Long-Term Safety and Performance of a Polymeric Clamplike Cranial Fixation System

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OBJECTIVE: **After a craniotomy procedure to access the brain, neurosurgeons have several options to fix the bone flap to the skull. The aim of this study was to assess if a polymeric clamplike fixation system (Cranial LOOP) is a safe and reliable system that maintains over time an appropriate alignment of the bone flap.**

METHODS: **This is an observational, retrospective, case series study of 60 patients who underwent a craniotomy and were subject to cranial bone flap fixation with the Cranial LOOP fixation system. Baseline clinical parameters, surgical variables, medical records, and all postoperative medical images available were reviewed to assess the bone flap alignment and potential adverse events.**

RESULTS: **A total of 182 Cranial LOOPs were implanted in the 60 patients (56.01 ± 20.21 years, 55% women) included in the study. The cranial fixation system maintained a good bone flap alignment in 95% of the patients studied immediately after surgery and in up to 96.7% of them at the end of follow-up. No intraoperative complications were reported. An ulcer potentially related to a device was detected, which was solved without the need for device removal. No artifacts were observed in any of the 219 medical images analyzed.**

CONCLUSIONS: **Cranial LOOP is a safe and reliable postoperative long-term cranial bone flap fixation system. This device can fix the bone flap after a wide range of craniotomy procedures, performed in multiple locations, and provides good bone flap alignment. Cranial LOOP does not interfere in patient follow-up through medical imaging.**

INTRODUCTION

After a craniotomy procedure to access the brain and subsequent brain surgery, the bone flap must be placed back in its original position and fixed to the skull. This should be done not only for obvious aesthetic reasons, but also to ensure the safety of the brain and therefore of the patient. Visible defects can cause psychosocial rejection and also a permanent risk of mechanical damage to the unprotected brain.[1]

The ideal fixation system of the bone flap should be safe, reliable, quick, and easy to implant; cause minimal foreign body reactions; and produce no artifacts on neuroimaging.[1]

Over the years, various systems have been used for this procedure: sutures, metal cables, titanium plates and screws, and metal-based clamplike cranial fixation systems.[1] Titanium fixation systems (plates and screws and clamplike devices) are currently the gold standard thanks to their good mechanical properties,[2] but they present some drawbacks that should be taken into consideration: titanium implants have been associated with localized inflammation, chronic infection, and leaching of metal ions into local tissues after long-term skull implantation,[3] which can lead to soft tissue erosion, irritation, and pain and necessitate immediate removal.[4]

Polymeric fixation devices, particularly those made of polyether ether ketone (PEEK), could offer an alternative to the titanium systems, as they also present excellent mechanical properties[5,6] and a long-term biocompatibility profile in neurosurgical applications.[7,8]

Cranial LOOP (NEOS Surgery S.L., Barcelona, Spain) is a PEEK-based, instrument-free, clamplike cranial bone flap fixation system that has been reported to be a fast, easy, and safe system causing no computed tomography (CT) or magnetic resonance imaging artifacts.[9] However, its long-term safety and efficacy profile has not been established. The main aim of this study was to assess if Cranial LOOP maintains an appropriate alignment of the bone flap over time after a craniotomy procedure. A group of 60 patients was evaluated to assess the long-term clinical

Key words
- Bone flap
- Craniotomy
- Cranial fixation devices
- Polyetheretherketone

Abbreviations and Acronyms
CT: Computed tomography
MRI: Magnetic resonance imaging
PEEK: Polyether ether ketone

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performance, focusing on bone flap alignment, of the 3 available sizes of Cranial LOOP.

MATERIAL AND METHODS

Study Design and Patient Characteristics

This is an observational, retrospective, case-series study of patients who underwent a craniotomy procedure and were subject to cranial bone flap fixation with the Cranial LOOP fixation system. Patients in whom other devices or fixation systems were implanted, or for whom no postoperative CT scan or magnetic resonance imaging was available, were excluded from the study. All the patients were operated in a tertiary hospital (Hospital de la Santa Creu i Sant Pau, Barcelona, Spain) between October 2009 and February 2017. The study protocol was approved by the Ethics Committee of the hospital (Ref 18/034 [PS]) and conducted according to the principles and rules laid down in the Declaration of Helsinki and its subsequent amendments.

