In a prospective, randomized multicenter study, Coric et al. evaluate the safety and efficacy of a metal-on-metal (MoM) TDR (Kineflex|C) versus anterior cervical discectomy and fusion (ACDF) in the treatment of single-level spondylosis with radiculopathy through a long-term (5-year) follow-up. METHODS An FDA-regulated investigational device exemption (IDE) pivotal trial was conducted at 21 centers across the United States. Standard validated outcome measures including the Neck Disability Index (NDI) and visual analog scale (VAS) for assessing pain were used. Patients were randomized to undergo TDR using the Kineflex|C cervical artificial disc or anterior cervical fusion using structural allograft and an anterior plate. Patients were evaluated preoperatively and at 6 weeks and 3, 6, 12, 24, 36, 48, and 60 months after surgery. Serum ion analysis was performed on a subset of patients randomized to receive the MoM TDR.

A total of 269 patients were enrolled and randomly assigned to undergo either TDR (136 patients) or ACDF (133 patients). There were no significant differences between the TDR and ACDF groups in terms of operative time, blood loss, or length of hospital stay. In both groups, the mean NDI scores improved significantly by 6 weeks after surgery and remained significantly improved throughout the 60-month follow-up (both $p < 0.01$). Similarly, VAS pain scores improved significantly by 6 weeks and remained significantly improved through the 60-month follow-up (both $p < 0.01$). There were no significant changes in outcomes between the 24- and 60-month follow-ups in either group. Range of motion in the TDR group decreased at 3 months but was significantly greater than the preoperative mean value at the 12- and 24-month follow-ups and remained significantly improved through the 60-month period. There were no significant differences between the 2 groups in terms of reoperation/revision surgery or device-/surgery-related adverse events. The serum ion analysis revealed cobalt and chromium levels significantly lower than the levels that merit monitoring. CONCLUSIONS Cervical TDR with an MoM device is safe and efficacious at the 5-year follow-up. These results from a prospective randomized study support that Kineflex|C TDR as a viable alternative to ACDF in appropriately selected patients with cervical radiculopathy. Clinical trial registration no.: NCT00374413 (clinicaltrials.gov) [1].

1)
Coric D, Guyer RD, Nunley PD, Musante D, Carmody C, Gordon C, Lauryssen C, Boltes MO, Ohnmeiss DD. Prospective, randomized multicenter study of cervical arthroplasty versus anterior cervical discectomy and fusion: 5-year results with a metal-on-metal artificial disc. J Neurosurg Spine. 2018 Jan 5:1-10. doi: 10.3171/2017.5.SPINE16824. [Epub ahead of print] PubMed PMID: 29303467.