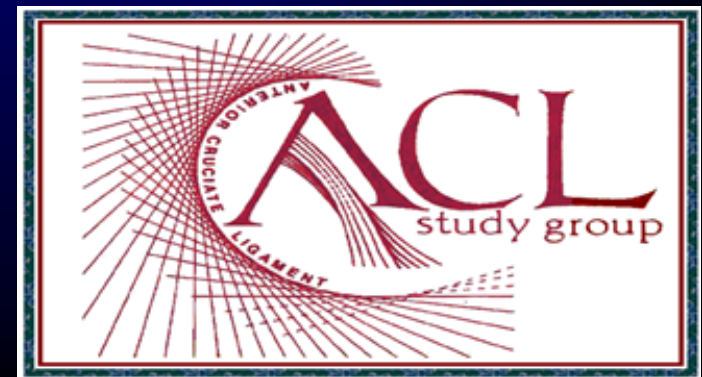


# Randomized clinical trial of femoral and tibial fixation in hamstring ACL reconstruction

DH Johnson, MD. Monika Volesky, MD.  
Andy Pickle, MD. Ari Pressman, MD

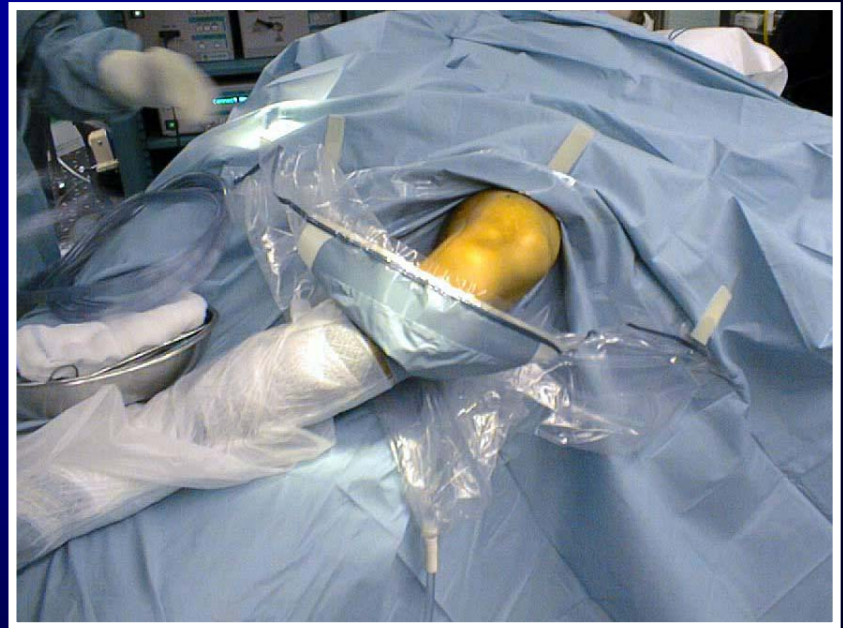
ACL Study Group  
Sardinia 2004

CARLETON  UNIVERSITY  
SPORTS MEDICINE CLINIC

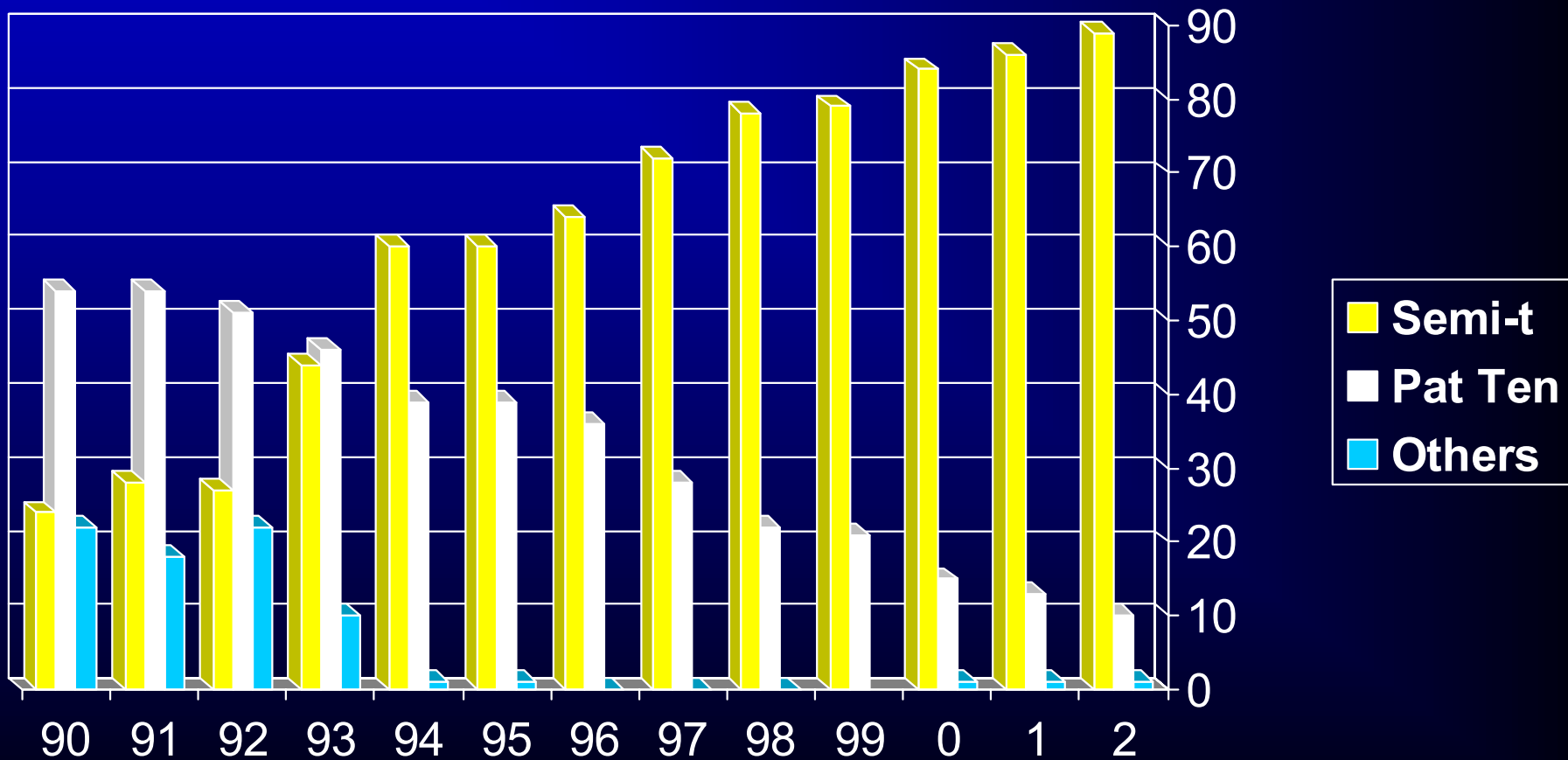


# Outcome of ACL Reconstruction

- Tunnel Placement
- Graft Choice
- **Graft Fixation**

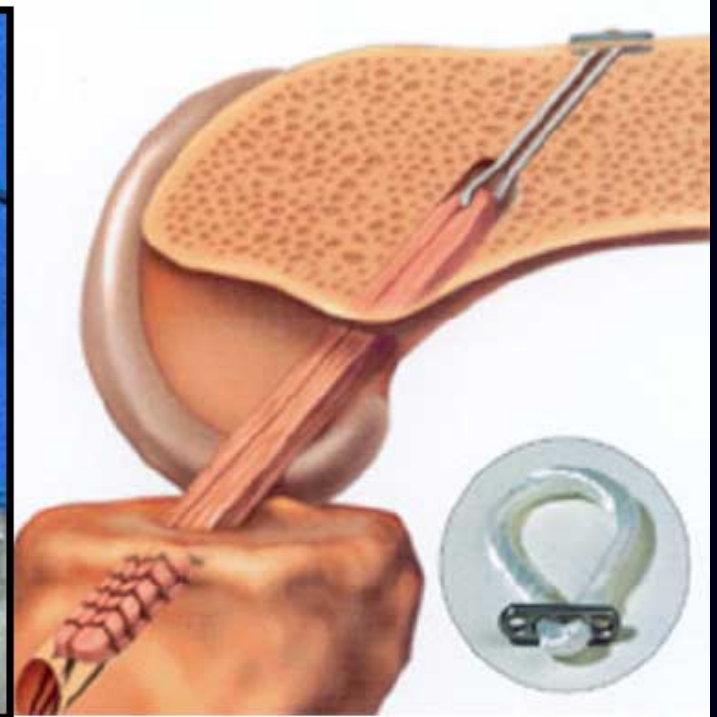
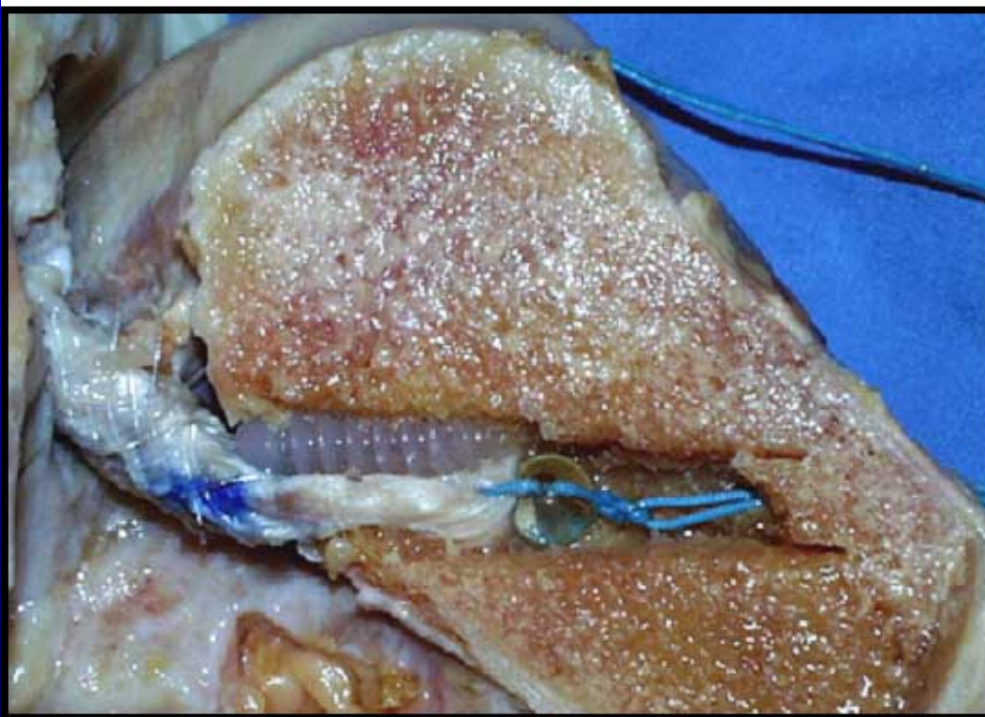


# *Evolution in Graft Choice*



# ***Femoral Fixation***

# RCT – BioScrew versus Endobutton



# Purpose

- Question – Is BioScrew/EndoPearl equal to Endobutton for femoral fixation in ACL hamstring reconstruction as measured by KT-1000 and IKDC outcome measurements?

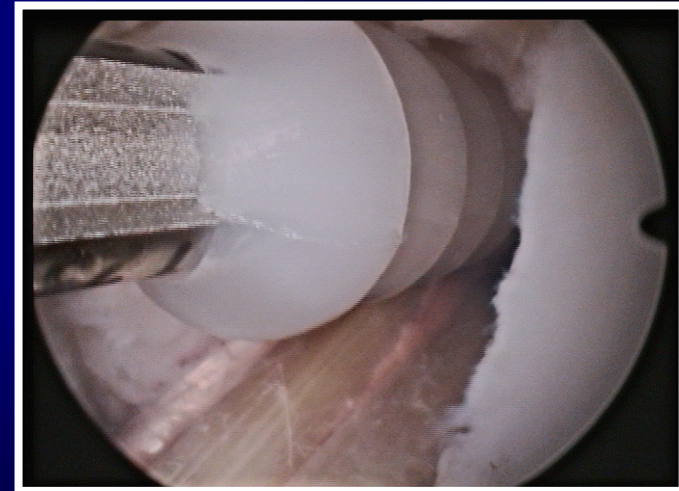
# Hypothesis

- That augmentation of interference screw fixation on the femoral side with a EndoPearl would improve the KT-1000 SSD results as compared to the Endobutton.



