Graft Fixation in ACL Reconstruction

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The Silent Epidemic

100.000 new ACL injuries occur in the US per annum

> 75.000 ACL reconstructions per annum

✓ \$ 1.000.000.000





The Jones Procedure as the "Gold Standard" ?





Direct Repair



Marshall's modification



It fines tunes the screw home mechanism during terminal knee extension

 It provides a check to internal tibial rotation, thereby affording rotatory control to the knee

Resists anterior tibial translation on the femur

 It is a secondary restraint to both varus and valgus forces in all ranges of flexion

Prevents hyperextension of the knee

Goals of ACL reconstruction

- 1) Abolition of pivot shift
- 2) A supple knee
- 3) Restoration to pre-injury activity levels
- Long term preservation of integrity of a healthy knee joint

Current problems with ACL Reconstruction

1. Donor site morbidity

2. Impingement

3. Incorrect femoral tunnel placement

4. Graft Fixation



Currently ACL reconstruction does not:

- 1) Restore normal proprioception of the ACL
- 2) Reproduce the multi-stranded structure of the ACL
- 3) Restore normal knee joint kinematics
- 4) Preserve the articular integrity of the knee joint



Sutures-post







 Current methods of anchorage rely upon biological fixation occurring in bony tunnels before the ligament fails at a point of high stress concentration A time interval of unknown duration exists between

time zero (when graft fixation is the weakest link)

and adequate biologic incorporation of the graft into the tunnel

(when the graft substitute tissue becomes the weakest link of the construct).

The duration of this period is unknown, but is longer for <u>soft-tissue grafts</u> than for grafts with <u>bone plugs</u>.



Graft fixation must resist slippage during cyclic loading during the first 2 months after surgery prior to conversion from mechanical to biologic fixation

No graft can reproduce the normal insertion site

Graft fixation is (not always) the weak link during this period

This is therefore a race against time





Forces Present in the Cruciate Ligaments During Activities of Daily Living

- Descending Stairs
- Level Walking
- Ascending Stairs
- Descending Ramp
- Ascending



Forces Present in the Cruciate Ligaments During Activities of Daily Living

The ACL graft is loaded to approximately 150 to 500 N during normal daily activities



Zero time fixation strength should

be at least 500 N

to permit safe post-operative mobilisation





During the postoperative period, the maximum loads to the graft substitute construct are provided by rehabilitation.

These loads should be less than or equal to the graft fixation strength achieved in the operating room, at time zero.

In cases where the surgeon is concerned about poor fixation, the rehabilitation program should be customized to the fixation. (low BMD, Tunnel lysis)

These patients must undergo a less aggressive rehabilitation protocol due to inferior fixation.



QHT graft + IFS Removal of tibial screw 4 weeks pop No residual laxity Arthroscopy 2003

Graft Fixation Devices

- Screws (blunted threads)
- Sutures over Post
- Staples ("belt buckle" technique)
- Cross pin designs
- Devices for cortical fixation
- Button
- Washer
- Other

Graft Fixation Devices

Site

- Femoral
- Tibial
- Cortical Cancellous

Method
Direct
Indirect

Material

- Absorbable
- Non-absorbable

Graft Fixation Device Choice

 Familiarity ✓ Price ✓ Ease of use Efficacy ✓ Availability ✓ Other



Direct vs Indirect Fixation

Direct

staples-washer-IFS-cross pins
Indirect
tapes+buttons- suture posts



✓ Direct fixation reduces graft motion.
 ✓ Significant in animals.
 ✓ Significance in clinical studies not shown

Sutures and post technique

 Postop immobilization
 Slower initial rehabilitation
 Bungee cord effect
 Higher failure rates



Pull out strength is not the only decisive factor ______ in ACL reconstruction

Shelbourne achieved excellent results using button fixation (UTL 248 N)

Shelbourne KD, Gray T. Anterior cruciate ligament reconstruction with autogenous patellar tendon graft followed by accelerated rehabilitation. Am J Sports Med 1997;25:786-795.



