Prodisc-C Vivo

Prodisc-C is an advanced total disc replacement device that is transforming the field of cervical spinal surgery. Prodisc-C produces superior balance and motion in the neck when compared to traditional fusion surgery.

Both the Prodisc-C Vivo artificial disc replacement and Zero-P fusion have satisfactory short-term effectiveness in treatment of single-segment cervical spondylosis. Prodisc-C Vivo artificial disc replacement can also maintain the cervical spine range of motion to a certain extent, while reducing the occurrence of excessive motion of adjacent segments after fusion [1)]

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study aimed to evaluate non-inferiority of ProDisc-C to anterior cervical discectomy and fusion (ACDF) in terms of clinical outcomes and incidence of adjacent segment disease (ASD) at 24-months post-surgery in Asian patients with symptomatic cervical disc disease (SCDD).

Methods: This multicentre, prospective, randomized controlled trial was initiated after ethics committee approval at nine centres (China/Hong Kong/Korea/Singapore/Taiwan). Patients with single-level SCDD involving C3-C7-vertebral segments were randomized (2:1) into: group-A treated with ProDisc-C and group-B with ACDF. Assessments were conducted at baseline, 6-weeks, 3/6/12/18/24-months post-surgery and annually thereafter till 84-months. Primary endpoint was overall success at 24-months, defined as composite of: (1) ≥ 20% improvement in neck disability index (NDI); (2) maintained/improved neurologic parameters; (3) no implant removal/revision/re-operation at index level; and (4) no adverse/severe/life-threatening events.

Results: Of 120 patients (80ProDisc-C,40ACDF), 76 and 37 were treated as per protocol (PP). Overall success (PP) was 76.5% in group-A and 81.8% in group-B at 24-months (p = 0.12), indicating no clear non-inferiority of ProDisc-C to ACDF. Secondary outcomes improved for both groups with no significant inter-group differences. Occurrence of ASD was higher in group-B with no significant between-group differences. Range of motion (ROM) was sustained with ProDisc-C but lost with ACDF at 24-months.

Conclusion: Cervical TDR with ProDisc-C is feasible, safe, and effective for treatment of SCDD in Asians. No clear non-inferiority was demonstrated between ProDisc-C and ACDF. However, patients treated with ProDisc-C demonstrated significant improvement in NDI, neurologic success, pain scores, and 36-item-short-form survey, along with ROM preservation at 24-months. Enrolment difficulties resulted in inability to achieve pre-planned sample size to prove non-inferiority. Future Asian-focused, large-scale studies are needed to establish unbiased efficacy of ProDisc-C to ACDF [2)].

In cervical spine biomechanical investigations, most authors have reported an increase in the segmental range of motion (ROM) and the intradiscal pressure (IDP) in the levels proximal and distal to a simulated mono- or bisegmental arthrodesis [3) 4) 5)].

The clinical and radiographic outcomes in cervical ADR patients using the ProDisc-C device (DePuy Synthes, West Chester, PA, USA) with a 5-9 year follow-up were collected through a prospective

registry, with retrospective analysis performed on 24 consecutive patients treated with cervical ADR by a single surgeon. All patients underwent single- or two-level ADR with the ProDisc-C device. Outcome measures included neck and arm pain (visual analogue scale), disability (neck disability index [NDI]), complications and secondary surgery rates. Flexion-extension cervical radiographs were performed to assess range of motion (ROM) of the device and adjacent segment disease (ASD). Average follow-up was 7.7 years. Neck and arm pain improved 60% and 79%, respectively, and NDI had an improvement of 58%. There were no episodes of device migration or subsidence. Mean ROM of the device was 6.4°. Heterotopic ossification was present in seven patients (37%). Radiographic ASD below the device developed in four patients (21%) (one single-level and three two-level ADR). No patient required secondary surgery (repeat operations at the index level or adjacent levels). Fourteen out of 19 patients (74%) were able to return to employment, with a median return to work time of 1.3 months. The ProDisc-C device for cervical ADR is a safe option for patients providing excellent clinical outcomes, satisfactory return to work rates and maintenance of segmental motion despite radiographic evidence of heterotopic ossification and ASD on long-term follow-up [6].

