

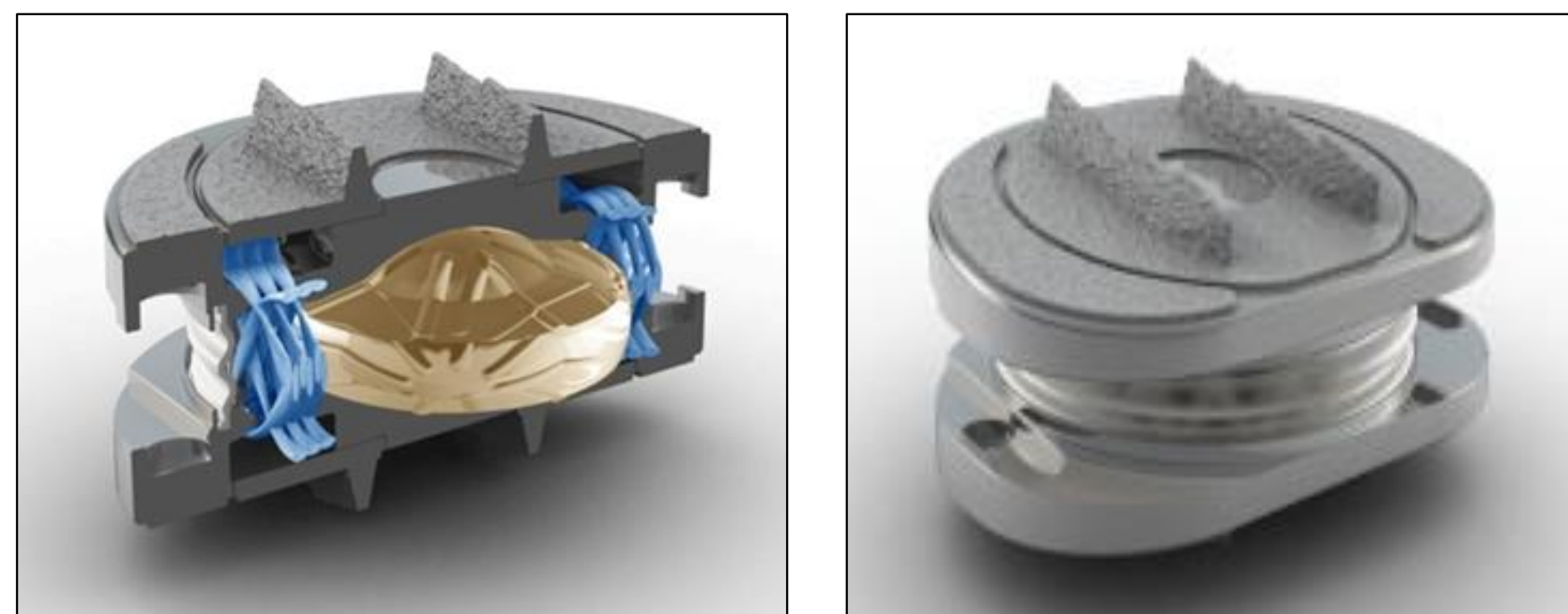
Two Year, Multi-Center Outcomes for the Treatment of Degenerative Disc Disease in the Lumbar Spine Using a Novel, Compressible Core Prosthesis

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BACKGROUND

Low back pain is one of the most prevalent problems in industrialized countries, affecting as many as 80% of all adults at some time in their lives. Among the significant contributors to low back pain is degenerative disc disease (DDD). Although fusion has been well accepted for treatment of DDD, high rates of complications and stress to adjacent segments remain a concern. Lumbar total disc replacement (TDR) was developed with a goal of preserving motion and avoiding various fusion-related complications, but the relative merits of single vs. multiple level arthroplasty remain unclear.



M6[®]-L Artificial Lumbar Disc (For Lumbar TDR)

METHODS

This is a multi-center, single arm, prospective post-market registry of the M6[®]-L, consisting of consecutive patients presenting with lumbar DDD who agreed to participate. This paper reports on those patients who have completed at least 24 months of follow-up to date. Clinical outcome measures include the Oswestry Disability Index (ODI) and back and leg Visual Analogue Scales (VAS). Radiographic analysis of disc angle and range of motion (ROM) was also performed.

