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Original Research Article

A radiological evaluation of loop length change in adjustable versus fixed loop femoral cortical fixation devices in arthroscopic anterior cruciate ligament reconstruction: a prospective study

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ABSTRACT

Background: In anterior cruciate ligament reconstructions, fixed devices require over-drilling to flip the button whereas loops of adjustable devices can be adjusted intraoperatively, and they minimize over-drilling. But they can loosen rendering the reconstruction incompetent. Most studies comparing them are bio-mechanical studies. Our aim was to record and compare loop length change radiologically in adjustable versus fixed devices in clinical settings.
Methods: 32 patients were divided into 2 groups of 16 patients each. Hamstring graft were prepared. It was loaded in the suspension device and the apex of the graft was marked using silicon vascular radio-opaque marker. In adjustable devices, lengthening was checked after cycling and re-tensioning was done intra-operatively. Post-surgery, digital X-ray of the knee was taken in true antero-posterior and lateral view. Distance between the centre point of the button and the centre-point of the radio-opaque inert silicon marker was recorded at immediate post-operative and at 6 weeks respectively and compared.
Results: 15 patients in each group were incorporated. Intra-operatively, loop lengthening was seen in all 15 patients with adjustable loop and re-tensioning was done. 2 of the 15 cases showed evidence of radiological loop lengthening however in both cases the lengthening was less than 3 mm and thus was not significant.
Conclusions: We in in vivo radiology based clinical study did not find any significant loop lengthening in patients with adjustable loop devices. Hence fixed and adjustable loop devices are comparable.

Keywords: Fixed, Adjustable, Loop-lengthening, Button, Radiological, ACL

INTRODUCTION

Arthroscopic anterior cruciate ligament reconstruction (ACLR) is currently the gold standard treatment for anterior cruciate ligament tear.[1-3] The success of anterior cruciate ligament reconstruction surgery depends on the surgical technique, graft selection, and the mechanical properties of the fixation device used to secure the graft before integration.[4] The most susceptible links in the early post-operative period are the fixation points of the reconstructed graft in femoral and tibial tunnels. Animal studies have reported that the most common tendon grafts may require 6 to 12 weeks for tendon-bone incorporation for autografts, and allografts may require up to 6 months. Therefore, if anterior cruciate ligament (ACL) grafts are not rigidly secured during the initial healing period, migration of the graft may occur and lead to persistent laxity, instability, and functional failure.[3,5] Cortical

suspension fixation devices are currently the method of choice for fixation of the femoral end of the graft and these can be either fixed loop or adjustable loop devices.[3,7,8] Fixed loop cortical suspension devices have been the first-generation loop devices which is still the standard device of choice for arthroscopic ACL reconstructions. But they have their own limitations, which include requirement for over-drilling of femoral socket for flipping the button, precise calculations for the length of tunnels, more technicality in the surgical procedures and bungee-cord effect.[3,10] In order to overcome these problems, adjustable or adjustable loop suspensory fixation devices were introduced.[3] They can be tightened intra-operatively and eliminates the need for multiple loop sizes thus reducing the inventory and is technically less cumbersome. They also ensuring that a minimal length of 2.5 cm of graft irrespective of the length of femoral tunnel is available for incorporation, which is particularly important with the relatively short femoral tunnels frequently produced with anatomic ACL reconstruction.[3,5] However, there has been some concern that the intended flexibility of these adjustable loop devices introduces the possibility of loop lengthening and subsequent graft displacement. A displacement of more than 3 millimetres, in the initial period of graft healing, have been found to cause significant laxity of the reconstructed anterior cruciate ligament graft and might lead to failure of the soft tissue graft as a whole, in biomechanical as well as in vivo models.[2,3,7] Hence, the best femoral suspensory device in ACL reconstruction remains controversial. Few studies have actually compared the fixation devices used for ACL reconstruction and most of them are bio-mechanical studies.[5] Our study aims to determine radiologically whether cortical suspension femoral fixation devices-particularly adjustable loop devices undergo loop lengthening in early pre-operative period, whether adjustable loop devices lengthen more compared to fixed loop devices in-vivo and to assess radiologically that whether this lengthening in vivo can be significant enough to cause laxity of the reconstructed anterior cruciate ligament and lead to failure of the reconstruction as a whole.

