Implant related complications in patients operated on with expandable pedicle screws and technical solutions for revision surgery
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RESEARCH

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ABSTRACT

Background
It is reported that expandable pedicle screws are effective and a safer alternative to pedicle screws with cement augmentation application in patients with poor bone quality.

Aims
To study implant related complications associated with expandable pedicle screws application and to propose revision options in case of implant failure.

Methods
A retrospective analysis of a heterogeneous cohort of patients operated on because of traumatic injuries and degenerative diseases of the lumbar spine and thoracolumbar junction was performed. 42 patients with osteopeny or osteoporosis were enrolled, the duration of the follow-up accounted for 18 months. Cases with implant failure (loosening and screw breakage) were registered and revision pedicle screws fixation was performed.

Results
Out of 42 enrolled patients 3 were presented with implant failure (a screw loosening in one case and a screw rupture and loosening in 2 cases). The attempts to remove retained fractured fragments were unsuccessful, therefore, alternative bypass creation and a direct screw placement into a retained fractured fragment were carried out and suggested as an alternative strategy to osteotomy with a fractured screw fragment removal.

Conclusion
In case of rupture, expandable screws have a poor feasibility for a revision pedicle screw fixation because of fractured fragments strong anchorage in bone. The alternative bypass for a revision screw without fractured fragment removal or tapping and direct screw placement into retained expanded fragment of a screw are less invasive alternatives to osteotomy that can help overcome the discussed issue.

Key Words
Pedicle screws fixation, expandable pedicle screws, pedicle screw breakage, revision pedicle screw fixation

What this study adds:
1. What is known about this subject?
Application of expandable screws in patients with poor bone quality is safer than augmentation of screws with bone cement provide while fixation strength of those techniques is comparable.

2. What new information is offered in this study?
Screw breakage is a plausible complication if expandable screws are used; those implants have a poor feasibility for revision surgery.
3. What are the implications for research, policy, or practice?
Rarely discussed complication of technique was pointed out and safe less traumatic solutions were suggested.

**Background**

Osteoporosis is frequently encountered in the elderly population that is described as a generalized disease with a decrease in bone mass and deteriorate in bone architecture, resulting in the decrease of bone strength and increased risk of low energy fractures. Poor bone quality strongly affects the results of surgical interventions and applying pedicle screw fixation, as far as it has been reported, that the rate of pedicle screws loosening can exceed 50 per cent in patients with osteoporosis. Taking into account a great number of interventions that are performed annually in the elderly group of patients with degenerative diseases and traumatic injuries, a high rate of screw loosening may cause a considerable postoperative morbidity and associated deleterious social consequences.

Several options were designed to provide higher stability of pedicle screws in patients with poor bone quality, the most frequently used are bone augmentation with cement and expandable screws. Potential hazards associated with bone cement application for augmentation are frequently discussed in literature; those are intracanal cement leakage, pulmonary embolism, cytotoxicity and poor feasibility for revision surgery. For those reasons, some authors consider the application of expandable screws safer than augmentation of pedicle screws with cement, although the anchorage strength of the former is lower.

The aim of our study is to report rarely discussed implant related complications in patients which are operated on using expandable pedicle screws and to propose revision options in case of implant failure.

**Method**

This is a retrospective analysis of a heterogeneous cohort of patients operated on because of traumatic injuries and degenerative diseases of the lumbar spine and thoracolumbar junction, finally the results of 42 spinal instrumentations were studied. Patients were enrolled during the period from January 2016 till March 2018. This study was approved by IRB committee as far as current study was retrospective, applied interventions and implants were conventional and no additional risks associated with study participation were detected.

The inclusion criteria were:

- Degenerative diseases of the lumbar spine with evident instability of spinal segments.
- Isthmic or degenerative spondylolisthesis grade 1-2.
- Traumatic injuries of the lumbar spine or thoracolumbar junction C, B1, B2, A3, A4 types.
- Osteoporosis or osteopeny confirmed by DXA results.
- The exclusion criteria were:
  - Screw malposition
  - Detected infringement of pedicle screw fixation technology.
  - Patients with tumour lesions
  - Cases with high grade spondylolisthesis

Pedicle screw fixation was used either as a stand-alone technique or in combination with interbody fusion. Perform pedicle screw fixation, the same type of 6, 5 and 7, 5mm diameter polyaxial expandable screws were used (Osseoscrew by Alfatec, 5818 El Camino Real Carlsbad, CA 92008). The expandable screw used in this study consists of three segments: proximal non-expandable standard 15mm segment; in the middle – the expandable 17mm segment and distal non-expandable segment of a various length (Figure 1). Expandable screw consists of an internal core part that provides a mechanism for expansion and prevents breakage and outer component that is expanded. After being expanded, the diameter of the middle segment reaches approximately 10-11mm. Surgical interventions were performed under the control of fluoroscopy, as described in manuscripts by Gazzeri and Vishnubhotla.

