

Title of Research Project: Effectiveness of ASTYM treatment when added to traditional therapy for treatment of de Quervain's tenosynovitis

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I. Purpose of Study and Background

- **Purpose of study:**

To determine if the addition of Astym treatment to traditional therapy produces a more positive outcome than traditional therapy alone for the treatment of de Quervain's tenosynovitis.

- **Background:**

de Quervain's disease is caused by a stenosis of the first dorsal compartment of the wrist^{1, 2 and 3} that contains the tendons and synovial sheaths of the abductor pollicis longus (APL) and the extensor pollicis brevis (EPB) muscles.⁴ The APL acts at the base of the first metacarpal to abduct the thumb while the EPB extends the metacarpophalangeal joint and contributes to radial abduction of the thumb.⁵ The narrowing of the compartment is a result of the thickening of its septum^{2 and 3} with no sign of acute inflammation^{1, 3, 6 and 7} but with signs of chronic degeneration.^{2, 8 and 9} During menopause age,^{1, 3, 7 and 9} women are especially vulnerable to this condition. A higher prevalence is also noted during pregnancy or in the postpartum period.^{10 and 11} Neither ethnicity¹ nor hand dominance^{1 and 7} have an influence on the appearance of symptoms. The disease affects 1.3% of working women and 0.5% of working men in general.¹²

The main presenting symptom is pain on the radial side of the wrist, which can radiate proximally or distally and is aggravated by thumb or wrist movements.^{1, 2, 3, 6 and 9} Other possible symptoms include impaired function of the thumb,^{1, 3 and 6} stiffness,¹ paresthesia,^{1, 6 and 9} sleep disturbance,^{1 and 6} swelling or tenderness over the radial styloid process,^{1, 2, 3, 6 and 7} and thumb weakness.^{13 and 14}

To date, there is no recognized, standardized, or consistent therapeutic treatment program that has been documented for the management of de Quervain's. Traditional treatments for de Quervain's tenosynovitis include: (1) injection of corticosteroids into the first dorsal compartment; (2) immobilization of the wrist and thumb in a neutral position with a forearm based thumb spica splint; (3) a combination of both. Several case series and clinical trials have studied corticosteroid injections alone and in combination with other modalities including splinting and NSAIDS. The success rate with injections of various corticosteroid formulations ranges from 62-93% ^{15, 16 and 17}. Other conservative treatments include adjusting the work environment, non-steroidal anti-inflammatory drugs (NSAIDS), ultrasound, manipulation, nerve and tendon gliding, stretching, and strengthening^{15, 16 and 17}. Although NSAIDS, splinting, and local corticosteroid injection often show promise in relieving symptoms initially, several researchers have found that long-term successful outcomes are poor²⁰

In a 3-armed study, Weiss et al. studies use of corticosteroid injections and splinting together and separately to determine their clinical effect. They observed a 67% improvement with injection alone, 57% improvement with both injection and splinting, and 19% improvement with splinting alone.²¹ Lane et al. separated their study population into minimal, moderate, and severe illness based on clinical symptoms. They identified a success rate of 88% with use of NSAIDS and splints in patients with "minimal" symptoms but only a 32% success rate with "moderate to severe" symptoms²². There are surprisingly few scientific studies that identify the efficacy of treatment for this relatively common condition. Systematic reviews that show inconclusive results because of poor quality studies indicates that clinicians have yet to discover the "magic bullet" that will resolve the most recalcitrant tendinopathies of the elbow, wrist, and hand²⁰. This is especially true if patients are hesitant or unwilling to receive a corticosteroid injection.

The Astym treatment technique (Performance Dynamics, Muncie, IN) has been used in the NYU Langone Medical Center for 4 years with level 5 evidence as an alternative to corticosteroid injections for the treatment of de Quervain's tenosynovitis. Astym is based on an expansion of soft tissue massage and manual therapy concepts. It incorporates the use of specially designed hand-held instruments that enable clinicians to deliver a controlled amount of microtrauma into specific areas of connective tissue structures. Astym tools are not FDA approved and meet the definition of a non-significant risk device secondary to not meeting the criteria for a significant risk device because:

1. It is NOT an implant with potential serious risk to subjects' health, safety or welfare.
2. It is NOT purported or represented for use supporting or sustaining human life with potential serious risk to subjects' health, safety, welfare.
3. It is NOT for substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment or human health with potential serious risk to subject health, safety, welfare.
4. It does NOT present a potential for serious risk to subject health, safety, welfare.

