



Introduction

Alloplastic cranioplasty is a common procedure in cranial reconstruction, yet factors related to success and failure have been incompletely characterized. Complications after cranioplasty remain high, with overall complication rates cited to be as high as 40%. These often include infection leading to implant explantation, hematoma, seroma, CSF leak, and wound breakdown. While alloplastic materials can provide sufficient brain protection, many patients also experience temporal hollowing after reconstruction related to soft tissue loss with temporalis muscle malposition and or atrophy. Prior studies have highlighted the risk of complications by material type and compared the risk of complications between alloplastic and autogenous cranioplasty. **However, few robust studies exist specifically for alloplastic cranioplasty, and literature is scant regarding aesthetic outcomes.**

Methods

- Retrospective review of patients who underwent alloplastic cranioplasty between 2014 and 2021 at a single institution
 - Cranial defects > 5 cm
 - Both neurosurgeons and plastics surgeons were included
 - All alloplastic implant types (PEEK, Titanium, and PEEK/Medpor)
- Exclusion criteria included missing operative data and patients lost to follow up
- Information was gathered regarding patient demographics, wound healing comorbidities, indications for surgery, operative information, and outcomes (complications, implant explantation, abnormal contour)
 - Wound healing comorbidities were defined as type I or II diabetes, smoking, steroid use, hypertension, and documented heavy alcohol use
 - Abnormal contour was defined as the presence of a temporal hollow, palpable implant edges, or paralysis of the frontal branch of the facial nerve.
- Continuous variables were described as means with standard deviations and categorical variables as percentages
- Factors associated with outcomes were identified using Mann-Whitney U and Chi-Squared tests on bivariate analysis
 - Variables with $P < 0.10$ were moved to multivariable regression analysis
- Logistic regression was performed, with results expressed as odds ratios with a 95% confidence interval and standard error
 - $P < 0.05$ were considered statistically significant

