

## *Return to activity following ACL Reconstruction with the Fertilized ACL: A retrospective study*

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### ABSTRACT

**INTRODUCTION:** The objective of this retrospective study is to evaluate outcomes in patients who underwent the fertilized anterior cruciate ligament (ACL) reconstruction procedure. We aim to investigate the return to previous level of activity, safety, and re-rupture rates of the ACL reconstruction augmented with bone marrow concentrate, demineralized bone matrix, autograft bone, and a suture tape (the fertilized ACL).

**METHODS:** A comprehensive review of medical records was conducted for patients treated with the fertilized ACL (FACL). Medical records of all the patients who underwent reconstruction surgery between July 2018 and January 2021 were evaluated. The inclusion criteria for the study were patients with a defined ACL tear based on clinical examination and magnetic resonance imaging testing who received FACL reconstruction between July 2018 and January 2021. Exclusion criteria included revision ACL reconstruction, non FACL reconstruction, and patients that underwent the FACL reconstruction outside of the defined time period. Thirteen patients underwent reconstruction using a Graftlink allograft (Lifenet Virginia Beach, Va) and 38 using quadriceps autografts. All patients received the FACL reconstruction using bone marrow concentrate, demineralized bone matrix, autograft bone, and suture tape. A phone survey was conducted to obtain patient-reported outcome measures including return to previous level of activity, International Knee Documentation Committee (IKDC), ACL Return to Sport After Injury (ACL RSI), and Visual Analogue Scale (VAS) values. A chart review was conducted for complications and questions were asked during the phone survey regarding return to operating room, infections, and re-ruptures.

**RESULTS:** Data analysis revealed 94% of the patients returned to their previous level of activity. The average IKDC and ACL RSI scores were 94% (SD, 9.0) and 92% (SD, 15.3), respectively. The average VAS score was .9/10 (SD, 1.2). One patient required reoperation for pain at 1 year. No re-ruptures were observed.

**CONCLUSION:** This retrospective study sheds light on the FACL, which adds biology and an internal brace to an ACL reconstruction, as a reliable and safe option when performing an ACL reconstruction. Very low complication rates were seen in this consecutive series followed for a mean of 2 years. Patients had an extremely high level of return to previous level of sport/activity.

### KEYWORDS

ACL, reconstruction, biologics, suture augment

### INTRODUCTION

Recent literature suggests that graft re-rupture rates following anterior cruciate ligament (ACL)

reconstruction are as high as 6-11%.<sup>1</sup> Athletes under the age of 25 are at a higher risk for secondary ACL injury of either the ipsilateral or contralateral side ranging from 23% to 33%.<sup>2,3</sup> These rates have

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been shown to persist even if delaying an athlete's return to play for 12 months. There is a proposed biomechanical rule of thirds in patients following an ACL injury with 1/3 of patients able to function well with no ACL, 1/3 that can do activities of daily living (ADLs) with no ACL but unable to return to sport, and 1/3 that cannot function or do ADLs without an ACL.<sup>4</sup> Secondary ACL injury rates also appear to be consistent with the rule of thirds, suggesting that there is a biomechanical basis for re-injury.<sup>4</sup>

