

DURAL REPAIR: EFFICACY ASSESSMENT OF DIFFERENT TECHNIQUES, A CADAVERIC STUDY COMPARING THE NAKED EYE AND SURGICAL LOUPES

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Abstract

Background: Watertight dural repair is crucial to achieve successful dural tear sutures. Microscopic or surgical loupes are recommended to use to magnify and assist repairing the dura. However, many spine surgeons repair dural tears under the naked eye. The efficacy of repairing dural tears by the naked eye compared with microscopic or surgical loupes has never been studied.

Objective: This study aimed to compare the efficacy of dural repairing techniques using the naked eye or surgical loupes.

Methods: A cadaveric experimental study was conducted. Four fresh human cadaveric specimens were used to harvest the spinal cord. Dural tear and CSF leakage were simulated with a water pressure control system (Arthrex AR-6475 arthroscopic pump). We compared surgical repair using the naked eye and surgical loupes. Surgical closure was achieved using Prolene 6-0 and Durepair®. A total of 32 experimental dural tears were subdivided to four groups. The 4 groups were Prolene6-0 with the naked eye (n=8), Prolene 6-0 with surgical loupe (n = 8), Durepair® with the naked eye (n=8) and Durepair® with surgical loupe (n=8). The total time used for sutures and postsuture CSF water leakage pressure were recorded and compared among the subgroups.

Results: Our results showed that surgical loupe assisted dural closure and sutures were significantly faster than the naked eye in both Prolene 6-0 (surgical loupe = 4.87 ± 0.19 min, naked eye = 7.18 ± 0.36 min, $p < 0.001$) and Durepair® groups (surgical loupe = 9.84 ± 0.21 min, naked eye = 13.27 ± 0.42 min, $p < 0.001$). CSF Leakage pressure in the surgical loupe groups were higher than in the naked eye groups in both Prolene 6-0 (surgical loupe = 100.00 ± 5.35 mmHg, naked eye = 96.88 ± 7.99 mmHg, $p = 0.373$) and Durepair® (surgical loupe = 96.88 ± 4.58 mmHg, naked eye = 95.63 ± 4.17 mmHg, $p = 0.577$) but without significant difference. Prolene 6-0 was significantly faster to use for sutures than Durepair® in both sutures by the naked eye and surgical loupe assisted ($p < 0.001$). Prolene 6-0 showed a higher leakage pressure than Durepair® in both the naked eye and surgical loupe assisted sutures but without significant difference (naked eye, $p = 0.701$, surgical loupe, $p = 0.230$)

CONCLUSION: Repairing a dural tear without using surgical loupes consumed more time and did not achieve similar maximum leak pressure compared with using surgical loupes. However, no statistically significant difference was observed in terms of CSF leakage pressure. Durepair® consumed more time than Prolene 6-0 while leakage pressure was similar. We recommended the use of surgical loupes when performing dural repair. Durepair® is suitable to repair larger dural defects that cannot be closed using a simple suture technique.

Keywords: Dural tear, Dural repair, CSF leakage

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Introduction

Incidental durotomy is a frequently encountered complication during spinal surgery. The incidence ranges from 1-17% in lumbar spine surgeries and 1% in cervical spine surgeries.^(1,2) Several studies have reported no changes in long term outcomes after incidental durotomy.⁽³⁻⁵⁾ However it can cause significant morbidity due to postural headaches, meningitis, nerve root entrapment, meningeal pseudocyst, dura-cutaneous fistula, arachnoiditis, delayed wound healing or wound infections. Indirect consequences associated with the prolonged flat bed rest that is often prescribed, include pneumonia, pressure ulcers, deep venous thrombosis, pulmonary embolism and aspiration. Incidental durotomy usually produces benign outcomes but as Goodkin and Laska reported, medicolegal implications often result from this complication.⁽⁶⁾ Therefore, incidental durotomy is generally accepted to be primarily repaired intraoperatively.