It is theorized that this treatment process leads to the reabsorption of fibrosis and soft tissue regeneration.

In a study by Davidson et al²⁴ Astym was utilized to introduce a controlled amount of micro- trauma into enzyme-induced injured rat Achilles tendons. This controlled injury caused a small amount of microvascular trauma and hemorrhage that induced a localized inflammatory response. In Davidson's study, a light microscope demonstrated increased fibroblast proliferation in the Astym study group²⁴. They concluded that although healing in rats may not translate directly to humans, the findings suggest that Astym treatment approach may promote healing via increased fibroblast recruitment. In a follow-up study by Gehlsen et al,²⁵ they examined morphological changes in the rat Achilles tendon after enzyme-

induced injury with collagenase and subsequent pressure variations with the Astym process. A pressure transducer was embedded into one of the Astym instruments and interfaced to a computer which controlled the pressure variations. They concluded that morphological evidence indicated that application of heavy pressure promoted the healing process to a greater degree than light or moderate pressure. During the Astym treatment process, a lubricant is applied to the patient's skin prior to treatment to reduce the coefficient of friction and prevent abrasive trauma to the overlying skin. The angled edge of the instruments 'catches' on the areas of fibrosis and triggers a localized inflammatory response. The instruments are then moved via longitudinal strokes along the affected musculotendinous structures²³. As the instruments glide over the skin, the clinician and patient can detect changes in the underlying soft tissues through the resonant properties of the instruments. The patient is treated in a seated position, addressing the extremity (hand, wrist, forearm, and elbow). In addition to the treatment at the wrist, the entire upper extremity is evaluated for compensatory strain patterns that may manifest as fibrosis. In therapy related research, Fowler et al. ²⁶ examined cumulative trauma disorders in a large manufacturing plant and found that 25 out of 29 extremities treated with the Astym system resolved. The criteria utilized for resolution were full return to pre-injury activities and functional ability with less than or equal to 3/10 pain on a visual analog scale.

In a case report by Baker and Wilson²³ examining Astym in the treatment of a bilateral carpal tunnel syndrome (CTS) patient, they found that Astym was shown to be an effective treatment approach for resolving the patient's symptoms. An article by Ettema et al²⁷ reported on the physiological changes that occur in the subsynovial layer of tissue during carpal tunnel. An electron microscope found fibrotic changes as a result of a shearing injury. The anatomy of the flexor tendons are similar to that of the tendons involved in de Quervain's. If Astym has been shown to be an effective treatment approach for

CTS, then it is reasonable to hypothesize that Astym would be an effective treatment for de Quervain's tenosynovitis. But does the Astym treatment along with stretching and exercise work better than the gold standard of care of splinting and exercise alone.

- **Study design:**

The research question for this study is:

Does adding an Astym treatment protocol to existing standard of care treatment of de Quervain's tenosynovitis increase outcomes of individuals with this condition?

The Alternative Hypothesis for this study is:

Participants receiving the Astym treatment protocol will have greater improvements in pain reduction and function as compared to those subjects in the control group receiving the standard of care therapy treatment

This is a randomized controlled study using repeated measure design with 2 groups:

- A. Control group who will receive standard of care rehabilitation intervention for the treatment of de Quervain's tenosynovitis.
- B. Experimental group will receive standard of care rehabilitation interventions plus Astym treatment protocol.

Three outcomes measures will be used for the study:

1. **Numeric Rating Scale for Pain-** This scale is a single point scale from 0-10. The participant picks one number to represent their pain, where 0 represents no pain and 10 represents worst pain imaginable.
2. **Quick Dash-** This is an 11 item questionnaire in which participants self-score themselves using a 1-5 point scale. One represents no difficulty in performing task whereas 5 represents unable to perform task.
3. **Sequential Occupational Dexterity Assessment-** This is a test to measure dexterity and bimanual abilities in activities of daily living. It includes 12 tasks with participants being scored on their ability, difficulty and pain during the task.

