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# Anterior Cruciate Ligament Repair Revisited. Preliminary Results of Primary Repair with Internal Brace Ligament Augmentation: A Case Series

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## Abstract

**Background:** There is renewed interest in ACL repair following rupture with the development of new repair techniques. The aim of the audit was to assess outcomes and complications of ACL repair with Internal Brace Ligament Augmentation (IBLA) at minimum one year follow-up.

**Materials and methods:** 68 consecutive patients who underwent Anterior Cruciate Ligament (ACL) repair with IBLA were followed for a minimum of one year following surgery. Knee Injury and Osteoarthritis Outcome Score (KOOS) and Western Ontario and McMaster osteoarthritis index (WOMAC) scores were collected at set time points via an online outcomes system. Improvements in scores from baseline were recorded and effect sizes for the five KOOS and three WOMAC domains were calculated. Patients suffering from re-rupture or undergoing re-interventions were identified and Kaplan-Meier survivorship calculated.

**Results:** Improvement was seen over the study period in all KOOS and WOMAC domains with the majority of improvement seen in the first three months. The results were comparable to the literature on ACL reconstruction. In the KOOS score, the greatest effect size at one year was seen in the Quality of Life (QoL) (2.82, 95% CI 2.25 to 3.39) and Sport domains (2.60, 95% CI 2.09 to 2.12). The lowest KOOS effect size was seen in the Activities of Daily Living (ADL) domain (1.1, 95% CI 0.68 to 1.51), with similar smaller improvements seen in the WOMAC domains.

There were four re-interventions including one for re-rupture, and one each for surgery for arthrofibrosis, meniscal tear and chondral parthology.

**Conclusions:** This audit provides early functional outcome and failure data that demonstrates the technique of ACL repair with IBLA is comparable with early results from ACL reconstruction, with the greatest improvements seen in return to sporting activity. Further randomised studies are required to directly compare repair against standard ACL reconstruction techniques.

**Keywords:** Anterior cruciate ligament; ACL; ACL reconstruction; ACL repair

## Introduction

Injury to the anterior cruciate ligament (ACL) is common, particularly in young active individuals. Current estimates suggest that in the United States alone 400,000 ACL reconstructions are carried out each year [1]. As the majority of ACL injuries occur in patients of working age, the economic burden to both patients and society is considerable.

The current 'gold standard' treatment for an ACL tear is ACL reconstruction [2]. The technique either involves removing or bypassing residual ACL tissue, without any attempt to repair the ligament. This is despite the fact that in the majority of cases, sufficient tissue remains for a repair to be considered, particularly if surgery is carried out within six weeks of injury [3,4]. One of the reasons surgeons do not currently attempt ACL repair, is that historically isolated repair of the ACL has met with only moderate success, with revision rates of up to 24% [5].

A number of problems have been identified with ACL reconstruction however, with autograft harvest associated with a degree of morbidity from tissue loss. Hamstring muscle weakness following harvesting averages 10% in most studies [4] with anterior knee pain common with patellar tendon grafts [5,6].

Although reconstructive surgery with autograft restores knee function, it does not produce a 'normal' feeling knee, with loss of proprioception a particular problem [7-9]. Not surprisingly therefore the majority of studies of gait after ACL reconstruction show abnormal gait patterns and altered knee kinematics which may be linked to the higher rate of early Osteoarthritis (OA) of the knee observed in this group [5,6,10-14].

Modern arthroscopic surgical instrumentation and implants might potentially allow more successful attempts to repair the ACL. ACL repair protected by the Internal Brace Ligament Augmentation (IBLA) system may offer an advantage over previous ACL repair techniques. The clinical benefits of a well repaired native ACL which retains host tissue and proprioceptive function are likely to be greater for patients than those offered by traditional ACL reconstruction surgery.

