

Arthroscopic ACL reconstruction using patellar bone tendon autograft and Rigidfix fixation - A midterm functional outcome

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Summary

Background: Arthroscopic reconstruction of torn Anterior Cruciate Ligament (ACL) with bone patellar tendon bone autograft (BTB) has become the gold standard in treating ACL tear with high success rate. The purpose of this study was to prospectively evaluate the functional outcome after arthroscopic ACL reconstruction using BTB via Rigidfix femoral fixation.

Materials and method: We evaluated the result of 21 knees that have been treated with arthroscopic ACL reconstruction using BTB autograft for femoral fixation and bioabsorbable interference screw for tibia from March 2014 to August 2015. The mean follow up period was 18 months.

Results and conclusion: The Lysholm score post-operatively was 89.04. 23.8% of the 21 patients have good to excellent outcome, 66.7% patients have good to fair outcome and 9.5% patient have fair outcome.

Level of Evidence: IV.

KEY WORDS: arthroscopic ACL reconstruction, bone patellar bone (BTB) graft, Rigidfix cross pin, Lysholm score, Tegner activity scale, anterior drawer Test.

Background

Anterior Cruciate Ligament (ACL) injury is a significant cause of disability in active individuals. There are 80,000 to 200,000 of ACL injuries occurring in the United States each year¹. After ACL injury, most patients experience recurrent episodes of instability, pain and decreased function². Reconstruction of ACL allows the patient to return to pre trauma activity level and delays the occurrence of associated meniscal injury and onset of osteoarthritis³. Arthroscopic reconstruction of torn ACL with bone patellar bone (BTB) has become the gold standard in treating ACL tears with high success rate⁴. It has the advantage of bone to bone healing and it does not sacrifice the knee stabilizers⁵⁻⁸. Recently, more aggressive rehabilitation protocol has been adopted in ACL reconstruction. This requires good initial fixation strength of the graft which will allow immediate range of motion exercises and rapid return to sports activities⁹.

For bony and soft tissue graft fixation quite a few different fixation devices like Metal or Bio-interference screws, Cross biodegradable or metal pins (Rigid Fix), Retro Screws (Arthrex) and EndoButton have been developed for the last couple of years¹⁰. The conventional technique is to fix both tibial and femoral tunnel with interference screws. We are presenting in favour of BTB graft fixed with Rigidfix femoral fixation and bio-absorbable interference screws for tibia. The bone plug in the femoral tunnel is flushed with the outlet and does not suffer the “windscreen wiper effect” that occurs when the hamstring tendon rubs over the rim of the outlet of tunnel^{11, 12}. The most rapid healing time at the insertion sites found with this graft choice with 360 degree bone-to-bone (block-to-tunnel) union occurs within 4 to 6 weeks, similar to fracture healing^{12, 13}. Even though some of the biomechanical and clinical studies came up with comparable pullout strength for cross pins¹⁴⁻¹⁸, a limited number of studies showed increased slippage and inferior pull out strength¹⁹. Even though there are some studies to evaluate Rigidfix femoral fixation in hamstring tendon there are no clinical studies to show the functional outcome of cross pin femoral fixation in BTB autograft in literature.

In our study, we have analyzed the midterm functional outcome of Arthroscopic ACL reconstruction using autologous ipsilateral BTB graft and Rigidfix femoral fixation.

