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Evaluation of the Effect of Cranioplasty Using Different Prosthetic Materials on Functional Improvement in Patients with Post-traumatic Brain Injury: A Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Cranioplasty is considered an essential step for restoring defects in the skull, generally due to the esthetic appearance, safety of the brain, or handling the adverse effect of the Trephined Syndrome (TS) or sinking skin flap syndrome. Moreover, many studies saw the unexpected enhancement of cognitive and motor function after cranioplasty. These favorable progressive effects can be helpful in further therapy preparations in association with cranioplasty effects. Nevertheless, the proof is mainly restricted to case studies that do not target comparison between different materials in post-traumatic brain injury (P-TBI) people even though it is helpful

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but not enough.
Objectives: To comparatively evaluate the effect of cranioplasty using autologous bone graft, polymethylmethacrylate (PMMA), titanium, and bone cement on cognitive and functional improvement in patients with P-TBI.
Methodology: 40 subjects will be allocated into four groups. Group A (10 using Autologous bone graft) Group B (10 using PMMA), Group C (10 using Titanium), and Group D (10 using Bone cement). Glasgow Coma Scale (GCS) and Mini-Mental State Examination (MMSE) will be used for cognitive improvement. For functional improvement, Muscle power and Barthel index will be used. The data will be compared before and after cranioplasty.
Expected Results: Cognitive and functional improvement will be present after cranioplasty. But the effect of cranioplasty using autologous bone graft, polymethylmethacrylate (PMMA), titanium, and bone cement has to be evaluated & compared to assess the patient's cognitive and functional improvement and provide desired intervention as required.
Conclusion: This study will comparatively evaluate the effect of cranioplasty using different prosthetic materials and determine which material is better for patients' cognitive and functional improvement.

Keywords: Cranioplasty; functional improvement; cognitive improvement; PMMA; cranial reconstruction.

1. INTRODUCTION

Decompressive craniectomy (DC) is a preliminary surgical technique that reduces the intracranial pressure for traumatic brain injury patients. DC followed by cranioplasty is regularly conducted everywhere to re-establish the protective barrier and esthetic appearance. It is not only related to enhanced cognitive outcomes but also neurological function [1,2].

The best material used in cranial renovation should be infection-resistant, easier to obtain, biocompatible, inexpensive, and malleable to fit defects. Various materials are used to rebuild cranial defects with different advantages and disadvantages. Autologous bone has always been considered a gold standard in cranioplasty since it mainly accomplishes all the necessities of the perfect restoration material [3]. A distinctive and frequent complication observed after autologous bone cranioplasty is the resorption of bone flap, which could lead to reconsideration of surgery followed by replacing with alloplastic material. And many times, the autologous bone flap is not available for cranioplasty. Hence, the need for searching for an ideal material for cranioplasty was the purpose of this study [3].

Numerous resources are considered that can be used as a substitute to avoid the resorption of the flap of bone and morbidity of the donor region. Polymethyl methacrylate (PMMA) is one of the oldest materials utilized in cranioplasty due to its lightness, strength, heat resistance, and malleability [3].

Titanium mesh is an alloplastic frequently utilized in cranioplasty due to its decent mechanical strength, negligible infection rate, and economic reasons. Also, newer titanium mesh is available, which is prefabricated with the help of 3-D CBCT, which provides a significant esthetic look [4]. However, titanium mesh also has some shortcomings, like patients showing metal allergies, and therefore substitute materials must be found out [5]. Cranioplasty is considered an essential step for restoring defects in the skull, generally due to the esthetic appearance, the safety of the brain, or handling the adverse effect of the trephined syndrome (TS) or sinking skin flap syndrome. Moreover, many studies saw the unexpected enhancement of cognitive and motor function after cranioplasty [6]. These favorable progressive effects can be helpful in further therapy preparations associated with cranioplasty effects. Nevertheless, the proof is mainly restricted to case studies that do not target comparison between materials in people with post-traumatic brain injury(P-TBI) [6]. So, the present study is conducted to evaluate and compare the effect of cranioplasty using different prosthetic materials on cognitive and functional improvement in patients with post-traumatic brain injury.

1.1 Aim

To comparatively evaluate the effect of cranioplasty using different prosthetic materials on cognitive and functional improvement in patients with post-traumatic brain injury.

1.2 Objectives

- To comparatively evaluate the effect of cranioplasty using autologous bone graft on cognitive and functional improvement in patients with post-traumatic brain injury
- To comparatively evaluate the effect of cranioplasty using polymethylmethacrylate (PMMA) on cognitive and functional improvement in patients with post-traumatic brain injury
- To comparatively evaluate the effect of cranioplasty using titanium on cognitive and functional improvement in patients with post-traumatic brain injury
- To comparatively evaluate the effect of cranioplasty using bone cement on cognitive and functional improvement in patients with post-traumatic brain injury

2. METHODOLOGY

2.1 Study Design

It is a type of retrospective cross-sectional study conducted in six months.

