History of Synthetic Ligaments

- From as early as 1903 surgeons have attempted to use synthetic material to repair damaged soft tissues in the body
  - The seventies and eighties saw intensive development and studies in synthetic ligaments
    - Carbon fibre, Dacron, Gore-tex
    - Many different ligament structures used

History of Synthetic Ligaments

- Many early attempts at reconstruction with synthetic ligaments met with failure because of a number of reasons including:
  - Poor definition of the ligament purpose
  - Poor anatomical understanding
  - Poor material selection

History of Synthetic Ligaments

- Potential purposes are divided into:
  - Permanent Replacement
  - Augmentation
  - Scaffolds
  - Each ligament purpose will have different physical requirements

History of Synthetic Ligaments

- Permanent Replacements
  - Require all of the functions of the native tissues to be replaced by the synthetic ligament
  - Strength, elasticity, recovery and durability are key criteria
    - In-growth is not a concern as the native tissue will usually be removed
    - Many failures due to poor understanding of functional mechanics and suitable material use
History of Synthetic Ligaments

- Augments
  - Require that the synthetic ligament will take the load from the native tissue during the motion
  - Strength, elasticity and recovery are key criteria
    - In theory the native ligament should recover the load from the synthetic ligament
    - Some doubt exists over the occurrence of this due to stress shielding

- Scaffolds
  - Require native tissue to grow into the synthetic material for support while healing
  - Bio-compatibility, in-growth potential, strength, elasticity, recovery and durability are key criteria
    - The most promising purposes in the use of synthetic ligaments

Scaffolds

<table>
<thead>
<tr>
<th>Device</th>
<th>Prosthesis type</th>
<th>Material</th>
<th>Design</th>
<th>Intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>GORE-TEX</td>
<td>Permanent</td>
<td>PTFE</td>
<td>Braid</td>
<td>Replacement</td>
</tr>
<tr>
<td>LAD</td>
<td>Stent</td>
<td>PP</td>
<td>Flat braid</td>
<td>Augmentations</td>
</tr>
<tr>
<td>STRYKER</td>
<td>Permanent</td>
<td>Dacron fabric</td>
<td>Knitted &amp; woven</td>
<td>Augmentations &amp; replacement</td>
</tr>
<tr>
<td>LEEDS-KEIO</td>
<td>Scaffold</td>
<td>Dacron mesh</td>
<td>Woven</td>
<td>Augmentations &amp; scaffolds</td>
</tr>
<tr>
<td>LIGASTIC</td>
<td>Permanent</td>
<td>PET</td>
<td>Knitted</td>
<td>Augmentation &amp; replacement</td>
</tr>
<tr>
<td>LARS</td>
<td>Permanent - scaffold</td>
<td>PET</td>
<td>Knitted &amp; Free Fibres</td>
<td>Augmentations &amp; scaffolds</td>
</tr>
</tbody>
</table>

Ligament failure rates

<table>
<thead>
<tr>
<th>Ligament</th>
<th>Rupture Rates</th>
<th>Synovitis</th>
<th>Foreign Body Reaction</th>
<th>Particular in Sloppy Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon fibre</td>
<td>No data</td>
<td>Extensive</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Gore-Tex™</td>
<td>10-33%</td>
<td>Yes in several studies</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Kennedy LAD</td>
<td>4-44%</td>
<td>Extensive and Severe</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Stryker Dacron</td>
<td>Up to 80%</td>
<td>Extensive</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Trevira-Dacron</td>
<td>4-25%</td>
<td>Extensive</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Leeds-Keio</td>
<td>Variable, several between 10-45%</td>
<td>Yes in several studies</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>LARS</td>
<td>One study with high rupture rate. Generally 1-7%</td>
<td>1 case in 1 study</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

* All studies evaluated ACL patients at up to 6 year follow up

Synthetics in the past

- Synthetic Ligaments of the past were known to have high failure rates
  - There was poor understanding of bio-compatibility, mechanical and durability characteristics of materials used and the demands on early synthetic ligaments

Why Synthetic Ligaments?

