Primary stability of the Activ L® intervertebral disc prosthesis in cadaver bone and comparison of the keel and spike anchoring concept

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Abstract

Background: High primary stability is the key 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 ActivL intervertebral disc prosthesis (5 x keel anchoring, 5 x spike anchoring) implanted in human cadaver lumbar spine specimens were tested in a spine movement simulator. Under axial load 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. Micromotion of the implants covering every single movement axis were measured for both anchor types and compared using Student's T-test for significance after calculating 95% confidence intervals.

Results: In the transverse axis, the keel anchoring concept showed lower statistically significant ($p<0.05$) mean values of micromotion compared to spike anchoring concept. The highest micromotion values for both types were observed in the longitudinal axis. The data achieved the threshold of primary stability (150-200 µm).

Conclusions: Both fixation systems fulfil the required criteria of primary stability. Independent of the selected anchorage type an immediate postoperative active mobilization doesn't compromise the stability of the prostheses.

Background

In recent decades, several surgical methods (e.g. dorsolateral spinal fusion, dorsoventral spinal fusion, ventral spinal fusion, disc arthroplasties) were developed to treat degenerative pathologies of intervertebral disc and the bony vertebra. In contrast to spinal fusion techniques the implantation of an artificial disc is intended to maintain the segmental mobility and to avoid an adjacent level disease.

Low back pain is very often related to intervertebral disc degeneration. As a consequence the successful treatment of disc diseases increases medical interest and the artificial disc offers a treatment option. The objective of this surgical treatment is to ensure the restoration of the hight and the biomechanical improvement of the altered disc. The development of cementless implants in the last years led to different anchoring concepts. The micromotion at the implant–bone interface has a significant effect on the primary stability of the prosthesis and affects therefore the required osseointegration for longterm stability. About the threshold for micromotions up to which osseointegration still takes place is no consensus in the literature. In in vivo dog experiments was shown that increased micromotions adversely affected the osseointegration. The spinal bone was reduced in favour of connective tissue formation and the implant was largely surrounded by connective tissue, if micromotions of 150 micrometres upwards were obeserved[1]. Pitto however postulated an osseointegration of cementless implants up to micromotions of 200 micro-meters [2].

Nevertheless human data about micromotion as an important parameter of primary stability of artificial discs were not published. .

The quality of primary stability given to the prosthesis by two different anchoring concepts (available are keel or spikes) was tested. We conducted experiments on human lumbar spine specimens and simulated the movements in three planes under axial loading with the disc prothesis in place. Our experimental model with fresh frozen human specimens for biomechanical testing of the spine has long been established and described repeatedly in the literature [3, 5, 6, 7].

The purpose of our study was to answer the following questions:

- Can each disc anchorage comply with the scheduled limit of 200 µm micromotion in order to achieve a successful osseointegration?
- Differ keel and spice anchoring concepts in the measured micromotion? Is the larger contact of the keel system to the spinal bone an advantage for a better primary stability?
- Do the biomechanical results recommend load restrictions in the early postoperative rehabilitation of patients to avoid a disturbance of the osseointegration?

Methods

The experiments were performed using 12 human lumbar spine specimens (L2-S2) from body donors. The gender distribution was male in all cases. Two specimens were used for the preliminary tests. All used specimens had a regular L4 and L5 vertebral body size to allow a safe anchor of the AcitvL prosthesis. In all specimens the size M was implanted to allow the comparability of the results and to exclude the potential influence of sizes.

The ethical standards of the Helsinki Declaration of 1975, as revised in 2000 (5), as well as the national law were respected.

10 preparations were available for the actual experiments. The average age in this cohort was 36.4 years with a range from 18 to 48 years. This subpopulation and age group was selected to largely exclude 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. The semiconstrained design allows a limited translation of an ultra high molecular weight polyethylene (UHMWPE) inlay in the sagittal plane. The implant endplates are made of Cobalt Chrome (CoCr) alloy. The spiked version (figure 1) owns three spikes in a row at the front edge. The keel of the second disc version (figure 2) is aligned in the prothesis midline in the antero-posterior direction. Controlled translational motions of the core in the antero-posterior direction let to a displacement of the rotation center, physiological approximation and normal mobility.

The experiments were carried out in the laboratory for Biomechanics and Experimental Orthopaedics of Ludwig-Maximilians-University in Munich. An existing simulator (figure 3, 4) 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 [3, 4]. The simulator complied with the requirements of DIN ISO 2631 [8] for the testing of spinal implants (figure 5, 6)

The segment L4/5 was dissected from the spine specimen as the test segment. The soft tissue around the vertebral body anteriorly and laterally including the anterior longitudinal ligament and periosteum was removed. The anterior longitudinal ligament was resected in the front plane of the disc L 4/L5. The natural disc itself was completely removed and the top and bottom vertebral endplates were cleared of the intervertebral cartilage. Care was taken to preserve the subchondral bone. All other structures of the segment L 4/5 were preserved. The prosthesis was implanted by only one experienced spine surgeon with a proper surgical technique using the original instruments provided. For the experiments we used only size M protheses with a superior plate angulation of 6° and a polyethylene (PE) inlay of 8.5 mm or 10 mm.

