CHAPTER 7

NONOPERATIVE MANAGEMENT

A Prospective Randomized Controlled Trial of Dynamic vs. Static Progressive Elbow Splinting for Posttraumatic Elbow Stiffness

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Preliminary Results
Abstract

Hypothesis: Both dynamic and static progressive (turnbuckle) methods of splinting are used to help regain motion after elbow trauma. There are advocates of each method, but no comparative data. Our null hypothesis was that there is no difference in improvement of motion and DASH scores between static progressive and dynamic splinting.

Methods: Sixty-six patients with post-traumatic elbow stiffness were enrolled in a prospective randomized trial: thirty-five in the static progressive and thirty-one in the dynamic cohort. Patients were evaluated at 3, 6, and 12 months after enrollment and completed the DASH questionnaire at the 6 and 12 months follow-up. Three patients asked to be switched to static progressive splinting. The analysis was according to intention-to-treat principles.

Results: Until the 12 month evaluation, fifteen patients had a subsequent surgery (due to infection in 2, removal of heterotopic bone in 7, ulnar neuropathy in 2, nonunion in 2, symptomatic implant removal in 1, and to release of a stiff long finger in 1). There were no significant differences in improvement in flexion and extension arc and DASH at any time point. The improvement in the arc of flexion (dynamic vs. static) averaged 30° vs. 28° at three months, 40° vs. 39° at six months, and 47° vs. 49° twelve months after initiating splinting. The average DASH score (dynamic vs. static) was 50 vs. 45 at enrollment, 32 vs. 25 at six months, and 28 vs. 26 points twelve months after enrollment.

Discussion: Post-traumatic elbow stiffness can improve with exercises and dynamic or static splinting over a period of 6 to 12 months and patience is warranted. There were no significant differences between static progressive and dynamic splinting protocols, and the choice can be left to patients and their physicians.

Level of Evidence: Level II

Introduction

Splinting devices are often used to help regain motion after injury or surgery to the elbow. Two types of splints are used. Static progressive (e.g. turnbuckle) splints apply a static stress relaxation force to the elbow tissues that is sequentially increased as motion is achieved. Dynamic splints apply a constant prolonged force to the tissues that persists as additional motion is achieved. Each splint type has advocates, but there is little scientific data available. In this prospective randomized clinical trial, the effectiveness of static progressive splinting and dynamic splinting for the restoration of motion after elbow trauma or surgery for contracture release were compared. Our primary null hypothesis is that there is no difference between static progressive and dynamic elbow splinting in terms of the final arc of flexion and extension and arm-specific disability six months after injury or surgery.
Methods

Participants

The Human Research Committee at our institution approved a prospective randomized clinical trial to compare dynamic vs. static progressive splinting for the restoration of motion after injury or surgery of the elbow. The inclusion criteria were age 18 or greater and loss of more than 30 degrees in flexion, extension or in both directions after an elbow injury or after elbow surgery for post-traumatic problems. Exclusion criteria included active infection, wound problems, inability to cooperate with a structured rehabilitation protocol, burn-related contractures, primary osteoarthritis, and arthroplasty.

Randomization

After informed consent, each patient was randomly assigned to a dynamic splint or a static progressive splint based on a randomized sequence determined by a computer random number generator (Windows Excel; Microsoft, Redmond, WA).

Intervention

We attempted to use dynamic splints manufactured by EMPI (St Paul, MN) and static progressive splints manufactured by Joint Active Systems (Effingham, IL), but alternative splints within these broad classes were accepted according to the preference of insurers and therapists. The splint was adjusted to fit the patient’s limb by a representative of the manufacturer. Patients were instructed to use the splint according to the standard daily wearing and use protocol by the respective device manufacturer and the occupational or physical therapist. According to the general instructions, the static progressive splint is worn for three times per day during a 30-minute period, whereas the dynamic splint is worn for approximately 6 to 8 continuous hours per day or night. Use of the splints was discontinued upon the patient’s discretion or if patients plateaued in active range of motion (defined as no measurable gains in active range of motion achieved in a 30-day period).

