Minimally invasive spinal fixation in an aging population with osteoporosis: clinical and radiological outcomes and safety of expandable screws versus fenestrated screws augmented with polymethylmethacrylate

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OBJECTIVE The goal of this study was to compare the clinical and radiological outcomes between fenestrated pedicle screws augmented with cement and expandable pedicle screws in percutaneous vertebral fixation surgical procedures for the treatment of degenerative and traumatic spinal diseases in aging patients with osteoporosis.

METHODS This was a prospective, single-center study. Twenty patients each in the expandable and cement-augmented screw groups were recruited. Clinical outcomes included visual analog scale (VAS), Oswestry Disability Index (ODI), and satisfaction rates. Radiographic outcomes comprised radiological measurements on the vertebral motion segment of the treated levels. Intraoperative data including complications were collected. All patients completed the clinical and radiological outcomes. Outcomes were compared preoperatively and postoperatively.

RESULTS An average shorter operative time was found in procedures in which expandable screws were used versus those in which cement-augmented screws were used (p < 0.001). No differences resulted in perioperative blood loss between the 2 groups. VAS and ODI scores were significantly improved in both groups after surgery. There was no significant difference between the 2 groups with respect to baseline VAS or ODI scores. The satisfaction rate of both groups was more than 85%. Radiographic outcomes also showed no significant difference in segment stability between the 2 groups. No major complications after surgery were seen. There were 4 cases (20%) of approach-related complications, all in fenestrated screw procedures in which asymptomatic cement extravasations were observed. In 1 case the authors detected a radiologically evident osteolysis around a cement-augmented screw 36 months after surgery. In another case they identified a minor loosening of an expandable screw causing local back discomfort at the 3-year follow-up.

CONCLUSIONS Expandable pedicle screws and polymethylmethacrylate augmentation of fenestrated screws are both safe and effective techniques to increase the pullout strength of screws placed in osteoporotic spine. In this series, clinical and radiological outcomes were equivalent between the 2 groups. To the authors’ knowledge, this is the first report comparing the cement augmentation technique versus expandable screws in the treatment of aging patients with osteoporosis.

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KEYWORDS spinal osteoporosis; vertebral fracture; spinal fixation; expandable screw; spinal fracture; listhesis; osseous screw; cemented screw; fenestrated screw; degenerative spinal disease; osteopenic vertebra

OSTEOPOROSIS is a major healthcare problem in an aging population and is characterized by decreased bone strength and increased skeletal fragility.1,2 Although osteoporosis predisposes patients to spinal deformity, stenosis of the canal and neuroforamina, and vertebral body fracture, surgical correction in such patients is technically demanding. A major potential complication may be hardware failure secondary to poor fixation in osteoporotic bone.3 Failure is a result of decreased holding strength of the pedicle screws in bone with low bone mineral density and can lead to screw loosening and pullout. A variety of methods and strategies have been developed...
to improve pedicle screw fixation in osteoporotic spine. These include the use of bigger and longer screws, with optimization of the pedicle fit of the screw; undertapping the screw trajectory; and optimal screw trajectory selection. Alternative methods, such as expandable screws or augmenting screws with polymethylmethacrylate (PMMA) bone cement, have been shown to increase the strength of the screw–bone interface. Older patients with osteoporosis who have comorbidities and who cannot tolerate traditional open surgery may be treated with percutaneous posterior fixation techniques.

To our knowledge, there have been no previous reports directly comparing the outcomes of expandable screws and screws augmented with cement based on clinical and radiological criteria. The purpose of this study was to compare the outcomes and the incidence of complications between vertebral fixation surgical techniques in which expandable pedicle screws and fenestrated screws augmented with cement were used for the treatment of thoracolumbar degenerative and traumatic pathologies in an elderly population with osteoporosis. We also investigated the safety and efficiency of both procedures, in which a percutaneous technique was used.

