

DuraSeal Exact is a Safe Adjunctive Treatment for Durotomy in Spine: Post-Approval Study

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Introduction

Water-tight dural closure after intentional or incidental dural opening is paramount to the prevention of cerebrospinal fluid (CSF) leakage and associated complications. Synthetic polyethylene glycol (PEG) hydrogel has been shown to be a safe and effective adjunct to sutured dural repair in both cranial and spinal applications.(1,2) Expansion of PEG hydrogel postoperatively was a concern for causing neurological complications. A modified low-swell formulation of PEG hydrogel sealant (PEG spinal sealant) was introduced as DuraSeal Exact Spine Sealant System. It was shown to be safe and effective in a previous randomized trial.(3) This Post-Approval Study was performed to evaluate the safety of PEG spinal sealant in conjunction with standard methods for spinal dural repair compared to current alternatives, in a large patient population, reflecting a real-world practice.

Methods

A nonrandomized, two-armed study across 36 sites in the United States was performed between October 2011 and June 2016. 429 patients treated with PEG spinal sealant as an adjunct to dural repair were enrolled prospectively in the spinal sealant group. The control arm included 406 patients treated with all other modalities. The primary endpoint was CSF leak within 90 days of operation. Secondary endpoints included deep surgical site infection and neurological serious adverse events.

Results

The CSF leakage rate in the PEG spinal sealant group (6.6%) was not significantly different from the control group (6.5%) ($p = 0.83$), and there was no significant difference in the time to first leak. The two groups had no significant differences in deep surgical site infection rate (1.6% versus control group 2.1%, $p=0.61$) or proportion of subjects with neurological serious adverse events (2.9 % versus control group 1.6%, $p= 0.516$).

Conclusions

PEG spinal sealant (DuraSeal Exact) is safe when compared to current alternatives for spinal dural repair

Learning Objectives

By the end of this session participants should be able to

- 1.Understand that DuraSeal Exact is the low-swell, modified formulation of the original DuraSeal, designed to have much less expansion postoperatively.
- 2.Recognize that DuraSeal Exact is a safe adjunctive treatment for durotomy in spine
- 3.DuraSeal Exact rather than the original DuraSeal formulation should be utilized for dural repair in spine

References

1. Osbun JW, Ellenbogen RG, Chesnut RM, et al. 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. *World Neurosurg.* 2012;78(5):498-504. doi:10.1016/j.wneu.2011.12.011.
2. Kim KD, Wright NM. Polyethylene glycol hydrogel spinal sealant (DuraSeal Spinal Sealant) as an adjunct to sutured dural repair in the spine: results of a prospective, multicenter, randomized controlled study. *Spine.* 2011;36(23):1906-1912.
3. Wright NM, Park J, Tew JM, et al. Spinal sealant system provides better intraoperative watertight closure than standard of care during spinal surgery: a prospective, multicenter, randomized controlled study. *Spine.* 2015;40(8):505-513.