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Cranial Bone Flap Fixation: Comparison of Titanium-Based Device (Skull Fix) and PEEK-Based Device (Cranial Loop): Technical Report

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Abstract

Background: Reconstruction of the cranial bone flap after craniocerebral surgery is crucial for preservation of skull symmetry, maintenance of aesthetics, brain protection, as well avoiding complications like floating or sunken skull flaps. A host of techniques and materials for fixation of the cranial flaps have emerged over the past several decades.

Aim of Study: The aim of this study was to compare the clinical outcomes of bone flap fixation using peek-based (cranial loop) versus titanium-based (skull fix) fixation systems.

Patients and Methods: Between July 2013 and December 2016 a series of 54 patients undergoing either an emergency or an elective craniotomy for different intracranial lesions in which the original bone flaps were refixed using cranial loop in 27 patients and skull fix in 27 patients. Clinical and radiological outcomes and complication rates were compared between these 2 groups.

Results: Satisfactory results were achieved in both fixation systems. Epidural collection occurred in 4 patients 3 in skull fix and one in cranial loop, subdural collection in 4 patients 2 in cranial loop and one in skull fix treated conservatively. One case with cranial loop experienced a bone flap dislocation which was revised and refixed. Subcutaneous effusion occurred in two patients one in skull fix and one in cranial loop. One patient in skull fix developed a mild postoperative wound infection. Post-operative imaging showed satisfactory anatomical and morphological position of the flap in all patients.

Conclusion: Skull fix and cranial loop are reasonable alternatives to present craniotomy fixation methods. They are easy to use, fast, safe, reliable with very acceptable cosmetic results. The main advantage of the cranial loop might ultimately lie in the absence of artifacts on post-operative CT or MR imaging.

Key Words: *Craniotomy – Cranial bone fixation – Cranial loop – Skull fix.*

Introduction

REALIGNMENT and fixation of skull bones following intracranial surgeries or skull fractures is an important issue for both neurosurgeons and patients [1].

A fixation device must therefore secure the cranial flap to protect the delicate brain, to obtain acceptable cosmetic appearance and to avoid complication or reoperation [2,3].

The techniques and materials of fixating a bone flap have evolved over time. Its evolution has been guided by technology, including surgical instrument development, anatomy and concerns about cosmosis and infection prevention. Multiple traditional in addition to newer techniques are available, each with pros and cons [4,5].

Bone flaps have been tied in place with sutures (silk, cotton, or chromic catgut) [6,7]. Wire (silver or stainless) [8,9], fixating metal pins [10], metal plates and screws (stainless steel, tantalum, titanium) and more recently Biodegradable and PEEK-based cranial fixation systems [11-14].

The purpose of this study was to describe the characteristics and possible complications of titanium clamp fixation system (Skull Fix; BMI Medical-Welling Instruments Co. USA-Taiwan Joint Venture Co.) and PEEK-based cranial fixation system (Cranial Loop, Neos Surgery, Spain).

Patients and Methods

This retrospectives study done in governmental hospitals in Saudia Arabia between July 2013 and December 2016 where the medical records of a series of 54 patients undergoing either an emergency or an elective craniotomy for different intracranial lesions in which the original bone flaps were refixed using cranial loop in 27 (14 male and 13 females) and patients and skull fix in 27 (15 male, 12 female) patients. Each patient was partially shaved and received perioperative antibiotics.

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For those patients where skull fix was used we use 3 clamps for each patient (4 clamps were used in 2 patients with larger bone flap and 2 clamps in 1 patient with smaller bone flap) the clamp system used in our cases consists of two concave discs, each with a diameter of 18mm and a thickness of 0.3mm, mounted on a 50-mm-long, 1-mm-thick pin with circumferential grooves. The clamps were positioned along the circumference of the cranial flap with the inner disc placed partly in the epidural space under the bone edge, the clamps were held by hand as the free craniotomy flap was lowered into position the outer disc then sequentially squeezed and advanced over the threaded pin down toward the outer table, the excess pin projecting above the outer disc was snipped off with the pin cutter Fig. (1).