Materials and methods

In this study, we prospectively evaluated patients who have signed for Arthroscopic ACL reconstruction using central third BTB autograft and Rigidfix femoral fixation, who met the inclusion criteria from March 2014 to August 2014. The inclusion criteria was, all patients who are willing to participate and follow up, With no prior knee surgery, Normal contra-lateral knee, Clinical evaluation of instability by surgeon, Confirmation by MRI and arthroscopy. ACL injuries with chondral and meniscal lesions were also included in this study. All the patients had magnetic resonance imaging (MRI) of the affected knee demonstrating complete ACL tear. Exclusion Criteria included patients who lost follow up, associated intra articular fractures, multiligament reconstruction, revision ACL surgery and patients with poor compliance like psychiatric disorders and severe addicts. There were 23 cases included initially in the study. Among these two cases were excluded: one patient sustained proximal tibial fracture following a road traffic accident and second one lost follow up. Subsequently 21 patients were included and were available for evaluation at completion of one and half year. The datas were collected using study proforma with emphasis on pre op and post op variables. All patients were reviewed periodically at 2 weeks, 4 weeks, 8 weeks, 12 weeks, 6 months, 12 months and 18 months for assessment. We also enrolled our patients into four groups on the basis of time of surgery since injury and adherence to physiotherapy protocol. The adherence to our physiotherapy protocol was assessed by questionnaire method. Subsequently these subsets of patients were statistically analyzed to find out whether it has any effect on Anterior drawer test, Lachman test, Lysholm

score and extension loss. The local medical ethical board approved the study protocol and informed consent was obtained from each patient. Current study meets the ethical standards of Muscles, Ligaments and Tendons Journal²⁰.

Surgical technique

The diagnosis of ACL tear was confirmed arthroscopically and associated chondral lesions and meniscal tears were diagnosed and managed accordingly. The central third of the patellar tendon (10 or 11 mm) autograft was used as graft. Anatomic placements of the tunnels were employed. The Rigidfix Cross Pin guide was placed through the tibial tunnel and into the femoral tunnel so that the shoulder of the femoral rod could be easily seen at the tunnel edge. The Rigidfix Cross Pin guide was placed relatively parallel to the floor. The sleeve was assembled over an interlocking trocar (Fig. 1). The sleeve trocar assembly was drilled through the bottom hole of the guide into the lateral side of the femur until the sleeve hub meets the guide. The exit of the smooth pin was directly visualized through the tunnel and central positioning was confirmed (Fig. 2). In case of eccentrically placed drill sleeve, we repositioned the drill sleeve by a free hand technique. This step was mandatory in our opinion to make sure the graft was transfixed and not eccentrically snared.

The second sleeve trocar assembly was drilled through the top hole of the guide. A long guide pin was used through both the tibial and femoral tunnel and out through the lateral cortex. The femoral bone plug was advanced into the femoral tunnel until the bone face was flushed with the opening of the femoral tunnel and then the longer trocar was drilled through one of the femoral sleeves. Using the



Figure 1. Sleeve trocar assembly - Arrow showing smooth pin drilling through the sleeve.



Figure 2. Confirmation of the central position of the smooth pin by direct visualization.

stepped pin insertion rod and mallet, a 2.7 mm Mitek Rigidfix Cross Pin was inserted into the sleeve (Fig. 3). This procedure was repeated in the other sleeve, advancing a second Mitek Rigidfix Cross Pin to complete the fixation. The graft was fixed in the femoral tunnel with two parallel pins. Interference screw fixation was done on tibial side in 30 degree flexion. A postoperative locked knee brace was applied at the conclusion of the procedure.

Postoperative knee rehabilitation

Closed chain exercises were started on day one, after attaining active straight leg raising (SLR). The wound was inspected on the second postoperative day. Weight bearing as tolerated was allowed with the knee immobilized in extension and a walker support. Suture removal was done on the 14th post-operative day. Active flexion and active assisted knee mobilization at a rate of 15 degrees per week was started initiating from 45 degree in a graded manner concurrently during the same interval with a locking ACL orthosis. Patients were advised for a gradual quadriceps strengthening exercises. Walker was discontinued once quadriceps control was acquired and knee extension was achieved. Physiotherapy was continued up to 9 months postsurgery. The essentials of the supervised rehabilitation programme included swimming at 8 weeks, straight ahead jogging at 20 weeks, and gradual return to sports at 6 to 8 months postoperatively, if rehabilitation criteria were successfully achieved. A locking ACL orthosis should be worn from 4 weeks to 6 months postoperatively and for sports activities from 6 months to 1 year.

