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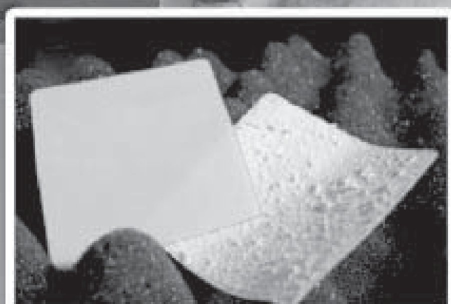

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REVIEW ARTICLE

THE EFFICACY OF FUNCTIONAL KNEE BRACES IN STABILIZING ANTERIOR CRUCIATE LIGAMENT DEFICIENT KNEES: A REVIEW

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Functional knee braces are devices designed to provide support to unstable knees by reducing translation and rotation of the knee. Although functional knee bracing has been extensively studied, its efficacy remains questionable. The purpose of this work was to review previously published studies on functional knee braces in an attempt to clarify the efficacy of these orthoses in providing support to unstable knees. Such insight could aid athletes in deciding whether a functional knee brace could be beneficial in supporting their unstable knee during sports and the clinicians to judiciously prescribe the appropriate treatment. A multistep approach was used to conduct this review of literature. A search of the PubMed electronic database was performed to identify articles relevant to functional knee braces and their effects on anterior cruciate ligament-deficient knees (ACLD). In total, we retained 17 articles based on our inclusion/exclusion criteria and they were considered for the review. Functional knee braces seemed to have only a modest effect on the ACLD knee during dynamic activity from a kinematic and kinetic perspective, especially when external forces were similar to those encountered during strenuous activity (sports). Perhaps the most significant changes due to the application of the functional brace were altered muscle timing and activation patterns in ACLD knees during dynamic activities. Functional knee bracing may not mechanically stabilize the knee but instead alter proprioception and motor patterns of the lower-limb muscles, reducing the variability of tibial rotation and anterior tibial translation of the ACLD knee. Review.

The knee is one of the most complex structures in the human body. It consists of three bones, four major ligaments, complex capsular structure, and several muscles crossing the joint. One of the main ligaments traversing the knee is the anterior cruciate ligament (ACL). Its role is to restrain posterior displacement of the femur on the tibia – also known as anterior tibial translation (ATT) – preventing hyperextension of the knee and limiting medial rotation of the femur. The quadriceps and hamstring muscles also contribute significantly to the stability of the knee. In particular, the quadriceps muscle group is the primary antagonist to the ACL; when activated, it increases ACL strain and ATT. On the other hand, the hamstring muscle group is the primary agonist to the ACL and, when activated, reduces ACL strain

Keywords: functional knee brace, anterior cruciate ligament (ACL), knee joint stability, ACL-deficiency, bracing efficacy, review

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DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.

and ATT (1).

Knee injuries account for up to half of all sport injuries and are most prevalent in ice hockey, team handball, football (soccer), basketball, downhill skiing and American football (2-3). Of knee injuries, ACL tears are the most common and debilitating, and are the most important cause of absence from sport (2,4). The majority of these injuries are caused by non-contact movements (5-6) usually involving planting and cutting maneuvers, straight knee landings, sharp decelerations with or without a change of direction, and pivot shift maneuvers (6-10). There is typically a forceful valgus collapse while the knee is slightly flexed and the tibia is minimally rotated about its long axis, causing the ACL to tighten with extremes of knee extension and muscle contraction (3, 10-12).

Functional knee braces (FKBs), devices often worn during sports, are designed to provide support to unstable/ACL-deficient (ACLD) knees by reducing ATT and rotation of the knee (13). There exist several types of FKB designs, however the two most common are: *hinge-post-sleeve* and *hinge-post-shell* models, both available custom-made or "off-the-shelf". The hinge-post-sleeve design (sleeve brace) (Fig. 1) has a neoprene or fabric sleeve covering the distal part of the thigh and proximal part of the shank whereas the hinge-post-shell design (shell brace) (Fig. 2) has a molded shell of plastic or aluminum and foam components secured to the leg with a strap system. Both types include medial and lateral vertical hinges (which may be uniaxial or polyaxial) and a mechanism to limit knee hyperextension (14).

Although functional knee bracing has been extensively documented in the literature, no clear consensus has been reached regarding its efficacy. The purpose of this paper was to examine previously published peer-reviewed articles on the effects of functional knee bracing on ACLD knees to determine its effectiveness in providing biomechanical support. Critically reporting the findings on the effects of FKBs could aid ACLD athletes in deciding whether these orthoses could be beneficial in supporting their unstable knees during sports, and clinicians to judiciously prescribe the appropriate treatment.

METHODS

A multistep hybrid methodology between a systematic and a narrative approach was used to conduct this review of literature. First, using a Boolean approach, a search of the PubMed electronic database was performed to identify articles relevant to FKBs and their effects on ACLD knees. Initial inclusion criteria included articles that were published in English between 1985 and August 2012, and that were found using the following search terms: ((*knee brac*) OR (knee orthos*) OR (knee orthotic*) AND ((anterior cruciate ligament*) OR (ACL))*, where an "*" indicates that the search returned all results beginning with the root word (e.g. *knee brac** would return results for knee brace, knee braces, knee bracing, etc.). The preliminary search yielded 102 results. The PubMed search was then refined to 47 papers by including only those that studied the effects of braces on ACLD knees, as identified by the following terms: *AND ((deficien*) OR (stability) OR (unstab*) OR (instab*))*. All studies were reviewed independently and critically appraised by two investigators. Studies were included in the review if they reported objective and quantifiable biomechanical effects of FKBs by comparing results from tests performed on ACLD knees with and without a FKB. Abstracts, review articles, unpublished studies, and papers that addressed the effects of bracing on athletic performance or brace types other than functional knee braces were excluded. Studies that evaluated only the psychological or subjective effects of FKBs, or the effects of FKBs on normal or ACL-reconstructed knees were also excluded. As underlined by Cawley and collaborators (15), the American Academy of Orthopedic Surgeons established knee brace classification in 1984. As a result, studies published before 1985 were excluded because in some cases the type of brace evaluated was unclear. Ultimately, 15 articles from the PubMed search were included, as well as 2 additional articles that were identified using the citation index Web of Science. In total, 17 articles evaluating the effects of FKBs on ACLD knees met our inclusion/exclusion criteria and were included in the review.

RESULTS

The studies retained for the review were divided into two categories: clinical studies and

Table I *Summary of findings from clinical studies (i.e. in vitro and functional tests) – effects of functional bracing on ACLD knees.*

Investigators	Methods	Results
In vitro tests		
Wojtys et al. (16)	Testing jig, cadavers, (n=4)	• ↓ ATT by 45.1% at 441.3 N of anteroposterior force • ↓ External rotation by 20.3% at 20 Nm of torque
Wojtys et al. (17)	Testing jig, cadavers, (n=6)	• ↓ ATT at 125 N of anterior force • ↓ Axial rotation at 12 Nm of torque
Liu et al. (18)	Testing jig, surrogates (n=1)	• ↓ ATT at 50 N of anterior force • No effect on ATT at forces >150 N
Functional tests		
Mishra et al. (19)	KT-1000 Arthrometer, (n=42)	• ↓ ATT at 89 N of passive anterior force • No effect on ATT at forces >130 N
Bagger et al. (20)	KSS laxity tester, (n=6)	• ↓ ATT at 100 N of anteroposterior force
Wojtys et al. (21)	VKLD, (n=5)	• ↓ ATT by 33.1% at 133.5 N of posterior force when muscles relaxed • ↓ ATT by 80.1% at 133.5 N of posterior force when muscles contracted
Wojtys et al. (21)	Isokinetic device (Biodex), concentric knee flexion and extension, (n=5)	• ↓ Quadriceps peak torque by 2.4% and hamstring peak torque by 5.8% (results were only significant for some of the participants)
Beynnon et al. (22)	VKLD, (n=9)	• ↓ ATT in non-weightbearing knees at 130 N anterior directed force • ↓ ATT in weightbearing knees at 120 N anterior directed force • No effect on ATT during transition phase

biomechanical investigations. Clinical studies pertained to in vitro tests conducted on cadaveric knees and knee surrogate models, and functional tests performed on humans passively or with use of an isokinetic dynamometer. Biomechanical investigations pertained to studies whose outcome measures included knee joint kinematics, kinetics and electromyography (EMG).

CLINICAL STUDIES

This section reports published peer-reviewed papers on the influence of knee bracing on cadavers, surrogate models and functional tests. The findings from clinical studies are summarized in Table I.

In vitro tests

Wojtys et al. (16) verified the effects of a FKB on the ACL strain response in four fresh ACLD cadaveric knees. The specimens, tested with and without a brace, were fixed to a specialized testing apparatus and loaded with pneumatic cylinders. The axially unloaded knees were flexed to 30° and 441.3 N of anterior-posterior force was applied to the tibia. Subsequently, 20 Nm of torque was applied to the femur (internal rotation). The brace was successful in reducing ATT from 10.2 mm to 5.6 mm (45.1%) and external rotation of the tibia from 20.2° to 16.1° (20.3%) compared to the unbraced condition.

Wojtys and associates (17) tested the efficacy of 14 FKBs in controlling ATT and axial rotation of the tibia in six ACLD cadaveric knees. The specimens, tested with and without a brace, were fixed to a specialized testing jig and loaded with pneumatic cylinders. The axially unloaded knees were tested at 30° and 60° of flexion under 125 N of anterior-posterior force. The same flexion angles were also used to load the knees with 12 Nm of axial tibial torque. All of the braces successfully restricted ATT and axial tibial rotation, to varying degrees, at both 30° and 60° of knee flexion. On average, with the knee flexed at 30°, bracing reduced ATT from 23.7 mm to 20.5 mm (13.5%) and axial tibial rotation from 54.3° to 49.1° (9.6%) compared to the unbraced condition. Likewise, with the knee flexed at 60°, bracing reduced ATT from 23.4 mm to 18.5 mm (20.9%) and axial tibial rotation from 59.3° to 50.9° (14.2%) compared to the unbraced condition.

Table II *Summary of findings from biomechanical investigations (i.e. kinematics, kinetics and electromyography) – effects of functional bracing on ACLD knees.*

Investigators	Methods	Results
Kinematics		
Knutzen et al. (13)	Electrogoniometry, running, (n=21)	• ↓ Flexion angles by 22% during the swing phase and by 13% during the stance phase • ↓ Total knee rotation by 38% and varus/valgus movement by 24%
Théoret et al. (30)	3-D motion analysis system, treadmill running, (n=10)	• ↓ Peak abduction values, total rotational ROM and total abduction/adducti ROM • No effect on knee flexion/extension angular displacements
Ramsey et al. (23)	Bone pins, one-legged jump for maximal horizontal distance, (n=4)	• No effect on ATT
Kinetics		
Knutzen et al. (13)	Force plate, running, (n=21)	• ↑ Relative time to first maximum force by 9% and to first minimum force 13% • ↑ First maximum force by 6% and first minimum force by 7%
Cook et al. (8)	Force plate, straight-line running and cutting, (n=14)	• ↓ Lateral and aft shear forces during running • ↑ Shear forces during cutting
Lu et al. (16)	Force plate, level walking, (n=15)	• ↑ Peak knee abductor moments
Ramsey et al. (24)	Force plate, one-legged jump for maximal horizontal distance, (n=4)	• No effect on peak vertical forces and peak posterior shear forces
Electromyography		
Branch et al. (6)	sEMG, side-step cutting, (n=10)	• ↓ Quadriceps total activity by 18% and peak activity by 14% during the stance phase • ↓ Hamstring total activity by 18% during the stance phase • No effect on muscle activity timing
Németh et al. (20)	sEMG, downhill skiing, (n=6)	• ↑ Muscle activity of all observed muscles in mid-phase during the upward push for the weight transfer • Modified muscle timing of peak EMG for all observed muscles
Ramsey et al. (24)	sEMG, one-legged jump for maximal horizontal distance, (n=4)	• ↓ Semitendinosus activity by 17% prior to foot strike • ↓ Biceps femoris activity by 44% after foot strike • ↑ Rectus femoris activity by 21% after foot strike
Théoret et al. (30)	sEMG, running, (n=11)	• No effect on EMG activity for any of the observed muscles
Wojtys et al. (34)	sEMG, anterior tibial stress test, (n=5)	• Some FKBs improved medial and lateral quadriceps, and lateral hamstring spinal cord reflex times • Had mixed effects on medial hamstring spinal cord reflex times and did no affect gastrocnemius spinal reflex time • Some of the FKBs slowed gastrocnemius intermediate response time • Some of the FKBs slowed medial and lateral quadriceps, as well as medial and lateral hamstring reaction times
Lam et al. (14)	sEMG, leg perturbation, (n=16)	• Shortened the hamstring reflex time by 27.9% before fatigue and by 24.1% after fatigue
Smith et al. (27)	sEMG, single-legged hop for maximal horizontal distance, (n=10)	• Slowed the onset latency of the vastus lateralis • Altered muscle firing patterns in some participants • No effect on time to peak EMG activity

Liu et al. (18) used an ACLD surrogate knee model to evaluate the efficacy of ten FKBs in restricting ATT. The knee model, fixed to a specialized testing jig, was positioned at 20° of flexion and was subjected to anteriorly directed forces on the tibia ranging from 50-400 N, for braced and unbraced conditions. Seven of the ten FKBs controlled ATT to less than 5 mm at 50 N, but only two of the ten braces had the same effect when 100 N of force was applied. At 150 N of force, none of the braces were able to limit ATT to less than 5 mm, and only four restricted this motion to less than 10 mm. At 200 N of applied force, no FKB was efficient in reducing ATT to less than 10 mm.

Functional tests

Mishra et al. (19) evaluated the effects of four FKBs on ATT in 42 ACLD participants. With knees positioned at 30° of flexion, an arthrometer (KT1000 Knee Ligament Arthrometer, MEDMetric Corp., San Diego, CA, USA) was used to measure passive ATT under 89 N of applied force, and for a manual maximum displacement test performed by the examiner, where a load ranging from 130 N to 180 N was directly applied to the proximal calf. In addition, a quadriceps active displacement test was performed, where participants lifted their heel off the table while their forefoot was held down. Each test was performed on the ACLD limb with and without a FKB. For all three tests, all four FKBs reduced ATT to varying degrees. On average and compared to the unbraced ACLD condition, bracing reduced ATT from 5.8 mm to 2.2 mm (62.1%) under 89 N of applied force, from 7.3 mm to 3.6 mm (50.7%) for the manual maximum test, and from 4.9 mm to 2.5 mm (49.0%) for the quadriceps active test.

Bagger and others (20) investigated the effects of a FKB on the passive ATT in six ACLD participants. Using a ligament laxity measurement device (Acufex KSS, Norwood, MA, USA), an anteroposterior translational force of 100 N was applied to the tibia with the knee positioned at 15°, 45° and 90° of flexion. Each test was performed on the ACLD limb with and without a FKB. Compared to the unbraced ACLD condition, the FKB reduced ATT from 7.8 mm to 2.8 mm (64.7%) and from 7.0 mm to 1.2 mm (82.8%) with knees flexed at 15° and 30°, respectively. Although bracing also reduced ATT from 2.0 mm to 0.5 mm (72.4%) with knees flexed at 90°, this change was not statistically significant. Besides, this subtle reduction in ATT would likely

Fig. 1. *Sleeve brace: Bauerfeind SofTec Genu (Bauerfeind USA Inc., Kennesaw, USA).*

Fig. 2. *Shell brace: Donjoy 4Titude (Donjoy Orthopaedics Inc., Vista, USA).*

not have an important effect on knee joint stability as the amount of ATT without the brace was well within the normal range.

The effects of six FKBs on ATT and muscle performance in five ACLD participants were investigated by Wojtys and collaborators (21). The deficient knees were tested with and without a brace. To measure ATT, knees were positioned at 30° of flexion and a specially designed device was used to apply an anteriorly directed force of 133.5 N to the tibia. These tests were performed with knee muscles responding and then with knee muscles relaxed. For the muscles relaxed conditions, on average, all six FKBs decreased ATT from 8.3 mm to 5.5 mm (33.1%) compared to the unbraced ACLD condition. Similarly, with muscles responding, on average, bracing reduced ATT from 6.3 mm to 1.3 mm (80.2%) compared to the unbraced ACLD condition. Furthermore, muscle performance during concentric knee flexion and extension movements was evaluated using an isokinetic dynamometer (Biodex, Biodex Medical Systems, Shirley, NY, USA). Five repetitions at 60°/second were used to evaluate quadriceps and hamstring peak torques, average work and average power. Different braces produced different results. Two of the six braces reduced quadriceps peak torque while four of the six braces reduced hamstring peak torque. None of the braces affected quadriceps average work while five of the six braces decreased hamstring average work. Quadriceps average power was also unaffected with brace application but hamstring average power was reduced with the application of four of the six braces.

