ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

Graft failures, surgical techniques and patient-reported outcome measures

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Anterior cruciate ligament reconstruction – Graft failures, surgical techniques and patient-reported outcome measures © Haukur Björnsson 2016 haukurbj@hotmail.com

ISBN 978-91-628-9658-4 (PRINT) ISBN 978-91-628-9659-1 (PDF) http://hdl.handle.net/2077/41846

Printed in Gothenburg, Sweden, 2016 / Ineko AB
Design by Annika Samuelsson Enderlein / A Little Company AB (design protected by Copyright)
Front cover art and illustrations by Pontus Andersson / Pontus Art Production

To Fanney, the love of my life, and our beloved children, Hildur, Bjarki and Sandra

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01 ABSTRACT

The anterior cruciate ligament (ACL) connects the femur to the tibia and plays an important role in the stabilisation of the knee by guiding normal joint motion. Injuries to the knee can result in a rupture of the ligament and thereby increased joint laxity. Significant joint laxity often ends participation in competitive sports and may, in the medium to long term, lead to degeneration of the knee. The occurrence of ACL injuries has increased in recent years and, today, ACL reconstruction is one of the most common procedures in orthopaedic surgery. Even though the research on ACL reconstruction is extensive, the optimal surgical technique is yet to be universally accepted.

Study I is a comprehensive systematic review evaluating all the clinical studies comparing primary single- and double-bundle ACL reconstruction in the current literature. After a thorough systematic electronic search, 60 studies comprising 4,146 patients (2,072 single-bundle, 2,074 double-bundle) were included. An analysis of graft failures revealed fewer reported re-ruptures after double-bundle reconstruction compared with single-bundle, 19 and 44 respectively. However, only two of the 23 studies reporting re-ruptures reported statistical difference, both in favour of the double-bundle reconstruction. Up to 45% of the studies revealed a superior outcome in double-bundle reconstruction. in terms of less antero-posterior laxity, and measurements of rotatory laxity revealed superior results in double-bundle reconstruction measured with pivot shift and navigation in 18/42 and 9/20 studies respectively. The other studies found no difference. Patient-reported outcome measures (PROMs) and functional outcomes did not differ to a large extent; however, differences when identified were almost exclusively in favour of the double-bundle reconstruction.

Study II is an observational comparative study based on data from the Swedish National Knee Ligament Register over a seven-year period with a total of 22,740 primary ACL reconstructions included. The purpose was to compare ACL revision rates and PROMs between single- and double-bundle ACL reconstructions. The study included 16,281 single-bundle and 510 double-bundle reconstructions, with a revision rate of 2.1% and 1.6% respectively. No differences were found in terms of either the revision rate between the groups or the KOOS or EQ-5D.

Study III is a retrospective comparative study based on 251 patients between 14 and 50 years of age at the time of a primary ACL reconstruction, with a mean 3.4 ± 1.3 years follow-up, to determine predictors of ACL revision. In overall, 21 (8.4%) patients underwent an ACL revision. A multivariate logistic regression analysis revealed that young age and the use of allografts at the primary reconstruction were independent predictors of an ACL revision.

Study IV is a randomised controlled trial consisting of 193 patients who underwent

a primary ACL reconstruction using either hamstring tendon (HT) or patellar tendon (PT) autografts, to investigate the longterm clinical and radiographic results. At the follow-up, 147 (76%) patients were examined; 86 patients in the HT group with a mean 191.9 ± 15.1 months follow-up and 61 patients in the PT group with mean 202.6 ± 10.4 months follow-up. Seven patients (8.1%) in the HT group and four patients (6.6%) in the PT group had an ACL graft failure in the ipsilateral knee, while six patients in both groups (7.0% HT group, 9.8% PT group) sustained an ACL graft failure to the contralateral knee. Knee laxity measurements revealed significantly more patients with a negative pivot shift in the HT group compared with the PT group (71% vs 51%; p=0.048); however, no differences were found in terms of antero-posterior laxity. The patients in the PT group had more difficulty knee-walking (p=0.049). There were no differences between the two groups in terms of PROMs, range of motion in the reconstructed knee or radiographic signs of osteoarthritis. However, in both groups, more radiographic signs of osteoarthritis were found in the reconstructed knee than in the contralateral healthy knee.

Keywords: Knee, anterior cruciate ligament, double-bundle, single-bundle, register, hamstring tendon, patellar tendon, graft failure, patient-reported outcome measures

ISBN: 978-91-628-9658-4 (PRINT) **ISBN:** 978-91-628-9659-1 (PDF)

02 SAMMANFATTNING

Främre korsbandet sitter centralt i knäleden och fäster både på lårbenet och skenbenet. Det är en viktig struktur för att bibehålla knäledens normala rörelsemönster och stabilitet. En främre korsbandsruptur kan därför orsaka instabilitet i knäleden, vilket ökar risken för artros och kan göra kontaktidrott på hög nivå omöjlig. Incidensen på dessa skador har ökat de senaste åren och främre korsbandsrekonstruktion är idag ett av de vanligaste ortopediska ingreppen. Men det råder dock fortfarande ingen konsensus om den optimala operationsmetoden, trots att det redan finns flera tusen behandlingsstudier avseende främre korsbandsrekonstruktioner.

Delstudie I är en omfattande systematisk översiktsartikel som utvärderar alla kliniska behandlingsstudier som jämför enkel- och dubbel-skänkel främre korsbandsrekonstruktion i nuvarande litteratur. Efter noggrann elektronisk sökning inkluderades 60 studier med totalt 4 146 patienter, var av 2 072 med enkel-skänkel rekonstruktion och 2 074 med dubbel-skänkel rekonstruktion. I de inkluderade studierna var det färre som ådrog sig re-rupturer efter dubbel-skänkel rekonstruktion (19 re-rupturer), jämfört med enkel-skänkel rekonstruktion (44 re-rupturer). Trots det hittade endast två av 23 studier som rapporterade re-rupturer statistisk skillnad, båda till dubbel-skänkel rekonstruktions fördel. I knappt 45% av studierna hade patienterna med dubbel-skänkel rekonstruktion bättre laxitet mätt "fram/bak", och rotationsstabilitet mätt med pivot shift var bättre i gruppen med dubbel-skänkel rekonstruktion enligt 18/42 studier och i 9/20 studier mätt med navigation. Andra studier påvisade ingen skillnad i stabilitetstester. Få statistiska skillnader fanns avseende patient-rapporterade utfallsmått eller funktionella utfallsmått, men den skillnad som förelog var alltid till gruppen med dubbel-skänkel rekonstruktions fördel.

Delstudie II är en jämförande observationsstudie baserad på data från det Svenska korsbandsregistret som når sju år tillbaka, där 22 740 korsbands operationer är registrerade. Syftet var att jämföra enkel- och dubbel-skänkel främre korsbandsrekonstruktioner beträffande frekvensen av revision och patient-rapporterade utfallsmått. Vi inkluderade, 16 281 enkel-skänkel och 510 dubbel-skänkel korsbandsoperationer. Revisionsfrekvensen var 2,1% i gruppen med enkel-skänkel rekonstruktion och 1,6% i gruppen med dubbel-skänkel rekonstruktion. Det förelåg dock ingen skillnad mellan grupperna avseende revisionsfrekvens eller patient-rapporterade utfallsmått.

Delstudie III är retrospektiv jämförande studie av 251 patienter som var mellan 14 och 50 år gamla när de genomgick en främre korsbandsrekonstruktion. Syftet var att identifiera prediktorer för revisionsoperation. Totalt, genomgick 21 (8,4%) patienter revisionsoperation. En multivariate logistik regression analys visade att ung ålder vid rekonstruktion och användning av graft från annan människa (allograft) vid rekonstruktion var oberoende prediktorer för revisionsoperation.

Delstudie IV är en randomiserad kontrollerad studie av 193 patienter som genomgick främre korsbandsrekonstruktion med antingen graft från hamstringssenorna (HS) eller patellarsenan (PT). I denna studie utvärderades kliniska och radiologiska långtidsresultat. Etthundrafyrtiosju (76%) patienter undersöktes vid långtidsuppföljningen; 86 patienter i HS gruppen med 191.9 ± 15.1 månaders medeluppföljningstid och 61 patienter i PS gruppen med 202.6 ± 10.4 månaders medeluppföljningstid. Sju patienter (8,1%) i HS gruppen och fyra (6,6%) i PS gruppen hade då ådragit sig en re-ruptur, sex patienter i båda grupper (7,0% i HS gruppen, 9,8% i PS gruppen) hade ådragit sig en korsbandsruptur i motsatt knä. Utvärdering av laxitet i knäleden visade att signifikant fler patienter i HS gruppen hade normalt pivot shift jämfört med PS gruppen (71% v 51%; p=0.048), men det förelåg dock ingen signifikant skillnad i "fram/bak" laxitet mellan grupperna. Patienterna i PS gruppen hade signifikant svårare att gå/krypa på knä (p=0.049). Det förelåg ingen signifikant skillnad mellan studiegrupperna avseende patient-rapporterade utfallsmått, rörelseomfång eller radiologisk artros. Dock hade båda studiegrupperna signifikant mer radiologiska tecken på artros i det rekonstruerade knät jämfört med det icke-opererade knät.

03 ÁGRIP Á ÍSLENSKU

Fremra krossbandið er liðband í miðju hnésins og tengir saman lærlegg og sköflung. Það er mikilvægt fyrir eðlilegar hreyfingar og stöðugleika hnésins. Því getur rifið fremra krossband valdið óstöðugleika, gert íþróttaiðkun erfiða og til lengri tíma valdið slitgigt. Þessum áverkum hefur fjölgað mikið undanfarin ár og fremri krossbandsaðgerð orðin ein algengasta aðgerðin innan bæklunarskurðlækninga. En þrátt fyrir að þegar séu til fleiri þúsundir vísindagreina um fremra krossbandið eru vísindamenn ekki enn sammála um hvernig best sé að framkvæma slíkar aðgerðir.

Grein I er víðtæk kerfisbundin yfirlitsgrein þar sem tilgangurinn var að meta allar klínískar vísindagreinar sem bera saman fremri krossbandaaðgerðir með annað hvort einum (single-bundle) eða tveimur strengjum (double-bundle). Eftir ítarlega rafræna leit voru valdar 60 greinar til rannsóknar, með samtals 4.146 sjúklingum (2.072 single-bundle, 2.074 double-bundle). Skoðuð var tíðni rofs á nýja krossbandinu og voru þau færri í double-bundle hópnum (19 vs. 44). Hins vegar sýndu aðeins tvær greinar af 23 marktækan mun, í báðum voru færri í double-bundle hópunum. Í tæplega 45% greinanna var betri framaftur stöðugleiki í double-bundle hópnum, og við mat á snúnings stöðugleika með pivot shift var double-bundle betra í 18/42 greinum og í 9/20 með "navigation". Í hinum greinunum fannst ekki marktækur munur við stöðuleikamat. Það voru fáar marktækar niðurstöður varðandi "patient-reported outcome measures" eða "functional outcomes", þegar það hins vegar fannst var það double-bundle tækninni í vil.

Grein II er samanburðarrannsókn sem byggir á niðurstöðum úr sænsku krossbandaskránni 7 ár aftur í tímann, þar sem 22 740 fremri krossbandsaðgerðir voru skráðar. Tilgangurinn var að meta muninn á fremri krossbandaaðgerðum með annað hvort single-bundle eða doublebundle tækni með tilliti til hættu á nýrri krossbandsaðgerð á sama hné og "patientreported outcome measures". 16 281 single-bundle og 510 double-bundle aðgerðir voru innvaldar, og var tíðni nýrra krossbandaaðgerða 2,1% eftir aðgerð með single-bundle tækninni og 1,6% með double-bundle tækninni. Hins vegar var enginn marktækur munur, hvorki á fjölda nýrra krossbandaaðgerða milli hópanna né á KOOS eða EQ-5D.

Grein III er afturskyggn samanburðarrannsókn á alls 251 sjúklingi, sem voru 14 til 50 ára þegar þeir fóru í fremri krossbandsaðgerð. Markmiðið var að rannsaka áhættuþætti fyrir nýrri krossbandsaðgerð á sama hné. Samtals reif 21 (8,4%) sjúklingur nýja krossbandið og fór í aðra krossbandsaðgerð. Samkvæmt margvíðri lógístískri aðhvarfsgreiningu reyndist ungur aldur við aðgerð og notkun sina frá öðrum einstaklingum (allograft) auka líkurnar á nýrri krossbandsaðgerð á sama hné.

Grein IV er slembuð samanburðarrannsókn á alls 193 sjúklingum sem gengust undir krossbandsaðgerð með annað hvort sinum frá aftanverðu læri (hamstringssinar (HS)) eða miðhluta hnéskeljasinar (patella sin (PS)). Markmiðið var að meta klínísk og röntgenológísk áhrif. Við eftirfylgd voru 147 (76%) sjúklingar skoðaðir; 86 sjúklingar úr HS hópnum, með 191.9 ± 15.1 mánaða meðaltals eftirfylgd og 61 sjúklingar úr PS hópnum, með 202.6 ± 10.4 mánaða meðaltals eftirfylgd. Sjö sjúklingar (8,1%) í HS hópnum og fjórir (6,6%) í PS hópnum höfðu þá slitið nýja krossbandið, á meðan sex sjúklingar í hvorum hóp (7,0% HS hópur, 9,8% PS hópur) höfðu slitið krossbandið á hinu hnénu. Stöðugleikaprófun leiddi í ljós að marktækt fleiri sjúklingar í HS hópnum voru með eðlilegt pivot shift próf samanborið við PS hópinn (71% vs 51%; p=0,048); hins vegar var enginn munur á fram-aftur stöðugleika. Auk þess áttu sjúklingarnir í PS hópnum marktækt erfiðara með að ganga á hnjánum (p=0,049). Það var enginn marktækur munur á hópunum varðandi "patientreported outcome measures", hreyfigetu eða slitgigt. Hins vegar sást marktækt meiri slitgigt á röntgenrannsókn í báðum hópunum í aðgerðahnénu samanborið við heilbrigða hnéð.

04 LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

Is double-bundle anterior cruciate ligament reconstruction superior to single-bundle?
 A comprehensive systematic review

Björnsson H, Desai N, Musahl V, Alentorn-Geli E, Bhandari M, Fu FH, Samuelsson K Knee Surg Sports Traumatol Arthrosc. 2015; 23(3): 696-739

II. No difference in revision rates between single- and double-bundle anterior cruciate ligament reconstruction. A comparative study of 16,791 patients from the Swedish national knee ligament register

Björnsson H, Andernord D, Desai N, Norrby O, Forssblad M, Petzold M, Karlsson J, Samuelsson K Arthroscopy. 2015; 31(4): 659-664

III. Predictors of revision surgery after primary anterior cruciate ligament reconstruction Yabroudi MA, Björnsson H, Lynch AD, Muller B, Samuelsson K, Tarabichi M, Karlsson J, Fu F, Irrgang JJ Submitted to Orthop J Sports Med

IV. A randomized controlled trial with mean 16 year follow-up comparing hamstring and patella tendon autografts in anterior cruciate ligament reconstruction

Björnsson H, Samuelsson K, Sandemo D, Desai N, Sernert N, Rostgård-Christensen L, Karlsson J, Kartus J

Manuscript accepted for publication in Am J Sports Med

Additional relevant papers by the author not included in this thesis:

Outcomes after ACL reconstruction with focus on older patients: results from the Swedish national anterior cruciate ligament register

Desai N, Björnsson H, Samuelsson K, Karlsson J, Forssblad M Knee Surg Sports Traumatol Arthrosc. 2014; 22(2): 379-386

Anatomic single- versus double-bundle ACL reconstruction: a meta-analysis

Desai N, Björnsson H, Musahl V, Bhandari M, Petzold M, Fu F, Samuelsson K Knee Surg Sports Traumatol Arthrosc. 2014; 22(5): 1009-1023

Surgical predictors of early revision surgery after anterior cruciate ligament reconstruction: results from the Swedish national anterior cruciate ligament register on 13,102 patients

Andernord D, Björnsson H, Petzold M, Eriksson BI, Forssblad M, Karlsson J, Samuelsson K Am J Sports Med. 2014; 42(7): 1574-1582

Patient predictors of early revision surgery after anterior cruciate ligament reconstruction: a cohort study of 16,930 patients with 2-year follow-up

Andernord D, Desai N, Björnsson H, Ylander M, Karlsson J, Samuelsson K Am J Sports Med. 2015; 43(1): 121-127

Predictors of contralateral anterior cruciate ligament reconstruction: a cohort study of 9061 patients with 5-year follow-up

Andernord D, Desai N, Björnsson H, Gillén S, Karlsson J, Samuelsson K Am J Sports Med. 2015; 43(2): 295-302

Additional relevant book chapter by the author:

The Anterior Cruciate Ligament: Reconstruction and Basic Science, 2nd Chapter 41

A Systematic Review of Single vs Double Bundle Results. Editors; Chadwick Prodromos & Susan Finkle (2016). Elsevier

05 ABBREVIATIONS

ACL Anterior Cruciate Ligament

ADL Activities of Daily Living

AM Antero-medial

AP Antero-posterior

BMI Body Mass Index

CI Confidence Interval

EMBASE Excerpta Medica Database

EQ-5D European Quality of Life-5 Dimensions, Europol

HT Hamstring Tendon

IKDC International Knee Documentation Committee

KOOS Knee injury and Osteoarthritis Outcome Score

MMT Manual Maximum Test

MRI Magnetic Resonance Imaging

N Newton

OA Osteoarthritis

OAK Orthopadische Arbeitsgruppe Knie

OARSI Osteoarthritis Research Society International

OR Odds Ratio

PCS Prospective Comparative Study

PL Postero-lateral

PRISMA Preferred Reporting Items for Systematic reviews and Meta-Analyses

PROM Patient-Reported Outcome Measure

PT Patellar Tendon

QoL Quality Of Life

QT Quadriceps Tendon

RCS Retrospective Comparative Study

RCT Randomised Controlled Trial

ROM Range Of Motion

SD Standard Deviation

SE Standard Error

Sport/Rec Function in sport and recreation

SR Systematic Review

ST Semitendinosus

ST/G Semitendinosus and Gracilis

VAS Visual Analogue Scale

WOMAC Western Ontario and McMaster Universities Osteoarthritis Index

06 DEFINITIONS

ACL reconstruction Reconstruction of the native ACL using a graft

Allograft Tissue from a donor of the same species as the recipient however

not genetically identical

Autograft Tissue taken from a part of an individual's own body and trans-

planted into another part

Bias A systematic error or deviation in results of inferences from the

truth. The main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into a study (attrition bias) or how outcomes are assessed

(detection bias)

Case series A study reporting observations on a series of subjects, usually all

receiving the same intervention, with no control group

Cohort study A controlled observational study that follows a defined group

of subjects (the cohort) over time with a given exposure that is

compared with a similar group without the exposure

Confidence interval A measure of the uncertainty around the main finding of a statis-

tical analysis. Often reported as a 95% CI specifying the range of values within which one can assume with 95% certainty, that the

true value for the whole population lies.

Confounding factor A factor that is associated with an exposure and has an impact

on an outcome that is independent of the impact of the exposure

Contralateral Relating to the side of the body opposite to that on which a con-

dition occurs

EQ-5D Descriptive system of health-related quality of life states consisting

of five dimensions (mobility, self-care, usual activities, pain/discom-

fort, anxiety/depression)

Graft failure Insufficiency of the reconstructed ACL graft

Ipsilateral Relating to the same side of the body to that on which a condition

occurs

Instability A symptom described by the patient

Laxity An objective finding

Meta-analysis A systematic review that uses quantitative methods to analyse

pooled data

P value The probability, under the null-hypothesis, of obtaining a result

equal to or more extreme than what was actually observed

Patient-reported outcome measure

An outcome based on a report that comes directly from the patient (i.e. study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PROM can be measured by self-report or by interview, provided that the interviewer records

only the patient's response

Prospective Forward in time

Randomised clinical trial A controlled clinical trial in which patients are randomly assigned

to groups and followed prospectively over time

Regression analysis Statistical method for assessing the degree of correlation of a

dependent variable adjusted to one or several independent var-

iable(s)

Retrospective Backward in time

Revision ACL surgery Replacement of a previous ACL reconstruction

Sensitivity Percentage of patients with an outcome who are classified as

having positive results

Specificity Percentage of patients without an outcome who are classified as

having negative results

Systematic review A review of a clearly formulated question that uses systematic and

explicit methods to identify, select and critically appraise relevant research. The data from the included studies are then collected

and analysed

Type I error Incorrect rejection of a true null hypothesis ("false positive")

Type II error Failure to reject a false null hypothesis ("false negative"), often

because of lack of power

07 PREFACE

Looking back, the journey towards this thesis has been extremely exciting, but long. It started for real approximately five years ago, but in hindsight it probably began much earlier. Because, as soon as I was at elementary school, I knew I wanted to become a doctor like my father. Thanks to my parents, who taught me to dream about things worth pursuing and then go for them, approximately six years ago I became an orthopaedic surgeon and have now written this thesis.

The reason I became an orthopaedic surgeon and sports medicine physician has definitely been influenced by my interest in sports and it has presumably also influenced my choice of topic for this thesis, as an ACL injury is common in the field of sports trauma and often has devastating results for the individual. Consequently, it is of the essence that we are able to treat ACL injures in the best possible way.

However, dreaming alone is not enough. This project has been immensely time consuming and, behind the scenes, I have had the enormous good fortune to have a supportive and caring wife and family, cheering me on and tolerating countless hours spent in the office, battling shoulder to shoulder with my colleagues and friends. However, it has also given me unique opportunities, like the collaboration with Dr. Freddie Fu, Dr. Volker Musahl and Dr. James Irrgang from the University of Pittsburgh Medical Center, which has been an honour and a privilege. This collaboration has resulted in several studies and

two visits, where we received exceptional hospitality. In addition, it is enjoyable to mention that one of the studies included in this thesis was conducted there.

However, the main reason that this thesis has become a reality is thanks to my tutor and great friend, Dr. Jón Karlsson. I have had the great privilege to work on his team at Sahlgrenska University Hospital/Mölndal, where I was extremely fortunate to be under his clinical guidance. When he offered me the opportunity to participate in scientific research projects and subsequently complete my PhD, I simply had to seize the chance.

In addition to Dr. Karlsson, I have had the good fortune to have both Dr. Kristian Samuelsson and Dr. Bengt Eriksson as supervisors. Without their encouragement, support and our valuable Gran Canaria Research Group meetings, this dream would not have materialised.

At last, thanks to you, dear reader. If you are reading this line after the others, you will at least have read one page of my thesis. Thank you.

