

Background

Autologous bone, while biocompatible and osteoconductive, is often limited by resorption, donor site morbidity, and insufficient volume for large defects.¹

PEEK

- ✓ Availability
- ✓ Durability and mechanical strength
- ✓ Radiolucent
- ✗ Bioinert²

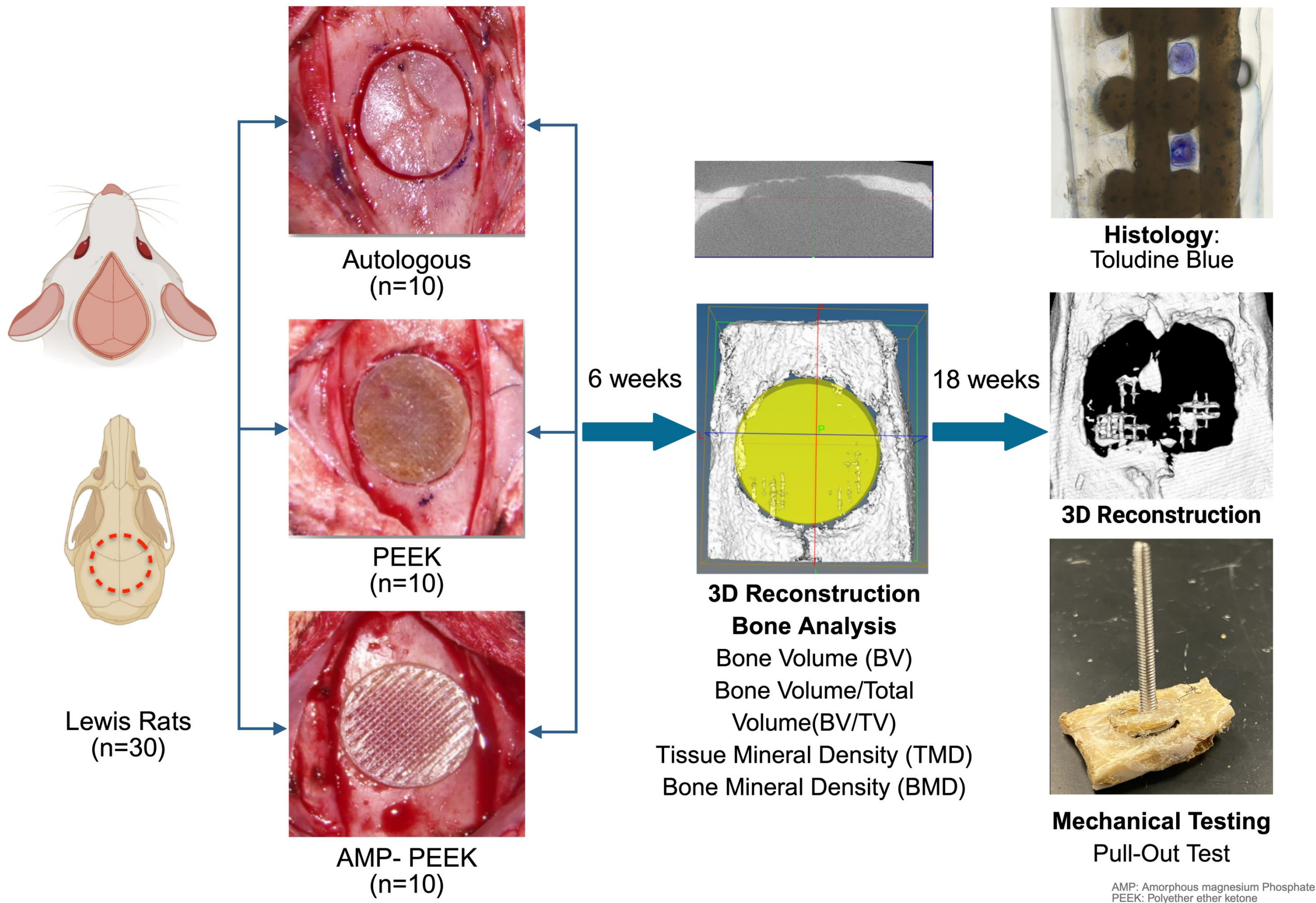
AMP- PEEK

- ✓ Availability, durable, radiolucent
- ✓ Demonstrated superior osteogenic potential, osteointegration, and bone–implant contact in **in vitro** and **in vivo** models²
- ✗ No data available on its impact on cranioplasty model

Hypothesis

We hypothesized that coating PEEK with AMP would improve its bioactivity, enhancing bone integration and implant performance. This study evaluates bone regeneration and osseointegration of AMP-coated PEEK implants in a critical-sized calvarial defect model in rodents.

