Original Article

An Overview Of Internal Brace Augmentation For Anterior Cruciate Ligament Construction

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Abstract

Background: Anterior cruciate ligament injury is one of the most common knee injuries, with approximately 250,000 ACL tears occurring in the United States per year. Historically, ACL injuries were described by ancient Egyptians in the famous Smith Papyrus (3000 BC). Hippocrates also (460– 370 BC) mentioned the subluxation of the knee joint with ligament pathology. However, the Greek physician Claudius Galen was the first to describe the true nature of the ACL. Synthetic grafts had been postulated to have both biological and biomechanical significance to induce new tendon synthesis around pure carbon scaffold. This was experimented in animal models by group from Cardiff during 1970s and 1980s. Giving the promising results; they shifted for human clinical trials which showed sinus formation over graft material as an only reported complication after maximum three years follow up. However, Rushton et al. reported complications for ten of thirty-nine patients who underwent synthetic carbon- fiber graft ACL reconstruction. These were synovitis, staining of cartilage and menisci and thin formed fibrous sheath around the graft alongside with the previously described skin ulceration over graft's securing knots. This valuable study was published in 1983.

Keywords: Inguinal Hernia

INTRODUCTION

Understanding the morphology of the anterior cruciate ligament (ACL) is essential for its anatomical reconstruction, which is the "restoration of the ACL to its native dimensions, collagen orientation and insertion sites" (1). The bony femoral ACL insertion is in the shape of a crescent, with the resident's ridge (lateral intercondylar ridge) as its straight anterior border and the posterior articular margin of the lateral femoral condyle as its convex posterior border

Mochizuki (1-5), Iwahashi (6), and Sasaki (7) histologically described the ACL midsubstance fibers to form a narrow "direct" insertion posterior and along the lateral intercondylar ridge which was continued by a fanlike "indirect" insertion towards the posterior femoral cartilage. Interestingly they found the configuration of the ACL midsubstance to be "rather flat, looking like lasagna" (5).

In all dissected knees, Mochizuki et al found that the intraligamentous part of the ACL from close to its femoral insertion to the midsubstance was observed to have a ribbon like structure. The femoral bony insertion of the ribbon was in exact continuity to the posterior femoral cortex (8-15).

Although the midsubstance fibers of ACL can be reconstructed by creating a tunnel at the femoral and tibial ends of each fiber bundle, few studies recommend creating a femoral tunnel in the attachment area of the fanlike extension fibers in order to reconstruct the AM bundle of the ACL (15-20).

Internal brace augmentation was described in repair of many ligaments as anterior tibio-fibular ligament (ATFL) repair. In 2013. Nicholas A. Viens et. al published a biomechanical study that compares Brostrom repair with the augmentation by high molecular weight polyethylene (UHMWPE) and polyester (FiberTape, Arthrex Inc) as an internal brace to native ATFL cadaveric ankles. They concluded that The ATFL with suture tape augmentation is at least as strong as the native ATFL at time zero in a fresh-frozen cadaveric model (20-25).

In 2014, internal brace augmentation by the same fiber tape was used to augment the knee medial collateral ligament and posteromedial corner repair by James H. Lubowitz. They intended to protect the repaired ligament from noncompliant patient activity, secondary injury, or construct elongation and failure during early rehabilitation. The augmentation could be considered as secondary stabilizer after return to sport, particularly when patient compliance with external orthotics may be poor (26).

Theory:

ACLR surgeries in large multicenter cohort studies have described the rate of revision anterior cruciate ligament reconstruction of 1.7% to 7.7% with an estimated 13,000 revisions performed annually in the U.S. A prospective study performed by the Multicenter ACL Revision Study (MARS) Group showed that isolated trauma accounted for 35% of first-time graft failures (27).

