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Effect of the Needle Tip Height on the Puncture Force in a Simplified Epidural Anesthesia Simulator

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Abstract **The purpose of the research is to create a safer needle used for epidural anesthesia. Medical doctors identify the location of the epidural space by feeling the drop of force in advancing the needle tip. A greater drop of force makes for a safer needle. The force pattern can be determined according to the tip shape. In this study, the effect of the height of the needle was examined. We fabricated two needles with 18-gauge diameters (1.2 mm). The shape of the needle tip was measured by X-ray computed tomography. One was 1.86 mm in height (A); the other was 1.4 mm (B). Both had tip angles that were the same: 27 degrees. A simplified simulator consisted of a motorized stage, a load cell, and a phantom as a substitute for the ligamentum flavum before the epidural space. The reaction force was measured while the needle punctured a silicone rubber (a hardness of 50 Hs in reference to ISO7619), and a porcine bone. The speed of insertion was set at 2, 4, and 8 mm/s. The results showed that the force increased up to the highest edge of the needle as it passed the phantom. The drop in the force was measured at all insertion speeds and in both the rubber and bone. The A needle observed twice the drop in force compared with the B needle. We found no obvious tendency regarding the effect of the insertion speed. The drop in the force in the rubber was one-fourth greater than that in the bone. Our conclusions are that 1) the higher the needle tip design, the greater the drop in force can be achieved; and that 2) silicone rubber with a hardness of 50 Hs is similar to the ligamentum flavum.**

Keywords **Needle design, Force analysis, Comparative phantom study, Porcine bone**

I. Introduction

Epidural anesthesia as a regional pain relief is used in more than 40% of all surgeries. The surgeries include obstetrics, child surgery, orthopedics, dermatology, urinary-organs surgery, and heart and blood vessel surgery. Moen surveyed severe neurological complications after epidural and spinal blockades in Sweden in 1990-1999 [1]. Seventy-one complications occurred in 450,000 cases of epidural anesthesia. In general, more complications have been found than expected. One of the reasons for the complications is the dural puncture.

Based on the resistance felt in inserting the needle in a patient's back, anesthesiologists search for the narrow "epidural space." Due to the difficulty of the insertion technique, low-skilled doctors often do not introduce the needle tip into the epidural space [2]. In order to prevent a dural puncture, a safer needle is required. Medical doctors identify the location of the epidural space by feeling a drop in force in advancing the needle tip. A greater drop in force makes for a safer needle. A force analysis can satisfy this requirement. The author has already reported a comparative phantom study on the resistance in inserting clinical needles manufactured by six companies [3][4]. The tip length is related to the peak force and the time required for the drop of force to begin. No results on the value of the drop in the force were obtained, because the tip angles, heights and the outer diameter of the needles were completely different.

The purpose of the current study was to examine the effect of the height of the needle on the drop in force. Two needles of different height but having the same tip angle and outer diameter were fabricated. The needles punctured a silicone rubber and a porcine bone as substitutes for the ligamentum flavum. The relationship between the force waveforms and the tip shape are discussed.

II. Methods

A. Tested Needles

We fabricated needles of 18-gauge diameters (with an outer diameter of 1.2 mm). The shape was measured by micro-focus X-rays computed tomography (Presto-90, Uni-Hite System, Kanagawa, Japan). The tube voltage was 90 kV. The tube current was 110 micro-amperes. The resolution of the images was 0.032 mm per pixel. The interval of each image was 0.032 mm. The needle was shown as white in each image. As shown in Figure.1, the area and circumference length of the white area was measured using the automatic function of image-processing software (Image-Pro PLUS, Media Cybernetics, MD, USA).

B. *Simplified Epidural Anesthesia Simulator*

We measured the axial force by a strain gauge type sensor (LMC-21023, Nissho Electric Works, Tokyo, Japan). The rated force of the sensor was 100 N. The tested needle was attached to the sensor with an acrylic attachment, and it was fixed on a one-axis motorized stage (SGSP 26-50, Sigma Koki, Tokyo, Japan). Insertion speeds were set at 2, 4, and 8 mm/s in reference to a previous study [5]. Force waveforms were recorded by a sampling frequency of 16 Hz by a data recorder. The interval of each data was 0.0625 seconds. The needle tip location was defined as zero when the needle tip reached the surface of the phantom and the reaction force began to increase. The tip location was calculated by multiplying the insertion speed and the interval of data (0.0625 seconds).

A piece of silicone rubber (IS-825, Irumagawa Rubber, Tokyo, Japan) and a porcine bone were employed as phantoms. The hardness of the silicone rubber was 50 Hs (ISO7619), and its thickness was 3 mm. The porcine bone from a slaughterhouse was cut by sagittal section, and the dura matter was removed. Figure 2 shows a top view of the experiment using the porcine bone. We cut the layer of fat and muscle attached to the bone. The needle punctured only the ligamentum flavum.

The silicone rubber was punctured ten times at different locations. The porcine bone was punctured twice. The average waveforms of each phantom were calculated.