In combination with the described selection of the specimens a nearly anatomical reconstruction of the motion segment was achieved. In particular, the height of the intervertebral disc space was meticulously reconstructed during the implantation. The lordosis angle adjusted itself according to the anatomical conditions and the current position of the mobile segment. Therefore, it can be assumed that the obtained measurement results correspond to the situation in vivo.

For the measurement of the micromotions specially attached measuring sensors were used. The sensors were connected via a measuring module to a computer. The system has a measurement precision for motion of just 1/1000 µm . The sensors were attached to the specimen in three planes. The holders for the specimens were aligned strictly in the sagittal and frontal planes on the L5 vertebral body so that the sensors touched the caudal plate of the prosthesis. For technical reasons it was not possible to install a sensor in the axial line. For this plane the sensors were attached ventrolateral at an a-angle of 45° and the measuring sensor touched the caudal surface of the prosthesis plate near the ventrolateral edge. In order to determine the actual values of the micromotions in the axial axis, a mathematical conversion by the cosine a was necessary.

The construct with the implanted prosthesis and the sensors were fixed with bone cement to the special holding device designed in the motion simulator (figure 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 (figure 5, 6) [10].

The simulation of the natural movement sequence in lower lumbar spine was performed analogue to the physiological conditions (figure 6). Each axis was tested with the frequency of one Hz. The different axes were not coupled. ®

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

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

The data were recorded via the measuring sensors connected to the receiver module. Processing and presentation of the results was done by the Catman software ® (HBM Germany).

For each of the two implants the experiment was carried out 5 times. The measurement of the micromotion started simultaneously to the movement simulation. The measurement data were recorded with a frequency of 50 Hz in all three axes. Each experimental setting included a simulation run for more than 1000 cycles (on average about 1050). The measurement graph showed a stabilization of the registered amplitudes about 400 cycles. In the phase between the 540th and the 600th cycle, 60 representative cycles each cycle with 3000 measured values were selected for the result evaluation. Thus we received 60 micromotion's amplitude values per experiment per plane (figure 7).

A representative mean value was calculated for the prosthesis movement in one particular axis from the determined values. For each of the two implant types all representative peak-to-valley-values were grouped according to the axis in an Excel spreadsheet and were fed for statistical analysis in the GraphPad Prism 6 program. For both prostheses, the mean peak-to-valley-values for each axis were calculated from these data.

For the further statistical analysis (IBM SPSS 25.0®) methods of descriptive statistics were used. At first, we tested our values with the Kolmogorov-Smirnov normality test to find out whether our results follow a normal distribution. After confirmation of the normal data distribution the Student's T-test was performed to investigate the significant differences in the micromotion of the intervertebral disc prosthesis in each axis for the two anchoring types. The significance level was set at 0.05. The results of each tested prosthesis are shown as box plots representing the three axes of motion. Median and interquartile range

(Q3 minus Q1) were used for the presentation of localization and dispersion. The median represents the movement level. The interquartile range defines the motion profile.

Results

In the Kolmogorov-Smirnov normality test all imposed data followed the normal distribution so that the further evaluation was carried out with the Student's T-test.

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

Micromotions in the transverse axis (table 2):

Table 2: Micromotions 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. The keel anchoring system showed a smaller mean micromotion value of 4.65 µm, compared to 15.65 µm and the difference was statistically significant ($p = 0.003$).

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

Table 3: Micromotions 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 micromotions values of both anchoring types lay also well below the threshold of 150 µm. 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: Micromotions 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 values for micromotions were observed, which lay close to 150 µm and in any case below 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 figure 8 are presented the motion ranges of the prosthesis in every axis in the form of box plots.

Discussion

To determine the primary stability of intervertebral disc prosthesis with two different anchoring concepts – keel and spike anchoring - ActivL intervertebral disc prosthesis (5 x keel anchoring, 5 x spike anchoring) were implanted in 10 human cadaveric lumbar spine specimens and tested in a spine movement simulator. The micromotions of the implants in the transverse, sagittal and longitudinal planes were determined. These results are a parameter of the primary stability. Both types of anchors met the given criteria of primary stability, independent of the selected anchorage type.

The in this study used biomechanical model for testing spinal disc prosthesis implanted in fresh frozen human specimens is well established. The technique was described repeatedly in the literature [3, 5, 6, 7]. Because of better comparability and to exclude early degenerative changes we used only male donor specimens of young age. Therefore osteoporosis and its potential negative influence on micromotion due sparsey structure was ruled out. Nevertheless it has been shown that the mechanical behaviour of spinal segments in the simulator remains unaffected by degenerative changes [10]. In addition, osteoporosis is a surgical contraindication for implantation of intervertebral disc prosthesis [12].

