



St. Paul hospital millennium medical college

Graduate study program

Cranioplasty outcomes and associated complications in Addis Ababa Burn, Emergency and Trauma Hospital: A retrospective Study

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Research thesis submission form

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Abstract

Background: Repairing cranial deformities surgically known as cranioplasty is performed for both cosmetic purpose and therapeutic purposes. This study is the first of its kind to access patterns of complications and clinical and cosmetic outcome of patients who underwent cranioplasty in Ethiopian set up to the principal investigators knowledge.

Objectives: This study describes patterns of complications and outcome of patients underwent cranioplasty and identify factors that affect outcome and complications.

Methods: Institutional based cross sectional study design was used to collect data on cranioplasty performed for patients with skull defect from December 1 ,2021 to December 1 ,2023, G.C. Structured questionnaire was used to collect data from the charts and structured GOS and functional outcome questionnaire was used to collect data using in depth phone interview. Model fitness is checked with Hosmer and Lemeshow test found to be insignificant (>0.05). Univariate analysis was done for descriptive statistics using frequency, mean, median, range and standard deviation. Multivariate regression analysis was used to determine predictors of complications and outcome.

Result: 40 patients were included in this study with 26 male 14 female patients and with male to female ratio of 1:1.8. The age ranges of the study population were 2 to 68 years of age with 77.5% of the study population were age below 40 years of age. The mean pre-cranioplasty GCS was 14.75 (R 11-15, SD 8.99) and the mean post cranioplasty GCS was 14.85 (R 11-15 SD 6.62). Postoperative GOS of the patients were 5 and 4 for 30(75%) and 9(22.5) respectively. All patients took perioperative antibiotics. All the study participants used postoperative sub-galleal drainage. Most of the cranioplasties 97.5% were performed on one side (unilateral). Duration of surgery for most cranioplasties extend from 1-3hours in 32(80%) of patients. Most patients have postoperative length of stay of 3 days 21(52.5%), while 10(25%), and of study participants have postoperative length of stay of more than 5 days. Intraoperative adverse event occurred in 2 (5%) of patients. 28(70%) of patients used autologous graft and remaining 12(30%) of patients used synthetic graft. All autologous bone was preserved in abdominal wall. 10(25%) of the patients underwent cranioplasty within 3 months while, 18(45%) of patients from 3-6months. The most common indication for cranioplasty is intraoperative brain swelling in 34(85%) of patients

secondary to trauma 27(67.5%). Over all complication rate was 37.5% with seizure and wound infection or dehiscence account for 5(12.5%) each. The reoperation rate was 5(12.5%) with most of the re-operations were for wound infection or dehiscence. 35 (87.5%) of patients were very satisfied or satisfied with post-cranioplasty cosmetic outcome.

Conclusion: Overall complication rate was 37.5% which is higher than reported in multiple studies. (2,3,7,22) Infection and seizure account for most of the complications. Patients who underwent cranioplasty for indication of assault by stone or stick were 14 times and by FDA were 3.892 times more likely to have complications. Patients with duration of surgery 3-4 hours were 6.28 times and 1-3hours have 1.34 times more likely to have complications with p value of <0.001. Favorable pre-cranioplasty GOS was 97.5% and Postoperative favorable GOS was seen in 97.5% of the study populations. 12.5% of the study population were not satisfied and request for cosmetic result. Patients favorable post-cranioplasty GOS has statistically significant association with pre-cranioplasty GOS with P value of <0.001.

Those patients underwent cranioplasty with autologous bone are 1.83 time higher likelihood of need for cosmetic re-operation than those with synthetic graft cranioplasty with p value of 0.609

Key words: Cranioplasty, Cosmetic outcome, Clinical Outcome, Cranioplasty complications

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Acronyms and Abbreviations

AABET: Addis Ababa Burn, Emergency and Trauma Hospital

AVM: Arterio-venous Malformation

DC: Decompressive Craniectomy

DM: Diabetes Mellitus

EVD: External Ventricular Drainage

FDA: Falling Down Accident

GCS: Glasgow Coma Scale

GOS: Glasgow Outcome Scale

HTN: Hypertension

PMMA: Polymethyl Methacrylate

PEEK: Polyether Ether Ketone

RTA: Road Traffic Accident

SD: Standard Deviation

SDH: Subdural Hematoma

SSI: Surgical Site Infection

SPHMMC: Saint Paul's Hospital Millennium Medical Colleges

VPS: Ventriculo-Peritoneal Shunt

1. Background:

It was recognized that cranioplasty was been used since 3000 B.C with Incas using gold to cover skull defect and previously the procedure was done for cosmetic purpose only. Currently it was understood that cranioplasty has both clinical and cosmetic advantages, (1). It has also been shown that cranioplasty can improve cardiovascular functioning while boosting cerebral blood flow by speeding up the blood flow in the ipsilateral middle cerebral and internal carotid arteries and enhance cerebral hydrodynamic conditions, encourage brain protection, and shield patients from seizures, (2, 3). Additionally, it enhances neurocognition, alleviates psychological aftereffects, and boosts social function, (2). A growing amount of research is demonstrating that cranioplasty helps in the treatment and prevention of the trephine syndrome (2).

Indications for a cranioplasty were listed in literature review of 209 studies, consisting mostly of trauma (n: 3352), cerebrovascular (n: 2100), tumor (n: 1365), or infection (n: 222), (4). The need for a craniectomy heavily influences the timing of the procedure. Rare circumstances call for immediate cranioplasty, which is sometimes combined with a craniectomy for cranial neoplastic invasion. When an intracranial infection or medically resistant cerebral hypertension is present, delayed cranioplasty is typically necessary, (5).

Different types of graft can be used to perform cranioplasty. Sophi E.C.M.et al. reported from literature review autologous bone usage in 28.5% with higher infection rate in autologous cranioplasties compared with synthetic materials 6.9% versus 5% except PMMA with higher infection rate 7.8%,(19). Basheer et al. studied 114 patients who underwent cranioplasty and 89.5% were autologous and the remaining were synthetic cranioplasties with comparable complication rate, (6).

Despite its perceived benefits cranioplasty is associated with numerous complications that vary in severity and frequency. Mahmoud et al. reported over all complication rate of 33.9% with infection accounting for 10.3%, hydrocephalus accounting for 6% and new onset seizure account for 4.4%, (7). Saleh Safi et al. reported complication rate of 12.5% with infections accounting for 3.8% and hydrocephalus in 2.3 %, (2). Syed M. Anderabi et al. also reported 15.25% complication rate and infection in 6.78% of patients,(3). Northam et al. reported complication rate of 27%, (8). Basheer et al. reported complication rate of 23% and re-operation rate of 14%, (6). Syed M. Anderabi et al. also reported re-operation rate of 7.59% for unilateral cranioplasty

and higher rate was seen in patients with bilateral cranioplasty and autologous cranioplasty, (3). Ee Shern et al. stated published studies signify wide range of complication rate, ranging from 3.3% to 40.8%. As a subset, infection alone has been reported to be as high as 33 %, (2).

Florian et al. reported out of 31 patients with 3D printer assisted cranioplasty 87.1% had pre-cranioplasty GCS score of 13-15 and 90.3% had post cranioplasty GCS score of 13-15 and 41.9% showed improvement in clinical symptoms and GCS improvement occurs in 3 %, (9).

