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Brief report

Can a modified interspinous spacer prevent instability in axial rotation and lateral bending? A biomechanical in vitro study resulting in a new idea

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Abstract

Background. Interspinous spacers are mainly used to treat lumbar spinal stenosis and facet arthrosis. Biomechanically, they stabilise in extension but do not compensate instability in axial rotation and lateral bending. It would therefore be desirable to have an interspinous spacer available, which provides for more stability also in these two planes. At the same time, the intervertebral disc should not completely be unloaded to keep it viable. To meet these requirements, a new version of the Coflex interspinous implant was developed, called "Coflex rivet", which can be more rigidly attached to the spinous processes. The aim was to investigate whether this new implant compensates instability but still allows some load to be transferred through the disc.

Methods. Twelve human lumbar spine segments were equally divided into two groups, one for Coflex rivet and one for the original Coflex implant. The specimens were tested for flexibility under pure moment loads in the three main planes. These tests were carried out in the intact condition, after creation of a destabilising defect and after insertion of either of the two implants. Before implantation, the interspinous spacers were equipped with strain gauges to measure the load transfer.

Findings. Compared to the defect condition, both implants had a strong stabilising effect in extension ($P < 0.05$). Coflex rivet also strongly stabilised in flexion and to a smaller degree in lateral bending and axial rotation ($P < 0.05$). In contrast, in these three loading directions, the original Coflex implant could not compensate the destabilising effect of the defect ($P > 0.05$). The bending moments transferred through the implants were highest in extension and flexion. Yet, they were no more than 1.2 N m in median.

Interpretation. The new Coflex rivet seems be a suitable option to compensate instability. Its biomechanical characteristics might even make it suitable as an adjunct to fusion, which would be a new indication for this type of implant.

Keywords: Lumbar spine; Interspinous spacer; Interbody fusion; Stability; Strain; Biomechanics

1. Introduction

The main indications for interspinous spacers are lumbar spinal stenosis and painful facet arthrosis. In vitro, these implants were shown to reduce facet loading and to widen the neuroforamina and the spinal canal (Richards et al., 2005; Wiseman et al., 2005), which supports their effectiveness concerning the above mentioned indications. Biomechanically, the different interspinous spacers, which are on the market today, i.e. X-Stop, Wallis, Diam and Coflex, all increase stability in extension but are not able to compensate instability in axial rotation, lateral bending and in some cases in flexion (Fuchs et al., 2005; Lindsey et al., 2003; Wilke et al., 2007). This lack of stability might impair the clinical long-term success, which has so far only been reported to be good in the short-term (Anderson et al., 2006; Kondrashov et al., 2006; Zucherman et al.,

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2005). It would therefore be desirable to have an interspinous spacer available, which is able to compensate instability not only in extension but in all loading planes. At the same time, it would be important to not completely unload the intervertebral disc. The more stability an implant provides the more it deprives the disc of being loaded and unloaded in a physiological way. Physiological loading and unloading, however, is necessary to keep the disc viable.

To meet these requirements, a slightly modified version of the Coflex implant was developed, called "Coflex rivet" (Paradigm Spine, Wurmlingen, Germany). It differs from the original Coflex implant in that it can be more rigidly attached to the spinous processes. At the same time its "U"-shaped design is assumed to still allow some movements and, thus, some load transfer through the intervertebral disc.

The aim of the present in vitro study was to investigate whether this modified implant provides more stability than the original Coflex implant but still allows some load to be transferred through the disc.

2. Methods

Basically, the Coflex interspinous implant has the shape of a "U" with four lateral wings (Fig. 1a). It is made of titanium. The two types of the implant tested in the present study only differed in the way how they were anchored to the spinous processes while shape and thickness were the same. In case of the original Coflex implant anchorage was achieved by crimping the wings to the spinous processes (Fig. 1b). In contrast, Coflex rivet was fixed using screws, which were drilled from right to left through holes in the wings and the spinous processes. These screws were secured with a nut and acted as rivets (Fig. 1c). These prototype "rivets" were easily implantable in vitro and were therefore adequate to get a first idea of whether additional fixation to the spinous processes results in more stability.

