STUDY TITLE: Trapeziectomy with Ligament Reconstruction Tendon Interposition (LTRI) versus Arthrex Internal Brace for the Treatment of Basilar Thumb Arthritis: A Prospective Cohort.

1. STUDY AIM, BACKGROUND, AND DESIGN ABSTRACT

Thumb basilar arthritis is a debilitating condition often accompanied by subluxation of the 1st metacarpal and attenuation of the ligamentous stabilizers of the 1st carpometacarpal (CMC) joint. Trapeziectomy with ligament reconstruction and tendon interposition (LRTI)—often using the flexor carpi radialis tendon—remains one of the most common procedures performed to restore pain-free thumb mobility and CMC stability. This procedure is meant to relieve arthritic pain via trapeziectomy and prevent subsidence/instability via tendon interposition. However, numerous studies have suggested that trapeziectomy without LRTI has similar functional outcomes as compared to trapeziectomy with LRTI. Our supposition is that tendon grafts attenuate overtime and do not accurately recreate the stout ligaments of the 1st CMC joint. We hypothesize that utilizing suture tape as a suspensionplasty between the 1st and 2nd metacarpals will better prevent subsidence, and lead to improved outcomes such as pinch strength and patient-reported outcome scores

2. SUBJECT POPULATION AND ELIGIBILITY

Subject Population

- Patients within the Henry Ford Health System with clinically significant and radiographically proven basilar thumb arthritis who have failed reasonable conservative measures. This may or may not including bracing, physical therapy, over the counter medications, and corticosteroid injection.

Enrollment and/or Screening

- Participants will be patients presenting to Orthopedic Surgery clinic for basilar thumb arthritis who have failed reasonable conservative management. These may be established patients or patients new to our service line.
- Medical records will be reviewed to obtain basic patient demographic data, comorbid conditions, risk factors for surgery, and prior treatment modalities for their thumb arthritis.
- Eligibility criteria
  - Symptomatic basilar thumb arthritis confirmed on plain radiographs
  - Failure of reasonable conservative management including but not limited to:
    - Bracing
    - Physical therapy
    - Over the counter and prescription anti-inflammatories
    - Corticosteroid injections
- Patients will be screened for eligibility in all HFH Hand Surgery Clinics.

Inclusion Criteria:

- Patients of Henry Ford Orthopaedic Service Line
- Symptomatic basilar thumb arthritis as described above refractory to conservative management

Exclusion Criteria:

- Significant medical comorbidity precluding safe surgery, as determined by the operating surgeon. This may include cardiac disease, renal disease, liver disease, pulmonary disease, or heavy substance abuse.
- Requirement for additional procedures at the 1st carpometacarpal joint, including trapezoid excision—whole or partial—or metacarpal osteotomy. Of note other existing conditions requiring intervention on a separate surgical site such as concomitant carpal tunnel syndrome or trigger fingers will NOT be used as exclusion criteria.

3. STUDY PROCEDURES

Patients will be enrolled in the study once it has been decided via discussion between patient and provider that they have not succeeded with non-operative management and that surgery is indicated to preserve function and relieve pain from basilar thumb arthritis. This is not a randomized trial. Certain providers in the HFH system preferably perform trapeziectomy with ligament reconstruction tendon interposition (LRTI) and the patients of these providers will serve as the control group. Other providers have already performed trapeziectomy with Internal Brace suspension for several years; the patients of these providers will serve as the experimental group. Patients will undergo an informed consent process for participation in the study (please see attached documentation).

Trapeziectomy will be performed on the date of surgery. Patients enrolled in the experimental group will have the Internal Brace suspension device deployed intra-operatively exactly per manufacturer's instruction by the attending surgeon under supervision of an Arthrex representative. Patients in the control group will undergo LRTI according to standard operating steps. Post-operative immobilization protocol is determined by the operating surgeon. Patients will follow up at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months post-operatively. At each clinic visit patient reported outcome measures (PROMs) as well as an abbreviated Disabilities of the Arm, Shoulder, and Hand (QuickDASH) will be obtained. We will also obtain grip and pinch grip strength measurements. Finally we will routinely obtain plain radiographs of the hand to assess for presence of 1st metacarpal subsidence.