METHODS

The study was a prospective cohort study. The study was conducted at Max Superspeciality Hospital, Shalimar Bagh, a 300 bedded tertiary care super speciality hospital in New Delhi. The duration of the study was from May 2019 to September 2020. All skeletally mature adult patient diagnosed clinically and radiologically with complete anterior cruciate ligament tear admitted for arthroscopic anterior cruciate ligament reconstruction who presented at this hospital within the time period for conduction of the study were included. Patients with associated multiple ligament injuries of the knee, with any other implant in the knee interfering with the radiological evaluation as per protocol, patients where the adjustable loop is being use by necessity of positioning short graft, patient with open epiphysis and patients who have had previous knee surgery, revision ACL reconstruction, or osteotomy performed at the time of ACL reconstruction were excluded. The mean displacement values and standard deviations used to calculate sample size of each group was taken from the results of a study published in 2014 by Eguchi et al.[5] For fixed loop femoral fixation device, mean displacement taken was 4.82 millimetres with standard deviation 0.97 mm. In case of adjustable or variable loop femoral fixation device, the mean cyclic displacement was 5.98 millimetres and standard deviation taken was 1.22 millimetres. Power to calculate the sample size was taken as 80%. Alpha was taken 5%. Confidence interval was 95%. Two-sided Z value for 95% confidence interval was 1.96. Minimal sample size for each group, derived using the above-mentioned values, was 15. Taking 15 as the minimal sample size for each group, it was increased by 5% in each group to include dropout rates. The final sample size was calculated to be 16 in each group. So total number of patients to be included in the study was calculated to be 32. Block randomization technique was used to decide on one of the two types of femoral fixation devices, for the participants of the study and to allocate them into one of the two groups. The block randomization was carried by an impartial third person. The size of the blocks and number of blocks was not revealed to the investigator till the end of the study to avoid selection bias and predictability. The participants of the study were contacted once they were registered and started receiving in-patient care. All the participants were made aware about the purpose of the study, outline of the surgery they were about to undergo, functions of femoral fixation device and about various type of femoral fixation devices used in arthroscopic anterior cruciate ligament reconstruction. Written informed consent was taken from all. Detailed history including time of injury, mode of trauma, chief complaints after injury, difficulty in daily activities and function of the knee pre- and post-injury was taken from each participant. Routine pre-operative investigations were done and pre-anaesthetic check-up was performed prior to surgery. The patients underwent arthroscopic anterior cruciate ligament reconstruction by a single team of surgeons. All routine steps of surgery were followed. Usage of implants from a single manufacturer was ensured. (Depuy Mitek Rigidloop™ cortical fixation system-J&J Medical Devices). Femoral fixation device to be used was decided as per the sequence of the blocks created during randomization. An inert silicon vascular loop marker (SurgX™ OT lab accessories vessel loop yellow maxi, silicone) was tied and sutured on the soft tissue graft at a fixed distance from the femoral fixation device button. Details of the surgery including length of femoral and tibial tunnels, length of reaming of each tunnel, diameter of the graft, type of femoral fixation device used and length of biodegradable screw for tibial fixation was recorded in each case. A digital X-ray of the participant's operated knee was taken post-operatively in true antero-posterior and true lateral view following surgery. The femoral fixation device button and the inert silicon vascular marker were identified in both the views. The distance between the button and the marker was

measured both in antero-posterior and lateral views and recorded. Participants were usually discharged one day after surgery. Standard post-operative rehabilitation protocol for anterior cruciate ligament reconstruction was ensured. X-ray of the operated knee in true antero-posterior and true lateral views with same magnification were repeated at 6-weeks post-operative period for all the participants. The femoral fixation device button and the inert vascular loop markers were identified in both the views and distance between them was calculated. The values were recorded and compared to the immediate pre-operative values noted previously. Difference in values was noted as lengthening of femoral fixation suspension device loop. Data was entered and managed in Microsoft excel 2010. Data was analyzed in Stata 12.0 (Stata Corp LP, College Station, Texas, USA). Continuous variables were reported as mean±standard deviation (SD). Categorical variables were expressed in proportions. For categorical variables Chi-square test and Fischer's exact test were used wherever appropriate. For continuous variables, t-test was applied. The p value less than 0.05 were considered statistically significant. Ethical clearance was obtained from the Max Healthcare Ethics Committee. Complete information regarding the study was provided to each of the participant. Informed written consent was obtained from all the participants.

