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Comparative Phantom Study on Epidural Anesthesia Needle

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Abstract **The purpose of the current study was to evaluate the clinically used epidural anesthesia needles based on quantitative comparative data. Precise measurement of the tip shape and puncture force analysis were conducted on six different needles. Tip angle (α+β) and tip length (L) were measured by X-ray computed tomography (CT). The one-axial puncture force through a silicone phantom (thickness of 3 mm) was obtained by a load cell. The speed was set at 4 mm/s, which equals the average of anesthesiologists' technique. The needle punctured twice at the same position to separate cutting and friction force. The X-ray CT revealed that 1) the α+β ranged from 27.5 degrees to 38.8 degrees (average of 33.8 degrees), 2) the higher α+β resulted in the lower L (ranges from 2.13 mm to 3.27 mm; average of 2.62 mm), and 3) the most popular needle was the one with average tip angle and length (the α+β of 33.6 degrees, the L of 2.57 mm.). Puncture force analysis showed that 1) the peak value related the L (correlation coefficient of r2=0.65), and the most popular needle was the third-largest value, 2) the slope of increasing force related the α+β (correlation coefficient of r2=0.79), and 3) the averaged force to cut of the most popular needle was the second-smallest value, which means less resistance for cutting.**

Keywords **Epidural anaesthesia needles, Puncture force, Tip shape, Silicone phantom**

I. INTRODUCTION

Epidural anesthesia is one of the regional anesthesias used for abdominal surgery and for obstetric analgesia during labor. An anesthesiologist must place the needle tip at the epidural space precisely. The epidural space is a small area taken up mostly with large masses of fat and connective tissues [1], located between the dura mater surrounding the spinal nerve tissues and the tough ligamentum flavum. It is important to avoid the accidental puncture of the dura mater (dural puncture). Mulroy et al. reviewed the literature pertaining to the frequency of dural punctures and reported the frequency to be more than 0.6% [2]. Especially during residency, the epidural technique has a relatively frequent failure rate [3]. The incidence of epidural needle-induced post-dural puncture headache has been reported to range from 76% to 85% [4]. To avoid dural punctures, anesthesiologists have created several types of needles [5][6]. The long, sharp, curved-tip needles are widely accepted now. As shown in Fig. 1, the needles consist of a stainless pipe and a stylet. The stylet is withdrawn after the puncture of skin and fatty tissue. A syringe containing saline solution is attached to the needle and held under slight pressure. While the needle tip is within dense ligaments, saline solution does not pass through the needle. On entering the epidural space, however, resistance to the advancing needle decreases and the saline solution can be easily expelled from the syringe. This provides confirmation that the tip has been placed in the epidural space. A plastic catheter is then introduced instead of the syringe. The curved tip 1) lessens the pain of an injection, 2) decreases the risk of depositing plugs of skin into underlying tissues, and 3) allows direction of the catheter in the epidural space.

Manufacturers design the needle tip, defining angle α, angle β, and inner & outer diameters. No data are open from manufacturers. Surface polishing and the material of the stylet are contrived according to anesthesiologists' requests. An ideal needle for most anesthesiologists 1) punctures easily at first and gradually grows dull so one can avoid a dural puncture, 2) has greatly decreased resistance on entering the epidural space, 3) causes less damage to the tissues. Puncture force analysis can facilitate a solution for such exacting requests and provide some design criteria for the manufacturers and a selection guideline for the anesthesiologists. No studies have been made that compare the needles made by several manufacturers.

The purpose of the current study was to evaluate the clinically used epidural anesthesia needles by quantitative comparative data using a silicone phantom. We present here a new methodology for measuring the tip shape using X-ray computed tomography. Only two dimensional projection images can be obtained by a microscope. We need the digitized volume data and surface area of a needle tip.

II. METHODS

A. Tested Needles

We compared six 18 Gauge (unit for needle diameter, O.D. = 1.2 – 1.3 mm, I. D. = 0.79 – 1.041 mm [7]) clinical quality epidural anesthesia needles from six different manufacturers. The shape of the needle tip was defined as the angle (α+β), the length L, and the height H (see Fig.1). The diameter of the needle d1, d2 was also measured. Measurement was done by X-ray computed tomography (ScanXmate-C100SS, Comscantecno Co., Ltd., Kanagawa, Japan). This system is compact and is not intended for human measurement. Several two-dimensional computed images reconstruct three-dimensional (3D) data, and then a long-axis cross-section image was obtained from the 3D data (Fig. 2). Angles and lengths were defined and measured as shown in Fig. 3. The distance of the cross-section image was 17 µm.