# Surgical Technique

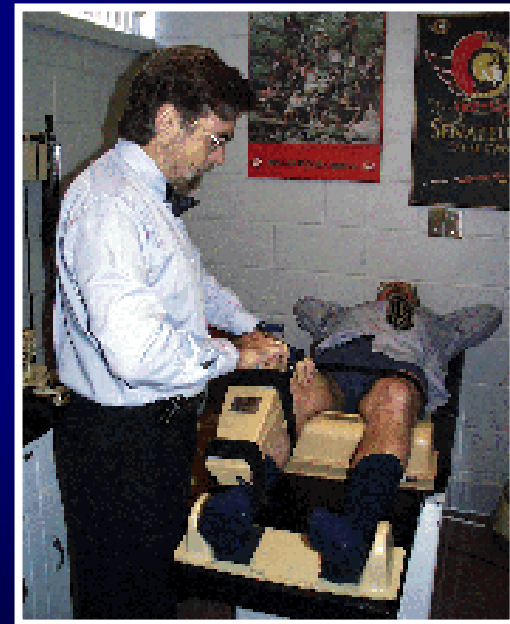
- Double-looped, four bundle semitendinosus-gracilis graft
- Trans-tibial drill technique
- Tunnels size = graft size
- Femoral screw same size as tunnel
- Tibial internal aperture screw one size larger with secondary button fixation





# Follow-up

- Independent examiner
- History & Examination
- KT-1000
- IKDC subjective evaluation



## Methods: ACL Reconstruction

- ❑ Sample size was derived to compare of clinical outcome with a variable femoral fixation at two years. Outcome measures were set at 2mm of KT-1000 side-to-side difference and a 10% difference in IKDC scores between groups with a power of 80% and a significance of 0.05.
- ❑ Randomization of 51 patients using a computer generated table to determine the selection of femoral fixation using either a femoral interference screw/EndoPearl or a closed loop Endobutton.
- ❑ Clinical results, IKDC results and KT-1000 data were analyzed using the student-t test with significance set at 0.05.

