Single-Bundle Versus Double-Bundle Anterior Cruciate Ligament Reconstruction—5-Year Results

Hermann O. Mayr, M.D., Ph.D., Silvia Bruder, M.D., Robert Hube, M.D., Ph.D., Anke Bernstein, M.D., Ph.D., Norbert P. Suedkamp, M.D., Ph.D., and Amelie Stoehr, M.D.

Purpose: To compare anatomic single-bundle (SB) with double-bundle (DB) anterior cruciate ligament reconstruction (ACL-R) and to evaluate the respective clinical outcome results. **Methods:** In a prospective randomized study, 64 patients were included and separated into 2 groups. Anatomic SB and DB ACL-Rs were performed with hamstring tendons. Five years after surgery, the follow-up (FU) examination comprised International Knee Documentation Committee (IKDC) 2000, Laxitester (ORTEMA Sport Protection, Markgroeningen, Germany) measurement, and radiograph evaluation. Power calculation was performed to achieve a 95% confidence interval and 80% power on the base of 7-point IKDC subjective difference between the groups. **Results:** A total of 53 patients (83% FU) were examined at 63.2 ± 4.7 months after surgery: 28 patients in the DB group and 25 patients in the SB group. IKDC subjective (SB: 92.8 ± 6.2, DB: 91.6 ± 7.1; $P = .55$) and objective scores (grade A SB/DB 20%/25%, B SB/DB 72%/57%, C SB/DB 8%/18%, D SB/DB 4%/0%; $P = .45$) showed no differences comparing both groups. The Laxitester measurements showed no significant difference in regard to anterior-posterior translation in neutral, internal, and external rotation or to rotation angles ($P = .79$). No difference was seen between the groups regarding osteoarthritic changes and tunnel widening. **Conclusions:** At the 5-year FU, no advantage for either the DB or SB technique in ACL-R can be seen with regard to patient-related and objective outcome measures. **Level of Evidence:** Level I, prospective randomized controlled clinical trial.

In recent years, the importance of anatomic anterior cruciate ligament reconstruction (ACL-R) regarding tunnel placement and double-bundle (DB) shape of the ACL has become more relevant for reconstruction techniques.[1] Therefore, DB ACL-R was established as a standard surgical procedure.[2] But higher implant costs and a prolonged, more sophisticated surgical technique questioned the effectiveness compared with anatomic single bundle (SB) ACL-R. The clinical advantage of anatomic DB over SB ACL-R has not been clearly proven so far.[3-5] Recently, several studies with a 5-year follow-up (FU) presented clinical outcomes and manual laxity measurements, without showing significant differences in subjective and objective outcome measures for both procedures.[3,5] Other studies claim more rotational stability for DB ACL-R.[5-7] Similar intraoperative observations using computer navigation were made by Seon et al.[8] and Plaweski et al.[9] Different meta-analyses failed to prove significant differences when comparing SB and DB ACL-R outcomes.[4,10]

Several prospective randomized studies comparing SB and DB ACL-R with a 3- to 5-year FU could be found that used a KT-1000 Arthrometer for instrumented knee laxity measurement. Yet, the KT-1000 can solely assess 1-dimensional knee laxity with regard to anterior-posterior (a.p.) translation. Rotational laxity in these studies was investigated by the examiner-dependent Pivot shift test.[11-13]

An experimental setup for instrumented in vivo determination of a.p. translation in regard to rotational laxity with the so-called Laxitester has been described by Mayr et al.[14] recently. It showed good intra- and inter-rater reliability and helped assess the influence of the rotational component of knee laxity better.

From the Department of Orthopedics and Trauma Surgery, Medical Center, Faculty of Medicine, Albert-Ludwigs-University of Freiburg (H.O.M., A.B., N.P.S.), Freiburg; Department of Knee, Hip and Shoulder Surgery, Schoen Clinic Munich Harlaching (H.O.M., S.B.), Munich; and Department of Orthopedic Surgery, OCM-Clinic (R.H., A.S.), Munich, Germany.

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Address correspondence to Hermann O. Mayr, M.D., Ph.D., Department of Orthopedic and Trauma Surgery, Albert Ludwig University of Freiburg, Hugstetter Str. 55, 79106 Freiburg, Germany. E-mail: hermann.mayr@uniklinik-freiburg.de

