TOTAL DISC REPLACEMENT vs FUSION: Clinical Outcomes with Work Status and Pain Medication Usage at Three Years Post-surgery

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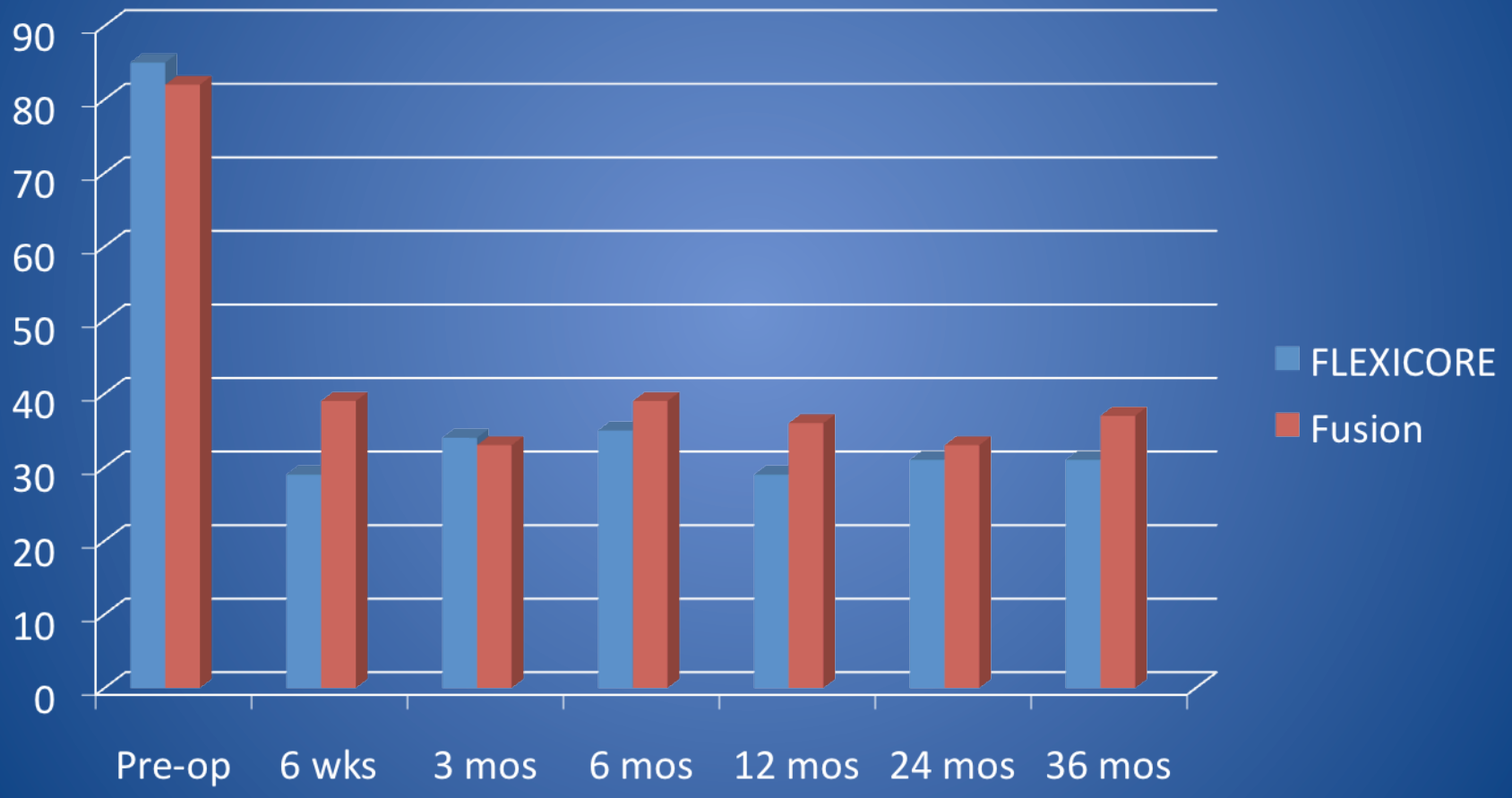
INTRODUCTION

Total disc replacement with Flexicore(TDA) is intended to reduce back pain associated with lumbar DDD while permitting motion. This paper reports the clinical outcomes from 4 of 23 sites participating in the Flexicore IDE trial. Further, pain medication usage and patient work status were also analyzed.

