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Influence of a dynamic stabilisation system on load bearing of a bridged disc: an in vitro study of intradiscal pressure

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Abstract In recent years, non-fusion implants to stabilise the lumbar spine have become more and more popular. However, little is known on the load bearing of such dynamic stabilisation systems. In order to investigate the load bearing of discs bridged with rigid and dynamic stabilisation systems, six lumbar cadaver spines were mounted in a spine tester and loaded with pure moments in the three main motion planes. Four different states of the specimens were studied: intact, destabilised, stabilisation with a Dynesys® and stabilisation with an internal fixator. Intradiscal pressure (IDP) measurements were used to assess the load bearing of the bridged disc. In the neutral unloaded position, there were small but not significant differences in disc pressure for the four states of the treated disc ($P > 0.05$). Concerning the disc pressure during the course of loading, both the Dynesys® and internal fixator did significantly reduce the pressure change from neutral to extension in comparison to the intact state (-0.05 , -0.04 and

$+0.24$ MPa, respectively) ($P < 0.05$). Compared to the intact state, there was no significant pressure change from neutral to flexion (0.14 , 0.15 and 0.18 MPa, respectively) ($P > 0.05$). The devices apparently eliminated the pressure change from neutral to lateral bending (Dynesys 0.01 MPa, Fixator 0.01 MPa and intact 0.24 MPa), but due to large variations in the intact and defect states the differences were not significant ($P > 0.05$). In axial rotation, the pressure change for the internal fixator was reduced compared to the intact state; however, the change was only significant in left axial rotation ($P < 0.05$). The Dynesys® showed no significant differences ($P > 0.05$) in axial rotation. No changes in IDP were seen in the adjacent discs for either the Dynesys or the internal fixator. Our results showed that the IDPs for both devices were similar, but altered compared to the intact disc.

Keywords Intradiscal pressure · Spinal instrumentation · Biomechanics · Dynamic stabilisation

Introduction

Lumbar fusion supported by rigid instrumentation is often used in the treatment of a wide variety of spinal disorders. However, there are numerous clinical studies reporting accelerated disc degeneration adjacent to fused

and/or rigidly instrumented segments [10–12, 22, 28, 30]. While some of these studies found degeneration in only a few cases, others reported degeneration in more than 40% of the patients [12, 30]. In order to maintain the mobility of a motion segment and to prevent negative effects on adjacent segments, dynamic non-fusion

systems have become more and more popular. The systems range from completely replacing the intervertebral disc with a prosthesis [13, 14], replacing the nucleus with an elastic spacer while preserving the annulus [9, 37], to a device that maintains the disc with a reduced and controlled motion of the segment [7, 8, 31, 32].

Despite the availability of new implant concepts, lumbar fusion is still the standard in the treatment of various spinal disorders. Generally, for lumbar fusions the nucleus is replaced by autologous bone graft, allograft or intervertebral cages to achieve a bony fusion. In many cases an internal fixator is added to assure the stability of the construct. From a biomechanical and clinical point of view, it may not be desirable to sacrifice a moderately degenerated disc, if it could be spared. Using only an internal fixator while attempting to preserve the disc may in some cases of non-successful bony fusion lead to fatigue failure of the implant system [6, 15, 21].

The dynamic neutralisation system (Dynesys®) (Zimmer GmbH, Winterthur, Switzerland) investigated in this study is designed to provide dynamic stabilisation and spinal alignment while maintaining the intervertebral disc and facet joints and to prevent implant fatigue failure. The Dynesys® consists of bilateral pedicle screws, polyethylene terephthalate (PET) cords and polycarbonate urethane (PCU) spacers (Fig. 1). In order to withstand compressive loads, the PCU spacers are placed bilaterally between the pedicle screw heads. To withstand tensile forces (e.g. occurring during flexion movements), the construct is stabilised by the PET

cords, which run through the hollow core of the spacers and are fixed to the pedicle screws with a tensile preload.

Intradiscal pressure (IDP) is often used to estimate the load in the spinal column. Nachemson first used the IDP to estimate the *in vivo* load acting on vertebral bodies for various posture positions [19]. Some *in vitro* studies extended the pressure measurement of the nucleus to the annulus to obtain a stress profilometry of the disc [3, 16, 23]. Since then a number of studies have investigated the effect of spinal instrumentation on the IDP of bridged and adjacent discs with varying and sometime controversial results [1, 4, 5, 18, 25, 32, 35].