Functions of Graft Fixation Devices

- **1.** Provide apposition of the graft with surrounding tissue
- 2. Resist slippage or migration under repeated loading
- **3.** Resist sudden traumatic loading
- 4. Restore normal anatomy (close to the joint, Double bundle)
- 5. Restore the load-displacement response to normal

The Ideal Graft Fixation Technique

- strong, rigid fixation
- anatomic fixation at the articular surface
- no inflammatory response
- ultimate reliance on good biological fixation
- Avoidance of damage or crushing of the graft at the point of fixation

 does not hinder future procedures or investigative techniques

The Ideal Graft Fixation Technique

does not exist yet!

The ultimate strength of the graft – fixation method complex equals the strength of its weakest part





Endobutton 1000 N

Sutures over Post 150 N

Graft Fixation Methods

Aperture fixation



Suspended fixation (outside fixation)

Aperture fixation

 Near anatomic origin adjacent to the articular surface

Interference Screw

 Anchoring the graft at the entrance into the joint, reduces graft length and elasticity




Intrafix leaves 15 mm tendon free



Suspended Fixation (outside fixation)







Aperture fixation vs distal fixation

Avoidance of:

- suture stretch
- graft-tunnel pistoning
- windshield-wipering

- delayed incorporation of the graft in the tunnel
- tunnel enlargement
- clinical failure

Disproving the current theory on the effect of location of the fixation within the drill hole, the shorter working length of the apertural methods did not improve the stiffness of the constructs



Biomechanics Of ACL Graft Fixation



Models of Biomechanical Testing of ACL Graft Fixation

 Test specimen has strong influence on biomechanical data

 Bovine, porcine, young human, and elderly human cadaveric knees



Biomechanics

Single Cycle Loading (sudden overload)

Cyclic Loading (Repetitive loading)

Fatigue Loading

Stress-Relaxation

All techniques describe graft properties at time zero



Initial Failure Load is not always the most important factor in fixation method selection



Elongation, mm



Boszotta & Anderl 2001

Caution should be used in extrapolating the results of any study to clinical estimates as we cannot assume that the structural properties of fixation devices determined in animal tissue predict its performance in human knees.



Porcine tissues used for surrogates for human

tissues underestimate graft slippage past the fixation and overestimate fixation strength





All forms of graft fixation are weaker and less stiff than ACL replacement grafts

The tibial fixation site is weaker and fails predominantly

Bone - Patellar Tendon - Bone Graft

Bone - Patellar Tendon - Bone Graft



Interference Screw Fixation
 Cross Pin Fixation
 Press Fit Fixation
 Other forms of fixation

Bone-Patellar Tendon-Bone Graft

Gold standard

Equal results with metallic, titanium, absorbable screws



Interference Screw Fixation of the BPTB graft is the gold standard for ACL reconstruction !!!!



Kurosaka, 1988

	Inte	Interference Screw Fixation					
		Porcine tibia					
		BPTB	ŀ	Hamstrings			
UTL		658		490		N	
Stiffness		400		3500		N/mm	
Slippage		2.5		6.3		mm	

Tendon Damage – IF Screw



Femoral fixation of the graft is stronger than the tibial tunnel fixation.

Greater bone mineral density of the distal femur
 Angle of stress relative to fixation
 The tibial fixation is subjected to more loads

The weak link in the system at time zero, immediately after surgery, is the tibial fixation point.