- Interest in synthetic ligaments has continued due to less than ideal outcomes with hamstrings and patellae
  - Cumulative survival at 4 years for native tissue ACLR was 90.7% in 4025 patients (Paxton et al – 2010)
  - Rupture is only one complication
Traditional ACL Reconstruction

- Traditional ACL reconstruction has been shown to achieve good-to-excellent results in only 60% of patients. (Shen & Fu et al, 2008)
- 63% of ACLRs had returned to their pre-injury level of participation, and 44% had returned to competitive sport at final follow-up. (Arden, 2011)
- Because of this high failure rate, we have been driven to explore alternative reconstruction techniques. (Shen & Fu et al, 2008)

Traditional ACL Reconstruction

- Over 50% of hamstring Graft recipients have been shown to experience donor site pain at up to 3 years post-operatively. (Arden & Feller et al, 2011)
- Up to 27% compared with the non-operated limb, indicating that hamstring strength deficits persist despite successful completion of rehabilitation. (Arden & Feller et al, 2011)
- Human hamstring grafts showed typical stages of graft remodelling, which was not complete up to 2 years after ACLR. (Janssen et al, 2011)

Traditional ACL Reconstruction

- Patellar tendon graft recipients showed kneeling pain in 44% of patients at 5 years and 69% of patients at 15 years. (Hui, 2010)
- At 10 years post-operatively, 35% of patients still suffered donor site irritation, tenderness or numbness. (Pinczewski et al, 2007)

Traditional ACL Reconstruction

- As many as 20% to 30% of athletes fail to achieve their previous level of performance, suggesting that there is room for improvement. (Shen & Fu et al, 2008)

WHY SYNTHETIC LIGAMENTS

- Why do surgeons still use synthetic ligaments, despite unsatisfactory results of former generations of synthetic ligaments?
- Why there is still ongoing research on the possibilities of synthetic ligaments?
History of Synthetic Ligaments

Answer I:
We learnt from the failures of the past!

- Better definition of the ligament purpose
- Better anatomical understanding
- Better Material Selection
- Better bio-compatibility of the synthetic ligament

Why Synthetic Ligaments?

Answer II:
- Interest in synthetic ligaments has continued due to "suboptimal" (Shen & Fu et al, 2008) outcomes with other graft options
- RCT’s report failure rates of up to 10% for Autografts
- Cumulative survival at 4 years for autografts was 90.7% in 4025 patients (Paxton et al – 2010)

Why Synthetic Ligaments?

- Pinczewski reported on the results of 90 hamstrings graft recipients versus 90 Patellar tendon graft recipients at 15 years postoperatively (Pinczewski, AOSSM, 2011)
- ACL graft rupture occurred in 16% of patients in the HS group and 8% of patients in PT group (Pinczewski, AOSSM, 2011)
  - Contra-lateral ACL rupture occurred in 24% PT vs. 12% HS (Pinczewski, AOSSM, 2011)

Traditional ACL Reconstruction

- Over 50% of hamstring graft patients experienced donor site pain at up to 3 years post-operatively (Arden & Feller et al, 2011)
  - Strength deficits up to 27% compared with the non-operated (Arden & Feller et al, 2011)

Traditional ACL Reconstruction

- Over 50% of hamstring graft patients experienced donor site pain at up to 3 years post-operatively (Arden & Feller et al, 2011)
  - Strength deficits up to 27% compared with the non-operated (Arden & Feller et al, 2011)

Traditional ACL Reconstruction

- 63% of ACLRs returned to their pre-injury activity level after 12 months (Arden, 2011)
  - 33% returned to competitive sport at final follow-up (Arden, 2011)

Traditional ACL Reconstruction

- Although, biopsies of human hamstring grafts show typical stages of graft re-modelling the re-modelling process is not completed up to 2 years after ACLR (Janssen et al, 2011)
- Various studies confirm these results (Clarice 2011, Garada 2000, Tonryama 2006, Unterhauser 2006, Yu 2009)
  - Does a graft reaches a sufficient strength if the ligamentization process is not completed?
  - Up to 12 months grafts approached only 50–60% of the intact ACL failure strength (Kanis 1995, NG 1995, Scheffler 2008, Yu 2009)
Traditional ACL Reconstruction

- The key finding of a recently published systematic review on the ligamentization of autografts demonstrate

“that although ACL reconstruction is performed as a routine surgical procedure all around the world, the underlying ligamentation process is still poorly understood in the human knee” (Cleas, Verdonk, Bellemans 2011).

