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Effect of an orthosis on the loads acting on a vertebral body replacement

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ABSTRACT

Background: The spinal load reduction by an orthosis is still a matter of debate. Some studies predicted a load reduction while others found no effect. The aim of this study was to measure the *in vivo* effect of the Lumbo TriStep brace and the hyperextension orthosis medi 3C on the spinal implant loads.

Methods: Telemeterized vertebral body replacements were implanted in 5 patients suffering from a severe fracture of the L1 or L3 vertebral body. The implant allows the measurement of 6 load components acting on it. For several activities during standing, sitting and walking, implant loads were measured in patients with and without an orthosis.

Findings: The average resultant force on the vertebral body for 26 activities was reduced by 9% with the Lumbo TriStep brace, and by 19% with the hyperextension orthosis. The force reduction is usually more pronounced for activities performed during sitting than it is for those performed while standing. However, considerable inter- and intra-individual variation was observed. In several cases, the measured implant forces were even higher when the patients were wearing an orthosis.

Interpretation: In some patients, for certain activities, an orthosis may reduce the force on a vertebral body replacement and thus on the anterior column of the spine. However, in other patients for the same activities, an orthosis may increase the force. The measurements do not allow a clear recommendation to wear an orthosis since the clinically relevant reduction of implant forces is unknown.

1. Introduction

Severe, unstable compression fractures of a vertebral body are often posteriorly stabilized with a pedicle-screw-based implant and anteriorly with a vertebral body replacement (VBR). One of the aims of this procedure is to restore the normal height of the vertebral body and hereby recover the spinal profile. However, subsidence of the VBR associated with correction loss is one of the complications often faced as a result of this treatment. Some surgeons try to decrease this risk by supplying their patients with an orthosis. However, it is still unknown how much the ventral spinal column is relieved by an orthosis. Orthoses are supposed to support and/or immobilize the spine after stabilization of the lumbar spine (White and Panjabi, 1990). The goals of an orthosis may be any combination of support, rest, immobilization, protection, correction and reminder.

Functional radiographs in patients wearing different spinal orthoses revealed that the reclination brace markedly reduced dorsoanterior motion when fitted perfectly (Maier, 1962). Brown and Norton (1957) inserted Kirschner wires into spinous processes and studied vertebral movements in several braces using photographs and radiographs. They observed that the braces tested only limited intersegmental flexion but never achieved immobilization.

The intradiscal pressure was measured in four subjects with normal disks when wearing a corset containing an inflatable pad (Nachemson and Morris, 1964). In all cases, a considerable decrease in the total load on the examined disks was found when the corset was inflated up to the subject's tolerance level. The loads in telemeterized, posteriorly implanted internal spinal fixation devices were measured in six patients wearing no orthosis, a Boston overlap brace, a reclination brace or a lumbotrain harness during several activities (Rohlmann et al., 1999). It was shown that a brace or harness had only a minor effect on the loads transferred by the pedicle-screw-based spinal fixators.

The loads on an anteriorly implanted VBR have been measured *in vivo* by Rohlmann et al. (2008, 2010, 2011, 2012, 2013) during many activities. They varied strongly from patient to patient, while the force direction within a patient was relatively constant when the implant was highly loaded. Under well controlled conditions, repeated measurements of the same activity delivered similar results but there was usually a great variety in the performance of the exercises and thus in the measured spinal loads. Such variation can also be expected in clinical practice.

The aim of this study was to measure the loads on a VBR for several activities in patients with and without an orthosis, and determine the extent to which implant loads can be reduced by an orthosis. The

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effects of the Lumbo TriStep brace and the hyperextension orthosis medi 3C were studied.

2. Methods

2.1. Telemeterized vertebral body replacement

The clinically proven VBR Synex (Synthes Inc., Bettlach, Switzerland) was modified. Six strain gauges served as load sensors. They were glued to the inner wall of the implant. A telemetry unit and a coil for the inductive power supply were also integrated in the hermetically sealed implant (Fig. 1). The telemeterized VBR allows the *in vivo* measurement of all three force and three moment components. The average measuring errors were within 2% for the force and 5% for the moment components, as related to the maximum calibration values of 3000 N and 20 Nm, respectively. The sensitivity of the measuring implant is smaller than 1 N and 0.01 Nm. Thus, the implant detects even minor load changes such as due to breathing in a relaxed supine position. This instrumented implant has been described in detail elsewhere (Rohlmann et al., 2007).

For the inductive power supply, a coil was placed around the patient's trunk at the implant level during measurements. An antenna on the patient's back received signals from the telemetry. The patients were videotaped during the measurements and the load-dependent signals were stored on the same tape. Simultaneously, the spinal loads were calculated online from the transmitted signals with the help of a notebook and synchronously displayed on a monitor.

