

Early Radiographic and Clinical Outcomes of the Fertilized ACL

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Abstract

Background: The aim of this research study is to examine the early radiographic and clinical outcomes as well as the safety of the Fertilized anterior cruciate ligament (ACL) reconstruction procedure.

Methods: A total of 14 patients with a mean age of 22.9 (range, 16-45), who had been treated with a Fertilized ACL were evaluated. Clinical outcomes including VAS at 2 and 6 weeks, rate of re-rupture, release to full activity, and incidence of complications were assessed. Radiographic outcomes were assessed through qualified orthopedic surgeons' ability to detect operative features of an ACL reconstruction on patient's ipsilateral tibia radiographs when compared to a standardized set of tibial radiographs.

Results: Mean VAS score at 2 weeks and 6 weeks follow up were 1.73 (range, 0-4) and .83 (range, 0-2.5), respectively. There were no cases of rerupture and all patients were returned to activity. One patient underwent a manipulation under anesthesia and diagnostic arthroscopy. There were 0 infections. On radiographic assessment, surgeons correctly identified 58/60 ($p < 0.05$) were correctly identified as having any operative features after undergoing a Fertilized ACL reconstruction.

Conclusion: Early pain scores after the Fertilized ACL reveal minimal pain at 2 and 6 weeks and clinical results show no signs of an increased risk compared to standard ACL reconstructions. The early radiographic appearance of the tibial tunnel in the Fertilized ACL technique is more similar to a healthy non-operative tibia than standard ACL reconstructions

Background

Recent literature suggests that graft re-rupture rates following anterior cruciate ligament (ACL) reconstruction are as high as 6–11%¹. Furthermore, athletes under the age of 25 years have been found to have rates of additional ACL injury of up to 23% when considering both the operative and contralateral sides². Despite newer techniques and evolutions in graft choices, significant reductions in re-rupture rates and return to play time have been elusive. Bone marrow concentrate has shown promise in the treatment of many orthopedic conditions including osteochondral injuries, avascular necrosis, and tendon injuries³. To encourage early biologic graft incorporation and prevent early graft re-rupture, a technique was recently created for augmentation of bone-patella tendon-bone ACL reconstruction with bone marrow concentrate and suture tape⁴. This technique can also be used to enhance an all-inside ACL reconstruction which allows grafting of both the femoral and tibial tunnels with bone marrow concentrate and demineralized bone matrix. (Image 1,2) Furthermore, a technique was recently described recovering the remainings of the femoral and tibial tunnels for use as autograft using the GraftNet Autologous Tissue Collector (Arthrex, Naples, FL).⁵ The possible advantages of these augmentation procedures for ACL reconstruction are numerous but could include improved bony consolidation decreased pain, increased stability, and lower rerupture rates. In this study we retrospectively review the early clinical results with the fertilized ACL reconstruction and we present the early radiographic outcomes in a controlled survey.

Methods

We obtained an institutional review board approval to retrospectively review 14 consecutive patients who underwent fertilized ACL reconstruction performed between July 2018 and April 2019. 11 patients underwent Quadriceps Tendon autograft ACL reconstruction, and 3 patients underwent allograft reconstruction. All patients received The Fertilized ACL technique with BMC augmentation and an internal brace (Arthrex). Patient's ages ranged between 45 and 16 with the average age being 22.9 years old. Five patients were female and 9 patients were male. All surgeries were performed by the senior author who is a sports fellowship trained Orthopaedic Surgeon. Patients' clinical outcomes consisted of pain scores as measured by Visual Analog Scale (VAS) post-operatively at 2 and 6 weeks as well as re-rupture rate, return to full activity, complications, and rates of reoperating. Return to full activity was based on functional testing at 6 months and clinical examination.

To test the early radiographic results on the tibia 10 of the patients had their tibial radiographs at 6 weeks post op further evaluated. These 10 radiographs had the button excluded to blind the surgeons to whether and ACL reconstruction surgery had been performed. Those images of the proximal tibia without the button were randomized into a quiz with a comparison group of 10 other tibial radiographs, which were a mixture of 5 non-fertilized ACL post-operative patients without buttons and 5 nonoperative control negative tibias. All radiographs were evaluated by 5 senior Orthopaedic Residents and 1 Orthopaedic Surgeon board certified in Sports Medicine. These surgeons were asked to identify which radiographs showed evidence of prior surgery. All 6 surgeons were blinded to the identity of the patient's xrays, and none of them participated in any of the cases in question. Statistical analysis for this quiz was performed using Chi square test with Yates correction to yield two tailed P value < 0.0001 for statistical significance.