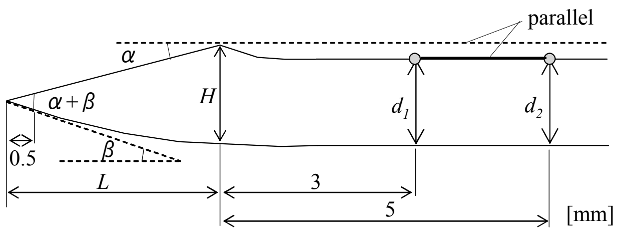

Fig.1 Definition of the tip shape parameters

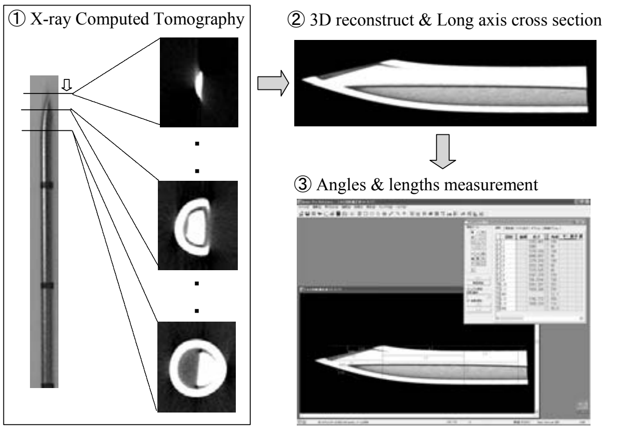

Fig.2 Precise measurement of the needle tip by X-ray computed tomography

B. Experimental Procedures

A one-axis motorized stage (SGSP26-50(X), Sigma Koki Co., Ltd., Tokyo, Japan) was employed. A load cell (LMC-21023, Nissho Electric Works Co., Ltd., Tokyo, Japan) was attached to a drill chuck with a tested needle. The rated force was set at 100 N, referring to Hiemenz [8] and Brett [9]. Axis force was recorded to a data logger. The stage motion and the recording were synchronized by the TTL (transistor-transistor-logic) signal from the stage controller. The sampling rate was 160 Hz, giving a resolution of 25 µm at 4 mm/s. The location of the needle was monitored by a slider-type variable resistance. The system configuration is summarized in Fig. 3.

C. Experimental Conditions

The silicone (IS-825, Irumagawa Rubber Co., Ltd., Tokyo, Japan) phantom was punctured with the needle at a speed of 4 mm/s, in accordance with the finding reported by Holton that the puncture speed by anesthesiologists ranged from 0.4 to 10 mm/s [10]. Thickness of the silicone phantom was 3 mm. Data were measured three times for each needle. Puncture force is the summation of the cutting and the friction forces [11] [12]. To separate the cutting and the friction, we had the needle puncture twice at the same position. The first puncture would represent both the cutting and the friction, and the second puncture would represent only the friction.

