



Functional stability: an experimental knee joint cadaveric study on collateral ligaments tension

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Received: 10 February 2021 / Accepted: 18 May 2021

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Abstract

Introduction Applying proper tension to collateral ligaments during total knee arthroplasty surgery is fundamental to achieve optimal implant performance: low tension could lead to joint instability, over-tensioning leads to pain and stiffness. A “functional stability” must be defined and achieved during surgery to guarantee optimal results. In this study, an experimental cadaveric activity was performed to measure the minimum tension required to achieve knee functional stability.

Materials and methods Ten knee specimens were investigated; femur and tibia were fixed in specifically designed fixtures and clamped to a loading frame; constant displacement rate was applied and resulting tension force was measured. Joint stability was determined as the slope change in the force/displacement curve, representing the activation of both collateral ligaments elastic region; the tension required to reach joint functional stability is then the span between ligaments toe region and this point. Intact, ACL (anterior cruciate ligament)-resected and ACL & PCL (posterior cruciate ligament)-resected knees were tested. The test was performed at different flexion angles; each configuration was analyzed three times.

Results Results demonstrated an overall tension of 40–50 N to be enough to reach stability in intact knees. Similar values are sufficient in ACL-resected knees, while significantly higher tension is required (up to 60 N) after cruciate ligaments resection. The tension required was slightly higher at 60° of flexion.

Conclusion Results agree with other experimental studies, showing that the tensions required to stabilize a knee joint are lower than the ones applied nowadays via surgical tensioners.

To reach functional stability, surgeons should consider such results intraoperatively and avoid ligament laxity or over-tension.

Keywords Functional stability · TKA · Soft tissue · Collateral ligaments · Experimental test

Introduction

Nearly 20% of patients undergoing TKA (total knee arthroplasty) report dissatisfaction after the procedure [1]. In the past, TKA main issues were related to materials wear [2], leading to eventual loosening of the implant and thus to pain and failure; nowadays most of the problems related to this topic have been reduced, and their impact as a cause of late-revision decreased from 44 to 4.3% [2, 3]. This improvement has nonetheless brought up a different kind of issues:

if the critical aspect is not to be expected in the prosthesis properties anymore, the focus has to be shifted to its implications on the surrounding soft tissue and to the research of the optimal restoration of the physiological biomechanical conditions [4–6]. The main subjects became then associated with stability, being it related to the bone–prosthesis interface or to joint itself; while the first one mainly focuses on micromotions and interface stress, the latter depends instead on a broader series of features, thus representing a challenging and complex topic to deal with [7–9].

To address knee stability, an introductory definition of joint stability itself is necessary: the most general definition states that “it is the ability of a joint to maintain an appropriate functional position throughout its range of motion” [7, 10], meaning that the joint is able to carry the required functional loads and to undergo contact forces of reasonable magnitude without causing any pain nor damage; this also implies that any small change in the loads

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applied is not able to produce any significant change in the position of the joint contact, one of the main prerequisites to achieve satisfying performances after knee replacement. [11–13]

There are three different mechanisms cooperating to achieve and maintain joint stability, one with active function and the other two with passive function [7, 10]: compressive forces generated by the muscles fall in the first category, while joint surface geometries and relative contacts areas are part of the latter, together with the constraining forces generated by ligaments stretching [14, 15].

It is nonetheless to be remembered that the knee joint is characterized by several degrees of freedom [16] as its purpose is to perform a broad variety of motor task, for which an excessively high level of stability would be as harmful as an excessively joint laxity [17, 18]. A physiological knee is then endowed of a “functional stability”, which allows the required freedom of motion yet maintaining the joint stable enough during the foresaid tasks; this concept must hence be considered one of the main goals for TKA surgeries, as it represents an optimal recovery of the joint situation prior to the pathological issue and the implant operation [7, 10, 19].

To obtain this functional target, during the surgery, the surgeon has to apply a certain tension to the joint (precisely to its ligaments) and this operation is usually performed either via tensioners or even manually by the surgeon [20, 21]; the industrial tensioner tools provided by companies are however topic of discussion, as controversies have been raised about the actual amount of force to be applied and their actual beneficial effects over the possible dangerousness [22, 23], but also the manual application resulted in being less precise than it was felt by the surgeon himself, returning then unsatisfactory results [24, 25].

