Clinical and Radiologic Evaluation of Cartilage Patients

ISMF 2019- Carlsbad Ca.

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Disclosures:

- Chief Medical Officer: Cartiheal Inc.
- Consultant: Aesculap Inc.
- Scientific Advisory Board member: Orthospace Inc.
- Zimmer Biomet: Research Consultant
- MiMedX: Research consultant
- Active Implants: Research consultant
- Past President: ICRS
Articular Cartilage Injury: A permanent injury

- Poor vascularity...No healing potential
- Adult chondrocytes don’t migrate or replicate to fill defects
- Injury begins an inexorable cascade of events both chemical and then mechanical leading toward degenerative joint disease.
Patient Profile

- Under 50—not arthroplasty candidates
- May be traumatic: if associated with ACL tear or Patellar Instability

However often atraumatic, associated with:

- Mal-alignment
- Ligamentous Insufficiency
- Meniscal Deficiency
- Obesity
Symptoms of Articular Cartilage Injury:

- Pain
- Catching / Clicking / Locking
- Instability
- Effusions
- Can significantly impair athletic activity and ADL’s
Comparison 1996 data to 2006

984,607 arthroscopic procedures on the knee (95% confidence interval) grade III-IV lesions

- Curl 5% 1997 = 50,000/year
- Engebretsen 6% 2004 = 60,000/year
- Widuchowski 7% 2007 = 70,000/year
236 subjects 45-55

Articular cartilage lesions in 74.6% per 3T MRI

Severity of lesions proportional to activity level

Independent of gender, age, BMI or OA risk factors
Goals of Cartilage Repair

- Relieve patient symptoms and improve function
- Restore articular cartilage surface
- Match biomechanical properties of normal hyaline cartilage & sub-chondral bone
- Prevent or slow progression of focal injury to end-stage arthritis
Building block of articular cart. matrix is type II collagen

- Middle arch. zone called “the netting” is made of aggregates of proteoglycans called gag’s (glycosamino glycans): This netting holds water i.e.: gives hydrophilic properties
Remember Knee is an organ: Not just joint surface

- Ligamentous stability
- Mechanical alignment
- Functional meniscus
- Synovial fluid milieux

Co-morbidities must be corrected prior to or concurrent with implantation

*slide courtesy of Bert Mandelbaum*
Cartilage and bone effect each other.

Cartilage provides low coefficient of friction and ability to distribute shear load evenly to the skeleton.

Sub-chondral bone needs to be flexible enough to absorb load, when it becomes too stiff it can increase chance of progressive cartilage wear.
Surgical choice has been stratified by lesion size or by primary vs secondary treatment:

<table>
<thead>
<tr>
<th>Lesion &lt; 2 cm²</th>
<th>Lesion ≥ 2 cm²</th>
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<tbody>
<tr>
<td><strong>Primary Treatment</strong></td>
<td><strong>Secondary Treatment</strong></td>
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<td>▪ D &amp; L</td>
<td>▪ ACI</td>
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<td>▪ Osteochondral cold stored alloGrafting</td>
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Cole, Farr algorithm
Clinical Decision Making Variables:

Treatment Decision with Cartilage Management

Knee Specifics

- Mechanical Alignment
- Ligament Stability
- Status of Meniscus
- PF Alignment
- Acute vs Chronic

Defect Specifics

- Depth/Number
- Contained/Non-contained
- Geometry

Patient Specifics

- BMI
- Gender
- Duration of Symptoms
- Number of Prior Surgeries

Gomoll A, Surgical Management of Articular Cartilage Defects of the Knee: 2012 Instructional Course AAOS: 322
Classic work-up

- History
- Previous surgery
- Physical Exam
- Pay close attention to determine the pain source
- Is it the cartilage lesion or PF problem or other soft tissue issue?
- Understand your patients current activity level and desired outcome? Is it realistic?
Knee Exam

- Presence of effusion
- Joint line tenderness
- Range of motion
  - Limited flexion
  - Extension lag
  - Locking
  - Crepitation
- Joint stability
  - Tibiofemoral
  - Patellar tracking
Radiologic work-up

- Standing AP/ Lateral
- Bilateral Rosenberg 45 degree flexion view
- Patella Merchant Views
- 54 inch Scanogram for full limb alignment
- Standard MRI to evaluate both the chondral surface and sub-chondral bone plus evaluate concomitant meniscal and ligament status
- TT-TG is measuring medial to lateral displacement or TT-PCL
- A TT-TG value of <15 mm is considered normal TT-TG value >20 mm may be considered for medialization
- Remember Trochlea dysplasia consider trochleaplasty if appropriate

- Caton-Deschamps index to measure patella height
- Patella Alta and Baja

A/B: Normal mean = 1


MRI imaging has been validated for articular cartilage in multiple pre-clinical studies.

- Know Grading system (Mocart)
- Functional (biochemical) images: dGEMRIC, T2 Mapping

Have relationship with a good MSK Radiologist in your community

T2 map of patella 24 months after MACT of patella (arrows = repair)
May take 2 stage procedure with scope for diagnosis and decision making plus taking cell biopsy if needed.

Deal with concomitant pathology if needed.

Patient should be counseled possible definitive surgery could occur if appropriate at time of scope.
PATIENT EDUCATION: TREATMENT OPTIONS

- Regenerative Biologic injectable therapies + Rehabilitation
- Augmented micro-fracture – single procedure
- Many new Matrices /implants coming from europe/Israel
- OA autograft for small lesions
- Osteo-Articular allograft
- MACI
DISCUSSION

- Patient counseling is essential/ a very personal decision
- Discussion of options
- Post op rehab and ability/desire to comply
- Work and sports restrictions which will apply
- What is the likely change in the lifestyle and activity level of the patient? Is the clinically relevant change (delta) in lifestyle worth the time and risk?
- Form relationship with the patient, make sure all concerns answered and patient had a full chance to air their thoughts
IND: Investigational new drug: an IND allows manufacturer to ship products legally to investigational sites while doing a study to obtain a BLA, NDA or PMA.

NDA: new drug application

BLA: biologic license application

PMA: process to evaluate the safety and effectiveness of Class III medical devices.

510K: abbreviated path for medical device approval

CAUTION: "ALLOGENEIC PRODUCTS LIKE ORGAN TRANSPLANT PRODUCTS MAY NOT NEED REGULATION AND THEREFORE WILL OFTEN COME ON MARKET WITH LITTLE TO NO CLINICAL AND PRE CLINICAL DATA."
Regulatory Categories for HCT/Ps

- **Exempt**: exclusions on previous slide, autologous product reimplanted during the same surgical procedure, minimally manipulated marrow for homologous use, or reproductive cells implanted into the partner of the donor.

- **“361 Product”**: PHS 361 and 21 CFR 1271 apply; no premarket review required if ALL of the following criteria are met:
  - Minimally manipulated, and
  - Intended for homologous use, and
  - Not combined with another article, and
  - Either does not have a systemic effect or require living cells; or has a systemic effect and is for autologous use, for 1st or 2nd degree related recipients, or for reproductive use

- **“351 Product”** – Not exempt and not solely a 361 product.
  - Premarket review required.
  - Regulatory path of Biologic or Device according to which definition is applicable.
THANK YOU – MERCI - GRACIAS
OBRIGADO - DANKE