A Novel Posterior Spinal Fusion Technology with Local Bone for a Degenerative Spine: A Preliminary Report of 48 Cases

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Abstract

Background: There were lower rate of solid bony union in the traditional posterolateral lumbar fusion. And previous studies have showed that paraspinal musculature provided predominant vascular ingrowth into the fusion mass. The purpose of this study was to introduce a novel posterior fusion technique which utilized orthotopic paraspinal muscle-pediculated bone flaps for increasing blood supply and accelerating the healing of local bone grafts. In addition, the feasibility, safety, and early outcome of this method were evaluated.

Methods: 48 patients of degenerative lumbar disorders were treated with the novel posterior lumbar fusion method. To analyze early complications, rate of fusion and clinical outcome. The fusion status was assessed by three-dimensional reconstruction of CT at at 6 months and 1 year after surgery. The VAS, ODI and SF-36 were assessed pre- and postoperatively.

Results: All the patients were followed up for 2 years at least. No operative or postoperative complications were encountered. There was significant statistical difference in VAS, ODI and SF-36 before and after operation (P<0.01). Satisfactory fusion was observed at 6-months follow-up. There was only one case not formed solid fusion at the last follow-up.

Conclusions: The posterior lumbar fusion method was such a novel and useful technique that made the position of bone graft more precise and stable that it can increase the fusion rate. This method has decreased the incidence rate of pseudarthrosis, and could get satisfactory clinical outcomes.

Introduction

It is considered that lumbar spine fusion is a primary procedure for patients with degenerative spinal disorders to maintain spinal stability and prevent postoperative instability.\(^1\) Though some kinds of lumbar fusion techniques have exist, posterolateral lumbar fusion (PLF) is always considered to be the gold standard for lumbar spinal fusion.\(^2\) Although anterior interbody fusion techniques have been developed and continue to be evolved, the traditional technique of posterolateral fusion is still the most commonly performed type of fusion in the lumbar spine.\(^3\) The lower complication rate, lesser surgical blood loss, shorter operative time, and lesser cost associated with this technique as compared with an interbody procedure make this an attractive option to treat spinal disease.\(^4\) Unfortunately, solid fusion is not always acquired. Documented nonunion rates range from 10–40% for posterolateral lumbar fusion,\(^5\) despite the extensive use of internal fixation in the clinical setting. Failure of fusion usually brings a number of troubles to patients and surgeons. Thereby, it is necessary to adopt several measures to reduce or eliminate the incidence of nonunion.

Recently, many researches are focused on biological substances of fusion by the addition of BMPs, demineralized bone matrix, and osteoprogenitor cells to the bone graft\(^6\)–\(^8\) However, many researchers have been concerns about the complications such as airway edema, seroma formation, soft tissue
swelling, retrograde ejaculation, carcinogenicity, bone osteolysis and ectopic bone formation. So these complications affect their extensive application.

Many areas can provide a blood supply for bone graft area, such as local bone and muscle tissue. Smucker and Walsh et al studied posterolateral transverse processes fusion in a rabbit model. They revealed that the fusion firstly took place at decorticated transverse processes. This suggested that local decorticated bone may offer a key vascular supply for fusion masses. However, Bawa et al investigated the contribution of paraspinal musculature to posterolateral fusion masses in a rabbit model. They considered that the paraspinal musculature provided crucial vascular ingrowth into the fusion site. The blood supply from local decorticated bone and muscle tissue were equally important for spine fusion, but little attention was paid to the role of muscle tissue. Presently, there were no a posterior arthrodesis that could simultaneously use the blood supply from local decorticated bone and muscle tissue.

For this reason, authors of this study designed a novel posterior lumbar spine arthrodesis with paraspinal Muscle-pediculated bone grafts, and hoped to provide a spinal fusion method with generally application, high union rate and minor paraspinal soft tissue injury. We have proved the advantage in bone formation rate and quality of the novel method by animal experiment. And we have applied the novel bone graft method to clinical patients. So we evaluated the initial clinical result.

