

Potential Risk Analysis and Experience Summarization of Unstable Factors of Cranial Fixation Devices in Neurosurgical Operations

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Research

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Abstract

BACKGROUND The use of cerebral fixation devices in neurosurgery is very common, which is considered to be an important auxiliary method for many craniotomies. However, previous studies have reported complications of using cerebral fixation devices. Some of the complications are serious and even potentially fatal, and the causes of which may be related to incorrect use of cranial fixation devices. Although there are no serious complications, the cause of that needs to be further summarized and analyzed, as so to minimize the serious consequences caused by the cerebral fixation devices slippage and ensure the safety of the patients' surgical procedure.

METHODS In our recent work, we have continuously found three cases of unstable cerebral fixation devices, which allowed us to analysis the possible factors and summarize experience combined with the review of other senior neurosurgeons from different departments of neurosurgery.

RESULTS Based on our recent unstable cranial fixation incidents and the experience of investigating and analyzing senior doctors from different neurosurgery centers, we conducted experience analysis and summary to minimize the risk of unstable cranial fixation pins. We tried a variety of options, including a safe anatomical location for cranial fixation, teamwork and communication with anesthesiologists and itinerant nurses to ensure the stability of the patient's cerebral fixation devices.

CONCLUSIONS The data obtained in this survey has great limitations, including the doctor's personal prejudice and dependence on anecdotal memories. Therefore, the data should be interpreted with caution. Despite these limitations, there are still some modes that can help to better understand the use of safe skull fixation. Based on the above research and analysis, we have made recommendations that may help avoid preventable complications

Background

The use of cerebral fixation devices in neurosurgery is very common, which is considered to be an important auxiliary method for many craniotomies. Gardner designed the first cerebral fixation devices for sitting surgery in 1935, and later Mayfield cerebral fixation devices was developed to locate the skull and prevent movement in the proceed of neurosurgery, which are considered safe equipment [1,2].

However, previous studies have reported complications of using cerebral fixation devices in adults and children [3-5]. Some of the complications are serious and even potentially fatal, and the causes of which may be related to incorrect use of cranial fixation devices [4,5]. Among many adverse events, injuries caused by falling of cerebral fixation devices are often the most serious and may be life-threatening.

Despite few cases published, several neurosurgeons discussed complications of cerebral fixation devices during their careers in informal conversations, suggesting that their risks must be underestimated [3]. In our recent work, we have continuously found three cases of unstable cerebral fixation devices, which

allowed us to analysis the possible factors and summarize experience combined with the review of other senior neurosurgeons from different departments of neurosurgery.

Methods

Recent Clinical Cases Presentation

Case 1. Male, 53-year-old, was diagnosed as cerebellar vermin meningioma. The patient was adopted left abdominal supine position and fixed with Mayfield head frame, where double pins were located in the left temporal part and single pin was located in the right temporal part. The pressure of pins achieved 70 pounds. The surgical approach adopted posterior median approach, and 2 holes were drilled during the operation. The whole operation time was 4 hours. The patient showed head movement when we sutured scalps. When the Mayfield head frame was removed after operation, the pressure of pins was changed into 50 pounds.

Case 2. Female, 42-year-old, was diagnosed as acoustic neuroma located in left CPA. The patient was adopted right abdominal decubitus and fixed with Mayfield head frame, where double pins were located in the left temporal part and single pin was located in the right temporal part. The pressure is 60 pounds. The surgical approach adopted right retro-sigmoid approach, and 2 holes were drilled during the operation. The whole operation time was 4 hours. The patient showed head movement when we sutured scalps. When the Mayfield head frame was removed after operation, the pressure of pins was changed into 40 pounds.

Case 3. Female, 61-year-old, was diagnosed as meningioma located in left frontraoparietal. The patient was adopted supine position and fixed with Mayfield head frame, where double pins were located in the right temporal part, and single pin was located in the left temporal part. The pressure is 60 pounds. The surgical approach adopted left frontraoparietal approach, and 2 holes were drilled during the operation, and the whole operation time was 4 hours. When the head frame was removed after operation, the head frame scale was found to be 50 pounds.

These incidents aroused our great attention. If we did not discover and summarize the experience in time, it may appear again in the subsequent work and cause serious consequences. To this end, we also communicated with senior physicians and investigated cerebral fixation devices instability events that occurred among different neurosurgeons.

A survey of senior doctors

We investigated the neurosurgeons from Beijing Tiantan Hospital, Jinzhong First People's Hospital, Linfen People's Hospital, and The Seventh Medical Center Of Chinese People's Liberation Army General Hospital, respectively.

