Posterior Cervical Transfacet Fusion with Facetal Spacer for the Treatment of Single-Level Cervical Radiculopathy: A Randomized, Controlled Prospective Study

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■ BACKGROUND: **Single-level cervical radiculopathy may be treated conservatively with cervical tractions. Posterior cervical transfacet fusion with a facetal spacer is a viable option. The aim of the present study is to compare posterior cervical transfacet fusion with conservative physical treatment in single-level cervical radiculopathy.**

■ METHODS: **A total of 80 patients were randomized in 2 groups, a surgical group in which patients were given posterior cervical transfacet fusion and a traction group in which patients were treated conservatively with mechanical cervical tractions. Visual analog scale for arm and neck, Neck Disability Index, and Short Form-36 (SF-36) questionnaires were administered preoperatively and after treatment up to 12 months.**

■ RESULTS: **After treatment, visual analog scale arm scores were greater in traction group (4.7 vs. 1.5 the day after treatment) and at follow-up controls (traction group vs. surgical group: 5.3 vs. 0.6 at 1 month, 3.6 vs. 0.3 at 6 months, 1.8 vs. 0.2 at 12 months). Neck Disability Index scores were lower in the surgical group (surgical group vs. traction group: 4.4 vs. 20.3 at 1 month, 1.3 vs. 10.5 at 6 months). SF-36 scores were greater in the surgical group (surgical group vs. traction group: 96 vs. 70 at 1 month, 96.5 vs. 82.6 at 6 months). Neck disability index and SF-36 scores were superimposable between the groups at 12-month follow-up. No adjacent-segment arthrosis or late complications were reported at 1-year follow-up in the surgical group.**

■ CONCLUSIONS: **posterior cervical transfacet fusion is a safe and effective procedure to treat single-level cervical radiculopathy.**

INTRODUCTION

Surgical management of single-level cervical spondylotic stenosis with concomitant myelopathy entails the use of anterior cervical disc fusion (ACDF) or total disc replacement (TDR). ACDF and TDR represent the conventionally adopted surgical options in these cases. When the stenosis, either bony or discal, involves predominantly the foraminal region, there is no spinal cord compression and cervical radiculopathy may be the only symptom. Cervical radiculopathy has an incidence of 1.79 per 1000 person-years.[1] The course of symptomatic cervical disc herniation with radiculopathy is benign. Improvement can be expected 4–6 months after the onset of symptoms.[2,3] It is expected that approximately 1–5 patients have a recurrence after conservative treatment.[2]

Although there is no general consensus about treatment choice between physical, infiltrative (epidural injections), and operative,[4] surgery is indicated when pain does not reduce after conservative therapy or if progressive motor weakness is present. In this setting, ACDF may be considered too invasive, and posterior

Key words
- Cervical disc herniation
- Cervical manipulation
- Cervical radiculopathy
- Cervical stenosis
- Cervical transfacet fusion
- Mechanical cervical traction
- Minimally invasive surgery
- Percutaneous cervical fusion
- Posterior cervical fusion
- Randomized controlled study

Abbreviations and Acronyms
ACDF: Anterior cervical disc fusion
AP: Anteroposterior
CT: Computed tomography
NDI: Neck Disability Index
PCTF: Posterior cervical transfacet fusion
SF-36: Short Form-36
TDR: Total disc replacement
VAS: Visual analog scale

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approaches may come in handy. Posterior foraminotomy is a consolidated technique, but it has a few drawbacks, such as chronic neck pain originating from the stripping of the muscle to expose the articular facets.[5]

Posterior cervical transfacet fusion (PCTF) with indirect foraminal decompression is a relatively new treatment modality for single- and/or multiple-level cervical spondylotic foraminal stenosis.[6,7] A titanium expandable washer with an internal screw composes the DTRAX expandable cages (Providence Medical Technology, Lafayette, California, USA). Once deployed and expanded between the 2 facets, it indirectly increases the foraminal volume, decompressing the exiting root. A rasp and a decorticator along with synthetic bone are used to promote fusion. The aim of this study is to assess the efficacy of PCTF compared with conservative therapy for the treatment of single-level symptomatic foraminal cervical stenosis without cervical myelopathy.