During non-weightbearing, weightbearing and the transition between these two conditions, Beynnon and his associate (22) measured the effects of three FKBs on passive ATT in nine ACLD participants. They were fastened to a specially designed device (Vermont Knee Laxity Device) that allowed measurement of anteroposterior displacement of the tibia under loaded and unloaded conditions. With knees flexed at 20°, an anteriorly directed load of 130 N and a posterior directed load of 120 N were applied separately to the tibia to replicate the non-weightbearing and weightbearing conditions, respectively. During the transition phase between non-weightbearing to weightbearing, a compressive load equal to 40% of the participant's bodyweight was applied to the ACLD limb. Each test was performed on the ACLD limb with and without a FKB. All three FKBs reduced ATT during both non-weightbearing and weightbearing tests from 17.4 mm to 12.4 mm (28.7%) and from 10.0 mm to 7.0 mm (30%), respectively, compared to the unbraced ACLD condition. Although bracing also reduced ATT during the transition phase from 4.6 mm to 3.1 mm, this change was not statistically significant.

BIOMECHANICAL INVESTIGATIONS

This section reports published peer-reviewed papers on the effect of FKB on biomechanical variables including kinematics, kinetics and muscle activation. The findings from the biomechanical investigations are summarized in Table II.

Kinematics

Knutzen et al. (23) used electrogoniometry to analyze the effects of two FKBs on knee motion in seven ACLD participants running at 3.33 m/s. Testing was performed with and without bracing of the ACLD limb. Compared to the unbraced ACLD condition, on average, bracing of the ACLD limb reduced the peak knee sagittal plane flexion angles from 75.8° to 59.5° (21.5%) during the swing phase and from 30.5° to 26.6° (12.8%) during the support phase, compared to the unbraced ACLD condition. Bracing also reduced total knee rotation and varus/valgus during the gait cycle from 15.6° to 9.7° (37.8%) and from 14.0° to 10.6° (24.3%), respectively.

In vivo three-dimensional motion analysis was used to measure the effects of a FKB on the tibiofemoral motion during one-legged jumps for maximal horizontal distance (push-off from unaffected limb and landing on ACLD limb) (24). They inserted intra-cortical Steinmann bone pins into the tibia and femur of four ACLD participants to measure the knee kinematics for both braced and unbraced conditions. Bracing the ACLD limb had mixed effects on angular and linear tibiofemoral joint kinematics. For all three planes of motion, the brace caused insignificant changes in tibiofemoral angular joint motions; increased range of motion (ROM) in some, and decreased ROM in others. Similarly, no significant reductions in linear knee joint displacements (i.e., anteroposterior, mediolateral and distraction displacements) were observed between the braced and unbraced conditions.

Ramsey and associates (25) inserted Hoffman bone pins into the tibia and femur of four ACLD participants and used a three-dimensional motion capture system to measure, in vivo, the effects of a FKB on ATT during one-legged jumps for maximal horizontal distance (push-off from unaffected limb and landing on ACLD limb). The ACLD limb was tested for both braced and unbraced conditions. No significant reduction in ATT was produced when the ACLD limb was braced; two participants demonstrated small reductions (1.1 mm and 3.1 mm) while the other showed a slight increase (1.3 mm).

Théoret et al. (26) used three-dimensional motion analysis to examine the effects of a FKB on knee kinematics in ten ACLD participants during treadmill running. The ACLD limb was tested both with and without brace. The average running speed was 2.18 m/s for the unbraced condition and 2.12 m/s for the braced condition. Kinematic data were only collected and analyzed for ten running cycles occurring within the last minute of a six minute running protocol. Compared to the unbraced condition, bracing reduced the peak knee abduction angle from 15.3° to 10.2°, total knee abduction/adduction ROM from 14.7° to 9.2° and total internal/external ROM from 15.9° to 10.9°. No differences were observed in knee flexion/extension between braced and unbraced conditions.

Kinetics

Knutzen et al. (23) used a force plate to examine the effects of two FKBs on knee kinetics in seven ACLD participants running at 3.33 m/s. Testing was performed with and without bracing of the ACLD limb. Compared to the unbraced condition, on average, brace application was shown to increase the relative time to the first maximum and minimum vertical forces by 8% (13.4 seconds vs. 12.3 seconds) and 11% (19.9 seconds vs. 17.7 seconds), respectively. Moreover, bracing increased the first maximum and first minimum vertical forces by 6% (19.5 N/kg body mass vs. 18.3 N/kg body mass) and 6% (16.3 N/kg body mass vs. 15.3 N/kg body mass), respectively. The ACLD participants were able to produce more vertical forces during the braced condition. This could have been due to a more secure knee under the braced condition.

Ground reaction forces were used to measure the effects of a FKB on knee kinetics in 14 ACLD participants during straight running, straight cutting and cross cutting maneuvers with and without bracing of the ACLD limb (27). Compared to the unbraced condition, braced ACLD limbs generated less lateral and aft shear forces compared to the unbraced condition. For straight cutting maneuvers, braced ACLD limbs generated increased forces in the sagittal, coronal and transverse planes of motion compared to the unbraced ACLD condition. Likewise, for cross-cutting tasks, bracing increased the forces in the sagittal and transverse planes of motion compared to the unbraced ACLD limb. The in-depth interpretation of these results is difficult, however, because this paper only reported p-values and did not report actual force values or percentage of change. Therefore, although force differences between braced and unbraced conditions were significant, the magnitude of these changes is unknown.

Ramsey et al. (24) used a force plate to verify the effects of a FKB on knee joint forces in three ACLD participants during one-legged jumps for maximal horizontal distance (push-off from unaffected limb and landing on ACLD limb). The ACLD limb was tested for both braced and unbraced conditions. During this jumping task, bracing of the ACLD limb was found to have no significant effect on peak vertical forces and peak posterior shear forces compared to the same unbraced limb, but did seem to reduce the overall intra-subject variability of these forces.

Lu et al. (28) used force plates to examine the effects of a FKB on peak knee moments and angular impulses in 15 ACLD participants walking at a self-selected pace. The ACLD limb was tested for both braced and unbraced conditions. Bracing increased the ACLD limb's peak knee abductor moments and the angular impulses compared to the unbraced condition. The magnitude of change of these variables cannot be accurately interpreted, however, because the results are only presented as figures from which it is difficult to determine exact values.

Electromyography

Branch et al. (29) used surface EMG to examine if bracing altered muscle-firing amplitude, duration or timing of the quadriceps and hamstring muscle groups. Ten ACLD participants performed side-step cutting maneuvers with and without a FKB. Compared to the unbraced condition, the braced ACLD limbs demonstrated a reduction of 18% in quadriceps total activity and 14% in peak activity during the stance phase. The hamstring showed a concomitant decrease of 18% in total activity. No timing differences were noted between the braced and unbraced conditions for both muscle groups. All muscles showed similar activation patterns, suggesting that bracing did not have a proprioceptive effect.

Wojtys et al. (21) used sEMG to investigate the effects of six FKBs on neuromuscular function during anterior translation stress tests using the VKLD. Five ACLD participants were seated and attached to the device with the knee positioned at 30° of flexion. Tests were performed with muscles responding and with muscles relaxed. During the responding trials, participants resisted the displacing tibial force after they felt its onset. During the relaxed trials, participants were asked not to respond to the tibial displacement. EMG activity was recorded for the gastrocnemius, hamstring and quadriceps muscles. Muscle spinal reflex, intermediate response and reaction time were analyzed. Three of the six FKBs improved the medial quadriceps spinal cord reflex times while only two FKBs improved the lateral quadriceps spinal cord reflex times. The spinal reflex in the lateral hamstring muscle was improved by the application of two FKBs. Conversely, the medial hamstring muscle response time showed mixed results. Gastrocnemius spinal reflex time was modestly affected. The gastrocnemius muscle's intermediate response time was slowed by two of the braces. Five braces slowed the muscle reaction times in the medial and lateral quadriceps muscle. Additionally, four braces delayed medial hamstring muscle response time while two braces delayed lateral hamstring muscle reaction time. It seems that muscle reaction times for most of the brace conditions were delayed. Thus, it can be concluded that bracing did not improve muscle contraction timing.

Németh et al. (30) used sEMG to examine the effects of functional knee bracing on muscle activity in six ACLD participants during downhill skiing. EMG was recorded for vastus medialis, gastrocnemius medialis, biceps femoris, semimembranosus and semitendinosus. Each participant completed four runs in a slalom course of ten turns on a slope rated black diamond. Bracing the ACLD limb increased the EMG activity level of all observed muscles in mid-phase during the upward push for the weight transfer (turn performed with the braced knee facing uphill). Also, peak EMG activity for these muscles occurred closer to maximal knee flexion in mid-phase and was more concentrated in time compared to the unbraced condition. It was noted that bracing modified muscle activity and timing, resulting in adaptations of motor control patterns.

Lam et al. (31) evaluated the effects of a knee brace on hamstring reflex latency in 16 participants with an ACLD knee. Muscle activity of the lateral hamstring was recorded using sEMG. Participants assumed a side-lying position while their ACLD limb was suspended with slings over the thigh and calf. The hip was positioned at 45° and the knee at 90° of flexion. The foot and ankle of the tested leg were connected to a force transducer, which was connected to a line that passed over a pulley in front of the leg. The other end of the cable was attached to a 5 kg mass, which was used to perturb the knee when dropped. Firstly, the participant's hamstring resting EMG was recorded. Then, the weight was dropped and perturbed the lower leg into extension, eliciting a stretch reflex in the participant's hamstring muscle, which was recorded. Participants then performed a flexion-extension protocol of the knee, in the supine position, until fatigue. Once fatigued, tests for hamstring reflex were repeated with and without a FKB. Knee bracing shortened the hamstring reflex time by 27.9% before fatigue and by 24.1% after fatigue.

Ramsey et al. (25) examined the effects of a FKB on the neuromuscular response in ACLD limbs during the transition from non-weightbearing to weightbearing. Four ACLD participants performed one-legged jumps for maximal horizontal distance consisting of a push-off from the unaffected leg and a landing on the ACLD leg. The brace decreased semitendinosus activity by 17% (250 ms) prior to foot strike and biceps femoris activity by 44% (125 ms) after foot strike. Conversely, the brace increased rectus femoris activity by 21% (125 ms) after foot strike. This suggests that bracing improved knee stability by inducing proprioceptive feedback rather than mechanical stability.

Smith et al. (32) examined the effects of functional knee bracing on muscle-firing patterns about the ACLD knee in ten participants during single-legged jump tests (push-off from ACLD leg and landing on the same leg). Muscle activity was recorded for the vastus medialis and lateralis, medial and lateral hamstrings, and medial and lateral gastrocnemius. FKBs were found to significantly delay the onset latency of the vastus lateralis compared to the unbraced condition, even though these effects were present in only one third of participants. Bracing also altered muscle-firing patterns. Without bracing, five of the ten participants fired the hamstrings or gastrocnemius muscles first while seven participants fired these muscles first when braced. Contrarily, FKBs did not affect time to peak EMG activity.

Théoret et al. (26) studied the effects of a FKB on lower-extremity muscular activity and three-dimensional kinematics of the knee in eight ACLD participants during running at a comfortable speed. Surface EMG was recorded for the vastus lateralis, vastus medialis, biceps femoris, semitendinosis, lateral gastrocnemius and medial gastrocnemius muscles. No significant differences were found in EMG activity between the braced and unbraced conditions for any of the observed muscles. Consistent trends of increased hamstring activity and decreased quadriceps activity were observed at heel-strike, suggesting that bracing may have resulted in added stability of the ACLD knee.

DISCUSSION

The knee is a complex structure that moves through six degrees of freedom. The intermediary joint of the lower-limb must provide stability to the athlete during sport maneuvers such as planting, cutting and landing. To avoid injury, muscle strength and synergy are essential to counteract extreme joint loading during sport maneuvers while the knee joint is in vulnerable positions. If dynamic knee stability is compromised, the ligamentous structures of the knee can be overloaded and irreversibly damaged. Once the knee ligaments have been damaged (particularly the ACL), there are very few alternatives to maintaining or improving the joint's stability. Functional braces are meant to help stabilize the knee joint by limiting the anteroposterior displacement and axial rotation in ACLD knees. An ideal brace would complement the muscular and ligamentous knee stabilizers during movements within the joint's normal ROM (14).

The use of functional braces to support ACLD knees remains controversial. Clinical studies have shown that FKBs do not prevent abnormal tibial displacement at physiological loads but they reduce the ATT at low level loads.

For this review, no distinction was made between hinge-post-sleeve and hinge-post-shell brace designs, or between custom-made and off-the-shelf models. It should be noted that previous studies have compared the sleeve and shell brace designs (29, 33) as well as the custom-made and off-the-shelf models (34-35), and found little to no difference between types.

The reviewed evidence from clinical and biomechanical investigations suggests that functional knee bracing may be beneficial in supporting ACLD knees during submaximal dynamic conditions. Results from clinical studies consistently demonstrated that knee bracing effectively reduced ATT at low forces (<150 N) but failed to do so when forces resembled those encountered during strenuous physical activity (>150 N) (16-22). These effects were apparent in non-weightbearing and weightbearing knees but not during the transition phase between the two conditions (22). FKBs also reduced ATT under anterior-directed loading of the tibia when leg muscles were relaxed and even more so when leg muscles were responding (21). Equally, FKBs reduced axial rotation of the tibia when low torques (<20 Nm) were applied to the unloaded cadaveric lower-limb where no muscle contributions were applied (16-17).

Kinematic findings from biomechanical investigations were also appraised. Knee brace application was shown to generally reduce knee ROM in all planes during running activities. Particularly, knee rotational and varus/valgus angular displacements were reduced throughout the gait cycle. Knee bracing showed conflicting results on knee flexion/extension angles as some studies observed a reduction in angular displacements while others found no effect (23, 26).

Kinetic outcomes showed that functional knee bracing increased the relative time to the first maximum and minimum vertical forces during running (23). Although FKBs increased shear forces during cutting tasks, their effect on ground reaction forces during running were mixed and no effect was found during horizontal jumping tasks (23-24, 27). Furthermore, knee bracing caused greater knee abduction moments during walking (28). They were also capable of decreasing quadriceps and hamstring peak torques during concentric knee flexion and extension movements under isokinetic testing (21). Since less muscle torque can be generated, this might limit the net knee moments of force.

FKBs were shown to influence lower-limb muscle activity during various dynamic activities. Mainly, peak and total lower-limb muscle EMG were either decreased, increased or unaffected with knee brace application, depending on the activity (25-26, 29-30). Interestingly, all studies, that verified lower-limb muscle activity, except for one (29), reported that FKBs affected muscle timing. Specifically, muscle-timing characteristics such as leg muscle reflex times, intermediate response times and reaction times were altered with the use of a brace (31). In addition, one study reported the ability of FKBs to favorably modify muscle-firing patterns during dynamic activities (32). The loss of the ACL has been associated with reductions in the ability of detecting knee joint motion due to disruption of normal afferent pathways. Some have speculated that knee braces can substitute for this lost pathway, and that subjective improvements while wearing a brace are due to heightened proprioception (position sense). The hypothesis of enhanced proprioception by knee brace wear is associated with the change of muscle-firing patterns during dynamic manoeuvres. However, more scientific evidence is needed to support the hypothesis of enhanced proprioception through the mechanical skin-brace stimulus. Some feel that psychological support may be the greatest benefit of FKBs (30). Despite the user's subjective stability improvement, giving way episodes of the knee can occur in spite of wearing the functional brace.

The effects of FKBs on normal knees were excluded from this study because these orthopedic devices are meant to support unstable (ACLD) knees and not normal, healthy knees. In this respect, a brace could affect a healthy knee differently than it would an ACLD knee. For a similar reason, the effects of FKBs on ACL-reconstructed knees were also omitted. Moreover, this paper only reviewed the effects of FKBs and not the effects of other knee brace types such as prophylactic or rehabilitative. The reason is that these types of braces are not meant to be used as stabilizing devices for ACL-deficient joints.

