

Original Article

Which patients are suitable for interspinous dynamic stabilization: a retrospective case series

Chen-Jun Liu, Zhen-Qi Zhu, Kai-Feng Wang, Shuo Duan, Shuai Xu, Hai-Ying Liu

Department of Spinal Surgery, PeKing University People's Hospital, 11th. Xizhimen South Ave, Beijing 100044, China

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Abstract: Objective: The aim of this study is to find out the indications for interspinous dynamic stabilization (IDS) to avoid revision surgery. Methods: We reviewed patients whom underwent IDS (with Wallis or Coflex) in Peking University People's Hospital since March 2009 to May 2013, and included those who had revision surgery after IDS from December 2010 to May 2016. The preoperative and postoperative plain radiographs, computed tomography, or magnetic resonance imaging of the lumbar spine were obtained and analyzed. Results: Twelve patients were included, 10 males and 2 females, with a mean age of 57 years (range 26-77 years). The average interval between the first surgery and the revision surgery is 3.7 years. The accurate evaluation of the clinical and imaging parameters revealed several main causes of reoperation: inappropriate indications, adjacent segment degeneration (ASD), spinous process fracture/bone resorption, and chronic infection. Moreover, inappropriate indications contained severe lumbar stenosis, obvious segmental instability, scoliosis and severe osteoporosis. Conclusion: Patients with severe lumbar stenosis, obvious segmental instability, scoliosis and severe osteoporosis were not recommended for IDS with Wallis/Coflex. Surgeons need to notice possible problems with ASD, spinous process fracture, bone resorption and chronic infection after IDS.

Keywords: Interspinous dynamic stabilization, revision surgery, chronic infection, adjacent segment degeneration, spinous process fracture, bone resorption, topping-off

Introduction

The interspinous dynamic stabilization (IDS) is one of the dynamic spinal stabilization and is designed for the minimally invasive treatment for lumbar pain diseases. It could distract the adjacent spinous processes, unload the intervertebral disc, improve central canal and neuroforaminal stenosis, and limit lumbar flexion or extension without requiring fusion. The first interspinous device, the Wallis system (Abbott Spine), was developed in 1986 [1] and used in patients with recurrent disc herniation. The second generation of the Wallis implant, made of elastic polyetheretherketone (PEEK), has been shown to decrease pain severity in patients with mild to moderate disc degeneration, central spinal stenosis, and significant low back pain. This device has a central core that restricts the extension, while the tension bands that are secured to the spinous processes limit the flexion of the lumbar. Some of them are

mere spacers able to induce an indirect decompression of neurological structures (dural sac and nerve roots) by distracting the spinous processes, such as Coflex. In spite of the interspinous devices used singly after decompression, many patients are operated with posterior lumbar interbody fusion (PLIF) combined with IDS on the adjacent segment (the Topping-off surgery) in order to reduce the damage and delay adjacent segment degeneration (ASD). IDS had been recommended for mild lumbar stenosis, large disc or recurrent herniation, disc herniation, lower back pain for degenerative instability and adjacent disc degeneration after fusion [2]; however it's difficult to define a clinical indication for IDS [3].

Although some articles have mentioned the failure of IDS, as we know, there have been no papers discussing about clinical and radiographic indications for IDS. The aim of the present work is to find out indications for IDS

