Primary spinal segment stability with a stand-alone cage

In vitro evaluation of a successful goat model

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Background Interbody cages have been developed to restore disk height and to increase stability of the spinal segment, and thereby enhance fusion. However, they often prove inadequate as a stand-alone device. It is unknown how much primary stability is required to facilitate fusion. In various goat studies, we have obtained spinal fusion routinely with a stand-alone cage device. However, data covering the mechanical conditions under which these fusions have been obtained are lacking. In this study, we addressed the issue of primary stability.

Methods We used an established goat model for spinal fusion in vitro. 48 native lumbar spine segments were mechanically tested in flexion/extension, axial torsion (left/right), anterior/posterior shear, and left/right lateral bending. Then all segments were provided with a titanium cage using the exact surgical procedure of our earlier in vivo studies, and the mechanical tests were repeated.

Under shear force and axial torsion, a significant loss of stiffness was seen in the operated segments as compared to nonoperated controls. No increase in stiffness was found in any of the loading directions.

Interpretation Cage implantation in a lumbar spinal segment does not increase immediate postoperative stability as compared to the native segment in this goat model. This is attributable to both the annular damage during cage implantation and the subsequent loss of segment height. Yet previous in vivo studies using this goat model have generally shown fusion. This implies that high primary segment stability is not required for fusion or, alternatively, that the tested range of motion of the spinal segment in vitro does not occur at these magnitudes in vivo.

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The goal of spinal fusion is to reduce pain and relieve neurological symptoms by re-aligning the spine and reducing excessive, uncontrolled motion between the vertebrae. To achieve these objectives, many different cage designs and materials have been developed and introduced in clinical practice (Weiner and Fraser 1998, McAfee 1999, Steffen et al. 2000, Zdeblick and Philips 2003). A rapid increase in fusion surgery was observed after the approval of the intervertebral fusion cage by the Food and Drug Administration in 1996 (Deyo et al. 2005); good and excellent clinical success has been claimed in studies with 2–4 years of follow-up (e.g. Ray 1997, Brantigan et al. 2000, Kuslich et al. 2000). However, recent reports have shown an increasing number of failed cages, especially with longer follow-up periods (Tullberg 1998, McAfee et al. 1999, Togawa et al. 2004, Button et al. 2005). The increasing complication rates after interbody fusion surgery have been related to cage design and material (Steffen et al. 2000, Sasso et al. 2005) as well as to the surgical procedure (Fritzel et al. 2003). In this context, much attention has been paid to the primary stability of intervertebral cages, with varying results. Some research groups have

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found a significant decrease in segmental range of motion (ROM) (e.g. Sengupta et al. 2002, Greene et al. 2003, Wang et al. 2003, Boskuz et al. 2004), while others have observed an increase (e.g. Shimamoto et al. 2001, Le Huec et al. 2002, Korinth et al. 2003) or no difference as compared to the intact spinal segment (e.g. Murukami et al. 2004). Thus, it remains unclear from these biomechanical studies how much stability is actually required to obtain spinal fusion or, conversely, how much instability is still allowed.

Several research groups have shown high fusion rates in vivo using stand-alone cages, both clinically (e.g. Haid et al. 2004, Sasso et al. 2004, Ryu et al. 2005) and preclinically in animal experiments (e.g. Brantigan et al. 1994, Toth et al. 2002). Also, our group observed high fusion rates using stand-alone cages of various materials in a goat model (e.g. Van Dijk et al. 2002a, Krijnen et al. in press). From these in vivo studies, however, it is unclear if and how the stand-alone cage influences primary segment stability. To better understand the contribution of the mechanical environment for fusion, we performed an in vitro study with spinal segments from a goat, and we determined the stability in 8 loading directions before and directly after placement of an interbody cage.

Animals and methods

Lumbar spines (L1–L6) were explanted from 24 skeletally mature female Dutch milk goats (3–7 years old, weight 55–70 kg), trimmed of soft tissue but leaving the ligaments intact, and the specimens were divided in 3 vertebral motion segments. The dimensions and distance of the vertebral endplates neighboring the intact discs were measured on lateral and anteroposterior radiographs. To also address the role of disk dimension in spinal stability, we used L1–L2 and L5–L6 of each spine for the mechanical study; L3–L4 was kept for separate studies. The specimens were wrapped in gauze soaked in 0.9% saline and kept frozen at –25°C in polyethylene bags until testing (Wilke et al. 1998).