Methods

This was a prospective, randomized, single-center study of patients with symptomatic osteopenia or osteoporosis who were affected by lumbar degenerative or traumatic pathologies. Patients were randomized in a 1:1 ratio for each group, following the CONSORT guidelines (Fig. 1). Informed consent was obtained before randomization, and the patients were free to refuse participation. The study was performed in accordance with the Declaration of Helsinki. A consecutive series of 40 patients underwent posterior spinal fixation with either expandable screws (group I) or fenestrated pedicle screws augmented with PMMA cement (group II) to treat spinal degenerative or traumatic pathologies. Inclusion criteria were as follows: 1) patient age 60 years or more; 2) spinal fracture, degenerative conditions, instability, or deformity requiring spinal fixation; 3) osteopenia to severe osteoporosis, with a T-score of less than −1.0 according to the WHO criteria, demonstrated by dual-energy x-ray absorptiometry (DEXA) bone mineral density examination; and 4) amenability to minimally invasive surgical technique. Exclusion criteria were as follows: 1) sensory and/or motor deficits; 2) relevant spinal canal stenosis; 3) acute severe trauma with spinal fracture and neurological deficit; 4) active systemic or local infection; and 5) known allergies to any of the device components. All patients with traumatic lesions were affected by an impending or an unstable fracture, so they had been considered not amenable to conservative treatment.

Surgical Technique

Each surgical procedure was performed after induction of general anesthesia, with the patient placed in a prone position. Under bilateral C-arm fluoroscopic (anterior-posterior and lateral) views of the spine, pedicle screws were inserted bilaterally via a percutaneous or minimally invasive approach.

In group I we used expandable pedicle screws (Osseoscrew—Illico Fixation System; Alphatec Spine) (Fig. 2 left). The Osseoscrew is an expansion screw made of grade 5 titanium in its inner portion, which guarantees the seal of the screw and prevents its breakage, and of commercially pure titanium in the outer part of the screw, which provides elasticity. The outer part of the screw can be expanded in its central portion and always at 26.85 mm from the head of the screw. This expansion is controlled by the operator manually under an intraoperative C-arm fluoroscopy view. In our series, expansion of the screw was always performed to the maximum amount in the osteoporotic trabecular bone of the vertebral body.

In group II we used polyaxial and cannulated screws (Viper MIS Spine System; DePuy Spine–Johnson & Johnson) with 6 fenestrations in the grooves of the distal portion of the thread and an opening at the distal tip (Fig. 2 right). A cement delivery cannula system was used to inject a high-viscosity cement under controlled pressure after connection with the cannulated screws. PMMA cement was extruded through the fenestrations of the screw inside the osteoporotic cancellous bone under image intensifier visualization. The amount of cement injected into each screw varied from 1.5 to 3 mL. To prevent cement leakage outside the vertebral body, the injection was performed in a higher-viscosity state of the cement (approximately 10 minutes after mixing). The injection of cement was immediately stopped once leakage outside the vertebral body was visualized on the image intensifier.

After placement and expansion of the expandable screws (group I) and cement augmentation of the fenestrated screws (group II), the bilateral connection of the ipsilateral pedicle screws with rods was performed (Fig. 3). Given the underlying vertebral osteoporosis, no reduction maneuvers were used other than patient positioning and rod insertion. A final intraoperative control radiograph to confirm correct position of the fixation system was obtained. Arthrodesis was not performed along with instrumentation.

Postoperative Care

Intravenous antibiotics were given for 24–72 hours after surgery. Depending on his or her clinical condition, the patient was allowed to ambulate with external orthosis 2–3 days after surgery. A minimum 2-month period of bracing was recommended. Supplementary calcium, bisphosphonate, or parathyroid hormone (PTH) was routinely given by the endocrinologist for medical therapy of osteoporosis.

