

STANDARD RADIOGRAPHY RELATED TO VERTEBRAL SEGMENT STABILITY AFTER LUMBAR INTERBODY FUSION IN A GOAT MODEL

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disclosure

Kroeze R.J.

None

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None

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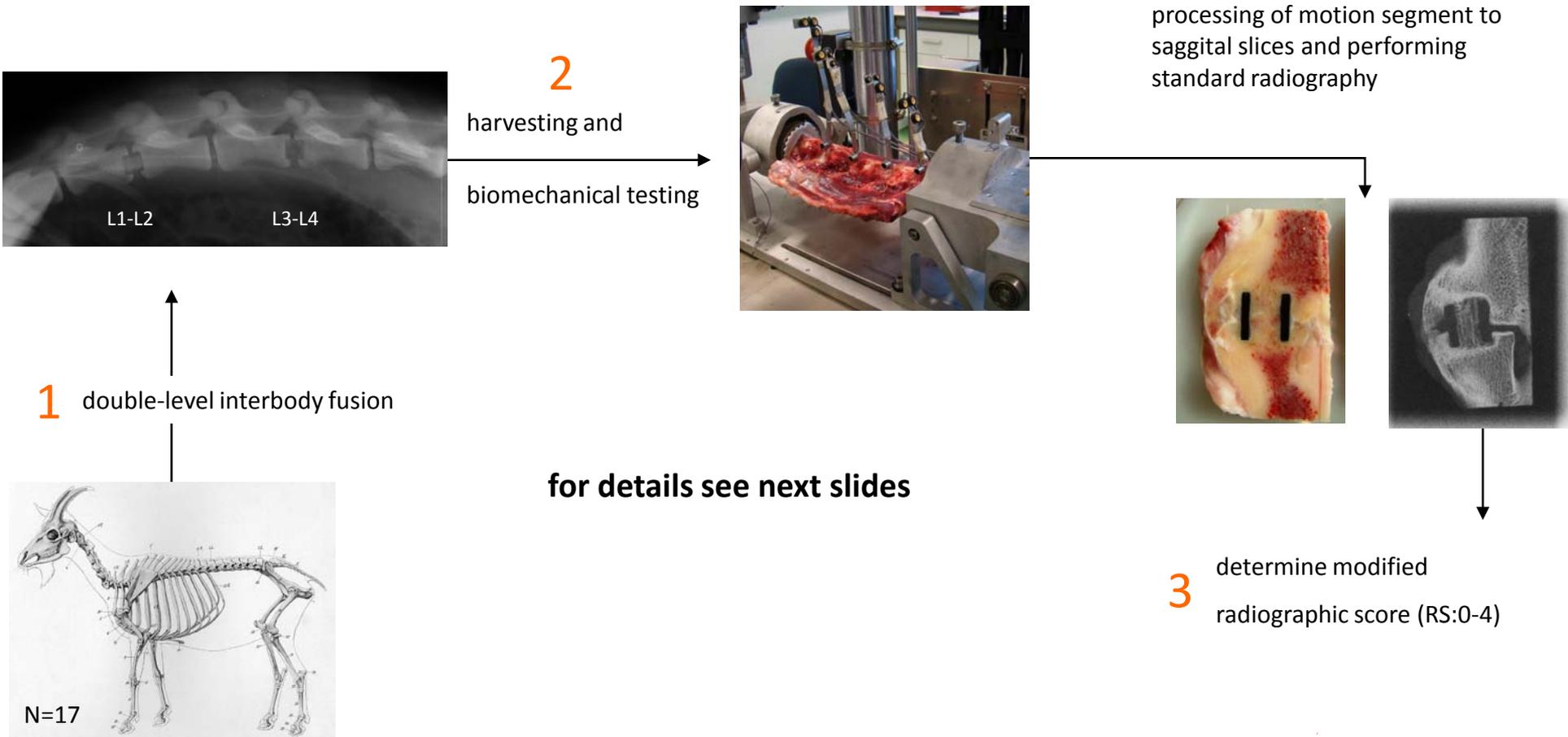
None



