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

ALIF; Loguidice et al, Spine, 1988

Wiltse system; Surg R Orthop, 1989

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

BAK cages Kuslich et al, Spine, 1998

Ray cages Ray, Spine, 1997

BMP (Boden et al, Spine, 2000)

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

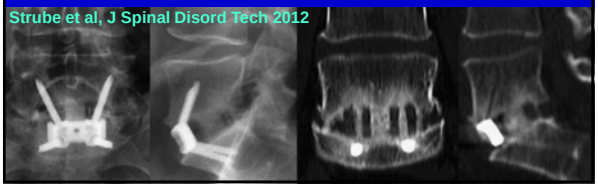
First Generation Devices
NOT STAND ALONE DEVICES

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



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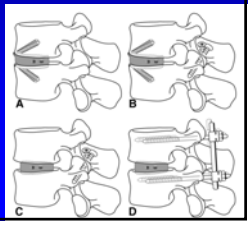
A New Stand-Alone Anterior Lumbar Interbody Fusion Device: Biomechanical Comparison with Established Fixation Techniques

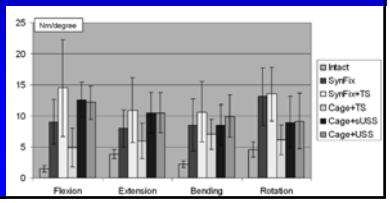
Christopher M. J. Cain, MD,* Philip Schleicher, MD,† Rene Gerlach,†
Robert Pflugmacher, MD,† Matti Scholz, MD,† and Frank Kandziora, MD, PhD†

- Biomechanical comparison of stand-alone ALIF device (SynFix), device with translaminar screws, cage + screws, 360 fusion



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 reproted
- 1,345 patients
- Follow-up: 2 - 6 yrs
- Majority IDE trials, including control groups for TDR studies

Kuslich et al, Spine 2000; Blumenthal et al, Spine 2005; Guyer et al, Spine J 2009; Burkus et al, JBJS 2009, J Spinal Disord Tech 2002, JBJS 2005; Gornet et al, Spine 2011; Li et al Spine 2012; Schimmel et al, J Spinal Disord Tech, in press

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 indcations as stand-alone ALIF studies
- 360 fusion: ALIF FRA + PLF w iliac crest autograft + pedicle screws
- 98 patients
- 2 – 5 yr follow-up

Zigler et al, Seminars Spine Surg 2012; Sasso et al, Spine, 2008

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%

J Spinal Disord Tech 2012; Oct;25(7):362-369

ORIGINAL ARTICLE

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

Patrick Strube, MD, Eike Hoff, MD, Tony Hartwig, MD, Carsten F. Perka, MD, Christian Gross, MD, and Michael Putzier, 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

J Spinal Disord Tech 2012; Oct;25(7):362-369

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

Patrick Strube, MD, Eike Hoff, MD, Tony Hartwig, MD, Carsten F. Perka, MD, Christian Gross, MD, and Michael Putzier, MD

- **Conclusion: For 1-level DDD, if posterior decomp and/or alignment is not needed, suggest stand-alone ALIF**

Clinical Outcomes

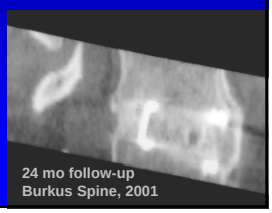
Largest Cage Series in the Literature

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

Burkus, J Spin Disord, 2003

Fusion Rate

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

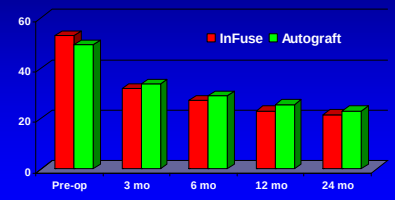


24 mo follow-up
Burkus Spine, 2001

Burkus, J Spin Disord, 2003

Clinical Outcome

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



Burkus, J Spin Disord, 2003

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

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A Multicenter Study to Evaluate the Safety and Efficacy of a Stand-Alone Anterior Carbon I/F Cage for Anterior Lumbar Interbody Fusion

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

Jingfeng Li, MD,* Mark L. Dumonski, MD,† Qinyi Liu, MD,‡ Adam Lipman, MD,†
Joseph Hong, BS,† Nuo Yang, PhD,† Zhengshuai Jin, MD,§ Yongxin Ren, MD, PhD,§
Worawat Limthongkul, MD,¶ Jason T. Bessey, MD,† John Thalgott, MD,‖
Greg Gebauer, MD,† Todd J. Albert, MD,† and Alexander R. Vaccaro, MD, PhD†