Radiological Outcome Measurements

All patients were evaluated using spinal CT scanning or MRI to define the surgical indication and to measure the pedicle diameter and length prior to surgery. Follow-up radiological examination with spinal radiographs and CT scans were performed in all patients immediately after surgery to check pedicle screw position and cement leakage, and at the 24-month final follow-up to assess possible implant failure or screw loosening. The evaluation of vertebral segment stability achieved at 24 months was performed by an independent radiologist.
Postoperative radiological analysis was performed using a computer software program (Syngo; Siemens). The immediate postoperative screw position was measured and compared with the final position evaluated on the lateral view of plain radiographs and axial view of CT scans. The distance from the deepest screw tip of each level to the anterior cortex of the vertebral body and to the upper endplate was measured and recorded on the lateral view of the radiograph. Segment stability was defined as the concurrence of no sign of radiolucency around the pedicle screws and no movement shown between the fixed segments in the dynamic radiographs (defined as rotational mobility < 3° and translational motion < 2 mm). Hardware-related complications were also evaluated based on clinical and radiological data (screw loosening, migration, or rupture with or without back pain, and cement leakage).

Clinical Outcome Measurements

All patients were interviewed by an independent researcher to assess clinical symptoms. All questionnaires were supplemented by review of patients’ medical records. Preoperative and postoperative pain was evaluated using a visual analog scale (VAS 0–10). The values obtained preoperatively, immediately after surgery, and 2 years after surgery were compared. Back pain–related disability assessed with the Oswestry Disability Index (ODI) scale (range 0%–100%) was compared between groups preoperatively and at final follow-up. Improvements of ≥ 15 points compared to baseline were regarded as clinically significant.

Statistical Analysis

Quantitative variables were expressed as means, and qualitative variables were expressed in terms of number and ratio. Continuous variables were analyzed by 2-sample t-test or ANOVA, and the categorical variables were analyzed by the chi-square test or Fisher exact test. Statistical calculations were performed with SPSS (IBM Corp.).
for Windows. A p value < 0.05 was considered to be a statistically significant difference.

Results

A total of 40 patients were enrolled in the study, with 20 patients randomized to expandable screws and 20 patients randomized to fenestrated/augmented screws. The mean age was 72.4 years (range 60–82 years). The mean age and BMI were similar for both treatment groups. There were 24 women and 16 men enrolled in this study. The expandable screw group had more women than the cemented screw group (65% vs 55%, respectively). Gender differences were not statistically significant. For both treatment groups, the most frequently reported indication for surgery was osteoporotic compression or burst fracture (24 cases; 11 in group I and 13 in group II). In vertebral fracture cases, injury dynamics included a fall in 16 patients, lifting of heavy objects in 2, and undetermined causes in 6. A preoperative diagnosis of spinal degenerative disease was made in 16 cases (40%; 9 cases in group I and 7 in group II). The location of the spinal disease was lumbar in 28 patients (15 cases in group I and 13 in group II); thoracic in 10 cases (7 patients in group II and 3 patients in group I); and the thoracolumbar junction in 2 patients (all expandable screws; group I). Fractures were located at the T12 level in 9 patients; at L1 in 12 cases; at L2, L3, and L4 in 2 cases each; and at T11 in 1 case. In 4 patients there was a double vertebral body fracture (in 3 cases with expandable screws and in 1 case with cement-augmented screws). Degenerative lumbar segment disease was located in L4–5 in 9 cases; in L3–4 in 2 cases; and in L2-L3-L4, L3-L4-L5, and L4-L5-S1 in 2 cases each. Diffuse idiopathic hyperostosis was noted in 35% of patients in group I and in 30% in group II. Vertebral fracture affected 37.5%, whereas 25% suffered from spinal degenerative conditions.

Demographics and baseline characteristics, clinical data, and location of the lesion in the enrolled patients are presented in Table 1. The DEXA bone mineral density examination performed preoperatively showed a mean T-score of −2.6 (range −1.7 to −4.3) with no statistical difference between the groups. The mean BMI was 24.5 kg/m² (range 17.4–35.6 kg/m²). Comorbidity factors were found in 23/40 patients, some of whom had more than one comorbidity. Overall, 204 pedicle screws were inserted, including 106 expandable screws and 82 fenestrated screws augmented with cement. Sixteen standard short screws were placed as supplemental fixation in fractured vertebrae or in a vertebral body that had previous vertebroplasty (Table 2). In group II, the mean cement injection per pedicle was 2.4 mL (range 1.5–3.0 mL). The mean operation time was 168 ± 75.3 minutes (range 56–290 minutes), and the mean perioperative blood loss was 90 mL (range 40–210 mL). A shorter operative time was found in the expandable screw group compared to the cement-augmented screw group (mean 152 vs 188 minutes) (p < 0.001). The

