



PIIA SUOMALAINEN

Anterior Cruciate Ligament

Double-bundle versus single-bundle reconstruction



ACADEMIC DISSERTATION

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for public discussion in the Small Auditorium of Building M,
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ACADEMIC DISSERTATION

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To Antti and Isabella

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1 ORIGINAL COMMUNICATIONS

- I Suomalainen P, Moisala AS, Paakkala A, Kannus P and Järvelä T (2011): Double-Bundle versus Single-Bundle Anterior Cruciate Ligament Reconstruction: Randomized Clinical and Magnetic Resonance Imaging Study with 2-Year Follow-up. *Am J Sports Med* 39: 1615–22.
- II Suomalainen P, Moisala AS, Paakkala A, Kannus P and Järvelä T (2013): Comparison of tunnel placements and clinical results of single-bundle anterior cruciate ligament reconstruction before and after starting the use of double-bundle technique. *Knee Surg Sports Traumatol Arthrosc* 21:646–653.
- III Suomalainen P, Järvelä T, Paakkala A, Kannus P and Järvinen M (2012): Double-Bundle versus Single-Bundle ACL Reconstruction: Prospective, Randomized Study with 5-Year Results. *Am J Sports Med* 40:1511–1518.
- IV Suomalainen P, Kiekara T, Moisala AS, Paakkala A, Kannus P and Järvelä T (2013): Effect of Tunnel Placements on Clinical and MRI Findings Two Years after Anterior Cruciate Ligament Reconstruction with Double-Bundle Technique. *Open Access Journal of Sports Medicine* (submitted).

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2 ABBREVIATIONS

ACL	Anterior cruciate ligament
AM	Anteromedial
BMI	Body mass index
BPTB	Bone-Patellar Tendon-Bone
DB	Double-bundle
IKDC	International Knee Documentation Committee
IM	Intermediate
LCL	Lateral collateral ligament
LFT	Lateral femorotibial
MCL	Medial collateral ligament
MFT	Medial femorotibial
MRI	Magnetic resonance imaging
OA	Osteoarthritis
PCL	Posterior cruciate ligament
PF	Patellofemoral
PL	Posterolateral
POL	Posterior oblique ligament
RCT	Randomized controlled trial
RoM	Range of motion
SB	Single-bundle
SBB	Single-bundle with bioabsorbable screws
SBM	Single-bundle with metallic screws
SD	Standard deviation

3 ABSTRACT

Anterior cruciate ligament (ACL) injury is one of the most common sports-related trauma and is often managed with operative treatment. The conventional treatment for ACL ruptures has been the single-bundle (SB) ACL reconstruction technique, in which the anteromedial bundle (AM) of the ACL only is reconstructed. The results have been fairly good, but long-term results have shown that after SB reconstruction residual laxity persists, especially in the rotational plane.

Biomechanical studies have revealed that the anteromedial bundle works in all flexion angles of the knee and the posterolateral (PL) bundle only in low flexion knee angles and during rotatory forces. They run parallel when the knee is near extension and embrace each other when the knee is in greater flexion. This has led to the idea that combining the PL bundle reconstruction with the conventional SB ACL method, should result in more stable knees and thus lead to less reoperations.

The objective of this dissertation was to compare single-bundle and double-bundle (DB) ACL reconstruction methods in short- and midterm follow-ups paying special attention to graft durability, stability measurements, MRI findings and other clinical aspects. Studies I and III were level I prospective and randomized trials, whereas Studies II and IV were prospective clinical studies.

Studies were conducted in the Hatanpää City Hospital, Tampere and Tampere University Hospital (TAYS), Tampere, Finland. The baseline data collection and the surgical operations were performed between 2003 and 2008. One experienced orthopaedic surgeon performed all the operations and the follow-up examinations were made by two independent researchers blind to the randomisation. One experienced musculoskeletal radiologist did all the interpretations of the radiologic images in Studies I, II and III and in collaboration with another musculoskeletal radiologist in Study IV. They were blind to the patients' clinical data.

The aim in Study I was to compare SB group and DB group focusing on clinical and MRI findings. The population was 153 participants (SB group $n = 78$, DB group $n = 75$). There were two groups in Study II, in which we compared the graft locations of the single-bundle method during the years when the double-bundle technique was used. Group A ($n = 25$) was from 2003, when the double-bundle ACL reconstruction technique was not routinely used while Group B from 2007 when the double-bundle

method was already common practice. The purpose of Study III was to compare SB and DB groups concentrating on clinical and radiograph findings. Patients were divided into three groups, 30 in each (single-bundle with bioabsorbable screws (SBB), single-bundle with metallic screws (SBM) and DB). The focus in Study IV was on the ACL graft visibility and locations in MRI and if there is an association with clinical findings. There was a population of 75 patients, all of whom were operated on with the DB technique.

The main findings in Studies I and III were that there were fewer graft ruptures and subsequent ACL revisions in the DB groups than in the SB groups. An additional finding was that the stability measurements were similar in both groups at two- and five-year follow-ups, and that the OA changes did not differ statistically significantly between groups at five-year follow-up.

MRI was evaluated in Studies I, II and IV. An important finding was that the graft locations were unchanged on the femoral side and changed only slightly on the tibial side in the SB group during the intervening years (Study II). Graft visibility was studied with MRI in Studies I and IV. Grafts were graded normal if all fibres were seen, partly visible if only some of the fibres were seen and invisible if none of the fibres were seen. MRI showed invisibility of the grafts in some cases at two-year follow-up, a finding that did not, however, have any effect on the stability measurements (Study I). The more anterior graft location in the tibia was associated with invisibility, but again this observation was not associated with the clinical results (Study IV).

In conclusion, the findings from our own studies and those reported in some of the recent literature the double-bundle ACL reconstruction method seems to be better than the single-bundle technique. There were fewer graft failures after double-bundle ACL reconstruction, which speaks for double-bundle method. In earlier studies double-bundle reconstruction has been reported to result in more stable knees, but this could not be proven in our studies. However, none of them concluded that the double-bundle ACL reconstruction method was inferior to its single-bundle counterpart.

4 TIIVISTELMÄ

Polven eturistisiderepeämä on yksi yleisimmistä urheiluvammoista. Sen esiintyvyys ei ole tarkkaan tiedossa, mutta sairaaloiden hoitoilmoitusrekisterin mukaan Suomessa tehtiin vuonna 2010 noin 2900 eturistisiteen repeämän korjausleikkausta. Repeämän aiheuttama polven väljyys voi olla hyvinkin haittaava ja nykykäsityksen mukaisesti tällöin suositellaan leikkaushoitoa, mikäli asianmukainen konservatiivinen hoito on ensin toteutettu.

Eturistiside koostuu kahdesta eri säiekimpusta. Anteromediaalinen kimppu vastaa polven tukevuudesta koko polven liikealassa ja posterolateraalinen kimppu toimii polven kiertoliikkeissä sekä polven ollessa lievässä koukistuksessa. Tällä hetkellä keskustellaan siitä, millä kirurgisella menetelmällä eturistisiderepeämä tulisi hoitaa. Anatomisessa kaksoissiirreteknikassa korvataan molemmat kimpot jännesiirteillä ja yhden jännesiirteen tekniikassa keskitytään lähinnä anteromediaalisen kimpun rekonstruktioon.

Tämän väitöskirjatutkimuksen tavoitteena oli selvittää eturistisiderepeämän leikkaushoidon lyhyen sekä keskipitkän aikavälin tuloksia ja verrata yhden jännesiirteen tekniikalla korjattuja polvia kaksoissiirreteknikalla korjattuihin. Tarkoituksena oli myös selvittää polvien magneettitutkimuksissa siirteiden näkyvyyden ja sijainnin merkitystä polven tukevuuteen.

Potilaiden rekrytointi ja perusaineiston kerääminen tapahtui Hatanpään sairaalassa vuosien 2003 ja 2008 välillä. Yksi kokenut ortopedi suoritti kaikki leikkaukset. Satunnaistaminen tehtiin suljetuin kirjekuorin osatöissä yksi ja kolme. Osatyössä yksi potilaat jaettiin kahteen eri ryhmään: yhden jännesiirteen ($n = 78$) ja kaksoissiirteen ryhmät ($n = 75$). Osatyössä kaksi toinen ryhmä ($n = 25$) oli vuodelta 2003, jolloin kaksoissiirreteknikka ei ollut vielä käytössä ja toinen ryhmä oli vuodelta 2007, jolloin kaksoissiirreteknikka oli jo vakiintuneessa käytössä. Osatyössä kolme jaettiin 90 potilasta kolmeen yhtä suureen ($n = 30$) joukkoon: yhden jännesiirteen ryhmä metalliruuville kiinnitettynä, yhden jännesiirteen ryhmä biohajoavilla ruuveilla kiinnitettynä ja kaksoissiirreryhmä biohajoavin ruuvein kiinnitettynä. Osatyössä neljä potilasryhmänä olivat kaikki kaksoissiirreteknikalla hoidetut potilaat ($n = 75$).

Päälöydös osatöissä I (keskimäärin kahden vuoden seuranta) ja III (keskimäärin viiden vuoden seuranta) oli, että yhden jännesiirteen ryhmissä oli enemmän siirteen

menetyksiä kuin kaksoissiirreryhmissä. Mielenkiintoinen havainto tutkimuksissa oli kuitenkin se, ettei polvien tukevuudessa ollut eroa ryhmien välillä. Osatyössä III havaittiin lisäksi, ettei tavallisella röntgenkuvalla arvioiden ryhmien välillä ollut eroa nivelrikon kehittämisessä seurannan aikana.

Osatyöissä I, II ja IV polvien tilanne arvioitiin myös magneettikuvauksella. Osatyössä II todettiin siirteiden paikkojen pysyneen reisiluussa ennallaan, mutta sääriluussa siirteiden paikat olivat hieman eri kohdissa jälkimmäiseksi operoidussa ryhmässä. Tällä ei kuitenkaan havaittu olevan kliinistä merkitystä.

Magneettikuvauksessa pystyttiin arvioimaan edellämainitun lisäksi siirteiden näkyvyyttä. Osatyöissä I ja IV havaittiinkin, että osa siirteistä oli magneettikuvassa osittain näkyviä tai kokonaan näkymättömiä, mutta polvet olivat silti kliinisesti testattuina tukevia sekä etu-taka- että kiertosuunnissa (pivot shift testi). Yhteys siirteiden näkymättömyydelle ja siirteiden paikoille todettiin osatyössä IV, jossa havaittiin, että mikäli siirre sijaitsi sääriluussa normaalia edempänä, sillä oli riski olla magneettikuvauksessa vain osittain näkyvä tai näkymätön. Tässäkään tapauksessa ei näkymättömyydellä ja polven kliinisellä statuksella havaittu olevan yhteyttä.

Yhteenvetona voitiin todeta, että eturistisiteen repeämän leikkaushoidon tulokset olivat paremmat kaksoissiirremenetelmällä, koska siirteen menetyksiä oli vähemmän kuin yhden jännesiirteen menetelmällä. Toisaalta kaksoissiirremenetelmä ei näyttänyt tuovan etua polvien stabiiliuden suhteen yhden jännesiirteen menetelmään verrattuna. Leikkauksen jälkeisten magneettikuvalöydösten kliininen merkitys on epävarma, mutta näyttää siltä, etteivät magneettikuvauksessa näkymättöminä olevat siirteet kuitenkaan olleet hajonneet vaan todennäköisesti ne olivat vielä ”kypsymisvaiheessa”.

5 INTRODUCTION

The anterior cruciate ligament (ACL) is the main restraint for the anterior movement of tibia with respect to the femur (Wunschel et al. 2010). The ACL consists of two bundles, named anteromedial (AM) and posterolateral (PL). The anteromedial bundle arises from the the anteromedial point of the tibia and inserts into the high and deep site of the femoral attachment in flexion, whereas fibres from the posterolateral bundle insert into low and shallow site of the femoral footprint (Siebold et al. 2008; Siebold et al. 2008).

The insertion sites in the tibia and also in the femur give distinctive functions for the bundles, which are explained by basic biomechanics and anatomy. The anteromedial bundle of the ACL tightens in all flexion angles of the knee and is therefore the main ligament to prevent the tibia from dislocating anteriorly. The posteromedial bundle of the ACL works only in low flexion angles of the knee and also restrains the internal and external rotational forces of the tibia (Wu et al. 2010).

A rupture of the ACL can be a disabling condition. The conventional method for operating on a torn ACL has been a single-bundle (SB) reconstruction, in which the anteromedial bundle only is reconstructed. The double-bundle (DB) method was developed to solve the problem of residual knee laxity seen after single-bundle reconstruction (Schindler 2012).

The best radiological method to visualize the ACL is magnetic resonance imaging (MRI). It shows native ACL very well, and in the case of a torn ACL, the MRI shows increased T2 signals and discontinued fibres, which do not run parallel to the right insertion site in the acute phase. Nonvisualization or angulation of the ligament can be seen in the chronic phase. In different postoperative stages, the visualization of the reconstructed ACL can be quite heterogeneous depending on the time elapsing since surgery (Miller 2009).

The purpose of this dissertation was to answer the question: “Is the double-bundle method better than the conventional single-bundle ACL reconstruction?”.

6 REVIEW OF THE LITERATURE

6.1 Anatomy of the ACL

6.1.1 Tibial side

The double-bundle structure of the ACL was introduced already almost two hundred years ago (Weber 1836). Since then various anatomical studies, cadaveric and clinical, have been presented, in which the anatomy of the ACL has been resolved thoroughly on the tibial side (Colombet et al. 2006; Takahashi et al. 2006; Edwards et al. 2007; Luites et al. 2007; Steckel et al. 2007; Purnell et al. 2008; Siebold et al. 2008; Tallay et al. 2008; Zantop et al. 2008; Doi et al. 2009; Katouda et al. 2011; Kopf et al. 2011; Pietrini et al. 2011; Ziegler et al. 2011; Ferretti et al. 2012; Otsubo et al. 2012) and femoral side (Mochizuki et al. 2006; Takahashi et al. 2006; Ferretti et al. 2007; Luites et al. 2007; Steckel et al. 2007; Edwards et al. 2008; Purnell et al. 2008; Siebold et al. 2008; Zantop et al. 2008; Iwahashi et al. 2010; Katouda et al. 2011; Kopf et al. 2011; Pietrini et al. 2011; Ziegler et al. 2011; Ferretti et al. 2012; Otsubo et al. 2012).

When the ACL arises from the tibia, it has two bundles, which can already be discerned macroscopically in the foetus (Ferretti et al. 2007). It has a wide attachment area located in the eminentia of the proximal tibia between the lateral and medial joint surfaces. The length and width of the tibial attachment area are 7.4–14.0 mm and 10.7–25.0 mm, respectively (Colombet et al. 2006; Edwards et al. 2007; Steckel et al. 2007; Purnell et al. 2008; Siebold et al. 2008; Tallay et al. 2008; Kopf et al. 2011; Ferretti et al. 2012) with a surface area of about 114–206 mm² (Siebold et al. 2008; Ferretti et al. 2012; Otsubo et al. 2012). The attachment is usually oval or triangular in shape (Colombet et al. 2006; Tallay et al. 2008; Ferretti et al. 2012). The individual insertion site areas are 60.9–69.3 mm² for AM bundle and 52.0–55.7 mm² for PL bundle (Takahashi et al. 2006; Steckel et al. 2007; Siebold et al. 2008; Katouda et al. 2011). Otsubo et al (2012) divided the AM bundle further into AM and IM bundles, in which the attachment areas were 34.5 mm² and 31.0 mm² respectively. Figure 1.

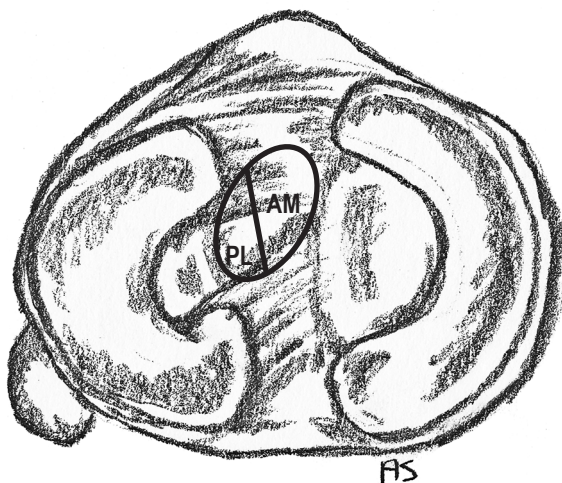


Figure 1. Anatomical picture of the tibial insertion sites.

The anteromedial bundle attaches 15.9–17.8 mm and PL bundle 8.4–13.9 mm anteriorly from over the back ridge (Colombet et al. 2006; Edwards et al. 2007; Doi et al. 2009; Ziegler et al. 2011). The AM bundle is located more medially than the posterolateral bundle, hence the names of these two structures. There is quite a lot variation in the sizes of the insertion sites, since the centres of the bundles have been reported to be 4.5–10.1 mm apart (Colombet et al. 2006; Luites et al. 2007; Siebold et al. 2008; Tallay et al. 2008; Ziegler et al. 2011). The length and width of the AM bundle insertion sites are 9.1–12.0 mm and 5.0–11.1 mm and that of PL bundle 7.4–10.0 mm and 4.0–7.9 mm respectively (Siebold et al. 2008; Kopf et al. 2011; Ferretti et al. 2012). Some fibres may also be attached to the anterior or posterior horn of the lateral meniscus.

The cross-sectional shape of the ACL is not circular, since the two bundles of the ACL work individually in the various flexion-extension angles of the knee joint. They intersect in the mid-substance area, in which the bundles have their narrowest diameters (AM 8.5 mm, PL 7.7 mm) and areas (AM 20.3 mm², PL 17.7 mm²) (Steckel et al. 2007). The total lengths of the bundles of the ACL have been reported to be 37.7–38.5 for AM mm and 19.7–20.7 mm for PL as measured from the tibia to the femur (Steckel et al. 2007; Zantop et al. 2008).

6.1.2 Femoral side

The attachment sites in the femoral side are more complex, but the anatomy can be seen more clearly because of bony landmarks, which obviously remain in the chronic phase of a rupture (van Eck et al. 2010). The lateral intercondylar ridge, alias resident's ridge, is found on the lateral wall of the intercondylar notch (Ferretti et al. 2007; Purnell

et al. 2008; Iwahashi et al. 2010; Shino et al. 2010; van Eck et al. 2010; Ziegler et al. 2011; Otsubo et al. 2012). It is divided by the lateral bifurcate ridge, which separates the insertion sites of the AM and PL bundles of the ACL (Ferretti et al. 2007; van Eck et al. 2010; Ziegler et al. 2011). The whole femoral insertion site of the ACL is located posterior to resident's ridge when the knee is fully extended. Figure 2.

