Patient Specific Implants in Cranioplasty: The Innovative Field of Neuroplastic Surgery

**INTRODUCTION**

Cranioplasty is a surgical repair of a defect or deformity of the skull and is performed for both functional reasons (i.e., to protect the brain) and aesthetic reasons. Traditionally, autologous bone grafts and/or osteotomies have served as the gold standard for the repair of cranial defects due to their minimal risk profiles and low costs. However, their use has been associated with difficulty in shaping the graft, donor site morbidity, long operative times, significant bone resorption of the autologous flap (when using free bone grafts), and risk of fragmentation and infection. Additionally, increasing costs and regulations of bone banks are leading to the discontinuation of storage options for autologous bone in healthcare facilities. In recent years, the surgeon’s options have broadened due to major advances in durable biocompatible materials and technologies for designing and modeling computer generated patient specific implants. Patient specific implants have the advantage of being preoperatively tailored to the exact shape and size of the defect which may avoid many of the complications and risks of autologous bone grafts (such as donor site morbidity) while reducing operative time, minimizing the need for intraoperative manipulation, and providing good reconstruction results.

Patient specific implants can be pre-fabricated in a number of biomaterials including titanium, hydroxyapatite, polymethylmethacrylate (PMMA), and polyetheretherketone (PEEK).

**CLINICAL VALUE: Low Rate of Complications**

Kwarcinski and colleagues (2017) undertook a literature review to examine the trends in infection rates using various implant materials for craniofacial reconstruction. The authors abstracted infection rates reported in individual studies and then merged these point estimates into a final comparison figure to provide a holistic overview of the average infection rate for each of the implant materials (Figure 2).

Autologous Bone infection rates varied between 5.93% and 25% (from 10 studies), with an average infection rate of 10.50%, a standard deviation of 7.03% and a relative risk of 1; PMMA hand formed Infection rates varied between 6.56% and 27.27% (from 7 studies), with an average infection rate of 10.98%, a standard deviation of 6.70% and a relative risk of 1.05; Ti plate infection rates varied between 0.00% and 14.17%, with an average infection rate of 8.31% (from 6 studies), a standard deviation of 4.58% and a relative risk of 0.79; PEEK Infection rates varied between 0.00% and 14.29% (from 8 studies), with an average infection rate of 7.89%, a standard deviation of 5.16% and a relative risk of 0.75.

The results of this analysis showed that the average infection rates (when averaged together) are: autologous bone 10.5% (from 10 studies); PMMA hand-formed 11% (from 7 studies); titanium plate 8.3% (from 6 studies); PEEK 7.9% (from 8 studies).
These results are consistent with other published comparative studies. Lethaus and colleagues (2014) conducted a retrospective chart review comparing complication rates following cranial reconstruction with either patient specific implants (PSI implants: n=7) or titanium implants: n=10) or autologous bone grafts (n=16) and found the patient specific implant group had a complication rate of 5.9% versus 43.8% in the autologous bone group.9 Similarly, a health economic analysis by Gilardino and colleagues (2015) comparing patient specific implants (n=12) to autologous bone implants (n=15) for cranial defects found 0% complications in the patient specific implant group versus 47% in the autologous bone group.3 A meta-analysis by Punchak and colleagues (2017) comparing patient specific implants and autologous bone cranioplasty outcomes found more than a 7.69-fold increase in the odds of developing postoperative complications following autologous cranioplasty compared to patient specific implants.2

Another major complication associated with autologous bone is the bone resorption. The reported incidence of bone flap resorption varies widely in current literature, from as low as 4% to as high as 50%.10 Recent published literature indicates that bone flap resorption is becoming increasingly apparent that many bone flaps undergo aseptic necrosis such that cranial protection is compromised.10