Femoral Fixation of a BPTB Graft

Construct	Failure (N)	Stiffness (N/mm)
EndoButton ⁶	554 (276)	$27.0\ (13.5)$
Mitek device ^b	511 (350)	18.3 (8.3)
Press-fit ^b	350 (48)	36.8 (16.3)
Interference screw from	423 (175)	46 (24)
Endoscopic interference screw ⁸⁷	588 (282)	33 (14)
Interference screw outside-in ¹⁴	235 (124)	82.8 (30.1)
Endoscopic interference screw ¹⁴	256 (130)	70.2 (28.9)
Metal endoscopic interference screw ¹⁹	558.3 (67.9)	No stiffness reported
BioScrew endoscopic interference screw ¹⁹	552.5 (56.4)	No stiffness reported
Metal interference screw ⁷⁰	640 N (201)	No stiffness
BioScrew interference screw ⁷⁰	418 N (118)	No stiffness
Metal interference screw ⁴⁴	436 (111–903)	No stiffness reported
Biodegradable interference screw ⁴⁴	565 (248–987)	No stiffness reported

Brand et al., 2000



Circular bone plugs > cylindrical

Fixation strength and stiffness are increased

Soft-tissue Grafts

screw diameter should >1 mm that of the
 osseous tunnel

use of a longer screw (28 mm vs 23 mm)









Optimal interference fixation occurs when screws are placed parallel to the bone plug or soft-tissue graft, thus allowing

maximal surface area contact between screw and graft.

screw divergence of >15° dramatically decreases
the fixation strength of the construct.

Divergence Prevention

Notching the anterior edge of the femoral tunnel prior to screw insertion

✓ Flexing the knee 100°-120°

Placing the screwdriver through the tibial tunnel



The in-line direction of pull in the tibial tunnel compared to the wedge effect in the femoral tunnel makes avoidance of screw divergence more critical on the tibial side than the femoral side



Although laboratory significance has been demonstrated, screw divergence has not been correlated with laxity clinically

Bioabsorbable Screws

Biocompatible, non-immunogenic, non-toxic

Polyglycolic acid (PGA)

Poly-L-lactic acid (PLLA)

Co-Polymers (PGA/PLLA, PGA/TMC, PGA/ PDS)



Lactic acid cyclic dimer monomer unit.

Poly-L or DL lactic acid polymers.

Interference Screw: Ideal Material?

- Retain sufficient strength over time
- Versatile processing
- Reproducible synthesis for consistency
- No inflammatory response
- Completely resorb without residual
- After resorption, body should "forget" that the implant was there
- The sharp threads of metallic interference screws used for bone plug fixation are blunted





Elimination via the Krebs cycle and excreted in the urine

 Little difference in the rate of degradation from the different locations in the body

Depends on MW, area, crystallinity, porous vs non-

porous

PLLA takes from 2-5 years to be completely absorbed

Bioabsorbable Screws

- High initial tensile strength@ crystallinity
- High crystallinity increases EtoF (less brittle)
- High modulus
- Low elongation to failure
- PLA maintains up to 75% of its initial mechanical strength 20 weeks in vivo



Clinically, bioabsorbable screws have provided good results

The literature is mixed regarding complete dissolution of the bioabsorbable implant

Potential disadvantages are:

- screw breakage during insertion
- inflammatory response
- inadequate fixation after partial degradation prior to biologic incorporation.





However,

more bone plug fractures have been seen with metal interference screws

 similar cysts have been seen with metallic fixation as those reported with bioabsorbable screws
Hamstring Tendon Graft

Hamstring Graft Fixation

Fixation has evolved from staples to endobutton to interference screws and ultimately to cross pins



Hamstring Reconstruction Techniques

- fixation devices
- fixation level
- fixation method (direct vs indirect)
- graft configuration



Quadrupled Hamstring Graft Fixation Prerequisites

Free tendon grafts rely on establishing bone to tendon incorporation over time, thus requiring direct apposition of tendon to bone without detrimental reduction of initial fixation

Quadrupled Hamstring Graft Fixation Prerequisites

Tight fit

Sufficient Tendon Length

Preservation of tendon integrity

Postoperative Protection

Outlet fixation



Brand et al., 2000

Early fixation techniques for soft-tissue grafts were limited to distal, indirect fixation techniques (suspensory fixation) which are hindered by

inferior stiffness

windshield-wipering (anterior/posterior)bungee cord effects (superior/inferior)

which may lead to delayed biological incorporation and tunnel enlargement.

