

## Study Protocol

### **Evaluation of Clinical Outcome of Cranioplasty Using Different Prosthetic Materials ~~in~~ Traumatic Brain Injury Patient: An Observational Study**

#### **Abstract:**

**Background:** Injuries of head, cerebral tumours, infections and ischemia are the most common causes of intracranial disorders and decompressive craniotomy may require to treat those patient followed by reconstruction later on. After loss of skull bone, cranial reconstruction or Cranioplasty ~~is~~ ~~is a~~ choice of treatment worldwide for the restoration ~~of~~ ~~the of the~~ skull integrity. There ~~are different~~ ~~are different~~ types of materials which can be used for Cranioplasty but all have their own advantages and pitfalls.

**Objective:** Evaluation of clinical outcome of Cranioplasty using different prosthetic materials (PMMA, Ti, PMMA Bone Cement) in traumatic brain injury patient.

**Method:** Type of study ????? local? Duration???

The ~~patients will~~ ~~patients will~~ be divided into 4 groups according to the material used for Cranioplasty. (PMMA, Ti, Autologous bone graft, PMMA Bone cement). The intra operative clinical data and post-operative data will be recollected from the previously collected records. (~~operative~~ Operative time, total hospital stay, including bone). Statistical analysis will be done.

**Results:** Collected data form 40 patients will be statistically analysed to obtain the result. Expected outcome is orthopaedic bone cement (PMMA Bone cement), ~~is~~, is an equally effective prosthetic material as compared to PMMA and Ti in terms of intra operative and post-operative clinical outcome for Cranioplasty in traumatic brain injury patients.

**Conclusion:** This study would help in knowing the feasibility of using PMMA bone cement as a Cranioplasty material and will evaluate the clinical outcome of PMMA, ~~Ti and~~ Ti and PMMA bone cement in Cranioplasty.

**Keywords:** Cranioplasty, Trauma, Prosthetic, PMMA Bone Cement.

#### **Introduction:**

Trauma, pathologies, congenital defects and adjunct surgical corrections often leads to Cranial defects which may put the brain in jeopardy and indicates for a secondary reconstructions which is a interdisciplinary action involving maxillofacial Prosthodontist and neurosurgeon. Such defects can be treated with Cranioplasty, for shielding the underlying brain. Along with providing protection to the brain it relieves pain, restores appropriate cosmetic appearance, improving neurological function, psychosocial rehabilitation and overall improves the quality of life.<sup>1-3</sup> There are many options which have been proposed for the reconstruction of these ~~defects~~ ~~defects~~. Autologous bone is generally used for Cranioplasty in a wide manner. It is comparatively inexpensive, easily obtainable, shows good fit and contour, there is no risk of disease transmission and is viable.<sup>4</sup> -The most commonly reported complications are bone resorption and infection, with a wide range in

timing, and occurrence<sup>5-6</sup>. There are various alternative options have been proposed in the literature for cranioplasty throughout the years. Among them PMMA and Ti are most widely used. At present, PMMA can be used in a customized 3- dimensional (3D) mould too for achieving better cosmetic outcome. The ideal material for cranioplasty should have some favourable characteristics, among them viability (~~i.e.~~, the ability of growth and resistant to infection) and ready availability is of utmost importance. It should be biocompatible, biologically inert, having the capability of osteoconduction and osteoinduction-, be able to withstand mechanical forces, easy to manipulate and allows customised designing and fabrication, so that the prosthesis fits the cranial defect exactly and obtains proper closure. It should gradually be replaced by bone, should be nonconductive of heat and of course the cost should be reasonable.<sup>7</sup> Orthopaedic bone cement (PMMA Bone cement), which is an essential component for joint arthroplasty procedure also,<sup>8</sup> contains some of the properties of ~~an-graftan-graft~~ material for Cranioplasty. But there is no study in the literature using this material as a Cranioplasty graft material in spite of having ideal properties and being cost effective, which is an important factor to be taken into consideration in the rural parts of a ~~developing-country~~ developing country like India<sup>9,10</sup>

This study is to examine the clinical outcome of orthopaedic bone cement (PMMA Bone cement) ~~and-teand to~~ suggest whether it is an equally effective material or not in clinical outcome as compared to PMMA and Ti for Cranioplasty in traumatic brain injury patients.