Device Description and Implantation Technique

The Cranial LOOP is a postoperative long-term cranial bone flap fixation system, which fixes the bone flap to the skull after a craniotomy, without requiring any specific surgical instrument for its handling or implantation. Cranial LOOP devices are based on the principle of a clamp. They consist of 2 platforms linked by two adjustable cable ties. In a first step, the lower platform is positioned in the subcranial area (between the dura and internal table of the cranium) and, in a second step, after positioning the bone flap back in its original position between the 2 device platforms, the upper platform is tightened to the skull with the aid of gentle pressure on the applier while pulling on the handle. The upper platform presents a double locking system (2 ratchets that engage with the lower platform's cable ties' teeth) that allows its movement toward the lower platform and, at the same time, impedes its backward movement. After tightening of the platforms, the nonimplantable parts (handle and applier) and the cable ties' excess are removed, first by cutting the ties with standard surgical scissors and then by taking advantage of their

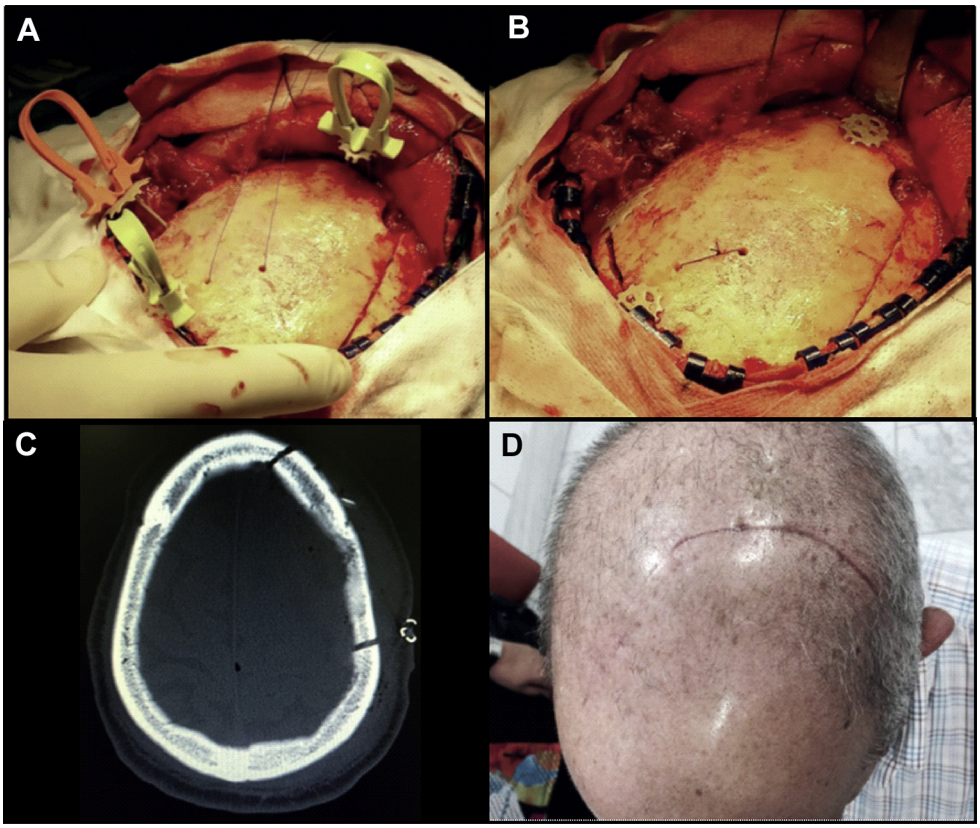

Figure 1. Cranial LOOP fixation system. (**A**) Intraoperative view of the positioning of 2 Cranial LOOPs (L) (green) and 1 Cranial LOOP (XL) (orange) in a frontoparietaltemporal craniotomy of a patient operated from a meningioma. (**B**) Fixed craniotomy. Note that the Cranial LOOP (XL) covers 1 of the burr holes performed. (**C**) Postoperative computed tomography scan showing the bone flap perfectly aligned. (**D**) Postoperative aesthetic result. Note that where the Cranial LOOP (XL) was placed, there is no burr hole depression visible, offering a good aesthetic result.

self-cutting feature. At the end of the implantation process, the devices remain adjusted to the skull bone surface. A minimum of 3 uniformly placed devices per craniotomy are necessary to maintain the stability of the bone flap in its final position (Figure 1).

