Stand Alone ALIF

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Overview of ALIF

- 1980s - stand-alone ALIF with allograft or autograft, fusion rates variable
- 1980 - 90s - Pedicle screws introduced and 360s criticized as too much surgery

Overview of ALIF

- 1990s – Metal cylindrical fusion cages for stand-alone ALIF; mixed results, unpopular
- Late 1990s - 2000s - ALIF with BMP; MIS PLF available for mini-360
- Late 2000s - 2010s - many options available, concerns about costs and safety of spine surgery
Introduction – Stand Alone ALIF

• Advantages:
  – No risk of posterior complications:
    • muscle damage
    • nerve root damage
    • Facet violation/damage
  – No cost associated with posterior fusion +/- instrumentation
  – Faster rehab
• Potential disadvantage:
  • lack of stability

Introduction

• Use of stand-alone ALIF (no supplemental posterior fusion or fixation) has been debated
• Over the course of several years, newer interbody fusion implant designs and material as well as newer graft materials have evolved
• BUT not all ALIFs are equal

First Generation Devices
NOT STAND ALONE DEVICES
Newer Interbody Devices with Fixation are the subject of this debate

Current ALIF Devices incorporate some variation of screw/plate fixation such as:

- SynFix cage (PEEK) packed with cancellous allograft
  - Strube et al, J Spinal Disord Tech 2012

- Biomechanical comparison of stand-alone ALIF device (SynFix), device with translaminar screws, cage + screws, 360 fusion
  - A New Stand-Alone Anterior Lumbar Interbody Fusion Device: Biomechanical Comparison with Established Fixation Techniques
    - Christopher M. Gao, MD / Ping Sietchter, MD / Rene Serafini
    - Robert Pligmaner, MD / Mari Salvo, MD / Rene Ramboz, MD, PhD
Biomechanical Study

- Stability of stand-alone ALIF device comparable to pedicle screw fixation in flexion, extension, and lateral bending, and superior in rotation

Cain et al, Spine, 2005

ALIF Literature

- 9 studies with re-op data for single-level ALIF clearly reported
- 1,345 patients
- Follow-up: 2 - 6 yrs
- Majority IDE trials, including control groups for TDR studies


ALIF Studies

- Re-op for pseudo, revision, removal, or addition of supplemental fixation at ALIF level: 9.9%
  - Range: 2.5% - 24.3%
ALIF Studies Compared with 360

- 360 control groups for ProDisc-L and Flexicore studies
- Single-level, same indications as stand-alone ALIF studies
- 360 fusion: ALIF FRA + PLF w iliac crest autograft + pedicle screws
- 98 patients
- 2 – 5 yr follow-up


ALIF Studies Compared with 360

- Re-op in ALIF: 9.9% range: 2.5% - 24.3%
- Re-op in 360: 12.2% range 9.3% - 21.7%


Stand-alone Anterior Versus Anteroposterior Lumbar Interbody Single-level Fusion After a Mean Follow-up of 41 Months

Patrick Struck, MD, Eric Rydell, MD, Tony Ricklis, MD, Cameron Perks, MD, Christian Gross, MD, and Michael Puzlar, MD

- Single -level stand-alone ALIF (Synfix) vs. 360
- 41 mo follow-up
  - Significantly better clinical outcome for stand-alone ALIF (VAS, ODI)
  - No difference in fusion rates
Conclusion: For 1-level DDD, if posterior decomp and/or alignment is not needed, suggest stand-alone ALIF

Clinical Outcomes

Largest Cage Series in the Literature

- 679 pts
- Single-level DDD
- Stand-alone ALIF with tapered fusion cages:
  - 277 InFuse (BMP)
  - 402 autograft

Burkus, J Spinal Disord, 2003
Fusion Rate

- 24 mo follow-up fusions rate:
  - InFuse: 94.4%
  - Autograft: 89.4%

Clinical Outcome

>50% improvement in Oswestry scores in both groups (both stand-alone ALIF with cages)

Poor Results Reported

- 74 single-level stand-alone ALIF
- 2 - 5 yr follow-up
- SynFix + iliac crest autograft
- 18 (24.3%; re-op symptomatic pseudo)
- NSAID use play a role?

