Novel Insights into Anterior Cruciate Ligament Injury

Duncan Edward Meuffels

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Promotor:
Prof.dr. J.A.N. Verhaar

Overige leden:
Prof.dr. S.M.A. Bierma-Zeinstra
Prof.dr. J.M.W. Hazes
Prof.dr. D.B.F. Saris

Copromotor:
Dr. M. Reijman

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Chapter 1

Introduction

Anterior cruciate ligament (ACL) injury is one of the most common sports injuries of the knee. ACL reconstruction has become, standard orthopaedic practice worldwide with an estimated 175,000 reconstructions per year in the United States.[6] The ACL remains the most frequently studied ligament in orthopaedic research. Hundreds of papers are published each year related to the ACL. However, the treatment options and techniques are still developing and increasing, indicating the difficulties in the treatment of this central knee ligament.

History

The first mention of the roll and glide mechanism of the knee and the tension pattern of the different bundles of the cruciate ligaments were made by the Weber brothers of Göttingen, Germany in 1836.[5] They also noted an abnormal anterior-posterior movement of the tibia after transection of the ACL. The first description of the injury mechanism was published by Amédée Bonnet in 1845.[5] The earliest surgical attempts to address ACL deficiency focused on primary repair of the torn ligament. Battle and later Mayo Robson described in respectively 1900 and 1903 the successful repair and outcome.[2] As the ligament is torn or destroyed, Hey Groves disagreed with the notion of primary repair, as "direct suture would have been utterly impossible".

Different grafts were used to enhance the torn ACL from silk to fascia lata grafts.[2] In 1918, Matti from Bern Switzerland described a successful extra-articular repair techniques using a free transplanted strip of fascia lata to "reduce subluxation". In 1933, Bircher published his results in 83 cruciate ligament injuries, using in some cases, a kangaroo tendon to replace the anterior and posterior cruciate ligament. One-year earlier, at the German Orthopaedic meeting, zur Verth described, the use of a strip of patella tendon. He, however, left it attached on the tibial side and reattached the proximal side on the posterior cruciate ligament.[5] By the early 1980s, the treatment of anterior instability began to focus, once more on intra-articularly reconstructing the ACL, than the capsular structures. The clinical importance of the Lachman test had recently been described by Torg. Intra-articular procedures were developed by numerous surgeons, such as Insall, Macintosh, Jones and later Clancy.[2] The widespread use of the arthroscope, made an arthroscopic ACL reconstruction possible. It changed from, an initially two-incision technique into a one-incision technique in the 1990s.

In the historical overview of operations for anterior cruciate ligament rupture Dandy however said in 1996:"The history of ACL reconstruction is both remarkable and depressing. Innovators have been forgotten, good ideas discarded and untried procedures adopted with uncritical enthusiasm only to be set aside without explanation. Our predecessors appear to have been influenced more by surgical fashion or personal whim than scientific objectivity".[1] This might still be true at present.

Personal research history

This thesis was started, because of a long lasting, deep-rooted interest in the knee and its function. During my medical school years, I was confronted regularly with the enormous impact an anterior cruciate ligament rupture had on an active person. Especially the frequency and outcome of this injury, in my close friends and relatives in the professional dance world, started my first research endeavor. As a medical student, I was consulted by several ballet dancers on this topic. Without any practical experience, I had to rely solely on the literature, which, at that time, was none existent for anterior cruciate ligament injury and dance. This resulted in the research set up of my prospective trial to register and follow-up on anterior cruciate ligament injury in professional dancers.[4]

During my following training period as a consultant in orthopaedic surgery, I was exposed to different treatment strategies and a wide array of surgical options. This opened my eyes even more and the first attempt was made to research the long-term follow-up of the clinical outcome of a large single surgeon cohort versus a non-operatively treated cohort group. The clinical ten-year follow-up examinations of the non-operatively treated ACL deficient patients taught me many things. It showed that research was rewarding and that the reported literature on ACL was showing many lacunas especially on patient outcome and especially for the long term. It was also the beginning of my research: Ten-year follow-up study comparing conservative versus operative treatment of anterior cruciate ligament ruptures. A matched control study.[3]

The academic position at the University Medical Centre Rotterdam gave me the opportunity to start my own research as a practising orthopaedic consultant. The drive to improve the clinical outcome of orthopaedic patients, in particular those with ACL injuries was the starting point of an innovative study using computer assisted surgery. The lack of a gold standard for placement of the new ACL graft, made a reproducible, accurate placement technique even more challenging, but essential. This resulted in the randomized trial computer assisted surgery versus conventional arthroscopic surgery for anterior cruciate ligament reconstruction.

As a test of research competence, this thesis is a holistic approach to anterior cruciate ligament injury. It investigates and travels through the total gamma of aspects concerning this common sports injury. This journey was undertaken not only in the orthopaedic field, but with assisting knowledge concerning epidemiology, radiology, biomechanics and bioinformatics.

It will follow, chronologically, the anterior cruciate ligament injury; from when it ruptures, to the different options to improve the treatment and its long-term outcomes. It also discovers new and better ways of visualizing and judging the quality of the anterior cruciate ligament reconstruction.

This thesis will investigate risk factors, such as injury mechanism, incidence for specific subgroups and its short and long term outcome of not only reconstructed, but also conservatively managed anterior cruciate ligament injuries. Using novel techniques for per-operative management, specifically the biomechanical consequence of different graft fixation methods in bone patella tendon bone anterior cruciate ligament reconstruction as in double bundle soft tissue fixation. and postoperative visualization of anterior cruciate ligament injuries in orthopaedic practise. During these travels there have been numerous interesting encounters with established ideas that could not withstand these novel insights. The New York Times called the study question "provocative". A related interview for the largest and most visited internet site of the U.S.A. showed its clinical and present relevance as it was the second most widely read article in that year.

Aim and outline of this thesis

The general aim of this thesis is to gain more insight in the incidence of this injury, its mechanism of occurrence and its treatment options. **Chapter 2** describes its current practice and historic path up till present day in The Netherlands. In **Chapter 3** incidence and injury mechanism are described for professional dancers. A ten-year matched control follow-up study comparing conservative versus operative treatment of anterior cruciate ligament ruptures is described in **Chapter 4**. A biomechanical evaluation of different fixation techniques is described in **Chapter 5** and **6**. The first study was undertaken to establish if it was possible to use a smaller bone block length with comparable fixation strength at the femoral side for a bone patella tendon bone anterior cruciate ligament. The second study was set up to look at the differences in pull-out mechanism, fixation strength and stiffness of the construct between single and double tibial tunnel anterior cruciate ligament reconstructions. In **Chapter 7** a novel 3-Dimensional technique for visualizing the post-operative anterior cruciate ligament reconstruction bone tunnels is described. A reliability study was undertaken and compared to standard radiographs and computer tomography. In **Chapter 8** a Cochrane meta-analysis search was performed for computer assisted surgery for knee ligament reconstruction. In **Chapter 9** a prospective randomised trial comparing arthroscopic ACL reconstruction with computer assisted arthroscopic ACL reconstruction is described. Finally, in **Chapter 10** the results and limitations of these studies are summarised and discussed and implications for future research are presented.

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Chapter 2

Caput selectum; Increase in operative treatments for Anterior Cruciate Ligament Tears

Duncan E. Meuffels

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- An anterior cruciate ligament (ACL) tear is an often-encountered lesion of the musculoskeletal apparatus.
- The number of ACL tears is increasing, not only in The Netherlands, but globally.
- Surgical reconstructive techniques are progressing: from open to arthroscopic procedure.
- An ACL reconstruction does not diminish the chance to progress to osteoarthritis and the kinematic properties of the knee will not return to pre-trauma properties.
- An ACL reconstruction does diminish giving-way complaints; this is the most important indication for a surgical reconstructive procedure.
- Literature shows insufficient evidence to favour either surgical or non-surgical treatment as a primary choice.
- Treatment should be individually tailored. This should take into consideration: type of complaint, amount of instability, athletic participation wishes, age and the willingness to rehabilitate for 9 months.

During a televised football match we can sometimes be "live" part of the occurrence of an ACL rupture. The reporter will often tell the viewers that surgical treatment is necessary and the player will be out for a longer period of time. There has been a clear shift in the presentation of this injury. Twenty years ago it was shown on TV how the goalkeeper of the Dutch national team could cope with his ACL insufficient knee, because of his strong upper leg musculature. At present a player of the Dutch team can be followed during his operative treatment in the U.S.A., which takes place in the same week. Is there a reason for this complete turn around from conservative to surgical treatment?

Incidence

The estimated incidence of suffering an anterior cruciate ligament tear (ACL) in a population of athletes older than 15 years is 1/556 per year.[1] Women are at three times greater a risk as men of suffering this injury. This is an equivalent risk of 5% per season for a female fotballer.[2] The exact risk factors for an ACL tear are unknown for the general population, nor are they known for the possible in-or decrease in the last few years. Anterior cruciate ligament reconstructions have shown a clear increase in The Netherlands, as well as worldwide, in recent years. In the year 2008 there were more than 5000 ACL reconstructions performed in The Netherlands[3] This is an increase of more than 40% compared to the year 2003.[4]

Traumamechanism

The trauma, most of the time is, sport-related. The Dutch are most at risk when participating in down hill skiing, football, handball, basketball and hockey. The trauma mechanism, most of the time is, a movement of the knee to the inside and at the same time a movement of the foot to the outside. This forced knee movement can be through a twisting of the knee by an sudden change of direction or by a direct trauma, for instance during a duel with an opponent.

The cruciate ligaments are ligaments that are positioned intra-articular and have no functional healing capacity after a complete rupture. 50% of the time an ACL rupture coincides with a simultaneous lesion such as a meniscal lesion (mostly lateral), medial collateral ligament rupture and sometimes a cartilage lesion.[5]

Diagnosis

The diagnosis "ACL rupture" can be made by history taking and physical examination. In the history taking the trauma mechanism, the sound of a snap and the occurrence of swelling in the knee direct after the trauma are important factors. The most suitable tests during physical examination are the Lachman test and the Anterior Drawer Test. Both tests research the increased anterior-posterior laxity of the tibia versus the femur. As an additional investigation in the acute fase, an X-ray is indicated to exclude a fracture. An MRI can be useful if the diagnosis is not clear or if there is a suspicion of a meniscal or chondral lesion.

Subgroups: "copers", "adapters" and" non-copers"

Patients with the diagnosis ACL rupture can be sub-divided in to three sub-groups. There are "non-copers"; patients, who keep persisting instability complaints and who would like to, but cannot reach their previous athletic level. Following this, there are "adapters"; these are patients who don't have instability complaints because of adapting their activity level. As final group there are the "copers"; these are ACL deficient patients who have no knee instability and have reached their previous activity level. Unfortunately, however, there is no predictive test to clarify to which group one will belong. Because of this, it can only be determined retrospectively to which group the individual patients will belong.[6]

TREATMENT

At present there is still a lot of uncertainty concerning all the different aspects of the treatment of an ACL rupture.

Acute phase

There is, however, a consensus concerning the initial treatment of an isolated ACL tear. The knee swollen because of a haemarthros, must first lose its swelling and regain its range of motion. This period can be followed by a period of exercise therapy to increase again the atrophied upper leg musculature. Especially the Quadriceps atrophies very quickly, but is also essential to train the hamstrings as these are also very important knee stabilisers. The Dutch Arthroscopy Society (www.scopie.info/vkb) has conveyed its point of view that there is no indication to operatively stabilise the knee acutely by an ACL reconstruction. This advice is sometimes given, and followed specifically, in winter sports countries. Operating in an acute setting does not have a proven better outcome, but does have a described increased risk of arthrofibrosis (a stiffening of the knee by scar tissue). The first phase treatment period has ended when there is a clear pain reduction, there is no swelling of the knee and there is a full recovery of the range of motion. This phase can take between 4-8 weeks.

Post-acute phase

There is a lack of consensus about the further treatment after the acute phase. Some of the patients with a complete ACL rupture can undertake all activities without any functional impairment, the aforementioned copers. How substantial this number of copers is, is still unclear and it varies in different studies between 14% and 48% of the ACL deficient knees.[7, 8] There are also patients who have no complaints after having adapted their athletic activities. For these adapters there is no reason to operate. Finally, only the instability complaint warrants an operative indication. After the initial trauma, it is often the choice of the patient if the complaint gives rise to an operative reconstruction. It should be explained to the patient with emphasis, that there is no operative necessity if there are no giving way moments. Contributing factors to the indication for reconstruction are: more rotational instability, younger age, accessory lesions to the knee, a pivoting sport activity, a higher level of sports activity and a wish to return to the previous activity level. The option of a conservative treatment, which possibly encompasses an alteration of their activities, versus operative treatment should be discussed extensively.

Conservative treatment

Conservative treatment is a continuation of the exercise therapy after the acute phase. The therapy is now aimed at a full recovery of the strength of the upper leg muscles and towards a functional recovery of the knee. This encompasses a build-up to the activity level striven for, with the help and guidance of a physiotherapist. [9]

Operative treatment

In the last 2 decennia, the ACL reconstruction has, technically, evolved from an open reconstruction to an arthroscopic operation (figure 1). The remains of the ruptured ACL are removed and replaced by a transplant. The most widely used techniques use the middle one third of the patient's own patella tendon or the hamstring tendons of the m. gracilis and m. semitendinosus. These are placed under arthroscopic control in the knee (figure 2). The patient can usually resume sports activities fully, after a rehabilitation process of approximately 9 months. Meta analysis of prospective studies shows that 93% of the patients are content at short-term follow up. A knee with no rotatory instability is achieved in 81% of the patients with a reconstructed knee.[10] The percentage of patients that can participate at their previous sports level however, lags behind, compared to the reached knee stability, depending on the pre-trauma sports-level, 37%-52% of the patients reach their old level. [11]

There haven't been any randomised clinical trials performed that have looked at the efficacy of an ACL reconstruction compared to a non-surgical treatment strategy. [12 13]

Figure 1: Arthroscopic ACL reconstruction of the right knee with reflecting reference balls for Computer Assisted Surgery.

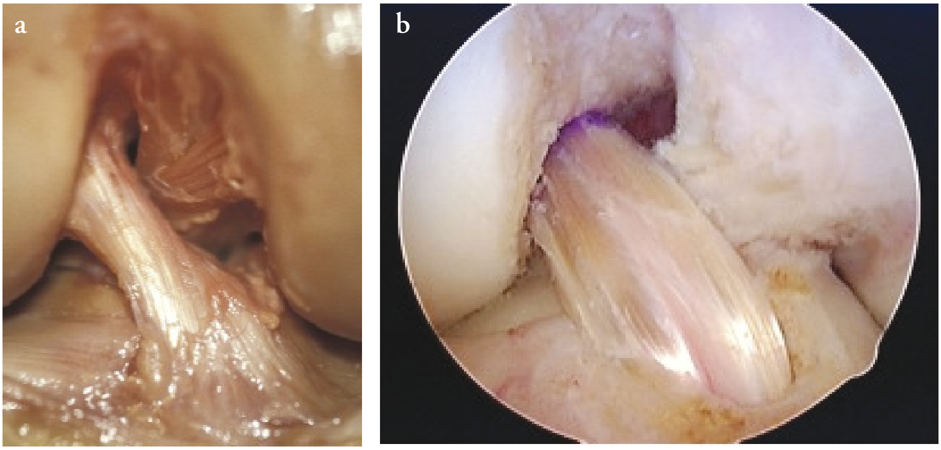

Figure 2: (a) *Frontal view of the right knee with an intact anterior cruciate ligament, and (b) with a reconstructed anterior cruciate ligament with a hamstring transplant.*

An ACL reconstruction has been shown to be unable to restore fully the normal kinematics of the knee. The form and function of the anterior cruciate ligament is so unique, that replacing it by a tendon can eliminate the instability of the knee (giving way), but it cannot restore normal kinematics.[14, 15]

There are no scientific grounds for the enormous increase in the number of reconstructions. The balance is not, that the simplicity of the procedure makes a serious conservative treatment attempt unwarranted. But the short-term gain for the top athlete, after an ACL reconstruction and the resulting media attention, could be an explanation. They give the false impression that conservative treatment is old-fashioned.

Complications

An ACL reconstruction is successful in restoring anterior posterior knee instability. This plus, however, has to be weighed against the possible operative risks. These risks encompass infection, bacterial arthritis of the knee, embolus of the a.poplitea and a fatal pulmonary embolism. There can also be complaints at the harvest place of the transplant, such as a patella fracture and localised pressure pain. [2, 16-19] In addition to that there is a possibility that following surgery has to be undertaken because of hardware complaints, necessitating implant removal such as a staple or screw. The transplant can also fail because of suboptimal bone tunnel placement or a new trauma to the knee. A new secondary ACL rupture in patients after an ACL reconstruction occurs in 6% of the patients in the first 5 years, this can occur in the reconstructed but also in the contra lateral knee. The sport intensity is the most important predictor of the (re) rupturing risk, specifically for the first year.[20]

Consequences

An ACL rupture has major consequences for athletes. The patient cannot bear weight initially, will forfeit work for a number of days and will be unable to participate in sport for a while. The patient will be expected to put forward an extensive effort to recover and rehabilitate, whereby the fear for a new giving way moment will still be present. Of all sports injuries the ACL rupture is the one with the highest direct and indirect costs.[21] If the instability complaints persist, the medical consumption will be extensive, because of the surgical intervention and the following 9 months of rehabilitation. One still has to consider the additional indirect costs of the necessary investment in time and energy with a loss of working hours, in a patient population which generally tends to be between 18 and 40 years of age.

Another consequence of an ACL rupture is a high probability of further damage to the knee. The risk for knee osteoarthritis within 10 to 15 years after the initial trauma is tenfold.[9] This osteoarthritis is not only attributed to the knee instability, but probably also to the initial trauma with direct chondral damage. An ACL rupture that coincides with a meniscal lesion has an additional risk factor for obtaining osteoarthritis in the long-term.[22]

There are relatively few long-term outcome data published of patients with an ACL rupture. This is because of a big loss to follow-up of this young and mobile patient group. Additionally, present treatment techniques have evolved compared to 20 years ago. Recently, in our clinic, we compared the results of a group of athletes who had had an ACL reconstruction with a pair matched group who were treated conservatively. These top athletes after a long-term follow-up of 10 years, showed no difference in activity level, nor in general satisfaction with the knee.[9] An ACL reconstruction, however, can be a possible protective measure for reducing the occurrence of a meniscal lesion.[9, 11] The long term percentage knee osteoarthritis was, however, not reduced by an ACL reconstruction.[11, 22 9]

CONCLUSION

An ACL rupture is a threat to the homeostasis of the knee. The rupture coincides with instability complaints that can be debilitating. A timely recognition and prevention of further damage is essential.

The treatment of an ACL rupture is an individual treatment and can be either conservative or surgical. There is insufficient knowledge of the long-term outcome to put one treatment in favour of the other. Multiple factors should be considered such as: complaint pattern, amount of instability, athletic participation wishes, age and the willingness to rehabilitate for 9 months. The choice for either a surgical or conservative treatment has to be made after the acute phase. The increase in the number of ACL reconstructions cannot fully be explained by available scientific literature. Multiple factors will play a part in this: technical progress with an arthroscopic technique, marketing by the orthopaedic industry, the patient's wish fed by treatment information about top athletes, the low per- and post-operative complication risk compared to the past, the possible doctor's preference and the economic health care development. Examples of economic development in The Netherlands are the introduction of B-DBC, a Diagnose Treatment Combination at a negotiable price, for instance for an ACL reconstruction, between insurance and provider or a reward for a short waiting time between trauma and operation. The patient needs to be informed about the fact that an ACL reconstruction will not reduce knee osteoarthritis risk. The knee articulation will not be restored to its pre-trauma state, but the giving way moment can be substantially reduced. This last fact remains the most important indication for an eventual operation, but not until a serious conservative effort has been undertaken.

ABSTRACT

An anterior cruciate ligament rupture is a very common musculoskeletal injury. The number of anterior cruciate ligament reconstructions is increasing in The Netherlands and globally. It is predominantly a sporting injury often resulting in knee instability. Substantial progress has been made with improving surgical technique from an open procedure to a minimal invasive arthroscopic operation. Treatment should always be tailored to each individual. There is insufficient long-term evidence to merit one specific treatment (operative or conservative) above the other. Multiple factors should be considered such as: complaints, amount of instability, sport wishes, age and willingness to commit to a nine-month rehabilitation program. An ACL reconstruction will not diminish the increased change for secondary knee osteoarthritis, neither will it restore normal knee kinematics, but it will reduce giving way complaints. These giving way complaints are still the most important indication for this operation.

TAKE HOME MESSAGES

- An anterior cruciate ligament rupture is a common knee injury with a great risk of knee osteoarthritis in the long-term.
- Giving way moments because of an instable knee can be successfully remedied by an anterior cruciate ligament reconstruction.
- An anterior cruciate ligament reconstruction will not reduce the risk of knee osteoarthritis, although it will possibly reduce the number of meniscal lesions.

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Chapter 3

Anterior cruciate ligament injury in professional dancers

Duncan E. Meuffels, Jan A.N. Verhaar.

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ABSTRACT

Background: Anterior cruciate ligament injury (ACL) is a common sport injury, however no data exists concerning dance and ACL injury. We report the incidence, injury mechanism and clinical follow-up of ACL injury in professional dancers.
Patients and method: In a retrospective cohort study involving the three major dance companies in the Netherlands, by interviewing all 253 dancers, who had had a full-time contract during 1991-2002, dancers with symptomatic ACL injury or past ACL reconstruction were identified and examined.
Results: 6 dancers (2 women) had had a symptomatic ACL rupture and reconstruction. Interestingly, all had been on the left side and had had a similar trauma mechanism: while dancing a classical variation they landed, after a jump, on their left leg, in the turned out position with a valgus force on their knee. There was a higher risk of ACL injury in the classical company than in the two contemporary companies. The risk of dancers having a rupture of the left ACL during a 10-year career in this classical company was 7%.
Interpretation: ACL injuries are not an infrequently seen type of injury in professional classical dancers, with a very specific mechanism of injury - a landing on the left leg in exorotation. More attention and prophylactic measures should be given to this specific injury mechanism.

Rupture of the ACL occurs frequently in pivoting sports such as soccer, American football, basketball and handball. The annual prevalence of ACL injuries in the general population has been estimated as 1 injury for every 3500 people.[7] In activities with more rotational forces as in skiing the incidence for ACL injury lies between 4.2 injuries per 100,000 skier-days for men and 4.4 for women .[9] The classical traumamechanism in ACL rupture is a valgus exorotation trauma. In ballet dancing jumping and landing in exorotation often occurs. To our knowledge, however, there have been no previous studies on the frequency of ACL injury in dancing.

PATIENTS AND METHODS

This study is based on the three major dance companies in The Netherlands; the Dutch National Ballet (HNB), the Netherlands Dance Theatre 1,2,3 (NDT) and Scapino Ballet Rotterdam. By interviewing all 253 dancers who had had a full-time contract in the period 1991-2002, 6 dancers were identified who had had a symptomatic ACL injury or reconstruction in this 10-year period.

A questionnaire was filled in by these dancers concerning, injury mechanism, past treatment and outcome and dance related complaints. Scoring was done through the IKDC 2000 questionnaire.[3, 5] A physical examination was performed with KT 1000 measurements (MEDmetric, San Diego, California).

Statistics.

Chi-Square tests were used to compare the proportion of symptomatic ACL ruptures between the two contemporary dance companies and the classical dance company. Because of the small proportion of symptomatic ACL ruptures we used Fisher's Exact test. Differences were considered significant at the 0.05 level (one-sided). We used SPSS version 12.1 (SPSS Inc., Chicago, USA).

RESULTS

From 1991 up till 2002, the Scapino Ballet and NDT, both of which are contemporary dance companies with an average of 81 dancers per season, had no dancers with symptomatic ACL injuries. HNB, a classical company, however, had 6 dancers with symptomatic ACL injuries. This company has an average of 82 professional dancers per year. The risk of dancers having a rupture of the left ACL during a 10-year career in this classical company was 7%. The classical company shows a significant increased risk of having symptomatic ACL injuries compared to the two contemporary companies (p = 0.02, power 55%).

With an average working year of 230 dancing-days for all 3 companies, these dancers occupy 374,900 dancing-days. This gives them a risk of 1.6 injuries per 100,000 dancing-days. This risk increases to 3.2 injury per 100,000 dancing days if we only consider the higher-risk classical company.

All injuries happened while landing on the left leg in the classical position of exorotation in the hip. The women had both performed a grand jeté (Figure 1). The 4 men landed on their left leg after a cabriole (Figure 2). In 50% of cases, these jumps were during performances.

The 6 dancers, all of whom had had a complete ACL tear of the left leg, underwent either auto-or allograft bone-patella-tendon-bone or a hamstring graft reconstruction. The dancers were examined by us on average 5 (2-10) years after surgery. 3 had nearly normal IKDC scores and 3 had abnormal scores (with an average subjective IKDC score of 85 (68 - 97)). Instrumented laxity testing at maximum showed 4 knees with less than 3 mm of side-to-side difference and the others with 4 and 5 mm of side-to-side difference.

Figure 1. A grand jeté.

Figure 2. A female dancer performing a cabriole.

After the injury, all 6 dancers had some persistent feeling of insecurity when landing on jumps. After returning to dancing, 3 of the 6 dancers subsequently stopped dancing because of this handicap.

DISCUSSION

6 dancers in the classical company had had ACL injuries, but no such injuries had occurred in the 2 more contemporary companies. This difference cannot be explained by the schedules, dancing hours or the stage floor, as these are very similar.[8] All three companies have a similar full-time dance load. On average they give more than 100 performances a year and the dancers normally work 5 to 6 days per week. One possible explanation is the difference in repertoire.[8] In a classical dance company, the number of jumps is far greater than in a more modern company and these landings will be in en dehors, the classical turned out position of the leg. Landing in this turned position is probably the most important risk factor behind such ACL injuries in dancers.

The injury mechanism was similar for all dancers. They landed from a jump with the hip and foot turned out and a valgus stress on the knee (Figure 3).

Figure 3. Landing in a turned out position with the knee in valgus

The mechanism that most often accounts for ACL injury is adduction/ internal rotation of the hip, valgus and external rotation of the knee and pronation of the foot.[2, 4] The only difference here is that, instead of an internal rotation of the hip, there is external rotation with a relatively more pronounced external rotation of the lower leg and foot.

One striking finding was that all injured cruciate ligaments were on the left side. This may not be a coincidence. In ballet, all turns and jumps are performed left and right in class; however, on stage and during rehearsal, the majority of the turns are performed to the right where the left leg is the supporting and landing leg. With a grand jeté, however, you push off with one leg and land on the other. The 2 female dancers pushed off with their right leg and landed on their left. In a solo, a dancer has his own choice. The majority chooses the left leg as the supporting leg.

Limitations of this study were the small numbers in this elite group and the fact that the follow-up was retrospective. However, the number of actual dancing years is high. It is possible that some ACL injuries were missed or were asymptomatic. This could give an underestimation of the number of true ACL ruptures. However, this group of athletes is watched continuously during training and performance, and a trauma on stage would be difficult to miss.

Because of the small numbers, the different reconstructive techniques used and the different rehabilitation programmes, it is difficult to comment on the clinical outcome of the ACL treatment. However, 3 out of 6 had to stop dancing at this high level. An ACL rupture appears to be a real threat to a dancing career.

The incidence rate of 3.2 symptomatic ACL rupture per 100,000 working days is nearly as high as a the well-recognized high ACL injury risk of professional skiers.[9] A soccer or basketball player - especially a female – does, however, have a 3-5 times greater chance of tearing her ACL per athletic event than a professional dancer.[1, 6] More awareness should be generated for this dance career threatening injury and more preventive measures should be undertaken, focusing on dance technique, neuromuscular training and an avoidance of an excessive knee abduction moment, with landing in a less exorotated, pronated foot position.[4]

Contributions of authors

DM set up of study design, examined all patients, collected and analyzed the data, wrote the manuscript. JV supervised the analysis and proofread the manuscript.

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Chapter 4

Ten year follow-up study comparing conservative versus operative treatment of anterior cruciate ligament ruptures. A matched-pair analysis of high level athletes

D.E. Meuffels, M.M. Favejee, M.M. Vissers, M.P. Heijboer, M. Reijman, J.A.N. Verhaar

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INTRODUCTION

The anterior cruciate ligament (ACL) is one of the most commonly injured ligaments of the knee. The incidence of ACL injuries is currently estimated at approximately 200,000 annually, with 100,000 ACL reconstructions performed each year in the U.S.A.[1]. The prognosis for 2008 in the Netherlands is that 5000 ACL reconstructions will be performed, this is 1 per 3200 habitants[2]. In a more active age group the incidence of ACL injuries could even be as high as 1/556 [3]. The goal of the treatment of ACL ruptures is to obtain the best functional level for the patient without risking new injuries or degenerative changes in the knee[4]. There are many factors to be considered when deciding whether an ACL rupture should be treated surgically or conservatively. Among these factors are the degree of instability, the presence of meniscal lesions, the patient's level of athletic activity and the patient's age [5]. A widely advocated treatment strategy is to recommend early reconstruction in the highly active patients and to start with a non-surgical treatment for the less active patients.