The duration of the follow-up period after primary instrumentation accounted for 18 months. Patients were given CT examinations at the period of 6, 12, and 18 months after interventions. Patients with screw loosening and breakage detected on CT images were registered and revision surgery was performed to maintain the stability of affected segments.

**Results**

A heterogeneous group of 42 patients with degenerative diseases or traumatic injuries of the lumbar spine or thoracolumbar junction who underwent spinal instrumentations using expandable pedicle screws was studied. The mean age accounted for 61, 62+1, 52; SD=9,78; 34 out of 42 patients were females (81 per cent). Implant related complications were detected only in 3 cases (7 per cent). All patients presented with osteopenia or osteoporosis, the results of t criterion estimated using DXA were m=2,3738 SD=0,6237. Out of those enrolled one patient was presented with screw loosening only while screw loosening and breakage were detected in other two...
cases (Figure 2). Those complications were detected at the 6-th month of the follow-up period and were associated with the exacerbation of axial pain. Presence of implant failure was confirmed by CT examination.

The revision surgery was administered to provide appropriate stability of the affected spinal segments. The removal of expandable screws was successfully performed only in patients without screw breakage, however, the attempts to make expandable segment collapsed using conventional technique failed. The success in that case can be explained by severe pedicle screw loosening. In other two cases, only core and proximal non-expandable segment of a ruptured screw were extracted. Because of a strong anchorage in the bone, all attempts to remove the remaining fragments with expanded screw segment failed. The following solutions were carried out to perform revision pedicle screws fixation: in one case with screw rupture, an alternative bypass for a screw placement was created without fractured screw segment removal, the results are present on Figure 3a and 3b.

This option was unavailable in the second patient with screw rupture because of the retained fragment firmly anchored in bone close to pedicle. The revision technique used in that case was the following: first, using a tap, a thread was cut in a fractured screw fragment, than a conical screw was introduced directly into the retained fragment of disrupted screw. The final result is presented on Figure 4, the retained expanded fragment looks like a sleeve over screw introduced during revision pedicle screw fixation.

Discussion
Pedicle screws fixation is a frequently used technique to treat spinal pathology that is formed by traumatic injuries and degenerative diseases in hefty majority of cases. The number of surgeries performed annually is still on the rise because of the aging population and growing number of spinal injuries including low energy trauma. It has been proven that poor bone healing with pseudoarthrosis formation and poor bone quality in elderly patients may cause a considerable increase in implant failure rate including pedicle screw breakage and screw loosening.\textsuperscript{3,8,9}

To prevent those complications, pedicle screw augmentation with bone cement and expandable screws were introduced into a clinical practice and it has been reported that expandable screws can provide a 25–50 per cent increase tolerance towards pull out forces applied to pedicle screws.\textsuperscript{4,5,10,11} An additional benefit is that the application of expandable screws seems to be safer because this technology provides the opportunity to get rid of challenges associated with liquid cement injection.\textsuperscript{10}

In a study with a sample of 331 patient it has been shown that implant related complications rate is low if expandable screws are used as far as no screw loosening was detected, while implant breakage accounts for only 2.8 per cent.\textsuperscript{11} According to the results of our study the complication rate was relatively higher forming 7 per cent, however, the design of screws differed from that used in the study by Cook et al.

It has been assumed that expandable screws are easy to remove if a revision surgery is required, however relevant studies were conducted either with screws of another design or just with biomechanical tests ex vivo.\textsuperscript{3,5,11} It is plausible that ingrowth of tissues into expanded segment of screw that may additionally increase the fixation strength was not taken into account. The second issue that can be associated with the expandable screws is that a stronger anchorage in bone will not prevent screw breakage completely because of metal fatigue. According to our experience it is supposed that the weakest part of screws used in this study is a junction of expandable and proximal non expendable screw segments. The attempts to remove distal fragments of fractured screws turned out impossible without osteotomy because of firm anchorage in bone that is almost challenging if revision pedicle screw fixation is required. The suggested and successively executed less invasive strategies were the creation an alternative bypass for a revision screw without fragment removal or tapping and direct screw placement into retained expanded fragment of a screw.

Limitations: The level of evidence of our work is limited, however, it points out challenging a complication that is associated with expandable screws application. On the other hand, the reported technical notes might help to overcome poor feasibility for revision surgery of expandable screws.

Conclusion
In case of rupture, expandable screws have a poor feasibility for a revision pedicle screw fixation because of fractured fragments strong anchorage in bone. The alternative bypass for a revision screw without fractured fragment removal or tapping and direct screw placement into retained expanded fragment of a screw are less invasive alternatives to osteotomy that can help overcome the discussed issue.
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Figure 2: CT axial images of a vertebra, radiolucent zone with double halo sign around the screw is evident, also screw breakage is detected.

Figure 3a: CT image of a lumbar spine in a frontal plane.

Figure 3b: CT image of a lumbar spine in a sagittal plane. Creating an alternative bypass a screw was introduced without removal of a fractured fragment.

Figure 4: CT image in axial plane, conical screws introduced into retained fragments of expandable screws.