The axial load and adjustment of motion range of a spinal segment was performed according to the ISO values. The recommendation to conduct the experiments without axial load was followed [4]. Under axial load the data lack of comparability due to the great individual variation of the biomechanical characteristics of the human spine. In our experiments, the axial load was adjusted between 600 to 2000 N. In the living body values of 2000 N are achieved only when lifting weights of 10 kg or leaning forward with simultaneous rotation of the upper body [4]. Such values seem unlikely in the direct postoperative phase in vivo due to appropriate therapeutic instructions in newly operated patients. This load-adjustment probably led to the observed increase of the micromotions 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 micromotion values. Both concepts guarantee a safe osseointegration because complex multi-axial movements combined with axial load, as mentioned, are not expected in newly operated patients.

In the sagittal axis the primary stability is given with both anchoring concepts. Our data showed no significant difference between both groups. The statistically significant difference, which was observed in the micromotion values in the transverse axis, gives a slight technical superiority for the keel anchoring concept. This effect was expected due to the larger contact area of the keel with the bone, which also provides a larger area for osseointegration. This advantage has only a relative 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 [11] and O´Rourke [13] 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 [14] reports excellent long-term results for the Pinnacle Cup. It can be concluded that a safe osseointegration of cement less implants is possible even in micro motions well over 150 micrometres. Pitto however postulated an osseointegration of cementless implants up to micromotions of 200 µm [2]. All prostheses examined in our study fell well below this limit of 200 µm, even in the longitudinal axis. In conclusion the measured micromotions in this study above 150 µm, but under 200 µm in the longitudinal axis seem to be without relevance in surgical practice.

Jasty (1) found osseointegration of the implants in his histological examinations of dogs 6 weeks after implantation of cementless implants if micromotions of 150 µm were not exceeded. After 6 weeks the process of osseointegration is not completed as indicated by scintigraphic examinations showing accumulations at the bony implant site over a period of 2 years [15].

Current clinical publications [16, 17, 18] confirm that the ActivL disc arthroplasty is a safe and effective procedure at least in a short-term two-year follow-up. The cautious conclusion suggests that the implants were successfully osseointegrated in this period of time.

The graphical representation of the measured values showed the stabilization of the measured amplitudes after a passage of about 400 cycles. This is due to subsidence of the prosthesis in the early phase of the experiment. Conclusions on additional subsidence of the prosthesis in vivo in the context of osseointegration are not permitted and can only be determined by imaging procedures on living patients.

The rehabilitation programs developed for the acute postoperative phase focus on stabilizing exercises strengthening the autochthonous back muscles. Lifting, twisting and hyperextension are prohibited. It is known, that the highest stresses and therefore probably the highest micromovements 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 both pegs and keel, 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. Corresponding recommendations for the recommendations should be given to the patients.

Despite many positive clinical results, an ambivalence remains about the lumbar intervertebral disc prosthesis. Currently several new models will be developed. This research is focused on the development of flexible slide cores [19]. In synopsis of the available literature and our results, we see intervertebral disc prostheses as an alternative to fusion operations in the lumbar spine in special cases. A well- considered surgical indication influences a good clinical outcome among patient in our opinion. An immediate active mobilization after surgery is possible because of the given primary artificial disc stability according to the results of this study.

Conclusions

Artificial disc types anchoring with spikes as well as with a keel meet the criteria of primary stability regarding micromotions < 200 µm.

The keel anchoring prothesis showed higher primary stability compared to the spikes model in the transverse axis.

Direct active mobilization after surgery does not 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.

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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.

