30th Annual International IEEE EMBS Conference
Vancouver, British Columbia, Canada, August 20-24, 2008

Epidural Insertion Simulator of Higher Insertion Resistance & Drop Rate after Puncture

K. Naemura, A. Sakai, T. Hayashi, H. Saito*
School of Bionics, Tokyo University of Technology, Tokyo, Japan
*Unisis Corporation, Tokyo, Japan

Abstract— **Accidents such as dural puncture remain one of the problems of epidural anesthesia, and unskilled doctors can repeat such accidents. The purpose of the current research was to provide a new simulator for epidural insertion training. No reference data regarding the resistance force used when inserting a needle into patients have been reported. A comparative study was conducted to aid in the development of a new simulator. Pork loin (n=5) were employed as a substitute for patients. Thickness was set at 2 cm so as to improve the reproducibility. The authors took the conventional simulator apart, and picked a block as an analogue of muscle and ligamentum flavum. A new simulator was made of a melamine foam resin block and a latex rubber sheet. An epidural needle fixed on a motorized stage was inserted at the speed of 2 mm per second. The reaction force was measured while the needle was inserted into each specimen. Waveform of the pork loin exhibited two slopes of different inclines up to peaks and then falls after puncture. The conventional simulator showed a simple increase up to peak and a slow fall after puncture. In contrast, the new simulator showed two slopes up to peak and then a sudden fall after puncture. The insertion resistances were 2.5 N/s for the porcine, 0.8 N/s for the conventional and 2.1 N/s for the new simulator. The drop rates were 5 N/s for the porcine, 0.6 N/s for the conventional and 24 N/s for the new simulator. The higher insertion resistance and drop rate for the new simulator than the conventional simulator will be suitable for epidural insertion training.**

Keywords **resistance force, drop rate, porcine specimen, melamine foam, latex rubber**

I. Introduction

Epidural anesthesia is a regional pain relief operation. Anesthesiologists insert a needle into the epidural space from the patient's back. The epidural space is located between the ligamentum flavum and the dura mater. The dura mater covers the central nerve. If a doctor fails to stop insertion after reaching the epidural space, the sharp needle tip can damage the dura mater (dural puncture). Accidents such as dural puncture remain one of the problems of epidural anesthesia, and unskilled doctors can repeat such accidents. Therefore, a simulator to aid in epidural insertion training epidural insertion is essential to reduce the rate of dural puncture. Dang et. al. have developed a computer-based simulator [1]. Feedback from the Phantom haptic interface device mimics interactions between the needle and bones or tissues. One reported shortcoming of the Phantom haptic interface device, however, is that it does not allow the user to control the orientation of the needle. In addition, the Phantom haptic interface device is too expensive for the entire system to be implemented in every hospital. In contrast, Daykin [2] has reported an epidural injection simulator for use as a teaching aid. In this simulator, resistance to needle advancement is simulated by two spring-loaded friction plates. The first has only light spring loading and represents the resistance encountered when pushing a needle through supraspinous and interspinous ligaments. The second has adjustable spring loading and represents the resistance against the ligamentum flavum. Langton et al. [3] have compared pressures exerted during insertion of lumber epidurals in obstetric patients with those obtained from the simulator. Although they reported no difference between the pressures obtained with the simulator and those measured in vivo, the data compared were only the maximum values. Details regarding the pressure pattern remain unclear.

Another simulator [4] is now commercially available. This simulator primarily mimics the anatomical orientation and softness of the tissue. No data regarding the insertion resistance of the conventional simulator have been reported. Furthermore, no reference data regarding the resistance force used when inserting a needle into patients have been reported. The purpose of the current research is to develop a new insertion simulator, which exhibits similar resistance to porcine meat and bone.

II. Methods

A comparative study was conducted to aid in the development of a new simulator. Porcine meat and bone (n=5) were employed as a substitute for patients. Pork loin from a slaughterhouse had excessive fat compared with human. Thickness was set at 2 cm by trimming the excess fat and muscle, so as to improve the reproducibility of the reaction force waveforms. Figure 1 shows a photo of the test piece. The needle is inserted between two vertebral bones.

