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ANALYSIS DEVICE FOR FEMORO-TIBIAL ROTATION MEASUREMENT: A CADAVERIC STUDY

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1. Introduction

Rupture of the anterior cruciate ligament (ACL) is one of the most frequent injuries of the knee joint in today's field of orthopaedic surgery [38, 80]. The operative reconstruction of the ACL using autogenic tendons is a common surgical procedure mainly performed using the single or, since anatomical studies have shown the double bundle characteristic of the ACL [4, 84, 117], double bundle technique. Expert discussions are ongoing since years and have not found definite advantage of one technique over the other [31, 34, 68, 120]. Different functional and anatomic studies have shown the specific stabilising effect of each bundle, so the anteromedial bundle (AM) is stabilising against anterior posterior (AP) motion during higher flexion and the posterolateral bundle (PL) resists rotational motion (RS) in lower knee flexion angles [116-118]. The loss of one bundle may result in a partial insufficiency with subjectively felt instability relative to the bundle's function [11, 87]. The total rupture of the ACL results in a decreased stability in both the AP and RS direction which can be detected during the clinical examination. To evaluate ACL insufficiency two main manoeuvres have been established: the AP translation can be categorised by using the Lachman-Test [13, 29, 88] and the examination of the rotational instability is detected by using the Pivot-Shift Test [5, 35]. Both tests are well proven for the evaluation of ACL insufficiency, but are highly dependent on the examiners` experience [78]. A reliable technique to measure objectively AP translation has been developed and established with the KT 1000 device but objective rotational measurements has not been examined in such a holistic manner as it is needed to establish a method or standard. The complexity of rotational instability has seen many approaches, but most of them lead to

inadequate results depending on the processing and mechanical limitations such as soft tissue artefacts [61, 63, 64]. Due to the non availability of satisfactory techniques the aim of this study is 1st the modification of a developed device to 2nd access rotation values with its relative strength pattern in an in-vitro setup on cadavers to analyse the results in respect to their reliability, validity and further graphical analysis. By using a custom made device with two point transtibial and transfemoral fixation equipment, the stabilising function of the ACL was conducted in full extension, low knee flexion and rectangular knee flexion. The setup was used to answer the questions whether

- A knee without ACL can be rotated to a greater extent as with intact ACL?
- The knees` rotation is relative to the torque (Nm) applied?
- The torque used for maximum internal rotation under the ACL intact situation is much higher than the torque used in the ACL absent situation?
- Changes in ligament restraints are detectable?
- The variation of flexion angles of the knee leads to resistant changes in internal rotation?
- The graphical displays of the values differ between the ACL intact and ACL absent situation?

Therefore the purpose of this study was to evaluate a newly developed measuring device for tibio femoral rotation and to compare the findings under the condition of intact versus absent ACL. To the best of our knowledge a practical concept for the measurement of knee rotational instability has not been developed so far.

2. Background

2.1. Epidemiology

The rupture of the ACL is a common diagnosis and occurs approximately 75 000 times each year in the USA [36] and approximately 47.500 in Germany [46]. It has to be mentioned that the appearance of ACL ruptures strongly depends on the age and sportive activity of the patients. The more affected group is found in sportive, active young males between 15 and 45 years [21]. For the group of patients between 15 and 25 years the incidence is at its highest level with 1 of 1000 [24] citizens. Handball, basketball, soccer and skiing are the top sports compromising the ACL. Approximately 70% of the injuries appear in non-contact situations [104]. Rochcongar et al. analysed 934 ruptures and found that mechanisms leading to ruptures happen significantly more often in non-contact situations (34.5%). These results have been confirmed by observations from previous investigations [92]. The cumulation of ACL ruptures in the general population has been analysed in the observation study of New Zealand's nofault injury compensation database. These data were obtained for knee ligament injuries between the years 2000 and 2005. The incidence rate per 100,000 person-years was 36.9 for ACL injuries. Males had a higher incidence rate for ACL surgeries [38]. On the other hand some investigations show that women are substantially more often affected than males [70, 75, 76, 108] depending on the sport. The risk of ACL ruptures in young female soccer players was three times higher than their male counterparts [59]. A Norwegian investigation among handball players showed a 5 times higher risk of ACL injuries for females [75]. Even the level and position of the player is important for the

cumulation of ACL injuries, so that Wedderkopp et al. found the highest injury rates in backfield players [111].

2.2. Anatomy of the human anterior cruciate ligament

The first citation of the cruciate ligaments dates back to the Egyptian times approximately 3000 B.C. Hippocrates (460-370 B.C.) described the anatomy and function of the anterior cruciate ligament 2000 years later, the Weber brothers from Goettingen, Germany, discovered and described the pathologic AP translation after dissection of the ACL [86]. The structures of the cruciate ligament can already be found after the 10th foetal development week [69], a long time before the joint gap develops.

Recent studies examined the origin of the femoral and tibial insertion of the ACL and found that the development starts early from syno-mesenchymal cells located between femur and tibia [107] and the fibroblasts are already arranged in the former strain direction. This early appearance of traction forces to the ACL possibly influences the entire development of the femur condyles and tibia plateau at this early stage.

The origin of the femoral insertion from the medial wall of the lateral condyle is fanshaped heading in a distal-anterior- medial direction to the insertion area at the top of the tibia plateau creating an 28°- angle to the femoral length axis in 90° knee flexion

shaped heading in a distal-anterior- medial direction to the insertion area at the top of the tibia plateau creating an 28°- angle to the femoral length axis in 90° knee flexion [79]. A precise look at the ACL's diameter shows that its fan-like characteristic can be split into many functional bundles (Figure 1), each with a unique insertion side [33] and correspondant part of stabilising effect at appropriate flexion angles. The characterisation into two main bundles has been widely accepted considering the surgical possibility of ACL reconstruction [84]. During knee flexion the portion of

bundles originating in the antero-medial tibia is set under tension and is pressed at the arch created by the intercondylar area, where the fibres of the postero- lateral bundle are simultaneously relaxed, set under tension and wrapped around the AM bundle when the knee joint is extended. The length and cross section dimensions are widely varying between 31±3 and 36±3 mm representing the inter individual differences and gender affiliation [79]. In the mid third the ACL has the smallest diameter looking like the shape of an hourglass, locking in AP direction. Interestingly, the ACL's orientation is not straight, but distorted. When all ligaments of the knee are dissected and only the ACL remains, the shank will internally turn for approximately 55° representing the arrangement of the fibres [93]. The fibres arise most cranially from the femoral condyle and insert in the most antero medial area of the tibia plateau. The most caudal arising fibres finally insert at the most postero lateral area [33]. Because of its configuration

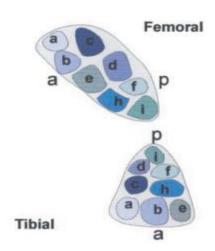


Figure 1: Anatomic differentiable bundle structure of the ACL with its insertion sites and anatomical course [84]

there is no fibre of the entire ACL showing isometric behaviour [4, 93]. The varying shape and dimension of the insertion sites assign the biomechanical moving ability of

the ACL [41, 79]. Comparing the femoral and the tibial insertion site, the femoral area is half moon shaped (Fig. 1 & 2) and the tibial area, embedded between the medial and lateral Tuberculum, which is often described as comma like (Figure 1 -3), the midpoint is approximately in the centre of the tibia plateau [79] 7-8 mm anterior to the insertion site of the PCL.

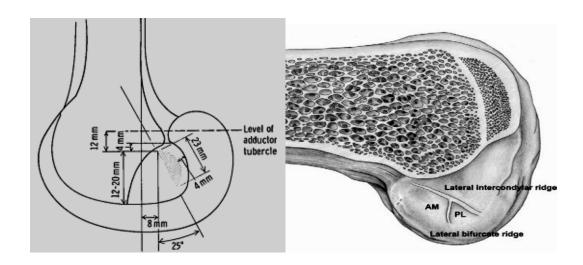


Figure 2: Left: Half moon shaped femoral insertion side of the ACL. Right: the anterior border of the ACL "lateral intercondylar ridge" is an often visible osseus landmark in anatomic preperations [39]

The ligamentious structures consist of mainly strong connective tissue and the collagen fibrils are separated from each other through low- density connective tissue. There is no difference between the functional bundles [17] from a histological point of view. The only area with different structure is the anterior distal part of the ACL where no synovialis is found and the ACL-tissue is most similar to chondral cells [85]. The extra cellular matrix consists mainly of Collagen Type I and significant lower concentrations of Collagen Type III [85]. The variation of tissue mixture has physiological reasons. The pull strength is mainly supplied by the Collagen Type I, but the Collagen Type III

with its distinct lower strength and its beneficial visco-elastic behaviour allows the recruitment of fibres under changing joint angulations [85].

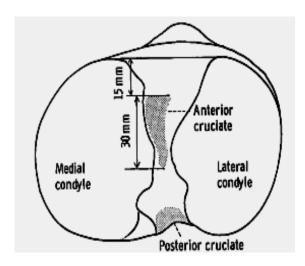


Figure 3: The comma shaped tibial insertion site of the ACL And PCL [39]

The histological analysis of the bony insertion areas shows similarities to chondral-apophyseal ligament attachments with tightconnecting tissue inserting at the top of the fibre areas at the tibia and femur [83]. The blood supply of the anterior cruciate ligament is provided by the Aa. genus inferioris medialis and lateralis creating a periligamentious net of supplying arteries and veins, whereas no blood vessels are traceable within the middle of the ACL [2, 8]. Also nerval supply was found for the ACL. Histological explorations of the anterior cruciate ligament bear three morphological types of mechanoreceptors and free nerve-endings, two of the slow-adapting Ruffini type and the third, as a rapidly adapting Father Pacinian corpuscle. Rapidly adapting receptors normally signal motion and slow-adapting receptors subserve speed, acceleration and deceleration. Free nerve-endings, which are responsible for pain, were also identified within the ligament [94]. Probably these findings explain the need for extensive physiotherapy and time for rehabilitation before

the patient is satisfied with control regarding gait and stability after ACL reconstruction.

2.3. Biomechanics of the knee

2.3.1. Physiologic motions

The human knee is a complex joint, which allows movements in different directions. The most apparent movement is the flexion and extension movement during the walking process. Another movement is the rotation between the femur condyle and the tibia plateau as well as minimal side translations during walking and running. Anatomically the human knee joint is divided into two joint parts: The femoro tibial joint and the femoropatellar joint. Each part articulates with its components [71].

It requires more detailed investigation to understand the movement of the knee joint. The kinematics of the femoro tibial joint in the sagittal plane can be reduced into a two-dimensional model to show the distinct roll-slide movements. The main aspect between the femur condyles and the tibia plateau during knee joint flexion and extension could be explained and compared with a turning and spinning wheel, with the result of a more circumferential rotation by less recline (Fig.4).

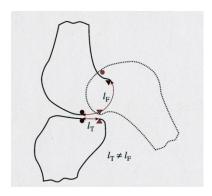
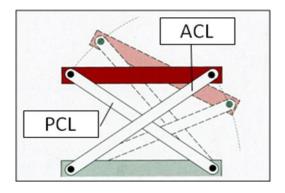


Figure 4: Rotation/Sliding concept of the femur condyle [71]

During flexion the drift of the femur condyles (IF) is different to the drift described for the tibia plateau (IT) [67]. The proportion of both components is not constant during flexion. At the beginning the rotation component exceeds the slipping component, whereas during further flexion the slipping component becomes more dominant [67]. To understand the complex mechanics the correlation of the parameters has to be integrated in a 3-dimensional model. Based on the sagittal view the movement of the cruciate ligaments (anterior and posterior cruciate ligament) is equal and comparable with a crossed- four- bar- linkage construction [54, 67, 72] (as seen in Figure 5 & 6).



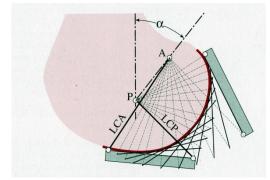


Figure 5: Four-bar-linkage as sagittal mechanical model [71]

Figure 6 Rotation schema of the tibia plateau regarding the insertion sites. [71]

In the model of a crossed- four- bar- linkage construction the maximum movement is determined through the limited distances of the bars. In Figure 5 the bar- linkage construct is merged in the sagittal outline of the femoro tibial joint. The α -angle is the connection of the insertion areas of the anterior cruciate ligament, the posterior cruciate ligament and the longitudinal axis of the femur (LCP Ligamentum cruciatum posterius, LCA Ligamentum cruciatum anterius). The angle is commonly named Insertion angle, its normal orientation is around 40° [67, 72] to the longitudinal axis of the femur.