Results

Radiographic Results

On radiographic evaluation of tibial radiographs the senior orthopaedic residents and board certified sports fellowship trained orthopaedic surgeon correctly identified an aggregate of 58/60 controls which were a mix of standard ACLs and control negative x rays. The same group was only able to correctly identify an aggregate of 38/60 tibias that had undergone fertilized ACL reconstruction. This difference in results was statistically significant. There is an obvious improvement on the tibia radiographs at 6 weeks compared to standard ACL reconstruction especially shown in this image of a patient who in included in our study and had an ACL 1 year prior on the opposite knee (Image 3).

Clinical Results

Average VAS score at 2 weeks was 1.73 with 1 patient not responding. The average VAS score at 6 weeks was .83 at 6 weeks with 2 patients not. Average follow up for all patients was 11 months (range 9–14 months). All patients have been released to full activity. Nine patients are more than 1 year from surgery. No patients have sustained a re-rupture. There were no cases of infection. There was one

complication of arthrofibrosis which required manipulation under anesthesia at 12 weeks post op to achieve full range of motion. This patient had pain at 1 year post op with multiple negative MRI's and had a negative second look knee arthroscopy.(image 4)

Table 1: Vas scores at 2 weeks and 6 weeks

2 weeks	1.73
6 weeks	.83

Conclusion

All-inside ACL reconstruction has been shown equivalent to the full tibial tunnel technique in functional outcome measures with the possible advantage of decreased pain based on visual analog scale⁶. When utilized with our technique, the all-inside approach allows for bone marrow concentrate grafting of both the femoral and tibial tunnels which we hypothesize will aid in early biologic graft incorporation, less tunnel widening, and more substantial graft incorporation on both the femoral and tibial sides. Our radiographic study on the tibia showed a statistically significant inability to identify if a tibia was operated on compared to controls. It is hopeful these x ray findings and those on MRI as we present here show promise in decreasing tibial tunnel widening in the future by using the Fertilized ACL technique. Our results showed minimal pain on VAS after The Fertilized ACL and this cohort shows promising results on early radiographic findings of the tibia using the fertilized technique. The lack of re-rupture or early failure is also promising that this technique can show equivalent or improved results from standard ACL reconstruction.

There are limitations of this study primarily related to the retrospective non-randomized nature of the study. Although there is no control group The Fertilized ACL procedure is shown to be safe with no increase in early complications in addition to showing no increase in early rerupture rate versus historical data. Other limitations are the small sample size and early follow up. We recognize complications such as reruptures and instability could be long term and not found during this early follow up period. Because of these limitations further study is warranted. A randomized control trial comparing The Fertilized ACL to a standard ACL reconstruction is currently underway to further study possible differences in outcomes.

Abbreviations

ACL -anterior cruciate ligament

BMC-bone marrow concentrate

VAS-Visual analog scale

Declarations

1)Ethics approval and consent to participate- IRB was obtained from Marshall University before proceeding with this study.

2)Consent for publication- Not applicable

2)Availability- The datasets during and/or analysed during the current study available from the corresponding author on reasonable request.

3)Competing Interests—ICJME forms were submitted with this paper for each author individually identifying conflicts of interest.

4)Authors Contributions- Dr. Lavender, Berdis, Singh, Kopiec, and Jasko were involved in the IRB process as well as the conceptualization of the study. All authors were involved in writing the paper as well as reviewing data. All authors except Dr. Lavender also answered the was radiographic quiz as well. Dr. Lavender created the blinded radiographic quiz.