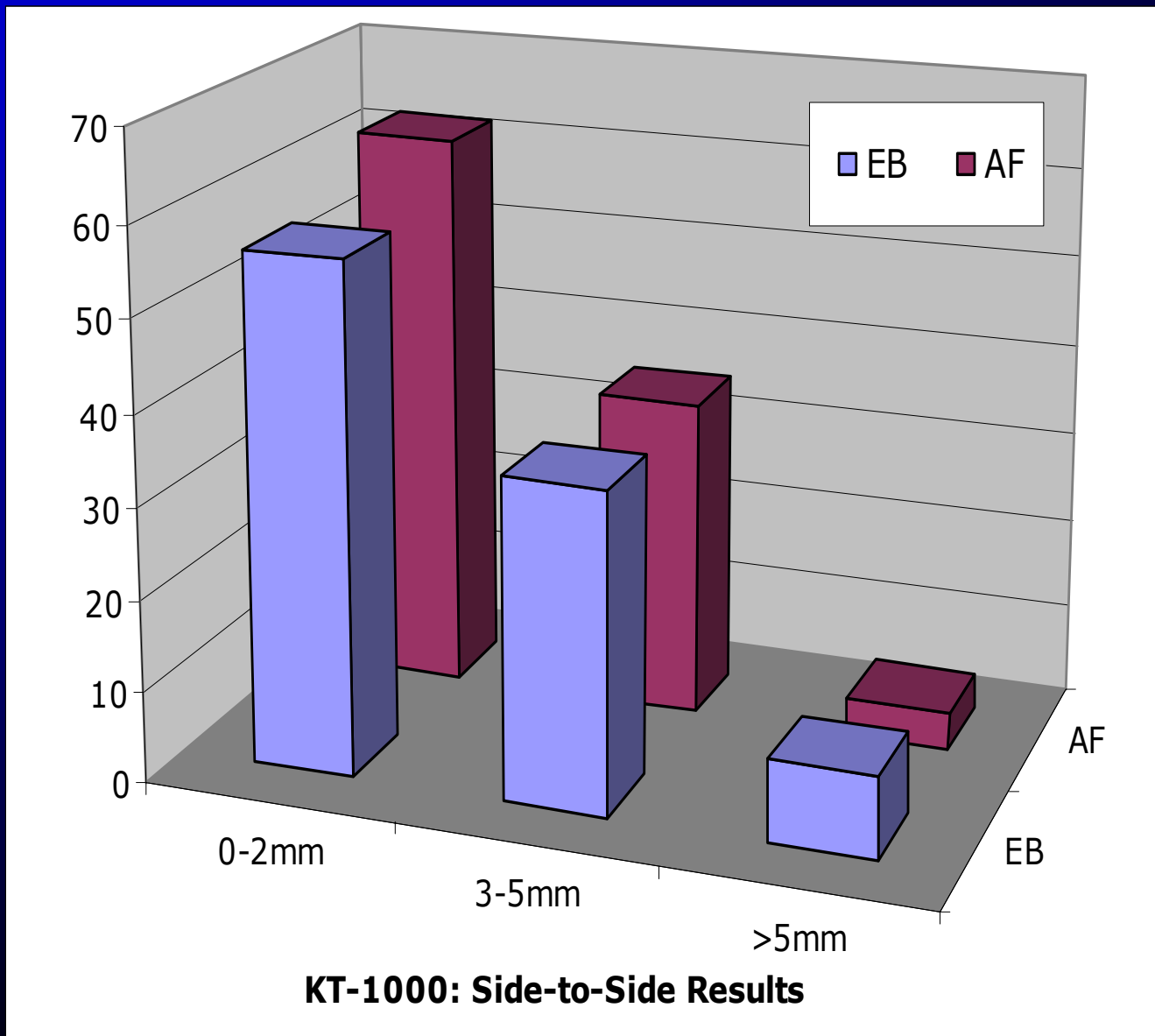
# Results

- ❑ The average follow-up time for the group was 2.3 years with a minimum 2-year follow-up.
- ❑ No significant differences were seen in the age and demographics of both groups.
- ❑ 26 patients BioScrew/EndoPearl group
- ❑ 23 in the Endobutton group.
- ❑ Two patients were excluded from the EB group due to contralateral ACL tear during the study period.
- ❑ No patients were lost to follow-up

# Results – Table 1

	KT-1000 side-to-side (2 yrs)	IKDC score
<b>ENDOBUTTON</b>	<b>1.8+/-2.4</b>	<b>85.9+/-9.8</b>
<b>BIOSCREW + ENDOPEARL</b>	<b>2.2+/-2.2</b>	<b>84.0+/-10.2</b>
Males	2.1+/-2.4	86.4+/-9.6
Females	1.9+/-2.3	82.9+/-10.3
Femoral Dilation	2.0 +/- 2.3	84.3+/-10.7
No Femoral Dilation	1.9 +/- 2.4	85.8+/-9.0
Tibial Dilation	1.9+/-2.3	84.7+/-10.5
No Tibial Dilation	2.2+/-2.6	85.5+/-8.3

# KT-1000 Side to side results



# Discussions

- Study Strengths:
  - Randomized, Blinded
  - Two year follow-up
- Two patient crossovers...
  - One AF → EB for post wall deficiency
    - » KT-1000 side to side 0-2mm, IKDC 80
  - One EB → AF for improper flipping
    - » KT-1000 side to side 0-2mm, IKDC 85
- ***In both cases alternate treatment represented a good back-up fixation option.***



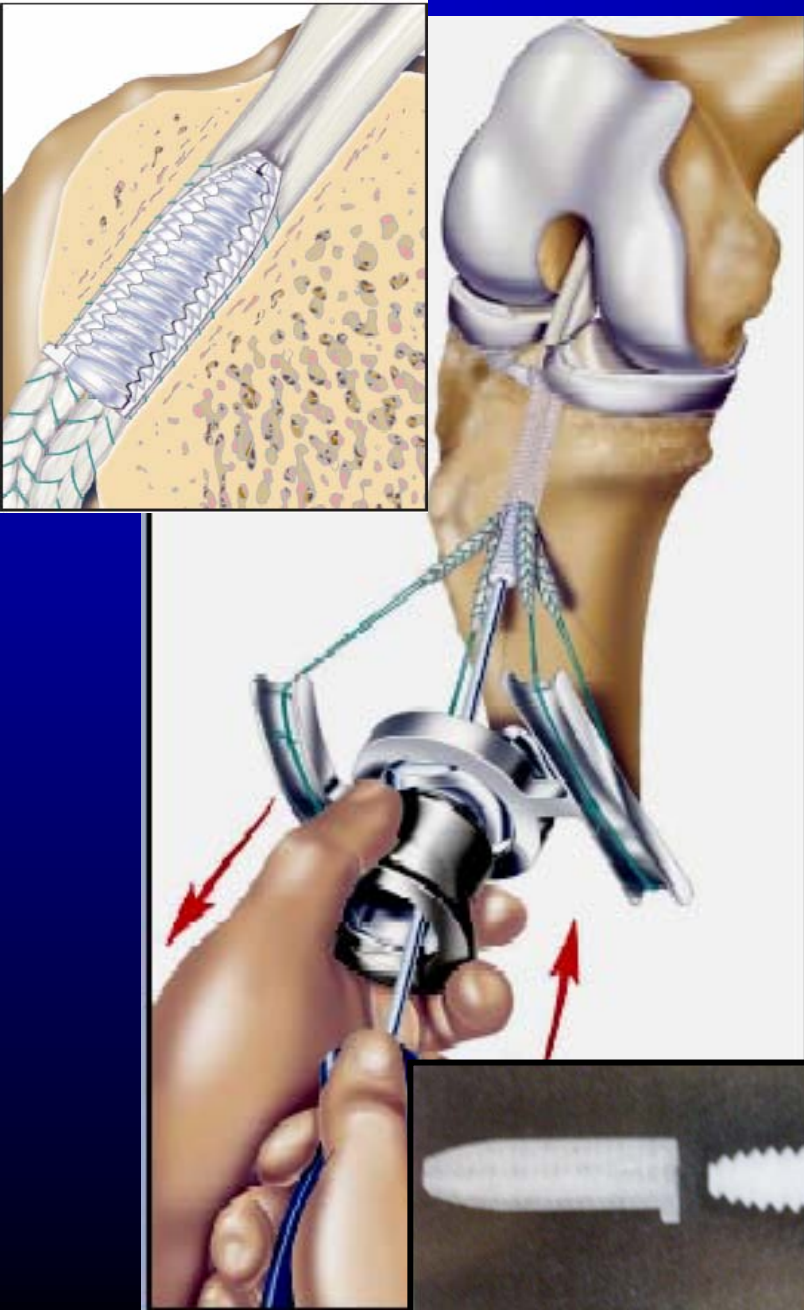
# Conclusions

- In conclusion, this study supports the use of both the aperture fixation technique with a Bioscrew and Endopearl(Linvatec, Largo, FL) or an Endobutton (Smith and Nephew, Memphis, TN) reconstruction on the femoral side in a randomized and blinded model of hamstring ACL reconstruction where the only variable was femoral fixation.