The primary goals of a dural repair include a watertight closure and containment of nerve fascicles. The actual treatment for an accidental durotomy depends on the size and location of the tear. Primary repair is recommended in the lumbar and cervical spine. When amenable to surgical repair, the dural tear should be addressed in an expedient manner; however, when not readily accessible, careful observation, glue or a cerebrospinal fluid shunt can be employed.⁽⁷⁾

Many dural repair techniques are available, ranging from simple interrupted or continued sutures, glue, bioabsorbable staples and many other types of grafts and patches.⁽⁸⁾ The suture technique employed often depends on surgeon's preference. The gold standard of microsurgical anastomosis is a simple interrupted suture technique.^(8,9) Cain et al.⁽¹⁰⁾ reported that no significant difference in leak pressure using interrupted versus running locked suture in a dural repair model. Erica et al.⁽¹¹⁾ showed that 6-0 Prolene, using either interrupted or locked techniques was the best at creating a watertight closure of an incidental durotomy. When a watertight seal cannot be obtained, a hydrogel of fibril glue sealant will improve the strength of repair. In the situation of a large defect that

cannot be primarily repaired, a synthetic dural patch such as Duragen (Dural Graft Matrix-Integra Lifesciences Corporation) and Durepair[®] or a fascial graft may be used.⁽¹²⁾

Microsurgery has traditionally required the use of a surgical microscope. Jacobsen and Suarez showed a 100% patency of 1-mm blood vessel anastomoses performed under a surgical microscope, which helped establish the method as a reference standard.⁽¹³⁾ Since then, microsurgery has grown to include anastomoses of different vessels, nerves and other structures. While the surgical microscope permits powerful magnification and illumination, it includes the costs of lengthier surgical setup time, greater initial expense, increased maintenance, less intraoperative positioning flexibility and the need for better coordination among surgical teams. With increased focus on occupational health and ergonomics; however, the microscope may decrease the risk of cervical spine pathology to the surgeon.⁽¹⁴⁾ Surgical loupes offer widely acknowledged portability, flexibility and cost benefits compared with surgical microscopes. These benefits have led to their routine use in hand surgical procedures. Comfort and ease of use with surgical loupes in the presence of microscope-honed technical experience have led some authors to increase the use of surgical loupes while performing microsurgical procedures.⁽¹⁵⁻¹⁷⁾ Compared with microscopes, loupes have many benefits: cost, flexibility, portability and time saving. Loupes allow closer access to the surgical field, wider orientation and rapid changes in viewing angle, depth of field and adjustment of gaze location within the surgical field through postural changes of the head and neck.⁽¹⁵⁾ Luca et al.⁽¹²⁾ recommended using a microscope and microsurgical instruments to repair incidental durotomy while Erica et al.⁽¹¹⁾ used surgical loupe magnification for dural tear repair. Many spine surgeons do not use either a microscope or surgical loupes for dural repair. Usually, dura tears are repaired using the naked eye.

In Thailand, microscopes and surgical loupes are not readily available in many hospitals due to high cost. Many studies compared the efficacy of many materials to repair tear dura; however no

study has investigated the efficacy of repairing tear dura using the naked eye. This study aimed to compare the efficacy of different dural repairing techniques, the naked eye versus surgical loupes, in terms of time spent for suturing and maximum sustainable CSF pressure. The efficacy of Prolene 6-0 vs. Durepair for dural tears was also compared.

Methods

This study was approved by the Institutional Review Board, Medical Department, Royal Thai

Army. The four fresh human cadavers were obtained according to standard procedure of a cadaver laboratory. Cadavers were obtained within 7-14 days of death and stored in crypts maintained at 5°C until 2 hours before use. The cadavers were dissected, and a laminectomy was performed along the spine (**Figure 1**). A spinal cord length of 20 cm per cadaver was removed and brought to the operation room for further testing (**Figure 2**).

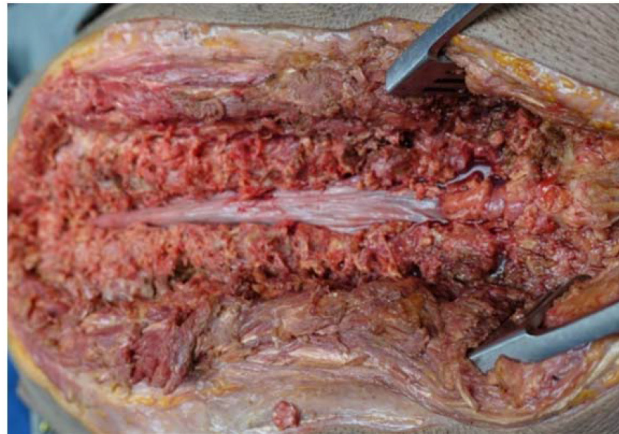


Figure1. Laminectomy along the cadaver spines before removing the spinal cord



Figure 2. A length of spinal cord recovered from a cadaver for the experiment

Model

The 20 cm intact spinal cord and dura from the cadavers was brought to an operation room. Two 14 French 2-way Foley catheters were placed in the dural space at the cranial and caudal end of the specimen. These were advanced until they were positioned above and below the dura to be tested. The most caudal Foley catheter was clamped with a hemostat. The cranial Foley catheter was connected to a reservoir of normal saline attached to an Arthrex AR-6475 arthroscopic pump for continuous saline flow at adjustable difference pressure (**Figure 3**). The inflatable balloons in each catheter were inflated to isolate the spinal segment to be tested. Between the Foley catheter and the reservoir, a pressure transducer, connected to a monitor, was used to determine the pressure within the system at the level of the spinal canal (**Figure 4**).

