Expandable Interbody Technologies

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Disclosers

- Royalties:
  - Stryker, Medtronic

History

- Some of the earliest expandable interbody patents were in mid and late 1990's
- Slow product development until recently

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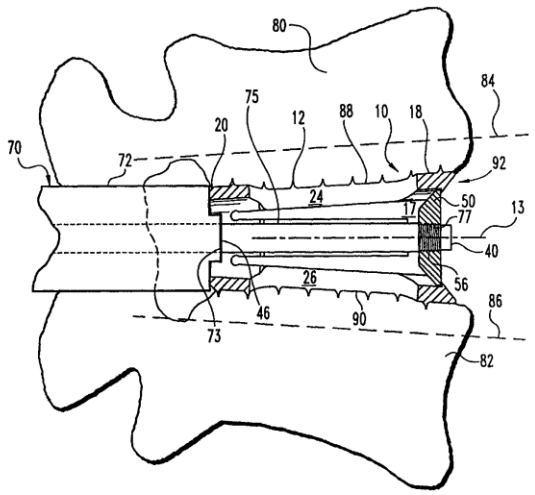
Published
With international search report.

(54) Title: EXPANDABLE INTERBODY FUSION CAGE

(57) Abstract

An expandable interbody fusion device in one embodiment includes a cylindrical body (10) defining a hollow interior (17) for receiving bone graft or bone substitute material. The body (10) is divided into a number of branches (24, 26, 40 and 41) connected to one another at a fixed end (20) and separated at an expandable end (18). The expandable cage may be inserted in its substantially cylindrical form and may be expanded by movement of an expansion member (50) to establish lordosis of the spine. The present invention provides an expansion member (50) that interacts with the interior surfaces of the device to maintain the cage in the expanded condition and provide a large internal chamber (17) for receiving bone in–growth material. Methods for insertion of the fusion device are also disclosed.



Mechanical Design

- 2 general categories
  - Vertical expansion
    - Wedge type ‘shim’, Expanding cylinder and Jack mechanism
  - Horizontal expansion

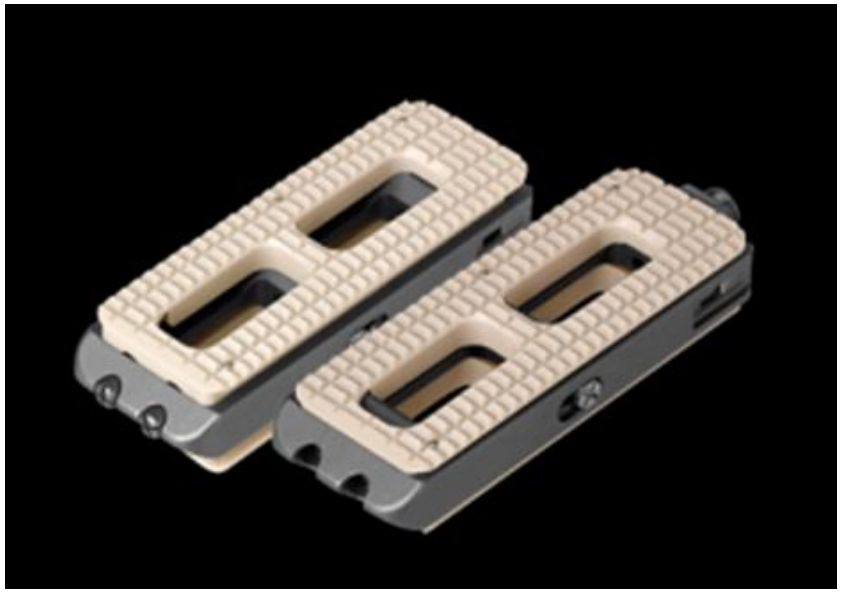
Catagories of Expandable Interbody Implants

- Posterior
  - TLIF, PLIF
- Lateral
  - Transpsoas, Anterior to the Psoas
- Anterior
  - ALIF