2.2. Patients

Telemeterized VBRs were implanted into five patients who had suffered from a compression fracture of a vertebral body. The patients were first treated with internal spinal fixation devices implanted using a posterior approach. In a second surgery, parts of the fractured vertebral body and the adjacent disks were removed and a telemeterized VBR was inserted into the corpectomy defect. Autologous bone material was added to cover the implant and enhance fusion of the adjacent vertebrae. Data about the patient's sex, age, height, body weight, fractured vertebra and postoperative time of the measurements are given in Table 1. The patients reported no pain during the time when measurements were performed.

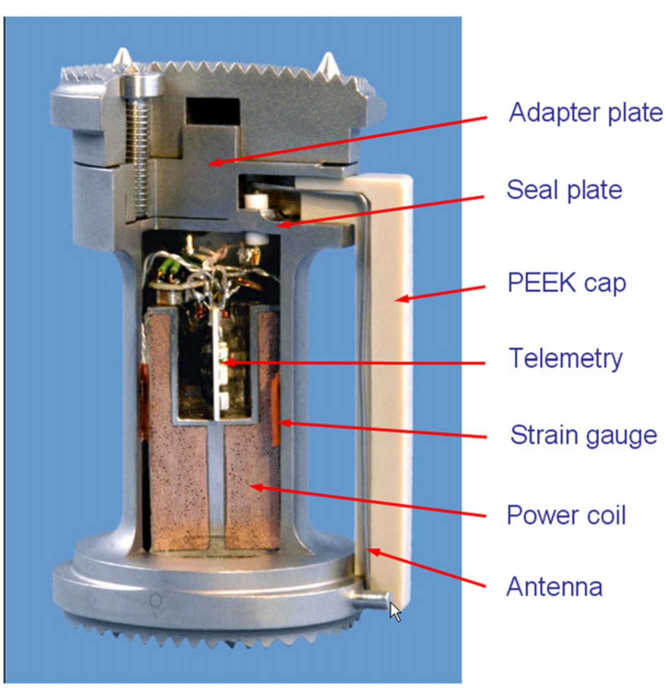

Fig. 1. Cut model of the telemeterized vertebral body replacement (adapted from Rohlmann et al., 2008a).

Table 1
Data on patients and surgical procedures.

Parameter	Patient				
	WP1	WP2	WP3	WP4	WP5
Sex (M/F)	M	M	F	M	M
Age at the time of surgery (years)	62	71	69	63	66
Height (cm)	168	169	168	170	180
Body mass (kg)	66	74	64	60	63
Fractured vertebra	L1	L1	L1	L1	L3
Level of internal fixation device	T12-L2	T12-L2	T11-L3	T11-L3	L2-L4
Bone material added	Yes	Yes	Yes	Yes	Yes
Implantation date (month/year)	09/2006	11/2006	03/2007	01/2008	07/2008
Time between implantation and measuring session (days)	208	154	774	150	241

The Ethics Committee of our hospital approved implantation of the modified implant in patients. Prior to surgery, the procedure was explained to the patients, and they gave their written, informed consent to implantation of the modified VBR, subsequent load measurements, and publishing of their images.

2.3. Orthoses

The Lumbo TriStep (LTS) brace (Otto Bock HealthCare GmbH, Duderstadt, Germany) and the hyperextension orthoses medi 3C (medi GmbH & Co. KG, Bayreuth, Germany) were used. The LTS brace (Fig. 2a) is assumed to be a stabilizing orthosis with a mobilizing function. The hyperextension orthosis medi 3C (Fig. 2b) is prescribed to immobilize the thoracic and/or lumbar spine after surgery. The orthoses were individually adapted to the patients by an experienced orthopedic technician.

2.4. Measurements

The patients were included in several different load-measuring studies (Dreischarf et al., 2010; Rohlmann et al., 2008a, 2008b, 2010, 2011, 2012, 2013). To limit their physical stress, measurements were performed in only one session, with the patients successively wearing no orthosis and the LTS brace. Four patients (WP1, WP2, WP4, WP5) also agreed on measurements with the hyperextension orthosis. Measurements were performed while the patients were standing and sitting on a stool, respectively, and included maximum flexion, extension, lateral bending and axial rotation of the upper body as well as 90° elevation of one or both arms in the sagittal plane. While elevating an arm the patients carried different weights between 0 and 5 kg in their hand (Table 2). In addition, the loads during level walking were measured. Overall 26 different activities (walking, 10 exercises while sitting, 15 exercises while standing) were studied. For each patient, the measurements evaluated in this study were performed on the same day.

2.5. Evaluation

From the measured load components the resultant force (geometrical sum of the three force components) was calculated. The transverse forces and the moment components were usually low. From the time course of the evaluated force throughout each activity, the absolute maximum was determined. As walking is an important loading case, which causes high implant loads, 12 to 36 steps of each patient and orthosis were investigated. From the maxima of the single steps the median value was determined. All other activities were performed only one to three times per