Furthermore, in the absence of technical errors and traumatic events; the cause of failure is defective graft integration. "Biological failure" is a used term to describe such failures because of inadequate graft "ligamentization" (28).
This term "ligamentization" was firstly used in 1986 by David Amiel et. al to describe histological and biochemical metamorphosis that occur to patellar tendon (PT) autografts as they transform to a substance very similar to normal ACL. He said: "This general process, which we refer to specifically as "ligamentization," was recognized by Wilhelm Roux in 1905. His "law of functional adaptation," stating that "an organ will adapt itself structurally to an alteration, quantitative or qualitative in function, "holds true for PT auto grafts" (29).
During this functional adaptation period, the graft shows multiple histological stages. They are necrosis, revascularization, cellular repopulation, proliferation and remodeling (30). Necrosis last for 3– 4 weeks and usually happens in the central portion of the graft (31). This is followed by revascularization phase that perfuse the graft well by the eighth week post operatively. This perfusion comes mainly from the fat pad distally and posterior synovial tissues proximally (30).
Cellular repopulation with mesenchymal stem cells and regenerative fibroblasts, as well as revascularization, have been shown to be completed 12 weeks after surgery (30).
Finally, collagen remodeling continues to happen during the first year after surgery by changing the non-reducible/ reducible crosslink ratio in collagen fibrils. These biochemical changes make the new graft have mechanical properties that resemble the native ACL (32). Alongside with theses biochemical changes that convert the implanted tendon by the ligamentization process to a tissue that mimic the native ACL; the mechanical loads over the implanted tissues are essential for healthy incorporation and healing (33).

Given the biomechanical bases for graft healing; protection of the graft during these phases in controlled manner lower chances for mechanical and biological graft failure. A non-biological "safety belt" that prevents graft over elongation in the remodeling phase. Consequently, this is the bases of internal bracing (34).

2. Biomechanics:

In 2016, Samuel Bachmaier et.al published a study testing biomechanical full construct model of internal brace augmentation of grafts. Some of this study's important points will be presented as a rational for internal bracing principle (35).
In this study the used tendons were hamstrings tendons which are stitched to a suspensory cortical device. Suture tape (Internal Brace, Arthrex, Naples, FL) is used as augmentation device and it is connected to the femoral device. Both the free ends of the graft and the tape are not connected. Consequently, this allows for "independent" tibial side fixation. Therefore, the graft and the tape "brace" have a synergistic load- sharing effect. Additionally, the slack fixed tape allows the mechanical loads to be exerted over the graft while the tape act as a safety belt against harmful loads.
Bovine flexor tendons were harvested from adult bovine hind limbs due to bovine flexor tendons are similar viscoelastic and structural properties to human hamstrings tendons (36). These harvested tendons are fashioned in four groups: two are 8mm tripled and 9 mm quad eagle grafts without suture tap. The other two samples are 8mm tripled and 9 quadrupled grafts with suture taps. Fifth sample has only suture tape has been experimented under the same settings. (**Figure1**)

