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ORIGINAL ARTICLE

Loads on a spinal implant measured in vivo during whole-body vibration

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Abstract After spinal surgery, patients often want to know whether driving a car or using public transportation can be dangerous for their spine. In order to answer this question, a clinically proven vertebral body replacement (VBR) has been modified. Six load sensors and a telemetry unit were integrated into the inductively powered implant. The modified implant allows the measurement of six load components. Telemeterized devices were implanted in five patients; four of them agreed to exposure themselves to whole-body vibration. During the measurements, the patients sat on a driver seat fixed to a hexapod. They were exposed to random single-axis vibrations in *X*, *Y*, and *Z* directions as well as in multi-axis *XYZ* directions with frequencies between 0.3 and 30 Hz. Three intensity levels (unweighted root mean square values of 0.25, 0.5 and 1.0 m/s^2) were applied. Three postures were studied: sitting freely, using a vertical backrest, and a backrest declined by an angle of 25°. The patients held their hands on their thighs. As expected, the maximum force on the VBR increased with increasing intensity and the number of axes. For the highest intensity level and multi-axis vibration, the maximum forces increased by 89% compared to sitting relaxed. Leaning at the backrest as well as lower intensity levels markedly decreased the implant loads. Driving a car or using public transportation systems—when the patient leans towards the backrest—leads to lower implant loads than walking, and can therefore be allowed already shortly after surgery.

Keywords Spine · Vertebral body replacement · Sitting · Vibration · Load measurement · Telemetry

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Introduction

Severe compression fractures of a vertebral body are often stabilized dorsally by an internal spinal fixation device and ventrally by a vertebral body replacement (VBR). Shortly after surgery, patients often want to know whether driving a car or using any public transportation system can lead to high loads on the implant and thus increase the risk of implant subsidence or even failure. The effects of such vibration exposure on the spine and the VBR have not yet been described in the literature.

In general, the effect of long-term whole-body vibration exposure on spinal health has been found to vary considerably [1–3]. The whole-body vibration exposure was described by the accelerations mainly measured at the interface between the driver and his seat cushion. But several additional factors can cause considerable variability of the relationship between vibration and the back partially considered by upper and lower boundaries in the Standards of health assessment [4, 5]. These additional factors can be identified by a systematic consideration of the stress–strain relationship during the exposure to whole-body vibration [6, 7]. Due to gravity, static forces cause a certain portion of internal forces in the spine which vary with posture and body mass distribution of the drivers [8]. Dynamic internal forces are additionally generated by exposure to vibration. The spine is stabilized by muscle forces. Perturbation of the equilibrium during vibration increases the muscle forces required for stabilization. These internal forces cause the strain (deformation) of spinal structures. Depending on the individual geometry and material properties of spinal structures the strain leads to a distribution of stress. The individual effects of the strain depend on the strength of spinal structure and their ability to recover from a repetitive load. The strength of vertebrae was shown to be a function of their size, mineral content and age [3, 6, 9].

Epidemiological studies have shown a significant increase of degenerative findings in the spine in groups with intensive occupational whole-body vibration exposure in comparison to that of the control groups. A detailed meta-analysis was published by Boshuizen et al. [10]. They found that a lower limit, which identifies a whole-body vibration exposure without any risk, is not detectable. The odds ratios for degenerative spinal diseases (multitude of diagnoses) and low back pain reach nearly 1.5. The reviews of Seidel and Heide [11] and Hulshof et al. [12] summarized all available data of published papers under consideration of their quality and reliability. Both reviews concluded that long-term occupational vibration exposure increases the probability of adverse health effects and the risk of low back pain. Recent studies confirm the association between whole-body vibration exposure in professional drivers with an excess for back symptoms and disorders of the lumbar region of the spine. In a multivariate data analysis, individual characteristics (e.g. age, body mass index) and a physical load index (e.g. awkward postures, manual material handling) were significantly associated with low back pain outcomes. Quantitative exposure–effect and/or dose–response relationships did not result, due to typical shortcomings of otherwise excellent epidemiological studies [6]. Factors which were not considered in the majority of studies but which can be surmised as yielding possible reasons include: the different contents of high transients in the vibration accelerations, the missing consideration of horizontal accelerations, the anthropometric status of the drivers together with awkward postures and the age involved when the exposure started.

