A Comparison Study of Three Standard Wrist Orthoses to Limit Forearm Rotation

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1 Introduction/Significance

Common upper extremity injuries often need to heal with no wrist and forearm range of motion. Forearm range of motion includes supination and pronation. Injuries that necessitate limiting forearm range of motion include fracture patterns involving the distal radioulnar joint (DRUJ), proximal radioulnar joint (PRUJ), triangular fibrocartilage complex (TFCC), both bone forearm fractures, ulnar shortening procedures, radial and ulnar osteotomies, DRUJ instability (Slaughter, Miles, Fleming & McPhail, 2010; LaStayo & Lee, 1996). Long arm orthoses, sugar tong orthoses and muenster style orthoses can all limit forearm rotation.

Past research has indicated common methods of immobilization to include the following: sugar tongs cast/orthosis, muenster cast/orthosis, long arm cast/orthosis/or short arm cast/orthosis, and an antirotation orthosis. A long arm cast/orthosis is excellent at limiting forearm rotation, yet it does not allow any elbow flexion and extension (Kim, Kook & Kim, 2012). In the study by Kim, Kook, & Kim (2012) the authors found that the sugar tong orthotic was as effective and limiting forearm rotation as the long arm orthotic. The sugar-tong can decrease forearm rotation to 30% of their normal values (Kim, Kook, & Kim 2012; Gil, DeFroda, & Hsu, 2016). A sugar tong limits rotation based on the circumferential fit, but can be difficult to don and doff.

The modified antirotation orthosis allows for elbow and wrist flexion and extension, yet it mainly limits pronation through proprioceptive input around 30 degrees and does not prevent rotation (Monsterio & Brou, 2007; Slaughter, Miles, Fleming, & McPhail, 2010). This type of orthosis can be helpful in non-surgical approach to limiting forearm rotation (Monsterio & Brou, 2007).

Lawton, Nicolls, and Charoglu (2007) compared a long arm cast thumb spica versus a muenster thumb spica cast. Results concluded that the muenster thumb spica allowed six more degrees of forearm rotation than the long arm cast; however, the muenster group maintained a 52 degree arc of elbow motion. In a small study done by Trocchia and Hammert (2012) a long arm cast allowed an 11 degree arc of forearm rotation, and the muenster cast allowed a 35 degree arc of forearm rotation. These results suggest if no forearm rotation is desired a cast or orthosis that immobilizes the elbow is required (Troccia & Hammert, 2012). Often though it is beneficial to allow elbow motion to prevent unnecessary elbow joint stiffness, and a muenster cast or orthosis is required.

A muenster style orthosis is designed to limit forearm rotation at the distal radioulnar joint (DRUJ) yet allowing elbow flexion and extension after an injury that necessitates limiting forearm rotation (Slaughter, Miles, Fleming & McPhail, 2010). Muenster orthoses can be radial based or ulnar based. A radial based muenster is another options and can reduce the pressure off the olecranon, yet it is difficult for a therapist to fabricate. In the study by Slaughter, Miles, Fleming and McPhail (2010), a radial based muenster was fabricated. This orthosis was compared with a sugar tongs orthosis, anti-DRUJ rotation orthosis, and a custom wrist orthosis. The muenster and sugar tongs

orthoses were the best at limiting forearm rotation in 5 subjects. The sugar tongs did the best at limiting pronation.

An ulnar based muenster places the wrist in neutral and blocks the elbow from full extension. In our literature search, research articles did not include an ulnar based muenster orthosis.

In addition to which orthosis limits rotation the best, the researcher must address measurement techniques to maintain accurate recording. In our literature search, the goniometric measurement of pronation and supination was used to determine which orthosis or cast limited forearm motion the best. Limiting factors include measuring motion with a hand held goniometers. A research study by Kim, Kook, and Kim (2012) limited measurement error by creating a custom-made goniometer device that placed all subjects in the same position.

Currently, there are no research studies that compare the amount of forearm rotation in a traditional thermoplastic orthoses to newer materials such as a Delta Cast orthosis, or prefabricated muenster orthoses such as the Hely and Weber MTC Fracture Brace. The purpose of this study is to assess which orthosis-a traditional thermoplastic ulnar based muenster, a delta cast style muenster and the Hely and Weber MTC Fracture Brace-allows for the least amount of supination and pronation in a healthy population in the dominant extremity.

Study Objectives

Primary Objective
To assess which orthosis-a traditional thermoplastic ulnar based muenster, a delta cast style muenster and the Hely and Weber MTC Fracture Brace- allows for the least forearm rotation (Supination/Pronation) in a healthy population in the dominant extremity.

Secondary Objective:
To assess through a questionnaire barriers of wearing an orthosis that limits forearm rotation such as the comfort of the fit, the weight of the orthosis, the ease of donning/doffing, does the orthosis cause pain, and the aesthetics of the orthosis.

2 Patients and Methods

2.1 Study Design

2.1.1 General Design

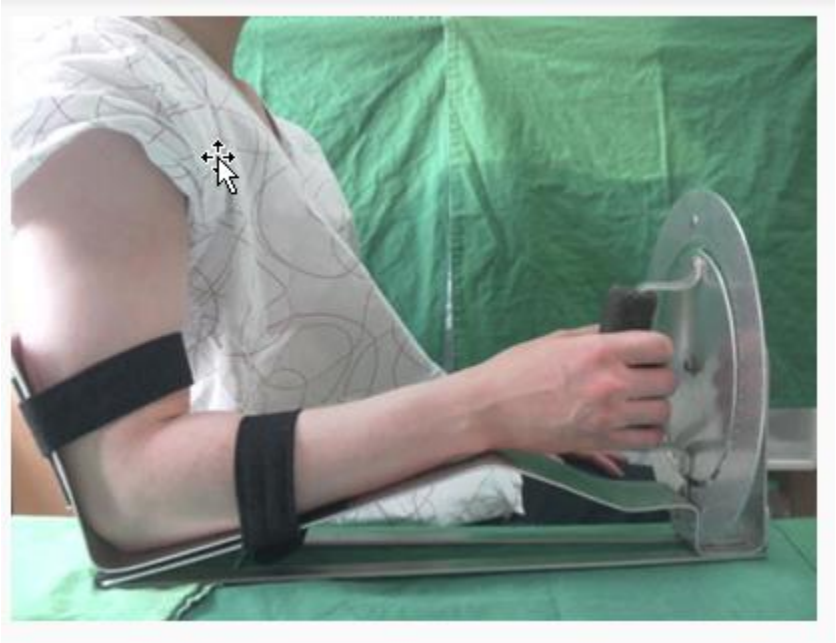
(B) Experimental Design
Definition: In this study, the same subjects (30) will have 2 custom orthoses fabricated by 2 different methods, and application of a prefabricated muenster

orthosis fit by the investigators. Within each orthosis, the subject will be measured for forearm rotation using the same measuring device with electronic read out.

