Tendon transfer arthroplasty vs. LRTI arthroplasty for surgical treatment of basal joint arthritis of the thumb: A randondized, double-blinded clinical trial

Benton E. Heyworth
Faculty Advisor: P. Melvin Rosenwasser

A. Summary of Proposed Research

Basal joint osteoarthritis (OA) of the thumb is a common, debilitating disease that can have a significant adverse effect on hand function. When conservative therapies, including NSAIDS, corticosteroid injection, splinting, and thenar muscle strengthening exercises, are ineffective, operative therapies such as simple trapeziectomy and trapeziectomy with interposition of tendon and/or muscle are generally pursued. All operative therapies are designed to preserve motion and prevent the complications of pain, instability, weakness, infection, and prolonged disability, which have been reported even after early post-operative success in some cases. To prevent these complications, careful selection of surgical candidates must be taken, along with attention paid to the specific procedural technique perfon-ned. Burton and Pellegrini developed and popularized the trapeziectomy with ligament reconstruction and tendon interpositon (LRTI) arthroplasty[1] which was improved upon by Eaton and Littler in 1983.[10] This technique is now the most commonly performed procedure for symptomatic treatment of the pain and instability that result from osteoarthritis at the basal joint of the thumb.[2] However, the specific technique championed by Burton and Eaton involves the creation of a suspensionplasty, in which the base of the first metacarpal is tethered to the second metacarpal for stability and prevention of dorsal subluxation during normal hand function. This suspensionplasty entails creating an oblique hole through the dorsal cortex of the base of the metacarpal to allow a freed segment of the flexor carpi radialis (FCR) tendon to pass through the hole and be secured on the radial side of the metacarpal in an attempt to provide additionally stability to the tendon arthroplasty. This boring process, as well as the freeing of the segment of the FCR, are associated with an inherent risk of severe complications, such as superficial and recurrent motor branch of the median nerve, princeps pollicis artery injury and hemorrhage, tendon transection, and bony fragmentation of the metacarpal. Several variations of the LRTI procedure are currently in use, but there is no long-term literature supporting the use of such variations. One technique that has been performed since the early 1980's by Rosenwasser omits the boring phase of LRTI, thus completely preserving the structural integrity of the base of the first metacarpal and placing surrounding neurovascular structures at significantly less risk. Metacarpal stability is instead achieved through a simpler and less invasive tendon transfer step, involving the proximal segment of the abductor pollicus brevis (APB) released from the trapezium and transferred to the FCR tendon, I cm proximal to its insertion on the second metacarpal. The purpose of this study is to investigate the safety and effectiveness of the interposition arthroplasty and tendon transfer technique employed by Rosenwasser by comparing it to the current standard of care for operative technique. The study will compare the two techniques based on complication rates and the differences of pre-operative and post-operative functional outcome measures at a minimum of 3 years and a maximum of 20 years to hand function and symptoms prior to the procedure. Patients will be asked to complete a questionnaire, undergo radiograph evaluation, and be subject to a simple physical examination of the hands. The questionnaire will include outcome domains assessing changes in subjective pain, through a visual analog pain scales (VAS) as well as a commonly used, validated, functional outcome measure for the upper extremity, known as the Disabilities of the Arm, Shoulder and Hand (DASH) score. The radiographic evaluation will assess changes in the average subluxation of the base of the first metacarpal upon pinch grasp and average loss of scaphometacarpal space at rest. The physical exam will assess changes in joint range of motion, grip strength, and pinch strength. This study is of significant clinical value because the long-term follow-up of this procedure has

the potential to widely introduce a less invasive, more efficient procedure for basal joint arthroplasty than the current standard of care.

B. Specific Aims

The purpose of this study is to assess the clinical and functional results of a variation of operative treatment for basal joint arthritis when compared to the standard of care. The clinical assessment will consist of radiographic evaluation of the hands, a standard physical exam of the hands employed by occupational therapists and hand surgeons, and collection of subjective, patient-based self-assessments, through use of 2 well-established functional and pain outcome measurements.

C. Background and Significance

a. Background

Osteoarthritis of the basal joint of the thumb is a debilitating, age-related disease that affects a huge segment of the adult population. Recent studies have estimated that in adults ages 47-76, approximately 42% of women and 26% of men will show radiographic evidence of basal joint arthritis, suggesting a disease incidence in the tens of millions of people in the U.S. [4] Many of these patients are symptomatic, with the most common presenting complaints being pain and decrease in manual activities essential to daily living, such as gripping objects.

