A hybrid, low-cost tissue-like epidural needle insertion simulator

B. Esterer\textsuperscript{1,2}, S. Gabauer\textsuperscript{1}, R. Pichler\textsuperscript{2}, D. Wirthl\textsuperscript{3}, M. Drack\textsuperscript{2}, M. Hollenstein\textsuperscript{1,2}, G. Kettlgruber\textsuperscript{3}, M. Kaltenbrunner\textsuperscript{4}, S. Bauer\textsuperscript{3}, D. Fürst\textsuperscript{1}, R. Merwa\textsuperscript{1}, J. Meier\textsuperscript{3}, P. Augat\textsuperscript{2} and A. Schrempf\textsuperscript{1}

Abstract—Epidural and spinal anesthesia are mostly performed “blind” without any medical imaging. Currently, training of these procedures is performed on human specimens, virtual reality systems, manikins and mostly in clinical practice supervised by a professional. In this study a novel hybrid, low-cost patient simulator for the training of needle insertion into the epidural space was designed. The patient phantom provides a realistic force feedback comparable with biological tissue and enables sensing of the needle tip position during insertion. A display delivers the trainee a real-time feedback of the needle tip position.

I. INTRODUCTION

Several diagnostic, therapeutic or interventional techniques (e.g. lumbar puncture, spinal anesthesia, or epidural catheterization) require the insertion of a needle into the patients spinal canal. Especially the last two mentioned are mostly carried out “blind” without any medical imaging modality. Paech et al. reported 12.71\% (1398) technical complications, including 3.2\% venous puncture and 0.6\% dural puncture in patients who received thoracic epidural catheterization (n = 10995)\cite{1}. The learning curve of these techniques shows a strong initial increase of the success rate up to 60\% after the first 20 attempts\cite{2}. One efficient way of improving medical skills is by allowing mistakes and learning from them\cite{3}. On the other hand, learning an intervention directly on the patient (hands on) only under the supervision of a clinical professional can lead to major complications\cite{1},\cite{4}.

A safe training environment is provided by surgical simulators. During training on a simulator, medical novices are allowed to make mistakes, to learn from them, to gather new information and to acquire surgical skills. Hybrid simulators combine a physical patient phantom with an intelligent quantificational component. Such hybrid simulators for the training of epidural or spinal anesthesia are highly demanded\cite{5}.

In our previous study, artificial structures used in a simulator for epidural needle insertion and lumbar puncture, were discussed. The haptic feedback provided by penetrating the phantom block with an 18 gauge Tuohy needle was compared to literature data and validated by clinical professionals\cite{6}.

The aim of this study was to design and develop a hybrid, low-cost simulator consisting of a smart patient phantom with sensor layers and a custom-made embedded circuit design including software. The simulator combines the benefits of realistic force feedback during needle insertion, direct visual feedback for the trainee (e.g. the position of the needle tip) and quantified recording of the needle trajectory over time.

II. MATERIALS AND METHODS

A. Design and Development of the Patient Phantom

A patient phantom was developed including three adjacent vertebrae surrounded by soft tissue-like structures mimicking the human lumbar region. In the human spine the ligamentum flavum connects the vertebral arches while the interspinous ligament stretches between the spinal processes of each adjacent vertebrae. The dorsal ends of the spinal processes are connected with the supraspinous ligament. To imitate these soft tissues, materials with tailored properties were used\cite{6}–\cite{10} and arranged as seen in Fig. 1.

First, the basic structure including artificial vertebrae, ligamentum flavum and surrounding soft tissues, like muscles and connective tissues, was manufactured. This was...
performed by using two custom-made casting molds (mold A and B). The basic structure was formed by three artificial vertebrae connected by a substitute for the spinal canal (silicone tube, Treske, Berlin, Germany). The vertebral section was fixed in polyurethane rubber (PMC 770, SmoothOn, Pennsylvania, USA) cast in mold A (see Fig. 2A). After curing the fixed vertebral section was exerted from mold A and placed in mold B (see Fig. 2B), where the first part of the artificial muscle and the connective tissue was molded (Ecoflex 0030, SmoothOn, Pennsylvania, USA and 50wt% silicone oil (AP 100, Wacker Chemie, Stuttgart, Germany)). After a curing time of 16h the block was removed from the casting mold, rotated by 180° and inserted in mold B again. The second part of the artificial muscle and connective tissue was cast with the same material combination. This molding process left a gap for the artificial ligamentum interspinale and the ligamentum supraspinale (see Fig. 2C).

