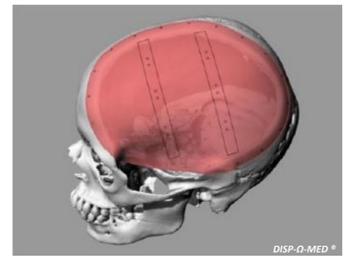


Background

Cranioplasty implants have evolved considerably in recent years. Until 2019 Custom Bone[®] was the leader of the customised cranial implant market. Nowadays a multitude of medical devices are available and the market for these implants is shared between several manufacturers. As implantable medical devices, these implants are under pharmaceutical perimeter in France. Because of their high cost, the french regulations require us to launch a competition procedure.

Objectives

➔ Provide an overview of the various refunded customised cranioplasty implants in France, so we can get highlight technical arguments to define the best procurement strategy in touch with the surgical team.

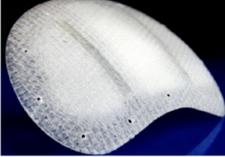
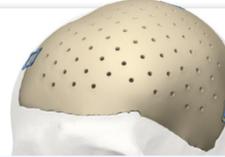


Material and Methods

- Identification of the refunded cranioplasty implants with the national healthcare database.
- Literature review of available studies and analysis on the technical data from of the suppliers.
- Survey of 20 University Hospitals to learn about their practices in cranioplasty implants

Results

Comparative table of the different customised cranial implants

	Custom Bone [®]	GLACE [®]	PEEK [®]	MEDPOR CCI [®]	OSSDSIGN CRANIAL PSI [®]
Supplier	INTEGRA	DISP-Ω-MED	STRYKER	STRYKER	OSSDSIGN
Biomaterials	Hydroxyapatite (HA)	Bioglass + dimethacrylate resin polymerized	Poly-ether-ether-ketone (PEEK)	High-density porous polyethylene	Calcium phosphate ceramic + Titanium skeleton
Picture					
Biomaterials and mechanical characteristics	+ Osteo-conductive and osteogenic - Significant expansion property - Non-irritant	Bioglass: - Osteo-conductive - Slow bio-resorption Polymerized Dimethacrylate: - Higher compression resistance than HA - Non-irritant - Non-thermally conductive	- Non-resorbable - Good elasticity - Radiolucent - Non-thermally conductive - Re-sterilizable without generating deformations	- Osteoconductive - Non resorbable - Inert - Radiolucent	Calcium phosphate ceramic: - Osteo-conductive - Non resorbable Titanium: - Good resistance
	- Fragility - Low mechanical resistance	Polymerized Dimethacrylate: - Low osteointegration - Low elastic limit: risk of fragmentation	- Low osteointegration		Titanium: - No osteogenesis - Expensive - Radiopaque (artifact to medical imaging)
	➔ Better for small lesions due to fragility	➔ Higher mechanical strength than HA implants	➔ Better for larger lesions due to good structural stability	➔ Few data in the literature	➔ Calcium Ceramic: Similar properties to HA, reinforced by titanium frame
Packaging	2 sterile implants (including 1 for backup)	1 sterile implant	1 non-sterile implant + 1 non-sterilizable model	2 sterile implants + 1 sterile model	1 sterile implant + accessories*
Is implant intraoperative adjustable ?	NO	NO	YES	YES	YES
Implant fixation	Non-absorbable suture	Screws	Screws + Plate	Screws	Screws+ predefined fixation arms
Manufacturing time	2-4 weeks	10 days	12 days (emergency order : 5 days)	12 days	4 weeks
Price	5 840 €	From 5250 to 6250 € (depending on the implant's size)	5 750 €	Refund file on going	5 750 €
Use in University Hospital Center (9 answers out of 20 centers surveyed)	7 out of 9 centers	2 out of 9 centers	2 out of 9 centers	/	1 out of 9 centers

+; Advantages, -; Drawbacks

* Anatomical model original (non-sterile) + Anatomical model modified (non-sterile) + Plastic drawing guide (sterile)+ Cranial implant trial (sterile)

➔ There are many comparative studies between synthetic implants and autologous bone. However, there are no comparative studies between different types of marketed implants.

Conclusion

➔ Custom Bone[®] implant seems to remain the most used implant at this time.

➔ The lack of data makes the objective choice of one implant difficult compared to another. Indeed, more comparative studies are necessary to assess the superiority of one method or biomaterial over others.

➔ This work shows that the most appropriate solution will certainly be to direct our purchasing strategy towards a multi-vendor market, so that patients can benefit from the implant most adapted to their clinical situation. This solution will be discussed collegially with the neurosurgical team.