

Results of Charité Artificial Lumbar Disc Replacement: Experience in 43 Thais

Pairoj Warachit MD*

* Department of Orthopedics, Hat Yai Regional Hospital, Hat Yai, Thailand

Objective: To demonstrate the results of artificial lumbar disc replacement in Thai patients with degenerative disc disease.

Material and Method: A prospective study had been conducted to evaluate the efficacy and safety of artificial lumbar disc replacement in patients from October 2004 to December 2007. Oswestry disability index (ODI) score and visual analogic scale (VAS) for pain had been used to assess the clinical result before and after surgery.

Results: Forty three patients diagnosed as degenerative lumbar disc disease underwent 50 artificial lumbar disc replacement. All patients markedly improved in both ODI and VAS. The mean ODI score decreased from 60.9 % preoperative to only 9.8 % postoperative. The VAS score also decreased from 7.44 to 1.3 at the final follow up period. No serious complication found from this procedure.

Conclusion: We demonstrated a good short term, a critical outcome of Charité artificial lumbar disc replacement in Thai patient with degenerative lumbar disc disease.

Keywords: Artificial disc replacement, Degenerative disc disease

J Med Assoc Thai 2008; 91 (8): 1212-7

Full text. e-Journal: <http://www.medassocthai.org/journal>

Degenerative disc disease (DDD) is a major cause of low back pain and disability. A number of surgical treatment have been developed to solve this problem especially - those whose are not response to conservative treatment. However, spinal fusion which is considered as a gold standard has some drawbacks such as persistent back pain, loss of mobility and adjacent level degenerative disease. These led to the development of prosthesis aimed to preserve this motion segment.

Kurt Schellnack and Karin Büttner-Janzen developed the Charité prosthesis in 1982 at the Charité Hospital in Berlin, Germany. The SB Charité I had problems with subsidence, while SB Charité II had fractures of the wings. Since 1987 the prosthesis was redesigned as SB Charité III so that the surface was modified to allow bony in growth for better anchoring of the end plates. Currently it has been used worldwide nowadays as an alternative surgery for candidate younger than 50 years, if more than this, the patient

should have good bone quality. Lemaire et al from France reported series of 105 patients for whom the mean follow-up period was 51 months, the results of 79% of the subjects had revealed excellent results, a relative gain of more than 70%, while the remain of 5.8%, and 15.2% had a relative gain ranging between 60-70% and less than 60%, respectively. Bad results were attributed to either inappropriate indications such as osteoporosis, posterior osteoarthritis, overlying lumbar thoracolumbar kyphosis, secondary progression of a posterior facet joint syndrome. The return to work status was 87%, which about two-third had maintained in the same work, and one-third had changed of the work while 13% were unemployment. Of the same work group, the quality of heavy workers had achieved to 45%⁽¹⁾.

In Thailand, there are limited a number of patients with DDD underwent artificial disc replacement despite it has been used world wide for 20 years. The aim of the study is to prospectively evaluate the results of artificial disc replacement in patients with DDD using Oswestry disability index (ODI) score and pain by visual analogic scale (VAS)^(2,3).

Correspondence to: Warachit P, Department of Orthopedics, Hatyai Hospital, Songkhla 90110, Thailand.

Material and Method

Artificial lumbar disc Charité had been performed from October 2004 to December 2007 among the patients who had DDD and failing nonoperative treatment were enrolled to be performed the lumbar disc replacement. There were 43 subjects, 26 males and 17 females and the mean age at the time of surgery was 42.3 years, range of 23-54 years. The primary diagnosis was chronic low back pain. There were ruptured disc in 19 cases (44.2%), all of them had radiculopathy, the rest had only chronic low back pain.

Diagnosis was done by plain X-Ray of L-S spine and magnetic resonance imaging (MRI), all were dark disc and 50% had narrow disc space.

