Clavicle pain and reduction of incisional and fascial pain after posterior cervical surgery

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OBJECT Incisional pain after posterior cervical spine surgery can be severe and very unpleasant to the patient. Ongoing incisional pain is one of the key disadvantages of posterior over anterior surgical approaches to the cervical spine. It prolongs hospital stays and delays return to work. In this study, the hypothesized that incisional pain in the immediate postoperative period is caused partially by tension on the skin as well as on the deep cervical fascia and the fascia overlying the trapezius, which are usually sewn together during closure. Reduction of this tension through retraction of the shoulders should therefore reduce pain as well as the amount of pain medication used in the early postoperative period.

METHODS In this prospective randomized controlled study, 30 patients who had undergone posterior cervical spine surgery were randomized into 2 groups who either wore or did not wear a clavicle brace to retract the shoulders. Patients in the brace group began wearing the brace on postoperative day (POD) 4 and wore it continuously throughout the 30-day study period. Outcome was assessed by two measures: 1) the daily level of self reported pain according to the visual analog scale (VAS) and 2) the number of pain pills taken during the 30-day postoperative period.

RESULTS Wearing a clavicle brace in the immediate postoperative period significantly reduced incisional pain and the amount of pain medication that patients took. Beginning on POD 4 and continuing until day POD 13, the mean daily VAS score for pain was significantly lower in the brace group than in the control group. Furthermore, patients who wore the clavicle brace took less pain medication from POD 4 to POD 12. At this point the difference lost significance until the end of the study period. Four patients were randomized but did not tolerate wearing the brace.

CONCLUSIONS Patients who tolerated wearing the clavicle brace after posterior cervical spine surgery had reduced pain and used less pain medication.

Clinical trial registration no.: NCT01977690 (clinicaltrials.gov)

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KEY WORDS clavicle brace; fascial pain; incisional pain; posterior cervical spine surgery

CERVICAL spinal pathologies are common in daily neurosurgical practice. The controversy over posterior versus anterior approaches to the cervical spine has a long history and is still under debate.^{3–5} One of the disadvantages of posterior cervical spine surgery compared with anterior approaches is the increased postoperative pain in the early and late postoperative period. This leads to longer hospital stays and greater delay in returning to work. This pain is especially well documented in the laminoplasty literature and can be long lasting and very common. Up to 70% of patients undergoing lamino-

plasty suffer from neck pain of long duration.⁹ Most likely this pain has partially muscular and myofascial origins, as muscular dissection is, with the exception of the omohyoid muscle and the longus colli muscle, not carried out in anterior approaches.

Not only muscle, but also fascia, carries pain fibers.^{1,7,10,11} After the senior author (J.P.) noticed that postoperative fascial dehiscence, occurring for example due to exaggerated physical and exercise therapy, led to postoperative pain and that surgical repair of the dehiscence completely ameliorated the pain, he hypothesized that tension on the fascia,

ABBREVIATIONS PCA = patient-controlled anesthesia pump; POD = postoperative day; VAS = visual analog scale.

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FIG. 1. A: Artist's illustration of the principal mechanism of the clavicle brace: reduction in skin-tension and fascia-tension after posterior procedures. Copyright Hannah Ahn. Published with permission. **B:** Photograph of a patient actually wearing the brace.

especially the trapezius and rhomboid muscles, contributed to the postoperative pain complex, consisting of incisional pain, deep-felt pain, and pain with movement, after posterior approaches. When patients reported immediate pain relief after manual retraction of both shoulders, he began to routinely use a clavicle brace to permanently retract patients' shoulders for pain relief and to prevent fascial dehiscence (Fig. 1). Following this period of routine use as an adjunct in every surgical procedure, we sought to test this hypothesis with a randomized controlled study.

Methods

After hypothesizing a mean pain reduction through the brace from a visual analog scale (VAS) score of 5 to a VAS score of 3 with an SD of 1, we calculated that at a power level of 99% and an alpha error of 5%, and given that the VAS numbers were normally distributed, we needed 22 patients to enroll into the study. We increased this number to 30 to account for early and late dropouts.

The study was performed at a single institution with patients treated by 2 different spine surgeons (J.P. and J.K.R.). Eligibility criteria are shown in Table 1. Patients were randomized prior to or the day after the procedure to either wear or not wear the clavicle brace. Randomization was done through closed envelopes that the patients drew. Dissection was performed by the two fellows at our institution and depended solely on the number of fused levels and whether a tumor had to be removed. Closure was also performed by the two spine fellows after instruction by the senior author. Cervical alignment was reviewed on lateral images using the C2–7 angle according to Cobb's method. The cervicothoracic angles were calculated according to Cobb's method by the addition of the cervical spine angle and the remaining angles of the thoracic spine to T-3.

The brace was provided by the hospital. Patients were instructed how to properly wear the brace by the first author, the senior author, or the hospital Rehabilitation Orthotics specialist. To complete the study, patients wore the brace for at least 30 days. (Patients of J.P. continued to wear the brace for 3 months outside of the study period.) All patients wore hard cervical collars until the end of the study period.