introduction

- Lumbar interbody fusion is performed to relieve the clinical symptoms associated with degenerative changes by stabilizing and realigning the spine with restoration of the intervertebral disc height. The interbody spacer (cage) can be used as an adjunct to posterior pedicle screw instrumentation or as a stand-alone anterior fusion cage¹. The surgical goal in spinal fusion surgery is the establishment of a bony bridge between adjacent vertebrae. The various techniques to obtain this bony bridge using either stand-alone cages, or cages with additional instrumentation, have been analysed biomechanically *in vitro*²⁻⁵. This experimental set-up actually investigates the direct post-surgical stability of the vertebral motion segment after spinal fusion, and any conclusions mainly relate to the first day after surgery⁶. In contrast, the end-stage of spinal fusion surgery is investigated in many *in vivo* studies, using various types of materials/techniques, with or without the addition of growth factors, to assess the occurrence of a bony bridge between adjacent vertebrae. Although the pursued solid fusion should result in little or no motion between the vertebrae⁷, limited data is present to address vertebral segment stability from surgery to solid fusion^{1,8}.
- Due to the limited data mentioned above and since interbody fusion can be seen as a large osteotomy gap in which the process of fracture healing takes place, we converted to the more substantial available literature concerning the fracture healing of long bones. Following the dictates of fracture healing there is a tendency for radiography to underestimate the biomechanical stability of the healing fracture⁹. Therefore, we hypothesized that substantial vertebral segment stability is already achieved prior to solid arthrodesis in our spinal fusion goat model.
- As part of a larger goat interbody fusion study we biomechanically evaluated 17 caprine lumbar spines, following double-level fusion procedures after 3 and 6 months. Ex-vivo segment stability was related to the stage of bone ingrowth as assessed by radiography. For the latter, plain radiography was used and we semi-quantified these stages of spinal fusion by modifying an existing radiographic score (RS), indicating the progression of a bony bridge between the adjacent vertebra or the presence of a ventral bony bridge (sentinel sign).

materials and methods



materials and methods II

1. *Double level interbody fusion:* L1-L2 and L3-L4 were identified via a left retroperitoneal approach after which the intervertebral discs were exposed. Under fluoroscopic guidance, a 2-mm guidewire was centred transversely in the disc. An 8-mm drill bit was placed over the guidewire through the disc and the adjacent endplates. The 10x10 mm box gauge was placed over the drill and used to punch a transverse rectangular defect, after which a cage was inserted.

Cage fillers: Four experimental cage filler groups were created; autologous iliac crest bone (AB) and three bioresorbable polymer groups which consisted of poly(L-lactide-co-caprolactone) (PLCL) alone, PLCL seeded with autologous freshly isolated adipose stromal vascular fraction (SVF) cells and PLCL seeded with previously harvested autologous adipose stem cells obtained by culturing SVF cells for at least two weeks. Since this study does not differentiate between these cage filler groups, but rather distinguish between groups based on a radiographic score, no further mention will be made in this e-poster with respect to the various cage fillers used.

2. *Harvesting and biomechanical testing:* Immediately after sacrifice, the spines were excised at the Th12-Th13 level and at the L5-L6 level. Subsequently, the spines were trimmed of residual musculature, while leaving all ligamentous tissue intact, wrapped in NaCl soaked towels and stored at 4°C. Within 24 hours, the spines were prepared by rigidly fix L-shaped markers in the ventral-midsagittal plane on each vertebral body (N=4), each marker containing 3 light-emitting diodes (LEDs) for optoelectronic 3D movement registration. Biomechanical testing was performed using a custom made four-point bending device in which flexion/extension and right and left lateral bending. Moments of 3 Nm were gradually applied in the tested direction, with a rotation speed of 1 degree/second. Specimens were tested for 10 continuous cycles and the average data of all cycles were analysed. Motions of the LED's were recorded by an optoelectronic 3D movement registration system.