Inappropriate indications for interspinous dynamic stabilization

Table 1. Basic data of included patients

Patient number	Sex	Age (years)	Diagnosis	First surgery	Time interval (years)	Revision surgery	Causes for revision						
							ASD	CI	CI	OSI	S	SLS	SO
1	M	46	LSS + PID	L4/5 Wallis L5/S1 Coflex	1.8	L4-S1 PLIF						P	
2	M	42	LSS + PID	L3/4 Wallis	L4/5 PLIF	3.4	Removal of internal fixation + Wallis	P					
3	M	26	PID	L4/5 Wallis		L4/5 PLIF		P		P			
4	F	58	LSS + PID	L4/5 Wallis	L5/S1 PLIF	3	L3-S1 PLIF	P	P	P			P
5	M	58	PID	L3/4 Wallis	L4/5 PLIF	3.2	Removal of Wallis		P	P			
6	M	59	LSS + LDS	L3/4 Wallis	L4/5 PLIF	0.75	L3-5 PLIF		P		P		
7	M	53	LSS + PID	L4/5 Wallis	L5/S1 PLIF	4.7	Removal of internal fixation + Wallis		P	P			
8	M	55	LSS + PID	L3/4 Wallis	L4/5 PLIF	5.5	L3-S1 PLIF	P	P				
9	M	72	LSS	L3/4 Wallis	L4/5 PLIF	3.6	L3-S1 PLIF	P	P				
10	M	72	LSS	L3/4 Coflex	L4/5 PLIF	5.8	T11-S1 PLIF	P		P			P
11	F	71	LSS	L4/5 Wallis	L2-S1 PLIF	4.3	L2-S PLIF	P					P
12	M	77	LSS	L3/4 Wallis	L4-S1 PLIF	4.2	L3-S1 PLF	P					P

ASD: adjacent segment degeneration; BR: bone resorption; CI: chronic infection; LDS: lumbar degenerative scoliosis; LSS: lumbar spinal stenosis; PID: protrusion intervertebradisc; PLIF: posterior lumbar interbody fusion; OSI obvious segmental instability; S: scoliosis; SLS: severe lumbar stenosis; SO: Severe osteoporosis.

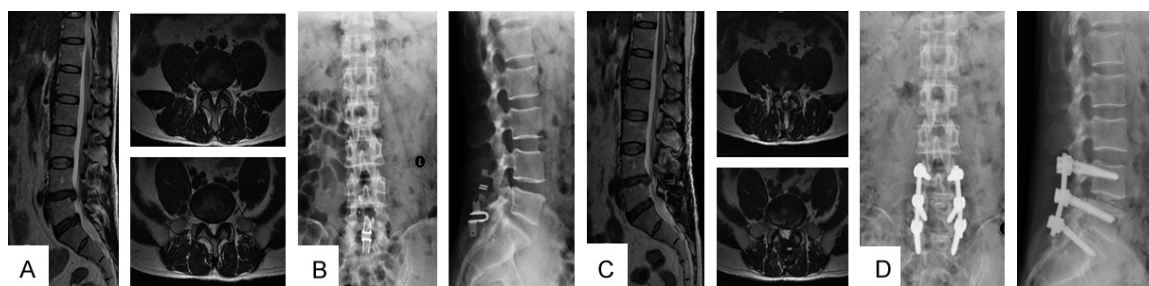


Figure 1. (case no. 1: a 46 year old male with low back pain and radiculopathy). A. Preoperative MRI showed L4/5 and L5/S1 severe stenosis. B. The first surgery: decompression, L4/5 Wallis and L5/S1 Coflex. C. 1.8 years later, low back pain with radiculopathy recurred. MRI showed recurrent L4/5 and L5/S1 lumbar stenosis. D. The revision surgery: L4-S1 PLIF.

through analyzing the causes of revision surgery of IDS with Wallis/Coflex in a series of 12 patients who received both first and revision surgery in spinal surgery department of Peking University People's Hospital from 2009 to 2016.

Materials and methods

We reviewed the patients who initially underwent IDS and then had revision surgery for various indications in the Peking University People's Hospital from March 2009 to May 2016. The indications of revision surgery were unimproved or recurrent lower back pain, radiculopathy after the device implantation, intermittent neurogenic claudication, and infection. All patients were evaluated with X-ray, MRI or CT scans before revision surgery. The following image features were considered: degree of bone resorption and position of the device with respect to the spinous process (X-rays), intervertebral disc disease of the adjacent levels (MRI), segmental instability (dynamic X-rays), and severity of canal stenosis (CT). All the included patients used second generation Wallis or Coflex for the IDS.