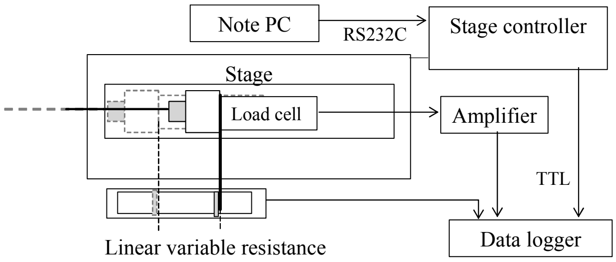

Fig.3 Schema of the experimental setups for the puncture force analysis

III. RESULTS

A. Shape of the Tested Needles

Figure 4 shows the angle α, β, and the tip angle (α+β). The angle α ranged from 8.6 degrees to 13.8 degrees (mean value of 11.5 degrees), whereas the angle β ranged from 16.7 degrees to 25 degrees (mean value of 22.3 degrees). The tip angle ranged from 27.5 degrees to 38.8 degrees (mean value of 33.8 degrees). Needles were given a number according to the tip angle. Figure 5 shows the d, the L, and the H. The measured d1 equaled d2 in all needles, so d = d1 = d2. Diameter d ranged from 1.27 mm to 1.36 mm (mean value of 1.32 mm). Length L ranged from 2.13 mm to 3.27 mm (mean value of 2.62 mm). Height H ranged from 1.25 mm to 1.36 mm (mean value of 1.32 mm). As the diameter of the needle is nearly equal, a higher tip angle resulted in a lower length L.

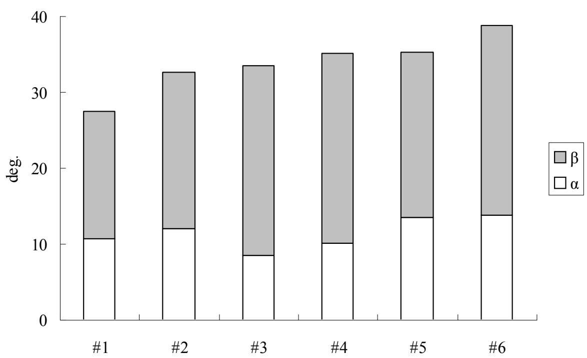

Fig.4 Comparison of the measured tip angles among the six different needles. #3 is the most popular needle.

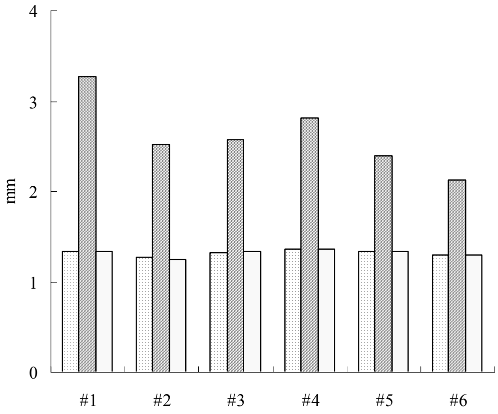

Fig.5 Comparison of the tip shape on *d*, *L* and *H* among the six different needles

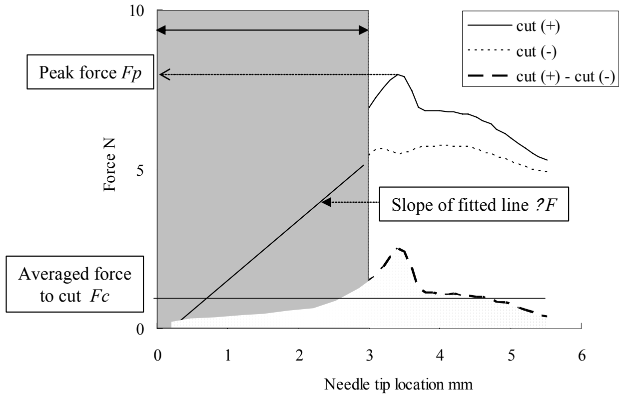

Fig.6 Typical puncture force curves and the explanation of the three parameters compared in this study.

B. Comparison of the Puncture Force

Typical force waveforms against the tip location are shown in Fig. 6. The needle tip started to puncture the phantom from the origin of the horizontal axis. The bold line (cut (+)) shows the first puncture. The dotted line (cut (-)) shows the second puncture in the same location. The force at the first puncture exceeded that at the second puncture. The broken line shows the result of calculation (cut (+) – cut (-)), which represents the force required to cut the phantom. The following three parameters were measured for each manufacturer: peak value at the first puncture (Fp), slope of the fitted line to the force curve inside the silicon phantom (ΔF), and averaged force to cut (Fc), as shown in Fig. 6.

Figure 7 shows the relation between the Fp and the L. The Fp increased for the longer L (correlation coefficient of r2=0.65). The most popular needle was that with the third-largest value, as shown in the broken circle. The ΔF against the α+β is shown in Fig. 8 at an insertion rate of 4 mm/s. Closed rectangles (cut (+)) represent the first puncture measuring both the cutting and friction force. Open rectangles (cut (-)) are the second puncture measuring only the friction. Large α+β resulted in higher ΔF (correlation coefficient of r2=0.79 in cut (+), r2=0.58 in cut (-)). Figure 9 shows the comparison of Fc. The most popular needle was that with the second-smallest value, which means less cutting force.