| Characteristic | All Patients | Group I, Expandable Screws | Group II, Cement-Augmented Screws | p Value |
|---------------|--------------|---------------------------|----------------------------------|---------|
| No. of patients | 40           | 20                        | 20                               | >0.05   |
| Mean age in yrs (range) | 72.4 (60–82) | 72.6 (63–82) | 71.3 (60–79) | 0.44    |
| Sex            |              |                           |                                  |         |
| Female         | 24           | 13                        | 11                               | 0.26    |
| Male           | 16           | 7                         | 9                                | 0.23    |
| Mean BMI       | 24.5         | 24.5                      | 24.6                             | 0.87    |
| Mean BMD, T-score | −2.6        | −2.7                      | −2.6                             | 0.66    |
| Treated pathology |            |                           |                                  |         |
| Vertebral fracture | 24           | 11                        | 13                               | 0.57    |
| Lumbar instability | 16           | 9                         | 7                                | 0.58    |
| Comorbidities  |              |                           |                                  |         |
| Cardiovascular | 18           | 10                        | 8                                | 0.21    |
| Endocrine & metabolic | 11           | 5                         | 6                                | 0.44    |
| Urogenital     | 4            | 3                         | 1                                | 0.04    |
| Respiratory    | 2            | 1                         | 1                                | 0.98    |

BMD = bone mineral density.
minimum follow-up period was 24 months for all patients (mean follow-up 35.2 months, range 24–52 months). Standard treatment for the underlying osteoporosis comprised PTH, bisphosphonate, or calcium. In this series, after surgery 35% of patients in group I and 40% in group II received PTH, whereas 40% and 30%, respectively, received bisphosphonate. There were no statistically significant differences in postoperative medical treatment between the 2 groups.

Clinical Outcome

No patient had symptoms, worsening scores on the functional scale, or ambulatory status deterioration after surgery. At 6 months and 12 months, both groups had a clinically significant mean change from baseline in ODI and VAS, with no significant difference between groups. The total mean VAS score showed a significant improvement compared with the preoperative scores (from 8.7 before surgery to 3.0 after surgery; p < 0.001). In the expandable screw group the mean VAS improved from 8.8 to 2.9, and in the augmented screw group the VAS improved from 8.6 to 3.0 after operation. At final follow-up there were no significant differences in pain decrease from baseline according to VAS score between the 2 groups of patients (p = 0.67).

At the 24-month follow-up, both groups had a clinically significant mean change from baseline in ODI scores (p < 0.001). The ODI scores significantly decreased from a mean of 78.4% preoperatively to 23.8% in group I, and from 77.4% to 22.9% in group II. The rate of patients with a clinically significant improvement in back pain–related disability (ODI) was not statistically different between groups at 24 months. At the 24-month follow-up, satisfaction with treatment of both groups was more than 85% (90% [18/20] of group I and 85% [17/20] of the group II; p = 0.58) (Table 3).

Radiological Outcome

On spinal radiographs, the average immediate postoperative horizontal and vertical screw distances from the screw tip to the anterior cortex and upper endplate of the vertebra were 11.7 and 9.8 mm (group I) and 11.3 and 9.6 mm (group II), respectively. At final follow-up, these distances were 12.4 and 11.4 mm (group I) and 12.1 and 11.2 mm (group II), respectively (Figs. 4 and 5). There were no statistical differences of screw distance from the anterior cortex and upper endplate after surgery and at final follow-up between the 2 groups. Motion segment stability of the treated level was present in all cases at the 24-month follow-up.

