Testing of primary stability of the Activ® L intervertebral disc prosthesis in cadaver bone and comparison of the two different anchoring concepts – keel and spike anchoring

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Research article

Keywords: primary stability of intervertebral disc prosthesis; micro-motions; Aesculap ActivL; anchoring concept; keel; spikes

Abstract

Background: High primary stability is the fundamental prerequisite for safe osseointegration of cementless intervertebral disc prosthesis. The aim of our study was to determine the primary stability of intervertebral disc prosthesis with two different anchoring concepts – keel and spike anchoring.

Methods: 10 human cadaveric lumbar spine specimens with an ActivL intervertebral disc prosthesis (5 x keel anchoring, 5 x spike anchoring) were tested on a spine simulator. Under axial load, moments of flexion, extension, left and right bending and axial rotation were applied on the lumbar spine specimens through a defined three-dimensional movement program as per ISO 2631 and ISO/CD 18192-1.3 standards. Micro-motion of the implant was measured in every axis for both anchor types and compared using statistical test for significance after calculating 95% confidence intervals.

Results: In the transverse axis, the keel anchoring concept showed lower mean values of micro-motion , which was statistically significant ($p < 0.05$) compared to spike anchoring concept. In the sagittal axis, the results were again in favour of the keel anchoring, but did not reach statistical significance ($p > 0.05$). The highest micro-motion values were observed in the longitudinal axis. Both concepts showed values around the threshold of primary stability (150 µm) with the spike concept showing lower mean values, but without a statistically significant difference.

Conclusions: Both types of anchors met the criteria of primary stability. The keel anchoring shows a slight advantage compared to anchoring with spikes. Direct postoperative active mobilization doesn't seem to compromise the primary stability of the prosthesis.

Background

In recent decades, several surgical methods were developed to treat degenerative pathologies of intervertebral disc and the bony components of a vertebra. A significant number of verified causes of low back pain are related to the intervertebral disc. As a consequence, the improvement and restoration of the biomechanics of the pathologically altered disc, has become the aim of many treatment alternatives. The developments in recent years have led to introduction of several anchoring concepts. Micro-motion at the implant –bone interface has significant effect on the primary stability of prosthesis, which in turn affects secondary stability by osseointegration [1]. Nevertheless, no scientific work on the investigation of micromotions as a measure of primary stability of intervertebral disc arthoplasties has been published to date.

To test the quality of primary stability given to the prosthesis by two different anchoring concepts, we conducted experiments, on human lumbar spine specimens and simulated the movements in three planes under axial loading. The purpose of our study was to answer the following questions:

• Can the prosthesis with two different anchors comply with the scheduled limit of 200 µm of micro-motion, in order to achieve successful Osseo-integration?

• Is there a statistically significant difference in the measured micro-motion between the two different anchoring concepts?
• Should the postoperative phase of patients be redesigned or optimized based on results of simulation study?

Methods

For our experiments, we had 32 lumbar spine specimens (L2-S2) from human donors (3 females and 29 males), two of which (the ones from the oldest donors) were used in the preliminary tests. The ethical standards in the Helsinki Declaration of 1975, as revised in 2000 (5), as well as the national law were respected. The average age was 38.3 years (28–44 years) in the female and 36.8 years (18–54 years) in male cohort. In this way, we largely excluded possible orthogeriatric metabolic bone disorders (e.g. osteoporosis).

The ActivL prosthesis (B. Braun/Aesculap, Tuttlingen AG, Germany) consists of three components and is available in two versions. It has a semiconstrained design, which allows a limited translation of an ultra high molecular weight polyethylene (UHMWPE) inlay in the sagittal plane. The endplates are made of Cobalt Chrome (CoCr) alloy. In the spiked version (Fig. 1) there is a row of three spikes along the front edge while the keel on the other version (Fig. 2) is attached along the midline in an antero-posterior direction. Controlled translational motions of the core in the antero-posterior direction lead to the displacement of the center of rotation, physiological approximation and normal mobility.