Surgical technique

All patients underwent surgical treatment through an open anterior approach. Patients were placed in the supine position on a folding operating table with the break in the table directly below the affected disc. Fluoroscopy was used to identify the approach angle and the location of the disc space to be addressed with markings on the patient's abdomen. The approach was performed in standard fashion, with the assistance of an access surgeon in the majority of cases. Following appropriate mobilization of vascular structures, great care was taken to protect the sympathetic plexus.

A complete disectomy was performed, including removal of the cartilaginous vertebral endplates, using standard anterior lumbar surgical instruments. The bony vertebral endplates were left intact and shaped to be parallel. Instruments specific to the artificial disc were used to assess proper footprint sizing, lordotic angle, core height, and placement of the prosthesis within the disc space under live fluoroscopy.

Once the correct prosthesis endplate footprint, core height, and lordotic angle were established, the prosthesis endplates were inserted into the disc space in a trajectory parallel to the vertebral endplates as determined from anteroposterior and lateral fluoroscopy. Assessment of the correct core height was made followed by implantation of the sliding core between the two prosthesis endplates. Final positioning was confirmed with fluoroscopy. A complete disectomy was performed with preservation of the peripheral annulus fibrosis to facilitate restoration of normal disc space height, the subchondral bone on the vertebral endplates provide stability and prevent implant subsidence, so the amount of subchondral bone was preserved⁽⁴⁻⁷⁾.

The distribution of the prosthesis size used in this study was shown in Table 1. The appropriate prosthetic size had been performed and the majority of cases elected to utilize the prosthesis size 3 of 32 in 50 discs (64%).

All patients completed the self-assessment ODI form and scored pain on a VAS preoperative and postoperative where is appendix A. ODI score and VAS pain score were filled at 1, 3, 6, 12 months and 2 years postoperative.

All patients were radiographic evaluation postoperative using plain radiograph of lumbar spine to check position and size of artificial disc.

Results

The total of 50 artificial lumbar disc replacements had been performed. L4-L5 level was the most common level of surgery, followed by L5-S1. The L3-L4 disc was substituted in one patient. Double disc replacement was done in 7 patients. The detail of end plate prosthesis was shown in Table 2.

The mean preoperative ODI score was 60.9% dramatically decreased to 9.8% at 1-month postoperative. The mean VAS pain score also decreased from 7.4 preoperative to 1.3 postoperative as shown in Fig. 1. Three patients demonstrated as unsatisfactory outcome due to one patient had malalignment of prosthesis more

Table 1. Distribution of prosthesis size utilization

Prosthesis size	Number (%) n = 50
2	7 (14)
3	32 (64)
4	10 (20)
5	1 (2)

Table 2. End plate prosthesis at different levels

Prosthesis level	Upper / lower end plate	Number of levels
L3-L4	0° / 5°	1
L4-L5	0° / 0°	4
	0° / 5°	23
	0° / 7.5°	6
L5-S1	0° / 5°	8
	0° / 7.5°	7
	0° / 10°	1

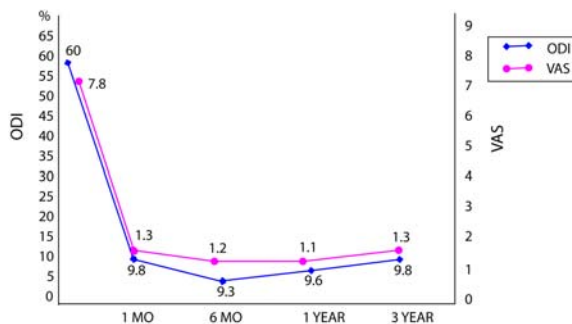


Fig 1. Mean Oswestry disability index (ODI) score and visual analogic scale (VAS) pain score of the patients

than 4 mm, one had loosening, and the last one due to inadequate removal of degenerative ruptured disc from anterior disectomy.

