In Situ Evaluation of De-cellularized Osteochondral Allograft at 18, 25 and 36 Months Following Implantation: A Case Report

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Disclaimers

- JAH, KR: None
- SKB
  - Zimmer Biomet
  - Depuy
  - Rotation Medical
  - Arthrex
Introduction

- Osteochondral Defects (OCDs)
  - Full thickness lesions are common in young active patients\(^1\)
  - Due to the low healing capacity of cartilage these lesions may lead to global joint degeneration\(^2\)
  - Multiple techniques are described for management of large OCDs

High rates of OA progression as early 9 years with fragment removal >2cm²
Limited use of microfracture for lesions >2cm²
ACI and Osteochondral Allograft good to excellent results 70% of patients
Viability 98% at 7 days, 70% at 28 days
Importance of limb alignment, meniscal deficiency and ligamentous stability
Refrigerated osteoarticular allografts to treat articular cartilage defects of the femoral condyles. A prospective outcomes study.

Robert F. LaPrade, MD, PhD, Jesse Botker, MD, Mary Herzog, MD, and Julie Agel, ATC


- 23 patients with implantation within average 20.3 days
- Significantly Improved Cincinnati knee ratings for Function, Symptoms and Overall
- Radiographical stability of graft at 3 year follow up
- Significant functional and clinical improvement at 3 years if implantation between 15 and 28 days.
OCD Management

- Goals of Intervention
  - Pain relief
  - Improve function
  - Delay/Negate Arthroplasty

- Osteochondral allograft (OCA)
  - Large Chondral Defects

Osteochondral Allografts

- The fundamental principle of fresh OCA:
  - Replacing damaged/diseased articular cartilage and underlying bone
    - Mature hyaline cartilage
      - Donor chondrocytes are found to survive transplantation, support the cartilage matrix, and maintain tissue homeostasis for an indefinite period of time.\(^3,4\)
    - Supporting subchondral bone
      - Osseous portion of allograft is gradually replaced by host bone via creeping substitution,\(^1,2\)

Osteochondral Allografts

Although good results are seen, challenges associated with OCA transplantation exist\(^1\)-\(^3\)

- Allograft storage
- Size matching
- Tissue availability
- Chondrocyte viability
- The possibility of immunologic graft response
- Demanding surgical technique

Chondrofix® OCA

- De-cellularized OCA
  - Terminally sterilized and virus-inactivated with low dose gamma irradiation (15 -18 kGy) at low temperatures (below 0°C).
  - Chemical lipid extraction of the allograft - decreases incorporation time
  - Process maintains the mechanical properties of the hyaline cartilage and allows for off-the-shelf logistics.
  - 24-month shelf life
Chondrofix® Processing

Recovery
- Human tissue is recovered by an accredited tissue bank
- Strict requirements have been specified to ensure highest quality donor tissue

Processing
- Tissue undergoes processing protocol that maintains biomechanical stability of tissue.
- Grafts are viral inactivated to remove viruses to non-traceable levels.
- Delipidization process.

Chondrofix®
- Grafts are packaged and terminally sterilized to provide off-the-shelf convenience.
- Grafts can be stored at room temperature for up to 18 months.
Purpose

- Chondrofix® is used to resurface osteochondral lesions in the knee
- Case report demonstrates unique situation in which a Chondrofix® allograft plug is inserted and arthroscopically evaluated at 18, 25 and 36 months post-implantation
Case Report

16 yo Male

- Presents to OSH 3 days s/p twisting injury of his left knee while playing competitive soccer
- Describes hearing “pop” and c/o of continuing pain and swelling
- Guarded and apprehensive on exam, unable to bear weight, effusion, 30° flexion contracture with limited ROM, +Lachman’s
- Xrays – Small to moderate sized radiolucent defect lateral aspect of medial femoral condyle
- MRI – Complete tear of the ACL with concomitant unstable OCD measuring 1.6 cm x 1.5 cm.
Initial Procedure

- OSH Surgery:
  - Trans-tibial ACL Reconstruction with BPTB Autograft and Microfracture of OCD
- WB at 2 weeks
- RTS with Brace 3 months
- Recurrent knee effusions, pain with activity, and intermittent feelings of “giving out”
- Repeat MRI: Ruptured ACL graft with no change in OCD, small radial tear body of medial meniscus
Second Procedure

- Patient referred for further management
- 5 Months post index procedure
- Revision Surgery:
  - Anatomic allograft ACL reconstruction
  - mini-open osteochondral allograft transplantation of OCD with Chondrofix OCA plug
(A) Outerbridge Grade IV osteochondral defect of medial femoral condyle.

(B) 15x11mm Chondrofix Osteochondral Allograft
Recovery

- **Postop Protocol:**
  - NWB in brace full extension for 2 weeks
  - PT for supervised ROM and gradual weight bearing to tolerance, closed chain at 6 weeks
- **Anticipated RTS 1 year**
- **5 months post op patient RTS AMA**
- **Patient sustained another twisting injury, c/o large effusion with pain**
MRI: Increased signal intensity in ACL graft - possible rupture, medial and lateral meniscal tears, incorporating OCA plug

After 4 weeks of elected non-op management, patient continued to have pain and elects surgical management.
Third Procedure

- 6 Months postoperative Revision ACL and Osteochondral Allograft
- Arthroscopic evaluation:
  - ACL Rupture
  - Irreparable Medial Meniscal Tear
  - Lateral Meniscal Tear
Third Procedure

- Procedure:
  - ACL debridement
  - Medial and lateral meniscectomy
- Future staged repeat revision ACL reconstruction and medial meniscal allograft transplantation
Fourth Procedure

- 18 months after Chondrofix OCA implantation
- Procedure:
  - Medial meniscal allograft transplantation
  - Bone grafting of femoral and tibial tunnels
Arthroscopic view of medial femoral condyle with intact Chondrofix osteochondral allograft 18 months after implantation. (B) Second outline represents adjacent osteochondral defect.
Preoperative CT: Sagittal cut showing osseous incorporation of OCA plug
T2 – weighted MRI: mild increased signal at anterior OCA implant with no articular step off
Fifth Surgery

- 25 months post Initial OCA
- Procedure:
  - Second stage of repeat revision ACL reconstruction with hamstring autograft
Arthroscopic examination of intact Chondrofix® Osteochondral Allograft 25 months after implantation the graft demonstrated complete bony incorporation with undetected articular cartilage margins, and restoration of native femoral condylar radius of curvature (A,B).
Sixth Surgery

- 1 year after second revision ACL reconstruction with hamstring autograft, 36 months post OCA
- Twisting injury
- Procedure: Repair of medial meniscal allograft with patellofemoral chondroplasty
Arthroscopic examination of intact Chondrofix® Osteochondral Allograft 36 months after implantation the graft demonstrated minimal demarcation of articular cartilage margins, and restoration of native femoral condylar radius of curvature.
Summary

- Allograft incorporation despite an extremely suboptimal healing environment
  - Smooth borders
  - Minimal Demarcation
  - Restoration of Radius of Curvature
- Chondrofix OCA may prove to be a valuable supplement or alternative to fresh OCA in treatment of large OCDs in certain situations.
Thank You!