**Aim:** To evaluate clinical outcome of Cranioplasty using different prosthetic materials (PMMA, Ti, PMMA Bone Cement) in traumatic brain injury patient.

#### **Objectives:**

1. To evaluate the clinical outcome of Cranioplasty using ~~autologous bone-graft~~ bone graft.
2. To evaluate the clinical outcome of cranioplasty using different prosthetic materials ~~i.e.~~, **polymethylmethacrylate (PMMA), titanium and orthopedic bone cement** (PMMA Bone cement),
3. To comparatively evaluate the clinical outcome of Cranioplasty using different prosthetic material.

#### **Methodology:**

This study will be performed In the Department of Prosthodontics and Crown & Bridge, Sharad Pawar Dental college, Sawangi (Meghe), Wardha.

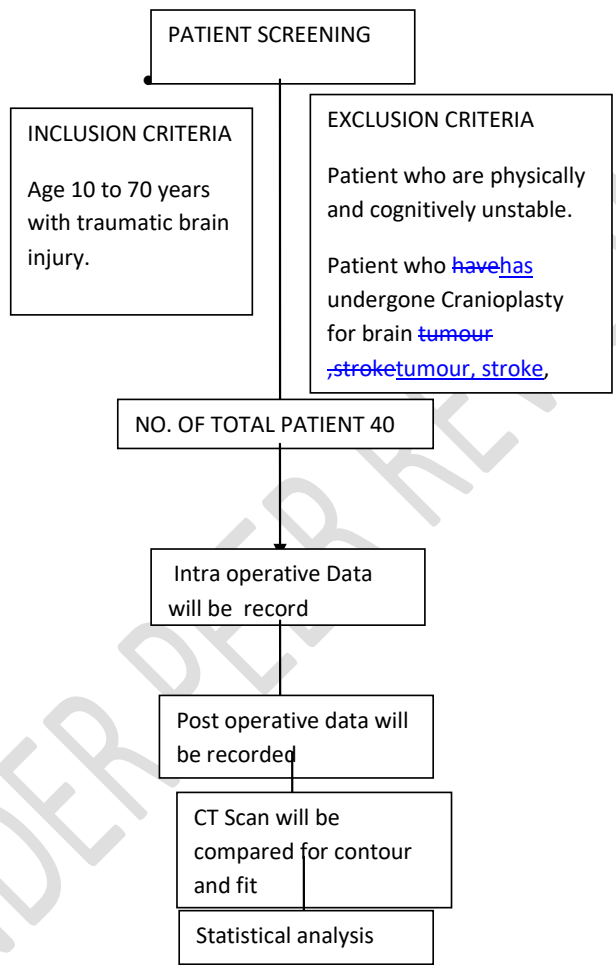
**Sample size calculation:** Sample size determination is 35 in number and considering the drop outs, sample size has been estimated 40. The total minimum sample size with 90% of confidence interval is 10 for each group. The study is divided into four groups which will include 10 participants in each group.

**Patient selection:** 40 patients will be selected who had post traumatic brain injury ~~and subsequently~~ and subsequently underwent cranioplasty from ~~2015-to~~ 2015 to 2020 in the Dept. of Neurosurgery of Acharya Vinoba Bhave Rural Hospital, ABVRH(Sawangi, Meghe), Wardha.

**Inclusion criteria:** Age 10 to 70 years with traumatic brain injury.

**Exclusion criteria:**

- Patient who havehas undergone Cranioplasty for brain tumor, stroke, aneurysm.
- Patient who are physically and cognitively unstable.



**Fig.1: Summary of research methodology**

The patients will patients will be divided into 4 groups according to the material used for Cranioplasty. Group 1 patients receiving fresh frozen autograft Cranioplasty. Group 2 patients receiving a custom-made prefabricated PMMA prosthesis. Group 3 receiving titanium plates for Cranioplasty and group 4 patients rehabilitating with bone cement (PMMA Bone cement), Cranioplasty, Cranioplasty. In order to comparatively evaluate the intra operative clinical outcome of Cranioplasty using different prosthetic materials all the basic clinical data i.e.e., (operative time, total hospital stay, including bone) will be collected from the Dept. of Neurosurgery of Acharya Vinoba Bhave Rural Hospital, ABVRH (Sawangi, Meghe), Wardha by using their digitalized database patient graft infection record

and personal/telephonic interview of patients and relatives. The fit and contour of the Cranioplasty will be compared with ~~the help~~ the help of CT.