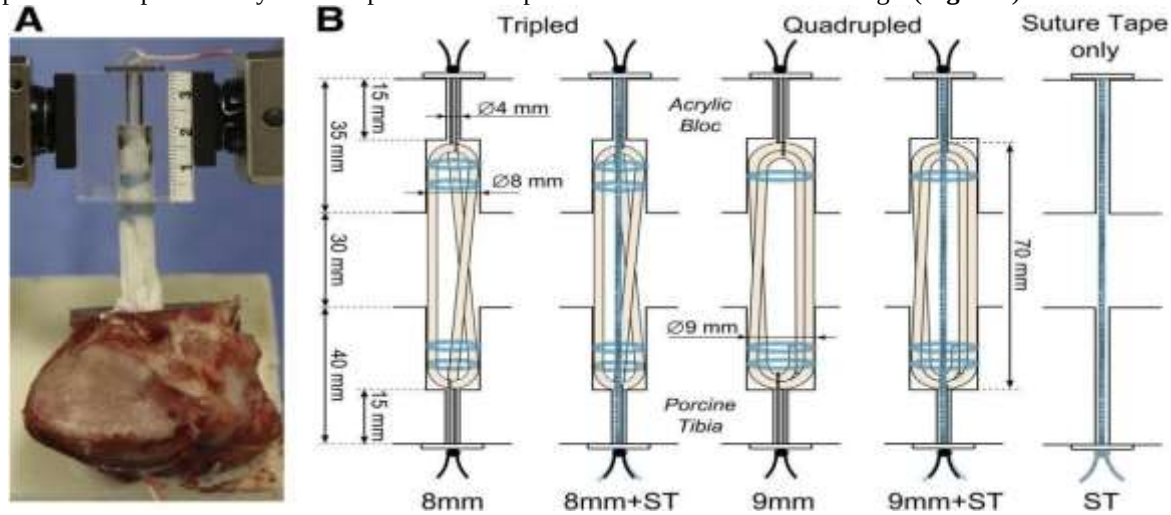

Figure 1: Samuel Bachmaier's experiment setup (A) Final experiment setup (36) (B) schematic illustration of bone tunnel and graft-related definitions for tripled, quadrupled all-inside anterior cruciate ligament graft constructs, suture tape only configuration assuming a 30-mm joint space. (ST, suture tape.).

It was found that the ACL experiences consistent length decreases of 1 and 3 mm at 30_ and 90_ respectively during flexion activity starting from full extension.
Therefore, a joint space of 30 mm would represent a knee in full extension, so that a 29- mm joint space represents 30_ of flexion and a joint space of 27 mm a knee in 90 of flexion. Thus, the suture tape fixation was performed with 1-mm tape slackness in reference to a knee in full extension (30-mm joint space) (37). This fact indeed influences the sequence of suture tape and graft fixation and tensioning in the actual situation to achieve the principle of "safety belt".
The results of mechanical testing of all groups have been demonstrated under three main properties.

Elongation:
The 8 mm þ ST group revealed a dynamic elongation decrease of 38% and 50% after the 250 N and 400 N force compared with the 8 mm group. The 9 mm þ ST group showed a dynamic elongation decrease of 15% and 26%, respectively. The final cumulative valley (ST) and peak elongation (sum of ST and HWF,400) during the last load cycle at 400 N for 8 mm þ ST were 59% and 53% decreased compared to the 8 mm group. The 9 mm þ ST group revealed an analogous decrease of 39% (valley) and 36% (peak). Final peak elongations at 400 N for both control (8 mm/9 mm) and suture tape only (ST) groups showed increased values compared with native ACL behavior during walking at late rehabilitation loads (400 N)
(38). For each soft tissue graft group, hysteresis curves of a representative test sample at the end of each force control block were used and referenced to native ACL behavior and the isolated ST group (**Figure 2**). All hysteresis curves for reinforced groups are within the defined native ACL function zone. A complete loose state was assessed for the 8 mm control group at the end of both loading levels. (**Figure 2**).