The 3 available sizes of Cranial LOOP have been evaluated in this study: Cranial LOOP and Cranial LOOP (L) are used within the osteotomy line (calvarial gap), while Cranial LOOP (XL) is used in standard 14 mm cranial burr holes (thus covering them in addition to fixing the bone flap).

Data Collection

Medical records of 67 patients who were implanted with the Cranial LOOP were reviewed for potential inclusion in the study. Seven patients presented an exclusion criterion (they had other devices or fixation systems implanted), and they were thus considered screening failures. Sixty patients fulfilled all inclusion/exclusion criteria, so these were finally included in the study and analyzed.

Sociodemographic, anthropometric, and baseline clinical parameters, such as the associated diagnosis, of all included patients were collected. Surgical variables, such as the surgical approach, craniotomy characteristics, and number of devices implanted, were also registered. Finally, all available postsurgical follow-up radiologic assessments (CT scan or MRI) of each patient included were reviewed in order to assess the bone flap alignment and artifact presence over time. The primary endpoint of the study was to assess the prevalence of patients who presented a good alignment of the bone flap immediately after the surgery, on one hand, and during the follow-up, on the other hand. Bone flap alignment was evaluated according to the following classification:

a) Bone flap perfectly aligned

b) Misalignment of the bone flap <50% with respect to the skull's external table

c) Misalignment of the bone flap >50% and <100% with respect to the external table

d) Misalignment of the bone flap >100% with respect to the external table

Categories a) and b) were considered a good bone flap alignment, whereas category c) was considered a suboptimal result with nonclinically significant misalignment, and category d) was a clinically significant misalignment. Moreover, postsurgical medical records of all the patients were reviewed to detect any potential adverse event.

Statistical Analysis

Descriptive statistics were used to characterize the population studied and the different variables evaluated, both in the preoperative period, as well as in the surgery visit, and at different follow-up times. For continuous variables (e.g., age, weight), arithmetic mean, standard deviation, median, minimum and maximum, and interquartile ranges are presented. Categoric variables (e.g., gender) are presented in relative and absolute frequencies. GraphPad Prism 6.01 (La Jolla, California, USA) was used to perform the analysis.

RESULTS

Demographics and Baseline Clinical Characteristics of Study Population

Patients included in the study had a mean age of 56.01 ± 20.21 years at the operation time, and 55.0% of them were women. Table 1 summarizes the main sociodemographic and baseline clinical characteristics of the population studied.

Surgery Data

A total of 182 Cranial LOOP devices were implanted in the 60 patients included in the study (58 patients had 3 devices implanted, while 2 patients were implanted with 4 devices). Up to 9 different surgeons implanted the devices. The leading craniotomy indication in the patients studied was tumor resection ($n = 43$, 71.7% of cases). The device was used to fix bone flaps of a wide range of craniotomy sizes (from 6 to 82.45 cm^2) and shapes and located in all the skull areas (although predominantly in frontal locations: $n = 44$, 73.3% of cases). Details on these surgical variables are provided in Table 2.

Patients' Follow-Up

Patients included in the study were followed until clinically discharged, lost to follow-up, or dead. Mean follow-up time was 1 year (367.3 ± 449.6 days), with a maximum follow-up time of 2077 days (5.7 years). A total of 219 radiologic assessments (65 MRI and 154 CT scans), performed from October 2009 to March 2018, were reviewed and analyzed during the study. Four of the included patients had 1 follow-up image, 8 patients had 2, 15 patients had 3, 11 patients had 4, and up to 22 patients had 5.

Bone Flap Alignment

Postsurgery Bone Flap Alignment. A postsurgical CT scan was available for all the patients studied, from the surgery date itself or from up to a maximum of 5 days after surgery. At this time point, 57 patients (95%) presented a good bone flap alignment while 3 patients (5%) presented a misalignment >50% but <100% of 1 of the devices implanted. None of the included patients presented a misalignment >100%.