First-line treatment of basal joint OA generally consists of conservative, non-operative therapies, the most common of which is rest.[5] This is achieved through immobilization of the thumb and wrist with splinting and modification of manual activities. The major disadvantages of this form of treatment, however, are patient discomfort, restricted range of motion, further limitation in hand function and high rates of noncompliance. Use of NSAIDs and intra-articular corticosteroid injections are other common forms of nonsurgical intervention that may be employed in conjunction with splinting. However, chronic NSAID use is associated with significant adverse effects, such as peptic ulcer disease and gastrointestinal bleeding. Relief of pain from steroids is usually temporary, and repetitive injections may have destructive effects on the joint capsule and on the already-degenerated articular cartilage of the joint'.

A number of surgical treatments for basal joint arthritis are available, but are generally pursued only after conservative treatment has failed to relieve night pain and functional pain. Because of the prevalence of the condition, however, operative treatment is relatively common. As Bagge asserted, the trapeziometacarpal joint is overwhelmingly the most common site in need of surgical reconstruction in the osteoarthritic upper extremity. [6] Those patients for which surgery is indicated include older age patients and those patients with a low demand hand. Contraindications include young patients, a high demand hand, history of prior hand infection, presence of pre-existent carpal or radiocarpal implant, and those patients with narrow web space for thumb-index clefts.

Though several alternative procedures have been pursued in previous decades, such as implantation of a prosthetic trapezium or arthrodesis, soft tissue interposition has become the gold standard, particularly for the procedure in elderly, female patients, in whom the disease is most common. While excision of the trapezium makes it possible to avoid the limited motion associated with an arthrodesis and the material wear associated with implant arthroplasty, weakness and instability limit the long-term functional results in the absence of ligament reconstruction according to Burton and Pellegrini [1]. The LRTI technique by Burton and Pellegrini involves removing the trapezium and boring a hole through the base of the radial cortex of the first metacarpal by passing a six mm gouge through the medullary canal to allow the tendon of the FCR to pass through and be used for ligamentous recontstruction as a suspensory force.[7]

Unsupported normal function of the thumb may be started 12 weeks following the surgery. Long-termfollow-up shows that the function of the thumb may continue to improve for as long as 6 years.[1] The technique employed by Rosenwasser involves a muscle and tendon transfer that utilizes tendon and muscle belly harvest from the proximal palmaris longus in the forearm and a distally freed

segment of the FCR, which is then wrapped around the abductor pollicus brevis. This transfer serves to substitute the ligamentous support removed by the trapeziectomy and maintains stable function of the metacarpal without subluxation of hyperextension. The procedure represents a relatively less invasive replacement, while still utilizing the soft tissue interposition with a rolled tendon graft. The graft is stabilized with soft tissues closed over the ball of tendon, but does not entail drilling of holes into bone, thereby protecting vital neurovascular structures and eliminating the risk of shattering the first metacarpal bone from drilling. Moreover, the technique allows for resumption of motion and function at three weeks post-op. While the surgeon's experience with the outcomes of the procedure are excellent, compared to those reported in the literature, a formal, long-term follow-up study is necessary to establish if the success rates are comparable to the less efficient, more invasive techniques.

b. Significance

Because tens of millions of people in the U.S. demonstrate evidence of basal joint OA and the trapeziometacarpal joint is the most common site in need of surgical reconstruction in the osteoarthritic upper extremity, the demand for a more efficacious form of operative treatment of the disease is considerable. Any intervention that could serve as a safe and effective alternative treatment would likely lead to significant improvements in the quality of life for a large segment of the population. Increasing clinician and patient awareness and confidence in an efficient, less invasive procedure through long-term follow-up could significantly enhance the spectrum of treatment regimens provided by hand surgeons and minimize well-established complications that adversely affect patients' manual function.

