W25: ICS Institute - School of Modern Technology: Adaptation of Technology to Functional Urology: New Era

Workshop Chair: Emre HURI, Turkey
04 September 2019 14:30 - 17:30

Start	End	Topic	Speakers
14:30	14:35	Introduction	Emre HURI
14:35	14:50	A new generation wireless implantable tibial nerve stimulator for refractory OAB	Alex Digesu
14:50	15:05	Stem cell therapy in functional urology	Sherif Mourad
15:05	15:20	The role of artificial urinary sphincter in male and female incontinence and new designs	Frank Van der Aa
15:20	15:35	Mesh implant technologies: why they fail ?	Vik Khullar
15:35	15:50	3D medical printing and augmented reality clinical applications in future of functional urology	Emre HURI
15:50	16:05	Discussion	Emre HURI Alex Digesu Sherif Mourad Frank Van der Aa Vik Khullar
16:05	16:20	Break	None
16:20	17:30	Hands-On Training Programme : Patient- specific CT-Reconstructed 3D Printed Pelvic Model (TOT and TVT Training) /Augmented Reality Cystoscopy and Laparoscopic Exercise	Emre HURI Alex Digesu Sherif Mourad Frank Van der Aa Vik Khullar

Aims of Workshop

The School of Modern Technology will work to deliver gold standard educational resources and project proposals in Modern Technology to ICS members through eLearning and work placements at international centres of excellence. The aims of the hands-on training course are: - talking on novel technological improvements related to functional urology - increasing awareness of 3D medical printing and simulation modalities - exercise on 3D printed model and augmented reality model as a novel training tools in new era.

Learning Objectives

learning novel technologies and application to functional urology

Target Audience

Urology, Urogynaecology, Basic Science

Advanced/Basic

Intermediate

Suggested Learning before Workshop Attendance

www.medtrain3dmodsim.eu
https://www.ics.org/institute/technology

A new generation wireless implantable tibial nerve stimulator for refractory OAB
Alex Digesu

The 3-years results of a prospective, multicenter, international clinical trial to assess the efficacy and safety of a novel wireless implantable tibial nerve stimulator for the treatment of patients with refractory overactive bladder (OAB) will be presented

The aims of study were to determine the long term safety and performance of a novel implantable tibial neurostimulation device (the BlueWind Medical RENOVA iStimTM System) for the treatment of OAB.

In this study a wireless peripheral neurostimulator device (BlueWind Medical Ltd.) was implanted on the posterior tibial nerve approximately 5 cm above the medial malleolus and 2 cm posterior to the tibia in patients with refractory OAB. Local anaesthesia was used unless general anaesthesia was clinically indicated. The implant that electrically stimulates the tibial nerve is wirelessly powered by an external control unit (ECU). The ECU controls the therapeutic parameters and is worn by the patient during a specified treatment period whilst at home. A Physician Programmer is also used to remotely set individual stimulation parameters for each patient to optimize therapeutic outcome.

Refractory OAB patients with symptoms of urinary frequency greater than 8 times/24 hours and/or urinary urgency leaks of at least 2 leaks/24 hours (both male and female) were enrolled, while those with clinically predominant stress urinary incontinence or those suffering from any neurological disease or disorder were excluded The efficacy and safety of BlueWind Medical RENOVA iStimTM system were assessed using a 3 day frequency volume chart, quality of life questionnaire (OAB-q) as well as clinical examination for up to 36-months post activation. The McNemar's test for paired proportions was applied to compare to the clinical improvement (i.e. ≥50% improvement in either number of urge-related incontinence episodes or number of urgent voids) at 6-months with that of longer follow-up periods.
A total of 36 patients were recruited for the original pilot study and were followed for 6 months post activation of the device. All 36 patients were implanted successfully with mean procedure duration of 34.8 minutes. These results have been previously reported.

Twenty-three OAB RENOVA iStim system implanted subjects were re-enrolled for the extended, 3-year follow-up study. Up to date, 11 patients have reached 30-months follow-up. No SAEs were reported during the extended follow-up. In the per-protocol analysis, 9 of the 11 patients (82%) have shown more than 50% improvement in either number of urge-related incontinence episodes or number of urgent voids as compared to baseline. In the intent-to-treat analysis, 18 out of the 23 patients have shown above 50% improvement (78%).
Therefore BlueWind Medical RENOVA iStim system demonstrates long term safety and efficacy. When comparing the results of the long term follow-up to the 6-months follow-up, responders' rates were similar at 6- and 30-months follow-up periods (74% and 78%, respectively).

The BlueWind Medical RENOVA iStim System for the treatment of OAB demonstrates safety as well as sustainable successful efficacy long-term results. A larger multicentre, international study is planned to confirm these promising preliminary data.

