Results of a Prospective Randomized Study Comparing a Novel Retractor With a Caspar Retractor in Anterior Cervical Surgery

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BACKGROUND: Retraction injury might explain the soft tissue complications seen after anterior cervical surgery. A novel retractor system (Seex retractor system [SRS]) that uses a principle of bone fixation with rotation has been shown to reduce retraction pressure in a cadaveric model of anterior cervical decompression and fusion.

OBJECTIVE: To compare the conventional Cloward-style retractor (CRS) with the SRS in a prospective randomized clinical trial.

METHODS: After ethics and study registration (ACTRN 12608000430336), eligible patients were randomized to either the CRS or SRS before 1- or 2-level anterior cervical decompression and fusion. The pressure beneath the medial retractor blade was recorded with a thin pressure transducer strip. Postoperative sore throat, dysphagia, and dysphonia were assessed after 1, 7, and 28 days.

RESULTS: Twenty-six patients were randomized. There were no serious complications. Complication rates were low with a trend favoring SRS that was not statistically different. Average retraction pressure with SRS was 1.9 mm Hg and with CRS was 5.6 mm Hg ($P < .001$ on F test; $P = .002$ on 2-tailed t test). Mean average peak retraction pressure with the SRS was 3.4 mm Hg and with the CRS was 20 mm Hg ($P < .001$ on F test; $P = .005$ on 2-tailed t test).

CONCLUSION: The new retractor is safe, and statistically similar complication rates were observed with the 2 systems. The SRS generated significantly less retraction pressure compared with the CRS. This difference can be explained by the different principles governing the function of these retractors. Bone fixation gives stability and rotation reduces tissue pressure, both desirable in a retractor.

KEY WORDS: Anterior cervical surgery, Dysphagia, Hoarseness, Retractor

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The anterior approach for cervical spine operations is associated with both short- and long-term complications. The incidence of postoperative dysphagia, dysphonia, and sore throat can reach 70%.[1-3] Retraction pressure–induced damage may explain these soft tissue complications.[4,5] Most previous studies have been conducted with conventional Caspar-style retractor systems (CRSs),[6,7] which rely on engaging and stretching the soft tissues for stability. Two recent nonrandomized studies have noted improved rates of soft tissue complications and reduced pressure when handheld retractors are used compared with the self-retaining style of retractors.[5,8]

A novel anterior cervical retractor system (Seex retractor system [SRS])[9] has been developed that uses the novel principle that bone fixation can be used to provide the retractor blade with an axis of rotation inside the wound. The basic system consists of a 2-piece frame fixed to the spine with distraction screws; this sits on top of longus colli (Figures 1 and 2).

ABBREVIATIONS: APRP, average peak retraction pressure; **ARP,** average retraction pressure; **CRS,** Cloward-style retractor; **SRS,** Seex retractor system

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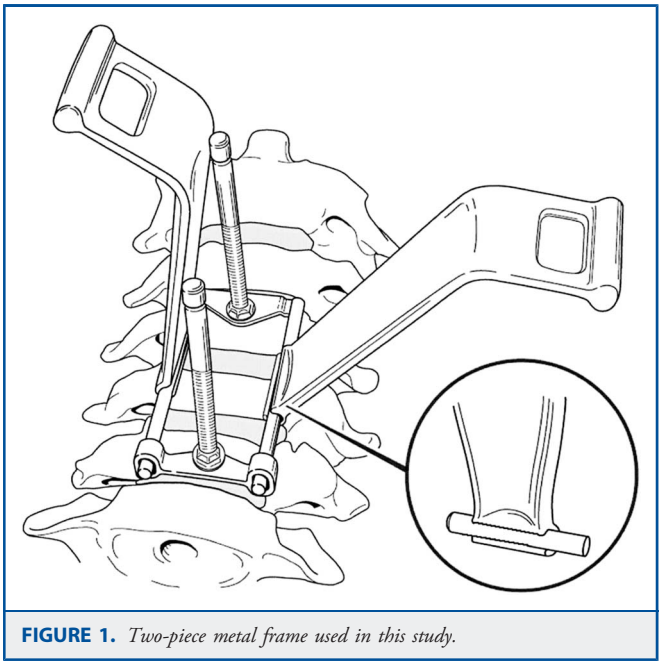