For those patient who underwent cranial bone flap fixation with cranial loop 3 loops (4 clamps were used in 5 patients with larger bone flap) were placed in situ, in all patients, the bone flap could be easily fixed with 3 or more cranial loops without difficulties the bone flap was positioned in the craniotomy opening and the cranial loops were tightened one by one till the bone flap was firmly fixed. Subsequently the cranial loops were cut and the yellow appliers are slid off. By bending the remaining Loops a few times they break just at the fixation point without having a sharp point Fig. (2).

Comments regarding the time taken, the number of clamps/loops, the stability of bone flaps and faced problems were recorded. Follow-up charts and files regarding clinical and radiological data were also recorded and evaluated.

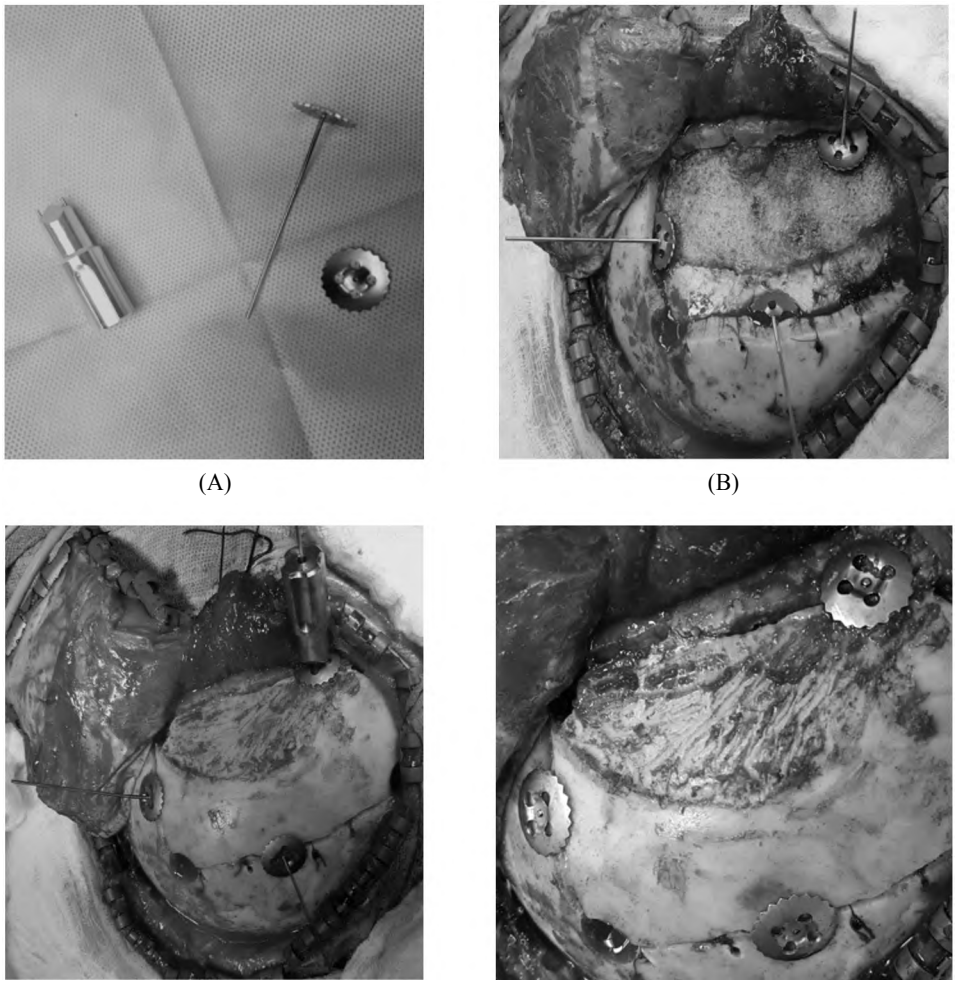
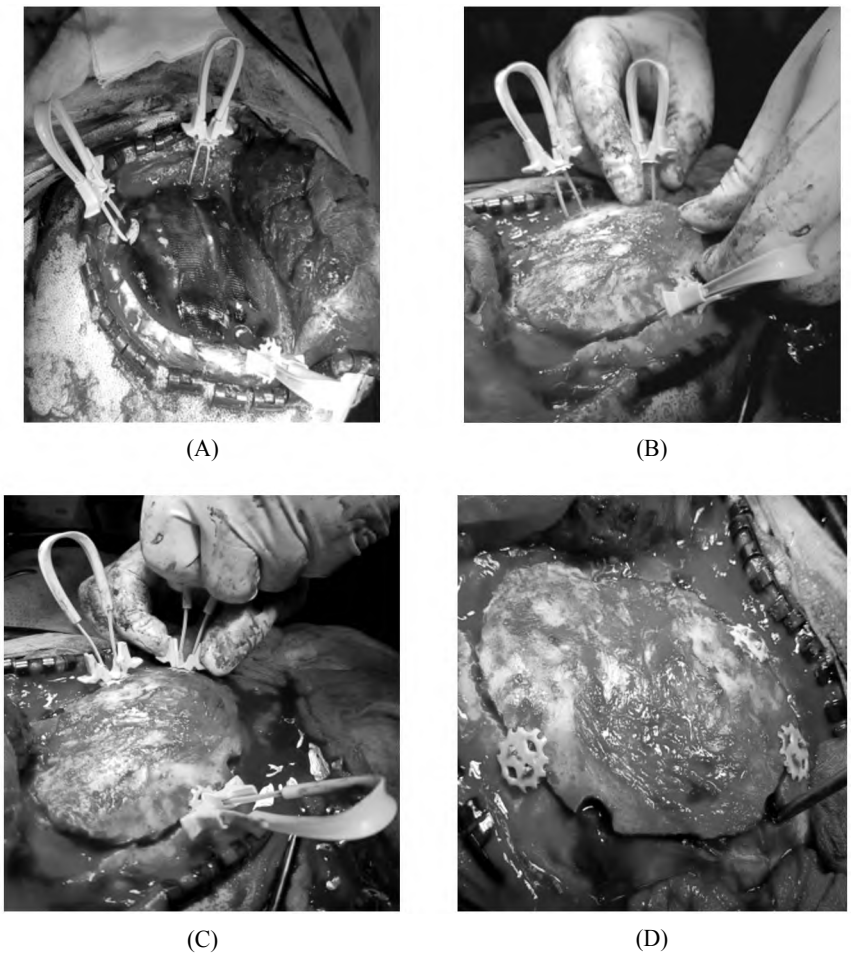