2.1.2 Primary Outcome Variable

Supination and pronation will be the primary outcome measures. An electronic goniometer device will be manufactured by PizzaCake. This device will hold the dominant upper extremity with straps above the elbow with a trough for the forearm and a handle for the hand to be held in a grip position. This will allow for rotation to occur only at the proximal radioulnar joint and the distal radioulnar device. Using electronic measurement will reduce bias and measurement error from the therapist.

Photo below is similar to what will be manufactured for the study:



2.1.3 Secondary Outcome Variables

The Orthotics and Prosthetics User's Survey (OPUS) is a well validated, self-report questionnaire consisting of five modules. Therapy will use 5 questions from the OPUS: Satisfaction with Device and Services Module. These five questions are scored on a 5-point likert scale from Strongly Agree to Strongly Disagree with a 6th option of "don't know".

The five questions include-

1). My orthosis fits well.
2). The weight of my orthosis is manageable.
3). It is easy to put on my orthosis.
4). My orthosis is pain free to wear.
5). My orthosis looks good.

The remaining 16 questions were excluded as it did not pertain to healthy volunteers wearing the orthosis only during his/her research participation.

2.2 Subject Selection and Withdrawal

2.2.1 Inclusion Criteria

Subjects will be selected to participate in the study if they have had no prior wrist or elbow injuries on the dominant side of his/her body, time of 90-120 minutes to complete the study in one sitting. All participants will be between the ages of 18-100, speak and read English and have the ability to follow directions.

2.2.2 Exclusion Criteria

Subjects will be excluded if they have had prior wrist or elbow injuries on the dominant side of his/her body. Examples include distal radius injuries with intraarticular involvement, ulna fractures with intraarticular involvement, ulnar sided wrist pain, known TFCC injuries, Elbow fractures that limited the PRUJ in forearm rotation. Subjects with known rheumatoid arthritis deformities of the wrist or any prior wrist surgeries are excluded.

2.3 Study Procedures

Subjects will be recruited from using an email sent to employees in the hand clinic, the PM&R fellowship, and PM&R residency, and Physical Therapy School for recruitment. Word of mouth will also be utilized to recruit subjects. Subjects will be screened to see if they have met the inclusion criteria.

Consent processes will be initiated if the subject has met the inclusion criteria.

The data collection sheet will collect gender, age, and hand dominance, height/weight for body mass index and arm circumferential measurements at the wrist, 1” below the antecubital fossa and 3” above the antecubital fossa. There will be a checklist on the data sheet to ensure participants are meeting inclusion criteria for the study.

All orthoses will be fit or fabricated on the dominant hand.

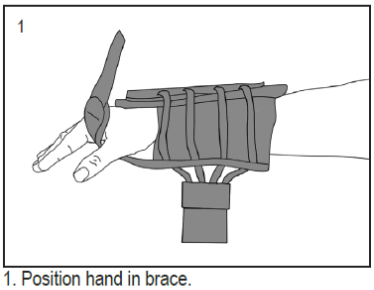
The subject will be fit with a prefabricated Hely & Weber MTC Fracture Brace. Directions for fitting are depicted below and retrieved from https://www.hely-weber.com/images/stories/instructions/641-642_IFU.pdf

Wrist Orthosis - Application

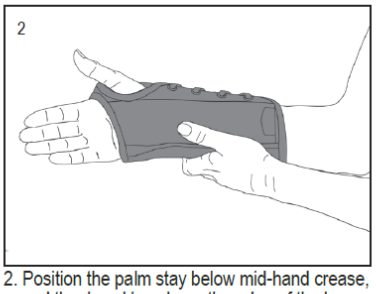
641
642

Warnings and Instructions: Review carefully, proper application is required

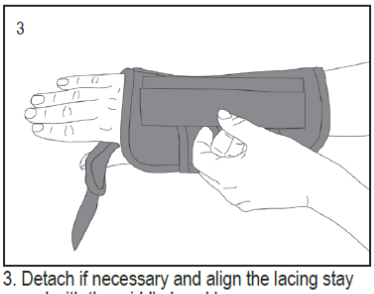
⚠**Warning:** This device will not prevent or eliminate risk of injury. Do Not Overtighten. If swelling, pain, skin irritation, or an unusual reaction occurs, discontinue use immediately and consult your medical professional.
Care: Hand wash using mild soap. Rinse thoroughly. Air dry only. Do not tumble dry.



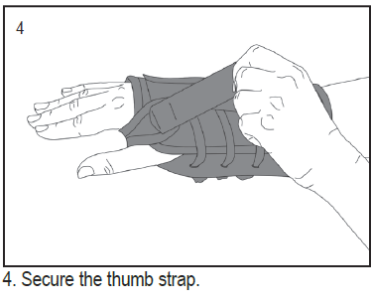
1. Position hand in brace.



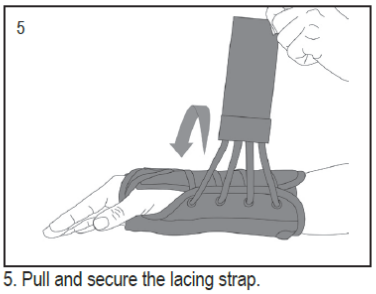
2. Position the palm stay below mid-hand crease, and the knuckles above the edge of the brace.



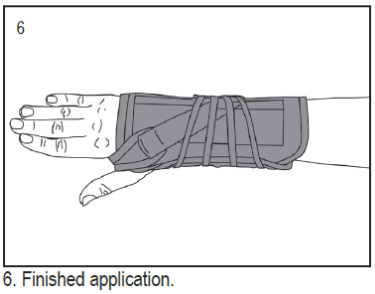
3. Detach if necessary and align the lacing stay pod with the middle knuckle.