5)Funding- No funding was obtained for this study

6)Acknowledgements- Not applicable

References

1. Crawford SN, Waterman BR, Lubowitz JH. Long-term failure of anterior cruciate ligament reconstruction. *Arthroscopy* 2013;39:1566-1571.
2. Wiggins AJ, Grandhi RK, Schneider DK, Stanfield D, Webster KE, Myer GD. Risk of secondary injury in younger athletes after anterior cruciate ligament reconstruction: A systematic review and meta-analysis. *Am J Sports Med* 2016;44:1861-1876.
3. Imam MA, Mahmoud SSS, Holton J, Abouelmaati D, Elsherbini Y, Snow M. A systematic review of the concept and clinical applications of Bone Marrow Aspirate Concentrate in Orthopaedics. *SICOT J.* 2017;3:17.
4. Lavender C, Johnson B, Kopiec A. Augmentation of Anterior Cruciate Ligament Reconstruction With Bone Marrow Concentrate and a Suture Tape. *Arthroscopy Techniques.* 2018, e1289-e1293
5. Lavender C, Johnson B, Singh V, Dennis E, Torres L. The Lavender Fertilized Anterior Cruciate Ligament Reconstruction: A Qhadriceps Tendon All-Inside Reconstruction Fertilized With Bone Marrow Concentrate, Demineralized Bone Matrix, and Autograft Bone. 2019, e1019-e1023
6. Lubowitz JH, Schwartzberg R, Smith P. Radomized Controlled Trial Comparing All-Inside Anterior Cruciate Ligament reconstruction Technique With Anterior Cruciate Ligament Reconstruction With a Full Tibial Tunnel. *Arthroscopy* 2013; 29: 1195-1200

Figures

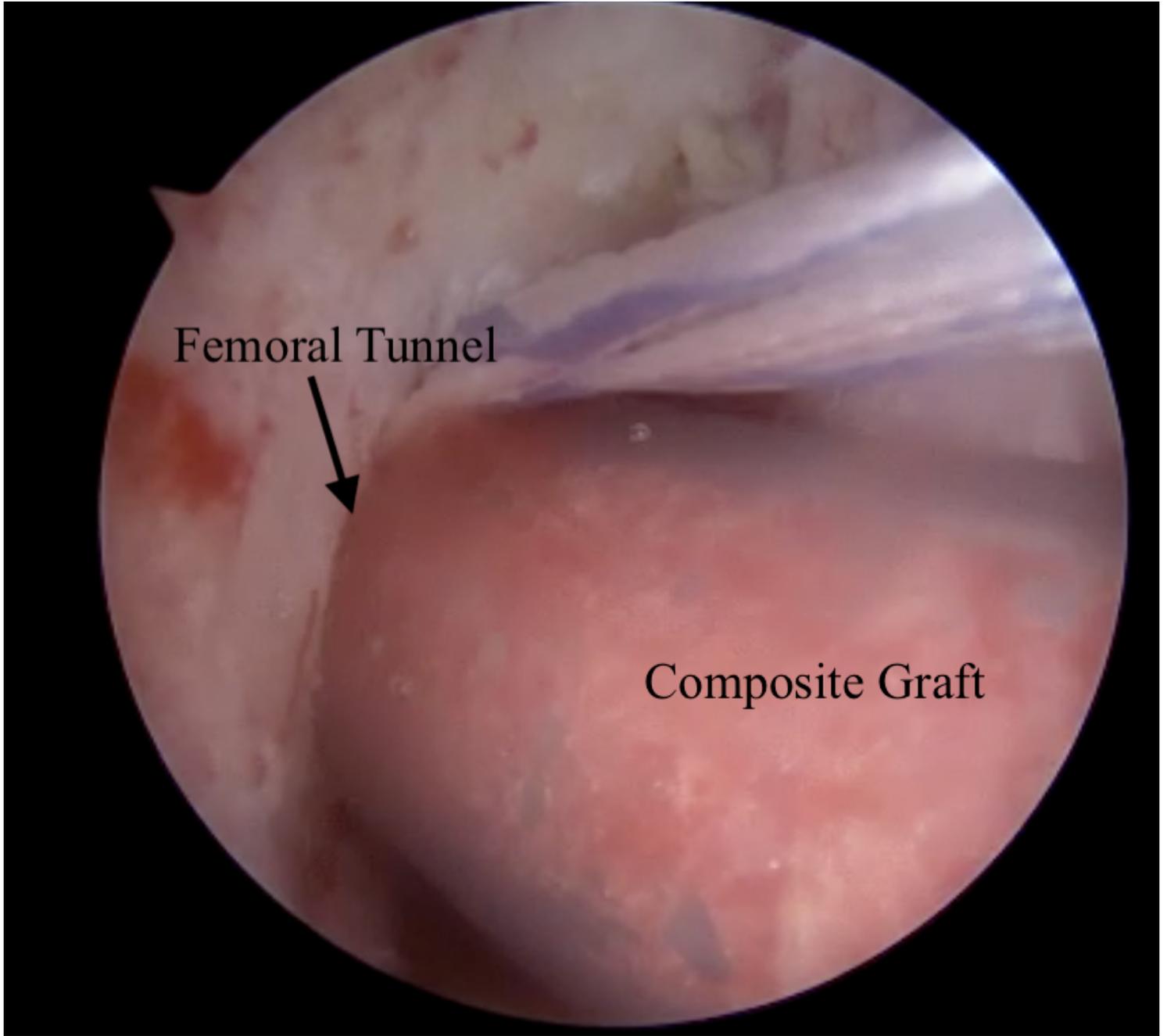


Figure 2

Viewing the right knee from the lateral portal of the knee you can see the BMC composite graft being injected into the femoral tunnel