‘Bullet’ PLIF Design

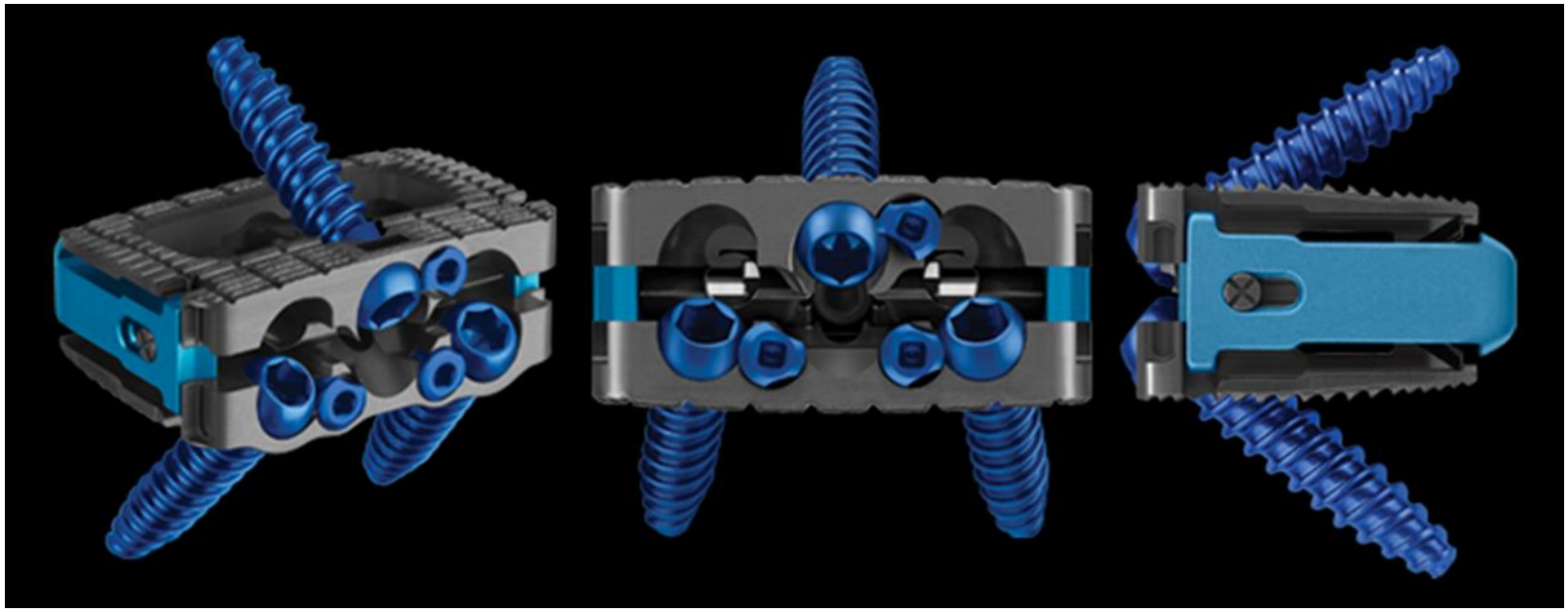
‘Kidney bean’ TLIF Design

Lateral Designs



Lateral Lordotic Design

ALIF Design



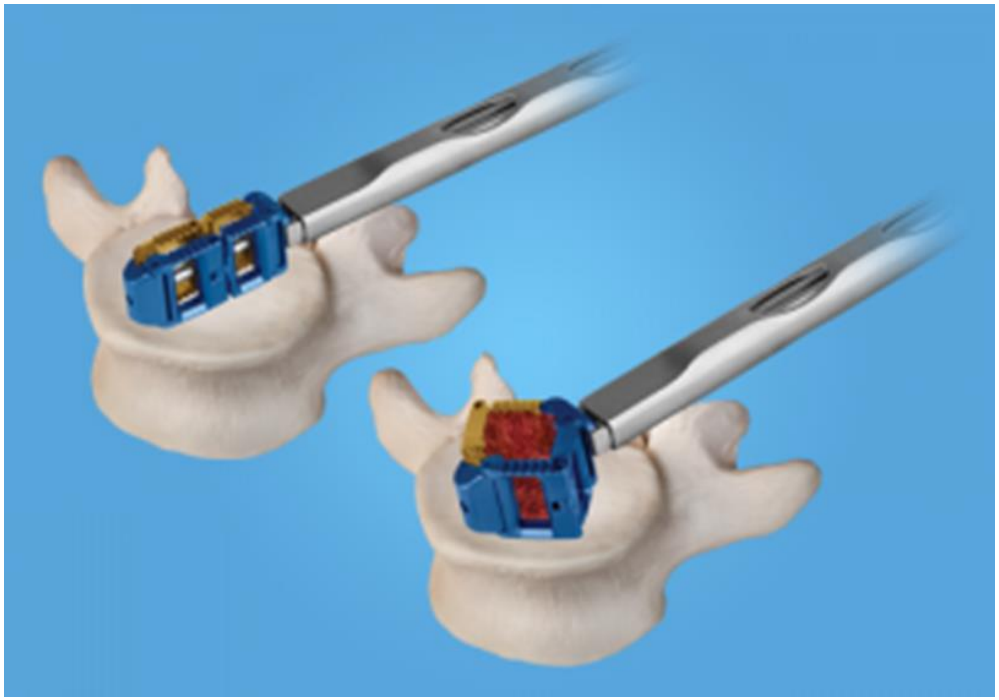
Vertical Expansion (PLIF, TLIF, LATERAL, ANTERIOR)

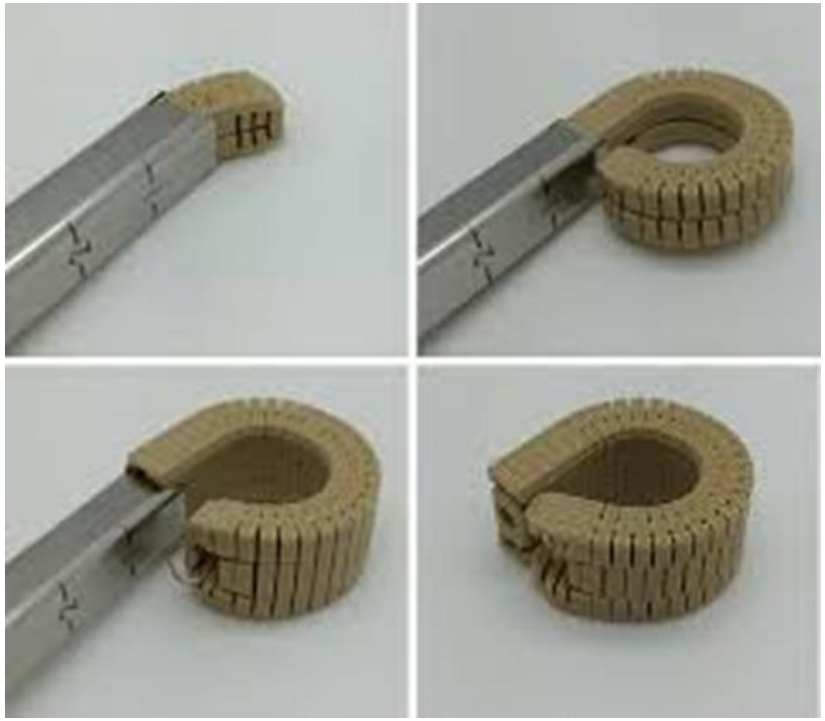
- Advantages:
  - Height restoration (anterior and posterior)
  - Lordosis restoration
  - 'Locks' the implant for immediate stability to prevent against migration

- Disadvantages
  - Implant subsidence
    - Often not placed on the apophyseal cortical ring
  - Understates ability to restore lumbar lordosis
  - Difficult post expansion bone grafting
  - Small area for bone graft within the implant
    - Most designs create voids in bone graft after expansion

Designs

- Horizontal Expansion





Horizontal Expansion

- Advantages:
  - Small entry footprint
  - Expands in-vivo for enlarge footprint
  - Bone graft can be packed after expansion

- Disadvantages:
  - Difficult to control for lordosis
  - May need to ‘undersize’ to be able to expand if endplates are concave

Cast Report:

- 60 year old female
- Progressive LBP and Left L3 radiculopathy
- Subjectively feels like she leans to the left and this is progressive
- ODI 60
- VAS 6-8 back and leg


