PETTERI KOUSA

Graft Fixation in ACL Reconstruction

ACADEMIC DISSERTATION
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<tr>
<td>ACL</td>
<td>Anterior cruciate ligament</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
</tr>
<tr>
<td>BMD</td>
<td>Bone mineral density</td>
</tr>
<tr>
<td>BPTB</td>
<td>Bone-patellar tendon-bone</td>
</tr>
<tr>
<td>E</td>
<td>Elastic modulus</td>
</tr>
<tr>
<td>LCL</td>
<td>Lateral collateral ligament</td>
</tr>
<tr>
<td>MCL</td>
<td>Medial collateral ligament</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>N</td>
<td>Newton</td>
</tr>
<tr>
<td>PLA</td>
<td>Polylactide</td>
</tr>
<tr>
<td>PLA96/4</td>
<td>Poly-L-lactide/D-lactide copolymer</td>
</tr>
<tr>
<td>PCL</td>
<td>Posterior cruciate ligament</td>
</tr>
<tr>
<td>QT</td>
<td>Quadriceps tendon</td>
</tr>
<tr>
<td>SR-PLLA</td>
<td>Self-reinforced poly-L-lactide</td>
</tr>
<tr>
<td>STG</td>
<td>Semitendinosus and gracilis tendons</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
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ABSTRACT

Intra-articular reconstruction with a biologic tendon graft is the procedure of choice for restoring stability of a knee after rupture of the anterior cruciate ligament (ACL). During the immediate postoperative period after ACL reconstruction the graft fixation site, not the graft material itself, is considered the weakest link. In this study series, the initial graft fixation strength of the different bone-patellar tendon-bone (BPTB) and hamstring tendon graft fixation alternatives were evaluated by single load-to-failure and cyclic loading tests.

In the first part of this study series, it was found that the bioabsorbable fibrillated self-reinforced poly-L-lactide (SR-PLLA) screw provided as good initial fixation strength as the Kurosaka interference screw and the AO cancellous screw in the fixation of a BPTB graft in the bovine knee, and thus, could be considered a suitable alternative for the metal screws in the BPTB graft fixation in the reconstruction of the ACL.

Also to validate the suitability of interference screws “design-wise”, the initial BPTB graft fixation strength of a bioabsorbable interference screw designed for endoscopic ACL reconstruction was evaluated in the second part of this study series. The bioabsorbable interference screw provided as good initial fixation strength as the standard metal interference screw in the fixation of a BPTB graft in the reconstruction of the ACL.

Although the interference screw fixation of the BPTB graft is safe and reliable in most cases, there are some pitfalls related to the operative technique, especially in the technically more demanding femoral site. To avoid these difficulties, a new plugging technique was developed. In the third part of this study series, the initial fixation strength of the new plugging and the standard interference screw techniques in the BPTB reconstruction of the ACL were compared. Considering the biomechanical testing results that we obtained with
these two techniques, the plugging technique and standard interference technique provide similar initial fixation strength in the fixation of a BPTB graft in the femoral tunnel in the reconstruction of the ACL.

The fixation strength of different hamstring tendon graft fixation devices in the ACL reconstruction were evaluated in studies four and five. The results show that the cross pin technique (BoneMulchScrew) provided superior fixation strength in the femoral tunnel and the central four-quadrant sleeve and screw system (Intrafix) was clearly superior in the tibial tunnel in securing the quadrupled hamstring graft in the ACL reconstruction. In the femoral site EndoButton CL, RigidFix, BioScrew and RCI screw and in the tibial site tandem spiked washers, BioScrew, SoftSilk and SmartScrewACL allowed increased residual displacement during cyclic loading. Therefore, some caution may be needed in the rehabilitation after ACL reconstruction when using these implants.
INTRODUCTION

The rupture of the anterior cruciate ligament (ACL) produces abnormal kinematics of the knee, which may lead to symptoms of knee instability particularly during cutting and pivoting activities, recurrent injury, damage to the menisci and the articular cartilage, and ultimately, osteoarthritis (Johnson et al. 1992, Frank and Jackson 1997, Roos and Karlsson 1998). It has been estimated that the annual incidence of anterior cruciate ligament injuries is about one in 3000 in the United States (Miyasaka et al. 1991). The goal of treatment for an ACL rupture is to prevent the progression of intra-articular damage by restoring the stability of the knee (Johnson et al. 1992, Frank and Jackson 1997).

The management of the anterior cruciate ligament deficient knee has developed dramatically during the past decades. Although it is commonly accepted that not all patients with ACL deficiency have progressive functional disability, it has been stated that in the majority non-operative treatment leads to functionally unacceptable outcome (Fu et al. 1999). Various surgical approaches have been used to treat the ruptured ACL. Despite encouraging short term results, current evidence indicates that primary repair, primary repair with augmentation, reconstruction with inadequate graft material, and extra-articular procedures are technically inferior, fail to restore satisfactory knee stability, and thus have generally been abandoned (Frank and Jackson 1997, Fu et al. 1999). Consequently, the intra-articular reconstruction with a biologic graft is currently the procedure of choice for the treatment of a rupture of the ACL (Frank and Jackson 1997, Fu et al. 1999, Fu et al. 2000).

Many factors influence the clinical success of the ACL reconstruction, including the graft material itself, the fixation of the graft, the placement of the graft, and the rehabilitation after the reconstruction (Johnson et al. 1992, Frank and Jackson 1997, Fu et al. 1999, Fu et al. 2000). Today, the two most commonly used ACL substitutes are the central third of the
patellar tendon and the hamstring (semitendinosus tendon alone or combined with gracilis tendon) tendon (Fu et al. 1999, Brand et al. 2000c). In the early postoperative period, the fixation of the graft is the most critical point of the anterior cruciate reconstruction limiting vigorous postoperative rehabilitation (Johnson et al. 1992, Frank and Jackson 1997). The fixation has to be strong enough to avoid failure due to sudden overload or repetitive submaximal loading and stiff enough to re-establish the stability of the knee and to minimize graft-tunnel motion. In addition to sufficient strength and stiffness, an ideal graft fixation is anatomic, biocompatible, safe and reproducible, allows undisturbed postsurgical magnetic resonance imaging (MRI) of the knee, and does not complicate possible revision surgery (Fu et al. 1999, Brand et al. 2000c, Fu et al. 2000, Martin et al. 2002).
REVIEW OF THE LITERATURE

1. Knee joint motion and stability

Although the principle motion of the knee is flexion and extension, the knee is not a simple hinge joint. In fact, it allows movement in six degrees of freedom (three translations and three rotations) (Woo et al. 1999, Dienst et al. 2003). The motion of the knee joint can be related to three principle axes perpendicular to each other (tibial shaft axis, epicondylar axis and anteroposterior axis) (Woo et al. 1999). Movements relative to these axes are referred to as proximal-distal translation, medial-lateral translation, anteroposterior translation, internal-external rotation, flexion-extension, and varus-valgus rotation (Woo et al. 1999).

The knee joint is between the long lever arms of the femur and the tibia, and consequently, according to basic principles of biomechanics, is extremely vulnerable to distortion injuries. Ligaments and other supporting soft tissue structures (joint capsule, muscles, tendons and menisci) control the stability of the knee (Swenson and Harner 1995). The role of menisci, restraining anterior-posterior translation, is particularly important in the ACL deficient knee (Swenson and Harner 1995). The ACL, in turn, is the primary restraint preventing posterior displacement of the femur relative to tibia, but also serves as an important secondary restraint to varus-valgus rotation, as well as internal-external rotation (Dienst et al. 2003). As regards the other ligaments about the knee and their stabilizing function, the posterior cruciate ligament (PCL) acts as the primary restraint to posterior translation of the tibia, as well as a secondary restraint to varus angulation and external tibial rotation, the medial collateral ligament (MCL) as a primary restraint to valgus stress and the posterolateral corner, being comprised of three major ligaments - the lateral collateral ligament (LCL), the oblique
popliteal ligament, and the arcuate popliteal ligament- restrains mainly varus angulation and external rotation (Swenson and Harner 1995).

2. Anatomy and function of the ACL

The cruciate ligaments are named for their tibial insertion sites. The tibial origin of the ACL is in the anterior part of the intercondylar area just posterior to the attachment of the medial meniscus and anterolateral to the medial intercondylar tubercle. It directs superiorly, posteriorly and laterally through the intercondylar notch to attach to the posteromedial aspect of the lateral femoral condyle (Figures 1 and 2). The ACL consists of two bundles grouped into anteromedial and posteromedial bundles, named according to their attachment site to the tibia. (Girgis et al. 1975, Dienst et al. 2003)

The two bundles are under variable stress during the whole range of passive flexion-extension motion (Swenson and Harner 1995, Fu et al. 1999, Dienst et al. 2003). As a result of anterior tibial translation, the anteromedial bundle is under relatively constant load throughout the flexion-extension, while the posterolateral bundle is tight near maximum extension (Sakane et al. 1997). It has also been stated that the ACL is under variable stress during rotation of the tibia and abduction of the knee (Swenson and Harner 1995, Frank and Jackson 1997).
Figure 1. Anterior view of the right knee.

Figure 2. The tibial plateau, menisci and cruciate ligaments of the right knee, viewed from above.
3. ACL reconstruction

3.1. Operative technique

Currently, endoscopic intra-articular reconstruction with a biologic graft is the procedure of choice for the treatment of an intrasubstance rupture of the ACL. Graft type, fixation technique and surgeons' attraction influence the surgical technique. Therefore, the following surgical steps should be considered outlines and vary between surgeons. Diagnostic arthroscopy is commonly performed initially to confirm associated injuries. The ACL stumps and intercondylar notch are cleared to ensure visibility, and the stenotic notch may require notchplasty to prevent graft impingement. After graft harvesting and preparation, the tibial and femoral tunnels are drilled to the corresponding graft size. In the two-incision technique both tunnels are drilled outside-in (rear entry). However, during endoscopic technique, the femoral bone tunnel is commonly drilled either through the tibial tunnel or medial portal in inside-out fashion. If the medial portal is used, the femoral tunnel is often drilled first to maintain fluid pressure in the joint. The prepared graft is then pulled through the tibial tunnel to the femoral tunnel with the aid of passing sutures and the femoral side of the graft is secured. Thereafter, the graft is preconditioned to tighten the graft and the femoral fixation, and finally the tibial side is secured while tension is applied to the graft.

3.2. Graft selection

The two types of biologic substitutes used in intra-articular reconstruction for ruptured ACL are autografts and allografts. Most commonly used autografts are bone-patellar tendon-bone (BPTB), multiple strand hamstring tendons and quadriceps tendon-bone, whereas the two most commonly used allografts are BPTB and Achilles tendon-bone (Fu et al. 1999, Brand et al. 2000c). Several factors are important in the selection of the graft tissue for ACL reconstruction, such as the initial mechanical properties of the graft tissue, morbidity resulting from graft harvesting, graft healing, and the initial mechanical properties of the graft fixation (Miller and Gladstone 2002).
The BPTB graft taken from the central third of the patellar tendon with adjacent tibial and patellar bone blocks has been the most popular autogenous graft for arthroscopic reconstruction of the ruptured ACL during the past two decades (Fu et al. 1999, Miller and Gladstone 2002). The popularity of BPTB graft is based on its structural properties, quality of fixation, excellent long-term clinical success and the fact that it provides bone-to-bone healing (Fu et al. 1999, Miller and Gladstone 2002). The major concern with the use of BPTB graft has been the associated donor-site morbidity, including anterior knee pain, kneeling discomfort, loss of motion, and weakness of the quadriceps muscle (Fu et al. 1999, Kartus et al. 2001, Miller and Gladstone 2002). Fractures of the patella have also been reported (Stein et al. 2002).

The improvements in the fixation methods, enabling the use of multiple strand hamstring grafts and the relatively low donor-site morbidity have resulted in the increased popularity of the hamstring graft (Fu et al. 1999, Brand et al. 2000c, Miller and Gladstone 2002). Multiply looped hamstring grafts have been shown to have initial ultimate tensile load and stiffness similar or higher to that of normal ACL (Woo et al. 1991, Rowden et al. 1997, Hamner et al. 1999, Ferretti et al. 2003). In addition, the hamstring tendon graft has a diameter close to that of a normal ACL and its multiple bundle construct is thought to mimic the double bundle construct of an ACL (Brown et al. 1993, Fu et al. 1999, Hamner et al. 1999, Brand et al. 2000c). However, the concerns associated with the use of the hamstring tendon graft include the failure to achieve rigid initial fixation to bone, the slower bone tunnel incorporation compared to the BPTB graft, the increased knee laxity, the potential hamstring muscle weakness, and the discomfort associated with some of the fixation hardware (Fu et al. 1999, Miller and Gladstone 2002). To date, there are several studies directly comparing patellar tendon and hamstring tendon autografts used in ACL reconstruction (Marder et al. 1991, Otero and Hutcheson 1993, Aglietti et al. 1994, O’Neill 1996, Corry et al. 1999, Aune et al. 2001, Beard et al. 2001, Eriksson et al. 2001, Beynnon et al. 2002, Pinczewski et al. 2002, Shaieb et al. 2002, Ejerhed et al. 2003, Feller and Webster 2003, Gobbi et al. 2003, Jansson et al. 2003). In general both grafts have provided similar stability and patient satisfaction. However, in some studies hamstring grafts have shown increased laxity compared with
BPTB grafts (Otero and Hutcheson 1993, O’Neil 1996, Corry et al. 1999, Beynnon et al. 2002, Feller and Webster 2003). The increased knee laxity can be, at least partly, explained by the use of two-strand hamstring tendon grafts (O’Neill 1996, Beynnon et al. 2002), by the fixation method (Otero and Hutcheson 1993), and the apparent risk for the increased laxity in the female patients (Corry et al. 1999). In contrast, the use of BPTB grafts appears to cause more donor-site morbidity compared to the use of hamstring tendon grafts (Corry et al. 1999, Pinczewski et al. 2002, Shaieb et al. 2002, Ejerhed et al. 2003, Feller and Webster 2003, Gobbi et al. 2003), although there is also somewhat contrasting evidence, as it has been shown that the current rehabilitation protocols which allow full weight bearing and full range of motion immediately after the reconstruction with BPTB graft result in lower prevalence of anterior knee pain and development of motion loss than reported earlier (Sachs et al. 1989, Shelbourne and Trumper 1997, Kartus et al. 2001). Both meta-analyses comparing the outcome using these two graft choices have concluded that patellar tendon autografts provide better stability than hamstring tendon autografts (Yunes et al. 2001, Freedman et al. 2003).

