Survival and clinical outcome of SB Charité III disc replacement for back pain

Between January 1990 and December 2000 we carried out 226 SB Charité III disc replacements for lumbar disc degeneration in 160 patients. They were reviewed at a mean follow-up of 79 months (31 to 161) to determine the clinical and radiological outcome. The clinical results were collected by an independent observer, who was not involved in patient selection, treatment or follow-up, using a combination of outcome measures, including the Oswestry Disability Index. Pain was recorded using a visual analogue score, and the most recent radiographs were reviewed.

Survival of the device was analysed by the Kaplan-Meier method and showed a cumulative survival of 35% at 156 months when radiological failure was taken as the end-point. The mean improvement in the Oswestry disability index scores after disc replacement was 14% (6% to 21%) and the mean improvement in the pain score was 1.6 (0.46 to 2.73), both falling below the clinically significant threshold. Removal of the implant was required in 12 patients, four because of implant failure.

These poor results indicate that further use of this implant is not justified.

Degenerative disc disease of the lumbar spine is common and has a wide spectrum of presentation. In most patients it is a self-limiting condition that can cause intermittent pain and inconvenience, but in a minority it is responsible for significant disability and reduction in the quality of life. The traditional surgical approach has been to fuse the affected levels. However, within the last 15 years prostheses for lumbar disc replacement have become available as an alternative to fusion. The theoretical benefits of disc replacement are preservation of motion of the operated segment and the prevention of pseudarthrosis, disease in adjacent segments and arthritis of the facet joints. It also avoids the morbidity associated with harvesting bone graft.

The Link SB Charité III disc replacement (Waldemar Link, Hamburg, Germany/Depuy Spine International Limited, Leeds, United Kingdom) is an unconstrained three-part lumbar disc prosthesis (Fig. 1). It was originally designed by Büttner-Janz. The current model represents the third version of the prosthesis and has been in use since 1987.

The prosthetic disc has a central sliding polyethylene core which attempts to mimic the coupled movement of a normal disc, and two chrome-cobalt steel endplates which are embedded into the subchondral bone. The free sliding polyethylene core is retained in place by the geometry of the implant and by the tension of the soft tissues. A hydroxyapatite coating to facilitate long-term ingrowth of bone was introduced to the European market in 1995, but as yet this is not available in the USA.

We present our experience of using this prosthesis over a nine-year period.

Patients and Methods

Between January 1990 and December 2000 a total of 226 SB Charité III discs were implanted in 160 patients. There were 62 men and 98 women with a mean age of 46 years (27 to 73). The indications for operation included chronic low back pain for at least 12 months, failure to respond to conservative treatment, an Oswestry disability index (ODI) score > 30%, one or more degenerative discs on MR scan and concordant pain on discography. Patients with spondylolytic spondylolisthesis with degenerative discs at the lytic level were excluded.

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Technique of operation. All the operations were performed by the senior author (RR). The patient is anaesthetised and placed in the supine position, and an anterior transperito-
neal or retroperitoneal approach to the spine is made. The majority of the surgery was carried out via a transperitoneal approach, as this has significant advantages over the retroperitoneal approach for replacement of the L5-S1 disc and may be easily adapted for access to L4-5. These two levels are those replaced most frequently. The abdomen is opened through a midline incision, which rarely needs to go above the umbilicus for an L5-S1 disc, but may be extended for higher levels. The small and large bowel are carefully displaced superolaterally, protected by moist swabs and a self-retaining retractor. The posterior peritoneum is opened in the midline, identifying the right ureter for the L5-S1 level and proceeding over the left common iliac vessels to approach the higher discs from the left side. At the lowest level the sacral promontory is obvious, as is the bifurcation of the great vessels. It is possible to identify the hypogastric plexus and displace it to the left with the retroperitoneal fat. The sacral vessels are divided. Diathermy should not be used at this level in order to reduce the incidence of injury to the hypogastric plexus. At higher levels the iliolumbar vein should be identified and ligated. The iliac artery and vein need to be retracted to the right, to expose the disc. The segmental vessel is divided above the disc rather than risking avulsing it from either major vessel.

