difference.

Results: Pressure readings at baseline (approximately 20 to 30 mmHg) through maximum of 150 mmHg were collected in the kidneys and ureter using 8 kidneys. A total of 1100 simultaneous recordings were collected overall. Example plot comparing test and control pressure readings in the upper pole of one kidney is shown in Figure 1. The mean overall error of the concept ureteroscope measurements was 2.2 ± 2.6 mmHg. At intraluminal pressures below 100 mmHg the mean error was 1.9 ± 1.6 mmHg and at intraluminal pressures greater than 100 mmHg, the mean error was 2.6 ± 3.5 mmHg.

Conclusion: The pressure measurements from the concept ureteroscope were comparable to the reference transducer. Routine monitoring of intraluminal pressure in the kidney and ureters during upper endourological procedures may be feasible with specialized instruments, such as the concept single-use digital flexible ureteroscope with pressure monitoring technology presented in this study. Such a device could enable further studies of intraluminal pressure and its clinical significance to potential complications.

Acknowledgement: The authors would like to thank Ruslan Korets, MD (funded by Boston Scientific) for his collaboration and surgical expertise.

Figure 1: Example pressure readings from the concept ureteroscope (Test) and the reference transducer (Control) obtained simultaneously in the upper pole of one kidney.
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FALSE NEGATIVE PROPORTIONS INCREASE WITH TEMPLATE DEVIATION DURING SIMULATED, SYSTEMATIC, SIDE-FIRE PROSTATE BIOPSY

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Introduction: During freehand systematic prostate biopsy (sPBx), it is difficult to distribute the cores according to sPBx templates [PMC3876458]. We call the average of the shortest distance in mm between each core center and its intended template location “template deviation”, a metric of how closely core centers match the template. PBx false negatives (PBxFN) range from 21-47\% in patients [PMC4104074]. We investigated in a new simulator if sPBx template deviation is related to PBxFN proportion.

Methods: With IRB approval, center B (n=12) and C (n=16) trainees performed simulated 12-core, double-sextant, side-fire, transrectal ultrasound (TRUS) sPBx. Baseline set Bl is before training; Tn after ~30 minutes training; Mt best score with continued training with a methodical pitch-neutral technique. We placed virtual 0.5 ml spherical lesions, invisible with TRUS, at the right and left medial apex of a simulated 24.4 ml prostate, Fig. 1. Unless a core and a lesion intersect in a core set, however slightly, a PBxFN occurs. We calculated PBxFN proportion (# of false negatives/# of sPBx 12-core sets) for each center at conditions Bl, Tn and Mt.

Results: For both lesions, there is significant correlation between template deviation and PBxFN proportion in both centers (p = 0.0015). The fitted model is: Odds of false negatives = \exp(-2.84 + 0.22 \times \text{Template Deviation}). On average, the odds of PBxFN increases by 25\% (95\%CI: 8.9\%-43.4\%) with each 1 mm increase in template deviation and did not differ significantly between centers or lesions. All 12 center B trainees completed competency-based training (competency = template deviation \leq 5 mm). Only 12 out of 16 center C trainees were able to come back for further training to reach competency (\leq 5 mm), explaining the center C Mt deviation > 5 mm.

Conclusion: We established that template deviation is related to PBxFN proportions for medial, apical, 4.9 mm radius lesions for a 24.4 ml prostate during simulated side-fire TRUS sPBx. Leveraging the measurement capabilities of the simulator, we plan to explore further the relationship between template deviation and PBxFN proportions for other lesion locations, shapes and sizes, different prostate shapes and sizes for side-fire, end-fire and transperineal sPBx. We are also exploring ways to reproduce our findings in patients undergoing side-fire TRUS sPBx.

Figure 1. Left: 12 cores (red cylinders) miss 2 lesions (spheres). Right: Plot of false negative proportion vs template deviation

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COMPARISON OF URETERAL STENT BIOMATERIAL ENCRUSTATION PROFILE IN LITHOGENIC ARTIFICIAL URINE MODELS

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Introduction: Encrustation complicates and limits ureteral stent indwell time. To date, no material has shown complete encrustation resistance over long-term urine exposure. Recently, 2-hydroxyethyl methacrylate (HEMA)-coated Pellethane showed promise as an encrustation-resistant biomaterial in a nonlithogenic artificial urine model. Accordingly, we evaluated the degree and composition of encrustation on this material in comparison to other leading stent brands using two lithogenic artificial urine environments (AUE); (1) calcium oxalate (CaOx) and (2) struvite (NH\textsubscript{4}MgPO\textsubscript{4}) and calcium phosphate (Ca\textsubscript{10}(PO\textsubscript{4})\textsubscript{6} - 2 H\textsubscript{2}O).

Methods: Five 8 mm pieces of HEMA-coated Pellethane, Boston Scientific Tria, Bard InLay Optima, Cook Universa Hydrogel, and Cook Black Silicone were suspended in each AUE batch flow model at 37°C. Every 24-hours, 50% of the AUE was replaced using a programmed peristaltic pump system. Stents were removed, air-dried, and subjected to scanning electron microscopy (SEM) to assess the degree of encrustation at the 2 and 4 week intervals. At the termination of the study (11 weeks), harvested stent specimens were weighed and analyzed to quantify the composition of any stent encrustation (i.e., calcium, magnesium, and phosphorus) using inductively coupled plasma mass spectrometry (ICP-MS).

Results: In the struvite-forming AUE, SEM revealed complete encrustation of both the HEMA-coated Pellethane and Cook Hydrogel after two weeks, with partial encrustation of all other stents. All stents were fully encrusted at 4-weeks. In the CaOx-forming AUE, HEMA-coated Pellethane and Cook Hydrogel stents were fully encrusted at 2-weeks with partial encrustation of the Boston Scientific and Bard stents; however, the latter two were fully encrusted by 4-weeks. Cook Silicone remained relatively resistant to encrustation, even after four weeks. After the 11-week trial, HEMA-coated Pellethane had the most significant average mass gain (189.8% CaOx AUE and 66.9% struvite AUE), and Cook Silicone had the least average mass gain (17.2% CaOx AUE and -5.3% struvite AUE) (Figure 1, Table 1).

Conclusion: In this study, HEMA-coated Pellethane was found to be a poor material for ureteral stent construction. Among the various stent materials tested, silicone performed the best.

![Figure 1](image.png)

**Table 1.** Average mass (mg) changes of all stent samples after 11-week incubation in artificial urine conditions. Average mass (mg ± SD) of elements detected encrusted on stents after 11-weeks of incubation in artificial urine solutions (AUS) using ICP-MS.
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A NOVEL FULL CORE 18 GAUGE PROSTATE BIOPSY NEEDLE COLLECTS MORE TISSUE VOLUME BY WEIGHT: RESULTS FROM INITIAL COMPARATIVE STUDY

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Introduction: Prostate core biopsy is the gold standard for establishing the diagnosis of prostate cancer. Most core-needle biopsy devices employ a core collector design that captures tissue in a notch located just proximal to the tip of the collection needle. A recent study demonstrates that deflection of the needle tip as it encounters tissue of varying densities, may impede accurate sampling of cancerous areas, and may reduce the volume of tissue captured within the notch up to 50%.

A novel needle design in which the collection needle is centered within the outer cannula and minimizes potential needle deflection has been developed. Physical dimensions of this 18-gauge needle, including the area in which the tissue core is collected, are similar to current 18-gauge standard of care (SoC) needles. We compared tissue cores sampled with an SoC needle and with this novel needle, recently cleared by the FDA, in an initial series of prostate biopsies.

Methods: Patients undergoing routine prostate biopsy, either trans-rectal (TR) or trans-perineal (TP) participated in the study. An extended pattern 12 core plus 4 transrectal ultrasound-guided prostate biopsy method was used. An SoC biopsy needle was used to sample the standard twelve areas. Before the procedure, the physician chose 4 distinct areas from which a second tissue core would be obtained using the test needle. Each tissue core from the areas of comparison was weighed immediately after sampling in a similar fashion.

Results: The following is a summary of the results from 104 pairs of tissue cores from 16 TR and 10 TP procedures:

<table>
<thead>
<tr>
<th></th>
<th>Trans-Rectal</th>
<th>Trans-Perineal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SoC Needle</td>
<td>Test</td>
</tr>
<tr>
<td>Mean weight (mg)</td>
<td>5.54</td>
<td><strong>6.21</strong></td>
</tr>
<tr>
<td>Variance</td>
<td>2.3894</td>
<td>2.1752</td>
</tr>
<tr>
<td>% difference</td>
<td><strong>11%</strong></td>
<td></td>
</tr>
<tr>
<td>Observations</td>
<td>64</td>
<td></td>
</tr>
<tr>
<td>t Stat</td>
<td>-3.0130</td>
<td></td>
</tr>
<tr>
<td>P(T&lt;=t) two-tail</td>
<td>0.004</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion: In this head-to-head comparator study, the novel test needle collected significantly more tissue volume by weight than the SoC needle, 11% in TR and 22% in TP. Additional studies are continuing to assess the impact and utility of this novel biopsy needle design on quantitative and qualitative aspects of histologic processing and diagnosis.
EVALUATING UTILITY AND EFFICACY OF LASER SPECKLE IMAGING FOR VISUALIZING PERFUSION DURING UROLOGIC SURGERY

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Ensuring tissue perfusion during surgical procedures remains a critical factor in tissue healing, avoiding complications and ensuring good clinical outcome. Real-time visualization of blood flow and tissue perfusion would potentially have critical impact on clinical outcome and reducing complications. An optical imaging technique based on monochromatic coherent light known as Laser-Speckle-Contrast-Imaging (LSCI) represents a label-free imaging method using coherent monochromatic light where blood flow and tissue perfusion can be detected. ActivSurgical™’s ActivSight, is a laser speckle contrast based endoscopic imaging module that is positioned between the laparoscopic lens and the camera and has the ability to visualize real-time perfusion during laparoscopic procedures. During an initial evaluation of this technology in a live porcine model, several urologic procedures were performed in simulation and the utility of ActivSight was evaluated. During the procedures performed, ActivSight appeared to demonstrate active blood flow to tissue structures that were within 2-3 mm of the surface tissue. Cystoscopically, there appeared to be visualization of submucosal vessels and appropriate lack of signal after tissue cauterization was performed (Figure 1). During renal hilar dissection, superficial and smaller caliber vessels were readily identified however, renal artery and vein were not as obvious. However, during renal artery clamping, there was noted to be immediate, significant loss of signal to renal parenchyma (Figure 2). Upon unclamping the artery, immediate return of signal was noted to the parenchyma. ActivSight’s LSCI module was able to discern superficial changes in blood flow and tissue perfusion. While information presented here demonstrates some early potential promise, further research and development will be required to increase visualization depth of perfusion as well as validated perfusion thresholds to increase its clinical utility.

Figure 1: Cystoscopic evaluation of ActivSight technology in a porcine model. Images (a) and (c) are traditional white-light cystoscopic visualization whereas images (b) and (d) correspond to ActivSight visualization in the same field of view. Submucosal vasculature on whitelight (a) is visualized readily with ActivSight in image (b) and appears to correspond with vessels noted. Similarly, upon performance of electrocautery under white-light (c), there is loss of laser speckle signal noted (d).

Figure 2: Laparoscopic evaluation of ActivSight in a porcine model. During renal hilar dissection (a), excellent perfusion signal is noted to the kidney during ActivSight (b) and overlay mode (d). During renal artery clamping, absence of signal is noted on ActivSight (c) and overlay mode (e). Not pictured, is the return of signal during release of the arterial clamp.
THE PANDMIA CHALLENGE: ROBOTIC ARM AS AN ALTERNATIVE TO UROLOGIC PHYSICAL EXAM APPROACH

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Introduction: Due to restrictions caused by the SARS-CoV2 pandemic, the educational landscape for students and residents is changing urological practice. E-learning is playing an increasing role in medical education, supporting problem-based and practice-oriented education, facilitating teaching and resulting in an interesting learning model. Objective: Develop a prototype of an articulated arm device with an amplification lens and joystick for remote urological physical examination. Thus, evaluating how such a device can assist the training of medical students in order to strengthen distance learning.

Methods: IDEAL stage 2a/b study reporting the idea, development and exploration of a new device specifically designed for training medical students during their activity in urology clinics. After proof of concept (IDEAL stage 1) and subsequent development of the prototype to final design (IDEAL stage 2a), the safe and effective application of the device must be demonstrated.

Results: We used the Arduino board configuration instructions provided by the robotic arm manufacturer. After the configuration and synchronization of the board with the joystick and the robot, through a notebook, the camera was configured (attached to the robot's claw), through an application, also provided by the manufacturer. After carrying out all the necessary configurations, the robot was fixed to a wall, parallel to the service stretcher. The clinic where the robotic device was inserted is consistent with the restrictions of the pandemic, respecting the social distance between doctor and patient, thus aiming to reduce the risk of infection by and spread of COVID-19. After the test was carried out with the patient, the prototic device proved to be effective and practical for performing the physical examination and teaching. The wide movements of the robotic arm provide a wide view of the entire scrotal penile/vulvar region. Camera functions such as zoom, painting and measurement realizations provided a fluid learning dynamic with all the safety required in the pandemic for the patient, students, and clinicians.

