PRESTIGE

The PRESTIGE® LP Cervical Disc System is designed to re-establish disc height and permit motion similar to a normal cervical functional spinal unit. The prosthesis is intended to treat stable cervical degenerative disc disease without fusion, thereby providing the patient with the capability for motion at the treated level.

While a fusion with an anterior cervical plate allows most patients to return to normal activities within a very short period of time, the cervical arthroplasty may provide an alternative solution for those patients suffering from degenerative disc disease.

A previously validated C2-First thoracic vertebra osteoligamentous finite element model was used to perform virtual C5-6 arthroplasty using three different FDA-approved cervical artificial discs. A motion-controlled moment loading protocol was used. The moment was varied until Bryan, Prodisc C, and Prestige LP models displayed the same total range of motion across C3-C7 as the intact spine model at 2 Nm of pure moment loading. Range of motion (ROM) and facet force (FF) were recorded at the index level. ROM, FF, and intradiscal pressure (IDP) were recorded at the adjacent levels.

Prodisc C and Prestige LP led to supraphysiologic ROM and FF at the index level while decreasing ROM and FF at the adjacent levels. In contrast, Bryan reduced ROM and FF at the index level. Bryan increased ROM and FF at the adjacent levels in flexion, but decreased ROM and FF in the adjacent levels in extension. Prodisc C decreased IDP at the adjacent levels. Bryan reduced IDP in extension only. Prestige LP increased adjacent-level IDP.

The distinct designs and material compositions of the three artificial discs result in varying biomechanical alterations at the index and adjacent levels in the cervical spine after implantation. The findings confirm the design and material influence on the spine biomechanics, as well as the advantages and contraindications of cervical arthroplasty in general [1)].

Case series

2017

A prospective multicenter FDA-approved randomized controlled trial, was conducted at 30 US centers, comparing the low-profile titanium ceramic composite-based Prestige LP ADR (n = 209) at 2 levels with ACDF (n = 188). Clinical and radiographic evaluations were completed preoperatively, intraoperatively, and at regular postoperative intervals to 84 months. The primary end point was overall success, a composite variable that included key safety and efficacy considerations.

At 84 months, the Prestige LP ADR demonstrated statistical superiority over fusion for overall success (observed rate 78.6% vs 62.7%; posterior probability of superiority [PPS] = 99.8%), Neck Disability

Index success (87.0% vs 75.6%; PPS = 99.3%), and neurological success (91.6% vs 82.1%; PPS = 99.0%). All other study effectiveness measures were at least noninferior for ADR compared with ACDF. There was no statistically significant difference in the overall rate of implant-related or implant/surgical procedure-related adverse events up to 84 months (26.6% and 27.7%, respectively). However, the Prestige LP group had fewer serious (Grade 3 or 4) implant- or implant/surgical procedure-related adverse events (3.2% vs 7.2%, log hazard ratio [LHR] and 95% Bayesian credible interval [95% BCI] -1.19 [-2.29 to -0.15]). Patients in the Prestige LP group also underwent statistically significantly fewer second surgical procedures at the index levels (4.2%) than the fusion group (14.7%) (LHR -1.29 [95% BCI -2.12 to -0.46]). Angular range of motion at superior- and inferior-treated levels on average was maintained in the Prestige LP ADR group to 84 months.

The low-profile artificial cervical disc in this study, Prestige LP, implanted at 2 adjacent levels, maintains improved clinical outcomes and segmental motion 84 months after surgery and is a safe and effective alternative to fusion. Clinical trial registration no.: NCT00637156 (clinicaltrials.gov) [2)].

2015

Data from 20 investigational sites were compared with data from 265 historical control anterior cervical discectomy and fusion (ACDF) patients in the initial PRESTIGE Cervical Disc IDE study. The 280 investigational patients with single-level cervical disc disease with cervical radiculopathy and/or myelopathy underwent arthroplasty with a low-profile total disc replacement. Key safety/efficacy outcomes included Neck Disability Index (NDI), Neck and Arm Pain Numerical Rating Scale scores, 36-Item Short Form Health Survey (SF-36) score, work status, disc height, range of motion, adverse events (AEs), additional surgeries, and neurological status. Clinical and radiographic evaluations were completed preoperatively, intraoperatively, and at 1.5, 3, 6, 12, and 24 months postoperatively. Predefined Bayesian statistical methods with noninformative priors were used, along with the propensity score technique for controlling confounding factors. Analysis by independent statisticians confirmed initial statistical findings.

The investigational and control groups were mostly similar demographically. There was no significant difference in blood loss (51.0 ml [investigational] vs 57.1 ml [control]) or hospital stay (0.98 days [investigational] vs 0.95 days [control]). The investigational group had a significantly longer operative time (1.49 hours vs 1.38 hours); 95% Bayesian credible interval of the difference was 0.01-0.21 hours. Significant improvements versus preoperative in NDI, neck/arm pain, SF-36, and neurological status were achieved by 1.5 months in both groups and were sustained at 24 months. Patient follow-up at 24 months was 97.1% for the investigational group and 84.0% for the control group. The mean NDI score improvements versus preoperative exceeded 30 points in both groups at 12 and 24 months. SF-36 Mental Component Summary superiority was established (Bayesian probability 0.993). The mean SF-36 PCS scores improved by 14.3 points in the investigational group and by 11.9 points in the control group from baseline to 24 months postoperatively. Neurological success at 24 months was 93.5% in the investigational group and 83.5% in the control group (probability of superiority ~ 1.00). At 24 months, 12.1% of investigational and 15.5% of control patients had an AE classified as device or device/surgical procedure related; 14 (5.0%) investigational and 21 (7.9%) control patients had a second surgery at the index level. The median return-to-work time for the investigational group was 40 days compared with 60 days for the control group ($p = 0.020$ after adjusting for preoperative work status and propensity score). Following implantation of the PRESTIGE LP device, the mean angular motion was maintained at 12 months (7.9°) and 24 months (7.5°). At 24 months, 90.0% of investigational and 87.7% of control patients were satisfied with the results of surgery. PRESTIGE LP superiority on overall success (without disc height success), a composite safety/efficacy end point, was strongly supported with 0.994 Bayesian probability.

This device maintains mean postoperative segmental motion while providing the potential for biomechanical stability. Investigational patients reported significantly improved clinical outcomes compared with baseline, at least noninferior to ACDF, up to 24 months after surgery [3].

2007

The PRESTIGE ST Cervical Disc System maintained physiological segmental motion at 24 months after implantation and was associated with improved neurological success, improved clinical outcomes, and a reduced rate of secondary surgeries compared with ACDF [4].

1)
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2)
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Gornet MF, Burkus JK, Shaffrey ME, Argires PJ, Nian H, Harrell FE Jr. Cervical disc arthroplasty with PRESTIGE LP disc versus anterior cervical discectomy and fusion: a prospective, multicenter investigational device exemption study. J Neurosurg Spine. 2015 Jul 31:1-16. [Epub ahead of print] PubMed PMID: 26230424.
4)
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