Injury to the ACL frequently leads to post-traumatic osteoarthritis (OA) and many surgeons had and have hope that ligament reconstruction would also lead to a reduction of post-traumatic OA [6]. However, the prevalence of degenerative changes after reconstruction of the ACL ranges between 10-87% [7 8]. This variance is due to operation technique and the presence of accompanying injuries, especially meniscal lesions and the time between the actual injury and the operative reconstruction[9]. One of the great difficulties in ACL rupture management is that there are no specific management guidelines to decide which patient benefits from operative versus non-operative treatment. This is partly because there are few prospective studies comparing operative and non-operative treatment of ACL injuries [10 11]. Linko et al. summarized in a Cochrane review the evidence concerning this issue and found two studies, published in the early 1980's that compared an operative treatment with a conservative treatment of an ACL injury. They found insufficient evidence to show that reconstructing the ACL was better than conservative treatment. [11-13]. Since then the operation technique has improved with the development of reliable fixation devices and the transition from open to arthroscopic surgery. Recently no randomized clinical trials have been published, maybe due to ethical concerns.

The purpose of this study was to compare treatment, specifically in high level athletes who had sustained an ACL rupture. We specifically chose this high demand group as they are considered a greater risk of failure with non-operative treatment and may have a higher incidence of OA. We evaluated our conservative treatment with the single incision bone-patella-tendon-bone ACL reconstruction. This technique is still considered the gold standard, together with the four strand hamstring reconstruction. The two groups were matched for three important predictors for outcome, namely age, gender and pre-injury sports activity level [14 15]. The patient groups were compared with regard to OA of the knee, meniscal lesions, instability, activity level during the ten year period and objective and subjective functional outcome.

METHODS

Patients

For this pair-matched study we used two cohorts. The first cohort were patients who had been treated conservatively for ten years after being diagnosed with an ACL rupture, which was confirmed either by MRI or arthroscopically. These patients were pair-matched with patients who underwent a reconstruction of the ACL rupture ten years previously, between 1994 and 1996. These patients were reviewed at the outpatient clinic in 2006.

None of the patients had had other intra- or extra-articular knee ligament reconstruction in the past and all patients had sufficient knowledge of the Dutch language to understand the purpose of the study and to fill in the questionnaire. In our hospital all patients with an ACL rupture were referred for a physiotherapist-led rehabilitation program. They were reevaluated after 3 months for knee instability complaints and a non-pivoting activity-lifestyle was offered versus an ACL reconstruction [16].

The patients who were treated conservatively were pair-matched with the patients who underwent a reconstruction with respect to age, gender and Tegner activity score before injury. In total 50 patients were pair-matched for the present study.

Prior to participation, each subject signed an informed consent.

Treatment

Conservative therapy consisting of swelling reduction and range of motion exercises were introduced by the physiotherapist. For a minimal period of 3 months, an active and intense hamstring and quadriceps strengthening program was followed.

All ACL reconstructions were performed by two orthopaedic surgeons. The interval between the index injury and ACL reconstruction was, on average, longer than 6 months (range 2-258 months). A single incision, central one third BPTP technique, was used. Tunnel placement was aided by Acufex tibial and femoral aimers. Tibial tunnel placement was 7 mm anterior of the posterior cruciate ligament. Femoral tunnel placement was at a eleven o'clock position for the right knee and at one o'clock for the left knee (Figure1. X-ray AP view ACL reconstruction, Figure 2. X-ray lateral view ACL reconstruction). Nonresorbable interference screws were

Figure 1. X-ray AP view ACL reconstruction

Figure 2. X-ray lateral view ACL reconstruct

used for the tibial and femoral bone block fixation. Post-operative rehabilitation consisted of protected weight-bearing for the first 4 weeks, after which rehabilitation was intensified. Sports return was allowed after 6 months.

Measurements

At the ten year follow-up at our outpatient clinic, all patients were reviewed regarding radiological OA of both knees, past meniscal lesions, stability of the injured knee, activity level and objective and subjective functional outcome. The review was performed by an independent surgeon (DM), who was not involved with the previous operative or non-operative treatment.

Radiological OA. Weight bearing posterior-anterior and Rosenberg-view radiographs of the knee were taken at follow-up, to assess OA of the injured knee[17]. Staging of radiographic OA was based on the Kellgren & Lawrence classification[18]. A person was considered to have radiographic OA of the knee if the Kellgren & Lawrence score was equal to or larger than two. Two experienced readers independently (D.M. and J.V.) evaluated the radiographs, unaware of the clinical status of the patients.

Meniscal lesions. For every patient the past medial, lateral and combined meniscal tears were noted.

Stability of the ACL. For the present study stability of the knee was evaluated by the pivot shift test and the KT-1000 arthrometer[19]. The pivot shift test was graded from 0 to 3+. A score of ≥ 1+ was defined as an instable ACL. Instrumented laxity testing of the knee was performed with the use of the KT-1000 arthrometer. The side-to-side difference at the maximal load was measured. A cut-off point of > 3mm side-to-side difference was used to define an instable ACL.

Activity level. The patient's level of activity was assessed using the classification of Tegner et al[20]. This a scale of 1-10, where 10 is equivalent to football at international level.

Functional outcome. The subjective functional outcome was assessed using the Lysholm score and the International Knee Documentation Committee. Both grading systems have a maximum score of 100, which means a perfect knee[21-23]. The objective functional outcome was evaluated with the one-leg-hop test, which calculates a quotient between the injured and non-injured leg[24].

Statistical analysis

Distribution analysis of all variables was tested by the Shapiro-Wilk test. For the normally distributed variables, statistical analysis of the results was performed using the independent sample t-test to evaluate between-group differences and the paired-sample t-test to evaluate within-group differences . For the variables that were not normally distributed, statistical analysis was performed using the Mann-Whitney-Wilcoxon U-test to evaluate between-group differences and the Wilcoxon signed rank test to evaluate within-group differences. For the normally distributed variables, the mean and standard deviation were presented. For the variables that were not normally distributed the median and range were presented. Differences were considered significant at the 0.05 level (two-sided).

We used SPSS version 12.1 (SPSS Inc., Chicago, USA).

RESULTS

Patients

The characteristics of the two study populations are presented in Table 1. The two groups were similar with respect to gender (P-value of 1.000), age (P-value of 0.808), body mass index (P-value of 0.443) and Tegner activity score before injury (P-value of 0.831).

Table 1: Patient characteristics at ten year follow-up evaluation.

	Operative treatment (n = 25)	Conservative treatment (n = 25)	P-value
Gender (men / women)	19 / 6	19 / 6	1.000
Age (years), mean (± SD)	37.6 (6.2)	37.8 (6.8)	0.808
BMI (kg/m²), median (min-max)	25.3 (22.2-30.9)	24.9 (20.9-28.7)	0.443
Preinjury Tegner score, median (min-max)	9 (6.0-10.0)	9 (6.0-10.0)	0.831

Radiological OA

12 patients (48%) in the operative group had knee radiographic OA with a score of ≥2 compared to 7 (28%) in the conservative group. This difference was not statistically significant (P-value of 0.145). The total of 50 contralateral knees showed 4% radiographic OA at the ten year follow-up (Table 2). Radiological assessment showed an interobserver Kappa value of 0.77.

Table 2: Radiological OA at ten year follow-up.

Description	Operative treatment (n = 25) number (%)	Conservative treatment (n = 25) number (%)	Contralateral knees (n = 50) number (%)
Kellgren & Lawrence, grade			
0	4 (16)	8 (32)	37 (74)
1	9 (36)	10 (40)	11 (22)
2	9 (36)	4 (16)	2 (4)
3	3 (12)	3 (12)	0 (0)
4	0 (0)	0 (0)	0 (0)

Meniscal lesions

In total 68% of the operative group had a meniscectomy and 80% of the conservative group (P-value of 0.333). There was, however, a significantly lower amount of 3 meniscectomies (12%) in the operative group post-reconstruction compared to the conservatively treated group with 10 patients (40%) with meniscectomies in the last ten years (P-value of 0.024).

Stability

Both groups differ, at our ten-year follow-up, in stability of the injured knee assessed with the pivot shift test and the KT-1000 arthrometer (Table 3).

Table 3: Knee stability at ten year follow-up.

	Operative treatment (n = 25) number (%)	Conservative treatment (n = 25) number (%)	P-value
KT-1000: max side-to-side difference			
> 3mm	6 (24)	17 (68)	0.002
Pivot shift			
- 0	20 (80.0)	4 (16)	<0.001
≥ 1+	5 (20)	21 (84)	

Level of physical activity

Both groups had a drop in activity level after their ACL lesion. The highest median Tegner score reached, by the reconstructed group, preoperatively was 4 (min.3-max. 9) but all with giving way complaints during this activity level, which, after reconstruction, rose significantly (P-value of 0.0001) again to a Tegner score of 8 (3-10). After the ACL lesion the conservative group achieved a highest median Tegner score of 7 (min.4-max.10) which was comparable to the previously mentioned Tegner score of 8 (3-10) (P-value of 0.420) of the ACL reconstructed group. At the ten year follow-up the operative group showed no statistical significant difference with a one point higher Tegner score compared to the conservative group 6 (min.3-max.9) and 5 (min.1-max. 9) respectively (P-value of 0.188).

Functional outcome

The evaluation of the subjective knee function, according to both the Lysholm's scoring system and the IKDC subjective knee evaluation, showed no statistical significant differences between the operative and conservative group (P-value of 0.442 and 0.683 respectively) (Table 4). The quotient of the injured and non injured of the one leg hop test was not statistically different between both groups (P-value of 0.522).

Table 4: Functional outcome at ten year follow-up

	Operative treatment (n = 25)	Conservative treatment (n = 25)	P-value
Lysholm score, median (min-max.)	88.0 (54.0 –96.0)	85.0 (38.0 –100.0)	0.442
IKDC subjective score, median (min.-max.)	77.1 (47.0 – 97.6)	77.1 (25.3 – 100.0)	0.683
One leg hop test:			
Injured/non-injured side, median (min.-max.)	93.7% (53.3 - 123.4)	96.7% (52.5 – 112.0)	0.522

DISCUSSION

This study was performed to give more insight into the long term outcome after ACL injury for patients with a high activity level. The relatively long-term follow-up of more than ten years of two groups of high level athletes with a previous ACL injury, can give us more knowledge to further advance our decision making. As expected there was a clear difference in stability in favour of the reconstructed group. However, our study showed no significant difference at ten year follow-up between operative treatment or conservative treatment in prevalence of knee OA, meniscal lesions and Tegner score. Neither functional objective (one leg hop) nor subjective scoring (IKDC subjective score, Lysholm) was significantly different. This is in contrast to some other reports showing differences in persistent giving way complaints in two thirds of the ACL ruptured patients[25 26].

There have been relatively few publications about the long term follow-up and the one-incision bone-patella-tendon-bone ACL reconstruction with interference screw fixation compared to conservative treatment[10 11 27]. None was a randomised clinical trial with operative techniques used nowadays to clarify this problem. This is probably due to patient or surgeon treatment preference and ethical concerns. Because of these issues, we opted for the presented design, a matched case control study correcting for the three possible known risk factors for outcome; age, gender and activity level[15]. Both groups had a median pre-trauma Tegner score of 9. This is compatible with a high level competitive pivoting sport such as football.

The functional outcome of these two groups showed no difference in the Lysholm and the subjective IKDC scores. This is emphasized by an equal functional level shown by the one leg hop score. These results are similar to previous results from other research done for either conservatively treated or reconstructed ACL injuries[7 12 26-34].There is a significant difference between these two groups in the greater objectively measurable instability of the non-operative group at the ten year follow-up. The reconstructed group showed a positive pivot shift in 20% of the cases, which is compatible with other long term results of present day ACL reconstruction[35 36]. This high level of rotational instability of the non-operative group with a 84% positive pivot shift, signifies the severity of instability of this group. This is, however, not shown clinically in a difference in co-morbidity, as there is no significant difference in total meniscal lesions 72% for the reconstructed group and 76% for the conservatively treated group. This high number of meniscal lesions has been generally seen in the literature in, for instance, a 35 year follow-up study of Olympic East-German athletes with ACL injury showed a meniscectomy rate of 79% at ten year follow-up and 95% at twenty years follow-up [34]. Our study, however, shows a significant reduction of the risk of subsequent meniscal injury in the reconstructive surgery group. One might expect that, as a consequence of this, there would be a lower ROA. At our ten year follow-up, however, there is a tendency to have more ROA in the reconstructed group 48% versus 28% in the conservative group. This discrepancy can not be explained at present by the difference in meniscal lesions. A possible explanation could be the operatively induced haemarthos and the intraarticular tunnel bone marrow.

The aim of each individual knee instability treatment is to restore, as much as possible, the homeostasis of this joint. This will enable each patient to undertake the activities that were previously possible without an increased risk for comorbidity in the short and long term. At present it is still not fully clear which individual will benefit most in the long term with operative or conservative treatment. This study shows that an ACL reconstruction is a good operation to stabilise the knee. This study also shows that a conservative ACL treatment gives these patients the same feeling and functional result as those with a stable knee.

CONCLUSION

In this pair-matched study of high level athletes with ACL rupture, both the conservatively treated and the operated group, performed similarly, except for a higher objectively measurable instability for the conservative group. They, however, are just as satisfied with their knee without an operation at ten year follow-up, showing no difference in radiologic OA, meniscal lesions, activity level and functional outcome subjectively and objectively. Therefore, conservative treatment should still be considered a treatment option for an ACL insufficient knee, even with a high level athlete.

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Chapter 5

Failure load of patellar tendon grafts at the femoral side: 10- versus 20-mm-bone blocks

Meuffels D.E., M.D., Niggebrugge M.J.N., M.D., Verhaar J.A.N., M.D. Ph.D.

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ABSTRACT

Introduction: The aim of the present study was to investigate whether use of short bone blocks is safe in anterior cruciate ligament (ACL) reconstruction. Our hypothesis was that the smaller 10 millimetre (mm) length bone blocks will fail at lower loads than 20 mm bone blocks.
Material and methods: Ten paired human cadaver knees were randomly assigned to the 10 or 20 mm group (group 1 and 2) and underwent bone-patellar tendon-bone femoral fixation with interference screw. Tensile tests were performed using a tensile testing machine (Instron). Stiffness, failure load and failure mode were recorded.
Results: Median stiffness was 72 N/mm (16 - 103) for 10 mm bone blocks and 91 N/mm (40 - 130) for 20 mm bone blocks. Median failure loads were 402 N (87 - 546) for 10 mm long bone block and 456 N (163 - 636) for 20 mm bone blocks. There was no statistically significant difference between groups ($p=0.35$). All bone-patellar tendon-bone grafts were pulled out of the femoral tunnel with interference screw, due to slippage.
Discussion: We concluded that a 10 mm long bone block is not significantly weaker than a 20 mm long bone block. Failure loads of a 10 mm bone block exceed loading values at passive and active extension of the knee under normal conditions. 10 mm bone blocks offer sufficient fixation strength in anterior cruciate ligament reconstruction.

INTRODUCTION

The bone-patellar-tendon-bone (BPTB) technique has evolved since its introduction by Jones in 1963 and by Clancy et al in 1982 [7,13,14]. Jones started off with a full-length strip of patellar bone including quadriceps tendon. Clancy reduced this to a 25 mm long bone block and we've been using this size ever since, without any scientific proof of it being the optimal length. For many years now, the bone-patella tendon-bone graft was considered the gold standard for anterior cruciate ligament (ACL) reconstruction, and is still widely used successfully, despite the rising popularity of hamstring tendon reconstructions[11,17]. However, ACL reconstruction with patellar tendon has been related to some complications, such as patellar tendonopathy, anterior knee pain, loss of range of motion and even patella fracture [6,9,15]. Because of these complications, attributed to harvest site morbidity, alternatives, such as three or four stranded hamstring tendon, have become more and more popular. Due to the removal of a patellar bone block there is increased strain on the patella surface, both medial and lateral to the defect [26]. Patients with a bone-patellar tendon-bone (BPTB) ACL-reconstruction have more pain on kneeling or knee walking, compared to patients with hamstring tendon (HT) reconstruction (53% vs. 23%) [11].

Shorter bone blocks may carry the advantage of less extensor morbidity and anterior knee pain in the post-operative period during and after rehabilitation. Theoretically, considering Steen's research, using smaller bone blocks, reduces the patellar area exposed to stress hopefully reducing anterior knee pain [26]. Furthermore this study would show if the fixation strength would be acceptable if a surgeon decides to use a bone block which fractured per-operatively to a size of 10 mm.

Many studies have focused on bone block and tunnel diameter, screw size and fixation strength of different fixation devices [1,3,10,19,25]. These factors are very important in the first weeks of rehabilitation and different combinations have shown great variety in fixation strength. Biomechanical testing of fixation strength and failure load has been performed, mainly on fresh frozen porcine and bovine bone and some on human cadavers [20,21,23].

To our knowledge no study has been performed to establish the effects of varying length of the bone block and their failure load in interference screw fixation of ACL grafts in the human bone. The graft-femoral complex failure load will probably be determined by the bone quality rather than bone block size or be limited by the properties of the fixation device [16]. It is this complex of graft, interference screw and femur that usually leads to failure of the graft rather than the tendon rupturing itself [2].

The purpose of this study was to evaluate the difference in graft failure load between 10 and 20 mm bone block in ACL reconstruction at the femoral fixation site. Our hypothesis is that 10 mm bone blocks fail at lower loads than 20 mm long bone blocks.

MATERIAL AND METHODS

For the present study ten elderly paired human cadaver knee joints were used; cadavers were embalmed in formaldehyde. The knees were randomly assigned to a 10 or 20 mm bone block reconstruction with a metal interference screw (Smith & Nephew, MA, USA). An anterior cruciate ligament reconstruction was performed using a 10 mm wide patellar tendon graft with placement in a 10 mm diameter tunnel. The femoral anterior cruciate ligament reconstructions are performed, creating two groups. Group 1 and 2 had reconstruction with a bone block length of 10 mm and 20 mm respectively.

Surgical Technique

A 10 mm wide bone patella tendon bone graft was harvested from the cadaver using one vertical incision and an oscillating saw. Two holes were drilled in the bone block using a 1.5 mm drill. 3-0 Atraumatic Vicryl sutures (Ethicon Inc., OK, USA) were passed through to pull the graft in place at the time of screw fixation. After harvesting the graft, all soft tissue, patella and tibia were resected. The femoral tunnel was drilled over a Kirschner wire with a cannulated 10 mm drill, using a standard eleven o' clock placement for the right knee and a one o' clock position for the left knee, with a posterior wall thickness of 1 mm. Bone blocks were made to fit using a 10 mm diameter metal sizing tube and rongeur. The bone block was placed within the tunnel with the cortical side of the graft facing posteriorly. The 7 x 25 mm metal interference screw (Smith & Nephew, MA, USA) was used for graft fixation in the femoral tunnel. The position of the bone block and interference screw in the bone tunnel was flush to the femoral intercondylar fossa.

Biomechanical testing

Failure load measurements were performed on the cadaver femurs after ACL reconstruction. Tensile testing was carried out using an Instron distraction machine (Testometric 250-2.5AX, Instron Corp., MA, USA). The specimen was cut at approximately 25 cm above the knee joint. The femur was positioned in the testing system so that the pulling force was parallel to the long axis of the graft. To achieve such a position the femoral condyles were independently adjustable in the horizon-

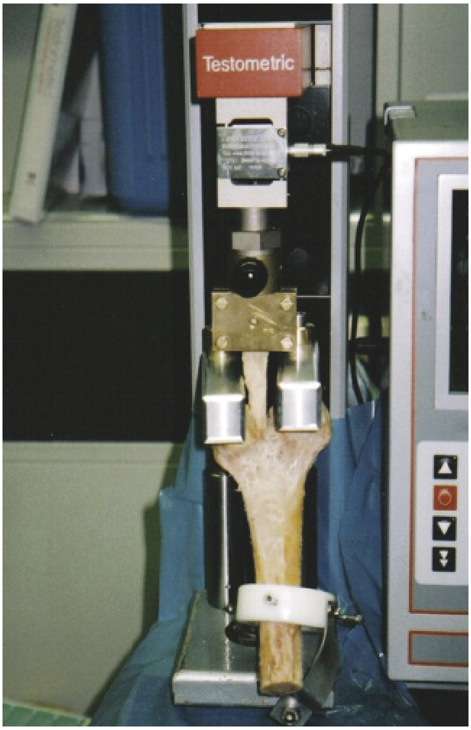

Figure 1 Tensile testing set up showing adjustability of femoral condyles

tal and vertical plane (Figure 1). The distal end of the graft was fixed in a clamp with small dents assuring firm grip on the tendon. The anterior cruciate ligament was placed under an increasing tensile load with a velocity of 1mm/s. Measurements were performed to establish maximal stiffness, ultimate failure load and mode of failure of the patellar tendon grafts.

Statistical analysis

The Mann-Whitney test was used to detect statistically significant differences in failure load between 10 mm and 20 mm bone blocks in each cadaver. Significance was set at $p < 0.05$. Data is presented using median value and range.

RESULTS

Stiffness

Median stiffness was 72 N/mm (16 - 103) for 10 mm bone blocks and 91 N/mm (40 - 130) for 20 mm blocks. This difference was not statistically significant ($p=0.34$) (Table 1).

Table 1. Stiffness of BPTB graft complex.

Cadaver	Stiffness of 10 mm bone block graft complex (N/mm)	Stiffness of 20 mm bone block graft complex (N/mm)
1	55.0	122.3
2	72.1	130.2
3	16.3	39.9
4	102.9	91.1
5	92.8	84.6
Median	72.1	91.1

Failure load

Median failure loads were 402 N (87 - 546) for 10 mm long bone block and 456 N (163 - 636) for 20 mm bone block without statistical significant difference (p=0.35) in graft failure load between both group (Table 2).

Table 2. Failure loads of BPTB grafts.

Cadaver	Failure load 10 mm bone block (N)	Failure load 20 mm bone block (N)
1	402.3	556.7
2	466.1	635.6
3	86.7	162.7
4	545.6	422.7
5	365.1	455.5
Median	402.3	455.5

Failure mode

All bone-patellar tendon-bone grafts failed at the graft-femoral complex. All grafts were pulled out with screw and bone block together. All bone-tendon junctions remained intact.

DISCUSSION

As 20 mm bone blocks are regularly used, we tried to reduce this to 10 mm. Our study shows no difference in failure load if we shorten the bone block by half in femoral fixation with interference screw. We have chosen for the comparison of two different lengths in bone block, since there is no known research on this topic in human cadavers. In both groups failure was by slippage of bone block and interference screw together. In contrast to many studies, human cadaver bone was used instead of porcine or bovine bone. We chose human bone, which is hard to come by, which resulted in a small population of higher age than the average patient undergoing an ACL reconstruction.

A clear example is our own cadaver number 3, showing considerably weaker fixation and lower failure loads in the ACL construct. The use of elderly human cadaver bone has previously been criticised by Brown et al. who showed significant differences in interference screw fixation between young and elderly human cadaver femora [2]. Still, human cadaver femora are used for biomechanical testing of ACL-reconstruction [2,5]. Our results resemble failure loads found in those studies.

Secondly, these cadavers were embalmed in formaldehyde. Formaldehyde fixation of bovine bone showed almost unaffected results in loading tests [8,29]. Nevertheless there was a decrease in the impact strength of the bone. Aforementioned factors may lead to lower values in this study than actual fixation strength in the clinical situation.

Force was applied parallel to the long axis of the graft and its tunnel. Tensile loading in this manner mimics a worst-case scenario because it is the easiest position to pull out the graft. When pulled out under an angle, failure loads tend to be higher [24]. This would be the case when a new event happened to a patient with an ACL reconstruction.

There is a noticeable drop in the stiffness and failure load of cadaver number 3 in both the 10 as the 20 mm bone block. This difference is probably due to high age and more so to the low quality of the bone. Excluding this cadaver from the study would result in overall higher forces in both groups, but it also confirms that failure load depends more on bone quality in general, than on bone block length.

Rupp et al. measured an ACL load of 128±15 N at passive and 219±25 N at active extension of the knee [23]. Initial fixation strength of the graft should greatly exceed these values to make safe rehabilitation possible during the first six weeks. Many studies and reviews on ACL reconstruction have been published and up until now bone-patellar tendon-bone and hamstring tendon graft have shown comparable results, where interference screw fixation is superior or equal to other fixation devices for initial fixation strength in BPTB ACL reconstruction [22].

The stiffness we measured is less than that of Zantop et al. and Weimann et al. (207.2±137.5 and 168±42 respectively) [27,28]. A possible explanation for these differences is the fact that both studies pulled their grafts from fresh (frozen) bovine tibia and used cross-pin fixation.

Our study shows comparable fixation strength of both bone block sizes. The failure loads are comparable to other studies with interference screw fixation [2,4,12,18]. This finding gives surgeons the freedom to still use a, per-operatively, fractured bone block instead of converting to contra-lateral harvesting of a second graft.

We can conclude from this study that a 10 mm long bone block is not significantly weaker than a 20 mm long bone block. Fixation strength of a 10 mm bone block exceeds loading values at passive and active extension of the knee. Our study shows it would be safe to clinically evaluate the use of smaller, shorter bone blocks, or accept intra-operative bone block fracture resulting in 10 mm length blocks.

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Chapter 6

Stiffer fixation of the tibial double-tunnel anterior cruciate ligament complex versus the single tunnel: a biomechanical study

Duncan E. Meuffels, M.D., Pieter T. Docter, M.Sc., Roland A. vanDongen, M.Sc., Gert-Jan Kleinrensink, Ph.D., Jan A. N. Verhaar, M.D., Ph.D., and Max Reijman, Ph.D.

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ABSTRACT

Purpose: The primary objective of this study was to evaluate the difference in graft pullout forces, stiffness and failure mode of double bundle anterior cruciate ligament (ACL), reconstruction of the tibial insertion by use of a single tunnel, compared to a double tunnel technique with interference screw fixation.
Material and methods: ACL reconstruction on the tibial site was performed on 40 fresh frozen porcine knees (mean bone mineral density of 0.64 g/cm^2 measured by dual-energy x-ray absorptiometry scan), randomly assigned to the single or double tunnel group. Interference screw fixation of the soft tissue graft was used for both types of tibial reconstruction. Maximum failure load, stiffness and failure mode were recorded.
Results: There was no significant difference in maximum failure load between the single (400± 26 N) and double tunnel group (440± 20 N).
Stiffness of the tibial tunnel complex was significantly higher in the double tunnel group (76± 3 N/mm) compared to the single tunnel group (62± 4 N/mm) (P-value of 0.013).
All but two (38 of 40) grafts failed by slippage of the tendon past the interference screw. Conclusions: There was a significantly stiffer fixation of the tibial double tunnel ACL complex when compared to the single tunnel. Our study did not show a different failure mode in the double tunnel reconstruction compared to the single tunnel reconstruction.
Clinical relevance: The present study shows a biomechanical advantage with no potential deleterious side effects to fixate the ACL with a double tunnel technique on the tibial side.

INTRODUCTION

The anterior cruciate ligament (ACL) is composed of 2 functional bundles, the anteromedial (AM) and the posterolateral (PL) bundle.[1] Reconstructive surgery of the ACL restores one bundle, primarily the AM bundle. Recently it has been hypothesized that reconstructing both the AM and PL bundles of the ACL (double-bundle reconstruction) can improve knee kinematics in comparison to the single-bundle technique.[2, 3] Theoretically, double bundle reconstruction has the advantage of giving the knee a more anatomic repair and increasing stability by diminishing pivot shift.[2, 3] The technique used most often for a double bundle ACL reconstruction consists of two tibial tunnels and two femoral tunnels.[2, 4] The ACL reconstruction is performed using a soft tissue graft most often the ipsilateral semitendinosus and gracilis. There is, however, no consensus on the exact double bundle technique. Some authors used one tibial tunnel combined with two femoral tunnels, others used two tibial tunnels with one femoral tunnel or one femoral tunnel combined with another femoral bundle in an over the top position. [4]

Many aspects of double bundle technique are still unknown. It is unknown if two tibial tunnels will give a different mode of failure from a single tunnel technique. Two tunnels, in close relation to each other, could cut through the metaphysis leading to a higher fracture risk.[5] Specific maximum failure loads and stiffness of double bundle tibial fixation using a two tibial tunnel technique with interference screw fixation are not known yet. This is important because the tibial-graft attachment is considered the weakest link in an ACL reconstruction because, the forces are more parallel to the tibial drill hole [6, 7] than at the femoral attachment and the bone quality of the tibial metaphysis is inferior to that of the femur. [7-9]

Therefore, our study was aimed at tibial fixation in double bundle ACL technique. The primary objective of this study was to evaluate the difference in graft pullout forces, stiffness and failure mode of double bundle ACL reconstruction of the tibial insertion using a two tibial tunnel technique compared to a single tunnel ACL reconstruction with interference screw fixation. Our hypothesis was that the maximum failure load is higher in the double bundle ACL reconstruction, using a two tibial tunnel fixation technique, compared to the single tunnel ACL reconstruction, possibly because of more screw volume and graft resistance.