In summary, FKBs seemed to only have a modest effect on the ACLD knee during dynamic activity (sports) from a mechanical perspective. These devices fail to limit ATT when forces are similar to those encountered during strenuous activity. They have been shown, however, to have some limiting effects on knee ROM in all planes, which can aid in restricting excessive lower-limb movements, and consequently, reduce the strain applied to the ACL. Kinetic findings revealed no real advantageous effects of FKBs on the ACLD knee. Forces and moments of force about the knee were modified during some activities and not affected during others, suggesting that these devices cannot consistently reduce the forces transmitted to the ACL during dynamics tasks. The effects of FKBs on lower-limb muscle activity found in this review are perhaps the most significant finding. Evidence suggests that functional knee bracing affects, in some way, peak and total-lower limb muscle EMG. Equally, muscle timing and activation patterns in ACLD knees are altered with brace application.

CONCLUSION

This paper reviewed previously published studies on FKBs in an attempt to assess their effects on ACLD knees. FKBs seem to have some desirable effects on the knee and can assist ACL-deficient athletes in continuing their sport practices, although sport performance may be compromised. As reviewed, FKBs do in fact modify knee kinetics and kinematics, however, their mechanisms of action might not necessarily be those initially speculated. FKBs may not mechanically stabilize the knee but alter proprioception and motor patterns of the lower-limb. The adaptation of muscle activation, timing and coordination during physical activity could be beneficial in reducing the variability of tibial rotation and translation of the affected knee.

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REVIEW ARTICLE

POSTERIOR-STABILIZED KNEE ARTHOPLASTY VERSUS CRUCIATE-RETAINING KNEE ARTHROPLASTY. A REVIEW

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Cruciate-retaining and Posterior-stabilized Total Knee arthroplasties are two design of Total Knee replacement that are different in the choice of preserving the Posterior Cruciate Ligament.The aim of this study was to determine if there are significant differences between a fixed posterior stabilized (PS) and a cruciate retaining (CR) total knee arthroplasty (TKA). We conducted a meta-analysis on 11 different studies that we reviewed. Nine outcomes have been analyzed, and we found very few differences between the CR and the PS TKAs with respect to their Knee Society clinical and functional scores. These findings suggest that with careful attention to surgical technique and knee balancing the, orthopedic surgeons should expect similar results whether they use CR or PS TKA. Level of Evidence: I - Systematic Review.

The posterior cruciate ligament (PCL) plays a very important role in knee kinematics (1). It correctly positions the upper segment of the lower limb, the thigh, on the lower segment, the leg. It produces a posterior translation of the femur over the tibia when the joint is flexed (roll-back) and provides an anterior-posterior contact setting of the femur over the tibia (2). This is due to its position of footprint, both posteriorly to the femur and to the tibia. For crippling pathologies of the knee joint, like osteoarthritis and rheumatoid arthritis, the last chance for proper treatment is radical surgery, "Total Knee Arthroplasty"(TKA) (3-4).

We could say that TKA is essentially an artificial coating of the articular surfaces of the knee.

When a surgeon implants a TKA, some natural structures of the joint are preserved, while some are substituted, and others are simply removed.

There is no clear consensus about using the technique of arthroplasty which provides PCL retention of the (cruciate retaining prosthesis) rather than the other which removes the PCL (posterior stabilized prosthesis). There is not enough evidence based information proving which of the two solutions is better (5).

Over the years, orthopedic surgeons and biomechanical engineers have tried to create prostheses and surgical techniques that could properly reproduce the natural movements of the healthy knee and an optimal stability in the flexion-extension movement.

The factors that influence the surgeon's choice are many: the extent of PCL degeneration, the different types of implant, personal experience, opinion (6).

In 2001, Lombardi et al. proposed a flowchart for the correct choice of implant based on several factors,

Keywords: total knee arthroplasty, cruciate-retaining TKA, posterior-stabilized TKA

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DISCLOSURE: ALL AUTHORS REPORT NO CONFLICTS OF INTEREST RELEVANT TO THIS ARTICLE.

such as the patient's clinical history, the clinical examination and an intraoperative assessment (7). In the following years, several randomized clinical trials and controlled trials have been carried out to study the post-operative outcomes of the two prostheses (4, 8-10).

These studies, considered individually, were insufficient for coming to a common conclusion on this topic. Moreover, the question of the significance of the results is still open: were they able to show a significant difference between the two prostheses?

The aim of our study was to identify and evaluate the post-operative functional and clinical differences between the two implants, thanks to a statistical study based on statistical methods for a meta-analysis.

Our meta-analysis was carried out by performing a systematic review of the instruments used to evaluate post-operative outcome in a 2-5 year follow-up that was conducted in randomized clinical trials (RCT), available in scientific reports.

MATERIALS AND METHODS

For our study, 11 RCTs of several levels were reviewed. The systematic review was based on a bibliographic search using top-class scientific literature databases, such as Medline, Pubmed and Google Scholar. Key-words for the search were: total knee arthoplasty, posterior cruciate retaining and posterior stabilized.

The studies analyzed 1458 patients (710 for CRP; 748 for PSP).

To select the published articles we used the PICO Criteria, the inclusion criteria drawn up by the guidelines of Advanced and Policy/Track for EBM (11).

The average age of the population for the CRP prostheses was 70.33 years old (64-74.3); for the PSP, the average age was 69.55 (65-73.8). All studies of populations that were not within the specific intervals or were not matched for age were excluded.

Other exclusion criteria were body weight (kg) and Body Mass Index (BMI). All selected studies fall in a narrow range, close to a weight of 73.4 kg for CRP and 66 kg for PSP.

Another exclusion criterion was time of follow-up. Only studies in which follow-up was performed at 2-5 years from surgery were considered.

The intervention criterion is based on two variables: basic diagnosis and type of surgery. Only studies with patients who suffered from: osteoarthritis (the majority), rheumatoid arthritis, inflammatory arthritis or avascular

Table I. Studies.

STUDY	SHOJI 1994	CLARK 2001	TANZER 2002	MISRA 2003	STRAW 2003	CATANI 2004	MARUYAMA 2004	MATSUDA 2005	HARATO 2008	KOLISEK 2009	YOUNG HOO KIM 2009
OUTCOMES	ROM; improvement of ROM; HSS	ROM; improvement of ROM; KSS	Flexion Angle; Improvement of flexion angle; KSS Complications	ROM; Improvement of ROM; HSS; complication	ROM; KSS	ROM; improvement of ROM;KSS; HSS; complication	ROM; improvement of ROM, flexion angle; improvement of flexion angle; KSS; Complications	ROM; improvement of ROM; HSS	Improvement of ROM; flexion angle; Improvement of flexion angle; extension angle;; KSS	ROM;KSS; complicatons	ROM; Improvement of Rom; KSS; Complications
NUMBER OF PATIENTS	56(28;28)	143(67;76)	40(20;20)	105(51;54)	167(66;101)	40(20;20)	20(10;10)	80(40;40)	192(99;93)	107(53;54)	512(256;256)
%MALE	-	-	23%	30%	54%	43%	40%	11%	52%	42%	4%
AGE	-	71.8	67	67	73.35	70.5	74.3	70	67.15	65	71.6
WHERE	-	Iowa university, hospital clinic Iowa; London health science clinic, Saint james University hospital, Leeds UK..	Division of orthopedic surgery, Montreal, Canada	J.Bone Joint Surgery, Bern, Switzerland	Durbishire royal infirmary, Derby, UK	Istituti ortopedici Rizzoli, Bologna; Italy	Kobe University graduate school of medicine, Kobe, Japan	Ishii orthopedic and rehabilitation clinic, Gyida, Saitama, Japan	Division of orthopedic surgery, Ontario, Canada ; London Health Surgery Clinic. UK	Rubin Institute for advanced orthopedics; Sinai hospital, Baltimore; USA	Joint replacement center of Korea, Seoul, Korea
TYPE OF	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective	Prospective
TIME OF FOLLOW-UP	37 months	24 months	24 months	57 months	42 months	48 months	31 months	24 months	60 months	60 months	28 months
NUMBER OF PATIENTS LOST TO FOLLOW-UP	0	15(8;7)	0	-	11	0	0	-	28(11;17)	16(7;9)	12(6;6)

Table II. *Outcome 1: ROM*

	CRP			PSP				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Catani 2004	97	15	20	114	21	20	2.8%	-17.00 [-28.31, -5.69]
Clark 2001	108.5	12.3	59	113.6	14.6	69	16.2%	-5.10 [-9.76, -0.44]
Kolisek 2009	125	20	46	118	24	45	4.3%	7.00 [-2.09, 16.09]
Maruyama 2004	122.2	14.8	10	129.6	13.9	10	2.2%	-7.40 [-19.98, 5.18]
Matsuda 2005	117.6	14.4	40	116.3	14	40	9.1%	1.30 [-4.92, 7.52]
Misra 2003	107.5	12.3	51	105.2	14.6	54	13.3%	2.30 [-2.85, 7.45]
Shoji 1994	114.2	9.5	28	117.4	10.3	28	13.1%	-3.20 [-8.39, 1.99]
Straw 2003	102.7	12.3	66	110	14.6	101	20.8%	-7.30 [-11.41, -3.19]
Young Hoo Kir 2009	121	25	250	122	25	250	18.3%	-1.00 [-5.38, 3.38]
Total (95% CI)			**570**			**617**	**100.0%**	**-2.86 [-4.73, -0.98]**

Heterogeneity: Chi² = 22.67, df = 8 (P = 0.004); I² = 65%
Test for overall effect: Z = 2.99 (P = 0.003)

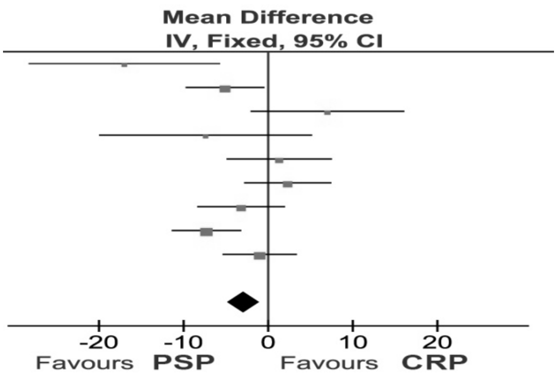
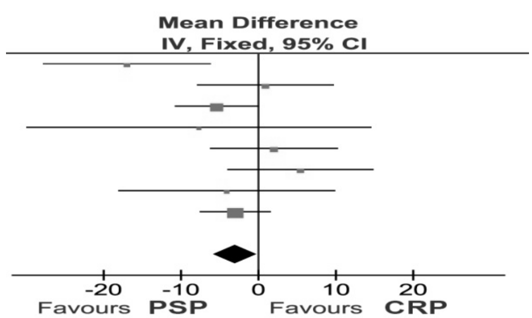


Table IV. *Outcome 3: Improvement of range of motion*

	CRP			PSP				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Catani 2004	-9	18	20	8	17	20	6.3%	-17.00 [-27.85, -6.15]
Clark 2001	-2.1	25.7	59	-3	25.2	69	9.4%	0.90 [-7.95, 9.75]
Harato 2008	5.2	18	99	10.6	20.1	93	25.2%	-5.40 [-10.81, 0.01]
Maruyama 2004	9.7	25.2	10	17.4	25.7	10	1.5%	-7.70 [-30.01, 14.61]
Matsuda 2005	7.8	21.5	40	5.8	15.8	40	10.8%	2.00 [-6.27, 10.27]
Misra 2003	25.5	24.7	51	20.07	24.7	54	8.3%	5.43 [-4.02, 14.88]
Shoji 1994	18.8	27.6	28	22.9	25.9	28	3.8%	-4.10 [-18.12, 9.92]
Young Hoo Kir 2009	-4	27	250	-1	25.5	250	34.8%	-3.00 [-7.60, 1.60]
Total (95% CI)			**557**			**564**	**100.0%**	**-2.99 [-5.71, -0.27]**

Heterogeneity: Chi² = 12.55, df = 7 (P = 0.08); I² = 44%
Test for overall effect: Z = 2.16 (P = 0.03)



necrosis were included.

Only studies that reported post-operative evaluation for the two types of surgery were included. Evaluations after different types of surgery were excluded. Comparison

Table III. *Outcome 2: Knee Society Score*

	CRP			PSP				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Catani 2004	170	14.5	20	166	14	20	17.9%	4.00 [-4.83, 12.83]
Clark 2001	156.5	53.2	59	157.1	57.8	69	3.8%	-0.60 [-19.84, 18.64]
Kolisek 2009	164	65	46	167	54	45	2.3%	-3.00 [-27.53, 21.53]
Maruyama 2004	173.1	14.2	10	172.8	10.1	10	12.0%	0.30 [-10.50, 11.10]
Tanzer 2002	163	40.5	20	152	49	20	1.8%	11.00 [-16.86, 38.86]
Young Hoo Kir 2009	174.2	27.5	250	178.7	26.5	250	62.3%	-4.50 [-9.23, 0.23]
Total (95% CI)			**405**			**414**	**100.0%**	**-1.95 [-5.68, 1.79]**

Heterogeneity: Chi² = 3.88, df = 5 (P = 0.57); I² = 0%
Test for overall effect: Z = 1.02 (P = 0.31)

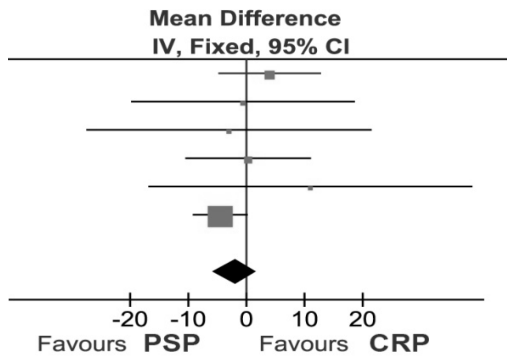
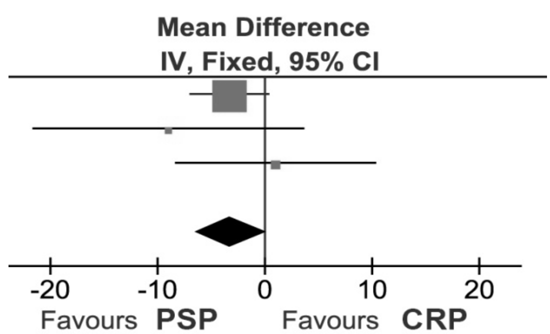


Table V. *Outcome 4: Flexion angle*

	CRP			PSP				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Harato 2008	113.7	12.8	99	117	13.5	93	80.4%	-3.30 [-7.03, 0.43]
Maruyama 2004	122.3	15	10	131.3	13.9	10	6.9%	-9.00 [-21.67, 3.67]
Tanzer 2002	112	13	20	111	17	20	12.7%	1.00 [-8.38, 10.38]
Total (95% CI)			**129**			**123**	**100.0%**	**-3.15 [-6.49, 0.19]**

Heterogeneity: Chi² = 1.58, df = 2 (P = 0.45); I² = 0%
Test for overall effect: Z = 1.85 (P = 0.06)



Criterion excluded studies that were not primarily focused on comparing the two types of surgeries. Finally, all studies that did not report the primary outcomes were excluded. Primary outcomes are the outcomes that are reported in all the studies. These choices made the studies homogeneous regarding "Goals". Some of the outcomes in our meta-

TableVI. *Outcome 5: Improvement of flexion angle.*

	CRP			PSP				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Harato 2008	0.4	12	99	7	10.1	93	8.1%	-6.60 [-9.73, -3.47]
Maruyama 2004	2.6	12.7	10	11	14.95	10	0.5%	-8.40 [-20.56, 3.76]
Tanzer 2002	2	1.5	20	10	1.5	20	91.4%	-8.00 [-8.93, -7.07]
Total (95% CI)			129			123	100.0%	-7.89 [-8.78, -7.00]

Heterogeneity: Chi² = 0.71, df = 2 (P = 0.70); I² = 0%
Test for overall effect: Z = 17.40 (P < 0.00001)

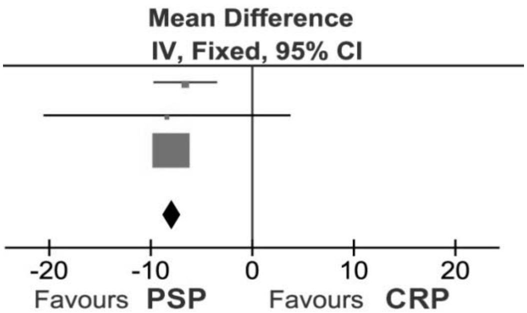


Table VII. *Outcome 6: Improvement of extension angle*

	CRP			PSP				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Harato 2008	4.8	4.2	99	3.7	4.3	93	94.1%	1.10 [-0.10, 2.30]
Maruyama 2004	6.9	5.5	10	6.4	5.5	10	5.9%	0.50 [-4.32, 5.32]
Total (95% CI)			109			103	100.0%	1.06 [-0.10, 2.23]

