

Prospective Randomized Comparison of Three Lumbar Artificial Disc Replacements (A.D.R.) with Minimum Three-Year Follow-Up

Kenneth A. Pettine, MD



I, Kenneth A. Pettine, MD, have a financial interest or affiliation with the following commercial corporation(s) whose products may be mentioned in this program.

Medtronic – Royalties from Maverick Disc

Spinal Motion – Research support

Purpose

To Establish Safety, Efficacy, and Possible Clinical Superiority Between:

⦿Maverick™ (M)

⦿Charité™ (C)

⦿Kineflex™ (K)



Method

Follow up on three ADR's performed by two surgeons,
at one I.D.E. site

◉ Combined ADR results from two FDA IDE studies:

- Maverick vs. ALIF: July 2003 – July 2004
- Kineflex vs. Charite: June 2005 – November 2005

- Maverick: 25 Patients

- Charite: 31 Patients

- Kineflex: 35 Patients

Total: 91 Patients

Demographics



- ⦿ Average Age: 42.5
- ⦿ Average BMI: 25
- ⦿ L4-5 / L5-S1 Ratio:
 - 6/19 Maverick
 - 12/19 Charite
 - 7/28 Kineflex

◎ Maverick

- Pre-op: 57.6
- One Year: 16.3
- Three Year: 14.6
- $P < 0.001$

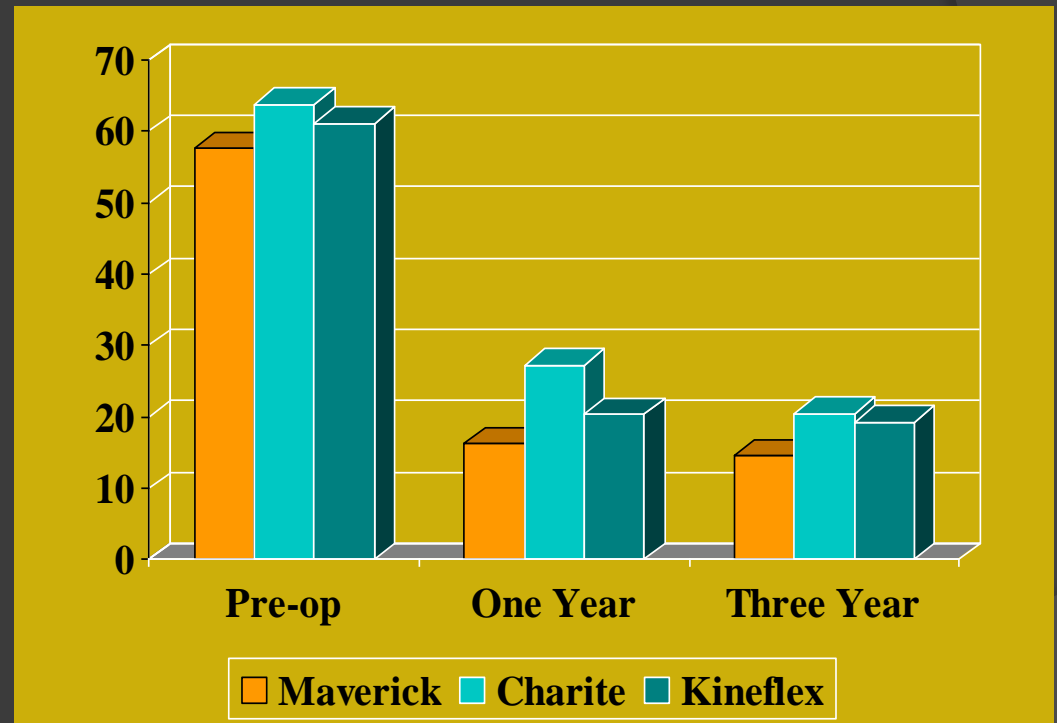
◎ Charite

- Pre-op: 63.8
- One Year: 27.3
- Three Year: 20.5
- $P < 0.001$

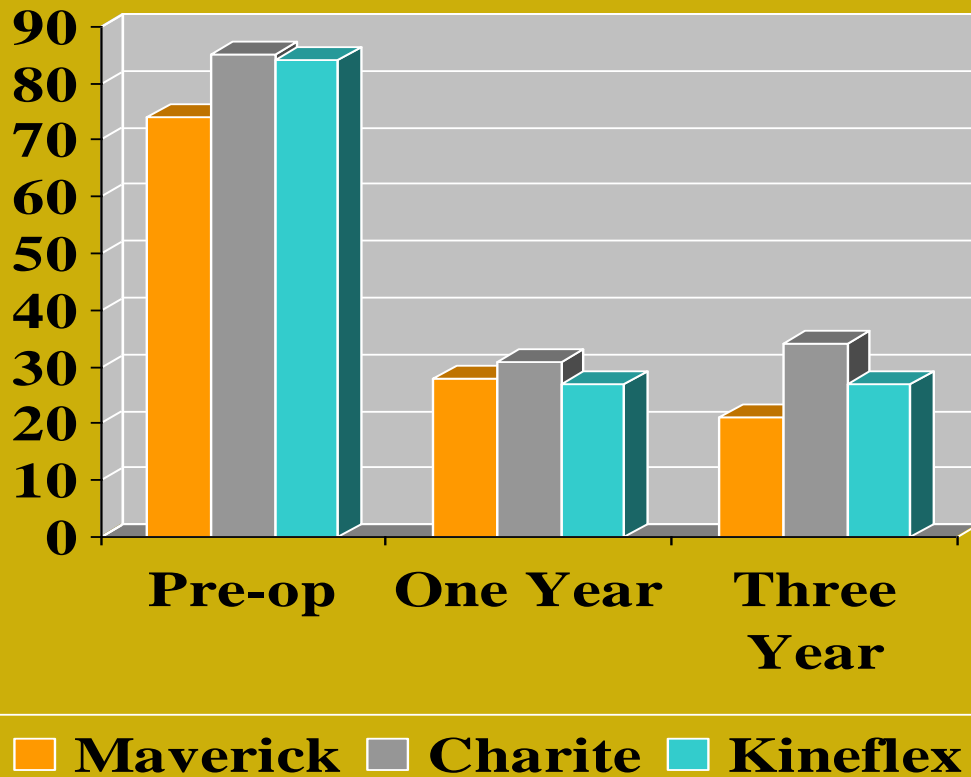
◎ Kineflex

- Pre-op: 61.1
- One Year: 20.4
- Three Year: 19.3
- $P < 0.001$

Oswestry



VAS



○ Maverick

- Pre-op: 74.1
- One Year: 27.9
- Three Year: 20.5
- $P < 0.001$

○ Charite

