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Original Article

In vitro stability analysis of the three-pronged Mayfield head clamp using pins in four different positions on the skulls

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Abstract: To investigate the stability of pins in different fixed positions on the skulls of cadavers to provide evidence for the proper application of the three-pronged Mayfield head clamp in posterior cervical spine surgery. The effects of changing pin positions and whether changing certain pin positions can improve the fixation position are still unknown. Three-pronged Mayfield head clamps were applied to 12 cadaveric heads. In group A (n = 6), three pins were inserted 2.5 cm above the apex auricle; in group B (n = 6), a single pin and double pins were inserted 2.5 cm and 3.5 cm above the apex auricle, respectively; in group C (n = 6), a single pin and double pins were inserted 3.5 cm and 2.5 cm above the apex auricle, respectively; and in group D (n = 6), three pins were inserted 3.5 cm above the apex auricle. The pins were screwed in to the skull with a pressure of 270 N (60 lbs). The biomechanical data were evaluated as a sign of the stability of skull fixation on the basis of the peak load at 3 mm of relative displacement obtained in compression or tensile tests. Biomechanical tests proved that applying pins 2.5 cm above the apex auricle could provide sufficient fixation to achieve basic head stability. Changing pin positions unilaterally resulted in no distinct differences in the compression and tensile test results. However, changing all pin positions to 3.5 cm resulted in the highest peak load and significant differences in the compression and tensile test results compared with the placement of all pins at 2.5 cm above the apex auricle. Our data indicated that positioning the pins at 2.5 cm above the apex auricle can theoretically ensure basic fixation of the head, although moving the pins up to 3.5 cm above the apex auricle can improve stability to satisfy the limited traction requirements of posterior cervical spine surgery.

Keywords: Pin stability, pin position, compression and tensile tests, peak load

Introduction

A three-pronged Mayfield head clamp is commonly used to maintain and stabilize the position of the head of a patient in posterior cervical spine surgical procedures. This device is already recognized as indispensable tool for the rigid and stable fixation of the skull using pins and a holder throughout the procedure. However, complications such as epidural hematoma, cerebrospinal fluid (CSF) rhinorrhea, scalp laceration and air embolism associated with fracture and/or penetration of the cranial vault can occur [1-4]. De Lorenzo et al. [5] demonstrated that these complications were related to displacements associated with the loads exchanged between the patient's head and restraint device.

Unlike brain surgery, in posterior cervical spine surgery, the Mayfield head clamp is used to not only maintain stability, but also specifically provide sufficient intraoperative traction during the treatment of cervical spinal fractures. This device maintains the slight extension of the cervical spine during open-door cervical laminoplasty, and the intraoperative adjustment of clamp assists with distraction reduction in basilar invagination and atlantoaxial dislocation [6, 7]. In clinical practices, a three-pronged Mayfield head clamp often requires the force provided by more pins to achieve a higher levels of stability and to avoid the potential of pin shifting. We have found that different pin positions result in different levels of stability. Intraoperative pins loosening and migration obviously decreases the safety of the spine surgery, and

Table 1. Baseline characteristics of cadaveric heads tested for groups A/D and groups B/C (Means ± SD)

	Heads for groups A/D	Heads for groups B/C	*P* value
Age	48.83±4.42	49.50±3.62	0.78
Head weight (kg)	3.60±0.17	3.65±0.22	0.64
Head circumference (mm)	57.77±0.99	57.97±0.79	0.71