Fig. (1): (A) The titanium clamp Skull fix. (B) The inner disc placed partly in the epidural space under the bone edge. (C) Bone flap reattached and Insertion of the outer disc with the wrench on top turned clockwise to secure it (D) Final position.



(A) (B)

(C) (D)

Fig. (2): Application of the cranial loop. (A) Insertion of the cranial loops at the bone edges, between the dura and the bone. (B) Putting back the bone flap and tightening of the cranial loop. (C) Breaking the strips of the loop at the fixation point without leaving a sharp point. (D) Final result.

Results

54 patients were operated where cranial flap was fixed using skull fix in 27 patients and cranial loop in 27 patients. All operative procedures passed uneventful. It was fast, easy without technical difficulties. Each bone flap was firmly fixed using 3 or more devices in not more than 1 minute for every device. In both devices there was excellent adaptation either at the epidural or the extracranial surface. No encountered intraoperative dural or scalp injuries or intracranial hemorrhage. Only one case of post-operative wound infection was recorded in skull fix group and was treated conservatively. Reoperation was done in only one patient who experienced bone flap dislocation that was attributed to inadequate number of cranial loops in relation a large sized bone flap. Subcutaneous effusion occurred in two patients (one for each group) and subsides spontaneously. Epidural collection occurred in 4 patients (3 patients in skull fix group and 1 patient in cranial loop group) all treated conservatively. Subdural collection in 4 patients (2 patients in skull fix group and 2 patients in cranial loop group) all treated conservatively. All patients were satisfied about the cosmetic result of the wound. Apart from the patient with bone flap dislocation; post-operative 3D CT imaging showed satisfactory anatomical and morphological position of the flap in all patients. Post-operative MRI brain showed satisfactory results with minor artifact in the skull fix group Fig. (3) in contrast to the cranial loop group that was completely artifact free Fig. (4).

