Development of percutaneously insertable/removable interspinous process spacer for treatment of posture-dependent lumbar spinal-canal stenosis: preclinical feasibility study using porcine model

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Abstract

Purpose A procedure using an interspinous process spacer (IPS) was recently developed for the treatment of posture-dependent lumbar spinal-canal stenosis (LSS) patients. We developed a novel IPS which can be inserted with simpler procedures and removed percutaneously. The objectives of this study were: (1) to evaluate the feasibility and safety of this novel technique, and (2) to assess the effectiveness of this spacer in terms of preventing an increase of epidural pressure in lumbar extension using a porcine model.

Methods Eight young pigs were used. Under general anesthesia and image guidance, the spacers were inserted. Three months after operation, MR images were taken and all spacers were removed. Blood samples were obtained before and 1, 3, 7 days after surgery. After killing the animals, the lumbar spines were observed macroscopically. Another six animals were used. Under general anesthesia and image guidance, a flexible pressure transducer was inserted into the epidural space and epidural pressure was measured in neutral and at maximum extension with and without spacer insertion.

Results Percutaneous insertion and removal of the spacer was successful for all animals through small skin incisions. MR images showed minimal damage to the muscle.

No significant up-regulation of Interleukin-6 (IL-6) and CRP was detected. Macroscopic observation of the lumbar spine 3 months after the operation revealed that the area of the interspinous process contacting with the inserted spacer showed some bone erosion/remodeling. Insertion of the spacer did not affect the epidural pressure in neutral but significantly prevented an increase of epidural pressure in lumbar extension.

Conclusions This study demonstrated that the percutaneous insertion and removal of a novel IPS was feasible and safe using a simple technique. Furthermore, this procedure can be recognized as minimally invasive surgery from the viewpoint of skin incision, short insertion track, inflammatory mediators, and muscle damage. Improvements should be attempted in future studies using softer or more elastic materials for the spacer to lessen bone erosion/remodeling at contacting area of the inserted spacer.

Keywords Lumbar spinal-canal stenosis · Minimally invasive surgery · Interspinous process spacer · Big animal study · Epidural pressure

Introduction

Lumbar spinal-canal stenosis (LSS) and associated neurological symptoms are among the most common spinal disorders in the elderly population. It is well known that most of the symptoms associated with LSS are posture dependent. Usually flexion of the lumbar spine minimizes, and extension maximizes or provokes neurological symptoms. A number of authors reported a decrease of the axial spinal canal area as well as intervertebral foramen in lumbar extension due to bulging of the disc and thickening of the ligament flavum in both in vitro and in vivo

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studies [3, 4, 8]. Takahashi et al. [15, 16] reported the importance of increased epidural pressure in provoking neurological symptoms in LSS. According to their report, the epidural pressure at the stenotic level in patients with LSS was changeable with posture. The highest pressure was measured during standing with extension, while the pressure with flexion was one-fourth of that with extension. In addition, the changes in epidural pressure correlated with the occurrence of neurological symptoms. These reports clearly revealed that part of the patho-mechanism of LSS is posture dependent.

When conservative treatment is not effective, surgical decompression of nerve tissue with or without spinal fusion is usually indicated [6]. Recently, a procedure using an interspinous process spacer (IPS) has also been developed to maintain segmental flexion or prevent extension of the lumbar spine with relatively less invasion [2, 9, 17, 18], and acceptable clinical outcomes for posture-dependent LSS using this method have been reported [10, 13, 17, 19]. However, inserting IPS mostly requires open surgery including a relatively large skin incision as well as detaching muscle from bone. More recently, a few percutaneously insertable IPSs have been developed, however, inserting methods still require relatively complicated procedures. Therefore, the development of a less invasive technique such as percutaneous insertion via a small skin incision using simpler procedure is desirable. Additional problem of this technique is that the revision rate is relatively high. Follow up studies have revealed a 6–20% revision rate that has required decompressive surgery [2, 9, 10, 13, 19]. However when revision surgery for the implanted IPS is required, usually destructive procedures including cutting ligaments or bone are inevitable to remove it. Accordingly, if we need to replace the implant with one of a bigger or smaller size or remove it, a less invasive procedure is also desirable. Therefore, we developed a novel IPS, which can be inserted and removed percutaneously via a small skin incision using a simple procedure.