Evaluation

At all time points, patients were evaluated by an independent research fellow that was not involved in the care of the patients. Prior to the intervention, demographic information and injury-related medical history were recorded, elbow motion was measured with a hand-held goniometer, and patients completed the Disabilities of Arm Hand and Shoulder (DASH) Questionnaire. The DASH questionnaire was developed by the American Academy of Orthopedic Surgeons in collaboration with the Council of Musculoskeletal Specialty Societies and the Institute for Work and Health as an outcomes instrument specific to the upper extremity, and applicable to a wide variety of problems. The questionnaire contains thirty
items: twenty-one evaluate difficulty with specific tasks, five evaluate symptoms, and one each evaluates social function, work function, sleep and confidence. The score is scaled between zero and 100 with higher scores indicating worse upper extremity function. It was attempted to follow-up with patients as close as possible to 3, 6, and 12 month time-points. At each evaluation elbow motion was measured with a hand-held goniometer, and at the six and twelve month evaluation, patients completed the DASH questionnaire again.

Statistical Analysis
The primary study question addressed improvement in flexion and extension arc at the six-month evaluation. A power analysis indicated that a total sample size of 48 patients (24 patients in each cohort) would provide 80% power ($\beta=0.20$, $\alpha=0.05$) to detect a difference of 10 degrees in improvement flexion arc. To account for a possible loss to follow-up of 20-25% we anticipated enrolling 30 patients in each cohort.

Continuous variables (flexion arc, flexion, flexion contracture, forearm rotation, pronation, supination, DASH scores, time between injury or the most recent surgery and enrollment, number of additional surgeries) were compared between cohorts using Student’s t-test. Differences in dichotomous variables (gender; limb dominance; laborer vs. non-laborer occupation; distal humerus fracture vs. other injury; elbow fracture-dislocation vs. other injury; treatment [original trauma or capsular release for stiffness]; ulnar neuropathy; presence of ipsilateral injury; and completion of the three, six, and twelve month follow-up) were compared between cohorts using Fisher’s Exact test.

This is a pragmatic trial that compared what happens when patients are prescribed specific splints, no matter how often those splints are used. Accordingly, patients were analyzed according to an intention-to-treat principle—patients that requested a change to the alternative splinting device or had surgery during the study period were analyzed according to their randomized cohort assignment.

Results
Recruitment and Participant Flow
Between October 2003 and May 2008, sixty-six patients were enrolled in the trial: 31 patients were assigned to the dynamic splinting cohort and 35 to the static progressive splinting cohort. Sixty-four patients completed the three months evaluation (31 in the dynamic cohort [100%] and 33 in the static progressive cohort [94%]), fifty-two completed the six months evaluation (24 in the dynamic cohort [77%] and 28 in the static progressive cohort [80%]), and forty-nine patients completed the twelve months evaluation (21 in the dynamic cohort [68%] and 28 in the static progressive cohort [80%]).
**Baseline Data**

**Dynamic Splinting Cohort**

Eighteen men and thirteen women with an average age of 45 years (range, 22 to 68 years) were assigned to a dynamic splint. Fourteen patients were employed in a desk-based job, ten as laborers, and seven were unemployed (including one patient that had retired). Fifteen patients were injured in a fall from standing height, ten in a fall from greater height, five in a motor vehicle accident, and one patient was injured by a gunshot. Sixteen patients had an elbow fracture-dislocation, ten patients had a distal humerus fracture, three patients had a radial head fracture, and two an olecranon fracture. Nine patients had open fractures. Seventeen patients injured their left elbow (two were left-hand dominant) and twelve injured their right arm (all right-hand dominant). Two patients with a terrible triad fracture-dislocation had contralateral elbow injuries: a radial head fracture in one patient and a posterior Monteggia fracture-dislocation in the other. Four patients had injuries of the same upper extremity: one patient with an anterior olecranon fracture-dislocation also had a proximal humerus fracture-dislocation and a posterior Monteggia fracture-dislocation of the forearm; one patient with a distal humerus fracture had fractures of the proximal humerus, the humeral shaft and the scaphoid; one patient with a terrible triad fracture had a distal radius fracture; and one patient with a radial head fracture-dislocation had a scaphoid fracture.