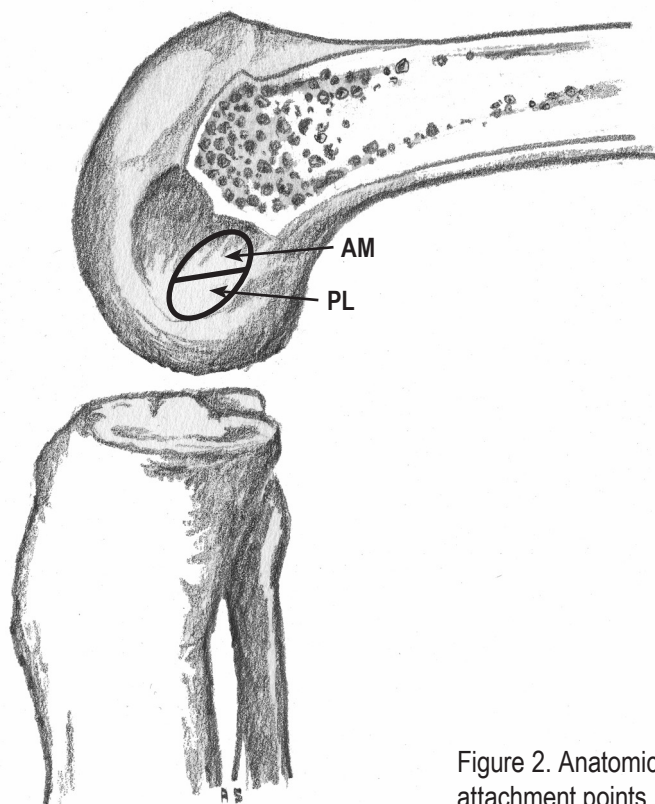


Figure 2. Anatomical picture of the femoral side attachment points.

The length and width of the ACL femoral insertion are 13.9–17.4 mm and 6.0–13.0 mm respectively (Colombet et al. 2006; Ferretti et al. 2007; Steckel et al. 2007; Edwards et al. 2008; Purnell et al. 2008; Siebold et al. 2008; Iwahashi et al. 2010; Kopf et al. 2011) and that of individual bundles AM 7.1–11.3 mm and PL 4.7–9.8 mm (Mochizuki et al. 2006; Takahashi et al. 2006; Ferretti et al. 2007; Edwards et al. 2008; Siebold et al. 2008; Kopf et al. 2011). The distance between the AM and PL bundle centres is 6.2–10.0 mm (Colombet et al. 2006; Luites et al. 2007; Siebold et al. 2008; Zantop et al. 2008; Ziegler et al. 2011). The area of the whole ACL insertion in the femur varies considerably (83.0–196.8 mm²) (Ferretti et al. 2007; Luites et al. 2007; Siebold et al. 2008; Iwahashi et al. 2010). The area of the AM bundle has been reported to be 36.1–120.0 mm² and the area of the PL bundle 32.1–103.0 mm² (Takahashi et al.

2006; Ferretti et al. 2007; Luites et al. 2007; Siebold et al. 2008; Katouda et al. 2011). Otsubo et al. (2012) also divided the AM bundle on the femoral side into AM and IM bundles, giving the areas of the separate bundles as AM 36.1 mm², PL 53.6 mm² and IM 34.9 mm².

The terminology frequently used in literature on femoral insertion sites differs from the traditional medical language. The reason for this is that it is easier to comprehend the femoral anatomy in the arthroscopic view when the terms used are shallow, deep, low and high instead of distal, proximal, posterior and anterior respectively. The anatomical placements of the individual bundles remain the same, obviously, regardless of the flexion angle of the knee, but the dynamic anatomy changes on arthroscopy. Hara et al. (2009) in their human cadaver study found that the bundles originating from the anteromedial portion of the tibial attachment were inserted into the high and deep portion of the femoral attachment in flexion, whereas those from the anterolateral portion were inserted into the high and shallow portion. Bundles originating from the posteromedial portion were inserted into the low and deep portion and posterolateral into the low and shallow portion of the femoral footprint. In another study by Steckel et al. (2010) the finding was that at full extension of the knee the PL bundle attached to the posterior-distal aspect of the femoral insertion site.

Wolters et al. (2011), in their clinical study of 82 patients, found a correlation between the femoral notch width and the insertion site size. Another finding was that women had smaller notch width than men. This was also the conclusion of the cadaver study by Siebold et al. (2008). A similar finding was reported by van Eck et al. (2011) in their clinical and MRI study of 100 patients. They concluded additionally that notch volume correlated with increased height and weight, but not with the BMI of the subject and that their ACL injury group had larger notch volume than the healthy control group.

6.2 Biomechanics of the ACL and other ligament structures of the knee

The knee is a very complex joint because the bony structures have very few stabilizing effects and therefore ligaments, muscles, the joint capsule and other soft tissues prevent dislocation of the joint.

The main function of the ACL is to prevent the anterior dislocation of the tibia from the femur in all flexion angles of the knee (Beynnon et al. 2005; Wunschel et al. 2010). It also works in rotations and varus-valgus angulation together with the other ligaments (Beynnon et al. 2005). The anteromedial bundle of the ACL tightens in all

flexion angles of the knee and is therefore the main ligament to prevent the tibia from dislocating anteriorly to the femur. The posteromedial bundle of the ACL only works in low flexion angles of the knee and it also restrains the internal and external rotational forces of the tibia (Zantop et al. 2007; Markolf et al. 2008; Lorbach et al. 2010; Wu et al. 2010; Fujie et al. 2011; Yasuda et al. 2011; Amis 2012; Kato et al. 2012).

The muscles of the thigh play a major role in the biomechanical stabilization of the knee. The quadriceps, when contracting, functions as an ACL antagonist, while the hamstrings muscles serve as an agonist (Li et al. 1999; MacWilliams et al. 1999; Alkjaer et al. 2012). The iliotibial band has been reported to participate in the knee stabilization process in large flexion angles as an ACL agonist (Yamamoto et al. 2006). The calf muscles also participate in stabilizing the knee joint, the gastrocnemius especially serves as an ACL antagonist and the soleus as an agonist (Elias et al. 2003).

The LCL (lateral collateral ligament) restrains varus angulation and also internal rotation of the tibia against the femur. The MCL (medial collateral ligament) consists of superficial and deep layers. The former is further divided into anterior and posterior portions. The anterior portion is tightened in 70–105 degrees of flexion and the posterior portion closer to extension. The main function of the MCL is to resist valgus angulation in all flexion angles of the knee. The deep layer of the MCL does not participate significantly in valgus stabilization, but it has a role in restraining against anterior translation. Another stabilizer on the medial side is POL (posterior oblique ligament), which arises from the posterior portion of the MCL and has the ability to resist valgus and hyperextension forces near extension together with the PCL (posterior cruciate ligament) (Petersen et al. 2008; Morgan et al. 2010). The PCL has also two bundles, which prevent tibia from moving posteriorly in relation to the femur (Voos et al. 2012).

6.3 Magnetic resonance imaging of the ACL

The best radiological method to diagnose an ACL tear is MRI (Miller 2009). When the ligament is torn, the signal intensity is completely different in the rupture site than in the native ligament (Yoon et al. 2010; Milewski et al. 2011).

MRI can also be used postoperatively when evaluating possible rerupture, the graft placement, tunnel positions and widening (Ahn et al. 2010; Illingworth et al. 2011; Tanaka et al. 2011; Kiekara et al. 2012). The graft appearance is different in the MRI postoperatively during the first two years because of the graft maturation process. First, the graft signal intensity is usually low on T1 and T2 weighted images, but when the synovialization takes place approximately one year after surgery, the intensity of the

graft signal rises. Over time the graft becomes more and more like a native ACL. The whole process usually takes two years (Hong et al. 2005; Sonoda et al. 2007; Muramatsu et al. 2008; Miller 2009; Poellinger et al. 2009; Claes et al. 2011; Gnannt et al. 2011; Ntoulia et al. 2011).

6.4 Reconstruction of the torn ACL

The main indication for the reconstruction of the torn ACL is a recurring giving way symptom of the knee despite proper knee rehabilitation (Frobell et al. 2010; Smith et al. 2010). There are also studies that conclude that high-demand patients such as young athletes should be treated operatively more often than others (Beynon et al. 2005; Delince et al. 2012).

6.4.1 Graft material

6.4.1.1 Hamstring tendons versus Bone-Patellar Tendon-Bone (BPTB) graft

There are 17 RCTs comparing hamstring grafts with BPTB grafts. Eight studies (12–120 months of follow-up) reporting no statistical differences between these two graft materials in any of the measurements (Beard et al. 2001; Jansson et al. 2003; Aglietti et al. 2004; Liden et al. 2007; Ahliden et al. 2009; Taylor et al. 2009; Holm et al. 2010; Gifstad et al. 2012).

Eight studies (4–96 months of follow-up) reported more donor site morbidity in the BPTB graft group (Aune et al. 2001; Feller et al. 2001; Ejerhed et al. 2003; Ibrahim et al. 2005; Laxdal et al. 2005; Matsumoto et al. 2006; Maletis et al. 2007; Barenius et al. 2010) and one, with follow-up of 132 months, reported more OA in the BPTB group (Sajovic et al. 2011). On the other hand, Aune et al. (2001) and Maletis et al. (2007) found that their hamstring tendon group had more hamstring muscle weakness. Complications using the BPTB include patellar fractures, quadriceps weakness, and patellar tendon inflammation or rupture (Lee et al. 2008).

6.4.1.2 The quadriceps tendon

Quadriceps tendon graft can be used with or without a boneblock. There are a couple of studies focusing on comparing quadriceps grafts with BPTB grafts, in which no difference was found between these graft options regarding knee stability, but quadriceps grafts have been reported to result in less donor site morbidity (Gorschewsky et al. 2007; Han et al. 2008; Kim et al. 2009).

6.4.1.3 Allograft versus autograft

ACL graft can be either allograft or autograft. Allografts obviously entail no donor site problems and the operation time has been reported to be shorter, however, they have a higher failure rate than their autograft counterparts. Failures seem to correlate with irradiated or chemically processed allografts (Marralle et al. 2007; Prodromos et al. 2007; Krych et al. 2008; Guo et al. 2012; Pallis et al. 2012). There is also a hypothetical risk of graft transmitted infections e.g. HIV and hepatitis C (Baer et al. 2007).

6.4.1.4 Artificial materials

A variety of artificial materials have been introduced over the years, but the results have been poor (Beynnon et al. 2005).

6.4.2 Graft fixation

Today there are several different commercially available ACL graft fixation methods. Biomechanical studies have shown that there are good and bad features in every device. The perfect fixation would be strong enough to allow full range of motion and full weight bearing from the beginning and durable enough to last until the graft has matured. The fixation should also be MRI compatible.

6.4.2.1 Metal screws

Metal screws have long been the gold standard and they are still a good choice, but there is signal disturbance in MRI (Kousa et al. 2003). They are usually used as an aperture fixation in the femur and therefore tunnel widening is not a problem.

6.4.2.2 Bioabsorbable screws

Bioabsorbable screws have gained acceptance after their introduction in the early 2000s. They are comparable in strength to metal interference screws and are usually also used in an aperture manner in the femur (Kousa et al. 2001; Kaeding et al. 2005; De Wall et al. 2011). They have been reported to produce slightly more tunnel widening than metal screws but this has not impaired the clinical outcomes (Laxdal et al. 2006; Moisala et al. 2008; Myers et al. 2008; Shen et al. 2010; Stener et al. 2010; Emond et al. 2011), although Moisala et al. (2008) found that after bioabsorbable screw fixation there were statistically more graft failures. The major advantage using bioabsorbable screws is their MRI compatibility and their ability to dissolve spontaneously in a few years after insertion. A downside with some materials is a slow degradation process combined with a potential for inflammatory response.

6.4.2.3 Other devices

Hamstring grafts can also be fixed in a suspensory manner in the femur. In this technique, the fixation device is located further from the articular surface than in the aperture fixation technique, thereby allowing more movement for the graft in the tunnel. This may lead to tunnel widening. There are also many different devices available to fix the graft on the tibial side (Kousa et al. 2003).

6.4.3 Graft placement

The optimal place for the graft is the site of the original ACL. The location of the graft should be precise in the sagittal and the coronal directions (Zantop et al. 2008; Sadoghi et al. 2011).

6.4.3.1 Femoral location

The correct placement for the graft is below the “resident’s ridge” in the lateral condyle of the femur when the knee is flexed. The graft should be as low and as deep as possible. If the graft is located too anteriorly in the femur, it results in impingement in the intercondylar notch in knee extension, while locating the graft too high in the intercondylar space may result in the graft becoming loose in flexion causing anteroposterior laxity (Jepsen et al. 2007; Lee et al. 2007; Scanlan et al. 2009; Kondo et al. 2011).

6.4.3.2 Tibial location

Usually the remnants of the torn ACL are still left in the tibia and the correct placement of the graft is therefore easy to determine. Cross et al. (2012) found that there is no difference whether the graft is inserted either in the centre of the AM remnant or in the centre of the whole tibial attachment when performing single-bundle ACL reconstruction (provided that the femoral attachment is in the correct place). The crucial point in earlier studies has been that in conventional single-bundle reconstruction the graft is sometimes placed in the PL tibial footprint and goes to the AM femoral footprint, which is inferior in stability compared AM to AM or central to central positions (Brophy et al. 2009).

In double-bundle ACL reconstruction the grafts should be in the centres of the AM and PL bundle attachment sites.

6.4.4 Drilling

6.4.4.1 Femoral drilling

A previously common method for drilling femoral tunnels was through the tibia. This transtibial method inevitably resulted in femoral tunnels which were too high in the intercondylar notch (Arnold et al. 2001). They were usually also too anterior in relation to the true anatomical site (Strauss et al. 2011). Some studies claim that the femoral tunnel can also be placed correctly in transtibial technique, but then the tibial tunnel can no longer be the anatomical site (Bowers et al. 2011; Piasecki et al. 2011).

Another known method to drill the femoral tunnel is through an anteromedial portal. It has its risks e.g. damage to the peroneal nerve, but these have proven to diminish when the flexion angle of the knee is increased (Nakamura et al. 2009; Otani et al. 2012). The femoral tunnel length has been reported to become shorter than with transtibial technique (Bedi et al. 2010; Chang et al. 2011; Miller et al. 2011; Ilahi et al. 2012), but this has not affected the stability of the knee. On the contrary, it is easier to get the graft locations more anatomically in sagittal and also in lateral view with this anteromedial portal method (Gavrilidis et al. 2008; Abebe et al. 2009; Dargel et al. 2009; Steiner et al. 2009; Bedi et al. 2011; Kopf et al. 2011; Xu et al. 2011; Gadikota et al. 2012; Pascual-Garrido et al. 2012; Silva et al. 2012; Tompkins et al. 2012) and therefore the stability has also been reported to be better (Alentorn-Geli et al. 2010; Schairer et al. 2011; Sim et al. 2011).

6.4.4.2 Tibial drilling

A drill guide is used on the tibial side in ACL reconstruction. The drilling is usually done with an outside-in technique. The angle of the ACL drill guide has an effect on the shape and length of the insertion site in the tibia, which determines the area of the ACL graft insertion site and therefore the width of the graft itself (Kopf et al. 2010; Miller et al. 2010; Hamilton et al. 2011).

6.4.5 Single-bundle vs. double-bundle ACL reconstruction

Conventional ACL reconstruction is carried out with a single-bundle method, in which only the AM bundle is reconstructed. It has been reported that there is sometimes still residual rotational laxity after the operation (Lewis et al. 2008). Therefore a more anatomical ACL reconstruction method called double-bundle technique was developed. Moreover, longer follow-up studies have shown that the single-bundle method does not

prevent osteoarthritis of the knee (OA), partly because the OA develops as a result of the primary trauma (Oiestad et al. 2009).

The surgical technique of the double-bundle technique is more complex than conventional single-bundle technique, since it entails two grafts and altogether four tunnels; two in the tibia and two in the femur (Järvelä 2007). It reconstructs both the AM and PL bundles of the ACL and is thus thought to produce a more stable knee than with single-bundle ACL reconstruction.

6.4.5.1 Randomized controlled studies

So far 14 Level I prospective randomized studies have been presented on single-bundle versus double-bundle ACL reconstructions. They report rather short-term (one to eight years) results comparing these two reconstruction methods (Table 1).

The main finding in some of these studies is the superior stability in the double-bundle group especially in rotational plane (Järvelä 2007; Muneta et al. 2007; Järvelä et al. 2008; Siebold et al. 2008; Zaffagnini et al. 2008; Ibrahim et al. 2009; Aglietti et al. 2010; Zaffagnini et al. 2011; Hussein et al. 2012), but other studies have not confirmed this conclusion (Adachi et al. 2004; Streich et al. 2008; Sastre et al. 2010). Another important finding favouring the double-bundle group is the better graft durability indicating a greater revision rate in the single-bundle group (Suomalainen et al. 2011; Suomalainen et al. 2012).

Table 1. Level I randomized controlled studies on single-bundle versus double-bundle ACL reconstruction.

Study	Year	Patients	Follow-up	Results
Adachi et al.	2004	108	33 mo	SB had more notchplasties than DB group
Aglietti et al.	2010	70	24 mo	DB had better VAS, anterior stability and final objective IKDC score
Hussein et al.	2012	281	51 mo	DB had the best anterior and rotational stability, the DB group also had better IKDC and Lysholm scores
Ibrahim et al.	2009	200	29 mo	DB had the best anterior and rotational stability
Järvelä	2007	65	14 mo	DB had better rotational stability
Järvelä et al.	2008	77	24 mo	DB had better rotational stability than either of the SB procedures
Muneta et al.	2007	68	24 mo	DB had better anterior and rotational stability
Sastre et al.	2010	40	24 mo	No difference
Siebold et al.	2008	70	19 mo	DB had better anterior and rotational stability and better objective IKDC score
Streich et al.	2008	49	24 mo	No difference
Suomalainen et al.	2011	152	24 mo	DB had fewer revisions
Suomalainen et al.	2012	90	60 mo	DB had fewer revisions
Zaffagnini et al.	2008	72	36 mo	DB had better anterior stability and better subjective, objective and fuctional evaluations
Zaffagnini et al.	2011	79	96 mo	DB had better rotational stability, RoM and functional scores, fewer degenerative changes and fewer reoperations

6.4.5.2 Non-randomized studies

There are several non-randomized studies, all of which conclude that double-bundle ACL reconstruction is at least as good as the single-bundle method. This was confirmed in four meta-analyses (Meredick et al. 2008; Zhu et al. 2012; Li et al. 2013; Xu et al. 2013) (Table 2).

Table 2. Non-randomized studies on single-bundle versus double-bundle ACL reconstruction.

Study	Year	Patients	Follow-up	Study design	Results
Aglietti et al.	2007	75	24 mo	Prospective therapeutic	DB had better subjective score, anteroposterior and rotational stability
Claes et al.	2011	20	6 mo	Prospective comparative	No difference
Fujita et al.	2011	60	24 mo	Prospective comparative	DB had better extensor strength than SB AM, better flexor strength than SB PL and better rotational and anterior stability than SB PL
Kanaya et al.	2009	33	-	Intraoperative trial	No difference
Kondo et al.	2008	328	24 mo	Prospective comparative cohort	DB had better anterior and rotational stability
Lee et al.	2012	42	24 mo	Prospective comparative	No difference
Misonoo et al.	2012	66	12 mo	Prospective comparative cohort	No difference
Park et al.	2010	113	24 mo	Prospective comparative	No difference
Seon et al.	2009	40	-	Prospective comparative	DB had better anterior and rotational stability
Song et al.	2009	40	24 mo	Prospective comparative cohort	No difference
Takeda et al.	2009	29	6 mo	Prospective comparative	DB had better anterior stability
Tsuda et al.	2009	125	24 mo	Prospective comparative	No difference
Yagi et al.	2007	60	12 mo	Prospective therapeutic	DB had better rotational stability
Yasuda et al.	2006	72	24 mo	Prospective comparative	Anatomic DB had better anterior stability

6.4.5.3 Cadaver studies

In addition, there are 13 cadaver studies comparing single- and double-bundle ACL reconstruction methods (Table 3). The main finding in these studies is that double-bundle ACL reconstruction results in more stable knees than the single-bundle method.