Methods



Category	AMP-PEEK Group	PEEK Group	Autologous Group
Implant Composition	PEEK blended with Amorphous Magnesium Phosphate (AMP) powder	Pure PEEK	Autologous calvarial bone
Implant Dimensions	9 mm diameter, 800 µm thick, macroporous (100–300 µm pores)	9 mm calvarial bone	
Animal Model	Lewis rats (16.4 weeks, 390g median weight); 10 rats/group		
Endpoints	Calvariae harvested at 18 weeks		
Micro-CT Imaging	Assessed at 6 & 18 weeks; evaluated BV, BV/TV, BMD, TMD		
Mechanical Testing	Instron testing for tensile strength and pull-out force		
Histology	2 samples/group; LR White embedding, Toluidine Blue staining		
Statistical Analysis	Mann-Whitney U for AMP-PEEK vs. PEEK; Kruskal-Wallis for 3-group comparison		

Results

Cranioplasty Procedure Outcomes

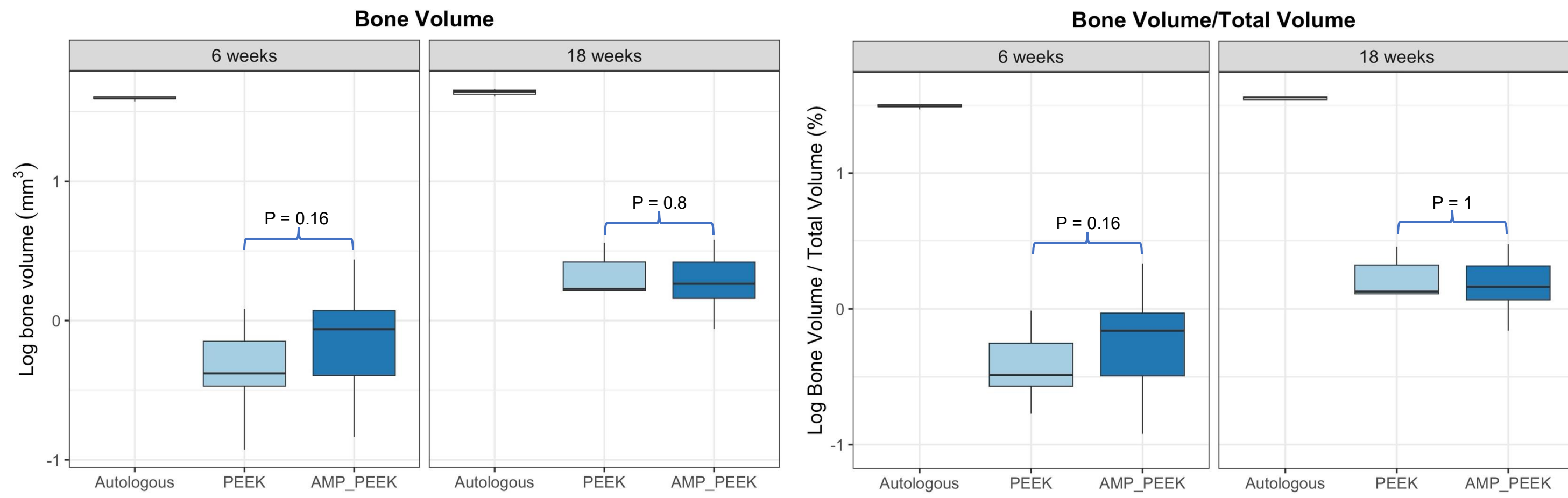
Wound dehiscence : 13.3% (4/30), managed with debridement and reclosure:

- 2 in autologous bone group, 1 in AMP-PEEK, 1 in PEEK
- No cases of infection, implant exposure, or death