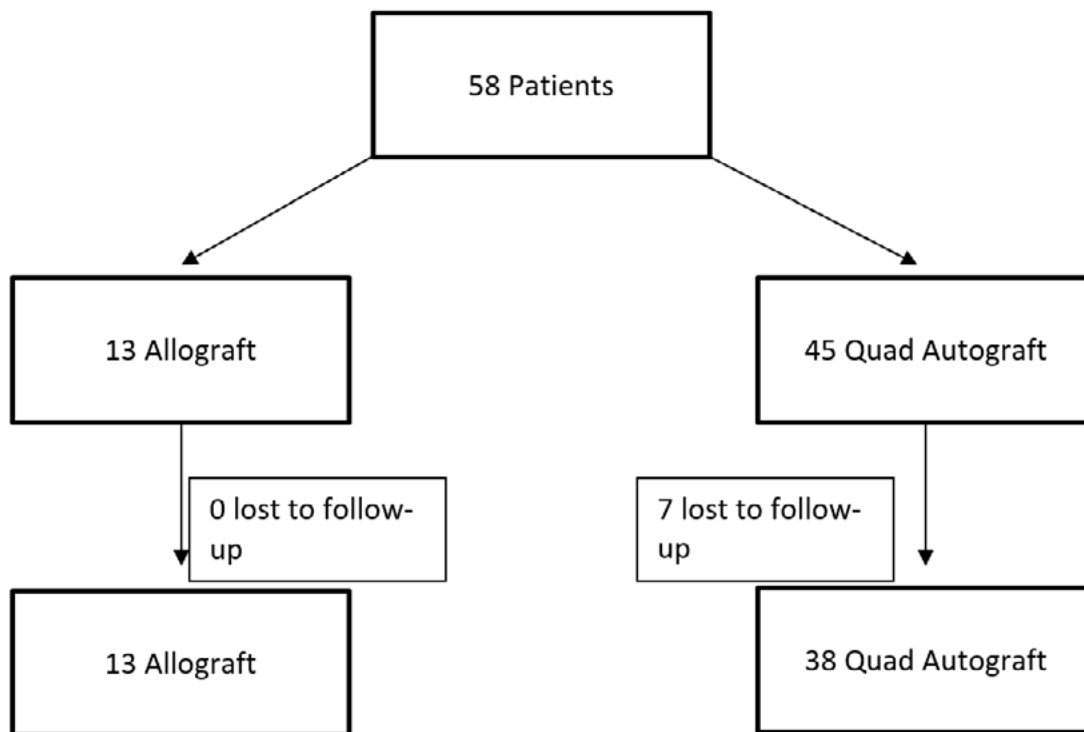
Despite newer techniques and evolutions in graft choices, significant reductions in re-rupture rates and return to play time have been elusive. One way to prevent early graft re-rupture and increase return to play rates may be to encourage early biologic graft incorporation into the femoral and tibial tunnels. A new technique has been developed to augment ACL reconstruction with bone marrow concentrate, bone grafting, and a suture tape.<sup>5-8</sup> Bone marrow concentrate has shown promise in the treatment of many orthopedic conditions including osteochondral injuries, avascular necrosis, and tendon injuries.<sup>9</sup> An additional technique was recently described for obtaining autograft bone from the femoral and tibial tunnels using the Arthrex Graftnet device. The results of this technique, the FACL reconstruction, in a smaller series of patients were previously reported and found to be safe and effective.<sup>8</sup> The possible advantages of these augmentation procedures for ACL reconstruction are numerous but could include improved bony consolidation, decreased pain, increased stability, and lower re-rupture rates. We retrospectively reviewed a cohort of consecutive patients treated with the FACL reconstruction which refers to adding demineralized bone matrix, autograft bone, and bone marrow concentrate to the tunnels of an All-Inside ACL reconstruction. Now that there is a larger group of subjects that have received the FACL reconstruction over a longer period of time, the goal of this study is to add to the previously published literature and compare the results of our group of patients to previously published literature on outcomes of ACL reconstruction.

## METHODS

Institutional review board approval was obtained through Marshall University (#1778293) to

retrospectively review patients who underwent FACL reconstruction performed between July 2018 and January 2021. The inclusion criteria for the study were patients with a defined ACL tear based on clinical examination and magnetic resonance imaging testing who received FACL reconstruction between the previously defined dates. Exclusion criteria included revision ACL reconstructions, standard non FACL reconstructions, and patients outside of the consecutive time period. Patients suffering an ACL injury requiring surgery were identified, and on chart review, 58 patients total underwent FACL reconstruction and met inclusion criteria. All patients received the FACL technique previously described in the literature.<sup>7</sup> This technique uses 60cc of aspirated bone marrow concentrated to 3cc of BMC, 5cc of AlloSync Pure (Arthrex), and 1cc of autograft bone collected from reaming the femoral and tibial tunnels. Either a quad tendon autograft or Graftlink allograft (Lifenet Virginia Beach, Va) construct was made on the back table with appropriate all-inside fixation devices applied. Patients older than 25 years of age received allograft, and all patients younger than 25 received autograft reconstruction. On the autografts, a Fibertag RT TightRope device (Arthrex) was added on the femoral side and a FiberTag ABS implant (Arthrex) was added on the tibial side. On the allografts, a BTB TightRope (Arthrex) was applied to the femoral end of the graft and an ABS (Arthrex) was placed onto the tibial side. The femoral TightRopes were lengthened to allow injection of the composite graft into the femoral tunnel through the medial portal later in the case. A suture augment was added to the femoral button of the construct for both autograft and allograft reconstructions. The surgeries were performed using an all-inside ACL reconstruction technique. All surgeries were performed by the lead author who is a sports fellowship-trained orthopaedic surgeon. Seven patients were lost to follow-up and not available for the phone survey leaving 51 patients included in the study. Thirty-eight patients underwent Quadriceps Tendon autograft ACL reconstruction, and 13 patients underwent allograft reconstruction (Figure 1). Patients' clinical outcomes at follow-up of a mean 2 years were obtained via phone survey by an IKDC subjective score, a VAS score, and an ACL RSI score. Patients were asked if they had returned to their previous level of sport or activity. Complications





**FIGURE 1.** Patient Allocation

including reoperation rates, infection, and re-rupture were also evaluated via chart review and phone survey.

