

Outcomes after motion-restricting heterotopic ossification in patients with cervical total disc replacement: how do they compare to primary ACDF?

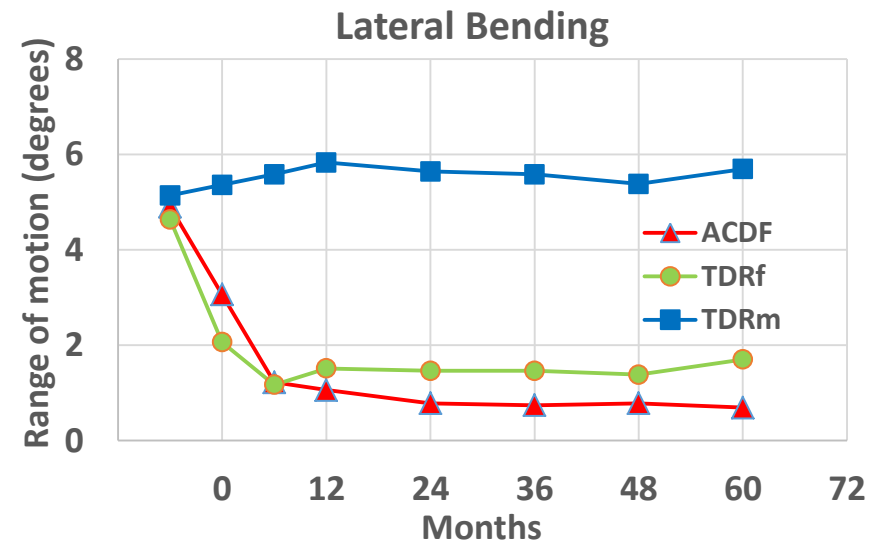
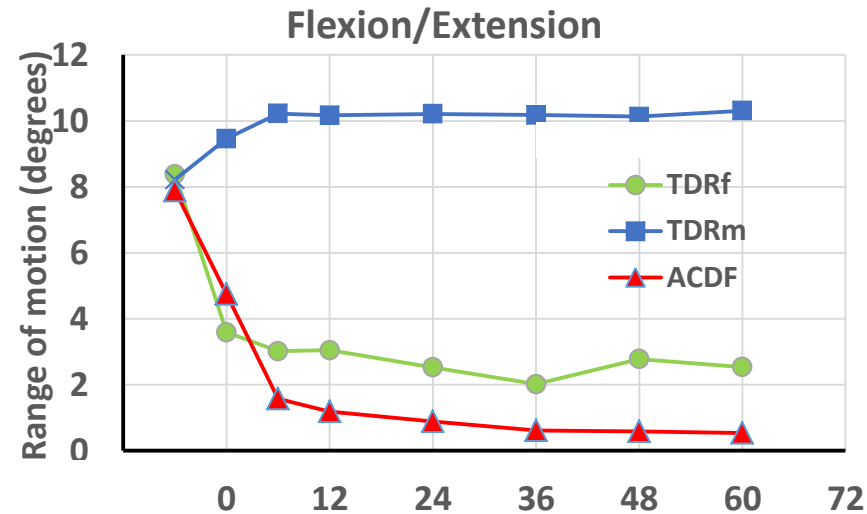
Jacques Beaurain, MD¹
Robert J. Jackson, MD²

¹ Neuro-surgery Department, University Hospital, Dijon, France

² Orange County Neurosurgical Associates, Laguna Hills, CA

Background

- ❑ Heterotopic ossification (HO) can occur after treatment with cervical total disc replacement (TDR).
- ❑ In severe cases, HO can limit range of motion and result in fusion of the segment.
- ❑ After onset of motion restricting HO, TDR patients have range of motion similar to ACDF patients.
- ❑ By some measures of clinical success, these cases have been considered “failures”.
- ❑ The long-term effects of HO resulting in unintended fusion have not been analyzed.
- ❑ Do TDR patients with motion restricting HO have outcomes similar to ACDF patients?



Note: Range of motion in TDRf cohort is after onset of motion restricting HO.

Study Design

Study Objective

To compare the clinical and radiographic outcomes of TDR patients with motion restricting HO to patients with primary ACDF or mobile TDR.



Study Design

- ❑ This was a *post hoc* analysis of a prospective, randomized, concurrently controlled, multi-center FDA clinical trial in the US.
 - TDR (Mobi-C[®], Zimmer Biomet)
 - ACDF with anterior plate and allograft bone

- ❑ All patients had symptomatic degenerative disc disease at one or two contiguous levels from C3-C7 and no prior cervical surgery.

- ❑ Independent radiologists conducted all radiographic evaluations.

