W31: ICS Institute Modern Technology: Advances in Neurostimulation: Technology-Based Approach (3D modelling, 3D printing, Surgical Planning and Navigation)

Workshop Chair: Emre Huri, Turkey

Start	End	Topic	Speakers
		Introduction and EuroSOMT Project Presentation	Emre Huri
		Standardisation of Sacral Neurostimulation and Pudendal Nerve Stimulation	Stefan de Wachter
		THE BEST TECHNOLOGICAL ADVANCES FOR CLINICAL SIDE OF SACRAL NEUROSTIMULATION: TECHNIQUES AND CLINICAL OUTCOMES	David Castro-Diaz
		Noval Technological Side of Peripheral Stimulation	John Heesakkers
		Patient-specific CT Reconstructed 3D Modelling and 3D Printed Guide Application, Surgical Planning and Noval Technology in Neurostimulation	Emre Huri

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 workshop are: - talking on novel technological improvements related to neurostimulation procedures - increasing awareness of 3D medical printing and simulation modalities within the scope of neurostimulation - approach to refractory OAB and pelvic pain syndrome patient with using new technological instruments - discuss new technology on neurostimulation modalities.

The WS will conduct usage of 3D modelling and presurgical planning for Neurostimulation and get feedbacks from audiences

Learning Objectives

Learning high-technology advances for neurostimulation

Target Audience

Urology, Bowel Dysfunction

Advanced/Basic

Intermediate

Suggested Learning before Workshop Attendance

3D modelling and 3D printing in functional urology: the future perspective.
Huri E, Mourad S, Bhide A, Digesu GA.
Int Urogynecol J. 2020 Oct;31(10):1977-1978. doi: 10.1007/s00192-020-04286-5. Epub 2020 Apr 2.

John Heesakkers
Noval Technological Side of Peripheral Stimulation

Since the introduction of neuromodulation for mainly OAB, the standard technique is the Interstim Sacral Nerve Modulation system, FDA approved in 1997. However other types and location of neuromodulation have been tested and introduced. Percutaneous tibial nerve stimulation was the first alternative in the beginning of this century whereafter transcutaneous tibial nerve stimulation was becoming routine practice. The advantages are obvious: cheaper, less or non invasive and the stimulation location is easy to access.
With the newest technological developments a new era of impantable stimulators has started. This presentation will focus on the technical aspects, advantages, drawbacks, and limitations of the latest available applications of nerve stimulation. The ideal form of tibial nerve stimulation is in our opinion home-based treatment and easy to operate for the patient. An implant, from our point of view should be easy to implant and should have an external energy source. Preferable, the implant has a long lifespan without surgical re-interventions, no leads and a minimal chance of migration. Moreover, there should be no interference withother diagnostics or treatments and accessible in terms of costs of the treatment.

The tibial nerve can be transcutaneous stimulated like with TENS. It is selfapplicating
which increases the mobility of patients during treatment. The advantage of the system is the noninvasive nature and high rates of patient satisfaction in usability terms . Disadvantages of this modality may be the fixed parameter settings and the lossof efficacy because of higher impedance of the skin. In addition, patients have to attach the TENS device by themselves which can lead to suboptimal positioning and less effective treatment.

There are a few tibial implants at the moment that have been used on patients with reported results.

- The Bluewind RENOVA system is a wireless batteryfree tibial nerve stimulation system Patients are provided with the stimulator, a 25mm implant with small fixating wings to prevent migration of the implant. The implant is fixated near the tibial nerve, in an open surgical procedure under local anesthesia. Patients wear the External control Unit, which provides the implant with the energy needed (closed-loop system) for treatment and allows the patient to adjust the amplitude. In a first study, a response rate of 71% during 6 months follow up (FU) period was described. 3-year Results were published with 75% responders.

- Another implantable neuromodulation device is the eCoin. The implantation is a minimal invasive open procedure, whereby a leadless and battery powered device is implanted under local anesthesia to the medial aspect of the lower leg. The device is nickel sized and shaped. After implantation, the device provides automatically 30-min treatment sessions every 2 days for 12 weeks. Advantage of this device is the relative short and easy implantation procedure. The battery powered system could be an advantage because it does not need patient involvement to be powered. On the other hand, battery powered means it has to be replaced. A disadvantage of the system are the fixed treatment parameters. The treatment session starts automatically (during maintenance treatment) every 15 days. which could also be unhandy. Clinical results show that after one year 65% of patients were responders.

- The Bioness Stimrouter neuromodulation can be easily implanted under local anesthesia near the desired peripheral nerve. It consists of a specially crafted lead that is transcutaneous powered by an external pulse transmitter (EPG). Patients wear the EPG on the skin during stimulation of the tibial nerve. A patient programmer can be used to change parameter settings and tracks usage. Advantage of the Stimrouter is the minimally invasive surgery to implant the lead. Another advantage of this system is the possibility to add up to eight different treatment/stimulation programs. Disadvantage of the system is the loss of energy because of the use of surface electrodes for energy transfer Therefore, it is likely that the optimal amplitude will have a 5–10 times higher value in daily practice comparing to test stimulation during implantation. At present, no studies of this neuromodulation system have been published. A prospective, multicenter, randomized, double blinded study is ongoing.

