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Titanium-alloy enhances bone-pedicle screw fixation: mechanical and histomorphometrical results of titanium-alloy versus stainless steel

Abstract Several types of pedicle screw systems have been utilized to augment lumbar spine fusion. The majority of these systems are made of stainless steel (Ss), but titaniumalloy (Ti-alloy) devices have recently been available on the market. Ti-alloy implants have several potential advantages over Ss ones. High bioactivity and more flexibility may improve bone ingrowth and mechanical fixation, and the material also offers superior magnetic resonance imaging (MRI) and computed tomography (CT) resolution and significantly less signal interference. However, no data are available from loaded spinal constructs regarding bony ingrowth and mechanical fixation. The aim of this study was to analyse the effect of Tialloy versus Ss pedicle screws on mechanical fixation and bone ingrowth in a loaded mini-pig model. Eighteen adult mini-pigs underwent total laminectomy and posterolateral spinal fusion at L3-L4, and were randomly selected to receive either Ss (n = 9) or Ti (n = 9) pedicle screw devices. In both groups, the device used was compact Cotrel-Dubousset instrumentation (Sofamore Danek) of an identical size and shape. The postoperative observation time was

3 months. Screws from L3 were used for histomorphometric studies. Mechanical testing (torsional tests and pull-out tests) was performed on the screws from L4. The Ti screws had a higher maximum torque (P < 0.05) and angular stiffness (P < 0.07), measured by torsional testing. In the pull-out tests, no differences were found between the two groups with respect to the maximum load, stiffness and energy to failure. No correlation between removal torque and the pull-out strength was found (r =0.1). Bone ongrowth on Ti was increased by 33% compared with Ss (P < 0.04), whereas no differences in bone volume around the screws were shown. Mechanical binding at the bone-screw interface was significantly greater for Ti pedicle screws than for Ss, which was explained by the fact that Ti screws had a superior bone ongrowth. There was no correlation between the screw removal torque and the pull-out strength, which indicates that the peripheral bone structure around the screw was unaffected by the choice of metal.

Key words Pedicle screw · Titanium · Stainless steel · Pull-out test · Torsion · Histomorphometry

Introduction

Spinal implants are used to treat a wide variety of painful and disabling spinal disorders. Most modular spinal in-

strumentation systems are based on the pedicle screw as a primary anchor.

Segmental posterior fixation of the spine by means of pedicle screws, bars and bone grafting normally provide a

stable and rigid internal construct [4, 14, 18, 34]. However, the overall stiffness of the construction probably never reaches the full stiffness of the implant, due to the semirigid interfaces between bone and instrumentation. The magnitude of the stresses on the instrumentation at the bone-screw and bone-rod interfaces will depend on the load distribution between the bone and the implant, as well as the number of sites of bone purchase of the implant. It has been shown that a change in the interface behaviour can occur with a change in the degree of loosening between the plate and screw, while keeping the same material [11], and that differences in implant constructs can result in a difference in bone mineral loss [5, 11].

Several types of pedicular screw systems have been utilized to augment lumbar spine fusion, and the majority of these systems are made of stainless steel (Ss). However, titanium (Ti) devices are marketed with increasing frequency and higher costs [8, 36]. Ti-alloy implants have several potential advantages over Ss:

- 1. High bioactivity and more flexibility (lower elastic modulus) may improve osseointegration and mechanical fixation [17, 25, 27, 32, 35], and
- 2. The material offers superior magnetic resonance imaging (MRI) and computed tomography (CT) resolution, and significantly less signal interference [9, 20, 36].

Ti versus Ss screws in vivo have been the object of only a few, exclusively non-weight/stress-loaded, investigations [10, 29]. It seems that Ti may enhance bone ingrowth and mechanical fixation compared to Ss; however, a weight/ stress-loaded study will have to confirm these findings.

The aim of this study is to investigate the effects of Ti versus Ss pedicle screws on mechanical fixation and bone ingrowth in a loaded mini-pig model.

Materials and methods

Eighteen skeletally mature female Göttingen mini-pigs, 24 months old, weighing approximately 30 kg, were assigned randomly to one of two groups – Ti pedicle screw fixation or Ss pedicle screw fixation. The Ti-alloy (Ti-6A1-4V) and Ss (316L) pedicle screw devices had the same geometry and were Compact Cotrel-Dubousset Instrumentation (CCD; pedicle screw dimensions, 4×25 mm; Sofamor Danek Corp). The surface roughness of the Ti and Ss implants was tested by the Danish Institute of Technology (Taastrup, Denmark). Surface roughness (R) of Ti-alloy screws was 0.90 μ m (range 0.82–0.98 μ m) and for Ss screws, 0.05 μ m (range 0.05–0.06 μ m).