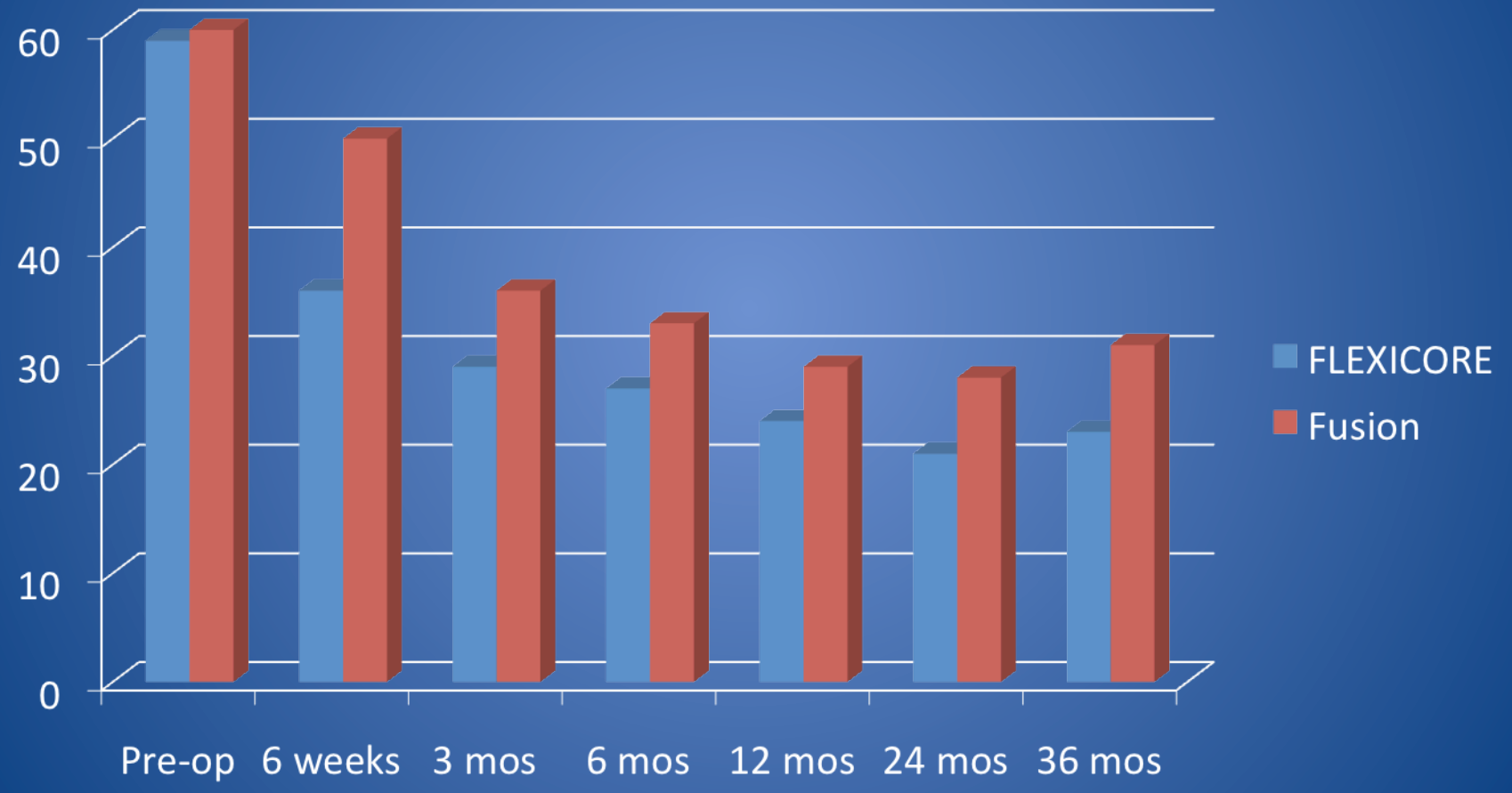
METHODS

Patients were randomized 2:1 (TDA vs fusion). Complete data is available for(TDA vs fusion): 81 vs 39 patients at pre-op, 60 vs 25 at 12 mos. and 39 vs 13 patients at 3 years. Not all patients from this subgroup are yet 3 years post surgery at this time; they are not lost to follow-up. Back pain(VAS) and function(ODI) were obtained along with pain medication usage and work status at standard intervals up to the 3 year follow-up.

