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ORIGINAL STUDY

Preliminary results with modified techniques of balloon kyphoplasty for vertebra plana, traumatic fractures and neoplasms

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Percutaneous vertebroplasty and balloon kyphoplasty are less invasive treatment options than open surgery for patients with vertebral compression fractures. With balloon kyphoplasty, the injection of bone cement is preceded by inflation and removal of bone tamps (balloons) inside the fractured vertebral body. This allows for the creation of a void, where viscous cement is delivered resulting in a lower risk for cement leakage than with vertebroplasty. Another advantage of the balloon inflation is the potential to correct the deformity and restore sagittal alignment. The percutaneous techniques normally require intact pedicles and intact posterior elements. We found that modifying the technique made it suitable for the management of vertebra plana, traumatic fractures, and neoplasms. Our study documents the different modified techniques and the clinical results obtained within the first 21 patients.

Keywords : kyphoplasty ; tumour ; trauma ; vertebral fractures ; osteoporosis.

INTRODUCTION

The management of vertebral compression fractures includes pain management, rehabilitation and prevention of subsequent fractures (*14*). Open surgical approaches have been considered for patients with a neurological deficit, but these are associated with increased risk (*10*). Percutaneous vertebroplasty and balloon kyphoplasty are less invasive and can be performed in an ambulatory setting for some patients. With balloon kyphoplasty, the injection of bone cement is preceded by inflation of bone tamps (balloons) inside the fractured vertebral body and their subsequent removal. This allows for the creation of a void, where viscous bone cement is delivered resulting in a lower risk for cement leakage. Cement selection is important. High radio-opacity and viscosity are required to allow for monitoring and to minimise the risk of leakage (*1*).

Balloon kyphoplasty offers the potential for restoration of lost vertebral height and sagittal alignment, although this was not evaluated in this study. Transpedicular balloon kyphoplasty has been reported at lumbar and lower thoracic levels using a bilateral transpedicular approach and usually a 20-mm bone tamp, while at the higher thoracic levels the extrapedicular approach and a 15-mm bone tamp is recommended. The selection of the

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Table I. — Patients treated with an adapted technique : details and evolution

Advanced indication	Number patients	Mean age	Nr of VF	VAS intake	VAS 2d	VAS 6 weeks	PCS pre	PCS post	MCS pre	MCS post
Stenosis, open kypho + decompression group	5	65	7	7.1	7	3	22.9	32.5	32	47
Endoscopic	2*	53	2	4	3	2	36.9	29.7	29.8	36.7
Vertebra plana	4	74	4	7	2	2.5	27.9	35.2	37.7	48.2
Posterior wall	4	71.5	4	7.25	2	2.5	32.6	33.5	42.8	47.6
Unilateral Approach	4	70	4	6.5	2.5	2	20.8	31.5	23.3	41.8
Extrapedicular Approach	2	75	2	6	2.5	2	21.6	29.2	29.6	36.4

* Twice the same patient.
VF = vertebral fractures ; PCS = physical component summary ; MCS = mental component summary.

balloon size depends on the size of the vertebral body. Because of the percutaneous approach, the indications were limited to osteoporotic fractures and osteolytic vertebral lesions (*2, 6, 8, 11*). Intact posterior elements are essential because balloon kyphoplasty stabilises only the anterior column. Likewise, a transpedicular approach requires intact pedicles, which is not always the case in patients with metastatic lesions. The transpedicular approach may also be problematic in patients with severe scoliosis (i.e., vertebral rotation of greater than Grade 2 Nash/Moe (*5*)) where the pedicle on the convex side is excessively rotated.

Nonoperative treatment of an osteoporotic fracture may lead to into vertebra plana within a few weeks (*15*). Because of the diminished vertebral height, vertebra plana has generally been considered a contraindication for balloon kyphoplasty or vertebroplasty (*15*).

However, we found that by modifying the approach, the balloon kyphoplasty technique can be considered suitable for the treatment of vertebra plana, traumatic fractures, and neoplasms in selected cases.

Our study describes the modified techniques and the clinical results obtained with the first 21 patients.

