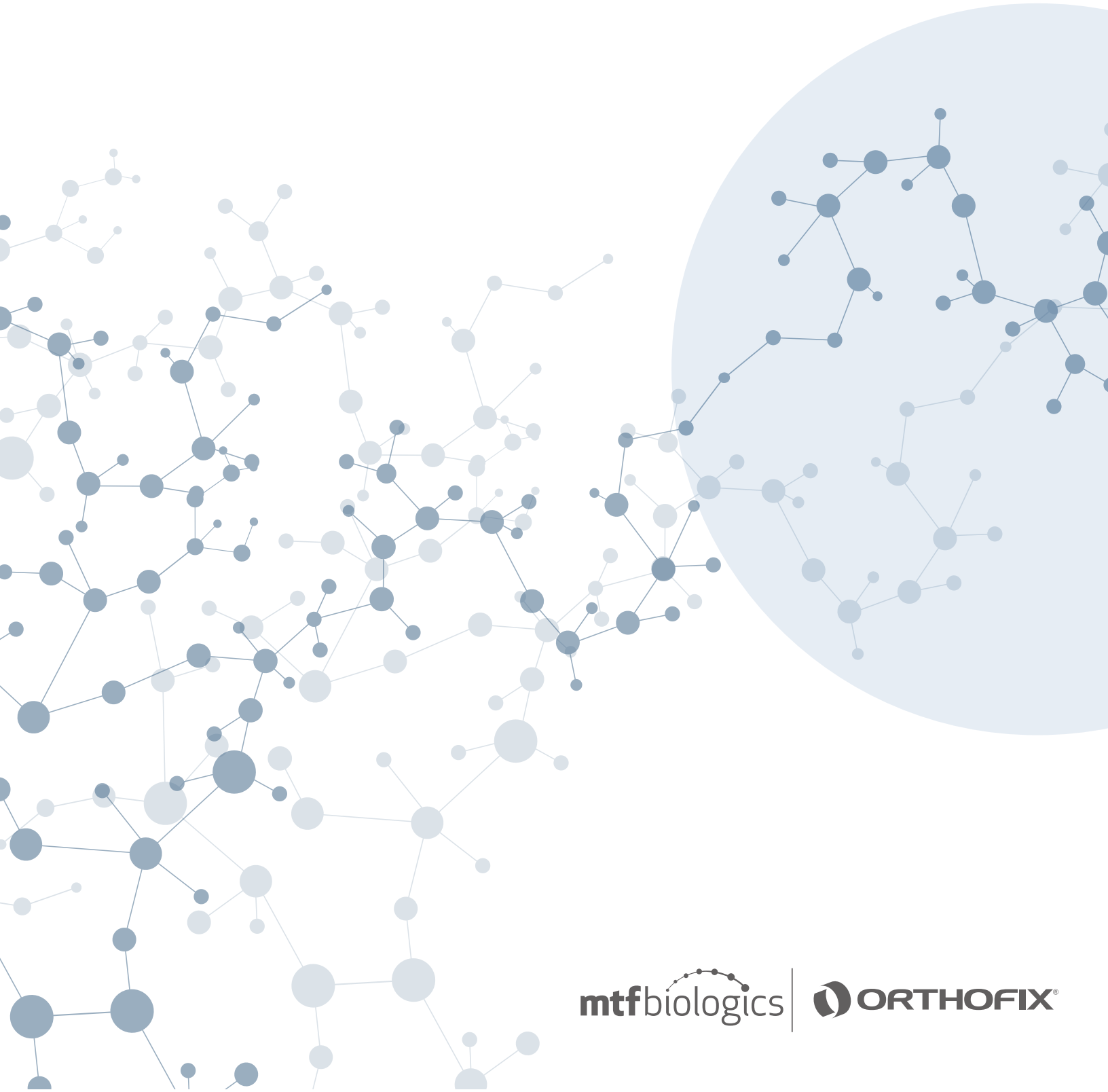
TRINITY® ALLOGRAFT

CLINICAL EVIDENCE



mtfbiologics | ORTHOFIX®

Introduction:

Trinity® allografts are bone grafts that contain all three properties needed for bone healing: osteoinductive factors through the demineralized bone component, an osteoconductive bone scaffold and viable cells retained within the cancellous matrix providing the osteogenic component. The combination of these three features, which define autograft as the gold standard, make Trinity allografts an ideal alternative for clinicians to fill any musculoskeletal defects.