MATERIALS AND METHODS

Study Design

The study was approved by the local ethical committee. A total of 119 patients were enrolled in the study. The study was concluded at the moment we had the first 40 patients from each group (surgical and tractions groups) (Figure 1). Overall mean age was 45.5 (standard deviation 12.7). Patients enrolled in the study were predominantly male, with a male/female sex ratio of 1.35. Demographic and preoperative data were substantially comparable between the 2 groups (Table 1). All patients had a physical examination documenting reduction or loss of reflex, sensory deficit, and motor weakness. Magnetic resonance imaging scan to confirm a single-level foraminal stenosis and an electromyogram that could confirm the compression of the cervical root were performed in all patients. If the anatomy of the facet was unclear due to spondyloarthrosis, a computed tomography (CT) scan was performed.

Inclusion criteria were age >18 and <75 years, single-level cervical foraminal stenosis involving the segment C3-C7 documented by magnetic resonance imaging and/or CT scan.

Patients with multiple level radiculopathy, cervical instability or kyphosis, who were pregnant, were affected by rheumatoid or connective tissue diseases, osteopenia or osteoporosis, cervical fractures, cervical column curve inversion at the level of the stenosis, and complete stenosis of the neuroforamen were excluded. All patients were treated conservatively with steroids and nonsteroidal anti-inflammatory drugs for 6 weeks. They were divided randomly in 2 groups: the surgical group was offered PCTF, and physical therapy with mechanical cervical tractions was offered to the traction group (Figure 1).

An online program was used for the purposes of randomization (www.randomization.com). Accordingly, the corresponding author prepared a randomization scheme that was sent to the other authors. According to the treatment followed by each patient, the corresponding author received information about when to call the patients for the telephone interview at 3, 6, and 12 months. All patients gave their informed consent. Initial evaluation included the visual analog scale (VAS) for both neck and arm pain, the Neck Disability Index (NDI), and Short Form-36 (SF-36). The VAS scores only were collected the day after surgery (surgical group) and after 10 sessions of cervical tractions (first 5 weeks of conservative treatment). Patients in the traction group repeated the mechanical

