Long Term Outcomes of Lumbar TDR & How They Compare To Fusion

Rolando Garcia Jr MD MPH
Disclosures

- Aesculap - Royalties & Consulting
What is missing?
“Mobility and stability are equal partners in the structure of the human spine,…a spine cannot function at full purpose or in longevity by stability alone- it also requires mobility.”

-Alvin H McKenzie

History of TDR

- 1984 – Charite I
- 1985 – Charite II
- 1987 – Charite III
- 1990 – Prodisc I
- 1999 – Prodisc II
FDA IDE APPROVED TDR

• 2000 - Charite IDE begins
• 2002 - Prodisc IDE begins
• 2004 - Charite FDA approved
• 2006 - Prodisc
• 2007 - Activ IDE begins
• 2015 - Activ FDA approved
2 Year Outcomes
Prospective, Randomized, Controlled Multicenter FDA IDE Trials: 2-Year Data

A Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemptions Study of Lumbar Total Disc Replacement With the CHARITÉ™ Artificial Disc Versus Lumbar Fusion

Part I: Evaluation of Clinical Outcomes

Scott Blumenthal, MD,* Paul C. McAfee, MD,† Richard D. Guyer, MD,* Stephen H. Hochschuler, MD,* Fred H. Geisler, MD, PhD,‡ Richard T. Holt, MD,§ Rolando Garcia, Jr., MD, MPH,¶ John J. Regan, MD,** and Donna D. Ohnmeiss, PhD††

Both found TDR at least as safe and effective as fusion, superior on some measures

Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-L Total Disc Replacement Versus Circumferential Fusion for the Treatment of 1-Level Degenerative Disc Disease

Jack Zigler, MD,* Rick Delamarter, MD,† Jeffrey M. Spivak, MD,§§§ Raymond J. Linovitz, MD, FACS,§ Guy O. Danielson, III, MD,¶¶ Thomas T. Haider, MD,¶¶¶ Frank Cammisa, MD,# Jim Zucherman, MD,** Richard Baldarston, MD,†† Scott Kitchel, MD,## Kevin Foley, MD,§§ Robert Watkins, MD,||| David Bradford, MD,¶¶¶¶ James Yue, MD,#§ Hansen Yuan, MD,*** Harry Herkowitz, MD,¶¶¶ Doug Geiger, MD,### John Bendo, MD,§§§ Timothy Peppers, MD,§ Barton Sachs, MD,* Federico Girardi, MD,# Michael Kropf, MD,† and Jeff Goldstein, MD§§§
Randomized Trial

Lumbar Disc Arthroplasty With MAVERICK Disc Versus Stand-Alone Interbody Fusion

A Prospective, Randomized, Controlled, Multicenter Investigational Device Exemption Trial

Matthew F. Cornet, MD,* J. Kenneth Burkus, MD,† Randall F. Dryer, MD,§ and John H. Pezoa, MD||

• 2:1 randomization
• 577 patients
  • 405 TDR with Maverick
  • 172 ALIF with LT cages and BMP
• The investigational group had statistically superior outcomes (P < 0.05) at all postoperative evaluations in:
  • ODI,
  • back pain
  • SF-36
  • Patient satisfaction.
  • Fewer implant or implant/surgical procedure-related adverse events (P < 0.001).
• Return-to-work intervals were reduced for investigational patients.
• In the investigational group, overall success superiority was found when compared to the control group as defined by the FDA IDE
324 patients

- 218 randomized to ActivL
- 106 randomized to control

Overall treatment success with ActivL was superior (p=0.02)

ActivL better in
- Radiographic success p<0.01
- ODI success (p=0.08)
5 - 10 Year Outcomes
Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion: Five-year follow-up

Richard D. Guyer, MD*a,*, Paul C. McAfee, MDb, Robert J. Banco, MDc, Fabian D. Bitan, MDb, Andrew Cappuccino, MDe, Fred H. Geisler, MD PhDf, Stephen H. Hochschuler, MDb, Richard T. Holt, MDb, Louis G. Jenis, MDb, Mohamed E. Majd, MDb, John J. Regan, MDg, Scott G. Tromanhauser, MDb, Douglas C. Wong, MDh, Scott L. Blumenthal, MDa

- ODI and VAS: no change between years 2-5
- ROM maintained in TDR group
- TDR had significantly greater RTW with fewer patients on long-term disability
- Re-operation rate of 7.7% for TDR vs 16.3% for fusion
Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease

Clinical article

Jack E. Zigler, M.D.,¹ and Rick B. Delamarter, M.D.²

- No significant changes between the 24- and 60-month follow-up in ODI or VAS
- At 60 months, successful radiographic ROM in 93.7% of TDR pts, mean 7.2°
- Re-operation rate of 6.8% for TDR vs 12% for fusion
• Compared to ALIF, improvement in the TDR grows was statistically greater in ODI & SF-36 at 1, 2, and 5 years

• Investigational group had lower device related & serious AE

• At 5 years, superiority is concluded for Maverick mean improvements in ODI (p=0.009), SF-36 (p=0.002), and patient satisfaction (p=0.043)
261 patients at 5 years