Results

Among the seven doctors surveyed, five doctors were found to have experienced cerebral fixation devices instability events, of which one doctor experienced one time, three doctors experienced two times, and one doctor experienced three times. There is no complete slip of head frame and serious complications, and the main phenomenon is partially displacement of cerebral fixation devices and reduction of pressure. In addition, with the growth of these senior doctors, the incidence of these events has declined significantly, and most of the incidents occurred during the period of serving as a young doctor.

In the events of cerebral fixation devices instability, the ratio of men and women is the same. Among these incidents, three patients appeared in the supine position, accounting for 30%, and seven patients were in the lateral/prone position, accounting for 70%. Among the ten patients, four incidents of them appeared in emergency surgery, and six incidents were routine surgery. Four incidents had involuntary movements before removing cerebral fixation devices. The pressure of cerebral fixation pins is strictly 60 pounds for women and 70 pounds for men. Among them, four patients are with thicker soft tissues in the head, and six patients with normal and thin skins. In the events of unstable cerebral fixation devices, there were no serious complications. Among them, four patients showed head pins displacement, and the distance was less than 1cm, and six patients showed pressure reduction to 40-50 pounds with no obvious tack displacement. Although there are no serious complications, the cause of that needs to be further summarized and analyzed, as so to minimize the serious consequences caused by the cerebral fixation devices slippage and ensure the safety of the patients' surgical procedure.

Discussion

Complications of cerebral fixation devices have been reported in the literature, including skull fractures, needle infections, venous air embolism, and subdural and epidural hematoma (6-7). Despite owning these potential risks, cerebral fixation devices provide the unique advantages of fixation and stability in cerebral operations, especially for high-precision surgery, that the head frame installation must be strictly fixed. At the same time, cerebral fixation devices fixation can be used to prevent concomitant pressure ulcers and eye complications (8-9). As our investigation showed, most neurosurgeon use cerebral fixation devices to fix the skull when performing neurosurgical operations. Based on the survey of multiple senior doctors in different hospital, we investigate the stability of the cerebral fixation devices installation, and the possible potential risks are summarized.

From these results, we found that patients in the lateral prone position were more prone to induce cerebral fixation devices instability, indicating that there were large instability factors in the prone/lateral prone abdominal position, which may be due to the weigh of bodies was more distributed on the cerebral fixation devices than the supine position. It required that we should pay more special attention to the stability of the cerebral fixation devices installation when patients were performed in the prone/ lateral prone abdominal position. Among the ten patients, 40% of them are emergency surgery and 60% are routine surgery. The proportion of routine surgery seems to be higher than emergency surgery, however, the overall number of routine surgery is much higher than that of emergency surgery. From this point, we can obtain that the probability of cerebral fixation devices instability in emergency surgery is much higher

than the proportion of routine surgery. These results showed that the preparation for emergency surgery might not be as full as in routine surgery, and errors were more likely to occur.

In addition, 40% patients had involuntary movements before removing the cerebral fixation devices. And in one patient who recently had unstable cerebral fixation devices, we paid special attention to the installation position and the amount of pressure applied after installing the headgear, and checked with the superior doctors and traveling nurse. At the end of the operation, we found that the patient's head appeared involuntary activities. We communicated with the anesthesiologist in time to enhance the control of anesthetic drugs. In the end, we found that the pressure of the cerebral fixation devices was changed from 70 pounds to 50 pounds. Two of the three patients who recently found the cerebral fixation devices unstable were accompanied by involuntary shaking of head during the operation. These results suggested that the depth of patient's anesthesia also plays an important role in the stability of cerebral fixation devices. The shaking of the patient's head during the operation may affect the stability of the cerebral fixation devices.

Among all patients, the pressure of cerebral fixation devices is strictly controlled for women 60 pounds and men for 70 pounds. Among them, there were four cases of unstable cerebral fixation devices in patients with thicker tissues, accounting for 40%, and six cases of normal and thin tissues patients accounted for 60%. These results indicated that in patients with thicker scalp, the pressure should be appropriately increased to prevent the head pins to shift or even slip. The length of the operation time is also closely related to the stability of the tissues. With the extension of the operation time, the higher proportion of cerebral fixation devices slipping or displacement happens.

