A Prospective Comparative Study Correlating the Efficacy of Biodegradable versus Metallic Interference Screw for Tibial Sided Anterior Cruciate Ligament Reconstruction - A Unicentre Pilot Study in Jaipur, Rajasthan

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ABSTRACT

BACKGROUND

Traditionally, metallic interference screws were considered to have increased resistance to load than bio absorbable screws in anterior cruciate ligament (ACL) reconstruction. We did a comparative evaluation of biodegradable and metallic interference screws for tibial sided ACL reconstruction and also analysed complications, compared clinical outcome, did imaging study of ACL single bundle reconstruction by using titanium & newer poly–L-lactic acid (PLLA) bio absorbable screws to determine as to whether bio absorbable screw which costs double the metallic screw, is functionally better than standard metallic screws.

METHODS

This is a prospective comparative study conducted among 50 patients aged between 15 and 55 years with clinical and MRI confirmation of complete ACL tear, treated arthroscopically with ACL reconstruction with either bio absorbable (group 1) or metallic (group 2) interference screw and both the groups were compared on follow up for an average duration of 12 months. Lysholm and Gillquist Knee Scoring Scale were used and outcome scores were divided into excellent, good, fair and poor.

RESULTS

In our study 41 patients were males and 9 were females. Bio screw was used in 24 males and 6 female patients. Metallic screw was used in 17 males and 3 females. Outcome score was excellent in 26 (52 %) cases, good in 18 (36 %) cases, fair in 4 (8 %) cases, poor in 2 (4 %) cases. The mean Lysholm score in bio absorbable group was 93.13 and in metallic group was 89.70. Knee effusion was higher in bio screw group and infection rate was higher in metallic group.

CONCLUSIONS

In our study, the difference between bio absorbable screw group and metallic screw group was insignificant with regard to final patient outcome. Final osseointegration was better with bio absorbable screw, but increased cost of implant and almost same results compared to metallic screw does not make the bio absorbable screw superior to its counterpart.

KEYWORDS

ACL, Bio Absorbable Interference Screws, Metallic Interference Screws

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BACKGROUND

The anterior cruciate ligament connects the femur to the tibia and plays an important role in the stabilization of the knee by guiding normal joint motion. Injuries to the knee can result in a rupture of the ligament and thereby increased joint laxity. Significant joint laxity often ends participation in competitive sports and may, in the medium to long term, leads to degeneration of the knee. The occurrence of ACL injuries has increased in recent years and, diagnosis is done by thorough clinical evaluation by clinical test such as Anterior drawer test, lachman test, pivot shift. It is very crucial to rule out other ligaments like posterior cruciate ligament (PCL), lateral collateral ligament (LCL), ACL and associated meniscus lesion while doing clinical assessment.

The MRI provides a non-invasive visualization of the ACL and other soft tissue structure in the knee joint, any other associated ligament injury, partial tear, chronic tear. There are certain primary signs of injury on MRI such as Non visualization of the ACL in its usual location, focal interruption, angulation / nonlinearity, flattened axis of distal ACL with poor visualization of proximal ACL. Arthroscopy is considered one of the greatest innovations in the diagnosis and treatment. Today, ACL reconstruction is one of the most common procedures in orthopaedic surgery. The goals of ACL reconstruction are to improve functional outcomes, restore knee joint stability, and prevent subsequent damage to the remaining intra-articular structures.[1]

Interference screws used in Hamstring tendon ACL graft fixation are low profile and allow intra-articular placement and rigid fixation, and also allow early range of motion. Till now titanium used to be the material of choice for this device. Titanium screws provide high initial fixation strength and promote early integration into the bone, but, in case of revision surgery, hardware removal may be technically challenging, and also certain disadvantages like there is risk of injury to the graft, loosening of the screw in posterolateral recess, blowing out of posterior cortex, while advancing the screw the graft can change its position. The advantages of absorbable screws consist of reduced MRI artifacts and no need to remove the implant, justifying the widespread use of bio absorbable screws.[2,3]

Bio absorbable materials were developed to overcome these perceived weak points, but some disadvantages like risk of foreign body reaction, viscoelastic deformation. Different combinations of synthetic materials have been used: PGA (polyglycolic acid), copolymers of PGA / PLA (polyglycolic acid / poly lactic acid), poly-p-dioxanone and various stereoisomers of lactic acid, poly-L-lactic acid and poly–D-lactic acid.[4,5,6]

Traditionally, metallic interference screws (MISs) have afforded reliably positive clinical outcomes, prevention of excessive laxity, and low complication rates.[7] MISs promotes early integration into bone with high initial fixation strength and has a higher failure-load than bio absorbable interference screws (BISs) in biomechanical studies.[8]

Objectives

To analyse complications, compare clinical outcome, do imaging study of ACL single bundle reconstruction by using titanium & newer poly–L–lactic acid (PLLA) bio absorbable screws and assess if the bio absorbable screw which costs double the metallic screw, is functionally better than standard metallic screws or not, also to further assess post-operative results of each of the above fixation methods using Lysholm knee score.

METHODS

This prospective comparative study was conducted in 50 patients aged between 15 - 55 years in The Department of Orthopaedics, Dhanwantri Hospital & Research Centre, Jaipur from June 2017 to May 2018. The permission from the ethical committee of the institute was taken prior to the study. Sample size calculation was done by the following formula.

$$n = \frac{Z^2\sigma^2}{\mathrm{E}^2}$$

Where "n" is the sample size,
E 2 Z = 2.576 for 99 % level of confidence
1.959 for 95 % level of confidence
1.645 for 90 % level of confidence

Confidence Level	95 %
SD	3.7
Standard error	1.049298
Alpha divided by 2	0.025
Z score	1.959964
Sample size	48

Table 1. Sample Size Calculation Variables

By calculation, the sample size was 48 and we took 50 patients for the study. Patients presenting with unilateral knee complaints and history of trauma to the knee attending the outpatient department of our hospital were evaluated by sequential general, physical and local examination of the knee. In a relaxed patient and in supine position, the uninjured knee was examined first to establish ligament excursions after which the affected knee was examined. The following specific tests were performed for diagnosing anterior cruciate ligament deficiency: Lachman test, anterior drawer test, pivot shift test. Injuries to the associated structures were assessed by performing the following clinical tests: Valgus / Varus stress test for collateral ligament injury, McMurray's test and Apley grinding test for meniscal injury. MRI was advised in suspected cases of internal derangement of knee and cases with ACL injury were admitted for further workup and planned for arthroscopic ACL reconstruction.

Inclusion Criteria

1) Clinically and radiologically confirmed ACL tear.
2) Patients of 15 to 55 years of age.

Exclusion Criteria

1) Chondral lesions.

2) Bilateral knee injury.
3) Infection.
4) Osteoarthritis knee with chronic ACL tear.
5) Collateral or PCL injury.
6) ACL re-tear.
7) Below 15 and above 55 yrs. age.
8) Tibial plateau injury.

Preoperative work up such as blood routine, triple serology, coagulogram, ECG, CXR along with x-ray of the affected knee anteroposterior (AP) & lateral views and MRI of the affected knee was done. The range of movement and quadriceps strength were noted pre-operatively. Quadriceps exercises (static & dynamic) were taught to patients before surgery. Physiotherapy department explained the post-operative rehabilitation protocol to all the patients.

Consent

All the patients in this study were explained about the injury, diagnosis, various management options, complication of non-operative treatment and operative management, per-operative & post-operative complications, donor site morbidity, injury to surrounding structures, infection, compartment syndrome, anaesthesia risks, post-operative knee pain, restriction of range of motion. Consent was obtained from all the patients who were included in this study prior to the surgery. Patients and their attenders were well explained about the advantages and disadvantages of procedure. Risk benefit ratio was explained.

Study Procedure

Patients in the study were operated in supine position under spinal anaesthesia. A pneumatic tourniquet was used. Before harvesting the graft, diagnostic arthroscopy was done first. In 90 degrees of knee flexion, anterolateral port (viewing port) was made using no. 11 blade at the level of inferior pole of patella just lateral to the patellar tendon and knee was examined in sequential manner starting from suprapatellar pouch, patellofemoral joint, medial gutter, medial meniscus, intercondylar notch, lateral meniscus, lateral gutter and finally posterolateral compartment. After doing the diagnostic round the working anteromedial portal was established. In all the cases ipsilateral hamstring graft was harvested. A 3 cm oblique skin incision was made starting 5 cm below the medial joint line and 1 cm medial to the tibial tuberosity. The oblique incision was preferred because it gave a wider exposure of pes anserinus and there was less chance of injury to the infrapatellar branch of the saphenous nerve. The notch was deepened by 2 – 3 cm starting anteriorly on the articular surface of the intercondylar notch 2 – 3 cm superior to the margin (notch preparation and notchplasty). Endobutton was used on the femoral side to fix the graft. The tibial tunnel was made with the help of the tibial guide. With the knee in 70 – 90 degrees of flexion, the tip of the tibial guide was placed 2 – 3 mm anterior to the anterior horn of lateral meniscus and slightly medial to the midline of the ACL tibial attachment area. Then the tibial tunnel was made by reaming over the guide pin using cannulated drill bit with diameter equal to the diameter of the graft. After the graft had been prepared, based on the length, the graft was quadrupled, and the loop part was attached with endobutton. Before fixing the graft on to the tibial side, cyclical stretching of the graft was routinely done. Decision of tibial sided ACL fixation with metallic screw or bio screw was decided by chit method. After the surgery the limb was immobilized with knee brace and an antero-posterior and lateral x-ray of the knee was taken to confirm the placement of tunnel, endobutton and interference screw. Intravenous antibiotics were given postoperatively for 3 days. Wound was inspected on 2nd and 7th post-operative day. The sutures were removed on 12th post-operative day. A standard ACL rehabilitation program was started from the post-operative day 1.