Before testing, the implants were equipped with strain gauges to measure the bending moments acting at the apex of the "U" and at the base of each of the four wings. For this purpose five uniaxial strain gauges (type 0,6/120LY11, Hottinger Baldwin Messtechnik, Darmstadt, Germany) were glued to the inner surface of the apex of the "U" and laterally to the base of each wing (Fig. 2). Another strain gauge, which was glued to an additional, unloaded implant, was used for temperature compensation. Before implantation, the strain gauges were calibrated. This calibration allowed to directly convert the strains into bending moments (resolution <0.01 N m). These measurements were used to indirectly estimate the load transferred through the intervertebral disc.

Twelve fresh frozen lumbar spine specimens L2-3 and L4-5 were tested. They were equally divided into two groups of three L2-3 and three L4-5 segments for the two implant types. Additionally, the specimens were matched according to their age: the specimens for the original Coflex implant were 55 years in mean (29–67 years) and those for Coflex rivet 56 years (20–73 years). Finally, the degree of intervertebral disc degeneration was determined according to a radiographic grading system ranging from 0 (no degeneration) to 3 (severe degeneration) (Wilke et al., 2006). The degrees of degeneration proved to be similar in both groups. In the group for the original Coflex implant, the mean degree was 1.2 while in the Coflex rivet group it was 1.0. Before testing, the specimens were thawed and all soft tissue surrounding the discoligamentous spine was removed. Then, half of the cranial and half of the caudal vertebral body were embedded in polymethylmethacrylate cement to allow to fix them in the spine tester.

The experiments carried out with each of the twelve specimens included flexibility tests in the intact condition,

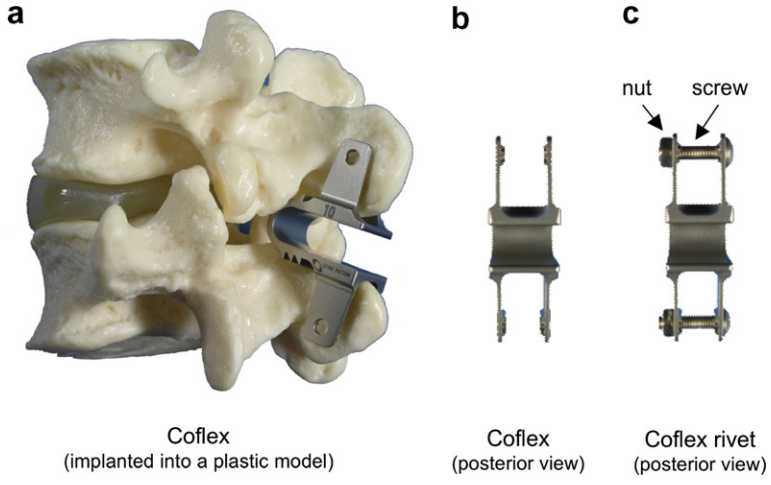

Fig. 1. Coflex interspinous implant (Paradigm Spine, Wurmlingen, Germany) (a). After resection of the supra- and interspinous ligament, the Coflex interspinous implant is introduced between the two adjacent spinous processes. Then-in case of the original Coflex implant (b) the wings are crimped to the spinous processes. In case of Coflex "rivet" (c) two additional screws, which are secured with a nut, are used to more rigidly attach the wings to the spinous processes. They act as prototype rivets.

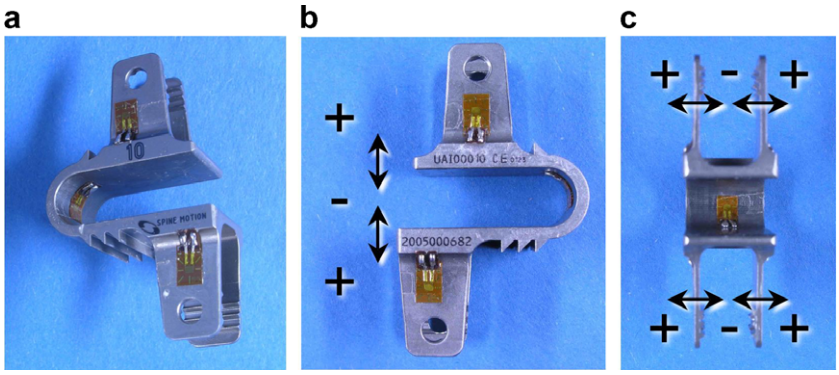

Fig. 2. Five strain gauges were glued on each implant: one on the base of each wing and one on the inner apex of the "U" (a). The signal was directly converted into the bending moments acting at each site. For the strain gauge at the apex of the "U", the negative direction for the bending moment was pointing inwards (b) as was the negative direction for the bending moments at the base of the wings (c).

after creation of a defect and after implantation. The defect was composed of a bilateral hemifacetectomy with resection of the flaval ligaments to simulate instability similar to that caused by decompression surgery. Additionally, the inter- and supraspinous ligaments had to be resected before insertion. Implantation was performed as recommended by the manufacturer.