Patient characteristics are summarized in (Tables 1,2).

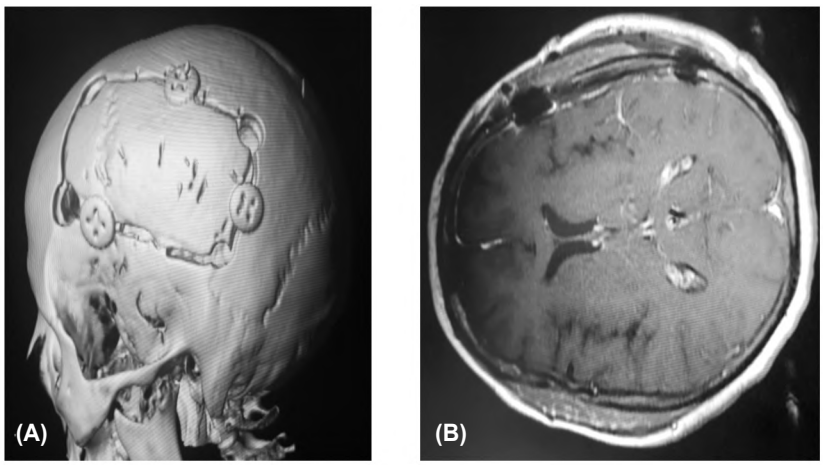


Fig. (3): Post-operative imaging of patient after skull fix implantation. (A) 3D CT showed good anatomical position of the bone flap. (B) MRI brain with noticed minor artifact

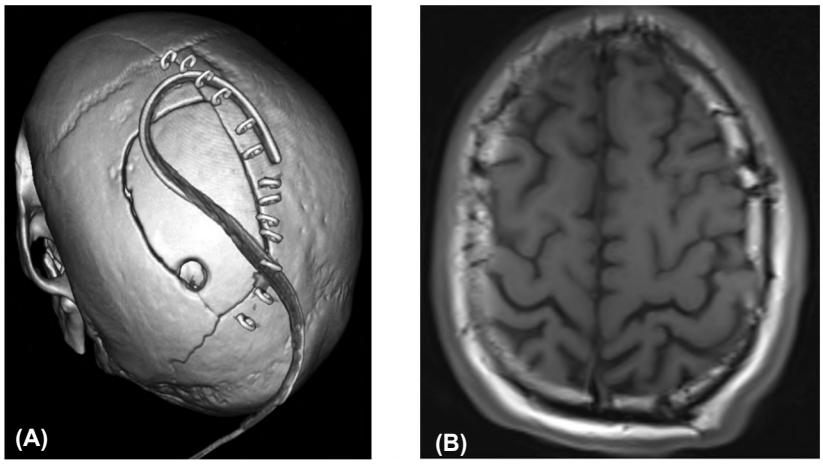


Fig. (4): Post-operative imaging of patient after cranial loop implantation. (A) 3D CT showed good anatomical position of the bone flap. (B) MRI brain without artifact.

Table (1): Results in the skull fix group.