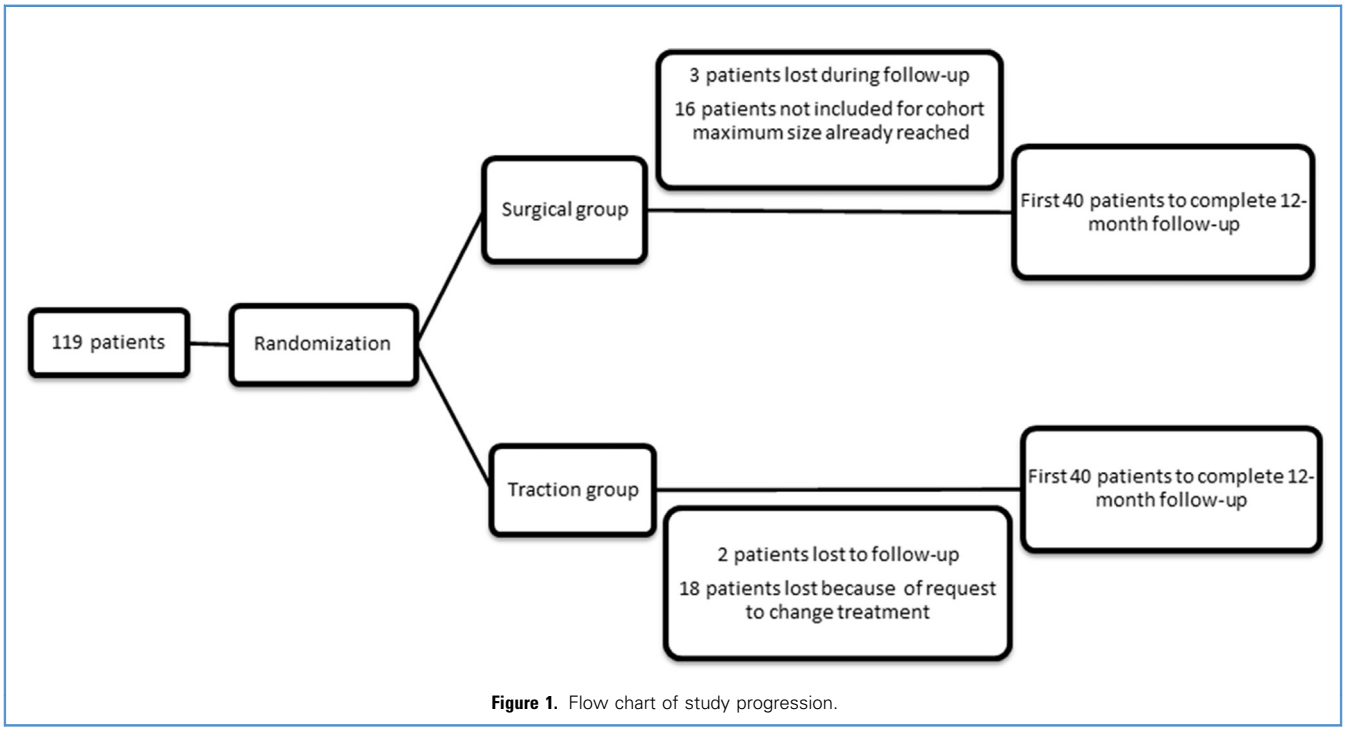

Figure 1. Flow chart of study progression.

Table 1. Demographic and Clinical Data

	Surgery Group	Traction Group	*P* Value
Male/female	1.1	1.6	
Age, years (SD)	46.1 (12.52)	45.02 (12.87)	0.7
BMI, kg/m^2	23.5	25	0.5933
Level, n			
C3-C4	5	4	
C4-C5	6	9	
C5-C6	14	14	
C6-C7	15	13	

SD, standard deviation; BMI, body mass index.

tractions once a week after the first pain and disability assessment. Regression of radiculopathy in the traction group was a primary endpoint for treatment but not for assessment. Nevertheless, treatment and assessment were terminated if patient requested surgery. Patients in the traction group could decide to interrupt the mechanical tractions; nevertheless, they were assessed for pain and disability until the 12th month if they did not ask for surgery. Patients in the traction group who asked for surgery did not enter the surgical group. Because this was an intention-to-treat study, it was considered finished when the first 40 patients from each group had terminated the programmed follow-up.

All patients were evaluated with VAS, NDI, and SF-36 scores at 1, 6, and 12 months after treatment. Pain and disability assessment was performed by a telephone interview by the corresponding author, who did not participate to the surgeries or to the physical therapy sections and was therefore blinded to the treatment.

Surgical Technique

After intubation, the patient was positioned prone with the head in a neutral position and slightly flexed. The Mayfield clamp was unnecessary. The shoulders were pulled down with tape. By the use of intraoperative anteroposterior (AP) fluoroscopic guidance, the surgeon drew 3 lines corresponding to the cutaneous projection of spinosus processes and medial and lateral facets lines on the dorsal cervicodorsal skin. To designate the adequate skin entry point, under laterolateral fluoroscopic control, a spinal needle was positioned aligned with the intended level facet orientation and entry point between the medial and lateral facet lines on one side. The side treated first was that of the radiculopathy or that where the symptoms were more intense.

After adequate local anesthesia was administered to the patient, a 1-cm long horizontal skin incision was made by advancing the scalpel deep through the muscular fascia. The chisel was then inserted through the fascia into the facet under laterolateral fluoroscopic control and advanced up to the pedicle. In case of degenerative arthrosis of the facet, hand pressure may not be sufficient for the chisel to penetrate the articular capsule and/or bone osteophytes and therefore a small hammer was used to penetrate the interfacetal space. The position of the chisel was controlled in AP projection. The chisel should be positioned on the lateral half of the facet to prevent any damage to the root.

A decorticator was used to remove some of the superficial bone to promote arthrodesis. Then, a guide was inserted and the chisel removed from the facet. The guide tube has radiologic markers to align the implant. A rasp was passed inside the facet to remove the cartilaginous endplates. The DTRAX implant was inserted inside the facet to the pedicle. The position was controlled in AP and lateral projections before the screw was inserted. If the position was correct, the screw was advanced until it sprang (meaning that it could not be removed). The facet distraction was controlled in lateral projection. The washer was removed and synthetic bone was inserted inside the working cannula and pushed inside the facet. The same procedure was repeated contralaterally. **Figure 2** shows a surgical case. **Figure 3** shows the implant kit and prosthesis.

Patients in the surgical group were given a soft cervical collar to wear for 7 days after surgery. They were discharged on the first postoperative day. Control cervical radiographs were performed 1, 6, and 12 months after surgery.