For the flexibility tests, the specimens were fixed in a spine tester (Wilke et al., 1994). The cranial vertebra was loaded with pure moments of ±7.5 N m in flexion/extension, right/left lateral bending and left/right axial rotation. Simultaneously, the rotary movements of the segment were recorded, and the signal from the strain gauges was collected. Since this experiment was meant to investigate how Coflex rivet behaves compared to the original implant under well known and standardised loading conditions, it was carried out as recommended for spinal implant testing (Wilke et al., 1998), i.e. pure bending moments were used, no axial preload was applied and the specimens were allowed to move unconstrained in the five uncontrolled degrees of freedom.

From the resulting load-deformation curves, range of motion (RoM) was determined at maximum load. Also, the bending moments acting on the implants were evaluated at maximum load. Since lateral bending and axial rotation showed a symmetrical behaviour to both sides, only the positive loading direction will be reported.

The statistical evaluation was focused on comparisons between the two implant groups (Wilcoxon rank sum test) and within each implant group (Wilcoxon signed rank test) for both, Range of motion and implant loading.

3. Results

Compared to the defect condition both implants had a strong stabilising effect in extension ($P < 0.05$) (Fig. 3). In this loading direction, the median RoM decreased from −4.7° with the defect to −1.4° with Coflex rivet and from −4.5° to −1.9° with the original Coflex implant. Coflex rivet also strongly stabilised in flexion ($P < 0.05$) (Fig. 4)

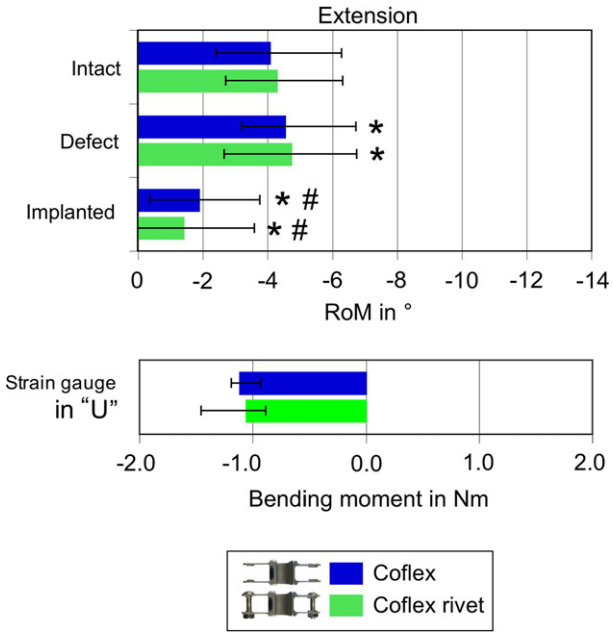

Fig. 3. Upper graph: range of motion (RoM) during extension loading with −7.5 N m in the intact condition after creation of the defect (bilateral hemifacetectomy) and after insertion of either the original Coflex implant (dark bars) or Coflex rivet (light bars). Lower graph: Bending moment at the apex of the "U" in both implant groups. Median with minimum and maximum. $^{*}P < 0.05$ compared to the intact condition within each implant group; $^{\#}P < 0.05$ compared to the defect condition within each implant group. Between the two implant groups all P-values were >0.05.

and was able to compensate the destabilising effect of the defect in axial rotation and lateral bending ($P < 0.05$) (Figs. 5 and 6). However, in these two loading directions, the RoM after implantation was still 2.8° and 4.2°, respectively, compared to 4.1° and 5.3°, respectively in the defect state.

In contrast to Coflex rivet, the original Coflex implant was not able to compensate the effect of destabilisation in the three loading directions flexion, axial rotation and lateral bending ($P > 0.05$). Yet, the difference between the two implant types was not significant (Fig. 4).

