



Internal Brace Ligament Augmentation versus Anatomical Repair with Hamstrings of the ACL – A Clinical Data Comparison Study

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Abstract

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AIM: Investigation into the clinical results of internal brace ligament augmentation technique compared to the simple anatomical repair of the anterior cruciate ligament (ACL).

METHODS: From May 2016 to November 2019, 128 patients underwent an operation using the internal brace technique. During the same time, 104 patients were operated on using the simple anatomical ACL repair. The mean age was 22.5-year-old for the first group and 26.8-year-old for the second one. The minimum follow-up was 24 months. All the patients performed an X-ray and magnetic resonance imaging. Two hypotheses were raised to assess the superiority of the internal brace technique versus the anatomical one in the early post-operative phase and the rehabilitation one.

RESULTS: The mean operation time was 71 (65–75) min for the internal brace (IB) and 62 (55–65) for the anatomical. We had two post-operative infected knees in the first group (IB) and no infection in the second one. The clinical stability test results were much better in the IB group using the KT 1000. The rehabilitation phase showed a superior IB technique. The return to sport-time of the sportsmen was 6 months for the first group and 7–8 months for the anatomical. All the IB-operated patients found physiotherapy significantly easier than the anatomical ones.

CONCLUSIONS: IB-technique performs better clinical outcomes than the anatomical repair. The presence of a foreign body (Ultrabraid) inside the knee may be a risk factor contributing toward the elevated infection rate. The IB technique costs are significantly more expensive compared to the anatomical but the low physiotherapy costs compensate for the final result.

Introduction

The internal brace is a relatively new technique in anterior cruciate ligament (ACL) repair. As a complementary of the anatomical hamstrings standard technique, it invaded the minds of knee surgeons. The first ACL repair was performed in 1895 by Mayo-Robson of Leeds and was followed by Grekow and Hey Groves who initiated ACL reconstruction with autologous tissue between 1914 and 1920, almost as we know it today [1]. Following the history of ACL repair, a lot of techniques tried to give a final solution to the question: Do we have the maximum success rate? The Kenneth-Jones was substituted in the early 2000s with the fully artificial ACL (PET, PETF, PA, and PF) [2] which provided a more stable knee, and quick operation time, but worse results regarding early arthritic changes in the operated knee. The first generation of ligament prostheses appeared in the 1980s but unfortunately, it was a disaster that could have been avoided if knowledge of material chemistry and biological response to biomaterials had been taken into account [2]. Today, ligamentoplasty remains the gold standard solution and many improvements in surgical techniques have and go on yielding excellent

results [2]. Hence, the aim is: Back to the full biological solution with autolog or heterolog hamstrings, BTB or even quadriceps tendons. The transtibial technique in the 1990s showed up with still high numbers of osteoarthritis [3] and after that with better clinical results the anatomical repair in the 2000s [4], postulated that initial trauma (articular cartilage damage) and tunnel placement may contribute to the onset of osteoarthritis [5]. Since the single use of the anatomical repair with hamstrings reports a high rate of graft failure [6], [7] the necessity for higher clinical results brought into the scene the internal brace so the artificial reinforcement of the anatomical hamstring ACL repair.

Materials and Methods

We have been using the internal brace technique (IB) as a reinforcement of the anatomical ACL with hamstrings since 2016. We studied 128 patients operated on using IB from May 2016 to November 2019 and 104 patients underwent surgery at the same time using the standard anatomical repair with hamstrings.

Table 1: Clinical Data Comparison

Clinical Data	OP mean time	Post-operative pain, 1 st day	Post-operative pain, 2 nd day	Post-operative hematoma	Post-operative hematoma	deep infections
IB	71 min	2.3 mean value	2.0 mean value	14 patients	2 patients	2 patients
AR	62 min	2.3 mean value	1.3 mean value	one patient	one patient	0 patients

The minimum follow-up was 24 months. Patients not followed up for a continuous period of 24 months were not included in the study.

All patients were operated on by the same team and were treated by the same physiotherapy team

Under the anatomical ACL repair with hamstrings, we meant the harvest of both gracilis and semitendinosus, inserting them anatomically, and fixing them with endobutton and bioabsorbable screws [7], [8].

As IB, we use ultrabraid sutures fixing with footprint anchors in the tibia [9].

The mean age of the patients was 22.5y.o. (17–53 years old) for the IB (76 men and 52 women) and 26.8 years old (17–49 years old) for the anatomical (64 men and 50 women). All the patients had the same possibility to have one of the operations, so the study was randomized and the evaluation was double-blinded.

In the IB group, the percentage of active sport-players was not significantly higher (51.5–48.5% in the anatomical).

More than 85% of all the patients of both groups had ruptured their ACL more than 2 months prior and from them, 45% had done so more than 1 year prior. We had also patients with ruptures more than 5 years old in both groups with the same number.

All the patients were diagnosed by the senior surgeon with positive Lachmann Test[dA1], drawer test and pivot shift-test [10], [11]. All the patients performed a standard X-ray and magnetic resonance imaging.

Meniscus repair was performed according to the case and the type of tear [12].

The International Knee Documentation Committee subject score was 54.2 ± 4.0 .

We raised two hypotheses to evaluate our early post-operative results: Ho: There is no difference in the early post-operative clinical results of the two techniques and H1: There is a clinical superiority outcome of the IB technique in the early clinical results. The level of significance used was set to 0.05 (alpha value). Two populations μ -IB 128 and μ -AR 104 were raised. In our data, we studied the mean OP time, the frequency of post-operative complications (level of pain, post-operative hematoma, superficial infection rate, and deep infections within 30 post-operative days).

