CLINICAL ARTICLE



Innovative training modality for sacral neuromodulation (SNM): Patient-specific computerized tomography (CT) reconstructed 3D-printed training system: ICS School of Modern Technology novel training modality

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Abstract

Introduction: Sacral neuromodulation (SNM) is an effective treatment of urinary and bowel dysfunction, including secondary to neurological disorders. The learning curve for the optimal electrode placement for SNM is steep, expensive, and limited by patient factors such as obesity and previous injuries. We aim to create a patient specific 3-dimensional (3D) model for successful SNM training.

Materials and Methods: A total of 26 urology residents who had different level of knowledge and experience were enrolled to the 3D SNM training program. The creation of 3D sacrum model has been started with evaluation of real patient computerized tomography images and creation of Digital Imaging and Communications in Medicine files. The segmented anatomic structures from the files then edited and stereolithographic files were generated for 3D-model prints via Mimics[©] software. The 3D-printed models were used for training and evaluation of participants during the SNM intervention was performed. The evaluation of 3D SNM model training was led by one mentor who is expert on SNM.

Results: On the preprinted 3D sacrum model all 26 participants were requested to perform the essential steps to complete a SNM procedure and individual procedure time was recorded. The mean and median scores were 18.8 and 19, respectively according to Likert scores (min 11 max 28).

Conclusions: SNM is increasing in popularity as a treatment option with physicians and patients with refractory symptoms. Few experienced specialists exist, and more effective training methods are needed to tackle the increasing demand, and individual patient anatomy.

KEYWORDS

3D-modeling, 3D-printing, 3D-reconstruction, sacral neuromodulation, SNM, training model

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1 | INTRODUCTION

Sacral nerve stimulation or sacral neuromodulation (SNM) is an effective treatment for many colorectal and urinary conditions, such as urinary retention, ¹ fecal incontinence, ² constipation, and other bowel dysfunctions. ^{3,4} The procedure involves the implantation of a stimulating electrode lead through the sacral foramina, which stimulates the nerve and appears to modulate colonic and urinary function locally and via central nervous activity. ⁵

SNM is Food and Drug Administration approved and has been recommended for refractory urinary and fecal incontinence by the National Institute for Health and Care Excellence, Royal College of Obstetricians and Gynecologists, and International Incontinence Society (ICS).⁶⁻⁸ The global prevalence on urinary incontinence is estimated to be 8.7% and fecal incontinence to be 5.9% worldwide.¹⁰ According to literature, a success rate over 70% can be achieved with SNM on patients with refractory idiopathic overactive bladder and non-obstructive urinary retention.¹¹ More, SNM is an alternative modality for patients with fecal incontinence or chronic constipation.¹¹

The procedure is currently carried out by specially trained physicians with use of cadavers which is time consuming, expensive, and limited. SNM delivers electrical stimulation to the nervous system by placing a stimulating electrode adjacent to the target neural tissues as a form of peripheral nerve stimulation with lowintensity chronic impulses especially to sacral spinal nerves.⁵ Matzel et al.⁵ have developed a standardized electrode placement technique to allow optimal electrode placement, and hence efficacy of SNM. The optimized lead placement should be placed cephalad and medial in the S3 foramen to obtain better efficacy, longer battery life, and decreased peripheral stimulation with lower voltages. 12-14 The key steps include correction of lumbar lordosis, radiological marking, and blind placement of lead through the S3 foramina.⁵ This is very difficult in patients who are obese, have a history of spinal or pelvic injuries where the anatomy may be distorted and difficult to identify by palpation or X-ray. Standardized fluoroscopy-guided implantation techniques have been suggested to enable a close contact between electrode and nerve, but the study also reported perforation of presacral fascia and sacral nerve. 15 There have been no methods of practicing of abnormal anatomy but trial and error on individual patients which involves increase in anesthetic time, patient discomfort, and suboptimal lead placement. The new developments in technology, 3dimensional (3D) printing, and modeling may be the solution. Many different models have been created to allow surgical training for electrode placement. 16-18 Currently there is not enough material for SNM education. The models previously manufactured by Medtronic were insufficient, not show the real anatomy. The cadaver models are used for this training purpose, and there are limiting factors such as limited number of people to receive cadaver training with high costs, cadaver supply restrictions. The ICS School of Modern Technology has been established to organize educational facilities with using technologic devices, instruments, and materials on 3D printed physical simulators, virtual reality, and augmented reality models. With this scope, we introduce 3D SNM model, based on individual patient anatomy, and evaluate the efficiency during SNM training under the conceptual design of the Med-TRain3DModsim Erasmus & European Union Project. 18

