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PROSPECTIVE RANDOMIZED TRIAL OF CONTINUOUS PASSIVE MOTION VERSUS PHYSICAL THERAPY AFTER ARTHROSCOPIC RELEASE OF ELBOW CONTRACTURE

SUPPLEMENTARY APPENDIX

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SUPPLEMENTAL METHODS

Trial procedures

At baseline, patients who were enrolled were given paper forms to complete questionnaires that were used to calculate the following outcome scores:

1. American Shoulder and Elbow Surgeons-Elbow (ASES-Elbow): The ASES-Elbow is a standardized elbow evaluation developed by the Research Committee of the American Shoulder and Elbow Surgeons(1). The patient self-evaluation form is divided into two subscales: pain and function. The pain subscale contains visual analogical scales (from 0 = no pain to 10 = worst pain ever) for pain evaluation. Scores on the ASES-Elbow pain subscale range from 0 to 50, with higher scores indicating worse pain. The function subscale contains questions relating to the function of the arm. The responses are scored on a four-point ordinal scale: 0 = **Unable** to do; 1 = **Very** difficult to do; 2 = **Somewhat** difficult; 3 = **Not** difficult. Scores on the ASES-elbow function subscale range from 0 to 36, with higher scores indicating better function
2. Disability of Arm, Shoulder and Hand (DASH) Questionnaire: The DASH Questionnaire is a standardized questionnaire which evaluates impairments and activity limitations, as well as participation restrictions for both leisure activities and work(2). All items of DASH are scored with a five-point scale: 1 = no difficulty; 2 = mild difficulty; 3 = moderate difficulty; 4 = severe difficulty; 5 = unable. For each module, the sum of the responses produces a score, which then is transformed to obtain the DASH scores. This score ranges between 0 (no disability) and 100 (severe disability) for each domain. Therefore, a high DASH score indicates severe disability.
3. European Quality of Life–5 Dimensions questionnaire (EQ-5D): The EQ-5D is a standardized questionnaire which assesses five dimensions of quality of life. Scores on the EQ-5D were converted into utility scores based on normative data for the United States. Utility scores range from 0 to 1, with higher scores indicating better quality-of-life status.

Additionally, at baseline patients who were enrolled underwent physical examination measurements and functional assessment of the elbow as follows:

1. Active elbow motion was measured on the affected side in the flexion-extension plane by a trained evaluator who was blinded to the group assignment using a goniometer. The arc of motion (ROM) was calculated as the difference between the maximum flexion and extension.
2. Forearm circumference was measured 1.5 centimeters distal to lateral epicondyle bilaterally. Each measurement was repeated two times and the average of the two measurements was used for analyses.
3. Bilateral grip strength was measured three times using a Jamar Hand Dynamometer with participants seated, their elbow by their side and flexed to right angles, and a neutral wrist position. The best of the three measurements was used for analyses. The results were presented as the absolute difference between the surgical and non-surgical side.
4. Isometric flexion strength, dynamic flexion strength and flexion endurance of the operative side were measured and compared with the contralateral side using a BTE machine (Baltimore Therapeutic Equipment, Simulator II, Hanover, MD, USA). All

measurements were performed bilaterally first on the non-surgical side and then on the surgical side under the following protocol:

a. The BTE machine was adjusted to correct lever arm length and isometric flexion strength was measured first. With the elbow flexed at 90° and the hand grasping the lever arm in supinated position, patients were asked to flex the lever arm as hard as possible and hold for six seconds. Patients were asked to perform this procedure two more times for a total of three trials. The strength measurement reported is the mean of 3 trials with a coefficient of variation < 10%.
b. Dynamic flexion strength was assessed with 50% of the peak isometric flexion strength recorded in the previous step moving through full ROM as fast as possible for 10 seconds. No resistance was set in extension. Dynamic strength was recorded in Engals as a function of power (work/time) (1 Engal is the effort required to move a load of 1 inch-pound 1° in 1 sec).
c. Flexion endurance was assessed also with 50% of the peak isometric flexion strength moving through full ROM at a steady pace of 15/minute for 2 minutes. Endurance was recorded as a function of total work done at the end of 2 minutes.

Measurements of forearm circumference, grip strength and BTE testing were performed by qualified therapists of our hand therapy department who were not blinded to the group assignment.

At day 3, patients underwent the same physical examination measurements and BTE testing described above.