The quadriceps tendon-bone graft has also been used for ACL reconstruction (Fu et al. 1999). It has been shown to have sufficient structural properties compared to BPTB and hamstring grafts (Miller and Gladstone 2002). The quadriceps tendon-bone graft, in turn, is commonly used for revision ACL reconstructions and for multiple ligament reconstructions (Fu et al. 1999).

Allografts are commonly harvested sterile and preserved by deep freezing, or secondarily sterilized by low-dose gamma irradiation (Fu et al. 1999). The interest in allografts has increased because harvesting of autografts increases the operation time and exposes the knee to donor-site morbidity (Fu et al. 1999, Miller and Gladstone 2002, Allen et al. 2003). The disadvantages of allograft include the fear for disease transmission and the apparently delayed graft incorporation (Fu et al. 1999, Miller and Gladstone 2002). In addition the preservation and sterilization procedures have been shown to have an adverse effect on structural properties of the allografts (Miller and Gladstone 2002). Accordingly the allografts are today most commonly proposed for multiple ligament reconstructions and for revision surgery (Fu et al. 1999, Allen et al. 2003).
Table 1. Ultimate tensile load and stiffness of the intact ACL and commonly used autografts.

STG (semitendinosus and gracilis tendons)

<table>
<thead>
<tr>
<th></th>
<th>Ultimate failure load (N)</th>
<th>Stiffness (N/mm)</th>
<th>Reference</th>
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</thead>
<tbody>
<tr>
<td>ACL</td>
<td>2160 ± 157</td>
<td>242</td>
<td>Woo et al. 1991</td>
</tr>
<tr>
<td>ACL</td>
<td>2195 ± 427</td>
<td>306</td>
<td>Rowden et al. 1997</td>
</tr>
<tr>
<td>ACL</td>
<td>2362</td>
<td>not reported</td>
<td>Stapelton et al. 1998</td>
</tr>
<tr>
<td>Two gracilis strands</td>
<td>1550 ± 369</td>
<td>370</td>
<td>Hamner et al. 1999</td>
</tr>
<tr>
<td>Tensioned with weights</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two semitendinosus strands</td>
<td>2640 ± 320</td>
<td>534</td>
<td>Hamner et al. 1999</td>
</tr>
<tr>
<td>Tensioned with weights</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four combined strands (STG)</td>
<td>4090 ± 295</td>
<td>776</td>
<td>Hamner et al. 1999</td>
</tr>
<tr>
<td>Tensioned with weights</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four combined strands (STG)</td>
<td>4590 ± 674</td>
<td>861</td>
<td>Hamner et al. 1999</td>
</tr>
<tr>
<td>Tensioned with weights</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four combined strands (STG)</td>
<td>2831 ± 538</td>
<td>456</td>
<td>Hamner et al. 1999</td>
</tr>
<tr>
<td>Tensioned manually</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doubled semitendinosus and</td>
<td>1709 ± 581</td>
<td>213</td>
<td>Ferretti et al. 2003</td>
</tr>
<tr>
<td>Gracilis graft</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doubled semitendinosus and</td>
<td>2428 ± 475</td>
<td>310</td>
<td>Ferretti et al. 2003</td>
</tr>
<tr>
<td>Gracilis graft (twisted)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quadrupled STG</td>
<td>2421 ± 538</td>
<td>238</td>
<td>Wilson et al. 1999</td>
</tr>
<tr>
<td>Bone-patellar tendon (10 mm,</td>
<td>1953 ± 325</td>
<td>423</td>
<td>Schatzmann et al. 1998</td>
</tr>
<tr>
<td>Unconditioned</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BPTB 10 mm</td>
<td>1784 ± 580</td>
<td>210</td>
<td>Wilson et al. 1999</td>
</tr>
<tr>
<td>Bone-quadriiceps tendon (10</td>
<td>2172 ± 618</td>
<td>312</td>
<td>Schatzmann et al. 1998</td>
</tr>
<tr>
<td>mm, unconditioned</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

(Mean ± SD)
3.3. **Graft placement**

Graft placement has been considered one of the most critical factors in determining the outcome of the ACL reconstruction (Bealle and Johnson 1999). Incorrect tibial or femoral tunnel placement results in changes in the graft excursion and either restricts knee motion or results in joint laxity (Bealle and Johnson 1999). Therefore, a lot of emphasis is in the correct position of tibial and femoral tunnels. Optimal graft placement, however, differs from patient to patient because of the variations in the individual anatomy of the knee and therefore the graft placement has to be customized at surgery.

In the tibia, a tunnel placed too anteriorly causes impingement, increases graft tension at full extension and full flexion, and is related to early graft failures (Howell and Clark 1992), whereas a tibial tunnel placed too posteriorly causes excessive laxity during flexion and also endangers the PCL during tunnel drilling (Jackson and Gasser 1994). Tunnels placed too medial and lateral are related to graft impingement. It has been reported that the PCL is the most reproducible landmark for anatomic placement of the tibial tunnel (Hutchinson and Bae 2001).

In the femur, the tunnel is currently placed to the insertion of the anteromedial bundle or partially anterior and posterior to the isometric point. The femoral tunnel is commonly drilled to the intercondylar roof at 11 o’clock position for the right knee and at 1 o’clock position for the left knee, which is believed to reproduce the anteromedial bundle of the ACL. If the graft is placed toward 12 o’clock position, it is less capable of resisting rotatory loads. Therefore, a more lateral tunnel position has been advocated. A femoral tunnel placed too posteriorly causes increased graft tension in flexion, while one placed too anterior is associated with increase in graft failure rates (Aglietti et al. 1997). Notchplasty is commonly performed to prevent graft impingement and to improve visualization, although a recent study suggests that it changes graft placement, excursion and function (Markolf et al. 2002).

Current reconstruction procedures replicating mainly the anteromedial bundle are successful in limiting anterior tibial load. However, in a recent study, the advantage of replication of both bundles during ACL reconstruction was clearly demonstrated (Woo et al. 2002). After
anatomic reconstruction the both bundles followed their known function. Namely, the level of the in situ force in response to anterior tibial translation in the posterolateral bundle was largest in full extension and decreased with increasing flexion angle, whereas the force in the anterolateral bundle increased during flexion (Woo et al. 2002). The importance of the two-bundle reconstruction was more clearly demonstrated when the knee was subjected to combined rotatory loads simulating the pivot shift test (Yagi et al. 2002).

3.4. Graft preconditioning and tension

The preconditioning of the graft prior to fixation and the initial graft tension at the time of fixation are considered as important factors determining the long-term function of the reconstructed knee (Amis and Jakob 1998). However, the need of graft preconditioning has been questioned recently (Nurmi et al. 2004b). The ACL grafts have time- and history-dependent viscoelastic properties resulting in decrease of the initial graft tension over time. Under a constant load, the intra-articular portion of the graft elongates (that is, creep) over time, and conversely, when the graft material is kept at fixed elongation the load will decrease overtime (that is, stress-relaxation). During cyclic loading, the peak load decreases rapidly in the early phase, but after multiple loading cycles, the curves become relatively repeatable, indicating that a steady state is reached as no further creep occurs (Schatzmann et al. 1998). In other words, cyclic loading can prevent stress-relaxation induced loss of initial graft tension and may therefore help in maintaining the correct graft tension, and ultimately, knee joint laxity. In addition, a proper graft tension has also been shown to be beneficial for the ligamentization process of the graft (Frank et al. 1983, Yamakado et al. 2002). The ideal amount of graft tension during graft fixation is, however, controversial and has to be defined, as an excessive graft tension might constrain joint motion and consequently result in damage to the articular cartilage. Excessive graft tension may also have adverse effects on the postoperative healing process and result in decrease in the biomechanical properties of the graft (Yoshiya et al. 1987, Amis and Jakob 1998, Numazaki et al. 2002, Yoshiya et al. 2002). Conversely, inadequate graft tension may possibly fail to re-establish the stability of the knee. In a prospective randomised study, Yasuda et al. (1997) observed that hamstring tendon grafts pretensioned to 80 Newtons (N) before fixation resulted in significantly less
knee laxity at 2 years compared with those pretensioned at 20 N or 40 N. Zeminski et al. (2000) used cadaver knees and quadrupled hamstring grafts to study the effect of high initial graft tension on the biomechanical outcome of an ACL reconstruction. In contrast to Yasuda et al. (1997), they concluded that the reconstructed knee is sufficiently stabilized by 44 N of initial tension and doubling the tension did not increase the in situ forces in the graft nor significantly increase the knee stability. In an ex vivo biomechanical study, Numazaki et al. (2002) showed that the effect of initial graft tension on the biomechanical properties of the femur-graft-tibia construct vary between graft tissues and fixation methods.

The position of the tibia relative to the femur during graft fixation has also been shown to affect knee kinematics and graft tension. It has been shown that in full extension the distance between the femoral tunnel and the tibial tunnel will be longest. As a consequence, a graft fixed at full extension will slacken during flexion. Conversely, a graft fixed at 30 degrees of knee flexion will tighten as the knee is extended. The anterior-posterior position of the tibia relative to the femur at the time of graft fixation has also major a impact on the graft function after the ACL reconstruction. In a cadaveric study, Höher et al. (2001) found that a graft fixed at 30 degrees of flexion with 67 N posterior tibial load most closely re-established the function of the ACL.

3.5. Graft healing

Several studies have investigated the healing of the biologic grafts histologically and biomechanically both in animals and in humans during second-look and revision procedures (Armoczky et al. 1982, Butler et al. 1989, Rodeo et al. 1993, Grana et al. 1994, Panni et al. 1997, Scranton et al. 1998, Goradia et al. 2000, Yoshiya et al. 2000, Papageorgiou et al. 2001, Weiler et al. 2002a, Weiler et al. 2002b, Nebelung et al. 2003). In animal studies, a complete incorporation of the BPTB graft has occurred between 6 and 12 weeks and a direct type of insertion site, similar to that of ACL, has also shown to develop by six months following ACL reconstruction (Panni et al. 1997, Yoshiya et al. 2000, Papageorgiou et al. 2001).
Different time frames for the healing of a soft tissue graft within the bone tunnel have been described: During the first 4 weeks, a fibrous interface develops between the tendon graft and the bone tunnel (Rodeo et al. 1993, Grana et al. 1994, Papageorgiou et al. 2001). The earliest sign of osseus integration is the development of specific collagen fibers, known as Sharpey-like fibers, perpendicular to the bone tunnel bridging the graft and the cancellous bone. The first Sharpey-like fibers have been found to develop as early as at 3 weeks, but the fibrous interface is first poorly organized and highly cellular maturing gradually into dense connective tissue (Rodeo et al. 1993, Grana et al. 1994). After 9 to 12 months, the fibrous interface between the graft and the bone tunnel becomes less well defined (Rodeo et al. 1993, Grana et al. 1994). By using interference fixation, a soft tissue graft has been shown to heal partially by direct contact healing without the development of a fibrous interface (Weiler et al. 2002a).

In biomechanical studies, the stiffness, strength and modulus of both BPTB and soft tissue grafts has been shown to decrease during the early postoperative period, but gradually improving over time (Butler et al. 1989, Rodeo et al. 1993, Weiler et al. 2002b). During ligamentization both BPTB and soft tissue grafts transform into a structure similar to that of the ACL between 6 and 12 months postoperatively (Arnoczky et al. 1982, Panni et al. 1997, Scranton et al. 1998, Goradia et al. 2000).

4. ACL graft fixation

Graft fixation site is the weakest link in the ACL reconstruction during the immediate postoperative period until biologic fixation occurs within the bone tunnel, after which the strength of the graft material becomes the primary factor in limiting aggressive rehabilitation (Rodeo et al. 1993, Weiler et al. 2002b). Normally graft incorporation takes 6 to 12 weeks after the reconstruction (Rodeo et al. 1993, Grana et al. 1994, Papageorgiou et al. 2001). Many methods of graft fixation have been used, including staples, sutures over a screw post, sutures tied to a button, polyester tape-titanium button, screws and washers, transfixations,
and interference screws of various designs, materials and sizes. Fixation devices have been classified as either direct or indirect (Fu et al. 1999). Indirect fixations rely on connecting material, which is attached to the graft, whereas in direct fixations, the graft is fixed directly to the bone.

4.1. Tibial and femoral fixations

ACL graft fixation is commonly considered more problematic at the tibia compared to femur, because forces are subjected to the ACL graft in line with the tibial bone tunnel (as opposed to the femur, in which the line of force does not come parallel with the femoral bone tunnel until 100° of flexion) and the bone quality is worse in the tibial metaphysis than in the femur (Vuori et al. 1994, Brand et al. 2000c). In addition, the four free tendons of the hamstring graft are usually fixed in tibia. Several biomechanical studies (Liu et al. 1995, Caborn et al. 1998, Giurea et al. 1999, Magen et al. 1999, Brand et al. 2000b) have raised the current concern on the suitability of the interference screws in the fixation of the hamstring grafts, especially in the tibia. To improve the strength of fixation with interference screws in the biomechanically more demanding tibial tunnel, larger (up to 10x35 mm) screws combined with back up fixations have been advocated for primary hamstring graft fixation (Martin et al. 2002).