MATERIALS AND METHODS

Specimens

We used 40 fresh-frozen intact porcine knees. They were harvested immediately after death (<4 hours) from 20 animals not used for musculoskeletal studies. All animals were female and weighed approximately 50 kg. The freshly harvested porcine knees were dissected in the joint line of the hip and stored at -21°C in double, sealed plastic bags. Specimens were thawed before preparation by placing them at room temperature (18°C) for 20 hours. Preparation was done by dissecting all soft tissues from the tibia. Flexor digitorum profundus and flexor digitorum superficialis tendons were harvested from the same porcine hindquarters to be used as ACL autografts. Flexor digitorum profundus and flexor digitorum superficialis were used because previous studies have demonstrated that the material properties of the flexor digitorum profundus tendons are similar to the human patellar tendon and hamstring tendons, respectively. [10-14] Throughout the preparation and the experiment the flexors were kept moist with 0.9% saline. The left and the right knee from the same porcine were randomly assigned into two study groups of 20 specimens each. Group 1 underwent a tibial single tunnel ACL reconstruction; group 2 underwent a tibial double tunnel ACL reconstruction.

Reconstruction procedure

Single tunnel reconstruction procedure

For the single tunnel reconstruction the looped flexor digitorum profundus and the single stranded flexor digitorum superficialis were combined to form the ACL graft. They were whipstitched using 1.0 vicryl (Ethicon, Johnson & Johnson, Somerville, NJ, U.S.A.) into a 3-strand graft. Using a tibial aiming device (Acufex, Smith & Nephew, Andover, Ma, U.S.A.) the k-wire was positioned in the footprint of the ACL. An 8 mm cannulated drill was used to create the tibial tunnel. The graft was prepared to fit the 8 mm diameter tunnel and was fixed using a non-resorbable interference screw with a length of 25 mm and a diameter of 9 mm (Smith & Nephew, Softsilk, Andover, Ma, U.S.A.). The graft was tensioned by hand at an estimated tension of 80 Newton.

Double tunnel reconstruction procedure

For the double tunnel ACL reconstruction, the looped flexor digitorum profundus was used as a 2-strand graft for the AM bundle and the flexor digitorum superficialis was used as a single strand graft for the PL bundle. They were whipstitched using 1.0 vicryl (Ethicon, Johnson & Johnson, Somerville, NJ, U.S.A.). The flexor digitorum profundus and flexor digitorum superficialis were prepared to fit respectively an

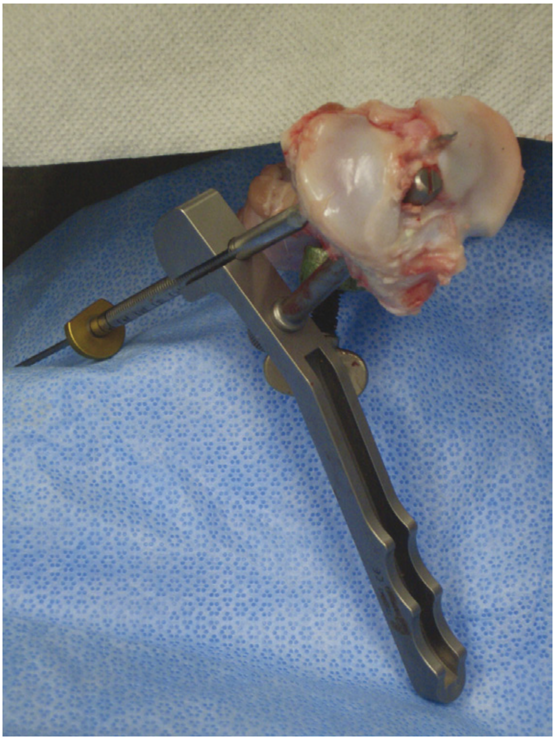

Figure 1. Porcine right tibia with aiming device in situ. 8 mm rod in position of the anteromedial insertion of the ACL and k-wire centrally positioned in posterolateral ACL footprint.

8 and 6 mm tunnel. An anatomic double tunnel was created in the tibia with the use of the double tunnel-aiming device (Smith & Nephew, Andover, Ma, U.S.A.). The more anteriorly located AM tunnel was drilled first similarly to the single tunnel technique. The aiming device was then positioned in this AM tunnel and subsequently a k-wire was placed at the PL tunnel position and over drilled with a 6 mm cannulated drill. The use of the aiming device ensured a 2 mm bridge between the two tunnels (Figure 1). The 8 mm AM bundle was fixed using a 9 mm non-resorbable interference screw (Smith & Nephew, Softsilk, Andover, Ma, U.S.A.). The 6 mm PL bundle was fixed with a 7 mm non-resorbable interference screw. Both grafts were tensioned by hand at an estimated tension of 80 Newton. All screws had a length of 25 mms. One orthopaedic surgeon (DM) performed all the single and double tunnel reconstructions.

Measurements

Dexa scan

Before preparation a dexa scan (Lunar DPX-L X-Ray Bone Densitometer, GE Healthcare, Buckinghamshire, England) was made to measure bone mineral density

(BMD). The region of interest (ROI) in our study was at the fixation site, the proximal part of the metaphysis of the tibia. All knees were positioned in the same way, supine in a holder, so the ROI was exposed. BMD was expressed in g/cm^2.

Testing protocol

Biomechanical testing was done using a tensile testing machine (Testometric 250-2.5AX, Instron Corp. Norwood, MA, USA). The tibia was positioned in the testing system in a specially designed testing device (Figure 2). The proximal ends of the grafts were fixated in a clamp to ensure a secure fixation of the specimens to the testing machine. In the single tunnel group, forces were applied in the axis of the bone tunnel (0 degrees); this transfers the greatest force to the fixation point. Zhang et al. [12] reported that the maximum load to failure would be overestimated when the angle of pullout is not as close as possible to 0 degrees. The double tunnel group was tested in an approximated worst-case scenario, which we tried to achieve, by using our customized apparatus that enabled the displacement vector to be applied in direct alignment with a vector made by the double tunnels, thus resembling our

Figure 2. Adjustable testing set up of distraction machine with tibial graft complex fixated.

single tunnel set up.[15] The ACL was placed under an increasing axial load by distraction at 1mm/sec. [16] Loading experiments were performed at room temperature (18°C). Measurements were performed to establish the maximum load to failure (N), stiffness (N/mm) and mode of failure. Stiffness was calculated at the steepest point in the force-displacement curve before maximum failure load. The mode of failure was recorded visually during testing.

Statistical analysis

Statistical analysis was done using the SPSS 15.0 software package (SPSS Inc, Chicago, Ill). First it was established whether the variables had a normal distribution, using the normality Kolmogorov-Smirnov test. Based on this analysis the results are presented as means (standard error of mean). The differences between the groups were tested by the independent samples T-test. The significance level was set at $P < 0.05$. Correlation between BMD and maximum failure load was investigated by assessing the Pearson's correlation coefficient.

Group size calculation

We performed a pilot study with ten cadaver knees randomly assigned to single or double tunnel. Maximum failure load for the single tunnel gave a mean of 518 N (S.D. 281) versus 689 N (S.D. 77) for the double tunnel group. To detect such a difference ($\alpha = 0.05$ and a power of 80%) we needed 12 cases per group.

RESULTS

Maximum Failure load and stiffness

The double tunnel reconstruction had a higher maximum failure load compared to the single tunnel reconstruction, this was, however not statistically significant (Table 1).

Stiffness of the tibial tunnel complex was significantly higher in the double tunnel group compared to the single tunnel group (P-value 0.013)(Table 1).

Table 1. Results of maximum failure load and stiffness

	Single tunnel (n=20)	Double tunnel (n=20)	P-value
Maximum Failure Load (N)	400 ± 26	440 ± 20	0.230
Stiffness (N/mm)	62 ± 4	76 ± 3	0.013

Values are presented as means ±standard error of mean.

Failure mode

Analysis of the failure modes showed that all 20 specimens in the double tunnel group failed by graft pullout. In the single tunnel group 18 (90%) specimens failed by graft pullout and two (10%) by fracture of the tibia plateau. In 38 of the 40 (95%) specimens the screws did not move from the initial position in the bone tunnel. We did not observe graft damage by the titanium interference screws.

Tibial bone density

The mean BMD (±standard error of mean) for the single tunnel porcine tibia group was 0.624 ± 0.013 g/cm^2, versus 0.649 ± 0.018 g/cm^2 for the double tunnel group. There was no statistical significant difference between the two groups (P-value of 0.269).

There was no significant relation between BMD and the maximum failure load (R^2 = 0.0257).

DISCUSSION

Using a Testometric distraction machine, we investigated the difference between maximum pullout strength and stiffness in a single tunnel versus double tunnel ACL reconstructed with interference screw on the tibia. We measured a significantly higher stiffness in the double tunnel porcine group compared to the single tunnel porcine group. This is in accordance with a recent study by Papachristou et al, which compared anterior translation ACL graft failure fixed to a post with either screw or button.[17] Based on our results we concluded that the resistance to elongation in the double tunnel group is higher compared to the single tunnel group. This could have a clinical advantage in favor of the double tunnel reconstruction, as this stiffness more closely resembles the stiffness of the intact ACL.

The maximum failure load in the double tunnel group was not significantly higher than the single tunnel group.

Bartz et al and Rupp et al reported loads of 250 N during an aggressive rehabilitation. [18, 19] We found 3 cases in our study that had a maximum failure load of less than 250 N. All these three cases were found in the single tunnel group.

The analysis of the failure modes in the present study showed that, by far, most reconstructions failed by graft pullout. This result suggests that the fixation between hamstring graft and the screw is the weakest link in an ACL reconstruction. Our study did not show a different failure mode in the double tunnel reconstruction compared to the single tunnel reconstruction.

A potential determinant of a lower pull out strength is a low BMD. Therefore BMD was assessed before randomization. Within the present study we did not find a correlation between BMD and maximum pullout strength.

Our maximum failure load and stiffness are lower than some other porcine studies show.[5, 15, 20] This difference could be explained by the direction of the extraction force, testing protocol which in the study of Lehmann et al was at a 90^0 angle with the femoral tunnel;[5] and possible by the difference in tibial versus femoral bone qualities. Our study was performed in a worst-case scenario by pulling parallel to the graft tunnel complex in a screw fixation of cancellous tibial bone. The higher stiffness and maximum failure strength in the hybrid fixation, with an added extra-cortical fixation of the tibial graft tunnel complex emphasizes that the weakest link of the ACL reconstruction is the cancellous tibial fixation.[20]

Our study has some limitations; we used fresh frozen porcine knees instead of testing with fresh young human anatomic specimens. The assumption is that porcine knees are comparable to human knees because maximal failure loads appear to be similar. [21, 22] In our study porcine knees were used, because they are more easily obtained than human fresh frozen specimen, free from disease and the porcine model is a well known and accepted model for pullout studies.[23] Fresh frozen preservation has no deleterious effect on the mechanical properties of the tendons or bones. [7, 24, 25]

Our testing protocol did not include cyclic loading testing. To approximate the worst-case scenario as close as possible, the testing protocol was aimed at the testing of the per-operative situation through a uniaxial, single cycle load to failure test. Thus resembling unexpected loading events such as that associated with the loss of balance or a fall.[24] Cyclic loading would have had the advantage of considering the cyclic behavior of the graft-fixation construct and allowing one to determine how changes may occur immediately postoperatively.[24] Previous testing protocols with cyclic loading excluded specimens which failed during cyclic loading.[26] We chose not to, accepting a possible lower stiffness and maximum failure load.

Although forces in the single tunnel group were applied parallel to the bone tunnel, referred to as the worst-case scenario in our double tunnel group, the forces were only applied in alignment with the displacement vector of the double tibial tunnel. This may have resulted in a limited overestimation of the maximum failure load in the double tunnel group. [12]

Forty porcine double bundle anterior cruciate ligament tibial reconstructions with interference screw fixation were performed. They were randomized for single or double tibial tunnel reconstruction. Biomechanical testing showed an increased, but not significantly higher, maximum failure load for the double tunnel technique. There were, however, three cases in the single tunnel group, with a maximum failure load less than would be appropriate for an aggressive rehabilitation. Both groups were similar in mode of failure on the tibial fixation side.

CONCLUSION

There was a significantly stiffer fixation of the tibial double tunnel ACL complex when compared to the single tunnel. Our study did not show a different failure mode in the double tunnel reconstruction compared to the single tunnel reconstruction.

The present study shows a biomechanical advantage with no potential deleterious side-effects to fixate the ACL with a double tunnel technique on the tibial side.

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Chapter 7

Visualisation of Post-Operative Anterior Cruciate Ligament Reconstruction Bone Tunnels. Reliability of Standard Radiographs, CT Scans and 3D Virtual Reality Images

Duncan E. Meuffels MD[1], Jan-Willem Potters MSc[1], Anton H.J. Koning PhD[2], Charles H. Brown Jr MD[3], Jan A.N. Verhaar MD PhD[1], Max Reijman PhD[1]

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[1]Department of Orthopaedic Surgery, [2]Department of Bioinformatics, Erasmus MC, University Medical Center Rotterdam, The Netherlands. [3]Abu Dhabi Knee and Sports Medicine Center, Abu Dhabi, United Arab Emirates.

ABSTRACT

Background and purpose: Non-anatomic bone tunnel placement is the most common cause of a failed ACL reconstruction. Since bone tunnel placement is such an important factor in the success and outcome of ACL reconstruction, accurate and reproducible methods to postoperatively visualize and document bone tunnel placement would be helpful in assessing patient outcomes. The objective of this imaging study was to post-operatively evaluate the reliability of standard radiographs, CT scans, and a three-dimensional (3D) virtual reality (VR) approach in visualizing and measuring ACL reconstruction bone tunnel placement.
Methods: Fifty consecutive patients who underwent single-bundle ACL reconstructions were evaluated post-operatively by standard radiographs, CT scans and 3D VR images. Tibial and femoral tunnel positions were measured by two observers using the traditional methods of Amis, Aglietti, Hoser, Staubli, and the method of Benereau for the VR approach.
Results: The tunnel was visualized in 50 - 82% of the standard radiographs versus 100% in the CT and the 3D VR images . Using the intraclass correlation coefficient (ICC) the inter- and intraobserver agreement was between 0.39 and 0.83 for the standard femoral and tibial radiographs. CT scans showed an ICC range of 0.49-0.76 for the inter- and intra observer agreement. The 3D VR agreement was almost perfect with an ICC of 0.83 for the femur and 0.95 for the tibia.
Interpretation: CT scans and 3D VR images show more reliability than standard radiographs in assessing postoperative bone tunnel placement following ACL reconstruction.

INTRODUCTION

Reconstruction of the anterior cruciate ligament (ACL) is one of the most commonly performed orthopaedic surgical procedures. The failure rate for ACL reconstruction has been reported to be between 11 – 30% .[12,22] Non-anatomic bone tunnel placement has been reported to be the most common cause of a failed ACL reconstruction.[12,22] Although the anatomic attachment sites of the ACL have been well described, the optimal bone tunnel placement for ACL grafts remains controversial. However, current surgical practice focuses on placing the bone tunnels within the anatomic insertion sites of the native ACL (anatomic placement). Given the importance of bone tunnel placement to the success of the procedure, radiographic methods of postoperatively assessing bone tunnel placement would be helpful in documenting postoperative outcomes.

Recent studies have validated the use of 3D CT scans and MRI to postoperative evaluation of ACL bone tunnel placement.[1,8] These studies have questioned the reliability of conventional standard two-dimensional x-ray images to evaluate ACL bone tunnel placement.[8] The standard reference in orthopaedic practice for ACL tunnel position measurement has been postoperative anterior-posterior and lateral radiographs. Several methods have been proposed so far in an attempt to standardize and systematize radiological measurements.[2,3,7,10-12] Standard postoperative radiographs are quick, simple, cheap, readily available, and subject the patient to a minimal dose of ionizing radiation. They can detect problems with implant positioning and they help evaluating loss of motion and recurrent laxity, which may influence postoperative rehabilitation. Magnetic resonance imaging (MRI) is a good imaging modality to directly visualize the ACL graft.[15,16] However, there have been no studies looking at the reliability of MRI scans to document bone tunnel placement following ACL reconstruction. Recently a new 3D viewing and measurement method has been developed for visualization of the ACL reconstruction. This method uses CT data and an immersive virtual reality system. The objective of this diagnostic imaging study was to evaluate the reliability of standard radiographs, CT scans and a 3D VR approach to postoperatively evaluate ACL bone tunnel placement.

MATERIALS AND METHODS

We prospectively evaluated fifty consecutive patients that underwent a primary ACL reconstruction in the period from January 2007 until May 2008 (trial number ISRCTN 40231111). The inclusion criteria were, patients eligible for ACL reconstruction, with a minimum age of 18 years. Exclusion criterion was an insufficient grasp of the Dutch or English language. The average age of the fifty patients was 27.0 (± 6.9 SD) years. Seventy-six percent of the patients were male, and 24% were female. The reconstructed ACL side was equally distributed among left and right knees. Patients gave written consent and permission to participate in the study and Institutional approval for the study was granted by the Medical Review Board of our Institute. The ACL reconstruction was performed using an arthroscopic, single-incision, single-bundle, transtibial surgical technique using either bone-patella tendon- bone (BPTB) or a looped semi-tendinosus, gracillis autograft. The femoral and tibial bone tunnels were positioned within the native anatomic ACL footprint. ACL reconstructions performed, using a BPTB graft, were fixed on both sides using a resorbable interference screw (BIORCI, Smith & Nephew, Andover, MA). Hamstring ACL reconstructions were fixed using an extra-cortical button technique (Endobutton, Smith & Nephew, Andover, MA) on the femoral side and a resorbable interference screw on the tibial side (BIORCI, Smith & Nephew, Andover, MA).

Imaging

Standard radiographs were taken six weeks post-operatively when the patient was able to fully weight bear and fully extend the knee. The AP radiograph was taken with the patient bearing full weight on the operative knee. The lateral radiogram was taken with the knee in extension with an optimal overlay of the femoral condyles.

A 64 channel multi-slice technology CT scanner (Somatom, Siemens Medical Solutions, Forchheim, Germany) with helical acquisition in 1.0 mm sections was used (120 kV, 160 mAs, rotation time 1.0 s) to perform CT scans. The knee CT imaging was performed from the top of the suprapatellar collection to the superior tibial and fibula diaphysis, one day post-operatively.

Measurements

Measurements were performed digitally on all radiographs and CT slices. For all radiographic measurements it was first established if the bone tunnel was visible on the radiograph or not. A tunnel was only rated visible if the tunnel and the necessary points to carry out the measurement were visible. The following radiological measurements were performed on each radiograph. In the AP image we measured the femoral tunnel according to Hoser et al. and the position of the tibial tunnel was measured as a percentage of the total tibial width from medial to lateral.[11] These two measurements were also performed on coronal CT reconstructions (Figure 1 and 2).

On the lateral radiograph the method of Aglietti et al. and Amis et al. was used to measure the femoral tunnel position (Figure 3a,b).[2,3] On the sagittal CT images the femoral tunnel was measured by the method of Aglietti (Figure 3c), since the Amis

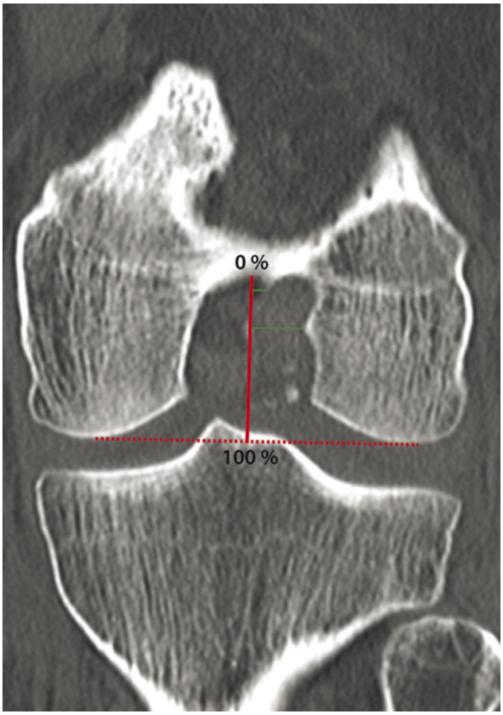

Figure 1. Measurement performed according to Hoser of the femoral tunnel on the coronal CT reconstruction. The tunnel is measured in comparison to the line perpendicular to the most distal points of the femoral condyles. The measurement is compared to the line from the intracondylar roof to the distal femoral condyles.

Figure 2. Medial-lateral measurement in the coronal CT reconstruction of the tibial tunnel. The tunnel measurement is compared to the line through the most medial and lateral part of the tibiaplateau.

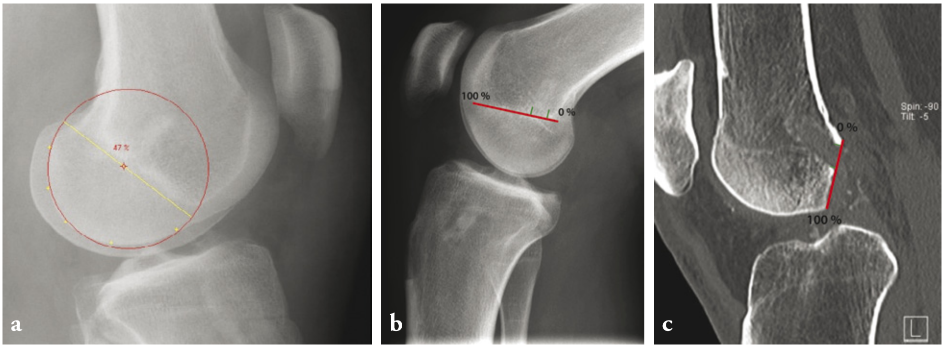

Figure 3a. Lateral view of the lateral femurcondyle with the method of Amis. The yellow dots are the user-defined edges of the posterior femoral condyle. A circle is automatically fitted on to the dots and can be rotated, in such a way that the diameter is parallel with Blumensaat's line. **b.** Lateral view of the lateral femurcondyle with the method of Aglietti. Aglietti compares the tunnel measurement with a line parallel to the most posterior and anterior part of Blumensaat's line. **c.** Measurement according to Aglietti on the sagittal femoral CT reconstruction.

method is not feasible because Blumensaat's line and the femoral condyles are never in one sagittal CT slice. The tibia tunnel position was measured as a percentage of the anterior to posterior tibia diameter in both the standard radiograph and CT images according to method of Stäubli et al. (Figure 4).[19]

Measurements were performed on blinded images in such a way that each method was performed in a random order for all patients before starting with another method. This protocol avoided the possibility that the observer could use the information from one measurement method in another method. Two observers carried out all measurements, independently. The experience of the observers with

Figure 4. Measurement according to Stäubli on the sagittal tibial CT reconstruction. The tibial tunnel aperture is compared to the line parallel to the joint line, through the most anterior and posterior points of the intracondylar tibia plateau.

interpreting ACL reconstruction positioning images ranged from none with the 3D VR system to more than twelve years with the standard radiographs. After six weeks, all measurements were performed a second time by one observer to calculate intra-observer reproducibility. In the second sequence of CT measurements, the observer had to decide again on which slide to perform the measurement.

3D virtual reality measurements

In addition to the traditional two-dimensional measurements, measurements were performed using an I-Space immersive virtual reality system (I-Space, Barco N.V., Kortrijk, Belgium). Measurements were performed in 3D, similar to the triangle method by Benareau (Figure 5).[6] The 3D VR approach uses a four-sided immersive virtual environment where, with the aid of eight projectors and polarizing glasses, the bony structures are projected as free floating three dimensional objects in the room. The system uses the V-Scope direct volume rendering software developed at our institute, and high resolution CT scans to visualize the bones.[14] Using a wireless joystick, it is possible to rotate the bones in three dimensions and point out distinctive points on the bony structure with a precision of 1/10th of a millimeter.[20]

Statistical analyses

The intraclass correlation coefficient (ICC) was calculated using the percentages of the different measurements. The calculation of the ICC is based on an analysis of variance (ANOVA) model. The first source of variance is the difference between the patients we measured. The second source of variability is the variance among the observers. The ICC calculations that were performed used the two-way mixed

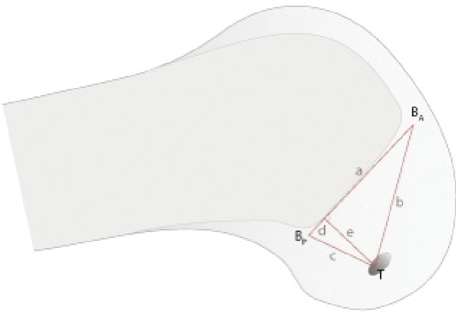

Figure 5. View of the lateral femurcondyle. The red triangle is used in the 3D visualization technique calculations. a = line equal to Blumensaat's line, B_A = Most anterior point of Blumensaat's line. B_P = Most posterior point. T = Tunnel entrance, e = is the line perpendicular to a from the tunnel entrance. Line b and c are the lines connecting T with respectively B_a and B_p, this makes it possible to calculate the length of d and this will give a percentage of the AP positioning of the tunnel position on the Blumensaat line comparable to Aglietti's method

model for absolute agreement. The ICC can be expressed on a scale from zero to one, where zero expresses disagreement and one is perfect agreement. A score of 0.7 and higher is generally considered as good, within reliability studies.[17] We used Chi-Square to determine difference in radiographic visibility of the tunnels between the graft types.

RESULTS

Tunnel visibility

Table 1 shows tunnel visibility for standard X-rays of the knee and CT post-operatively. CT allowed visualization of the femoral and tibial tunnels in both the AP and lateral planes in all cases, visualization was less for the standard X-rays. It is significantly more difficult to visualize the femoral tunnel 26/50 (52%) than the tibial tunnel 41/50 (82%) (P-value of 0.01). Femoral tunnel visibility was significantly lower in the ACL reconstruction with hamstring 4/16 (25%) versus BPTB 22/34 (65%) on the lateral knee X-ray (P-value of 0.01).

Table 1. Tunnel visibility of Standard X-ray and CT in two planes, for tibia and femur.

	AP direction	Lateral direction
X-ray Femur	**50%** (25/50)	**52%** (26/50)
X-ray Tibia	**94%** (47/50)	**82%** (41/50)
CT Femur and Tibia	**100%** (50/50)	**100%** (50/50)

Interobserver reliability

In the AP radiograph, the ICC of the femoral method was 0.39 and of the tibia 0.43. On the lateral radiograph, the method of Amis gained the highest ICCs. Amis' method yielded 0.62 versus 0.53 for Aglietti's. The ICC for the tibial position on the lateral radiograph was 0.53.

The CT provided higher ICCs compared to the radiographs. The femur in the coronal plane was the lowest (0.49). The ICC of the tibia in the coronal plane (0.76) was considered good. The ICC of the femur (0.71) and tibia (0.61) in the sagittal plane gave substantial agreement.

The 3D VR approach resulted in the highest interobserver ICCs of all methods: 0.83 for the femur and 0.95 for the tibia. The inter-and intraobserver agreement ICCs of the radiological measurements are shown in table 2.

Table 2: intraclass correlation coefficient (ICC)

		Inter-observer	Intra-observer
		ICC 95% confidence interval	*ICC* 95% confidence interval
AP Radiograph	Femur (Hoser)	**0.39** (–0.32 - 0.81)	**0.47** (–0.12 - 0.83)
	Tibia (med-lat)	**0.43** (0.12 – 0.66)	**0.43** (0.05 - 0.71)
Lateral Radiograph	Femur (Aglietti)	**0.53** (0.03 – 0.82)	**0.83** (0.50 – 0.95)
	Femur (Amis)	**0.62** (0.20-0.84)	**0.72** (0.23 – 0.92)
	Tibia (Stäubli)	**0.53** (0.21 – 0.75)	**0.82** (0.60 – 0.92)
CT coronal	Femur (Hoser)	**0.49** (0.25 – 0.68)	**0.60** (0.39 – 0.75)
	Tibia (med-lat)	**0.76** (0.27 – 0.90)	**0.90** (0.83 – 0.94)
CT sagittal	Femur (Aglietti)	**0.71** (0.47 – 0.84)	**0.87** (0.79 – 0.93)
	Tibia (Stäubli)	**0.61** (–0.05 – 0.84)	**0.63** (0.18 – 0.82)
3D Virtual Reality femur (Benareau)		**0.83** (0.70 – 0.90)	**0.85** (0.75 – 0.92)
3D Virtual Reality tibia (Stäubli)		**0.95** (0.92 – 0.97)	**0.96** (0.93 – 0.98)

Discussion

The 3D VR approach resulted in the highest ICCs and proved that measuring the complex anatomy of the knee anatomy can be carried out reliably. The existing methods, using standard X-rays, showed a significantly lower visibility, especially concerning the use of the hamstring graft. The inter- and intra observer agreement was, at its best, substantial. The CT showed optimal visibility, but only showed slightly better agreement, especially for the femur, because of its complex three-dimensional shape.

We elected to compare our findings with the previously described and commonly used measurements for tunnel placements in ACL reconstruction. There are limited studies that investigated the reliability of measurements and the best modality to assess the post-operative position of the ACL. There is only one study that determined the reliability of measurements on the lateral femur.[13] The authors reported an ICC of 0.68 with the method of Amis, but with fluoroscopic controlled placement before drilling a femoral tunnel. The ICC found is in concordance with our findings, where the method of Amis produced the best ICC (0.62) of the radiographs. Furthermore, only one study investigated the best modality.[11] It was concluded that there was no significant difference in the values of the tunnel position in the lateral femur measured in the radiograph and the CT. Based on our study, however, the CT is more reliable in the lateral femur measurements compared to the radiograph.

