Original article

ACL reconstruction using femoral Rigid-fix and tibial Bio-intrafix devices

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ABSTRACT

Objectives: The objective of this study is to report the clinical and functional outcomes of Hamstring graft ACL reconstruction fixed with femoral Rigid-fix and tibial Bio-intrafix devices.

Methods: In a prospective study, the clinical (Lysholm score) and functional outcomes (International Knee Documentation Committee, IKDC) of 44 patients who underwent autologous hamstring graft ACL reconstruction using femoral Rigid-fix and tibial Bio-intrafix devices, were evaluated at the end of one year. Joint laxity was assessed with KT-1000 arthrometer (MEDmetric, San Diego, CA).

Results: None of the patients complained of instability, joint swelling or severe pain in the postoperative period. The IKDC score improved from 66.62 ± 5.36 to 92.36 ± 5.30 ($P < 0.001$). Lysholm scores in the preoperative and follow up period were 68.28 ± 5.54 and 93.87 ± 4.75 respectively; the improvement was statistically significant with P value < 0.001 . Similarly, the mean anterior translation of tibia improved from 7.45 mm in the preoperative period to 3.89 mm after one year of ACL reconstruction. Associated meniscus injury didn't have significant impact on the overall outcome. No intraoperative or postoperative complications were documented.

Conclusion: Hamstring graft fixation using femoral Rigid-fix and tibial Bio-intrafix devices provide secure graft fixation and allows aggressive rehabilitation. The clinical and functional outcome of this hybrid fixation technique is rewarding.

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1. Introduction

In anterior cruciate ligament (ACL) reconstruction, hamstring tendon grafts are replacing the popular bone-patellar tendon bone grafts that have been associated with femoro-tibial joint pain, loss of extension, and patellar tendon rupture.^{1–6} However, tendon-to-bone fixation using hamstring tendon grafts allows for less fixation strength compared to bone-to-bone fixation using bone-patellar tendon-bone grafts and is not conducive to early rehabilitation as revealed in several studies, where complete union was obtained ≥ 12 weeks after ACL reconstruction.^{2,6–8} Therefore, secure graft fixation appears to be crucial for early weight-bearing and aggressive rehabilitation after ACL reconstruction using hamstring tendon grafts. Currently, different fixation devices are being used in clinical settings. Several biomechanical and clinical studies have shown that femoral cross-pin and tibial Intrafix or Bio-intrafix devices provide increased strength and stiffness to the graft fixation.^{2,9–19} In this study, we evaluate the clinical and functional

outcomes of the knee joint after ACL reconstruction with hamstring graft, fixed with femoral cross pin (Rigid-fix) and tibial Bio-intrafix devices.

2. Materials and methods

All patients between 18 and 45 years of age who were operated for their ACL deficient knee (between Jan 2009 and Dec 2010) with autologous hamstring graft fixed by rigid-fix device in the femoral tunnel and bio-intrafix device in the tibial tunnel were prospectively evaluated. Patients with multi-ligamentous injury, infective, inflammatory or degenerative pathologies or previous history of surgery on the affected knee were excluded from the study. Presentation of the patients within 3 months of their injury was an inclusion criterion for the study. Institutional ethics committee permission was obtained and consent from the patients was taken prior to their recruitment in the study.

Preoperative evaluation included history, clinical examination, ligamentous laxity measurement using KT-1000 arthrometer, radiographs and magnetic resonance imaging of the knee joint. After complete clinical and radiological evaluation, patients were

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arthroscopically treated with ACL reconstruction using hamstring graft.

3. Surgical technique

All reconstructions were carried out under regional or general anaesthesia, with the patient in a supine position. Perioperative antibiotic prophylaxis comprised 1.5 g of cefuroxime axetil. The tourniquet was applied to the thigh with pressure maintained at 280 mmHg. The knee joint was accessed through two to three standard portals (anteromedial and anterolateral). Meniscal injuries are addressed with partial resection or balancing. Hamstring tendons (Gracilis and Semitendinosus) were harvested via a small incision over the insertion of the Pes anserinus at the anterior medial tibia by a tendon stripper, and prepared as quadruple-stranded graft (Fig. 1). The graft diameter was measured using a graft-sizing block. The femoral guide wire was drilled with appropriate femoral jig through the anteromedial portal. The femoral tunnel was drilled up to 30-mm depth with a reamer (Fig. 2) that corresponds to graft diameter and then the Rigidfix cross pin guide frame (Fig. 3) was inserted in the tunnel over the guide wire under arthroscopic control. The sleeves of the Rigidfix frame should be at the center of the lateral femoral condyle. Then the femoral guide wire was removed and the 3.3-mm sleeve-trocar assembly was inserted through the jig. Slow and gentle drilling was done so that the trocar doesn't miss the locking

Fig. 1. Preparation of quadrupled hamstring graft with four stranded separate on one side for tibial Bio-intrafix fixation.