Rectangular Snip
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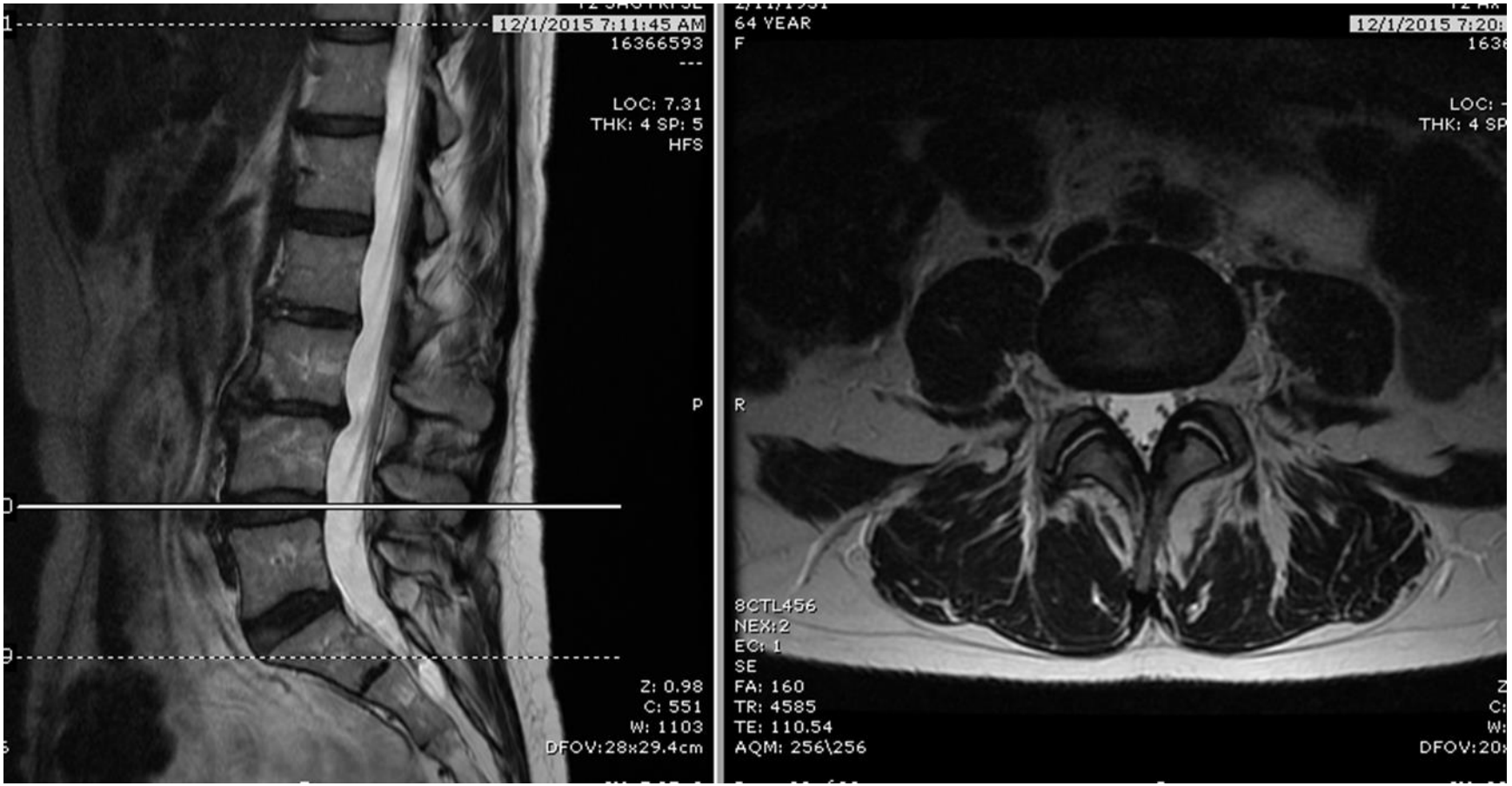