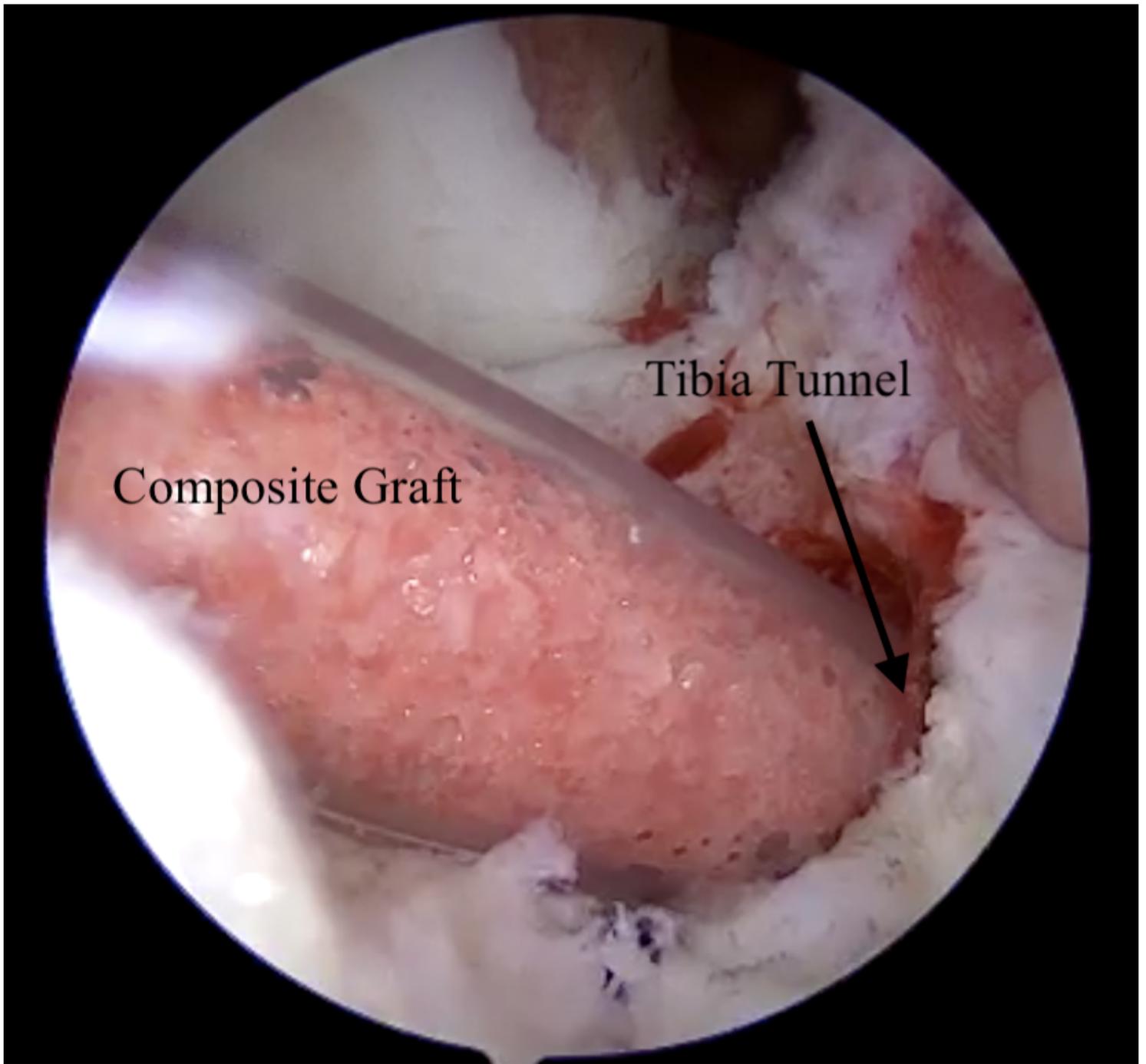


Figure 4

Viewing the right knee from the medial portal of the knee you can see the BMC composite graft being injected into the tibial tunnel