Disadvantages of Hamstring Graft Fixation ???

Less secure initial and long term fixation

Increased knee laxity after reconstruction

Lack of regrowth or regeneration

Recently there has been a surge of interest in the use of hamstring tendon grafts due in part to improvements in graft fixation techniques.

Femoral Fixation of a QHT Graft

Construct	Failure (N)	Stiffness (N/mm)
QHT with Trans-Fix ^c	523 (263)	34.2 (14.3)
QHT with Bone Mulch ^c	583 (108)	24.4 (4.17)
QHT with an EndoButton, mersilene tape ^c	520 (50)	34.8 (22.3)
QHT with EndoButton and Endotape ^c	618 (242) 663 (211)	$22.4 (6.9) \\ 18.1 (6.9)$
1	678 (179)	20.6 (7.8)
QHT with EndoButton and three #5 suture ^c	699 (210)	30.2 (8.5)
QHT with EndoButton and 2 loops of Endotape ^e	628 (359)	21.2 (5.5)
Semitendinosus fixed with the EndoButton and tibial post ⁷⁴	612 (73)	47 (19)
QHT with Mitek ^e	412 (189)	20.3 (5.6)
QHT with the RCI titanium screw ¹⁸	242 (90.7)	No stiffness reported
QHT with BioScrew ¹⁸	341(162.9)	No stiffness reported
QHT BioScrew, 0.5 mm graft sleeves ⁸⁶	530 (186)	No stiffness reported

Brand et al., 2000

Femoral Fixation



Endobutton, Bone Mulch Screw, Rigid Fix, Bio-Screw, Rigid Fix Bioscrew, RCI screw, Smartscrew ACL

Fresh Hamstring Tendons

Kousa et al. Am J Sports Med 2003

Results of Single-Cycle Loading Test for Each Fixation Device

Fixation	Ν	Yield load (N) (mean ± SD)	$\frac{\text{Stiffness (N/mm)}}{(\text{mean } \pm \text{SD})}$
EndoButton CL	10	1086 ± 185	79 ± 7.2^{a}
Bone Mulch Screw	10	1112 ± 295	115 ± 28
RigidFix	10	868 ± 171	77 ± 17^{a}
BioScrew	10	$589 \pm 204^{a,c,e}$	$66 \pm 28^{a,f}$
RCI screw	10	$546 \pm 174^{a,c,e}$	$68 \pm 15^{a,f}$
SmartScrew ACL	10	$794 \pm 152^{b,d}$	96 ± 20

1500 Loading Cycles 50-150 N

Results of Single-Cycle Loading after Cyclic Loading for Each Fixation Device

Fixation	N	Yield load (N) (mean \pm SD)	$\frac{\text{Stiffness}(N/mm)}{(\text{mean} \pm SD)}$
EndoButton CL Bone Mulch Screw RigidFix BioScrew RCI screw SmartScrew ACL	$10 \\ 10 \\ 10 \\ 9 \\ 9 \\ 10 \\ 10$	$\begin{array}{l} 781 \pm 252 \\ 925 \pm 280 \\ 768 \pm 253 \\ 565 \pm 137^d \\ 534 \pm 129^{d,f} \\ 842 \pm 201 \end{array}$	$105 \pm 13^{a,b,c}$ 189 ± 38 136 ± 13^{a} $113 \pm 15^{a,e}$ 134 ± 23^{a} 162 ± 28

Only Screws failed during the cyclic loading

Considerable differences are shown between static and cyclic loading

The structural properties of a fixation method may not be the same in animal and human tissue

Interference screws perform better in animal tissue



Tibial Fixation



WasherLoc, Tandem spiked washer, Intrafix, Bioscrew, Softsilk IFS, Smartscrew ACL

