Zigler JE, Delamarter R, et al. ProDisc-C and Anterior Cervical Discectomy and Fusion as Surgical Treatment for Single-Level Cervical Symptomatic Degenerative Disc Disease. Spine 2013;38:203-209.

Design: Five year follow-up of a randomized clinical trial

Population/sample size/setting:

- 209 patients 95 men, 114 women, mean age 43) who participated in an FDA Investigational Device Exemption (IDE) trial at 13 centers in the USA
- Primary inclusion criteria were symptomatic cervical disc disease with disabling radiculopathy at one vertebral segment between C3 and C7, not responding to at least 6 weeks of nonoperative treatment, with a neck disability index (NDI) of 30% or greater

Main outcome measures:

- The original IDE trial randomized patients to cervical total disc replacement (TDR, n=103) or to anterior cervical discectomy and fusion with allograft bone (ACDF, n=109)
- The IDE trial assessed patients at baseline and again at 6 weeks, 3 months, 6 months, 12 months, and 18 months; subsequent evaluations were done annually up to 5 years
- Main outcomes were the NDI, two subscales of the SF-36 (physical component summary, PCS, and mental component summary, MCS), neck pain on a 100 point VAS scale, arm pain on the same VAS scale, and patient satisfaction on a scale from 0 to 100
- At 5 years, follow-up rates were 72.7% for TDR and 636.5% for ACDF
- At 2 years and again at 5 years, the NDI decreased significantly by 50 to 60%, with equal improvements in both groups
- Similarly, both groups had significant declines in neck and in arm pain by 50% or more
    - At 2 years, the improvements were statistically equal between groups for neck and arm pain
    - At 5 years, both groups approximately maintained the 2 year improvements in neck and arm pain; however, the TDR group had a lower neck pain average score (about 21 points) compared to the ACDF group (about 30 points), while the arm pain scores were equal at 5 years (about 28 points)
- Similarly, both groups had similar improvements on both SF-36 summary components, and similar high levels of satisfaction (86.56% for TDR and 82.74% for ACDF)
- Neurologic status improved in both groups with no group differences at 2 or 5 years
- Radiographic criteria were different for the groups; for TDR, the flexion-extension range of motion at the index level was maintained from baseline values (8.49° at baseline, 8.14° at 5 years) and was reduced in the ACDF group (1.02° at 5 years)

    - In the ACDF group, radiographic nonunion was seen in 14 patients at 2 years and in 8 patients at 5 years
- The groups did differ in the frequency of secondary spinal operations, with TDR patients having fewer secondary procedures than the ACDF patients, with details reported in Delamarter and Zigler (in press)
    - At 5 years, the secondary surgery rate for TDR was 2.9% vs 11.3% for ACDF
    - 3 TDR patients had secondary surgery at the index level due to ongoing pain (2 had disc removal and conversion to ACDF)
    - 12 ACDF patients had secondary surgery, and 3 had more than one procedure, for a total of 16 secondary procedures
        - 8 were at the index level alone (mostly for symptomatic pseudarthrosis); 8 procedures included an adjacent level
        - Most adjacent level procedures involved plate removal at the index level and ACDF at the adjacent level
- For TDR, no implant breakages or device failures were reported, and no visible evidence of polyethylene wear has been observed

Authors' conclusions:

- Total disc replacement with the ProDisc-C is a safe and effective treatment for disabling single level cervical disc disease with radiculopathy
- Reoperation rates for ProDisc-C are lower than for ACDF
- At 5 years, patients with ProDisc had less neck pain than ACDF patients

Comments:

- The 5 year attrition rates were greater than the 2 year rates, with somewhat higher attrition in the ACDF than in the TDR group; this is unlikely to bias study results in favor of TDR
- It appears that most of the ACDF patients with pseudarthrosis at the index level were symptomatic and had reoperations with revision ACDF or posterior fixation
- It is possible that the lack of blinding could have influenced some of the decisions to reoperate, since reoperation is not an observed "condition" but is a decision made by a participating surgeon; this may lead to bias which cannot be avoided but may be present
- Although there was no reported evidence of polyethylene wear with TDR, evidenced by osteolysis or particulate debris, one patient had >3 mm of device subsidence and 1 patient had >3 mm loss of disc height

Assessment: Adequate for some evidence that cervical total disc replacement requires fewer revision operations than ACDF after the first two years of treatment; also for some evidence that total disc replacement has an advantage over ACDF for long-term neck pain

Reference:

Delamarter RB, Zigler J. Five-Year Reoperation Rates, Cervical Total Disc Replacement *Versus* Fusion, Results of a Prospective Randomized Clinical Trial. Spine 2013;38(9):711-717.