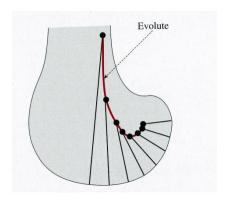


Figure 7: Sagittal views. The Evolute is representing the centre of each radius resulting the condyles shape [71]

The bar at the bottom of Figure 6 is the moving part of the system and symbolises the tibia plateau. If the tibia- plateau is moved, it describes approximately the outline of the condyle. The sagittal view allows for the conclusion that the curvature of the condyles is increasing from anterior to posterior. This implies that the curvatures radius is decreasing (r`<r). If the centre of each radius is attached to a consecutive line, a curve is the result. This curve is named Evolute [30]. The correct mathematical description of the Evolute has been the subject of many different studies; recent magnetic resonance imaging (MRI) studies described the shapes of the articular surfaces and their relative movements with gold standard correlation in terms of dissection. The medial femoral condyle in sagittal orientation is composed of the arcs of two circles [47]. The most exact mathematical description was made by Rheder who found a mathematical formula with \pm 0.2mm approximation [90]. In observations of the specific movement of the cruciate ligaments during the flexion and extension phase the cruciate ligaments rotate around their distal insertion points at the top of the tibial plateau. Simultaneously the proximal ligament fixation on the inner side of the lateral femur condyle remains nearly unchanged.

During flexion the ACL comes close to the surface of the tibia plateau, the (PCL) approximates the longitudinal axis of the tibia. Both femoral insertion points move along a half-moon shaped curve towards the posterior edge, which might be recognized as proof for the roll-slip- concept. As mentioned above the rotational centre of a crossed- bar- linkage describes a curved line (Evolute) indicating the rotational centre at any flexion angle. During flexion the Evolute moves in posterior sagittal direction.

Changes in the length of the cruciate ligaments or differing insertion areas may have an

immense effect on the knee kinematics. The normal range of motion of the human knee joint varies between 5° hyperextension and 140° flexion.

2.3.2. Pathologic motions

When the proximal insertion angle of the ACL is changed (normal angle 40° to the longitudinal axis of the femur) a difference in the knee movement will result. For example an increase of the insertion angle from 40° to 60° will lead to an increase of extension in terms of hyperextension. In the case of an operative ACL reconstruction it is extremely important to find the anatomical insertion sites of the cruciate ligaments. Either a change in the place of fixation or the length of ligament leads to severe biomechanical changes. In case of an elongation or shortening of the cruciate ligament a change in the outline of the condyles will follow caused by the change of the rotational centres. The change in the pivot leads to a new outline of the condyles' surface and different moving abilities. In case of a decreased radius of the curvature an impingement of the dorsal condyle will be the result

- the mechanical deficit will be a decreased flexion angle
- an increased compression force to the articulating surface
- a possible overexpansion of the ligament
- a possible rupture of the graft

In reality, the increased length of the ligament or missed insertion after surgical reconstruction in far distal and anterior position to its origin leads to:

- slackening of the joint
- increased drawer sign

• increased anterior/ posterior moving ability.

The limits of movement are highly associated with the insertion of the ligaments. Looking to the crossed- four- bar- linkage construction in the 2-dimensional sagittal plane the insertion of the ACL and PCL has to be at 40° angle to the axis of the femur. The natural limits of range of motion (ROM) 5°/0°/145° will only be achieved in this configuration. Many complications appear when the insertion has been placed in a too far ventral position. During knee flexion the ligaments will begin to slacken as long as the rolling of the femur continues. In the phase of femur gliding the lever of femur expands the ligaments and possibly ends in a rupture of the ligament transplant [71]. An example is given in Figure 8. In full extension the cerclage wires are close together suggesting integrity of the ACL fixation. In flexion the illusory situation is visible with the cerclage parts being without any connection. In comparison, when the ACL femoral inserting point is chosen too far dorso proximal, the flexion angle cannot be provided due to extensive tightening in extension.

The movement is highly constricted, the leg becomes stiff. Taking a closer look at the moving parts of the knee joint, the cruciate ligaments are not only responsible for physiologic motions but present one of the most common reasons for pathologic moving ability [9]. Under this condition the physiological circular course, described by the femoral insertion site of the ACL's origin during knee flexion is disconnected. Here the femur slides over the posterior horn of the meniscus with possible damage of the meniscus fibres. When the circumferential shape of the meniscus is interrupted, meniscal symptoms with pain and ongoing destruction can take place. In some cases the vicious circle of meniscectomy and further destabilising of the knee joint is likely to happen [40, 96]. Increased AP translation after ACL rupture is one of the objectively

measurable symptoms [23, 58]. Work conducted by Slocum and Larson [101] with the focus on rotation instability of the knee, subluxation as the Pivot-Shift-Phenomena [35] can be visualised and explored. Rotation was henceforth studied using computerized measurement devices [98], the anatomic resection of the anterior cruciate ligament showed that the deficit of the ACL is a fundamental condition for the pathologic Pivot-Shift sign [50, 51]. Only after the rupture of both functional bundles the sign becomes evident.



Figure 8: ACL reconstruction with fake insertion areas, in Extension the cerclage wire seems to be intact, at higher flexion angles the wire endings drift apart [71]

2.4. Pathophysiology

2.4.1. Trauma mechanism and Symptoms

Anamnesis and awareness of the accidents` mechanisms play a great role in discovering ligament ruptures. Many patients report from a clear audible snapping sensation during the accident. Afterwards the most common signs are effusion, swelling, blocking

sensation and pain in the lateral joint gap. 25% of the patients present instability (giving way) most likely during climbing stairs. Sometimes 4-6 weeks after ACL rupture, the Lachman Test is more or less negative, caused by scar tissue amongst the sumps of the ACL [106]. The mechanisms leading to ACL rupture are

- Internal rotation with hyperextension
- Hyperflexion with internal rotation
- Abnormal forced valgus or varus flexion
- Flexion and valgus external rotation

2.4.2. Diagnostics

During clinical testing the comparison of both knee joints is important to find abnormalities of the joint's motion. It is recommended to start the examination with the healthy, followed by the affected joint. For the correct examination the examiner has to keep in mind that the knee joint consists of two parts, the femoropatellar joint and the femoro tibial joint whereas either one may be the source of the complaints. It is also not rare that the pain of the knee may arise through a painful projection from the hip or ankle of the same limb. Instability of the joint may be the result of injuries of muscles, tendons, capsule, meniscal tears or insufficient ligaments. The lack of stability can be measured and graded as follows.

- Slight instability (+), dislocation differs approximate ca. 3-5 mm
- Mean instability (++), dislocation differs ± 5 -10 mm
- Severe instability (+++), dislocation < 10mm

An abrupt stop points to partial lesions or intact ligaments, in contrast an absent stop aims for total ruptures or missing ligaments. In this case the anamnesis in terms of a history of trauma and the understanding of the pathological mechanisms are important. A radiological examination is imperative to eliminate fractures or deformities of the affected knee joint.

2.4.3. Clinical Examination

The Lachman-Test is the most reliable method [40] to discover instabilities or ruptures of the anterior cruciate ligament. One hand fixes the distal femur of the patient laying in a supine position while the knee is flexed to approximate 20°. The other hand pulls the proximal tibia in an anterior direction. If the tibia reacts like a drawer anterior with no abrupt stopping, a rupture of the ACL can be assumed [88, 113].

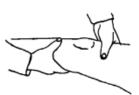


Figure 9: The examiner grasps the medial proximal tibia with one hand and the distal thigh with the other. Then a postero medial to antero lateral force is applied to the knee, essentially pulling the tibia anteriorly to the femur. The amount of translation is compared bilaterally to determine the presence and/or extent of instability.[103]

The Pivot- Shift- Test is a manual test to identify ACL ruptures or maximum laxity of the knee joint. The test's name derives from the Pivot (axis), Shift (dislocation) and was first described by Macintosh in 1971. To perform this test, the patient lies in a relaxed supine position. The examiner takes the heel with one hand by slightly rotating the shank internally whereas the other hand is used to drive a valgus force to the tibia head.

While the knee is slowely flexed, in case of an ACL rupture, the tibial head slides anteriorly in to a subluxation position. At 30°-40° knee flexion the tibia head jumps back into the physiological position. Normally this appears with a snapping sensation or a visible bounce emitted by the Tractus iliotibialis sliding over the lateral femoral epicondyl to its posterior location. If the examiner feels this effect the test is positive and consecutively there are firm doubts of a normal ACL. The test result can be wrong if a medial-capsule-ligament instability or a ruptured Tractus iliotibialis is present [5, 35].



Figure 10: The examiner holds the ankle and the knee joint with the other hand. Applying valgus stress to the flexed knee the joint is extended slowly. ACL absence produces a snapping sensation and tibial jump when the tractus is changing from a flexor to extensor position.[103]

The Drawer Test for the knee is used to examine the integrity of the anterior cruciate ligament. The patient is placed in a supine position on the table with the knee in 90° of flexion and the hip in 45° flexion. The examiner places the hands around the proximal tibia with the thumbs crossing the anterior joint line. The patient's foot is anchored in a neutral position by the examiner's thigh. The examiner tells the patient to relax the hamstrings. Once the patient is relaxed the examiner attempts to pull the tibia anteriorly. An instability is determined by examining bilaterally and comparing the amount of present excursion.

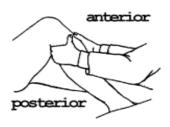


Figure 11: Patient in a supine position. Knee flexed to 90°. Foot anchored through sitting on the foot. The hands encompassing the proximal tibia applying force from posterior to anterior position. Comparing those translations the injured knee will show distinct increase of anterior-posterior translation.[103]

2.4.4. Radiological Examination

The magnetic resonance imaging (MRI) examination of the injured knee has been established as good method to identify musculoskeletal pathologies in acute or degenerative knees [73] and through its accuracy it may avoid frivolous arthroscopies [20]. Many injuries show characteristic MR- signal patterns according to the injured anatomic structure. According to the dimension, the intensity and the position of signalling the specific pathology can be identified and described [15]. The cruciate ligaments are located intracapsular and extrasynovial. Acute ACL tears are mostly associated with heamarthros [52]. For the routine MRI of the knee, the positioning of the knee is in 10-15 ° external rotation, with 1-mm-slice-thickness images. The shortest time and cost effective sequence is the Fast Spin Echo Proton Density weighted sequence showing great performance in diagnosing tears of the cruciate ligaments [115] by less time. Even the collateral damage of the knee can be detected and may lead to different therapy. In this context the detection of a bone bruise can be helpful and is most common cumulated, deeper and more intense in the lateral compartment after ACL rupture and persists for at least 4 months [16, 110]. The appearance of a deep sulcus in the lateral femur condyle on MR images in patients with torn ACL's is deeper

(> 1.5 mm) compared with the sulcus of ACL sufficient knees (1.2 mm). The deep sulcus sign of the lateral condyle is a useful indirect sign of a torn ACL [18] in cases where the slices do not allow for a detailed view of the ACL.

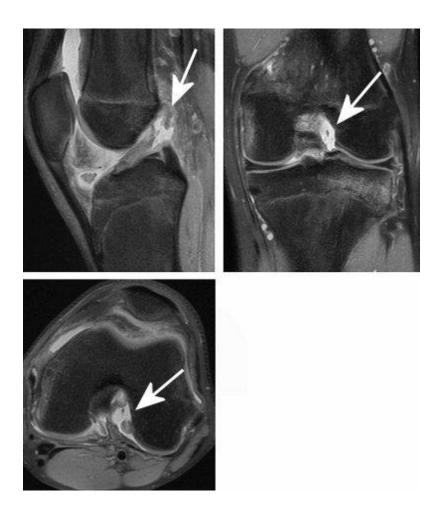


Figure 12: Fast Spin Echo Proton Density weighted sequence of an ACL avulsion. The arrows point to the remaining stump as well as haemarthros and effusion.

2.5. Therapy

The treatment of ACL ruptures depends on different factors such as:

- Age
- Functional disability
- Functional requirements.