MTF Biologics, one of the nation's largest tissue banks is the exclusive processor of Trinity allografts with viable cells since 2009. With a large recovery network, MTF accepts less than 2% of donated tissue. MTF will not accept any donors deferred by another tissue bank and exceeds industry standards with stricter donor acceptance criteria, such as cancer and donor age.

Trinity ELITE® allograft is a third generation cellular allograft with viable cells and the latest technology offered by Orthofix. Trinity ELITE allograft is processed using FiberLock™ technology, providing moldable handling with no carrier added. FiberLock technology withstands irrigation and blood flow, giving the surgeon confidence that Trinity ELITE allograft will stay precisely where implanted.

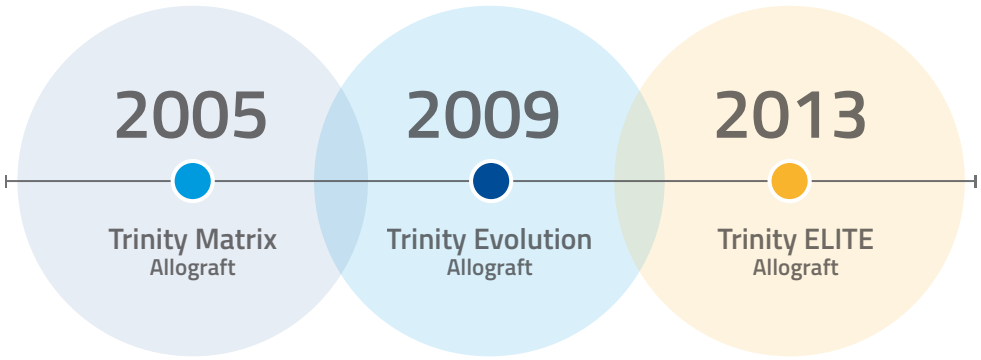
mtf biologics | TRINITY ELITE® OSTEOCONDUCTIVE OSTEOINDUCTIVE OSTEOGENIC ALLOGRAFT WITH VIABLE CELLS

Trinity Allograft Clinical Evidence

Orthofix and its tissue partner, MTF Biologics, have been at the forefront of cellular allograft technology since 2009 with the launch of Trinity Evolution allograft. Continually innovating, Orthofix and MTF Biologics partnered to provide Trinity ELITE allograft with FiberLock technology in 2013, introducing the first moldable cellular allograft to the market.

Together, there has been more than 200,000 procedures recorded to date between the two grafts.

Market Timeline:



As a part of our efforts to provide clinical data to surgeons, we continue to invest in a number of prospective and retrospective studies that evaluate the clinical efficacy and safety of Trinity allografts.

Trinity Allograft Clinical Data Summary:

Study	# of Patients	Fusion at 12 Months
One Level Cervical[1]	31	93.5%
Two Level Cervical[2]	76	93.4%
One & Two Level PLF[3]	43	90.7%
One & Two Level PLIF[4]	103	89.5%
Foot & Ankle Study 1[5]	103	86.8%
Foot & Ankle Study 2[6]	75	84.0%
Study		**Fusion at 6 Months**
Triple Arthrodesis[8]	15	93.3%
	TOTAL 446	

Spine

A prospective clinical and radiograph 12-month outcome study of patients undergoing single-level anterior cervical discectomy and fusion for symptomatic cervical degenerative disc disease utilizing a novel viable allogeneic, cancellous, bone matrix (Trinity Evolution) with a comparison to historical controls[1].

