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The use of cranial resection templates with 3D virtual planning and PEEK patient-specific implants: A 3 year follow-up

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ABSTRACT

Purpose: The aim of this study was to evaluate the accuracy of resection templates in cranioplasties in order to facilitate a one-stage resection and cranial reconstruction. Patients and methods: In three cases, cranial resections were combined with direct reconstructions using the principles of computer-aided design, manufacturing, and surgery. The precision of the resection template was evaluated through a distance map, comparing the planned and final result.
Results: The mean absolute difference between the planned and actual reconstructed contour was less than 1.0 mm. After 3 years, no clinical signs of infection or rejection of the implants were present. The computed tomography scans showed no irregularities, and the aesthetic results remained satisfactory.
Conclusion: One-stage resection and cranial reconstruction using a resection template, control template, and a prefabricated patient-specific implant of poly(ether-ether-ketone) (PEEK) proved to be a viable and safe method.

1. Introduction

The skull is a complex part of the skeleton, with convex and concave areas. It protects the brain from external impact and can be seen as the base for the facial skeleton. During decompressive craniectomy, a part of the cranial vault is removed for surgical access to reduce intracranial pressure caused by trauma, tumor, haemorrhage, and empyema (Malcolm et al., 2016).

The removed part of the cranial vault can be re-inserted immediately after decompressive craniectomy. In some cases this is not possible because of swelling or increased intracranial pressure. In this situation the cranial reconstruction is performed at a later stage, when the patient is neurologically stable (Hutchinson et al., 2016). Resorption and infection are frequently seen in cranial reconstruction, which makes removal of the affected cranial vault necessary (Morton et al., 2016). The remaining defect may cause both functional and aesthetic problems, making reconstruction necessary. Ideally, the appropriate cranial reconstruction does not affect the patient's anatomy, thus ensuring optimal fit and contouring.

The design of a patient-specific implant (PSI) can be based on the patient's computed tomography (CT) data, using computer-aided design, manufacturing, and surgery (CAD/CAM-CAS). Small inaccuracies in the design can lead to an impaired intraoperative fit. CAS aims to predict and mitigate intraoperative obstacles, ensuring an optimal fit of the PSI. If removal of the autologous bone is required, the original outline of the cranial defect may be difficult to predict. An example is the presence of persistent bony bridges in cases of partial resorption of the autologous bone flap (Fig. 1A). A resection template may be used to create a predetermined outline (Fig. 1B,C).

In a non-acute setting, as in tumor removal, a combined craniectomy and cranioplasty can be preoperatively planned with the use of CAD/CAM-CAS. In preoperative virtual planning, a resection template may be designed to enable a one-stage surgical procedure for resection and reconstruction with a PSI. This prevents a lidless period (in which the patient needs to wear a helmet), avoids the need for a second surgical procedure, and may lower complication

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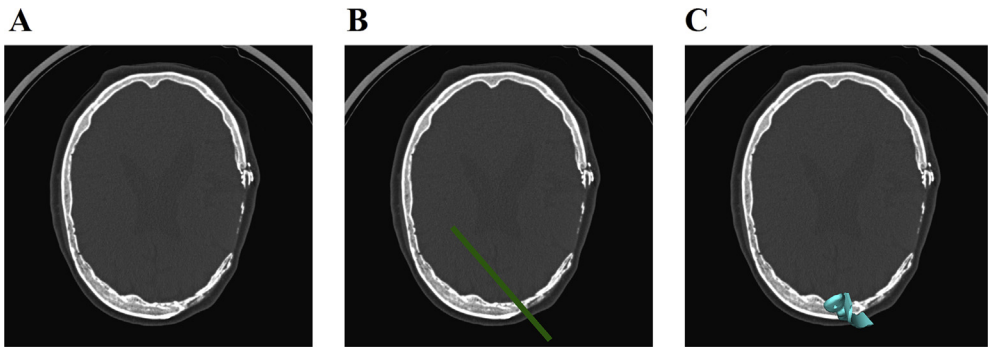

Fig. 1. CT axial slice with (A) resorption of autologous bone, (B) resection outline, (C) planned resection template.

rates and costs. In this study, the accuracy of resection templates for cranioplasty is critically evaluated with the aim of developing a reliable, fail-safe, and time-sparing cranial reconstruction using CAD/CAM-CAS technology.