Twenty-four patients had operative treatment of the initial injury: open reduction and internal fixation in twenty-four patients (6 of these also had a radial head replacement), and excision of the radial head after attempted replacement in one patient. One patient with an open fracture was treated with an external fixator after irrigation and debridement. Five patients had closed reduction of the elbow. Eight patients had a total of ten additional surgeries prior to enrollment in the trial: one patient had four procedures address nonunion, stiffness and ulnar neuropathy; one patient had a second procedure for irrigation and debridement of an open fracture, and a third procedure to address a malunion, stiffness and heterotopic bone, and ulnar nerve compression one year later; one patient with stiffness had a radial head replacement four months after the initial treatment, and a release with excision of heterotopic bone and removal of the radial head prosthesis one year later; two patients had an elbow release with excision of a radioulnar synostosis and ulnar nerve transposition in one and decompression in the other patient; one patient with an unstable elbow after closed reduction of a terrible triad injury had fixation of the coronoid fracture, radial head replacement, repair of the lateral collateral ligament, application of an external fixator, and a carpal tunnel release one month after the injury, followed by removal of the hinge and manipulation under anesthesia after two months; one patient had an ulnar nerve release; and one patient had a second procedure for open reduction and internal fixation of a nonunion of the distal humerus; and one patient.

Twenty-four patients were enrolled after treatment of the initial trauma, at an average 8 weeks (range, 2 to 31 weeks) after injury or the most recent surgical procedure, and in three patients
following an additional procedure for hinge removal. Seven patients were enrolled after open contracture release, at an average 6 weeks (range, 1 to 22 weeks) after that procedure.

**Static Progressive Splinting Cohort**

Twenty-two men and thirteen women with an average age of 43 years (range, 19 to 70 years) were assigned to a static progressive splint. Fifteen patients were occupied in a desk-based job, nine were laborers, one was an athlete, two were students, seven were unemployed (one patient had retired).

Fourteen patients were injured in a fall from greater height, ten in a fall from standing height, six in a motor vehicle accident, three in a fight, one in a sport-related injury, and one patient was injured by a gunshot. Seventeen patients had a distal humerus fracture, sixteen had an elbow fracture-dislocation, one patient had a radial head fracture, and one patient an olecranon fracture. Twenty patients injured their left elbow (two were left-dominant) and fifteen injured their right elbow (thirteen were right-dominant). Four patients had an ipsilateral distal radius fracture, together with a concomitant scaphoid fracture in one patient, a radial shaft and scaphoid fractures and a compartment syndrome in one patient, and a metacarpal fracture in another patient. Two other patients had ipsilateral metacarpal fractures, and one patient had a scapholunate interosseous ligament tear. One patient had a contralateral distal radius fracture.

Ten patients had an open fracture.

Twenty-nine patients had open reduction and internal fixation of the initial injury and in three of these patients the radial head was replaced by a metal prosthesis, and in one patient an external fixator was applied. Among the remaining six patients that were treated by closed reduction of the fracture, two patients had open reduction and internal fixation of associated fractures of the same limb and extensive forearm fascia releases because of compartment syndrome, and in one of these the elbow was stabilized with a percutaneous pin. Nine patients had a total of 24 operative procedures on their elbow prior to enrollment in this trial: one patient had undergone thirteen previous procedures for infection, nonunion and stiffness; three other patients had a total of four procedures to address stiffness including excision of heterotopic bone in all three and ulnar nerve release or transposition in two; two patients needed one additional surgery to address a nonunion (of an olecranon osteotomy in one patient); one patient had a transposition of the ulnar nerve; one patient had two additional procedures to address compartment syndrome; one patients with a compound fracture had two procedures for irrigation and debridement after initial open reduction and internal fixation.

Twenty-eight patients were enrolled after treatment of the initial trauma, at an average 11 weeks (range, 3 to 34 weeks) after closed reduction or the most recent surgery. Seven patients were enrolled an average 5 weeks (range, 2 to 10 weeks) after the most recent surgery for contracture release or nonunion.
Baseline Comparison of Cohorts
Prior to initiation of splint use, there were no differences between the dynamic and static progressive splinting cohorts in type of treatment prior to enrollment (treatment of the acute trauma vs. subsequent surgery for stiffness or nonunion; \( p = 1.00 \)), presence of ipsilateral upper extremity injury (\( p = 1.00 \)), number of additional surgeries (\( p = 0.37 \)), time between initiation splint use and closed reduction or last surgery for treatment of the initial trauma (\( p = 0.16 \)) or the most recent surgery for release or nonunion (\( p = 0.53 \)), laborer vs. non-laborer occupation (\( p = 0.21 \), elbow fracture-dislocations vs. other injury (\( p = 0.33 \)), limb dominance (\( p = 1.00 \)), gender (\( p = 1.00 \)) and age (\( p = 0.74 \)). In the static progressive splinting cohort were relatively more patients that had a distal humerus fracture (\( p = 0.01 \)).