Saleh Safi et al. reported out 132 patients who underwent cranioplasty 64.4% of the patients had good post cranioplasty GOS. Pre-cranioplasty GOS, trauma as indication for DC and cranioplasty within 3months have statistically significant association with good postoperative GOS, (2)

The lack of consensus on the optimal timing, material selection based on availability, and surgical techniques to decrease complications result in complexity of the procedure and it is determined by indications for cranioplasty, availability of different types of graft materials, and availability of appropriate setup to perform cranioplasty.

2. Statement of the problem

Cranioplasty is a surgical procedure performed to reconstruct a skull defect that occurs due to trauma, infection, or surgery, (1). Despite the advancements in surgical techniques and materials used for cranioplasty, there is a high incidence of complications associated with the procedure, (2). These complications can result in poor outcomes and increased morbidity for patients undergoing the surgery, (2). The lack of consensus on the optimal timing, material selection based on availability, and surgical techniques further adds to the complexity of the procedure. Thus, gaps remain in our understandings, which have examined cranioplasty outcomes and complications in our country. Therefore, there is a need for research to explore the outcomes and patterns of complications associated with cranioplasty and identify the factors that contribute to the complications and better outcome.

3. Rationale of the Study

While cranioplasty is generally considered safe and effective, there are several factors that can influence the outcome and potential complications of the procedure, (2). The rationale for studying cranioplasty patterns of complications and outcome is to better understand the factors that contribute to successful outcomes and to identify strategies for minimizing complications. By examining factors such as surgical implant material, patient characteristics, and postoperative care, and to identify best practices for cranioplasty that optimize patient outcomes.

Some potential outcomes that could be measured in a study of cranioplasty include clinical outcome measured using Glasgow coma scale (GCS) and Glasgow outcome score (GOS) and cosmetic outcome measured by size of bone defect and level of patient satisfaction. Specific complications that can occur with the procedure, such as infection, implant associated complications, or neurological complications can be examined. By identifying the factors that contribute to these complications, strategies for reducing their occurrence and improving patient safety can be developed.

Additionally, studying cranioplasty patterns of complications and outcome can help identify areas for further research and development. For example, new surgical techniques implant materials based on availability in the current Ethiopian setup, 3D printing implant materials that can improve outcomes and reduce complications can be investigated. Ultimately, the goal of this type of research is to improve the overall quality of care for patients undergoing cranioplasty and to promote better outcomes for this patient population.

4. Literature review

As early as 3000 B.C., the Incas used gold to hide cranial abnormalities brought on by trauma, (1). The surgery was initially primarily carried out to restore normal appearance, but it has since been discovered that cranioplasty also has clinical advantages and should be utilized not only as a cosmetic procedure but also as a therapeutic one, (1). Cranioplasty is a surgical treatment used to correct cranial deformities as both cosmetic and functional manner, (10).

Increased intracranial pressure brought on by malignant cerebral edema from head trauma, brain infarction, intracranial hemorrhage, or postoperative complications is treated successfully more often by decompressive craniectomy (DC). As a result, there is mounting evidence supporting the increasing frequency of surgeries connected to cranioplasty, (2). The abnormalities of cerebrospinal fluid (CSF) circulation caused by decompressive craniotomy (DC) are well documented. In addition, DC alters the dynamics of local cerebral blood flow and the pace at which glucose and oxygen are metabolized in the brain, impairing both normal brain metabolism and function. The patient's total neurological status might theoretically be improved by performing a cranioplasty by restoring all the altered conditions, (3).

In addition to improving cardiovascular functioning, it has been shown that cranioplasty can increase cerebral blood flow by accelerating the blood flow through the ipsilateral middle cerebral and internal carotid arteries, (3). Along with its aesthetic advantages, cranioplasty tends to encourage brain protection, improve cerebral hydrodynamics, and protect patients from seizures. Additionally, cranioplasty enhances neurocognition, alleviates psychological aftereffects, and boosts social functioning, (2). There is growing evidence in the literature that suggests cranioplasty aids in trephine syndrome recovery and, or prevention, (11). Following cranioplasty, there were significant changes in the patients' cognitive status that ranged up to 48.3% in the Cognistat scores, with the language and reasoning skills showing the greatest changes, (12).

The cognitive analysis provides more information on the long-term outcome of patients who underwent cranioplasty for large cranial defects, and good cranioplasty techniques allow a better evaluation of the patient's ability to cope with a regular life and return to work as soon as

possible. The changes in cerebral blood flow are correlated with the changes found in the patients' cognitive analyses, (12). At three months and six months post-cranioplasty and compared to pre-cranioplasty, Saraj et al. argued that both mean values of Glasgow coma scale (GCS) and Glasgow outcome score (GOS) shown a substantial improvement, (10). Following cranioplasty, there was a significant increase in neurologic function, according to a systematic review and meta-analysis of 7 studies involving 528 patients that included equivalent pre- and postoperative assessments of neurologic function (mean follow-up: 3y 180 days), (2).

When compared preoperative neurologic status with post-cranioplasty dichotomized GOS, Saleh Safi et al. found a significant improvement in neurologic function based on GOS. After correcting for covariates discovered in bivariate analysis, multiple regression analysis showed that the probabilities of a satisfactory recovery for GOS grades 4 and 5 were 28.77 in comparison to poor grades (2 and 3), (2). In comparison to non-traumatic patients, traumatic DC patients had higher odds of a positive neurologic outcome (higher odds 5.15, P 0.003), according to Saleh et al. According to the findings of Osti et al., a successful cranioplasty coupled with a favourable pre-cranioplasty clinical status foretells a positive prognosis one year after the procedure, (2). Early cranioplasty (within 3 months) has been linked to improved neurologic recovery, with adjusted a likelihood for early cranioplasty (12 weeks) being 3.04 times higher compared to cranioplasty done after 3 months. Taco Goedemans et.al. reports 30% of patients required shunting for post cranioplasty hydrocephalus in early cranioplasty group compared with 3% in late group, (13).

In contrast to alloplastic cranioplasties, which have a complication rate of 4.8 to 63.6 percent, autologous bone cranioplasties have a complication rate of 0 to 53.3 percent, (2,14). Shun Yao et.al. stated Ventriculo-peritoneal shunt (VPS) before cranioplasty was an independent risk factor for postoperative overall complications, and infection was also mentioned as risk factor for implant failure in alloplastic cranioplasties,(14). The published studies to date, according to Ee Shern et al, have revealed a wide range of complication rates, ranging from 3.3% to 40.8%. Infection alone has been estimated to reach as high as 33% in this subset, (15). Syed M. Andrabi et al. record the rate of complications was 15.25%, and the most frequent complication was wound infection/dehiscence (6.78%), (3). Following cranioplasty, postoperative hematoma was another important consequence. Seizures, bone resorption, and sunken bone plates were among the additional problems, each accounting for 2.54%, 1.69%, and 0.85% of the total. Males were

more likely than females (16.06% vs. 11.63%) to experience complications.(3) According to Walcott et al., the most frequent complication following cranioplasty was wound infection, which occurred in 12.13 percent of cases (n = 29) and *Staphylococcus aureus* was the most commonly identified organism They experienced a net complication rate of 23.85% (n = 57), (10,16). The overall complication rate was 22.4%, according to Saraj et al. Subgaleal collection (5.6%), hydrocephalus (4.2%), seizures (4.2%), bone flap infection (2.8%), intracerebral hematoma (2.8%), empyema (1.4%), and subdural hematoma (SDH) (1.4%) were the most frequent complications, (10). About 8.4% of operations require complications, the most of which being infections and hydrocephalus,(10).

