EVOLUTION

Of the Mark II Button Hole Soffix

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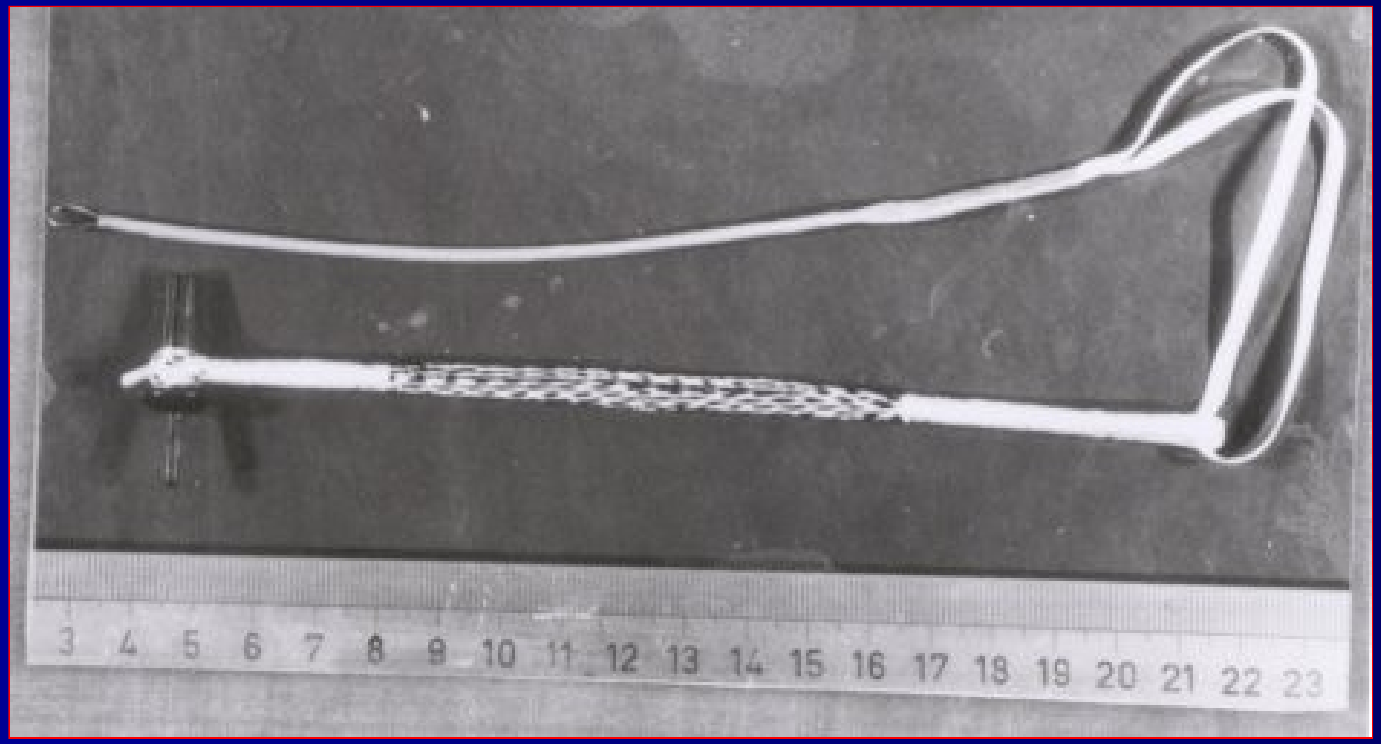
Historical Background

The Surgicraft Active Biosynthetic Composite (ABC) Prosthetic Ligament was introduced in 1985



Historical Background

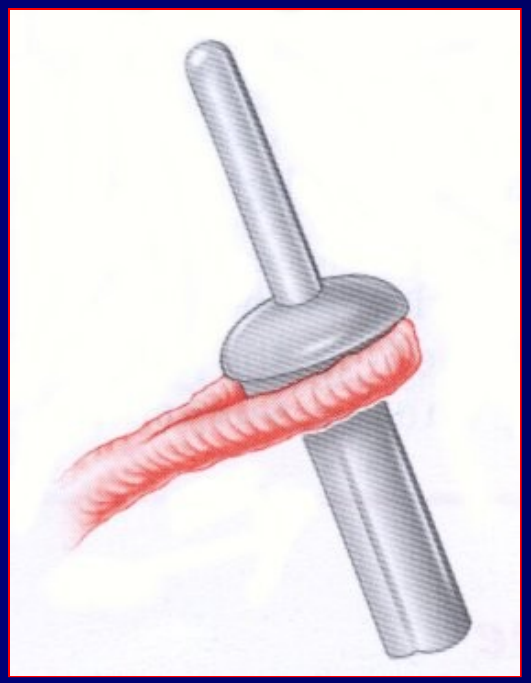
PRINCIPLES of SURGERY

- The ABC is a scaffold-class prosthetic implant.
- It is routed via a tibial tunnel and fixed proximally over the top.
- It should lie retrosynovially in the knee joint.

Historical Background

FIXATION

- Double polysulphone bollards placed through loops at either end of the implant are used for proximal and distal unicortical fixation.



Bollard Fixation

Bollard Fixation

Bollard in Bone Tunnel

Expanded Bollard in Tunnel

Historical Background

High Incidence of Early Ligament Failure

(50% in the first 2 years)

Due To:

- ✓ Rupture
- ✓ Stretching

This led to a Mode of Failure Analysis at UMIST, Manchester University, Textiles Department, UK

Historical Background

Results of Mode of Failure Analysis at UMIST Textiles Dept.

Methodology:

- Light microscopy
- SEM examination of retrieved broken ligaments

Historical Background

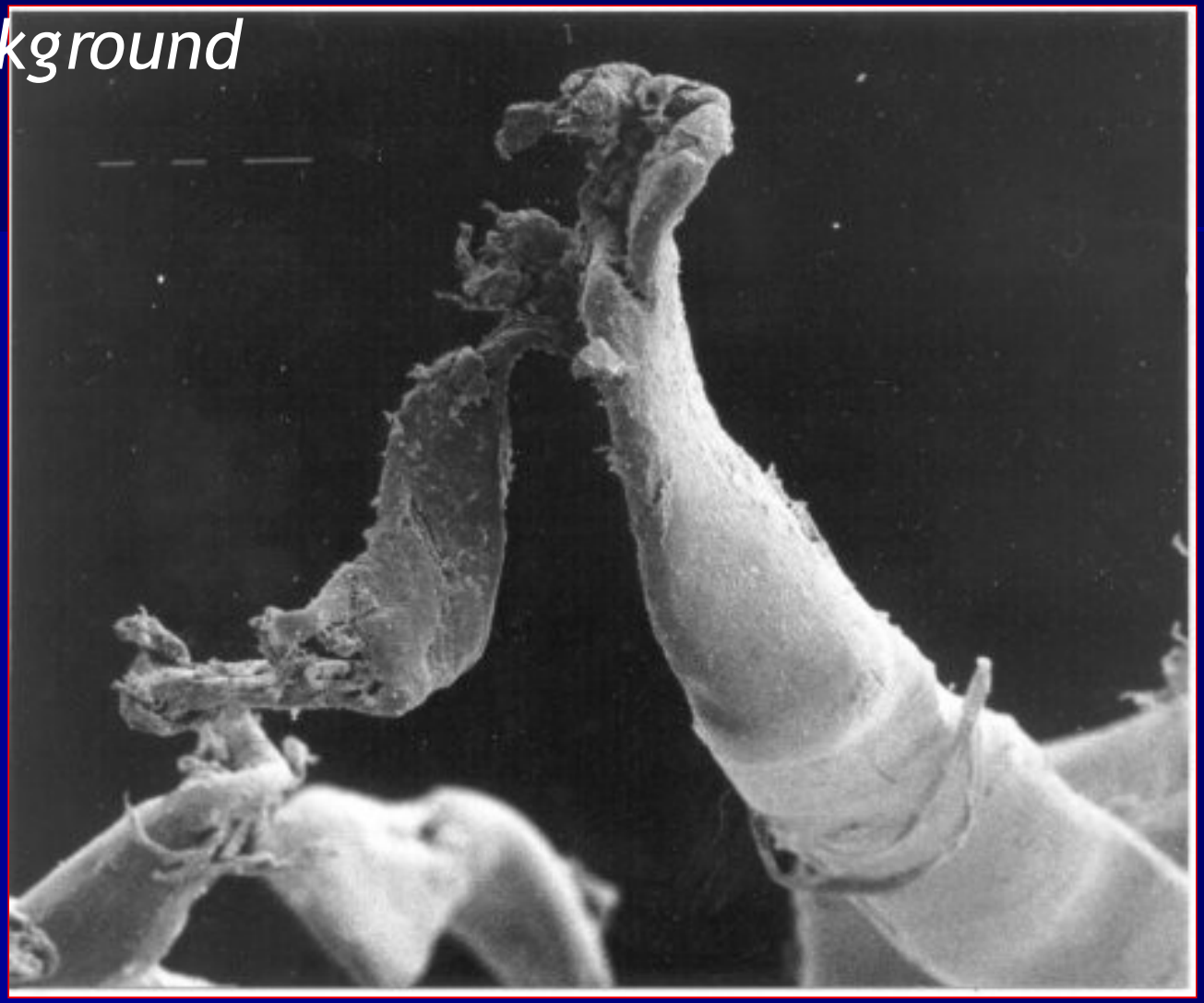
Results of Mode of Failure Analysis at UMIST Textiles Dept.

