e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com doi: 10.25258/ijpqa.16.9.64

International Journal of Pharmaceutical Quality Assurance 2025; 16(9); 368-374

Original Research Article

Superiority of Titanium Mould Cranioplasty over Autologous Bone Flap in Preventing Infection and Resorption: A Retrospective Cohort Single-Institution Study of Post-Craniectomy Outcomes

Karthik C.[1], Rehana Begum[2], Rahul Jain[3], Rajesh R. Raykar[4], Shailesh A.V. Rao[5]

[1]Senior Resident, Department of Neurosurgery, St. Johns Medical College and Hospital, Bengaluru, Karnataka, India

[2]Senior Resident, Department of Neurosurgery, St. Johns Medical College and Hospital, Bengaluru, Karnataka, India

[3]Senior Resident, Department of Neurosurgery, St. Johns Medical College and Hospital, Bengaluru, Karnataka, India

[4]Professor and Head, Department of Neurosurgery, St. Johns Medical College and Hospital, Bengaluru, Karnataka, India

[5]Professor, Department of Neurosurgery, St. Johns Medical College and Hospital, Bengaluru, Karnataka, India

Received: 12-08-2025 / Revised: 28-08-2025 / Accepted: 01-10-2025

Corresponding Author: Dr. Rahul Jain

Conflict of interest: Nil

Abstract:

Background: Cranioplasty following decompressive craniectomy is a common neurosurgical procedure aimed at restoring cranial contour and protecting the brain. The choice between autologous bone flap and alloplastic materials like titanium remains debated, with concerns over autologous bone flap resorption and infection being prominent.

Objective: This study aimed to compare the outcomes of autologous bone flap cranioplasty versus titanium mould cranioplasty, specifically focusing on rates of infection and bone flap resorption.

Methods: A retrospective study was conducted on 150 patients who underwent cranioplasty at St Johns Medical College between December 2023 and July 2025. Patients were divided into two groups: those receiving autologous bone flap cranioplasty (n=40) and those receiving titanium mould cranioplasty (n=110). Data on demographics, underlying pathology, cranioplasty complications (specifically infection and resorption rates), and reoperation rates were collected and analyzed. Statistical comparisons between groups were made using Fisher's exact test and chi-square tests where appropriate, with significance set at $p<0.05$.

Results: Of the 150 patients included, 40 received autologous cranioplasty and 110 received titanium mould cranioplasty. The autologous group demonstrated a significantly higher infection rate of 17.5% (7/40) compared to 5.5% (6/110) in the titanium mould group (p=0.042). Furthermore, bone flap resorption was observed in 10% (4/40) of the autologous group, necessitating reoperation in all these cases, whereas no cases of resorption were observed in the titanium mould group (0/110) (p=0.0045). Additionally, the overall complication rate was notably higher in the autologous group (27.5%, 11/40) relative to the titanium group (5.5%, 6/110) (p=0.0005). The majority of titanium patients (94.5%, 104/110) experienced an uneventful postoperative course compared to 72.5% (29/40) in the autologous cohort.

Conclusion: Our findings indicate that titanium mould cranioplasty offers superior outcomes compared to autologous bone flap cranioplasty, with significantly lower rates of infection and a complete absence of bone flap resorption. These data challenge previous assumptions regarding infection equivalency between materials and underscore the durability and reliability of titanium implants. We recommend preferential consideration of titanium cranioplasty, especially in patients at risk for bone graft failure or infection.

Keywords: Cranioplasty, Autologous, Titanium Implants.

Introduction

Decompressive craniectomy is a crucial life-saving procedure performed to relieve elevated intracranial pressure resulting from conditions such as traumatic brain injury, stroke, tumors, or severe infections. While effective at reducing intracranial pressure, this surgery leaves patients with defects in the skull that necessitate reconstruction through cranioplasty to protect the brain and restore the normal contour

of the skull. Furthermore, cranioplasty plays an important role in enhancing cerebral blood flow, cerebrospinal fluid dynamics, and overall neurological and cosmetic function.