RESULTS

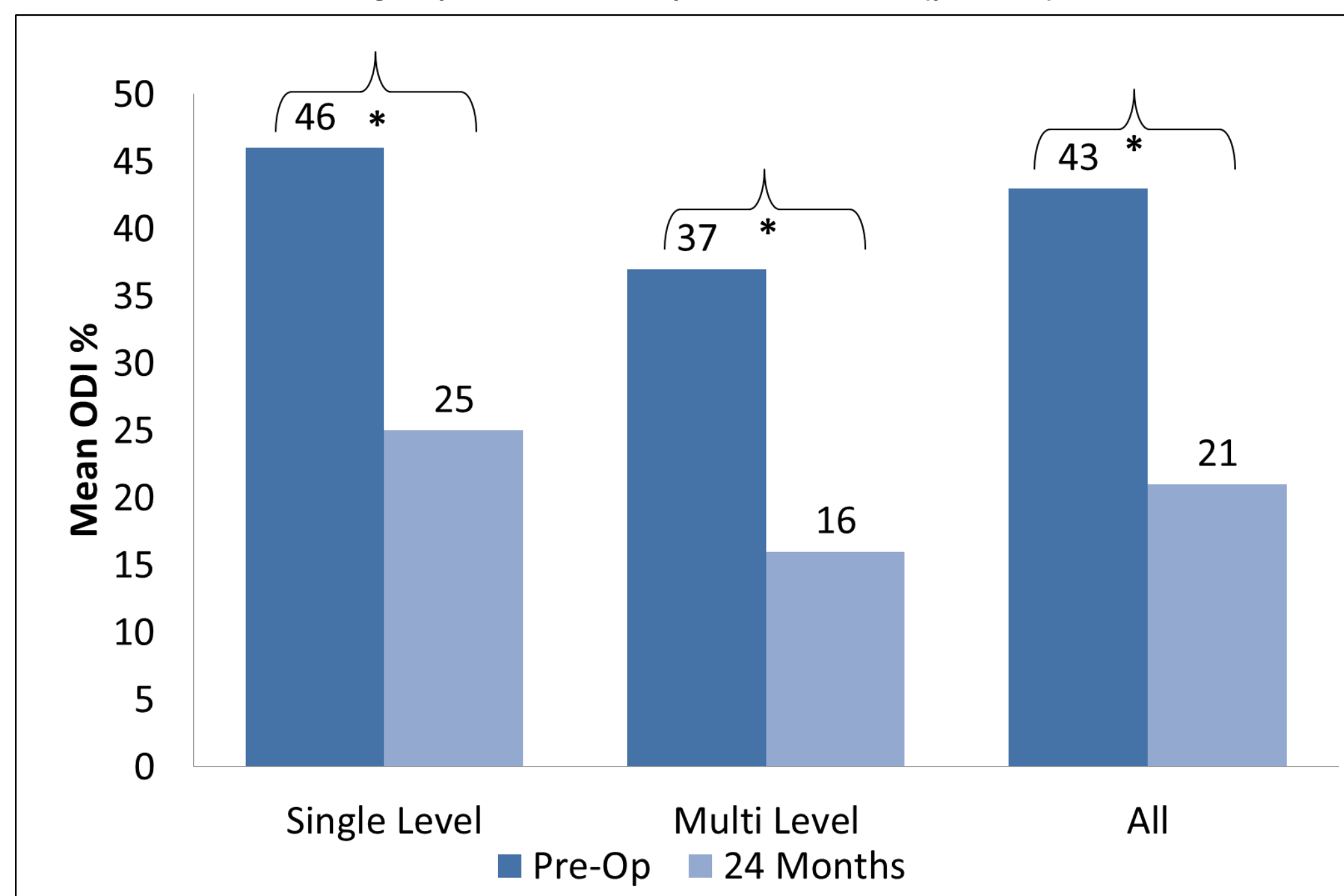
Eighty three patients had completed their 24 month follow-up visits by October 2014. There were 35 males and 48 females with a mean age of 42.1 years. The mean height and weight were 172.0 cm and 76.5 kg, respectively. Average BMI for the study patients was 25.7. There were no significant differences in these variables between the SL and ML subgroups ($p > 0.05$). A total of 121 discs were implanted in the 83 patients: forty-nine (49) patients were treated at 1 level, and 34 at multiple levels, between L2 and S1. As would be expected, the average surgery time was shorter for the single level cases relative to the multiple level cases: the surgery took 79.4 ± 30.6 minutes for single level (SL) cases and 127.5 ± 52.9 for multiple level (ML) cases. Similarly, blood loss during surgery was 180.8cc (median 105cc) for the SL group and 359.4cc (median 245cc) for the ML group. The overall mean hospital stay duration was 5.7 days (median 6.0) and 6.3 days (median 6.0) for the SL and ML groups, respectively, which is longer than one might expect to see in some markets, but is consistent with standard local healthcare practices.