Revealed a Biphasic Failure Pattern

EARLY (<6 months): due to mechanical failure

LATE (> 2 years) : due to mixture of mechanical failure, fretting & fatigue

Historical Background



SEM views of early ligament failure

Historical Background

SEM views of late ligament failure

Historical Background

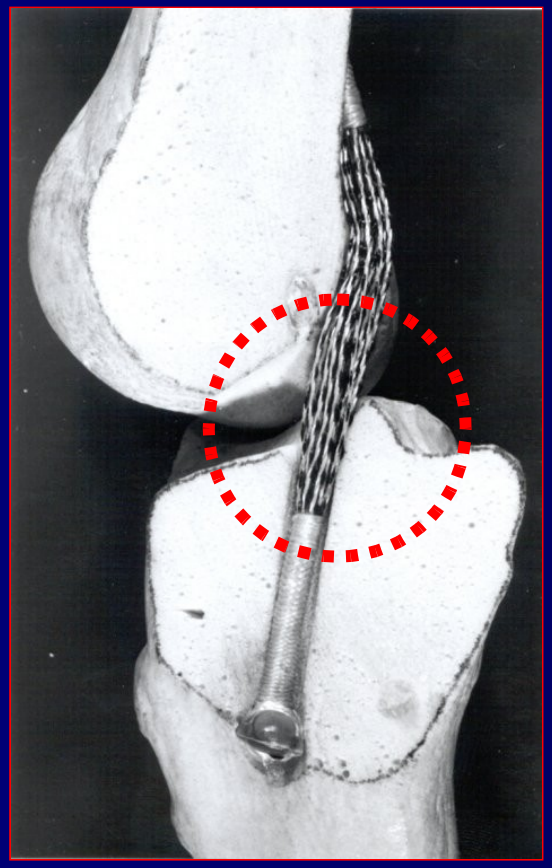
MODE OF FAILURE ANALYSIS

FINDINGS:

1. All ligaments failed at tibial tunnel exit.

1. Ligaments examined at the OTT route showed no signs of fretting or fatigue.

1. There was no bollard fixation failure.



Historical Background

CONCLUSION

- The cause of early failure was mechanical impingement at the tibial tunnel exit.
- The cause of late failure was a mixture of both mechanical impingement and fatigue occurring again at the same site.

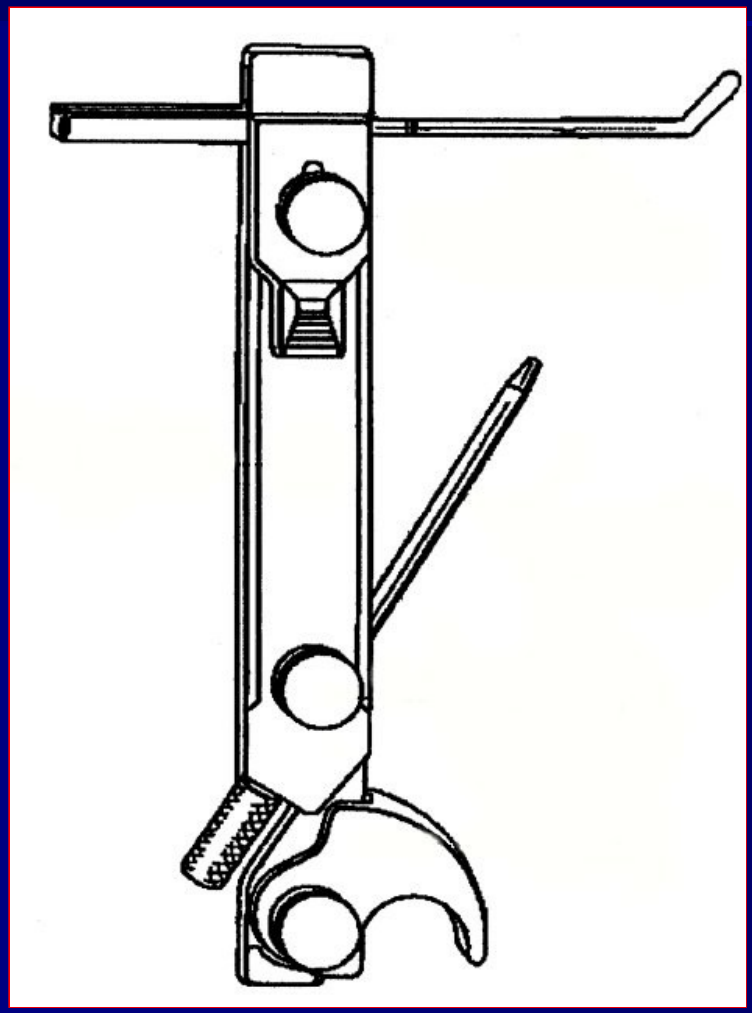
SOLUTIONS

- Redesign of instrumentation to prevent mechanical impingement and fretting at the tibial tunnel exit.

- Continued use of the OTT route for proximal fixation.

NEW INSTRUMENTATION (1)

