Clinical Neurology and Neurosurgery 136 (2015) 100–106

Contents lists available at ScienceDirect

Clinical Neurology and Neurosurgery

journal homepage: www.elsevier.com/locate/clineuro

Comparison of clinical and radiographic results between isobar posterior dynamic stabilization and posterior lumbar inter-body fusion for lumbar degenerative disease: A four-year retrospective study

Yi Yang[a], Ying Hong[b], Hao Liu[a,*], Yueming Song[a], Tao Li[a], Limin Liu[a], Quan Gong[a]

[a] Department of Orthopedics, West China Hospital, Sichuan University, Chengdu, China
[b] Operation Room, West China Hospital, Sichuan University, Chengdu, China

ARTICLE INFO

Article history:
Received 3 February 2015
Received in revised form 4 June 2015
Accepted 5 June 2015
Available online 9 June 2015

Keywords:
Posterior dynamic stabilization
Isobar
IPDS
PLIF
Fusion
Lumbar degenerative disease

ABSTRACT

Purpose: A retrospective study was conducted to compare clinical outcome with radiographic data and clinical complications between isobar posterior dynamic stabilization (IPDS, Scient'x, France) and posterior lumbar inter-body fusion (PLIF) for lumbar degenerative disease.
Methods: 113 consecutive patients (IPDS group, $N=62$; PLIF group, $N=51$) with lumbar degenerative disease were operated on between March 2009 and November 2011. Patient charts, radiographic films and medical records were reviewed. Clinical outcomes including the visual analog scale (VAS), Oswestry disability index (ODI) scores, and radiographic outcomes, including disk height index (DHI) and range of motion (ROM) were retrospectively analyzed.
Results: The ODI and VAS leg and back pain scores in two groups were significantly improved at 6 and, 24 months and at the final follow-up (all, $P<0.05$). The degree of improvements in the ODI and VAS back pain scores, the incidence of complications and the rate of adjacent segment degeneration were similar in both groups ($P>0.05$). However, operation times and blood loss were significantly reduced in the IPDS group ($P<0.05$).
Conclusion: In summary, with similar symptoms improvement and complication rates, the results of this study demonstrate that IPDS is an effective and safe treatment for lumbar degenerative disease. There is currently insufficient evidence to indicate that the IPDS can avoid adjacent segment degeneration therefore, it is essential to conduct prospective, randomized, controlled multicenter studies with larger sample size and longer follow-up.

1. Introduction

Posterior lumbar inter-body fusion has been regarded as the standard treatment for serious lumbar degenerative disease [1]. Owing to the application of new devices and techniques, lumbar fusion surgery has been an efficacious method for the treatment of various lumber degenerative diseases. Fusion rates have been demonstrated to be as high as 100% with some techniques, although good clinical outcomes have been shown to vary between 60% and 80% [2–5]. Therefore, a rigid fusion does not always result in an excellent clinical outcome [6]. Several recent studies support the hypothesis that fusion at a specific level or levels may cause adjacent segment disease engendered by aberrant forces and motion at those segments [7].

Owing to the limitations and disadvantages associated with fusion, some motion preserving surgeries including artificial nucleus replacement, artificial lumbar disk replacement and dynamic stabilization, have been explored by both researchers and surgeons [8–12]. In an attempt to overcome the adverse effects of fusion, dynamic stabilization of the lumbar spine has been introduced as a motion preserving instrument with a series of potential advantages which include the provision of adequate

* Corresponding author at: Department of Orthopedics, West China Hospital, Sichuan University, No. 37, GuoXueXiang, Chengdu, Sichuan 610041, China. Tel.: +86 18980601369.
E-mail address: liuhao6304@163.com (H. Liu).

http://dx.doi.org/10.1016/j.clineuro.2015.06.003
0303-8467/

stability to restore normal segmental kinematics enabling greater physiological load transmission and decreasing the acceleration of adjacent segment degeneration [13].

Khoueir et al. [13] classified posterior dynamic stabilization system devices into three main categories: (1) posterior inter-spinous devices; (2) pedicle based dynamic rod devices, and (3) total facet replacement systems. Pedicle based dynamic rod devices consist of rigid/dynamic screws inter-connected with flexible or semi-flexible rods and aim to preserve intact motion and balancing of load sharing between the anterior and posterior columns at the index level [14]. Several Pedicle based dynamic rod devices such as Graf ligament, Dynesys, AccuFlex rod and Medtronic PEEK rod have been widely studied since 1990s [15]. However, none of these systems has proven efficient at the biomechanical or clinical levels. Schmoelz et al. [16] investigated the biomechanical effect of Dynesys on the index level and an adjacent level and reported that the motion at the adjacent level was no different from that in fusion treatment. Mageswaran et al. [17] proposed that dynamic stabilization system displayed stability characteristics similar to a solid, all-metal construct.