Study Cohort

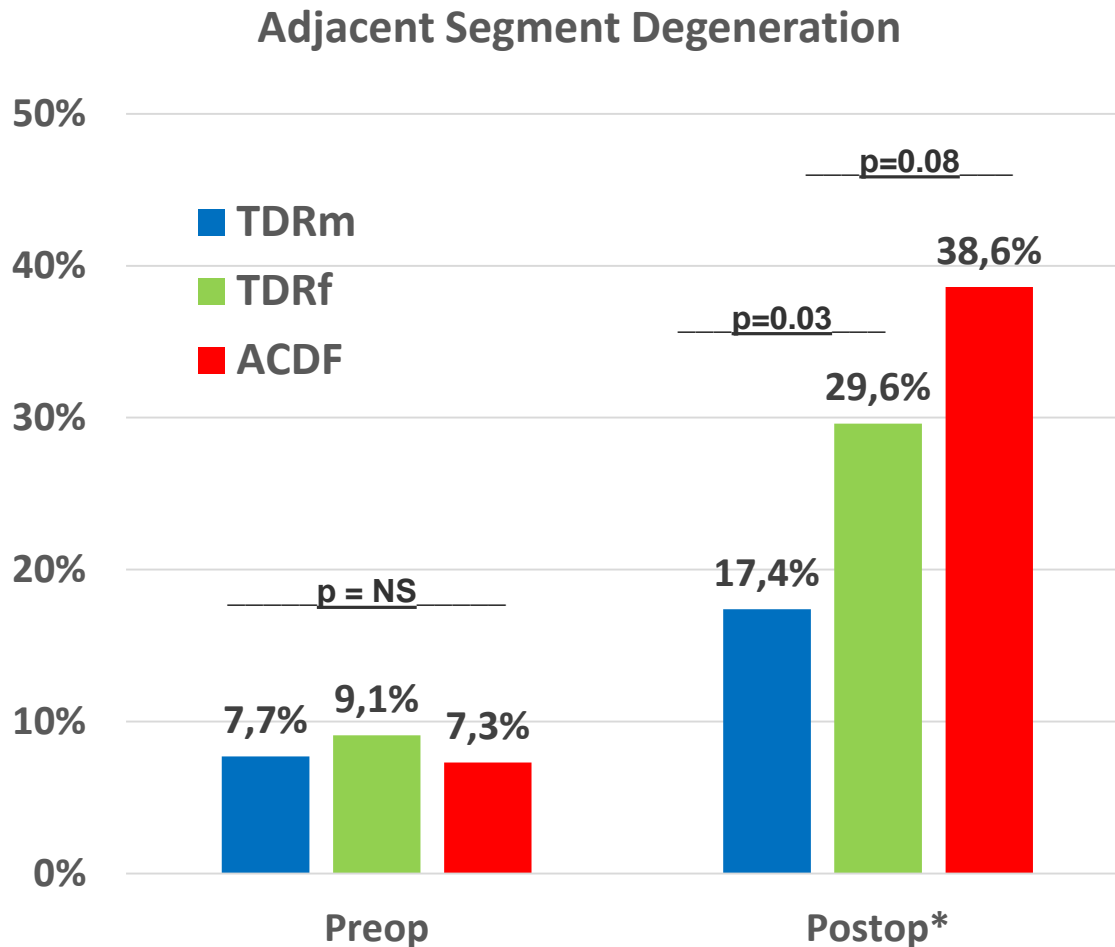
- Grade 4 HO occurred in 46 of 413 TDR patients (11%).
 - Mean time to Grade 4 HO was 39.7 months (11-87 months).
 - Mean follow-up after onset of Grade 4 HO was 36.4 months (range 0-75 months).

- These patients were compared to primary ACDF and mobile TDR patients matched by gender and operated level (C4-C7).
 - TDR – 413 subjects
 - ✓ Motion restricting HO (TDR l) – 46 subjects
 - Mobile TDR (TDR m) – 367 subjects
 - ✓ Case matched – 300 subjects
 - ACDF – 186 subjects
 - ✓ Case matched – 152 subjects

- Patient cohorts were well matched.
 - Similar operated levels, baseline range of motion, sagittal alignment, and preop PROs
 - Patients with HO grade 4 had more males and slightly older.