Table 3. Cadaver studies on single- versus double-bundle ACL reconstruction.

Study	Year	Knees	Operative technique	Results
Bedi et al.	2010	10	Open arthrotomy	DB had improved rotational stability
Belisle et al.	2007	4	Transtibial	DB replicates native ACL mean strain patterns more closely
Ho et al.	2009	8	Anteromedial portal	No difference
Kondo et al.	2010	8	Transtibial	DB had better anterior and rotational stability
Kondo et al.	2011	8	Anteromedial portal	DB and lateral SB were better than non-anatomic SB in internal rotational laxity and anterior translation
Morimoto et al.	2009	19	Transtibial/ anteromedial portal	DB restores normal contact area and pressure more closely mainly at low flexion angles
Musahl et al.	2010	12	Open arthrotomy	DB had better rotational stability
Musahl et al.	2011	10	Open arthrotomy	DB had better rotational stability
Seon et al.	2010	10	Open arthrotomy	DB had better anterior and rotational stability
Tajima et al.	2010	7	Open arthrotomy	DB restores normal PF contact area more closely than SB
Tsai et al.	2010	7	Open arthrotomy	DB had better rotational stability
Yagi et al.	2002	10	Arthroscopically	DB had better anterior and rotational stability
Zantop et al.	2010	10	Anteromedial portal	DB had better anterior stability

6.4.6 Graft ruptures

The main reasons for ACL graft ruptures are graft misplacement and subsequent impingement. Located too anteriorly in the tibia, the graft impinges on near extension and may cause extension deficiency. Too posterior in the tibia, the problem is in flexion when the graft becomes too loose and may cause excess laxity. The graft location needs to be correct on the femoral side, too. Too anterior graft placement causes over-tightening of the graft in extension and can therefore lead to graft failure. If the graft is too high in the intercondylar notch, it will lack the ability to restore the rotational

forces subsequently resulting in rotational laxity, which can also lead to graft failure. Too posterior placement of the ACL graft can result in laxity in flexion with graft rupture (Marchant et al. 2010; Trojani et al. 2011; Hosseini et al. 2012).

Traumatic reinjury can cause a graft rupture independently (Salmon et al. 2005). It can be also a contributory factor when there are technical errors (graft in a wrong position) or biological issues (graft incorporation problem) (Wright et al. 2010). In addition, the risk factors for graft rupture are younger age and strenuous sports and when an allograft is used (van Eck et al. 2012).

6.5 Osteoarthritis and ACL rupture

It has long been known that ACL deficient knees have more OA than knees with an intact ACL (Kannus et al. 1987). The cause of OA is unknown. There has been discussion about the impact of the original trauma with subsequent knee laxity and that of the associated injuries on the development of OA (Lohmander et al. 2007). Also, if surgery has been performed, surgical trauma may initiate or foster OA development (Louboutin et al. 2009).

6.5.1 Osteoarthritis in an ACL deficient knee

The main reason for OA in ACL deficient knees is that there is abnormal movement between the tibial and femoral joint surfaces in the anteroposterior and rotational planes (Louboutin et al. 2009). There may be subluxations of the knee and also subsequent meniscal damage.

A meniscal rupture has been shown to be an independent risk factor for the development of OA (Neuman et al. 2008). A knee with a resected meniscus in combination with an ACL rupture especially has a high probability of developing OA (Liden et al. 2008; Keays et al. 2010). Some studies have concluded that a meniscus fixation protects against OA (Brophy et al. 2012), but there are other studies in which this has not been affirmed (Lohmander et al. 2007).

The original trauma may also cause initial osteochondral damage, which is difficult to treat and may lead to OA in a fairly short period of time regardless of the method used in the treatment of the ACL tear (Li et al. 2011).

6.5.2 Osteoarthritis in an ACL reconstructed knee

The literature includes several studies on ACL reconstruction and OA. These studies reported on numerous reconstruction methods and also various fixation devices, making direct comparison difficult. Despite the differences these studies concluded that ACL reconstruction does not prevent the development of OA (Lohmander et al. 2007) and that ACL reconstructed knees with combined injuries have more radiological OA than those without accompanying injuries (Oiestad et al. 2009; Oiestad et al. 2010).

No clinical studies on double-bundle ACL reconstruction were found in the literature with a specific focus on OA, the reason being that double-bundle reconstruction is still a fairly new method and the development of OA takes several years.

Li et al. (2011) investigated in a retrospective clinical study the risk factors for OA in an ACL reconstructed knee. Their main finding was that the best predictors for OA were chondral lesion at the time of the injury, resection or removal of the medial meniscus and overweight. Louboutin et al. (2009) came to similar conclusions in their review article.

7 AIMS OF THE STUDY

The main purpose of this study was to compare in a randomized study setting double-bundle and single-bundle ACL reconstruction methods. The locations of the reconstructed grafts were also analysed. Although much research has been published on this subject in the past, there is still controversy as to whether ACL reconstruction should be carried out using single-bundle or double-bundle technique.

This study had the following aims:

- To evaluate the short-term (two-year) results of ACL reconstruction using single-bundle and double-bundle techniques.

- To find out if the graft locations of the single-bundle method changed during the years when the double-bundle technique was used.

- To assess the mid-term (five-year) results of the ACL reconstruction comparing three different reconstruction methods: double-bundle with bioabsorbable screws, single-bundle with bioabsorbable screws, and single-bundle with metallic screws.

- To evaluate ACL graft visibility and measure their locations in MRI and to find out if there is an association with clinical findings.

8 MATERIALS AND METHODS

8.1 Patients

The inclusion criteria for all the studies were: primary ACL reconstruction, closed growth plates, and absence of ligament injury to the contralateral knee. The operations were performed by one experienced orthopaedic arthroscopy surgeon.

Preoperatively all groups were equally engaged in sport, the main types of sports being soccer, downhill skiing and floorball. The local ethics committee approved the studies, and written informed consent was obtained from every participant. The randomization was done with closed envelopes.

The baseline data collection was done in Hatanpää Hospital in Tampere. The demographic data and baseline characteristics of the studies are shown in Table 4.

8.1.1 Study I

Altogether 153 patients were randomized (Figure 3). Ninety percent of the patients (71 in the SB group, 67 in the DB group) were available at two-year follow-up (range 24 to 37 months). Seven patients in the SB group and one in the DB group had a graft failure during follow-up and underwent revision ACL surgery. Another nine patients (four in the SB group and five in the DB group) had an ACL reconstruction to the contralateral knee during the two-year period postoperatively and were therefore excluded from the study thereafter. The statistical analysis was done on data from 121 patients (60 in the SB group, and 61 in the DB group) (Figure 3).

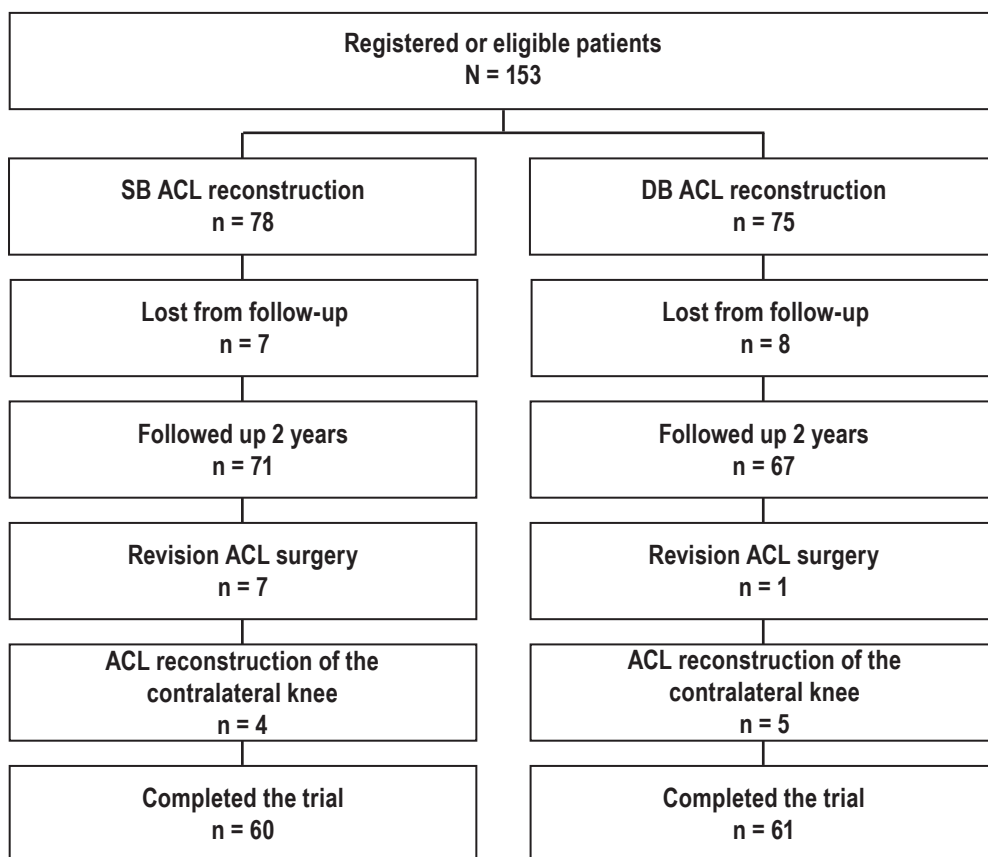


Figure 3. CONSORT flow diagram of the study I.

8.1.2 Study II

The first group (A) (n=25) was operated on before the initiation of regular double-bundle technique in ACL reconstructions in 2003. The patients in Group B (n=25) were operated on in 2007, when double-bundle technique was already routinely used.

Forty-six patients (92%; 22 in Group A, 24 in Group B) completed the two-year follow-up. Four patients in Group A underwent revision ACL surgery during follow-up so the final statistical calculation could be made for 42 patients.

Table 4. Demographic data of Studies I, II, III and IV.

Study	Study type	Year	Group	N	Sex (male/ female)	Age (years)*	Height (cm)*	Weight (kg)*	Operation time (min)*	Follow- up time (months)*	Time from injury to operation (months)*
I	Level I RCT	2003–2008	SB DB	78 75	54/24 56/19	32 (10) 32 (10)	175 (9) 177 (9)	81 (16) 83 (16)	64 (17)** 73 (16)**	28 (4) 26 (2)	
II	Prospective comparative clinical study	2003 2007	A B	25 25	18/7 16/9	30 (8) 32 (11)	174 (10) 175 (10)	79 (14) 85 (17)	69 (11)*** 50 (12)***	28 (3) 25 (2)	
III	Level I RCT	2003–2011	SBB SBM DB	30 30 30	21/9 19/11 21/9	30 (8) 33 (10) 34 (10)	176 (9) 173 (10) 176 (9)	81 (16) 80 (14) 80 (15)	67 (19) 67 (13) 82 (17)	62 (3) 63 (3) 63 (2)	12 (6) 11 (5) 13 (6)
IV	Prospective MRI and clinical study	2003–2007	DB	75	56/19	32 (10)	177 (9)	82 (16)	73 (16)	25 (2)	

* Mean (SD)

** $p = 0.003$ *** $p < 0.001$

8.1.3 Study III

Altogether 90 patients were randomized (Figure 4). During the five-year follow-up there were 11 patients (seven in the SBB Group, three in the SBM Group, and one in the DB Group), who underwent ACL revision surgery due to a graft failure and were excluded from the final clinical statistical analyses. A further 14 patients were lost to follow-up (two in the SBB Group, three in the SBM Group, and nine in the DB Group) as long distances prevented their attendance at follow-up. Seven of the DB Group drop-outs were successfully contacted by telephone and they were all reportedly satisfied with their knees and no ACL revision surgery had been performed. One patient in the SBM Group had had an ACL re-reconstruction. The remaining four could not be reached (Figure 4).

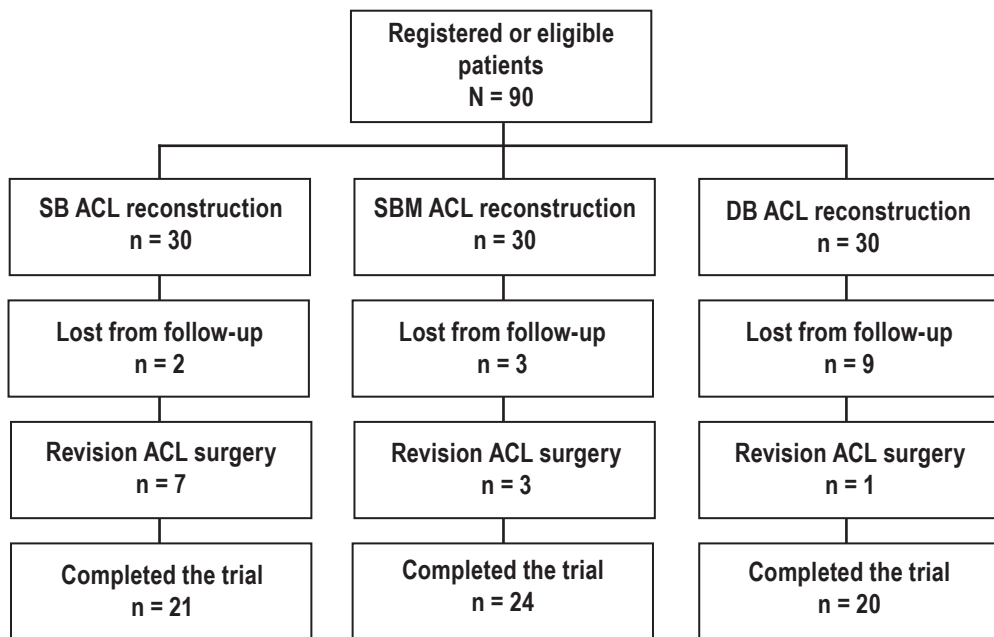


Figure 4. CONSORT flow diagram of Study III.

8.1.4 Study IV

All 75 participants underwent double-bundle anterior cruciate ligament reconstruction. Fourteen patients did not attend the two-year follow-up, but nevertheless three of them had MRI done at that point.

8.2 Surgical techniques

8.2.1 Single-bundle technique

The single-bundle method used in this study has been described in detail (Pinczewski et al. 2002). First a complete diagnostic arthroscopy was made to diagnose the ACL tear and to ascertain if there were any other injuries to the knee joint. Then hamstring grafts (semitendinosus and gracilis) were harvested from the same extremity and doubled to form a four fold graft.

The femoral tunnel was made through an anteromedial portal (not transtibially) as low and as posterior as possible without breaking the posterior wall of the femoral condyle. The tunnel was approximately ten o'clock in the right knee and two o'clock in the left one. The tibial tunnel was made with the aid of a tibial guide (Acufex®, Smith & Nephew) in the centre of the remnants of the ACL.

The graft was inserted through the tibial tunnel to the femur and then fixed with a bioabsorbable interference screw (or with metallic screws in Study III) in aperture manner inside out on the femoral side and from outside in to the tibial tunnel (Figure 5).

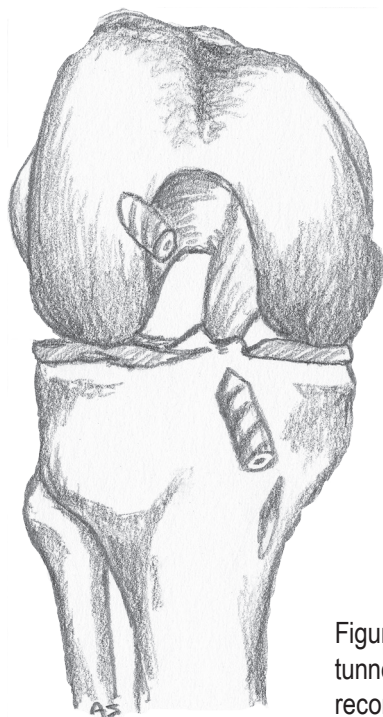


Figure 5. Schematic drawing of the right knee showing the tunnel and screw placements of the single-bundle ACL reconstruction.

8.2.2 Double-bundle technique

Järvelä (2007) has described in detail the double-bundle technique applied in these studies. Briefly, first a complete diagnostic arthroscopy was performed and then hamstring grafts were harvested.

The ligament remnants of the tibial ACL insertion site were left intact but the femoral attachment point was debrided. The anatomical sites of the individual bundles were identified and then the femoral tunnels were drilled via the anteromedial portal using freehand technique, the AM tunnel at 120° of flexion and the PL tunnel 90° of flexion of the knee.

The AM tunnel was made first as posterior and low as possible without breaking the posterior wall of the femoral condyle, approximately ten o'clock in the right knee and two o'clock in the left knee. Thereafter the PL tunnel was also drilled via the anteromedial portal to an anteroinferior position in relation to the AM tunnel. The wall between these two tunnels was at least 1–2mm. No bony notchplasty was performed unless there were osteophytes in the intercondylar space.

Tibial tunnel drillings were done with a tibial guide at an angle of 55°. The AM guide wire was inserted first into the anteromedial part of the remnants and thereafter the PL tunnel guide wire was positioned into the posterolateral point of the tibial attachment. The tunnels were drilled and the grafts inserted. The PL graft was inserted first via the tibial tunnel to the femur and fixed with a screw in aperture manner. It was tensioned at full extension by manual pulling. The AM graft was tensioned at 30° flexion of the knee also with manual pulling. The tibial side was also fixed with screws. Figure 6.

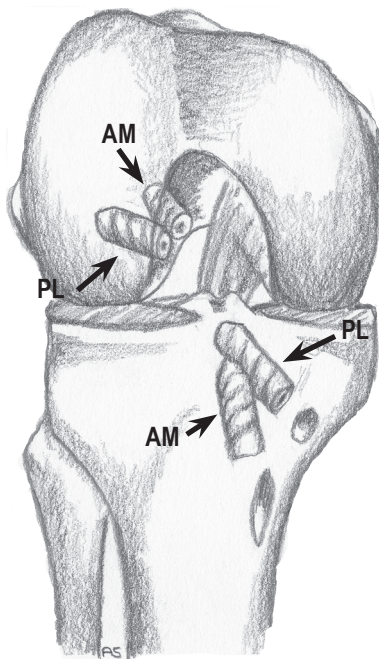


Figure 6. Schematic drawing of the right knee showing the tunnel and screw placements of the double-bundle ACL reconstruction.

8.3 Postoperative rehabilitation

Full weight bearing was allowed immediately after surgery. No rehabilitation brace was used. Patients used crutches for three to four weeks. They started closed-chain exercises immediately postoperatively. Cycling with an ergometric bicycle was begun at four weeks, running at three months and pivoting sports at six months if the patient had regained full functional stability of the knee.

If a meniscal repair was done in the same procedure as the ACL reconstruction, the patient was allowed knee flexion of 0-90 degrees for six weeks and no brace was used. Otherwise the rehabilitation programme was the same as described above.