Physical examination

Physical examinations of each patient were done by two examiners during the assessment. Range of motion (ROM) was assessed by goniometer and thigh circumferences were measured in centimeters. Lachman, anterior and posterior drawer, and pivot shift tests were performed manually. Ligamentous laxity in anterior drawer test was graded as 1 (0 to 5 mm), 2

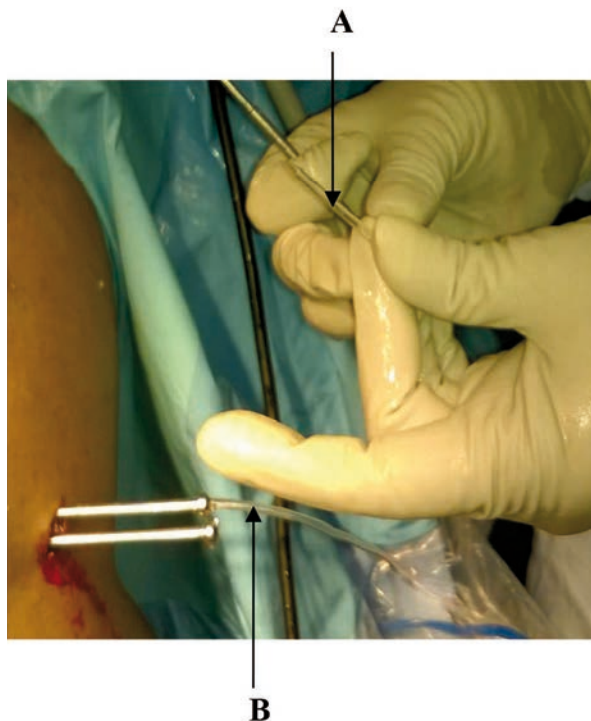


Figure. A) 2.7 mm Mitek Rigidfix Cross pin. B) Outflow of water through the sleeve confirms the position of the trocar in the femoral tunnel.

(6 to 10 mm), or 3 (10 mm). The Lachman test was quantified as Grade I (proprioceptive appreciation of a positive test) Grade II (visible anterior translation of the tibia) Grade III (passive subluxation of the tibia with the patient supine) and Grade IV (ability of the patient with a cruciate-deficient knee to actively sublux the proximal tibia)²¹. The pivot shift was done under anaesthesia preoperatively, but not graded.

Functional Scoring Scales

All the tools used in the study were validated. The patients were evaluated using the Lysholm Scoring Scale, Tegner activity scale, The Anterior Knee Pain scale and Visual Analogue scale (VAS). The patient satisfaction factor was evaluated by a pretest semi structured Questionnaire method. Lysholm postoperative rating score (0 to 100 points), and Tegner activity level (0 to 10), were calculated. The anterior knee pain questionnaire was evaluated as Mild, Moderate and Severe. Each variable was scored with visual analogue scale from 1 to 10.

Data analysis

Analysis was done by using appropriate statistical analytical method. Wilcoxon Signed Rank Test was used to assess whether there was any significant changes in Anterior drawer test, Lachman test, VAS, Score of Lysholm and Tegner activity score between preoperative stage and postoperative stage. Critical value (α) was fixed at 0.05. P Value less than 0.05 was taken as significant and less than 0.01 was taken as highly significant. The statistical correlation between compliance of the patients to physiotherapy and knee scores were tested with Kruskal Wallis Test. SPSS 17.0 version was used to analyze data.

Results

Twenty one patients who were prospectively evaluated consisted of mean age group falling into 27.7 ± 8.4 (range, 18 to 53 years). There were 19 males and 2 female patients. Left knee injuries were predominating over right. The majority of the study populations were students (38%). Thirty-eight percent of the patients sustained sports related injuries which were the most common mode of injury. About fifty-two percentage of the patients who clinically reported were those patients who sustained the injury over a period of 6

weeks. The most common presenting complaint observed was knee pain which was followed by instability and locking. The most common associated injury observed was the menisci injury, in which the medial meniscus tear was the predominating (33.33%) (Tab. I). Fifteen patients out of the total study group underwent ACL reconstruction exclusively and rest of the patients were subjected for additional surgical procedures like meniscal repair, partial and complete medial meniscectomy, complete lateral meniscectomy and medial meniscal debridement.