In a second step, silicone layers for the artificial interspinous ligament and the supraspinous ligament were added. All three artificial ligaments were separated by thin electrically conductive sensor layers (see Fig. 1). A conductive sensor layer (S3) positioned on top of the artificial ligamentum flavum recognized the transition of the needle tip from the interspinous ligament to the ligamentum flavum. The 2mm thin sensor layer consisted of individual small areas between adjacent vertebrae (see Fig. 2E). A filament coil connected the sensor areas in the intervertebral regions and served as electrical connector (see Fig. 2D). Mixing 2wt% chopped carbon fibers (3mm, R&G GmbH, Waldenbuch, Germany) into a silicone matrix (Ecoflex 0030, SmoothOn, Pennsylvania, USA) resulted in a conductive material. Adding 10wt% silicone oil (AP 100, Wacker Chemie, Stuttgart, Germany) reduced the friction coefficient and led to an appropriate haptic feedback. The interspinous ligament was molded on top of the partially cured sensor layer to achieve a tough interface between the two silicones (see Fig. 2F). The artificial interspinous ligament consisted of a silicone elastomer (Dragonskin 20A, SmoothOn, Pennsylvania, USA) and 33wt% silicone oil (AP 100, Wacker Chemie, Stuttgart, Germany) to adapt the friction coefficient between the inserted needle and the artificial tissue. A further conductive sensor layer (S2) was positioned between the interspinous and the supraspinous ligament directly on top of the spinous processes to detect the penetration of the needle tip into the interspinous ligament. The 2mm thin sensor layer was manufactured and applied in the same way as sensor layer S1. Again, a filament coil embedded in the sensor layer served as connector. The thin sensor layer left enough space to accurately place the fiber reinforced supraspinous ligament in the gap between the dorso lateral muscles (see Fig. 2G). The ligamentum supraspinale was designed according to the work of Esterer et al. [6].

A top layer covered the patient phantom and mimicked the human skin (see Fig. 2H). The top layer consisted of two conductive sheets separated by the insulating layer (Dragonskin 20A + 50wt% AP 100) and covered by the artificial skin (Dragonskin 20A). The conductivity of the two sheets was achieved by combining Ecoflex 0030 and 30wt% silicone oil with 9wt% carbon nanoparticles (Black Pearl 2000, Cabot Corporation, Boston, USA). Individual fabrication of artificial skin and supraspinous layers resulted in the benefit of interchangeable skin and supraspinous layers.

B. Circuit Design

The block diagram in Fig. 3 shows the schematic design of the evaluation circuit.

The signal input and data communication with the Bluetooth module and display was managed by an MCU (Atmel ATMega8L, Atmel Corporation, California, USA).

A Bluetooth 4.0 module (BC127, Blue Creation, Cambridge, United Kingdom) enabled wireless transfer of data via
Fig 3. Block diagram of the circuit design consisting of a microcontroller unit (MCU), a Bluetooth module, a display, a signal preprocessor and a power supply.

Fig 4. Schematic design of the preprocessor with pull-down resistors and resistance of the conductive path connecting voltage feed and sensor layers (S1-S3) by inserting the needle.

C. Verification Measurement

To verify correlation between sensor signals and the needle insertion force, both were recorded time synchronized (with an accelerometer) versus the insertion depth. The phantom block was positioned in a testing machine (Z005, Zwick GmbH, Ulm, Germany) and an 18 gauge Tuohy needle was mounted on a clamping device (see Fig. 5). Insertion force measurements were performed according to Esterer et al. [6] at a constant feed rate of 1mm/s and a maximum insertion depth of 45mm. The needle insertion was repeated for 12 times at different locations aiming for the penetration of the ligamentum flavum. The maximum forces of the supraspinous ligament and the ligamentum flavum were tested for normal distribution with the Shapiro-Wilk Test with a significance level of 5%.

Fig 5. Phantom block (1) positioned in a testing machine with a 5kN force sensor (4) penetrated by a Tuohy needle (2) mounted on a clamping device (3). Circuit design with the LCD on top (5).