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Figures

Fig. 1

Figure 1

prosthesis with spike anchoring concept

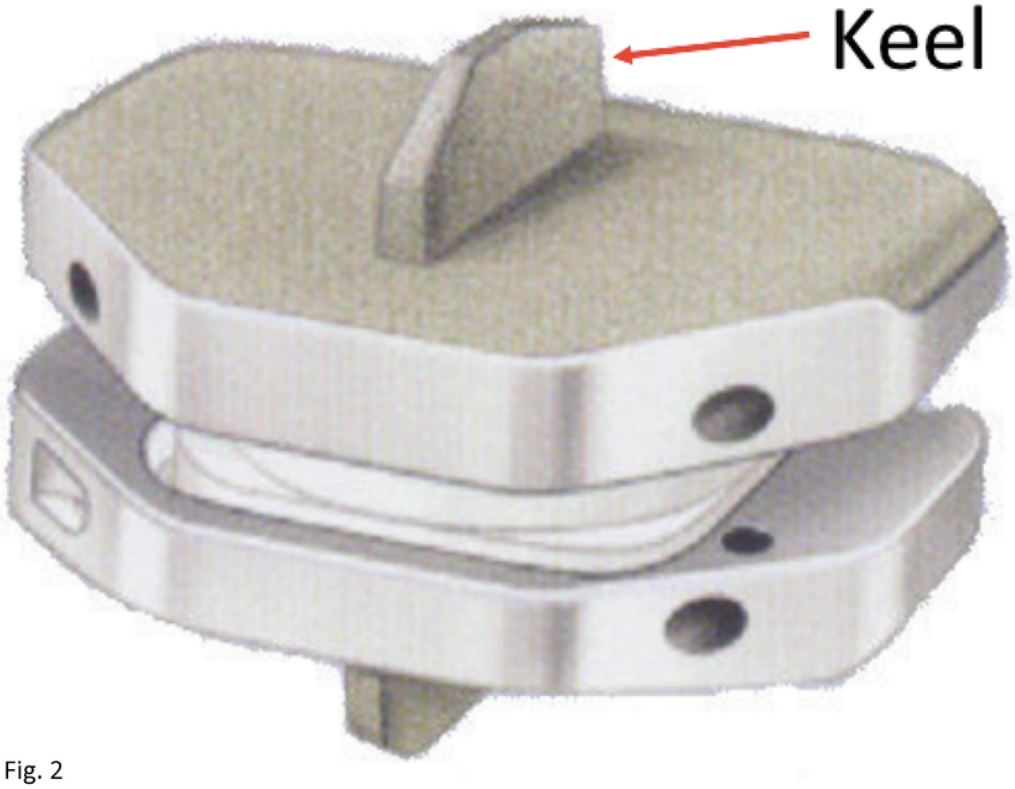

Figure 2

prosthesis with keel anchoring concept

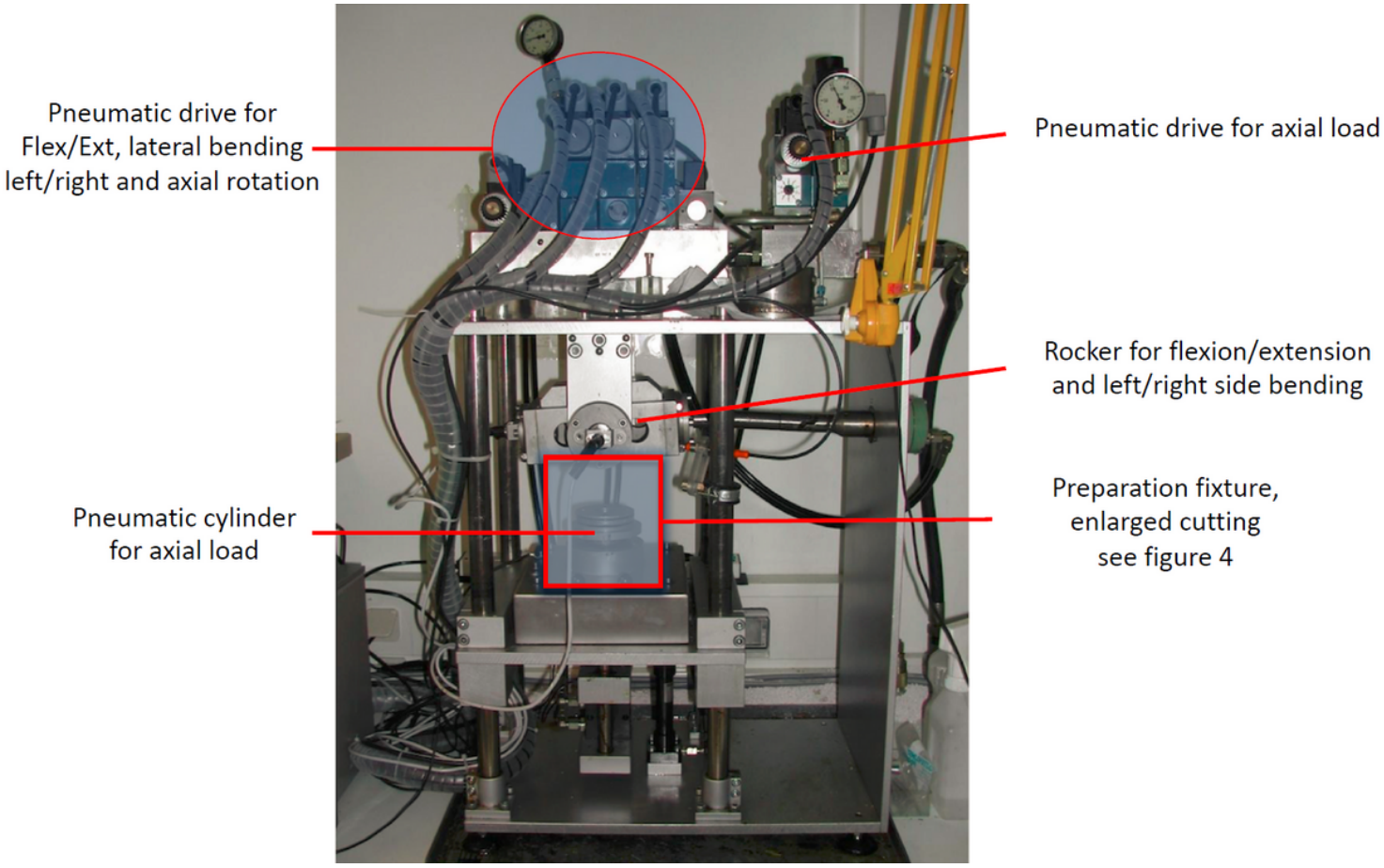

Figure 3