As a control, the lumbar spines of 4 goats, sacrificed for an unrelated experiment, were collected. The first biomechanical test of these control spines comprised the native situation. To gain insight in the biomechanical situation directly post-operative, biomechanical testing was performed after the insertion of an interbody spacer (cage) at the L1-L2 and L3-L4 level of the native spines, identical to the surgical procedure. A customized program written in Matlab (Mathworks, Natick MA, USA) was used for data analysis.

materials and methods III

3. *Radiographic score*: Lateral radiographs of the sagittal sectioned specimens were used to estimate interbody fusion, based on a validated radiographic score (RS)¹⁰ although modified for this study. For the modified radiographic score, the rectangular cage on the radiograph was divided in three equal parts along the spinal axis. When no bone ingrowth was observed, a radiographic score of 0 was given to the segment. For RS 1, bone ingrowth was present in the outer one-third of the cage, and when bone had grown into the middle third, a radiographic score of 2 was set. RS 3 was achieved when bony contact was present throughout the sagittal plane of the cage, while the presence of a ventral bony bridge (sentinel sign) was always given a RS 4 score, irrespective of the RS score inside the cage (for a schematic lateral diagram, see next slide)
- *Statistical analysis* was performed using SPSS software (SPSS Inc, Chicago USA). Comparing the differently scored segments of the spine was done using a univariate general linear model and Tukey's post hoc test. To test the differences between the native segments before and after cage insertion, a Wilcoxon matched-pairs signed-ranks test was used. The interobserver agreement for the RS score was calculated using Cohen's kappa value. Differences were considered statistically significant when $p < 0.05$.

results I

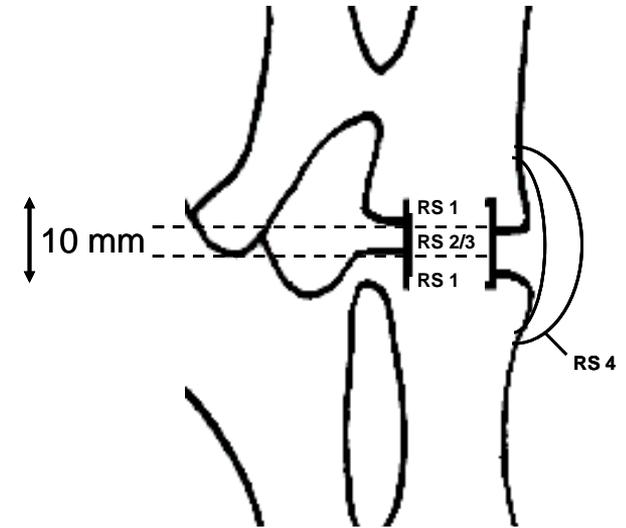
radiographic score (RS)

Validation of radiographic score

The lateral radiographs taken from the paramidsagittal section for all goats, were scored by two observers (RJK and MH). The kappa value concerning the inter-observer reliability of this modified RS score was 0.82. In the event of a unidentical RS score, both observers discussed the most appropriate score, which was then assigned to the corresponding segment.

Of 34 analysed segments, only 2 segments score RS 0. For statistical reasons, these segments were not included in the analyses. The remaining segments are shown in the table below.

	<i>flexion/extension ROM reduction</i>	<i>lateral bending ROM reduction</i>
cage insertion	-	-
RS 1 (N=8)	37%	71%
RS 2 (N=7)	71%	87%
RS 3 (N=6)	72%	91%
RS 4 (N=11)	86%	95%