Pins are inserted into the vertebral bodies above and below the disc to retract the soft tissues. The anterior annulus is incised in a rectangular fashion and removed. The central disc material is removed to expose the posterior longitudinal ligament. The posterior annulus is excised. It may be necessary to use spacers to restore the height of the disc.

All the disc material is removed and the endplates exposed to bleeding bone. Once preparation is complete, the appropriate size of prosthesis is implanted using the instrumentation designed to ensure a snug fit. The position is checked using an image intensifier.

Of the prostheses, 114 were placed at the L5-S1 level, 92 at L4-5 and 20 at L3-4.

An independent observer (HEN) who was not involved in the care of the patients reviewed the records and arranged for the completion of a questionnaire. Oswestry disability index scores, visual analogue scales and psychological questionnaires were administered to all patients pre-operatively but collected retrospectively with some loss of pre-operative data. The same information and a patient satisfaction measure was obtained post-operatively by telephone. Those patients who were not contactable by telephone were sent the questionnaire by post.

The mean follow-up was 79 months (31 to 161). Anteroposterior (AP) and lateral flexion/extension radiographs of the lumbar spine, taken at the last available review of each patient were reviewed by the senior author (RR) and quantitative measurement of the movement at the prosthesis was recorded. A pre-designed proforma was used to list
these findings. The radiographs were assessed to record the following information: evaluation of the position of the disc in the AP and lateral views, quantitative assessment of spinal movement in flexion and extension with an overall value of the range of movement, measurement of the disc height, evidence of osteolysis around the prosthesis or of heterotopic ossification and evidence of degenerative change in the facet joints.

Information about 37 patients was excluded as 24 were lost to follow-up, two died post-operatively from unrelated causes, one declined to participate in the study, and ten had 12 implants removed, thereby causing them to fall outside the assessment proforma for technical reasons. This left 123 patients available for follow-up.

Statistical analysis was carried out using XLSTAT version 7.0 statistical software (Addinsoft, New York, New York). The non-parametric distribution of variables was established by the Shapiro-Wilk test, and Wilcoxon’s signed-ranks test was used to compare the variables. Kaplan-Meier survival analysis was performed using various end-points.

**Results**

The ODI and pain scores are shown in Table I. The minimal clinically important difference of improvement in the ODI was a change of 15% or more between the pre-operative score and that at the final follow-up, and with the pain score a change of two points or more between the pre-operative score and that at final review. The mean pre-operative ODI score was 51 (95% confidence interval (Cl) 47.7 to 54.5) and this fell to 37 (95% CI 33.1 to 41.6) at the time of the final review. This mean difference of 14 falls below the benchmark for clinical improvement. The mean pre-operative pain score was 6.3 (95% CI 5.75 to 6.89), and this fell to 4.7 (95% CI 4.16 to 5.29) at the time of final review.
Patient satisfaction and the final ODI and pain scores are shown in Table II. Patients who were satisfied with the outcome of treatment had better ODI and pain scores.

Radiological assessment showed that the movement at the lumbosacral level was greater than at the more proximal levels (Table III). Movement was defined as more than 4° on the flexion/extension lateral views, a definition accepted by the Federal Drug Administration as a definition for fusion. It has been clearly shown that radiological measurement of range of movement, particularly using the Cobb technique, is susceptible to variability and measurement error. We used a number of factors to reduce this error, including inter-observer discussion.

The Kaplan–Meier survival analysis was performed, with removal of the implant or radiological failure, as defined by a broken wire, subsidence and lack of movement as the end-points (Fig. 2).

The cumulative rate of survival for implants using removal of the implant as the end-point was 90% at 101 months. The mean survival was 147 months (95% CI 140 to 154). The cumulative survival when all radiological failures were taken as the end-point was 90% at 101 months, reducing to 35% at 156 months (Fig. 3). The mean survival was 124 months (95% CI 116 to 133).

Complications. The causes for failure of the implant and removal are shown in Table IV. Early deep infection requiring removal of the implant was not seen in this series. Removal of the implant within one month was necessary because of a peri-operative fracture of S1 in one patient.