Our patients were clinically evaluated both pre and postoperatively at one and half year by the same surgeon using Anterior drawer test, Lachman test and range of movement (ROM). Preoperatively 13 patients showed positive anterior drawer test. It was Grade 1 in eleven patients and Grade 2 in two patients. Postoperatively 19 (90.5%) patients showed negative anterior drawer and two patients improved their grades from Grade 2 to Grade 1 (Tab. II). Preoperatively the Lachman test was graded as negative in one patient, Grade 1 in five patients (23.8%) and Grade 2 in twelve patients (57.1%), and Grade 3 in three patients (14.3%). Postoperatively 17 (81.0%) patients became Lachman negative and 4 (19.0%) patients showed grade 1 laxity (Fig. 4). The above two tests were proved statistically significant at 0.01 level. When examined under anesthesia preoperatively, all patients had a demonstrable pivot shift test. The ROM were assessed based on flexion and extension loss post operatively. The mean postoperative flexion loss when compared to the normal contralateral knee was 10.47 degree (range, 0 to 20; SD, 5.45). The mean postoperative terminal extension loss was 2.38 degree (range, 0 to 5; SD, 2.06).

The functional assessment of these patients were done by using Lysholm scale, Tegner activity scale, the Anterior Knee pain and VAS both pre and postoperatively (Tab. III). The mean Lysholm score postoperatively was 89 (range, 80 to 96; SD, 4.14) (Fig. 5). Five (23.8%) of the 21 patients have good to excellent outcome and 14 (66.7%) patients had good to fair outcome. Two patients had fair outcome and none of the patients had poor outcome. We analyzed the association between knee laxity and Lysholm score with compliance of the patient to physiotherapy. The first group and third group, those who adherent to physiotherapy, have got higher Lysholm score, 90.38 and 92.80 respectively. The extension loss

Table I. Associated meniscal injury among the patients. Medial meniscal injury is more (33.3%) in our series.

Associated meniscal injury	No: of patients	Percentage (%)
Medial meniscus	7	33.3
Lateral meniscus	2	9.5
Both menisci	1	4.8

Table II. Distribution of Anterior drawer test among preoperative and postoperative patients shown.

Anterior drawer test	Pre		Post		Z#	p
	Count	Percent	Count	Percent		
Negative	8	38.1	19	90.5	3.36**	0.001
Grade 1	11	52.4	2	9.5		
Grade 2	2	9.5	0	0.0		

Wilcoxon Signed Rank Test; **: - Significant at 0.01 levels.

Table III. Postoperative scoring scales.

Scores	Mean	Range	Standard deviation (SD)
Lysholm scale	89.04	80 to 96	4.14
Tegner activity scale	5.42	4 to 7	1.12
VAS	1.7	1 to 3	0.6

