Main Question: how people do after undergoing an anterior cruciate ligament (ACL) reconstruction?

Goal: identify predictors of who does well and conversely, the risk factors for poorer outcomes following an ACL reconstruction.

NIH-funded consortium consists of 18 sports medicine physicians across 7 sites.

To establish the consistency of measurements and techniques across 7 sites, multiple validity studies have been performed:

1. Inter-rater Agreement of Meniscus Tears and Treatment. Dunn, AJSM, 2004
2. Inter-rater Agreement of Articular Cartilage Classification. Marx, AJSM, 2005
4. Intra- & Inter-surgeon Agreement on Femoral and Tibial Tunnels ACLR. Wolf, submitted

The Clinical Study DESIGN

- COHORT: patient specific risk factors for given outcome
- Clinically Meaningful Difference: decisions based on absolute differences convert NNT
- Outcome: perspective of society (EQ5D or SF-36) or individual (sport IKDC or KOOS)
Required Measurement & Sample Size for PREDICTORS (i.e. risk factors)

1. FAILURE: Rev ACLR, ~1000
2. ACTIVITY: Marx, ~400
3. PAIN: Pain Subscales WOMAC and KOOS ~400
5. SPORTS FUNCTION: KOOS & IKDC ~1000
6. General health: SF-36 ~500-1000
7. OA: MTP XR ~300
8. AP laxity: RCT ~125, Predictors ~400
9. Relationship: PRO with “objective” ~400

What Predicts Activity Level Two Years after ACLR from MOON Cohort?

Dunn AOSSM 2007, AJSM 2010

- 88% two-yr f/u 446 ACLR met inclusion criteria
- Multivariable logistic regression evaluate predictors Marx activity level adjusting for confounders (p<0.05)
- Median Baseline: 12 decreased to 9 (scale 0-16)
- Lower Activity: Female (0.60), BMI (0.74), current smoker (0.55), revision ACLR (0.41)

Cost-Effectiveness Analysis of Early Reconstruction versus Rehabilitation & Delayed Reconstruction for ACL Tears

- Markov Decision Modeling
- Costs based 2012 US
- SF-6d (component of SF-36)
- RESULTS: Early ACLR Results had both:
  - Increase 0.30 QALYs (Quality adjusted life yrs)
  - Lower Cost $1797 (2012$)
- **Societal Point of view – Based on this data, early ACLR is preferred strategy**
  
Mather et al., AJSM 2014

The Prognosis, Predictors of Sports Function & Activity 6 Years after ACL Reconstruction - A Population Cohort Study

- Methods: Patients w/ unilateral ACLRs from 2002 MOON cohort were evaluated.
- Patients completed the validated PROMs preoperatively. Physicians documented intra-articular pathologic abnormalities, treatment, and surgical techniques used at the time of surgery.
- At 2 and 6 years postoperatively, patients completed the same PROM (outcome instruments).

The Prognosis, Predictors of Sports Function & Activity 6 Years after ACL Reconstruction - A Population Cohort Study

- Results: F/U 2 years (88%), 6 years (84%).
  
Cohort : 57% male, median age of 23 yrs at enrollment.
- Sports function maintained at 6 yrs, Marx activity level
- Revision ACLR and use of allograft predicted worse outcomes on the IKDC and both KOOS subscale.
- Lateral meniscus treatment, smoking status, and body mass index at baseline were each predictors on 2 of 3 scales.
- The predictors of lower activity level were revision ACLR and female sex.

Spindler K et al., AJSM 2014

Patient Outcomes at 6-Year Follow-up Meniscal Repair With Concurrent ACLR: Operative Success

- Results: In total, 286 patients with 1440 primary ACLRs w/ meniscal repairs (298 meniscal repairs).
- 235 (82.2%) were available for follow-up at 6 years (154 medial, 72 lateral, and 9 both lateral and medial meniscal repairs).
- Meniscal repair failure rate :14% (medial: 21/154; lateral: 10/72; both: 2/9)
- Medial repairs failed earlier than lateral repairs (2.1 vs 3.7 years, respectively

Robert W. Westermann et al., AJSM 2014

TWO -Year Outcomes & Predictors

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Predictors</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does Bone Bruise cause pain at ACLR?</td>
<td>No</td>
<td>BMI &amp; female</td>
<td>Longer term bone bruise outcomes</td>
</tr>
<tr>
<td>What is the predicted Activity Level 2 yrs post-ACLR?</td>
<td>Decrease by 4</td>
<td>Revision, Age, Female</td>
<td>Clinically meaningful change</td>
</tr>
<tr>
<td>What is the likelihood of Contralateral ACL Tear?</td>
<td>3%</td>
<td>Unknown (requires greater sample size)</td>
<td>Predictors</td>
</tr>
<tr>
<td>What is the likelihood of ACLR Graft Failure?</td>
<td>1-20%</td>
<td>Allograft, younger age, higher activity</td>
<td>Types of allografts</td>
</tr>
<tr>
<td>What is the likelihood of Meniscus Repair Success?</td>
<td>94%</td>
<td>Unknown</td>
<td>% union of tear</td>
</tr>
<tr>
<td>What is the predicted KOOS at 2 yrs?</td>
<td>Improved, Not normal</td>
<td>Revision, Smoking, G2 LCL</td>
<td>Underpowered for Men and Art cart</td>
</tr>
<tr>
<td>What is the likelihood of return to play for football players?</td>
<td>~70%</td>
<td>Fear of re-injury reported by~50% HS and college who don’t return</td>
<td>Predictors</td>
</tr>
</tbody>
</table>

Is Allograft vs Autograft a Cause of Primary ACLR Failure?