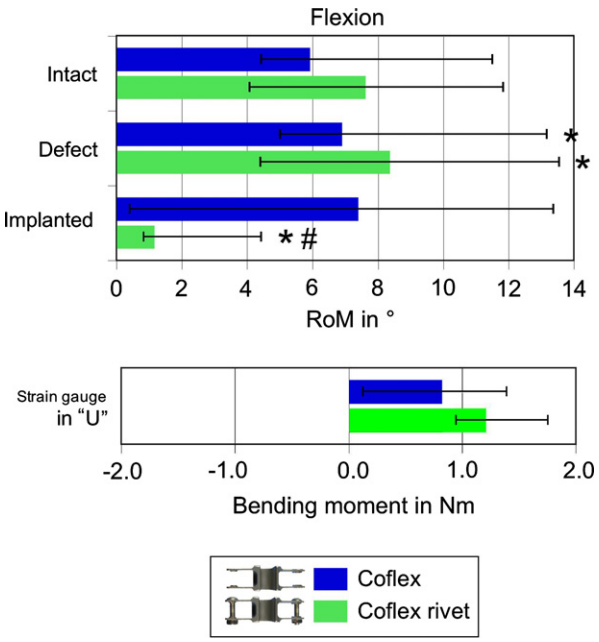

Fig. 4. Upper graph: range of motion (RoM) during flexion loading with 7.5 N m in the intact condition after creation of the defect (bilateral hemifacetectomy) and after insertion of either the original Coflex implant (dark bars) or Coflex rivet (light bars). Lower graph: bending moment at the apex of the "U" in both implant groups. Median with minimum and maximum. $^{*}P < 0.05$ compared to the intact condition within each implant group; $^{\#}P < 0.05$ compared to the defect condition within each implant group. Between the two implant groups all P-values were >0.05.

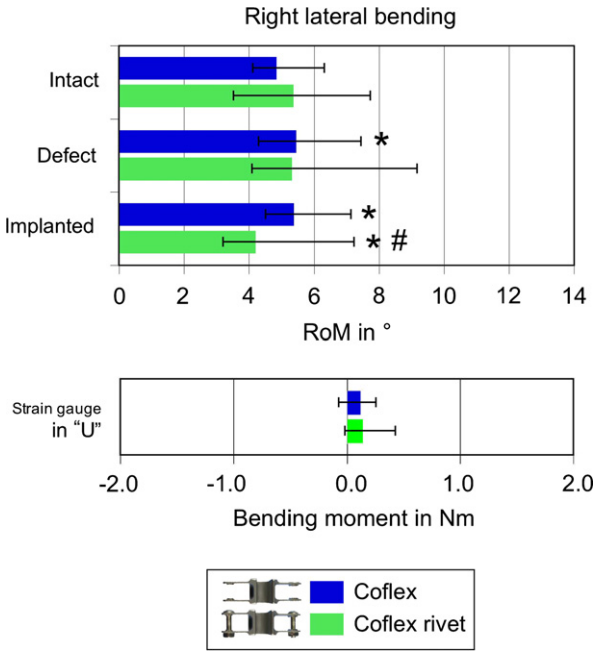

Fig. 5. Upper graph: range of motion (RoM) during lateral bending loading with 7.5 N m in the intact condition after creation of the defect (bilateral hemifacetectomy) and after insertion of either the original Coflex implant (dark bars) or Coflex rivet (light bars). Lower graph: bending moment at the apex of the "U" in both implant groups. Median with minimum and maximum. $^{*}P < 0.05$ compared to the intact condition within each implant group; $^{\#}P < 0.05$ compared to the defect condition within each implant group. Between the two implant groups all P-values were >0.05.