You'll never walk alone





08 INTRODUCTION

One of the first anatomical descriptions of the ACL can be found written on an Egyptian papyrus scroll dating back to 3000 BC (3). Hippocrates from the Greek island of Kos (460-370 BC), although unaware of the cruciate ligaments as such, was the first to suggest that knee laxity following trauma might be attributable to torn internal ligaments (4). However, Galen from Pergamon in Greece (131-201 BC) is credited

with providing the cruciate ligaments with their name, when, based on their appearance of crossing over, he coined the term "ligament genu cruciata" (5). However, it was not until 1836 that two brothers and professors, Wilhelm and Eduard Weber, described the exact anatomical position of the cruciate ligaments and demonstrated that the anterior cruciate ligament consists of two distinct fibre bundles, AM and PL

bundles, which are tensioned at different times during knee motion (6, 7). During the next two centuries, the ACL has been frequently studied and many studies have been published. By the beginning of the 21st century, the orthopaedic community had acquired a sophisticated understanding of the functional behaviour and anatomy of the ACL.

8.1 ANATOMY

At ultrastructural level, the ACL is composed of longitudinally oriented fibrils of collagen consisting primarily of type I collagen with a small amount of type III and VI close to the insertion sites (8). The length of the ACL fibres ranges from 22 mm to 41 mm, with a mean of 32 mm (3). The ACL is covered by a synovial fold and therefore, despite being intra-articular, it is extrasynovial (9). The predominant blood supply comes from the middle genicular artery, but there is also a contributory blood supply from the infrapatellar fat pad and adjacent synovium. Innervation is provided by a branch of the tibial nerve and the ACL has also been shown to have mechanoreceptors that provide the central nervous system with important proprioceptive feedback (10).

The ACL originates from the posteromedial aspect of the intercondylar notch on the lateral femoral condyle and inserts distally on the anterior aspect of the tibial articular surface, just medial to the attachment of the anterior horn of the lateral meniscus. The size and shape of the footprints have been shown to have high diversity, as illustrated in a systematic review by Kopf et al. (11). However, compared with the cross-sectional area of the midsubstance of the ligaments, the tibial and femoral insertion sites are broad expansions of the ligament and approximately three times larger. The mean length of the tibial footprint ranges from 14 mm (range 9-18 mm) to 29 mm (range 23-38 mm), while the area ranges

from 114 mm2 to 229 mm2. The area of the femoral footprint ranges from 83 mm2 to 197 mm2 (11). The femoral footprint can also be defined by two bony ridges. The intercondylar ridge forms the anterior border of the footprint and there are no fibres of the ACL anterior to this ridge. The lateral bifurcate ridge, which runs perpendicular to the lateral intercondylar ridge, separates the AM and PL bundles. The AM bundle originates at the most posterior part of the intercondylar wall and the PL bundle at the more distal part, closer to the cartilage border of the femoral condyle. Recently, Smigielski et al. (12) have proposed that the ACL forms a flat ribbon-like ligament, without any clear separation between the AM and the PL bundles, and that the ribbon is in exact continuity with the posterior femoral cortex.

The terminology of the bundles is determined according to their tibial insertion, with the fibres of the AM bundle inserting at the anteromedial tibial insertion and the PL bundle inserting on the posterolateral part of the tibial insertion. When the knee is extended, the PL bundle is tight and the AM bundle is moderately lax. As the knee is flexed, the femoral attachment of the ACL moves to a more horizontal orientation, causing the AM bundle to tighten and the PL bundle to loosen up (3). It is generally accepted that the ACL is the primary restraint to anterior tibial translation, but, due to the orientation of the bundles, it is suggested that the AM bundle mainly controls anteroposterior loads and the PL bundle is thought to control tibial rotation more effectively. However, it appears that both the bundles work in a synergistic manner during the range of motion to stabilise the knee under both anteroposterior and rotational tibial loads (13). In addition, the differentiation into two functional bundles is probably an oversimplification; for example, Odensten and Gilquist (14) examined the ACL histologically and

found no evidence of separation of the ligament into two bundles, while Amis and Dawkins (15) divided the ACL into AM, intermediate and PL bundles. However, even though there is disagreement on the actual anatomic division of the ACL, there is general consensus that two functional bands can be distinguished, as the tension varies between the fibres in the ligament with range of motion (3).

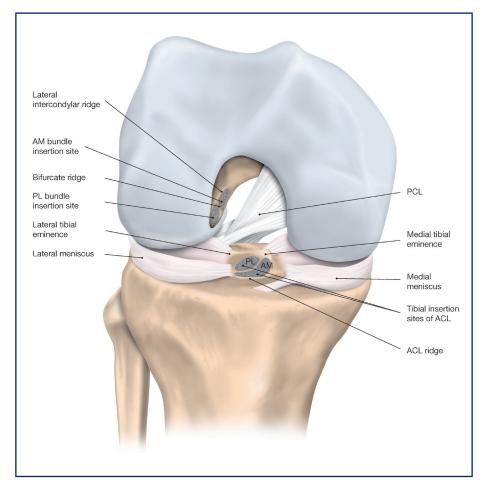


FIGURE 1

Image of the right knee at approximately 90° flexion, showing the locations of the AM and PL bundle insertion sites.

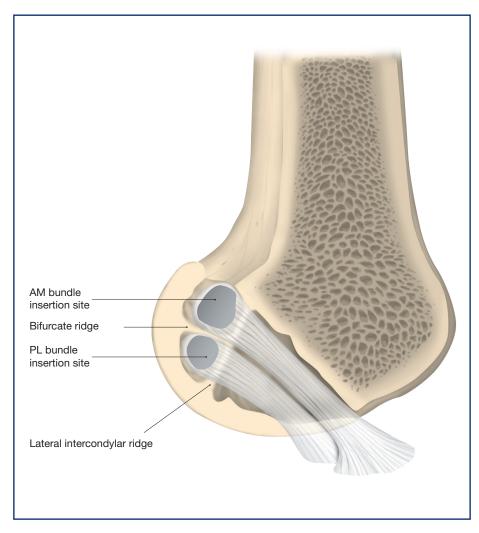


FIGURE 2

Image of the lateral wall of the intercondylar notch with the knee in full extension. The AM and PL bundle insertion sites are marked and their relationship to the lateral intercondylar ridge and the lateral bifurcate ridge is illustrated.

8.2 EPIDEMIOLOGY

Injury to the ACL is common, particularly in the athletic population. It is estimated that approximately 200,000 ACL injuries occur in the USA each year (16). The incidence in the general population in Sweden is estimated at 81 per 100,000 (17), which means that around 5,800 individuals suffer ACL injuries every year. According to the Swedish National Knee Ligament Register, 3,746 ACL reconstructions were performed in 2013 (18). The incidence of ACL reconstructions in the USA was approximately 130,000 or 43.5 per 100,000 in 2006 (19).

The average age of patients undergoing ACL surgery in Sweden is 28 years. Women comprise 43% of all patients undergoing ACL surgery and they generally have surgery at a younger age than men, 27 and 28 years respectively in 2014 (18). This is very similar to the USA, where, in 2006, women comprised 42% of the total number of ACL reconstructions and the average age was 29 years (19).



FIGURE 3
Arthroscopic image of the right knee showing an ACL rupture.

8.3 ETIOLOGY

Approximately 70% of all ACL injuries occur during a sporting activity (20). Most of them occur as a result of non-contact injury. Two common scenarios causing ACL injury in sports are either when the foot is planted and the individual changes direction or when landing from a jump. The mechanism usually includes valgus collapse in slight flexion in combination with rotation, or hyperextension and rotation (21). In Sweden, soccer is the most common activity associated with an ACL injury, among both men (49%) and women (32%). The second most common activity is downhill skiing, among both women (21%) and men (9%). The third most common activity is handball for women (8%) and floorball among men (9%) (18). In the USA, the three most common sports are basketball (20%), soccer (17%) and American football (14%) (22).

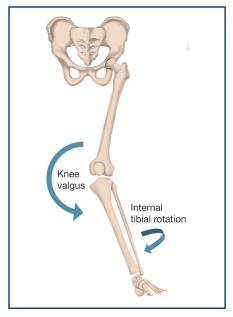


FIGURE 4
Image showing the injury mechanism usually leading to non-contact ACL injury.

8.4 SURGICAL TECHNIQUES

8.4.1 Open

Sir Arthur Mayo-Robson (1853-1933) performed the first repair of a torn ACL, on a 41-year-old miner in 1895, even if William Battle (1855-1936) was the first to publish a similar case of an open ACL repair with a silk suture in 1900. What followed was a period in which ACL reconstructions were

considered formidable procedures, never attained the level of popularity they have today and were only performed by a few surgeons. However, their startling ingenuity created a variety of different surgical procedures, where the absence of a satisfactory alternative drove the refinement (4).

8.4.2 Arthroscopic

The introduction of the arthroscope in the late 1970s for the improved diagnostics and treatment of meniscal lesions began

to play a role in ACL surgery in the 1980s. Dandy (23) performed the first arthroscopically assisted ACL reconstruction using a synthetic ligament in April 1980 (4). Arthroscopic ACL reconstruction in those days was a complex and challenging procedure, but studies comparing open with arthroscopic techniques finally confirmed the benefits of arthroscopically performed ACL reconstruction in terms of less post-operative morbidity, improved cosmesis, increased speed of recovery and enhanced range of motion (24).

Initially, the procedure required a two-incision technique; one incision to harvest the graft and prepare the tibial tunnel, while a second incision over the lateral condyle of the femur was required for the

outside-in drilling of the femoral tunnel. However, the introduction of arthroscopic drills and off-set guides made the second incision unnecessary and, by the end of the 1990s, most surgeons had adopted the one-incision technique, also called the all-inside or endoscopic technique (4). For roughly a decade, the one-incision ACL reconstruction with transtibial drilling was the gold standard ACL reconstruction, but, with a better understanding of the anatomy of the ACL by the beginning of the 21st century, greater emphasis was placed on anatomical graft placement, which transtibial drilling does not allow.

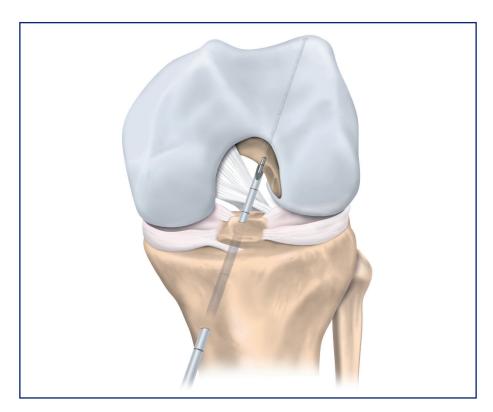


FIGURE 5

Image illustrating the transtibial drilling technique whereby the femoral bone tunnel is drilled via the tibial bone tunnel. The limitations of the transtibial drilling technique are evident, with resulting non-anatomic femoral bone tunnel placement outside the native ACL insertion site.

8.4.3 Isometry

The biomechanical concept of "graft isometry" was developed in the 1960s and was based on the notion that the ideal ACL graft should be isometric. Isometric graft placement means that the distance between the femoral and tibial attachments is constant during the full range of knee motion and can be achieved without causing ligament elongation. It was claimed that the exact isometric placement of the

graft was critical to the success of an ACL reconstruction and that non-isometric placement would produce irreversible slackening of the graft or limited ROM (25). However, by the 1990s, surgeons started to recognise that the goal of achieving isometry was proving elusive and created non-physiological conditions, as none of the identifiable native ACL bundles are isometric in their own right (4).

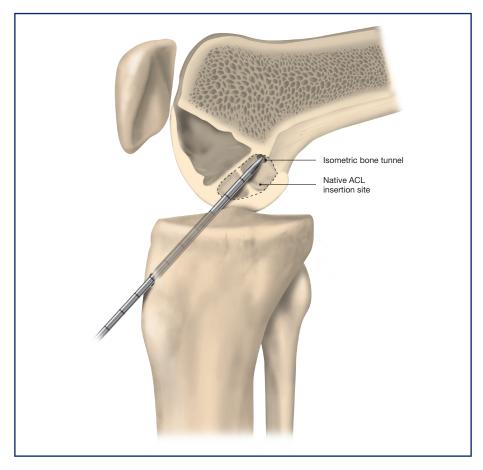


FIGURE 6

Image illustating isometric bone tunnel placement using transtibial drilling. The bone tunnel is high and deep in the intercondylar notch, outside the native ACL insertion site.

8.4.4 Single-bundle

With increased knowledge and improved instruments, ACL reconstruction has become a standard procedure for almost every knee surgeon. Initially, the procedure focused on replacing the ACL with a single-bundle graft and, for a long time, this was the traditional ACL reconstruction,

focusing on replacing the AM bundle of the ACL. Despite promising outcomes, it is suggested that single-bundle reconstruction is mainly effective in controlling AP laxity and less effective in restoring rotatory laxity.

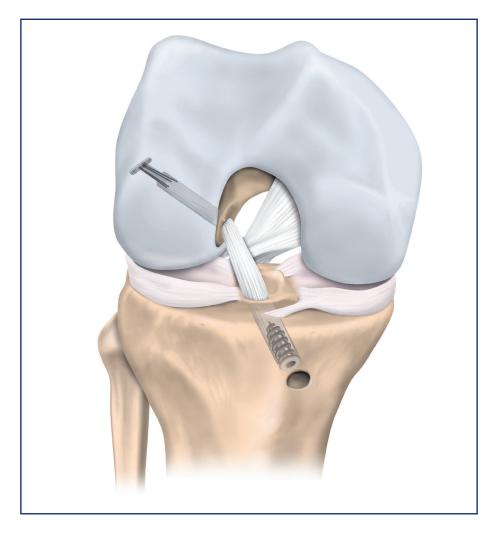


FIGURE 7

 $Image\ showing\ a\ single-bundle\ ACL\ reconstruction.$

In 1983, William Mott was the first to publish a double-bundle ACL reconstruction in the English literature. However, it was not until 1994 that Tom Rosenberg introduced an arthroscopically assisted technique for double-bundle ACL reconstruction (4). The transition to a double-bundle reconstruction was an evolution linked to a

better understanding of the ACL anatomy, with the emphasis on replacing not only the AM bundle but also the PL bundle. As a result, the double-bundle technique restores rotatory laxity more effectively, but it remains unclear whether the increased complexity and surgical trauma outweigh the proposed long-term benefits.

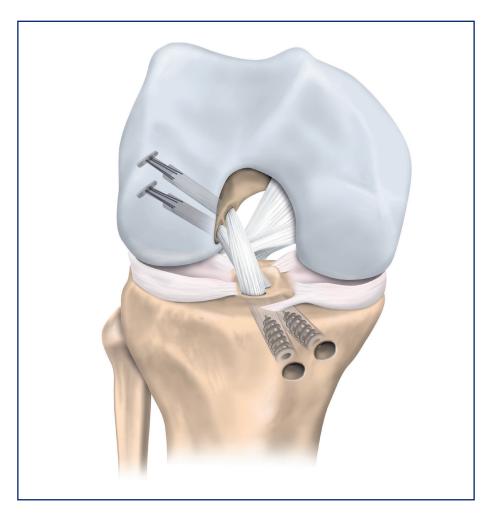


FIGURE 8
Image showing a double-bundle ACL reconstruction.

8.4.6 Anatomic

It was not until the beginning of the 21st century that the concept of anatomic ACL reconstruction was introduced, as it became apparent that the non-anatomic techniques were unable fully to restore normal knee kinematics. Moreover, there have been suggestions in the literature that a significant number of patients have less than optimal results. Although the short-term results have been generally good, there is still room for improvement.

The aim of the anatomic reconstruction is to reproduce the native anatomy of the ACL and restore normal ligament function. In order to do so, it is necessary to identify the anatomical insertion sites and to re-establish the position of the ACL bundles in their respective anatomical

footprints. If this is done, the biomechanical results have shown that both anatomic double-bundle and centrally placed anatomic single-bundle reconstruction can restore knee function significantly more closely to the normal knee as compared with non-anatomic procedures (26).

Recently, however, in a cadaver study, Siebold et al. (27) have proposed that the tibial ACL midsubstance is flat and resembles a "ribbon" and that the tibial insertion is "C"-shaped. Consequently, anatomic ACL reconstruction may therefore require a flat graft and a "C"-shaped tibial footprint reconstruction. However, the effect of these findings on future ACL reconstruction remains unclear.

8.5 DIFFERENT GRAFT MATERIALS

8.5.1 Fascia lata (ilio-tibial band)

The fascia lata or the ilio-tibial band was a popular graft choice for a large part of the twentieth century. It was first used in 1914, by Ivan Grekov in what is believed to be the first attempt at an anatomic reconstruction of the cruciate ligaments.

He used a free fascia graft, which he routed through drill holes in the femur and stitched against the ligament remnants on the tibia. However, the fascia lata has not been widely used during the past two or three decades.

8.5.2 Allografts

Anterior cruciate ligament reconstruction with an allograft is an attractive proposition, as it can reduce operative time, donor-site morbidity and post-operative pain. In the 1980s and at the beginning of the 1990s, some studies reported good results using allografts and paved the way for them to achieve relatively high popu-

larity, particularly in the USA (28-30). A few years later, the increased risk of viral disease transmission resulted in a significant setback for the use of allografts. Sterilisation methods were developed to reduce this risk, but radiation has been shown to negatively affect the strength of grafts at doses higher than 2.5 megarads (31). With

frozen allografts, the risk of rejection from immunogenicity is negligible and the risk of disease transmission is minimal, with appropriate donor screening and gamma irradiation (32, 33). With these sterilisation methods, allograft reconstruction has recently recovered some of its former ground and, as in the case of revision surgery or multiligamentous knee injury, the use of allograft tissue provides many more reconstructive options. It is, however, an

expensive option and access to a freezer with a temperature of -70°C is essential. In 2014, 15 (0.5%) allografts were used in primary surgery in Sweden, according to the Swedish National Knee Ligament Register, and this number has remained stable in recent years (18). Allografts are probably most frequently used as a complement in conjunction with multiple-ligament injuries and revision surgery.

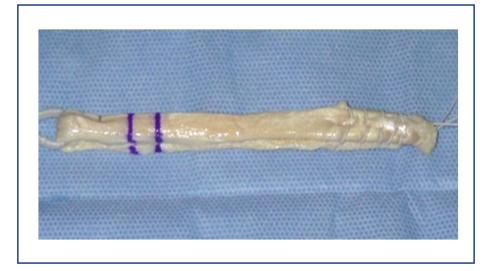


FIGURE 9
Picture of a double tibialis anterior allograft prepared for ACL reconstruction.

8.5.3 Synthetics

For more than 100 years, the use of synthetic materials has intrigued surgeons and different types have been tested for various methods of ACL reconstruction. The hope was to find an equivalent to available autografts that would avoid graft harvest morbidity and shorten operation time. However, improved results using autografts and disappointing results with reports of an increased risk of foreign-body reactions, re-ruptures,

tunnel widening through osteolysis, chronic synovitis and poor incorporation of the synthetics into host bone (34, 35) saw the end of synthetics in ACL reconstruction at the end of the 1980s. Something Ejnar Eriksson suspected back in 1976 when stating that he preferred an autograft, as he was not convinced that any of the artificial ligaments had the same biomechanical properties as the native ligaments of the knee (36).

8.5.4 Quadriceps tendon

In 1979, Marshall et al. described the use of the QT for ACL reconstruction (37). Five years later, Walter Blauth reported his technique for harvesting the QT with a patellar bone block (38). Despite experimental studies confirming its excellent mechanical properties as a tendon graft (39), the QT has never gained the same level of popularity as the PT or the HT. Today,

it remains less studied and less used compared with the PT and the HT, even if it is most probably gaining more ground. With or without a bone block, it is a versatile and very suitable graft choice and, according to a recent systematic review, there is support in the current literature for using the QT as a graft for ACL reconstructions (40).



FIGURE 10
Picture of a quadriceps tendon graft prepared for ACL reconstruction.

8.5.5 Patellar tendon

Langworthy is reported to have been the first surgeon to replace the ACL using part of the PT in 1927 (4). Through the decades, it has been a popular graft for ACL reconstruction and has been used as a free tendon graft or with bone plugs. However, after Franke's publication in 1976 (41) on the clinical long-term results with a free bone-PT-bone graft, it became one of the most popular graft sources and has

remained so ever since. Its main advantage is that it has bone plugs on both ends of the graft, which should facilitate healing. In addition, it is easy pre-operatively to assess the thickness of the graft using MRI. One of the concerns in relation to PT harvest is the anterior knee sensory deficit that follows after iatrogenic injury to the infrapatellar nerve branch. Moreover, the risk of patellar fracture and secondary problems of

patellar tendinitis, pain on kneeling, residual flexion contracture and anterior knee

pain are at least a potential problem, but it appears that it decreases with time (42).



FIGURE 11
Picture of a patellar tendon graft prepared for ACL reconstruction.

8.5.6 Hamstring tendons

The PT graft was the gold standard for a long time. However, for reasons relating to frequent secondary pain problems, mainly anterior knee pain, several surgeons gradually moved towards the HT. Before becoming a now widely used technique, many surgeons had previously used this graft. The first descriptions are attributable to R Galeazzi in 1934 and H Macey in 1939, using the semitendinosus and gracilis tendons (43). While HT grafts have been the dominant graft source in primary ACL reconstruction in Sweden for many years and rose from 80% in 2005 to 98% in 2012, their use during the past two years has declined

to some degree in favour of the PT and QT grafts (18). Even if studies have confirmed that soft tissue-to-bone has a longer healing time than bone-to-bone, it is unclear whether this has any effect in clinical studies. Moreover, biomechanical studies have shown that the quadrupled HT graft is not only stronger than the PT graft, 4,590 N compared with 2,977 N, it is also stiffer, 861 N/mm compared with 620 N/mm (44). In spite of this, there are concerns in terms of the reduced flexion strength in the knee, even if retaining the gracilis and only using the semitendinosus (triple or quadruple ST graft) might reduce this problem.



FIGURE 12

Picture of a quadruple semitendinosus and gracilis tendon graft prepared for ACL reconstruction.

8.6 GRAFT FAILURE

Graft failure or insufficiency of the reconstructed ACL graft is difficult to define and definitions differ between studies. However, graft failure must be considered when a patient reports functional instability in sports or activities of daily living, a reduced frequency or level of athletic activity with respect to pre-injury status, increased pain, loss of motion, recurrent episodes of giving way, increased pathological anterior laxity on physical examination with a positive Lachman or pivot shift test and a side-to-side difference of more than 5 mm on arthrometric testing (45). There are many factors that can lead to graft failure and possible revision surgery. They include trauma/re-injury, technical and "biological" failure.

Re-injury may occur shortly after the initial surgery, before graft incorporation, due to an overly aggressive physiotherapy program during the early rehabilitation period. Or it may occur later, in case of traumatic re-injury, often in athletic individuals. According to the Danish ACL register, re-injury (36.2%) is the main reason for revision (46).

Technical failure is frequently implicated in revision cases, up to 77% (47) in one series. Specific reasons for technical failure include non-anatomic tunnel placement, graft impingement, inappropriate graft tensioning, graft fixation failure, insufficient graft size, incorrect graft selection between autograft, allograft and occasionally synthetic graft and laxity of secondary restraints (48).