The aim of this audit was to assess the patient reported functional outcome and re-operation rate of a technique of ACL repair that combined repair with a synthetic Internal Brace to protect the healing ligament. The secondary aim of this audit was to provide pilot data to

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assist in the design of a prospective trial to compare ACL repair with the more commonly provided ACL reconstruction technique.

## Patients and Methods

All patients undergoing ACL repair and Internal Brace Ligament Augmentation (IBLA - Arthrex, Naples, Florida) for isolated acute ACL injury between Sept 2011 and Sept 2014 in the lead author's (GM) practice were included in this audit. Inclusion criteria were clinical and radiological confirmation of a complete isolated ACL rupture within three months of initial injury. Only patients who had completed one year of follow-up were included. Exclusion criteria were: patients younger than 16 years of age, chronic ACL ruptures, multi-ligament injuries, bilateral injuries and polytrauma patients. Patients were considered eligible for repair and IBLA if they were within six weeks of injury, although during the period of the audit, the maximum time from injury to surgery was increased to three months. Associated tears of either menisci were treated with resection or repair depending on type and location of the tear.

Overall 82 consecutive patients were assessed, deemed suitable and consented for the procedure, with 68 patients actually undergoing repair and IBLA once the ability to repair the torn ACL had been confirmed at the time of surgery. For those patients with mid-substance ruptures in whom ligament repair was not feasible, all 14 underwent ACL reconstruction instead. Twenty-seven patients had a complete dataset of patient reported outcome measures (PROMs) suitable for analysis. This group forms the study group for PROMs analysis. The overall group of 68 patients who underwent ACL repair are considered when examining re-rupture and re-intervention during the study period and in the calculation of Kaplan-Meier survivorship.

Patients Reported Outcome Measures (PROMs) were routinely recorded prospectively using the Surgical Outcomes System (SOS) (Arthrex, Naples, Florida). This online system collected PROMs data by automatically emailing surveys to patients at predefined time points.

Knee Injury and Osteoarthritis Outcome (KOOS) scores [15] and Western Ontario and McMaster osteoarthritis index (WOMAC) scores [16] were collected pre-operatively and at three, six and 12 months post-operatively. Data on complications from repair failure, reoperation and infection were also collected.

### Surgical technique

The surgery was performed under general anaesthetic and as a day case procedure. Local anaesthetic infiltration was used to assist post-operative pain management and patients were allowed to mobilise fully weight-bearing without bracing. The ACL repair technique involved repair of the ligament where it had avulsed from its femoral attachment on the medial wall of the lateral femoral condyle. The technique was used only for proximal detachment injuries of the ACL where the ligament had avulsed from its femoral attachment. The surgery was carried out within three months of the original injury. Beyond this time the ACL remnant begins to remodel and retract, and the tissue is no longer able to be placed back at its original attachment point.

The ACL remnant was 'whip stitched' using an arthroscopic suture passing instrument developed for shoulder surgery (Scorpion FastPass - Arthrex, Naples, Florida). A single 'whip stitch' was sufficient in the majority of cases although an additional suture was passed if the remaining host tissue was friable. The proximal end of the ACL was then re-approximated against the medial wall of the lateral femoral condyle, in an anatomical mid-bundle position. The bone on the femoral condyle at the anatomical insertion point was freshened with a microfracture probe.

The repair was then protected using the Internal Brace Ligament Augmentation Repair device, a 2.5 mm polyethylene tape bridging from tibia to femur, with the aim of creating the ideal mechanical environment to allow healing to occur in the ligament at an appropriate length. The Internal Brace bridges the anatomical attachments of the ACL in the mid-bundle position on both femur and tibia, protecting the repair. Tensioning of the Internal Brace was carried out with the knee in extension.

3.5 mm tunnels were drilled in the tibia and femur to facilitate the repair and for the Internal Brace fixation. Fixation of the repair stitch and Internal Brace proximally was carried out with the ACL TightRope (Arthrex, Naples, Florida) whilst distal fixation of the Internal Brace was carried out with the SwiveLock Suture Anchor (Arthrex, Naples, Florida).