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

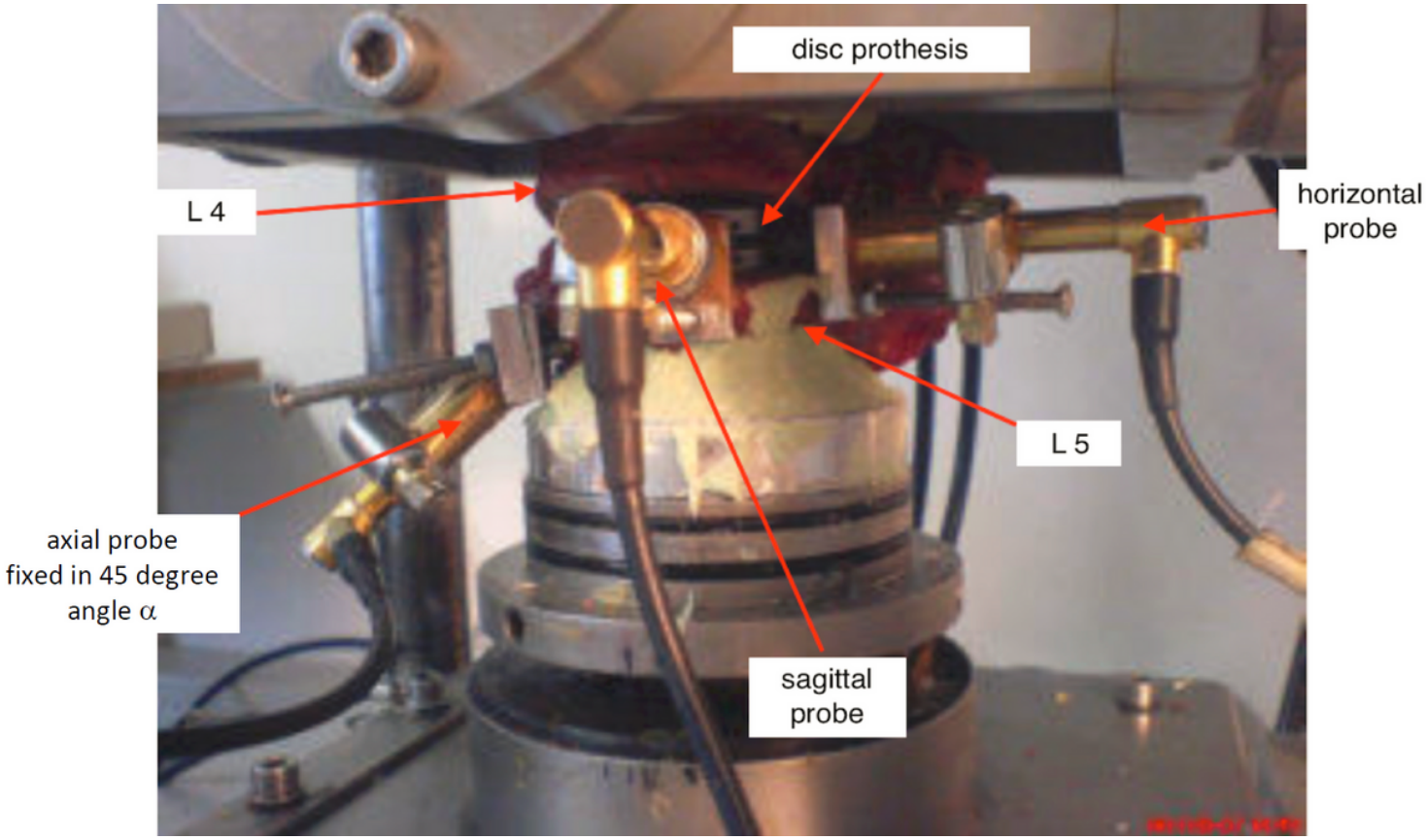

Figure 4

Preparation fixture, enlarged cutting from figure 3. 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 (α) fixed probe for the axial micro motions were trigonometrically converted by the cosine α.

