Augmentation Of Medial Patellofemoral Ligament Repair With A Bio-Inductive Scaffold

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Disclosures

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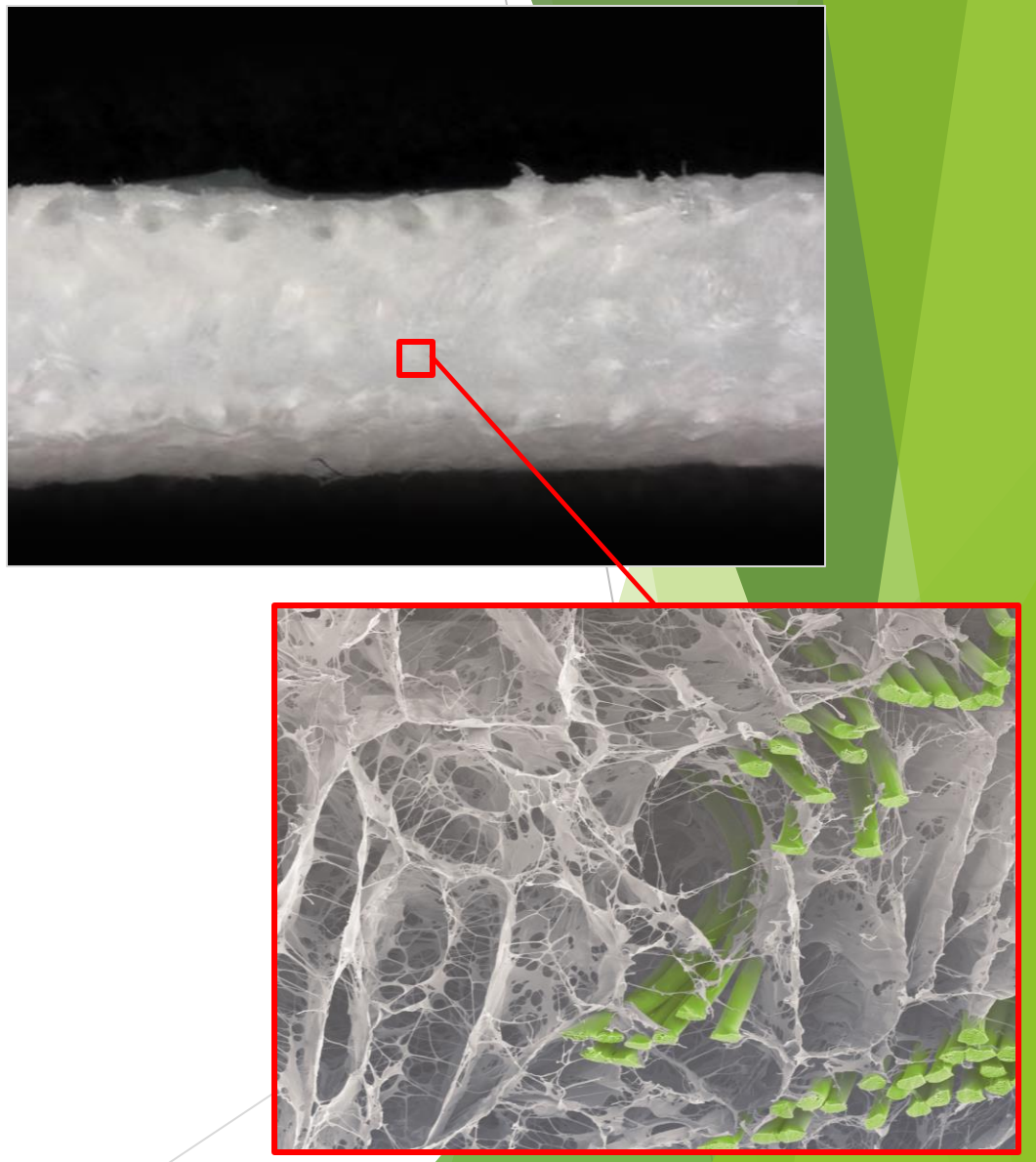
Introduction

