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Short Communication

Anterior Cruciate Ligament Reconstruction Comparison between Single Bundle and Double Bundle-Double Tunnel Techniques: Pilot Study

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Abstract

This study aim was to compare results of single bundle and double bundle double tunnel surgical procedures for anterior cruciate ligament reconstruction. All anterior cruciate ligament reconstruction procedures used an allograft and were performed by the same surgeon. Patients were enrolled from April to November 2016 and two postoperative short term follow-up visits (one and 3 months) where completed. Patient´s clinical examination included Pivot Shift, KT1000, Tegner-Lysholm and International Knee Documentation Committee (IKDC) questionnaires before surgery, after surgery (except questionnaires) and at each visit. Comparison between preoperative results and three months clinical follow-up showed statistical differences in KT1000 values and side to side KT1000 difference, despite the type of surgery. The effect of type of surgery within time was significantly different between single bundle and double bundle double tunnel for side to side KT1000 difference. Analysis for Tegner-Lysholm and IKDC score improvement showed statistical difference in double bundle double tunnel group, as early as three months. Patients recovered despite the type of anterior cruciate ligament reconstruction technique used; however, a tendency towards better results with double bundle double tunnel procedure is clear; this has to be further confirmed in a larger study with longer term evaluation.

Keywords: *Single Bundle; Double Bundle Double Tunnel; Anterior Cruciate Ligament; Allograft; Arthroscopy*

Abbreviations

SB: Single Bundle; DBDT: Double Bundle Double Tunnel; ACL: Anterior Cruciate Ligament; AM: Anteromedial; PL: Posterolateral; IKDC: International Knee Documentation Committee

Introduction

The knee joint strong ligamentous structure includes external and internal collateral ligaments, lateral and medial meniscus, as well as the anterior and posterior cruciate ligaments, all involved in the position, direction, and kinetics of the knee. The anterior cruciate ligament (ACL) two bundles: anteromedial (AM) and posterolateral (PL) are tight in flexion and extension respectively and work together to control and limit the knee axial rotation and translation. ACL tear represent in the Unites States (US) 40% of total ligament injuries, most frequent in athletes. The injury mechanism involves deceleration, hyperextension and rotation of the knee, inducing instability that interferes on patient's daily activities. Approximately 65% of patients with ACL rupture go under surgical reconstruction, representing one of the most frequently orthopedic procedures in the US, with approximately 250,000 reconstructions per year [1,2].

A good clinical history and a systematic physical examination are crucial to establish an ACL injury diagnosis. Multiple maneuvers and scores have been recommended to diagnose ACL rupture, including Lachman test, pivot shift test, and anterior drawer test, as well as an objective KT1000 arthrometer test. Tegner-Lysholm, IKDC among other scores has been established to grade functional disability secondary to knee injury [3,4].

The two main procedures to repair ACL are single bundle (SB) and double bundle (DB) reconstruction; however, the most frequently performed is a SB. According to Tashman., *et al*. SB has been proven to successfully reestablish the anterior-posterior movement of the knee, but failed to restore rotational stability [5]. DB repair shows better rotational stability of the knee, due to a closer anatomical reconstruction of AM and PL bundles [6,7]. However, it is more expensive, complex and implies a longer recovery time. Recently, a variation of DB technique has been described by Berumen., *et al*. and Morales-Trevizo., et al. named double bundle and double tunnel technique (DBDT), using an allograft fixed by two screws on the femur as the graft is connected on the tibia by a "U" configuration [8,9].

Many studies compare SB and DB techniques; however, the aim of this study is to compare ACL reconstruction stability between SB and new DBDT procedure.

