Influence of Custom Orthosis Post Carpometacarpal (CMC) Arthroplasty

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THE ELEMENTS OF A RESEARCH PROTOCOL

Influence of custom orthosis post CMC arthroplasty

1. Background, Review of the Literature, Significance

Carpometacarpal (CMC) osteoarthritis (OA) can cause severe pain and loss of hand function, thumb motion and thumb strength (Fontana et al., 2007). CMC arthroplasty, surgery on the thumb joint, is conducted when conservative treatments for CMC OA fail (Grenier et al. 2016). In 2011, 6,960 CMC arthroplasties were conducted in the United States (Werner et al., 2015). Splints or orthoses are typically used after surgery to immobilize the joint as the wound heals. Previous studies have reported mixed results in the comparison of outcomes related to use of custom orthoses and prefabricated splints (Baradaran et al., 2018; Sillem et al., 2011; Marotta et al., 2020; Bani et al., 2013). This study aims to compare post-surgical outcomes, including wound dehiscence, pain, function, and satisfaction with device and care from individuals who receive either a custom orthosis or prefabricated splint after CMC arthroplasty. This study will allow for increased understanding about the pros and cons of prefabricated splints versus custom orthosis which can inform clinical decisions in order to decrease wound dehiscence, the pain associated with wound dehiscence, and enhance function post-surgery for individuals who have CMC arthroplasty.

2. Objectives/Specific Aims

- To determine the difference in the incidence of wound dehiscence after a CMC arthroplasty when using a custom orthosis as compared to a prefabricated splint.
- To determine the difference in subject reported pain levels after a CMC arthroplasty between those who received a custom orthosis as compared to those who received a prefabricated splint.
- To determine the difference in function as measured by the QuickDASH, active range of motion measurements of the thumb, and subtests within the applied dexterity section of the Arthritis Hand Function Test (AHFT) between those wearing a custom orthosis as compared to those wearing a prefabricated splint.
- To determine the difference in subject satisfaction with device and services at the first and second post-operative appointment.

3. Methods

a) **Study Design**

- Experimental, two groups with random assignment

b) **Method of treatment assignment**

Subjects will be randomly assigned using at the initial follow-up appointment following CMC arthroplasty. The surgeon may exclude the subject, following assessment, if the subject cannot be randomly assigned to an intervention group. Open-label blinding will be used since every member of the team will be able to perceive whether the subject has

received a custom orthosis or prefabricated splint. Random assignment to the two groups will be completed in SPSS.

c) **Inclusion/exclusion criteria**

Inclusion criteria for subjects include status post CMC arthroplasty (within 4-5 weeks), 18 or older, able to read and understand English, capable of independently consenting to health care procedures.

Subjects will be excluded from the study if the surgeon identifies risk factors that would preclude random assignment to the control or experimental group. Subjects will also be excluded if they request a prefabricated or custom orthosis.

d) **Justification of the number of subjects**

Anticipated number of subjects that will be requested for enrollment is 125 subjects. A sample size of at least 96 is required for a power of 60 with $\alpha = .05$.

e) **Study setting**

University of Toledo Medical Center (UTMC) outpatient.

f) **Primary and secondary outcome measures**

Primary Outcomes include:
Function - as measured by the QuickDASH
Wound dehiscence – as measured by the Sandy Grading System
Pain - as measured by the Visual Analog Pain Scale
Thumb CMC Active Range of Motion (AROM) measurements
Subtests within the applied dexterity section of the Arthritis Hand Function Test
Satisfaction with device and services – as measured by the OPUS.

Secondary variables of interest include:
Demographic data such as age, gender, race, handedness, pre-existing conditions current medications and supplements, smoking history, and alcohol consumption.

h) **Procedures, interventions, schedule**

FIRST POST-OP APPOINTMENT

Standard of care: At the initial post-op appointment with the surgeon, the client will check in and register for the appointment. A member of the surgical team will assess the client and document the Sandy Score.

Research specific: As a member of the surgical team assesses the client he/she will determine if the client meets the inclusion criteria. If the client does meet the inclusion criteria, the study will be briefly explained using the recruitment flyer. The client will then be asked if he/she is interested in participating.

If the client is interested in participating, a member of research team will meet with the client to review the consent form and answer any questions. Once any questions have been answered, if the subject agrees to participate, he/she will sign the informed consent form. The subjects will be informed both verbally and in writing that they can take consent away at any

time during the research study. A copy of the informed consent form will be given to the subject. The client will be randomly assigned to intervention A or intervention B.

Standard of Care: The subject will receive either a prefabricated splint (Intervention A) or custom orthosis (Intervention B).

*Research specific: T*he subject will then be asked to complete the demographic questionnaire, QuickDASH, and the Pain VAS. Thumb CMC active range of motion measurements will then be collected (radial and palmar abduction). Participants will also complete subtests within the applied dexterity section of the Arthritis Hand Function Test and OPUS survey.

Subjects who are assigned to Intervention A (the prefabricated splint group) will be provided a splint by a member of the surgical team. Subjects who are assigned to Invention B (the custom orthosis group) will be evaluated by an occupational therapist and a custom orthosis will be fabricated.

SECOND POST-OP APPOINTMENT

Standard of Care: Approximately 4-5 weeks later, subjects will attend a second post-op appointment and be assessed by a member of the surgical team. The Sandy score will be documented.

Research specific: At this time, a member of the research team will ask the subject to complete the, QuickDASH, and the Pain VAS. Thumb CMC active range of motion measurements will then be collected (radial and palmar abduction). Participants will also complete subtests within the applied dexterity section of the Arthritis Hand Function Test and OPUS survey.

i) **Planned data analysis**

Means and standard deviations will be calculated for the demographic information such as age and alcohol consumption per week. In-group and between-group percentages will also be calculated for demographic information, such as gender, pre-existing diabetes, and smoking history. The means and standard deviations of scores received on the QuickDASH, Sandy Grading System, Pain VAS, and AROM will be calculated. In-group and between-group descriptive statistics will be calculated for scores on the OPUS and Applied Dexterity section of the Arthritis Hand Function test. Independent student t-tests will be conducted to compare the means between Interventions A and B. Dependent student t-tests will be conducted to compare the initial post-op assessment mean data to the second post-op assessment mean data within groups. P-values will be considered significant if they are less than or equal to 0.05.

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