CLINICAL OUTCOMES

Paired ODI data (patients reporting ODI at both baseline and 24 months) was available for 80 patients (47 SL, 33 ML). The mean ODI of the combined cohort was $43 \pm 18\%$ at baseline, and had improved to $21 \pm 19\%$ at 24 months. Similarly, the SL group, which reported a mean score of $46 \pm 16\%$, improved to $25 \pm 21\%$ at 24 months, and the ML group had an ODI score of $37 \pm 19\%$ at baseline, improving to $16 \pm 16\%$ at 24 months. The results of the paired t-tests indicated that both groups, as well as the overall cohort, were significantly improved at 24 months relative to baseline ($p < 0.001$, **Figure 2**).

While there was a statistically significant difference between the SL and ML groups both at baseline and at 24 months ($p < 0.05$), each subgroup experienced an average decrease of 21 percentage points in ODI from its respective baseline, resulting in a non-significant difference in this measure between the two groups ($p > 0.05$). According to the literature, a 10-point improvement in ODI is considered the minimum clinically important difference (MCID)¹⁹. In this study, 71% of the responding patient cohort (72% of SL patients, and 70% of ML patients) achieved MCID at 24 months.

Fig. 2 Mean Oswestry Disability Index. * $p < 0.001$. There was a significant difference between the SL and ML groups at both Pre-Op and 24 months ($p < 0.05$).



According to ODI criteria, 94% (n=44) and 85% (n=28) of the single level and multi level groups, respectively, and 90% (n=72) of the total study population, had a disability of moderate to bed-bound pre-operatively, with only 6%, 15% and 10%, respectively, reporting minimal disability at baseline. At the 24-month follow-up, disability was significantly improved relative to baseline, with 51% (n=24) of the SL patients and 73% (n=24) of the ML patients reporting minimal disability ($p < 0.001$). The level of patient disability pre-operatively and at 24 months is shown in Figure 3 and Figure 4 for the SL and ML groups.