In the cases investigated, there were no serious complications. Four cases showed cerebral fixation devices displacement, and the distance was less than 1 cm. Another six patients showed pressure reduction to 40-50 pounds, and no obvious head displacement occurred. Although there were no serious complications, the cause of its occurrence needs to be further summarized and analyzed, so as to minimize the serious consequences and ensure the safety of patient's surgical procedure.

Among the doctors surveyed, about 71% doctors experienced unstable incidences of cerebral fixation devices, and 80% occurred in the first three years of their work career, rarely in the subsequent work period. This showed that the stability of the cerebral fixation devices in the beginning of the work was closely related to the doctor's experience. This was also related to the communication between the anesthesiologist and the traveling nurse through the operation.

Based on our recent unstable cranial fixation incidents and the experience of investigating and analyzing senior doctors from different neurosurgery centers, we conducted experience analysis and summary to minimize the risk of unstable cranial fixation pins. We tried a variety of options, including a safe anatomical location for cranial fixation, teamwork and communication with anesthesiologists and itinerant nurses to ensure the stability of the patient's cerebral fixation devices. Although the statistical value of these 10 cases is limited, just based on empirical analysis and retrospective studies, more

clinical studies can be conducted to assess related risks and make recommendations for the safe installation of the cerebral fixation devices.

Conclusion

The data obtained in this survey has great limitations, including the doctor's personal prejudice and dependence on anecdotal memories. Therefore, the data should be interpreted with caution. Despite these limitations, there are still some modes that can help to better understand the use of safe skull fixation. Based on the above research and analysis, we have made recommendations that may help avoid preventable complications.

The following suggestions are based on the survey responses and our own practical experience:

1. Strictly follow the process to install cerebral fixation devices, and at least two doctors are present to verify the stability of cerebral fixation devices. The junior doctors need to install the head frame with the assistance of the senior doctors, and gradually accumulate experience;
2. Fully assess the patient's head circumference size, weight, and skin thickness. In patients with heavier head and thicker scalp, we should increase the pressure appropriately to ensure the stability of the cerebral fixation devices
3. The position of the cerebral fixation devices needs to be carefully analyzed to ensure that the center of the head is located at the upper part of the three-point center of gravity of the head frame, so that it is possible to ensure that the cerebral fixation devices supports the head effectively;
4. In some complex surgical positions, more attention should be paid to the stability of the cerebral fixation devices. Due to various changes in its body angle, there are many variable influencing factors
5. The prolonged operation time may increase the factors of cerebral fixation devices instability. In patients with long surgical events, the stability of the cerebral fixation devices can be checked intraoperative;
6. During the operation, try to avoid unnecessary pressure on the patient's head to cause the instability of the head nail;
7. Fully communicate with the anesthesiologist to determine the end time of the operation, so that the anesthesiologist can better evaluate the use of the anesthetic drugs;
8. The re-check with the itinerant nurse is an indispensable part. In our recent incidents, it is that the itinerant nurse discovered and rigorously verified consequent operations that the discussion and empirical analysis of this article.

List Of Abbreviations

None.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of the Beijing Tiantan Hospital (KYSB2017-052). As this article is a retrospective study, ethics committees have granted exemption of patient informed consent.

Consent for publication

Informed consent has been obtained from the patients.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Qiang Hao designed the whole experiment, and Gaopeng Cheng participated in the whole procedure and wrote this manuscript. Pro Shuyu Hao, Zhifen Ye, Bao Wang, Bin Huangpu, Pengfei Wang and Hao Wang participated the discussion part and provide some cases in this article. All authors read and approved the final manuscript, and the Figure 4 is provide by Pro Shuyu Hao.

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Disclosures

There is no conflict in this manuscript.

References

1. Baerts WD, De Lange JJ, Booij LH, Broere G. Complications of the Mayfield skull clamp. *Anesthesiology*. , 1984;61:460–461.
2. Cabezudo JM, Gilsanz F, Vaquero J, Areitio E, et al. Air embolism from wounds from a pin-type head-holder as a complication of posterior fossa surgery in the sitting position. *J Neurosurg*; 1981; 55:147–148.
3. Grinberg F, Slaughter TF, McGrath BJ. Probable venous air embolism associated with removal of the Mayfield skull clamp. *Anesth Analg*; 1995; 80:1049-50.
4. Sade B, Mohr G. Depressed skull fracture and epidural haematoma: an unusual post-operative complication of pin headrest in an adult. *Acta Neurochir (Wien)* 2005;147:101-103 .
5. Yan HJ. Epidural hematoma following use of a three-point skull clamp. *J Clin Neurosci*;2007;14:691-693.
6. Aoki N, Sakai T: Modified application of three-point skull clamp for infants. *Neurosurgery*; 1989;25:660–662.
7. Lee M, Rezai AR, Chou J: Depressed skull fractures in children secondary to skull clamp fixation devices. *Pediatr Neurosurg*; 1994; 21:174–178.
8. Cherisse Berry, David I. Sandberg, Daniel J. Hoh, Mark D. et al. Gordon McComb. Use Of Cranial Fixation Pins In Pediatric Neurosurgery. *Neurosurgery*; 2008; 62:913-919.
9. Jacopo C. Poli, Cesare Zoia, Desiree Lattanzi, Sergio Balbi. Epidural haematoma by Mayfield head-holder®: Case report and review of literature. *Journal of Pediatric Sciences*; 2013;5:e195.

