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Outcomes of Cranioplasty Strategies for High-Risk Complex Cranial Defects: A 10-year experience

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Abstract

Introduction: While the literature contains reports of the risks and complications of calvarial vault reconstruction for acquired defects, there are few publications addressing the specific patient population who require such reconstructions in cases in preceded by prior infection, radiation, massive associated soft tissue trauma etc. We define such clinical presentations as a hostile environment for large surface area reconstruction. Our objective is to compare the safety and efficacy of autologous bone and alloplastic reconstruction in hostile cranial defects.

Methods: An IRB approved retrospective review of patients who underwent cranioplasty of a hostile site at the University of Alabama - Birmingham between January 2008 and December 2018 was performed. The patients were stratified into three groups based on the type of implant used: autogenous (bone), alloplastic (PEEK, Titanium, PMMA), or mixed (combination of bone and prosthetic). The primary outcome metric was a complication in the year following cranioplasty, identified by implant failure, necrosis, or infection. Statistical analysis included t-tests and chi-square tests where appropriate using SPSS.

Results: There were 55 total cases in this time period; 27 autogenous, 23 alloplastic, and 5 mixed. The purely autogenous group had the highest complication rate (44%) and the alloplastic group had the lowest complication rate (38%) that was not statistically different between the three groups (p=0.121). When stratified by specific material used for reconstruction (27 bone, 14 PEEK, 10 titanium, and 5 PMMA), overall complication rate was statistically significant (p=0.009; chi square test) with PEEK implants having the lowest complication rate (21%).

Conclusion: This analysis interestingly found that in the setting of hostile cranial defects, cranioplasties would benefit from the use of prosthetic implants instead of autologous bone grafts, not only for avoidance of donor site morbidity but also for decrease in overall complications.

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Keywords

cranioplasty; hostile cranial defects; prosthetic implants; autologous bone grafts; calvarial reconstruction

Introduction:

Scalp and calvarial defects in patients may result from a number of etiologies including trauma, burns, tumor resections, infections, osteoradionecrosis, or congenital lesions.[1] When primary restoration cannot be achieved these defects require scalp and calvarial reconstructions to restore normal function and prevent complications from exposed bone such as sequestration and sepsis.[2,3] The goal of wound closure and cranial reconstruction in these patients is to provide protection for the brain, normalize appearance, and minimize cerebrospinal fluid hemodynamics.[4,5]

Cranioplasties can be performed with autologous bone and soft tissue as well as with various alloplastic materials such as titanium, polymethylmethacrylate (PMMA), high density porous polyethylene (MEDPOR), and polyetheretherketone (PEEK).[4] Autologous bone grafts provide ideal structural properties and have a low incidence of infection (3.3%) but are at risk for bone reabsorption (11.3%), donor-site morbidity (10.4%), and may present difficulties in reshaping.[2–4,6] Alloplastic materials allow for excellent restoration due to malleability and maintenance of strength over time without reabsorption (0.2%) but suffer from increased susceptibility to infection (6.5%−11.3%) and have a greater risk of fracture of the cranium.[3,6] Alloplastic implants may also be customized to the patient and case whether for trauma or oncologic reconstruction.[7] Prior studies have shown that the choice of reconstructive material may affect the risk of developing postoperative complications.[7] One of the goals of surgical planning is patient optimization to create a more favorable environment for reconstruction especially in a hostile setting. For example, if there is a known untreated frontal sinus fracture, it may be of benefit to correct the frontal sinus first and subsequently delay definitive reconstruction with cranioplasty, even if it requires a bridging cranioplasty in the interim.[8] Occasionally, there are also circumstances where immediate treatment of the frontal sinus with calvarial reconstruction may be indicated as judgement allows in these circumstances. The entire clinical picture should be considered including the soft tissue envelope, presence of a shunt, the sinuses, and any pre-existing cranial or scalp defects.