The incidence of bone resorption increased from 14% to 42% in children whose cranioplasty was delayed for 6 weeks or longer, but the cohort's characteristics for sex, the reason for the craniectomy, the site of the cranioplasty, the presence of a ventriculo-peritoneal shunt at the time of the cranioplasty, the use of surgical sub-galeal drains after the cranioplasty, and the average follow-up time were similar (17). According to Gerald A. et al. Patients less than 18 years old who had symptoms of bone resorption were 50%. Bone resorption significant enough to raise concerns about the possibility of brain injury or produce an aesthetic flaw disapproved of by the family or treating physicians is referred to as symptomatic bone resorption, (18).

Clinical outcome was predicted using a variety of heterogeneous factors, such as patient-centered risks, DC indications, pre-cranioplasty neurologic status, timing of the procedure, postoperative complications, rehabilitation effectiveness, and follow-up time, (2). There was a 36% to 64% range in the rate of good recovery. According to Giese et al., all patients (42.6%) experienced a considerable long-term neurologic improvement following cranioplasty, with a 30-day death rate of 0.49%, (2).

Subcutaneous pockets for storing bones versus tissue banks and discovered that there is no statistical difference in the complication rate, the requirement for a second surgery, or the need for fusion. Operation time and blood loss varied significantly between the two groups. Patients who had bone maintained in subcutaneous pocket experienced additional complications such as abdominal wound morbidity, bone resorption, bone contamination and patient discomfort, (6,19). Trauma was the most frequent cause of craniectomy in both the early and late cohorts (75% early vs 82% late), while vascular reasons (18% early vs 15% late), which included Arterio-Venous malformation (AVM) rupture and nontraumatic subarachnoid haemorrhage, came in second

(18% early vs 15% late), (17). Ee shern liang et al reported the common indications for cranioplasty as 52% trauma, 11.3% infectious pathology, 9% subarachnoid hemorrhage, 9% tumor with bone infiltration and 3.4% stroke, (15).

Indications for a cranioplasty were listed in 209 studies, consisting mostly of trauma (n ¼ 3352), cerebrovascular (n ¼ 2100), tumor (n ¼ 1365), or infection (n ¼ 222)(19). The need for a craniectomy heavily influences the timing of the procedure. Rare circumstances call for immediate cranioplasty, which is sometimes combined with a craniectomy for cranial neoplastic invasion. When an intracranial infection or medically resistant cerebral hypertension is present, delayed cranioplasty is typically necessary, (5). The area around the prior incision needs to heal completely and be vascularized. The timing of a cranioplasty may be influenced by inflammatory markers including C-reactive protein and erythrocyte sedimentation rate, serial imaging, the patient's neurologic condition, and the stabilization of intracranial pressure, (5).

There are a variety of materials that could be used to repair skull defects, including autografts, allografts, xenografts, and bone replacements. For cranioplasty, autologous grafts such rib, iliac crest, and calvarium has been widely used. The ideal material is biocompatible, non-thermo conductive, radio transparent, nonmagnetic, lightweight, rigid, simple to prepare, easily applicable and inexpensive, radiolucent, pliable, sterilizable and able to be quickly fastened to an existing skull, (5,20).

5. Objectives

5.1 General Objective:

The overall purpose of the study was to examine the Cranioplasty outcomes and associated complications at SPHMMC, AABET Hospital.

5.2. Specific objectives

- 1) To assess the patterns of complications of cranioplasty in Neurosurgery department AABET Hospital.
- 2) To access the outcome of patients underwent cranioplasty in Neurosurgery department AABET Hospital.

6. Methodology

6.1 study setting

- The study was conducted in Neurosurgery department of AaBET hospital, an affiliate of SPHMMC inclusive of 4 major departments: neurosurgery, Emergency medicine and critical care, orthopedics and traumatology, plastic reconstructive and hand surgery . It is one of the largest government based trauma and emergency center in the country. The hospital has 190 bed ward and 13 ICU beds. Additionally it is a higher center in the referral system across the nation. The hospital annual reports showed neurosurgical patients occupy a sizable amount of the hospital's case load. Neurotrauma, Neuro-oncology, Degenerative spine surgery are major services given under the department of neurosurgery at AaBET. On average a total of 21, 84 and 960 patients are operated for neurological related disease per week, month and year respectively as it was collected from monthly clinical audit report over the past 1 year.

6.2 Study period

The study was from **March 1, 2021 – March 1, 2023.**

6.3 Study design

A retrospective cross-sectional single institution-based study was conducted on patients for whom cranioplasty was done at SPHMMC AABET Hospital.

6.4 Population

6.4.1 Source population

All patients who were admitted in SPHMMC AaBET hospital department of Neurosurgery during study period, from **March 1, 2021 – March 1, 2023.**

6.4.2-Study population

All patients undergone cranioplasty at SPHMMC from **March 1, 2021 – March 1, 2023.**

6.4.3 Inclusion and exclusion criteria

Inclusion criteria: `

All patients who underwent cranioplasty at SPHMMC AABET hospital from **March 1, 2021 – March 1, 2023**.

Exclusion criteria:

Patients with lost charts were excluded from the study.

Patients not available for phone interview

Patients who did not give consent for phone interview

6.5. Sample size determination

All patients who underwent neurosurgical procedure at SPHMMC, AABET Hospital during the study period were reviewed (March 1, 2021 – March 1, 2023) and those patients whose case notes were available in the hospital registration archive were included. Hence, a total of 40 patients who underwent cranioplasty in the study period found in the operation logbook, admission logbook and phone call.

6.6. Sampling procedures:

Finally, all patients for whom cranioplasty was done during specified study period were taken.

6.7. Measurement

6.7.1. Dependent variable

- ✓ Cranioplasty complication
- ✓ Cranioplasty outcome (which was measured by GCS and GOS and by level of patient satisfaction with cosmetic outcome).

6.7.2. Independent variable

- ✓ Sex, Age, Occupation
- ✓ DM
- ✓ HTN
- ✓ Cardiac disease
- ✓ Coagulopathy

- ✓ Smoking
- ✓ Intra-operative adverse events
- ✓ Elective vs emergency
- ✓ Duration of surgery
- ✓ Indication for cranioplasty
- ✓ Timing of cranioplasty
- ✓ Complications
- ✓ Laterality of cranioplasty
- ✓ Type of graft used
- ✓ Perioperative antibiotic
- ✓ Drain used
- ✓ Frontal sinus opened

6.8. Data Collection and Procedures:

First, the operation theatre logbook and morning report records were reviewed to develop lists of patients for whom cranioplasty was done during the study period. Then, using the patient's Medical record number on the operation theatre log book or morning report paper, patient's charts were sought from the hospital's card room. Finally, data was collected from patient's chart, operation logbook, admission logbook and phone call to access clinical and cosmetic outcome using a structured questionnaire by principal investigator and residents throughout data collection period. The questionnaire was pretested on 5% of the records.

6.9. Operational definitions

Cranioplasty- surgical procedure performed to reconstruct a skull defect that occurs due to trauma, infection, or surgery using autologous or synthetic bone graft and it includes immediate post-tumor excision repair of the defect for infiltrative tumors and excludes patients who had immediate bone replacement after craniotomy.

Autografts- Bony material either cranial bone (split calvarial or skull bone stored in deep freezer, subcutaneous tissue or subgaleal space) itself or bone from other parts of the body (Ribs or fibula) of the patient

Clinical outcome- Post cranioplasty outcome of patients measured by immediate post cranioplasty GCS and GOS which was measured at 6months post cranioplasty.