Each pig underwent laminectomy and posterolateral spinal fusion at the second lowest level (L3-L4). Postoperatively, the pigs were kept in individual cages and were allowed free activity. All animals were sacrificed 12 weeks after the operation, by an overdose of saturated KCl, while under general anaesthesia. The investigations complied with the Danish Law on Animal Experimentation and were approved by the Danish Ministry of Justice.

Surgery

The surgical procedures were performed using general anaesthesia, aseptic conditions, and prophylactic perioperative antibiotics (ampicillin). The L3-L4 spine was exposed through a posterior midline incision. A guide pin was inserted, under a C-arm X-ray image intensifier, into the pedicle area. Four tulip screws were then screwed into the pedicle and the body of the vertebra. A standard L4 total laminectomy was performed. Rods were fixed tightly and 8 g autogenous iliac crest bone graft was packed along the decorticated transverse process and facet joint on both sides.

Preparation

The L3-L4 spine was harvested with four screws in situ and rods dismantled. The vertebral body and the pedicle area were separated by a vertical cut into two parts, leaving each screw alone in the bone; a water-cooled diamond band saw (EXAKT-Cutting Grinding System, standard, Norderstedt, Germany) was used. Then the specimens were fixed in 70% ethanol for histomorphometry analysis. Screws from L4 were stored at -18 °C for subsequent mechanical testing.

Mechanical testing

Mechanical testing was performed on an MTS mini Bionix 858 testing machine (MTS Corp., Minneapolis, USA). The inaccuracy of the measurement devices was less then 1%. As a prestudy, the



Fig.1 A schematic illustration of the mechanical test frame (MTS model 858 testing machine) used for analysing torsion and pull-out strength (*A* specimen embedded in polymethylmethacrylate, *B* pedicle screw grip, *C* universal joint)

implant stiffness (N/cm) was tested in an established artificial vertebral corpectomy model (two ultrahigh-molecular-weight polyethylene blocks), by use of axial compression load [6]. It showed that the stiffness ratio of the Ti-alloy implants was 68%, normalized to the mean stiffness of the Ss implants.

After sacrificing the animals, a torsion test was performed on the right-side screws and a pull-out test on the left-side screws. The specimens were thawed at room temperature, wrapped in latex to prevent cement from penetrating the bone, embedded in polymethylmethacrylate [27], and fixed into a metal holder. With the tissue block tilted to orient the screw axis vertically, the exposed end of the transpedicular screw was attached with two special adapters fixed to the upper load cell (Fig. 1). The torque angle, pull-out force, load cell displacement and moments were recorded directly with a Teststar II acquisition system (790-10 Testware-SX Application, MTS Corp., Minneapolis, USA). The load-displacement data were analysed using NIH Image 1.51 producers and Excel 4.0 software producers. For the torsion tests, the screws were rotated 30° counter-clockwise at the speed of 0.5°/s. From the torsion tests, the maximum torque (Nmm) and angle-related stiffness (Nm/°) were calculated. For the pull-out tests, the screws were pulled out 10 mm at a rate of 0.2 mm/s. From the pull-out testing, the stiffness (N/mm), strength (N), and energy (Nmm) to failure of each screw were calculated. Stiffness was determined by calculating the slope of the early, linear portion of the load-displacement curve. To calculate the slope, a least-squares regression was performed on the raw data. Pull-out strength was defined as the maximum load to failure, and energy to failure was obtained by integrating the area under the load-displacement curve to the maximum load.

Histological examination

Specimens were dehydrated in graded ethanol (70–99%), containing 0.4% basic Fuchsin, and embedded in PMMA. Serial sections were cut to obtain vertical sections, using the vertical section technique to get unbiased estimates [2, 26]. A section axis parallel to the long axis of the screw was chosen. The sections were randomly chosen for evaluation of histomorphometry. These were cut, ground and polished to a thickness of 50 μ m, using a micro-grinding system (EXAKT-Micro Grinding System, Norderstedt, Germany). The section surface was counterstained with 2% light green for 15 min [12].



Fig.2 Histomorphometric analysis was done using linear intercept techniques. The figure shows the direct contact between the implant (*black*) and bone (*green*), without an intervening fibrous tissue layer (*red*) at the interface, on the light microscopic level. A typical photograph from the titanium (Ti) group (original magnification, \times 25)



Fig.3 Histomorphometric analysis using linear intercept techniques. A line is drawn between each peak of the thread. Bone volume inside the thread of the screw was measured as a percentage of total volume

Blinded quantitative evaluation of bone ongrowth was performed using the linear intercept technique [16], and a special software program (CAST-Grid, Olympus Denmark A/S, Glostrup, Denmark). Bone ongrowth was defined as bone in direct contact with the screw surface as a percentage of the total screw surface (Fig. 2). Fibrous tissue and bone marrow with screw contact were also measured as percentage values.