- Patella instability and dislocations are very common injuries, especially in adolescent individuals.
- The medial patellofemoral ligament (MPFL) is the major medial restraint of the patella and acts as a checkrein to prevent the patella from dislocating laterally.
- When MPFL is disrupted, the literature indicates that the risk of recurrence of a patella dislocation can be from 50-90%. Typically, these injuries occur in younger individuals with the highest incidence occurs in those under the age of 21.
- Recurrent instability of the patella can result in progressive injury to the soft tissue and articular cartilage of the patella and femur.
- Studies have shown that simply repairing the MPFL may be inadequate to restore the strength of the native MPFL and prevent recurrent patella instability.
- Techniques have been developed to augment the MPFL reconstruction and prevent recurrent instability. Each method uses to augment the MPFL requires securing a graft to the medial side of the patella and to the attachment of the MPFL on the femur recurrent instability.

Introduction

- The BioBrace® (Biorez/CONMED, New Haven, CT) is a bio-inductive scaffold cleared by the FDA (K203267) intended to reinforce soft tissue where weakness exists and promote soft tissue healing.
- This implant has an open architecture consisting of highly porous resorbable type 1 collagen matrix reinforced with a bioresorbable poly-l-lactic acid (PLLA) backbone.
- It has significant tensile strength that allows load sharing during healing to reinforce the tissue repair .
- In an animal model, implant has been demonstrated to provide strength and promote bio-inductive healing. (1)



1. Walsh et al., 2021

Purpose/Hypothesis

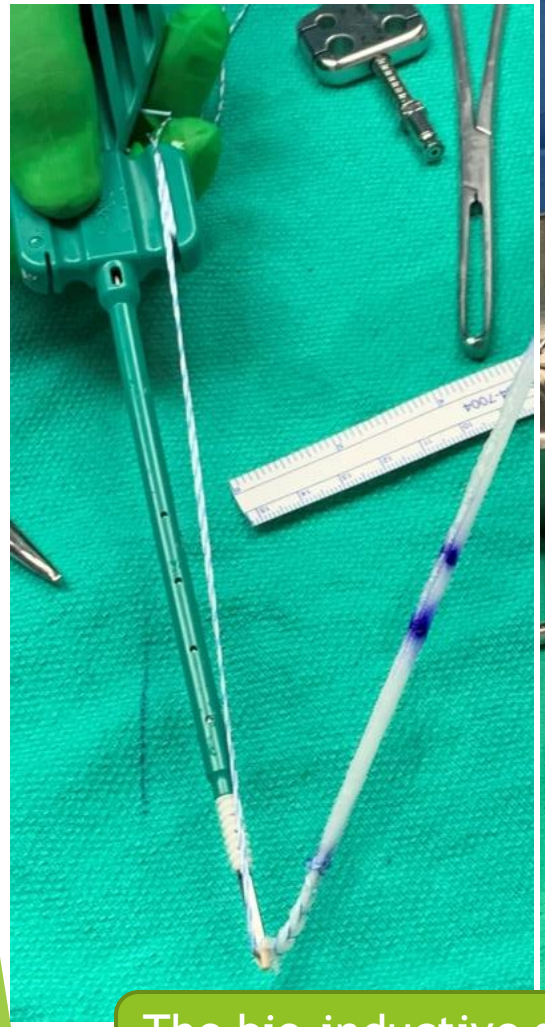
Clinical Experience

- Present preliminary case series (n=7) of MPFL repairs augmented with **Bio-inductive scaffolding**
- **Hypothesis:** No recurrent patellar dislocation at 1-year follow-up