Number	Age	Sex	Diagnosis	Approach	Number of clamps	Post op CT	Post op complications
1	18	Male	Acute subdural hematoma	• Cranioplasty following decompressive craniotomy	3	In place	–
2	57	Male	Glioma	• Parietal	3	In place	Minimal extradural collection
3	63	Female	MCA infarction	• Cranioplasty following decompressive craniotomy	3	In place	
4	53	Male	Meningioma	• Parasaggital	3	In place	
5	45	Female	Metastases	• Frontal	3	In place	–
6	24	Male	Brain abscess	• Frontal	3	In place	Wound infection
7	67	Female	Intracerebral hematoma	• Parietal	3	In place	
8	43	Male	Glioma	• Frontoparietal	3	In place	–
9	32	Male	Extradural Hematoma	• Frontal	3	In place	–
10	44	Male	Glioma	• Frontotemporal	3	In place	–
11	63	Female	MCA infarction	• Cranioplasty following decompressive craniotomy	3	In place	Minimal subdural collection
12	20	Male	Extradural hematoma	• Temporal	3	In place	–
13	70	Female	Intracerebral hematoma	• Occipital	3	In place	–
14	57	Male	Meningoma	• Parasagittal	3	In place	–
15	36	Female	Traumatic CSF leak	• Bifrontal	4	In place	Minimal extradural collection
16	43	Male	Acute subdural hematoma	• Frontoparietal	3	In place	
17	41	Female	Brain abscess	• Temporal	3	In place	–
18	46	Female	Meningioma	• Parietal	3	In place	–
19	36	Female	Metastases	• Occipital	3	In place	–
20	59	Male	Glioma	• Temporal	3	In place	
21	39	Male	Depressed skull fracture	• Parietal	3	In place	Subcutaneous effusion
22	66	Female	Metastases	• Frontal	2	In place	
23	48	Female	Intracerebral hematoma	• Frontotemporal	3	In place	–
24	43	Male	Extradural h	• Frontal	3	In place	Minimal subdural collection
25	18	Male	Acute subdural hematoma	• Frontoparietal	4	In place	
26	39	Male	Depressed skull fracture	• Temporal	3	In place	–
27	65	Female	Intracerebral hematoma	• Frontoparietal	3	In place	Minimal extradural collection

Table (2): Results in the cranial loop group.

Number	Age	Sex	Diagnosis	Approach	Number of loop	Post op CT	Post op complications
1	46	Female	Acute subdural	Frontoparietal	3	In place	–
2	57	Female	Meningioma	Temporal	3	In place	–
3	63	Female	Meningima	Bifrontal	4	In place	
4	67	Male	Brain abcess	Parietooccipital	3	Dislodged bone flap	Dislodged bone flap
5	47	Female	Glioma	Frotopaietal	4	In place	–
6	56	Male	Meningioma	Frontal	3	In place	–
7	37	Male	Glioma	Fronto Temporal	4	In place	Minimal epidural collection
8	39	Male	Metastases	Pterional	3	In place	–
9	42		Extradural hematoma	Pterional	3	In place	–
10		Female	Glioma	Frontoparietal	3	In place	–
11	63	Male	Glioma	Occipital	3	In place	Minimal subdural collection
12	42		Extradural hematoma	Temporal	3	In place	
13	55	Female	Intracerebral hematoma	Pterional	3	In place	–
14	61	Male	Meningoma	Frontal	3	In place	–
15	39	Female	Glioma	Temporoparietal	4	In place	–
16	53	Male	Meningioma	Pterional	3	In place	–
17	41	Female	Glioma	Frontal	3	In place	
18	43	Male	Extradural	Pterional	3	In place	–
19	26	Male	Metastases	Temporal	3	In place	–
20	59	Female	Glioma	Occipital	3	In place	
21	27	Male	Acute subdural	Temporoparietal	3	In place	
22	43	Female	Meningioma	Pterional	3	In place	
23	62	Male	Metastases	Frontal		In place	Subcutaneous effusion
24	33	Female	Glioma	Fronttemporal	3	In place	–
25	23	Female	Extradural h	Petrional	3	In place	Minimal sudural collection
26	61	Female	Acute subdiral	Temporoparietal	4	In place	–
27	38	Male	Extradural hematoma	Temporal	3	In place	–

Discussion

Bone flap fixation after craniotomy is a standard part of neurosurgical practice.