Cosmetic outcome- measured by the level of satisfaction of patients with post cranioplasty aesthetic and size of post cranioplasty bone defect. The size of defect was measured by patients' subjective perception as small, medium or large defect. The level of satisfaction was also measured using patients' subjective satisfaction level as very satisfied, satisfied or dissatisfied, and by patients' requirement to undergo corrective surgery.

Favorable GOS - GOS 4 and 5

Unfavorable GOS- GOS 3, 2 and 1

Wound infection/dehiscence- All superficial and deep postoperative wound infection and partial or total separation of wound edges diagnosed by treating physician, while the patient was in the hospital or after discharge after underwent cranioplasty.

6.10. Data Quality Control and Management:

The quality of the data was controlled starting from the time of Questionnaire preparation. The data, then was cleaned, checked, and cross checked for the completeness and internal consistency by the data collector and then data was entered. Then, soft copies of the data was stored on a hard drive and a backup copy was stored on a separate drive. Besides this, data was handled by a flash disks and CD tools. Latter both hard and soft copies of the data were kept safely.

6.11 . Data Analysis and Procedures:

Data processing and analysis were done using Statistical Package for the Social Sciences (SPSS) version 27 software. Univariate analysis was done using frequency, median, interquartile ranges for categorical and nominal variables. The mean, range, and standard deviation were calculated for continuous variables. Model fitness is checked with Hosmer and Lemeshow test found to be insignificant (>0.05). Bivariate analysis was done to identify independent predictor variables for multivariate analysis. Multivariate logistic regression was done to look for the presence of predictor variables for outcome and complications. P value of less than 0.05 considered statistically significant.

6.12. Ethical consideration:

A formal letter was written from the SPHMMC Neurosurgery department to the institutional review board of SPHMMC and ethical clearance was given by the IRB for this study. All the respondents were informed clearly about the purpose of the study and verbal informed consent was taken from the patient or primary caregiver of the patient during the phone interview for the GOS assessment. Consent was not required for the collection of data from the patient's chart.

7. Results

7.1. Socio-demographic characteristics of the study population.

During the study period a total of 50 patients underwent cranioplasty. 43 charts were retrieved resulting in 86 % chart retrieval rate. Patients who did not meet inclusion/exclusion criteria were 3 and all of the three patients were not available for phone interview were excluded and 40 patients were included in this study. The gender distribution consisted of 26 male 14 female patients and with male to female ratio of 1:1.8. The age range of the study population were 2 to 68 years of age with 19(47.5%) and 12 (30%) were in range of 20-40years and under 20 years of age respectively. Based on the marital status 20 of the patients were married and the other 20 patients were single with ratio of married to single population is 1:1. Regarding the educational status of the population 12 (30%) of the patients were uneducated and the same number of patients were secondary school level, the remaining patients were 10(25%) were elementary school, 4(10%) level III diploma and 2(5%) were tertiary level education. Most of the study population live in Rural 25(62%) and the remaining population lives in urban area. 14(35%) of the study population were farmers, 12(30%) were students, 5(12.5%) have private job, 7(17.5%) were working in government institutions and 2(5%) were unemployed, (Table 1).

Table 1 : Socio-demographic characteristics of the study participants at SPHMMC AABET hospital from March 1, 2021 – March 1,2023.

VARIABLES	CATHEGORY	FREQUENCY	PERCENTAGE
Age, mean (Range, %)		33.99(R2-68)	
	<20	12	30%
	20-40	19	47.5%
	40-60	18	20%
	>60	1	2.5%
Sex			
	Male	26	65%
	Female	14	35%
Marital status			
	Married	20	50%
	Single	20	50%

Educational status			
	Uneducated	12	30%
	Elementary	10	25%
	Secondary school	12	30%
	Level III diploma	4	10%
	Tertiary	2	5%
Residence			
	Urban	15	37.5%
	Rural	25	62.5%
Occupation			
	Farmer	14	35%
	Student	12	12%
	Private job	5	15.5%
	Government institution	7	17.5%
	Unemployed	2	5%

7.2. Co-morbidity and other characteristics of the study participants

Regarding co-morbidity status 5(12.5%) of the study population have 1 or more co-morbid illness. From those 2 patients have both cardiac disease and hypertension, 2 patients have hypertension only and 1 patient has cardiac disease only. 3 (7.5%) of the study population were taking anticoagulants. None of the study population were smokers. Frontal sinus was opened on one patient intra-operatively before immediate cranioplasty. Trephine syndrome was diagnosed on 1 patient. The mean pre-cranioplasty GCS was 14.75 (R 11-15, SD 8.99) and the mean post cranioplasty GCS was 14.85 (R 11-15 SD 6.62). All patients took perioperative antibiotics, both pre and postoperative periods. Most of the patients took ceftriaxone alone 38(95%) and 2(5%) of patients took combined antibiotics. Most of the patients took the antibiotic for 3 days 31(77.5%) with mean duration of antibiotic intake was 2.3days. All the study participants used postoperative drainage. Most of the cranioplasties were performed on Right side 21(52.5%) and 18 (45%) was on the left side and 1(2.5%) was bi-frontal, (Table 2).

Table 2 : Co-morbidity and other characteristics of the study participants at SPHMMC AABET hospital from March 1, 2021 – March 1, 2023 .

Characteristics	All patients, N(40)
Co-morbidity N (%)	5(12.5%)
Hypertension	2(5%)
Cardiac disease	1(2.5%)
Hypertension and cardiac disease	2(5%)
Anticoagulant intake N (%)	3(7.5%)
Frontal sinus opened N (%)	1(2.5%)
Trephine syndrome	1 (2.5%))
Pre-cranioplasty GCS N mean (range, SD)	Mean 14.75 (R 11-15, SD 8.99)
Perioperative antibiotic N (%)	40(100%)
Preoperative and post-operative antibiotic	Both 40(100)%
Ceftriaxone alone	38(95%)
Combined antibiotic	2(5%)
Postoperative drainage use N (%)	40(100%)
Laterality of cranioplasty N (%)	
Right	21 (52.5%)
Left	18 (45%)
Bi-frontal	1(2.5%)

7.3. Surgical and related conditions

Duration of surgery for most cranioplasties extend from 1-3hours 32(80%)` of patients, and 8(20%) of patients have duration of surgery more than 3 hours. Most patients have postoperative length of stay of 3 days 21(52.5%), while 10(25%), of study participants have postoperative length of stay of more than 5 days and 9(22.5%) have 4days of postoperative length of stay.

Intraoperative adverse event occurred in 2 (5%) of patients and the adverse event was dural tear and CSF leak. Regarding the type of graft used for cranioplasty 28(70%) of patients used autologous graft and remaining 12(30%) of patients used synthetic graft. From autologous graft used cranial bone 27(67.5%) and 1(2.5%) patient used both cranial bone and ribs because of small size of cranial bone. From patients used autologous cranioplasty, the bone was preserved in abdominal wall in all patients 28(70%). From patients used synthetic graft 11(27.5%) of the patients used PMMA and 1(2.5%) patient used titanium graft. Time between craniectomy and cranioplasty 10(25%) of the patients underwent cranioplasty within 3 months while, 18(45%) of patients from 3-6months, 9(22.5%) of patients from 6-12 months and 3(7.5%) of patients underwent after 1year. The most common indication for cranioplasty is intraoperative brain swelling in 34(85%) of patients secondary to trauma 27(67.5%), cerebrovascular accident 4(10%), subdural/brain abscess 2(5%) and brain tumor 1 (2.5%). From 6(15%) of patients who underwent cranioplasty without intraoperative brain swelling, all of them were secondary to infiltrating brain tumors and the cranioplasty was done same time with tumor excision. From patients underwent cranioplasty after traumatic craniectomy FDA, assault by stick or stone, RTA each account 7(17.5%) and penetrating TBI account for 6(15%) of the patients. From cerebrovascular accident causes 2 (5%) was due to ischemic and hemorrhagic stroke each.