Bone Flap Alignment During Follow-up. During follow-up, 55 patients (91.7%) presented a good bone flap alignment of all the devices implanted in all the medical images recorded, while 5 patients (8.3%) presented a misalignment >50% but <100% of 1 of the devices implanted in at least 1 of the available medical images. The 5 cases were protrusions of the bone flap. None of the studied patients presented a misalignment >100% in any of the medical images analyzed. Regarding the 5 patients with misalignment, it should be noted that, in all of them, misalignment >50% was only present in 1 of the devices implanted. Moreover, in 3 patients, misalignment >50% was corrected in the subsequent follow-up medical images. Thus at the end of follow-up, only 2 patients (3.3%) presented a misalignment >50% in 1 of the devices implanted, while 58 patients (96.7%) presented a good bone flap alignment.

Medical Imaging Artifacts

None of the 182 devices implanted generated any kind of artifact in any of the 219 medical images evaluated.

Safety Data

From a safety point of view, no intraoperative complications were recorded in any of the surgical procedures performed. On the other hand, only 1 adverse event that was probably device related was present in 1 of the patients studied during follow-up: an ulcer was observed around 1 of the devices 118 days after implantation.

Table 1. Demographic and Clinical Characteristics of Patients Included in Study

Age (years)	
Number	60
Mean (SD)	56.01 (20.21)
Median (Min–Max)	60.50 (5.8–85.2)
IQR	47.03–70.55
Age (distribution) (*n* [%])	
<18 years	4 (6.7%)
18–65 years	33 (55.0%)
>65 years	23 (38.3%)
Gender (*n* [%])	
Female	33 (55.0%)
Male	27 (45.0%)
Diagnosis (*n* [%])	
Glioma	18 (30.0%)
Meningioma	16 (26.7%)
Neurocytoma	1 (1.7%)
Metastasis	8 (13.3%)
Hematoma or hemorrhage	8 (13.3%)
Aneurysm	2 (3.3%)
Colloidal cyst	1 (1.7%)
Cavernoma	2 (3.3%)
Dural arteriovenous fistulas	2 (3.3%)
Arteriovenous malformation	2 (3.3%)
Craniotomy history	
First craniotomy	54 (90.0%)
Second or posterior craniotomy	6 (10.0%)
BMI (kg/m^2)	
Number	39
Mean (SD)	25.10 (4.54)
Median (Min–Max)	24.91 (16.65–34.05)
IQR	21.22–28.91

SD, standard deviation; IQR, interquartile range; BMI, body mass index.

The ulcer was treated and solved with antibiotics and performance of an ulcer debridement under local anesthesia. Explantation of the device was not necessary. It should also be noted that no cases of bone flap movement or displacement, nor any cases of device migration, were detected in the study.

Reoperations and Fixation Removal

Removal of Cranial LOOP devices was necessary in 10 (16.7%) of the studied cases. However, the cause of reoperation and Cranial LOOP explantation was not related to the device in any of the cases: 7 patients were reoperated on because of tumor recurrence, 1 patient underwent debridement of an ulcerated surgical wound, 1 case was due to an epidural hematoma, and, finally, 1 case was associated with a malignant cerebral infarction and intracranial hypertension. In all cases, the removal of the device was considered easy and did not present any complication.

DISCUSSION

Several techniques for bone flap fixation after a craniotomy, such as suturing, wiring, plating, and clamping, have been used historically to minimize complications after brain surgery. Sutures (made of silk, cotton, silver wire or catgut, among others) were 1 of the first approaches to fix the bone flap, while steel wire championed later as the material to replace the suture. However, mechanically, these systems (and particularly sutures) are not safe enough with regard to the strength of the fixation to the skull because there is only a low-grade connection between the bone flap and surrounding skull. Frequent problems have therefore been observed, such as dislocation, depression, or protrusion of the bone flap.[1]

To solve this, the fixation of cranial bone flaps using plates and screws was gradually introduced at the end of the 1980s and beginning of the 1990s.[10] These systems consist of small plates of different sizes that are placed between the bone flap resulting from the craniotomy and surrounding skull, bridging the saw gap and/or covering the burr holes. With respect to sutures and wires, the plates provide a rigid fixation of the bone flap and thus present 2 key advantages: offering greater security in postsurgery stabilization and facilitating bone healing.[11] However, these plates and screws, which are commonly made of different titanium alloys, can protrude more than sutures and thus be palpable sometimes. Skin inflammation at the area of protrusion can lead to ulcer formation, and complications may require surgical removal of the implants.[4] Moreover, miniplates may add significant time and cost to the procedure.