Fig. 3 Disability Level at baseline and 24 Months for the Single Level Patients

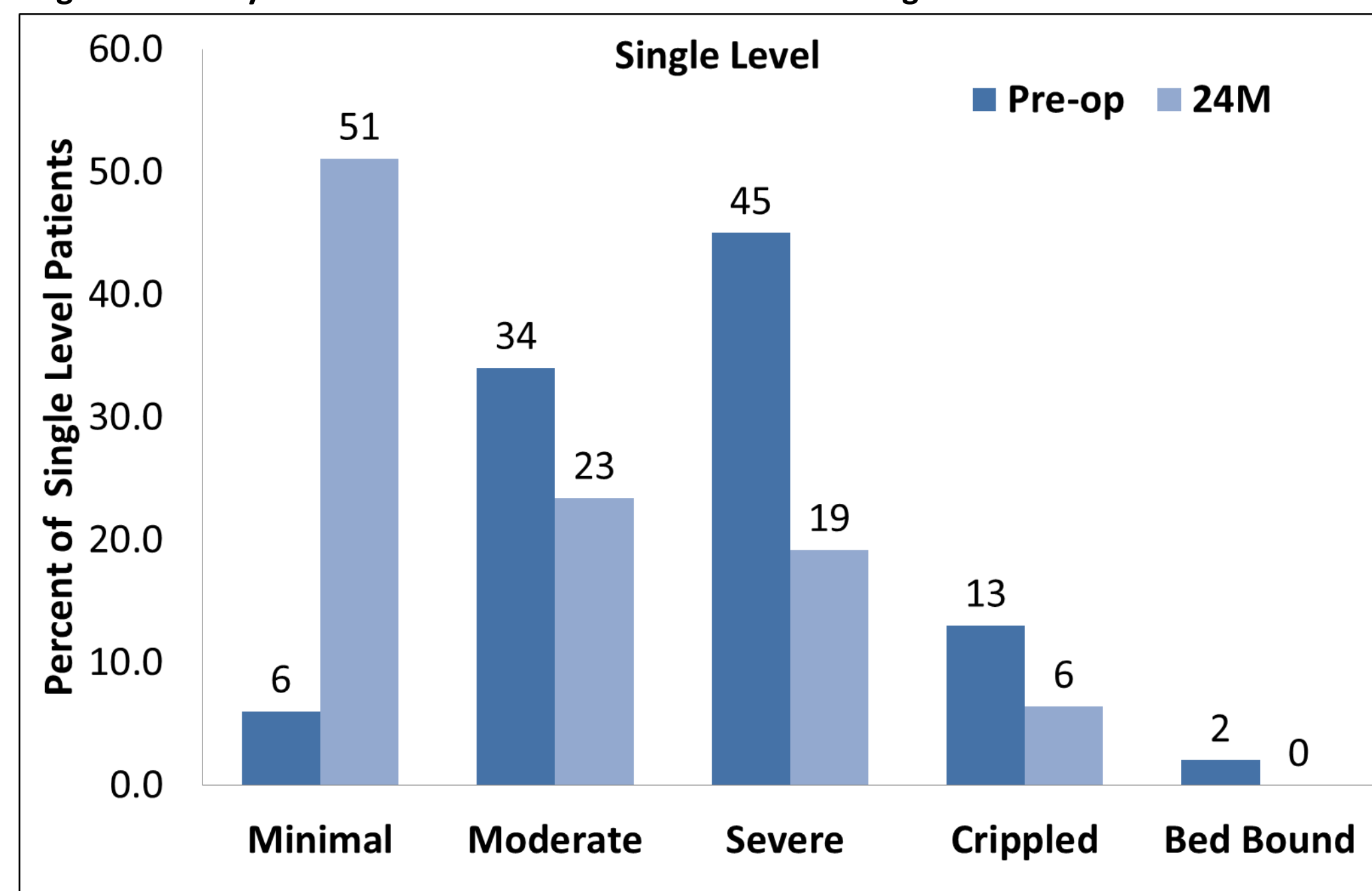