Cervical Traction Technique

Patients in the traction group were treated with mechanical traction. They were positioned supine and mechanical traction equipment was adjusted manually. A pulling force was applied equal to 10% of patient's weight for 10 seconds followed by 5 seconds rest for a total of 15 minutes. The force was applied parallel to the cervical spine. The sessions were repeated biweekly for 5 weeks before the first pain and disability assessment.

Statistical Analysis

The sample size calculation was performed with the aid of an online calculator (http://powerandsamplesize.com/Calculators/Compare-2-Means/2-Sample-Equality). To have a 99% chance of detecting a significant (at 2-sided 5% level) difference of 3 points between the 2 groups at VAS scores, with an assumed standard deviation of 3, a minimum of 37 patients were required in each group. The Student unpaired t test was used for to compare the preoperative and postoperative global results. A positive significance level was set at $P < 0.05$. Data were analyzed with the aid of SPSS v21 (IBM Inc., Armonk, New York, USA).

RESULTS

VAS (arm and neck), NDI, and SF-36 scores are shown in **Figures 4–6**, respectively. Fourteen patients (35%) from traction group asked to be operated on between the first and sixth month of follow-up. Four patients (10%) from traction group asked to be operated on between the 6-month and 12-month follow-up control. They were all operated on with PCTF, although they reached their endpoint once out of the traction group and were not included in the surgical group. In total, 18 patients (45%) from the traction group reached their endpoint by asking for the surgical treatment.

Although the 1-year overall outcomes documented good clinical results in both groups, patients belonging to the surgical group showed better results than patients from the traction group after the first and sixth month from surgery or beginning of the physical therapy sessions, as clearly demonstrated in **Figures 4–6**. VAS neck

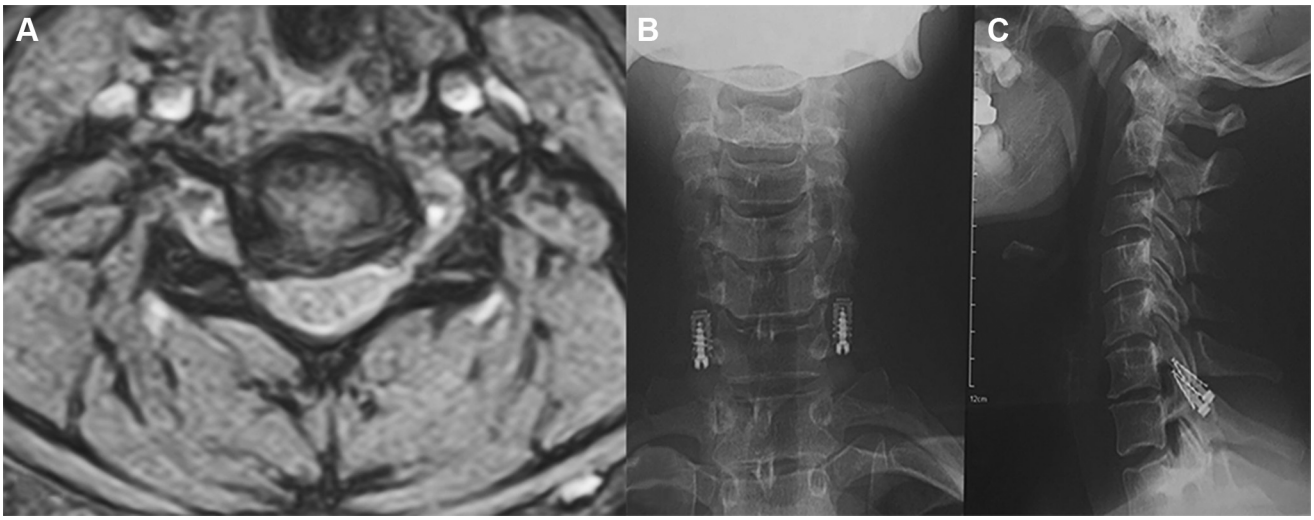

Figure 2. Illustrative case showing (**A**) C6-C7 lateral right disc herniation with C7 root compression. Postoperative radiograph control shows the position of the DTRAX implant inside the articular space at C6-C7 bilaterally, in (**B**) anteroposterior and (**C**) laterolateral projection.

scores were greater the first day after treatment in the surgical group due to the surgery. Pain was treated with conventional analgesic therapy and regressed 3–4 days after surgery. Control radiographs did not show any sign of adjacent-segment arthrosis a follow-up. Fusion rate at one year in the operated patients was 89.5%.