Results

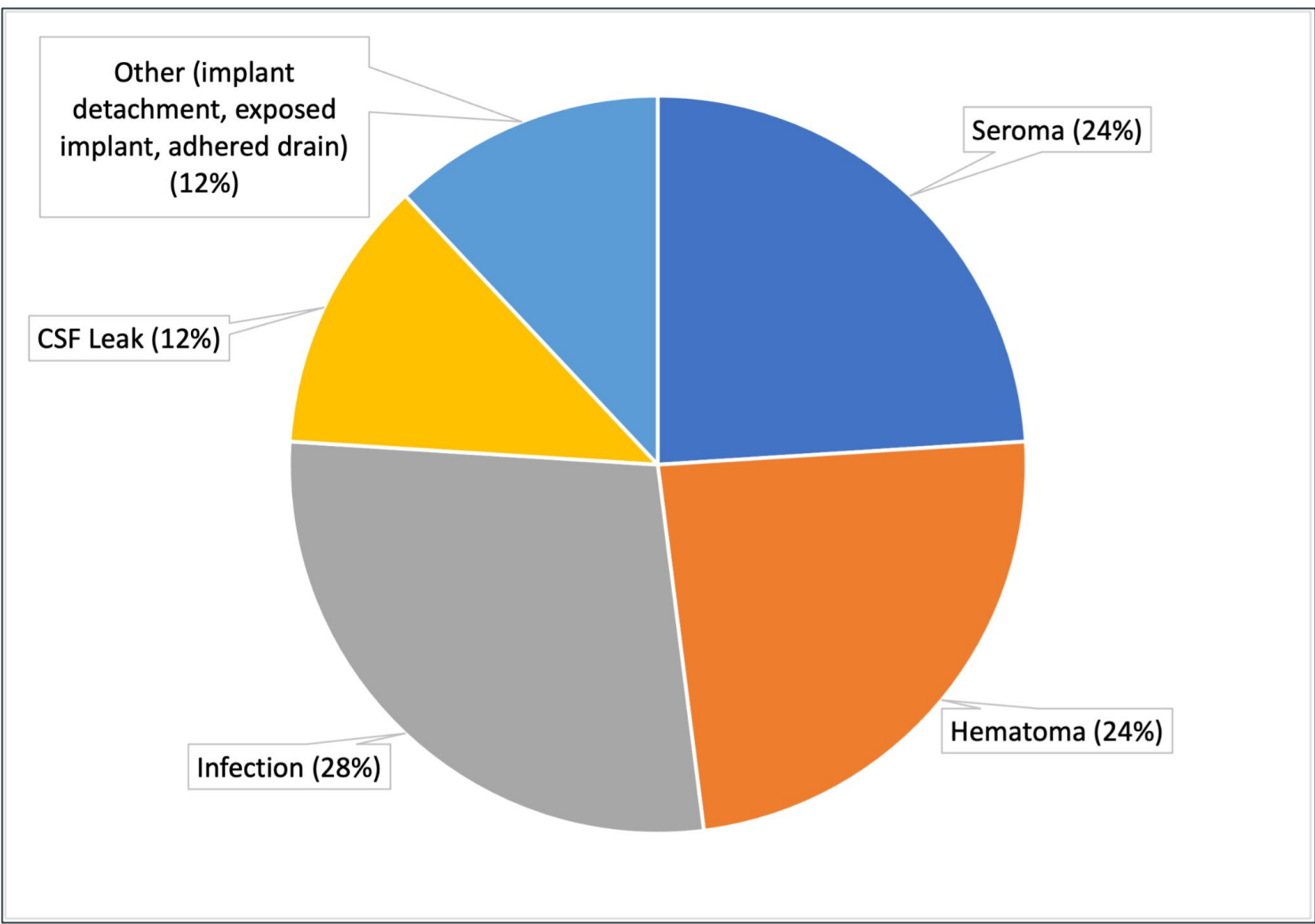
Operative Data

- 101 patients underwent alloplastic cranioplasty
 - Average age 42 ± 18 years
 - 28% (28/101) female and 72% (73/101) male
- 57% (58/101) had at least one wound healing comorbidity
- Median time to surgery from craniectomy: 5 months
- Median time to follow up: 1.5 years

Complications and implant explantation

- 24% (24/101) operative complication rate (Figure 1)
- 16% (16/101) Implant explantation rate
 - Most common reason was infection (44%, 7/16)
- 99% (100/101) at final follow up had a successful primary or secondarily placed implant

Figure 1. Distribution of Operative Complications



Postoperative Contour

- 36% (36/101) of patients had a contour abnormality
 - 89% (32/36) of these patients had a temporoparietal implant
 - PEEK implants had the highest rate of contour abnormalities (83%, 30/36)
 - 44% (16/36) had further operations related to cosmesis
 - Fat grafting, Alloderm, Medpor, scar revision