The authors took the conventional simulator apart and picked a block as an analogue of muscle and ligamentum flavum (Fig.2). The thickness of the block was 2 cm, the same as the porcine specimen. The block was made of an elastic material. The hardness was highest compared to another skin or fat analogue.

A new simulator was made of a melamine foam resin block and a latex rubber sheet (Fig.3). The thickness of the melamine block was 5 mm, and that of the rubber was 2 mm.

The melamine block was commercially available for florist shops as a water-absorbing sponge. Weights of 2.4 grams were used to pull the rubber sheet to provide tensile force.

Details of the experimental setups were the same as those reported previously [5][6]. In short, an epidural needle and a load cell (LMC-21023, Nissho Electric Works, Tokyo, Japan) were fixed on a motorized stage (SGSP 26-50, Sigma Koki, Tokyo, Japan). A Tuhoy-type needle of 18 Gauge was employed. The insertion speed was 2 mm per second. The reaction force was measured while the needle was inserted into each specimen. Force waveforms were recorded by a sampling frequency of 16 Hz by a data recorder. The interval of each data was 0.0625 seconds. Figure 4 shows an experimental view of inserting a needle into a pork loin. A CCD camera recorded the images around the ligamentum flavum.

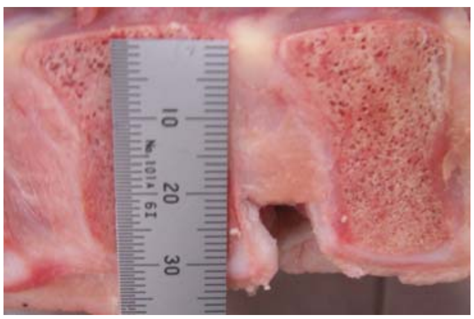


Fig.1 Pork loin after trimming excess fat and muscle

Fig.2 Analogue of muscle & ligamentum flavum of the conventional simulator

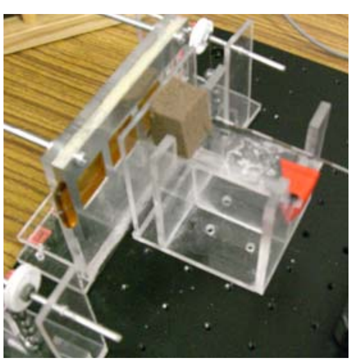


Fig.3 New simulator consisted of melamine foam & latex rubber.

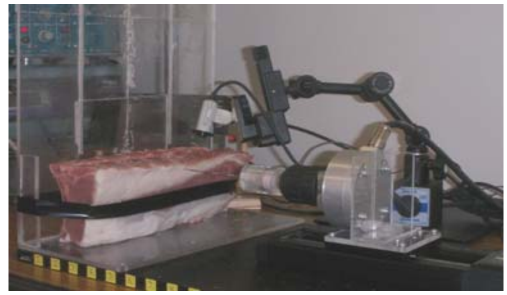


Fig.4 Experiment in inserting needle into a pork loin

III. Results

The insertion force was measured five times for each porcine specimen. Waveforms were averaged to clarify the characteristics. Averaged waveforms are shown in Fig. 5. Waveform of the pork loin exhibited two slopes of different inclines up to peaks and then falls after puncture. The first slope from 0 to 4 seconds was observed when the needle tip passed through a fatty or muscular layer. Within such a layer, the needle can easily break. Second slope after 4 seconds corresponded to the needle tip inside the ligamentum flavum. Figure 6 shows the CCD image before and after needle puncture. The surface of the ligamentum flavum was extended by the needle.

Compared with the porcine data, the conventional simulator showed a simple increase up to peak and a slow fall after puncture. In contrast, the new simulator showed two slopes up to peak and then a sudden fall after puncture. The first slope was observed when the needle tip was located in the melamine foam block. The second slope was measured when inserting the needle into the latex rubber sheet.