Follow-up visits were scheduled at 6 weeks, 3 months and 1 year postoperatively. At each visit, patients underwent the same physical examination measurements and completed the questionnaires to calculate the outcome scores described at baseline with the addition of the Summary Outcome Determination Score (SOD) which is only collected postoperatively. The SOD score is a validated global score(3) which is used to obtain an overall perspective of a patient's response to treatment. Patients are asked "If 10 is a perfectly normal elbow, 0 is the same as you were before the surgery, and -10 would mean that you died from complications of the surgery, which number best describes your elbow? Scores on the SOD score range from -10 to 10 from the worst possible to the best possible outcome respectively.

The timetable for trial procedures is summarized in Table 1

In addition, starting from the first postoperative day and for 90 days postoperatively, patients completed a paper diary (Fig. 1). To confirm completion of their diaries, patients received a reminder call every week for the 90 days by the trial coordinator. To discourage participants from dropping out of the study, each patient in each group received a remuneration of $400 at the completion of the study.

Table 1. Timetable for trial procedures

	Baseline: Pre-operative	3 days	6 weeks	3 months	1 year
ROM	✓	✓	✓	✓	✓
Forearm circumference	✓	✓	✓	✓	✓
Grip strength	✓	✓	✓	✓	✓
BTE testing	✓	✓	✓	✓	✓
ASES-Elbow (Function/Pain)	✓		✓	✓	✓
DASH	✓		✓	✓	✓
EQ-5D	✓		✓	✓	✓
SOD Score			✓	✓	✓

Adverse events

In addition to serious surgery-related adverse events and complications, we defined an adverse event as a persistent worsening of symptoms resulting in additional treatment outside the trial. We asked patients at every follow-up to report any complications, signs, or symptoms they perceived as an adverse outcome related to their treatment. Adverse events were elicited during three-time windows: the time from the procedure to hospital discharge, the time from discharge to the 3-month postoperative visit collected in patients diaries, and the time from the 3-month postoperative visit to the end of the trial.

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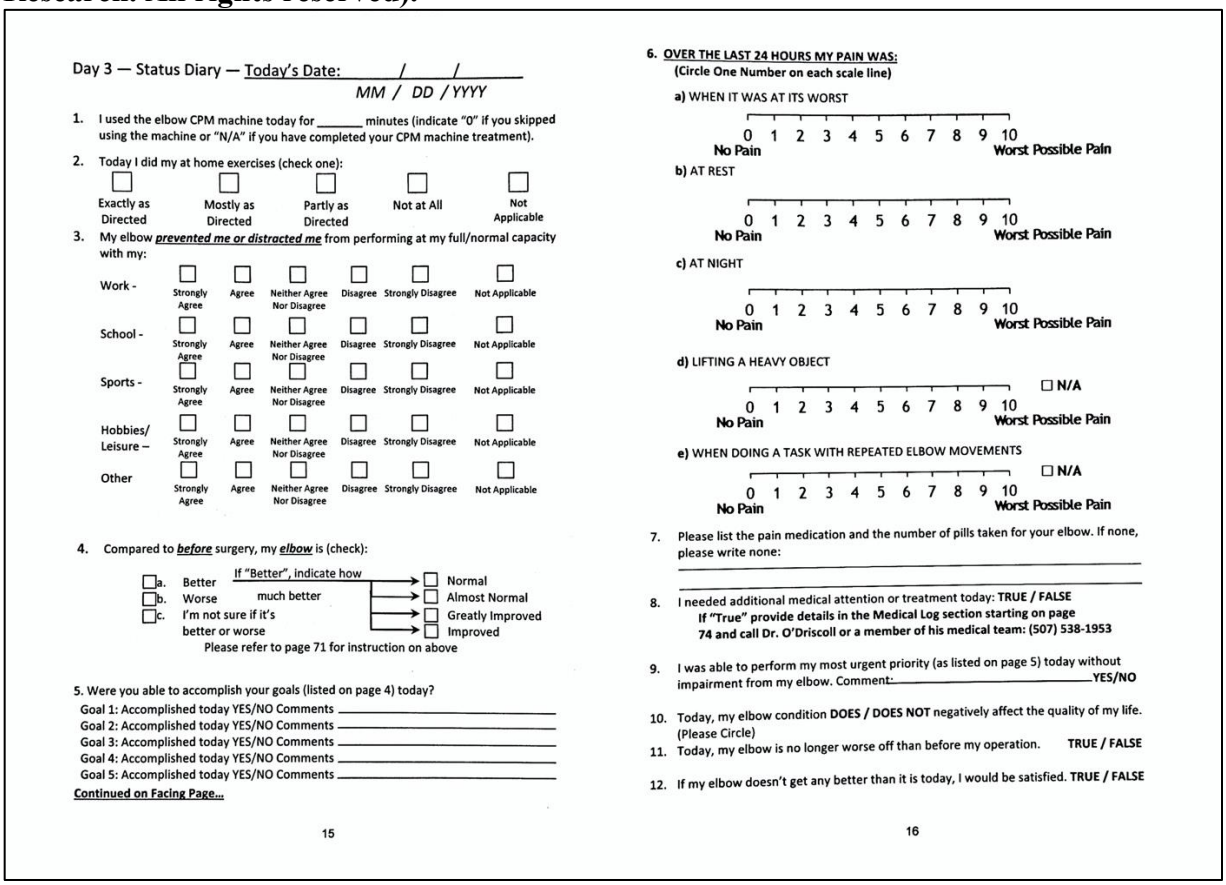
Fig 1. Patient diary (By permission of Mayo Foundation for Medical Education and Research. All rights reserved).



