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Evolution and efficiency of customized 3D printed Sacral Neuromodulation(SNM) physical simulator used for practical training

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Hypothesis / aims of study Sacral Neuromodulation is a treatment method that stimulates the sacral spinal nerve (S3) in the sacral region and aims to solve the existing neural problem. In this operation, the anterior surface of the sacral nerve root is constantly stimulated by placing an electrode and bladder battery that can be developed. This stimulation is not felt by the person - it does not hurt - there is no pain. Therefore, it provides solutions to problems such as overactive bladder and inability to urinate. This surgical simulator is used by the developer company of the product to train physicians and to teach the general features of surgery before the operation in question. This model includes the sacrum, which is the lowest part of the spine where the electrode is placed in surgery, rather than the entire pelvic floor. Physicians and physician candidates can experiment with various methods in this model in order to understand the basic steps and anatomical steps of sacral neuromodulation surgery, and develop a methodological practice for the electrode to reach the right place.

Surgical Step Evaulation (*1 Poor; 2 Marginal; 3 Acceptable; 4 Good; 5 Very Good)		OSATS (*1 Poor; 2 Marginal; 3 Acceptable; 4 Good; 5 Very Good)	
STEP 1: Patient Position and Preparation	4,50	Gentelness	2,98
STEP 2: Use of X-Ray and Marking Equipment	4,50	Time and Motion	2,83
STEP 3: Foramen Needle - Placement Equipment	2,98	Instrument handling	2,76
STEP 4: Introducer - Placement Equipment	3,10	Flow of operation	2,92
STEP 5: Tined Lead Electrode - Placement Equipment	3,20	Tissue exposure	2,81
STEP 6: Removal of the Introducer Equipment	3,18	Summery score	2,84
STEP 7: Tunneling, IPG Pocket, and Percutaneous Extension Lead Equipment	3,75		

Figure 2. Surgical Step Evaluation and OSATS results of the 3D printed SNM anatomical model

Study design, materials and methods

The main technical problem that the product aims to solve is instead of models with low anatomical accuracy, which are not obtained from real patient data; Thanks to the processing of 3D images, the data of which are provided legally, and transforming into a simulator with minimum intervention, the person who receives the training and performs the application encounters a form that closely simulates the bone of the sacrum region and the fat-muscle tissue of the human. This situation offers an opportunity to increase the success in surgical practice. The reason for this sensitivity is that the sacrum and mold structure modeled in the three-dimensional modeling program are produced in accordance with the original by a 3D SLA printer with 0.100 mm layer precision. Thanks to the flexibility offered by this modeling and suppression, the model can be transformed into a case with the desired symptoms and customized while keeping the idea the same. MIMICS Innovation suite was used for the segmentation and digital anatomical model production. FormLabs 3B and other FDM based 3D printers used for 3D printing. All models were designed by quoting the anatomy of real person. Over the past years we modified and improved the model from first version to fourth one. First version (2017, in Figure 1 on the upper row 1st(external view) and 3rd (internal view) pictures) had really hard black bony part and thick muscular and cutaneous gray part, Second version (2019, in Figure 1 on the upper row 2nd(external view) and 4th (internal view) pictures) had more flexible white sacrum and silicone like white covering, third version (2022, in Figure 1 on the lower row 1st(external view) and 3rd (internal view) pictures) had a realistic colorful appearance of both external features of both male/female genders and finally fourth version (2023, in Figure 1 on the lower row 2nd(external view) and 4th (internal view) pictures) had a mannequin model like external appearance with a more flexible sacrum has sacral nerves on it.

