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### RESEARCH ARTICLE

#### RETROSPECTIVE PROSPECTIVE COMPARATIVE ANALYSIS OF RECONSTRUCTION OF ACL TEAR WITH QUADRUPLED HAMSTRING GRAFT VERSUS QUADRUPLED HAMSTRING GRAFT INTERNALLY BRACED WITH FIBER TAPE

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#### Manuscript Info

##### Manuscript History

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#### Abstract

**Background:** Reconstruction of anterior cruciate ligament is a widely done surgery. The surgical outcome is dependent upon the strength of the graft used. Quadrupled hamstring graft is a commonly used graft as it provides good strength and functional outcomes. However graft re-rupture and laxity of the graft are amongst the known complications which lead to repeat surgeries and unsatisfactory outcomes. Various techniques have been described to strengthen the graft. This study compares the cumulative effect of internally bracing quadrupled hamstring graft using fibertape with quadrupled hamstring graft alone in terms of functional outcome and laxity.

**Materials and Method:** The study was done at the Department of Orthopaedics at King George's Medical University in Lucknow on 60 patients with anterior cruciate ligament tears from October 2021 to October 2022. The patients were divided into two groups: Group 1 had quadrupled hamstring graft reconstruction done alone, and Group 2 had quadrupled hamstring graft reconstruction done with fibertape braced internally. Lysholm knee score was used as a measure of functional outcome along with standardized Pivot shift test, Lachman test and anterior drawer test to measure and compare the pre- and postoperative variation in laxity.

**Results:** On comparing the improvement in grades at subsequent follow-up, group 2 showed significant improvement in functional outcomes in terms of Lysholm knee score.

**Conclusion:** We concluded that reconstruction of anterior cruciate ligament using quadrupled hamstring graft internally braced with fiber tape gives a better functional outcome in form of Lysholm knee score although there was no significant improvement in grades of Anterior Drawer and Lachman test. Although follow up period of six months was a limiting factor. Further clinical evaluation over a longer period of follow up to evaluate the effect of fibertape on shielding and creeping of graft is essential and also to study the resultant collagen fibertape's clinical behavior.

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## Introduction:-

The most prevalent knee ligament injury is anterior cruciate ligament (ACL) injury[1] and one of the most widely done surgery in sports medicine is anterior cruciate ligament (ACL) reconstruction. [2] Notwithstanding its high success rates, graft rupture and persistent laxity remain obstacles.[3] The main structural stabilizer of the tibia's anterior translation with regard to the femur is the ACL. [4] However, it also plays a part in limiting internal tibial rotation, which lowers the possibility of anterior subluxation of the lateral and medial tibiofemoral components[5]. ACL is composed of anteromedial and posterolateral bundles. The posteromedial bundle, in contrast, originates in femur and inserts posterolaterally at its tibial insertion side. Anteromedial bundle, on the other hand, originates in the proximal part of the femoral origin and inserts in the anteromedial portion of the tibial insertion[6]. The medial surface of the lateral femoral condyle in the intercondylar notch is where the ACL emerges as a segment of a circle. [7] If ultimate tensile force on these fibres exceeds, usually occurring during sudden, non contact twisting of semi flexed knee leading to damage and eventually partial or complete tear of macrostructure.

There are numerous techniques for repairing the ligament involve the use of hamstring tendons, quadriceps tendons, and patellar tendons autografts materials for allografts, artificial ligaments, and tapes. However ACL reconstruction, typically using autograft, has been the gold standard due to concerns about the ACL's capacity for healing. Nonetheless, residual laxity, inconsistent performance results, rerupture, and donor-site morbidity present difficulties for ACL restoration[8-10].

New changes that integrate suture augmentation have been used to assist prevent future anterior cruciate ligament (ACL) failures[11-13]. The tape blends seamlessly into the design of the quadrupled semitendinosus tendon graft improving the ACL graft construct's biomechanical characteristics [14]. This addition's purpose is to safeguard the recently repaired ligament during the ligamentization process and the quicker rehabilitation by functioning as a safety belt during the knee joint's terminal extension. In order to strengthen the ligament and serve as a secondary stabilizer, the internal bracing procedures may include a braided suture tape inside the graft that is independently attached with a knotless bone anchor. ACL surgery with internal bracing is a relatively recent idea. Synthetic suture tapes were first used as a reinforcing adjunct for primary ACL repair as described by Mackay et al.[16]. Smith et al.'s[17] description of internal bracing for juvenile ACL surgery included further information.

Standardised Lachman test, Anterior Drawer test, pivot shift test, and Lysholm score is determined by the differential in laxity from side to side before and after surgery. The kinematics and flexibility of the knee joint are considerably altered by an anterior cruciate ligament (ACL) rupture [20,21,22]. The typical medical treatment for adults who are active, ACL restoration, is unable to fully restore the kinematics of the affected joint [20, 22]. The pivot-shift test, which is designed to evaluate rotatory and dynamic knee laxity, has been shown in the literature to be linked with ACL deficit and to be the most specific clinical instrument for the investigation of ACL ruptures [23]. The pivot-shift test has been linked to meniscal and articular injury, decreased athletic participation, and subjective instability [24, 25]. When compared to the amount of laxity prior to injury, full recovery of postoperative laxity is not always attained [26, 27]. Van der List et al. [28] found that different techniques of primary ACL repair were safe with failure rates between 7 and 11%, and good functional outcome scores in 1,101 patients.

## Materials and Methods:-

The Retrospective Prospective Cohort study was carried out in the Department of Orthopaedic Surgery, King George Medical University, from October 2021 to October 2022.

Two groups divided as per on arthroscopic surgical technique practised by operating surgeons. The two groups are as follows:

1. Group A:- Patients with ACL tear treated arthroscopically by ACL reconstruction with Quadrupled hamstring graft internally braced by fibertape.
2. Group B:- Standard ACL reconstruction protocol was followed. Surgical procedure, anaesthesia, tourniquet application and rehabilitation protocol were followed as per standard

## Study design:

Retrospective Prospective cohort study

**Sample size at 90% Power:**

The formula is used to determine sample size based on the variance in final Lysholm Knee Score between the two study groups,

$$n = \frac{(z_{\alpha} + z_{\beta})^2 (\sigma_1^2 + \sigma_2^2)}{d^2}$$

Where  $\sigma_1 = 4.77$ , The SD of the first group's final Lysholm Knee Score

$\sigma_2 = 4.98$ , The SD of final group's final Lysholm Knee Score

$d = \min(\sigma_1, \sigma_2)$  the minimum mean difference consider to be clinically significant

type I error  $\alpha = 5\%$  corresponding to 95% confidence level

type II error  $\beta = 10\%$  for detecting results with 90% power of study

Loss to follow up 10%

Hence the sample size is calculated as

**n = 30 each group**

**InclusionCriteria:**

1. Clinical/radiological/arthroscopic evidence of anterior cruciate ligament deficiency symptomatic even after conservative therapy of adequate duration with the normal contralateral knee.
2. Patients between the ages of 18 and 60 who are motivated, energetic, and have a future interest in competitive or leisure sports or who engage in strenuous activities and are unwilling to quit their active lifestyle.
3. The injury's early inflammatory phase has subsided, and the patient has healed with no extensor lag, a full range of motion, and good quadriceps strength. (usually after 4-6 weeks of injury).