II. Characteristics of research population

- **Number of subjects:** N=32 (16 in each group)
- **Gender of subjects:** Both male and female participants will be included in the study. Demographic data will be included in the analysis of results.
- **Age of subjects:** 18-65yrs old
- **Racial and ethnic origin:** There will be no racial or ethnic restrictions to this study. Data on racial/ethnic origin will not be gathered by the researchers. It is assumed based on current client population that the sample will be diverse.
- **Inclusion criteria:**
 - i. Positive Finkelstein's test: The client will report pain over the first compartment of the extensor retinaculum when the thumb is tucked in the hand and deviated ulnarly.
 - ii. Persistent symptoms for >3 wks which have not resolved after an additional 3 weeks of splinting
 - iii. A diagnosis by a physician of "de Quervain's", "first compartment tenosynovitis", or "radial styloid tenosynovitis"
 - iv. Patients must agree and comply to a predetermined splinting regimen
- **Exclusion criteria:**
 - i. History of cortical steroid injection to affected wrist and/or thumb
 - ii. Comorbidity such as osteoarthritis, rheumatoid arthritis, auto-immune disease or inflammatory conditions.
 - iii. Clotting deficits
 - iv. Positive Cozen's sign which would indicate intersection syndrome³⁸
 - v. Post-partum mothers <6 months and pregnant women¹⁰⁻¹¹
 - vi. Cleared c-spine via Spurling's Test³⁴⁻³⁵ performed by combining cervical extension, side-bending, and axial compression to the cervical spine.
- **Vulnerable subjects:**
No vulnerable subjects will be included in this study

III. Methods and Procedures:

- **Methods and procedures:**
 - i. Randomized selection of 2 groups both seen for one evaluation and 12 therapy sessions scheduled 2x/week for 6 weeks (total of 12 sessions) for either traditional therapy including splinting and exercises or traditional therapy with Astym protocol. At least 2 days in between therapy sessions to allow sufficient healing.
 - ii. Randomization using computer-generated random numbers. The 3 Outcome measurements will be taken during evaluation and re-evaluation will be collected by two designated hand therapists other than the treating therapist. The data collectors will be blinded.

- iii. Data collection are taken at baseline, and after 12 sessions of therapy at discharge. . Quick DASH and VAS scale scores and questionnaire regarding patient compliance will be completed by phone interview at 3 month follow up.

Research design:

Patients with the diagnosis of de Quervain's from referring physician will be provided with a pre-fabricated Ossur thumb spica splint for use as indicated in splinting program^{13,15-17}, instructed on a home exercise program as part of standard of care along with being educated about the research study. If interested, they will be consented, and scheduled for a follow-up visit 3 weeks later. If not interested, they will be scheduled for a 3 week follow-up session and treated if needed. Upon their return, the patients will be screened by the researcher OT for inclusion and exclusion criteria. If subject meets the criteria, they will be randomized into either (1) control or (2) Astym group and then evaluated by a blinded Certified Hand Therapist or hand therapist. Fine motor coordination will be tested by using the Sequential Occupational Dexterity Assessment (SODA)³⁹. Pain and functional loss will be measured via the Visual Analog Scale (VAS)⁴⁰ and Quick Dash⁴¹⁻⁴⁵. They are then seen for formal therapy 2/x for 6 weeks for a total of 12 therapy session. If the subject does not meet criteria or decide not to participate in

the study, they are deemed a screen failure, dismissed from study, and will continue with treatment if needed.