In the case of failed cranioplasties occuring for a variety of reasons, the literature supports utilizing alloplastic material for reconstruction.[3,9,10] Alloplastic materials come in two forms. Surgeons can choose to use a custom-tailored implant designed preoperatively specific to the patient or, alternatively, choose from one of the shelf stock options and adjust it as needed during the operation. In the last 10 years, patient specific implants (PSIs) designed using the CT scan of the patient and computer aided design software/computer aided manufacturing (CAD-CAM) have become available for cranioplasty. Particularly in cases requiring repeat attempts at definitive reconstruction, PSIs may benefit the surgical team through the extensive planning required preoperatively.[11] Furthermore, the utilization of PSIs have been demonstrated to improve patient quality of life in comparison to autologous bone, reduce postoperative pain, and provide aesthetic results.[12,13]

A variety of studies have independently investigated primary calvarial reconstruction, but few have examined high risk complex cranial defects.[1,5,9] Up to 33% of patients who undergo reconstruction have hostile defects with coexisting soft tissue and osseous defects due to prior radiation, prior failed cranioplasty or concurrent infections.[7] Additionally, patient factors such as diabetes mellitus, brain volume loss, smoking, steroid use, malnutrition, and collagen disorders are associated with poor wound healing when reconstructing these defects.[5,6,9] Complex cranial defects present a unique challenge for the reconstructive surgeon. The complication rate for all cranioplasties is estimated to be approximately 20%, and several studies have suggested higher complication rates for hostile defects.[3,9,10,14] Despite the higher complication rate for hostile defects there are only a few studies available to guide decision making for these complicated procedures.[7] Fong and associates have evaluated autologous reconstruction for hostile craniums. Giese and associates have examined PMMA implants in reconstruction of complex and revision cranioplasties demonstrating comparable results to primary or non-complex cranioplasties.[15] To our knowledge no direct comparison between alloplastic reconstruction and autologous reconstruction for hostile defects has been performed.[1,4,9,10] The objective of this study was to retrospectively compare outcomes between patients with hostile reconstructive environments after cranioplasty.

Methods

We performed an IRB approved retrospective chart review of patients over the age of 18 with hostile defects who underwent scalp and calvarial reconstruction with cranioplasty between January 2008 and December 2018 at a tertiary care facility utilizing CPT codes to identify our cohort. Hostile cranial environment inclusion criteria included patients having a history of failed cranioplasty, radiation, persistent infection, CSF leak, osteomyelitis, or meningitis. Patients with a cranial defect that was classified as a congenital lesion, primary lesion, or benign were excluded from the study. The patients were stratified into three groups based on the type of implant used: autogenous (bone), alloplastic (PEEK(Polyether ether ketone), Titanium, PMMA (poly-methyl metracolate)), or mixed (combination of both autologous and prosthetic).

Data collected included the patient’s age at cranioplasty, reason for procedure, estimated greatest linear dimension of bone flap, type of reconstruction, and any previous or subsequent operations involving the native bone piece. Information was also recorded on previous or concurrent infections, hardware malfunction, pre- or post-operative radiation use, patient co-morbidities, history of smoking, diabetes mellitus, evidence of collagen disorder, malnutrition, corticosteroid use, number of inpatient days, and subsequent complications. Patients who had one of the four major co-morbid comorbid conditions as well as any other type of comorbidity such as evidence of collagen disorder, hypercoagulability, malnutrition, or coronary artery disease were coded as more than one co-morbidity. The size of cranial defect was calculated with the formula of the segment of a sphere above the craniectomy area.[16]

The primary outcome metric was a complication in the following 12 months: flap or bone graft failure, necrosis, or infection from the medical records. We compared the results from the three groups. Data was summarized using standard descriptive statistics including the mean, standard deviation, median, quartiles and range for continuous variables and counts and percentages for categorical data. Study interventions for continuous variables were compared using either a t-test or Wilcoxon rank sum test, depending on the normality of the distributions. Categorical data were compared using either the chi-square or Fisher's exact test in the presence of small cell counts (< 5). Multivariate linear analysis was employed when appropriate. IBM SPSS version 9.2 or higher was used for all analyses. A p-value ≤0.05 was considered statistically significant for all comparisons.

Results

Patient Characteristics

Between 2008 and 2018 there were 55 patients who underwent cranioplasty with hostile cranial reconstructive environment. Of these patients, the reconstruction in 27 (49%) involved autogenous bone graft, 23 (41%) involved alloplastic implant for reconstruction, and 5 (9%) involved a combination of autogenous bone and prosthetic implant in reconstruction. Sixteen of the patients were female and 39 patients were male. The mean age was 39 ± 18.2 years and average BMI was 26.1 ± 6.34 kg/m^2. The most common comorbid conditions was a prior history of smoking (18%). There was no significant difference in age, gender, BMI or comorbidities between the groups. Patient characteristics and complications are listed in Table 1.