4. Secure the thumb strap.

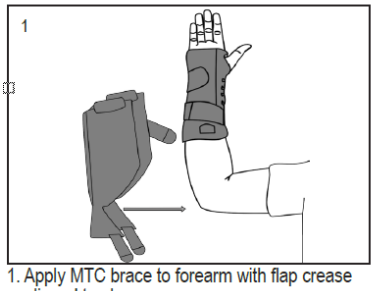


5. Pull and secure the lacing strap.

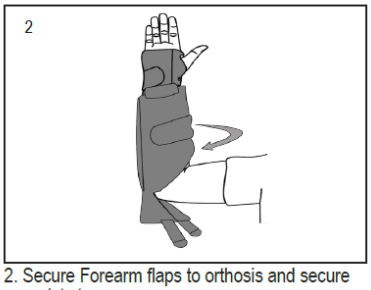


6. Finished application.

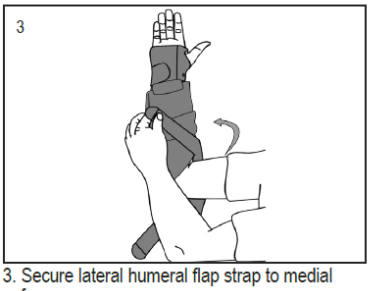
MTC Fracture Brace - Application



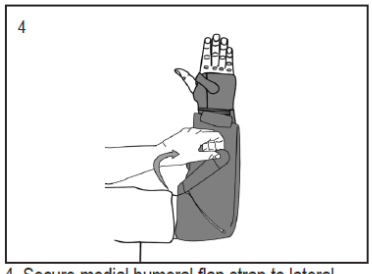
1. Apply MTC brace to forearm with flap crease aligned to olecranon.



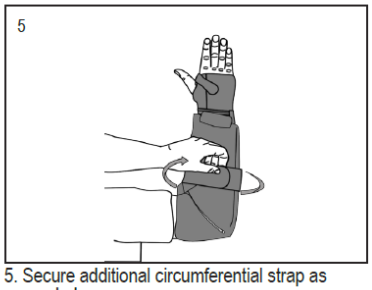
2. Secure Forearm flaps to orthosis and secure assist strap.



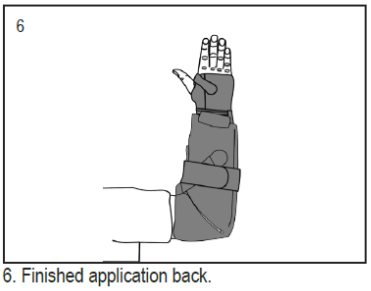
3. Secure lateral humeral flap strap to medial forearm.



4. Secure medial humeral flap strap to lateral forearm.



5. Secure additional circumferential strap as needed



6. Finished application back.

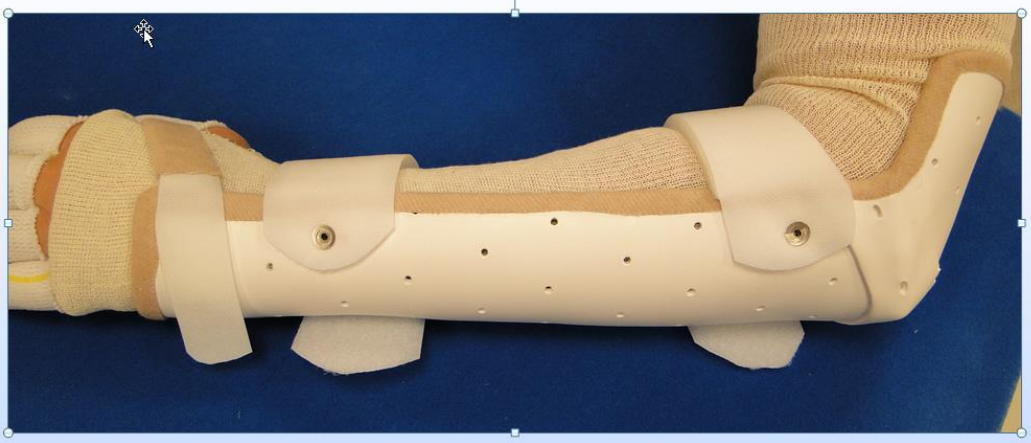
1185 E Main St., Santa Paula, California 93060
California: 800-221-5465, National: 800-654-3241
International: 805-525-4244, fax: 805-933-2348
U.S. fax: 800-559-5975, www.hely-weber.com

