Clinical, radiological, and patient-reported outcomes 13 years after pedicle screw fixation with balloon-assisted endplate reduction and cement injection

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Abstract

Purpose In management of traumatic thoracolumbar burst fractures, short-segment pedicle screw fixation with balloon-assisted endplate reduction (BAER) and cement injection is a safe, feasible, and effective technique to maintain radiological alignment with minimum spinal segments involved. However, 20% of patients report daily discomfort despite good spinal alignment and fusion after this technique. This study provides clinical, radiological, and patient-reported outcomes after a minimum 13 years of follow-up.

Methods Eighteen patients were invited at the outpatient clinic for clinical/radiological examinations. The cohort (originally 20 patients) was treated 13–14 years earlier with pedicle screw fixation, BAER, and cement injection for traumatic thoracolumbar burst fractures. Patient-reported outcome measures were obtained at time of examinations. Current data were compared with data obtained at 6 years of follow-up.

Results Seventeen patients (median age 50; range 32–80) cooperated. No/minimal back pain was reported by 15 patients, and 12 patients returned to their previous heavy labor work. Median visual analog score of health (80%; 50–100%) was similar to results at 6 years (80%; 60–100% $p = 0.259$). An Oswestry Disability Index score of less than 20% (reflecting minimal disability) was reported by 14 patients, compared with 15 patients at 6 years of follow-up. No significant differences were found in wedge or Cobb angle between the time points. Intravertebral cement resorption was not observed.

Conclusion Results from this study suggest that, 13 years after pedicle screw fixation with BAER and cement injection for traumatic thoracolumbar burst fractures, functional performance, pain and radiological outcomes of the current cohort were stable or had slightly improved.

Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.

Key points

1. Short-segment pedicle screw fixation with balloon assisted endplate reduction for thoracolumbar burst fractures is safe and feasible.
2. Neurologically intact & minimal residual deformity at 6 year follow-up.
3. Unfortunately: 1 in 5 report daily discomfort at 6 year follow-up.
4. Lack of longer follow-up, therefore follow-up of > 13 years is presented!

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Take Home Messages

13 years after short segment pedicle screw fixation with balloon assisted endplate reduction for thoracolumbar burst fractures:

1. Good functionality of patients
2. No/minimal pain reported by patients
3. Unchanged radiological outcomes

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Keywords Long-term follow-up · Burst fracture · Patient outcome · Thoracolumbar fracture · Balloon-assisted endplate reduction

Introduction

Traumatic thoracolumbar burst fractures (AO type A3/A4, previously A3.1 and A3.3) are the result of sudden forceful axial compression of the spine [1]. The fractured endplate(s), widening of the distance between pedicles and retropulsion of bone into the spinal canal, can create an unstable two-column fracture with concurrent risk of kyphosis and potentially symptomatic compression of the spinal cord or cauda equina [1, 2]. The current management of thoracolumbar burst fractures includes conservative and operative treatment strategies. Operative treatment usually consists of anterior vertebral body fixation, posterior pedicle screw fixation, or a combination of both [3, 4]. Balloon-assisted endplate reduction (BAER) with injection of an intravertebral bone void filler, for example, calcium phosphate cement (CPC), has been developed as an adjunct to posterior pedicle screw fixation to prevent intrusion of the intervertebral disc through the fractured endplates into the vertebral body by restoring the anatomical boundaries of the adjacent disc space(s) [5, 6]. The intention of this procedure is to increase the load-bearing capacity of the anterior column, thereby limiting the risk of implant failure and subsequent loss of spinal alignment, while minimizing the number of segments necessary for sufficient posterior fixation [1, 7]. This treatment has been shown to be safe, feasible, and effective for patients with thoracolumbar burst fractures [5, 8]. A recent study reporting on the mid-term follow-up of this technique demonstrated satisfactory clinical and radiological outcomes with a low prevalence of secondary surgical procedures [6].