Materials and Methods

A prospective randomized pilot study to compare clinical outcome of knee stability after ACL reconstruction using an allograft, between two different techniques: SB and DBDT. The study was conducted in Chihuahua, México, The protocol was approved by Christus Muguerza Hospital Ethics Committee in accordance to Helsinki Declaration and its later amendments. Inclusion criteria: patients within 12 to 60 years old with ACL rupture symptoms that agreed to participate after reading and signing an informed consent. Subjects were screened for eligibility, with maneuvers including pivot shift and KT1000 (Knee Ligament ARTHROMETER, Medmetric Corp. San Diego CA) and an MRI to verify the diagnosis. Patients with degenerative knee disease or knee prosthesis or with previous ACL reconstruction were excluded. 16 subjects screened for eligibility, 2 were excluded for presenting a re-rupture of the ACL. Only 14 subjects underwent randomization. Seven subjects were randomly assigned to undergo SB ACL reconstruction, and 7 to DBDT procedure. Same clinician performed Pivot Shift and KT1000 evaluation to allow consistency. Tegner-Lysholm and IKDC tests were applied to the patients before surgery and at programed visits. Tegner-Lysholm scores were classified as poor < 65; fair > 65 - 83; good 84 - 90 and excellent > 90. Once the patient was under spinal anesthesia, anteroposterior stability of the ACL was measured before and after surgical procedure in both knees using KT1000 arthrometer and in reconstructed knee at each visit. KT1000 measurement was taken for maximum displacement at 30° flexion and 30 lbs. pull out. Side to side KT1000 difference was obtained by subtracting intervened knee maximum displacement minus normal knee maximum displacement.

Allografts were immersed in 80 mg of gentamicin and braided with a bio absorbable suture Vicryl® #2. After spinal anesthesia patients were on supine position and a tourniquet was applied at the thigh. ACL tear was confirmed during arthroscopic examination. In SB group one anatomic femur tunnel through the medial portal and one tibial tunnel were done between the AM footprints. In DBDT group two anatomic tunnels on femur and one tunnel on tibia were done using AM and PL footprints, fixed with bio absorbable interference screws.

Statistical analysis

Two-Sample T-Test was used to compare general characteristics among patients within the two study groups. Independent variables: type of reconstruction and time, whereas dependent variables included KT1000 values at different time evaluation, KT1000 side to side difference, Tegner-Lysholm and IKDC improvement scores. Statistical assessment for KT1000 included variance analysis using the General Linear Model and means comparison between types of surgery groups, time and their interaction using Bonferroni's method. Paired T-Test was used to compare scores between pre surgical results and three months follow. Significance was considered when $p \leq 0.05$. Power and sample size analysis with two sample t Test. MINITAB v16.0 software was used for statistical analysis.

Results

SB group included 57% females and 71% left knee ACL injuries, whereas, DBDT group 71% males and 71% right knee ACL injuries. No significant differences within general characteristics from SB and DBDT patients (Table 1). However, BMI average showed a pre-obese state in both groups, according to the International Classification by WHO [10]. There were different causes for ACL tear: 50% of the cases by sport injury, 35.71% after a fall and 14.29% by occupational injury.

Characteristic	Mean ± SD	SB	DBDT	p value
Gender (M/F)	8/6	3/4	5/2	
Age (years)	30.93 ± 12.03	33.29 ± 14.87	28.57± 8.92	0.486
Height (m)	1.65 ± 0.09	1.61 ± 0.081	1.69 ± 0.10	0.089
Weight (Kg)	77.5 ± 17.21	70 ± 19.98	85 ± 10.86	0.106
BMI (Kg/m^2)	28.3 ± 6.05	26.61 ± 5.81	29.94 ± 6.56	0.335
ACL rupture (Right/Left)	7/7	2/5	5/2	
Two-Sample T-Test p ≤ 0.05				

Table 1: *General Characteristics of Patients in Each Group.*

According to variance analysis, interaction between type of surgery and time did not show statistical difference for KT1000 values, p = 0.765 and side to side KT1000 difference, p = 0.86. However, response through time was significant for KT1000, p = 0.001 and side to side KT1000 difference, p=0.001, despite the type of ACL repair technique used (Figure 1).

Bonferroni pairwise comparisons test between preoperative results vs three month follow up showed a statistical difference in KT1000 values in both groups, for SB p = 0.0005 and for DBDT p = 0.0025, and side to side KT1000 difference p = 0.008 for both types of surgery (Figure 1).

Three months follow up showed no statistical differences between type of surgery for KT1000 (mean ± SE): 3.86 ± 0.53 (3 - 4) mm in SB group and 4.2 ± 0.62 (3 - 6) mm in DBDT group, p = 0.809; however statistical difference was observed in side to side KT1000 difference between SB and DBDT procedures (-0.143 ± 0.645 for SB and -0.86 ± 0.645 for DBDT, p = 0.019) (Figure 1). Pivot shift test was negative in all cases, no extension or flexion loss was observed, as any other complication, in patients from either group in last visit.