2 | MATERIALS AND METHODS

2.1 | Engineering and technique

The 3D SNM modeling started with computerized tomography (CT) data from cadavers, generated from Digital Imaging and Communications in Medicine (DICOM) files as per the MedTrain3DModsim project¹⁸ guidelines. The Materialise Interactive Medical Image Control System (Mimics) software programs (Materialise NV) was used to create segmented anatomic structures from the files. Further 3DS MAX and Z-brush 3D model editing tools were used for modifications and repairments. The texturing process with Photoshop to create realistic anatomic structures was performed. Polygonal mesh (stereolithography) files were generated for 3D-printing.

2.2 | Anatomic features and variables

For 3D SNM training model, sacrum, sacral plexus (nerves), posterior surface with muscle layers, and SNM tools are essential. The 3D sacrum model (Figure 1) has some characteristics as; 0.5 mm pixel size, 1 mm slice thickness of radiologic images, 4 h modeling time, ±1 mm anatomic suitability, fused deposition modeling production technology, 0.2 production resolution, 18 h production period, 2 h postprocess period, and composed of Resin/hard (soft/hard) material type. The bony, neuronal structures, and muscle tissue were separately constructed via 3D-printing method. They were brought together with completion of postprocess steps (Figure 2).

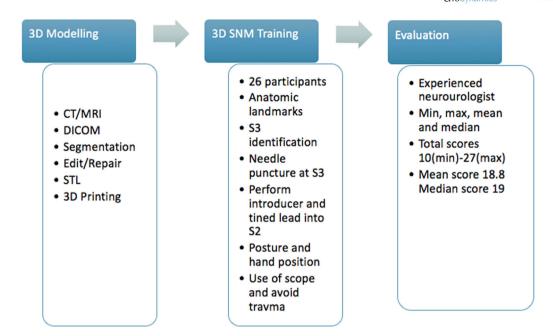


FIGURE 1 The flow chart of the study design. CT, computerized tomography; DICOM, Digital Imaging and Communications in Medicine; SNM, sacral neuromodulation; 3D, 3-dimensional.



FIGURE 2 The 3D printed sacrum model. 3D, 3-dimensional.

2.3 | Group selection

During MedTRai3DModsim EU Project, ICS School of Modern Technology members announced the training activity related to SNM surgery. The inclusion criteria for training sessions were identified as being a resident, no previous experience on SNM and enthusiastic to novel training modalities and technologies. A total of 26 urology residents from European countries with no previous experience were enrolled to the 3D SNM model training session. Before the hands-on training session, each participant has theoretical and audio-visual training part. Following this part, practical session was started. All technical skills were evaluated in terms of standard

surgical procedure. The 3D SNM model training has multiple steps, and all participants were requested to perform each essential step. These included; (1) puncture needle at level of S3 nerve, (2) placement of introducer sheath with aid of guidewire, (3) placement of the electrode while using C-arm fluoroscopy and avoiding from any trauma. The variables which were evaluated by mentors (1) Identify anatomic landmarks of SNM, (2) Identify S3 foramina, (3) Perform needle puncture at S3, (4) Perform introducer and tined lead into S3, (5) Good posture (appropriate positioning of patient and needle with correct angulation of needle) and hands position (holding the needle with two hands under supervision of mentor), (6) Keep needle direction at the right position

and avoid trauma. The evaluation scores of each step were assessed using the Likert scale (from 0 score to 5 score) while minimum, maximum, mean, and median were calculated. ¹⁹ The timing of each step was evaluated. The evaluation was performed by mentors who are expert in field of functional urology. The study flow chart was shown in Figure 1.