Fig. 2. Femoral tunnel drilling through anteromedial portal.

Fig. 3. Rigidfix frame.

aperture of the jig (Fig. 4). At this point it is important to check that the pins will be placed in the center of the femoral tunnel and hence through the graft (Figs. 5 and 6). The Rigidfix guide frame was detached and removed. The graft was then pulled through and it was secured in the femoral tunnel with bio-absorbable femoral ST cross pin (Depuy, Mitek, Fig. 7).

Similarly the ACL footprint on the tibial attachment site was identified (Fig. 8) and appropriate tibial tunnel drilling was done with a tibial jig. The graft was retrieved through the tunnel and fixed with bio-Intrafix screw after the sheath placement (Depuy, Mitek, Fig. 9A,B), with knee in 20° flexion to achieve firm tension. During tibial screw fixation 30 N tension was applied to the quadrupled graft (Fig. 10). Wound was closed in layers.

4. Postoperative rehabilitation

Postoperatively, the knee was stabilized for three days by a zero-degree splint. Afterwards, flexion was limited to 90° for six weeks. Patients were allowed partial weight bearing with walking crutches immediately after surgery. Subjects were prescribed intense physical therapy for motion exercise, and to strengthen thigh muscles. Normally, full range of motion and weight bearing was achieved at 12 weeks of surgery. Patients were followed up in outpatient clinic at the end of one month, three months, 6 months,

Fig. 4. Drilling the rigid fix hole through sleeve.

9 months and 12 months. They were evaluated clinically (IKDC score and Lysholm score²⁰) and knee joint stability was measured using KT-1000 arthrometer (MEDmetric, San Diego, CA) at the end of one year. Statistical analysis was performed using SPSS software (ver. 16.0, SPSS Inc., Chicago, IL, USA).

5. Results

The mean age of patients included in this study was 29.75 years (minimum of 18 years and maximum 32 years). There were 39 males (88.6%) and 5 females (11.4%). Left side involvement was noticed in 20 patients (45.5%) and right side in 24 (54.5%) patients. The mechanisms of ACL injury in our study included sports activity ($n=26$, 59.1%) followed by road traffic accident ($n=10$, 22.7%) and daily activities ($n=8$, 18.2%). There was no obvious meniscal pathology in majority (54.5%) of the patients. In patients with meniscal tears, the medial menisci ($n=12$, 27.3%) were more commonly involved than the lateral menisci ($n=8$, 18.2%).

The preoperative Pivot shift test was +1 in 18 patients (40.9%), +2 in 22 patients (50%) and +3 in 4 patients (9.1%). At final follow up, none of the patients had grossly positive Pivot shift except one patient who had +1 Pivot shift. The mean pre-op IKDC score was 66.62 ± 5.36 . This score improved to 92.36 ± 5.30 in the postoperative period. Statistical analysis using paired *t*-test showed significant improvement ($P < 0.001$). Lysholm score in pre-op and post-op period was 68.28 ± 5.54 and 93.87 ± 4.75 respectively; the improvement was statistically significant with *P* value < 0.001 . Similarly, ligamentous stability as measured by KT-1000 showed significant improvement after ACL reconstruction. The mean anterior translation of tibia in the pre-op period was 7.45 mm and it improved to 3.89 mm after one year of ACL reconstruction. A positive correlation was observed between pre-op and post-op IKDC score with correlation coefficient of 0.808 (excellent correlation). Similarly, preop and postop Lysholm score showed significant correlation with correlation coefficient of 0.718. The correlation coefficient of preoperative and postoperative KT-1000 was 0.786 ($P < 0.0001$).