2.2 Sample Size Calculation

With the significance level at 5%, i.e., 95%, and a confidence interval of 1.96, a sample size of 35.70 was obtained. Four samples will be placed considering a 5% loss to follow up. Thus, a total sample size of 40 cranioplasty patients will be considered for the proposed study.

2.3 Patient Selection

2.3.1 Inclusion criteria

- Trauma patients who have undergone cranioplasty
- Age group 18-60 yrs.

2.3.2 Exclusion criteria

- Patients who were physically or cognitively unstable.
- Patients who have systematic conditions

Sample size: 40 (10 PER GROUP)

Participants: Four groups are made:

Group A: Cognitive and functional improvement in patients using autologous bone graft.

Group B: Cognitive and functional improvement in patients using polymethylmethacrylate (PMMA).

Group C: Cognitive and functional improvement in patients using titanium.

Group D: Cognitive and functional improvement in patients using bone cement.

Data collection tool: Digitalized patient database.

2.4 Assessment

A retrospective cross-sectional study will be performed in the Department of Prosthodontics of Sharad Pawar Dental College (SPDC) along with the Neurosurgery Department of Jawaharlal Nehru Medical College (JNMC) affiliated Acharya Vinobha Bhave Rural Hospital (AVBRH). Atleast40 people who have suffered from P-TBI and have undergone cranioplasty using Autologous bone graft, PMMA, Titanium, or Bone cement from January 2015 to November 2020 will be included in this study.

The subjects will be allocated into four groups. Group A will comprise 10 subjects using Autologous bone graft, Group B will comprise 10 subjects using PMMA, Group C will comprise ten subjects using Titanium, and Group D will comprise ten subjects using Bone cement.

All the information will be gathered from the digitalized patient database from the Dept. of Neurosurgery of Acharya Vinoba Bhave Rural Hospital (Sawangi, Meghe) and old files and documents from the Medical Record Department (MRD).

To compare the effect of cranioplasty on ‘cognitive improvement’ using different prosthetic materials, we will use the cognitive function tests including ‘Glasgow Coma Scale (GCS)’ and ‘Mini-Mental State Examination (MMSE).’ Similarly, to check the ‘functional improvement,’ we will use the functional tests including ‘Muscle power’ and ‘Barthel index.’ The attending physician will calculate the score for all the scales and indexes.

Furthermore, we will compare the data before and after cranioplasty to analyze the effect of cranioplasty using different prosthetic materials on cognitive and functional improvement in patients.

2.5 Statistical Analysis

Statistical analysis will be performed using inferential & descriptive statistics where $p<0.05$ is considered the level of significance. Software executed in the analysis will be SPSS 21.0 & Graph Pad Prism 7.0 version. Intergroup comparison will be made using One-way Analysis of variance (ANOVA) with Post-Hoc Tukey test & intragroup comparison will be made using paired t-test.

2.6 Expected Outcomes

The effect of cranioplasty using autologous bone graft, polymethylmethacrylate (PMMA), titanium, and bone cement would be evaluated & compared to assess the patient's cognitive and functional improvement propose a desired intervention for such patients. A cognitive and functional improvement would be present after cranioplasty since it can recover the cognitive discrepancies possibly by reversing the physiological mechanisms including intracranial pressure (ICP), alterations of the cerebral-spinal fluid (CSF) circulation, glucose metabolism, cerebral blood flow (CBF), and, ultimately the Volume Transmission (VT) signal communication [7].

3. DISCUSSION

A retrospective study was conducted by J. M. Joffe et al. [8] of 66 titanium cranioplasties to determine the consequence of management in subjects given titanium prostheses. They concluded that titanium is a brilliant material when concerned with cranioplasty, mainly due to its specialized preparation technique [8]. Mahy Eldin Ibrahim et al. (2015) compared to repair of skull defects with titanium mesh and methyl methacrylate. They found that cranioplasty is relatively safe and gives a satisfactory cosmetic reconstruction alternative and leads to improvement in neurological function. They also stated that although PMMA is more economical and easy to mold than titanium, it has a greater risk of causing infection to the patient [9].