Multiple materials have been employed to reconstruct skull defects [1,2] including autologous bone grafts, polymethyl methacrylate, and titanium mesh or molds. Autologous bone grafts have traditionally been favored [1] due to their compatibility with the patient's anatomy and relative cost-effectiveness. However, these grafts are associated with notable complications, particularly bone flap resorption and postoperative infections, [3,4] which often lead to repeat surgeries. Various factors contribute to these complications, including how the bone is stored, the timing of the reconstruction, patient health conditions, and the size of the cranial defect.[5]

On the other hand, titanium implants have become increasingly popular, [2,6] especially with advancements in customized, computer-assisted design and fabrication techniques. Titanium offers a durable and biocompatible alternative, showing lower rates of long-term failure and infections comparable to or even better than autologous bone. [2,4] Additionally, titanium is known to provide better cosmetic outcomes, especially for larger defects, and notably resists the problem of resorption that plagues biological grafts.[6]

Despite a growing number of studies investigating both autologous and synthetic cranioplasty materials, direct comparisons are complicated by differences in patient populations, surgical techniques, and varying risk factors. While overall complication rates can be similar, specific issues such as infection, implant exposure, and resorption vary with the material used and patient-related factors. Moreover, demographic and geographic differences further highlight the importance of tailoring surgical decisions to individual patient needs and contexts.

This study aims to critically compare clinical outcomes, complication rates, rates of revision surgeries, and durability associated with titanium mould and autologous bone cranioplasty. Through this comprehensive evaluation, it seeks to provide guidance for evidence-based surgical decision-making and optimized approaches to cranial reconstruction.

Objective: This study aimed to compare clinical outcomes focusing on infection and bone flap resorption rates between autologous bone flap and titanium mould cranioplasty in a contemporary patient cohort.

Materials & Methods

Study Design and Patient Selection: We retrospectively reviewed 150 consecutive patients who underwent cranioplasty at St Johns Medical College between December 2023 and July 2025. Indications for decompressive craniectomy included traumatic brain injury (TBI) and malignant infarct. Patients were categorized according to cranioplasty material: autologous bone flap (n=40) or titanium mesh/mould (n=110).

Data Collection: Demographic information (age, sex), etiology, comorbidities (hypertension, diabetes mellitus), and perioperative details were recorded. Primary outcome measures included:

- Infection rate
- Bone flap resorption rate
- Overall postoperative complications
- Rate of uneventful recovery

All postoperative complications were documented as per CDC guidelines.[7] Bone flap resorption was identified both clinically and radiographically, with reoperation rates noted.

