What Is The Science Behind Lumbar Hybrid Constructs?

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Jack E Zigler MD
Medical Director
Texas Back Institute

Dr. Webb tried to convince you that fusion is the best option for 2 level lumbar DDD

Scott Webb, D.O.
Orthopaedic Surgeon/Spine Surgeon
Baylor Scott & White Main Campus

DON’T BUY IT!!!

- These patients are 43 years old (mean)
- That means half of them will be younger than 43 (mid-career with kids in school)
- 30% will break down and need transition level surgery in 10-15 years
- They will be in their mid-40’s - mid-50’s when their spines will be trashed

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Transition Disease Stinks in your 40’s and 50’s

- Facet pain
- Limited motion
- Radicular irritability
- Stenosis with neurogenic claudication
- Meds
- Injections
- Limited activity

Hybrids Are A Better Option...
and I've Got Data To Prove It!

Is There Science Behind Hybrid Constructs?

- In the US,
  - Lumbar Arthroplasty was “born” in Science with Level I IDE studies, and then came to market
  - Hybrids were developed out of frustration and insurance necessity as a way to treat patients with multiple level disease w/o 2 level fusion
- We continue to do hybrid surgeries globally, based on observational clinical comfort, but not based on any similarly strong Level I scientific data
I Thought There Was Limited Published Data on Hybrid Constructs

But there’s more than you think!

• The earliest discussion of hybrids
• Examples shown of ALIF combined with ADR
  – 2, 3, and 4 level constructs
• Bertagnoli also described anterior and posterior reconstruction

Hybrid Constructs

2005

2009

Hybrid/ALIF constructs performed similarly in vitro to 2 level TDR
Demographics

- 42 patients studied prospectively (NR)
  - 25 F, 17 M
  - Age 31-60 (mean 43)
  - 57% prior lumbar surgery (no fusions)
  - Failure of > 1 year of CC
  - Follow-up 21-50 months (mean 26.3 m)

Levels of surgery

- 35 L5-S1 ALIF/L4-5 ADR
- 3 L4-5 ALIF/L3-4 ADR
- 2 L5-S1 ALIF/L4-5 ADR/L3-4 ADR
- 1 L5-S1 ADR/L4-5 ALIF
- 1 L5-S1 ALIF/L4-5 ALIF/L3-4 ADR
Clinical Outcomes at 24 Months

- Radiographic range of motion averaged:
  - 7.8° (cranial)
  - 6.2° (caudal) in the investigational group

- Index level 2° surgical procedures
  - 2.4% of TDR patients
  - 8.2% of Fusion patients  \( p = 0.0497 \)

- Narcotics usage was significantly lower in TDR (36.4%) compared to Fusion patients (61.0%)  \( p = 0.0017 \)
Hybrid vs 2L TDR

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<thead>
<tr>
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<th>2L Hybrid</th>
<th>2L TDR</th>
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<tr>
<td>ODI improvement</td>
<td>Aunoble</td>
<td>Delamater</td>
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<tr>
<td>from Preop</td>
<td>53%</td>
<td>53%</td>
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<tr>
<td>VAS improvement</td>
<td>65%</td>
<td>58%</td>
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<tr>
<td>from Preop</td>
<td>(fusion 50%)</td>
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Prospective, randomized study
- 62 pts (31 per group)
- Mean follow-up 37 mo
- Symptomatic DDD L4-5 and L5-S1
  - Modic changes and disco

Hybrid vs. TLIF

- ALIF/ADR Hybrid pts had:
  - Significantly shorter OR time
  - Lower VAS scores early after surgery and at last follow-up visit
  - Similar complication rates
  - Increased motion at ADR levels
  - Fusion pts had increased motion at L3-4 (significantly more motion at this transition level than in hybrids)

Hoff et al, Europ Spine J, 2016
Survivorship and clinical outcomes after multi-level anterior lumbar reconstruction with stand-alone anterior lumbar interbody fusion or hybrid construct.

Chen B, Akpolat YT, Williams P, Braray D, Cheng WC.


Retrospective review of 64 patients (2 and 3 level DDD)

33 pts with Hybrid; 31 with SA ALIFs

Telephone follow-up

Hybrid group showed significant improvement in VAS and ODI

52.2% and 50.0% improvement vs 28.3% and 25.5% in ALIF group

Kaplan-Meier analysis showed 80.5% survivorship for Hybrids at 5 years versus 75.9% for ALIFs

1015 articles identified by key words

9 papers considered relevant

3 papers included for meta-analysis

Lackey Meta-analysis 2015

Baseline patient characteristics

<table>
<thead>
<tr>
<th>First author</th>
<th>Year</th>
<th>Age (years)</th>
<th>Males (%)</th>
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<tr>
<td>Chen 2016</td>
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<td>Ishi 2015</td>
<td>2015</td>
<td>45</td>
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<td>Le Bier 2010</td>
<td>2010</td>
<td>45</td>
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Data presented as average age and percentage of group male.

- 3 studies included in this meta-analysis –
  - 1 RCT, 1 prospective nonrandomized study, 1 retrospective observational study
- Results “slightly favour clinically significant improved VAS back pain score outcomes” postop and at 2 years for hybrids over fusion or TDR
SpineWeek 2012; Amsterdam

Treatment Options for Two-Level Symptomatic Disc Degeneration: Comparison of Total Disc Replacement, Fusion, and Hybrid

Internal TBI Study
Compared 2-level TDR, 360 fusion, and hybrid
• 360 fusion: longer op time and length of stay
• No significant differences in ODI outcome scores among these 3 options
• 2L TDR or hybrid were both viable alternatives to fusion

What Fusion Option is Best in a Hybrid?
• Is there a difference in clinical outcomes depending on the technique at the fusion level in a hybrid construct?
• There are many fusion options:
  – ALIF, 360, TLIF, XLIF, AxiaLIF
  – Posterior instrumentation, or not?

Internal Study at TBI
• Using a stand-alone ALIF at the Fusion level in a hybrid has rarely been addressed scientifically
• We compared the outcomes of hybrid surgery using ALIF vs. 360 Fusion at the fusion segment: first 135 patients
  – 83 patients with SA ALIF
  – 52 patients with 360 Fusion
Both groups improved significantly (p<0.01) from pre-op with no significant differences between groups.

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Re-operations

- Re-operation was performed in:
  - 3.6% of hybrid/ALIF group (3/83)
  - 23.1% of hybrid/360 (12/52)

* significantly lower in the hybrid patients with Stand-Alone ALIF’s

p<0.01
CONCLUSIONS

- Lumbar hybrid was shown to be a reasonable option to 2-level ADR, and performs better than a 2 level fusion.
- Good clinical outcomes were consistently observed across several studies with hybrids.
- TDR appeared to reduce stress at the segment adjacent to the treated levels, with lower ALD and lower reop rates observed than with 2 level Fusion.

CONCLUSIONS

- Unless there is a clear indication for posterior surgery, stand-alone ALIF is a viable option for the arthrodesis level in a two-level hybrid construct.
- Although there is limited high level scientific evidence, ongoing observational outcomes for lumbar hybrid constructs are more encouraging than 2 level lumbar fusion.

Who Do You Want to Believe?