RESULTS

A total of 32 patients were included in the study. The patients were divided into two groups of 16 patients each based on the type of femoral fixation device used. One patient in each group was lost to follow-up. So, 15 patients were finally available in both the groups for post-operative x-rays immediately and at six weeks. Hence, the response rate for participants in both the fixed and variable group was 93.75%. Out of the 15 patients in the fixed loop group 11 were males (73.3%) and 4 were females (26.7%). In the variable loop group, 13 out of the 15 participants were males (86.7%) and 2 were females (13.3%). The mean age of participants in the fixed loop group was 25.9 years (SD=11.2). For the variable loop group, the mean age was 29.3 years (SD=8.6). Age wise distribution of participants is enlisted in Table 1. The mean interval between the injury and surgery was 43.7 days (SD=29.0) for the fixed loop group and 35.3 days (SD=19.0) for the variable loop group. The earliest a patient underwent surgery was 21 days after injury. The maximum number of days between injury and surgery for a patient in the study was 120.

The mean diameter of the femoral end of the autologous hamstring grafts in fixed loop group measured was 7.9 millimeters (SD=0.5). In the variable loop group, the mean femoral end diameter was also 7.9 millimeters (SD=0.3). The highest and lowest graft diameters recorded in both the groups were 8.5 millimeters and 7 millimeters respectively. The mean tibial diameter of the participants of the fixed loop group was recorded as 7.9 millimeters (SD=0.5). The mean tibial diameter of the patients in the adjustable group was found to be 7.9 millimeters (SD=0.3). The highest and lowest diameters of the tibial end of the grafts were recorded as 8.5 millimeters and 7 millimeters respectively. The mean length of femoral tunnel in the fixed loop group was 38.7 millimeters (SD=1.8). The mean length of the femoral tunnel, in case of the adjustable loop group, was calculated to be 37.9 millimeters (SD=0.9). The mean tibial tunnel length in millimeters, for patients in the fixed loop group was calculated to be 38.9 millimeters (SD=1.0). For the adjustable loop group, the mean tibial tunnel length was found to be 38.1 millimeters (SD=1.6). Subsequently, the femoral tunnel was reamed with a wider reamer as per the measured graft diameter. The mean length of the femoral tunnel up to which it was reamed with a wider reamer for the fixed loop group was recorded as 29.7 millimeters (SD=2.6). For the variable loop group, the mean length was recorded to be 25 millimeters. (SD=1.5). The p value was calculated to be 0.01 and the difference was calculated to be significant (Table 2). Thus, over-reaming of bone was necessary in patients operated with fixed loop group.

Intra-operative loop lengthening was observed in eight out of fifteen patients in the variable loop group after the tibial fixation, varying between two to four millimetres as measured using the arthroscopic probe. In all these cases, the loop had to be shortened again by re-tightening the loop. On re-evaluation, no further slippage was observed arthroscopically in any of these patients following cycling of the knee. In the subsequent follow up as per our protocol at 6 weeks, none of these eight patients showed lengthening of loop after retightening of the loop intra-operatively. In the fixed loop group, we found associated meniscal injury in four patients. Two of them had partial tear of the lateral meniscus and debridement of the damaged part was done. Radial tear in the white zone was identified in the medial meniscus one patient and partial menisectomy was performed. In the other patient Menisco-capsular tear was found in and was repaired. Length of the harvested tendon were found to be short in one patient.

Table 1: Distribution of demographic variables (p value <0.05 is considered to be statistically significant).

Variables	Fixed loop	Variable loop	P value
Age in years (mean±SD)	25.9±11.2	29.3±8.6	0.37
Sex distribution with percentage			
Male	11 (73.3)	13 (86.7)	0.47
Female	4 (26.7)	2 (13.3)	
Interval between injury and surgery in days (mean±SD)	47.3±29.0	35.3±19.0	0.19

Table 2: Intra-operative variables of the participants (p value <0.05 is considered to be statistically significant).