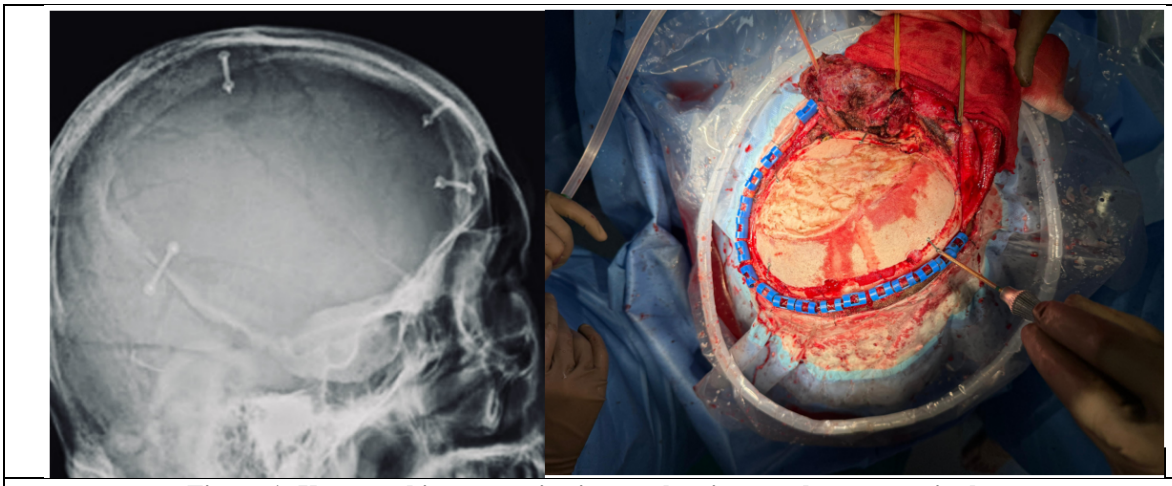


Figure 1: X-ray and introperative image showing autologous cranioplasty

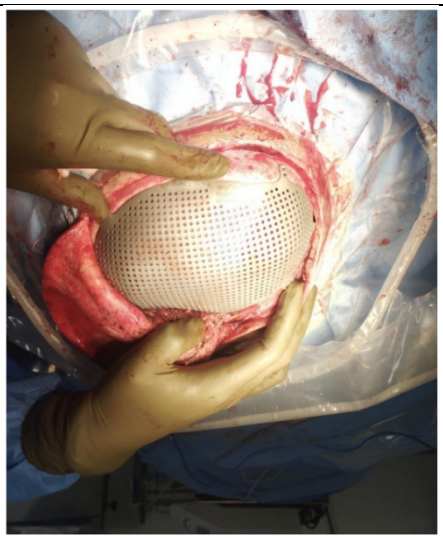