In the long term, patients with traumatic thoracolumbar burst fractures may, regardless of successful initial treatment, experience persisting local or lower back pain and/or impaired functioning [9]. In some cases, this undesired outcome could be related to posttraumatic local residual kyphosis which subsequently may require a secondary intervention, often an osteotomy to correct this deformity and maintain spinal balance [1, 6, 9]. After 6 years of follow-up, 20% of patients previously treated with pedicle screw fixation and BAER reported daily discomfort not obviously related to spinal alignment, fusion or other known factors [3, 6].

The optimal treatment of thoracolumbar burst fractures is, despite numerous publications on this topic, not yet known, also because clinical, radiological, and patient-reported outcomes have rarely been published beyond a follow-up period of 2–6 years [3, 4, 10]. As patients with traumatic

burst fractures tend to be young (with a mean age of 30–45 years typically), long-term follow-up is necessary to assess the effects of the treatment initially administered [11].

The aim of the current study was to present the longer-term results by assessing clinical, patient-reported, and radiological outcomes at least 13 years after posterior pedicle screw fixation combined with transpedicular BAER and subsequent intravertebral CPC injection for traumatic thoracolumbar fractures.

Methods

The study protocol was approved by the institutional review board of our hospital. A prospective cohort was originally conducted with 20 consecutive patients with traumatic burst fractures (AO-classification type A3–A4, previously A3.1, A3.2, A3.3) without neurological deficits, treated between January 2002 and December 2003 (twelve females, eight males, mean age 42 years at time of trauma, fracture levels ranged between thoracic 12 and lumbar 4). Between 12 and 18 months postoperative, all instrumentation was removed (as was common practice at the time) to maintain a uniform cohort [5, 6]. All 18 living patients were approached for participation (July–August 2016) in this follow-up study and were asked for their informed consent. No funding was received for this study. The STROBE statement was used for this study.

Clinical examination and PROMs

Standardized clinical and neurological examinations were performed by the senior author at the outpatient clinic. This examination included locomotor and neurologic function tests to assess the current ASIA-scale (American Spine Injury Association) [12].

Patient-reported outcome measurements (PROMs) were assessed with the Denis working scale (DWS), numeric pain rating scale (NRS), EQ-5D-3L (EQ-5D), visual analog scale of perceived health (VAS), and Oswestry Disability Index (ODI) [13].

DWS is a ranking based on work status ranging from W1 “Return to previous employment (heavy labor) or physically demanding activities” to W5 “No work, completely disabled” [9]. NRS is the average amount of pain experienced in an average week ranging from 0 (no pain) to 10 (extreme pain), subdivided in back pain and leg pain [14]. Both the DWS and NRS were asked during the visit by the senior author. The EuroQol-5D (EQ-5D) Dutch paper questionnaire was used

and the five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) were rated on a three-point scale (1: no problems, 2: some problems, 3: severe problems) [15]. The VAS of perceived health is a scale of a 0% to a 100% to assess current perceived health. The ODI health questionnaire is comprised of 10 dimensions (pain, self-care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling). These dimensions are scored on a six-point scale ranging from 0 (no problems) to 5 (extreme problems) and are subsequently calculated as a percentage of disability. This percentage leads to a five-scale disability index, ranging between 0% (no disability) to 100% (completely disabled). An adjusted score was calculated when (up to two) answers could not be answered or were not applicable for the individual patient [16–18].

Radiological examination

Plain radiographs (anteroposterior and lateral) of the complete spinal column were obtained in a standardized standing position where patients were instructed to place their hands on both zygomatic arches and achieve spinal balance. The presence of CPC was observed and qualitatively compared to previously obtained radiographs. Wedge angle and Cobb angle were measured on lateral radiographs by two independent observers to test for inter-rater differences. The wedge angle was measured at the level of the previously fractured vertebra. The Cobb angle was measured one level above and one below the previously fractured vertebra. Sagittal balance was measured using the C7 plumb-line. A sagittal vertical axis of more than 2 cm from the anterior point of S1 was interpreted as misbalance [19].