Figures

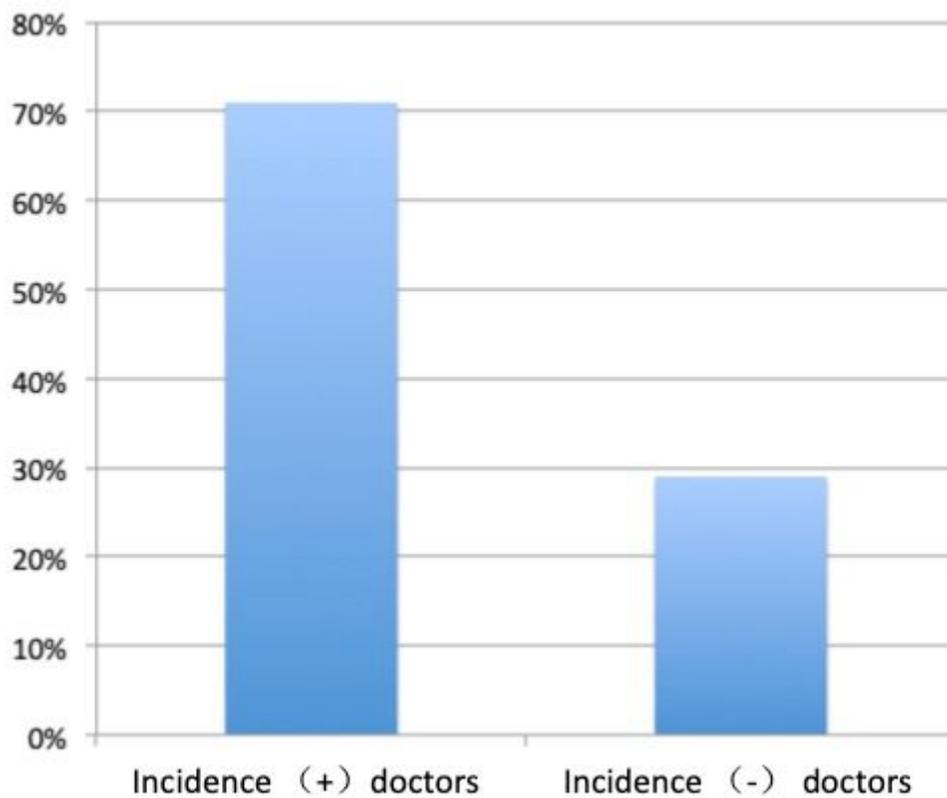


Figure 1

Rate of doctors with cranial fixation incidents. Among the doctors surveyed, about 71% doctors experienced unstable incidences of cerebral fixation devices.