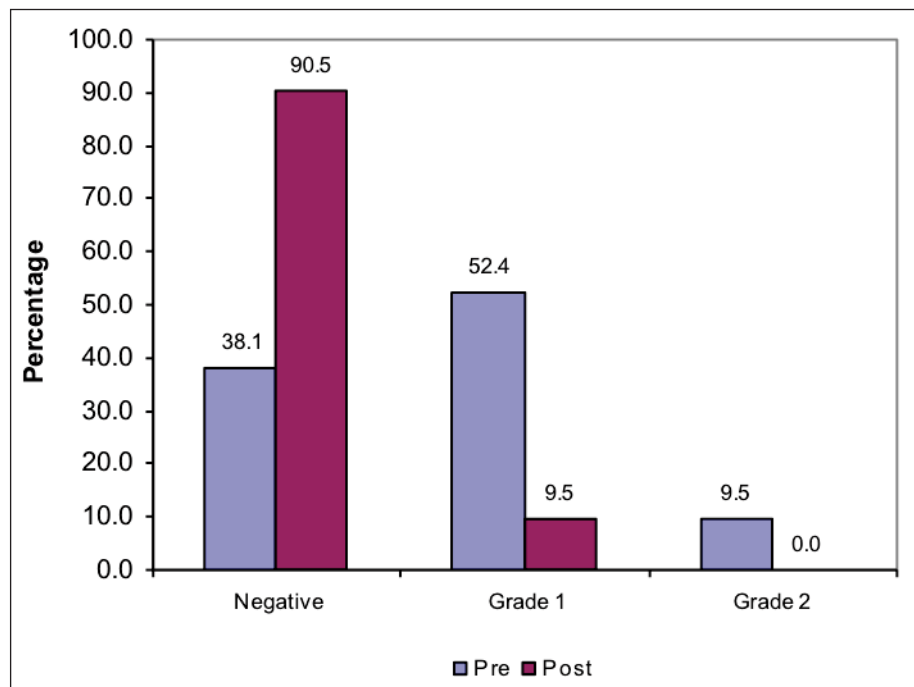


Figure 4. The distribution of the preoperative and postoperative Lachman test. Note that there is significant decrease in knee laxity from pre operative level. (Significant at 0.01 level).

documented were 4.75 degrees and 4.0 degrees in group 2 and group 4 respectively. However we couldn't find any association between knee laxity and adherence to physiotherapy among the groups. Regarding the Tegner Activity scale, the mean retrospective score before injury was 5.42 (range, 4 to 7; SD 1.12) and this decreased to 3.04 (range, 0 to 5; SD, 1.32) after injury. The mean Tegner score at the final evaluation was 5.61 (range, 2 to 9; SD, 1.6).

There was a statistically significant difference in the Tegner rating from the preinjury to the preoperative value, and from the preoperative to the postoperative value (Significant at 0.01 level). The average visual analogue scale (VAS) score at the final evaluation was 1.7 (range, 1 to 3; SD, 0.6). There was a statistically significant difference in the VAS rating from the preoperative value to the postoperative value (Significant at 0.01 level). Twenty-nine percentage of the pa-

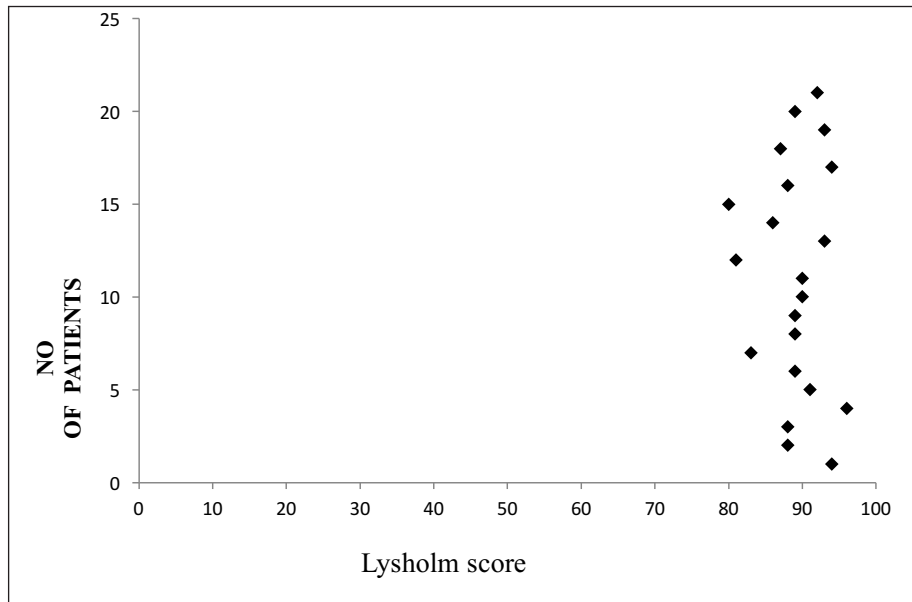


Figure 5. The distribution of postoperative Lysholm scores at follow-up is shown. The mean Lysholm score postoperatively was 89 (range, 80 to 96; SD, 4.14).

tients reported mild to moderate anterior pain while squatting and in lotus position. All the 21 patients who responded to the subjective questionnaire declared that they were completely or mostly satisfied. None of them were dissatisfied.