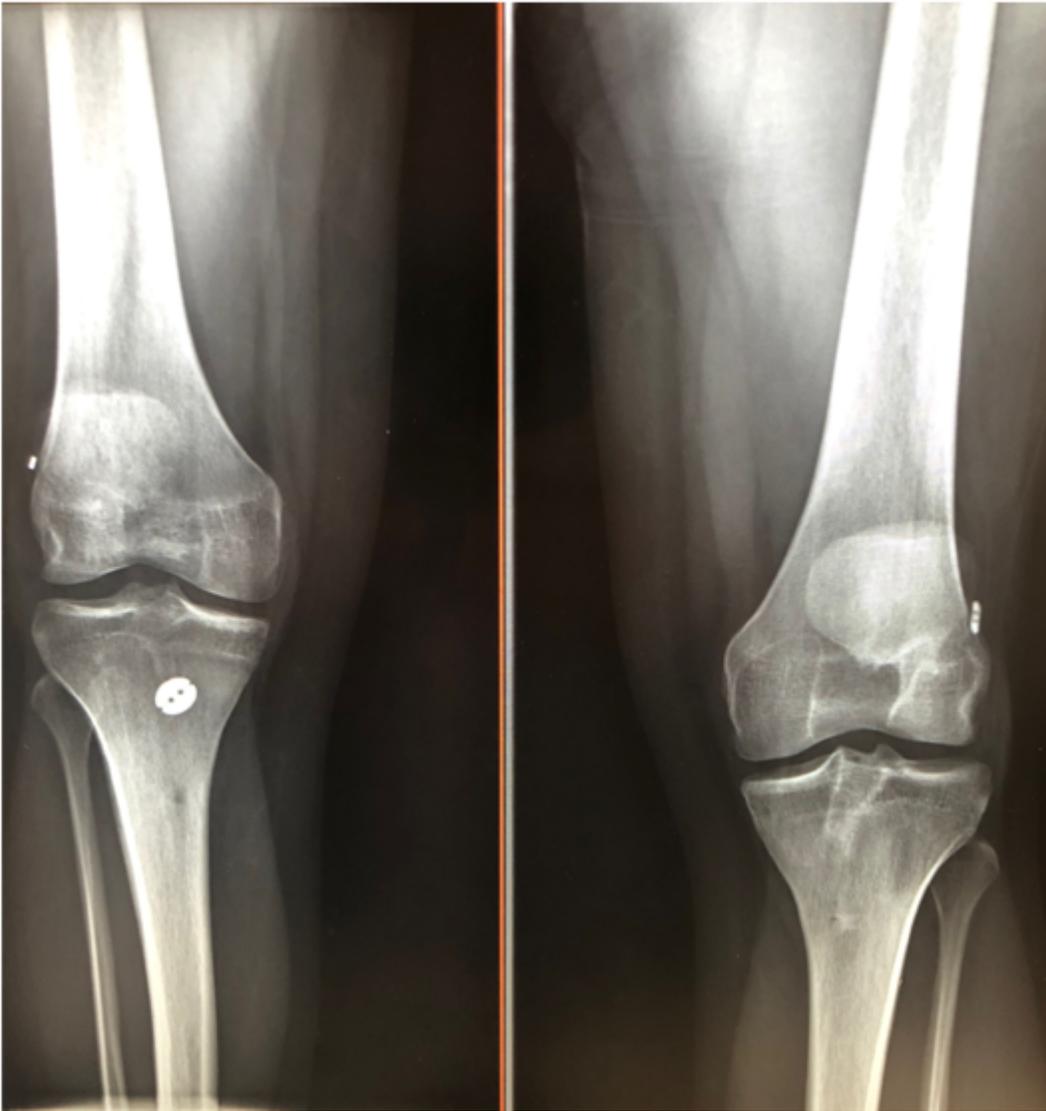


Figure 6

The left x ray is an anteroposterior view of the right knee 6 weeks after a Fertilized ACL while the left knee is 1 year after BTB acl reconstruction in the same patient by the same surgeon.



Figure 8

Sagittal MRI post operative from The Fertilized ACL at 7 weeks. Signal characteristics of the graft are the same as the native PCL. Notice distal to the graft the area composite graft is similar in signal to host bone surrounding the area.