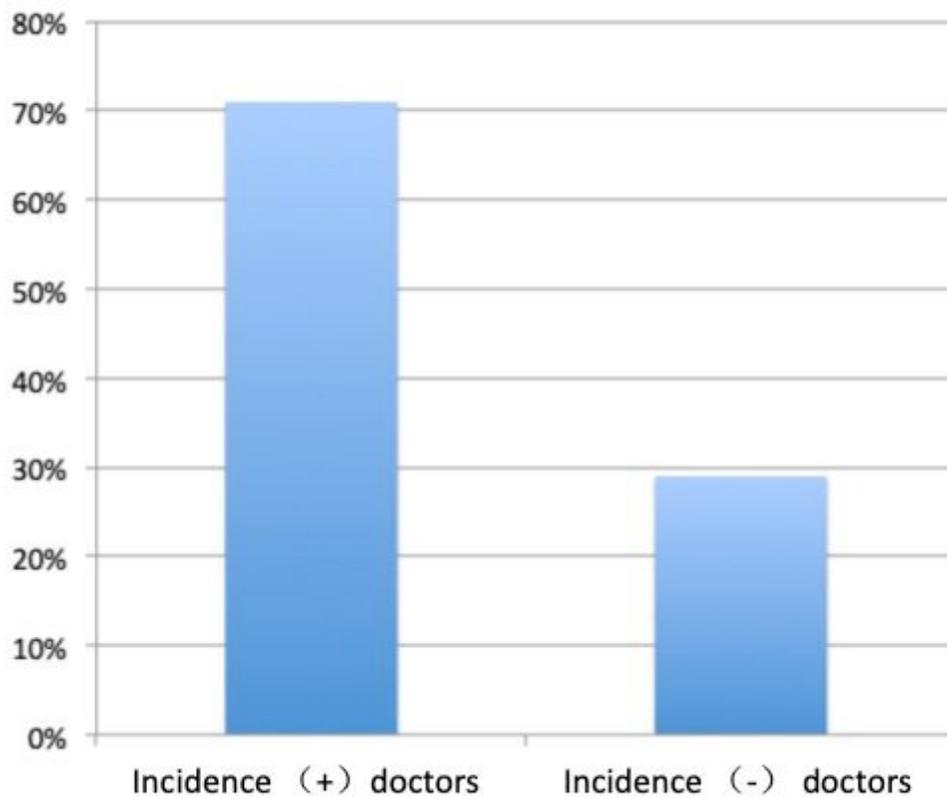


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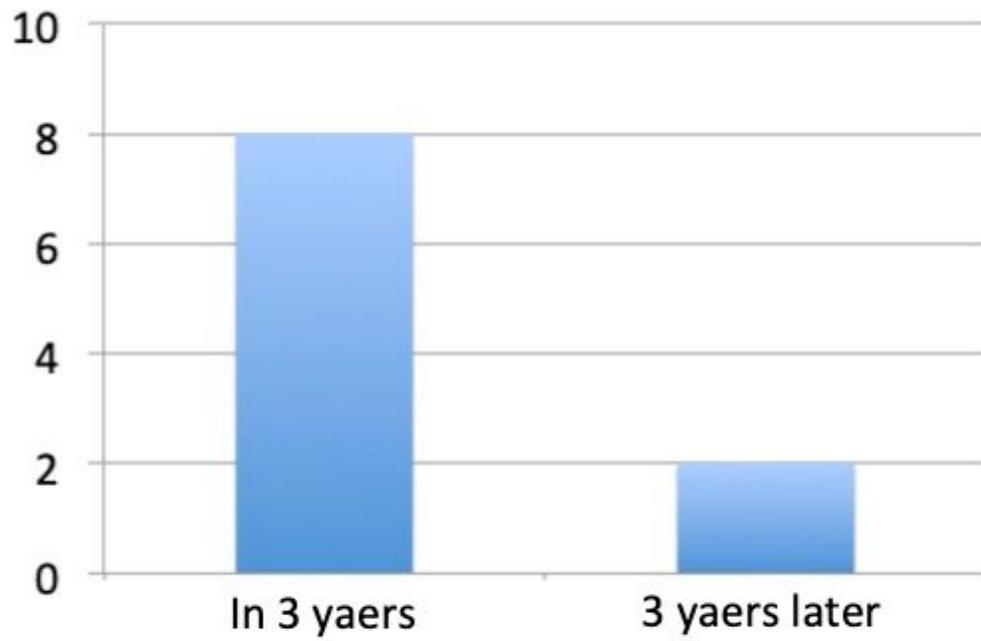


Figure 2

Working years of doctors with cranial fixation incidents. About 80% occurred in the first three years of their work career, rarely in the subsequent work period.