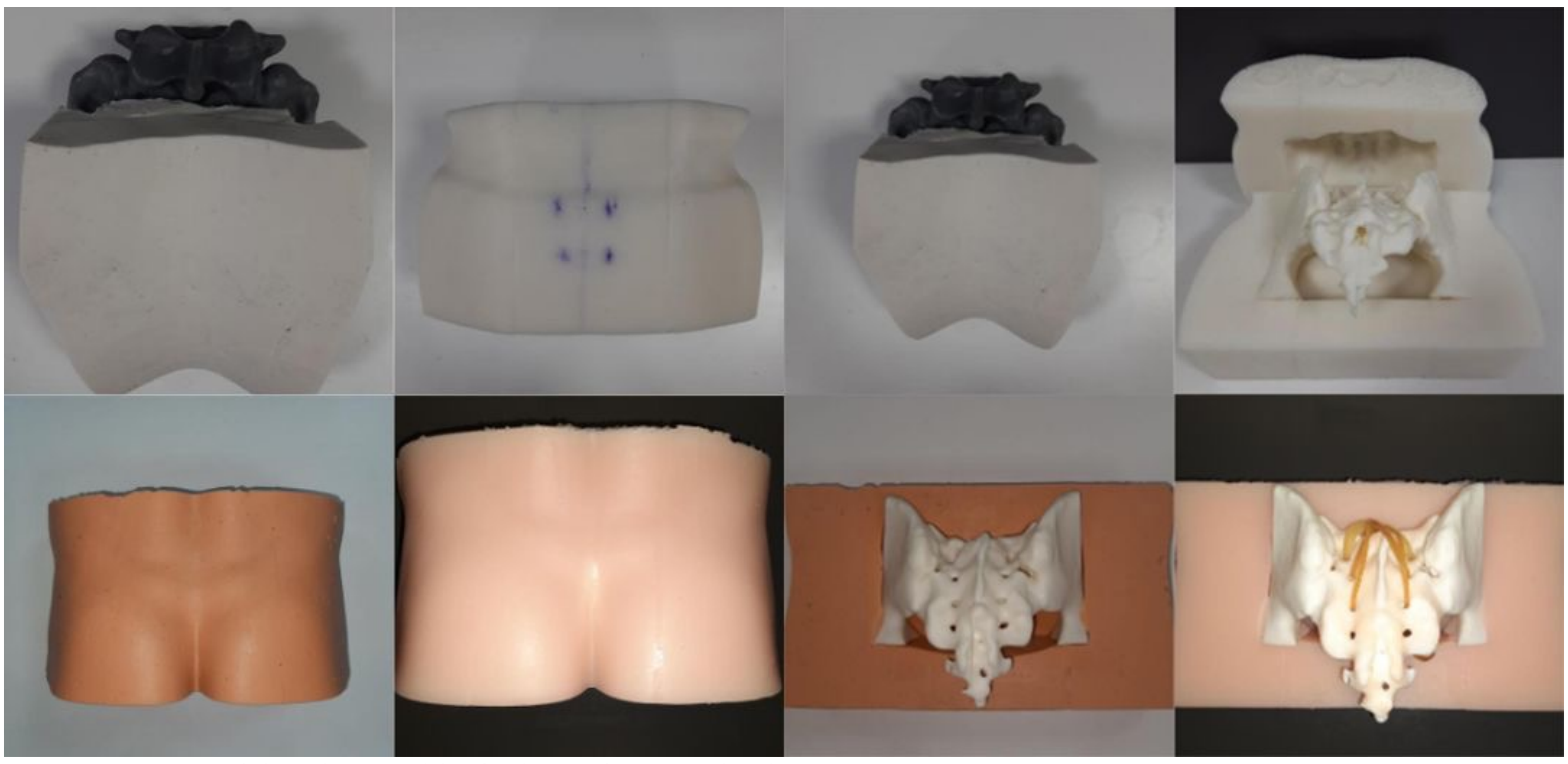

Figure 1. Four version of physical SNM model (Left side outer features, Right side inner structures)

Results

In order to determine the effectiveness of the model, a 7-step "surgical step evaluation" test including STEP 1: Patient Position and Preparation, STEP 2: Use of X-Ray and Marking Equipment, STEP 3: Foramen Needle - Placement Equipment, STEP 4: Introducer - Placement Equipment, STEP 5: Tined Lead Electrode - Placement Equipment, STEP 6: Removal of the Introducer Equipment and STEP 7: Tunneling, IPG Pocket, and Percutaneous Extension Lead Equipment determined by the surgeons applying the surgical method was applied to 50 participants. 36 of these participants are men and 14 of them are women; 5 urologists, 16 medical school students, 24 urology residents, the rest are clinical engineers and engineering students. The participants listened to the theoretical training one day before practicing on the simulator. About the surgical step evaluation, mean value was 3,60 in Likert scale (1 poor, 2 marginal, 3 acceptable, 4 good and 5 very good). We also assessed objective structured assessment of technical skill (OSATS) of the participants including Gentleness, Time and Motion, Instrument handling, Flow of operation, Tissue exposure and Summary score with the mean value 2,86 in same Likert scale. The detailed results can be seen in Figure 2.

Interpretation of results

At the end of the training activities with the analysis of the results; all participants completed the end-to-end surgery training and were successful in placing the needle. We have similar results after standard education at different educational levels. Because of the heterogeneity of the participants and depending on the covering material used in the early versions (Version 1 and 2) of the model, the placement of the instrumentation was the difficult part of the application to the participants.

Concluding message

As a conclusion, we believe that the customized 3D printed SNM anatomical model produced from real patient's radiological data with anatomical accuracy will be the one of the complimentary educational tool for training purposes. It can be modified to more realistic and efficient versions with increasing numbers of the participant's feedback.

References

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Disclosures

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