Conclusion: The use of prototypes becomes convenient, since they are affordable and easy to formulate, allowing continuous training in this practice. This is a Brazilian experience that should be improved and encouraged, especially during the pandemic.
FRAGMENTING STONES TO DUST WITH BURST WAVE LITHOTRIPSY

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Introduction: It is hypothesized a 2.6-mm stone was too small to break with 390-kHz burst wave lithotripsy (BWL), which is the transcutaneous application of focused, cyclic ultrasound pulses.1

Methods: In clinical trial NCT03873259, a 2.6-mm lower pole stone was treated transcutaneously with 390-kHz BWL, failed to break, and was basketed. The stone was then treated by 390-kHz and 650-kHz BWL in a water bath. The stress from shock wave lithotripsy (SWL) and different BWL frequencies created inside spheres of different sizes, shapes, and compositions was calculated with a linear elastic model.3 Matched pairs of stones (1-7 mm) were treated at two separate frequencies (390 and 830 kHz with equal beam width) and with low frequency followed by high frequency. The mass of fragments greater than 1 and 2 mm was measured after 10 minutes of BWL.4

Results: The clinical stone measured 2.6 x 2.5 x 1.8 mm and comprised a calcium oxalate monohydrate (COM) core surrounded by a thin calcium oxalate dihydrate (COD) shell. The stone failed to break after 10 minutes in vivo and after another 30 minutes ex vivo at 390 kHz. The stone broke into 4 pieces in 4 minutes ex vivo at 650 kHz. The model predicts above a certain frequency the maximum principal stress inside a stone is more than 5 times the pressure applied in the ultrasound wave regardless of composition, and thus, smaller stones are likely to break a higher frequency but not lower frequency. Amplification remains even with irregularly shaped stones but is not seen with an SWL waveform. The threshold frequency is proportionate to the wave speed divided by the stone diameter. In water tank experiments, stones smaller than the threshold size broke fastest at high frequency while larger stones broke most completely with sequential application of low then high frequency.

Conclusions: BWL above a certain frequency amplifies the stress in the stone causing the stone to break. As a result, stones of all sizes may be turned to dust with BWL.

Literature Cited
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ROBOTIC-ASSISTED VERSUS OPEN LOWER URINARY TRACT RECONSTRUCTION (LUTR): CONTEMPORARY UROLOGIST PERCEPTIONS AND EXPERIENCES

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Introduction: The proportion of robotic radical prostatectomies performed robotically in the U.S. increased from 59% to 81% while robotic cystectomies increased from 12% to 25% between 2009 and 2015. [PMID30931607] Following qualitative interviews to define thematic influences on robotics use across stakeholders, a survey was developed for international distribution. The aim of this study was to determine urologist satisfaction with specific procedural steps in LUTR using an open versus robotic approach and to define current drivers and barriers to robotics adoption in LUTR to inform future device development.

Methods: An international survey was distributed through targeted social media channels, including Twitter, Facebook, LinkedIn, and Urologic List-Servs. Respondents were excluded if <50% of the survey was complete. Initial questions assessed practice location and setting, training, and targeted procedural volume. The remainder of the survey assessed general and surgical technology adoption, suitability of open versus robotic approaches for specific procedural steps in continent neobladder (CN) and augmentation cystoplasty (AC) (range 0-10, 10 best), and drivers/barriers influencing robotic use in these procedures. Frequencies by provider specialty and their use of robotic versus open approaches in LUTR were analyzed for each survey section.

Results: A total of 174 individuals initiated the survey. Of those, 64 were excluded due to incompleteness; 110 were included in the analysis. 54 (49%) practiced in academic institutions while 56 (51%) reported non-academic, private, or other practice settings. Specializations were distributed as pediatrics (39, 36%), oncology or robotics (28, 25%), or other (43, 39%). 75 (68%) completed training in the past 10 years. Of the 84 (74%) who have access to a da Vinci robotic system, 38 (45%) conducted >10 robotic procedures in the past year. In the past year, 24 (55%) completed only open CN or AC, 16 (36%) only robotic, and 4 (9%) both open and robotic. Of those that performed either robotic or both open and robotic CN or AC, 1 (5%) used only an intra-corporeal approach, 17 (85%) used only an extra-corporeal approach, and 2 (10%) used both approaches.

When asked to rate procedural steps of CN or AC for overall satisfaction with open versus robotic approaches, surgeons who performed robotic LUTR alone expressed high satisfaction with all anastomoses (bowel, bowel-bladder or bladder-bladder, ureteroenteric or urethrovesical; median range 8-10, IQR 7-10). Regardless of robotic experience or subspecialty, urologists found urethrovesical anastomoses more satisfactory by a robotic approach. Impression of suitability of robotics for completion of each of the remaining anastomoses reflected subspecialty and robotic experience.

Across the entire cohort, the 3 factors most frequently selected as major drivers of robotic CN were surgeon preference, improved perioperative outcomes, and equivalent oncologic outcomes. The top 3 major barriers were cost of robotic purchase and maintenance, surgeon support for robotics, and a difficult learning curve. The top 3 major drivers for robotic adoption of AC were increased robotic training in urology, surgeon preference, and operative dissection and visualization. The top 3 major barriers were increased operative time, cost of robotic purchase and maintenance, and minimal perceived benefit of extracorporeal procedures.

Conclusion: Urologic oncologists and surgeons who perform robotic LUTR alone were highly satisfied with the robotic approach for varied sutured anastomoses. Major drivers are robotic training and improved perioperative outcomes. Cost and operative time continue to be major barriers across subspecialties to robotics use in LUTR. Training modifications to maximize surgeon experience with all procedural steps and targeted innovation to address high complication rates regardless of approach are anticipated to facilitate the ongoing trend toward increased robotics use in LUTR.
ONCOLOGICAL AND FUNCTIONAL OUTCOMES AFTER SALVAGE PROSTATE CRYOTHERAPY FOR THE MANAGEMENT OF PRIMARY BRACHYTHERAPY VERSUS CRYOTHERAPY FAILURES: A PROPENSITY SCORE MATCHED COMPARISON

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INTRODUCTION: To compare the outcome of prostate cryotherapy as a salvage modality for treatment of primary brachytherapy versus cryotherapy failure.

METHODS: Following IRB approval, we queried the Cryo-On-Line Database (COLD) registry and the Duke prostate cancer database for men treated with salvage cryotherapy (SC) following treatment failure of primary brachytherapy (group A=113) vs primary cryotherapy (group B=81). Biochemical recurrence (BCR) using Phoenix criteria was the primary endpoint assessed at 2- & 5-years post SC. Secondary endpoints assessed functional outcomes including 12-month urinary incontinence, rate of effective intercourse; recto-urethral fistula and urinary retention. We estimated the association between treatment and biochemical progression-free survival (BPFS) using inverse probability weighted (IPTW) Cox proportional hazards regression. Propensity score analysis, adjusting for Gleason, risk, and PSA, was implemented to account for non-random assignment of primary treatment. To test for differences in the secondary functional outcomes between treatment modalities, we used Pearson’s χ2 test or Fishers exact test, corrected for IPTW.

RESULTS: 194 unweighted subjects were included who had complete data for the primary analysis. There was no statistical difference in 2-year BCR (HR 0.9; 95% CI, 0.5–1.7) or 5-year BCR (HR: 0.86; 95% CI, 0.5-1.5) between the 2 groups (Figure 1). There was no statistical difference between the 2 groups regarding the adverse functional outcomes, although the incidence of incontinence and urinary retention was higher in group A than in group B.

CONCLUSIONS: Salvage cryotherapy after failed primary cryoablation and failed primary brachytherapy has similar oncological and functional outcomes, except salvage cryotherapy after primary cryoablation had a lower rate of retention and incontinence. This information should be considered when selecting primary in-situ organ-preserving therapy for prostate cancer. Additional work with larger numbers of patients is needed to further validate these results with longer follow-up.
NONINVASIVE MANIPULATION OF KIDNEY STONES USING ACOUSTIC FORCEPS

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Introduction: After kidney stone treatments, residual fragments can remain in the kidney and serve as nidi for future growth or symptoms to recur. Here, we evaluate the safety and utility of a transcutaneous method for noncontact controlled manipulation of solid objects in vivo in a complex three-dimensional (3D) path using focused ultrasound beams.

Methods: Three pigs were placed under anesthesia and used to demonstrate the acoustic manipulation remotely in the bladder. A focused, 1.5 MHz, multi-element ultrasound array transducer was used to produce an acoustic trap around a stone model made from a glass sphere in the bladder. The array acoustic output was optimized to transmit ultrasound beams through the skin to steer the stone electronically. The array was synchronized with a P6-3 ultrasound imaging probe for targeting and submerged in a water tank to execute and observe the acoustic manipulation. A cystoscope was inserted into the bladder for visualization of the resulting motion. The motion was also recorded by ultrasound imaging. The acoustic trapping beam was moved along 3 different paths to determine how well the stone model tracked it. The absolute difference between the measured and intended path was calculated to quantify the accuracy. After experiments, the bladder was excised and analyzed histologically for injury.

Results: Manipulation in 3D of a 3-mm glass sphere along three different paths was achieved over maximum excursions of 3-6 mm. The models could be both levitated and held suspended in the urine space, as well as laterally and vertically translated controllably. The average discrepancy from ultrasound for the three paths was 0.18±0.09, 0.21±0.08, and 0.32±0.06 mm, and from the cystoscope recordings 0.21±0.11, 0.24±0.09, and 0.07±0.05 mm. The maximum exposure had a maximum peak pressure of 1.4 MPa, spatial peak pulse averaged intensity \( I_{sppa}\) of 133 W/cm\(^2\), and a mechanical index of 1.14. Histology showed no signs of thermal or mechanical injury to the bladder wall.

Conclusion: This work demonstrated the controlled manipulation of stone models in a living body at safe ultrasound power levels. This work potentiates the use of noninvasive acoustic forceps to reposition and remove stones from the kidney, or to guide medical instruments during minimally invasive procedures. Work supported by NIH P01-DK043881.
INITIAL PRECLINICAL RESULTS OF A PROTOTYPE TRANSRECTAL HISTOTRIPSY DEVICE FOR PROSTATE CANCER ABLATION

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Objective: Histotripsy ablation of the prostate may offer benefits over currently utilized focal therapies due to its non-thermal mechanism and real-time visualization on B-mode ultrasound (US). We assessed the feasibility and efficacy of transrectal boiling histotripsy (BH) ablation of the prostate in a canine model.

Methods: Using a custom-built preclinical prototype BH device (2 MHz, focal length 4 cm) with in-line B-Mode US, in vivo transrectal BH was assessed in N=6 intact male canines and N=2 ACE-1 prostate cancer-bearing canines. Tumor subjects were immunosuppressed and received bilateral intraprostatic injection of ACE-1 tumor cells, after which tumor growth was monitored with serial US. Under B-Mode US guidance, transrectal BH treatments (single and volumetric) were administered with input power 10% above bubble threshold, pulse durations of 2-10ms, duty factor of 1%, and 5-60 pulses/focus. In ACE-1 subjects, unilateral tumor treatment was performed with the contralateral prostate serving as control. After euthanasia, the prostate was harvested and processed for histologic evaluation.

Results: In all subjects, hyperechoic bubbles were produced on US consistent with BH. After treatment, hypoechoic regions on US and corresponding lesions on gross pathology were observed suggesting mechanical ablation. In benign subjects, histology demonstrated lesions of homogenized tissue with fine margins between treated/intact tissue. In ACE-1 subjects, carcinoma was confirmed in the control side, while homogenized tumor with surrounding tumor remnants was observed in the treatment side. Minimum threshold for cellular damage was observed at 5 pulses/focus, while complete treatment was achieved at 30 pulses/focus.

Conclusion: Transrectal BH ablation of the prostate is feasible in vivo producing precise mechanical ablation. Further studies are needed to characterize the impact of tissue/anatomic properties and optimize future clinical implementations.
CO-REGISTRATION OF MICRO-ULTRASOUND, MAGNETIC RESONANCE IMAGING AND WHOLE-MOUNT PATHOLOGY FOR PROSTATE CANCER

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Introduction: Conventional ultrasound (US) is widely used in a biopsy setting for visualizing the prostate and measuring the size of the gland, but US alone has poor sensitivity and specificity for detecting prostate cancer. Magnetic resonance imaging (MRI) is more effective, but can still fail to detect tumors in 20% of cases, and underestimates tumor volumes by as much as 300%. Furthermore, as a diagnostic tool, MRI is resource intensive, can have large interobserver variability, and requires an additional procedure for the patient. Recently, high-resolution ultrasound, referred to as micro-ultrasound (microUS), has been introduced for visualizing prostate cancer during biopsy, and preliminary studies indicate similar performance to MRI. However, the current system lacks validation with whole-mount (WM) pathology, the gold-standard. Here, we present and validate a methodology for in-plane co-registration of ex vivo microUS imaging, MRI, and WM pathology for resected prostates.

Methods: Four subjects undergoing radical prostatectomy with a pre-operative MRI were enrolled in the study. Following the procedure, the specimen was placed in a patient-specific mold, submerged in saline in a custom imaging tank, and imaged in the axial plane with a microUS probe from apex to base using a translation stage. The prostate was then placed in a 3D printed pathology mold and sectioned to produce slides in the same orientation as the MRI and microUS scan, as described in earlier studies. Digitally scanned histological slides at 20X magnification were created from each specimen. Matched corresponding images from both T2 MRI and ex vivo microUS were chosen for each histology slide. For each slide the prostate capsule was segmented and at least four anatomical landmarks (urethra, BPH nodules, cysts, ejaculatory ducts) were marked that were visible in all 3 image sets. Using only the prostate capsule segmentations, a rigid registration step followed by a thin-plate spline (TPS) non-rigid registration step was performed to co-register each set of image triplicates (Figure 1). The in-plane target registration error (TRE) was calculated for each landmark.

Results: Matched microUS and MRI images were co-registered to a total of 22 pathology slides. A total of 88 anatomical landmarks were evaluated. Based on previously published results, the out of plane error between MRI and microUS matched with WM pathology slides is expected to be around 1.5-3mm. The TRE following TPS registration was 2.16mm ± 1.02mm for microUS and 2.34mm ± 1.35mm for MRI.

Conclusion: The methodology presented here facilitates accurate in-plane co-registration of microUS and MRI with WM pathology. An average TRE of 2.16mm and 2.34mm for microUS and MRI is acceptable and similar to published values for co-registration of MRI with WM pathology, which range from 1-5mm. MicroUS and MRI landmark co-registration TRE will be evaluated further on more subjects. Quantitative analysis using this co-registration process to compare microUS and MRI against ground truth WM pathology for clinically significant tumor identification is ongoing.

