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Bio-Absorbable Screw Fixation In ACL Reconstruction

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Kurosaka first demonstrated customized interference fit screws to be superior to the AO Screws for the fixation of bone/patella tendon/bone grafts in anterior cruciate ligament reconstruction. Since 1987 there has been an explosion in the variety of interference fit screws and other methods of anterior cruciate ligament graft fixation.

Bio-absorbable fixation potentially has many advantages. It allows post-operative radiography and MRI investigation and it requires no removal. Many different prototypes have been released onto the market. Alas, most of these have had very little evaluation either bio-mechanically or from animal experiments.

The basic substances for absorbable screws are a polyglycolic acid and polylactic acid. The polyglycolic acid is polymer of sugars. It tends to dissolve quite quickly within six to twelve weeks and is associated with surrounding oedema, inflammatory reaction, swelling and osteolysis. Clinical studies involving mandibular plates and in animal knee studies have shown a high instance of infection and aseptic wound discharge. This may be up to 9%. The other material is polylactic acid. This comes in two isomers: the L isomer which is crystalline, which, although it fragments, takes a considerable length of time, at least 5 years, to dissolve. Small crystals are then formed and these may lie dormant within in the macrophages for some time. The material undergoes hydrolysis and is metabolized to lactic acid. Alternatively the D-isomer may be used, which has a much quicker rate of absorption of some 6 - 12 months.

The Bio-absorbable screws are brittle. Because of the large internal diameter used by the screwdriver in order to gain purchase on the screws, they are liable to crack. The strength of the screws to torque before failure has been shown to be approximately 50% of that with titanium screws. The ability to withstand pull-out stresses has also been

shown to be less in the 7 millimetre bio-screw. However, comparable results were found with the 9 millimetre screws. There are preliminary results available. This was a multi-centre study involving several surgeons. Forty-two patients were undertaken using the 7 mm Bio-screws. The results demonstrated an increased incidence of Pivot Shift. A 7% incidence of broken screws and 15% of extension loss in the Bio-screw fixed population.

Stanhelm also undertook a review of bio-absorbable interference fit screws on 36 patients. A 9% incidence of aseptic wound discharge was noted.

The aims of this study was to analyze the use of a bio-absorbable screw. This was the Linvatec Poly L-lactic Acid Screw. It was undertaken to analyze the ease of insertion. The instance of operative complications and infections. The long term review of the stability and any tunnel widening or granuloma formation was assessed. The patients were randomly divided into 2 groups and followed to a minimum of 12 months post-operatively. The vast majority of patients had chronic unstable knees. They all had positive a Pivot Shift. 7 out of the 50 patients had an additional postero-lateral rotary instability. A number of patients had undergone previous surgery in both groups. At the index procedures, many other procedures were undertaken. This included 13 medial meniscectomies, 11 lateral meniscectomies and 2 medial meniscal repairs. 2 patients were submitted to postero-lateral rotary stabilizing procedures.

The femoral fixation in the titanium group was with 7 millimetre titanium screws. This 10 millimetre femoral hole was routinely used. A 7 millimetre femoral Bio-screws were used initially, however, once the pull-out strength data became available 9 millimetre screws were used.

Femoral fixation problems were found in 20% of the Bio-screws. This was particularly serious in that starting the thread with only a femoral tunnel notcher and not a tap resulted in one patient had fraying of the graft and was the one patient with recurrent instability. In 3 cases the screw cracked and could not be tightened. This often happened once the screwdriver was removed from the screw after insertion. The compressive forces on the screw caused it to collapse and crack. It was then not possible to re-insert the screwdriver in order to tighten the screw. One screw fractured and could not be advanced or removed. The fragments were therefore removed using an osteotome. The proximal half of the screw was driven further into the femoral hole and a second screw was inserted. This patient went on to obtain successfully a stable knee.

There were no problems with inserting the titanium screws at the femoral end of the graft.

Tibial fixation was undertaken routinely into 10 millimetre drill holes. 9 millimetre titanium and Bio-screws were used. Problems were found inserting 8% of the Bio-screws. In one the screw cracked and could not be tightened and in the second inadequate fixation was achieved and a second screw was inserted successfully.

One patient had problems whilst inserting the titanium screw in that the attached threads were cut by the screw. However insertion was able to be undertaken without loss of tension and no instability occurred in this case. The initial fixation was noted to be good in all but one case. That was the case in which difficulty was found in starting the femoral screw. Isometry was found to be less than 2 millimetres in all but 2 cases.