4.2. Ideal graft fixation

Optimal initial ACL graft fixation requires not only sufficient initial strength to avoid fixation failure, but also sufficient stiffness to restore the stability of the knee and to minimize graft-tunnel motion, as well as sufficient resistance to slippage under cyclic loading conditions to avoid gradual loosening in the early postoperative period after ACL reconstruction. In addition, an ideal graft fixation is anatomic, biocompatible, safe and reproducible, allows undisturbed postsurgical MRI evaluation of the knee, and does not complicate the revision surgery, if required (Fu et al. 1999, Brand et al. 2000c, Fu et al. 2000, Martin et al. 2002).
The fixation has to be both strong enough to avoid failure during unexpected loading events and also be able to prevent the gradual slippage or deterioration under repetitive loading prior to biologic healing. The strength requirements of the graft fixation are not clearly known, but is has been estimated that the graft is loaded to approximately 150-500 N during normal activities (Noyes et al. 1984, Rupp et al. 1999a, Toutoungi et al. 2000). Noyes et al. (1984) estimated that the ACL is loaded to approximately 454 N (20 % of its strength in biomechanical testing) during normal activities. Toutoungi et al. (2000) have recently shown that an isokinetic/isometric extension of the knee produces peak forces 0.55 x body weight in the ACL. In addition, Rupp et al. (1999a) showed that quadriceps pull against gravity alone produces resultant forces up to 247 N (mean peak force 219 ± 25 N) in the native ACL. In addition, in a cadaver study, Markolf et al. (1996) have demonstrated that after the ACL reconstruction the BPTB graft experiences higher in situ forces compared to the native ACL and a 45 N initial tension further increased the graft forces up to 497 N. In a normal knee, strains of the ACL have been estimated to be approximately one-quarter of their failure capacity during intensive rehabilitation exercises (Beynnon et al. 1995). It can be speculated that strains and their resultant forces may be lower in reconstructed knees, which are protected because of pain.

Currently, the fixation is regarded as the least stiff point in the graft-fixation device-bone construct. Sufficient stiffness of the graft fixation construct not only restores the normal load-displacement response of the knee, but also diminishes graft motion within the bone tunnel. When using the indirect fixation methods, the low stiffness of the graft and the connecting materials allow motion of the tendons within the bone tunnel wall and the graft. In addition, graft fixations at distance from the articular tunnel opening (e.g. extra-articular fixations) allow the graft to move in sagittal plane during knee motion (Morgan et al. 1995, Fu et al. 1999). Longitudinal and sagittal graft motions within the bone tunnel are also known as the **bungee cord effect** and **windshield wiper effect**, respectively. Excessive graft-tunnel motions have been accused of impairing the graft incorporation and resulting in enlargement of the bone tunnels, and altering the biomechanical function of the knee after ACL reconstruction (Fu et al. 1999, Weiler et al. 2002b). Both BPTB and soft tissue grafts have been shown to cause tunnel enlargement (L’Insliata et al. 1997).
An ideal fixation is at the tunnel opening (aperture fixation) minimizing graft motion relative to the bone tunnel and preventing synovial fluid access within the graft and the bone tunnel (Weiler et al. 2002a). In addition, aperture fixation has been shown to increase anterior knee stability and graft isometry (Morgan et al. 1995, Ishibashi et al. 1997). However, it has been stated that the improvement in anterior knee stability is actually rather attributable to the difference in the stiffness of the two fixation methods, not from shortening the graft (Magen et al. 1999, To et al. 1999). In fact, it has been shown that the stiffness of the graft fixation bone construct is actually more influenced by the stiffness of the fixation than the length of the graft (Magen et al.1999, To et al. 1999).

5. Biomechanics of ACL graft and fixation

The biomechanical properties of ACL graft fixation have been evaluated extensively in numerous laboratory studies. It is somewhat difficult to compare the studies because the experimental methods of the studies have varied so widely. In principle, the biomechanical testing can be divided into characterization of the material and structural properties of the given specimen.

5.1. Material properties of the graft

The material properties of the graft tendon material are represented by a stress-strain curve. When an external tension load is applied, the graft responds by elongating and resists the elongation with equal force. The stress of the tendon is determined as the externally applied load per cross-sectional area of the tendon (N/mm²=MPa). The strain, in turn, characterizes the stretching of the tendon during externally applied tensile loading and defines the amount of stretching per unit length of the original tendon. The strain is typically expressed as a percentage. The elastic (or tangent or Young’s) modulus (E) is determined as the slope of the stress-strain curve and represents the inherent stiffness of the graft material. Other parameters that can be obtained from the stress-strain curve include the ultimate stress, ultimate strain and strain energy. (Woo et al. 1999)
5.2. Structural properties of graft fixation complex

When a graft fixation complex is subjected to biomechanical testing, we are determining the structural properties of the entire specimen. During the uniaxial tensile testing, the response of the specimen to loading is obtained in the form of force-displacement curve (Figure 3), which typically consists first of the concave toe region with small increase in load producing large elongation (low initial stiffness). During this phase of testing the whole graft-fixation construct undergoes tightening (some of the natural creep of the tendons is eliminated and to some extent the fixation site and specimen fixation to testing machine are tightened). Loading beyond the toe region produces nearly linear curve (linear region). Since the stiffness of any loaded construct is calculated as the ratio of force to displacement, this linear portion of the curve provides us with the slope of the curve, based on which it is also simple to evaluate the stiffness: the more vertical the line, the stiffer the construct. The yield/linear load is defined as the force at which the slope of the force-displacement curve first clearly decreases, this point having also significance in terms of clinical relevance. As the first significant slippage of the ACL graft typically occurs at a yield load point, it thus represents the beginning of abnormal laxity. After the yield point, the specimen undergoes significant stretching (presumably because both the fixation fails and the graft tissue itself deteriorates), but the construct often shows a strong resistance to loading and the load values keep increasing until the maximum load is reached. Beyond the yield point, the force-displacement curve is usually non-linear, indicating the accumulation of permanent deformation and stretching on the graft fixation construct. The stiffness of the construct typically decreases dramatically after the yield point. The other parameters used to characterize the structural properties of graft fixation construct are the ultimate failure displacement and energy absorbed at failure. (Woo et al. 1999)
1500 N

Figure 3. A typical force-displacement curve obtained from the single load-to-failure testing of a graft fixation (ΔF is the increase in force and Δd is the corresponding change in displacement).

5.3. Biomechanical testing of ACL reconstructions

It is generally agreed that prior graft incorporation the ACL graft is subjected to periodic incidental high loads and thousands of loading cycles during currently used rehabilitation protocols. Therefore, it has been proposed that in addition to the conventional single load-to-failure testing, the testing protocol evaluating the biomechanical characteristics of the graft fixation should also include cyclic loading tests (Beynnon and Amis 1998). The single load-to-failure test is designed to determine the structural properties of a graft fixation construct during a single overload mimicking a traumatic incidence. The cyclic loading test, in turn, attempts to simulate the repetitive loads that the graft fixation construct is believed to be subjected to during the early postoperative period. Single load-to-failure tests are also
performed after the cyclic loading test to determine the cyclic loading-induced deterioration in fixation strength.

The cyclic loading protocols used to test the ACL graft fixation vary considerably between studies. Beynnon and Amis (1998) recommended to use a cyclic loading protocol, in which the graft fixation construct is loaded at low levels over multiple cycles (Dalldorf et al. 1998, Seil et al. 1998, Giurea et al. 1999, Höher et al. 1999, Yamanaka et al. 1999, Brand et al. 2000a, Höher et al. 2000, Nakano et al. 2000, Nagarkatti et al. 2001, Honl et al. 2002, Miller et al. 2002, Numazaki et al. 2002, Nurmi et al. 2002, Harvey et al. 2003, Lee et al. 2003, Musahl et al. 2003, Nurmi et al. 2003, Nurmi et al. 2004a, Nurmi et al. 2004c). However, several authors have used a cyclic creep test, in which the loading is progressively increased (Reznik et al. 1990, Liu et al. 1995, Magen et al. 1999, Stadelmaier et al. 1999, Rittmeister et al. 2001, Weiler et al. 2001, Rittmeister et al. 2002, Scheffler et al. 2002, Starch et al. 2003). Magen et al. (1999) determined the slippage of the soft tissue graft fixation using a cyclic loading protocol in which progressively higher loads were applied in 50 N increments under load control for subsequent cycles until failure. The slippage was compared at load levels of 250 N and 500 N. Magen et al. (1999) concluded that “a fixation method should function to loads at least 500 N if a reconstructed knee is to be intensively rehabilitated, assuming that the graft is not overtensioned”. Giurea et al. (1999) have demonstrated the justification of a more vigorous loading regimen. For example, an eight mm soft titanium interference screw provided good initial fixation strength (879 ± 74 N) and survived 1100 loading cycles simulating walking (0 - 150 N), but all specimens failed very rapidly when loaded cyclically to simulate jogging (0 - 450 N).

5.4. Factors influencing the biomechanical testing of ACL graft fixation

There are several biological and experimental factors that can affect the results and conclusions of different studies comparing various different graft fixation alternatives in failure tests, making between-studies comparison often difficult. These include the difference in bone quality, graft material, orientation of load, number of tested fixation sites, and strain
rate. However, proper storage of the specimen has been shown not to have a deleterious effect on the biomechanical properties (Pelker et al. 1984, Woo et al. 1986).

5.4.1. Biologic factors

fixations. In addition, Magen et al. (1999) found substantially lower yield loads and greater slippage when interference screws were used to fix hamstring tendon grafts in human bone compared with porcine tendons fixed in porcine bone. They concluded that caution is warranted when animal tissues are used for predicting the performance of interference screws in human ACL fixation.

As the quality of human bone specimens often varies considerably, porcine and even bovine knee specimens with more uniform bone quality offer a reasonable alternative to human bone. It has been speculated that the increase in bone density mainly affects in fixations that rely on friction to secure the graft within the bone tunnel (i.e. interference screws). Therefore, results from animal studies evaluating interference fixation are presumably overly optimistic in comparison with the situation in humans (Nurmi et al. 2004c).

5.4.2. Experimental factors

The tests evaluating the fixation characteristics are typically conducted by applying a load in one direction while other motions are constrained. One approach to evaluate graft fixation characteristics is to perform an ACL reconstruction and test both the fixations (tibia and femur) simultaneously in the same test and another is to isolate a single attachment site (Beynnon and Amis 1998).

The orientation of the applied load is also expected to affect the fixation characteristics. The more physiologically applied directions enhance the fixation strength by developing shear forces typically at the screw-graft-tunnel interface. Application of force parallel to the bone tunnel transfers the highest forces directly to the fixation site, representing the worst-case scenario for a fixation technique, and thus, providing the purest test for pullout strength.

The influence of strain rate to failure characteristics of graft fixation has been speculated. High strain rates (100%) in a single load-to-failure test have been advocated, as such protocol is believed to better mimic a traumatic incidence. However, it has been shown that strain rates have no apparent effect on the tensile strength, as no difference was observed in the
6. Current ACL graft fixation options

6.1. Bone-tendon graft fixation

In the interference technique introduced by Lambert (1983), where the graft is secured in bone tunnels with metallic interference-fit screws placed parallel to the osseous part of the BPTB graft has been shown to provide superior biomechanical properties compared to other methods. Consequently, metal interference screw fixation of the BPTB graft has become the most widely used operative procedure for the fixation of the intra-articular replacement of the ruptured ACL. In addition to superior fixation strength, the BPTB graft fixation using interference technique has been shown to provide good and reproducible clinical outcome. The major concern with the use of interference technique has been the damage of the bone block, tendon or the passing sutures during the screw insertion. The fixation may also fail due to divergent screw placement or the breakage of a bioabsorbable screw (Matthews et al. 1989, Barber et al. 1995, Pierz et al. 1995, Safran and Harner 1996, Marti et al. 1997, Brown and Carson 1999).

6.1.1. Cortical fixation

Steiner et al. (1994) used a human cadaveric model to evaluate four different BPTB graft fixation options. They found that suture fixation of BPTB grafts produced lower stiffness compared to interference screw fixation. Combination of interference screw and suture techniques provided highest failure load and stiffness (Steiner et al. 1994). Recently, Honl et al. (2002) compared three different BPTB graft fixation methods (EndoButton, interference screw and sutures tied over a screw post) using a cyclic loading test. They found that...
interference fixation had age dependency and for patients over 40 to 45 years, EndoButton may provide a better fixation. They also concluded that sutures tied over a post technique is not suitable for graft fixation under clinical circumstances. In addition to inferior stiffness of the sutures, the prominent screw post on the anterior surface of the tibia may irritate and require later removal, and at femoral side sutures tied over a screw post technique requires a lateral thigh incision.

6.1.2. Interference fixation

Various factors affect the initial graft fixation strength of the interference screw, including the quality of the bone, the shape of the bone block, the gap between the screw and the bone block, the magnitude of the insertion torque, the divergence of the screw, and the design, material and size of the screw (Brand et al. 2000c). To date, there are several studies showing improved strength of fixation of the BPTB tissue graft with increased screw diameter (Brown et al. 1993, Butler et al. 1994, Kohn and Rose 1994, Gerich et al. 1997, Pomeroy et al. 1998), while Hulstyn et al. (1993) and Shapiro et al. (1995) did not find any extra benefit in increasing the screw diameter. Matthews et al. (1998) compared the fixation strength of large-diameter (9, 11, 13, and 15 mm) metal interference screws. The so-called interference (screw diameter-gap size) was kept at 4.5 mm. They did not find any differences between the fixation strengths, and therefore the “extra”-large interference screws were advocated only for revision reconstructions where the diameter of the tunnel has widened for one reason or another. The effect of the interference screw length on the fixation properties of the BPTB graft is also controversial (Brown et al. 1993, Hulstyn et al. 1993, Kao et al. 1995, Gerich et al. 1997, Black et al. 2000). Gerich et al. (1997) found that the strength of the fixation increases with increase in the screw length. Hulstyn et al. (1993) had also similar findings with 5.5 mm diameter screws, although, the fixation strength did not improve with increase in the screw length when 7 mm or 9 mm diameter screws were used.