With the Foley catheters positioned, the clamp was opened from the reservoir to the cranial Foley catheter and saline was infused in the dural space. The pressure in the system was able to be adjusted and controlled by the arthroscopic water pump and was subjected to a wide range of pressures to simulate both bed rest and upright active positioning of the spinal column. Previous dural repair models have investigated hydrostatic pressures ranging from 14 mmHg to 80 mmHg for continued CSF leaks.^(11,13) Given that leaks were previously observed at a pressure of 35 mmHg when using sutures alone and at 80 mmHg with the use of sealants, the decision was arbitrarily made to report on CSF leaks when present at 40 mmHg or until a leak was identified.

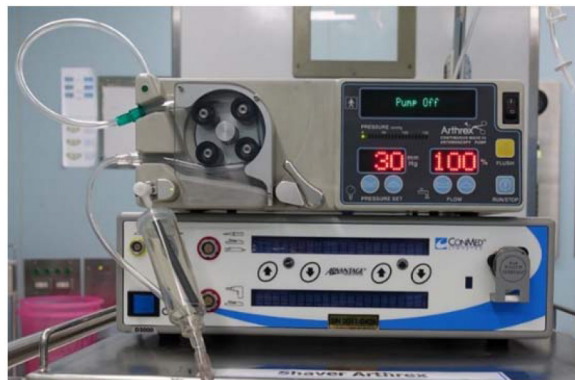


Figure 3. An arthroscopic water pump for pressure control

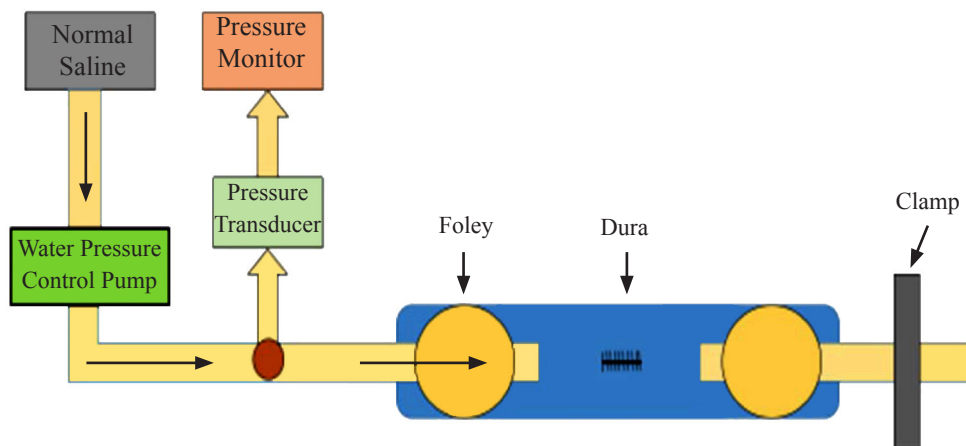
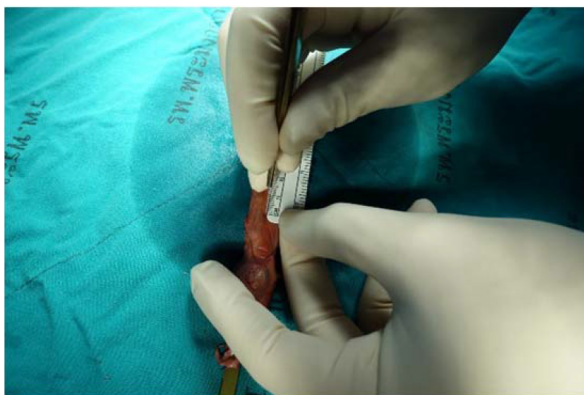