Follow Up

Patients were followed up on 2nd & 6th weeks, 6 months and 1 year and plane x-rays of operated knee was taken in antero-posterior & lateral view on each visit, to assess the graft related complications. The patients who were operated using bio absorbable screws were tagged as group 1 and patients with metallic implant group 2. Both the groups were given scores using Lysholm and Gillquist Knee Scoring Scale and outcome evaluated based on following parameters:

1) Knee swelling (max. 10 - min. 0)
2) Climbing of stairs (max. 10 - min. 0)
3) Knee pain (max. 25 - min. 0)
4) Knee instability (max. 25 - min. 0)
5) Episodes of knee locking (max. 15 - min. 2)
6) Limping (max. 5 - min. 0)
7) Aided walking (max. 5 - min. 0)
8) Squatting (max. 5 - min. 0)

The above parameters were scored on the patient's functional ability from maximum to minimum. The maximum score corresponds to a favourable outcome and calculated as mentioned against each parameter. The total score was 100. The patients were categorised as Excellent if scores were 95 – 100, good if 84 – 94, fair if 65 – 83 and poor if scores were 64 or less. At the end of follow up, both the groups of patients were compared by their post-operative complications and Lysholm knee score and detailed observation & results were formed.

Statistical Analysis

Data obtained was coded and entered into Microsoft Excel spreadsheet. The categorical data was expressed as rate, ratio and percentage. The continuous data was expressed as mean ± std. deviation. A 'P' value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

The data obtained was coded and entered into the Microsoft excel Spread Sheet. The data was analysed and results obtained were tabulated. In our study 41 patients were male

and 9 patients were female and male to female Ratio was 4.6:1. Age of the patient varies from 15 to 55 years. Minimum age was 15 years and maximum age was 55 years. In our study 38 patients had right knee ACL tear in which 23 (76.7 %) were operated with bio screws and 15 with metallic screws. The 12 patients having left knee ACL tear, 7 (23.3 %) were operated with bio screws and 5 with metallic screws. In the study 35 patients had ACL insufficiency due to renal tubular acidosis (RTA), 11 patients had injury due to sports i.e., cricket, football, kabaddi. 4 patients had trauma by other means i.e. hit by object, self-fall. In our study 41 patients were males and 9 patients were females, out of that bio screws were used in 24 male patients and 6 female patients. Metallic screw was used in 17 male patients and 3 female patients. Mean age group for bio-screws was 28.40 with std. deviation of 9. 287. Mean age group for metallic screw was 35. 30 with std. deviation of 7. 320.

Complication	Tibial Sided Fixation Device		Percentage
	Bioabsorbable Screw	Metallic Interference	
Screw breakage	Nil	Nil	0 %
Graft damage	Nil	Nil	0 %
Knee effusion	3	0	6 %
Infection	2	1	4 %
Graft failure	Nil	1	2 %
Total	5	2	10 %

Table 2. Complications of Implant

Lysholm Score (Grade)	Bio Screw Group			Metallic Screw Group		
	Frequency	%	Valid %	Frequency	%	Valid %
Excellent	19	63.3	63.3	7	35.0	35.0
Good	8	26.7	26.7	10	50.0	50.0
Fair	3	10.0	10.0	1	5.0	5.0
Poor	0	00.0	00.0	2	10.0	10.0
Total	30	100.0	100.0	20	100.0	100.0

Table 3. Statistical Analysis of Two Fixation Methods

	N	Minimum	Maximum	Mean	Std. Deviation
Age (yrs)	30	17	46	28.40	9.287
Time since injury (months)	30	1	12	6.57	2.861
Lysholm score (value)	30	80	97	93.13	4.614
Follow up (months)	30	8	16	11.57	1.995

Table 4. Descriptive Statistics for Bio Screw Fixation Device

	N	Minimum	Maximum	Mean	Std. Deviation
Age (yrs)	20	18	49	35.30	7.320
Time since injury (months)	20	2	12	7.40	3.050
Lysholm score (value)	20	64	97	89.70	10.408
Follow up (months)	20	7	15	11.55	2.373

Table 5. Descriptive Statistics for Metallic Screw Fixation Device

	Fixation Device	N	df	Mean	Std. Deviation	T-Value	P-Value
Lysholm score (value)	Bio screw	30	48	93.13	4.614	1.37	0.18
	Metallic screw	20		89.70	10.408		

Table 6. Group Statistics

The interval between injury and surgery ranged from date of injury to 1 year with maximum patients (42 %) getting operated within 4 to 6 months. The most common presenting symptom was knee pain and instability in the series. The other less common presenting symptoms were locking of the knee and knee pain with instability. Total number of cases according to fixation device–bio screw was used in 30 patients and metallic screw was used in 20 patients in total.