Before mechanical testing, the motion segments were thawed to room temperature. The native L1–2 and L5–6 segments were randomly divided into 4 groups, to be tested under flexion/extension, bilateral bending, left/right torsion, and anterior/posterior shear (n = 6 in each case). For every loading direction, a set-up was developed to create a pure moment or shear without preload. The free endplates of the motion segments were fixed in a low-melting-point bismuth alloy (melting point 48°C) (Sonderweichlot 301, A 301; Degussa AG, Wolfgang, Germany) and mounted on an Instron 8872 testing machine (Instron Corp., Canton, MA). Bending and torsion were applied in both directions with a speed of 0.6 degrees/min up to 1.0 Nm. A shear force (anteriorly and posteriorly) was applied with a speed of 1.0 mm/min to a maximum of 200 N, to stay within the viscoelastic range and to avoid damaging the specimens (Wilke et al. 1998). During the experiments, the segments were intermittently sprayed with 0.9% saline to prevent dehydration. Force-deformation data acquisition was performed for each direction separately using materials testing software (Fast Track 2; Instron Corp., Canton, MA).

After testing the intact motion segments, the specimens were mounted in a bench device for a simulated interbody fusion procedure through a left lateral approach (Van Dijk et al. 2002a). The intervertebral disk was identified and penetrated transversely with a 2-mm guide-wire. An 8-mm drill bit was positioned over the guide-wire and a round channel was drilled through the intervertebral disk and adjacent vertebral endplates, leaving the anterior and posterior longitudinal ligaments intact. Then a 10-mm drill bit was positioned over the guide-wire and the round channel was enlarged. The intervertebral disk and approximately 2–3 mm of endplate and subchondral bone of both adjacent vertebral bodies within the transverse rectangular defect were then removed using a custom-made box gouge (10 × 10 mm). All the tissue within the rectangular defect was removed. Care was taken during drilling and preparation of the rectangular defect not to place the intervertebral disk under distraction or compression. Custom-made titanium cages with a wall thickness of 1.5 mm and rectangular configuration (10 × 10 × 18 mm; see Figure 1) were impacted with bone graft and gently pushed into the intervertebral lumen (Figure 2). The specimens were re-mounted on the mechanical testing devices and the experiments were repeated for each loading condition.

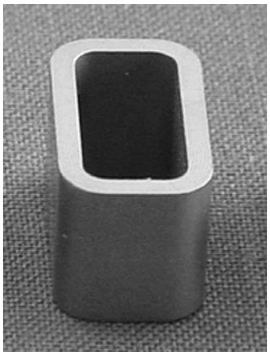

Figure 1. The titanium cage used for all experiments in this study. The external dimensions are 10 × 10 × 18 mm. The wall thickness is 1.5 mm. The same cage, made of both titanium and several bioresorbable polymers, has been used in earlier in vivo studies in the goat.

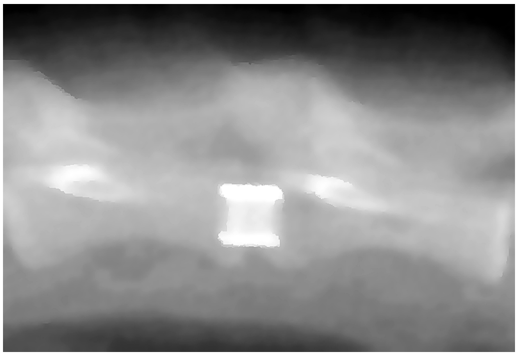

Figure 2. Lateral radiograph of a titanium cage implanted in a lumbar motion segment, showing the penetration of both adjacent vertebral endplates by 2–3 mm.

Statistics

Repeated-measures ANOVA was performed comparing the amount of movement (in mm or degrees) at fixed forces or bending moments between the instrumented and non-instrumented group. An overall analysis included instrumentation (instrumented versus control), movement direction (eight levels: anterior and posterior shear, flexion, extension, left and right lateral bending, and left and right torsion), and loading magnitude (8 levels) as independent variables, and spinal level (L1–2 versus L5–6) as a between-subjects factor. Post-hoc analyses were performed for each movement direction except for lateral bending and torsion, where left and right movements were combined, with left versus right as an extra factor. For all statistical tests, the significance level was set at $p < 0.05$.