Variables (mean±SD)	Fixed loop group	Variable loop group	P value
Femoral graft diameter in millimeters	7.9±0.5	7.9±0.3	0.82
Tibial graft, diameter in millimeters	7.9±0.5	7.9±0.3	0.82
Femoral tunnel length in millimeters	38.7±1.8	37.9±0.9	0.14
Tibial tunnel length in millimeters	38.9±1.0	38.1±1.6	0.11

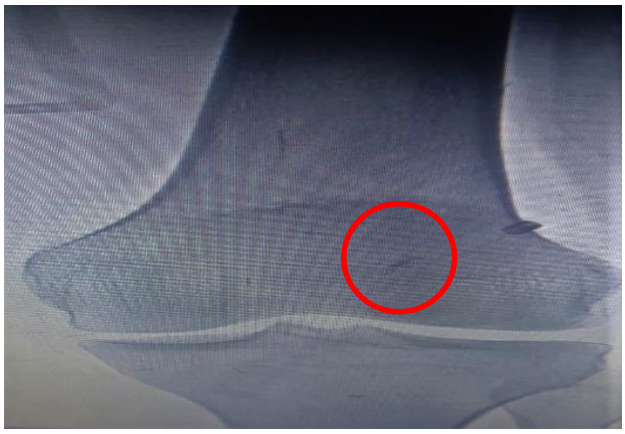

Figure 1: X-ray of participant with button and marker (highlighted) in A-P view.

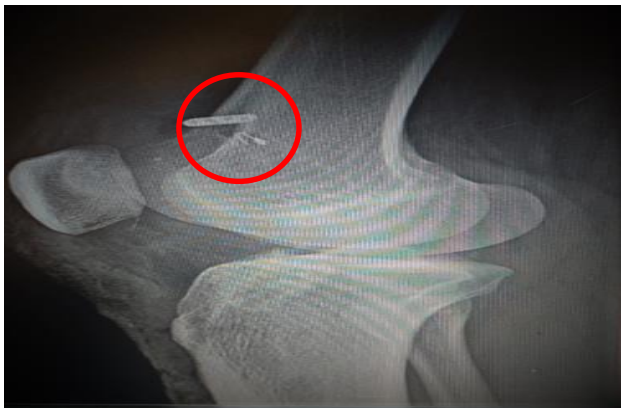

Figure 2: X-ray of participant with button and marker (highlighted) in lateral view.

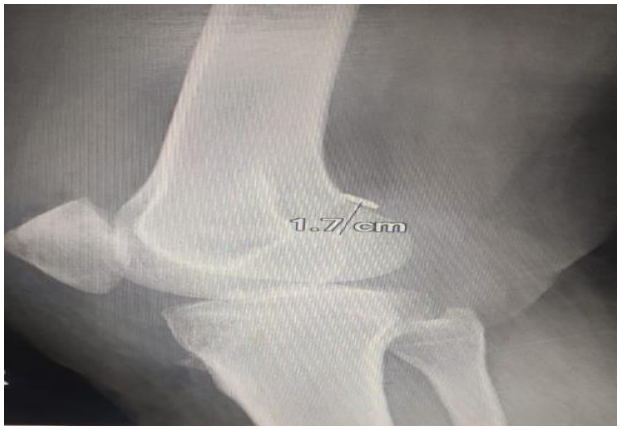

Figure 3: X-ray with distance between button and marker in lateral view immediate post-op fixed loop.

In the adjustable loop group, partial medial menisectomy was done for two patients with medial meniscus tear. As per the study design, distance between the button and the radiological marker for each patient was measured at immediate post-operative period and at 6 weeks. A loop length change of more than 3 millimeters (0.3 centimeters) was considered significant. Loop length changes of all the participants in both the groups were recorded and it was determined whether significant loop length change occurred to cause laxity of the construct. In the fixed loop group, no increase in the distance between button and marker was found in any of the patient in both the views-antero-posterior and lateral.