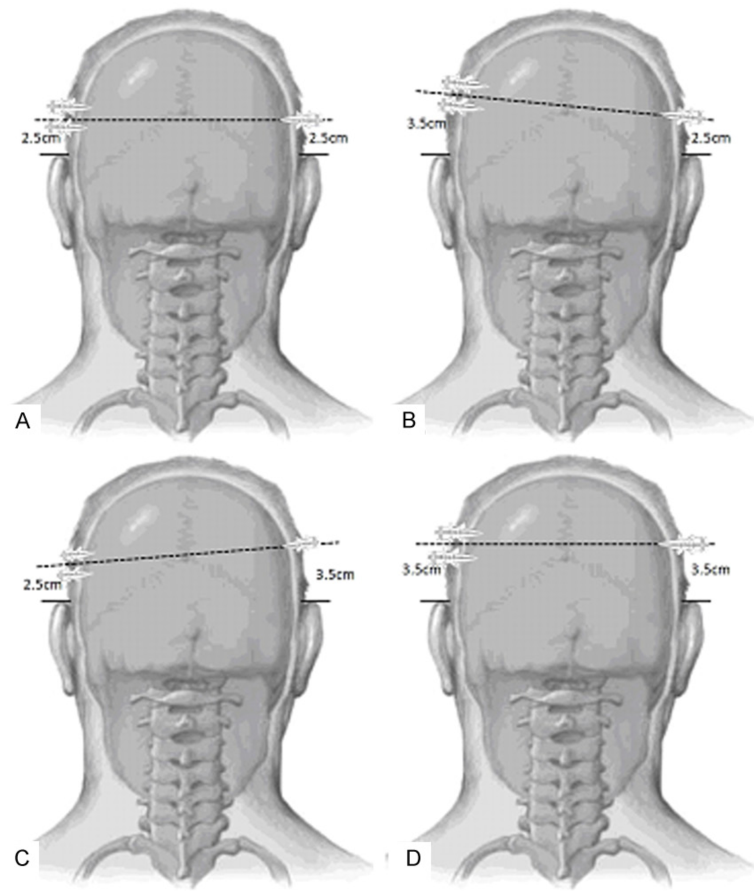

Figure 1. Pin positions in groups (A-D). (A) Three pins were inserted 2.5 cm above the apex auricle; (B) A single pin and double pins were inserted 2.5 cm and 3.5 cm above the apex auricle, respectively; (C) A single pin and double pins were inserted 3.5 cm and 2.5 cm above the apex auricle, respectively; and (D) three pins 3.5 cm were inserted above the apex auricle.

cal spine surgery. To the best of our knowledge, this is the first biomechanical study to analyze the fixation intensity associated with the pin positions.

Methods

Specimen preparation

Twelve cadaveric heads with intact soft tissue were dissected from formalin-fixed adlt cadavers aged 40 to 55 years. The identities of the cadavers were protected, and the university policy for the handling donor specimens was strictly followed. All cadaveric heads were without any bone-related diseases or skull injury (**Table 1**).

The study included 4 groups: in group A (n = 6), three pins were inserted 2.5 cm above the apex auricle; in group B (n = 6), a single pin and double pins were inserted 2.5 cm and 3.5 cm above the apex auricle, respectively; in group C (n = 6), a single pin and double pins were inserted 3.5 cm and double pins 2.5 cm above the apex auricle, respectively; and in group D (n = 6), three pins were inserted 3.5 cm above the apex auricle. A total of 6 cadaveric heads were tested in each group. No interference from the pin holes were detected between groups A and D or between groups B and C (**Figure 1**).

the effective fixation of the device could reduce these adverse events. However, the effects of changing the pin position on the skull remains unknown, and whether changing the position of a certain pin can improve fixation intensity is currently unclear [8, 9].

The purpose of this study is to investigate the effects of changing the pin positions changes on the skull during fixation and to provide evidence for the proper application of the three-pronged Mayfield head clamp in posterior cervi-

Mechanical testing, surgical implantation, and data collection

The three-pronged Mayfield head clamp (Do-ro Headrest System, Pro Med Instruments GmbH, Botzinger Str. 38 D-79111 Freiburg, Germany) weighs 1600 g and includes an aluminum cast and materials made of stainless steel and Teflon. The clamp system consists of three skull pins measuring 4 mm in diameter (Adult reusable skull pins A-1047, Doro Headrest System, Pro Med Instruments GmbH, Botzinger Str. 38

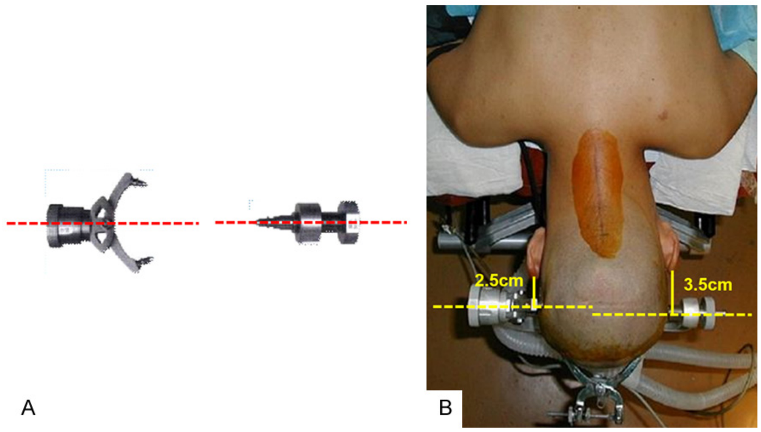

Figure 2. Central axis lines on the both sides. A. Central axis in the one Doro single pin holder and the one Doro double pin holder; B. Three-pronged Mayfield head clamp with a single pin and double pins inserted 3.5 cm and 2.5 cm above the apex auricle, respectively, during the operation.