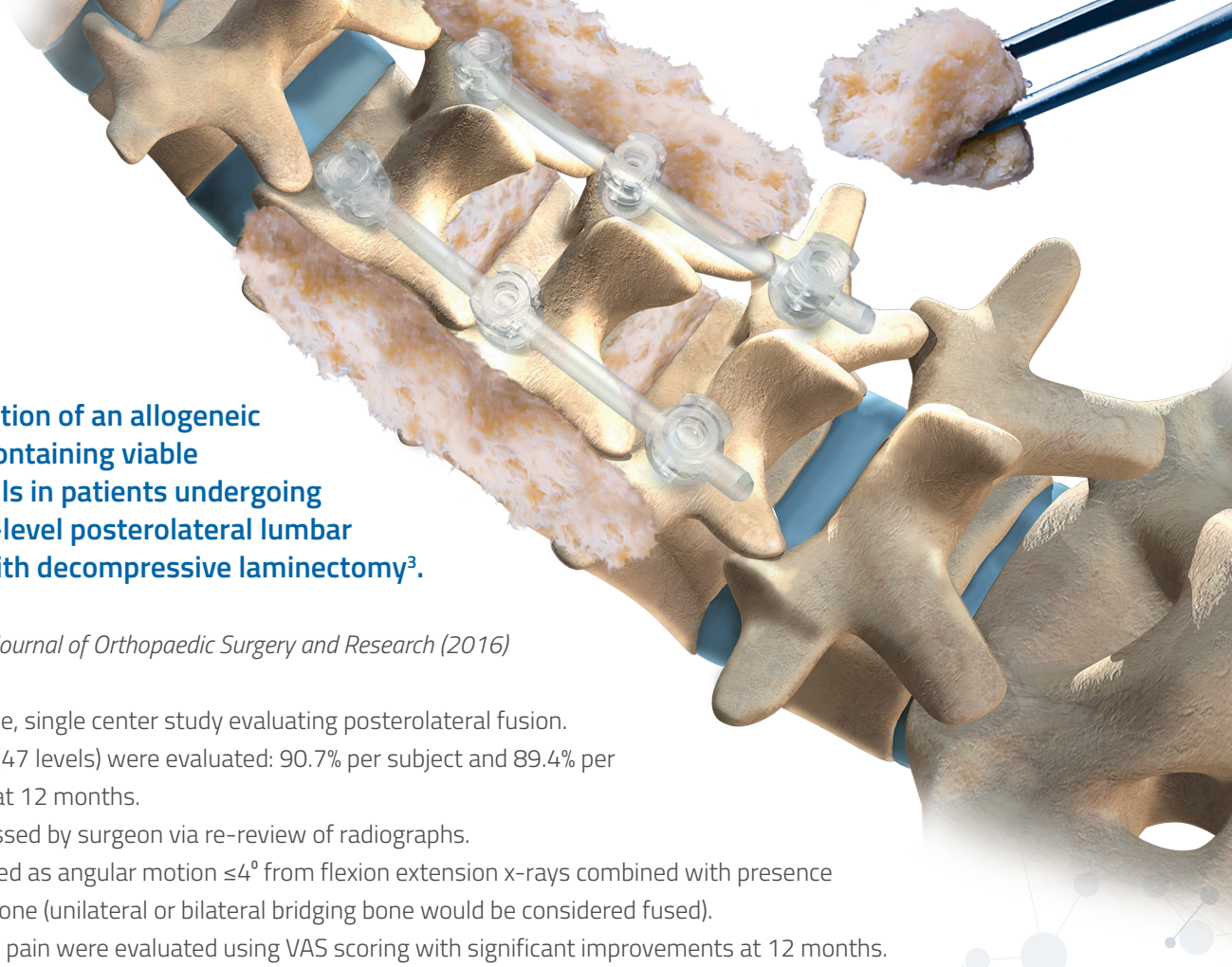
J. Vanichkachorn et. al. European Spine Journal (2016)

- Prospective, multi-center study evaluating anterior cervical discectomy and fusion (ACDF).
- Study included subjects with the following risk factors: >65-year-old, smokers, diabetics and obese patients.
- 31 subjects were evaluated: 93.5% fusion at 12 months.
- Fusion assessed by an independent reviewer, Medical Metrics, Inc. (MMI).
- Fusion defined as angular motion ≤4° from flexion extension x-rays combined with presence of bridging bone across the adjacent endplates on thin cut CT scans.
- Function via Neck Disability Index (NDI) and neck and arm pain were evaluated using Visual Analog Scales (VAS) scoring as secondary endpoints with significant improvement at 6 and 12 months.

Prospective clinical and radiographic evaluation of an allogeneic bone matrix containing stem cells (Trinity Evolution Viable Cellular Bone Matrix) in patients undergoing two-level anterior cervical discectomy and fusion[2].

T. Peppers et al. Journal of Orthopaedic Surgery and Research (2017)

- Prospective, multi-center study evaluating ACDF.
- Study included subjects with the following risk factors: >65-year-old, smokers, diabetics and obese patients.
- 40 subjects (80 levels) were evaluated: 89.4% per subject and 93.4% per level fusion at 12 months.
- Fusion assessed by an independent reviewer, MMI.
- Fusion defined as angular motion ≤4° from flexion extension x-rays combined with presence of bridging bone across the adjacent endplates on thin cut CT scans.
- Clinical pain and function assessments included the NDI, neck and arm pain evaluated by VAS and SF-36 with significant improvement at 6 and 12 months.