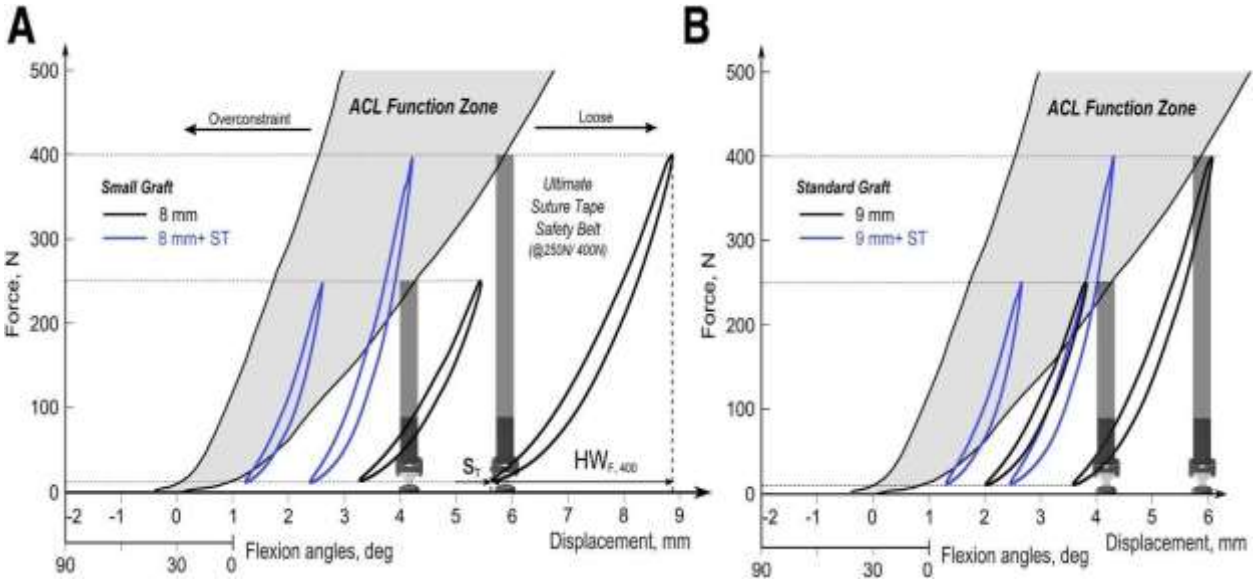

Figure 2: Representative hysteresis curves of small (A) and standard diameter grafts (B) at the end of each dynamic force control test bloc with total elongation (ST) as well as hysteresis width (HWF,400). It is indicator for the final loading situation in reference to final isolated suture tape peak elongation. this act as the ultimate safety belt function and native ACL behavior. (ACL, anterior cruciate ligament; HW, hysteresis width; ST, suture tape.) (35)

Dynamic stiffness:
The 8 mm þ ST group exhibited a 41% increased initial dynamic stiffness (DI,250) compared with the 8 mm group with a higher percentage increase until reaching a 70% higher final value (DF,400). The 9 mm þ ST group had a 31% and 47% increased initial and final stiffness compared with the 9 mm group. For each soft tissue graft group, a representative stiffness over peak elongation progression during force control is shown and referenced to native ACL behavior during walking activity (**Figure 3**). Final dynamic stiffness and peak elongation of both reinforced groups at late rehabilitation loads (400 N) are in the range of the native ACL behavior indicated by the ACL function zone. In addition, the final peak elongation of the isolated ST group at late rehabilitation loads is shown representing the ultimate safety belt function.

