Learning curve and cement leakage after use of a cement augmented pedicle screw.
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INTRODUCTION

Pedicle screws are used for fixation of spine implants for dorsal instrumentation. In some cases (osteoporotic bone, tumor) the use of pedicle screws alone is limited, since it is likely to come to a loosening. Cannulated screws seem to be the better hardware for facilitating augmentation with cement and instrumentation in osteoporotic spine. However, clinical reports using such screws are rare.

In our clinic we use for dorsal spine instrumentation a cannulated pedicle screw fabricated with side openings leading to the cannulated part of the screw (Biomet®, Omega 21®). The purpose of this study was to classify the patterns of cement leakage occurred after pedicle screw instrumentation and cement injection through the implant. Moreover, we examined the rate of cement leakage before and after completion of learning curve. Finally, the subjective clinical outcome by means of visual analogue scale (VAS) and Oswestry Disability Index (ODI) was evaluated.

METHODS

A total of 114 patients [82 female, 32 male, mean age 77.2 (57–92) years] with osteoporotic compression/burst fracture, spinal stenosis, or spinal tumor metastasis underwent spine instrumentation and instrumentation with cement augmentation of pedicle screw from March 2005 to January 2009. The location of lesion was lumbar spine for 60 patients, thoracolumbar junction for 42 patients, and lower thoracic spine for 12 patients. The mean T-score was -2.8 (-2.1 to -4.3).

Posterior midline approach was used for all patients. After preparing the pedicle screw tract, pedicle screws were inserted on minimum one level from above and below of the lesion. PMMA Cement was injected with 1ml-syringes. The diameter of the screw was 6.35 mm and the length of the screw was 45 to 55 mm. Osteopal V® (Biomet, Germany) PMMA bone cement powder was prepared, mixed and injected in its toothpaste like phase according to instructions. A total cement volume of three to four milliliters of cement were then injected through the screws. However, if under fluoroscopy control a cement leakage was detected the amount of cement was decreased in order to avoid further cement leakage.

After 6 months a CT scan was performed for precise radiological evaluation of the construct.

Using the CT scan performed after 6 months postoperative analysis was undertaken by two independent radiologists who classified the patterns of cement leakage according to Yeom et al. [Yeom 2003] in types B, S and C. Type B is a leakage via the basivertebral vein, type S via the segmental vein and type C through a cortical defect.

The preoperative and postoperative visual analog scale (VAS) for pain and Oswestry low back disability questionnaire (ODI) were used for the assessment of pain and function and analyzed with paired t-test. The rates comparison before and after completion of the learning curve was performed with z-test. Statistical significance level was defined as p<0.05.

RESULTS

We used 484 cannulated screws and evaluated 269 vertebrae (VT). The first 97 were used in 54 vertebrae. 35(65 %) vertebrae showed cement leakage. 28(80 %) of them showed a type S leak (segmental veins), 9(26 %) VT a type B leak (basivertebral vein) and 5(14 %) VT showed a type C leakage (cortical cleft). After that 387 screws were used on 215 vertebrae. 123(67 %) of them showed a type S leak, 94(52 %) VT a type B leak and 42(22 %) showed a type C leakage. During the hospital stay and the first 2 to 14 months after operation we did not see a loosening of the pedicle screws. Before completion of the learning curve 65% of the instrumented VT showed a cement leakage. After achieving the end of the learning curve 63% of the segmented vertebra showed a leakage. Type B and Type C leakage were significantly decreased after completion of the learning curve (p<0.05). From the first 97 cannulated screws 18 (18.5%) had a length of 40 mm, 60 (61.8%) a length of 45 mm and 19 (19.5%) a length of 50 mm. 206 (53%) of the next 387 screws had a length of 50 mm, 88 (23%) a length of 45 mm and 93 (24%) a length of 55mm. Before completion of the learning curve the longest possible distance (screw insertion point to ventral wall – Figure 6) was occupied in an average of 68% and after completion of the learning curve 82% of this distance was occupied by pedicle screw.

The ODI scale improved from 80.3% before surgery to 33.8% after surgery, and the VAS improved from 9.3 to 2.8. Six screws (1.2%) showed a malposition without clinical consequences. One neurological L5 root deficiency was temporary and not correlated to a cement leakage.

DISCUSSION

Many possibilities exist for augmentation of pedicle screw such as adding lamina hook on upper and/or lower end of the construct, using larger diameter pedicle screw, adding segments of instrumentation, and using cement in patients with osteoporosis. The most concerning issue of cement augmentation probably is cement leakage with spinal cord and nerve compression. Purpose of this study was to classify cement leakage after using a cement augmentable cannulated screw and report the effect of the learning curve on implant choice and cement leakage.

In the present study we use a cannulated screw with four side openings, a pair of oval formed side openings distally placed and a pair of round formed side openings proximally placed (Biomet, Germany). These pairs are shifted 90° to each other.

The optimal cement amount for augmentation of each pedicle screw is not known. However, both safety and strength of augmentation must be balanced. Theoretically, the higher strength of screw fixation correlates with the larger amount of injected cement, but this may have higher risk of cement leakage. According to experimental studies the amount of various cement injection was 1 to 3 ml and the increase of pull out strength was somewhere between 147% and 300%.

In the present study three to four milliliters of cement for each vertebrae was injected. Although the direct injection method with cement amount of 1.5 to 2 ml for each pedicle is safe, fluoroscope monitoring during the cement injection is suggested to avoid major cement leakage. While Type B leakage is contained in the epidural veins, there is no barrier in type C and the cement can extend without restriction. In addition, it is presumed that if a type C leak entrap a nerve root and proceeds into the spinal canal, the dura and its contents will also be involved because of a decreased mobility. Thus a type C leak into the spinal canal can be much more dangerous than a type B leak. Type C leakage into the spinal canal may occur as a result of either a pre-existing defect such as fracture gap or a defect produced during dilatation of the pedicle tract. Apparently, by placing the cement dough in the ventral third of the vertebra Type B and Type C leakage could be avoided. Type S leakage could not be reduced after completion of the learning curve. This is due to the fact that during cement injection lateral fluoroscopy views are used, thus deteriorating the possibility of detecting such leaks. This type of leakage could cause embolism because the segmental veins directly contact the large veins. Although there were no cases of symptomatic pulmonary embolism associated with such leakage type further clinical studies are required.

Limitation of the study is that the delivery pressure was not measured but according to other studies it could not exceed 1.7 MPa which can be achieved in case of vertebroplasty after cement hardening. As far as the application method is concerned the internal diameter of the syringe is twice the diameter of the central screw cannula. Baroud et al. showed that increasing the internal diameter of the syringe by any more than twice its distal internal diameter would contribute only minimally toward reducing the delivery pressure. In conclusion, cement augmentable cannulated screws offer a safe cement augmentation technique through the implant. Although cement leakage is comparable to cement leakage after vertebroplasty, dangerous types of leakage could be avoided after completion of learning curve. This study suggests that learning of the technique is not as difficult, is practical for osteoporotic patients who need spinal instrumentation and is recommended as a promising option for osteoporotic spinal instrumentation.