We raised the same hypotheses to evaluate the rehabilitation and late clinical result: Ho: There is no difference in the clinical results of the two techniques and H1: There is a clinical superiority outcome of IB

technique clinical results, using the same population and same level of significance, taking into consideration this time the knee-ROM gaining after 2-, 4-, 6-, 8-, and 12-week post-operative, quadriceps muscle gain after 3, 6, 12, and 24 weeks, necessity of using crutches and return to sport.

The data from the samples were grouped in Excel tables and graphics.

Using the t-test in Excel, we received our results of the p-value for both hypotheses in both circumstances (early post-operative and rehabilitation results).

Results

The operation time was almost the same: for the IB group 65–75 min and 55–65 min for the anatomical. The level of pain in the IB-operated patients was evaluated the same as in the other group (AR) on the 1st day with a mean value of 2.3 (on a scale from 1 to 5 where 1 is minimum). The next day after the drainage removal the level of pain augmented in the IB group (2.0–1.3) which could be attributed to the elevated number of post-op hematomas in this group (14 hematomas at the hamstring-harvested site in the IB group compared to only one in the AR group).

In the patients operated on with the IB technique, we noticed two superficial infections and two intrarticular infections within the 3rd week post-operative that required hospitalization, drainage, and a long period of antibiotherapy. None of the patients demonstrated the need to remove the new ACL or IB. We had one infected hematoma in the hamstring-harvested site in the anatomical repair group.

Elaborating the data in the t-test excel during the early post-operative phase, we received $p \geq 0.05$ so we could not reject the Ho hypothesis in the first round.

Getting more results from the patients in the rehabilitation phase such as muscle mass regaining, ROM, and RtS (return to sport) timelines, we received very interesting data as shown in Tables 2 and 3.

Table 2: Postop ROM Progression

ROM Comparison	Full ROM 2 weeks	Full ROM 4 weeks	Full ROM 6 weeks	Full ROM 8 weeks	Full ROM 12 weeks
IB	12 patients	98 patients	120 patients	127 patients	127 patients
AR	0 patients	15 patients	54 patients	100 patients	104 patients

The return to sport evaluations are often complex, nevertheless, we decided that a negative Lachmann Test using a KT 1000 (<3 mm), the

quadriceps mass evaluation and the stability-jump test were enough to return to sport.

Table 3: Quadriceps Mass Advance in Comparison

Quadriceps mass comparison	Quadriceps the same as other side after 3 weeks	Quadriceps the same as other side after 6 weeks	Quadriceps the same as other side after 12 weeks	Quadriceps the same as other side after 24 weeks
IB	No patient	two patients	33 patients	103 patients
AR	No patient	No patient	four patients	85 patients

In the early sport phase, we noticed that 18 patients from the AR group had a sudden (acute) or chronic instability due to ACL-plastic laxity. These cases were judged as failed.

During the same phase, we noticed that only one of the patients from the IB group had an acute (contact-trauma in professional-match) instability. This case was judged as failed.

Regarding the second round of hypothesis we received in the computing t-test elaboration that the p-value (0.001) was significantly lower than the alpha value (0.05).

Hence, we rejected the Ho hypothesis and admitted the fact that the internal brace technique provided far better results in rehabilitation and the possibility of returning to sport of the patients.

The anatomical repair performed the standard rehabilitation with 4 weeks of immobilized and 6 weeks of crutches [13], [14].

The internal brace group removed the crutches during the 2nd or 3rd post-operative week. No external brace was necessary from the 1st day.

Discussion and Conclusions

The clinical result of 128 patients with an ACL tear operated on using the internal brace technique was compared to a group of 104 patients operated on using the simple anatomical repair with the hamstring. All the patients were operated on by the same operation team and underwent the same post-operative treatment, following the same rehabilitation protocol (each group the same) from the same physiotherapy team. Only patients with a minimum of 24-month follow-up were included in the study. The study was randomized including the patients in the groups and double-blinded in estimations of the results. The study is limited only to one clinic and could not be more inclusive. The number of participants is relatively small because not all the patients could fulfill the minimum of 24 months in the follow-up.

With the anatomical repair technique, we evaluate a failure (knee instability) rate of 17% (18 patients at the end of the 2nd year).

With the internal brace technique, we evaluate a failure rate (Knee instability) of 1.5% (two patients).

We concluded that in the early post-operative period the internal brace technique tends to have more early complications such as post-operative hematomas and even intrarticular infections. This is probably because of double trauma at the site of footprint fixation and the screw insertion and the presence of an intra-articular foreign body (ultrabraid). We suggest taking care of hemostasis carefully at the hamstrings-harvesting site to avoid the hematomas there. The single shot antibiotherapy that we standard use may be is to be continued some days more as a treatment at least 5 days full treatment.

Regarding the late post-operative period, the internal brace technique showed a clear superiority in early rehabilitation, ROM and muscle-mass regain, and return to sport possibilities. About 90% (115) of the patients were walking without crutches or immobilizers at two to 3-week post-operative. All the professional athletes operated on using IB returned to sport.

The anatomical repair performed the standard rehabilitation with 4 weeks of immobilized and 6 weeks of crutches.

The clear result of knee stability after 1 year from the operation puts the internal brace technique as the golden standard one.

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