**ExclusionCriteria:**

1. Patient with bilateral knees with Anterior cruciate ligament tear.
2. Patients having systemic disease leading to compromise in pre anaesthetic fitness.
3. Patients with fractures involving lower limbs

ACL reconstruction with quadrupled hamstring graft standard surgical technique followed for controls

ACL reconstruction with quadrupled hamstring graft bracing with fibretape surgical technique followed for Cases

- 1) Standard Patient Positioning for ACL reconstruction
- 2) Standard incision used
- 3) Sartorial fascia incised and gracilis and semitendinosus tendon identified
- 4) Tendons harvested as per standard procedure
- 5) Graft prepared and fibretape adjunct to the graft
- 6) Stump of remnant ligament debrided and footprint marked
- 7) Femoral and tibial tunnel drilled as per standard procedure
- 8) Graft passed along with the fibretape
- 9) Fixation done on the femoral side and tibial side

Post-Operative Rehabilitation - As per standard protocol

**Results and Observations:-**

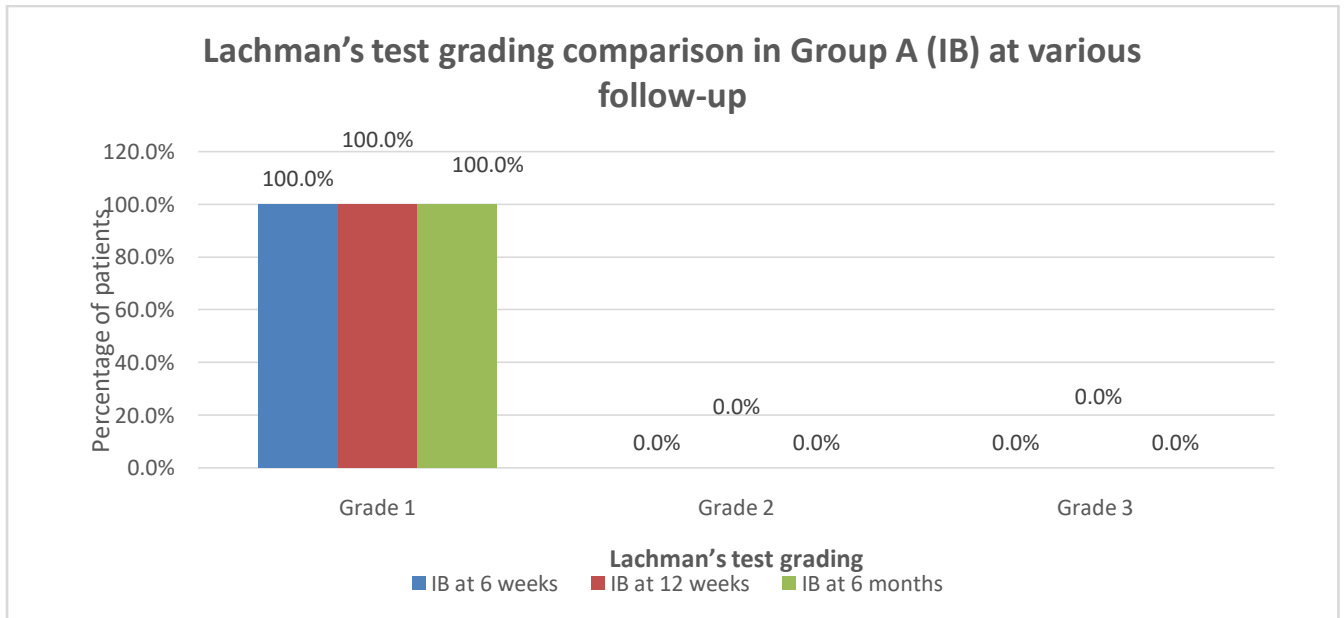
The distribution of the studied patients on the basis of group allotment in which a total of 60 patients were included, 30 in each IB and Non-IB group.

All 30 patients in Group A (IB) had anterior drawer test grading 1 at all follow-ups and it showed statistically non-significant association between grading at 6, 12 weeks and 6 months ( $p > 0.05$ ).

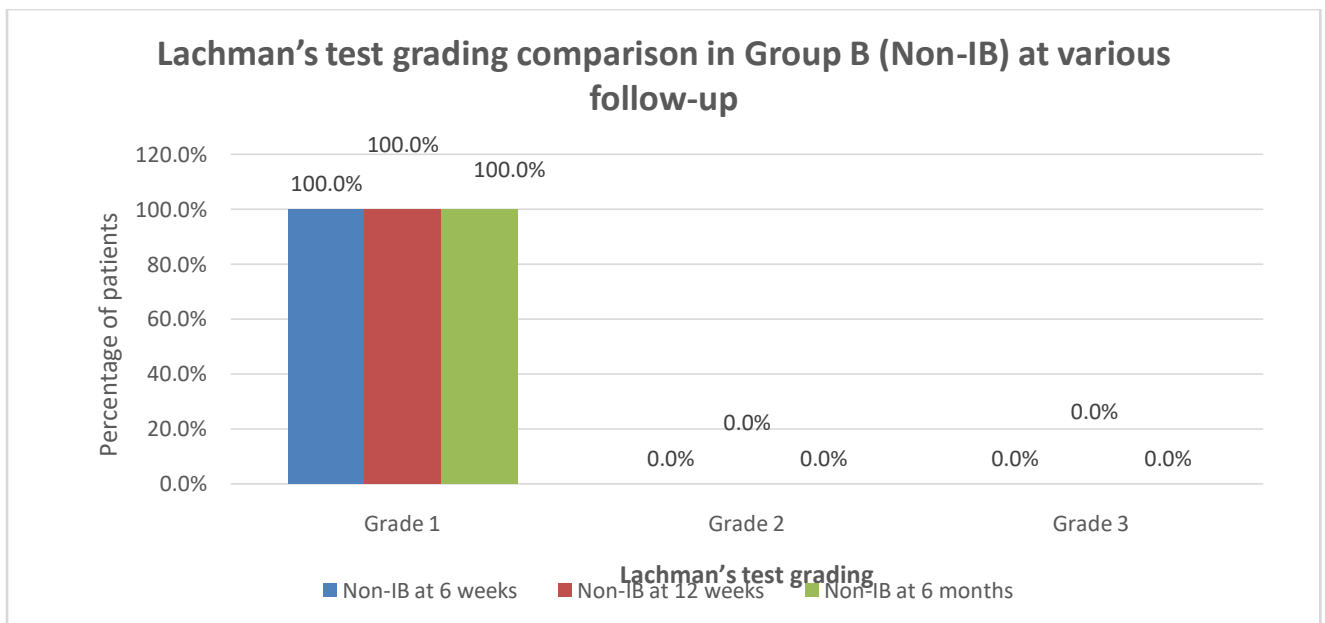
All 30 patients in Group B (Non-IB) had anterior drawer test grading 1 at all follow-ups and it showed statistically non-significant association between grading at 6, 12 weeks and 6 months ( $p > 0.05$ ).