8.4 Follow-up evaluation

8.4.1 Subjective evaluation

Patients completed the Lysholm Knee Score (Lysholm et al. 1982), which measures subjective functions e.g. squatting and running. The scale is 0–100, 100 being perfect functioning of the knee. In addition the Tegner Activity Score (Tegner et al. 1985) was used, in which the patients report their activity level. Function score section of the International Knee Documentation Committee subjective knee evaluation form (IKDC (Irrgang et al. 1998) scale: 0–10) was used to evaluate patients' daily functions. Full function without any limitations was scored as 10, while zero indicated that those patients were unable to perform their daily activities.

8.4.2 Clinical and functional evaluation

The clinical evaluations in Studies I, II and IV were made by two researchers blind to the randomization (Study I) or study group (Study II). In Study III the evaluations were done by one researcher blind to the randomization.

The clinical evaluation was performed on the basis of IKDC knee examination form (Irrgang et al. 1998), which gives the classification from A to D, in which A is normal, B nearly normal, C abnormal and D severely abnormal. The clinical examination included knee alignment assessment, passive and active knee RoM measurement, knee joint effusion assessment as well as stability measurements including pivot shift, Lachman and KT1000.

The patients were asked to do a “one-leg-hop” test, in which the best result of three hops was recorded and compared to that of the contralateral leg. Medial and lateral crepitus was evaluated while performing the McMurray test.

In the “Knee walking test” the patients were invited to walk on their knees on a hard floor with the upper body erect and the knees therefore taking the whole bodyweight. When this was performed perfectly, the performance was graded as normal; a performance that felt unpleasant was graded as nearly normal; a performance that felt difficult as abnormal; and inability to perform the test as severely abnormal. In addition to knee function, this test measured the level of anterior knee pain.

8.4.3 Range of motion of the knee

The range of motion of the knee was measured with a goniometer with the patient lying supine on the examination couch first from the healthy and then from the ACL reconstructed knee. Patients were asked first to actively extend and flex their knee and RoM measured. Thereafter the passive range of motion was measured.

The difference of range of motion between the injured and uninjured knee was documented on the IKDC knee examination form. The range of motion was recorded as normal if the lack of extension was less than three degrees and lack of flexion less than five degrees. Three to five degrees’ deficiency in extension was reported as nearly normal, likewise a lack of flexion of six to fifteen degrees. Abnormal knees were those with extension deficiencies of six to ten degrees and 16 to 25 degrees of lack of flexion. Greater abnormalities in the range of motion were considered to be severely abnormal.

8.4.4 Instrumented side-to-side laxity measurement

The anteroposterior stability measurement was done at 30 degrees of flexion with a KT-1000 arthrometer (MEDmetric® Corporation, San Diego, CA) using a force of 134N. The measurement was done three times and the average was calculated and compared to the uninjured knee. The side-to-side laxity difference was graded according to the IKDC knee examination form and considered normal (0–2mm laxity), nearly normal (3–5mm laxity), abnormal (6–10mm laxity) or severely abnormal (over 10mm laxity).

8.5 MRI examination

MRI was conducted using a 1.5T imager Signa Exite HD (General Electric, Milwaukee, WI) using an eight-channel receiver/transmitter coil. An experienced musculoskeletal radiologist made all the interpretations of the MRI in Studies I and II and in consensus with another radiologist in Study IV. The radiologists were blind to the patients' clinical data.

In Study I, the main focus was on the visibility of the grafts and they were graded as intact, partially visible and invisible. A graft was considered visible when intact graft fibres were seen. The graft was considered partially visible when only few graft fibres were seen. The graft was considered invisible when no graft fibres were seen.

In Study II, the main idea was to evaluate the graft locations in two separate groups of single-bundle ACL reconstructions. The graft locations were measured using a method described earlier by Lorenz et al. (2009). On the femoral side, the maximum diameter of the femoral condyle was first visualized from the sagittal images in x-y orientation to Blumensaat's line and then the graft location from its own plane. The centre of the graft was divided by the maximum diameter of the femoral condyle. On the tibial side the graft location and the maximum diameter of the tibial plateau were determined and divided in the coronal and also in the sagittal views respectively.

In Study IV we combined the graft locations and graft visibility information with the clinical measurements.

8.6 Radiographic evaluation of OA

In Study III, roentgenograms included anteroposterior, mediolateral and patellar views of the patients' knees. An experienced musculoskeletal radiologist blind to the patients' clinical and surgical data interpreted the images. Special attention was paid to OA changes, which were graded according the Kellgren and Lawrence classification system (Kellgren et al. 1957).

8.7 Statistical methods

Statistical analysis was conducted using the SPSS 11.0 software package (SPSS Inc, Chicago, Ill). The calculations between the differences of means were done using analysis of variance (ANOVA) or paired samples t test, and those of the frequencies by chi-square test. The test significance level was set at $P < .05$.

9 RESULTS

There was no statistically significant difference between any of the groups included in this study regarding the Lysholm Knee Score, the IKDC function score or the IKDC classification either preoperatively or at two- or five-year follow-ups. On the contrary, all scores improved significantly compared to preoperative and the two- and five-year status (Table 5).

Table 5. Clinical outcomes of all studies preoperatively and at two-year and five-year follow-up.

	Study I		Study II		Study III			Study IV
	SB	DB	A	B	SBB	SBM	DB	DB
<i>Preoperatively</i>								
N	78	75	25	25	30	30	30	75
Lysholm, Mean (SD)	67	69	68 (18)	62 (19)	71 (14)	64 (18)	68 (19)	69 (17)
IKDC function score	4	4	4	4	4	5	5	4
IKDC classification								
Normal A	0	0	0	0	0	0	0	0
Nearly normal B	3	0	0	0	2	1	0	0
Abnormal C	65	72	24	18	17	21	19	72
Severely abnormal D	10	3	1	7	2	2	1	3
<i>Two-year follow-up</i>								
N	60	61	18	24				61
Lysholm, Mean (SD)	88	88	89 (17)	84 (14)				89 (13)
IKDC function score	8	8	8	8				8
IKDC classification								
Normal A	24	25	7	9				26
Nearly normal B	26	23	9	8				23
Abnormal C	10	11	2	7				11
Severely abnormal D	0	2	0	0				2
<i>Five-year follow-up</i>								
N					21	24	20	
Lysholm, Mean (SD)					86 (13)	87 (17)	90 (9)	
IKDC function score					8	8	8	
IKDC classification								
Normal A					3	3	5	
Nearly normal B					13	12	11	
Abnormal C					5	9	4	
Severely abnormal D					0	0	0	

SBB, single-bundle reconstruction with bioabsorbable screw; SBM, single-bundle reconstruction with metallic screw

Anteroposterior stability was measured with the KT-1000 arthrometer (Table 6) and the side-to-side difference was graded according to the IKDC knee examination form. No differences between the groups were found. Rotational stability was measured with the pivot-shift test. These results were also similar between groups and no statistically significant difference was found at two- or five-year follow-up, although the status improved remarkably in all groups when compared to the preoperative state in anteroposterior and in rotational planes ($p < 0.001$) (Table 7).

Table 6. Anteroposterior stability measured with the KT-1000 arthrometer and side-to-side difference graded according to the IKDC classification.

	Study I		Study II		Study III		Study IV	
	SB	DB	A	B	SBB	SBM	DB	DB
<i>Preoperatively</i>								
N	78	75	25	25	30	30	30	75
KT-1000	4.2 (2.7)	4.3 (2.0)	4.6 (2.7)	4.6 (2.4)	4.0 (3.0)	4.7 (2.4)	4.4 (1.8)	4.3 (1.7)
KT-1000 arthrometer measurements								
Normal A	5	0						
Nearly normal B	19	25						
Abnormal C	52	50						
Severely abnormal D	2	0						
<i>Two-year follow-up</i>								
N	60	61	18	24				61
KT-1000	2.0 (2.4)	2.0 (3.0)	2.1 (2.4)	2.0 (2.7)				1.9 (3.0)
KT-1000 arthrometer measurements								
Normal A	37	40						40
Nearly normal B	16	12						12
Abnormal C	7	9						9
Severely abnormal D	0	0						0
<i>Five-year follow-up</i>								
N				21	24	20		
KT-1000				1.2 (2.8)	2.3 (3.8)	1.6 (3.0)		
KT-1000 arthrometer measurements								
Normal A								
Nearly normal B								
Abnormal C								
Severely abnormal D								
<i>Revision ACL surgery because of graft failure</i>	7	1	4	0	7	3	1	1

Table 7. Rotational stability evaluated with the pivot-shift test and graded according to IKDC classification.

	Study I		Study II		Study III			Study IV
	SB	DB	A	B	SBB	SBM	DB	DB
<i>Preoperatively</i>								
N	78	75	25	25	30	30	30	75
Pivot-shift								
Normal A	0	0	0	0	0	0	0	
Nearly normal B	28	18	7	6	5	10	5	
Abnormal C	47	57	18	17	15	14	15	
Severely abnormal D	3	0	0	2	1	0	0	
<i>Two-year follow-up</i>								
N	60	61	18	24				61
Pivot-shift								
Normal A	38	41	11	16				41
Nearly normal B	18	17	7	5				17
Abnormal C	4	3	0	3				3
Severely abnormal D	0	0	0	0				0
<i>Five-year follow-up</i>								
N				21	24	20	7	
Pivot-shift								
Normal A					10	9	10	
Nearly normal B					9	9	3	
Abnormal C					2	6	0	
Severely abnormal D					0	0		

9.1 Study I

9.1.1 Graft failure

The main finding was that there were seven graft failures in the SB Group (9%) and only one in the DB Group (1%) leading to ACL revision surgery during two-year follow-up ($p = 0.04$) (Table 6). All graft failures in the SB Group were due to minor trauma and the one in the DB Group was because of a major accident involving bone fractures.

9.1.2 Meniscal status

The meniscal status is shown in Table 8. There was no statistically significant difference between the groups regarding either resection or fixation of the rupture. No new ruptures were seen in MRI at two-year follow-up, but five partial meniscal resections

were done during this period (three patients in the SB Group, and two patients in the DB Group).

Table 8. Meniscal status and treatment at the time of ACL surgery.

	Study I		Study III		
	SB	DB	SBB	SBM	DB
Status					
Isolated ACL rupture	37	32	16	11	15
ACL and medial meniscus rupture	15	20	2	9	7
ACL and lateral meniscus rupture	17	19	8	7	6
ACL and both meniscus rupture	9	4	4	3	2
Treatment					
Fixation with endoscopic manoeuvre	10	7	2	4	2
Partial resection	30	31	11	15	10
Left in situ	1	5	1	0	3

9.1.3 MRI evaluation

MRI revealed that the grafts in the SB Group were intact in 46 cases, partially visible in seven, and invisible in five at two-year follow-up. In the DB group both grafts were evaluated separately: 60 patients had intact AM bundles, two partially visible, and two entirely invisible AM bundles, while 52 patients had intact PL bundles, nine patients partially visible PL bundles, and three patients invisible PL bundles. Together in the DB Group, 52 patients had both grafts intact and two patients both grafts invisible. The MRI findings did not correlate with the clinical findings of the knees. (Figure 7.)



Figure 7. MRI evaluation two years after double-bundle anterior cruciate ligament reconstruction. Both bundles (antero-medial [AM] and posterolateral [PL]) are visible and intact.

9.2 Study II

9.2.1 Graft failures and operation time

The average operation time was reduced by 19 minutes from 2003 to 2007 (from 69 minutes to 50 minutes) ($p = 0.001$). There were significantly more graft failures in Group A (four patients) than in Group B (none) ($P=0.045$) (Table 6).

9.2.2 Tunnel placement

The tunnel placements of the ACL grafts were measured from MRI at two-year follow-up. In Group A the tunnel placement was significantly more lateral on the tibial side than in Group B ($p = 0.024$). The other measurements regarding the tunnel placements were similar in both groups (Table 9).

Table 9. Tunnel placements of the SB ACL reconstruction measured with MRI.

	Group A	Group B
N	18	24
Tibia		
From lateral (%)*	57 (3)**	54 (3)**
From anterior (%)*	45 (5)	45 (4)
Femur		
From Blumensaat line (%)*	27 (9)	26 (6)
From posterior (%)*	32 (5)	29 (6)
* Mean (SD)		
** $p = 0.024$		

9.3 Study III

9.3.1 Graft failures

There were 11 graft failures (seven in the SBB Group, three in the SBM Group, and one in the DB Group) at five-year follow-up and these all underwent ACL revision surgery ($P=0.043$). Seven of them (five in the SBB Group, one in the SBM Group, and one in the DB Group) occurred within the first two years of follow-up and the remaining four (two in the SBB Group and two in the SBM Group) during the latter period (two to five-year follow-up) (Table 6).

9.3.2 OA changes and meniscal ruptures

The OA changes are presented in Table 10 at five-year follow-up. There were neither statistically significant nor clinically relevant group differences regarding OA in any of the three compartments of the knee joint either preoperatively or at five-year follow-up. There was a correlation with the OA and meniscal ruptures, but there was no statistically significant difference between the three groups regarding meniscal status, resection or fixation perioperatively, or at five-year follow-up (Table 8).

9.4 Study IV

The main finding in this double-bundle ACL reconstruction study was that the location of the ACL graft tunnel in the tibia had an impact on the visibility of the graft in MRI at two-year follow-up. The more anterior graft location in either of the DB grafts in the tibia was associated with partial graft visibility or invisibility (Table 11). In contrast, there was no such association between the anteroposterior or rotational stabilities and the MRI-based graft locations.

Table 10. OA changes of knees preoperatively and at five-year follow-up graded according to the Kellgren-Lawrence classification.

Compartment	SBB			SBM			DB		
	MFT	LFT	PF	MFT	LFT	PF	MFT	LFT	PF
Preoperatively									
Normal	18	20	28	21	23	19	17	19	17
Grades I	3	1	3	3	1	5	3	1	3
Grades II	0	0	0	0	0	0	0	0	0
Grades III–IV	0	0	0	0	0	0	0	0	0
Five-year follow-up									
Normal	15	17	13	15	20	18	16	18	15
Grades I	5	2	7	6	3	4	3	1	4
Grades II	1	2	1	2	0	2	1	1	1
Grades III–IV	0	0	0	1	1	0	0	0	0

MFT, medial femorotibial; LFT, lateral femorotibial; PF, patellofemoral

Table 11. Relationship between the tunnel placements of the ACL reconstructions and visibility of the graft as evaluated by MRI at two-year follow-up. Mean (SD)

	Visibility of the graft		
	Intact	Partially visible	Invisible
N	59	2	3
Tunnel placement			
AM graft			
Tibia			
From anterior*	43 (6)**	34 (1)**	36 (7)**
Femur			
From Blumensaat's line***	19 (6)	24 (2)	21 (10)
From posterior*	28 (5)	28 (9)	31 (4)
N	51	9	4
Tunnel placement			
PL graft			
Tibia			
From anterior*	57 (6)****	52 (5)****	51 (6)****
Femur			
From Blumensaat's line***	44 (6)	43 (7)	43 (7)
From posterior*	42 (8)	47 (8)	43 (9)

*percentages of the total length of the tibial or femoral condyle
 ** p = 0.017
 ***percentages of the total length of the condyle from Blumensaat's line to the distal cortex of the femoral condyle
 **** p = 0.012

10 DISCUSSION

Anterior cruciate ligament injury is among the most common sports-related trauma. The true incidence of ACL ruptures in population is not known, but the Finnish National Hospital Discharge Register shows that annually there are approximately 2,900 surgically treated ACL ruptures in Finland, a country with a population of 5.4 million in 2012. The incidence of ruptures is probably much higher. There is currently a recommendation for more conservative treatment of ACL ruptures because recent studies indicate that invasive treatment of the ruptured ACL does not prevent OA changes and the procedure should be performed only on patients suffering from instability symptoms despite proper rehabilitation (Frobell et al. 2010; Smith et al. 2010).

All the studies in this dissertation revealed that there was a statistically significant difference concerning the anteroposterior and rotational stabilities between the preoperative and the two- and five-year follow-ups favouring the postoperative status. Also, the Lysholm and IKDC final scores improved remarkably. On the other hand, there was no statistical difference between the groups in any of the studies in the measurements reported above, neither were there statistically or clinically relevant inter-group differences regarding OA in any of the three compartments of the knee joint when the roentgenograms were evaluated in Study III.

The main finding in the prospective and randomized Studies I and III in this dissertation was that double-bundle ACL reconstruction surgery resulted in fewer graft failures than did the single-bundle method. One hypothesis explaining this feature is that single-bundle ACL reconstruction is not as anatomical as the double-bundle technique since the reconstruction is done with only one bundle instead of two, which is the original human anatomy. Therefore it allows more postoperative laxity than the double-bundle reconstruction. However, this assumption was not confirmed in the clinical measurements.

The graft material, fixation and size were the same in all of these ACL reconstruction groups. Also, the operating surgeon was already an expert arthroscopist at the beginning of our study. The finding in Study II showed that the majority of the graft ruptures in the single-bundle group occurred among the first operated group. In addition the

results in Study III show that the graft ruptures occur during the first two years after surgery. This could be explained by the so-called learning curve (Hohmann et al. 2010).

This learning curve theory is also supported by the fact that the mean operation time was reduced by 19 minutes in the single-bundle ACL reconstruction in Study II from 2003 to 2007. In addition, the MRI analysis in Study II revealed that the graft locations were anatomical, but the insertion sites in the tibia were significantly more lateral in the early years than in 2007. Most likely there is no single reason for the graft ruptures and the explanation is more complex.

The anatomy of the ACL with its double-bundle structure was introduced almost two hundred years ago (Schindler 2012). The anteromedial and posterolateral bundles, named according to the insertion sites in the tibia, work together and also separately to stabilize the knee joint. The anteromedial bundle functions in all flexion angles of the knee and the posterolateral bundle only in near extension (Zantop et al. 2007; Markolf et al. 2008; Lorbach et al. 2010; Wu et al. 2010; Fujie et al. 2011; Amis 2012; Kato et al. 2012). The double-bundle structure was long forgotten partly because of the technical issues but also because the conventional single-bundle ACL reconstruction eventually yielded quite satisfactory results (Bourke et al. 2012). Only in the last ten years has the focus shifted to more anatomical ACL reconstruction, which would result in more stable knees and hopefully less OA.

OA is a disabling condition, which usually has a negative effect on daily life. It has been widely acknowledged that ACL ruptures and OA have a certain connection. The impact on the cartilage during the original trauma has been proposed to be the origin of the OA seen after an ACL rupture. Another possible cause of OA is the posttraumatic residual knee laxity. Genetics may also partly explain why some knees are protected against OA and some are not. Finally, associated injuries, especially meniscal ruptures, affect the stability of the knee joint and may thereby cause recurrent knee subluxations thus damaging the cartilages (Lohmander et al. 2007).