FIGURE 1. *Two-piece metal frame used in this study.*

Different length frames are used for 1 or 2 levels. The frame has 3-mm-diameter rods with an internal width of 19 mm. One end of the frame slides during distraction, and the surgery is carried out through the frame. Independent retractor blades are clipped to the craniocaudal sides of the frame, which allows them to rotate and provide retraction or relaxation. Compared with conventional systems, the fixation to bone improves mechanical efficiency and stability. The blades are held apart by the use of Babcocks as handles, and rotation of the blades allows a more oblique approach than with the vertical blades of conventional systems. The potential disadvantages of the new system are that the use of oblique angles and the lack of rotation in the long axis of the blades could lead to increased amounts of soft tissue retraction. To investigate these factors, we conducted a cadaver study of anterior cervical decompression and fusion and found that the SRS generated less retraction pressure than the CRS.[10] This article reports a clinical investigation comparing the SRS and CRS in which we performed intraoperative pressure measurements and collected data on the soft tissue complications of postoperative dysphagia, dysphonia, and sore throat.

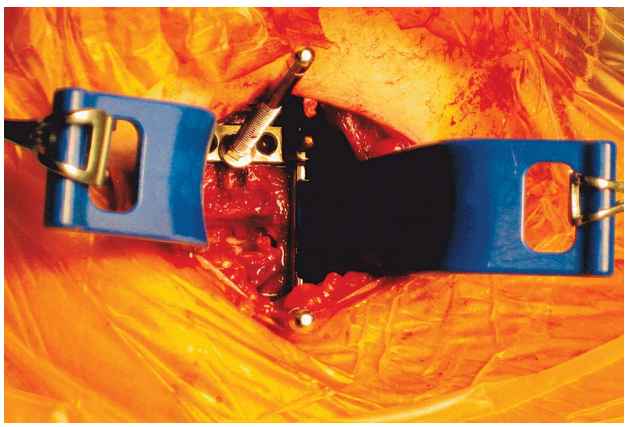

FIGURE 2. *Intraoperative picture of the Seex retractor system.*

MATERIALS AND METHODS

The study was designed as a prospective, randomized, controlled trial. Approval from Sydney West Area Health Service Human Research Ethics Committee (HREC project 07/047) was obtained. The study was registered in the ANZ trial registry (ACTRN12608000430336).

All patients scheduled for an anterior cervical diskectomy fusion procedure during the 18-month period beginning July 2007 were considered for inclusion in the study. Patients <18 years of age and those with a history of tumor, trauma, radiation, or prior surgery to the neck were excluded. Study participants were prospectively randomized with an online computer-generated sequence (www.graphpad.com/quickcalcs/randomN1.cfm) into 2 groups, the CRS and the SRS groups. Allocation concealment was ensured by keeping the randomization sequence in consecutively numbered opaque sealed envelopes. Once the patient was anesthetized, the sealed envelope with the same serial number was opened to reveal the retractor system to be used. In all patients, an online pressure transducer (Tekscan pressure measurement system, a tactile sensor system; Sensor model 4201; area, 46×21 mm^2) was placed between the medial retractor blade and the trachea and esophagus. The pressure on the trachea and esophagus was recorded and stored in a laptop for the entire retraction period. There are 276 sensels (pressure-picking points) in the sensor. One pressure recording (1 frame) consisted of 276 pressure readings obtained in a 2-dimensional plane. Pressure recordings were made at a rate of 2 per second. Thus, 120×276 pressure readings were recorded during every minute of retraction. Average retraction pressure (ARP) was calculated as the arithmetic mean of all the retraction pressure readings made during the entire period of retraction. Peak retraction pressure was the highest pressure reading in each frame. Average peak retraction pressure (APRP) is the arithmetic mean of peak pressure readings of all the frames during the period of retraction. For each patient, the ARP and APRP were determined and compared.

Pressure data were analyzed by use of the F test and unpaired t test; values of $P < .05$ were considered significant. All patients completed a self-assessment of sore throat, difficulty in swallowing, and voice change at 24 hours, 1 week, and 4 weeks after operation. A 6-point Likert scale (score, 0-5) was used. Scores of 0 and 1 were grouped as grade 1 with no or only mild symptoms; scores of 2 and 3, as grade 2 with moderate symptoms; and scores of 4 and 5, as grade 3 with severe symptoms (Table 1). Responses after 1 and 4 weeks were collected by mail. All scores at 24 hours and 7 days were returned on time. One patient from each group failed to return the completed rating scale chart after 28 days. The 2 omissions were noted to have 0 scores for sore throat, dysphagia, and dysphonia in their 7-day response. They were contacted by phone and confirmed that there was no change in their scores. Data from the charts were used for statistical evaluation with Pearson χ^2 test and 2-tailed Fisher exact test.

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TABLE 1. Likert Scale Used for Symptom Evaluation

Grading	Rating Scale	Sore Throat	Dysphagia	Dysphonia
1 (None/mild)	0	None	Able to eat normally	Normal voice
	1	Very minimal or occasional pain not requiring pain medications	Requires liquids with meals	Mild hoarseness or voice change but fully understandable
2 (Moderate)	2	Uncomfortable or occasional pain requiring pain medications	Able to take only semisolid food	Moderate voice changes; may require occasional repetition
	3	Dreadful or frequent pain requiring pain medications almost daily	Able to take only liquids	Severe voice changes, including predominantly whispered speech; may require frequent repetition
3 (Severe)	4	Horrible or continuous pain requiring 24-h pain medication	Able to swallow saliva but not liquids	Disabling; nonunderstandable voice
	5	Agonizing or pain not responding to continuous pain medication (needing hospital admission for pain management)	Complete	Aphonic (no voice at all)

RESULTS

Twenty-six patients were randomized equally, and the data set was complete. Demographic data in the 2 groups were similar. Retraction was kept to the minimum amount required to perform the surgery. No major complications, eg, hematoma, reoperation, infection, tracheal/esophageal fistula, or death, occurred in either of the groups.

The total amount of measured retraction was 673 minutes with the CRS and 655 minutes with the SRS (average, 50 and 52 minutes). The pressure data (Table 2) showed highly significant differences.

None of the patients in either group had grade 3 symptoms. There were no significant differences in the postoperative outcome measures.

DISCUSSION

Recently published data on anterior surgical surgery show that the incidence of postoperative dysphagia reaches 60% to 70%[7,8]; dysphonia, 60%[2]; and sore throat, 74%.[1] Figures 3 and 4 show the incidence of sore throat, dysphagia, and dysphonia with the CRS and SRS. The commonly cited causes for these symptoms are neuronal,[8,11] muscular,[5,12] and mucosal.[5] Damage of the aerodigestive pathway may occur during insertion and inflation of the endotracheal tube or surgically during dissection or retraction. Retractors with teeth may bruise or lacerate tissues directly, and all retractors may cause injury as a result of pressure.[13,14] A correlation between pressure and early dysphagia (5 days) after anterior cervical surgery was not shown by Papavero et al[6] but was noted by Mendoza-Lattes et al.[5] Pressure-induced ischemic damage has also been demonstrated in other contexts.[14,15] Our cadaver study demonstrated that the retraction pressure is not uniform over the retracted surface but varies widely.[10] Pressure recordings in this in vivo study were similar (Figure 5). These observations were made possible by the use of a sensor capable of simultaneous pressure recordings over a 46 × 21-mm^2 area; hence, both ARP and APRP were used to compare the 2 retractor systems. Tracheo-esophageal symptoms are likely to be secondary to mucosal or muscular ischemia,[1] but the minimum area and duration of ischemia required to cause damage are not known; intraluminal investigations assessing perfusion may clarify this. Because even a small focal injury could cause perforation with grave consequences,[16] APRP was thought to be clinically relevant.