Figure 2: Intraoperative image showing titanium mould cranioplastyty

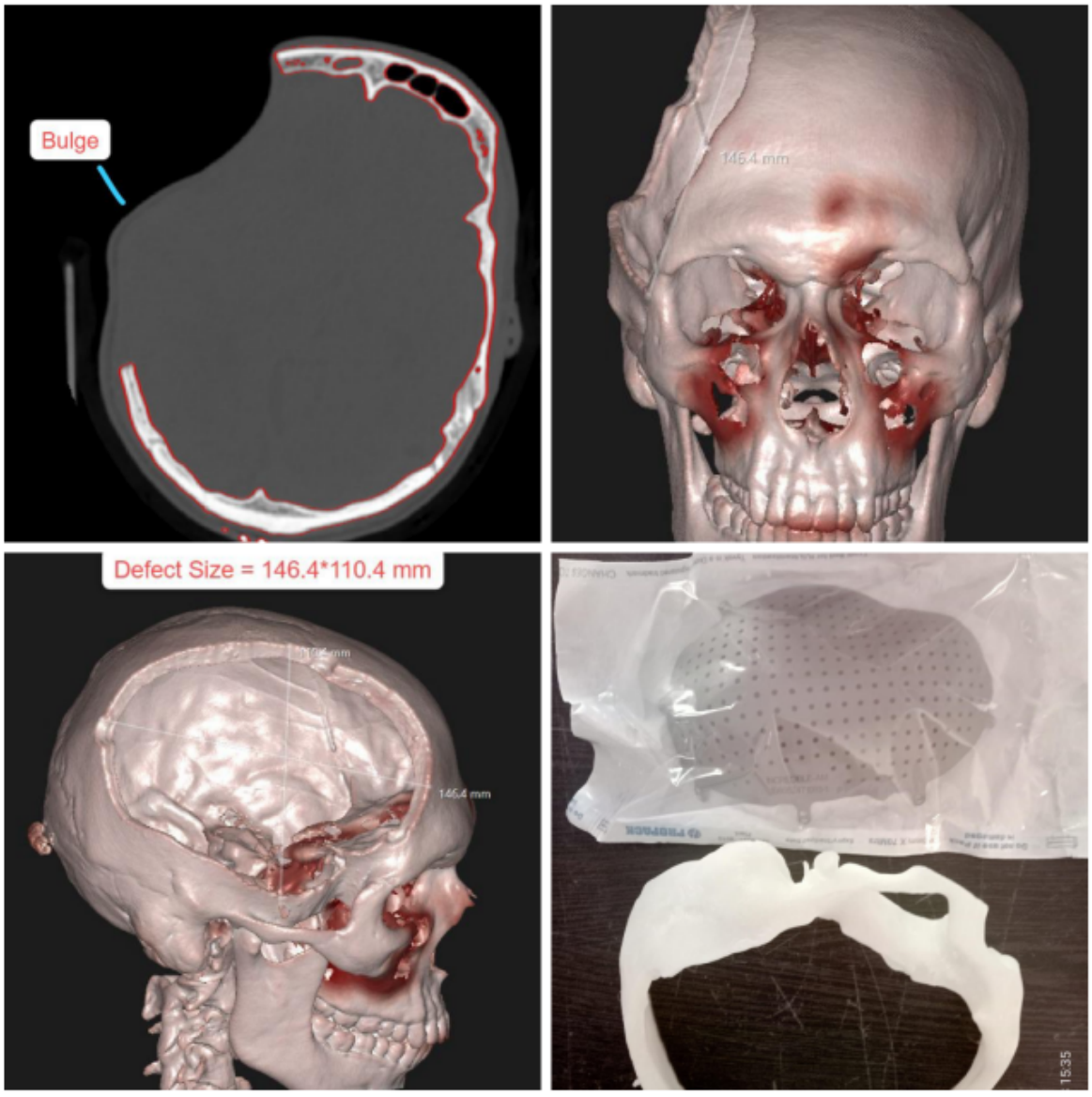
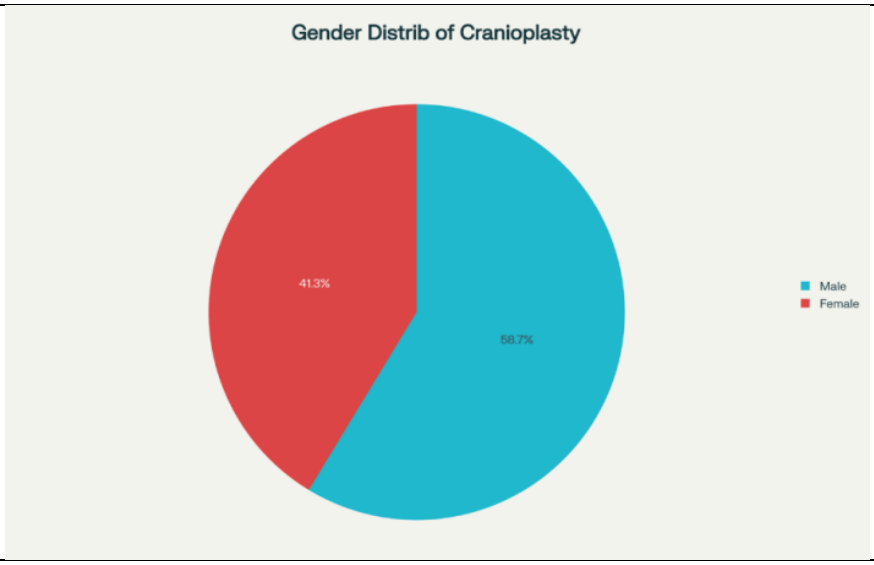
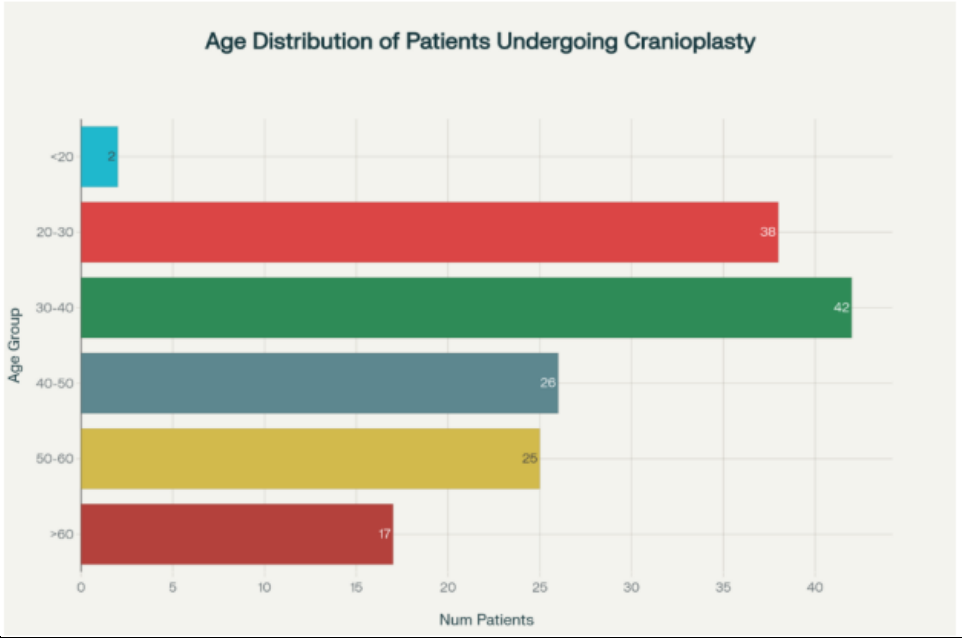


