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Percutaneously placed lumbar interspinous stabilization devices – a review of current clinical research

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Abstract. – OBJECTIVE: There are generally two categories of interspinous stabilization devices widely used in clinics: (1) Static spacing systems, such as X-STOP, Wallis. (2) Dynamic stabilization systems, such as Coflex, DIAM, stenofix. However, with the advancement of minimally invasive techniques, interspinous stabilization devices paced through percutaneous minimally invasive approach have been invented and applied in daily clinic. Its advantages, such as simple operation, small trauma and short hospitalization time are gradually recognized by doctors and patients. Percutaneous minimally invasive approach will become the future direction in the field of interspinous stabilization devices. This paper therefore reviewed the current clinical research progress of interspinous stabilization devices performed under percutaneous minimally invasive approach.

MATERIALS AND METHODS: We searched studies related to percutaneously placed lumbar interspinous stabilization devices from PubMed, since January 1, 2007.

RESULTS: The main types and characteristics of currently used and percutaneously placed interspinous stabilization devices were summarized. Meanwhile, clinical studies relevant to currently used and percutaneously placed interspinous stabilization devices were also summarized.

CONCLUSIONS: The future of interspinous stabilization devices is bright, we would like to see more advanced and newly invented percutaneously placed interspinous stabilization devices, meanwhile, it is fundamentally crucial to enroll more clinical studies with long-term follow-up to determine the best indications for each device therefore to achieve more satisfactory clinical outcomes.

Key Words:
Interspinous spacer, Interspinous device, Minimally invasive surgery, Static spacing, Dynamic fixation.

Introduction

Interspinous devices are minimally invasive devices that are able to decrease facet joints overload through a "shock-absorber" mechanism shifting forces to the posterior column which further reduces discal pressure[1]. It has been gradually abandoned due to the advent of fusion techniques, especially intervertebral fusion[2]. However, the various fusion techniques commonly used in clinical practice today still have their own limitations that are difficult to overcome[3]. Therefore, interspinous stabilization devices are still suitable for diseases that can be relieved or cured by indirect decompression, such as mild to moderate lumbar spinal stenosis, lumbar disc herniation combined with no segmental instability, nerve root canal stenosis due to intervertebral space collapse, and even under some circumstances, degenerative spondylolisthesis within II Grade, specifically to the old patients[4-6]. Currently, interspinous stabilization devices have been introduced to obtain dynamic or static decompression. With the advantages of minor damage, less degeneration of contiguous vertebral segments, shorter procedural time, and fewer procedural complications[7], it is worthwhile therefore to mention that interspinous stabilization device has a wider application prospect[8-10]. We therefore performed a literature

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review about clinical research progress of interspinous devices inserted through percutaneous approach.

Materials and Methods

Articles were searched using the National Library of Medicine PubMed database. We included English publications since January 1, 2007, using the search terms "interspinous" and "percutaneous"; "interspinous devices" and "percutaneous" or "interspinous spacer" and "percutaneous". We also included a few landmark articles published before 2007 for their historic contributions to this topic.

Results

Categories

The main percutaneously placed interspinous stabilization devices currently used are Aperius PercLID, BacJac, Falena, HeliFix, In-Space, Superion, etc. Products images were summarized in our figure (Figure 1).

Main Types and Characteristics

The main types and characteristics of currently used and percutaneously placed interspinous stabilization devices were summarized in our table (Table I).

Aperius PercLID (Figure 1A)

The Aperius PercLID stand-alone spacing system was invented by Palmer et al[11] in 2007 and is the first transdermally placed interspinous spacing device in the world. It has been certified as safe and effective by 12 institutions in Germany, Belgium and the UK since its debut[12]. The device is inserted through trans-parietal median access, usually a 1 cm skin incision is made 5-7 cm from the midline, later the lumbodorsal fascia and interspinous ligament are crossed under C-arm X-ray. This system is generally indicated for the L5/S1 segment[13]. Nardi et al[12] retrospectively analyzed the data of 152 patients, the results showed that the aperiusperclid system is a simple, safe and effective treatment for degenerative lumbar spinal stenosis and could be used as an alternative treatment to conventional surgery in the future. Galarza et al[14] conducted a multicenter prospective case study, which showed a 1-year follow-up pain score from visual analog scale (VAS): 8.1±2.19 to 3.44±2.89, mobility, and self-care functions were significantly improved. Menchetti et al[15] retrospectively analyzed the data of 70 patients and found that the patients' postoperative pain scores decreased significantly, from VAS 8.2 to 3.6 with an overall satisfaction rate of 76% and no complications within 6 months. Fabrizi et al[13] retrospectively analyzed the clinical data of 1575 patients, in which 260 patients underwent Aperius. The results showed that 1,505 of these patients had satisfactory clinical outcomes, and that DIAM and Aperius are both safe and effective minimally invasive treatment modalities when the indications for the procedure are well grasped. Surace et al[16] prospectively analyzed the data of 37 patients and showed that the mean postoperative VAS of patients decreased from 7 to 2 (p<0.001). Zurich claudication questionnaire (ZCQ) scores decreased significantly, reaching a mean of 21.89% (p<0.001), and Oswestry disability index (ODI) scores also decreased significantly, amounting to a mean of 26.09% (p<0.001).

