

U-Dos Double-Bundle and Single-Bundle Allograft Anterior Cruciate Ligament Reconstruction: A Comparative Study

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abstract

Anterior cruciate ligament (ACL) injuries are very common among athletes. If these injuries are not repaired, meniscus and cartilage damage will arise, with serious consequences in the joint. Different options for ACL reconstruction have been described, aiming for anteroposterior, lateral, and rotational stability. Using single- or double-bundle grafts has been one of the most discussed topics, aiming for better rotational stability. We performed a prospective randomized study to evaluate the outcomes of ACL reconstruction using double- or single-bundle grafts for 72 patients with acute ACL injuries. Patients were blindly randomized into 2 groups of 36 knees before surgery using a blind envelope that contained the technique to be used: double-bundle U-Dos technique (DB group) or single-bundle technique (SB group). All patients had a preoperative and postoperative evaluation and were followed with the same parameters at 2, 4, 6, 12, and 24 months. Both anteroposterior and rotational stability were evaluated using a KT-1000 arthrometer (MEDmetric) and an experimental Pivot-Shift Meter (ORMEDS) device. Functional outcomes were measured using the Tegner-Lysholm scale. The DB group had fewer ACL re-tears, fewer meniscal injuries, and better Tegner-Lysholm and International Knee Documentation Committee scores. This group also had better KT-1000 and Pivot-Shift Meter values. After 2-year follow-up, the DB group had significantly better results than the SB group. [*Orthopedics*. 2023;46(1):13-18.]

thrititis.^{1,2} Arthroscopic reconstruction of the ACL is a standard procedure in knee and sports medicine clinics, but there are still questions regarding the best options for fixation and grafting.³⁻⁶ There are many techniques, systems, and protocols that have been described and may be used, offering advantages in the final outcomes.⁷⁻¹¹ The choice of an adequate graft has the option of autologous or allogenic inserts, used in single or double bundles, with or without bony tissue on the ends. There is not a real gold standard, and both techniques of bone-patellar tendon-bone and hamstring grafts are the most used in the world. Other autologous grafts, such as the quadriceps tendon, are also becoming

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Knee joints are subjected to loads and forces in all directions and angles during regular gait and sports. The anterior cruciate ligament (ACL) is biomechanically responsible for anteroposterior (AP), mediolateral, angular, and rotational stability, and injuries to this ligament are common in contact sports. An unstable knee without a competent ACL has a higher risk of osteoar-

popular, with potential advantages over the classic techniques. The use of allografts is also common, with the advantages of avoiding donor site complications, reducing surgical time, and offering size choices. This study focused on the clinical outcomes, arthrometer results, and further injuries at follow-up of the 2 techniques using a tibialis tendon allograft.

Using a single-bundle reconstruction technique has shown a higher rate of post-operative rotational instability.^{3,4,12-17} Many authors have described techniques of double-bundle reconstruction, trying to restore the original anatomic configuration of the ACL with an anteromedial and posterolateral bundle.^{3,4,7-9,13,17-19} An adequate single-bundle and single-tunnel technique may provide adequate AP and rotational stability, but patients with associated ligament or capsular injuries may require an additional approach to achieve the goal of a stable knee. Sports injuries usually damage more than 1 anatomic structure. The traditional single-bundle reconstruction with remaining rotational instability has been described as one of the most important factors seen in failures and revisions.⁷⁻¹⁹ In many ways, there is a tendency to perform surgical procedures to add rotational stability, either by extra-articular augmentation or double-bundle grafting.

We have designed a double-bundle technique with a loop in a double tibial tunnel, described as the U-Dos ACL reconstruction.^{3,4} We have seen excellent results in terms of rotational stability and return to sports.