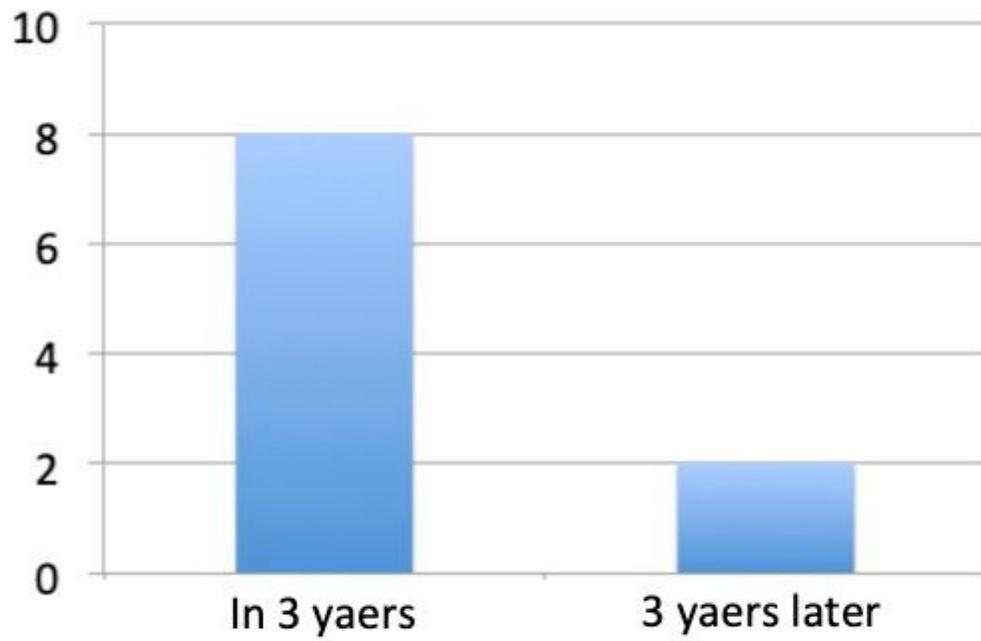


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Working years of doctors with cranial fixation incidents. About 80% occurred in the first three years of their work career, rarely in the subsequent work period.

Total Num	10 cases	Num of unstabilisation	Percentage
Operation position	Supine position:	3	30%
	Lateral abdominal position:	7	70%
Emergency operation	Yes	4	40%
	No	6	60%
Depth of anesthesia	Deep: 6	6	60%
	Shallow: 4	4	40%
Pressure of pins	>70 pounds	5	50%
	<70pounds	5	50%
Skin Of head	Thick	4	40%
	Normal	3	30%
	Thin	3	30%
Time of operation	>3 hours	10	100%
	<3 hours	0	0%
Appearance of unstabilisation	Slipping>1cm	0	0%