All 60 patients in Group A and Group B had Lachman's test grading 1 at all follow-ups and it showed statistically non-significant association between both groups at 6, 12 weeks and 6 months ( $p > 0.05$ ).

All 30 patients in Group A (IB) had Lachman’s test grading 1 at all follow-ups and it showed statistically non-significant association between grading at 6 , 12 weeks and 6 months ( $p>0.05$ ).



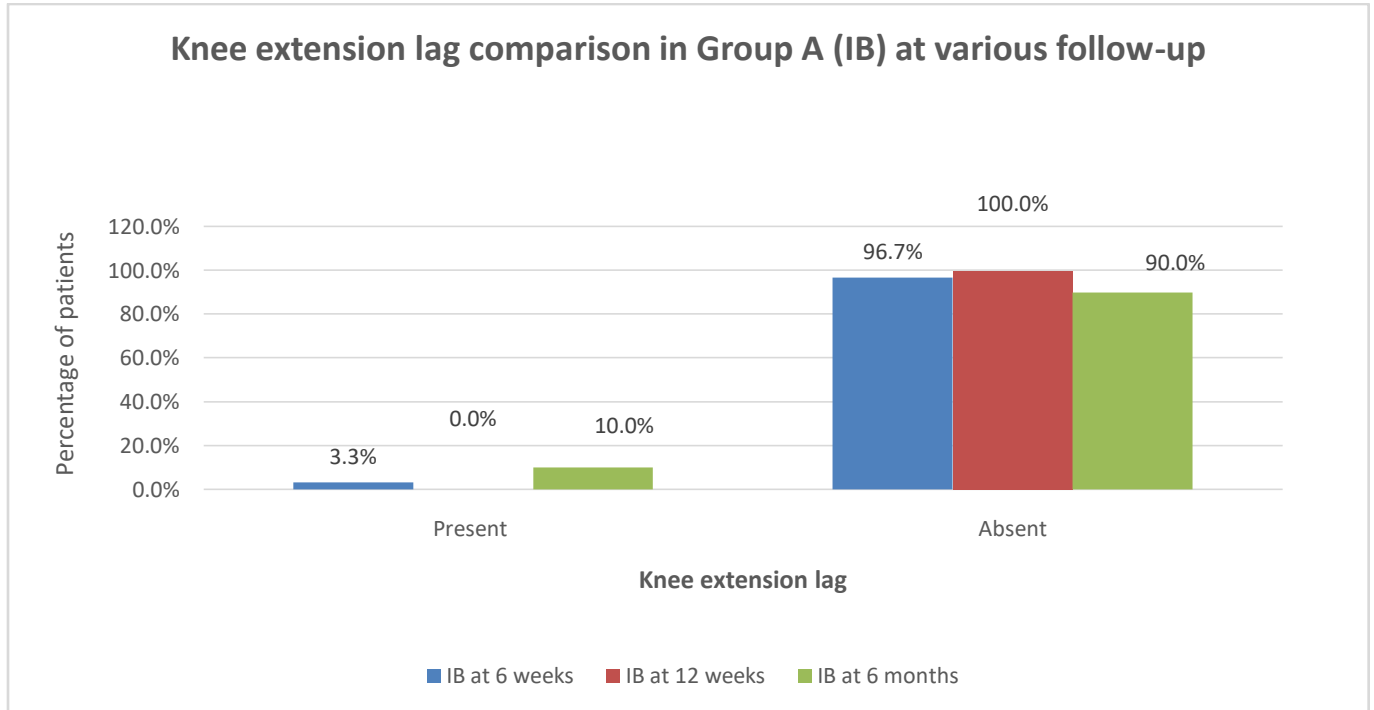
All 30 patients in Group B (Non-IB) had Lachman’s test grading 1 at all follow-ups and it showed statistically non-significant association between grading at 6 , 12 weeks and 6 months ( $p>0.05$ ).



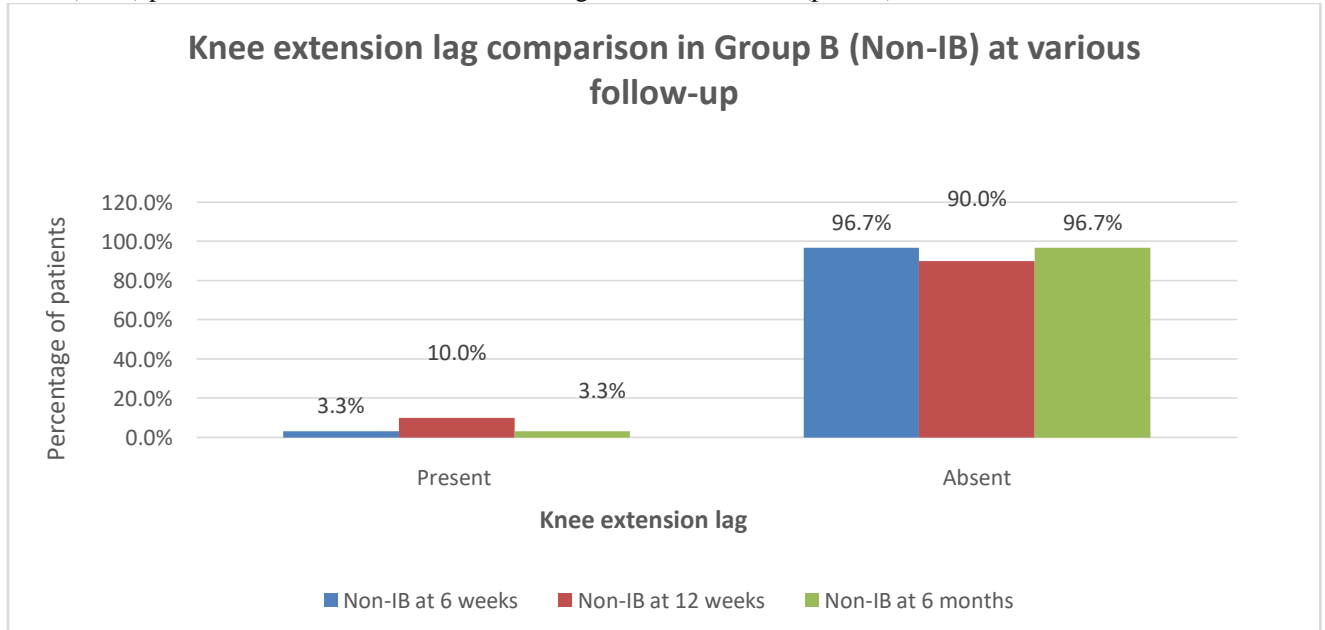
Out of total 60 patients, at 6 weeks, Knee extension lag was present in 1 (3.3%) patient of Group A (IB) and in 1 (3.3%) patient of Group B (Non-IB). At 12 weeks, Knee extension lag was present in 30 (100.0%) patients of Group B (Non-IB). At 6 months, Knee extension lag was present in 3 (10.0%) patient of Group A (IB) and in 1 (3.3%) patient of Group B (Non-IB).