An additional measurement describing the ACL reconstruction is the use of the clock. The clock is a popular reference method for intra-operative positioning of the femoral tunnel and has been used in numerous studies, both clinical (Behrend et al.) and anatomical studies (Amis et al. and Giron et al..[3,5,9] The way of measuring the ACL reconstruction with the use of a clock has certain disadvantages, both per and postoperative with the aid of radiology. The disadvantages are that there is no standardized clock shape or position and it is very difficult to standardize the measurement, since there are a number of variables that influence the measurement. The variables to consider are: -1- the position of the knee and its flexion angle and coronal positioning, -2- the viewpoint of the observer and -3- the shape of the intercondylar space. Yoo et al. already proved that the use of the clock face in post-operative images is likely to suffer from errors due to viewpoint of the observer or the X-ray beam.[21] Due to these caveats we didn't include this method in our measurements.

An important implication is that, bearing in mind the relative low ICCs that the existing methods showed, one could argue that it is not reliable to accept or compare ACL graft positioning / tunnel placement from past articles using these methods.

Another shortcoming in the use of radiographs in post-operative measurements is the poor visibility, especially in the AP radiograph. We encountered a relatively low visibility rate compared to other articles. The reason for our low visibility rate is the use of the biological resorbable fixation screw, which is not radiopaque. The previous studies may have measured the metal interference screw position, which does not have to correlate with the actual tunnel or graft position. In addition, the time between the surgery and the radiograph was very short, so there were no sclerotic lines present, which could help to identify the tunnel position.

Regarding the imaging techniques that are already widely used in clinical practice, namely radiographs and CT scans, the CT scan produced more reliable measurements than the radiographs. However, one has to bear in mind that CT scans are more expensive and that the patient is exposed to a higher radiation dose. There has been a growing interest in visualizing the ACL insertions and their relationship to bony landmarks using high-resolution volume rendering CT.[4,18] This technique uses the same CT images as in our study, but visualizes and measures on a computer screen. This measurement, however, limits their measurements to the two dimensions of the viewed screen and makes it possibly more susceptible to positioning inaccuracies, as was shown in the moderate ICCs for our CT measurements.

Based on our study, this 3D VR approach is the most reliable system for performing measurements on the reconstructed ACL. The possibility to visualize the bone from any desired perspective, opens many possibilities measuring other distances as well, and is a great enhancement in evaluating the anatomy. However, using virtual reality solutions to evaluate patients in clinical practice remains somewhat futuristic and this phenomenon has not yet been introduced in clinical practice. Drawbacks of an immersive virtual reality system are, for example, that the system is expensive and labor-intensive. At present, a tabletop VR system offering the same functionality is being developed to overcome some of the aforementioned disadvantages.

Tunnel visibility on standard X-rays directly post-operatively is poor. If the tunnel is visible the method of Amis is the most reliable for assessing the femoral tunnel position. Assessing the tunnel position by means of a CT scan and 3D virtual reality images produced better ICCs. CT scans and 3D virtual reality images are more reliability in assessing post-operative bone tunnel placement following ACL reconstruction than standard radiographs.

Authors contribution

DM designed the study, performed the measurements and analyzed the data and wrote the manuscript. JP collected data and also performed the measurements and proofread the manuscript. AK assisted with the virtual reality data acquisition and proofread the manuscript. CB commented on and corrected the draft manuscript. JV supervised the analysis and proofread the manuscript. MR performed the statistical analysis and edited the manuscript

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Chapter 8

Computer assisted surgery for knee ligament reconstruction (Review)

Duncan E. Meuffels, Max Reijman, Rob JPM Scholten, Jan AN Verhaar

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ABSTRACT

Background: Anterior cruciate ligament (ACL) reconstruction is one of the most frequently performed orthopaedic procedures. The most common technical cause of reconstruction failure is graft malpositioning. Computer assisted surgery aims to aid graft placement.

Objectives: To assess the effects of computer assisted reconstruction surgery versus conventional operating techniques for ACL or posterior cruciate ligament (PCL) deficient knees in adults.

Search strategy: We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (October 2010), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 3), MEDLINE (1966 to March 2010), EMBASE (1980 to March 2010), CINAHL (1937 to March 2010), article references and prospective trial registers.

Selection criteria: Randomised controlled trials (RCTs) and quasi-randomised controlled trials that compared computer assisted surgery (CAS) of the ACL and PCL with conventional operating techniques not involving CAS, were included.

Data collection and analysis: Two authors independently screened search results, assessed risk of bias and extracted data. Where appropriate, data were pooled using risk ratios or mean differences, both with 95% confidence intervals.

Main results: Four randomised controlled trials were included (266 participants). All involved ACL reconstructions performed by experienced surgeons. Risk of bias assessment was hampered by poor reporting of trial methods. Pooled data from two trials showed no statistically or clinically significant differences at two years or more follow-up in self-reported quality of life outcomes: International Knee Documentation Committee (IKDC) subjective scores (mean difference 2.05, 95% CI -2.16 to 6.25) and Lysholm scores (mean difference 2.05, 95% CI -2.16 to 6.25). A third trial also found a minimal difference in IKDC subjective scores (mean difference = 0.2). Pooled data from three trials for normal or nearly normal IKDC knee examination grades at final follow-up showed no significant differences between the two groups (risk ratio 1.01, 95% CI 0.96 to 1.06). No significant differences were found for other objective measures of knee function. The only adverse effects reported were some loss in range of motion in two versus three participants in one trial. CAS use was associated with longer operating times (range 9.3 to 26 minutes).

Authors' conclusions: A favourable effect of computer assisted surgery for cruciate ligament reconstructions of the knee compared with conventional reconstructions could neither be demonstrated nor refuted. There is insufficient evidence to advise for or against the use of CAS. There is a need for improved reporting of future studies of this technology.

PLAIN LANGUAGE SUMMARY

Computer assisted surgery for knee ligament reconstruction

Injury to the anterior cruciate ligament (a centrally located ligament in the knee) is common in sports such as football and basketball. The operative reconstruction of this ligament is one of the most frequently performed orthopaedic procedures. It is very important to perform this operation accurately to obtain a satisfactory outcome. This review set out to examine the evidence for using an additional computer during the operation to help with the positioning of the new anterior cruciate ligament.

Four randomised controlled trials were included. These involved 266 participants aged between 14 and 53 years. All four trials involved anterior cruciate ligament reconstruction. We were unclear about the reliability of study findings due to poor reporting of methods. The trials found no important differences between computer assisted and conventional surgery for patient reported quality of life outcomes. Likewise there were no significant differences between the two treatment groups in the numbers with normal or early normal knee function. The only adverse effects reported were some loss in range of motion in two versus three participants of one trial. Computer assisted surgery resulted in longer operations.

The review concluded that there is insufficient evidence to advise for or against the use of computer assisted surgery in knee ligament reconstruction.

BACKGROUND

Description of the condition

The anterior and posterior cruciate ligaments (ACL and PCL) are located within the knee joint. These connect the femur (thigh bone) to the tibia (shin bone) and play a crucial stabilising role. The ACL restrains the anterior translation (forward movement) of the tibia relative to the femur. The PCL restrains posterior translation (backward movement) of the tibia relative to the femur. Both are also important for varus/valgus (sideward) and rotational stability of the knee joint during movement.

ACL injury is a common orthopaedic problem with an annual incidence of approximately 200,000 cases per year in the United States.[1] It often results from an abrupt change in direction or rapid deceleration during sports, typically football or skiing. As well as knee instability, an ACL rupture can give rise to recurrent complaints of the knee ‘giving way’ and pain, and result in discontinuation or limitation of sporting activities.[3,4,20] Although the natural history is not clearly defined, the ACL injury predisposes the knee to chronic instability and further damage, such as meniscal tears, with a consequent impairment to quality of life.[18] An ACL injury may also predispose to early osteoarthritis.[6,16,26] PCL injury is less common, comprising 1 to 20% of knee ligament injuries. This is most often sustained through a traffic accident (e.g. a dashboard injury) or after athletic trauma.[25] Complaints after a PCL injury can include instability or knee pain, especially patellofemoral, and a progression to a degenerative knee.[14]

Description of the intervention

An ACL rupture with recurrent instability is most often treated with a tendon graft reconstruction. The latter comprises reconstruction of the damaged ligament using a strip of tendon, often from the patient's knee (the patellar tendon or hamstring). In most cases, the surgery is done arthroscopically. The primary goal of surgery is to restore a stable knee without extra morbidity. Approximately 100,000 ACL reconstructions are performed annually in the United States.[1] PCL reconstruction is usually reserved for more complex knee injuries.[22]

Navigation systems have recently been introduced to surgery, including orthopaedic surgery.[28] These systems are known as computer assisted surgery (CAS) or computer assisted orthopaedic surgery (CAOS). The most common types use images acquired pre-operatively by fluoroscopic CT (computerized tomography) or intra-operatively by fluoroscopy (dynamic X-rays) or an image-free system using pre-specified anatomical landmarks. During surgery the CAS system uses infrared feedback, enabling orientation of the surgical instruments relative to the anatomical structures of interest. In cruciate ligament reconstruction CAS has the potential to optimise the preparation for grafting, which involves drilling into the femur and tibia to form a bone tunnel, and subsequent placement of the graft. The system also has the capacity to monitor femur and tibia positions and movements. With this information, stability and range of motion can be optimised.

For a clinically successful outcome, an accurate graft placement is essential. This is accomplished by an exact and reproducible tunnel placement. A malposition of the graft can lead to limited range of motion, impingement of and damage to the graft, instability and re-injury. The most common cause of technical failure of cruciate ligament reconstruction is the misplacement of the bone tunnel.[8,19]

How the intervention might work

CAS could possibly give a more reproducible ACL reconstruction with an exact bone tunnel placement, which is likely to improve the patient outcome, potentially by giving increased knee stability and lowering the risk of complications, especially those associated with limited range of motion, and knee discomfort. However, CAS requires an increased operating time, an extra investment for the necessary equipment and additional fixation of navigation probes to the patient's leg. As with every new development, using CAS will involve a learning curve for the surgeon. However, compared with traditional surgical techniques this may shorten the learning curve for the novice surgeon.[24]

Why it is important to do this review

Cruciate ligament reconstruction is a very common orthopaedic procedure. The pressure to implement technological advances is unrelenting. Thus it is important to systematically review the current evidence comparing the effects of computer assisted knee ligament reconstruction versus conventional surgery for the reconstruction of the ACL or PCL deficient knee.

OBJECTIVES

To assess the effect of computer assisted reconstruction surgery compared with conventional operating techniques for ACL or PCL deficient knees in adults.

To investigate possible effect-modification by the following: 1. The type of system used for CAS (e.g. intra-operative use of X-rays, pre-operative use of radiology (CT, MRI, X-rays), intra-operative landmarks or bone morphing (this is using data, for instance intra-operative acquisition of points on the bone surface, to compute the shape (geometrical features) of the bone to aid in surgical planning). 2. The type of ligament reconstruction: ACL or PCL, or both.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-randomised controlled trials (for example, allocation by hospital record number or date of birth) that compared CAS with conventional operating techniques.

Types of participants

Skeletally mature people undergoing reconstruction of the ACL, PCL or both ligaments. Studies involving a policy of surgical treatment of other concomitant soft-tissue knee injuries, such as meniscal tears, in the same operation as cruciate ligament reconstruction were also included, provided this applied to both groups.

Types of interventions
Reconstruction of the ACL or PCL, or both using either CAS or conventional techniques. There was no exclusion on the type of graft or the method of graft fixation.

Types of outcome measures

Primary outcomes

1. Validated self-reported health and quality of life measures
These could include, for example, SF36, the Tegner scale[27], Lysholm scale[13], International Knee Documentation Committee (IKDC) subjective part[12], the Cincinnati knee scales[21], Knee injury and Osteoarthritis Outcome Score (KOOS)[23] and the ACL Quality of Life outcome measure[18] .

2. IKDC Knee Examination Grade
International Knee Documentation Committee (IKDC) objective part.[9] The IKDC 2000 forms can be accessed at IKDC forms.

Secondary outcomes

Objective measures of knee function
These could include, for example, range of motion, static stability (measured by arthrometric (for instance KT 1000 or 2000) or other stability assessment devices, strength (Cybex muscle testing or equivalent).
Technical and anatomical outcomes
-Tunnel positions and positioning of the graft
-Development of radiological osteoarthritis
Adverse post-surgical events
-Re-rupture of the ACL
-Loss of knee motion
-Infection
-Venous thrombo-embolism
Measures of resource use
-Duration of surgery
-Radiological screening time
-Reoperation
-Formal economic evaluation

We assessed the effect of the interventions for the short term (within six months of ACL/PCL reconstruction), intermediate term (between six months and two years of ACL or PCL reconstruction) and long term (more than two years after ACL or PCL reconstruction).

Search methods for identification of studies

Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (October 2010), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2010 Issue 3), MEDLINE (1966 to March 2010), EMBASE (1980 to March 2010) and CINAHL (1937 to March 2010). There were no constraints based on publication status or language.

In MEDLINE (PubMed), the first two levels of the optimal trial search strategy were modified slightly and combined with the subject specific search.[10] The complete search strategy is shown in Appendix 1. The search strategies that were used in *The Cochrane Library* (Wiley Online Library), EMBASE (Embase.com) and CINAHL (Ebsco online) are also shown in Appendix 1.

We also searched the WHO International Clinical Trials Registry Platform Search Portal and the Current Controlled Trials Meta Register (both March 2010) for ongoing and recently completed trials.

Searching other resources

We searched reference lists of articles. The bibliographies of relevant papers identified were checked. Where appropriate and possible, the corresponding authors of studies identified by the search strategies were contacted to obtain other relevant studies not previously included for review.

Data collection and analysis

Selection of studies

Two review authors (DM and MR) independently assessed potentially eligible trials identified by the search *strategy.*

Data extraction and management

Two review authors (DM and MR) used pre-piloted data extraction forms to independently extract the data. They compared the data extracted for each study to achieve consensus. Any differences were resolved by discussion. In case of missing data, we contacted the trial authors.

Assessment of risk of bias in included studies
Two review authors (DM and MR) independently assessed the risk of bias of included studies using The Cochrane Collaboration's 'Risk of bias' tool.[11] For the item "blinding" we assessed blinding of 1) patient reported outcomes, 2) outcomes assessed by a physician and 3) radiological outcomes. Additional to the items from the five domains listed in the tool (sequence generation; allocation concealment; blinding; incomplete outcome data; selective outcome reporting), we also assessed the surgeon's experience with the techniques being compared.

Measures of treatment effect
For each study, risk ratios (RR) with accompanying 95% confidence intervals (95% CI) were calculated for dichotomous outcomes, and mean differences (MD) with 95% CI for continuous outcomes.

Dealing with missing data
We contacted trial investigators for missing data. Where appropriate, we performed intention-to-treat analyses to include all participants randomised to the intervention groups. We investigated the effect of drop outs and exclusions by conducting worst and best scenario analyses. If missing standard deviations could not be derived from confidence interval data or retrieved from the study authors, we did not impute standard deviations for the analyses.

Assessment of heterogeneity
The forest plots were visually examined for heterogeneity and the chi-squared test and I-squared statistic were considered.

Assessment of reporting biases
When sufficient studies were available, we planned to assess publication bias by examining a funnel plot. We tried to pursue trials listed in prospective clinical trial registers to help to assess publication bias. We compared the method description of the included studies with the actual reported outcome in the result section to establish outcome reporting bias.

Data synthesis
If the patients, interventions, outcomes and the timing of the outcome measurements were sufficiently similar, we pooled the results by the use of a fixed-effect model. In the presence of clinical or methodological heterogeneity, we used the random-effects model. For dichotomous outcomes we pooled risk ratios and mean differences for continuous outcomes. We planned to calculate standardised mean

differences for pooling data when an outcome was measured in different units or scales.

Subgroup analysis and investigation of heterogeneity

We planned, where appropriate, to explore heterogeneity by subgroup analyses by the type of lesion (ACL, PCL or both) and by CAS system used (CAS systems with or without preoperative use of fluoroscopy, or pre-operative use of radiological data as X-rays, CT or MRI). We also planned to test whether the subgroups were statistically significantly different from one another, using the test for interaction outlined in.[2]

Sensitivity analysis

We planned, where appropriate, to conduct sensitivity analyses to explore the effects of various aspects of trial and review methodology, including the effects of missing data, whether allocation was concealed, and surgeon's experience.

RESULTS

Description of studies

Results of the search

A total of 517 articles were retrieved from the search (EMBASE (326), MEDLINE (50), CINAHL (114) Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (9), CENTRAL (17), international registries of prospective randomised clinical trials and handsearches (1)). Of these, five reports of randomised clinical studies were found and subsequently evaluated (Chouteau 2008; Endele 2009; Hart 2008; Mauch 2007; Plaweski 2006). Two reports (Mauch 2007a and Endele 2009) appeared to involve the same participants, because these studies were performed at the same hospital in the same time interval, and are therefore considered as one study (Mauch 2007). The earlier report (Mauch 2007a) described 53 participants (24 treated with CAS and 29 with conventional treatment) and reported on X-ray visualisation of the tibial tunnel placement, whereas the second report (Endele 2009) involved 40 participants (20 in each group) and reported on MRI findings after a median of 24 months (range 22 to 26 months). One ongoing study (Meuffels) was identified (*see* the Characteristics of ongoing studies).

Included studies

We included four published studies (Chouteau 2008; Hart 2008; Mauch 2007;

Plaweski 2006), conducted respectively in single centres in France, Czech Republic, Germany and France. Details of each trial are shown in the Characteristics of included studies Cochrane library 2011, Issue 6.

Participants

The included studies reported data from a total of 266 participants (186 males and 80 females). Three studies (Chouteau 2008; Hart 2008; Plaweski 2006) included patients younger than 18 years of age. The ages of the trial participants ranged from 14 to 53 years. All studies concerned ACL reconstruction; no studies involved PCL reconstruction.

Interventions

All included trials compared computer assisted ACL reconstruction with conventional surgery. The studies differed, however, in the type of CAS used and in the techniques used for the conventional reconstruction. Chouteau 2008 tested the only CAS system that used intra-operative radiographic images to template the preferred femur and tibial tunnel placement. Both Hart 2008 and Mauch 2007 used the image free OrthoPilot (Braun-Aesculap) system to aid in selecting the femoral and tibial tunnel placement. The image free system of Surgetics using the Julliard protocol (Praxim) was used in Plaweski 2006.

All studies concerned arthroscopic reconstructions, using devices to aid in tunnel placement. The tibial aperture of the tunnel was chosen using a guided cannulated aiming device (Acufex) in two studies (Mauch 2007; Plaweski 2006). Mauch 2007 placed the tunnel at 7 mm and Plaweski 2006 at 6 mm anterior to the PCL on the tibia. Neither Chouteau 2008 nor Hart 2008 described the tibial tunnel placement in sufficient detail.

For the conventional femoral tunnel placement, Hart 2008 and Mauch 2007 planned the tunnel position by positioning the femur at 10.30 o'clock on the right side and 1.30 o'clock on the left side. Plaweski 2006 planned the femoral tunnel in a slightly more vertical position of the femur at 11 o'clock on the right side and 1 o'clock on the left side. Chouteau 2008 did not describe the type of femoral placement.

Plaweski 2006 used a four stranded hamstring autograft to reconstruct the ACL. The other included studies used bone-patella-tendon-bone (BPTB) autografts. A miscellaneous array of fixation techniques (press-fit, interference screw and extra-cortical fixation) were used.

Outcomes

In Chouteau 2008, outcomes were assessed at an average of 2.2 years (range 1 to 4.5

years). In the other three included studies, long term outcomes at two or more years post-operatively were reported.

Functional assessment of the patient's ACL reconstructed knee was assessed by the IKDC subjective score and the Lysholm score in two studies (Hart 2008; Mauch 2007), and by the post-operative IKDC knee examination grade in three studies (Chouteau 2008; Mauch 2007; Plaweski 2006). No study addressed return to previous activity level or quality of life.

Secondary outcomes were reported infrequently and when reported the authors used different measurement tools for the same type of outcome, for instance femoral and tibial aperture tunnel position. All included studies reported tibial tunnel position on the lateral X-ray. Mauch 2007 also added MRI measurement of the tunnel position and of the graft quality. The measurements that were used consisted of absolute or relative measurements from the anterior to the posterior tibial plateau or looked at the position in relation to the Blumensaat's line (roof of the intercondylar notch) in full extension.

Femoral position was assessed using the triangle method by Chouteau 2008, the quadrant method by Mauch 2007, and the relative position towards the Blumensaat line and the lateral femoral codyle by Hart 2008 and Plaweski 2006.

Stability measurements were assessed separately by the pivot-shift and Lachman test by Plaweski 2006 and the pivot-shift by Hart 2008.The IKDC objective score was assessed by Chouteau 2008, Mauch 2007 and Plaweski 2006 .

No study performed an economic evaluation, but length of operation was reported by all studies. None of the studies reported on intra-operative complications, or the need to abandon the CAS or to alter the CAS proposed tunnel placement.

Excluded studies

No studies were excluded.

Risk of bias in included studies

Overall, it was hard to judge risk of bias or the methodological quality of the four included studies due to poor reporting. The results of the risk of bias assessment are shown in Figure 1.

Allocation (selection bias)

Mauch 2007 drew lots and Plaweski 2006 used sealed envelopes. All four trials were rated at unclear risk of selection bias except for Mauch 2007 and Plaweski 2006 which were rated at low risk of bias relating to sequence generation and allocation concealment respectively.

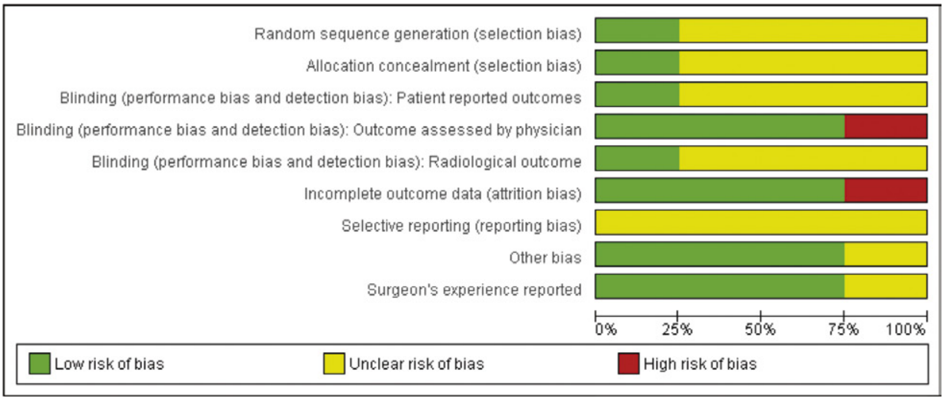

Figure 1. Risk of bias graph: review author's judgements about each risk of bias item presented as percentages across all included studies.

Blinding (performance bias and detection bias)
Blinding was assessed for trial participants, surgeon and outcome assessor. In a surgical trial, the surgeon cannot be blinded. Patient blinding was described in Hart 2008 but not in the other three studies. The outcome assessor was blinded or was independent in all studies but Mauch 2007.

Incomplete outcome data (attrition bias)
Three out of four studies described their loss to follow-up or had no loss to follow-up. Mauch 2007 did not describe a loss to follow-up; however, 13 participants were excluded from some analyses in a later report.

Selective reporting (reporting bias)
It was unclear whether there was selective reporting in any of the included studies.

Other potential sources of bias
No other bias was likely in Chouteau 2008 or Plaweski 2006. There was a possible bias in Mauch 2007 relating to the lack of acknowledgement of the earlier report of the this trial in the later report and the omission of 13 participants from investigations in the later report. There was an unclear risk of performance bias relating to surgeon experience in Chouteau 2008.

Effects of interventions

Primary outcomes
1.Self-reported health and quality of life measures

Pooled data from two studies (Hart 2008; Mauch 2007) showed no statistically significant differences between groups in the subjective IKDC scores at two or more years follow-up (mean difference 2.05, 95% CI -2.16 to 6.25; *see* Analysis 1.1). Chouteau 2008 found no significant differences in the mean IKDC subjective scores at follow-up of between one and 4.5 years (89.7 versus 89.5); no standard deviations were reported for this outcome. Two studies (Hart 2008; Mauch 2007) reported Lysholm scores. Pooled data showed no significant difference between the two groups in this outcome (mean difference 0.25, 95% CI -3.75 to 4.25; *see* Analysis 1.2).

2. IKDC Knee Examination Grade

Three studies (Chouteau 2008; Mauch 2007; Plaweski 2006) reported the IKDC knee examination grades at final follow-up. There was no statistically significant difference between CAS and conventional reconstruction in those with normal or nearly normal grades (RR 1.01, 95% CI 0.96 to 1.06; *see* Analysis 1.3).

Secondary outcomes

Other objective measures of knee function

Rotational stability was measured using the pivot shift test which was dichotomised as either negative (0) or positive (+,++,+++). Three studies (Hart 2008; Mauch 2007; Plaweski 2006) provided data; there was no statistically significant difference between the two groups in those with a normal (negative) pivot shift test at follow-up (RR 1.06, 95% CI 0.91 to 1.22; *see* Analysis 1.4).

Reported arthrometric testing was performed with a KT-1000 in two studies (Chouteau 2008; Hart 2008) and with a Telos device at 200 Newtons in Plaweski 2006. None of the trials found significant differences between the two groups (Figure 2). We found no reports of strength outcomes (Cybex muscle testing or equivalent).

Technical and anatomical outcomes

Tunnel placement is an important aspect of ACL reconstruction surgery. However, although all four studies reported the tibial tunnel position visualised on post-operatively acquired X-ray images, (Mauch 2007 also visualised tibial tunnel position using MRI), different measurement methods were used to determine the tibial tunnel position. This made pooling of the tunnel placement position data impossible. No significant differences were reported for overall placement between the two groups in any of the four trials (Figure 3).

Chouteau 2008, Hart 2008 and Plaweski 2006 also reported the femoral tunnel position on post-operatively acquired X-ray images. Mauch 2007 visualised the femoral tunnel on post-operatively acquired MRI. Chouteau 2008 showed a signifi-

	CAS pre-operatively	CAS post-operatively	Conventional pre-operatively	Conventional post-operatively
Chouteau 2008	n = 37	n = 37	n = 36	n = 35
Maximal KT-1000	15.3 mm (range 12 to 19)	8.9 mm (range 6 to 12)	14.9 mm (range 10 to 22)	9.5 mm (range 7 to 17)
Hart 2008		n = 40		n = 40
Maximal KT-1000 equal to other knee		12 (30%)		18 (45%)
< 2 mm		14 (35%)		12 (30%)
3-5 mm		14 (35%)		10 (25%)
> 5		0		0
Plaweski 2006	n = 30	n = 30	n = 30	n = 30
Laxity measurements with Telos device 200 N.	11.0 mm (SD 3.5)	1.3 mm (SD 1.0)	9.6 mm (SD 2.0)	1.5 mm (SD 1.5)

Figure 2. Arthrometric testing results

	Computer assisted surgery	Manually navigated
Chouteau 2008	N = 37	n = 35
Agliette's method	28.5% (SD 5.4)	34% (SD 6.8)
Howell's method	38.4% (SD 4.8)	43% (SD6.6)
Hart 2008	n = 40	n = 40
Correctly placed in zone 2 (no impingement)	39 (97.5%)	38 (95%)
Mauch 2007	n = 20	n = 20
X-ray - Anterior	21 mm (SD 2.5) (32%)	20 mm (SD 4.9) (30%)
- Central	27 mm (SD 2.2) (41%)	25 mm (SDS 3.2) (39%)
- Posterior	32 mm (SD 2.9) (50%)	30 mm (SD 3.7) (47%)
Impingement	0	2
MRI		
Average centre tibia position	46% (range 39 to 52%)	46% (range 31 to 58%)
Plaweski 2006	n = 30	n = 30
ATB (distance from projected Blumensaat line)	0.4 mm (range 0 to 3)	-1.2 mm (range -5 to 4)
W (tibial tunnel width)	10.6 mm (range 8 to 15)	11.5 mm (range 8 to 14)
CTT/ STD x 100	31.4% (range 18.2 to 40)	34.4% (range 22.2 to 43.4)

Footnotes

Hart 2008: Tibia antero-posteriorly divided in 4 equal zones (according to Harner), zone 2 is the tibial zone without impingement in extension.
Mauch 2007: X-ray results apply respectively to distances from the anterior edge of the tibial plateau, the centre and the posterior tibial border. The percentages data apply to the total anteroposterior tibial diameter.

Plaweski 2006: "Definition of geometrical measurements performed on postoperative radiographs in extension and relative to standard anatomical landmarks. A, measurement of potential notch impingement. B, measurement of femoral tunnel position. CTT, distance between the centre of the tibial tunnel and the anterior edge of the internal tibial plateau; STD, anteroposterior width of the internal tibial plateau; W, width of the tibial tunnel; ATB, distance between the projection of the Blumensaat line on the tibial plateau and the anterior edge of the tibial tunnel; AB, distance between the anterior condyle edge and the anterior edge of the femoral tunnel; AC, length of the Blumensaat line, as referenced by the condyle cortical edges." (as described in Plaweski 2006)

Figure 3 Tibial tunnel position results

cantly more accurate tunnel placement for the femur in favour of the CAS group. None of the other studies showed a statistically significant difference between CAS and the conventional ACL reconstruction groups (Figure 4).

