Lumbar total disc replacement

History

Lumbar arthroplasty history.

Devices

Lumbar arthroplasty devices

Indications

Lumbar total disc replacement emerged as an alternative to lumbar fusion, but its use and indications are still subject to debate.

The indications for total disc replacement (TDR) remain specific and the procedure should only be done in valid cases of discogenic pain in selected patients.

Charité III (LINK SB, DePuy, Warsaw, IN, USA) was the TDR of choice in much of America and Europe during the late 90s and onwards. The design is modular, comprising two metal endplate components fashioned with convex articulating surfaces which oppose a central polymer inlay component. Much of the long-term data for TDR has been generated from the largely successful Charité III design.

Complications

Complications following TDR are poorly understood and remedies to salvage function following complications are in their infancy.

Short-term complications of TDR include disruption to vascular and neurological structures during the approach, retrograde ejaculation, and haematoma. In the last decade there have been a handful of unfortunate cases of anterior dislocation of the polyethylene inlay of Charité III and ProDisc-L (Synthes, USA) prostheses [1)].

Outcome

Lumbar total disc replacement prognosis

Case series

2017

A series of 51 patients operated on for a one or two level DDD, were evaluated at one year after the surgical procedure. HRQOL was compared to that of paired age and gender general population using the EQ-5D-5L questionnaire. Disability, back (BP) and leg pain (LP) were compared to the preoperative values.

ODI showed a mean improvement of 31.78 ($p<0.001$, 95% CI 27.39-36.17), BP-VAS of 5.29/10 (95% CI 4.56-6.02), LP-VAS of 4.03/10 (95% CI 3.15-4.92) at one year compared to the preoperative assessment. HRQOL had similar values to the general population in 32 patients and inferior in 19 patients. “Pain” was the HRQOL dimension in which most of the patients had inferior results compared to data from the general population. Patients with previous spinal surgery had lower improvements in HRQOL index, disability, and pain than those without previous surgery.

The majority of patients improved their HQOL to values similar to those of the general population. Disability and pain are significantly reduced compared to preoperative evaluations. Larger scale studies are needed to identify the best candidates for LTDR [2)].

2016

A study included 204 patients receiving Kineflex L (investigational) and 190 receiving CHARITÉ (control). Outcome measure included Oswestry Disability Index, visual analog scales (VAS), patient satisfaction, neurological status, complications, reoperations, and a composite success score. Radiographic assessment included range of motion, subsidence, and heterotopic ossification. In 32 investigational patients, serum ion analysis was performed for cobalt and chromium. These values were compared with Medicines and Healthcare Products Regulatory Agency values to merit monitoring total hip replacement patients for potential wear problems.

Mean Oswestry and VAS scores in both groups improved significantly by 6 weeks and remained improved during 5-year follow-up (Oswestry Disability Index, scores in both groups were approximately 60 preoperatively vs. 20 at 2- and 5-year follow-up; $P<0.01$; VAS scores improved >50% by 6 weeks and remained significantly improved; $P<0.05$). Approximately 11% of both groups underwent reoperation. Radiographic analysis found segmental range of motion decreased at 3 month, then increased through 24 months, and was maintained thereafter. Serum ion level analysis found the greatest mean value at any follow-up point was less than 20% of Medicines and Healthcare Products Regulatory Agency recommended minimum value to merit monitoring hip replacement patients.

This prospective, randomized study comparing two TDRs found no significant differences in outcomes during 5-year follow-up. Both provided statistically significant improvements by 6 weeks that were maintained. This results support other studies. Serum ion levels in TDR patients were well below the recommended threshold levels to merit monitoring [3)].

2014

TDR was performed in 457 patients from 21 sites (261 patients in the investigational group (Kineflex-L Disc; metal-on-metal design anchored with keels, 204 randomized and 57 nonrandomized training cases), and 196 in the control group (CHARITE artificial disc; metal with polyethylene core with teeth

for anchoring; 190 randomized and 6 nonrandomized training cases). All patients were treated nonoperatively for single-level symptomatic disc degeneration for at least 6 months prior to surgery. Perioperative data were collected. Clinical outcome data were collected prospectively, as approved by the Food and Drug Administration, through 24-month follow-up. Primary outcome measures used were the Oswestry Disability Index, visual analogue scales assessing pain, patient satisfaction, and reoperations. Success was defined to be at least 15-point improvements in Oswestry Disability Index scores, no reoperation, and no major adverse events. Radiographical measures included range of motion, disc space height, and assessment for device migration, subsidence, and fusion at the TDR level.

There were no significant differences between the groups when comparing operative time, blood loss, or length of hospital stay. Both groups improved significantly on Oswestry Disability Index and visual analogue scale scores ($P < 0.01$) with no differences between the groups. Success rates were similar (68.1% investigational vs. 67.4% control). At 24-month follow-up, 94.1% of the investigational group and 91.9% of controls were satisfied with outcome. Reoperation was performed in 10.3% of the investigational group and 8.4% of the control group.

This prospective, randomized, controlled study comparing 2 TDRs, the first to the authors' knowledge, found the devices produced very similar clinical outcomes. Both groups improved significantly by 6 weeks postoperatively and remained improved throughout follow-up with a high patient satisfaction rate [4].

1)
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2)
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3)
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