MATERIALS AND METHODS

We retrospectively reviewed the records of 86 patients with 162 balloon kyphoplasties performed in 2002 and 2003. Twenty-three procedures in 23 patients (14%) were done with one of the modified techniques (table I). Twenty one patients were followed in our hospital. During the same period, we treated and followed-up 46 patients with a conventional technique. A multidisciplinary team screened patients presenting to our institution with vertebral body fracture (VBF) for possible balloon kyphoplasty treatment. The technique used was selected according to the specific patient's problem.

Procedure for fractures with a posterior wall defect

Fractures with a posterior wall defect are generally not treated with balloon kyphoplasty because of the risk of posterior wall failure and cement leakage. In patients with a posterior wall defect without neurological deficit, smaller balloons than recommended for the standard balloon kyphoplasty were used in order to ensure anterior positioning and to avoid pressure over the posterior part of the vertebral body. In practice at the lumbar level up to Th10, a 15-mm balloon was used instead of a 20-mm one, and at the thoracic level a 10-mm balloon instead of a 15-mm one was used (fig 1). Initially, an intraoperative myelogram was performed in addition to the standard use of the image intensifier, to detect a possible pathway for cement leak. No leaks were observed, and intraoperative myelogram was frequently omitted in subsequent cases.

Procedure for patients with a neurological deficit

In patients with a neurological deficit, compression of the spinal canal, or Type B and Type C fractures according to the AO classification (*13*), a combination of open decompression, posterior stabilisation, and open balloon kyphoplasty was performed (fig 2). Open decompression and internal fixation was done through a midline