The aim of the current study was to investigate the load transfer through discs bridged with a dynamic or rigid stabilisation system by means of the IDP and to evaluate the effect of the stabilisation on the IDP of adjacent segments.

Material and methods

For the biomechanical testing, six fresh frozen human lumbar spines (L2–5) were used. The mean age of the specimens was 43, ranging from 33 to 59 years. The specimens were kept frozen in triple sealed bags at -20°C and thawed at 6°C before testing. The trabecular bone mineral density (BMD) of the cranial adjacent vertebra (L1) was measured in a qCT (XCT 960, Stratec, Pforzheim, Germany). The BMD measurement was performed to exclude osteoporotic specimens, in which the screws may loosen in the course of testing. Lateral and anterior–posterior X-rays of each specimen taken before the test did not reveal any pathologic findings. The degeneration of the L3–4 discs was graded on a scale of 1–4 on standardised X-rays (Table 1) according to the method of Mimura et al. [17].

All soft tissue was dissected, keeping the supporting structures, ligaments and capsules intact. In order to fix the specimens in a spine tester, the cranial and caudal vertebra (L2 and L5) were embedded in PMMA (polymethylmethacrylate) cement (Technovit 3040, Heraeus Kulzer, Wehrheim, Germany). Care was taken to align the L3–4 discs in the horizontal plane.

Prior to fixing the specimens in a spine tester, flexible pressure transducers (Mammendorfer Institute for Physics and Medicine, Hattenhofen, Germany) were inserted in the nuclei of the three discs. X-rays were taken to ensure the correct placement of the pressure transducer in the middle of the nucleus pulposus. The flexible pressure transducers had a diameter of 1.2 mm and were calibrated to atmospheric pressure [38].

The specimens were loaded at room temperature in a spine tester [36]. The caudal vertebra was fixed rigidly to the frame of the spine tester. The cranial vertebra was mounted to a gimbal, which allowed rotation around all

Fig. 1 Dynesys® with PCU spacers, PET cords and pedicle screws

Table 1 Details of the specimens used in the experiment

No.	Age	Sex	BMD (g/cm ³)	Bridged L3–4 disc grading ^a
835	51	M	122.0	1
847	36	M	156.6	1
848	33	M	93.7	2
849	34	M	169.6	1
850	59	M	85.6	1
852	43	M	126.7	1
Mean	42.6		125.7	
SD	± 9.5		± 30.4	

^aDisc degeneration was graded on lateral and anterior–posterior X-rays according to Mimura et al. [17]

three coordinate axes. The gimbal was connected to the frame by a travelling gantry, a guidance and a slide to enable translations in the three main motion planes (Fig. 2). Three stepper motors integrated in the main axes of the gimbal were used to apply a continuous moment to the specimens at a loading rate of 1°/s. The specimens were loaded with pure moments of ± 10 Nm in each of the three principal motion planes (flexion/extension, left–right lateral bending and left–right axial rotation), while the remaining five degrees of freedom were allowed to move freely. A six-component load cell

Fig. 2 Specimen mounted in the spine tester instrumented with intradiscal pressure sensors and a motion analysis system

recorded all moments and forces acting on the specimens. During loading, the IDPs were sampled continuously with 20 Hz.

Four states of the specimens were studied (with alternating sequences of three and four):

1. Intact spine.
2. Destabilised spine. A controlled defect was created in the middle segment (L3–4). The defect model included dissection of the supraspinous ligament, the interspinous ligament, ligamenta flava and transection of facet joint capsules [24].
3. Stabilisation of the defect in L3–4 with the internal fixator.
4. Stabilisation of the defect in L3–4 with a modified Dynesys[®].

Testing each specimen first in the intact state before creating the destabilisation and mounting the implants allowed each specimen to act as its own control and ensured normalisation of the data.

The PCU spacer stiffness varies with temperature. Since the test was carried out at 21°C (range 19–23°C) and not body temperature (37°C), the tested spacer had to be manufactured of stiffness different from the commercially available product so as to reproduce the in vivo stiffness of the Dynesys[®] spacer.