Summary

Generally, traditional ACLR has achieved good-to-excellent results in only 60% of patients

(Shen & Fu et al, 2008)

Summary

Because of high failure rates, we have been driven to explore alternative reconstruction techniques

(Shen & Fu et al, 2008)

Summary

As many as 20% to 30% of athletes fail to achieve their previous level of performance, suggesting that there is room for improvement

(Shen & Fu et al, 2008)

Material Properties

- Material selection is vitally important to the viability of a synthetic ligament
- As mentioned, the demands placed on the ligament vary depending on its purpose in terms of:
  - Performance
  - Durability
  - Biocompatibility
Material Selection

- Ideally a synthetic fibre used should:
  - Have similar or superior strength to the tissue being replaced / augmented / scaffolded
  - Have similar elasticity and recovery to native tissue and resist permanent deformation
  - Be able to move in a similar manner to native tissues
  - Be durable enough to withstand repetitive use
  - Be bio-compatible

LARS and PET

- A number of synthetic PET ligaments have been trialled in the past
- Over 500 different PET polymers are available commercially
  - Each has its own physical characteristics
    - Strength
    - Elasticity
    - Resistance to torsion
    - Elastic deformation

LARS – Ligament Advanced Reinforcement System

- LARS is the result of research in better selection of fibres
  - Mechanical Properties
    - Elasticity without elongation
  - Biological Properties
    - Perfect Tolerance
    - Fibroblast friendly

Selection Criteria

1. Mechanical selection criteria of PET fibres
   - Maximum strain resistance
   - Hysteresis
   - Elasticity without Elongation

Selection Criteria

- Biological properties of the selected material (ie fibroblast friendly)
  - Previous PET ligaments suffered poor fibroelastic ingrowth
    - Due to residual oils and lubricants from the spinning and carding processes in fibre production
    - Cleaning procedures are pivotal to ingrowth success

LARS and Fibroblastic Ingrowth

- Number of cells × 1000
- Comparison of simple culture and culture on fibers after LARS cleaning process
- Comparison of culture on fibers without cleaning process

INRA RESEARCH CENTER, Dijon, France
Ingrowth in Synthetic Ligaments

Selection criteria
- The LARS macrostructure is vital to the survivability of a ligament in situ
- Synthetic ligaments must be able to withstand forces that naturally occur in the knee

First Generation ligaments
- Braided
- Woven

Surgicraft ABC – Woven PET
- Early PET ligaments were not designed to cope with torsional forces
  - Predominantly bands or chords
- Early PET ligaments did not achieve good ingrowth due to residual lubricants from production

Leeds Keio / Neo Ligaments
- Woven PET structure
- Mixed clinical results
  - Some reports of synovitis, foreign body reactions and poorly organised collagen formation

Kennedy LAD (Polypropylene)
- Polypropylene (PP) was found to not be suitable due to its brittle nature
  - Resulted in:
    - Early rupture
    - Synovitis
    - Effusion
    - Return to pre-op levels of laxity

with kind authorization of B. PELLETIER & A. DURAND - INRA
Gore-Tex™ (PTFE) - braided

- Braided structure
- Resulted in:
  - High rupture rates
  - Effusion
  - Synovitis
  - PTFE particles found in biopsied synovium with giant cell reaction

Early Synthetic Ligaments

First Generation
- Warp knitted (WK) independent threads 45° bonds
- Deformation of the structure
- Elongation

Second Generation
- W.K. + Multiple longitudinal fibres insertions
- Properties of these fibres:
  - Elasticity

Ligament Demands

- ACL ligaments don’t just elongate and shorten during flexion and extension; there is also torsion
  - Clockwise in the right knee
  - Anti-clockwise in the left knee