The failure of graft incorporation and ligamentisation is commonly referred to as the "biological failure" of the graft. This definition lacks precision and is more a diagnosis established by the exclusion of re-injury and in the presence of no detectable technical errors. "Biological failure" is a complex pathological entity not completely understood, with reasons including factors such as graft necrosis, the impairment of revascularisation because of over-tensioning of the graft or patient factors such as smoking and diabetes, the lack of cellular repopulation and proliferation caused by hypoxia and limited growth factor production, inappropriate collagen remodelling and ligamentisation, immunological reaction and stress shielding with the right magnitude of post-operative load (48).

In addition to previously mentioned reasons, individual patient factors such as healing potential and compliance undoubtedly play a role in graft failure.

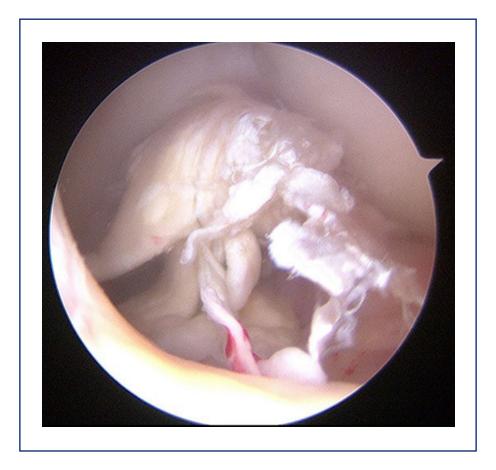


FIGURE 13

Arthroscopic image of the right knee showing a graft rupture following a knee injury two years after a single-bundle ACL reconstruction using a hamstring tendon graft.

8.7 PATIENT-REPORTED OUTCOME MEASURES

A patient-reported outcome measure is any report coming directly from patients about how they function or feel in relation to a health condition and its therapy, without any interpretation of the patient's responses by a clinician, or anyone else. PROMs include any treatment or outcome evaluation obtained directly from patients through interviews, self-completed questionnaires, diaries or other data collection tools such as

hand-held devices and web-based forms (49).

PROMs provide patients' perspective on treatment benefit, directly measure treatment benefit beyond survival, disease and physiological markers and are often the outcomes of greatest importance to patients (49).

PROMs are sometimes used as primary outcomes in clinical trials, particularly

when no surrogate measurement of direct benefit is available to capture the patient's well-being. More often, PROMs complement primary outcomes such as survival, disease indicators, clinician ratings and physiological measurements (49).

8.8 OSTEOARTHRITIS AFTER ACL INJURY

An ACL injury is often associated with functional impairments and disabilities, with the subsequent development of post-traumatic knee OA. The most frequently reported risk factors in previous studies are meniscal injury and meniscectomy. Other risk factors, such as chondral lesions, high BMI, < 90% on a single-leghop test compared with the uninjured side one year after surgery, loss of extension, knee joint laxity, higher age, more than six months between injury and surgery, a high level of sports activity and OA of the contralateral knee, have also been reported (Figure 14) (50). No previous studies have shown that an ACL reconstruction prevents the development of knee OA (51, 52).

The reported prevalence of OA after ACL injury ranges from 1-100%, according to a systematic review by Oiestad et al. (50) including 31 studies. However, according to the highest rated studies in the study, the prevalence of OA is lower for individuals with isolated ACL injury (0-13%) and higher for patients with combined injuries (21-48%). The high variation in prevalence can be explained in part by the fact that there are many different radiographic classification systems, each with a different cut-off to define the presence of knee OA, and there is no gold standard for the radiological assessment of knee OA. Numerous classifications have been proposed, of which Fairbank (53), Kellgren and Lawrence (54), Ahlbäck (55), the IKDC (56) and the Osteoarthritis Research Society International (OARSI) classification system (57) are some of the more commonly used. The radiographic abnormalities most frequently used to define joint pathology in these classification systems are joint space narrowing, osteophytes and/or subchondral sclerosis.

In 1948, Fairbank presented a grading system, which is still in use (53). The classification was originally proposed for the documentation of radiological changes after meniscectomy and relates primarily to mild degenerative changes. The anteroposterior view is used and one point is given for flattening (F) of the femoral condyles, one point for ridge (R) formation and one point for joint space narrowing (N) (Figure 15). Three is the maximum score for each compartment, with a maximum of a total of six points for the tibiofemoral joint. In 1957, Kellgren and Lawrence (54) introduced a radiographic classification, followed by an OA grading system for the knee presented by Kellgren alone in 1963 (58). In 1968, Ahlbäck (55) proposed a grading system for OA in the knee from stages with joint narrowing to severe re-modelling of the bone (Table 1).



FIGURE 14
Plain weight-bearing radiograph of the left knee after ACL reconstruction, showing osteoarthritic changes predominantly in the lateral compartment.



Plain weight-bearing radiograph of the right knee with osteoarthritic changes described according to the Fairbank classification. Narrowing (N) of the medial compartment, flattening (F) of the tibial surface and ridging (R) of the lateral and medial femoral condyle. © Sven Stener

| TABLE 1. Ahlbäck and Kellgren & Lawrence radiographic classifications of osteoarthritis | | | | | | |
|---|-----------------------------------|---------------------|---|--|--|--|
| | Ahlbäck | Kellgren & Lawrence | | | | |
| Grade | Radiographic findings | Grade | Radiographic findings | | | |
| 1 | JSN < 50% | 0 | No features of OA present | | | |
| 2 | Joint space obliteration | 1 | Doubtful JSN and possible osteophytic lipping | | | |
| 3 | Minor bone attrition (0-5 mm) | 2 | Possible JSN and definite osteophyte formation | | | |
| 4 | Moderate bone attrition (5-10 mm) | 3 | Definite JSN, multiple osteophytes, sclerosis and possible bony deformity | | | |
| 5 | Severe bone attrition (> 10 mm) | 4 | Marked JSN, large osteophytes, severe sclerosis and definite bony deformity | | | |
| JSN, joint space narrowing | | | | | | |

In recent years, the IKDC and the OARSI classification system have been introduced. Both have recommended an evaluation system based on four grades. The IKDC (56) has similarities to Ahlbäck's classification but focuses more on minor changes (Table 2).

| TABLE 2. IKDC radiographic classification of osteoarthritis | | | | |
|---|---|--|--|--|
| Grade | Radiographic findings | | | |
| Α | Normal | | | |
| В | Minimal changes and barely detectable joint space narrowing | | | |
| С | Minimal changes and joint space narrowing up to 50% | | | |
| D | More than 50% joint space narrowing | | | |
| IKDC, International Knee Documentation Committee | | | | |

In an attempt to increase the usefulness of the plain radiograph as an assessment tool, the OARSI (57) developed a radiographic atlas in 1996 for use as a guide in the evaluation of OA. In 2007, the original atlas was replaced with a new one that was intended to provide better quality images with the ability to access electronic imag-

es. It includes radiographic features (e.g. osteophytes, joint space narrowing) of the medial and lateral compartments and they are sequenced for normal (0), mild (1+), moderate (2+) and severe (3+) changes. Moreover, an evaluation of attrition and sclerosis is performed (Table 3).

| TABLE 3. OARSI radiographic classification of osteoarthritis of the knee | | | | |
|--|--|--|--|--|
| Marginal osteophytes | Medial femoral condyle (0 - 3+) | | | |
| | Medial tibial plateau (0 - 3+) | | | |
| | Lateral femoral condyle (0 - 3+) | | | |
| | Lateral tibial plateau (0 - 3+) | | | |
| | Medial compartment (0 - 3+) | | | |
| Joint space narrowing | Lateral compartment (0 - 3+) | | | |
| | Medial tibial attrition (absent/present) | | | |
| Other | Medial tibial sclerosis (absent/present) | | | |
| | Lateral femoral sclerosis (absent/present) | | | |
| OARSI, Osteoarthritis Research Society International | | | | |





09 AIMS

Study I

To describe the current evidence from clinical studies comparing single- and double-bundle ACL reconstruction, in terms of differences in graft failure, knee kinematics, functional outcomes and patient-reported outcome measures

Study II

To compare revision rates and patient-reported outcome measures between single- and double-bundle ACL reconstruction in the Swedish National Knee Ligament Register

Study III

To identify predictors of ACL revision surgery after failed primary ACL reconstruction

Study IV

To compare the results after an ACL reconstruction using an HT or PT autograft in terms of patient-reported outcome measures, functional outcomes, graft failure, clinical evaluation including knee laxity measurements and radiographic evaluation





10 PATIENTS

Study I

In the 60 studies included, the total number of patients was 4,146: 2,072 of them were operated on using single-bundle and 2,074 using double-bundle ACL reconstruction (Table 4). Anatomic reconstruction was performed on 1,177 patients in 18 of the 60 studies and 2,969 patients underwent non-anatomic reconstruction in 42 studies.

All the included patients had a primary isolated ACL rupture (no collateral or posterior cruciate ligament injuries) and underwent either a single- or double-bundle ACL reconstruction. Only skeletally mature patients were eligible for inclusion.

| TABLE 4. Number of patients for every outcome measurement | | | | | | |
|---|------------------------------|----------------------------------|------------------|--|--|--|
| Ou | Total number of studies | Total number of patients (SB/DB) | | | | |
| | Lachman | 17 | 1097 (597/500) | | | |
| | Anterior drawer | 9 | 725 (394/331) | | | |
| 1 26 | KT-1000/2000 | 40 | 3291 (1643/1648) | | | |
| Laxity | AP laxity using navigation | 17 | 815 (386/429) | | | |
| | Pivot shift | 42 | 3102 (1568/1534) | | | |
| | Quantified rotatory laxity | 20 | 829 (401/428) | | | |
| | IKDC | 35 | 2968 (1477/1491) | | | |
| | KOOS | 3 | 202 (88/114) | | | |
| | Lysholm score | 31 | 2443 (1234/1209) | | | |
| | Tegner activity level scale | 19 | 1187 (640/547) | | | |
| | Marx activity rating scale | 2 | 132 (65/67) | | | |
| Patient-reported outcome measures | Cincinnati Knee Score | 3 | 187(93/94) | | | |
| | WOMAC | 1 | 92 (41/51) | | | |
| | VAS | 2 | 124 (63/61) | | | |
| | Subjective recovery score | 2 | 203 (90/113) | | | |
| | OAK | 1 | 113 (50/63) | | | |
| | Hospital for Special score | 1 | 61 (32/29) | | | |
| | Muscle strength | 10 | 1026 (497/529) | | | |
| | ROM | 32 | 2616 (1290/1326) | | | |
| | Graft failure | 23 | 1961 (946/1015) | | | |
| | Thigh circumference/diameter | 5 | 452 (207/245) | | | |
| | One-leg-hop test | 3 | 164 (86/78) | | | |
| | Pain | 4 | 368 (170/198) | | | |
| Other | Sports activity | 9 | 544 (267/277) | | | |
| Omer | Osteoarthritic changes | 5 | 385 (212/173) | | | |
| | Radiographic changes | 5 | 383 (168/215) | | | |
| | Joint position sense | 1 | 108 (55/53) | | | |
| | SF-36 | 1 | 52 (23/29) | | | |
| | Bone mineral density | 1 | 52 (35/17) | | | |
| | Femoral graft bending angle | 1 | 49 (20/29) | | | |
| | Tunnel length | 1 | 49 (20/29) | | | |

Study II

On 31 December 2011, a total of 22,740 unique registrations had been included in the Swedish National Knee Ligament Register (Figure 16). Of these, 4,338 were excluded because of concomitant fractures, medial/lateral collateral ligament, posterior

cruciate ligament, nerve, vessel (circulatory) or tendon injuries. Only HT autografts were included, thereby excluding 1,611 patients who were operated on with other grafts (Table 5). This left 16,791 primary ACL reconstructions, of which 16,281 were single-bundle and 510 were double-bundle.

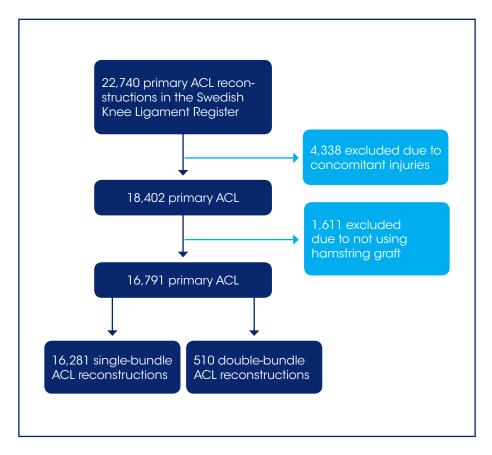


FIGURE 16

Flow diagram of included and excluded primary anterior cruciate ligament reconstructions for Study II

| TABLE 5. Inclusion and exclusion criteria | | | | |
|---|---|--|--|--|
| | Primary anterior cruciate ligament reconstruction | | | |
| Inclusion criteria | Single- or double-bundle | | | |
| | Hamstring tendon autograft | | | |
| | Allograft | | | |
| | Patella or quadriceps tendon autograft | | | |
| | Concomitant fracture | | | |
| Exclusion criteria | Posterior cruciate ligament injury | | | |
| | Medial or lateral collateral ligament injury | | | |
| | Nerve or vessel injury | | | |
| | Patella, quadriceps or hamstring injury | | | |

The mean age of the patients undergoing surgery with a single-bundle reconstruction was 26 years (±9.8) and the male:female ratio was 56.5:43.5 (Table 6). The patients

that were reconstructed with a double-bundle had a mean age of 28 years (±9.9) and the male:female ratio was 62.4:37.6.

| TABLE 6. Demographic data and characteristics of study samples (n = 16,791) | | | | | |
|---|---------|--------------------------|-----------------------|---------|--|
| | | SB group (n = 16,281) | DB group (n = 510) | P-value | |
| Mean age, y (SD) | | 26 ±9.8 | 28 ±9.9 | 0.005 | |
| Gender, n | Male | 9,200 (56.5%) | 318 (62.4%) | 0.009 | |
| Gender, n | Female | 7,081 (43.5%) | 192 (37.6%) | | |
| Cido a | Right | 8,426 (51.7%) | 268 (52.5%) | 0.732 | |
| Side, n | Left | 7,847 (48.2%) | 242 (47.5%) | | |
| Mean height, cm (SD) | | 175 ±9.0 | 175 ±8.4 | 0.076 | |
| Mean weight, kg (SD) | | 75 ±14.1 | 78 ±12.5 | 0.001 | |
| Maniagaliaium | Medial | 4,216 (25.9%) | 172 (33.7%) | <0.001 | |
| Meniscal injury, n | Lateral | 3,671 (22.5%) | 126 (24.7%) | 0.251 | |
| Cartilage injury, n | | 4,342 (26.7%) | 141 (27.6%) | 0.623 | |
| SB, single-bundle; DB, double-bundle; y, years; SD, standard deviation | | | | | |

Study III

Seven hundred and ninety-seven potential subjects were identified by medical records, of which 494 could be located and contacted. Two hundred and fifty-one of them, 139 females and 112 males, were included (Figure 17). The included patients underwent a primary ACL reconstruction

between 1 January 2007 and 30 April 2011, at the University of Pittsburgh Medial Center. Patients between 14 and 50 years of age at the time of surgery with concomitant meniscus, ligament, or cartilage injury were included. All subjects with a prior knee injury or surgery on either knee were excluded.

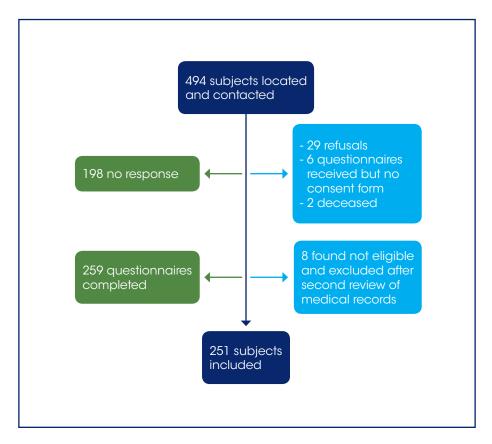


FIGURE 17
Flow diagram of subjects' recruitment process for Study III

The mean age of the included patients at the time of surgery was 26.1 ± 9.9 years and their mean length of follow-up was 3.4 ± 1.3 years (Table 7). The non-responders

were younger (21.1 \pm 8.3 years) than those who responded (p<0.001) and more likely to be males (60% male vs. 40% female) (p<0.001).

| TABLE 7. Demographic data and characteristics of study samples (n = 251) | | | | | | |
|--|--------------------------------------|-------------|--|--|--|--|
| Mean age at time of surgery, y (SD) 26.1 ±9.9 | | | | | | |
| | ≤ 18 years | 78 (31.1%) | | | | |
| Age at the time of surgery, n | 19-23 years | 55 (21.9%) | | | | |
| | ≥ 24 years | 118 (47.0%) | | | | |
| Canadan | Male | 112 (44.6%) | | | | |
| Gender, n | Female | 139 (55.4%) | | | | |
| Time from initime to aureone n | < 6 months | 210 (83.7%) | | | | |
| Time from injury to surgery, n | ≥ 6 months | 41 (16.3%) | | | | |
| Perceline activity level a | Competitive | 147 (58.6%) | | | | |
| Baseline activity level, n | Other | 104 (41.4%) | | | | |
| | Autograft | 131 (52.2%) | | | | |
| Graft type, n | Allograft | 110 (43.8%) | | | | |
| | Mixed | 10 (4.0%) | | | | |
| Curaical technique n | Single-bundle | 196 (78.1%) | | | | |
| Surgical technique, n | Double-bundle | 55 (21.9%) | | | | |
| Dati un ta anarta n | Yes | 209 (83.3%) | | | | |
| Return to sports, n | No | 42 (16.7%) | | | | |
| Length of follow-up, y (SD) | Length of follow-up, y (SD) 3.4 ±1.3 | | | | | |
| y, years; SD, standard deviation | | | | | | |

Study IV

This long-term multicentre study consists of two previous randomised trials including patients who had sustained a unilateral ACL rupture and had undergone arthroscopic ACL reconstruction using either an ipsilateral HT or a PT autograft (1, 2). The reconstructions were performed between September 1995 and January 2000 and 193 patients with an isolated ACL rupture with or without additional minor meniscal or chondral lesions (Outerbridge grade I and II) were included. The exclusion criteria were multi-ligament injuries, previous ACL reconstruction and gross meniscal or chondral lesions that mandated surgical intervention. The patients were randomised pre-operatively with non-transparent white sealed envelopes to ACL reconstruction with an ipsilateral triple semitendinosus

(ST) tendon autograft, an ipsilateral quadruple ST tendon autograft, an ipsilateral quadruple semitendinosus and gracilis (ST/G) tendon autograft or an ipsilateral patellar tendon (PT) autograft (Figure 18). The reconstructions were performed by six experienced ACL surgeons with well-documented experience of ACL reconstruction at three different centres.

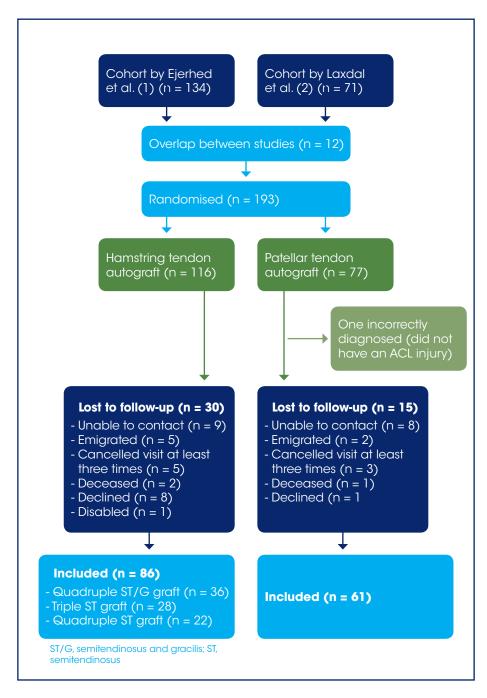


FIGURE 18

Flow diagram of included patients for Study IV

One hundred and forty-seven (76%) patients were examined at the long-term follow-up; 61 patients in the PT group (19 females and 42 males) and 86 patients in the HT (33 females and 53 males). The mean follow-up time was 191.9 ± 15.1 months for the HT group and 202.6 ± 10.4 months for

the PT group, with a significantly shorter mean follow-up time for the HT autograft group (p<0.001). Both groups were similar in terms of gender, age at the time of surgery, time between the index injury and surgery and the number and type of associated injuries (Table 8).

| TABLE 8. Demographic data and characteristics of study samples (n = 147) | | | | | | |
|---|--------|----------------------|----------------------|---------|--|--|
| | | PT group (n = 61) | HT group (n = 86) | P-value | | |
| Mean age at surgery, y (SD) | | 28.2 ±9.1 | 26.8 ±7.6 | 0.54 | | |
| Mean age at follow-up, y (SD) 44.7 ±9.1 42.3 ±7.8 0.17 | | | | | | |
| Gender, n | Male | 42 (68.9%) | 53 (61.6%) | 0.37 | | |
| Gender, n | Female | 19 (31.1%) | 33 (38.4%) | | | |
| Mean time injury to surgery, m (SD) | | 29.9 ±46.9 | 38.1 ±60.4 | 0.48 | | |
| Associated meniscal/chondral lesions, n 39 (63.9%) 58 (67.4%) 0.59 | | | | | | |
| Length of follow-up, m (SD) 202.6 ± 10.4 191.9 ± 15.1 < 0.001 | | | | | | |
| PT, patellar tendon; HT, hamstring tendon; y, years; m, months; SD, standard deviation; n.s., not significant | | | | | | |



METHODS

11.1 SYSTEMATIC REVIEW (STUDY I)

The systematic review (Study I) was conducted according to the PRISMA guidelines (59) that were developed to improve the reporting of systematic reviews. The PRISMA statement consists of a 27-item

checklist and a four-phase flow diagram. The checklist includes items deemed essential for the transparent reporting of a systematic review.

11.1.1 Terminology

The Cochrane Collaboration defines a systematic review as "a review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research and to

collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies" (60).

11.1.2 Eligibility criteria

Most often, systematic reviews only include RCTs, but sometimes the question of interest demands the inclusion of non-RCTs. The format and basic steps of the process are nevertheless the same, even if special assessments of study design and potential biases are recommended. Study

I included RCTs, PCSs and RCSs that compared single- and double-bundle ACL reconstruction on primary isolated ACL rupture. All the studies that were categorised as therapeutic with clinical outcome measurements related to the reconstruction were included.

11.1.3 Information sources and search

One of the key characteristics of a systematic review is that it attempts to identify all the studies that meet the eligibility criteria. In Study I, a systematic electronic search was performed using PubMed (MED-LINE), EMBASE and the Cochrane Library. Studies that were published in

the English language from January 1995 to August 2011 were included from all three databases and an updated search was performed in July 2012 solely in PubMed. Two experts in electronic search methods at the Sahlgrenska University Hospital Library executed and validated the search.