D. Experimental Methods and Design

a. Study Design:

i. General

The study will be a prospective clinical trial with clinical and radiographic assessment of patients who undergo excisional arthroplasty with a rolled tendon graft interposition followed be randomly assigned metacarpal stabilization technique. The randomization process and study protocols will be discussed with patients as part of pre-operative planning office visits. The follow-up clinical assessment will be also be described as consisting of radiographic evaluation, a physical exam of the hands, and subjective self-assessment through a questionnaire. The patients will, of course, be offered the opportunity to pursue additional treatment, in the form of persistent conservative therapies and pain-relief methods.

ii. Statistical Analysis

Among the outcome metrics will be difference scores, visual analogue pain scores, DASH scores, and range of motion and strength scores. Categorical analyses will be performed for applicable outcome measures using chi-squared testing, while continuous measures will be analyzed using Student's T-tests.

b. Study Procedure

c. Informed Consent

The details and requirements of study enrollment and the study protocol will be explained to all patients verbally, as well as through informed consent documentation, the signing of which will be required for all patients prior to enrollment. This informed consent form will consist ofstandard sections and has been included in this submission for review by the IRB. All investigators have been educated and certified in Good Clinical Practice (GCP) standards, as offered by the instructional course offered by the medical center. All investigators and study protocols, including the informed consent process, will comply with HIPAA regulations.

d. Radiographic Assessment

Patients will receive radiographic staging of their osteoarthritis upon study enrollment, if not performed in the previous 6 months. Radiographs, to be read and assessed by an orthopedic surgeon, are classified in a standard osteoarthritis staging system, as follows: [5]

Stage 1: Shows no degenerative changes. Cartilage-space widening or mild subluxation may be present.
Stage 11: Characterized by narrowing of the cartilage space and the presence of osteophytes less than 2mm in diameter.
Stage III: Displays more narrowing and subchondral sclerosis and osteophytes measuring more than 2 mm in diameter.
Stage IV: Characterized by advanced degenerative changes involving both the TM and ST joint.

Radiographic stage will be analyzed as an additional subset, with regard to patient improvement and response to treatment. However, nearly all patients will be either stage III or stage IV.

Submetacarpal space on AP radiographs and metacarpal base subluxation on stress radiographs will both be used as independent measures and correlated with clinical and functional outcomes.

e. Medical History

A brief medical history will be taken from all enrolled patients, to ensure that any preexisting medical illnesses or comorbid conditions are identified and documented that could alter functional outcomes or may limit safe and effective participation in the study.

f. Physical Exam Evaluation

Patients will be assessed by a clinician for range of motion in the affected thumb, as well as grip strength and pinch strength in the affected (and unaffected) hand. Range of motion will be measured in with a standard finger goniometer. Grip strength will be assessed by a Jamar dynamometer. Pinch strength with be assessed by a 30-lb pinch dynamometer. All measurements will be made according to hand therapy standards described in the Journal of Hand Therapy[7]

g. Administration of Questionnaires

The original difference score, a visual analog pain scale forin and the Disabilities of the Arm, Shoulder and Hand (DASH) form will be given to patients, and their completion overseen by the clinical evaluator or research assistant.

h. Outcome Assessment

Four methods will be used to determine treatment effectiveness in each subject. The four methods include: 1) Difference score, 2) Disabilities of the Arm, Shoulder and Hand (DASH) scores 3) Visual Analogue score. 4) Complication Rate.

E. Study Drugs

None

F. Medical Devices

None

G. Study Questionnaires

All patients will complete the Disabilities of the Arm, Shoulder and Hand (DASH) and VAS questionnaires. The Principal Investigator and research assistants will gather the data.

H. Study Subjects

The subject population will consist of patients who undergo excisional arthroplasty with a rolled tendon graft interposition by any of the four listed surgeons for treatment of basal joint osteoarthritis. The inclusion and exclusion criteria will be as follows:

a. Inclusion criteria

- Patients scheduled to undergo excisional arthroplasty with a rolled tendon graft interposition for treatment of basal joint osteoarthritis
- Patients demonstrating a history of failed conservative treatment or minimal improvement over time
- Patients 40 years and older at time of surgery
- Patients who are capable of providing informed consent

b. Exclusion criteria

- Patients younger than 40 years old at the time of surgery
- Patients with significant previous trauma to the basal joint of the affected hand after the time of surgery, such as fracture
- Patients with known comorbid, debilitating conditions currently in the affected hand
- Patient's with neuromuscular disease affecting the operated hand, not caused by the operation
- Patients with known inflammatory arthritic conditions, such as rheumatoid or psoriatic arthritis
- Patients with basal joint infection of the affected hand
- Patients who are demented or are unable to provide informed consent
- Patients unable to comply with study guidelines

I. Recruitment of Subjects

Patient's will be identified during office visits of any of the four participating surgeons. All willing and eligible patients will be asked to provide written consent.