The most common hostile cranial environment resulted from prior radiation (32.7%) and prior or concurrent infection of the scalp (29%). Between the groups, there was no significant difference in history of prior failed cranioplasty, open wound, radiation, infection, or CSF leak. The diagnoses leading to craniectomy included trauma (42%), tumor (34.5%), and infection (23.6%). The site of the defect was unilateral hemispheric in most cases (79%) with 20 being right sided and 23 being left sided. The remaining 11 cases had a bilateral cranial defect (21%). The size of the cranial defect ranged from 20 cm^2 to 500 cm^2 (mean size 155 cm^2) with the bi-hemispheric craniectomies had the largest cranial defect size. Among the autogenous group the most common bone graft location was the calvarium (80%) and the rest of the locations included iliac or rib (20%). The majority were harvested on-site (73%) and the remainder were cryopreserved. Among the alloplastic group 52.2% of patients utilized a custom PEEK implant, 30% of patients utilized a titanium implant, and 17% utilized a PMMA implant (Table 3). Among the combination group 40% utilized a PEEK implant and 60% utilized a titanium implant (Table 3). There was no significant difference in the type of hostile cranial site, size of cranial defect, side of defect, or etiology of craniectomy (p>0.05).

Complications

Overall, there was a 32.6% minor complication rate and 24.6% major complication rate reported for hostile cranioplasties performed at our tertiary care facility. Autogenous cranioplasties were most strongly associated with a post-operative complication (44%)

in the year following surgery compared with the alloplastic (38%) and combined group (40%) though this was not a significant difference in univariate analysis (p=0.12). The complications ranged from hematoma and infection (32.6%), hardware malfunction or CSF leak (16.3%), and soft tissue necrosis (16.3%). Deep vein thrombosis, pulmonary embolism, and pneumonia (2.3%) were the other medical complications noted in patients. There were no reported deaths. There was no difference in the rate of complication between left right or bi-hemispheric cranioplasties, the hostile environment, the etiology of craniectomy, the size of the defect, co-morbid conditions, or bone graft harvest location.

A subgroup analysis of the type of prosthetic material noted significantly fewer complications observed among PEEK implants (21%) (p=0.009) when compared to the other prosthetic materials and cryopreserved or on-site harvested bone (Figure 3).

Multivariate analysis showed that the only factor independently associated with a risk of complication following cranioplasty of a hostile defect was the type of material used in cranioplasty (p=0.021) (Table 3). In particular, logistical regression showed that patients with alloplastic cranioplasty had a 10-fold decrease in failure (CI 95 0.010–0.461) when compared with patients with autogenous cranioplasty (p=0.006) (Table 4). Moreover, patients with two or more comorbidities also had a 2.5-fold increased risk of developing complication (CI 95 1.3–4.9) compared with patients with no comorbidities (p=0.211).

Discussion

In this study we present our recent (2008 to 2018) experience with cranioplasty of high risk complex cranial defects. This retrospective review suggests that in the setting of high risk calvarial environment the reconstructive material has a significant effect on the complication rate of cranioplasties. Specifically, PEEK implants were demonstrated to have the lowest overall complication rate and alloplastic materials had similar complication profiles to autogenous bone. In addition,

One of the most fundamental techniques of reconstructive surgery is to replace deficient structures with similar tissue.[17] Typically, the autogenous bone, harvested during a craniectomy procedure, can be replaced, or new bone can be harvested from a donor site in the same patient. Disadvantages of autogenous bone include donor site morbidity and may not be possible in cases in which there is insufficient area of bone to serve as a suitable donor site to restore the defect. In hostile cranial sites where donor sites are limited, when patient comorbidities can hinder microsurgical reconstruction, or when defects have highly complicated geometry, autogenous calvarial reconstructions can be challenging. These challenges were reflected in our study's 27 patients who utilized autogenous reconstruction.

Reviewing the literature, there are mixed conclusions represented on the topic of autologous versus alloplastic reconstruction of hostile cranial defects. A recent large systematic review of alloplastic reconstructions compared to autologous reconstructions in cranioplasties described that native bone is associated with a higher overall complication rates, higher infection rates, and higher resorption rates leading to subsequent higher rates of graft explantation.[18] On the other hand, Reddy and associates observed a higher infection rate among patients with an alloplastic reconstruction contradictory to our series.[7] Furthermore, a systematic review by Yadla and colleagues in 2011, concluded that implant material had no effect on complication rate.[19] At the time of that review, CAD-CAM was not as readily available and was not as broadly applied to allow for the creation of patient-specific implants (PSIs). The development of CAD-CAM and PSI represents an important evolution for alloplastic reconstruction. A PSI aims for a perfect fit, as the design is based on the patient's computed tomography (CT) or cone-beam CT data.[11] The alloplastic implants used in this study such as PEEK and PMMA tend to be tailored individually to each patient pre-operatively (Figure 1 and Figure 2). The advances made by the individualization of alloplastic implants through PSIs may be responsible for the reduced complication rates observed in the alloplastic groups in this study. PSIs have been demonstrated to reduce operative time and allow surgical teams to place more time into carefully planning these operations.[11]