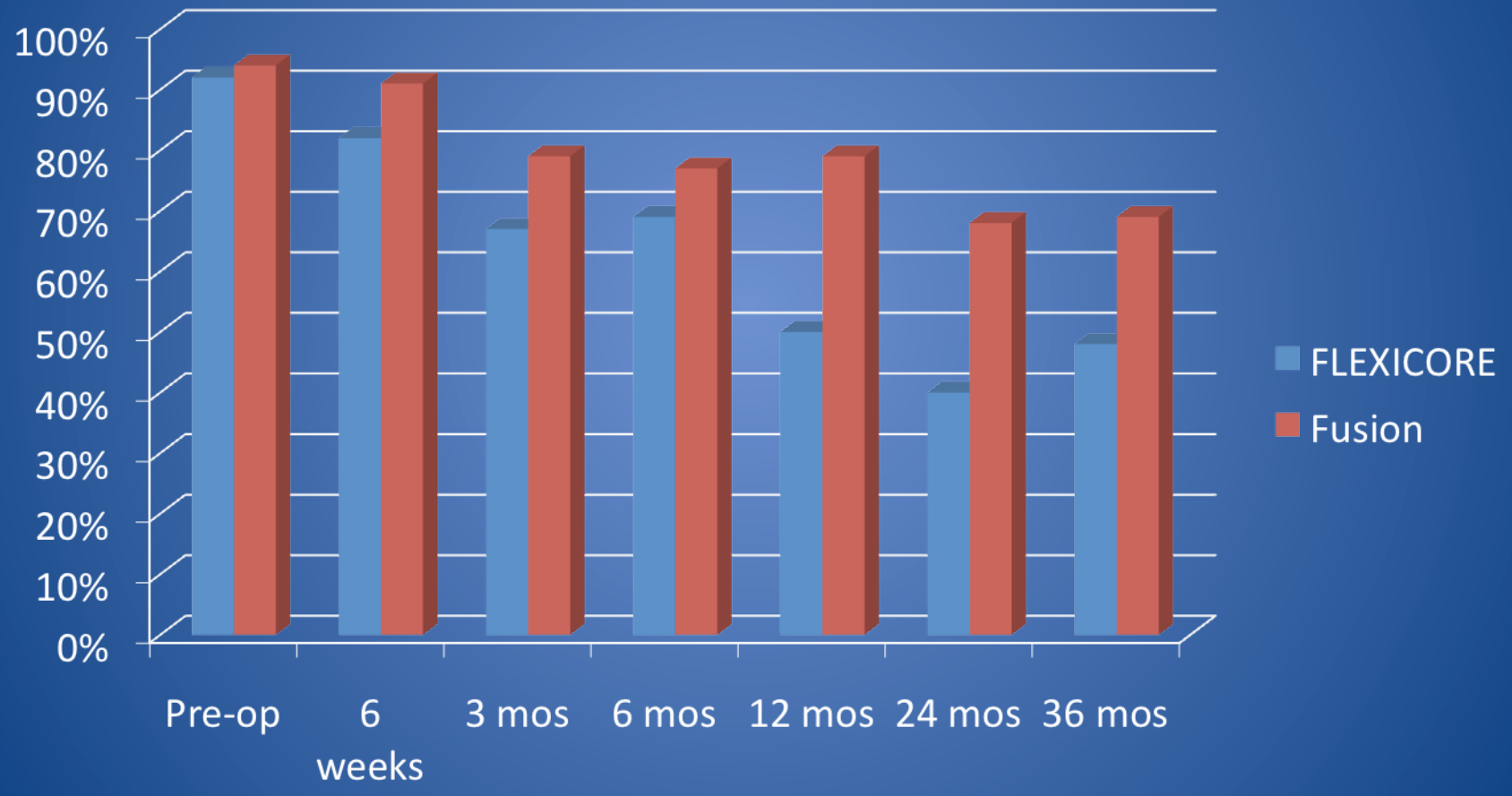
VAS


90
80
70
60
50
40
30
20
10
0
Pre-op
6 wks
3 mos
6 mos
12 mos
24 mos
36 mos
FLEXICORE
Fusion