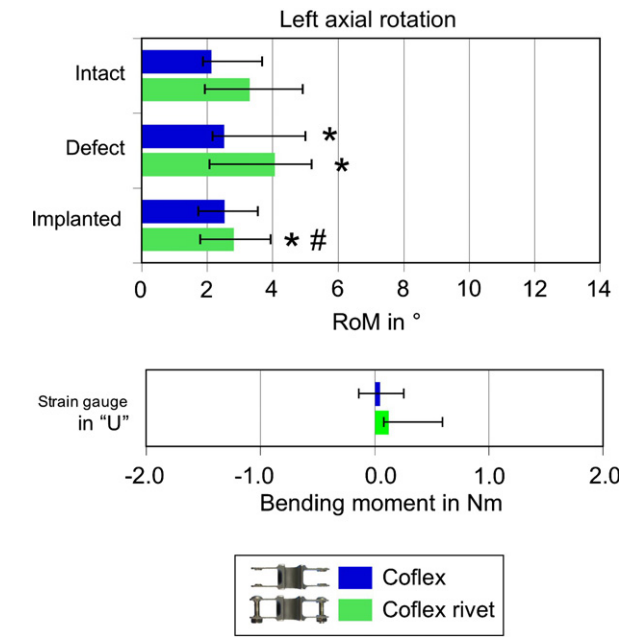

Fig. 6. Upper graph: range of motion (RoM) during axial rotation loading with 7.5 N m in the intact condition after creation of the defect (bilateral hemifacetectomy) and after insertion of either the original Coflex implant (dark bars) or Coflex rivet (light bars). Lower graph: Bending moment at the apex of the "U" in both implant groups. Median with minimum and maximum. $^{*}P < 0.05$ compared to the intact condition within each implant group; $^{\#}P < 0.05$ compared to the defect condition within each implant group. Between the two implant groups all P-values were >0.05.

The strain gauge measurements could successfully be carried out in five out of the six specimens in each of the two groups. The results showed that the bending moments acting at the apex of the "U" tended to be larger for Coflex rivet than for the original Coflex implant in flexion, lateral bending and axial rotation. The largest difference was found in flexion (Figs. 3–6). This is well in accordance with the differences in RoM between the two implant types. In both groups the bending moments at the apex of the "U" were larger in flexion and extension than in lateral bending and axial rotation. But even in flexion and extension the values were no more than 1.2 N m in median, which is only about one sixth of the bending moment, which was applied.

The bending moments acting at the base of the wings were small and similar in both implant groups. The largest values were measured in lateral bending with up to 0.23 N m in median.

4. Discussion

In this study a new version of the Coflex interspinous implant, called Coflex rivet, was tested for flexibility and load transfer and compared to the original Coflex implant. The aim was to evaluate whether Coflex rivet is able to prevent instability also in axial rotation and lateral bending while still allowing the intervertebral disc to transmit some load.

Coflex rivet only differed from the original Coflex implant in the way it was attached to the spinous processes. Screws were drilled from right to left through the wings and acted as rivets. This fixation requires a sufficient strength of the spinous processes, which can probably not be guaranteed in severe osteoporosis. Also the size of the spinous processes plays a crucial role. Mainly the vertebra L5 with its relatively small spinous process may therefore be prone to fracture.

The additional fixation of the Coflex rivet implant prevented the wings from slipping along the spinous processes as observed with the original Coflex implant, where the wings were only crimped to the spinous processes. Thus, crimping was less effective in preventing movements than the rivets. This was most obvious in flexion but also detectable in axial rotation and lateral bending. Also crimping was less reproducible, which is reflected by the large error bar for the original Coflex implant in flexion (Fig. 4). Only in extension, both versions of the Coflex implant behaved almost identical. They had both a strong stabilising effect compared to the intact and to the defect condition, which is well in accordance with data reported for other interspinous spacers such as X-Stop, Wallis and Diam (Fuchs et al., 2005; Lindsey et al., 2003; Wilke et al., 2007). These studies were carried out under application of pure bending moments. However, in some cases an additional axial preload was applied. Nevertheless, they all showed similar results. Whether these results would be the same or at least similar under real physiological loading is still unknown. However, it is suspected that the application of pure moments in vitro produces loading conditions, which are similar to those in vivo if the tested segment does not show any significant anterior instability (Wilke et al., 2001).

The strain gauge measurements were carried out to get a rough idea of how much load is transferred through the implant and how much might still act on anatomical structures such as the intervertebral disc. The results showed that the loads transferred through the implant tended to be higher for Coflex rivet than for the original Coflex implant. However, even for Coflex rivet the bending moments did not exceed 1.2 N m in median. Therefore, presumably, most of the load still acted on the intervertebral disc, while the facet joints became unloaded due to posterior distraction caused by implantation (Fuchs et al., 2005; Lindsey et al., 2003; Wilke et al., 2007). This finding and data interpretation is supported by in vitro intradiscal pressure measurements, which showed that after implantation the disc remains almost physiologically loaded in all loading planes except for extension (Swanson et al., 2003; Wilke et al., 2007).