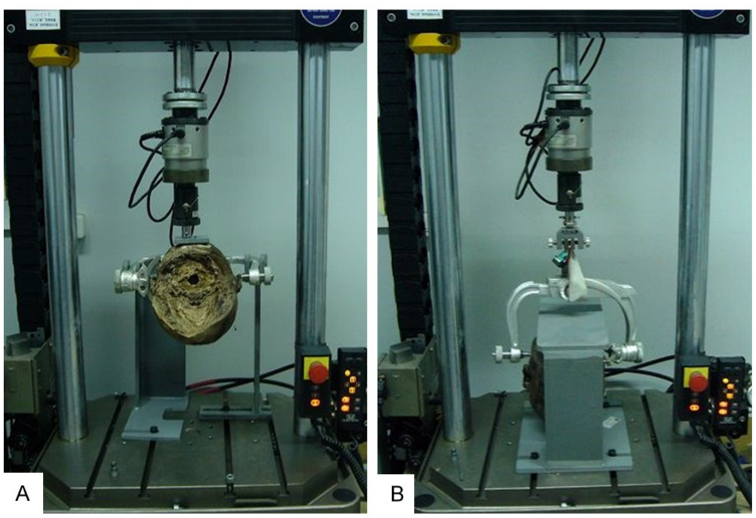

Figure 3. Biomechanical test with the base unit of the electromagnetic motion analysis device. A. Skull in the compression test; B. Skull in the tensile test.

D-79111 Freiburg, Germany), one Doro single pin holder and one Doro double pin holder. The maximum load for the Mayfield skull clamp is 12.5 kgs (27.5 lbs.).

The skull clamps were adjusted to the widths of the cadaveric heads such that the two skull pins in the rocker arm were equidistant from the centerline of the head and that the single skull pin in the extension assembly was in line with the centerline. Then, the rocker arm was adjusted to the desired position described above. The index knob was turned from "OPEN" until it was engaged in the "CLOSE" position. The torque screw was turned to drive the skull pins at an angle of 90 degrees into the skull. The clamping force was adjusted via the torque screw. The adjusted clamping force was readable on a scale in stages of up to 360 N (80 lbs.). In this study, 270 N (60 lbs.) of pin pressure was used based on the standard requirements for an the adult cadaveric head according to the Doro instrument manual (**Figure 2**).

Biomechanical tests included compression and tensile tests, which imitated the vertical forces and axial traction applied during posterior cervical spine surgery. In the compression test, the heads were screwed with three skull pins of the Mayfield clamp. The clamp was rigidly mounted on the base unit of an electromagnetic motion analysis device (INSTRON 8874 Biomechanical testing system, Instron Co, USA). The cadaver heads were positioned face-down, and the vertical force exerted on the occipital region was increased gradually across the pressure plate of the device. In the tensile test, the specimens were fixed with the Mayfield skull clamp and constrained using a cadaveric head restrictor (Dong Feng Apparatus Plant, China). The three-pronged Mayfield head clamp was completed fixed with a pressure plate that generated a gradually increasing upward axial force (**Figure 3**).

The axial force was loaded under the displacement-control mode. The speed of the pressure plate in the compression and tensile tests was 10 mm/min. The peak load was obtained when 3 mm of relative displacement occurred between the head and the Mayfield skull clamp. As a conical configuration of the pin track on the skull was made by handling the fastener, 3 mm was the minimum displacement that we could directly observe.