**Materials And Methods**

A total of 48 consecutive cases, operated during 2011 and 2014 by the senior author for degenerative spinal disorders, were reviewed. One spinal surgical team treated all enrolled patients, and all patients were operated by the same surgeon. Before surgery, patients underwent dual-energy x-ray absorptiometry to assess bone mineral density. All participants met the following inclusion criteria: (1) failure of conservative treatment after a minimum of 6 months; (2) age, 65 years or less; (3) undergoing lumbar fusion surgery at a single level (L4-5); and (4) a follow-up period of 2 years or more after surgery. Exclusion criteria were as follows: (1) Severe osteoporosis; (2) Patients who have had lumbar surgery; (3) abnormal muscle activity or ambulation due to neuromuscular disease; and (4) unable to accurately complete the pre- and postoperative questionnaires due to certain problems such as a stroke or dementia.

**Surgical Technique**

Using standard aseptic techniques, a midline skin incision was made from levels of L4–L5. Paraspinal muscles were stripped subperiosteally from the spinous processes and laminae until superior articular processes (SAPs) were seen. After C-arm examining for determining the segment, pedicle screws were inserted to L4 and L5, bilateral decompression by fenestration at the level of L4-5. The bilateral outer margin of SAPs of L5 and outer margin of pars interarticulares (PIs) and inferior border accessory process of L4 were lengthways split by sharp osteotome. Blunt dissection was used to separate the split bone flaps and the adherent longissimus and multifidus muscles to form cuboid bed of bone graft that four walls next to fresh sclerotin. Autologous corticocancellous from decompression by fenestration was
cleaned, trimmed, and morselized with a rongeur and placed over the graft bed. Suitable length titanium rods were placed over the graft bed and were used to connect pedicle screws. Screwed up the screw cap, and placed drainage tube. The wound was closed in a standard manner. (Figure 1)

Radiographic Assessment

Radiologic outcome was assessed independently by three orthopedic surgeons, and the radiographic fusion rate was calculated at each time-period by averaging the results of the three observers. Plain anteroposterior were presented before and 3, 6, 12 months after surgery, and at the last follow-up, and were used to evaluate the position of internal fixation. Because of the occlusion of internal fixation, the fusion status was assessed by three-dimensional reconstruction of CT at at 6 months and 1 year after surgery. Sequential bony bridges formed in coronal Plane and sagittal plane between intertransverses or SAPs was considered as solid fusion. CT scans were graded according to the method of Glassman.\textsuperscript{15} CT scans were graded as demonstrating no fusion (grade 1), partial or limited unilateral fusion (grade 2), partial or limited bilateral fusion (grade 3), solid unilateral fusion (grade 4), or solid bilateral fusion (grade 5).

Clinical evaluation

Postoperative follow-up was performed at 3 months, 6 months, 12 months and the last follow-up. Preoperative baseline and postoperative outcome measures at 6 months, 12 months and the last follow-up included Visual Analogue Scale (VAS, range 0–10) for back and leg pain, the Oswestry Disability Index (ODI) and the Short Form-36 (SF-36). The mean score (range: 0, normal to 5, impossible) for each of the 10 ODI items was determined separately. Analysis of the item related to sex life was not included owing to the small number of respondents. Thus, scores ranged from 0 to 45.

Statistical analysis

Statistical analysis was performed using the SPSS 22.0 software package. The VAS ODI, and SF-36 scores were analyzed by Kruskal-Wallis one-way analysis of variance (ANOVA). The fusion results were compared statistically using McNemar’s $\chi^2$ test. Significance was defined by P values $<$ 0.05.

Results

Patient Characteristics

The patient cohort included 22 men and 26 women, with an average age of 60.3±11.7 years (range, 37–65 years). All the cases had decompression by fenestration and novel posterior lumbar fusion with pedicle screw instrumentation. The diagnosis included degenerative spinal stenosis in 15 (31.3%), degenerative spondylolisthesis with stenosis in 28 (58.3%), spondylolisthesis with disc degeneration in 5 (10.4%). Fusion was performed at level of L4-5. Minimum follow-up was 28 months (mean, 39.4 months; range, 28-51 months). Typical case images are shown in Figure 2.
Operation data

All patients successfully completed the operation without iatrogenic nerve injury. The surgical time was 1.85±0.4 hours and the estimated blood loss was 158.6±18.3mL. The drainage tubes were pulled out 48-72 hours after operation, and the patients got out of bed with brace 3 days after surgery.