11.1.4 Data collection and analysis

Study selection

Systematic reviews aim to minimise bias by using explicit, systematic methods. For this reason, three researchers sorted the studies based on the abstracts and full text when necessary. Each reviewer sorted one database, which was in turn validated twice by the other researchers. The included studies were sorted into study types as proposed by the Oxford Centre for Evidence-Based Medicine (www.cebm.net) and into the categories of single-bundle, double-bundle or single-bundle versus double-bundle recon-

struction. Only studies comparing singleand double-bundle ACL reconstruction were included in this systematic review. The study was then processed in full text if the abstract did not provide enough data to make a decision. The analysis was not performed in a blinded fashion. Disagreement between the reviewers was resolved by consensus or by discussion with the senior author when consensus was not reached.

Data collection process

The first two authors separately extracted data from all the included papers. Disagreements in terms of data extraction or assessments were resolved by discussion with the senior author when necessary.

The obtained data included surgical details, clinical tests, patient-reported outcome measures and other outcomes. Only descriptions of significant and non-significant findings relating to these tests and outcomes were presented (Table 9).

| TABLE 9. Data items obtained from included studies | | | | | | |
|--|---------------------------------|------------------------------------|-----------------------------------|-----------------------------|--|--|
| Article-related items | Surgical details | Clinical tests | Patient-reported outcome measures | Other outcomes | | |
| Author | Type of procedure | Lachman test | IKDC | Cincinnati Knee Score | | |
| Year of publication | Drilling technique | Anterior drawer test | KOOS | Muscle strength | | |
| Title | Knee flexion during drilling | KT-1000/2000 arthrometer | Lysholm score | ROM | | |
| Journal | Tunnel placement on femur | Pivot shift test | Tegner scale | Thigh circumfer- ence | | |
| Volume | Tunnel placement on tibia | Rotational laxity using navigation | Marx scale | One-leg-hop test | | |
| Issue | Fixation angle | AP laxity using navigation | WOMAC | Pain | | |
| Pages | Graft type | | VAS for pain | Graft failure | | |
| ISSN | Fixation method | | Subjective recovery score | Sports activity | | |
| DOI | | | Hospital for Special Surgery | Radiographic changes | | |
| Abstract | | | OAK score | Joint position sense | | |
| Author's address | | | | Kinematics | | |
| Database provider | | | | SF-36 | | |
| Category | | | | Bone mineral density | | |
| Study type | | | | Femoral graft bending angle | | |
| Level of evidence | | | | Tunnel length | | |
| Country | | | | | | |
| Sample size | | | | | | |
| Follow-up time | | | | | | |

ISSN, International Standard Serial Number; DOI, Digital Object Identifier; AP, anteroposterior; IKDC, International Knee Documentation Committee; KOOS, Knee Osteoarthritis Outcome Score; WOMAC, Western Ontario and McMaster Universities Arthritis Index; VAS, Visual Analogue Scale; OAK, Orthopadische Arbeitsgruppe Knie Score; ROM, range of motion; SF-36, Short Form Health Survey

Synthesis of results

Greater heterogeneity can be expected in systematic reviews including non-RCTs due to the increased potential for methodological diversity. A statistical analysis of the data in Study I, for the purpose of a meta-analysis, was not possible due to the heterogeneity in surgical technique, study design and populations in the included studies. Instead, a best evidence synthesis approach was used; this is a method that combines the strengths of meta-analyses and traditional reviews. It incorporates the quantification and systematic literature search methods of meta-analysis with the detailed analysis of critical issues and study characteristics of the best traditional reviews in an attempt to provide a thorough and unbiased means of synthesising research and providing clear and useful conclusions (61).

Assessment of risk of bias

One of the key characteristics of a systematic review is that it assesses the validity of the findings of the included studies, through an assessment of risk of bias, for example. Several tools for assessing the quality of studies are available, both scales (which score the

studies) and checklists (which assess studies without producing a score).

Since the Cochrane Collaboration explicitly discourages the use of scales, the Cochrane Collaboration's tool for assessing the risk of bias in randomised trials was chosen (62). It was adapted and applied not only to the RCTs but also to the PCSs and RCSs, as it has a comprehensive approach to assessing the potential for bias and transparency and explicitly targets the risk of bias rather than the reported characteristics of the trial.

The assessment tool covers six domains of bias: selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias. An independent judgement, by the first two authors, of high, low or unclear risk of bias was made within each domain. If insufficient details were reported on what was done in the study, a judgement of unclear risk was made. If what was done was clearly stated, a judgement of high or low risk was made. Any discrepancies were resolved by consensus or by discussion with the senior author if consensus was not reached.

11.2 GRAFT FAILURE

There have been many different definitions of what counts as a graft failure after an ACL reconstruction. Different objective and subjective variables have been used to determine what constitutes an unsatisfactory result, including increased pain, reduced motion, recurrent episodes of instability, reduced level of athletic activity, a positive Lachman or pivot shift test, a side-to-side difference of more than 5 mm on arthrometric testing (e.g. KT-1000 or similar equipment) or MRI.

Study I

Only a few of the included studies stated how they defined graft failure and the majority of the studies only stated the total number of graft failures. Kondo et al. (63) defined graft failure as anterior laxity of > 5 mm. Soumalainen et al. (64) diagnosed graft failure on MRI performed at follow-up. Asagumo et al. (65) performed second-look arthroscopy one year post-operatively and there were five cases showing PL bundle rupture. Kim et al. (66) wrote

that one patient underwent revision because of "grade 2" instability without new injury and Sadoghi et al. (67) reported two "grade 3" graft failures, as a result of a new trauma in sports.

Study II

The primary end-point in Study II was graft failure, which was defined as an ACL revision.

Study III

The primary end-point in Study III was

graft failure, which, in this study, was determined by asking subjects to report ACL revision surgery. A report of ACL revision surgery was confirmed by evaluating the subject's medical records.

Study IV

One of the end-points in Study IV was graft failure, which was defined as an ACL revision. A report of ACL revision surgery was confirmed by evaluating the subject's medical records.

11.3 PATIENT-REPORTED OUTCOME MEASURES

11.3.1 EuroQol 5-dimensions

Health status and quality-of-life outcomes are an important category of PROMs. Different types of instrument are available for measuring health status and quality of life. The EQ-5D questionnaire is a generic (non-disease-specific) instrument for measuring health-related quality of life, developed by a group of European researchers, and it has been validated and tested for reliability (68, 69). It consists of five questions relating to five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each with three different answer levels (no prob-

lems, moderate problems and severe problems), plus a 20 cm vertical visual analogue scale(10). An index value is calculated from these five dimensions, giving a score that ranges from -0.594 (worse than death) through 0 (worst possible health status) to 1 (best possible health status), whereas the VAS is a scale ranging from 0 (worst) to 100 (best) (70). The total index is computed using a regional tariff to adjust for cultural differences. Sweden uses the British tariff, which has been shown to be valid for the Swedish population (71).

11.3.2 The International Knee Documentation Committee

The IKDC was developed in 1987 to report a standardised international documentation system for knee conditions. The IKDC Standard Knee Evaluation Form, which was designed for knee ligament injuries, was subsequently published in 1993 (56) and revised in 1994 (72). The IKDC Subjective Knee Evaluation Form was developed as a revision of the Standard Knee Evaluation

Form in 1997 and has subsequently undergone minor revisions since its publications in 2001 (73). The revised version of the Subjective Knee Form can be used to assess various knee conditions (72). More recently, it has been shown to be significantly associated with patient satisfaction after ACL reconstruction (74) and it has been validated and tested for reliability (73).

The IKDC Subjective Knee Form consists of 18 questions in the domains of symptoms (7 items), functioning during activity of daily living (9 items) and sports participation (1 item) and current function of the knee (1 item) (72).

The score is calculated as (sum of items)/ (maximum possible score) x 100. The possible score range is 0-100, where 100 means no limitation in daily or sporting activities and the absence of symptoms (73).

11.3.3 Knee injury and Osteoarthritis Outcome Score

The KOOS questionnaire was developed in the 1990s and is a knee-specific score. It was originally developed as an extension of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (75) and is an instrument to assess the patient's opinion of his/her knee and associated problems at short- and long-term follow-up (one week to decades). The intention is to evaluate knee injuries in young and middle-aged people that can result in post-traumatic osteoarthritis (OA), such as ACL injuries. The KOOS consists of five subscales; Pain (9 items), Other (7 items), Function in daily living (ADL) (17 items), Function in sport and recreation (Sport/ Rec) (5 items) and knee-related Quality of life (OoL) (4 items). Each subscale is graded from 0 (extreme knee problems) to

100 (no knee problems) (76). The subscales are scored separately and a total score has not been validated and is not recommended. The KOOS fulfils the desired criteria for research outcomes, demonstrating adequate reliability for use in groups and validity when used in those with knee injuries and knee OA (73).

The KOOS4 is an average score of four KOOS subscales, in which ADL is excluded to avoid any ceiling effects, because relatively young and active patients, like most ACL-injured patients, rarely have difficulties with ADL. The KOOS user's guide recommends that incomplete questionnaires are regarded as invalid and are therefore not included (77).

11.3.4 Lysholm knee scoring scale

The Lysholm rating system was developed by Lysholm and Gillqvist and was originally presented in 1982 (79). However, the version that is currently used was published in 1985 by Tegner and Lysholm (78). It evaluates outcomes of knee ligament surgery, particularly symptoms of instability, and consists of eight different items. The items are scored differently (limp 5, support 5, locking 15, instability 25, pain 25, swelling 10, stair climbing 10 and squatting 5), with the score ranging from 0-100 (no symptoms or disability). The scores are

categorised as excellent (95-100), good (84-94), fair (65-83) and poor (≤64) (73).

11.3.5 Tegner activity level scale

The Tegner activity rating system was developed by Tegner and Lysholm as a measurement of activity level (78). It was first presented in 1985. The rating system scores a person's activity level between 0 and 10,

where 0 is "sick leave or disability pension because of knee problems" and 10 is "participation in competitive sports such as soccer at national or international elite level".

11.3.6 Other tests

The Marx activity rating scale was introduced by Marx et al.(79) in 2001. Unlike the Tegner activity level scale, which is based on participation in specific work and sports activities, the activity level of the Marx activity rating scale is determined by measuring components of physical function (running, cutting, deceleration, pivoting) that are common to most sporting activities.

The Western Ontario and McMaster Universities Osteoarthritis Index (80) was developed in 1982 to evaluate patients with OA of the knee and hip, but it has since undergone several revisions and modifications. It is self-administered and involves 24 questions; five relating to pain, two relating to stiffness and 17 relating to difficulty with activities of daily living. It is a valid, reliable and responsive measurement of outcome.

Subjective recovery scores are reported twice in Study I. Both studies were performed by Muneta et al. (81, 82) and the score was developed by them. It is based on an analogue scale indicating the patient's assessment of the percentage of overall recovery of his/her operated limb at follow-up

in comparison with his/her un-operated healthy contralateral limb (83).

The first version of the Cincinnati knee rating system was published by Noyes et al. in 1983 (84, 85), with additional scales and modifications subsequently described for occupational activities, athletic activities, symptoms and functional limitations in sports and daily activities (86-88). The goal when developing the additional scales and overall rating scheme was to generate an assessment instrument that could be used to determine the clinical outcome of many different knee operations. Accordingly, the Cincinnati knee rating system is not strictly a PROM, as it is a combination of PROMs and clinical outcomes. The overall rating score is calculated on a 0- to 100-point scale. A maximum of 20 points is possible for rating symptoms; 15 points, for daily function and sports activities; 25 points, for the physical examination (knee effusion, range of motion, tibiofemoral and patellofemoral crepitus); 20 points, for the knee stability tests (arthrometer and pivot shift); 10 points, for radiographic findings; and 10 points, for functional testing (89).

11.4 CLINICAL EXAMINATIONS

In Study IV, a research associate performed all the long-term follow-up assessments and independent physiotherapists performed the pre-operative assessments. None of them had been involved in the surgery or rehabilitation of the patients. A special protocol was developed for the pre-operative clinical evaluations, which was also used at

the follow-up (Appendix 1).

11.4.1 Lachman test

The Lachman test is the most sensitive test for diagnosing an acute, complete ACL rupture both in the office setting and under (92). The original description was submitted by J.S. Torg (90) and, in appreciation of his mentor, J Lachman, he called it the Lachman test and popularised its value in assessing ACL integrity (4).

With the patient supine, the knee is flexed 20-30°. The examiner stabilises the femur

with one hand and attempts to translate the tibia anteriorly with the other hand. An intact ACL prevents forward translation and a "firm" end-point is felt, while an ACL deficient knee will demonstrate an increased forward translation and a "soft end-point".

The Lachman test was graded as +1 (<5 mm), +2 (5-10 mm) or +3 (>10 mm), compared with the uninjured contralateral knee.

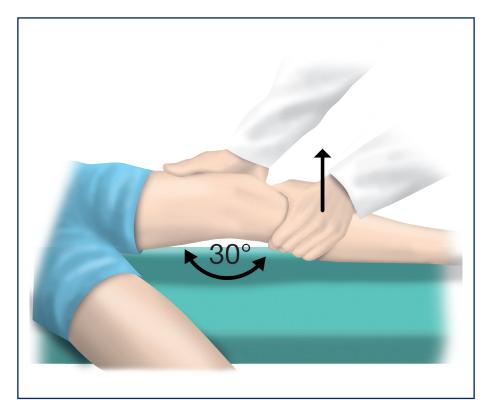


FIGURE 19

The manual Lachman test.

11.4.2 Anterior drawer test

The patient is supine with the hips flexed to 45°, the knees flexed to 90° and the feet flat on the table. The examiner grasps the tibia just below the joint line of the knee and draws it forward. An increased amount of anterior tibial translation compared with

the opposite limb or the lack of a "firm" end-point indicates an ACL injury.

The anterior drawer test is graded as +1 (<5 mm), +2 (5-10 mm) or +3 (>10 mm), compared with the uninjured contralateral knee.

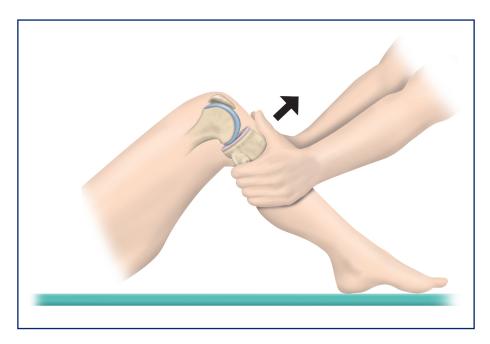


FIGURE 20

The anterior drawer test.

11.4.3 Pivot shift test

The pivot shift test is the most specific test to establish the diagnosis of an ACL injury (91). It evaluates a combination of translational and rotatory laxity and replicates the typical "giving-way" that patients with an ACL injured knee can experience.

The test is performed with the patient supine with the hip passively flexed to 30°.

The lower leg and ankle is grasped, maintaining 20° of internal tibial rotation with the knee extended. While maintaining the internal rotation, a valgus force is applied to the knee while it is slowly flexed. During flexion, the lateral compartment of the knee will go from subluxation and relocate and it is the relocation that can be felt.

The pathological motion during the pivot shift is graded by the examiner as a negative, glide (grade I), clunk (grade II), or gross (grade III).

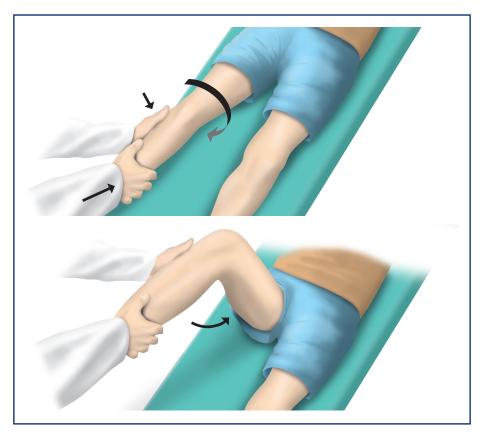


FIGURE 21
The pivot shift test. First, the extended starting position and, second, the flexed end position.

11.4.4 Range of motion

The studies included in Study I presented range of motion (ROM) in several different ways; total ROM, extension and flexion deficit, difference in maximum extension and flexion angle of the knee and heel-height difference.

In Study IV, the ROM was measured with the patient supine using a hand-held

goniometer (95). Full active extension and flexion were measured on both legs, first on the uninjured leg, after which the side-to-side difference was calculated. If the side-to-side difference was $\geq 5^\circ$, the patients were classified as having an extension or flexion deficit.

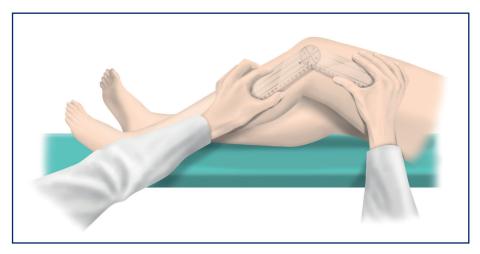


FIGURE 22Range of motion measured using a goniometer.

11.4.5 Loss of skin sensitivity

Loss of skin sensitivity was evaluated in Study IV. The examiner palpated the anterior knee region to measure the loss of disturbance in skin sensitivity. The length multiplied by the width was registered and the result is shown in cm2 (92).

11.5 FUNCTIONAL TESTS

11.5.1 One-leg-hop test

The one-leg-hop test was performed in Study IV by jumping and landing on the same foot with the hands behind the back (93). Three attempts were made for each leg and the longest hop was registered for each leg separately. A quotient (%) between the index and uninjured leg was calculated.

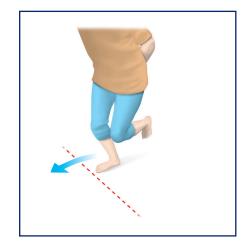


FIGURE 23
One-leg-hop test.

11.5.2 Knee-walking test

The knee-walking test was performed in Study IV to assess kneeling discomfort compared with the contralateral knee. It was performed on the floor and the patients were not allowed to use any protection or

clothing during the test. They knee-walked six steps and then subjectively classified the test as OK (normal), unpleasant, difficult or impossible to perform, as described by Kartus et al. (92).

11.6 QUANTIFIED LAXITY TEST

11.6.1 KT-1000/2000

The KT-1000 knee arthrometer (MED-metric® Corp, San Diego, Ca) was developed in an attempt to quantitate antero-posterior translation of the knee. It measures anterior and posterior translation of the tibia relative to the femur (95).

The test is performed with the patient supine. Both legs are placed on a thigh support with the knees in 30° of flexion. A foot rest and a strap around the thighs keep the legs in a neutral position (96, 97). Before each test, the instrument is calibrated. The uninjured leg is tested first and the translation is registered at 134N and using a manual maximum test. The only needle position accepted when the tension in the handle is released is if the needle returns to 0 ± 0.5 . At least three measurements on each knee are made and the average value is registered.

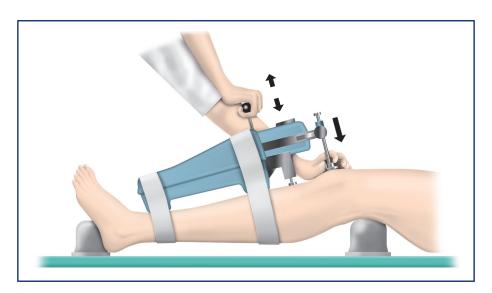


FIGURE 24 KT-1000 arthrometer.

11.6.2 Quantified antero-posterior laxity using navigation

The use of navigation allows a quantitative evaluation of joint laxities during/after ACL reconstruction and was used in some studies in Study I. It is an accurate and extensive computer-assisted in-vivo evaluation and can be very useful in assessing graft performance. The OrthoPilot (B. Braun Aesculap, Tuttlingen, Germany) navigation system was used in nine studies and was the most commonly used navigation method for measurements of antero-posterior laxity. It is an image-free, wireless system that does not require a pre-operative CT or intra-operative fluoroscopy. The system is not only able to give intra-operative information, such as the position of tibial and femoral tunnels, but also knee kinematics, such as antero-posterior translation and rotation. Femoral and tibial transmitters are fixed with two K-wires and both extra- and intra-articular landmarks are registered in the system. The accuracy of the system is extremely precise and is estimated according to the manufacturer to be < 1 mm and < 1°(98). Zaffagnini et al. (99) used a surgical navigation system (BLU-IGS, Orthokey, Lewes, Delaware, DE, USA) equipped with software specifically dedicated to kinematic acquisitions (KLEE, Orthokey, Lewes, Delaware, DE, USA)(100). After registration of the anatomical landmarks, the clinical tests are performed and the antero-posterior and rotatory laxity is acquired by the system. The intra-tester repeatability is approximately 1 mm and 1-2°. Plaweski et al. (101) used the Praxim navigation system (Praxim La Tronche, France) equipped with ACL logic software, in two studies. It is an application that uses the so-called bone morphing technology (102) that requires the registration of landmarks that are used to recreate a 3D representation of the knee on a screen. This image can then help with positioning the tunnel and assessing the antero-posterior translation and the rotatory laxity. The accuracy has been found to be less than 1 mm for translation and 1° for rotations (95). Park et al. (103) objectively assessed antero-posterior stability with the Telos device (Telos, Marburg, Germany) pre-operatively and at follow-up. Stress radiographs were obtained with the device and taken with the knee flexed at 90°. Sastre et al. (104) performed standardised and forced radiology to evaluate antero-posterior translation both pre-operatively and at follow-up. In two studies (105, 106), patients were scanned post-operatively with an open MRI system (0.3 T/ 0.5 T, AIRIS, Hitachi, Tokyo, Japan) in a nonweight-bearing decubitus position with the knees in extension, 30°, 60°, 90° and 120° of flexion at follow-up and compared with the normal contralateral knee. Sagittal images were used to measure the distance between the flexion facet centre and a line drawn from the posterior tibial cortices for each position.

11.6.3 Quantified rotatory laxity using navigation

The OrthoPilot (B. Braun Aesculap, Tuttlingen, Germany) navigation system has previously been described. It was used in nine studies in Study I and was the most commonly used navigation system for measurements of rotatory laxity.

The Praxim navigation system (Praxim La Tronche, France) and the Orthokey surgical navigation system have also been previously described and were used in two and one studies respectively. At follow-up, Misonoo et al. (107) performed a 3D mo-

tion analysis to evaluate rotatory laxity with a nine-camera VICON MX motion analysis system (Oxford Metrics Ltd., Oxford, England). Reflective markers are secured to the lower limb and nine cameras are used to detect the markers during a pivoting task. This method has been shown to provide precise hip and knee joint centres of rotation, within 1-3 mm and 3-9 mm respectively, and knee axis alignment with a deviation of 2° (108). The same motion analysis was performed with eight cameras in three studies (109-111). Hemmerich et al. (112) assessed rotatory laxity with an MRI-compatible torsional loading device. Images were taken both with internal and external rotation of the knees in full extension and at 30° of flexion. Izawa et al. (113) also used MRI to assess rotatory laxity. They performed the Slocum anterolateral rotatory instability test with open MRI. With the patient lying on the unaffected side, the knee is scanned under rotational stress. Branch et al. (114) examined rotatory laxity with a custom-made robotic knee-testing system. The system consists of motors, a tibial electromagnetic sensor and ankle- and hip-entrapment devices to isolate rotation at the knee and ankle. The patient is positioned supine with the knees flexed at 25° and the system rotates the tibia internally and externally (115).