After the completion of technical developments using human cadaver [12], the current study was conducted. The objectives of this study were: (1) to evaluate the feasibility and safety of this novel system and technique, (2) to assess the effectiveness of this spacer in terms of preventing an increase of epidural pressure in lumbar extension using a big animal model.

Materials and methods

Principal design/concept of the implant and insertion/removal system

The implant (current prototype) was made by titanium alloy (Kinoshita-giken Corporation, Japan). The principal

concept of the implant is a combination of interference screw and interspinous process spacer, which can be inserted percutaneously. For this purpose, the outer contour of the entire shape of the implant is elongated in an ellipse or spindlic shape. The implant is basically composed of three sections: interference screw, spacer, and head (Fig. 1). The interference screw section is designed to gradually enlarge the interspinous interval by screwing into the interspinous space. The diameter of the spacer section is a little smaller than the largest interference screw section and the head section. The implant has a pass-through hole formed in the shaft to insert the guide-wire. The head section has a hexagonal hole which can be attached with a hexagonal driver.

Feasibility and safety assessment of percutaneous insertable/removable interspinous spacer

A young porcine model (3-month-old, female, LWD) was selected due to its relative similarity in size in spinous processes to adult human beings [1], especially in the upper level of the lumbar spine such as L1-2 and 2-3. A total of 14 animals were used for this current study. All animal procedures were performed under the guidance and approval of the Animal Experiment Committee at Intervention Technical Center (Kobe, Japan).

Percutaneous implant insertion procedure

Eight animals were used for the feasibility and safety evaluation. Under general anesthesia and image guidance, approximately 8 cm laterally from the midline, a small skin incision (approximately 15 mm) was made and a guide-

Fig. 1 Overview of the implant: the outer contour of the entire shape of the implant is elongated in an ellipse or spindle shape. The implant has to pass through a hole formed in the shaft to insert the guide-wire. The implant is basically composed of three sections: interference screw, spacer, and head. The head section has a hexagonal hole, which can be attached with a hexagonal driver. The major axis of the implant is approximately 5 cm

wire was inserted into the targeted inter-spinous space. When the tip of the guide-wire passed over the contralateral side facet joint, insertion of the guide wire was stopped. Then the implant was inserted through the guide-wire using a multi-axial screw driver. When the interference screw section of the spacer was inserted between the spinous processes, the guide-wire was removed and screwing torque was applied to the implant, thereby gradually enlarging the interval between the spinous processes. When the interference screw portion passed between the spinous processes, the spacer section was pinched between them due to the elasticity of the inter/supra spinous ligaments and thus stabilized. After adjustment of the implant orientation, the multi-axial driver was removed and a skin suture was applied (Fig. 2). Antibiotics were supplied to the animals immediately after the operation.

Percutaneous implant removal procedure

Three month after implant insertion surgery, the same animals were used for implant removal surgery. Again under general anesthesia and image guidance, the same small skin incision used for implant insertion was made and a multi-axial driver designed for spacer removal was inserted into the hexagonal hole of the head section of the implant to adjust alignment. Then a guide-wire was inserted by passing it through the hole formed in the shaft center of the driver. The multi-axial driver was removed and the mono-axial driver designed for spacer removal was inserted, then the guide-wire was replaced with the

threaded guide pin with a stopper designed to fix the spacer and driver. Finally, reverse screwing torque was applied to the spacer via the driver and removed from the interspinous space and subsequently removed from the body (Fig. 3).

Safety assessment

The condition of the animals was checked daily after surgery, especially for neurological symptoms such as limping, paralysis or any abnormal behavior. Before and 1, 3, 7 days after surgery, blood samples were harvested and white blood cells (WBC), Interleukin-6 (IL-6), C-reactive protein (CRP) were measured (Mitsubishi Chemical Medience, Kobe, Japan). Before and right after surgery, plane lateral radiographs (neutral, flexion and extension), T2-weighted (repletion time 3,500 ms/echo time 116 ms; field of view $26 \times 26 \text{ cm}^2$; slice thickness 3 mm) sagittal and axial MRIs (Signa EXCITE TwinSpeed 1.5T Ver.11, GE Healthcare, Milwaukee, WI, USA) were taken and damage of muscle, nerve (spinal cord) and other soft tissues was evaluated. Three months after operation, MR images were taken and the same evaluation was performed again. After killing the animals, the lumbar spines were harvested and soft tissues were removed. The lumbar spines were observed macroscopically, especially at the spacer insertion segment.