	Computer assisted surgery	Manually navigated
Chouteau 2008	n = 37	n = 35
Linear distance between actual and ideal position (Triangle method)	2.5 mm (SD 1.1)	7.0 mm (SD 1.5)
Hart 2008	n = 40	n = 40
a/t (posterior to anterior ideal 24.8%)	25.5% (SD 1.63)	27.5% (SD 2.76)
b/h (height of femoral condyle)	27.3% (SD 2.01)	27.9% (SD 2.87)
AP 10.30/1.30 position	40 (100%)	37 (92.5%)
Deviation ventrodorsal: < 7%	27 (67.5%)	14 (35%)
7 to 14%	13 (32.5%)	14 (35%)
> 14%	0	12 (30%)
Mauch 2007	n = 20	n = 20
MRI quadrant method	20 correct in 4/4 quadrant	19 correct in quadrant 4/4
	0 in other quadrants	1 in quadrant 3/4
MRI graft remodeling - Cat. A (low, tense, smooth)	13 (65%)	8 (40%)
- Cat. B (low/int, tense, rough)	7 (35%)	9 (45%)
- Cat C (high, elongated, rough)	0	3 (15%)
Plaweski 2006	n = 30	n = 30
AB/AC x 100	60.1% (SD 4.68)	61.3% (SD 6.4)

Footnotes

Hart 2008: a/t is the distance on the lateral radiograph of Blumensaat's line (t = sagittal diameter of the lateral condyle) divided by the length from posterior to the femoral tunnel (a);
b/h (h) is the maximum height of the notch and (b) the distance between the Blumensaat's line and the femoral tunnel aperture.

Plaweski 2006: see Footnotes in Appendix 3

Figure 4. Femoral tunnel position results

We found no reports of development of radiological osteoarthritis.

Adverse post-surgical events

Chouteau 2008 reported two participants with some loss of range of motion in the CAS group and three in the control group. Hart 2008 reported there was no re-rupture of the ACL, loss of motion, infection, or venous thrombo-embolism in either group. Post-operative complications were not reported by Mauch 2007. Plaweski 2006 did not observe any infection, clinical thromboembolic events, or haematoma requiring intervention.

Measures of resource use

Reported additional operation time for the CAS groups was 9.3 minutes in Chouteau 2008, 11 minutes in Hart 2008, 15 minutes in Mauch 2007, and 26 minutes in Plaweski 2006). Standard deviations were not reported.
Chouteau 2008 reported radiological screening time in the CAS group of “15±5” seconds.

We found no data on frequency of re-operation. No formal economic evaluations were identified.

DISCUSSION

Anterior cruciate ligament reconstruction is one of the most frequently performed orthopaedic interventions, especially in the young active population. An improved surgical outcome has the potential to reduce time lost from work or athletic activity, additional suffering and lower medical costs. This systematic review looked at the evidence from randomised clinical trials for computer assisted anterior cruciate ligament surgery.

Summary of main results

We included four randomised clinical trials (266 participants) who underwent ACL reconstruction. The trials were heterogeneous but all involved anterior cruciate ligament lesions eligible for ACL reconstruction.

We found no statistically or clinically significant differences in self-reported quality of life outcomes, namely the IKDC subjective and Lysholm scores, or in objective knee function assessment, or in reported secondary outcome measures such as knee stability, tunnel placement or adverse post-surgical events. Therefore, apart from a consistent increased operating time (between 9.3 to 26 minutes) for participants randomised to CAS, a positive effect of CAS versus conventional ACL reconstruction could neither be demonstrated nor refuted.

Overall completeness and applicability of evidence

The applicability of the results from this review is strengthened by the studies having been performed by research groups from different countries, and by the diversity in the CAS ACL reconstruction systems used. Incomplete reporting of results and heterogeneity, however, hampered the drawing of firm conclusions regarding the effect of CAS. As the included trials focused on ACL reconstruction, we cannot make any conclusions regarding other ligament reconstructions.

All studies were performed by ACL surgeons or surgical groups with ample experience in reconstructive procedures. This may have left less room for improvement from the uses of CAS. There were no reports on the experience level of any of these surgeons with the use of the CAS system, which may have resulted in a learning curve problem. It is conceivable that less experienced orthopaedic surgeons may derive more benefit from the use of CAS technology including in terms of a training intervention, with a potential for improved clinical outcomes for the patient. However, this has not been researched.

A complete analysis of the effect of the CAS system for these knee ligament reconstruction can only be given when the intra-operative goal can be measured with a universal validated objective gold standard, such as an optimal graft placement. The present outcome measures (rotational stability measurements and radiological measurements for tunnel placement and osteoarthritis) are limited in the ability to measure small but possibly significant clinical differences for the short and longer-term outcome. In other words, the responsiveness of these related ACL reconstructed knee scores is insufficient to identify improvements or differences that could be clinically important.

Quality of the evidence

We included only randomised clinical trials as these are considered to have the lowest risk of bias compared to other study designs. However, assessment of the risk of bias was hampered by poor reporting. Therefore, we were mainly unclear about the methodological quality of these studies and the associated risk of bias. The included studies were small and underpowered.

Potential biases in the review process

We are confident that we were exhaustive in our search strategy. In an effort to locate all relevant trials, sensitive searches were conducted across a comprehensive list of electronic databases. We performed citation tracking and searched for unpublished studies through clinical trials registers. However, it is still possible that we missed some trials. Despite our efforts to contact authors, this review is limited by the availability of data from the included studies.

Agreements and disagreements with other studies or reviews

To our knowledge this is the first systematic review on this specific topic. There have been reviews looking at CAS and total knee prosthesis implantation. They have shown no significant difference in clinical outcome but have shown in some instances that there are fewer outliers using computer assisted surgery.[5] Our study however was inconclusive, possibly because all included studies in our review compared CAS with conventional ACL reconstructions performed by experienced ACL surgeons. This might have reduced the differences expected between the groups because of an already accurate ACL reconstruction with fewer outliers, due to the surgeons' greater experience.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence from randomised controlled trials to draw conclusions on the effectiveness of computer assisted surgery for knee ligament reconstructions compared with conventional reconstructions.

Implications for research

The reporting of the existing studies assessing the effects of CAS ACL reconstruction is generally poor, which hampers proper assessment of their methodological quality and the interpretation of results. Before further uptake of this technology, more rigorous studies are needed to establish whether CAS can play an important role in ACL reconstruction. Future studies should follow the CONSORT guidelines for reporting of randomised trials, use adequate methods of randomisation with adequate concealment of allocation of the participants to treatment groups, blind the participants and outcome assessors to treatment allocation, include reliable and validated outcome measures, and be of sufficient duration to assess medium and long-term effects.[17]

Although the emphasis should remain on clinically important outcomes, we also advise research into the ideal anatomic placement of the aperture of the femoral and tibial tunnel. A validated and reliable reference standard is needed for this and should be used in further research as well as informing on graft placement and future approaches for computer assisted surgery.

Acknowledgements

We would like to acknowledge Bill Gillespie, Helen Handoll, Peter Herbison and David Sands Johnson for valuable comments about the review.

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Contributions of authors

DM drafted the protocol and the review. MR and DM searched the data and assessed for methodological quality and the risk of bias. MR and JV edited the protocol and review for content and formatting. RS edited the review and performed the statistical analysis.

DATA AND ANALYSES

1 COMPUTER ASSISTED SURGERY VERSUS CONVENTIONAL SURGERY

Outcome or subgroup	Studies	Participants	Statistical methods	*Effect estimate*
1.1 IKDC subjective	2	120	Mean Difference (IV, Fixed, 95% CI)	2.05 [-2.16, 6.25]
1.2 Lysholm score	2	120	Mean Difference (IV, Fixed, 95% CI)	0.25 [-3.75, 4.25]
1.3 IKDC knee exam (normal or near normal)	3	173	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.96, 1.06]
1.4 Pivot shift (negative)	3	180	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.91, 1.22]

APPENDICES

1. Search Strategies

Cochrane CENTRAL Register of Controlled Trials (Wiley Online Library)

#1. MeSH descriptor Anterior Cruciate Ligament, this term only
#2. MeSH descriptor Posterior Cruciate Ligament, this term only
#3. ((anterior or posterior) NEAR/3 cruciate):ti,ab,kw
#4. (#1 OR #2 OR #3)
#5. MeSH descriptor Surgery, Computer-Assisted, this term only
#6. MeSH descriptor Therapy, Computer-Assisted, this term only
#7. (computer* NEAR/3 (assist* or aid* or control* or navigat* or surg*)):ti,ab,kw
#8. (CAS or CAOS):ti,ab,kw
#9. (#5 OR #6 OR #7 OR #8)
#10. (#4 AND #9)

MEDLINE (PubMed and PubMed in process)

((anterior cruciate ligament[mesh] OR posterior cruciate ligament[mesh] OR "anterior cruciate"[tw] OR "posterior cruciate"[tw]) AND (computer-assisted therapy[mesh:noexp] OR computer-assisted surgery[mesh] OR (computer*[tw] AND (assist*[tw] OR aid*[tw] OR control[tw] OR controlled[tw] OR navigat*[tw] OR surgery[tw] OR surgical[tw] OR therapy[tw]))) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials [mh] OR random allocation [mh] OR double-blind method [mh] OR single-blind method

[mh] OR clinical trial [pt] OR clinical trials [mh] OR "clinical trial"[tw] OR ((singl* [tw] OR doubl* [tw] OR tripl* [tw]) AND (mask* [tw] OR blind* [tw])) OR placebos [mh] OR placebo* [tw] OR random* [tw] OR research design [mh:noexp]) NOT (animals [mh] NOT humans [mh])))

EMBASE (Embase.com)
('knee ligament'/exp OR 'knee ligament surgery'/exp OR 'anterior *2 cruciate' OR 'posterior *2 cruciate') AND ('computer assisted therapy'/de OR 'computer assisted surgery'/de OR (computer*:ti,ab,de AND (assist*:ti,ab,de OR aid*:ti,ab,de OR control:ti,ab,de OR controlled:ti,ab,de OR navigat*:ti,ab,de OR surgery:ti,ab,de OR surgical:ti,ab,de OR therapy:ti,ab,de))) AND ('randomized controlled trial'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR 'crossover procedure'/exp OR 'controlled study'/de OR ((clinical:ti,ab,de OR controlled:ti,ab,de OR comparative:ti,ab,de OR placebo:ti,ab,de OR prospective*:ti,ab,de OR randomi?ed:ti,ab,de) AND (trial:ti,ab,de OR study:ti,ab,de)) OR (random*:ti,ab,de AND (allocat*:ti,ab,de OR allot*:ti,ab,de OR assign*:ti,ab,de OR basis*:ti,ab,de OR divid*:ti,ab,de OR order*:ti,ab,de)) OR ((singl*:ti,ab,de OR doubl*:ti,ab,de OR trebl*:ti,ab,de OR tripl*:ti,ab,de) AND (blind*:ti,ab,de OR mask*:ti,ab,de)) OR (crossover*:ti,ab,de OR cross-over:ti,ab,de) OR ((allocat*:ti,ab,de OR allot*:ti,ab,de OR assign*:ti,ab,de OR divid*:ti,ab,de) AND (condition*:ti,ab,de OR experiment*:ti,ab,de OR intervention*:ti,ab,de OR treatment*:ti,ab,de OR therap*:ti,ab,de OR control*:ti,ab,de OR group*:ti,ab,de))) NOT (animal*:ti,ab,de NOT human*:ti,ab,de)

CINAHL (Ebsco)
((MH anterior cruciate ligament OR MH posterior cruciate ligament OR TX "anterior cruciate" OR TX "posterior cruciate") AND (MW therapy, computer-assisted OR TX "computer-assisted surgery" OR (TX computer* AND (TX assist* OR TX aid* OR TX control OR TX controlled OR TX navigat* OR TX surgery OR TX surgical OR TX therapy))) AND ((randomized controlled trial OR controlled clinical trial OR MH clinical trials OR MH random assignment OR MH double-blind studies OR MH single-blind studies OR PT clinical trial OR TX "clinical trial" OR ((TX singl* OR TX doubl* OR TX tripl*) AND (TX mask* OR TX blind*)) OR TX "latin square" OR MH placebos OR TX placebo* OR TX random* OR MH study design OR comparative study OR evaluation studies OR MH prospective studies OR TX "cross-over studies" OR TX control OR TX controlled OR TX prospectiv* OR TX volunteer*)))

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Included studies

Chouteau 2008
* Chouteau J, Benereau I, Testa R, Fessy MH, Lerat JL, Moyen B. Comparative study of knee anterior cruciate ligament reconstruction with or without fluoroscopic assistance: a prospective study of 73 cases. Archives of Orthopaedic Trauma Surgery 2008;128(9):945-50.
Chouteau J, Rollier JC, Benareau I, Lerat JL, Moyen B. Comparative study of anterior cruciate ligament reconstruction with and without computer assistance: a prospective analysis of 73 knees [abstract]. Journal of Bone and Joint Surgery - British Volume 2008;90(Suppl II):287.

Hart 2008
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Mauch 2007
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Plaweski 2006
Plaweski S, Cazal J, Rosell P, Merloz P. Anterior cruciate ligament reconstruction using navigation: a comparative study on 60 patients. American Journal of Sports Medicine 2006;34(4):542-52.

Excluded studies: none

Studies awaiting classification: none

Ongoing studies

Meuffels: Unpublished data only [ISRCTN: ISRCTN40231111]

Meuffels DE. Computer assisted surgery versus conventional arthroscopic anterior cruciate ligament reconstruction: a prospective randomised clinical trial. Current Controlled Trials http://www.controlled-trials.com/ISRCTN40231111/Meuffels (accessed 14 January 2011).

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Chapter 9

Computer assisted surgery is not more accurate than conventional arthroscopic anterior cruciate ligament reconstruction: a prospective randomized clinical trial

D.E. Meuffels, M. Reijman, J.A.N. Verhaar

Revision submitted Journal of Bone and Joint Surgery (Am)

Background: Accurate and precise tunnel placement is critical to the success of anterior cruciate ligament (ACL) reconstruction. A new development has been computer assisted surgery (CAS), aiding in the ACL bone tunnel placement during surgery. Our hypothesis is that CAS will allow for more accurate and precise tunnel placement in ACL reconstruction as compared to conventional surgery.
Methods: This study is set up as a prospective double-blinded randomized clinical study. 100 patients eligible for ACL reconstruction were stratified per surgeon and randomized for either conventional or CAS. 3-dimensional CT measurement of the femoral and tibial tunnel placement was used as primary outcome to compare conventional ACL surgery to CAS.
Results: No difference in placement of the femoral tunnel for the conventional group was seen compared to the CAS group (respective mean 39.7% versus 39.0% on the proximal-distal intracondylar axis (P = 0.70)). The anterior-posterior placement of the tibial tunnel was not significantly different, 38.9% in the conventional group and 38.2% in the CAS group (P = 0.58). There was no significant difference in variance of either the femoral or the tibial placement in the two groups.
Conclusions: There is no significant difference in accuracy or in precision of the tunnel placement between conventional and CAS ACL reconstruction.
Level of Evidence: Level 1

INTRODUCTION

Anterior cruciate ligament (ACL) reconstruction has become standard orthopaedic practice worldwide with an estimated number of 175,000 reconstructions per year in the United States.[20] The patient desires a full recovery of the knee after surgery. There is, however, still an estimated failure rate of between 10% and 25%, the majority of which is caused by technical problems.[24] An estimated 80% of these technical failures are caused by malpositioning of the femoral and/or tibial tunnel.[8,18]

Computer assisted surgery (CAS) has shown additional value in improving accuracy in total knee replacement by approaching the mechanical axis more closely.[1] CAS has the potential ability to increase the accuracy and precision of ligament positioning. In ACL surgery, CAS uses an infrared reference system to track the surgical tools and the tibial and femoral bone position, thus enabling per-operative templating of the planned ACL graft position and offering an additional check of the surgical procedure. There have been favorable reports showing some improved accuracy in tunnel placement using CAS with ACL reconstructions.[4,9,17] A recently published Cochrane review of randomized clinical trials (RCT) of CAS ACL reconstructions, however, showed no significant improved clinical outcome for CAS in ACL reconstruction.[15] However, the literature about CAS ACL reconstruction shows a variety of different outcome data and all published RCT's have significant limitations. [3,6,9,17] A main determinant of a successful ACL reconstruction is tunnel placement, and CAS is directed primarily at improving accuracy of tunnel placement and increasing reproducibility. This study was set up to study CAS ACL reconstruction compared with traditional surgical technique using a 3-D tunnel placement measurement technique of the femoral and tibial intraarticular aperture.[7,14] This novel 3-D measurement has shown to be a better outcome measurement for ACL tunnel placement and thus, could shed more light on the value of CAS ACL reconstruction.[14] Our hypothesis is that CAS will allow for more accurate and precise femoral and tibial tunnel placement in ACL reconstruction as compared to conventional surgery.

METHODS

Study design

A double blind, prospective randomized controlled study of CAS versus conventional ACL reconstructions was performed on consecutive patients between January 2007 and November 2009. This trial was registered with the International Standard Registration Controlled Trial Number Register. Our Medical Ethics Committee approved the study protocol. All patients provided written informed consent.

Patients
All patients 18 years of age or older, who were eligible for primary ACL reconstructions without any additional posterior cruciate ligament or lateral collateral ligament injury, were included. Exclusion criteria were: insufficient grasp of the Dutch or English language and patients unable or unwilling to comply with regular post-operative follow-ups.

Randomization
Participants were randomized according to a computer-generated procedure (block randomization, with variable size of the blocks); the randomization codes were held by an independent observer to ensure masked blocking. The participants were randomly allocated to their groups, after informed consent had been obtained and all baseline measurements were completed. The randomization was stratified for technique used, bone-patella-tendon-bone (BPTB) or hamstring, and the surgeon performing the reconstruction.

Surgery
Two experienced orthopaedic surgeons performed the ACL reconstructions, each with an experience of at least 500 cruciate ligament reconstructions. They were proficient in the use of the CAS system, by having performed more than 20 CAS procedures together. The ACL reconstruction was performed using an arthroscopic, single-incision, single-bundle, transtibial surgical technique, using either BPTB or a looped semi-tendinosus, gracilis autograft. The choice for either graft was made individualized by each surgeon pre-operatively, depending on the athletic demands and specific wishes of the patient and on the surgeon's preference.

The Computer assisted surgery was performed using a stand-alone infrared controlled computer (Version 1.0, Brainlab, München, Germany). Reference aimers are used which are recognized by the infrared system. The passive infrared transmitters are fixed to the femur and to the tibia using 4 mm. Steinmann pins. At the beginning of the intervention, true lateral and AP X-rays are acquired of the femur and the tibia, by using a calibrated C-arm, connected to the CAS system, with an infrared reflective ring. These X-ray are then used in the CAS system, to aid in the templating of the tibial and femoral tunnel position. We aimed for an anterior to posterior placement percentage of the tibial plateau of 44% according to Stäubli et al., this is shown in Figure 1.[21] The lateral and AP position is then cross-checked with intra-articular acquired landmarks on the tibial plateau, which are registered into the CAS system. The templated central point of the tibial drill tunnel can be matched with the footprint of the ACL.

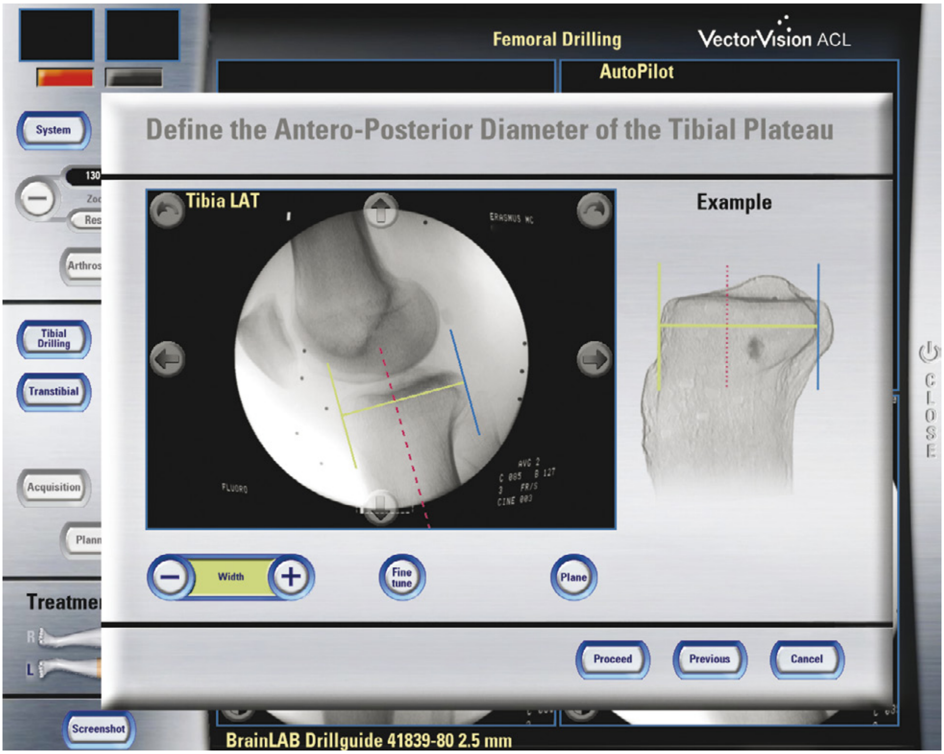

Figure 1. Screenshot of intra-operative template of the tibial tunnel aperture positioning according to Stäubli.

For the femoral tunnel position we used the radiographic quadrant method according to Bernard and Hertel et al. (Figure 2).[2,7] The aim, according to this method, is the center of the femoral insertion of the ACL on the true lateral projection. This would be approximately at the intersection line of the most posterior and proximal quadrant. 24.8% from the most posterior contour of the lateral condyle parallel to Blumensaat's line and 28.5% of the height measured perpendicular to Blumensaat's line. The radiographically templated lateral and AP position is then cross-checked with intra-articular acquired landmarks, which are acquired to the CAS system, with a reference guide. The acquired points on the medial side of the lateral femoral condyle are then added to the CAS image, to encompass the central point of the femoral drill tunnel within the origin of the ACL.

Navigation is the last step. The CAS system assists the surgeon in positioning the tibial and femoral tunnel position. A tibial tip aimer and a femoral aimer without offset are used to target the guide wire (Figure 3)(Brainlab, München, Germany).

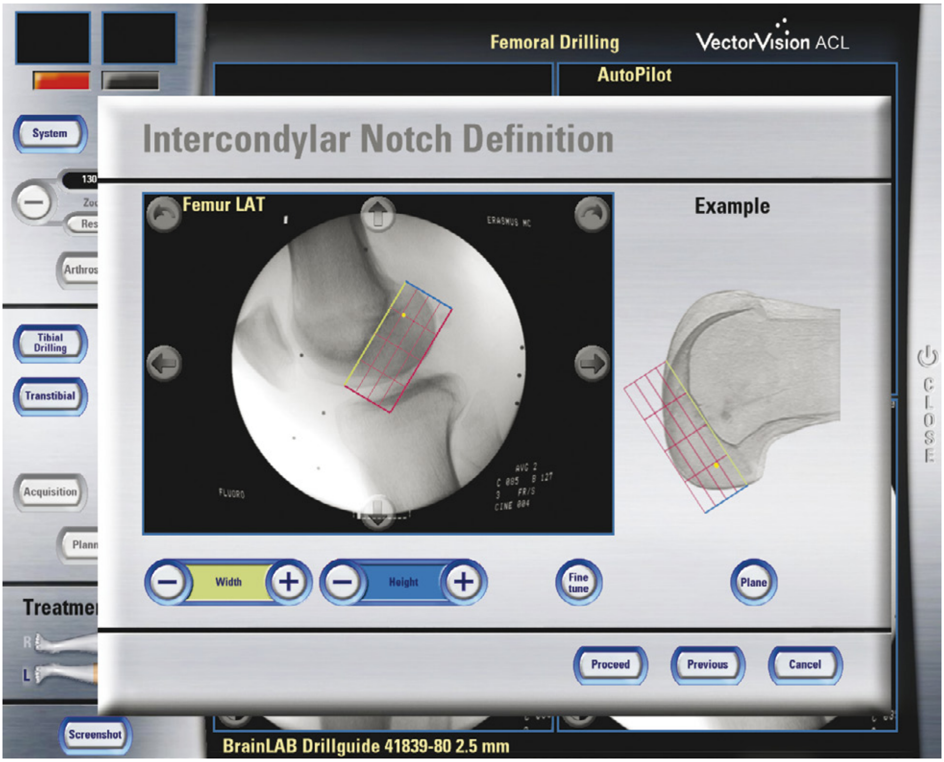

Figure 2. Screenshot of the intra-operative templating of the femoral tunnel aperture positioning according to the quadrant overlay method.

For the conventional ACL reconstruction we aimed at similar femoral and tibial bone tunnel positioning within the native anatomic ACL footprint. The tibia was positioned with the tibial elbow guide (Acufex, Smith & Nephew, Andover, MA) approximately 7mm anterior of the most anterior border of the posterior cruciate ligament, in a slightly more oblique tunnel direction to facilitate femoral aiming. The femur was aimed at a 2 o'clock position for the left and at a 10 o'clock position for the right knee. Positioning was checked, using a 30° scope, with the femur at 90 degrees, this was done through the central portal when using BPTB and through the antero-medial portal when performing a hamstring ACL reconstruction.

ACL reconstructions performed; using a BPTB grafts were fixed on both sides using a resorbable interference screw (BIORCI, Smith & Nephew, Andover, MA). Hamstring ACL reconstructions were fixed using an extra-cortical button technique (Endobutton, Smith & Nephew, Andover, MA) on the femoral side and a resorbable interference screw on the tibial side (BIORCI, Smith & Nephew, Andover, MA).

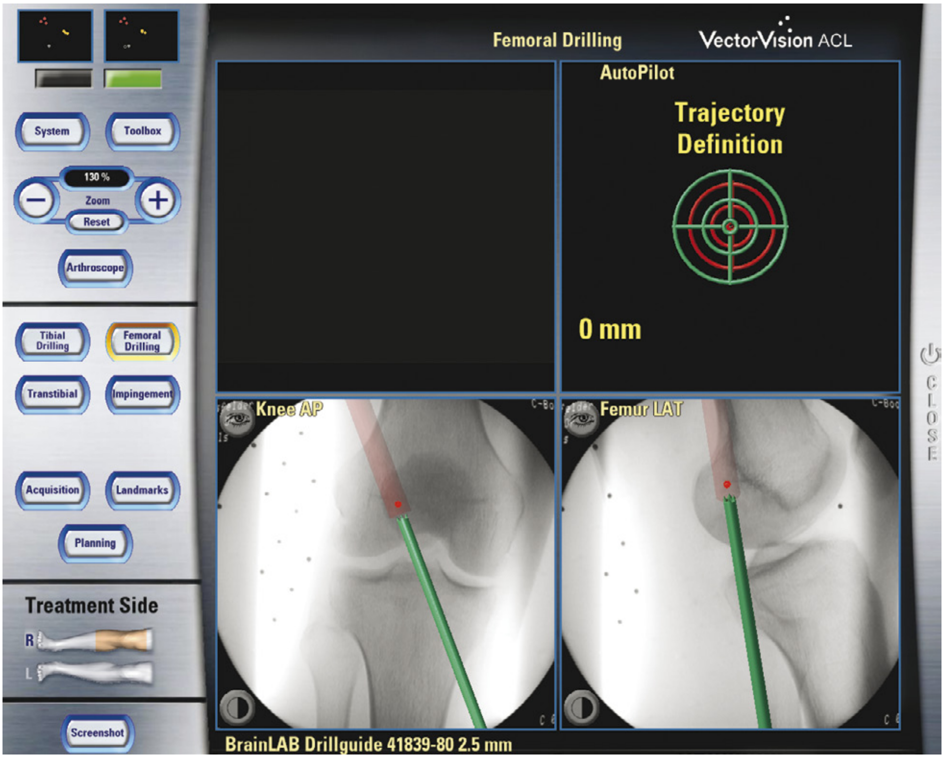

Figure 3. Screenshot of the femoral placement of the central guide wire. The trajectory definition is a bull's eye that aids in reaching the planned femoral position.