2. Materials and methods

Three consecutive patients underwent cranial resections and reconstructions with the use of resection templates, control templates, and a pre-fabricated poly(ether-ether-ketone) (PEEK) PSI.

Patient one: This 60-year-old female underwent a right temporal decompressive craniectomy because of acute subdural hemorrhage after trauma. She used acenocoumarol for atrial fibrillation and had hypertension in her medical history. After 4 months, the patient was neurologically stable and underwent a cranial reconstruction with autologous bone, which was stored in a bone bank at −80 °C. Twenty-two months after reinsertion of the autologous bone the patient complained about headache and vertigo. A CT-scan was performed and resorption of the autologous bone was observed (Fig. 2A). Removal of the autologous bone was planned in the same procedure as the insertion of the PSI, with the use of resection templates (Fig. 2B,C). After the reconstruction, a postoperative CT-scan was acquired to verify the position of the implant (Fig. 2D). A distance map was generated between the planned position of the PSI and the location achieved postoperatively in order to quantify the result (Fig. 2E).

Patient two: This 45-year-old male underwent a craniotomy because of a left frontal ossifying meningioma. He had obstructive sleep apnea in his medical history. After 6 weeks, the autologous bone was removed due to infection and an antibiotic treatment was started. Sixteen months later, when the patient was medically and neurologically stable, the cranial reconstruction was planned. Since bone resorption was observed on the CT-scan, a resection template was used to create a clear outline of the defect (Fig. 3). The PEEK PSI was inserted immediately, without intraoperative adjustments to the PSI.

Patient three: This 40-year-old female, without comorbidities, was diagnosed with a left frontal ossifying meningioma and was scheduled for one-stage resection and reconstruction with a PEEK PSI. The actual procedure is described in detail below.

3. Results

3.1. Representative case of one-stage resection and reconstruction

3.1.1. Preoperative planning

A CT-scan (Philips Brilliance 64, 120 kV, 285 mAs, 25 × 15 cm FOV, 512 × 512 matrix size, 1.0 mm slice thickness, 0.5 mm slice increment, kernel D (hard-tissue)) of the cranium was acquired for preoperative planning (Fig. 4). A volumetric segmentation of the meningioma was defined and the resection of the meningioma was planned with a 2.0 cm margin. To create a symmetrical and aesthetically satisfying PSI, mirroring was applied to overlay the