Bone ingrowth was defined as bone volume as a percentage of total volume. A line was drawn between each peak of the thread. Bone volume was counted as a percentage inside the thread enveloped by the line (Fig. 3). Both bone ingrowth and ongrowth examinations were done in the body part according to the location of the spinal canal. The test systems for evaluation of bone ongrowth and ingrowth were calibrated to have approximately 200 intercepts or points counted for each parameter per specimen [13].

Statistics

The Student's *t*-test for unpaired observations was used to analyse the difference between Ti and Ss, and the Pearson correlation test was used to analyse the correlation between removal torque and the pull-out strength. The results are given as mean (SD); *P*-values less than 0.05 (two-tailed) were considered statistically significant. Data were all normally distributed and analysed by normality plots. SPSS was the statistical software used.

Results

Seventeen animals completed the study. One animal from the Ti group was excluded due to deep infection around the implant. Thirty-four screws were available for analysis (17 mechanical and 17 histomorphometrical).

Mechanical testing

The torsional test showed that the maximal removal torque for Ti screws was increased as compared with Ss screws (P < 0.05) (Fig. 4). The angle-related stiffness of the Ti screws was also larger than that of Ss screws (P < 0.07) (Fig. 5). There were no significant differences in the



Fig.4 Comparison of maximal torque values shows a higher mean value for Ti screws than for stainless steel (Ss) screws. Student's *t*-test for unpaired observations was used. Values are mean and error bars represent standard deviation



Fig.5 The angle-related stiffness of the Ti screws was larger than that of Ss ones. Student's *t*-test for unpaired observations was used. Values are mean and error bars represent standard deviation

Table 1 Pedicle screw pull-out test data for titanium- (Ti-) alloy and stainless steel (Ss) screws (values are mean \pm SD)

	N	Pull-out strength (N)	Stiffness (N/mm)	Energy to failure (Nmm)	Sig.
Ti-alloy	8	2232 ± 259	1124 ± 118	4989 ± 644	NS
Ss	9	2128 ± 277	1275 ± 126	4244 ± 860	NS

pull-out strength, stiffness, and energy to failure between these two groups (Table 1). For the pull-out testing, failure occurred through simple stripping of the bone at the periphery of the screw thread.

There was no linear correlation between removal torque and the pull-out strength (r = 0.1, NS)

Histologically, bone, bone marrow and fibrous tissue occupied screw surfaces from both groups. Some surfaces obviously had direct contact between implant and bone



Fig.6 The amount of bone in direct contact with the screw surface, as a percentage of the total screw surface, was significantly higher for Ti than for Ss screws. Student's *t*-test for unpaired observations was used. Values are mean and error bars represent standard deviation

Table 2 Results of bone volume (presented as a percentage) in thevertebral body and pedicle part (values are mean \pm SD)

	Screws	Vertebral body	Pedicle part	Sig.
Ti-alloy	8	55 ± 8	63 ± 6	NS
Ss	9	56 ± 12	62 ± 21	NS

without an intervening fibrous tissue layer at the interface (Fig. 2). Bone ongrowth was 29.4% for Ss and 43.8% for Ti (P < 0.04) (Fig. 6). The bone volume purchased by the screw threads was analysed in the body area. There were no differences in bone volume between the Ti group and Ss group (Table 2).

Discussion

The advantages of Ti systems are claimed to be: a more "physiological" modulus of elasticity, lower density, improved biocompatibility, and MRI compatibility.

The modulus of elasticity is an important physical property of materials, and indicates the flexibility or rigidity of a component before permanent deformation occurs. The elastic modulus for cortical bone is 16.5 GPa); for Ti-6A1-4V alloy, 105 GPa; and for 316 stainless steel, 193 GPa [28]. A material with a low modulus of elasticity possesses the advantage of reduced stress shielding, because more stress will be transferred to the bone.

Most mechanical bone-pedicle screw interface studies have been performed in human cadaver spines [3, 7, 15, 19, 22, 24, 30, 33, 37, 38], and a number of these papers have shown a linear correlation between the insertional torque and the pull-out strength [3, 7, 24, 30, 33, 37]. These and other cadaver studies have been important in testing and optimizing new and existing screw designs. However, these mechanical test data do not reflect the biological response (bone remodelling) to altered mechanical loading, to metal implants or to wear debris. From this point of view, a weight/stress-loaded in vivo model is required.

The Göttingen mini-pig was chosen as a model because of its vertebral anatomy, with well-defined pedicles well suited for pedicle screw instrumentation, early growth plates closing, and opportunities for genetic monitoring by having animals from the same sub-colony. Our previous mini-pig studies have shown that a solid posterolateral spinal fusion can be achieved within a 3-month observation period.