Due to technical difficulties in carrying out the in vitro experiment in a wet bioactive environment at body temperature, the material properties of the used spacer were modified and the experiment was carried out at room temperature. For comparison of the static compression stiffnesses of the two different materials, spacers were compressed up to 500 N for three consecutive load cycles, at room temperature in air and at body temperature. The average deviation between the standard material at body temperature and the modified material at room temperature was 9.2%. This was deemed to sufficiently mimic the behaviour of the standard material at body temperature. The PCU spacers of either material demonstrated a linear behaviour ($R^2 = 0.99$) and were comparable over the entire range which is deemed to extend the physiological range. Different behaviours caused by differences in viscoelastic properties of the materials are expected to be negligible due to testing duration and velocity chosen for the in vitro test. Trommsdorff et al. [33, 34] investigated the degradation of up to 5.5 years-implanted PCU spacers and PET cords and found that the materials are biostable.

Both fixation systems were manufactured by Zimmer GmbH and implanted by an experienced surgeon in the neutral unloaded position without any distraction or compression of the treated segment. To be able to use the same titanium alloy pedicle screws for both the internal fixator and the Dynesys[®], special connectors were designed to fix the rod of the fixator in a more

Fig. 3 Exemplary intradiscal pressure in the L3–4 discs for one specimen (847) as a function of the applied bending moment, showing the three parameters used for data analysis

medial position than the Dynesys®. The fixator rods had a diameter of 6 mm and were manufactured of titanium alloy (TiAlNb). Both stabilisation systems were moun-

ted to the specimens in the neutral unloaded position without distraction of the treated segment. However, the surgical technique for Dynesys® required the application of a pre-tension to the implant, which results in a neutral position of the segment if the spacer length is determined according to the surgical technique. This technique includes the use of specific pliers-like tool provided in the instrumentation set of the manufacturer.

According to the recommended testing criteria for spinal implants [40], for all measurements, two pre-cycles were applied to the specimens and the third cycle was used for data analysis. To evaluate the changes in IDP for the four different states, three characteristic points were taken from each loading cycle, the IDP in the neutral unloaded position (unloaded) and the IDP changes (IDP change) from the neutral unloaded position to the minimum and maximum bending moments (± 10 Nm) applied in the three main motion planes (Fig. 3).

To analyse for differences in the three loading directions, a Friedman analysis of variance (ANOVA) for repeated measures was conducted. When differences were found, Wilcoxon matched-pairs signed rank tests

Fig. 4 Median IDP in bridged L3–4 discs in flexion/extension for the unloaded neutral position and median IDP change for maximum/minimum bending moment. The error bar shows the range of the measurements and an asterisk indicates statistical significance ($P < 0.05$). An example of the IDP during the course of loading

Fig. 5 Median IDP in bridged L3–4 discs in left/right lateral bending for the unloaded neutral position and median IDP change for maximum/minimum bending moment. The *error bar* shows the range of the measurements and an *asterisk* indicates statistical significance ($P < 0.05$). An example of the IDP during the course of loading

were performed to check for differences between the four tested conditions. A correction for multiple comparisons (Bonferroni correction) was not performed because all P -values would have exceeded the level of significance. Therefore, the term significant ($P < 0.05$) when used in this study is to be considered as a trend.

Results

IDP in neutral unloaded state

For the static pressure in the neutral unloaded position of the segment, the IDP measurements of the three main motion planes showed the same trends (Figs. 4, 5, 6). For the intact state, the pressure in the treated L3–4 discs was 0.10 MPa (range 0.05–0.13 MPa). With the dissection of ligaments and the transection of the facet joint capsules for the defect model, the IDP decreased to

0.08 MPa (range 0.05–0.11 MPa). By the treatment of the created defect with the Dynesys[®], the IDP increased to a magnitude above the intact state to a median of 0.14 MPa (range 0.03–0.26 MPa). Using an internal fixator for stabilisation, the median IDP in the neutral unloaded position decreased to 0.06 MPa (range 0.02–0.16 MPa). However, none of these changes were statistically significant (Friedman ANOVA; $P = 0.44$ in flexion–extension, $P = 0.49$ in lateral bending and $P = 0.26$ in axial rotation).