Adjacent Segment Degeneration



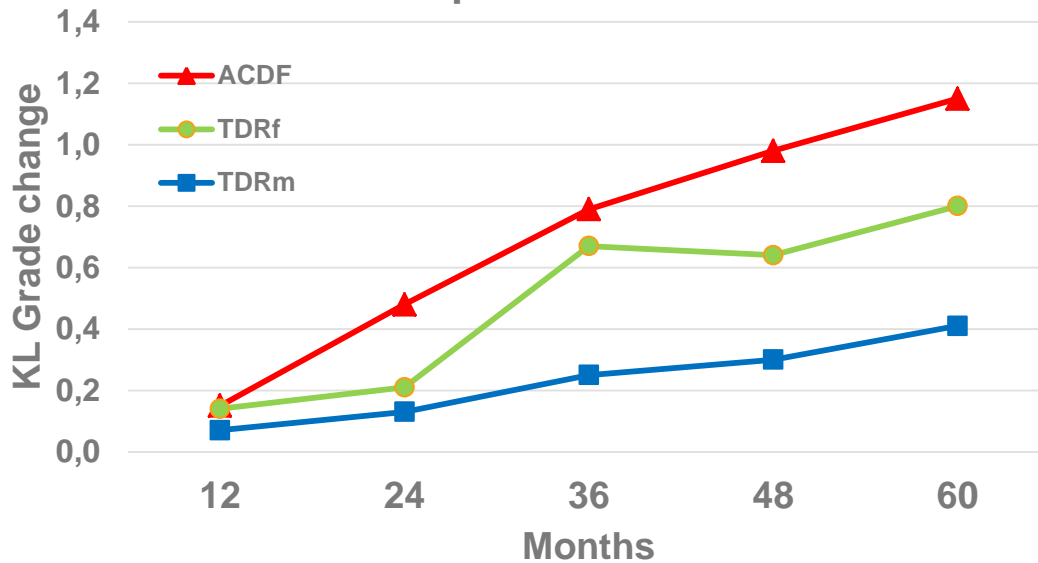
Out to 5 years after HO, TDRf patients had more progression of ASD than mobile TDR, but less than primary ACDF.

As TDRf patients get more follow-up, progression of ASD may become more similar to ACDF patients.

* % of patients with KL Grade 3/4 at last postoperative follow-up. P-values based on Fisher's Exact test.