11.7 STANDARD RADIOGRAPHY

Study I

Four studies performed standard radiographs pre-operatively and at the final follow-up to assess OA changes. Tunnel enlargement was assessed with radiographs taken immediately post-operatively and at follow-up in three studies.

Study IV

Standard weight-bearing anteroposterior and lateral radiographs were taken with the knee in 30° of flexion and the degenerative changes were graded and classified according to the Kellgren & Lawrence (54), Ahlbäck (55) and Fairbank (53) rating systems. For the Fairbank system, the cumulative number of positive findings, from 0-6, was calculated for each patient. An independent musculoskeletal radiologist, blinded to the type of graft, interpreted the radiographs. The intra-rater reproducibility analysis revealed kappa values between 0.55 and 1.00, when classifying and re-classifying the results of the Ahlbäck and Fairbank rating systems for 20 randomly selected patients. The time

period between these classifications was 12 months. The OA changes in the femoro-patellar joint were classified as none (0), minor (1), moderate (2) or severe (3). Correspondingly, the femoro-patellar osteophytes were classified as none (0), small (1), moderate (2), or large (3).



12 STATISTICAL METHODS

Study I

A best evidence synthesis approach was used and descriptive statistics, including frequency counts and percentages, were calculated.

Study II

The probability of revision in the single- and double-bundle groups was estimated using Kaplan-Meier analysis. Means ± standard deviations were reported for the KOOS sub-

scales and EQ-5D. Fisher's exact test was used for binary data, Student's t-test was used for continuous data and the log-rank test was used for survival data. P < 0.05 was considered statistically significant. All the statistical analyses were calculated using Stata (StataCorp, College Station, TX). Tables and diagrams were generated using Microsoft Excel, version 12 (Microsoft, Redmond, WA).

Study III

Frequency counts and percentages were calculated for normal variables and measurements of central tendency (means) and dispersion (standard deviations) were calculated for continuous variables. To evaluate the difference in demographic variables between the subjects, an independent t-test and chi-square test were used. To identify factors that increased the risk of ACL revision, univariate logistic regression analyses were performed for all variables. Variables with a p-value of < 0.25 were entered in a multivariate stepwise logistic regression model to determine the best predictors of ACL revision, taking account of other predictor variables in the model. The odds ratio

and 95% confidence interval were provided. An alpha level of p < 0.05 was considered statistically significant. All statistical analyses were performed using IBM SPSS Version 22.0 (SPSS Inc., Chicago, IL).

Study IV

Median and range values are presented. In terms of both continuous and non-continuous variables, the Mann-Whitney U-test was used. The Wilcoxon signed-rank test was used for comparisons of the pre-operative and post-operative data within the groups. The χ -square test was used to compare the dichotomous variables between the two groups. An alpha level of < 0.05 was considered statistically significant.



13 ETHICS

Study I

No ethical approval was needed.

Study II

Participation in the Swedish Knee Ligament Register is voluntary, on the part of both the surgeon and the patient. The database complies with the Swedish legislation on data security, which means that access to data is limited to authorised persons

only. All data extracted from the register are anonymous to ensure that researchers only have access to non-identifiable data. The study was approved by the Regional Ethics Committee in Stockholm, Sweden (Dnr: 2011/337-31/3).

Study III

The study was approved by the University of Pittsburgh Institutional Review Board

using an expedited review process (IRB Protocol Number PRO11120006).

Study IV

Ethical approval was obtained for the long-term follow-up from the Human Ethics Committee at the Medical Faculty at Gothenburg University, Sweden (Dnr: 986-12). All subjects gave their informed and written consent. The two original trials were approved by the Human Ethics Committee at both the University of Gothenburg (Dnr: L 280-97) and the University of Stockholm (97-338), Sweden.



14 SUMMARY OF PAPERS

Study I

Is double-bundle anterior cruciate ligament reconstruction superior to single-bundle? A comprehensive systematic review

Introduction

With a better understanding of the anatomy of the ACL, interest has increased in recreating two separate bundles of the ACL instead of one and performing a double-bundle ACL reconstruction. The goal of this systematic review was to evaluate all comparative clinical studies comparing single- and double-bundle reconstruction in the current literature.

Methods

This systematic review was conducted according to the PRISMA guidelines. A PubMed database search was performed

and clinical studies comparing single- and double-bundle ACL reconstruction were obtained. The data were extracted and descriptions of significant and non-significant findings were presented for clinical tests, PROMs and other outcomes. All the studies were assessed for risk of bias.

Results

After an electronic search, 7,154 studies were analysed, of which 49 were categorised as comparative trials comparing single- and double-bundle ACL reconstruction. An updated search subsequently included 11 studies, which gave a total of 60 studies (25 RCTs, 23 PCSs and 14 RCSs).

Graft failures were reported in 23 studies, of which two (64, 116) reported statistically significantly better results in the double-bundle group. In the 23 studies, a total of 44 and 19 re-ruptures in single- and double-bundle reconstruction respectively were reported.

Evaluating knee laxity measurements in the 60 included studies revealed that Lachman was assessed in 17 studies. Four studies showed that double-bundle reconstruction yielded less AP laxity (81, 82, 117, 118), but no difference was found in 13 studies. Anterior drawer was evaluated in nine studies and three (81, 118, 119) showed that double-bundle reconstruction produced less laxity, whereas six did not find any differences. Side-to-side AP laxity was measured using the KT-1000/2000 in 40 studies and double-bundle reconstruction yielded less AP laxity in 18 studies (63, 66, 81, 82, 106, 113, 114, 117-127). No difference was shown in 22 of the reviewed studies. Seventeen studies assessed AP laxity with navigation during operation and significant differences in favour of double-bundle reconstruction were found

in five (101, 105, 128-130). Single-bundle, reconstruction with the addition of lateral extra-articular tenodesis was superior in one study (99). Pivot shift was evaluated in 42 studies and, in 18 studies (63, 67, 81, 99, 101, 118-120, 122-124, 127, 131-136), double-bundle reconstruction resulted in better stability. No difference was shown in 24 of the studies. A total of 20 studies assessed rotatory laxity with navigation. Nine of them showed that double-bundle reconstruction was better in terms of rotatory laxity restoration than single-bundle (101, 113, 114, 128-130, 132, 137, 138) and nine found no difference. Single-bundle, with the addition of lateral extra-articular tenodesis, was superior in two studies (99, 139) (Table 10).

The IKDC was evaluated in 35 of the 60 studies and eight reported improved results in favour of double-bundle reconstruction (118, 120, 121, 123-125, 132, 140). No differences were shown in 27 studies. The KOOS scale was assessed in three of the studies and none of them revealed any significant difference. Thirty-one studies measured the Lyshom score and only two (123, 132) found significant differences, both of which reported better results in the double-bundle group. The Tegner activity level scale was evaluated in 19 studies and one of them showed a significant difference in favour of double-bundle reconstruction (125). The Marx activity scale was measured in two studies; one reported better results after double-bundle reconstruction (135), while the other found no difference. The Cincinnati Knee Score was assessed in three studies, the WOMAC in one, the subjective recovery score in two, OAK in one and the HSS score in one and none of them found any significant differences. The VAS score was assessed in two of the 60 studies and both showed a significant difference in favour of the double-bundle group (118, 121) (Table 10).

Extensor muscle strength was assessed in ten studies and just one showed a significant difference at final follow-up (122) in favour of double-bundle reconstruction. Flexor muscle strength was also assessed in ten studies and two found significant differences, one in favour of the double-bundle group (122) and one for the single-bundle group (141). ROM was measured in 32 studies and four demonstrated a difference. three in favour of double-bundle reconstruction (123, 125, 135) and one reported greater extension deficit in double-bundle reconstruction, but no difference with regard to flexion deficit (65). Thigh circumference was assessed in four studies and thigh diameter in one and none of them showed any statistical differences. The one-leg-hop test was measured in three studies and no differences were found. Pain was reported in four studies and one (67) found less anterior knee pain in double-bundle reconstruction. Sports activity was reported in nine studies; in five of them, return to sports activity at the same pre-operative level was evaluated and no difference was found. In three of them, the time to sports resumption was evaluated and two (125, 135) reported better results after double-bundle reconstruction. One study assessed sports activity with the sports performance recovery score and found no difference (Table 10).

Osteoarthritic changes were reported in five studies and two (125, 142) found significant differences, both in favour of double-bundle reconstruction, with fewer osteoarthritic changes (Table 10).

Conclusion

The significant differences reported between single- and double-bundle ACL reconstruction regarding graft failures and AP and rotatory laxity were almost exclusively in favour of double-bundle reconstruction. A total of 44 and 19 re-ruptures in single- and double-bundle reconstruction respectively were reported. In addition, the current evidence does not reveal any differences in short-term PROMs or differences in objective findings.

| TABLE 10. Total number of studies revealing significant findings | | | | | | |
|--|------------------------------|-------------------------|---|---|--|--|
| | Outcomes | Total number of studies | Significant difference in favour of DB group | Significant difference in favour of SB group | | |
| | Lachman | 17 | 4 | 0 | | |
| | Anterior drawer | 9 | 3 | 0 | | |
| Laxity | KT-1000/2000 | 40 | 18 | 0 | | |
| Laxily | AP laxity using navigation | 17 | 5 | 1* | | |
| | Pivot shift | 42 | 18 | 0 | | |
| | Quantified rotatory laxity | 20 | 9 | 2* | | |
| | IKDC | 35 | 8 | 0 | | |
| | KOOS | 3 | 0 | 0 | | |
| | Lysholm score | 31 | 2 | 0 | | |
| | Tegner activity level scale | 19 | 1 | 0 | | |
| Patient-report- | Marx activity rating scale | 2 | 1 | 0 | | |
| ed outcome | Cincinnati Knee Score | 3 | 0 | 0 | | |
| measures | WOMAC | 1 | 0 | 0 | | |
| | VAS | 2 | 2 | 0 | | |
| | Subjective recovery score | 2 | 0 | 0 | | |
| | OAK | 1 | 0 | 0 | | |
| | Hospital for Special score | 1 | 0 | 0 | | |
| | Muscle strength | 10 | 1 | 1 | | |
| | ROM | 32 | 4 | 0 | | |
| | Graft failure | 23 | 2 | 0 | | |
| Other | Thigh circumference/diameter | 5 | 0 | 0 | | |
| | One-leg-hop test | 3 | 0 | 0 | | |
| | Pain | 4 | 1 | 0 | | |
| | Sports activity | 9 | 2 | 0 | | |
| | Osteoarthritic changes | 5 | 2 | 0 | | |

DB, double-bundle; SB, single-bundle; IKDC, International Knee Documentation Committee score; KOOS, Knee injury and Osteoarthritis Outcome Score; WOMAC, Western Ontario and McMaster Universities osteoarthritis index; VAS, Visual Analogue Scale; OAK, Orthopadische Arbeitsgruppe Knie score; ROM, Range Of Motion

^{*}Significantly better results in single-bundle ACL reconstruction with the addition of lateral extra-articular tenodesis

Study II

No difference in revision rates between singleand double-bundle anterior cruciate ligament reconstruction: A comparative study of 16,791 patients from the Swedish National Knee Ligament Register

Introduction

The treatment of ACL injuries has evolved considerably over the years. Currently, single-bundle ACL reconstruction is the most commonly used surgical technique. However, in recent years, double-bundle ACL reconstruction has been developed and studies indicate that it more effectively restores rotational laxity and reduces the risk of graft failure. However, the literature is not unanimous and the purpose of this study was to compare revision rates and PROMs between the two techniques.

Methods

The Swedish National Knee Ligament Register utilises a web-based protocol consisting of two parts, one patient section, which includes the KOOS and EQ-5D, and a second section which is surgeon based, where factors relating to the initial injury, previous surgery and surgical procedures performed on the injured knee are registered.

Results

According to the Kaplan-Meier cumulative risk-of-revision estimate, there was no significant difference between primary single-and double-bundle ACL reconstructions (p=0.30). During the 7-year observation period, 347 of 16,281 patients (2.1%) in the single-bundle group and eight of 510 patients (1.6%) in the double-bundle group had undergone revision surgery. The incidence of revision was highest during the second post-operative year in both groups. This trend gradually decreased with time, albeit not significantly (Figure 25).

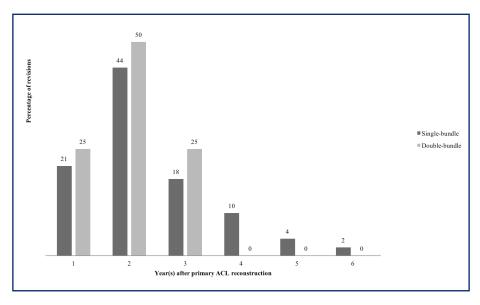


FIGURE 25

Percentage of revision rate each year after primary single- and double-bundle anterior cruciate ligament (ACL) reconstruction.

The incidence of single-bundle ACL reconstruction increased every year during the study period. During the first two years, no double-bundle ACL reconstructions were performed. In 2008, 190 double-bundle

ACL reconstructions were performed, accounting for 7.5% of all reconstructions. The incidence then decreased and was only 1.2% of all reconstructions in 2011 (Table 11).

| TABLE 11. Annual incidence of primary SB and DB ACL reconstructions and revision | | | | | | | |
|--|-----------------|-----------------|------------------|------------------|------------------|------------------|------------------|
| | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 |
| SB, n (%) | 1448 (100 %) | 1905 (100 %) | 2149 (96.7 %) | 2346 (92.5 %) | 2592 (95.0 %) | 2906 (97.5 %) | 2935 (98.8 %) |
| DB, n (%) | | | 74 (3.3 %) | 190 (7.5 %) | 136 (5.0 %) | 73 (2.5 %) | 37 (1.2 %) |
| Revision SB, n (%) | 1 (0.07 %) | 13 (0.7 %) | 32 (1.5 %) | 52 (2.2 %) | 62 (2.4 %) | 84 (2.9 %) | 103 (3.5 %) |
| Revision DB, n (%) | | | | 2 (1.1 %) | 3 (2.2 %) | 2 (2.4 %) | 1 (2.7 %) |

The first and second rows represent the annual incidence of primary SB and DB ACL reconstruction. The percentages represent how many SB ACL reconstructions there were compared with DB ACL reconstructions. The third and fourth rows represent the incidence of revision for each group. The percentages represent annual incidence of revision in the each group.

ACL, anterior cruciate ligament; SB, single-bundle; DB, double-bundle

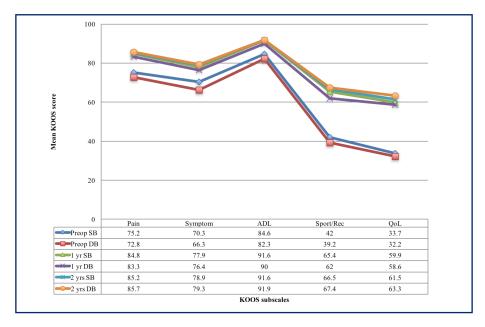


FIGURE 26

Knee Injury and Osteoarthritis Outcome Score (KOOS) profiles pre-operatively and one and two years after single-bundle (SB) and double-bundle (DB) anterior cruciate ligament reconstruction.

Pre-operatively, the double-bundle group reported inferior scores compared with the single-bundle group for three of five KOOS subscales (pain, symptoms and function in daily living) and the KOOS4, but no differences in the EQ-5D were shown. At one and two years after the reconstruction, there were no differences between the groups in either the KOOS or the EQ-5D (Figure 26, Table 12).

TABLE 12. The KOOS and EQ-5D (means ± standard deviations) pre-operatively and one and two years after single- and double-bundle ACL reconstructions respectively

| | | Pre- | operative | ; | One year post-operative | | | Two years post-operative | | |
|-------------|-----------|-----------------------------------|--------------------------------|----------|----------------------------------|--------------------------------|---------|----------------------------------|--------------------------------|---------|
| | | Single- bundle (n = 10,831) | Double- bundle (n = 375) | P-value | Single- bundle (n = 7,539) | Double- bundle (n = 220) | P-value | Single- bundle (n = 5,907) | Double- bundle (n = 221) | P-value |
| | Pain | 75.2±14.4 | 72.8±17.2 | 0.008 | 84.8±15.6 | 83.3±15.8 | 0.177 | 85.2±15.2 | 85.7±15.2 | 0.678 |
| | Symptoms | 70.3±18.2 | 66.3±17.8 | <0.001 | 77.9±17.7 | 76.4±18.1 | 0.231 | 78.9±17.7 | 79.3±17.6 | 0.742 |
| кооѕ | ADL | 84.6±16.6 | 82.3±17.3 | 0.010 | 91.6±13.1 | 90.0±14.8 | 0.073 | 91.6±13.2 | 91.9±13.3 | 0.774 |
| | Sport/rec | 42.0±27.4 | 39.2±27.2 | 0.052 | 65.4±27.4 | 62.0±27.4 | 0.063 | 66.5±27.3 | 67.4±26.7 | 0.622 |
| | QoL | 33.7±18.7 | 32.2±17.3 | 0.117 | 59.9±24.2 | 58.6±25.0 | 0.442 | 61.5±24.4 | 63.3±23.1 | 0.283 |
| KOOS4 | | 55.3±17.3 | 52.6±16.4 | 0.002 | 72.0±19.0 | 70.1±19.5 | 0.141 | 73.0±19.2 | 73.9±19.0 | 0.498 |
| EQ-5D index | | 0.70±0.21 | 0.67±0.22 | 0.336 | 0.81±0.19 | 0.80±0.18 | 0.558 | 0.82±0.18 | 0.82±0.19 | 0.612 |
| EQ-5D VAS | | 63.5±23.5 | 64.3±26.1 | 0.407 | 76.7±20.4 | 75.0±20.8 | 0.688 | 77.6±20.1 | 77.3±19.4 | 0.824 |

KOOS, Knee injury and Osteoarthritis Outcome Score; KOOS4, KOOS excluding the ADL subscale; EQ-5D, a measurement of health status from the EuroQol Group; ADL, Function in daily living; Sport/rec, Function in sport and recreation; QOL, knee-related quality of life; ACL, anterior cruciate ligament

Both groups had improved significantly on all the KOOS subscales and the EQ-5D at the one- and two-year follow-ups, however no differences in improvement were found between the two groups on the KOOS or EQ-5D at the one- and two-year follow-ups compared with pre-operatively.

Conclusion

The revision rates after single- and double-bundle ACL reconstructions were low according to the Swedish National Knee Ligament Register. No differences were found in revision rates, KOOS and EQ-5D between the two techniques.

Study III

Predictors of revision surgery after primary anterior cruciate ligament reconstruction

Introduction

Graft failure is an important clinical outcome after ACL reconstruction and, according to recent studies, varying rates of graft failure and ACL revision have been reported (0-14%) (133, 144, 145). The factors that predict ACL revision after failed primary ACL reconstruction are not well defined and there is inconsistency in terms of these factors in the literature. Some factors that predict ACL revision, such as young age, smoking and different activities at the time of the initial injury, have been identified in other studies (146, 147). The purpose of this study was to identify predictors of ACL revision surgery after failed primary ACL reconstruction.

Methods

A medical records review for the dates

between 1/1/2007 and 4/30/2011 was performed to identify eligible subjects between 14 and 50 years of age at the time of primary unilateral ACL reconstruction. Invitation letters along with the questionnaire and consent forms were sent to all potential subjects. Afterwards, predictors of ACL revision surgery were identified from the questionnaire and medical records. They included subject characteristics, details of the initial injury and surgical details of the primary reconstruction and the post-operative course.

Results

Of the 251 subjects, 21 (8.4%) reported that they had undergone ACL revision and 18 of them were injured during sports participation.

In the univariate logistic regression model, participants who underwent ACL revision were significantly more frequently 18 years of age or younger (OR=9.5; p=0.004), or 19-23 years old (OR=9.9; p=0.005) compared with 24 years or older. In addition, participants who participated in competitive sports activities prior to surgery ran a significantly increased risk of undergoing ACL revision in comparison with those who had lower activity levels prior to surgery (OR=3.3; p=0.023). Predictors not significantly associated with an increased risk of ACL revision were gender, BMI, time from injury to surgery, graft type, baseline activity level, surgical technique and return to sports (Table 13).

| Pred | dictors | ACLR | OR | 95% CI | P-value |
|----------------------|----------------------|------------|------|------------|---------|
| | ≤ 18 years (78) | 11 (14.1%) | 9.52 | 2.05-44.26 | 0.004 |
| Age at the time of | 19-23 years (55) | 8 (14.5%) | 9.87 | 2.02-48.22 | 0.005 |
| surgery, n (%) | ≥ 24 years* (118) | 2 (1.7%) | | | |
| Gender, | Male (112) | 18 (16.1%) | 1.34 | 0.54-3.36 | 0.527 |
| n (%) | Female (139) | 13 (9.4%) | | | |
| Body Mass Index | , , | 25.15±4.47 | 0.96 | 0.86-1.07 | 0.434 |
| Time from injury | < 6 months (210) | 20 (9.5%) | 0.27 | 0.04-2.08 | 0.129 |
| to surgery, n (%) | ≥ 6 months (41) | 1 (2.4%) | | | |
| Baseline activity | Competitive (147) | 17 (11.6%) | 3.27 | 1.07-10.02 | 0.023 |
| level, n (%) | Other* (104) | 4 (3.9%) | | | |
| | Autograft* (131) | 7 (4.7%) | | | |
| Graft type, n (%) | Allograft (110) | 13 (11.1%) | 2.37 | 0.91-6.18 | 0.076 |
| 11 (70) | Mixed (10) | 1 (10%) | | | 0.189 |
| Surgical technique, | Single-bundle* (196) | 11 (5.6%) | | | |
| n (%) | Double-bundle (55) | 9 (16.4%) | 3.00 | 1.19-7.55 | 0.024 |
| Return to sports, | Yes* (209) | 19 (19.1%) | 2.00 | 0.45-8.93 | 0.324 |
| n (%) | No (42) | 2 (4.8%) | | | |

Patients who underwent double-bundle ACL reconstruction ran a significantly increased risk of undergoing revision ACL compared with those that underwent single-bundle ACL reconstruction (OR=3.0;

p=0.024) (Table 13). In a further analysis, the combination of use of allografts and double-bundle ACL reconstruction had the highest frequency of revision (18.4%) (Table 14).

| TABLE 14. Correlation between | graft type and surgical technique by anterior cruciate |
|-------------------------------|--|
| ligament revision | |

| Graft type | Surgical t | Total | |
|------------|---------------|---------------|--------|
| | Single-bundle | Double-bundle | |
| Autograft | 7/135 (5.2%) | 0/6 (0%) | 7/141 |
| Allograft | 4/61 (6.6%) | 9/49 (18.4%) | 13/110 |
| Total | 11/196 | 9/55 | |

Moreover, patients who underwent double-bundle ACL reconstruction were predominantly of younger age and a higher proportion participated in competitive baseline activities (Table 15). The same things applied to patients who underwent double-bundle ACL reconstruction with an allograft (Table 16).