Clinical evaluation of an allogeneic bone matrix containing viable osteogenic cells in patients undergoing one- and two-level posterolateral lumbar arthrodesis with decompressive laminectomy[3].

D. Musante et. al. Journal of Orthopaedic Surgery and Research (2016)

- Retrospective, single center study evaluating posterolateral fusion.
- 43 subjects (47 levels) were evaluated: 90.7% per subject and 89.4% per level fusion at 12 months.
- Fusion assessed by surgeon via re-review of radiographs.
- Fusion defined as angular motion ≤4° from flexion extension x-rays combined with presence of bridging bone (unilateral or bilateral bridging bone would be considered fused).
- Back and leg pain were evaluated using VAS scoring with significant improvements at 12 months.

Clinical evaluation of an allogeneic bone matrix containing viable osteogenic cells in patients undergoing one- and two-level lumbar interbody fusion[4].

D. Bullard et al. TE-1701: Executive Summary, Orthofix

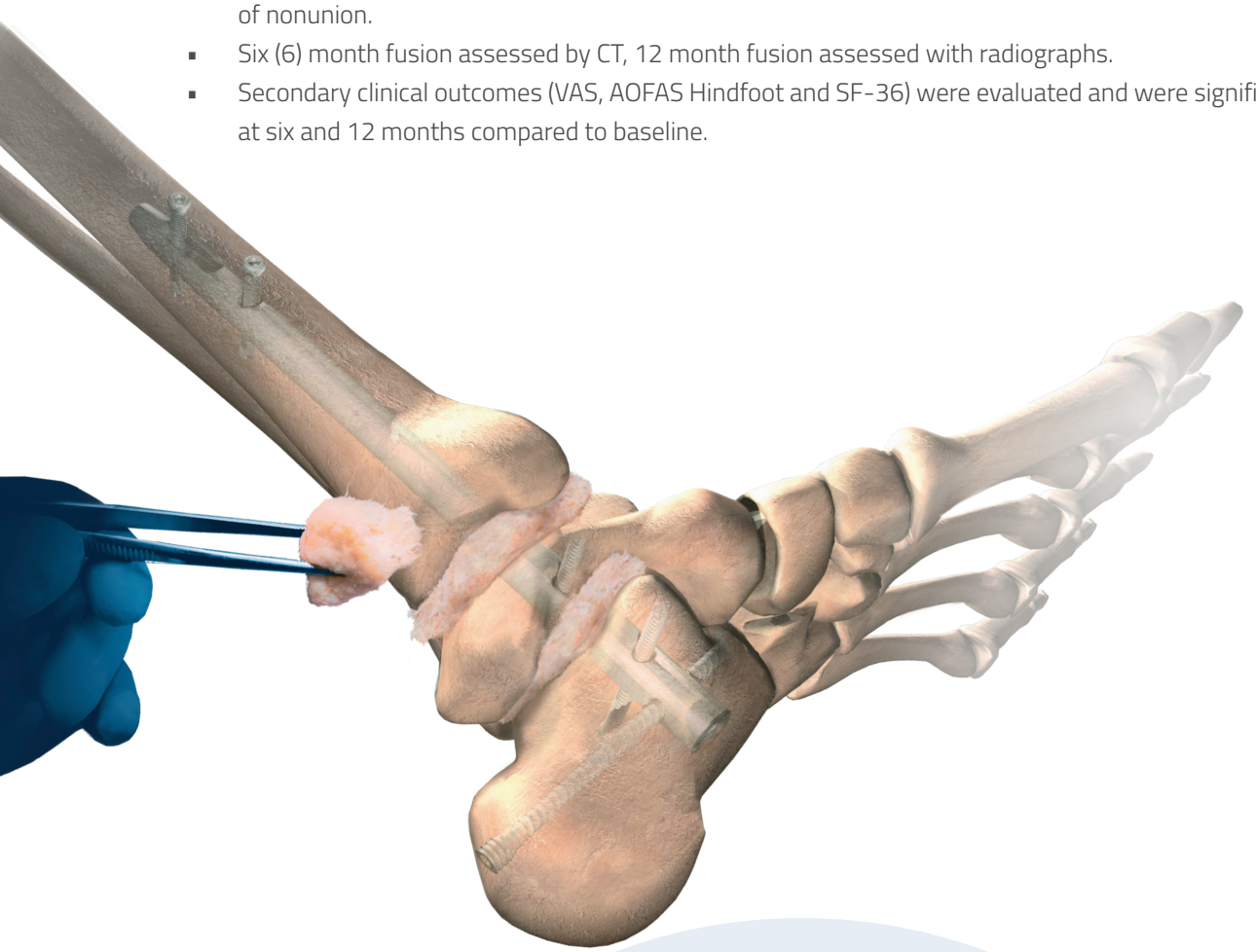
- Prospective, multi-center study evaluating transforaminal interbody fusion (TLIF) or posterior lateral interbody fusion (PLIF).
- Study included subjects with the following risk factors: >65-year-old, smokers, diabetics and obese patients.
- 103 subjects (147 levels) were evaluated: 89.50% per subject fusion at 12 months.
- Fusion assessed by an independent reviewer, MMI.
- Fusion defined as ≤3° of angular motion between fused vertebral segments using dynamic motion plain radiographs. For multilevel subjects, all levels had to be deemed fused for the subject to be fused.
- Back pain was evaluated using VAS scoring. At 12 months, 91.9% subjects had a clinical improvement in back pain.