Effects of ACL torsion

- Early ligaments had transverse fibres
- Early synthetic ligament designs ignored torsion effects which lead to significant issues
  - SHEARING FORCES = Ruptures
  - MICRO PARTICLES = Synovitis

3rd Generation ligaments

- 3rd Generation ligaments, such as LARS ligaments have free intra-osseous fibres
- Minimises destructive shearing forces

KEY CRITERIA FOR A SUCCESSFUL LARS ACLR
Key Criteria for a successful ACL Reconstruction using LARS ligaments

- Preservation of residual and vital ACL stumps (healing potential and proprioception of the ACL)
- Encourage primary ACLR within the acute phase after injury for the best results
- Position the femoral and tibial tunnel in the best isometric position possible

Key Criteria for a successful ACL Reconstruction using LARS ligaments

- The ligament should not be over tightened (stress-shielding);
- an over-constrained knee must be avoided (compressive forces on the joint may lead to OA: nut cracker effect)
- Full range of motion should be checked before tibial fixation
- Graft fixation using the appropriate screws-sizes
- Follow-up the outcome and rehabilitation

Successful LARS implantations

- Examples of successful regrowth of the ACL after LARS reconstructions at 8 months post-op.

Successful LARS implantations

- Examples of successful regrowth of the ACL after LARS reconstructions at 8 months post-op.

Successful LARS implantations

- Examples of successful regrowth of the ACL after LARS reconstructions at 18 months post-op.

HEALING POTENTIAL OF THE RUPTURED ACL
Healing potential of the ACL

- “The current emphasis on the removal of the torn ACL stems from adherence to a long held, and widely accepted doctrine that the ACL has only a limited healing response and therefore cannot heal or regenerate”
  (Murray, Clin Sports Med, 2009)

Can an ACL heal?

- Typical rates of non-union in the ACL are between 40-100%.
  (Murray, Clin Sports Med, 2009)

Non-union

- Hypothesis for non-union included:
  - The “hostile” environment of the synovial fluid
    (Woo, J Am Acad Orthop Surg, 2000)
  - Changes in the cellular metabolism after injury
    (Amiel, J Orthop Res, 1989)
  - Intrinsic cell deficiencies
    (Kobayashi, Tissue Eng, 2000)

Healing potential of the ACL

Is the histological response of an extra-articular ligament different from that of an intra-articular ligament?

Healing Potential of the ACL

- The vasculature (of the ACL) appears sufficient to support a reparative response & would suggest the preservation & utilization of these soft tissue structures in the repair & reconstruction of the ACL.
  Arnoczky SP CORR 1983;172:19-25

Healing potential of the ACL

- Like MCL cells, the ACL cells proliferate and the ligament re-vascularises after rupture.
  (Murray, J Bone Joint Surg, 2000)
- Like MCL cells, ongoing collagen production is noted within the torn ligament up to 1 year out from injury.
  (Spindler, J Orthop Res, 1996)
- Like in MCLs, in the ruptured ACL cells migrate easily into a simulated wound site.
  (Murray, J Orthop Res, 2000)
Healing potential of the ACL

- The provisional scaffold that reconnects the torn collagen fascicles in the wound site on the MCL is missing in the ACL. (Murray, J Bone Joint Surg, 2000)
- The 2 ends on the ruptured ACL are left floating in the synovial fluid

Healing potential of the ACL

- The cells and vascularity of the ACL are capable of mounting a histological healing response.
- There is no structural evidence of a filling in at the wound site. (Murray, Clin Sports Med, 2008)

Healing potential of the ACL

- Animal Studies:
  - Creation of central defects in extra-articular ligaments (MCL) and an intra-articular ligament (ACL) in canine knees (Spindler, J Orthop Res, 2006)
  - At any point of time, MCL defects exhibited significantly greater filling of the wound site and increased presence of:
    - Fibrinogen
    - Fibronectin
    - Platelet derived growth factor-A (PDGF-A)
    - Transforming growth factor-beta1 (TGF-b1)
    - Fibroblast growth factor (FGF)
    - Von Willebrand’s factor (vWF)