Experimental studies can support the understanding of the fundamental effects of whole-body vibration on the human body and can deliver data concerning the vibration behaviour of the human body under defined conditions which can be used as basis for modelling [8, 13]. In experimental studies, the influence of different postures on the vibration behaviour (apparent mass or impedance) was tested for different sitting conditions, e.g. with or without backrest contact, with or without muscle tension, with hands on a steering wheel or with hands on the lap [8]. The qualitative changes in postures resulted in apparent mass curves with altered peak magnitudes and peak frequencies during exposure in all three vibration directions. The apparent mass functions were found to depend mainly on the body mass in the low frequency range [8].

The results of epidemiological studies have shown in general that a vibration exposure, e.g. car driving and/or bus riding, cannot be allowed a priori for patients. But the vibration intensities which affect professional drivers during their working life were clearly higher than those registered in cars and busses driving on asphalt streets, which were registered in the range between 0.1 and 1.1 weighted root mean square (rms) values [14].

Telemeterized VBR [15] introduces the unique possibility of measuring directly in patients with VBR those loads which act on the implant, and estimating the effects of vibration on the spinal loads. The aims of this study were to measure the loads acting on a VBR for single and multi-axis vibration of different intensity levels. The effect of a backrest on the implant loads was also to be determined.

Methods

Instrumented vertebral body replacement

In order to measure the loads, the clinically proven implant Synex (Synthes Inc. Bettlach, Switzerland) was modified. Six load sensors and a telemetry unit were integrated into the inductively powered implant (Fig. 1). The modified implant allows the measurement of three force and three moment components. This has been described in detail elsewhere [15]. Typical, average measuring errors are below 2% for force and 5% for moment components related to the maximum calibration values of 3,000 N and 20 Nm, respectively.

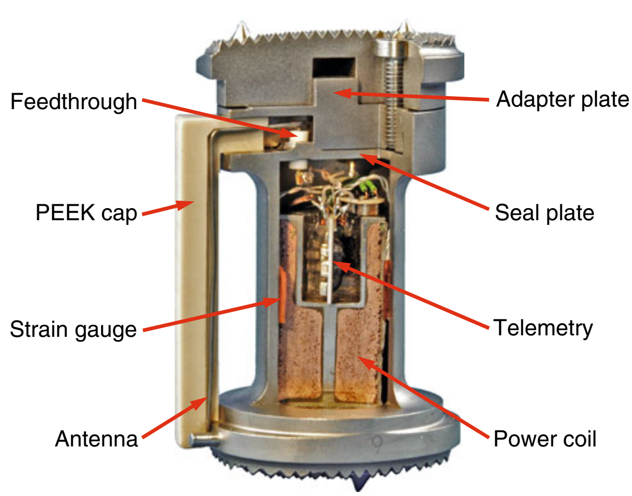

Fig. 1 Cut model of the telemeterized VBR

Telemeterized devices were implanted into five patients, four of them (WP1, WP2, WP4 and WP5) agreed to exposure by whole-body vibration. Patient WP2 also agreed to repeat parts of the measurements about 1 year later. Data about the patients' gender, age, height, body mass and fractured vertebra are given in Table 1. All patients had a compression fracture of a vertebral body. In four patients, the implants were inserted at level L1 and in one patient (WP5) at level L3. The patients were first treated with internal spinal fixation devices implanted from the posterior. In a second surgery, parts of the fractured vertebral body and the adjacent discs were removed and the VBR was inserted into the corpectomy defect. Autologous bone material was added to the VBR in order to enhance fusion of the adjacent segments.

During the measurements, a power coil was placed around the patient's trunk at the level of the VBR for an inductive power supply, and a loop antenna on the patient's back received the signals of the telemetry. The patients were videotaped during the measurements and the load-dependent signals were stored on the same videotape. In addition, the spinal loads were calculated from the signals with the help of a notebook and the loading curves were shown online on its monitor.

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

Load measurement during vibration

A control system of the hexapod simulator modified for human experiments was used to generate the exposures. The requirements of ISO 13090-1 [2, 16] were considered.