IDP changes for loading in the sagittal plane

- Creating a defect significantly increased the median pressure change during the course of loading for extension from 0.24 MPa (range 0.15–0.37 MPa) in the intact disc to 0.26 MPa (range 0.17–0.38 MPa) for the defect ($P < 0.05$) and for flexion from 0.18 MPa

Fig. 6 Median IDP in bridged L3–4 discs in left/right axial rotation of the unloaded neutral position and median IDP change for maximum/minimum bending moment. The *error bar* shows the range of the measurements and an *asterisk* indicates statistical significance ($P < 0.05$). An example of the IDP during the course of loading

(range 0.12–0.27 MPa) in the intact disc to 0.24 MPa (range 0.13–0.34 MPa) for the defect ($P < 0.05$) (Fig. 4).

- In extension, the median pressure change occurring during the course of loading was 0.24 MPa in the intact disc while it was -0.05 for the Dynesys® (range -0.02 to -0.07 MPa) and -0.04 (range -0.01 to -0.07 MPa) for the internal fixator. These differences were statistically significant ($P < 0.05$).
- In flexion, treatment of the segment with the Dynesys® or the internal fixator decreased the pressure change during the course of loading to 0.14 MPa (range 0.13–0.27 MPa) and 0.15 MPa (range 0.08–0.23 MPa), respectively. However, with respect to the intact level, none of these changes were statistically significant ($P > 0.05$).

IDP changes for loading in the frontal plane

IDP change for the intact state was 0.24 MPa (range -0.08 to 0.37 MPa) for left lateral bending and

0.27 MPa (range -0.08 to 0.38 MPa) for right lateral bending (Fig. 5). Creating the defect decreased the pressure change to 0.22 MPa (range -0.05 to 0.37 MPa) and 0.23 MPa (range -0.12 to 0.38 MPa) for left and right lateral bending, respectively. These changes were not statistically significant. Instrumentation decreased the pressure change during loading to values of 0.01–0.02 MPa (range -0.02 to 0.05 MPa). Although the differences of the median values were substantial, no statistically significant differences were found since there were large variances for the intact and the defect states.

IDP changes for loading in the transverse plane

For left and right axial rotation, the median IDP change during loading was symmetrical for all tested states except for the internal fixator state (Fig. 6). The intact IDP change was 0.07 MPa (range 0.05–0.10 MPa).

- The fixator significantly decreased the median IDP changes during the course of loading to 0.06 MPa

Fig. 7 Intradiscal pressure in adjacent disc L2–3s for flexion/extension. All values were normalized to the intact intradiscal pressure. The plotted results represent the medians and error bar shows the range of the measurements

(range -0.03 to 0.08 MPa) in right axial rotation with respect to Dynesys (0.09 MPa, range 0.04 – 0.11 MPa) ($P < 0.05$).

- For left axial rotation, the fixator significantly decreased the IDP change to 0.03 MPa (range 0.03 – 0.08 MPa) with respect to intact and the defect states (0.09 MPa, range 0.05 – 0.14 MPa) ($P < 0.05$).

IDP of adjacent segments

In general, the IDP in the adjacent discs was not affected by the creation of the defect or the instrumentation of the defect with the Dynesys® or the internal fixator. In all tested motion planes, the median IDPs in the neutral unloaded positions for the defect and both stabilisation systems were in the range of the intact spine (Fig. 7). For the unloaded spine, the median IDP of all tested states normalised to the intact specimen varied between 86 and 106%. The IDP change during loading showed similar results. However, the median pressure changes for the two adjacent discs in all three tested motion planes for the various states showed a wider range (82–124% normalised to the intact state).

Discussion

The present study investigated the effects of a dynamic and rigid stabilisation on the load transfer of the treated and adjacent lumbar spine segments by the IDP. Six cadaver spines were loaded in a spine tester in the three main motion planes. The IDP was measured during the

course of loading for four different states (intact, defect, Dynesys® and fixator) of the specimens.

The static pressure measurements were analysed after the second cycle of pre-conditioning and the resulting median values for all loading directions are very repeatable. This means that the specimen always returned to its original position when all constraints were removed after loading. It can be concluded that the static pressure measurements represent a neutral position and are not an artefact of the testing method.