The mean of differences of IKDC preoperative-postoperative, Lysholm preoperative-postoperative and KT-1000 preoperative-postoperative were statistically analysed to look whether there was really any difference or not. The mean of difference of IKDC score in preoperative and postoperative period was -25.75 ± 3.30 (95% CI; -26.75 to -24.75). The mean of difference of Lysholm score in preoperative and postoperative evaluation was -25.59 ± 3.93 (95% CI; -26.75 to -24.75). The mean of difference

Fig. 6. The guide pin passes exactly at the center of the femoral tunnel.

of KT-1000 in preoperative and postoperative evaluation was 3.57 ± 0.85 (95% CI; -26.75 to -24.75). Statistical analysis of differences of the scores was significant with *P* value < 0.001 . This suggests that all the patients had significant improvement after ACL reconstruction with this technique of fixation.

Further evaluation of the effect of meniscus injury on the outcome revealed no significant difference between patients with ACL + meniscus injury and isolated ACL injury. Again, no significant difference in outcome was noticed between patients with medial and lateral meniscus injury after ACL reconstruction.

Average duration of surgery in this study was 80 min (range 60 min–120 min). No intraoperative complications (i.e.,

Fig. 5. Confirmation of pin placement at the centre of the tunnel with a guide pin.

Fig. 7. Bio-absorbable St cross-pin.

neurovascular injury, femoral posterior cortex blow out, tendon injury, screw breakage etc.) were observed. In the postoperative period also none of the patient presented with infection, graft failure, graft slippage, restriction of movements or knee pain.

6. Discussion

In the early postoperative period, the strength of fixation of the graft is the critical point limiting aggressive rehabilitation. The fixation has to be strong enough to withstand sudden overload or repetitive submaximal loading and stiff enough to re-establish the stability of the knee and minimize graft-tunnel motion. In addition to sufficient strength and stiffness, the fixation of the graft should be anatomic, biocompatible, safe, and reproducible and should allow undisturbed magnetic resonance imaging (MRI) of the knee. The fixation technique also should not hamper in revision ACL reconstruction surgery.² Expansion fixation that is based on press-fit fixation of a graft into the femoral tunnel by employing more than one cross pin has been reported to render satisfying results in biomechanical and clinical studies.^{10,12,14,19} This fixation provides secure fixation to the graft as the cross pins applied transversely through the graft, imparts a centrifugal pressure on the femoral tunnel. Nevertheless, the treatment results depend on the press-fit of the graft, bone density around the femoral tunnel, and correct placement of the cross pins through the graft tendon.¹⁰ The femoral rigid-fix device as employed in our study is an example of expansion fixation technique and in agreement with the literature, the outcome of rigid fix technique in our study was rewarding.

Bio-intrafix screw and its sheath (Depuy Mitek) are molded from a composite of Poly-L-lactide and osteoconductive TCP (Tricalcium Phosphate). TCP provides the osteoconductive bio-ceramic material necessary to promote bone growth into the

sheath and screw. β -TCP has been shown to dissolve and reabsorb more quickly than Hydroxyapatite. It forms a strong bone-implant interface, bonding to bone and exhibiting osteoconductive characteristics. In addition, the screw imparts uniform pressure on the four strands of hamstring graft through the sheath without causing tendon damage. The concentric placement of the screw within the sheath ensures 360° graft-to-bone placement with improved engagement. Tibial fixation in ACL reconstruction is considered as the 'weakest link'. Bio-intrafix screw with sheath design was found to be effective in providing a secure fixation to the graft in this study.

The femoral rigid-fix cross-pin and tibial bio-intrafix fixations are technically simple and reproducible.^{9,10,12,13,16,18,19} We believe that both experienced and inexperienced surgeons can fix the soft tissue graft with these devices without peroperative hurdles. Certain technical tricks definitely helped us in avoiding intra-operative hurdles. The femoral jig should be adjusted properly so that the screws do not penetrate the articular surface. The accuracy of screw track meeting the femoral tunnel was tested with a thin k-wire and it was visualized under the scope through the joint. The cross pins were inserted as close to the joint line as possible to provide outlet graft fixation. Additionally, posterior wall blow-out does not seem to be a serious problem because the graft was fixed within the tunnel proximal to its intra-articular outlet.⁹ For tibial fixation a bigger screw was always preferred. The bio-absorbable screw made up of poly-L-lactide didn't show any tissue reaction which was a potential complication of this bio-absorbable material,⁹ and the screw also sustained the initial impact of hammering. We didn't encounter an episode of screw breakage or maltracking in this study. Because of the bio-absorbable properties, the screw doesn't seem to cause problem in future magnetic resonance imaging and revision surgery.