The gap between the bone tunnel wall and the bone block also affects the initial fixation strength. For example, Butler et al. (1994) has demonstrated that when the gap size is 3 or 4 mm the ultimate failure load is significantly increased when a 9 mm diameter screw is
substituted for 7 mm diameter screw. Reznik et al. (1990) found also correlation between gap size and failure loads. In contrast, Brown et al. (1996) did not find significant correlation between gap size and failure load. Several studies have found correlation between the magnitude of screw insertion torque and initial fixation strength of the interference screw fixation (Brown et al. 1993, Kohn and Rose 1994, Brown et al. 1996, Black et al. 2000). However, excessive insertion torque may predict damage to the graft (Kohn and Rose 1994). Rupp et al. (1998) used a porcine model to compare the influence of the position of the screw relative to cancellous or cortical surface of the bone block to the initial fixation strength of a metal interference screw. Cortical fixation resulted in more tendon ruptures, but there was no effect on the initial fixation strength.

The influence of inside-out and outside-in screw placements has been evaluated in several studies (Brown et al. 1993, Piez et al. 1995, Bryan et al. 1996, Dalldorf et al. 1998, Stapleton et al. 1998). When the screw is placed parallel to the bone block both inside-out and outside-in screw placements provide similar results (Brown et al. 1993, Piez et al. 1995, Bryan et al. 1996, Dalldorf et al. 1998). Stapleton et al. (1998) used cadaveric knees to compare two-incision technique with one incision-technique. After the ACL reconstruction the knees were tested to failure by placing the tibia anteriorly with the knee at 30 degrees of flexion and 30 degrees of internal rotation. They concluded that one-incision technique is significantly stronger than two-incision technique. However, the tibial sides of the fixations were done similarly in both techniques and eleven fixations out of twelve tested knees failed on the tibial side.

Interference screw divergence, the angle of the interference screw with respect to the bone block, is a common clinical concern, and consequently, its effect on the strength of fixation of BPTB graft has been evaluated biomechanically. It has been shown that an increase in the divergence angle decreases fixation strength at angles greater than 20 degrees (Jomha et al. 1993, Piez et al. 1995). Further, a divergent screw placement has more influence on the outside-in screw placement (i.e. rear entry technique) than the inside-out (Piez et al. 1995). Lemos et al. (1995) found no difference in fixation strength when the divergence angle was 15.

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During single incision endoscopic ACL reconstruction using the BPTB graft, the surgeon may encounter problems associated with graft-tunnel mismatch, the length of the BPTB graft exceeding the combined tunnel and intra-articular distance with the consequent protrusion of the bone block out of the tibial tunnel. The incidence of graft-tunnel mismatch has been reported to be as high as 28% (Shaffer et al. 1993), however, it can be decreased by increasing the length of the tibial tunnel. Alternative techniques have been introduced to deal with the graft-tunnel mismatch, such as advancing the femoral bone block further within the femoral socket, which has been associated with an increase in the risk of graft laceration, though. Also, after the femoral fixation, the BPTB graft can be shortened by flipping the patellar tendon or by recessing the tibial bone block (Pomeroy et al. 1998, Hoffmann et al. 1999, Black et al. 2000). Based on biomechanical studies, Pomeroy et al. (1998) have stated that the bone block should be at least 1 cm long to provide sufficient interference screw fixation strength. In addition, Black et al. (2000) have found similar fixation properties with 12.5 mm and 20 mm long interference screws. Other suggested fixation options for the BPTB bone block protruding distally outside the tibial tunnel are sutures tied over a screw post, staples, and free bone block interference screw fixations (Novak et al. 1996, Gerich et al. 1997).

Bioabsorbable interference screws may offer many advantages over their metal counterparts, including the decreased risk for graft laceration, decreased stress protection, undistorted postsurgical MRI, no need for hardware removal, and lack of corrosion (Black 1988, Shellock et al. 1992, Safran and Harner 1996, Jacobs et al. 1998, Suh et al. 1998, Brown and Carson 1999). The increased popularity of the ACL reconstruction surgery has also increased the number of ACL revisions (Jaureguito and Paulos 1996, Safran and Harner 1996). In revision surgery, the metal screws that have been inserted in the primary reconstruction have to be normally removed to achieve a proper graft replacement (Safran and Harner 1996, Brown and Carson 1999).

Kurzweil et al. (1995) have suggested that metallic tibial interference screw may cause pain. Twenty-three knees of the 458 ACL reconstruction using BPTB autografts and allografts
underwent tibial interference screw removal because of persistent pain. In three knees the metallic interference screw protruded above the tibial tunnel. Radiographs failed to show any cyst formation and the bone blocks appeared to have incorporated. However, a bursal sac was developed over the metal screw in three cases. At follow-up evaluation 2 years after hardware removal, the pain and tenderness over the tibial site were resolved in 21 of the 23 patients. In a follow-up of 604 patients (Kartus et al. 1998), 39 metal implants used for BPTB autograft fixation were removed on the tibial site due to pain. The retained metallic devices may cause pain due to the obvious mismatch of the elastic modulus between the bone (cancellous bone 0.2-0.7 GPa and cortical bone 9-20 GPa) and the metallic device (for example, titanium alloy 110 GPa) (Ruluff and McIntyre 1982, Anderson et al. 1992, McCalden et al. 1993). The less rigid bioabsorbable implants (PLA96/4 4.6-7.5 GPa) may decrease the incidence of this problem (Pohjonen and Törmälä 1996).


Although bioabsorbable interference screws have demonstrated good short- and mid-term results in clinical studies, some complications have been reported. Namely, the breakage of the screw during insertion, loose intra-articular bodies, mild inflammatory reactions and osteolytic cyst formation (Barber et al. 1995, Imhoff et al. 1998, Martinek et al. 1999, Macdonald and Arneja 2003).

6.2. Soft tissue graft fixation

Various graft fixation devices have been developed to be used with the soft tissue grafts. Despite the reduced donor site complications and sufficient initial mechanical properties of the hamstring tendon graft, there remains concern for sufficient fixation of the graft among the ACL surgeons. Free tendon grafts are generally fixed far away from the joint using either
staples, screws and washers, so-called endobuttons, cross pins or tying sutures over buttons or screw posts (Fu et al. 1999, Brand et al. 2000c, Martin et al. 2002). Currently, many of these hamstring graft fixation techniques provide high fixation strength, even higher than interference fixation for BPTB graft (Steiner et al. 1994, Clark et al. 1998, Magen et al. 1999, To et al. 1999). However, the increased length and the possible connecting materials of the graft-fixation construct are believed to allow graft motion within the bone tunnel wall (Fu et al. 1999). Currently, common concern about soft tissue aperture fixation methods (e.g. interference screw fixation) is their low resistance to slippage under repetitive loads during early postoperative period, as the strength of the fixation relies on friction to secure the tendons in the tunnel drilled in bone.

6.2.1. Cortical fixations

A soft tissue fixation using a single staple has provided poor results in biomechanical studies (Robertson et al. 1986, Kurosaka et al. 1987). However, the results have improved considerably when two staples have been used (Magen et al. 1999, Yamanaka et al. 1999). Magen et al. (1999) fixed the porcine extensor tendon to the tibial cortex using a “belt-buckle” technique. The failure load of the graft fixation bone construct was 704 ± 174 N and the stiffness was 118 ± 47 N/mm. Staple fixation is, however, at distance from the joint surface and the prominence of the staples may cause irritation at the fixation site and require later removal. Staple is currently commonly recommended to back-up other fixations of the soft tissue graft (Martin et al. 2002).

Indirect soft tissue graft fixation options rely on connecting materials (sutures, and polyester tapes), which connect the graft to the point of actual fixation. Tying sutures over a screw post and washer or button placed at the cortex outside the bone tunnel has been used both on the femoral and tibial side. Yamanaka et al. (1999) and Nakano et al. (2000) reported the same results of single load-to-failure and cyclic loading studies evaluating the fixation strength of the sutures-tied over a button technique in a doubled flexor graft in the porcine knee. The ultimate failure load was 458 ± 72 N and the stiffness was only 19.8 ± 1.4 N/mm. The
disadvantages of these techniques are the lateral thigh incision on the femoral side and the strength and stiffness of the sutures connecting the graft and the fixation device. Steiner et al. (1994) evaluated the fixation strength of four hamstring fixation techniques using gracilis and semitendinosus grafts in human cadaver knees. They showed that the fixation of a quadrupled hamstring graft with sutures tied over a screw post provided inferior fixation properties compared to fixation with soft tissue washers.

Tandem washers are commonly used at the tibial side. In addition to good initial failure strength and stiffness, they have been shown to provide good resistance to slippage (Magen et al. 1999). Using bovine bone and bovine extensor tendons, Beynnon et al. (1998) found a significant correlation between the ultimate failure load and insertion torque magnitude. WasherLoc is designed to secure the tibial end of the quadrupled hamstring graft within the tunnel, at the distal tunnel opening, whereas cortical fixations (tandem spiked washers, sutures over a screw post and washer or buttons) have longer working length, as they are placed completely outside the tibial tunnel. Cortical fixations are also prone to cause irritation at the fixation site, and thus, may require hardware removal. Magen et al. (1999) used human tendons and bones to show that tandem washers and WasherLoc provided significantly higher yield load and significantly less slippage compared with titanium interference screw in resisting rapidly increasing progressive cyclic loading protocol. All three graft fixation constructs provided stiffness values similar to that of native ACL.

Brown and Sklar (1998) have stated that the endoscopic EndoButton technique provides a quick, simple, accurate, reproducible and strong method for the femoral site hamstring graft fixation. EndoButton consists of a titanium button and a connecting material. The button is placed on the lateral femoral cortex of the femur and the connecting material is attached to the button creating a loop for the graft. The disadvantage of the endoscopic EndoButton technique is the mobile fixation allowing both longitudinal and sagittal graft motions relative to the bone tunnel. Höher et al. (1999) showed that titanium button/polyester tape fixation allowed 1 to 3 mm graft tunnel motion when loading to 100 and 300 N, respectively. Tsuda et al. (2002) have also demonstrated that EndoButton fixation of a soft tissue graft allows both increased sagittal and longitudinal motion, and greater anterior knee laxity compared to
interference screw fixation. EndoButton technique has been associated with tunnel enlargement in clinical studies (L’Insalata et al. 1997, Nebelung et al. 1998). The knots of the connecting material have been the weakest link of the fixation. As a result, a continuous loop EndoButton (EndoButton CL) was developed, providing a factory-attached loop eliminating the need for knot tying of the connection material.

6.2.2. Interference fixation

Extra-articular soft tissue graft fixation constructs have been accused of allowing motion of the tendons and the access of synovial fluid within the bone tunnel, both of which may impair graft healing and ultimately result in increased knee laxity. In contrast the resulting, short graft fixation construct in interference fixation has been shown to increase anterior knee stability. The use of interference screws has also become safer because of blunt threaded and round headed interference screws, reducing the risk for graft laceration. Weiler et al. (2002a) recently demonstrated that interference fixation may improve the incorporation of the tendon within the bone tunnel (tendon-to-bone healing). However, there has been concern of the aperture fixation methods due to their low resistance to slippage under repetitive loads during immediate postoperative period.

Recent reports comparing the interference fixation with that of other fixations in soft tissue graft have been controversial (Giurea et al. 1999, Magen et al. 1999, Miyata et al. 2000, Scheffler et al. 2002). Several biomechanical studies have evaluated the fixation properties of the soft tissue interference screw fixation. Recently, Magen et al. (1999) evaluated biomechanically the fixation properties of six tibial soft tissue fixation methods using a two-phase study design. They first compared six different fixation devices using porcine bone and porcine extensor tendons, after which the three best fixation techniques were compared again using human cadaveric tissue. Although interference screw performed well in the porcine specimens (first part of the study), in the second part using the human tibia and the quadrupled hamstring grafts and progressively increasing loading both the tandem washers and WasherLoc provided significantly higher yield load and significantly less slippage compared with the interference screws The yield load value provided by interference fixation
was only 350 ± 134 N. In addition, four of seven interference fixations failed at 500 N or a lower load. In the report by Giurea et al (1999), four different hamstring graft fixation devices (stirrup, clawed washer, RCI screw, and “soft” and round-headed interference screws) were compared in pull out and cyclic loading tests. The interference screws specifically designed for the fixation of soft-tissue graft in the femoral tunnel and stirrup anchoring the looped end of the quadrupled hamstring tendon graft into the tibial tunnel showed superior resistance to slippage at low loading levels (0-150 N) of constant cyclic loading compared to clawed washer and normal round-headed cannulated interference (RCI) screw.

The BPTB graft interference screw fixation in young human bone is commonly considered the golden standard fixation. Liu et al. (1995) used porcine bone to show that bone-hamstring-bone graft had inferior initial fixation strength compared to BPTB grafts. Similarly, in cyclic relaxation tests, Yamanaka et al. (1999) and Nakano et al. (2000) found that unloading was higher and failure strength lower in soft tissue graft interference screw fixation compared to BPTB graft interference screw fixation.

Although the results from biomechanical studies of hamstring graft interference screw fixation in human bone have not been very encouraging (Aune et al. 1998, Caborn et al. 1998, Magen et al. 1999, Stadelmaier et al. 1999), the method has gained wide acceptance, because clinical outcome reports have been promising (Corry et al. 1999, Piczewski et al. 2002).

Many factors contribute to the strength of the initial fixation of the soft tissue graft including the density of the bone, the insertion torque of the screw and the diameter, length, design and material of the screw (Weiler et al. 1998a, Brand et al. 2000b, Weiler et al. 2000). Weiler et al. (2000) and Selby et al. (2001) found that the strength of the fixation of the soft tissue graft improves with increase in the length of the screw, but the opposite has also been described (Stadelmeier et al. 1999, Harvey et al. 2003). Weiler et al. (2000) also found that increasing the screw diameter improves the fixation strength.
Brand et al. (2000b) have evaluated the effect of bone mineral density and insertion torque on the biomechanical properties of hamstring graft interference fixation in ACL reconstruction. They concluded that the interference screw fixation strength is directly related to the metaphyseal bone mineral density in both the femur and tibia. Furthermore, femoral metaphysis has a greater bone mineral density compared to tibia, and insertion torque is directly correlated to maximum failure load. Weiler et al. (2000) have also found that the magnitude of insertion torque correlates to the maximum failure load. Harvey et al. (2003) recently showed that there is less slippage in cortico-cancellous than in cancellous only fixation.