Numbers Analyzed
At enrollment, motion measurements and DASH questionnaires were completed in all 26 patients in the dynamic splinting cohort and in all 31 patients in the static progressive splinting cohort (both 100%). At the three-month evaluation, motion was measured in 26 patients in the dynamic splint cohort (100%) and 30 patients in the static progressive splint cohort (97%). At the six month evaluation, motion was measured in 24 patients in the dynamic (892%) and 28 patients in the static progressive (90%) splint cohort, and the DASH questionnaire was completed by 18 patients in the dynamic (69%) and 24 in the static progressive (77%) splint cohort. At the twelve month evaluation, motion was measured in 21 patients in the dynamic splint cohort (81%) and in 28 patients in the static progressive splint cohort (90%), and 19 patients in the dynamic (73%) and 23 in the static progressive (74%) splint cohort completed the DASH questionnaire.

Subsequent Treatment
Three patients in the dynamic splinting cohort (12%) requested a change to a static progressive splint prior to the three months evaluation because of discomfort and pain using the dynamic splint. Two patients in the static progressive splinting cohort had an infection that required irrigation and debridement with partial removal of implants at two and three weeks after enrollment.

Between the three and six month evaluation, one patient in the dynamic splinting cohort that had changed to a static progressive splint, had surgery to remove heterotopic bone that blocked flexion. In the static progressive splinting cohort, there were five patients that had a total of eight additional surgeries during this time interval: three patients had a contracture release with excision of heterotopic bone that interfered with motion; one patient had an ulnar nerve release, and one patient had four surgeries for an infected nonunion.

Between the six and twelve month evaluation, two patients in the dynamic splinting cohort had an elbow contracture release, with excision of heterotopic bone and an ulnar nerve release.
in one, and with excision of a proximal radioulnar synostosis in the other. In the static progressive splinting cohort, five patients had additional elbow surgery between six and twelve months: three patients had a contracture release, with excision of heterotopic bone in one patient, release of the ulnar nerve in one patient, and with exploration of a suspected ulnar nonunion (that was found to be healed) and capsular release in the third patient; one patient had surgery for symptomatic implants; and one patient had a release of a stiff long finger during this period. One patient was noted to have an ununited fracture of the radial head after plate and screw fixation, but declined additional surgery.

**Outcomes**

**Enrollment**

In the dynamic splinting cohort, the flexion arc averaged 53 degrees (range, 30 to 95 degrees) with an average flexion of 102 degrees (range, 85 to 130 degrees) and an average flexion contracture of 48 degrees (range, 20 to 70 degrees). The arc of forearm rotation averaged 123 degrees (range, 20 to 180 degrees) with an average pronation of 70 degrees (range, 25 to 90 degrees) and an average supination of 53 degrees (range, -20 to 90 degrees). The average DASH score was 50 points in this cohort (range, 8 to 93 points). Two patients had signs or symptoms of ulnar nerve dysfunction.

In the static progressive splinting cohort, the flexion arc averaged 54 degrees (range, 20 to 90 degrees) with an average flexion of 101 degrees (range, 75 to 125 degrees) and an average flexion contracture of 48 degrees (range, 20 to 75 degrees). The arc of forearm rotation averaged 129 degrees (range, 70 to 180 degrees), with an average 64 degrees pronation (range, 0 to 90 degrees) and an average 65 degrees supination (range, 20 to 90 degrees). The DASH score averaged 45 degrees (range, 8 to 85 degrees). Two patients had signs of ulnar nerve dysfunction.