Complications

One patient from the surgical group suffered from persistent postoperative radicular pain on the symptomatic side without any new-onset neurologic signs. A cervical CT scan showed a radicular impingement resulting from malpositioning of the implant. He was reoperated on the third postoperative day. Although the implant could be removed percutaneously, given the high number of intraoperative fluoroscopy controls needed to do so, we decided to replace it with an open technique. Through a median posterior cervical skin incision, open foraminal decompression was performed, which allowed repositioning the implant more laterally. After surgery, the pain resolved, and he did not develop any form of cervical instability during the following 6 months of follow-up.

One patient was involved in a motor vehicle accident on the fourth postoperative day. Although he did not describe any focal neurologic sign, a cervical radiograph documented dislocation of one implant and a partially pulled-out screw on the brachialgia side. We decided not to perform any revision surgery because he did not complain of any pain; 6 months afterwards, no further implant migration was documented on control cervical radiographs. No complications were recorded in the traction group.

DISCUSSION

The invasiveness and potential complications of currently available surgical options for single-level cervical radiculopathy have seen increased interest toward conservative management

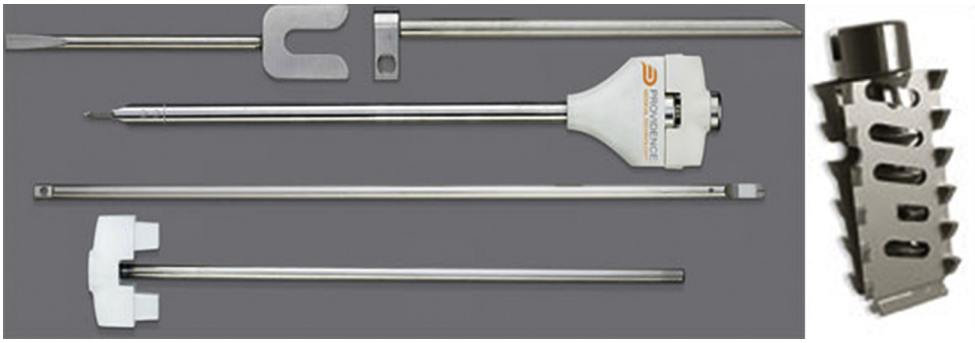

Figure 3. Implant kit and the prosthesis.