Day 3 — Status Diary — Today's Date: ____/____/____
MM / DD / YYYY

1. I used the elbow CPM machine today for _____ minutes (indicate "0" if you skipped using the machine or "N/A" if you have completed your CPM machine treatment).
2. Today I did my at home exercises (check one):
   ☐ Exactly as Directed ☐ Mostly as Directed ☐ Partly as Directed ☐ Not at All ☐ Not Applicable
3. My elbow ***prevented me or distracted me*** from performing at my full/normal capacity with my:

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree	Not Applicable
Work -	☐	☐	☐	☐	☐	☐
School -	☐	☐	☐	☐	☐	☐
Sports -	☐	☐	☐	☐	☐	☐
Hobbies/ Leisure –	☐	☐	☐	☐	☐	☐
Other	☐	☐	☐	☐	☐	☐

4. Compared to ***before*** surgery, my ***elbow*** is (check):
   ☐a. Better → If "Better", indicate how much better: ☐ Normal ☐ Almost Normal ☐ Greatly Improved ☐ Improved
   ☐b. Worse
   ☐c. I'm not sure if it's better or worse
   Please refer to page 71 for instruction on above
5. Were you able to accomplish your goals (listed on page 4) today?
   Goal 1: Accomplished today YES/NO Comments _____
   Goal 2: Accomplished today YES/NO Comments _____
   Goal 3: Accomplished today YES/NO Comments _____
   Goal 4: Accomplished today YES/NO Comments _____
   Goal 5: Accomplished today YES/NO Comments _____
   Continued on Facing Page...

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6. **OVER THE LAST 24 HOURS MY PAIN WAS:**
   (Circle One Number on each scale line)
   a) WHEN IT WAS AT ITS WORST
   b) AT REST
   c) AT NIGHT
   d) LIFTING A HEAVY OBJECT ☐ N/A
   e) WHEN DOING A TASK WITH REPEATED ELBOW MOVEMENTS ☐ N/A

   0 1 2 3 4 5 6 7 8 9 10
   No Pain — Worst Possible Pain
7. Please list the pain medication and the number of pills taken for your elbow. If none, please write none:
   _____
   _____
8. I needed additional medical attention or treatment today: **TRUE / FALSE**
   If "True" provide details in the Medical Log section starting on page 74 and call Dr. O'Driscoll or a member of his medical team: (507) 538-1953
9. I was able to perform my most urgent priority (as listed on page 5) today without impairment from my elbow. Comment: _____ **YES/NO**
10. Today, my elbow condition **DOES / DOES NOT** negatively affect the quality of my life. (Please Circle)
11. Today, my elbow is no longer worse off than before my operation. **TRUE / FALSE**
12. If my elbow doesn't get any better than it is today, I would be satisfied. **TRUE / FALSE**

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Trial interventions

CPM protocol

In hospital

The senior's author physician assistant who has several years of experience in the use of CPM in the elbow set up the CPM machine in all the included patients. At day 1, the CPM machine was set to reflect the passive ROM achieved in surgery with minimal force (less than 1 kg. force). Patients were in the machine for 55 minutes out of every hour. At days 2 and 3, patients were allowed to be out of the machine for 10 minutes and 15 minutes out of every hour respectively.

At home

Patients were discharged from the hospital on day 3 with a home CPM program on a standard protocol in which they came out of the CPM machine for as long of the elbow could tolerate without becoming swollen or painful until reaching a point where they were able to stay out of the machine for 8 to 10 hours. At that point, they would start using the machine for 3 sessions per day of 30 minutes then gradually decrease the number of sessions and minutes until they were free of the use of the machine. This could take up to 4 weeks.