Upon enrollment, there were no differences between the dynamic and static progressive splinting cohorts in terms of flexion arc (p = 0.96), flexion (p = 0.90), flexion contracture (p = 0.84), forearm rotation (p = 0.62), pronation (p = 0.36), supination (p = 0.15), DASH scores (p = 0.46), and ulnar neuropathy (p = 1.00). (figure 1)

**Three Month Evaluation**

The three month evaluation took place after an average 10 weeks in both cohorts (ranges, 6 weeks to 4 months in the static progressive cohort, and 7 weeks to 4 months in the dynamic cohort; p = 0.70).

In the dynamic splinting cohort, the flexion arc averaged 83 degrees (range, 35 to 130 degrees) with an average flexion of 117 degrees (range, 90 to 145 degrees) and average flexion contracture of 34 degrees (range, 15 to 70 degrees). The average improvement in flexion arc was 30 degrees (range, 0 to 75 degrees; p < 0.001). The arc of forearm rotation...
averaged 133 degrees (range, 20 to 180 degrees) with an average pronation of 70 degrees (range, 10 to 90 degrees) and an average supination of 64 degrees (range, 0 to 90 degrees). One patient had signs of ulnar nerve dysfunction.

In the static progressive cohort, the flexion arc averaged 82 degrees (range, 25 to 130 degrees) with an average flexion of 118 degrees (range, 95 to 145 degrees) and an average flexion contracture of 36 degrees (range, 10 to 75 degrees). The alteration in flexion arc averaged 28 degrees (range, a loss of 25 degrees to a gain of 70 degrees; \(p < 0.001\)). The arc of forearm rotation averaged 144 degrees (range, 70 to 180 degrees) with an average pronation of 75 degrees (range, 30 to 90 degrees) and an average supination of 69 degrees (range, 0 to 90 degrees). Three patients had signs of ulnar nerve dysfunction.

There were no statistically significant differences between cohorts in terms of flexion arc (\(p = 0.88\)), flexion (\(p = 0.86\)), flexion contracture (\(p = 0.67\)), improvement in flexion arc (\(p = 0.80\)), the arc of forearm rotation (\(p = 0.40\)), pronation (\(p = 0.37\)), supination (0.51), and ulnar nerve dysfunction (\(p = 1.00\)). (figure 1)

Six Month Evaluation

The six months evaluation took place after an average 6 months (range, 4 to 8 months) in the dynamic splinting cohort and after an average 6 months in the static progress splinting cohort (range, 4.5 to 8 months ; \(p = 0.114\)).

In the dynamic splinting cohort, the flexion arc averaged 93 degrees (range, 15 to 130 degrees) with an average flexion of 122 degrees (range, 95 to 145 degrees) and an average flexion contracture of 29 degrees (range, 15 to 85 degrees). The average improvement in flexion arc was 40 degrees (range, a loss of 15 degrees to a gain of 70 degrees ; \(p < 0.001\)). The arc of forearm rotation averaged 140 degrees (range, 20 to 180 degrees) with an average pronation of 75 degrees (range, 20 to 90 degrees) and an average supination of 64 degrees (range, 0 to 90 degrees). The DASH score averaged 32 degrees (range, 5 to 83 degrees). One patient had signs of ulnar nerve dysfunction.

In the static progressive splinting cohort, the flexion arc averaged 91 degrees (range, 50 to 140 degrees) with an average flexion of 123 degrees (range, 90 to 145 degrees) and an average flexion contracture of 31 degrees (range, 0 to 60 degrees). The average alteration in flexion arc was 39 degrees (range, a loss of 10 degrees to a gain of 85 degrees; \(p <0.001\)). The arc of forearm rotation averaged 150 degrees (range, 45 to 180 degrees) with an average pronation of 76 degrees (range, 30 to 90 degrees) and an average supination of 74 degrees (range, 10 to 90 degrees). The DASH score averaged 25 degrees (range, 3 to 50 degrees). Three patients had signs of ulnar nerve dysfunction.