TABLE 15. Correlation between age at the time of surgery, surgical technique and activity level at baseline by anterior cruciate ligament revision

| G0. | delivit, level at baseline by anience orderate ligament tevision. | | | | | | | |
|-------------------------|---|--------------|--------------|-------------|---------------|--|--|--|
| Baseline activity level | | ≤ 18 years | 19-23 years | ≥ 24 years | Total | | | |
| Commotitivo | Single-bundle | 6/54 (9.3%) | 4/35 (11.4%) | 0/25 (0%) | 10/114 (8.8%) | | | |
| Competitive | Double-bundle | 5/21 (23.8%) | 2/9 (22.2%) | 0/3 (0%) | 7/33 (21.2%) | | | |
| Othor | Single-bundle | 0/2 (0%) | 1/9 (11.1%) | 1/71 (1.4%) | 2/82 (2.4%) | | | |
| Other | Double-bundle | 0/1 (0%) | 1/2 (50%) | 1/19 (5.3%) | 2/22 (9.1%) | | | |

TABLE 16. Correlation between age at the time of surgery, surgical technique and activity level at baseline by anterior cruciate ligament revision in subjects undergoing surgery with allografts

| Baseline activity level | | ≤ 18 years | 19-23 years | ≥ 24 years | Total |
|-------------------------|---------------|--------------------------|-------------|-------------|--------------|
| Compositivo | Single-bundle | 2/8 (25%) | 2/5 (40%) | 0/9 (0%) | 4/22 (18.2%) |
| Competitive | Double-bundle | 5/17 (29.4%) 2/9 (22.2%) | | 0/3 (0%) | 7/29 (24.1%) |
| Other | Single-bundle | 0/1 (0%) | 0/2 (0%) | 0/36 (0%) | 0/39 (0%) |
| Omer | Double-bundle | 0/1 (0%) | 1/2 (50%) | 1/17 (5.3%) | 2/20 (10%) |

None of the other variables including mechanism of injury (sports vs. other) (p=0.476); concomitant injury (meniscus, ligament and cartilage) (p=0.366); Lachman test (p=0.757) and pivot shift (p=0.793) under anaesthesia; femoral drilling technique (transtibial vs. medial portal) (p=0.585); length of rehabilitation (p=0.118) and complications after primary ACL reconstruction (p=0.677) were found to be predictors of ACL revision.

In the *multivariate logistic regression model*, participants who were 18 years or younger ran a significantly increased risk of ACL

revision compared with those 24 years or older (OR=11.5; p=0.001). Moreover, there was a significantly increased risk of ACL revision in patients between 19 and 23 years compared with 24 years or older (OR=12.9; p=0.003) (Table 17). In addition, the multivariate logistic regression model indicated that, when other variables in the model were also considered, participants who underwent primary ACL reconstruction with allografts in comparison with autografts ran a significantly increased risk of ACL revision (OR=3.8; p=0.010) (Table 17).

| TABLE 17. Multivariate logistic regression model for predictors of ACL revision surgery after primary anterior cruciate ligament reconstruction | | | | | | | | |
|---|----------------|------|-----|-------|------------|---------|--|--|
| Predictor | | β | SE | OR | 95% CI | P-value | | |
| Age at the time of surgery | ≤18 Vs. ≥24* | 2.44 | .84 | 11.46 | 2.24-58.87 | 0.001 | | |
| | 19-23 Vs. ≥24* | 2.56 | .88 | 12.94 | 2.32-72.07 | 0.003 | | |
| Graft type | Auto* Vs. Allo | 1.32 | .51 | 3.75 | 1.38-10.22 | 0.010 | | |
| * Reference group for each predictor | | | | | | | | |

Conclusion

The overall reported ACL revision rate after primary unilateral ACL reconstruction was 8.4%. Univariate predictors of revision ACL reconstruction included younger age at the time of surgery, competitive baseline activity level and double-bundle ACL reconstruction. However, multivariate logistic regression analysis indicated that age and reconstruction performed with allografts were the only independent predictors of revision ACL reconstruction.

Study IV

A randomised controlled trial with a mean 16-year follow-up comparing hamstring and patella tendon autografts in anterior cruciate ligament reconstruction

Introduction

There is no consensus in the current literature on the surgical option, including graft choice, which renders the best long-term results after ACL reconstruction in terms of PROMs, functional outcomes, clinical evaluation including knee laxity measurements and radiographic evaluation. The purpose was therefore to compare the long-term results after ACL reconstruction using either patellar tendon or hamstring tendon autografts.

Methods

One hundred and ninety-three patients from two previous randomised cohorts with a unilateral ACL rupture were prospectively randomised for reconstruction using either an ipsilateral PT or HT graft. Pre- and post-operatively, the KT-1000 arthrometer, Lachman test, pivot shift test, Lysholm score, Tegner activity level, IKDC evaluation system, ROM, disturbances in sensitivity in the anterior knee region, knee-walking test, one-leg-hop test and radiographic assessment were performed. The reconstruction was performed at three different centres by six experienced senior ACL surgeons. All patients took part in a similar rehabilitation programme with immediate full weight-bearing without a brace and full ROM training.

Results

Four patients (6.6%) in the PT group and seven patients (8.1%) in the HT group suffered an ACL graft rupture. Six patients in both groups (9.8% in PT group; 7.0% in HT group) sustained an ACL injury to the contralateral knee. However, no differences were found between the two groups in terms of additional surgery during follow-up and surgery on the contralateral knee. The most frequent cause of additional surgery on the index knee was meniscal problems, while it was ACL injury in the contralateral knee (Table 18).

| TABLE 18. Incidence and cause of additional surgery | | | | | | | | |
|---|-------------------|---------------|---------------|---------|--|--|--|--|
| | | PT group n=61 | HT group n=86 | P-value | | | | |
| Additional surgery on index knee, n | | 32 (52.5%) | 42 (48.8%) | 0.67 | | | | |
| | ACL graft rupture | 4 (6.6%) | 7 (8.1%) | | | | | |
| | Chondral lesion | 2 (3.3%) | 3 (3.5%) | | | | | |
| | Extension deficit | 1 (1.6%) | - | | | | | |
| Cause of additional surgent p | Meniscal problems | 14 (23.0%) | 21 (24.4%) | | | | | |
| Cause of additional surgery, n: | Other | 7 (11.5%) | 8 (9.3%) | | | | | |
| | PCL injury | 1 (1.6%) | - | | | | | |
| | Screw problems | 2 (3.3%) | 2 (2.3%) | | | | | |
| | Septic knee | 1 (1.6%) | 1 (1.2%) | | | | | |
| Surgery on contralateral knee, n | | 11 (18.0%) | 12 (14.0%) | 0.50 | | | | |
| | ACL injury | 6 (9.8%) | 6 (7.0%) | | | | | |
| Cause of surgery on | Chondral lesion | - | 1 (1.2%) | | | | | |
| contralateral knee, n: | Meniscal problems | 4 (6.6%) | 4 (4.7%) | | | | | |
| | Other | 1 (1.6%) | 1 (1.2%) | | | | | |
| PT, patellar tendon; HT, hamstring | tendon | | | | | | | |

The only significant difference between the groups in terms of *knee laxity measurements* was in the pivot shift test, which revealed less laxity in the HT group when re-injured patients and patients with a contralateral ACL injury were excluded (p=0.048). Pre-operatively, patients in the HT group had significantly higher manual Lachman values (p=0.021) and this was also found

when patients with an ACL injury to the index knee or the contralateral knee were excluded (p=0.042) (Table 19). Both groups had significantly less knee laxity post-operatively in terms of the Lachman test (PT, p<0.0001; HT p<0.0001) and the pivot-shift test (PT, p=0.001; HT p<0.0001). No differences were found in terms of the KT-1000 arthrometer measurements.

| TABLE 19. Knee laxity measurements | | | | | | | |
|--|-------------------|--------------------|--------------------|---------|---|--------------------|---------|
| | | Total | | | New ACL injury on same or contralateral side excluded | | |
| | | PT group n=61 | HT group n=86 | P-value | PT group n=51 | HT group n=73 | P-value |
| | 0 | 1 (1.6%) | - | | 1 (2.0%) | - | |
| | 1 | 10 (16.4%) | 19 (22.1%) | | 10 (19.6%) | 15 (20.5%) | |
| Pre-operative manual Lach- | 2 | 26 (42.6%) | 46 (53.5%) | 0.021 | 20 (39.2%) | 43 (58.9%) | 0.042 |
| man test, n | 3 | 22 (36.1%) | 12 (14.0%) | 0.02. | 18 (35.3%) | 7 (9.6%) | 0.0.2 |
| | Missing values | 2 (3.3%) | 9 (10.5%) | | 2 (3.9%) | 8 (11.0%) | |
| | 0 | 30 (49.2%) | 34 (39.5%) | | 25 (51.0%) | 32 (43.8%) | |
| Manual Lach- | 1 | 24 (39.3%) | 32 (37.2%) | 0.11 | 20 (39.2%) | 27 (37.0%) | 0.50 |
| man test at follow-up, n | 2 | 6 (9.8%) | 17 (19.8%) | 0.11 | 5 (9.8%) | 12 (16.4%) | 0.50 |
| | 3 | 1 (1.6%) | 3 (3.5%) | | - | 2 (2.7%) | |
| | 0 | 7 (11.5%) | 9 (10.5%) | | 6 (11.8%)* | 6 (8.2%) | 0.24 |
| | 1 | 44 (72.1%) | 50 (58.1%) | | 36 (70.6%) | 44 (60.3%) | |
| Pre-operative pivot shift | 2 | 6 (9.8%) | 15 (17.4%) | 0.54 | 5 (9.8%) | 12 (16.4%) | |
| test, n | 3 | 2 (3.3%) | - | | 2 (3.9%) | - | |
| | Missing values | 2 (3.3%) | 12 (14.0%) | | 2 (3.9%) | 11 (15.1%) | |
| | 0 | 34 (55.7%) | 58 (67.4%) | | 26 (51.0%) | 52 (71.2%) | 0.048 |
| | 1 | 14 (23.0%) | 15 (17.4%) | | 13 (25.5%) | 10 (13.7%) | |
| Pivot shift test | 2 | 12 (19.7%) | 12 (14.0%) | 0.21 | 11 (21.6%) | 10 (13.7%) | |
| at follow-up, n | 3 | - | 1 (1.2%) | 0.21 | - | 1 (1.4%) | |
| | Missing values | 1 (1.6%) | - | | 1 (1,9%) | - | |
| Pre-opera- | Mean (SD) | 4.1 (4.0) | 4.3 (4.0) | | 4.1 (4.2) | 4.8 (3.9) | 0.90 |
| tive KT 1000 side-to-side difference | Median (range) | 4.0 (-4.0-17.0) | 3.5 (-2.0-24.0) | 0.96 | 4.0 (-4.0-17.0) | 3.5 (-2.0-24.0) | |
| 89N | Missing values | 3 | 9 | | 2 | 8 | |
| KT 1000 side- to-side differ- | Mean (SD) | 1.0 (2.7) | 1.5 (3.0) | 0.32 | 1.1 (2.5) | 1.5 (2.9) | 0.63 |
| ence 134N at follow-up | Median (range) | 1.0 (-5.0-6.0) | 1.5 (-6.0-8.0) | 0.32 | 1.0 (-5.0-6.0) | 2.0 (-6.0-8.0) | 0.03 |
| KT 1000 side- to-side differ- | Mean (SD) | 1.0 (2.8) | 1.8 (3.0) | 0.14 | 1.2 (2.6) | 1.8 (3.1) | 0.20 |
| ence MMT at follow-up | Median (range) | 1.0 (-5.0-7.0) | 2.0 (-7.0-8.0) | 0.14 | 1.0 (-5.0-6.0) | 2.0 (-7.0-8.0) | 0.20 |

^{*} Significant difference between the pre-operative and follow-up values, p=0.006

PT; patellar tendon; HT, hamstring tendon; ACL, anterior cruciate ligament; SD, standard deviation; MMT, Manual Maximum Test

Both patient groups had reduced ROM in both flexion and extension at the follow-up compared with the pre-operative values. However, there were no differences in terms of ROM between the groups in the injured knee at follow-up. Patients in the HT group significantly increased their performance in the one-leg-hop test (PT p=0.382, HT p<0.0001) at follow-up compared with the pre-operative values. In addition, the HT group had a significantly better knee-walking ability at follow-up (p=0.049) and the difference was also seen when patients with a new ACL injury on the same or contralateral side were excluded (p=0.03). Both groups had an increased disturbance in knee sensitivity compared with the pre-operative values (PT and HT p<0.0001).

Post-operatively, both patient groups had a significant increase in the *Lysholm score* (PT p=0.002, HT p<0.0001) compared with the pre-operative values. Post-operatively, there was a significant decrease

in terms of the *Tegner activity scale* compared with the pre-injury levels (PT and HT p<0.0001). This was also seen when patients with a graft rupture and contralateral ACL rupture were excluded. There were no significant differences between the two groups in terms of the subjective *IKDC score*.

Both groups revealed significantly more post-operative *radiographic changes* in the injured knee compared with the contralateral knee (p<0.001). These results were consistent, regardless of the classification system that was used (Ahlbäck, Fairbank and Kellgren & Lawrence) and whether patients with a new ACL injury on the index side or contralateral side were excluded. No significant differences were found between the study groups.

No differences were found in terms of *cause of injury*; the most common cause of injury was contact sport, 70.5% in the PT group and 66.3% in the HT group (Table 20).

| TABLE 20. Cause of injury | | | | | | | |
|---|---------------|---------------|---------|--|--|--|--|
| | PT group n=61 | HT group n=86 | P-value | | | | |
| ADL, n | 2 (3.3%) | 2 (2.3%) | | | | | |
| Contact sport, n | 43 (70.5%) | 57 (66.3%) | | | | | |
| Non-contact sport, n | 8 (13.1%) | 12 (14.0%) | 0.8 | | | | |
| Other, n | 6 (9.8%) | 7 (8.1%) | | | | | |
| Work, n | 1 (1.6%) | 0 (0.0%) | | | | | |
| PT, patellar tendon; HT, hamstring tendon; ADL, activity of daily life; n.s., not significant | | | | | | | |

Conclusion

In this long term randomised controlled trial there were no differences between the PT and HT autograft groups regarding graft failure or contralateral ACL injury. In both groups, significantly more radiographic signs of osteoarthritis were found

in the reconstructed knee than in the contralateral healthy knee.





15 DISCUSSION

15.1 GRAFT FAILURES

Graft rupture often has major consequences in both the short and long term and, for this reason, an effort to minimise the risk of graft failure is important. The definition of graft failure is currently not clear, which has made it difficult for researchers and forced them to use ACL revision surgery instead. However, even if

revision is a very evident outcome, the accuracy is insufficient. For instance, patients may have a poor result without choosing to undergo revision. This is a limitation of the ACL registers, but it is inevitable without substantial extra resources. The Scandinavian arthroplasty registers share the same dilemma, using revision surgery

as an end-point. However, in general, the ACL registers have major advantages and serve as a good means of quality control. The registers allow comparisons between different surgical techniques, hence make it possible to identify pros and cons of established techniques and new methodology.

Incidence of graft failure

The incidence of graft failure is reported in the literature as anywhere from zero to 23% (144, 149). Our knowledge relating to the incidence of ACL revision is often based on case series or high evidence level studies with limited sample sizes. However, in the last decade, national registers have been established in Scandinavia and they are able to generate demographic data for revision ACL reconstruction for entire nations, thereby providing more reliable data for the true risk of revision ACL reconstruction. According to the Swedish National Knee Ligament Register (Study II), revision rates are low in Sweden after both single- (2.1%) and double-bundle (1.6%) ACL reconstruction. Findings similar to those in Study II have been reproduced by other register studies from Scandinavia (150, 151). They include a large number of individuals and report relatively low frequencies of revision ACL reconstructions. However, in Study III, the overall ACL revision rate was 8.4%, 5.6% after single-bundle reconstruction and 16.4% after double-bundle reconstruction. Moreover, in Study IV, 6.6% in the PT group and 8.1% in the HT group had an ACL graft failure. The reason for higher revision frequencies in some studies, and especially the double-bundle group in Study III, is a potential selection bias and different patient cohorts in Studies I, III and IV compared with Study II. Another potential reason is that graft failure in Studies II-IV was defined as revision surgery, which probably leads to an underestimation of the true occurrence of graft failures, as some of the re-injured patients do not undergo surgery and adapt their lifestyle to a lower activity level and an unstable knee. Other patients are simply not suitable candidates for re-operation and revision surgery for various reasons. As a result, the actual number of graft failures and re-ruptures is probably higher than the number of ACL revision surgeries, at least as shown in register studies.

The revision incidence in Sweden (Study II) is highest during the second year after reconstruction, which is in accordance with Salmon et al. (144) and can perhaps be explained by patients returning to sport six to twelve months post-operatively. It then takes some time to establish a diagnosis of a re-injury, such as a graft failure, and after that it takes time before the patient undergoes any kind of treatment, including surgery.

The annual incidence of ACL revision in Sweden (Study II) is very low during the first two to three years of the study period following single-bundle reconstruction and also following double-bundle reconstruction the first two years after surgeons began to perform double-bundle reconstruction. The reason for this is that every revision is handpicked and paired with a previous ACL reconstruction within the study period. This makes it impossible to compare the incidence between the two techniques in 2008 when a substantial part of the double-bundle reconstructions were performed, as the first patients undergoing surgery with double-bundle reconstruction have not had time to sustain a graft failure and subsequently be revised. Another potential reason for few revisions after double-bundle reconstruction is that surgeons might avoid performing a revision after a double-bundle reconstruction if they recently adopted the technique.

Single-bundle vs double-bundle ACL reconstruction

One of the many reasons for performing double-bundle reconstruction instead of single-bundle is that the double-bundle reconstruction mimics the native ACL to a greater extent and should therefore yield a superior outcome, especially in terms of restoring rotatory knee laxity. Moreover, double-bundle reconstruction might also have an advantageous knee kinematic profile and recruitment of fibres, which potentially reduces the incidence of graft failure. However, according to data from the Swedish National Knee Ligament Register (Study II), there is similar risk of revision between the two techniques. Moreover, only two (64, 116) of 23 studies included in Study I reporting graft failure found a difference in favour of double-bundle reconstruction, while 21 found no difference. However, the 23 studies found a total of 44 re-ruptures in the single-bundle groups compared with 19 in the double-bundle groups. In Study III, somewhat surprisingly, the double-bundle reconstruction was associated with a higher risk of revision according to the univariate analysis. However, after a further analysis, a combination of using an allograft and the double-bundle technique had the highest frequency of revision. Furthermore, it has previously been shown that the use of allografts increases the risk of ACL re-rupture. Moreover, patients who underwent double-bundle reconstruction were predominantly of a younger age and had a higher activity level. A new analysis was performed according to a multivariate logistic regression model and it revealed that the increased risk of ACL revision with the double-bundle technique could probably be attributed to the fact that a higher activity level and the use of allografts were confounding factors. This may appear contradictory, but it is consistent with previous studies that have

predominantly found no significant differences in terms of graft failure between the two techniques or fewer graft failures with double-bundle reconstruction. For instance, in their meta-analysis, Li et al. (152) found that double-bundle reconstruction was shown to be advantageous in terms of graft failure (P=0.002). Moreover, in their Cochrane meta-analysis, Tiamklang et al. (153) found six studies presenting data on graft failure, with no significant differences between the two techniques, and Mascarenhas et al. (154) did not identify any differences in terms of graft failure rates in their systematic review of overlapping meta-analyses.

The potential reduction in graft failure in double-bundle reconstruction could not be demonstrated in the present studies. Even though the double-bundle reconstruction in itself appears more advantageous theoretically, few differences are reported in clinical studies. One potential reason is the lack of power, which makes it difficult to obtain statistical differences. A type II statistical error is therefore a common denominator in most of these studies.

Age and activity level

Young age at the time of primary ACL reconstruction predicted a significantly increased risk of ACL revision in Study III. This is consistent with previous studies, in which young age has been associated with a higher risk of graft failure and revision surgery (147, 155-157). In addition to the assumed increase in activity level in younger patients, the reason for this could also be that they are less compliant in terms of rehabilitation and return too early to pivoting sports. These active lifestyle differences are difficult to assess and evaluate in order to establish whether they are true confounders and there is no available evidence to date to support or disregard these frequently used assumptions. However, it appears reasonable that younger individuals have a different and more active lifestyle compared with those who are a decade older, have probably started a family and are in full-time employment. In this study, at least the baseline activity level appears to be a predictor of ACL revision surgery, as subjects who underwent ACL revision were more likely to participate in a competitive sport compared with those with lower activity levels. This is both reasonable and logical due to the fact that competitive sports not only mean that the subject might exercise more often but also expose the subject to more intense situations.

Gender

An increased risk of primary ACL injuries in women has been reported in several studies (42, 144, 145, 158) and this could lead to the assumption that women also run a greater risk of graft failure. However, no effect of gender with respect to the risk of revision was found in Study III, which is in accordance with previous studies (116, 151, 153, 156, 159, 160). Interestingly, Salmon et al. (161) reported significantly greater laxity on physical examination after ACL reconstruction in female patients, but no effect on graft failure, activity level, or subjective or functional assessment. One possible reason is that a change in anatomical, biomechanical and neuromuscular control after ACL reconstruction (162, 163) outweighs the effect of gender in patients suffering primary ACL injuries. It is therefore possible that there is a gender difference with regard to primary ACL injuries but not with respect to the risk of revision.

Body Mass Index

An increased BMI leads to greater mechanical loads and might at least theoretically increase the risk of graft failures and

revisions. However, there are only a few studies in the current literature that investigate the effect of BMI on ACL revision. According to Study III, there was no correlation between ACL revision and BMI, which was also replicated in the study by Hettrich et al. (155). However, van Eck et al. (163) found that higher body weight was associated with an increased rate of graft failure after ACL reconstruction with allografts, although it is possible to suspect that the use of an allograft might have acted as a confounder. On the other hand, Persson et al. (164) found a higher risk of revision surgery in patients with a BMI of < 25 kg/m2 compared with patients with a BMI of > 25 kg/m2. One possible explanation could be that there was a correlation between a higher activity level and a lower BMI and consequently a higher risk of revision. Nonetheless, data from Study III and current evidence do not demonstrate a potential increase in the risk of revision with a higher BMI.