Our primary outcome is pinch strength at 6 months; secondary outcomes include PROMIS, QuickDASH, and pinch strength at all time points as well as metacarpal subsidence. We hypothesize that the Internal Brace is a stronger construct than tendon interposition, and this will lead to improved grip strength and patient outcome measures, as well as decreased radiographic subsidence.

Sample Size:

The minimum clinically important difference (MCID) for pinch strength in patients with basilar thumb arthritis has been found to be around 0.35kg; for grip strength it's 0.84 kg[1]. This is the meaningful difference that this study will be powered to detect. The same study demonstrated a standard deviation of pinch grip strength in the CMC OA population of 0.7kg. To be powered to 80% with alpha 0.05 in detecting a difference of 0.35kg, we would need around 50 total patients (25 per trial arm).

These numbers unfortunately are based on relatively low-quality evidence, as this is truly a pilot study of how the Internal Brace affects grip strength. Thus, it is almost impossible to do an accurate power analysis. We anticipate the 25 patients per treatment arm is the maximum number we'd be able to achieve in a reasonable time frame, and so this is our goal.

Surgical Technique:
Surgical technique for both treatment arms is generally identical until device implantation. All surgeons at our institution perform the trapeziectomy under a pre-operative axillary block and tourniquet. Patients are administered sedation by the anesthesia team and positioned supine with the operative extremity extended onto a hand table. One of two approaches is generally used; either the radiopalmar (Wagner) approach or a dorsal approach. Both require careful protection of the radial artery and superficial branch of the radial nerve during the approach, and once capsulotomy of the 1st CMC joint has been made the surgery is generally identical regardless of the approach used. After capsulotomy portable fluoroscopy is used to correctly identify the trapezium and 1st CMC joint. The trapezium is then either removed whole or fragmented and removed piecemeal.

At this point surgical technique diverges based on the treatment arm. For the InternalBrace group, the InternalBrace anchor is placed in the base of the 2nd metacarpal according to Arthrex instructions. Fluoroscopy confirms position. Next the second anchor (with suture tape fed through) is placed into the base of the 1st metacarpal. This can either be on the radial side of the metacarpal base perpendicular to the shaft to form a sling, or directly into the base collinear with the shaft. The internal brace is tensioned with the thumb in maximum abduction. Overall procedure is very similar to what has been demonstrated by Arthrex educational materials, particularly Dr. Steven Lee's tutorial on CMC SuspensionPlasty with the InternalBrace. Positioning is again checked on fluoroscopy. Closure of the capsule, deep tissues, and skin is performed. The patient is placed into a thumb spica splint with the thumb abducted.
For patients undergoing LRTI, the FCR is generally the graft of choice. This is divided proximally at the musculotendinous junction in the forearm through a separate incision. The tendon is delivered through the thumb incision and woven through the fenestrated base of the 1st metacarpal and then sutured back to itself. The remaining tendon length is used to fill the trapeziectomy defect. Closure is again performed in layers, and the patient is placed into a thumb spica splint.

Follow-up:
Patients are seen post-operatively at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months. At each post-operative visit they complete the following questionnaires: PROMIS Upper Extremity, PROMIS Depression, PROMIS Pain Interference, QuickDASH. They are also asked an anchor question: "Since treatment, how would you rate your overall function", to which they may reply on a 7-level Likert Scale from "Much Worse" to "Much Improved". Plain films are obtained to look for any metacarpal subsidence. Finally, pinch grip and grip strength measures are obtained as well. These data are all recorded in the EMR. Data analysis is done at each time point, with the primary outcome measure being pinch grip strength at 6 months.

Statistical Analysis:
-Net changes in grip strength from pre- to post-operatively between the three treatment groups will be compared using ANOVA testing
-Mean post-operative PROMIS and QuickDASH scores at each time point will also be compared using ANOVA

4. ANTICIPATED RISKS

We do not anticipate that the study itself introduces any additional risks to the patient population. Trapeziectomy with LRTI and with InternalBrace suspension are both procedures that have been performed by our department for several years. We do not plan to change our indications or procedure volume based on the performance of this study. Rather we hope to prospectively compare the outcomes of the two surgeries.