The subjects will be seen twice a week for 6 weeks for 30 minute sessions by a separate treating therapist from the evaluating therapist. The patient will start at phase I; however, will not progress to the next phase of treatment if symptoms and pain are provoked.. When he/she tolerates exercises without pain or exacerbation of symptoms, the patient is progressed to Phase II and then phase III .Prior to discharge, if the subject has not achieved phase III, the therapist will incorporate Phase III exercises, for strengthening and functional movements of the hand, forearm, elbow and shoulder to be completed at home. . All subjects, either in control or Astym group, will receive only 12 sessions of therapy regardless if they progress through the all 3 phases. Astym group will receive traditional therapy with Astym every session, while the control group will only receive traditional therapy. See protocol below.

Control group: Traditional therapy for de Quervain's Tenosynovitis^{17-19, 21-22, 30-33:}

Phase I: Reduction of splint use and strengthening initiated once patient can perform pain free AROM (monitor symptoms to not exacerbate condition)

- Goals include: teaching self-management techniques for long-term control, ergonomics education, regaining flexibility and tolerance to light functional tasks without pain, initiation of splint wean off program
- Moist heat pack for 10 minutes²⁸ at beginning of treatment session
- Stretching 4x/day for 30-45 seconds, including stretching prior to and after exercise:
 - UD of wrist with thumb tucked under fingers and wrist in neutral
 - Wrist flexion with elbow extended forearm pronated
 - Wrist extension with elbow extended forearm supinated
- Isometric grip/pinch strengthening
 - Submaximal contractions to avoid increased microtrauma to musculotendinous unit
 - Strengthening started at 1 set of 5 reps with 2 second hold per repetition and working up to 6 seconds (as pain allows) 3x/day

Phase II: Progress to strengthening of wrist and hand with emphasis on eccentric loading

- Goals include: increasing patient tolerance to heavier demands of tasks without exacerbation of symptoms, return to normalcy of function without use of splint
- Moist hot pack for 10 minutes²⁸ at beginning of treatment
- Advance patient once they can perform AROM, passive stretching of wrist, thumb and composite wrist/thumb, and isometrics pain free
- Using light theraband, 2 second count concentric motion followed by 4 second count eccentric motion for wrist strengthening in flexion, extension, radial and ulnar deviation with elbow flexed at 30-45 degrees and forearm supported
- Gentle grip, chuck pinch, lateral pinch and thumb opposition strengthening into soft- medium putty starting at 15 repetitions building to 30 repetitions each without exacerbation of symptoms
- Thumb abduction and extension with yellow power web or light resistance rubber bands 3 sets of 10 reps
- Continue stretching 4x/day for 30-45 seconds, with stretching prior to and after exercises:
 - UD of wrist with thumb tucked under fingers and wrist in neutral
 - Wrist flexion with elbow extended forearm pronated
 - Wrist extension with elbow extended forearm supinated

Phase III: Continue therapy, incorporate strengthening and functional movements for forearm, elbow and shoulder and prepare patient for discharge to home exercise program

- Goals include: Pain free functional use of affected extremity during all tasks without use of splint
- Replace moist heat pack with Upper Body Ergometer for 10 min
- Continue stretching 4x/day for 30-45 seconds, with stretching prior to and after exercises:
 - UD of wrist with thumb tucked under fingers and wrist in neutral
 - Wrist flexion with elbow extended forearm pronated
 - Wrist extension with elbow extended forearm supinated
- Adding multi joint strengthening exercises to match job demands using dumbbells

Patient discharged to home exercise program after 12 sessions of therapy with review of ergonomics, stretches, and exercises at last session. **Astym group: Traditional therapy WITH Astym protocol for De Quervain's Tenosynovitis¹⁷:**

Phase II: Reduction of splint use and strengthening once patient can perform AROM pain free (monitor symptoms to not exacerbate condition)

- Goals include: teaching self-management techniques for long-term control, ergonomics education, regaining flexibility and tolerance to light functional tasks without pain, initiation of splint wean off program
- Moist heat pack for 10 minutes²⁸ at beginning of treatment
- **Astym treatment to affected extremity per de Quervain's protocol, including de Quervain's strokes (See Appendix I)**
- Stretching 4x/day for 30-45 seconds:
 - UD of wrist with thumb tucked under fingers and wrist in neutral
 - Wrist flexion with elbow extended forearm pronated
 - Wrist extension with elbow extended forearm supinated
- Isometric grip/pinch strengthening
 - Submaximal contractions to avoid increased microtrauma to musculotendinous unit
 - Strengthening started at 1 set of 5 reps, 2 seconds per rep working up to 6 seconds (as pain allows) 3x/day