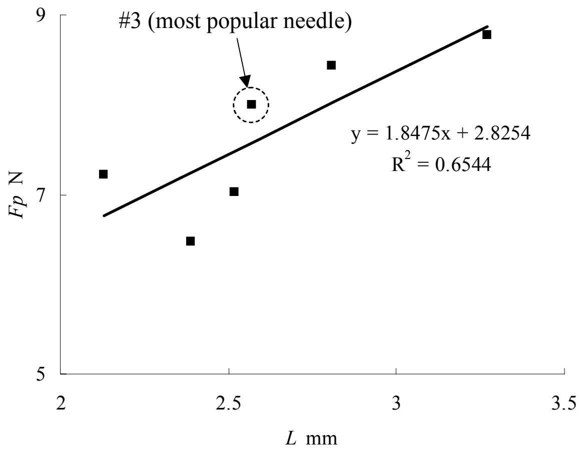

Fig.7 Relation between the peak force and the tip length

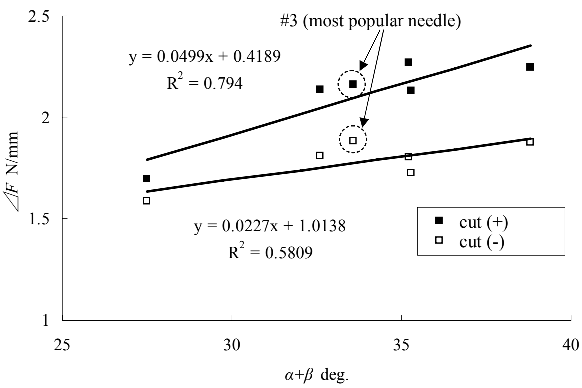

Fig.8 Relation between the slope of the fitted line to the force curve inside the silicon phantom and the tip angle at an insertion rate of 4 mm/s

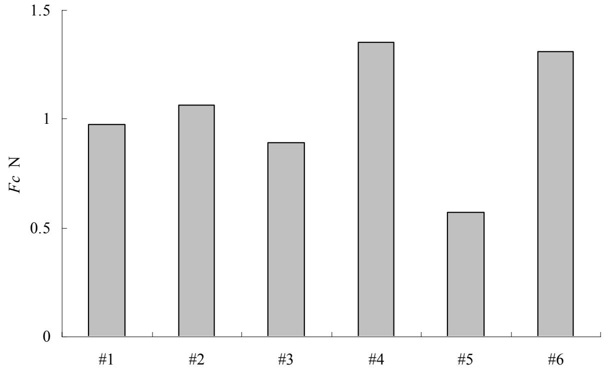

Fig.9 Comparison of the averaged force to cut among the six different needles

IV. DISCUSSION

Three parameters on the force curves were measured and compared in this study. The examined needles are listed in the order of lowest to highest on Fp, ΔF, and Fc (Table 1). Less Fp, ΔF, and Fc would give anesthesiologists the feeling of easy puncturing. Thus, the comparative experiment showed that the #5 makes the easiest puncture among the examined needles.

Table.1 Summary of the comparative data on the three force parameters

	Easy---------- puncture ------------Rigid					
Fp	**#5**	#2	#6	#3	#4	#1
⊿F	#1	**#5**	#2	#3	#6	#4
Fc	**#5**	#3	#1	#2	#6	#4

Anesthesiologists have no chance to compare among various needles, so there is no study to support the current result. We plan to interview anesthesiologists about how they perceive several different needles feel when making punctures.

In conclusion, the precise measurement of the tip by X-ray CT and the comparative phantom study on the puncture force clarified 1) the relation of the tip shape and the force curves, and 2) the preference in a list of six clinical quality needles. The most popular needle had average shape, and it did not show the lowest puncture force among the six needles. A future study will examine the effect of the puncture speed on the anesthesiologists' perceptions during puncturing.

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