Micro-CT

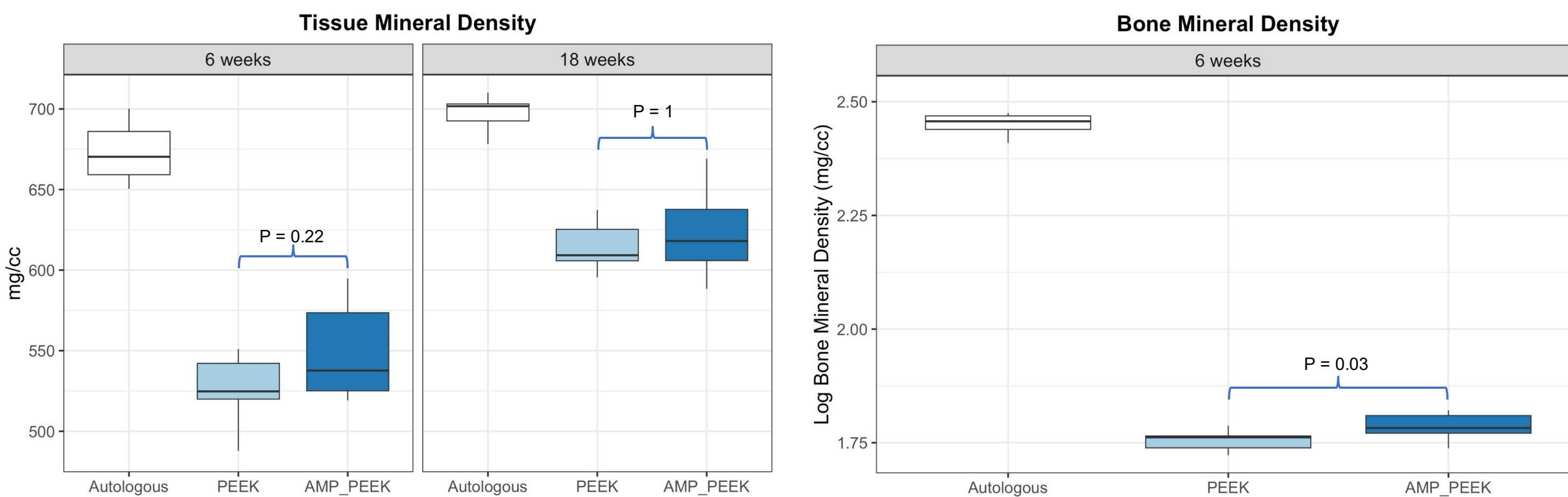
Cranioplasty Material	6 weeks		18 weeks	
	Bone Volume (BV) [Median (IQR), mm ³]	p-value	Bone Volume (BV) [Median (IQR), mm ³]	p-value
Autologous bone	39.3 (IQR 38.2-42.5)	0.16	44.1 (IQR 40.7-46.15)	0.8
PEEK	0.41 (IQR 0.27-0.78)		1.68 (IQR 0.67-3.6)	
AMP-PEEK	0.85 (IQR 0.4-1.2)		1.88 (IQR 0.86-6.68)	

Cranioplasty Material	6 weeks		18 weeks	
	Bone Volume/Total Volume (BV/TV) [Median (IQR), %]	p-value	Bone Volume/Total Volume (BV/TV) [Median (IQR), %]	p-value
Autologous bone	62 (IQR 60.3-67.4)	0.16	72.12 (IQR 62.2-82)	0.9
PEEK	1.3 (IQR 0.61-2.03)		2.68 (IQR 1.06-5.72)	
AMP-PEEK	3.1 (IQR 2.2-5.5)		2.97 (IQR 1.38-10.54)	



Cranioplasty Material	6 weeks		18 weeks	
	Tissue Mineral Density (TMD) [Median (IQR), mg/cc]	p-value	Tissue Mineral Density (TMD) [Median (IQR), mg/cc]	p-value
Autologous bone	670.3 (IQR 657.3-687.3)	0.22	701 (IQR 678.2-710.1)	1
PEEK	523.5 (IQR 503.8-547.7)		609.23 (IQR 595.5-686.1)	
AMP-PEEK	536.4 (IQR 525.1-574.1)		618.05 (IQR 557.3-669.1)	

Cranioplasty Material	6 weeks	
	Bone Mineral Density (BMD) [Median (IQR), mg/cc]	p-value
Autologous bone	286.4 (IQR 265.8-296.4)	0.03
PEEK	57.7 (IQR 53.7-58.2)	
AMP-PEEK	60.3 (IQR 59-65)	