Results

Through the review, about 450 patients received IDS with Wallis or Coflex in our department since 2009 to 2013. Twelve of these patients had revision surgery, and the revision rate was 2.7%, which was much lower than previously reported. The series included 10 males and 2 females with a mean age of 57 years (range 26-77 years). The mean time interval between the first IDS surgery and the revision was 3.7 years.

The patients' clinical data are listed in **Table 1**. As to IDS surgery, ten patients underwent Topping-off surgery, while the other two had only decompression and implantation of Wallis/Coflex. Only Case 1 had IDS with Wallis and Coflex at the same time. Ten of the twelve patients had Wallis implantation, and only one patient had Coflex for IDS.

According to the symptoms for revision surgery, two patients had only lower back pain, two patients had lower back pain with radiculopathy and intermittent neurogenic claudication, five patients had lower back pain with radiculopathy, and three patients had lower back pain with intermittent neurogenic claudication. In the revision surgery, all interspinous devices were removed, and nine of the twelve patients had additional PLIF surgery. All the causes for revision were summarized in **Table 1**. The most common cause of revision surgery is bone resorption, and the second is ASD.

The analysis of our series was presented according to major causes of revision surgery: ASD, spinous process fracture/bone resorption and chronic infection. In some cases, more than one cause was recognizable as what is responsible for revision surgery (**Table 1**).

We analyzed the twelve patients according to the causes for treatment failure and revision surgery.

Severe lumbar stenosis (NO. 1)

The 46 years-old male had preoperative MRI which indicated severe lumbar stenosis and protrusion of intervertebral disc of L4/5 and L5/S1. Due the patient's strong willingness for

Inappropriate indications for interspinous dynamic stabilization

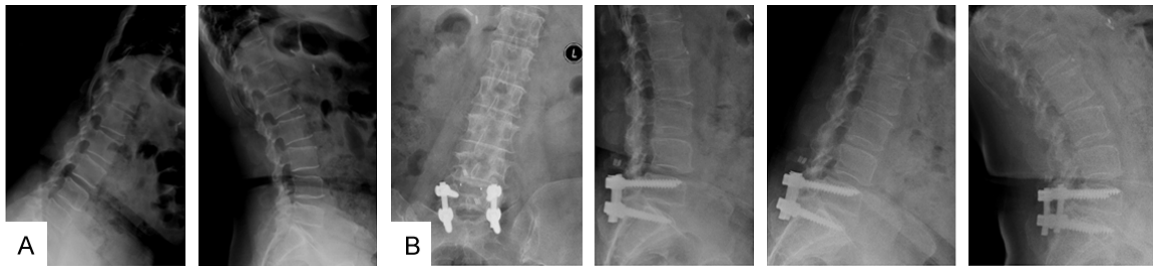


Figure 2. (case no. 4: a 58 year old female with low back pain). A. Preoperative dynamic X-rays indicated L4/5 obvious segmental instability. B. 3 years later, worse instability and degeneration of L3/4 and L4/5.

