Integrating New Expandable Technologies into a Minimally-Invasive Spine Practice

Vertebral Compression Fractures: The Case for Using Expandable Implants

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FDA Labeling

The Kiva VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.
Prevalence of osteoporotic fractures

Burge R et al. (2007) JBMR 22(3): 465
United States Cancer Statistics 2005, American Heart Association
Objectives of implant based VCF treatment system

- Better and more predictable outcomes
  - Clinical
  - Financial
  - Operational

- Better for everyone involved:
  - Patients
  - Treating physicians
  - The hospital (-system)

- Broad indication
  - Pathologic Fractures (Osteoporosis, Cancer) and Trauma
Limitations of existing VCF treatments

Limitations of existing VCF treatments
• Subsequent/adjacent-level fractures
• Limited or no fracture reduction
• No durable change in kyphotic angle
• Cement extravasation and resulting clinical sequelae

Objectives of implant based VCF treatment
• Provide permanent kyphotic angle reduction
• Use less bone cement
• Reduce subsequent/adjacent-level fracture rate
• Provide treatment through a single-pedicile approach
Overview of Implant VCF Treatment System

- **Implant** reduced economic burden of traditional VCF treatments\(^1,2\)
- **Multiple Level 1**, randomized clinical trials completed\(^3\)
- **12 peer reviewed papers** published in last 4 years\(^3\)

3. Please see Appendix
Overview of Implant VCF Treatment System

• Significant benefits in pain relief, function, height restoration, reduction in volume of cement and reduction in cement extravasation

• Broadest labeling for any compression fracture treatment system on the market

• Implant (Benvenue Medical, Kiva VCF Treatment System) added to Novation agreement through “innovation” award (April ‘15)
Why **Implants** for VCF

- Better pain relief$^1$
- Cement volume reduced$^2, 3$
- Less cement extravasation$^2$
- Cobb angle correction$^2$
- Reduction in subsequent fractures$^3$
- Reduction in procedure time$^2$
- No serious adverse events$^{1,2,3}$
- Reduction in part numbers to stock; only 2 catalog numbers for all cases

**Sources**
Kiva Difference

Features

• Expands to 15mm in height
• Flexible PEEK-Optima® Structure
• Flat, circular 20mm diameter

Benefits

• Designed to restore and maintain sagittal alignment
• Provide more compliant construct than cement alone
• Predictable endplate support
Clinical data

Over the past 20 years there have been 1,587 papers written on the treatment of vertebral compression fractures

8 articles met criteria (Level I or II studies) based on 1° Research as adopted by NASS (see link below)

2 of the 8 papers are related to the Benvenue Medical Kiva VCF Treatment System.

- KAST (see appendix, paper #2)
- Korovessis (see appendix, paper #5)

Level 1 data: High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals. Systematic Review of Level I RCTs and study results were homogenous.  
https://www.spine.org/Portals/0/Documents/ResearchClinicalCare/LevelsOfEvidence.pdf
Kiva for L1 fracture in patient with 6 prior vertebral body compression fractures

- Excellent height restoration from a combination of positional reduction, 5 coils of Kiva deployed
- Patient immediately regained a sensation of stability, pain control was absolutely immediate and she left the hospital same day.
Case Discussion

- 85 y/o female vertigo: fall
- Attempted bracing / narcotics
- Failed over 3 weeks
- Upright Radiographs showed:
  - Vertebra “plana” T12
  - Global kyphosis increase
  - Stiff spine leads to: “three-column fracture” with perceived instability
Case Discussion

- CT-scan clearly shows ‘vacuum’ phenomenon at the Fx.
- Fracture “opens up” when patient supine in the scanner
- Concerns for global instability and not just anterior compression
Case Discussion

• Instead of “Stand-Alone” Kiva...
• Screw and rod construct with internal support of T12 with Kiva deployment.

Overnight stay in hospital for observation (85 y/o)
Up-and-walking with immediate sense of stability
Much improved global alignment and local pain control
Additional Information....
Robust Clinical Data
Clinical Images of Implant vs. Vertebroplasty

- Significant cement extravasation
- Significant cement volume (~10 cc)
-Adjacent level fracture potentially caused by volume of cement

Benvenue Medical Kiva VCF Treatment System
- Cement contained with implant
- Reduced volume of cement (~ 2 cc)
- Kyphotic height restoration

We all recognize these pictures more than we like to admit...
Peer reviewed papers

**2016 (expected publication date)**

1) (Garfin S, Beall DP, Tutton S, Hornberger J). Incidence and Cost of Serious Adverse Events Requiring Hospital Readmission with Kiva VCF Treatment System Compared to Balloon Kyphoplasty: KAST Randomized Trial Analysis. IN PROGRESS FOR SUBMISSION TO JAMA OR SPINE—publish 2016

**2015**


**2014**


2012


2011

Thank you for your attention!
Integrating New Expandable Technologies into a Minimally-Invasive Spine Practice