Discussion

There are existing conflicts and limitations regarding the initial fixation method of the BTB graft in the femoral tunnel with bioabsorbable transcondylar pin against the conventional surgeries. Even though some studies²⁰ have revealed mechanical disadvantages of Rigidfix, it does have some biological and technical advantages. Also, Rigidfix gives biological advantage of circumferential bone growth compared to interference screws. It is technically easy and fixation can be confirmed under direct vision by centering the pins in the tunnel. Further Rigidfix can be fixed without any compromise in fixation even in cases with posterior blowout. Windshield wiper effect is lower in patellar tendon ACL reconstruction²².

On the basis of our study we could conclude that Arthroscopic ACL reconstruction using central third BTB autograft and Rigidfix femoral fixation gave good stability at 1 to 1.5 year follow up. Postoperatively seventeen (81.0%) of them became Lachman negative and four (19.0%) patients showed Grade 1 laxity. Lachman, and anterior drawer test results, were all statistically significant when compared with the preoperative examination. Our results are comparable with various other studies^{23, 24}. The Lysholm score and the Tegner activity scales are the measures of health-related quality of life and patient satisfaction which has direct positive correlation with early return to activities²⁵. Five out of the 21 patients had good to

excellent outcome and fourteen patients had good to fair outcome. In our study the patients with a poor outcome score was nil. Shaieb et al.²⁶ in 2002 had done a prospective randomized comparative study, where BTB was fixed with interference screws. They studied 31 cases in total in the BTB group and had excellent and good results in 88%, fair results in 6% and poor outcome in 6%. Fox et al.²⁷ published that Lysholm knee scoring scale was used in 12 studies and the mean score was 91 (range, 85-96). In their study, Ibrahim et al.²⁴ at 2005 achieved a mean Lysholm and Gilquist score of 91.6 and 92.7 for the bone-patellar tendon-bone graft and semitendinous-gracilis (STG) groups, respectively.

Even though our mean score was comparable to the other studies, there was no excellent outcome in our study. This observation could be due the fact that our patients showed non adherence to physio rehabilitation and our follow up duration was less. Despite the fact that there were confusing evidence regarding the timing of surgery and functional outcome, non adherence during rehabilitation sessions were associated with less desirable functional outcome and greater knee laxity²⁸. To find out whether there is any positive correlation between these variables; patients were analyzed on the basis of time of surgery since injury and adherence to physiotherapy protocol. Thirteen of our patients showed compliance to the rehabilitation protocol irrespective of the time of surgery since injury. The first group and third group, who followed rehabilitation protocol strictly, resulted in higher Lysholm score, 90.38 and 92.80 respectively. Lower educational level, lower sense of personal control, poor social or family support for activity, longer treatment duration, ethnicity and recreational sports are the common barriers to the treatment²⁸. The patients with good to excellent outcome had no episodes of

locking or instability. The patients with good outcomes were able to walk without support and did not have any locking. Only minor percentage of the patients had difficulty in squatting, limping in their gait and pain on severe exertion. The patients with fair outcome had marked pain on exertion and problems in squatting. We identified the patients with associated meniscal injuries had a lower Lysholm score than those with isolated tears.

Bach Jr²⁹ had got an average Tegner score of 6.3 (range, 2 to 9; SD, 1.6) at the final evaluation. There was a statistically significant difference in the Tegner rating from the pre injury to the preoperative value and from the preoperative to the postoperative value. We demonstrated a less average score both preoperatively and postoperatively since our cohort had no patients participating in competitive sports. In literature 7 to 17 percentage of the patients were reported to be suffering from loss of motion after ligament reconstruction of knee joint which is a troublesome problem for the patients³⁰. Thirteen patients had loss of terminal extension and were advised vigorous rehabilitation programme. The mean postoperative terminal extension loss was 2.38 degree and flexion loss was 10.47 degree in our series. The extension loss was more in patients those who were absent in the most of the rehabilitation sessions. The patients with an extension loss may walk with a flexed knee resulting in patellofemoral pain and fatigue, but not necessarily quadriceps weakness. These patients were advised vigorous rehabilitation in the initial period of the study. In the present study, one of our patient had a fall on the third month of the rehabilitation who presented with stiff knee latter. The Patient Knee MRI revealed no slippage of graft or bony injury. Patient had regained 5 to 90 degree of range of motion and was advised vigorous physiotherapy after a period of immobilization of 3 weeks for soft tissue injury. We could not find any statistically significant correlation between loss of extension and patellofemoral pain.