PMMA is widely used for cranioplasty and has been available since 1960s. It is relatively inexpensive, light in weight, easy to use, radiolucent, and chemically inert. Nonetheless, PMMA is associated with disadvantages, including higher infection rates and the material does not facilitate bone ingrowth and revascularization.[20] In this study, we found that PMMA had the highest complication rate amongst the alloplastic materials. Others, however, have shown low complication rates using this material in non-high risk situations though a limitation of those studies is the short follow-up period reported.[15] PEEK is a newer material with advantages similar to PMMA; it additionally benefits from its lack of thermal conduction, low density and is relatively expensive when compared to other materials.[20] Our results suggested that reconstruction with PEEK implants had significantly fewer complications in comparison to other alloplastic materials. There may be bias confounding this finding as our surgical team is less inclined to use a PEEK implant when there is a high risk of infection. Practically, PEEK implants allow for quicker turnaround time for PSI as they can be ready with one week's notice whereas PMMA and Titanium implants typically require a fabrication time of 3–4 weeks.[21] Selective laser melting has improved the efficiency of titanium implants fabrication to 10 days or less.[22] Titanium implants share many of the same advantageous properties, however they are more expensive and are unmodifiable.[20] Though not used for reconstruction in any patients in this study, MEDPOR is a porous implant designed specifically to allow for tissue integration and reduced infectious risk. Because of its structure, it is readily malleable and allows for concomitant correction of temporal hollowing..[23] It has primarily been used for single-staged cranioplasties for neoplasm resections.[21,24]

In this comparative study we found titanium and PEEK implants to significantly decrease complication rates in a hostile cranial environment. As there was no statistically significant difference between our cohorts in terms of age, BMI, co-morbidities, or high-risk environment we believed we controlled for factors that might confound this analysis. This is further reflected in the multivariate logistic regression model that found that the material cohort predicted a complication in these patients. Limitations in this study are the relatively small number of patients in our cohort and the biases associated with retrospective reviews, sampling errors, systematic errors, selection bias and lack of randomization. Complex cranioplasties are rare and randomization is challenging. The gold standard approach to evaluating hostile cranioplasties would be a prospective study but the rate of applicable cases per year limits the number of available subjects to recruit. In addition, long-term results of placement are still missing and a multi-center study that compares the effect of staging high risk cranioplasties could be beneficial. Future directions for this study can focus on the overall costs between autologous bone graft and synthetic cranioplasties and on long-term aesthetic outcomes of the soft tissue.[25,26]

Conclusion

Although advancements in cranioplasty methods have enhanced the predictability and aesthetic results of repairs, these procedures still have a high incidence of complications. In the setting of a high-risk cranial defect, the odds of complications are significantly increased. This analysis interestingly found that in the setting of hostile cranial defects, cranioplasties would benefit from the use of prosthetic implants instead of autologous bone grafts, not only for avoidance of donor site morbidity but also for decrease in overall complications.

Conflicts of interest and sources of funding:

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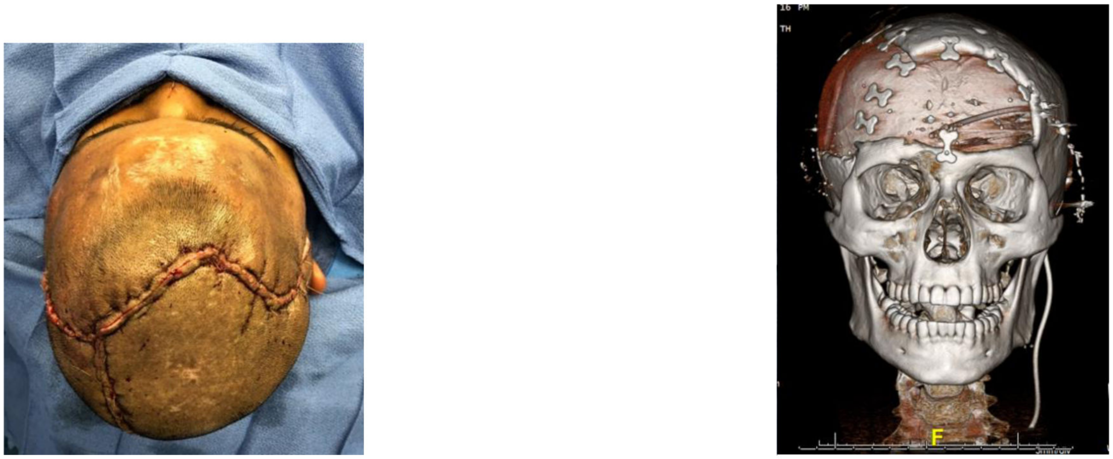
A. B. C.