Foot & Ankle

Prospective, multi-center evaluation of allogeneic bone matrix containing viable osteogenic cells in foot and/or ankle arthrodesis[5].

C. Jones et al. Foot and Ankle International (2015)

- Prospective, multi-center study evaluating arthrodeses of the foot and ankle.
- Study included subjects with the following risk factors: >65-year-old, smokers, diabetics and obese patients.
- 92 subjects (153 arthrodeses) were evaluated: 86.8% per joint fusion at 12 months.
- Fusion assessed by an independent reviewer, MMI.
- Fusion by subject defined as the presence of bridging bone, no radiographic signs of nonunion, and maintenance of fixation across all treated joints.
- Fusion by joint defined as the presence of bridging bone across the joint and no radiographic signs of nonunion.
- Six (6) month fusion assessed by CT, 12 month fusion assessed with radiographs.
- Secondary clinical outcomes (VAS, AOFAS Hindfoot and SF-36) were evaluated and were significantly improved at six and 12 months compared to baseline.



A retrospective clinical comparison of two allogeneic bone matrices containing viable osteogenic cell in patients undergoing foot and/or ankle arthrodesis[6].

J. Loveland et. al. Journal of Stem Cell Research and Therapy (2017)

- Retrospective, single center study evaluating arthrodeses of the foot and ankle.
- 75 subjects (141 arthrodeses) were evaluated: 93.3% per subject and 95.7% per joint fusion at 12 months.
- Fusion assessed by surgeon via re-review of the radiographs.
- Fusion was assessed from three views of radiographs (A/P, lateral, and oblique). Successful joint fusion required the presence of >50% bridging bone across the joint in at least one view as defined by DiGiovanni et al[7]. Successful overall fusion for the subject required that each joint be fused.

Clinical and Radiographic Evaluation of Live Cell Allograft following Triple Arthrodesis[8].

M. Campbell, MD. BC-1803, Executive Summary, Orthofix

- Retrospective, single site study evaluating Trinity Evolution® allograft (n=4) and Trinity ELITE® allograft (n=11) in triple arthrodesis.
- Study included subjects with the following risk factors: >65 year-old, smokers, diabetics and obese patients.
- 15 subjects were evaluated: 93.3% fusion at 6 months.
- No significant differences in fusion rates were observed between normal and high risk patient populations, or seen between the two allografts.
- Six (6) month fusion evaluated via radiographs by the physician. All x-rays were re-reviewed at time of data collection.
- Fusion defined as bony bridging across the joint without any hardware loosening.
- There were no adverse events attributable to the implantation of Trinity allografts in this study.

References:

1. Vanichkachorn et al., Eur Spine J (2015)
2. Peppers et al., Journal of Orthopaedic Surgery and Research (2017) 12:67
3. Musante et al., Journal of Orthopaedic Surgery and Research (2016) 11:63
4. TE-1701, Bullard et al., Multi-Center Executive Summary (2017)
5. Jones et al., Foot & Ankle International (2015) 1-9
6. Loveland et al., Journal of Stem Cell Research and Therapy (2-17) 7:10
7. Digiovanni et. al., JBJS (2013) 95:1184-92
8. BC-1803, Campbell, Single Site Executive Summary

To find electronic instructions for use with indications, precautions and warnings for each of these products go to: www.Orthofix.com/IFU

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