Intradiscal pressures before kinematics testing (static measurements) did not reveal statistically significant differences between the various specimen conditions. The small decrease in static pressure in the defect state may be explained by the lost pre-tension of the disc by dissecting the posterior ligaments and joint capsules. Compared to the intact state, stabilising the defect with the Dynesys® produced slightly higher median IDP values, whereas mounting the internal fixator resulted in slightly reduced IDP values. This can be attributed to a combination of the PCU spacer length and the pre-tension applied to the cords while mounting the system. The material of the spacers used in this study was chosen according to the compressive stiffness of a standard spacer at body temperature since PCU is temperature sensitive. This implies—when using standard surgical technique with the same pre-tension in the cords as intraoperatively—that the spacers are more compressed than the standard spacer, which is stiffer and implanted at room temperature. Thus the position of the segment may be different compared to the intraoperative environment and may result in an increased hydrostatic pressure in the intervertebral disc in the tested case. If Dynesys® were to be used as a distraction device, one may expect a decrease of the

static IDP. However, this was not observed for any of the investigated loading directions.

During flexibility testing (loading), the two posterior stabilisation devices unloaded the intervertebral disc in extension by a significant amount and also unloaded the disc in lateral bending. For lateral bending, large variances for the intact and the defect states were found and therefore, differences were not statistically significant. However, the differences of the median values were substantial. In flexion, both systems reduced the IDP after the defect to values slightly below the intact state.

The change in IDP occurring during loading of the specimens in flexion, extension and lateral bending was similar for both the rigid and dynamic stabilisations of the bridged segment.

In axial rotation, compared to the intact state, the Dynesys® and the defect had a non-significant increase in IDP change during loading, whereas the fixator had a reduced IDP change ($P < 0.05$). IDP changes under loading were small and showed trends similar to the range of motion (ROM) of stabilised segments [29].

Compared to the intact state, for segments treated with the Dynesys®, the reduction of ROM [29] and the IDP change in the present study were most pronounced in lateral bending and least in axial rotation. The total load bearing of the bridged disc can be estimated by the sum of the IDP in the neutral unloaded position and the IDP change occurring for the minimum/maximum bending moment [19].

Other authors have evaluated the influence of instrumentation on the spinal segment in similar cadaver experiments. In an in vitro experiment, Cunningham et al. [5] studied the IDP in destabilised and posterior instrumented spines. They reported only absolute pressure magnitudes of the various states normalised to the intact segment. For loading in flexion, they also found an IDP increase in a destabilised segment and a decrease in a rigidly bridged segment. Swanson et al. [32] loaded specimens in flexion/extension superimposed with an axial preload and measured the IDP before and after mounting an interspinous implant. Taking the IDP in neutral position as base value, they reported a pressure increase in flexion and extension for the intact state. After mounting a posterior implant, they also found a pressure increase for loading in flexion and a decrease for loading in extension. Using a different set-up, but the same bending moment as in the present study, Molz et al. [18] measured the IDP for intact and with an internal fixator instrumented segments. For the internal fixator, they found similar trends as in the present study. They hypothesised that the reason for the IDP increase in flexion and decrease in extension in the bridged segment is due to a posterior shift of the instantaneous axis of rotation caused by the posterior instrumentation. However, the absolute pressure magnitudes for the in-

tact and instrumented states reported by Molz et al. [18] were only about half of those measured in the present study.

Other studies only partially confirm our findings. The negative pressure changes for loading in extension compared to the intact state and the reduced pressure change in axial rotation found by Rohlmann et al. [25] were confirmed in the present study. However, in flexion, Rohlmann et al. [25] and Weinhoffer et al. [35] reported an increase in pressure change for loading in flexion compared to the intact state, whereas in the present study we found a decrease in pressure change for bridged discs. Rohlmann et al. [25] measured the IDP changes under pure moments of ± 3.75 Nm of an intact segment and two segments bridged with an internal fixator. Due to the difference in loading magnitude, only the trends can be compared. It is not known if the amount of loading [25] and the type of loading [35] are the only reasons for this discrepancy or if this is due to other factors.