(Fig. 1) (Fig. 2)

The experiments were carried out in the laboratory for Biomechanics and Experimental Orthopaedics of Ludwig-Maximilians-University in Munich. An existing simulator (Fig. 3) was used, which consists of three major parts: a motion simulator, a control block and a connected computer. The motion simulator allows the simulation in three planes with simultaneous axial load. Thus, there occur six "true moments": in the sagittal plane flexion and extension, in the frontal plane lateral-bending and in the transverse plane left and right rotation [2].

(Fig. 3)

From our 32 cadaver specimens we chose 10 male specimens with similar L4 and L5 vertebral body dimensions fitting to the Acitve L prosthesis size M to allow comparability of results.

The segment L4/5 was deducted from the remaining spine specimens in order to be our test segment. It was prepared with removal of the tissue around the vertebral body anteriorly and laterally including the anterior longitudinal ligament and periosteum. The disc tissue was completely removed and the top and bottom endplates were cleared of cartilage remnants. Care was taken to preserve the subchondral bone. The prosthesis was implanted with a proper surgical technique using the original instruments provided. For the experiments, we used prosthesis of only size M with a superior plate angulation of 6° and

polyethylene (PE) inlay of 8.5 mm or 10 mm. In combination with the described selection of the specimens this allowed a nearly anatomical reconstruction of the motion segments. Therefore, it can be assumed that the obtained measurement results correspond to the values in vivo.

For the measurement of the micro-motions specially attached measuring sensors were used, which were connected via a measuring module to a computer. This allows very precise recording of the motion amplitudes accurate to 1/1000 µm. The construct with the implanted prosthesis and the sensors were fixed with cement to specially designed adaptors and these in turn to the motion simulator (Fig. 4).

(Fig. 4)

The setting of the simulator (Table 1) was carried out according to the ISO 2631 standard for defined three- dimensional coordinate systems. The movement areas were set using default values according to ISO/CD 18192-1.3 [3].

Goal was a simulation of the natural movement sequence, under physiological conditions, in the lower lumbar spine. Each axis was moved with the frequency of one Hz. The axis were not coupled.

Table 1
Range of motion and values of the axial load according to ISO/CD 18192-1.3 for a motion segment in the lumbar spine.

	Flexion/Extension	Lateral rotation	Axial rotation	Axial load
Maximum	$+6^0$	$+2^0$	$+2^0$	2000 N
Minimum	-3^0	-2^0	-2^0	600 N

The recording of the data was done via the measuring sensors connected to the receiver module. The processing and presentation of the results was done with the software Catman (HBM Germany).

For both implants 5 cycles of measurements were performed. The measurement of the micro-motion started parallel to the movement simulation. The measurement data were recorded with a frequency of 50 Hz in all three axis. In each experiment, the simulation ran for more than 1000 cycles (on average about 1050). The graphical representation of the measured values showed the stabilization of the measured amplitudes after passage of about 400 cycles. In the phase between the 540th and the 600th cycle, 60 representative cycles with 3000 values were selected for the evaluation of the results. Thus, we had 60 micro-motion's amplitude values per experiment per plane. A calculation of a representative mean value for the amount of movement of the prosthesis in one particular axis was done from these determined values. All mean values of the tested prosthesis were grouped according to the axis in an Excel spreadsheet and were fed for statistical analysis in the GraphPad Prism 6 program.

For the statistical analysis (IBM SPSS 25.0®) methods of descriptive statistics were used. At first, we tested our values with the Kolmogorov-Smirnov normality test and we found out that our results follow a

normal distribution. Then the Student's T-test was performed to investigate the significant differences in the micro-motion of the intervertebral disc prosthesis in each axis for the two anchoring types. The significance level was set at 0.05. The graphic presentation of the results of the tested prosthesis was made in the form of box plots representing the three axis of motion. In particular, for the presentation of localization and dispersion, we used the median and interquartile range (Q3 minus Q1) respectively. The median represents the movement level. The interquartile range defines the motion profile.