Statistical methods

The software package SPSS (IBM Statistics version 21, Armonk, NY) was used for all analyses. Agreement and reliability between the radiological results of the two observers were analyzed using Bland–Altman plot and intraclass correlation coefficient (ICC). The clinical and radiological parameters and PROMs were compared with data obtained at the 6 years of follow-up time-point [5, 6]. The PROMs at 6 years and final follow-up were compared with paired-sample *t* tests. The radiographic measurements were checked for normality, using histograms, Q–Q plots, and Shapiro–Wilk's test. Repeated measurement analysis was performed to detect statistical differences in wedge and Cobb angles, *p* values < 0.05 were considered significant.

Results

Baseline characteristics

Of the 20 patients, 18 patients were alive and 17 patients agreed to participate. The outpatient clinic was visited by 16 patients. For the one patient not visiting the hospital, all data except for the radiographs were obtained. The number of patients lost to follow-up was therefore 1/20 (5%). All participating patients (six males (median age of 51 years at follow-up; range 32–80 years); 11 females (median age of 49 years; 32–75 years at follow-up) completed the questionnaires (EQ-5D, VAS of perceived health and ODI). The other PROMs were asked during the visit. Two patients of the original cohort had died before 13 years of follow-up; one patient had died 5 years after trauma due to an (unrelated) subarachnoid hemorrhage, and the other patient died of myocardial infarction 6.5 years after trauma. A lumbar osteotomy and pedicle screw fixation of L3–S1 was required in one patient (female, 49 years of age at the time of trauma), 11.5 years after trauma for a newly developed neuropathic leg pain due to late-onset recurrent kyphosis at the previously fractured vertebra and an associated lumbar canal stenosis on L3–L4.

The average final follow-up at time of the outpatient visits was 166 months (13.8 years), ranging from 155 to 176 months.

Clinical outcome, pain, and employment

Locomotor function was intact for all patients; all could walk independently without any aids. All patients scored ASIA-scale E at time of trauma and all remained in this scale during final follow-up.

Patients reported a median NRS for back pain of 1, ranging from 0 to 6. For leg pain, patients reported a median NRS of 0, ranging from 0 to 5. Eight patients reported no back pain at all, and 13 patients reported no leg pain. Twelve patients (71%) could return to their previous employment (DWS: W1) of heavy labor including farming, carpeting, construction work, and tending to horses. Four patients (24%) restricted their physical activities or returned to a sedentary job (DWS: W2). One patient had to adapt her working environment to sedentary work but could still work full time (DWS: W3).

EQ-5D-3L

No restrictions were reported by 11 patients (65%) on mobility and usual activities. The other six patients reported some problems, such as pain or stiffness after a

longer period of standing. Seven patients (41%) reported no pain or discomfort, and 10 patients experienced some pain or discomfort, such as morning stiffness of the spine. None of the patients reported problems with self-care or anxiety/depression. Seven patients reported no problems at all when combining scores for individual patients for all five dimensions. Three patients had some problems in one dimension, two patients had some problems in two dimensions, and five patients had some problems in three dimensions. Comparison of the combined EQ-5D scores at 6 years (median 84; range 65–100) and 13 years of follow-up (median 84; range 78–100) showed no significant differences ($p=0.506$) (Fig. 1).

Perceived health

The VAS of perceived health ranged from 50% to 100% with a median of 80%. The mean VAS at 6 years and at 13 years of follow-up were not statistically different (80%; range 60–100%; $p=0.259$) (Fig. 2). The poorest VAS score of perceived health recorded (50) was mainly influenced by unrelated systemic health problems (the presence of active autoimmune hypothyroidism) as reported by this individual patient.

Oswestry Disability Index

Fourteen patients were categorized as minimally disabled (0–20%), one patient as moderately disabled (20–40%), and two patients as severely disabled (40–60%). Compared to the 6-year follow-up results, the two patients in the severely disabled category deteriorated from the moderately disabled category (Fig. 3). Patients reported severe problems at four dimensions (pain, lifting, standing, and social life). The median ODI at 13 years (8%, range 0–52%) was not significantly different from the median ODI at 6 years (4%, range 0–36%, $p=0.071$).