To compare the three specimens quantitatively, two parameters were calculated from the waveforms. One was the insertion resistance and the other the drop rate. The insertion resistance was defined as the second slope of the porcine and new simulator, and as the one slope of the conventional simulator. The drop rate was defined as the decrease from peak occurring over 0.1 seconds. Figure 7 summarizes the results. The insertion resistances were 2.5 N/s for the porcine, 0.8 N/s for the conventional and 2.1 N/s for the new simulator. The drop rates were 5 N/s for the porcine, 0.6 N/s for the conventional and 24 N/s for the new simulator. The higher insertion resistance and drop rate for the new simulator than the conventional simulator will be suitable for epidural insertion training.

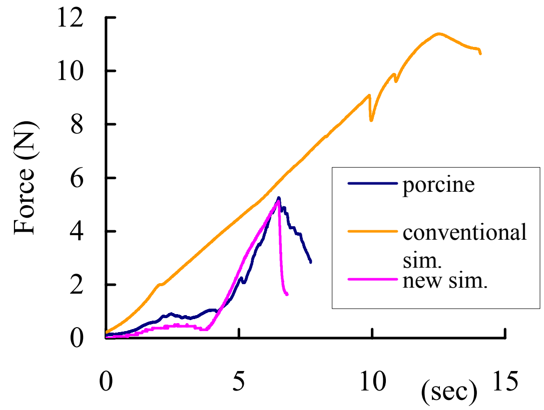
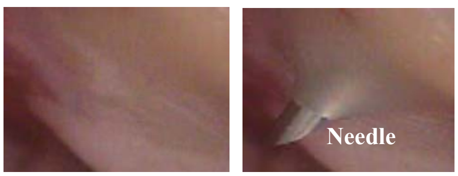


Fig.5 Averaged waveforms of the reaction force against time.



Before After

Fig.6 Images of surface of the ligamentum flavum before and after needle puncture

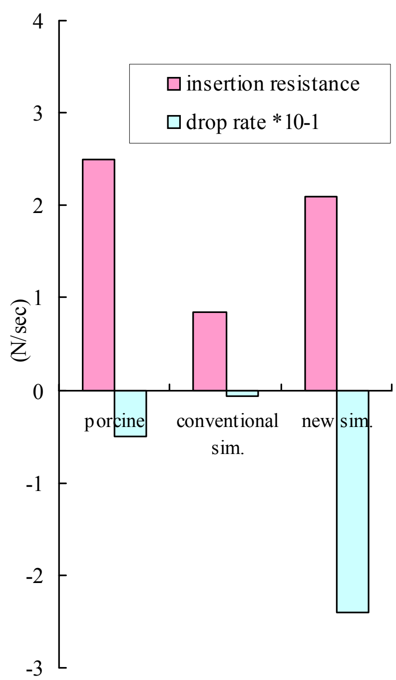
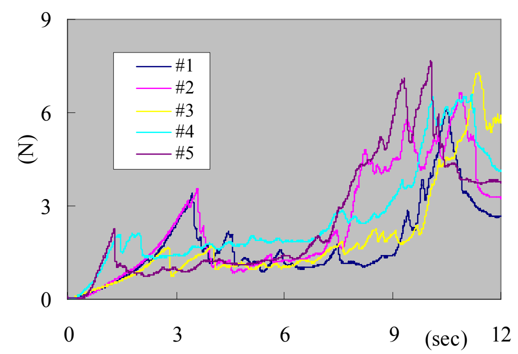


Fig.7 Comparison of insertion resistance up to peak & drop rate after puncture.