Progression of Adjacent Segment Degeneration

Superior ASD



Superior ASD

TDRf vs. ACDF: $p = 0.08$

TDRf vs TDRm: $p = 0.14$

ACDF vs. TDRm: $p < 0.001$

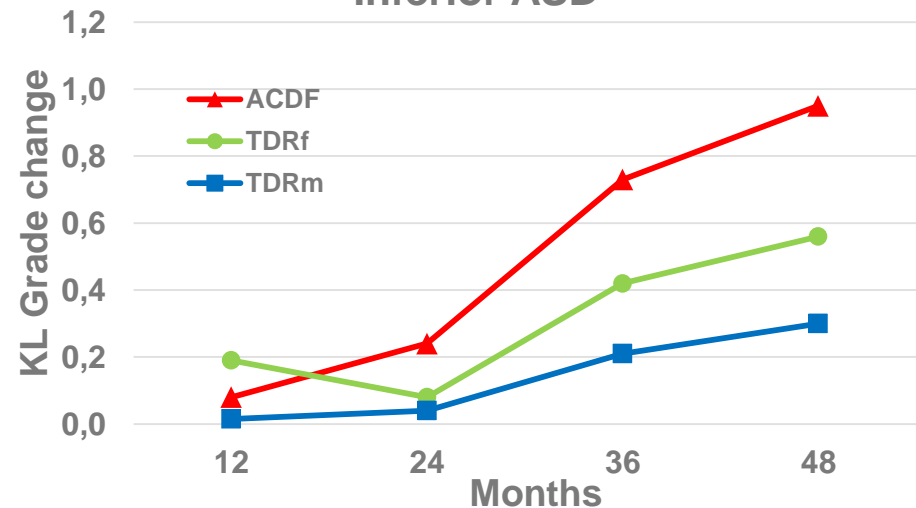
Inferior ASD

TDRf vs. ACDF: $p = 0.22$

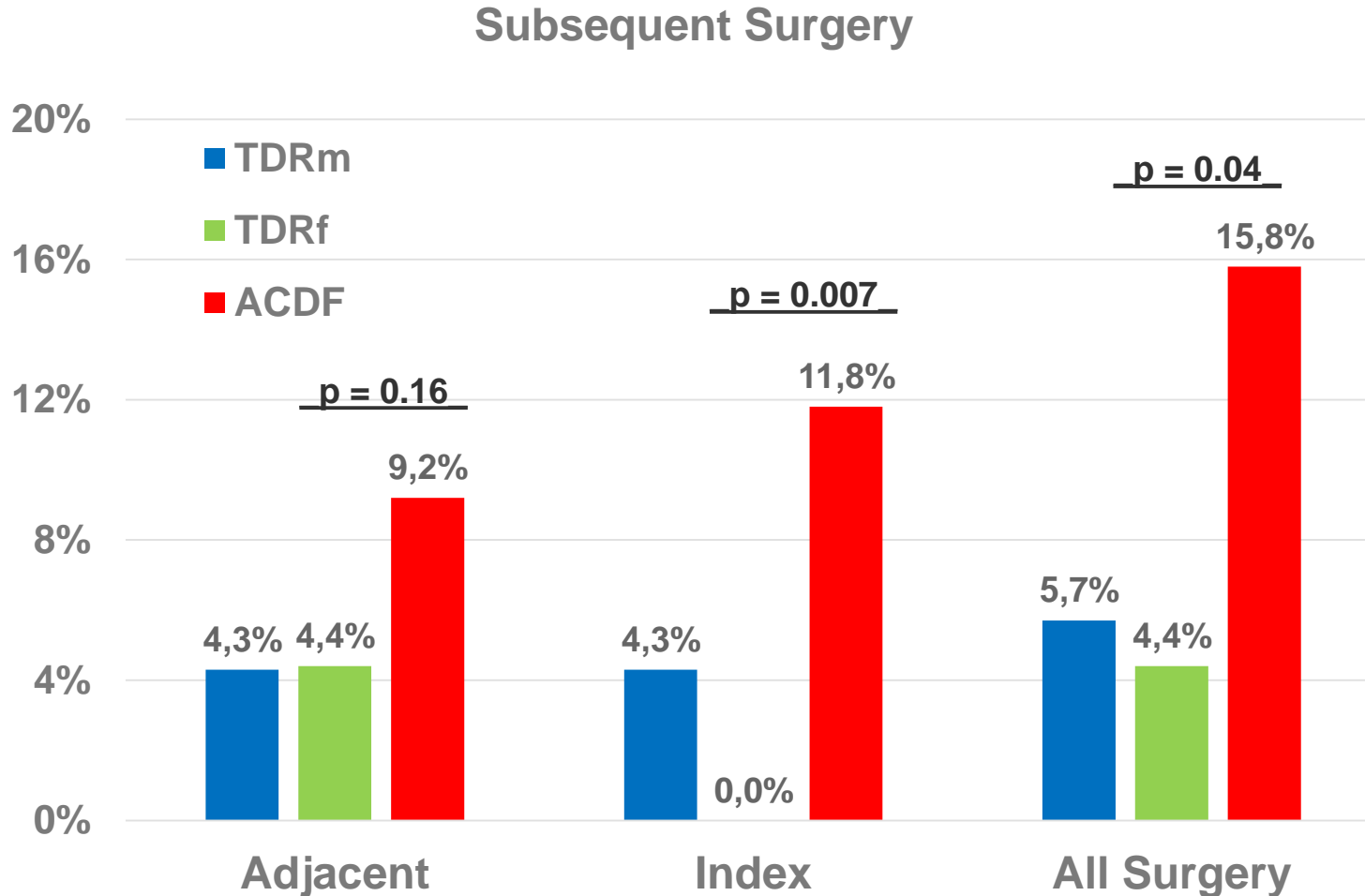