Figure 3: Ct Brain And 3d Ct of the Defect and the Titanium Mould



Graph 1



Graph 2

Statistical analysis: Comparisons utilized Fisher's exact or chi-square tests, with $p<0.05$ considered statistically significant. Statistical analyses were performed using SPSS v26.0.

Results

Patient Demographics: Of the 150 patients included, there were 88 males and 62 females. The majority underwent cranioplasty for TBI (n=103) the remainder for infarct (n=47). Common comorbidities included hypertension (n=98) and diabetes mellitus (n=88). Age ranged from <20 to >60 years, most commonly 30–40 years.

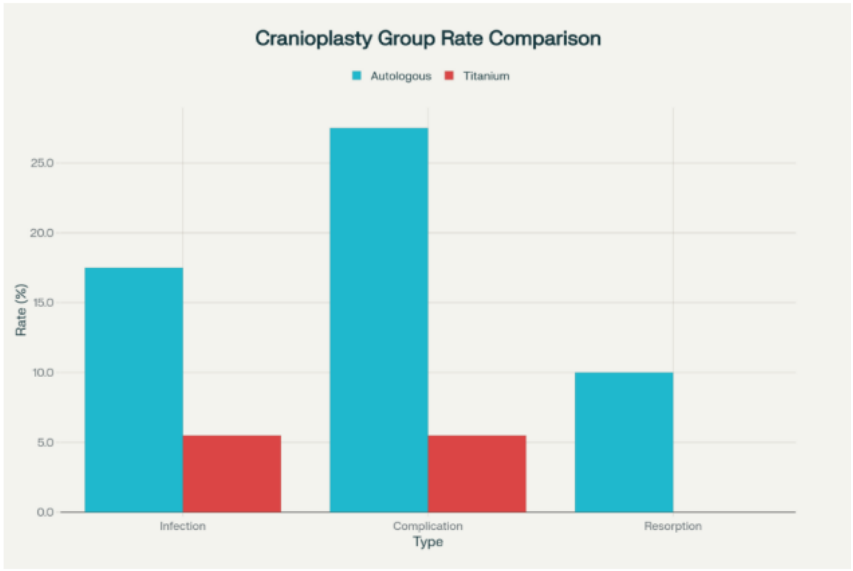
Clinical Outcomes

Table 1: Autologous Bone Flap Group (n=40)