The principal finding of the study was that CRS produced significantly higher retraction pressures than SRS (Table 2). Both ARP and APRP were significantly different and consistent with the cadaver study results.[10]

TABLE 2. Pressure Data Summary[a]

	APRP (Range), mm Hg	*P*, *F* Test	*P*, 2-Tailed *t*-Test	APRP (Range), mm Hg	*P*, *F* Test	*P*, 2-Tailed *t*-Test
CRS	5.6 (2-13)	<.001	.002	20 (4-56)	<.001	.005
SRS	1.9 (1-3)			3.4 (1-8)		

[a]APRP, average peak retraction pressure; ARP, average retraction pressure; CRS, Cloward-style retractor; SRS, Seex Retractor System.

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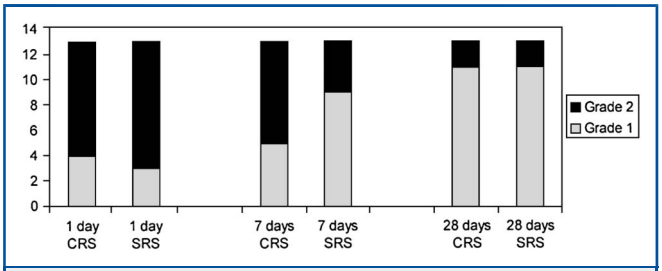

FIGURE 3. *Incidence of sore throat. CRS, Cloward-style retractor; SRS, Seex retractor system.*

Importantly, the areas of highest pressure with CRS were not recorded along the base of the transducer, which would occur if the toothed blades slipped and engaged the transducer. Because both systems have smooth curved blades, the most likely explanation for lower APRP and lower ARP found with SRS is likely to be a difference in sustained tissue displacement.

The lower APRP means less maximal displacement with SRS, indicating that the concerns about excess retraction with the rotating blades of the SRS are unfounded. Both findings can be explained by the mechanism of action; with the SRS, the maximum blade displacement occurs temporarily to allow the surgeon to see and to insert tools, whereas with the CRS, the displacement is sustained to achieve stability.

This study found lower retraction pressures than other similar studies.[5,6] This difference can be explained by the differences in sensors used for pressure recordings and in methodologies. The sensor that we used is <0.5 mm thick; other investigators used sensors 2 mm thick and single-point pressure reading per unit of time.[6,11,12] In this study, multiple pressure readings were recorded simultaneously over the entire area of retraction, and an average was used for comparisons. In comparisons of pressure generated by retractor systems, measuring pressure immediately behind the retractor blade rather than elsewhere is logical. To investigate the pathophysiology of postoperative symptoms further, other techniques such as endoesophageal pressure measurement, endotracheal tube balloon pressure, endoscopic or indirect laryngoscopy evaluations, and infrared mucosal blood flow studies may be more helpful.[5,17-19]

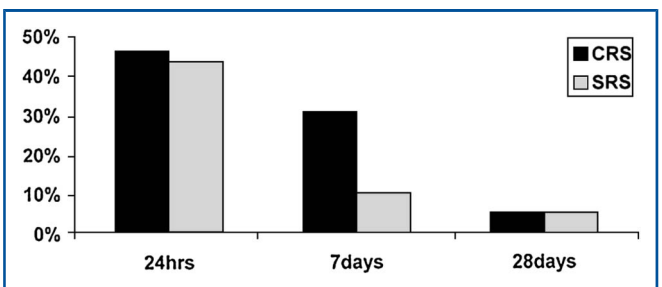

FIGURE 4. *Cumulative incidence of grade 2 (moderate) sore throat, dysphagia, and dysphonia. CRS, Cloward-style retractor; SRS, Seex retractor system.*