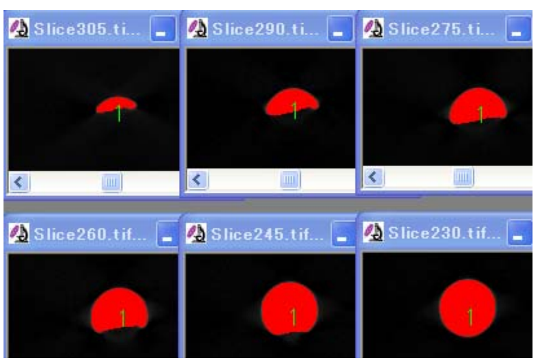


Fig. 1 Measurement of the area and circumference length of the cross section of the needle

Fig. 2 Simplified epidural anesthesia simulator. The needle punctures a porcine bone.

III. RESULTS

A. *Shape of the Tested Needles*

Measured data are shown in Figure 3. One is for a needle with 1.86 mm height (named needle A); the other is for a needle with 1.4 mm height (needle B). Both of the tip angles were the same: 27 degrees. The tip length of needle A was shorter than that of needle B.

Figure 4 shows a comparison between the cross-sectional area and the circumference length of the needle from its tip. Differences in the peak value were negligible. The cross-sectional area of the needle A was 0.06 mm^2 larger than that of the needle B. The circumference length differed by only 0.06 mm.

B. *Drop of Force*

Figure 5 shows the relationship between the measured reaction force and the calculated needle tip location. The reaction force increased up to 4 mm of the tip location. Slopes up to 2 mm were the same for both needles A and B, which meant the tip angles of the needles were the same. After reaching the peak value, a gradual decrease in the force was observed. From the tip location of 7 mm, the force showed a nearly constant value. We defined an inclination of drop for each insertion speed as the force from the peak to the constant divided by the insertion length. The absolute value was calculated. Figure 6 summarizes comparisons between insertion speeds and the phantoms. Needle A showed a value twice that of needle B. No obvious tendency regarding the effect of the insertion speed was found. The inclination of drop in the rubber was one-fourth greater than that in the bone.

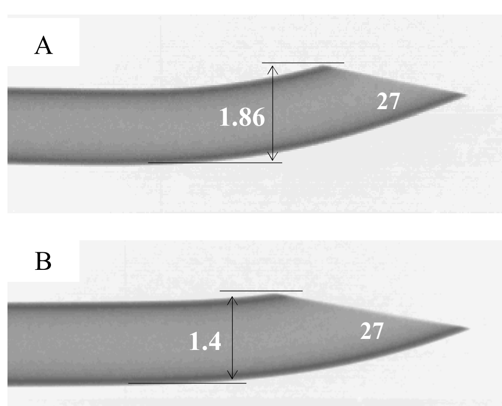


Fig. 3 X-ray image of the compared needles. Height in mm and the tip angle in degrees are shown.

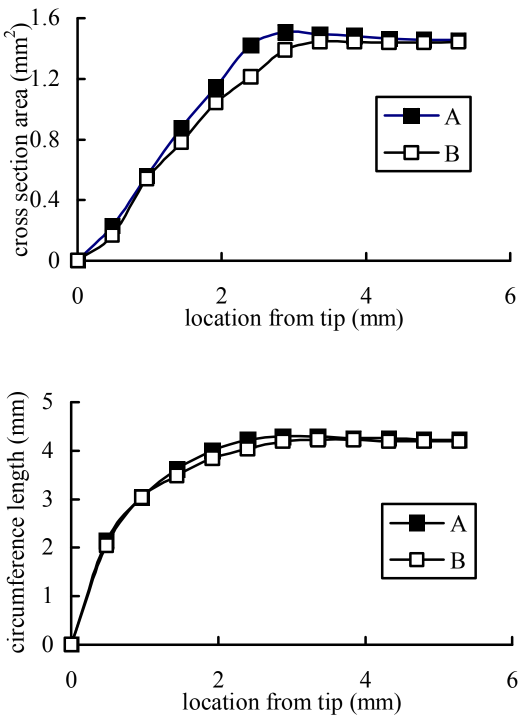


Fig. 4 Graphs show a comparison between the cross-sectional area and the circumference length from the tip of the needles.

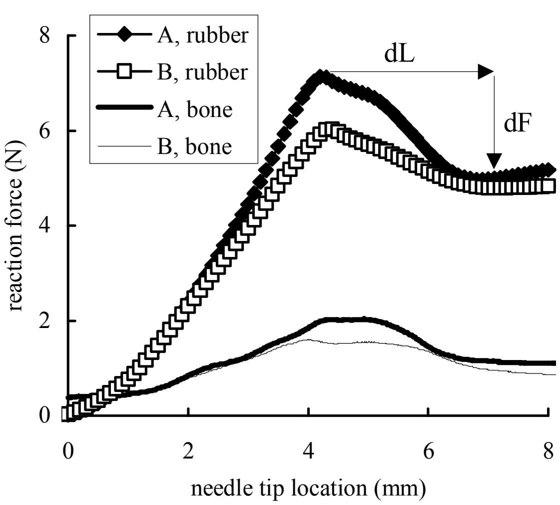


Fig. 5 Relationship between the reaction force and the needle tip location. The inclination of drop is defined as the absolute value of dF divided by dL.