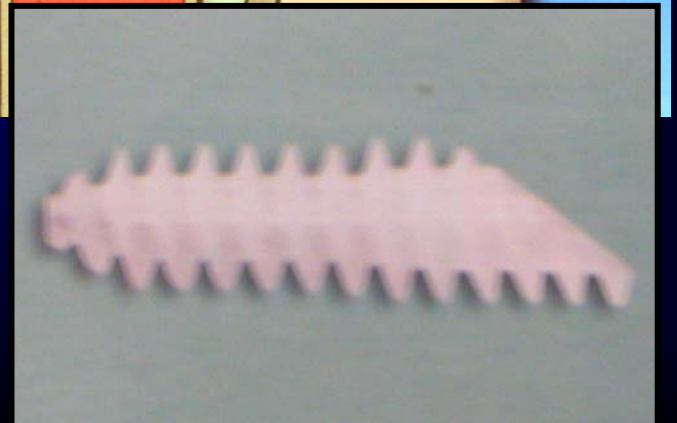
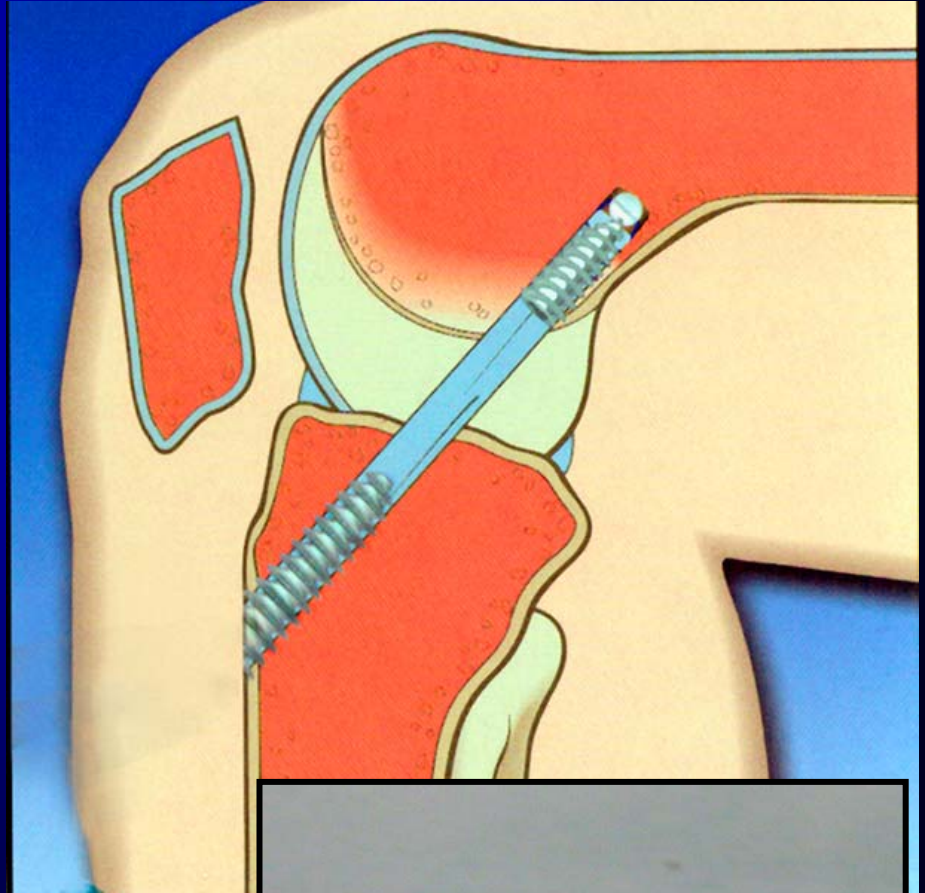


# ***Tibial Fixation***

# Intrafix<sup>®</sup>



# BioScrew XtraLok<sup>®</sup>



# Purpose

- Question – Is ExtraLok BioScrew equal to Intrafix for tibial fixation in hamstring ACL reconstruction as measured by KT-1000 and IKDC outcome measurements?

# Hypothesis

- ❑ The ExtrLok Bioscrew is equal to the Intrafix for tibial fixation of soft tissues.
- ❑ That the ExtraLok BioScrew tibial fixation would reduce the KT-1000 3-5 mm SSD results.

# Methods

- Prospective randomized clinical trial
- Ottawa Hospital; 3 surgeons
- Standard ACL 4 bundle semi-tendinosus/gracilis trans-tibial arthroscopic reconstruction

# Methods

- 105 sequential patients from the Ottawa Hospital undergoing ACL reconstruction were recruited
  
- Inclusion criteria:
  - Able to complete 2-year follow-up
  - No previous knee surgery
  - No evidence of multiple-ligament injury
  - Normal ACL contra-lateral knee
  - Closed proximal tibial physis

# Methods



- ❑ Femoral fixation is same for both groups: EndoButton<sup>®</sup> (Smith & Nephew, Andover, MA).
- ❑ After drilling tunnels, a computer-generated randomization table used to allocate patients to a study arm.



# Methods

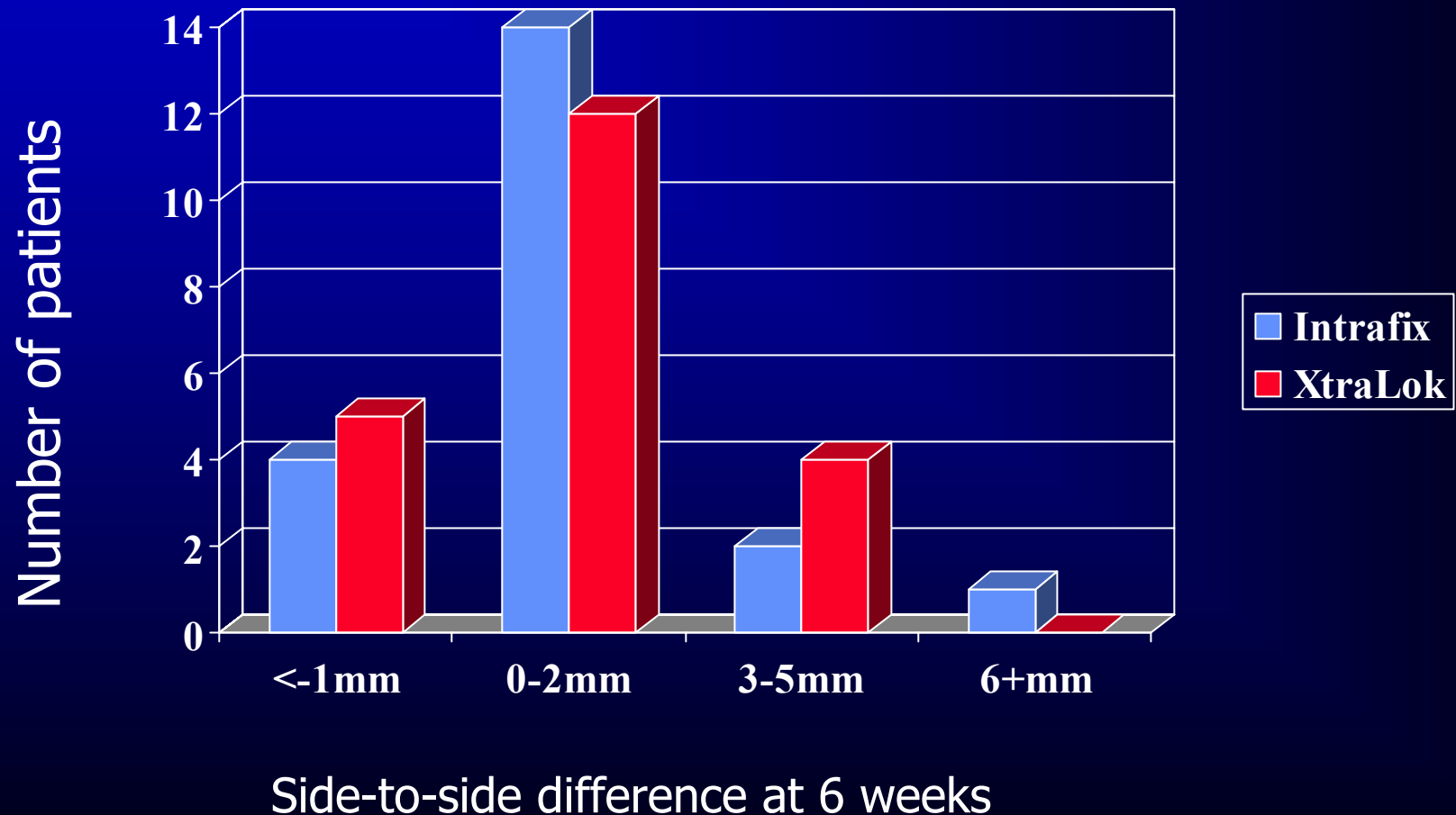
- Assessment:
  - Clinical assessments at 6 weeks, and 3, 6, 12, and 24 months post-op.
  - KT-1000 arthrometer scores at each visit to compare side-to-side difference between knees (manual maximum)
  - IKDC scores pre-op, and at 12 and 24 months post-op