Heterogeneity: Chi² = 0.06, df = 1 (P = 0.81); I² = 0%
Test for overall effect: Z = 1.79 (P = 0.07)

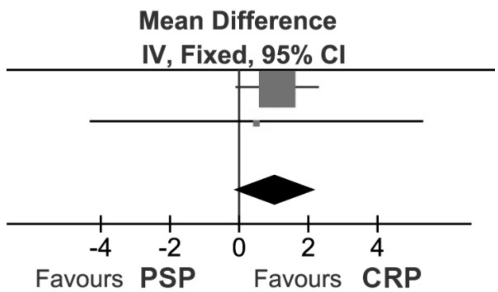


Table VIII. *Outcome 7: HSS.*

	CRP			PSP				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Catani 2004	86	8	20	89	7	20	4.8%	-3.00 [-7.66, 1.66]
Matsuda 2005	92	2	40	90	4	40	53.8%	2.00 [0.61, 3.39]
Misra 2003	81.4	6	51	83.6	5.4	54	21.6%	-2.20 [-4.39, -0.01]
Shoji 1994	87.5	4.5	28	88.2	4.2	28	19.9%	-0.70 [-2.98, 1.58]
Total (95% CI)			139			142	100.0%	0.32 [-0.70, 1.34]

Heterogeneity: Chi² = 13.46, df = 3 (P = 0.004); I² = 78%
Test for overall effect: Z = 0.61 (P = 0.54)

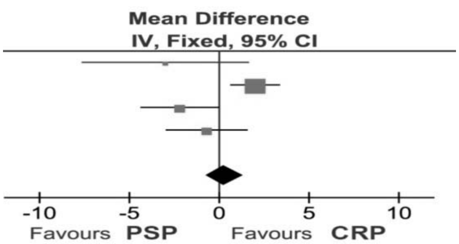
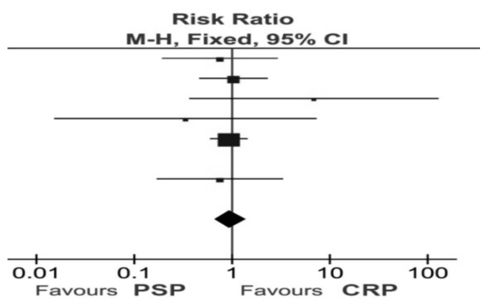


Table IX. *Outcome 8: Complications*

	CRP		PSP			Mean Difference
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Catani 2004	3	20	4	20	9.2%	0.75 [0.19, 2.93]
Harato 2008	11	99	10	93	23.6%	1.03 [0.46, 2.32]
Kolisek 2009	3	46	0	45	1.2%	6.85 [0.36, 128.97]
Maruyama 2004	0	10	1	10	3.4%	0.33 [0.02, 7.32]
Misra 2003	21	51	24	54	53.4%	0.93 [0.59, 1.44]
Tanzer 2002	0	20	0	20		Not estimable
Young Hoo Kir 2009	3	250	4	250	9.2%	0.75 [0.17, 3.32]
Total (95% CI)		496		492	100.0%	0.97 [0.67, 1.39]
Total events	41		43			

Heterogeneity: Chi² = 2.47, df = 5 (P = 0.78); I² = 0%
Test for overall effect: Z = 0.18 (P = 0.86)



analysis have been reported in the majority of the studies we reviewed; others, even if not evaluated by the majority of studies, were reported in a sufficient number of studies to be included in our meta-analysis. Outcomes that have been evaluated in only one study or in only a few studies were not taken into consideration.

Comparisons and meta-analysis

The outcome scores reviewed for our meta-analysis are reported in the following tables. A chart reading of the differences between the two surgeries is associated with each table.

In the first table (Table I) we reported all the characteristics of the studies we included.

DISCUSSION

As can be seen from the tables and graphs, the results seem quite ambiguous. Regarding the first primary outcome, post-operative Range of Motion (ROM), (Table II), we found a significant difference in favor of the PSP. Evidence in the graph corresponds to the score in the table. Six of 9 studies present scores in favor of the PSP. These studies, based on the number of patients evaluated at follow-up, have a large percentage for the outcome ROM.

Regarding the second primary outcome, the Knee Society Score, Table III shows a slight tendency in favor of PSP, but there is no significant difference. In addition, this result derives from the high percentage value found in only one study (17). Other studies, with low percentage values, do not show important differences.

Improvement of ROM, third outcome shows a significant difference in favor of PSP (Table IV).

For the outcome “Flexion Angle”, (Table IV) the “diamond” in the graph of Table V, just grazes the vertical axis of graph. Although the difference cannot be considered significant, there is an important tendency in favor of PSP.

“Improvement of Flexion Angle” shows a highly significant difference in favor of PSP (Table VI). In fact, all the studies report scores in favor of PSP.

Regarding “Improvement of extension angle”, the graph shows a tendency towards the CRP (Table VII). However the difference is not significant and the studies for this outcome are too few.

For “HSS”, the graph of Table VIII shows that the majority of studies are in favor of PSP; however the graph does not show any significant difference. Probably this result derives from the high percentage value of the study by Matsuda et al. (18). It is the only study in favor of CRP but it has a high percentage value, so it balances the graph.

The graph for complications (Table IX) clearly shows there are no differences between the two surgeries for this outcome. The results in the graph correspond perfectly to the values in the table.

In our EBM study, we also took in to consideration biomechanical evaluations. They are novel parameters with which to obtain a complete assessment of the differences between the two prostheses.

Unfortunately, scientific literature is very poor in this field. Probably, the lack of articles about biomechanical evaluations is for two reasons. The first is the difficulty of finding appropriate means to conduct these kinds of evaluations. There are few specialized centers capable of performing biomechanical evaluations with the latest equipment. The second reason is a lack of interest in this kind of approach in recent years; in fact, the results of studies performed in recent years have not allayed controversy on this topic.

CONCLUSIONS

Total knee arthroplasty is a very successful surgical procedure (20-21), although quite complex. To improve this kind of surgery, attention needs to be paid to some specific details. One of them is the difficult choice between using a cruciate retaining prostheses which does not exclude the PCL and the posterior-stabilized prostheses, which sacrifice PCL. Choices regarding the use of one prostheses rather than another should be based on randomized and controlled clinical trials.

We cannot draft specific guidelines on the topic based on our review alone. It would be neither possible nor desirable. The number of studies reviewed is too small to draw any conclusions. Only some of the studies have a high-level of evidence. Scores and chosen outcomes do not appear homogeneous. Reports of studies are poor. Very often ranges of evaluations are too broad. Information about the study population is insufficient.

Therefore we must be very cautious when we analyze the results, although some differences do appear to be significant. Some graphs are influenced by studies that statistically have influenced too much the percentages.

In our meta-analysis, the comparison between PSP and CRP showed a significant difference only for 3 of the 8 outcomes: post-operative ROM, improvement of ROM and improvement of flexion angle. All three outcomes are in favor of PSP. Only one of the 8 outcomes showed a tendency to favor CRP, improvement of extension angle. Risk of complication, Knee society score and hospital for surgery score showed no significant differences.

In our meta-analysis important outcomes are missing, such as the Womac score, the SF12 questionnaire, radiographic and biomechanical outcomes, because they did not respond to choice-parameters.

For all these reasons and based on our limited data, we can conclude that orthopedic surgeons should find similar results whether they use one or the other type of prosthesis; in our meta-analysis only a clinical gap exists, flexion and extension angles and final Rom.

Hence, at present, the choice is based only on the surgeon's personal judgment and experience.

A separate consideration regarding the preoperative condition of the PCL is necessary. We think that a ligament that has undergone significant degeneration or trauma could guide the surgeons' choice towards PSP, because of impairment to the nervous system within cruciate ligaments due to pathologic conditions (22).

All these considerations must be considered reductive in this still open dispute.

More research needs to be performed on this topic. Studies should be carried out as homogeneously as possible and they should be based on clinical, radiographic and biomechanical outcomes. All these factors could well represent the starting-point for new systematic reviews and new meta-analyses.

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CASE SERIES

AUTOLOGOUS CHONDROCYTE IMPLANTATION IN THE OSTEOCHONDRAL LESIONS OF THE ANKLE JOINT FROM OPEN TO ARTHROSCOPIC TECHNIQUES

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Osteochondral lesions of the talus are defects of the cartilaginous surface and underlying subchondral bone of the talar dome. These lesions are often caused by a single or multiple traumatic event, mostly inversion or eversion ankle sprains in young, active patients. It is widely known that articular cartilage has a limited potential to heal so premature arthritis can be established in the joint and can causes important damage to the joint surface. 56 total patients, 10 patients treated by ACI with open field techniques (AOT), 46 patients treated by ACI with arthroscopic techniques (AAT). All the patients were affected by focal osteochondral lesions of the ankle joint. The patients were evaluated clinically with the AOFAS score preoperatively, at 12 months, at 36 months and at 5 years after surgery up to a mean follow-up of 36 ± 19.5 months. Regenerated tissues are evaluated with MRI using mocart score at 7 ± 3 years. Furthermore in 20 patients a T2 mapping MRI analysis was performed. Aim of the study was to report the clinical and imaging results obtained at long term by ACI in the ankle, with particular focus on the outcome differences between open and arthroscopic techniques. Level of Evidence: IV - Case series.

Osteochondral damage to the joint surface can lead to premature arthritis. The options for surgical treatment of osteochondral lesions in the ankle joint have substantially increased over the last decade. The surgical strategies include fixation for acute cases, whereas for chronic lesions excision, curettage, drilling/microfracturing, autologous osteochondral transplantation, autologous chondrocyte implantation (ACI), and newer techniques basing on bone marrow derived cell transplantation (1-20). The latter three techniques, in particular, focus on replacement and regeneration of hyaline cartilage to provide the patient with a durable, load-bearing tissue, relieve pain and improve function as similar as possible to native tissue. Autologous chondrocyte implantation (ACI), developed and validated by Peterson et al (21) for the treatment of osteochondral lesions of the knee, has become one of the most popular cartilage repair procedures, also in the ankle, giving satisfactory results (4, 11, 21). However very little information regarding the durability of clinical results of ACI repair over time in the ankle are available. furthermore, the lack of randomized trials, the great diversity in existing studies concerning patient characteristics, staging of the defect, duration of follow-up and outcome measures, along with the exiguity of objective criteria in the evaluation of results (i.e. bioptic sample histological examination, MRI evaluation), do not enable any definitive conclusions to be drawn regarding the best treatment

Key words: osteochondral lesions, ankle joint, autologous chondrocyte, arthroscopic

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available for cartilage repair in the ankle (22). Recently, MRI showed to be a valuable tool for follow-up evaluation after osteochondral lesion repair in the ankle joint (23-24). Standard MRI can provide important structural information, such as percentage of defect filling, integration of the reparative tissue with the cartilage surrounding the lesion edge or integrity of the surface, about all the repaired area (25), but it cannot be used to evaluate the biochemical or molecular composition of reparative tissue (26). Conversely, an advanced MRI T2-mapping sequence (27-30) provides supplemental information about the matrix of reparative tissue and, for this reason, it is becoming increasingly popular for the evaluation of knee's lesions and has recently been proposed as a reliable tool to study ankle pathology as well (10, 31, 32). These advanced MRI techniques are becoming increasingly popular in the knee, but very limited experience on the ankle has been reported (9, 25). The ankle joint, with its thin cartilage layers, remains a challenge in T2-mapping evaluation; nevertheless, its feasibility and high reproducibility have recently been shown (32). In a study evaluating the healthy cartilage appearance in the ankle, Quirbach et al. (33) stated that with a 3.0- T magnetic resonance (MR) scanner, the mean relaxation time for their series of healthy volunteers was 51.1 ms (SD 4.6), whereas for healthy control areas in patients previously treated after MACT, the mean T2 value was 47.6 (SD 9.3). Aim of the study was to report the clinical and imaging results obtained at long term by ACI in the ankle; furthermore differences in the outcomes between open and arthroscopic techniques are described.

MATERIALS AND METHODS

56 total patients; 10 patients (5 males and 5 females; mean age of 25.8 ± 6.4 years) treated by ACI open-field technique (AOT), 46 patients (17 females and 29 males; mean age 31.4; range 20-47 years) treated by arthroscopic ACI technique (AAT) and, were included in this study. All the patients were affected by focal osteochondral lesions of the talar dome, and had chronic lesions, according to Giannini's Classification for osteochondral lesions of the talus Table I (6), were rated as Type II and Type IIA.

The AOT patients mean size of the lesions was 3.1 cm^2 (range, 2.2-4.3 cm^2). In the AAT patients the ankle joints had a lesion with a mean size of 1.6 cm2 (range 1.0-4.0). In particular, the lesion was medial in 35 cases, lateral in 7 case while in 4 cases two lesions were found (medial and lateral). Sixteen patients were previously operated with microfractures (7 cases), arthroscopic ankle debridement (4 cases), chondrectomy (2 cases), drilling (1 case), mosaicplasty (1 case), or lateral ligament reconstruction (1 case). The exclusion criteria included arthritis of the ankle joint, "kissing" lesions, and rheumatoid arthritis. Instability or axial defects were corrected when present. Sport activities were performed by eight patients (one of them was a professional) in AOT group and 29 (4

Table I. *Giannini's Classification for osteochondral lesions of the talus*

ACUTE LESIONS		
	Surface	**Size of lesion**
TYPE I	Damaged	< 1 cm^2
TYPE II	Damaged	> 1 cm^2
CHRONIC LESIONS		
	Surface	**Cartilage lesion size**
TYPE 0	Intact	
TYPE I	Damaged	< 1.5 cm^2
TYPE II	Damaged	> 1.5 cm^2, thickness < 1 cm^2
TYPE III	Damaged	> 1.5 cm^2, thickness > 1 cm^2
TYPE IV	Damaged	Massive damage

professionals) in the AAT group.

Patients were evaluated clinically with the American Orthopaedic Foot and Ankle Society(AOFAS) score preoperatively, at maximum follow up of 7 years (mean 6 ± 1). The comeback to sport activities was also assessed. Basing on the protocol proposed by the International Cartilage Repair Society (34), the MRI evaluation was performed at 7 ± 3 years' follow-up in all cases using the Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) scoring system (35). Images were obtained using a 1.5-T MR scanner HDxt GE and a dedicated phased array coil. The following sequences were used as follows: **(1)** coronal DPFSE high-resolution fat sat (TR 2,700 ms, TE 24 ms, FOV 17, matrix 416 9 416, gap spacing 0, slice thickness 2 mm, number of acquisitions 2) and coronal DPFSE without fat suppression; **(2)** coronal 3DSPGR fat sat (TR 325 ms, TE 6 ms, flip angle 20, FOV 17, matrix 256 9 256, gap spacing 0, slice thickness 2 mm, number of acquisitions 4); **(3)** sagittal DPFSE high-resolution fat sat (TR 1,720 ms, TE 24 ms, FOV 17, matrix 416 9 416, gap spacing 0, slice thickness 2 mm, number of acquisitions 2). A 3D SPGR sequence was not considered because of the high amount of artifacts due to small ferromagnetic particles released by the shaver during surgery.

Mocart score parameters considered for cartilage evaluation were as follows: **(1)** degree of osteochondral defect filling (complete, hypertrophic, incomplete less than or more than 50% of the defect, exposure of subchondral bone); **(2)** integration to the border zone (complete, incomplete); **(3)** surface of the repair tissue (intact, damaged less than or more than 50% of the surface repaired); **(4)** signal intensity of the repair tissue DPFSE fat sat (isointense, moderately hyperintense, markedly hyperintense); **(5)** integrity of the lamina and subchondral bone; and **(6)** presence of joint effusion and subchondral edema. Both depth (mm) and volume of the repaired defect (mm3) were calculated with manual trace and repeated twice. The volume was calculated with the formula of the ellipsoid (A 9 B 9 C 9 4/3p). The mean of the two measurements obtained was used as final value.

