Posterior lumbar interbody fusion with stand-alone Trabecular Metal cages for repeatedly recurrent lumbar disc herniation and back pain

Clinical article

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Object. Patients with recurrent sciatica due to repeated reherniation of the intervertebral disc carry a poor prognosis for recovery and create a large burden on society. There is no consensus about the best treatment for this patient group. The goal of this study was to evaluate the 12-month results of the placement of stand-alone Trabecular Metal cages in these patients.

Methods. The authors performed a retrospective analysis of 26 patients with recurrent disc herniations treated with stand-alone posterior lumbar interbody fusion (PLIF) with Trabecular Metal cages. At 1 year patients were evaluated using the Roland Morris Disability Questionnaire (RMDQ) and a visual analog scale (VAS) for back and leg pain. Furthermore, Likert scores of perceived recovery and satisfaction with the treatment were recorded. Lumbar spine radiographs after 1 year were compared with postoperative radiographs to measure subsidence. Stability of the operated segment was assessed using dynamic radiography.

Results. The patient group consisted of 26 patients (62% male) with a mean age of 45.7 ± 11.4 years (± SD). Patients had a history of 1 (31%), 2 (42%), or more (27%) discectomies at the same level. The mean follow-up period was 15.3 ± 7.3 months. At follow-up the mean VAS score for pain in the affected leg was 36.7 ± 27.9. The mean VAS score for back pain was 42.5 ± 30.2. The mean RMDQ score at follow-up was 9.8 ± 6.2. Twelve (46%) of the 26 patients had a global perceived good recovery. With respect to treatment satisfaction, 18 patients (69%) were content or very content with the operation and would recommend it. Disc height was increased immediately postoperatively, and at the 1-year follow-up it was still significantly higher compared with the preoperative height (mean 41% ± 38.7%, range −25.7 to 126.8, paired t-test, both p < 0.001), although a mean of 7.52% ± 11.6% subsidence occurred (median 2.0% [interquartile range 0.0%–10.9%], p < 0.003). No significant correlation between subsidence and postoperative back pain was found (Spearman’s rho −0.2, p = 0.459). Flexion-extension radiographs showed instability in 1 patient.

Conclusions. Although only 46% of patients reported a good recovery with significant reductions in back and leg pain, 85% of patients reported at least some benefit from the operation, and a marked improvement in working status at follow-up was noted. In view of previously published poor results of instrumented lumbar fusion for patients with failed back surgery syndrome, the present data indicate that Trabecular Metal interbody fusion cages can be used in a stand-alone fashion and should not always need supplemental posterior fixation in patients with recurrent disc herniation without spinal instability, although a long-term follow-up study is warranted.

Key words • recurrent lumbar disc herniation • spondylosis • stand-alone cages • Trabecular Metal

Abbreviations used in this paper: FBSS = failed back surgery syndrome; IQR = interquartile range; PEEK = polyetheretherketone; PLIF = posterior lumbar interbody fusion; RMDQ = Roland Morris Disability Questionnaire; VAS = visual analog scale.

Recurrence or back pain after lumbar disc surgery occurs more frequently than commonly thought. Whereas case series and retrospective studies have reported recurrence rates between 3% and 12%, more recent data from prospective cohort studies have revealed that up to 20% of patients will experience recurrent back or leg pain within 2 years after surgery, half of whom will undergo a reoperation in 2–5 years. Patients with recurrent sciatica due to reherniation of the intervertebral disc carry a poor prognosis for recovery and cause a large burden to society due to the secondary economic effects.

There is no consensus about the best treatment for this group of patients. Generally, a course of conservative therapy is recommended as the first option. When nonsurgical therapy fails, reoperation is often considered. The most commonly used intervention is reoperative microdiscectomy, using the same route and technique as the original operation. However, simple decompressive sur-
surgery for recurrent disc herniation seems to have a worse outcome than the initial microdiscectomy, resulting in persistent leg or back pain in 2%-18% of cases.\textsuperscript{10,21,25} Therefore, interbody fusion has been suggested as an alternative, especially if back pain is predominant or in cases of repeated recurrences.\textsuperscript{7,8} Generally, additional posterior fixation using pedicle screws is recommended. However, one may question the need for supplemental posterior fixation in cases in which no spinal instability or spondylolisthesis is present preoperatively. In these cases, the goal of surgery is to prevent further recurrences and restore disc height, rather than achieve a fusion per se, so the placement of intervertebral cages without posterior fixation (“stand alone”) may be considered.