Outcome Measures

As primary outcome measurement the 3-D intraarticular femoral and tibial tunnel aperture was chosen. For the primary outcome a 64 channel multi-slice technology CT scanner (Somatom, Siemens Medical Solutions, Forchheim, Germany) with helical acquisition in 1.0 mm sections was used (120 kV, 160 mAs, rotation time 1.0 s). The knee CT imaging was performed from the top of the suprapatellar collection to the superior tibial and fibula diaphysis, one day post-operatively. The primary analysis was performed after the inclusion period had ended and after all patients had received their post-operative follow-up with a CT of the operated knee. The data were then transferred and blinded for patient into the 3-dimensional measurement software. (MeVisLab Version 2.0, MeVis Medical solutions AG, Bremen, Germany).[11]

Measurement of the three dimensional images was performed by two experienced observers and was blinded for allocation and patient. By using the three dimensional tri-axial properties of the desktop version of Mevis, the contour of the femur (the intracondylar axis and medial side of the lateral femoral condyle) and tibia (circumference of the tibial plateau) was mapped.[14] Each tibial and femoral tunnel was registered, using the osseous contour of the intra articular aperture and the extra articular aperture. All these data points enable the software to calculate position and distances to any chosen point or points and to match these to contours or transpose them to any chosen grid (for instance the quadrant overlay). An example of the femoral 3-D visualization is shown in Figure 4. To be able to compare our 3D measurements to previously published CT measurements we translated our data to a true medial view of the lateral femoral condyle and a true proximal to distal view of the tibia.[7] Tibial tunnel position was then calculated in percentages, using the centre of the tibial tunnel aperture in a medial-lateral and an anterior-posterior direction.[7] The femoral position of the centre of the tunnel aperture was calculated in percentages, using a modified quadrant method.[2,7] The placement measurements were plotted separately for the femoral tunnel and the tibial placement. This method compares the intra-articular central point of the femoral tunnel aperture to the contour of the intra-condylar medial side of the femoral condyle on CT, not the X-ray contour of the lateral femoral condyle. This was chosen, because it is a contour that is reliable to measure and because the intra-condylar contour of the lateral femoral condyle is the arthroscopically seen contour and reference for the tunnel placement.[14]

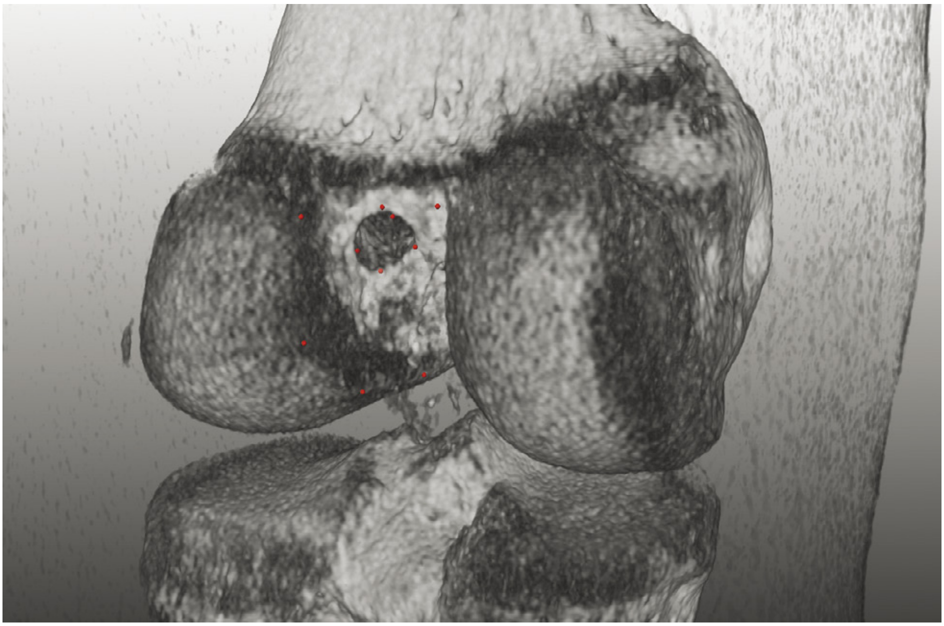

Figure 4. Posterolateral view of a 3-D CT of the ACL reconstructed left knee. The red dots show the 3-dimensional (MeVis) measurement points of the femoral tunnel opening and the intracondylar contour of the lateral femoral condyle.

Patients' age, weight (kg), height (cm) were registered as was the time between trauma and surgery. All patients completed International Knee Documentation Committee (IKDC) objective and subjective forms[10], Tegner [23](also pre trauma), Knee Injury and Osteoarthritis Outcome Score (KOOS)[5,19] and Lysholm[12] questionnaires pre-operatively and post-operatively at 6 weeks, 3, 6, 12 and 24 months. The subjective IKDC form was filled in and arthrometric laxity measurements were performed using the KT-1000 (Medtronic, Cal. U.S.A.). Intra-operatively findings were recorded and the surgical procedure was timed. Adverse events were registered if they occurred.

Statistical analysis

As a primary outcome measure we used the tunnel position of the graft on the femoral and on the tibial side. To detect a minimum difference of 1.5 mm for the femoral tunnel and 1.5 mm for the tibial tunnel we would need, respectively 25 and 38 patients (one-side testing alpha = 0.05 and beta = 0.20).[16] With a possible loss to follow-up of 20% we would have to include a minimum of 45 patients per group.

Statistical analysis was done with the SPSS software package, version 15.0 (SPSS, Chicago,Il.). We established whether the variables had a normal distribution using the normality Shapiro-Wilk test. Based on these analyses, the results were presented as means and standard deviations (SD). The primary analysis was "by intention to treat". Two observers performed the femoral and tibial tunnel placement measurements independently, for all patients. The intraclass correlation coefficient (ICC) was calculated using the percentages of the different measurements. The calculation of the ICC is based on an analysis of variance (ANOVA) model. The ICC calculations that were performed used the two-way mixed model for absolute agreement.

The following statistic analyses were performed with the use of R Development Core Team 2.11.1 (R foundation for statistical computing, Vienna, Austria). To answer the primary question we calculated the variance of the tibia and femur measurements in each randomization group separately. These were compared using Levene's test. We also compared the achieved position for both groups in two dimensions for the femoral and the tibial tunnel aperture.

Source of funding

This work was supported by a research grant from Nuts-Ohra. The grant was used for employment of a research nurse. The sponsor of the study had no role in the study design, data collection, data analysis, data interpretation or writing of the report.

RESULTS

The flow of patients through the study is presented in Figure 5.

The baseline characteristics of the study population are presented in Table 1. The intra-operative findings are shown in Table 2.

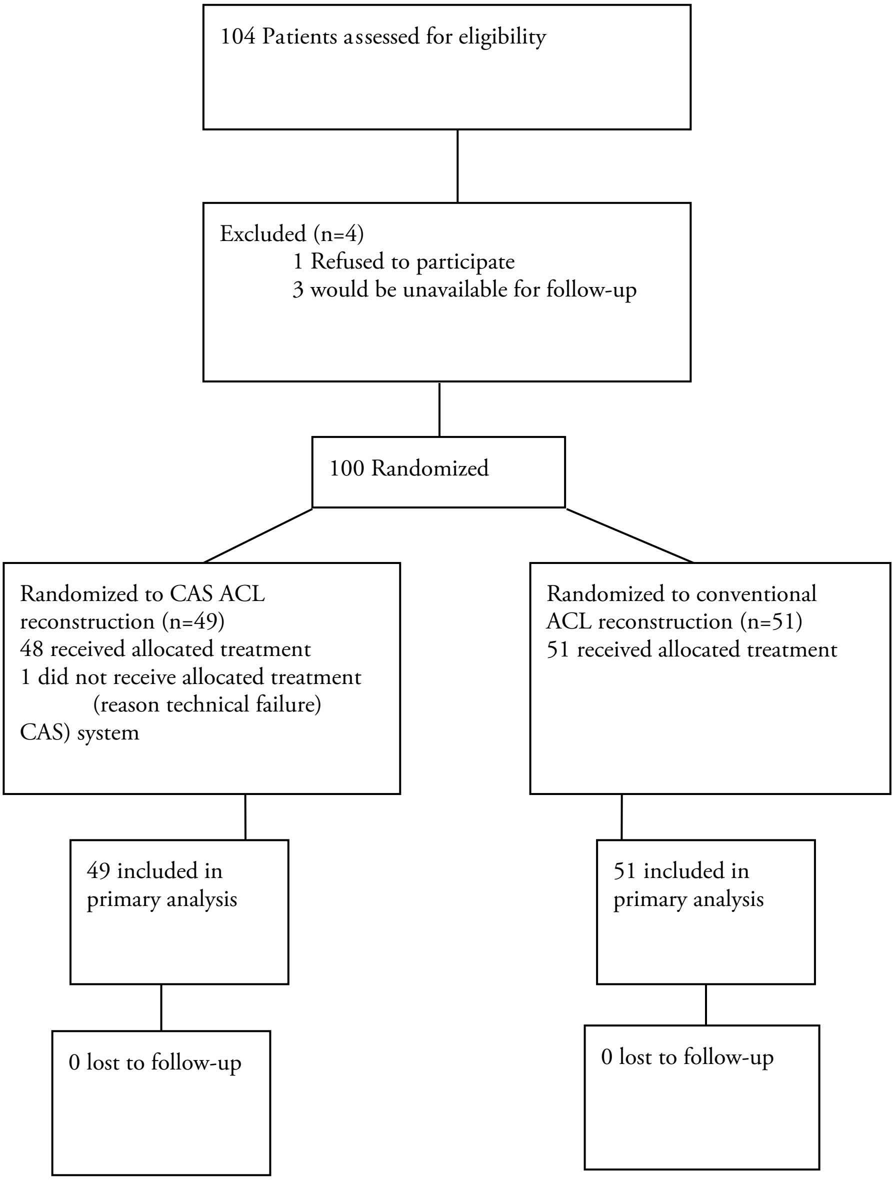

Figure 5. Flow chart of patients throughout the study.

Table 1. Baseline Characteristics of the study population

	CAS group n = 49	Control group n = 51
Age, years	26.9 (± 6.4)	26.3 (± 8.2)
Gender, % women	28.6	19.6
BMI, kg/m^2	24.2 (± 3.6)	25.0 (± 3.5)
Time between trauma-surgery, months.	27.2 (±37.2)	28.8 (± 33.2)
Tegner		
- Pretrauma	8.1 (± 2.0)	8.1 (± 2.0)
- Preoperative	3.7 (± 1.8)	3.7 (± 2.0)
IKDC subjective form	64.2 (± 14.6)	63.4 (± 13.6)
KOOS		
- Pain	90.3(± 12.5)	92.5 (± 9.0)
- Symptoms	81.4 (± 11.2)	81.8 (± 10.8)
- ADL	93.3(± 13.1)	95.9 (± 6.3)
- Sport	74.5 (± 23.3)	71.3 (± 21.1)
- Quality of life	54.0 (± 15.3)	56.7 (± 14.1)

Values are presented as mean (± standard deviation)

Table 2. Intra-operative characteristics

	CAS group n = 49	Control group n = 51
Operation time in minutes, mean (± SD)	131.9 (± 14.8)	105.2 (± 20.7)
BPTB graft, %	46.9	49
Chondral lesion, %	34.7	29.4
Meniscal lesion, %	26.5	31.4

One procedure, in the CAS ACL reconstruction group, had difficulties with the accurate visualization of the femoral reference guide. This procedure was continued with the use of the conventional femoral guide, without complications. The patient was analyzed as an intention to treat in the allocated group. In the remaining 48 CAS, the templated position was aimed for and reached within 1mm or less. No other peri-operative complications occurred.

An inter observer measurement of the 3-D measurements was established, which showed a good intraclass correlation (ICC) of 0.90 (CI 0.85-0.93) for the femoral intra articular aperture position and an ICC of 0.99 (CI 0.98-0.99) for the tibial intra articular aperture position of the tunnel.

The mean femoral tunnel aperture was positioned parallel to Blumensaat 39.7% (SD±9.1) from the most proximal point for the conventional group and slightly more proximal for the CAS group at 39.0% (SD±9.6). There was no significant

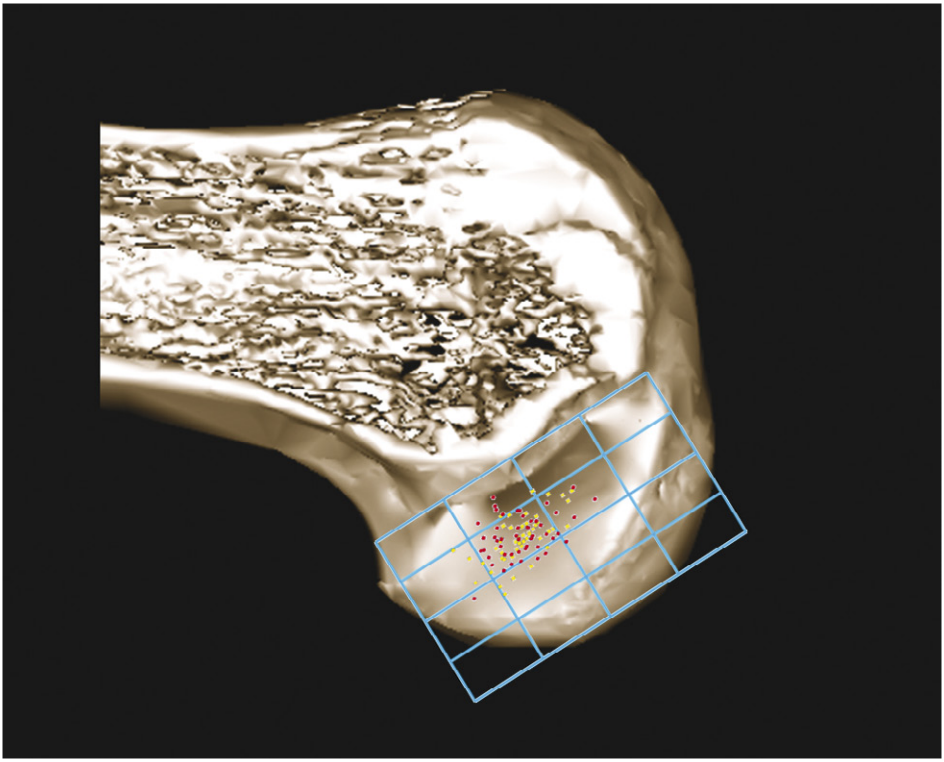

Figure 6. CAS (red dots) versus conventional (yellow squares) femoral tunnel intra-articular aperture position. They are displayed for clarification on a knee CT image of a randomly chosen image of a lateral condyle viewed from the medial side, with the quadrant overlay projected.

difference in mean aperture position of the femoral tunnels of the CAS versus the conventional group (P = 0.70).

There was no significant difference in variance of the femoral tunnel aperture position between the two groups (P = 0.76) (Figure 6 Results femoral tunnel position.)

There was no significant difference in mean aperture position of the tibial tunnels of the CAS versus the conventional group (P = 0.58). The antero-posterior (AP) tunnel position on the tibia plateau, according to Stäubli etal., was 38.2% (SD±5.8) for the CAS group and 38.9% (SD±6.8) for the conventional group.

The variance showed no significant difference in intra-articular tibial tunnel aperture position between the CAS and the conventional group (P = 0.87). (Figure 7 Tibial tunnel placement results) No significant difference in accuracy or precision was determined for other possible tunnel placement contributing factors such as; earlier versus later procedure, hamstring versus BPTB graft and inter surgeon.

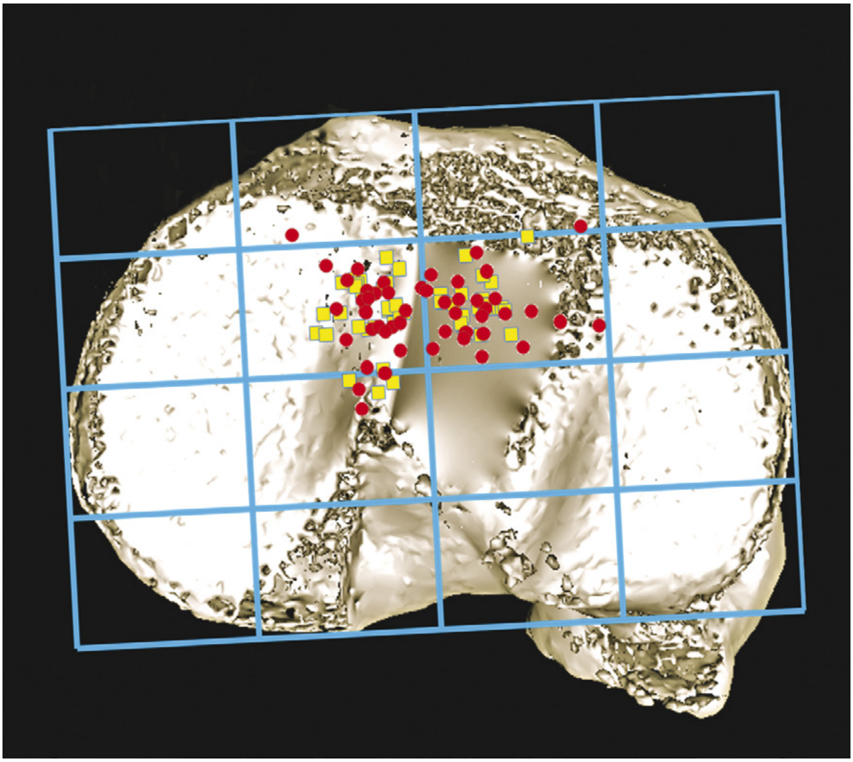

Figure 7. CAS(red dots)versus conventional(yellow squares) tibial intra-articular tunnel aperture position, projected for clarification on a cranial view of a fitted CT tibial plateau image of a randomly chosen right knee.

DISCUSSION

The results of this randomized, controlled trial involving ACL reconstruction did not show better tunnel placement using CAS compared to conventional surgery in femoral or tibial tunnel placement. There was no significant increased accuracy, nor was there an increased precision in the tunnel placement at the femoral origo or the tibial insertion of the ACL graft. This study used 3-D CT imaging as a primary parameter. It has been chosen as our main outcome, because the CAS ACL reconstruction should be judged on its capabilities to aid in a more precise and accurate placement of reference tools.

A recently published meta-analysis found 4 randomized clinical trials for CAS ACL reconstruction.[15] None of these studies found a significant difference in clinical outcome after CAS ACL surgery compared to conventional ACL reconstruction. The study of Chouteau et al. found more accurate tunnel placement for both the femoral and the tibial tunnel placement.[4] The study of Mauch et al. found less variance in the tibial placement for the CAS group.[13] All four studies, however, used smaller sample sizing than this study and none of them used CT or 3-D measurement tools to visualize and measure their post-operative ACL tunnel placement outcome.[15] The CT measurement is more accurate than the X-ray measurements used in the other studies, which may be an explanation for the different results.[14] Our larger study, with validated 3-D CT measurement, does not confirm the superior results for CAS ACL surgery in tunnel placement described by others.

The CAS system used a defined gold standard, according to Stäubli et al., for the tibial placement at 44% of the anterior-posterior length of the tibial plateau on a true lateral knee X-ray. Although the anatomic attachment sites of the ACL have been well described, the optimal bone tunnel placement for ACL grafts remains controversial. However, current surgical practice focuses on placing the bone tunnels within the anatomic insertion sites of the native ACL (anatomic placement). Defining the universal optimal position is therefore not possible, which makes an individualized approach necessary. We found a deviation from our defined gold standard of 4.4% for the conventional group and 5.1% for the CAS ACL group. The average plateau length of the operated knees was 54 mm. This means that 5% equals approximately 3.0 mm anterior displacement from the per-operatively determined central position of the ACL footprint.

It has been suggested that experienced surgeons operate with less variance and possibly a more accurate tunnel placement than less experienced surgeons while performing conventional arthroscopic ACL surgery. [13,26] All RCT's including ours, looking at CAS versus conventional ACL reconstruction were performed by experienced ACL surgeons.[15] It is possible that the window for improvement by CAS surgery for ACL reconstruction by experienced surgeons is too small to establish significance.

Although the two surgeons were highly experienced in ACL surgery, there was a considerable and unexpected high variance in tunnel placement in both groups for the tibia and the femur. We had expected this to be less in the CAS group, but there was no significant difference. A possible explanation for the variance is the great anatomical variety that we have seen in intracondylar and femoral condylar shapes. Blumensaat's line is not a straight line, as one might think on the lateral x-ray image, but is more S curved in reality. Also the position of Blumensaat's line varies in angle and the position of the femoral condyle, in correlation to the intracondylar axis, which can be more posterior, centrally, or more anterior. To evaluate outcome with this great anatomic variety in relative measurements, percentages to fixed chosen references (such as femoral condyle and tibial plateau length and height) might induce a measurement bias and could explain some of the variance. The study by Sudhahar et al. showed poor correlation between the intra-operative expected position and the actual post-operative position on lateral X-ray of the AP tibial measurement. Both anatomical differences as intra-operative inaccuracies could contribute to the measured variance.

Another way of looking at the precision is comparing outliers in both groups. Topliss et al. arbitrarily chose Femoral (sagittal): 27%±7, Tibial (sagittal) 44%±4 and Tibial (coronal) 45%±5 as the standards.[25] We transposed his radiological criteria to our 3-D CT data, which introduces a possible bias in adapting the intra-condylar lateral femur condyle CT contour into the X-ray contour of the lateral femoral condyle. We found approximately 40% outliers in both groups for the tibial tunnel placement and nearly 60% outliers in the femoral tunnel position. This is just slightly better than the 59% malpositioned tibial and 64% malpositioned femoral tunnels on the sagittal X-ray image reported by Topliss et al..[25] A possible explanation is the previously mentioned anatomical difference, which was noted more on the 3-D CT images especially on the femoral side. On the tibial side Stäubli et al. described in his study in 1994 of 5 cadaver tibial attachment a range of 38.7-47.9% for the center of the ACL.[21] Even in these small numbers the actual center of the original ACL would be an outlier in 1 specimen (20%). We feel there is still much to learn about the individual size, shape and position of each ACL especially its relation to our used referenced landmarks of the reconstructed knee, which could explain the measured outliers..

We must point out that the use of the CAS ACL reconstruction system has also several down-sides; the extra costs that occur with longer operating time (26.7 minutes) and the usage of the disposable reflective reference balls, the usage of per-operative X-ray imaging, which is cumbersome, and produces additional radiation exposure. The limitation of our study lies in the fact that there is no universal gold standard for the positioning of the single bundle ACL reconstruction. The conventional technique is based on arthroscopic recognition of intracondylar anatomical landmarks, whereas the CAS system also uses an additional radiological knee contour template. This could be considered an outcome bias in favor of the CAS group as the main outcome was based on radiological (3-D CT) measurement.

In conclusion, this study shows no significant difference in precision, nor in accuracy between conventional ACL reconstruction and CAS ACL reconstruction, with the use of intra-operative radiological support.

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Chapter 10

General discussion

This chapter focuses on two main themes.

- To operate or not on the anterior cruciate ligament deficient knee and it's long term outcome.
- Novel insights into computer assisted surgery and 3D measurement of anterior cruciate ligament reconstruction.

The strengths but also the limitations of the studies will be addressed and the implications for daily practice and recommendations for further research will be discussed.

TO OPERATE OR NOT TO OPERATE

Existing evidence and main findings

An anterior cruciate ligament (ACL) injury is a common, but also devastating injury to the knee of a young and active person. It has immediate disabilitating consequences for the athlete, both professional and recreational.[12] The pain and the following swelling will halt any activity immediately. The knee will regain most of its mobility within a few weeks. Secondary instability complaints, after the initial reaction has subsided, can occur especially in more knee demanding activities such as cutting and pivoting sports. Some patients, however, already feel giving way of the knee in normal activities in daily living, such as walking or stair climbing.

The exact incidence of ACL injuries is not known. Orthopaedic surgeons just see the tip of the iceberg, the majority of traumatic knees are largely seen through sport departments, general practitioners and accident and emergency departments. It is unknown, how many of the ACL injured patients seek medical attention. It is probable, that the trauma mechanism and consecutive complaints are so great, that medical attention is sought in a great number of cases, but there is no exact data to substantiate this. Even if the patients are seen with an acute knee, the diagnosis ACL injury is often missed; between 75 to 93% of ACL injuries are missed.[6, 7]

What we do know is that the number of ACL reconstructions is increasing each year not only in The Netherlands but worldwide.[10] Our operative interventions, for an ACL injury, have improved significantly in the last decades from an extra-articular intervention to an intra-articular arthroscopic procedure.[9] An ACL reconstruction nowadays is a predictable giving way reducing operation, with a high patient satisfaction of nearly 90-95%.[10]

However, if we look at sports resumption to the patient's previous level, the predictability is reduced to only 60%. If we look at knee osteoarthritis after ACL reconstruction, the percentage of a non-arthritic knee at 20 years is less than 10 percent.[13] Thus, an ACL reconstruction has not been able to prevent long-term complications of the injury. So we have to realise that our reconstructive efforts have mainly been focused on improving the short-term benefits. ACL reconstruction is able to reduce giving-way moments, in the majority of the treated cases. This operation should therefore be offered to any ACL deficient patient with persisting giving way not responding to conservative treatment, the so-called non-coper. How large this number of non-copers is, is unclear and it varies in different studies between 37% and 100% of the ACL deficient knees (Figure 1 Flow diagram Patient with an ACL Deficient knee).[2, 4]

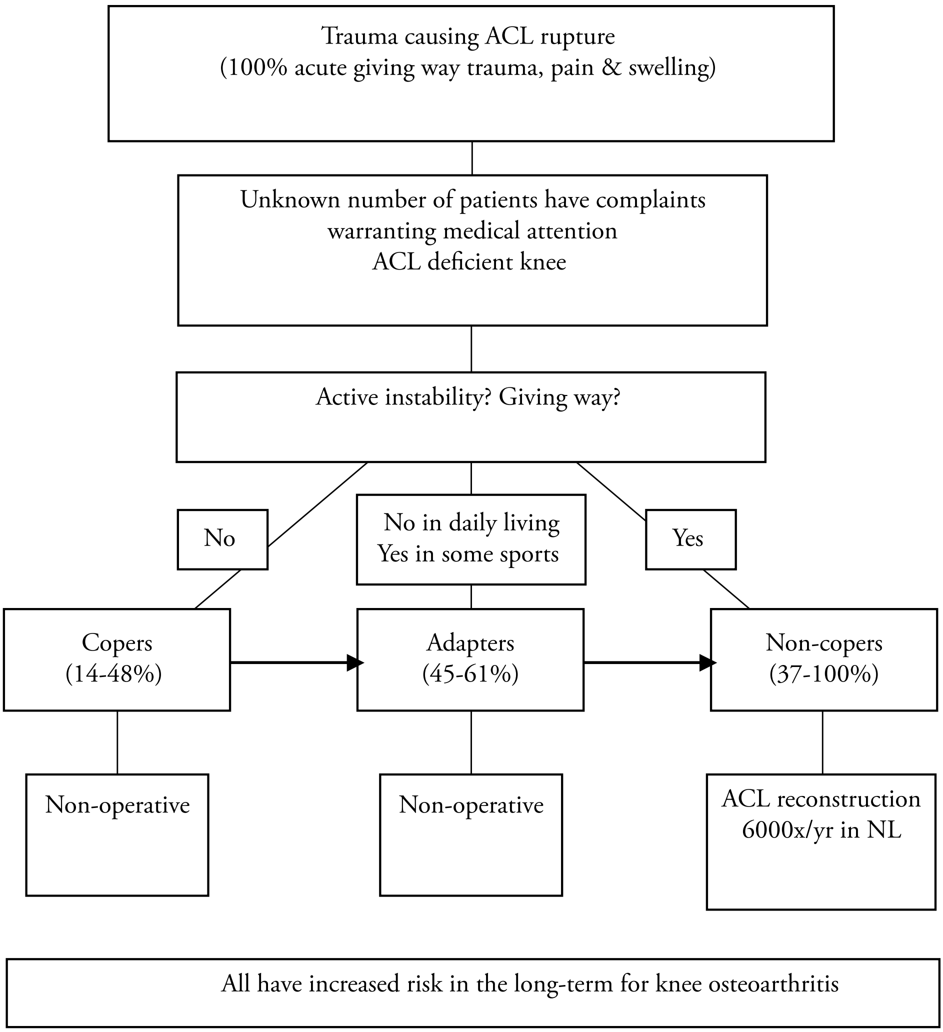

Figure 1: Patient with an ACL deficient knee flow diagram

Our long-term follow-up study of high level athletes who were either treated with a bone-patella-tendon-bone ACL reconstruction or were treated none-operatively showed similar clinical outcome for both groups.[11] It emphasizes the existence of a patient group that deals well with an ACL deficient knee even at a high sports level. These 50 matched-paired athletes had an average functional knee score of 93% in comparison to the non-injured knee. Both groups were able to return to a median Tegner score of 9, post-injury. Other studies such as the randomized clinical trial of Frobell et al. also found that a significant number of patients with an ACL deficient knee deal functionally, subjectively and radiologically well without a reconstruction.[4] Our study reopened the discussion that there does exist a group of ACL deficient high-level athletes, who can cope well with their passive instability and do not need an operative intervention. It also showed that this specific group of high level athletes, had a similar risk of obtaining osteoarthritis at 10 year follow-up compared to the matched paired ACL reconstructed group.

The challenge lies in discovering an accurate and reliable method predicting which ACL deficient patient will be able to cope and which patient will need to adapt or will be unable to cope. Different algorithms have been tried with some success, using risk factors for non-coping such as activity level, objective knee laxity measurements and patient motivation.[3]

Strengths and Limitations

The long-term outcome study in this thesis, on ACL deficient high-level athletes is the first study to compare operative to non-operative treatment. This study challenged the unproven presumption that a conservatively treated ACL deficient knee would not be able to perform at a high-level athletic activity level. It also showed that in this matched-paired analysis there was no difference in patient related outcome and no difference in function or osteoarthritis of the injured knee at long-term follow-up between these two groups. However, we did not recruit all consecutive high level athletes treated for an ACL injury, but pair-matched on age, gender, body mass index and Tegner activity pre-injury, so a selection bias may be present. In a non-randomized study, comparability of both groups is uncertain. We matched on known outcome confounders, but this does not fully exclude possibly unknown group differences.

