Retrospective Study on Effectiveness of Activ L Total Disc Replacement

Clinical and Radiographical Results of 1- to 3-Year Follow-up

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Study Design. Retrospective case series study.
Objective. To assess the effectiveness of activ L total disc replacement (TDR) on degenerative disc diseases with the clinical and radiographical results.
Summary of Background Data. There are few reports on activ L TDR. This is the first one from China.
Methods. From March 2009 to March 2012, 32 patients with degenerative disc diseases underwent mono- or bisegmental lumbar TDR. Mean age was 45.1 years (32–58 yr). Clinical outcomes were measured by Oswestry Disability Index and Visual analogue scale pre- and postoperatively (1, 2, and 3 yr). Radiographical parameters as range of motion and intervertebral disc height of the index- and adjacent segments were also measured. Prosthesis subsidence and heterotopic ossification were observed during the follow-up period. Work status was also tracked.
Results. Thirty patients were available for a mean follow-up of 28.8 months and had complete radiographical data. At the final follow-up, the success rate was 86.7%. Visual analogue scale score for low back pain and leg pain, and Oswestry Disability Index scores significantly improved after surgery. Average intervertebral disc heights of patients with more than 3 years’ follow-up at the index segment and upper and lower adjacent segments were 12.87 mm, 12.61 mm, and 11.62 mm, respectively, showing no significant difference compared with preoperative scores. The range of motion of the index and upper adjacent segments showed a significant increase for patients with more than 3 years’ follow-up. Changes of range of motion at lower adjacent segment were not significant. We observed tears of the iliac vein in 2 patients, prosthesis subsidence in 3 patients, and heterotopic ossification in 1 patient. At the final follow-up, 18 patients went back to their original work, 8 patients changed jobs, and 4 patients stopped working.
Conclusion. The 1- to 3-year follow-up of this cohort of patients showed satisfactory clinical outcomes. The long-term results of activ L TDR need more investigation.
Key words: total disc replacement, retrospective case series, degenerative disc disease, activ L, Oswestry Disability Index, range of motion, intervertebral disc height, lumbar disc.
Level of Evidence: 2
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Currently, spinal fusion is the standard surgical treatment of painful lumbar degenerative disc disease (DDD) that is unresponsive to conservative treatment modalities. However, due to the immobility of the index segment, spinal fusion may lead to increased stress and subsequent degeneration of the adjacent segments. To solve the problem, many nonfusion methods have been developed, including lumbar total disk replacement (TDR). The advantages of lumbar TDR treatment are motion preservation of the affected and surgically treated segment, prevention of adjacent segment degeneration, and better or equivalent clinical results than fusion.

However, the clinical outcomes of lumbar TDR have been conflicting. The first long-term arthroplasty study was conducted by Lemaire et al, with excellent or good clinical outcomes in 90% cases. But these promising results were challenging by Putzier et al, reporting 17-year follow-up data with CHARITÉ. In Putzier’s report, 60% of the patients developed spontaneous ankylosis leading to the conclusion that the long-term efficacy of lumbar TDR still needed to be verified. Other randomized controlled trials showed that the outcomes of TDR are not superior over fusion. We previously reported the midterm results of total disc replacement with SB CHARITÉ III prosthesis. For the past several years, we have been focusing on the second generation of artificial disks because of the unstable long-term success.
rates of the CHARITÉ TDR. The aim of this study was to evaluate the safety and effectiveness of the activ L artificial disc, which is a semiconstrained prosthesis. Clinical and radiographical results after TDR with activ L during 1- to 3-year follow-up were summarized. Our data showed that activ L prosthesis would be able to achieve satisfactory clinical results while preserving segmental motion.

MATERIALS AND METHODS
Between March 2009 and March 2012, 32 patients underwent TDR with the activ L artificial disc (Aesculap AG & Co. KG, Tuttingen, Germany), 30 of whom had complete radiographical data and were available for at least 1 year’s follow-up. Two patients were not able to complete 1-year evaluation. However, both had satisfactory results at the 6-month postoperative evaluation. Both CHARITÉ and ProDisc are purchased from Depuy Synthes, Inc., Raynham, MA.

Study Protocol and Patient Selection
Inclusion and exclusion criteria are shown in Table 1. All patients included in the study were diagnosed with DDD. DDD was defined as low back pain of discogenic origin, which must have consistent symptoms of primarily back pain and, in some cases, leg pain without overt nerve root compression. In addition, one of the following observations had to be confirmed by magnetic resonance imaging: Modic changes, high-intensity zones, loss of disc height (no more than 40% decrease in disc height) and/or decreased hydration of the disc, and disc degeneration Pfirrmann of grades 2 to 3 at the segment to be treated between L2 and S1.