For all patients, MRI acquisition protocol at 7 ± 3 years' follow-up was performed by coronal and

sagittal T2-mapping high-resolution sequence (TR 1,000 ms, TE ranges from 10 to 80 ms to study hyaline cartilage, FOV 17, matrix 256 9 256, gap spacing 0, slice thickness 2 mm, number of acquisitions 1).

T2 mapping is a multiecho (8 echoes train) and multislice (18 slices) sequence (144 final images acquired). A specific post-processing T2 map software is necessary, achieving a final T2-grading color maps for normal and pathologic hyaline cartilage. The image elaboration was preceded by the choice of two presets (Preset1: 20–50 ms; Preset2: 51–80 ms) instead of a single one (Preset 20–80 ms), in order to improve a clearer visualization. The final information was not affected. As an high ‘‘magic angle'' artifact may influence the chromatic homogeneity, only coronal MRI views were preferred for the evaluation. Measurement of the spatial distribution of the T2 mapping appreciated the content of water in the different areas. These areas were measured by manual trace for single-acquired slices, and the percentage of altered tissue was related to the whole repaired defect volume.

Surgical technique

1. ***AOT patients:*** The original technique was described by Brittberg et al for the knee and then adapted for the ankle joint. The main steps were the initial arthroscopic evaluation and harvest, the culture, and eventually, after four weeks, the re-implantation of autologous chondrocytes. First, arthroscopy of the ipsilateral knee was performed to harvest the cartilage samples from the superolateral femoral condyle. Cartilage samples were sent to a US Food and Drug Administration–licensed facility for cell culture (Genzyme Tissue Repair Laboratories, Cambridge, Massachusetts), using a biopsy specimen transport shipping kit. The detailed report of this step is described in previous works. Roughly, after the enzymatic digestion of the cartilage, the chondrocytes were isolated and cryopreserved. Approximately 2 to 3 weeks before the implant date, the chondrocytes were unfrozen and processed in a cell-culturing phase. The aims were expanding the cell population to achieve an appropriate amount and completing the quality control lot–release testing regarding sterility, endotoxin, and cell viability. In the interval between cell-sample harvest and implantation, the patients were allowed activity as tolerated. In the second procedure, which took place after an average time of four weeks, a medial or lateral arthrotomy was performed according to the site of the lesion (Fig. 1). The malleolus was reflected to permit a complete inspection of the ankle joint. The chondral and bony tissues were evaluated and a fibrous and osseous impingement was removed whenever present (six cases). The cartilage defect was debrided, sparing the subchondral bone plate. Then, the surgical incision was enlarged to harvest a periosteal flap, from the proximal diaphyseal tibia (3 patients) or from the distal tibia (7 patients). Reabsorbable 6-0 Vicryl (polyglactin 910) suture (Ethicon Inc, Somerville, New Jersey) of the flap over the chondral defect was sealed with Tissucol fibrin glue (BaxterHealthcare, Vienna, Austria). The chondrocytes in liquid media were injected under the flap, then sutured and sealed with fibrin glue (Fig. 2). The medial malleolar osteotomy was reduced and fixed with either a screw; plate and screws were needed in the lateral approach. The wound was closed in a standard

fashion.

2. ***AAT patients***: Two arthroscopic steps were performed. In the first procedure, the lesion was detected and debrided (Fig. 3). Chondrocytes were taken from the detached osteochondral fragment, when present, or from a small slice of chondral tissue from the margins of the lesion (7). After the expansion phase in the laboratory, they were seeded on a Hyaff 11 scaffold (Fidia Advanced Biopolymers Laboratories (Abano Terme, Italy). The second procedure (performed at an average time of four weeks) required the detection and the measurement of the lesion. According to the size and shape of the defect, the biomaterial was cut and arthroscopically applied to the lesion area thanks to a custom-made specific instrumentation (Citieffe, Calderara di Reno, Bologna, Italy) (Fig 4). Lesion type IIA (deeper than 5 mm) required an autologous cancellous bone graft of the lesion before the biomaterial implantation (one case).

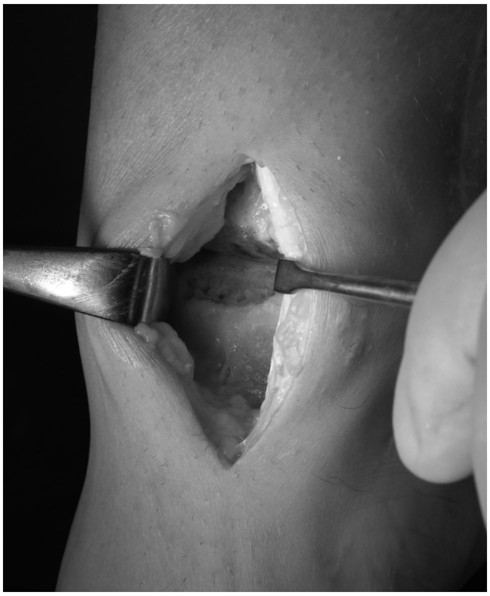

Fig. 1. *In the second procedure a medial or lateral arthrotomy was performed according to the site of the lesion.*

Fig. 2. *The chondrocytes in liquid media were injected under the flap, then sutured and sealed with fibrin glue.*

Postoperative treatment

For the AOT patients the ankle was held in a short-leg cast for 15 days after surgery. A walking boot was then applied for 2 months. Continuous passive motion was started after cast removal. Initially, continuous passive motion was maintained low (1 cycle/min). The range of motion was gradually increased during the first 3 weeks according to pain tolerance. Weightbearing was allowed at 3 months and, at 6 months after surgery, low-impact sports activity was resumed. After 10 to 12 months, running and progressive training for high impact activities, such as tennis and soccer, were permitted.

For the AAT patients Continuous passive motion (CPM) was advised the day after surgery. During the first days, CPM was maintained low (1 cycle/min) for an average of 6 to 8 hours a day. The range of motion was gradually increased according to pain tolerance; CPM was maintained for 3 weeks. Walking with crutches and no weight bearing on the affected ankle was advised.

Partial weight bearing increasing to full weight bearing was permitted from 6 to 8 weeks after surgery, and at 4 months after surgery, low-impact sport activity could be resumed. After 10 to 12 months, running and progressive training for high-impact activities, such as tennis and soccer, were permitted.

RESULTS

Clinical scores

No intraoperative or postoperative complications were reported. For the AOT, before surgery, the mean score was 37.9 ± 17.8 points; at 12 months, it was 89.4 ± 14.5 (P < 0.0005); at 36 months, 93.9 ± 8.5 (P < 0.0005); at 60 months, 92.7 ± 9.5 (P < 0.0005) and at final follow-up, 92. ± 9.9 (P<.0005). The overall scores at final follow-up were 7 excellent (70%), 2 good (20%), and 1 fair (10%).

No statistically significant relationship was found between the clinical outcomes and the size of the

Fig. 3. *In the first procedure, the lesion was detected and debrided.*

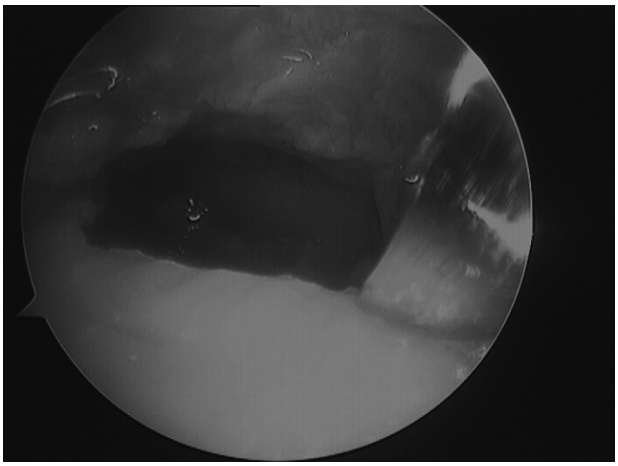

Fig. 4. *According to the size and shape of the defect, the biomaterial was cut and arthroscopically applied to the lesion area thanks to a custom-made specific instrumentation (Citieffe, Calderara di Reno, Bologna, Italy).*

lesion (more or less than 2 cm2) or the location of the lesion (medial or lateral).

A statistically significant relationship was found between the age of the patients and the clinical outcome; in particular, a significant negative correlation was found between age and the AOFAS score at 12-month follow-up ($P = 0.009$, $R = .768$), 36-month follow-up ($P = 0.021$, $R = 0.713$), and at final follow-up ($P = 0.011$, $R = 0.761$).

Among the eight patients who played sports, treated with AOT, five (professional included) return to sport activities at the same level, 2 resumed sports at a lower level. One patient gave up sport activities.

For the AAT before surgery, the mean score was 57.2 ± 14.3 points; at 12 months, it was 86.8 ± 13.4 ($P < 0.0005$); at 36 months the mean score was 89.5 $\pm$ 13.4 ($P < 0.0005$), at 60 months, it was 90.5 ± 12.6 ($P < 0.0005$); while at final follow-up it was 92 $\pm$ 11.2 ($P < 0.0005$). The overall scores at final follow-up were 24 excellent, 13 good, 6 fair and 3 poor. No significant influence of age, sex, and area of the lesion was found on the clinical score. The clinical score was influenced by the depth of the lesion ($R = -0.565$, $P = 0.009$). In fact, lesions with depth <3 mm gained a clinical score >80, whereas lesions deeper than 5 mm (1 lesion) gained a clinical score<60.

20 of 29 patients who played sport activities resume their activities at the same level, five at a lower level and four gave up sports. The four professional came back to their previous sport activities.

Magnetic resonance imaging results

T2 mapping and Mocart score were used to evaluate 20 patients (43.4%). About AOT at final follow up we performed traditional MRI according to the MOCART scoring system, that showed complete integration of the regenerated tissue with the surrounding cartilage. In only two cases image showed moderate hypertrophy of the regenerated tissue.

Limited foci of higher signal with respect to normal hyaline cartilage were found in the proton density and T2-weighted sequences. In two cases was still evident subchondral edema at the repair site and small subchondral pseudocysts were present at the repair site in other 2 cases. No intra-articular fluid was found. Normal control subjects were found to have a mean T2 value of 40 microseconds (range, 30-50).

The regenerated tissue at the repair site had T2 values suggestive of normal hyaline cartilage in all cases. Patients treated with AOT were found to have a mean T2 value of 46 microseconds (range, 34-50). In 5 cases, a few microfoci of tissue with higher T2-mapping values (range, 55-60 microseconds) were noticed. In 1 case, a larger area with higher T2 mapping (>60 microseconds) value was found within the regenerated area . In 1 case, a small focus with a lower T2-mapping signal (<20 microseconds), suggestive of fibrous tissue within the regenerated area, was found.

About AAT, Mocart score showed that the two patients with low clinical scores had their defects only partially filled. In general, superficial defects healed better, showing a better integrity of the repaired tissue. The normal value of T2 mapping, compatible with an healthy hyaline tissue, is considered between 35-45 msec, while fibrocartilage values are inferior. Over 45 msec, the values are compatible with a tissue in remodelling phase, due to the fluid infiltration. In the arthroscopic series, all the patients showed signs of fibrocartilage in the 17.2% ± 16.6 of the repaired site. In one case, fibrocartilage was found in the majority of the lesion. Three cases showed almost no sign of fibrocartilage. In 17 patients a value higher than 45 suggested a remodelling tissue in a small area (10.3% ± 13.3); in one case it was larger site (60% of the lesion). T2 mapping was correlated with Mocart score, differently, clinical outcomes were not similar to radiological ones.

DISCUSSION:

The aim of the autologous chondrocyte implantation is to restore a durable tissue whose properties are close to hyaline cartilage. Initially it was used open field technique that has shown a good efficacy both from the clinical and MRI point of view. As the graph shows, in the first postoperative year there is a considerable increase in AOFAS clinical scores, then from 12 to 36 months, the curve reflects a clinical improvement that although this is less marked than that present in the first 12 months; from 36 months to final follow-up the graph shows a slight reduction of the trend related to clinical scores slightly lower. The MRI shows good results both in terms of amount of tissue regenerated you quality. The limitations of the techniques are the high costs and the major insult to the soft tissues

Thanks to the development of an instrumentation able to overcome the disadvantages given by the tangential perspective and the narrow space available (8), and the good results obtained with the AAT in the knee, the same techniques was applied at the ankle.

As shown by the shape of the curve of patients treated with AAT clinical results show a very marked improvement in the first 12 months after surgery, and from 12 months up to about 36 the curve continuous in a less marked demonstrating a lower clinical improvement. From 36 months up to the final follow-up the curve tends to a plateau type performance while maintaining a slight improvement. The MRI images in AOT group it was noticed a good results both in terms of amount of tissue regenerated you quality.

The develop of the arthroscopic techniques has led to a drastic improvement in terms of time, costs and morbidity. The clinical results at the final follow up for open-field and arthroscopic techniques are very similar. The main difference is the baseline, which was critically worse for the patients doomed to open-field procedure. The MRI results show regeneration of hyaline cartilage and limited foci of fibrocartilage. Open-field and arthroscopic procedures are comparable in terms of outcomes at the AOFAS score.

Nowadays, arthroscopic procedure, relying on the dedicated instrumentation, is preferred, although it is technical demanding. The arthroscopic technique reduces the traumatism to the soft tissues that results in a lower morbidity for the patient and a more early functional recovery; further allow a better point of view improving the definition of the lesion and the articular environment. On the other hand, the arthroscopic technique requires dedicated instruments and a longest learning curve. Furthermore it was found a higher difficulty to view lesions particularly rear, with an increase of the surgical time and the necessity to use a traction sling.

The autologous chondrocyte implantation is a valid technique to treat osteochondral lesions of the ankle, graded II or IIA according to Giannini's classification both in arthrotomic and arthroscopic procedure. The damaged chondral tissue is well regenerated, showing MRI signs compatible with hyaline cartilage. The clinical outcomes at 7 years are stable, with no evident sign of time-dependent degeneration.

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CASE SERIES

MATRIX AUTOLOGOUS CHONDROCYTE IMPLANTATION FOR THE TREATMENT OF ARTICULAR CARTILAGE DEFECTS IN THE FEMORAL CONDYLES

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Numerous options of treatment have been developed throughout the years in order to repair cartilage lesions in the knee joint. Matrix-associated autologous chondrocyte implantation (MACI→®) represents an innovative therapeutic option for the treatment of chondral and osteochondral defects of the knee. Our study was carried out in order to evaluate clinical and radiographic results with the MACI→® technique over a period of up to 5 years after operation. The goal was to assess the suitability of this procedure for the treatment of isolated or multiple localized osteochondral defects of the femoral condyles. Forty-six patients (46 knees) with MRI-documented osteochondral lesions of the femoral condyle were treated with MACI→®. Clinical assessment was assessed using VAS score, Lysholm score and Tegner activity level after an average follow-up of 27 months (SD:2.3). MRI scans were performed at 12 and 24 months after surgery. Sixteen patients were re-evaluated after an average time of 55 months (SD: 6.1). Two years after transplantation mean Lysholm score increased from 72 (SD: 12.1) preoperatively to 95 (SD: 5.9); the average VAS score decreased from a pre-operative mean value of 5.1 (SD: 2.7) to 1.8 (SD: 2.0) . The difference with respect to Tegner activity level did not prove to be significant. MRI scans showed that the results were excellent in 13 cases, good in 38 cases and poor in 3 cases. Satisfying outcomes were confirmed on sixteen patients who were re-evaluated 60 months after surgery. At 60 months, MRI scans showed worsening in one out of 17 cases. The MACI→® technique represents a valuable therapeutic option for the treatment of osteochondral defects of the femoral condyles. Level of Evidence: IV - Case series.

Chondral and osteochondral lesions of the knee are frequently associated with articular strain that occur during the practice of sports (1). Since cartilage lacks an inherent capacity to heal spontaneously, untreated lesions can lead to pain, significant activity impairment and may evolve to degenerative osteoarthritis (2-3). Symptoms usually involves pain, swelling, and false blockage of the joint. Several treatment options exist in order to restore knee function and relieve pain.

Autologous chondrocyte implantation (ACI) allowed to implant autologous cultured chondrocytes into focal cartilage lesions under an autologous periosteal patch (4). The main advantage of this treatment was the development of hyaline-like cartilage (5-7), its limitations included high costs, two-stage execution, a technically demanding procedure and complications related to the use of periosteal graft (8-9). Collagen covered ACI (CACI), a second generation cell therapy, avoided

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the need for an autologous periosteal cover by using a bioadsorbable collagen type I/III membrane (10-11). However, the drawback of this technique was still the need for open surgical procedure with sutures (12). The third-generation cell-therapy called MACI→® (Matrix-induced Autologous Chondrocyte Implantation) utilizes a solid collagen scaffold seeded with cultured autologous chondrocytes. This procedure eliminates the use of periosteum and its associated disadvantages (13-18), and avoids dedifferentiation of chondrocytes during the culturing process (19).