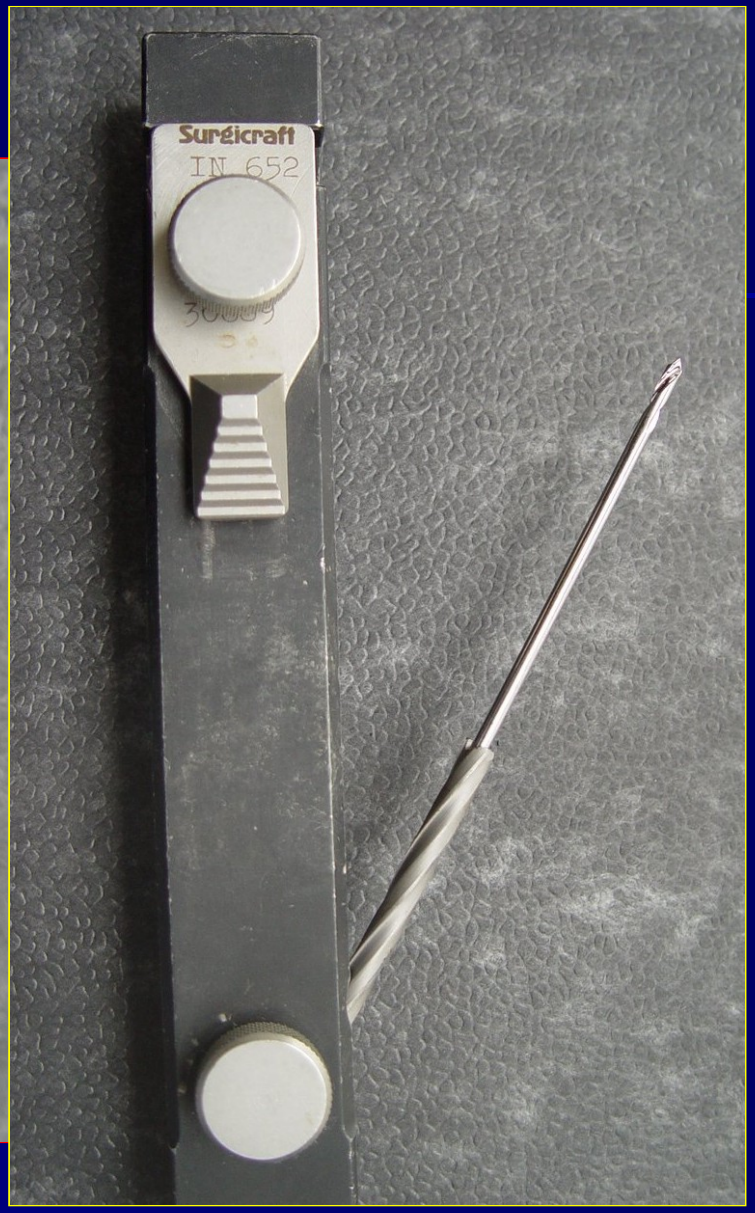
Mayday Rhino horn Jig



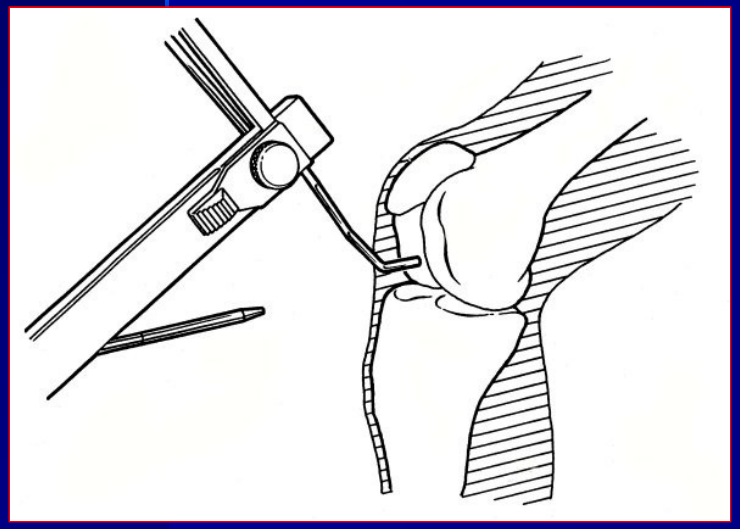
Mayday Rhino horn Jig

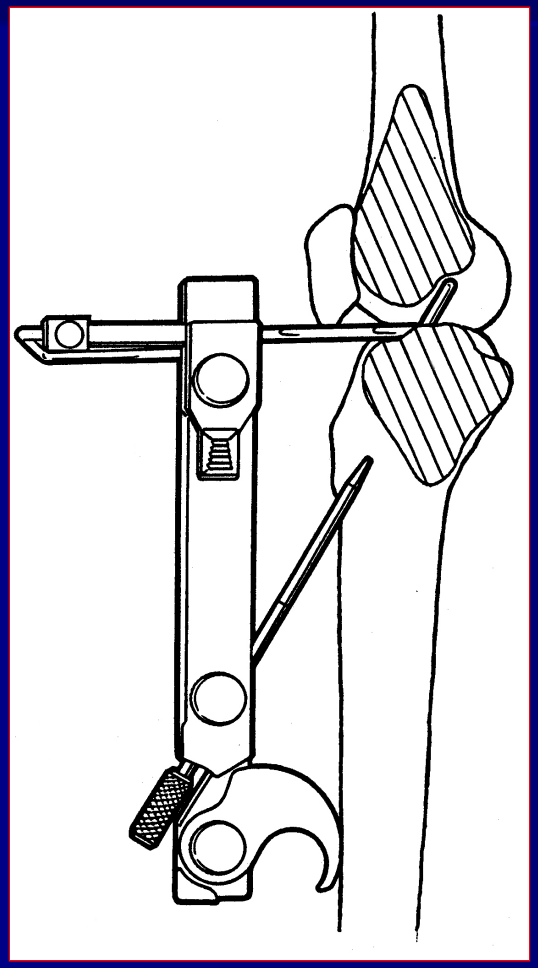

Surgicraft
IN 652

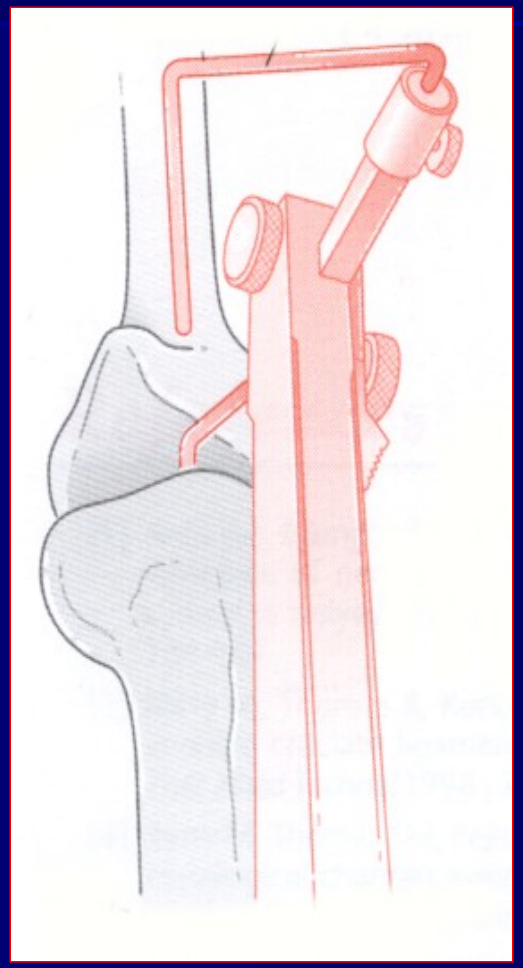

Surgicraft
IN 652


Surgicraft
IN 652

Mayday Rhino horn Jig

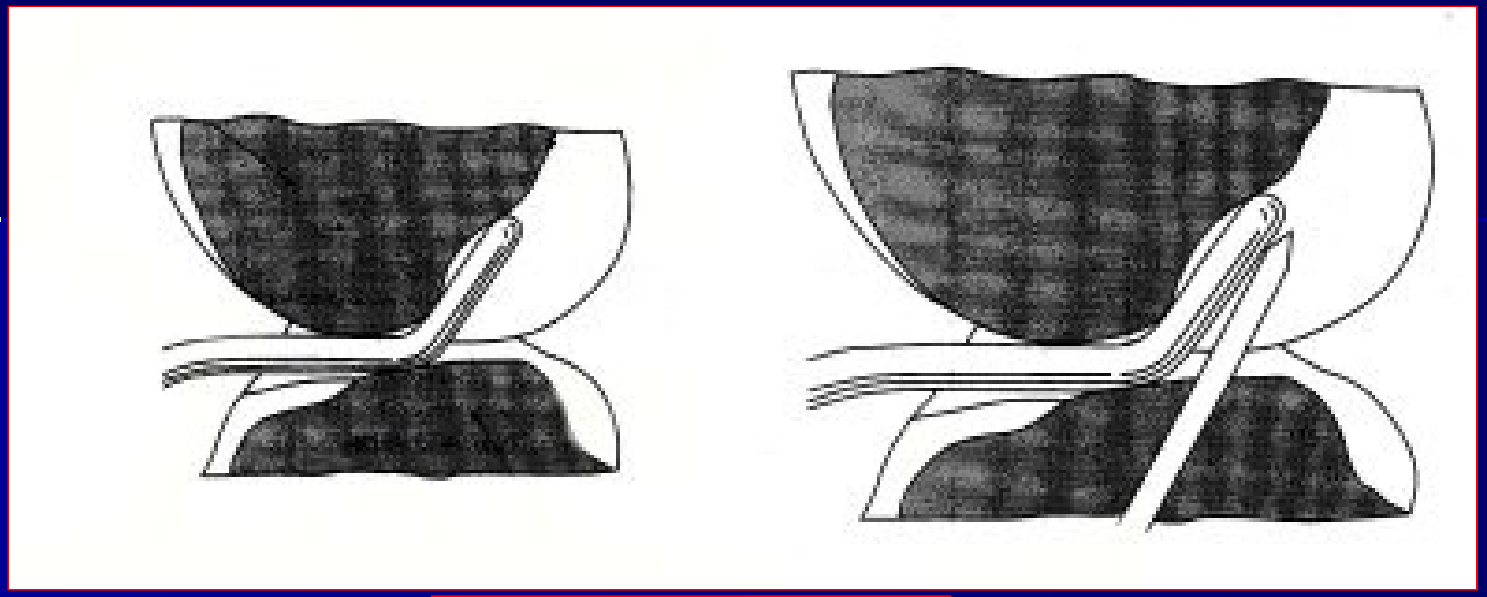