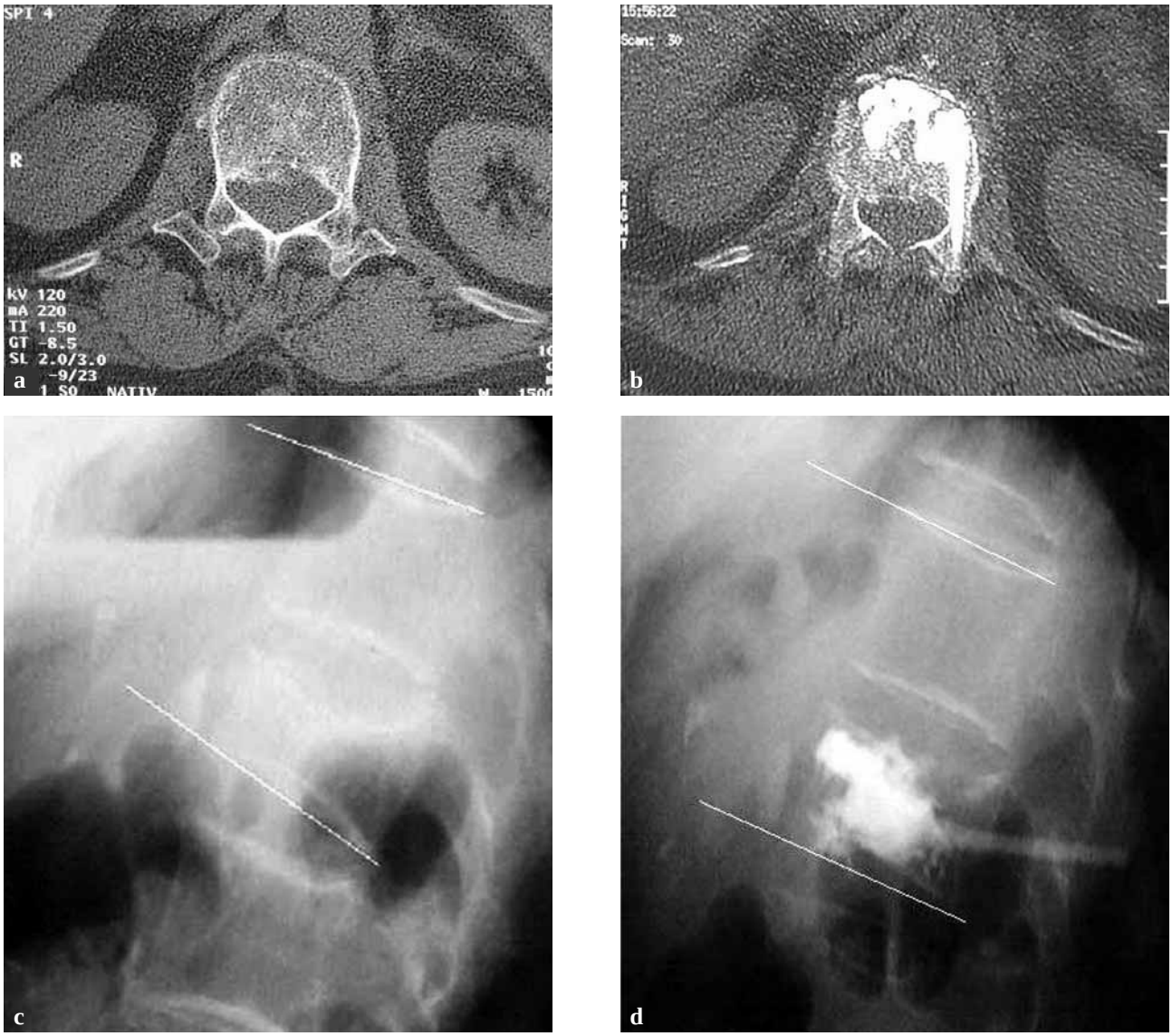

Fig. 1. — Female, 79 y, L1 # type A3.1.1 (after AO/ASIF) with posterior wall defect : (a) preoperative CT ; (b) postoperative CT, posterior wall remains unchanged, kyphoplasty with 15-mm balloons placed anteriorly ; (c) Preoperative radiograph ; (d) Postoperative radiograph shows reduction of fracture, note accidental PMMA in pedicle due to premature removal of working channel. We observed no clinical consequence.

skin incision centered over the spinous process of the fractured vertebra as generally recommended. The balloon kyphoplasty technique was performed as described above. Open decompression using a microscopic technique was always performed. After internal fixation, an attempt to reduce the fracture was made, with special attention to avoid screw loosening in osteoporotic vertebrae. Balloon kyphoplasty was performed under direct microscopic visualisation and cement injection (KyphX®-HVR™, Kyphon, Sunnyvale, USA) was closely monitored. After mixing, cement was left to harden for 8 minutes prior to injection. A prophylactic dorsolateral Wiltse fusion (*21*) with autologous bone graft and tri-calcium-phosphate (TCP) (fig 2d) was always done because of the risk of screw loosening in non-cemented vertebrae (*16*).