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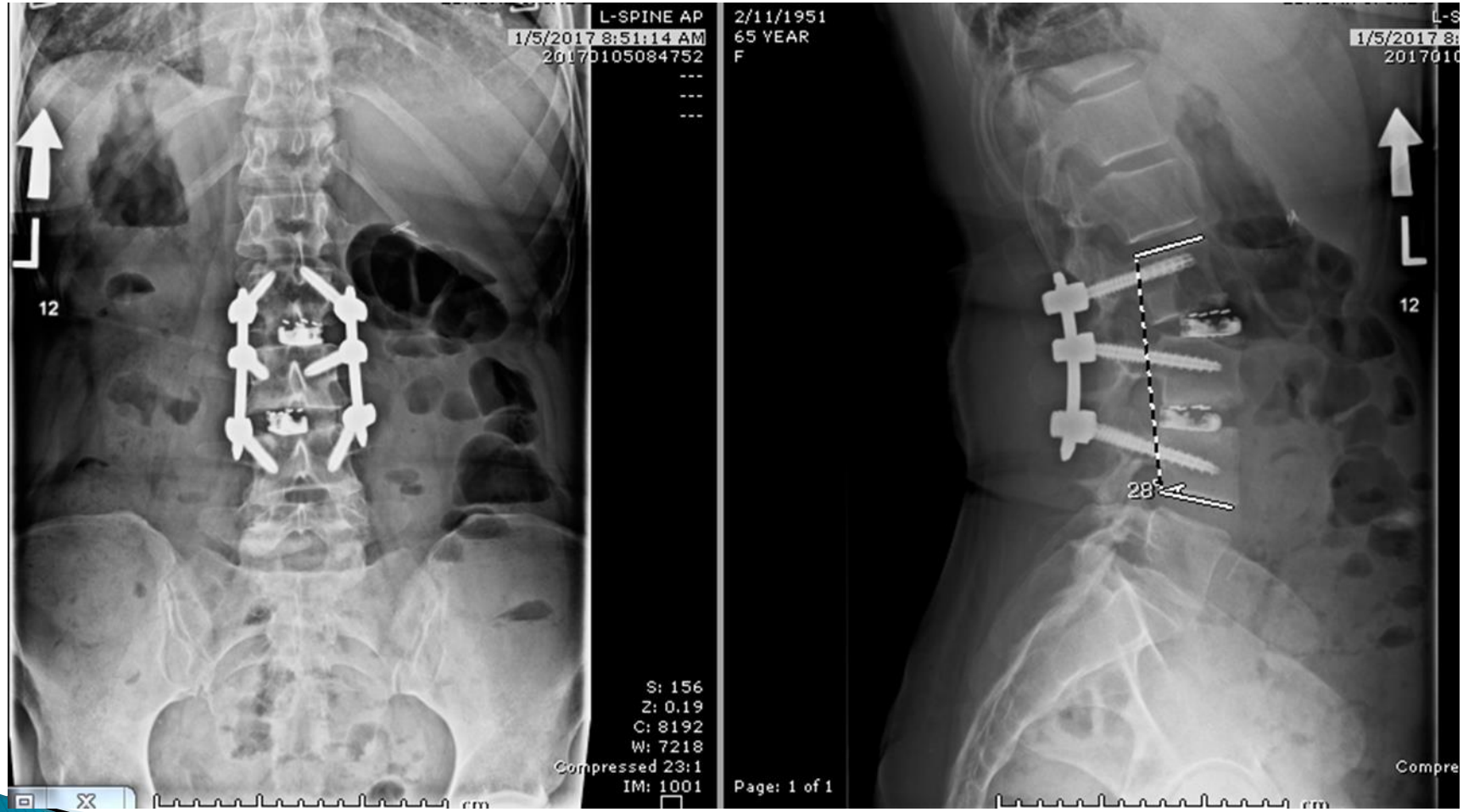
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