Complications were divided into intraoperative and postoperative. No patient had intraoperative complication; two patients had developed superficial infection which was managed with IV antibiotics. One patient had developed deep infection which was managed with IV antibiotics followed by wound debridement. Wound healed completely after 10 days. Three patients had developed knee effusion in which bio screw was used. Effusion had subsided at repeated follow up. One patient had graft failure at 9th month follow up in which metallic screw was used. Arthroscopic debridement done in this patient and revision ACL reconstruction was done. On tibial side fixation, rate of complication was higher in bio absorbable screw then metallic screw. Knee effusion was higher in bio screw group and infection rate was higher in metallic group. Outcome according to Lysholm score in the present series was excellent in 26 (52 %) cases, good in 18 (36 %) cases, fair in 4 (8 %) cases, poor in 2 (4 %) cases because of infection in one patient and graft failure in one.

DISCUSSION

Metal interference screws were first described in ACL reconstruction surgery and bio absorbable interference screws were developed to overcome some weak points related to their ferromagnetic quality and the difficulty in removal during revision surgery.[9] There are some disadvantages of bio-screw, like, higher chance to break during surgery and may also lead to inflammatory reactions which may lead to knee effusion. As for the specific measures taken into account to assess clinical results obtained by the procedure using the two different materials, all the studies[10,11] presenting range of motion of the knee did not show significant differences between two groups at long-term follow-up.

Our study tries to give clinically relevant evidence analysing imaging assessment and complication and comparing clinical outcome of the metallic and bio absorbable screws for single bundle ACL reconstruction to assess whether bio absorbable screws are more effective or as effective as standard metallic screws despite being more recent and costlier.

In our study lysholm knee score was higher in bio absorbable groups with maximum follow up of up to 12 months. The mean lysholm score in bio absorbable group was 93.13 and in metallic group the mean lysholm score was 89.70. On the other hand, McGuire et al.[12] reported that measured clinical outcome by Tagner activity level was better with bio absorbable screw group than the counterpart, though the sample size was small in his study.

Tunnel widening, considered as an inflammatory reaction to the implanted screw mediated by inflammatory cytokines.[13] Tunnel widening was observed more with bio absorbable screws compared with metallic interference screws.[14,15,16] The final outcome achieved by the patients did not seem to be ultimately affected by a wider diameter of the tunnel measured at MRI assessment. In our study, till the end of follow up, none of the patients showed tunnel widening on MRI or any clinical signs of the same.

McGuire et al.[12] suggested that screw breakage was another complication which can be prevented by an additional 0.125 mm to the core diameter of 7 mm screw, it increases the strength of the screw. Cases were having graft damage due to wrong technique while applying torque.

In our study, complications were divided into intra-operative (graft damage, screw breakage), and postoperative (graft failure, infections, knee effusion). The student t-test with unequal variance was computed to analyse the significance of difference between mean score of the groups. The t-value was 1.37 and P-value was 0.18. The P-value in analysis was greater than alpha ($P > 0.05$), implying there is no strong evidence against null hypothesis. It shows that difference in complication between bio and metallic screw was not significant, but bio absorbable screw group are slightly more commonly associated with intra and postoperative complications. In particular, we considered remarkable how screw breakages were associated only with procedures using bio absorbable screws, which may suggest a lower intrinsic mechanical resistance of this class of device. However, screw breakages occurred more frequently in the early studies, and only when screws > 7 mm in diameter were used.[12,14,17-20] Likewise, no overall significant differences in incidence could be found regarding infections and graft failure, but there was a slight increase in the risk of effusion in the bio absorbable screw groups.

Moisala et al.[17] reported that due to difference in the mechanical properties of Bio and metallic screw, bio absorbable screw puts a negative effect on graft healing, that's why graft failure is more common with bio absorbable screw. In our study graft failure was reported in one case in which metallic interference screw were used.

Finally, we evaluated the methodological quality of the studies using Coleman methodological score,[21] a validated score already adopted by authors reviewing the literature published about many orthopaedic techniques and disorders[2-5] and the average score 74 / 100 suggests good methodological quality. Indeed, most of the studies included in this systematic review were prospective randomized controlled trials, providing conclusions supported by a solid level of evidence because of protocol and study design.

CONCLUSIONS

In our study, the difference between bio absorbable screw group and metallic screw group was insignificant with regard to final patient outcome. Final osseointegration was better with bio absorbable screw, but increased cost of implant and almost same results compared to metallic screw does not make the bio absorbable screw superior to its counterpart.

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