

## Fast fatigue testing of spinal implant systems with the LSP-test method

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**Spinal implant systems for posterior fixation must have a good biomechanical stability. The methods used for testing spinal instrumentation require a relatively long time for valid results of the new or improved implants. The aim of this study was to scrutinise the usefulness of the Load-Stage-Product -test in testing spinal implants, and to determine the maximum fatigue values of differently surfaced titanium spinal rods of comparable diameters. The LSP-test showed to be a fast and reproducible fatigue test method, and spared considerably time used in testing the biomechanical properties of the spinal rods. The cp-titanium grade 4 which was shot peened with steel balls and glass beads was found to be the best material for the fatigue tested rods.**

Spinal implant systems for posterior fixation are required to have a good biomechanical stability. The first spinal implant systems were made of stainless steel, the latest of biocompatible materials such as titanium (rods) and titanium alloys (pedicle screws and hooks)(1-5). Pedicle screws for spinal fixation systems are made of the titanium alloy Ti6Al4V ELI according to the standard of the American Society of Testing Materials, ASTM F 136 (6, 7). Longitudinal interconnecting rods applied to the line of pedicle screws are made of cp-titanium grade 2 (Ti-2), or cp-titanium grade 4 (Ti-4) according to ASTM F 67 (8, 9). The quality assurance systems according to ISO 9000 (10) by law have led to detailed standardisation of testing implants. The tests ASTM F 1717 (11), and ASTM F 1798 (12) for spinal instrumentation have been proved to be relevant with their experimental set ups, loading, and test frequency. When these test methods are used to simulate the loading of the spinal implants, e.g. while walking, they although require a relatively long testing time for valid results of the new or improved implants with changed geometrical properties. The LSP-test allows within a relatively short time (from 48 hours for a single test) an expressive evaluation of the dynamic constant stress of the tested system. The aim of this study was to scrutinise the usefulness of the Load-Stage-Product -test in testing spinal implants, and to determine the maximum fatigue values of differently surfaced titanium spinal rods of comparable diameters to achieve an optimal bending behavior, and a

sufficient stiffness to guarantee a minimum loss of the correction angle.

### Materials and methods

The cp -titanium grade 2 (Ti-2) spinal rods and the cp-titanium grade 4 (Ti-4) spinal rods were surfaced differently to achieve variations of the surface roughness. The Ti-2 rods, alumina blasted Ti-2 rods, and Ti-4 rods were shot peened either with steel balls and glass beads, or with glass beads only (Table 1). The different shot peening surfacing creates negative internal stresses on the outer area of the surface (13). The science of strength of materials allows to add internal stresses within the area of yield strength according to the principle of superposition of stresses at static load situations (14). Tensile stress is defined as a positive stress, and compression as a negative stress (15). For example, when a rod with a bending load value of 600 MPa (which is equal to +600 MPa tensile strength) at the outer surface is shot peened with steel balls and glass beads, and the internal stress on the outer surface after shot peening is measured to be - 550 MPa (a compression stress), the final load at the outer surface of the rod is + 50 MPa , which is a tensile strength. A posterior spinal instrumentation system receives a similar load when a patient walks.

The tested Ti-2 rods had a diameter of 6.3mm, and the Ti-4 rods the diameter of 6.0 mm (Table 1). This difference of the diameter was selected to obtain a similar stiffness behaviour, and a similar

bending value  $f$  according to a patient's load situation. The bending value  $f$  was defined as follows:  $f = Fl^3/3EI$ , where  $F$  is the load,  $l$  is the lever arm, and  $E$  is the Young's modulus. The stiffness  $I$  is represented by the moment of resistance to the bending stress, and is calculated

by  $I = d^4 \cdot \pi / 64$ , where  $d$  is the diameter of the rod. The difference in material properties, e.g. the yield strength, was  $R_{p0.2} = 350$  MPa for Ti-2, and  $R_{p0.2} = 480$  MPa for Ti-4.

