There is a trend towards the use of double-bundle techniques for the reconstruction of the anterior cruciate ligament. This has not been substantiated scientifically. The functional outcome of these techniques is equivalent to that of single-bundle methods. The main advantage of a double-bundle rather than a single-bundle reconstruction should be a better rotational stability, but the validity and accuracy of systems for the measurement of rotational stability have not been confirmed.

Despite the enthusiasm of surgeons for the double-bundle technique, reconstruction with a single-bundle should remain the standard method for managing deficiency of the anterior cruciate ligament until strong evidence in favour of the use of the double-bundle method is available.

Reconstruction of the anterior cruciate ligament (ACL) is a common procedure, with reported clinical success ranging between 80% and 95%. Between 75,000 and 100,000 reconstructions of the ACL are performed annually in the United States, but 85% of orthopaedic surgeons carry out fewer than ten such procedures per year. The ACL consists of two major functional bundles, namely the anteromedial and posterolateral. The former originates more proximally on the femur and inserts anteromedially on the tibia, while the latter originates more distally from the femoral site and inserts posterolaterally into the tibia. Both are nearly parallel when the knee is extended and twist around each other as the knee flexes.

Many techniques for reconstruction of the ACL have been described. There is no true consensus as to the optimal positioning of the femoral tunnel or for determining the landmarks which best identify its true location. Generally, as the tension varies among the fibres during flexion and extension of the knee, two bands can be distinguished. In the absence of a functional ACL the axis of rotation shifts more medially and tibial rotation causes a coupled anterior tibial translation, magnifying the movement of the tibial plateau.

The exact orientation of the different bands of the ACL is controversial. There is no evidence of the histological separation of the individual bands, and two, three or multiple bundles may be seen. Generally, as the tension varies among the fibres during flexion and extension of the knee, two bands can be distinguished.

In order to assess the success of an ACL reconstruction, quantitative measurements of the pivot shift, rotational laxity in the transverse plane and patient satisfaction must be considered. The long-term outcome of the reconstruction in terms of preventing or slowing down the progression of degenerative joint disease should be taken into account. This paper considers the evidence for the advantages of double-bundle as opposed to single-bundle techniques for the reconstruction of the ACL.

**Cadaver studies**

The exact orientation of the different bands of the ACL is controversial. There is no evidence of the histological separation of the individual bands, and two, three or multiple bundles may be seen. Generally, as the tension varies among the fibres during flexion and extension of the knee, two bands can be distinguished.

In the absence of a functional ACL the axis of rotation shifts more medially and tibial rotation causes a coupled anterior tibial translation, magnifying the movement of the tibial plateau. The ACL also plays a role in stabilisation against rotatory loading. Cadaver studies have shown that single-bundle reconstruction is successful in limiting anterior tibial...
translation in response to anterior loading but cannot fully control a combined rotatory load of internal and valgus torque.\(^{23,30-34}\) In single-bundle reconstruction, positioning of the graft at 10 o’clock instead of 11 o’clock has been proposed in order to restore knee function in response to both externally-applied anterior tibial and combined rotatory loads.\(^{35}\)

The addition of a lateral extra-articular procedure with hamstring tendon grafts reduces internal rotation of the tibia in 30° of knee flexion compared with a standard single-bundle reconstruction.\(^{36}\)

Radford and Amis\(^{37}\) first described the mechanical results of double-bundle reconstruction in cadaver knees showing restoration of anterior laxity to nearly-normal at 20° and 90° of flexion. The force distribution between the anteromedial and posterolateral bundles in the reconstruction was similar to that found in the normal ACL. There was a higher in situ force in the posterolateral bundle at 0° and 15°, whereas in the anteromedial bundle this force was higher at 90° of flexion.

Yagi et al\(^{12}\) used a robotic/universal force-moment sensor-testing system to study ten cadaver knees subjected to external loading with an anterior load and a combined rotatory load. This showed superior restoration of the biomechanics in double-bundle rather than in single-bundle reconstructions, especially with respect to rotatory loads.

Sbihi et al,\(^{38}\) investigating cadaver specimens with an arthrometer, found the double-bundle to be superior to the single-bundle reconstruction as regards anteroposterior laxity at 20° of flexion, but not at 60° or 90°.

Ishibashi et al\(^{39}\) showed improvement in anteroposterior laxity in patients who had a double-bundle reconstruction performed using the OrthoPilot navigation system (B. Braun-Aesculap, Tuttlingen, Germany) compared with patients who had a single-bundle procedure.

**Single-bundle versus double-bundle techniques**

As yet there is no clinical evidence to show that the double-bundle is superior to the single-bundle technique in reconstruction of the ACL. Many authors have described a double-bundle technique,\(^{3,6-13}\) and several have reported outcome studies at two years, but only five randomised, controlled trials (RCTs), two-quasi-RCTs and two prospective, comparative cohort studies have compared the two procedures. All showed a comparable clinical outcome between the two techniques. No study has detected any statistically significant differences when using patient-based outcome measures.