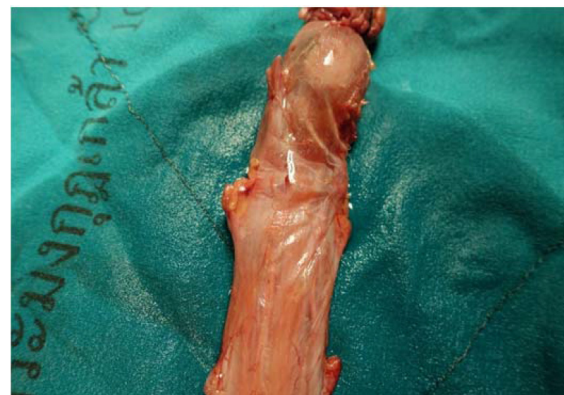
Figure 4. Tear dural experimental model

A midline 1 cm durotomy was made using a ruler and no.15 scalpel blade. The tubing was opened to allow leakage from the durotomy site to ensure flow in the system (**Figure 5**). The dura was then repaired using Prolene 6-0 or Durepair®. All suture repairs were performed using microsurgical instruments (Castroviejo needle holders, fine tip tissue forceps etc.) and repair was performed under the naked eye or using surgical loupes. For simple repairs, a simple suture technique was used with approximately 1 mm of space between the sutures (**Figure 6**). For Durepair®, a Durepair® patch, formed as a square piece measuring 1x1 cm, was placed under

the dural tear and then sutured with Prolene 6-0 in the previously described simple suture technique (**Figure 7**). Time used for sutures in each group was recorded using a digital stopwatch. Once the durotomy was repaired, the pressure was determined from 40 mmHg until a leak was seen and the breakthrough pressure was recorded. The Foley balloons were repositioned on a new dural segment that had not been previously tested, and another dural repair was performed. Dural tears repaired using Prolene 6-0 or Durepair® under the naked eye and surgical loupes were tested 8 times in each group.



a



b

Figure 5 a, b. A standard 1 cm durotomy in spinal dura



Figure 6. Dural tear repaired by Prolene 6-0 simple suture



Figure 7a. Durepair® cut to square 1 x 1 cm **and 7b** Dural tear repaired by Durepair®

Table 1. Mean suture time and mean leak pressure of dural repairs using Prolene 6-0 and Durepair with the naked eye and using surgical loupes

| Material | Mean Suture Time (min) | | p-value | Mean Leak Pressure (mmHg) | | p-value |
|--------------------|------------------------|----------------|---------|---------------------------|----------------|---------|
| | Naked eye | Surgical Loupe | | Naked eye | Surgical Loupe | |
| Prolene 6-0 | 7.18±0.36 | 4.87±0.19 | <0.001* | 96.88±7.99 | 100.00±5.35 | 0.373 |
| Durepair® | 13.27±0.42 | 9.84±0.21 | <0.001* | 95.63±4.17 | 96.88±4.58 | 0.577 |

Suture material

Routinely used sutures were tested clinically. The monofilament Prolene 6-0 suture is a nonabsorbable sterile surgical suture that comprises an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The suture is pigmented blue to enhance visibility in the surgical field.

Dura substitute

Durepair® Dura Regeneration Matrix is a dura substitute for the repair of the dura mater, manufactured by Medtronic. It consists of a collagen implant to repair large defects in the dura mater. Sterile Durepair is supplied in sheet form, in a variety of sizes to be trimmed and sutured by the surgeon to meet the individual patient’s needs.

Statistical analysis

The leakage pressure and time using the same material for sutures were compared using the independent t-test. One-way ANOVA was used

to compare among all groups. A p-value less than 0.05 was considered statistically significant.

Results

Comparison of Prolene 6-0 under the naked eye vs. using surgical loupes

The time used for sutures using surgical loupes of Prolene 6-0 was significantly less than sutures under the naked eye ($p < 0.001$). Mean time for sutures using surgical loupes was 4.87±0.19 min while mean time for sutures under the naked eye was 7.18±0.36 min. All dural repairs by Prolene 6-0 both under the naked eye and surgical loupes did not leak at a pressure of 40 mmHg. The mean leak pressure using Prolene 6-0 sutures under surgical loupes was 100.00±5.35 mmHg, while the leak pressure using Prolene 6-0 sutures under the naked eye was 96.88±7.99 mmHg. For the naked eye group, the leak pressure was less than that of the surgical loupes group without significant difference ($p = 0.373$) (**Table 1**)

Comparing Prolene 6-0 vs. Durepair®

Results of the mean time to close dural tears using Prolene 6-0 both under surgical loupes and

