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In vitro validation of a novel mechanical model for testing the anchorage capacity of pedicle screws using physiological load application

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ABSTRACT

Biomechanical in vitro tests analysing screw loosening often include high standard deviations caused by high variabilities in bone mineral density and pedicle geometry, whereas standardized mechanical models made of PU foam often do not integrate anatomical or physiological boundary conditions. The purpose of this study was to develop a most realistic mechanical model for the standardized and reproducible testing of pedicle screws regarding the resistance against screw loosening and the holding force as well as to validate this model by in vitro experiments.

The novel mechanical testing model represents all anatomical structures of a human vertebra and is consisting of PU foam to simulate cancellous bone, as well as a novel pedicle model made of short carbon fibre filled epoxy. Six monoaxial cannulated pedicle screws (Ø6.5 × 45 mm) were tested using the mechanical testing model as well as human vertebra specimens by applying complex physiological cyclic loading (shear, tension, and bending; 5 Hz testing frequency; sinusoidal pulsating forces) in a dynamic materials testing machine with stepwise increasing load after each 50.000 cycles (100.0 N shear force + 20.0 N per step, 51.0 N tension force + 10.2 N per step, 4.2 N m bending moment + 0.8 N m per step) until screw loosening was detected. The pedicle screw head was fixed on a firmly clamped rod while the load was applied in the vertebral body. For the in vitro experiments, six human lumbar vertebrae (L1-3, BMD 75.4 ± 4.0 mg/cc HA, pedicle width 9.8 ± 0.6 mm) were tested after implanting pedicle screws under X-ray control. Relative motions of pedicle screw, specimen fixture, and rod fixture were detected using an optical motion tracking system.

Translational motions of the mechanical testing model experiments in the point of load introduction (0.9–2.2 mm at 240 N shear force) were reproducible within the variation range of the in vitro experiments (0.6–3.5 mm at 240 N shear force). Screw loosening occurred continuously in each case between 140 N and 280 N, while abrupt failures of the specimen were observed only in vitro. In the mechanical testing model, no translational motion was detected in the screw entry point, while in vitro, translational motions of up to 2.5 mm in inferior direction were found, leading to a slight shift of the centre of rotation towards the screw tip. Translational motions of the screw tip of about 5 mm in superior direction were observed both in vitro and in the mechanical testing model, while they were continuous in the mechanical testing model and rapidly increasing after screw loosening initiation in vitro.

The overall pedicle screw loosening characteristics were qualitatively and quantitatively similar between the mechanical testing model and the human vertebral specimens as long as there was no translation of the screw at the screw entrance point. Therefore, the novel mechanical testing model represents a promising method for the standardized testing of pedicle screws regarding screw loosening for cases where the screw rotates around a point close to the screw entry point.

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1. Introduction

Posterior spinal fixation systems are often used in clinics to prevent spinal instability, for example in case of deformities, loss of integrity, or vertebral fractures. These systems generally consist of a combination of metal rods as well as metal screws which are placed in the vertebral body via the pedicles and therefore ensure a high stability. However, pedicle screw loosening is reported to be a typical complication in clinical observations, possibly leading to pseudarthrosis and reoperation. Former retrospective in vivo studies which investigated screw loosening in more than 100 patients detected a loosening rate ranging between 1% and 21% of the patients (Louis, 1986; Roy-Camille et al., 1986; Steffee et al., 1986; Dick, 1987; Ohlin et al., 1994; Pihlajamäki et al., 1997; Okuyama et al., 1999; Glaser et al., 2003; Li et al., 2010). Due to the great variability within the data, missing standards for the radiological evaluation of screw loosening, as well as a probable publication bias, loosening of pedicle screws is supposed to happen in at least 20% of all patients (Galbusera et al., 2015).

Pedicle screw loosening is assumed to be related to stress shielding as well as microfractures of the vertebral bone which are promoted by reduced bone mineral density, since both the stress and failure load capacity decrease. Therefore, osteoporotic as well as osteopenic patients are more likely subjected to pedicle screw loosening, which represents a severe clinical problem due to the ageing society; in prospective clinical studies with osteoporotic patients, significant loosening rates of 13% (Wu et al., 2012) and 21% (Ohtori et al., 2013) were detected in 157 and 62 patients, respectively. Moreover, a strong correlation between bone mineral density and the number of loading cycles until failure of the spinal stability was found in vitro using pedicle screw systems (Wilke et al., 2016). Hence, novel methods for the standardized mechanical testing of pedicle screws including the material properties of bone are essential for the development of new screw designs as well as the validation of existing screws.