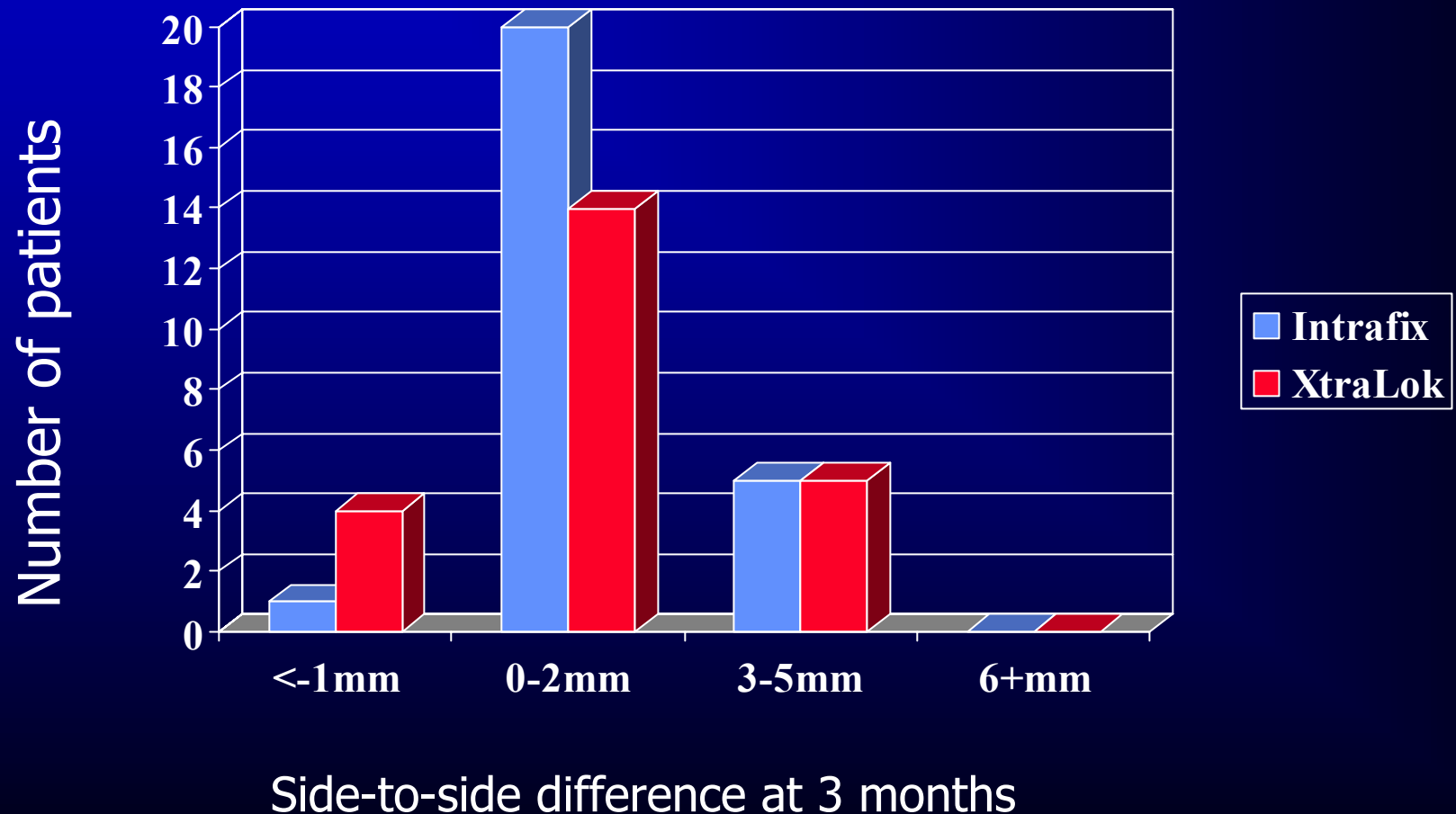
# Results

- 105 patients
  - 74 (71%) available for follow-up at this time
    - » 36 XtraLok
    - » 38 Intrafix
- Preliminary data
  - » 6 weeks: 42 patients
  - » 3 months: 49 patients
  - » 6 months: 51 patients
  - » 12 months: 21 patients

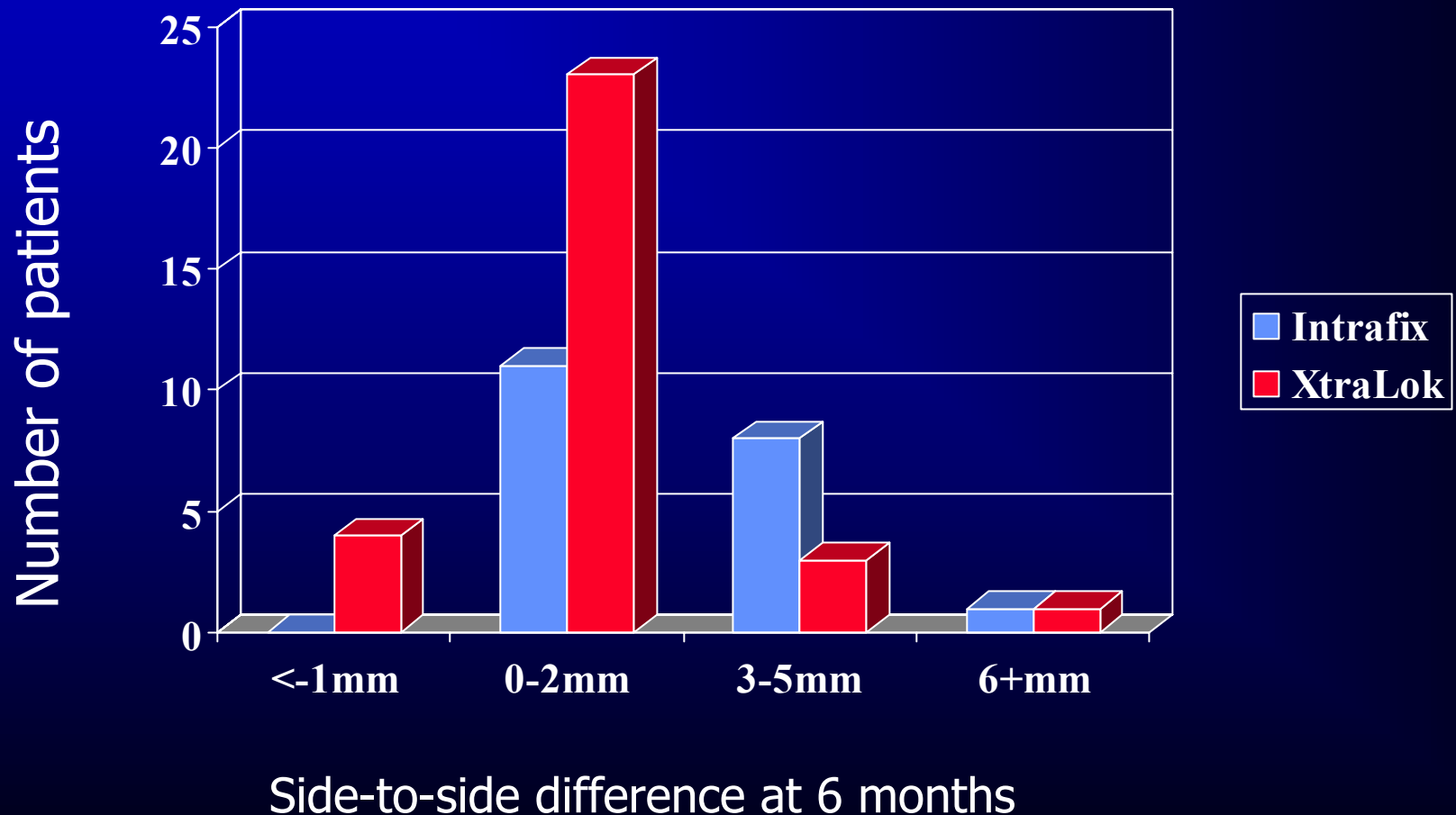
# Comparison of KT-1000 arthrometer side-to-side difference