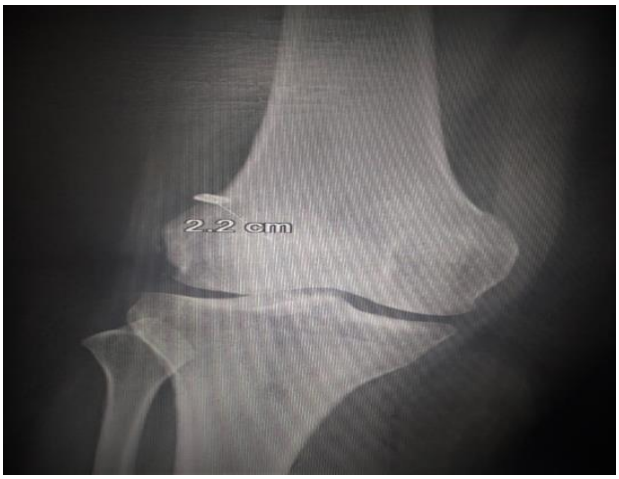

Figure 4: X-ray with distance between button and marker in AP view immediate post-op fixed loop.

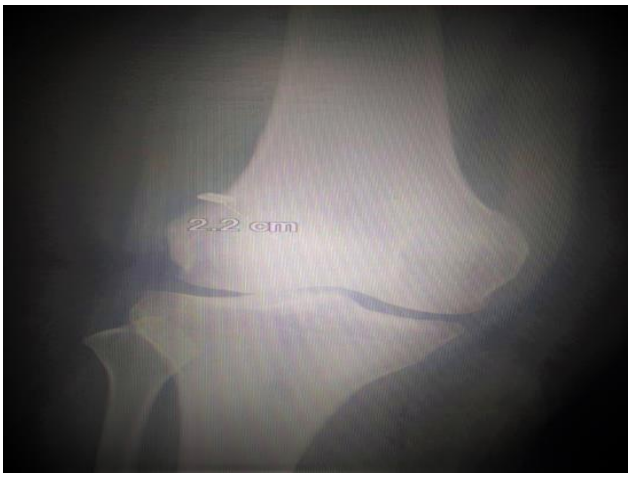

Figure 6: X-ray with distance between button and marker in lateral view at 6 weeks-fixed loop.

Thus, the construct was stable in all of the 15 patients included in the group. In the variable loop group, radiological loop length change was observed in 5 out 15 participants included in the group. Out of these 5 cases, loop length change in 3 cases was less than 3 millimeters (0.3 centimeters) and thus was not significant enough to cause laxity of the reconstructed ligament. Of the remaining two patients, one had loop length change of 0.3 centimeters and the other 0.4 centimeters respectively in both antero-posterior and lateral views and hence was significant enough factor to cause laxity of the ligament. This difference in these two groups was not statistically significant (p value=0.483).

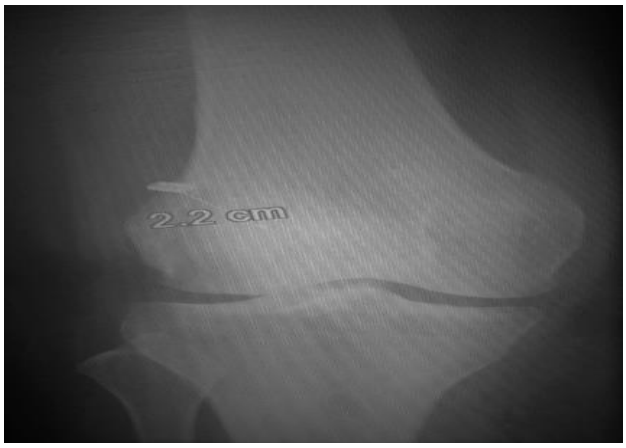

Figure 7: X-ray with distance between button and marker in AP view at 6 weeks-variable loop.

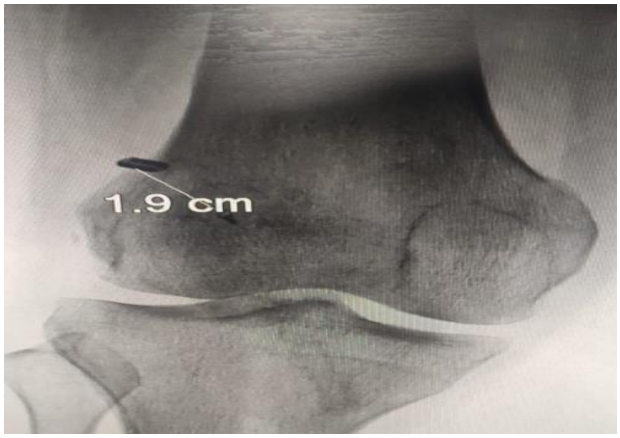

Figure 8: X-ray with distance between button and marker in lateral view at 6 weeks-variable loop.