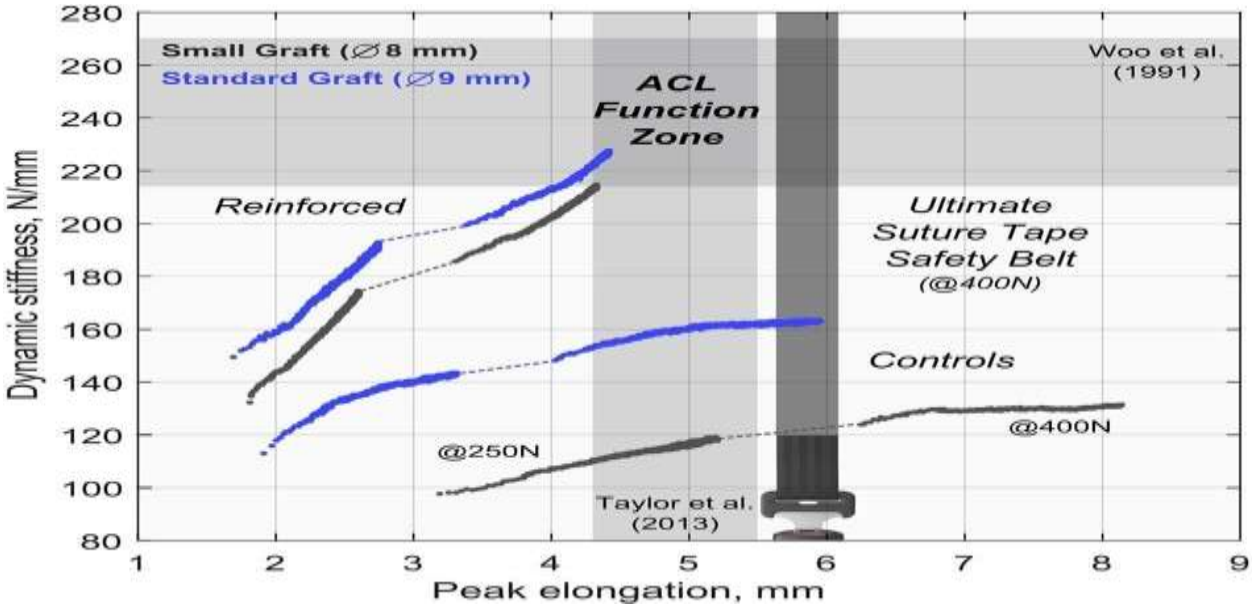

Figure 3: Exemplary stiffness over peak elongation progression during force control loading (250 N, 400 N) for each test group (35). Final isolated suture tape peak elongation represents the ultimate safety belt function at late rehabilitation loads with native ACL references. (ACL, anterior cruciate ligament).

Ultimate failure:

None of the test specimens failed during cyclic testing; therefore, all constructs were subject to a final load-to failure test. Independent suture tape augmentation of the tripled graft improved the ultimate load and stiffness for a 64% and 77% increase. augmentation of a quadrupled graft revealed a 40% and 45% increase in ultimate failure load and stiffness. Control and suture tape augmented groups‟ common modes of failure were damage of the adjustable loop sutures and fixation site damage of the suture tape and the adjustable loop sutures.

Noonan et. al published another biomechanical study that test the same outcomes with Samuel Bachmaier et. al study using the same test protocol and methodology. The difference was that Noonan et. al used a tibial interference screw instead of cortical suspensory device. This study shows that tibial screw using construct has less dynamic elongation at higher stiffness in comparison to cortical suspensory button fixation. Additionally, Placement of the screw tip in line with the tibial joint line results in a decreased free graft length compared with the all-inside technique, that could be the cause for reduced elongation and increased construct stiffness (39). This could be supported by previous data that compare suspensory fixation and interference screws at tibial side in ACLR (40).

Recent evidence reported that ACLR with small diameter grafts (less than 8mm) shows higher failure rate regardless the fixation devices (41). However, this study demonstrated that independent augmentation enhances the construct stiffness, resulting in higher resistance to dynamic elongation, as well as ultimate failure strength. Therefore, independent suture tape augmentation technique particularly improves the operating characteristics of tripled smaller-diameter soft-tissue grafts with tibial screw fixation to allow shifting them toward the mechanical properties of more stable quadrupled grafts (9 mm) (39). This augmentation of small grafts by suture tape could be a highly effective method to augment such graft rather than using allograft augmentation which showed suboptimal clinical outcomes (39).

Besides restricting ACLR graft lengthening during cyclic loading, soft-tissue augmentation gives protection of weak graft fixation sites, leading to distinct failure modes during ultimate strength testing at significantly higher failure loads. Some control samples failed because of rupture of the femoral suture, whereas the augmented samples showed a common mode of failure with tibial graft and suture tape slippage out of the retaining tunnels representing the weakest combined construct fixation site. This study also concluded that quadrupled augmented grafts showed no over-constraining and structurally behaved similarly to tripled grafts with augmentation (39).

In another biomechanical laboratory study that tests the internal brace augmentation of bone patellar bone graft in several mechanical properties, the following are the most relevant results. Cyclic displacement was significantly decreased by 31% for a patellar BTB allograft by adding suture tape as an independent internal suture augmentation compared with the same fixation without internal suture augmentation. Additionally, stiffness was not significantly increased by adding the suture tape as an internal suture augmentation. There was no stress shielding of the graft from use of the suture tape. Therefore, Internal brace augmentation of an ACL graft could allow for more progressive rehabilitation related to early weight-bearing and strengthening exercises (42). Finally, independent fixation of the graft and fiber tape on femoral suspensory device allows for final graft tensioning after tibial fixation which usually leads to minimal slackness of the graft especially when it done by screw fixation (43).