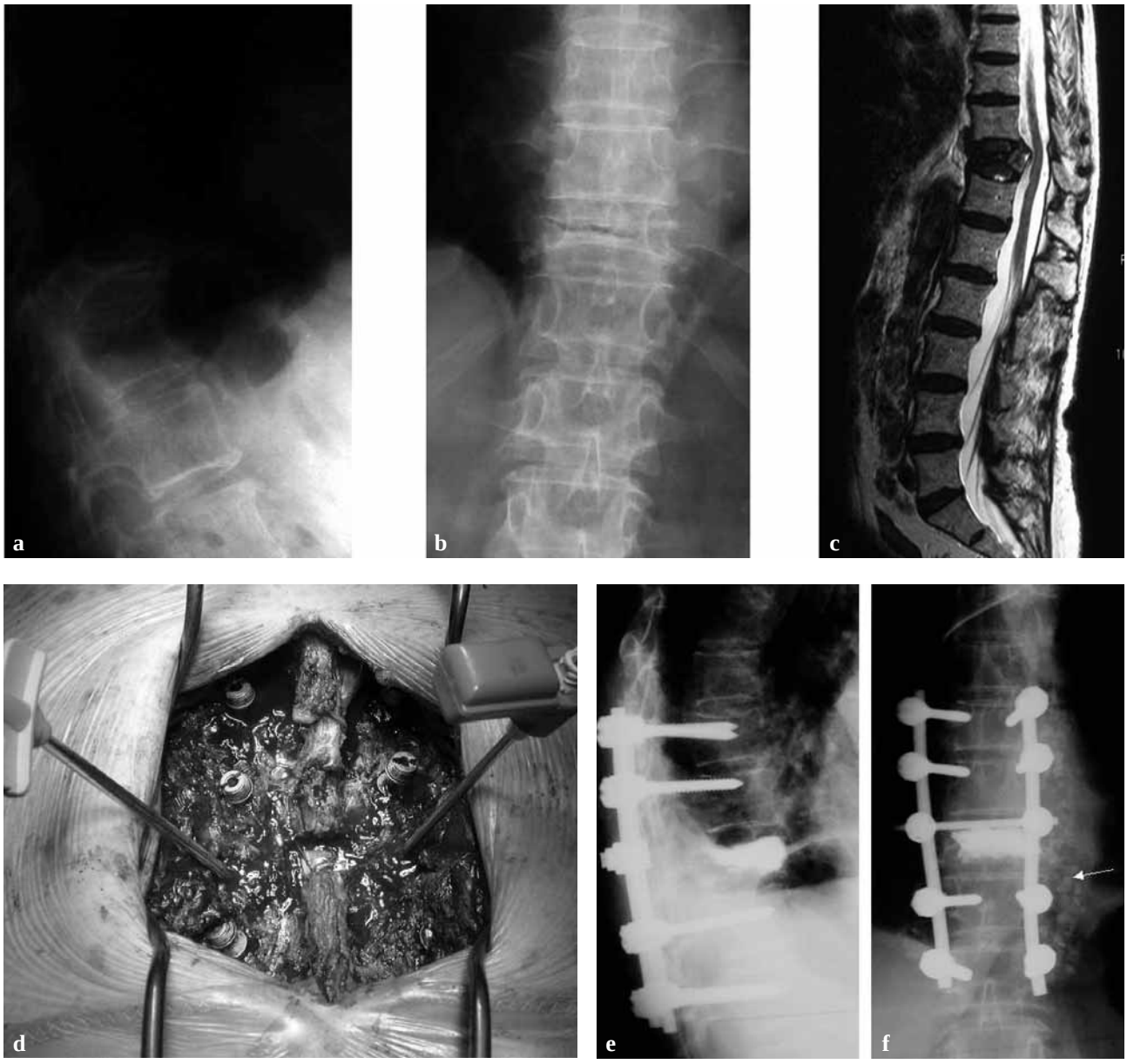

Fig. 2. — Female, 89 years, 6 weeks after sudden onset of pain, Th11 # (vertebra plana) : (a) lateral radiograph ; (b) AP radiograph ; (c) MRI shows protrusion of posterior wall into spinal canal with deviation of spinal cord ; (d) Intraoperative picture – open decompression / kyphoplasty and instrumentation, working channel in place (left), Jamshidi needle in place (right), dura visible, adjacent vertebrae with transpedicular screws ; (e) lateral postoperative radiograph ; (f) AP postoperative radiograph after open decompression / kyphoplasty and instrumentation with autologous / synthetic β-tri-calcium-phosphate (ChronOS™, Synthes, USA) bone graft transplantation (arrow).

Procedure for vertebrae with metastases and non-intact pedicles

In vertebrae with metastases involving one pedicle, and for patients with severe scoliosis, a 20-mm balloon was introduced unilaterally through the intact pedicle. The desired convergence induced by the balloon inflation was strictly controlled. If both pedicles of the lumbar vertebrae were destroyed, an extrapedicular approach was used. In this approach it was deemed important not to use an extrapedicular inferior approach, which could put the nerve root at risk ; the introducer

was positioned superior to the pedicle and angled downward.

In severe thoracic deformities, tumours, or in cases with previous dorsal surgery with destroyed or distorted anatomy, an anterior endoscopic balloon kyphoplasty was performed. A single 15-mm balloon was placed just above the segmental vertebral vessels. The balloon could be inserted under direct vision into the vertebra. The portals of the endoscope were chosen according to the generally accepted techniques for thoracoscopic approach (*12*), but special attention was paid to the orientation and localisation of the portals in order to reach the desired vertebra.