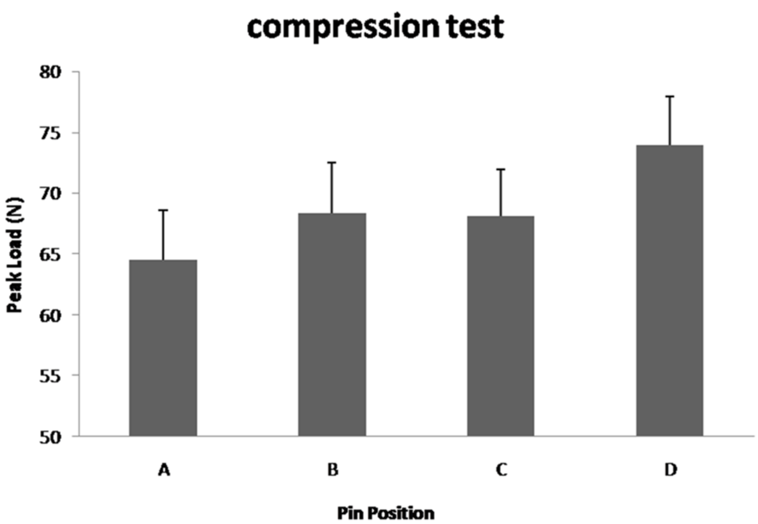

Figure 4. Comparison of the peak loads on different pin positions in the compression test. Compared with the other three groups, group A showed basic fixation stability effect at peak load.

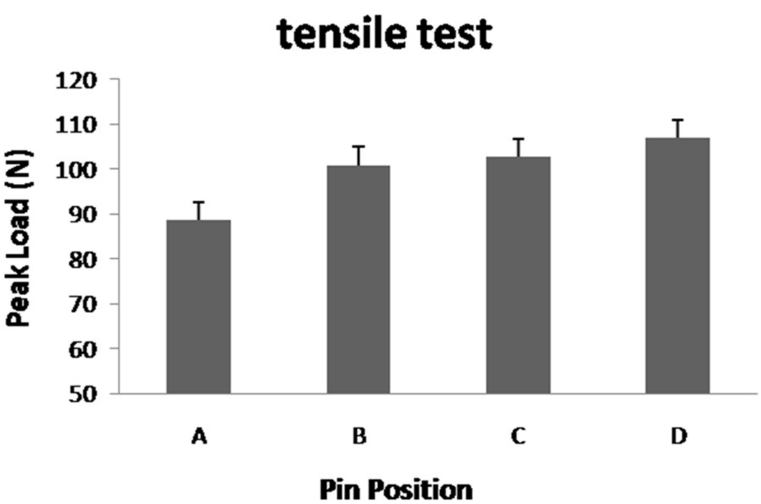

Figure 5. Comparison of the peak loads on different pin positions in the tensile test. Compared with the other three groups, group D showed the highest fixation stability effect at peak load.

To avoid any evaluation bias caused by the gravitational weight of the head itself, we zeroed the instruments after positioning the cadaveric head to eliminate the effects of gravitation and to ensure that the data more closely reflected the clinical situations.

Statistical analysis

Comparisons of imposed forces among different groups were carried out by using one-way analysis of variance (ANOVA). When there were significant differences among groups, multiple comparison tests between groups were performed using the post hoc Student-Newman-Keuls (SNK) test. Differences were considered significant at $P < 0.05$, and the quantitative data were expressed as the means ± standard deviation (SD). All data were analyzed using SPSS 19.0 for Windows (Chicago, IL).

Results

Data in the compression test

Three pins at 2.5 cm: Three pins were fixed 2.5 cm above the apex auricle and obtained peak loads of 64.50±4.09 N in the compression test (**Figure 4**).

Pins unilateral change: Under vertical compression loading, the average peak loads in groups B and C were 68.31±4.17 N and 68.11±3.80 N, respectively. There were no statistically significant differences when the pin placements of groups B and C were compared with the placement of three pins 2.5 cm above the apex auricle ($P > 0.05$). An upward, unilateral change in the pin positions showed no significant differences in the peak load.

Three pins at 3.5 cm: In the study, changing the positions of the three pins to 3.5 cm above the apex auricle showed high fixation stability. The peak load increased more dramatically for this group than in any other groups in the compression test, which reached 73.91±4.04 N ($P < 0.05$).

Data in the tensile test

Three pins at 2.5 cm: Three pins were fixed 2.5 cm above the apex auricle and obtained the peak loads of 88.61±8.14 N in the tensile test (**Figure 5**).

Pins unilateral change: Under tensile loading, the peak loads of groups B and C were 100.78±7.27 N and 102.79±6.80 N, respectively, which showed a similar trend in terms of increasing fixation stability without significant differences when compared with the fixation of three pins at 3.5 cm above the apex auricle ($P > 0.05$).