Biocompatibility:
As mentioned early in this review; synthetic grafts had been used intra-articular to replace injured ACL to prevent the hazards of autografts donor sites morbidity and facilitate early return to sports. However, the results were unsatisfactory (13). Second wave of synthetic grafts are introduced such as: carbon fiber, dacron, Leeds-keio and finally The Ligament Augmentation Reinforcement System (LARS). Chen S. et. al reported in their systematic review that While most synthetic grafts for ACL reconstruction have been abandoned, one device (LARS) continues to be used, particularly in China. Additionally, these results were more pronounced with above 30- year- old age group and post-operative synovitis was less severe than old synthetic grafts (44).
Smith, P. et al published a canine model in which a Multi stranded Long-Chain Polyethylene Suture Tape (FT, Arthrex Inc.) is implanted arhtroscopically as internal brace augmentation in dogs‟ knees. Moreover, the implanted tapes 50% of them was intact, and the other half was cut and frayed to be as "worst-case" scenario according to intra-articular exposure to the tape‟s synthetic material. All the groups were examined arthroscopically at 4, 6 months postoperatively for synovium and cartilage grading. Furthermore, histological assessments were done in comparison of partial tear and ACL reconstruction cohorts as well as historical sham controls. The conclusion of the study is "No severe inflammatory or immune responses, bony erosions, or premature OA development were noted during the 6- month study period, even in a "worst-case" scenario model (45).

4. Advantages:
Functional deficit in knee flexion beyond 70 degrees has been found to be less with all- inside ACL reconstruction compared to standard anatomical ACL reconstruction. That was referred to the need for one tendon, mostly semitendinosus, in All- inside technique (46).

Suspensory fixation devices have been found to exert two effects at the intra- articular sides of both femoral and tibial sides due to graft motion. These mechanisms are called windshield-wiper and bungee cord phenomena (47). Consequently, this leads to tunnel expansion and delayed graft healing at intra-articular sides of both tunnels (48). However, this tunnel widening does not correlate with any clinical significance (49). Furthermore, all-inside technique creates incomplete tunnel that make less graft length subjective for windshield- wiper and bungee cord phenomena and less tunnel widening (49).
This incomplete tunnel property gave lower VAS pain scores at early post- operative (day 1, on day 7, at 1.5 weeks) periods (50).
All-epiphyseal all-inside ACL technique has been described in skeletally immature patients. Follow up MRI showed the area of mean area violated surface about
57.2 mm2 compared to 145.1 mm2 in transphyseal ACL reconstruction. However, no growth arrest, articular surface violation or avascular necrosis were observed in both groups (51).

5.Disadvantages:
A biomechanical study comparing adjustable loops with fixed loops found that the ultimate load to failure of both exceed the loads that could be applied to knees in early post-operative periods. However, adjustable loops experienced significant elongation (about 3 mm) during cyclic loading. Furthermore, the most common point of graft failure in adjustable loops is near the sutures contact with the loop (52).
One study conducted in France compared the cost difference between an all- inside ACL and standard ACL technique (36). They found that the all-inside ACL technique was 18% more expensive and cost on average 931.06 euro versus the standard ACL reconstruction cost 791.59 euro. This increase in cost was mostly attributed to the single use equipment required for the retrograde drilling and suture pass in the all-inside ACL (53).

6.Outcomes:
The Evolution of knee surgeries including ACL reconstructions has been predicted to introduce new techniques and principles that have different evaluation and measurement prospectives. Historically, empiric assessment by various assessors in unscientific approach which led to erroneous conclusions. This made O‟Donoghue to state, "results from various methods have been unsatisfactory despite the rather glowing reports by the promulgator of each."(54).
Faegin and Blake were the first to realize the increasing needs to establish a standard method to evaluate several surgical procedures‟ outcomes (55). This was mandatory as 1980s was crowded by several newly invented and growing knee surgical techniques and principles which were in real need to be criticized in standard fashion by standard rating system (56). Therefore, the international knee documentation committee (IKDC) was formed in 1987 to introduce a one-page evaluation form that can be used by all clinicians, even if they are not researchers, to evaluate the different surgical procedures outcomes. Since that date, several revisions and measurements‟ validations were done in association with other committees such as AAOSM in 1997. By March 1998 the committee agreed that a testable form had been drafted. The purpose of this manuscript is to report the process used to develop the IKDC Subjective Knee Form as well as its reliability and validity (54). Consequently, IKDC subjective knee form could be considered as a reliable and a valid mean to assess several knee functions, symptoms and sport activities in variety of knee problems. The outcomes measured by this form can be reported then compared in numerical data and finally to take a decision regarding recommending or not of modifications in surgical procedures.
Furthermore, another subjective score, the Lysholm score, was first described in the Orthopedic literature to measure the