	Slipping<1cm	4	40%
	Reduction of Pounds	6	60%

Figure 3

Summarization of unstable factors of cranial fixation devices in neurosurgical operations.

Total Num	10 cases	Num of unstabilisation	Percentage
Operation position	Supine position:	3	30%
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Emergency operation	Yes	4	40%
	No	6	60%
Depth of anesthesia	Deep: 6	6	60%
	Shallow: 4	4	40%
Pressure of pins	>70 pounds	5	50%
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Skin Of head	Thick	4	40%
	Normal	3	30%
	Thin	3	30%
Time of operation	>3 hours	10	100%
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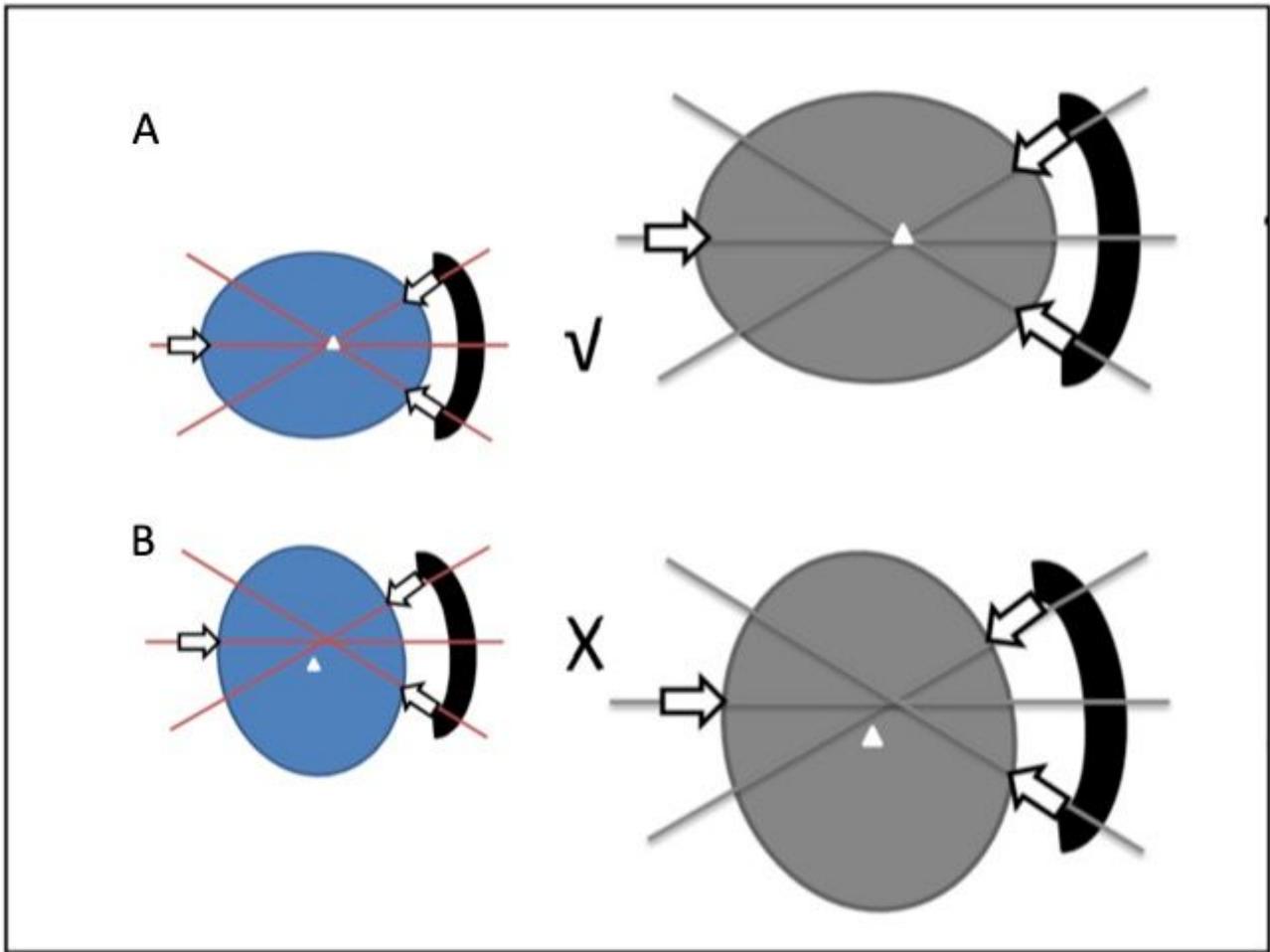