Results

Disk dimensions (Table)

The dimensions of L1–L2 segments were not significantly different to those of L3–L4. L5–L6 were significantly broader than the other lumbar segments, and less deep (NS). The disk height was larger in L5–L6 than in L3–L4 and L1–L2 (NS)

Average dimensions of the intervertebral discs of the lumbar spine segments of a goat. Values are mm (SD)

Level	n	Width	Depth	Height, anterior	Height, posterior
L1–L2	6	26 (1.4)	19 (0.8)	6.3 (0.8)	4.6 (0.6)
L3–L4	6	27 (0.5)	19 (0.5)	6.3 (0.5)	4.4 (0.4)
L5–L6	6	32 (0.9)	18 (1.0)	6.9 (0.4)	4.7 (0.5)

Mechanical stability (Figure 3)

Overall, the instrumented group showed significantly more motion at the same force or bending moment ($p = 0.02$). The surgical procedure showed no significant effect on sagittal bending ($p = 0.3$). Also, flexion showed no difference ($p = 0.3$) whereas extension showed a non-significant increase in movement ($p = 0.07$) (Figure 3a). Lateral bending (left and right) also showed a non-significant increase in movement ($p = 0.05$) (Figure 3b). Despite the left lateral opening of the annulus, there was no asymmetry between left and right bending. L5–L6 was consistently stiffer than L1–L2. Shear ($p = 0.03$) and torsion ($p < 0.001$) displacements were significantly increased due to the insertion of the cage (Figure 3c, d). Anterior and posterior shear displacements were not significantly different.

Level differences

There was a correlation between vertebral level and surgical procedure ($p = 0.01$), involving a stronger increase in movement under torsion in the L1–2 group than in the L5–6 group (Figure 3c). There were no significant differences between lumbar levels for other loading directions.

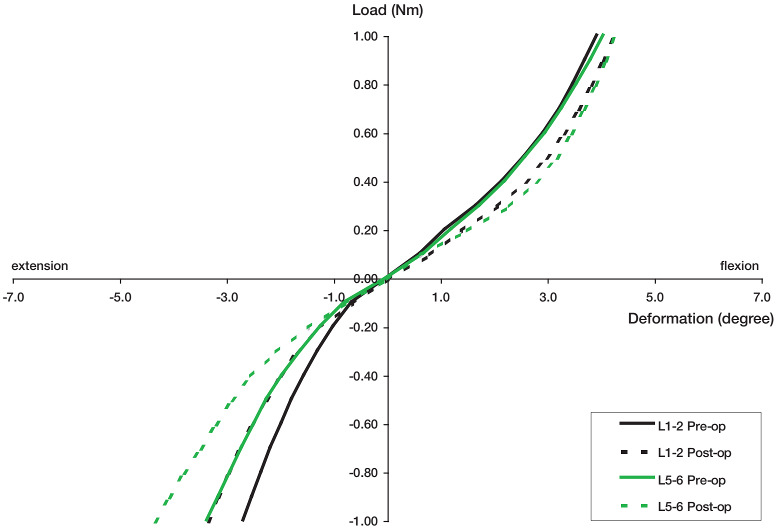

Figure 3a. Average load-deformation curve under flexion-extension. The curves show a non-significant decrease in stiffness after surgery.

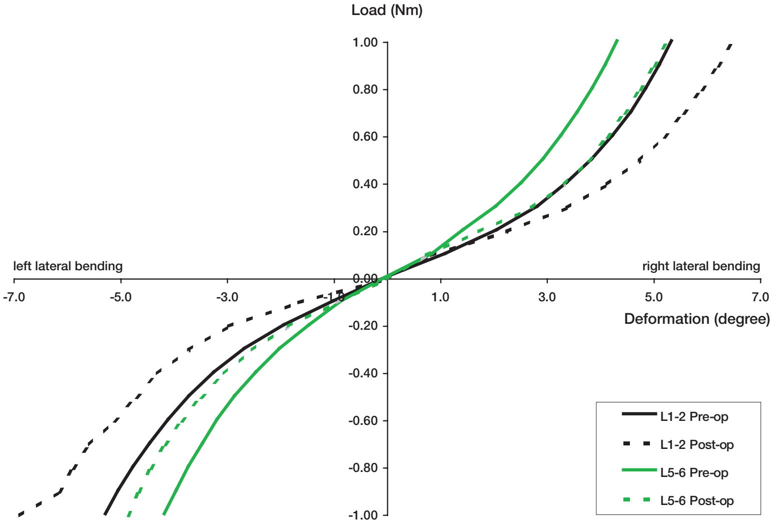

Figure 3b. Average load-displacement curve of lateral bending. Steeper slopes indicate higher stiffness. The curves show a non-significant decrease in stiffness after surgery.

