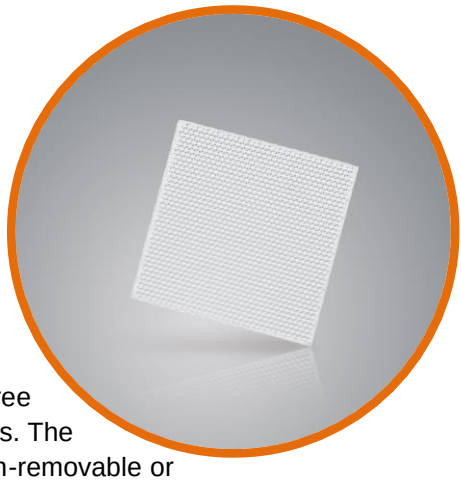
Osteomesh®

Structural support in cranial floor reconstruction

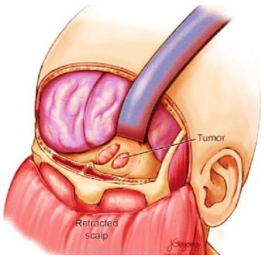


Introduction

The discipline of skull base surgery has significantly improved over the past three decades owing to the advent of sophisticated reconstructive surgical procedures. The medical community can now smoothly excise tumors that were considered non-removable or partially excisable before. The new regimes also tend to reduce the risks of severe complications. The cranial floor, also known as the base of the skull, is in the inferior region of the skull and is further divided into endocranium and calvaria. Skull base reconstruction is a complex process requiring constant separation of the contents present in the cranium from those in the extracranial regions [1].

Skull base surgery is advised when the patient is diagnosed with cysts, infectious growths, non-cancerous meningiomas, pituitary tumors, or abnormal growth near the pituitary gland [2]. It is also needed to manage veins or arteries that have been linked abnormally. Moreover, treatment of cerebrospinal-fluid fistulas, trigeminal neuralgia, and cerebral aneurysm also require skull base surgery [3, 4].

Skull base surgery can be categorized into two approaches: minimally invasive endoscopic surgery or open skull base surgery. Where possible, minimally invasive endoscopic surgery is usually preferred. However, the choice of surgery depends upon the nature of the growth to be excised and its site of occurrence. For advanced-stage tumors, open skull base surgery is usually adopted. Differences between endoscopic [4] and traditional (open) skull base surgery [5] are indicated in the table below.

Characteristics	Endoscopic	Open
Surgical approach	Trans-nasal 	Incisions in the face and skull 
Incision size	Small	Large
Extent of bone drilling	Less	More

Skull base surgery: Reconstruction of the cranial floor

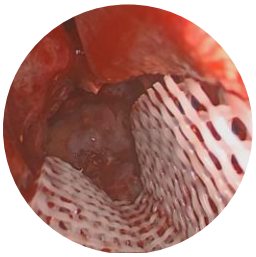
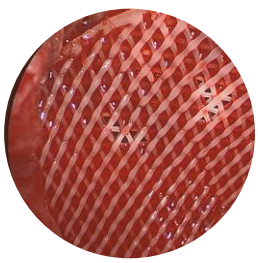
After the barrier between cerebrospinal fluid (CSF) and the sino-nasal cavity has achieved 'watertight' closure, bony reconstruction of the cranial floor may be required to provide structural support and prevent tissue prolapse[6]. Among the various reconstruction material options available, most of them are non-absorbable (e.g. titanium, polyethylene) while the absorbable versions are predominantly bone grafts of collagen-based grafts. The table below summarizes the benefits and limitations of various materials that can be used for repair.

Characteristics	Osteomesh®	Bone graft	Soft tissue graft	Other synthetic grafts
Rate of bioresorption vs. bone growth	+ + +	+ + + [7]	+ + [8]	+ (non-absorbable) [9]
Ease of handling	+ + +	+ [7]	+ + + [8]	+ + + [9, 10]
Structural stability upon contact with blood, bone marrow	+ + +	+ + + [11]	+ [4]	+ + [4]
Material strength	+ +	+ + + [12]	+ [9]	+ + [9]
Availability	+ + +	+ [7]	+ + + [10]	+ + + [10]
Rate of complication	0.01%	23.6% [13]	31-35% [14, 15]	35% [16]

Osteomesh®: Providing structural support for cranial floor reconstruction

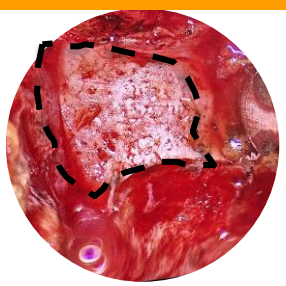
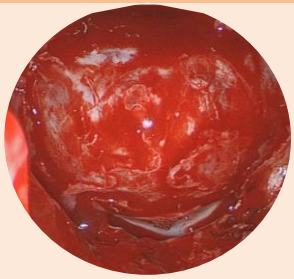
In order to provide sufficient support to the cranial floor, the reconstruction material should exhibit sufficient strength while being flexible, particularly when an endoscopic repair is performed. Osteomesh® is a structural support mesh 3D printed via fused-deposition modeling (FDM). This technique confers an interconnected honeycomb-like microstructure that has been proven to enable bone and vessel ingrowth [17]. Made of polycaprolactone (PCL), the Osteomesh® combines flexibility and rigidity to enhance usability while retaining sufficient strength to function as a support mesh. It can be trimmed into any required shape with a pair of surgical scissors. In addition, it can be rolled-up and delivered through a small channel, making it compatible with minimally invasive procedures. The illustration below demonstrates the technique of deploying the Osteomesh.

ILLUSTRATION OF SURGICAL TECHNIQUE OF DEPLOYING THE OSTEOMESH®

Insert Osteomesh®	Osteomesh® deployed	Packing with grafts
Rolled-up to deploy trans-nasal	*Unfolded to deploy flat, blood retention in the pores*	*Combined with grafts*
		

Osteomesh® has been clinically applied over the past 15 years, with an overall complication rate of 0.01%. In contrast to Gelfoam, collagen, and other similar grafts that are highly soft and pliable, Osteomesh® retains its structure stability upon interaction with bodily fluids such as blood and bone marrow, with the added ability to retain blood and bone marrow in its pore structure. This is an important feature to support *in situ* tissue regeneration. Osteomesh® is bioresorbable and has been demonstrated to delay or reduce associated complications [18].

Based on the collective clinical experience (25 cases), representative evidence of successful cranial floor reconstruction is presented below. In 3 different cases, the Osteomesh was used in the repair of the cranial floor. Consistently across these 3 cases, evidence of bone formation can be observed whether through scans of post-operative re-exploration.

	Pre-op scan indicating tumour location	**6 months post-op scan**
Case 1 **Meningioma**	 *Pre-op showing tumor growth and involvement of cranial floor*	 *Signs of bony consolidation at cranial floor (circled region)*
	Intra-op	**Post-op 6 months**
Case 2 **Acromegaly**	 *Intra-op showing in-situ positioning of Osteomesh*	 *In-situ exploration verifies tissue ingrowth (highlighted region)*
	Intra-op	**Post-op 3 years**
Case 3 **Prolactinoma**	 *Intra-op exposure of cranial floor*	 *Evidence of new bone formation*

Closing remarks

Osteomesh® has shown promise to revolutionize cranial floor repair by being capable of regenerating bone at the cranial floor. It is also flexible enough to be considered in endoscopic approaches.

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