MDSS GmbH, Schiffgraben 41
30175 Hannover, Germany

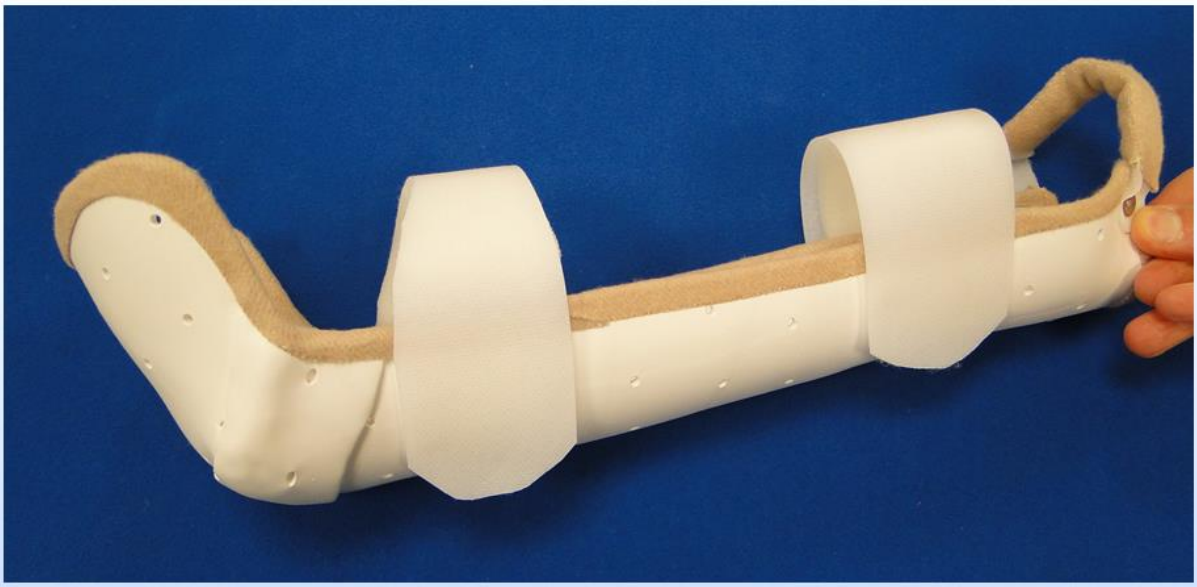
Rev B 2/14

The subject will have a muenster orthosis fabricated out of thermoplastics and secured with Velcro. Directions for fabricated are written below.

1). Place desired width stockinet on the subjects arm from the metacarpal phalangeal joints to 4” above the elbow
2). Pad the ulnar styloid with Reston
3). Measure the length of material required from metacarpal phalangeal joint to 4” above the elbow
4). Measure the 75% of the circumference of the arm at the metacarpal phalangeal joints, wrist, and elbow.
5). Cut out orthoplast with measurements
6). Use the 2” high stretch bandage and start at the metacarpal phalangeal joints mold the orthoplast to the arm using the high stretch bandage with the shoulder at 90 degrees, elbow at 90 degrees, neutral forearm, wrist in 10-20 degrees extension, and neutral deviation.
7). Draw cutting lines on the orthosis for these principles
    a). Full metacarpal phalangeal joint flexion of digits II-V
    b). Follow the line of the third metacarpal for trim placements volar and dorsal.
    c). At the elbow the lateral and medial epicondyle must be in the orthosis.
    d). On the posterior side and from the olecranon trim the orthosis 4.5 inches proximally
8). Trim the orthosis at marked lines
9). Try on orthosis make modification and draw lines to rivet straps
    a). strap at the first web space 1” wide, rivet volar side
    b). strap over the DRUJ 2” wide, rivet dorsal side
    c). strap at the proximal forearm 2” wide, rivet dorsal side
10). Moleskin the edges
11). Rivet straps in place. On other side place heated Velcro tap.
12). Place rest at the elbow.



Ulnar based Muenster splint – wrist in neutral, elbow blocked from full extension



The final orthosis will be a muenster orthosis fabricated out of Delta Cast and secured with Velcro. Directions for fabricating are depicted below and retrieved from
http://handtherapyhub.com/GoaIndia/docs/HandoutForNO.pdf

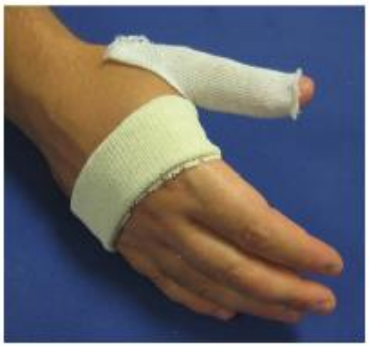


Figure 1. Prepare and protect hand.

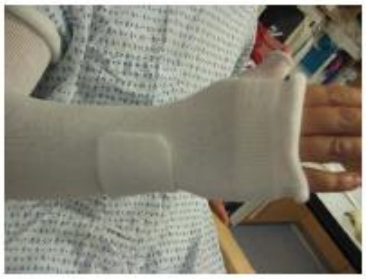


Figure 2. Sleeve and foam.

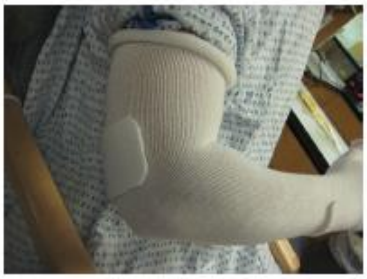


Figure 3. Distal humeral foam

Figure 4. Insert Zip Stick. Mark base of thumb/radiocarpal joint

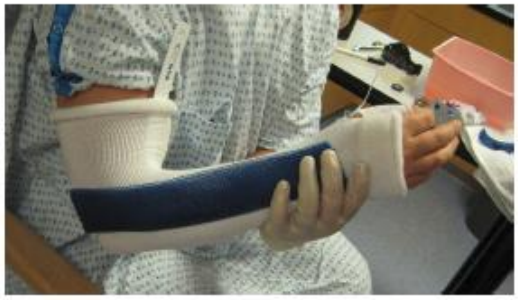


Figure 5. Place reinforcing strut.

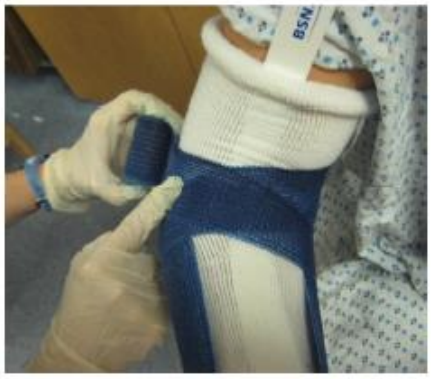


Figure 6. Create 2-layer figure-of-8. Cross at antecubital fossa. See schematic on last page.

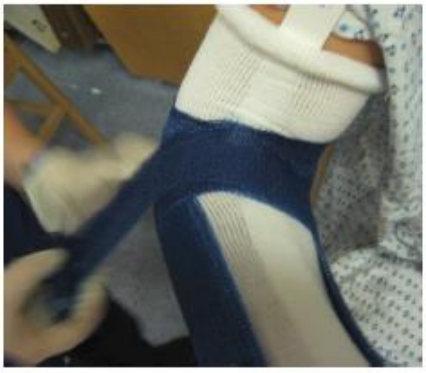


Figure 7. Begin spiral toward hand. Overlap 2/3.