### Rehabilitation

Patients underwent a standard ACL rehabilitation programme following ACL repair, avoiding open chain exercises for 6 weeks post-operatively. Limited pain and swelling facilitated early range of movement, muscle control and restoration of function, allowing accelerated early phase rehabilitation.

### Statistical analysis

Statistically analysis was performed with SPSS (Version 19, IBM UK Ltd, Hampsire, UK). Mean ages were compared between men and women using the Student t-test. KOOS and WOMAC domains at each time point are reported as means with Standard Deviations (SD). KOOS and WOMAC scores at each time point were compared with the adjacent time points using the repeated measures analysis of variance (ANOVA) test. This test provides an overall p value for change over the whole times series. Post-hoc paired testing was performed for individual time periods (baseline-3 months, 3 months to 6 months, 6 months to 1 year), and was adjusted for multiple testing with the Bonferonni correction. The overall difference from baseline to one year was also calculated and tested for significance using a paired t-test. The mean difference and 95% confidence intervals for this change are also reported as effect sizes [17]. A small effect size is generally considered to be 0.2 to 0.3, a medium effect to be 0.3 to 0.8 and a large effect to be greater than 0.8 [17]. The effect size is the change divided by the baseline Standard Deviation (SD). The level of statistical significance was set at $p<0.05$. Two tailed tests were used throughout.

Kaplan-Meier survivorship methodology was used to calculate the cumulative reintervention rate. This allowed for compensation for different periods of follow-up as all patients in the original series were considered for this analysis. All cause reintervention was considered along with specific failure of the ACL repair.

## Results

The mean age was 34 years, (standard deviation (SD) 15.5, median 28, range 16 to 60). There were 14 men (51.9%) and 13 women (48.1%). There was no significant difference in mean age between genders (t-test; $p=0.146$). There was a significant improvement over the study period in all KOOS and WOMAC domains (Table 1, Figure 1). The majority of the improvement was seen in the first three months. In the Sport and Symptoms domains, further improvements were noted between six and twelve months.

In the KOOS score, the greatest effect size at one year was seen in the Quality of Life (QoL) (2.82, 95% CI 2.25 to 3.39) and Sport domain (2.60, 95% CI 2.09 to 2.12) (Figure 2). The lowest KOOS effect size was seen in the Activities of Daily Living (ADL) domain (1.1, 95% CI 0.68 to 1.51). Similar improvements were seen in the WOMAC domains (Table 2).

The one year cumulative reintervention rate for any cause was 6.0% (n=4, 95% CI 5.9 to 28.8) (Figure 3). This group comprised four patients: one patient whose repair failed at 18 weeks on return to collision sports, a release and manipulation for stiffness, one for recurrent meniscal pathology and one for a patellofemoral osteochondral lesion. Arthroscopy in these three latter patients demonstrated the ACL repair to be intact (Figure 4). The cumulative reintervention rate for a rerupture was 1.5% (n=1, 95% CI 1.5 to 54.0). There were no further failures beyond one year.

## Discussion

The results of this audit suggest that at short-term follow-up, repair and IBLA appears at least as effective in restoring stability and function to the knee as traditional ACL reconstruction surgery, with similar PROMS to those reported in the literature for traditional ACL reconstruction techniques [18]. In particular the effect size is greatest in the KOOS Sport, Symptoms and QoL which are the most discriminating domains of the score for high activity levels. Additionally a low all cause reintervention and ACL repair failure rate are seen in our patients.

In the late 1970s through to the late 1980s ACL repair was widely used, but with mixed outcomes. Although some reported good outcomes [19-21] other studies suggested high revision rates of up to 24% [22] or poor clinical outcome scores (mean KOOS Score 68.6) [23]. The concept of successful ACL repair however remains attractive, with retention of proprioceptive fibres in the healed native ligament more likely to occur than following reconstruction. Loss of proprioception is important as it may lead to overloading of the ACL graft and the loss of confidence in the knee after ACL reconstruction. It is estimated that less than 50% of patients return to sport after ACL reconstruction, and those that do often find that they cannot perform at the same level as pre-injury/pre-surgery [24,25]. The fear of movement (kinesiophobia) is high after an ACL injury and although this generally improves after ACL reconstruction, many patients still report some degree of kinesiophobia post-surgery [26].