Patients recorded their average level of pain on a scale

with scores from 1 to 10 for each postsurgery day beginning on postoperative day (POD) 2. They also recorded the number of pain pills they took each day. On the sheet used to record medication use, patients were instructed to record each day whether they were able to wear the brace or if they experienced problems. At their 1-month postoperative visit the incision was inspected and palpated by the first or senior author for the presence of fascial dehiscence, and its occurrence was recorded.

Every patient routinely received narcotic and nonnarcotic pain medication on an as-needed basis in the hospital. No nonsteroidal antiinflammatory drugs, such as ibuprofen or ketorolac, were given. If, on a particular postoperative day, patients were still on an intravenous narcotic patient-controlled analgesia pump (PCA), that day's data were not recorded for the study.

Prior to the study, approval was granted by Stanford's Institutional Review Board. This study was registered with the ClinicalTrials.gov database (<http://clinicaltrials.gov>), and its registration no. is NCT01977690. Mean pain levels and numbers of pain pills taken were compared using ANOVA (repeated measures analysis).

Results

Patient baseline parameters and surgical data are summarized in Table 2.

Prior to surgery, 75% of the patients were on pain medication. None of the parameters (age; preoperative average VAS score per day; mean number of preoperative pain medications per day; C2–7 angle and C2–T3 angle) were significantly different between the groups in the two analyses. Four patients were randomized to the brace group but did not tolerate wearing the brace. Data for 2 of the

TABLE 1. Inclusion and exclusion criteria for the study

Inclusion Criteria	Exclusion Criteria
Posterior cervical spine surgery w/ possible extension into the thoracic spine	Previous posterior cervical spine surgery
Age 18–90 yrs	Impaired decision-making capacity
	Pregnancy
	Incarceration

TABLE 2. Basic demographics and procedures performed for all randomized patients*

Variable	Brace Group	No Brace Group
No. of patients	14 [11]	13 [16]
Mean age in yrs (range)	57 (45–84) [55 (45–84)]	55 (41–79) [58 (41–79)]
Mean preop average VAS score/day ($\pm$ SD)	3.2 ($\pm$ 3.4) [3.4 ($\pm$ 3.4)]	3.4 ($\pm$ 3.6) [3.3 ($\pm$ 3.7)]
Mean no. of preop pain medications/day	4 ($\pm$ 2) [4 ($\pm$ 2)]	4 ($\pm$ 2) [4 ($\pm$ 2)]
Procedures		
C1–2 fusion	3 [3]	2 [2]
Single-level posterior cervical fusion & decompression	0 [0]	1 [1]
Multilevel posterior cervical fusion w/ or w/o decompression	7 [5]	8 [10]
Multilevel cervicothoracic fusion & decompression	4 [2]	3 [5]
High thoracic tumor removal & cervicothoracic fusion	1 [1]	1 [1]
Mean no. of fused segments	5 (2–8) [5 (2–8)]	5 (2–8) [5 (2–8)]
C2–7 angle ($^{\circ}$)	6.29 $^{\circ}$ $\pm$ 5.70 $^{\circ}$ [6.79 $^{\circ}$ $\pm$ 4.21 $^{\circ}$]	6.81 $^{\circ}$ $\pm$ 5.35 $^{\circ}$ [6.29 $^{\circ}$ $\pm$ 4.54 $^{\circ}$]
C2–T3 angle ($^{\circ}$)	6.89 $^{\circ}$ $\pm$ 5.55 $^{\circ}$ [6.24 $^{\circ}$ $\pm$ 4.12 $^{\circ}$]	5.99 $^{\circ}$ $\pm$ 5.78 $^{\circ}$ [6.11 $^{\circ}$ $\pm$ 4.19 $^{\circ}$]

* Data are expressed as mean with SD or range in parentheses. Data in brackets are the as-treated analyses. The C2–7 angle and C2–T3 angle were not statistically significantly different between groups in the two analyses.

4 patients were incorporated and used to calculate an intention-to-treat and an as-treated analysis. The remaining 2 patients were not available for further data collection. One patient in the control group developed postoperative delirium and dropped out of the study (Fig. 2).

Although we wanted to apply the clavicle brace as early as possible, mostly due to logistical reasons, a significant number of patients could not start wearing it until POD 4;

thus we started recording on that day. Two patients in each group were on a PCA on POD 4 and their data from that day were deleted. Four patients who had been randomized into the no-brace group inadvertently received the brace on POD 4, as its use was a long-standing routine for patients of one surgeon (J.P.). Their data were deleted for that day. None of the 11 patients who wore the brace reported problems with it.

FIG. 2. Flow chart summarizing treatment of the patients by group.

FIG. 3. Left: Using ANOVA to perform repeated measures analysis, use of a brace ($p = 0.0002$) and early use of a brace ($p < 0.0001$) were significant predictors of lower VAS score in the as-treated analysis. **Right:** For the VAS score, both the group variable ($p = 0.0070$) and interaction between group and postoperative day ($p < 0.0001$) were highly significant in the intention to treat analysis.

