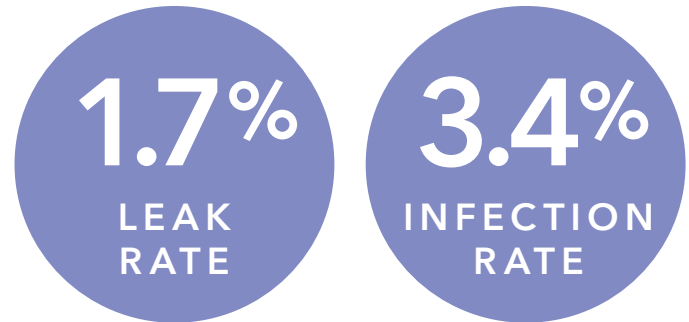


Study: Biodesign Dural Graft yields high success rate as dural substitute¹

Fifty-nine patients who underwent dural reconstruction with a small intestinal submucosa (SIS) dural graft were **prospectively analyzed** to evaluate the **safety and efficacy** of the graft.



Eligible patients were included if they suffered from a cranial or spinal dural defect requiring placement of an SIS graft for dural repair.

| Surgical site | Number of patients |
|--------------------------------|--------------------|
| Posterior fossa | 40 |
| Frontal | 6 |
| Spinal: cervical | 4 |
| Spinal: thoracic and lumbar | 4 |
| Frontal/temporal or temporal | 3 |
| Parietal/occipital or parietal | 2 |

| Neurosurgical diagnosis | Number of patients |
|-------------------------|--------------------|
| Chiari malformation | 32 |
| Tumor/meningioma | 18 |
| Aneurysm | 3 |
| Spinal cord tethering | 3 |
| Other | 3 |

The study included 43 females and 16 males. Mean patient age was 46 ± 16 years.

In all procedures, the graft was trimmed to size and used to repair the dural defect utilizing standard surgical technique. A Valsalva maneuver was used to visually assess for any cerebral spinal fluid (CSF) leakage. Surgical sites were closed using standard methods.

A scoring system was utilized intraoperatively to define device success. Device handling characteristics—including ease of use, strength, suture capability, and quality of the seal at the suture line—were also collected.

1. Bejjani GK, Zabramski J; Durasis Study Group. Safety and efficacy of the porcine small intestinal submucosa dural substitute: results of a prospective multicenter study and literature review. *J Neurosurg.* 2007;106(6):1028-1033.

Mean follow-up was 7.3 ± 2.2 months. Fifty-eight patients completed at least 6 months of follow-up. Eighteen patients were followed for 7-12 months, and 4 patients were followed for longer than 12 months.

At follow-up, complications included CSF leak (n=1, 1.7%) and infection (n=2, 3.4%). The surgeons concluded that these results are significant given that most cases in this study involved the posterior fossa or spine, which are more prone to CSF leaks.

Leak rate



1 in 59 patients

Infection rate



2 in 59 patients

This study concluded that the SIS graft has excellent handling characteristics and is associated with a high success rate.

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