Effect of the spacer insertion on epidural pressure

A total of six animals and ten segments (L1-2: $n = 6$, L2-3: $n = 4$) were used in this study. Under general anesthesia

Fig. 2 Percutaneous implant insertion procedure. **a-1** Approximately 8 cm laterally from the midline, a small skin incision was made and a guide-wire inserted into the targeted inter-spinous space. **a-2** The implant was inserted through the guide-wire using a multi-axial screw driver. When the interference screw section of the spacer was inserted between the spinous processes, the guide-wire was removed and

screwing torque was applied to the implant. **a-3** When the interference screw section passed between the spinous processes, the spacer section was pinched between them and stabilized. After adjustment of the implant orientation (if needed), the multi-axial driver was removed and a skin suture was applied. **b, c** X-ray images after insertion of the spacer (**b** anteroposterior and **c** lateral views)

Fig. 3 Percutaneous implant removal procedure. **a** A multi-axial driver was inserted via small skin incision into the hexagonal hole of the head section of the implant and alignment adjusted and a guide-wire inserted by passing it through the hole formed in the shaft center of the driver. **b** The multi-axial driver was replaced with the mono-axial driver designed for spacer removal. **c, d** The guide-wire was replaced with the threaded guide pin with a stopper designed to fix the spacer and driver. **e** Reverse screwing torque was applied to the spacer and removed from the interspinous space. **f** Subsequently the spacer was removed from the body. **g** Multi-axial screw driver (upper), mono-axial screw driver (lower). **h** Mono-axial screw driver (upper), threaded guide pin with a stopper (lower)

and image guidance, a flexible pressure transducer (ICP monitoring system, Codman, USA) was inserted into the epidural space at the targeted disc level (supposed to insert the spacer) and fixed by skin suture. Epidural pressure was measured in neutral and maximum extension of the lumbar spine (no spacer group). The maximum extension was achieved by manually compressing the upper lumbar region from the posterior. Then the spacer was inserted into the same interspinous space percutaneously and epidural pressure was recorded in the same manner (spacer insertion group). Finally, the spacer was percutaneously removed and the pressure was recorded again (spacer

removal group). The measurement was performed three-times each and the average in triplicate was used for analysis.

Statistical analysis

The differences in the epidural pressures between before and after insertion of the spacer, before and after removal of the spacer, as well as before insertion of the spacer and after removal were statistically analyzed with the Wilcoxon's signed rank test. $P < 0.05$ was considered statistically significant.

Results

Percutaneous implant insertion/removal procedure

Percutaneous insertion of the spacer was possible for all animals via small skin incision under image guidance. All animals recovered well and no obvious neurological deficits or abnormal behavior were observed throughout the follow-up period. One superficial infection at the wound was observed but healed without major problem. Three months after surgery, no dislodgment of the inserted spacer or fracture of the spinous process was observed. Percutaneous removal of the inserted implant via the same small skin incision was also possible for all implants without major problems.

Safety assessment

T2-weighted axial MR image evaluation showed that immediately after surgery, a high-intensity line could be seen at the implant insertion track. However 3 months after operation, these high-intensity lines were not detected and a minor high-intensity area was observed in the fascia area (Fig. 4). No detectable nerve tissue damage was observed. Although there was no control group, our results demonstrated an increase of WBC up to two-times compared with pre-surgery. However, we could not detect any significant up-regulation of IL-6 or CRP (data not shown). Macroscopic observation of the lumbar spine 3 months after the operation revealed that the area of the interspinous process contacting with the inserted spacer showed bone erosion/remodeling, which could potentially lessen the effect of enlargement of the interspinous interval (Fig. 5).

Effect of the spacer insertion on epidural pressure (Fig. 6)

There were no significant differences between L1-2 and L2-3 in terms of epidural pressure (data not shown) in

Fig. 4 Representative T2-weighted axial MR images after insertion of the implant. *Upper*: MRI immediately after surgery. A high-intensity line was observed in the muscle at the implant insertion track (*big arrows*). *Lower*: MRI 3 month after surgery. The high-intensity lines were not detected but a minor high-intensity area was observed in the fascia area (*small arrows*)