The use of stand-alone cages is somewhat controversial, however. Previous studies have shown poor clinical results from stand-alone application of threaded titanium or polyetheretherketone (PEEK) cages, with high rates of pseudarthrosis and persistent pain.\textsuperscript{18} Therefore, stand-alone posterior lumbar interbody fusion (PLIF) with threaded cylindrical or PEEK cages has been largely abandoned. However, recent introduction of Trabecular Metal Technology (Zimmer) into the field of spinal surgery has opened up new perspectives.\textsuperscript{13,14} The inherent stability of Trabecular Metal cages is very high because of a high resistance to movement on the interface between cage and bone and rapid bone ingrowth, leading to a higher fusion rate than PEEK cages.\textsuperscript{26} Therefore, Trabecular Metal cages may be suitable for stand-alone placement in cases without overt spinal instability, thus obviating the need for pedicle screw placement, reducing operation time, and avoiding the associated risks of nerve injury or other complications.

In this study we retrospectively analyzed 26 patients who were treated with stand-alone PLIF using Trabecular Metal cages without additional bone graft for recurrent disc herniation. The goal of treatment was achieving a satisfactory clinical outcome, rather than obtaining radiological fusion.

**Methods**

Between 2007 and 2009, 26 patients with sciatica and back pain due to recurrent lumbar disc herniation (same side and level) were treated with stand-alone placement of Trabecular Metal cages (TM500, Zimmer). Eighteen of these patients had previously undergone 2 or more discectomies at the same level. Eight patients had a single disc reherniation but were also considered for treatment with stand-alone cages because they had severe back pain and considerable disc height loss. In all cases, the diagnosis was confirmed by MRI, and spinal instability was ruled out by flexion-extension radiographs. In 2010, all patients were asked to participate in this study to evaluate the results of this procedure. All 26 patients gave informed consent and were subsequently evaluated by independent research personnel. Evaluations included the illness-specific Roland Morris Disability Questionnaire (RMDQ) for sciatica, a questionnaire consisting of 23 questions regarding the functional status of the patient with sciatica; a 0- to 100-mm visual analog scale (VAS) score for leg pain (affected and unaffected side) and a VAS score for back pain (0–100 mm), with higher scores indicating more severe pain; a 7-point Likert score of global perceived recovery, with scores ranging from complete recovery (1) to worse than ever (7); and a 7-point Likert score for overall satisfaction with the operation by asking if the patient would have the surgery again and recommend it, with scores ranging from very satisfied with the result of the operation and would recommend it to everyone (1) to very unsatisfied with the result and would advise everyone against this operation (7). The VAS scores were dichotomized as ≥ 40 and < 40, and Likert scores were dichotomized as good recovery (Likert Score 1–2) or bad recovery (Likert Score 3–7). Furthermore, any improvement or worsening of neurological symptoms after the operation was noted. In addition, working status was evaluated. Physical and neurological examinations were performed, and the results were compared with those from the preoperative examination reported in the medical record. In addition, anteroposterior and lateral radiographs were obtained, which were compared with the preoperative and immediate postoperative radiographs to measure the differences in disc height. Flexion and extension radiographs were obtained to assess stability of the operated segment.

**Surgical Technique**

Under general anesthesia, the patient was positioned prone on a roll placed beneath the pelvis to obtain a physiological lordosis. Through a 5-cm incision in the existing median scar, the paraspinal muscles were spread for a standard bilateral interlaminar exposure. The operated level was identified and was checked with fluoroscopy as necessary. A bilateral partial medial facetectomy was performed to open the lateral recess at both sides and to allow some working space laterally. The compressed nerve roots and the thecal sac were completely dissected free from any scar tissue, and extruded disc material was removed until the nerve roots were fully mobilized. A complete discectomy was performed after a bilateral incision of the annulus. If the disc space was very narrow, an 8-mm disc distractor was introduced horizontally and then rotated 90° so as to distract the endplates (Fig. 1A). Any loose fragments and extruded disc were then removed easily from the disc space. The disc space was further distracted to a proper height, usually between 8 and 12 mm. The endplates of the disc were prepared with reamers and curettes to remove any remaining cartilage. Trial cages were placed bilaterally (Fig. 1B) and checked by fluoroscopy. Finally, after removal of the trial cages, Trabecular Metal cages were placed in the intervertebral space while protecting the nerve root and the dural sac. No additional bone graft was used. Proper placement of the cages was confirmed by fluoroscopy (Fig. 1C).