## RESULTS

Fifty-eight patients met inclusion criteria and were followed with clinical exams for 6 months post-procedure. All 58 patients were released to full activity at 6 months. They all had negative Lachman examinations and reported no subjective instability. Seven patients were lost to follow-up or were not available for phone survey leaving 51 patients for the current study. Patient’s ages ranged between 15 and 52 with the average age being 24 years old. Nineteen patients were female and 33 were male. With regards to returning to previous level of sport or activity 48/51 (94%) patients reported they were back to their previous level. The average IKDC and ACL RSI scores were 94% (SD, 9.0) and 92% (SD,15.3), respectively (Table 1). The average VAS score was .9/10 (SD, 1.2). No patient sustained a re-rupture of the graft, and there were no infections. There was 1 patient who had a reoperation for persistent pain at 1 year post-

operatively despite repeat imaging not showing any new injuries. The patient underwent a diagnostic arthroscopy which demonstrated that the ACL and internal brace remained intact with no injuries to the meniscus or other cartilage lesions.

## DISCUSSION

This retrospective review adds to growing data that the FACL is a safe and reliable ACL reconstruction technique. It was encouraging to find very high patient-reported outcome measures, high return-to-play rates, and a low re-rupture rate. Previous outcomes of the FACL reconstruction were published, but the study only had 16 patients. The sample has now increased to 51, and some subjects are now over 3 years out from their FACL reconstruction.

As mentioned, rates of re-rupture can vary in the literature but have been reported to be as high as a third of patients that return to sport.<sup>3</sup> We had a return to previous activity level of 94% with no re-ruptures in this patient set. The rate of return to

Graft Type	Age (At time of Surgery)	Return to Previous Activity (Yes or No)	Re-rupture (Yes or No)	Reoperation (Yes or No)	VAS Pain	IKDC Score	ACL-RSI Score
Allograft	34	Yes	No	No	0	97.70%	89.90%
Allograft	36	Yes	No	No	0	100.00%	97.50%
Quad Autograft	17	No	No	Yes	0	77.00%	73.60%
Quad Autograft	18	Yes	No	No	0	100.00%	90.80%
Quad Autograft	15	Yes	No	No	3	95.40%	70.50%
Quad Autograft	16	Yes	No	No	2	100.00%	100.00%
Quad Autograft	18	Yes	No	No	0	100.00%	100.00%
Allograft	30	Yes	No	No	0	94.30%	45.80%
Quad Autograft	19	Yes	No	No	0	87.40%	94.20%
Allograft	45	Yes	No	No	2	100.00%	95.20%
Quad Autograft	16	Yes	No	No	0	100.00%	100.00%
Quad Autograft	19	Yes	No	No	4	79.30%	86.70%
Quad Autograft	22	Yes	No	No	1	90.80%	70.40%
Quad Autograft	17	Yes	No	No	0	95.40%	95.80%
Quad Autograft	23	Yes	No	No	0	86.20%	55.80%
Quad Autograft	16	Yes	No	No	0	100.00%	99.60%
Quad Autograft	17	Yes	No	No	3	100.00%	100.00%
Allograft	33	Yes	No	No	0	100.00%	91.70%
Quad Autograft	21	Yes	No	No	2	94.30%	96.30%
Allograft	31	Yes	No	No	1	100.00%	100.00%
Quad Autograft	27	Yes	No	No	0	94.30%	96.30%
Quad Autograft	23	Yes	No	No	0	100.00%	99.20%
Quad Autograft	18	Yes	No	No	0	95.40%	100.00%
Quad Autograft	24	Yes	No	No	2	98.90%	100.00%
Allograft	34	Yes	No	No	0	100.00%	80.60%
Allograft	44	Yes	No	No	4	73.60%	94.60%
Quad Autograft	16	Yes	No	No	1	100.00%	100.00%
Quad Autograft	15	Yes	No	No	1	98.90%	99.20%
Quad Autograft	15	Yes	No	No	0	100.00%	100.00%
Quad Autograft	17	Yes	No	No	0	98.90%	100.00%
Quad Autograft	17	Yes	No	No	0	95.40%	91.00%
Quad Autograft	20	Yes	No	No	3	82.30%	96.00%
Quad Autograft	17	Yes	No	No	0	100.00%	100.00%
Quad Autograft	15	Yes	No	No	3	97.50%	96.60%
Allograft	38	Yes	No	No	0	96.60%	94.60%