Knee extension lag showed statistically non-significant association between both groups at 6 , 12 weeks and 6 months ( $p>0.05$ ).

In group A (IB), knee extension lag was present in 1 (3.3%) patient at 6 weeks and 3 (10.0%) at 6 months. It also showed non-significant association ( $p>0.05$ ).

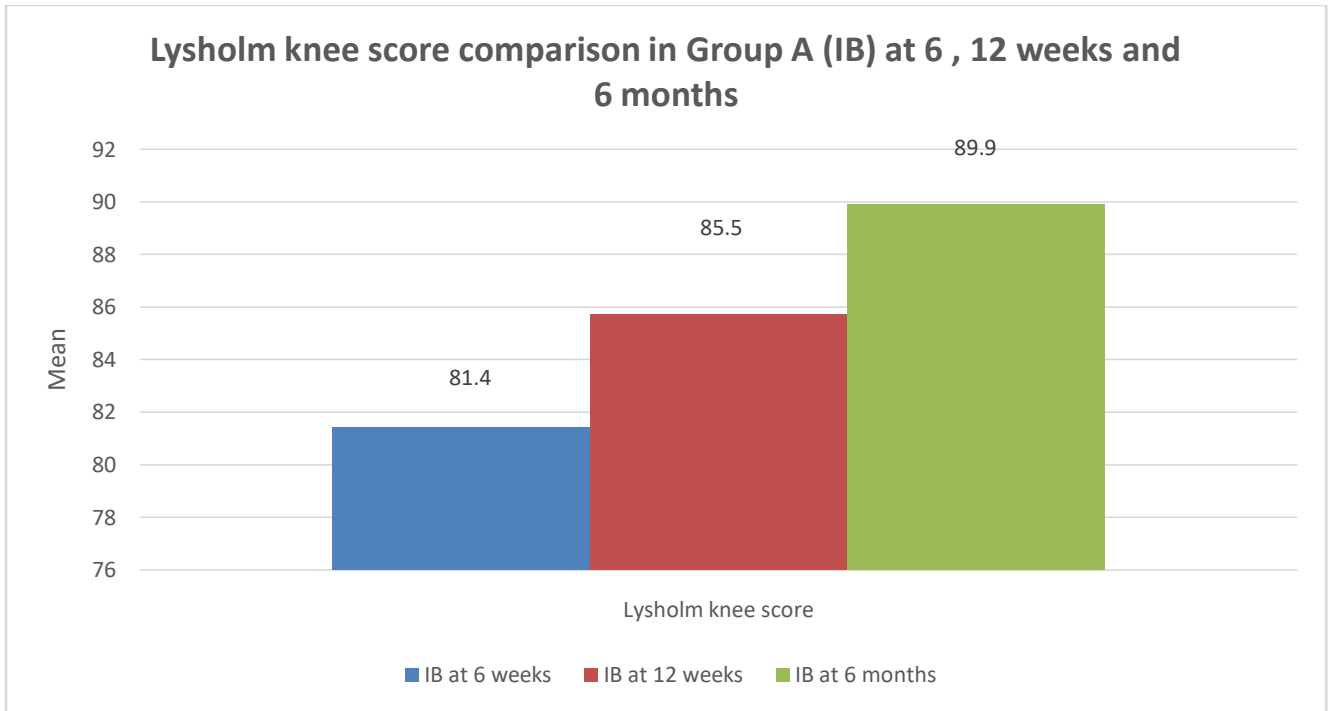


In group B (Non-IB), knee extension lag was present in 1 (3.3%) patient at 6 weeks, 3 (10.0%) patients at 12 weeks and 1 (3.3%) patient at 6 month It also showed non-significant association ( $p>0.05$ ).