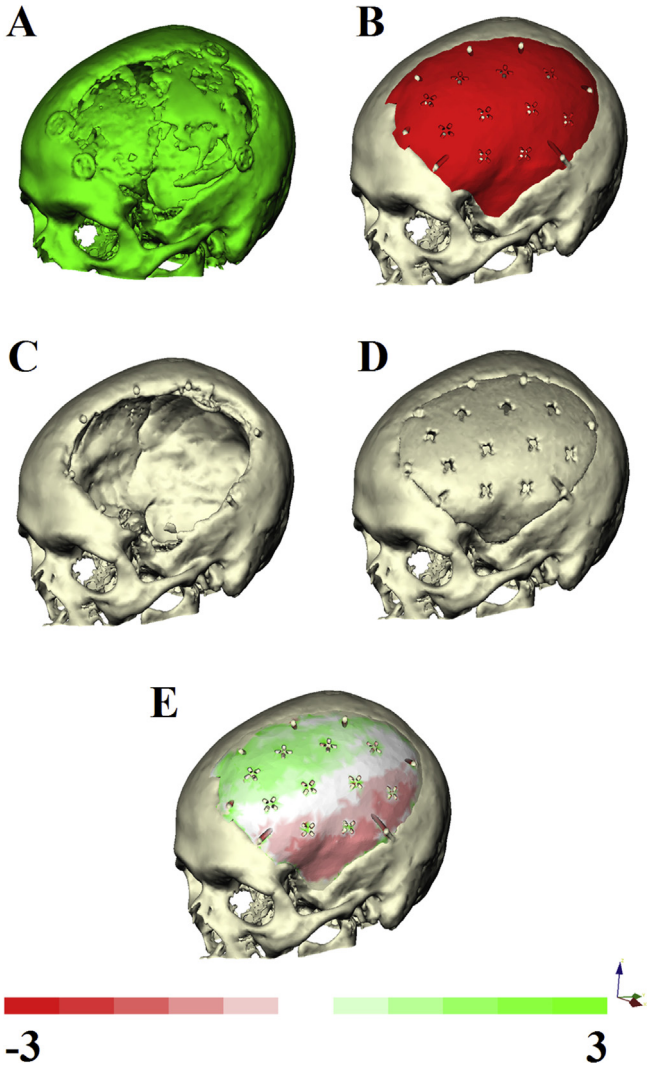

Fig. 2. (A) Resorption of autologous bone/bony bridges. (B) Preoperative planned patient-specific implant of poly(ether-ether-ketone) (PEEK). (C) Postoperative resection. (D) Postoperative inserted PSI. (E) Distance map between the planned contour of the patient-specific implant and the achieved contour postoperatively. Green indicates a positive displacement; red indicates a negative displacement.

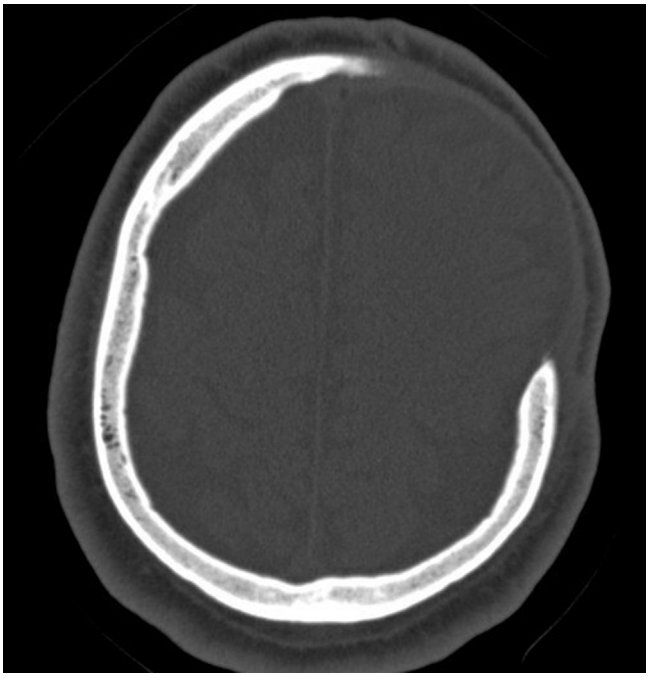

Fig. 3. Axial slice of a CT-scan of the skull contour without patient-specific implant.

unaffected, contralateral half of the cranium on the affected side. The resection template was designed based on the planned resection and existing patient's anatomy. A second template with a shape identical to the PSI (control template) was designed to fine-tune the resection and verify that the PSI would fit in one try (Fig. 4).

After agreement on the design of the PSI, it was fabricated in poly(ether-ether-ketone) (PEEK) using a milling technique (Xilloc Medical BV, Geleen, the Netherlands). The resection template and fitting template were 3D printed in nylon using selective laser sintering.

3.1.2. Surgical procedure

Intraoperatively, the meningioma was surgically exposed and the temporal muscle was partially detached from the orbit and pterion (Fig. 5A). The resection template was temporarily fixed with ten 10 mm screws. The resection of the meningioma was performed with a piezo-surgical instrument (Fig. 5B). The resected meningioma and pathologically involved dura mater were consequently removed (Fig. 5C). A subgaleal flap was transferred and sutured to close the dural defect. The control template was used to resect excess bony ledges that would hamper a good fit. Tangential burr holes were created following the InterFix® guide and the PSI was fixed to the surrounding bone (Fig. 5D). The temporal muscle and fascia were partially sutured to the PSI with Xsuture® (Fig. 5E). Total operating time was 430 min. No intraoperative complications occurred. After 3 years, no clinical signs of infection, haemorrhage, or other complications relating to the implant were observed. The aesthetic result remained satisfactory, as subjectively judged by patient and clinician. The postoperative CT-scan showed no irregularities.