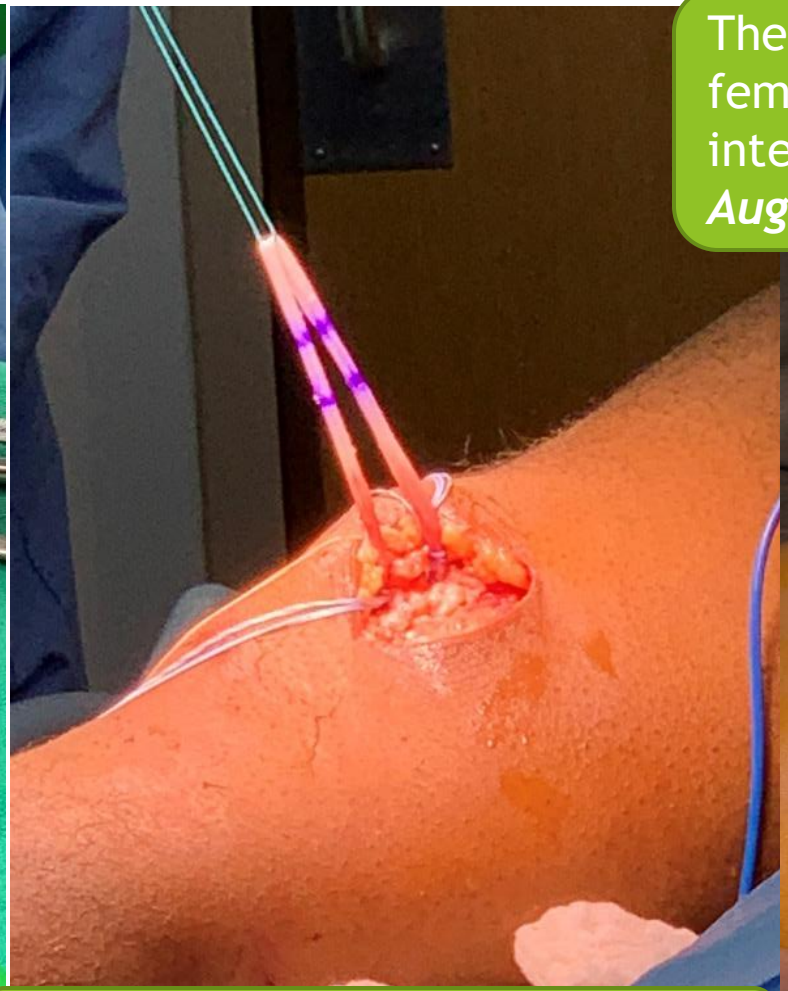
Biomechanical Pullout Testing

- Compare pullout strength between **Bio-inductive scaffold** and the Semi-T autograft in match paired cadaveric knees
- Hypothesis: The **Bio-inductive scaffold** and Semi-T pullout strengths are not statistically significantly different.