All patients were not responding to intensive conservative treatment programs for at least 6 months, either inpatient or outpatient. The treatments included physical therapy, facet joint injections, epidural steroids, acupuncture, behavior modification, anti-inflammatory medications, muscle relaxant, and other nonoperative attempts to reduce the mechanical back disability. Diagnosis was made on the basis of clinical signs and symptoms, lumbar radiographs in standard, anteroposterior and lateral views as well as functional images in extension and flexion, and also magnetic resonance imaging of the lumbar spine. Discography was used in identifying discogenic pain and in distinguishing the symptomatic segment.

Outcome Assessment
Outcome evaluation took place postoperatively at 3, 6, and 12 months. After completing 12 months of follow-up, patients were asked to consent to additional follow-up at 24 and 36 months. Parameters evaluated include clinical and radiographical results.

Clinical questionnaires examined lumbar function (Oswestry Disability Index [ODI]) and lumbar visual analogue scale (VAS). Pain was assessed using 2 separate VASs for low back and leg pain. Defined by the Food and Drug Administration (nonvalidated clinical scale), a case was considered as successful when all the following criteria were met: (1) disability (ODI) improvement of at least 15 points versus baseline; (2) no device failure; (3) no major complication associated with the prosthesis or surgery; and (4) no neurological deterioration. Device failure was considered when reoperation was required to modify or remove implants or supplemental fixation was needed. Major complications were defined as major vessel injury resulting in blood loss of more than 1500 mL, neurological damage, or nerve root injury.

Radiographical parameters such as range of motion (ROM) and intervertebral disc height (IDH) of the index and adjacent segments were obtained preoperatively and postoperatively. For patients who underwent implantation at L5–L1, the ROM was evaluated at L4–L5 as well as L3–L4 and L5–S1. For patients who underwent implantation at L5–S1, the ROM was evaluated at L5–S1 and L4–L5.

We use the Cobb technique to determine the ROM. We measured the anterior and posterior disc height using digitized radiographs in the neutral position to obtain IDH as shown in Figure 1. Heterotopic ossification was also evaluated with a 6-point scale adapted from McAfee et al. All radiographs were analyzed by the same system to avoid inter- and intraobserver variability.

Operative and rehabilitative data collected included operating time, intraoperative blood loss, and duration of

| TABLE 1. Inclusion and Exclusion Criteria |
|------------------------------------------|
| **Inclusion Criteria**                    |
| Age, 25–60 yr                             |
| Degenerative disc disease confirmed by magnetic resonance imaging and computed tomography |
| Discogenic low back pain with or without leg pain |
| Disc herniation that can be removed by anterior approach |
| Unsuccessful conservative therapy of at least 6 mo |
| **Exclusion Criteria**                     |
| Spinal stenosis requiring decompression |
| Spinal spondylolisthesis or instability of the spine |
| Major spinal deformity |
| Age >60 yr                                |
| Severe osteoporosis                       |
| Compromised vertebral body                |
| Previous spinal infection or tumor     |
| Moderate or worse facet joint arthritis   |
| Major segmental instability              |

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hospitalization, if patients return to work. Postoperative controls and examinations were performed by an independent observer not involved in preoperative decision making.

Surgical Technique
All patients underwent surgical treatment through an open anterior retroperitoneal approach. Patients were placed in the supine position on a folding operation table. Fluoroscopy was used to identify the location of the disc space and the approach angle with markings on the patient's abdomen. A complete discectomy was performed through anterior lumbar surgical instruments. For patients with a herniated disc, complete decompression was performed to relieve the symptoms. Care was taken to preserve the peripheral annulus fibrosis when performing discectomy, which can provide ligamentotaxis.

Before putting the prosthesis, disc space preparation was identical for a proper position of the prosthesis. The anterior longitudinal ligament and anterior annulus fibrosis were resected. The posterior longitudinal ligament was stretched to facilitate restoration of normal disc space height. The bony vertebral endplates were left intact and shaped to be parallel. The subchondral bone on the vertebral endplates was preserved to provide stability and prevent implant subsidence. In some cases, the posterior osteophytes were carefully removed to allow satisfactory placement of the prosthesis. A flat surface was made to maximize the bone-implant contact area. Final positioning was assessed with fluoroscopy. When the prosthesis was in position, the anterior longitudinal ligament was not fixed to avoid heterotopic ossification.