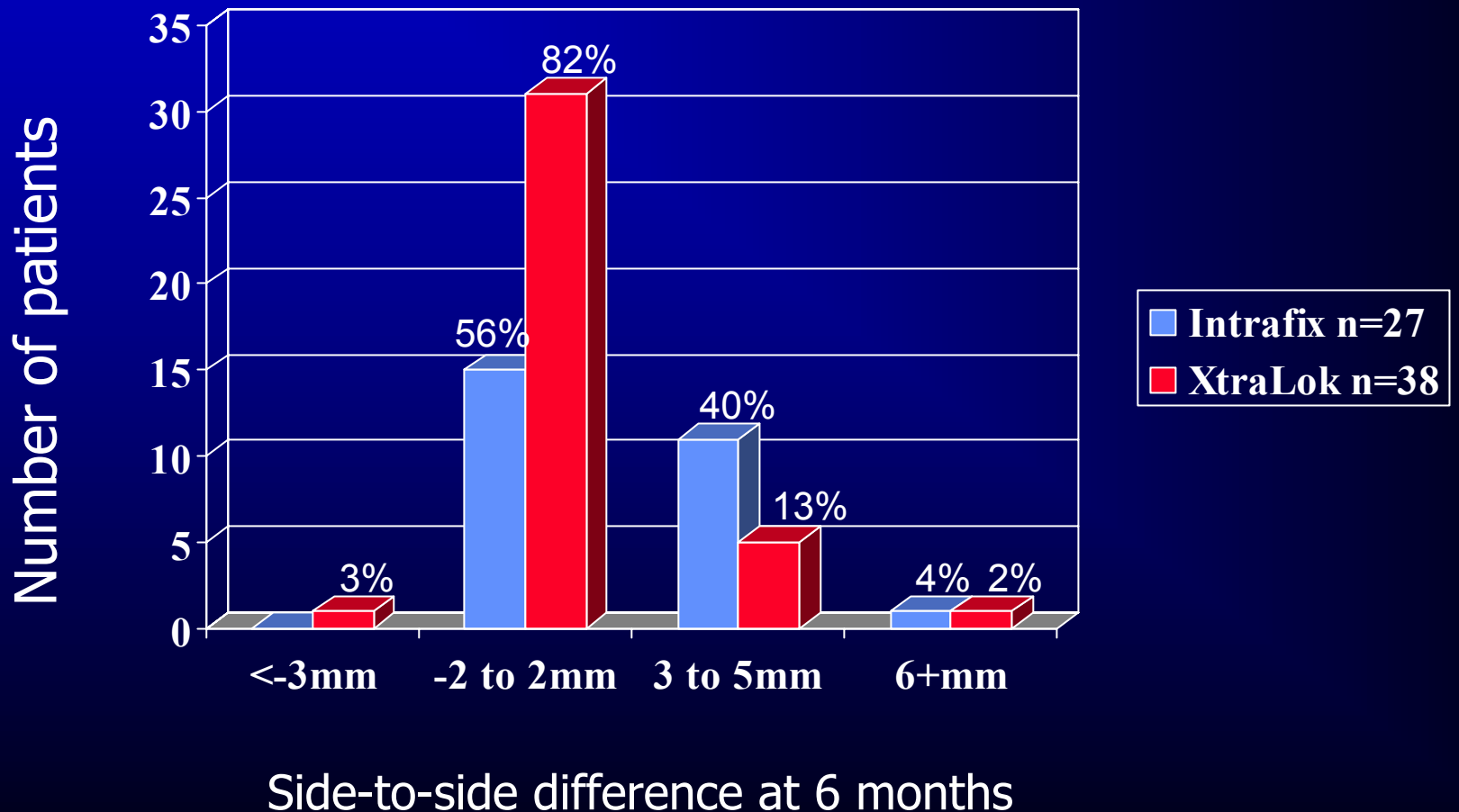
# Comparison of KT-1000 arthrometer side-to-side difference