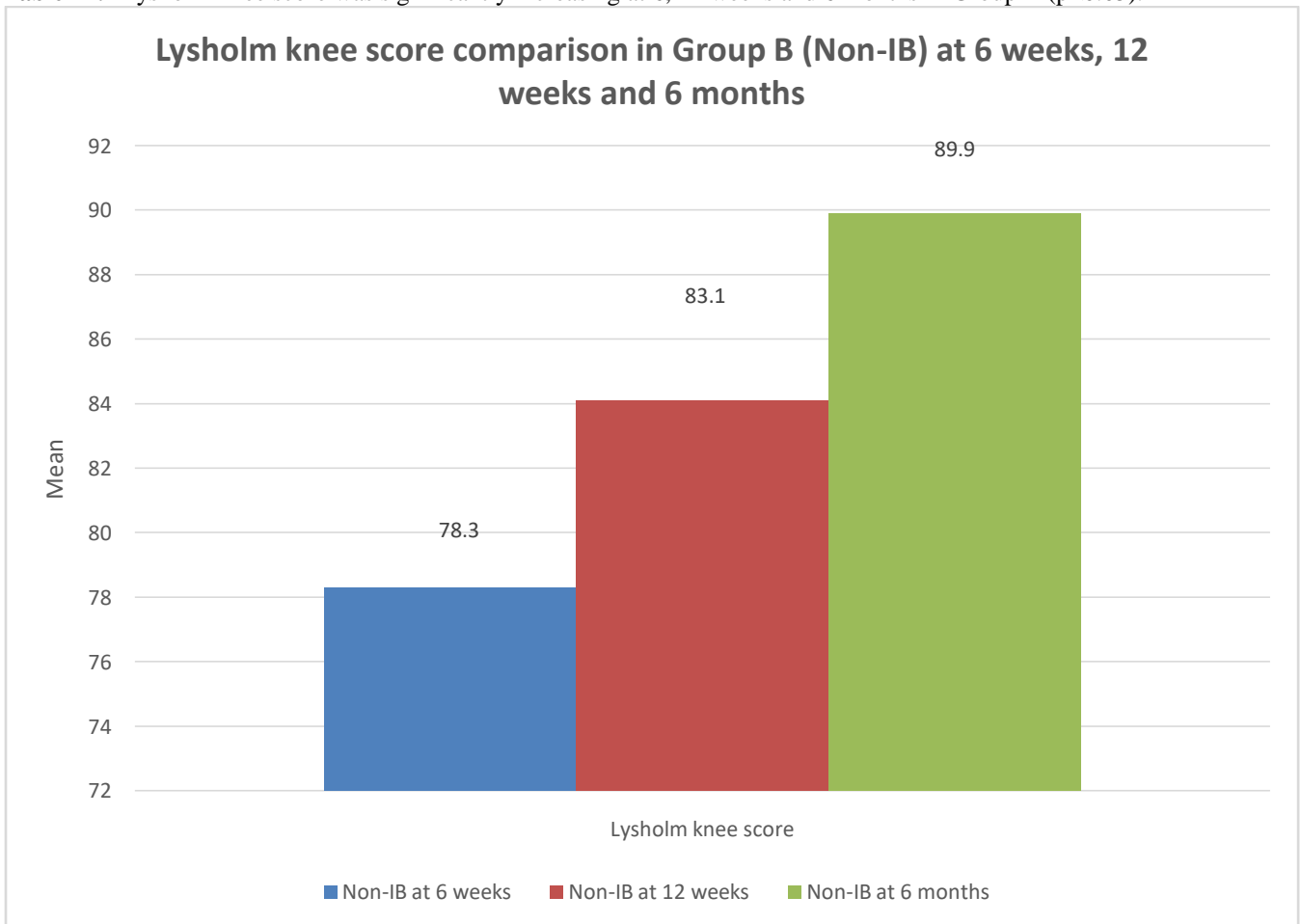


Lysholm knee score was found to be high in Group A than Group B at 6 , 12 weeks and 6 months and there was a statistically significant association between both groups at 6 weeks.

Lysholm knee score was significantly increasing at 6 , 12 weeks and 6 months in Group A ( $p<0.05$ ).



**Table 11:-** Lysholm knee score was significantly increasing at 6, 12 weeks and 6 months in Group B ( $p < 0.05$ ).



On the basis of numerical pain rating score, at 6 weeks majority 19 (63.3%) patients had mild pain and 11 (36.7%) patients had moderate pain in Group A while 16 (53.3%) patients had mild pain and 14 (46.7%) patients had moderate pain in Group B.

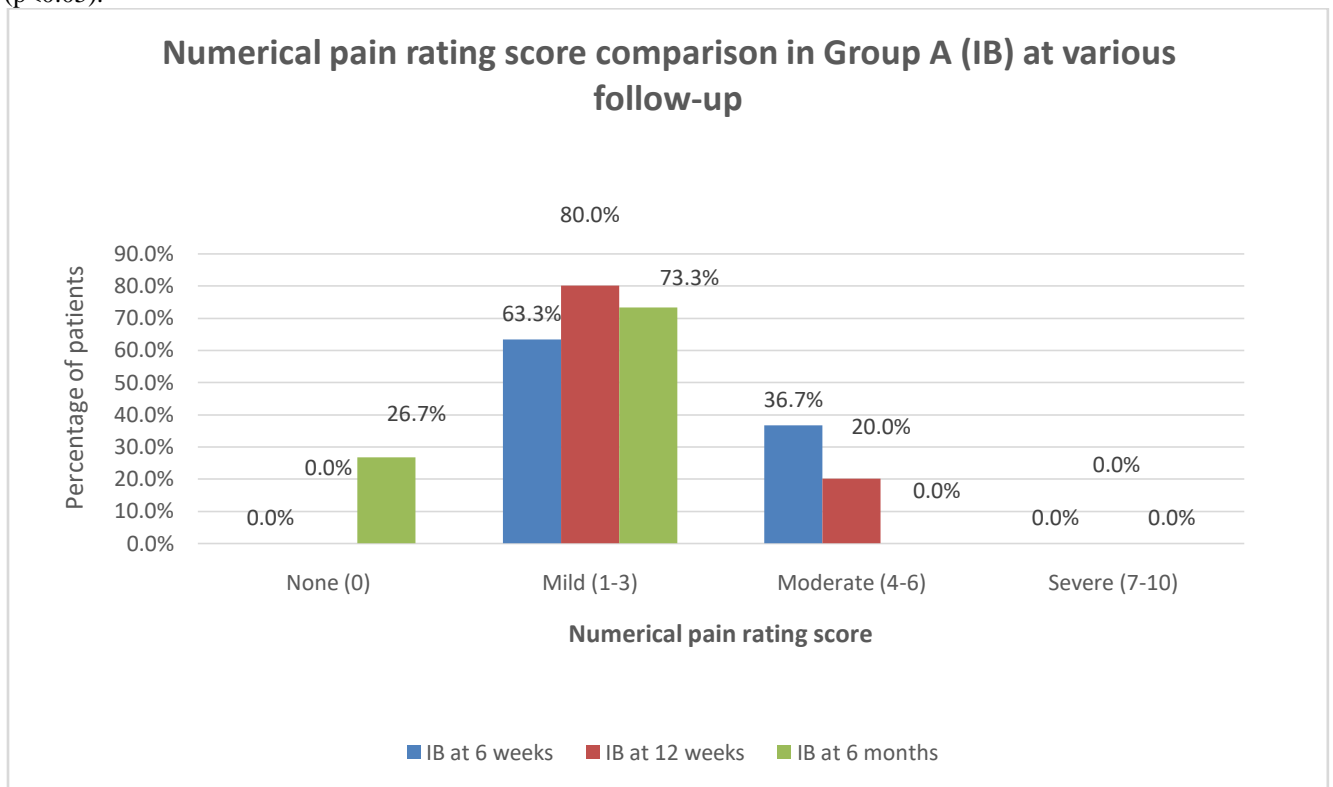
At 12 weeks, majority 24 (80.0%) patients had mild pain and 6 (20.0%) patients had moderate pain in Group A while 23 (76.7%) patients had mild pain and 7 (23.3%) patients had moderate pain in Group B.

At 6 months, majority 22 (73.3%) patients had mild pain and 8 (26.7%) patients had no pain in Group A while 20 (66.7%) patients had mild pain and 10 (33.3%) patients had no pain in Group B.

Numerical pain rating score showed a statistically non-significant association between both groups at 6 , 12 weeks and 6 months ( $p>0.05$ ).