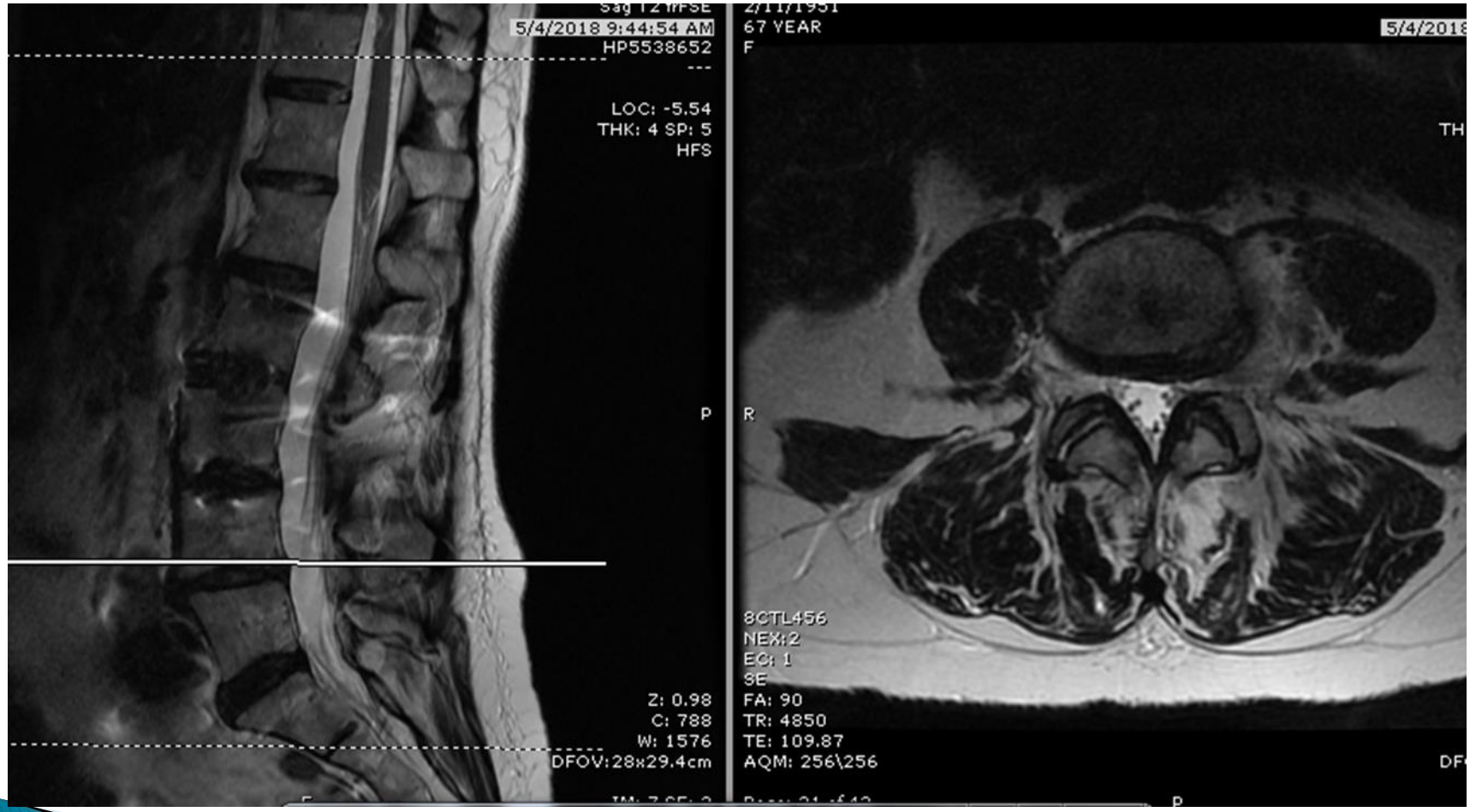
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Expandable Implant Costs Manufacturer and Payers