Figure 4

The relation between position of the cerebral fixation devices and the center of the head. A, center of the head is located at the upper part of the three-point center of gravity of the head frame; B, center of the head is located at the lower part of the three-point center of gravity of the head frame.

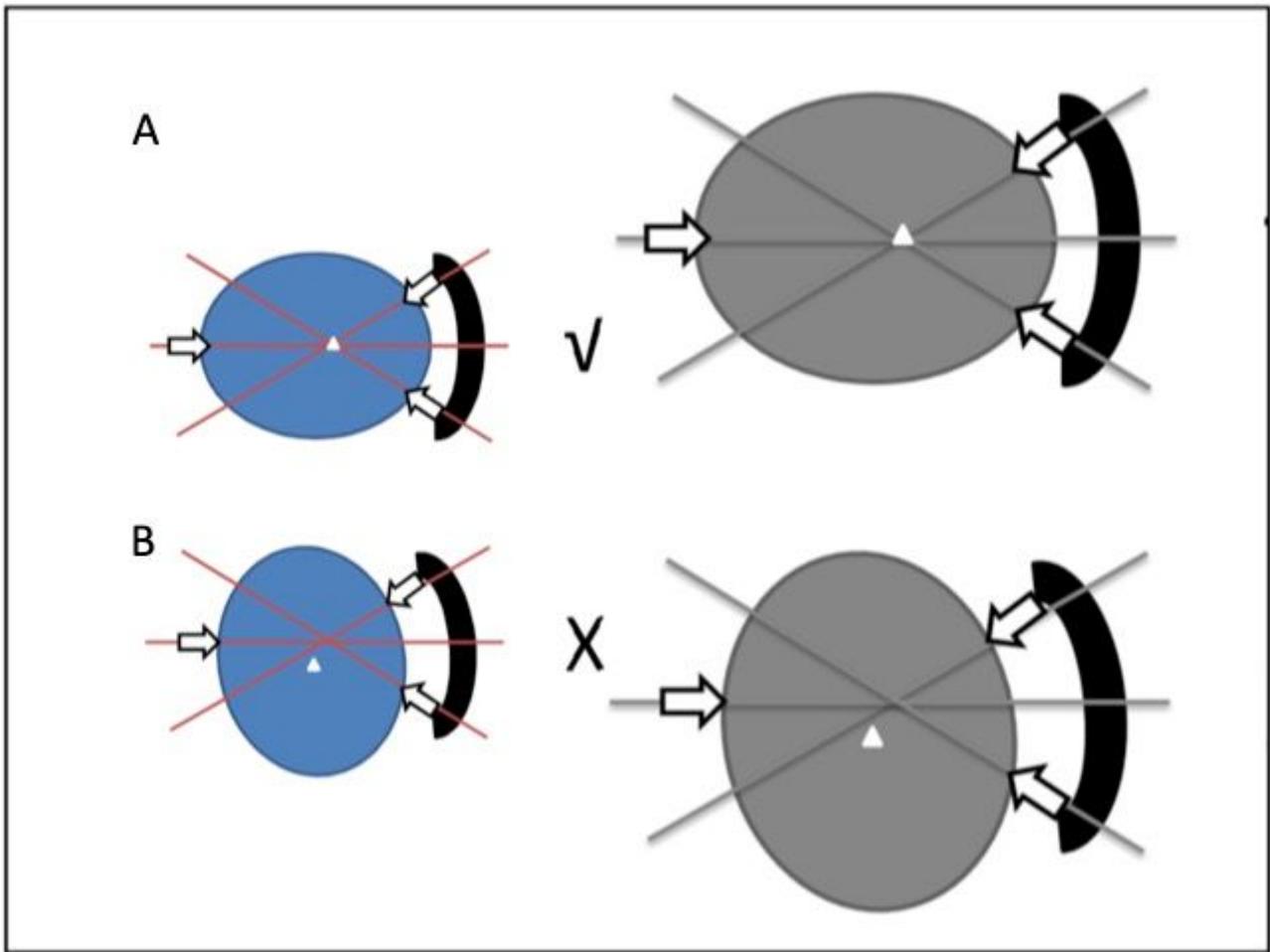


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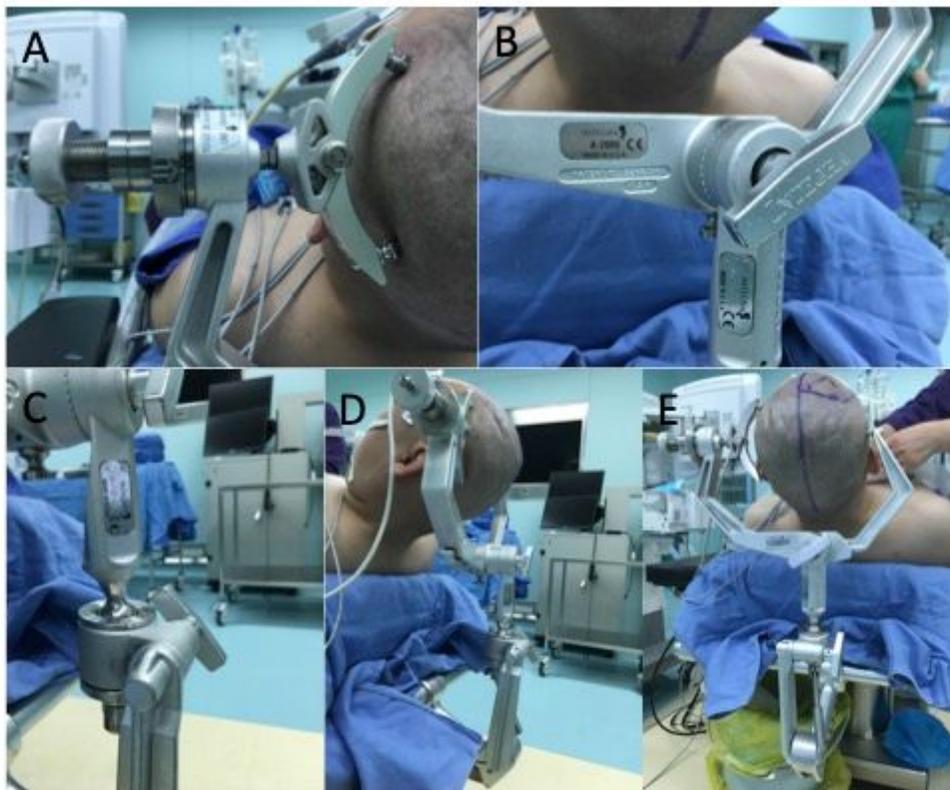


Figure 5

The Standard positions of the cerebral fixation devices. A, Two pins located up and down position of fixes position blancedly; B, the head frame is tightly connected with the fixing device; C, the cardan shaft keep vertical; D, side view of standard position of cranial fixation devices; E, positive view of standard position of cranial fixation devices.



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