

Introduction

This investigational test, performed by Dr. George Muschler at the Cleveland Clinic Lerner Research Institute in 2017, tested the suitability of BioCera Fibers, a totally synthetic bone substitute, for use as a bone graft material.

BioCera Fibers

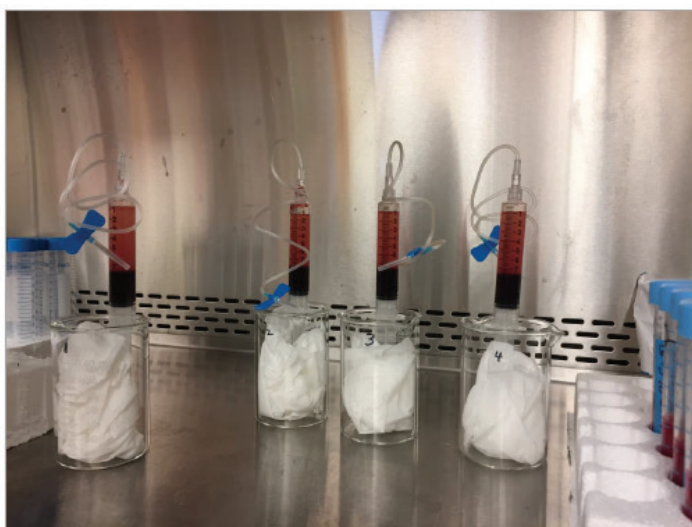
BioCera Fibers is a cotton-like graft that, when hydrated, becomes cohesive and moldable, easily conforming to fit and fill bone voids. It was cleared by the FDA in late 2014 and commercialized in 2015. It is a product of composite materials, including β -tricalcium phosphate (β -TCP), siloxane-containing vaterite (SiV), and polylactide polymer. The microfibers of BioCera Fibers are prepared by an electrospinning method. The diameter of these fibers is less than 0.25 μ m, and the amount of silicon in BioCera Fibers is approximately 0.5-1.0 percentage by weight. The entwined structure of its fine fibers makes BioCera Fibers an ideal scaffold for cell infiltration and colonization, and previous research has suggested the efficacy and osteogenic capacity of similar electrospun material (Obata et al, Acta Biomater 2010;6:1248-57). BioCera Fibers is manufactured in Japan and distributed by ORTHOREBIRTH USA.

Hypothesis

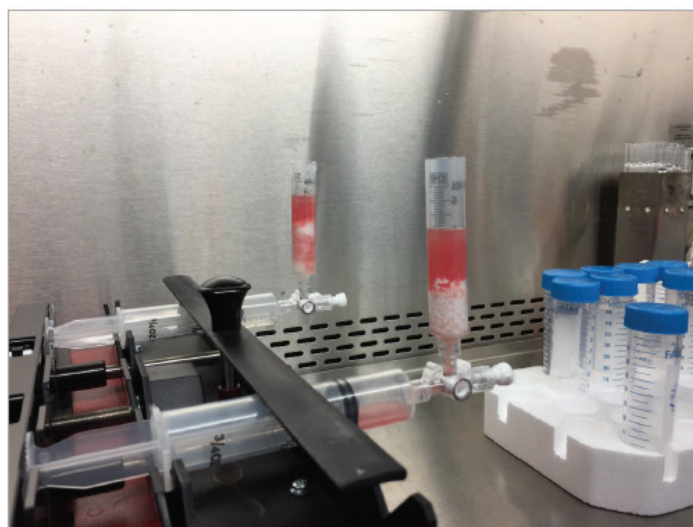
BioCera Fibers synthetic bone scaffolding will function as a suitable bone substitute for bone grafting, and will support cell vitality and cell adherence, thereby fostering cell growth and cell proliferation sufficient to promote *de novo* osteogenesis and bone healing.

Materials and Methods

Red blood cells were removed from bone marrow using the Fortus separation media. The resulting progenitor-rich supernatant was divided in half and was drawn through TCP fiber (ie, BioCera Fibers) and 1000-2000 μ m granules at a controlled rate. The cell-seeded graft (ie, BioCera Fibers) was cultured for 14 days. Viable cells were imaged by DAPI staining and Brightfield imaging, and SEM images were also acquired.