- The CAN-stim frm Micron Medical is an implanted lead that resembles the tined lead used for SNS. Patients receive an implanted stimulator with embedded receiver through a 5mm skin incision. The energy source is a small, external, rechargeable transmitter, which is worn by the patient. The energy source is connected to an external antennae and is worn near the internal antenna of the implant. The system uses an open-loop system which implies the energy which is given from the wearable to the electrode is stable but not secondarily monitored by the external unit. Patients are asked to use the implant during the night, with a maximum treatment durability of 8h. An RCT compaint the device to Interstim in 200 patients is ongoing.

Stefan De Wachter
Standardisation of Sacral Neuromodulation

Sacral neuromodulation has become an established therapy for patients with overactive bladder syndrome dry and wet, non-obstructive urinary retention, and faecal incontinence. Despite it's widespread use, published efficacy results vary and in an significant proportion of patients, this treatment fails to improve symptoms. Several factors can attribute to this varying results, such as patient selection, but also suboptimal lead placement, leading to inefficient stimulation of the target nerves.

This presentation will give an insight into the possible underlying factors and will go into dept on a standardized optimal lead placement. Also the scientific background behind this placement will be discussed.

At the end of the presentation, the participant will have a detailed overview of the standardized lead placement which, together with the suggested reading, will enable to finetune his current clinical practice.

Suggested reading: Matzel KE, Chartier-Kastler E, Knowles CH, et al. Sacral Neuromodulation: Standardized Electrode Placement Technique. Neuromodulation 2017; 20: 816-824.

David Castro-Diaz

The best technological advances for clinical side of sacral neurostimulation: techniques and clinical outcomes

Sacral Neuromodulation (SNM), introduced in clinical practice more than two decades ago, has passed the test of time with more than 300 patients implanted for the indications of refractory overactive bladder, non-obstructive urinary retention and faecal incontinence. This therapy has evolved from open implantation of the electrode and bigger devices to percutaneous implantation of the quadripolar tined lead electrode and smaller device, becoming an established minimally invasive therapy. Response rate for the different indications ranges from 77% to 88% while reoperation rate due to several reasons ranges in between 3% and 33%.

Limitations of SNM include among others, the need of surgical revision for either technical issues or battery replacement and the incompatibility with Magnetic Resonance Image (MRI).
Recent advances in technology have allowed the introduction of smaller and rechargeable devices and MRI compatible electrode which with no doubt will impact the future of clinical practice.

The need of full-body MRI compatibility is clear because at least half of patients with neurostimulators will have a clinical indication for MRI sometime over their life. In addition, 1 in 4 of SNM explants are usually due to the need of MRI. Furthermore, the absence of MRI compatibility has traditionally been a contraindication for the subgroup of neurological patients with multiple sclerosis are they would need MRI in the follow up. An MRI compatible device will allow to apply this therapy to this subgroup of patients.
The battery life of the current Interstim II is estimated in between 5 and 7 years. The introduction of a rechargeable device is expected to reduce the number of reoperations which at the same time might be more comfortable for the patient due to the smaller size and lower pain at the neurostimulator. However, there are several pitfalls associated with rechargeable devices. Patients need to be skill with the periodical recharging procedure and have appropriate cognitive function and manual dexterity. In addition obesity might be an issue as well because the risk of twiddle of the device occasioning dislodging of the leads from their intended location and programming difficulties.

Criteria for patient selection: recharge-free versus rechargeable devices

Recharge-free SNM preferred	**Patient´s choice and the impact of external factors**	**Rechargeable SNM preferred**
History of therapeutic non-compliance	Patient choice versus physician recommendation	Technology-savvy, compliant, and highly motivated patient
Reduced compliance expected in the next 10–15 years	Reimbursement and socioeconomic factors	Need for a high energy stimulation with expected battery life of 3 years or less
Patients with forgetfulness; lack of motivation	Helpline in case of technical questions?	Thin patient
Patients with physical difficulties (finding the right spot to recharge)	Easy access in case of lost recharger?	Patient with a history of pain
Lack of technical knowledge	Cost issues (insurance in case of lost recharger?)	Patient with significant infection risk for device replacements
Incompatibility with lifestyle		

Adapted from De Wachter S, Adv Ther (2020) 37:637–643 641

Emre Huri

Patient-specific CT reconstructed 3D printed guide application, surgical planning and novel technology in neurostimulation

Sacral neuromodulation (SNM) is a therapy system used to improve bladder function, including in people with overactive bladder (OAB). It is safe and can improve quality of life. It helps improve symptoms through direct modulation of nerve activity; mostly effects afferent nerves, it involves electrically stimulating the sacral nerves that carry signals between the pelvic floor, spinal cord and the brain and is thought to normalise neural communication between the bladder and brain. Technical properties and fine surgical technique may cause long-term learning time, and also finding the good position of needle for S3 can be problematic during surgery. Therefore, preoperative surgical planning is crucial in complex cases, such as anatomical abnormalities, secondary cases or obese patients. An important issue in which three-dimensional medical technologies can be beneficial is the pre-surgical planning stage. The data obtained by the patient's imaging methods can be made three-dimensional in the virtual environment, and the neighborhoods of the tissues and organs and the anatomical location of the

structure to be intervened can be evaluated in detail before surgery, and a more realistic assessment opportunity can be obtained while planning in the preoperative period. Models obtained with 3D printer technology can be used by offering in vitro work environment for different studies besides preoperative planning, medical education and patient information. 3D printed guide can be produced with using 3D medical printer, it can help to find S3 without X-ray.