- 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

J Bone Joint Surg [Br] 2007; 89-B:342-5

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

R. Vaidya, R Wier, A Sethi, S. Meisterling, W. Hakeos, Wybo C.D.

SPINE Volume 31, Number 10, pp E277-E284
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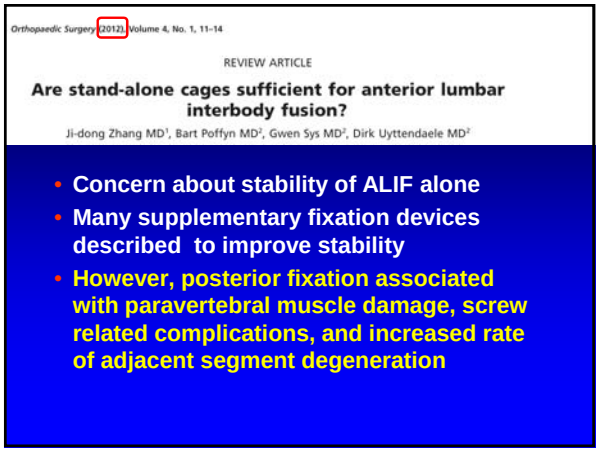
Graft Resorption With the Use of Bone Morphogenetic Protein: Lessons From Anterior Lumbar Interbody Fusion Using Femoral Ring Allografts and Recombinant Human Bone Morphogenetic Protein-2

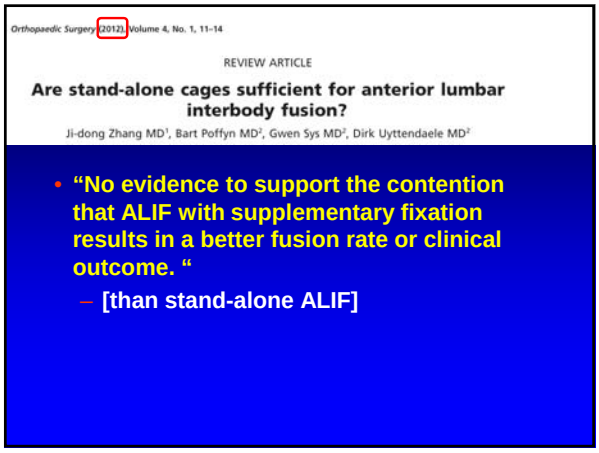
Ben B. Pradhan, MD, MSE,* Hyun W. Bae, MD,* Edgar G. Dawson, MD,*
Vikas V. Patel, MA, MD,† and Rick B. Delamarter, MD*

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. "
  - [than stand-alone ALIF]

Cost Comparison

		360
Direct costs	[illegible]	[illegible]
Indirect costs	11,494	15,254
Total costs	26,767	39,233
Total costs (including InFuse)	32,167	44,633

Difference of $12,466 ALIF costs less !

Note: ALIF included anterior plate that is not commonly used and adds expense

Patel et al, J Spinal Disord Tech 2008

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

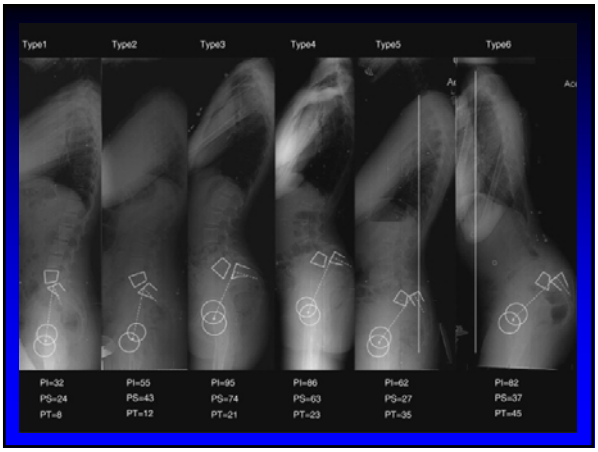
Spinal Alignment

Lumbar Lordosis (LL) L1-S1

- Mean -62+or- 10 degrees
- Closely correlated to PI

Thoracic Kyphosis T4-T12

- 39 +or- 10 degrees



PELVIC PARAMETERS

Normal Values

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

Values of spondylolisthesis in accordance with the degree of slippage

	Grade I	Grade II	Grade III	Grade IV	Grade V
PI	57.7°	66°	78.8°	82.3°	79.4°
SS	43.9°	49.8°	51.2°	48.5°	45.9°
PT	13.8°	16.2°	27.6°	33.9°	33.5°