PRO maintained from 2 to 5 years

Activ L significantly better ROM

Adjacent Segment Re-Op:

• Activ L. - 0.9%

• Prodisc L - 4.7%
Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial

Caroline Sköld - Hans Tropp - Svante Berg

- Prospective, Randomized
- 152 patients: 80 TDR, 72 fusion
- Follow-Up at 5 year 99%
- Totally pain-free at 5 years: 38% vs 15%
- Back VAS & ODI improvement better in TDR (p=0.02)
Activ L IDE Trial: 7 Year Results

- 206 patients at 7 years
- Activ L significantly better ROM
  - Activ L - 5.3%
  - Prodisc L - 4.1%
- Class IV HO
  - 0% Activ L
  - 3.1% Prodisc L
- Re-operations 4.6%

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<td>Prodisc L</td>
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10+ Year Outcomes
Clinical and Radiological Outcomes With the Charité™ Artificial Disc
A 10-Year Minimum Follow-Up

Jean-Philippe Lemaire, MD, Hélène Carrier, MD, El-Hadi Sari Ali, MD, Waffa Skalli, MD, and François Lavaste, MD

• 100/107 patients
• 54 1-level
• 45 2-levels
• 1 3-levels
• Minimum 10 yer follow up (range 10 - 13.4)
• 90% Excellent/Good Results
• Mean ROM 5.4 degrees
• Mean Follow Up 13.2 years (range 10-16.8)

• Follow up in 106/108 - 98%

• 82% Excellent/Good Results

• Mean ROM 10.1 degrees
Long Term Clinical Results Following Charite III Total Disc Replacement

- Spine J, 2018
- 30 patients (35 implants)
- All Charite
- Average 15.4 year follow-up
- Cumulative survival: 100%
- Clinical Success: 93.3%
- Reoperations: 2/30 (6.7%)
Long-Term Outcomes Following Lumbar Total Disc Replacement Using ProDisc-II

Average 10-Year Follow-Up at a Single Institute

Se-Jun Park, MD, Chong-Suh Lee, MD, PhD, Sung-Soo Chung, MD, PhD, Keun-Ho Lee, MD, Wan-Seok Kim, MD, and Jun-Young Lee, MD

• 54 Patients

• Prodisc L

• Mean Follow Up - 10 years

• Successful Outcomes - 87%

• Re-Operations - 9.3%
Motion = Outcomes
Impact of L5-S1 ROM on VAS Success

For every 2° increase in ROM, a greater % of patients had clinical success in VAS back pain at 5 years.

With ≥6° of motion at L5-S1 all patients demonstrated VAS success.
Impact of L5-S1 ROM on ODI Success

For every 2° increase in ROM, a greater % of patients reached clinical success based on ODI scores at 5 years.
Motion = Lower ASD
Range of motion and adjacent level degeneration after lumbar total disc replacement

Russel C. Huang, MD\textsuperscript{a,*}, Patrick Tropiano, MD\textsuperscript{b}, Thierry Marnay, MD\textsuperscript{c}, Federico P. Girardi, MD\textsuperscript{a}, Moe R. Lim, MD\textsuperscript{a}, Frank P. Cammisa, Jr., MD\textsuperscript{a}

- 42 patients 8.7 yr follow-up

- Pts with $\geq 5^\circ$ at TDR level had significant lower rate of ASD: 0\% vs. 34\%
  - Results suggest motion has preventive potential for ASD
Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion

Clinical article

Jack E. Zigler, M.D.,1 Jamieson Glenn, M.D.,2 and Rick B. Delamarter, M.D.3

- 123 TDR; 43 fusion at 5 years
- Radiographs evaluated by independent radiologist
- ASD degeneration rates
  - 28.6% for fusion
  - 9.2% for TDR
  - \( p < 0.01 \)
- New ASD (No pre-op ASD)
  - 23.8% for fusion
  - 6.7% for TDR
  - \( p < 0.01 \)
Reviewed 27 Class I and II fusion and TDR studies

- 314/926 fusion patients developed AgDD = 31%
- 31/313 TDR patients developed AgDD = 3%
  - p<0.0001
Adjacent segment degeneration after lumbar spinal fusion compared with motion-preservation procedures: a meta-analysis

Aixing Pan¹ · Yong Hai¹ · Jineai Yang¹ · Lijin Zhou¹ · Xiaolong Chen¹ · Hui Guo¹

• 15 studies, 1,474 patients

• TDR had significantly lower rates of ASDegen, ASDis, and re-op for ASDis compared with fusion
  • ASDegen: 18.6% vs. 37.5%
  • ASDis: 5.1% vs. 14.4%
  • Re-op for ASDis: 1.1% vs. 7.7%
Conclusions

• Early, intermediate, & long term data supports the use of lumbar.

• Patient reported outcomes favor TDR over fusion.

• Motion affects clinical outcomes.

• Motion affects adjacent segment degeneration & disease.
Wisdom comes from Experience
Experience comes from Bad Judgement
Bad Judgement comes from Wine Fun!