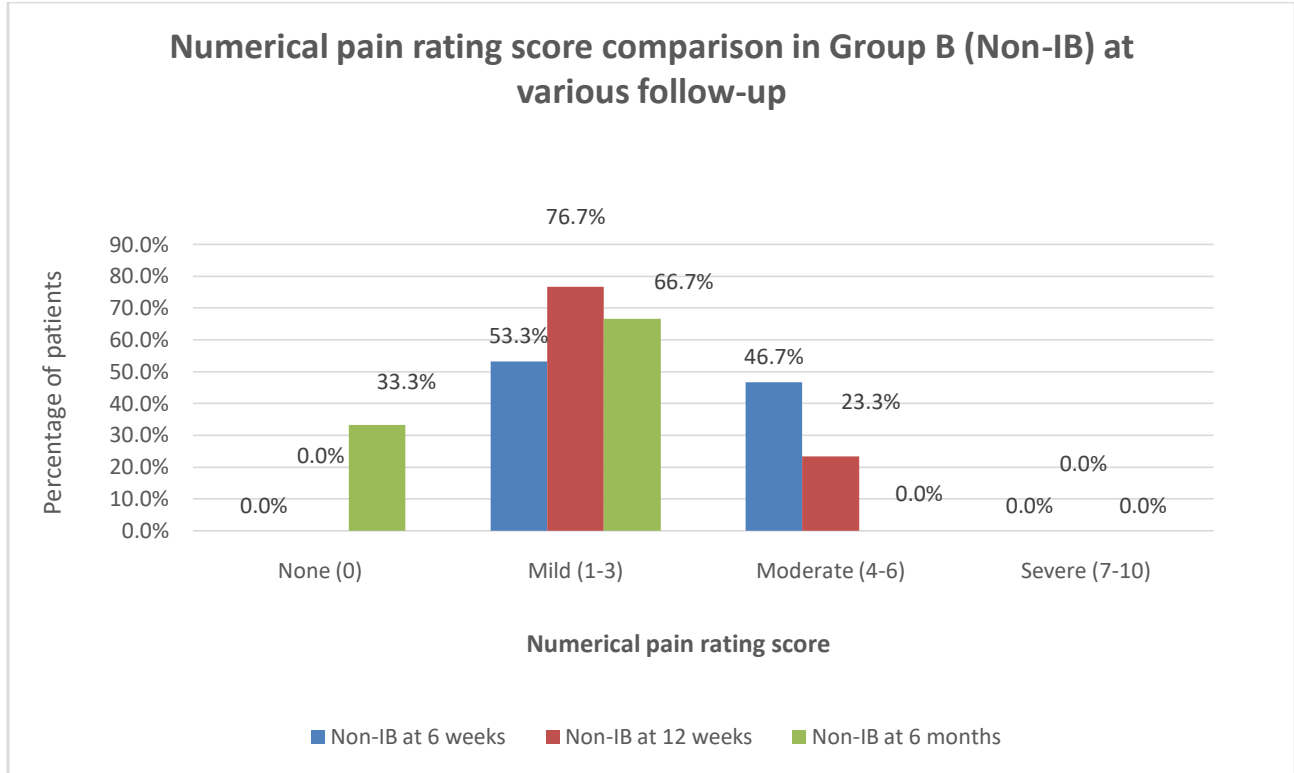
In Group A, on the basis of numerical pain rating score, at 6 weeks majority 19 (63.3%) patients had mild pain and 11 (36.7%) patients had moderate pain, at 12 weeks majority 24 (80.0%) patients had mild pain and 6 (20.0%) patients had moderate pain and at 6 months majority 22 (73.3%) patients had mild pain and 8 (26.7%) patients had no pain.

Numerical pain rating score in group A showed a statistically significant association at 6 , 12 weeks and 6 months ( $p<0.05$ ).



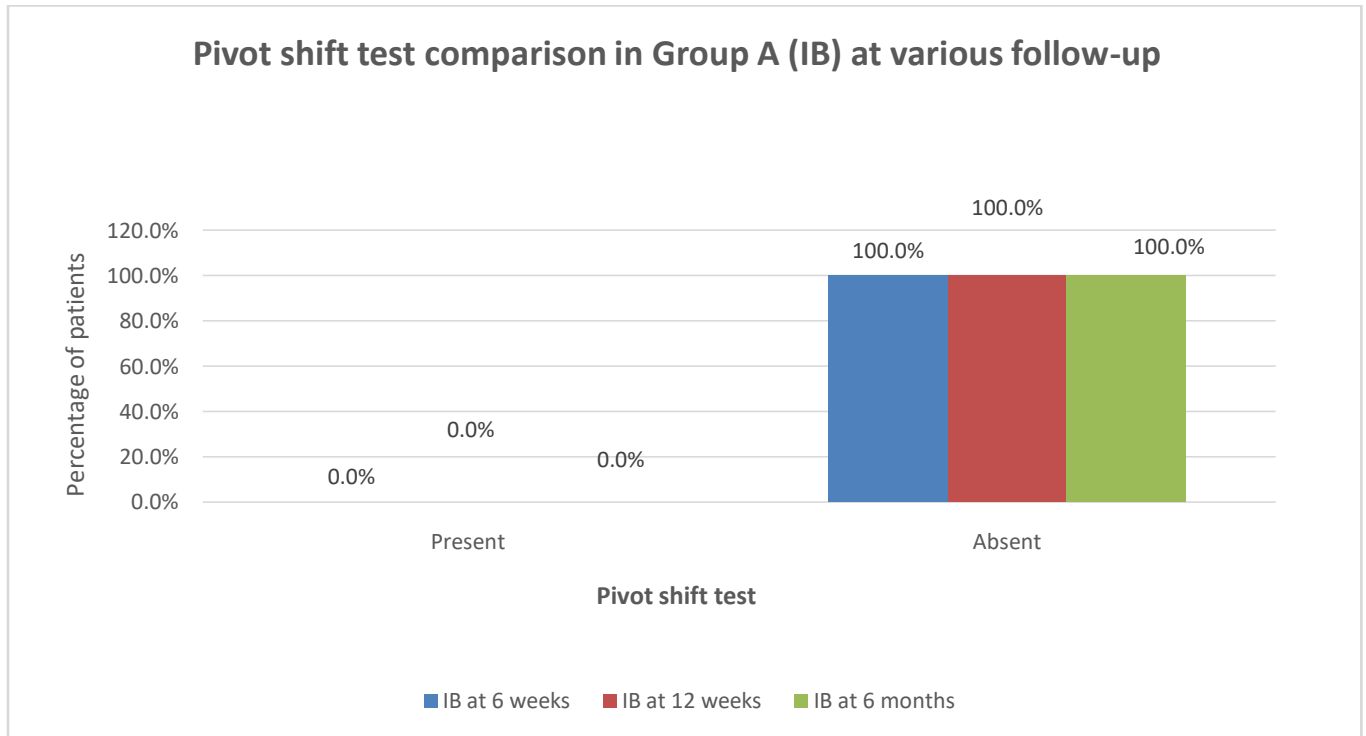
In Group B, on the basis of numerical pain rating score, at 6 weeks majority 16 (53.3%) patients had mild pain and 14 (46.7%) patients had moderate pain, at 12 weeks majority 23 (76.7%) patients had mild pain and 7 (23.3%) patients had moderate pain and at 6 months majority 20 (66.7%) patients had mild pain and 10 (33.3%) patients had no pain.

Numerical pain rating score in group B showed a statistically significant association at 6 , 12 weeks and 6 months ( $p<0.05$ ).



All 60 patients in Group A and Group B had Pivot shift test reported as absent and it showed statistically non-significant association between both groups at 6 , 12 weeks and 6 months ( $p>0.05$ ).

