

Controversy : The place of synthetic ligament

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Introduction

- Structural properties identical to intact PCL
- Identical geometrical shape
- No harvest site morbidity
- Easy graft insertion (graft passage)
- Secure fixation in an anatomic position
- Fast graft incorporation

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Biomechanical properties

	Maximum strength (N)	Stiffness (N/mm)	X-area (mm ²)	Length (mm)
Intact ACL	2160±157	242±26		
PCL-AL bundle	1494±390	306±130		
PCL PM bundle	242±66	75±31		38 38–42
BPTB (10 mm)	2977±516	455±56	36.8±5.7	52.2±4.8
Quadriceps tendon (10 mm)	2352±495	325,6±70	64.6± 8.4	86.4±9.0
Quadruple semi-t./gracilis	4090±295	776±204	52±5	100–120

Synthetic ligament

- Advantages :
 - Ability to preserve a patient's own healthy tissues
 - Technically less demanding technique
 - Post operative stability : immediate

Mechanical properties of synthetic grafts compared to natural ligaments

Properties	Natural ligament	Carbon fibre	Gore-Tex	Dacron	Kennedy-LAD	Trevira	Leeds-Keio
Ultimate tensile strength (N)	1730	660	5300	3631	1500	1866	2000
Stiffness (N/mm)	182	230×10^9	322	420	280	68.3	270

History of synthetic

- A huge variety of synthetic ligament has been used in the 20th century
- Three types of synthetic
 - Prosthesis: permanent, no tissue ingrowth
 - Scaffolds: provide a lattice with new ingrowth tissue
 - Mechanical augmentation devices: protect autografts

Approval

- In USA, The FDA must be approved the device prior to use it
- The FDA has the responsibility to determine the safety and the effectiveness of the device
- In Europe, CE marks and in France FNAH

Synthetic ligament

- Three ligaments were approved in USA (1986-1989)
 - Gore tex (polytetrafluoro ethylene)
 - Dacron (polyester)
 - Kennedy LAD (polypropylene)

Clinical studies

- Case report about a synovitis after rupture of Kennedy LAD 15 MO after the implantation

Synovial reaction associated with disruption of Kennedy LAD-augmented intra articular ACL reconstruction Roth, Shukrum, Bray, AJSM 1988, 16 : 301-305

Clinical studies

- Del Pizzo et al in 1990
- 269/721 patients with K LAD
 - F.U. 2 Years
- 10 infections
- 28 effusions without infection
- 10 ruptures of LAD

Del Pizzo US experience with Kennedy LAD AOSSM 1996 International symposium

Wear debris

- Gloussman et al
- 8/82 patients with Gore Tex
- Persistent sterile effusions
- 4 had rupture of the graft (7-10 MO)
- Small wear particles

Gore Tex prosthetic ligament in ACL deficient knee Gloussman, Shield, Kerlan AJSM
1988, 16 :321-326

Clinical studies

- Indelicato et al
 - 2 Years FU
- 23/39 sterile effusion
- 7/39 had breakage of the graft
- At 4 Y FU, 34% of effusion and 12% of ligament rupture.

Early experience with Gore Tex ACL prosthesis Indelicato, Pascale, Huegel AJSM
1989, 17: 55-62

Clinical studies

- Many of the synthetic ligaments have induced similar undesirable effects with intra articular responses.

Synovitis, articular damage, bone effects...



In vitro studies

- Seven materials have been tested in vitro.
 - Striker-Meadox Dacron
 - Kennedy LAD
 - Gore Tex
 - Carbon
 - Leeds Keio
 - Xénograft
 - Allograft

Werb et al 1974, Gowen 1983

In vitro studies

- After 72 Hours of contact of wear materials
- The synovial cells were induced to produced statistically significant quantity of enzymes capable of digesting articular and soft tissues
- FDA has forbidden that types of synthetic ligament.
- In France, ANAES in 1994 has written the same recommendation

Synthetics in the year 2000

- Despite the discouraging results and loss of confidence by the scientific community in the use of synthetic materials, recently a resurgence of interest in the use of artificial ligaments has occurred since some studies indicate that, under particular conditions, artificial ACL or PCL reconstruction can be successful

Literature

- 36 patients were divided into two groups : retrospective continuous
 - 15 HG
 - 21 Lars
- Outcome : 2 Y FU; post op regim different
 - IKDC
 - KT 1000

Arthroscopic single-bundle posterior cruciate ligament reconstruction: retrospective review of hamstring tendon graft versus LARS artificial ligament. Bin Li & Yu Wen & Haishan Wu & Qirong Qian & Yuli Wu & Xiangbo Lin

International Orthopaedics (SICOT) (2009) 33:991–996

Criticisme

- KT 1000 not a good evaluation for PCL
- 2 Y FU insufficient
- Post op regim different

Clinical study

The follow-up made on 47 patients, 8 to 45 months after implantation, showed good average results according to subjective parameters (average KOOS score 93), and a satisfying Tegner activity level.

A subsequent study from the same scientific group compares two-year results after LARS ligament ACL reconstruction with the BPTB graft technique. Their findings were that the LARS ligament gave better subjective and objective outcomes during the initial years, while no difference with the autologous procedure could be found 24 months after surgery.

Lavoie P, Fletcher J, Duval N. Patients satisfaction needs as related to knee stability and objective findings after ACL reconstruction using the LARS artificial ligament. *Knee*. 2000;7:157–163.

Clinical study

Experience based on 14 patients in 6 years with a mean follow-up time of 34 months (range 10-80).

The laxity was isolated in 3 patients, and combined in 11 patients lateral in 6, medial in 5.

The preoperative laxity varied between 15 and 57 mm

They used the LARS ligament

Brunet, Charrois, Degeorges, Boisrenoult,
Beaufils, RCO 2005

Results

- No chronic synovitis nor osteolysis were observed
- One rupture
- Telos measurement for laxity
 - 8 mm average of gain; 63%

Clinical study

- Dejour et al 17 knee dislocations
- F.U. 3 years
- Residual laxity : 9 mm average
- No complications related to the implant

Conclusion

Research in the field of artificial ligaments demonstrates that the ultimate characteristic required for these materials is biocompatibility

Chemical stability,

Degree of polymerization,

Absence of soluble additives,

Scarce water adsorption, presence of pores for fibroblasts ingrowth

on the other hand, mechanical characteristics (traction resistance, stiffness, elongation, torsion and abrasion resistance) should be as similar as possible to those of the natural ligament.