Bone Implant Contact

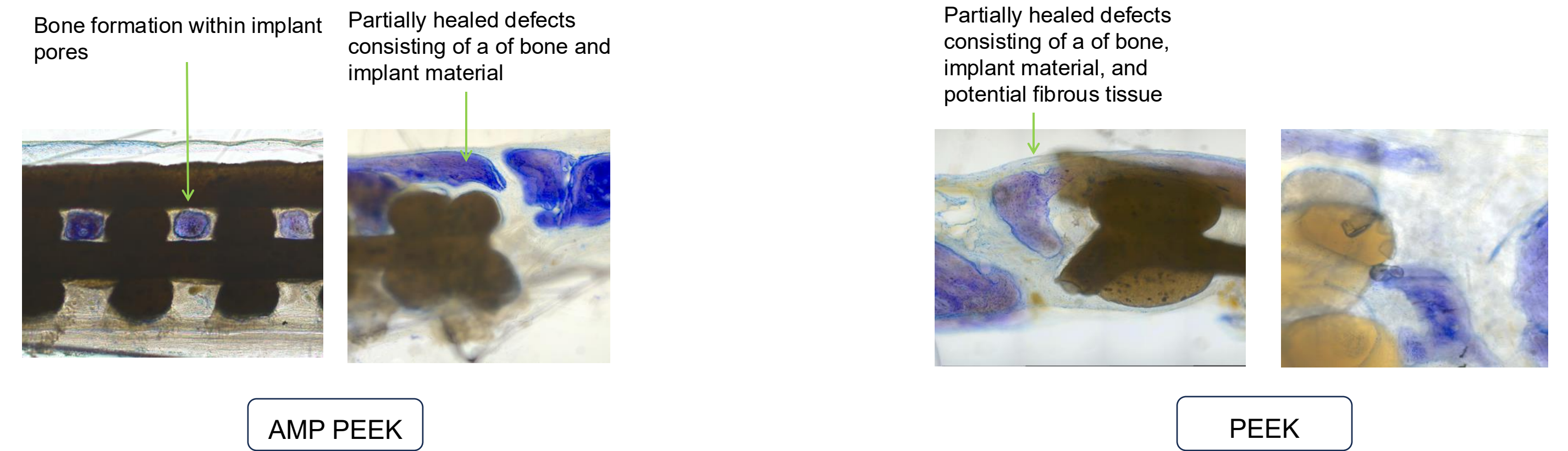
	6 weeks			AMP PEEK	PEEK	Autologous
	Bone Implant Contact (%[IQR])	p-value				
Autologous	61.43 [48.38-73.94]	<0.001	6 weeks			
AMP	19.5 [12.24-44.36]					
PEEK	14.67 [9.12-18.30]					

	18 weeks			AMP PEEK	PEEK	Autologous
	Bone Implant Contact (%[IQR])	p-value				
Autologous	62.56 [51.1-71.51]	0.03	18 weeks			
AMP	23.22 [18.3-72.44]					
PEEK	20.-2 [11.69-39.25]					

Mechanical Testing

Cranioplasty Material	6 weeks	
	Maximum Load [Median (IQR), N]	p-value
Autologous bone	41.98 (IQR 34.39-47.35)	0.56
PEEK	40.13 (IQR 38.59-47.35)	
AMP-PEEK	35.03 (IQR 30.78-44.3)	

Histological Analysis



Conclusion

Both AMP-PEEK and PEEK porous implants showed promising outcomes in bone formation and integration in a rat calvarial defect model.

AMP coating led to an increase in early bone mineral density but did **not** significantly improve:

- Bone volume
- Implant mechanical strength

Preliminary data suggest that both implant types offer mechanical resistance comparable to autologous bone.

References

1. Malcolm JG, Mahmooth Z, Rindler RS, et al. Autologous cranioplasty is associated with increased reoperation rate: a systematic review and meta-analysis. *World Neurosurg.* 2018;116:60–68. doi:10.1016/j.wneu.2018.05.009
2. Perozzo FAG, Ku YC, Kshetry VR, et al. High-density porous polyethylene implant cranioplasty: a systematic review of outcomes. *J Craniofac Surg.* 2024;35(4):1074–1079. doi:10.1097/SCS.00000000000010135
3. Sikder P, Ferreira JA, Akbari Fakhrabadi E, et al. Bioactive amorphous magnesium phosphate-polyetheretherketone composite filaments for 3D printing. *Dent Mater.* 2020;36(7):865–883. doi:10.1016/j.dental.2020.04.008