Figure 1.A.

Image of pre-op complex bi-frontal cranial defect CT (1.A), alloplastic implant (1.B) and pre-op recipient site (1.C).



A. B.

Figure 2.A.

Image of post-op recipient site (4.A) and post-op CT scan (4.B) of bi-frontal alloplastic cranioplasty.

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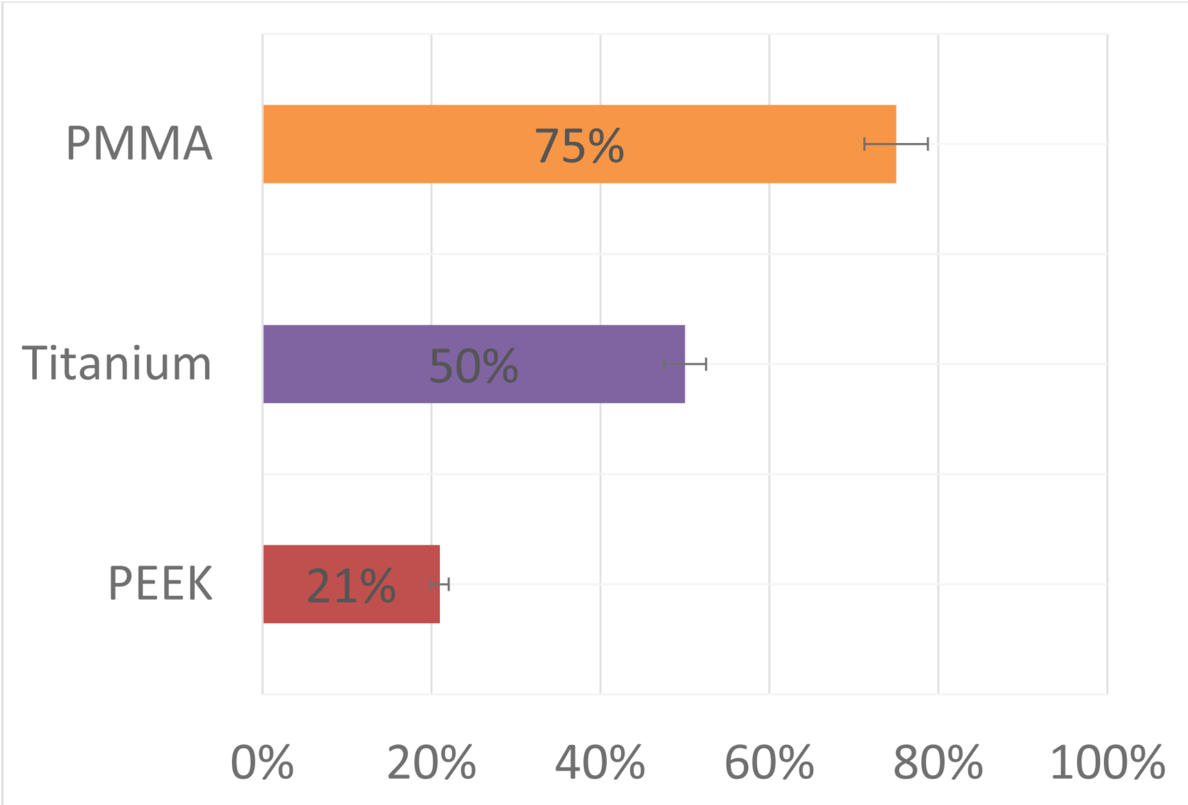

Figure 3.
Sub-group ≥1 Complication Rate for type of prosthetic implant (p=0.009)

Table 1:

Patient demographic data.