Novel Hypothesis: Part 1

“…it is the lack of a provisional scaffold between the 2 ends of the torn ACL that is the key mechanism behind the failure of the ACL to heal…” (Murray, Clin Sports Med, 2008)

Healing potential of the MCL

In extra-articular ligaments, the first phase of the healing response is the filling of the defect with a fibrin-platelet plug that bridges the wound edges

This scaffold is subsequently invaded by reparative cells that remodel the plug into a healing fibro-vascular scar

ACL Healing Response

- Inside the joint, even though bleeding occurs after ACL injury, no fibrin platelet plug is observed to form, even at the injury site.
- Circulating intra-articular Plasmin, which is up-regulated, breaks down the fibrin plug as fast as it can form.
Plasmin inhibits the development of a fibrin-platelet plug which is the essential first step for wound healing, preventing extensive joint scarring and stiffness (arthrofibrosis).

**ACL Healing Potential**

Key differences between the intra- and extra-articular ligaments

**Novel Hypothesis: Part 2**

“...the loss of this fibrin-platelet plug inside the key mechanism behind the failure of the tissues in the joint to heal...”

(Murray, Clin Sports Med, 2008)

**Healing response and Time**

- The effects of growth factors on functional healing diminish with age.
- Younger and more active patients benefit from such approaches that encourage biological repair.
- Most recently it was observed that both age and the amount of time between rupture and repair play an important role in outcomes. (Vavken & Murray – 2011)

**Proprioceptive capability of the ruptured ACL**

- The purpose of proprioception is the ‘functional stability’ of the knee joint, which is transmitted by proprioceptors to the brain

(Dhillon 2010).
Proprioceptive capability of the ruptured ACL

What is functional stability?

- The stability of a knee joint mainly relies on the interaction of the surrounding muscles and the neuro-muscular system during physical activities (functional stability).
- Functional stability not possible without proprioceptors, because the necessary information cannot be processed.
- Decreased proprioception is thought to be the key factor in functional instability.

Proprioceptive capability of the ruptured ACL

- Altered neuromuscular function due to diminished proprioception from the injured ACL is thought to be the key factor in functional instability after ACL injuries.
- Studies demonstrate that knee proprioception, rather than clinically satisfactory mechanical restoration, may lead to both good functional outcome and high patient's satisfaction following ACL reconstruction.

Proprioceptive capability of the ruptured ACL

- The ACL contains receptors that detect changes in:
  - tension
  - speed
  - acceleration
  - direction of movement
  - position of the knee joint
  - pain
  - temperature

Proprioceptive capability of the ruptured ACL

- A published study demonstrates that good vascularity with free nerve endings in ACL stumps can still be present up to 60 months after injury.
- The authors found a statistically significant correlation between lesser duration of injury and higher proprioceptive potential of injured ACL stumps.
- Mechanoreceptors were found 42 months after injury.

Proprioceptive capability of the ruptured ACL

- The study demonstrates that persistent proprioceptive fibres in injured ACL’s, especially early cases with PCL adherence, are significant.
- Previous studies confirm these results.
- The presence of proprioception is the key requirement for an early return to sports after ACLR.
IMPORTANCE OF STUMP CLASSIFICATION

The importance of stump classification

- Often a surgeon will observe a well vascularized and vital ACL stump in chronic ACL cases (Dhillon 2010)
- In contrast, very rarely an acute ACL rupture offers a ligament which is not suitable for an ACLR using LARS

Existing classifications of ligamentous injuries just provide information about the severity of a sprain and the location
- Severity (Grade I to Grade III)
- ACL Specific Location (Grade I to Grade III and Grade A to Grade C)

These classifications do not provide any information about the whether a particular ACL stump is suitable for the ACLR using a LARS ligament in regards to:
- stump vascularization
- stump quality
- stump length