A gaining situation occurs when active young patients want to return to sportive activity after ACL reconstruction. In the event of acute fresh ruptures the best time for surgical reconstruction appears when the swelling is decreased so that a surgical intervention is not complicated through soft tissue swelling and reduced flexion ability. Reviewing the literature of the last decade there is no consensus regarding early versus late surgical reconstruction [14, 102]. Other studies found increased range of movement strength in the group of delayed intervention after 12 weeks, but no more advantages have been seen [66]. In our department we follow the philosophy of delayed surgical intervention and consider a presurgical period of physiotherapy and detumescing lymphatic drainage as good preparation. To summarize; a surgical procedure has to be considered if

- The patient suffers from distinct instability, or
- An ACL reconstruction will decelerate the development of osteoarthritis

 Also the ACL reconstruction may provide long-term symptom relief and improved

 function in patients with medial knee arthrosis [97].

2.5.1. Single bundle reconstruction

The single bundle technique is the most common and also the most time effective, cost saving surgical procedure to regain anterior-posterior knee stability. In many surgical interventions either the medial third of the ligamentum patellae or a graft from the hamstring muscles are used. Using the mid third of the patella tendon, a tendon graft of approximately 10 mm width with a remaining bone chip at one end is harvested. The bone free end of the tendon is sewed with shuttle fibres to ease the graft feed to the drill

holes. During a diagnostic arthroscopy the remaining ACL structures are milled off and the insertion sides at the medial side of the distal lateral femur condyle as well as the tibial insertion side are prepared through drilling.

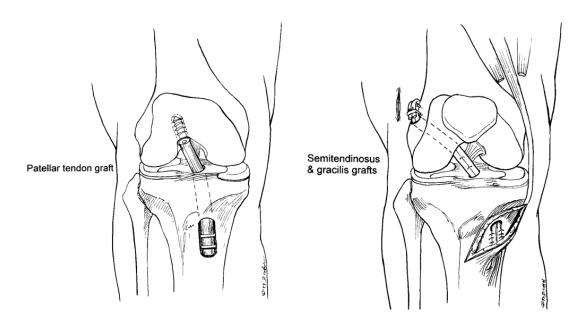


Figure 13: Surgical technique using the patellar tendon in the Bone-Tendon-Bone Technique and using the semitendinosus and gracilis tendon technique [6]

The positioning of the tibial drill hole is 7mm anterior to the posterior cruciate ligament, the femoral insertion side is drilled through a drill guide which allows the right positioning, projected to the 11 o'clock position (left) and the 2 o'clock position (right) in a 90° bended knee. The graft is shuttled into the drill holes and fixed by either polylactid or metal interference screws or different fixating devices according to the drilled diameter. The outcome of single-bundle anterior cruciate ligament (ACL) reconstruction has been favourable, but during the last years multiple authors have noted persistent instability in anterior to posterior translation and also rotational instability [105].

2.5.2. Double bundle reconstruction

The specific anatomical ACL structure with its functional double layer morphology is the reason for the most recent developments in ACL reconstruction surgery performing a reconstruction of both, the antero medial (AM) and the postero lateral (PL) bundles of the ACL which seems to improve anterior to posterior translation as well as rotational stability. For reconstruction, the hamstring tendons are used and the terminology of AM and PL bundles is chosen according to the tibial insertion and determined by their functional tensioning during knee flexion. After the Hamstring tendons are harvested the respective ends are also sewed with shuttle fibres. The diameter of the tendon is measured and according to these diameters the femoral inserting sites are drilled. Next, a guide wire is placed 5 mm anterior to the posterior cruciate ligament in the centre of the intercondylar eminence. The aiming device should be set to 55° and tilted to 50° in the frontal plane. For the antero medial tunnel (second drill hole) the aiming device is changed to 45° (tilt 20° to the frontal plane), and the guide wire for the (AM) tunnel is placed 3 mm in front of the PL wire in the centre of the ACL insertion. The PL tunnel is enlarged to 5 mm, followed by an enlargement of the antero medial tunnel to 7 mm. The grafts are shuttled through the drill holes. The postero lateral bundle is tensioned to 80 N by using a spring scale, and at 10° of knee flexion, a bio absorbable interference screw is placed in an antegrade fashion. The antero medial bundle is then tensioned to 80 N in the same fashion at 45° of knee flexion, and a bio absorbable interference screw is placed for fixation [19]. In 90° flexion in the frontal plane the femoral antero medial tunnel is located at the 11 o'clock position (right knee), 1 o'clock position (left knee) respectively. The postero lateral femoral hole is located at a 9:30 o' clock position (right knee), in the left knee the 2:30 o'clock position is suitable [27, 62].

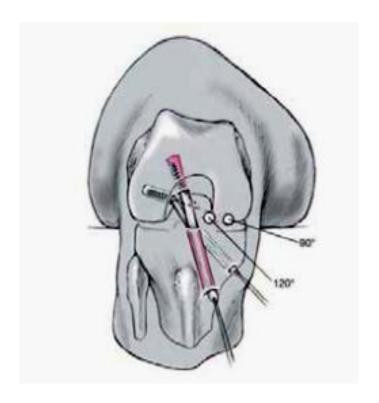


Figure 14: The position of the femoral and tibial tunnels for anatomic double bundle reconstruction. [62]

2.5.3. Postoperative Rehabilitation after ACL rupture

Surgical intervention for the reconstruction of the ACL and the early-rehabilitation [95] phase have under-gone a rapid development over the past 25 years. In addition, there is an absence of standardized, objective criteria to accurately assess an athlete's ability to progress through the end stages of rehabilitation and safely return to sportive activity [74]. Reviewing the last years rehabilitation protocols they can be divided into acute, subacute, functional progression and return to activity schemes [114]. These protocols usually focus on acute and subacute management with relatively stringent guidelines regarding progression of weight-bearing, increase of range of motion (ROM) and introduction of specific types of exercises in early rehabilitation. The

guidelines and supervised therapy can significantly improve the early post-surgical outcome [44]. Late-stage rehabilitation and return to sportive activity in terms of training after ACL reconstruction without guidelines for training may lead to deficits in lower extremity neuromuscular control, strength, and ground reaction attenuation. These deficits may increase the risk of recurrent injury or limit the achievement of optimal performance levels [1, 25, 43]. Our developed protocol has the potential to target post surgical deficites and address them through systematic progression during the stages of the return to sportive training. The "release for full activity" is a potentially sensitive landmark for the athlete who has a strong desire to immediately return to high-level sportive activity. However, over the last years we developed our own postoperative scheme including a postoperative cooling of the elevated limb. From the first day after the operation there are no restrictions for flexion and extension but full weight bearing is not recommended. Instead, 20kg weight bearing adapted to individual pain levels and the presence of effusion for at least two weeks is recommended. After week three to week seven sensomotoric exercises are useful and approximately after the 8th week we recommend treadmill, cycle or crawling training. After 3 months impacting activity such as jogging can be started. Individual sport specific training can be started after 6 months. Body contact sports like Karate should not be started until at least 9 months have elapsed.

2.6. Measurement devices

2.6.1. Radiologic Measurement

The Telos Stress Radiography Device may be used to measure laxity in the injured knee by comparing the forced displacement of corresponding bones in a joint. The outstanding attribute allows the reproducibility of the measurements among different examiners. The device is equipped with a screw-threaded shaft allowing for a gradually application of stress meanwhile the pressure is displayed on the readout. The patient is positioned in a lateral position on the site of the examination. To test for anterior knee laxity, the pressure plate is positioned posteriorly at the mid level with one counter bearing placed at the level of the ankle joint and the other approximately 5 cm above the patella.

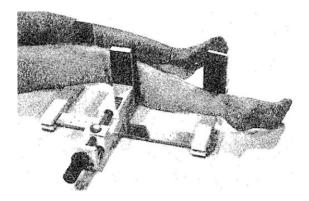


Figure 15: The Telos device is the most reliable device to process stress radiographs. The leg is clamped to the device and force is applied in anterior to posterior direction or vice versa.

The knee is flexed to 90° and the patient is instructed to relax the leg muscles. The stress is steadily increased and radiographs are taken after application of pressure of an anteriorly directed force. Posterior knee laxity is tested in a similar manner with the pressure plate positioned anteriorly approximately 2.5 cm under the tibial tuberosity.

The contralateral knee is subject of the same examination for comparison purposes. The anterior and posterior drawer displacements are calculated from the radiographs taken by measuring the displacement of the midpoint between the tangents to the posterior contours of the tibial condyles drawn perpendicular to the tibial plateau and relative to the position of the corresponding midpoint between the two posterior aspects of the femoral condyles [48, 49]. Rijke et al. used this system and characterized a mechanical anterior drawer of 0 to 5mm to be normal and a drawer of 7 mm to represent abnormal ACL function [91]. Jung et al. compared different radiographic techniques and found that simple kneeling and Telos are comparable but kneeling indicates a greater rotational error than the Telos device. Thus it seems to be a reliable alternative for quantifying only posterior tibial displacement in a simpler and faster way [53, 81, 89].

2.6.2. Mechanical Devices

In general measurement devices have been developed to provide objective measurements of sagittal motions in respect to the slide of the tibia to the femur. This motion, clinically labelled as the drawer sign, occurs when an examiner or a device applies force to the lower limb or when the quadriceps muscle is contracted in knee flexion. Both the KT1000 and KT2000 (MEDmetric® Corporation, San Diego, USA) have been widely accepted and provide reliable measurements of anterior-posterior translation. Thus, an objective measurement system for this aspect of ACL related instability is generally available. The aspect of the "giving-way- symptom" which is clinically tested by the Pivot-Shift-Test cannot be examined by such a device. To our knowledge there is no device available on the market which can objectively measure the rotational instability of the knee joint and has found its way into clinical practice yet.

The Vermont Knee Laxity Device (VKLD) (University of Vermont, Burlington) was developed to evaluate AP displacement of the tibia relative to the femur during non weight bearing, weight bearing, and the transition between these two conditions. The device consists of a reclined seat in which the subject is in a supine position. Each foot is supported by a binding that can either slide freely along horizontal rails allowing unrestricted flexion at the knee's level and a constant reaction force at the level of the foot, or can be locked in place to support the subject's knee at a desired flexion angle. With locked foot cradle, AP shear loads can be applied to the non weight bearing knee. The weight bearing condition is created by unlocking both feet cradles, allowing them to slide freely along the rails, and applying a compressive force to the foot through two weight stacks, each equal to 40% of the subject's body weight. Sixdegree-of-freedom force sensors measure the reaction forces at each foot. Two pivots are located lateral to each leg, one fixed to the seat and aligned with the hip axis of rotation and the other fixed to the foot binding aligned with the ankle axis of dorso plantar flexion. Each pivot supports a swing arm assembly through which AP loads are applied to the mid portions of the thigh and shank. A recent study by Shultz et al. showed that the VKLD provided reliable measures of both varus-valgus and internalexternal rotation knee laxities with sufficient measurement precision to yield clinically relevant differences [99, 100]. Systematic differences were found between examiners. Thus, the VKLD was demonstrated to obtain repeatable and reliable measurements of anterior to posterior translation. The principle advantage of the VKLD is its ability to evaluate laxity under weight bearing conditions. This is not possible using the KT-1000 or stress radiography techniques [99].

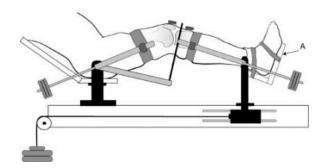


Figure 16: The Vermount Knee Laxity Device, the weight produces the weight bearing situation to the tibia, the weight of the hinge accounts for the weight of the thigh. The Tigh can be rotated against the tibia [99].