Rehabilitation was the same in both groups. This included early mobilization and discharge. Discarding the walking aids as soon as possible. Analgesia was taken as necessary. There was no difference in the rate of mobilization in the two groups.

When analyzed for fixed flexion deformity throughout the first post-operative year there was no significant difference between the two groups. Both groups obtained full knee extension. In a similar way there was no difference in the range of flexion in the two groups. No patients had loss of flexion of more than 5 degrees.

Although symptomatic effusions did not occur after the 6 week assessment, fluid was detectable on clinical examination in some knees beyond this time. The rate of detection of such fluid appeared to be slightly higher in the group having Bio-screws. Further surgery was undertaken in x patients. This was for anterior knee pain in 8 cases and for removal of the tibial screw which was painful and tender in 6 cases, five of these were metallic screws. There was a higher incidence of pain from the tibial screw in patients receiving the titanium screws.

At final review patients were assessed for crepitus, anterior knee pain, and tenderness of the tibial tuberosity. There was not noted to be any significant difference between the two groups in this regard.

98% of patients rated their knee as good or excellent. Pivot shift was abolished in 96% of patients, although 2 additional patients had an equivocal Pivot glide.

At final review there was no significant fixed flexion deformity or loss of flexion overall. 2 patients had a fixed flexion deformity of less than 5 degrees, and 4 patients had a loss of flexion, once again of 5 degrees. IKDC scores demonstrated that 94% of patients were in the nearly normal or normal group. There was a higher proportion of normal patients in patient receiving titanium screws. This appeared to be due to higher incidence of quadriceps wasting in patients receiving the Bio-screw.

Giving way only occurred in the patient with the failed Bio-screw due to operative complications. Two other patients had a positive Pivot Shift but were not symptomatic. KT 1000 Manual Maximum Assessment demonstrated that 92% of patients had a less than 3 millimetres of side to side difference and were considered normal. Only one patient had greater than 5 millimetres difference.

Tegner and Lissholm scores demonstrated similar levels of activities in the two groups.

Analysis of the haematology was undertaken at 3 weeks, 6 weeks, 6 months and 12 months. Analysis of White Cell Count, ESR and Creatinine were all normal. Analysis of CRP was normal as was Complement C3. However assessment of Complement of C4 demonstrated a higher number of patients with abnormal results in the Bio-screw group at 3 weeks. There was also a higher number albeit not significant statistically in the Bio-screw patients at one year.

Radiographs were taken in all patients at one year. These demonstrated no abnormal radio-lucencies, no evidence of granuloma formation or tunnel widening. 50% of the patients had been submitted for MRI examination at 12 months. In a similar way these have demonstrated no cavitation or granuloma formation around the screws. However the screws are still clearly visible. Bio-screws have been biopsied in 4 patients. At removal it was noted that the screws had not dissolved or even softened in any way. Osteotomes were necessary to remove the screws. Histology revealed no particular foreign body reaction at the interface. There was also a known tendency at 12 months to fragment and re-absorb.

Further identification of the soft tissue interface was undertaken histologically. This demonstrated no fibrous screw-bone interface, no inflammation, granulation or histological foreign body reaction to the screws.

In conclusion we have analyzed the use of the Bio-screw in a controlled randomized perspective way. Initial experience demonstrated difficulty in 20% of femoral insertions, 8% of tibial insertions. There is no haematological abnormality over the first 12 months. Radiological examination reveals no tendency to cavitate or for frank granuloma formation in the first year. There were no instances of delayed wound healing. MRI Scans demonstrated no tibial tunnel widening in either group. The Bio-screw therefore provided excellent stability at one year. It was associated with a lower instance of tibial screw tenderness. There were fewer screw removals. However there was no evidence of softening or any fragmentation or dissolution at 12 months.

We would suggest that at the femoral end a 10 millimetre drill hole and graft is used. A tap is used to start the femoral screw. The screw is placed in a superior position using a guide wire. The screw must be kept fully on the screwdriver as once the screwdriver is removed cracking of the screw may prevent re-insertion and tightening. A 9 millimetre rather than a 7 millimetre screw is advised.

At the tibial end a 10 millimetre hole and graft is again suggested. The screw should be placed in an anterior position. 9 millimetre screws should be used. Good soft tissue cover should be obtained burying the screw within the tunnel.

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