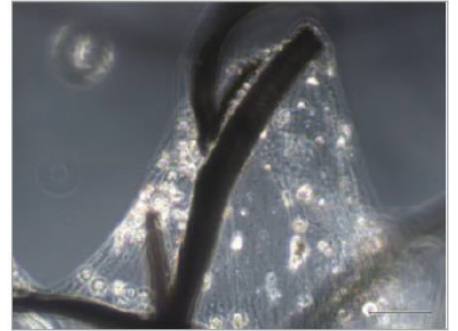
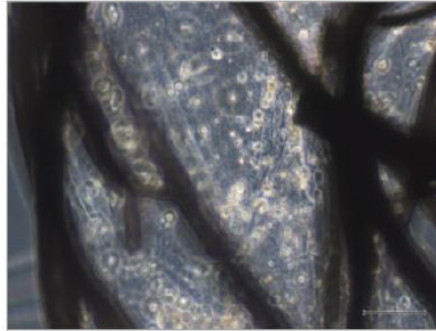
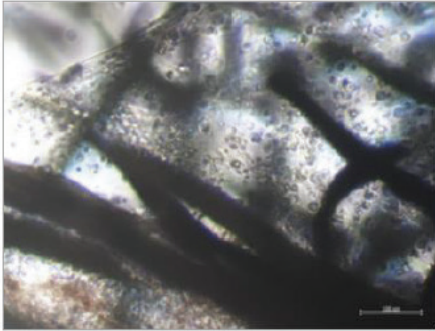


Separation of red blood cells from bone marrow



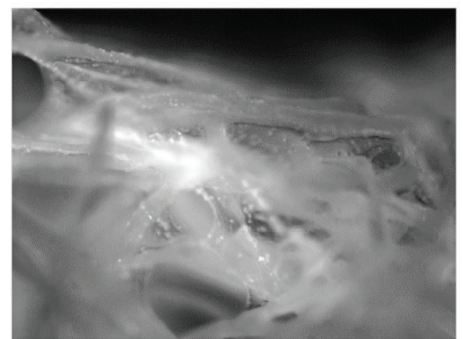
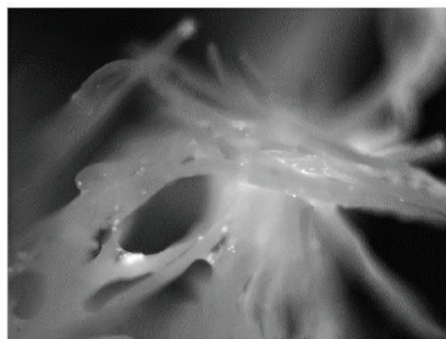
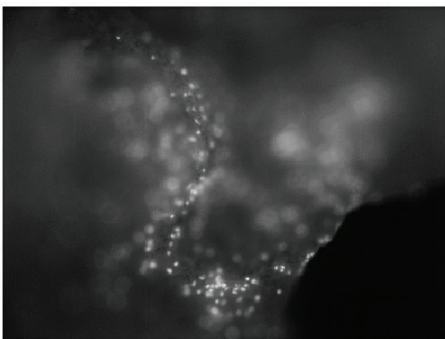
Syringe pump to draw supernatant through BioCera Fibers (rear)

BioCera Fibers: Brightfield Images - 3 days



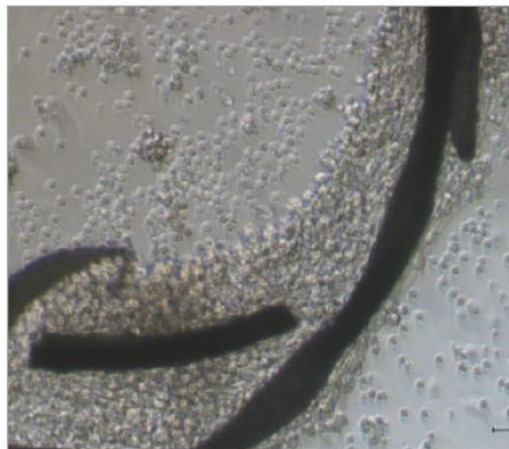
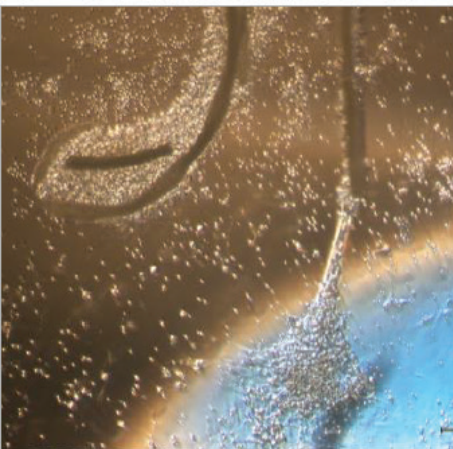
- Robust cell growth is apparent.
- The cells are known to be biologically active. This is evident based on the growing cell colonies. The formation of an ECM membrane and the subsequent migration of cells onto this membrane indicates that the cells are on the pathway to bone formation.