Our study presents clinical and radiographic results of 46 patients with osteochondral lesions of the femoral condyle treated with the use of the MACI→® technique over a period of up to 5 years after operation. The aim was to assess the suitability of this procedure for the treatment of osteochondral defects of the femoral condyle in the knee joint.

MATERIALS AND METHODS

Study design

Fifty-one patients with osteochondral lesions of the knee were treated by implantation of autologous chondrocytes using the MACI® (Verigen, Leverkusen, Germany; Genzyme Biosurgery, Cambridge, MA, USA) technique. All the operations were performed in our Institute by the senior surgeon (AV). Forty-six patients (46 knees) with symptomatic osteochondral defects on the femoral condyle (2 to 10 cm^2) were enrolled in the study. Six patients presented concomitant condylar and patellar lesions. Mean age was 39 years (range 18-58 years). Exclusion criteria were inflammable arthritis, osteonecrosis, osteoarthritis, patelladysplasia, prior total meniscectomy, an inoperable valgus or varus abnormality, obesity (BMI >30). One patient was lost at follow-up. Four patients were excluded from the present study since they underwent simultaneous quadrupled-hamstrings ACL-reconstruction.

Surgical technique

Diagnostic arthroscopy was carried out to confirm the diagnosis and identify the chondral defect. A cartilaginous sample was extracted from a non-weight-bearing area and sent to specialized laboratories, where autologous chondrocytes were isolated from cartilage slices by means of enzymatic digestion of the surrounding matrix. Cells were cultured in autologous serum for 15 days (Fig. 1A). When approximately 9 million cells had been obtained *in vitro*, the chondrocytes were seeded on a porcine collagen I/III membrane (ACI-Maix membrane, Matricel GmbH, Herzogenrath, Germany). The collagen-loaded matrix was then cultured for 5 days until about 1 x 10^6 cells/cm^2 were obtained (Fig. 1B). In a second surgical procedure, the lesion site was debrided and the loaded matrix was cut to size to properly fit the defect area. It was then implanted by mini-arthrotomy with the cell-seeded surface facing the subchondral bone. Fibrin glue was used to provide graft adhesion (Fig. 1C,D).

Outcome measures

Forty-six patients (46 knees) were evaluated with an average follow-up of 27 months (SD:2.3) from surgery. Clinical assessment included objective examination, visual analog scale (VAS), Lysholm knee scoring scale (20) and Tegner activity level (21). Assessment was done pre-operatively and patients were followed-up 1, 3, 6, 12 and 24 months after surgery. Magnetic resonance imaging (MRI) scans were taken 12 and 24 months after surgery. Mean size of the lesions was 4.1 cm^2 (SD: 1.7). The lesion was located in the medial femoral condyle in 36 cases, in the lateral femoral condyle in 10 cases. Six patients were diagnosed with a concomitant condylar and patellar defect: both lesions were treated at the same time.

For 20 patients it was possible to obtain long-term results as 5 years had elapsed since the operation. Sixteen (80%) were successfully contacted and re-evaluated after an average follow-up of 55 months (SD: 6.1) with VAS, Lysholm and Tegner scales. Subgroup average age was 36 years (SD: 8.4).

Statistical analysis

Data were analyzed using the program SPSS Version 19.0 (SPSS Inc., Chicago, IL, USA). Paired *t*-test (two sided test and $\alpha=0.05$) was utilized to compare the pre-operative and follow-up status. Differences with a p value <0.05 were considered statistically significant.

RESULTS

No intraoperative and postoperative complications were observed in any of the patients considered. A detailed overview of the results is presented in Table I.

The average VAS score significantly decreased, reaching a mean value of 1.8 (SD: 2.0) after 2 years from surgery ($p<0.001$). The mean Lysholm score increased between all follow-up times over 24 months up to 95, SD: 5.9 ($p<0.001$). Median Tegner rating remained unchanged during the follow-up period, from 4 (range: 1-9) at baseline to 4 (range:

2-8) at the 2-year follow-up, documenting no statistically significant variations in the activity level of the subjects (p = n.s.).

MRI scans were taken 12 and 24 months after surgery. At one year, 10 cases (22%) revealed complete integration with the surrounding native cartilage without any sign of detachment nor bone marrow oedema. Thirty-five cases (76%) showed a completely repaired defect with slight subchondral bone abnormality. In one case (2%), visible defects in integration were observed. At 24 months, MRI findings remain unchanged in all patients, none of them showing additional visible defects in the repaired tissue.

Fig. 3 shows the improvement from pre-operative (Fig. 3A) to 24-month follow-up (Fig. 3B) in a patient with a medial femoral condyle lesion.

Sixteen patients were re-evaluated after an average follow-up of 55 months (SD: 6.1) (Table II). MRI scans documented excellent/good results in 14 cases (88%). In 2 cases (12%), bone marrow oedema was detected.

DISCUSSION

Our results demonstrate that MACI® is a valid therapeutic option for the treatment of osteochondral defects in the femoral condyles since it contributes to effective hyaline cartilage regeneration and confirms subjective and objective clinical improvement over a period of up to five years after surgery. Secondly, the clinical and functional results of our study are similar

Table I. *Overview of the results at mid-term follow-up.*

	Pre-operative	1 month	3 months	6 months	12 months	24 months
VAS	5.1 (SD: 2.7)	2.7 (SD: 1.9)	1.7 (SD: 2.2)	1.6 (SD:2.1)	1.5 (SD: 1.8)	1.8 (SD: 2.0)
Lysholm score	72 (SD: 12.1)	-	-	88 (SD: 9.7)	94 (SD: 6.8)	95 (SD: 5.9)
Tegner score	4 (1-8)	-	-	3 (2-7)	4 (2-7)	4 (2-8)
Effusion	19 moderate 8 severe	32 moderate 6 severe	24 moderate	3 moderate	1 moderate	1 moderate
Flexion/extension deficit	11 >15° flex 13 >3° ext	18 >15° flex 16 >3° ext	6 >15° flex 9 >3° ext	1 >15° flex 4 >3° ext	1 >3° ext	2 >3° ext
Femoral-patellar clicking	19	10	10	9	9	5
Clicking in the medial compartment	18	7	7	2	2	1
Clicking in the lateral compartment	10	7	1	1	0	0
Climbing stairs (patients experiencing difficulty):	21	-	-	11	8	5
Crouching (patients experiencing difficulty)	38	-	-	24	21	18
Jumping on one leg (patients with <75% ability as compared with healthy leg)	25	-	-	-	4	2

Table II. *Results of the long-term follow-up subgroup.*

	Pre-operative	24 months	60 months
VAS	5.2 (SD: 2)	0.8 (SD: 2)	0.6 (SD: 1)
Lysholm score	70 (SD: 12.2)	90 (SD: 5.2)	91 (SD: 3.7)
Tegner score	4 (1-9)	4 (2-8)	4 (2-8)

or superior compared with those previously reported in patients which underwent other chondrocyte implantation techniques (6-7, 13, 22- 26), with no increased risk of complications.

Forty-six patients (46 knees) with osteochondral lesions in the femoral condyle were treated with MACI®. The results were analysed after a minimum follow-up of 2 years. No serious adverse events were recorded. In all patients reduced VAS pain levels and

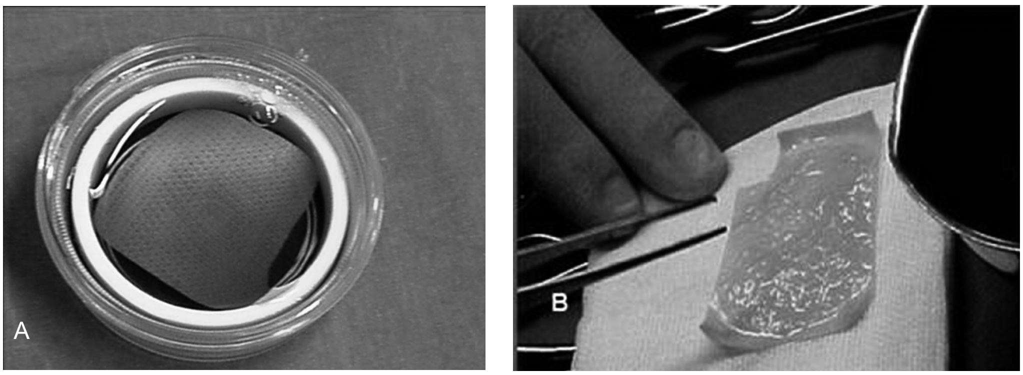

Fig. 1. ***A)*** *Autologous chondrocytes were isolated from cartilage slices and cells were cultured in autologous serum for 15 days.* ***B)*** *Intra-operative setting showing collagen membrane with chondrocytes.*

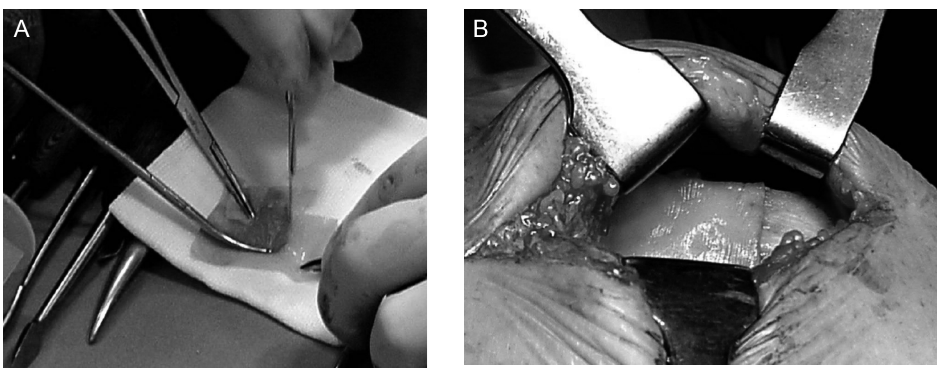

Fig. 2. A) *Intraoperative setting showing collagen membrane being cut to size and* **B**) *positioning of the implant*

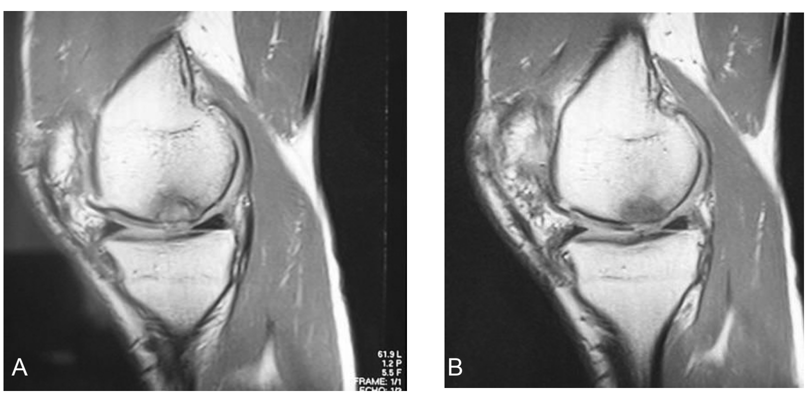

Fig. 3. ***A)*** *MRI findings taken pre-operatively and* ***B)*** *two years after surgery (reporting a completely repaired defect in the treated area, without signs of detachment of the implant on the medial femoral condyle.*

improvements in the Lysholm score were observed ($p<0.001$). This correlates with the results reported by other authors (13, 23, 27-28).

MRI examination supported clinical results and documented good survival of grafted cartilage. In most cases, at the 24 months follow-up the structure of the repair tissue was homogeneous and the signal intensity was similar to that of the surrounding endogenous cartilage. These observations concur with previous findings and suggest that results obtained with the MACI® technique are durable over time (17, 28).

Bone marrow oedema was detected in 12% of patients at 60 months. This documents that oedema may persist at 60 months even if the clinical outcomes are positive. This finding has been previously observed (28).

The MACI® procedure does not require an autologous periosteal patch, thus donor site morbidity and the need for microsuturing which characterized first and second-generation cell therapy are eliminated, and the MACI® technique can be performed via mini-arthrotomy or arthroscopically (29-30).

Limitations of the present study include the lack of a control group and the relatively small sample size.

According to our results, the MACI® technique provides the formation of hyaline cartilage and leads to subjective and objective outcomes that do not significantly worsen at medium- to long-term follow-up. Disadvantages include the fact that the surgery occurs in two stages and that the expensiveness of the procedure.

Based on the results obtained, the MACI® technique represents a safe and clinically effective therapeutic option for the treatment of osteochondral defects of the femoral condyles even over the long term.

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OBSERVATIONAL STUDY

MUSCULAR FUNCTION AND QUALITY OF LIFE BETWEEN PATIENTS WITH KNEE OSTEOARTHRITIS AND WITH TOTAL KNEE REPLACEMENT

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Knee osteoarthritis is characterized by a degenerative process of the joint cartilage and of subchondral bone. Pain usually changes muscle structure and function, and is the most important parameter in the advanced cases for decision making on the replacement of the joint by the surgical implantation of a knee prosthesis. Assuming that pain cessation improves the quality of life, but few studies showed improved muscle and joint functionality after total knee replacement (TKR), the purpose of this study was to compare knee extensor and flexor torques, knee flexor/extensor torque ratios, and WOMAC scores between patients with knee osteoarthritis (OA=20) and patients with total knee replacement (TKR=13). The muscle torque and torque ratios were evaluated during maximal voluntary isometric contractions at a knee joint angle of 60°, and during maximal voluntary isokinetic contractions at the angular velocity of 60°/s. Knee flexor and extensor muscle torques and torque ratios were similar between groups. The OA group showed higher mean scores compared to the TKR group. These results support the idea that TKR produces an improvement in the quality of life, but does not improve the knee functionality as determined by the torques and torque ratios around the knee joint. Level of Evidence: III - Observational study.

The inflammatory process present in patients with knee osteoarthritis (OA) leads to muscle inhibition, hypotrophy and pain. However the total knee arthroplasty (TKA) is the most adequate surgery for the treatment of advanced levels of OA, seeking a reduction in pain, functional rehabilitation and improvement in quality of life.

Aging leads to degeneration of the musculoskeletal tissues and osteoarthritis (OA). The main changes observed due to this natural process are: sarcopeny or the loss in muscle mass (1), loss of motor units or decreased capacity for motor unit activation (2), and a reduction in muscle force production capacity (3). Aging also changes the structure and function of bone, cartilage and connective tissues leading to changes in the musculoskeletal system homeostasis and also degeneration in these tissues (4).

These changes in muscle mechanics may lead to joint overload that might be directly related to the degenerative process. Changes in muscle forces, for example, may decrease the capacity of the muscular system for shock absorption thereby increasing joint loading, and has been related to knee OA (3). Associated to muscle imbalance, there are evidence

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that joint instability, muscle force reduction, muscle inhibition and reduction in the afferent feedback are amongst the main aging processes that contribute for the development of knee OA (3). Independent of the overload type or of the type of injury over the joint tissues, a reduction in the functionality of the neuromuscular system leads to a higher risk of OA incidence, and to a more accentuated progression of the disease in those that already have OA.

Osteoarthritis is a degenerative, chronic and prevalent disease that brings social, psychological and financial loss to 10% of the general population and to more than 50% of the elderly (5-8). Knee OA causes pain, dysfunction, reduction in muscle forces, muscle inhibition and joint instability (7, 9-14). Knee joint deficiency and muscle imbalance are amongst the main prejudicial factors in patients with OA (15-19). At high levels of OA (III and IV), total knee replacement (TKR) is the final option for the treatment of OA (19), and is done seeking functional rehabilitation and improvement in the quality of life in these patients. In addition, improvement in the muscle forces around the knee joint is an important factor for the clinical rehabilitation after TKR (17, 21-22).

Previous studies on the relation between muscle weakness and OA have shown that the presence of joint injury is related to a reduction in muscle force, which may be related to muscle inhibition (3, 23-24). Muscle inhibition may also change muscle balance. Muscle imbalance that occurs around a joint in the presence of degeneration may be evaluated through the torque ratio between antagonistic muscles. This allows for the evaluation of possible deficits related to joint instability, and may help in the injury diagnostic and treatment (25-26).