Different maneuvers, scales, and evaluation instruments are used today by orthopedic surgeons for the evaluation of joints, especially the knee. Different complementary diagnostic methods are used, with the use of some in decline, perhaps because they have not been updated, and the use of others enduring and making great contributions to both diagnostic and therapeutic decisions, as is the case with the KT-1000 arthrometer (MEDmetric), a device used for the quantitative evaluation of sagittal

plane laxity of the knee, based mainly on comparison of the values of the injured knee with the contralateral knee, which is normal for each patient. Introduction of the KT-1000 arthrometer has been a very important milestone in this work, providing the basis for new discoveries and the development of new diagnostic technologies that will support current and future orthopedists in the diagnosis and treatment of ACL injuries.^{3,4,15,18-22} The Pivot-Shift Meter (PSM; ORMEDS), a device that measures the rotational stability of the knee with accelerometers, provides a result by measuring the injury as a Del Parque classification,²³ ranging from 0, meaning no injury, to 3, meaning severe trauma.^{5,6} The International Knee Documentation Committee (IKDC) clinical scale, together with the Tegner-Lysholm scale, assesses the functional level of the knee based on different measures that focus on the presence of a limp, the use of walking support, instability, pain, blockage, inflammation, ability to climb stairs, and ability to bend.¹³⁻²²

The current study compares the outcomes of a single-bundle technique and the U-Dos double-bundle technique, looking at rotational instability, revision rates, and articular complications.

MATERIALS AND METHODS

A prospective randomized study was carried out at the Christus Muguerza del Parque Hospital in Chihuahua, Mexico. The study was approved by the hospital ethics committee and followed 72 patients who were 14 to 60 years old and had a clinical and magnetic resonance imaging diagnosis of acute ACL. Participants were randomly divided into 2 groups of 36 knees.

The study group (DB) was treated with the U-Dos ACL double-bundle reconstruction technique, and the control group (SB) was treated with a single-bundle ACL reconstruction technique. The average age was 38.8 years in the DB group and 37.8 in the SB group. There were 20 male and 16 female patients in the DB group and

19 male and 17 female patients in the SB group. In the DB group, 30 patients had sports-related injuries and 6 had other types of trauma, and in the SB group, 28 patients had sports-related injuries and 8 had other types of trauma. Associated injuries diagnosed before surgery included 9 cartilage and 12 meniscal in the DB group and 7 cartilage and 14 meniscal in the SB group. Regarding the mechanism of injury, no significant differences were found by group, as described in **Table 1**. The patients were informed of the study in the consultation and gave their consent by signing an informed consent document. Subsequently, the surgical technique was chosen randomly before surgery.

All patients had an anterior tibial tendon allograft as a graft for ACL reconstruction. The allografts came from a tissue bank in Guadalajara, Mexico. For patients with the single-bundle technique, the graft was doubled, and with the double-bundle technique, each bundle had a single tibial tendon graft. The average tibial tendon graft diameter was 7 mm. The surgical technique was performed by arthroscopy, and the graft was fixed in the tibia and femur with a biodegradable screw.

The U-Dos double-bundle technique, originally described by Morales-Trevizo et al³ and Berumen-Nafarrate and Leal-Contreras,⁴ uses a single long tibialis tendon allograft that is passed through the tibia across 2 separate tunnels as a loop that requires no implant fixation. It is secured in the femur using 2 separate tunnels and an interference screw for each bundle.

Patients had follow-up at 2, 4, 6, 12, and 24 months by an independent reviewer. Clinical outcomes, adverse effects, complications, and additional surgical procedures were recorded. The functional scores were measured using the Tegner-Lysholm and IKDC scales. The AP stability was evaluated using a KT-1000 arthrometer, and rotational stability was estimated using PSM, an experimental arthrometer that determines the degree of injury through positional accelerometers that transmit ro-

tational movement to a measurable signal visible on a computer device.

The *t* test for comparison of 2 means was used to compare the scores of the clinical tests (IKDC and Tegner-Lysholm) as well as the maximum AP displacement in millimeters measured with the KT-1000 arthrometer (quantitative variables). The chi-square test was used to compare the objective IKDC test results and the degree of injury on a scale of 0 to 3, according to the PSM, after 2, 4, 6, 12, and 24 months of follow-up (qualitative variables). Differences with *P*<.05 were regarded as statistically significant.