As a new pedicle screw-based posterior dynamic stabilization, the isobar posterior dynamic stabilization (IPDS) was designed to alter the biomechanics of the troubled segment by decreasing the load of intervertebral disk and improve clinical results by avoiding limitations and adverse effects of fusion. IPDS consists of a metallic semi-rigid pedicle screw-based posterior dynamic stabilization (PDS) made of titanium. The PDS contains a damper component in its longitudinal element, a 5.5 mm titanium alloy rod. The dynamic component allows limited amounts of angular and axial micromotion and reduced stiffness. The damper allows for ±0.4 mm axial ROM, ±2.25° angular ROM in flexion-extension and lateral bending with no limitation in axial rotation [18].

Previous studies have reported the application of the IPDS with a range of follow-up duration and controversial clinical outcomes. We hypothesized that IPDS is an effective treatment for lumbar degenerative disease and performed a retrospective study in an attempt to compare the clinical outcomes with radiographic data and complications between IPDS (Scient'x, France) and posterior lumbar inter-body fusion for lumbar degenerative disease.

2. Materials and methods

2.1. Patient inclusion and exclusion criteria

A total of 51 consecutive patients who underwent PLIF and 62 consecutive patients who underwent posterior decompression and placement of an IPDS between March 2009 and November 2011 were retrospectively reviewed in this study. All patients operated with PLIF or IPDS during this period were included in this study. The study was approved by Medical Ethical Committee of West China Hospital, Sichuan University, China. All of the 113 patients provided informed consent for the retrospective analysis of their clinical and radiological data.

The surgical indications included spondylolisthesis lower than Grade 1, recurrent disk herniation, symptomatic lumbar spinal stenosis and degenerative disk disease with discogenic pain associated with intractable radicular pain, back pain or neurogenic claudication who had failed conservative treatment.

Exclusion criteria consisted of body mass index (BMI)> 40 kg/m^2, severe osteoporosis of the lumbar spine, presence of active infections, pathologic fractures of the vertebrae and those with spinal deformity. Similarly, patients suffering from acute or chronic serious diseases which might increase the perioperative risk were also excluded. All patients were treated and followed-up at the West China Hospital, Sichuan University in Chengdu city, China.

2.2. Preoperative evaluation

The following data for each patient including age, gender, the body mass index (BMI), location and duration of pain, the visual analog scale for pain (VAS), Oswestry disability index (ODI) scores, range of motion (ROM), disk height index (DHI), were collected. Lumbar Plain radiographs (including flexion/extension views) and Lumbar magnetic resonance imaging (MRI) were performed prior to surgery. Patients were chosen to undergo either IPDS or PLIF following discussion with clinical specialists.

2.3. Surgical technique

All surgeries were carried out on a standard midline dorsal approach by experienced surgeons after induction of general anesthesia. Patients were placed in the prone position of neutral lumbar lordosis with adequate cushioning. When adequately decompressed, the titanium alloy pedicle screws were inserted. The length and diameter of the screws were determined by preoperative computerized tomography scanning and confirmed intra-operatively by fluoroscopy (Fig. 1). Connecting dynamic rods were then implanted and compression applied across the instrumentation to restore segmental lordosis and to lock the rods in place. The PLIF procedure was conducted according to standard techniques which included a midline skin incision, sub-periosteal dissection of the paraspinal muscles, posterior decompression accompanied by partial laminectomy and bilateral facetectomy, and bilateral pedicle screw fixation with fluoroscopic guidance [19]. PEEK Cages (Capstone, Medtronic) fulfilled with autogenous iliac bone were used for the PLIF (all bilateral). Negative pressure drainage and prophylactic antibiotics were routinely used post-operatively. Ambulation was allowed three days after surgery and all patients were required to wear a brace for 12 weeks.

2.4. Clinical evaluations

Charts and medical records for each of the 113 patients were reviewed. Neurological examination and functional assessment were recorded pre-operatively, at 6, 12 and 24 months and at the latest follow-up assessment. The assessment including the VAS for back and leg pain and the ODI score for lumbar functional disability was performed by 2 specialists under supervision of the attending physicians [20,21].

2.5. Radiographic evaluations

All of the patients underwent pre-operative imaging, including plain radiographs, MR imaging, and CT scanning. Antero-posterior, lateral and functional radiographs were performed at each follow-up. Range of motion was measured as the difference in angulation between extension and flexion X-rays. The disk height index was measured on the lateral view according to the Kim method (Fig. 2) [22]. Implant failure, including screw loosening or breakage was recorded. An initial halo sign, defined as aradiolucent line around the implant >1 mm wide, followed by a double halo sign on later plain radiographs or computerized tomography scans was recognized as screw loosening [23]. Disk degeneration was also graded on T2-weighted sagittal and axial MRI according to the Pfirrmann Grading System [24]. The Pfirrmann grading system assesses degenerated intervertebral discs by MRI for the asymmetry in disk structure, distinction of the nucleus and the annulus, signal