Papadopoulos stump classification system

- In 428 patients with acute and chronic ACL ruptures, Papadopoulos compared the intra-operatively status of the ACL stumps directly to the postoperative outcomes
- His findings demonstrated that acute ACL ruptures having a vital stump are more likely to result in a successful outcome than chronic cases with an insufficient ACL stump
- Based on his finding Papadopoulos introduced a four grade classification system

Grade I
- Describes an elongated, but anatomically intact and well-vascularized native ACL (looks like elongated hamstrings)
- The ACL is not functional due to elongation and has to be stabilized, because of a plastic deformation
- No degenerated tissue or scar tissue has to be debrided
- The vital stumps should be left untouched

Grade II
- While 2/3 of the stumps are vital, minor parts of the ACL are degenerated and have to be debrided
- Usually the ACL is avulsed from close to the femoral insertion and the tibial stump is attached to the intact PCL and has to be released.
- Degenerated tissue has to be debrided.
Grade III
- ACL stumps, which are less than half of the length of a normal ACL
- The residual stumps are vascularized and vital
- The vast amount of the ACL is degenerated and must be debrided
- Generally, the ACL stump is attached to the PCL and has to be released

Grade IV
- Detectable if the torn ACL is degenerated and there is no vital or vascularized ACL stump remaining
- Most of the surrounding tissue is scar tissue has to be debrided
- The femoral notch of the knee joint is literally empty

**Papadopoulos stump classification system**

- ACL stump shaving of vital tissue may:
  - diminish notch impingement / lateral wall impingement
  - decrease the incidence of a Cyclops tumour
  - increase intra-operative visibility
  - improve tunnel positioning
- ACL stump shaving provides the surgeon with short term benefits during surgery

**Papadopoulos stump classification system**

- After a quick learning curve, the surgeon will learn to how to perform ACLR, while retaining the ACL stump and its associated benefits including:
  - maintaining residual proprioception
  - early revascularization
  - having the potential to re-grow into a native ACL
- An increasing number of authors recommend that only in selective cases (ACLs with heavily degenerated tissue) the ACL stump should be shaved off

**Papadopoulos stump classification system**

- If the ACL stumps have to be removed or if there is an empty notch, the implantation of a LARS ligament is **not recommended**.
- If a notch is empty, biological tissue should be used additionally to a LARS ligament.
Isometric tunnel position

- A recent Australian pilot study shows that the femoral insertion of a LARS ligament should be located close to the insertion of the A.M. bundle of the ACL (Gilles 2010)
- The A.M. bundle is typically more isometric than the P.M. bundle
- Using this femoral insertion the ligament will not elongate more than 2mm during flexion-extension cycle (Gilles 2010)

Isometric tunnel position

- The study showed that Laboureau’s landmarks are “physiologically” isometric (no elongation of the ligaments of more than 2mm)
- Several further femoral points in the anterior-superior region of the notch were also shown to be isometric
- This indicates a small region of choice for the femoral insertion (Gilles 2010)

Isometric tunnel position

Are the landmarks of J.P. Laboureau different to the landmarks chosen by other surgeons?

According to J.P. Laboureau the femoral insertion of the LARS ligament is located at 59% of the AP length of the femoral condyle, measured on a line parallel to the Blumensaat’s line.

The tibial isometric point is defined as approximately 43% of the distance between the anterior and posterior borders of the medial tibial plateau.

Identification of Blumensaat’s line

Identification of a circle formed by the posterior condyles
The importance of appropriate graft fixation

- It has been reported that the healing potential of any graft in a bone tunnel is extremely poor since a layer of scar tissue develops in the bone-tunnel-interface and prohibits early bony ingrowth (Gulotta 2008; Sasaki 2008).