Kousa et al. Am J Sports Med 2003

Results of Single-Cycle Loading Test for Each Fixation Device				
Fixation	Ν	Yield load (N) (mean ± SD)	$\frac{\text{Stiffness}(N/mm)}{(\text{mean} \pm \text{SD})}$	
WasherLoc Tandem spiked	$\begin{array}{c} 10 \\ 10 \end{array}$	975 ± 232^{a} 769 ± 141^{b}		
Intrafix BioScrew SoftSilk SmartScrew ACL	$10 \\ 10 \\ 10 \\ 10 \\ 10$	$\begin{array}{r} 1332 \pm 304 \\ 612 \pm 176^{b,c} \\ 471 \pm 107^{b,d,e} \\ 665 \pm 201^{b,g} \end{array}$	$\begin{array}{r} 223 \pm 62 \\ 91 \pm 34^b \\ 61 \pm 12^{a,f} \\ 115 \pm 34^b \end{array}$	



Direct soft-tissue fixation with interference screws still allows considerable graft slippage, which can be limited by using a bone block or application of a backup or hybrid fixation, especially on the tibial fixation site.

IFS demonstrate the tendency for the tendon to slip past the screw.

Augmentation with sutures tied to an intraarticular anchor (ball-disc) or external post, staple or button improves initial fixation strength







Combined Fixation

Screw + Outlet fixation Cross pin + Screw



Graft Pretensioning
 Preconditioning
 Initial Tensioning

Have been recommended for elimination of viscoelastic tendon creep and prevention of postoperative knee laxity

10N? 20N? 30N ? 80N? 100N? 120N? ???

Enough load should be applied:
To prevent slippage
To eliminate pathological anterior laxity
To maintain physiologic laxity and kinematics

Preconditioning of the Graft

StaticCyclic



Pre-implantation Intraoperative



Graft Preconditioning





Clinically applicable preconditioning protocols do not fully eliminate the intrinsic tendon creep.

The initially set tension decreases considerably postoperatively due to the remaining tendon creep

Graft tension affects remodeling of the autograft in ACL reconstruction.

Not only stress-deprivation but also stressenhancement significantly affect the mechanical properties of tendon autografts.

High initial tension reduces the postoperative anterior laxity of the knee joint after ACL reconstruction using the doubled hamstring tendons

Increase of initial tension from 20 to 80 N significantly increases the initial stiffness of the fixation



Additional increase of initial graft tension above 80 N does not increase the stiffness of the FT graft using an interferencescrew-fixation for ACL reconstruction after cyclic loading.

Pathological changes in the graft such as increased central necrosis rate or cartilage damage due to 'overconstraining' of the knee may occur



Graft Tensioning







There is a range of tensions at which ACL grafts can be fixed

Most surgeons do not tension the graft maximally



Inadequate Tension results in

continued instability

Excessive graft tension

restriction of ROM

arthrosis acceleration

Alternative Fixation Methods

Over The Top Femoral Fixation



 Primary and Revision Surgery
 Avoids problems associated with drilling a femoral tunnel

- Clinically successful
- Biomechanically sound
- Reproducible

Over The Top Femoral Fixation

Indications

Posterior wall perforation
 Adolescent ACL reconstruction
 Revision surgery
 Surgeon's Preference



BH Soffix + Bollard OTT Fixation





Press Fit Femoral and Tibial Fixation
Press Fit Femoral and Tibial Fixation





Cyclic Elongation - Creep



Press fit fixation, Musahl 2000

Advantages - Disadvantages

No hardware

Bone to bone healing

No intraarticular defects

Easier revision surgery

Mini-Arthrotomy



ACL PROSTHESES



Permanent Prostheses

- Non Degradable Scaffolds designed for tissue ingrowth
- Graft Augmentation Devices
- Resorbable Synthetics and Tissue-Derived Biomaterials
- Fibroblast Seeded Scaffolds



Scarcity of literature

- Not relying on permanent bone-polyester fixation
- The strength of the fixation is static and declines with time
- ✓ The ligament material fails progressively with time
- Ultimate rupture and failure is inevitable
- Foreign Body Reaction Synovitis
- Not recommended for ACL reconstruction





Stress shielding (28-45%)
Unknown biological impact
Clinically not necessary
Probably useful in insufficient
graft material



✓ Intraoperatively achieved fixation strength guides

the postoperative regimen.