4. Discussion

This study reports the use and accuracy of resection templates and control templates in cranial reconstructions. Cranioplasty with autologous bone has a relatively high complication rate. Resorption and infection are the most mentioned complications in the literature, leading to removal of the cranioplasty (Corliss et al., 2016; Malcolm et al., 2016; Morton et al., 2016). One-stage

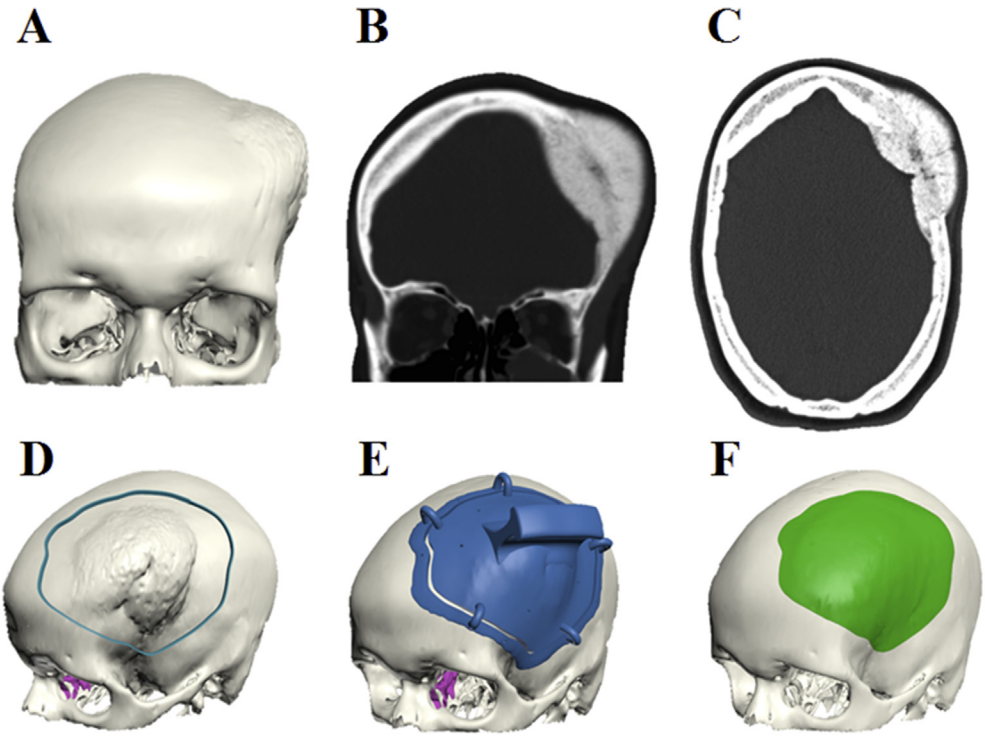

Fig. 4. (A) 3D rendering of CT data. (B) CT coronal coupe. (C) CT axial slice. (D) Preoperative planned resection outline of the meningioma. (E) Nylon resection template. (F) Patient-specific implant designed using a mirroring technique.