TDRf vs. TDRm: $p = 0.30$

ACDF vs. TDRm: $p < 0.001$

Inferior ASD



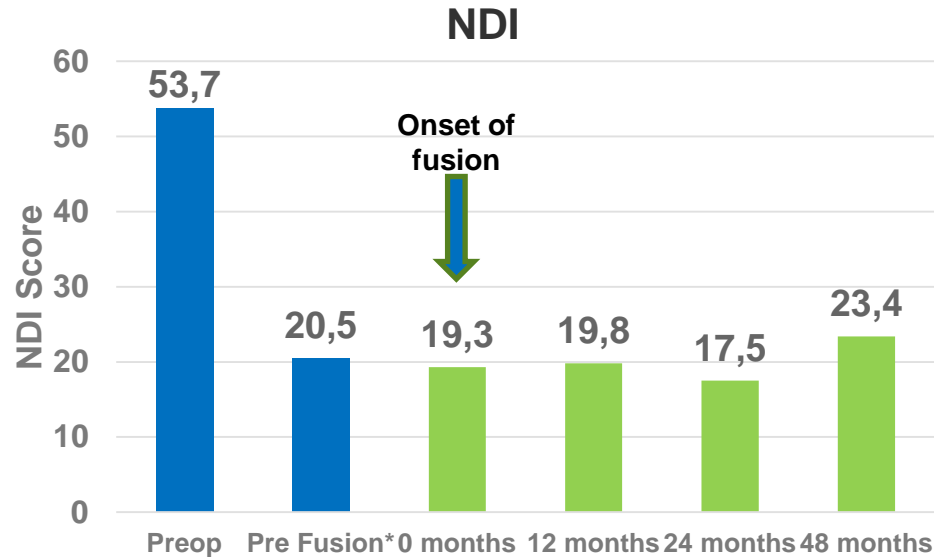
Subsequent Surgery



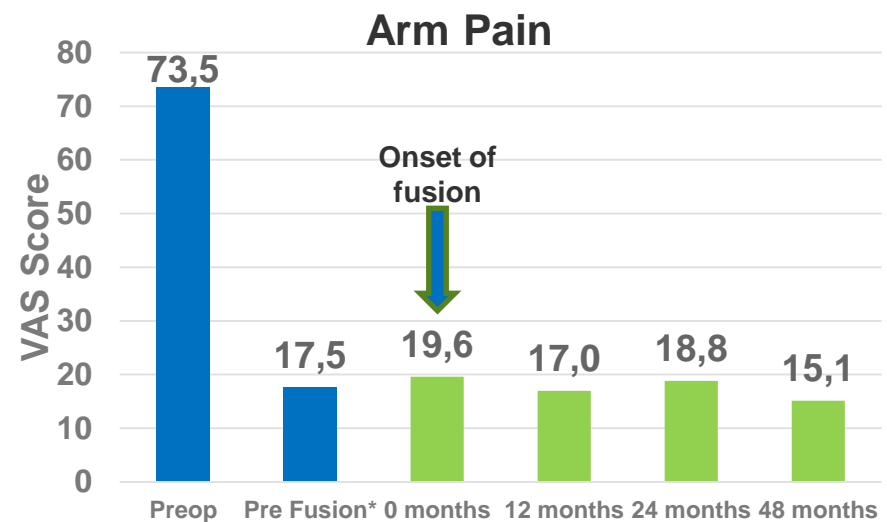
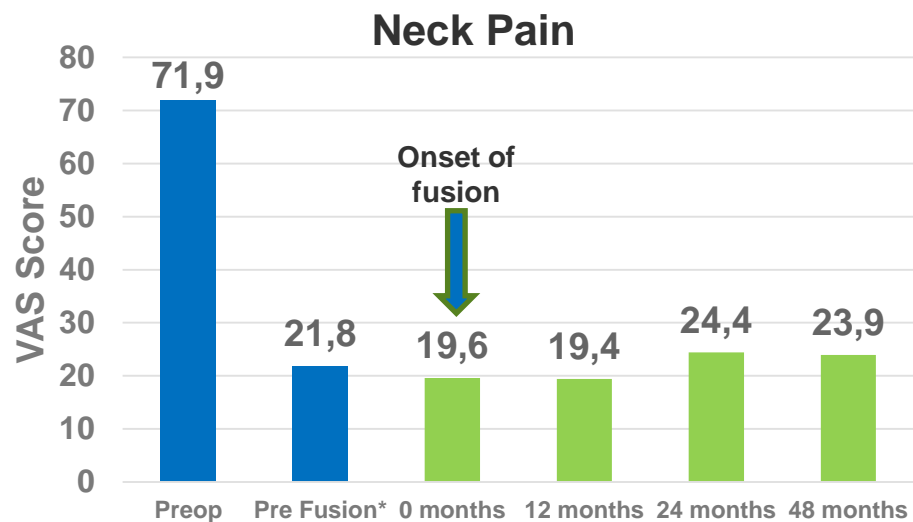
P-values based on Fisher's exact test.