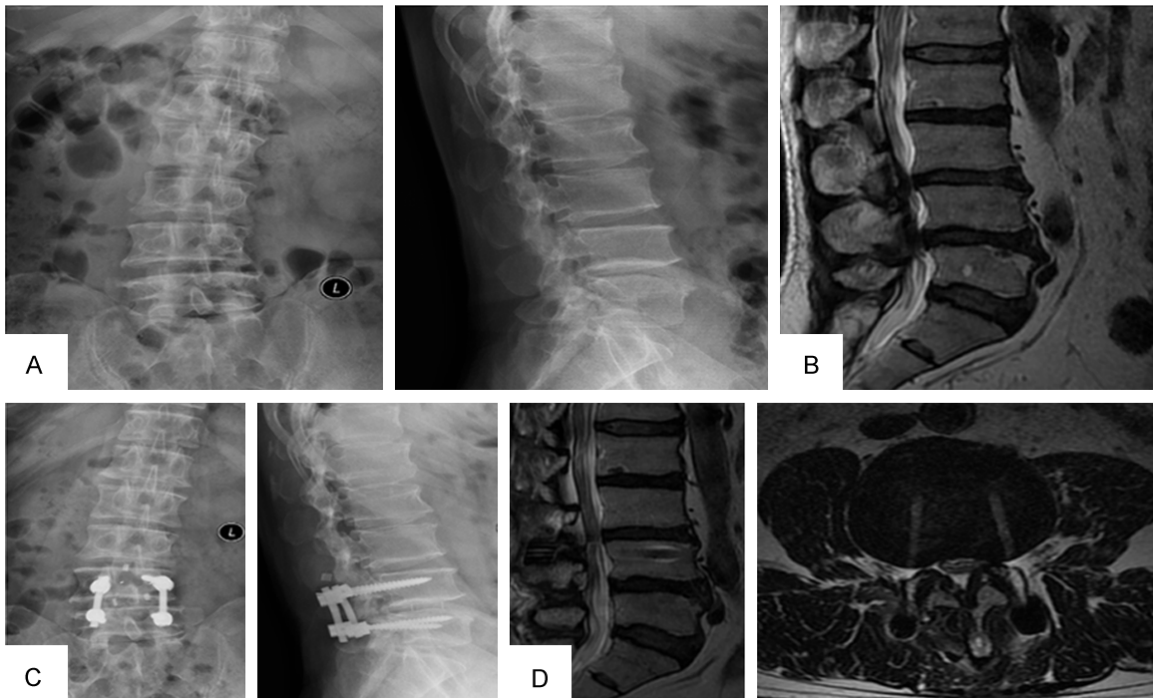


Figure 3. (case no. 6: a 59 year old male with low back pain and claudication). A. Preoperative X-rays showed lumbar degenerative scoliosis (Cobb' angle 17.9°). B. Preoperative MRI indicated L3/4 and L4/5 lumbar stenosis. C. The patient received L4/5 PLIF and L3/4 Wallis implantation. D. 9 months later, L3/4 lumbar stenosis caused symptoms again.

minimally invasive surgery, decompression and implantation of L4/5 Wallis and L5/S1 Coflex were accomplished. After 1.8 years, lower back pain with radiculopathy and intermittent neurogenic claudication forced him to receive the reoperation of L4-S1PLIF (**Figure 1**).

Obvious segmental instability (NO. 3, 4, 10)

Case NO. 4. The 58 years-old female had preoperative dynamic X-rays which showed L4/5 segmental instability. After three years of the Topping-off surgery, worse L4/5 instability

and degeneration, as well as severe osteoporosis and bone resorption were observed (**Figure 2**).

Scoliosis (No. 6)

The 59 years-old male was diagnosed degenerative scoliosis and lumbar stenosis through X-rays and MRI (Cobb angle 17.9°). The patient received L3/4 Wallis implantation and L4/5 PLIF; however progressive lower back pain and intermittent neurogenic claudication have recurred. The interspinous device was

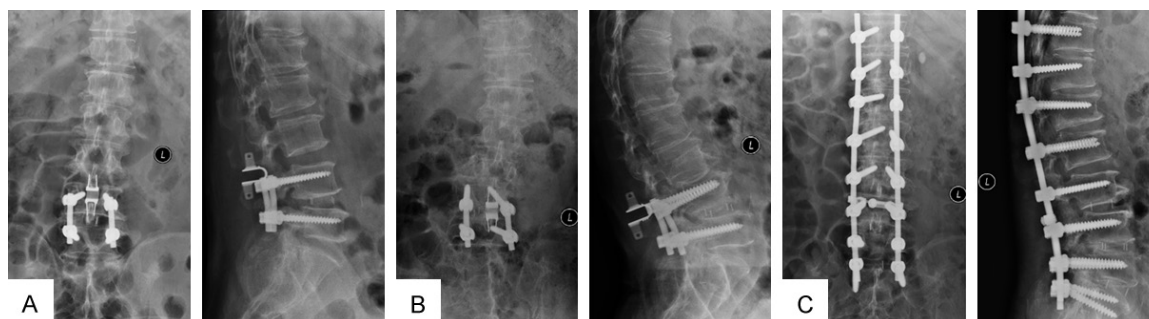


Figure 4. (case no. 10: a 72 year old male with low back pain). A. Severe osteoporosis was diagnosed, and the patient had the first surgery: L4/5 PLIF and L3/4 Coflex. B. 5.8 years later, serious coronal and sagittal imbalance happened. C. The revision surgery: T11-S1 PLIF.