3 | RESULTS

All participants completed the evaluation forms in terms of methods of the study. All mentors followed the guidelines while evaluating the participants. All requested surgical steps with min, max, and mean Likert scores were recorded and listed in Table 1. The least score was shown for perform needle puncture at S3

(mean: 2.46), while the best score was seen for identify anatomic landmarks of SNM (mean: 3.69). The scores of good posture and hand orientation, keep needle at the right position and avoid trauma were 3, 3, out of 5 respectively which were acceptable scores for novice urologists. Among all the participants, the minimum and maximum times needed to identify anatomic landmarks, identify S3 with crosshair technique, perform needle puncture at S3, perform introducer and tined lead into S3 were 12 versus 120 s, 10 versus 200s, 60 versus 200 s, 60 versus 200 s, respectively (Table 1).

In terms of the distribution of the number of participants according to scores among the steps of SNM procedure, none of them could reach 5 point considering the step of "performing introducer and tined lead into S3" and "good posture, hands positioning" (Table 2). However, the most difficult step for the

TABLE 1 Standard 3D-printed sacral neuromodulation (SNM) model (26 participants)

Variable	Mean	Median	SD	Min	Max
Identify anatomic landmarks of SNM	3.69	4	0.97	1	5
Time to identify anatomic landmarks of SNM (s)	67.4	60	31.9	12	120
Identify S3 with crosshair technique	3.46	3	1.02	2	5
Time to identify S3 with crosshair technique (s)	62	60	37.9	10	200
Perform needle puncture at S3	2.46	2	1.2	1	5
Time to perform needle puncture at S3 (s)	128	120	45.0	60	200
Perform introducer and tined lead into S2	3.08	3	0.89	2	4
Time to perform introducer and tined lead into S2 (s)	102.2	95	50.0	60	200
Good posture and hands position	3.15	3	0.78	2	4
Satisfaction from training	4.30	4	0.77	3	5
Total score	18.8	19	4.61	11	28

Abbreviation: 3D, 3-dimensional.

TABLE 2 The distribution of the number of participants according to scores among the steps of the SNM procedure

Scores	1	2	3	4	5	n
Identify anatomic landmarks of sacral neuromodulation (n)	1	1	8	11	5	
Identify S3 with crosshair technique (n)	-	5	9	7	5	26
Perform needle puncture at S3 (n)	7	8	5	4	2	
Perform introducer and tined lead into S2 (n)	-	9	6	11	-	
Good posture and hands position (n)	-	6	10	10	-	
Keep C-arm fluoroscopy centered and avoid trauma (n)	1	5	10	9	1	

Abbreviations: n, total number of participants; SNM, sacral neuromodulation.

participants seemed to be needle puncture at S3. Considering this step majority of participants obtained lowest scores (1-2).

4 | DISCUSSION

SNM is successful and cost-effective minimally invasive treatment modality for urinary and bowel dysfunction. The learning curve of SNM is steep with many difficult steps. This includes identification of the opening of the sacral foramen, correct angulation of needle, and correct positioning of electrodes.^{20,21} Previously a few studies well described the effectivity of 3D-printed modeling.

In 2017, Tayerner et al.²² first emphasized the advantage of usage of 3D-printing in epidural access during neuromodulation on a severe kyphoscoliosis patient. Up to now, just a few recent publications emphasized different aspects of advantages in usage of the 3D-printing on SNM. 16,17 In 2018, Cui et al. 16 described a 3-printed guiding device which composed of liquid photopolymer material, for electrode implantation during SNM intervention. They applied 3D SNM guiding device on two patients. CT scans were taken to obtain a digital 3D image of sacrum in each patient. Six simulated test needles were inserted into the sacral foramen opening via S2-S4 under 60° of angulation according to the 3D image of sacral bone. They obtained a digital prototype of guiding device with 3D data preparation software (Materialise Magics 3D Print Suite). Moreover, they emphasized some advantages of their 3Dprinted guider; portable usage with availability on remote application of SNM, no need of 3D-printed guide removal during the temporary screening electrode placement.¹⁶