Phase II: Progress to strengthening of wrist and hand with emphasis on eccentric loading

- Goals include: increasing tolerance to heavier demands of tasks without exacerbation of symptoms, return to normalcy of function without use of splint
- Moist heat pack for 10 minutes²⁸ at beginning of treatment
- **Continue Astym to affected extremity per de Quervain's protocol, including de Quervain's strokes**
- Advance patient once they can perform AROM, passive stretching of wrist, thumb and composite wrist/thumb, and isometrics pain free
- Using light theraband, 2 second count concentric motion followed by 4 second count eccentric motion for wrist strengthening in flexion, extension, radial and ulnar deviation with elbow flexed at 30-45* and forearm supported
- Gentle grip, chuck pinch, lateral pinch and thumb opposition strengthening into soft- medium putty starting at 15 repetitions building to 30 repetitions each without exacerbation of symptoms

- Thumb abduction and extension with yellow power web or light resistance rubber bands 3 sets of 10 reps
- Continue stretching 4x/day for 30-45 seconds, with stretching prior to and after exercises:
 - UD of wrist with thumb tucked under fingers and wrist in neutral
 - Wrist flexion with elbow extended forearm pronated
 - Wrist extension with elbow extended forearm supinated

Phase III: Continue therapy, incorporate strengthening and functional movements for forearm, elbow and shoulder and prepare patient for discharge to home exercise program

- Goals include: Pain free functional use of affected extremity during all tasks without use of splint
- Replace moist heat pack with Upper Body Ergometer for 10 min
- **Continue Astym to affected extremity per de Quervain's protocol, including de Quervain's strokes for a max of 12 sessions**
- Continue stretching 4x/day for 30-45 seconds, with stretching prior to and after exercises:
 - UD of wrist with thumb tucked under fingers and wrist in neutral
 - Wrist flexion with elbow extended forearm pronated
 - Wrist extension with elbow extended forearm supinated
- Adding multi joint strengthening exercises to match job demands using dumbbells
- Patient discharged to HEP after 12 sessions of therapy with review of ergonomics, stretches, and exercises at last session.

Three months after discharge from CMC, Quick DASH and VAS scale scores and questionnaire regarding patient compliance will be completed by phone interview.

Data Analysis and Monitoring

Descriptive statistics will be used along with inferential statistics. The alternative hypothesis will be addressed using a mixed design analysis of variance to test for differences between-groups and within-groups. In addition we will also analyze the interaction effect between study group and time. All analyses will have an alpha of 0.05. Malchy's test for sphericity will be performed along with a Bonferroni comparison. If Malchy's test for sphericity is significant then a Greenhouse-Geisser or Huynh-Feldt correction will be used. In addition a repeated measure MANOVA may be used to test the dependent variables in a multivariate method if in fact the dependent variables demonstrate a relationship of linearity.

Based upon the planned analyses for the primary hypothesis, a mixed repeated measure design with 1 between factor (group membership) and 1 within factor (repeated measures) has 2 groups with 16 subjects each for a total of 32 subjects. This design achieves a 80% power to test the between factor using the above mentioned mixed methods ANOVA using a 5% significance level with an actual Cohen's F effect size of .398

Data Storage and Confidentiality

All written data will be stored in a locked drawer in a locked office. For data analysis purposes all data will also be stored using Microsoft Excel/ReCap Software. To ensure confidentiality all participants will be categorized alphanumerically.

IV. Risk/Benefit Assessment

- Risk

Potential side effects of Astym treatment include:

- 1) Ecchymosis to the treatment area, typically where fibrotic tissue and healing is indicated.
- 2) Increased pain or soreness for 24-48 hrs after treatment.
- 3) Increased inflammation of affected extremity after treatment.
- 4) Vagal response during treatment due to neural effect on tissue from the Astym treatment that include but are not limited to light headedness, feeling faint and nausea.