Proposed further research

Further research is needed to evaluate predictors of ACL deficient knees that are able to distinguish copers versus non-copers. We have already started a multicentre trial to compare the clinical and cost effectiveness of an early ACL reconstruction versus a conservative approach (COMPARE trial). This study is aimed at increasing our knowledge about the short and long-term outcome of timing and operative intervention of an ACL deficient knee and the kind of coping possibilities that can be monitored. Further research into measuring early osteoarthritis is essential to be able to monitor a change in effect modalities to decrease long-term symptomatic osteoarthritis. To increase our knowledge in this field and to find risk factors that can be modified, we have started a study using new imaging modalities for osteoarthritis in ACL deficient knees, such as MRI (KNALL study). This study, and the use of other direct quantitative cartilage imaging, such as d-Gemric is expected to aid in the early outcome measurement and should be used to detect possible positive interventions.

NOVEL INSIGHTS

Existing evidence and main findings

Operative technique has changed from an arthroscopic bone-patella-tendon-bone (BPTB) graft to a hamstring graft. This change was a result of meta-analysis research, showing similar clinical outcome in BPTB versus hamstring with a reduction in co-morbidity, mainly anterior knee pain.[5] This coincided with an increased emphasis on the positioning of the ACL graft. This emphasis was a secondary effect of the rise in attention on newer techniques, specifically double bundle ACL reconstruction.

These days an ACL reconstruction is a surgical technique with a low complication rate.[10] Improvements can be made by reducing the number of complications, by diminishing the number of reinjuries/failures, by improving the general outcome of each individual patient and the long-term outcome by reducing co-morbidity such as additional meniscal or chondral lesions, resulting in osteoarthritis. However, measuring these improvements is difficult. Each individual has different demands and has a varied knee kinematic and anatomy. The position of the implant is important. In 88% of the reoperated cases, this is caused by misplacement of the graft.[8] Good positioning of the graft is extremely important for reducing the failure rate. Surgeons assume that placing the tunnels for the ACL graft more anatomically will improve the outcome for each patient, although there is no hard evidence. In the last years the planned ACL placement has changed from a more vertical (isometric) graft position to a more horizontal position, by changing the femoral aperture tunnel position more proximally on the medial side of the lateral condyle. This concept of anatomic ACL reconstruction encompasses the principles of restoring the native insertion sites of the ACL more closely. [14]

Although there are many hypotheses of tunnel placement, little has been published on how to measure the actual position of the tunnels. No validated and reliable tool for tunnel placement measurement was yet available. This thesis describes a novel method of visualising the ACL reconstructed knee in a 3D Virtual Reality CT method. This 3D Virtual Reality measurement enables us to measure the tunnel position, created during surgery, accurately and will offer the possibility to study which clinical consequences occur with different tunnel positioning. Once we know what the relation is between the different tunnel placement and clinical results, a more successful reconstruction can be performed.

We studied if the tunnel positioning could be improved by using Computer Assisted Surgery (CAS). Improvements in ACL CAS could be fewer outliers and less variance in tunnel placement. CAS has been established to reduce the number of outliers in total knee replacement surgery and knee osteotomies, even though superior long-term clinical outcome is still missing.[1] In theory CAS for ACL reconstruction encompasses many advantages. It enables the surgeon to use an extra reference to check the anatomy and tunnel placement, it can give immediate accurate and reliable per-operative stability measurements and it could decrease the learning curve.[15] The Cochrane meta-analysis in this thesis looked at knee ligament surgery and CAS. We analysed all randomized clinical studies, which compared CAS ACL reconstruction with conventional ACL reconstruction. Based on the selected studies we concluded that there is insufficient evidence from randomized trials to draw conclusions on the superiority of computer assisted surgery for knee ligament reconstructions compared to conventional reconstructions. We, therefore, performed a randomized clinical trial, which studied computer assisted ACL reconstruction using a validated novel outcome measurement for tunnel placement in 3-D CT. The study could not show a significant difference in precision, nor in accuracy, between conventional ACL reconstruction and CAS ACL reconstruction, with the use of per-operative radiological support. The orthopaedic community should reconsider the present used systems, as there is no scientific evidence to support the extra cost and longer operating time that are associated with CAS in cruciate ligament surgery.

Strengths and limitations

The CAS study is the first to establish the reliability of 3D measurements for ACL reconstruction. It is also the only study describing this new Virtual Reality visualisation of the knee. The problem with previous methods was that an ACL reconstruction was simplified to 2D, overlooking the fact that it's 3-dimensional character is of great importance for a successful operation. The door is now open to unveil the characteristics of this new third dimension. The downsight of this described technique is that it is very high tech and is therefore not generalisable. Secondly, the 3D data were accumulated by CT scans, which use ionising radiation.

Proposed further research

Further research is necessary to correlate the exact tunnel position with clinical outcome; the randomized clinical trial CAS versus conventional arthroscopic ACL reconstruction is an excellent opportunity to accumulate this evidence. We have established through viewing more than a hundred 3D CT scans in a Virtual Reality environment the great diversity in anatomy especially of the distal femur. More knowledge should be acquired about these anatomic variances and the possible kinematic and treatment related consequences.

Conclusions and implications of this thesis for clinical practice

It is shown that at long-term follow-up in high-level athletes without an ACL reconstruction there was a similar patient outcome compared to reconstructed knees. There are highly active patients who will thrive with non-operative treatment of an ACL injury. Further research is still needed to recognise these specific patients.

It is also shown that a novel 3D Virtual Reality CT is a better and more reliable post-operative visualisation tool, compared to standard knee radiographs, for ACL reconstructed knees.

However, this thesis could not offer proof in a meta-analysis of randomized clinical trials, nor in a self performed RCT, that CAS was superior to conventional arthroscopic ACL reconstruction.

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Chapter 11

Summary

This thesis was undertaken to give more insight into the treatment of a common knee ligament injury; the anterior cruciate ligament rupture.

We looked at the well-established controversy, still existing to operate or not to operate. Through a literature review and a long-term follow-up, matched control study of high level athletes and professional dancers, we showed that it is not necessary to operate all ACL tears.

The following chapters were aimed at the ACL tears which do need reconstruction, we showed ways of improving this by biomechanically testing the ACL graft fixation and showing that smaller is not worse and double tunnels are better.

The most essential part of a ACL reconstruction is the placement of the graft; a new and improved method of visualizing and measuring in 3-D tunnel placement was developed and was proven superior to previously used methods.

A literature review and a clinical randomized trial were undertaken, which showed no significant improvement in ACL reconstruction by using computer navigation.

In **Chapter 2** the different aspects of increased operative treatment for anterior cruciate ligament tears were discussed. An anterior cruciate ligament rupture is a very common musculoskeletal injury. The number of anterior cruciate ligament reconstructions is increasing in The Netherlands and globally. It is predominantly a sporting injury, often resulting in knee instability. Substantial progress has been made with improving surgical technique, from an open procedure to a minimal invasive arthroscopic operation. Treatment should always be centered on each individual. There is insufficient long-term evidence to merit one specific treatment (operative or conservative) above the other. Multiple factors should be considered such as: complaints, amount of instability, sports wishes, age and willingness to commit to a nine-month rehabilitation program. An ACL reconstruction will not diminish the increased change for secondary knee osteoarthritis, neither will it restore normal knee kinematics, but it will reduce giving way complaints. These giving way complaints are still the most important indication for this operation.

No data exist concerning dance and ACL injury. **Chapter 3** reported the incidence, injury mechanism and clinical follow-up of ACL injury in professional dancers.

This was done by interviewing all 253 dancers, who had had a full-time contract during 1991-2002, with the three most renowned dance companies in the Netherlands. Dancers with symptomatic ACL injury or past ACL reconstruction were identified and examined in a retrospective cohort study of the three major dance companies in the Netherlands.

6 dancers (2 women) had had a symptomatic ACL rupture and reconstruction. Interestingly, all on the left side and with a similar trauma mechanism: while dancing

a classical variation they landed, after a jump, on their left leg, in the turned out position with a valgus force on their knee. There was a higher risk for an ACL injury in the classical company than in the two contemporary companies. The risk, for dancers of having a rupture of the left ACL during a 10-year career in this classical company was 7%. More attention and prophylactic measures should be given to this specific injury mechanism.

Chapter 4 was a long term outcome study of highly active patients with anterior cruciate ligament ruptures treated operatively versus non-operatively. We reviewed high level athletes with an anterior cruciate ligament rupture on either MRI or arthroscopic evaluation more than 10 years previously, who were treated conservatively. They were pair-matched with patients who had had an anterior cruciate ligament reconstruction with bone-patella-tendon-bone, with respect to age, gender and Tegner activity score before injury. In total 50 patients were pair-matched. We found no statistical difference between the patients treated conservatively or operatively with respect to osteoarthritis or meniscal lesions of the knee, as well as activity level, objective and subjective functional outcome. The patients who were treated operatively had a significantly better stability of the knee at examination. We conclude that the instability repair using a bone-patella-tendon-bone anterior cruciate ligament reconstruction is a good knee stabilising operation. Both treatment options, however, show similar patient outcome at 10 year follow up. The New York Times called the study question “provocative”. A related interview for the largest and most visited internet site of the U.S.A., showed its clinical and present relevance, as it offered the second most read article of that year.

In **Chapter 5** we examined the possibility of the usage of smaller bone blocks. The aim of the study was to investigate whether use of short bone blocks is safe in ACL reconstruction. Our hypothesis was that the smaller 10-mm-length bone blocks would fail at lower loads than 20-mm-bone blocks. Ten paired human cadaver knees were randomly assigned to the 10- or 20-mm group (group 1 and 2) and underwent bone-patellar tendon-bone femoral fixation with interference screw. Tensile tests were performed using a tensile testing machine (Instron). Stiffness, failure load and failure mode were recorded. Median stiffness was 72 N/mm (16-103) for 10-mm-bone blocks and 91 N/mm (40-130) for 20-mm-bone blocks. Median failure loads were 402 N (87-546) for 10-mm-long bone block and 456 N (163-636) for 20-mm-bone blocks. There was no statistically significant difference between groups (P = 0.35). All bone-patellar tendon-bone grafts were pulled out of the femoral tunnel with interference screw, due to slippage. We concluded that a 10-mm-long bone block was not significantly weaker than a 20-mm-long bone block. Failure loads of a 10-mm-bone block exceeded loading values at passive and active extension of the knee under normal conditions. Ten millimeter bone blocks offered sufficient fixation strength in ACL reconstruction.

The primary objective of **Chapter 6** was to evaluate the difference in graft pullout forces, stiffness, and failure mode of double-bundle anterior cruciate ligament (ACL) reconstruction of the tibial insertion by use of a single tunnel compared with a double-tunnel technique with interference screw fixation. ACL reconstruction on the tibial side was performed on 40 fresh-frozen porcine knees (mean bone mineral density of 0.64 g/cm(2) measured by dual-energy x-ray absorptiometry scan), randomly assigned to the single- or double-tunnel group. Interference screw fixation of the soft-tissue graft was used for both types of tibial reconstruction. Maximum failure load, stiffness, and failure mode were recorded. There was no significant difference in maximum failure load between the single-tunnel group (400 +/- 26 N) and double-tunnel group (440 +/- 20 N). Stiffness of the tibial tunnel complex was significantly higher in the double-tunnel group (76 +/- 3 N/mm) than in the single-tunnel group (62 +/- 4 N/mm) (P = .013). All but 2 grafts (38 of 40) failed by slippage of the tendon past the interference screw. There was significantly stiffer fixation of the tibial double-tunnel ACL complex when compared with the single tunnel. Our study did not show a different failure mode for the double-tunnel reconstruction compared with the single-tunnel reconstruction. This study shows a biomechanical advantage with no potential deleterious side effects for fixation of the ACL with a double-tunnel technique on the tibial side.

Chapter 7 looked at visualization of post-operative ACL reconstruction bone tunnels. reliability of standard radiographs, CT Scans and 3-D virtual reality images. Anatomic placement of the bone tunnels is critical to the success of anterior cruciate ligament (ACL) reconstruction. Non-anatomic bone tunnel placement is the most common cause of a failed ACL reconstruction. Since bone tunnel placement is such an important factor in the success and outcome of ACL reconstruction, accurate and reproducible methods to postoperatively visualize and document bone tunnel placement would be helpful in assessing patient outcomes. The objective of this imaging study was to post-operatively evaluate the reliability of standard radiographs, CT scans, and a 3-D virtual reality imaging method in visualizing and measuring ACL reconstruction bone tunnel placement.

Study Design: A diagnostic imaging study. Fifty consecutive patients who underwent single-bundle ACL reconstructions were evaluated post-operatively by standard radiographs, CT scans and a 3-D virtual reality technique. Tibial and femoral tunnel positions were measured by two observers using the traditional methods of Amis, Aglietti, Hoser, Staubli, and a variant of the method of Benereau for the 3-D virtual reality approach. The tunnel was visualized in 50 - 82% of the standards radiographs radiographs versus 100% in the CT and the 3-D virtual reality technique. Using the intraclass correlation coefficient (ICC) the inter- and intraobserver agreement was between 0.39 and 0.83 for the standard femoral and tibial radiographs. CT scans showed an ICC range of 0.49-0.76 for the inter- and intra observer agreement. The 3D virtual reality agreement was almost perfect with an ICC of 0.83 for the femur and 0.95 for the tibia. CT scans and 3-D virtual reality images show more reliability in assessing postoperative bone tunnel placement following ACL reconstruction than standard radiographs.

In **Chapter 8** we performed a Cochrane meta-analysis to assess the effects of computer assisted reconstruction surgery versus conventional operating techniques for ACL or posterior cruciate ligament (PCL) deficient knees in adults. We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (March 2010), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 3), MEDLINE (1966 to March 2010), EMBASE (1980 to March 2010) and CINAHL (1982 to March 2010), article references and prospective trial registers. Randomised controlled trials (RCTs) and quasi-randomised controlled trials that compared computer assisted surgery (CAS) of the ACL and PCL with conventional operating techniques not involving CAS, were included. We independently screened search results, assessed methodological quality and extracted data. Four randomised controlled trials were included, encompassing 266 patients. All addressed ACL reconstructions. We were unclear about the methodological quality of the studies due to poor reporting. The trials addressed a variety of different outcomes. There were no significant differences, in effect, between computer assisted surgery and conventional surgery for ACL reconstruction. A favourable effect of computer assisted surgery for cruciate ligament reconstructions of the knee compared to conventional reconstructions could be demonstrated nor refuted. There is insufficient evidence to advise for or against the use of CAS.

Chapter 9 described the RCT computer assisted surgery versus conventional ACL reconstruction. It is of the utmost importance for the final outcome to ensure an accurate, reproducible tunnel position of the transplanted ligament. A new development has been computer assisted surgery (CAS), aiding in the ACL bone tunnel placement during surgery.

Hypothesis: Using CAS for ACL surgery will show a more accurate tunnel placement compared to conventional surgery. This study is set up as a prospective double-blinded randomized clinical study. 100 patients eligible for ACL reconstruction were randomized for either conventional or CAS. As primary measurement, the tunnel position of the transplant using conventional surgery will be compared to the computer assisted technique using 3 dimensional CT measurement.

No difference in placement of the femoral tunnel for the conventional group was seen compared to the CAS group (respective mean 39.7% versus 39.0% on the proximo-distal intracondylar axis (P-value 0.70)). There was no significantly different anterior-posterior placement of the tibia tunnel 38.2% in the conventional group and 38.9% in the CAS group (P-value 0.58). There was no significant difference in variance of the femoral or the tibial placement in the two groups.

This study shows no significant difference in accuracy or in precision of the tunnel placement between conventional and CAS ACL reconstruction.

Chapter 10 concluded with a discussion encompassing the results found and implications of our studies. It also looked at future research and had some interesting recommendations for the future.

Chapter 12

Summary in Dutch / Nederlandse samenvatting

Dit proefschrift werd opgezet om meer inzicht te verschaffen in een veel voorkomende sport gerelateerde blessure, het voorste kruisband (VKB) letsel. In **hoofdstuk 1** werd een algemene inleiding gegeven over de ontstaanswijze en reden tot deze proeve van bekwaamheid in de wetenschap.

In **hoofdstuk 2** werden de verschillende aspecten besproken betreffende de operatieve behandeling van VKB letsels. Een VKB ruptuur is een veel voorkomend letsel van het bewegingsapparaat. Het aantal jaarlijks uitgevoerde VKB reconstructies neemt toe, zowel in Nederland als mondiaal. Het letsel komt met name voor bij sporters en gaat vaak gepaard met instabiliteitsklachten. Er is een duidelijke vooruitgang geboekt met de chirurgische techniek, van een open procedure naar een minimaal invasieve arthroscopische techniek. De behandeling is individueel, waarbij er onvoldoende lange termijn resultaten bekend zijn om één specifieke behandeling (operatief of conservatief) te adviseren. Meerdere factoren moeten in ogen schouw genomen worden zoals: klachten patroon, mate van instabiliteit, wensen ten aanzien van sportbeoefening, leeftijd en bereidheid tot een 9 maanden durende revalidatie. Door een VKB reconstructie te verrichten zal de verhoogde kans op secundaire knie artrose niet afnemen, ook zal het de knie kinematica niet herstellen, maar het zal wel de kans op doorzakken verminderen. Deze doorzak klachten zijn de belangrijkste indicatie voor een operatief ingrijpen.

Er is geen literatuur beschikbaar over professionele dans en VKB letsel. In **hoofdstuk 3** wordt de incidentie, ontstaansmechanisme en de klinische follow-up van VKB blessures bij professionele dansers beschreven. Hiervoor werden alle 253 dansers, die een full-time contract hadden gedurende de periode 1991-2002, bij één van de drie gerenommeerde Nederlandse dansgezelschappen geïnterviewd. Dansers met symptomatische VKB letsels of een VKB reconstructie in de voorgeschiedenis werden geïdentificeerd en onderzocht in een retrospectieve cohort studie. Zes dansers (waarvan 2 vrouwen) hadden in de voorgeschiedenis een symptomatische VKB ruptuur en reconstructie ondergaan. Frappant genoeg waren deze allemaal aan de linker zijde en met een vergelijkbaar traumamechanisme: terwijl zij een klassieke variatie aan het dansen waren landdden zij na een sprong op hun linker been in de naar buiten gedraaide positie met een valgus kracht op de knie. Er was een significant hoger risico voor een VKB letsel in het klassieke gezelschap in vergelijking met twee moderne gezelschappen. Het risico voor dansers om een letsel van de linker VKB gedurende een 10-jarige carrière in dit klassieke gezelschap op te lopen was 7%. Geadviseerd wordt meer aandacht te besteden aan profylactische maatregelen, die genomen worden ten aanzien van dit specifieke ontstaansmechanisme en letsel.

Hoofdstuk 4 bevatte een studie die over lange termijn uitkomsten gaat van zeer actieve atleten/patiënten met een VKB ruptuur, die operatief of non-operatief werden behandeld. Atleten op hoog niveau werden onderzocht met een VKB ruptuur. Deze VKB rupturen waren of op MRI bewezen of arthroscopisch. De follow-up werd verricht tien jaar na het ongeval. Patiënten die conservatief waren behandeld werden gematched met patiënten die een VKB reconstructie hadden ondergaan met een bone-patella-tendon-bone transplantaat. Deze patiënten werden gematched met betrekking tot leeftijd, geslacht en Tegner activiteit. Deze Tegner activiteit werd gerelateerd aan de activiteit voor het initiële trauma. In totaal werden 50 patiënten geïncludeerd. Wij vonden geen statistisch significant verschil tussen deze patiënten die behandeld werden non-operatief versus operatief ten aanzien van het ontstaan van artrose van de knie of opgelopen meniscusletsels. Er was ook geen verschil in activiteiten niveau en functionele uitkomst, objectief of subjectief, na 10 jaar. De patiënten die operatief zijn behandeld hadden wel een significant betere stabiliteit van de knie bij onderzoek. Geconcludeerd wordt dat de VKB reconstructie met bone-patellatendon-bone een goede stabiliserende operatie is. Operatieve behandeling laat echter een vergelijkbare patiëntenuitkomst, na tien jaar follow-up, zien als niet-operatieve behandeling.

In **hoofdstuk 5** werd de mogelijkheid onderzocht of het gebruik van een korter botblokje bij een bone-patellatendon-bone reconstructie van de voorste kruisband veilig zou zijn. De hypothese was dat een 10 mm lang botblokje eerder zou falen dan een 20 mm botblokje. 10 gepaarde knieën van humane kadavers werden na randomisatie toegewezen aan de 10 of 20 mm lengtegroep. Deze ondergingen een bone-patellatendon-bone femorale fixatie met metalen interferentieschroef. Trekkrachttesten werden verricht, gebruik makend van een trekkrachtmachine (Instron). Stijfheid, maximale belasting en faalmechanisme werden vastgelegd. De mediane stijfheid was 72 N/mm (16-103) voor 10mm botblokjes en 91 N/mm (40-130) voor 20 mm botblokjes. De mediane maximale (faal) belastingskracht was 402 N (87-546) voor 10 mm lange botblokjes en 456 (163-636) voor 20 mm botblokjes. Er was geen statisch significant verschil tussen beide groepen (P waarde = 0.35). Alle bone-patellatendon-bone transplantaten werden uit de femorale tunnel getrokken waarbij het transplantaat langs de interferentieschroef gleed. De conclusie luidt dat een 10 mm lang botblokje niet significant zwakker is dan een 20 mm lang botblokje. De maximale fixatie krachten van een 10mm botblokje zijn voldoende om zowel passieve als actieve extensie van de knie onder normale condities te verdragen. 10mm botblokjes geven een sufficiënte fixatiekracht voor een VKB reconstructie.

In **hoofdstuk 6** werd de studie beschreven die onderzocht of VKB dubbel tibia tunnel fixatie eerder, en met een metafysaire tibia fractuur, zou falen dan een enkele tunnel fixatie. Evaluatie vond plaats van het verschil in maximale trekkracht, stijfheid en faalmechanisme van het transplantaat van een dubbelbundel VKB reconstructie in de tibia bij het gebruik van een enkele of dubbel tunneltechniek met interferentie schroeffixatie. De VKB reconstructie werd verricht bij 40 vers gevroren varkensknieën (de gemiddelde botmineraaldichtheid was 0.64 gram/cm^2, gemeten met dual-energy x-ray absorptiometriscan). Ze werden gerandomiseerd toegewezen aan de enkel- of dubbeltunnelgroep. Interferentie schroeffixatie van de weke delen graft werd verricht voor beide typen van tibiale reconstructie. De maximale faalkrachtbelasting, stijfheid en faalmechnisme werden gemeten. Er was geen significant verschil in maximum faalkracht tussen de enkeltunnelgroep (400 ± 26 N) en de dubbeltunnelgroep (440 ± 20 N). Stijfheid van het tibiale tunnelcomplex was significant hoger in de dubbeltunnelgroep (76 ± 23 N/mm) dan in de enkeltunnelgroep (62 ± 4 N/mm). (P waarde = 0.013). 38 van de 40 reconstructies faalden door het glijden van de pees langs de interferentieschroef. De stijfheid van het tibiale dubbele tunnel VKB complex was significant hoger dan die van de enkele tunnel. Onze studie liet geen verschillend faalmechnisme voor de dubbele tunnelreconstructie zien in vergelijking met de enkele tunnelreconstructie. Deze studie toont een biomechanisch voordeel zonder potentiële nadelige bijeffecten van de fixatie van de VKB met een dubbel tunneltechniek aan de tibiale zijde.

Hoofdstuk 7 beschreef de studie naar de visualisatie van de bottunnel van de VKB reconstructie postoperatief en deze studie beoordeelt de reproduceerbaarheid van standaard röntgenfoto's, CT-scans en 3-D virtueel beeld. Het doel van deze beeldvormende studie was om de reproduceerbaarheid van röntgenfoto's, CT-scan en 3-D virtueel beeld te onderzoeken van een VKB reconstructie bij 50 opeenvolgende patiënten, die een enkelbundel voorste kruisbandreconstructie hadden ondergaan. De knie werd postoperatief geëvalueerd door middel van standaard röntgenfoto's, CT-scans en een 3-D virtueel beeldvormende techniek. De tibiale en femorale tunnelposities werden gemeten door twee onderzoekers die gebruik maakten van de traditionele methode van Amis, Aglietti, Hoser en Stäubli. Tevens werd er een variant van de methode van Benereau gebruikt voor het meten van de 3-D virtuele meting. De tunnel kon worden gevisualiseerd in 50-82% van de standaard röntgenfoto's versus 100% in de CT-scan en 3-D virtuele techniek. Gebruik makend van de Intraclass Correlation Coëfficiënt (ICC) was de inter- en intraobserver overeenkomst voor de standaard röntgenfoto's femoraal en tibiaal tussen de 0.83-0.94. De CT-scan liet een ICC range zien van 0.49-0.76 voor de inter- en intraobserver overeenkomst. De 3-D virtuele overeenkomst was zeer goed met een ICC van 0.83

voor het femur en een 0.95 voor de tibia. CT-scans en 3-D virtuele beeldvorming geven de postoperatieve bottunnel beter weer en reproduceren de tunnelplaatsing na een VKB reconstructie in vergelijking met standaard röntgenfoto's beter.

In **hoofdstuk 8** werd een Cochrane review verricht om de meerwaarde van computer geassisteerde VKB reconstructie versus conventionele operatie technieken voor voorste en achterste kruisband deficiënte knieën bij volwassenen te analyseren. De Cochrane Bone, Joint en Muscle Trauma Group Specialised Register (maart 2010), de Cochrane Central Register of Controlled Trails (CENTRAL) (The Cochrane Library 2010, uitgave 3), Medline (1966 tot maart 2010), EMBASE (1980 tot maart 2010) en CINAHL (1982 tot maart 2010), artikel referenties en randomized trial registers werden doorzocht. Gerandomiseerde gecontroleerde- en quasi gerandomiseerde gecontroleerde studies, die computer geassisteerde chirurgie (CAS) van de voorste en/of achterste kruisband gebruikten, werden vergeleken met conventionele operatietechnieken waarbij geen gebruik werd gemaakt van CAS. De methodologische kwaliteit van de geïncludeerde studies en de dataextractie werd uitgevoerd door twee onafhankelijke beoordelaars. Vier studies werden geïncludeerd, dit betrof 266 patiënten met een VKB reconstructie. De methodologische kwaliteit van de geïncludeerde studies was matig, met name door matige rapportage. De onderzoeken beschreven een grote variatie van verschillende uitkomstmaten en tonen geen significant verschil in effect tussen CAS in vergelijking met conventionele chirurgie voor VKB reconstructie. Een gunstig effect van CAS voor VKB reconstructies kon niet gedemonstreerd of verworpen worden in vergelijking met conventionele VKB reconstructies. Er is onvoldoende bewijs om een gegrond advies te kunnen geven of het gebruik van VKB reconstructie met CAS toegevoegde waarde heeft.

Hoofdstuk 9 beschreef een gerandomiseerd klinisch onderzoek waarbij CAS werd vergeleken met conventionele VKB reconstructie. CAS is een techniek die de chirurg ondersteunt bij de keuze van de plaats van de bottunnel tijdens een VKB reconstructie. De hypothese van deze studie was dat, het gebruik van CAS tijdens een VKB reconstructie een accuratere en reproduceerbare tunnelplaatsing oplevert in vergelijking met conventionele chirurgie. Deze studie is opgezet als een prospectief dubbelblind gerandomiseerd klinische studie. Er werden100 patiënten geïncludeerd, die gerandomiseerd werden voor CAS of conventionele reconstructie. De femorale en tibiale tunnel positie van de VKB reconstructie werden als primaire uitkomst gekozen. Deze uitkomst werd gemeten met 3-dimensionale CT beeldvorming. Er kon geen verschil in plaatsing van de femorale tunnel voor de conventionele groep in vergelijking met de CAS groep getoond worden. (gemiddeld 39.7% versus 39.0% op de proximo-distale intracondylaire as) (P waarde van 0.70). Er was ook geen significant verschil in de voorachterwaartse tunnel positie op het tibiaplateau tussen de conventionele groep (38.9%) en de CAS groep (38.2%)(P waarde van 0.58). Er was geen significant verschil in variatie noch voor het femur noch voor de tibiaplaatsing in beide groepen. Deze studie laat geen significant verschil zien in accuraatheid of in precisie van de tunnelplaatsing tussen conventionele en een CAS VKB reconstructie.

Hoofdstuk 10 concludeerde, met een discussie, die inging op de gevonden resultaten en op de implicaties van de gevoerde studies. Eveneens werd beschreven waar onderzoeksmogelijkheden bestaan en er werden voorstellen gedaan voor toekomstig onderzoek.

Chapter 13

Summary in Spanish / Resumen en Español

Esta tesis se hizo para profundizar en el tratamiento de una afección común de los ligamentos de la rodilla: la rotura de los ligamentos cruzados anteriores (ACL en inglés).

Examinamos la largamente establecida controversia entre operar y no operar. Revisando la literatura y un estudio de control cruzado a largo plazo realizado en atletas de alto nivel y bailarines profesionales, demostramos que no es necesario operar todas las lesiones de ligamentos anteriores cruzados.