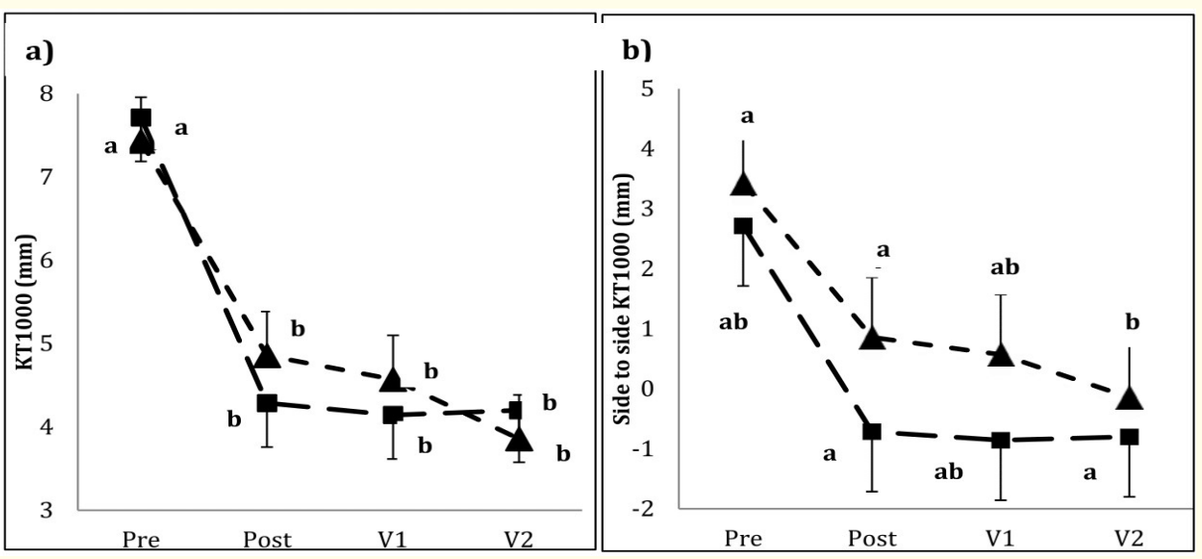

Figure 1: *a) Effect of type of surgery and clinical evolution time on KT1000 response b) Effect of type of surgery and clinical evolution time on side to side KT1000 difference (Bonferroni test p < 0.05).*

▲= SB, ■ = DBDT. Pre (before surgery), Post (after surgery), V1 (Visit after one month), V2 (Visit after three months), a, b different letters inside the graph show statistical difference p ≤ 0.05.

Paired T-Test analysis for Tegner-Lysholm score improvement was not statistically significant after three months, for SB, (from 52.3 to 65.9, p= 0.140), neither for IKDC (41.7 to 62.9, p = 0.073). However, a statistically difference was observed in DBDT group, for Lysholm score improving from 58.6 to 79.4 (p = 0.001), as well as for IKDC score values from 50.3 to 71.7 (p = 0.003) (Figure 2).