Radiological evaluation

The plain anteroposterior showed that loosening and breakage of internal fixation were not take place at the last follow-up. (Figure 3) At 6 months after surgery, the results from the three-dimensional reconstruction of CT displayed that solid fusion was observed in 44 of 48 (91.7%) segments, and the unilateral fusion was showed in 3 of 44 (6.8%) segments. At 1 year after surgery, the results from the three-dimensional reconstruction of CT displayed that solid fusion was observed in 46 of 48 (95.8%) segments, and the unilateral fusion was showed in 2 of 46 (4.3%) segments. There was no significant difference in fusion rate between 6 months and 1 year after operation (P>0.05). Mean fusion grade (scale 1–5) was 4.71 at 6 months after surgery and 4.77 at 1-year after surgery (Table 1). Typical CT images after operation are shown in Figure 4 and Figure 5.

Clinical Score

At every postoperative interval, statistically significant improvement from baseline was observed for VAS back and leg pain scores (P<0.01). However, VAS back pain score seems to maintain a better score. (Table 2) Statistically significant improvement was also seen for ODI, SF-36(PCS) and SF-36(MCS) (P<0.01). All the postoperative scores except SF-36 (MCS) were the best at 6 months postoperatively compared with the other time nodes. And there was little change in SF-36 (MCS) score at three time points after operation.

Discussion

Failure or delay in spinal arthrodesis can result in contumacious low back pain, which bring about tremendous pain to patients, and usually need the second operation. Successful spinal fusion requires a suitable local environment that has sufficient surface area of decorticated host bone, adequate graft material, absence of excessive motion, and a rich vascular supply.\textsuperscript{16} In a rabbit’s posterolateral intertransverse process fusion model, Smucker\textsuperscript{11} et al found neovascularization derived mainly from the decorticated transverse processes, and healing initially occurred near the transverse processes and delayed in the central site. So they considered that the main reason of nonunion might be the fusion mass delay in vascularization of the central region. Bawa\textsuperscript{13} presumed that the muscle helped fasten attach the graft to the local bone, but sometimes its interposition may lead to a fibrous cleft within the fusion mass, which might cause the nonunion.

Thereby, in order to decrease the rate of pseudarthrosis, we created a novel posterior spinal fusion method. In this technique, we utilized the advantages of the SAP and PI that they have sufficient blood supply, and there was also abundant paraspinal musculature adhered to them, successfully built the
bone graft bed that four walls next to fresh bone. We have constructed the novel posterior lumbar spine fusion with orthotopic paraspinal muscle-pediculated bone aps in canine model. And the results showed that this novel method obviously surpassed the traditional posterolateral fusion in the rapidity and quality of bone formation. So the animal experiment laid substantial foundation for its clinical application.

Blumenthal et al. reported that the overall agreement between radiographic assessment of fusion and actual surgical results was 69%. It have been reported that it is difficulty to determine fusion status by radiography. Axelsson et al. reported that there were some limitations in assessing fusion status with conventional radiography and flexion/extension functional radiography at early postoperative times. Hereby, three-dimensional reconstruction of CT was adopted to evaluate the fusion rate in this study. Three-dimensional reconstruction of CT estimated lumbar fusion from three different viewing angles, which was more accurate and comprehensive than radiography. In this study, the overall fusion rate determined by CT scan was more than 90%, significantly higher than the traditional posterolateral fusion described by An and Wang. In their study, CT was not used to evaluate the fusion rate, so our results have great advantages.

Parvizi considered that blood supply of bone graft was extremely important for bone union. In this study, the initial clinical result showed that solid fusion was formed at three months after surgery in several cases, which was better than six months of posterolateral lumbar fusion which reported by Howard. It is obviously the novel posterior spinal fusion possessed significant dominance in the rapidity of bone formation. In the animal and clinical experiment, we discovered that the bone healing initially occurred near the muscle-bone flaps. This phenomenon coincided with Parvizi’s view point again: the blood supply of bone graft had a direct influence on bone union.