PT protocol

Patients in the PT group were discharged the same day of surgery but were required to stay locally for 3 days if from out of town in order to be assessed and treated by members of our hand therapy department. The additional costs related to the study such as accommodation, food and elbow functional assessment and therapy were reimbursed. During these three days, PT included mobilization of edema, soft tissue manual therapy and passive and active ROM exercises. A home-therapy program was given to the patients in which they were instructed to perform 10-15 repetitions of active ROM and 5 repetitions of 1-minute holds at the tolerated end ROM at least 5 times per day. Patients were fitted with an anterior custom-made orthosis set to the patient's maximal extension that was worn only at night. Following the 3 days of therapy at our institution, patients found a physiotherapist near their home where they were to be seen 3 times a week for 4 weeks while continuing daily home exercises in that period. The study coordinator called the patients every week to confirm they had been able to establish and start the supervised PT sessions.

Definition of the ROM-related outcomes

1. Percentage of lost motion recovered: The relative improvement in elbow ROM at 1 year was defined as the percentage of lost motion recovered from baseline to 1 year. Recognizing that the normal arc of elbow motion is 145°, the change as a percent of lost normal motion that was recovered at 1 year was calculated from the formula:

$$\frac{(arc\ of\ motion\ at\ 1\ year) - (preoperative\ arc\ of\ motion)}{145 - (preoperative\ arc\ of\ motion)} x\ 100\%$$

2. Functional ROM: A functional ROM was defined according to Morrey et al(4) as an arc of elbow motion with at least 30° of extension and at least 130° of flexion. Accordingly, a functional flexion was defined as a flexion ≥ 130° and a functional extension was defined as an extension ≤ 30°.

Blinding methods

In this trial a single-blinding method was implemented in which one trained evaluator who was blinded to the group assignment throughout the trial period measured the primary outcome (elbow ROM).

The performing surgeon was blinded until the end of the surgical procedure. Since only the patients in the CPM group would receive a postoperative brachial plexus block, during the trial period the performing surgeon was not allowed to check the details of the surgical schedule and the surgical team were made aware to not discuss anesthetic blocks or pain management with the performing surgeon before or during surgery to prevent accidental unblinding. Similarly, although normally the performing surgeon coaches/encourages patients one-on-one in the use of the CPM machine while they are in hospital, during the trial period the performing surgeon was not allowed to do this with patients in the CPM group this study since the same type of one-on-one coaching/encouragement by the surgeon could not be offered to the patients in the PT group.

Post-randomization exclusions.

Nine patients were excluded after randomization. Four patients withdrew consent after randomization and before surgery. Five patients had intraoperative or postoperative exclusion criteria as follows:

Patient 1.

- Exclusion criteria: Altered anatomy that might limit elbow motion.
- Description: A severe intraarticular malunion with severe erosive arthritis due to chronic renal disease was found intraoperatively. These changes were not evident during the preoperative assessment when the participant consented to randomization.

Patient 2.

- Exclusion criteria: Significant portion of the procedure performed in an open manner
- Description: After examination under anesthesia instability was diagnosed and it was determined that a ligament reconstruction was needed. This required a significant portion of the procedure to be performed open and required postoperative immobilization for 2-3 weeks which precluded participation in the trial.

Patient 3.

- Exclusion criteria: Intra-operative or postoperative complication that could affect outcome
- Description: Intraoperative median nerve partial laceration and repair

Patient 4.

- Exclusion criteria: Intra-operative or postoperative complication that could affect outcome
- Description: Rapidly progressive delayed onset ulnar neuritis with rapidly deterioration of motion, interrupting rehabilitation

Patient 5.

- Contraindication to use of CPM.

Description: Patient with very short stature randomized to CPM could not fit in the CPM machine.

SUPPLEMENTAL STATISTICAL ANALYSIS

All analysis were planned to be performed on an intent-to-treat basis, however, given that there were no major protocol violations during the study, the modified intention-to-treat population was the same as the per protocol population. Initial analyses compared the baseline characteristics of patients between CPM and PT groups using means, medians, or percentages depending on the type of variable. Differences at baseline were examined with the use of a Student's t-test or Mann U Whitney test as appropriate for continuous variables and with the use of the chi-square test or Fisher's exact test for categorical variables. Fisher's exact test was used

to compare the number of patients with at least 1 surgery-related adverse event and the surgical adverse event rate.

