

Short Forearm Casting Versus Below-elbow Splinting for Acute Immobilization of Distal Radius Fractures

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JHM IRB - eForm A – Protocol

- **Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
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1. Abstract

- a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Problem:

There is no consensus regarding the need to immobilize the elbow in immediate immobilization of closed distal radius fractures post-reduction. Decreased functionality of the upper extremity is a notable morbidity associated with below-elbow splinting of distal radius fractures post-reduction. Few studies have provided evidence comparing sugar tong splinting versus short-arm casting as methods of immediate post-reduction immobilization.

Research Hypothesis:

There is no significant difference in maintenance of reduction, changes in radiographic parameters, or functional scores at two weeks in patients with distal radius fractures treated acutely with a short arm cast versus a sugar tong splint.

Importance:

The study will provide guidance regarding the need for short forearm cast immobilization versus sugar tong splinting in early maintenance of reduction of closed distal radius fractures, as well as functional effects of sugar tong splinting versus short forearm casting.

2. Objectives (include all primary and secondary objectives)

To determine the success of sugar tong splinting versus short arm casting for maintenance of reduction of closed distal radius fractures and to compare the functional outcomes in patients treated with sugar tong splinting versus short forearm casting as guidance for immediate post-reduction immobilization of these fractures.

Primary objectives:

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

- Koval et al. randomized patients to long-arm versus short-arm splinting of post-reduction closed distal radius fractures and reported comparable maintenance of reduction with better functional scores in patients immobilized in a short-arm splint and thus recommended this method for immediate post-reduction immobilization of closed distal radius fractures (Koval et al. 2006).
- Grafstein et al. randomized 101 adult patients with closed distal radius fractures to sugar tong splinting versus above-elbow circumferential casting versus above-elbow volar-dorsal splinting for immediate post-reduction immobilization and followed patients closely for 3 to 4 weeks. They reported no significant difference in loss of reduction, pain scores, range of motion, or ADLs between the three methods of immobilization and thus recommended treatment with any method with which the treating physician is most comfortable (Grafstein et al., 2010).
- Millet and Rushton randomized 99 women with closed distal radius fractures to below elbow plaster casts versus initial plaster casting followed by flexible casting to allow early joint range of motion and reported increased comfort, grip scores

and joint mobility in early treatment period without negative effects of early motion and thus concluded that early mobilization can be a beneficial treatment option (Millet and Rushton, 1995).

- Pool prospectively studied range of motion and radiographic parameters over a two year period in over 200 patients with Colles' fractures treated with five different combinations of above- and below-elbow immobilization and concluded that while all patients went onto union and adequate function, those immobilized in above-elbow plaster lost some degree of supination. He found no benefit to above-elbow immobilization and recommended only below-elbow post-reduction immobilization (Pool, 1973).
- Sarmiento reviewed a case series of 44 patients with intra-articular distal radius fractures treated initially with an above-elbow cast initially and transitioned early to a brace allowing elbow and wrist range of motion while restricting pronation-supination and concluded that although fracture collapse did occur, functional results were good and the early mobilization reduced the stiffness and incapacitation associated with treatment of distal radius fractures (Sarmiento et al.)

4. Study Procedures

- a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).
 - b. Study duration and number of study visits required of research participants.
 - c. Blinding, including justification for blinding or not blinding the trial, if applicable.
 - d. Justification of why participants will not receive routine care or will have current therapy stopped.
 - e. Justification for inclusion of a placebo or non-treatment group.
 - f. Definition of treatment failure or participant removal criteria.
 - g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
- Prospective, randomized, controlled trial
 - One hundred twenty adult patients with closed fractures of the distal radius will be randomized to below-elbow, sugar-tong splinting versus short arm casting for immediate post-reduction immobilization.
 - Residents will undergo a teaching session specifically for instruction on sugar tong splinting versus short arm casting. On-call resident will have access to an electronic folder containing randomization of patient to sugar tong splint versus bivalved short arm cast. All reductions will be performed under local hematoma block with 1% lidocaine and traction and less than three attempts at reduction.
 - Patients will follow up at one, two and four weeks for repeat AP and lateral radiographs of the forearm to measure radiographic parameters to determine maintenance of reduction and will complete the Disabilities of the Arm, Shoulder and Hand Score (DASH) for functional scoring of the upper extremity at two weeks.
 - Maintenance of reduction, as defined below, will be compared between splint constructs overall and in stable versus unstable fractures in each immobilization group. Specific changes in radial height, radial inclination and volar tilt as continuous variables will also be compared, as will DASH scores measuring functionality.
 - Maintenance of reduction will be defined as: loss of reduction of < 2 mm radial height, < 5 degrees of radial inclination or < 10 degrees of volar tilt and/or < 2 mm intra-articular step off, in follow up radiographs as compared to immediate post-reduction radiographs (Koval et al., 2006).
 - Unstable fractures will be defined as, at injury: > 4 mm radial shortening, > 10 degrees dorsal tilt, radial-ulnar translation of radius > 2 mm, dorsal comminution > 50% diameter of radius, > 2mm intra-articular displacement (Koval et al., 2006; Stoffelen and Broos, 1998). Fractures meeting these criteria will undergo ORIF after reduction and at a later time. However, reduction parameters and maintenance of reduction will be evaluated and compared for both splinting techniques until ORIF.

5. Inclusion/Exclusion Criteria

- Inclusion criteria: adult > 18 years of age, closed fracture, isolated injury, no prior injury to ipsilateral forearm, less than or equal to two attempts at reduction.

6. Drugs/ Substances/ Devices

- a. The rationale for choosing the drug and dose or for choosing the device to be used.
- b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.

- c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

Not Applicable

7. Study Statistics

- a. Primary outcome variable.
- b. Secondary outcome variables.
- c. Statistical plan including sample size justification and interim data analysis.
- d. Early stopping rules.

Primary outcome variable: Maintenance of reduction

Secondary outcome variables: Radiographic parameters analyzed individually: radial height, radial inclination, volar tilt, DASH scores

Statistical plan including sample size: Sample size was calculated based on standard deviations for the above-noted outcomes variables reported in the literature and selected a sample size based on the largest calculated sample size. This was increased from 167 to 200 to account for expected dropout.

Early stopping rules: Less than 50% patient follow-up.

8. Risks

- a. Medical risks, listing all procedures, their major and minor risks and expected frequency.
- b. Steps taken to minimize the risks.
- c. Plan for reporting unanticipated problems or study deviations.
- d. Legal risks such as the risks that would be associated with breach of confidentiality.
- e. Financial risks to the participants.
 - No medical risks outside of standard of care.
 - Patients will be treated with standard of care.
 - Research committee of Department of Orthopaedic Surgery follows the progress of the project.
 - No legal risks.
 - No financial risks.

9. Benefits

- a. Description of the probable benefits for the participant and for society.

Below-elbow splinting is associated with decreased morbidity

10. Payment and Remuneration

- a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Not Applicable

11. Costs

- a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

Not Applicable