RESULTS

Patients were called in for clinical analysis 2, 4, 6, 12, and 24 months after surgery. No major complications or adverse effects were recorded. Surgery failure measured as ACL reintervention occurred for 4 patients in the SB group (11%) and no patients in the DB group. In addition, 5 patients (14%) from the SB group and 1 patient (3%) from the DB group required arthroscopic intervention for meniscal lesions.

A year after the surgery, the results of the IKDC category ranges started to show a significant difference between groups. Patients who were severely symptomatic before surgery, with IKDC scores of less than 60 points, showed improvement from 34 to 6 in the SB group, and scores dropped from 30 to 0 in the DB group. Moderately symptomatic patients with IKDC scores in the range of 60 to 80 points increased from 4 to 20 in the SB group and from 6 to 18 in the DB group. Mildly symptomatic patients with scores in the range of 81 to 90 points improved from 0 in both groups to 10 in the SB group and 8 in the DB group. Patients with minimal or no symptoms had IKDC scores of up to 90 points, and only the DB group had an improvement of almost 30% after 12 months of follow-up (Table 2).

At 2 years of follow-up, the level of significance was noticeable. In both groups, 0 patients were severely symp-

Table 1

Demographic Data			
Characteristic	Single bundle	Double bundle	<i>P</i> ^a
Knees, No.	36	36	Not significant
Age, average (range), y	37.8 (14-59)	38.6 (16-60)	Not significant
Male/female, No.	19/17	20/16	.987
Concomitant injury, chondral/meniscal, No.	7/14	9/12	.525
Mechanism of injury, sports/trauma, No.	28/8	30/6	.551

^aChi-square.

tomatic; the number of moderately symptomatic patients increased to 8 patients (22% of 36 patients) in the SB group and decreased to 0 in the DB group; mildly symptomatic patients improved to 18 (50%) and 10 (28%) in the SB and DB groups, respectively; and finally, none of the patients in the SB group reached an IKDC level greater than or equal to 90 (minimal or without symptoms) at 24 months, however, 26 patients (72% of 36 patients) in the DB group reached this level (Table 2).

The average IKDC functional score showed an improvement from 44 to 80 points in the SB group as well as an improvement from 47±13 to 94±3 points in the DB group. The SB group showed an increase of 36 points, and the DB group showed an increase of 47 points. The Tegner-Lysholm functional scores increased from 52 to 84 points in the SB group and improved from 55 to 97 points in the DB group. The SB group showed an increase of 32 points, and the DB group showed an increase of 42 points (Table 3).

The analysis of the average KT-1000 maximum millimeters of displacement started to show a significant improvement 12 months after surgery, and after 24 months, the results showed an even greater improvement, from 8 to 4.3 mm in the SB group, and a progression from 7.7 to 3 mm in the DB group. The improvement from preoperatively to 24 months postoperative-

ly was 3.7 mm in the SB group and 4.7 mm in the DB group (Table 4).

The experimental PSM arthrometer showed improvement in the first 2 months after surgery in the DB group compared with the SB group; however, the significance of the difference between groups started to decay until 6 months, when the difference showed no significance. Regardless, the difference between groups started to be noticeable again a year after surgery and remained until the last evaluation (Table 5).

DISCUSSION

The current study analyzed the long-term outcomes of 2 different techniques for ACL reconstruction. There has been a scientific debate in the past decade regarding the benefits of using a single- or double-bundle ACL reconstruction procedure, mainly in terms of residual rotational instability that may result in failure or revision.^{19-22,24} Our results show the differences in clinical outcomes of a double-bundle tibial looped ACL reconstruction technique compared with the standard single-bundle and single-tunnel procedure.