One of the main reasons at the root of these issues is that quantitative thresholds for the forces to be applied have not yet been documented: the properties of the materials involved in the joint biomechanics indeed deeply change when replacing cartilage and bone with metal and plastic, moreover varying the physiological width between the ligaments extremities as a result of the bone cuts, affecting then collateral ligaments tension [19].

It is then important to recall the biomechanical behavior of those fibers, as their properties, in terms of force–length curve, do not follow a linear relationship in all conditions, changing accordingly to the level of tension (force): three different regions can indeed be identified (see Fig. 1), namely the toe region (where the fibers begin their alignment process), the elastic region (where the soft tissue assumes the typical linear behavior and all the fibers are aligned) and finally the rupture region (happening gradually with the breaking of single tissue fibers, then turning into general failure). The regions span and properties however change from patient to patient, and differences in shape and

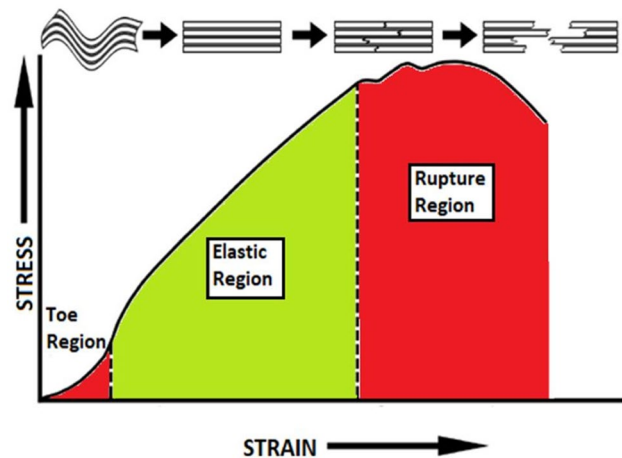


Fig. 1 The stress–strain curve of a generic ligament: in green, the elastic region in which the ligaments are activated; in red the regions of laxity (toe) or damage (rupture). The pictures above the graph represent the fibers status according to the different region

mechanical behavior can be found even between medial and lateral collateral ligaments of the same person [7, 19, 26].

It is thus clear that, to provide passive stability through ligaments, a proper tension (force) must be applied to these structures to avoid the initial laxity (toe region) and to prevent damages to the fibers (failure region); no agreement has however been found about the actual magnitude of this minimal force required to reach functional stability. Therefore, in this study, an experimental test has been performed to identify the lower boundary of this stability region and to check the change of such value in relation to the knee joint cruciate ligament configuration. The tension values measured will be then compared to the tensions currently applied during surgery.

Materials and methods

In this experimental study, a total of 10 fresh frozen cadaveric knee joint specimens were investigated. Medical records of the donors showed that they had no known history of musculoskeletal problems at the investigated knee joint and each specimen presented intact ligaments prior the test. Further information can be found in Table 1.

A LS5 Ametek loading frame equipped with a 1kN load-cell (Lloyd Instrument Ltd, Bognor Regis, UK) was used to perform traction test on the specimens. This testing technique was chosen as it enables to apply measurable tension force to the collateral ligaments in the same way as it would be exerted by a tensioner during a surgery, since both are “pulling-based” approaches.

The femur and tibia were rigidly fixed with polyurethane foam in specifically designed and 3D printed fixtures and

Table 1 Specimens' demographic data

Specimen #	Age (Y)	Height (m)	weight (kg)	BMI	Side	Gender
1	58	1.60	66.7	26.05	R	F
2	68	1.65	61.7	22.66	R	M
3	58	1.55	67.6	28.14	R	F
4	64	1.68	41.7	14.77	R	M
5	56	1.60	54.0	21.09	R	F
6	58	1.60	66.7	26.05	L	F
7	68	1.65	61.7	22.66	L	M
8	58	1.55	67.6	28.14	L	F
9	64	1.68	41.7	14.77	L	M
10	56	1.60	54.0	21.09	L	F
Average	60.8	1.62	58.3	22.54		

then clamped to the loading frame in full extension (Fig. 2a). A constant displacement rate of 0.05 mm/s was then applied to the femoral clamp and the relative resulting force was measured by the machine (Fig. 2b); this displacement rate was chosen as considerable quasi-static and thus comparable to the one applied by the surgeon during the operation, which is evaluated in a static condition [27].

The same procedure was applied to the specimens at 30°, 60° and 90° of flexion, to simulate the effects of a surgical tensioner between femur and tibial plateau during TKA procedure; to perform these tests a specific device designed to allow collateral ligaments traction along the tibial mechanical axis regardless of the flexion angle was used (Fig. 2c). This device, as shown in Fig. 2d, interfaces itself with the testing frame via a component equipped with a hinge (in orange) that can be manually adjusted and fixed at different angles to change the flexion of the system. This hinged component is then connected to the longer segment of the L-shaped component (in gray) through a unidirectional sliding trolley, and same concept is adopted for the femoral fixture (in light blue) on the shorter segment; these two degrees of freedom are used to adjust the device to the different specimens' dimensions without altering the axis of application of displacement (in red), and are rigidly fixed after their setting and before performing the tests.

Each flexion angle was tested in three different cruciate ligaments conditions: initially, both ACL (anterior cruciate ligament) and PCL (posterior cruciate ligament) were preserved (simulating then the soft tissue arrangement in native knee); secondly, after having performed a parapatellar cut to expose the joint and thus the cruciate ligaments, ACL resection was performed by an experience surgeon (TP) and the test was repeated (comparably to what happens during a cruciate-retaining TKA) and finally both the ACL and the PCL were resected and the specimens tested (reproducing the configuration found for a Posterior-Stabilized TKA).

Each combination of flexion and cruciate conditions was tested three times for the sake of repeatability.

During each test, the force/displacement curve of the ligament in the joint was recorded and post-processed (Fig. 3). The analysis of the trends found was then performed, to recognize the different regions of ligament mechanical response; it is to be noted that the results refer to the complete system, considering the whole soft tissue envelope and thus both collateral ligaments action together.

The first region corresponds to the toe region of both the collateral ligaments, in which no linear pattern can be found as both ligaments fibers are still in their alignment process; in this region the joint is unstable as the ligaments are lax. The following region corresponds to the activation of one of them (identifiable by the beginning of an almost linear segment, Fig. 3a); it is to be pointed out that the knowledge of which is the first collateral ligament activating is not a necessary information as the aim of the experience is to find the minimum force at which both of them are exerting elastic response. The first linear segment then undergoes a variation in its slope and then it's followed by a second and longer linear segment (Fig. 3b); this represents the mutual action of both the ligaments, this linearity reflects the fact that the two collateral ligaments are in their elastic region at this point and thus they have achieved the passive stability for the joint. The lowest force necessary to gain this stability can then be found in correspondence with the change of the slope (considered as the intersection of the tangents of the two consecutive sections of the force–displacement function, see Fig. 3c and Fig. 3d), meaning the activation of the second collateral ligament; the force span between the slack region and the found point was then considered to be the force required to guarantee the proper functional stability of the joint. The experimental approach followed is comparable to other studies on knee joint stiffness and stability found in literature but, for this study, the definition of stability is not based on the value of the stiffness itself (i.e. as done in [28]) but rather on the variation of this value, representing the different level of engagement of soft tissue structures.

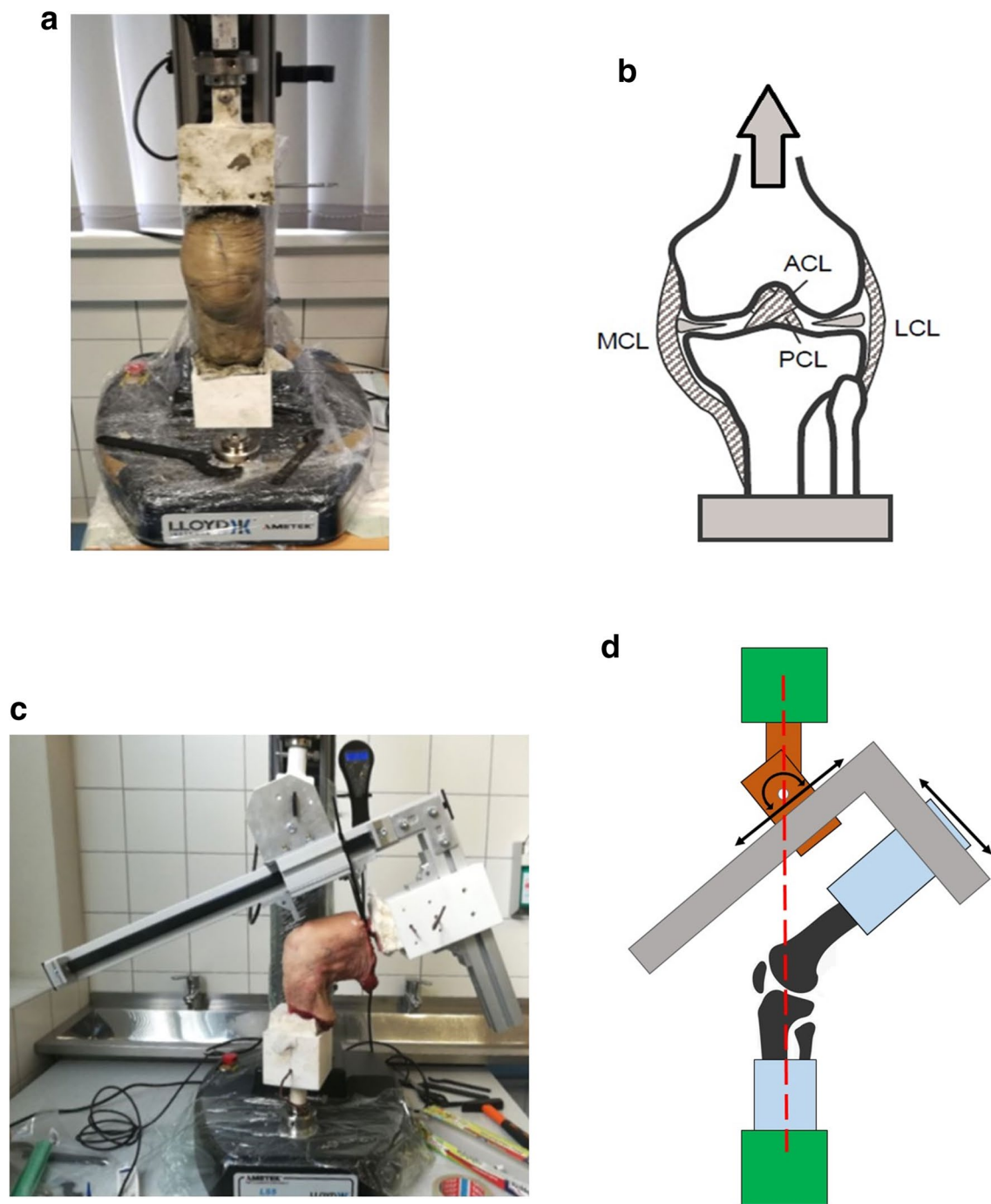


Fig. 2 (a) Experimental Set-up for the Full extension configuration; (b) Schematic Representation of the displacement applied; (c) Experimental Set-up for the other flexed configuration (d) Schematic rep-

resentation of the experimental set-up (the Fig. 2B illustrates the test at a knee flexion of 60°)

All relevant data were then entered in a spreadsheet program and analyzed using Matlab (Matworks, Natick, MA, USA). The normality of the samples was proved via the Pearson Normality test and descriptive analysis was followed for this study, using the mean and standard deviations for continuous variables. To check statistically significant

differences, paired t tests were performed with the Bonferroni correction to properly avoid problems of multiple comparisons [29]: a difference with a p value lower than 0.05 was considered to be statistically significant in all the tests.

All experiments and methods were performed in accordance with relevant guidelines and regulations. All

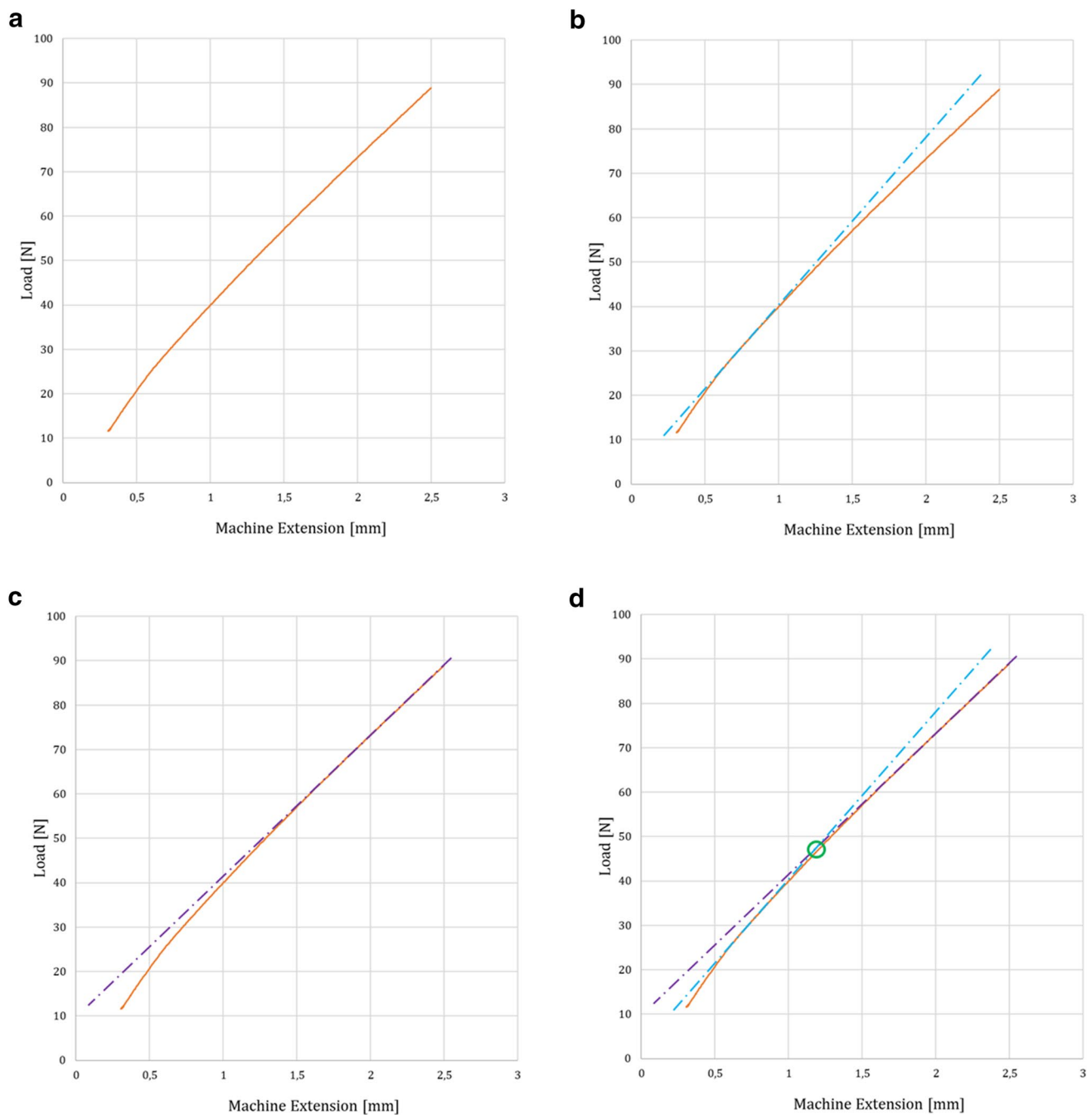


Fig. 3 (a) Force–displacement curve of a generic tensile test (black curve), (b) First ligament elastic region (red curve) overlapped with the black curve; (c) Second ligament elastic region (blue curve) overlapped with the black curve; (d) Identification of the force required to guarantee the functional stability of the joint as intersection of the red and blue curve (green circle)

experimental protocols were approved by the Ethics Committee Erasme Hospital (P2015/439). The specimens were obtained from an ethically approved commercial supplier, Science Care, USA. Science Care ensure that appropriate consent is obtained and their supply includes medical history, serology results and osteoporosis status of the

donors. Donors have given their informed consent during their lifetime.

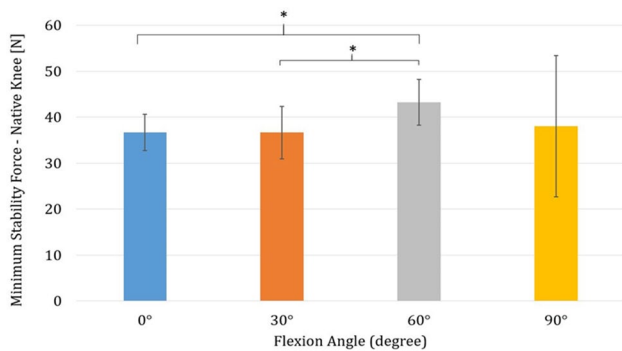


Fig. 4 Results of the minimum force required to reach functional stability for the native knee at 0°, 30°, 60° and 90° of flexion. The bars report the average values while the whiskers the standard deviation. The couples marked with * are statistically different ($p < 0.05$)

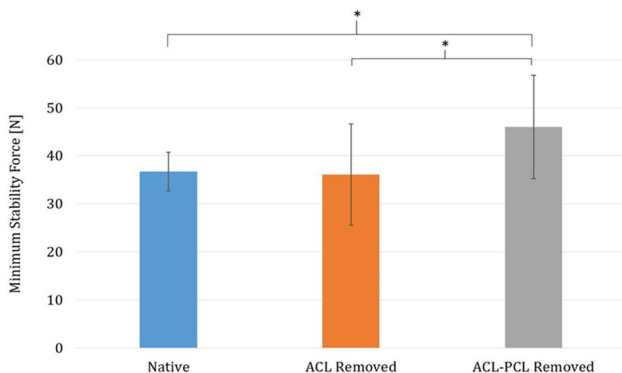


Fig. 5 Results of the minimum force required to reach functional stability for the native knee (blue bar), ACL removed Knee (orange bar) and ACL+PCL removed knee (gray bar) at 0° of flexion. The couples marked with * are statistically different ($p < 0.05$)

Results

Figure 4 reports, for different flexion angles in a native intact knee, the average lower force necessary to achieve functional stability. Results demonstrate how a force of 36.7 N (SD = 4.0 N, Range 30–45 N) is able to guarantee stability at 0°; similar values, with a slight higher variability, were also found for 30° (36.7 N, SD = 5.7 N, Range 32–43 N) and 90° (38.1 N, SD = 15.4 N, Range 20–70 N). At 60°, a slightly statistically significantly higher tension was required (43.3, SD = 5.0 N, Range 35–53 N).

Figure 5 reports, for the different ligament configurations at a flexion of 0°, the average measured minimum force. Results showed that native knee required a force

of 36.7 N (SD = 4.0 N, Range 30–45 N), similar to the one required by an ACL-resected configuration knee (36.1 N); this latter presented however higher variability (SD 10.5 N, Range 24–69 N). When the PCL was also resected, the minimum force statistically significantly rose to a value of 46.0 N (SD = 10.8 N, Range 37–68 N).

Discussion

To provide guidelines to help the surgeon reach functional stability during TKA surgery, in this experimental study, the minimum required force in the knee joint was defined analyzing 10 knee specimens in native, ACL-resected and ACL & PCL resected conditions at different flexion angles.

The results found showed that in average a total tension of 50 N is already sufficient to guarantee functional stability in most of the different configurations; these relatively low tension values find agreement with recently published studies [27, 30, 31], and the higher tensions encountered at 60° of flexion are furthermore in agreement with the mid-flexion instability [32, 33], thus showing that the results obtained can be considered reliable since in agreement with several validated studies.