Swetet Al Ulkar et al. (2020) published multiple case-reports regarding restoration of the defect and gaining psychological confidence in the individuals [10]. One unique technique was used in this case-report which demonstrated the use of bone cement in conjunction with PMMA [10]. In this technique, the bone cement was mixed in proper proportions, due to which there was a change in its consistency from luting to dough stage. This was molded and applied on top of the PMMA prosthesis intra-operatively on the junction between the prosthesis and bone. During the setting of the bone cement there is an exothermic reaction due to which heat dissipates. Hence, in order to reduce this effect, the layer of bone cement must be lesser than 5mm. The main advantage of this alloplastic material is that it gets reabsorbed as well as substituted by human bone [10]. This study stated that restoration of the neurological deficits with prosthesis acts as a protective shell as well as enhances the neurological status of the individual [10]. The objective of cranioplasty is to aesthetically rehabilitate the defect as well as provide relief to the psychological problems. This enhances the individual's acceptance in society and various activities [10].

Cristina Di Stefano et al (2012) performed a study with multiple case-reports to assess the consequence of cranioplasty on motor and cognitive functions in patients with severe brain-injury. They found a descent of motor function as well as neuropsychological discrepancies before cranioplasty which was followed by a succeeding unanticipated development in the functional activity after cranioplasty. They concluded that the restoration of the skull defect can generate a relevant enhancement in neurological function in motor as well as cognitive provinces [11]. Stephen Honeybul et al (2013) described a study for evaluating alterations in neurological functioning after cranioplasty. They accomplished that minor yet substantial amount of individuals appeared to recover considerably after cranioplasty due to enhancement of their motor functioning [12].

Nela Jelcic et al (2013) conducted a study depicting case-reports of 5 individuals having a large P-TBI, which had undergone cranioplasty from 1-3 yrs after initial trauma. Neurological and brain MRI studies were conducted before and 12 weeks after cranioplasty. They determined that cranioplasty has the ability to recover the neurological function even when conducted after an extended span of period from craniectomy, probably due to reversing of the physiological mechanisms and thereby reestablishing the VT signal communication [7]. Jyong-Huei Su et al (2017) accomplished that during in-patient therapy, enhancement of quality of life and neurological activity is perceived due to intervention with cranioplasty. This is useful in formulating rehabilitation approach in extreme

traumatic brain-injury individuals, that will mostly help in improvement in cognitive and functional domains subsequent to cranioplasty [6].

A study was performed by Byung Wook Kim et al (2017) in which they concluded that early cranioplasty following craniectomy in TBI individuals can be useful in restoring cognitive deficits, particularly language ability, movement as well as orientation of these individuals [13]. Adilson Jose Manuel de Oliveira et al (2019) in their experiment assessed the connection amongst cranioplasty and enhancement of vision which was not known earlier. There were no former studies of enhancement of vision following cranioplasty, excluding the cases with optic nerve decompression. The study demonstrated that the enhancement of the individual was due to the stabilization of the intracranial pressure. This study depicted the significance of cranioplasty in association with the functional improvement of the patient. So, further research should be carried out to investigate into this field [14]. A number of studies on related aspects of trauma and brain injury were reported [15-17]. Related studies by Sheikh et al. [18], Kakani et. al. [19] and Abbafati et al. [20] were reviewed.

So various studies have been conducted which shows a significant improvement in the neurological function of the patient. But there is limited data available regarding the comparison between various materials that might improve the neurological outcome.

4. SCOPE

The current study will help in identifying the success of cranioplasty in neurological functioning by using specific material. This might help the clinician to choose a particular material for better cognitive and functional neurological outcome. In cumulation, this will play a key role for the prosthodontist in deciding the type of material and also to the neurophysician for determining the treatment plan of the patient. Since there are many mortalities due to traumatic brain injury in Central India, this study would provide a great insight in the field of maxillofacial prosthodontics.

5. LIMITATION

Apart from being a unique study, the proposed sample size is small in comparison to the huge prevalence of the deformity. Thus, studies with greater sample size will be required in future to give a statistically significant outcome. Also, the study is not a case-controlled trial since there are very limited studies available about these. So, further research must be carried out in continuation of this study.

6. CONCLUSION

Conclusion will be drawn based on the study.