Femoral tunnel drilling technique

Drilling the femoral tunnel through an AM portal instead of through a tibial tunnel aids in reaching the anatomical ACL footprint and thereby also in providing better rotational laxity restoration and, accordingly, functional outcome. As opposed to the AM portal technique, the transtibial drilling technique is limited by the angulation of the tibial tunnel, which restricts the placement of the femoral tunnel and places it high in the femoral notch and non-anatomically. Several previous studies have compared the two techniques (165-171), but it still remains unclear which technique provides superior results. According to Study III, there was no difference in graft failure when drilling the femoral tunnel through a AM portal versus transtibial drilling. On the other hand, data from the Danish Knee Ligament Reconstruction Register showed an increased risk of revision ACL surgery when drilling the femoral tunnel through an AM portal compared with transtibial drilling (172). This could be related to a learning curve, as drilling the femoral tunnel through an AM portal is a new and technically more complex surgical procedure, with an increased risk of shorter tunnel length, damage to the peroneal nerve, iatrogenic cartilage damage and slipping of the aimer during hyperflexion, thereby entailing potential problems with graft selection, fixation method and an inadequate amount of graft in the tunnel (173, 174). Moreover, a new and more complex procedure could result in a proportion of the tunnel placements being inadequate and non-anatomic because of technical problems. In addition, studies have shown that, compared with a non-anatomic graft placement, a greater force is carried by the anatomic ACL reconstruction. Xu et al. (175) showed that an anatomically reconstructed AM bundle displayed significantly higher in-situ forces than the non-anatomic placement of the AM bundle. A greater load is therefore carried by an anatomically reconstructed graft, which makes it more vulnerable than a non-anatomically placed graft, because it transfers a greater load to other structures of the knee (175). This could partly explain why the revision rate is higher in the Danish Knee Ligament Reconstruction Register, when the femoral tunnel is drilled through an AM portal. Moreover, a confounder might be present, explaining the higher revision risk with AM portal drilling. The new and more complex procedure could result in a proportion of the tunnel placements being inadequate and non-anatomical because of technical problems related to poor visualisation.

Hamstring vs patellar tendon autografts Graft choice has been a hot topic for many

years and it is still a frequent research topic. The PT graft has clear advantages, with its bone plugs at both ends, and it thereby creates an exceptionally good interface with the bone tunnels. The structural strength of the quadrupled HT graft, on the other hand, is superior to that of the PT graft and the soft tissue-to-bone interface of the HT graft heals only a few weeks after the PT graft (176). Moreover, PT grafts have been reported to result in more harvest-site morbidity, with subsequently more patellofemoral pain problems (42, 177). Some studies have also found an increase in the prevalence of OA using PT grafts (42, 177). However, advocates of the PT graft have indicated that the PT graft produces less knee joint laxity than the HT graft (42). The data from Study IV did not reveal any increase in the risk of graft failure in patients undergoing surgery with an HT autograft in the long term. Revision surgery and graft rupture have recently attracted more attention, due to recent register studies that have shown a significant increase in the risk of revision surgery in patients who have received an HT autograft (150, 164, 178, 179). However, the reason for the proposed increase in the risk of revision surgery in patients in the above-mentioned studies might not be graft related. A confounder might be involved, as it has been proposed that the PT autograft is more frequently used in isometric transtibial ACL reconstruction. This technique does not restore rotatory laxity as successfully and thus also results in lower tension forces to the graft than a more anatomically placed graft. Not only do the data in Study IV contradict the five-year data from the above-mentioned register studies, they also suggest that both autograft groups run a greater risk of revision surgery in the long term. The reasons for this might be the three times longer follow-up period in Study IV and

possibly the high loss to follow-up in the register studies. Moreover, the results from Study IV are reproduced in the majority of published studies, including long-term studies, systematic reviews, meta-analyses

and a Cochrane review (31, 94, 177, 180-185). Taken together, there does not seem to be a difference between HT autograft and PT autograft ACL reconstruction in terms of the risk of graft failure.

15.2 SURGICAL TECHNIQUES

15.2.1 Single-bundle vs double-bundle ACL reconstruction

The last decade has been a transitional period, in which many surgeons in Sweden have adopted the anatomic single-bundle technique and the double-bundle technique. This transition reflects an attempt to restore the native anatomy, in an endeavour to improve laxity and reduce the risk of re-rupture. Double-bundle ACL reconstruction has proven to be more technically challenging, which entails a longer learning curve and could explain why the implementation of double-bundle reconstruction has gradually decreased in recent years according to the data from the Swedish National Knee Ligament Register. Moreover, it still remains unclear whether the increased surgical complexity and trauma associated with this technique outweigh the proposed long-term benefits. In addition, surgeons are progressively individualising their surgical approach, which means that anatomic single- and double-bundle ACL reconstruction can have different indications, e.g. depending on the insertion site size and orientation of the ACL and the notch size (186). One consequence of this individualisation might be seen in Study II, as males underwent double-bundle reconstruction to a greater extent and usually have larger knees.

AP laxity

AP laxity measured with the Lachman test, anterior drawer test and KT-

1000/2000 is most important when diagnosing an ACL injury. The tests for AP laxity can be instrumented and thus include quantitative data as feedback for the success of the surgery. In Study I, as many as half the included studies reported a significant difference in terms of AP laxity, with a superior outcome in the double-bundle group. No clear conclusion can be drawn from this, as there was not a majority of studies with significant findings in favour of either single- or double-bundle reconstruction. However, the significant differences in terms of AP laxity found in the included studies were all in favour of double-bundle reconstruction.

Rotatory laxity

The most important outcome measurements in the short term are probably those of rotatory laxity. Theoretically, there should not be any major difference between single- and double-bundle reconstruction in terms of AP laxity, as the strength of the double-bundle technique is mostly the control of rotatory laxity. Measurements with pivot shift in Study I revealed that 18 of 42 of the included studies reported a difference between the groups in terms of rotatory laxity in favour of double-bundle reconstruction. Rotatory laxity measured with a more precise method, i.e. navigation, revealed similar results, with nine of 20 studies reporting a difference in favour

of double-bundle reconstruction. Other systematic reviews, meta-analyses and Cochrane reviews have produced similar results, with superiority in some in terms of rotatory knee laxity for double-bundle reconstruction (153, 187, 188). Approximately half the studies reported significant differences in post-operative rotatory laxity and they were all in favour of double-bundle reconstruction, but it is still difficult to draw any major conclusions from this, even if it appears that double-bundle ACL reconstruction produces less rotatory laxity.

General clinical outcomes

Muscle strength is probably one of the most important general clinical outcomes because of the fact that increased muscle strength stabilises the knee joint and thus protects the ACL. Muscle strength and ROM are the two objective findings that are most frequently reported in the studies included in Study I. Only four studies of 32 demonstrated a difference in ROM, three in favour of double-bundle reconstruction (123, 125, 135) and one reported greater extension deficit in double-bundle reconstruction, but no difference with regard

to flexion deficit (65). In terms of muscle strength, two of ten studies reported a difference. One reported better muscle strength with double-bundle reconstruction (122) and one reported better flexor muscle strength with single-bundle reconstruction (141). One explanation for the different ROM and muscle strength could be different graft types in the two groups that were compared. However, a review of the studies reporting differences revealed only one study using different graft types (HT and PT) in the two groups. Of the 60 included studies, only seven did not use HT grafts in all groups. In conclusion, there are no obvious differences in terms of muscle strength or ROM between the two surgical techniques, even though a few studies showed better ROM after double-bundle ACL reconstruction. However, the general idea behind double-bundle reconstruction is to restore native knee kinematics to a greater extent and thus provide improved long-term knee health, so any difference in general clinical outcome would most probably not be seen in short- to mid-term studies, like the ones included.

15.2.2 Graft choice

Osteoarthritis is the leading cause of knee-related pain and disability in middle-aged people (189, 190), which makes preventing the development of post-traumatic OA after ACL injuries extremely important. Researchers have implied that the PT graft is more likely to lead to OA, especially patellofemoral OA, than the HT graft. However, the studies on this topic are divergent, where some show no difference between the graft types and some show a greater risk of OA after ACL reconstruction with PT grafts. The most important finding in Study IV was that

patients operated on using either HT or PT autografts revealed significantly more radiographic signs of OA in the injured knee compared with the healthy contralateral knee. This is consistent with previous studies (1, 2), in which ACL injury and reconstruction have been associated with a higher risk of OA (191, 192). However, no differences were found between the two graft types in terms of OA, which is in accordance with previous RCTs (177, 191-196). Only two of them have more than 10 years' follow-up, Barenius et al. (191), with 14 years' follow-up and Webster et al.

(193) with 15 years' follow-up. However, as stated above, previous studies have been inconclusive and Leys et al. (177) found an increase in the development of OA in patients operated on using PT autografts. However, their study is not an RCT, which increases the risk of selection bias. The same results have been reported in three RCTs with five- to seven-year follow-ups (197-199). We found no major difference in the distribution of OA grade between the graft types in Study IV. According to Kellgren Lawrence, 13.7% of the patients operated on using PT autografts had severe OA (grades III-IV), compared with 8.2% in the HT group, and moderate OA (grades I-II) was present in 54.9% of the patients in the PT group, compared with 57.6% in the HT group. Study IV provides the longest RCT follow-up currently available on endoscopic ACL reconstruction surgery and confirms what has been assumed and previously shown, i.e. that an ACL injury and subsequent ACL reconstruction lead to an increased risk of OA compared with the healthy contralateral knee. Moreover, it demonstrates that there is no difference between ACL reconstructions using PT autografts compared with HT autografts in terms of OA, which might indicate that the choice of autograft does not affect the outcome in terms of long-term knee health.

As previously mentioned, no differences were found between the graft types in terms of graft failure in Study IV. The same thing was demonstrated in terms of contralateral ACL injuries, which were approximately as common as graft ruptures. Three other long-term studies with 14- and 15-year follow-ups have assessed this issue (177, 191, 200). Barenius et al. in a RCT and Bourke et al. in a case series reported similar results; however, the study by Leys et al. found that patients with PT autograft reconstruction had sustained more than twice as many

contralateral injuries at the final follow-up, 26% versus 12% for the HT autografts (177). The study by Leys et al. was not an RCT and a selection bias might therefore be present. In conclusion, there is no difference between PT and HT autograft ACL reconstruction in terms of contralateral ACL injuries in the current literature.

There has been some concern that the HT autograft might be inferior to the PT autograft in terms of residual laxity and laxity over time, although the structural strength of the quadruple HT autograft is superior to that of the PT. According to Study IV, few differences were found between HT and PT autograft ACL reconstruction in terms of knee laxity measurements. This is in line with previous studies on this topic. Both groups had significantly less knee laxity post-operatively, indicating that the reconstruction was successful in restoring clinically relevant knee kinematics and laxity. Moreover, the clinical assessments revealed only a few significant differences between the two study groups. Several previous studies, including the short-term reports on the same cohorts, only found differences related to harvest-site morbidity, with increased morbidity in patients undergoing PT autograft reconstruction (1, 2). In Study IV, the differences between the two groups in terms of harvest-site morbidity were small yet statistically significant. The reasons for the small differences might be that harvest-site morbidity from PT autograft harvest diminishes with time and that patients in both groups start to develop degenerative changes, thus minimising the difference between groups. Moreover, some patients had their PT graft harvest through a potential nerve sparing two-incision technique. The development of degenerative changes might also be the reason for both groups having less ROM at the follow-up compared with the pre-operative values.

The main theoretical advantages of allografts compared with autografts are the lack of harvest-site morbidity, a less traumatic surgical technique, reduced post-operative pain and easier early rehabilitation. However, allografts are an expensive option and carry a higher failure risk (201-204). In Study III, a multivariate logistic regression model revealed that the allograft was an inferior graft choice in terms of ACL revision frequency compared

with the autograft. This is not only in line with most previous studies in this area (205, 206), it is also biomechanically and histologically reasonable. Moreover, previous studies have found that ACL reconstruction with allografts combined with an early return to sports is a risk factor for graft failure (144, 159, 203). Consequently, the previously described higher failure risk after ACL reconstruction with allografts was established in Study III.

15.3 PATIENT-REPORTED OUTCOME MEASURES

Patient-reported outcome measures are often used in clinical research and it is essential that they are sensitive enough to detect clinically relevant changes, especially if they are related to different surgical techniques. PROMs are perhaps more useful with time when differences between groups increase. The most commonly used PROMs in Study I were the IKDC, Lysholm score and Tegner activity level scales. The differences that were shown were in favour of double-bundle reconstruction, eight of 35 in the IKDC, two of 31 in the Lysholm score and one of 19 related to the Tegner activity level. The KOOS, Cincinnati Knee Score, Marx activity rating scale, VAS and subjective recovery score are also occasionally reported; a total of three of twelve studies reported differences. A few other PROMs were also reported, but none of them was able to detect any differences.

Both the KOOS and EQ-5D are used in the Swedish National Knee Ligament Register. Their profiles were presented for the single- and double-bundle groups in Study II and both improved significantly in all subgroups post-operatively. However, there was no difference in the between-group comparisons. This is in accordance with

the results of previous studies of PROMs when comparing single- and double-bundle ACL reconstruction (42, 146, 207). The double-bundle group had significantly lower pre-operative KOOS scores in three subscales (pain, symptoms, ADL) and the KOOS4, but, at the one- and two-year follow-ups, no significant differences were found between the groups. The reasons for the pre-operative differences between the groups are unclear, but selection bias could be one explanation, as it is possible that surgeons preferred performing double-bundle ACL reconstruction in patients who had more severe knee symptoms. No significant differences were found between the groups in terms of the EQ-5 D, either pre-operatively or post-operatively.

The questionnaires included in Study IV were the Lysholm score, Tegner activity level scale and IKDC subjective score. There were no significant differences between the graft types in terms of the subjective IKDC score. However, patients reconstructed with either HT or PT autografts had a significant post-operative increment in the Lysholm score and a decrease in the Tegner activity scale; however, no significant differences were found between the graft types. The Tegner activity level had de-

creased to half that of the pre-injury values and both the Tegner activity level and the Lysholm score were lower compared with the normal healthy population (208). The reasons for this are most probably changes in lifestyle and preferences when ageing, in addition to increased degenerative changes in the knee, indicating that the ACL-in-

jured and reconstructed knee limits the patient's function and activity more than normal ageing.

According to these results there was an increase in PROM values post-operatively but there was, however, no differences when different surgical techniques were compared.



16 STRENGTHS AND LIMITATIONS

Study I

The strengths of Study I are its comprehensiveness and the fact that it includes all the clinical studies comparing single- and double-bundle ACL reconstruction. In addition, the execution and validation of the search were performed by two experts in electronic search methods at the Sahlgrenska University Hospital Library. However, the electronic search was only made in three databases,

PubMed (MEDLINE), EMBASE and the Cochrane Library, and only for studies that were published in English from January 1995 to August 2011. An updated search was performed in July 2012 on PubMed alone, which could cause a publication bias. Despite the extensive search, it is possible that some studies were not discovered. In addition, only articles in English were included, which can create a language bias and publication

bias. Moreover, due to the number of studies, there is a risk of studies being missed during the process. Unpublished studies were not included, thereby increasing the risk of publication bias. Authors were not contacted for unpublished data and references in included studies were not scanned for missed studies. Finally, this systematic review included not only level 1 studies but also levels 2 and 3. This lowers the level of evidence of the systematic review, while it also creates a more complete picture of the best evidence available at present.

The quality of the included studies was assessed in the original systematic review using an adapted version of the Cochrane Collaboration's tool for assessing the risk of bias in randomised, controlled trials (62). According to the Cochrane Handbook for Systematic Review, including non-randomised studies is justified, but it is important to realise that potential biases are likely to be greater and the results should be interpreted with caution (209). However, with the emphasis on clinical results, no quality assessment is included in this thesis. In spite of this, there is no question that methodological errors in the study design in many of the included studies directly affect this systematic review. In addition, some of the differences in the outcomes in a systematic review comprising so many studies from many different institutions and surgeons can be explained by other factors, independent of the single- or double-bundle techniques. These factors include graft choice and fixation, rehabilitation, rate of return to sports, drilling technique and so on. However, we chose these limits intentionally to minimise complexity in the writing of Study I.

Study II

The strengths of Study II are the large number of patients included and the

fact that the evaluation of the results was performed by the patients (PROM). Further strengths include the fact that population-based clinical registers with large sample sizes provide high-precision estimates and enable generalisation, but, simultaneously, a risk of registration bias exists with data registered by many surgeons. In addition, the registers reveal problems before they are reported by RCTs. In spite of this, RCTs represent the gold standard and the highest level of evidence. Moreover, register studies are hypothesis generating and their results often need to be validated with RCTs. The main limitation of this study is that the primary outcome is revision surgery, which probably leads to an underestimation of the true occurrence of graft failures. Moreover, several patients were lost to follow-up and did not complete the KOOS and EQ-5D questionnaires. One reason for this might be that only KOOS questionnaires with all the items completed are registered. In addition, the double-bundle group is smaller, with slightly different demographics compared with the single-bundle group, which could affect the comparability and create a selection bias. The fact that the register is lacking objective outcome measurements and radiological documentation is an obvious limitation. There is also a risk of selection bias in the double-bundle cohort, as surgeons' preconceptions may cause them to perform double-bundle reconstruction on the most unstable patients. Another limitation is that the double-bundle technique was fairly new and under development during the given time period, thus having a substantial learning curve.

Study III

The strength of Study III is that the patients were asked to report all subsequent surgeries, not only revision ACL reconstruction. Given the significance of sur-

gery to patients, it is not likely that they would under-report revision ACL surgery. Moreover, the determination of revision surgery was not solely dependent on the patient returning to the UPMC Center for Sports Medicine, which minimises the risk of underestimating the true rate of ACL revision, because patients may elect to go to another provider for their revision surgery. Retrospective case control studies are often used to identify potential risk factors for adverse outcomes. The main limitations are poor follow-up and the fact that non-responders to the study invitation were younger and more likely to be males than those that responded. Since younger individuals, in both the current study and previous reports, are more likely to undergo revision surgery, missing data from younger individuals could affect the prevalence of ACL revision and result in an underestimation of the true overall revision surgery rate. Moreover, the fact that objective outcome measurements were not included is an obvious limitation. Finally, revision surgery was used as a measurement of graft failure and it is likely that some individuals who experienced graft failure chose not to undergo revision surgery, which probably underestimates the graft failure rate.

Future studies that prospectively evaluate the incidence of ACL revision surgeries are necessary in order more accurately to determine the rate of ACL revision surgery after primary ACL reconstruction, as well as the factors that are associated with ACL revision. The validity of these prospective studies will be dependent on achieving adequate long-term follow-up (more than 80% over five years or more) to determine the true estimate of revision ACL reconstruction. In addition to determining the incidence of ACL revision, to determine the true rate of ACL graft failure, other

indicators of graft failure that should be considered are complaints of knee instability, pathological laxity (both anterior and anterolateral) and MRI evidence of graft failure.

Study IV

The strengths of Study IV are the randomised design and the long follow-up. Further, strengths are the large number of patients included and the independent blinded observer assessment. The fact that a radiological follow-up was performed on both knees is also a strength. The limitations include the fact that the follow-up rate is just below 80% (76%) and that the study consists of a merger of two previous randomised studies. It is, also, an obvious limitation that the HT autografts in the previous studies were either a quadruple ST/G tendon or a triple or quadruple ST tendon. Moreover, the PT autograft harvest technique in the previous studies was not consistent. Another limitation is that no sample size calculations were made prior to the initiation of the original studies. The fact that the KT-1000 arthrometer anterior side-to-side difference was only measured at 89 N preoperatively and at 134 N and manual maximum test at follow-up is another limitation. Moreover, the use of both the transtibial and the medial portal approach during femoral tunnel drilling must also be regarded as a weakness. However, at the time when the patients underwent reconstruction, the anatomic principles were not known and both techniques aimed to place the femoral tunnels in the same position. Finally, it is also important to consider that the non-significant differences that were found could still be caused by a type-two error.





17 CONCLUSIONS

17.1 GRAFT FAILURES

No major differences regarding graft failure are reported in the present literature comparing single- and double-bundle ACL reconstruction (Study I).

The revision rates after both single- and double-bundle ACL reconstruction are low according to the Swedish National Knee Ligament Register (Study II).

No difference in revision rates between single- and double-bundle ACL reconstruction exists according to the Swedish National Knee Ligament Register (Study II).

Younger age at the time of surgery increases the risk of revision ACL reconstruction/ graft failure (Study III). ACL reconstruction performed with allografts increases the risk of revision ACL reconstruction/graft failure (Study III).

No difference in the revision rates between ACL reconstructions with HT grafts or PT grafts (Study IV).

17.2 SURGICAL TECHNIQUES

Double-bundle ACL reconstruction might have less rotatory laxity than single-bundle (Study I).

Significantly more radiographic signs of OA in the ACL reconstructed knee than in the contralateral healthy knee after ACL reconstruction with either HT or PT autografts (Study IV).

No differences in the radiographic signs of OA after ACL reconstructions with HT grafts or PT autografts (Study IV).

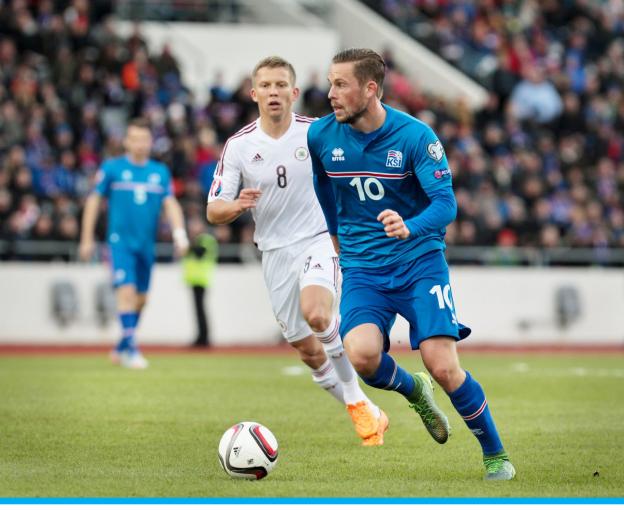
Significantly better knee-walking ability after ACL reconstruction with HT autografts compared with PT autografts at the long-term follow-up (Study IV).

17.3 PATIENT-REPORTED OUTCOME MEASURES

No differences in short-term PROMs between single- and double-bundle ACL reconstruction (Study I).

No differences in the KOOS or EQ-5D between single- and double-bundle ACL reconstruction according to the Swedish National Knee Ligament Register (Study II).

No differences in the Lysholm score, Tegner activity level or IKDS after ACL reconstruction using either HT or PT autografts (Study IV).



18 FURTHER CONSIDERATIONS AND FUTURE PERSPECTIVES

The incidence of ACL injuries has risen exponentially in recent years, in connection with both increasing enthusiasm for professional sports and an increased activity level in the general population. This has resulted in a move from performing occasional ACL surgery, in the nineteenth century, to the present time, where ACL reconstructions are a common procedure. Moreover, the treatment of ACL injuries

has moved from open to arthroscopic ACL reconstruction and many of us may not even remember the days when ACL reconstruction required the joint to be opened.