**HUMANISTIC VALUE: Satisfying Reconstruction Results**

Patient specific implants are custom-made from a high-resolution CT scan making it possible to obtain personalized reconstruction of the cranial defect that is anatomically correct.11 One of the main benefits of PSI cranioplasty are the fit achieved in complicated anatomies verses flatter cranial regions. Several studies have evaluated patient satisfaction and patient outcomes associated with Patient Specific Implants. Brandicourt and colleagues (2017) evaluated patient satisfaction in 30 patients who received Patient Specific Implants for reconstruction of a cranial vault defect and found that a majority of patients (90%) were either satisfied or very satisfied with their reconstructive results (Figure 4).11

These results are consistent with other published studies. Rosenthal and colleagues (2014) evaluated patients undergoing cranioplasty with patient specific implants and found that 81% of the 37 respondents were either somewhat satisfied or very satisfied with their reconstructive results.12 Similarly, Zegers and colleagues (2017) examined the therapeutic effect of patient specific implants in cranioplasty and found that 88% of patients (n=22) rated their reconstructive results as good or very good.13 This study also examined patient reported quality of life using the Glasgow Benefit Inventory measure and found an improvement of +26.1 points (95% CI 16.8-35.4; p<0.001) for the entire study population reflecting a statistically significant benefit from patient specific implants on overall quality of life.13

Independent of the implant material and/or vendor selected, all cranioimplants implants should be designed to help prevent soft tissue, temporal hollowing that could lead to revision procedures.14 The approach and care to achieve symmetry in the skull should be similar to the special care given to the breast cancer patient population following oncologic breast surgery—analogous to restorative breast reconstruction and goals for absent deformity.14 As such, one could argue that the craniofacial deformity postneurosurgery is even more critical for one’s recovery and overall well-being. Temporal wasting/hollowing is now considered the number one reported complication—with an incidence approaching 52%.14 Also, the increased need for repeat or corrective procedures places a significant financial burden on the health care system at large. Furthermore, in the most extreme cases, PTH can lead to low self-esteem, chronic depression, and even suicidal ideations.14

![Figure 4. Patient Satisfaction Results from Retrospective Evaluation of Patient Specific Implants (n=3)](source: Brandicourt et al. World Neurosurgery 2017;105:783-789.)
ECONOMIC VALUE: Cost-beneficial Alternative with Improved Outcomes

The costs involved in cranioplasty are important factors to consider when choosing the ideal reconstruction method. Patients specific implants have gained popularity with surgeons because of potential advantages which include preoperatively planned contour, obviated donor-site morbidity, operative room time savings, less complications, shorter length of stay, and reduced need for secondary procedures. In each case of absolute cranioplasty failure, the patient requires readmission, a second operation to remove the bone flap, prolonged antibiotic therapy (in the case of infection), a custom-made implant constructed, and readmission for a third surgical procedure. The question addressed in this study is whether it would be more efficacious and cost-effective to insert a custom-made cranioplasty as a primary procedure.

Gilardino and colleagues (2015) examined many of these factors costs associated with Patient Specific Implants compared to autologous bone cranioplasty (Figure 7).

Figure 7. Comparison of Overall Treatment Costs (Canadian Dollars) For Patient Specific Implants versus Autologous Bone Grafts

| Source: Gilardino et al. The Journal of Craniofacial Surgery. 2015;26:113-117. Asterisk denotes statistically significant differences (p<0.05). |

Gilardino et al. found that the cost of the patient specific implant was offset by a reduction in operating room time, shorter length of hospital stay, less time in the intensive care unit (ICU), no reoperations, and less complications compared to autologous bone cranioplasty over a 1-year period (Figure 7). Similarly, a health economic analysis by Mrad and colleagues (2017) found that the cost of the patient specific implant was almost entirely offset by a reduction in operating room time, less time in the ICU, and a shorter hospital stay.

CONCLUSION

Overall, studies from the literature have shown that patient specific implants are associated with low rates of complications, low rates of implant failures, satisfying aesthetic results, reduced operative time, shorter length of stay, and no significant increase in costs when compared to autologous bone grafts for the reconstruction and repair of cranial defects. Ultimately, selection of the cranioplasty technique should depend on the surgeon’s preference and the individual characteristics of the defect in need of reconstruction.

CITATIONS


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