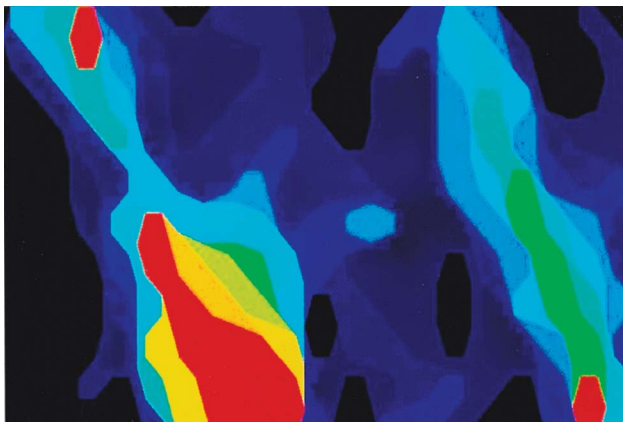

FIGURE 5. *Retraction pressure recording in the 2-dimensional plane. Red area corresponds to high pressure.*

None of the patients had any major complications, nor was there a difference in time required for the diskectomy after retractor placement, but only time after retractor placement was measured. The averages were 50 and 52 minutes. The SRS retractor frame was 25 mm wide and required careful positioning for accurate screw placement, but the avoidance of longus colli dissection made the insertion time similar, anecdotally at least.

There are other differences between the systems that are important to surgeons, but they were not evaluated because they were too subjective, were prone to bias, or were too difficult to measure. These include overall ease of use, learning curve for insertion, quality of exposure, time for insertion, longus colli injury and bleeding, and time spent repositioning during procedure. Since this study, there have been design changes in the SRS to reduce the "fiddle factor" and to prevent the ends of the frame from catching the tissue during insertion.

Why were the highly significant differences in pressure readings between the systems not reflected by a difference in complication rates? There may be no relationship between pressure and injury, which is counterintuitive; it is more plausible that the threshold for retractor-related pressure injury was barely reached by either system in this study, resulting in the low rate of complications. Such a threshold is likely to be time and pressure related. The length of the monitored retraction was approximately 50 minutes per patient, which may be less than in other studies. Another explanation is that because the complication rate in the CRS group was lower than expected, the sample size was too small to show a difference if one exists. If the trend demonstrated at 7 days is real, with a similar complication rate, a further study with total sample size of 130 is needed to give a statistically significant result with adequate power (power target, 80%; α = 5%).

Retractor-related injury by some mechanism is the most credible explanation for postoperative symptoms, with 2 recent

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clinical studies demonstrating favorable clinical findings when handheld retractors were used compared with traditional self-retaining retractor systems, but neither study set out to compare the retractor systems scientifically.[5,8] Nevertheless, whatever the mechanism, these studies support the use of handheld toothless retractors and reinforce the intuitive belief that reducing retraction pressure and using intermittent relaxation for reperfusion are likely to benefit the soft tissues.

CONCLUSION

The retraction pressures recorded in the new retractor (SRS) group were significantly less than those recorded in the conventional retractor (CRS) group. Efforts by surgeons to reduce the magnitude and duration of pressure applied to the tissues are supported by different types of evidence, but clinical trials are needed.

Disclosures

Dr Seex has patents pending in regard to the device and its principles. The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENTS

This is a brief, prospective, straightforward article about a new, clinically available anterior cervical retractor system. The comparison to the Cloward-type retractor is fair, and the results are nonbiased. This retractor seems to reduce the severity and duration of dysphagia in the group tested. It is interesting to note that despite the lower retraction pressures, there was still no statistically significant difference in the rate of dysphagia.

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The authors present a randomized single-blind study of the use of the Seex retractor system in anterior cervical spine surgery. Twenty-six patients were included in the study and randomized to use the Seex retractor or the Caspar retractor. Patients were assessed intraoperatively for medial retractor blade pressure and postoperatively, at 1 week and at 4 weeks for symptoms of sore throat, dysphagia, and dysphonia.

The results showed that that average retraction pressure and peak retraction pressure were significantly less using the Seex system. There were no significant differences between groups for symptoms of sore throat, dysphagia, or dysphonia. The authors concluded that the Seex system is safe and does not affect operative time. I agree that the benefit of decreased retraction pressure is intuitive, but also agree that a larger study is warranted to further explore this concept. As has been shown repeatedly in medicine, not everything that is intuitive proves to be true.

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