Results

The obtained results of the descriptive analysis are presented in the following three tables according to the axis of prosthesis movement. These indicate the mean and median, interquartile range (IQR), the standard deviation, standard error of mean and the confidence intervals in μm. The descriptive analysis and graphical presentation were done by entering the usual 95% confidence interval.

Micro-motions in the transverse axis (Table 2):

Table 2

Micro-motions of the prosthesis in the transverse axis in μm.

Anchoring Type	Mean	Median	IQR[1]	Std. Deviation	Std. Error of Mean	Lower 95% CI	Upper 95% CI
Aesculap Keel	4.65	4.80	4.48	2.29	0.93	2.25	7.05
Aesculap Spikes	15.85	15.65	5.85	4.60	1.88	11.03	20.67
1IQR: inter-quartile range.							

In both anchor types the value for micromotion were below the required threshold of 150 μm, which is a criterion for primary stability. The keel anchoring system showed a smaller mean micro-motion value of 4.65 μm, compared to 15.65 μm and the difference was statistically very significant (p = 0.003).

In the sagittal axis we obtained the following results (Table 3):

Table 3

Micro-motions of the prosthesis in the sagittal axis in μm.

Anchoring Type	Mean	Median	IQR[1]	Std. Deviation	Std. Error of Mean	Lower 95% CI	Upper 95% CI
Aesculap Keel	39.97	39.20	24.10	12.79	5.22	26.55	53.39
Aesculap Spikes	45.75	42.95	15.20	7.73	3.16	37.64	53.86
1IQR: inter-quartile range.							

In the sagittal axis the micro-motions values of both anchoring types lay also well below the threshold of 150 μm, thus fulfilling the criterion of primary stability. The keel anchoring system again showed smaller micromotion, but on this occasion it did not reach statistical significance. (p-value is 0.365)

Finally, in the longitudinal axis we obtained the following results (Table 4):

Table 4

Micro-motions of the prosthesis in the longitudinal axis in μm.

Anchoring Type	Mean	Median	IQR[1]	Std. Deviation	Std. Error of Mean	Lower 95% CI	Upper 95% CI
Aesculap Keel	157.00	155.40	21.90	11.37	4.64	145.00	168.90
Aesculap Spikes	141.40	135.10	73.98	42.70	17.43	96.55	186.90
1IQR: inter-quartile range.							

In the longitudinal axis the highest micro-motion values were observed, which lay close to the primary stability threshold of 150 μm, and in any case below the limit of 200 μm. Here, the spike anchoring concept shows better values, but a greater dispersion, as shown by the standard deviation and interquartile range values. The p-value is 0.408 indicating that difference is not statistically significant.

In Fig. 5 are presented the motion ranges of the prosthesis in every axis in the form of box plots.

(Fig. 5)

Discussion

The experimental model with fresh frozen human specimens for biomechanical testing of the spine and testing of spinal disc prosthesis has long been established and described repeatedly in the literature [2, 4, 5, 6]. We used specimens of both sexes, with early degenerative changes. It has been shown that the

mechanical behaviour of spinal segments in the simulator remains unaffected by "degenerative changes" [7]. The main criterion for selection of the specimens was the young age of the donor. This ensures that osteoporosis is ruled out of equation as it can potentially affect the micromotion of disc prosthesis owing to sparse bony structure. In addition, osteoporosis is a contraindication for implantation of intervertebral disc prosthesis[57].

The axial load and adjustment of motion range of a spinal segment was performed according to ISO values. However, there exists in the literature a recommendation to conduct the experiments without the axial load [3]. The reason is the otherwise lack of comparability due to great individual variation of the biomechanical characteristics of the human spine. In our experiments, the axial load was adjusted between 600 to 2000 N. Values of 2000 N are achieved only when lifting weights of 10 kg or leaning forward with simultaneous rotation of the upper body [3]. Such values are unlikely to appear directly postoperatively in vivo, due to appropriate therapeutic instructions in newly operated patients. This load-adjustment probably led to the observed increase of the micro-motions in the longitudinal axis. The results did not show a statistically significant difference between the two anchoring concepts in this axis.