Both study groups showed good results after 2 years in terms of return to activities and sports, with low complication and reintervention rates. However, the SB group had an ACL graft failure rate of 11%, whereas no patients in the DB group required reoperation. Associated meniscal

Table 2

Number of Patients With Each IKDC Symptom Evaluation Score

Evaluation score	Preoperative		2-mo follow-up		4-mo follow-up		6-mo follow-up		12-mo follow-up		24-mo follow-up	
	SB	DB	SB	DB	SB	DB	SB	DB	SB	DB	SB	DB
IKDC≥90	0	0	0	0	0	0	0	6	0	10	0	26
80≤IKDC<90	0	0	6	2	6	6	8	6	10	8	18	10
60≤IKDC<80	4	6	2	2	20	22	20	20	20	18	18	0
IKDC≤60	34	30	28	32	10	8	8	4	6	0	0	0
<i>P</i> (chi-square)	NS		NS		NS		NS		<.001		<.0001	

Abbreviations: DB, double bundle; IKDC, International Knee Documentation Committee; NS, not significant; SB, single bundle.

Table 3

Significance Level of Average Score in Clinical Scale Scores

Clinical scale	Technique	Pre-operative	2-mo follow-up	4-mo follow-up	6-mo follow-up	12-mo follow-up	24-mo follow-up
IKDC	SB	44±12	57±13	66±13	69±14	72±12	80±5
IKDC	DB	47±13	54±11	66±12	75±11	81±10	94±3
IKDC	<i>P</i> (t test)	NS	NS	NS	.059 ^a	.023	<.01
Tegner-Lysholm	SB	52±11	69±17	73±15	78±15	80±11	85±6
Tegner-Lysholm	DB	55±11	65±17	79±12	85±9	93±5	97±3
Tegner-Lysholm	<i>P</i> (t test)	NS	NS	.115 ^a	.0346	.001	<.001

Abbreviations: DB, double bundle; IKDC, International Knee Documentation Committee; NS, not significant; SB, single bundle.

^aNot significant.

lesions were also different in both groups, with only 3% that required arthroscopy in the DB group compared with 14% in the SB group. Our results show better long-term results using the double-bundle technique, with fewer failures and reintervention rates.

Functional scores started to show better results for patients treated with the double-bundle technique after 12 months. Even though all study patients showed significant improvement in function after 24 months, we found that the IKDC scores were 14 points better in the DB group compared with the SB group. The Tegner-Lysholm scores had a similar tendency, showing 13 points of improvement in the DB group. We found a high number of symptomatic patients in the preoperative evaluation, an

expected finding because most of the ACL injuries are highly symptomatic. Both study groups showed significant improvement after 2 years. However, all patients in the DB group had IKDC scores indicating mild or no symptoms, whereas half of the patients in the SB group had moderate symptoms. This result clearly favors the DB group, doubling the good and excellent results compared with the SB group.

Anterior stability measured with the KT-1000 device showed improvement in both groups, with a relatively small difference of 1.3 mm or less residual displacement in the DB group. The rotational stability assessment given by the experimental arthrometer PSM suggests faster improvement in the DB group in contrast to the SB group; notwithstanding, more

studies are required to prove the sensitivity and specificity of this technology. However, several reports in the literature have shown that the reconstruction of both ACL bundles provides better restoration of knee kinematics, particularly external and internal rotation of the tibia.^{3,4,16-21} Similarly, a meta-analysis of 4 randomized clinical trials by Meredith et al⁸ showed that 2-bundle reconstruction of the ACL results in a significant decrease in the injured knee with the healthy knee measured with the KT-1000, with no differences in pivot shift tests. This meta-analysis showed that 88% of patients treated with the double-bundle technique had a normal pivot shift after surgery, compared with 62% of those who were treated with the single-bundle technique. For many years, orthopedic