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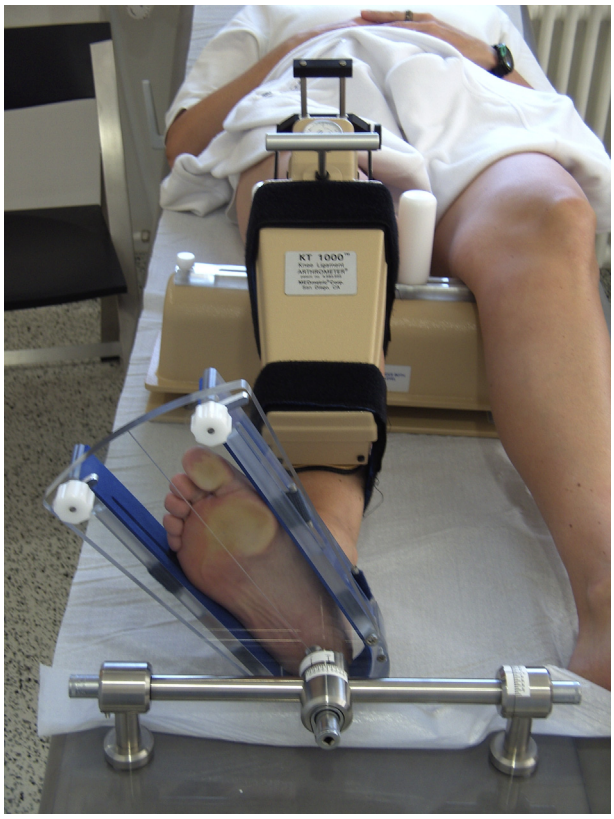

Fig 1. Laxitester test setup with the patient lying in a supine position; the right knee is flexed at 30° and the right lower leg externally rotated with a torque of 2 N m.

To evaluate short-term results, the work group has already assessed 2-year data of the same study population.[15]

The purpose of the study was to compare anatomic SB with DB ACL-R and to evaluate the respective clinical outcome results. The work group hypothesized that anatomic DB ACL-R would be superior to the anatomic SB surgical technique in regard to patient-related outcome. In contrast to other studies, validated instrumented rotational laxity measurement is performed with the Laxitester.

Methods

All consecutive patients presenting to the outpatient department with an ACL rupture were recruited for the planned prospective randomized study according to inclusion and exclusion criteria. Institutional review board approval was granted by local university authorities. Included were patients with a unilateral ligamentous injury isolated to the ACL, 20-55 years of age, American Society of Anesthesiologists (ASA) classification I or II, and a body mass index of 18-30. Exclusion criteria were collateral ligament instabilities > I° (2-5 mm), posterior instabilities, previous knee surgery of any kind, meniscal sutures at the time of surgery (due to a different rehabilitation program), cartilage damage International Cartilage Repair Society grade >2, axis deviation (varus or valgus) of more than 5°, and knee osteoarthritis grade 2 or higher according to the Kellgren and Lawrence classification.[16]

The preoperative clinical examination was performed by 2 independent orthopaedic surgeons and took place no more than 24 hours before surgery.

Preoperatively, patients were randomly distributed into different groups: either anatomic SB (30) or DB (34) ACL-R with autologous hamstring tendon graft (semitendinosus and gracilis). Based on the ethics committee's guidelines for statistical calculation, it is just allowed to include the minimum number of patients that will create reliable data. Central computer randomization (Randomizer Version 2.0.1-pl1, Institute for Medical Informatics, Statistics and Documentation, Medical University of Graz/Austria) was executed and afterward the respective group allocation was transmitted to the surgical team. Surgery of all included patients took place between April 2009 and August 2010 and was performed by a single surgeon with long-time experience in ACL surgery. Anatomic SB and DB ACL-R with hamstring tendons in the anteromedial portal technique as well as a standardized rehabilitation management was carried out.[14]

A total of 64 consecutive patients (34 male, 30 female, mean age 38.5 ± 9.8 years at the time of index surgery) were included in the study. The time interval between ACL injury and ACL-R was similar in both groups with a median of 3.1 months. The 5-year FU examinations were again conducted by 2 independent orthopaedic surgeons from November 2014 until May 2015.

Clinical outcome data were assessed by International Knee Documentation Committee (IKDC) 2000 objective and subjective forms.[17] Conventional radiographs in 2 planes in the standing position and a tangential view of the patella in 45° knee flexion before surgery and at the 5-year follow-up were made. Because of the Ethics Committee requirements, long leg standing radiographs were not allowed at any time point of the study. Therefore, the leg axis was measured clinically. Two independent examiners according to the Kellgren and Lawrence classification and position of the drill holes and tunnel widening carried out evaluation of degenerative changes.[16] Tunnel widening was assessed in a.p. and lateral radiographs. The mean value of both was taken to calculate the tunnel diameter. In cases of superimposition, the width was simply determined in 1 plane.

Knee laxity was measured with the Laxitester (Fig 1). Internal and external rotation angles of the lower leg were determined with a torque of 2 N m. The accuracy of the device has been described to be 5°.[14] In addition, a.p. translation was measured using the KT-1000 Arthrometer in the neutral position of the lower leg,