Complications

There were no deaths or cases of myocardial infarction or pulmonary embolism (PE). None of the patients in this study showed signs of postoperative neurovascular injury. In the cement-augmented screw group, all 20 patients underwent CT examination during the follow-up period for the evaluation of cement leakage. The injection of PMMA was performed after a minimum of 10 minutes of mixing to obtain a high-viscosity consistency of the cement but, despite this waiting time, asymptomatic extravasations of cement were observed in 4/20 patients. PMMA leakages were spotty or linear and were noted through the small segmental veins. There was no significant compression to the surrounding tissue of the vertebral body, namely the external segmental veins. There was no significant compression to the surrounding tissue of the vertebral body. In 1 case of spondylolisthesis L4–5, an osteolysis around the 2 cemented screws at the L4 level was noted in the spinal radiographs 3 years after surgery. There was no screw loosening at flexion–extension radiographs and the patient had no back pain, needing no pain medication and no revision surgery. Expandable screw loosening occurred in 1 patient (5%) with severe osteoporosis (T-score −4.3) at 36 months after surgery. Although the expansion of the screw was locked inside the neck of the pedicle, the patient reported local discomfort and underwent reoperation for screw removal and elongation of the fixation cranially.

Discussion

The main goal of the present investigation was to determine the efficacy and safety of 2 different percutaneous spinal fixation techniques in the treatment of degenerative and traumatic spinal conditions in an aging population of patients with osteoporosis. We analyzed 2 groups (patients treated with expandable screws and those treated with cement-augmented screws). The study showed that both expandable screws and cement-augmented screws were effective in reducing back pain and improving functional outcomes in patients with osteoporosis. However, there were no significant differences in pain decrease or functional outcomes between the 2 groups. The radiological outcome showed that the average immediate postoperative screw distances from the screw tip to the anterior cortex and upper endplate were similar between the 2 groups at 24 months. There were no significant complications related to the procedure, such as neurovascular injury or cement leakage. The results of this study suggest that expandable screws and cement-augmented screws are both effective and safe options for the treatment of degenerative and traumatic spinal conditions in an aging population of patients with osteoporosis.
with cement-augmented screws) comparably matched in terms of demographic data and treated pathologies. Our results, supported by radiographic evidence, indicate that increased holding strength of either type of fixation techniques may avoid screw loosening in patients with poor bone density. Furthermore, the clinical findings of the present study indicate that expandable screws and cement-augmented screws are mostly equivalent in the treatment of traumatic and degenerative thoracolumbar osteoporotic spinal pathologies.

In recent years, the need for spinal fixation in older patients with comorbidities who cannot tolerate traditional open surgery has led to the use of minimally invasive surgical techniques. One limitation of the percutaneous technique is the lack of arthrodesis. A solid fusion is a standard surgical option for spinal traumatic and degenerative conditions, yet relief of neurological compression and pain may be considered as a primary aim of surgery. This is especially true in the early postoperative period, in which the clinical outcome of the patient is not dependent on fusion. Moreover, rigid instrumented fixation may provide a favorable environment accompanying the natural healing process of biological progression to ankylosis." In this series, we did not encourage fusion using interbody devices or fusion grafts for arthrodesis. In cases in which expandable screws were placed, we used a trial probe to calculate under fluoroscopy the location of the center of the expansion area of the screw. To achieve the desired screw depth, in all cases decortication of the facets was performed with cutting flutes located on the probe, thus promoting the fusion process around the head of the screws. At final follow-up, fusion of the facets or bridging osteophytes were observed in 9 patients in group I, whereas 6 cases in group II achieved spontaneous fusion after pedicle screw fixation.

Although the lack of arthrodesis may increase and prolong the stress of the bone–screw interface, in our series no instability was detected at the 2-year follow-up. We emphasize that the majority of treated cases were in patients with traumatic injuries.

Spinal fixation in the severely osteoporotic spine represents a challenge, regardless of technique. The pullout and loosening of pedicle screws remains a significant clinical problem in patients with low bone mineral density, leading to a failure rate of 0.6%–11%.13–18

FIG. 5. A 76-year-old man with osteoporosis (T-score −3.3) presented with back pain, neurogenic claudication, and bilateral leg pain. Lumbar MRI showed a listhesis at L4–5. A and B: The patient underwent posterior percutaneous spinal fixation at the L4–5 level with cement-augmented screws and was mobile the day after surgery. Lumbar radiographs showing L4–5 fixation. C: Axial spinal CT image showing the fenestrated cement-augmented screws.