There is controversy over the effects of the screw placement relative to individual hamstring tendon strands (eccentric vs. concentric). Shino and Pflaster (2000) recently showed that concentric placement of the screw could improve the fixation of hamstring graft in tibial tunnel, although the opposite was shown by Simonian et al. (1998) when hamstring tendons were fixed with interference screws in polyurethane foam blocks. Starch et al. (2003) showed that "central four-quadrant sleeve and screw system" (Intrafix) allows less hamstring graft slippage compared to interference screw fixation.

According to Weiler et al. (1998a) bioabsorbable screws provide a better fixation strength than their metal counterparts. They speculated that the bioabsorbable material itself was responsible for the enhanced strength. Caborn et al. (1998) reported that the strength provided by bioabsorbable interference screw was 40 % higher than that with RCI screw. However, the difference was not statistically significant. In addition, Giurea et al. (1999) recently showed that interference screw design affects the possibility for slippage of the soft tissue fixation when tested under cyclic loading conditions. After 1100 loading cycles at 150 N, the RCI screw allowed a mean displacement of 6.8 ± 5.6 mm, which was over three times higher than that observed with the interference screws specifically designed for the fixation of soft tissue grafts.

Compaction drilling or compaction with serial dilators is a common procedure to create a denser bone tunnel wall and to provide a snug fit for the graft. The denser bone tunnel wall is believed to enhance the strength of interference screw fixation of the soft tissue grafts.
However, neither dilation using serial dilators nor compaction drilling with a stepped router has been shown to improve hamstring graft fixation in tibia (Rittmeister et al. 2001, Nurmi et al. 2002, Nurmi et al. 2003, Nurmi et al. 2004a).

For the interference screw soft tissue fixation in tibia, a back-up fixation is often recommended, especially when the bone is soft, the bone tunnel large, and the patient either noncompliant or heavy (Martin et al. 2002, Scheffler et al. 2002). It has been shown that free bone block increases initial interference screw fixation strength and limits graft slippage (Weiler et al. 1998a, Scheffler et al. 2002).

6.2.3. Transfixation

In transfixation technique the implant is placed transversely through the femoral or tibial bone tunnel to secure the graft. Various transfixation devices (TransFix, RigidFix, BoneMulchScrew) have been introduced. Most of them can be considered toggle fixation where the tendon is looped around a part of the implant to suspend the graft within the bone tunnel. RigidFix, is a cross pin similar to TransFix, however, it actually should be considered a “semitoggle” fixation since it is not possible to “wrap” the loops of the tendons around the cross pins. The fixation relies on the pins crossing the tightly sutured tendon loop bundle in the femoral tunnel. For the toggle fixation, the tendon is looped over a crossbar inserted into the metaphyseal bone of lateral femoral condyle allowing tensioning of the individual strands which has been shown to result in significant increase in graft strength and stiffness (Hamner et al. 1999). Transfixation seems to approach our current need in terms of initial fixation strength and stiffness. To et al. (1999) compared the strength of fixation of a BoneMulchScrew with that of EndoButton and Mitek Anchor in a double looped semitendinosus and gracilis graft in the young human femur. They found that the ultimate failure load provided by BoneMulchScrew averaged 1126 ± 80 N and was significantly higher than the ultimate failure load provided by the EndoButton (430 ± 27 N) and Mitek Anchor (312 ± 35 N). The stiffness of the femur-BoneMulchScrew-graft was also significantly higher compared to femur-EndoButton-graft and femur-Mitek Anchor-graft constructs. Clark et al. (1998) evaluated the fixation strength of two metal cross pins using
ovine tendons and porcine femora. The ultimate failure load and yield load ranged from 1003 ± 33 N to 1604 ± 134 N and 725.5 ± 87 N to 1363 ± 166 N, respectively.
AIMS OF THE STUDY

1. To validate biomechanically the suitability of the bioabsorbable fibrillated SR-PLLA screw in the BPTB reconstruction of the ACL in terms of its initial fixation strength and to compare it with the Kurosaka interference screw and the AO cancellous screw.

2. To compare the initial fixation strength of a bioabsorbable interference screw with that of a standard titanium interference screw in the fixation of a BPTB graft in the femoral tunnel in the reconstruction of the ACL.

3. To compare the initial fixation strength of the new plugging and the standard interference screw techniques in the BPTB reconstruction of the ACL.

4. To evaluate the fixation strength of commonly used femoral and tibial fixation devices of a quadrupled hamstring tendon graft in the ACL reconstruction.
MATERIALS AND METHODS

1. Specimens

A total of 353 graft fixation constructs were evaluated in this thesis (Table 2). Knee specimens (bovine and porcine) were obtained from local slaughterhouses, fresh-frozen at -20-25 °C and thawed for 12 hours at room temperature before testing. In studies I to III, the BPTB grafts were used. The patella, the patellar tendon, and the triangular bone block were removed as one block from each knee specimen. A 9 mm wide section from the middle third of the patellar tendon was then sharply dissected, leaving the patella intact. The bone blocks were further trimmed into a cylindrical (I) or rectangular shape (II, III). In studies IV and V, 240 freshly harvested human cadaveric semitendinosus and gracilis tendons were used as graft material. The tendons were cleared from adherent muscle and soft tissue, wrapped in saline soaked gauze and stored frozen (-25°C) in small plastic bags. The National Authority for Medicolegal Affairs in Finland had approved the use of human cadaver tissue.

The tibial tunnels (I, II, V) were directed from the original tibial insertion site of the ACL to the anteromedial wall of the proximal tibia. The femoral tunnels (III, IV) were drilled from the original femoral insertion site of the ACL towards the lateral wall of the lateral femoral condyle of the knee (at 1 o’clock for the left and at 11 o’clock for the right knee).
Table 2. Specimens.

<table>
<thead>
<tr>
<th>Study</th>
<th>Bone</th>
<th>Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (n = 33)</td>
<td>Bovine tibia</td>
<td>BPTB (Cylindrical (9 mm) tibial bone block with middle third of the patellar tendon and the whole patella)</td>
</tr>
<tr>
<td>II (n = 40)</td>
<td>Porcine tibia (20 pairs)</td>
<td>BPTB (Rectangular tibial bone block measuring 7 x 9 x 20 mm (thickness x width x length) with middle third of patella tendon and the whole patella)</td>
</tr>
<tr>
<td>III (n = 40)</td>
<td>Porcine femur (20 pairs)</td>
<td>BPTB (Rectangular tibial bone block measuring 7 x 9 x 25 mm (thickness x width x length) with middle third of patella tendon and the whole patella)</td>
</tr>
<tr>
<td>IV (n = 120)</td>
<td>Porcine femur</td>
<td>120 quadrupled human cadaveric STG</td>
</tr>
<tr>
<td>V (n = 120)</td>
<td>Porcine tibia</td>
<td>120 quadrupled human cadaveric STG</td>
</tr>
</tbody>
</table>

2. Study groups and fixation procedures

In studies I, IV and V, the specimens were assigned into study groups of 11 (I) or 20 (IV,V) specimens in each. In studies II and III, the 20 pairs of knee specimens were divided into two treatment groups so that the left and right knee of each animal were randomly assigned into different groups.

2.2. Bone-tendon graft fixation techniques (studies I, II and III)

In study I, the trimmed tibial bone block was inserted into a 10 mm tibial tunnel. A 1.5 mm tunnel was then drilled along the cortex of the bone block parallel to the long axis of the tibial bone tunnel. That tunnel was further enlarged to 2.5 mm for Kurosaka and AO-cancellous screws, and to 4.5 mm for SR-PLLA screws. Kurosaka and AO-cancellous screws were inserted into these 2.5 mm holes, and for the SR-PLLA screw a tapping device was
used prior to the screw insertion. All screws were inserted with an outside-in technique (Figure 4).

Figure 4. The implants used in study I from left to right: Kurosaka interference screw; Acufex Microsurgical Inc., Mansfield, Massachusetts (7 mm diameter, 25 mm length), bioabsorbable SR-PLLA screw; Biofix, Bioscience, Tampere, Finland (6.3 mm in diameter, 25 mm thread length) and AO cancellous screw; Stratec, Hegendorf, Switzerland (6.5 mm diameter and 25 mm thread length).

In study II, the rectangular tibial bone blocks were fixed into a 9 mm tibial tunnel. Before the insertion of the bioabsorbable screw, a 4.5 mm drill and dilator provided by the manufacturer were used to enhance starting. Both screws were inserted over a guide pin using an outside-in technique into the 3 mm gap that was available between the graft and the tibial bone tunnel.
Figure 5. The implants used in study II from left to right: Titanium interference screw (SoftSilk); Acufex Microsurgical Inc, Mansfield, Massachusetts (7 mm diameter, 25 mm length) and bioabsorbable poly-L-lactide/D-lactide (PLA96/4) copolymer interference screw; Bionx Implants Ltd, Tampere, Finland (7 mm diameter, 25 mm length).

Figure 6. The tibial BPTB graft fixation with an interference screw.
In study III, the tibial bone block of the graft was first pulled into a 9 mm femoral tunnel, placing the cancellous side anteriorly. The plug was placed at the tunnel opening anterior to the graft, so that the groove was next to the tendon. Thereafter, the plug was tapped into the tunnel. The interference screws were inserted with the inside-out technique, placing the screw into the 2 to 3 mm gap between the tibial bone tunnel wall and the bone block. A K-wire was used to prevent screw-graft divergence.

**Figure 7.** The implants used in study III from left to right: Titanium SoftSilk interference screw; Acufex Microsurgical Inc, Mansfield, Massachusetts (7 mm diameter, 25 mm length) and bioabsorbable (PLA96/4) copolymer plug; Bionx Implants Ltd, Tampere, Finland.

**Figure 8.** The femoral BPTB graft fixation techniques used in study III. (A) Plugging technique and (B) interference technique.
2.3. Soft tissue graft fixation techniques (studies IV and V)

In studies IV and V, the quadrupled semitendinosus and gracilis (STG) grafts were prepared and fixed according to the specific instruction provided by the manufacturer of the implants and using device specific instrumentation. The looped end of the quadrupled STG graft was fixed in the femur (study IV) and the four free strands of the STG graft were fixed in the tibial tunnel (study V).

2.3.1. Study IV

**EndoButton CL:** The diameter of the graft was measured in 0.5 mm increments by using Graft Sizing Tubes (Acufex Microsurgical, Inc.). A femoral socket equal to the graft diameter was drilled with a compaction drill (Acufex Microsurgical, Inc.). The tendons were doubled over the loop of the EndoButton CL device and then the button was pulled through a 4.5 mm passing channel and deployed on the lateral cortex. The length of the continuous loop was chosen so that 20-25 mm of the graft was in the femoral socket.

**BoneMulchScrew:** The diameter of the prepared graft was measured by using Arthrotek sizing sleeve (Arthrotek, Inc., Warsaw, Indiana) in 1 mm increments. A femoral socket matching the graft diameter was drilled with a cannulated reamer. The 10.5 x 25 mm BoneMulchScrew was inserted into an 8 mm tunnel in the lateral femoral cortex perpendicular to the femoral socket. The graft was then placed around the tip of the screw. Thereafter, a compacting rod was used to compact the cancellous bone through the BoneMulchScrew into the femoral socket.

**RigidFix:** The diameter of the quadrupled graft was measured with a Graft Sizing Tube in 0.5 mm increments. A cannulated reamer corresponding to the diameter of the graft was selected to drill a 25 mm femoral socket. Two parallel drill tunnels were drilled for bioabsorbable (PLA) RigidFix crosspins (Mitek Products, Norwood, Massachusetts) from the lateral femoral condyle perpendicular to the femoral socket using a RigidFix crosspin guide.
(Mitek Products, Norwood, Massachusetts). The graft was then pulled into the socket and two cross pins were inserted across the graft.

**Interference screws:** The prepared graft was measured in 0.5 mm increments (Graft Sizing Tubes, Acufex Microsurgical, Inc.) and a corresponding compaction drill was selected to drill the femoral socket. The interference screws were inserted in inside-out fashion to fix the graft into the femoral socket. For bioabsorbable interference screws a notcher provided by the manufacturer was used to enhance starting and to accommodate the screw heads. A conventional RCI (Acufex Microsurgical Inc.) titanium screw was used in the left knees and a reverse-threaded screw was used in the right knees.

![Figure 9](image)

**Figure 9.** The implants used in study IV from left to right: EndoButton CL; Acufex Microsurgical, Inc., Mansfield, Massachusetts, BoneMulchScrew; Arthrotek, Inc., Warsaw, Indiana (10.5x25 mm), two bioabsorbable (PLA) RigidFix cross pins; Mitek Products, Norwood, Massachusetts, bioabsorbable (PLA96/4) copolymer SmartScrewACL interference screw; Bionx Implants Inc., Blue Bell, Pennsylvania (7 mm diameter, 25 mm length), bioabsorbable (PLA) interference screw BioScrew; Linvatec, Inc., Largo, Florida (7 mm diameter, 25 mm length) and titanium RCI interference screw; Acufex Microsurgical Inc, Mansfield, Massachusetts (7 mm diameter, 25 mm length).
Figure 10. The femoral hamstring graft fixations used in study IV. (A) EndoButton CL, (B) BoneMulchScrew, (C) RigidFix and (D) interference screw (BioScrew, RCI screw and SmartScrewACL).
2.3.2. Study V

**WasherLoc:** The diameter of the prepared graft was measured in 1 mm increments and the appropriate size tibial tunnel drilled using a cannulated reamer. The 20 mm WasherLoc was impacted at the distal tunnel opening perpendicular to the tibial tunnel and fixed with a self-tapping WasherLoc compression screw.

**Tandem spiked washers:** Two 14 x 1.3 mm spiked metal washers and two 4.5 mm bicortical screws were used in tandem fashion using a figure-of-eight technique to fix the graft to the anteromedial tibial cortex distal to the tunnel opening. The diameter of the graft was sized in 0.5 mm increments and a corresponding compaction drill was used to drill the tibial tunnel.

