Jacobs WC, van der Gaag NA, et al. Total Disc Replacement for Chronic Discogenic Low Back Pain. Spine 2013;38:24-36.

Design: Meta-analysis of randomized clinical trials

PICOS:

- Patient population: patients scheduled for surgery for degenerative disc disease (DDD) lasting longer than 12 weeks
- Intervention: Total disc replacement
- Comparison: Any other intervention for lumbar DDD
- Outcomes: Pain, overall improvement, patient satisfaction, disability or general functional measures
- Studies: Randomized clinical trials published as full articles in peer-reviewed journals with a minimum of 6 months follow-up

Study type and selection:

- Databases were searched through Dec 22, 2011, and included PubMed, MEDLINE, EMBASE, BIOSIS, FDA register, clinicaltrials.gov, Web of Science, and references of included studies
- Two authors independently selected articles and assessed them for risk of bias using Cochrane criteria (randomization, allocation concealment, blinding, attrition, etc)
- Overall quality of evidence was judged by the GRADE criteria, which begin with risk of bias assessment, and add judgments of consistency/inconsistency, directness/indirectness of comparisons, precision/imprecision, and presence or absence of publication bias

Results:

- 7 studies were included in the analysis
    - 6 studies compared disc replacement with fusion, 5 of which provided outcome data for 24 months of follow-up time
    - 1 study compared disc replacement with rehabilitation
- Primary outcomes were measured at 24 months, which was the longest follow-up time available across studies
- The 5 studies (1301 patients) comparing disc replacement with fusion at 24 months had a pooled difference in the Oswestry disability index of 4.27 points (95% confidence interval, 1.85 to 6.68) in favor of disc replacement; this was less than the predefined clinically relevant difference of 10 points
- 4 studies had 24 month comparisons for patient satisfaction, which was more prevalent in the disc replacement groups than in the fusion groups (Odds ratio 1.93, 95% CI, 1.36 to 2.76)
- Only 2 studies had 24 month data for back pain; the pooled difference was also in favor of disc replacement, and was 5.2 on a 100 point scale (95% CI, 0.2 to 10.3); this was also less than the predefined clinically relevant difference of 15 points

- One study compared disc replacement with rehabilitation, and reported an average effect in favor of disc replacement of 12.3 points, less than the clinically relevant difference of 15 points
    - The Oswestry score difference was also in favor of disc replacement, but was 8.4 points, which is also less than the clinically relevant 10 point difference

Authors' conclusions:

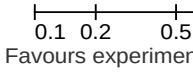
- Most of the included studies show clinically relevant improvement for both disc replacement and fusion, but show small and clinically non-relevant superiority of disc replacement over fusion for back pain and disability at 24 months follow-up
- Patients reported higher satisfaction with disc replacement than with fusion
- None of the included studies provided satisfactory data on adjacent level degenerative change; the data pertaining to motion were poorly reported, and no conclusions regarding adjacent segment degeneration could be made
- Because the studies were done for FDA approval of the devices, and these studies have stringent inclusion/exclusion criteria, the external validity of the studies is uncertain
- Because harm and complications of disc replacement may take years to appear, the spine surgery community should be prudent about adopting disc replacement despite its apparent equivalence to fusion
    - There need to be mandatory registries for disc replacement similar to those being maintained for metal-on-metal hip prostheses

Comments:

- The results of this 2013 meta-analysis do not differ greatly from those of the 2010 systematic review by Van den Eerenbeemt et al
    - Although the 2010 review did not report that there was any superiority of disc replacement over fusion, the current meta-analysis reports superiority, which falls short of clinically relevant levels
- Patient satisfaction is reported in terms of an odds ratio which appears to favor disc replacement (pooled OR=1.93)
    - However, odds ratios can inflate an apparent effect size when the outcome of interest (patient satisfaction) is common
    - A risk ratio is probably a more appropriate summary effect measure for patient satisfaction; this is 1.14 (95% CI 1.01 to 1.30) rather than 1.93 (1.36 to 2.76)

Study or Subgroup	Disc replacement Events	Total	Fusion Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Berg 2009	57	80	48	72	21.7%	1.07 [0.86, 1.32]
Blumenthal 2005	130	176	39	74	19.5%	1.40 [1.11, 1.77]
Gornet 2011	330	379	110	145	43.0%	1.15 [1.04, 1.27]
Moreno 2008	12	14	16	18	15.9%	0.96 [0.74, 1.26]
Total (95% CI)		**649**		**309**	**100.0%**	**1.14 [1.01, 1.30]**
Total events	529		213			

Heterogeneity: Tau² = 0.01; Chi² = 5.21, df = 3 (P = 0.16); I² = 42%
Test for overall effect: Z = 2.08 (P = 0.04)



- This estimates that patient satisfaction for disc replacement was 14% greater for disc replacement than for fusion, and that the high end of the 95% confidence level is 30% greater patient satisfaction rather than 176% greater satisfaction

Assessment: High quality meta-analysis which supports strong evidence that disc replacement is not inferior to fusion at 24 months for relief of back pain, reduction of disability, and provision of patient satisfaction, but that no conclusions can be drawn regarding adjacent level degeneration or concerning longer term performance of the artificial disc