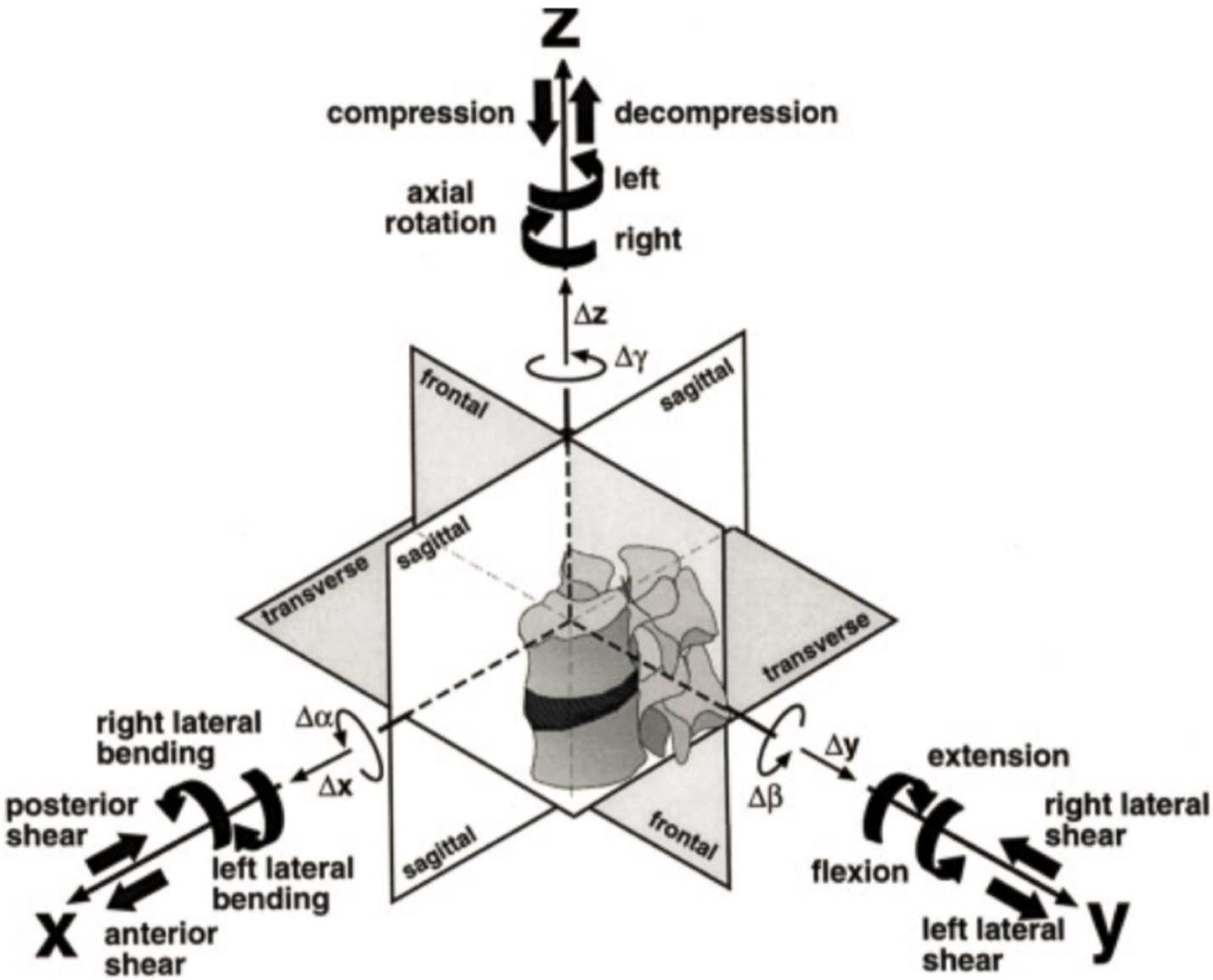

Figure 5

Three-dimensional coordinate system of the spine simulator (according to ISO 2631). All possible load and motion components are illustrated (3).