Table 1 Data on patients and surgical procedures

Parameter	Patient			
	WP1	WP2	WP4	WP5
Gender (M/F)	M	M	M	M
Age at the time of surgery (years)	62	71	63	66
Height (cm)	168	169	170	180
Body mass (kg)	66	74	60	63
Fractured vertebra	L1	L1	L1	L3
Level of internal fixation device	T12-L2	T12-L2	T12-L2	L2-L4
Bone material added	Yes	Yes	Yes	Yes
Implantation date (month/year)	09/2006	11/2006	01/2008	07/2008

During the vibration measurements, the patients sat on a driver seat fixed to the hexapod (Fig. 2). In the right-handed, orthogonal coordinate system, the *X* axis points to the front, the *Y* axis to the left and the *Z* axis upwards. The patients were exposed to random single-axis vibrations in *X*, *Y*, and *Z* directions as well as in multi-axis *XYZ* directions with frequencies between 0.3 and 30 Hz. Three intensity levels (unweighted rms values of 0.25, 0.5 and 1.0 m/s^2) were applied. Three postures were studied: sitting freely, leaning against a vertical backrest, and leaning against a backrest declined by an angle of 25°. The patients placed their hands on their thighs. Each of the 36 measurement sequences per patients lasted 60 s. For the evaluation, the sequences were divided into several blocks lasting between 10 and 20 s., for which the maximum resultant force on the implant was determined. From the maxima of the three to five measurement sequences, the median value is chosen and presented. Since the absolute values of the force on the VBR vary strongly from patient to patient, the values were related to the median force value for relaxed sitting with the hands on the thighs measured several times during a session.

Fig. 2 Patient sitting on a driver seat fixed to a hexapod

Results

Implant forces versus time

The resultant force varies considerably for a patient during vibration exposure (Fig. 3). The highest force component (Fz, red curve) is in the axial direction and shows the greatest variation in magnitude while the other two force components (in transverse directions) are much smaller and nearly constant. There are great interindividual differences in the magnitude, these depending among other things on postoperative time. The moments measured in the implants are generally low.

Influence of intensity level

As expected, the maximum force on the VBR increased with increasing intensity (Fig. 4). Related to the value for sitting, the maximum force increased on the average by 84% (WP1), 17% (WP2, 1st session), 40% (WP2, 2nd session), 28% (WP4) and 50% (WP5) when the intensity level was increased from 0.25 to 1.0 m/s^2. The median values for the highest intensity level (1.0 m/s^2) in the same order were 189, 123, 151, 141 and 145%. For the two low intensity levels, the maximum force differed only slightly from that derived from patients who were sitting relaxed. For patient WP5, implant loads were even lower for