The analysis of torque ratios between antagonistic muscle groups is a parameter used to describe muscle force properties acting upon a joint and to infer about musculoskeletal function and balance. The torque ratio around the knee joint may be calculated by the peak isokinetic torque of knee flexion (hamstrings) by the peak isokinetic torque of knee extension (quadriceps) (H/Q ratio) (27-29).

Functional changes due to musculoskeletal imbalances may also affect the general health state of OA patients or their quality of life. Health, functional level and quality of life have been used interchangeably, and the term "quality of life" refers to each individual's perception of wellness, more than to objective health aspects, with a multidimensional character that encompasses the physical, psychological, social and spiritual dominium (30). The correlation between health-related situations, functional matters and quality of life, as well as health interventions and their consequences lead to the birth of a new concept: health-related quality of life (31). Health-related quality of life may be evaluated through instruments based in questionnaires and indexes. The WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) questionnaire is a specific instrument to evaluate the quality of life of OA patients, and involves the aspects of pain, joint rigidity, physical activity and social activity and emotional state (32).

However, the compare between torque ratios, joint degeneration and quality of life of OA patients has not been well described in the literature. Similarly, the functional adaptations or plasticity of skeletal muscles to OA and after TKR have not been clearly established. Morever, the population is aging more, more people have this problem, and until is difficult that all population have access the correct treatment and until not is definite the better and definitive treatment. Therefore, the purpose of this study was to compare the H/Q ratio and the quality of life of patients with OA with that of patients with TKR. We hypothesized that patients with TKR should to present higher in torque ratios and smaller in WOMAC scores compared to that of OA patients due to the decreased in pain after TKR, which might demonstrate a good neuromuscular function and skeletal functionality after surgery.

MATERIALS AND METHODS

All patients signed an informed consent form prior to participating in the study, which was approved by the university's Ethics Research Committee (number 2007740). Patients were assigned intentionally into two groups according to their health problems: OA group (n=20; 63±7 years of age; 77±1 kg; 158±7 cm) and TKR group (n=13; 70±7 years of age; 81±2 kg; 161±5 cm). OA patients were selected after been diagnosed by an Orthopedic surgeon and classified into one of the three degrees of joint degeneration (II, III or IV) (17, 33) with 5 patients II degree, 9 with III degree and 6 with IV degree;

whereas TKR patients had between one and three years post-surgery (19). All the patients were oriented to realize the rehabilitation, but it was not controlled. The patient population in this study is the same that has been already involved in another study (34).

Exclusion criteria included: previous knee surgery; prostheses revision; previous rheumatic disease; rheumatoid arthritis; neurological, musculoskeletal, metabolical and cardiological diseases that impaired patients of executing maximal voluntary contractions; blood pressure above 240/120 mmHg, angina and electrocardiographic changes suggestive of ischemia; cognitive changes (35).

Maximal knee extensor and flexor torques were obtained from the OA side and TKR side in each group, respectively, with an isokinetic dynamometer (Biodex System 3, Biodex Medical System, Shirley – NY, USA). Patients were fixed on the dynamometer chair by Velcro straps in order to maintain body stability during maximal effort. The hip and knee joint were maintained at an angle of 90° (0° = full knee extension). The apparent knee joint axis was aligned with the dynamometer mechanical arm axis of rotation.

All patients warmed up for five minutes executing flexion and extension concentric actions at an angular velocity of 240°/s prior to the test. A familiarization session followed the warm up period and consisted of two submaximal isometric contractions of the extensors and flexors muscle groups at a knee joint angle of 75° and three concentric and eccentric isokinetic contractions at the angular velocity of 90°/s. After familiarization, patients executed three maximal isometric voluntary contractions (MIVCs) at a knee joint angle of 60° (36), which has been shown in previous studies to be the optimal joint angle for knee extensor torque production (37-39). Patients were instructed to produce maximal torque in approximately one second and to maintain it for two seconds (40). After isometric tests, subjects were instructed to produce three maximal voluntary isokinetic contractions of knee extension and flexion at an angular velocity of 60°/s.

Peak isometric and isokinetic torques were obtained directly from the dynamometer and used to determine the H/Q torque ratios similar to previous studies (23-24, 41-42).

Quality of life of all patients was evaluated using the WOMAC (Western Ontario and McMaster Universities) questionnaire (32, 43-45). The three dominions evaluated were pain, joint rigidity and physical activity.

Statistical Analysis

Inter-group comparison for torque and torque ratio analysis was obtained by the non-parametric Mann Whitney test for independent samples because these results were not normally distributed. The WOMAC scores presented normally distribute and were compared using a one-way ANOVA and a Bonferroni post-hoc test was used to identify the differences amongst the different dominions of the test. All tests were performed using the SPSS 13.0 software package with a 0.05 level of significance adopted for all tests.

RESULTS

Maximal isometric knee extensor (p=0.507) and flexor (p=0.658) torque values were similar between groups. The OA group had a median knee extensor peak torque value of 97.3 Nm (25%=70 Nm; 75%=128 Nm; IQR) whereas TKR group had a median value of 91.9 Nm (25%=87 Nm; 75%=111 Nm; IQR). For the knee flexor muscle group median values were 62.6 Nm (25%=51 Nm; 75%=91 Nm;!QR) for the OA group, and 60.8 Nm (25%=51 Nm; 75%=69 Nm; IQR) for the TKR group.

Similarly, there was no difference between groups for knee extensor isokinetic peak torque values both for knee extensors (p=0.357) and knee flexors (p=0.358). Median peak isokinetic concentric torque values were 76.8 Nm (25%=52 Nm; 75%=124 Nm; IQR) and 64.7 Nm (25%=57 Nm; 75%=87 Nm; IQR) for the OA and TKR groups, respectively. The OA group also had a median peak isokinetic concentric torque value of 58.3 Nm (25%=43; 75%=73 Nm; IQR) while the TKR group had a median value of 62.2 Nm (25%=41 Nm; 75%=65 Nm; IQR).

There was no difference between groups in both torque ratios: H_{iso}/Q_{iso} isometric ratio p=0.347 (Figure 1) and H_{con}/Q_{con} isokinetic ratio p=0.484 (Fig. 2). The OA group had a median H/Q isometric ratio of 0.66 (25%=0.55; 75%=0.78; IQR) while the TKR group had values of 0.69 (25%=0.60; 75%=0.82; IQR), (median; 25%,75%; IQR). The median values for the isokinetic H/Q ratios were 0.76 (25%=0.59; 75%=0.87; IQR) and 0.84 (25%=0.63; 75%=1.01; IQR) for the OA and TKR groups, respectively.

WOMAC scores were different between groups (p=0.022). The OA group showed higher mean scores (24.8 $\pm$ 17; mean$\pm$SD) compared to the TKR group (11.08 $\pm$ 13; mean$\pm$SD) (Figure 3).

DISCUSSION

Assuming that aging, joint degenerative disease

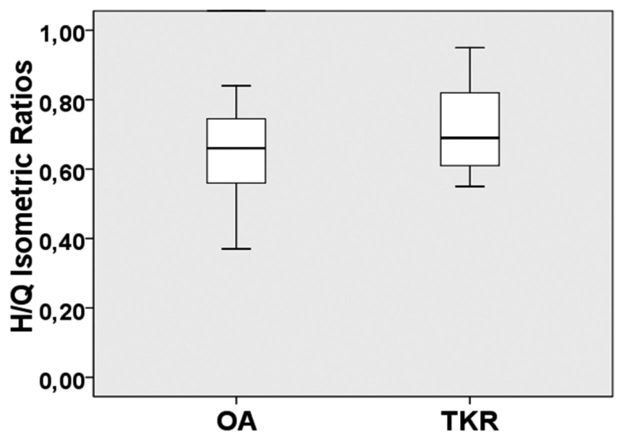

Fig. 1. *Conventional isometric torque ratios (Hiso/Qiso) at the knee joint angle of 60° for the osteoarthritis (OA) and total knee replacement (TKR) groups.*

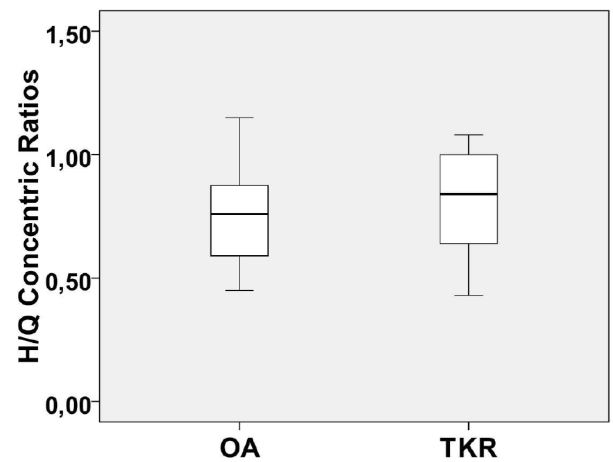

Fig. 2. *Conventional isokinetic concentric torque ratios (Hcon:Qcon) at the angular velocity of 60°/s for the osteoarthritis (OA) and total knee replacement (TKR) groups.*

and pain lead to a reduction in the maximal capacity of elderly to exert maximal effort or to produce torque, thereby altering the natural balance between antagonistic muscle groups around the knee joint (28, 36, 42, 46), and that TKR leads to a different in joint function [17], differences were expected between torque ratios of OA and TKR groups. Torque ratios of the TKR group were expected to lie close to normal values (0,5-0,6) (47) when compared to the OA ratio values. In addition, a different in the maximal or peak torques was expected after TKR and corresponding rehabilitation (although we did not control how rehabilitation was applied in this group).

This expectation was further emphasized by the evidences of force increment after TKR found in the literature (15, 17, 21-22, 48). Berman et al. (1991) (21) reported that two years after surgical replacement of the knee the knee extensors and flexors force of the surgical side were about 83% of the contralateral healthy side, showing an improvement of the force capacity after TKR.

Berth et al. (2002) (22) compared the knee extensor force production between two different groups: no symptoms and no injury VS OA group pre-surgery and group OA post-surgery or TKR group. But in this study was considered in the group OA operated side and nonoperated side. The TKR group (group OA operated side) improved the torque capacity (84.8 Nm) compared to that before surgery (OA= 66.3 Nm), but there was no full recovery of knee extensor torque production as the TKR group was still weaker compared to the healthy control group (105 Nm).

Despite these evidences in the literature regarding the improvement of maximal knee extensor torque production after TKR (15, 21), we were unable to find an improvement in the torque ratios between the OA and TKR group. Huang et al (1996) (15) did not find differences in the torque ratios between TKR patients 6 and 13 years post-surgery compared to the torque ratios of healthy subjects. According to the authors, patients presented full recovery of their musculoskeletal functions.

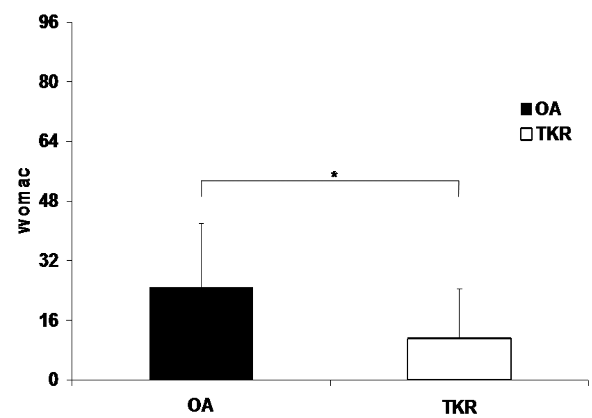

Fig. 3. *WOMAC scores between the osteoarthritis (OA) and total knee replacement (TKR) groups (mean ± SD). Black squares = Osteoarthritis Group; white squares = TKR – Total Knee Replacement Group. * indicates p<0.05.*

The reason for the difference in our results compared to results described in the literature might be due to the fact that in previous studies patients participated in rehabilitation programs from post-surgery until full recovery. Due to the differences observed in the health system of different countries, different procedures are taken during the rehabilitation period. The OA patients of the present study underwent only a clinical evaluation, whereas the TKR patients received physical therapy only during the time they were in the hospital (immediately after surgery) and the majority did not participate in any rehabilitation program after they were discharged from the hospital. All patients were prescribed rehabilitation, but their compliance was not controlled.

Considering that the H/Q torque ratios of healthy subjects is between 0.5 and 0.6 (50%-60%) (24, 36, 49-53), the torque ratios of the patients in the present study are above these normal values, showing muscular imbalance between knee flexor and extensor muscle groups.

Most studies that evaluated knee flexor/extensor torque ratios evaluated these ratios between healthy subjects and patients with anterior cruciate ligament (ACL) injury before and after ACL repair. Some studies report that the the H/Q isokinetic concentric ratios are higher in the injury group, and that higher ratios are observed in both groups with increasing angular velocities (28, 54). However, in some of these studies there was no difference in the isometric torque ratios between their studied groups.

These authors justified their findings to the presence of muscle hypotrophy and the corresponding reduction in muscle force in these patients with ACL injury. They also found a higher reduction in muscle forces in the quadriceps muscle group compared to the hamstrings. It is interesting to observe that this injury mechanism for muscle hypotrophy is similar to that observed in joint degeneration in the elderly.

Our H/Q results are similar to one study that evaluated 20 women with TKR between 12 and 36 months post-surgery and that were not engaged in any physical therapy treatment (55). Their knee extensor and flexor torques were compared to those of healthy women. The TKR group showed values below normality for maximal torque and similar values for muscle imbalance as the ones observed in our study. The authors (49) ascribe the results of previous muscle imbalance to the fact that individuals have not participated in a rehabilitation program, mainly because of the placement of the prosthesis is seen as a treatment for partial recovery of the functionality of individuals (55).

Although muscle function as observed by the maximal capacity to produce torque was similar between OA and TKR groups, WOMAC scores in the TKR group were smaller compared to those of the OA group. This was true for the total scores as well as for the partial scores from the different all aspects of the questionnaire: pain, joint rigidity and functionality. This means that TKR without engagement in a rehabilitation program does not improve the torque ratios, but improves the quality of life in these patients.

Several studies have demonstrated a significant improvement both in physical capacity and in psychological aspects when comparing the pre-surgical with the post-surgical period. However, all patients in these studies received physical therapy treatment after surgery until full recovery (56-58).

CONCLUSIONS

TKR patients showed a score smaller in their quality of life (as measured by the WOMAC questionnaire) compared to OA patients. However, muscle function (as measured by maximal knee extensor and flexor torques and H/Q ratios) is similar in these patients compared to OA patients.

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BASIC SCIENCE

MECHANICAL CHARACTERIZATION OF COLLATERAL LIGAMENTS OF A HUMAN KNEE

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The importance of collateral ligaments in providing joint stability and the incidence of injuries dictate a need to increase our understanding of their structural and mechanical properties. Moreover, one of the challenges in TKA surgery appears to be designing ligament-friendly prostheses that will preserve the surrounding structures and restore the joint function. This requires a priori knowledge of "normal" knee function, in which the passive stability is the consequence of an extremely complex envelope of soft tissues around the joint structure. Therefore, the knowledge of the mechanical behaviour of collateral ligaments is fundamental. For this reason, our study aims to define, and to apply, an ad hoc methodology to mechanically characterize collateral ligaments of native human knees. Each ligament was independently tested during a displacement control uniaxial tensile test, performed on a testing machine. The specimens were tested along their main direction. To characterize the material properties at different strain rates, three different displacement speeds were considered in this study: 0.1 mm/s, 0.2 mm/s and 0.4 mm/s simulating low, normal and fast deformation speed during gait. For each speed, five repetitions were executed. Moreover, a tensile test until failure was performed for each ligament. Axial force and deformation were recorded continuously during each test. Each ligament exhibited the typical non-linear behavior reported in the literature. As expected, different ligaments are characterized by different force/displacement curves. High repeatability in the results is observed among the different repeated tests, for each investigated speed, for all the ligaments, confirming the robustness of the used methodology. Moreover, the results highlighted the speed-related mechanical behavior of the ligaments. This information will be helpful for clinicians, engineers and researchers to improve the biomechanical learning about knee, to develop better implants and to be able to improve the currently available numerical models of the human knee. Basic Science.