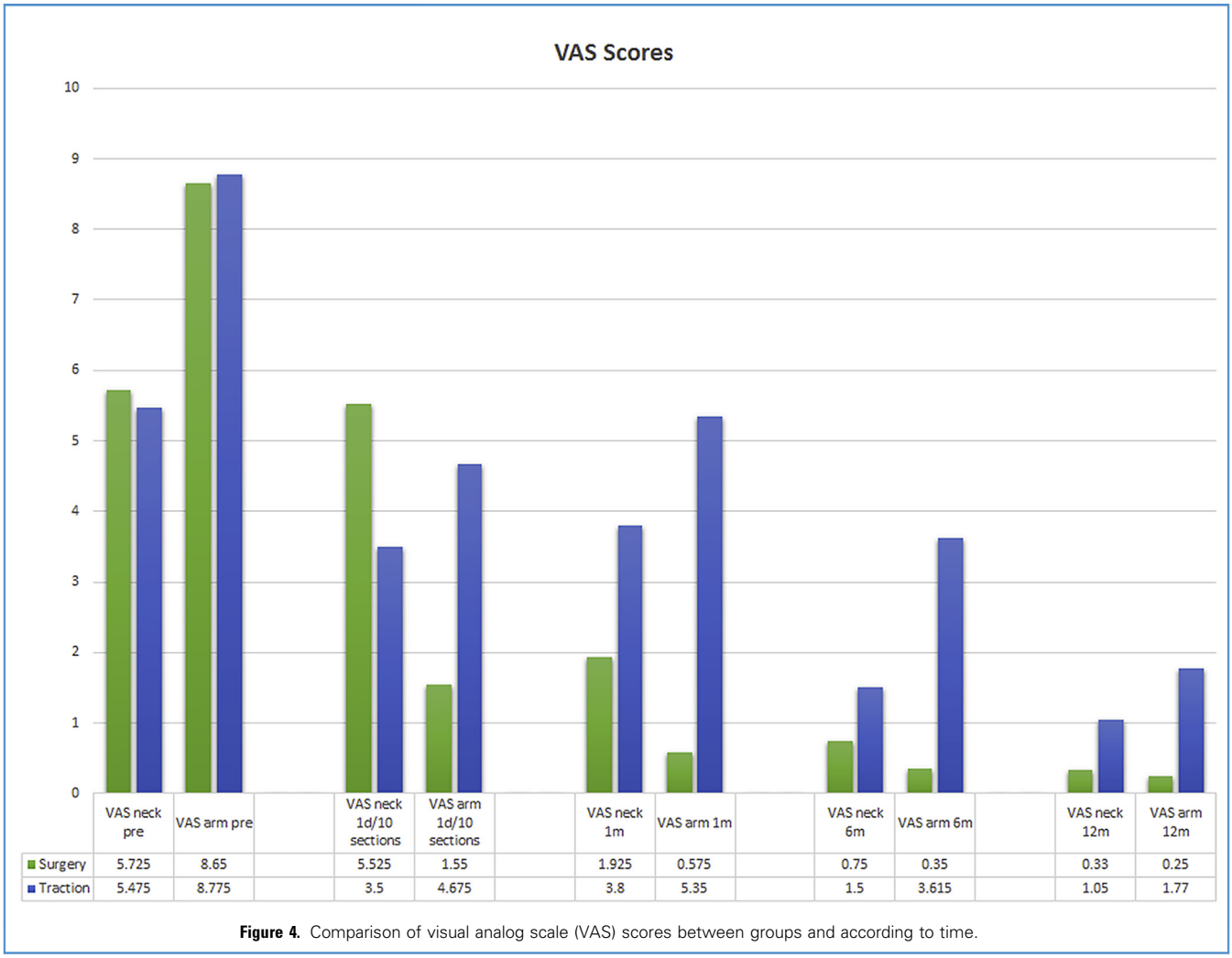

Figure 4. Comparison of visual analog scale (VAS) scores between groups and according to time.

strategies. ADCF and TDR are considered invasive when treating a foraminal stenosis without spinal cord compression. Although posterior approaches are safe, they are burdened by complications such as chronic neck and shoulder pain, mainly due to the xstripping of muscles required to expose the facet.[5] Ruetten et al.[8] have described a full endoscopic posterior approach and reported good results, but this technique has a shallow learning curve and mandates an in-depth knowledge of the regional anatomy.

Although conventional approaches are recommended in cases of complete occlusion of the foramen, milder stenosis should always prompt the surgeon to consider minimally invasive approaches. In these cases, although ACDF provides a decrease in symptoms, it requires removing an otherwise relatively healthy intervertebral disc with potential adjacent cervical segment complications in the long run, which is unfortunate especially when treating young patients.[9] In contrast, we observed that conservative treatment has good results, but only after few months of cervical tractions.

According to the author's experience, PCTF is a minimally invasive procedure that offers short operating times and provides immediate resolution of the symptoms. It requires 24 hours of hospitalization; moreover, it is well accepted by the patients themselves because they do not need to wear a rigid cervical collar postoperatively (7 days with a soft collar). The probability of obtaining clinically significant indirect root decompression is inversely proportional to the disc fragment size and positively related to the reliability of the DTRAX system on augmenting the foraminal area. The DTRAX device provides neuroforaminal volume increase, which remains significant during bending activities and neck extension.[10]

The postoperative increase of the foraminal area is reported to vary from 5.8% to 33%,[10,11] probably attributable to each patient's specific anatomy and pathologic features of the stenosis. Despite not being reported on previously published works,[10,12] according to the authors of the present study, this facet spacer is not indicated for the treatment of complete occlusion of the foramen. In fact, considering that the cervical nerve root normally occupies one third of the foraminal area,[13] a severe stenosis of the neuroforamen cannot be treated with a facet spacer regardless of the widening achieved (a widening of approximately one third of the foraminal area may be obtained at most). Consequently,