Statistical Analysis
Continuous data were expressed as mean ± standard deviation. All statistical analysis were conducted using SAS, version 9.2 (SAS Institute, Cary, NC), and statistical significance was accepted at the P < 0.05 segment. Specifically, a multisegment model was used to analyze ODI score, VAS score for low back and leg pain, ROM, and IDH of the index and adjacent segments. Data from all time points including the end of follow-up were included in the analysis, and Turkey-Kramer analysis was used to estimate comparisons of interest. All available data were used for the analysis and no imputation of missing data was performed.

RESULTS

Patient Demographics and Intraoperative Data
A total of 32 patients received a TDR between March 2009 and March 2012, 30 of whom were enrolled in this study: 18 males and 12 females. Twenty-four of them received a single-segment TDR, and 6 of them received a 2-segment TDR. There were 3 TDRs carried out at L3–L4 segment, 2 at L4–L5 and 1 at L5–S1. The mean age at the time of surgery was 45.1 ± 6.7 years (32–58 yr). The average follow-up time was 28.8 ± 11.6 months (12–46 mo). Intraoperative data were collected after each surgery. The mean estimated blood loss was 472.3 ± 121.7 mL, and the mean intraoperative time was 168.7 ± 38.1 minutes. The average length of hospital stay was 7.7 ± 1.8 days. Table 2 illustrates patients’ demographics.

Clinical Successful Rate
As previously described, all 4 criteria needed to be met to demonstrate individual clinical success: (1) disability (ODI) improvement of at least 15 points versus baseline; (2) no device failure; (3) no major complication associated with the prosthesis or surgery; and (4) no neurological deterioration. At the final follow-up, 26 of the 30 patients (86.7%) had a successful outcome.

Clinical Parameters

Visual Analogue Scale
Mean back pain decreased significantly after surgery, and the situation was well maintained during the follow-up time. Comparing with preoperative values, the values of patients with more than 3 years’ follow-up were significantly decreased (P < 0.0001). Changes of mean leg pain showed a similar trend. The decrease of leg pain intensity for patients with more than 3 years’ follow-up showed significant improvement compared with that before surgery (P < 0.0001). Table 3 illustrates the pain scores over time.

Oswestry Disability Index
ODI scores were plotted as mean values ± standard deviation at each time point (Table 3). ODI scores (range: 0–60) were significantly lower at all postoperative time points comparing with baseline (P < 0.0001). At the final follow-up, 26 patients (86.7%) showed at least 15 points improvement in ODI score versus baseline. The cutoff value of 15 points was specified by the Food and Drug Administration and a prior publication by Hagg et al., indicating that the minimal clinical important difference in ODI was 10 points, a value that should be exceeded for clinical decision making.

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TABLE 2. Patients’ Demographics

| Patient No. | Age | Sex | Affected Segment | Hospital Stay (d) | Operation Time (min) | Blood Loss (mL) | Reoperation | Follow-up (mo) |
|-------------|-----|-----|------------------|------------------|----------------------|----------------|-------------|--------------|
| 1           | 38  | F   | L4–L5            | 6                | 210                  | 500            | No          | 37           |
| 2           | 54  | M   | L4–L5            | 7                | 180                  | 350            | No          | 41           |
| 3           | 39  | M   | L4–L5            | 7                | 150                  | 400            | No          | 12           |
| 4           | 54  | F   | L4–L5            | 8                | 150                  | 500            | No          | 41           |
| 5           | 51  | M   | L5–S1            | 7                | 190                  | 550            | No          | 36           |
| 6           | 47  | M   | L4–L5            | 10               | 140                  | 300            | No          | 38           |
| 7           | 47  | M   | L4–L5            | 5                | 140                  | 400            | No          | 40           |
| 8           | 45  | M   | L5–S1            | 7                | 140                  | 450            | No          | 36           |
| 9           | 49  | M   | L5–S1            | 9                | 190                  | 380            | No          | 36           |
| 10          | 42  | F   | L4–L5            | 7                | 180                  | 320            | No          | 40           |
| 11          | 58  | F   | L3–L4            | 6                | 120                  | 440            | No          | 40           |
| 12          | 53  | M   | L4–L5            | 8                | 160                  | 500            | No          | 36           |
| 13          | 50  | F   | L5–S1            | 8                | 110                  | 500            | No          | 42           |
| 14          | 46  | F   | L4–L5            | 8                | 120                  | 580            | No          | 31           |
| 15          | 32  | M   | L4–L5            | 10               | 120                  | 380            | No          | 12           |
| 16          | 36  | M   | L3–L4, L4–L5     | 11               | 210                  | 700            | No          | 27           |
| 17          | 49  | F   | L4–L5, L5–S1     | 10               | 200                  | 650            | No          | 12           |
| 18          | 43  | F   | L4–L5            | 5                | 150                  | 550            | No          | 20           |
| 19          | 46  | M   | L4–L5            | 7                | 150                  | 440            | No          | 17           |
| 20          | 39  | M   | L4–L5            | 6                | 170                  | 480            | No          | 28           |
| 21          | 49  | F   | L5–S1            | 9                | 140                  | 350            | No          | 35           |
| 22          | 40  | F   | L4–L5            | 5                | 190                  | 400            | No          | 29           |
| 23          | 50  | M   | L4–L5            | 7                | 140                  | 350            | No          | 12           |
| 24          | 35  | M   | L4–L5, L5–S1     | 10               | 240                  | 750            | No          | 12           |
| 25          | 45  | M   | L4–L5, L5–S1     | 9                | 270                  | 600            | No          | 41           |
| 26          | 48  | M   | L4–L5, L5–S1     | 9                | 200                  | 650            | No          | 19           |
| 27          | 41  | M   | L4–L5            | 6                | 160                  | 450            | No          | 46           |
| 28          | 41  | F   | L4–L5            | 7                | 180                  | 350            | No          | 24           |
| 29          | 54  | M   | L3–L4, L4–L5     | 11               | 220                  | 600            | No          | 14           |
| 30          | 33  | F   | L5–S1            | 5                | 140                  | 300            | No          | 13           |