DISCUSSION

From the results of our study, both the fixed and adjustable loop devices appear comparable. In our study, 73.3% patients in the fixed loop group were males and 26.7% were females. In the adjustable loop group 86.7% of the total participants were males and 13.3% were females. The mean age of the population in the fixed loop group was 25.9 years (SD=11.2) and in the adjustable loop group was 29.3 years (SD=8.6). The population of the two groups in our study in terms of demographic characteristics were comparable and there was no significant difference between the two groups. The mean interval between injury and surgery in participants of fixed loop group was 47.3 days (SD=29.0) and for participants in adjustable loop group was 35.3 days (SD=19.0) in our study. This difference between the two groups were non-significant and did not interfere with the outcome of the study. Our finding was similar to the study by Ranjan et al where although the mean injury-surgery interval was longer than the participants in our study, the overall difference between the two groups in this study was not significant.[1] Their two groups were comparable, similar to the results in our study. Hence, both of our study groups were comparable based on population characteristics and demographic criteria. The mean femoral and tibial diameter of the autologous hamstring grafts in participants of the fixed loop group measured was 7.9 millimeters (SD=0.5). In the adjustable loop group, the mean diameter in millimeters of the autologous hamstring grafts was also 7.9 millimeters (SD=0.3) both for femoral and tibial end. The mean end diameters for the hamstring graft were therefore 7.9 millimeters for both the groups and the grafts for both the groups were comparable. There was no significant statistical difference in the mean femoral tunnel length and tibial tunnel length in the two groups. The mean femoral tunnel length was 38.7 millimeters (SD=1.8) and mean tibial diameter was 38.9 millimeters (SD=1.0) for fixed loop group and 37.9 millimeters (SD=0.9) and 38.1 millimeters (SD=1.6) for adjustable loop group respectively (p values 0.14 and 0.11). The length up to which the femoral tunnel was reamed with a wider reamer (as per the measured graft diameter) was more in case of the participants of the fixed loop group as compared to the participants of the adjustable loop group. This is a procedural requirement, as approximately 6-8 millimeters of extra reaming of the femoral tunnel is required for the purpose of flipping the button in case of fixed loop. The mean length up to which the femoral tunnel was reamed in our study was 29.7 millimeters (SD=2.6) for fixed loop group and 25 millimeters (SD=1.5) for adjustable loop (p value=0.01). Hence the adjustable loop requires less reaming of the femoral tunnel, thus more bone stock of the femoral tunnel in preserved if adjustable loop is used. Since it requires no excess reaming, the femoral tunnel is reamed only up to which we need to put the graft, ensuring complete filling of the femoral tunnel with the graft. Adjustable loop thus becomes an obvious choice where the femoral tunnel length is short to ensure minimum graft within the tunnel. These finding corresponds to the similar findings reported in the literature, where it shows that some amount of extra reaming of the femoral tunnel in fixed loop group is required for flipping the button. In the study by Lanzetti et al they reamed six to ten millimeters more in the fixed loop group for flipping the button.[15] Our study corroborates to the fact that adjustable loop minimizes over-drilling as observed by Eguchi et al and Johnson et al.[3,5] Our results are also at par with findings of Lanzetti et al who mentioned that adjustable-length loops enhance bone preservation by not leaving excess space in

the bone tunnel.[15] Hence, our study reaffirms the conclusions of study by Ahn et al that since adjustable loop allow adaptation at different tunnel length, they might prove to be more effective in varied surgical conditions.[12]