Table 3: Cranioplasty and related conditions of study participants at SPHMMC AABET hospital from March 1, 2021 – March 1,2023.

Surgical procedure and related conditions	All patients, N(40)
Duration of surgery N (%)	
1-3hours	32(80%)`
>3hours	8(20%)
Postoperative length of stay N (%)	
3days	21(52.5%)
4days	9(22.5%)
5 or more days	10(25%)
Intraoperative adverse event N (%)	2(5%)
Dural tear and CSF leak	2(5%)
Time between craniectomy and cranioplasty N (%)	10(28%)

<3months	
3-6months	18(45%)
6-12months	9(22.5%)
After 1 year	3(7.5%)
Type of graft material used N (%)	
Autologous	28(70%)
Cranial bone	27(67.5%)
Split thickness cranial bone	0
Ribs	1(2.5%)
Synthetic	12(30%)
PMMA	11(27.5%)
Titanium	1(2.5%)

7.4. Postoperative Complication characteristics in the study population

From all study population 15(37.5%) had one or more postoperative complications after cranioplasty. From postoperative complications 5(12.5%) of the study population had postoperative seizure and postoperative wound infection/dehiscence each. New onset seizure occurred in 3 (7.5%) of the study population. Bone resorption occurred in 1(2.5%) of the study population and seroma with seizure occurred on 1(2.5%) of the patients. 1(2.5%) of the patients have sunken bone plate with wound infection /dehiscence. 1 (2.5%) patient died after reoperation for recurrent tumor after cranioplasty. Most of the complications occurred within 1 month of the cranioplasty 8(20%) and the remaining 6(15%) of the complications occur with 1-3 months. 5(12.5%) of the patients underwent reoperation for different complications. From the reoperations 4 (10%) of the patients re-operated for wound infection/dehiscence and 1(2.5%) patient underwent reoperation for recurrent tumor, (Figure 1).

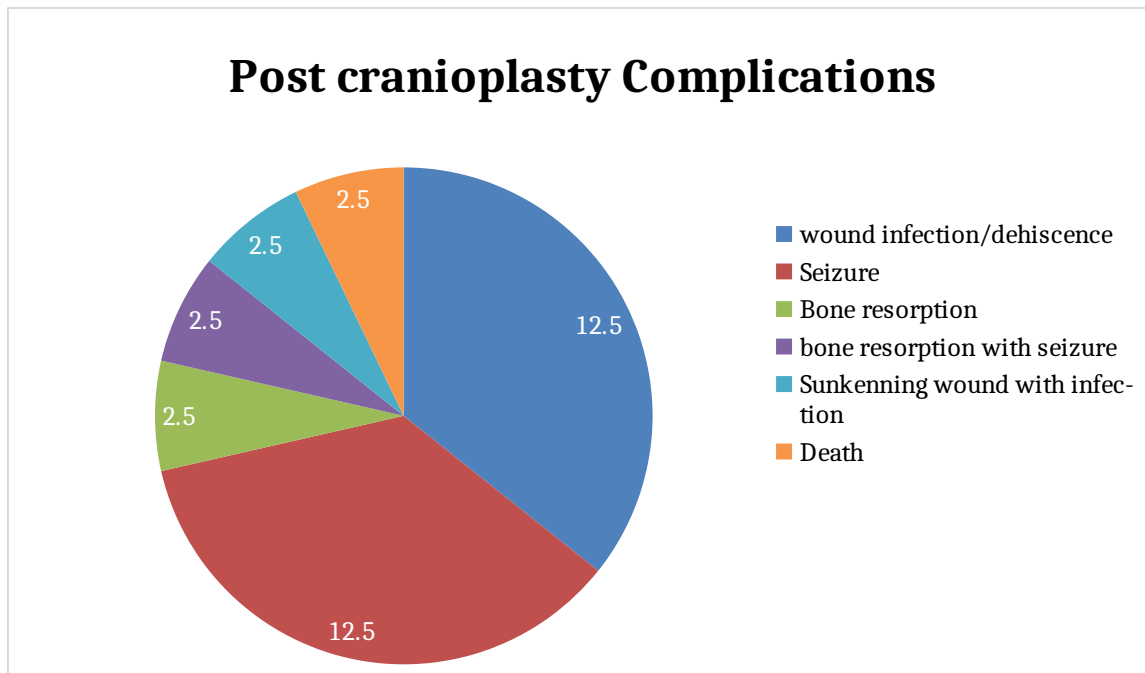


Figure 1: Prevalence of post-cranioplasty complications of the study population at SPHMMC AABET Hospital from March 1, 2021 – March 1, 2023.

7.5. Cosmetic and clinical outcome

The mean pre-cranioplasty GCS was 14.75 (R 11-15, SD 8.99) and the mean post cranioplasty GCS was 14.85 (R 11-15 SD 6.62). Favorable pre-cranioplasty GOS was 97.5% (5 and 4 for 30(75%) and 9(20%) and favorable post-cranioplasty GOS of the patients was 97.5% with 5 and 4 for 30(75%) and 9(22.5) respectively and 1(2.5%) patient died as a result of post cranioplasty tumor recurrence. Estimated post cranioplasty bone defect was medium, small and large for 26(65%), 10(25%) and 4(10%) of study population respectively. Based on level of patient satisfaction patients were classified as satisfied 27(67.5%), very satisfied 8(20%) and not satisfied 5(12.5%) on post-cranioplasty cosmetic outcome and 5(12.5%) of patients request corrective cosmetic surgery, (Figure 2 and 3).