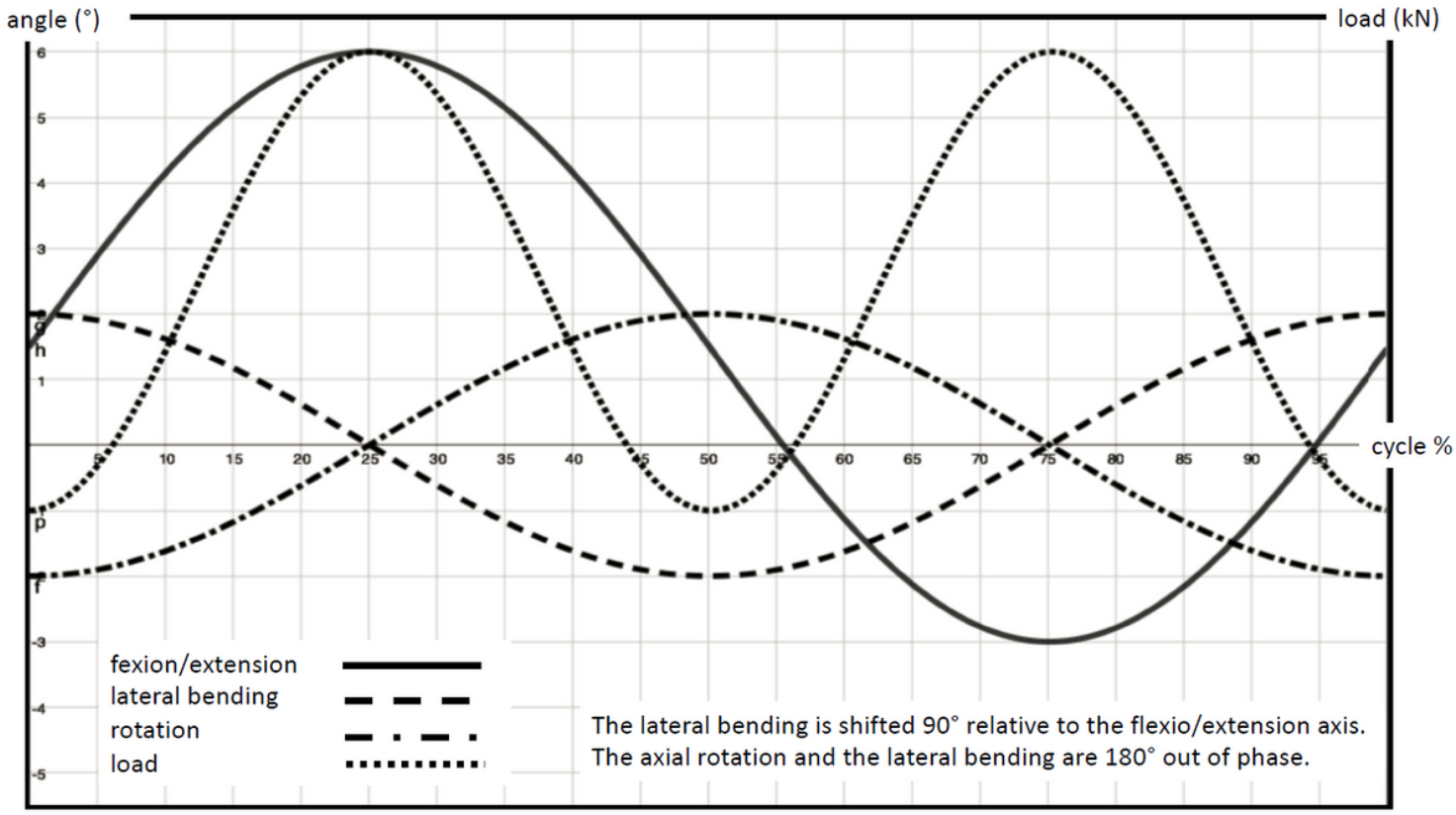

Figure 6

Phasing of the displacement and load curves (alternative) for lumbar prothesis

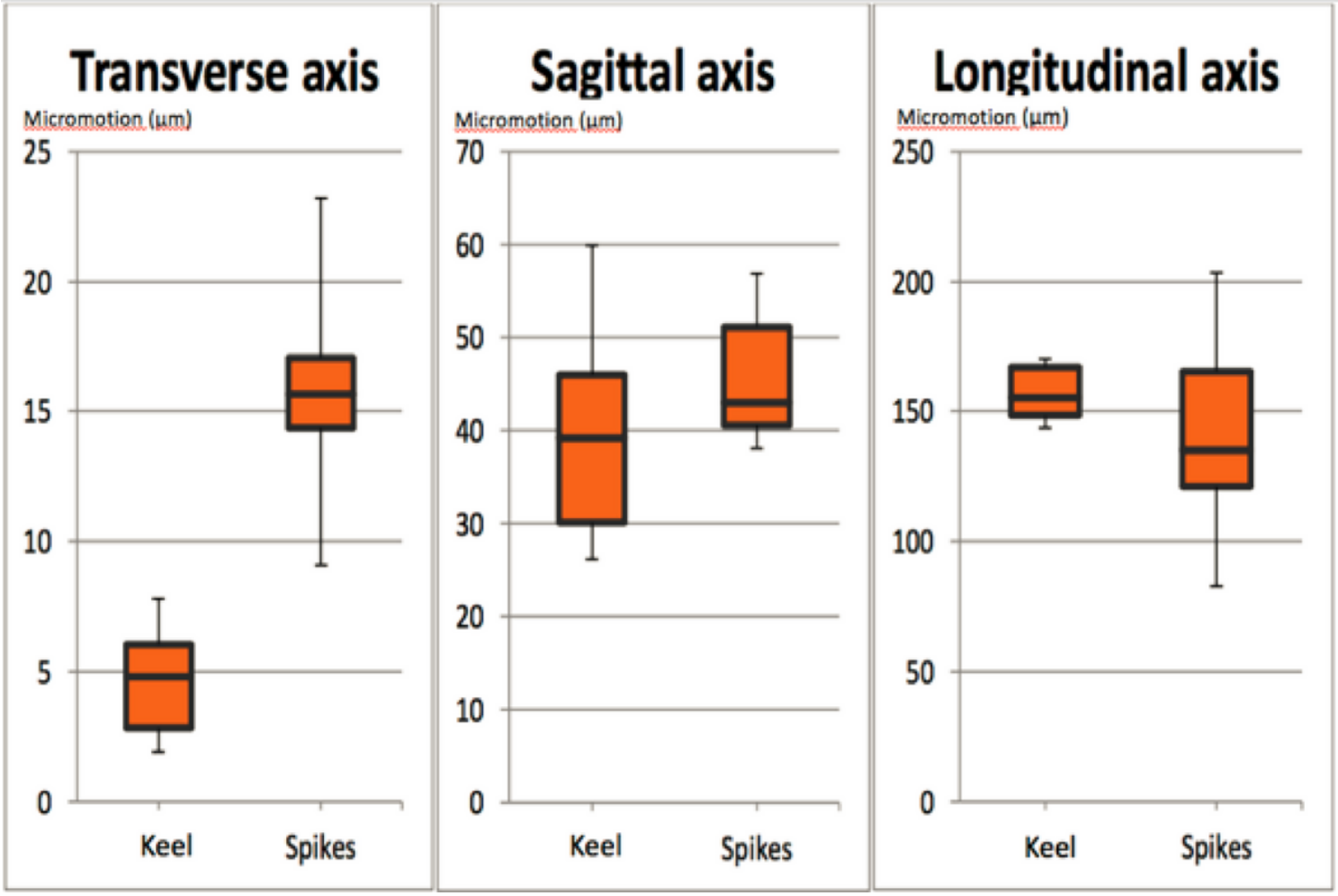

Figure 7

The graphical representation of the measured