The KT-1000 and KT-2000 Knee Ligament Arthrometer (MEDmetric® Corporation, San Diego, USA) has been established as the most commonly used and frequently studied knee ligament testing device. Over the last years, it has retained its original design and provides objective measurements of the sagittal plane motions of the tibia relative to the femur, thereby providing information useful for the clinical assessment of ACL and PCL integrity. The KT-2000 Knee Ligament Arthrometer (KT-2000; MEDmetric Corp) uses the same components as the KT-1000 with the added feature of graphic documentation via an X-Y plotter display. This plotter produces data regarding the amount of tibial displacement relative to the magnitude of applied force. In 1985 the first study based on the KT-1000 emerged[22]. 10 subjects were tested in the supine position, with both lower limbs supported in a position of flexion ($30^{\circ} \pm 5^{\circ}$) and limb rotation (15°-25° of external rotation). The device was then placed on the anterior aspect of the leg and secured with tape plaster straps. The instrument detects the relative antero posterior motion between two freely movable sensor pads; one at the patella and the other in contact with the tuberosity of the tibia. Displacement loads are applied via a force-sensing handle. The millimetres of displacement are then measured and displayed by a dial on the device [22, 89]. A wide variety of studies have been performed since

the introduction of the device only to testify the accuracy and reliability of the KT-1000 and to compare the technique to other methods [7, 12, 42, 45, 55, 112]. In the examination of Bach et al. [10] the knee laxity of acute and chronic ACL tears, as well as control subjects were tested showing that the clinical diagnosis correlated highly with their results for all of the tests. The test was shown to be the strongest discriminator for differentiating normal from abnormal knees, with a sensitivity of 92% and a specificity of 95%.



Figure 17: The KT 1000 Device to measure the femoro tibial translation. The punch with the handle applies force against the tibia, on a scale the examiner can read the translation in mm.

3. Material and method

3.1. Testing Setup

For the validation process six fresh human total lower limb specimens were enrolled.

Before the clinical testing the knees were prepared via passive maximum flexion and maximum extension movements repeated 10 times in a row to primarily break the rigor mortis. Solid conditions between the limb and the device were achieved using Schanz screws (4.5 mm, Synthes, Solothurn, Switzerland) to attach the tibia and femur, each at two points to its corresponding frame of the device. After the attachment the free joint flexion and extension was assessed again and the joint line was adjusted to the hinge between the thigh and tibial holder. The stress lever was positioned in 0° degree rotation. A calibration of the device was processed before each measurement cycle. Each measurement started with internal rotation, followed by external rotation. The fractions' deflection endpoint was accomplished after approximately 180 measuring points for each deflection side. The measurements were subdivided into four force patterns as follows: (1) loaded internal rotation, (2) unloaded internal rotation, (3) loaded external rotation and (4) unloaded external rotation. Measurements of the intact knee were repeated in 0°, 30° and 90° flexion. Thereafter the ACL was resected through standard antero lateral and antero medial arthroscopic portals using an arthroscopic basket forceps (WideBiter Punch Tip, Arthrex, Naples, USA) shaving instrument (Full Radius Resector, Arthrex, Naples, USA). Again the measurement protocol was repeated as before. Figure 18 depicts the main steps of the experimental protocol. All measured values were formatted and saved in Excel files (Office, Excel, Microsoft, USA).

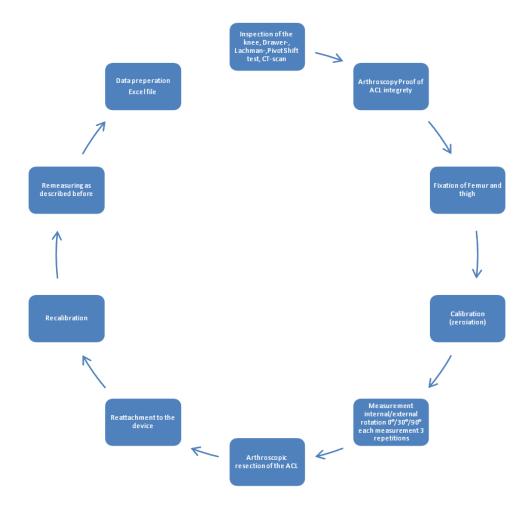


Figure 18: The rectangular boxes are representing the visible results of the single steps. The arrows are the defined processing steps, the data processing was automatized using Visual Basic Macros (Excel, Microsoft).

3.2. Biomechanical Testing

This stage was the evaluation in the cadaver setting; these results are the main subject of this study. The literature reveals several biomechanical approaches and varying concepts. The most realistic concepts use splints or binding based approaches to connect the device to the specimen. Therefore all of these approaches suffer from soft tissue artefacts and inaccurate measurements. Because of that the decision was made to develop a device with a basic frame and additional modular attaching frames embedded into the main frame. Once the shank and thigh are attached to the device the

rotational axis of the tibia in respect to the thigh should be stable and allow only deflection movements without anterior- to- posterior or lateral motion. To maintain this situation, the thigh and shank were fixed using bicortical Schanz screws (4.5 mm Schanz screw, Synthes, Soluthurn, Switzerland). The other leading features were primarily the concept of high warp resistance and secondly the idea of keeping the way open to further developments for example the possibility of connecting splints to the device for later in-vivo studies.

The device was evaluated and a descriptive analysis between the rotational restraints in

- human knee joints with intact ACL and
- human knee joints without ACL

was performed.

The measurements were performed in different flexion angles to detect changes in the resistance pattern in

- 0° Internal / External Rotation
- 30° Internal / External Rotation
- 90° Internal / External Rotation

Each measurement was repeated three times to achieve reproducible results and to minimize the bias. After approximately 180 measuring points the deflection direction was changed so that at the end of each measurement a closed loop of values was recorded. The range of deflection was limited to 45° degrees either internal or external deflection but turned out to be unnecessary. The recorded values produced a close loop in the graphical display.

3.3. Inclusion criteria

For this validation study we included six total lower limb specimens of six cadavers. Inclusion criteria were intact skin, full passive range of motion, intact collateral ligaments, negative Lachman[88] and Pivot- Shift- Tests[88]. In addition a CT scan of each knee was performed to select non-malformation knees for the setup.

3.4. Exclusion criteria

Exclusion criteria were previous knee surgery in the history, scares on the knee, macroscopic haematoma, anatomical deformities, positive Lachman and Pivot Shift Test and insufficient collateral ligaments as well as osseous changes in the CT scan.

3.5. Arrangement

According to the arrangement used in the surgical theatre the setup was adapted to the situation in the lab. The arthroscopic workstation consists of a water- pump (Wave III, Arthrex, Naples, USA), Shaverdrive (APS II, Arthrex, Naples USA), Monitor (Sony Color Video Monitor, Sony, Tokyo, Japan), HF (Orthopaedic Procedure Electrosurgical System, Arthrex, Naples, USA) Light source (300W VISERA, CLV-S40, Olympus, Tokyo, Japan) were always placed on the ipsilateral side of the specimen. The specimen itself was placed in a supine position. The cadaver was covered with surgical coverage.

3.6. Construction

The developed instrument consists of five main parts (Figure 19 & 20).

f) Femoral holder

- c) Frame with ball bearing and suspension of the
- b) Tibial holder
- a) Stress lever
- j) Electronic components with sensor and strain gauge

The thigh holding bracket frame is connected via linear bearing to the frame of the device and can be adjusted vertically by a hinge so that varying flexion angles can be achieved after the knees joint line is adjusted to the hinge's pivot between the femoral and tibial unit. The tibial holding unit is attached to the main frame of the instrument through the ball bearing suspension allowing for rotation movement and sensor conduction of the rotation. The rotational force is introduced to the instrument through a stress lever which is attached rectangular onto the tibial holding unit. At each side of the stress lever strain gauges are attached conducting the applied forces to expand the strain gauges. The rotation radius is limited to 45° degrees for internal and external rotation caused by the construction of the device's frame. The tibia and the femur are attached by to two point Schanz screw fixation (4.5 mm, Synthes, Soluthurn, Switzerland). Ordinary Jaw chucks (Synthes, Soluthurn, Switzerland) are used for the fixation to the device. According to the mechanical properties and demands, the development and assembly of the Torsiometer was completed as a modular system. To compensate resistance against torsion the completion of the Torsiometer has been made of aluminium parts.



Figure 19: Torsiometer from above and from side with explanation. a) delfection lever, b)tibial unit, c) main frame, d)upper tibial Schanz screw holder, e) stilts, f) femoral unit, g) femoral Schanz screw fixature, h) Saw bone, i) fenoral-tibial hinge, j) potentiometer holder.



Figure 20: The assembled device with a) lever, b) tibial unit, c) main frame, d) proximal tibial holder, e) stilts, f) femoral holder, g) femoral pins, h) saw bone of the femur, i) hinge between the tigh and tibial holder, j) ball bearing and potentiometer.

Parts which are set under high stress were built of stainless steel. The frame is the most stable construction due to its function as the suspension holder of the femoral and tibial unit, always able to keep the tibial fixing component as well as the thigh fixing component in a linear relation so that the correlation between the two axes is given. The constructions loading capacity was designed to bear forces up to 100 Nm, transferred into the testing environment forces near 28 Nm were adequate. For the conduction of the rotation movements and angular deflection a precision potentiometer (MEGATRON)

MPA20, Megatron Munich, Germany) was used. Applied forces were conducted through two strain gauges (1-DY-13-3/350, HBM, Darmstadt, Germany) attached to each side of the stress lever. The deflection measurement results from the applied force to the lever and the appropriate expansion of the strain gauges. The strain gauges are connected via a Wheatstons bridge and loaded with a basic potential representing the unstressed situation, forces applied produces different potentials and allow the counting of the torsion moment in Nm.

The general concept was to design a measuring tool for the objective assessment of rotational stability with an implementation of improved approaches described in the literature and to evaluate the tool in a cadaver setting. To achieve a reliable progress, a two- stage approach was chosen. In the first stage the modification and completion of the device was processed to clarify the feasibility of the measurement device. Also the appropriate computer based software for analysing purposes was developed. Furthermore, our approach was to improve the Torsiometer already designed and constructed by the Department of Ergonomics at Technical University Munich in 2005. The last model of the Torsiometer was constructed by Martin Brenner who had worked on the subject as a semester work and finished the Torsiometer as a splint version. To find measurements to be used in normal adolescent dimensions the construction was built in accordance with the European Standard EN ISO 7250 which describes the basic human body measurements for technological design and constructions. All components were scaled to fit the 5. to 95. percentile of man and woman. For the evaluation on cadavers some modifications have been made. The use of splints as designated for the clinical setup were changed into a version where the thigh and the tibia were kept in position via two point fixation through bicortical

Schanz screws (4.5 mm Schanz screw, Synthes, Soluthurn, Switzerland). By using this way, the true rotation of the tibia in relation to the thigh was measurable and soft tissue artefacts as described in the literature have been excluded. The rotational resistance per angular degree (°) was measured as physical work (Nm) using strain gauges and the angle of rotation was measured using a potentiometer.

3.7. Specimen preparation

Intact, fresh, whole human cadavers with complete head, trunk and extremities were used for the setup. Before the surgical intervention the cadaver was passively moved in the knee and hip joint to break the rigor mortis. To reach a sufficient range of motion, the chosen leg was flexed and extended as long as it was nessesary to allow full flexion and extension. Afterwards the clinical examination was performed. After inspection and clinical examination the specimens were prepared on the operating table and the measurements performed in a supine position. The cadaver limb was prepared using a single leg fenestrated sheet. The specimens were positioned on the table and by using K-wires the two positions for the femoral Schanz screws were explorated through 0.5 cm incisions. After inserting the two Schanz screws the femoral frame of the device was fixed to the screws and the tibial insertion sites were utilised. Two Schanz screws (4.5mm, Synthes, Solothurn, Switzerland) were inserted, the proximal screw 10 cm distal to the joint line, the distal screw 5 cm proximal to the sub-talar joint line. The Tibia was fixed to the device in 0° rotation and the screws attached to the solid parts of the device. The femoral holder was connected to the frame and the tibial part after adjusting the hinge of the device to the joint line. After the fixation the calibration of the device was processed, the angles` zero-point is defined and possible restraints zeroized.

From this point of 0° rotation and 0° Nm loading the measurements were processed. The measurement recording and utilisation were carried out using the Labview software (Labview 8.0, National instruments 2005). For each specimen three full excursions of internal and external rotation were recorded and after compilation saved in an Excel (Office Excel, Microsoft 2003) file.

3.8. Pin Fixation

It is important that the skin incisions are sited to allow safe and correct pin placement. For this reason, the place of insertion was premarked with a pen. The skin incision was (1.5 cm) over the mid shaft and for the second femoral pin approximately 10 cm proximal to the knee joint gap on the femoral and 5 cm proximal to the upper ankle joint line as well as in the mid third of the tibia. Blunt dissection of the soft tissue, mainly the M. Quadriceps and the M. tibialis anterior on the shin was used until the cortex was reached. The Schanz screw (Synthes, Soluthurn, Switzerland) was set in a power driver and, using a protecting sleeve, the pin was gently drilled to the far cortex. The pins itself were clamped into jaw chucks (Synthes, Synthes, Soluthurn, Switzerland) which were connected to the femoral and tibial frame of the Torsiometer.