Biomechanical analysis

Scarce references could be found and compared regarding the cervical ADR devices' biomechanical differences that are consequently related to their different clinical results.

One fusion device (CJ cage system, WINNOVA) and three different cervical artificial discs (Prodisc-C Nova (DePuy Synthes), Discocerv (Scient'x/Alphatec), Baguera C (Spineart)) were inserted at C5-6 disc space inside the FE model and analyzed. Hybrid loading conditions, under bending moments of 1 Nm along flexion, extension, lateral bending and axial rotation with a compressive force of 50 N along the follower loading direction, were used in this study. Biomechanical behaviors such as segmental mobility, facet joint forces, and possible wear debris phenomenon inside the core were investigated.

The segmental motions as well as facet joint forces were exaggerated after ADR regardless of type of the devices. The Baguera C mimicked the intact cervical spine regarding the location of the center of rotation (COR) only during the flexion moment. It also showed a relatively wider distribution of the contact area and significantly lower contact pressure distribution on the core compared to the other two devices. A 'lift off' phenomenon was noted for other two devices according to the specific loading condition.

The mobile core artificial disc Baguera C can be considered biomechanically superior to other devices by demonstrating no 'lift off' phenomenon, and significantly lower contact pressure distribution on core [7].

Surgical Technique Animation

<html><iframe width="560" height="315" src="https://www.youtube.com/embed/Q2SNTQRNUDo" title="YouTube video player" frameborder="0" allow="accelerometer; autoplay; clipboard-write; encrypted-media; gyroscope; picture-in-picture" allowfullscreen></iframe></html>

Case series

From May 2011 to May 2013, a total of 44 cervical spondylosis patients that received cervical disc

arthroplasty (Prodisc-C), dynamic cervical implant (DCI) or ACDF were retrospectively reviewed in Orthopedics Department, Beijing Chaoyang Hospital, Capital Medical University.The patients were divided into three groups by surgical methods.Parameters as gender, age, the operation time, blood loss and average hospital stay of three groups were compared.The patients were followed 3 months, 6 months, 12 months and 24 months postoperatively.Neck disability index (NDI), Japanese Orthopaedic Association (JOA) Score and Visual Analogue Scale (VAS) were used to evaluate the clinical outcomes of the three groups.We also measured the cervical lordosis, range of motion of surgical segment and adjacent segment and height of disc at pre-op and post-op.

All the patients were got at least 24 months follow-up.The differences between postoperative JOA, NDI and VAS scores and preoperative scores were of statistical significance ($P<0.05$). There was no statistical difference in average hospital stay, JOA, NDI and VAS recovery rate ($P>0.05$) among three groups.But the operative time and intraoperative blood loss were statistically different ($P<0.05$). Compared the pre-and postoperative ROM of C2-7, operative, upper and lower levels of each group respectively, the difference between pre-and postoperative ROM of ACDF group were of statistically significant [(16.6±3.6)°, (22.3±4.6)°, (18.1±3.1)°, $P<0.05$], while was no statistically significant of non-fusion group($P>0.05$). There was no statistically significant difference between pre-and postoperative ROM of upper and lower levels among three groups ($P>0.05$), but had statistically difference in operative levels [(7.0±1.0) mm, (9.2±1.5) mm, (6.8±1.4) mm, $P<0.05$]. And there are no serious postoperative complications.

Two cervical non-fusion surgery and ACDF have received good clinical effects in the treatment of spondylotic myelopathy or radicular spondylosis.The artificial cervical disc replacement and dynamic cervical implant can not only recover cervical lordosis and keep the range of motion and stability of the surgical segment, but also reduce the incidence of compensatory motion at adjacent segments and will prevent from adjacent segment degeneration [8)].

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