- Pre-op: 85
- One Year: 31.4
- Three Year: 33.8
- $P < 0.001$

○ Kineflex

- Pre-op: 83.9
- One Year: 27.3
- Three Year: 26.9
- $P < 0.001$

⊙ Patients with a VAS less than 2 at three year follow-up occurred in

- Maverick: 68%
- Charite: 29%
- Kineflex 47%

⊙ Patients with a ODI less than 10 at three year follow-up occurred in

- Maverick: 67%
- Charite: 33%
- Kineflex 52%

F.D.A. Clinical Success

◎ Maverick: 90.0%

◎ Charite: 83.5%

◎ Kineflex: 90.5%

Infection

◎ One:

- Maverick
 - 18 months post-op
 - Removed, debrided (x2)

Device Complications

⦿ Kineflex

- One device subluxation L5–S1 at 24 hours post–op.
- Converted to ALIF

⦿ Charite

- One bilateral pedicular fracture at 6 weeks post–op, converted to TLIF
- One subsidence at 6 weeks post–op, converted to PLIF
- One implant replaced into more central position at 24 hours post–op

◎ Lumbar Pedicle Screw Fusion Results

- Class I Data

- ODI 15% improvement **64.8%**
- FDA Clinical Success **45%**

Conclusions

- ⦿ All three ADR's demonstrated safety with more device related complications with Charite (3) compared to Maverick (1) and Kineflex (1).
- ⦿ They all showed efficacy with statistically significant improvement in ODI and VAS at three year follow-up ($p < 0.001$).
- ⦿ F.D.A. clinical success was (M) 90%, (C) 83.8% and (K) 90.5%. Fusion 45%
- ⦿ This is the only class on data comparing three ADR's from one IDE site.