Primary outcome

The aim of the primary outcome was to show that CPM was superior to PT for ROM improvement. The P-value considered to indicate statistical significance was corrected for tests on ROM data rounded at 5° adjusting the level of significance as follows. Given that the standard deviation (lower value of the 2 samples) was in the range between 5° and 20° (16.4°), the P-value was adjusted using the following formula (SD2/100) – 0.25)/100 and was set to .026 instead of .05(5). The hypothesis was tested using a mixed model analysis for repeated measures where trial group, postoperative visit, the interaction between trial group and visit, baseline ROM and baseline patient preference for treatment were fixed variables and subject a random variable. The adjusted mean difference between groups in the primary outcome was tested at 1 year, 3 months and 6 weeks. Results were reported as least-squares means and 95% confidence intervals, including the mean differences between groups.

There were no missing values at any time point and therefore no sensitivity analyses or data imputation were required.

Secondary outcomes

Continuous secondary outcomes were analyzed separately with the same type of mixed model for repeated measures as specified for the primary outcome, but without the patient preference at baseline as a covariate given that it was not a confounder nor an effect modifier for any of the secondary outcomes.

The categorical secondary outcomes of the percentage of patients who had a functional arc of motion, functional flexion, and functional extension at 1 year were evaluated with Cochran-Mantel-Haenszel chi-squared tests, controlling for the severity of the contracture at baseline. The stratification factor for the severity of the contracture included three levels: mild contracture (arc of motion >90°), moderate contracture (arc of motion 61° - 90°) and severe and very severe contractures together (arc of motion ≤ 60°). The relative difference in proportions between the CPM and PT groups was calculated as Relative Risk (RR) with 95% CIs; no important qualitative interaction was detected, and therefore a unique combined RR was presented.

To address multiplicity across end points, secondary end points were assessed hierarchically in the following order:

1. Percentage of lost motion recovered at 1 year
2. Percentage of patients who had a functional arc of motion at 1 year
3. ROM at 3 months
4. ROM at 6 weeks
5. PROMs at 1 year
6. PROMs at other time points.

Once an end point did not reach significance, no further significance would be inferred for the end points lower down the statistical hierarchy and these outcomes were reported as point estimates with multiplicity unadjusted 95% confidence intervals, without P-values, from which no definite clinical inferences can be made.

Post hoc analyses of exploratory outcomes (Patient's diary data)

Given the exploratory nature of the data collected in patients' diaries all analyses were performed in a post-hoc fashion as follows:

1. The time to following events was estimated for each patient
    a. First improvement defined as the first day in which patients reported their elbow was better compared to before surgery
    b. Perceive a normal or almost normal elbow
    c. Achieve patient's number one goal
    d. Opioid discontinuation

   As the time to event data was non-normally distributed, the median time to events was calculated and compared between groups using quantile regression.
2. The median total number of opioid pills taken within 90 days of surgery in each group was compared using quantile regression.
3. For the following variables:
    a. Days with no or minimal pain (No or minimal pain was defined as a pain score of no more of 2, as assessed on the numerical rating scale)
    b. Days that the elbow prevented to perform work at full capacity
    c. Days that the elbow prevented to perform sports at full capacity
    d. Days that the elbow prevented to perform hobbies at full capacity
    e. Days that patients achieved their number one goal
    f. Days patients performed their most urgent priority without impairment from the elbow
    g. Days patients perceived the elbow affected their quality of life
    h. Day elbow was perceived improved as compared to before surgery
    i. Days elbow was perceived as normal/almost normal

   The percentage of days that the condition evaluated in each variable was fulfilled during the first 90 days was calculated for each patient with the use of 90 days as the denominator. Days with missing values in the diary were counted as 0 days. If a patient had more than 30 days with missing values was excluded of the analysis. The median percentage of days for each variable was calculated and compared between groups using quantile regression.

SUPPLEMENTAL RESULTS

Patients' treatment preference

Pre-randomization preferences were: 3 patients (6%) for CPM, 14 patients (27.5%) for PT, and 34 (40%) patients gave no preference. Table 2 shows that demographic and baseline clinical characteristics were similar between patients who had a preference for treatment and those who did not have a preference before randomization. Severity of symptoms in terms of motion, function and pain were similar between the two groups. Although the presence of ulnar neuropathy was more common among patients who had no preference for treatment before randomization, the difference was not statistically significant.