Adachi et al\(^{9}\) prospectively randomised 108 patients with unilateral instability of the knee associated with rupture of the ACL for arthroscopic single-bundle or double-bundle reconstruction of the ligament using hamstring tendons. The method of randomisation was not given. The patients were followed up for a mean of 32 months (24 to 36). No significant difference (p > 0.05) was found between the two groups with regard to the mean anterior laxity as measured by the KT-2000 arthrometer (MEDmetric, San Diego, California) with the knee at 20° or 70° of flexion, or with regard to proprioception.

Yasuda et al\(^{13}\) carried out a prospective, comparative cohort study to compare the clinical outcomes in patients who had reconstruction of the ACL with single-bundle or double-bundle hamstring autografts. There were 72 patients with unilateral ACL-deficient knees who had been assigned to one of three techniques of reconstruction: single-bundle, non-anatomical double-bundle or anatomical double-bundle. Each group included 24 patients. They had a clinical examination before surgery and after two years. There were no significant differences in the three groups in regard to muscle torque, range of movement and the International Knee Documentation Committee (IKDC) score, although the side-to-side anterior laxity of the anatomical double-bundle was better than that of the single-bundle reconstruction.

Aglietti et al\(^{10}\) carried out a prospective, comparative cohort study to evaluate whether one of two techniques of the double-bundle reconstruction was superior to a single-incision single-bundle procedure in controlling anterior tibial translation and reducing pivot shift. The first 25 patients (group I) had a single-bundle transtibial ACL reconstruction, the next 25 (group II) a double-bundle single-incision transtibial procedure and a further 25 (group III) a double-bundle two-incision outside-in operation. The mean side-to-side anterior laxity and the amount of residual pivot shift were significantly lower in group III than in group I (p < 0.05). The mean IKDC subjective evaluation score was significantly higher in group III than in group I (p < 0.05). No significant differences were observed between groups II and III.

Yagi et al\(^{22}\) carried out a quasi-randomised trial to evaluate whether rotational stability differed in three techniques, namely anteromedial single-bundle and posterolateral single-bundle and double-bundle. A total of 60 patients was allocated into three groups. There were no significant differences in the groups in regard to side-to-side anterior laxity, peak isokinetic torque or the IKDC score. Patients in whom the ACL had been reconstructed with the double-bundle technique had significantly better control of pivot shift.

Muneta et al\(^{21}\) conducted a quasi-randomised trial on 68 patients with unilateral ACL deficiency to compare the outcome between double-bundle and single-bundle ACL reconstructions with four-strand semitendinosus tendon. The patients were assigned to one of two treatment groups according to their birth date, and were followed up for a mean of 25 months. There were no significant differences between the two groups with regard to the mean range of movement, girth of the thigh, muscle strength, and the Lysholm score. Manual testing showed that positive Lachman and pivot-shift tests were less common in the double-bundle group than in the single-bundle group. The KT measurements were statistically significantly different, with better
results on average in the double-bundle group. Statistical analysis showed no significant difference regarding all of the modified IKDC categorised data between the two groups. The authors concluded that double-bundle reconstruction was superior to the single-bundle technique with regard to anterior and rotational stability, but they failed to show any difference between the two techniques when considering subjective variables.

Järvelä conducted a prospective, randomised clinical study to compare the outcome of ACL reconstruction using either the double-bundle or single-bundle techniques with similar regimes for rehabilitation. He randomised 65 patients into either double-bundle (n = 35) or single-bundle (n = 30) groups using hamstring tendons and bio-absorbable screw fixation. Double-bundle reconstruction with hamstring grafts using bio-absorbable screw fixation on both tibial and femoral sides resulted in better restoration of rotational laxity of the knee than single-bundle ACL reconstruction, when measured by the pivot-shift test (p = 0.002).

Streich et al carried out a randomised trial in male athletes to compare the clinical results of a single-bundle with that of a double-bundle reconstruction using an autologous semitendinosus tendon graft with extracortical fixation. A total of 50 men with a mean age of 29.4 years was prospectively randomised consecutively into one of the two procedures. After two years, there was no significant difference in the side-to-side measurement of anterior laxity with the KT-1000 arthrometer in the groups. As evaluated by the pivot-shift test, no significant correlation was noted between rotational stability and the use of either technique. Statistical analysis showed a significant increase in the IKDC and the rotational stability and the use of either technique. Statistical analysis showed no significant difference between the two methods.