Figure 1: Co-registration of microUS (red), WM pathology (blue), and T2 MRI (green). The four corresponding landmarks are marked as circles.
COMPREHENSIVE ASSESSMENT OF BLADDER BIOMECHANICS DURING VOIDING USING MRI

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Introduction: Lower urinary track symptoms (LUTS) generally increase with age in men[1]. As a result, noninvasive uroflowmetry and invasive filling cystometry and pressure-flow studies are frequently performed urological exams to provide functional information[2]. While these tests can provide information about the reason for abnormal voiding[3], they lack anatomical information that can be used to further assess the source of the symptoms. Previous studies[4-5], have demonstrated that magnetic resonance imaging (MRI) is a noninvasive tool that provides anatomical information of the lower urinary tract. Therefore, the aim of this study is to implement an MRI urodynamics protocol for the comprehensive assessment of bladder biomechanics during voiding.

Methods: In this IRB approved and HIPAA compliant study, healthy males are recruited to void in an MRI scanner. A single weight-based dose (0.1 mmol/kg) of gadolinium-based contrast was prepared and 1/3 of the dose was injected prior to the MRI. The subject applied a condom catheter in order to void supine in the scanner. The scans were completed on a clinical 3T scanner (Premier, GE Healthcare, Waukesha, WI), using the sequence, 3D Differential Subsampling with Cartesian Ordering (DISCO) Flex. MR images were imported into Mimics (Materialise, Leuven, Belgium), where the bladder lumen and bladder wall were segmented at each of the 15 time points (Figure 1). The segmentations where then used to create 3D renderings of the bladder lumen and wall. These 3D renderings were used to calculate bladder lumen volume and bladder wall volume from which the amount of voided urine and flow rate (Q) were calculated. Each bladder wall rendering was also exported into 3-matic (Materialise, Belgium), where a thickness gradient was applied to the bladder wall to determine median bladder wall thickness.

Results: In subject one, the bladder volume before voiding was 531.42 cc. During the scan, the subject voided 521.79 cc in 42 seconds, resulting in a Q_{avg} of 12 cc/s and a post void residual of 9.64 cc. Their Q_{max} during the void was 31 cc/s (Figure 2). The bladder wall’s volume decreased from 119.89 cc to 52.80 cc, while its thickness increased from 2.67 mm (IQR: 1.96-3.27) to 10.37 mm (IQR: 9.38-11.76). The bladder wall did not begin to thicken until the 24 second mark, when the bladder had already voided 71.2% of its urine and the flow had already peaked.

Conclusion: MRI can be used to obtain both anatomical and functional information, providing a more complete assessment of bladder biomechanics during voiding, than urological exams alone. This study demonstrates the feasibility of this method to gather this information, while future studies will be aimed at using this information to further deduce the source of LUTS in a variety of conditions.
LOW INTENSITY SHOCKWAVE THERAPY FOR ERECTILE DYSFUNCTION DURING ERECTION BASED ON ACOUSTIC IMPEDANCE PRINCIPLES

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Introduction: In 2010, low intensity shockwave therapy (LiSWT) for ED was first reported. LiSWT continues to be performed the same way: in the flaccid state. The proposed regenerative mechanisms of action of LiSWT in treating ED are to: i) activate endogenous mesenchymal stem cells to synthesize healthy corporal erectile tissue, and/or ii) induce corporal vascular smooth muscle relaxation. These mechanisms depend upon the energy from the shockwave being transferred to the cavernosal erectile tissue, and not passing through it. Acoustic impedance (Z) in the penis is related to erectile tissue density (p) and the shockwave acoustic velocity (V), defined as Z = pV. Thus, performing LiSWT in the flaccid state occurs in a low penile volume, low penile blood flow state, resulting in a low p value. In contrast, performing LiSWT in the erect state maximizes penile volume and blood flow, increases acoustic impedance and energy delivery to the erectile tissue. We review our experience with LiSWT treating ED during pharmacologic erection.

Methods: A retrospective chart review was performed. Prior to LiSWT (Urogold 100 MTS), ED patients underwent a baseline penile Grayscale/Doppler ultrasound (G/DUS) with Grade 3-4/4 erection following appropriate visual/pharmacologic stimulation. A B-mode ultrasound (Aixplorer 15.4 MHz transducer) was then performed at specific settings to avoid reader bias. This included 20 total axial images obtained at proximal, midshaft and distal dorsal penis, as well as right and left crurae, at a fixed dynamic range of 70 dB with B-mode gain values of increased brightness (45%, 55%, 65%). The fourth image at each axial location was taken at a dynamic range of 49 dB and a B-mode gain value identified as the best discrimination between Grayscale black/white. Subsequently, in the erect shaft right/left sagittal planes, cavernosal artery peak systolic velocity (PSV) and end diastolic velocity (EDV) values were obtained. ED patients then underwent 6 erect penile LiSWT treatments over varying intervals. The protocol included: appropriate visual/pharmacologic stimulation to obtain Grade 3-4/4 erection, 600 shocks using a parabolic reflector probe (OP-155), energy flux density 0.13mJ/mm², 3 Hz, membrane pressure 3, applied each to dorsal, ventral, right/left lateral erect penile shafts, and right/left erect crura (total shocks 3600). Approximately one month after the 6th erect penile LiSWT, a post-treatment penile G/DUS with Grade 3-4/4 erection was repeated. Baseline and post-treatment G/DUS were de-identified and read by two experts reaching consensus concerning erectile tissue homogeneity/inhomogeneity on Grayscale with 0/3 no inhomogeneity, 1/3 mild inhomogeneity (<25% of cross-sectional area revealing hypo- or hyper-echoic regions), 2/3 moderate inhomogeneity (25% - 50%), and 3/3 severe inhomogeneity (>50%), respectively. PGI-I scores, obtained after each treatment, were compared to ultrasound findings.

Results: 79 patients (mean age 44 +/- 21, range 19 – 85) met inclusion criteria. 53/79 (67%) had improved erectile tissue homogeneity post-LiSWT from baseline, 10/79 (13%) were unchanged, 15/79 (19%) worsened. Of the 53 patients with improved G/DUS findings, 40/53 patients (75%) rated PGI-I as improved. 37/53 (70%) patients had PSV increase and 18/53 (34%) had EDV decrease.

Conclusion: Performing LiSWT in the erect state with higher acoustic impedance is associated with objective increases in erectile tissue homogeneity and cavernosal arterial blood flow. More research is needed to understand the benefits to LiSWT ED treatment outcomes by increasing acoustic impedance.
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AUTOMATIC ABLATION SITE SELECTION FOR FOCAL THERAPY

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**Introduction:** Partial gland ablation for treatment of prostate cancer (PCa) frequently relies upon placement of interstitial treatment applicators (ITAs) to generate ablation volumes (AVs). Planning ITA locations can be a complex and time-consuming process, since the optimal arrangement depends upon the ITA orientation, expected registration accuracy, AV size, and AV shape associated with the ablation modality. Herein we describe a fully automatic and modality-agnostic method for ablation site selection.

**Methods:** An algorithm was written in Python, requiring as inputs the ITA point of origin and 3D surfaces for the prostate, region of interest (ROI), margin intended for treatment, and ablation volume.

1. The first AV was placed on the margin apical/basal edge closest to the ROI.
2. AVs were placed sequentially to continuously encompass the margin’s lateral edge.
3. AVs were placed sequentially to continuously encompass the margin’s medial edge.
4. Additional AVs were placed via raster-scanning to encompass any central cavities.
5. If a single AV was insufficient to encapsulate the margin along an ITA trajectory, additional “pullback” AVs were defined with even spacing (Fig C).

The algorithm was evaluated on 11 unilateral and 6 bilateral margins derived from 11 patients who had previously received focal treatment. The margin encapsulation of the AV aggregate was measured for 18 variations of AV size (transverse diameters = 12, 18, 26 mm) and geometry (spheres, ellipses, rounded cylinders i.e., “capsules”, cubes, prisms, and custom). Thus, a total of 18x17 = 306 instances were tested. Manually generated treatment plans using large custom AVs were available for the 11 unilateral margins; these were directly compared to automatically generated treatment plans using the same margins and AVs.

**Results:** Exemplary algorithm outputs are shown in Figure A-C. The algorithm completed after an average of 2.25 seconds (range 0.4-6.5) and placed an average of 11 AVs (range 1-41). The algorithm achieved mean margin coverage between 86% and 99% for each AV size/shape. Compared to manual planning, mean margin coverage was significantly improved from 87% to 94% (p = 0.005). Margin coverage was invariant to AV volume and margin volume. However, margin coverage increased for less rounded AV geometries (Fig D), due to the relative ease of continuously packing straight versus rounded contours.

**Conclusion:** This methodology could potentially be used to automate ablation site placement for a variety of treatment modalities, simplifying the planning process for focal treatment of prostate cancer.

![Example algorithm output](image)

**Figure:** Example algorithm output. (A) shows placement of large (17x26mm) custom AVs and (B) shows placement of small (12x22mm) custom AVs, both in coronal view. (C) shows exemplary “pullback” AV placements in sagittal view, with ITA trajectories shown as dotted lines. (D) Shows mean margin coverage versus shape.

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CONTRIBUTION OF PEDENDAL NERVE TO STRESS URINARY INCONTINENCE IN MALE RATS

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Introduction: One contributor to post prostatectomy stress urinary incontinence (SUI) is injury to the pudendal nerve (PN) during apical dissection or ligation of the dorsal venous complex. We sought to evaluate the contribution of the PN to urethral resistance to leakage in male rats.

Methods: Six male Sprague-Dawley rats were anesthetized with urethane (1.2g/kg IP) and underwent insertion of a suprapubic bladder catheter, which was connected to a pressure transducer and syringe pump. The bladder was filled with saline (5ml/hr) for 3 filling and voiding cycles. With the bladder refilled to approximately half capacity, we performed a Credé maneuver until urine leaked. This was repeated 3 times. Leak point pressure (LPP) was calculated as baseline pressure subtracted from peak pressure during the Credé maneuver. This represented the Intact situation. We then bluntly dissected the prostate, grossly identified the external urethral sphincter (EUS), and placed a bipolar surface electrode on the exposed EUS. We repeated LPP testing in the Urethra Exposed (UE) situation. The increase in amplitude and firing rate of simultaneous EUS electromyography (EMG) was calculated as the difference from baseline to peak activity during LPP testing. We then exposed the PN bilaterally from a postero-gluteal approach and repeated LPP and EUS EMG measurement for the Nerve Exposed (NE) situation. We then transected the PN bilaterally and repeated LPP and EUS EMG measurement for the Nerve Transected (NT) situation. A one way ANOVA followed by a Dunn’s post-hoc test were used to compare LPP and EUS EMG of each situation to the NE situation. Data is shown as mean ± standard error of the mean from 6 animals. P < 0.05 was taken to indicate a statistically significant difference.

Results: LPP in the Intact (57.8 ± 4.8 cm H2O) and UE (57.7 ± 4.7 cm H2O) situations were not significantly different from the NE situation (61.9 ± 6.6 cm H2O). In contrast, after PN transection, the NT situation had significantly decreased LPP (35.0 ± 3.8 cm H2O; p=0.0086; see Figure). The NT case also had significantly decreased EUS EMG amplitude (2.2 ± 1.0 μV) and firing rate (215 ± 38 Hz) compared to NE (amplitude: 11.8 ± 4.6 μV, p=0.016; firing rate: 522 ± 57 Hz, p=0.046). UE had EUS EMG amplitude (14.7 ± 4.0 μV) and firing rate (563 ± 41 Hz) not significantly different from that of NE (see Figure).

Conclusion: PN injury alone can induce decreased urethral resistance to leakage and SUI in male rats. This finding may be useful for future studies using this model to investigate novel therapeutics to prevent and treat post prostatectomy stress urinary incontinence.
CHARACTERIZATION OF FLUID DYNAMICS AND TEMPERATURE PROFILES DURING URETEROSCOPY WITH LASER ACTIVATION IN A MODEL URETER

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Introduction: Ureteral thermal injury has been reported in patients following ureteroscopy with laser lithotripsy due to overheating of fluid within the ureter. Proper understanding of temperature elevation necessitates knowing the volume of fluid available to absorb laser energy. This can be approximated by determining the volume of fluid that mixes within the ureter during laser activation, since energy transfer through fluid is dominated by convective effects. Objectives of this study were to determine the volume of fluid that mixes during laser activation at different irrigation rates and to characterize the temporal/spatial temperature distribution in a model ureter.

Methods: The model ureter consisted of a plastic tube – 160 mm length, 5.3 mm inner diameter. A 13/15 Fr ureteral access sheath was inserted into the distal end. A balloon was attached to the proximal end simulating a renal pelvis. Irrigation was first applied with clear, then switched to green deionized water at rates from 8-40 ml/min. The laser was activated at 20 W (0.5 J x 40 Hz). The distance that green fluid propagated was measured and the volume was calculated. Temperatures were recorded from six thermocouples - five embedded within the tube and one affixed to the ureteroscope. Thermal dose was calculated using the Dewey and Sapareto methodology.

Results: The volume of fluid mixing ranged from 1.10 to 1.26 cm³ based on irrigation rate. Laser activation produced a sharp temperature increase 20 mm beyond and 10 mm behind the laser tip. Minimal temperature increase was observed 50 mm beyond the laser tip. Calculated thermal dose exceeded the threshold of tissue injury for irrigation rates ≤ 12 ml/min. Threshold was surpassed along a 50 mm length of the ureter with 0 ml/min, a 30 mm length with 8-10 ml/min irrigation, and only at the 15 mm location with 12 ml/min irrigation.

Conclusion: Within the model ureter, the volume of fluid mixing was small (≤ 1.26 cm³). Greater lengths of ureter were exposed to thermal doses exceeding the threshold of tissue injury at lower irrigation rates. With only a small volume of fluid available to absorb laser energy within the ureter, urologists should minimize power settings and maximize irrigation rates to prevent ureteral thermal injury.