Graft stabilization with absorbable pins inserted perpendicular to the femoral tunnel provides a secure fixation when compared with other soft-tissue fixation devices. The yield load of bio-absorbable rigid fix cross pins in a single-cycle load-to-failure test using human hamstring tendon was 868–171 N, and the stiffness was 77–17 N/mm.^{21–23} Numerous studies have evaluated the clinical outcome of rigid fix technique in ACL reconstruction and some studies have compared this method of fixation with others to have a definite conclusion.^{10,12} While comparing the Rigid-fix (n = 71) and PINN ACL cross pin techniques (n = 56) in 127 patients (N), Seo et al.¹⁰ did not observe any statistical difference in IKDC

Fig. 8. Identification of ACL foot print on tibial articular surface.

Fig. 9. A, Tibial Bio-intrafix sheath mounted on the guide; B, Bioabsorbable Intrafix screw.

Fig. 10. Graft fixation on tibial side with Bio-intrafix screw after tensioning the graft with a tensioner (30N force).

score and Lysholm score; however, 5 cases (7%) in rigid fix group and 40 cases (71%) in PINN ACL cross pin group were found to be associated with perioperative complications with statistical difference ($p < 0.0001$). They concluded that there was no resultant difference between the employment of PINN-ACL Cross Pin and Rigid-fix as femoral graft fixation for ACL reconstruction with hamstring tendon. But, PINN-ACL Cross Pin was associated with more complications with extensive operation times.

In a comparative study between femoral Rigid-fix and femoral Bio-intrafix devices (tibial side was constant with Intrafix technique) for hamstring graft fixation, Choi et al.¹⁴ found progressive increase in tibial tunnel widening after 6 months of ACL surgery in femoral Bio-intrafix group but, no such progressive widening was noticed in femoral Rigid-fix group. In fact, another study by Choi et al.¹⁷ showed less tunnel widening with femoral Rigid-fix and tibial Intrafix devices fixation. In a randomized control trial, De wall et al.¹⁵ didn't observe any significant difference in IKDC score, Lysholm score and knee stability (as measured by KT-1000 arthrometer) between standard tibial fixation with metal interference screw+staples and centrally placed polyethylene screw with sheath. They concluded that centrally placed polyethylene screw with sheath provided equivalent clinical outcomes to that of interference screw and staples at minimum 2-year follow-up. Wang et al.¹⁶ found higher failure load with tibial Intrafix fixation ($719.094 \pm 160.478 \text{ kg} \times \text{m/s}^2$) compared to bio-absorbable interference screw ($476.640 \pm 64.226 \text{ kg} \times \text{m/s}^2$). It seems that femoral rigid fix and tibial Intrafix is one of the strongest fixations in ACL reconstruction using hamstring graft.

Blagojevi et al.¹² described their result of ACL reconstruction in 30 patients. The Mitek rigid fix pins were used for femoral tunnel where as bio-absorbable screws were used for the tibial tunnel. Lysholm score and knee clinical tests were parameters used for outcome evaluation. After mean follow up of 6 months, they found excellent postoperative Lysholm score in 85% and very good in 15% of cases. Postoperative Lachman was 1+ in 15% and postoperative pivot shift was 0%. Full rehabilitation was achieved in 85% and with modifications in everyday activities in remaining 15% of patients. Donor localization morbidity was markedly reduced and they had no complications. On the basis of the improved results in graft compression as well as stability with this technique, they recommended their applied method for the reconstruction in ACL deficient knees.

Our observation of ACL reconstruction using hamstring graft with femoral Rigid-fix and tibial Intrafix techniques were outstanding. All our patients had significant improvement in IKDC score and Lysholm score. Ligamentous laxity as measured with KT-1000 also showed significant improvement with postoperative laxity of 3.89 mm only. We did not encounter any complication during the intraoperative or postoperative periods. No evidences of neurovascular injury, infection, iatrogenic fracture or graft slippage or failure were documented. An early rehabilitation could be initiated in all patients because of minimal donor site morbidity and secure graft fixation. None of the patients complained of knee pain or instability after one year follow up. The average duration of surgery was only 80 min.

The clinical and functional outcomes of soft tissue graft ACL reconstruction using femoral Rigid-fix and tibial bio-intrafix fixation devices are gratifying. These fixation devices securely fix the graft to the tunnels till biological fixation has occurred and allows aggressive rehabilitation.

Conflict of interest disclosure

None.

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