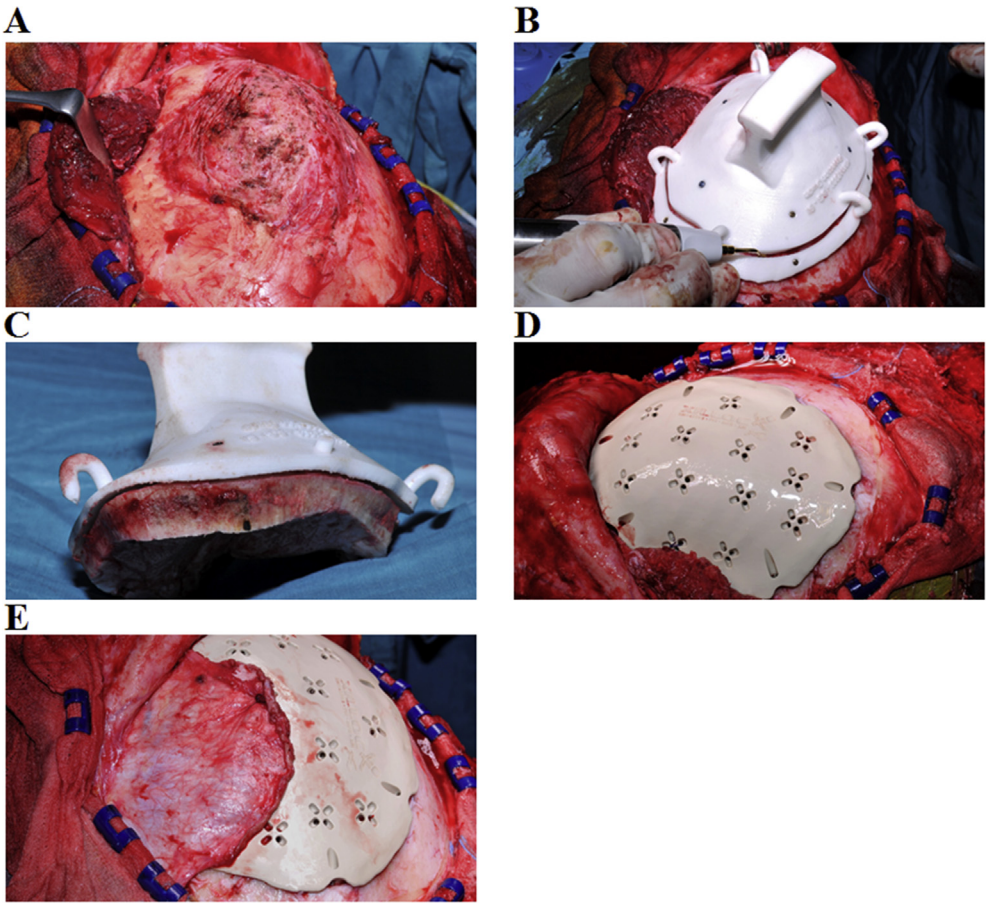

Fig. 5. Intraoperative photographs of (A) exposed meningioma, (B) fixed nylon resection template, (C) total resection of the meningioma, (D) fixed patient-specific PEEK implant, (E) suspension of temporal muscle.

reconstruction can reduce postoperative complications, due to an accurate fit of the PSI, avoidance of a second procedure, and a reduction in overall operating time.

A representative case of a total resection of an ossifying meningioma and reconstruction with a PEEK PSI in a one-stage surgical procedure using a resection template is described in detail. This technique has been developed to reduce the burden on the patient. Since only one surgical procedure is required, hospitalisation time is reduced and no helmet needs to be worn during revalidation. During surgery, this technique prevents extensive intraoperative positioning, achieves an accurate PSI fit (absolute mean difference <1.0 mm), and seems to reduce operation time. In this case, after 3 years, no complications were observed and the aesthetic result was satisfactory.

The procedure is relatively new, although similar techniques are described in the literature (Rohner et al., 2013; Guerrini et al., 2017; Abdel Hay et al., 2017; Broeckx et al., 2017). In our study, the resection outline of the meningioma was virtually preplanned according to the CT-scan. Other studies describe intermediary steps. For example, the craniectomy of the affected bone can be preplanned on a plaster head phantom based on a CT-scan. This allows the surgeon to draw the outline of the desired resection on the phantom (Rohner et al., 2013). Other surgeons perform the craniectomy on the gypsum phantom, acquire a CT-scan of the phantom with the defect, and create a silicon mold based on this CT-scan (Guerrini et al., 2017).

The use of an indirect molding technique is well described in the literature. With a CT-scan and mirroring technique a mold can be created in different materials (Guerrini et al., 2017; Abdel Hay et al., 2017). Different techniques for fabricating the final PSI are mentioned. Poly(methyl methacrylate) — PMMA — can be mixed by hand intraoperatively and cast into the mold. Post-processing of the implant on the operation room is required because the burrs will prevent a good fit. Due to limitations in the operation room, post-processing is performed with a surgical knife (Abdel Hay et al., 2017). The preoperative manufacturing of PMMA PSIs is also described (Broeckx et al., 2017). This reduces the aforementioned limitation, yet still often involves fabrication using an indirect molding technique (Jonkergouw et al., 2016).