3-Dimensional Interbody Expandable for TLIF Procedures

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Disclosures

Consultant:  Depuy Spine
            Aesculap Spine
            JoiMax
            K2M

Royalties:  Children’s Hospital of Los Angeles
            Depuy Spine
            Springer Publishing
            Quality Medical Publishing

Stock:      Innovative Surgical Devices
            Spinicity

Grants:     Department of Defense
FDA Labeling

INDICATIONS
The Luna 360 Interbody Fusion System consists of a Luna 360 Implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). The Luna 360 Interbody Fusion System is to be used with autogenous bone graft. Patients receiving the device should have had at least six months of nonoperative treatment prior to receiving the Luna 360 Implant. The Luna 360 Interbody Fusion System is to be used with supplemental fixation.
TLIF APPROACH

• Various approaches to lumbar interbody fusion
  • TLIF
    – Extensively studied in literature
    – Consistent positive outcomes
    – Remains surgery of choice (38% of total lumbar fusion procedures in US)

• TLIF Shortcomings
  – Nerve root retraction
  – Narrow surgical corridor = interbody device size constraints
  – Lumbar lordosis, disc collapse and spondylolisthesis make interbody insertion challenging
  – Cage placement can require aggressive impaction / bone removal
EXPANDABLE INTERBODY DEVICES

- Recent proliferation of expandable interbodies
- Wide variation in material and expansion mechanisms
- All designed to be inserted in collapsed configuration and expanded vertically in-situ
- Solve issues around cephalad-caudal constraints
REMAINING UNMET NEEDS

• Nerve retraction

• Need for implant not limited in width by neural structures

• Implant footprint
  - Subsidence concerns
  - Growing emphasis on restoration of lordosis and sagittal alignment
    - Places greater biomechanical demands on implant
    - Footprint critical factor

• Need for large-footprint TLIF interbody
Expandable Interbody.
Redefined.

*In-situ* 3-Dimensional Expansion
Zero-Impaction Delivery
Bone Grafting After Distraction

Luna 3D
Interbody Fusion System

25mm Diameter
Bone Graft Window
8-13mm Height
6-8mm Cannula
Animation
LUNA 3D EXPANDABLE INTERBODY

• Expansion mechanism accommodates graft insertion post-expansion

• Implant designed for both open and MIS TLIF procedures
LUNA | ADVANTAGES

6-8 mm Cannula Delivery

- Controlled, atraumatic insertion
- Designed to minimize nerve retraction and implant migration
LUNA | ADVANTAGES

**In-situ 3D Expansion**

- Zero-impaction delivery
- Intended to preserve and protect vertebral endplates
- Expands 25 mm in diameter, 8-13 mm in height
- Designed to provide stable implant for spine alignment goals
LUNA | ADVANTAGES

Post-Expansion Bone Grafting

• Designed to place bone in direct contact with vertebral endplates
• Generous area for graft containment
• Large window for graft insertion
LUNA | INSERTION & DEPLOYMENT

- Top and bottom implant segments deployed from cannula in stacked configuration
- Guide wires used to direct linear PEEK segments into curved deployment path
- Creates circular footprint approximately 25mm in diameter
- Third, middle segment follows the first two out the cannula
- Delivered between them to achieve distraction
- Expands vertically in-situ
LUNA | INSERTION & DEPLOYMENT

- Luna can restore disc height up to 13mm from 6-8mm cannula
- 5.0mm window in assembled implant allows bone graft to be delivered directly into the lumen
- Graft delivered post expansion with accompanying bone graft inserter
Zone 1: Initiate Channel
(standard discectomy instrumentation)

Zone 2, Zone 3:
Focus area for successful deployment
(specialized curved, bayonetted tools)

Discectomy
Discectomy & Endplate Preparation  
Zone-Specific Approach  

Degree of difficulty using Standard Tools

Zone 1: Relatively Straightforward  

Zone 2: More Challenging  

Zone 3: Difficult  

Pay special attention to Zone 3 for proper Trial and Implant deployment.
CASE EXAMPLE

- 67 yo female
- 6 months of R>L neurogenic claudication
- Failed 6 weeks of PT and epidural injections
- MRI/XRAYS
  - Large R L4-L5 facet cyst with lateral recess and foraminal compression
  - Advanced facet arthropathy bilateral
  - 3-4mm subluxation of L4 on L5 with standing XRAYS
- Treatment
  - Right L4-L5 MIS TLIF thru a 22mm fixed tubular retractor
  - Implantation of 10mm expanded LUNA 360 with autograft

Pre-Op L4-L5 MRIs
CASE EXAMPLE
Pre-Op Images

Case Courtesy of Joshua Ammerman, MD
CASE EXAMPLE
Post-Op Images

Case Courtesy of Joshua Ammerman, MD
Six Week Post-Op
L5-S1 Bone Growth Within Device

Case Courtesy of Joshua Ammerman, MD
Six Week Post-Op
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