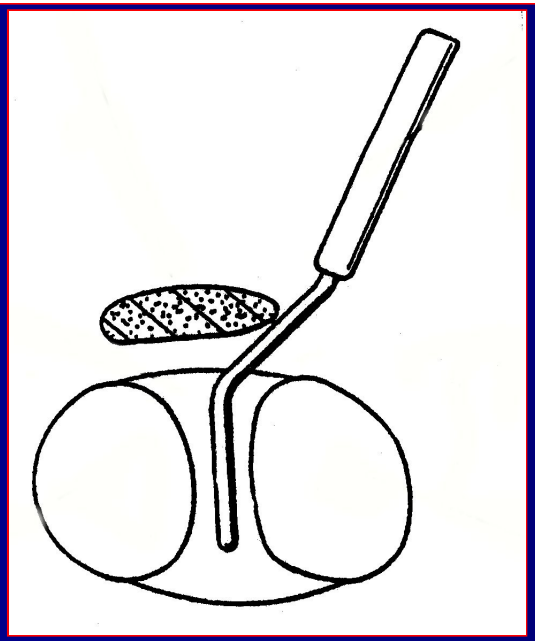




Mayday Rhino horn Jig

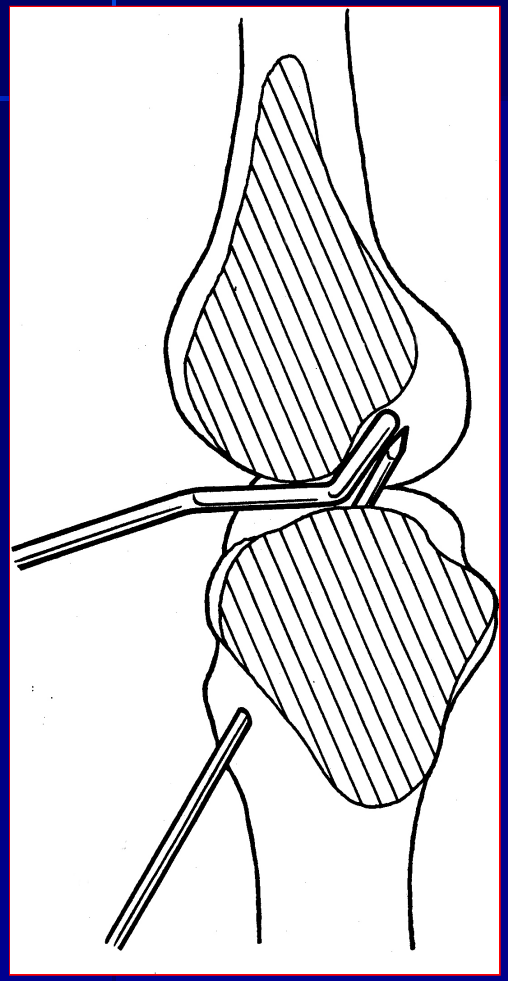
Mayday Rhino horn Jig

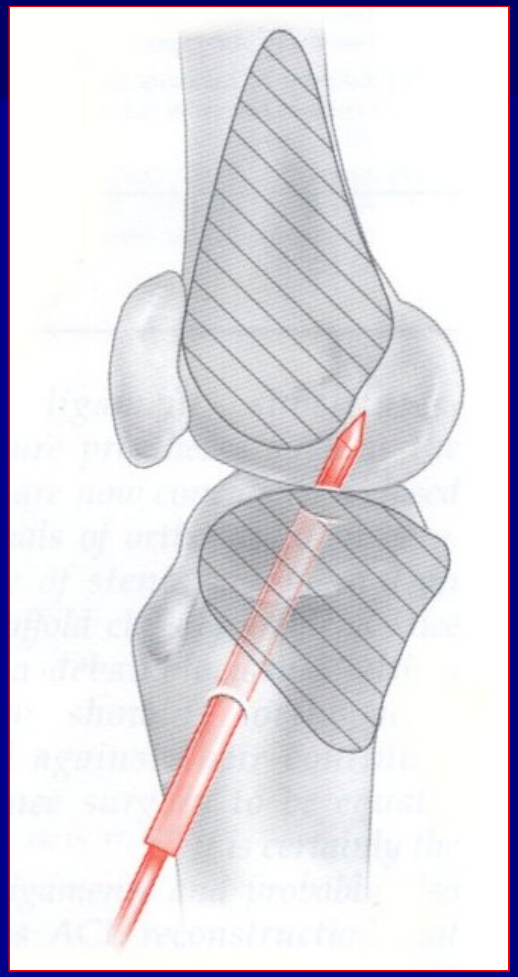


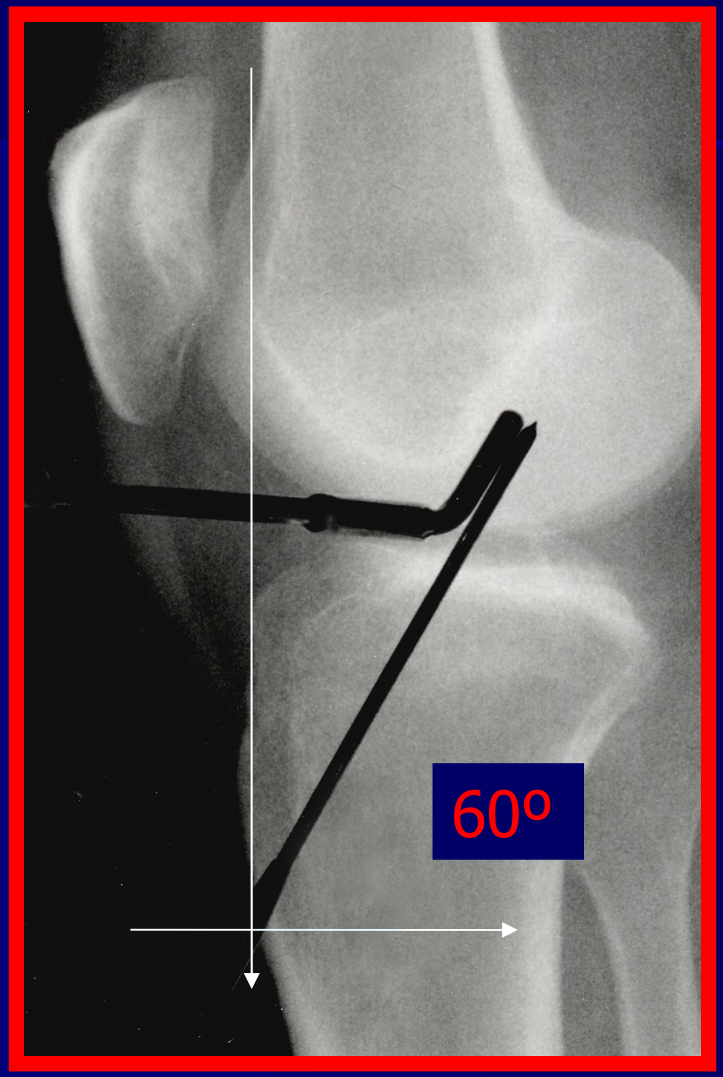


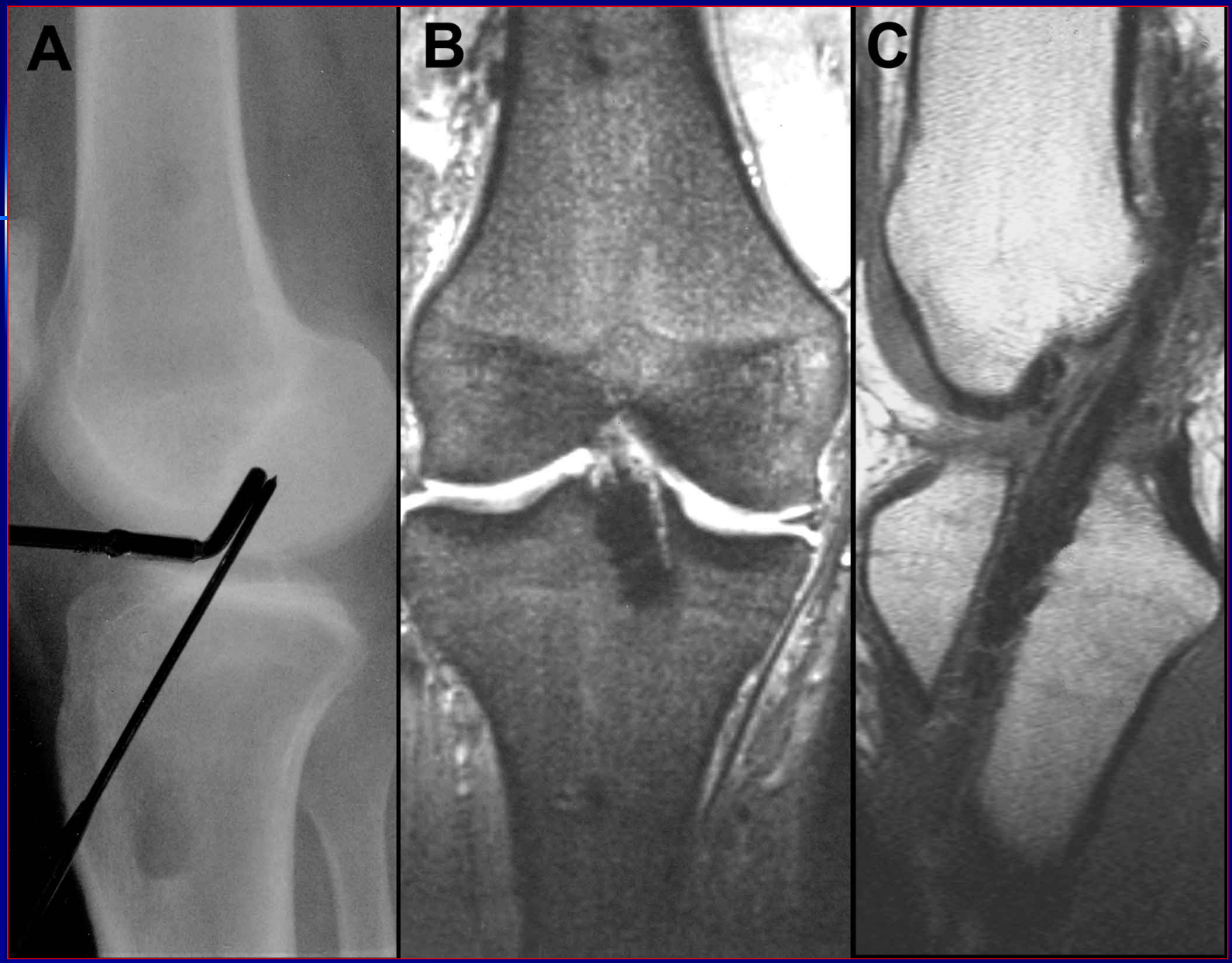
Left and Right Rhinohorn Probes

Mayday Rhino horn Jig