In our study, no loop lengthening was observed in the participants of the fixed loop group in any of the two views in the X-ray immediately after post-p and at 6 weeks. Out of the fifteen patients in the adjustable loop group, loop lengthening was observed in as much as five patients (33%) at 6 weeks. However, out of these five, significant loop lengthening was observed in two patients (loop length change >0.3 centimeter), which could cause laxity of graft (13% of the total participants in adjustable group). However, this difference in these two groups were not statistically significant (p value=0.483). In our study, the significant cut-off extent of lengthening of the loop which can cause laxity of the graft was determined as three millimeters (3 mm or 0.3 cm). This cut-off was decided based on a number of evidences obtained in literature. Eguchi et al in their study mentioned that displacement less than 3 millimeters has been reported as being necessary to ensure graft healing.[5] Barrow et al in their bio-mechanical study used 3 mm of loop lengthening as benchmark of clinical failure.[4] Petre et al in their bio-mechanical studies also used 3 millimetre as the cut-off for failure.[8] The benchmark in both these studies were based on reports that 3.0 mm or more of side-to-side difference in anterior tibial translation, as measured by KT-1000 arthrometer testing, signifies an ACL failure in nearly all instances. Pasquili et al in their study also concluded that a displacement of three millimetres can cause clinical failure of the graft.[2] The concern with usage of adjustable loop device has been loop lengthening after tibial fixation, post cycling and rehabilitation -which leads to increase in the loop graft system length and possible instability as a result of that. We compared the results of our study with various bio-mechanical and clinical studies and the finding are as follows. The lengthening of the loop in case of adjustable loop femoral suspension device, as observed in our study was in accordance to findings reported in literature in various model-based studies. Our result corresponded with the bio-mechanical study by Eguchi et al where they had concluded that although specimen setup did not show any significant displacement between the two devices, significant lengthening is seen in isolated set-up and this might be clinically relevant and may result in clinical failure of graft.[5]

In another study, Petre et al evaluated 4 types of cortical suspensory fixation methods, including 2 fixed loop and 2 adjustable loop devices bio-mechanically and their most crucial finding was increased displacement as a result of device slippage that occurred with the adjustable loop de-sign.[8] Our study included one each of fixed and adjustable loop devices corroborated to their findings in a clinical setting and although the difference with the fixed loop group was statistically insignificant, loop laxity was found to be commonly associated with adjustable loop device. Pasquali et al's study of three adjustable loop devices in 2015, found that all of the three lengthened but displacement was less than 3 millimetres.[2]

In our study, in the group which included participants operated with adjustable loop device, five patients showed loop lengthening out of which in three patients the loop lengthening was less than 3 millimetres and two had lengthening that was significant. (>3 millimetres or 0.3 centimetres). Our study corroborated to the fact that lengthening of loop is associated with adjustable loop devices.

Limitations

The comparative follow-up x-ray for all the patients was taken at 6 weeks after surgery which is the minimum time required for an autologous hamstring graft to get incorporated in the bony tunnel as per literature. Longer follow-ups could not be done because of the onset of the COVID-19 pandemic.

In our study, we had used digital X-ray for the radiological evaluation of our patients, which proved to be an easy, safe and economically feasible option to assess loop lengthening in all our participants. However, it has its own limitations as the images obtained through it are two-dimensional, and various factors like magnification can have an effect on precision of the measurements obtained. CT-scan preferable with 3D reconstruction could be a better method of radiological evaluation in terms of better imaging properties and precision of measurement.

CONCLUSION

From our study we conclude that a small percentage (13.36%) of the total number of patients who underwent arthroscopic anterior cruciate ligament reconstruction with adjustable loop showed significant loop lengthening at 6-weeks post-operative radiological evaluation but the incidence and the amount of loop lengthening seen was statistically insignificant. Intra-operative lengthening and slippage was observed in eight out of fifteen patients in the adjustable loop group and in all these cases, the loop had to be shortened again by re-tightening the loop before final locking. Thus, the phenomenon of loop lengthening, occurs both in the intra-operative period and during rehabilitation, in patients in whom anterior cruciate ligament was reconstructed using adjustable loop device. However, the results were statistically insignificant when compared with patients operated using the fixed loop device and the clinical outcomes in both sets of patients were comparable. So, the adjustable loop is a viable alternative to the fixed loop femoral suspension devices for arthroscopic anterior cruciate ligament reconstruction if intra-operative re-tensioning of the graft is taken care of. More studies comparing the two devices are required with larger population and longer follow-up with detailed radiological-clinical follow-up to determine the best femoral suspension device for ACL reconstruction.

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