The position of the artificial disc was considered as good in 93% of cases. There were no serious complications in all 43 cases. Two cases with malalignment denied to be reoperated. One case had loosening of L5-S1 and underwent reoperation by retrograde peritoneal approach on the right side to avoid adhesion. But finally interbody fusion with cage and pedicular screw fixation posterior was done with clinical improvement.

Discussion

Spinal fusion is an option to treat chronic low back pain patients from DDD that is not responding to conservative measure. However, significant complications such as donor site pain, prolonged period of postoperative recovery, pseudoarthrosis adjacent degenerative level, facet joint arthritis and instability had been reported⁽⁵⁾. Artificial disc replacement has been innovated an alternative with an aim to preserve segmental motion, to reduce force on the adjacent segments and facilitates postoperative mobilization.

Guyer et al⁽⁶⁾ compared the results of Charité artificial disc arthroplasty (100 cases) with anterior lumbar interbody fusion using cages (40 cases) using ODI score by prospective randomized study and they found that both surgical groups improved significantly. Blumenthal et al⁽⁷⁾ reported a prospective, randomized, multicenter, Food and Drug Administration-regulated Investigational Device Exemption clinical trial in 304 patients compared Charité artificial disc and anterior interbody fusion and found that patients in the Charité artificial disc recovered faster with lower levels of ODI score at every time interval and had statistically lower

pain scores ($p < 0.05$) and shorter hospital stay ($p < 0.05$).

Gioia et al⁽⁸⁾ reported 36 patients using 45 disc replacements for medium-term results in 7 years and found the mean ODI score dropped from 44% to 9% and the VAS pain score dropped from 8 to 1.4%. Ninety two percent of patients had excellent or good results. Our study showed that all 43 patients were safe without serious complication. The mean ODI score dropped from 60.9% to 9.8% and the VAS pain score dropped from 7.44 to 1.3 postoperative. However, as artificial disc replacement is a new technique in Thailand, it needs long term follow up as in a series of Putzier et al⁽⁹⁾ with 71 patients treated with 84 Charité disc type I-III and found 60% rate of spontaneous ankylosis after 17 years although there were no adjacent segment degeneration in all those cases but 11% had to reoperate. Besides Punt et al⁽¹⁰⁾ reported late complications such as subsidence, migration, wear of the disc prosthesis, facet joint degeneration or adjacent degeneration in various combinations.

In conclusion, we confirmed a good short term clinical result in patients diagnosed as degenerative lumbar disc disease treated with Charité artificial lumbar disc replacement in Thais.

References

1. Lemaire JP, Skalli W, Lavaste F, Templier A, Mendes F, Diop A, et al. Intervertebral disc prosthesis. Results and prospects for the year 2000. *Clin Orthop Relat Res* 1997; 64-76.
2. Fairbank JC, Pynsent PB. The Oswestry disability index. *Spine* 2000; 25: 2940-52.
3. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. *Physiotherapy* 1980; 66: 271-3.
4. DePuySpine. Surgical technique [homepage on the Internet]. 2003-2008 [cited 2008 Jun 24]. Available from: <http://www.depuyspine.com/>
5. Lee CK, Parsons JR, Langrara NA, Zimmerman MC. Scientific basis: relative efficacy of the artificial disc versus spinal fusion. In: Weinstein JN, editor. *Clinical efficacy and outcome in the diagnosis and treatment of low back pain*. New York: Raven Press; 1992: 237-44.
6. Guyer RD, McAfee PC, Hochschuler SH, Blumenthal SL, Fedder IL, Ohnmeiss DD, et al. Prospective randomized study of the Charite artificial disc: data from two investigational centers. *Spine J* 2004; 4: 252S-9S.
7. Blumenthal S, McAfee PC, Guyer RD, Hochschuler

- SH, Geisler FH, Holt RT, et al. A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the Charité III artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. Spine 2005; 30: 1565-75.
8. Gioia G, Mandelli D, Randelli F. The Charité III Artificial Disc lumbar disc prosthesis: assessment of medium-term results. J Orthopaed Traumatol 2007; 8: 134-9.
9. Putzier M, Funk JF, Schneider SV, Gross C, Tohtz SW, Khodadadyan-Klostermann C, et al. Charite total disc replacement - clinical and radiographical results after an average follow-up of 17 years. Eur Spine J 2006; 15: 183-95.
10. Punt IM, Visser VM, van Rhijn LW, Kurtz SM, Antonis J, Schurink GW, et al. Complications and re-operations of the SB Charite lumbar disc prosthesis: experience in 75 patients. Eur Spine J 2008; 17: 36-43.