Patient Reported Outcomes

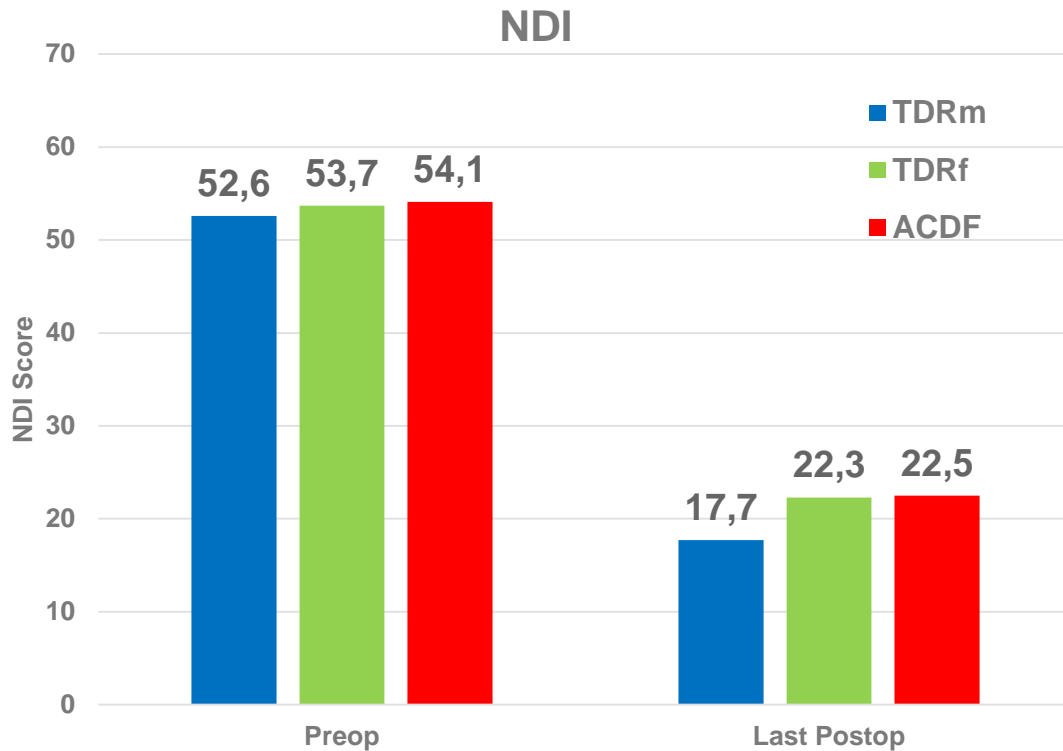
What happens after TDR fusion?



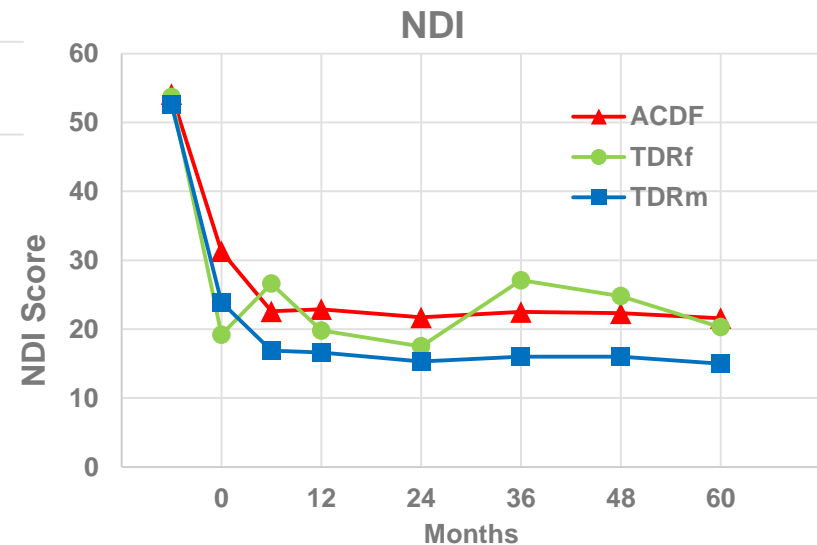
At the onset of ankylosis, NDI, neck pain, and arm pain are similar to pre fusion levels and remain stable after fusion.



Patient Reported Outcomes



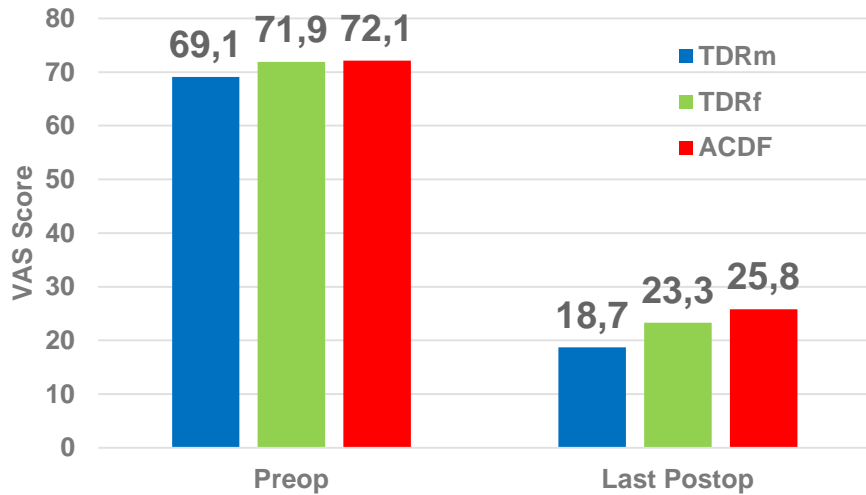
All differences at each time point are less than the MCID for NDI (15 / 100).