Finally, around the turn of the century, another bone flap fixation technique was established: clamping.[2,12] This system is a double-sided fixation that subjects the bone flap to the skull edge. The first devices based on this principle were also titanium based. Clamplike systems present excellent mechanical results[2] and also provide the advantage of being quickly implanted[12]; however, they have also been related to several reports of product malfunction and/or injuries in, for example, the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience database (see for instance[13]).

The study presented here explored the long-term reliability of a clamplike fixation system that is not metal based but rather based

Table 2. Surgery Characteristics of Patients Included in Study

Craniotomy Indication (*n* [%])	
Tumor Resection	43 (71.7%)
Hemorrhage or hematoma evacuation	8 (13.3%)
Aneurysm clipping	2 (3.3%)
Open biopsy	1 (1.7%)
Cavernoma resection	2 (3.3%)
Closure of dural arteriovenous fistula	2 (3.3%)
Arteriovenous malformation resection	2 (3.3%)
Surgeon (*n* [%])	
A	17 (28.3%)
B	1 (1.7%)
C	4 (6.7%)
D	8 (13.3%)
E	3 (5.0%)
F	11 (18.3%)
G	6 (10.0%)
H	3 (5.0%)
I	6 (10.0%)
Unknown	1 (1.7%)
Craniotomy shape (*n* [%])	
Circle	2 (3.3%)
Oval	24 (40.0%)
Triangle	5 (8.3%)
Square/rectangle	22 (36.7%)
Irregular	7 (11.7%)
Craniotomy area (cm^2)	
N	60
Mean (SD)	39.29 (17.21)
Median (Min–Max)	38.45 (6.00–82.45)
IQR	23.85–51.82
Craniotomy location (*n* [%])	
Frontal	11 (18.3%)
Temporal	2 (3.3%)
Parietal	5 (8.3%)
Occipital	2 (3.3%)
Frontotemporal	16 (26.7%)
Frontoparietal	7 (11.7%)
Frontoparietotemporal	10 (16.7%)
Temporoparietal	2 (3.3%)
Parietooccipital	5 (8.3%)
Craniotomy laterality (*n* [%])	
Left	29 (48.3%)
Right	30 (50.0%)
Bilateral	1 (1.7%)
Total number of devices implanted (*n*)	
Cranial LOOP	66
Cranial LOOP (L)	102
Cranial LOOP (XL)	12
Size unknown	2

Continues

on a biocompatible polymer (PEEK): the Cranial LOOP device. We evaluated 60 patients who underwent a craniotomy procedure and were implanted with this device. This sample size represents 1 of the biggest populations in which a cranial fixation system has been evaluated.[9,14-16]

Cranial LOOP devices were used to fix bone flaps in a wide range of craniotomies, with multiple sizes and shapes, and located in all the skull areas, although predominantly in frontal locations. This is of particular interest in terms of aesthetic results, as this is the skull area more susceptible to presenting with visible cosmetic defects. In this regard, the use of the Cranial LOOP (XL) in burr holes, particularly those performed in the frontal area, helps to achieve a good cosmetic result, as it avoids the skin concavities that can be caused by the burr holes, in addition to providing a good bone flap alignment.

It is also worth noting that we have obtained long-term follow-up data on the device safety and performance, with some patients being followed for more than 5 years. This largely exceeds the time during which the products have to exert their main function (allow the formation of a firm bony healing in the craniotomy gap), which is considered to require 3–4 months[2] since the surgery date.