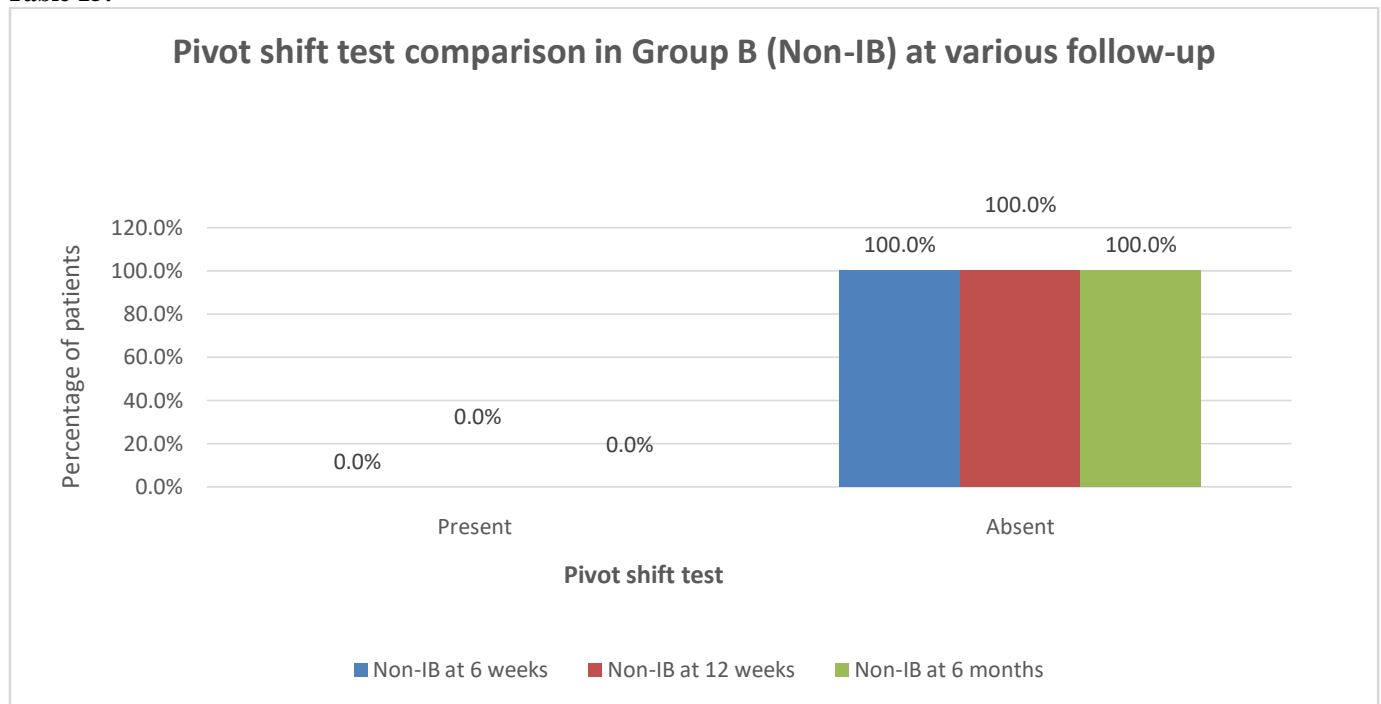
All 30 patients in Group A had Pivot shift test reported as absent at 6 , 12 weeks and 6 months and it showed statistically non-significant association between both groups at 6 , 12 weeks and 6 months ( $p>0.05$ ).





All 30 patients in Group B had Pivot shift test reported as absent at 6 , 12 weeks and 6 months and it showed statistically non-significant association between both groups at 6 , 12 weeks and 6 months (p>0.05).

**Table 15:-**



**Discussion:-**

Graft healing is a slow process and the exact time it takes for the graft to resemble native ACL characteristics is not known. The study included 60 patients out of which 30 were randomly divided into two groups of : Group 1 included – Quadruple hamstring graft ; Group 2 included: hamstring graft augmented with fibertape. In their study, Mark D Santi et al [15] compared a group of twenty eight patients with a ligament augmentation device with hamstring graft with thirty two patients with hamstring graft alone. Von Essel et al in their study compared 20 patients of autologous hamstring graft or quadriceps graft with suture tape and 20 patients without addition of suture tape .Szwedowski D et al in their retrospective study compared 12 patients who underwent primary ACL repair with internal bracing with 15 patients who underwent primary ACL repair without internal bracing. Heusdens et al compared ninety eight consecutive patients (55 patients of ACL reconstruction and 43 patients with Independent Suture Tape reinforcement techniques) followed upto a period of two years with KOOS ( Knee Osteoarthritis Outcome Score ) , VAS pain (visual analogue scale ) , Veteran RAND 12 physical score. Murray et al in their study compared 64 patients of brige enhanced ACL repair with 35 patients of ACL reconstruction.

The mean age of patients in Non Internally braced group was 28.0±15.7 years which was comparable to the internal bracing group with the mean age of patients 28.0±14.8 years. The difference in mean ages between the two groups was not found to be significant (p=1.0). The mean age in ACL repair group was 36 ( range 15-55) years in Szwedowski D et al . Young patients with active lifestyle and motivated for active physiotherapy are better suited for ligament reconstruction surgeries. There is no statistical significant difference in the age related data between the two groups.

The male-female ratio in non fibertape group was found to be 80.0%: 20.0% , while in the fibertape group it was found to be 90.0%: 10.0% . Szwedowski D et al included 6 males and 5 females out of the internal bracing group. No statistical significant difference was seen in the demographic data of both groups. Murray et al found no significant statistical difference in the age and gender index of the two groups. Maximum of the patients in both the groups are males. Adult males are more lively and exposed to injuries compared to females in our indian set up. Since the patients in each groups are similar in terms of age and sex distribution, we can infer that both are similar and consequently comparable.

The functional recovery was assessed using the Lysholm knee score at subsequent post operative follow ups . Lysholm knee score in nonfiber group 87.83, 83.1 and 89.9 at 6 , 12 weeks and 6 months follow-up respectively, the intragroup improvement being statistically significant. While in fiber group it was 81.4, 85.5 and 89.9 at 6 , 12 weeks and 6 months follow-up respectively, the intragroup improvement being statistically significant. The difference in Lysholm knee score between the two groups during the follow up weeks was significant in the 6 week and 12 week followup. Mark d Santi et al [15] had mean Lysholm knee score 89.8 in the ligament augmentation device group and 92.0 in the non-ligament augmentation device group. However the mean postoperative Lysholm score for the ligament augmentation device group was not statistically different from that of the non- ligament augmentation device group. Szwedowski D et al in their study had mean Lysholm score after 12 months of 89.2 (range 57-100) in the internal bracing cohort and 89.9 in the non internally braced group . No significant differences between both groups was found in Lysholm knee score . Heusdens et al had meaningful KOOS change and significant VAS pain and VR-12 improvements at 2 year followup . Murray et al found no significant difference between the BEAR and ACL reconstruction group for IKDC subjective score (  $p < 0.001$  )