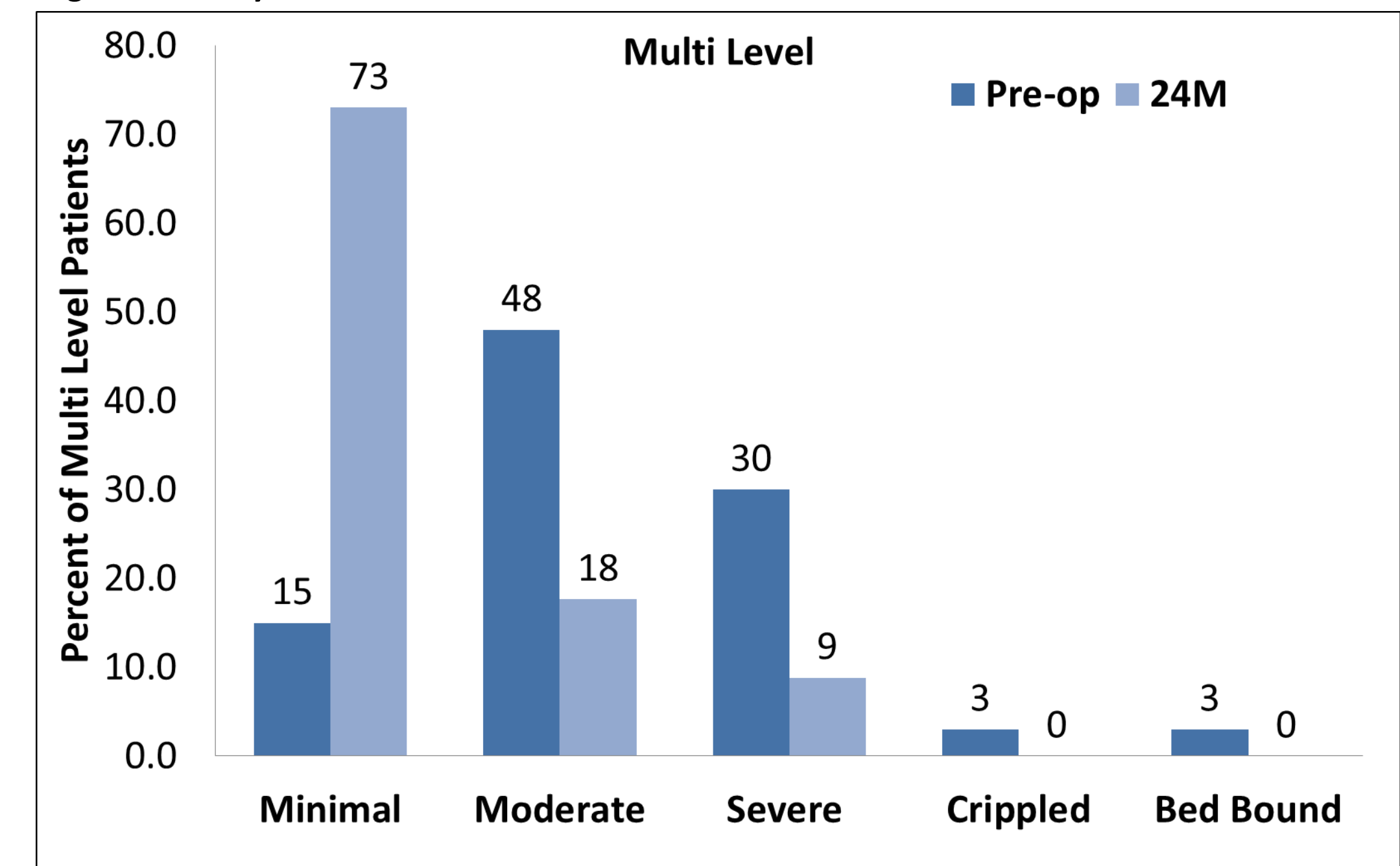
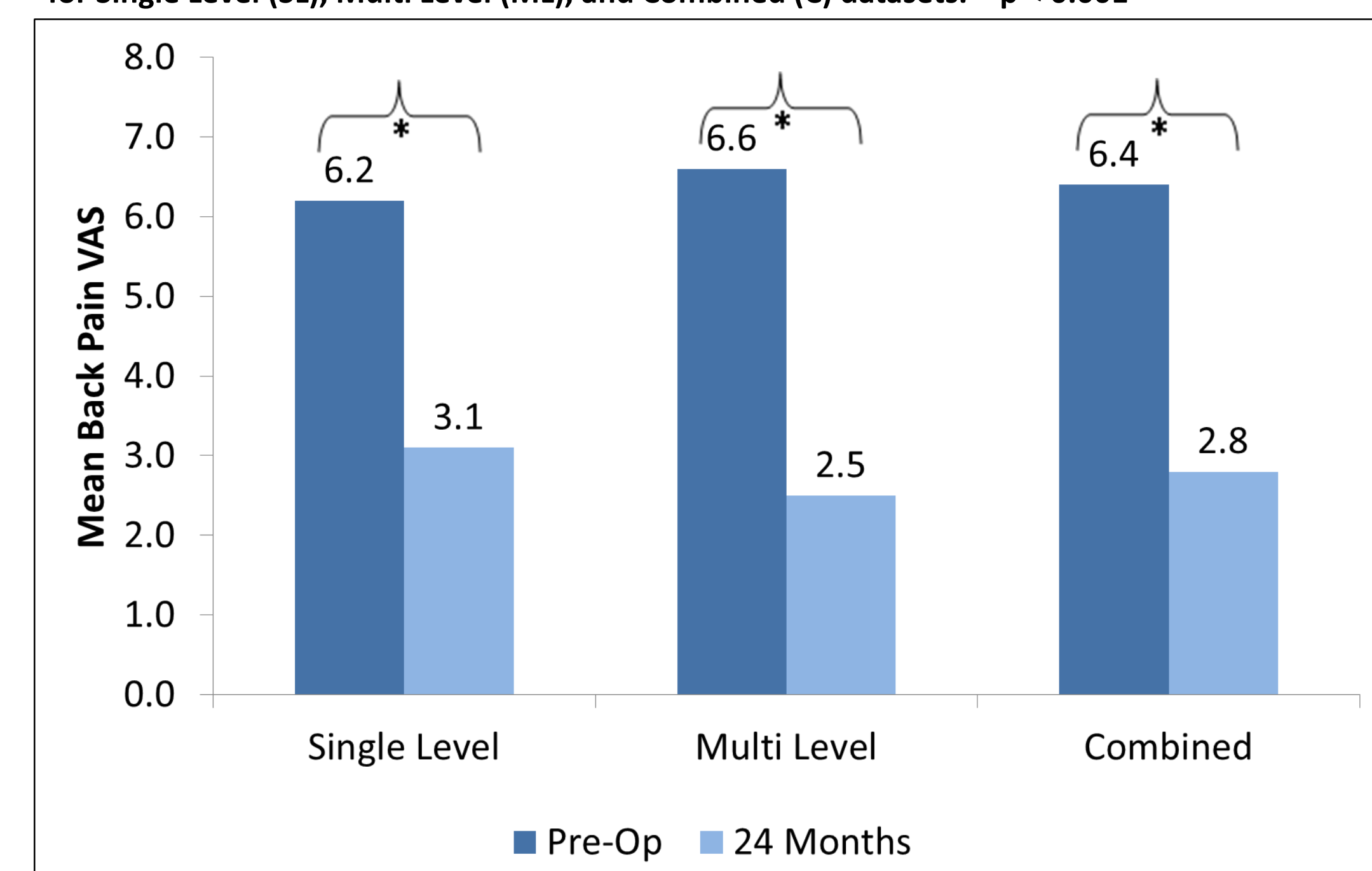