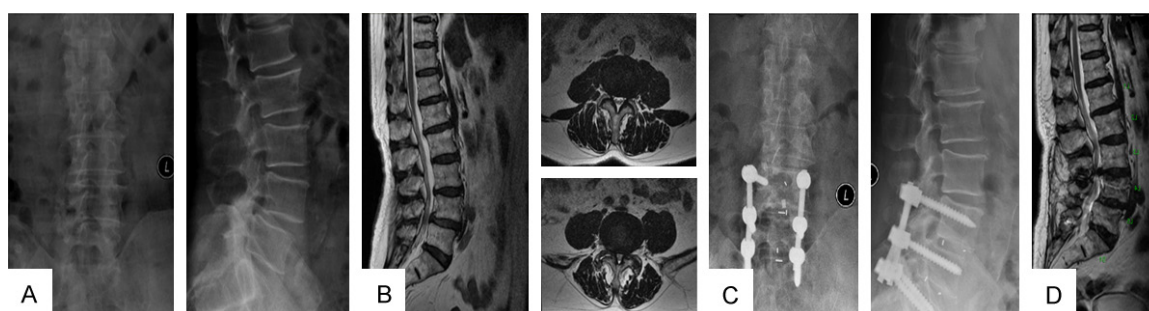


Figure 5. (case no. 12: a 77 year old male with low back pain). A and B. X-ray and MRI showed L4 spondylolisthesis and L4/5 and L5/S1 lumbar stenosis. C and D. 4.2 years after L4-S1 PLIF and L3/4 Wallis, L3/4 severe disc protrusion and lumbar stenosis happened.

removed; and eventually, L3-5 PLIF were performed. The symptoms have relieved after the revision surgery (**Figure 3**).

Severe osteoporosis (NO. 4, 10-12)

Case 10 is a 72 years-old male. He had L4/5 PLIF and L3/4 Coflex. 5.8 years after the IDS surgery, serious coronal and sagittal imbalance occurred, in which process severe osteoporosis played a crucial role. To regain the coronal and sagittal balance, T11-S1 PLIF was performed (**Figure 4**).

Adjacent segment degeneration (NO. 4, 8-12)

Case 12 is a 77 years-old male with L4-S1 PLIF and L3/4 Wallis implantation for lumbar stenosis and spondylolisthesis. However, Wallis couldn't delay ASD, and the L3/4 severe disc protrusion and stenosis led to revision surgery in 4.2 years (**Figure 5**).

Bone resorption (NO. 2-9)

Case 3 is a 26 years-old male whom underwent IDS surgery with decompression and

L4/5 Wallis implantation for protrusion of intervertebral disc. After 4.6 years, lower back pain and radiculopathy occurred, which resulted from obvious bone resorption and instability shown in imaging. The revision surgery was performed (**Figure 6**).

Chronic infection (NO. 5, 7)

Case 5 is a 58 years-old male. Surgical site infection occurred with abscess formation flowing into skin sinus 3.2 years after the IDS surgery. During the process of reoperation and debridement, it was observed that L4 spinous process disappeared with tissue necrosis. Removal of Wallis and strict debridement led to satisfactory recovery. The pathology reported inflammatory granulation tissue and abscess, as well as tissue necrosis (**Figure 7**).