Schimmel, JSDT, in press
A Multicenter Study to Evaluate the Safety and Efficacy of a Stand-Alone Anterior Carbon Fiber Cage for Anterior Lumbar Interbody Fusion

Two-Year Results From a Food and Drug Administration Investigational Device Exemption Clinical Trial

Jingyi Li, MD; Mark L. Donohoe, MD; E. Gary Liu, MD; Adam Granat, MD; Jin-Woo Kang, MD; Stephen Wilkin, MD; James Wang, MD; Jong Hoon Yoo, MD; Greg Johnson, MD; and Todd L. Albert, MD; and Alexander F. Vagers, MD

- Overall patient success 25%
- Clinical success 46.3%
- Fusion success 57.5%

ALIF Carbon Fiber Cage

- Maintained significant increase in disc space height
- Re-op: 15%
- Suboptimal radiographic and clinical outcomes
- Suggestion: Additional benefit may be gained from adjunctive posterior stabilization

Li et al, Spine, 2010

We do know that BMP + Allograft in ALIF doesn’t work

- Two studies suggest not using BMP with allograft for stand-alone ALIF


Interbody fusion with allograft and rhBMP-2 leads to consistent fusion but early subsidence

K. Vaidya, R. War, A. Selhi, S. Meisterling, W. Hakeos, Wybo C.D.

Graft Resorption With the Use of Bone Morphogenic Protein: Problems Lessons From Anterior Lumbar Interbody Fusion

Using Tissue-Engineered Allografts and Recombinant Human Bone Morphogenetic Protein-2

Ben R. Puffer, MD; Moe, MD; Jesus M. Vindel, MC; Edgar E. Dawson, ME; and Ronald K. Puffer, MD; and David E. Treadwell, MD.
Causes of Variation in ALIF Results

- May be attributable to differences in implants and graft materials
  - Have not used state of the art ALIF devices with incorporated screws/plates
  - Unlikely that a simple cage without additional fixation will be equivalent to a 360
  - Little research to identify which combination of device and graft yields optimal outcome

Concern about stability of ALIF alone
- Many supplementary fixation devices described to improve stability
- However, posterior fixation associated with paravertebral muscle damage, screw related complications, and increased rate of adjacent segment degeneration

"No evidence to support the contention that ALIF with supplementary fixation results in a better fusion rate or clinical outcome."
Cost Comparison

<table>
<thead>
<tr>
<th></th>
<th>ALIF</th>
<th>360</th>
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<tbody>
<tr>
<td>Direct costs</td>
<td>11,494</td>
<td>15,428</td>
</tr>
<tr>
<td>Indirect costs</td>
<td>26,767</td>
<td>39,233</td>
</tr>
<tr>
<td>Total costs</td>
<td>38,257</td>
<td>54,661</td>
</tr>
<tr>
<td>Total costs (including InFuse)</td>
<td>44,633</td>
<td>44,633</td>
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</tbody>
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Note: ALIF included anterior plate that is not commonly used and adds expense.

Cost Savings

• ~10% of ALIF undergo re-op for revision / addition of supplemental fixation
• In the remaining 90% of stand-alone ALIFs, there is at least a $12,500 savings compared with 360 fusion — surely this amount is less than the cost of revising 10% of ALIFs
  → Remember, there are costs of re-ops 360s also!

Advantage of Stand-alone ALIF Compared with 360 Fusion

• In 100% of pts eliminates potential for:
  → Posterior muscle injury
  → Nerve injury from malpositioned posterior fixation
  → Facet injury
  → Re-operation for HWR
• In 100% of pts eliminates:
  → Costs of posterior procedure and related screws/rods
  → Reduces costs through reduced OR time and hospital stay
Disadvantage of Stand-alone ALIF Compared with 360 Fusion

- ~ 10% of pts will later undergo re-op to add PLF

Stand-alone ALIF

- Single-level for DDD, recurrent HNP, low grade spondy
- Proper patient selection
  - No obvious need for posterior procedure
  - Good psych profile

Stand-alone ALIF

- Appropriate disc space preparation
- Optimal device selection
  - Size fits well into disc space
  - Maintains disc space height
  - Preserves lordosis
  - Preserve endplates
  - Avoid large threaded metallic cages
  - Carbon fiber?
Grading/Slip Angle

Spondylolisthesis
Meyerding
Grade 1  0-25%
Grade 2  25-50%
Grade 3  50-75%
Grade 4  >75%

SLIP ANGLE
rotational relationship
between L5 and S1
normally 0% or less

Spinal Alignment

Lumbar Lordosis (LL) L1-S1
• Mean ±2° ±10 degrees
• Closely correlated to PI

Thoracic Kyphosis T4-T12
• 39° ±10° ±10 degrees

5/27/2016
PELVIC PARAMETERS

Normal Values
- PI = 48-55 deg
- SS = 36-42 deg
- PT = 12 – 18 deg