Each procedure does include risks which are explained to the patient during the consent process. These risks are not different between the two procedures. Risks include risks of general anesthesia, risks of the pre-operative nerve block, damage to neurovascular structures such as the radial artery or superficial branch of the radial nerve, bleeding, pain, infection, and potential re-operation.

5. ANTICIPATED BENEFITS

We hope that InternalBrace suspension shows less attritional wear over time than a tendon graft, and that this will lead to greater preservation of grip strength, namely pinch grip. This will hopefully lead to earlier return to work, higher levels of function, and greater patient satisfaction.

6. RENUMERATION/COMPENSATION

There is no compensation for participating in the study.

7. COSTS

There are no additional costs associated with the study procedures. We are seeking a grant from Arthrex; this is to cover the salary of a research assistant who is critical to the study as well as conferences and associated travel expenses.

8. ALTERNATIVES

The alternative is non-operative management, which is generally exhausted prior to performing trapeziectomy and includes OTC anti-inflammatories, corticosteroid injections, and bracing. Even if electing to undergo operative management the patient may elect to not be included in the study.

9. CONSENT PROCESS AND DOCUMENTATION

Patients will be presented with consent for the clinical trial at the time of surgical consent, in the preoperative area before surgery, or via phone with the consent emailed to the patient. Understanding will be ascertained using the teach-back method of informed surgical consent. Language used in the surgical consent will mimic a sixth grade reading level. The patient must be able to verbally state their diagnosis and planned intervention. The risks and benefits of the proposed treatment will be detailed and the patient must repeat these back to the person obtaining consent. Voluntary withdrawal at any point will be stressed. The alternative to study inclusion (no randomized treatment) will be presented as a perfectly reasonable course of action. Patients will be allowed unlimited time to ask and have their questions answered by an M.D. involved in the study. Non-English speaking persons will be consented according to IRB guidelines in the following manner: A certified non-family member fluent in the patient's native language and English will be present to review the English patient consent form with the patient and a Short Form Consent from the IRB website in the patient's native language. If freely consenting non-English speaking patients represent more than 5 enrolled patients at any point in the study conduction, the full IRB consent form will be translated into the native language of those represented languages and this new consent will be submitted as a "request for planned changes" to the Henry Ford IRB Committee before any further non-English speaking patients are enrolled.

10. WITHDRAWAL OF SUBJECTS

Subjects may elect to withdraw from the study at any point in time and this will not affect their care from that

point onward. They will be withdrawn from the study by the investigator if they are unable to make adequate post-op follow-up appointments.

11. PRIVACY AND CONFIDENTIALITY

Data will be stored on a password protected computer. Patient data will either be located in the chart or kept in a locked spreadsheet that contains no patient identification aside from the patient MRN. This will only be accessible to the investigators. We will also obtain HIPAA authorization in order to access the medical record.

12. DATA AND SAFETY MONITORING PLAN

The principal investigator will perform safety monitoring. The principal investigator will be responsible for premature cessation of the study if unacceptably high risks are incurred.

We will report any problems or adverse events to the IRB via email.

13. QUALIFICATIONS OF THE INVESTIGATOR(S)

Charles Day, MD. Principal investigator. University of California San Francisco School of Medicine, University of Pittsburg Medical Center Orthopaedic Surgery Residency, Washington University Hand Surgery Fellowship. Extensive experience in research and academics within orthopaedics. All co-investigators are medical students or orthopaedic surgery residents operating under the guidance of Dr. Day.

14. REFERENCES

1. Villafañe JH, Valdes K, Bertozzi L, Negrini S. Minimal clinically important difference of grip and pinch strength in women with thumb carpometacarpal osteoarthritis when compared to healthy subjects. *Rehabilitation Nursing*. 2017;42(3):139-145. doi:10.1002/rnj.196