Three pins at 3.5 cm: Changing the positions of the three pins to 3.5 cm above the apex auricle also showed high fixation stability in the tensile test, and the average peak load (108.35±7.02 N) for this group was significantly higher than that achieved with three pins placed 2.5 cm above the apex auricle ($P < 0.05$).

All pin holes and clamps were observed after the tests. No pin breaks or skull perforations were found.

Discussion

When spine surgeries such as repositioning or screw insertion are performed, an indirect force is produced on the head fixation system [10, 11]. Therefore, spine surgery intraoperatively requires intraoperative application of stabilizing forces to avoid injuring the spinal cord or nerve roots. If necessary, preoperative or intraoperative traction can be executed using three-point clamps to assist with posterior cervical spine surgery [12-14]. Our results confirm that changing the pin position to a more beneficial location can provide further fixation and stability during cervical spine surgery [15].

Surgeons determine the pin position and clamping force based on the thickness of the skull and bone structur. In the anatomical position, the center of the parietal bone is located 2.5 cm ~ 3.5 cm above the apex auricle and between the frontal and occipital bones, which form the top and sides of the cranium. A uniform bone matrix can provide enough space for pin insertion which can effectively decrease the occurrence of potential complications such as injury to the frontal sinus, temporal fossa, blood vessels or nerves [16, 17].

According to the DORO series instruction manual, the maximum load that can be applied to the skull clamp in the compression test is 12.5 kg (27.5 lbs.). In addition, the weight of the head (approximately 6% of adult body weight) should be taken into account to evaluate the fixation stability. Based on a gravity conversion formula, the maximum load (P max) for the skull clamp is 122.5 N, and the weight load (W) of the adult head is approximately 35 N. According to the formula Load = P max-W, the load can be 87.5 N, which is significantly higher than the peak load tested when the pin position is 3.5 cm above the apex auricle. Therefore, this compression load without pin slipping is safe for the routine application of the Mayfield skull clamp.

With respect to cervical surgery in the prone position, there is always force forward or backward on the lamina and spinous processes that can indirectly influence the stability of the clamps [2, 18, 19]. Therefore, if the indirect load is lower than 64.50±4.09 N when the pin position is 2.5 cm above the apex auricle, the head and neck are stable. However, the pin position should be prospectively moved up to 3.5 cm if the indirect loads increased.

The results of the tensile tests showed that stability of the clamp could be improved to a certain extent by changing the pin position symmetrically and unilaterally. However, in clinical practice, moving the pin position up unilaterally is not safe due to rigid axial cervical traction and may result in adverse cervical repositioning during the operation. Therefore, only symmetrical pin positions are recommended. Accordingly, the tensile loads without pin slipping are safe for the routine application of the Mayfield head clamp.

However, because of the prone position, the peak load (P) determined in the test should be seen as a balancing force produced by two components: the head gravitational force (W) and the axial traction force (T). According to the formula P2 = W2 + T2, the axial traction force (T) can be calculated from the peak load and the head gravitational force. According to the type of cervical fracture, surgeons should limit traction loads to less than 80 N when the clamps are symmetrically installed at 2.5 cm above the apex auricle. If the operation requires additional traction loading of up to 100 N, surgeons should symmetrically move the pin position up to 3.5 cm above the apex auricle to ensure maximal fixation stability and avoid excess loading, which may cause secondary injuries to due to pin loosening or slipping.

However, as for the selection of pin positions, the reference from this study still has limitations. In clinical practice, the factors of position of pins includes the actual thickness of object region of skull, the subcutaneous vascular distribution of object region and the individual difference of the head. Even we need to evaluate in advance the angles and positions of wearing ring of Mayfield head clamp in individual surgery, and access whether it is needed to apply external force. This study makes comparison of pin positions on 2.5 cm above the apex auricle as well as 3.5 cm, which is bases on common pin positions during posterior cervical spine surgery and neurosurgical procedures. Hence, the results from this study cannot apply to all the patients who need immobilization of head and neck in prone position.

Conclusion

According to the results of the current study, it can be concluded that positioning the pins at 2.5 cm above the apex auricle theoretically ensures the basic fixation required for head holding. However, positioning the pins at 3.5 cm above the apex auricle results in additional fixation stability that can achieve limited traction in posterior cervical spine surgery. Rational treatment plans and accurate pin locations are essential for the proper application of the Mayfield head clamp. This approach should be applied in additional large-scale, prospective studies to support further clinical practices.

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Disclosure of conflict of interest

None.

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