F indicates female; M, male.

Radiographical Parameters

**IDH at the Index and Adjacent Segments**
The data of IDH at the index and adjacent segments before surgery and at each postoperative time point were illustrated in Figure 2.

IDH value at the index segment increased immediately after surgery, and the differences between preoperative IDH values and postoperative IDH values (excluding those at the 3-yr follow-up) were significant (*P* < 0.0071). But at the 3-year follow-up, the IDH values showed no significant difference compared with preoperative data (*P* = 0.0597). IDH values at both adjacent segments were not significantly affected by the operation (*P* > 0.6669).

**ROM at the Index and Adjacent Segments**
The data of ROM at the index and adjacent segments before surgery and at each time point postoperatively were illustrated in Figure 3. ROM at the index segment showed a tendency of increase after surgery, increasing from 5.53 ± 0.39°...
TABLE 3. Clinical Parameters

|               | Preop (N = 30) | 1 yr Postop (N = 30) | 2 yr Postop (N = 20) | 3 yr Postop (N = 15) | P  |
|---------------|----------------|----------------------|----------------------|----------------------|----|
| VAS (back pain) | 8.40 ± 0.19    | 1.25 ± 0.19          | 1.40 ± 0.25          | 1.46 ± 0.32          | 0.001 |
| VAS (leg pain)  | 5.63 ± 0.64    | 0.85 ± 0.24          | 0.72 ± 0.24          | 0.51 ± 0.22          | 0.001 |
| ODI           | 40.83 ± 1.77   | 14.57 ± 0.85         | 15.45 ± 1.17         | 15.20 ± 1.14         | 0.001 |

Preop indicates preoperative; postop, postoperative; VAS, visual analogue scale; ODI, Oswestry Disability Index.

Working Status
Before surgery, all patients were at full-time job. At the end of follow-up, 18 patients went back to their original work, and 8 patients changed jobs, with the last 4 patients stopping working. When asked whether they were going back to work, only 2 of the 4 patients said yes. But the exact timing when an individual returned to original work or changed jobs was not captured.

Complications
In this study, no device failure or major complications occurred, nor did neurological deterioration. At the final follow-up, only 1 patient complained of residual low back pain (VAS 5) and leg pain (VAS 4) at 35 months after surgery, and the ODI score was 20 points. There were 2 patients (6.7%) with early complications: both experienced a tear of iliac vein and were repaired immediately, leaving no hematoma after surgery. Prosthesis subsidence was observed in 3 (10.0%) patients (1 was 3.2 mm at 1 yr postoperatively, 1 was 4.1 mm at 2 yr postoperatively, and 1 was 3.6 mm at 3 yr postoperatively) but no symptoms appeared. An example of prosthesis subsidence is shown in Figure 4. Comparing with radiography at 1 month postsurgery (Figure 4A), patient showed obvious prosthesis subsidence at 12 months postsurgery (Figure 4B), and it was worse 26 months postsurgery (Figure 4C). Heterotopic ossification was observed in 1 (3.3%) patient at 36 months postoperatively without any symptom. Of all the male patients, no retrograde ejaculation was observed. During our 1- to 3-year follow-up, no revision surgery was performed.

