

The Use of an Acellular Connective Tissue Matrix in Hindfoot and Ankle Fusions: Understanding the Cellular Bench Top Data with a Consecutive Patient Series: A Pilot Study.

Brigido SA^a, Scott Carrington^a, Protzman NM^b, Yong Mao^c, Thomas Pashuck E^c, Joachim Kohn^c and Mohit Bhatia^d

The purpose of this study was two-fold: to evaluate the adhesion and proliferation of human osteoblasts on connective tissue matrix (CTM) *in vitro*, and to assess the efficacy of CTM in hindfoot and ankle fusions.

THE USE OF INTERFYL, WHEN MIXED WITH CANCELLOUS AUTOGRAFT, MAY ACCELERATE HEALING BY OFFSETTING SOME NEGATIVE PATIENT HEALTH FACTORS.

Autogenous bone graft is the gold standard for reconstruction of bone defects and the preferred adjunctive tissue for arthrodesis procedures. But, there are limitations to this method of treatment:

- Limited supply of autogenous bone
- A risk of donor site morbidity
- 47% non-union, complication rate

Study hypothesis: Using CTM as a scaffold would enhance the cell-friendly environment of autograft bone and accelerate healing.

IN VIVO (CLINICAL) STUDY RESULTS

97%

Of joints achieved bony union within 6 months of procedure

61.4 ± 68.8
days

Mean time to fusion

49
days

Mean time to fusion (after removing outliers)*

^a Department of Foot and Ankle Surgery, Coordinated Health, Bethlehem, Pennsylvania, United States

^b Department of Clinical Integration, Coordinated Health, Allentown, Pennsylvania, United States

^c New Jersey Center for Biomaterials, Rutgers University, Piscataway, New Jersey, United States

^d Research Consultant, Celularity Inc., Warren, New Jersey, United States

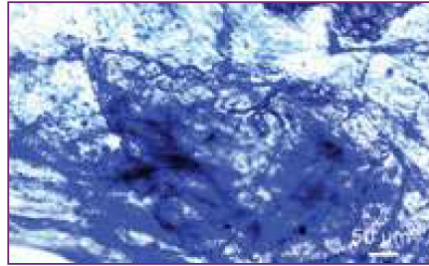
* Outliers - diabetic patient with Charcot foot took 14.0 months and patient with tibio-talar-calcaneal fusion after failed total ankle arthroplasty took 13.3 months

IN VITRO (BENCH TOP) ASSAY

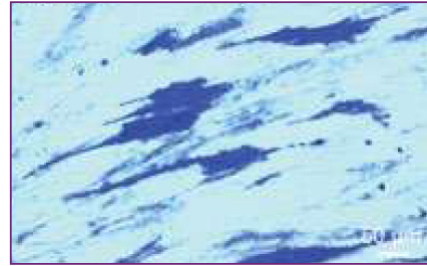
- Human osteoblast (HO) cells were placed in Ultra Low Adhesion Polystyrene (ULAP) plates and adhered to CTM.
- The proliferation of the HO cells in these plates was observed using AlamarBlue for visualization and compared to a CTM-coated well that was treated identically, but without cells plated.

In vitro results:

Results demonstrate that a CTM-rich environment encourages cellular proliferation and release of endogenous growth factors to support healing.



Connective Tissue Matrix (CTM)



Tissue Culture Treated Polystyrene (TCPS)

IN VIVO (CLINICAL) STUDY DESIGN

For the hindfoot and ankle fusions (*in vivo*) portion of this study, a review was performed to evaluate time to fusion in patients undergoing arthrodesis with the use of autogenous bone graft mixed with 100 mg of allogeneic, decellularized, particulate human CTM.

Inclusion Criteria:

- Age at time of surgery, ≥ 18 years
- Diagnosis with end-stage joint arthritis
- Exhausted all forms of conservative treatment
- Elected to undergo foot and/or ankle arthrodesis

Exclusion Criteria:

- Use of post-operative bone stimulator
- History of active target joint infection in 6 months prior to surgery

Clinical (*in vivo*) data demonstrated:

57 out of **59** joints fused in an average of 49 days

TIME TO FUSION BY JOINT

Joint	Time to Fusion (days)
1st TMT	43.3 \pm 8.9
2nd TMT	41.5 \pm 12.0
Ankle	67.8 \pm 21.2
NC	38.0 \pm 4.2
STJ	51.8 \pm 17.9
TN	45.8 \pm 9.8

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