Post operatively at 6 weeks, grade 3 anterior drawer test was excluded in both internally braced and non internally braced group. Improvement was therefore implied in both the groups. Grade 2 was still present in 2 non-fiber group cases whereas only one case in fiber group still had grade 2 anterior drawer . Yet the difference between the groups was found to be non significant in statistical analysis ( $p = 0.552$ ). Anterior drawer test was performed in the 12 week follow up and grade 3 was still found to be absent in all patients. However one patient of non-fiber group persisted with anterior drawer test grade 2 . Grade 1 was present in rest of non-fiber and all the patients of fibretape group. No statistically significant difference was present between both group at the 12 weeks ( $p = 0.684$ ). Post operatively after 6 months anterior drawer test grade 2 was still present in 1 case of non fibretape group. All the other patients had grade 1 anterior drawer test. Still no significant difference was found between the two groups ( $p = 0.297$ ) Therefore among 30 patients in non-fiber group undergoing ACL reconstruction, one patient had grade 2 anterior drawer test, rest all patients had grade 1 anterior drawer test at 6 months follow-up. But among the 30 patients in the fiber group, all patients had grade 1 anterior drawer test at 6 months follow-up. On comparing the improvement in grades at 12 weeks and 6 months follow-up, fiber group did not show any significant improvement compared with the nonfiber group.

Post operatively at 6 weeks, grade 3 Lachman test was excluded in both internally braced and non internally braced group. Improvement was therefore implied in both the groups. Grade 2 was still present in 2 non-fiber group cases whereas only one case in fiber group still had grade 2 Lachman. Yet the difference between the groups was found to be non significant in statistical analysis ( $p = 0.552$ ). Lachman test was performed in the 12 week follow up and grade 3 was still found to be absent in all patients. However one patient of non-fiber group persisted with Lachman test grade 2 . Grade 1 was present in rest of non-fiber and all the patients of fibretape group. No statistically significant difference was present between both group at the 12 weeks ( $p = 0.684$ ). Post operatively after 6 months Lachman grade 2 was still present in 1 case of non fibretape group. All the other patients had grade 1 Lachman. Still no significant difference was found ( $p = 0.297$ ) Therefore among the 30 patients in non-fiber group undergoing ACL reconstruction, only one patient had grade 2 Lachman test, rest all patients had grade 1 Lachman at 6 months follow-up. But among the 30 patients in the fiber group, all patients had grade 1 Lachman at 6 months follow-up. Szwedowski D et al found that ACL repair with internal bracing resulted in significantly smaller anterior knee laxity than ACL reconstruction group . They used GNRB for testing anterior knee laxity which they demonstrated to be superior in intra and inter-examiner reproducibility than methods like KT-1000. GNRB measurements demonstrated a significantly decreased mean side to side difference at 1.87 ( range 0.2-0.49) mm in internal bracing group as compared to ACLR group ( range 1.2 to 5.6 mm,  $p = 0.0107$ ).

Murray et al found no significant difference between the BEAR and ACL reconstruction group for AP knee laxity (expressed as side to side difference ) not exceeding the non inferiority criterion of +2.0 at 95% CI.

There was no statistically significant difference between the ligament augmentation device group and the nonligament augmentation device group in the study by Mark D. Santi et al. At a six-month follow-up, neither group's cases demonstrated grade 3-positive results for the Lachman and anterior drawer tests. None of the cases in both the groups showed positive pivot shift test at 6 months follow up. Harvesting the semitendinosus tendon alone without the gracilis avoids flexion and internal rotation strength deficits [17, 18]. Fiber tape can be applied to the semitendinosus graft to prevent gracilis harvesting and its associated problems, such as a loss of flexion and internal rotation strength. Although there are theoretical benefits to using synthetic fibertape in addition to hamstring

autograft for ACL rehabilitation, many uncertainties remain. The early revascularization phase of the autograft may benefit from stress shielding, but it is still unclear how long-term stress shielding may affect the graft's ultimate tensile characteristics.

The objective parameters (KT-1000 arthrometer testing, the existence of pivot shift, or the Lachman knee score) did not differ enough, according to Mark D. Santi et al., to imply that the ligament augmentation device enhanced graft performance. There was also no discernible difference between the two groups when subjective data (such as the Lysholm knee score, return to Tegner activity levels, and overall subjective rating) were compared.

In the internal bracing group, Szwedowski D et al discovered two complications: one patient experienced a rupture, while the other had restricted extension and underwent arthroscopic debridement of scar tissue in the intercondylar notch.

Mark D. Santi et al [15] in their study, 4 of 28 patients (14%) with ligament augmentation device had recurrent symptomatic effusions. Removal of the synthetic material was helpful in all patients.

In our study, none of the participants experienced such a complication. Major limitation of our study was the number of patients included and the short period of follow up as we could not assess the long term effect of fibretape on the graft and long term complications

### **Conclusion:-**

The anterior cruciate ligament repair technique incorporates the augmentation of hamstring autograft with fibretape. Improvement in grades of anterior drawer test and Lachman's test were present in both bracing and non internally braced group post operatively. The improvement in laxity was statistically insignificant therefore it can be concluded based on the observations in our study that fibretape plays no significant role in improvement in grades of Anterior drawer test and Lachman's test. On comparing the improvement in subjective functional improvement by Lysholm knee score among both the groups, the difference was significant, hence quadriceps hamstring graft braced with fibretape had beneficiary effect in improving lysholm knee score. At 6 months follow up all the patients had complete extension of knee without any extension lag. In the internally braced group post surgery pivot shift test was negative in all cases, therefore indicating the rotational stability of the knee. Augmentation with fibretape did not develop any complications like effusions or allergic reactions. We harvested semitendinosus graft in all our patients. As the fibretape was applied to semitendinosus graft it prevented harvesting of gracilis tendon in most of the cases. Hence in only few cases gracilis tendon's addition was required to the semitendinosus graft thereby improving the overall result. Fibretape augmentation in ACL reconstruction aids in graft protection, especially in the healing process. It acts as a safety belt providing protection from extreme loads. It serves as supplementary knee stabilizer, avoiding damage and graft elongation over time. The fibretape may increase thickness of the graft with diameter less than 8 mm. The hamstring graft internally braced with fibretape is used in primary reconstructive approach and patients can begin active physiotherapy as per rehabilitation protocol immediately after surgery and can return to usual functional activity level sooner. Improvement in functional capacities of the internally braced with fibretape group showed significant improvement at 12 weeks and 6 months than non-internally braced group which was comparable to other studies done on the similar subject. Follow up period of 6 months was a limiting factor as we could not access the effects of quadriceps hamstring graft braced with fibretape in ACL reconstruction in the long term. Due to financial issues we could not do MRI evaluation of our subjects in the follow ups which could have also yielded more information.

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