Figure 21: Schanz screws with Standard trocar tip (a) and (b) Self-drilling tip (Seldrill).

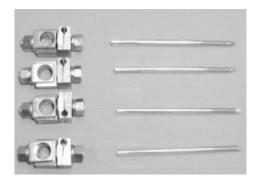


Figure 22: Jaw chucks and Schanz screws, the jaw chucks were used to attach the pins to the device.

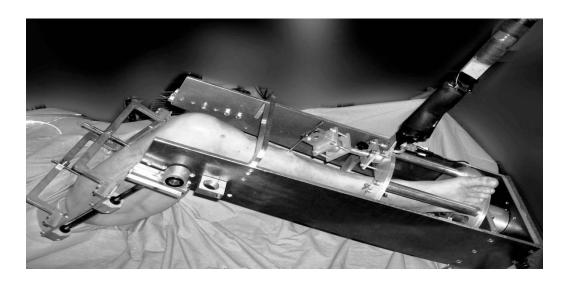


Figure 23: Shows the Torsiometer connected to the lower limb of a cadaver and the knee flexed to 90°

3.9. Calibration

The Torsiometer is equipped with different sensors for the measurement of the moment applied and the deflection angle reached. The sensors are producing no direct values, but instead the electric potentials of the sensors have to be adapted and computerized so that further statistical procedures and graphical analysis are possible. To achieve exact moments (Nm) four strain gauges, two on each side of the hand lever were attached. The applied basic potential suits the strain of the material. The calibration of the strain gauges has been carried out using weights on the lever at defined distances. The lever

was clamped to a bench in a horizontal direction. The ground potential was applied and assigned to be the zero potential. Weights from 0.1 kg to 5 kg were applied to the middle of the lever (this is the defined area for the later manual). The potentials were recorded and the arithmetic media for the documented 300 values was counted. This procedure was repeated for both sides of the lever. The measurements produced a linear correlation for all of the applied weights. To calculate the moment in Nm the measured potential was multiplied with the counted factor $K = \frac{Nm}{V}$. The factor was derived from the inversed linear regression line, $K = 8.40 \, \frac{Nm}{V}$.

3.10. Software Development

Each measurement produced approximately 1500 (including 3 measures per condition) pairs of values consisting of an angle with its corresponding force. The potentiometer and the strain gauges produced no direct values; instead the changes in the electric potentials of the sensors were read and computed into Microsoft Excel files (Microsoft Office Excel 2003). To handle this amount of values Microsoft Excel Macros (Microsoft Office Excel 2003) had been written in Visual Basic (Microsoft Office Excel 2003) to ease the calculation and graphical analysis. After collecting the values the decision was made that the ascending and descending values can be displayed and analysed in relation to their inclination, their maximum values and force patterns.

Macros had been written to ease the handling

- Creating a chart with defined legends
- Cleaning Macro to erase repetitions and outliers

- Diagram plotter
- Inclination Macro

3.11. Data processing

Analysing the movements a physiological linear joint-tension was recognized over a long angular area followed by a progressive ascent in the graphical demonstration. For the analysis of the ascent and descent two areas were defined. The excursion between 3° to 13° and between 3° to 25° were taken and graphically splitted into four parts. Every 32 milliseconds one pair of values was recorded. After150 measuring points (MP) a diversion of at least 11° up to 15° was counted. This diversity prohibits an averaging related to time which would lead to a comparison of values with the greatest difference. Too different values would be compared. A graphic analysis was undertaken to develop the most reliable technique. Starting with the forced phase of internal rotation, followed by the deforced reverse internal phase, forced external rotation and deforced reversed external rotation. These parts could be easily compared with the graphs resulting from other trials.

3.12. Limitations

Major and minor difficulties have been tackled into the described setting. Major difficulties can be seen in the application of the Schanz screws on the femoral and tibial side. Varying bone diameters and cortical thickness led to the proceeding of primary drilling using K- wires and posterior application of the Schanz screws. Differing thickness of soft tissue hindered the predrilling but was manageable in every specimen.

Minor difficulties can be seen in the loss of water dripping out of the arthroscopic portals contaminating the device and sensors. The use of water soaking rags was useful and facilitated the work.

3.13. Statistics, Reliability and Reproducibility

The single measure Intra Class Correlation Coefficient (ICCC) was used to evaluate the interobserver reliability. Statistical significance for torques expected for the maximum averaged rotation between different ACL conditions was determined using Wilcoxon-Test. To compare the different ACL conditions we additionally calculated the area under the curve for internal and external knee joint rotation using trapezoidal rule to map the whole course of the rotation. All statistical analyses were done using a 0.05 level of significance. Data are given as mean ± standard deviation. PASW 17.0 software package (SPSS® Inc., Chicago, USA) and R 2.9.2 (R Foundation for Statistical Computing, Vienna, Austria) were used for statistical analysis. For the analysis of maximum internal and maximum external rotation the non-parametric Friedman-Test was performed.

Each measurement arranged showed exact values, in all situations the values were varying only in numbers behind the decimal point. To avoid variations of measuring points the deflection's direction was changed after 180 measuring points. The measured points created a looped curve, as seen in Figure 24, the curves were nearly similar to each other. The evaluation of the three repeated measures of each subject showed high inter-tester ICCs. The ICC for the maximum deflection angles for ACL intact and absent were between 0.87 and 0.97 for the internal rotation and between 0.94 and 0.98 for the external rotation.

4. Results

4.1. Graphic display

The values were transformed into a graphical diagram representing the forced internal, deforced internal, forced external and deforced external characteristics of the measurements. It is obvious that not every diagram started at point zero. This represents the individual characteristic of each knee. Each measurement was zeroized which means that after fixation, each knee had the possibility to find its position of lowest forces and restraints in an unloaded condition. This was done before the measurement, so that the aberration of point zero can be explained by small existing tensions unique for each knee.

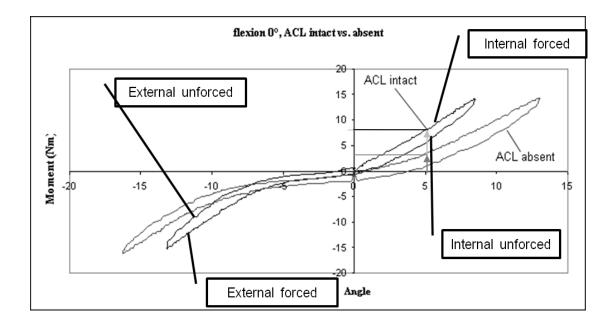


Figure 24: The graph shows the distinct change of the measurement under 0° knee flexion. The dark curve represents the intact condition the lighter curve the absent condition. An increase of the deflection angle and Nm is eminent.

ligamentious deficiency can be represented in characteristic changes of the curve emerging from the values. Exemplarily this is shown in Figure 24. In an ACL intact situation the example shows that at 5 Nm forced internal rotation the deflection reaches an angle of 3° (light grey arrow) whereas in the absent situation the 5 Nm probe reaches an approximate deflection of 8°. This can be shown in a slower onset of the inclination. Using the formula $\frac{y_1 - y_2}{y_1 - y_2} = m$ the inclination is very characteristic for the change and represents the loss of stability. (0-8)/(0-5) = 1,6 for the intact version and (0-4)/(0-5) =0,8 for the absent version in this example the loss of the ACL halved the stability represented in the inclination. The other characteristic is the growth of deflection under the situation of ACL absence. Comparing the maximum deflection in these changes was obvious. Due to the function of the ACL in limiting the internal rotation this pattern was read and interpreted. In this example the maximum internal deflection is about 14° in the situation of ACL integrity and growing about 1° in the absent situation. This change becomes much more obvious for the deflection pattern of external rotation when the intact situation bears -15 degree and the absent +16.5°.

The measurements and related diagrams show that the loss of stability in the meaning of

4.2. Total internal and external rotation

The inter-individual difference of femoro-tibial rotation was high. In 0° flexion the angle for the intact ACL accounted for $10.3^{\circ}\pm 1.8^{\circ}$ internal and $12.3^{\circ}\pm 1.8^{\circ}$ external rotation. In contrast the assessment of the absent ACL revealed an internal rotation of $17.1^{\circ}\pm 2.0^{\circ}$ and an external rotation of $17.9^{\circ}\pm 1.83^{\circ}$. In 30° flexion analysis of the intact ACL yielded a maximum internal rotation of $12.2^{\circ}\pm 5^{\circ}$ and external rotation of $12.6^{\circ}\pm$

 2° . Again values increased following the excision of the ACL (rotational angle: internal $19.1^{\circ}\pm~7.7^{\circ}$, external $17.4^{\circ}\pm~1.8^{\circ}$. In 90° flexion the rotation of the intact ACL accounted for $11.2^{\circ}\pm~1.8^{\circ}$ in internal rotation and for $9.4^{\circ}\pm~1.5^{\circ}$ in external rotation. Values of the absent ACL increased to $23.8^{\circ}\pm~2.5^{\circ}$ in internal and to $14.5^{\circ}\pm~2.5^{\circ}$ in external rotation. The values are average values from Table 1.

Maximum deflection angles ACL intact vs. absent								
	ACL Intact ACL Absent							
Knee	Internal Rotation		External Rotation		Internal	Rotation	External Rotation	
Flexion	Angle [°]	Nm	Angle [°]	Nm	Angle [°]	Nm	Angle [°]	Nm
0°	13.3	12.5	-9.2	-11.4	19.0	18.4	-13.6	-16.7
	13.5	16.1	-11.3	-19.4	23.1	28.3	-17.8	-23.9
	3.9	7.6	-10.0	-14.0	12.0	16.2	-17.9	-18.2
	7.5	12.9	-10.3	-13.6	13.5	20.2	-15.1	-17.4
	15.1	13.8	-19.8	-15.5	21.9	20.6	-26.3	-21.9
	8.4	13.7	-13.1	-14.6	13.0	14.4	-16.7	-15.8
Mean	10.3	12.8	-12.3	-14.8	17.1	19.6	-17.9	-19.0
STEM	1.8	1.2	1.6	1.1	2.0	2.0	1.8	1.3
30°	18.5	13.8	-9.6	-13.1	21.4	17.0	-15.6	-19.1
	13.8	11.8						-23.6
	7.1	6.2						
	8.4	11.3		-16.6	13.0			-22.2
	13.6	11.1			_			
	12.0	12.4	-12.9	-				
Mean	12.2	11.1	-12.6	-13.9	19.1	18.8	-17.4	-19.8
STEM	-5.0	-4.5	2.0	1.1	7.8	7.7	1.8	1.5
90°	18.3	18.5	-8.2		_			
	10.1	17.6	-5.4					-30.1
	6.7	12.9	-10.8					
	8.2	16.8	-6.2		_			
	14.9	10.8	-15.2					-19.9
	9.0	13.8	-10.8					
Mean	11.2	15.1	-9.4	-18.5	18.1	23.8		-23.2
STEM	1.8	1.2	1.5	1.7	2.2	3.0	2.5	2.1

Table 1: Values of maximum internal and external rotation and their corresponding averages

4.3. Combined internal and external rotation

The addition of internal and external rotation produced significant changes under the condition of ACL integrity and absence. The increase was near 10° at all flexion angles as seen in Table 2. The arc of rotation shows clear increase whereas the differences were heterogeneous instead.

Knee	Combined In	nternal And External	Rotation		
	Sum intact IRO+ERO Sum absent IRO+ERC Difference				
0°	22.5	32.6	10.1		
	24.7	40.9	16.2		
	13.9	29.9	16.0		
	17.8	28.6	10.8		
	34.9	48.2	13.3		
	21.5	29.6	8.2		
Mean	22.6	35.0	12.4		
STEM	2.7	2.9	0.3		
30°	28.0	37.0	9.0		
	24.2	41.0	16.8		
	17.8	31.0	13.2		
	18.3	26.1	7.9		
	36.1	47.7	11.6		
	24.9	35.8	10.8		
Mean	24.9	36.4	11.6		
STEM	3.3	4.4	1.1		
90°	26.6	35.2	8.6		
	15.5	29.1	13.6		
	17.6	20.6	3.0		
	14.4	24.3	9.9		
	30.1	48.9	18.9		
	19.8	37.4	17.7		
Mean	20.6	32.6	11.9		
STEM	2.4	4.2	1.8		

Table 2: Values of total internal and external rotation and corresponding differences

4.4. Area Under The Curve

Beside the measured internal rotation under ACL intact and absent conditions and the recording of these values in 30 millisecond steps, we compared the applied torque of the maximum internal rotation (ACL intact) with the torque applied to reach the same amount of internal rotation under the ACL absent situation. The area under the curve has been calculated and compared for both situations (maximum internal rotation with intact ACL and absence ACL) the area is representing the physical work applied (Figure 20, Table 3.).