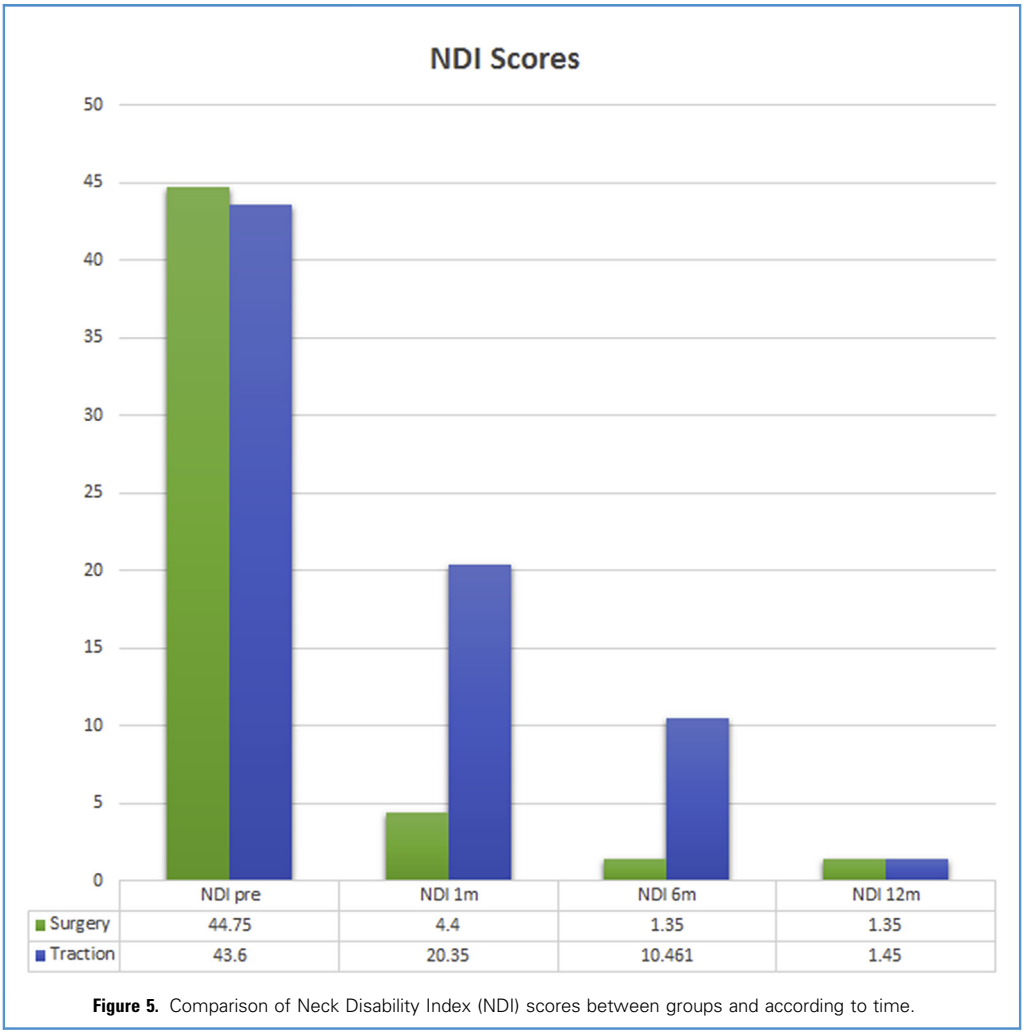

Figure 5. Comparison of Neck Disability Index (NDI) scores between groups and according to time.

these patients were excluded from the study and currently managed with ACDF or TDR.

Thirty-five percent of patients from the traction group chose surgery. A subanalysis of this population revealed that most of these patients were young (<50 years old) and could not face a period of inactivity, especially in relation to occupational issues and therefore needed to return to work and/or physical activity as soon as possible. Conservative treatment is documented to give the best results on cervical single-level radiculopathy in the long run[14]; moreover, the results of our study also showed this trend: at 12 months' follow-up, the pain scales were statistically superimposable. One may speculate that older patients are much more keen to postpone surgery hoping for conservative treatment to show its effects rather than younger patients, who preferred to be operated on when facing a relatively longer period of inactivity to achieve a faster relieve from pain and a relatively more immediate functional improvement, especially in the setting of a sooner return to work. When a decision to be operated on was taken during the conservative treatment protocol, the patient was automatically excluded from the study.

Stability of the PCTF

Leasure et al.[10] compared the stiffness of the DTRAX system with that of transarticular screws in cadaver specimens and concluded that the former is more stable in flexion, axial rotation, and lateral bending but not in extension. Moreover, there was no arthrosis development in the adjacent segments at follow-up on cervical radiographs. No changes were also reported at 1-year follow up by authors from the international literature.[6] Two-year follow-up revealed adjacent segment arthrosis in 17.6% of a previously published series.[12] A 5-year follow-up will provide new insights on the possible long-term development of adjacent segment arthrosis and instability or on recurrences.