Funding: Research Grant from Boston Scientific Corporation

Figure: Laser activation at 20 W (0.5 J x 40 Hz, SP) with 10 ml/min irrigation. (A) Distance of green fluid propagation from the end of the ureteroscope (0 mm). (B) Temperature at each thermocouple location within the model ureter.
DETRUSOR PRESSURE ESTIMATION FROM SINGLE CHANNEL BLADDER PRESSURE RECORDINGS

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Introduction. Currently catheter based urodynamic studies require measuring bladder (vesical) pressure, PVES, along with abdominal pressure, PABD, to distinguish pressure changes arising uniquely from the detrusor (PDET). Urodynamics systems assume that all changes in PABD are reflected within PVES, allowing for a linear subtraction of PABD to obtain PDET, the latter of which is not directly measurable. This implies that all the signal information of PABD is contained within the measurement of PVES. Because PDET is generated by the smooth muscle detrusor contraction, this signal has specific temporal behavior controlled by bladder physiology. Algorithmically detecting the PDET signal within a single PVES measurement would simplify urodynamics by eliminating the need for a separate catheter to measure PABD, or could improve abdominal pressure artifact rejection in standard urodynamics. This study presents a novel, parameterized framework, which facilitates real time estimation of detrusor pressure from a single pressure sensor in the bladder.

Methods

Data collection: A set of urodynamic data were collected retrospectively from 20 subjects using a standard urodynamic testing protocol. The data were divided into two groups, each containing 10 urodynamic studies. The first group was used for analysis and model development. The second group was used to test predictions of PDET.

Data analysis: A two-fold analysis process was considered to explore the difference/correlation between PVES and subtracted calculated PDET. At first, the difference between the frequency bands of PVES and calculated PDET were investigated to identify a feasible approach for filtration. Secondarily, wavelet multiresolution analysis was utilized to decompose PDET to find correlation levels between PDET and PVES.

Algorithm design: Using the analysis data set, statistical inference was used to extract the basic features of each bladder event. The features included localized statistical mean, median, standard deviation, maximum, zero-crossing rate, and the level of wavelet resolution. An algorithm was developed which included a band-pass filter to remove artifact and noise and a wavelet transformation to extract time-frequency features. To evaluate the effectiveness of the proposed framework, the algorithm was developed using MATLAB® software and tested by processing the data in a frame-wise manner to simulate analysis in real-time with data collection. During this scenario, the test dataset was used to evaluate the performance of the algorithm. The F-score statistical test was utilized to measure algorithm accuracy with the equation: \(ACC = \frac{TP+TN}{P+N}\) where, ACC is accuracy of the algorithm, TP and TN are the true-positive and true-negative detected outliers (coughs and valsalvas). P and N are the number of overall positive and negative outliers detected by the algorithm since detection and elimination of artifacts is essential to estimate PDET without artifacts or outliers.

Results. The accuracy of detecting cough events in the test dataset (10 UDS) was 99.5%. In contrast, the algorithm detected Valsalva events with an accuracy of only 86.5%. The algorithm detects voiding within 0.5 sec from its start with accuracy of 66.4%.

Conclusions. We have developed a real-time, accurate bladder voiding contraction detrusor estimation system that does not require an abdominal reference sensor. The algorithm was most successful in detecting cough events. For a majority of events, it was able to distinguish voiding events from changes in posture, coughs, and other non-voiding events using only bladder pressure data. Further work is underway to detect non-voiding valsalva events related contraction events. This system may be used to augment existing diagnostic and treatment techniques for voiding dysfunction and urinary incontinence.

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3D RECONSTRUCTION OF HUMAN BLADDER FROM FLEXIBLE CYSTOSCOPY VIDEO

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Introduction: The high recurrence rate of bladder cancer leads to frequent in-office surveillance using flexible cystoscopes [1]. 3D reconstructions of the bladder from cystoscopic videos embed detailed information about the bladder wall contour, texture, appearance, and relative locations of abnormalities, which will enable more comprehensive review, guidance for intervention, longitudinal comparison, and development of remote robotic cystoscopy as a future diagnostic tool. Previous bladder reconstructions have been limited to phantom models [2, 3], computer simulations [4, 5], or videos from rigid cystoscopes [6, 7]. Here, we present preliminary results of the first 3D reconstruction of human bladder from flexible cystoscopy, with an emphasis on greater completeness. We also investigate necessary requirements on the cystoscopy procedure and possible refinements to the reconstruction algorithm to achieve the next level of comprehensive 3D reconstruction of bladder from clinical flexible cystoscopy.

Methods: We collected de-identified clinical cystoscopy data using a flexible cystoscope (Olympus CYF-VHR HD) under IRB approval from seven human subjects presenting for routine cystoscopy in the office. We used each video to reconstruct a 3D bladder model using the following modules: (1) Camera calibration [8], which calculates the camera parameters from cystoscopic video of a printed target; (2) Frame selection, which chooses video frames with minimum motion blur, reasonable sample rate, near-perpendicular view angle and sufficient amount and contrast of vascular features; (3) Image preprocessing [6], which reduces noise and enhances contrast; (4) Surface shape reconstruction, which uses Structure from Motion (SfM) (both hierarchical [9] and incremental [10] SfM were tested) to reconstruct a sparse point cloud model, followed by Poisson surface reconstruction [11] to reconstruct a surface mesh model from the point cloud; (5) Texture mapping [12], which maps a texture onto the mesh surface model to create a textured surface model that matches both the shape and texture of the bladder.

Results: We achieved reconstruction with 2/3 coverage of the inner surface of a representative bladder (Fig. 1). By testing two variations of SfM (the core of 3D reconstruction), we observed that the bottleneck for improving reconstruction performance is the quality of input frames, as poor quality leads to reconstruction failure. In our dataset, the poor quality of cystoscopy frames is caused by too large or too small imaging distance, oblique view angles and fast-moving speed of the scope relative to the bladder wall, which leads to low contrast and density of vascular features. In addition, bladder filling determines stationarity and clarity of the urothelium in the scope view. All these influence SfM performance (shape quality) and texture quality.

Conclusion: We achieved the first near-complete 3D reconstruction of human bladder from clinical flexible cystoscopy videos. We analyzed reconstruction outcomes to identify that improvement in video quality by use of appropriate imaging distance, near-perpendicular view angle, minimal motion blur, stationarity of the bladder and clarity of view would improve performance. The need for strict requirements on data quality suggests that robot-assisted cystoscopy may provide a promising clinical solution for bladder 3D reconstructions.

Fig. 1: A reconstructed 3D model of the bladder from clinical flexible cystoscopy video. The inset shows zoom-in view of the texture containing vascular patterns.
**SINGLE PORT ROBOTIC TRANSVESICAL PARTIAL PROSTATECTOMY: FEASIBILITY AND INITIAL OUTCOMES**

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**Introduction:** Subtotal prostatectomy has recently been described as an alternative to focal therapy for management of localized low and intermediate risk prostate cancer in carefully selected patients. Preclinical studies show technical feasibility of single port (SP) transvesical partial prostatectomy. Here we describe the early experience with the SP transvesical robotic partial prostatectomy using the da Vinci SP surgical system.

**Methods:** SP transvesical partial prostatectomy was offered to six patients as an alternative to focal therapy, radical prostatectomy or XRT in patients with low volume, localized, and low to intermediate risk prostate cancer (Gleason 6 or 7). Surgery was performed through a 3cm suprapubic incision, the bladder was incised and a DaVinci SP access port was used for docking. Through the access port, robotic instruments, a 12 mm assistant port, and flexible suction tubing were introduced. Transrectal ultrasound was used for intraoperative guidance in select cases.

**Results:** All patients had preoperative MRI fusion prostate biopsies showing unifocal, localized disease. All cases were completed successfully without need for extra ports or conversion. There were no intraoperative complications, no transfusions, and no patients required an inpatient stay (median LOS of 3.8 hours). Median operative time was 211 minutes. Pain scores at discharge were median 3/10 and no patients required opioid prescriptions at discharge. There were no postoperative complications or readmissions. Catheter duration was 3 days and all were able to void spontaneously. Pathology reports showed GG1 disease in 1 case and GG2 disease in 5 cases. There were 2 focal positive margins (<3mm) on final pathology despite intraoperative frozen sections in both cases. The median PSA at 6 weeks was 0.59. Median SHIM score at 6 weeks was 15. All patients were fully continent with a median pad count of 0 at 6 weeks.

**Conclusion:** We demonstrated technical feasibility of SP robotic transvesical partial prostatectomy. To date, functional outcomes show impressive return to continence and erectile function. Continued attention to follow up will evaluate the long-term oncologic outcomes.
ROBOTIC CYSTOSCOPY
FOR DETAILED CHARACTERIZATION OF URETHRAL STRicture

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Introduction: The current gold standard for diagnosis of urethral stricture disease (USD) is retrograde urethrogram. This diagnostic test is limited to a two dimensional output of a three dimensional problem. Determining accurate length of pathologic findings is highly dependent on x-ray angle, penetrance, and penile traction, which is not conserved across studies. The proximal appearance of the urethra, in particular near the prostatic urethra, is not well captured by this type of study, and may lead to underdiagnoses in severity, location, or length of stricture complicating surgical management. Adaptions and miniaturization of current cystoscopic technology would greatly improve diagnosis and consistency across research for USD and other urethral pathology. Our objective is to develop an adjunct to cystoscopy which could reproducibly identify the a) exact location b) exact length of USD as well as retain the ability to assess health of surrounding urethral mucosa.

Methods: A simulated male urethra was created in Computer Aided Design (CAD) software, using an anatomic diagram as guide. An anatomicallly appropriate marker was placed relative to the meatus at distance consistent with the verumontanum. Furthermore a 10 mm narrowing in the proximal bulb created as example USD. This was 3D printed of standard material using a Form 2 (FormLabs) printer. This was then painted with pink-pigmented oil based paint to replicate human visual optics on camera. We utilized robotic hands-free manipulator previously developed for robotic US guided biopsy to precisely control the cystoscope [EUS2017 Abs.34, PMC30624210]. Custom software development in Microsoft Visual C++ with VTK and OpenGL open-source software libraries was used to drive the robot and process images from the cystoscope acquired over a HDMI to USB converter. The software was used to determine the location of the cystoscope in space relative to the verumontanum. Tests in the mock-up were used to assess accuracy in detecting location and length of urethral stricture in the 3D printed model.

Results: This early work was foundational. We consistently and accurately identified both the location of the narrowing and the relative distance and length of the narrow area.

Conclusion: Our results represent a proof of concept for a next generation diagnostic test for bladder or urethral pathology, particularly USD. Next steps include miniaturizing components to allow for accommodation through narrow strictures, development of 3D reconstruction models from the 2D images of the cystoscope coupled with positional information from the robot, as well as implementing machine learning algorithms from anatomic samples.

Disclosure: Author DS and Johns Hopkins have a financial or other interest in this study. The results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins’ policies.

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Figure 1: a) Robotic apparatus with cystoscope and mockup 3D printed urethral model b) endoscopic view of narrow segment with relative distance to verumontanum c) cross sectional diagram of 3D printed urethral obstruction and verumontanum.
NOVEL ENDOSCOPE TIP DESIGNS FOR ASPIRATION OF RENAL STONE FRAGMENTS: AN IN-VITRO STUDY

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Introduction: Basket removal of kidney stone debris after laser lithotripsy fails to clear the smallest (< 1-2 mm) remnants, leaving nidi for future stone formation. Comparing laser lithotripsy fibers, thulium produces significantly finer fragments (U 1000 microns) than holmium; debris too small for basket extraction. We evaluated novel endoscope tip designs to aspirate these finer stone remnants.

Methods: Six unique designs were created in CATIA™ V5 (Dessault Systèmes®) and 3-D printed using PrusaSlicer (Figure 1). To ease handling, all tip prototypes were scaled up to 27 Fr and attached to a suction apparatus (Aeros Moblvac III, Ardus Medical Inc.®). For each trial, one gram of pre-measured stone fragments (1 mm, 1.25 mm, 1.70 mm, 2 mm, 2.50 mm, 3 mm, 3.55 mm, 4 mm, 5 mm) were sequentially placed in a basin and aspirated (suction pressure 100 mmHg). All tips were first evaluated using whole millimeter sized debris, and high performing tip designs (A - batwing, C – power bar and E – half moon configuration) were compared using more targeted trials. Percent clearance, suction rate, and number of channel occlusions were recorded.

Results: All tips that were tested on fragment sizes up to 1.70 mm achieved 100% clearance and no occlusions. The fastest suction rates for 1 mm were tips A, C, and E at 266, 265, and 260 mg/sec, respectively. At 2 mm, only A, C, and E had 100% clearance. At 2.50 mm, tip A cleared all debris with the fastest aspiration rate (387 mg/sec) and no occlusions, while E and C encountered 1 and 4 occlusions, respectively. For both 3 mm and 4 mm, E had the highest percent clearance and suction rate (3 mm - 86.2% at 53 mg/sec; 4 mm - 18.87% at 16.3 mg/sec). At 3.55 mm, C had the highest clearance (14.55%), followed by A (13.17%), then E (9.48%) (Figure 2). At 3–5 mm all tips clogged equally; no tip successfully aspirated 5 mm.

Conclusion: Tips A, C, E all show promise as future aspiration-enabled endoscope tip designs which, when downsized, could be incorporated into a future flexible ureteroscope.

Figure 1: 3D rendering of six novel aspiration endoscope tip lumen arrangements.