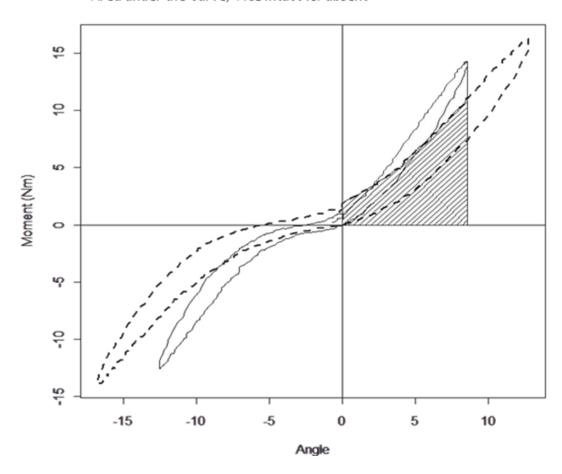


Figure 25: Graph of the Area under the curve, representing the physical work applied. The graph is representing the intact internal rotation as well as the absent (dashed line) situation.

Flexion angle 0° 61.9 59.9 49.7 37.8 95.4 74.2 72.7 37.4 14.7 6.9 13.8 2.8 41.0 32.9 35.1 14.5 92.3 87.4 77.3 58.4 54.6 31.7 43.9 19.8 30° 72.0 74.9 66.2 66.2 60.1 46.3 26.5 19.3 66.2 60.1 46.3 26.5 19.3 66.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2 87.2 83.0 76.1 61.5			Area und	der the curve		
0° 61.9 59.9 49.7 37.8 95.4 74.2 72.7 37.4 14.7 6.9 13.8 2.8 41.0 32.9 35.1 14.5 92.3 87.4 77.3 58.4 54.6 31.7 43.9 19.8 30° 72.0 74.9 56.5 38.3 66.2 60.1 46.3 26.5 19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2	Flexion angle		IRO int. Forced	IRO int. Deforced	IRO abs. forced	IRO abs. deforced
95.4 74.2 72.7 37.4 14.7 6.9 13.8 2.8 41.0 32.9 35.1 14.5 92.3 87.4 77.3 58.4 54.6 31.7 43.9 19.8 30° 72.0 74.9 56.5 38.3 66.2 60.1 46.3 26.5 19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2						
41.0 32.9 35.1 14.5 92.3 87.4 77.3 58.4 54.6 31.7 43.9 19.8 30° 72.0 74.9 56.5 38.3 66.2 60.1 46.3 26.5 19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2						37.4
92.3 87.4 77.3 58.4 54.6 31.7 43.9 19.8 30° 72.0 74.9 56.5 38.3 66.2 60.1 46.3 26.5 19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2			14.7	6.9	13.8	2.8
54.6 31.7 43.9 19.8 30° 72.0 74.9 56.5 38.3 66.2 60.1 46.3 26.5 19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2			41.0	32.9	35.1	14.5
30° 72.0 74.9 56.5 38.3 66.2 60.1 46.3 26.5 19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2			92.3	87.4	77.3	58.4
66.2 60.1 46.3 26.5 19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2			54.6	31.7	43.9	19.8
19.3 6.6 15.9 8.7 42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2	30°		72.0	74.9	56.5	38.3
42.5 49.5 32.0 33.7 67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2			66.2	60.1	46.3	26.5
67.3 49.9 54.0 22.2 65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2			19.3	6.6	15.9	8.7
65.7 31.1 52.2 15.2 90° 155.8 175.5 122.9 122.2			42.5	49.5	32.0	33.7
90° 155.8 175.5 122.9 122.2			67.3	49.9	54.0	22.2
			65.7	31.1	52.2	15.2
87.2 83.0 76.1 61.5	90°		155.8	175.5	122.9	122.2
			87.2	83.0	76.1	61.5
37.4 31.0 28.6 21.4			37.4	31.0	28.6	21.4
67.9 59.9 56.6 24.9			67.9	59.9	56.6	24.9
80.8 62.9 60.2 25.8			80.8	62.9	60.2	25.8
61.6 37.2 55.0 24.0			61.6	37.2	55.0	24.0
Area under the curve on averaged values			Area under the cu	rve on averaged va	lues	
IRO forced int. IRO forced absent IRO unforced int. IRO unforced abs.			IRO forced int.	IRO forced absent	IRO unforced int.	IRO unforced abs.
0° MW 60.0 48.8 48.8 28.4	0°	MW	60.0	48.8	48.8	28.4
STEM 12.6 12.3 9.7 8.2		STEM	12.6	12.3	9.7	8.2
30° MW 55.5 45.3 42.8 24.1	30°	MW	55.5	45.3	42.8	24.1
STEM 8.4 9.7 6.5 4.5		STEM	8.4	9.7	6.5	4.5
90° MW 81.8 74.9 66.6 46.6	90°	MW				
STEM 16.4 21.5 12.9 16.3		STEM	16.4	21.5	12.9	16.3

Table 3: Measured areas und each deflection curve of each specimen

4.5. Force

The force applied varied in high dimensions, caused by the individual difference and the restraints of the ligaments, as seen in Table 2. Differences in the force pattern were very inconsistent for the measured flexion angles. No consistent graph could be extracted from the recorded data. However, differences were only statistically significant for internal rotation. Comparing the forces expended for the maximum averaged internal rotation in the intact condition with the ACL absent condition, the force decreased from intact 16.3 ± 3.4 to 15.1 ± 2.4 Nm to the absent situation at 0° knee flexion. In 30° knee

flexion loads were $20.8^{\circ} \pm 1.8^{\circ}$ Nm for averaged maximum internal rotation, decreasing to 11.8 ± 2.0 Nm in the absent condition. In 90° knee flexion the absence of the ACL decreased the forces for the averaged internal rotation from 19.5 ± 2.6 Nm to 15.1 ± 1.9 Nm.

Maximum internal rotation with							
corresponding Moments							
Specimen	Flexion	Angle [°]	Nm intact	Nm absent			
1	0°	13.3	12.5	10.1			
H		13.5	16.1	11.9			
Ш		3.9	7.6	4.0			
IV		7.5	12.9	10.0			
V		15.1	13.8	12.6			
VI		8.4	13.7	8.8			
1	30°	18.5	13.8	13.3			
П		13.8	11.8	9.8			
Ш		7.1	6.2	3.7			
IV		8.4	11.3	12.3			
V		13.6	11.1	3.9			
VI		12.0	12.4	9.0			
1	90°	18.3	18.5	21.3			
H		10.1	17.6	14.2			
Ш		6.7	12.9	6.7			
IV		8.2	16.8	14.7			
V		14.9	10.8	6.1			
VI		9.0	13.8	7.8			
Averraged values of maximum internal							
rotation and corresponding Moments							
	Flexion	IRO [°]	Nm	Nm			
MEAN	0°	10.3	12.8	9.6			
STEM		1.8	1.2	1.2			
MEAN	30°	12.2	11.1	8.7			
STEM		1.7	1.1	1.7			
MEAN	90°	11.2	15.1	11.8			
STEM		1.8	1.2	2.4			

Table 4: Loading of the deflection layer in Nm of internal rotation for the condition of ACL integrity and absence. Values were averaged from Table 1

4.6. Growth of deflection

In the ACL intact situation the arc of internal rotation decreased from 0° (10.4°) to 30° (10.2°) and increased to 90° (11.6°) knee flexion. Again the external rotation decreased from 0° (14.3) to 30° (13.5°) and increased to 90° (14.7°). For the absent condition the picture changed, starting with an increase during 0° knee flexion and maximum internal rotation of 16.3° a higher internal deflection of 20.8° was measured. At 90° knee flexion the range of deflection nearly persisted at 19.5° internal rotation. The external rotation was consistent with lowering deflections coming from 17.1° at 0° knee flexion to 15.1° at 30° and 15.1 at 90° knee flexion.

Flexion	[°] IRO intac[°] IRO abs. Difference [°]						
0°	10.4	16.3	5.9				
30°	10.2	20.8	10.6				
90°	11.6	19.5	7.9				
Flexion	[°] ERO inta[°] E	RO abs. Diff	erence [°]				
0°	14.3	17.1	2.8				
30° 90°	13.5	15.1	1.6				
90°	14.7	15.1	0.5				

Table 5: Countable changes according to the measured degrees under the situation of ACL integrity and absence

4.7. Graphical analysis of the inclination

In a physical way the ACL generated resistance is comparable to the resistance generated from a torsion spring. Those torsion springs produce a resistance dependent on the material, the elasticity module combined to the applied force.

The force normally is applied tangentially to the spring's axis and can be displayed as an inclination in Moment (Nm) in relation to the deflection angle. The resistance of the knee joint is a visco elastic tension with different phases as seen in Figure 27. For the measurements it is useful to read the deflection between characteristic inclination areas in both (internal and external) directions. Measuring points near the beginning or near the end have not been used for the inclination to stay away from falsification of the results. The curve of internal and external rotation was subdivided into four parts each part representing either the forced internal [1]/external [3] or deforced internal [2]/external [4] deflection. The torque always increases depending on the angle of deflection. Even during the deforced deflection force is required to hinder the leg flipping back into the untorqued position. As it is seen in Figure 24, the sample curve is not accurately parallel between forced and deforced deflection. It seems that also the speed of forced flections or deforced flections contributes to the measurement; technically this factor is the so called Hysteresis Effect. During the measurement of internal/external rotation the diagram shows the distribution of the needed forces.

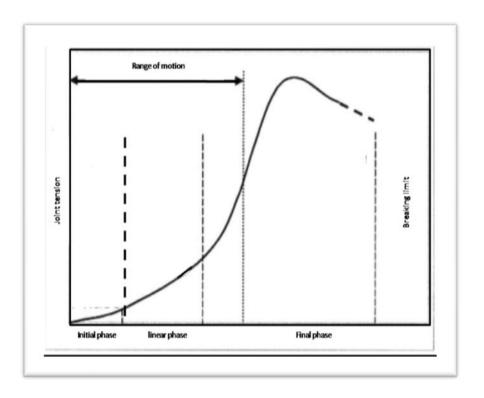


Figure 26: Visualisation of the visco elastic joint tension deformation course. During the deflection there is a long range deflection pattern. At the beginning and at the end there is a progressive inclination

4.8. Descriptive analysis

As shown in the graphical demonstration the whole measuring procedure with the four deflection fractions includes forced internal rotation, unforced internal rotation, forced external rotation and unforced external rotation. The described curve is representing the values measured in Angle [°] and Nm [Figure 24]. Analysing the graphs, the curve can be divided into four main patterns. Each curve can be analysed regarding forces, deflection and the expansion for angle [°] and Nm (Newton meter) respectively (Figure 24). For example a full series of looped curves have been chosen to display the obvious changes. The changes are distinctive not only the range of internal or external rotation increases between the intact and absent condition, also the moment shows distinct changes.

0° knee flexion, ACL intakt vs. absent

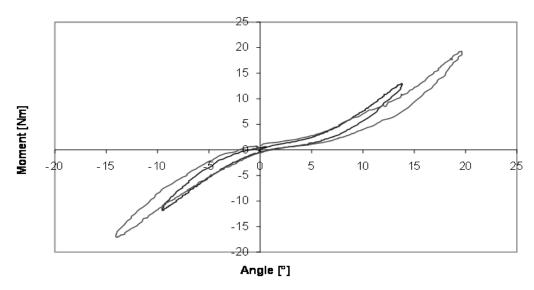


Figure 27: Graphical display as example of Cadaver I. Confrontation of intact versus absent condition. The curve has been led once upon the other. Distinct changes in expansion and force according to the intact and the absent condition at 0° knee flexion.