 Rehabilitation and reintroduction of activities should correlate with fixation strength achieved in the operating room.

Clinical results are good with most fixation techniques





Improvement of biological incorporation of replacement grafts will lead to better insertion site healing and faster ingrowth of the graft.





Cell therapy

Tissue Engineering







If the surgeon performs < 30 ACL reconstructions/year he should use 1 technique If he performs > 50 ACL reconstructions/year he should be familiar with more techniques



Over-tensioning of the graft increases the forces in the graft at all angles of flexion

causing:

- Posterior tibial subluxation
- Tensioning of the PCL

 Decreased range of AP laxity It is not possible to find levels of graft tension that restored AP laxities at all
 flexion positions and restored forces in both grafts to those of their native cruciate counterparts during passive motion.

Goals of ACL reconstruction

- Sufficient initial strength to avoid fixation failure
- Sufficient stiffness to restore stability of the knee
- Anatomic fixation to minimize graft movement within the tunnel
- Sufficient resistance against slippage under cyclic loading

454 N is the critical graft substitute strength required to endure daily activities, which are recreated during rehabilitation

Noyes FR, Butler DL, Grood ES, Zernicke RF, Hefzy MS. Biomechanical analysis of human ligament grafts used in knee-ligament repairs and reconstructions. J Bone Joint Surg (Am) 1984;66:344-352



Flexion Angle, Degrees



Intraoperative Knee Kinematics



the effect of reconstruction on the anterior translation characteristics of the centre of the tibia during the pivot-shift test



- Autograft BPTB, QHT, Quadriceps
- Allograft BPTB, Achilles Tendon
- ✓ Xenograft Bovine
- Synthetic Grafts Prosthetic Ligament, Ligament
 Augmentation Device, Scaffold
- Tissue Engineering— Future of ACL reconstruction

Hamstrings vs BPTB

✓ 7 prospective studies BPTB and QHT grafts

✓ 4 have found similar laxity values and functional results between the two types of graft tissues

 found statistically tighter instrument measured values with the BPTB graft that <u>did not</u> correlate with functional outcome

The ideal fixation for hamstring graft should have the following features

- Minimum length of free graft to reduce the bungee cord effect
- Ultimate reliance on good biological fixation
- Zero time fixation strength should be at least 500N



Brand et al., 2000



Concellous thread



Screw & Washer System



































Intrafix





Cross pin fixation





slingshot

In tension most ligament reconstructions fail at or near the fixation to bone

Modes of Failure Suture knot Cracking of bone block Slipping of sutures through soft tissue Slipping of graft past an IFS





Bone-Tendon-Bone (BTB)





Gobbi et al., 2002

Braiding of the Hamstring Tendons



Reduction in Strength and Stiffness

- Failure at the midsubstance
- Braiding is not advisable
Postmortem examination of poly-L lactic acid interference screws 4 months after implantation during anterior cruciate ligament reconstruction

McGuire et al. Arthroscopy, 2001



No histologic evidence of foreign-body reaction or inflammatory response was seen in the area surrounding the femoral screw.















"There are many choices of device to use for femoral fixation of a hamstring tendon graft, but none of the currently used soft tissue fixation devices has been proven to be biomechanically superior to the others." Graft load can be a high as 560 N with a 1500 N quadriceps contraction

Extension exercises can induce loads in ACL greater than the strength of most fixation methods Most devices appear to achieve this



Graft-tunnel motion 2.4 vs 0.5 mm Elongation of tendon 0.4 mm vs 0.1 mm

The elongation of the tendon accounts for only a small amount of graft-tunnel motion

Graft Fixation in the ACL

- BPTB graft has slightly higher initial strength than intact ACL
- In multiple studies conducted to characterize strength of different screws, failure always occurred at fixation site
- Fixation rigidly depends on screw design