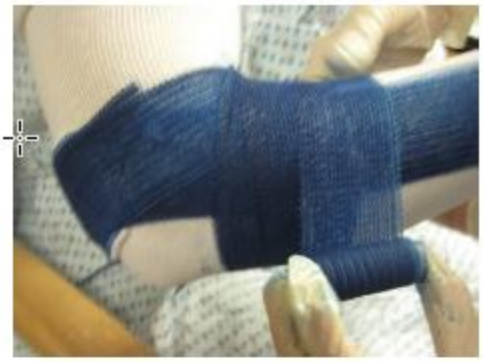


Figure 8. Continue toward hand.

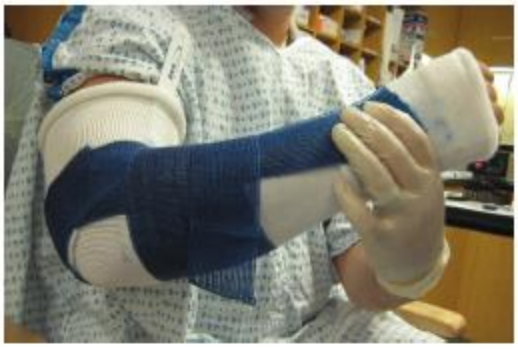


Figure 9. End of first roll of cast tape.

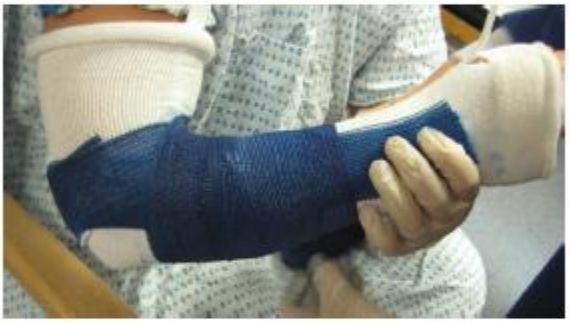


Figure 10. Begin 3" roll.

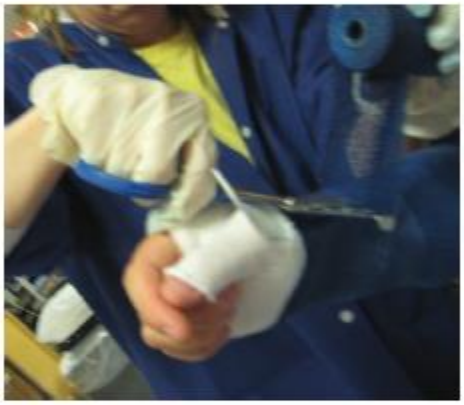
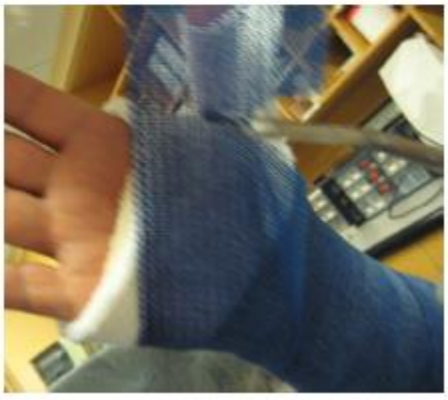
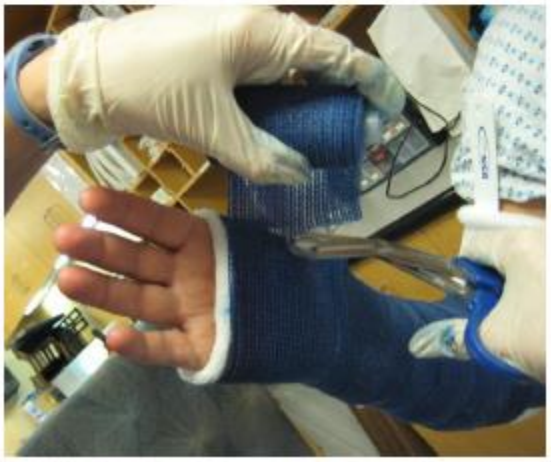


Figure 11. Cut tape to accommodate thumb





Figures 12 & 13. Cutting tape to accommodate thumb.

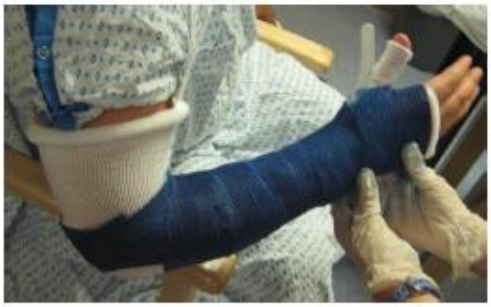


Figure 14. Rolling is done.

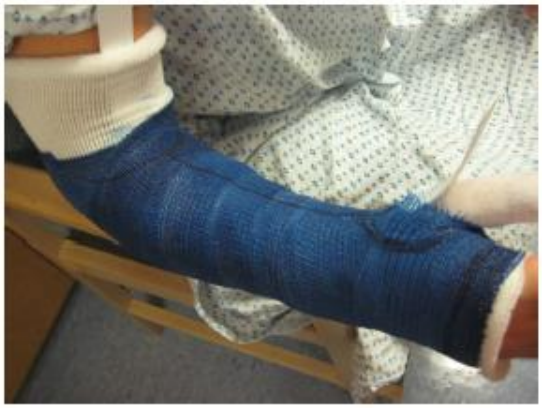


Figure 15. Draw outline final splint.

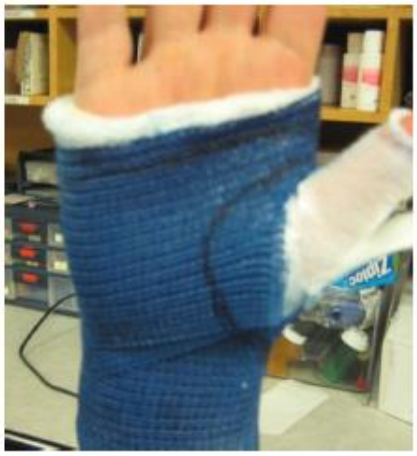


Figure 16. Draw edges of splint.

Figure 17. Cut along cutting line and stick.