The majority of studies assessing gait and knee kinematics post-ACL reconstruction show an improvement in gait pattern compared to pre-surgery, but compensatory mechanisms of muscle use persist in the majority of patients indicating sub-optimal performance of the reconstructed graft [5,12,27-31]. Graft donor site morbidity from tissue loss and scarring is well documented with hamstring weakness and anterior knee pain problematic after hamstring and patellar tendon harvesting respectively [5,6].

The current evidence base does not provide clear data on whether the loss of proprioception, donor site morbidity or abnormal gait patterns and altered knee kinematics causes or contributes to the development of early osteoarthritis of the knee observed in these patients, but the failure of ACL reconstruction to prevent the development of osteoarthritis is recognized [6,10].

A number of modifications have been introduced to the ACL reconstruction technique to try to improve outcomes and these include: changes in graft tunnel position, double bundle rather than single bundle grafts, retention of the ACL remnant and variations in graft fixation techniques. However, none of these modifications have been shown to make a significant difference to patient reported outcomes.

A recent systematic review by Crawford et al. of studies with minimum 10 year follow-up data, indicates that the cumulative ACL graft failure rate requiring revision surgery at 10 years is 11.9% [32]. The actual rate of failure of the graft may be higher than this if patients declining further surgical intervention were to be included. Shorter term data from the Danish Ligament Registry (n=12,193) indicates a 4.1% revision rate for ACL reconstruction at five years after surgery, with those under the age of 20 having a higher revision rate of 8.7% [33].

Proximal detachment of the ACL is the most common scenario following injury and our experience suggests that sufficient ACL tissue can remain for up to 3 months following ACL injury to allow a repair to be carried out. Not all patients in our series were suitable for repair however with 14 out of the original 82 patients (17%) undergoing ACL reconstruction as they had mid-substance ruptures. Importantly both

| | | Baseline | 3 Months | 6 Months | 1 Year | P Value |
|---|---|---|---|---|---|---|
| **KOOS** | | | | | | |
| **ADL** | Score (SD) | 53.0 (37.7) | 74.7 (36.5) | 77.9 (37.9) | 94.4 (18.8) | |
| | Change (95% CI) | | 21.7 (8.2 to 35.2) | 3.2 (-12.0 to 18.2) | 16.5 (-0.6 to 33.6) | P<0.001 |
| **Pain** | Score (SD) | 58.0 (29.1) | 85.2 (12.6) | 87.0 (12.8) | 91.1 (7.4) | P<0.001 |
| | Change (95% CI) | | 27.1 (13.7 to 40.7) | 1.8 (-3.7 to 7.2) | 4.1 (-0.6 to 8.8) | |
| **QOL** | Score (SD) | 20.1 (18.3) | 48.0 (28.8) | 50.5 (29.3) | 71.7 (21.1) | P<0.001 |
| | Change (95% CI) | | 27.9 (19.6 to 36.2) | 2.5 (-10.6 to 15.5) | 21.2 (6.7 to 35.7) | |
| **Sport** | Score (SD) | 21.3 (22.7) | 52.7 (28.8) | 59.1 (36.1) | 80.4 (21.8) | P<0.001 |
| | Change (95% CI) | | 31.4 (20.2 to 42.6) | 6.4 (-8.8 to 21.7) | 21.3 (5.0 to 37.5) | |
| **Symptoms** | Score (SD) | 38.8 (30.0) | 63.8 (35.2) | 67.5 (35.9) | 85.7 (12.8) | P<0.001 |
| | Change (95% CI) | | 25 (12.6 to 37.4) | 3.7 (-10.9 to 18.3) | 18.3 (3.2 to 33.3) | |
| **WOMAC** | | | | | | |
| **Pain** | Score (SD) | 57.0 (38.9) | 75.2 (37.1) | 76.6 (37.7) | 92.5 (18.8) | |
| | Change (95% CI) | | 18.2 (5.4 to 31.0) | 1.4 (-13.8 to 16.7) | 15.9 (-1.3 to 34.1) | P<0.001 |
| **Stiffness** | Score (SD) | 44.6 (35.4) | 66.5 (34.9) | 71.0 (36.7) | 85.7 (21.2) | P=0.001 |
| | Change (95% CI) | | 21.9 (8.2 to 35.6) | 4.5 (-10.4 to 19.3) | 14.7 (-2.8 to 32.3) | |
| **Function** | Score (SD) | 53.1 (38.4) | 73.9 (36.9) | 77.4 (38.5) | 94.3 (19.1) | P<0.001 |
| | Change (95% CI) | | 20.9 (6.9 to 34.8) | 3.5 (-12.2 to 19.1) | 16.9 (-0.8 to 34.7) | |

