American Board Spinal Surgery: Board of Directors
Spinal Research Foundation: Board of Directors
Titan Spine
Stock/ Royalty/ Advisor
Spine: Editorial Reviewer Board Member

Titanium (Ti) was used in the past
Clinical results were variable
Use declined
Threaded
End-plate destructive
Small openings for graft
Often Stand-alone

CT scans on 7 patients/ 11 surgical levels
No obvious evidence of pseudarthrosis
Surgical exploration yielded positive evidence of pseudarthrosis in 9/11 levels
Concluded that the bone within cage or absence of subsidence/ peri-implant lucency does not necessarily indicate solid fusion
Basic science studies find *acid-etching* the surface of Titanium
- Induces better osteoblast differentiation than PEEK
- Stimulates physiologic BMP production
- Stimulates TGF beta/VEGF
- These factors are osteogenic and may facilitate bone integration with the implant surfaces

Electron Microscopy
Micron-level=cellular response

Results: Cell Culture
- *p<.05 versus TCPS*
- #p<.05 versus PEEK
- $p<.05$ versus Smooth Titanium Alloy
Slosar ALIF Evolution: 1993-2013
- Allograft
- Stand-alone threaded Ti cages
- Allograft or Ti Cages + BMP
  - Biologics Revolution (Market explosion)
- (PEEK* + BMP)
- Acid Etched Ti + BMP (study)
- Acid Etched Ti + “non-BMP” biologics (study)

*XLIF only

Methods
- Prospective consecutive enrollment and data collection (2008-2010)
- ALIF at 1-3 lumbar spinal segments

Surgical technique:
- Mini-open anterior retroperitoneal approach
- ALIF interbody cage + Titanium Interbody Cage
- Pedicle screw fixation

Results
- 77 patients: 42 male and 35 female
  - 24 month follow up
- Ave age 46 years (range 23-67)
- Diagnosis
  - DDD n= 52 (67%)
  - Spondylolisthesis n=19 (25%)
  - Nonunion n=6 (8%)

Results
- 48 (63%) ALIF + decompression + pedicle screw fixation
- 24 (31%) ALIF + percutaneous pedicle screw fixation
- 5 (6%) stand-alone ALIF
Clinical Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>6 mo.</th>
<th>12 mo.</th>
<th>24 mo.</th>
</tr>
</thead>
<tbody>
<tr>
<td>VNS Back</td>
<td>7.1</td>
<td>3.7*</td>
<td>3.6*</td>
<td>3.4*</td>
</tr>
<tr>
<td>VNS Leg</td>
<td>5.1</td>
<td>2.3*</td>
<td>2.1*</td>
<td>2.4*</td>
</tr>
<tr>
<td>ODI</td>
<td>55</td>
<td>36*</td>
<td>32*</td>
<td>30*</td>
</tr>
</tbody>
</table>

*P<0.001

- 1 case of retrograde ejaculation (2.3%) resolved by 3 months.
- 2 posterior infections
- No permanent neurological injuries
- No Device related complications

Weaknesses
- No control group for comparison
- Small single center study

Strengths
- Prospective/ Consecutive with 24 month data
- Common Diagnostic categories
Clinical Results

- Meaningful Clinical Improvements
  - ODI >15 and VNS >3
  - Achieved in the majority of cases

- DDD 67% of the patient population studied

- The clinical outcomes at 12 and 24 months were not significantly different than the results at 6 months.

Methods

- Patients underwent ALIF at L3-S1 had CT scan analysis as part of a separate clinical outcomes study*
- Titanium implant
- 2 sponges of InFuse® (3.0 mg per fusion level)
- 1-3 cc. of HA/TCP

Radiographic

Methods

- Fine cut CT scans with reconstructed images were performed randomly at 6, 9, or 12 months.
- Two independent radiologists reviewed the scans were blinded to clinical results and the other’s interpretations.
- Interobserver Agreement calculated for each radiographic variable
Results

- 33 patients
- 56 spinal fusion segments
  - 17 males / 16 females
  - Average age 46 years (range 23-66 yrs)
  - 6 patients (18%) were nicotine users.

CT Scan

- 17 patients at 6 months
- 9 patients at 9 months
- 7 patients at 12 months

There were no differences in radiographic results among the patients evaluated at each time point nor between males, females, or nicotine users.

Results

Artifact/ Subsidence

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Artifact</th>
<th>Subsidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Grade 0</td>
<td>Grade 1</td>
</tr>
<tr>
<td>A</td>
<td>43 (77%)</td>
<td>12 (21%)</td>
</tr>
<tr>
<td>B</td>
<td>54 (96%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td></td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>56 (100%)</td>
<td>53 (98%)</td>
</tr>
</tbody>
</table>

Agreement 0.80 0.95

Artifact: Grade 0: Mild; Grade 1: Moderate; Grade 2: Non-diagnostic
Subsidence: >3 mm

Lucency/ Cystic Changes

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Lucency</th>
<th>Cystic Changes Vertebral Body</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>A</td>
<td>1 (2%)</td>
<td>55 (98%)</td>
</tr>
<tr>
<td>B</td>
<td>2 (4%)</td>
<td>54 (96%)</td>
</tr>
</tbody>
</table>

Agreement 0.96 0.95
Results

Overall Fusion Grade

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Grade 5</th>
<th>Grade 4</th>
<th>Grade 3</th>
<th>Grade 2</th>
<th>Grade 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>45 (80%)</td>
<td>8 (14%)</td>
<td>2 (4%)</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>B</td>
<td>51 (91%)</td>
<td>5 (9%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Agreement

Same Grade: 0.77
Within 1 Grade: 0.95

Grade 5: Definitely Fused;
Grade 4: Probably Fused;
Grade 3: Indeterminate;
Grade 2: Probably Not Fused;
Grade 1: Definitely Not Fused

Artifact

EDGE OF IMPLANT

Fusion Grade 4

SURFACE INTEGRATION
LINEAR LUCENCY/NO SUBSIDENCE
Results

- The interobserver agreement for the overall study was 0.88 (p<.001)
  - 100% agreement noted on 345 of the 392 data points reviewed
  - Agreement for fusion formation was 0.77 (p<.001)
  - All measurements reached statistical significance (p<.001)

Weaknesses

- No direct surgical exploration/confirmation
- No comparison group

Strengths

- Large study sample
  - 56 fusion segments/392 data points
  - Results comparable to other authors confirming CT is an accurate tool for fusion assessment
  - Independent radiologists (no surgeon reviewers)

Radiographic Conclusions

- The titanium implant studied demonstrated minimal artifact, minimal subsidence, and trabecular bone was easily visualized.

- Radiographic fusion criteria can be reliably assessed using CT scans with a high degree of interobserver agreement.

Clinical Conclusions

- Acid etched Ti Interbody fusion cage is safe and effective in achieving rapid and sustainable clinical outcomes with BMP
- DDD can be treated reliably with interbody fusion
- Outcomes at 6 months were predictive of 12 and 24 month results
  - Early osseous integration (implant-host bone)?
- Fusion rate was 94-99%
  - Ongoing investigation is underway to determine the most cost effective biologic that may be used without sacrificing clinical results.
References