Surgical Technique

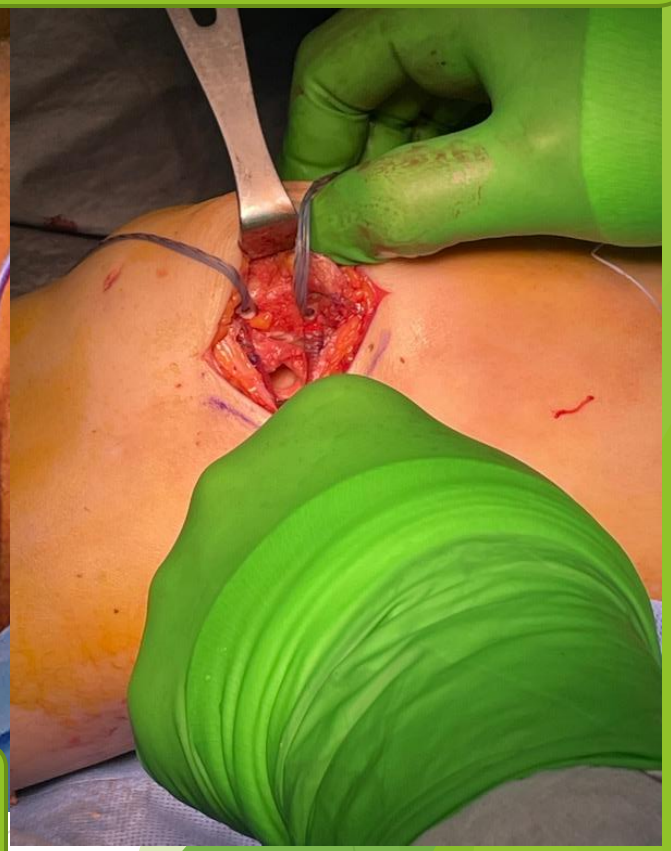


The bio-inductive scaffold is prepped on back table



The scaffold is secured to patella using two biocomposite anchors

The scaffold is secured to the femoral insertion of the MPFL via interference screw fixation. ***Augmentation is complete.***



Methods

- Seven patients underwent augmentation of a MPFL repair with the bio-inductive scaffold.
- The range of patients ages were 14 to 36 years with five patients being < 20 years of age (71.4%).
- A standard repair was performed and augmented with a 5-millimeter x 220-millimeter implant.
- Five of the seven patients (71.4%) had associated osteochondral injuries of the lateral femoral condyle or patella and had surgery acutely. Two patients (28.6%) had surgery after at least one additional episode of lateral dislocation. All patient has at least one year of follow-up

Biomechanical Test Method

- Six matched pairs of cadaveric legs without any history of previous surgery were obtained.
- Each matched pair was randomized into a semitendinosus autograft reconstruction group or bio-inductive scaffold repair group .
- A Semi-T graft was harvested from one leg of each matched pair (n=6).
- The bio-inductive scaffold implant were trimmed to be equal to the length of the harvested Semi-T grafts (220 mm).
- A #2 high tensile strength suture was used to whip-stitch the ends of all Semi-T and bio-inductive scaffold.
- Using standard surgical technique, each whip-stitched end was docked into the upper 2/3 of the patella.
- The patella was then dissected from each cadaveric specimen, and each patella was fixed in a methyl methacrylate base to allow for pull to failure testing.