**Table 1:** KOOS and WOMAC domain scores at baseline, 3 months, 6 months and 1 year. P-value represents repeated measures ANOVA test for within subject variation over the time periods. The change represents the mean difference (95% confidence interval) between each time point. Significant differences are highlighted in bold type (p<0.05).

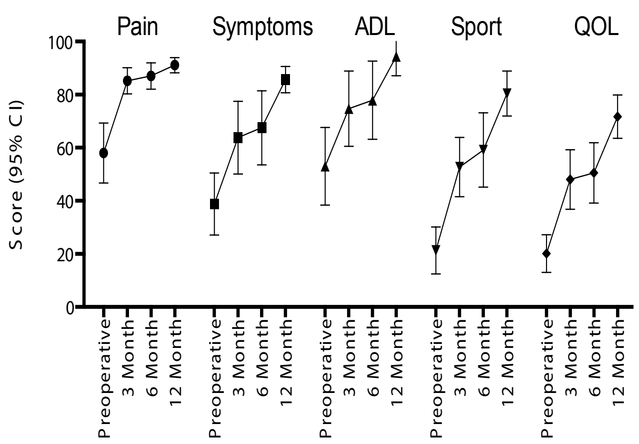


**Figure 1:** Individual KOOS Domains (mean +/- 95% confidence interval).

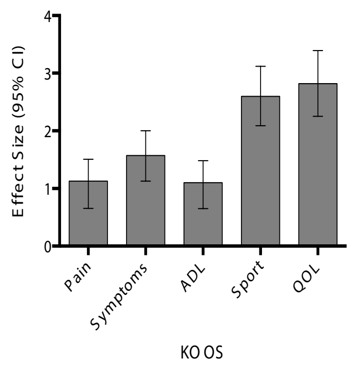


**Figure 2:** Effect sizes (mean +/- 95% confidence intervals) for the baseline-one year change in KOOS domains.

| | Change: Baseline to 1 Year | Baseline SD | Effect Size | P Value |
|---|---|---|---|---|
| **KOOS** | | | | |
| **ADL** | 41.3 (25.7 to 57.0) | 37.7 | 1.1 (0.68 to 1.51) | <0.001 |
| **Pain** | 33.0 (19.2 to 46.9) | 29.1 | 1.13 (0.66 to 1.61) | <0.001 |
| **QOL** | 51.6 (41.1 to 62.1) | 18.3 | 2.82 (2.25 to 3.39) | <0.001 |
| **Sport** | 59.1 (47.4 to 70.8) | 22.7 | 2.60 (2.09 to 3.12) | <0.001 |
| **Symptoms** | 47.0 (34.0 to 60.0) | 30.0 | 1.57 (1.13 to 2.00) | <0.001 |
| **WOMAC** | | | | |
| **Pain** | 35.5 (18.3 (52.8) | 38.9 | 0.91 (0.47 to 1.36) | <0.001 |
| **Stiffness** | 41.1 (23.0 to 59.2) | 35.4 | 1.16 (0.65 to 1.67) | <0.001 |
| **Function** | 41.3 (25.1 to 57.5) | 38.4 | 1.08 (0.65 to 1.50) | <0.001 |

**Table 2:** Overall change from baseline to 1 year. P value represents Paired t-test. The effect size (change divided by standard deviation) is reported for the overall change from baseline to 1 year.