The spiked prosthesis has shown lower mean and median values, but greater dispersion of the measured values. On the other hand, the keeled implants showed more homogenous results, but nonetheless high micro-motion values. Both concepts guarantee a safe Osseo integration, because complex multi-axial movements combined with axial load, as mentioned, are not expected in a newly operated patient.

In the sagittal axis the primary stability is guaranteed with both anchoring concepts and there hasn't been any significant difference between them. The statistically significant difference, which was observed in the micro-motion values in the transverse axis, gives a slight advantage for the keel anchoring concept. That was expected due to the larger contact area with the bone, which also provides a larger area for osseointegration. Nevertheless, it seems to be of little clinical importance, because the observed motion ranges of both concepts lie, with exception of the longitudinal axis, very well below the primary stability threshold of 150 μm postulated from Jasty [1].

Bah [8] and O´Rourke [9] report in their current publications on cement-free hip prosthesis (Furlong Evolution cement less short stem, Pinnacle Cup) about calculated micro motions well over 150 micrometres. Nevertheless, the Swedish hip arthroplasty register [10] reports excellent long-term results for the Pinnacle Cup. It can be concluded that a safe Osseo integration of cement less implants is possible even in micro motions well over 150 micrometres. This explains why the micro motions above 150 micrometres in the longitudinal axis in our experiments seem to be without relevance in practice. Current clinical publications [11, 12, 13] confirm that the ActivL disc arthroplasty is a safe and effective implant at least with a short-term follow-up of 2 years.

The rehabilitation programs developed for the acute postoperative phase; focus on stabilizing exercises with strengthening of the autochthonous back muscles. Lifting, twisting and hyperextension are prohibited. It is known, that the highest stresses and therefore probably the highest micro-movements in

the disc tray, arise in combined flexion and lateral bending under axial load. Our results show that after the implantation of the prosthesis with either anchors, the primary stability is provided. Therefore, the osseointegration of the prosthesis is not compromised. By avoiding the complex combination of movements (axial load with combination of complex multi-axial movement) the active mobilization of the spine in the direct postoperative course is feasible.

Despite many positive experiences in clinical results, an ambivalence remains about the lumbar intervertebral disc prosthesis. Currently, there are several new models undergoing development. The focus of the research is placed on the development of flexible slide cores [14]. In synopsis of the available literature and our results, we see intervertebral disc prosthesis as an alternative to fusion operations in the lumbar spine in special cases. A carefully selected indication significantly influenced the good clinical outcome among patients who underwent surgery. Direct postoperative active mobilization of the patients operated in the lower spinal segments appears possible from the perspective of the primary stability of the prosthesis.

Conclusions

The Anchorage of disc arthroplasty with spikes as well as with a keel meets the criteria of primary stability. The keel anchoring shows a slight advantage compared to anchoring with spikes. Direct postoperative active mobilization doesn't seem to compromise the primary stability of the prosthesis.

Abbreviations

Hz
Hertz
ISO
International Organization for Standardization
ISO/CD
International Organization for Standardization/ Committee Draft
μm
micrometer

Declarations

Ethics approval and consent to participate

Ethics Vote of the Ethics Commission of the Medical Faculty Rostock, Registration Number A 2012-0090: The Commission has no professional or ethical objections to the implementation of the research project.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

We acknowledge the company Aesculap for the free provision of the implants and the support by the DFG Open Access Publication Funds of the Ruhr-Universität Bochum. No further support was received from other parties.

Authors' contributions

Von Schulze Pellengahr designed the research, while Klein extracted and collated the data. Wegner performed the data analyses. Büttner procured the used preparations. Von Schulze Pellengahr and Teske were major contributors in writing the manuscript. Lahner corrected the content of the paper several times. Saurabh carried out the English correction. All authors have read and approved the final manuscript.

Acknowledgements

We thank all colleagues involved in the study for their contributions and acknowledge support by the DFG Open Access Publication Funds of the Ruhr-Universität Bochum.