BacJac (Figure 1B)

The device is made of polyetheretherketone (PEEK) material, with a percutaneous unilateral approach, which is less invasive and has a faster recovery time, it achieves decompression mainly by limiting spinal hyperextension, and can adequately prevent prosthesis loosening due to

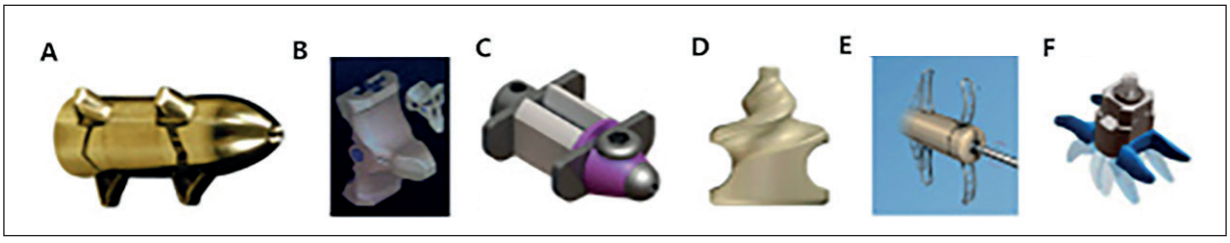

Figure 1. A, Aperius PercLID; **B,** BacJac; **C,** Falena; **D,** HeliFix; **E,** In-Space; **F,** Superion

Table I. The main types and characteristics of currently used and percutaneously placed interspinous stabilization devices.

Name	Producer	Material	Methods of fixation	Way of placing	Whether it conserves the superaspinous ligament or not	Whether it conserves the interspinous ligament or not	Category
Aperious PercLID	Medtronic	Titanium	Wings	Percutaneous	Yes	Partially conserves	Static spreading
BacJac	Pioneer	PEEK	Clips	Percutaneous	Yes	Partially conserves	Static spreading
Falena	Mikai	Titanium and PEEK	Wings	Percutaneous	Yes	Partially conserves	Dynamic fixation
HeliFix	Alphatec Spine	PEEK	Helical tip	Percutaneous	Yes	Partially conserves	Static spreading
In-Space	Synthes	PEEK and titanium	Wings	Percutaneous	Yes	Partially conserves	Dynamic fixation
Superion	VertiFlex	Titanium	Wings	Percutaneous	Yes	Partially conserves	Dynamic fixation

its large contact area with the spinous process. It is mainly used for lumbar disc herniation and lumbar spinal stenosis due to lumbar degenerative pathology[17]. Irace et al[18] conducted a prospective study that included 50 patients with a 2-year follow-up, and the results showed that 83% of patients had symptom relief, a significant decrease in pain scores, no major complications were detected except those 5 patients who developed a spinous process fracture. Spallone et al[19] retrospectively analyzed the data of 41 patients and confirmed that the patients' postoperative ODI scores improved significantly, however only 41% of the patients had clinically significant results and postoperative weight gain was a predisposing detrimental factor.

Falena (Figure 1C)

The Falena system consists of a columnar titanium core, a pointed cap-like structure, two lateral spacers made of PEEK, and columnar. The diameter of the columnar titanium core varies from 8-15 mm to facilitate matching different spinous process gap distances. The procedure is done under fluoroscopy and the interspinous gap is placed by percutaneous puncture[20]. Masala et al[20] carried out a retrospective case analysis and the results showed that the patients' postoperative pain score VAS decreased from 7.6 to 3.9 at 1 month postoperatively and 3.6 at 3 months postoperatively. MRI showed an increase in the spinal canal and bilateral foraminal area in all patients. Masala et al[21] conducted another retrospective study, which demonstrated significant improvement in VAS and ODI scores in both Aperius™ PercLID™ system and Falena® interspinous spacers groups at 6 months and 1 year postoperatively, and an increase in spinal canal area in both groups.

