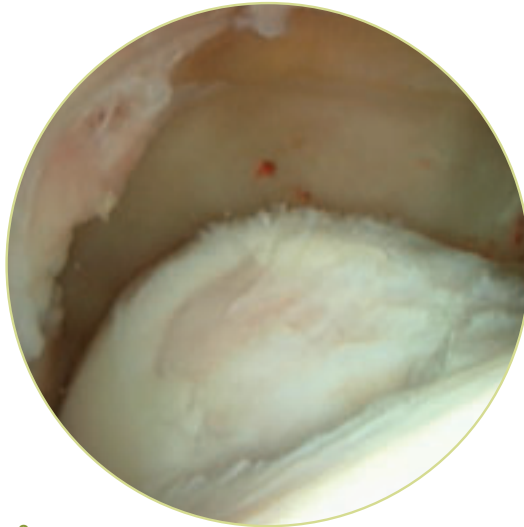


1.



2.

Case study courtesy of Jason M. Scopp, MD. Salisbury, MD.

See important safety information about CARTICEL inside.

▶ **Carti**
(autologous cultured chondrocytes)

CASE STUDY: TROCHLEA DEFECT

CARTICEL IMPLANTATION

Implantation of CARTICEL occurred after patient failed to respond to initial chondroplasty.

1. Following tibial tubercle osteotomy (Fulkerson) cut to correct lateral subluxation, the patella is reflected, exposing the trochlea defect.

2. Trochlea defect post-implantation with CARTICEL.



1.



2.

POST-CARTICEL REHABILITATION

Early

Initiate CPM 6-8 hours after implantation
 Immediate partial weight-bearing in full extension as tolerated
 Brace locked at 0° during ambulation and weight-bearing
 Knee flexion to 90° by 2-3 weeks
 May begin pool therapy by week 4

Mid

Progress to full weight-bearing by 6-8 weeks
 Quad strengthening; balance and proprioception drills
 Discontinue brace by 6 weeks
 Flexion to 120° to 125° by week 8
 Closed kinetic chain exercises by week 8
 Open kinetic chain knee extension without resistance

Late

Swimming, walking, cycling by 6 months
 Gradually return to full, unrestricted activity by 8 months
 Jumping and pivot sports should not be performed for 12 months

CLINICAL RESULTS

Patient returned to activities of daily living as well as participation in recreational sports. Subsequent surgical procedure after nine months (arthroscopic evaluation after patient sustained new traumatic injury) showed fully integrated hyaline-like cartilage at the defect site, with no hypertrophy or delamination.

Improvement in Symptoms:

No instability

Improvement in Function:

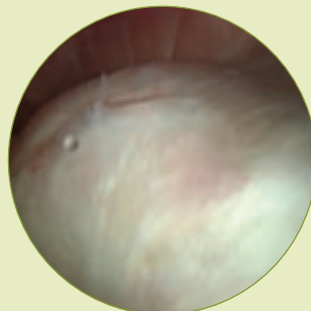
Returned to employment
 Returned to sports activity

Improvement in Activities of Daily Living:

No limitations
 Full recreational sports participation: basketball

Arthroscopic examination

Integrated trochlea cartilage with no hypertrophy or delamination.



See important safety information about CARTICEL on facing page.

IMPORTANT TREATMENT CONSIDERATIONS

CARTICEL is for autologous use and is indicated for the repair of symptomatic cartilage defects of the femoral condyle (medial, lateral or trochlea), caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft). CARTICEL should only be used in conjunction with debridement, placement of a periosteal flap and rehabilitation. The independent contributions of the autologous cultured chondrocytes and other components of the therapy to outcome are unknown. It is not indicated for the treatment of cartilage damage associated with generalized osteoarthritis. It is not recommended for patients whose knee meniscus has been surgically removed unless the patient has undergone surgical reconstruction prior to or concurrent with CARTICEL implantation.

Pre-existing conditions including meniscal tears, joint instability or malalignment of the joint should be corrected prior to or concurrent with CARTICEL implantation. It should not be used in patients with a known history of hypersensitivity to gentamicin, other aminoglycosides or materials of bovine origin. CARTICEL is not routinely tested for transmissible infectious diseases and may transmit disease to the healthcare provider handling CARTICEL. In addition, it should not be used in patients who have previously had cancer in the bones, cartilage, fat or muscle of the treated limb. Use in children, patients over age 65, or in joints other than the knee has not yet been assessed.

The occurrence of subsequent surgical procedures (SSPs), primarily after arthroscopy, following CARTICEL implantation is common. In the Study of the Treatment of Articular Repair (STAR), forty-nine percent (49%) of patients underwent an SSP on the treated knee, irrespective of their relationship to CARTICEL, during the 4-year follow-up. The most common serious adverse events ($\geq 5\%$ of patients), derived from STAR, include arthrofibrosis/joint adhesions, graft overgrowth, chondromalacia or chondrosis, cartilage injury, graft complication, meniscal lesion, graft delamination, and osteoarthritis.

Please see enclosed full prescribing information.

Please note that individual results may vary and not all patients will achieve full function.

genzyme

Biosurgery

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(autologous cultured chondrocytes)