Fig. 1 “EQ-5D: different dimensions”. This figure shows the number of patients that reported problems (some and severe combined) in the various dimensions of the EQ-5D questionnaire. A decrease in reported problems is shown

VAS of perceived health at 6- and 13 years follow-up

Fig. 2 “VAS of perceived health”. Each line represents one subject. The VAS of perceived health was consistent between six and 13 years of follow-up. One patient deteriorated because of unrelated systemic health problems

Radiological outcome

For all radiographs obtained at final follow-up, the intravertebral calcium phosphate cement was still clearly visible, roughly similar to the images obtained at 6 years of follow-up (Fig. 4). The ICC agreement score was 0.83 for the wedge angle and 0.96 for the Cobb angle. The Bland–Altman plot showed one outlier for both wedge angle (mean difference -0.57 , $p=0.47$) and Cobb angle (mean difference 1.77 , $p=0.21$). The mean wedge angle at 13 years of follow-up was $5.8^\circ \pm 5.0^\circ$ compared with $5.3^\circ \pm 4.5^\circ$ at 6 years, the results not being significantly different ($p=0.12$, 95% CI $-1.33; 0.18$). The mean Cobb angle at 13 years of follow-up ($4.6^\circ \pm 13.6^\circ$) was not significantly different from the Cobb angle at 6 years of follow-up ($5.8^\circ \pm 12.3$; $p=0.23$, 95% CI $-0.88; 3.37$). When data of the wedge and Cobb angle at 6 years and 13 years of follow-up were compared with

Fig. 3 “ODI: overall scores”.

This graph shows the number of patients per disability category derived from the ODI questionnaire. In both graphs, 6 years of follow-up (gray) was compared to 13 years of follow-up (blue)

Fig. 4 Case 8, female, age 50, A3 fracture of L2. The radiograph on the left shows the consolidated L2 vertebra with the cement in situ 6 years after trauma. The radiograph on the right (13 years after trauma) shows a similar disc height between L1 and L2 compared to the radiograph on the left. The amount of calcium phosphate cement in situ appears approximately the same for both time points

the data collected before 6 years of follow-up (preoperative, directly postoperative and after removal of the pedicle screw system), a stabilization of the radiological parameters was observed (Fig. 5). All patients but one (the female who underwent revision surgery and osteotomy was well balanced after) were well balanced in the sagittal plane.

Discussion

In the current study, the long-term follow-up of 17 patients treated with short-segment pedicle screw fixation and BAER with CPC injection for traumatic thoracolumbar burst fractures was evaluated using clinical, radiological and patient-reported outcome measurements. The evaluated

parameters at 13 years of follow-up were not different from those at 6 years of follow-up.

As expected, all patients remained neurologically intact and all could function independently in daily life during follow-up. Eight patients reported no back or leg pain at all. All other patients still reported pain in different severity. One patient had required secondary surgery due to symptomatic late-onset deformity at the index level, while in the other patients, no mechanical failure or recurrent kyphosis was observed.

The EQ-5D showed no significant differences between 6 years and 13 years of follow-up. Compared with the general population of the Netherlands, our patients did worse on mobility (no problems: 86.9% vs. 65%, respectively), usual activities (no problems: 88.1% vs. 65%), and pain/

Fig. 5 “Trend in wedge and Cobb angle”. This figure shows all combined data on wedge and Cobb angles measured in this cohort collected over the last 13 years. Wedge and Cobb angles were measured after trauma, within 1 week after the surgery, after the removal of the pedicle screw systems, at 6 years of follow-up and finally at 13 years of follow-up

discomfort (no problems: 68.1% vs. 41%) [20]. Despite scoring worse on three dimensions, the patients in our current study reported a mean VAS score of perceived health that was comparable to the general population of the Netherlands 80.6 ± 10.9 versus 80.7 ± 17.2 respectively [20].