It remains to be seen if the more anatomical ACL reconstruction methods can eventually prevent OA. There are 14 level I prospective, randomized controlled trials published to date on single-bundle versus double-bundle ACL reconstructions with rather short-term follow-ups. The DB technique resulted in better rotational stability in seven studies (Järvelä 2007; Muneta et al. 2007; Järvelä et al. 2008; Siebold et al. 2008; Ibrahim et al. 2009; Zaffagnini et al. 2011; Hussein et al. 2012), better anteroposterior stability in six studies (Muneta et al. 2007; Siebold et al. 2008; Zaffagnini et al. 2008; Ibrahim et al. 2009; Aglietti et al. 2010; Hussein et al. 2012), better knee scores in five studies (Siebold et al. 2008; Zaffagnini et al. 2008; Aglietti et al. 2010; Zaffagnini et al. 2011; Hussein et al. 2012), three trials reported fewer reoperations in the DB group (Suomalainen et al. 2011; Zaffagnini et al. 2011; Suomalainen et al. 2012) and one

study reported fewer notchplasties among the DB group (Adachi et al. 2004). None of the studies reported the SB technique to be superior, although two studies graded these two reconstruction methods equally good (Streich et al. 2008; Sastre et al. 2010). The development of OA takes several years and therefore the focus in this dissertation was on the short- and mid-term results, e.g. the durability of the grafts, knee stability measurements, and graft locations.

A misplaced graft or other technical errors have been reported to be the main reason for graft ruptures (Wright et al. 2010). In this dissertation the graft locations were measured from MRI in Studies I, II and IV and they were all in their anatomical place. In the revisions performed due to graft rupture there was likewise no need to change the location of the grafts.

The MRI revealed in Study I that some grafts were still invisible at two-year follow-up. Other studies have shown that the maturation process, during which the graft goes through ligamentization and vascularization, takes approximately two years (Hong et al. 2005; Sonoda et al. 2007; Muramatsu et al. 2008; Miller 2009; Poellinger et al. 2009; Gnannt et al. 2011; Ntoulia et al. 2011). During this phase the graft may appear quite heterogeneous. The graft invisibility in this study was not associated with anteroposterior or rotational instability of the knees and therefore we did not judge these to be graft ruptures. This finding can help orthopaedic surgeons in a situation where the operated knee is clinically stable but the graft cannot be seen in MRI.

The visibility of the grafts was also studied in Study IV. MRI was done at a two-year follow-up for 75 patients who had undergone double-bundle ACL reconstruction. The main finding in this study was that the graft visibility was diminished if either AM or PL grafts were located more anterior in the tibia. However, this phenomenon did not affect the stability results and was therefore not graded as graft rupture. One explanation for the invisibility of the grafts can be a minor postoperative impingement, which irritates the developing neoligament, although all patients have a good range of motion and no clinical symptoms of graft distress.

11 SUMMARY AND CONCLUSIONS

The main finding in the two-year follow-up study was that there were statistically more graft failures in the single-bundle group than in the double-bundle ACL reconstruction group. A surprising finding was also that there was no statistical difference between the groups regarding the stability measurements. In addition we found that graft invisibility in MRI did not affect the stability of the knees, a finding which can help orthopaedic surgeons in their clinical decision-making.

The goal in the second study was to ascertain whether the introduction of the double-bundle ACL reconstruction method has an impact on the single-bundle technique. The locations of the single-bundle grafts were measured from MRI at the beginning of our study and then again in 2007. There was a statistically significant difference between the groups only in the tibial insertions when measured from the lateral condyle, but not in the stability results. An additional finding was that there were more graft failures during the first two years of the study than in the latter period, which might indicate that there is a learning curve phenomenon in question.

An interesting finding in the five-year follow-up study was that the graft failure outcome found at two-year follow-up was still present at five years and again favoured the DB group. The majority of the graft failures occurred in the early years of the study. There were three patients in the single-bundle group who had a graft failure during the latter follow-up period in contrast to the double-bundle group, which had only one graft failure, which occurred during the first two years of follow-up. Stability measurements did not reveal any statistical differences between the groups, which was also the case concerning OA changes.

The fourth study was based on MRI and clinical findings among the DB group. The main finding was that graft visibility was influenced by the graft insertion in the tibia. Graft location anteriorly in the tibia was associated especially with graft invisibility in AM as well as PL grafts. However, this did not affect the clinical findings.

In conclusion, in light of our own studies and the recent literature, the double-bundle ACL reconstruction method seems to be better than the single-bundle technique. In many aspects the differences are not great, but there were fewer graft failures after double-bundle ACL reconstruction favouring the double-bundle method, but in earlier studies double-bundle reconstruction has been reported to result in more stable knees,

but this could not be proven in our follow-ups. None of the studies reviewed concluded that the double-bundle ACL reconstruction method was inferior to its single-bundle counterpart.

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14 ORIGINAL COMMUNICATIONS

Double-Bundle Versus Single-Bundle Anterior Cruciate Ligament Reconstruction

Randomized Clinical and Magnetic Resonance Imaging Study With 2-Year Follow-up

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Background: One aspect of the debate over the reconstruction of the anterior cruciate ligament is whether it should be carried out with the single-bundle or double-bundle technique.

Hypothesis: The double-bundle technique results in fewer graft failures than the single-bundle technique in anterior cruciate ligament reconstruction.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: A total of 153 patients were prospectively randomized into 2 groups of anterior cruciate ligament reconstruction with hamstring autografts using aperture interference screw fixation: single-bundle technique (SB group, $n = 78$) and double-bundle technique (DB group, $n = 75$). The evaluation methods were clinical examination, KT-1000 arthrometric measurement, the International Knee Documentation Committee (IKDC) and the Lysholm knee scores, and magnetic resonance imaging (MRI) evaluation. All of the operations were performed by 1 experienced orthopaedic surgeon, and all clinical assessments were made by 2 blinded and independent examiners. A musculoskeletal radiologist blinded to the clinical data made the MRI interpretation.

Results: There were no differences between the study groups preoperatively. Ninety percent of patients ($n = 138$) were available at a minimum 2-year follow-up (range, 24-37 months). Eight patients (7 in the SB group and 1 in the DB group) had graft failure during the follow-up and had anterior cruciate ligament revision surgery ($P = .04$). In addition, 7 patients (5 in the SB group and 2 in the DB group) had an invisible graft on the MRI assessment at the 2-year follow-up. Also, the anteromedial bundle was partially invisible in 2 patients and the posterolateral bundle in 9 patients. Together, the total number of failures and invisible grafts were significantly higher in the SB group (12 patients, 15%) than the DB group (3 patients, 4%) ($P = .024$). No significant group differences were found in the knee scores or stability evaluations at the follow-up.

Conclusion: This 2-year randomized trial showed that the revision rate of the anterior cruciate ligament reconstruction was significantly lower with the double-bundle technique than that with the single-bundle technique. However, additional years of follow-up are needed to reveal the long-term results.

Keywords: anterior cruciate ligament; double bundle; randomized controlled trial; hamstring graft; magnetic resonance imaging

The anatomy of the human anterior cruciate ligament (ACL) with its 2 bundles, the anteromedial (AM) bundle and posterolateral (PL) bundle, was described as early as 1938.²⁵

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Recently, many anatomic studies have evaluated femoral and tibial insertion sites of these bundles.^{5,6,9,33} Biomechanically, the AM bundle is tensioned in all flexion angles of the knee, while the PL bundle is functioning only in low knee-flexion angles.^{13,14,41} The PL bundle is also tightened during external and internal rotation of the tibia.

Currently, one aspect of the debate concerning the reconstruction of the ACL is whether it should be carried out using single-bundle or double-bundle technique.¹¹ Some studies have shown that the anatomic double-bundle technique restores knee kinematics and especially rotational stability of the knee more closely than the single-bundle technique, although anterior stability of the knee

can be restored well with the anatomic single-bundle technique too.[¶] In addition, some studies implicate similar knee stability after double-bundle and single-bundle surgery.[#]

The best radiologic method to assess the ACL graft is MRI.⁴ The normal ACL is seen as a hypointense structure on T1- and T2-weighted sequences. In the postoperative situation, the graft is seen as hypointense in all pulse sequences. This will, however, change as the graft goes through revascularization and synovialization between the fourth and eighth postoperative months.⁴ Evaluation of graft failure by MRI during the revascularization period can be difficult because the appearance of the reconstructed graft can be rather heterogeneous in different postoperative time periods.²³ However, after 2 years the graft usually looks like a normal ACL.³⁶

In the final MRI, increasing signals in T2-weighted sequences can be indicated as graft failure in combination with fiber discontinuity and graft thickness. Also, fiber discontinuity and graft thickness can point to graft failure.²² Sonoda et al³⁵ found in their MRI study that anterior laxity of the knee correlated with high-intensity signals on the AM bundle, and rotational laxity correlated with high-intensity signals on the PL bundle.

The purpose of this study was to compare the clinical results and MRI findings of patients with single-bundle or double-bundle ACL reconstruction. The study was a randomized clinical trial with a minimum 2-year follow-up.

MATERIALS AND METHODS

Patients

The patient recruitment (N = 153) and baseline data collection were done at our institute between March 2003 and February 2008. The inclusion criteria were as follows: (1) primary ACL reconstruction, (2) closed growth plates, and (3) absence of ligament injury to the opposite knee. Randomization was done by a closed envelope technique dividing the participants into 2 different groups of ACL reconstruction with hamstring autografts: single-bundle technique with aperture interference screw fixation (SB group) (n = 78) and double-bundle technique with aperture interference screw fixation (DB group) (n = 75). The preliminary results of the first 65 patients (SB, n = 30; DB, n = 35) were previously published in 2007.¹⁵ A sample size analysis was performed and the power was 0.8. The original size of the groups was approximated to be SB 100 and DB 100. The primary outcome was the rupture of the graft. The rate of ruptures of the ACL graft is 10% to 15% according to the literature.^{3,27} Preoperatively, both groups were equal in sports participation. The main events were soccer, downhill skiing, and floor ball.

Demographic data, operation time, and follow-up time of the patients are provided in Table 1. The study was approved by the local ethics committee, and each participant

TABLE 1
Demographic Data, Operation Time,
and Follow-up Time of the Patients^a

	SB (n = 78)	DB (n = 75)	Significance
Sex, male/female	54/24	56/19	NS
Age, y	32 (10)	32 (10)	NS
Height, cm	175 (9)	177 (9)	NS
Weight, kg	81 (16)	83 (16)	NS
Operation time, min	64 (17)	73 (16)	P = .003
Follow-up time, mo	28 (4)	26 (2)	NS

^aWith the exception of sex, all data are presented as the mean, with the standard deviation in parentheses. SB, single bundle; DB, double bundle; NS, not significant.

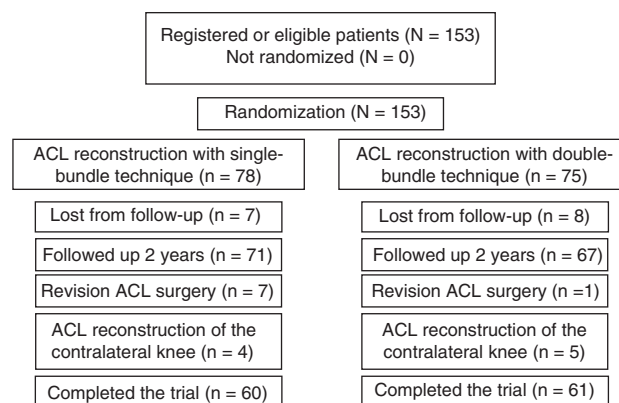


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

provided written informed consent. One experienced orthopaedic surgeon performed all ACL reconstructions.

The minimum 2-year follow-up (range, 24-37 months) was successfully passed by 138 patients (90%; 71 in the SB group, 67 in the DB group). Eight of these patients (7 in the SB group and 1 in the DB group) had graft failure during the follow-up and had ACL revision surgery. In addition, 9 patients (4 in the SB group and 5 in the DB group) had ACL reconstruction of the contralateral knee during the follow-up, and were excluded from the study. Therefore, the statistical analysis concerning the knee scores was made from data of 121 patients (60 in the SB group and 61 in the DB group) (Figure 1).

Clinical Evaluations

The evaluation methods preoperatively and at the 2-year follow-up were clinical examination and stability measurement with the KT-1000 arthrometer (MEDmetric, San Diego, California) with a force of 134 N. Also, the International Knee Documentation Committee (IKDC) and the Lysholm knee scores were used in evaluation of the knee. The IKDC functional score was used to evaluate the knee function in daily activities. All clinical assessments were made by 2 blinded and independent examiners.

[¶]References 2, 12, 13, 15, 16, 18-20, 24, 28, 30-32, 38, 39, 42-44.

[#]References 1, 7, 8, 10, 11, 17, 21, 26, 29, 34, 37, 40.

MRI Evaluation

The MRI evaluation was made with a 1.5-T Signa Excite HD imager (GE Healthcare, Milwaukee, Wisconsin) by using an 8-channel receiver/transmitter extremity coil. A sagittal and coronal scout view was used to place parallel the oblique coronal and sagittal images to the longitudinal axis of the AM ACL graft in the joint. Interpretation of the images was made with the Impax DS 3000 workstation (Agfa HealthCare, Mortsel, Belgium) by a musculoskeletal radiologist, who was unaware of the patients' clinical data.

Surgical Technique of the Double-Bundle ACL Reconstruction

A complete diagnostic arthroscopy was performed first for every patient to visualize the ACL tear and to delineate associated injuries (meniscal or chondral injury) in the injured knee. The ruptured ACL was examined with an arthroscopic probe, dissected, and debrided from the femoral side. The tibial footprint was left intact. A bony notchplasty was performed only if there were osteophytes in the intercondylar space.

The double-bundle technique used in this study has been described earlier in detail.¹⁵ In brief, 2 tunnels were used for both the tibial and femoral sides. The femoral tunnels were created through the AM portals (not trans-tibially) using a freehand technique without a guide to the anatomic insertion sites of the AM and PL bundles of the ACL on the femur. The tibial tunnels were created with a tibial guide (Acufex, Smith & Nephew Endoscopy, Andover, Massachusetts) to the anatomic insertion sites of the AM and PL bundles of the ACL on the tibia. Semitendinosus and gracilis tendons were harvested with a standard tendon stripper. The AM graft was made by doubled semitendinosus tendon, and the PL graft by doubled gracilis tendon. Both grafts were inserted via the tibial tunnels into the femoral tunnels. Both the femoral and tibial sides of the grafts were fixed by using aperture fixation with bioabsorbable interference screws (Figure 2). The arthroscopic result of the double-bundle ACL reconstruction after 2 years can be seen in Figure 3.

Surgical Technique of the Single-Bundle ACL Reconstruction

Standard AM and anterolateral arthroscopy portals were used to perform the ACL reconstruction. The femoral tunnel was drilled with a freehand technique through the AM portal as posterior as possible without breaking the posterior wall of the femur, at approximately 10 o'clock in the right knee and 2 o'clock in the left knee. The tibial tunnel was made with the aid of a tibial guide in the middle of the ACL remnant in the tibia. Semitendinosus and gracilis tendons were harvested. They were doubled and this 4-strand autograft was inserted to its place in the femur through the tibial tunnel. The graft was fixed by using aperture fixation with interference screws as in the double-bundle technique described above.

TABLE 2
Meniscal Status and Treatment at ACL Operation^a

	SB	DB	Significance
Status			
Isolated ACL rupture	37	32	NS
ACL and medial meniscus rupture	15	20	NS
ACL and lateral meniscus rupture	17	19	NS
ACL and both menisci rupture	9	4	NS
Treatment			
Fixation with endoscopic maneuver	10	7	NS
Partial resection	30	31	NS

^aACL, anterior cruciate ligament; SB, single bundle; DB, double bundle; NS, not significant.

The grafts used were all thicker than 5 mm. The PL grafts were 5 to 6 mm in diameter (mean, 5.9 mm) and the AM grafts were 6 to 7 mm (mean, 6.6 mm). There was no statistically significant difference between patients concerning the graft thickness. The meniscal status was also the same between the groups in the ACL surgery and at the 2-year follow-up (Table 2).

Rehabilitation

Both groups had the same postoperative rehabilitation program. Immediate full weightbearing and full range of motion were permitted. Patients used crutches for 3 to 4 weeks, but no rehabilitation brace was used. Closed kinetic chain exercises were started immediately postoperatively. Cycling was allowed with an ergometer bicycle at 4 weeks, and running at 3 months. Pivoting sports were permitted at 6 months postoperatively if the patient had full functional stability.

Statistics

The SPSS 11.0 software package (SPSS Inc, an IBM Company, Chicago, Illinois) was used to perform the statistical analysis. The calculations between the differences of means were done by an analysis of variance and the paired-sampled *t* test, and those of frequencies by the χ^2 test. The significance level was set at $P < .05$.

RESULTS

The anterior stability of the knee was measured with the KT-1000 arthrometer at a force of 134 N. There was no statistically significant difference between the SB group and the DB group either preoperatively or at the 2-year follow-up (Table 3). The KT-1000 arthrometer measurements were also graded according to the IKDC form. The results between the 2 groups were similar and there was no statistically significant difference (Table 4). The pivot-shift test was used to evaluate the rotational stability of the knees. Also in this method, the results were not significantly

TABLE 3
KT-1000 Arthrometer Measurements at a Force of 134 N Preoperatively and at 2-year Follow-up^a

KT-1000 Arthrometer Difference	SB	DB	Significance
Preoperatively	n = 78	n = 75	
Mean KT-1000 arthrometer difference, mm (SD)	4.2 (2.7)	4.3 (2.0)	NS
At 2-year follow-up	n = 60	n = 61	
Mean KT-1000 arthrometer difference, mm (SD)	2.0 (2.4)	2.0 (3.0)	NS

^aDifference between the injured knee and the contralateral knee. SB, single bundle; DB, double bundle; SD, standard deviation; NS, not significant.

TABLE 4
Evaluation of the Knee by KT-1000 Arthrometer Measurements According to the IKDC Form Preoperatively and at 2-year Follow-up^a

KT-1000 Arthrometer Measurements	SB	DB	Significance
Preoperatively	n = 78	n = 75	
Normal	5	0	NS
Nearly normal	19	25	NS
Abnormal	52	50	NS
Severely abnormal	2	0	NS
At 2-year follow-up	n = 60	n = 61	
Normal	37	40	NS
Nearly normal	16	12	NS
Abnormal	7	9	NS
Severely abnormal	0	0	NS

^aIKDC, International Knee Documentation Committee; SB, single bundle; DB, double bundle; NS, not significant.

different between the SB group and the DB group (Table 5). However, in both groups, the anterior stability ($P < .001$) and the rotational stability ($P < .001$) significantly improved at the 2-year follow-up compared with the preoperative status.

Range of motion stayed the same in both groups at the 2-year follow-up. Fifty patients in the SB group and 52 in the DB group had normal range of motion in their knees. Both groups had 7 patients who had nearly normal range of motion. In the SB group, there were 3 patients who had abnormal range of motion and in the DB group there were 2 severely abnormal knees at the 2-year follow-up. One of these patients in the DB group had injured his knee just before the follow-up examination and there was effusion in his knee causing the limited range of motion of the knee, although this particular patient was otherwise satisfied with his knee. The other patient in the DB group had degenerative changes and limited range of motion of his knee preoperatively because of a chronically unstable knee, and the range of motion of his knee did not improve but remained similar after the ACL reconstruction.

