STUDY

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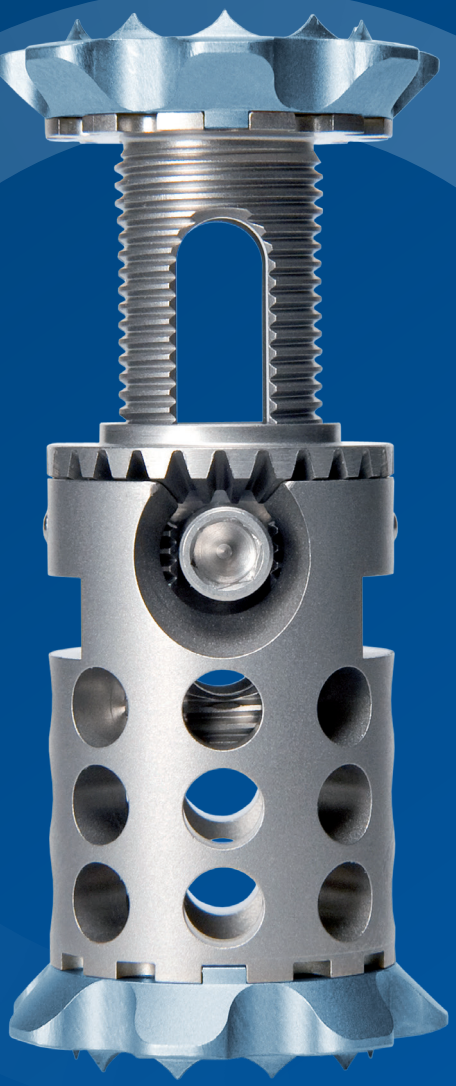
vertebral body replacement



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Radiological and mid- to long-term patient-reported outcome after stabilization of traumatic thoraco-lumbar spinal fractures using an expandable vertebral body replacement implant

Lang, S., Neumann, C., Schwaiger, C., Voss, A., Alt, V., Loibl, M., & Kerschbaum, M. (2021). Radiological and mid-to long-term patient-reported outcome after stabilization of traumatic thoraco-lumbar spinal fractures using an expandable vertebral body replacement implant. BMC Musculoskeletal Disorders, 22(1):744.

Go to study: https://doi.org/10.1186/s12891-021-04585-y

Study type:
Retrospective, single-center cohort study with 96 patients

Aim of the study:
The aim of this study was to analyze the radiological results as well as the mid- to long-term patient-reported outcome; (PRO) after dorso-ventral stabilization of traumatic fractures of the thoracic and lumbar spine with an expandable vertebral body replacement (VBR) for the reconstruction of the anterior spine.

Outcome:
- Reduction of the bisegmental kyphotic end plate angle (BKA)
- Improvement in the neurological status
- Bony fusion
- Complication and revision rate

Prospective collection of the following data with questionnaires (patient-reported outcome measures, PROM):
- Oswestry Disability Index (ODI):
  Questionnaire for assessing functional status and the impairment of quality of life; scale from 0-100, whereby 0 = no impairment and 100 = maximum impairment
- EuroQol in 5 Dimensions (EQ-5D) – VAS:
  Visual Analogue Scale for pain assessment; scale from 0-100, whereby 0 = the most severe pain and 100 = the most mild pain
- German Short-Form 36 (SF-36):
  Scale from 0 to 100, whereby higher values indicate better physical (PCS) and mental health (MCS)

Patient population and indications:
- Bisegmental (n=90; 93.8%) and monosegmental (n=6; 6.3%) traumatic fractures of the thoraco-lumbar spine:
  - AO type A2 (7.3% of patients)
  - AO type A3 (9.4% of patients)
  - AO type A4 (83.3% of patients)
  - Critical narrowing of the spinal canal and a significant deviation of the end plate angle and/or the scoliosis angle
- Patients with two radiological follow-up examinations, the second of which was performed at least 24 months after the VBR intervention
- Age > 18 and < 69 years
- No pathological fractures and no previously diagnosed osteoporosis

Surgical techniques:

- For fractures of the thoracic spine, up to L2 fractures: thoracoscopic-assisted surgical approach
- For fractures of the lumbar spine: minimally invasive ventral/retroperitoneal approach
- Prior to vertebral body replacement, dorsal instrumentation, anatomical reduction and stabilization with a minimally invasive internal fixator system were performed in the prone position
- Two-stage, sequential procedure in 67 (69.8%) patients
- Posterior decompression in 43 (44.8%) patients
- Posterior spinal fusion in 51 (53.1%) patients
- Bone grafting around the VBR

Results:

Demographic data:

- Quantity of patients analyzed:
  - Total cohorts: n=96
  - Sub-group of PROM surveyed/questionnaires: n=51/96
- Average time between surgery and filling out the questionnaires: 106.4 ± 44.3 (26-179) months (approx. 8.9 years)
- No significant difference between the sub-group of those surveyed and the sub-group of those not surveyed with regard to BMI, fracture localization, morphology of the vertebral body fracture or the presence of an additional injury

Surgical data:

- Surgical level:
  - Thoracic spine: 24.0%
  - Lumbar spine: 76.0%, of which thoraco-lumbar junction (Th11 - L2): 61.5%
  - most often affected: L1 (26.0%)
- Average surgery time (two-stage procedure): 115.8 ± 35.4 minutes
- Average surgery time (one-stage procedure): 174.6 ± 65.7 minutes
- No statistically significant difference in the surgery time between the different surgical approaches

Clinical parameters:

- **Bisegmental kyphotic end plate angle (BKA)**
  - **Significant reduction by surgery ($p < 0.01$)**
  - Significant loss of correction in the first and second follow-up examination (in each case $p < 0.05$)
  - No evidence of connection between the loss of correction and
    a. the patient's age ($p = 0.70$)
    b. the position of the fracture (thoracic/lumbar) ($p = 0.44$)
- Neurological status:
  - n = 22 patients suffered from neurological symptoms preoperatively.
  - Change in ASIA status (parameter for neurological deficits) after surgery:
    a. Improvement in 13 patients (59.1%)
    b. No change in 7 patients (31.8%)
    c. No documentation in 2 cases (9.1%)
  - No new neurological deficits occurred postoperatively
- **Fusion rate:**
  - **97.9% (94/96) in the second radiological follow-up examination**
- Complication rate:
  - Total: 10.4% (10/96)
  - No significant difference regarding the occurrence of complications between the different surgical approaches
- **Revision rate:**
  - **Total: 4.2% (4/96)**
  - **There were no cases where a revision had to be carried out due to the VBR**
- ODI:
  - On average 28.2 ± 18.3% (corresponds to medium impairment) at the time of the follow-up examination
  - No significant difference
    a. as regards the position of the fracture (thoracic/lumbar) ($p = 0.50$)
    b. between patients with multiple traumas, compared to patients with monotrauma ($p = 0.65$)
    c. depending on the severity of the trauma (ISS Score <16 vs. ≥16) ($p = 0.76$)
- EQ-5D VAS:
  - On average 60.7 ± 4.1 points at the time of the follow-up examination
  - No significant difference as regards
    a. the position of the fracture (thoracic/lumbar) ($p = 0.59$)
    b. the markedness of the neurological deficit ($p = 0.76$)
  - Significant difference
    a. between patients with multiple traumas compared to patients with monotrauma ($p < 0.05$)
    b. depending on the severity of the trauma (ISS Score <16 vs. ≥16) ($p < 0.05$)
- SF-36:
  - Lower values in all parameters (PCS, MCS and others) compared to healthy reference population, irrespective of the severity of the trauma (ISS Score).
  - No significant differences
    a. as regards the position of the fracture (thoracic/lumbar)
    b. between patients with multiple traumas compared to patients with monotrauma