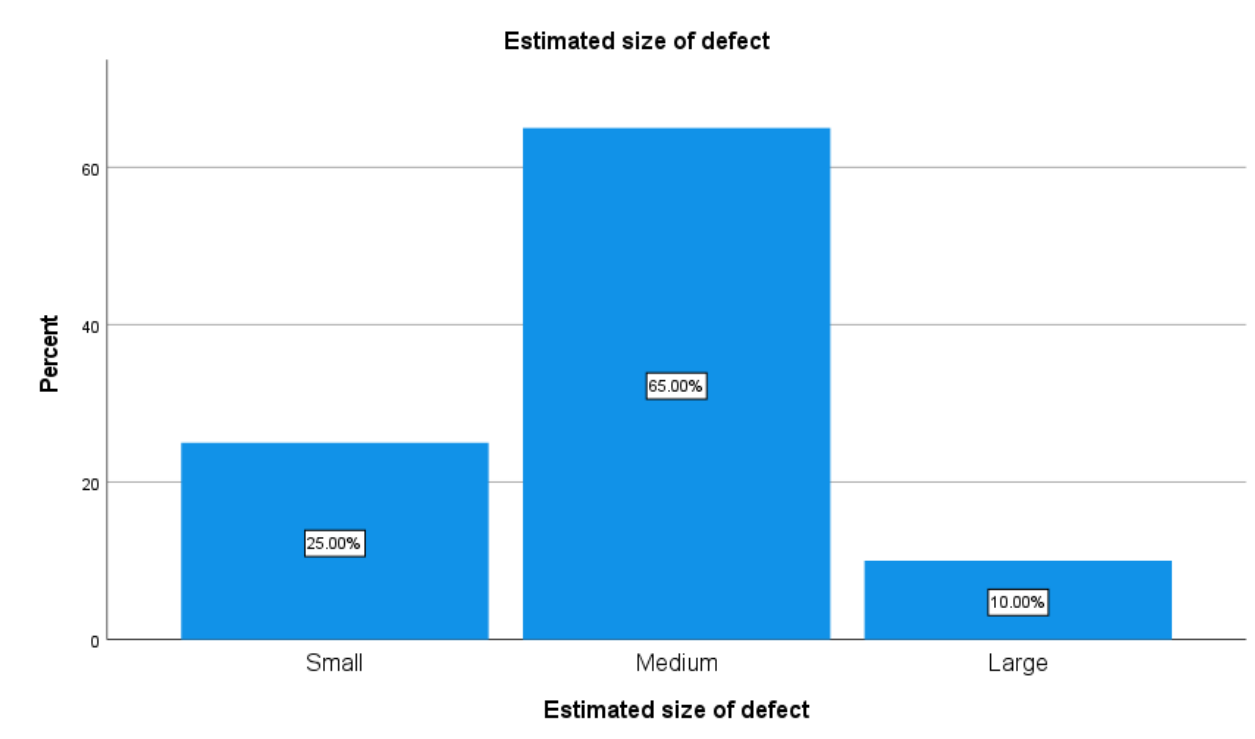


Figure 2: Estimated size of post-cranioplasty skull defect of the study population at SPHMMC AABET hospital from March 1, 2021 – March 1,2023.

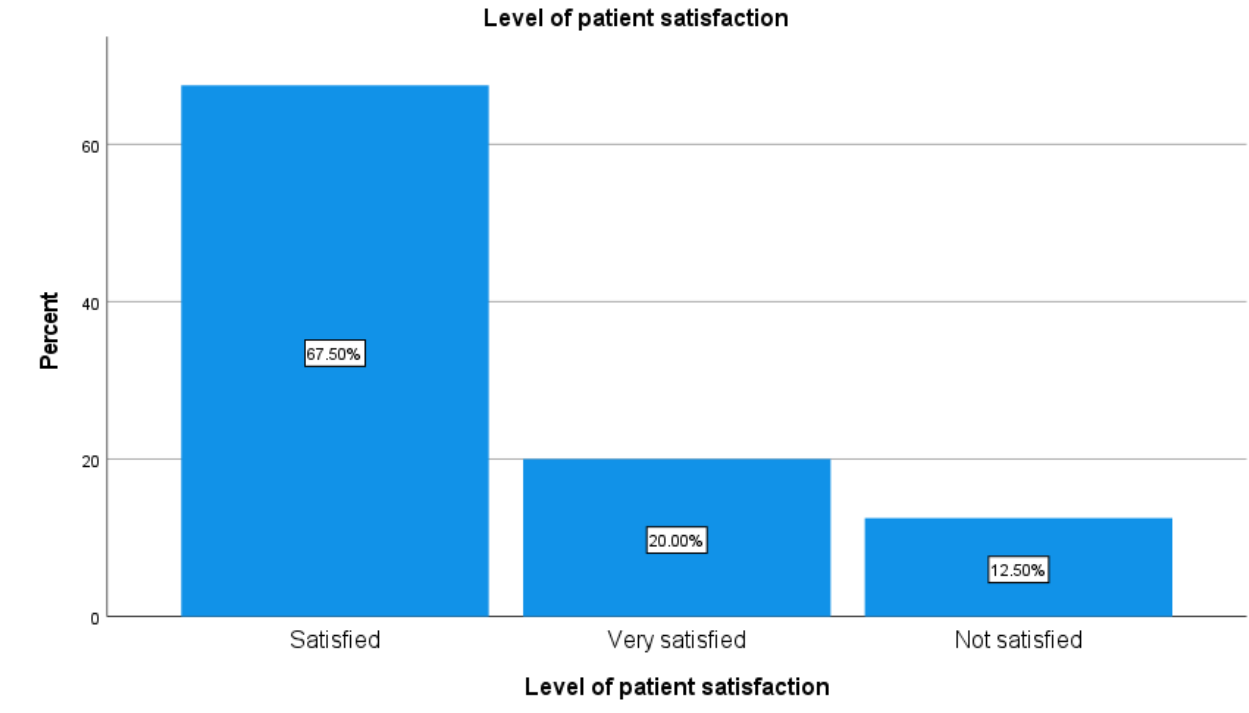


Figure 3: *Level of satisfaction of study population for post-cranioplasty cosmetic outcome at SPHMMC AABET hospital from March 1, 2021 – March 1, 2023.*

7.6. Factors affecting clinical and cosmetic outcome and post-cranioplasty

complications

Multivariate logistic regression analysis was done using forward stepwise selection method using independent variables identified by bivariate analysis. The assumption of no multicollinearity was met and there were no outliers. The model was statistically significance $P < 0.01$, suggesting that it could distinguish factors contributing to complications.

Accordingly, patients who underwent cranioplasty for indication of assault by stone or stick were 14 times more likely to have complications [$P = < 0.067$; AOR= 14; 95% CI= 0.834-235)] than other indications for cranioplasty. Meanwhile patients who underwent cranioplasty for indication of FDA were 3.892 times more likely to have complications [$P = < 0.001$; AOR= 3.892; 95% CI= 2.826-5.35] than other indications for surgery. Patient with duration of surgery 3-4 hours were 6.28 times more likely to have complications [$p = < 0.001$; AOR= 6.28; 95% CI= 5.22 -

7.55] than other ranges of duration of surgery. While patients with duration of surgery from 1-3 hours were 1.34 times more likely to have complications [P= <0.001; AOR= 1.34; 95% CI =1.119-1619] than the other ranges of duration of surgery, (Table 4).

Table 4; Bivariate and multivariate analysis of factors associated with complications of study participants at SPHMMC AABET hospital from March 1, 2021 – March 1,2023.

Predictor variable	Complication	AOR(95 % CI)	P-value
Duration of surgery			
1-3 hours	32(80%)	1.34(1.119-1619)	<0.001
3-4 hours	5(12.5%)	6.28(5.22-7.55)	<0.001
>4hours	3(7.5%)		<0.001
FDA as indication for surgery	7(17.5%)	3.892(2.826-5.35)	<0.001
Assault by stone or stick as indication	7(17.5%)	14(0.834-235)	0.067
Re-operation requirement	5(12.5%)		<0.001
Intra-operative adverse event	2(5%)		

Patients with post cranioplasty medium sized defect were 9.9 times more likely to be categorized as satisfied than those classified as very satisfied or not satisfied [P= 0.003; AOR= 9.9; 95% CI 2.151 - 45.559].

Patients favorable post-cranioplasty GOS has statistically significant association with pre-cranioplasty GOS [P= <0.001; COR= 0.026; 95% CI= 6.565-6.566].

Most of the study population have favorable post-cranioplasty GOS 39(97.5%) and 1(2.5%) have unfavorable GOS of 1. Those patients underwent cranioplasty with autologous bone are 1.83

time higher likelihood of need for cosmetic re-operation than those with synthetic graft cranioplasty with p value of 0.609, (Table 5).