**Intrafix:** The prepared graft was measured in 0.5 mm increments and a compaction drill 0.5 mm greater than the graft was selected to drill the tibial tunnel. During graft fixation the tendons were first separated with a trial instrument. Thereafter, the Intrafix Sheath was inserted into the tibial tunnel and fixed with the Intrafix Tapered screw.

**Interference screws:** The graft diameter was measured in 0.5 mm increments using Graft Sizing Tubes and the tibial tunnel equal to the graft diameter was drilled using a compaction drill. As with the bioabsorbable screws in the femur, a notcher provided by the manufacturer was used to ease the insertion and to accommodate the screw heads of the bioabsorbable interference screw. All interference screws were inserted in outside-in fashion over a guide pin flush with the intra-articular tunnel opening.
Figure 11. The implants used in study IV from left to right: WasherLoc; Arthrotek, Inc., Warsaw, Indiana (20 mm diameter), tandem spiked washers; Linvatec Inc., Largo, Florida (two 14x1.3 mm washers and two 4.5 mm bicortical screws), Inrafix; Innovative Devices Inc., Marlborough, Massachusetts, bioabsorbable (PLA) BioScrew interference screw; Linvatec, Inc., Largo, Florida (8 mm diameter, 25 mm length), titanium SoftSilk interference screw; Acufex Microsurgical, Inc. (8 mm diameter, 25 mm length), bioabsorbable (PLA96/4) copolymer SmartScrew ACL interference screw; Bionx Implants Inc., Blue Bell, Pennsylvania (8 mm diameter, 25 mm length).
Figure 12. The tibial hamstring graft fixations used in study V. (A) WasherLoc, (B) tandem spiked washers, (C) Intrafix and (D) interference screw (BioScrew, SoftSilk and SmartScrewACL).
3. Biomechanical testing

The biomechanical testing protocols are summarized in Table 3. Biomechanical testing was performed using Lloyd 6000R (I) and Lloyd LR 5K (II-V) materials testing machines (J.J. Lloyd Instruments, Southampton, UK). The tibia (I, II, V) and femur (III, IV) were securely mounted to the testing machine by specially designed clamps. The patella (I-III) was secured to the testing machine with an 8 mm bar inserted through a drill hole made perpendicular to the long axis of the patella. The STG graft (IV, V) was prepared for biomechanical testing by suturing the tendons together in whipstitch fashion (No. 2-0 Vicryl suture, Ethicon, Johnson & Johnson, Arlington, Texas), while maintaining constant tension. The graft was then secured to a specially designed soft tissue clamp, leaving 25 mm length of graft between the clamp and the intra-articular tunnel opening (Figure 13). The biomechanical testing consisted of single load-to-failure tests (I-V), cyclic loading tests (II-V) and single load-to-failure tests after cyclic loading (II-V).

Figure 13. The specimen in study V is mounted in the materials testing machine so that the orientation of the load is parallel to the long axis of the tibial tunnel.
Table 3. Biomechanical testing protocols used in this study series.

<table>
<thead>
<tr>
<th>Biomechanical testing</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single load-to-failure test</strong></td>
<td><strong>Cyclic loading test</strong></td>
</tr>
<tr>
<td>Vertical loading parallel to the long axis of the tibia at a rate of 50 mm/min.</td>
<td></td>
</tr>
<tr>
<td>10 pairs (n=20)</td>
<td>10 pairs (n=20)</td>
</tr>
<tr>
<td>Vertical loading in line with the tibial bone tunnel at a rate of 50 mm/min.</td>
<td>50 N preload.</td>
</tr>
<tr>
<td>Vertical loading in line with the tibial bone tunnel.</td>
<td>Vertical loading in line with the tibial bone tunnel.</td>
</tr>
<tr>
<td>Cyclic loading started with 100 loading cycles between 50 and 150 N (1 cycle in 2 seconds). The load was progressively increased in 50 N increments after each set of 100 cycles. After 100 cycles at 850 N the specimens were loaded to failure at a rate of 50 mm/min.</td>
<td></td>
</tr>
<tr>
<td>10 pairs (n=20)</td>
<td>10 pairs (n=20)</td>
</tr>
<tr>
<td>Vertical loading in line with the tibial bone tunnel at a rate of 50 mm/min.</td>
<td>50 N preload for 10s.</td>
</tr>
<tr>
<td>Vertical loading in line with the tibial bone tunnel.</td>
<td>Vertical loading in line with the tibial bone tunnel.</td>
</tr>
<tr>
<td>1500 loading cycles between 50 and 200 N (1 cycle in 2 seconds). After 1500 loading cycles the surviving specimens were loaded to failure at a rate of 50 mm/min.</td>
<td></td>
</tr>
<tr>
<td>(n=60)</td>
<td>(n=60)</td>
</tr>
<tr>
<td>Vertical loading in line with the tibial bone tunnel at a rate of 50 mm/min.</td>
<td>50 N preload for 10s.</td>
</tr>
<tr>
<td>Vertical loading in line with the tibial bone tunnel.</td>
<td>Vertical loading in line with the tibial bone tunnel.</td>
</tr>
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<td></td>
</tr>
<tr>
<td>(n=60)</td>
<td>(n=60)</td>
</tr>
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<td>50 N preload for 10s</td>
</tr>
<tr>
<td>Vertical loading in line with the tibial bone tunnel.</td>
<td>Vertical loading in line with the tibial bone tunnel.</td>
</tr>
<tr>
<td>1500 loading cycles between 50 and 200 N (1 cycle in 2 seconds). After 1500 loading cycles the surviving specimens were loaded to failure at a rate of 50 mm/min.</td>
<td></td>
</tr>
</tbody>
</table>
3.1. Single load-to-failure test

A vertical load was carried out at a rate of 50 mm/min until failure. The specimen’s response to the loading was automatically obtained in the form of a force-displacement curve (Figure 3), and the ultimate failure load (I-III), yield load (linear load) (I-V), elastic modulus (I), stiffness (II-V) and mode of failure were determined (I-V). The yield load was described as the point at which the force-displacement curve entered into the non-linear region. Stiffness was determined as the slope of the linear region of the force-displacement curve. In study I, the apparent elastic modulus of the graft was calculated from the force displacement curve in the lower tensile load range between 0 and 500 N (equation 1) as well as in the upper load range between 500 N and linear load (equation 2).

Equation 1: \[
\frac{500 \text{ N} \times \text{Initial length of the graft (mm)}}{\text{Displacement at 500 N load (mm)} \times \text{Cross-section of the graft (mm}^2)}
\]

Equation 2: \[
\frac{(\text{Linear load (N)} - 500 \text{ N}) \times \text{Initial length of the graft (mm)}}{(\text{Displacement at linear load (mm)} - \text{Displacement at 500 N load (mm)}) \times \text{Cross section of the graft (mm}^2)}
\]

3.2. Cyclic loading test followed by a single load-to-failure test

In study II, the specimens were first subjected to a 50 N preload. Thereafter, the graft-construct was loaded cyclically at a frequency of one cycle in two seconds. The cyclic loading started with 100 load cycles between 50 and 150 N. The load was then progressively increased in increments of 50 N after each set of 100 cycles. After 100 cycles at 850 N, the surviving specimens were pulled to failure at a rate of 50 mm/min. Similar to the single load-to-failure test, the specimen’s response to loading was obtained in the form of a force-displacement curve, and the ultimate failure load, yield load and the failure mode were determined (Figure 14). The yield load was determined as the load at which the displacement...
first increased significantly. The graft displacement at the first peak of load at each force level was also measured to estimate the resistance of fixation to slipping.

Figure 14. An example of a force-displacement curve of the cyclic loading test in study II. The cyclic loading started with 100 loading cycles between 50 and 150 N. The loading was then increased in 50 N increments after each set of 100 cycles. At yield load the displacement first increased significantly.

In studies III to V, a 50 N preload was first applied to the specimens for 10 seconds, after which the graft-fixation constructs underwent 1500 loading cycles between 50 and 200 N at one cycle every two seconds parallel with the long axis of the bone tunnels. Similar to the single load-to-failure test, the force-displacement curve was recorded (Figure 15). The rigidity of the fixation was evaluated by determining the loading-induced increase in the displacement from the preload level after 1, 10, 50, 100, 250, 500, 1000, and 1500 loading cycles. After 1500 loading cycles, the surviving specimens were loaded to failure at a rate of 50 mm/min, and the ultimate failure load (III) and yield load (III-V) were determined.
Figure 15. An example of a force-displacement curve of the cyclic loading test in studies III-V ($d_0 =$ displacement after preload, $d_1 =$ displacement after first load cycle and $d_{1500} =$ displacement after 1500 load cycles).

4. Statistical analysis

The results of the continuous variables were reported as mean ± standard deviation (SD). A $p$ value less than 0.05 was considered statistically significant throughout this study series.
In studies I, IV and V, one-way analysis of variance (ANOVA) with the Tukey’s test as a post hoc test was used to test the difference between the study groups. In studies II and III, the differences between the groups were determined using paired sample t-test. The difference in yield load values between single load-to-failure and cyclic loading tests were further compared using unpaired t-test (II, IV and V). A McNemar test was performed in study II to test the relationship between the screw type and the number of bone block fractures.
RESULTS

1. Single load-to-failure tests

1.1. Study I

The results are summarized in Table 4. The mean linear loads for the interference screw (1231 ± 420 N), bioabsorbable SR-PLLA screw (1174 ± 392 N) and AO cancellous screw (951.3 ± 269 N) were not significantly different, nor were the mean ultimate failure loads or the elastic modulus of the fixation.

Table 4. Single load-to-failure test in study I.

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Ultimate failure load (N)</th>
<th>Yield load (N)</th>
<th>Elastic modulus (N/mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interference</td>
<td>1358 ± 348</td>
<td>1231 ± 420</td>
<td>186 ± 34</td>
</tr>
<tr>
<td>AO-cancellous</td>
<td>1081 ± 331</td>
<td>951.3 ± 269</td>
<td>201 ± 18</td>
</tr>
<tr>
<td>SR-PLLA</td>
<td>1211 ± 362</td>
<td>1174 ± 392</td>
<td>189 ± 47</td>
</tr>
</tbody>
</table>

(Mean ± SD)

1.2. Study II

Table 5 gives the results of the single load-to-failure test. The yield load was 621 ± 139 N in the bioabsorbable group and 774 ± 154 N in the titanium group (p=0.07). Significant group
differences were found neither in the ultimate failure loads nor in the stiffness of the fixations.

**Table 5.** Single load-to-failure test in study II.

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Ultimate failure load (N)</th>
<th>Yield load (N)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioabsorbable</td>
<td>837 ± 260</td>
<td>621 ± 139</td>
<td>76 ± 20</td>
</tr>
<tr>
<td>Titanium</td>
<td>863 ± 192</td>
<td>774 ± 154</td>
<td>80 ± 15</td>
</tr>
</tbody>
</table>

(Mean ± SD)

1.3. Study III

The results of the single load-to-failure tests are presented in Table 6. The mean yield load was $821 \pm 281$ N for the plugging technique and $791 \pm 166$ N for the interference technique ($p=0.82$). There was no significant difference in the groups with regard to the ultimate failure load or the stiffness of the fixation technique.

**Table 6.** Single load-to-failure test in study III.

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Ultimate failure load (N)</th>
<th>Yield load (N)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plugging</td>
<td>1061 ± 342</td>
<td>821 ± 281</td>
<td>75 ± 17</td>
</tr>
<tr>
<td>Interference</td>
<td>971 ± 260</td>
<td>791 ± 166</td>
<td>83 ± 11</td>
</tr>
</tbody>
</table>

(Mean ± SD)
1.4. Study IV

The results of the single load-to-failure test are summarized in Table 7. The mean yield loads for the BoneMulchScrew and EndoButton CL groups were significantly greater than those in the interference screw fixations. The mean yield load of the RigidFix group was also significantly higher than in the BioScrew and the RCI screw groups. The highest stiffness was found in the BoneMulchScrew group (115 ± 28 N/mm), which was significantly higher than that in the EndoButton CL, RigidFix, RCI screw and BioScrew groups, but no significant difference was observed between the BoneMulchScrew and SmartScrewACL groups. The stiffness of the SmartScrewACL group was also significantly higher than in the BioScrew and RCI screw groups.

Table 7. Single load-to-failure test in study IV.

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Yield load (N)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EndoButton CL</td>
<td>1086 ± 185</td>
<td>79 ± 7.2</td>
</tr>
<tr>
<td>BoneMulchScrew</td>
<td>1112 ± 295</td>
<td>115 ± 28</td>
</tr>
<tr>
<td>RigidFix</td>
<td>868 ± 171</td>
<td>77 ± 17</td>
</tr>
<tr>
<td>BioScrew</td>
<td>589 ± 204</td>
<td>66 ± 28</td>
</tr>
<tr>
<td>RCI screw</td>
<td>546 ± 174</td>
<td>68 ± 15</td>
</tr>
<tr>
<td>SmartScrewACL</td>
<td>794 ± 152</td>
<td>96 ± 20</td>
</tr>
</tbody>
</table>

(Mean ± SD)

1.5. Study V

The results of the single load-to-failure test are summarized in Table 8. The mean yield load for the Intrafix group was significantly higher than those for the other groups and the mean yield load for the WasherLoc group was significantly greater than that for the interference screws. The stiffness of the Intrafix (223 ± 62 N/mm) was significantly higher than in the other fixations. The stiffness of the SmartScrewACL group was also significantly higher than that for the SoftSilk group.
Table 8. Single load-to-failure test in study V.