BioCera Fibers: DAPI Staining - 3 days



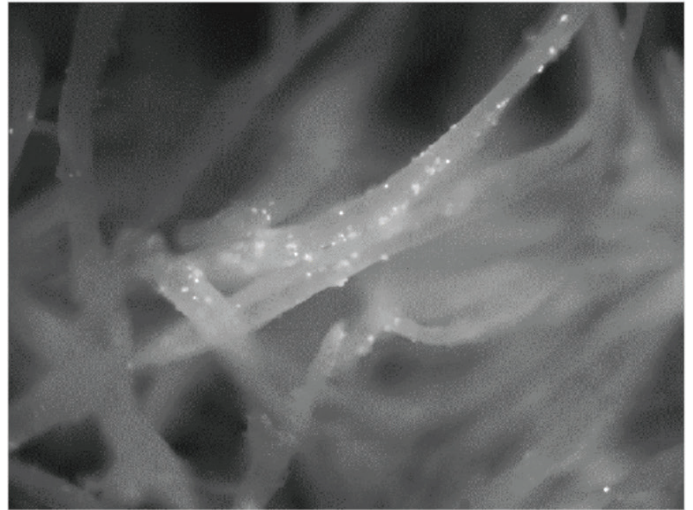
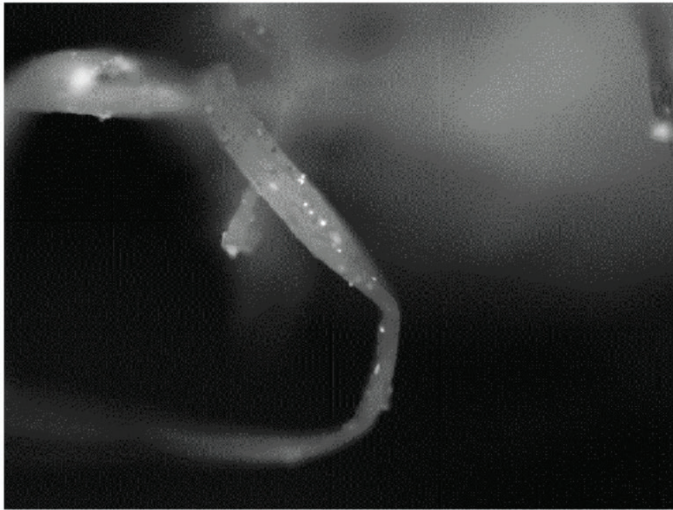
- Top of graft column – first exposure area to cells

BioCera Fibers: Brightfield Images - 11 days



- Robust cell growth is apparent.
- A very dense concentration of cells indicates that cells are alive, growing, and expanding.

BioCera Fibers: DAPI Staining - 14 days



- The cells are adhered, as the daily media exchange washes away any cells that are not adhered.

Results

In this test, osteoprogenitor cells separated from bone marrow were applied to BioCera Fibers, and the resulting cultures were carefully scrutinized at various stages.

Staining and microscopic analysis showed robust cell growth migration and proliferation of cells on the fiber scaffold, indicating growing cell colonies adhering and expanding on the microfibers, well on their way to active bone formation.

SEM images and Brightfield images of BioCera Fibers at 3, 11, and 14 days indicate the BioCera Fibers supports cell vitality (ie, ECM formation at 3 days) and enhances cell proliferation as well as cell adherence to the scaffold.

Conclusion

This laboratory test confirms the hypothesis that BioCera Fibers synthetic bone scaffolding would function as a suitable bone graft, supporting robust cell proliferation and vitality sufficient to promote *de novo* bone osteogenesis and bone healing.

This test may be of particular interest to clinicians who are interested in avoiding the potential hazards of immunologic reactions and disease transfer that may arise from using allograft or xenograft bone.

Disclosure: Dr. George Muschler has no affiliation with ORTHOREBIRTH USA and operates an independent laboratory.



BIOCERATM
FIBERS

The only biosynthetic scaffold with
electrospun microfiber construction



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