FIG. 4. This 74-year-old woman with osteoporosis (T-score −3.2) presented with neurogenic claudication, difficulty in walking, and intense back pain. Spinal MR images revealed L3–4 spondylolisthesis. A and B: Spinal radiographs showing posterior percutaneous spinal fixation at the L3–4 level with expandable screws. C: Axial spinal CT image showing the expansion of the titanium pedicle screw inside the L3 and L4 vertebral body.
In our study we are the first to describe the clinical and radiological outcomes of elderly patients with osteoporosis who have symptomatic degenerative and traumatic thoracolumbar spinal diseases, and to compare the safety and effectiveness of 2 different surgical percutaneous fixation techniques: expandable screws versus cement-augmented screws.

Previous studies have shown that the stiffness and strength of pedicle screw fixation is increased when the pedicle screw is augmented with cement. \textsuperscript{19–24} Screws with cement augmentation offer a higher resistance to pullout forces compared to the standard screws. \textsuperscript{5,6,8,23–29} Cement leakage is the most common and major complication, with a rate up to 26.2\%. \textsuperscript{28,30–32} Although a higher strength of screw fixation is obtained with a large amount of cement injection, a higher volume of cement leads to an increased risk of cement leakage. This implies that safety and strength of augmentation must be well balanced.

In our series the amount of cement injected to augment each fenestrated pedicle screw was 2–3 mL. We used a high-viscosity cement and we maintained a strict usage of bilateral fluoroscopic control to detect immediately any radiological sign of PMMA extravasation and prevent major neurovascular complications. The viscosity and the timing of cement injection are extremely important. We suggest that a higher viscosity of cement causes less risk of leakage, although it causes a shorter time for injection of PMMA. In our study, the PMMA was not injected until it had a toothpaste-like viscosity. Optimal positioning of the fenestrated screws is mandatory to prevent the risk of cement extravasation. The aim was to place the lateral holes of the fenestrated screw as far as possible from the posterior vertebral wall. In our series the cement, after being injected in the fenestrated screw, was extruded through the fenestrations to fill the spaces inside the middle and anterior osteoporotic vertebral. The postoperative CT scan evaluation in group II patients revealed a cement leakage rate of 4.9\% (4/82 screws). All patients were asymptomatic and in all cases there was only a linear, minor leakage with no sign of neurovascular injury and no leakage into the spinal canal.

No cases of PE were observed. Asymptomatic PE is a known complication of cement injection in spinal surgery. When cement emboli are encountered in an asymptomatic patient, they are probably of no clinical significance and should not alter medical treatment, having no known long-term sequelae. It is questionable if a CT scan that has a higher sensitivity for the detection of PE is justified for screening asymptomatic patients. In our series we did not perform pulmonary CT scans routinely. We performed postoperative chest radiography only in cases of cement leakage, even in asymptomatic patients, and all had normal radiographs.

An alternative surgical technique to improve pedicle screw fixation in the presence of compromised bone is the expandable pedicle screw fixation. \textsuperscript{23,33–35} Compared with the standard screw the fixation strength of the expanded screws is higher, with an increase in the pullout resistance ranging from 20\% to 50\% compared with standard screws. \textsuperscript{21,36–39}

In the Osseoscrew pedicle screw, the expansion mechanism is located between the 2 distal thirds of the screw and it has a radial expansion to 10 mm, with an increase of pullout load by 30\%. \textsuperscript{7} The energy required to cause the ultimate failure of the bone–implant interface is approximately 160\% greater for the expansion screw compared with the standard screw. The expansion of the screw is designed to optimize pedicle fixation, improving the fixation strength by allowing greater bone contact in the vertebral body ventrally to the pedicle insertion. Thus, the location and geometry of the expansion of the screw is extremely beneficial, because 60\% of the pullout strength of a pedicle screw is dependent on the cortical bone of the pedicle itself. \textsuperscript{40,41}