Table 4

Significance Level of Maximum Anteroposterior Displacement

Arthrometer ^a	Technique	Preoperative	2-mo follow-up	4-mo follow-up	6-mo follow-up	12-mo follow-up	24-mo follow-up
KT-1000	Single bundle	8±2.4 mm	4.6±1.7 mm	4.4±1.4 mm	4.1±1 mm	4.2±1.1 mm	4.3±0.8 mm
KT-1000	Double bundle	7.7±2 mm	3.3±1.3 mm	3.7±0.9 mm	3.4±0.9 mm	3.5±0.6 mm	3±0.7 mm
KT-1000	<i>P</i> (t test)	NS	NS	NS	.059 ^b	.023	<.01

Abbreviation: NS, not significant.

^aMEDmetric Corp.

^bNot significant.

Table 5

Del Parque Injury Classification With Pivot-Shift Meter Device

Pivot-Shift Meter device ^a	Preoperative		2-mo follow-up		4-mo follow-up		6-mo follow-up		12-mo follow-up		24-mo follow-up	
	SB	DB	SB	DB	SB	DB	SB	DB	SB	DB	SB	DB
Degree 0	2	6	12	25	16	28	28	20	22	30	24	32
Degree 1	18	14	20	8	16	6	6	15	14	6	12	4
Degree 2	14	14	4	3	4	2	2	1	0	0	0	0
Degree 3	2	2	0	0	0	0	0	0	0	0	0	0
<i>P</i> (chi-square)	NS		.007		.014		.18 ^b		.035		.023	

Abbreviations: DB, double bundle; NS, not significant; SB, single bundle.

^aORMEDS.

^bNot significant.

surgeons have focused mainly on the anteromedial bundle.^{9,10} This approach has worked well in terms of avoiding anterior translation of the tibia, but has had very little effect on the rotational stability of the knee. Horizontalizing the femoral tunnel has improved rotational stability, reducing anterior knee translation.^{13,15} The double-bundle technique has proved to offer better anterior and rotational stability. The U-Dos technique described by the authors offers the advantages of double-bundle stabilization, avoiding the potential complications of the tibial tunnels being too close and reducing surgical time and implant costs. All patients in our study had an anterior tibialis allograft. Even though there is opposition to using allografts for ACL reconstruction, our study showed good results with allogeneic implants. Allografts offer less surgical

time and less morbidity by avoiding harvesting an autologous tendon.^{18,20}

Xu et al¹⁶ reported a systematic review that included 13 prospective studies. They concluded that double-bundle procedures were better in terms of rotational stability, but they were not better on clinical assessment of anterior translation and complications. Anandan et al²¹ have shown that at follow-up of 10 years patients who had the double-bundle technique achieved better rotational stability and returned to their preinjury level of activity faster than single-bundle groups. These findings reinforced our findings on clinical and rotational outcomes, even though our studies included 2 years of follow-up.^{18,19}

A meta-analysis that included more than 1600 patients carried out by Li et al²⁴ in 2014 showed that the double-bundle

technique showed better rotational stability using the KT-1000. Our study showed not only better results using the KT-1000 but also better results using the PSM in terms of addressing anterior translation and rotational stability.²⁰⁻²⁷

One of the factors that could improve the current study is the number of patients. A larger number of cases could give us stronger results in favor of the double-bundle technique. Also, we have noticed that all re-tears occurred among athletes who returned to training; a study focused on measuring the failure rate of the U-Dos technique among athletes is also considered for the future.

CONCLUSION

In the current study, the double-bundle technique provided better results than the

single-bundle technique for ACL reconstruction at 24-month follow-up, with better IKDC and Tegner-Lysholm functional scores, a lower number of failures and reinterventions, and better AP and rotational stability. The use of the PSM as a novel device that measures rotational stability with gyroscopes and accelerometers proved to have an important correlation with the final outcomes for our patients. More studies and larger numbers of patients are required to reach a final recommendation, but our results are encouraging and provide solid reasoning to recommend the use of the U-Dos double-bundle technique as a primary procedure for patients with ACL lesions.

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