**Table 1. Collecting Basic Clinical Data:**

Age (years) Mean + SD	Group 1 Autograft (control)	Group 2 PMMA	Group 3 Ti	Group 4 Bone cement
Age (years)/ sex				
Operation time (min)				
Operative blood loss (ml)				
Total hospital stay (day)				

After collection of all the data the clinical outcome will be evaluated in terms of the following parameters:

**Intraoperatively:** Intraoperative blood loss, operating time and surgical complications (intraoperative).

**Postoperatively:** ~~Infection, fit~~ Infection, fit and contour.

Thus the obtained data will be tabulated for further statistical analysis. Data will be analyzed using statistical methods.

#### RESULTS:

Results would be aimed at determining that whether orthopaedic bone cement (PMMA Bone cement), is an equally effective prosthetic material as compared to PMMA and Ti in terms of intra operative and post-operative clinical outcome for Cranioplasty in traumatic brain injury patients as an alternative to autogenous bone graft.

#### DISCUSSION:

Intracranial disorders may occur due to several reasons among ~~them head~~ them head injuries, cerebral tumours infections and ischemia are the common causes. Treatment of intracranial disorders ~~may include~~ may include decompressive craniotomy followed by ~~reconstruction~~ reconstruction. Once ~~the cranial~~ the cranial bone flap is removed, it should be reconstructed ~~for restoring~~ for restoring the integration of the skull, ~~providing adequate~~ providing adequate biological and mechanical protection of the brain tissues lying underneath skull, and to maintain normal intracranial ~~pressure, hence~~ pressure, hence consequently re-establishing cerebrospinal fluid dynamics and cerebral blood flow. It carries a noticeable importance for preventing the consequences of ~~psychological~~ psychological issues and deformed aesthetic appearance.<sup>7</sup> Polymethylmethacrylate is a mouldable acrylic resin ~~and it is as~~ as strong ~~as~~ as natural bone tissue, so it can provide adequate protection. Hence this material is very much useful in Cranioplasty ~~and that~~ and that has been established from long back. This material is stable, not affected by ~~the temperature~~ the temperature of body, tissue compatible, nonconductive of heat ~~and allows~~ and allows easy placement and modification along with being cost effective. Biocompatibility of PMMA is also very good. G.H Vince et. al. in 2018<sup>11</sup> found in their study that no marked difference in the overall ~~rate of~~ rate of ~~complication~~ complication among the groups ~~of patients~~ of patients who underwent the procedure with autologous bone graft versus free-hand modelled substitution of acrylic. Lee.S. et. al.<sup>10</sup> concluded in their studies that when an autologous bone graft is not available,

the CAD/ CAM PMMA prosthesis can be an excellent choice of treatment. Titanium on the other hand is relatively radiolucent, nonferromagnetic, and non-paramagnetic. On a comparative note, titanium possesses a low density, minimum rate of corrosion, and modulus of elasticity equal to that of bone.<sup>11,12</sup> Bone cements is available in two-component system namely powder consisting of Pre-polymerized forms and liquid which comprises monomer, inhibitors, and stabilizers. When mixed in proportions the viscosity changes from a luting or liquid to a rubbery dough and can be moulded and applied onto the prosthesis intra-operatively onto the plastic /prosthesis- bone junction. The material hardens after the setting time and has to be manipulated quickly. The exothermic reaction takes place and heat dissipates therefore to minimize the effect the bone cement layer should not be exceeding more than 5mm. these synthetic compounds tends to undergo reabsorption and replaced by natural bone later on.<sup>13,14</sup> Related studies on brain injury investigations<sup>15,16</sup> and prosthetic rehabilitation of orofacial structures<sup>17,18</sup> were reviewed.

### CONCLUSION:

This study would help in knowing the feasibility of using PMMA bone cement as a Cranioplasty material and will evaluate the clinical outcome of PMMA, ~~Ti~~ and Ti and PMMA bone cement in Cranioplasty.

**Scope:** The current study will help in identifying whether orthopaedic bone cement will be as effective as the other widely used material (~~PMMA~~(PMMA, TI)) for Cranioplasty.

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