Mean daily self-reported VAS scores for pain in the two groups are shown in Fig. 3. Mean daily self-reported medication use is shown in Fig. 4 for the two groups. Using ANOVA to perform repeated measures analysis, use of a brace ($p = 0.0002$) and early use of a brace ($p < 0.0001$) were significant predictors of lower VAS scores and use of less medication in the intention-to-treat and the as-treated analysis. One patient who wore the clavicle brace showed evidence of fascial dehiscence on POD 30 (Fig. 5).

Discussion

To our knowledge this is the first study to report on the

use of a clavicle brace to reduce postoperative pain after cervical spine surgery. Our results indicated that patients experienced immediate pain relieve that lasted for several days after the procedure.

The idea of bracing to reduce skin tension has a long tradition. The German surgeon Johann Schultes invented a brace to reduce abdominal incisional tension in the 15th century.¹³ His device was widely adopted and was also mentioned as a regular tool employed by the Mayo brothers starting in the 1950s.⁸

We believe, however, that the simple reduction of skin tension does not completely explain this effect. The idea of fascial nociception is old and has led the way to a number

FIG. 4. Left: Mean number of daily pain medications that patients took after the surgical procedure. Postoperative days ($p < 0.0001$) and use of brace ($p < 0.0001$) were both highly significant, as well as the interaction term ($p < 0.0001$) in the as-treated analysis. The ANOVA was run with missing values omitted. **Right:** For mean number of pain pills, both the group variable ($p = 0.0134$) and interaction between group and POD day ($p < 0.0001$) were also significant in analysis.

FIG. 5. Photograph of a patient with fascial dehiscence.

of different treatments for neck pain.^{1,7,10,11} This idea needs to be transferred to postoperative care. Anatomically, during a posterior cervical spine exposure, the surgeon must pass 2 different fascia layers while dissecting through the posterior cervical space: the trapezius muscle and the deep cervical fasciae, which lie over the deeper cervical muscles.^{6,12} These fasciae are usually sewn together; thus, postoperatively tension on one fascia is transferred to tension on the other fascia. Both fasciae can thus cause postoperative neck pain.

We therefore recommend strict and meticulous fascial closure with nonabsorbable sutures. The two fascial layers can be marked with stay sutures during exposure to prevent malalignment during closure as they tend to retract deep under the subcutaneous tissue.

Furthermore, fascial dehiscence seems to be an overlooked phenomenon in the surgical literature. Fascial dehiscence is not reported in one of the largest reports on surgical complications.² We advise the readership to pay attention to this phenomenon (see Fig. 5), especially when patients complain about an increase in neck pain after they start postoperative exercise.

In our study, 1 patient developed fascial dehiscence. As he was wearing the clavicle brace, we cannot state that simply wearing the brace prevents this complication. We can only speculate that he may not have worn it properly or he may have misjudged his limitations due to pain relief. Nevertheless, this is probably coincidental. A much larger study sample will be needed to compare the rate of fascial dehiscence, although the true rate of fascial dehiscence after posterior cervical spine surgery has not been reported in the literature so far.

Our high rate of nontolerance of the brace and the fact that we saw immediate pain relief after its use make the clavicle brace a tool, but not a requirement, after posterior cervical spine surgery. If manually bringing back the shoulders leads to pain relief, a clavicle brace, which in essence does nothing else, is an appropriate tool. In patients in whom a brace can only reduce the tension of the skin and fascia to a small extent, it is not advisable to wear it.

The main limitations of this study are the number of patients and its location at a single institution. Results also may be under the influence of treatment bias as patients knew that the brace was supposed to reduce their pain. Therefore, they might have self-reported lower values to please the doctor. The 4 patients who inadvertently received a brace and then had it removed could have perceived the loss of a device. However, these patients had previously been notified of their randomization results and knew that they had not been selected to wear the brace. Patients were comprehensively informed through the consent process that the benefit of the brace was unclear. Furthermore, patients could not be blinded and 20% of the patients dropped out because of nontolerance. The recording of daily pain pill use was delegated to the patients or their relatives and not further monitored, nor was compliance with wearing the brace. Type and strength of the medication was not differentiated. Thus we could not standardize our data based on morphine equivalence nor exclude an imbalance of medication strength, and thus bias, between groups. Nevertheless, we suppose that inequalities were evened out by the randomization process.

Conclusions

Using the instruments of evidence-based medicine, we have proved that the clavicle brace can effectively reduce postoperative neck pain and use of pain medication.

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Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Duetzmann, Park. Acquisition of data: Duetzmann. Analysis and interpretation of data: Duetzmann. Drafting the article: Duetzmann. Critically revising the article: Senft, Seifert. Statistical analysis: Cole. Administrative/technical/material support: Ratliff, Park. Study supervision: Ratliff, Park.

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