A
B
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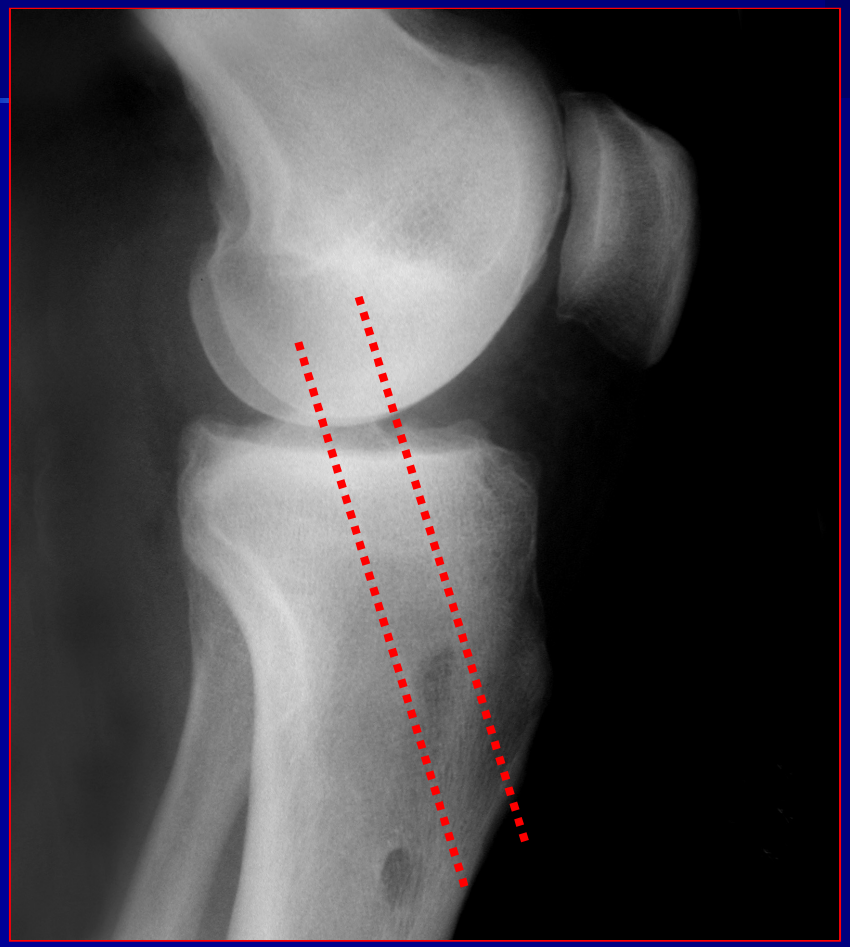
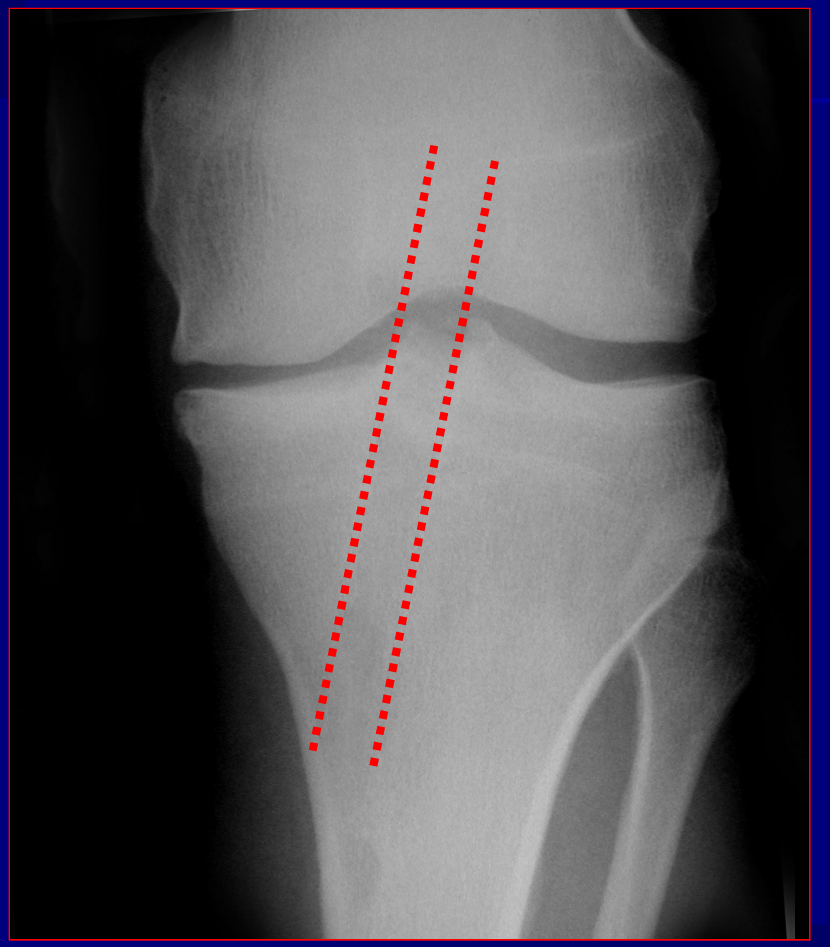




NEW INSTRUMENTATION (2)

Tunnel Edge Radiusing / Chamfering

Back Radius Cutter

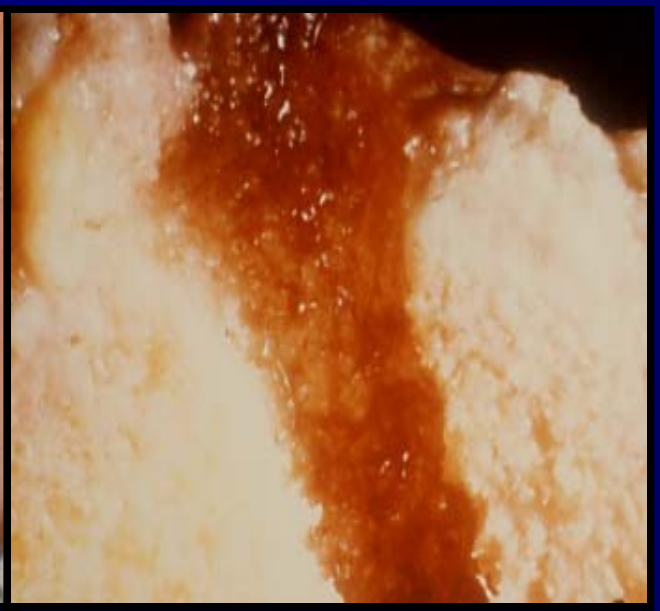
Position on AP & Lateral X-ray

NEW INSTRUMENTATION (2)