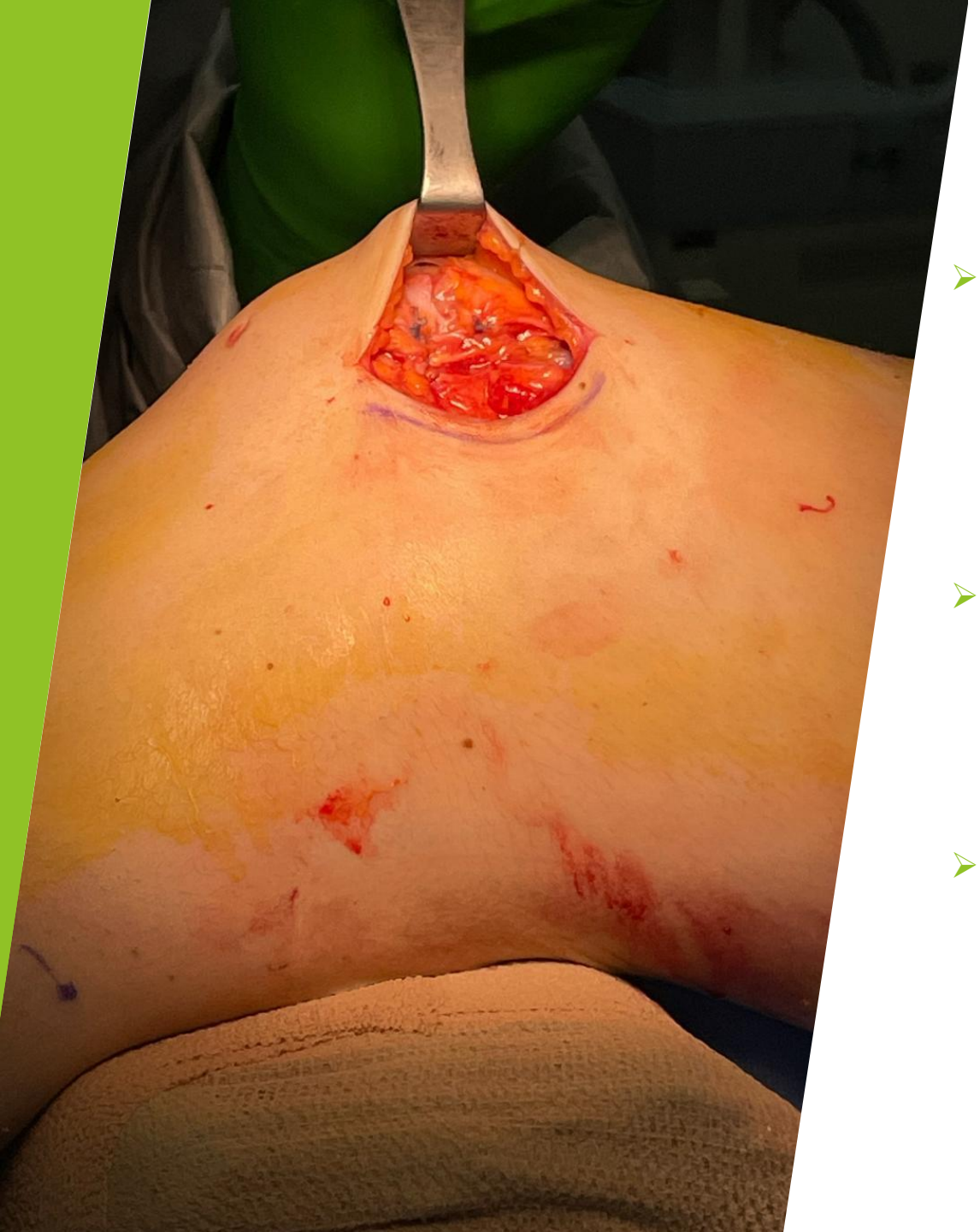
Semi-T Autograft Construct

BioBrace Construct

Test Parameters:

Preconditioning: 10 cycles from 0 to 30 N at 1 Hz

Pull to failure: 25mm/min



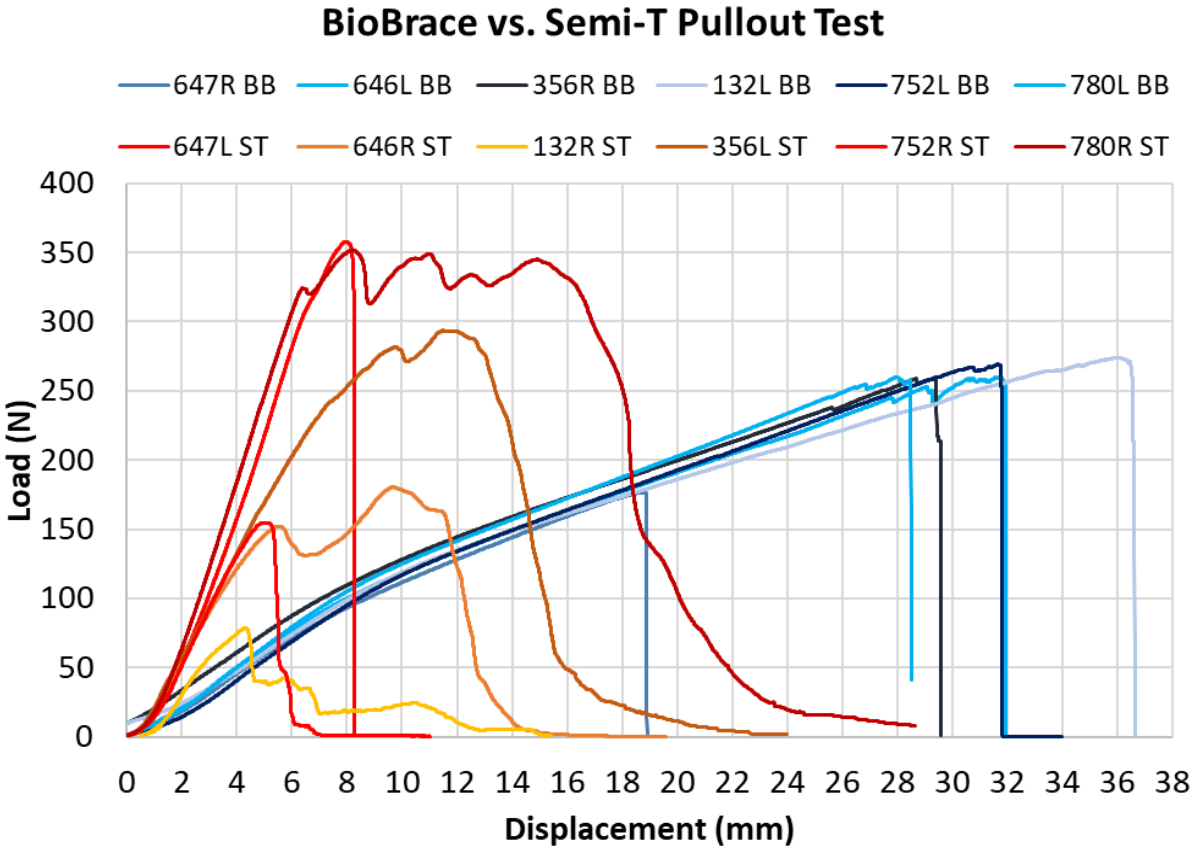
Results

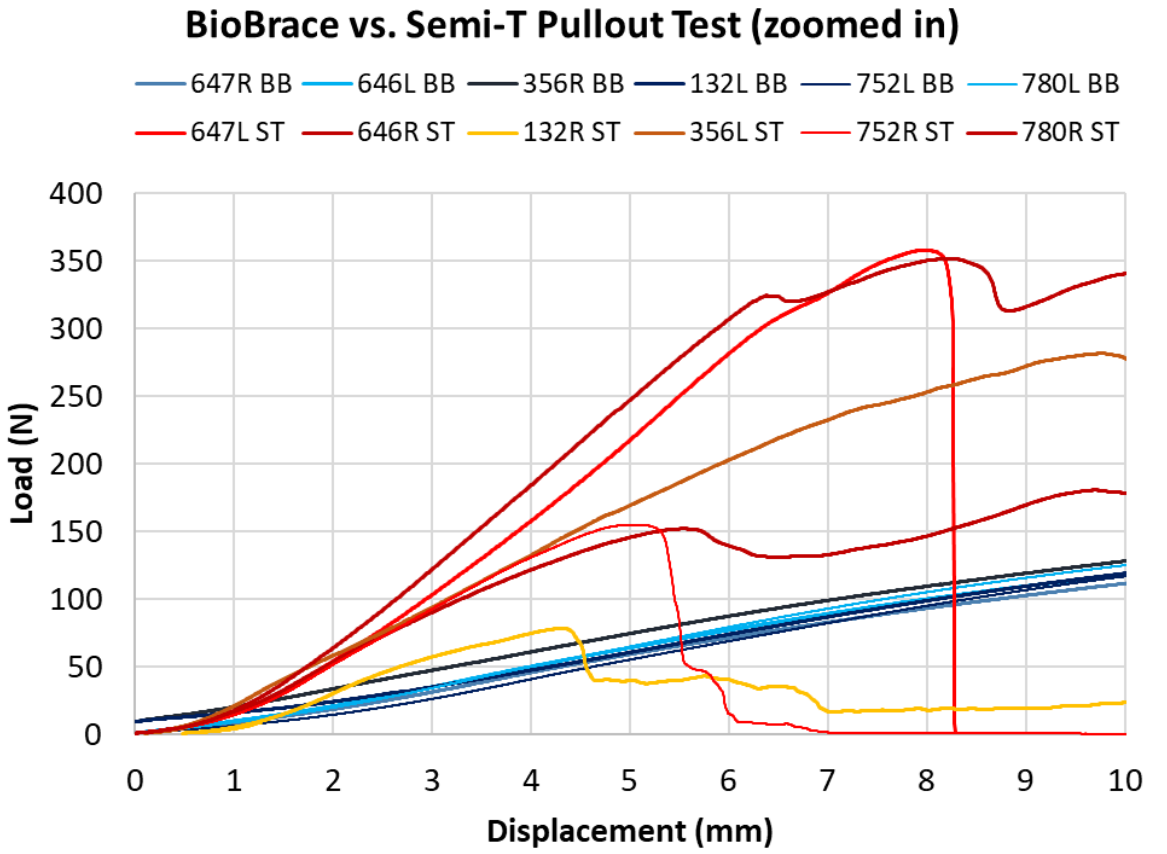
- All patients returned to pre-injury level of activities with one patient (chronic instability) was able to do a higher level of activity than prior due to the chronic nature of the patient's patella instability.
- All patients have full range of motion. with good patella mobility and solid end point on lateral glide. The range of return to sports/work was 3 to 10 months with an average of 6 months.
- There were no wound or graft complications. One patient required arthroscopic lysis of adhesions and manipulation under anesthesia due to decreased flexion and now has full range of motion.