Because of the approach to the vertebrae, the length of the working channel delivered with the balloon kyphoplasty set may be too short. The length of the bone tamp is however sufficient. Therefore we developed, especially for use in obese patients, a cement injection device with a handle and a longer working channel.

The indication for balloon kyphoplasty in vertebra plana depended on the size of the pedicles, the kyphosis developed after the fracture, and the time interval after fracture. When kyphotic deformity was present, a prophylactic balloon kyphoplasty at the adjacent level, generally the superior level, was performed. In recent fractures (less than 4 months prior to consultation) a balloon kyphoplasty at the fractured level was also attempted (fig 3). An advanced stage of bone collapse and vertebral body deformation requires the use of small balloons (e.g., 15 mm). In these patients a lower approach was used (e.g., at 7-8 o'clock, 3-4 o'clock position) compared to the conventional technique (10-11 o'clock and 1-2 o'clock position). This approach could only be used in larger pedicles. If the pedicles were less than 4-5 mm in diameter or were rotated, balloon kyphoplasty was considered to be contra-indicated. The drill/bone filler had to be positioned exactly in the middle of the vertebra. The reduction of the fracture in patients with vertebra plana was generally limited to restoring the height of the posterior wall, to avoid overcorrection. In case of overcorrection, a stabilising balloon kyphoplasty of both adjacent levels is proposed to avoid any postoperative fracture risk. In patients with severe bony protrusion into the spinal canal, an additional open decompression and stabilisation may be necessary (fig 2).

Pain intensity was measured with the visual analogue scale (VAS) preoperatively, 2 days postoperatively, and 6 weeks after the intervention. The short form 36 (SF-36) questionnaire was filled out preoperatively and at 6 weeks postoperatively. Time to mobilisation and to discharge from the hospital was documented.

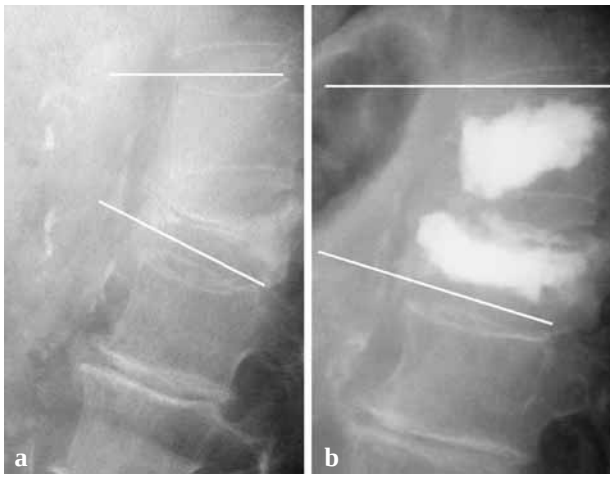

Fig. 3. — Female, 80 years, L1#, 4 months old, vertebra plana : (a) Preoperative radiograph ; (b) Postoperative result after kyphoplasty L1 and prophylactic kyphoplasty Th12.

RESULTS

All but one patient (who presented preoperatively with incomplete paraplegia after a burst fracture) were mobilised on the day following the procedure. Patients with classic indications were discharged 2-3 days postoperatively. Patients with an indication for the modified technique stayed in the hospital for 7-14 days postoperatively.

The VAS in the conventional group (n = 46) decreased by 4.8 points (from 7 to 2.2 points) two days after the procedure, and by an additional 0.6 point (from 2.2 to 1.6 points) between two days and 6 weeks after the intervention. A similar decrease in pain intensity was observed in patients who underwent a modified procedure. The pain reduction was somewhat slower in the group that underwent open balloon kyphoplasty and decompression (table I).

Overall, the SF-36 score improved in both groups (conventional group : physical component summary [PCS] : 30.4 preoperatively, 34.9 six weeks postoperatively ; mental component summary [MCS] : 25.9 preoperatively, 29.5 six weeks postoperatively ; modified group see table I). We corrected the deformity in vertebra plana in three of the four patients (fig 3). No complications were seen intra-operatively and postoperatively.