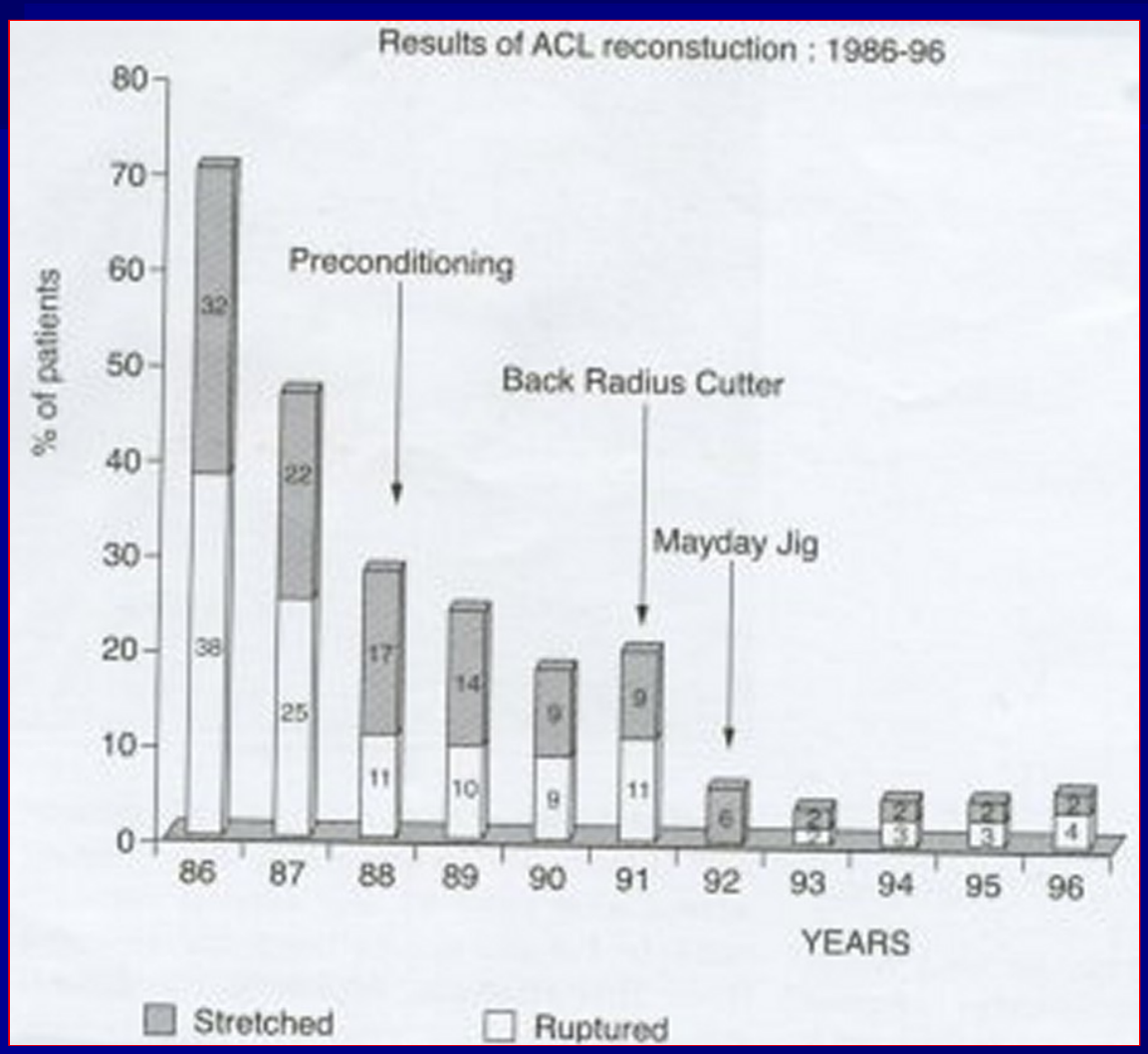
Tunnel Edge Radiusing / Chamfering

Back Radius Cutter in Bone Tunnel

Chamfered tunnel outlets



RESULTS (1)


Results of ACL reconstuction : 1986-96
% of patients
80
70
60
50
40
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10
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Preconditioning
Back Radius Cutter
Mayday Jig
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YEARS
Stretched
Ruptured

RESULTS (2)

- 15 Years Experience with the ABC ligament
- Second Cohort of Patients reviewed (1992-2000)

after introduction of the new instrumentation showed an extremely low initial failure rate over the first 5 years.

RESULTS (3)

- However 21% of the ligaments failed 6 and 7 years after implantation in the second cohort!

- Whilst there remain many long term satisfactory results following implantation of the ABC scaffold the above analysis has led us to discontinue using this implant on a regular basis.

Conclusion

Whilst there remain many long term satisfactory results following implantation of the ABC scaffold it is clear that mechanical failure and fatigue persist after 5 years and this has led us to discontinue using this implant on a regular basis.

MARK I SOFFIX (1993-1998)

This was designed to utilise the best aspects of the ABC implant but using autologous material instead.

We therefore retained the following features:

1. Dedicated instrumentation to avoid impingement and fretting
2. Double loop – double bollard fixation
3. Transtibial tunnel and OTT route fixation

Mark I superseded by Mark II Button Hole Soffix in 1998

Why Change?

1. Two failures occurred at the site of proximal loop fixation (possibly due to stress concentration).
2. Technically more demanding to attach hamstring tendon to a single tape.
3. Unable to provide tendon fixation complex of given length.
4. Passage of the graft was more difficult in the Mark I Soffix because of bunching.

The Button Hole Soffix (Soft Tissue Fixation Device) Mark II

Various Lengths: 15.5 cm, 17.0 cm and 18.5 cm

Mark II Button Hole Soffix (1998)