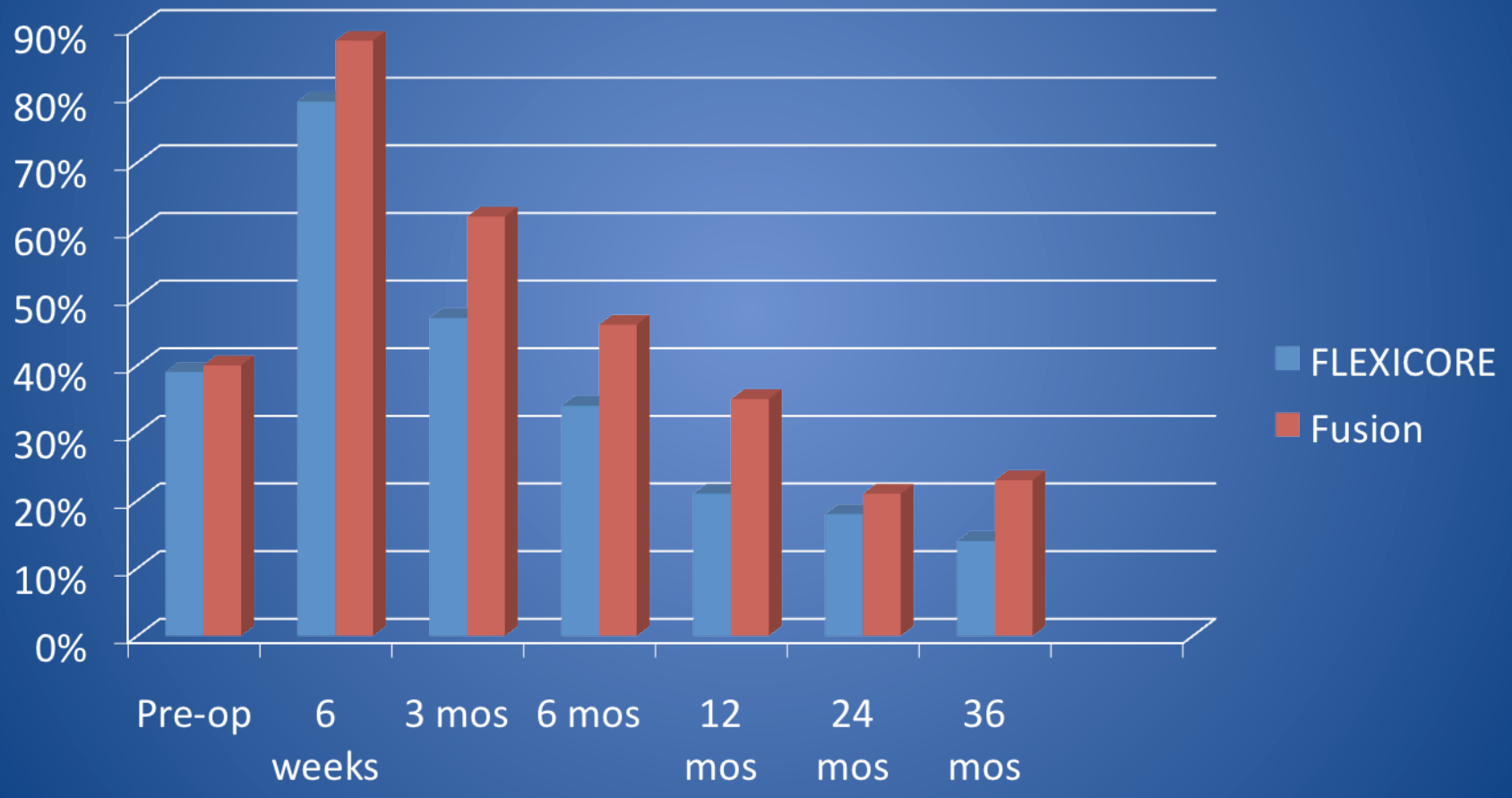
ODI


60
50
40
30
20
10
0
Pre-op
6 weeks
3 mos
6 mos
12 mos
24 mos
36 mos
FLEXICORE
Fusion

NARCOTIC USAGE



WORK STATUS
(Unable to work due to low back condition)



RESULTS SUMMARY

Within each group, mean VAS and ODI were significantly improved from baseline($p<0.001$ for TDA;$p=0.0015$ for fusion). Although not significant between groups, at 3 years the mean reduction in VAS score for TDA patients was 53, and 47 in fusion patients. Mean improvement in ODI score in TDA patients was 37 points, and 27 in fusion patients. Reduction in pain medication usage in both groups was statistically significantly reduced from pre-op ($p=0.0113$;$p=0.0305$), with a greater reduction in the arthroplasty group. This trend in the arthroplasty group was present at all follow-up intervals from 6 wks through 3 years. At 3 years only 14% of TDA patients were unable to work because of their low back condition. This was significantly lower($p=0.0215$) compared to pre-op where 39% were unable to work. In the fusion group, 23% were unable to work post-op compared to 41% pre-op. These differences were not statistically significant between groups.

CONCLUSIONS

VAS and ODI improved, stabilized and did not deteriorate at 3 years in both groups. Moreover, pain medication use in TDA patients had a greater reduction and more patients in the TDA group were able to resume work as compared to fusion. This may have significant cost-effectiveness implications in the surgical management of DDD. Long-term outcomes from all 25 sites are needed to confirm these findings.