Figure 2: Percent stone clearance by stone particle diameter for each novel endoscope tip design.
*Only tips A, C and E were evaluated as they outperformed the other tip designs during the initial part of the study.
AUTOMATIC FRAME CLASSIFICATION AND ENHANCEMENT FOR CYSVIEW CYSTOSCOPY VIDEO

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Introduction: Cystoscopy videos carry rich information that may aid in analysis and detection of early cancers. For example, blue light cystoscopy (BLC) with CYSVIEW® is often used as an adjunct to white light cystoscopy (WLC) for more sensitive detection of bladder cancers, as lesions at risk of cancer appear as pink, fluorescent patches under blue light illumination. Here, we introduce new methods for automatic frame classification and contrast enhancement of cystoscopy videos containing WLC and BLC datasets. Methods: We collected cystoscopy videos comprising mixed WLC and BLC data from patients (n = 15) undergoing rigid cystoscopy for TURBT (IRB #211206). To classify frames as WLC, BLC or BLC with fluorescence, we calculated the mean intensities from the RGB color channels and compared them with the mean gray level per frame (Figure 1(a)). To enhance the contrast in BLC where saturation of the green channel leads to loss of features, we leveraged information in the red channel to create an enhanced contrast map in which we equalized its intensity distribution to the L* channel and replaced the resulting contrast map as the new L* channel in the L*a*b* color space, following the steps shown in Figure 2(a). Results: Color channel intensities allow automatic classification of cystoscopy frames (WLC: R> B; BLC: B>Gr>R; BLC with fluorescence: B>R>Gr), Figure 1(b) and (c). We observed that green channels carry the most vessel features for both WLC and BLC frames, and tissue features lost due to saturation can be recovered with our proposed method: our feature-enhanced frames show vessel patterns not visible in the original image. The method is also applicable to WLC frames, enabling better visualization of vascular features against a background of inflammation, Figure 2(b). Conclusion: Our work provides an automatic, convenient means of cystoscopy video analysis. The frame classification will be useful to seed future work to automatically detect suspicious lesions. Moreover, the enhanced contrast images permit better distinction of important features needed to identify early-stage cancer and distinguish inflammation.

Figure 1: (a) Mean color channel intensities are extracted from each color channel (R, G and B) and from the mean gray level (Gr) per frame, then (b) plotted for a given video. BLC frames are shaded with blue, BLC fluorescent frames with pink-overlay and WLC frames are not shaded. (c) Representative frames, indicated in (b) as F₁, F₂ and F₃, are shown for comparison.

Figure 2: (a) Image enhancement pipeline. Black arrows point at missing vessel features, and red arrows point at vessel features recovered after processing. (b) Original and enhanced WLC frames. Red arrows point at visible vessels from inflammation.
CLINICAL MEASUREMENT OF MAXIMUM SAFE URETERAL INTERNAL CIRCUMFERENCE USING A NOVEL FORCE SENSOR

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Introduction: Deployment of larger ureteral access sheaths (UAS) may allow for improved ureteroscopic treatment of urolithiasis. Currently, the largest UAS clinically available is 16 French (F). To our knowledge, no studies have explored the maximum physiological diameter to which the human ureter can be atraumatically dilated. Using a novel UC Irvine developed UAS force sensor, we explored the largest luminal circumference to which the human ureter could be dilated at <6 N (Newtons), a level of force that we have previously found to be below the threshold for ureteral injury.

Methods: During a ureteroscopic or percutaneous stone removal procedure, 44 ureters (15 male and 29 female patients) were sized using the UCI force sensor which measures force in 1/100ths of a Newton. A 35 cm 10F Cook® urethral dilator was inserted at forces <6 N followed by passage of dilators in 2F increments (i.e., 12F, 14F, 16F, 18F, 20F, 22F, and 24F) until a force measurement of 6N was recorded. A similar size UAS (max 16F) was then placed.

Results: Among 44 ureters, 18% accepted a ≥18F dilator (18-24F); 28% reached 6N at 16F, 25% at 14F and 20% at ≤12F. In 4 cases (9%), 6N was recorded at only 10F. The mean size was 14F. In this study, a 16F UAS was deployed in 41% of cases, while 14F and 12F UAS were deployed at <6N in 32% and 27%, respectively. Despite adhering to a 6N threshold, a Post-Ureteroscopic Lesion Scale (PULS) score of 3 was noted in 3 ureters (7%), all sized at ≥14 F. These ureteral PULS 3 were individually noted in the proximal, mid, and distal ureter. Pre-existing stents alone and in combination with preoperative Tamsulosin were associated with the passage of a larger sized dilator (p = 0.023 and p= 0.049 respectively); however, tamsulosin by itself (23 patients) did not result in passage of larger dilators (p = 0.818). Prestented ureters allowed the insertion of dilators ≥16 F in 82% and ≥18 F in 36% of the ureters versus 33% and 12%, respectively, when a stent was not present.

Conclusion: Most human ureters readily accept a 14F dilator. Prestenting increases safe passage in the majority of patients to 16F; indeed, among prestented patients, an 18F sheath could have been safely placed in over one third of cases.

Table 1. Characteristics of Dilator Groups

<table>
<thead>
<tr>
<th>Max Successful Dilator Size</th>
<th>ALL DILATORS</th>
<th>10-12 F</th>
<th>14 F</th>
<th>16 F</th>
<th>≥18 F</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Ureters</td>
<td>44</td>
<td>33 (75.0%)</td>
<td>11 (25.0%)</td>
<td>12 (27.3%)</td>
<td>8 (18.2%)</td>
<td>n/a</td>
</tr>
<tr>
<td>Pre-existing Stents*</td>
<td>11</td>
<td>2 (18.2%)</td>
<td>11 (90.9%)</td>
<td>0 (0.0%)</td>
<td>5 (45.5%)</td>
<td>4 (36.4%)</td>
</tr>
<tr>
<td>Post-op Tamsulosin*</td>
<td>23</td>
<td>7 (30.4%)</td>
<td>6 (26.1%)</td>
<td>5 (21.7%)</td>
<td>5 (21.7%)</td>
<td>3 (13.3%)</td>
</tr>
<tr>
<td>Total: Pre-op Tamsulosin + Stent*</td>
<td>28</td>
<td>8 (28.6%)</td>
<td>7 (25.0%)</td>
<td>5 (17.8%)</td>
<td>4 (14.3%)</td>
<td>3 (10.7%)</td>
</tr>
</tbody>
</table>

* Fisher Exact Test. p<0.05 was considered statistically significant.

Figure 1. Novel UAS Force Sensor developed by UC Irvine
DESIGN AND VALIDATION OF A 3D PRINTED VAS DEFERENS MODEL REPRESENTS AN OPPORTUNITY FOR MALE FERTILITY MICROSURGICAL TRAINING

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Introduction: Three-dimensional (3D) printed models of anatomic structures offer a potential alternative to animal or cadaveric specimens for surgical training. The utility of 3D printed models of the vas deferens for microsurgical skill acquisition has not been reported. This study aimed to design and assess the feasibility of using 3D printed models of the vas deferens as a training tool for urology residents and fellows. We hypothesized a 3D printed model could be developed that is substantially equivalent in size, shape, and tissue properties to human vas deferens for use as a urologic microsurgical trainer.

Methods: Through an iterative design process we developed a 3D printed vas deferens model. Solidworks was used for computer-aided design (Dassault Systèmes, Vélizy-Villacoublay, France). Stereolithography 3D printing was completed with a Form 3 printer and elastic resin with a durometer of 50A (Formlabs, Somerville, MA, USA). Formlabs elastic resin 3D prints are not rated to print internal channels below 1.5mm [1, 2]. We were able to reliably print a patent 300µm lumen via a tapered end design and with post-processing pumping isopropyl alcohol through the lumen prior to UV curing the prints. As a comparator, discarded human vas deferens samples were collected during vasovasostomy or vasoepididymostomy under an IRB approved protocol. For biosafety these samples were preserved in formaldehyde. To assess face validity, the 3D printed vas deferens models and discarded human vas deference samples were quantitively compared by urology residents, fellows and attendings.

Results: A 3D printed vas deferens model was created matching the dimensions of a human vas deferens with an outer diameter of 3mm and an inner diameter of 300µm (Figure A). These models had a patent lumen with 80% print success. Each print costs $0.21 as a small resin volume is required.

Eight of nine study participants found the 3D printed model had a feel sufficiently similar to that of a human vas deferens and was appropriate for use in microsurgical training. One resident study participant found the material inappropriately stiff when passing sutures compared to human vas deferens. 3D printed vas deferens models were successfully anastomosed by study participants with 8-0 nylon sutures (Figure B and C).

Conclusion: We produced a realistic, humane, and cost-effective 3D printed vas deferens model for urologic microsurgical vasovasostomy training. According to feedback, the model has face validity and recapitulated a real-life simulation of the desired procedure. Future efforts will quantify content and criterion validity to determine whether practicing microsurgical technique on the synthetic vas deferens translates to practical microsurgical skill acquisition.

Source of Funding: The American Urologic Association Urology Care Foundation 2021 Residency Research Award awarded to MT

Figure: Computer-aided design of vas deference with tapered and leur-lock ends (A). 8-0 nylon anastomosis of two 3D printed vas deferens (B). Side-by-side comparison of 3D printed and human vas deferens (C).
DIFFERENTIATION OF BLADDER CANCER FROM INFLAMMATION WITH POLARIZATION-SENSITIVE OPTICAL COHERENCE TOMOGRAPHY

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Introduction: Blue light cystoscopy is known to improve the sensitivity of bladder cancer detection, but it suffers from a high false positive rate leading to unnecessary biopsies. We aim to increase the specificity of bladder cancer detection. Polarization-sensitive (PS) OCT is a non-invasive, non-destructive method to image tissue microstructure in vivo.¹ In particular, PS-OCT can detect birefringence in collagen-rich structures, such as those found in bladder wall tissues.¹,² Prior studies have shown that changes in tissue birefringence are indicative of cancer.³,⁴

Methods: Biopsy samples (n = 40) of normal, inflamed, and carcinoma in situ (CIS) tissues were obtained from patients undergoing TURBT. Specimens were kept in saline prior to and during PS-OCT imaging and were then processed with H&E staining and immunohistochemistry (IHC) staining of collagen. After co-registering the PS-OCT images with the histology, the attenuation coefficient (AC)⁵ and tissue birefringence (related to the slope of the optical intensity and optical retardation, respectively) were computed from lamina propria (LP)-like regions (i.e., defined as the region 75-275μm below the urothelium surface).

Results: The resulting AC and retardation mappings derived from PS-OCT data showed visible differences between benign and cancerous tissue samples that matched features identified on histology, as shown in Fig1 (a). AC mappings enabled accurate co-registration to histology images and region-specific estimation of AC values in the bladder, Fig1 (b). AC measurements from inflamed tissues (3.38 mm⁻¹) and confirmed CIS samples (2.12 mm⁻¹) were distinct (p < 0.001), as shown in Fig1 (c). We determined the tissue birefringence of the LP-like layers, illustrated in Fig1 (d). The birefringence in CIS samples (2.98×10⁻⁵) is significantly lower (p < 0.001) than in inflamed (7.64×10⁻⁵) and normal tissues (1.18×10⁻⁴), Fig1 (e).

Conclusion: We hypothesize that our observations are due to the deterioration of collagen in the LP that precedes tumor formation, which is evident in IHC staining.⁶ Our work suggests that the use of PS-OCT is a promising strategy to differentiate flat bladder tumors such as CIS from benign states; hence, clinical translation of PS-OCT as an adjunct for white light and blue light cystoscopy may help reduce false positives.

Figure1: (a) OCT intensity, AC mapping, retardation, H&E and IHC Collagen 1 staining of normal, severe inflammation and CIS sample. Yellow circle shows lymphoid aggregate, black triangle points to normal or tumorous urothelium. (b) Identification of LP region on AC mapping. (c) 10-90 percentile box plot of AC measured from LP-like region. (d) Birefringence calculation from LP-like region. (e) 10-90 percentile box plot of birefringence measured from LP-like region (*** indicates p < 0.001)
UTILITY OF A STEERABLE INNER SHEATH FOR FLEXIBLE URETEROSCOPY: A BENCHTOP INVESTIGATION

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Introduction: Dextrous control during flexible ureteroscopy is often challenged by acute infundibulopelvic angles and/or compound angles. Here, we propose a disposable, thin-walled, steerable sheath that fits within the endoscope lumen to provide another degree of freedom to the working instrument. The technology utilizes asymmetric elasticity to flex a tube in two directions without tendons. This is achieved using nested tubes that are notched on opposite sides, thus providing a stiff side and flexible side to each tube. The tips of these nested tubes are attached such that pulling/pushing on one tube relative to the other flexes the entire tube (figure 1a & b).

Methods: A 1.72 mm prototype steerable sheath made from PEEK thermoplastic and controlled via a lever-actuated interface secured to the endoscope working channel (figure 2b), was used in this preliminary study. A tabletop kidney phantom comprising the collecting system and proximal ureter was designed using segmented CT imaging and 3D printed from elastic resin. The phantom was scaled 2x to accommodate a 15Fr flexible cystoscope while each papilla was replaced with an access port to facilitate stone insertion (figure 2c). 13 mm (diameter) stone was molded from Begostone Plus at a concentration mimicking the properties of calcium oxalate monohydrate stone. The entire phantom was submerged in water and irrigated using a gravity-fed IV bag.

Stone was lasered using a Lumenis Plus 100H and 365 \textmu m fiber via dusting and fragmenting techniques. 5 stone fragments were then retrieved with a 1.9Fr nitinol tipless basket. The times required to accomplish these tasks with and without the steerable sheath were compared over 3 experiments.

Results: Lasering of 13 mm stones required 41.5±11.6 minutes using a conventional technique versus 35.0±7.5 minutes via endoscopy augmented by the steerable inner sheath. Particularly, the ability to steer the laser tip separately from the endoscope facilitated precise dusting of the stone. Similarly, basketing improved from 5.0±1.7 minutes to 2.4±0.02 minutes with the assistance of the steerable sheath. As expected, the device allowed basketing of stone fragments located at more acute angles to the infundibulum.

Conclusion: The ability to independently steer an endoscopic instrument may improve ureteroscopy. Further experiments performed at scale are underway, which have already confirmed that adequate irrigation rates are achievable with the sheath in a ureteroscope.