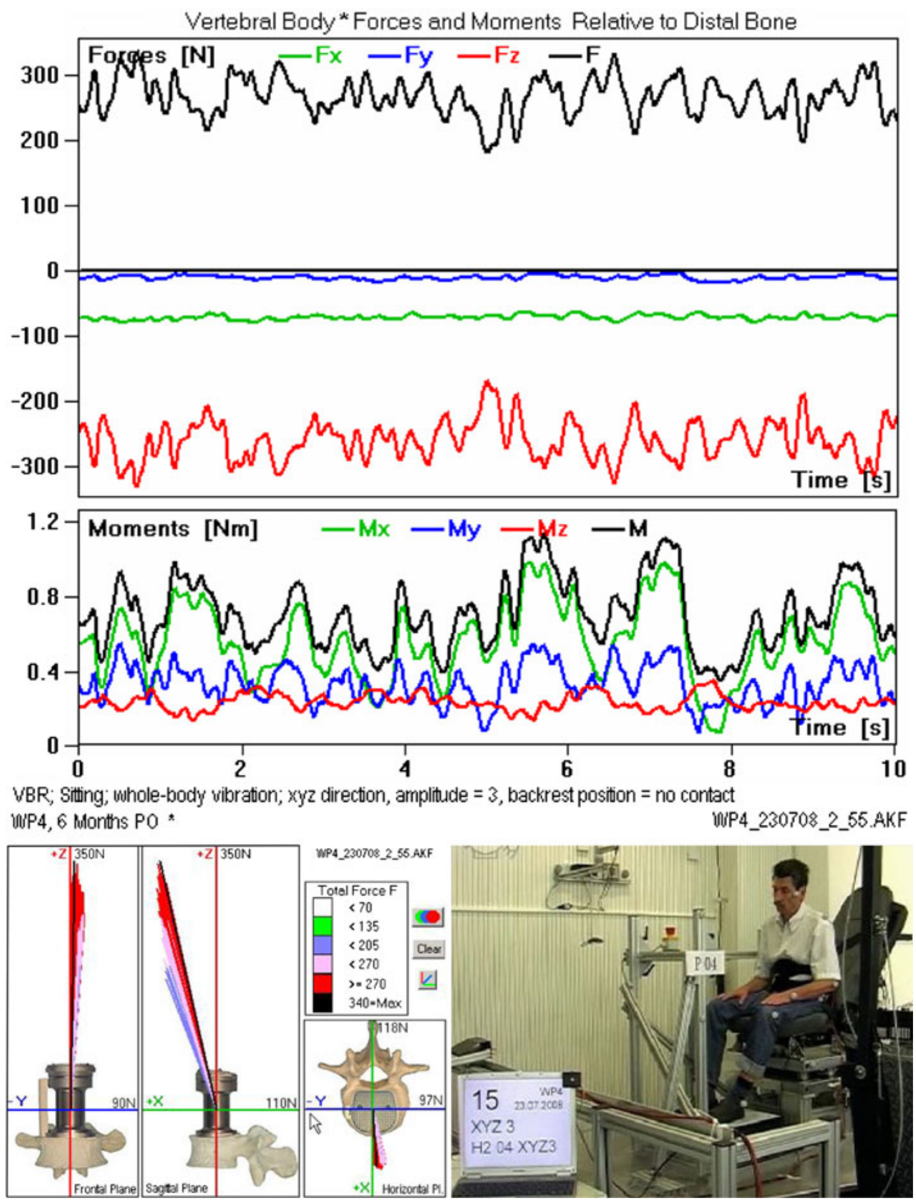

Fig. 3 Components and resultant force (*black line*) versus time (*top*), components and resultant moment versus time (*middle*) and force vectors in three planes (*bottom*). Patient WP4 had no contact with the backrest during multi-axis vibration at the highest intensity level

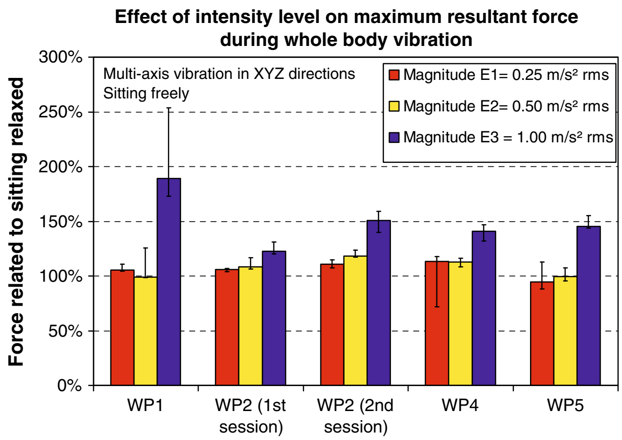

Fig. 4 Effect of intensity level on the maximum resultant force on VBR during multi-axial vibration. The forces are related to those for sitting relaxed. The patients were sitting freely with their hands placed on the knees. Median and range of maximum values are shown

intensity levels of 0.25 m/s^2 than they were when sitting relaxed.

Influence of single- and multi-axis vibration

The effect of the number of axes is shown in Fig. 5. For the highest intensity level, the highest maximum forces were measured during three-axis vibration. The maximum average value related to sitting relaxed are between 123% (WP2, 1st session) and 189% (WP1). For patient WP5 the average resultant force during whole-body vibration in the *Y* and *Z* direction was slightly lower than when sitting relaxed. For these two exposures, the inclination of his upper body during vibration differed from that when sitting relaxed.

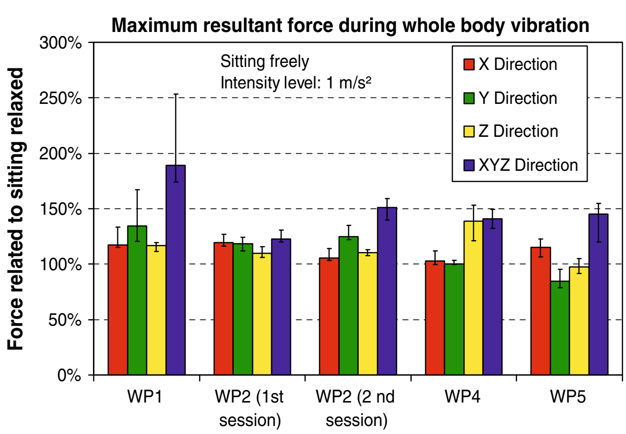

Fig. 5 Effect of random single- and three-axis vibration on related forces on VBR. The patients were sitting freely and exposed to the highest intensity level (1.0 m/s^2). Median and range of maximum values are shown

Influence of posture

Leaning at the backrest during the whole-body vibration markedly decreased the implant loads to values below those found when sitting freely without any vibration exposure (Fig. 6). With a vertical backrest, the maximum resultant force is reduced to 50% (WP1), 60% (WP2), 50% (WP4) and 48% (WP5) when compared to sitting freely. For a backrest declined by an angle of 25°, the reduction was even more pronounced except for patient WP4 (55%).