Fig. 5 Representative picture of bone erosion/remodeling, which observed at the area of the interspinous process contacting with the inserted spacer. Macroscopic observation of the lumbar spine 3 months after the operation revealed that some area of the interspinous process contacting with the inserted spacer showed bone erosion/remodeling

neutral lumbar position. The average epidural pressure in neutral position was 6.5 ± 1.2 mmHg in the no spacer group (before insertion), 6.3 ± 1.3 mmHg in the spacer insertion group, and 6.5 ± 1.6 mmHg in the spacer removal group. There were no significant differences among each group. Epidural pressure obviously increased in lumbar extension up to 12.0 ± 1.4 , 9.4 ± 1.3 , and 11.7 ± 1.7 mmHg,

Fig. 6 Lumbar epidural pressure with or without spacer insertion. Epidural pressure obviously increased with a 1.85-folds in lumbar extension compared with neutral position. Insertion of the spacer did not affect the epidural pressure in neutral, but significantly prevented an increase of epidural pressure only with a 1.49-folds in lumbar extension (* $P < 0.05$). After removal of the inserted implant, the effect of preventing an increase in epidural pressure was lost (** $P < 0.05$)

respectively. Although insertion of the spacer did not affect the epidural pressure in neutral, it significantly prevented an increase of epidural pressure in lumbar extension ($P < 0.05$). After removal of the inserted implant, the effect of preventing increases in epidural pressure was lost and there was no significant difference between the no spacer group and the spacer removal group.

Discussion

Surgical treatment for LSS has mainly aimed at decompressing nerve tissues with or without segmental fusion. Recently, progress has been made in minimizing the surgical approach using, for example, microscope or endoscope [5, 7, 14]. Another approach has been to insert an IPS to maintain segmental flexion or prevent extension, thereby indirectly decompressing nerve tissues. The use of various IPSs has been reported with acceptable clinical outcomes [2, 9, 10, 13, 19]. However, most currently available IPSs require open surgery which includes detaching muscles from bone or cutting ligaments. Therefore, some surgeons believe these procedures do not provide significant benefits over decompression surgery using minimally invasive approaches. In contrast, the insertion of IPSs can indirectly decompress the nerves by maintaining flexion or preventing extension of the lumbar spine, and therefore, exposure of the dural tube or nerve roots is not required, meaning adhesion to the surrounding tissues can be minimized after surgery. Since adhesion of the nerve tissue obviously increases the risks of nerve damage during surgical procedures, this is a significant advantage of IPSs over

decompressive surgery. Accordingly, the technique of inserting an IPS with reduced invasion such as by percutaneous technique is an attractive option for treatment of patients suffering from posture-dependent LSS symptoms. Recently, a few percutaneously insertable IPSs have been developed, however, insertion procedures still require relatively complicated procedures including sequential insertion of dilators (small to large) to enlarge the interspinous space and stabilize the inserted implant.

For successful percutaneous insertion of an IPS at the targeted interspinous space, at least two different steps are inevitable. In the step one, the targeted interspinous process space is percutaneously enlarged, and in the step two, the spacer is inserted into the enlarged interspinous space and stabilized using a percutaneous technique. To simplify these complicated procedures, we combined the interference screw and interspinous spacer. The interference screw was originally reported to fix bone-tendon-bone (BTB) graft to the tibia or femur in the reconstruction procedure of the anterior cruciate ligament of the knee [11]. Insertion of the interference screw between the inner surface of the bony hole made on the tibia or femur and the inserted bone parts of the BTB graft resulted in fixing the BTB graft to the tibia or femur. In this fixing process, the expansive force produced by inserting an interference screw is altered into a graft compressive force against the inner surface of the bony hole, resulting in fixation of the graft. We utilized this expansive force by inserting an interference screw for gradually enlarging the interval between the adjacent interspinous processes. The results of the current study successfully demonstrated that the interspinous interval was gradually enlarged by screwing the interference screw

section of the implant into the interspinous space. Furthermore, a combination of interference screw and interspinous process spacer enabled us to insert our implant between targeted interspinous processes in a continuous, simple and quick procedure without using sequential dilators or adding stabilizing procedures.