There were no statistically significant differences between cohorts in terms of flexion arc (\(p = 0.84\)), flexion (\(p = 0.75\)), flexion contracture (\(p = 0.70\)), improvement in flexion arc (\(p = 0.78\)),
forearm rotation ($p = 0.38$), pronation ($p = 0.90$), supination ($p = 0.20$), ulnar nerve dysfunction ($p = 1.00$), and DASH scores ($p = 0.21$). (figure 1)

Figure 1. flexion and extension arc after a static or dynamic splinting program

One Year Evaluation

The one year evaluation took place after an average 13 months (range, 10 to 18 months) in the dynamic splinting cohort, and after an average 14 months in the static progressive cohort (range, 10 to 22 months; $p = 0.06$)

In the dynamic splinting cohort, the flexion arc averaged 100 degrees (range, 25 to 135 degrees) with an average flexion of 128 degrees (range, 95 to 150 degrees) and an average flexion contracture of 28 degrees (range, 0 to 70 degrees). The average alteration in flexion arc was 47 degrees (range, a loss of 5 degrees to a gain of 85 degrees; $p < 0.001$). Forearm rotation averaged 154 degrees (range, 20 to 180 degrees) with an average pronation of 83 degrees (range, 40 to 90 degrees) and an average supination of 71 degrees (range, -20 to 90 degrees). The DASH score averaged 28 points (range, 3 to 76 points). One patient had signs of ulnar nerve dysfunction.

In the static progressive splinting cohort, the flexion arc averaged 105 degrees (range, 60 to 140 degrees) with an average 126 degrees flexion (range, 90 to 140 degrees) and an average 21 degree flexion contracture (range, 0 to 50 degrees). The average improvement in flexion arc was 49 degrees (range, 0 to 95 degrees; $p < 0.001$). Forearm rotation averaged 156 degrees (range, 90 to 180 degrees) with an average pronation of 79 degrees (range, 30 to 90 degrees) and an average supination of 76 degrees (range, 40 to 90 degrees). The DASH score averaged
26 points in the static progressive splinting cohort (range, 2 to 77). Two patients had signs of ulnar nerve dysfunction.

There were no statistically significant differences between cohorts in terms of flexion arc (p = 0.54), flexion (p = 0.54), flexion contracture (p = 0.15), improvement in flexion arc (p = 0.79), forearm rotation (p = 0.89), pronation (p = 0.45), supination (p = 0.46), ulnar nerve dysfunction (p = 1.00), and DASH score (p = 0.74).

Discussion

The results of our trial of dynamic vs. static progressive splinting demonstrate that both types of splints may be effective adjunctive tools to restore motion in the rehabilitation from elbow trauma or elbow contracture release. With the numbers available, we did not find significant differences in flexion arc or improvement in flexion arc between the two cohorts at any of the evaluation points. Based on these results, the choice between both devices can be left to physicians, therapists, insurers and patients.

The most important finding of this study may be that none of the patients had a subsequent surgery for capsular release alone. The need for surgery was associated with concrete causes in each of the patients, such as heterotopic bone blocking motion, nonunion, infection, or prominent hardware. If there is no heterotopic bone interfering with motion, it would seem that contracted elbow capsules may be stretched successfully with a continuous or a static stress relaxation force to achieve functional motion and avoid surgery.

Our results (an average improvement of 40 degrees with dynamic splinting and 39 degrees with static progressive splinting at six months, and 49 vs. 47 degrees at twelve months) compared favorably with or were better than results for static progressive2-5 and dynamic splinting6-8 as reported previously. Although the major gains in motion were made during the first months after trauma or surgery, patients kept improving until six to twelve months after the injury or surgery, indicating that patience is warranted.

Three patients that were initiated on a dynamic splint requested a change to a static progressive splint because of pain and discomfort with splint use. It has been speculated that wearing a dynamic splint is more demanding as compared to a static progressive splint9, although this cannot be confirmed based on our data.

The most important shortcoming of our study is the loss to follow-up. It demonstrates the difficulties of getting patients back at regular intervals during an intensive and sometimes painful rehabilitation. There was no significant difference in the number of lost patients between the two cohorts.

Based on our results both dynamic as static progressive splinting may facilitate exercises during the rehabilitation after elbow trauma and thereby help stretching the soft tissues surrounding the elbow. The surgeon and patient will need to be patient as regaining motion takes time. Previous studies suggested that psychosocial aspects may be important during...
recovery: e.g., depression, ineffective coping skills and pain have been associated with worse outcome after upper extremity interventions. Postoperative stretching exercises and splinting may be painful in the majority of patients. A good communication between physician and patient may be essential in improving the patient’s self-efficacy and confidence with painful exercises.

References