



PROSPECTIVE CASE-SERIES OF ARTIFICIAL LUMBAR DISC REPLACEMENTS FOR THE TREATMENT OF SYMPTOMATIC DEGENERATIVE DISC DISEASE: INITIAL INTERIM CLINICAL RESULTS FROM A LONG-TERM FOLLOW-UP STUDY IN POTSDAM, GERMANY

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Summary

- This is an ongoing prospective observational study, part of a multi-site post market surveillance outside the United States. The 31 patients included in this analysis underwent disc replacement surgery and completed twelve-month follow-up.
- By twelve months, mean back pain VAS had decreased by more than 70% compared to pre-operatively. Right and left leg pain VAS scores also decreased significantly at each follow-up time point, and by twelve months, mean right and left leg pain VAS scores were 65% and 74% lower, respectively.
- 94% of the patients demonstrated improvement in ODI scores compared to pre-operative, and 90% responded that they would do the surgery again.
- Clinical outcomes from the M6-L Artificial Disc Study in Potsdam, Germany, demonstrated improvement in overall pain and disability through twelve-month follow-up and thereby provide excellent results to support the effectiveness and safety of the device for the treatment of degenerative disc disease.

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Introduction

When conservative treatments fail to treat intractable pain due to degenerative disc disease (DDD), fusion or total disc replacement is then considered. Fusion eliminates instability and reduces low back pain, but can lead to adjacent disc level degeneration. Alternatively, total disc replacement (TDR) will restore and maintain motion without affecting adjacent levels. The purpose of this study was to assess clinical outcomes and safety of a prospective case series using a next generation artificial lumbar disc at a single site in Potsdam, Germany.

Materials & Methods

This is an ongoing prospective observational study, part of a multi-site post market surveillance outside the United States. Beginning in February 2009, skeletally mature patients with DDD of the lumbar spine who failed at least a 6-month course of conservative therapy and signed informed consent for implantation were enrolled in this registry. The implantation procedure was done using the M6®-L Artificial Lumbar Disc (Spinal Kinetics, Inc., Sunnyvale, CA) (Figure 1) at Potsdam, Germany.



Figure 1: M6®-L Artificial Lumbar Disc

At each visit, patient evaluations included a routine neurological assessment, back pain and left/right leg pain visual analogue scales (VAS), Oswestry Disability Index (ODI), patient's self-assessment of current condition and satisfaction with treatment and any report of adverse event. Patients' outcomes were evaluated pre-operatively, at 3 months, 6, 12 and continue through 24 months post-operatively.

Results

Thirty one patients (19 males, 12 females) with mean age of 46.2±7.1 years and BMI 26.6± 3.4 kg/m² underwent disc replacement surgery and completed 12-month follow-up and are included in this analysis (Table 1).

		N=31
Sex	Male	19 (61%)
	Female	12 (39%)
Age in years (Mean ± SD)		46.2 ± 7.1
Height in cm (Mean ± SD)		174.5 ± 12.3
Weight in kg (Mean ± SD)		81.6 ± 16.6
BMI in kg/m ² (Mean ± SD)		26.6 ± 3.4

Table 1: Baseline Characteristics

Seventeen patients (55%) had one level disc replacement, 42% had two levels replaced and one patient underwent three level disc replacements (Table 2).

Index Level(s)	n (%)
L4/L5	5 (16%)
L5/S1	12 (39%)
L3/L4 & L4/L5	1 (3%)
L4/L5 & L5/S1	12 (39%)
L3/L4, L4/L5 & L5/S1	1 (3%)

Table 2: Surgery Levels

Pre-operatively, all patients complained of back pain and reported mean back pain VAS of 6.6±1.9, right and left leg pain VAS of 3.9±3.1 and 3.5±3.3, respectively. At 3-month, 6-month and 12-month follow-up back pain VAS scores had significantly decreased from baseline (p<0.001) (Figure 2).

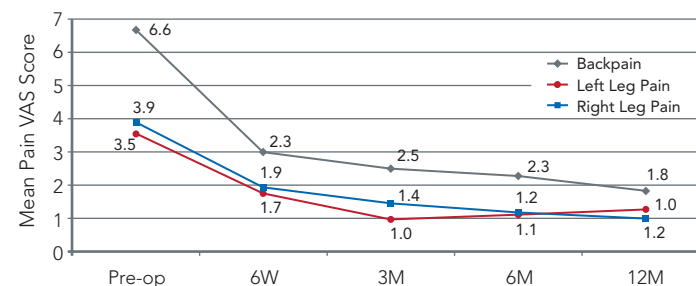


Figure 2: Back and Leg Pain VAS

By 12 months, mean back pain VAS had decreased by more than 70% compared to pre-operatively. Right and left leg pain VAS scores also decreased significantly at each follow-up time point (p<0.01) and by 12 months mean right and left leg pain VAS scores were 65% and 74% lower, respectively.

Overall, at each follow-up time point and through the 12-month visit, mean ODI significantly improved from baseline (p<0.001). Pre-op mean Oswestry disability score was 44.9±19.3 compared to 15.4 ± 11.6 at 12 months (Figure 3).

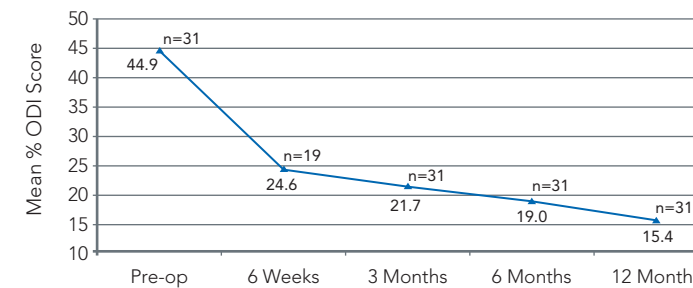


Figure 3: Oswestry Disability Index

Twenty nine (94%) patients had demonstrated improvement in their ODI scores compared to pre-operative, with 77.4% reporting minimal disability (Figure 4). Two patients (1%) continued to have moderate disability unchanged from baseline. When patients were asked about their condition at their 12-month visit, 26 (90%) responded that their condition had greatly improved and would do the surgery again.

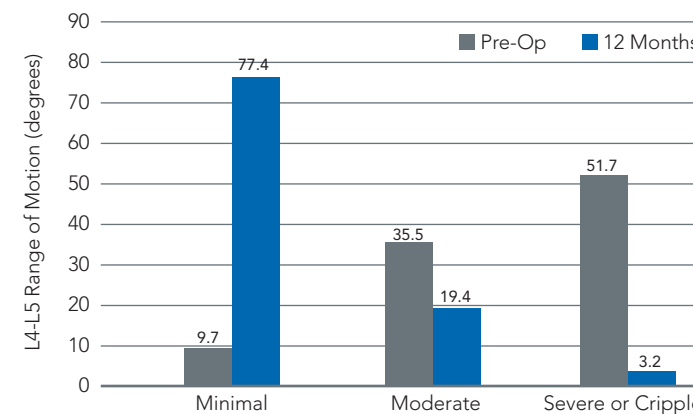


Figure 4: Disability Level at Baseline and 12 Months

No complications were reported for the patients included in this analysis. So far, more than 80 patients have been enrolled with M6-L artificial discs in Potsdam, Germany, and by mid-year 2012 more than 30 patients will have completed their 24-month follow-up visits.

Conclusions

Clinical outcomes from the M6-L Artificial Disc Study in Potsdam, Germany, demonstrated improvement in overall pain and disability through 12-month follow-up and thereby provide excellent results to support the effectiveness and safety of the device for the treatment of degenerative disc disease.

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