30° knee flexion, ACL intact vs. absent

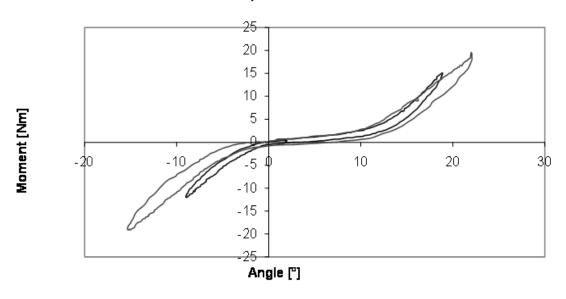


Figure 28: Graphical display as example of Cadaver I. Confrontation of intact versus absent condition. The curve has been led once upon the other. Distinct changes in expansion and force according to the intact and the absent condition at 30° knee flexion.

90° knee flexion, ACL intact vs. absent

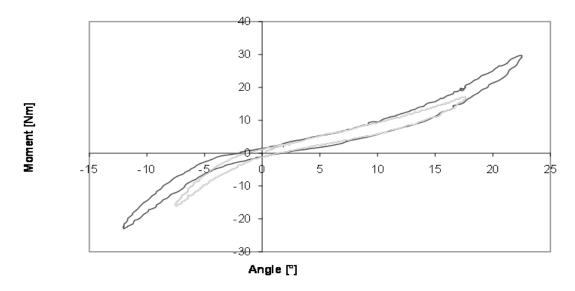


Figure 29: Graphical display. Confrontation of intact versus absent condition. Distinct changes in expansion and force, related to the condition of integrity and absence at 30° and 90° knee flexion. The darker loop represents the intact situation, the lighter curve the absent version.

5. Discussion

5.1. Comparative discussion

The main objective of this study is the evaluation of the developed measuring device. The analysis included objective measurement of rotation stability at varying knee flexion angles and its feasibility. In this cadaver setting six specimen lower limbs builded the basis for the dynamic acquisition, recording and analysis of knee restraints concerning internal and external forced and passive rotation. The general distinct interest in rotational stability versus instability of the knee can be recognized in the numerous publications and experts discussions focusing on the state of the art ACL reconstruction as well as experiments explaining pathological knee kinematics after ACL rupture. Since the reconstruction of rotational stability in ACL deficient knees has become a major issue for orthopaedic surgeons, several attempts have been made to measure tibial rotation in the condition of pathologic (ACL absence) and physiologic (ACL intact) knee kinematics.

To the best of our knowledge no adequate device and method has been established and no dynamic measurement system has been described and processed so far in the literature for this kind of measurement. In this study a new way has been chosen to gain information about restraint patterns. This study showed that the loss of the ACL always increases rotational instability, expressed in the growth of overall deflection and corresponding torques. Furthermore, torques needed to reach the maximum deflection for the ACL intact condition were always higher than needed for the ACL absent condition. The values emerged from this study were all exact and reliable, even smallest

changes of deflection and torques were detectable, so the device appeared to be sufficient. Due to the measurements every angle degree of either internal or external deflection showes its dependant value of expeded torque. Every flexion angle of the knee produces a distinct restraint pattern due to the specimen's anatomical specification. All this can be seen for each condition in the comparison of the graphical display of deflection curves.

The leadoff concentrated on the modification and adaption of a formerly assembled splint version, non-invasive device to the needs of an invasive cadaver setup. To withdraw from approaches mentioned in the literature of the last 50 years, those approaches can be divided into two main analysis branches. Biomechanical testing devices [26, 32, 60, 65, 77, 109, 119] tested at cadaver knees on the one hand and on the other hand optoelectronic or electromagnetic approaches [3, 37, 56, 60, 82] tested in vivo or on cadaver specimen. The second methodology branch is mainly affected by soft tissue artefacts and results in extreme inaccurate measures of rotation. Thus these studies are interesting for inspiration but have not been taken in account for this setup. In contrast the first methodology branch in terms of biomechanical testing has to be subdivided into cadaver studies after muscle and soft tissue removal [32, 60, 65, 77, 82] and studies with an in-vivo setup[3, 119] using casts, splints or bindings as fixation method to the measurement device, whereas also these studies suffer from soft tissue artefacts and disproportional results so that a transfer to clinical utilisation has not been realised. The approach of this study is based on the device described before and is also the basis for an already submitted scientific article. Because complete lower limbs were used the bone fixation was guaranteed using a two point bicortical fixation method for the thigh as well as for the tibia. To avoid the difficulties of soft tissue disturbances, a

static two point bicortical, tibial and femoral fixation has been arranged to allow for rotation in the longitudinal axes of the joint line. Due to our different approach the findings of this study may be partially compared with results of selected studies of the literature, underlining the usefulness and technical realisation of the use of our device. Fukubayashi [32] applied passive force in anterior posterior direction to the tibia of nine cadaver knees, with a resulting internal rotation between 30° and 45° with intact ACL (approx. 9°) knee flexion and maximum external rotation (approx. 12°) of 75° flexion applying 100 Nm. After resection of the ACL internal rotation was absent. In the study of Almquist et al. [3] an external device was used and compared with the results of a roentgen stereo metric measurement system based on implanted tantalum markers. The aim of their study was to analyse the complex rotational behaviour of the knee joint. The setting with the device showed internal rotations in 90° knee flexion of 11±4° with an applied force of 3 Nm and 30±9° using 9 Nm. At 60° knee flexion the applied 3 Nm lead to internal rotation of $11 \pm 5^{\circ}$, the applied 9 Nm to $31 \pm 3^{\circ}$. External rotation at 90° knee flexion under loads of 3 Nm was 18±6° increasing to 36±7° with 9 Nm loading. Under 60° flexion the corresponding deflection was $16\pm6^{\circ}$ for 3 Nm and $34\pm5^{\circ}$ for 9 Nm loading. All measurements were examined under ACL intact conditions and the roentgen stereo metric measurements under ACL reconstructed conditions respectively. Further measurements with lower flexion angles were unfortunately not available. The roentgen stereo metric comparison showed significantly lower deflection angles (90° ranged from 6±3° at 3 Nm, to 13±5° at 9 Nm and the corresponding figures at 60° were 6±5° and 13±4°). Another interesting study quantifying internal and external rotation in vivo of 17 healthy subjects without knee instability compared to 19 subjects with history of ACL tears was performed by Zarin et al.[119] in the seventies. Rotation

motion of the tibia in relation to the femur was measured using a position potentiometer mounted on the input shaft of a Cybex II isokinetic dynamometer (Lumex, Bay Shore, NY). The knee was positioned at angles of 90°, 60°, 30°, 15°, and 5°flexion. Full extension of the knee was recorded at 0°. In each position, passive internal and external rotation was measured. Three separate measurements of internal and external rotation were performed. The authors found no significant difference between the right and left knees in the range of passive rotation. No significant change in the arc of rotational motion was found at 30°, 60° or 90° of knee flexion. As the knee was extended from 15° to 5° of flexion, rotator motion decreased. At 15° of flexion, the knee had 47° external rotation and 16° internal rotation, a total range of 63° rotation in uninjured knees. At 30°, 60°, and 90° of flexion, the range of rotation of the unstable knee was similar to the patient's intact knee and to other intact knees tested. At 15° of flexion, the knee with a torn ACL had a slightly greater arc of internal and therefore total rotation. At 5° of flexion, the knee with a torn ACL had a significantly greater external and internal rotation compared to the normal knee as well as the control knees. These study results are different from many other studies and the main disadvantages were the limitations of performing the measurements lying in a lateral position with possible undetected motion of the hip effecting the measurements. It is also conceivable that motions of the foot and ankle were not totally eliminated. Newer approaches use robotic controlled devices applying predefined motions and forces. Markolf et al. [65] compared 14 cadaver knees for ligament restraints and tibial rotation with and without loads under passive flexion and extension in the condition of ACL integrity, absence and Single versus Double Bundle reconstruction. Applied internal torques under ACL absent condition, significantly increased internal rotation with mean increases of $7.3^{\circ} \pm$

3.4° at 0° of flexion and $4.0^{\circ} \pm 2.8^{\circ}$ at 30° of flexion 90° flexion produced deviations of approximately $+3^{\circ}$ for the absent condition measurement of external rotations have not been mentioned. The latest experimental setup of Lorbach [60] compared a device for rotational measurements in 30° knee flexion with a knee navigation system. This approach used knees of 20 human cadavers peeled off the whole muscle and soft tissue, leaving only the intact capsule and bones for the examination. Optical tracers were bicortically fixed to the bone in order to measure tibial rotation with a knee navigation system. Internal and external rotation values were measured at an applied torque of 5, 10 and 15 Nm. The "Rotameter" testing device showed high correlations compared with the knee navigation system. Only measurements in 30° knee flexion were completed depending on the achievement chosen, predefined loads as mentioned before were applied. However, 5 Nm achieved internal rotation of 22.1°± 8.0° with the Rotameter, the knee navigation showed $18.9^{\circ} \pm 8.5^{\circ}$. At 10 Nm, $31.7^{\circ} \pm 9.8^{\circ}$ were found with the Rotameter and $24.7^{\circ} \pm 9.4^{\circ}$ with the navigation. At 15 Nm of applied torque, $39.2^{\circ} \pm$ 8.8° was measured with the Rotameter and $27.9^{\circ} \pm 8.4^{\circ}$ with the knee navigation. External rotation at 5 Nm gained $20.3^{\circ} \pm 6.9^{\circ}$ with the Rotameter, the knee navigation showed 17.3° \pm 6.9°. At 10 Nm, 30.9° \pm 9.5° was found for the Rotameter, and 22.5° \pm 8.0° with the navigation respectively. The highest applied torque of 15 Nm measured $41.0^{\circ} \pm 12.1^{\circ}$ with the Rotameter and $26.8^{\circ} \pm 8.8^{\circ}$ with the knee navigation. But both techniques may not be regarded as reliable methods because of deficiencies in the study design as in terms of the single examination position and the missing dynamic measurements.

In the second section the mean aim was the evaluation of the developed device using six knee cadaver specimens for the setup as well as the analysis of the measurements.

Differences in internal and external rotation varied in every flexion angle because of individual restraints, but showed congruent patterns in comparison among each other in the graphical analysis. Internal rotation was measured in 0°, 30° and 90° knee flexion. At 90° of knee flexion the averaged internal rotation was 11.6°±2.1° with a corresponding average force of 19.5 ±2.1 Nm. Almquist et al. [3] reported a maximum of 9 Nm internal rotation of $30^{\circ} \pm 9^{\circ}$. In a roentgen stereo metric analysis the subjects showed, with 9 Nm loading an internal rotation of 13°±5°. In our study the measurements associated with external rotation showed a maximum of averaged 13.1° $\pm 0.9^{\circ}$ and forces of 23 Nm. In comparison, Almquist et al. [3] reached $36^{\circ}\pm7^{\circ}$ with the splint based method, whereas with roentgen stereometric measurement 19°±8° were measured using a loading of 9 Nm. In both comparisons, internal and external rotation measured under the condition of the splint based setup produced much higher ranges of rotation applying much lower forces. In both situations our measurements were much more in the range of roentgen stereometric measurement. Zarin et al. [119] measured the differences in femoro-tibial rotation in ACL intact and ACL deficient knees with a splint based approach and the patient lying in a side way position. At 90° knee flexion the internal rotation reached approximately 25° in the group of ACL intact and approximately 30° in the group of ACL absence. Significance in internal rotation was found for the group of ACL absent knees in 90°, 15° and 5° knee flexion. Exact values have not been published; instead the results have been printed as graphical displays in the literature. Astonishing is the finding and conclusion of the work but is of limited value for the testing setup. The range of rotational motion does not change significantly between 30° and 90° of flexion in normal subjects. Abnormal increase in rotation is not found in patients with antero lateral rotatory instability at these degrees of flexion. Our