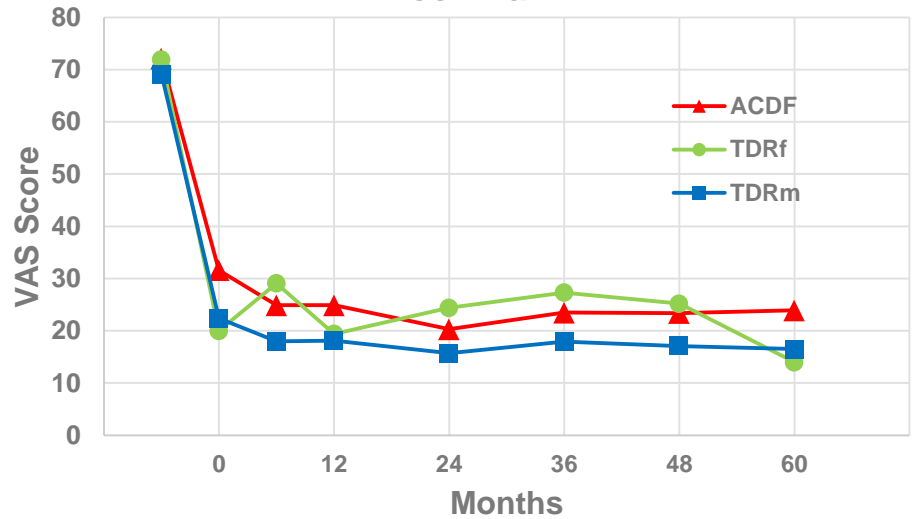
Patient Reported Outcomes

All differences at each time point are less than the MCID for pain (10 / 100).