Believing that a preserved vascular supply to the bone fragment would reduce the risk of infection, Wagner recommended the preservation of a connecting hinge of overlying soft tissue, in the form of pericranium or temporalis muscle, “turning a Wagner flap” **[15]**.

Historically, bone flap fixation was performed with steel wire which was somewhat complicated; the scalp may be punctured by the wire end in some cases **[8]**. And it showed extensive metal artifacts on CT imaging **[10]**.

Sutures are cheap and do not require special equipment or tools **[4]** but it is time-consuming, carries a higher risk of damaging the dura and the brain during bone perforation **[10,11]**, and could not provide a stable attachment of the bone flap leading to either bone flap settling or dislocation (frequently resulting in depression or protrusion) **[11,16]**.

Artificial fixation systems have been used to secure cranial bone flaps since the 1990s. They are easily manipulated, provide superior rigid fixation, promote primary bone healing, produce a superior cosmetic result, and are CT and MRI compatible. They may even be useful in infected bone flap fixation **[5,8,17,18]**.

The skull fix titanium clamp system is a titanium-based fixation system which consists of two titanium smooth-surfaced discs attached to a pin **[3,14]**. While cranial LOOP is the first-ever cranial fixation device totally made of PEEK which is broadly accepted as a leading high performance candidate for replacing metal implants **[19]**.

The titanium discs act as a clamp across the cut edge of both the skull and the bone flap **[14,20,21]**. Sandwiching the cranial flap margins for a better purchase against the bone surface, with the edges of cranial flap matching the edges of skull defect exactly producing an excellent cosmetic result **[3,14]**.

The shape and flexibility of the cranial loop adjusts to the curvature and shape of the cranium, thus improving security of the device, guaranteeing the minimal possible profile at both the epidural and epicranial surfaces of the skull creating an overall smooth, adapted structure and satisfactory cosmetic results **[13]**.

In our study, post-operative follow-up showed satisfactory results on close inspection or palpation where there were no esthetically objectionable

bulges, areas of tenderness, skin abnormalities or palpable devices.

We found skull fix easy to use, fast and non-time consuming (3 minutes for 3 point fixation system) and this was comparable to other studies **[3,14]**.

Cranial LOOP is implanted with no additional instruments. Its unique design makes it a self-cutting device. The surgeon totally controls the bone flap fixation. The principle of cranial loops is the same as that of a cable tie with a simple fast and easy "pull-and-tighten" action. If a reoperation is necessary, the device is easily removed by using a rongeur **[13]**.

In our study using three Cranial LOOPs, a standard bone flap is fixed in less than 3 minute and this was in agreement of other studies.

Skull fix enjoys a characteristics tensile strength leading to a reliable rigid fixation with a good spring elastic-reserve. During follow up period we had no bone flap deformity (either depression or protrusion). These data was in agreement of previous studies **[3,8,14,20,21]**.

Cranial loop has a unique design which guarantees the same fixation strength as titanium plates and screws, or other standard metallic non-instrument-free cranial fixation devices **[22]**.

Apart from one case we had no evidence of cranial flap settling or dislocation either clinically or on the post-operative images which revealed a good anatomic position for all patients except for one case which needs revision because of dislodged flap due to inadequate number of loops for the large sized flap.

Skull fix is CT and MRI compatible with minor artifact related to its metallic component. Experiments in a 1.5 T MR tomograph with titanium clamps revealed no magnetic field attraction, minimal heating, and minor artifactual signal void **[23]**. We noticed this artifact but it does not interfere with proper postoperative radiological evaluation.

On the other side cranial loop is completely artifact-free in different medical imaging systems, such as X-rays, CT scanning and MRI **[19]**. In our study the total absence of artifacts on post-operative MR or CT imaging is favorable in patients who require post-operative follow-up imaging and this is going with other study by Van Loock et al., **[13]**.

Skull fix proved high safety margin with no device related complications e.g dural injury, infection or skin erosion), again the cranial loop had a high safety margin since the pulling force is away from the dura and this implies no risk for damaging the dura or other intracranial tissues.