Figure 1 a & b (top): Steerable sheath with basket actuated to flex in two directions by pulling/pushing inner tube.
Figure 2 a-f (bottom pane): (a) Experimental setup is shown. (b) Steerable sheath user interface secured via leur-lock to working channel. (c) Kidney phantom with plugs for stone attachment. (d-f) Steerable sheath extended to laser/basket stone
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CYSTOCOPY TRACKING, MAPPING, AND NAVIGATION ENABLED BY IMAGE STITCHING

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Introduction: Diagnosis, monitoring, and surveilling of bladder carcinoma requires image review and may require repeat assessment. Orientation can be challenging, which may complicate returning to the site of previous biopsies. Mucosal features such as vascular patterns provide a reference for mapping biopsy locations with image processing to create a composite image for orientation during subsequent procedures. A vision-based software was developed and evaluated in a bladder phantom. It was retrospectively tested in real patient videos, with attention to navigation and orientation.

Methods: A software was developed with 2 functions: 1) generation of 2D stitched maps from video frames, by sequentially stitching images from matching image features such as vessels, and 2) localization & tracking by detecting matched image features. The method and software were evaluated on a 2D model, an anthropomorphic bladder phantom, in vivo porcine subjects, and retrospectively in patient images. To test camera calibration, whole bladder stitched image generation, and the ability to navigate from stitched images were tested in the 2D model and a 3D printed bladder phantom. Both were marked with vascular patterns (Figure C). To evaluate the robustness of the tool, porcine subjects underwent cystoscopy while anesthetized with full bladders. A disposable cystoscope captured intravesical images with a minimum of two different patterns of motion. Stitched images were compared to the ground truth or still images of the full phantom or excised bladder. Clinical patient cystoscopy videos were utilized to evaluate the feasibility of map stitching in real cases.

Results: The algorithm was capable of stitching together phantom images captured by two different sweeping patterns (Figure A). The stitched maps reproduced the bladder surface, subjectively matching ground truth. During a second sweep, the tools was able to accurately identify the location within the phantom, suggesting the ability to navigate the lesions or tumors upon a repeat assessment (Figure B). Patient-specific images also were stitched in a similar fashion to create a virtual mucosal surface for referencing and mapping (Figure D).

Conclusion: Image-based navigation and mapping and referencing uses mucosal landmarks to successfully orient the surgeon during repeat cystoscopy. An image stitching algorithm using a conventional cystoscope can generate a composite map of the whole bladder and be retrospectively applied to cystoscopic procedures to potentially aid in serial procedures.

Figure: A. Stitched image from 3D phantom. B. Repeat cystoscopy procedure. C. 3D phantom used and ground truth comparison. D. Stitched patient image.
A PROSPECTIVE RCT OF EFFICACY OF TRILOGY VS SHOCKPULSE IN MINIPERC: AN INTERIM ANALYSIS


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Introduction: Improving stone clearance efficiency in MiniPCNL is the need of hour. There are many novel intracorporeal Lithotripters which are being miniaturized for use in MiniPCNL. We aim to compare the efficiency of two novel lithotripters: Trilogy and ShockPulse-SE, which is not available in the current literature.

Material and Methods: This is a prospective randomized controlled trial between September 2021 till present. We performed mini-PCNL for renal calculi 1.5 -2.5 cm using SWISS LITHOCLAST® TRILOGY(EMS, Switzerland) or ShockPulse-SE (Olympus, Japan). Preoperative demographic parameters-age, sex, stone location, stone volume and density were measured. We used 12 Fr MiniPCNL nephroscope with 15 Fr sheath across all patients. Primary endpoint was stone fragmentation rate, defined as stone volume per stone disintegration time. Secondary end points were stone-free rates at one month(Xray/USG KUB), hemoglobin drop, postoperative complications and pain score.

Result: There were two arms- Trilogy(n=11) and ShockPulse(n=16). Both groups were comparable in terms of stone size(p=0.89), volume(p=0.41) and density(p=0.16). Stone disintegration time(10.13 ± 6.82v/s11.81 ± 13.01min, p=0.70), stone fragmentation rate(0.26 ± 0. 15v/s0.22 ± 0.14 , p=0.49) and total operative time(25.32 ± 16.78v/s28.75 ± 16.59, p=0.62) was comparable in both the arms. There was complete stone clearance at 1month. There was one case of fever in Trilogy and one case of ileus in ShockPulse. There was no device malfunction in either of the arms. Pain score at postoperative 6(p=0.41), 12(p=64) and 24 hours(p=0.92) was comparable in both the arms.

Conclusion: Both the energy sources- Trilogy and ShockPulse are equivalent in terms of stone fragmentation rate. They have comparable efficiency, stone-free rates, postoperative pain and safety in stone clearance in MiniPCNL.
A COMBINED AUGMENTED REALITY AND ROBOTIC SYSTEM FOR ASSISTANCE IN PERCUTANEOUS NEPHROLITHOTOMY PROCEDURES

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Introduction: The success and treatment outcomes of percutaneous nephrolithotomy (PCNL) are very well known to be highly dependent on the precision and accuracy of the puncture step. In this contribution, we present an innovative solution, based on an AR application combined with a robotic system, that can assist both an expert surgeon in improving the performance of the surgical operation and a novel surgeon in strongly reducing his/her learning curve.

Methods: Starting from pre-operative images from Computed Tomography (CT) of the interested area, a 3D reconstruction of all the structures was performed for the pre-operative planning of the desired trajectory for the needle to be inserted. During the procedure, the surgeon wears an augmented reality device and he/she will see the 3D reconstruction and the planned trajectory superimposed on the body of the patient. A KUKA LWR 4+ robot holds the PCNL needle and guides the surgeon, thanks to the implementation of guiding virtual fixtures, to the right access point with the right orientation.

Results: The overall architecture was validated by a sample of 11 users on a laboratory setup. The results showed the effective usefulness and usability of the proposed system, such as increased performances.

Conclusion: Augmented reality and robotics were merged to provide assistance to the surgeon in reaching the renal target in a PCNL procedure. The proposed system architecture could be easily adopted in all the surgical procedures that require pre-operative planning and intra-operative navigation for gaining access to a specific target, especially in cases where the intervention learning curve for novel surgeons is very steep.

Figure 1: Procedure set-up, pre-operative planning and intra-operative navigation.
A NOVEL PROBE FOR MONITORING FOCAL LASER ABLATION OF PROSTATE CANCER

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Introduction: Focal laser ablation (FLA) presents a promising modality for the minimally invasive treatment of prostate cancer. To ensure efficacy, it is crucial that the physician is able to create ablation zones of a desired size. To facilitate this, we have developed a novel interstitial optical probe that identifies the ablation boundary by performing real-time analysis of laser-tissue interaction.

Methods: FLA at 980nm and 14W was performed on fresh bovine liver using the optical probe to inform the decision to terminate laser exposure. The probe was placed parallel to and 6mm from the laser fiber. Custom software (Python) was used to analyze the optical signal in real-time and notify the user upon detection of the coagulation boundary. After laser exposure, the tissue sample was snap-frozen in liquid nitrogen and sectioned along the laser fiber track. A 7µm slice was cut and stained following a previously established protocol (PMC3570648).

FLA (980nm at 14W) was also performed in a patient as part of an IRB approved clinical trial (NCT04305925). Here the optical sensor was positioned 7mm from the laser fiber but only passively collected data. Immediately after treatment multi-parametric magnetic resonance imaging was undertaken to assess the extent of the ablation zone.

Results: In the bovine liver study (Fig. 1a), the desired ablation radius (6mm) was achieved with negligible error by terminating the procedure once the acquired photovoltage (Vp) reached a plateau \( \frac{dV_p}{dt} = 0 \). The plateau occurs once all of the tissue between the probe and laser fiber has been coagulated as discussed in our prior work (PMC35148260). Similarly, in the clinical study the ablation zone has reached the probe just as the photovoltage plateaus (Fig. 1b).

Conclusion: This work suggests that ablation zones of a pre-defined size can be accurately obtained using an interstitial optical probe as a feedback modality.

Fig. 1: a) Sectioned and stained bovine liver after FLA (top). The corresponding signal acquired by the optical probe (bottom). b) MRI (top) and optical signal (bottom) during FLA in a human prostate. Note that in both cases, the optical signal plateau indicates complete ablation and the ablation zone has reached the probe [Scale bars = 10mm]
DEFINING PROSTATE CANCER FOCAL THERAPY TREATMENT MARGINS WITH A MACHINE LEARNING MODEL: IMPROVEMENT UPON HEMI-GLAND ABLATION

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Introduction: A machine learning (ML) algorithm was developed to estimate voxel-level risk of clinically significant prostate cancer (csPCa), resulting in a 3D lesion heat map (LHM). Treatment margins created by thresholding the LHM were retrospectively assessed using whole mount (WM) prostatectomy data as ground-truth. ML margins were compared to standard of care (SOC) methodology, i.e. hemi-gland margins or a 10-mm isotropic expansion of MRI-visible regions of interest (ROIs).

Methods: A machine learning model was developed using multi-institutional data from 875 patients. Input data consisted of T2-weighted MRI, surface models of the prostate, ROIs defined using PI-RADS v2, and tracked biopsy cores (Fig A-B). The model combined a convolutional neural network with a gradient-boosted decision tree, and was trained using 5-fold cross validation.

WM data from an external institution (N = 50, Stanford University) was used to evaluate the LHM. All test cases bore MRI-visible, biopsy-confirmed GG2-3 disease apparently isolated to a single hemisphere or the anterior gland. LHMs were generated for each case (Fig C), from which the ML algorithm selected a default margin (Fig E) intended to maximize csPCa encapsulation while limiting margin volume. SOC margins were likewise generated (Fig F). Using WM (Fig D) as ground truth, csPCa-bearing voxels were compared to ML and SOC margins using sensitivity, specificity, and complete csPCa encapsulation rate.

Results: ML margins significantly improved sensitivity for csPCa-bearing voxels (97% versus 94%, p < 0.001, Wilcoxon signed-rank test) and the per-patient rate of complete csPCa encapsulation (80% versus 56%, p = 0.01, chi squared test) relative to hemi-gland margins. ML margins had higher mean sensitivity and csPCa encapsulation than 10-mm margins, though the differences fell short of statistical significance.

Conclusion: A ML model produced margins that were superior to hemi-gland margins, dramatically improving rates of complete csPCa encapsulation without significantly reducing specificity. This treatment planning approach may improve outcomes in focal therapy and warrants further study.

Figure: Example case (A-B) input data on T2-MRI and in 3D; (C) LHM, with voxels shading black=>white for low=>high csPCa risk; (D) WM Slide defining ground-truth csPCa; (E) ML margin; (F) SoC margins; (G) summary statistics
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REMOVING A FIBERSCOPE-INDUCED PATTERN FROM FLEXIBLE CYSTOSCOPY FRAMES TO ENABLE 3D BLADDER RECONSTRUCTIONS

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Introduction: White light cystoscopy is the gold standard in the diagnosis and follow up of patients with bladder cancer. Clinicians often reference cystoscopy data from the medical record in their decision-making, particularly when the cystoscopy or transurethral resection of bladder tumor was performed by a different clinician. However, the medical record usually contains only notes and a few frames (images), as the video is too cumbersome to review. We previously developed a pipeline to convert cystoscopy videos into 3D bladder reconstructions that enable convenient, comprehensive review [1]; however, this pipeline does not work for videos obtained with fiberscopes. Fiberscopes are often used in clinical settings and contain a honeycomb-like pattern that inhibits feature detection, an important step in the reconstruction pipeline. Existing methods used to remove this pattern in non-biological images rely on the detection of each fiber center [2, 3], which is impractical in the bladder due to lighting variation, or remove details needed to ensure a sufficient number of features for use in the reconstruction [4, 5, 6, 7]. Given that a lack of features is the primary cause for reconstruction failure [1], we propose a new method to remove artifacts from fiberscope cystoscopy frames that is robust to lighting variations and preserves details, resulting in a higher number of meaningful features.

Methods: We saved the cystoscopy videos of patients receiving flexible cystoscopies (collected with a fiberscope) as part of their standard medical care (IRB #201269). Each frame (Fig. 1(A)) was cropped and underwent spectral filtering in the Fourier domain with a mask that targets the artifacts surrounding the center of the magnitude spectrum in a star-like pattern. The mask consists of a binary mask with an applied Gaussian blur to reduce artifacts that result from abrupt changes in intensities within frames (Fig. 1(B)). The unfiltered and filtered videos were then fed through the 3D reconstruction pipeline (Fig. 1(C)).

Results: The proposed mask successfully removed the fiberscope-induced pattern, as seen in the magnified images of a frame before and after this process (Fig. 1(B)). Unfiltered videos were not able to yield 3D reconstructions. Fig. 1(C) shows the partial reconstruction resulting from the filtered video.

Conclusion: To our knowledge, this is the first method to remove fiberscope-induced artifacts while preserving details needed for feature detection. As a result, we have also produced the first 3D bladder reconstruction from a fiberscope cystoscopy video. This work enables the use of 3D bladder reconstructions in settings with a fiberscope, which could improve pat

Figure 1: Each (A) cystoscopy frame contains a (B) fiberscope-induced pattern that we remove by way of spectral filtering. The pattern is visible in the magnified views of the frame before (left) and after (right) spectral filtering with a point mask that is applied in the Fourier domain to remove the fiberscope-induced artifacts (black arrows), as seen in the magnitude spectrum before (left) and after (right) this filtering. While the original cystoscopy video did not produce a 3D reconstruction, the video after removing fiberscope pattern does produce a (C) 3D reconstruction of the bladder.
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URETEROSCOPIC THULIUM LASER LITHOTRIPSY AUGMENTED WITH A NOVEL REVERSE THERMAL HYDROGEL IN AN IN VIVO PORCINE MODEL

Pengbo Jiang, Sohrab Ali, Douglas Schneider, Andrew Brevik, Akhil Peta, Roshan Patel, Jaime Landman, Ralph Clayman
Department of Urology, University of California, Irvine

Introduction:
We sought to evaluate the benefits of a novel reverse thermal hydrogel (Hydrogel) developed by UroGen Pharma to augment retrograde ureteroscopic laser lithotripsy and stone removal. Hydrogel is a liquid at room temperature and transforms into a viscous, semisolid gel at body temperature. We hypothesized that the gel would entrap fragments and enhance stone removal.