Stem cell therapy in functional urology
Sherif Mourad

The role of artificial urinary sphincter in male and female incontinence and new designs
Frank Van der Aa

Artificial urinary sfincter remains to date the best solution for severe incontinence both in males and females.
The design of the most frequently used device hasn't changed over the last 30 years. Due to the vast experience clinicians have with this device, we know several points were improvement for our patients could be achieved, for example better continence rates, lower revision rates and easier device handling.

Currently, new devices with different design features are becoming available. We will discuss the differences in design and the possible advantages of these new devices. Are these novel designs an answer to clinicians and patients expectations? Another promising and imminent evolution is the incorporation of electronics into the device.

Besides new designs of the devices themselves, minimal invasive implantation techniques are also of interest. Pre-connected devices decrease operation times and flaws in preparation of the filling solution or in connections. Certainly in females, robot assisted implantation of AUS seems to deliver lower morbidity and even superior results.

As with all implants, high quality studies are sparse. When novel devices are introduced on the market, clinicians are confronted with the dilemma to use the old device with its known values and defaults or to use the novel device that claims to have similar or superior results.

Finally, the area of AUS is changing and innovations are coming on the market. These are exciting times for urologists using these devices and for patients seeking help with severe incontinence.

3D medical printing and augmented reality clinical applications in future of functional urology
Emre Huri

Simulation has become widely accepted as a supplementary method of training. Within urology, the greatest number of procedure-specific models and subsequent validation studies has been carried out in the field of endourology. Of the available modalities, VR simulators are most commonly used for endourology and robotic surgery training, the former also employing many high-fidelity bench models. Smaller dry-lab and ex vivo animal models have been used for laparoscopic and robotic training, whereas live animals and human cadavers are widely used for full procedural training. Newer concepts such as augmented-reality (AR) models and patient-specific simulators have also been introduced. Recently, the effectiveness of the various type of simulations was indicated by many authors in the subdivisions of urological surgery training including urolithiasis and stone treatment procedure , prostate surgery, transurethral surgery, ureteroscopy , percutaneous renal access(PCA) and pediatric urological surgery . Additive manufacturing, or 3D printing (3DP) as it is commonly known, is a process used to create 3D objects from computer-aided designs (CAD). Using sophisticated software, the CAD-image files are graphically sliced into successive two-dimensional layers representing the entire 3D object. These CAD images are then processed by 3D printers to be assembled from an array of assorted materials. It was invented by Charles Hull in 1986. The advent of 3DP technology has enabled the creation of a tangible and complex 3D object that goes beyond a simple 3D-shaded visualization on a flat monitor. Since the early 2000s, 3DP machines have been used only in hard tissue applications. The potential applications of 3DP in clinical medicine are numerous. It can allow physicians to create patient- specific models of pathology with such precise anatomic detail that it facilitates pre-procedural planning prior to treatments. 3DP can also serve as an important teaching tool and training adjunct in medical education not only for medical students and residents, but also in the counseling of patients and their families with regards to disease management and procedural description. Finally, 3DP can allow for the creation of bio-printed cells for the testing and development of novel medications or targeted agents to better replicate its potential use and efficacy in actual patients. The most important surgical procedures in functional urology can be mimicked by 3D models and bio-cad applications to obtain good surgical results and surgical education

Mesh implant technologies: why they fail?
Vik Khullar

The development of prosthetic materials for the treatment of pelvic organ prolapse is based on previously published reoperation rates for POP of being as high as 30%. The main rationale for mesh use was the potential improvement of anatomical restoration of pelvic floor structures and hypothetical reduction of the presumably high recurrence after standard vaginal surgery. The material must be biologically compatible, chemically and physically inert, non-carcinogenic and mechanically strong while remaining flexible, non-allergenic, non-modifiable by body tissue and non-inflammatory. However, none of the currently available materials fulfills these requirements. This is one reason why the use of mesh is associated with a non-negligible risk of complications such as vaginal exposure and extrusion, potential consecutive infections, granulomas, dyspareunia, vesico-vaginal fistulas and chronic pain.

Many of these complications required further surgical intervention. In 2011, after the FDA issued a warning concerning transvaginal mesh kits, many of these kits were voluntarily withdrawn from the market under economic and juridical pressure and the use of synthetic material in POP surgery has dramatically decreased. Among the few studies which have analyzed the risk factors for mesh exposure or retraction, one publication clearly identified tobacco use as a risk factor. Other potential risk factors are diabetes mellitus, obesity, age, associated total hysterectomy, and surgical experience. However, little is known about the exact role and the reaction of the host during and after mesh surgery. The inflammatory response as well as the microbiological vaginal environment may be a determinant factor in the outcome after mesh implantation.
There will be a discussion about mesh, the problems and how complications could be reduced.