In the present study the load transfer through the intervertebral disc was estimated based on the load acting on the implant but not on intradiscal pressure measurements, since pressure measurements are limited to discs which are not or only mildly degenerated. In more severely degenerated discs the pressure within the nucleus is no more hydrostatic and, thus, the results become uninterpretable. Therefore, in the literature, the intradiscal pressure is often only reported for representative non-degenerated specimens (Wilke et al., 2007), which makes statistical evaluations impossible. In contrast, measurements of the load transferred through the implant is possible irrespectively of the degree of disc degeneration. Furthermore, such measurements can be used to adapt the implant's dimensions to the load it has to bear.

In summary, the findings of the present study showed that the stability of the treated segment can be increased if the anchorage of the interspinous spacer to the spinous processes is improved mainly in flexion but to a smaller degree also in lateral bending and axial rotation. At the same time, despite of this increase in stability, the intervertebral disc was still allowed to transmit some load. These biomechanical characteristics are helpful to prevent or compensate instability. Yet, they are also required for implants used as an adjunct to fusion, which would be a completely new indication for interspinous spacers.

Interbody fusion is still one of the most commonly used surgical procedures to treat severe intervertebral disc degeneration. The intervertebral disc is removed and, in most cases, replaced by interbody fusion cages (Zdeblick and Phillips, 2003). If implanted ''stand alone'', such cages tend to destabilise the treated segment mainly in extension and axial rotation (Harris et al., 2004; Kettler et al., 2005; Lund et al., 1998; Oxland and Lund, 2000; Rathonyi et al., 1998). This lack of stability is made responsible for the high non-union rates associated with this procedure (Lee et al., 2004). Additional posterior or anterior instrumentation with pedicle screw systems, translaminar screws or plates is often used to improve stability. Such instrumentation was shown to provide a significant stabilising effect (Harris et al., 2004; Le Huec et al., 2002; Lund et al., 1998; Niemeyer et al., 2006; Rathonyi et al., 1998). Implantation of pedicle screw systems or plates, however, is an invasive procedure, which generally requires large surgical approaches. Instead, much smaller approaches are required to implant interspinous spacers. However, as mentioned above, as an adjunct to fusion, they would need to increase stability in extension and rotation. As to extension, interspinous spacers generally seem to fulfil this requirement (Fuchs et al., 2005; Lindsey et al., 2003; Wilke et al., 2007). In contrast, in axial rotation, the stability only increased using Coflex rivet. However, it was still several degrees in magnitude.

Despite of this increase of the segmental stability using Coflex rivet, some load was still transferred through the disc, which would help to prevent stress shielding and, thus, would be beneficial for the formation of new bone in the intervertebral space.

A possible disadvantage of interspinous spacers could be their effect on the alignment of the spine since they tend to cause a kyphotic deformation (Fuchs et al., 2005; Wilke et al., 2007). The magnitude of this kyphosis depends on the type of implant (Wilke et al., 2007), the size of the defect (bilateral versus unilateral and medial versus total

facetectomy) (Fuchs et al., 2005) and probably also on the size of the implant and the way it is implanted. In cases where nerve roots or other posterior structures need to be decompressed, a slightly kyphotic alignment could be beneficial. However, if the kyphosis becomes too large it could have adverse effects on the overall alignment and the loading of the adjacent levels. Therefore, especially in combination with posterior lumbar interbody fusion, care should be taken not to create a too strong kyphotic alignment.

5. Conclusions

In conclusion, the new Coflex rivet interspinous spacer was able to compensate the destabilising effect of the defect in all loading directions. At the same time, there seems to be still enough load transferred through the intervertebral disc to keep it viable. Coflex rivet might therefore become an option if additional stability is needed. The findings of this study also indicate that an interspinous spacer such as Coflex rivet might even become useful as an adjunct to interbody fusion, which would be a new indication for this type of implant. However, for this purpose some more modifications will be necessary especially concerning the implant's stabilising effect in axial rotation. Also the screws and nuts used as rivets so far should be replaced by rivets, which are easily and safely implantable also in the clinical setting. Re-evaluation would then be necessary also compared to conventional fusion instrumentation and under cyclic loading with respect to spinous process fracture and implant loosening.

Conflict of interest statement

The authors have received or will receive benefits for professional use from a commercial party related directly or indirectly to the subject of this manuscript. Benefits have been or will be directed to a research fund, foundation, educational institution, or other nonprofit organization with which one or more of the authors are associated.

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