In our study we use 3 devices of both types for each craniotomy bone flap. More than 3 devices was only indicated in multi-fragmented bone flap pieces such as in trauma patients or in larger flaps **[13,21]**. For small bone flaps, the use of 2 devices is sufficient to provide optimal alignment of the bone flap and to provide firm fixation **[13,21]**.

Conclusion:

Skull fix and cranial loop are reasonable alternatives to present craniotomy fixation methods. They are easy to use, fast, safe, reliable with very acceptable cosmetic results. The main advantage of the cranial loop might ultimately lie in the absence of artifacts on post-operative CT or MR imaging. Further experience may be necessary to elucidate the benefits that support their widespread use.

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تثبيت عظام الجمجمة مقارنة النتائج الإكلينيكية والإشعاعية لتثبيت عظام الجمجمة بإحدى طريقتين الأولى عن طريق مثبت مصنوع من التيتانيوم والآخر من البولى إيثر كيتون

تعتبر عملية تثبيت الرقعة العظمية من الخطوات المهمة جدا فى جراحات المخ وذلك ليس فقط لحماية المخ بل أيضا للمحافظة على الشكل المظهرى والجمالى للجمجمة وتجنب المضاعفات مثل طفو أو إنخفاض الرقعة العظمية. وقد ظهرت مجموعة من التقنيات والمواد اللازمة لتثبيت عظام الجمجمة على مدى العقود العديدة الماضية.

الهدف من هذه الدراسة مقارنة النتائج الإكلينيكية والإشعاعية لتثبيت عظام الجمجمة بإحدى طريقتين الأولى عن طريق مثبت مصنوع من التيتانيوم والآخر من البولى إيثر كيتون.

وقد تم إجراء هذه الدراسة الإسترجاعية عن طريق مراجعة الملفات الطبية وسجلات أربع وخمسين مريضا ممن أجرى لهم جراحات روتينية أو طارئة فى المخ وتم تثبيت الرقعة العظمية بإحدى الطريقتين (سبع وعشرون مريضا عن طريق قرص التيتانيوم وسبع وعشرون مريضا عن طريق قرص البولى إيثر كيتون) وذلك خلال الفترة من: بين يوليو ٢٠١٣ إلى ديسمبر ٢٠١٦ فى بعض المستشفيات الحكومية السعودية ثم دراسة النتائج الإكلينيكية والإشعاعية ومقارنتها بين الطريقتين.

تم الحصول على نتائج مرضية فى كلا طريقتى التثبيت وعند متابعة المرضى تبين حدوث تجمع خارج الأم الجافية فى أربع حالات وتحت الأم الجافية فى أربع حالات وتجمع تحت الجلد فى حالتين كما عانى أحد المرضى من إلتهاب سطحى فى الجرح وهذا كله تم معالجته تحفظيا وإحتاج أحد المرضى لإعادة تثبيت الرقعة العظمية بعد إكتشاف عدم ثباتها نظرا لعدم كفاية عدد المثبتات. كما أظهرت صور الأشعة نتائج مرضية من الناحية الشكلية والتشريحية فى جميع الحالات مع وجود أثر طيفى بسيط فى أشعة الرنين المغناطيسى للحالات التى تم فيها إستخدام التيتانيوم وإنعدام ذلك الأثر فى الحالات التى تم فيها إستخدام البولى إيثر كيتون.

يتضح من خلال هذه الدراسة أن نظام تثبيت الرقعة العظمية سواء بذلك القرص المصنوع من التيتانيوم أو بذلك المصنوع من البولى إيثر كيتون هما من الطرق الفعالة والآمنة والقوية والتى يمكن إستخدامها بسهولة فى وقت قصير جدا لتثبيت الرقعة العظمية للجمجمة بعد جراحات المخ مما يؤدى إلى نتائج ممتازة من الناحيتين الجمالية والتشريحية. ولكن وجد أنه من الناحية الإشعاعية أن مثبت البولى إيثر كيتون أفضل.