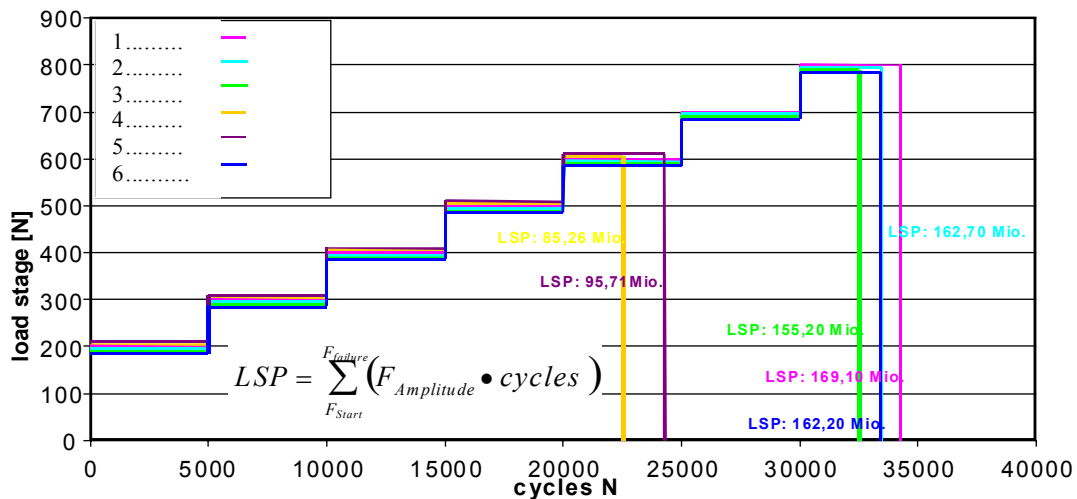


Figure 1. Load Stage Product for the tested rod types.

Table 1. The types of the tested spinal rods with different shot peening parameters

Type	Surface modification	Material	Diameter
Type 1	Shot peened with steel balls and glass beads	cp-titanium grade 2	6.3 mm
Type 2	Alumina blasted and shot peened with steel balls and glass beads	cp-titanium grade 2	6.3 mm
Type 3	Alumina blasted and shot peened with glass beads	cp-titanium grade 2	6.3 mm
Type 4	Shot peened with glass beads only	cp-titanium grade 2	6.3 mm
Type 5	Shot peened with glass beads only	cp-titanium grade 4	6.0 mm
Type 6	Shot peened with steel balls and glass beads	cp-titanium grade 4	6.0 mm

Table 2: The LSP values of the tested spinal rods

Rod type	Test 1 LSP	Test 2 LSP	Test 3 LSP	Tests 1 – 3 The mean LSP
Type 1 (Ti-2)	162,70	148,98	158,63	158,90
Type 2 (Ti-2)	169,10	166,34	154,89	161,31
Type 3 (Ti-2)	155,20	135,75	144,19	145,05
Type 4 (Ti-2)	85,26	76,74	83,55	81,85
Type 5 (Ti-4)	95,71	95,39	75,17	88,76
Type 6 (Ti4)	162,20	163,3	175,73	167,08

All dynamic tests of the differently surfaced Ti-2 or Ti-4 rods were performed three times with a monoaxial servohydraulic test equipment MTS 810 (MTS Minneapolis, Minnesota, USA) according to ASTM F 1717 and ASTM F 1798 with standardised lever arms and distances. A load cell was fixed to the upper end allowing the adjustment of the desired stress in axial direction. The tension and compression loads of the rods began from 200 N. With every 50 000 cycles the

amount of loading grew in steps of 100 N until the final fatigue failure of the rods. The LSP - value was defined by calculating the sum of the single load stage cycle product: the amplitude force multiplied with the number of cycles (Figure 1).

## Results

The LSP -test proved to be a fast fatigue testing method of spinal rods. The results of 18 testst were achieved within 2 weeks compared with 6-8 months needed with the common test procedures.

The fatigue values of the rod types 4 and 5 were found to be higher than the values of the other rod types (Figure 1, Table 2). The cp-titanium grade 4 rods that were shot peened with steel balls and glass beads had the highest fatigue values (an average LSP -value of 167.08 millions). The cp-titanium grade 2 rods that were similarly shot peened showed almost similar fatigue values (an average value of 161.31 millions for alumina blasted rods, and an average value of 158.90 millions for rods that were not alumina blasted). The rods that were shot peened with glass beads only without alumina treatment had significantly lower LSP fatigue values (81.85 for Ti-2, and 88.76 for Ti-4).

## Discussion

The repeatable and fast LSP -fatigue test method spared considerably time used in testing the biomechanical properties of the spinal rods, although the LSP test can not yet replace the required testing procedures used in developing and marketing of spinal implants. With the LSP-test the testing time during the development process of spinal implants could be reduced.

The levels of fatigue values of the rods are influenced by both the base material and the surface treatment process. The values with shot peening with glass beads only were almost 50 % of the values achieved with the rods that were shot peened with steel balls and glass beads. The phenomenon can be explained by the low mass of glass beads, as well as the highest value of energy, and therefore the highest value of internal stresses related to the shot peening with steel balls and glass beads. This treatment could almost compensate the lower level of yield strength. The alumina blasting improved the average fatigue value of the Ti-2 rods that were shot peened with steel balls and glass beads: an average LSP -value of 161.31 compared with the mean value of 158.90 without alumina blasting of Ti-2 rods, and with the mean value of 167.08 of Ti-4 rods. In conclusion, the Ti-4 material with the higher values of yield strength showed to be the best material considering the possibility of the lowest loss of correction angle, and the best long term stability achieved in operations where these kind of spinal rods are used.

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