DISCUSSION
Total disc replacement in the lumbar spine attempts to preserve or restore motion at the index segment and to eliminate pain at the operated segment. In this study, we provide a 1- to 3-year follow-up data on patients operated with activ L total disc replacement.

First of all, safety and effectiveness of active L total disc replacement were demonstrated with successful rate of 86.7% at the final follow-up. Our results are similar to those previously published about TDR.17,18 Most patients showed significant improvement of VAS and ODI scores. This improvement may not just be related to replacement of the degenerative painful disc but also to the unloading of the facet joints after restoration of the disc height. Trouillier et al19 confirmed this theory in a prospective morphological study of facet joint integrity after a CHARITÉ disc replacement, concluding that decreases in subchondral bone density of the facet joint at the replaced segment suggest a reduction in the loading of the posterior column after a disc replacement. But 1 patient in our study had an atypical outcome. The patient complained of residual low back pain (VAS 5) and leg pain (VAS 4) at 35 months after surgery, and the ODI score was 20 points. Plain radiographs showed that the prosthesis was in correct position, and the ROM of index segment was 7° by then. Neurological assessment revealed no abnormality of the lower limbs. Conservative treatment was effective to relieve the pain, but when asked to be re-evaluated, he refused the advice.
In this study, dynamic radiographs were obtained from patients. Patients were told to maximally flex and extend in order to recruit the lower lumbar segments because they were the last to be recruited. Although there is no standard method for obtaining dynamic radiographs, seating position seems to be better. Burkus et al. noted that dynamic radiographs obtained with the standing patients are not reliable because the technician is not always able to properly center the beam on the appropriate interspace, and also the pelvis is not locked allowing motion through the hip joints rather than the lumbar spine during the desired motion. Thus, our results may not be exactly the precise ROM, probably a little higher. Because of the relatively small sample size, we did not analyze the data by different index segments and that might also affect our results.

In a study comparing CHARITÉ with ProDisc L, Shim et al. found that, in ProDisc L group, postoperative ROM was 11.9° in L4–L5 and 5.6° in L5–S1, which were significantly less than those of the CHARITÉ group. Ziegler et al. reported a mean ROM for ProDisc L TDR of 7.7°, 2 years after surgery but did not report the method of measurement. In our study, ROM was slightly increased at the index segment and the upper adjacent segment from 5.52 ± 0.39° and 5.07 ± 0.39° preoperatively to 7.68 ± 0.60° and 8.43 ± 0.69° at the 3-year follow-up, with significant differences (P1 = 0.0128, P2 = 0.0007). But these differences can be partly explained by the fact that patients with lumbar disc herniation cannot maximally flex or extend preoperatively because of pain, which resulted in a smaller ROM. The mean sagittal ROM of 8.43° of the index segment is little higher than that in other results, which is partly contributed by the position of the patients when taking radiographs. Although Huang et al. reported a positive but weak correlation between ROM and several clinical outcomes, the association between postoperative ROM and clinical outcome has not been established. The IDH of the index segment increased immediately after surgery and slowly decreased over time. But at the 3-year follow-up, neither index segment nor adjacent segments showed significant difference in IDHs compared with the preoperative IDHs.

In this study, 2 patients experienced a tear of iliac vein, which was repaired immediately, leaving no hematoma after surgery. Prosthesis subsidence was observed in 3 patients but no symptoms appeared. Two of the 3 patients had bisegmental TDR. Prosthesis subsidence seems more likely to appear in bisegmental TDR patients. Because there was no significant increase of ROM in the index segment, the more severe biomechanical changes brought about by bisegmental TDR may contribute to the prosthesis subsidence of the 3 patients. Heterotopic ossification was observed in 1 patient at 36 months postoperatively without any symptom. The rate of heterotopic ossification and its reason are still controversial. David found that early mobilization and active physiotherapy play a significant role in preventing ossifications.

Taken together, this 1- to 3-year follow-up of patients operated with activ L prosthesis showed satisfactory clinical and radiographical outcomes, but the small increase of ROM for patients with more than 3 years’ follow-up at index segment was our major concern. The long-term results of activ L total disc replacement still need to be evaluated.

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**Key Points**

- Effectiveness of activ L TDR on DDDs was evaluated with the clinical and radiographical results.
- The general successful rate was 86.7% at 3 years postoperatively.
- VAS score for low back pain and leg pain, and ODI scores significantly improved after surgery.
- ODI at the index segment and upper and lower adjacent segments were showing no significant difference compared with preoperative scores.
- ROM of the index and upper adjacent segments showed significant increase at year 3, whereas ROM at lower adjacent segment was not significantly changed.