Discussion

In our research, 12 patients had revision surgery for symptoms including lower back pain, radiculopathy and intermittent neurogenic claudication, which resulted from recurrent herni-

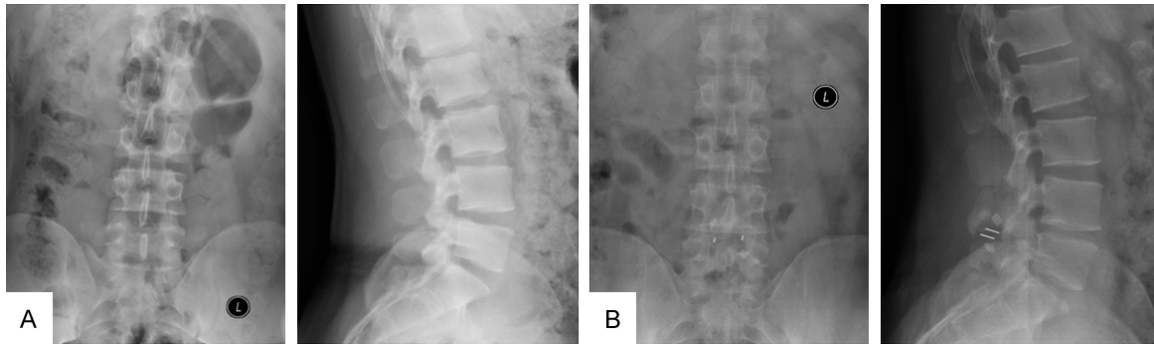


Figure 6. (case no. 3: a 26 year old male with protrusion of intervertebral disc). 4.6 years after L4/5 decompression and implantation of Wallis, obvious bone resorption and segmental instability happened.

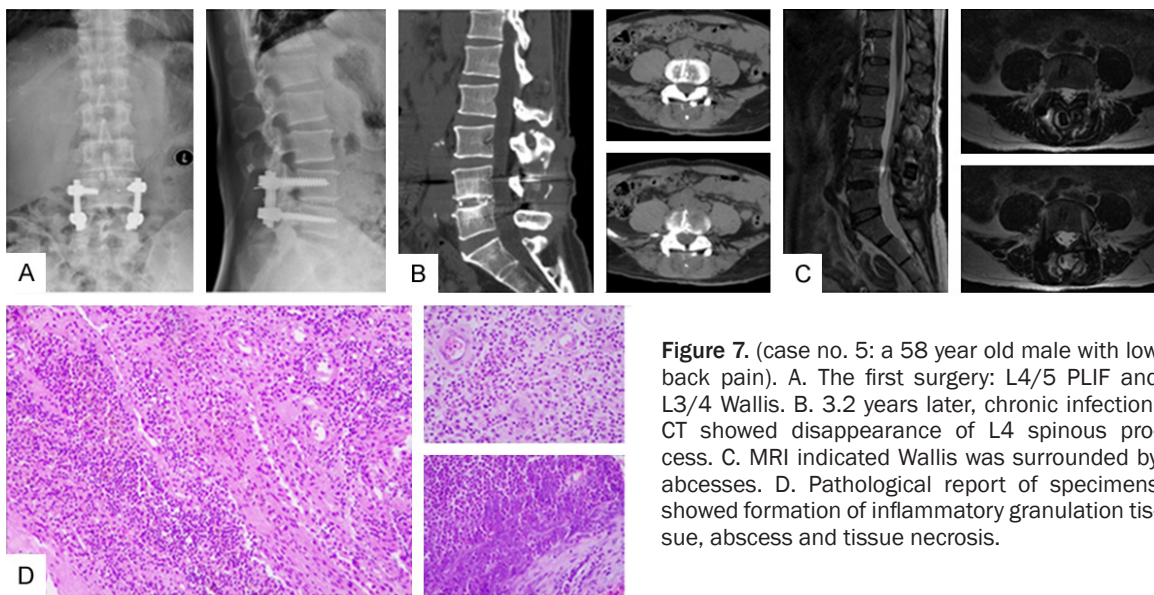


Figure 7. (case no. 5: a 58 year old male with low back pain). A. The first surgery: L4/5 PLIF and L3/4 Wallis. B. 3.2 years later, chronic infection; CT showed disappearance of L4 spinous process. C. MRI indicated Wallis was surrounded by abscesses. D. Pathological report of specimens showed formation of inflammatory granulation tissue, abscess and tissue necrosis.