Patient Characteristics	Total N=55	Autogenous N=27	Alloplastic N = 23	Combo N =5	p
Age (range)	38.65 (18 – 81)	39.6 (18 – 78)	37 (18 – 81)	43.4 (20 – 72)	0.904
Gender					0.605
Female	30.9%	37%	26%	20%	
Male	69.1%	63%	74%	80%	
BMI, kg/m^2 *(range)*	26.1 (16 – 31)	24.7 (19 – 29)	27.0 (18 – 30)	26.1 (16 – 31)	0.455
Comorbid Conditions					0.722
None	10.9%	14.8%	4%	20%	
Hypercoagulability	2%	3.7%	4%	20%	
Hypertension	14.5%	14.8%	13%	20%	
Smoking	18.2%	37%	30%	20%	
Diabetes	3.6%	0%	9%	0%	
More than 1 co-morbidity	27.3%	18.5%	39%	20%	
Hostile Setting					0.064
Prior Radiation	32.7%	52%	13%	20%	
Prior or Concurrent Infection	29%	19%	35%	60%	
Previously Failed	21.6%	15%	30%	20%	
Pre-op open wound	20.9%	19%	22%	0%	
Etiology of Craniectomy					0.093
Tumor	34.5%	55%	17%	40%	
Trauma	42%	29.6%	52%	40%	
Infection	23.5%	14.8%	30%	20%	
Side of Cranial Defect					0.142
Left side	37%	20%	44%	60%	
Right Side	42%	53%	39%	20%	
Bi-hemispheric	21%	27%	17%	20%	
Size of Cranial Defect, cm^2(range)	154.8 (20 – 500)	126.4 (20 – 325)	157.44 (65 – 250)	126.4 (100 – 500)	0.703

Table 2:

Postoperative Outcomes

Patient Characteristics	Total N=55	Autogenous N=27	Alloplastic N = 23	Combo N =5	p
Number of Inpatient Days	8.81 (2 – 81)	9.73 (2 – 30)	7.48 (3 – 10)	12.2 (2 – 20)	0.147
Complications					0.124
Yes	41%	44%	38%	40%	
No	59%	56%	62%	60%	
Type of Post-operative complication					0.245
None	59%	56%	61%	60%	
Infection	32%	37%	13%	20%	
Hardware Malfunction	14%	7%	17%	20%	
Pulmonary Embolism	2%	0%	4%	0%	
Pneumonia	2%	0%	4%	0%	
Corticoid Steroid Use	2%	7%	0%	0%	
Deep Vein Thrombosis	2%	7%	0%	0%	

Table 3:

Type of alloplastic material utilized.

Material	**Total N= 28**	**Alloplastic N = 23**	**Combo N =5**
PEEK	*50%*	52.2%	*40%*
Titanium	*36%*	30.4%	*60%*
PMMA	*14%*	17.4 %	*0%*

Table 4:

Factors affecting the occurrence of complications. Univariate analysis for each variable and multivariate analysis if univariate analysis showed p<0.2.

Variable	**Univariate P-value**	**Multivariate P-Value**
Age	0.461	
Gender	0.545	
BMI	0.677	
Comorbid Conditions	0.101	0.173
Hostile Setting	0.377	
Etiology of Craniectomy	0.216	
Side of Defect	0.406	
Size of Cranial Defect	0.180	0.225
Number of Inpatient days	0.271	
Type of Material	*0.012*	*0.021*
Type of Prosthesis	*0.009*	0.251
Bone Graft Harvest Location	0.212	
Time between Graft Harvest and Cranioplasty (Onsite vs Delayed)	0.360	

Table 5:

Logistical Regression model of Possible Predictive Factors for Complication in Hostile Cranioplasties. Covariates were included if univariate analysis showed $p<0.2$.

	P value	Odds Ratio	Lower 95% CI	Upper 95% CI
Type of Material (Alloplastic vs Autogenous)	0.006	0.101	0.010	0.461
Type of Material (Combined vs Autogenous)	0.126	0.125	0.009	1.790
Presence of Comorbidity (Chronic Condition vs None)	0.498	1.295	0.109	15.341
Presence of Comorbidity (Smoking vs None)	0.173	1.652	0.026	9.652
Presence of Comorbidity (Two or more comorbidities vs None)	0.211	5.202	0.399	67.713
Size of Cranial Defect (cm^2)	0.225	1.101	0.991	1.006