Evaluation of a Novel Dural Repair Device in a Simulated Durotomy Model
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Introduction
Incidental durotomy (ID) is one of the most common complications in spine surgery\(^1\)\(^2\), affecting up to 17% of lumbar procedures\(^3\). Creating a primary, sutured repair of the dura is the gold standard treatment of ID\(^4\) and the best-known way to prevent persistent cerebrospinal fluid (CSF) leak\(^5\).

Persistent CSF leakage can increase treatment costs by increasing the length of hospitalization, and/or requiring additional treatments such as subarachnoid drain, flat bed rest, additional surgery or readmission\(^6\). Patients may experience reduced quality of life and delayed recovery from complications including spinal headache, wound infection, fistula, meningitis, epidural abscess, pseudomeningocele and arachnoiditis\(^7\), which may lead to a tremendous economic burden to the healthcare system.

Conventional suturing methods can be time consuming and technically challenging, especially when working through a limited surgical exposure. Additionally, creating an adequate working space to use conventional instruments may necessitate unplanned tissue disruption and bone removal.\(^8\)

DuraStat, a novel device for dural repair, is designed to enable quality repairs of the dura in a time-efficient manner while allowing the surgeon to access difficult to reach locations. This sterile packaged device has retracted, deployable needles that allow for an automated inside-to-out repair technique with the press of a button, helping to protect nerve tissue, while increasing reproducibility and saving time.

This study compared the time to repair in a simulated durotomy model using either DuraStat or conventional techniques.

Method
The model used for this study builds upon a previously validated model\(^9\) and included lumbar spine Sawbones covered by silicone rubber soft tissues. The dural sac was placed in the anatomic location and made of a thin latex rubber tube which contained simulated nerve roots and cerebrospinal fluid (CSF) under physiologic pressure of 30 cm H2O. The surgical site was bathed in a continuous flow of simulated blood for further realism. Access to the dural tear was provided by a 22 mm tubular retractor. A 16 mm central laminectomy was utilized to expose the dura and a 7 mm dural defect was placed centrally using a 10 blade scalpel to simulate a durotomy in a restricted space. (Fig.1)

Surgeons wore loupe magnification and had surgical lighting for proper visualization. Surgeons were offered suction and traditional surgical instruments. Each surgeon completed one repair with DuraStat and one repair with a conventional technique based on a randomized schedule. Study endpoints included Time to Place Suture and surgeon questionnaire. A total of 9 spine surgeons (4 residents, 4 fellows and 1 attending) from Thomas Jefferson University completed the study.

Results
DuraStat took 57% less time and with less variation to place the 1st suture compared to conventional technique. The result was statistically significant (DS: 3.38 min. ± 1.00, Conv.: 7.91 min. ± 4.48; p=0.013).

89% of surgeons agreed DuraStat is safer than conventional techniques. 100% agreed DuraStat is safer than using adjuncts alone. 100% agreed DuraStat is easy to use.

Discussion
Difficult to access dural tears can occur during any spinal procedure and passing the first suture to gain control of the tear is one of the most challenging aspects, which can lead to substantial variation in time to closure.

Given the range of surgeon experience levels, familiarity with conventional repair technique and all surgeons using DuraStat for the first time in the study, DuraStat was demonstrated to significantly reduce the time to pass the first suture and to do so reproducibly as reflected in the tight distribution of the data.

DuraStat allows for enhanced access, accuracy and a more rapid dural closure. This may lead to increased surgeon confidence in the repair with reduced need for post-operative bed rest and a reduced risk of persistent or recurrent CSF leakage.

Limitations of the study include a small sample size and simulated model used in the study.

Conclusion
DuraStat resulted in a >50% time savings to place the 1st suture for incidental durotomy repair.

This simulated durotomy model serves as a viable teaching tool given the steep learning curve and lack of training opportunities for dural repair.

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