Methods:
Two pigs (four renal units) were studied; each kidney was randomized to experimental (with Hydrogel) or control (without Hydrogel). Pre-weighed canine calcium oxalate stones were implanted into an upper pole calyx via a pyelotomy in an in-vivo porcine model. A temperature probe was placed percutaneous into the calyx of interest. In the experimental kidneys, 5cc of Hydrogel was instilled in the calyx with the stone via a 5Fr molded ureteral catheter. A 12-14 Fr 35cm ureteral access sheath was used in each trial. Next, laser lithotripsy with a superpulse thulium fiber laser performed via a Storz video flexible ureteroscope utilizing a 200-micron fiber (settings of 0.2J and 80Hz). Once the stone was sufficiently dusted, the fragments were basketed with a 1.7Fr NCompass basket to remove any visible fragment. Afterwards, we then passed an ureteroscopic brush to entrap any residual dust or fragments. At the conclusion of the experiment, the animal was euthanized. The kidneys and ureters were harvested. The kidneys were then bivalved and washed to capture all residual stone fragments within the collecting system. The fragments were then dried, sieved, and weighed.

Results:
99.3% of stone was removed from the experimental Hydrogel kidneys compared to 92.2% of stone removed in the control kidneys. Peak intra-calyceal temperature without Hydrogel was 55°C and the system exceeded 44°C four times during lithotripsy. In kidneys with Hydrogel, the peak intra-calyceal temperature was 36°C.

Conclusion:
The use of Hydrogel to augment ureteroscopic stone removal resulted in near complete stone removal at 99.3% while preventing high intra-calyceal temperatures during thulium laser lithotripsy.

<table>
<thead>
<tr>
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<th>Experimental</th>
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<td>Mean Initial Stone Mass</td>
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<td>Mean Stone Mass Retrieved</td>
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<tr>
<td>(mg)</td>
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<td>Mean Stone Mass Remaining</td>
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<tr>
<td>in Kidney (mg)</td>
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<td>Percent Mass Cleared (%)</td>
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<td>92.2</td>
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<tr>
<td>Mean Procedure Time</td>
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<td>80.5</td>
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<tr>
<td>(minutes)</td>
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<tr>
<td>Peak Intracalyceal</td>
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<td>55</td>
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<tr>
<td>Temperature (°C)</td>
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</table>
ABSTRACTS

ABSTRACT 103

EFFECTIVENESS OF VISUAL GUIDANCE USING A 2D STANDARD MODEL FOR ROBOTIC RIRS

Jung-Min Han¹², Jiun Jeon¹, Dong-Soo Kwon¹²
¹EasyEndo Surgical, Inc., Daejeon, Korea, ²Korea Advanced Institute of Science and Technology (KAIST), Daejeon, Korea

Introduction: Recently, robotic systems for flexible ureteroscopy (fURS) have emerged as an attractive alternative to manual retrograde intrarenal surgery (RIRS) owing to various advantages such as convenient operability, integrated equipment operation, and remote control. However, robotic RIRS, like manual RIRS, is associated with difficulty in locating the ureteroscope due to the complexity of kidney anatomy and impaired views caused by the mucous membrane or bleeding. This study presents a 2D visual guidance method and shows its effectiveness through test results in robotic RIRS.

Methods: Standard kidney and ureteroscope models were developed as two-dimensional images using the Visualization Toolkit (VTK, v9.0). The pose of the ureteroscope model was calculated based on motor driving data and kinematics of the robot. In addition, we compensated for the physical interaction with surrounding renal tissue to increase the accuracy of pose estimation. The dimensions of the models were determined according to the simulator and ureteroscope. These models were implemented in the software of easyUretero (EasyEndo Surgical, Inc.), which is a robotic RIRS system that provides teleoperation of the flexible ureteroscope, laser, and stone basket so that the surgeon can confirm the location of the ureteroscope inside the kidney on video (Figure 1). The easyUretero and a flexible ureteroscope were prepared, along with its workstation and simulators, including bladder, ureter, and kidney structures. Two experiments were conducted: 1) a deflection test inside the simulator, and 2) a user test with the model display. In the deflection test, the pose of the ureteroscope was well-estimated on the screen when manipulated inside the kidney simulator (Figure 2). In the user test, participants with different experience-levels were selected and divided into two groups: five novices and five seniors. Participants were requested to move the ureteroscope to the lower calyx, middle calyx, and upper calyx of the left kidney with and without the help of visual guidance, and completion times were measured.

Results: The results showed a statistically significant difference (P = .007 < .05/5). In particular, the novice group showed a significant difference in completion time compared to the senior group. Overall, those who performed the test expressed that the visually guided models helped to understand the ureteroscope’s movement.

Conclusion: This work demonstrates that the proposed 2D guidance method using standard models has advantages in robotic RIRS and preliminary user tests showed that this proposed method can help an operator recognize the pose of the ureteroscope inside the kidney. As a result, the total operating time can be shortened in robotic navigation procedures.
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A METRIC TO PREDICT THE UTILITY OF CYSTOSCOPY FRAMES IN 3D BLADDER RECONSTRUCTIONS

Rachel Eimen\textsuperscript{1,2}, Mayaank Pillai\textsuperscript{3}, Kristen Scarpato\textsuperscript{4}, Audrey K. Bowden\textsuperscript{1,2,5}

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Introduction: White light cystoscopies are the gold standard for diagnosis and follow up in the bladder, and clinicians often refer to cystoscopy data to inform patient care. The medical record, however, contains only notes and a few frames from the cystoscopy video, as video data are too cumbersome to review. We developed a pipeline to produce three-dimensional (3D) reconstructions of the bladder, which present the full cystoscopy data in a form that clinicians can quickly review. However, the quality of a reconstruction is inherently limited by the quality of its underlying video, and a lack of features in the video is the most common cause for reconstruction failure. With an eventual goal of providing feedback to improve the video and reconstruction quality, we developed a method to classify frames as useful or not useful for the reconstruction (high- or low-quality frames, respectively) based on the number of features in the frames.

Methods: We saved the videos of patients undergoing flexible cystoscopies (collected with a fiberscope) as part of their standard medical care (IRB #201269). We then used the 3D reconstruction pipeline to determine ground-truth classifications for frames as high or low quality based on their inclusion in the reconstruction. To develop a novel metric to predict frame quality, we detected the number of features in each frame using the scale invariant feature transform (SIFT) and established two thresholds, which we applied separately: low-quality frames were those deemed as having either 1) a low feature count (Fig. 1(A)) or 2) a highly differing number of features relative to surrounding frames. The latter threshold was used because the reconstruction pipeline can only use frames with features that can be adequately matched to those in surrounding frames. Hence, frames with large fluctuations in the number of features are unlikely to be matched, Fig. 1(B). We selected a threshold for the derivative that prioritizes sensitivity by maximizing the partial area under the curve (pAUC) over the region of the receiver operating characteristic (ROC) for which the specificity exceeds 0.5 (Fig. 1(C)).

Results: We assessed three cystoscopy videos and achieved sensitivities of 63%, 54% and 71% and specificities of 57%, 82% and 91% for each video, respectively, Fig. 1(C).

Conclusion: To our knowledge, this is the first metric to identify frames that will be used or unused in 3D reconstructions. The metric could be used for clinician feedback so they can improve the quality of frames (avoiding bladder debris and motion blur) and their reconstructions. This metric would benefit from improved sensitivity and specificity, which may be achievable through preprocessing methods to remove a fiberscope-induced pattern that interferes with feature detection in the frames.

Figure 1: Select regions of a cystoscopy video with reconstruction-inhibiting frames (shaded in red) as compared in the (A) number of SIFT features versus frame position, where frames below the threshold of 250 features (dashed line) are classified as low quality, and compared in the (B) derivative of the number of SIFT features versus frame position, where the threshold (dashed line) is that which maximizes the sensitivity and specificity found in the (C) ROC curve of the specific video. The ROC curve and its respective threshold are calculated for each video.
ABSTRACTS

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OPTIMAL CONTROL OF PHASED-ARRAY ULTRASOUND TRANSDUCER FOR BURST-WAVE LITHOTRIPSY USING INPUT-OUTPUT

Shunxiang Cao¹, Tim Colonius¹, Adam Maxwell², GaWon Kim², Oleg Sapozhnikov², Michael Bailey²

¹ Department of Mechanical and Civil Engineering, California Institute of Technology
² Applied Physics Laboratory, University of Washington

Introduction: Burst-wave lithotripsy (BWL) is a non-invasive treatment of kidney stones using low-magnitude, multi-cycle pulses of focused ultrasound generated by a multi-element array medical transducer. Each element is an individual pulse generator whose frequency, amplitude and phase can be altered to form different beam profiles, generating certain stress patterns in the stone. In this work, we propose to use state-of-the-art simulation tools to optimize the design and control of the transducer elements to achieve optimal stone breakage.

Methods: An optimization framework for BWL is developed. It employs a finite-difference model of acoustic and elastic wave propagation from the acoustic source (transducer elements) and through a stone of assumed shape, size, and composition. An input-output analysis (a frequency domain approach) is applied to determine the optimal frequency and optimal distribution of the phase and amplitude across the aperture, that maximizes the total strain energy in the stone. The optimal parameters are determined using a state-of-the-art, computational fast algorithm based on singular value decomposition (SVD) and modern randomized linear algebra. Validations of the optimal setup are carried out using high-fidelity simulations and in-vitro experiments.

Results: Numerical experiments show that, compared to the uniform input, applying the optimal distribution of phased and amplitude can lead to an increase of total strain energy by a factor of 2-3 for axisymmetric setup and by a factor of >10 for planar setup. The improvement is primarily attributed to the optimal phase distribution which forms specific guided wave mode in the stone, producing stress concentration patterns that maximize strain energy. In particular, the optimal input for the planar setup features an antisymmetric phase distribution which gives rise to more constructive interference of shear waves generated along the lower and upper edges of the stone.

Conclusion: Under the same input energy, carefully controlling the relative phase and amplitude between elements can increase strain energy in the stone compared to a uniform distribution. This suggests that stone fragmentation can be accelerated or performed with lower energy for safer treatment. Work supported by NIH P01-DK043881.
ABSTRACTS

ABSTRACT 106

NEEDLE LOCALIZATION FOR PROSTATE BIOPSY USING LOW-FIELD MRI
Meredith Sadinski¹, Muller Gomes¹, Srirama Venkataraman¹, Aleksandar Nacev¹
¹Promaxo, Oakland, CA

Introduction: Ultrasound is the current standard of care for real-time guidance of prostate biopsies [1], but MRI’s improved soft tissue contrast may allow for better target visualization and more accurate fusion (cognitive or quantitative) with prior, diagnostic MRI exams. Low-field MRI may make such guidance possible and the visualization of inserted needles to confirm accurate placement, particularly as the gland moves or deforms in reaction to needle insertion, is important. Due to SNR challenges of low field scanners, imaging of needles using conventional sequences and reconstruction techniques may not be feasible in a clinical setting. We present an imaging protocol designed for visualizing needles in the prostate using a single-sided, low field, FDA cleared MRI scanner for prostate biopsy and treatment guidance. The sequence was developed in a homogenous gel phantom and validated in an ex-vivo phantom.

Methods: Six needles of various sizes (gauge 12-18; Bard Trugui de, Tempe AZ; Innovative Tomography Products, Bochum, Germany) were inserted into a tissue-mimicking gel phantom, oriented to mimic a transperineal biopsy using a prostate biopsy grid template. The needles were spaced 1.7 cm apart laterally, and 1.3 cm vertically corresponding to positions C6, E6, H6, C4, E4 and H4 on the template. Depth stops were used to ensure the needles were inserted to the same depth. 5mm Vitamin D capsules were used as surface fiducial markers and placed 1.5 cm apart on top of the gel block for localization along the z (corresponding to craniocaudal) axis. 3D images were acquired using a multi spin echo sequence with four echoes (TR=0.8, echo spacing 10.2 ms, encoded x/y 50x50, FOV=12x12x10 cm, reconstructed resolution 1x1mm in-plane, slice thickness 2.5mm). Reconstruction was performed using an iterative, conjugate gradient least squares reconstruction with a modeled system matrix incorporating the scanner’s nonlinear gradient fields. Needles were identified on the images and compared to template grid locations and known insertion depths. A 15-gauge needle was chosen for validation and inserted into a chicken breast. 5 vitamin D capsule fiducials were placed on the surface of the chicken breast at the depth of insertion to provide a ground truth measurement for the needle tip on subsequent imaging. The phantom was then imaged using the same sequence. The needle was identified on transverse, coronal, and sagittal views. The location of the needle tip in the image was then measured and compared with the fiducial markers to determine whether it could be accurately identified. The chicken breast was cut open to view the location of the needle in the x-y plane, which was compared visually with the needle on the image.

Results: Five needles were visible on MRI in the gel phantom. The needle inserted in the chicken breast was clearly visible on MRI (Figure 1). The tip was identified and marked in the coronal view. The z location of the needle tip was within the bounds of the fiducial markers.

Conclusion: We have presented a sequence for imaging needles on a low-field MRI scanner during a prostate biopsy. This data indicates the opportunity for confirmatory scans during MR guided biopsies. This potential improvement in localization would allow for automatic robotic lesion targeting for biopsy and treatment guidance. Future work will focus on accelerating the imaging sequence so that it can be used within a real-time intraoperative setting. This could be aided by the addition of post-processing techniques to enhance the tubular structure of the needle and/or the use of contrast media in a mandarin or needle sheath.