Discussion

The loads on a VBR were measured during whole-body vibration by simulating the driving of a car or by using public transportation. The patients were exposed to single and multi-axis vibration of three different intensity levels while sitting on a driver seat freely, with a vertical backrest and with a backrest declined by an angle of 25°.

This study has some limitations: only four patients could be included in the study. The postoperative time and thus the magnitude of the measured load on the VBR varied from patient to patient. Therefore, the loads were related to those who were sitting relaxed. All patients were older than 60 years. In order not to endanger any patients, only intensity levels up to 1 m/s^2 were investigated.

For the highest intensity level, the resultant force on the VBR during sitting freely was significantly higher than it was for sitting relaxed. During the vibration the patients had to balance their upper body. This requires additional muscle forces which in turn leads to higher implant loads. The disturbance of the natural sitting position was quite pronounced for this intensity level and the patient's upper body moved also forward and backward. Peak loads occurred typically when the upper body was most flexed. For exposure at a low intensity level, the resultant force on

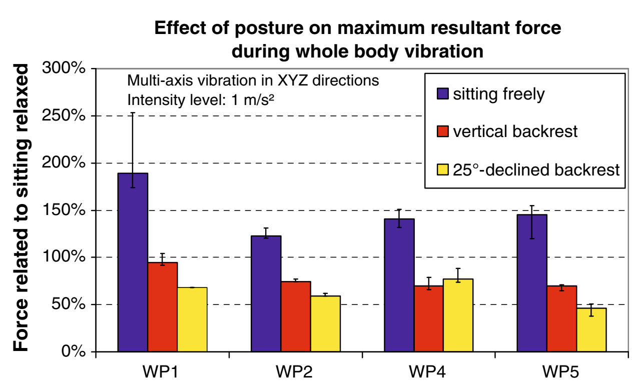

Fig. 6 Effect of posture on related forces on VBR. The patients were exposed to multi-axis vibration at the highest intensity level (1.0 m/s^2). Median and range of maximum values are shown

the VBR was only slightly higher or even lower than it was when sitting relaxed. The disturbance of equilibrium was small for low intensity levels. Patient WP5 had slightly lower implant forces for intensity levels of less than 0.5 m/s^2. This patient has a distinct thoracic kyphosis and thus the centre of gravity of the upper body during sitting is more anterior than in the other patients. During vibration, this patient moved the centre of gravity slightly to the posterior which reduced the resultant force on the VBR.

Forces on the VBR were usually higher for multi-axis than for single-axis vibration. Mostly, it is easier for the patients to be prepared for single-axis vibration. Thus, lower muscle forces are required for stabilizing the upper body in that case. Only for patient WP4 did vibration in the *Z* (axial) direction lead to similar force magnitudes as seen in the *XYZ* direction while they were distinctly lower for the other patients.

Leaning against a backrest strongly reduces the force magnitudes on the VBR. This agrees with findings from intradiscal pressure measurements [17] and load measurements on internal spinal fixation devices [18]. A backrest which is declined generally reduces the implant's loads even more. This finding also agrees with earlier studies [18].

The loads on a VBR decrease over the postoperative time because the added bone material takes over a greater part of the spinal load when its stiffness increases during fusion [19]. Measurements during whole-body vibration were not performed shortly after surgery since we wanted to avoid putting the patient at a high risk. At the time of the measurements for this study, the loads on the VBR were already reduced in comparison with the situation directly after surgery. Thus, only relative values measured on the same day were compared in this study. The measurement at different postoperative times for the patients is one reason for the variation of the results between patients.

The high stiffness of the VBR allows only little deformation of the pedicle screws of the internal spinal fixation device during most activities, and this leads to only minor load changes in the posterior implant. A finite element study [20] predicted that more than 90% of the load is transferred by the anterior column consisting of the VBR and the remainder of the resected vertebral body. We assume that a similar load distribution is present in our patients, especially after fusion has occurred.

When the back leans against a backrest in a sitting position, the implant loads were lower than they were for standing. From the mechanical point of view, driving a car or using public transportation in this position can therefore be allowed already shortly after surgery. However, exposure to vibration while sitting freely may lead to implant loads which are nearly twice as high as they are during sitting in a relaxed position. Similar values can be expected for standing, e.g. in a bus. In regards to the spinal loads only, people with back problems should travel in a sitting position with their back leaned against the backrest of a seat, if possible, a seat which has been designed ergonomically.

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