INTRODUCTION. Recurrent kyphosis is a complication after operative treatment of thoracolumbar compression type fractures. Patients in whom this treatment failed are characterized by a narrowing of the intervertebral disc space inferior or superior to the fractured vertebra. Recent studies demonstrated that the narrowing is a result of the disc creeping into a central depression of the fractured bony end plate, rather than degeneration of the disc itself. Thus, when the disc containing tissues are damaged by a vertebral compression type fracture, the disc will redistribute into the deformed disc space. Common posterior restoration and fixation techniques are based upon indirect reposition, and result mainly in restoration of the periphery of the fractured vertebra. It was hypothesized that a direct reposition of the central part of the impressed end plate(s) would result in better containment of the disc space, and thus reduce the risk of recurrent kyphosis. The purpose of the current study was to investigate in human cadaveric spines whether a direct transpedicular reconstruction of a traumatic thoracolumbar compression type fracture can be performed using an Inflatable Bone Tamp and subsequent augmentation of the defect with an injectable calcium phosphate cement. The main questions are whether the method will result in a decrease of the impressed central area of a fractured end plate, and whether the method is safe with respect to the risk of displacement of the vertebral body walls.

MATERIALS AND METHODS. A total of 12 osteoligamentous hemic-spines, 4-6 vertebrae in length, were carefully prepared out of the lumbar or lower thoracic regions of 7 male human cadavers (55-77 years). There was no radiographic evidence of previous fracture, severe osteoporosis, tumor metastasis, or infection. The proximal and distal segments of each specimen were casted in a PVC cup using polyurethane foam, leaving 1-2 motion segments free, and mounted in cylindrical proximal and distal metal holders. Compression type fractures were created using a specially designed device, in which a mass of 10-25 kg is dropped from a distance of 150 cm onto the proximal holder. Routine posterior fracture reduction and fixation with a titanium pedicle screw and rod system (Stryker-Howmedica) was performed. Next, the fractured vertebral body was entered through both pedicles, and Inflatable Bone Tamps (one on each side, Kyphon Inc.) were inserted and positioned in the corpus. Both balloons were gradually inflated to restore the corpus and the disc supporting proximal endplate, and subsequently deflated and retracted. The resulting cavity was augmented through both pedicles by injection of a resorbable calcium phosphate cement, 10 g mixed in 3 ml saline (BoneSource®, Stryker-Howmedica). An experienced spinal surgeon performed all surgical procedures under fluoroscopic control. Injection of the cement was stopped when radiographically the complete defect was filled. Plain AP and lateral radiographs, and sagittal MR images (Philips Gyroscan, T2 and TSE weighted images) were made at three time points: after creation of the fractures (t0), after placement of the posterior fixation device (t1), and after injection of the cement (t2). At t0, the fractures were classified using the AO classification scheme according to Magnel.1 All MRI’s were digitized, blinded, and the following parameters were measured on two mid-sagittal sections of each specimen: anterior bulging (AB) and posterior bulging (PB) of the anterior and posterior vertebral body walls, and the impression of the proximal (PI) or distal (DI) end-plates. Since the main purpose was to study the additional effects of the Inflatable Bone Tamp and augmentation procedure (t2) as compared with routine posterior fracture reduction and fixation (t1), a single-tailed paired t-test was performed for AB, PB, PI and DI at t1 and t2 (p<0.05).

RESULTS. In the 12 spine segments, a total of 14 fractures were created, classified as A1 (2x), A2 (2x), A3 (9x), and C1 (1x). In all fractures, the bone tamp procedure was performed without complications. Subsequent injection of the CaP bone cement resulted in radiographic filling of the vertebral defect without leakage of the cement outside the vertebral body. The maximum pressure in the balloons varied between 50 and 175 psi (mean 105 psi), and the total weight of CaP cement injected in the corpora varied between 12.5 and 22.1 g (mean 17.2 g). For the individual measurements, in 6/14 fractures AB showed an increase, which was in two cases more than 1 mm (2.8 and 1.6 mm respectively). In 4/14 fractures, PB increased, but this was never more than 1.0 mm (0.1, 0.2, 0.4 and 1.0 mm respectively). In table 1, the results from the MRI measurements are summarized. There were no statistically significant differences between t1 and t2 for the AB, PB and DI. However, the decrease in proximal impression of the end-plate (PI), which ranged from −0.8 to 3.7 mm, was significantly different (p<0.013) as a result of the procedure.

DISCUSSION. We investigated a new technique for direct restoration of a non-osteoporotic compression type fracture of the thoracolumbar spine. With the Inflatable Bone Tamps, a defect was created that could easily be augmented by injection of a CaP bone cement, without pressurizing the cement. This may reduce the risk of a fausse route or of leakage of the cement, and thus reduce the risk of iatrogenic damage to surrounding structures, such as the spinal cord. We indeed did not find radiographic evidence of unforeseen localization of the cement. In the current study, 10 out of 14 fractures were “real” burst fractures with involvement of the anterior and posterior wall. However, the procedure did not result in significant displacement of the anterior or posterior wall. Since the consequences of damage to surrounding structures can be very serious, analysis of individual translations is required, especially for the posterior wall, where we measured in one case only a minimal posterior displacement of 1.0 mm. In addition, we measured a significant decrease in impression of the proximal end plate, which, in combination with the augmentation of the underlying defect, creates optimal conditions for the fracture to heal in its restored shape. In clinical patients, it usually takes 1-2 years until a posterior fracture fixation device is removed, thus during this period the augmented defect with the CaP bone cement will not be (fully) load bearing. Although in vivo studies have suggested complete remodeling of the bone cement during a course of approximately one year, it should be realized that the current study is an in vitro cadaveric study. Dedicated in vivo studies need to demonstrate the load bearing capabilities of a (partially) remodeled defect after removal of the posterior fixation device at 1-2 years post surgery.

References

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