PCTF in patients affected by cervical kyphosis is not contraindicated in the current literature. Even so, cervical kyphosis was a contraindication to surgical treatment in our series. The possible aggravation of cervical curve inversion after PCTF already has been taken into consideration by previous reports,[6,15] in which multiple levels up to 4 were treated. Range of motion was not significantly reduced,[6] nor did the Ishihara index change after treatment.[15] The present series did not include patients treated on multiple levels.

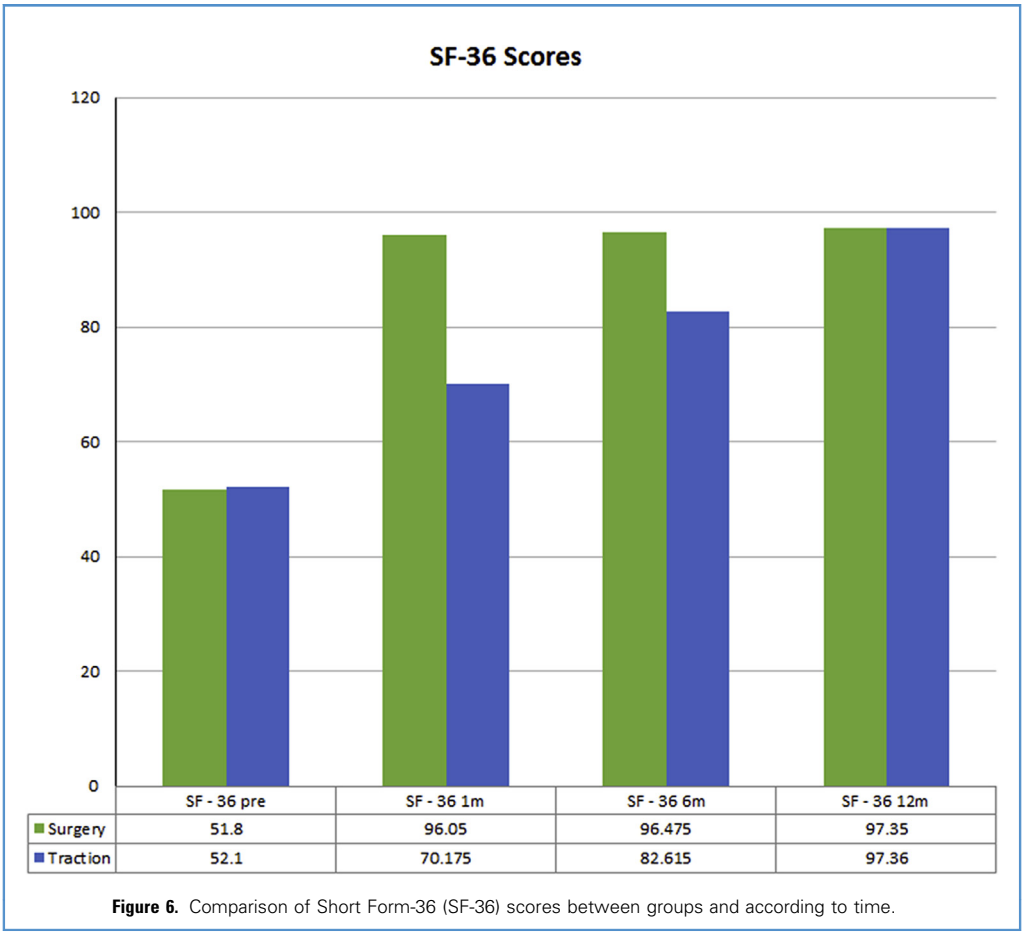

Figure 6. Comparison of Short Form-36 (SF-36) scores between groups and according to time.

Given the data already present in the literature and for the fact that our study primarily analyzed the clinical outcome, we chose not to assess this particular issue.

CONCLUSIONS

The PCTF, through a minimally invasive surgical procedure, provides good results in adequately selected patients harboring single-level cervical radiculopathy due to foraminal stenosis resistant to pharmacologic treatment. Conventional surgical approaches such as ADCF or open posterior surgery should be considered in case of complete occlusion of the foramen. Conservative physical therapy does not provide comparable results in the short term. The technique is therefore effective and safe.

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