ETHICAL APPROVAL AND CONSENT

The study approval has been acquired from the IEC (Institutional Ethical committee) Ref no– DMIMS (DU)/IEC/2020-21/53 dated 30/01/2021. The subjects involved will be informed of the study, and written consent will be obtained from the subjects before starting the study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Shahid AH, Mohanty M, Singla N, et al. The effect of cranioplasty following decompressive craniectomy on cerebral blood perfusion, neurological, and cognitive outcome. J Neurosurg. 2018;128:229–35.
2. Halani SH, Chu JK, Malcolm JG, et al. Effects of cranioplasty on cerebral blood flow following decompressive craniectomy: A systematic review of the literature. Neurosurgery. 2017;81:204–16.
3. Yang J, Sun T, Yuan Y, Li X, Yu H, Guan J. Evaluation of titanium cranioplasty and polyetheretherketone cranioplasty after decompressive craniectomy for traumatic brain injury: A prospective, multicenter, non-randomized controlled trial. Medicine. 2020;99(30).
4. Cabraja M, Klein M, Lehmann TN. Long-term results following titanium cranioplasty of large skull defects. Neurosurg Focus. 2009;26:E10.
5. Sun Y, Hu Y, Yuan Q, et al. Association between metal hypersensitivity and implant failure in patients who underwent titanium cranioplasty. J. Neurosurg. 2018;1:1–7.
6. Su JH, Wu YH, Guo NW, Huang CF, Li CF, Chen CH, Huang MH. The effect of cranioplasty in cognitive and functional improvement: Experience of post traumatic

brain injury inpatient rehabilitation. The Kaohsiung journal of medical sciences. 2017;33(7):344-50.
7. Jelcic N, Della Puppa A, Mottaran R, Cecchin D, Manara R, Dam M, Cagnin A. Case series evidence for improvement of executive functions after late cranioplasty. Brain injury. 2013;27(13-14):1723-6.
8. Joffe JM, Aghaheigi B, Davies EH, Harris M. A retrospective study of 66 titanium cranioplasties. British Journal of Oral and Maxillofacial Surgery. 1993;31(3):144-8.
9. Ibrahim ME, Michel M, Raslan S, Khalek EA. Cranioplasty; methylmethacrylate versus titanium mesh. Al-azhar Assiut Medical Journal. 2015;13(2).
10. Pisulkar SK, Purohit H, Mistry R, Dahihandekar C, Iratwar S. Encasing the Encephalon: Enhancing Psychosocial Rehabilitation. Int J Cur Res Rev. 2020;12(14).
11. Di Stefano C, Sturiale C, Trentini P, Bonora R, Rossi D, Cervigni G, Piperno R. Unexpected neuropsychological improvement after cranioplasty: A case series study. British Journal of Neurosurgery. 2012;26(6):827-31.
12. Honeybul S, Janzen C, Kruger K, Ho KM. The impact of cranioplasty on neurological function. British Journal of Neurosurgery. 2013;27(5):636-41.
13. Kim BW, Kim TU, Hyun JK. Effects of early cranioplasty on the restoration of cognitive and functional impairments. Annals of Rehabilitation Medicine. 2017;41(3):354.
14. De Oliveira AJ, Junior JR, Costa DS, Teixeira MJ. Improvement of visual acuity after cranioplasty: A new window for functional recovery of post-traumatic visual loss?; 2016.
15. Agrawal, Amit, Rajeev M. Borle, Nitin Bhola, Akshay Daga, Smriti Bora, Sachin Sachdeva. "Multiple fractures involving the orbit and incidental finding of large fourth ventricular epidermoid." Journal of Craniofacial Surgery. 2009;20(1):261–62. Available:https://doi.org/10.1097/SCS.0b013e318184339b.
16. Bhole, Anil M., Rahul Potode, Amit Agrawal, Joharapurkar SR. "Demographic profile, clinical presentation, management options in cranio-cerebral Trauma: An experience of a rural hospital in Central India." Pakistan Journal of Medical Sciences. 2007;23(5):1:724–27.
17. Gadre, Kiran S., Rajshekhar Halli, Samir Joshi, Shandilya Ramanojam, Pushkar K. Gadre, Ranjit Kunchur, Gururaj Bhosale, Deepak Kaul. "Incidence and pattern of cranio-maxillofacial injuries: A 22 year retrospective analysis of cases operated at major trauma hospitals/centres in Pune, India." Journal of Maxillofacial and Oral Surgery. 2013;12(4):372–78. Available:https://doi.org/10.1007/s12663-012-0446-7.
18. Sheikh, Shakib H, Vaishali Moreshwar Tembhare. "To assess the knowledge and practice of home care regarding post craniotomy care among caregivers of craniotomy patients." Journal of Evolution of Medical And Dental Sciences-JemDS. 2020;9(45):3377–81. Available:https://doi.org/10.14260/jemds/2020/742.
19. Kakani, Anand, Amit Agrawal. "midline frontal depressed skull fracture with venous infarct." Indian Journal of Neurotrauma. 2010;7(1):97–98. Available:https://doi.org/10.1016/S0973-0508(10)80022-X.
20. Abbafati, Cristiana, Kaja M. Abbas, Mohammad Abbasi, Mitra Abbasifard, Mohsen Abbasi-Kangevari, Hedayat Abbastabar, Foad Abd-Allah, et al. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: A Systematic Analysis for the Global Burden of Disease Study 2019. Lancet. 2020; 396(10258):1204–22.

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