Table 2. Comparing of mean suture time and mean leak pressure of Prolene6-0 VS Durepair with the naked eye and using surgical loupes

| Group | Mean Suture Time (min) | | | Mean Leak Pressure (mmHg) | | |
|----------------|------------------------|------------|-----------------|---------------------------|------------|-----------------|
| | Prolene 6-0 | Durepair | <i>p</i> -value | Prolene 6-0 | Durepair | <i>p</i> -value |
| Naked eye | 7.18±0.36 | 13.27±0.42 | <0.001 | 96.88±7.99 | 95.63±4.17 | 0.701 |
| Surgical loupe | 4.87±0.19 | 9.84±0.21 | <0.001 | 100.00±5.35 | 96.88±4.58 | 0.230 |

the naked eye were significantly less than those repaired using Durepair® under surgical loupes and the naked eye ($p < 0.001$). The leak pressure of Durepair® in both the surgical loupes and the naked eye groups was less than that of repairs made by Prolene 6-0 only, in both surgical loupes and the naked eye groups but without significant difference ($p=0.23$ in the surgical loupe, $p=0.701$ in the naked eye group) (Table 2).

Discussion

Primary repairs of dural tears are commonly employed to prevent potential postoperative complications. The goals of dura repair include a watertight closure and containment of fascicles. Many research studies have investigated the proper materials to repair dural tears. Although microscopes or surgical loupes are recommended to assist with dural tear sutures, many spine surgeons still repair dural tears using the naked eye only. Our study showed that surgical loupes were significantly faster than naked eye dural sutures. A study by Andrades et al. used loupes (x2.5) and microscopes (x10) to repair rodent vessels that were grouped as large (>2.5 mm), medium (1.5-2.5 mm) and small (<1.5 mm).⁽¹⁸⁾ For vessels in the small group, both surgical time (31 minutes for microscope vs. 52 minutes for loupes) and 24-hour patency (80% microscope vs. 10% loupes) strongly favored the microscope. However, in medium and large group vessels, no statistically significant differences were observed in procedure time or 24-hour patency. The results of the large vessel group revealed the microscope repairs to be quicker than loupe repairs (48 vs. 52 min, respectively) and boasted greater patency (90% vs. 60%) despite the lack

of statistical significance. Rooks et al. measured the precision of suture placement in grafts with loupes (x3.5 to x4) and microscopes (x8 to x30).⁽¹⁹⁾ They found that microscope suture placement was 0.03 mm closer to the target (edge of the graft) and that the variability from the mean was 0.01 mm less, both statistically significant differences in favor of the microscope. In a review of 251 free tissue transfers performed with only loupe magnification, Shenaq et al. found an overall success rate of 97.2% with a 1.2% partial flap necrosis rate and an 8.3% revision rate for anastomoses during the initial procedure.⁽²⁰⁾ The overall loupe-only success rate in that study for free tissue transfers was 98.5%, with 96.4% success with toe-to-hand transfers and 79.2% for digital replantation. In a retrospective review of 151 consecutive microvascular free tissue transfers in the head and neck performed with either loupes or microscope, Ross et al. found no significant difference in complication rates.⁽²¹⁾ The only significant difference was decreased surgical time in the loupe group. This was the reason surgical loupes significantly decreased suture time than that of the naked eye. The magnification might relate to the time for surgery. Our study showed that water leakage pressure was slightly higher in the group using surgical loupes than in the group of repairs simply using the naked eye; however, this finding did not differ significantly. Magnifying surgical loupes may play a role in watertight sutures. We observed that in the surgical loupes group, the number of suture stitches was greater than that performed in the naked eye group (10 stitches vs. 6 stitches). Good magnification provided meticulous sutures and helped the surgeon achieve goals of dural repair.

Comparing Prolene 6-0 vs. Durepair® in both surgical loupe and the naked eye groups assisted dural closure regarding that Prolene 6-0 sutures could tolerate more pressure than Durepair® but without significant difference. Durepair® took a significantly longer suture time than Durepair® in both surgical loupe and the naked eye groups. Durepair® is used for large defects that cannot be repaired by simple techniques, explaining why Durepair® takes a longer suture time than using Prolene alone.

Conclusion

Repairing dural tears under the naked eye consumed more time than surgical loupe assisted repairs and did not achieve a similar maximum leak pressure compared with closures using surgical loupes. However, no statistically significant difference was found in terms of CSF leakage pressure. Durepair® consumed more time than using Prolene 6-0 while leakage pressure did not differ. We recommended using surgical loupes when performing dural repair due to providing a better visualization, increasing the number of stitches with higher leakage pressure. Durepair® was suitable to repair large dural defects that cannot use simple suture techniques to repair.

Conflict of interest

The authors declare they have no conflict of interest.

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