outcomes after knee ligamentous injuries in 1982 (57). In 1985, the Lysholm score was modified to be adjusted for evaluation of meniscal injuries. This modification was achieved by introducing the domain of locking (58). Over 25 years; this scale underwent multiple modifications and verifications. However, Briggs,
K. K et. al stated that "After 25 years of changes in the treatment of ACL injuries, the Lysholm score and the Tegner activity scale continue to demonstrate acceptable psychometric parameters" (58).
Unfortunately, all these scores were developed in English. Thus, this could be an obstacle in introducing them in the Arabic cultures as some of its terminology and cultural prospective are inconsistent with Arabic societies. Consequently, Cross-cultural adaptation protocols are becoming mandatory to adjust the health-related evaluation with languages to reach a comparable results with the original form (59). This operation includes not only to language translation but also to the adaptation across the cultures, and adoption manners of different life. This was achieved in 2019 by K.M. Ahmed et al when he published his translated and validated form of both IKDC subjective knee form and Lysholm score (60)**.**
The previously described and validated scores are subjective scores that depends on patient‟s personal experience and perception. Therefore, another objective measurements of knee function after ACL injuries were invented to improve the results quality and to add another method to assess outcomes after any specific intervention.
Instrumented arthrometry has become an accepted part of knee assessment following injury and reconstruction. The KT-1000 and KT-2000 (MEDmetric Corp, San Diego, Calif., USA) have become introduced as devices providing acceptably accurate and reproducible laxity measurements, with certain limitations (61). However, KT- 1000 and KT – 2000 devices are not easily transported and even sterilized, The Rolimeter (Aircast, Europe) is a simple, new device that overcome these obstacles and provides a comparable measurement to KTs devices. A. Ganko et. al stated that "In this study the Rolimeter was as accurate as the KT-1000 in differentiating an ACL-deficient knee from a normal knee. In patients with chronic ACL-deficiencies there was no significant difference between the two devices, with a strong correlation between side-to-side differences." (62).
On the other hand, Rolimeter is instrumented device that depends on manual force applied to the knee during examination which could be a questionable issue regarding intra and inter-examiner reliability and comparability. Muellner et al. found that there is not a significant difference on the test between examiners. Furthermore, as the examination technique is standardized; the intratester correlation was higher in the re-test. This was applicable to non-experienced hands compared to experienced hands (63).
Lachmeter - The digital Rolimeter (Aircast, Europe) is the selected device in our study that follows all the principles, validation and technique of the Rolimeter®, but it provides its measured values of laxity on a digital screen rather than a metered scale as in the original Rolimeter (**Figure 4**).

Figure 4: Lachmeter device

Finally, Rolimeter is used to measure and compare knee laxity before and after ligaments reconstruction surgeries between normal and injured sides, but it cannot predict functional outcomes after such reconstructions. Validated questionnaires e.g. IKDC and Lysholm score are the preferred tools to judge functional outcomes (64).

7.Technique:
Many articles described the sequence of steps during tensioning and fixation of ACL graft and the corresponding suture tape augmentation. One of these articles is the technical note published by Mohamed Aboalata, M.D. Et.al (65). However, these articles fix the graft firstly then the brace which could be against the principle of applying the actual tension over the graft to stimulate "ligamentization". In addition, the joint space is proved to be shortened during knee range from full extension to 30 and 90 flexion by 1 mm and 3 mm respectively (37). Therefore, we proposed to use the same technique but with a different sequnce of tensioning steps that will be demonstrated in this thesis later.
Vancomycin wrapping technique during graft preparation has shown reducing infection rate down to 0% in some literature (66). However, this should not be taken for granted. The importance of simple theatre steps and etiquette cannot be overemphasized. Effective hand washing, gowning, patient preparation, hair removal, laminar flow, and staff movement have always been the mainstay of reducing infection in modern surgery and always will be (67).

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