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Figures

Fig. 1

Figure 1

prosthesis with spike anchoring concept
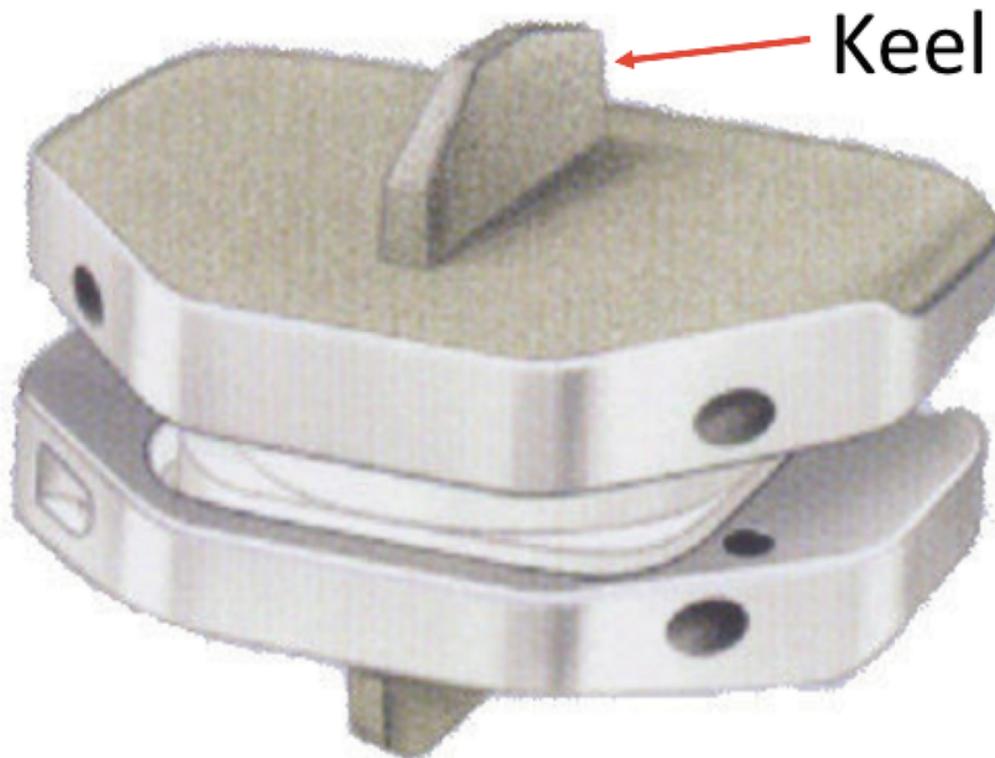
Fig. 2

Figure 2

prosthesis with keel anchoring concept
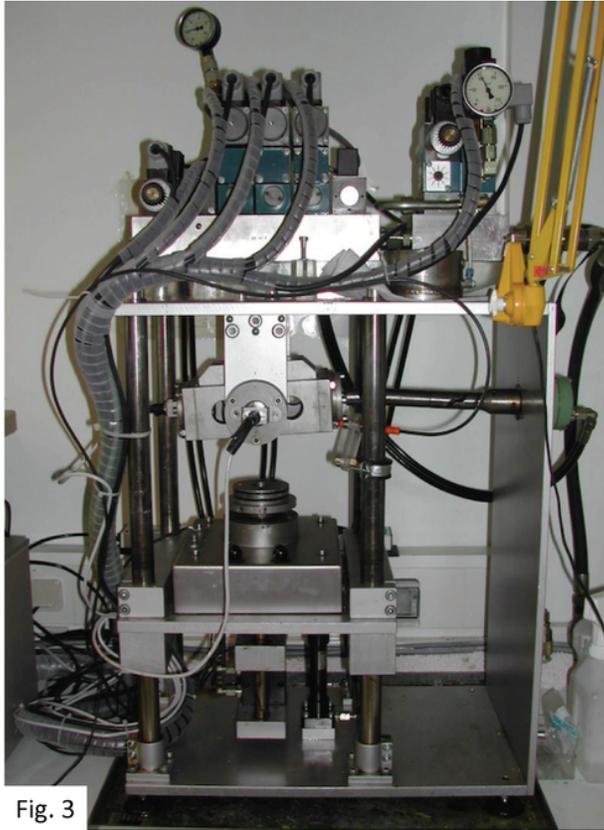
Fig. 3