There was no statistical difference between the groups concerning the meniscal status at the ACL reconstruction (Table 2). The fixation of the meniscal rupture was made with an arthroscopic method using bioabsorbable screws or arrows. Partial resection of the torn meniscus was

TABLE 5
Pivot-Shift Test of the Injured Knee Preoperatively and at 2-year Follow-up^a

Pivot-Shift Test	SB	DB	Significance
Preoperatively	n = 78	n = 75	
Normal	0	0	NS
Nearly normal	28	18	NS
Abnormal	47	57	NS
Severely abnormal	3	0	NS
At 2-year follow-up	n = 60	n = 61	
Normal	38	41	NS
Nearly normal	18	17	NS
Abnormal	4	3	NS
Severely abnormal	0	0	NS

^aSB, single bundle; DB, double bundle; NS, not significant.

TABLE 6
Evaluation of the Injured Knee by the IKDC Final Score Preoperatively and at 2-year Follow-up^a

IKDC Final Score	SB	DB	Significance
Preoperatively	n = 78	n = 75	
Normal	0	0	NS
Nearly normal	3	0	NS
Abnormal	65	72	NS
Severely abnormal	10	3	NS
At 2-year follow-up	n = 60	n = 61	
Normal	24	25	NS
Nearly normal	26	23	NS
Abnormal	10	11	NS
Severely abnormal	0	2	NS

^aIKDC, International Knee Documentation Committee; SB, single bundle; DB, double bundle; NS, not significant.

performed in 30 patients in the SB group and 31 patients in the DB group. No new ruptures were seen on MRI scans at the 2-year follow-up, but 5 partial meniscectomies were made during the 2-year follow-up period (SB, 3 patients; DB, 2 patients) (difference not significant).

The Lysholm scores at 2 years showed that there had been improvement in both groups in patients' daily living. Preoperatively, the Lysholm score was 67 in the SB group and 69 in the DB group (difference not significant). The

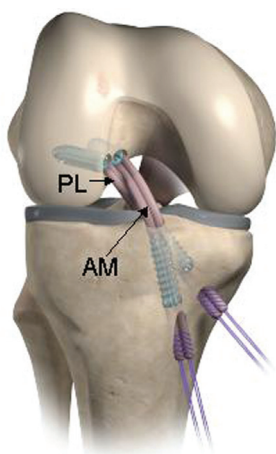


Figure 2. Schematic view of the double-bundle technique used in the study. AM, anteromedial bundle; PL, posterolateral bundle.

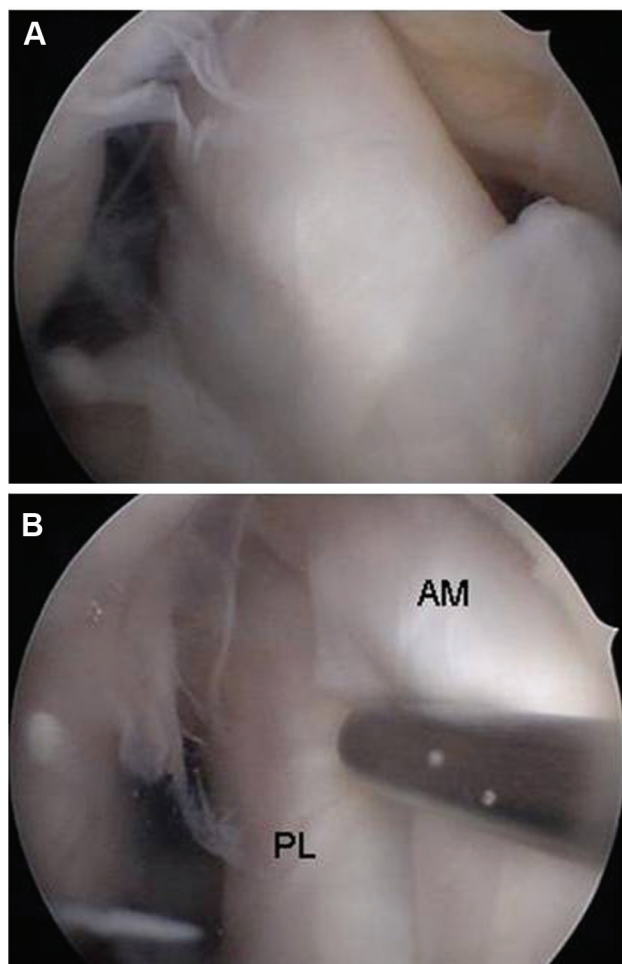


Figure 3. A, arthroscopic view of the right knee 2 years after double-bundle anterior cruciate ligament reconstruction. B, each bundle (anteromedial [AM] and posterolateral [PL]) can be seen separately after pulling the AM bundle with an arthroscopic probe.

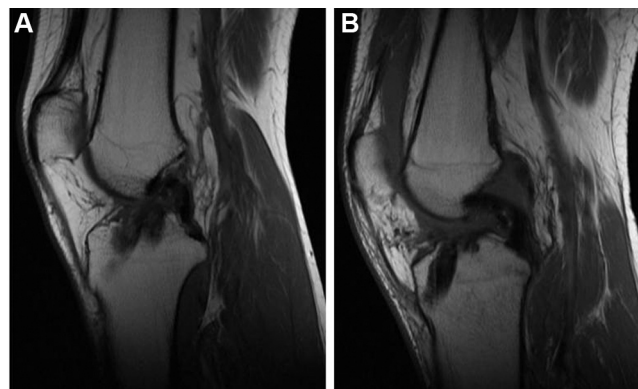


Figure 4. A, sagittal T1-weighted magnetic resonance image 2 years after double-bundle anterior cruciate ligament reconstruction. Both bundles (anteromedial [AM] and posterolateral [PL]) are partially invisible; only some fibers are visible. B, sagittal T1-weighted magnetic resonance image 2 years after double-bundle anterior cruciate ligament reconstruction. Both bundles (AM and PL) are totally invisible.

score was 88 in both groups at the 2-year follow-up. The IKDC score was abnormal (SB 83%, DB 96%) or severely abnormal (SB 13%, DB 4%) in 98% of the patients preoperatively. At the 2-year follow-up, there were 41% normal and 40% nearly normal knees according to this IKDC final score (Table 6). The improvement was also seen in the IKDC function score, where patients evaluated their knees before the injury as 9, preoperatively as 4 (scale, 0-10), and at the 2-year follow-up as 8. Only 6 patients could not return to sports after ACL reconstruction.

Altogether, no statistically significant differences were found in any of the knee scores between the 2 groups. However, according to these scores, both groups did significantly better at the 2-year follow-up than preoperatively ($P < .001$).

Significantly more graft failures leading to ACL revision surgery were observed in the SB group (7 patients, 9%) compared with the DB group (1 patient, 1%) ($P = .04$). All graft failures that occurred in the SB group were caused by a minor trauma. In the DB group, the 1 graft failure was caused by a major accident. These patients were excluded from the MRI analysis.

The MRI evaluation at the 2-year follow-up revealed that in the SB group, 46 patients had intact ACLs; 7 patients, a partially visible ACL; and 5 patients, an invisible ACL. In the DB group, 60 patients had an intact AM bundle; 2 patients, a partially visible AM bundle; and 2 patients, an invisible AM bundle (Figure 4). Respectively, 52 patients had an intact PL bundle, 9 patients a partially visible PL bundle, and 3 patients an invisible PL bundle. Together in the DB group, 52 patients had both grafts intact (Figure 5) and in 2 patients, both grafts were invisible. However, the MRI findings did not correlate to the clinical stability evaluation of the knees. For example, an invisible AM bundle did not correlate either to anterior or rotational instability of the knee, and an invisible PL

bundle did not correlate either to rotational or anterior instability of the knee, respectively.

The total number of failures of the ACL reconstruction (seen on revision ACL surgery) was 7 in the SB group (9%) versus 1 in the DB group (1%). This difference was statistically significant ($P = .04$). Also, 5 patients in the SB group had grafts that were totally invisible compared with 2 in the DB group. However, this difference was not statistically significant ($P = .175$).

DISCUSSION

This 2-year study revealed that, in contrast to many previous studies, the knee stability in the SB group and the DB group was the same. Both groups had similar results on the pivot-shift test, which measures rotational stability, and in KT-1000 arthrometer measurements, which revealed anterior stability of the knee. In previous studies, the double-bundle method has been shown to be better in restoring the rotational stability.^{**} However, most of these studies have shown that the anterior stability can also be restored well with the single-bundle method.

The major finding of this study was that the SB group had significantly more graft failures than the DB group. In addition, all failures in the SB group were caused by a minor trauma, whereas the 1 failure in the DB group was caused by a major accident in conjunction with bone fractures of the patient. The tunnel placements of the failed ACL grafts were thought to be appropriately placed by the surgeon without the need to change at revision. Both groups had basically 4-strand autograft made of doubled semitendinosus and doubled gracilis tendons, so the amount of the graft fibers should be the same. Also, the fixation was performed with the same kind of screws in both groups. In addition, the insertion area of the grafts was larger in the DB group than that in the SB group because of the 2 tunnels instead of 1 tunnel in both the tibial and femoral sides of the knee. Perhaps, because of the above-mentioned differences between the single- and double-bundle techniques, the patients who had double-bundle graft in their knees were able to resist rotational forces better than their single-bundle equivalents, as seen with a lower failure rate in the DB group. The MRI findings revealed that the SB group had more invisible grafts than the DB group, although the MRI findings did not correlate with the clinical stability evaluation of the knees. One explanation for this can be that the grafts are still in the maturation stage and therefore do not show as a normal graft. We will continue our study to see if these patients will have instability symptoms of the knee in the future.

Sonoda et al³⁵ found in their study that there is a correlation between MRI findings and knee stability. They demonstrated that the AM graft is basically responsible for anterior-posterior translation and the PL graft for rotational stability. In contrast to our study, they reported no graft failures. We had the MRI done at the 2-year follow-up, which is when the graft should already



Figure 5. MRI evaluation 2 years after double-bundle anterior cruciate ligament reconstruction. Both bundles (anteromedial [AM] and posterolateral [PL]) are visible and intact.

look like a normal ACL.³⁶ In our material, there was no correlation between knee stability and MRI findings. One reason that can explain this is that Sonoda et al³⁵ had the MRI done at 1-year follow-up, when the graft can still be in the maturation stage. Meyers et al²² concluded that the radiologist who interprets the MRI should be familiar with the ACL graft appearance at different time frames. The radiologist who evaluated our MRI scans was a specialist in musculoskeletal radiology, particularly in MRI findings after ACL surgery.

Recently, Aglietti et al² found in their prospective and randomized 2-year follow-up study that the patients had better results in the DB group on the visual analog pain scale score, final objective IKDC score, and anterior knee stability compared with the SB group using the outside-in technique. Siebold et al³² and Muneta et al²⁴ had similar results. They both used hamstring autografts and Endo-Button (Smith & Nephew Endoscopy) fixation on the femoral side. However, Streich et al³⁷ performed a prospective randomized study comparing the single- and double-bundle techniques in ACL reconstruction with male athletes, and found that there was no difference between the groups according to knee laxity. In addition, Sastré et al²⁹ concluded in their study that when the tunnels in the single-bundle method were made in the 2- and 10-o'clock positions, the stability between the SB and DB groups was the same. Kanaya et al¹⁷ revealed similar results in their

^{**}References 2, 12, 13, 15, 16, 18-20, 24, 28, 30-32, 38, 39, 42-44.

randomized study comparing single- and double-bundle techniques, where they tested knees intraoperatively in 30° and 60° of flexion and in extension. They concluded that lower femoral tunnel placement of the single-bundle technique results in similar stability to the double-bundle technique. Also, in our study, the femoral tunnels were made at 2 or 10 o'clock in the SB group, and the clinical results (stability and knee scores) were comparable with the DB group. Järvelä¹⁵ found previously that there was significantly more rotational instability in the SB group than in the DB group. Our study did not support this statement. Our material is partially the same but the follow-up time is longer and the population is larger. Our major finding was that there were more graft failures in the SB group than in the DB group. It seems that the rotational instability that Järvelä found in the 1-year follow-up can result in time as a graft failure seen in our study at the 2-year follow-up.

The limitation of our study is that 7 patients from the SB group and 8 patients from the DB group were not available for the 2-year follow-up, and we could not reach them by phone either so we do not know whether their ACLs are intact. On the other hand, these 15 patients lost from the follow-up represented only 10% of the total population of the study, so the follow-up rate of our study was quite high and acceptable. A 100% follow-up rate for a 2-year clinical study is very difficult to reach. The strength of our study is that it is a prospective and randomized study. Also, the follow-up evaluation was done in a blinded fashion, so that the initial surgical group assignment was not known by the outcome assessors. Also, the radiologist did not know the clinical results of the patients when evaluating the MRI.

In conclusion, in this randomized trial, we determined that the SB group and the DB group did not have statistically significant differences regarding anterior or rotational laxity of the knee. The knee scores were similarly good in both groups. However, a major finding in this study was that in the DB group there were fewer revisions attributable to ACL graft failure. This was a statistically significant finding. We will continue the study follow-up to elucidate the long-term results of these 2 methods in treating an ACL rupture.

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Comparison of tunnel placements and clinical results of single-bundle anterior cruciate ligament reconstruction before and after starting the use of double-bundle technique

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Abstract

Purpose To investigate whether the locations of the grafts in single-bundle (SB) anterior cruciate ligament (ACL) reconstruction have changed to more anatomical as the double-bundle (DB) method has become more familiar. **Methods** Operation using anteromedial (not transtibial) portal and freehand technique [Group A ($N = 25$) in 2003, Group B ($N = 25$) in 2007]. The evaluation methods pre-operatively and at the 2-year follow-up (two blinded examiners): clinical examination, stability measurement (KT-1000 arthrometer), the International Knee Documentation Committee (IKDC), and the Lysholm knee scores. A musculoskeletal radiologist made tunnel measurements from the magnetic resonance imaging (MRI).

Results The average tunnel placement in the femoral side: from Blumensaat's line 27 % (Group A) and 26 % (Group B), from the posterior edge of the femur 32 % (Group A) and 29 % (Group B). The average tunnel placement in the tibial side: from the anterior edge 45 % (Group A) and 45 % (Group B), from the lateral side 57 % (Group A) and 54 % (Group B) ($P = 0.024$). Graft failures ending up to revision ACL surgery: 4 (Group A) and 0 (Group B) ($P = 0.045$). Operation time reduced 19 min ($P = 0.001$).

Conclusion Tunnel placement at the femoral side was already very low (anatomical) in patients operated in 2003.

No significant difference was found when comparing to the patients operated in 2007. There were significantly more graft failures in the Group A, suggesting that the use of the DB method in ACL surgery in 2007 may have also improved the technique and results of the SB ACL reconstruction.

Level of evidence Prospective comparative study, Level II.

Keywords Anterior cruciate ligament reconstruction · Graft location · Magnetic resonance imaging · Double-bundle method · Anatomical single-bundle method

Introduction

About 100,000 anterior cruciate ligament (ACL) reconstructions are made in the United States annually [13]. Because the prevalence is so high, there has been enormous development to invent treatment options for the injury over the past years. Various different techniques to reconstruct the torn ACL are available today [8, 17, 25]. The development is partly due to the fact that none of the past reconstruction methods have shown to be superior to another.

The anatomy is the basic to everything in surgery. Cadaver studies have revealed that human ACL has not been built from one but at least two bundles [4, 9–11, 20, 27, 28, 30]. Hara and his colleagues found out in their cadaver study that ACL consists of many small bundles, which together make the anteromedial and posterolateral bundles of the ACL [14]. This has led to understanding that reconstruction of the torn ligament should aim to restore the ACL as anatomically as possible.

The double-bundle ACL reconstruction mimics the original anatomy of the torn ACL better than the traditional

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single-bundle technique [16]. However, recently, the anatomical single-bundle ACL reconstruction with low femoral tunnel position has been introduced as one option to have more anatomical reconstruction [26, 31]. This method has given rise to the surgical technique where an accessory anteromedial portal is used to drill the femoral canals instead of transtibial drilling [2, 3, 6, 22, 23, 33]. There is also a study about single tunnel but double-bundle anterior cruciate ligament reconstruction [12]. Although this was a cadaveric study and the sample size was low, the authors conclude that the double-bundle method did better than the conventional single-bundle group.

Yamazaki et al. have released a radiographic o'clock description method for determining the location of the ACL grafts [34]. They measured the tunnels from a plane radiograph and concluded that it is a simple and practical method. Still the best way to evaluate injuries and the ligaments of the knee is magnetic resonance imaging (MRI) [19]. The location of the graft can be determined from the MRI also in the postoperative stage [1, 7].

The purpose and also hypothesis of this study was to examine whether the location of the grafts in the single-bundle technique has changed to a more anatomical position as the surgical procedure of double-bundle ACL reconstruction has become more familiar. The other aim was to reveal whether the development of the surgical technique has any impact on clinical outcome.

Materials and methods

The patient recruitment ($N = 50$) and baseline data collection were done at our Institute in years 2003 (Group A) and 2007 (Group B). The patients in the Group A were operated before we started to use double-bundle technique regularly in the ACL reconstructions. The patients in the Group B were operated in parallel with routinely performed double-bundle reconstructions. The inclusion criteria were as follows: (1) primary ACL reconstruction, (2) closed growth plates, and (3) absence of ligament injury to the opposite knee. Preoperatively, both groups were equal to sports. The main events were soccer, downhill skiing, and floor ball.

Demographic data, operation time, and follow-up time of the patients are given in the Table 1. The study was approved by the local ethics committee, and a written informed consent form was given by every participant. One experienced orthopaedic surgeon performed all ACL reconstructions.

The minimum of 2-year follow-up was successfully passed by 46 patients (92 %; 22 in the Group A, 24 in the Group B). However, four patients in the Group A had graft

Table 1 Demographic data, operation time, and follow-up time of the patients

	Group A ($N = 25$)	Group B ($N = 25$)	Significance
Sex (male/female)	18/7	16/9	NS
Age (years)*	30 (8)	32 (11)	NS
Height (cm)*	174 (10)	175 (10)	NS
Weight (kg)*	79 (14)	85 (17)	NS
Operation time (min)*	69 (11)	50 (12)	$P < 0.001$
Follow-up time (months)*	28 (3)	25 (2)	NS

Group A = patients operated in the year 2003, Group B = patients operated in the year 2007

* Mean (SD)

failure during the follow-up and went to ACL revision surgery.

Clinical evaluations

The evaluation methods preoperatively and at the 2-year follow-up were clinical examination and stability measurement with the KT-1000 arthrometer (MEDmetric, San Diego, CA) with a force of 134N. Also, the International Knee Documentation Committee (IKDC) and the Lysholm knee scores were used in evaluation of the knee. The IKDC functional score was used to evaluate the knee function in daily activities. All clinical assessments were made by two blinded examiners in consensus.

MRI evaluation

MRI evaluation was made with a 1.5-T Signa Excite HD imager (GE Medical Systems, Milwaukee, WI, USA) by use of an 8-channel receiver/transmitter extremity coil. Graft locations were measured using coronal T1-weighted and sagittal proton density-weighted fast spin echo images. Slice thickness was 4 mm and gap between slices 1 mm. Interpretation of the images was made with the Impax DS 3000 workstation (Agfa HealthCare, Mortsel, Belgium) by a musculoskeletal radiologist, who was unaware of the patients' clinical data. The measurements of the graft location were made by the method of Lorenz et al. [21].