Since insertion torque and pullout strength do not simulate physiological loading conditions and were found to be an unsuitable predictor for pedicle screw loosening (Okuyama et al., 2000; Sandén et al., 2010; Schmoelz et al., 2012; Kueny et al., 2014), cyclic fatigue loading tests, also referred to as toggle tests, are considered as gold standard for pedicle screw testing in basic research; nevertheless, pullout testing still represents the exclusive standardized method to test the anchorage strength for medical bone screws (ASTM, F543-13e1, 2013). The development of new testing methods for pedicle screws using physiological loading is therefore also of high importance for the approval of novel products.

Several dynamic test setups were used in the past to simulate screw loosening in human vertebra specimens (Zindrick et al., 1986; Law et al., 1993; Tan et al., 2004; Brasiliense et al., 2013; Kueny et al., 2014). However, using human specimens produced high standard deviations within these studies due to a high variability in vertebral bone mineral density, pedicle size, as well as pedicle geometry. To overcome this problem, mechanical substitute models can be used where cancellous bone is represented by plastic foam (Hsu et al., 2005; Chao et al., 2008; Brasiliense et al., 2013; Yaman et al., 2015; Krishnan et al., 2016; Varghese et al., 2017) as well as cortical bone by foam with higher density (Brasiliense et al., 2013). These kind of models were mainly used for pullout tests in the past and therefore do not exhibit physiological loading conditions. Choma et al. (2011) investigated pedicle screw loosening using a test setup with multicomponent loading to simulate in vivo conditions as well as polyurethane foam and fibre-filled epoxy sheets to simulate cancellous bone and the vertebral endplates. However, the anatomical structures of the pedicle were not included, which could possibly have led to a non-physiological screw loosening pattern within this model. Nowak (2013) hence developed an experimental setup based on ASTM standard F1717 (F1717-15 2015) including a pedicle model, but the results were not confirmed by in vitro experiments.

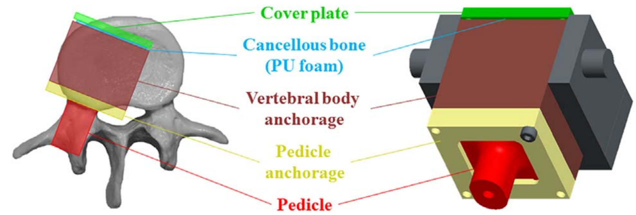

Fig. 1. Structural design of the novel vertebra model analogous to the anatomy of a human vertebra.

The purpose of the present study was therefore (1) to develop a mechanical testing model for the standardized, reproducible, and most realistic evaluation of the holding force and loosening pattern of pedicle screws and (2) to validate this model by in vitro tests using human cadaveric specimens.

2. Materials and methods

2.1. Mechanical testing model development

2.1.1. Structural design of the vertebra model

Based on the model of Choma et al. (2011), which included substitute materials for cancellous bone and the superior bony endplate, a vertebra model was developed whose components represent all anatomical structures of a human vertebra (Fig. 1). The cover plate as well as the vertebral body and pedicle anchorage were made of aluminium plates to ensure a firm fixation of a PU foam cuboid with the dimensions 40 × 32 × 32 mm, which approximately corresponds to the size of a large lumbar vertebra (Scoles et al., 1988). Additionally, a pedicle model was included to mimic the structural properties of the specific vertebral anatomy.

Regarding its dimensions, the newly developed pedicle model was designed using anatomical parameters from the literature (Table 1). Since the pedicle model was constructed for lumbar vertebrae as a first step, the dimensions were derived for the spinal level L3. Using these parameters as well as technical considerations regarding stability and durability and experiences from preliminary tests, a final pedicle model was designed (Fig. 2).

2.1.2. Specification of the material properties

Open-pored, highly porous PU foam (15 pcf, Sawbones Europe AB, Sweden), which has similar but lower strength properties compared to cancellous bone (Table 2), was used to simulate osteopenic bone. For the pedicle model, a custom-made tempered cast composite material made of epoxy resin and 10% 0.2 mm carbon fibres was selected after some preliminary tests with PU foam, PE, POM, and PEEK, since these materials showed non-physiological failure patterns such as early breakage in static compression and endurance testing. Moreover, the custom-made short fibre filled epoxy exhibited compressive strength properties similar to cortical bone (Table 2).

2.1.3. Definition of physiological loading parameters

Data regarding the loading conditions of pedicle screws in patients were gathered from previous studies, since direct in vivo measurements were not feasible. Therefore, data of Rohlmann and colleagues were used, which modified an internal spinal fixator by means of strain gauges and telemetry to measure the implant loads within the fixator rods in several patients during various activities (Rohlmann et al., 1994, 2000). The raw data of their experiments, which are web published (Bergmann, 2008), were examined and combined to obtain maximum axial forces and bending moments within the spinal fixator rods (Table 3). Based on these data, forces on the pedicle screw were defined as tension forces in anterior direction of about 100 N, shear forces in inferior direction of about 200 N, as well as bending moments around the screw-rod fixation point of about 8 Nm, which corresponds