DISCUSSION

In our institution, we adapted the standard balloon kyphoplasty technique to make it usable in vertebra plana, traumatic fractures and neoplasms. During the observation period, only 14% of the procedures needed to be done with one of these adapted techniques. Patients experienced a similar degree of pain reduction as those treated with the standard technique, although the onset of pain reduction seemed to be somewhat slower, mainly because the group contained patients treated with open surgery.

Since balloon kyphoplasty has only recently been described for minimally invasive stabilisation of vertebral defects (*11, 20*), the follow-up periods are limited to 1-2 years (*6, 18*). The reports on side effects and complications suggest a lower risk for cement leakage with balloon kyphoplasty than with vertebroplasty, with a consequent reduced risk of neurotoxicity (*7, 16-18*).

Balloon kyphoplasty has been traditionally performed using the transpedicular approach of vertebral compression fracture between Th10 (Th12) to L5. The extrapedicular approach has been indicated for vertebral compression fractures between Th7 and Th10 (Th12). However, this approach cannot be used in some patients. For such patients, the modified techniques offer a less invasive alternative to open surgery.

In our series, the hospital stay was longer for patients treated with the modified technique compared to the patients treated with the extrapedicular technique (*7*). This could be attributed to the additional internal fixation and the combination with a more invasive approach.

We used polymethylmethacrylate (PMMA) cement in all patients. PMMA has been proven effective and safe in vertebroplasty (*16*) ; however, its use has generally been limited to older patients. The importance of cement viscosity with respect to leakage has been demonstrated (*3*).

Balloon kyphoplasty offers considerable advantages compared to the anterior or anterior-posterior approaches. Since our goal was achieving stabilisation, balloon kyphoplasty should not be used in patients with such unstable injuries as those with disc disruption after severe burst fracture, or rotational injuries.

The technique for fractures AO - type A 1-3 with posterior wall defect has been described (*4*). We used a smaller balloon for reduction. An internal fixation should be added for patients with dorsal ligament instability. Balloon kyphoplasty should be limited to type A1, A2, A3.1, and A3.2 fractures (e.g., fractures without gross damage to the disc). As shown in our series and in the literature (*4*), open balloon kyphoplasty was a safe method for fractures with posterior wall defect.

In patients with tumours, the limitations were bone visibility and the need to have at least one intact pedicle. In endoscopic anterior techniques, the limitations resulted from general contraindications of endoscopy, such as limited experience, previous thoracic surgery, and difficulty with single lung ventilation (*9*).

Balloon kyphoplasty was generally difficult to perform in patients with vertebra plana, and it is important to recognise the limits of the technique (size of pedicles and age of fracture). If the pedicles do not permit a safe transpedicular approach, we advise an extrapedicular approach. If it is not possible to position the balloon properly, there is a risk of injuring adjacent tissues and structures. In vertebra plana and certainly in older fractures it is almost impossible to restore the vertebral body height to such extent that the pressure on the adjacent level is brought back to levels that do not cause an increased risk for adjacent fractures. Furthermore, the risk of fracturing an endplate is increased in those patients. In the literature, we did not find any biomechanical evaluation of whether the upper or lower vertebra adjacent to the kyphoplasty was under increased biomechanical stress, so we decided to stabilise the upper vertebra. Stabilising this vertebra acted as a counter lever against which the balloon could enact pressure without fracturing the upper vertebra. The selection of balloon kyphoplasty for prophylactic stabilisation of adjacent segments is justified by the fact that it seems to be safer than vertebroplasty because of the lower leakage risk (*19*). Although we achieved limited reduction, we still preferred a balloon kyphoplasty to a vertebroplasty because some

authors report fewer complications than with vertebroplasty (*2, 8, 10, 11*).

Our technique could eventually lead to using balloon kyphoplasty for a larger group of patients. Use of PMMA cement limits the technique to older patients. Future developments with resorbable bone cement should enable our technique to be used in younger patients. Our technique requires a thorough anatomical knowledge and substantial surgical experience to limit operation time and minimise complications. If those conditions are not met, an open technique with either anterior, anteroposterior, or posterior stabilisation may be considered.

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