The anterior knee pain after reconstruction of the anterior cruciate ligament (ACL) has different origins. Morbidity at the donor site is the main cause of pain with rates ranging from 11.5 prior to 22% depending on the registry used³¹. In our study reported anterior knee pain was 28.5%. Ibrahim et al.²⁶ in there comparative study made observation similar to our study i.e., anterior knee pain was recorded in 10 patients (24%) in the BTB group and 3 patients (5%) in the semitendinous-gracilis (STG) group. We could attain a good patient satisfaction in our study population by treatment with Non Steroidal Anti Inflammatory Drugs and physical therapy and modified rehabilitation program to avoid any concentric-resisted quadriceps exercises. 22.5% patients are relieved of pain by 6 months. This observation in the present study is supported by the work of Bach Jr et al.²⁹, who did a subjective analysis on arthroscopically assisted anterior cruciate ligament reconstruction using BTB autograft. In their analysis 89 of the 92 patients who responded to the subjective ques-

tionnaire declared they were completely or mostly satisfied. Three patients indicated that they were moderately satisfied. Anterior knee pain and loss of ROM were noted to be the most common complications. Recently, one of our patient developed protrusion of the interference screw at tibial side and received treatment in the form of removal of the screw.

Ahn et al.²³ conducted a clinical study on 117 knees, treated with arthroscopic ACL reconstruction by use of hamstring auto graft with femoral fixation via 2 bioabsorbable cross pins. The mean follow up period was 26.9 months. The mean Lysholm score was 93.7 postoperatively. They could eliminate anterior tibial translation in 93.1% of patients. There is also a recent study by Stephan Frosch et al.³² on 2012 which reported similar functional outcome when they used femoral bioabsorbable cross pin for femoral fixation of hamstrings graft at one year follow up. The outcomes of these studies were in harmony with our study. We evaluated the femoral tunnel size in four of our patients for an ongoing study by MRI. The tunnel shrinkage was greater in femoral cross pin group when compared to our Endobutton group. Our study had limitations like small sample size and short term follow up. However, ours represents the first study which assessed the midterm functional outcome against contemporary graft fixation techniques.

Conclusion

After understanding the biomechanics of the knee, various studies concluded that the strength of fixation is the weak point during the early postoperative period. Hence, the ideal graft fixation would allow for aggressive postoperative rehabilitation. However, conflicting conclusions are upcoming regarding initial graft fixation. Our study has reached a conclusion that the patients who had undergone this fixation method have comparable functional scoring scales, clinical outcome and minimum knee laxity with other modes of fixation. Hence this method is one of a dependable initial fixation method with no fixation failure. Transfixing options should be available in cases with posterior blowout; Rigidfix could be a valuable tool for it. Post surgery rehabilitation should be aggressive using early mobilization protocol for better functional outcome and Rigidfix is a valuable option in obese and overweight patients. Moreover, a randomized and Long-term studies are required for better understanding the outcome of arthroscopic assisted anterior cruciate ligament reconstruction using bone-patellar tendon-bone (BTB) graft and rigidfix femoral fixation.

Disclosure

Arthroscopic ACL reconstruction using patellar bone tendon autograft and Rigidfix fixation - A midterm functional outcome meets the ethical standards of the journal.

Acknowledgments

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Conflict of Interest

Each Author certifies that, no benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this study.

Human Rights

All Authors accepted ethical standards. The experimental protocols were approved by the institutional review committee and met the guidelines of the governmental agency.

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