Discussion

Primary segmental stability after insertion of an intervertebral cage is generally assumed to be a key factor for successful fusion (e.g. McAfee, 1999). However, there have been no studies published that have explicitly dealt with the primary stability of a successful fusion model using stand-alone cages. Furthermore, few comparable data exist on the influence of laterally inserted cages on primary stability. This biomechanical investigation was performed to validate our existing protocol of in vivo spinal fusion in a goat lumbar spine model.

In axial torsion, we found reduced primary stability after surgery as compared to the native situation. This finding supports the results of other

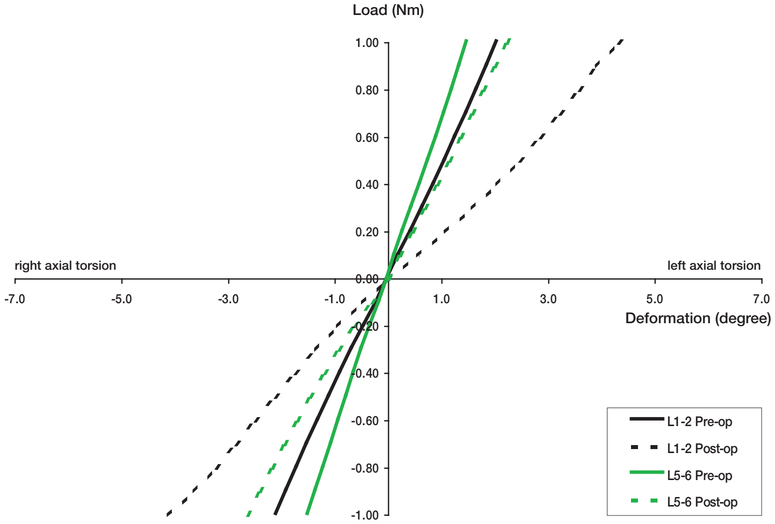

Figure 3c. Average load-deformation curve of axial torsion. Movement increases at the same moment after surgery (p < 0.001). After surgery, L1–2 shows significantly more motion at the same load than L5–6 (p = 0.01).

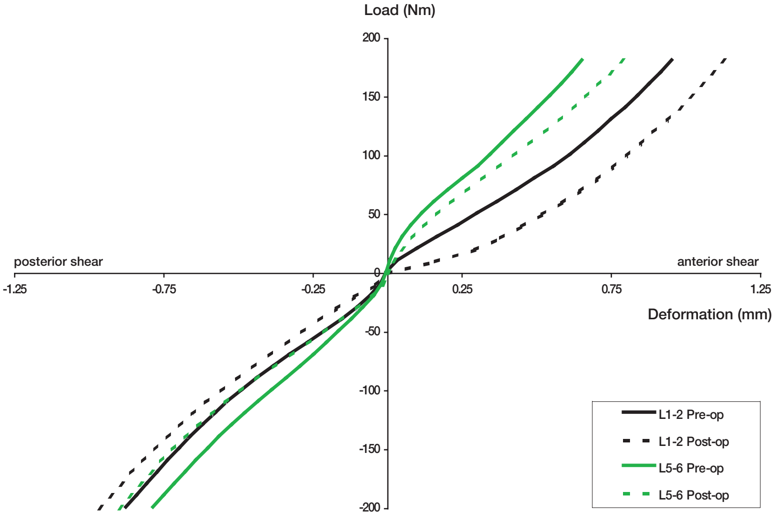

Figure 3d. Average force-deformation curve of shear. After instrumentation, the stiffness decreases significantly (p = 0.03).

investigations showing a decrease in stability of the motion segment in axial torsion, both in the human spine (Nydegger et al. 2001, Le Huec et al. 2002, Harris et al. 2004) and in the calf spine (Schneid et al. 2002). Annular damage thus reduces torsion stiffness of the spinal segment regardless of the facet joint orientation—which is different in humans and quadrupeds (Cotteril et al. 1986)—and despite the placement of an intervertebral device. We had assumed that a press-fit placement of a cage through both endplates would surely increase segment stability under torsion, but this situation was quite clearly not achieved.