Figure 3

The spine simulator of laboratory for Biomechanics and Experimental Orthopaedics of Ludwig-Maximilians-University in Munich.
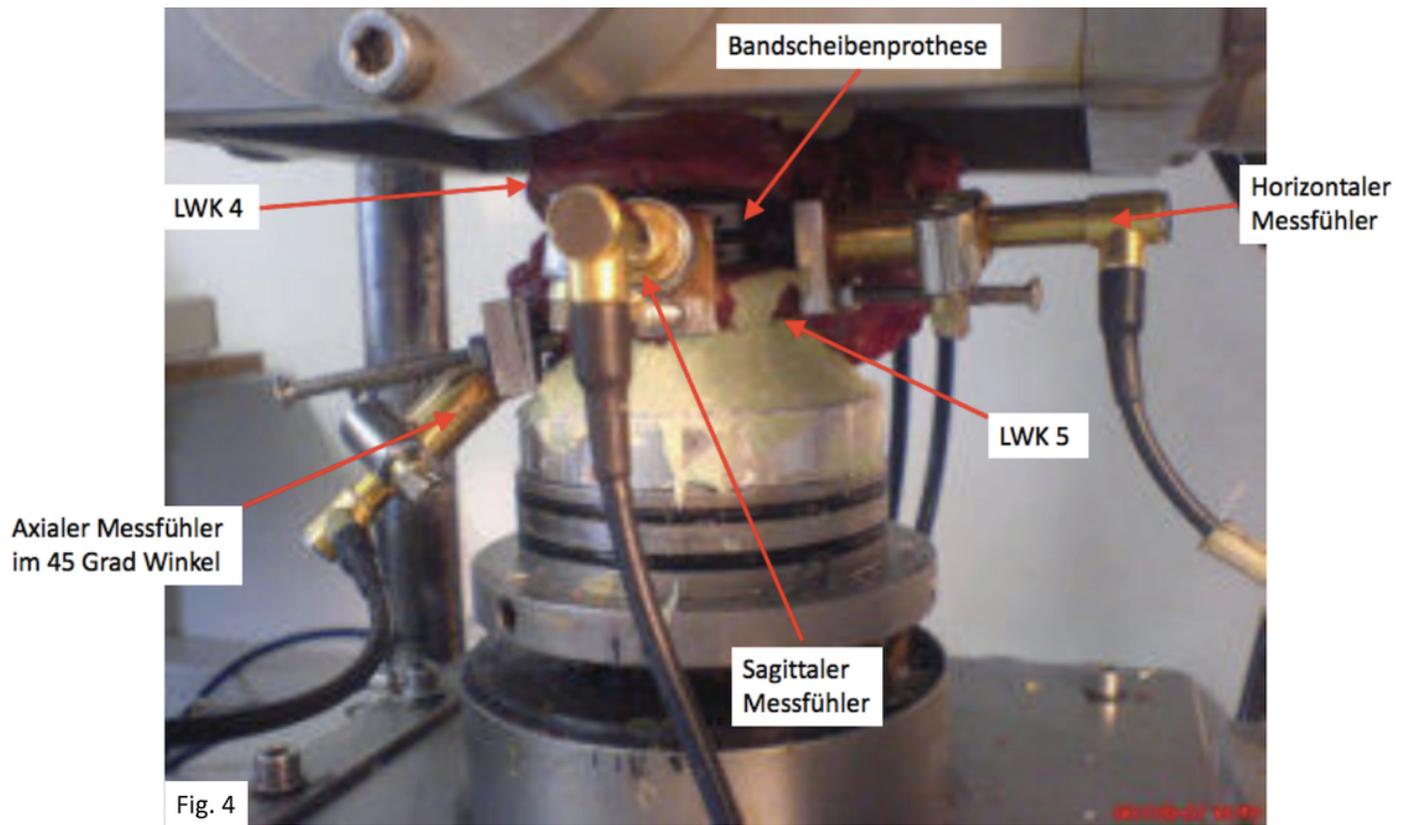
Figure 4

