

Randomised controlled trial of titanium versus bio-absorbable (PLLA-HA) screw fixation for anterior cruciate ligament reconstruction. 5 year results

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INTRODUCTION

There has been a developing interest in nonmetallic interference screw fixation for ACL reconstruction in recent years due to their theoretical advantages over their metal counterparts. These new implants are radiologically transparent and can simplify revision surgery by negating the need for screw removal.

In an effort to improve bony replacement of the screw, there has been development of biocomposite screws, combining PLA copolymers with osteoconductive substances. Studies in animals using bioabsorbable screws incorporated with hydroxyapatite (HA) or tricalcium phosphate (TCP) have had favorable results.

In this prospective, randomized controlled study of hamstring tendon graft ACL reconstruction, we compare outcomes of a metal interference screw to a screw made of PLLA (70-80%) and hydroxyapatite (20-30%).

METHODOLOGY

40 patients who met the inclusion and exclusion criteria below were recruited to participate in the trial after giving their signed informed consent.

Inclusion criteria

- Undergo ACL reconstruction between June 2002 and October 2003
- Be willing to participate in a randomized controlled trial and provide written informed consent

Exclusion criteria

- previous ACL reconstruction to either knee
 - contralateral ACL deficiency
 - concurrent ligamentous injury or significant pathology to the index knee
 - seeking compensation for their injury
- Patients were randomised to receive either the titanium RCI or BioRCI screw for tibial fixation of the ACL graft. Subjects were assessed at 1 week, 6 weeks, 12, 24 and 60 months following surgery with the IKDC Evaluation, KT1000 arthrometer, Lysholm Knee Score, effusion, and kneeling pain. MRI scans were performed at 2 and 5 years to assess the rate and extent of screw resorption and bony ingrowth.

RESULTS

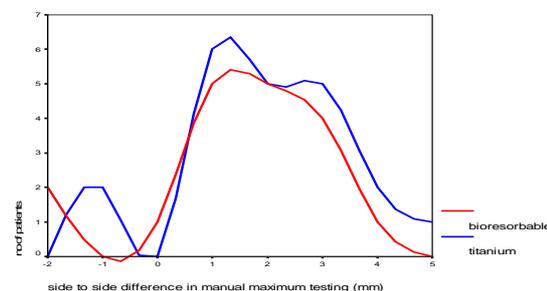
At 5 years after surgery 1 patient with a titanium screw had an ACL graft rupture and had undergone revision surgery. Of the remaining 39 patients, 38 (97%) were reviewed at 5 years. There was no significant difference between the 2 groups in the volume of the tibial (p=0.99) or femoral (p=0.16) tunnels at 5 years. Significant screw resorption at 5 years was seen in 77% on the tibial side and 88% on the femoral side in the PLLA group. Good ossification was evident on 5 yr MRI in 94% of the tibial screws and 56% of the femoral screws.

There was a significant increase in the tibial tunnel volume (p=0.01) and a significant decrease in femoral tunnel volume (p=0.03) in the PLLA-HA group between 2 and 5 years.

There was no significant difference between the PLLA-HA group and the titanium group on any of the other clinical parameters at 2 and 5 years (see Table below)

5 year outcomes	Bio	Tit	p
IKDC Subjective Score mean	93	93	0.92
Overall IKDC norm or nearly norm (%)	100	100	0.26
Lachman Grade 0 (%)	78	68	0.52
Pivot Shift Grade 0 (%)	83	80	0.73
Extension deficit <3 (%)	89	100	0.12
Current Regular Activity Moderate to strenuous(%)	95	95	0.32
Kneeling pain (%) No or minimal difficulty	84	95	0.29
KT1000 mean (mm) <3mm (%)	1.5 72	2.0 58	0.26 0.30
No Effusion (%)	94	79	0.16

Figure 1: Comparison of instrumented ligament



testing between the 2 groups

In the PLLA-HA group at 5 years, 24% (4) patient had cyst in the proximal tibial tunnel and 18% had cyst in the distal femoral tunnel near the PLLA-HA screw head. In the titanium group at 5 years, 16% (3) had cyst in proximal and middle one third tibial tunnel and 11%(2) had cyst in the middle one third and distal femoral tunnel. The difference in occurrence of cyst between the two groups was not significant.

CONCLUSION

ACL reconstruction with PLLA-HA bioabsorbable screws affords comparable clinical and subjective results to titanium screws at 5 years after surgery. Significant progression of PLLA HA screw resorption occurs between 2 and 5 years with over 75% of screws demonstrating some resorption by 5 years. However complete resorption was only evident in a small number of patients. ACL reconstruction with a PLLA HA screw has excellent clinical outcomes and progressive screw resorption and ossification is evident at 5 years.