Displacement of the implant was evident from two months after operation and onwards, and required its removal in three patients. A further four required removal due to implant failure at 13, 26, 40 and 106 months, respectively after operation. The pain after operation was significantly worse than before in two patients. Whereas a posterior fusion might have been carried out in these cases, the senior author elected to remove the implant to try to assess why failure had occurred to assess the prosthesis for ultra high molecular weight polyethylene (UHMWPE) deformation and wear.

The general surgical complications are shown in Table V.

### Discussion

Lumbar disc replacement is a revolution in spinal surgery, heralding a similar change in practice as did Charnley’s total hip prosthesis. The preservation of mobility at a diseased spinal level is a laudable aim. However, as Lemaire has pointed out, there are other equally important objectives if replication of disc function is to be achieved. These include variable stiffness characteristics and the ability to respond to vibrating and rapidly varying loads.

Numerous short-term studies are available on clinical outcome, but to date there are only two long-term clinical, radiological and survival reviews of disc replacement. That by Lemaire et al described a review of 147 prostheses in 100 patients with a minimum follow-up of ten years. Clinically, 62% had an excellent outcome, 28% were good and 10% were poor. The authors recorded movement...
of 12˚ at L3-L4, 9.6˚ at L4-L5 and 9.2˚ at L5-S1. This is in marked contrast to the series by Putzier et al., who described the outcome in 53 patients with 63 disc replacements and a follow-up of 17 years. Spontaneous fusion was noted in 60%, although this may just have been an expression of lack of movement.

Our study shows that meaningful mobility of the lower lumbar levels may not be achieved over any length of time using this device. In addition, there appears to be no variable compressibility of the implant.

Some authors have suggested that the patterns of movement for this particular prosthesis may be very abnormal. The ODI scores in our series show that no clinically meaningful improvement in pain has been achieved. This contrasts with Lemaire’s findings. The study by Putzier et al. suggests that those patients with spontaneous fusion were clinically better than those whose implants continue functioning.

Prospective randomised studies initially showed little difference between disc replacement and fusion, but further analysis has shown disc replacement to be marginally superior.

Our findings suggest that patient satisfaction on a more subjective level was more encouraging, with 68% of the 123 patients feeling ‘better’ or ‘much better’. This is far below the results achieved by Lemaire et al., but 12% better than those of Putzier et al.

Kaplan-Meier cumulative survival analysis of our cohort showed a fall in implant survival after 100 months. Other published studies with a shorter follow-up have shown early evidence of a similar fall in implant survival, but chose to attribute this at least partly to the youth of the patients and their levels of activity.

The modes of failure we encountered were subsidence, displacement or mechanical failure, suggesting that improvement in the design of the implant is required. This may be related to the fact that the cobalt-chromium endplates bear three small projections at the front and back. In several cases these have been seen to afford insufficient bony purchase.

Other authors describing the short-term results of the Charité III prosthesis have shown subsidence, perhaps linked to the anchoring teeth, to be of concern. In our series implant failure occurred from 13 to 106 months after insertion.

In two patients there was severe intractable back and/or leg pain, necessitating removal of the implant at 12 and 22 months after operation, respectively. As any revision and removal will require an anterior approach to the spine, it becomes a significantly more serious undertaking and may even pose a threat to life. We have noted that, on removal the polyethylene component of the Charité III implant has shown an inordinate amount of wear, considering the length of time in situ (Fig. 4), and this may result in excessive load bearing by the facet joints, causing pain. Overall rates of success quoted in the literature range from 60% to 83%, but our findings corroborate other studies showing revision rates of up to 25%. There are no published comparative studies on the role of the hydroxyapatite coating. Other factors, such as patient selection, the incidence of cigarette smoking and body mass index, may well need further investigation, and comparison with other implants in a randomised study is needed.

Recipients of Charité III disc replacements, the majority of whom are young, should be counselled regarding the high risk of re-operation, and the further use of this prosthesis should be abandoned.

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References