In flexion, the operated motion segments were almost as stiff as the native segment. This compares closely with results found in other models (Schneid et al. 2002, Harris et al. 2004). However, it contrasts to other studies, in which motion segments were substantially stabilized with stand-alone cages of different design (Tsantrizos et al. 2000a, b, Nydegger et al. 2001, Le Huec et al. 2002). Extension has been shown to be poorly stabilized in other procedures (Lund et al. 1998, Oxland and Lund 2000, Oxland et al. 2000). We found almost same values for native and instrumented specimens at both levels, although we did not distract the disk where others did. We attribute the lack of stabilization in flexion and extension to the laxity of the longitudinal ligaments as a result of damage to the healthy discs. Indeed, it has been found from radiostereometric analysis in vivo that the segment height becomes reduced by about 1 mm during the fusion procedure using this goat model (Krijnen et al. 2004). Tension of the longitudinal ligaments can be restored by distraction of the operated segment before surgery, which is in fact done routinely in human fusion surgery.

The relationship between annular damage and increased instability was further shown by the significant difference between the spinal levels under torsion: a relatively larger defect was created in the annulus of L1–L2, as the average width of the endplate is 6 mm smaller than the endplate of L5–6 (Table). The width and depth of the tunnel did not change, however—leading to damage of the annulus on the contralateral side at the L1–2 level and not at the L5–6 level. This caused a significantly larger decrease in stiffness under torsion (Figure 3c), and confirms the idea that damage to the annulus should be minimized.

In the present study, the postoperative stability was compared to the stability of a vertebral segment of a young, healthy goat. This may seem an irrelevant condition from the clinical point of view, because cages are normally applied in degenerate, unstable spinal segments. Nevertheless, the results are comparable to those of most other biomechanical studies with stand-alone cages in both animal and human spinal segments. Studies that have found an increase in segment stability in one or more directions have used more degenerate (i.e. less stable) spinal units, have used devices with a larger cross-sectional area and/or placed more laterally, and distracted the segment before cage implantation. Indeed, preoperative spine conditions, cage design, and operative procedure may strongly affect the outcome of biomechanical studies like the present one.

This raises the important question of the validity of our goat model. The mechanical condition of a spinal unit in a young healthy goat certainly differs from that of a degenerate human segment, and the cages used in our studies are of a different design than most clinical cages. The mechanical loading conditions in vivo, however, do not differ as much as one would intuitively expect: the main loading component in the spines of humans and quadrupeds is axial compression, and the most important secondary loading components are anterior shear and axial torsion (Smit 2002). In addition, the strengths of lumbar spinal segments are comparable between goats and humans, indicating that the absolute axial compression load in vivo is of the same order of magnitude (Smit 2002). Only the cross-sectional area of a goat disk is about one-quarter of that of a human disc, which is compensated for by a trabecular bone density that is almost twice as high (Smit 2002). The validity of any model depends on the questions addressed. In the case of spinal fusion, we found striking histological similarities between a goat segment with a titanium cage after 6 months of follow-up with a titanium tumor cage retrieved from a 4-year-old child (Van Dijk et al. 2002b, Smit et al. in press). In both cases, a mineralizing cartilage layer separated the bone fronts that grew in from two sides, and there was considerable formation of fibrous tissue at the implant interface. This suggests that the process of spinal fusion is well simulated in our goat model, and that the mechanical loading conditions are also comparable. This indicates that the goat model is valid for the study of the role of primary stability in spinal fusion.

In summary, we now have good experimental data on the mechanical conditions directly after insertion of a cage in a vertebral segment of a young, healthy goat, and we have found that stability becomes reduced rather than increases as compared to the native, intact disc. Even so, we routinely obtain successful fusion with this goat model in vivo (Van Dijk et al. 2002a, Krijnen et al. in press). This leads us to conclude that primary segment stability is not a key factor for successful fusion or, alternatively, that the tested range of motion of the spinal segment does not reach these magnitudes in vivo. The latter hypothesis can only be challenged using intervertebral motion analysis in the goat model in vivo.

Contributions of authors

MRK performed the spinal fusion surgeries in vitro and wrote the manuscript. THS designed the mechanical protocols, interpreted the results and edited the manuscript. DM performed the mechanical studies. JHD interpreted the results and performed the statistical analyses. PIW initiated the studies and edited the manuscript.

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