Nowadays, ACL reconstruction has become a standard procedure, but it is important that we continually review our results in an attempt to provide the best treatment possible. In order to do so, we

require sensitive outcome measurements and end-points that are easily accessible. However, confirming graft failures is often complicated and the available PROMs struggle to distinguish differences between surgical techniques.

This probably explains, to a certain extent, why we are still searching for the best surgical technique. Nevertheless, anatomic ACL reconstruction appears promising. The purpose of anatomic reconstruction is to restore knee function by recreating the native anatomy. However, the large diversity in the size and shape of the ACL femoral origin and tibial insertion described by Kopf et al. (11) makes it challenging. These diversities make the clinical application of the specific quantitative data as presented in the literature difficult to use in the best possible way. Understanding the individual variations in the ACL femoral origin and tibial insertion anatomy is therefore of paramount importance. To aid in establishing consistent reconstruction techniques, the use of remnant tissue and anatomical landmarks is more reliable than relying on the numbers of the ACL femoral origin and tibial insertion size from published studies or generalised distances. Using anatomical landmarks and the individual ACL femoral origin and tibial insertion size can more effectively account for patient-to-patient anatomical variability.

This patient-to-patient variability has recently led to individualised ACL reconstruction that allows for the customisation of the reconstruction to each individual patient. However, individualised ACL reconstruction accounts not only for the anatomy but also for graft choice, lifestyle and activity preferences as well. By individualising anatomical ACL reconstruction, we can hopefully improve both clinical and objective outcomes and reduce

post-traumatic-related OA. We should not, however, forget Jack Hughston's advice that there is no knee injury which could not be made worse by inappropriate surgical management. With this advice in mind, prevention programmes designed to reduce ACL injuries are a feasible option. Studies have shown that these programmes are successful in the short term and reduce the risk of injury (210). In addition, Engebretsen et al. (211) have demonstrated that individuals with a significantly increased risk of injury can be identified. It is to be hoped that this will enable us to identify the individuals with an increased risk of ACL injury and help them reduce the risk with proper training programmes. Despite this, compliance has been a frustrating problem that will provide food for thought for years to come.

19 ACKNOWLEDGEMENTS

I wish to express my deepest gratitude to all those who have contributed to and made this thesis possible. In particular, I would like to thank:

Jón Karlsson, Professor, MD, PhD, whom I deeply respect as a great tutor and clinical mentor and regard as one of my dearest friends. Your remarkable generosity and willingness to teach from your vast knowledge in the field of research and clinical sports medicine has truly enriched my life and made it a pleasure and honour to work with you. This thesis would never have been written if it were not for you. You are my role model.

Kristian Samuelsson, MD, PhD, my dear and gifted friend, tutor and colleague, for your motivation and encouragement. I am really grateful for all your constant support and endless generosity. Thanks for making this journey a great experience.

Bengt Eriksson, Professor, MD, PhD, for all your help and inspiration. It has been a privilege to work with you and have you as a mentor.

Freddie H. Fu, Professor, MD, DPs, DSc, for opening the door to the Department of Orthopaedic Surgery in Pittsburgh and for outstanding hospitality.

Volker Musahl, Associate Professor, MD, for your guidance and giving me the opportunity to do research at the Department of Orthopaedic Surgery in Pittsburgh, which has broadened my horizons. Special thanks for your great hospitality and exhausting training sessions.

James J. Irrgang, Professor, PT, PhD, ATC, FAPTA, for very gratifying collaboration and tremendous hospitality. Special thanks for inviting me to my first tailgate.

Neel Desai, MD, my colleague and friend, for great collaboration and for always providing a positive attitude.

Páll Sigurgeir Jónasson, MD, my like-minded friend and colleague, for all the invaluable discussions and for being a brother in suffrage.

Valtýr Stefánsson Thors, MD, and Snorri Donaldsson, MD, my dear friends, for all the great times together far away from research and for all the fantastic moments from our golf trips. I really hope there will be many more.

My colleagues and friends, Mikael Sansone, Mattias Ahldén, Nicklas Olsson, Olof Westin and Daniel Andernord, for all the fantastic moments and interesting discussions.

The Gran Canaria Research Group, for productive collaboration in friendly environments and a great climate.

Leif Swärd, Associate Professor, MD, PhD, for taking me in and sharing your expertise and clinical advice.

Helena Brisby, Professor, MD, PhD, Chairman of the Department of Orthopaedics at the Sahlgrenska Academy, for giving me the opportunity to do research.

Magnus Karlsson, MD, Head of the Department of Orthopaedics at Sahlgrenska University Hospital, Mölndal, for giving me the opportunity to combine research with clinical work.

All my **colleagues** and **friends** at the Orthopaedic Department at Sahlgrenska University Hospital, Mölndal, Orthocenter/IFK-kliniken and Orkuhúsið, for your clinical guidance and support.

Linda Johansson, research administrator, for your invaluable knowledge and guidance in all matters relating to the Sahlgrenska Academy.

Annika Samuelsson Enderlein, graphic designer, for excellent work on the layout and design of this thesis.

Pontus Andersson, for excellent illustrations.

Jeanette Kliger, language editor, for excellent editing of the English language in this thesis.

My parents, **Sólrún** and **Björn/Ingibjörg**, for your unwavering support and love. You taught me to believe in myself and inspired me always to do my very best. This triumph is yours as much as it is mine. I cannot express how grateful I am for all the sacrifices you have made. Thanks for always being there for me.

My brothers, **Tryggvi**, **Jónas** and **Davíð**, for being my best friends. I feel so lucky to have you around and treasure the moments we have together.

My parents-in-law, **Ófeigur** and **Anna Magga**, for their selfless love and great support. You welcomed me into your family and home from the first day and for that I will be eternally thankful.

My children, **Hildur**, **Bjarki** and **Sandra**, for your unconditional love and inspiration. You mean more to me than words can ever say. I am blessed to have you in my life.

Most of all, **Fanney**, for constantly reminding me of what is true and important. You have been so unselfishly understanding and supportive and given me the strength to succeed. You are the love of my life, my wife. I adore you.

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21 APPENDIX

 \boldsymbol{A} special protocol was developed for the pre-operative and post-operative clinical evaluations in Study IV.

| Name | No |
|--------------------------------|---|
| Sex | ○ female ○ male Hospital |
| Age at op | Single v Double |
| Injuried side | ○ left ○ right |
| Dominant side | left right |
| Contralateral side normal | ○ yes ○ no |
| Cause of injury | ○ contact sport ○ none contact sport ○ ADL ○ work ○ other |
| Previous surgery | □ none □ diagn arthro □ ACL □ other □ open men □ arthro men |
| Date of reconstruction | |
| Type of operation | ○ within 2 months after injury weeks after injury ○ more than 2 months after injury months after injury ○ Revision surgery months after recon |
| Injuries at reconstruction | None but ACL □ MCL □ Cartilage □ Med men □ PCL □ Other □ Lat men □ P cap □ ACL □ LCL □ Artrosis |
| Type of graft | □ BTB II □ BTB reharvest □ ST+G □ BTB 2I □ ST □ Other |
| Index procedure | □ BTB contra lat □ FL □ ACL endo □ MCL □ Men sut lat □ Other □ ACL 2I □ LCL □ Part men med □ PCL □ Men sut med □ Part men lat |
| Twisted graft fixation | yes ○ no Graft |
| Pretension | ○ yes ○ no |
| Hospital stay | day/s |
| Brace | ○ yes ○ no |
| Sickleave | days |
| Early problems (< 3 months) | □ None □ Ext def □ Other □ Delayed wound healing □ Deep inf □ Wound inf □ Trombosis |
| Fp I months pop | Fp II months pop Fp III months pop FpIV months pop |
| ROM Preop | ext flex ext flex ext flex ext flex Fp I Fp II Fp IV |
| ROM contralateral side | ext flex |

| Manual MC | CL co | mpar | ed wi | th co | ntrala | teral sic | le | | | | | | | |
|-------------|-----------------------------|-------|----------|-----------------------------|---------------------|-----------|---------------------------|-----|-------|---------------------------|----------|--------|------------------------------|--------|
| Preop | 0 0 1: 0 2: 0 3: | + | FpI | 0 | 0 1+ 2+ 3+ | Fp II | 0 01+ 02+ 03+ | F | p III | 0 0 1+ 0 2+ 0 3+ | | Fp IV | 0 0 1+ 0 2+ 0 3+ | |
| Manual LC | L con | npare | d wit | h con | tralat | eral sid | е | | | | | | | |
| Preop | 0 01 02 03 | + | Fp | 0000 | 1+ 2+ | Fp II | 0 0 1+ 0 2+ 0 3+ | | FpI | 0 1- 0 2- 0 3- | + + | Fp | IV 0 0 1- 0 2- 0 3- | + + |
| KT 1 000 | 15 lb | s | | 20 lbs | | l | KT 1 | 000 | 15 II | bs | | 20 lbs | | pre I |
| Prop I | NI | D | I | NI | D | | Fp I | I | NI | D | I | NI | D | pre NI |
| A P T | | | | | | | A P T | | | | | | | 30 lbs |
| KT 1 000 | 15 lb | s | | 20 lbs | | | KT 1 | 000 | 15 [| bs | <u> </u> | 20 lbs | | |
| Fp II I | NI | D | I | NI | D | | Fp III | I | NI | D | I | NI | D | |
| A P T | | | | | | | A P T | | | | | | | |
| KT 1 000 | 15 lb | s | <u> </u> | 20 lbs | | | | | | | | | | |
| Fp IV I | NI | D | I | NI | D | 1 . | MMT N | | | | | MMT I | | |
| A P T | | | | | | | III MMT I MMT NI | | | | | pIV MM | | |
| Manual La | chma | ınn c | ompa | red w | ith co | ntralate | eral side | • | | | | | | |
| FIOD C | 0 1+ 2+ 3+ | | FpI | 0 0 0 1+ 0 2+ 0 3+ | - | (| 0 0 1+ 0 2+ 0 3+ | Fp | (| 0 1+ 2+ 3+ | F | | ○ 0 ○ 1+ ○ 2+ ○ 3+ | |
| Total AP 7 | | mpar | red wi | | | | | | | | | | | |
| Prop | ○ 0 ○ 1+ ○ 2+ ○ 3+ | | Fp I | 0 0 0 1- 0 2- 0 3- | + + | Fp II | 0 0 1+ 0 2+ 0 3+ | Fp | Ш | 0 0 1+ 0 2+ 0 3+ | F | | 0 0 1+ 0 2+ 0 3+ | |

| Posteri | or sag 70° co | ompar | ed with co | ontrala | teral side | | | | |
|----------|---------------------------|---------|----------------------------------|----------|----------------------------------|---------------------|---------------------------|-----------------------------------|--|
| Prop | 0 01+ 02+ 03+ | FpI | 0 01+ 02+ 03+ | Fp II | 0 01+ 02+ 03+ | Fp III | 0 0 1+ 0 2+ 0 3+ | ○ 0 Fp IV ○ 1+ ○ 2+ ○ 3+ | |
| Pivot sh | ift compare | d with | contralate | eral sic | ie | | | | |
| Prop | 0 0 1+ 0 2+ 0 3+ | FpI | 0 0 1+ 0 2+ 0 3+ | Fp II | ○ 0 ○ 1+ ○ 2+ ○ 3+ | Fp III | 0 0 1+ 0 2+ 0 3+ | Fp IV 0 0 1+ 2+ 3+ | |
| Reverse | d pivot shift | comp | ared with | contra | ılateral sid | de | | | |
| Prop | 0 0 1+ 0 2+ 0 3+ | | 0 0 1+ 0 2+ 0 3+ | Fp II | 0 0 1+ 0 2+ 0 3+ | Fp III | 0 0 1+ 0 2+ 0 3+ | □ 0 □ 1+ □ 2+ □ 3+ | |
| Firm e | nd point | | | | | | | | |
| Prop | ⊃ yes ⊃ no | Fp I | yesno | Fp II | yesno | Fp III | ∪ yes ○ no | Fp IV yes no | |
| Firm en | d point cont | ralate | ral side | | ○ yes ○ no | | | | |
| One leg | hop | | | | | | | | |
| Prop | % | Fp I | % | Fp II | % | Fp III | % | Fp IV % | |
| Pareste | sia (ant-post |) x (pr | ox-dist) | | | | | | |
| Prop | cm ² | FpI | cm ² | Fp II | cm | ² Fp III | cm ² | Fp IV $_$ cm 2 | |
| Subjec | tive femoro- | patella | ar pain | | | | | | |
| Prop | ○ yes ○ no | | ⊖ yes ⊖ no | | ⊖ yes ⊖ no | Fp III | ○ yes ○ no | Fp IV ○ yes ○ no | |
| Femore | Femoro-patellar score | | | | | | | | |
| Prop | | Fp I | | Fp I | ı | Fp II | ı | Fp IV | |
| | | | | | | | | | |

| Donor site pain no prop yes Fp I apex mid tuberositas pes thigh dorsal screw | no yes F apex mid tuberositas pes thigh dorsal screw | no p yes apex mid tuberositas pes thigh dorsal screw | pes | x erositas h dorsal | no yes apex mid tuberositas pes thigh dorsal |
|---|--|---|--------------------------|---------------------------|--|
| Patellar tendon dono | _ " | | | | |
| | Fp I ⊖ yes ⊖ no | Fp II ⊖ yes ⊖ no | Fp III O y | es Fp IV | ○ yes ○ no |
| O Not pleasant O Difficult | OK Fp Not pleasant Difficult Impossible | II OK Not pleasant Difficult Impossible | ○ Diff | pleasant | OK Not pleasant Difficult Impossible |
| Knee walking OK Not pleasant Difficult Impossible | OK Fp II Not pleasant Difficult Impossible | OK Fp Not pleasant Difficult Impossible | | pleasant | OK Not pleasant Difficult Impossible |
| IKDC (Group grade) Subjective function | Preop O A O B O C O D | Fpl | FpII A B C D | FpIII | FpIV |
| Subjective symptoms | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D |
| Range of motion | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D |
| Ligament evaluation | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D |
| IKDC Final evaluation | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D | ○ A ○ B ○ C ○ D |

TEGNER ACTIVITY SCALE Competitive sports Work soccer - national or international level heavy labour (eg building, forestry) Competitive sports cycling Competitive sports cross-country skiing soccer - lower divisions icehockey Recreational sports jogging on uneven ground at least twice weekly wrestling gymnastics Work Competitive sports moderately heavy work bandy (eg lorry-driving, charring) squash or badminton Recreational sports athletics (jumping, etc) downhill skiing cycling cross-country skiing jogging on even ground at least twice weekly Competitive sports athletics (running) Work motocross or speedway light work (eg nursing) tennis handball or basketball Competitive and recreational sports Recreational sports soccer walking in rough forrest terrain bandy or icehockey squash athletics (jumping) Work light work cross-country track findings (orienteering) both recreational and competitive walking on uneven ground Work Recreational sports sedentary work tennis or badminton walking on even ground handball or basketball downhill skiing jogging at least 5 times weekly Sickleave or disability pension because of knee problems Performed level Desired level Pre injury Fp I Prop Fp II Fp III Fp I Fp II Fp IV Fp III Fp IV

| Limp | | | | | | Pain | | | | | |
|--|--------|----|------|--------|--------|--|------|----------|----------|----------|---|
| None | | | | Fp III | | None | Prop | | | Fp III | |
| Slight and/or periodical | 5 | | 5 | 5 | 5 | Inconstant and slight during heavy exertion | | 25 20 | 25 20 | 25 20 | 2 |
| Severe and/or periodical | 0 | | 0 | 0 | 0 | Marked, during heavy | | 20 | 20 | 20 | 4 |
| | | | | | | exertion | 15 | 15 | 15 | 15 | 1 |
| Support | | | | | | Marked, on or after walking >2 km | 10 | | | | |
| None | 5 | 5 | 5 | 5 | 5 | Marked, on or after | 10 | 10 | 10 | 10 | 1 |
| Stick or crutch | 2 | | | 2 | 2 | walking <2 km | 5 | 5 | 5 | 5 | |
| Weight-bearing impossible | 0 | 0 | 0 | 0 | 0 | Constant | | | | | |
| Locking | | | | | | | 0 | 0 | 0 | 0 | |
| No locking and no catching Catching sensations but no | 15 | 15 | 15 | 15 | 15 | Swelling | | | | | |
| 1 1: | 10 | | | | 10 | None On beauty exertion | | | | | |
| Locking occasionally Locking frequently | | | | | | On heavy exertion On normal exertion | 10 | 10 | 10 | 10 | 1 |
| | | 6 | | | 6 | Constant | 6 | 6 | | | |
| Locked joint on examination | 0 | 2 | | | 2 | | 0 | 2 | | | |
| Instability | U | 0 | U | U | U | Stair-climbing | U | U | 0 | 0 | |
| No giving way | | | | | | No problems | | | | | |
| Rarely, during athletics or other | 25 | 25 | 25 | 25 | 25 | Slightly impaired | 10 | 10 | 10 | 10 | 1 |
| heavy exertion Frequently, during athletics or | | | | | 20 | One step at a time | 6 | | | | |
| other heavy exertion (or unable | | | | | | Impossible | 2 | 2 | | | |
| to participate) | 15 | 15 | 15 | 15 | 15 | | 0 | 0 | 0 | 0 | |
| Occasionally, in daily activities | | | | | | Squatting | | | | | |
| Often, in daily activities At every step | 10 | 10 | 10 | 10 | 10 | No problems | | | | | |
| rat every step | 5 | | | | 5 | Slightly impaired Not beyond 90° | 5 | 5 4 | | | |
| | 0 | 0 | 0 | 0 | 0 | Impossible | 2 | | | | |
| | | | | | | | 0 | 0 | 0 | 0 | |
| Instability | | | | | | | | | | | |
| Prop Fp I | | - | Fp | II | | Fp III | Fp | IV _ | | | |
| Pain | | | _ | | | F- W | _ | | | | |
| Prop Fp I | | - | гp | II | _ | Fp III | гp | IV | | | |
| Total | | | | | | | | | | | |
| Prop Fp I | | - | Fp | II | _ | Fp III | Fp | IV _ | | | |
| Cause of additional No si surgery Ext diwithin 2 years | | | | | | ☐ ACL-rein ☐ Other 1 ACL) | jury | | | | |
| Patients evaluation at 2 | year | s | ○ Po | or 🗆 | Fair (| Good CExcellent | | | | | |
| Patients expectansy at a | 2 year | rs | ∩ Po | or 🗀 | Fair (| Good © Excellent | | | | | |
| · allowed ampostalloy at | • | | | | | Good C Enconom | | | | | |

| X-ray | findings | | | | | | | |
|--|-------------------------|--|-----------|------------------------------|-------------|---------|---|--|
| | osteophytes trosis | | rtrosis | ☐ Ant fem o | drill-holes | | | |
| | osteophytes trosis | | rtrosis | ☐ Ant fem o | irill-holes | | | |
| | osteophytes trosis | | rtrosis | ☐ Ant fem o | drill-holes | | | |
| Fp III ☐ None ☐ Notch o ☐ Med ar | osteophytes trosis | Lat artrosi Fem-pat a Ant tib dri | rtrosis | ☐ Ant fem o | irill-holes | | | |
| Fp IV □ None | | Lat artrosi | is | ☐ Ant fem o | irill-holes | | | |
| ☐ Notch ☐ Med ar | osteophytes trosis | Fem-pat a Ant tib dri | | Other | | | | |
| Med ar | rthotron at 9 | Ant tib dri | ill-holes | | | | 7 | |
| ☐ Med ar | trosis | Ant tib dri | ill-holes | ☐ Other | extension | flexion | 1 | |
| Med ar | rthotron at 9 | Ant tib dri | ill-holes | | extension | flexion |] | |
| Med ar Cybex or Preop | rthotron at 9 | Ant tib dri | ill-holes | Fp I | extension | flexion | | |
| Med ar Cybex or Preop | rthotron at 9 | Ant tib dri | ill-holes | Fp I | extension | flexion | | |
| Med an Preop I NI I/NI | rthotron at 9 extension | Ant tib dri O° / secon flexion | ill-holes | Fp I I NI I/NI | | | | |
| Med ar Cybex or Preop I NI | rthotron at 9 | Ant tib dri O° / secon flexion | ill-holes | Fp I I NI | extension | | | |
| Med an Preop I NI I/NI | rthotron at 9 extension | Ant tib dri O° / secon flexion | ill-holes | Fp I I NI I/NI | | | | |
| Med ar Cybex of Preop I NI I/NI Fp II | rthotron at 9 extension | Ant tib dri O° / secon flexion | ill-holes | Fp I I NI I/NI Fp III | | | | |
| Med ar Cybex of Preop I NI I/NI Fp II | rthotron at 9 extension | Ant tib dri O° / secon flexion | ill-holes | Fp I I NI I/NI Fp III I | | | | |
| Med ar Cybex of Preop I NI I/NI Fp II I NI | rthotron at 9 extension | Ant tib dri O° / secon flexion | ill-holes | Fp I I NI I/NI Fp III I NI | | | | |
| Med ar Cybex of Preop I NI I/NI Fp II I NI I/NI | extension | Ant tib dri O° / secon flexion flexion | ill-holes | Fp I I NI I/NI Fp III I NI | | | | |
| Med ar Preop I NI I/NI Fp II I NI I/NI Fp IV | extension | Ant tib dri O° / secon flexion flexion | ill-holes | Fp I I NI I/NI Fp III I NI | | | | |

BMA

| Preop | BMA | BMA korr |
|-------|-----|-------------|
| I | | |
| NI | | |
| I/NI | | |

| 6 months | BMA | BMA korr |
|----------|-----|-------------|
| I | | |
| NI | | |
| I/NI | | |

| 24 months | BMA | BMA korr |
|-----------|-----|-------------|
| I | | |
| NI | | |
| I/NI | | |

| 6 weeks | BMA | BMA korr |
|---------|-----|-------------|
| I | | |
| NI | | |
| I/NI | | |

| 18 months | BMA | BMA korr |
|-----------|-----|-------------|
| I | | |
| NI | | |
| I/NI | | |

MRI patellar tendon

| 6 weeks | length | width | thick ness | gap |
|---------|--------|-------|---------------|-----|
| I | | | | |
| NI | | | | |
| I/NI | | | | |

| 6 months | length | width | thick ness | gap |
|----------|--------|-------|---------------|-----|
| I | | | | |
| NI | | | | |
| I/NI | | | | |

| 18 months | length | width | thick | gap |
|-----------|--------|-------|-------|-----|
| | | | ness | |
| I | | | | |
| NI | | | | |
| I/NI | | | | |

| 24 months | length | width | thick | gap |
|-----------|--------|-------|-------|-----|
| | | | ness | |
| I | | | | |
| NI | | | | |
| I/NI | | | | |