Siebold, Dehler and Ellert conducted a prospective, randomised clinical study to compare the outcome of ACL reconstruction using either the double-bundle or the single-bundle technique. The 70 patients undergoing arthroscopic reconstruction were prospectively randomised to double-bundle (n = 35) or single-bundle (n = 35) groups. Fixation was by means of a femoral EndoButton CL (Smith & Nephew, Andover, Massachusetts) and a tibial biodegradable interference screw. The subjective results were similar in both groups. There was no significant difference between the groups as evaluated by the IKDC-2000 score, the Cincinnati knee score, or the Lysholm score. The objective IKDC score was significantly higher for the double-bundle technique compared with the single-bundle technique. The mean KT-1000 side-to-side difference was 1.0 mm for double-bundle and 1.6 mm for single-bundle (p < 0.054) and the pivot-shift test was negative in 97% of patients for double-bundle and 71% for single-bundle (p < 0.01).

Järvelä conducted an RCT to compare the clinical results of a double-bundle technique using doubled semitendinosus and doubled gracilis autografts with bio-absorbable interference screw fixation and two tunnels on both the femoral and tibial sides, with a single-bundle, four-stranded hamstring autograft technique using interference screw fixation. There were 77 patients who were randomised into three different groups: double-bundle with bio-absorbable screw fixation (n = 25), single-bundle with bio-absorbable screw fixation (n = 27) and single-bundle with metal screw fixation (n = 25). The rotational stability of the knee, as evaluated by the pivot-shift test, was best in the patients in the double-bundle group (p = 0.005). Measurement of the anterior stability of the knee with the KT-1000 arthrometer showed no statistically significant differences in the groups; nor were there significant differences in the knee scores between the groups.

Discussion

There is, as yet, no evidence to show that fully anatomical double-bundle reconstruction of the ACL results in a better functional outcome.

Many major issues remain in considering reconstruction of the ACL, particularly in regard to the indications for this procedure such as laxity, or instability. Although there is a correlation with anteroposterior laxity, not all patients with a tear of the ACL develop instability. Rotatory laxity seems to be of greater significance than anteroposterior laxity. Many patients have anteroposterior and rotatory laxity, but do not develop instability. They do not need a reconstruction. All tears of the ACL do not automatically produce functional impairment and the patient may be able to resume pre-morbid levels of activity without reconstruction. However, others may experience repeated giving-way.

Measurements of laxity and the IKDC ratings are incapable of distinguishing the functional status of the ACL-deficient patient. Alternatively, the Lysholm Knee Outcome Survey (KOS)-Sport, KOS-ADL and the global knee function rating scores may be capable of discriminating between symptomatic and asymptomatic deficiency. No single measurement tool is sufficient. Measurement of anterior laxity does not correlate with measures of functional outcome. Assessments which are based partially on measures of joint laxity, such as the IKDC score, may artificially overestimate the disability after rupture of the ACL.

The main advantage of double-bundle compared with single-bundle reconstruction should be better rotational stability, but the validity and accuracy of the measurement systems for rotational stability have not been confirmed, and this remains the major weakness in the evaluation of the results of a double-bundle reconstruction.

Incorrect placement of the femoral and tibial tunnels is the main reason for technical failure in single-bundle reconstruction. The question remains as to whether the use of four tunnels in a double-bundle construct rather than two in a single-bundle repair increases the rate of failure. No study has yet had sufficient power to disprove this. A double-bundle procedure may also produce more problems at revision surgery.
Several techniques of double-bundle reconstruction have been described, but there is no evidence that one is superior to another. Failure of the graft and requirements for revision procedures should also be considered. It is uncertain whether one should depend on instrumented testing, which does not measure rotational laxity, or accept functional scores as an accurate assessment of patient outcome.

In order to determine whether a double-bundle reconstruction is superior to a single-bundle procedure a randomised controlled trial would be required. Calculation of sample size, based on a power analysis, should be included in the design of such a trial. However, there is little agreement among surgeons on a suitable outcome measure, so calculation of the sample size remains a point of debate; such a study would require a large number of patients.

Loss to follow-up after recruitment and attrition are common in RCTs. The former occurs when information as to the progress of the patient cannot be obtained, whereas attrition is the exclusion or drop-out of individuals for a particular reason after randomisation to the intervention or control group. It forms one of the four predominant biases in clinical trials, as follows: selection, performance, attrition and detection.

Considering these aspects, the number of patients required to perform a suitable RCT is considerable and it is unlikely that such a trial will ever be carried out. Given the commercial pressures inevitable in this field, we fear that trials involving much smaller numbers of patients will be performed instead. However, the question remains as to whether it is ethical to carry out such investigations to identify an effect which may be small and not clinically relevant, although statistically significant and wholly measurable by present techniques, since a large number of participants would be exposed to a potentially less beneficial intervention.

Currently, there is no evidence that a double-bundle reconstruction provides a better clinical outcome than a single-bundle procedure. A simple single-bundle reconstruction is a suitable technique, provided that it is performed in a technically correct fashion with up-to-date tunnel placement, using appropriate fixation techniques and rehabilitation programmes. It should not be abandoned until stronger scientific evidence in favour of double-bundle reconstruction can be produced.

Supplementary Material

A further opinion by Mr A. Williams is available with the electronic version of this article on our website at www.jbjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