3.5 mm femoral and tibial tunnels placed for repair were in exactly the same location as the larger tunnels drilled for placement of the hamstring or patellar tendon autografts used for ACL reconstruction, should failure of the ACL repair technique occur. In the single patient requiring revision surgery in this series, a routine patellar tendon reconstruction was carried out as a primary type of procedure.

Earlier return to function could result in less hospitalisation and healthcare usage post-operatively, with an earlier return to work and

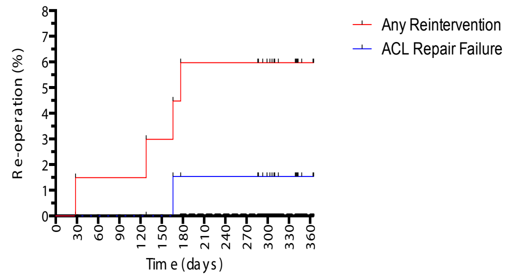


**Figure 3:** Cumulative reintervention for all causes and for ACL repair failure.

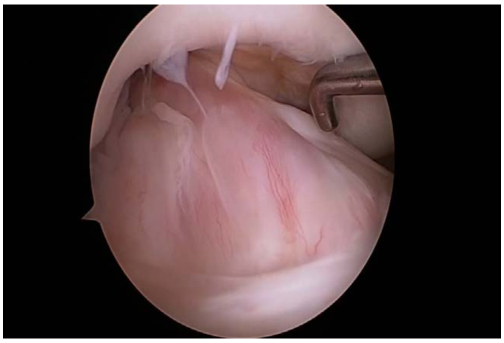

**Figure 4:** Healed ACL following repair and Internal Brace.

sport. This could potentially have benefits not only to the patient but to the health service and society as a whole. None of these factors could be specifically assessed in this audit and all require to be prospectively investigated. This audit also has limitations in terms of the sample size, completeness of the dataset and length of follow-up. A power calculation was not relevant as we were primarily performing a clinical audit. A post-hoc power calculation however showed that this study had a 25% power to detect a small effect on the KOOS Sport, a 81.6% power to detect a medium effect and a 98.9% power to detect a large effect. This audit was also at risk of experiencing potential selection bias as patients opting for early repair may have been more likely and motivated to comply with rehabilitation and return to sporting activities. In particular the time to surgery in patients undergoing acute ACL repair with IBLA is likely to be shorter than those undergoing ACL reconstructions, the majority of whom will have failed a period of conservative care. The results of this audit may reflect the results of early intervention, rather than that of the repair itself.

We have no way of assessing whether the ACL had healed or not and it is theoretically possible that stability of the knee at this early stage is being maintained only by the Internal Brace, with limited healing of the repaired tissue. Future studies should include the use of MRI to assess healing of the repair. Longer term follow-up will also determine the risk of secondary meniscal tears and the subsequent development of osteoarthritis.

This audit provides early functional outcome and failure data that demonstrates the technique of ACL repair with IBLA is at least comparable with early results from ACL reconstruction, while avoiding donor site morbidity and speeding return to sporting activity. It provides useful early pilot data that may assist with the development of a protocol for a randomised controlled trial comparing this technique with standard ACL reconstruction.

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**ICJME Conflict of Interest**

The senior author has received payment for services from a third party (Arthrex, Naples, Florida) whose products were used in the surgery of the submitted work.

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