Twelve of the 17 participants (70%) who gave a pre-randomization preference actually received their preferred treatment. Among those with no initial preference, similar numbers were randomized to the two treatment groups (Table 2).

We examined the effect of patients' baseline preference for treatment on ROM after adjusting for baseline scores and main effects. While patient preference seemed to affect the ROM at 1 year, with patients with a pre-randomization preference improving on average 4° more than those who did not, there was no modification of the effect of the interventions by patient preference (i.e., the interaction term preference by random allocation was not significant). The rehabilitation protocols (CPM and PT) had similar effects on ROM regardless of baseline preference.

Table 2. Demographic and clinical characteristics of participants by their pre-randomization treatment preferences.

	Pre-randomization preference		
Characteristic	**Yes (N = 17)**	**No (N = 34)**	**P value**
Age-yrs.	50 ± 15	47 ± 15	0.59
Sex – no. (%)			
Male	14 (82)	29 (85)	0.78
Female	3 (18)	5 (15)	
Elbow contracture etiology – no. (%)			
Primary osteoarthritis	8 (47)	21 (62)	0.55
Posttraumatic	7 (41)	9 (26)	
Inflammatory	2 (12)	4 (12)	
Preoperative arc of elbow motion-degrees			
Mean	77 ± 22	84 ± 21	0.31
Range	25-110	5-115	
Severity of elbow contracture – no. (%) †			
Mild (arc > 90°)	4 (23)	13 (38)	0.69
Moderate (arc 61° - 90°)	11 (65)	18 (53)	
Severe (arc 31° - 60°)	1 (6)	2 (6)	
Very severe (arc ≤ 30°)	1 (6)	1 (3)	
ASES-elbow function score-points	27 ± 6	25 ± 5	0.29
ASES-elbow pain score-points	28 ± 11	25 ± 12	0.32
DASH score – points	26 ± 19	34 ± 16	0.12
History of previous surgery for elbow contracture – no. (%)			
No	13 (76)	29 (85)	0.46
Yes	4 (24)	5 (15)	
Ulnar nerve neuropathy – no. (%)			
No	14 (82)	19 (56)	0.06
Yes	3 (18)	15 (44)	
Randomization group – no. (%)			
CPM	6 (35)*	18 (53)	0.23
PT	11 (65)**	16 (47)	

***** Among these 6 patients, 2 actually preferred CPM and 4 preferred PT instead.

** Among these 11 patients, 10 actually preferred PT and 1 preferred CPM instead.

Compliance with treatment assigned

Among patients assigned to CPM, all patients reported using the CPM machine as indicated and discontinuing its use according to the recommended protocol. The median reported exposure to the CPM machine was 24 days (range, 4 – 42). Among patients assigned to PT, the median number of postoperative PT sessions was 16 (range, 6 – 32), and 24 of 27 patients (89%) reported performing their at-home exercises exactly or mostly as directed for ≥ 80% of the days during the first 90 days. All patients in the PT group started the supervised PT sessions at home within 10 days of the last session at our institution.

Table 3. Opioid prescribing and consumption data

	CPM Group (N = 24)	PT group (N = 27)	All Patients (N = 51)
Type of opioid prescribed– no. (%)			
Oxycodone 5 mg and Tramadol 50 mg	16 (67)	13 (48)	29 (57)
Only Oxycodone 5 mg	8 (33)	13 (48)	21 (41))
Only Tramadol 50 mg	0 (0)	1 (4)	1 (2)
Number of pills prescribed *			
Total	1520	1590	3110
Median	60	58	58
Range	10-117	13-133	10-133
Number of pills taken *			
Total (%) †	465 (31)	602 (38)	1067 (34)
Median	8	13	10
Range	0-96	0-127	0-127
Prescription refill– no. (%)			
No	22 (92)	25 (93)	47 (91)
Yes	2 (8)	2 (7)	4 (9)

* Oxycodone 5-mg pill equivalents
† Percentage of the initial quantity prescribed

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Figure 2. Distribution of (A) initial prescription size and (B) total opioid consumption (converted to oxycodone 5-mg pill equivalents) (By permission of Mayo Foundation for Medical Education and Research. All rights reserved)