ผลลัพธ์ของการเปลี่ยนใส่หมอนรองกระดูกสันหลังเอเวเทียม Charité ประสบการณ์ในผู้ป่วยไทย 43 ราย

ไพโรจน์ วราชาติ

วัตถุประสงค์: เพื่อแสดงให้เห็นผลลัพธ์ของการเปลี่ยนใส่หมอนรองกระดูกสันหลังเอเวเทียม ในผู้ป่วยไทยที่เป็นโรคหมอนรองกระดูกเสื่อม

วัสดุและวิธีการ: เป็นการศึกษาแบบมุ่งหน้าเพื่อประเมินประสิทธิผล และความปลอดภัยของการเปลี่ยนใส่หมอนรองกระดูกสันหลังเอเวเทียม ในผู้ป่วยตั้งแต่เดือนตุลาคม พ.ศ. 2547 ถึงเดือนธันวาคม พ.ศ. 2550 ประเมินผลลัพธ์ทางคลินิกก่อนและหลังผ่าตัดด้วยคะแนน Oswestry disability index (ODI) และอาการปวดด้วย visual analogic scale (VAS)

ผลลัพธ์: ผู้ป่วย 43 รายที่ได้รับการวินิจฉัยว่าเป็นโรคหมอนรองกระดูกเสื่อม ได้รับการเปลี่ยนใส่หมอนรองกระดูกสันหลังเอเวเทียมจำนวน 50 อัน ผู้ป่วยทุกรายมีอาการดีขึ้นทั้งการประเมินด้วย ODI และ VAS ค่าเฉลี่ยของคะแนน ODI ลดลงจากร้อยละ 60.9 ก่อนผ่าตัดเหลือเพียงร้อยละ 9.8 หลังผ่าตัด ส่วนอาการปวดประเมินด้วย VAS ลดลงจาก 7.44 เหลือ 1.3 เมื่อสิ้นสุดการติดตามผลการรักษา ไม่มีภาวะแทรกซ้อนอย่างรุนแรงจากการเปลี่ยนใส่

สรุป: การศึกษานี้เป็นการแสดงผลระยะสั้น และผลที่ได้รับจำเป็นของการเปลี่ยนใส่หมอนรองกระดูกสันหลังเอเวเทียม Charité ในผู้ป่วยไทยที่เป็นโรคหมอนรองกระดูกเสื่อม

Appendix A. Oswestry disability questionnaire

The Oswestry disability index (ODI) is considered the gold standard for assessing the disability level of back pain and is published here for those, who suffer back pain, to assess their disability level. Please answer every section. Mark one block only in each section that most closely describes you today.

Section 1: Pain Intensity

- I can tolerate the pain I have without having to use pain killers. [0 points]
- The pain is bad but I manage without taking pain killers. [1 point]
- Pain killers give complete relief from pain. [2 points]
- Pain killers give moderate relief from pain. [3 points]
- Pain killers give very little relief from pain. [4 points]
- Pain killers have no effect on the pain and I do not use them. [5 points]

Section 2: Personal Care

- I can look after myself normally without causing extra pain. [0 points]
- I can look after myself normally but it causes extra pain. [1 point]
- It is painful to look after myself and I am slow and careful. [2 points]
- I need some help but manage most of my personal care. [3 points]
- I need help every day in most aspects of self care. [4 points]
- I do not get dressed wash with difficulty and stay in bed. [5 points]

