Clinical relevance of current materials for cranial implants

Towards an optimal patient-specific implant material

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CHAPTER 6

The use of cranial resection templates with 3D virtual planning and PEEK patient-specific implants

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ABSTRACT

Purpose: The aim of this study was to evaluate the accuracy of resection templates in cranioplasties 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-assisted design, manufacturing and surgery. The precision of the resection template was evaluated through a distance map between 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 aesthetical 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) proves to be a viable and safe method.
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.

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 intra-cranial pressure. In this situation the cranial reconstruction will be performed at a later stage, when the patient is neurologically stable. Resorption and infection are frequently seen in cranial reconstruction, which makes removal of the affected cranial vault necessary. 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 intra-operative 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 case of partial resorption of the autologous bone flap (Figure 1A). A resection template may be used to create a predetermined outline (Figure 1B and 1C).

Figure 1: CT axial slice with A) resorption of autologous bone B) resection outline C) planned resection template.
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 rates and costs. In this study, the accuracy of resection templates for cranioplasty is critically evaluated with the aim in developing a reliable fail-safe and time-sparing cranial reconstruction using CAD/CAM-CAS technology.

**Material and Methods**

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

**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 has 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 (Figure 2A). Removal of the autologous bone was planned in the same procedure as the insertion of the PSI with the use of resection templates (Figure 2B, 2C). After the reconstruction, a post-operative CT-scan was acquired to verify the position of the implant (Figure 2D). A distance map was generated between the planned position of the PSI and the achieved location post-operatively for quantification of the result (Figure 2E).
Figure 2: A) Resorption of autologous bone / bony bridges B) Preoperative planned patient specific implant of poly (ether ether ketone) (PEEK) C) Post-operative resection D) Post-operative 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.
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 six 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 (Figure 3). The PSI of PEEK was inserted immediately without intra-operative adjustments to the PSI.

Figure 3: Axial slice of the CT-scan of the skull contour without patient specific implant

RESULTS

Patient three: This 40-year old female, without co-morbidities, 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 on the next page:
Representative case of one-stage resection and reconstruction

Preoperative planning

A CT-scan (Philips Brilliance 64, 120 kV, 285 mAs, 25x15 cm FOV, 512x512 matrix size, 1.0 mm slice thickness, 0.5 mm slice increment, kernel D (hard-tissue)) of the cranium was acquired for preoperative planning (Figure 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 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 (Figure 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.

Figure 4: A) 3D rendering of CT data, B) CT coronal coupe, C) CT axial slice. Preoperative planned, D) resection outline of the meningioma, E) nylon resection template, F) patient specific implant designed by using a mirroring technique.
Surgical procedure

Intraoperatively, the meningioma was surgically exposed and the temporal muscle was partially detached from the orbit and pterion (Figure 5A). The resection template was temporarily fixed with ten 10 mm screws. The resection of the meningioma was performed with a piezo-surgical instrument (Figure 5B). The resected meningioma and pathologically involved dura mater were consequently removed (Figure 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 (Figure 5D). The temporal muscle and fascia were partially sutured to the PSI with Xsuture® (Figure 5E). Total operating time was 430 minutes. No intra-operative complications occurred. After three 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 post-operative CT-scan showed no irregularities.

Figure 5: Intra-operative photographs of A) exposed meningioma, B) fixed nylon resection template, C) total resection of the meningioma, D) fixed PEEK patient specific implant, E) suspension of temporal muscle.
DISCUSSION

This study reports the use and accuracy of resection templates and control template in cranial reconstructions. Cranioplasty with autologous bone has a relatively high complication rate. Resorption and infection are the most mentioned complications in literature, that lead to removal of the cranioplasty\(^1,3,4\). One-stage 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 intra-operative positioning, achieves an accurate PSI fit (absolute mean difference <1.0 mm), and seems to reduce operation time. In this case, after three years, no complications were observed and the aesthetic result was satisfactory.

The procedure is relatively new, although similar techniques are described in literature\(^5–8\). In this 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 is pre-planned 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\(^5\). Other surgeons perform the craniectomy on the gypsum phantom, acquire a CT-scan of the phantom with the defect, and a silicon mold is created based on this CT-scan\(^6\).

The use of the indirect molding technique is well described in the literature. With the use of a CT-scan and mirroring technique a mold of different materials can be created\(^6,7\). Different techniques to fabricate the final PSI are mentioned. Poly (methyl methacrylate)(PMMA) can be mixed by hand intra-operatively and casted into the mold. Post-processing of the implant on the operating room is required because the burrs will prevent a good fit. Due to limitations in the operating room, post-processing is performed with a surgical knife\(^7\). The preoperative manufacturing of PSI of PMMA is also described\(^8\). This reduces the aforementioned limitation, yet still often is fabricated by an indirect molding technique\(^9\).
The cranioplasty 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, has long term stability in wet environments, and can resist temperatures up to 260°C. PEEK can be sterilized in an autoclave or with gamma-sterilization without significant changes to the material properties; it can be repeatedly sterilized. It is radiolucent without artefacts on (postoperative) imaging. The mechanical properties of PEEK are comparable to cortical bone; biocompatibility is good without release of ions or constituents. These properties make PEEK a suitable material for medical implants. PEEK is a versatile material, suitable for CAD-CAM technology using a direct production method: no mold or intra-operative production procedures are necessary.

PEEK is not bioactive, so a PEEK surface will not integrate with the surrounding tissues as bone. PEEK cranioplasty is recommended to be used with fixation material, e.g. osteosynthesis. The risk of infection is one of the main disadvantages and the most important complication reported in literature. Higher costs are an important issue too. A PEEK PSI, including a resection template and a control template, adds up to approximately 7500 EUR including work-up in the Netherlands. However, the preoperative planning time is approximately 1 hour. With only one procedure is needed, total cost and surgical time are likely lower compared to 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.

Other designs for resection templates in cranial defects have been recently described. In the design of Carolus et al., only the outline of the resection is established in the template. 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 (figure 4C). The design of the resection template is important to make the surgical intervention easier and reduce operation time.
A one-stage approach, with the use of saw templates, is used in other surgical, for instance in secondary orbitozygomatic complex reconstruction after trauma.\textsuperscript{21,22,23,24,25} Fixation of the resection template is planned on 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 oncologic resection with bony mandibular reconstruction with vascularized fibula grafts.\textsuperscript{24,5} Three surgical guides can be designed for different intra-operative 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\textsuperscript{22}.

Evaluation of the accuracy of templates is describes in several studies.\textsuperscript{21,25,26} Weijs et al. calculated the difference in angulation of the screws and actual resection plane compared to the planned resection in oromandibular reconstructions.\textsuperscript{25} Mascha et al. evaluated the accuracy of oromandibular reconstructions by measuring distances between corresponding landmarks on the mandibular rami on the pre- and postoperative CT-scans.\textsuperscript{26} Here, the accuracy was calculated with the use of a continuous distance map of the PSI compared with its planned location.

**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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REFERENCES


Resection templates with 3D virtual planning