finding was a significant increase comparing the full arc of motion under the condition of ACL integrity and ACL absence. The arc showed an increase of 9.9° ±3.5° in 90° knee flexion and an increase in 30° flexion from 10.1°±1.2° and in full extension of 9.1°±2°. Within an overall approximate increase of 10 ° occured. Markolf et al. [65] used a cadaver setup, in which tibia and femur were fixed and attached into a load cell equipped measuring device and torques were applied in 6 flexion angles. Tibial rotations under the condition of ACL integrity and absence were measured. For applied internal torque, removal of the anterior cruciate ligament lead to significantly increased internal rotation with a mean increase of 7.3° at 0° of flexion and 4.0° at 30° of flexion. 90° knee flexion showed approximately 30° internal rotation and under the condition of ACL absence a non significant increase of $+3^{\circ}$ resulted. They concluded that the absence of the ACL significantly increases internal rotation. The setup used is hardly comparable to our model, but gains because of the use of a system, measuring the bony rotations as we did. The increased internal rotation angles over the bandwidth from 0° , 30° knee flexion is equivalent to our findings, only varying in the point of no significant increase at 90° knee flexion. They only measured internal rotation. The individual variability, the values and patterns of increased internal rotation showed a constant decline of growth from 0°-30° to 90° flexion. Compared to our results we found increased values of total rotation (internal + external), internal rotation and external rotation at all flexion angles (Figure 27 -29 & Table 1). The more distinguished look showed that the growth varied. For the ACL eminent condition the increase of internal rotation between 30° and 90° (1.4°) is higher than between 0° and 30° (0.2°) knee flexion, compared to the ACL absent situation between 0° -30° the increase is higher (4.5) as it is between 30° to 90° (1.3°) . Comparing the single pattern of external rotation

the growth is lowering between 0° - 30° (0.8°) and slightly decreasing between 30° and 90°(1.2°) with ACL absence the same characteristic is valid, showing rates between 0°-30° (1.9°) and between 30° and 90° (0°) (Table 5). Ferretti et al. [28] used a navigated approach to measure the changes of knee rotation under the condition of ACL absence, again after implantation the AM bundle, as equivalent for a single bundle reconstruction, and another measurement after a full anatomic reconstruction using the Double bundle technique. They varied the flexion angles from 0°, 15°, 30°, 45°, 60° and 90° finding no significant changes regarding both surgical procedures. However, the internal rotation measured under the condition of ACL absence showed 13.4°; 20.27°; 18.10° the external rotation 12.2°; 18.10°; 15.9° and the overall rotation was about 23.27°; 38.36°; 31.55°(all measurements followed the scheme 0°, 30°, 90° knee flexion). In comparison to our results 14.6°, 18.6°, 18.4° at 0°, 30°, 90° flexion is similar to their values encouraging our method to be further developed. The external rotation is also near to our findings 16.1°;15.9°;12.7° (0°,30°,90°), the comparison of the overall deflection 31.6°; 35.3°;31.1° of our results compared to the measurements of Ferretti et al. [28] showed nearly similar results (22.91°; 33.50°; 28.45°). Overall their findings compared to ours support our theory of exact and reliable measurements. The diversity of publications with their unique approaches shows again, that the measurements are as good as the method and the examiners. The controversial results found in the literature are widely varying, but most publications show an increase of total or at least internal rotation after the loss of the ACL. But never the less also publications showing no significant effect on rotational stability, either in internal or external rotation[57] and with intact or absent ACL are known. The setup used in this study could clearly show that the loss of the ACL always increases rotational instability

and even massively reduces restraint forces against rotation. Also the setup showed that this approach is useful and highly reliable in its reproducibility. The values emerged from this study are all exact and the dynamic measurement of rotational restraints have several advantages compared to the studies in the literature. Due to the measurements every angle degree of either internal or external deflection shows its dependant value of expended force. Using this setup a distinguished examination of rotation patterns can be examined. Inclinations as well as declinations and aera under the curve for the exact analysis of work applied may be analysed for specific stress patterns.

5.2. Drawbacks

A major point of criticism in the described study is the subjective approach during the process. Different efforts have been made to minimise bias and to regulate the time of each deflection, the environment has been standardised for the whole study, which included same room, same instruments and surgical setup condition, same composition of apparatus and arrangement in the room. Also a software based program has been used to eliminate amplitudes. Another point of criticision is the time and efforts wich have to be considered when taking the device into action. The analysis of comparative data is a major part in the described setup. To investigate a specific restraint characteristic, thousands of values have to be prepared and arranged and common used computer programs are insufficient to tackle this data, so further studies will gain using custom made software.

5.3. Relevance

The use of dynamic measurements seems to be a new valuable approach for the investigation assessing knee joint rotation. The advantage for this approach is the possibility of specific examination and analysis related to any disposition as partial loss of restraints under varying flexion angles and anatomical features. The evaluated setup and device may help to compare varying stabilisation procedures for example specific examination and characterisation of the Single Bundle technique using varying femoral and tibial insertion areas as well as measurements of the Double Bundle technique and its account according to rotational restraints, it may also lead to a more sophisticated understanding of certain pathologies such as partial rupture of the ACL.

5.4. Conclusion

Our development had passed the paper and computer based experimental stage to a physical, fully utilised in vitro measurement system with custom made computer programmes for specific analysis. The advantage of the in vitro measurements using cadavers is the quantitative nature which enables the analysis of ligament deficiency on knee joint rotation without soft tissue artefacts. Furthermore, this in vitro test also provides quantitative data on the in situ forces affecting the knee under ACL integrity or absence, under controlled rotation loadings and flexion angles.

Our data demonstrate how a rupture of the anterior cruciate ligament initiates a cascade of events that possibly results in abnormal tibio femoral motion and further cartilage damage. If the restoration of normal knee stability is the ultimate goal of ligament reconstruction, normal function of the anterior cruciate ligament should be restored as

closely as possible in all degrees. This study has demonstrated that the developed measuring device delivers exact, reliable measures and may be useful, either for defined questions on rotation, or should be refined and transferred into clinical work. The sectioning of the two ACL bundles finds its correlation in increased internal, external and over all rotation.

5.5. Outlook

Finally, to make another step forward into clinical application this device has to be modelled and arranged with a cast. A cast has to be developed holding the thigh and the shank instead of Schanz screws. In vivo measurements have to be evaluated and compared to the findings of the in vitro measurements. The differences between in vitro and in vivo measurements may lead to adequate calculation processes to discriminate soft tissue artefacts from distinct femoro tibial rotation. Afterwards averaging could be processed to open the door for further clinical investigations. Also it will be an advantage to bring down the measurements to a clear physical dimension.

6. Summary

The traumatic rupture of the anterior cruciate ligament (ACL) is one of the most frequent injuries in the field of orthopaedic surgery. The discussion about the proper reconstruction technique has been going on for years. While Single Bundle reconstruction addresses the anterior posterior instability, anatomic Double Bundle reconstruction aims to stabilize anterior posterior as well as rotational instability patterns. Up to now no definite evidence to favour the one over the other technique exists and the literature is still controversial. This is especially due to the fact that no objective method for quantification of the knee's rotational stability exists. In this context recently several authors reported on devices for analysis of femoro-tibial rotation. However, most of these tools are still in the developmental stage and suffer from distinct technical drawbacks. Therefore the aim of this study was

- 1st to develop an capable instrument for assessing rotational knee stability
 and
- 2nd to establish the possible field of application of this device in a human cadaver study.

The so-called *Torsiometer* was designed to objectively assess internal and external knee joint rotation in different flexion angles with its associated forces. Measurements were performed in the right and left knees of 6 human specimen applying internal and external rotation at 90°, 30° and 0° flexion in knees with sufficient and absent ACL respectively.

This study shows that the device is a useful instrument to access the pure osseus rotation between the thigh and the tibia in each flexion angle adjusted. In the same setup the validity of the device in respect of the measurements was experienced and the device revealed valid and reproducible values so that ongoing counts of deflection angles and forces were available.

The study enabled measurements which underline the knowledge of increased rotation freedom in respect to the status of the ACL. The analysis shows that the loss of the ACL destabilises the knee joint rotation in all flexion angles and that the deflection achieved correlates with the force applied. It should be noted that an ACL rupture allows increased internal and external rotation. So the destabilisation affects both directions of rotation and not only the internal rotation as clinically experienced with the Pivot Shift test. The intact ACL knee showed much higher resistance patterns as the ACL absent knee. So the same predefined applied force allowed wider deflection in the absent situation. The restraint in ACL absent knees is clearly lower and the course of rotation explicitly higher than in knee joints with intact ACL.

Using the new device, even small changes in force and deflection angle were detectable and found their representation in characteristic changes related to the graphical analysis. Beside of these changes the knee flexion angle influences the restraint patterns, due to increased capsular and ligamentious basic stress.

The graphical display of the measurements is a reliable procedure to show changes in the analysis of the deflection as well as related forces by creating characteristic curves. So with the Torsiometer used in this study a device is found which achieves continuous measurements with no loss of information and a wide variety of possible calculations and graphical ways of analysis. Further studies have to concentrate on the transfer of the device into a clinical non- invasive setup. To improve the setting and to ease this

methodical transfer into in vivo studies all configurations have been launched to a splint version.

7. References

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Glossar

ACL Anterior cruciate ligament

α-Angle Orientation of the anterior cruciate ligament regarding to the femoral

axis

AM Antero Medial Bundle part of the anterior cruciate ligament, labeled due

to the location of the tibial insertion site

AP Anterior-posterior forward-backward movement

B.C. Before Christ

BTB Bone Tendon Bone

Bungee Effect Axial translation of the graft, due to nonanatomic extracortical fixation

and higher elasticity of the fixation material

Cerclage Reconstruction technique, where fibre or. wire is used as osteosynthesis

material

Condyles Joint roll, distal ending of the femur

Crossed-four-bar-linkage Model of predefined bio mechanic joint motion of the knee, due to four

fixed suspensions (insertion of the ACL/PCL)

CT Computer tomography

Cybex Biomechanical Testing device

Drawer sign Comparable test for the anterior posterior tibial translation in knee

flexion

EN ISO 7250 European standard/ International organisation for Standardisation

Evolute Consecutive line emerging from all the rotation centres of the femur

condyle

EXCEL Office Excel, Microsoft Program

Father Pacini Corpuscel Quick adapting mechano receptors of the skin

Giving way Symptomatic feeling of knee joint instability often during climbing stairs

Haemarthros Effusion mainly of blood inside the joint capsule

Hysteresis Physikal description for the lag arising from a higher energetic situation

to the lower after removal of the energetic source

IL-1 Interleukine 1, main Peptidohormon of the Immunsystem, regulating the

interaction of the white blood cells

IL-6 Interleukine 6, Peptidohormons of the Immunsystem, regulating the

interaction of the white blood cells

Ipsilateral Same side opp. contralateral

Isometric point of insertion where no changes in fiber length occures

Jaw chucks Clamps for the fixation of screws to a Fixature

KT1000 Measuring device for the measure of translation
 KT2000 Measuring device for the measure of translation
 K-wire Kirschner wire, surgical drilling and aiming wire

Lachman-Test Clinical test to examine the banging of limited joint translation due to

the ACL

Menisectomy Surgical removal of the meniscus

MRI Magnetic resonance imaging
Nm Physical unite Newton meter
PCL Posterior cruciate ligament

Pivot-Shift-Test Clinical test for the combined rotational/translation movement limited

through the ACL

PL Posterolateral bundle

Roentgen Explorer of the X-Ray, Name for the use of X-Ray

ROM Range of motion

Rotameter Device for the measurement of Rotation

RS rotation stability

Ruffini Proportional mechanoreceptor for pressure

SPSS Data analysis software

Stereometric Device based measuring method using two optoelectronic cameras

Strain gauges Measuring gauges reacting on elongation due to changes in electrical

potentials

Supine lying on the backside

Telos Measuring device applying mechanical pressure to defined areas for

stressed radiologic examination

TNF- α Tumor necrosis factor- α

Torque Physical unite for rotation force

Torsiometer Apparatus to stress rotation

VKLD Vermond Knee Laxity Device

Wheatstone Circuit for the measurement of electric resistance

Windshield Effect Swinging of the extracortical fixed graft and impression of the osseous

edges of the graft tunnel

8. Curiculum Vitae

08/2006

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Auszeichnungen/Preise/Patent	
03/2006	Auszeichnung Initiative Mittelstand der deutschen Industrie Innovationspreis 2006 innovativstes Produkt/ Medizintechnik
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Versicherung an Eides statt

Hiermit erkläre ich, dass die vorliegende Dissertationsschrift von mir ohne Hilfe Dritter verfasst wurde. Ich versichere, keine außer den angegebenen Hilfsmitteln und den angegebenen Literaturstellen verwendet zu haben.

München, den 12.05.2010