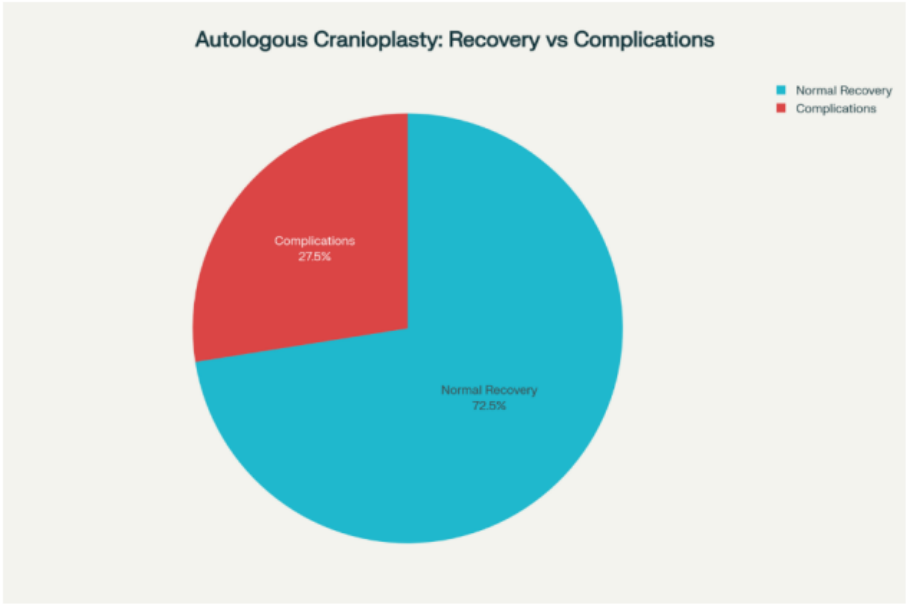
Outcome	Number of Patients	Percentage (%)
Infection	7	17.5%
Bone Flap Resorption	4	10.0%
Overall Complications	11	27.5%
Uneventful Recovery	29	72.5%

Table 2: Titanium Mould Group (n=110)

Outcome	Number of Patients	Percentage (%)
Infection	6	5.5%
Bone Flap Resorption	0	0%
Overall Complications	6	5.5%
Uneventful Recovery	104	94.5%



Graph 3



Graph 4

Statistical Comparisons: Infection was significantly more common in the autologous group (p=0.042)

Bone flap resorption occurred exclusively in the autologous group (p=0.0045)

Overall complications favored titanium cranioplasty (p=0.0005)

Table 3: Clinical Outcomes: Autologous vs Titanium Mould Cranioplasty

Outcome	Autologous (n=40)	Titanium (n=110)	p-value
Infection rate	17.5% (7/40)	5.5% (6/110)	0.042
Overall complications	27.5% (11/40)	5.5% (6/110)	0.0005
Bone flap resorption	10% (4/40)	0% (0/110)	0.0045
Uneventful recovery	72.5% (29/40)	94.5% (104/110)	—

Discussion

Cranioplasty remains a vital reconstructive procedure after decompressive craniectomy to restore cranial integrity, protect the brain, and optimize neurological and cosmetic outcomes. The choice of reconstructive material profoundly influences complication rates, long-term durability, and patient satisfaction. Traditionally, autologous bone grafts have been the mainstay due to their anatomical fit, biocompatibility, and cost-effectiveness.[1] However, they carry well-known risks such as bone flap resorption and infection, which frequently lead to revision surgeries. [3,4]

In this study, infection rates were significantly higher in the autologous bone group (17.5%) compared to the titanium group (5.5%), which reflects established concerns that autologous bone grafts are more vulnerable to bacterial colonization and osteomyelitis. This vulnerability can be attributed partially to possible contamination during storage or reimplantation, compromised bone viability, and prolonged surgical times needed for flap preparation.[3,5] In contrast, titanium, being inert and highly biocompatible, exhibits resistance to infection by minimizing bacterial adherence and biofilm formation.[2,6] This finding is consistent with multiple large-scale studies reporting lower infection rates with titanium implants relative to autologous grafts.[1,4]