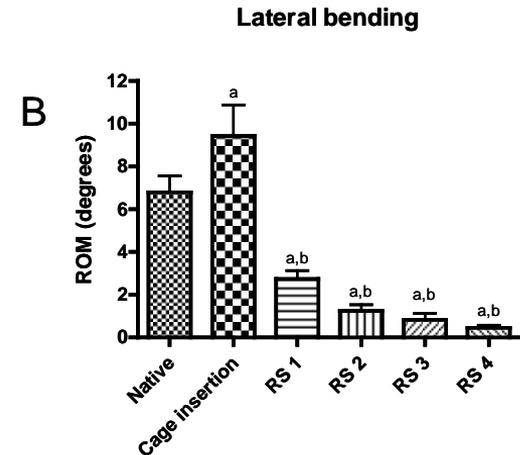
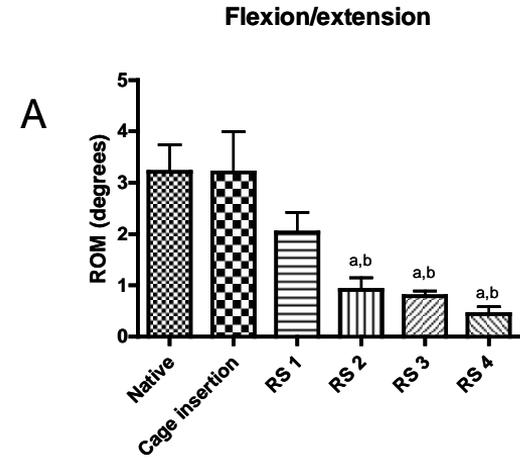
schematic lateral diagram of radiographic score used

results II

biomechanical testing

Schematic representation of the range of motion (ROM) for the RS scores 1-4 and the native segments, before and after cage insertion.

- (A) Range of motion for flexion/extension. Significant lower values ($p < 0.05$ for RS 2 and 3, $p < 0.001$ for RS 4) are indicated by either a: compared to native, or b: compared to cage insertion.
- (B) For lateral bending. Significant different values ($p < 0.001$, except for cage insertion with $p < 0.05$) are indicated by either a: compared to native, or b: compared to cage insertion.



conclusions

- The paired testing of the control spines before and after interbody cage insertion showed an increased instability of the segment after lateral insertion of the device. This significant increase in ROM during lateral bending after cage insertion was likely due to the unilateral destruction of the annulus fibres.
- Presumably, cage fillers go through a phase of RS 0, 1 and 2 before reaching solid fusion (RS 3). Therefore, it is reasonable to assume that with cage fillers in the process of creeping substitution, several stages can be identified. Thus, the possible early stabilization of the vertebral segment with the lower radiographic scores, might explain the limited additional effect of the use of instrumentation in spinal fusion. ^{11, 12}
- Significant reduction in flexion/extension and lateral bending is achieved with only moderate (RS 2) and even mediocre (RS 1) bone ingrowth respectively and therefore radiography underestimates vertebral segment stability after spinal fusion. Solid fusion, whether or not in the presence of a sentinel sign, does not eliminate motion but reduces motion considerably.



discussion

- Despite the fact that this study shows the clear reduction in range of motion at an early/intermediate stage of fusion, the question remains whether or not a significant reduction in motion is sufficient to reduce or eliminate the pain for the patient. The stabilization needed to eliminate pain, is already a challenging study parameter in clinical studies, but lacking reliable pain scores in the goat, this correlation cannot be studied.
- Although this study does not differentiate between the four cage filler groups, but rather distinguish between groups based on a radiographic score, it remains uncertain whether the measured ROM was influenced by the various cage fillers. Different RS groups were distributed more or less evenly among the various cage fillers, but no statistical analyses could be made between similar RS groups from different cage filler groups due to the small numbers.
- Taken together, and in contrast to the objective of spinal fusion surgery⁷, from a biomechanical point of view, vertebral consolidation might not necessarily be the pursued end-point. And although from both a legal as well as traditional point of view this conclusion might not be shared, still, these results may obviate the need for long-term follow up of the surgically treated patients, corroborating with Brantigan, stating that “when a successful clinical result is obtained, it is probably unnecessary to prove bony arthrodesis in these patients.”⁷



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