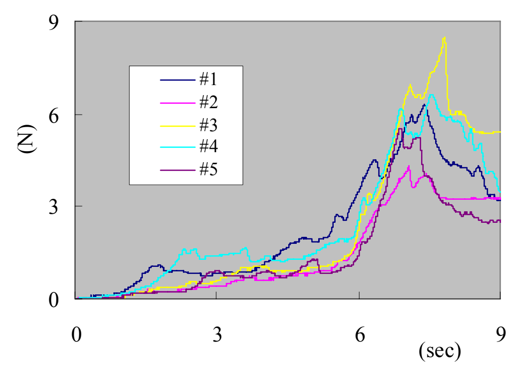
IV. Discussion

A. *Preparation for the porcine specimen*

In this study, the thickness of the porcine specimen was set at 2 cm by removing excess fat and muscle. Five measurements were made for each specimen. Figure 8 shows raw data measured for two other specimens. One was measured without removing excess fat and muscle (i), while for the other the fat and muscle were removed (ii). The coefficient of correlation for waveforms in the (i) condition was 0.79, and that in the (ii) condition was 0.92. Reproducibility of data was improved.



(i) without removing excess fat and muscle



(ii) specimen of 2 cm thickness

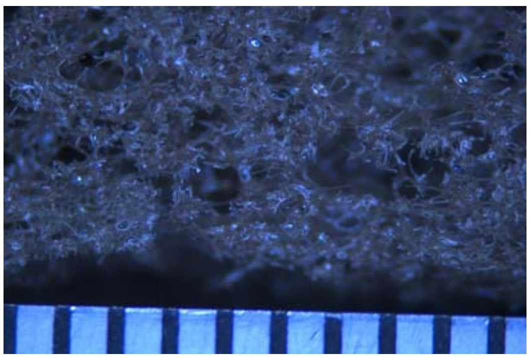
Fig.8 Raw data measured during inserting needle into a pork loin

B. *Comparison of the porcine data with literature reports*

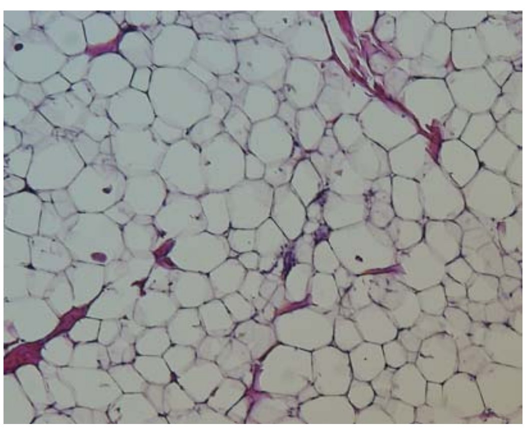
Brett et al. [7] have tested needle insertion into porcine samples. They reported that the typical force response shows the two peaks corresponding to important tissue interfaces. One peak force corresponded to the needle penetration of the supraspinous ligament. The second peak of 15 N was experienced as the needle penetrated the ligamentum flavum. The constant value observed between the two peaks represents the needle penetrating through muscle fiber. Figure 8 (i) shows the same force pattern. The first peak diminished after removal of the excess fat and muscle. The value of the second peak was less than 9 N. This difference is due to the needle diameter. Brett used a 16-gauge needle (outer diameter of 1.6 mm), while in our study an 18-gauge needle (outer diameter of 1.2 mm) was used. The smaller diameter needle exhibited less resistance to insertion. Hiemenz et al. [8] measured force vs. displacement curves for an 18-gauge Tuohy needle, and a canine specimen. The peak force was reportedly 10 N, which corresponds to our current data.

C. *Structure of the melamine foam*

The new simulator consisted of melamine foam and latex rubber. Figure 9 (i) shows a microscopic view of the melamine foam. Many holes were observed. The reduced insertion resistance was due to these holes. In contrast, hematoxylin-eosin staining of the porcine specimen showed the structure of the tissue. Figure 9 (ii) shows a fatty tissue. The sphere- filled structure and the low elasticity of the fat result in a reduced insertion resistance.



(i) melamine foam



(ii) porcine fatty tissue

Fig.9 Microscopic view of the melamine foam & the porcine fatty tissue

V. Conclusion

The needle insertion resistance of the new simulator showed the same pattern as that measured in the porcine loin. In a future study, we will ask medical doctors to use the new simulator and to determine whether the insertion resistance is similar to that observed clinically.

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