- Much more expensive for the manufacturer to produce (10-20X)
- More expensive for the hospital to purchase
  - (2-3X)
- Is it worth the additional cost??

Expandable Implant Pros

J Spine Surg. 2017 Mar;3(1):9-15. doi: 10.21037/jss.2017.02.05.

One and two level posterior lumbar interbody fusion (PLIF) using an expandable, stand-alone, interbody fusion device: a VariLift® case series.

Barrett-Tuck R[1], Del Monaco D[2], Block JE[3].

METHODS:

Retrospective case series

25 patients PLIF with a stand-alone VariLift® expandable interbody device

1level in 18 patients, 2 levels in 7 patients

RESULTS:

.71% (15 of 21) of patients reported only mild residual pain.

.There were no revision surgeries

.Fusion was achieved 12 of 13 patients (92%) who returned for a 12-month radiographic follow-up.

CONCLUSIONS:

In this single-physician case series, the VariLift® device used in single or two-level PLIF provided effective symptom relief and produced a high fusion rate without the need for supplemental fixation.

Neurol Neurochir Pol. 2017 Jan - Feb;51(1):53-59. doi: 10.1016/j.pjnns.2016.11.001. Epub 2016 Nov 17.

Unilaterally posterior lumbar interbody fusion with double expandable peek cages without pedicle screw support for lumbar disc herniation.

Kale A[1], Oz II[2], Onk A[3], Kalaycı M[4], Büyükuysal Ç[5].

METHODS:

.40 patients were treated with simple discectomy (Group 1)

.20 patients were treated with PLIF using double expandable PEEK cages without instrumentation (Group 2)

.PLIF patients were evaluated with computerized tomography (CT) scan

RESULTS:

.Both leg and low back pain VAS scores were significantly improved 18 months after surgery in both of the groups ($p<0.001$).

.Significant decrease in VAS low back pain scores was seen in group 2 when compared to group 1 ($p<0.001$).

.80% fusion rate was achieved in group 2

CONCLUSION:

Unilateral PLIF with double expandable PEEK cages without pedicle screw support is sufficient in the management of single segment lumbar disc herniation in patients whom are thought to need lumbar stabilization.

Spine (Phila Pa 1976). 2012 Jun 1;37(13):1164-9. doi: 10.1097/BRS.0b013e318257f12a.

Risk factors for cage retropulsion after posterior lumbar interbody fusion: analysis of 1070 cases.

Kimura H[1], Shikata J, Odate S, Soeda T, Yamamura S.

METHODS:

1070 patients with various degenerative lumbar spinal diseases treated with Bullet shaped unilateral cages with bilateral pedicle screw fixation

RESULTS:

.9 cases of cage retropulsion

.6 of the 9 patients at L5-S1

.All of the cages were inserted at the end disc level of multilevel fusion procedures.

.The disc heights and ranges of motion were significantly greater in these patients

CONCLUSION:

These results indicate that PLIF at L5/S, a wide disc space with instability, multilevel fusion surgery

The identification of these risk factors should allow us to avoid this complication, and the use of expandable cages is an effective option for such cases.

J Korean Neurosurg Soc. 2010 Dec;48(6):496-500. doi: 10.3340/jkns.2010.48.6.496. Epub 2010 Dec 31.

Clinical and radiological outcomes of unilateral facetectomy and interbody fusion using expandable cages for lumbosacral foraminal stenosis.

Park JH[1], Bae CW, Jeon SR, Rhim SC, Kim CJ, Roh SW.

METHODS:

34 patients with lumbosacral foraminal stenosis who were treated with unilateral facetectomy L5-S1and PLIF using stand-alone cages

RESULTS:

.Excellent and good with regard to Odom's criteria were 31 cases (91%)

.3 cases (9%) were fair

.Pre-operative mean ODI of 28.4 decreased to 14.2 at post-operative 24 months.

.The change in disc height was from 8.11 mm to10.02 mm at 24 months

CONCLUSION:

In the treatment of lumbosacral foraminal stenosis, unilateral facetectomy and interbody fusion using expandable stand-alone cages may be considered as one treatment option to maintain post-operative alignment and to obtain satisfactory clinical outcomes.

J Craniovertebr Junction Spine. 2018 Jul-Sep;9(3):196-201. doi: 10.4103/jcvjs.JCVJS_56_18.

Transforaminal lumbar interbody fusion with expandable cages: Radiological and clinical results of banana-shaped and straight implants.

Tassemeier T[1], Haversath M[1], Jäger M[1].

RESULTS:

61 patients were studied (33 banana-shaped and 28 straight cages).

.DH changed in the banana group from 4.8 mm to 10.4

.DH changed in the straight group from 6.2 mm to 9.6 mm.

.Lordosis correction higher in the banana group with 5.8° vs 3.7°

.Subsidence in four patients (6.6%) in the banana-shaped group and nine cases (14.8%) in the other group.