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Yield load (N)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WasherLoc</td>
<td>975 ± 232</td>
<td>87 ± 23</td>
</tr>
<tr>
<td>Tandem Spiked Washers</td>
<td>769 ± 141</td>
<td>69 ± 14</td>
</tr>
<tr>
<td>Intrafix</td>
<td>1332 ± 304</td>
<td>223 ± 62</td>
</tr>
<tr>
<td>SoftSilk</td>
<td>612 ± 176</td>
<td>91 ± 34</td>
</tr>
<tr>
<td>BioScrew</td>
<td>471 ± 107</td>
<td>61 ± 12</td>
</tr>
<tr>
<td>SmartScrewACL</td>
<td>665 ± 201</td>
<td>115 ± 34</td>
</tr>
</tbody>
</table>

(Mean ± SD)

2. Cyclic loading tests

2.1. Study II

The cyclic loading induced graft displacement at each force level was not significantly different between bioabsorbable or titanium interference screws (Figure 16). After cyclic loading, the mean linear loads for the bioabsorbable interference screw (605 ± 142 N) and titanium interference screw (585 ± 103 N) were not significantly different, nor were the mean ultimate failure loads 708 ± 115 N and 683 ± 136 N, respectively. The number of bone block fractures was neither significantly different between the screws. The decrease in yield load values between the single load-to-failure test and the single load-to-failure test subsequent to cyclic loading was significantly greater in the titanium group (p=0.03).
Figure 16. The mean displacement of the fixation at the first peak of load at each force level up to the average yield point in the cyclic loading test in study II. There was no significant group difference between bioabsorbable and titanium interference screws. The values are given as the mean and standard deviation.

2.2. Study III

The mean residual displacements of the fixations were not significantly different between the interference technique and the plugging technique (Figure 17). The mean yield was $576 \pm 189$ N for the plugging technique and $679 \pm 286$ N for the interference technique ($p=0.28$), and the mean ultimate failure loads were $994 \pm 376$ N and $1001 \pm 343$ ($p=0.97$), respectively.

2.3. Study IV

The only failures occurring during the cyclic loading test were one in the BioScrew group and one in the RCI screw group. After 1500 cycles the BoneMulchScrew group showed the lowest cyclic loading induced residual displacement ($2.2 \pm 0.7$ mm) followed by the
SmartScrewACL (3.2 ± 0.9 mm), RigidFix (3.7 ± 1.0 mm), EndoButton CL (3.9 ± 0.7 mm), RCI screw (3.9 ± 1.4 mm) and the BioScrew (4.0 ± 1.4 mm) groups (Figures 17 and 18). The residual displacement in the EndoButton CL, RigidFix, BioScrew and RCI screw groups was significantly greater than that in the BoneMulchScrew group. However, the residual displacements between the BoneMulchScrew and SmartScrewACL groups did not differ statistically significantly from one another.

Figure 17. The mean displacement of the femoral graft fixation options used in this study series after 10, 250, 500 and 1500 cycles.

Table 9 gives the results of the single load-to-failure test after the cyclic loading. The mean yield load for the BoneMulchScrew group was significantly higher than those for the BioScrew and RCI screw groups and the mean yield load for the SmartScrewACL group was significantly greater than that for the RCI screw. The stiffness of the BoneMulchScrew group (189 ± 38 N/mm) was significantly higher than that in the EndoButton CL, RigidFix, BioScrew or RCI screw groups. The stiffness of the RigidFix group was also significantly
higher than that for the EndoButton CL group, and the stiffness of the SmartScrewACL group was significantly higher than that in the EndoButton CL and BioScrew groups. The decrease in yield load values between the single load-to-failure test and the single load-to-failure test subsequent to cyclic loading was significant in the BoneMulchScrew and EndoButton CL groups.

Table 9. Single load-to-failure test after cyclic loading test in study IV.

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Yield load (N)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EndoButton CL</td>
<td>781 ± 252</td>
<td>105 ± 13</td>
</tr>
<tr>
<td>BoneMulchScrew</td>
<td>925 ± 280</td>
<td>189 ± 38</td>
</tr>
<tr>
<td>RigidFix</td>
<td>768 ± 253</td>
<td>136 ± 13</td>
</tr>
<tr>
<td>BioScrew</td>
<td>565 ± 137</td>
<td>113 ± 15</td>
</tr>
<tr>
<td>RCI screw</td>
<td>534 ± 129</td>
<td>134 ± 23</td>
</tr>
<tr>
<td>SmartScrewACL</td>
<td>842 ± 201</td>
<td>162 ± 28</td>
</tr>
</tbody>
</table>

(Mean ± SD)

2.4. Study V

In the cyclic loading test the only failure of fixation occurred in the SoftSilk group (one specimen failing). After the cyclic loading tests the Intrafix showed the lowest residual displacement (1.5 ± 0.3 mm) followed by the WasherLoc (3.2 ± 1.5 mm), SmartScrewACL (3.8 ± 1.5 mm), BioScrew (4.1 ± 1.2 mm), tandem spiked washers (4.2 ± 2.6 mm) and the SoftSilk (4.7 ± 1.5 mm) (Figure 18). The mean residual displacement after the cyclic loading test in the tandem spiked washer, BioScrew, SoftSilk and SmartScrewACL groups was significantly greater than that in the Intrafix group, however, there was no significant difference in the Intrafix and WasherLoc groups.
Figure 18. The mean displacement of the hamstring graft fixation options used in this study series after 10, 250, 500 and 1500 cycles.

In the single load-to-failure test after the cyclic loading test, the Intrafix was again the strongest (1309 ± 302 N) followed by WasherLoc (917 ± 234 N), SmartScrewACL (694 ± 173 N), tandem spiked washers (675 ± 190 N), BioScrew (567 ± 156 N) and SoftSilk (423 ± 75 N). Identically to the single load-to-failure test alone, these differences were highly significant (p<0.001) for the Intrafix over all the other devices, except of WasherLoc (p<0.01). The difference was also significant for the WasherLoc over the SoftSilk (p<0.001), BioScrew (p<0.01) and tandem spiked washer (p<0.05). Similarly to the single load-to-failure test, the highest stiffness was found in the Intrafix group (267 ± 36 N/mm), being significantly higher than that in the other fixation groups. The stiffness of the SmartScrewACL group (159 ± 25) was significantly higher than that in the tandem spiked washer (108 ± 26), BioScrew (125 ± 23), and SoftSilk (120 ± 18) groups. The decrease in yield load values was not significant after cyclic loading.
DISCUSSION

The graft fixation site, not the graft material itself, is commonly considered the weakest link during the early postoperative period after ACL reconstruction until the biologic fixation to the host bone and the graft degradation begins, after which the strength of the graft material becomes the major factor in limiting the rehabilitation (Johnson et al. 1992, Fu et al. 1999, Brand et al. 2000c). Current grafts are initially stronger than the native ACL and the postoperative rehabilitation protocols allow full weight bearing and full range of motion immediately after the reconstruction, thus subjecting the graft to increased loading and placing a special emphasis on the importance of secure initial graft fixation (Fu et al. 1999, Brand et al. 2000c). The primary concern has been the fixation of soft tissue grafts, especially their ability to resist repetitive in vivo forces during the rehabilitation period. Consequently, the implant manufacturers have been seeking stronger and stiffer fixations and have introduced various new graft fixation devices every year. Subsequently ACL graft fixation research has become increasingly popular. A high number of these published ACL graft fixation studies have certainly helped the orthopaedic surgeons to make better decisions regarding the ACL reconstruction. However, the apparent influence of the implant business casts a shadow on many of the previously published ACL graft fixation studies, which makes the abundant information somewhat controversial and difficult to analyse and compile.

Although the strength requirements of the graft fixation have not been clearly demonstrated, it has been shown that peak ACL forces may reach 0.55 x body weight during isokinetic/isometric extension of the knee (Toutoungi et al. 2000). In a cadaver study, Rupp et al. (1999a) demonstrated that extension of the knee against gravity produces 219 ± 25 N resultant forces in the ACL. However, much lower fixation strength may be sufficient, because excellent long-term outcomes have been reported for both BPTB and hamstring tendon graft fixations, which have been found to provide poor stiffness and fixation strength
in biomechanical studies (e.g., sutures tied over a button and RCI) (Steiner et al. 1994, Shelbourne and Nitz 1990, Pinczewski et al. 2002). In addition, the graft material itself becomes considerably weaker than the initial fixation during the early postoperative period (Butler et al. 1989, Rodeo et al. 1993, Weiler et al. 2002b).

1. Methodological issues

To compare the data between biomechanical studies, one has to keep in mind that practically all biomechanical test modes are extremely case-sensitive i.e., small differences in study design [e.g., specimen (animal vs. human tissue, young vs. old donors), biomechanical testing protocol (loading rate, orientation of the applied load and number of loading cycles)] can seriously influence the results of one test, and thus, comparisons between studies should be done with extreme caution.

On the basis of the current literature, it is impossible to determine the testing protocol that would mimic the loading experienced by the ACL substitute during the rehabilitation. Beynnon and Amis (1998) have described guidelines for the biomechanical evaluation of the ACL graft fixation. They emphasized the importance of the cyclic loading test and recommended to evaluate anterior-posterior laxity with constant forces ranging between 150 (anterior) and -150 N (posterior). This method allows to mimic the Lachman and anterior drawer tests by applying anteriorly directed load to the tibia in different knee flexion angles, and therefore the results can be considered to be more relevant clinically. They also suggested an alternative approach for testing ACL graft fixation constructs, in which one bone (tibia or femur) and the other end of the graft are secured to the testing machine. The latter approach was used in this study series and it allows to monitor a specific fixation at a specific location, which gives more precise information about the specific fixation technique. Despite these guidelines, the cyclic loading protocols have varied considerably.

The possible failure of the fixation in the bone tunnel during cyclic loading was not directly analysed in this series of five successive experiments. The displacement values of the graft-
fixation construct observed during the cyclic loading test could be assumed to result from either the creep of the tendon or the gradual slippage/failure of the graft fixation. Considering the carefully standardized testing protocols, the displacement seen in the cyclic loading tests was apparently mostly a result of the creep of the tendons and the increase in the displacement values was most likely due to the gradual failure of the fixation. In fact, Rittmeister et al. (2002) recently showed that over 90% of the total displacement seen in the biomechanical testing of ACL reconstructs is attributable to soft tissue graft slippage past the interference screw.

Porcine knees are the most commonly used sources of bone for testing various ACL fixation methods despite having clearly higher (volumetric) bone density than human bones (Nurmi et al. 2002, Nurmi et al. 2004c). As the quality of human bone specimens often varies considerably, porcine and even bovine knee specimens with more uniform bone quality can be considered to offer a reasonable alternative to the human bone. In studies using porcine or bovine bone the results are presumably over optimistic compared with human bone, which probably more influences the evaluation of fixations that rely on the friction to secure the graft, such as interference screws and Intrafix in comparison with extra-articular techniques (EndoButton CL, BoneMulchScrew, RigidFix, WasherLoc and tandem spiked washers).

2. BPTB graft fixation

At the time this series of experiments was carried out, the BPTB graft fixation with metal interference screws was clearly the procedure of choice (“golden standard”), and accordingly, the basis of comparison in ACL surgery. Bioabsorbable implants were developed to offer benefits compared to their metal counterparts. They were introduced clinically in the treatment of fractures and osteotomies in 1984 (Rokkanen et al. 1985, Böstman 1991). Along with the popularity of ACL reconstruction surgery, the number of ACL revisions also increased dramatically (Jaureguito and Paulos 1996, Safran and Harner 1996, Allen et al. 2003). As the retained metal screws may severely complicate the revision
ACL surgery and disturb MRI (Shellock et al. 1992, Suh et al. 1998), there was an apparent benefit associated with the use of fixation implants made of bioabsorbable material, but their suitability had to be properly validated.

On the basis of our biomechanical testing (study I), the bioabsorbable fibrillated SR-PLLA screw provided as good initial fixation strength as the Kurosaka interference screw and the AO cancellous screw in the fixation of a BPTB graft in the bovine knee, and thus, could be considered a suitable alternative for the metal screws in the BPTB graft fixation in the reconstruction of ACL. These pullout test results were similar to those of other reports using the BPTB graft fixation and bovine knee specimens (Hulstyn et al. 1993, Lemos et al. 1995, Shapiro et al. 1995, Brown et al. 1996, Bryan et al. 1996, Abate et al. 1998, Pomeroy et al. 1998, Weiler et al. 1998b).

Also to validate the suitability design-wise, the results of study II showed that both the bioabsorbable and the titanium interference screws provided similar fixation strength in the single load-to-failure and cyclic loading tests. The single load-to-failure test results of the titanium interference screw were also very comparable to those obtained by other investigators using either young human cadaveric or porcine knee specimens and metal interference screws for the BPTB graft fixation (Liu et al. 1995, Pierz et al. 1995, Brown et al. 1996, Pena et al. 1996, Rupp et al. 1997, Rupp et al. 1998, Seil et al. 1998, Stapelton et al. 1998, Rupp et al. 1999b, Honl et al. 2002).

Bioabsorbable and metal interference screws have provided comparable initial fixation strength in the single load-to-failure testing of BPTB graft fixations (Johnson and vanDyk 1996, Caborn et al. 1997, Rupp et al. 1997, Abate et al. 1998, Weiler et al. 1998b). However, Pena et al. (1996) found that the metal interference screw provided superior fixation strength compared to the bioabsorbable interference screw. Beevers (2003) speculated that the quality of the bones between the two study groups explained their finding and that bioabsorbable and metal interference screw groups were similar when a correction for different bone mineral density was done.
Seil et al. (1998) were the first to compare under cyclic loading conditions the initial fixation strength of bioabsorbable and metal interference screws in the fixation of BPTB graft in ACL reconstructions. The cyclic loading test consisted of 500 loading cycles between 60 to 250 N at a rate of 300 mm/min, after which the specimens were loaded to failure. With regard to the ultimate failure load and bone block slippage observed during cyclic loading, no significant difference was found between the bioabsorbable and titanium interference screws. In our study, the displacement values were similar at each loading level between the two interference screws, confirming the previous findings by Seil et al. (1998).

