



KYOCERA Medical Technologies, Inc.

BIOCERA

FIBERS

The only biosynthetic scaffold with
electrospun microfiber construction

CASE STUDY 03

SURGEON PROFILE

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Patient Profile

History of Present Illness: A 33-year-old woman presented with reports of pain and swelling in the right lower leg. Her pain was refractory to conservative treatment such as anti-inflammatory medication. She reported no specific injury that precipitated the onset of pain.

Physical Examination: The patient's physical examination was notable for pain and tenderness of the right knee and proximal tibia upon palpation.

Diagnosis: After various imaging studies showed a mass in the right proximal tibia, a tissue sample was obtained with needle biopsy. Diagnosis of a large cystic bone tumor of the proximal tibial metaphysis was established.

Treatment

Based upon the above-described history and biopsy sample analysis, the patient underwent surgery to remove the bone tumor. A medial curvilinear proximal tibial metaphyseal incision was made, the periosteum was incised, and an osteotome was used to create a window in the tibia around the proximal metaphysis. Brown material was present in the large cavity, encompassing approximately 60% of the proximal metaphysis, with complete involvement of the medial metaphysis past the midline. The brown material was removed through the curettage and sent for pathological analysis. After thorough irrigation of the tumor within the bone, no cortical disruption was identified. The tumor appeared to be self-contained, and no lining was sent for analysis.

After the shaft of the tibia was noted to allow blood and bone sounds to migrate in a proximal direction, 150 cc's of BioCera Fibers were packed into the bone. The metaphyseal area of the lateral side was likewise penetrated to allow for cellular growth and bone response. Gelfoam was applied and the incision was closed with 0 Vicryl and skin staples. Protective gauze and a light compression dressing were applied, and the patient was returned to the recovery room in stable condition.

Case Study

Not approved by the FDA for the above indication.

Postoperative Course

At her 2-week follow-up appointment, the patient reported drastic reduction in pain. No tumoral recurrence was observed on radiography at 2-week follow-up (Figure 1), and new bone growth was apparent. Additional radiographic study obtained at 7 weeks demonstrated robust growth of new bone in the area where BioCera Fibers were implanted (Figure 2).



Figure 1. Radiograph obtained 2 weeks postoperatively demonstrates no tumor recurrence.

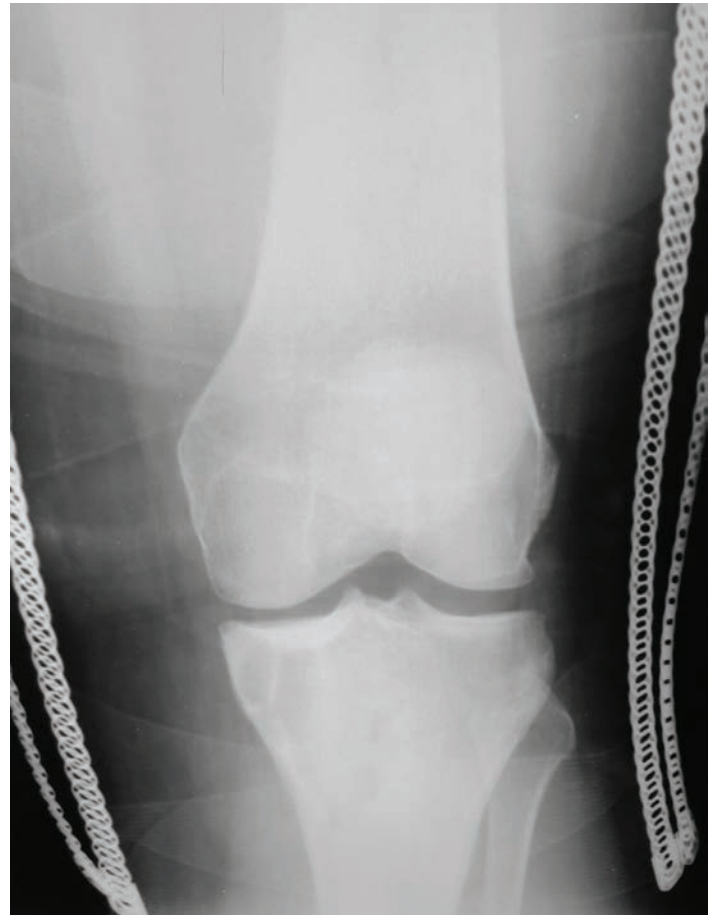


Figure 2. Radiograph obtained 7 weeks postoperatively shows robust growth of new bone at implantation site.



ELECTROSPUN MATRIX

Composed of β -TCP, CaCO₃, silicon and PLGA.
Contains 0.5% to 1% silicon by weight, which is
comparable to the level found in natural bone.



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