HeliFix (Figure 1D)

The device is made of PEEK and titanium alloy and is placed posteriorly under fluoroscopy through the skin. The main feature of this device is that the posterior half of the intervertebral disc is opened by propping up the interspinous distance, thus indirectly enlarging the area of the spinal canal. Alexandre et al[31] prospectively analyzed the clinical data of 100 patients and found that the early symptoms and mobile function of the patients improved significantly within 1 year, and 2% of patients underwent surgical procedures to remove the endograft due to poor outcome.

In-Space (Figure 1E)

The In-Space device consists of a cylindrical body made of PEEK and a curved arm made of titanium. The procedure is performed under local anesthesia with a lateral approach, and the procedure is completed by using a sight and a guide wire to enter the interspinous space[22]. Kantelhardt et al[22] did a prospective case analysis showing that 72% of the patients received a satisfactory result while 2% of patients received a second surgery. Hrabálek et al[23] conducted a prospective clinical study and the results showed that there was a significant improvement in the mean ODI scores in 63% of patients postoperatively (52% improvement at 1

year postoperatively), the mean VAS decreased from 6.64 to 2.96 six months postoperatively (2.8 one year postoperatively), with a poor clinical outcome in two patients who underwent a second-stage decompression fusion surgery. Yingsakmongkol et al[24] prospectively analyzed the clinical data of 56 patients and the results showed that In-Space is a good minimally invasive treatment for lumbar spinal stenosis. Its postoperative symptoms of low back pain and leg pain were significantly relieved with a 2-year follow-up, and longer-term results were still acceptable.

Superion (Figure 1F)

The device is constructed with a single longitudinal axis and a single channel. The main body is connected to a longitudinal axis consisting of the upper and lower arms. Each arm has an extended "U" shaped saddle structure allowing the responsible spinous process to snap into place and to move with lumbar motion. This device is positioned under C-arm fluoroscopy or direct vision, and the procedure is completed with a 12-15 mm incision in the mid-dorsal region[25]. Bini et al[26] conducted a prospective study including 121 patients and the results showed that 92% of patients achieved a satisfactory outcome, 76% still maintained a satisfactory outcome one year after surgery, and 5% of patients complained of complications. Patel et al[27] conducted a multicenter randomized controlled trial, and the results of the 3-year follow-up showed that the success rate of the procedure was above 80% in both groups, with the Superion group (81%-91%). Nunley et al[28] continued a RCT study and the results showed that at 4-year follow-up, 84.3% of patients achieved a relatively satisfactory clinical outcome. Welton et al[29] conducted a retrospective study and the results showed that compared to conventional laminectomy and laminoplasty, the incidence of complications was comparable between the two groups, with 44.4% of patients in the Superion group suffering of prosthesis-related complications.

Others

There are other percutaneously placed interspinous stabilization devices, such as Bullet, Flexus, for which however, no clinical study has been reported[30].

Clinical studies relevant to current use and percutaneously placed interspinous stabilization devices are summarized in our table (Table II).

Discussion

Benefiting from minimal surgical trauma of percutaneously placed interspinous stabilization devices, this technique appears to have a strong anatomical, scientific, pathophysiological basis and is expected to play an important role in the future minimally invasive treatment of degenerative lumbar spine diseases, especially in the elderly population[32]. We therefore hope to see the emergence of novel percutaneously placed interspinous stabilization devices, and more biomechanical trials, as well as more randomized controlled trials to verify their effectiveness, in order to better guide clinical practice. The most important direction of developing new devices will be the use of more advanced materials and the improvement of the design of lumbar interspinous stabilization devices, such as 3D printing for individualized treatment of different cases, the use of auxiliary techniques and equipment, such as augmented reality (AR) technique, robotic assisted surgery[33], navigation system and mixed reality (MR) eyeglass[34] would be further encompassed.

Limitations

From a statistical point of view, our study is not a systematic review, and it only reviewed the results from PubMed, therefore, few studies with percutaneously placed lumbar interspinous stabilization devices might be leaked.