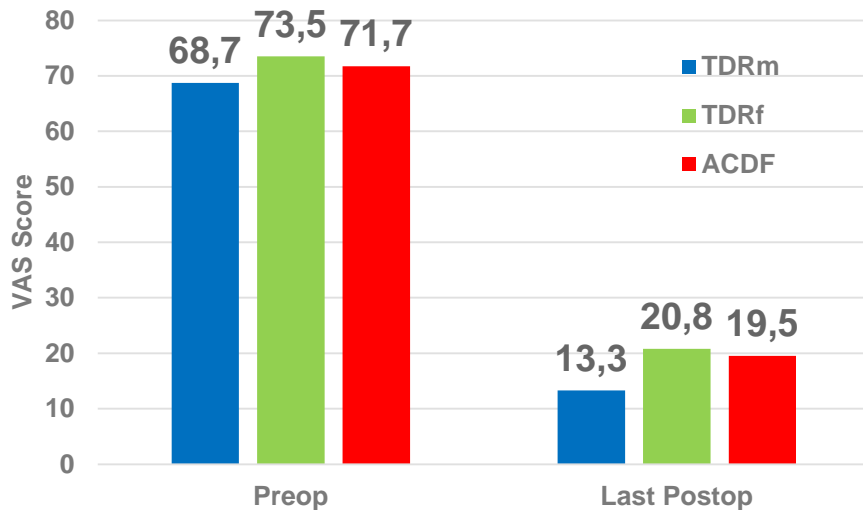
Neck Pain



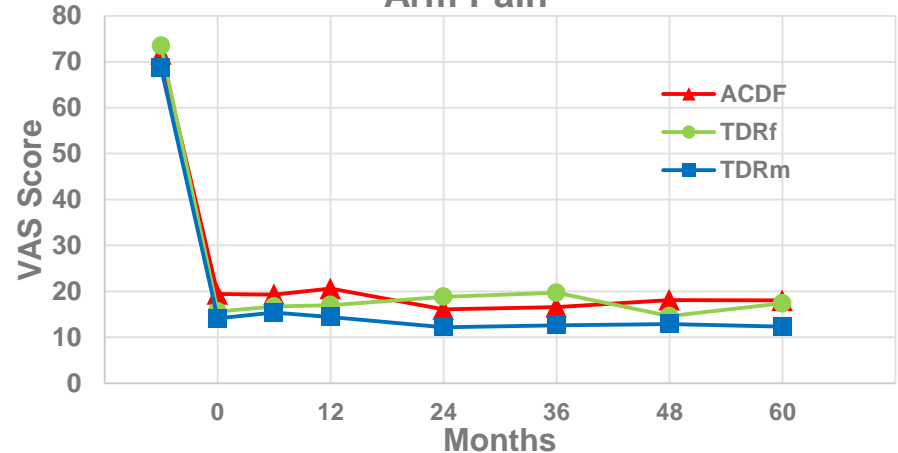
Neck Pain



Arm Pain

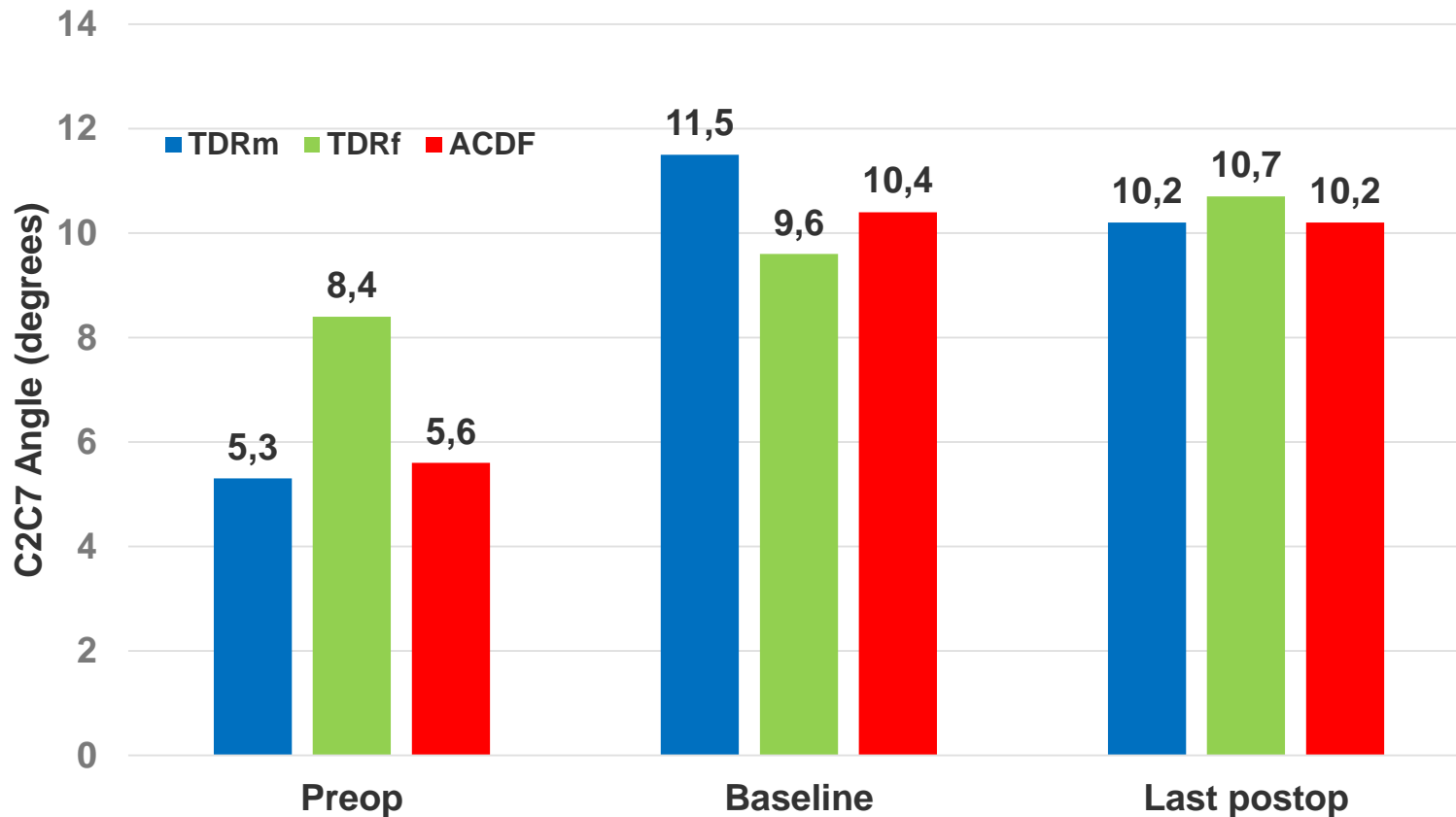


Arm Pain



Sagittal Alignment

- Patients that developed grade 4 HO were more lordotic prior to surgery, but underwent less correction in Cobb angle after surgery.
- After onset of HO fusion, sagittal alignment in TDR patients was similar to both ACDF and mobile TDR.



Conclusions

Up to 5 years after onset of Grade 4 HO, patients with motion-restricting HO:

- Did not demonstrate clinically significant change in clinical or radiographic outcomes.**
- Benefited from over 3 years of improved Quality of Life over primary ACDF**
- Had less progression of ASD compared to primary ACDF**
 - The incidence of any subsequent surgery after HO-induced fusion was significantly lower than after primary ACDF.