**Statistical Analysis**

Categorical variables are presented as percentages. Continuous variables were tested using the Kolmogorov-Smirnov test for normal distribution; normally distributed variables are presented as the mean ± SD. From data that were not normally distributed, a median with the interquartile range (IQR) is presented. Differences between
two paired measurements of normally distributed variables were tested with a paired sample t-test. Spearman’s rho was used to assess the relationship between two continuous variables, of which at least one variable was not normally distributed. Values of p < 0.05 were considered as statistically significant. All analyses were performed using Statistical Package for the Social Sciences Software (version 19.0, IBM SPSS).

Results

The patient group consisted of 26 patients (62% male) with a mean age of 45.7 ± 11.4 years and a mean body mass index of 25.9 ± 4.2 at follow-up (Table 1). All patients had a history of at least one lumbar disectomy, but most of them had undergone 2 (42%) or more (27%) previous discectomies. The mean follow-up period was 15.3 ± 7.3 months.

At follow-up (Table 2), the mean VAS score for pain in the affected leg was 36.7 ± 27.9. In the contralateral leg the mean VAS score was 13.4 ± 22.5 (median [IQR] 0.0 [0.0–17.5]), with 5 patients reporting a VAS score greater than 40. The mean VAS score for back pain was 42.5 ± 30.2. The mean RMDQ score at follow-up was 9.8 ± 6.2. Twelve (46%) of the 26 patients had a global perceived good recovery (Likert Score 1 or 2), while 22 (85%) indicated to have at least some benefit of the operation (Likert Score 1–3). With respect to treatment satisfaction, 18 patients (69%) were content or very content with the operation and would recommend it (Likert Score 1 or 2). Before the operation, 8 patients (31%) were working with no restrictions and 8 (31%) with many restrictions, which improved at follow-up to 11 patients with no restrictions and 4 with many restrictions. At follow-up, 9 patients (35%) had an improved working status, 9 patients (35%) had an unchanged working status, and 5 patients (19%) had a worse working status.

Disc height measurement revealed a significant increase immediately postoperatively as well as at follow-up compared with the preoperative situation (paired t-test, both p < 0.001; Fig. 2). At 1-year follow-up the disc height still was significantly higher than preoperatively (mean 41% ± 38.7%, range −25.7 to 126.8).

Subsidence (loss of disc height between the immediate postoperative and follow-up assessment) was also significant (p < 0.003). The mean relative subsidence was 7.5% ± 11.6% (median 2.0% [IQR 0.0%–10.9%]), with 5 patients having more than 20% subsidence. However, no significant correlation between the relative subsidence

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* Values represent the number of patients unless otherwise indicated.
† Mean values are presented as the mean ± SD.
† Scores were available for 5 of 26 patients.
and postoperative back pain was found (Spearman’s rho \(-0.2, p = 0.459\)). Flexion-extension radiographs showed instability in 1 patient, who subsequently underwent additional posterior stabilization.

Four patients (15%) underwent reoperation, 2 because of a postoperative hematoma, 1 for persistent CSF leakage, and 1 patient underwent late additional posterior fusion for recurrent severe back pain associated with instability and lucency around the cage (Fig. 3). Further complications included 1 superficial wound infection treated with oral antibiotics and 1 dural tear that was repaired intraoperatively. Four patients (15%; including one of the patients who underwent reoperation) had postoperative worsening of their neurological status, a mild sensory deficit in 2, and a motor deficit (worsening by one Medical Research Council grade, for example, from Grade 5 to 4) in 2 patients.

### Discussion

Treatment of recurrent disc herniation after one or more operations remains a difficult challenge. Varying results of reoperative microdiscectomy have been reported,\(^6,11,23,25,26,28,29\) and, overall, there is a 25.1% cumulative risk of further spinal surgery in the first 10 years after surgery.\(^22\) The prognosis of repeated back surgery is considered poor in terms of pain-free recovery and return to work.

When multiple recurrences occur at the same level, a fusion procedure is often recommended, although the superiority of fusion over reoperative discectomy alone has not been proven.\(^8\) Wide decompression and neurolysis of the entrapped nerve root with removal of epidural fibrosis, followed by complete discectomy, restoration of disc height, and subsequent fusion, will mechanically prevent any further reherniation at that level. It can be questioned, however, if in these cases a full 360° instrumented fusion including pedicle screws is always warranted. In most of these cases, the facet joints are intact and, apart from disc collapse, there may be no instability or spondylolisthesis. The main goal of surgery in these cases is to decompress the nerve root, restore disc height, and prevent reherniation. Although poor fusion results have been reported with stand-alone cylindrical or PEEK cages,\(^18\) the use of Trabecular Metal implants may provide better results, even without posterior instrumentation. Because of the high resistance at the implant-bone interface and the rapid ingrowth of bone in the porous material,\(^30\) these cages may provide immediate stability.