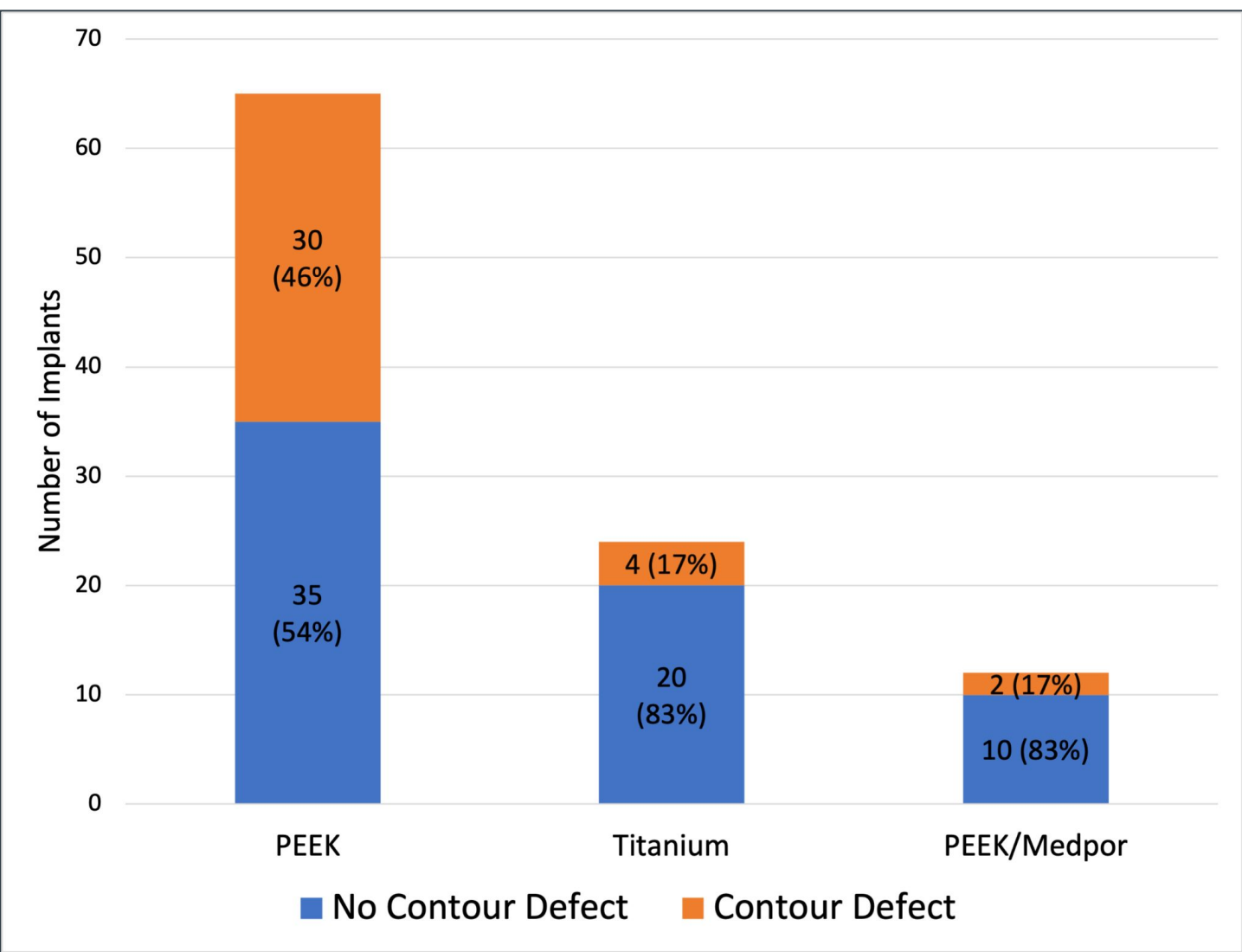


Figure 2. Distribution of Contour Defects by Implant Material

Bivariate Analysis

Table 1. Bivariate analysis of factors associated with operative complications, contour irregularities, and implant explantation								
	Complications			Contour Irregularities			Implant Explantation	
	No	Yes	P-value	No	Yes	P-value	No	Yes
Gender			0.73			0.16		0.79
Male	75% (55)	25% (18)		68% (50)	32% (23)		84% (61)	16% (12)
Female	79% (22)	21% (6)		54% (15)	46% (13)		86% (24)	14% (4)
Race/Ethnicity			0.77			0.90		0.49
White	77% (63)	23% (19)		65% (53)	35% (29)		85% (70)	15% (12)
Other	76% (14)	24% (5)		63% (12)	37% (7)		84% (15)	16% (4)
Diabetes			0.25			0.12		0.25
No	74% (63)	26% (22)		61% (52)	39% (33)		82% (70)	18% (15)
Yes	88% (14)	12% (2)		81% (13)	19% (3)		94% (15)	6% (1)
ASA classification			0.10			0.93		0.43
ASA 1/2	83% (25)	17% (5)		63% (19)	37% (11)		87% (26)	13% (4)
ASA 3	77% (47)	23% (14)		66% (40)	34% (21)		85% (52)	15% (9)
ASA 4	50% (5)	50% (5)		60% (6)	40% (4)		70% (7)	30% (3)
Active tobacco smoking			0.54			0.64		0.93
No	75% (67)	25% (22)		65% (58)	35% (31)		84% (75)	16% (14)
Yes	83% (10)	17% (2)		58% (7)	42% (5)		83% (10)	17% (2)
Hypertension			0.92			0.35		0.63
No	77% (49)	23% (15)		61% (39)	39% (25)		83% (53)	17% (11)
Yes	76% (28)	24% (9)		70% (26)	30% (11)		86% (32)	14% (5)
Obstructive sleep apnea			0.57			0.32		0.23
No	77% (73)	23% (22)		63% (60)	37% (35)		85% (81)	15% (14)
Yes	67% (4)	33% (2)		83% (5)	17% (1)		67% (4)	33% (2)
Heavy alcohol use			0.001			0.47		0.05
No	81% (73)	19% (17)		66% (59)	34% (31)		87% (78)	13% (12)
Yes	36% (4)	64% (7)		55% (6)	45% (5)		64% (7)	36% (4)
Wound healing comorbidity			0.19			0.80		0.17
No	83% (34)	17% (7)		66% (27)	34% (14)		90% (37)	10% (4)
Yes	72% (43)	28% (17)		63% (38)	37% (22)		80% (48)	20% (12)
Number of comorbidities			0.22			0.15		0.58
0	82% (36)	18% (8)		61% (27)	39% (17)		89% (39)	11% (5)
1	66% (21)	44% (11)		56% (18)	44% (14)		78% (25)	22% (7)
2	83% (19)	17% (4)		83% (19)	17% (4)		83% (19)	17% (4)
3	50% (1)	50% (1)		50% (1)	50% (1)		100% (2)	0% (0)
Impaired Neurological Status			0.32			0.08		0.56
No	80% (41)	20% (10)		73% (37)	27% (14)		88% (44)	14% (7)
Yes	72% (36)	28% (14)		56% (28)	44% (22)		82% (41)	18% (9)
Indication for surgery			0.64			0.001		0.16
Hemorrhagic stroke	83% (15)	17% (3)		44% (8)	56% (10)		89% (16)	11% (2)
Trauma	75% (33)	25% (11)		52% (23)	48% (21)		89% (39)	11% (5)
Cancer	67% (12)	33% (6)		94% (17)	6% (1)		67% (12)	33% (6)
Others	81% (17)	19% (4)		81% (17)	19% (4)		86% (18)	14% (3)
Craniectomy			0.01			0.25		0.61
Hemispheric	71% (60)	29% (24)		62% (52)	38% (32)		83% (70)	17% (14)
Bifrontal	100% (17)	0% (0)		76% (13)	24% (4)		88% (15)	12% (2)
Type of implant			0.12			0.01		0.62
PEEK/Medpor	67% (8)	33% (4)		83% (10)	17% (2)		75% (9)	25% (3)
PEEK	72% (47)	28% (18)		54% (35)	46% (30)		85% (55)	15% (10)
Titanium	92% (22)	8% (2)		83% (20)	17% (4)		87.5% (21)	12.5% (3)
CSF manipulation			0.63			0.32		0.70
No	77% (70)	23% (21)		66% (60)	34% (31)		85% (77)	15% (14)
Yes	70% (7)	30% (3)		50% (5)	50% (5)		80% (8)	20% (2)
Continuous variables								
Age	42 (24-58)	42 (31-56)	0.82	45 (27 - 59)	36 (25 - 43)	0.02	42 (26 - 55)	44 (32 - 58)
Time to surgery	7 (0-10)	7 (3-8.5)	0.65	6 (0 - 7)	10 (4-12)	0.02	7 (0-10)	8 (2-6)
Continuous variables as mean ± standard deviation; categorical variables as percentage (number). All variables with $P < 0.10$ were moved to multivariable analysis.								