- This fibro-vascular scar tissue becomes the weakest attachment of the tendon graft which could possibly hamper early rehabilitation and return to sports. (Li 2008)

The importance of appropriate graft fixation

- A recent rabbit study demonstrated that no obvious new bone formation occurred at the tibial graft-to-bone interface at 8 weeks after LARS implantation. (Li 2010)

- All specimens failed by pullout from the tunnel at four and eight weeks; no graft rupture occurred (Li 2010)

- The type I collagen mRNA level at week four was low (Li 2010)

The importance of appropriate graft fixation

- The bony ingrowth into a LARS ligament takes long time

- Anecdotal evidence from revision surgery supports the results of this study

- The larger the screw diameter, the better the fixation
- The longer the screws, the better the fixation
  - 25mm screw might not be appropriate
  - J.P. Laboureau recommends at least 30mm screws
  - A secondary tibial fixation may be appropriate in every case
LARS Literature

Functional Studies: 25 Level of Evidence I*: 1
Other Studies: 6 Level of Evidence II*: 0
Reviews: 8 Level of Evidence III*: 6
In Total: 39 Level of Evidence IV*: 22
In Total: 39

*Ranks of Evidence for Primary Research Question correspond to the actual guidelines of the Journal of Bone and Joint Surgery
Available on: http://www2.ejbjs.org/misc/instrux.dtl
Updated on: Updated August 27, 2010

Early Breakage

• No signs of short term, mid term or long term LARS related ACL breakage up to a period of 8 years postop., if implanted thoughtfully (isometrically, not too tight and using the ACL remnants) (Ranger, 2010; Hamido, 2010; Gao, 2010; Fan, 2008)
• No higher breakage rate compared to hamstring transplants up to 4 years postop. (Liu 2009; Fan 2008)
• No higher breakage rate compared to patellar transplants up to 2 years postop. (Nau 2002)

Early Breakage

• LARS ligament have up to 2 times higher tensile strength compared to hamstrings immediately after implantation and much more during the phase of ligamentisation
• This will protect the healing of the native ACL during rehabilitation

LARS ACL Rupture Rates

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Ruptures</th>
<th>Follow up period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamido et al, 2010</td>
<td>112 cases</td>
<td>0 (0%)</td>
<td>45.2 months (33-60 months)</td>
</tr>
<tr>
<td>Gao et al, 2010</td>
<td>159 cases</td>
<td>3 (1.9%)</td>
<td>50 months (36-62 months)</td>
</tr>
<tr>
<td>Huang et al, 2010</td>
<td>81 cases (43 ACL)</td>
<td>0 (0%) overall</td>
<td>29.4 months (10-49 months)</td>
</tr>
<tr>
<td>Lui et al, 2010</td>
<td>60 cases (28 LARS, 32 4SHG)</td>
<td>0 (0%) LARS, 0 (0%) 4SHG</td>
<td>48 months (48-52 months)</td>
</tr>
<tr>
<td>Nau et al, 2002</td>
<td>53 cases (26 LARS, 27 BPTB)</td>
<td>0 (0%) LARS, 0 (0%) 4SHG, 1 (3.7%) BPTB</td>
<td>2, 6, 12, 24 months</td>
</tr>
<tr>
<td>Delkis, 1995</td>
<td>220 cases</td>
<td>9 (4.1%)</td>
<td>30 months (4-54 months)</td>
</tr>
</tbody>
</table>

Traditional Graft Rupture Rates

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Ruptures</th>
<th>Follow up period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harlainen et al, 2006</td>
<td>79 cases</td>
<td>4 (5%)</td>
<td>60 months</td>
</tr>
<tr>
<td>Ejerhed et al, 2003</td>
<td>66 cases</td>
<td>3 (4%)</td>
<td>24 months</td>
</tr>
<tr>
<td>Eriksson et al, 2003</td>
<td>154 cases</td>
<td>4 (3%)</td>
<td>33 months</td>
</tr>
<tr>
<td>Jansson et al, 2003</td>
<td>79 cases</td>
<td>2 (2%)</td>
<td>24 months</td>
</tr>
<tr>
<td>Laxdal et al, 2005</td>
<td>66 cases</td>
<td>3 (4%)</td>
<td>24 months</td>
</tr>
<tr>
<td>Marder, 1991</td>
<td>154 cases</td>
<td>5 (3%)</td>
<td>29 months</td>
</tr>
</tbody>
</table>
Traditional Graft Ruptures
- Over similar periods of follow up, LARS ACL reconstructions have similar overall rupture rates to traditional grafts.
- Both Harlainen et al, 2006 and Roe et al, 2005 much higher hamstring failure rates vs patella tendons
  - 10% vs 0% at 60 months (Harlainen et al, 2006)
  - 10% vs 4% at 83 months (Roe et al, 2005)