1. Ease of preparation
2. Low stress fixation

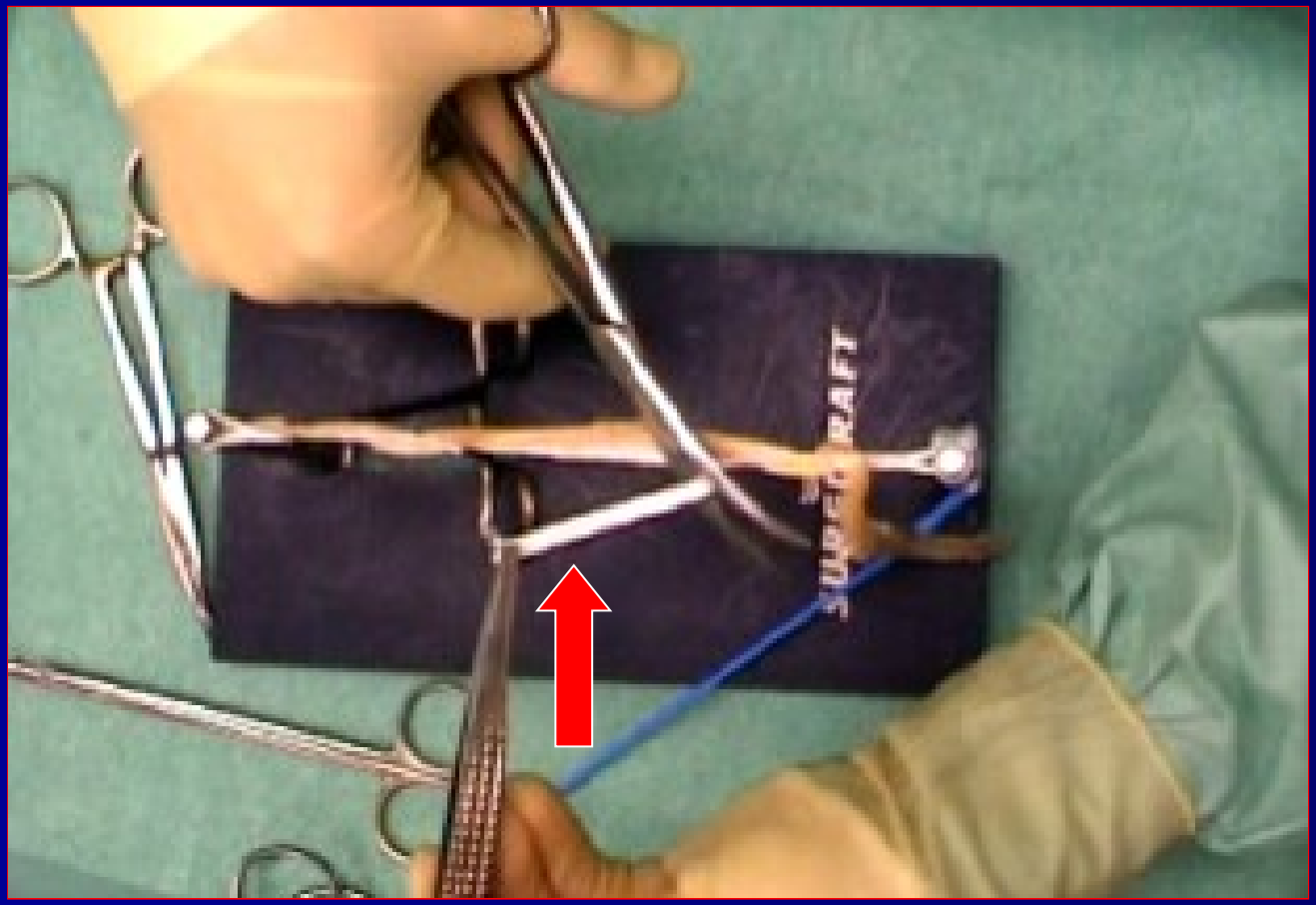
Soffix Mounted on Adjustable Frame

4 Strand STG-Soffix Complex Preparation

4 Strand STG-Soffix Complex on Frame Following Graft Preparation

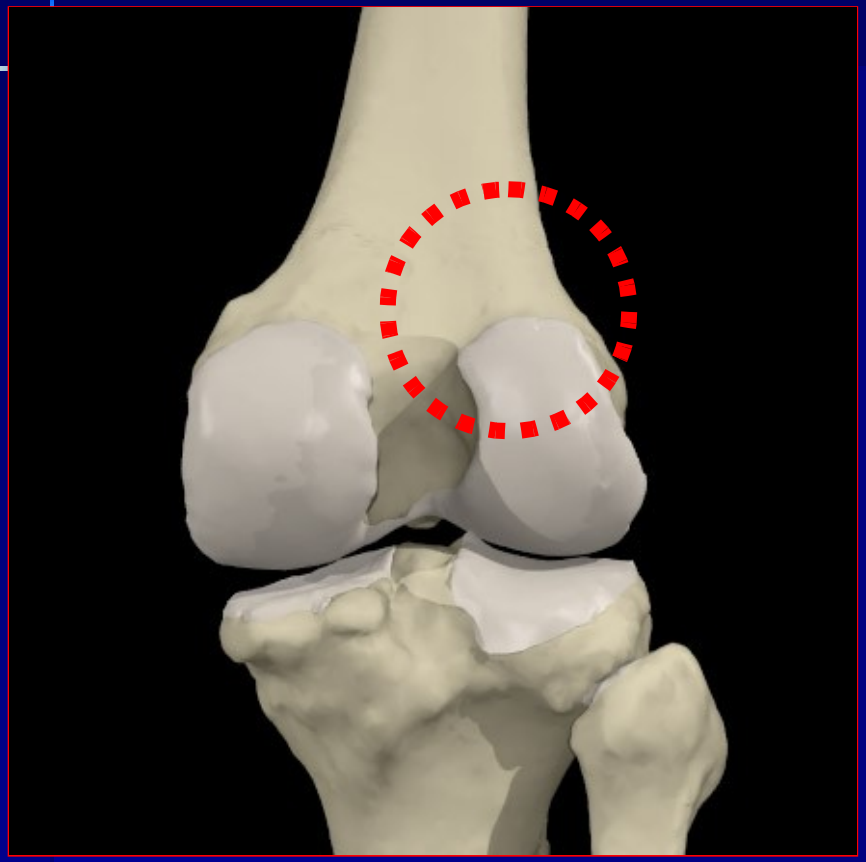
4 Strand STG-Soffix Complex on Frame
Suturing of the Four Strands

The central 4 – 6 cm of Soffix tape is excised prior to implantation



Graft Railroading

Over-the-Top Femoral Routing



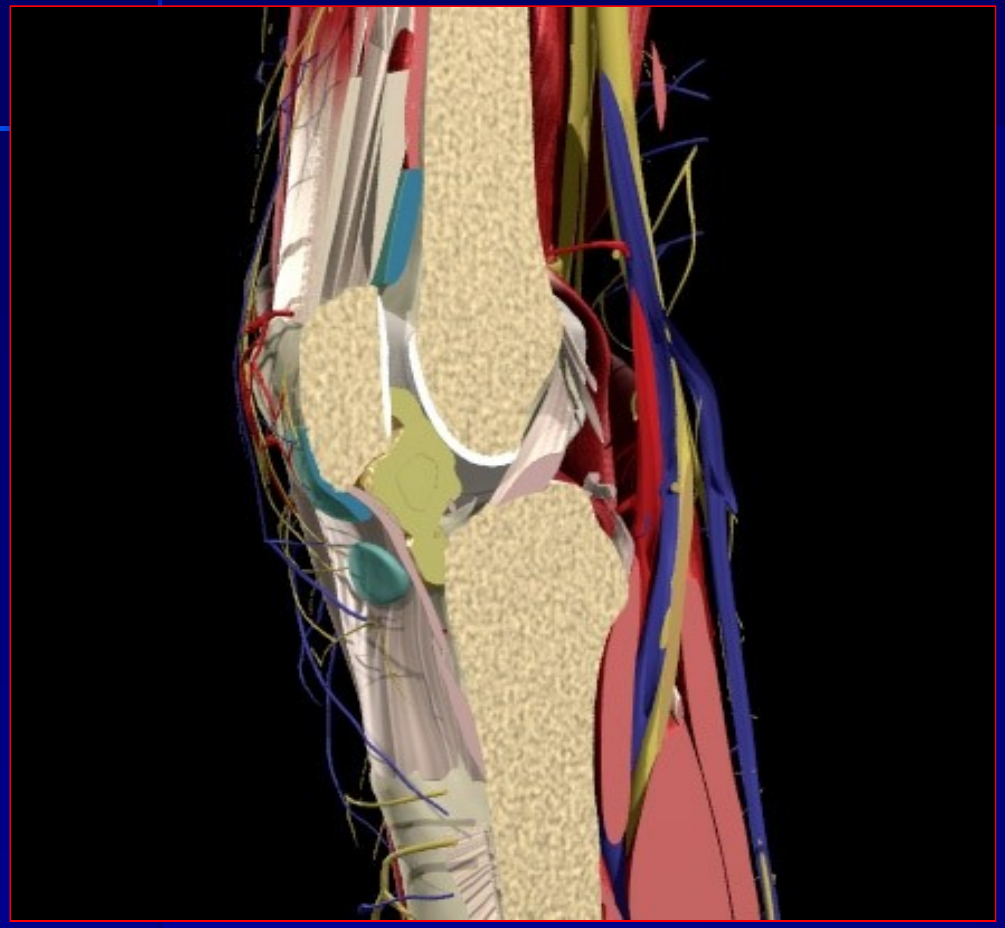
Over - the- Top Site Preparation

British troops go ' Over The Top' during fighting in World War I

Why go Over-the-Top ?

- Avoids femoral tunnel and its attendant complications
- Experience with failed prosthetic implants confirms the reliability of the OTT route
- Graft placement is technically less demanding
- Robust fixation
- Reproducible
- Safe

Safety



Femoral Tunnel Misplacement

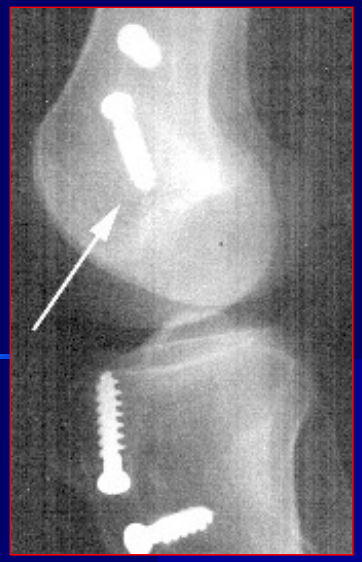
The most common error in ACL surgery

is femoral tunnel misplacement (40%)

Sommer C, Friederich NF, Muller W. Improperly placed anterior cruciate ligament grafts: correlation between radiological parameters and clinical results.