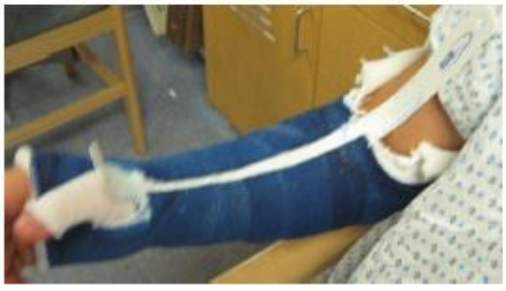


Figure 18. Cutting is complete. Carefully remove from patient.

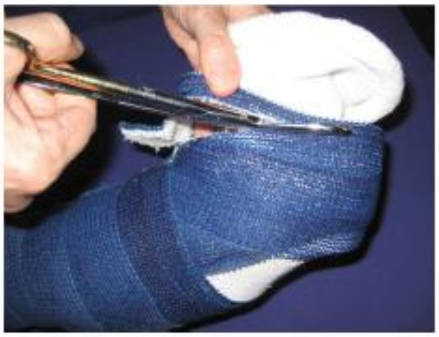
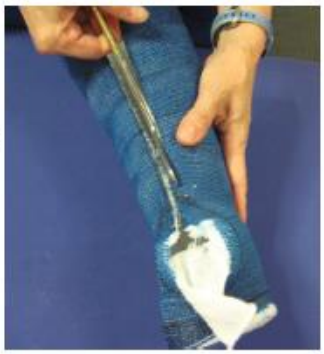
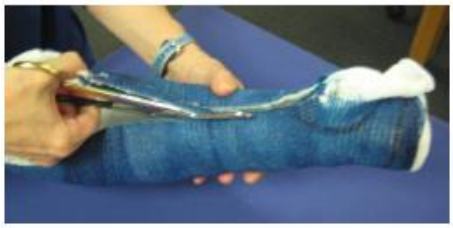


Figure 19. Trim and shape.

Figures 20-28 (below)
Trim and shape splint edges.



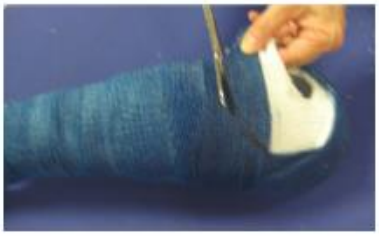


Radial Opening

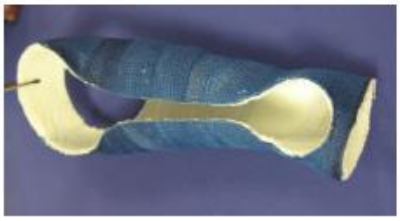
Thumb Opening

Metacarpal Head Opening

Metacarpal Head Opening



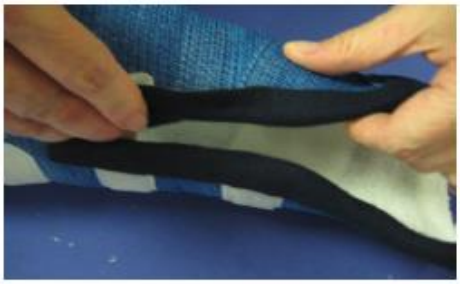
Olecranon Opening



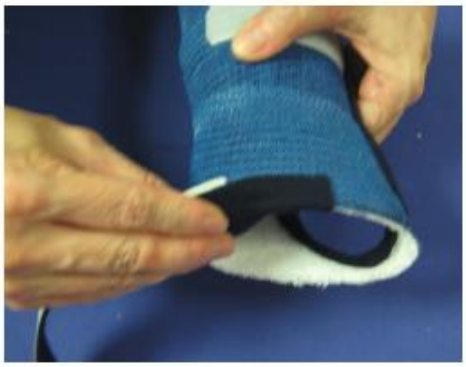
Final Shape

Figure 29. Apply sticky back hook Velcro tabs for straps. Apply to dorsal side.

Figures 30-35 (below) Apply fleece edger.



Olecranon Opening



Metacarpal Head Opening

Delta Cast Sugar Tong/Munster Splint

1. Gown to protect patient's clothing.
2. Cut desired length of 3" Terry-Net sleeve. Slip small hole in sleeve for the thumb. Leave at least 4" between the hole and the end of the sleeve.
3. Use Surgitube thumb sleeve to protect the patient's thumb from the resin if desired. (Figure 1)
4. Place 4-layer ring of 2" stockinette just proximal to metacarpal heads if desired. This will loosen the fit of the cast around MCPs and ease don/doff. (Figure 1)
5. Slip stockinette sleeve on patient's arm.
6. Place foam as shown to ulnar head and distal humerus. (Figures 2 & 3))
7. Place Zip Stick anteriorly as shown. (Figure 4)
8. Open a roll of 2" BSN Delta Cast Polyester Cast Tape.
9. Create a 2-3 layer strut. (Figure 5)
10. Submerge roll of cast material in water. Do not squeeze. Remove and gently blot on towel.
11. While patient holds reinforcing strut, create a figure-of-8 (x2) around the elbow joint, with the cross at the antecubital fossa. (Figure 6)
12. Then begin spiral toward the hand. (Figures 7 & 8)
13. Overlap about 2/3.
14. Start second roll when first roll runs out. This will be a 3" roll of tape. (Figures 9 & 10)
15. As you approach the hand, cut into the tape to accommodate the thumb (same technique as used in the wrist splint and the posterior elbow shell). (Figures 11-13)
16. When splint is complete, cut tape and discard excess portion of rolled cast tape. (Figure 14)
17. Shape splint as desired.
18. Rub surface of material with wet gloves.
19. Allow material to dry and set.
20. Remove gloves.
21. Using a Sharpie® draw shape of splint and cutting line. (Figure 15 & 16)
22. Cut along cutting line. (Figure 17)
23. Take great care to stay on the cutting stick and be careful at the antecubital fossa.
24. Remove splint. (Figure 18)
25. Trim edges of the splint to create final shape. (Figures 19-28)
26. Place sticky-back Velcro tabs. (Figure 29)
27. Apply fleece edger. (Figures 30-35)
28. Apply straps

The traditional orthosis will be fabricated by Sara Gross. The Delta Cast orthosis will be fabricated by Sarah Cashman. Maggie Malecha will fit each patient with the prefabricated muenster orthosis. Adam Orlando will obtain goniometric measurements from all subjects. Stephanie Kannas, will ensure all orthoses are fabricated to the standards listed above in fitting and fabrication. Stephanie Kannas is a certified hand therapist with 18 years of experience. Sara Gross, Sarah Cashman, and Maggie Malecha have all passed the Mayo competency in fabricating muenster orthoses.