The cranioplasty described in this study is made of PEEK, a relatively new material used for this purpose. PEEK shows good chemical resistance because of its resonance-stabilized and aromatic structure (Sasuga and Hagiwara, 1987), has long-term stability in wet environments, and can resist temperatures up to 260 °C (Stober et al., 1984; Boinard et al., 2000). PEEK can be sterilized in an autoclave or with gamma radiation without significant changes to the material properties; it can be repeatedly sterilized (Godara et al., 2007; Steinberg et al., 2013). It is radiolucent, without artefacts on (postoperative) imaging (Kurtz, 2012). The mechanical properties of PEEK are comparable to cortical bone, whilst biocompatibility is good, without release of ions or constituents. These properties make PEEK a suitable material for medical implants (Toth et al., 2006; Kurtz, 2012). PEEK is a versatile material, suitable for CAD-CAM technology using a direct production method: no mold or intraoperative production procedures are necessary (Kim et al., 2009).

PEEK is not bioactive, so a PEEK surface will not integrate with the surrounding tissues as bone. PEEK cranioplasty is recommended for use with a fixation material, e.g. osteosynthesis (Kurtz, 2012; Toth et al., 2006). The risk of infection is one of the main disadvantages, and the most important complication reported in literature (Vijfeijken et al., 2018). Higher costs are an important issue too. A PEEK PSI, including a resection template and a control template, costs approximately 7500 euros (including work-up) in the Netherlands. However, the preoperative planning time is approximately 1 h. With only one procedure needed, total cost and surgical time are likely to be lower compared with a two-staged surgical procedure. Raw PEEK is a relatively expensive material, which has to be milled; in this process, a great portion of the material becomes unusable (Lethaus et al., 2014).

Other designs for resection templates in cranial defects have been recently described. In that by Carolus et al., only the outline of the resection is established in the template (Carolus et al., 2017). In our study the resection template forces the surgeon to follow the resection outline through the use of an inner and outer piece of the template. The inner part of the resection template ensures that the meningioma can removed in one piece (Fig. 4C). The design of the resection template is important in making the surgical intervention easier and in reducing operation.

A one-stage approach, with the use of saw templates, is used in other surgical procedures, for instance in secondary orbitozygomatic complex reconstruction after trauma (Ng et al., 2012; Coppen et al., 2013; Schreurs et al., 2017; Schepers et al., 2016; Rohner et al., 2013). Fixation of the resection template is planned using the existing screw hole positions to ensure accurate resection and enable subsequent reconstruction. The saw template technique is also used to combine resection and reconstruction in head and neck oncological resection with bony mandibular reconstruction with vascularized fibula grafts (Schepers et al., 2016; Rohner et al., 2013). Three surgical guides can be designed for different intraoperative steps in this comprehensive procedure: a resection template for the resection of the mandibular tumor; a resection template for the execution of the fibular osteotomy, and a reconstruction template for the final reconstruction (Coppen et al., 2013).

Evaluation of the accuracy of templates is described in several studies (Ng et al., 2012; Weijs et al., 2016; Mascha et al., 2017). Weijs et al. calculated the difference in angulation of the screws and actual resection plane compared with the planned resection in oromandibular reconstructions (Weijs et al., 2016). Mascha et al. evaluated the accuracy of oromandibular reconstructions by measuring distances between corresponding landmarks on the mandibular rami on pre- and postoperative CT-scans (Mascha et al., 2017). Here, the accuracy was calculated by comparing a continuous distance map of the PSI with its planned location.

5. Conclusion

One-stage craniectomy and reconstruction using a prefabricated resection template, control template, and PEEK PSI seems to be a viable and safe technique. Resection templates enable the use of a PSI for secondary cranial reconstruction in a one-stage surgical procedure. It can reduce operation time and number of surgical procedures, and may reduce cost. A major advantage for the patient is absence of a lidless and risky period, with an immediate aesthetically satisfying result.

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Conflicts of interest

The authors have no conflicts of interest to report.

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Appendix

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