Conclusions

The future of interspinous stabilization devices is bright, we would like to see more advanced and newly invented percutaneously placed interspinous stabilization devices, meanwhile, it is fundamentally important to enroll more clinical studies and improve the long-term follow-up to determine the best indications for each device therefore to achieve more satisfactory clinical outcomes.

Table II. Clinical studies relevant to currently used and percutaneously placed interspinous stabilization devices.

Authors	Category	Year	Cases	Research case type	Evaluation items	Conclusions
Nardi et al[12]	Aperius	2010	152	Retrospective case study	Clinical outcomes	The Aperius system is a simple, safe and effective treatment for degenerative lumbar spinal stenosis and could be used as an alternative to traditional surgery in the future.
Galarza et al[14]	Aperius	2010	40	Multicenter prospective case study	Clinical outcomes	It is an effective treatment for lumbar spinal stenosis with intermittent claudication at age > 65 years, with significant clinical results within 1 year.
Menchetti et al[15]	Aperius	2011	70	Retrospective case study	Clinical outcomes	The patients' postoperative pain scores decreased significantly, with an overall satisfaction rate of 76% and no complications within 6 months.
Fabrizi et al[13]	DIAM and Aperius	2011	1575	Retrospective case study	Clinical outcomes	With a good grasp of the indications for surgery, DIAM and Aperius are both safe and effective minimally invasive treatment modalities.
Surace et al[16]	Aperius	2012	37	Prospective case study	Clinical outcomes and imaging changes	In the case of traditional decompression surgery, Aperius may also be an alternative treatment modality.
Irace et al[18]	BacJac	2014	50	Prospective case study	Clinical and radiographic outcomes	It can reduce back pain and radicular symptoms to some extent and improve intermittent claudication, especially in patients with central spinal canal and intervertebral foraminal stenosis.
Spallone et al[19]	BacJac	2019	41	Retrospective case study	Clinical outcomes	Patients' ODI scores improved significantly after surgery, however only 41% of patients had significant clinical outcomes, with postoperative weight gain being a detrimental factor.
Masala et al[20]	Falena	2012	26	Retrospective case study	Clinical and radiographic outcomes	The same clinical results as demonstrated in other literature.
Masala et al[21]	Aperius and Falena	2016	24	Retrospective case study	Clinical and radiographic outcomes	Both techniques are effective in the medium term and both are good treatments.
Alexandre et al[31]	HeliFix	2014	100	Prospective case study	Clinical and radiographic outcomes	The majority of patients achieved a good clinical outcome within 1 year.
Kantelhardt et al[22]	In-Space	2010	87	Prospective case study	Clinical outcomes	The recurrence rate within 1 year is high, and its recent indications for surgery need to be further investigated.

Continued

Table II *(Continued)*. Clinical studies relevant to currently used and percutaneously placed interspinous stabilization devices.

Authors	Category	Year	Cases	Research case type	Evaluation items	Conclusions
Hrabálek et al[23]	In-Space	2012	25	Prospective case study	Clinical and radiographic outcomes	In-Space is an excellent minimally invasive treatment with few postoperative complications.
Yingsakmongkol et al[24]	In-Space	2014	56	Prospective case study	Clinical and radiographic outcomes	VAS scores for postoperative low back pain decreased significantly.
Bini et al[26]	Superion	2011	121	Prospective case study	Clinical outcomes	Superion is an excellent option for patients with mild to moderate lumbar spinal stenosis who have failed to conservative treatment.
Patel et al[27]	Superion	2015	391	Multicenter RCT	Clinical outcomes	Superion is highly effective in the treatment of moderate lumbar spinal stenosis.
Nunley et al[28]	Superion	2017	89	Multicenter RCT	Clinical outcomes	Superion has a satisfactory long-term clinical outcome for patients with mild to moderate lumbar spinal stenosis.
Welton et al[29]	Superion	2021	189	Retrospective case study	Clinical outcomes	Complications were comparable between the two groups at 1 month postoperatively, with a relatively increased probability of reoperation at 2 years postoperatively in the Superion group.

Conflict of Interest

The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. All device images are authorized and permitted by their companies for public use.

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Authors' Contribution

H. Wang contributed to study conception and design. Y.X. Hu, Y.F. Wang and J. Han collected, analyzed clinical data and wrote the manuscript. Y.X. Hu, and S.M. Liu were involved in submitting and revising the paper. The final version of manuscript was read and approved by all authors.

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