MPFL Biomechanical Pullout Testing Results

Graft Reconstruction	Bio-inductive scaffold (BB)	Semi-T (ST)	Native MPFL [1]
Displacement @ failure (mm)	31.5 ± 4.8	10.0 ± 4.5	~12
Max Load (N)	249.3 ± 36.3	235.0 ± 113.6	178 ± 46
Stiffness @ 5mm (N/mm)	13.8 ± 0.6	49.5 ± 14.1	23 ± 6
Load @ 5mm (N)	63.0 ± 6.6	162.1 ± 71.5	~60

1) LaPrade, Arendt, Chahla et al. AJSM 2018





Discussion

- **Clinical Experience:**
- The patients in this clinical cases series had no recurrent patellar dislocations and no graft related complications at a minimum of one year follow-up.
- All the patients in this series returned to their pre-injury activity levels after MPFL repair and augmentation using the bio-inductive scaffold with interference screw fixation in the patella and femur.

- **Biomechanical Discussion:**
- There was no statistically significant difference in pullout strength (p-val = 0.77) between the bio-inductive scaffold (249.3N ± 36.3N) and Semi-T (235.0N ± 113.6N) double bundle constructs.
- While Semi-T was statistically significantly stiffer than the bio-inductive scaffold ($p < 0.01$), its pullout strength was highly variable: 50% (3 of 6) Semi-T constructs failed at or less than 5mm of displacement.
  - These early failures can be attributed to the inconsistency of autografts/allografts and the difficulty of working with variable graft diameters when using the same tunnel diameter and same anchor size.
- The bio-inductive scaffold is always the same size and length and therefore, provides consistent and reliable mechanical fixation compared to Semi-T. The bio-inductive scaffold had a much lower standard deviation in pullout strength compared to the Semi-T.

Discussion

- The bio-inductive scaffold provides a reliable solution to recurrent patellar instability in MPFL repairs.
- Adding a bio-inductive scaffold to an MPFL repair adds 60N at 5mm of displacement to the repair construct (native MPFL max load = 178N[1])
- The bio-inductive scaffold is consistent in size and shape and can be reliably docked into a 4.5 mm socket without any additional manipulation.
- Unlike allograft, the bio-inductive scaffold can be used off the shelf and is stored at room temperature with no prep required (i.e. thawing or hydration)
- A Semi-T autograft/allograft almost always has to be trimmed, and it can be difficult to secure it into the 4.5 mm sockets in the patella. Biomechanical testing demonstrated that the strength of the Semi-T/anchor/socket interface is less consistent than that of the bio-inductive scaffold's interface.
- Reproducible and secure fixation of the bio-inductive scaffold fixation is more consistently obtained in this study.

1) LaPrade, Arendt, Chahla et al. AJSM 2018

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