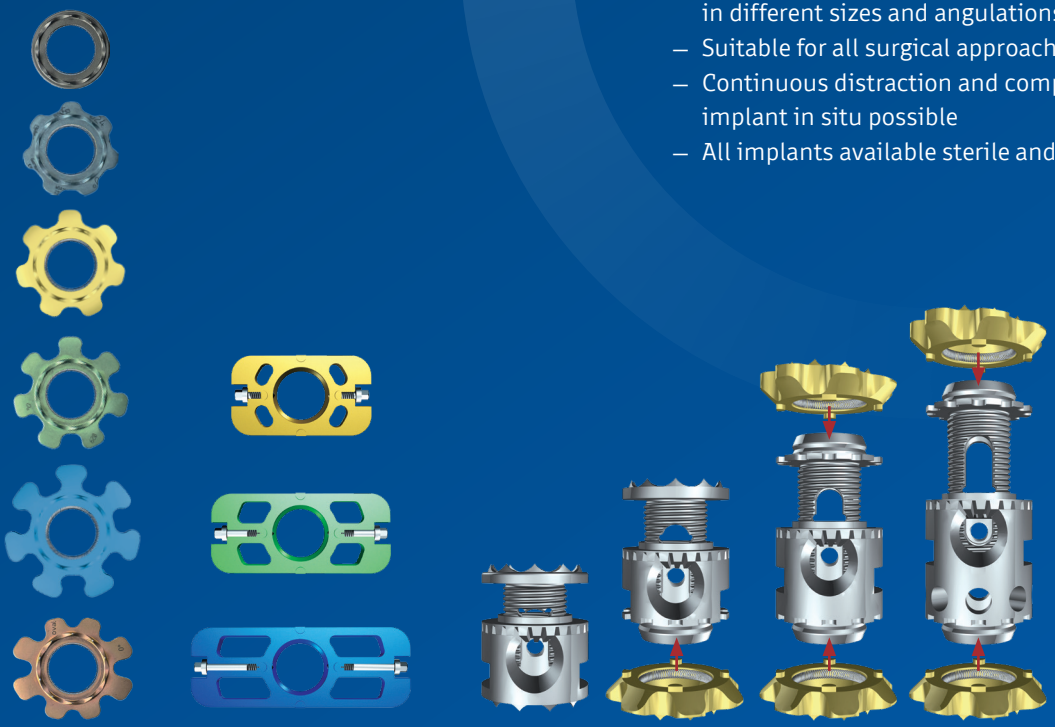
Authors' conclusion:
The reconstruction and stabilization of traumatic, unstable thoraco-lumbar spinal fractures with an expandable VBR implant has proven itself to be a practical procedure in the current study population. Further prospective studies must be carried out in order to confirm the safety and efficiency of this procedure. **A significant correction of the BKA was demonstrated on both the thoracic spine and the lumbar spine.** No clinically relevant loss of correction was identified during the follow-up examination. **Furthermore, a high bony fusion rate of 97.9% could be achieved. No revision surgery due to VBR dislocation was required.** Satisfactory PROM (questionnaires) results were obtained for a large part of the test subject group. However, quality of life did not reach the normative population values, irrespective of the severity of the trauma. Postoperatively persistent neurological symptoms, additional traumas and an ISS ≥ 16 were factors that tended to be connected with a poor quality of life.

Significant correction of the BKA

High bony fusion rate of 97.9%

No revision due to the VBR implant required

Product:
obelisc™
vertebral body replacement
- Distractable vertebral body replacement for the anterior thoracic and lumbar spine
- Modular implant system with center pieces for heights from 17 mm to 132 mm
- Round and oval as well as rectangular end plates in different sizes and angulations
- Suitable for all surgical approaches
- Continuous distraction and compression of the implant in situ possible
- All implants available sterile and non-sterile



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The user has to ensure that the latest versions of the complete product materials provided as overall documentation of the system are available and taken into account. The required product materials are: system related instructions for use, surgical techniques and, if applicable, supplements, system configuration, assembly and disassembly instructions as well as "Processing manual implants and instruments" UH 1100. These are also available at: **www.ifu.ulrichmedical.com**

This document is a summary of the above-mentioned study which has been put together with care. Nevertheless, we cannot completely rule out the possibility of errors in this document.

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