Quad Autograft	30	Yes	No	No	0	100.00%	100.00%
Quad Autograft	19	Yes	No	No	1	97.70%	100.00%
Quad Autograft	19	Yes	No	No	0	100.00%	100.00%
Quad Autograft	19	Yes	No	No	2	100.00%	100.00%
Quad Autograft	16	Yes	No	No	0	95.40%	99.00%
Allograft	53	Yes	No	No	0	98.90%	100.00%
Allograft	40	No	No	No	2	75.90%	73.00%
Allograft	49	Yes	No	No	2	81.70%	95.80%
Quad Autograft	26	Yes	No	No	0	100.00%	100.00%
Quad Autograft	26	Yes	No	No	1	97.70%	100.00%
Allograft	33	Yes	No	No	3	85.10%	98.10%
Quad Autograft	16	Yes	No	No	0	97.70%	98.80%
Quad Autograft	18	Yes	No	No	0	100.00%	100.00%
Quad Autograft	19	Yes	No	No	2	95.60%	92.90%
Quad Autograft	21	Yes	No	No	0	100.00%	100.00%
Quad Autograft	17	No	No	No	1	56.30%	23.00%

**TABLE 1.** Complete data set including demographic information and outcome scores for all patients.

competitive sport following ACL reconstruction was as low as 55% previously.<sup>10</sup> A meta-analysis performed in 2011 showed a return to previous level of activity of 63%, while we had a return rate of 94%.<sup>11</sup> Due to the retrospective nature of the study, a limiting factor in conclusiveness is the wide range of activity levels of our patients, ranging from getting back to jogging, division 1 college football, and track and field. The fact that not all our patients were high-level competitive athletes influences our return to activity rates and may inflate our return to activity results. A current study is underway prospectively following only high-level athletes to assess return-to-play rates and time to return to play. However, our current return to previous level of activity still compares favorably to previously published literature. Our IKDC of 94% compares favorably with those previously reported in the literature with similar quad tendon ACL reconstruction. Galan et al. showed 59% of patients to have normal IKDC scores; however, that study had a larger population and followed patients for 5 years.<sup>12</sup> We feel this is another step to show the FACL can be a great addition to the all-inside ACL technique in the future. Our theory is that the addition of biologics to both

the femoral and tibial tunnels will lead to early graft incorporation of the tunnels and a decrease in tunnel osteolysis which is a known significant problem following ACL reconstruction seen in 25-100% of patients.<sup>13</sup> AlloSync pure is 100% human allograft bone that preserves bone morphogenetic proteins and growth factors, allowing it to have osteoinductive and osteoconductive effects.<sup>14</sup> The addition of autograft bone and bone marrow aspirate concentrate adds mesenchymal stem cells and hematopoietic progenitor cells to improve healing. Through trial and error, the combination of 5cc AlloSync pure, 3cc of bone marrow aspirate concentrate, and 1cc autograft bone was determined to be the best combination as this formed a texture that was liquid enough to be injected into the tunnels directly while still having enough substance to remain in the tunnels and not be driven out with the irrigation fluid from the arthroscopy equipment.

Unfortunately, 1 patient did go back to the operating room for "pain." He underwent a repeat MRI which did not demonstrate any new injuries. Because the patient continued to have pain despite physical



therapy 1 year out from his surgery, he underwent a diagnostic arthroscopy for further evaluation. The repeat arthroscopy was negative, as it demonstrated an intact ACL and internal brace as well as no meniscal injury or other cartilage. Unfortunately, this has left the patient without a clearly identifiable cause of his pain.

One consideration for this procedure is the additional cost of \$1,000-2,000 compared to a standard ACL reconstruction. This is variable across different operating rooms and regions but is considerable. An area of future research will be a cost-analysis study to determine if the benefits of this procedure outweigh the additional cost.

In this study, the FACL procedure is shown to be safe with no increase in early complications versus historical data. There are limitations to this study due to its non-randomized retrospective nature. Another major limitation is a lack of a control group. Not having a control group prevents us from comparing outcomes of patients with the FACL reconstruction to standard all-inside reconstruction, but the main focus of this study was an update on the safety and efficacy of the procedure which we believe we have demonstrated at this time. We currently have a randomized controlled trial that is ongoing, and we will be releasing early results from this trial soon. Another limitation of this study is the mean 2-year follow-up which shows encouraging results, but complications such as re-rupture rates may not be captured in this short-term follow-up period. A longer-term follow-up will be needed to determine if the FACL reconstruction has a decreased re-rupture rate compared to standard all-inside ACL reconstruction.

## CONCLUSION

This retrospective study sheds light on the role of the Fertilized ACL in reconstructive procedures. The study determines that the fertilized ACL is a reliable and safe option when performing ACL reconstruction. This study was found to be very comparable to historic results, and the procedure results in a high return to previous level of activity at 2 years post-surgery. There was a very low complication and re-rupture rate in this retrospective review. Given the

limitations of this study, no conclusions can be made whether the FACL reconstruction is an improvement over previous techniques, but this study adds to the growing sample with longer follow-up updating the safety and efficacy of the procedure. Understanding the impact of FACL on return to activity can help healthcare practitioners make informed decisions while planning reconstructive surgeries and postoperative rehabilitation protocols.

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