CONCLUSIONS:

Banana-shaped expandable cages offer higher potency restoring the intervertebral DH and show less rates of subsidence compared to straight expandable cages.

World Neurosurg. 2016 Jun;90:228-235. doi: 10.1016/j.wneu.2016.02.075. Epub 2016 Feb 24.

Minimally Invasive Transforaminal Lumbar Interbody Fusion Using Expandable Technology: A Clinical and Radiographic Analysis of 50 Patients.

Kim CW[1], Doerr TM[2], Luna IY[3], Joshua G[3], Shen SR[4], Fu X[5], Wu AM[4].

METHODS:

Retrospective analysis of 50 patients (62 operative levels) when an expandable interbody spacer with transpedicular posterior stabilization

RESULTS:

.Mean ODI scores decreased significantly from preoperative to all postoperative assessment times (6, 12, and 24 months) ($P < 0.05$).

.Intervertebral disc height (8.3 ± 2.7 vs. 11.3 ± 1.9 mm) increased significantly, with increases sustained over 24 months ($P < 0.05$).

.Postoperative radiographs showed no evidence of cage migration, subsidence, or collapse and suggested fusion at 24 months (97%, 28/29)

CONCLUSIONS:

An expandable interbody cage led to significant improvement in clinical and radiographic outcomes after MIS TLIF, including intervertebral disc height restoration and high fusion rates, with no evidence of device-related complications.

Expandable Implant Cons

Risk of Over Expansion

- Endplate violation
  - Subsidence, loss of fixation, concern with certain biologics
- Over distraction
  - Tension on nerve roots
- Coronal plane imbalance
  - Unilateral implants with wide decompression and facetectomies

Implant Cost (cap pricing)

- TLIF/PLIF Cage
  - $2,500
- Polyaxial Pedicle Screw
  - $575
- One Level Construct
  - $4,800

- Expandable Cage
  - $5,500
- Cannulated Pedicle Screw
  - $975
- One Level Construct
  - $9,400
  - **$4,600 More**

Spine (Phila Pa 1976). 2012 Jan 15;37(2):E79-85. doi: 10.1097/BRS.0b013e3182226ba6.

Biomechanical evaluation of an expandable cage in single-segment posterior lumbar interbody fusion.

Bhatia NN[1], Lee KH, Bui CN, Luna M, Wahba GM, Lee TQ.

METHODS:

.5 fresh frozen cadavers at L4-L5

.Tested intact, postdiscectomy, after interbody cage placement, and after cage placement and pedicle screw fixation.

.Each specimen was tested for extension, flexion, lateral bending, and rotation

RESULTS:

.When the cage was supplemented with pedicle screw fixation, the mean angular displacement for rotation and lateral bending was significantly less than all other conditions ($P < 0.05$).

.For all motions, stiffness of the cage and pedicle screw construct was greater than intact

CONCLUSION:

PLIF using expandable lumbar interbody cage requires pedicle screw fixation.

Neurosurgery. 2017 Jul 1;81(1):69-74. doi: 10.1093/neuros/nyw177.

Expandable vs Static Cages in Transforaminal Lumbar Interbody Fusion: Radiographic Comparison of Segmental and Lumbar Sagittal Angles.

Yee TJ[1], Joseph JR[1], Terman SW[2], Park P[1].

OBJECTIVE:

To compare changes in segmental lordosis (SL) and lumbar lordosis (LL) after TLIF with nonexpandable vs expandable cages

RESULTS:

.89 patients (48 nonexpandable group, 41 expandable group)

.SL: median improvement was 3° for nonexpandable and 2° for expandable

.LL: median improvement was 1° for nonexpandable and 2° for expandable

.After excluding parallel expandable cages, there was still no difference in SL or LL improvement at 1 year postoperatively between static and expandable cages.

CONCLUSION:

Patients undergoing single-level TLIF experienced similar improvements in SL and LL regardless of whether nonexpandable or expandable cages were placed.

Summary (My prospective)

- Expandable implants are here to stay
- Expandable implants have their role in treatment of spinal degenerative and deformity conditions
- Surgeons should be aware of the added cost of these implants

Thank You