The intervertebral disk prosthesis is implanted in the prepared motion segment L4 / L5 that is fixed in the simulator with bone cement. The measuring probes are attached to the caudal prosthesis component. The results of the 45-degree-angle fixed probes for the axial micro motions were trigonometrically converted.
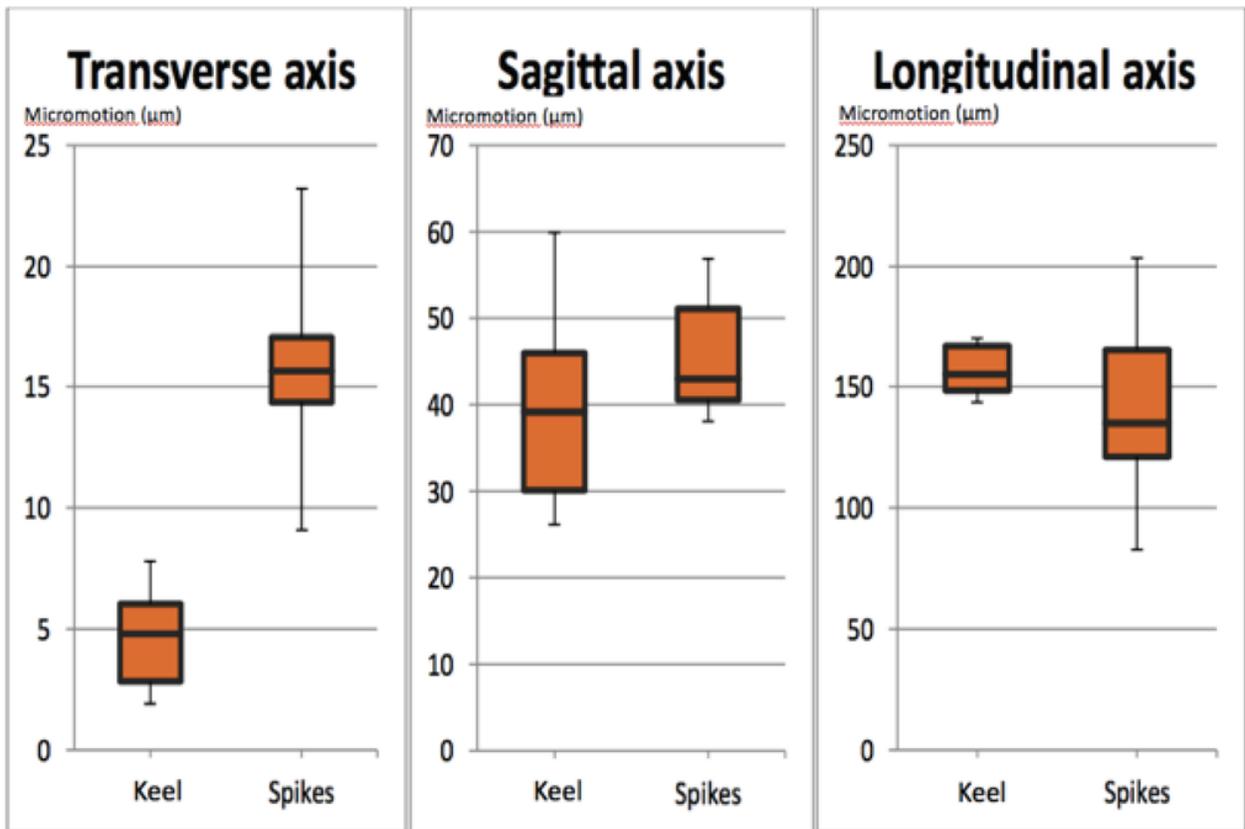
Fig. 5

Figure 5

Range of motion of the prosthesis in µm sorted by the three different axes of motion.