Fig. 4 Disability Level at baseline and 24 Months for the Multi Level Patients



Back pain was 6.2 ± 2.3 and 6.6 ± 2.0 pre-operatively on the visual analogue scale for the SL and ML groups, respectively; the combined cohort (totaling 79 patients, 46 SL and 33 ML, with available VAS data at both time-points) had a VAS back pain score 6.4 ± 2.2 . At 24 months follow-up, mean back pain VAS decreased significantly for the SL, ML, and combined cohorts relative to their respective baseline values ($p < 0.001$; **Figure 5**).

Fig. 5 Back Pain VAS at Baseline and 24 Months for Single Level (SL), Multi Level (ML), and Combined (C) datasets. * $p < 0.001$



Mean pre-operative VAS leg pain was 3.2 ± 2.1 for the combined dataset; the SL and ML scores were similar to the combined dataset (3.2 ± 1.9 for the SL group and 3.2 ± 2.3 for the ML group). A similar pattern of significant decrease was observed in the leg pain VAS data for all cohorts at 24 months (SL 1.9 ± 2.2 , ML 1.9 ± 2.0 , Combined 1.6 ± 2.1 ; $p < 0.001$). There were no statistically significant differences between the SL and ML groups in either the pre-op or the 24 month cohorts for either of the VAS measures ($p > 0.05$). It has been reported that an improvement of 1.8-1.9 cm in VAS back pain can be equivalent to the minimum clinically important difference¹⁹. In this cohort, 68% of the patients (65% SL, 73% ML) achieved MCID based on 1.8cm improvement in back pain VAS.

CONCLUSION

This is the first study to report clinical and radiographic outcomes of TDR with the M6-L in SL vs ML procedures with two years of follow-up. The results suggest initial device safety and effectiveness when used for the treatment of lumbar degenerative disc disease at one or more levels.

Conflicts: No conflicts to disclose
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