The main aim of the present study was to assess if the fixation system maintains an appropriate and stable alignment of the bone flap over time after a craniotomy procedure. We found that, at the end of follow-up, only 2 patients (3.3%) showed clear protrusions of the bone flap in the area of 1 of the 3 devices implanted, but these were nonetheless not clinically significant (<100% misalignment with respect to the external table). Few are the studies that have systematically evaluated (through CT scan and MRI) the long-term performance of a cranial fixation system as we did in our study, but similar results have been reported for all of them in terms of bone flap stability and planarity.[1,14,15] In addition, we have observed that, in most of the cases, in patients who presented small misalignments of the cranial bone flap at a particular time point during the follow-up (for instance, due to a momentary increase of intracranial pressure), these defects tended to be spontaneously corrected and bone flap planarity was recovered in the subsequent follow-up medical images.

We have also confirmed that Cranial LOOP does not generate artifacts in the medical images (neither on CT scans nor MRI). This is another advantage that a polymeric system offers when compared with a metallic one, as it has been reported that metallic

clamps can produce artifacts slightly larger than themselves. These artifacts may affect diagnostic capability if a pathologic condition is present or if the area of interest is close (within a few millimeters) to the clamps.[17]

From a safety point of view, no intraoperative complications were registered in the study and only 1 adverse event that was probably device related (1.7%) was registered during the patients' follow-up: an ulcer was observed around 1 of the cranial fixations. The ulcer was treated with antibiotics and ulcer debridement and did not need device explantation. A potential explanation of this event could be a combination of the advanced age of the patient (aging is associated with thinning of the epidermis and dermis, fragmentation of collagen and elastic fibers, and decrease in skin lipids, vascularity, and supporting structures); patient's comorbidities (diabetes); and the fact that the device associated with the ulcer was located at the point of rotation of the skin flap during surgery. This rate of complications is lower than the rate reported for other cranial fixation systems such as miniplates (2.8%).[4]

Moreover, in those cases in which the studied fixation system had to be removed (the cause of reoperation and Cranial LOOP explantation was not related to the device in any of the cases), the devices could be easily explanted, which is a further advantage for the use of these products.

Finally, it is of particular interest to highlight that the implant was used in 4 pediatric cases, showing no complications and good clinical follow-up results. The Cranial LOOP can be implanted in patients older than 3 years of age and represents a good alternative to metallic or absorbable plates and clamps in this population. The use of metallic plates and screws in children has been associated with intracranial migration in around 10%–14% of cases, some of them even penetrating the dura.[18,19] Bone growth restriction has also been associated with the use of this metallic rigid fixation systems.[18] Bioabsorbable materials present better clinical results in these patients; however, granuloma or sterile abscess formation has been observed in association with some of the absorbable plates.[20] Despite the fact that a bigger sample size of pediatric population would be necessary to make a final conclusion regarding the use of Cranial LOOP in infants, our results show that this cranial fixation system can be considered as a valid alternative in this population.

We must acknowledge that the study presents some limitations, mainly due to its retrospective and single-arm design. However, it should be emphasized that thanks to the accurate collection of data of the medical records and the revision of all available medical records and medical images, little data are missing in the study. Moreover, this is one of the studies with a larger sample size and a longer follow-up evaluating cranial fixation systems, thus offering one of the highest levels of evidence on the behavior of these devices. Future prospective studies comparing different cranial fixation systems would be useful to discern which cranial fixation system offers better clinical results in different clinical situations and to facilitate the decision-making process of implant selection.

In summary, we have demonstrated that the Cranial LOOP offers the good mechanical performance of other clamplike fixation systems together with an excellent safety profile because of special characteristics (including the flexibility and the biocompatibility) provided by the PEEK polymer.

CONCLUSIONS

Cranial LOOP is a safe and reliable postoperative long-term cranial bone flap fixation system. The devices can adequately fix the bone flap after a wide range of craniotomy procedures, performed in multiple locations, and provide a good bone flap alignment, both immediately after the surgery and at long-term follow-up. This has been demonstrated in both the general (adult) and pediatric population. No surgical or relevant postsurgical follow-up complications have been associated with the device. Furthermore, it has been confirmed that Cranial LOOP does not interfere in patient follow-up through medical imaging, as it does not generate any kind of artifact in the medical images.

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