Figure 1. (a) cross section of chicken breast showing the needle location in the x-y plane. Following imaging, the chicken breast was cut just past the needle insertion depth (fiducials marking insertion depth are visible at the top of the image) and the needle was inserted further until it was visible. (b) transverse view of the needle on low field MRI. The edges of multiple fiducials are visible on the anterior surface of the phantom. (c) coronal view of the needle.
RELAXATION BASED MR THERMOMETRY WITH A LOW FIELD SINGLE SIDED MRI SCANNER
Muller Gomes¹, Srirama Venkataraman¹, Alek Nacev¹.
¹Promaxo, Oakland, CA

Introduction: MRI can be used to guide thermal ablations of soft tissues by measuring temperature in vivo using MR thermometry techniques. However, conventional high-field MRI systems can be clinically impractical for thermal therapies due to their high cost, operational complexities and difficult to access form factors. So, a method for generating temperature maps with a low magnetic field MR system would be clinically advantageous for better guiding thermal ablations. Here we present our preliminary results for temperature mapping with an FDA cleared, low-field, single sided MRI system.

Methods: It is impractical to resolve chemical shift differences in a weak, inhomogeneous magnetic field. Temperature changes can instead be monitored by using tissue relaxation. T₂ relaxation times for tissue are affected by temperature, making it possible to convert T₂ maps to temperature maps with a model correlating the two. For this study, T₂ maps were collected with an FDA cleared single sided, open system with a permanent gradient and a main magnetic field strength operating at 58-74 mT. Phantoms made from bottles filled with honey were used for this proof-of-concept study. For calibration, the phantom was subjected to controlled heating in a water bath to various temperatures and then placed in a receive coil that is surrounded by insulation. The bulk T₂ of the bottle was measured and then its temperature immediately measured with a FLIR-E6390 thermal camera. This was repeated for six temperatures ranging from 50 to 85 degrees Celsius. T₂ times were determined by fitting the echo amplitudes against the echo time to a monoexponential decay. After finishing the calibration, the phantoms were heated and then placed in the insulated coil to be imaged. A 3D SPI scan with an echo train was used to collect the map. A T₂ map for the heated phantoms was generated and used to make a temperature map.

Results: Measured T₂ times and the corresponding temperatures are shown in figure 1a. T₂ times were generated by using each echo in the image to reconstruct an image. The decay of signal intensity in these images were then fitted to a monoexponential decay. Fitting was done using a model that assumes bulk relaxation is dominated by changes in the rotational correlation time \( ^{3} \). A temperature map generated with this calibration data and model is shown in Figure 1b.

Conclusion: A low-field temperature mapping technique was implemented with a single sided open MRI system. As a next step T₂ changes in ex-vivo tissue as a function of temperature will be measured to support the use of low-field MRI for in vivo temperature monitoring.

Figure 5: A) \( R_2 (1/T_2) \) data at different temperatures. B) Temperature map of two honey filled bottles, each heated to different temperatures. C) Image of two vials reconstructed from first two echoes. Contrast caused by temperature differences is clearly visible.
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2021 BEST ABSTRACT AWARDS:

SAFETY, FEASIBILITY, AND ACCURACY OF THE UROMONITOR: A CATHETER-FREE, WIRELESS AMBULATORY CYSTOMETRY DEVICE; Brendan T. Frainey¹, Steve J.A. Majerus²,³, Samir Derisavifard¹, Anna R. Williams¹, Brian M. Balog³, Robert S. Butler⁴, Howard B. Goldman¹, Margot S. Damaser¹,²,³; ¹Glickman Urological and Kidney Institute - Cleveland Clinic, Cleveland, OH, ²Advanced Platform Technology Center - Louis Stokes VA Medical Center, Cleveland, OH, ³Department of Biomedical Engineering - Cleveland Clinic Lerner Research Institute, Cleveland, OH, ⁴Quantitative Health Sciences Department - Cleveland Clinic, Cleveland, OH

NONINVASIVE MANIPULATION OF KIDNEY STONES USING ACOUSTIC FORCEPS; Mohamed A. Ghanem,¹ Adam D. Maxwell,² Yak-Nam Wang,¹ Vera A. Khokhlova,¹,³ Oleg A. Sapozhnikov,¹,³ Bryan W. Cunitz,¹ Michael R. Bailey¹,²; ¹Center for Industrial and Medical Ultrasound, Applied Physics Laboratory, University of Washington, Seattle, WA 98105, ²Department of Urology, School of Medicine, University of Washington, Seattle, WA 98195, ³Physics Faculty, Moscow State University, 119991, Moscow Russia

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ULTRASOUND TOMOGRAPHY FOR PROSTATE CANCER IMAGING: AN EX VIVO PRELIMINARY STUDY; Jacob J. Enders¹, Cheyenne Williams¹, Michael B. Rothberg¹, Zoe Blake¹, Jibriel Noun¹, Yixuan Wu², James Wiskin³, Michael Daneshvar¹, Reza Seifabadi¹, Ayele H. Negussie¹, Peter L. Choyke¹, Emad M. Boctor², Antoun Toubaji¹, Maria J. Merino¹, Baris Turkbey¹, Bradford J. Wood¹, Peter A. Pinto¹; ¹National Cancer Institute, National Institutes of Health, Bethesda, MD; ²Department of Biomedical Engineering, Johns Hopkins University, Baltimore, MD; ³QT Imaging, Inc. Novato, CA

SINGLE PORT ROBOTIC TRANSVESICAL PARTIAL PROSTATECTOMY: FEASIBILITY AND INITIAL OUTCOMES: Ethan Ferguson¹, Alp Tuna Beksaç¹, Mahmoud Abou Zaineb¹, Aaron Kaviani¹, Mohamed Eltemamy¹, Jihad Kaouk¹; ¹Cleveland Clinic, Department of Urology
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2021 TOP 10 ABSTRACTS:

VECTO® PROSTATE BIOPSY: A NOVEL ELECTRO-MAGNETIC (EM) BIOPSY TECHNIQUE FOR MPMRI/US FUSION PROSTATE BIOPSIIES UNDER LOCAL ANESTHESIA. Christof Kastner¹, ², Peter Fletcher², Marta De Santis³, Lucy Chinnery⁴, Ilias Skalkidis⁵, Georgios Sakas⁶. ¹GenesisCare Cambridge, ²Cambridge University Hospitals, ³Intern Medical School University of Rome ‘Tor Vergata’, ⁴University of Cambridge School of Clinical Medicine, ⁵MedCom GmbH, ⁶Technische Universität Darmstadt

TRANPERINEAL ROBOTIC PROSTATE BIOPSY WITH PROST: A PILOT STUDY. Bogdan Maris¹, Chiara Tenga¹, Rudy Vicario¹, Andrea Calanca¹, Stefano Puliatti², Mino Rizzo², Salvatore Miceli², Paolo Fiorini¹. ¹Dept. of Computer Science, University of Verona, Italy, ²Dept. of Urology, University of Modena and Reggio Emilia, Italy

VISUALIZED PROSTATE BIOPSY: AN INTUITIVE 3D USER INTERFACE FOR SYSTEMATIC AND TARGETED BIOPSY. Samsun Lampotang, PhD, FSSH, FAIMBE¹, Thomas Stringer, MD, FACS¹, David E. Lizdas, BS¹, ¹University of Florida

A METHODICAL PITCH-NEUTRAL TECHNIQUE FOR SIDE-FIRE SYSTEMATIC PROSTATE BIOPSY. Zhou Zhang, MD¹, Thomas Stringer, MD, FACS², Yichao Yu, PhD², Gulsen Tasdelen-Teker, PhD³, Jonathan Wakim, BS⁴, Patrick Shenot, MD⁵, Jason Lee, MD⁶, Nathan Perlis, MD⁶, Louis Moy, MD⁵, William T. Johnson, BS², Andre Bigos, BS², Anthony DeStephens, MSE², David E. Lizdas, BS², Samsun Lampotang*, PhD, FSSH². ¹Chongqing General Hospital, ²University of Florida, ³Hacettepe University, Ankara, Turkey, ⁴UPenn Medicine, ⁵Thomas Jefferson University, ⁶University of Toronto

DEVELOPMENT OF URINARY TRACT REMOTE PRESSURE MONITOR. Benjamin Huang¹, Dan Stoianovici¹,², Doru Petrisor², Brian R. Matlaga², Jared S. Winoker². ¹Johns Hopkins University, Baltimore, MD, USA ²Brady Urological Institute, Johns Hopkins University School of Medicine, Baltimore, MD, USA

IN VITRO VALIDATION OF A REAL-TIME 3D MRI URODYNAMICS PROTOCOL. James Rice¹,²,³, Colin Kim¹,²,³, Cody Johnson¹,²,³, Alejandro Roldán-Alzate¹,²,³. ¹University of Wisconsin – Madison: Department of Mechanical Engineering, ²University of Wisconsin – Madison: Department of Medical Physics, ³University of Wisconsin – Madison: Department of Radiology

INITIAL PRECLINICAL RESULTS OF A PROTOTYPE TRANSRECTAL HISTOTRIPSY DEVICE FOR PROSTATE CANCER ABLATION. Rishi R. Sekar MD¹, Zorawar Singh MHS¹, Tatiana D. Khokhlova PhD², Alex T. Peek MA³, Yak-Nam Wang PhD¹, Helena Son BS², Stephanie Totten BS², Wayne Kreider PhD³, Oleg A. Sapozhnikov PhD³, Adam D. Maxwell PhD³, Vera A. Khokhlova PhD², ³George R. Schade MD¹,³. ¹Department of Urology, University of Washington, Seattle, Washington, USA, ²Department of Gastroenterology, University of Washington, Seattle, Washington, USA, ³Center for Industrial and Medical Ultrasound, Applied Physics Lab, University of Washington, Seattle, Washington, USA
2022 TOP 10 ABSTRACTS:

ROBOTIC CYSTOSCOPY FOR DETAILED CHARACTERIZATION OF URETHRAL STRICTURE: Andrew J. Cohen, Dan Stoianovici, The Brady Urological Institute, Robotics Laboratory, Department of Urology, School of Medicine, Johns Hopkins University.

DEVELOPMENT OF FREEHAND TRANSPERINEAL ULTRASOUND-MRI FUSION PROSTATE BIOPSY WITH ELECTROMAGNETIC TRACKING AND NEEDLE AND ULTRASOUND FULLY OUTSIDE THE RECTUM: Sheng Xu, Nicole Varble, Jacob Enders, Reza Seifabadi, Michael B. Rothberg, Ming Li, Baris Turkbey, Peter A. Pinto, Bradford Wood, Center for Interventional Oncology, National Institutes of Health, Bethesda, MD; Philips Research North America, Cambridge, MA; Urologic Oncology Branch, National Cancer Institute, National Institute of Health, Bethesda, MD; Molecular Imaging Program, National Cancer Institute, National Institutes of Health Bethesda, MD; Department of Radiology and Imaging Sciences, National Institutes of Health, Bethesda, MD; National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD.

A NOVEL PROBE FOR MONITORING FOCAL LASER ABLATION OF PROSTATE CANCER: Rory Geoghegan, Griffith Hughes, Songping Sun, Anthony Sisk, Alan Priester, Shyam Natarajan, Leonard Marks, Department of Urology, University of California, Los Angeles; Department of Bioengineering, University of California, Los Angeles; Department of Pathology, University of California, Los Angeles; Avenda Health Inc., Santa Monica.

PROSTATE BIOPSY PLAN PERSONALIZATION: Dan Stoianovici, Katarzyna J. Macura, Bruce Trock, Doru Petrisor, Christian Pavlovich, Amin Herati, Robotics Laboratory, Urology and Radiology Departments, Johns Hopkins University.

NOVEL ENDOSCOPE TIP DESIGNS FOR ASPIRATION OF RENAL STONE FRAGMENTS: AN IN-VITRO STUDY: Kelvin Vo, Andrew Shin, Rohit Bhatt, Kalon L. Morgan, Sohrab N. Ali, Akhil Peta, Pengbo Jiang, Roshan M. Patel, Jaime Landman, Ralph V. Clayman, Department of Urology, University of California, Irvine, Orange, CA, USA.

COMPARISON OF URETERAL STENT BIOMATERIAL ENCRUSTATION PROFILE IN LITHOGENIC ARTIFICIAL URINE MODELS: Rohit Bhatt, Yi X. Wu, Kalon L. Morgan, Eric J. Choi, Amberly A. Vu, Pengbo Jiang, Sohrab N. Ali, Roshan M. Patel, Jaime Landman, Ralph V. Clayman, Department of Urology, University of California, Irvine, Orange, CA, USA; Department of Chemistry, University of California, Irvine, Irvine, CA, USA; Department of Biology, Stanford University, Stanford, CA, USA.

AUTOMATIC FRAME CLASSIFICATION AND ENHANCEMENT FOR CYSTVIEW CYSTOSCOPY VIDEO: Shuang Chang, Sam S. Chang, Kristen R. Scarpato, Amy N. Luckenbaugh, Soheil Kolouri, Audrey K. Bowden, Vanderbilt University, Department of Biomedical Engineering, Nashville, TN, United States; Vanderbilt University Medical Center, Department of Urology, Nashville, TN, United States, 37232; Vanderbilt University, Dept of Electrical and Comp. Engineering, Nashville, TN, United States, 37232.

HOW TO EVALUATE A FLEXIBLE URETEROSCOPE: Nabil Shalabi, K.F. Victor Wong, Kyle Searles, Roman Herout, Alina Reicherz, Ben H. Chew, Naem Bhojani, University of British Columbia, Vancouver, BC, Canada; Université de Montréal, Montréal, QC, Canada.
### BEST REVIEWER AWARDS (LAST 5 YEARS):

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AWARDS:

REVIEWERS:

We gratefully acknowledge the contribution of the following reviewers to the success of the meeting and thank them for taking the time to promote the best science.

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Dr. George Nagamatsu founded the Engineering and Urology Society 1985.

Dr. Jack Vitenson was the first Society Treasurer in 1985.

Special thanks to Dr. Thomas Lawson for his help in formatting this program.

We thank Michelle Paoli and Debra Caridi for organizing this Annual Meeting.
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