In our mini-pig laminectomy model, we found no correlation between the removal torque and the pull-out strength, and we found no differences between Ti and Ss in relation to the pull-out strength and stiffness. This is consistent with the results from the only non-published report on in vivo fixation of unloaded Ti and Ss pedicle screws [29]. The authors investigated various pedicle screws of differing material and found that, although materials had similar pull-out forces, a better interface was achieved with the commercially pure Ti and Ti-alloy as compared to vitallium and 316 Ss.

Through torsional testing we found that, although the screw had the same geometry, the maximum removal torque exerted on the screw was significantly higher for Ti than for Ss. Our study also showed that screws from both groups had direct bone contact with the surface, but the Ti screws had more bone binding than the Ss. More bone binding of the screw is the likely cause for increase in the resistance of the screw to torsional force and enhanced fixation.

The biocompatibility of Ti implants over Ss implants has been demonstrated in some studies. Albrektsson and Hansson [1] used light and electron microscopy to study the metal/bone interface between unthreaded Ti and Ss implants, and found direct integration with Ti, while the Ss implants had a connective tissue layer, one or two cells thick, surrounding them. An in-vivo rabbit tibia study showed that Ti screws improved bone contact and had higher removal torques than Ss [10]. The few reported tensile tests with Ti implants show tensile strength of the Ti-bone interfaces, indicating a chemical bond [17, 35]. Skripitz et al. [32] demonstrated that when the implants were heat or alkali treated, chemical bonding between bone and a Ti implant takes place after as little as 4 weeks. Recently it has been shown that Ti has an anti-inflammatory interaction in a rat arthritis model [25]. However, there seems to be some disagreement about the reaction to Ti and Ss unthreaded implants in bone. In contrast, Linder and Lundskog [21] found that unthreaded implants of Ti and Ss inserted into cortical bone of rabbit tibias produced similar responses, with lamella bone abutting directly onto each metal surface. A histological study by Millar et al. [23] compared the tissue response of Ti and Ss screws when inserted into the calvaria of dogs for different periods. They found no discernible difference in the tissue reaction between the two types of screw.

There is concern in regard to how Ti implants will compare in stiffness and fatigue life with implants made of Ss. In a corpectomy model, Pienkowski et al. [28] showed that the stiffness of Ss transpedicular implants is clearly greater than that of Ti-alloy devices of identical size and design. However, fatigue life is very much dependent on design, and for those designs in which Ti-alloy is superior, enlargement of the implants can compensate for the reduced stiffness of the Ti-alloy. They found that the stiffness ratio of the Ti-alloy implants was 59% that of Ss implants (TSRH and Isola implants). For CCD implants, our corpectomy model study showed a stiffness ratio of 68% for Ti-alloy, normalized to mean stiffness of the Ss implants.

Mechanically, it is well known that the loading power of the screw produced by the bone purchase is related to the screw size, thread design and bone quality [6, 18, 31]. An axial pull-out represents bone strength and does not reflect screw failure in the clinical situation. It does, however, reflect the magnitude of screw purchase prior to the effects of micromotion and cyclic loading [22]. The surface bone remodelling may not change the amount of bone volume purchased by the thread. In fact, in our study, bone volume purchase did not show differences between the Ti and Ss groups. To the contrary, the surface bone remodelling may change the binding strength of the screw. Any motion or micromotion of the segments may affect the fusion of the graft. Rotational stability of the screw becomes essential to maintain the stability of the whole construct, especially for short-segment fixation without transverse bar and fixation. One limitation of this study is that the surface roughness was higher for Ti implants than for Ss implants. However, the implants are commercially available and therefore this study reflects a clinical situation. In addition, an unloaded in vivo study has shown that Ti polished screws and Ti glass-ballblasted screws both had a higher removal torque than Ss screws with same surface roughness [10].

Finally, one must be cautious in extrapolating results from this animal study to the human situation, due to the fact that the longitudinal load on a pig spine is much lower than that in humans, and also because in vivo screws loosen step by step due to repeated loading, which is not simulated with pull-out tests and torsional tests that use a single nonrecurring pull-out force and torsional load. However, repeated loading on the bone-screw interface did take place over the 3-month observation period.

Conclusion

Mechanical binding at the bone-screw interface was significantly greater for Ti pedicle screws for than those of Ss. This could be explained by the fact that the Ti screws had a superior bone ongrowth. There was no correlation between screw removal torques and the pull-out strength.

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Clinically, the use of Ti or Ti-alloy pedicle screws may be preferable in osteoporotic and elderly patients with decreased osteogenesis.

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