In our study, the VAS back pain score of postoperative was significantly better than Owens and Park's report. The analysis may have preserved the spinous process ligament system and the function of muscle ligament complex with our operation, so as to reduce the occurrence of low back pain symptoms. Therefore, it shows the advantage of our operation with less injury.

We conclude that the reasons of the rapid bone formation in this novel model could be speculated as follows: (1) Larger graft beds and shorter distance for fusion: In this novel posterior spinal fusion model, we split the bilateral outer margin of SAPs and superior border of transverse processes of L5 and outer margin of pars interarticularis (PIs) and inferior border of L4, and constructed a graft bed that four walls next to fresh sclerotin, which obviously increased the area of graft bed. The more fresh sclerotin of the graft bed, the more nutrient was supplied by the tissues of surrounding. (2) Bone grafts could get blood supply from paraspinal muscle: Bawa reported that paraspinal muscle can provide a rich vascular supply for the fusion mass. In this study, paraspinal muscle adhered to the lateral parietes of graft bed, and provided blood supply for bone graft. So the bone grafts can get better blood supply than posterolateral intertransverse process fusion. (3) Mechanically holding the bone graft, limiting the movement of the graft: the bone grafts were placed in the proximate cuboid graft bed, and were closely presses by superior titanium rods. So the graft beds could limit the movement of the graft. Meanwhile,
the lateral bone flaps prevented paraspinal muscles interposing in grafts, which removed the influence of soft tissue in bone healing. (4) Might help induce the expression of bone growth factors: Kakar\textsuperscript{24} and Chen\textsuperscript{25} report that some morphogenetic factors and their receptors that promoted the growth of skeletal tissues, such as BMPs and FGFs, which were expressed during fracture healing. In our study, the process of splitting bone equivalently created minor fracture which might help induce the expression of bone growth factors and accelerate bone healing. In addition, we found that local autologous corticocancellous from decompression by fenestration was enough for fusion in the novel technology, avoiding the morbidity of harvesting the iliac wing for autogenous bone. In my opinion, the novel posterior spinal fusion method had extremely wide perspective for clinical application.

Conclusions

The novel posterior lumbar fusion method decreased the incidence rate of pseudarthrosis, and could get well-content clinical effect. Nevertheless, further researches are needed to determine the long-term clinical result of this novel technology. Therefore, we believe that this technique can be widely used in lumbar degenerative instability disease substitute for posterolateral transverse process fusion and most interbody fusion.

Declarations

Ethics approval and consent to participate:

In accordance with local and institutional laws and data protection regulations, no approval by the local ethics committee was necessary for this study.

Consent for publication: Not applicable

Availability of data and materials:

All data generated or analysed during this study are included in this published article.

Competing interests:

The authors declare that they have no competing interests.

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Authors' contributions:
ChunyangXi and HuiChi analyzed and interpreted the patient data. JinglongYan performed the operation. WenxiaoXu, GuangxiWang, PengyuKong and YufuWang draft the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1. Grades of fusion as observed by computed tomography
Table 2. VAS, ODI and SF-36 of preoperation and at the different follow-up intervals

| Time            | VAS (leg pain) | VAS (back pain) | ODI       | SF-36(PCS) | SF-36(MCS) |
|-----------------|----------------|-----------------|-----------|------------|------------|
| preoperation    | 7.08±1.77      | 6.25±2.17       | 49.72±14.17 | 28.48±16.18 | 39.64±14.84 |
| 6 months        | 2.36±0.97*     | 1.97±0.79*      | 17.21±6.91* | 68.55±11.06* | 73.62±13.32* |
| 1 year          | 2.55±0.95*     | 2.22±0.82*      | 18.26±4.25* | 67.83±10.57* | 70.68±11.91* |
| last follow-up  | 2.69±1.05*     | 2.39±0.95*      | 18.75±4.64* | 65.91±9.97*  | 73.76±8.06*  |

Note: *=P<0.01, (postoperation vs preoperation)