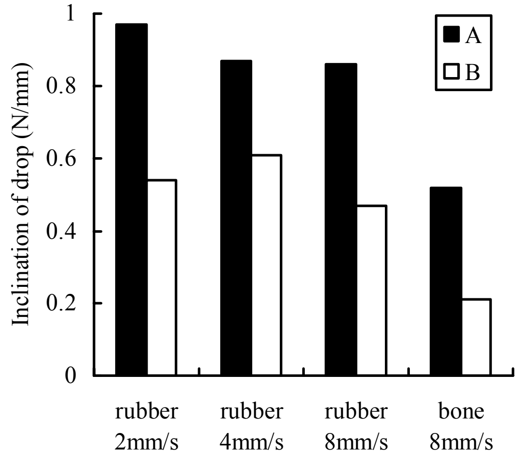


Fig. 6 Comparison of the inclination of drop for insertion speeds and phantoms.

IV. DISCUSSION

Brett et, al. measured the reaction force against a porcine specimen [6]. We estimated the drop of force from their reported waveform. After entering the epidural space, a force of twelve N dropped during a 1.7 mm advance of the needle. Thus, the inclination of drop was calculated as 7 N/mm. Lechner et, al. measured the pressure during clinical epidural anesthesia [7]. They employed an acoustically-guided puncture system consisting of an infusion pump, a pressure transducer, and a loudspeaker. One of the results reported in their paper showed a pressure drop from 530 to 50 mmHg in 3 seconds. They used an 18-gauge needle, so the drop of force was estimated as 0.05 N when the inner diameter of the needle was 1 mm. The inclination of drop was not calculated due to a lack of information about the insertion speed. Currently, our results in Figure 6 show middle values in comparison with former research [6][7].

Figure 7 shows the ten waveforms measured in puncturing the silicone rubber at the same insertion speed. Values for the first puncture always exceeded later punctures. To clarify the reason, the surface of a virgin needle and a punctured needle were observed by a scanning electron microscope (JSM7700F, JEOL, Tokyo, Japan). Conditions were set at 10 kV and 2.562 nA. As shown in Figure 8, no obvious difference was found on the surface. A composition analysis indicated an increase in silicone after the puncture (Table.1). The material of the needle was stainless steel (SUS304). Composition of Si in the SUS304 was less than 1%. The silicone coating may have reduced the resistance to the insertion.

We conclude that 1) the higher the needle tip design, the greater the drop in force achieved; and that 2) a silicone rubber with a hardness of 50 Hs is similar to the ligamentum flavum. Future studies need: 1) to model the phenomenon observed in this experiment in order to explain the effects of the tip shape and the punctured material, and 2) to determine the difference between the rubber and bone by examining other materials.

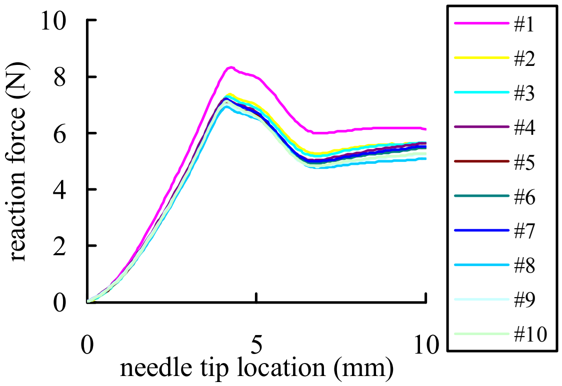
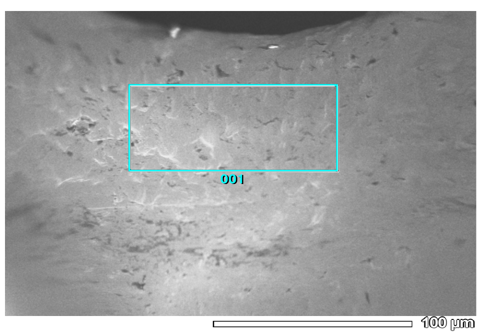
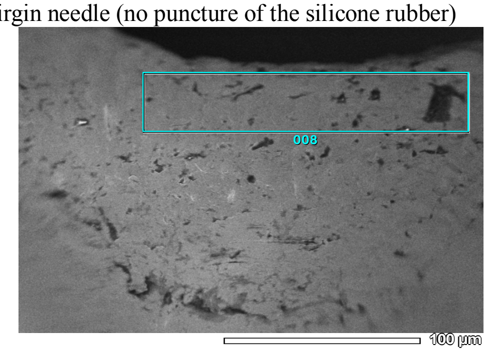


Fig. 7 Ten waveforms measured in puncturing of the silicone rubber at the same insertion speed (2 mm/s).



(i) virgin needle (no puncture of the silicone rubber)



(ii) needle after puncture of the silicone rubber

Fig. 8 Scanning electron microscopic image of the needle surface.

Table 1 Comparison of the composition analysis for Si

	Mass %	Atom %
Virgin needle	0.49	0.76
Punctured needle	1.04	1.3

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