Multivariable Analysis

Table 2. Logistic regression analysis of factors associated with operative complications				Table 3. Logistic regression analysis of factors associated with contour irregularities			
Variables	Odd's ratio (95% Confidence Interval)	Standard Error	P-value	Variables	Odd's ratio (95% Confidence Interval)	Standard Error	P-value
Impaired Neurological Status				No	reference value		
Yes	1.6 (0.6 to 4.4)	0.83	0.35	Indication for surgery			
Others	reference value			Trauma	3.4 (0.9 to 12.5)	2.25	0.07
Cancer	0.4 (0.04 to 4.7)	0.52	0.48	Hemorrhagic stroke	6.1 (1.2 to 30.7)	5.04	0.03
Type of implant				Heavy alcohol use			
PEEK/Medpor	reference value			No	reference value		
PEEK	5.3 (0.95 to 29.2)	4.61	0.06	Yes	6.2 (1.5 to 25.5)	4.46	0.01
Titanium	2.4 (0.3 to 19.6)	2.58	0.41	Bold indicates statistical significance, $P < 0.05$. Craniectomy location is not included because there were no complications in the bifrontal group.			
Age	0.98 (0.95 to 1.01)	0.02	0.24	Bold indicates statistical significance, $P < 0.05$. Time to surgery has been dropped due to collinearity with the indication of surgery.			

Conclusions

- We present one of the largest reviews of alloplastic cranioplasty in a civilian cohort to **assess both complications and cosmesis**.
- A high degree of success can be achieved with alloplastic cranioplasty.** At final follow-up 99% (100/101) of patients maintained a primarily or secondarily placed implant
- ASA Classification of 4 (OR 5.9, 95% CI [1.03, 33.1], p = 0.05) and heavy alcohol use (OR 6.2, 95% CI [1.5, 25.5], p = 0.01) were significant predictors for postoperative complications.
- Heavy alcohol use was the only predictor of implant explantation (p = 0.05). **Surgeons should consider screening for and treated increased alcohol consumption before surgery, as these patients may be at higher risk.**
- PEEK implants were a significant predictor for contour irregularities in bivariate analysis, possibly due to poor soft tissue adherence to the smooth PEEK material. In contrast, PEEK/Medpor composite implants had a low rate of contour irregularities.
- The most significant predictor for postoperative temporal irregularity was CVA, as the primary indication for surgery (OR 6.1, 95% CI [1.2, 30.7], p = 0.03)

Future Work

- Conduction of larger prospective studies in alloplastic cranioplasty with inclusion of patient reported outcomes
- Development of a validated assessment measure for cosmesis
- Analyze the effects of CAD/CAM technology for implant design