ated disc and lumbar stenosis, segmental instability, scoliosis or interspinous processes fracture/bone resorption. In 2009, Senegas J followed up 107 patients with the first generation Wallis for average of 13 years and reported that in 20 patients, the implant was removed and fusion was performed [4]. The rate of revision surgery in our study is 2.7%, which is much lower than previously reported. There are some possible reasons for this number. First, the devices indeed play the role of delaying ASD. Second, some patients showed new symptoms but improved after conservative therapy as treatment for intervertebral disc herniation, which eventually avoided surgery. Third, although patients usually returns to the same hospital when relative symptoms occurred, some patients still might have received revision surgery in other hospitals outside

of our knowledge. Fourth, many factors can contribute to maintain the surgical effectiveness; such as postoperative physical exercise and protection, surgeon's operative skills, timely therapy, and so on.

The IDS consist of two major types with different biomechanical behaviors, which can be classified as semi-constrained and non-constrained. The first type of devices, with bands looped and tensioned around the adjacent spinous processes, is designed to restrict the flexion and extension and to restore stability of degenerated segments. Therefore, the so-called "dynamic stabilization" is intended to relieve instability-induced lower back pain; hence postponing the need for further invasive surgical treatment [1]. The second type of IDS, one without tension bands, just limits the seg-

mental extension. This type of device is mainly used to expand the intervertebral space, enlarge both the central canal and the neuroforamina and indirectly decompress neurological structure [5]. Therefore, the favored indications for this device were lower back pain, radiculopathy and neurogenic claudication due to lumbar spine degenerative disc disease (such as mild lumbar stenosis, large disc herniation, and recurrent disc herniation).

After three decades of clinical practice, indications of this technique have expanded to some inappropriate conditions, such as severe lumbar stenosis, obvious segmental instability, scoliosis and severe osteoporosis. However, through reviewing the case series, we could see that these indications for IDS would lead to failed results and revision surgeries.

To relieve relevant symptoms of severe lumbar stenosis, the key surgical procedure is enough decompression for herniated disk, hypertrophy of ligamentum flavum and hyperplasia of facet joints. However, only limited decompression is completed before the implantation of Wallis/Coflex. Complete decompression may negatively affect the stability of the device. Inadequate decompression and relatively poor degeneration can result in the recurrence of symptoms.

As noted above, Wallis is designed to restrict the lumbar flexion and extension for the purpose of reconstruction of segmental stability. But for patients with obvious segmental instability, the central core and tension bands can not provide enough biomechanical strength. Severe degeneration of anterior and middle column aggravates the movement between the device and adjacent spinous processes. After spinous process fracture, bone resorption develops gradually and the associated symptoms lead to the revision surgery. Besides, improper size of devices cannot effectively improve segmental stability.

Degenerative scoliosis is usually caused by asymmetric degeneration of the intervertebral complexes, including the intervertebral disc and facet joints. These changes induce asymmetric and progressive lateral listhesis or rotation of the vertebra; and ultimately lead to scoliosis, loss of lumbar lordosis, lateral or anterior vertebral translation, and lateral rotational subluxation [6-8]. Because of structural

deformity and uneven stress delivery, the implants couldn't provide adequate stability and delay ASD. As to Case NO. 6, the recurred time interval was obviously shorter than other patients (0.75 years), which might be a hint that degeneration scoliosis was an improper indication for IDS.

In recent years, the relationship between bone density and surgical effectiveness caught scientific attention; and the importance of bone density improvement during the perioperative period has been emphasized by orthopedists. In theory, the bone stress-bearing ability is reduced in the presence of osteoporosis, thereby balance between bone resorption and reconstruction is affected, and stress-induced bone resorption occurs [9, 10]. Clinical follow-up showed that in some patients, especially old females with severe osteoporosis, had a higher rate of internal fixation complications after orthopedic surgery. Moreover, osteoporosis itself is an important aspect in the process of lumbar degeneration.