Table 5: Bivariate and multivariate analysis of factors associated with clinical and cosmetic outcome of study participants at SPHMMC AABET hospital from March 1, 2021 – March 1, 2023

Predictor variable	Favorable post-cranioplasty GOS	AOR(95 % CI)	P-value
Favorable Pre-cranioplasty GOS	39(97.5%)		<0.001
	Requirement of corrective cosmetic surgery		
Autologous		1.833(0.183-18.3)	0.606
	Medium sized defect		
Satisfied level of satisfaction	26(65%)	9.9(2.151-45.559)	0.003

8. Discussion

8.1 Baseline characteristic of the study population

In this study, 40 patients meeting inclusion criteria were included. Most of the study population were male (65%) and 80% of the study population were under 40 years of age. Journal of pediatric neurosurgery, (17) depicted risk of bone resorption rate was higher in children under age 18 years who underwent delayed cranioplasty after 6 weeks up to 42%. But in this study size of the defect and patient satisfaction level are comparable to other age group of study population. The male to female ratio and age of patients who underwent cranioplasty are compared with the study that was done by Saleh Safi et al with 92.4% patients were male and 52.3% were less than 40 years of age, (2).

Comparing co-morbidity status of the study population of 12.5% from which hypertension accounting for 5% and hypertension with cardiac disease account for another 5%. Journal of neurology reported 20% and 4% of the population have hypertension and diabetes respectively, (13). 7.5% of the population were taking anticoagulants compared with 10 % reported on journal of neurology, (13). In our study 2.5% of the patients had pre-cranioplasty trephine syndrome while 10% of patients had pre-cranioplasty trephine syndrome as mentioned by Cassagne et al., (21). All of the study population took perioperative antibiotics with ceftriaxone only was used in 95% of patients comparable to other studies, all patients who are taking 3 to 5 days of perioperative antibiotics reduced risk of SSI from 5.3% to 2.2% with P value of <0.001, (21). Most cranioplasties were performed for unilateral skull defect in 97.5% which is comparable to the study by Syed M et al. which reported 94.92% of unilateral cranial defect as indication for cranioplasty,(3).

8.2 Surgical procedure, Type of graft used and complications in the study population

The most common indication for cranioplasty is intra-operative brain swelling in 85% of patients secondary to trauma in 67.5% of the study population which is comparable with 75 to 82% of trauma cases reported by Mark P. Piedra et al. from 61 patients who underwent cranioplasty, (17). Patients who underwent cranioplasty for indication of assault by stone or stick were 14 times times more likely to have complications than other indications for cranioplasty with p

value of 0.04; meanwhile patients who underwent cranioplasty for indication of FDA were nearly 4 times (3.892) times more likely to have complications.

Unlike to our study Tor et al. reported equal incidence of complications and bone flap resorption for different indications of cranioplasty, (22). M.P.Piedra et al. reported there is no statistically significant association between reason for craniectomy and post cranioplasty infection and hydrocephalus, (17).

Most patients who underwent cranioplasty 3-6months post craniectomy in 45% and within 3 months in 25%. Syed M. Anderabi et al. reported 47.5% patents underwent cranioplasty 3-6 months and 17.8% underwent within 3 months with increased complication rate(18.29%) and higher re-operation rate 10.98% in those who underwent cranioplasty after 6 months from 236 patients who underwent cranioplasty, (3). Taco et al. demonstrated higher complication rate, (23%) in early cranioplasty(within 3months) compared with late cranioplasty,(13). But in this study there is no statistically significant association between timing of cranioplasty and complication or re-operation rate. The possible explanation for this may be due to subjective assessment of the cosmetic outcome in our study compared with Syed M. Anderabi et.al, (3).

Duration of surgery for most cranioplasties extend from 1-3hours 80%`of patients. In our study patients with duration of surgery 3-4 hours were 6.28 times more likely to have complications with p value of <0.001, while patients with duration of surgery from 1-3 hours were 1.34 times more likely to have complications with P value <0.001. Saleh Safi et al. Studied 132 patients who underwent cranioplasty and reported 65.4% of the procedures were done in less than 2 hours with statistically non-significant association between operative time and post cranioplasty GOS, (2). Syed M. Anderabi et al. conducted a study in which 69.5% of the patients were operated within 1-2 hours and found statistically non-significant association with complications, (3).

In our study 75% of the study population had post-operative length of stay less than 5 days which is comparable with report from Weston Northam et al. study which reported out of 148 patients the average postoperative length of stay was 5.7 days, (8). Intraoperative adverse event occurred in 5% of patients and this signifies higher rate of postoperative complication occurrence with p value of 0.99. Mahmoud et al. reported intraoperative complication rate in 2.5% of the patients, (7).

In our study 70% of patients used autologous graft and remaining 30% of patients used synthetic graft. Sophi E.C.M.et al. reported from literature review involving 10,346 cranioplasties autologous bone was used in 28.5% and the remaining were synthetic. They reported higher infection rate in autologous cranioplasties compared with synthetic materials 6.9% versus 5% except PMMA with higher infection rate 7.8%,(4). While in our study over all complication rate and wound infection or dehiscence rate 1.5 times and 2.7 times higher respectively in patients used synthetic graft compared with autologous graft with p value of 0.564 and 0.259 respectively. Basheer et al. studied 114 patients who underwent cranioplasty reported non-significant difference in complication rate between autologous and synthetic materials used like in our study population. (6). The possible explanation for this may low proportion of synthetic with autologous graft material used for comparison by Basheer et al. (11.5%) synthetic graft used compared with our study (30%) was synthetic graft, (6) .

All patients with autologous cranioplasty had their bone preserved in abdominal wall; Syed M. Anderabi et al. reported 80.51% preservation in deep freezer,(3). Lal et al also reported deep freezer storage of bone flap is the most common method of preservation. Patient discomfort and wound complications are discouraging use of subcutaneous fat, (3). Basheer et al. reported 83.2% of the patient preserved autologous bone in abdominal wall fat which is slightly lower than our study population, (6). Sophie E.C.M et al. reported infection rate of 7.08% and bone resorption rate of 7.69% in abdominal wall preserved bone grafts which is higher than which was found in our study the infection rate is 3.6% in bone flap stored in abdominal wall with P value of 0.259, (4).

Overall complication rate was 37.5% in this study with seizure and postoperative wound infection/dehiscence account for 12.5% each. Mahmoud et al. reported over all complication rate of 33.9% which is comparable to our study with infection accounting for 10.3%, hydrocephalus account for 6% and new onset seizure account for 4.4%, (7). Saleh Safi et al. reported lower complication rate 12.5% with infections accounting for 3.8% and hydrocephalus in 2.3 %, (2). Syed M. Anderabi et al. also reported lower 15.25% complication rate compared to our study and infection was the most common complication occurring in 6.78% of patients, (3). Northam et al. reported complication rate of 27% which is slightly lower than which was seen in our study,(8). Basheer et al. reported complication rate of 23% and re-operation rate of 14% slightly higher re-operation rate (10%) than our study,(6). Syed M. Anderabi et al. also

reported re-operation rate of 7.59% for unilateral cranioplasty and higher rate was seen in patients with bilateral cranioplasty and autologous cranioplasty, (3).