Overall complication rates in our study also significantly favored titanium, with only 5.5% of patients affected compared to 27.5% in the autologous group. These complications include not only infections but also hematomas, wound healing issues, and implant exposure or failure. The complication profile underscores the clinical challenges with autologous bone, including the mechanical weakness and biological limitations imposed by natural bone flaps, especially after storage and reimplantation.

Notably, our data show a 10% rate of bone flap resorption in the autologous group, a major limitation of this technique, while no resorption occurred with titanium implants. Bone resorption is a particularly problematic complication, as it leads to structural failure and cosmetic deformity, often necessitating repeat surgery.[3] The resistance of titanium to resorption, coupled with its mechanical strength and durability, reinforces its suitability for both small and large cranial defects.

The high rate of uneventful recoveries in the titanium group (94.5%) further supports its safety and efficacy. Improvements in surgical technology, such as computer-aided design and 3D printing, allow for precise customization of titanium implants, which enhance cosmetic outcomes and reduce operative times. Titanium implants also facilitate easier postoperative imaging due to minimal artifact production.

Conversely, although autologous bone grafting remains widely used, these results highlight the inherent drawbacks associated with it, especially in the context of high-risk patients or larger defects. Complication risks can be mitigated by careful storage methods, minimizing surgical time, and rigorous perioperative care, but such measures cannot eliminate the biological challenges tied to autologous bone survival.

Cost considerations remain important, as titanium implants typically entail higher upfront expenses than autologous bone grafts. [1,6] However, when factoring in the reduced revision surgeries, shorter hospital stays, and superior functional and aesthetic outcomes associated with titanium, the initial investment may be justified, particularly in centers equipped to deliver customized implant solutions.

Conclusion

This study provides compelling evidence that titanium mould cranioplasty significantly outperforms autologous bone grafting in terms of infection rates, overall complications, and prevention of bone flap resorption. The enhanced biomechanical properties and biocompatibility of titanium implants facilitate higher rates of uneventful recovery, reducing the need for revision surgeries and improving long-term cranial protection and aesthetics. While autologous bone remains a cost-effective and anatomically congruent option, its inherent biological limitations result in substantial morbidity related to resorption and infection. Advancements in custom fabrication of titanium implants contribute to optimized operative efficiency and postoperative imaging quality. These outcomes support the preferential consideration of titanium mould cranioplasty in appropriate clinical settings. Further large-scale, prospective trials are warranted to validate these findings and assess long-term functional, cosmetic, and economic outcomes to refine material selection strategies.

References

1. Zanaty M, Chalouhi N, Starke RM, et al. Complications following cranioplasty: incidence and predictors in 348 cases. Journal of Neurosurgery 2015;123(1):182-8.
2. Honeybul S, et al. The incidence of bone flap resorption: A comparative analysis using two different techniques. Acta Neurochirurgica 2017.
3. Zanaty M, et al. Complications of cranioplasty: risk factors and treatment options. Surg Neurol Int. 2021.
4. Malcolm JG, et al. Autologous cranioplasty is associated with increased risks of resorption and infection compared with alloplastic implants. World Neurosurgery 2014.
5. Mangram AJ, Horan TC, Pearson ML, et al. Hospital Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection, 1999. Infection Control & Hospital Epidemiology 1999;20(4):247-80.
6. Xu H, et al. Titanium mesh versus autologous bone in the treatment of large cranial defects: a systematic review and meta-analysis. Neurosurg Rev 2020.
7. Rosinski CL, et al. Cranioplasty outcomes: Titanium mesh versus custom-molded polyethylene implants. World Neurosurgery 2017.