Los capítulos siguientes tratan a las lesiones de ligamentos cruzados anteriores que necesitan reconstrucción. Mostramos procedimientos para mejorar esto, probando biomecánicamente la fijación del injerto en el ligamento anterior cruzado y mostrando que lo pequeño no es necesariamente peor y que los túneles dobles son mejores.

La parte más importante de una reconstrucción de ACL es la colocación del injerto. Se ha desarrollado un nuevo y mejorado método para visualizar y medir en 3 dimensiones el emplazamiento del túnel, y se ha demostrado que este método es superior a métodos usados previamente.

Se hizo una revisión de la literatura y se llevó a cabo un test clínico aleatorio, que mostró que no hay una mejora significativa de la reconstrucción del ACL con el uso de navegación por ordenador.

En el **capítulo 2** se discuten los diferentes aspectos del alto número de operaciones de rotura de los ACL. Una ruptura de los ACL es una lesión musculoesquelética muy común. El número de reconstrucciones de los ACL está incrementándose en Holanda y en todo el mundo. Es predominantemente una lesión deportiva que a menudo lleva a una inestabilidad en la rodilla. Se ha hecho un progreso sustancial con técnicas quirúrgicas mejoradas, desde la operación abierta a una cirugía artroscópica mínimamente invasiva. El tratamiento debe estar siempre centrado en cada paciente. No hay suficiente evidencia a largo plazo para decantarse por un tratamiento específico (quirurgico o conservador). Deben considerarse múltiples factores como: quejas, grado de inestabilidad, deseos de practicar deporte, edad y compromiso en realizar un tratamiento de rehabilitación que dura nueve meses. Una reconstrucción de ACL no reducirá el incrementado riesgo de desarollar una osteoartritis secundaria en la rodilla, ni restaurará la cinemática normal de la rodilla, pero reducirá las quejas sintomáticas. Estas quejas sintomáticas son todavía la razón más importante para esta operación.

No hay datos que relacionen la lesión de ACL y la danza. El **capítulo 3** reporta la incidencia, el mecanismo de la lesión y el seguimiento clínico de la lesión de ACL en bailarines profesionales. Esto se hizo entrevistando a un total de 253 bailarines, que tenían un contrato a tiempo completo entre 1991 y 2002, con las tres compañías más importantes de danza en Holanda.

Se identificaron los bailarines con lesión de ACL sintomática o una pasada reconstrucción de ACL y se estudiaron en un estudio retrospectivo de cohorte (estudio comparativo) de las tres mayores compañías de danza de Holanda. 6 bailarines (de ellos 2 mujeres) sufrieron una rotura sintomática de ACL y fueron tratados mediante una reconstrucción. Curiosamente, todas acontecieron en la parte izquierda y con un perfil similar de mecanismo traumático: mientras bailaban una variación clásica, cayeron, tras un salto, con la pierna izquierda girada con una fuerza descentrada en su rodilla en valgus. Había un mayor riesgo de lesión de ACL en la compañía clásica que en las dos compañías contemporáneas. El riesgo para bailarines de sufrir una lesión de ACL en la rodilla izquierda, durante una carrera de 10 años en esta compañía clásica, era del 7%. Se debe prestar más atención y llevar a cabo medidas profilácticas a este mecanismo específico de lesiones.

El **Capítulo 4** es un estudio a largo plazo sobre pacientes muy activos con una rotura anterior de ACL con o sin operación. Revisamos a atletas de alto rendimiento con una anterior rotura de ACL (acontecida más de 10 años antes), bien con resonancia magnética o con evaluación artroscópica, que fueron tratados de forma conservadora. Fueron comparados con pacientes que tuvieron una reconstrucción de ACL con hueso-rotula-tendón-hueso, en referencia a su edad, sexo e índice Tegner de actividad, antes de la lesión. Un total de 50 pacientes fueron comparados. No encontramos diferencia estadística entre pacientes tratados de forma conservadora u operados con respecto a osteoartritis o lesiones de menisco en la rodilla, así como en referencia al nivel de actividad, o resultado funcional objetivo o subjetivo. A los pacientes que fueron operados se les detectó una significativa mejor estabilidad de la rodilla. Concluimos que la técnica de reparación de la inestabilidad, usando una reconstrucción de los ACL hueso-rótula-tendón-hueso, es una buena operación de estabilización de la rodilla. Ambos tratamientos sin embargo mostraron resultados similares en los pacientes, tras una evaluación 10 años después.

En el **capítulo 5** examinamos la posibilidad de usar bloques óseos más pequeños. El objetivo del estudio es investigar si el uso de bloques óseos cortos es seguro en la reconstrucción del ACL. Nuestra hipótesis es que los bloques más pequeños de 10 mm de longitud fallarían a cargas más bajas que los bloques de 20 mm. Se asignaron de forma aleatoria 10 pares de rodillas de cadáveres humanos a los bloques de 10 y 20 mm (grupo 1 y 2) y se practicó una fijación femoral hueso-rótula-tendón-hueso con tornillos de interferencia. Se realizaron pruebas de flexión con una prensa de pruebas (marca Instron). Se midió la rigidez, carga de fallo y modo de fallo. La rigidez media fue de 72 N/mm (16-103) para los bloques de 10 mm y 91 N/mm (40-130) para los bloques de 20 mm. Las cargas de fallo medias fueron de 402 N

(87-546) para los bloques de 10 mm y 456 N (163-636) para los bloques de 20 mm. No hubo diferencia estadísticamente significativa entre los grupos (P= 0.35). Todos los injertos hueso –rótula y tendón-hueso fueron arrancados del túnel femoral con tornillos por deslizamiento. Concluimos que un bloque óseo de 10 mm de longitud no era significativamente más débil que uno de 20 mm. Las cargas de fallo rotura de un bloque de 10 mm excedían las cargas de una extensión pasiva y activa de la rodilla bajo condiciones normales. Los bloques de 10 mm ofrecían suficiente robustez de fijación en la reconstrucción de ACL.

El objetivo primario del **capítulo 6** era evaluar la diferencia entre la fuerza de arrancamiento del injerto, rigidez y el mecanismo de fallo de la reconstrucción de la inserción tibial del ligamento doble cruzado anterior (ACL), comparando las técnicas de túnel simple contra túnel doble, con fijación mediante tornillos. La reconstrucción del ACL en el lado tibial se practicó en 40 muestras congeladas de rodillas porcinas (densidad ósea media 0.64 g/cm(2) medida por escáner de absorciometría de rayos x de energía dual). Estas muestras fueron asignadas aleatoriamente a grupos de túnel simple y túnel doble. Se usaron tornillos para la fijación del injerto de tejido blando en ambos tìpos de reconstrucción tibial. Se midieron la carga de fallo, la rigidez y el mecanismo de fallo. No hubo diferencia significativa en la carga máxima de fallo entre el grupo de túnel simple (400 +/- 26 N) y el grupo de túnel doble (440 +/- 20 N). La rigidez del complejo del túnel tibial fue significativamente mayor en el caso del grupo del túnel doble (76 +/-3 N/mm) que en el caso el grupo del túnel simple (62 +/- 4 N/mm). Todos los injertos salvo dos (38 de 40) fallaron por deslizamiento del tendón con respecto al tornillo de interferencia. Hubo una fijación significativamente más rígida del complejo tibial- ACL de doble túnel que en el caso del túnel simple. Nuestro estudio no mostró un mecanismo diferente de fallo de la reconstrucción de túnel doble comparada con la de túnel simple.

Este estudio muestra una ventaja biomecánica sin efectos secundarios perjudiciales para la fijación del ACL con una técnica de túnel doble en el lado tibial

El **capítulo 7** se ocupa de la visualización de la fiabilidad post-operatoria de los túneles óseos en la reconstrucción de ACL por medio de técnicas de radiografía estándar, TAC e imágenes 3-D virtuales. La localización anatómica de los túneles óseos es crítica para el éxito de la reconstrucción de ACL. Una colocación no anatómica del túnel óseo es la causa más común de fallo en una reconstrucción de ACL. Dado que la colocación de los túneles óseos es un factor tan importante en el éxito y en el resultado de una reconstrucción de ACL, sería útil disponer de métodos precisos y reproducibles para visualizar y documentar tras la operación la colocación del túnel óseo para determinar el resultado en el paciente.

El objetivo de este estudio de visualización fue evaluar, tras la operación, la fiabilidad de las radiografías estándar, el TAC y un método de visualización 3-D por realidad virtual, en visualizar y medir la colocación del túnel óseo en una reconstrucción ACL.

Diseño del estudio: un estudio de visualización diagnóstica. Cincuenta pacientes consecutivos que sufrieron reconstrucciones de ACL de túnel simple fueron evaluados tras la operación por medio de radiografías estándar, el TAC y un método de visualización 3-D por realidad virtual. Las posiciones tibial y femoral del túnel fueron medidas por dos observadores utilizado las técnicas de Amis, Aglietti, Hoser, Stäubli, y una variante del método de Benereau para la técnica de realidad virtual 3-D. El túnel fue visualizado en 50-82% de las radiografías estándar contra un 100% de los TACs y el método de visualización 3-D por realidad virtual. Usando el coeficiente de correlación intra-clase (ICC), la correlación intra e inter-observadores estuvo entre 0.39 y 0.83 para las radiografías tibial y femoral estándar. Los TACs mostraron un rango de ICC de 0.40 – 0.76 para la correlación intra e inter-observadores. La correlación del sistema 3D fue casi perfecta con un ICC de 0.83 para el fémur y 0.95 para la tibia. Los TACs y la realidad virtual 3-D son más fiables que las radiografías estándar para determinar la colocación del túnel óseo tras una operación de reconstrucción de ACL.

En el **capítulo 8** llevamos a cabo un meta-análisis de Cochrane para determinar los efectos de una reconstrucción asistida por ordenador contra la técnica de operación convencional, para rodillas deficientes en adultos con lesiones de ACL y PCL (Ligamentos posteriores cruzados)

Investigamos el “Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (Marzo 2010)”, el “Cochrane Central Register of Controlled Trials (CENTRAL) *(The Cochrane Library* 2010, Issue 3)”, “MEDLINE (1966 a Marzo 2010)”, “EMBASE (1980 a Marzo 2010)” y “CINAHL (1982 a Marzo 2010)”, referencias de artículos y registros de pruebas prospectivas. Se incluyeron pruebas controladas aleatoriamente y cuasi-aleatoriamente que comparaban cirugía asistida por ordenador (CAS) de los ACL Y PCL con técnicas quirúrgicas convencionales que no incluían CAS. Revisamos independientemente los resultados de la búsqueda, valorando la calidad metodológica y los datos obtenidos. Se incluyeron cuatro pruebas controladas aleatoriamente, con un total de 266 pacientes. Todas valoraban la reconstrucción de ACL. No pudimos juzgar la calidad metodológica de los estudios debido a una pobre descripción en las fuentes. Las pruebas revelaron una variedad de resultados. No habían diferencias significativas en el efecto entre cirugía asistida por ordenador o convencional para la reconstrucción del ACL. No se pudo demostrar o refutar efectos favorables de la cirugía asistida por ordenador para la reconstrucción de los

ACL, en comparación con las reconstrucciones convencionales. No hay evidencia suficiente para aconsejar o desaconsejar el uso de CAS.

El **capítulo 9** describe un test clinico aleatorio de reconstrucción convencional de ACL contra reconstrucción con cirugía asistida por ordenador (CAS). Es de gran importancia para el resultado final asegurar un posicionamiento preciso y reproducible de los ligamentos transplantados. Un nuevo desarrollo ha sido la cirugía asistida por ordenador. Esta nueva técnica asiste en la colocación de los túneles óseos en la cirugía de ACL .

Hipótesis: Usando CAS para la cirugía de ACL se obtendrá un posicionamiento más preciso del túnel en comparación con la cirugía convencional. Este estudio se propone como un estudio clínico aleatorio (randomizado) doble-ciego prospectivo. Cien pacientes eligibles para reconstrucción de ACL fueron clasificados aleatoriamente para cirugía CAS o convencional.

Como primera medida, se compara la posición del túnel del transplante usando cirugía convencional contra la técnica de CAS, por medio de la técnica de TAC tridimensional. No se encontró diferencia en la localización del túnel femoral entre el grupo convencional y el grupo de CAS (media respectiva 39,7% contra 39,0% en el eje intracondilar proximo-distal (Valor de P = 0,39). La antero-posterior posición del túnel tibia fue 38,9% del grupo convencional y 38,2% del grupo CAS (Valor de P = 0,58). No hubo diferencia significativa en la varianza del posicionamiento femoral ni del tibial en ambos grupos. Este estudio no muestra diferencia significativa en la precisión de la localización del túnel entre la reconstrucción de ACL por medio de CAS o cirugía convencional.

El **capítulo 10** concluye con una discusión sobre los resultados encontrados y las implicaciones de nuestros estudios. También considera la investigación futura y brinda algunas recomendaciones interesantes para el futuro.

Erasmus MC
Universitair Medisch Centrum Rotterdam

Summary of PhD training and teaching activities 2006-2011

PHD TRAINING

RESEARCH

General academic & research skills

Biomedical English Writing and Communication, Pennsylvania State University

Courses

2009 OTC Clinical Research
2010 Course Erasmus MC Methodology
2011 Development programme clinical scientist AAOS Webinar

Publications

Kraemer W.J., Fry A.C., Triplett-Mcbride T., Gordon S.E., Koziris L.P., Lynch J.M., Volek J.S., Meuffels D.E., Newton R.U., Fleck S.J.. *Physiological and performance responses to tournament wrestling* Med Sci Sports Exerc 2001; 33(8): 1367-78.

Horsting P., Meuffels D.E., Rutgers P.. *The Hypothenar Hammer Syndrome* Eur J Vasc and Endovasc Surg Extra 2003; 5(5):67-87.

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Presentations

(Inter) national conferences

2007 *Effect of varying patella tendon bone block lengths on failure load in anterior cruciate ligament reconstruction.* Dutch Orthopaedic Society Annual Meeting, Rotterdam

2008 *10 year follow-up study comparing conservative versus operative treatment of anterior cruciate ligament ruptures. A matched control study of high level athletes*. Dutch Orthopaedic Society Annual Meeting, Maastricht

2008 *10-year follow-up study comparing conservative versus operative treatment of anterior cruciate ligament ruptures. A matched control study of high level athletes.* AAOS 75thAnnual Meeting, San Francisco, USA

2008 *Anterior cruciate ligament ruptures in professional dancers. Annual meeting* Dutch Arthroscopic Society (NVA), Ermelo.

2008 *10-year follow-up study comparing conservative versus operative treatment of anterior cruciate ligament ruptures. A matched control study of high level athletes.* Annual meeting Dutch Arthroscopic Society (NVA), Ermelo.

2009 *Stiffer fixation of the tibial double-tunnel anterior cruciate ligament complex versus the single tunnel –a biomechanical study-* Annual meeting Dutch Arthroscopic Society (NVA), Ermelo.

2009 *Visualization of Post-Operative Anterior Cruciate Ligament Reconstruction Bone Tunnels. Reliability of Standard Radiographs, CT Scans and 3-D Virtual Reality Images.* Annual meeting Dutch Arthroscopic Society (NVA), Ermelo.

2009 *The posterior bone block procedure in posterior shoulder instability. –A long-term follow-up study-* European Shoulder and Elbow Society Annual Meeting. Madrid, Spain.

2010 *Anterior cruciate ligament ruptures in professional dancers* – International Association Dance Medicine Science (IADMS) Annual Meeting 2009. The Hague 3-D Virtual Reality measurement of ACL reconstructions. AAOS 77thAnnual Meeting, New Orleans, USA

2010 *Computer assisted surgery versus conventional ACL reconstruction – a randomized clinical trial.* Computer Assisted Orthopaedic Surgery (CAOS) International Annual Meeting Versailles, France.

2010 *Voorste kruisband letsel bij kinderen.* Werkgroep kinderorthopaedie, Utrecht

2010 Moderator, Masterclass Dutch Arthroscopy Society *The Treatment of the Anterior Cruciate Ligament Injury*, Utrecht

posters

2008 *Effect of varying patella tendon bone block lengths on pull out strength for anterior cruciate ligament reconstruction. How small a bone block can we afford to use?* European Society of Sports Traumatology, Knee surgery and Arthroscopy,13th congress, Porto

2008 *Ten year follow-up study comparing conservative versus operative treatment of anterior cruciate ligament ruptures. A matched control study*. European Society of Sports Traumatology, Knee surgery and Arthroscopy, 13th congress, Porto

2010 *Stiffer fixation of the tibial double-tunnel anterior cruciate ligament complex versus the single tunnel –a biomechanical study-* European Society of Sports Traumatology, Knee surgery and Arthroscopy,14th congress, Oslo

Guideline development

2009-2011 vice-chairman National guideline Anterior Cruciate Ligament Injury

Reviewer

Journal of Sports Sciences, Sports Health, Arthritis Research & Therapy, Knee Surgery, Sports Traumatology and Arthroscopy.

Board Membership

Board member Dutch Arthritis Scientific Committee
Board member scientific committee Dutch Arthroscopy Society (NVA)

Didactic skills

2009 Teach the Teacher
2010 Course and personal evaluation lecture skills
2010 Course Examining skills
2011 University Teaching Qualification (BKO full qualification)

Teaching activities

Lecturing

2005-present Lecturer Erasmus MC, University Medical Centre Rotterdam
2006-present Guest lecturer Hogeschool Rotterdam Master (manual therapy)

Supervising practicals

2004-present Medical curriculum anatomy lecturer
2009-present Surgical demonstrations (EARP)

Supervising Master's theses

2006-present Supervisor research thesis medical students

Other

Head educational program orthopaedic residency program

Professional activities

2004-present Consultant Orthopaedic Surgery Erasmus MC, University Medical Centre Rotterdam

2009-present External consultant (buitengewoon lid) Rehabilitation Centre Rijndam Rotterdam
2004-present Medical consultant Conny Janssen Danst
2009-present Orthopaedic consultant Scapino Dansgezelschap

Society member

Dutch Orthopaedic Society (NOV)
Dutch Arthroscopic Society (NVA)
Dutch Society for Sports medicine (NOTS)
Society for Healthcare and Dance
Computer Assisted Orthopaedic Surgery (CAOS) International
American Academy of Orthopaedic Surgeons (AAOS)
European Society for Sports Traumatology, Knee surgery and Arthroscopy (ESSKA)

Curriculum Vitae

Duncan was born in the South of Holland where a pleasant youth was spent participating in football and whitewater slalom kayaking competitions at international level. He attended the Lorentz Lyceum (Grammar School) in Eindhoven. After graduating in 1987, he spent a year studying in the United States. He was then accepted to the medical faculty of the Free University in Amsterdam to start his medical studies. After his doctoral studies he spent six months at Pennsylvania State University, Pa, U.S.A., at the Center of Sports Medicine as a research student (prof. H.G. Knuttgen, prof. W.J. Kraemer and J.S. Cox M.D.). During his internships in Amsterdam he also kept a part-time job working as a paramedic on the ambulance of the GGD Helmond. He passed his American Medical ECFMG exams, but started his first job as a senior house officer in 1996 in orthopedic surgery in Newcastle General Hospital, Newcastle upon Tyne, England. He moved back to the Netherlands to become an assistant in orthopedic surgery in the Medical Centre Alkmaar (dr. W.J. Willems). His general surgery was followed in the Gelre Hospital in Apeldoorn (dr. W.H. Bouma) after which his orthopaedic training was finished at the Leyenburg Hospital in The Hague (dr. A.J.M. Sauter / dr. L.N.J.E.M. Coene) and the University Medical Center Rotterdam (prof. J.A.N. Verhaar). During this period he was also the consultant of the Royal Conservatory of Dance in The Hague and of the dance company Conny Janssen Danst. As an orthopaedic surgeon he moved to Spain to train as a sports medicine fellow in the Clinica Quiron with drs. N. Nebot Sanchis and R. Llombart Ais. In 2004, he then joined the Academic Orthopaedic Group Rotterdam, to further specialize in arthroscopic and sports medicine surgery. He worked partly in the periphery (IJsselland Hospital, Capelle a/d IJssel) and partly at the university hospital in Rotterdam (Erasmus MC, University Medical Centre Rotterdam). He became a full-time academic orthopaedic surgeon in 2007. This has resulted in this thesis "Novel insights into anterior cruciate ligament injury".

Theorems

Professional classical dance is a high-risk activity for anterior cruciate ligament injury. (This thesis)

Non-operative treatment of an anterior cruciate ligament injury of a high level athlete gives equal patient outcome as operative treatment. (This thesis)

Anterior cruciate ligament reconstruction does not decrease the risk of long-term osteoarthrosis. (This thesis)

There is no difference in the failure mechanism of a single versus a double tunnel tibial anterior cruciate ligament reconstruction. (This thesis)

Computer assisted anterior cruciate ligament reconstruction does not achieve a more accurate tunnel placement than conventional reconstruction. (This thesis)

Surgical resection of non-obstructive degenerate meniscal lesions merely removes evidence of the disorder while the osteoarthritis and associated symptoms proceed. (Stefan Lohmander)

Non-randomised operative intervention studies overestimate the treatment benefit by failing to take into account the favorable natural history of the condition. (Rachelle Buchbinder)

In art (as in life) it is hard to say something, which is as good as to say nothing. (Ludwig Wittgenstein)

Evolution advances, not by a priori design, but by the selection of what works best out of whatever choices offer. We are the products of editing rather than of authorship. (George Wald)

Make everything as simple as possible, but no simpler (Albert Einstein)

The multiplication of knowledge is the multiplication of doubt.

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Appendix

Guideline Anterior Cruciate Ligament Injury

INITIATIVE

Dutch Orthopaedic Association (Nederlandse Orthopaedische Vereniging (NOV))

IN COOPERATION WITH

The Association of Surgeons of the Netherlands (Nederlandse Vereniging voor Heelkunde (NVvH))
Dutch Society of Rehabilitation (Vereniging van Revalidatieartsen (VRA))
Royal Dutch Society for Physical Therapy (Koninklijke Genootschap voor Fysiotherapie (KNGF))
Society for Sports Medicine (Vereniging voor Sportgeneeskunde (VSG))
Dutch Society for Artroscopy (Nederlandse Vereniging voor Arthroscopie (NVA))
Patient Representatives

WITH SUPPORT BY

Dutch Association of Medical Specialists (Orde van Medisch Specialisten)

The group consists of:

Prof. dr. D.B.F. Saris, orthopaedic surgery, University Medical Centre Utrecht (chairman; NOV)
Drs. D.E. Meuffels, orthopaedic surgery, Erasmus MC, Rotterdam (vice-chairman; NOV)
Prof. dr. R.L. Diercks, orthopaedic surgery, University Medical Centre Groningen (NOV)
Drs. A.W.F.M. Fievez, orthopaedic surgery, Clinic Zestienhoven, Medinova Clinic, Rotterdam (NOV)
Dr. T.W. Patt, orthopaedic surgery, St. Maartenskliniek, Woerden (NOV)
Drs. C.P. van der Hart, orthopaedic surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam (NVA)
Dr. E.R. Hammacher, trauma surgery, St. Antonius Ziekenhuis, Nieuwegein (NVvH)
Col. A. van der Meer, consultant PMR, Military Rehabilitation Centre Aardenburg, Doorn (VRA)
Drs. E.A. Goedhart, sport physician, AFC Ajax, Amsterdam (VSG)

Dr. A.F. Lenssen, physiotherapy/researcher, Academic Hospital Maastricht/Hogeschool Zuyd, Heerlen (KNGF)

RICHTLIJN VOORSTE KRUISBANDLETSEL

Bruistensingel 128
5232 AC 's-HERTOGENBOSCH
Tel. 073 - 700 34 10
Email: NOV@orthopeden.org
Website: http://www.orthopeden.org/m_home

SUMMARY OF THE RECOMMENDATIONS

This is a summary of the recommendations from the multidisciplinary clinical guideline "anterior cruciate ligament injury". This guideline was set up, using the evidence based guide line development method (EBRO). In this summary, we did not convey the different considerations that led to these recommendations. The reader of this summary is referred to the original document of this guideline, for these considerations. The guideline is available on the internet through the Dutch Orthopaedic Society website. This summary of recommendations is not a sole reference by itself.

QUESTIONS ADDRESSED IN THE GUIDELINE

What is the role of physical diagnostics and additional diagnostic tools?

MRI has no additional value, when physical examination has shown anterior-posterior or rotational instability of the knee, suggesting an anterior cruciate ligament injury. However MRI is a reliable additional investigation to establish other intra-articular lesions.

It is recommended to perform the Lachman test, pivot shift test and anterior draw test of the knee in order to maximise the diagnostic accuracy for an anterior cruciate ligament injury.

The reliability of this physical examination is enhanced by having an experienced investigator.

Patient related outcome measures for the evaluation and follow-up of patients with anterior cruciate ligament injury?

It is recommended to use the IKDC subjective and the KOOS, as a patient related outcome measures.

We recommend the combination of the Lachman test, pivot shift test and anterior draw test as a clinical outcome measurement.

It can be useful to use the Tegner score, as an outcome measurement for activity.

What are the relevant parameters that influence the indication for an anterior cruciate ligament reconstruction?

If symptomatic instability of the knee, as a result of an anterior cruciate ligament injury does not decrease after physiotherapy, nor after adjustment of activity, an anterior cruciate ligament reconstruction can be recommended. This might prevent multiple interventions, because of further meniscal and cartilage damage.

When considering, in adults, conservative versus operative treatment, age should not be weighed as an important factor.

After considering the advantages and disadvantages, it deserves preference to wait with surgical intervention until the growth plates are (nearly) closed.

An anterior cruciate ligament reconstruction should only be performed in a "quiet knee with a normal range of motion.

Which findings or complaints are predictive of a bad result of an anterior cruciate ligament injury treatment?

An anterior cruciate ligament reconstruction should be performed only when a full extension of the knee is possible and the synovial reaction is minimal.

During the pre-operative preparations a possible muscle strength difference of the injured leg should be treated.

In the presence of knee mal alignment and anterior cruciate ligament insufficiency, correction of the leg alignment should be considered, possibly in combination with an anterior cruciate ligament reconstruction.

It is recommended to inform the patient, that participation in high-risk sports or heavy knee labour, increases the risk of cartilage damage, meniscal damage and damage to the reconstructed anterior cruciate ligament, which could result in a re-rupture, secondary surgery or knee osteoarthritis.

What is the optimal timing for surgery for an anterior cruciate ligament injury?

The indication for a reconstruction is persisting instability of the knee with giving way complaints. This diagnosis is difficult to make in an acute situation. We therefore recommend not to perform anterior cruciate ligament reconstruction in the first weeks after trauma in order to minimise the risk of operating on an asymptomatic patient.

We recommend, if the indication for anterior cruciate ligament reconstruction has been defined, performing the reconstruction in a timely manner so as to minimise the risk of additional damage to the cartilage and/or meniscus.

The patient with a delayed reconstruction can resume his physical activity sooner with a greater chance of obtaining higher activity scores, than a patient with a late reconstruction.

In the long-term delayed reconstruction gives a better range of motion and less degenerative changes than a late reconstruction.

What is the outcome of different treatment modalities?
It deserves recommendation to rehabilitate patients with an anterior cruciate ligament injury with physiotherapy by following an exercise program that trains multiple ground -motoric abilities.

We strongly recommend incorporating senso-motoric training (balance and propriocepsis) into the rehabilitation program after an anterior cruciate ligament injury.

It deserves preference to incorporate into the rehabilitation program, after an anterior cruciate ligament injury, both open and closed chain strength training.

There are no indications for a brace in the standard treatment of an anterior cruciate ligament injury.

A brace could possible be considered for patients with instability, who do not qualify or don't want to qualify for operative treatment.

Which kind of graft gives the best result in an anterior cruciate ligament reconstruction?
Autograft or allograft?
Taking in consideration clinical outcome measurement there is no direct preference for the use of either autograft or allograft for anterior cruciate ligament reconstruction. Both graft types lead to similar good clinical results.

Preparation of the allograft.
Radiated allografts significantly fail more often than non-radiated allografts.

Stretching of allografts before the reconstruction is unnecessary.

Bone-patellar-tendon-bone or hamstring graft.
Bone-patellar-tendon-bone and hamstring reconstructions lead to good results, stability and low complication percentages. Hamstring reconstruction leads to significantly less anterior knee pain.

Single or double bundle hamstring reconstruction
Both single and double bundle hamstring reconstruction lead to good functional results. With present scientific knowledge there is no preference for either technique. Double bundle reconstruction is a more time consuming and technically more demanding procedure than single bundle reconstruction.

***Synthetic graft*.**
Use of synthetic graft or ligament augmentation is not recommended because of inferior results and increased complications in long term follow up.

Fixation technique.
There is no scientific basis for making recommendations in the choice of the type of fixation device for the different grafts.

What is the optimum post-operative treatment? (after the first post-operative check-up concerning rehabilitation, sport resumption and physiotherapy).
We recommend combining strength with neuromuscular training in the post-operative treatment.

It is recommended to solely use closed chain exercises in the early rehabilitation phase.

There is no reason for the usage of a brace in the post-operative treatment period after an anterior cruciate ligament reconstruction.

Resuming heavy physical activity in labour or sports, within three month post-operatively, is irresponsible.

We, therefore recommend, that no heavy physical rehabilitation, running, cutting- or pivoting-sports or other risk activities that necessitate full knee reliance, be undertaken in the first three months.