# Comparison of KT-1000 arthrometer side-to-side difference

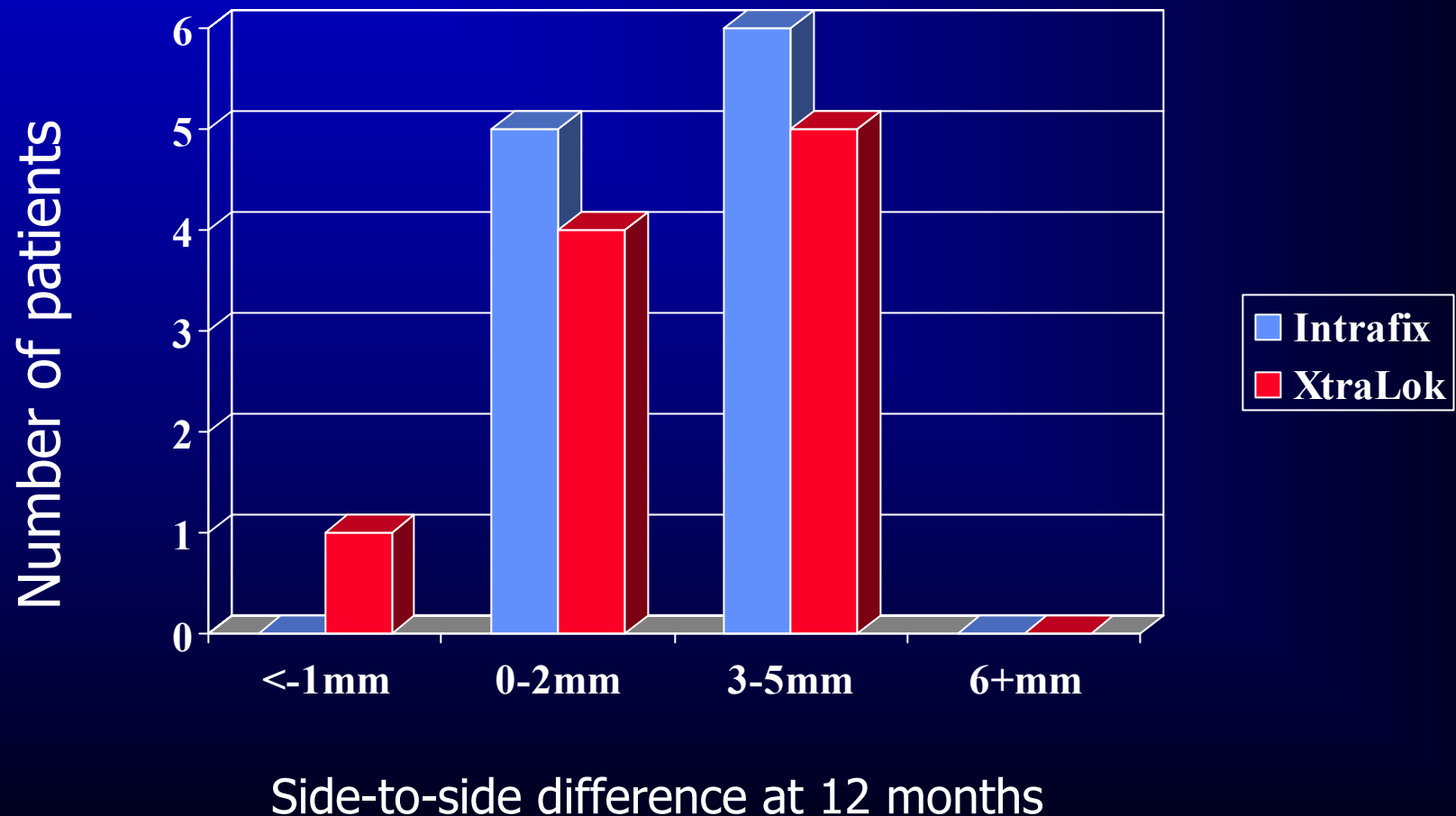


# Comparison of KT-1000 arthrometer side-to-side difference



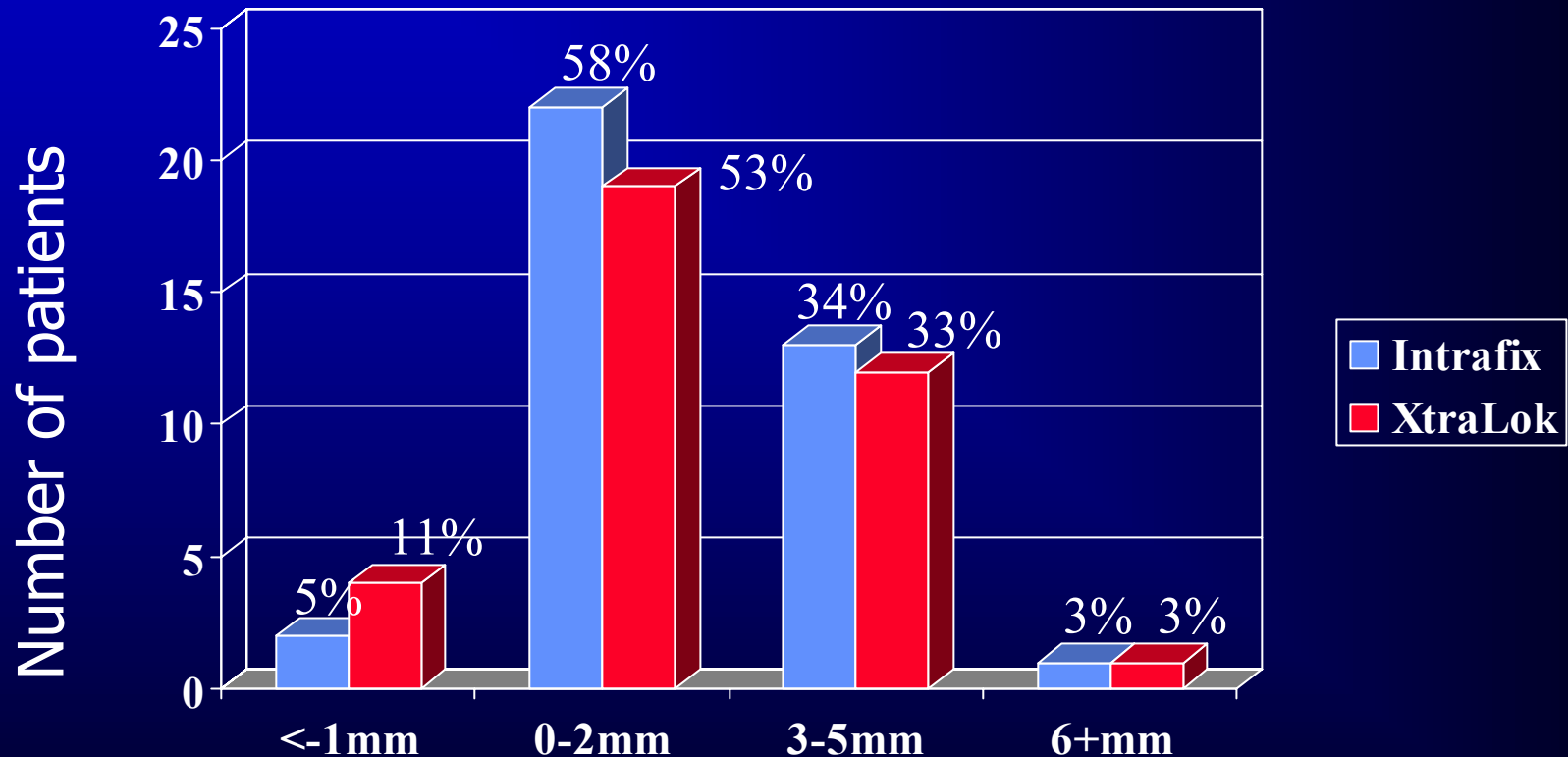
Chi-square  $p=0.08$

# Comparison of KT-1000 arthrometer side-to-side difference





# Comparison of KT-1000 arthrometer side-to-side difference

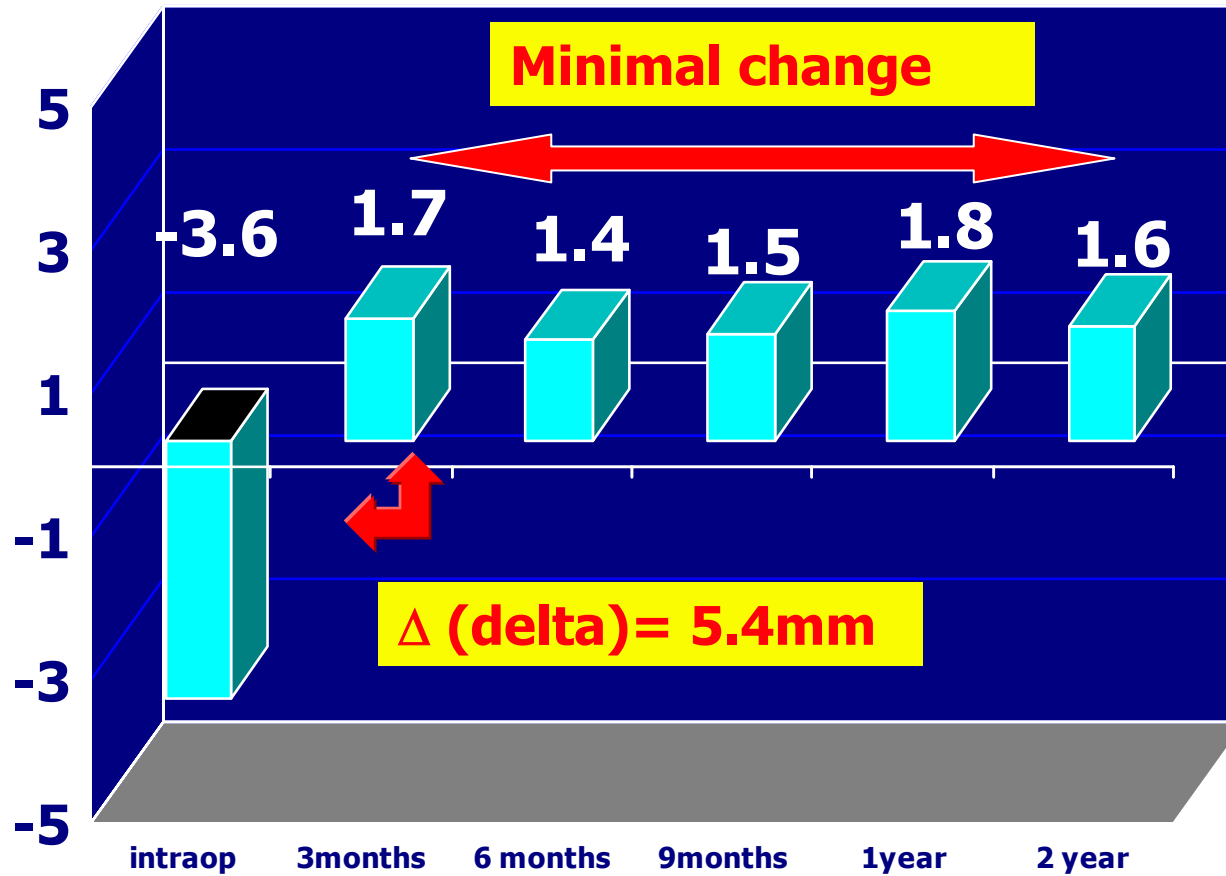


Side-to-side difference at latest follow-up

# Preliminary Results

- KT-1000 arthrometer scores are early follow-up at 12 months or less.
- KT-1000 side-to-side difference between groups at 6 weeks, and 3, 6, and 12 months are not statistically significant (ANOVA).

