Revision strategies of the Charité lumbar disc prosthesis: clinical results after a follow-up of 3 years

+1Punt, IM; 1Willems, PC; 2Kurtz, SM; 1van Rhijn, LW; 1,3van Ooij, A
+1Maastricht University Medical Centre and Research School CAPHRI, Maastricht, the Netherlands, 2Drexel University and Exponent, Philadelphia, PA, 3VieCuri Medical Centre, Venlo, the Netherlands, i.punt@mumc.nl

INTRODUCTION:
Total disc replacement (TDR) with the SB Charité lumbar disc is a frequently used alternative to spinal fusion in the treatment of degenerative disc disease (DDD). The aim of the disc prosthesis is preserving the vertebral motion at the operated level(s) and to prevent adjacent disc degeneration. In 2004, the United States Food and Drug Administration (FDA) approved the use of the SB Charité lumbar disc prosthesis. Recently, Guyer et al. [1] showed that there were, after a follow-up period of 5 years, no differences in safety and clinical outcomes between the use of spinal fusion vs. TDR. These findings were comparable with the 2 year follow-up results. They also showed that only in the TDR group device failures were observed between the 2 and 5 year time points, while no failures were seen in the fusion only group [1]. Although the discussion concerning the advantages and the durability of the disc prosthesis compared to spinal fusion is still ongoing; the introduction of every new device, unfortunately, warrants the need for surgical revision strategies.[2]

The purpose of this study was to compare the clinical results at 3 year follow-up of two salvage operations of the SB Charité III lumbar disc prosthesis in patients with severe back and leg pain. Posterior fusion without disc prosthesis removal was compared with removal of the disc prosthesis combined with posterior and anterior fusion.

METHODS:
Study design:
Ninety patients with persistent pain complaints after insertion of the Charité disc prosthesis were seen at the Maastricht University Medical Centre, the Netherlands. Thirty-four out of these 90 patients needed one or more salvage operations. In 15 patients posterior fusion without removal was performed, and in 27 patients the prosthesis was removed and posterior and anterior fusion was performed (Figure 1). In eight of these 27 patients posterior fusion alone was performed several years earlier (range 1 ½ - 7 ½ years).

Figure 1: Lateral X-ray of a) posterior fusion L5-S1 without removal of the disc prosthesis,
       b) removal disc prosthesis and posterior and anterior fusion L3-4.

Clinical outcome measures:
Clinical evaluations were completed before revision surgery and at 1, 2 and 3 years post-surgery. This included a 10-point Visual Analogue Scale (VAS) for pain, Oswestry Disability Index (ODI) and Short Form 36 (SF36) health survey questionnaire. Clinical success rate was defined as a ≥15-point improvement in ODI.

Statistical analysis:
Analyses were performed using SPSS 16. Non parametric tests, i.e. Mann-Whitney and Wilcoxon were used to test means. P-values <0.05 were considered statistically significant.

RESULTS SECTION:
VAS pain scores:
In the removal group the VAS scores were significantly lower at all postoperative time points compared to preoperative (p<0.02). In the fusion only group, only a significant decrease at 2 year follow up compared to preoperative was found (p<0.03). At three year follow-up, the VAS score was significantly lower in the removal group (5.5) compared to the fusion only group (7.7), p<0.01 (Figure 2).

Figure 2: Mean VAS for both groups at all time points. The error bars represent the standard deviation.

Oswestry Disability Index:
The ODI decreases in the first year in the fusion only group from 60.4 (sd 13.1) to 49.2 (sd 19.8) (p=0.05), and in the disc removal group from 54.9 (sd 15.1) to 43.4 (sd 18.9) (p=0.02). No differences were found at the time points two and three year after revision surgery compared to one year follow up. There were no significant differences between the two groups in time.

The clinical success rates were equal in both groups. The percentage of patients with a 15-pt improvement in ODI versus baseline was tabulated per group and time point (Figure 3).[1]

Figure 3: Percentage of patients with at least 15-pt improvement in ODI, for each group and at all time points.

Short Form 36 (SF36) health survey questionnaire:
No significant differences were found in any SF36 sub score between the two groups at all time points.

DISCUSSION:
Revision surgery strategies of failed TDR’s still have largely unknown long-term follow-up results. Our results indicate that the removal gives slightly better results than posterior fusion alone after a follow-up of three years. The VAS pain score differs significantly between the two groups 3 years after revision surgery.

A limitation of this study is that the results are based on a relatively small number of patients (27 vs. 15 patients). Larger groups with longer follow-up periods are necessary for a more definitive conclusion.

In a previous study, fibrous tissues of the first 16 patients with removal of the prosthesis were studied with light microscopy. Results of this study demonstrate the presence of polyethylene wear particles and of peri-prosthetic inflammatory reactions around symptomatic artificial intervertebral discs in 15 out of 16 patients. [3] An important point of consideration is that removal of the prosthesis has increased risks compared to fusion only. Possibly the inflammatory reaction around the prosthesis is eliminated by removal and fusion and hence the pain diminishes more than after fusion without removal.

REFERENCES: