Functional Stability: An Experimental Knee Joint Cadaveric Study on Collateral Ligaments Tension

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Research Article

Keywords: ligaments, surgery, cadaveric

Posted Date: December 2nd, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-110851/v1>

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Abstract

Introduction

Applying proper tension to ligaments during Total-Knee-Arthroplasty surgery is fundamental for optimal implant performance: low tensions lead to joint instability, over-tensioning to pain and stiffness. "Functional stability" must then be defined and achieved. An experimental cadaveric activity was performed to measure the minimum tension required to achieve this stability.

Methods

Ten knee specimens were investigated; femur and tibia were 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 ligaments' elastic-region activation; the tension required to reach functional stability is 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. Different flexion angles were tested.

Results

Results demonstrated an overall tension of 40-50N to be enough to reach stability in intact knees. Similar values are sufficient in ACL-resected knees; higher tension is required (up to 60N) after ACL&PCL resection; slightly higher values were found for 60° flexion. Results agree with other experimental studies, showing that the tensions required to stabilize the joint are lower than the ones currently applied via surgical tensioners.

Conclusion

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

54 **Introduction**

55 Nearly 20% of patients undergoing TKA (Total Knee Arthroplasty) report dissatisfaction after the procedure
56 (1). In the past, TKA main issues were related to materials wear (2), leading to eventual loosening of the implant and
57 thus to pain and failure; nowadays most of the problems related to this topic have been reduced, and their impact as
58 a cause of late-revision decreased from 44% to 4.3 % (2) (3). This improvement has nonetheless brought up a different
59 kind of issues: if the critical aspect is not to be expected in the prosthesis properties anymore, the focus has to be
60 shifted to its implications on the surrounding soft tissue and to the research of the optimal restoration of the
61 physiological biomechanical conditions (4) (5) (6). The main subjects became then associated with stability, being it
62 related to the bone-prosthesis interface or to joint itself; while the first one mainly focus on micromotions and interface
63 stress, the latter depends instead on a broader series of features thus representing a challenging and complex topic to
64 deal with (7) (8) (9).

65 In order to address knee stability, an introductory definition of joint stability itself is necessary: the most
66 general definition states that “it is the ability of a joint to maintain an appropriate functional position throughout its
67 range of motion” (7) (10), meaning that the joint is able to carry the required functional loads and to undergo contact
68 forces of reasonable magnitude without causing any pain nor damage; this also implies that any small change in the
69 loads applied is not able to produce any significant change in the position of the joint contact, one of the main
70 prerequisites to achieve satisfying performances after knee replacement. (11) (12) (13)

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

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

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

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

91 It is then important to recall the biomechanical behavior of those fibers, as their properties, in terms of force-
92 length curve, don't follow a linear relationship in all conditions, changing accordingly to the level of tension (force):
93 three different regions can indeed be identified (see Figure 1), namely the toe-region (where the fibers begin their
94 alignment process), the elastic region (where the soft tissue assumes the typical linear behavior and all the fibers are
95 aligned) and finally the rupture region (happening gradually with the breaking of single tissue fibers, then turning into
96 general failure). The regions span and properties however change from patient to patient, and differences in shape
97 and mechanical behavior can be found even between medial and lateral collateral ligaments of the same person (7)
98 (19) (26).

99
100 It is thus clear that, to provide passive stability through ligaments, a proper tension (force) must be applied
101 to these structures in order to avoid the initial laxity (toe-region) and to prevent damages to the fibers (failure region);
102 no agreement has however been found about the actual magnitude of this minimal force required to reach functional
103 stability. Therefore, in this study an experimental test has been performed to identify the lower boundary of this
104 stability region and to check the change of such value in relation to the knee joint cruciate ligament configuration. The
105 tension values measured will be then compared to the tensions currently applied during surgery.

106 Materials and Method

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

110 *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		

111

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

116 The femur and tibia were rigidly fixed with polyurethane foam in specifically designed and 3D printed fixtures
 117 and then clamped to the loading frame in full extension (Figure 2A). A constant displacement rate of 0.05 mm/s (27)
 118 was then applied to the femoral clamp and the relative resulting force was measured by the machine (Figure 2B). The
 119 same procedure was applied to the specimens at 30°, 60° and 90° of flexion using a specific device designed to allow
 120 collateral ligaments traction along the tibial mechanical axis regardless of the flexion angle (Figure 2C), again in order
 121 to simulate the effects of a surgical tensioner between femur and tibial plateau during TKA procedure.

122 Each flexion angle was tested in three different cruciate ligaments conditions: initially, both ACL (Anterior
 123 Cruciate Ligament) and PCL (Posterior Cruciate Ligament) were preserved (simulating then the soft tissue
 124 arrangement in native knee); secondly ACL resection was performed by an experience surgeon (TP) and the test was
 125 repeated (comparably to what happens during a Cruciate-Retaining TKA) and finally both the ACL and the PCL were
 126 resected and the specimens tested (reproducing the configuration found for a Posterior-Stabilized TKA).

127 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 (Figure 3). The analysis of the trends found was then performed, in order 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, Figure 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 (Figure 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 (Figure 3C and Figure 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.

146

147 All relevant data were then entered in a spreadsheet program and analyzed using Matlab (Matworks,
 148 Natick,MA,USA). Descriptive analysis was followed for this study, using the mean and standard deviations for
 149 continuous variables. To check statistically significant differences, paired t-tests were performed with the Bonferroni
 150 correction to properly avoid problems of multiple comparisons (28): a difference with a p value lower than 0.05 was
 151 considered to be statistically significant in all the tests.

152 All experiments and methods were performed in accordance with relevant guidelines and regulations. All
 153 experimental protocols were approved by the Ethics Committee Erasme Hospital (P2015/439). The specimens were
 154 obtained from an ethically approved commercial supplier, Science Care, USA. Science Care ensure that appropriate
 155 consent is obtained and their supply includes medical history, serology results and osteoporosis status of the donors.
 156 Donors have given their informed consent during their lifetime.

157

158 **Results**

159 Figure 4 reports, for different flexion angles in a native intact knee, the average lower force necessary to
160 achieve functional stability. Results demonstrate how a force of 36.7N (SD=4.0N, Range 30-45 N) is able to guarantee
161 stability at 0°; similar values, with a slight higher variability, were also found for 30° (36.7N, SD=5.7N, Range 32-43N)
162 and 90° (38.1N, SD= 15.4N, Range 20-70N). At 60° a slightly statistically significantly higher tension was required
163 (43.3, SD= 5.0N, Range 35-53N).

Figure 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 ($p<0.05$).

164

165 Figure 5 reports, for the different ligament configurations at a flexion of 0°, the average measured minimum
166 force. Results showed that native knee required a force of 36.7N (SD=4.0N, Range 30-45N), similar to the one required
167 by an ACL resected configuration knee (36.1N); this latter presented however higher variability (SD 10.5N, Range 24-
168 69N). When the PCL was also resected, the minimum force statistically significantly rose to a value of 46.0N (SD=
169 10.8N, Range 37-68N).

Figure 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 (grey bar) at 0° of flexion. The couples marked with * are statistically different ($p < 0.05$).

Discussion

In order 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 (29) (30) (27), and the higher tensions encountered at 60° of flexion are furthermore in agreement with the mid-flexion instability (31) (32), 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 appears 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 (33). 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 (34) (35) (36) (37). 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 (30); 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 (38).

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

192 tissues in the long term, even if providing stability at first. It is indeed to be considered that these tools aim is providing
193 stability so the amount of force is chosen from a precautionary point of view, but on the other hand application of
194 excessive pre-strain can lead to alteration in the collateral ligaments elongation patterns during the different daily
195 activities, thus to patient unsatisfaction. (39) (40)

196 For what concerns the upper limit of the applicable force, however, various cadaver tests examined single
197 ligaments strain up to the ultimate tensile strength of 600 N, in order to obtain stiffness calculations over a larger
198 linear section of the force-displacement curve (41) (42) (43) . A different study (27) showed then that the fracture
199 limit for the medial collateral ligament can reach values of 1400 N, while lower values are sufficient for the lateral
200 collateral ligament (540 N); all these values are however far higher than the ones usually adopted in any kind surgery,
201 as they represent the extreme border and would lead to degeneration over time.

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

206 It is however to be noted that this study had its limitations, mainly consisting in the fact that the forces
207 analyzed were the global ones and then not referred specifically to medial or lateral collateral ligament (7) (29) (30)
208 (44); it is however to be kept in consideration that this issue does not affect the conclusion of the study itself, namely
209 that the overall tension to be applied to reach functional stability happens to be lower than the nowadays suggested
210 ones (22) (23).

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

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

219 Finally, only 10 specimens were tested; a wider sample pool could provide more realistic and robust results,
220 but it is noticeable that the quality of the ones that underwent testing (fresh-frozen) already provides a great validation
221 for what concerns mechanical properties fidelity, thus giving relevance to the results extracted (1) (44) (46) (47).

222

223

224 Conclusions

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

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

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

236

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Figures

Figure 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.

Figure 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 (the figure 2B illustrates the test at a knee flexion of 60°)

Figure 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).

Figure 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 ($p<0.05$).

Figure 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 (grey bar) at 0° of flexion. The couples marked with * are statistically different ($p<0.05$).