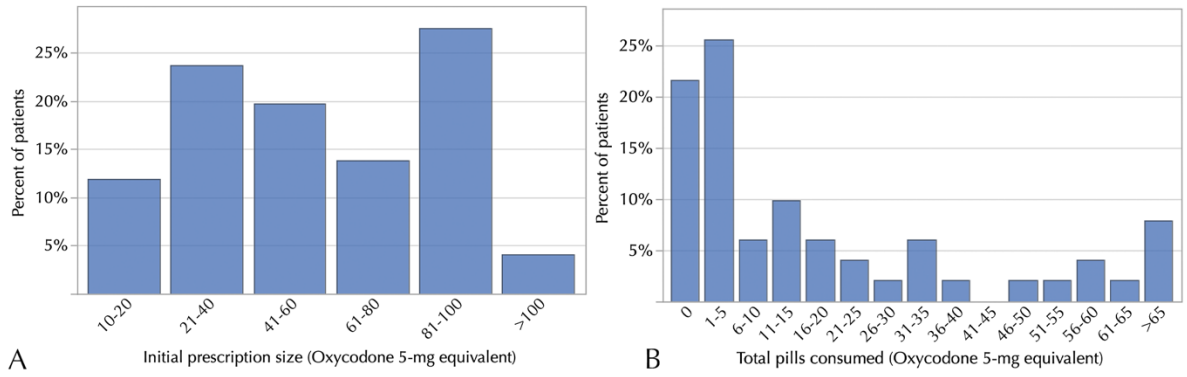
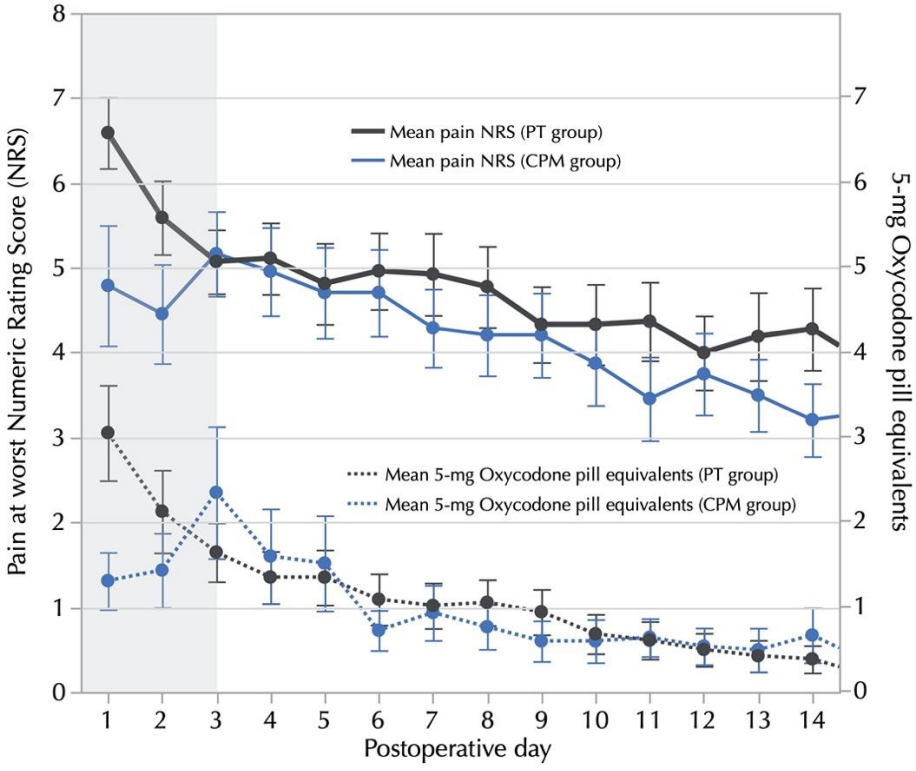


Figure 3. Mean numeric rating scores for pain at worst and mean opioid consumption (converted to oxycodone 5-mg pill equivalents) for each postoperative day within 14 days of surgery. (By permission of Mayo Foundation for Medical Education and Research. All rights reserved).



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Shadowed area represents the period of time patients in the CPM group were in hospital.

Table 4. Detailed results of flexion and extension at 1 year

Outcome	CPM group (N = 24)	PT group (N = 27)	Difference (95% CI)
Elbow Extension at 1 yr.	17 ± 1.8	21 ± 1.7	4 (-3 to 10)
Elbow Flexion at 1 yr.	132 ± 1.6	126 ± 1.4	6 (1 to 11)