A number of studies have shown a consistent phenomenon of more bone block fractures with metal interference screws than bioabsorbable interference screws in the single load-to-failure test (Pena et al. 1996, Caborn et al. 1997, Rupp et al. 1997, Weiler et al. 1998b). Similarly, there were more bone block fractures in the specimens fixed with a titanium interference screw compared to bioabsorbable interference screws in our study (II), although the difference was not statistically significant. The difference in failure mode can be partly explained by the difference in the elastic modulus between the bone (cancellous bone 0.2-0.7 GPa and cortical bone 9-20 GPa), and the interference screws (titanium alloy 110 GPa, PLA96/4 4.6-7.5 GPa) (Ruluff and McIntyre 1982, Anderson et al. 1992, McGalden et al. 1993, Pohjonen and Törmälä 1996). It appears, however, that the failure of bone blocks in the metal interference screw fixation is not of clinical significance.

Although the interference screw fixation of the BPTB graft is safe and reliable in most cases, there are some pitfalls related to the operative technique, especially in the technically more demanding femoral site. Damage to the bone block, the tendinous part of the graft or passing sutures during screw insertion, and divergent screw insertion are some of the reported problems associated with the femoral interference screw fixation of the BPTB graft in ACL reconstruction. Furthermore, if the single-incision technique is used, surgeons occasionally face problems with graft-tunnel mismatch, that is, the graft “being too long” and protruding out of the tibial drill tunnel. Then alternative fixation techniques are often required (Taylor et al. 1996, Denti et al. 1998, Fowler et al. 1998, Olszewski et al. 1998, Hoffmann et al. 1999). To avoid these problems, a new plugging technique was developed. With this technique the
groove of the implant (plug) protects the graft during insertion (graft fixation), while the plug is tapped behind the bone block instead of being forced into the gap between the bone tunnel wall and the bone block (Figure 8). In addition, the plug insertion (tapping) advances the femoral bone block deeper into the femoral tunnel, subsequently pulling the tibial bone block into the tibial tunnel diminishing the possibility for mismatch. In addition, as the implant obstructs the femoral tunnel opening, a smaller bone block is needed, and the risk of a patellar fracture in the BPTB graft harvest can be reduced (Moholkar et al. 2002, Stein et al. 2002). The plug is also made of bioabsorbable material providing the previously mentioned material advantages.

In the biomechanical validation of the novel BPTB graft fixation technique (study III), no significant difference was found in failure loads between a metal interference screw and a bioabsorbable plug in the single load-to-failure and cyclic loading tests. The load-induced increase in the displacement was similar in both study groups indicating that both fixations failed equally. The failure loads of the interference technique were also similar to those of the previous studies using young human or porcine knee specimens and the BPTB graft fixation with metal interference screws (Reznik et al. 1990, Matthews et al. 1993, Butler et al. 1994, Paschal et al. 1994, Pierz et al. 1995, Brown et al. 1996, Pena et al. 1996, Rupp et al. 1997, Pomeroy et al. 1998). However, as mentioned before, mechanically weaker graft fixations could be strong enough to prevent a fixation failure and slippage during rehabilitation. This may particularly concern the femur where shear forces enhance the fixation, as the line of force does not come parallel with the femoral bone tunnel until 100° of flexion. It is also commonly considered that the highest forces are acting near the extension of the knee. Further, although the press-fit fixations of the BPTB graft (femoral bone plug) have yielded relatively low values in pull out testing and poor resistance to repetitive loading, the clinical outcome has proved highly satisfactory (Boszotta 1997, Rupp et al. 1997, Seil et al. 1998).
3. Hamstring graft fixation

Many variables in graft fixation seem to influence the overall long-term outcome after the reconstruction of the ACL, particularly when the soft tissue grafts (hamstring tendon) are used. The donor-site morbidity associated with the use of BPTB grafts is the most persuasive argument favouring the use of hamstring grafts. Studies have shown that the initial structural properties (failure strength and stiffness) of the four strand hamstring grafts are comparable or even higher than those of the BPTB graft and the hamstring graft fixation techniques have considerably improved, resulting in a steady increase in the use of the hamstring tendon grafts during the past decade. However, concerns with the hamstring grafts still include the initial strength of graft fixation, possibly increased knee laxity and graft-tunnel motion, slower biological fixation to the bone tunnel compared to the BPTB graft, possibly increased graft tunnel motion, hamstring muscle weakness, and discomfort associated with cortical hardware (Fu et al. 1999, Miller and Gladstone 2002). Whether the increased knee laxity observed in some clinical studies comparing hamstring tendon and BPTB autografts in ACL reconstruction is due to the method of fixation or the difference in graft material itself is unclear (Otero and Hutcheson 1993, O’Neil 1996, Corry et al. 1999, Beynnon et al. 2002, Feller and Webster 2003).

Interference screw fixation has become popular also with hamstring grafts. Anatomic (aperture) fixation, in which the fixation is close to the original ACL insertion site e.g., an interference screw placed in the drill tunnel adjacent to the joint surface, has been shown to improve knee stability and graft isometry (Morgan et al. 1995, Ishibashi et al. 1997). Anatomic fixation also potentially minimizes graft motion relative to the bone tunnel wall and prevents the access of synovial fluid between the graft and the bone tunnel wall decreasing the risk for tunnel widening and enhancing graft healing at the articular tunnel aperture (Weiler et al. 2002b). However, concern has been raised of the soft tissue graft interference screw fixation with regard to the possible slippage of the graft past the screw under repetitive loads during the immediate postoperative period prior to graft incorporation, as the fixation depends on the friction between the tendons and walls of the bone tunnels (Giurea et al. 1999, Magen et al. 1999, Scheffler et al. 2002). In contrast, the extra-articular
methods, in which the fixation site is at a distance from the joint line, have been implicated to cause graft elongation, graft-tunnel motion and enlargement of the bone tunnels and ultimately increase in knee laxity (Jansson et al. 1999, Scheffler et al. 2003). Unexpectedly, Singhatat et al. (2002) recently demonstrated in an ovine model after 4 weeks of extra-articular fixation technique (WasherLoc) improved graft healing to the bone tunnel in comparison with interference screw fixation. The extra-articular WasherLoc maintained the strength and improved the stiffness of the graft-fixation complex, whereas the strength and stiffness of the fixation with bioabsorbable interference screws decreased considerably. The major weakness of the study was the absence of intra-articular healing environment. The possible synovial fluid access between the bone tunnel and the healing tendon combined with potential graft-tunnel motion could have a considerable effect on the results. It has also been shown that the improvement in knee stability is strongly influenced by the rigidity and stiffness of the fixation, not solely by the length of the graft fixation construct (Magen et al. 1999, To et al. 1999).

In studies IV and V, the fixation strength of the commonly used femoral (EndoButton CL, BoneMulchScrew, RigidFix and three different interference screws) and tibial (WasherLoc, tandem spiked washers, Intrafix and three interference screws) hamstring ACL graft fixation methods were compared biomechanically. The extra-articular hamstring graft femoral fixation methods (study IV) differed from each other by their principle of fixation: EndoButton CL and BoneMulchScrew can be considered “true” toggle fixations, which suspend the graft within the tunnel, and the tendon is looped around a part of the implant. In the EndoButton CL, the tendon is fixed to the cortex of the femur via continuous polyester loop (indirect fixation) and in the BoneMulchScrew, the tendon is looped over a crossbar inserted into the metaphyseal bone of the lateral femoral condyle. RigidFix, in turn, should be considered a “semi-toggle” fixation because it is not possible to wrap the tendon loops around the cross pins. Therefore the strength of fixation depends on the pins engaging the tight tendon loop against the walls of the tunnel.

In study IV, the extra-articular techniques generally provided better pullout strength of the fixation than the apertural (interference screws) with no significant difference between the
three extra-articular techniques. As the BoneMulchScrew was found superior to EndoButton CL and RigidFix, it appears that the rigidity of the device itself improves the fixation strength. In the cyclic loading test, in turn, the EndoButton CL and RigidFix groups showed more residual displacement compared to the BoneMulchScrew, although the single cycle loading results were comparable. Because there were no visible changes in the titanium button of the EndoButton CL during the cyclic loading test, changes in the continuous loop or tendon-loop interface may have been the reason for the increased residual slippage. In the RigidFix group, the increased residual displacement was most likely attributable to the gradual bending or fracture of the bioabsorbable pins. Of the interference screws, the SmartScrewACL was found to be comparable to the BoneMulchScrew, whereas the BioScrew and RCI screws allowed significantly higher residual displacement than the BoneMulchScrew.

Although all the extra-articular methods gave significantly better strength of fixation than the RCI screw and BioScrew, the difference in the yield load values between the RigidFix and SmartScrewACL was not statistically significant, indicating that some difference in the characteristics of the three interference screws had a considerable effect on the strength of fixation. While the bioabsorbable material used in manufacturing interference screws and the surface finish have been speculated to enhance the strength of fixation of interference screws (Weiler et al. 1998a), our results rather suggest that the design (geometry, core diameter, pitch/thread thickness, etc.) of certain bioabsorbable screws is more likely the reason for the improved fixation strength of soft tissue grafts in the ACL reconstruction. In accordance with our findings, Giurea et al. (1999) recently showed that the interference screw design has an effect on the slippage of the soft tissue fixation under cyclic loading conditions. After 1100 loading cycles at 150 N, the titanium RCI screw allowed a mean displacement of $6.8 \pm 5.6$ mm, which was over three times higher than that observed with the titanium interference screws specifically designed for the soft tissue graft fixation.

In study V, the two extra-articular fixation methods differed in their effective graft lengths. The WasherLoc secures the graft within the bone tunnel opening, whereas the tandem spiked washers fixes the graft completely outside the tibial tunnel, which results in an even longer
effective graft length. The Intrafix, in turn, secures the graft inside the distal tunnel leaving approximately 5 to 15 mm of free graft within the proximal opening (aperture) of the drill tunnel. Finally, the interference screws can be considered truly apertural fixations, as the screws can be driven flush with the intra-articular tunnel opening. The Intrafix provided superior pullout strength and stiffness in single load-to-failure tests and it was also superior in resisting slippage under cyclic loading when compared to other implants. In the cyclic loading test, although the stiffness values were comparable, the yield load for WasherLoc was significantly higher than for the interference screws. Although SmartScrewACL was consistently better than BioScrew and SoftSilk, the only statistically significant difference was found in stiffness of the fixation.

Bioabsorbable interference screws have been in clinical use for the fixation of ACL replacements at least since 1992 (McGuire et al. 1999, Stähelin 1997). Some complications have been reported, such as breakage of the screw during insertion, inflammatory reactions and osteolytic cyst formation (Barber et al. 1995, Imhoff et al. 1998, Martinek et al. 1999). The short- and mid-term clinical studies have suggested that bioabsorbable interference screws provide a reasonable alternative to metal interference screws in the fixation of both BPTB and hamstring grafts (Barber et al. 1995, Marti et al. 1997, McGuire et al. 1999, Charlton et al. 2003).

To summarize the results, the concern about the use of interference screws in securing soft tissue grafts was supported by the results of our studies on the femoral and tibial fixation devices (studies IV and V). The only complete failures of fixation observed during the cyclic loading testing of the specimens were one in the BioScrew group, one in the RCI screw group and one in the SoftSilk group. However, in the femur (study IV), SmartScrewACL was the second best of all the implants tested in the cyclic loading test. The clinical correlation can be found from Corry et al. (1999) and Pinczewski et al. (2002), who have shown that hamstring graft fixation with metal interference screws provides good clinical outcome and restores satisfactory knee stability. Our results indicate that both BPTB and hamstring tendon graft fixation methods can provide rigid fixation without concern about increased knee laxity due to loosening of the fixation under repetitive loading conditions. However, it seems that
the design and material characteristics of the implant have a major impact, especially on the strength of hamstring graft fixation.

This study series evaluated biomechanically the initial fixation strength of various femoral and tibial fixation devices of both BPTB and quadrupled hamstring tendon grafts in ACL reconstruction. It is important to be critical and cautious when interpreting these test results. Also it is essential to understand that the highest fixation strength, superior stiffness and the best resistance to repetitive loading in biomechanical studies do not necessarily mean that the fixation is superior to the long-term survival of the graft. For example, a stronger and stiffer graft fixation construct is less forgiving in case of incorrect tunnel placement and may restrict knee motion and ultimately jeopardize grafts survival (biologic incorporation and ligamentization) in long-term. As mentioned earlier, time zero biomechanical ACL graft fixation studies have been abundant. Whether we like it or not, in retrospect it appears safe to conclude that the importance of the strength of the ACL graft fixation has been exaggerated, apparently at least partly due to commercial reasons. We must remember that the goal of an ACL reconstruction is not the immediate postoperative period, but rather to re-establish the normal function and stability of the knee for decades. Therefore, in the future, to better validate the suitability of various implants or fixation techniques in the reconstruction of the ACL, it is essential to focus on in vivo research.
CONCLUSIONS

1. On the basis of the biomechanical testing results that we obtained with the three different screws, the bioabsorbable fibrillated SR-PLLA screw is suitable for the fixation of a BPTB graft in the reconstruction of the ACL.

2. Considering the biomechanical testing results that we obtained with the two interference screws in this study, the bioabsorbable and standard titanium interference screws provide similar initial fixation strength in the fixation of a BPTB graft in the ACL reconstruction.

3. The results show that in terms of initial fixation strength the new plugging technique is as good as the standard interference screw technique in the fixation of a BPTB graft in the femoral tunnel in the reconstruction of the ACL.

4. On the basis of the results, the cross pin technique (BoneMulchScrew) provided superior fixation strength in the femoral tunnel and the central four-quadrant sleeve and screw system (Intrafix) was clearly superior in the tibial tunnel in securing the quadrupled hamstring graft in the ACL reconstruction. In the femoral site, EndoButton CL, RigidFix, BioScrew and RCI screw and in the tibial site, tandem spiked washers, BioScrew, SoftSilk and SmartScrew ACL allowed increased residual displacement during cyclic loading. Therefore, some caution may be warranted in the rehabilitation after the ACL reconstruction when using these implants. Soft tissue specific titanium interference screws (RCI screw in femur and SoftSilk screw in tibia) showed inferior pullout strength in single load-to-failure tests.
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