Followingly, Zhang et al. 17 evaluated the application of an individualized and reassemble 3D navigation template for accurate puncture with a trial composed of 24 SNM patients. During SNM application, there exist two main stages as Stage I (tined lead implantation using a standardized electrode placement) and Stage II (permanent pulse generator implantation for the patients with ≥50% clinical symptom improvement). The 3D-printed navigation template was provided by Beijing ThousandMed Innovation Technology Co. Ltd. under standard production circumstances as; CT reconstruction of the sacrum and coccyx, reconstruction of images from DICOM data, 3D-printed template with 0.6 mm puncture holes. Considering the Stage I, they used conventional X-ray guidance for the control group (n = 14)and 3D-printed template for study group (n = 10). They compared some main parameters during SNM intervention in between the groups. The number of punctures, X-ray output (mAs/110 kv, 3 mA), mean puncture time (min), mean intraoperative testing time (min), and initial effective

voltage (V) were all significantly lower in 3D model group (p < 0.05).¹⁷

The use of 3D-printing in SNM applications made on patients before, gave us the idea that these models will also be used for educational purposes. Up to now in literature, ICS School of Modern Technology created 3D-printed SNM training model which is unique and first described teaching model as a kind of educational curriculum. In addition, it can be predicted that good training will supply an increased technical skill to shorten the time of placement of the needle to S3 by the surgeon, diminish exposure to radiation and increase in success of correct localization of the electrode. The distribution of participants on achievement of good posture and positioning of hands, keeping the C-arm fluoroscopy centered and avoidance of any trauma were mainly over the average. The identification of anatomic landmarks is a must and majority of participants have succeeded (Table 2). When we analyzed Table 1, the mean (2.46) and median (2) evaluation scores on performing needle puncture at S3 seem to be lower than other steps. Most participants got score of <3 concerning this step (Table 2). This step might be the steep learning curve point during the SNM procedure. More, the correct needle puncture at S3 is directly correlated with performing introducer and tined lead into S3.

It can be considered as a limitation that it would be better to obtain SNM application parameters without a 3D-printed model and compare between participants. In this study, we have shown for the first time that such a model can be used in education. This is a simulator based simulator, research, and development model. Comparisons with cadaver, SNM tool, and live surgery can be made in future studies.

More, previously Zhang et al.¹⁷ showed that an individualized 3D-printed model is adequate for SNM application by single experienced surgeon. According to our study we strongly underline the necessity of widespread use of 3D-printed models during urology training. On the other hand, our study has some restrictions to obtain comparable groups and a lack of statistical analysis. This study is a pilot one in the literature. Our aim is to demonstrate the applicability of 3D printing technology for SNM surgical models, usability of SNM tools, and feedbacks from novice residents who did not have previous experience on SNM. Our next step will be to make validation of 3D printed SNM physical simulators in terms of content, face, and construct parameters with including nontechnical skills.

The 3D-printed modeling technology should be a cornerstone of future modern surgical training. With current outcomes they should be more commonly used and supported in residency training programs especially in field of urology where various instrumentation and

interventions are commonly used. SNM is an important treatment for functional urological and colorectal symptoms, which depends on exact learning curve including proper tined lead placement.

5 | CONCLUSIONS

3D printing technology is promising modality to teach stepwise SNM procedure. Residents can be evaluated with 3D printed physical surgical simulators in terms of realistic anatomic structures with using real SNM devices. The 3D-printed models may increase the capabilities and experiences of surgeons without causing harm to patients, including those with abnormal anatomy or spinal injuries, with less expense rather than using cadavers, providing higher treatment success. We believe that also in future comparative studies, it will be seen that the 3D SNM model can be used in educational purpose.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data is available whenever needed.

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How to cite this article: Aydogan TB, Patel M, Digesu A, et al. Innovative training modality for sacral neuromodulation (SNM): Patient-specific computerized tomography (CT) reconstructed 3D-printed training system: ICS School of Modern Technology novel training modality. *Neurourol Urodyn.* 2023;42:297-302. doi:10.1002/nau.25083