Knee Surg Sports Traumatol Arthrosc

2000;8(4):207-13



Femoral Tunnel Misplacement

In a simulated surgical study undertaken by experienced arthroscopic knee surgeons only 16.6% of cadaveric knees had correct femoral and tibial tunnel

Kohn D, Busche T, Carls J. Drill hole position in endoscopic anterior cruciate ligament reconstruction. Results of an advanced arthroscopy course. Knee Surg Sports Traumatol Arthrosc 1998;6 Suppl 1:S13-5

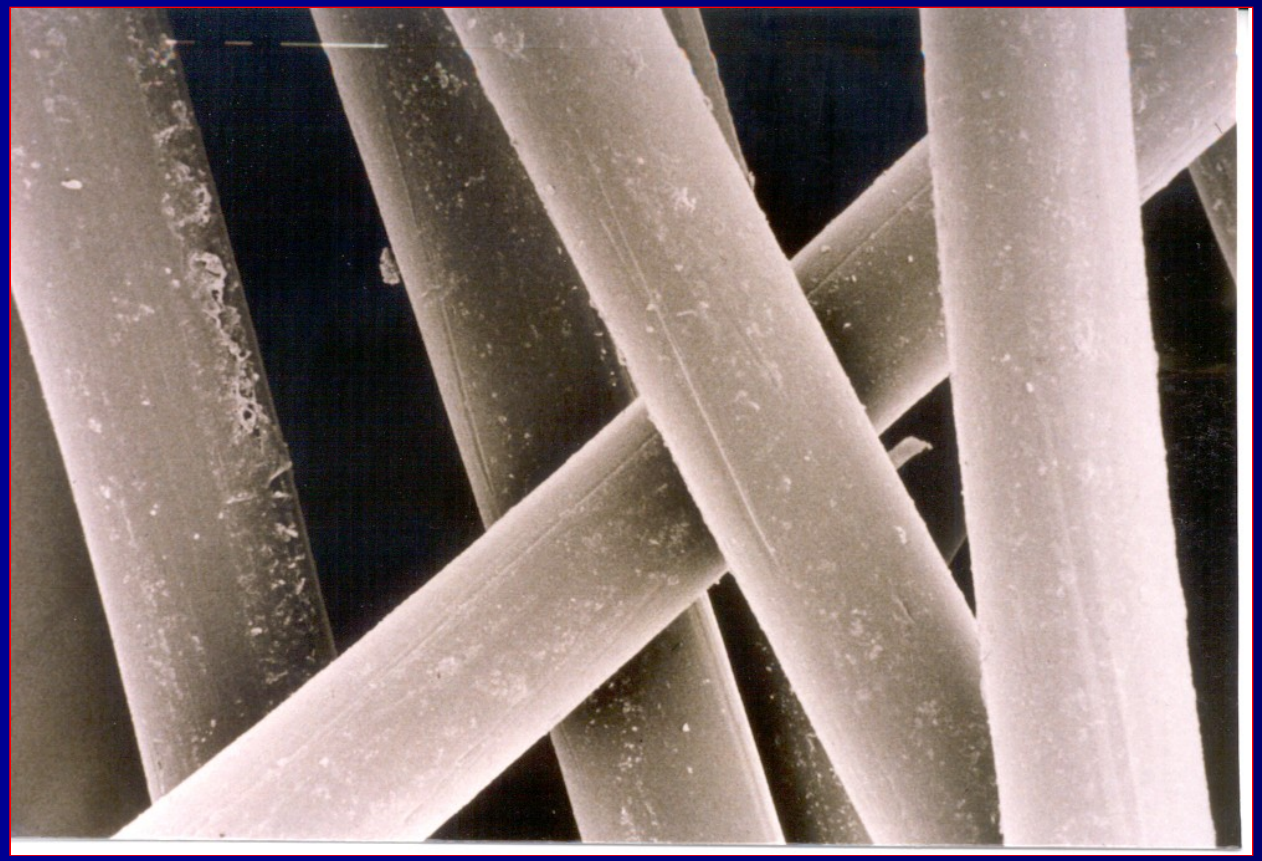
Why go Over-the-Top ?

- No bollard failure reported.
- Mode of failure analysis revealed

  no evidence of failure of a

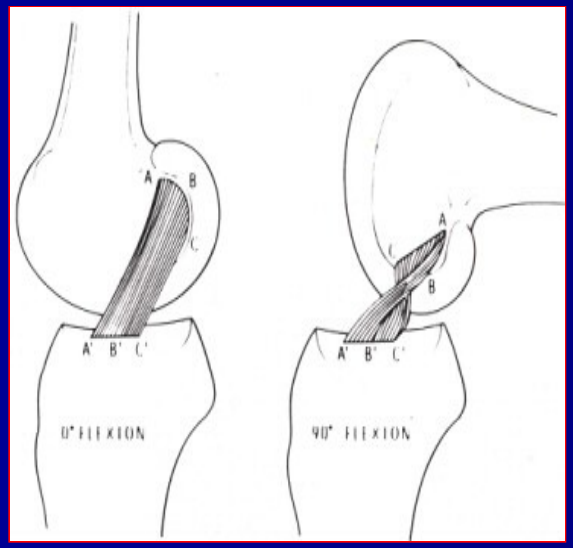
  prosthetic implant at the OTT site.

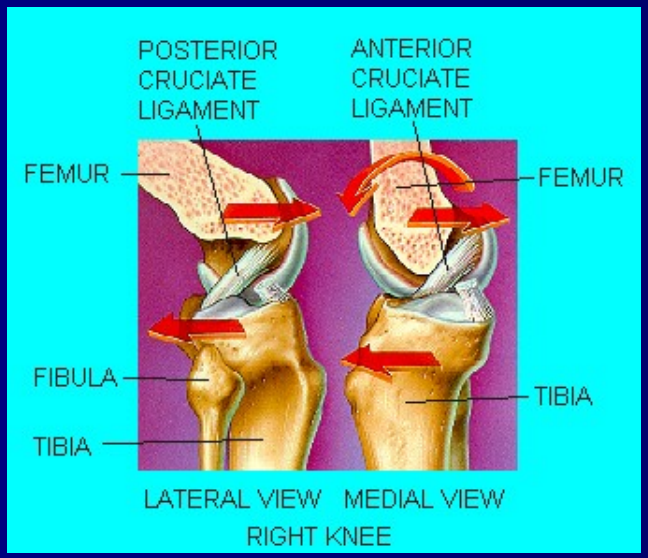
Polyester Fibres from the OTT site



Biomechanical Properties of the Normal ACL Favouring the OTT route

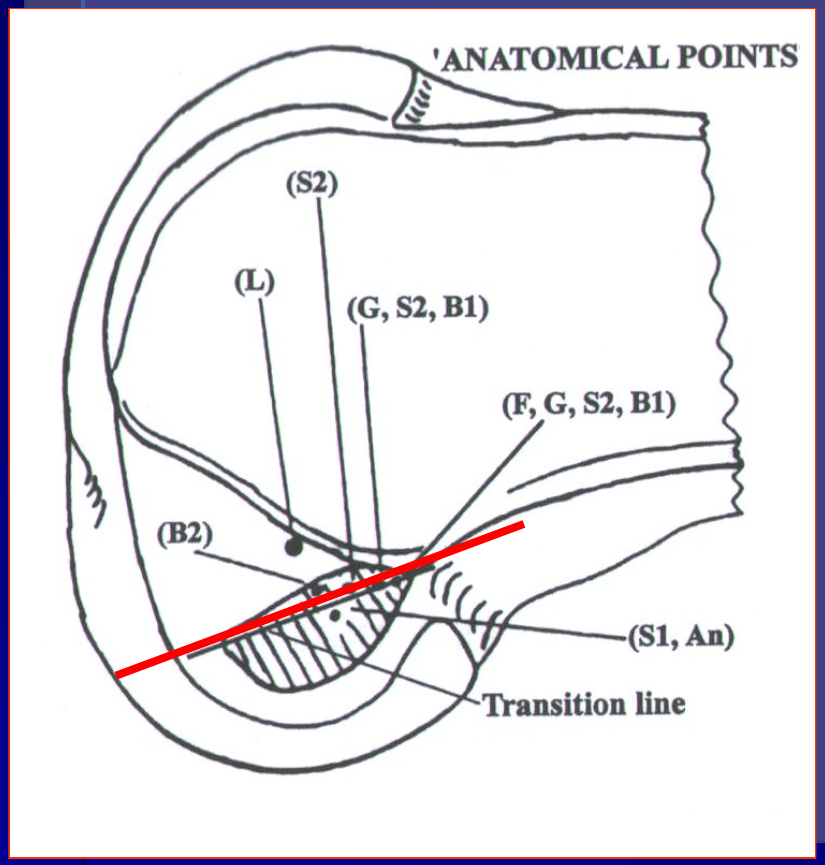
Individual bundles in the ACL tighten and relax during flexion and extension. However taken as a whole the ACL tends to be tight in extension relaxing slightly in flexion





Why go Over-the-Top ?

A study using navigationally guided probes
to determine ideal femoral siting
established the transition line.



- The Transition Line
  (Amis + Zavras)
- Placing all the graft fibres posterior to the transition line ensures that it is tight in extension and slackens in flexion
- Placing the graft over the top ensures this.

Why go Over-the-Top ?

The surgery is

reproducible

and easier to perform

than current methods

employing two tunnel fixation

Advantages of the Soffix fixation method

- Exact choice of length (15.5, 17, 18.5 cm)
- Choice of graft material (autologous grafts, allografts)
- Can be performed open or arthroscopically
- Dedicated instrumentation
- Preconditioning of the graft is possible

DISADVANTAGES

1. Two incisions
2. Cost

Conclusion

5 years experience with the Mark II Soffix has confirmed that this method of ACL fixation and reconstruction provides results which match the best for those reported in the Orthopaedic Literature.

THANK YOU