An additional advantage of this system is the short insertion track from skin surface. If we hope to avoid or minimize supra- or interspinous ligaments destruction, the implants must be inserted laterally. However, insertion laterally to the interspinous space requires a relatively long track from the skin surface in a percutaneous approach (Fig. 7). In our system, the implant has generally entire elliptical shape and the multi-axial screw-driver is used for percutaneous insertion procedure. Due to the entirely elliptical shape, when the apex of the interference screw section comes into contact with the contra-lateral side of the facet joint or bony structure, the implant changes the orientation to a less resistant direction resulting in the achievement of an appropriate orientation. These mechanisms make it possible for a percutaneous straight insertion from obliquely lateral to the interspinous space using a shorter access from the skin surface, leading to reduced invasion to the body (Fig. 7). The current study revealed that all procedures for inserting implants can be performed using a straight oblique track via a small size skin incision without detaching muscles from bone or cutting ligaments. In addition, up-regulation of IL-6 and CRP after operation was not observed and MR images showed that muscle damage due to the surgical procedure is also minimal. These results clearly reveal our technique can be performed with a significantly smaller invasion to the body.

Fig. 7 Mechanism for the shortest insertion track. Due to the elliptical shape of the implant, when the apex of the interference screw portion comes into contact with the contra-lateral side of the facet joint, the implant changes the orientation in a less resistant direction resulting in appropriate orientation

Fig. 8 Proposed treatment strategy for LSS. Current IPSs require open surgery including cutting ligaments or bone for removal from body. Therefore, after removal of these spacers, the performance of decompression surgery with a minimally invasive approach is already impractical. In contrast, our spacer can be removed with a small skin

incision without cutting ligaments or bone. Accordingly, the placement of our method between conservative treatment and minimally invasive decompressive surgery (microscopic or endoscopic surgery) seems a reasonable strategy sequence for LSS treatment

As far as we can ascertain, there are currently no other available interspinous process spacers which can be removed from the body using percutaneous techniques. Although the clinical outcomes of the IPS technique are acceptable, one of the problems of this technique is that the revision rate is relatively high. Follow up studies have revealed a 6–20% revision rate that has required decompressive surgery [2, 9, 10, 13, 18]. However, the current type of IPSs require open surgery with cut ligaments or bone for removal meaning that after removal of these spacers, decompressive surgery with a minimally invasive approach such as microscopic or endoscopic decompression is already impractical. In contrast, the use of our method after conservative treatment but before minimally invasive decompressive surgery seems a reasonable strategy sequence for LSS treatment (Fig. 8). Firstly, our procedure is simple and quick with minimal invasion and secondly, when direct decompression surgery with or without segmental fusion after removal of the inserted IPS is required, it is still possible to perform this using a minimally invasive approach by removing the implanted spacer without making a major skin incision, or cutting ligaments or bone.

The limitations in the current study mainly occur due to the anatomical difference between animals and humans. The shape of the spinous processes are different, especially the spinous processes of the porcine lumbar spine are much thinner than that those of humans and therefore radiological evaluation using X-ray image is impracticable. Furthermore, because of the very thin spinous processes, the contact area between spacer and the spinous process is small, leading to larger mechanical stresses on the contacting bone surface with the result that potential bone erosion can easily occur around the spacer (Fig. 5). Improvements should be attempted in future studies, for

example, using softer or more elastic materials for the spacer. Furthermore in this current feasibility study, it is difficult to estimate the effects of clinical symptoms. As there is currently no larger animal model which can simulate the LSS condition, a true evaluation of the effect of spacer insertion on LSS, including advancements of this spacer comparing with currently available IPSs, remains unknown. However, our results clearly demonstrate that insertion of the interspinous spacer can affect postural change in epidural pressure. The fact that insertion can effectively prohibit the increase of epidural pressure in lumbar extension is the objective effect that directly correlates with clinical symptoms of LSS.

Conclusions

In conclusion, this study demonstrated that percutaneous insertion of a novel IPS was feasible and safe using a simple and quick technique. Furthermore, this procedure can be recognized as minimally invasive surgery from the viewpoint of skin incision, the short insertion track, inflammatory mediators such as CRP or IL-6, and muscle damage, and allows for percutaneous removal of the inserted implant if required. Future studies are required using a softer or more elastic material to reduce bone erosion on the contact surface of the spacer, and allow clinical trials targeting LSS patients so that its effectiveness for neurological symptoms can be evaluated. However, because insertion of the spacer can effectively inhibit an increase in epidural pressure in lumbar extension, this can be a considerable evidence that the use of our system can potentially reduce the symptoms associated with posture dependent LSS.

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Conflict of interest The authors do not report any conflict of interest concerning the materials or methods used in this study.

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