Graft location measurement

On the tibial side, the graft locations are presented in terms of percentage in true lateral and in anterior-posterior view. The maximum diameter of the tibial condyles was measured first from the coronal view. Then, the centre of the graft was measured from the lateral side (Fig. 1a, b). The same procedure was done also from the sagittal

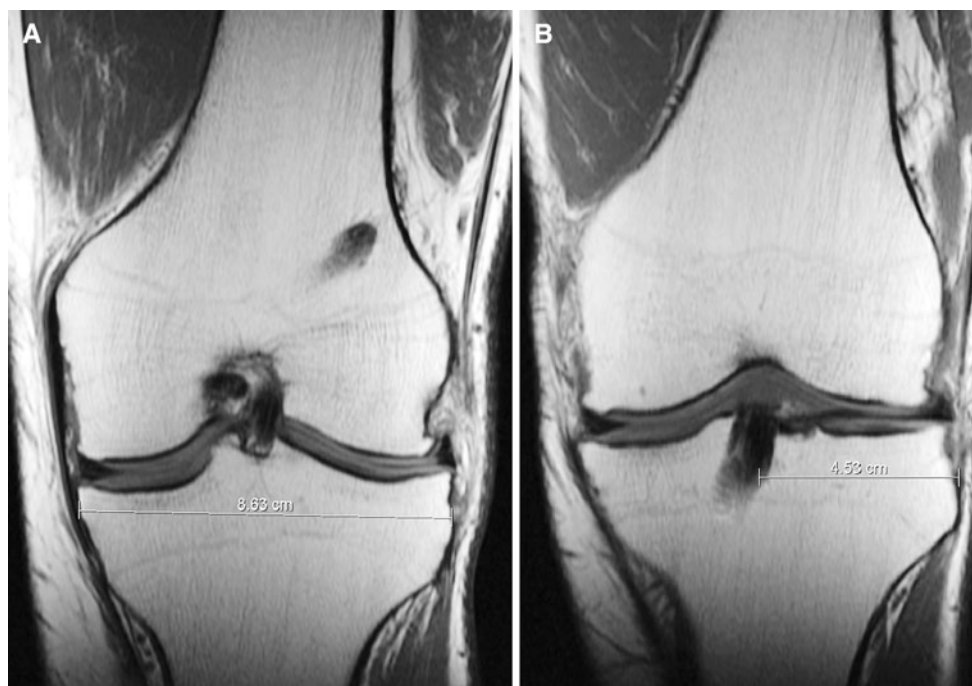


Fig. 1 **a** The maximum diameter of the tibial condyles was measured from the *coronal* view in millimetres. **b** The *centre* of the graft was measured from the *lateral side* in millimetres



Fig. 2 **a** The maximum diameter of the tibia was measured from the *sagittal* images in millimetres. **b** The *centre* of the graft was determined from *anterior* wall of the tibia in millimetres

images, where the graft location was determined from anterior wall of the tibia (Fig. 2a, b). The percentages were calculated dividing the centre of the graft with the maximum diameter of the tibial condyle both in lateral and in anterior-posterior view. The measurements were all

in millimetres, and no decimals were used. The femoral insertion sites are presented in terms of percentage of the x–y orientation in the true lateral radiography. On the femoral side, the maximum diameter of the femoral condyle was visualized from the sagittal images in x–y

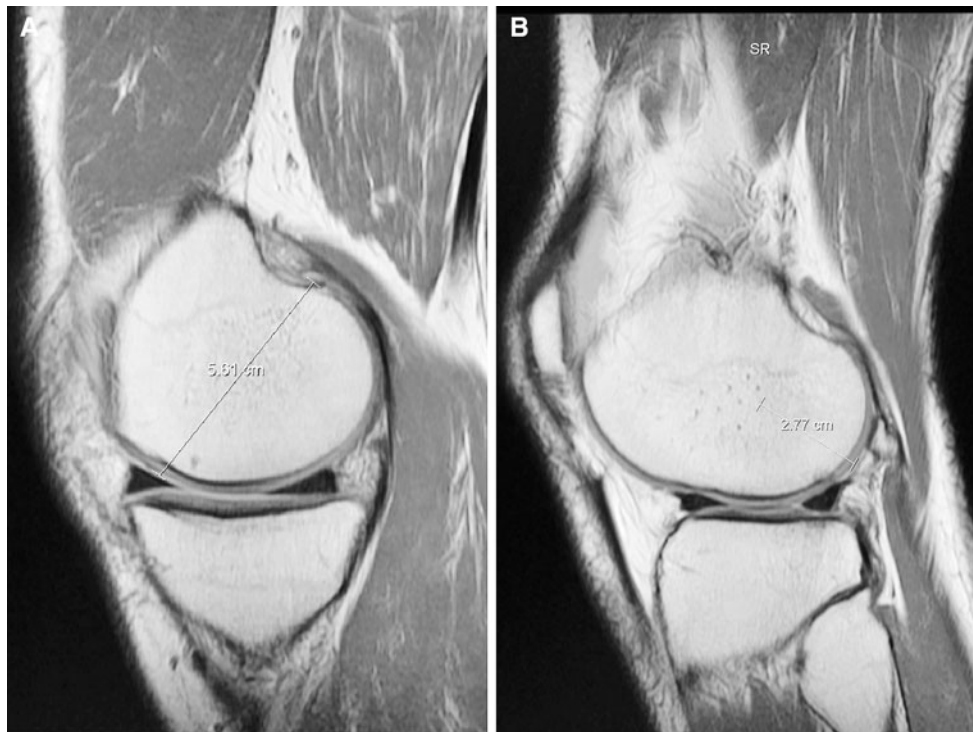


Fig. 3 The maximum diameter of the femoral condyle was measured from the sagittal images in x-y orientation to the Blumensaat's line in millimetres



Fig. 4 The graft location in the femur was measured from its own plane in millimetres

orientation to the Blumensaat's line (Fig. 3a, b) and then the graft location from its own plane (Fig. 4a, b). The percentages were calculated from these measurements dividing the centre of the graft with the maximum diameter of the femoral condyle.

Surgical technique

Standard anteromedial and anterolateral arthroscopy portals were used to perform the ACL reconstruction. The femoral tunnel was drilled with a freehand technique

through anteromedial (not transtibially) portal as posterior as possible without breaking the posterior wall of the femur, at approximately 10 o'clock in the right knee and 2 o'clock in the left knee. The tibial tunnel was made with the aid of a tibial guide in the middle of the ACL remnant in the tibia. Semitendinosus and gracilis tendons were harvested. They were doubled and this 4-stranded autograft was inserted in its place in femur through the tibial tunnel. The graft was fixed by using aperture fixation with interference screws.

Statistical analysis

SPSS 11.0 software package (SPSS Inc, Chicago, Ill, USA) was used to perform the statistical analysis. The calculations between the differences of means were done by an analysis of variance (ANOVA), paired sampled *t* test, and those of frequencies by the chi-square test. The significance level was set at $P < 0.05$.

Results

The tunnel placements of the ACL grafts were determined by MRI. In the Group A, the femoral tunnel placement was an average 27 % from the Blumensaat's line compared to the maximum diameter of the femoral condyle and 32 % from the posterior edge of the femur. The average tibial tunnel placement was 57 % from the lateral side of the knee and 45 % from the anterior edge of the tibia. In the Group B, the corresponding figures in the femoral side were 26, and 29 %, and in the tibial side 54, and 45 %. The tunnel placement was significantly more lateral in the tibial side in the Group A than in the Group B ($P = 0.024$). In the other measurements of tunnel placements, no significant differences were found between the groups. (Table 2).

Both groups had similar results in Lysholm scores preoperatively and postoperatively. Functional score and pivot

shift tests were also comparable between the groups. There was significant finding in the preoperatively IKDC Final score in which the Group B had 7 severely insufficient knees but the Group A had none. At two-year follow-up, there were no severely abnormal knees in either group. Another statistically significant finding was that there were four graft failures in the Group A and none in the Group B ($P = 0.045$) (Table 3). The average operation time has reduced from 2003 to 2007 19 min (from 69 to 50 min), which was also a statistically significant finding ($P = 0.001$) (Table 1).

Discussion

The most important finding of our study was that regardless the fact that the graft locations did not change remarkably, the earlier operated group had more graft failures. Also, the operation time reduced significantly.

There are few articles about the anatomy of the graft location in the literature [4, 11, 20, 27, 28, 30]. Although there has been discussion about the effect of the double-bundle ACL reconstruction to the single-bundle method, there are no studies focusing on this subject.

This study revealed that the locations of the grafts were similar in both single-bundle groups, but there were more graft failures in the Group A that were operated in the year 2003. Reasons for this can be multifactorial. The SB surgical method as such may have become more familiar by time. Also, introduction of the anatomical double-bundle method probably led to better understanding of the anatomy of the insertion sites and thus more anatomical ACL reconstructions in the SB technique, too. In addition, despite the fact that the basic postoperative rehabilitation protocol was the same in 2003 and 2007, it cannot be totally ruled out that rehabilitation became more precise and focused by time.

This study also showed that the tunnel locations were anatomical (low position on the femoral side) already in the year 2003. The main reason for this is that the femoral drilling was made from an accessory anteromedial portal (not transtibially) also in the beginning of the study. It has become clear that with the transtibial technique, the femoral drilling to anatomical site is more difficult, maybe even impossible [3, 20, 22]. Kawakami et al. pointed out that use of a computer tomography navigator results in anatomical ACL graft locations [18]. Instead of using any devise to determine the graft locations, we relied on patients' own anatomical landmarks.

Hohmann et al. investigated in their study the learning curve of ACL reconstruction [15]. In contrast to our study, they measured retrospectively the graft locations from plain radiographs. They found out that the so-called

Table 2 Tunnel placements of the ACL reconstructions measured by MRI

	Group A (<i>N</i> = 18)	Group B (<i>N</i> = 24)	Significance
Tibia			
From lateral (%)	57 (3)	54 (3)	$P = 0.024$
From anterior (%)	45 (5)	45 (4)	NS
Femur			
From Blumensaat's line (%)	27 (9)	26 (6)	NS
From posterior (%)	32 (5)	29 (6)	NS

Group A = patients operated in the year 2003, Group B = patients operated in the year 2007

The numbers are mean (SD)

Table 3 Clinical findings preoperatively and at the 2-year follow-up

	Group A (<i>N</i> = 25)	Group B (<i>N</i> = 25)	Significance
Preoperatively			
KT-1000 difference (mm)	4.6 (2.7)	4.6 (2.4)	NS
Pivot shift			
Normal	0	0	
Nearly normal	7	6	
Abnormal	18	17	
Severely abnormal	0	2	NS
Function score	4 (2)	4 (2)	NS
Lysholm score	68 (18)	62 (19)	NS
IKDC final score			
Normal	0	0	
Nearly normal	0	0	
Abnormal	24	18	
Severely abnormal	1	7	<i>P</i> = 0.049
	(<i>N</i> = 18)	(<i>N</i> = 24)	
At the 2-year follow-up			
KT-1000 difference (mm)	2.1 (2.4)	2.0 (2.7)	NS
Pivot shift			
Normal	11	16	
Nearly normal	7	5	
Abnormal	0	3	
Severely abnormal	0	0	NS
Function score	8 (1)	8 (2)	NS
Lysholm score	89 (17)	84 (14)	NS
IKDC final score			
Normal	7	9	
Nearly normal	9	8	
Abnormal	2	7	
Severely abnormal	0	0	NS
Back to sports			
Same level	13	12	
Lower level	5	9	
Could not go back to sports	0	3	NS
Revision ACL surgery because of graft failure	4	0	<i>P</i> = 0.045

Group A = patients operated in the year 2003, Group B = patients operated in the year 2007
The numbers are mean (SD)

learning curve is about 100 procedures. Snow et al. also studied the learning curve of the ACL reconstruction especially in double-bundle ACL surgery. They measured the graft locations from computer tomography and concluded that for an experienced arthroscopic surgeon, it is possible to swift from a single-bundle ACL reconstruction to double-bundle procedure, although there is a learning curve of several patients [29]. We could not find this kind of improvement in our material, maybe because our orthopaedic surgeon was already in the beginning of our study an expert in arthroscopic ACL surgery. We also measured the locations of the grafts by MRI. MRI is more precise technique than radiographs in visualization of the

insertion sites of the ACL grafts—especially when using bioabsorbable screws for the fixation of the grafts as we did in this study.

The average operation time reduced 19 min (from 69 to 50 min) from the year 2003 to the year 2007. This is, of course, beneficial to the patient, but the reduced operation time has also remarkable financial relevance [24]. Bonsell found out that it is also worthwhile to pay attention to the costs of the ACL reconstruction [5]. The faster the operation time, the more cost efficient is the ACL surgery.

The limitations of our study are the relatively limited group sizes and a non-randomized study design. However, the strength of the study is that it is prospective by nature.

Also, all the operations were made by one orthopaedic surgeon, and the follow-up assessments were done by blinded examiners.

The clinical relevance of this study is easier to comprehend when it is combined with an earlier publication in which we concluded that the double-bundle group had less graft failures than the single-bundle group [32]. Now this study has proofed that the graft locations were anatomical also in the single-bundle group and therefore the graft ruptures are not due to poor position but simply the superiority of the double-bundle method.

Conclusion

Tunnel placement at the femoral side was already very low (anatomical) among patients operated in 2003, and no significant difference was found in femoral tunnel position when comparing to the patients operated in 2007. However, there were significantly more graft failures in the former group, suggesting that the use of the DB method in ACL surgery in 2007 may have also improved the technique and results of the SB ACL reconstruction.

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Double-Bundle Versus Single-Bundle Anterior Cruciate Ligament Reconstruction

A Prospective Randomized Study With 5-Year Results

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Background: Surgical technique is essential in anterior cruciate ligament (ACL) reconstruction.

Purpose: This randomized 5-year study tested the hypothesis that double-bundle ACL reconstruction with hamstring autografts and aperture screw fixation has fewer graft ruptures and rates of osteoarthritis (OA) and better stability than single-bundle reconstruction.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: Ninety patients were randomized: double-bundle ACL reconstruction with bioabsorbable screw fixation (DB group; n = 30), single-bundle ACL reconstruction with bioabsorbable screw fixation (SBB group; n = 30), and single-bundle ACL reconstruction with metallic screw fixation (SBM group; n = 30). The following evaluation methods were used: clinical examination, KT-1000 arthrometer measurement, and International Knee Documentation Committee (IKDC) and Lysholm knee scores. Additionally, radiographic evaluation was made by a musculoskeletal radiologist who was unaware of the patients' clinical and surgical data. A single orthopaedic surgeon performed all the operations, and clinical follow-up assessments were made in a blinded manner by an independent examiner.

Results: Preoperatively, there were no differences between the groups. Eleven patients (7 in the SBB group, 3 in the SBM group, and 1 in the DB group) had a graft failure during the follow-up and went on to ACL revision surgery ($P < .043$). Of the remaining 79 patients, a 5-year follow-up was performed for 65 patients (20 in the DB group, 21 in the SBB group, and 24 in the SBM group) who had their grafts intact. At 5 years, there was no statistically significant difference in the pivot-shift or KT-1000 arthrometer tests. In the DB group, 20% of the patients had OA in the medial femorotibial compartment and 10% in the lateral compartment, while the corresponding figures were 33% and 18% in the single-bundle groups, again an insignificant finding. Further, no significant group differences were found in the knee scores.

Conclusion: The double-bundle surgery resulted in significantly fewer graft failures and subsequent revision ACL surgery than the single-bundle surgeries during the 5-year follow-up. Knee stability and OA rates were similar at 5 years. In view of the size of the groups, some caution should be exercised when interpreting the lack of difference in the secondary outcomes.

Keywords: anterior cruciate ligament reconstruction; double-bundle versus single-bundle ACL reconstruction; osteoarthritis of the knee; radiograph

There are several ongoing studies on anterior cruciate ligament (ACL) reconstruction. Many of them focus on comparing surgical techniques, especially single-bundle

versus double-bundle procedures.^{||} These trials have shown that in the short term, there are differences in knee stability, particularly in the rotational plane.[¶] On the other hand, some of the studies have not found differences between the 2 techniques.[#]

Despite the above-noted studies, the debate is still going on whether ACL ruptures should be operated on by a single-bundle or double-bundle method. One reason for this controversy is the fact that the follow-ups have been

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^{||}References 1-12, 15-18, 22, 23, 26, 27, 29-31, 36, 37, 39, 40, 43-46, 48-58.

[¶]References 2, 3, 5-7, 10, 11, 15-18, 22, 23, 26, 30, 31, 37, 39, 43, 44, 50, 53, 55-58.

[#]References 4, 8, 9, 12, 27, 29, 36, 40, 45, 46, 48, 51, 52.

rather short, with 1 to 3 years only.** This is quite a short time, given the nature of ACL ruptures and their propensity to cause osteoarthritis (OA) changes in the knee joint.

Earlier studies on ACL ruptures have reported about OA knee changes with similar results between ACL-deficient knees and ACL-reconstructed knees.^{††} However, these studies included many different and often nonoptimal operative techniques. Today, surgeons concentrate rather heavily on restoring the anatomy of the ACL because this may improve knee stability and help in preventing the development of postoperative OA.

Our short-term 2-year study comparing double-bundle ACL reconstruction (using bioabsorbable interference screws) and its single-bundle counterpart has been published previously.⁴⁸ The conclusion in that study was that the single-bundle group had more graft failures than the double-bundle group. The difference was statistically significant. On the other hand, there was no difference in OA or stability testing between the groups.

The hypothesis tested in this prospective 5-year clinical study was that the double-bundle ACL reconstruction method with hamstring autografts and aperture screw fixation results in a lower graft rupture rate, less OA, and better knee stability than the single-bundle method.

MATERIALS AND METHODS

Patients

Collection of the baseline data was made at our institute between 2003 and 2005. The inclusion criteria were primary ACL reconstruction, closed growth plates, and absence of ligament injury to the contralateral knee. Ninety patients were randomized with closed envelopes into 3 groups of ACL reconstruction with hamstring autografts using aperture interference screw fixation: double-bundle ACL reconstruction with bioabsorbable screw fixation (DB group; $n = 30$), single-bundle ACL reconstruction with bioabsorbable screw fixation (SBB group; $n = 30$), and single-bundle ACL reconstruction with metallic screw fixation (SBM group; $n = 30$). The division into the 3 groups was done because single-bundle ACL reconstruction with metallic screw fixation was the standard at the time this study was originally begun. The ethics committee at our institute approved the study, and written informed consent was provided from every patient. All the operations were performed by a single experienced orthopaedic surgeon (T.J.).

Evaluations

The evaluation methods were clinical examination, which included a pivot-shift test and stability measurement using a KT-1000 arthrometer (MEDmetric Corp, San Diego, California) with a force of 134 N. Also, the International Knee Documentation Committee (IKDC) and Lysholm knee scores

were used to evaluate the knee preoperatively and at the 5-year follow-up. All clinical assessments were made by a single blinded and independent examiner (P.S.). Radiographic evaluation was made at the 5-year follow-up with weight-bearing anteroposterior and lateral knee radiographs. The axial patella projection was also used. Femorotibial and patellofemoral OA findings were evaluated using the Kellgren-Lawrence classification system.²⁰ A musculoskeletal radiologist (A.P.) interpreted the images. He was unaware of the patients' clinical and surgical data.