The expandable area of the Osseoscrew locks the screw into the neck of the pedicle, similarly to how a molly bolt is used in drywall. \textsuperscript{7} One limitation of the expandable screws used in this study is their size (diameter ranging from 6.5 mm to 7.5 mm), thus allowing fixation only in the sacrum, and in the lumbar and lower thoracic spine, where the pedicles are well represented. The large diameter of expandable screws may limit their usefulness in vertebrae with small pedicles. In such cases, a more viable option may be the use of cement-augmented screws. In our study, in all cases the size of the pedicles was checked preoperatively on CT images. Percutaneous pedicle screw fixation offers several advantages that help minimize approach-related morbidity, while achieving similar clinical outcome compared to traditional invasive procedures. \textsuperscript{4,9–12} Percutaneous and minimally invasive procedures are associated with a low rate of perioperative blood loss, less postoperative pain, and fast recovery time. In this study, a shorter operative time was found in the expandable screw group, and no differences were found in perioperative blood loss between the 2 groups. The clinical outcome variables showed an average reduction in pain intensity based on the VAS score, from 8.7 to 3.0 at final follow-up, and both groups also had a clinically significant mean change from baseline in ODI. The ODI scores significantly decreased from a mean of 78.4\% preoperatively to 23.8\% at final follow-up in the expandable screw group, and from 77.4\% to 22.9\%, respectively, in the cement-augmented screw group. In our series, no short-term major and minor complications were observed after surgery with either of the techniques. Significant pain relief and good functional results suggested that the percutaneous technique was effective in treating patients with osteoporosis. No cases of functional worsening after surgical treatment were observed.

The screw loosening rate was 5\% in each group, confirming that both expandable and cement-augmented screws can decrease the screw loosening risk, contributing to achievement of better fixation strength in osteoporotic spine at satisfying rates. One limitation of the expandable screw is its removal in revision surgery. Although during primary surgery the screw can be backed out easily, resizing the expansion of the screw with a specific screwdriver, during revision surgeries bone tissue may have already grown inside the expanded screw, and it may not return to its original shape and size. In our case we could resize the loosened screw, removing it easily 3 years after surgery. During revision, the fixation system was reinforced with a cranial elongation of the fixation implant. This was the only reoperation in our series.
One drawback of cement-augmented screws may be eventual revision of the spinal fixation. Removal of a screw presenting rigid interdigitations of cement remnants attached to it and entering in the fenestrations of the pedicle screw may result in large vertebral body defects with limited backup strategies. Although in our study we reported only 1 case with a halo sign around 2 screws inside the cement 3 years after surgery, the patient was asymptomatic and no revision surgery was done. The limitation of this study is the small sample size. The follow-up period was sufficient for evaluating the safety of the 2 surgical procedures as well as the clinical and radiological outcomes, but it was not sufficient to evaluate the effect of osteoporosis on screw pullout in long-term follow-up. To do so, larger series with longer follow-up are necessary; nonetheless, this is the first report comparing cement augmentation versus expandable screws in the treatment of aging patients with osteoporosis treated with a percutaneous technique. Also, our preliminary results can be used as a pilot study in a future meta-analysis.

Conclusions

This study suggests that expandable screws and cement-augmented fenestrated screws are a safe and effective technique in patients with osteoporosis who need posterior thoracic and lumbar spinal fixation. Although the expandable screw method avoids the complications related to cement, these screws come in larger diameters (from 6.5 mm), which may limit their usefulness in cases of small pedicles. Despite the poor bone density of our cases, the increased fixation strength prevented screw pullout: the rate of screw loosening was low, with only 1 patient requiring reoperation. The increase in holding power due to the expansion of the screw or cement augmentation may improve patients’ outcomes and possibly lead to fewer implant-related complications. Both groups of patients had a clinically significant mean improvement from baseline in VAS and ODI scores. Larger series with long-term follow-up randomized controlled trials should be performed to provide more powerful conclusions.

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