Examining the Efficacy of a Tri-Compartment Unloader Knee Brace During Physical Rehabilitation in Non-Surgical Patients with Anterior Knee Pain

Study Protocol

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Study: Examining the Efficacy of a Tri-Compartment Unloader Knee Brace during Physical Rehabilitation in Non-Surgical Patients with Anterior Knee Pain

- **Brief Summary:** This study will examine clinical outcomes related to pain and function in patients with anterior knee pain (i.e. focal patella and/or trochlea cartilage defect(s), patellofemoral arthritis) before and after standard of care, non-surgical management with and without the addition of a Tri-Compartment Unloader (TCU) knee brace during activities of daily living. Randomly selected participants will wear a TCU brace for several weeks during physical therapy and activities of daily living that is designed to reduce compressive forces in all three compartments of the knee during weight-bearing flexion. Our hypothesis is that TCU bracing will improve clinical outcomes related to pain and function.
- The standard of care will be the same for all patients and will include NSAIDs, tylenol, PT at Stanford, counselling regarding weight optimization.
- Injection therapy for knee osteoarthritis will not be performed during the study period. Patients will be excluded if they have had an injection within 3 months of study enrollment.
- Patients with major mechanical symptoms or those otherwise considered surgical candidates will be excluded from this study during initial evaluation.
- The length and follow up schedule will be the same for all patients.
- The only difference in groups will be the presence or absence of TCU brace usage.

Study Design

- **Participants**: Non-surgical patients with patellofemoral defects and chronic patellofemoral knee pain
- **Sample size:** 20 participants (10 per group)

Study Groups:

Group	Interventions/ Treatments
Experimental: TCU bracing	Device: TCU Knee Brace (Levitation 2) - Participants will be instructed to wear a TCU knee brace for a minimum of 3 hours per day during activities of daily living and undergo Dr. Sherman's standard of care rehabilitation protocol. - Participants will use the TCU knee brace during PT exercises, as determined by the PT team - Participants will undergo Dr. Sherman's standard of care rehabilitation protocol, including NSAIDs, tylenol, PT.
Control:	No Device - Participants will undergo Dr. Sherman's standard of care rehabilitation protocol only.

Outcomes Measures Outcomes will be measured at baseline (before any intervention), 6 weeks after commencing rehabilitation, and 3 months after commencing rehabilitation.

Primary Outcome Measures:

1. Knee Injury and Osteoarthritis Outcome Score (KOOS)
2. Pain intensity during activities of daily living (including walking, going up and down stairs, squatting, and sit to stand) measured with a Visual Analog Scale (VAS)

Secondary Outcome Measures:

3. Quality of life (EQ-5D)
4. Physical activity levels (Lower Extremity Activity Scale/LEAS)
5. Quadricep strength (girth)
6. Effusion grade
7. Painful crepitus with deep knee flexion
8. Knee range of motion
9. PET-MRI at baseline, 3 months and 6 months per Feliks Kogan protocol

Inclusion Criteria:

1. Anterior knee pain that worsens when the knee is flexed and bearing weight
2. Patellofemoral chondral defect(s) or patellofemoral arthritis detected with standard of care x-ray and/or MRI
3. Kellgren and Lawrence grade 0-3 of PF joint
4. Able to wear the TCU knee brace for a minimum of 3 hours per day
5. Over 18 years old, can understand written English
6. Coronal knee alignment within 7 degrees of neutral
7. Must be able to fit within an off-the-shelf knee brace size provided by Company
8. Must be able to participate in rehabilitation through Stanford

Exclusion Criteria:

1. Surgical intervention definitely indicated (major mechanical symptoms/failed substantial previous conservative measures) on the affected knee within the next year
2. Use of another brace designed to unload the knee or manage knee pain during the study
3. Varus/Valgus joint alignment > 7 degrees
4. Inability to be fit properly in an off-the-shelf brace provided by the Company
5. BMI >40
6. Bilateral knee symptoms