Kaeding, AOSSM 2008, Sport Health 2011

MOON 2002 & 2003

- Min 2-yr f/u phone or ?
- n= ~1000
- 94 % follow-up
- failure defined as revision

- Results:
  - <18yr: ALLO 20% vs. Auto 6%
  - > 40yr: ALLO 3% vs. Auto 1%

The Prognosis, Predictors of Sports Function & Activity 6 Years after ACL Reconstruction - A Population Cohort Study

- Methods: Patients w/ unilateral ACLRs from 2002 MOON cohort were evaluated.
- Patients completed the validated PROMs preoperatively. Physicians documented intra-articular pathologic abnormalities, treatment, and surgical techniques used at the time of surgery.
- At 2 and 6 years postoperatively, patients completed the same PROM (outcome instruments).
Patient Outcomes at 6-Year Follow-up
Meniscal Repair With Concurrent ACLR:
Operative Success

- All-inside techniques were performed in 208 of 235 patients (88.5%) available for follow-up. There were 31 failures w/ this technique, representing a 14.9% failure rate.

- Medial repairs: 135 of 154 were repaired using all inside techniques; of these, 19 (14.1%) failed at 6-year follow-up. Inside-out techniques were used in 12 of 154 medial meniscal repairs.

Robert W. Westermann et al., AJSM 2014

Patient Outcomes at 6-Year Follow-up
Meniscal Repair With Concurrent ACLR:
Operative Success

- Lateral menisci were commonly repaired with all-inside techniques; all-inside repairs represented 90.3% (65/72) of lateral meniscal repairs.

- All lateral meniscal repair failures (n = 10) were treated with all-inside techniques.

Robert W. Westermann et al., AJSM 2014

Patient Outcomes at 6-Year Follow-up
Meniscal Repair With Concurrent ACLR:
Operative Success

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- Meniscal repair failure rate :14% (medial: 21/154; lateral: 10/72; both: 2/9)

- Significant improvements in outcome scores were sustained at 6-year follow-up. No differences in the suture number or type were detected between repair failures and successes.

Robert W. Westermann et al., AJSM 2014

KOOS International Outcomes

Compare KOOS results across other registry db in the World!
EUROPE: SWEDEN, NORWAY, DENMARK
UNITED STATES: MOON & MARS

<table>
<thead>
<tr>
<th>db</th>
<th>Pain</th>
<th>Sx</th>
<th>ADL</th>
<th>Sp Rec</th>
<th>QOL</th>
<th>N=</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOON</td>
<td>90%</td>
<td>72</td>
<td>82</td>
<td>46</td>
<td>35</td>
<td>713</td>
</tr>
<tr>
<td>NKLR</td>
<td>85%</td>
<td>74</td>
<td>72</td>
<td>43</td>
<td>35</td>
<td>4928</td>
</tr>
<tr>
<td>Sweden</td>
<td>72</td>
<td>70</td>
<td>84</td>
<td>40</td>
<td>34</td>
<td>2138</td>
</tr>
</tbody>
</table>

Patient Outcomes at 6-Year Follow-up
Meniscal Repair With Concurrent ACLR:
Operative Success

- Improvements in patient-oriented outcome scores were sustained at 6-year follow-up. Surgeons may expect good clinical outcomes.

- 6 years after combined ACLR and meniscal repair.

Robert W. Westermann et al., AJSM 2014

Global Lessons Learned

- Validated patient-reported outcome forms (KOOS, WOMAC, Marx, IKDC & SF-36) successful in tracking longitudinally large populations over years.

- Created a “culture of collaboration” to clinical outcomes research in our field.

- Patient F/U >80% (excellent) but... requires significant time / resources
  F/U by fulltime person monitor ~600 pts.
  Surgeons call 30-40% annually

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- Choosing autograft vs. allograft, not smoking, and having normal BMI improve long-term outcomes.

- Activity levels decline after ACL reconstruction.

- Meniscus repair combined with ACLR has good success at 6 yrs. Post op. (EAA comment: more teaching necessary at resident/ fellow level)

- ACLR does not re-establish a ‘normal’ knee.

MOON : Specific Findings to Date

- Early ACL Reconstruction is a preferred societal strategy based QOL - PROM & cost.

- Choosing autograft vs. allograft, not smoking, and having normal BMI improve long-term outcomes.

- Activity levels decline after ACL reconstruction.

- Meniscus repair combined with ACLR has good success at 6 yrs. Post op. (EAA comment: more teaching necessary at resident/ fellow level)

- ACLR does not re-establish a ‘normal’ knee.
Follow-up Problem?

- ACL registry Norway, Denmark, Sweden all struggle f/u yet only < 50% follow-up!
- Total Joints routine f/u requested at 2 yr, the published follow ~40% (Clohisy, JBJS)
- MOON f/u = ~85% 2340 ACLR @ 2 & 6 years

What have we learned?

- Answers we need to assess efficacy of surgery requires physician agreement on patient care and surgical technique.
- This kind of needed outcomes is costly
- Who should be responsible for incorporating study results into clinical practice?
  (average time from clinical finding to incorporation into clinical practice : 7 years)

Follow-up Problem?

- MOON f/u = ~85%
- however requires FTE @ 40K per year for ~600 pts per year AND Surgeons call ~30% of their patients.
- These pts prospectively entered with IRB consent – IMPRACTICAL “real world”
- Need a FOLLOW-UP SOLUTION for Future Comparative Effectiveness Cohort Studies

Thank You

Orthopaedic Surgery
Sports Medicine
University of Minnesota