Patients will be randomized into one of 5 groups. Randomization will be conducted using sealed envelopes prepared using a randomization schedule provided by the study statistician. The schedule will randomize in 5 blocks of 6 (123; 132; 213; 231; 312, 321) to avoid over allocation of the subjects into one group.

The Hely & Weber MTC Fracture Brace is 1
The thermoplastic orthosis is 2
The delta cast orthosis is 3

In efforts to reduce subject fatigue and bias, goniometric measurements will be taken following each randomization sequence of orthotic fabrication. Subjects will be placed in the goniometric measurement device, and the subject's dominant arm will be covered to reduce bias. Each subject will have 3 trials of goniometry for pronation and supination. Terminal motion will be based upon the patient experiencing increased pressure or felt restriction from the orthosis. The odd number subjects will supinate/pronate, supinate/pronate, supinate/pronate. The even number subjects will pronate/supinate, pronate/supinate pronate/supinate.

At the completion of measuring all three orthoses, the subjects will fill out the 5 question survey regarding each orthosis. After completion of the survey, the subject will be thanked for their time and dismissed from the study.

We have attempted to reduce bias through having each therapist perform fabrication or fitting of the same orthosis and having the measurement device be electronic versus a therapist using a standard goniometer. The subjects will be blinded to the recorded data while performing supination/pronation as well.

2.3.1 Sample Size Estimation

The sample size estimation came from Dirk Larsen.
Based on previously published papers, it is assumed that the standard deviation of the pronation-supination range of motion will be approximately 10°. Assuming that similar variability will be observed in the proposed study, a sample of 24 subjects will be required to have 80% power to detect a difference of at least 6° between any two of the 3 orthoses with respect to pronation-supination range of motion. In order be conservative, and to protect against potential subject attrition due to being unable to

complete the testing under all experimental conditions, a total of 30 subjects will be recruited and enrolled in the study.

2.3.2 Statistical Methods

All data will be summarized and reported using appropriate summary statistics including means and standard deviations for continuous variables, and counts and percentages for categorical variables. Results will be reported with 95% confidence intervals where appropriate. The analysis will focus on comparing the mean pronation-supination range of motion between the 3 different orthoses. This will be accomplished using repeated measures analysis of variance (ANOVA). If the overall ANOVA result is statistically significant, further analysis will be undertaken to perform pairwise comparisons between the 3 study groups using an appropriate multiple comparisons procedure (such as the Tukey-Kramer method) to control the overall type-I error rate. All statistical tests will be two-sided and p-values less than 0.05 will be considered significant.

3 Data Handling and Record Keeping

3.1 Confidentiality

Subjects will be asked to fill out the screening questionnaire, but their name will not be recorded or gathered on the questionnaire. On the questionnaire, we will ask for gender, age, and hand dominance. The questionnaire will also house the data for the 3 separate trials of the orthotics.

3.2 Record Retention

The questionnaires filled out by Mayo Clinic patients will be maintained for five years at the completion of the study. The records will be kept in a locked filling cabinet at Mayo Clinic. The data will also be housed in a secure data form such as an Excel Spreadsheet or Red Cap data base.

4 References

Armstrong, A.D., MacDermid, J.C., Chinchalkar, S., Stevens, R.S., & King, G. J. W. (1998). Reliability of range-of-motion measurements in the elbow and forearm. *Journal of Shoulder and Elbow Surgery, 7*, 573-580.

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Kim, J.K., Kook, S. H., & Kim, Y. K., (2012). Comparison of forearm rotation allowed by different types of upper extremity immobilization. *The Journal of Bone and Joint Surgery, 94*, 455-460.

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Trocchia, A., Elfar, J.C., & Hammert, W. C. (2012). Biomechanical measurements of forearm pronosupination with common methods of immobilization. *Journal of Hand Surgery, 37*, 989-994.

*Appendix A (Budget)****

	Price	Quantity	Total
Delta cast costs			
Material (5 orthoses/box)	47.56	7	332.92
Edging (15 yds)	12.19	4	48.76
Cloth/foam	45.59	3	136.77
Neoprene straps (1/16x2in, 7 yds)	54.95	2	109.9
Stockinet (15 yds)	20.37	2	40.74
Thermoplast munster costs			
Material (4 orthoses per sheet)	90	7	630
Velcro (for delta too; 1 in, 25 yds; Rolyan 1 in non-adhesive hook)	44.23	1	44.23
Straps (Rolyan 2 in, 25 yds adhesive)	48.93	2	97.86
Stockinet (3 in, 25 yds)	13.15	1	13.15
Pre-fab costs			
Left wrist component (regular)	20.33	1	20.33
Left wrist component (long)	26.85	1	26.85
Measurement device			
PizzaCake (Goniometry measure device)	1750	1	1750
Statistical support (data management, analysis, etc.)	2660	1	2,660.00
Grand total			$6,001.51