In 15 patients, the ODI score remained in the same category or improved one category at 13 years of follow-up. In two patients, the ODI score deteriorated from moderate disability to severe disability. One of these two patients did not worsen radiographically. The other required the secondary surgery as described before. Wood et al. [21] presented the results of 16- to 20-year follow-up of patients treated operatively and nonoperatively for stable thoracolumbar burst fractures. The ODI of the operative group (ODI=20%) was significantly higher than that of the nonoperative group (ODI=2%). In contrast, our cohort showed an ODI of 8% (median). The difference in ODI at follow-up may be explained by the different surgical techniques employed.

Radiographic measurements such as the wedge and Cobb angles showed no significant differences when 6-year and 13-year data were compared. The differences in measurements between the observers were consistent with the current literature and showed no systematic difference [19, 22].

Aono et al. and Wang et al. described a loss of postoperative correction of the Cobb angle when short-segment pedicle screws were used without cement injection, possibly due to intrusion of the intervertebral disc (IVD) through the fractured endplates into the

vertebral body [23, 24]. Progressive deterioration of the Cobb angle with a concurrent stable wedge angle, as viewed on plain lateral radiographs, is suggestive of this phenomenon. In our cohort, the wedge and Cobb angles at 13 years of follow-up were not different from the values at 6 years, suggesting no or limited intrusion of the IVD into the fractured vertebral body. The ideal method to observe the intrusion of the IVD is on a magnetic resonance scan (MR scan). Our cohort underwent MR scan preoperatively, at 1 month after surgery and at 1 month after removal of instrumentation (12–18 months after implantation) and because of the promising earlier results and the stable radiographs, additional MR scanning was not performed [8, 25].

CPC is considered a slowly resorbable bone substitute and was promoted by the manufacturer to be resorbed and replaced by bone through the process of creeping substitution [26]. The resorption of the intravertebral cement was exceedingly limited in the radiographs at 13 years of follow-up, and the visible amount was comparable to the radiographs at 6 years of follow-up.

A different bone void filler, polymethylmethacrylate (PMMA), is more cost-effective, easier to handle in the operating theatre and, for the current authors, presently the preferred bone void filler for spinal applications [27, 28].

The patients from our cohort were treated with short-segment pedicle screw instrumentation through an open approach. The percutaneous approach is, provided the absence of neurological deficits and/or gross fracture displacement, currently favored over the open approach,

because of lower intraoperative blood loss, shorter operation time, and lower infection risk [29].

Low-profile pedicle screw systems are nowadays used in many practices and rarely require elective removal. In the year 2001, (the year the original study protocol was drafted) low-profile systems were not yet available and complaints of screw head protrusion led to routine removal of the instrumentation. Recurrent kyphosis can occur after removal of the pedicle screw system which was performed for all our study patients. However, our cohort showed a stable Cobb and wedge angle with no recurrent kyphosis after removal.

In the primary study, all but one of the eligible patients, meeting the inclusion criteria, were willing to participate in the primary study, limiting selection bias. The small group size and lack of a control group are due to the fact that this study was primarily set up as a Clinical Phase II Trial to test the safety, feasibility, and efficacy of this brand-new treatment in 2001. Therefore, limited statistical tests could be performed. The performed statistical tests did support that no deterioration of clinical or radiological parameters was present after 13 years of follow-up, compared with 6 years of follow-up.

Our study showed a cohort of patients with thoracolumbar burst fractures treated with short-segment pedicle screw fixation, BAER, and CPC implementation and was followed for a unique duration of 13 years with a minimal number of patients lost to follow-up. Most of the published literature on treatment of thoracolumbar burst fractures have a maximum follow-up of around 2 years. In current practice, information about long-term follow-up of thoracolumbar burst fractures is lacking, leading to limited data to inform patients about how these traumatic events may affect daily life in the future.

After 13 years of follow-up, functional performance, reported pain, and radiological parameters were stable for most patients and, for some patients, even improving compared to follow-up at 6 years. Our patient cohort showed low rates of recurrent kyphosis 13 years after treatment with pedicle screw instrumentation and BAER with CPC for thoracolumbar burst fractures.

Compliance with ethical standards

Conflict of interest JJ Verlaan receive an educational grant by Depuy Synthes outside of this publication. The other authors declare no conflict of interest.

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