The importance of collateral ligaments in providing joint stability and the incidence of injuries dictates a need to increase our understanding of their structural and mechanical material properties. Intraoperative collateral ligaments balancing are very important for the orthopedic surgeon. A tight medial collateral ligament may lead to a painful knee, lack of extension and an abnormal gait pattern

Keywords: collateral ligaments, human knee, tissue mechanical characterization, force-displacement curve, tensile test

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(1-2). On the other hand a loose collateral ligament may leave to instability during daily activities as stair climbing, stand up from a chair or even walking that can compromise the results. Although several papers have been published about methodology for a correct balance of the soft tissues obtaining a right tightness still depends mostly by the experience of the surgeon. Moreover, one of the challenges in TKA surgery appears to be designing ligament-friendly prostheses that will preserve the surrounding structures and restore function (3). This requires a priori knowledge of "normal" knee function, in which the passive stability is the consequence of an extremely complex envelope of soft tissues around the joint structure (4). Among them, collateral and cruciate ligaments provide the major stability in anterior and posterior translation, abnormal tibial rotation, and varus and valgus rotation (5).

From a material science point of view, the ligaments are biological composite materials consisting of a ground substance matrix reinforces by collagen and elastin (6). From a biomechanical perspective, the relative independence of the collagen bundles in ligaments allows these organs to respond in different ways to changes in loading conditions, taking most of the load for twisting or translating (6). In particular, if we consider a knee, in the anterior cruciate ligament (ACL) the collagen bundles are spirally wound about each other, whereas in the collateral ligaments they lie parallel to the length of the ligament (6-7). Thus, it is important to realize that ligaments often have heterogeneous substructures and that their mechanical characteristics therefore can depend on the orientation of the applied loads with respect to the organ (6-9).

Ligament insertion sites transfer loads between components of the skeleton. They are designed to reduce the stress concentration that naturally occurs as forces are transferred across the ligament-bone interface (1). Direct insertion sites are generally well-defined areas with a sharp boundary between the bone and the attaching ligament (6). The different tissue microstructure found at insertion sites introduces inhomogeneous deformations throughout ligaments. Tissue strains near the insertion sites have been shown to differ from strains measured in the midsubstance of ligaments (10).

Functionally, in the physiological knee, the medial collateral ligament complex (MCL), due to its location, acts as the primary restraint to valgus rotation of the tibia, providing as much as 80% of the restraining force to valgus loads (11). The lateral collateral ligament (LCL), in contrast, provides the primary restraint to varus rotation of the knee and also acts as a secondary restraint to external rotation and posterior displacement of the tibia. During normal gait, the LCL is the primary passive structure resisting the knee adduction (varus) moment, which has been implicated in the progression of knee osteoarthritis (11).

From the best of authors' knowledge, few literature studies (12-16) are focused on the characterization of the material properties and mechanical behavior of the human ligaments of the knee. However, the needs of such information are becoming more and more popular and important due to the increasing request of improving the knowledge on the knee (4), the research of new total knee arthroplasty designs more ligaments-friendly (4) with respect to the existing ones and also the expansion in the use of numerical modeling of the knee in which a good representation of material model and properties is requested to develop realistic models (17-22).

For these reasons, the aim of this study is to define, and to apply, an ad hoc methodology to mechanically characterize collateral ligaments of a native human knee during a displacement-controlled tensile test. Each ligament was independently tested during a displacement control uniaxial tensile test at different strain rates.

MATERIALS AND METHODS

Collateral ligaments in this study were dissected from a fresh frozen cadaver knee from a Caucasian donor (woman, 72 years old, 61 kg). The specimen did not present any deformity of the articular joint. The dissection was performed preserving the proximal and the distal bone attachments.

An overview of the tissues specimens used in this study is reported in Fig. 1.

Even if ligaments are not isotropic materials, we decided to proceed with an uniaxial tensile test for this pilot experiment, considering that the ligaments work basically only in its longitudinal direction (23-25). Moreover, ligaments can be considered as quasi-linear elastic materials for their behavior in the majority of the daily activities (25-27), in which the non-linear part is the first part of the force deformation curve, in which, usually, all the fibres align.

The uniaxial test was performed, for each ligament separately, on a standard 3-ton tensile testing machine (Lloyd LR 30kN load cell, Ametek Inc., MI, USA).

During the tensile test, the bony attachments of each ligament were connected to the machine using flat roughened clamps. The set-up of the testing procedure is shown in Fig. 2.

To be able to characterize the material properties at different strain rates, three different crosshead speeds were considered in this study: 0.1mm/s, 0.2mm/s, 0.4mm/s. These values were chosen because they are representative of low, normal and fast deformation speed during gait.

For the sake of repeatability, five repetitions for the same ligament were performed for each speed.

During the test, the machine applied a controlled displacement on the upper clamp to maintain a certain constant speed. Due to this controlled movement, the tissue underwent to a force. Axial force and displacement were recorded simultaneously (data sampling rate 1000 Hz).

To avoid any rupture, each test was stopped as soon the linear trend on the Force –Displacement curve was achieved consistently.

To fully characterize the entire behavior of the ligaments, after the analysis of all the speeds, for each ligament, a tensile test, until rupture, was also performed, using a strain rate of 0.2 mm/s.

RESULTS

Results show that each ligament is characterized by a proper force/displacement curve. Fig. 3 shows, for the same used crosshead speed (0.1 mm/s), the average force/displacement curve and the standard deviation for both the analyzed ligaments. High repeatability in the results is observed among the different repeated test for each investigated speed for all the ligaments (maximum observed standard deviation is 13 N for medial collateral ligament). Results show that the two collaterals are characterized by different stiffness because they present different slopes in the Force/Displacement curve.

Results highlight also the speed-related mechanical behavior for both ligaments (Fig. 4). If the strain rate increases, the slope of the characteristic behavior increases for both ligaments, but medium and fast speeds reach almost the same inclination.

As previously described, the repeated test for several crosshead speeds were manually stopped when each specimen was considered in its elastic region that is the range in which ligaments work. Fig. 5 shows the failure curves, obtained for 0.2

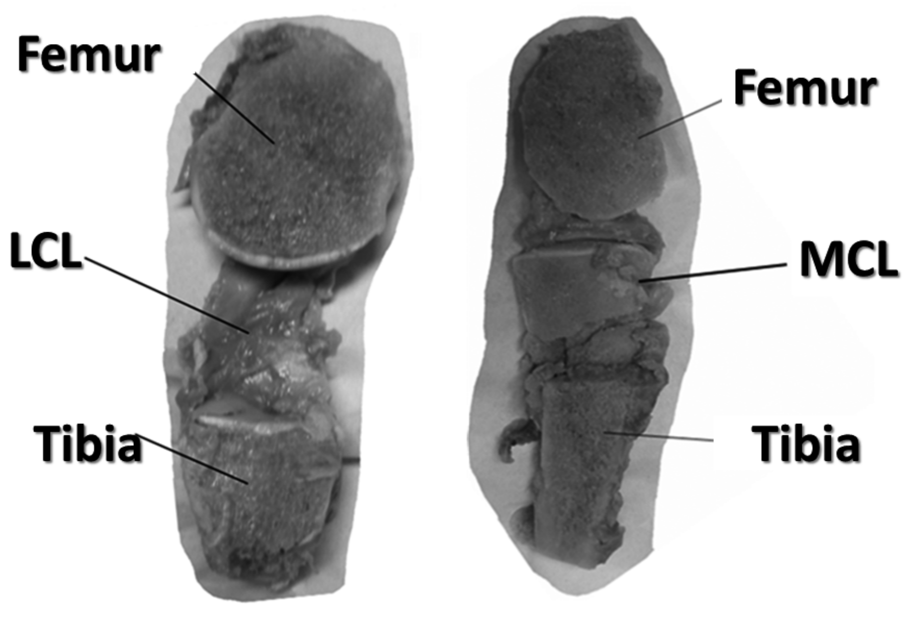

Fig. 1. *Collateral ligament specimens used for the test.*

Fig. 2. *Experimental set-up.*

mm/s cross speed, for both the analyzed ligaments and it also indicates where all the repeated tests were stopped. Failure curves underline different material behavior for the two collaterals. The first quadratic behavior is characterized by a different slope, but then we have a first bump with a first plasticization region. After that, the linear behavior seems to be almost parallel for the two specimens and a second bump concludes the linear region for both collaterals presenting immediately a yield stress for the lateral one while the medial one presents also a second phase of plasticization.

DISCUSSION

In this study the mechanical behaviour, in terms of Force/Displacement relation, of collateral ligaments from a native human knee was determined from experimental tensile tests performed at several speeds.

The main limitation of this study is lack of specimens to be tested. However, results find the feasibility of the methodology presented for this pilot test, considering the repeatability on the obtained results with a maximum standard deviation of 13 N.

Another limitation to be considered is the impossibility of directly measuring the strain of the tested tissues. To avoid this limitation, we tried to sew a sensor directly on the tissues but we discovered that its weight compromised the natural behaviour of the analysed tissues during the tensile tests. Moreover, even if thawed tissues were used for this analysis, from literature is turned out that mechanical properties are not changed.

Even if there are some limitations, our data are in good agreement with the literature (9) especially for the lowest speed in use.

Looking at the failure curves, results show two characteristic bumps, the first of those can be associated to a pretence plasticity that can correspond to the instant in which all the fibres of the ligament are aligned, while the second occurs early before the yield stress, for the lateral collateral ligament, or before a plasticity phase before rupture for the medial collateral ligament. Both these points are important to characterize the behaviour of the ligament and to identify where the linear trend starts and ends. The use of this information is fundamental to check if the application of the hypothesis of linearity for ligaments is suitable in a specific developed knee numerical model, during a specific movement (29-31).

The two characteristic slopes, especially for the quadratic phase and before failure, presented in the results for the collaterals can be explained in different stiffness of the two specimens as also presented in the literature (6).

As expected, different speed-related mechanical behavior is shown for both ligaments (6), but with the increasing of the crosshead speed, the increasing of the slope of the force/displacement curve is not linear.

For all the reasons mentioned before, we believe that the outputs obtained in this pilot test are extremely important because they could be helpful for clinicians, engineers and researchers to improve the biomechanical learning about knee and to be able to develop accurate numerical models of the human knee. In trustable numerical model of the knee, it is needed to replicate the collateral ligaments function

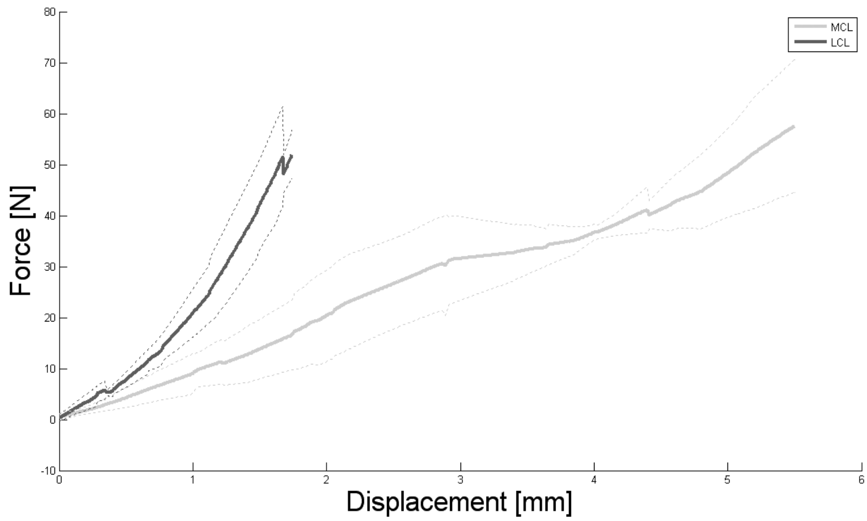

Fig. 3. *The average force/deformation curve and the standard deviation for both analyzed ligaments at 0.1 mm/s crosshead speed.*

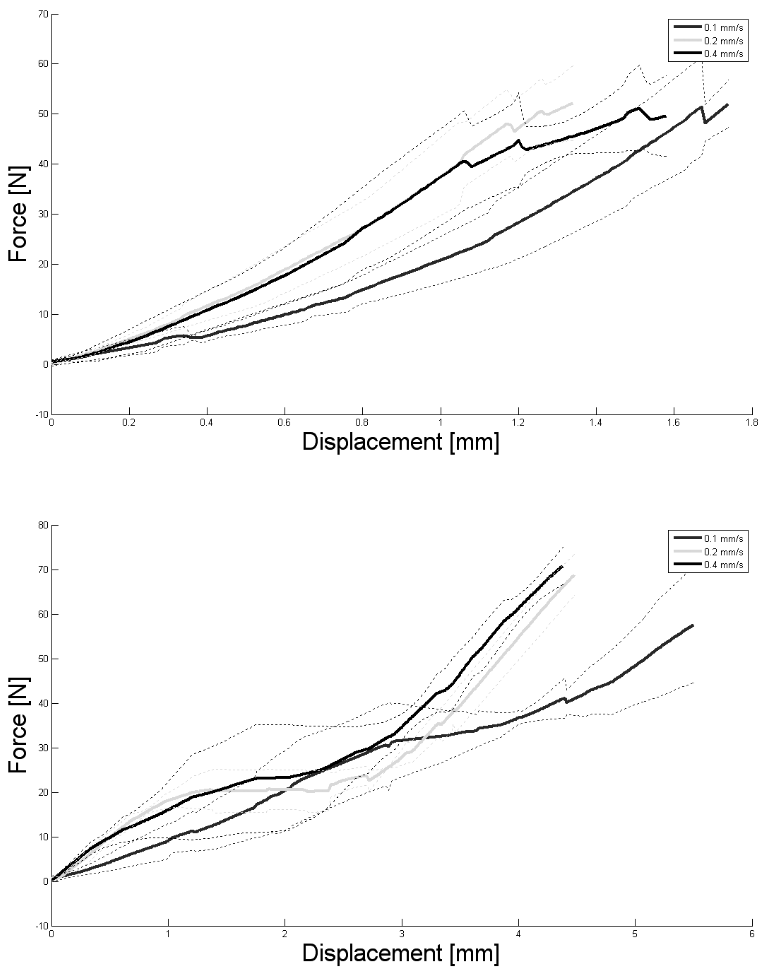

Fig. 4. *The average force/deformation curve and the standard deviation for the three used crosshead speeds for **A)** the lateral collateral ligament and **B)** the medial collateral ligament.*

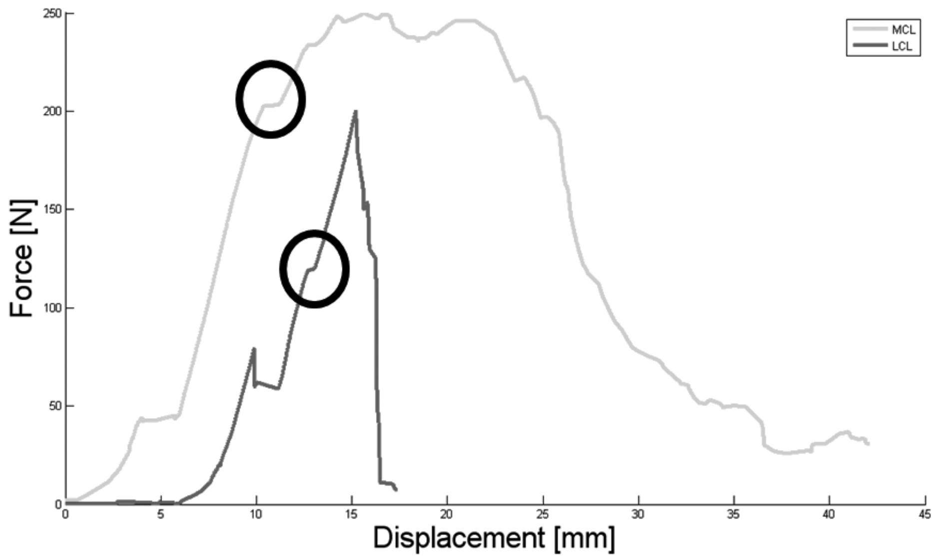

Fig. 5. *The failure curves for both the analyzed ligaments. The black circles indicate the range in which all the repeated tests were stopped for both collaterals.*

them as isotropic, linear and elastic materials, in fact as cited in the results section, the analysed ligaments could be considered as linear elastic material for the region of interest affect from daily activity movements.

We believe that the adopted procedure should be applied in the analysis of a larger group of specimens, in order to achieve a more statistical valid behavior for the analysed kinds of ligaments. Moreover, the same approach could be also integrated for the analysis of other ligaments. Eventually, to improve the procedure and the final knowledge on the behavior of these tissues, an implementation of a method that does not affect results and that directly measures the strain during the tests, should be added. Furthermore a deeper knowledge of characterization of these structures can be helpful for the surgeon to obtain a well balanced knee, according to the implant design, and to guide his choices about bone cuts or level of correction.

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