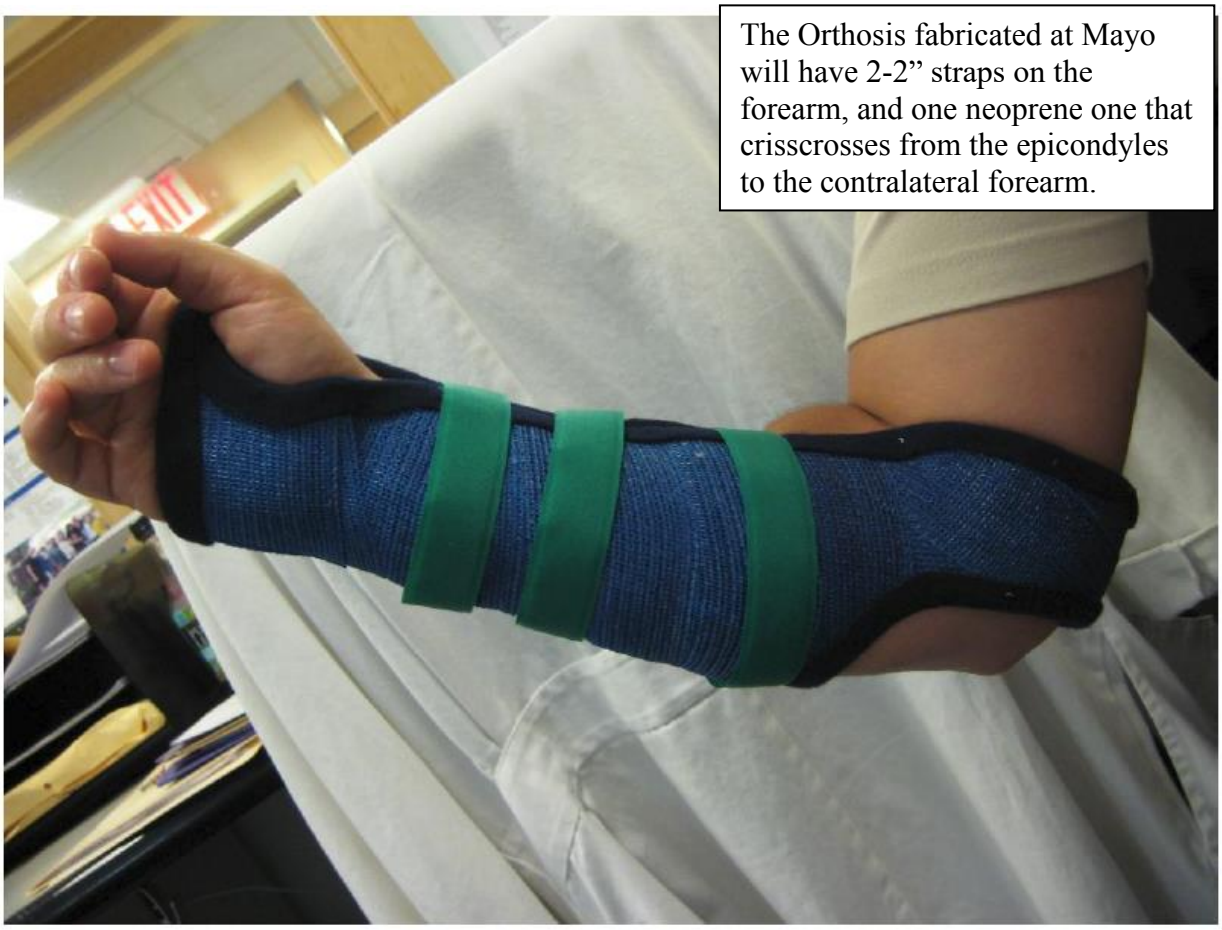
*****This is a requirement through the hand fellowship. Stephanie Kannas, Sarah Cashman and Sara Gross time is free. Due to Maggie Malecha and Adam Orlando now being staff therapists, we will need approximately 90 hours of time total to complete the data collection for the two of them.**

Of note, we have attempted to recruit funds through the Orthopedic department, but Dr. Sanj Kakar is not eligible at this time for further internal funding through orthopedics.

Appendix B

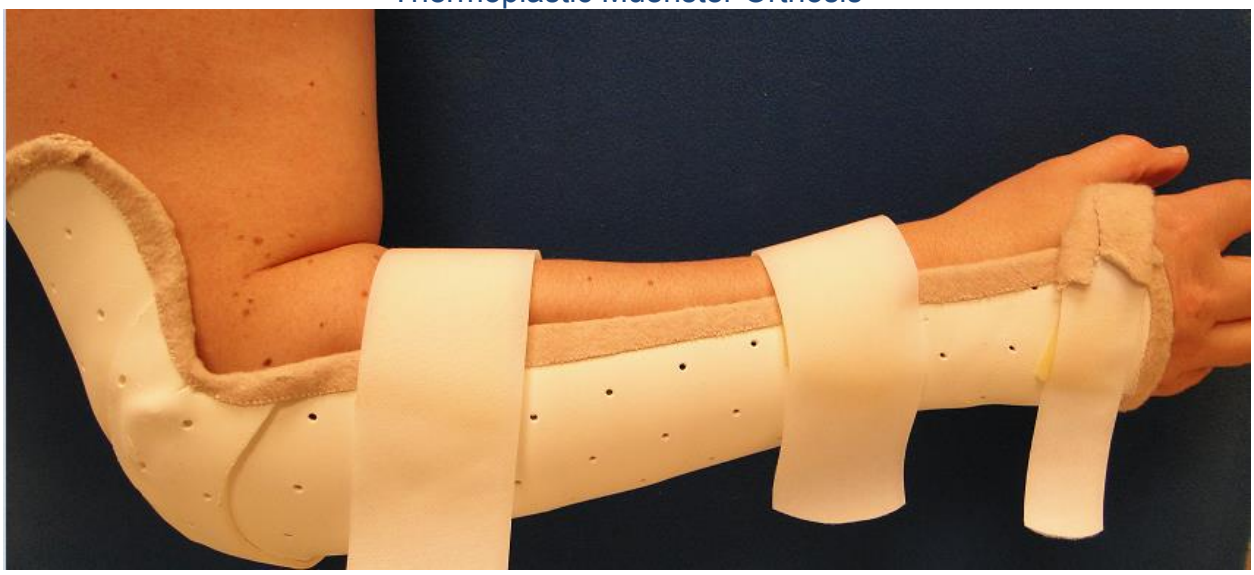
Hely & Weber MTC Fracture Brace

Delta Cast Muenster



The Orthosis fabricated at Mayo will have 2-2" straps on the forearm, and one neoprene one that crisscrosses from the epicondyles to the contralateral forearm.

Thermoplastic Muenster Orthosis



Appendix C

U.S. Department of Health & Human Services

a A A

FDA U.S. FOOD & DRUG ADMINISTRATION

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[Title 21, Volume 8]
[Revised as of April 1, 2018]
[CITE: 21CFR890.3475]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 890 -- PHYSICAL MEDICINE DEVICES

Subpart D--Physical Medicine Prosthetic Devices

Sec. 890.3475 Limb orthosis.

(a) *Identification.* A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, regarding general requirements concerning records and 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38816, July 25, 2001]