Retrospective study confirms performance of Biodesign grafts for transcranial dura mater repair

Abstract

Purpose: The purpose of this study was to assess the real-world performance of the Biodesign graft as a dura substitute for repairing dura mater. This report specifically analyzes a subset of patients who underwent transcranial dura mater repairs with the Biodesign graft.

Endpoints: The primary endpoint was the postoperative integrity of the graft 1 month after surgery as defined by the lack of need to return to the operating room to repair a cerebrospinal fluid (CSF) leak. Secondary endpoints included postoperative graft integrity at the last available patient follow-up visit (with a minimum of 6 months' follow-up) and the assessment of adverse events for normal, widespread use of the graft in the short-term postoperative period. Data were collected from 81 patients at Toronto Western Hospital, Toronto, Ontario, Canada.

Results: Eighty-one patients were included in the final analysis.

- **Short-term (1 month) postoperative integrity rate: 81/81 (100%)**
- **Mid-term (≥6 months) postoperative integrity rate: 72/72 (100%)**
- **None of the reported adverse events were determined to be device related. The most common complications included CSF leak (not requiring reoperation), headache, and wound infection.**

Conclusion: This study confirms the safety and effectiveness of using Biodesign grafts for dura mater repair when used in a transcranial approach. No unexpected or serious adverse events were reported among the 81 patients in the study, and no patients examined were returned to the operating room for a postoperative CSF leak.

POSTOP INTEGRITY
100%
after 1 month,
after 6 months

Background

The human dura mater is a protective membrane surrounding the brain and spinal cord. It can distend, allowing for pressure variations in the skull, and it serves as the framework for cranial blood vessels. It consists of two layers—the outer endosteal layer and the inner meningeal layer, firmly connected by collagen fibers. The dura mater is the outermost layer of the meninges, crucial for brain and spinal cord protection.[1,2]

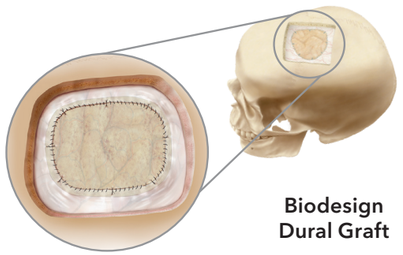
CSF is vital for maintaining brain function. It provides buoyancy, which protects against injury, and prevents ischemia by regulating intracranial pressure. CSF also facilitates homeostasis, waste removal, and distribution of substances in the brain.[1-3]

The dura mater and CSF play crucial roles in protecting the brain and spinal cord. CSF leaks have various etiologies and require different treatments, operative approaches, and graft materials. Careful consideration of patient-specific factors is essential for successful repair.

The ideal dural graft material should have the handling characteristics of human dura, be easy to manipulate when hydrated, achieve a watertight seal, resist scarring and inflammation, and provide a scaffold for new dura formation.[4,5] Additionally, the ideal dural graft material should be nontoxic, non-immunogenic, and nonadherent to local structures.[6,7] Autologous and non-autologous graft materials are used, each with its advantages and disadvantages.

Device description

The Biodesign Dural Graft is made from porcine small intestinal submucosa (SIS). SIS is processed to remove cells and nuclear matter, leaving a decellularized, collagen-rich extracellular matrix (ECM). The graft is non-pyrogenic and has sufficiently low endotoxin levels to make it suitable for use in contact with CSF. The graft is supplied sterile in a sealed double-pouch system and can be stored at room temperature for up to 18 months.



Biodesign Dural Graft

Study methods

Retrospective data were collected at 1 site in Canada. Patients who underwent transcranial dura mater repair using a Biodesign graft were included in this analysis. Descriptive statistics were used to summarize findings including demographics, medical history, tumor/pathology, defect information, operative data, and postoperative data (including CSF leak, adverse events, and the need for reoperation).

Study results

Data from 81 patients were collected from Toronto Western Hospital in Canada.

Primary endpoints	n/N (percent)
CSF leak that required a return to the operating room (short-term follow-up, median 46 days)	0/81 (0%)
Postoperative CNS infection	0/81 (0%)
Required lumbar drain placement	0/81 (0%)
Secondary endpoints	**n/N (percent)**
CSF leak that required a return to the operating room (mid-term follow-up, median 175 days)	0/72 (0%)

Of the 10 patients reporting complications, CSF leak (not requiring reoperation) (n=2, 2.5%), headache (n=2, 2.5%), and wound infection (n=2, 2.5%) were the most frequently reported complications. None of these complications were considered unexpected or serious. They were also not reported to be device related.

Study population details

Demographics	
• Mean age	55
• Age range	26–89
• Male	28.4%
• Female	71.6%
Pertinent medical history	
• Previous related surgeries	25.9%
o Due to tumor recurrence	76.2%
• Prior radiation to the area	14.8%
Tumor/pathology	
• Meningioma	53.1%
• Glioma (all types)	9.9%
• Craniopharyngioma	7.4%
• Skull base malignancy	7.4%
• Vestibular schwannoma	3.7%
• Other	18.5%
Defect location	
• Anterior fossa	21%
• Posterior fossa	13.6%
• Base of skull	8.6%
• Middle fossa	8.6%
• Infratentorial	7.4%
• Frontal sinus posterior table	6.2%
• Frontoparietal	4.9%
• Sella	4.9%
• Supratentorial	4.9%
• Anterior and middle fossa	2.5%
• Temporal	3.7%
• Occipital lobe	2.5%
• Other	9.9%

Discussion

Biodesign grafts support the repair of dura mater by providing a conducive environment in which the body's cells can attach, proliferate, and differentiate to restore organized, remodeled tissue.[8-11] At the same time, the graft is slowly replaced during the normal process of collagen turnover such that no graft material remains after this process is complete.[9,12]

Compared to other surgical treatments of dura mater repair, there are several benefits associated with the use of Biodesign grafts.[13,14]

Benefits of Biodesign grafts in dura mater repair

- **No donor site required and no donor site morbidity**
- **Easy to handle and suture, allowing for a watertight seal**
- **Provides the strength required for a durable repair**
- **Functions as a scaffold for the ingrowth of host cells for a natural repair**
- **Produces little to no scar formation**
- **Does not swell upon hydration**
- **Provides a leak-free repair**

Published literature reviews have observed overall postoperative CSF leak rates of 4–7.2%[15–19] and infection rates of 0.3–8%[15,16,18,20] when dural grafts are used for dura mater repair.

The data collected in this post-market clinical follow-up study showed adverse events typical for a transcranial surgical approach and patient population.

Moreover, the primary endpoint, short-term (1 month) rate of postoperative integrity (with no clinically significant CSF leaks), was 100%. These rates compare favorably to the literature demonstrating that the Biodesign graft is a safe and effective material for use in dura mater repair.

Although retrospective studies have their limitations, this study confirms the performance of the Biodesign graft and supports its value as a dura substitute for the repair of dura mater.

Conclusions

No unexpected adverse events were reported during this clinical study in this subset of patients.

This analysis confirms the safety and effectiveness of the Biodesign graft for dura mater repair. These results support its continued use in accordance with the labeled indication. Further data from ongoing studies will contribute to the long-term assessment of the graft's performance and safety.

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