Surgical Technique of the Double-Bundle ACL Reconstruction

A complete diagnostic arthroscopic procedure was performed first for every patient to confirm ACL tear, evaluate the meniscal status, and record all chondral injuries. The remnant of the torn ACL was debrided, but the tibial footprint was left intact. A bony notchplasty was not performed. The surgical technique of the double-bundle method has been described earlier in detail.¹⁷ In brief, 2 tunnels on the femoral side were made via an anteromedial portal (not transtibially) with a free-hand technique without a guide to the anatomic position of the insertion sites of each bundle. Tibial tunnels were made with a tibial guide to the anatomic insertion site of the ACL tibial footprint. The hamstring grafts were harvested from the same leg and doubled. Grafts were inserted in a retrograde manner through the tibial tunnels into the femoral tunnels and fixed with bioabsorbable interference screws (D-lactide, L-lactide, and trimethylene carbonate [TMC]; Hexalon, Inion Co, Tampere, Finland) with an outside-in technique in the tibia and an inside-out manner in the femur. The locations of the grafts were determined with magnetic resonance imaging (MRI) at the 2-year follow-up by a musculoskeletal radiologist, and they were all anatomic.

Surgical Technique of the Single-Bundle ACL Reconstruction

A diagnostic arthroscopic procedure and debridement were made first as described above. The femoral tunnel was drilled through an anteromedial portal (not transtibially) as posterior as possible without breaking the posterior wall of the femur with a free-hand technique, at approximately 10 o'clock in the right knee and 2 o'clock in the left knee. The tibial tunnel was made with a tibial guide through the center of the ACL tibial footprint. The semitendinosus and gracilis tendons were harvested, doubled, and inserted through the tibial tunnel and into the femur. They were fixed with either aperture bioabsorbable interference screws or aperture metallic ones, depending on the randomization. The locations of the grafts were determined with MRI at the 2-year follow-up, and they were all anatomic.

Postoperative Rehabilitation

Each group had the same rehabilitation program. Full range of motion was permitted from the start, and no

**References 1-4, 6, 7, 9, 15-18, 22, 23, 29, 30, 36, 37, 40, 43-46, 48, 51, 53, 54, 58.

††References 13, 14, 19, 21, 24, 25, 28, 32-35, 38, 41, 42, 47.

TABLE 1
Demographic Data of the Patients^a

	DB (n = 30)	SBB (n = 30)	SBM (n = 30)	Significance
Sex, male/female, n	21/9	21/9	19/11	NS
Age, mean \pm SD, y	34 \pm 10	30 \pm 8	33 \pm 10	NS
Time since injury, mean \pm SD, mo	13 \pm 6	12 \pm 6	11 \pm 5	NS

^aDB, double-bundle reconstruction with bioabsorbable screw; SBB, single-bundle reconstruction with bioabsorbable screw; SBM, single-bundle reconstruction with metallic screw; SD, standard deviation; NS, not significant.

TABLE 2
Initial Surgical Findings in the 3 Study Groups^a

	DB (n = 30)	SBB (n = 30)	SBM (n = 30)	Significance
Status, n				
Isolated ACL rupture	15	16	11	NS
ACL and medial meniscus rupture	7	2	9	NS
ACL and lateral meniscus rupture	6	8	7	NS
ACL and both menisci ruptures	2	4	3	NS
Treatment of meniscus rupture, n				
Endoscopic fixation	2	2	4	NS
Partial resection	10	11	15	NS
Left in situ	3	1	0	NS

^aDB, double-bundle reconstruction with bioabsorbable screw; SBB, single-bundle reconstruction with bioabsorbable screw; SBM, single-bundle reconstruction with metallic screw; ACL, anterior cruciate ligament; NS, not significant.

rehabilitation brace was used. Immediate full weightbearing was also allowed. Patients used crutches for 3 to 4 weeks. Closed kinetic chain exercises were started immediately postoperatively. Cycling was permitted with an ergometer bicycle at 4 weeks, running at 3 months, and pivoting sports at 6 months postoperatively, if the patient had full functional stability. If a meniscal repair was made in the same operation, the range of motion was 0° to 90° for the first 6 weeks. Otherwise, the rehabilitation program was the same as described above.

Statistics

Statistical analysis was performed using the SPSS 11.0 software package (SPSS Inc, Chicago, Illinois). The calculations between the differences of means were made by an analysis of variance (ANOVA), paired-sample *t* test, and those of the frequencies by the χ^2 test. Test significance level was set at $P < .05$.

RESULTS

Initially, there were 30 patients in each group (DB, SBB, and SBM), and the groups were homogeneous regarding age, sex, weight, height, and delay from the injury to surgery (Table 1). The mean age at the time of the surgery was 33 years. The follow-up time was the same between the groups. Surgical findings and treatment of the injured knees were also similar between the groups (Table 2).

Eleven patients (7 in the SBB group, 3 in the SBM group, and 1 in the DB group) had a graft failure during

the follow-up, and they all went on to ACL revision surgery ($P = .043$) (Figure 1). Further analysis showed that there were 7 revisions (5 in the SBB group, 1 in the SBM group, and 1 in the DB group) during the first 2 years of follow-up and 4 revisions (2 in the SBB group and 2 in the SBM group) during the latter period (2-5 years' follow-up). These revision cases were judged as failures of the primary surgery and were not followed further.

There were 14 patients lost to follow-up (9 in the DB group, 2 in the SBB group, and 3 in the SBM group) because of long distance. In the DB group, we were able to contact all but 2 of these patients via telephone. They were all satisfied with their knees, and no ACL re-reconstruction was performed. In the single-bundle groups, 1 patient had an ACL re-reconstruction (SBM group), while the remaining 4 could not be reached. A total of 65 patients (20 in the DB group, 21 in the SBB group, and 24 in the SBM group) underwent a 5-year follow-up; their clinical and radiological results are presented below.

There were neither statistically significant nor clinically relevant differences between the groups in the Lysholm score, IKDC final score, pivot-shift test results, or KT-1000 arthrometer measurements at the 5-year follow-up (Table 3). However, the 5-year follow-up results were significantly better in all groups when compared with the preoperative situation according to the Lysholm score, IKDC final score, and the stability measurements and evaluations ($P < .001$). As noted above, none of the patients who had a graft rupture during follow-up were included in these analyses.

The OA changes in the medial compartment of the injured knees are presented in Table 4. There were neither statistically significant nor clinically relevant group differences

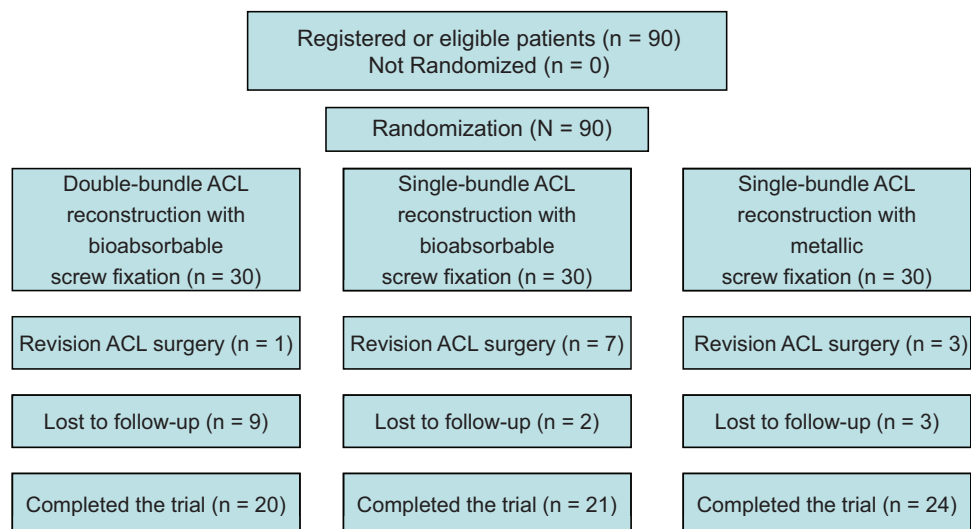


Figure 1. CONSORT flow diagram.

TABLE 3
Clinical Evaluation Outcomes Preoperatively and at 5-Year Follow-up
in Patients Who Had Their Grafts Intact^a

	DB (n = 20)	SBB (n = 21)	SBM (n = 24)	Significance
Lysholm score				
Preoperatively	68 ± 19	71 ± 14	64 ± 18	NS
5-year follow-up	90 ± 9	86 ± 13	87 ± 17	NS
IKDC final score				
Preoperatively				
Normal	0	0	0	NS
Nearly normal	0	2	1	NS
Abnormal	19	17	21	NS
Severely abnormal	1	2	2	NS
5-year follow-up				
Normal	5	3	3	NS
Nearly normal	11	13	12	NS
Abnormal	4	5	9	NS
Severely abnormal	0	0	0	NS
Pivot-shift test				
Preoperatively				
Normal	0	0	0	NS
Nearly normal	5	5	10	NS
Abnormal	15	15	14	NS
Severely abnormal	0	1	0	NS
5-year follow-up				
Normal	7	10	9	NS
Nearly normal	10	9	9	NS
Abnormal	3	2	6	NS
Severely abnormal	0	0	0	NS
Mean KT-1000 arthrometer difference, ^b mm				
Preoperatively	4.4 ± 1.8	4.0 ± 3.0	4.7 ± 2.4	NS
5-year follow-up	1.6 ± 3.0	2.2 ± 2.8	2.3 ± 3.8	NS

^aValues are expressed as mean ± standard deviation or number. DB, double-bundle reconstruction with bioabsorbable screw; SBB, single-bundle reconstruction with bioabsorbable screw; SBM, single-bundle reconstruction with metallic screw; NS, not significant; IKDC, International Knee Documentation Committee.

^bDifference between the injured knee and the contralateral knee.

TABLE 4
Osteoarthritis Changes of Knees Preoperatively and at 5-Year Follow-up
in Patients Who Had Their Grafts Intact According to the Kellgren-Lawrence²⁰ Classification^a

	DB (n = 20)	SBB (n = 21)	SBM (n = 24)	Significance
Medial femorotibial compartment, n				
Preoperatively				
Normal	17	18	21	NS
Grade I arthrosis	3	3	3	NS
Grade II arthrosis	0	0	0	NS
Grade III-IV arthrosis	0	0	0	NS
5-year follow-up				
Normal	16	15	15	NS
Grade I arthrosis	3	5	6	NS
Grade II arthrosis	1	1	2	NS
Grade III-IV arthrosis	0	0	1	NS
Lateral femorotibial compartment, n				
Preoperatively				
Normal	19	20	23	NS
Grade I arthrosis	1	1	1	NS
Grade II arthrosis	0	0	0	NS
Grade III-IV arthrosis	0	0	0	NS
5-year follow-up				
Normal	18	17	20	NS
Grade I arthrosis	1	2	3	NS
Grade II arthrosis	1	2	0	NS
Grade III-IV arthrosis	0	0	1	NS
Patellofemoral compartment, n				
Preoperatively				
Normal	17	18	19	NS
Grade I arthrosis	3	3	5	NS
Grade II arthrosis	0	0	0	NS
Grade III-IV arthrosis	0	0	0	NS
5-year follow-up				
Normal	15	13	18	NS
Grade I arthrosis	4	7	4	NS
Grade II arthrosis	1	1	2	NS
Grade III-IV arthrosis	0	0	0	NS

^aDB, double-bundle reconstruction with bioabsorbable screw; SBB, single-bundle reconstruction with bioabsorbable screw; SBM, single-bundle reconstruction with metallic screw; NS, not significant.

regarding medial OA (Figure 2). The finding was similar in the lateral (Figure 3) and patellofemoral compartments (Figure 4 and Table 4). There was a correlation with OA and meniscus ruptures, but there was no statistically significant difference between the 3 groups regarding meniscal status, resection, or fixation. Patients who had a graft rupture during the follow-up were excluded from these analyses.

The main finding in our previous 2-year follow-up study was that the graft rupture rate was significantly higher in the single-bundle groups than the double-bundle group.⁴⁸ In the current 5-year follow-up study, the finding was similar. There were no statistically significant group differences in the stability tests or OA changes either at the 2-year follow-up study⁴⁸ or the current 5-year follow-up study.

DISCUSSION

The main finding of our study was that the SBB and SBM groups had more graft failures than the DB group

($P = .043$). The graft ruptures in the single-bundle groups were all caused by a minor accident, and the single rupture in the DB group was because of a major trauma with bone fractures. The majority of the failures occurred in the early years of our study. One reason for this can be that the single-bundle technique improved with time along with the use of the double-bundle method. Another reason for the graft ruptures in the single-bundle groups can be that there may have been excess micromovement, especially in the rotational plane of the knee, resulting in single-bundle graft ruptures.

Previous longer term studies on ACL reconstructions have shown that the reconstruction method has no or little effect on the development of the OA changes of the knee.^{††} However, these studies included various surgical methods and were performed before the concept of anatomic ACL reconstruction was released. In our study, patients in the double-bundle group who had their grafts intact had fewer

^{††}References 13, 14, 19, 21, 24, 25, 28, 32-35, 38, 41, 42, 47.



Figure 2. Anteroposterior radiograph of the left knee (single-bundle reconstruction with bioabsorbable screw). Definite osteophytes and possible narrowing of the medial femorotibial joint space (grade II).²⁰

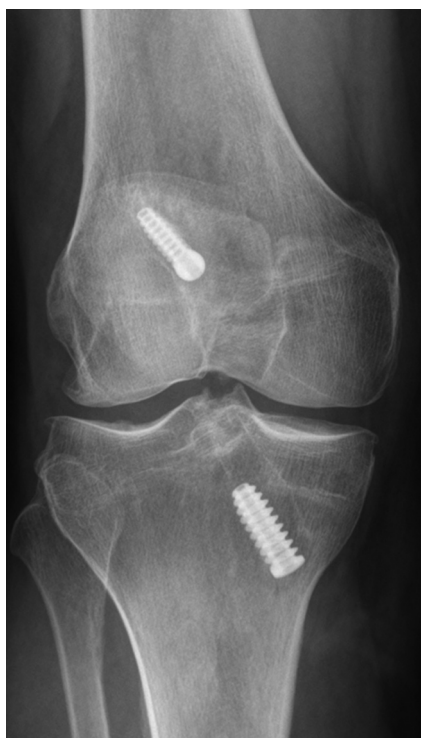


Figure 3. Anteroposterior radiograph of the knee (single-bundle reconstruction with metallic screw). Definite osteophytes and possible narrowing of the lateral femorotibial joint space (grade II).²⁰

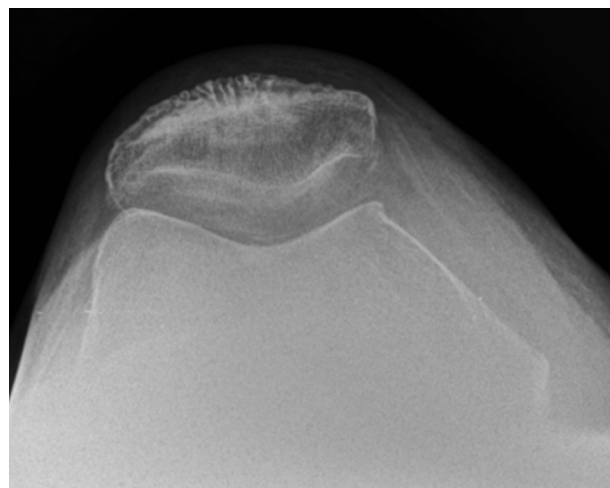


Figure 4. Axial patellar projection of the right knee (single-bundle reconstruction with metallic screw). Definite osteophytes and possible narrowing of the patellofemoral joint space (grade II).²⁰

OA changes than those in the single-bundle groups, although this was not a statistically significant finding. This could be explained by the fact that the double-bundle method results in more anatomic ACL reconstructions and therefore more stable knees than the single-bundle method,⁴⁸ although this was not proven in stability testing of the current study.

Zaffagnini et al⁵⁷ recently reported 8-year results of a study in which they compared a lateralized patellar bone-tendon-bone group and nonanatomic double-bundle hamstring graft group. They found that the double-bundle group had fewer OA changes in their knees and fewer reoperations due to meniscal problems. They discussed that these results could be a consequence of better dynamic stability that the double-bundle ACL reconstruction method offered.

The clinical testing showed no differences between the 3 groups among the patients who had their grafts intact at the 5-year follow-up. Also, the Lysholm and IKDC scores were similar between groups. However, it was important that in all patient groups with their grafts intact, the 5-year results were significantly better than those in the pre-operative situation ($P < .001$).

There are 17 randomized controlled trials published to date about single-bundle versus double-bundle ACL reconstruction.^{§§} Most of them vary in fixation methods and other details in the operative technique, and therefore, it is difficult to make direct comparisons. Suomalainen et al⁴⁸ showed that there were more graft failures in the single-bundle groups already at the 2-year follow-up. In addition, they found no difference in the stability measurements between the single-bundle and double-bundle groups. Park et al³⁶ and Sastre et al⁴⁰ also had similar stability results. In contrast, Aglietti et al³ found that the double-bundle group had better visual analog scale scores, final objective IKDC scores, and improved anterior knee

§§References 1-4, 15, 17, 18, 30, 36, 40, 44, 46, 48, 52, 53, 57, 58.

stability. Araki et al⁴ revealed that the double-bundle group was biomechanically superior to the single-bundle group, although their results were only from a 1-year follow-up. Ibrahim et al,¹⁵ Muneta et al,³⁰ Siebold et al,⁴⁴ and Zaffagnini et al^{57,58} also had similar results in their prospective and randomized studies. A meta-analysis performed by Meredick et al²⁷ failed to prove the superiority of the double-bundle method; however, they required longer follow-up times and better study plans.

Our previous study with bioabsorbable screws showed that there were more graft ruptures in the single-bundle group than the double-bundle group already at the 2-year follow-up. This has been discussed in detail by Suomalainen et al.⁴⁸ The main finding in the current 5-year follow-up study was also a higher rerupture rate in the single-bundle groups. There were neither statistically significant nor clinically relevant group differences in stability testing among the patients who had their grafts intact either at the 2-year or 5-year follow-up. The OA changes are usually visible in plain radiographs, which was the reason why plain radiographs were taken from patients who had their grafts intact at the 5-year follow-up. In our previous 2-year follow-up study, an MRI examination was made.

The main limitation of our study is that the group sizes were relatively small at the 5-year follow-up (Figure 1), as a total of 14 patients were lost during this follow-up period. This naturally limits all the conclusions concerning the insignificant findings in group comparisons. A positive factor was that 8 of these 14 patients could be contacted via telephone, and they were satisfied with their knees. Also, our study had 90 patients at baseline, which was more than in many previous clinical studies of ACL reconstruction comparing the single-bundle technique with its double-bundle counterpart. An obvious additional strength of our study is that it was prospective and randomized and that the follow-up examinations were made in a blinded fashion. Also, the follow-up time was 5 years, which is more than previously reported.

In conclusion, the main finding of our 5-year follow-up study was that the double-bundle ACL reconstruction produced fewer graft ruptures than its single-bundle counterparts. Knee stability and OA rates were similar in all groups. Our intention is to continue the follow-up to reveal the truly long-term results of these methods in treating an ACL rupture.

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