Topping-off surgery, which combines rigid fusion with an interspinous process device in the adjacent segment, is designed as semi-rigid in order to delay ASD [11]. The purpose of interspinous process devices is to provide stability after decompression, restore foraminal height and unload the disc and facet joints. They not only allow for the preservation of ROM in the implanted segment, but also restrict its hyperflexion and hyperextension, thus avoiding or limiting possible overloading and early degeneration of the adjacent segments as induced by fusion [12]. Topping-off surgery is expected to have the following advantages: (1) reduce total fusion levels by avoiding the fixation of pre-existing degenerative segment adjacent to responsible intervertebral disc; (2) protect the adjacent segment of long segment fusion by offering a transition between fusion level and non-operated level; (3) reduce the difficulty of revision surgery, which may be needed in the future [13]. In 2009, Panagiotis K et al. reported that the Wallis interspinous implant changed the natural history of ASD and saved the two cephalad adjacent unfused vertebra from fusion, while it lowered the radiographic ASD incidences up to 5 years postoperatively [14].

The appearance of spinous process fracture/bone resorption has caught attention to our

eyes during the follow-up period. After the implantation, there is a change in the stress distribution of the spine and the device, in particular, impacts the spinous process itself. Moreover, even with proper placement, relative motion between the bone and the PEEK core inevitably causes friction, while the tension on the bands used to fix the device further increases stress on the contact surface. In 1970, Justus and Luft [15] suggested a biomechanical hypothesis for bone remodeling induced by mechanical stress. In 1990, Takuma et al. [16] reported that mechanical stress could induce varying degrees of bone resorption and bone remodeling. Similarly, Tanne et al. [17] reported that bone resorption was related to traction and compressive stress. There was a positive correlation between the degree of stress and the degree of deformation at the midpoint of the bone, and that mechanical stress could result in bone resorption and bone remodeling. The results of these studies support the hypothesis that increased stress on the adjacent spinous processes leads to bone resorption around the implant. At the same time, local inflammation and microenvironment change aggravate the lower back pain and instability, while the disc degeneration, hypertrophy of facet joints and ASD all lead to the recurrence of symptoms.

Surgical site infection is not rare after the implantation of internal fixation. However, in these two patients of our report, infection with obvious bone resorption occurred more than three years after the first surgery. We speculate that foreign body reaction and serious bone resorption possibly play a key role in the process of chronic infection. In theory, a certain degree of interspinous elastic device loosening may occur after bone resorption, which can result in a mild decrease of the lumbar stability and subsequent postoperative pain and discomfort due to the stimulation of inflammatory factors produced during friction and bone resorption [18]. Moreover, potential infection of other organs and immunocompromising condition may be the trigger factors. Jerosch J et al. [19] presented a case with foreign body reaction due to polyethylene's wear after a DIAM implantation. In this case, 5 months after the surgery, a significant amount of fluid around the DIAM extended up to the subcutaneous tissue, but there were no local signs of infection.

The fact that the wear of polyethylene can cause body reaction with macrophages, granuloma and inflammation is well known in the field of alloarthroplasty since Willert (1977) [20]. As noted previously, the persistence of local inflammation caused by serious bone fracture and resorption can change the local microenvironment, resulting in tissue edema or fluid accumulation. In the case that internal infection of other organ deterioration or when the body immunity was weakened, chronic infection in the surgical site may occur. The limitation in this study is that there were only twelve patients included. If the sample size is larger, it may be possible to identify risk factors that contribute to reoperation, as well as compare patients with and without reoperation.

Conclusions

Patients with severe lumbar stenosis, obvious segmental instability, scoliosis and severe osteoporosis are not recommended for IDS with Wallis/Coflex. In addition, surgeons need to notice possible problems of ASD, spinous process fracture, bone resorption and chronic infection after IDS.

Acknowledgements

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Disclosure of conflict of interest

None.

Address correspondence to: Dr. Hai-Ying Liu, Department of Spinal Surgery, Peking University People's Hospital, 11th. Xizhimen South Ave, Beijing 100044, China. Tel: +86-13651247795; Fax: +86-10-88324110; E-mail: lhydoctorpkuph@sina.com

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