J. Confidentiality of Study Data

All study data will be uniquely coded using a numeric system starting with the number 01. No identifiers such as hospital unit number, social security number, initials, phone numbers, addresses or names will be used. The data will be stored on secure servers that can only be accessed by password. The key to the codes will be kept in a folder placed in a locked drawer and will exist only in this hard copy.

K. Potential Conflict of Interest

Neither the investigator nor the University has a proprietary interest in the therapeutic technique under investigation, and they will not benefit financially in any way from the results of the investigation.

L. Location of the Study

The study will be conducted at New York Presbyterian Hospital, Columbia Campus, Hospital for Special Surgery, or The New York Hand Center affiliated with St. Luke's/Roosevelt Hospital system.

M. Potential Risks

The risks of participation in this study do not exceed those stemming from operative treatment of basal joint surgery. No patients for whom such treatment would not otherwise be pursued outside of study inclusion will be allowed to enroll.

N. Potential Benefits

Patients who participate in the study may improve their manual functioning and their quality of life as a result of the operation they receive during their period of involvement in the study.

O. Compensation to Subjects

Subjects will not receive compensation for their participation in this study. All treatments and office visit charges will be the same as those for patients not in the study undergoing similar surgical and medical treatment.

P. Costs to Subjects

Subjects will not incur any additional costs as a result of participating in this study.

Q. Minors as Research Subjects

Minors will be excluded as research subjects in this study.

R. Radiation or Radioactive Substances

If patients have not received radioagraphic staging of their basal joint osteoarthritis in the 6 months prior to enrollment in the study, standard radiographs of both hands will be taken for these purposes. Both lateral and AP views will be performed as part of the standard post-operative assessment for basal joint OA and basal joint arthroplasty. The two radiographs, together, will expose a portion of a patient's upper extremities, specifically all structures distal to the proximal forearm, to an effective dose of approximately 0.35 microSievert of radiation; such a level of exposure is considered of negligible risk to the patient, with an associated risk of I in one hundred million of developing a fatal cancer[9]. If any patients have received an extremely large number of previous upper extremity radiographs or significant levels of lifetime exposure to radiation, of any kind, they will be excluded from the study.

S. References:

1 Burton RI, Pellegrini VD, Jr. Surgical management of basal joint arthritis of the thumb. Part 11. Ligament reconstruction with tendon interposition arthroplasty. Journal of Hand Surgery - American Volume 1986; 11(3):324-32.

2 Yang SS, Weiland AJ. First metacarpal subsidence during pinch after ligament reconstruction and tendon interposition basal joint arthroplasty of the thumb. Journal ofHand Surgery - American Volume 1998; 23(5):879-83.

5 Barron OA, Glickel SZ, Eaton RG. Basal joint arthritis of the thumb. Journal of the American Academy of Orthopaedic Surgeons 2000; 8(5):314-23.

6 Bagge E, Bjelle A, Eden S, Svanborg A: Factors Associated with Radiographic Osteoarthritis: results from the population study 70-year-old people in Goteberg. J Rheumatology. 18:1218-22, 199 1.

7 Poole JU, Pellegrini VD, Jr. Arthritis of the thumb basal joint complex. Journal of Hand Therapy 2000; 13(2):91-107.

8 Chaisson CE, Zhang Y, MacAlindon TE, et al. Radiographic hand osteoarthritis: incidence, patterns, and influence of pre-existing disease in a population based sample. J Rheum 1997; 24(7):1337-1343.

9 Poole JU, Pellegrini VD, Jr. Arthritis of the thumb basal joint complex. Journal of Hand Therapy 2000; 13(2):91-107.

10 Barron OA, Glickel SZ, Eaton RG. Basal joint arthritis of the thumb. Journal of the American Academy of Orthopaedic Surgeons 2000; 8(5):314-23.

11 Navsarikar A, Gladman D, Husted J, Cook R. Validity assessment of the disabilities of arm, shoulder, and hand questionnaire (DASH) for patients with psoriatic arthritis. J Rheumatol 1999; 26(10):2191-4.

12 Huda W, Gkanatsios NA. Radiation dosimetry for extremity radiographs. Health Phys 1998; 75(5):4929.

13 Adams ME, Lussier AJ, Peyron JG. A risk-benefit assessment of injections of hyaluronan and its derivatives in the treatment of osteoarthritis of the knee. Drug Saf 2000; 23(2):115-30.