McAfee PC, Reah C, et al. A Meta-Analysis of Comparative Outcomes Following Cervical Arthroplasty or Anterior Cervical Fusion. Spine 2012;37(11):943-952.

Design: Meta-analysis of randomized clinical trials

PICOS:

- Patient population: Adults with single level degenerative cervical conditions with radiculopathy or myelopathy who met inclusion criteria for trials of four arthroplasty devices
- - Only one level could be treated
- - No previous operations at the index level were allowed
- - Exclusion criteria included severe facet joint pathology, diabetes, radiographic instability, osteoporosis or any metabolic bone disease
- Intervention: Any of four artificial discs for the cervical spine: Prestige, Bryan, ProDisc-C, and PCM
- Comparison: Anterior cervical discectomy and fusion (ACDF) with interbody allograft and titanium plates
- Outcomes: All 4 trials reported on the Neck Disability Index (NDI), neurological status, survivorship (avoidance of further surgery), and a composite outcome of overall success, with all outcome comparisons done at 24 months follow-up
    - Results were combined with two analytical methods, a pooled odds ratio with a random effects model, and a Bayesian analysis using a beta-binomial model
    - For the Bayesian analysis, a posterior probability of 0.95 or greater was considered to provide a basis for a claim of superiority
- Study types: Randomized clinical trials carried out under FDA regulations for Investigational Device Exemptions (IDE) applications

Study search and selection:

- Study data was taken from the FDA approval documents submitted by each manufacturer in each IDE trial
- For 3 of the devices, FDA approval had been secured, and was pending for the PCM device
- Each of the devices had published reports, but databases such as MEDLINE were not searched in addition to the FDA approval data

Results:

- Results were available for 4 completed randomized trials involving 1226 patients
- For the NDI, a 15 point improvement from baseline was defined as a success; this was reported for 82.3% of the arthroplasty patients and for 78.6% of the ACDF patients
    - The pooled odds ratio was 0.79 (odds of failure lower with arthroplasty than with ACDF), with 95% confidence intervals between 0.59 and 1.05

    - The Bayesian analysis yielded a posterior probability of superiority of arthroplasty of 0.947 (arthroplasty probably superior to ACDF)
- For neurological status, the success rate was 93.5% for arthroplasty and 88.8% for ACDF; the Bayesian analysis was 0.999 probability of superiority for arthroplasty
    - The pooled odds ratio was 0.552 (95% CI, 0.364 to 0.865) in favor of arthroplasty over ACDF
- For survivorship, the success rate was 96.5% for arthroplasty and 93.3% for 93.3% for ACDF; the Bayesian posterior probability of superiority for arthroplasty was 0.999
    - The pooled odds ratio was 0.510 (95% CI, 0.275 to 0.946) in favor of arthroplasty over ACDF
- For overall success, the success rate was 77.5% for arthroplasty and 70.7% for ACDF; the Bayesian posterior probability of superiority for arthroplasty was 0.997
    - The pooled odds ratio was 0.699 (95% CI, 0.539 to 0.908) in favor of arthroplasty over ACDF
- For all four outcomes, the heterogeneity of the pooled success rates was low
    - I^2 , which is considered to show heterogeneity when it is 50% or greater, was 0% for three outcomes and was 33% for neurological status

Authors' conclusions:

- There is a strong argument for single level disc arthroplasty being at least as safe and effective as the prior "gold standard" of fusion for chronic neck pain with radiculopathy/myelopathy due to single level degenerative disc disease
- The control groups had ACDF with allograft and plates rather than with iliac crest autograft, which some clinicians believe to be preferable
    - However, the presence of donor site pain is likely to compromise overall success with the ACDF procedure

Comments:

- The systematic review was not a result of a literature search strategy, but was a pooling of FDA data for IDE applications to obtain FDA approval
- This is not necessarily a disadvantage, since the FDA requirements for reporting and for definition of success may be more stringent than for commonly reported outcomes in published literature
    - However, it does limit the generalizability of the analysis, since the inclusion and exclusion criteria were very similar and the control interventions were standardized, which may account for the homogeneity of the meta-analyses
- The Bayesian analyses seem to have been done following appropriate methods, using functions which enable prior probabilities to be converted into posterior probabilities, starting from a prior probability that the operations are equivalent in effectiveness

- However, the high Bayesian probability of superiority of arthroplasty does not quantify the superiority, which may be better estimated by the pooled odds ratio of about 0.7 for overall success (odds of not being successful 30% less with arthroplasty)
    - It is not clear how robust this estimate of superiority is and whether further research could change the estimate
    - The claim of non-inferiority of arthroplasty is well-supported, and is not likely to be overturned by further research
- Published RCT data were not cited for the PCM device, and were taken from the FDA reports; for the other three devices, published RCTs were available

Assessment: High quality meta-analysis which supports strong evidence that for patients with single level degenerative disc disease with radiculopathy or myelopathy, a cervical artificial disc produces 2-year success rates at least equal to those of ACDF with allograft interbody fusion and an anterior plate

References:

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Mummaneni PV, Burkus JK, et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine 2007;6:198-209.

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