The results at 0° flexion for native and ACL-removed specimens appear to be similar, and this may be traced back to the fact that, in full extension, ACL effects on the joint are negligible and so they do not alter excessively the stability force required, if not in terms of variability [34]. Removing also the PCL, instead, led to a variation in needed tension also at this flexion angle since in this configuration, all the stability must be provided by the collateral ligaments [35–38]. It is indeed to be considered that the contribution of the soft tissue envelope and of the cruciate ligaments to joint stability is a component not to be neglected, even if the main stabilizing function is provided by the collateral ligaments [31]; this is indeed evident when comparing the results, and the contribution of the different structures can be traced back to their function according to the knee configuration analyzed [39].

It is remarkable that the standards proposed by companies and applied nowadays appear to be noticeably higher than the outcomes of this study, hence representing a cue to question if those high tensions are really the best solution to be applied during surgical operations or if they may be over-tensioning and then induce damage to the tissues in the long term, even if providing stability at first. It is indeed to be considered that these tools' aim is providing stability, so the amount of force is chosen from a precautionary point of view; but on the other hand, application of excessive pre-strain can lead to alteration in the collateral ligaments elongation patterns during the different daily activities, thus to patient unsatisfaction [4, 40].

For what concerns the upper limit of the applicable force, however, various cadaver tests examined single ligaments strain up to the ultimate tensile strength of 600 N, to obtain stiffness calculations over a larger linear section of the force–displacement curve [41–43]. A different study [27] showed then that the fracture limit for the medial collateral ligament can reach values of 1400 N, while lower values are sufficient for the lateral collateral ligament (540 N); all these values are however far higher than the ones usually adopted in any kind surgery, as they represent the extreme border and would lead to degeneration over time.

A relevant element to consider is moreover that collateral ligaments are just one of the foretold three stability mechanisms, with which the other two will cooperate during the actual joint movement; this specification then reinforces the idea that the force provided by the ligaments is not supposed to guarantee stability on its own and then does not need to be excessively high.

It is however to be noted that this study had its limitations, mainly consisting of the fact that the forces analyzed were the global ones and then not referred specifically to medial or lateral collateral ligament [7, 30, 31, 44]; it is however to be kept in consideration that this issue does not affect the conclusion of the study itself, namely that the overall tension to be applied to reach functional stability happens to be lower than the nowadays suggested ones [22, 23].

Furthermore, only one displacement rate was applied to the specimens during the tension tests hence neglecting viscous effects of the tissues; the results, nonetheless, are in agreement with other studies found in literature [26, 27, 45].

Moreover, the tests have been always interrupted before reaching the failure region of the ligaments, due to testing device limits preventing the application of greater loads; the quantitative results we found are consequently related only to the lowest boundary of the tension values guaranteeing functional stability, so the eventual failure threshold has not been defined. However, this information can be found in the literature [27] so the testing methods were defined choosing not to investigate the failure point.

Finally, the specimens tested were only ten and a wider sample pool could provide more realistic and robust results. It is however noticeable that the quality of the ones that underwent testing (fresh-frozen), as reported in literature [1, 44, 46, 47], is able to provide reasonable fidelity for what concerns the mechanical properties on which this study was focused; furthermore, similar number of specimens have been used in similar experimental studies [44].

Conclusion

Drawing conclusions, in this study, the importance of achieving a functional stability rather than stability itself was highlighted; the different soft tissue configurations have to be addressed accordingly and stability has to be guaranteed at each level of flexion, but the results extracted from the tests showed that the tension required is lower than the ones currently adopted.

Surgeon must then recall this information to provide better long-term surgery outcomes, avoiding any form of ligament over-tensioning (even if finalized to a greater stability) but aiming to restore in the most accurate way possible the soft tissue physiological condition.

With the present affirmation, this study however does not negate the efficacy of the devices currently on market or the correctness of the tensions applied by surgeons during implants; instead the main aim of the research resides in pointing out that similar (if not better) results can be achieved by applying lower ranges of forces, preventing then the soft tissue to incur in wear damages and inflammation.

Authors' contributions BI: conception and design, data analysis and interpretation, critical revision of the manuscript. EB: data collection, data analysis and interpretation, writing of the manuscript. TP: conception and design, surgical assistance, critical revision of the manuscript. All authors have read and approved the final submitted manuscript.

Declarations

Conflict of interest The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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