# KT change over time (SSD)



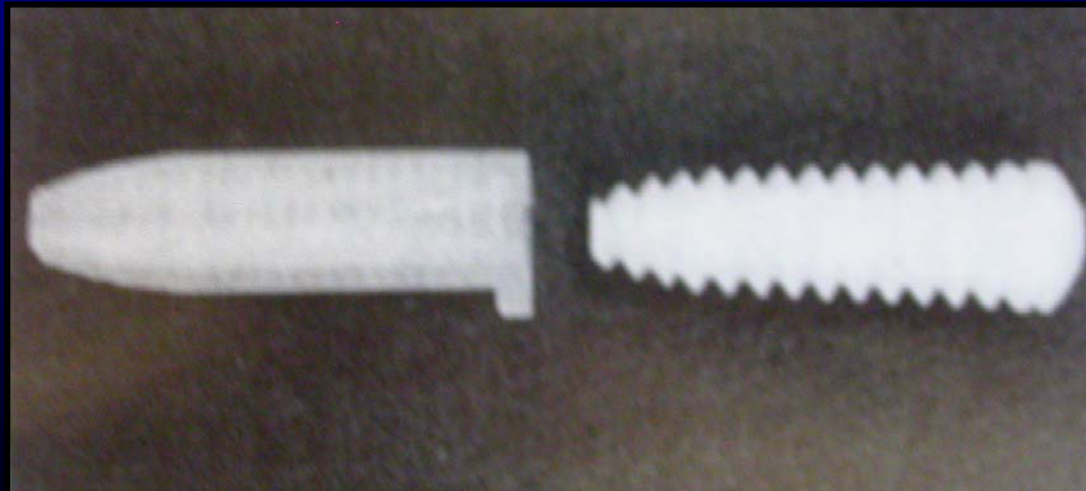
# Discussion

- KT-1000 arthrometer literature:
  - Highly sensitive and predictive of stability of knee
  - Good objective measure
  - Validated

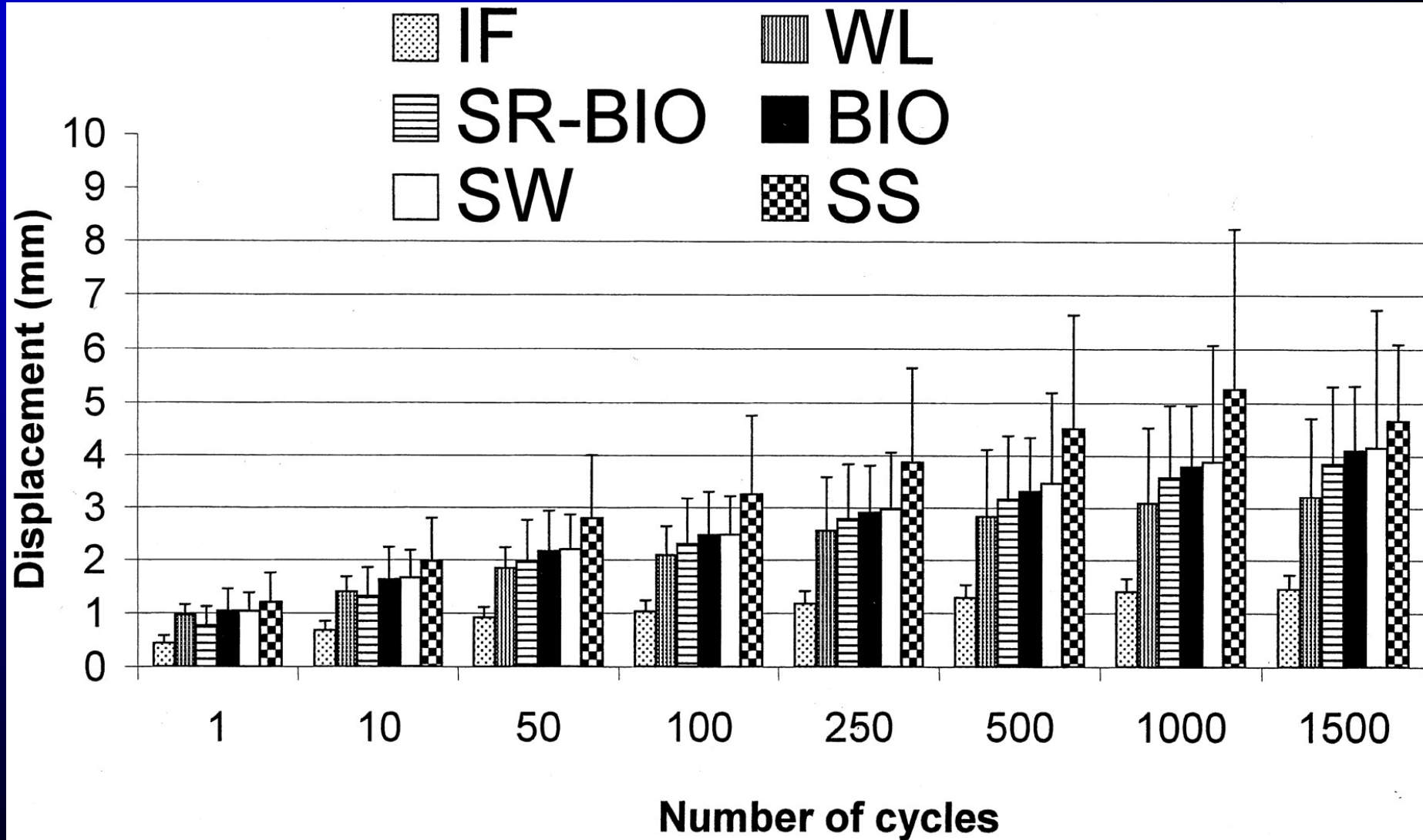
# Discussion

- The Intrafix<sup>®</sup> tibial fastener has good clinical results and improved pullout strength in lab testing compared to eccentrically placed cancellous-type bioabsorbable screws.

(Richmond JR, personal communication)

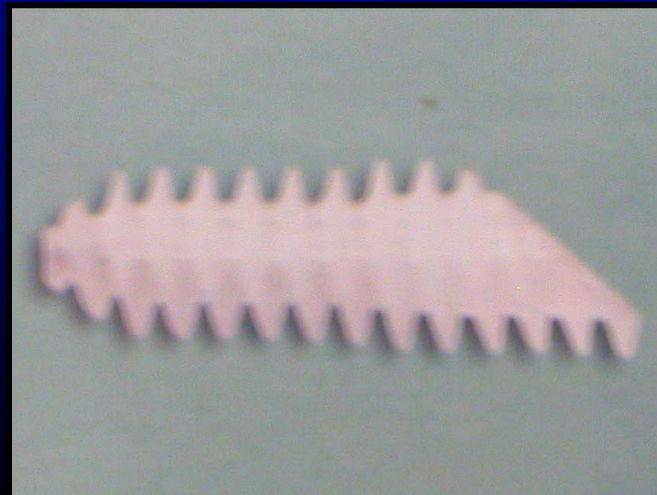


# Discussion



# Discussion

- ❑ Traditional interference BioScrews have been shown to be inferior to Intrafix<sup>®</sup> on lab testing (Kousa et al)
- ❑ No clinical studies available comparing cortico-cancellous interference BioScrew and Intrafix<sup>®</sup>



# Conclusion

- ❑ Early mechanical results support the null hypothesis: BioScrew XtraLok<sup>®</sup> and Intrafix<sup>®</sup> provide equal graft fixation
- ❑ Both tibial fixation devices have a low clinical failure rate to one year
- ❑ EtraLok screws show a trend to reduce the KT 3-5 mm SSD



***Thank You***