III. RESULTS

A. Patient Phantom Development and Circuit Design

The improved smart patient phantom shown in Fig. 2H combined three artificial vertebrae, ligamentum flavum, ligamentum interspinale, ligamentum supraspinale, skin muscle and connective tissue. The sensor layers (S1-S3, see Fig. 1) between the artificial tissues enabled a discrete localization of the needle tip in the patient phantom. A circuitry was designed to interpret the signals from the patient phantom, to display them on an LCD, to transfer them via Bluetooth 4.0 and to record them on a workstation.

B. Verification Measurements

The penetration force of the needle into the patient phantom at a constant feed rate of 1mm/s and the sensor signals are depicted in Fig. 6. The maximum forces for the supraspinous ligament and the ligamentum flavum were normal distributed (p = 0.031* and p < 0.001*, respectively), thus mean and standard deviations were calculated. The average maximum forces were 6.9 ± 1.0N and 14.9 ± 2.1N (n = 12).

After 12 epidural needle insertions into the simulator the detection of the needle tip position with the sensor layers (S1-S3) was fully functional. Due to the number of needle perforations the force feedback of the artificial ligaments significantly decreased (see outliers in Fig. 6).
Fig 6. Upper chart: force over insertion depth, with boxplots of force of the artificial supraspinous ligament and ligamentum flavum; mean values of the force peaks are indicated by a pink asterisks; outliers are shown by red crosses; vertical lines indicate the rising edge of the three sensor signals (S1-S3). Lower charts: signals from the sensors S1- S3 versus insertion depth.

### IV. DISCUSSION

We here present a hybrid, low-cost simulator for epidural needle insertion that enables determination of the needle tip position in real-time. The simulator is able to detect whether or not the needle tip is inserted, and when it penetrates the ligamentum flavum to account for patient-specific variances.

Several conductive elastomers were tested to implement the sensor layers within the present study. Whereas carbon nanoparticles incorporated into a silicone matrix exhibit a rather high resistance of approximately 10-150kΩ with a distance of 1cm for the contact. Silicone layers containing carbon fibers are readily fabricated with a lower resistance of 100-300kΩ.

Force feedback measurements indicated that the conductive sensor layers do not significantly contribute to the needle insertion forces and hence do not adversely influence the authentic haptics of the artificial ligaments. Such elastomer sensor layers may thus also prove suitable for various needle insertion training devices like Kyphoplasty and vertebroplasty simulators.

Future research will focus on including the detection of epidural space penetration and cerebrospinal fluid to simulate dura penetration and leakage to reflect training success. Our design already features exchangeable artificial skin and ligamentum flavum to account for patient-specific variances (e.g., age, obesity).

Perforational wear now requires periodic replacement of the exchangeable parts (skin, supraspinous ligament, ligamentum flavum). The force outlier for the ligamentum flavum can be explained by a penetration of the needle into an already existing hole. We here plan to employ self-healing materials to further increase the lifetime of the hybrid, low-cost epidural anesthesia simulator. These materials prevent the artificial structures from wear out and enable a higher number of epidural procedures.

In conclusion, our study verified, that the insertion of sensor layers did not influence the force feedback of a patient phantom. Further it could be demonstrated, that these structures enable the recording of the needle tip position. The assembly of the extended patient phantom and an electrical circuitry resulted in a hybrid, low-cost epidural needle insertion simulator with visual anatomical feedback for the trainee.

### ACKNOWLEDGMENTS

The Research Group for Surgical Simulators Linz (ReSSL) acknowledges the financial support by the Austrian Research Promotion Agency (FFG) project number 851479 as well as from the program “Innovative Upper-Austria 2020”. The authors would also like to thank the Clinic for Anaesthesiology and Intensive Care, Kepler Universitätsklinikum Medizinische Universität Linz, Austria for the successful cooperation and support. The Department of Soft Matter Physics is grateful for the financial support by ERC within the Advanced Investigators Grant “Soft-Map”. M. Kaltenbrunner acknowledges funding through the LIT startup Grant LIT013144001SEL.

### REFERENCES


学霸图书馆

www.xuebalib.com

本文献由“学霸图书馆-文献云下载”收集自网络，仅供学习交流使用。

学霸图书馆（www.xuebalib.com）是一个“整合众多图书馆数据库资源，提供一站式文献检索和下载服务”的24小时在线不限IP图书馆。

图书馆致力于便利、促进学习与科研，提供最强文献下载服务。

图书馆导航：

图书馆首页 文献云下载 图书馆入口 外文数据库大全 疑难文献辅助工具