Summary
- Preservation of residual and vital ACL stumps
- If possible, ACLR should be carried out within the acute phase after injury
- Position the femoral and tibial tunnel in the best "functional isometric position" possible

Summary
- The ligament should not be over tightened
  - stress-shielding
  - nut cracker effect
- Graft fixation using the appropriate screws-sizes
- Appropriate rehabilitation

Complication Rates
- As with autografts, allografts and other synthetic ligaments, some complications with LARS ligaments have been reported.
- With the exception of Gäbler’s study, reports of these complications have been remarkably low (Gäbler 2006)

Complication Rates
- The most common complications have been loosening of femoral or tibial screws and associated pain, limited flexion and/or extension, rupture and superficial infection (Derricks 1995; Gao 2010; Huang 2010, Liu 2009; Nau 2002)
- The complication rate for LARS ACLR’s in peer-reviewed studies generally is reported less than 6% (Nau 2002 (4%); Liu 2009 (3.6%); Hamido 2010 (less than 1%); Gao 2010 (5.7%))
Complications

- No evidence of tunnel widening at up to 5 years follow up (Hamido 2010)
- No evidence of giant cell or foreign body reactions (Trieb, 2004)

Synovitis

- LARS ligament are designed to decrease/avoid micro-particle production due to the absence of transverse fibers in the intra-articular section
- Only one case of minor synovitis has been reported in 17 peer reviewed papers amongst over 900 patients that evaluated intra-articular LARS applications up to 8 years (Ranger 2010; Shen 2010; Hamido 2010; Gao 2010; Huang 2010; Liu 2009; Li 2008; Brahimi 2008; Fan 2008; Xu 2008; Brunel 2005; Cerulli 2005; Talbot 2004; Nau 2002; Lavoie 2000; Teule 2000; Derricks 1995)
  - This case was treated conservatively and no further complications could be observed (Gao 2010)
- No higher synovitis rate at any postoperative stage compared to hamstring transplants up to 4 years postop. (Liu 2009; Fan 2008)
- No higher synovitis rate at any postoperative stage compared to patellar transplants up to 2 years postop. (Nau 2002)
- Independent studies demonstrated no inflammatory reactions, infections or immunological reactions in cellular cultures (LARS - Material properties Brochure, INRA Testing)

Osteoarthritic Changes

- ACL and PCL rupture are generally associated with early osteoarthritic changes, with or without surgical reconstruction (Oistadt 2010; Feller 2000)
- As more and more systematically gathered long-term follow-up data on ACL reconstructions are becoming available, evidence shows high rates of osteoarthritis despite treatment with ACL reconstruction (Murray 2011)
- Rates of radiographically observed osteoarthritis in ACL reconstructed knees with autografts vary widely and in some studies are reported to be in excess of 70% (von Porat 2004)
Osteoarthritic Changes

- Pinczewski et al reported osteoarthritic changes in 51% of patients treated with a patellar tendon autograft at 15 years postop. (Hui & Pinczewski, 2011)

- In a RCT comparing the 10 years outcome of hamstring tendon versus patellar tendon, he found OA changes in both groups (Pinczewski et al, 2007)

- There is no evidence that reconstruction of the ACL provides any protection from degenerative changes in the knee (von Porat 2004)

- To date, no paper has reported an increased incidence of OA in LARS reconstructions (Ranger 2010; Shen 2010; Hamido 2010; Gao 2010; Huang 2010; Liu 2009; Li 2008; Ibrahim 2008; Fan 2008; Xu 2008; Brunet 2005; Cerulli 2005, Talbot 2004; Nau 2002; Lavoie 2000; Teule 2000; Derricks 1995)

- Only Shen has reported a low incidence of 5% (2 of 41) of stage 1 (Ahlbäck) OA in LARS PCL reconstructions at 3 yr follow up (Shen 2010)