The present study has demonstrated good fusion results (defined by no movement on the flexion-extension radiographs) after 1 year in patients treated by stand-
alone PLIF using Trabecular Metal cages for recurrent disc herniation, with only 1 (4%) of 26 patients requiring additional posterior fixation at a later stage.

Subsidence

In the present study, we found a mean subsidence of 7.5% (median subsidence of 2%), which seems to be in accordance with the literature. Notably, 19% of patients had more than 20% subsidence; this rate has also been found in previous studies, even when additional posterior pedicle screw fixation was performed. Moreover, there was no clear correlation between subsidence and clinical outcome, which raises questions about the clinical significance of subsidence. However, long-term effects of subsidence on back pain and function cannot be excluded, and therefore longer follow-up may be necessary to reach definite conclusions on this matter.

The overall clinical outcome in this study was only moderately satisfying, with 12 patients (46%) reporting a good recovery and significant reductions in back and leg pain and overall 69% reporting satisfaction with treatment. These somewhat disappointing results are in accordance with a recent study by Arts et al., who reported even worse recovery after PLIF with pedicle screws for patients with failed back surgery syndrome (FBSS). Although our patient population may seem different from that of Arts et al., almost all of our patients would have met their criteria for FBSS (persistent low-back and/or leg pain lasting more than 1 year despite 1 or more surgical procedures). Furthermore, 46% of their patients also had a history of 1 or more discectomies.

In a larger series by Costa et al., 119 patients were treated with stand-alone cages for degenerative disc disease and back pain with or without leg pain. They used titanium-threaded cages, which were inserted into the disc space after bilateral discectomy, with minimal medial facetectomy and dural retraction needed because of the small diameter of the implant. Their reported results after 1 and 2 years were much better (back VAS Score 26 after 2 years and 94% of the patients showing a good response on a functional scale). This difference is probably explained by different inclusion criteria for that study, which included patients with degenerative disc disease and back pain without leg pain, with only 44% of the patients having undergone prior surgery at the operated level. In the present series, all patients had undergone prior lumbar surgery, while 18 patients (69%) even had 2 or more prior operations, thus representing a more difficult group with aspects of chronic pain and poorer prognosis from the outset, comparable to FBSS. From this perspective, our treatment results with 85% of patients reporting at least some benefit from the operation and a marked improvement in working status at follow-up may not be that bad after all. It is important to note that the complication rate of PLIF in reoperations is considerably higher than in primary surgery, because of the need for bilateral exposure and completely mobilizing the thecal sac and nerve roots from scar tissue. The use of additional pedicle screw fixation has its own complications, such as violation of the superior facet joint and misplacement of pedicle screws sometimes needing reoperation. From a health cost perspective, the question is whether additional pedicle screw fixation in all patients is justified to prevent reoperation with the placement of additional pedicle screws. These risks should be taken into account when discussing the therapeutic options with the patient.

Conclusions

The present study indicates that Trabecular Metal interbody fusion cages may be used in a stand-alone fashion and do not always need supplemental posterior fixation in patients with recurrent disc herniation without spinal instability. To corroborate these results, further (long-term) study is needed to compare standard reoperative microdiscectomy with PLIF using stand-alone Trabecular Metal cages and PLIF augmented with pedicle screws and rod fixation for recurrent sciatica due to a lumbar disc reherniation.
Disclosure

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

Author contributions to the study and manuscript preparation include the following. Conception and design: Bouma. Acquisition of data: Lequin, Bouma. Analysis and interpretation of data: all authors. Drafting the article: Lequin, Bouma. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Lequin. Statistical analysis: Verbaan. Study supervision: Bouma.

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Manuscript submitted June 10, 2013. Accepted February 17, 2014. Please include this information when citing this paper: published online March 28, 2014; DOI: 10.3171/2014.2.SPINE13548. Address correspondence to: Michiel Bastiaan Lequin, M.D., Department of Neurosurgery, Academic Medical Center Amsterdam, Meibergdreef 9, 1105 AZ, Amsterdam, the Netherlands. email: m.b.lequin@amc.uva.nl.