The IDP values of the intact, unloaded disc in the neutral position measured in the present study were in the range of the IDPs reported in in vivo measurements by Nachemson [20], Sato et al. [27] and Wilke et al. [38] for lying in supine or prone position. The IDPs obtained for maximum loading in the present study were in the range obtained for in vivo measurements for postures like sitting slouched in a chair or standing upright in a relaxed position [38]. For all three motion planes, the qualitative characteristics of the load–pressure graphs of the intact specimens in the present study are comparable with those found by Wilke et al. [41]. The similarity of IDP profiles and magnitudes of this study compared with in vivo measurements indicates that the loading may represent reasonably well certain in vivo conditions.

An additional follower preload was not applied to the specimens. In a study comparing in vivo and in vitro loads acting on a posterior fixation implant, Wilke et al. [39] showed qualitatively comparable results for loading with pure moments when the intervertebral disc was left intact. In a study investigating the effect of a follower load on IDP, Rohlmann et al. [26] showed that by applying a follower preload, IDP in the neutral position is elevated to more physiological values. However, the characteristics of the IDP change under loading are comparable to loading with pure moments.

Potential limitations with in vitro IDP measurements in general may be initial degeneration of the specimens as well as deterioration or creep in the intervertebral disc during testing. Adams et al. [2] reported an IDP loss of 13–36% in the nucleus due to water loss and creep in the specimens after sustained loading of intervertebral discs. Taking the adjacent untreated discs as controls, in the present study, the maximum pressure loss in the unloaded neutral posi-

tion compared to the intact state was 14%. However, because each disc acted as its own control and due to the alternating sequences of the two stabilisation systems, the effects of sustained loading on the IDP were small and comparable for both implants.

The degree of degeneration of the bridged discs in the present study was radiographically assessed according to Mimura et al. [17]. Only one of the bridged discs has shown minor signs of degeneration. Due to a nucleotomy conducted at a later stage, the specimens were not available for a macroscopic investigation of the disc degeneration after the experiment.

Results in literature regarding the influence of instrumentation on adjacent segment loading are controversial. For the moment-controlled load applied in the present study, the creation of a defect and the stabilisation of it with a rigid or dynamic system had a negligible effect on the IDP of the adjacent segments. Similarly, using load control, other studies [25, 32] found no or only a small effect of posterior instrumentation on the IDP of adjacent discs. Because the stiffness of the adjacent level segments is not altered by the treatment of one segment (injury, implants), IDP changes for an applied moment have to be the same for all specimen conditions. However, using deformation-controlled loading protocols, Cunningham et al. [5] and Weinhover et al. [35] found a strong increase in IDP for discs adjacent to a posterior instrumentation. The differences in the effect of a posterior instrumentation on the adjacent segments clearly depend on the kind of loading protocol used for testing. While a deformation-controlled load protocol assumes that patients bend their spines to the same degree no matter whether they have an intact or instrumented spine, a moment-controlled load protocol assumes that patients accept their limited motion during daily activities. There are arguments for both testing models, while the reality probably lies somewhere in between the two testing models. However, in order to ensure repetitive testing in different conditions

without creating structural damage by overloading the specimens and in accordance with the recommendations for in vitro stability testing of spinal implants [40], we tested the specimens in the current study under load control.

The comparison to existing in vitro and in vivo literature confirms that the models used herein are deemed valid and relevant findings. Our results suggest that posterior instrumentation significantly unloads the disc in extension by a significant amount and also unload the disc in lateral bending. In flexion and axial rotation, they seem to restore the load distribution similar to an intact segment.

Conclusions

Mounting a posterior stabilisation device to a spinal segment affects the IDP of the bridged disc. In the neutral unloaded state, the influence of a defect and subsequent treatment with a posterior implant system had only a small but not significant effect on the hydrostatic pressure. In general, compared to the intact spine, stabilising a defect with either the modified Dynesys® or the internal fixator unloads the bridged disc during loading in extension and lateral bending. During axial rotation, the load bearing of the disc is only slightly altered by the posterior instrumentation. In flexion, both devices decreased the IDP to magnitudes in the range but slightly below the intact level and showed a good support of the anterior column. Compared to the rigid fixator, the modified Dynesys® does not show substantial differences in IDP of a bridged disc.

For the moment-controlled load protocol used in the present study, the effects of a stabilisation system on the IDP of the adjacent discs were negligible. Further studies are needed to get a full picture of the dynamic stabilisation and to investigate the effect of the stiffness and length of the spacers.

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