Section 3: Lifting

- I can lift heavy weights without extra pain. [0 points]
- I can lift heavy weights but it gives extra pain. [1 point]
- Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned for example on a table. [2 points]
- Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned. [3 points]
- I can lift only very light weights. [4 points]
- I cannot lift or carry anything at all. [5 points]

Section 4: Walking (bad question)

- Pain does not prevent me walking any distance. [0 points]
- Pain prevents me walking more than 1 mile. [1 point]
- Pain prevents me walking more than 0.5 miles. [2 points]
- Pain prevents me walking more than 0.25 miles. [3 points]
- I can only walk using a stick or crutches. [4 points]
- I am in bed most of the time and have to crawl to the toilet. [5 points]

Section 5: Sitting ("Favorite chair" includes a recliner)

- I can sit in any chair as long as I like. [0 points]
- I can only sit in my favorite chair as long as I like. [1 point]
- Pain prevents me sitting more than 1 hour. [2 points]
- Pain prevents me from sitting more than 0.5 hours. [3 points]
- Pain prevents me from sitting more than 10 minutes. [4 points]
- Pain prevents me from sitting at all. [5 points]

Section 6: Standing (Remember, standing is NOT walking)

- I can stand as long as I want without extra pain. [0 points]
- I can stand as long as I want but it gives me extra pain. [1 point]
- Pain prevents me from standing for more than 1 hour. [2 points]
- Pain prevents me from standing for more than 30 minutes. [3 points]
- Pain prevents me from standing for more than 10 minutes. [4 points]
- Pain prevents me from standing at all. [5 points]

Section 7: Sleeping

- Pain does not prevent me from sleeping well. [0 points]
I can sleep well only by using tablets. [1 point]
Even when I take tablets I have less than 6 hours sleep. [2 points]
Even when I take tablets I have less than 4 hours sleep. [3 points]
Even when I take tablets I have less than 2 hours of sleep. [4 points]
Pain prevents me from sleeping at all. [5 points]

Section 8: Sex Life (by pain = for fear of causing pain)

- My sex life is normal and causes no extra pain. [0 points]
My sex life is normal but causes some extra pain. [1 point]
My sex life is nearly normal but is very painful. [2 points]
My sex life is severely restricted by pain. [3 points]
My sex life is nearly absent because of pain. [4 points]
Pain prevents any sex life at all. [5 points]

Section 9: Social Life

- My social life is normal and gives me no extra pain. [0 points]
My social life is normal but increases the degree of pain. [1 point]
Pain has no significant effect on my social life apart from limiting energetic interests such as dancing. [2 points]
Pain has restricted my social life and I do not go out as often. [3 points]
Pain has restricted my social life to my home. [4 points]
I have no social life because of pain. [5 points]

Section 10: Traveling

- I can travel anywhere without extra pain. [0 points]
I can travel anywhere but it gives me extra pain. [1 point]
Pain is bad but I manage journeys over 2 hours. [2 points]
Pain restricts me to journeys of less than 1 hour. [3 points]
Pain restricts me to short necessary journeys under 30 minutes. [4 points]
Pain prevents me from traveling except to the doctor or hospital. [5 points]

Interpretation:

Now, simply add up your points for each section and plug it in to the following formula in order to calculate your level of disability: **point total / 50 X 100 = % disability (aka: 'point total' divided by '50' multiply by '100 = percent disability)**
For example: my Current level of disability, 11-11-04 is calculated as follows: 14 / 50 X 100 = 28%

ODI Scoring:

0% to 20%: minimal disability: The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.

21%-40%: moderate disability: The patient experiences more pain and difficulty with sitting lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.

41%-60%: severe disability: Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.

61%-80%: crippled: Back pain impinges on all aspects of the patient's life. Positive intervention is required.

81%-100%: These patients are either bed-bound or exaggerating their symptoms.