values showed the stabilization of the measured amplitudes after 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.

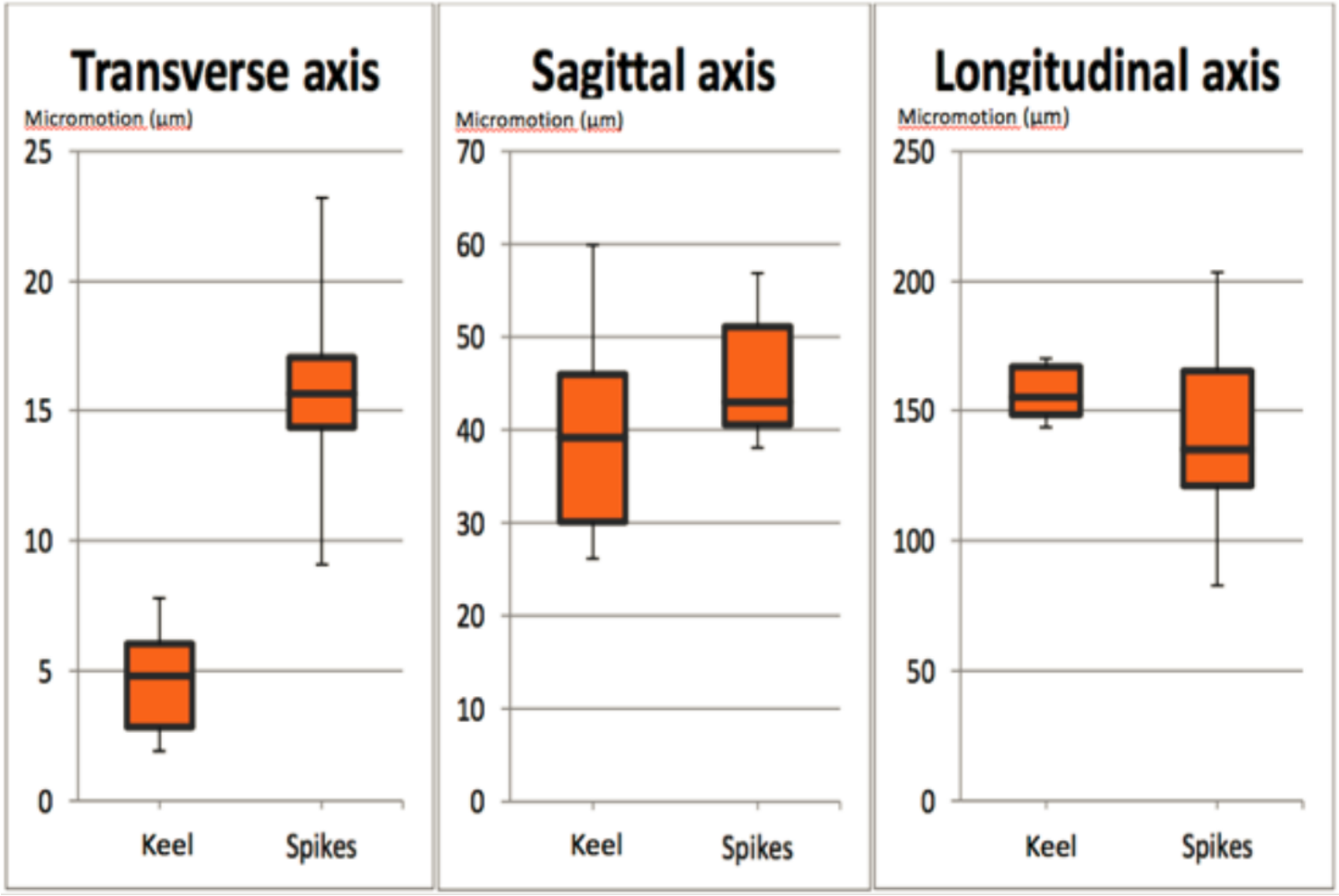

Figure 8

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