- Protection against risks

Patient education of these risks will help the patient understand some of the temporary side effects that they may experience. Icing 3-4 hrs after treatment can limit some of the side effects and help with pain and inflammation. Eating 1 hour prior to treatment will also limit vagal response during the Astym treatment. Prior to therapy, the patients will be encouraged to tell their therapist to stop treatment if they do not wish to continue if they are experiencing any of these symptoms and/or do not wish to continue in the study.

- Potential benefits to subjects:

Patients will receive Astym treatment to the affected extremity in addition to traditional therapy they would normally receive when being treated for de Quervain's tenosynovitis. Astym treatment will be delivered by a qualified, specially trained occupational therapist where instruments will be applied topically to the skin with moderate pressure to stimulate a healing and regenerative response. . We believe the additional Astym protocol will increase functional levels for patients along with a greater social benefit of the knowledge gained from this experimental study.

- Subject Compensation:

There will be no compensation to patients for this study.

V. Investigators Qualifications & Experience

- Curriculum Vita for each investigator in study related documents

VI. Subject Identification, Recruitment and Consent/Assent

Method of subject identification and recruitment

Clients referred to NYU Langone Center for Musculoskeletal Care with a diagnosis of de Quervain's, radial styloid tenosynovitis, or first compartment tendonitis will be screened by investigators. After initial evaluation by a non-treating, blinded therapist, the patient will be provided with consent form and information on study (Appendix VIII). The client will be given the opportunity to ask questions to clinician and/or any member of the research team at this time or throughout the course of their treatment.

Process of Consent

Clients will be provided with consent form and information on study following the

clinician's inspection and determination of appropriateness to participate.

Subject Capacity

All clients who are unable to provide informed consent will not be included in this research study.

Subjects Representation Comprehension

Clients who are unable to understand the informed consent sheet and/or the educational hand outs and home exercise plan will not be considered for this study. The participants will be able to ask questions and request further information upon consent.

Debriefing Procedures

Clinicians will provide participants with measurements and results at any time throughout this study upon participant request. As is standard procedure at NYU Langone Medical Center clients have the right to access their medical records at any time which will include all measurements.

Consent forms-See study related documents

Documentation of Consent

All signed consent forms will be stored in a locked draw of a locked office. Consent forms along with all patient documentation will also be scanned into Epic and be available within the clients chart as is standard protocol here at NYU Center for Musculoskeletal Care. Participants will also be provided with a copy of signed consent form.

Costs to Subjects

There will be no additional cost to subjects for participation in this study. The use of the ASTYM therapy technique is combined with other therapeutic techniques and modalities and is billed accordingly at NYU Center for Musculoskeletal Care.

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Appendix I

Astym Protocol for de Quervain's Tenosynovitis

Patient sitting, forearm pronated

Forearm and arm from wrist to deltoid tuberosity (E,L) 2 strokes in each direction

Thumb muscles (EPB, APL) (L) (only distal to proximal) 4 strokes

Lateral epicondyle (L,I) 2 strokes both directions; straight into upper arm, fan into forearm

Wrist retinaculum (I) 2 strokes both directions

Patient sitting, forearm supinated

Forearm and arm from wrist crease through biceps (E, L) 2 strokes both directions

FCU from wrist to just below medial epicondyle (L on tip) 2 strokes both directions

Medial epicondyle (L,I) 4 strokes away from epicondyle only; straight proximal, fan distal

Wrist retinaculum and around pisiform (I), 2 strokes both directions

Flexor retinaculum in palm (E) with 90° pivots 2 strokes in each direction

Flexor retinaculum (L,I) distal to proximal only, “walk” instruments if necessary, 2 strokes per instrument

Thenar eminence (I) 2 strokes in each direction

Hypothenar eminence (I) 2 strokes in each direction

Thumb flexors (I) 2 strokes in both directions

Patient sitting, radial surface facing up

EPB and APL tendons and muscle bellies (I) 2 strokes in each direction

Anatomical Snuff Box (I) 2 strokes in each direction

Web space (I) 2 strokes in each direction