Table 5. Other secondary outcomes

Outcome	CPM group (N = 24)	PT group (N = 27)	Difference (95% CI)
Isometric flexion strength relative to contralateral side (%)			
At day 3	66 ± 4	50 ± 4	16 (4 to 28)
At 6 wk	88 ± 4	85 ± 4	3 (–8 to 15)
At 3 mo	95 ± 4	91 ± 4	4 (–8 to 16)
At 12 mo	106 ± 4	100 ± 4	6 (–6 to 18)
Dynamic flexion strength relative to contralateral side (%)			
At day 3	65 ± 4	46 ± 4	19 (8 to 30)
At 6 wk	88 ± 4	92 ± 4	–4 (–15 to 8)
At 3 mo	95 ± 4	94 ± 4	1 (–11 to 13)
At 12 mo	105 ± 4	105 ± 4	0 (–12 to 12)
Flexion endurance relative to contralateral side (%)			
At day 3	90 ± 3	74 ± 3	16 (7 to 24)
At 6 wk	97 ± 3	98 ± 3	–1 (–10 to 8)
At 3 mo	102 ± 3	102 ± 3	0 (–9 to 9)
At 12 mo	106 ± 3	98 ± 3	8 (–1 to 17)
Grip strength relative to contralateral side (%)			
At day 3	73 ± 5	57 ± 5	16 (2 to 30)
At 6 wk	87 ± 5	77 ± 5	10 (–4 to 24)
At 3 mo	89 ± 5	87 ± 5	2 (–12 to 17)
At 12 mo	99 ± 5	100 ± 5	– 1 (–15 to 13)
Difference forearm circumference contralateral side – cm			
At day 3	1.9 ± 0.3	3.3 ± 0.3	–1.4 (–2.2 to –0.7)
At 6 wk	1.0 ± 0.3	0.7 ± 0.3	0.3 (–0.5 to 1.0)
At 3 mo	0.8 ± 0.3	0.5 ± 0.3	0.4 (–0.4 to 1.1)
At 12 mo	0.5 ± 0.3	0.2 ± 0.3	0.3 (–0.4 to 1.1)

* Plus–minus values are means ± SE. Means are derived from mixed-model repeated-measures analysis. Fixed effects were the trial group, the postoperative visit as a categorical variable, and the interaction between trial group and visit. The values at baseline were included as covariates. The patient was included in the model as a random effect. CI denotes confidence interval.

Table 6. Exploratory outcomes

Outcome	CPM group (N = 24)	PT group (N = 27)	Difference (95% CI)*
Median time to first improvement (IQR) – days	4 (1 – 30)	4 (1 – 32)	0 (–16 to 16)
Median time to perceive normal/almost normal elbow (IQR) – days	54 (23 – 34)	87 (34 – 90)	–33 (0 to 66)
Median time to achieve patients' number one goal (IQR) – days	26 (7 – 35)	31 (11 – 63)	–5 (–17 to 27)
Median time to opioid discontinuation (IQR) - days	6 (0 – 12)	4 (1 – 12)	2 (–5 to 9)
Median number of opiod pills taken (IQR)†	8 (0 –96)	13 (0 – 127)	–5 (–9 to 19)
% Days with no or minimal pain, median	52 (35 – 82)	56 (7 – 84)	–4 (–32 to 39)
% Days elbow prevented to perform work at full capacity, median‡	29 (6 – 57)	80 (19 – 99)	–51 (8 to 95)
% Days elbow prevented to perform hobbies at full capacity, median¶	36 (6 – 57)	40 (10 – 87)	–4 (–32 to 39)
% Days elbow prevented to perform sports at full capacity, median§	53 (21 – 85)	36 (17 – 68)	17 (–59 to 26)
% Days patients achieved their number one goal, median	74 (53.1 – 93.3)	58 (25.8 – 57.8)	16 (–12 to 45)
% Days patients performed their most urgent priority without impairment from the elbow, median	51 (9 – 90)	43 (22 – 89)	8 (–38 to 54)
% Days patients perceived the elbow affected their quality of life, median	48 (15 – 91)	33 (6 – 92)	15 (–31 to 61)
% Days elbow was perceived improved as compared to before surgery, median	83 (66 – 98)	92 (63 – 99)	–9 (–28 to 10)
% Days elbow was perceived as normal/almost normal, median	41 (0 – 67)	6 (0 – 55)	35 (2 to 69)

* Difference between groups and its 95% confidence interval are derived from quantile regression comparing the 50th percentile between groups.
† Oxycodone 5-mg pill equivalents
‡ 37 patients were included in this analysis. 20 in the CPM group and 17 in the PT group.
¶ 1 patient in the CPM group was excluded from this analysis
§ 33 patients were included in this analysis. 17 in the CPM group and 16 in the PT group.

References

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