

A multicenter, single-blind, prospective randomized trial to evaluate the safety of a polyethylene glycol hydrogel (Duraseal Dural Sealant System) as a dural sealant in cranial surgery.

Abstract:

Incisional cerebrospinal fluid (CSF) leakage after cranial surgery is a significant cause of morbidity due to poor wound healing and infection, meningitis, and pseudomeningocele formation. Many common dural closure techniques, such as sutures, autologous grafts, gelatin or collagen sponges, and fibrin glues, are used to achieve watertight closure, although none are US Food and Drug Administration approved for this use. DuraSeal Dural Sealant System is a polyethylene glycol (PEG) hydrogel approved by the U.S. Food and Drug Administration for obtaining watertight dural closure when applied after standard dural suturing. This multicenter, prospective randomized study further evaluated the safety of a PEG hydrogel compared with common dural sealing techniques. **METHODS:** A total of 237 patients undergoing elective cranial surgery at 17 institutions were randomized to dural closure augmented with the PEG hydrogel or a control "standard of care" dural sealing technique after Valsalva maneuver demonstrated an intraoperative nonwatertight dural closure. Data were collected on complications resulting in unplanned postoperative interventions or reoperations, surgical site infections, CSF leaks, and other neurological complications within 30 days. Surgeons also provided data on the ease of use of the dural sealing techniques, as well as preparation and application times. **RESULTS:** The incidences of neurosurgical complications, surgical site infections, and CSF leaks were similar between treatment and control groups, with no statistically significant difference between the measures. In the PEG hydrogel group (n = 120), the incidence of neurosurgical complications was 5.8% (n = 7), the incidence of surgical site infections was 1.7% (n = 2), and the incidence of CSF leak was 0.8% (n = 1). In the control group (n = 117), the incidence of neurosurgical complications was 7.7% (n = 9), the incidence of surgical site infection was 2.6% (n = 3), and the incidence of CSF leak was 1.7% (n = 2). Sealant preparation time was less than 5 minutes in 96.6% of the PEG hydrogel group compared with 66.4% of controls (P < 0.001). The dural augmentation was applied in less than 1 minute in 85.7% of the PEG hydrogel group compared with 66.4% of the control group (P < 0.001). **CONCLUSIONS:** The PEG hydrogel dural sealant used in this study has a similar safety profile to commonly used dural sealing techniques when used as dural closure augmentation in cranial surgery. The PEG hydrogel dural sealant demonstrated faster preparation and application times than other commonly used dural sealing techniques.