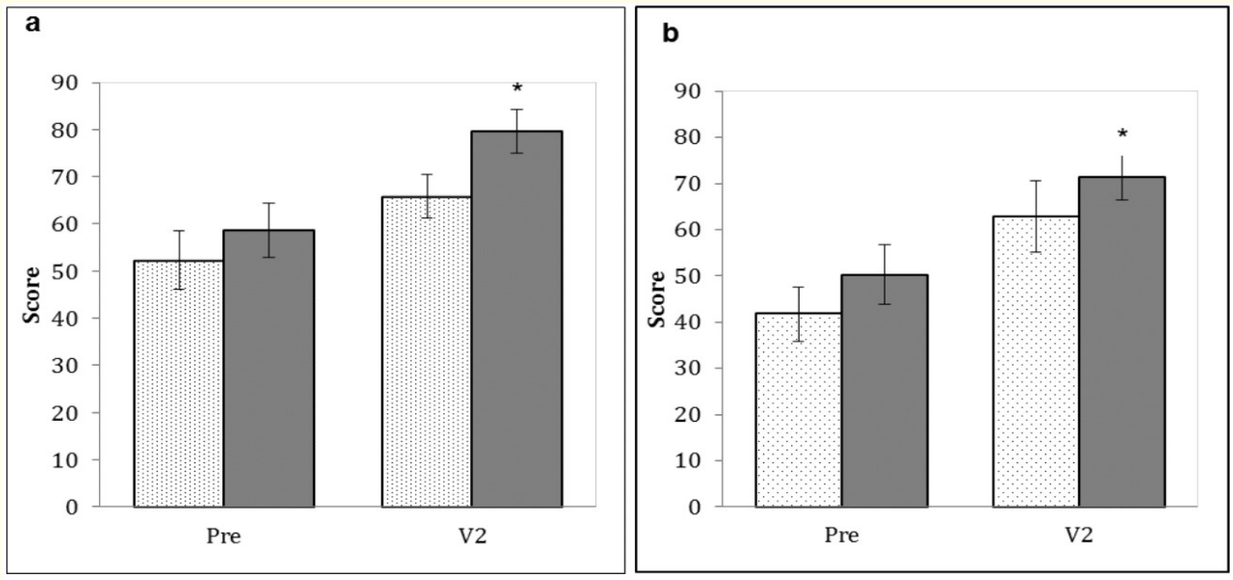

Figure 2: *a) Tegner-Lysholm score before surgery and after three month visit (V2) b) IKDC score before surgery and after three month visit (V2) (Paired T-Test p < 0.05)* = *SB* = *DBDT*

Since this is the first study that compares SB with DBDT procedure, we considered important to estimate the sample size that is needed for each study group. We used the average difference, regarding side to side KT1000 results from last visit within SB and DBDT procedures (0.714), with an alpha = 0.05, a pooled SD=1.61 and with a target power of 0.8, giving a sample size of 81 for each group.

Discussion

Jeong-Ku Ha., *et al.* compared ACL repaired between SB and DB groups, after 2 year follow, reporting no statistical differences between groups for KT2000 side to side difference (SB 1.93 vs. DB 1.87 p = 0.844). In our study, after three months, a statistically difference in average side to side KT1000 differences between SB and DBDT procedures was observed [11]. It is important to consider ACL graft re-modeling process; as described by Scheffler., *et al.* proliferation phase occurs between 4th and 12th postoperative weeks, inducing an in situ tension, which is required for later ligamentization phase that begins between 3 to 6 months after ACL procedure, including intense revascularization and restoration of collagen orientation [12]. Our side to side KT1000 differences negative values can be explained by the allograft stiffness due to initial remodeling phase, a lax allograft is expected after six months.

Jeong-Ku Ha., *et al*. also reported significant improvement for Lysholm score from 66.3 to 92.9 after 2 years in SB and 63.2 to 90.6 in DB (p = 0.000), as well as for IKDC score showing values from 59.8 and improving to 88.7 in SB and from 58.6 to 87.0 in DB (p = 0.000) [11]. Our results for DBDT procedure, even at short term follow up, showed statistical improvement for Lysholm and IKDC scores values, but not for SB.

Torkaman., *et al*. reported improvement in Lysholm score, showing good to excellent results in 64.3% of patients with SB repair and 80% of patients within DB group. Our three months results for same score ranged from fair to excellent in 86% of patients from DBDT group, whereas for from SB group only 43% [13].

Mundi and Bhandari, described a meta-analysis including randomized and quasi-randomized trials with a large number of patients (n = 1433), and observed no differences between SB and DB ACL repair techniques for functional outcomes at long term follow up (5 years)

or for total adverse events. However, DB technique showed better knee stability as well as less time to return to pre-injury level activities, and with lower association rate of new meniscal tears and repeated ACL injuries [14]. A longer follow up in our patients is necessary to see how the DBDT procedure behaves in comparison to SB and DB actual techniques. It is worth to mention that DBDT new technique combines the cost benefits of SB and DB procedures used to repair ACL. This preliminary study shows good results with DBDT group as soon as three months, however it has to be followed for a longer period of time and inclusion, of at least 81 patients per type of surgery, is needed to increase the study power.

Conclusion

Patients recovered despite the type of ACL reconstruction technique used; however, the effect of type of surgery within time was significantly different between SB and DBDT for side to side KT1000 difference. Tegner-Lysholm and IKDC clinical scores improvement showed statistical difference in DBDT group, as early as three months. These early results encourage the use of DBDT procedure. The study is still going on, giving a longer follow up to the 14 patients included and increasing the study sample. Other tools such as pivotshift meter are under analysis to further support results.

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Conflict of Interest

Authors: Rubio-López E, Berumen-Nafarrate E, Aguirre Madrid A, Carmona-Maynez O, Moreno-Brito V, Licón-Trillo A and Leal-Berumen I, declare that they have any financial interest or any conflict of interest exists.

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