8.3 Post-cranioplasty outcome and factors affecting outcome of the study population

The mean pre-cranioplasty GCS was 14.75 and the mean post cranioplasty GCS was 14.85 in the study population. Slight increment on post-cranioplasty GCS was attributed by 1 patient who had trephine syndrome which improved on immediate postoperative day. Favorable pre-cranioplasty GOS was 97.5% and postoperative favorable GOS was 97.5% and 2.5% (N=1) of patient died due to postoperative recurrence of the brain tumor. Florian et al. reported out of 31 patients with 3D printer assisted cranioplasty 87.1% had pre-cranioplasty GCS score of 13-15 and 90.3% had post cranioplasty GCS score of 13-15 and 41.9% showed improvement in clinical symptoms and GCS improvement occurs in 3% which is comparable to our study, (9). Saleh Safi et al. reported out 132 patients who underwent cranioplasty 64.4% of the patients had good post cranioplasty GOS. Pre-cranioplasty GOS, trauma as indication for DC and cranioplasty within 3months have statistically significant association with good postoperative GOS, (2). Likewise in our study patients favorable pre-cranioplasty GOS have statistically significant association with favorable post-cranioplasty GOS with P value of <0.001.

Based on level of patient satisfaction 87.5% were satisfied or very satisfied comparable with result reported by Florian et al. In which 80% of the patients were satisfied or very satisfied and 5% were dissatisfied,(9). 12.5% of the patients were not satisfied and want corrective cosmetic surgery which is comparable with result from Fischer et al. reported unsatisfactory cosmetic outcome in 17.4% and 8.7% requested revision surgery out of 46 patients underwent free hand cranioplasty,(9). Those patients underwent cranioplasty with autologous bone were 1.83 time higher likelihood of need for cosmetic re-operation than those with synthetic graft cranioplasty with p value of 0.609. Estimated post cranioplasty bone defect was small to medium size in 80% of the patients. Florian et al. reported palpable gaps in 20% and asymmetry in 35% of patients, (9).

9. Strength and Limitations of the study

Exploring patients who underwent cranioplasty in the study area might be alternative to other approaches used in exploring the clinical outcomes of patients who underwent craniectomy for different indications. The retrospective nature of this study might affect the quality of data collected. The other limitation is lack of validated objective measurement tool to assess cosmetic outcome of the study population. The cosmetic outcome remains subjective parameter and is assessed within our study subjectively by the patient themselves reflecting their own opinion of good cosmetic result.

10. Conclusions

Based on our study overall complication rate was 37.5% which is higher than reported in multiple studies.(2,3,24,25) Infection and seizure account for most of the complications. Patients who underwent cranioplasty for indication of assault by stone or stick were 14 times and by FDA were 3.892 times more likely to have complications than other etiologies. Patients with duration of surgery 3-4 hours were 6.28 times and 1-3hours 1.34 times more likely to have complications with p value of <0.001 than those with duration of procedure more than 4 hours. Favorable pre-cranioplasty GOS was 97.5% while, post-cranioplasty favorable GOS was seen in 97.5% of the study populations. Patients with favorable pre-cranioplasty GOS have statistically significant association with favorable post-cranioplasty GOS with P value of <0.001 .

Based on level of patient satisfaction with cosmetic result 87.5% were satisfied or very satisfied. While 12.5% of the study population were not satisfied and request for cosmetic result. Patients with post cranioplasty medium sized defect were 9.9 times more likely to be categorized as satisfied than those classified as very satisfied or not satisfied with P value of, 0.003.

Those patients underwent cranioplasty with autologous bone are 1.83 time higher likelihood of need for cosmetic re-operation than those with synthetic graft cranioplasty with p value of 0.609.

11. Recommendations

In order to reduce the high rate of SSI, infection prevention strategies at study center must be assessed and improved in accordance with standards. Great emphasis has to be given on cosmetic outcome and strategies to improve cosmetic outcome has to be developed including 3D printer assisted cranioplasty. Prospective studies with a large sample size are needed in the future to develop institution based uniform guideline on management of patients who needs cranioplasty and to improve surgical decision-making.

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13. Annexes

Annex i – questionnaire

Ser. №	Question	Finding
1	Sex	a) Male b) Female
2	Age	_____
3	Marital status	a) Married b) Single c) Divorced
4	Educational status	a) Primary b) Secondary c) Level III diploma d) Tertiary
5	Residence	a) Urban b) Rural
6	Occupation	a) Unemployed b) Farmer c) Student d) Private institution e) Government institution
7	Comorbid illness	a) Hypertension b) DM c) Coagulopathy

		d) Cardiac disease e) Liver disease f) Other_____
8	Smoking status	a) Yes b) No
9	Anticoagulant intake	a) Yes b) No
10	Frontal sinus	a) Opened b) Intact
11	Preoperative GCS	
12	Postoperative GCS	
13	Pre-operative GOS	a) Death b) Persistent vegetative state c) Severe disability d) Moderate disability e) Good recovery
14	Post-operative GOS	a) Death b) Persistent vegetative state c) Severe disability d) Moderate disability e) Good recovery
15	Preoperative trephine syndrome	a) Yes b) No
16	Duration of surgery	a) 1-3hrs b) 3-4hrs c) >4hrs
17	Postoperative length of stay	_____

18	Perioperative antibiotic given	a) Yes b) No
19	Timing of antibiotic	a) Preoperative b) Intraoperative c) Postoperative
20	Specific antibiotic given	_____
21	Drain Left	a) Yes b) No
22	Intraoperative adverse event	a) Yes b) No
23	Specific intraoperative adverse event	a) Bleeding b) Dural tear and cerebrospinal fluid (CSF) leak c) Damage to venous sinus d) Pleural tear e) Fragmentation during harvesting for autologous cranioplasty
24	Type of graft used	a) Autologous bone graft b) Synthetic
25	Autologous graft type	a) Cranial bone b) Split thickness calvarial graft c) Ribs d) Other specify_____
26	Method of preservation of autologous cranial bone	a) Deep freezer b) Abdominal wall c) Subgaleal

27	Synthetic graft type	a) PMMA b) Titanium c) PEEK d) Other _____
28	Laterality	a) Right b) Left c) Bifrontal
29	Time between craniectomy and cranioplasty	a) <3months b) 3-6 months c) 6months to 1year d) >1year
30	Complications	a) Yes b) No
31	Specific complications	a) Wound infection/dehiscence b) Hematoma c) Seroma d) Seizure e) Bone resorption f) Sunken bone plate g) Hydrocephalus h) CSF Leak i) Alopecia j) Death k) Other _____
32	Time between cranioplasty and complications	_____
33	Does the patient underwent re-operation	a) Yes b) No

34	If yes reason for re-operation	_____
35	Indications for cranioplasty	a) Infection/osteomyelitis b) Intraoperative brain swelling c) Post-infiltrating tumor resection d) Other_____
36	Intraoperative brain swelling causes	a) Post subdural or brain abscess b) Post tumor surgery c) Post neurovascular incident d) Post traumatic
37	Neurovascular incident type	(a) Stoke a) hemorrhagic b) ischemic (b) AVM (c) Others_____
38	Traumatic causes	(a) RTA (b) Assault by stone/ stick (c) FDA (d) Penetrating (e) Others_____
39	Estimate size of bone defect after cranioplasty	a) Small b) Medium c) Large
40	Level of patient satisfaction	a, Satisfied b, Very satisfied (my appearance not affected) c, Not satisfied i) If not satisfied Reason for dissatisfaction_____
41	If not satisfied	Underwent or need corrective reoperation Yes No

