A commentary by Jennifer Moriatis Wolf, MD, PhD, is linked to the online version of this article.

Prospective Randomized Trial of Continuous Passive Motion Versus Physical Therapy After Arthroscopic Release of Elbow Contracture

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Background: Continuous passive motion (CPM) has been used for decades, but we are not aware of any randomized controlled trials (RCTs) in which CPM has been compared with physical therapy (PT) for rehabilitation following release of elbow contracture.

Methods: In this single-blinded, single-center RCT, we randomly assigned patients undergoing arthroscopic release of elbow contracture to a rehabilitation protocol involving either CPM or PT. The primary outcomes were the rate of recovery and the arc of elbow motion (range of motion) at 1 year. The rate of recovery was evaluated by measuring range of motion at 6 weeks and 3 months. The secondary outcomes included other range-of-motion-related outcomes, patient-reported outcome measures (PROMs), flexion strength and endurance, grip strength, and forearm circumference at multiple time points.

Results: A total of 24 patients were assigned to receive CPM, and 27 were assigned to receive PT. At 1 year, CPM was superior to PT with regard to the range of motion, with an estimated treatment difference of 9° (95% confidence interval [CI], 3° to 16°; p = 0.007). Similarly, the use of CPM led to a greater range of motion at 6 weeks and 3 months than PT. The percentage of lost motion recovered at 1 year was higher in the CPM group (51%) than in the PT group (36%) (p = 0.01). The probability of restoring a functional range of motion at 1 year was 62% higher in the CPM group than in the PT group (risk ratio for functional range of motion, 1.62; 95% CI, 1.01 to 2.61; p = 0.04). PROM scores were similar in the 2 groups at all time points, except for a difference in the American Shoulder and Elbow Surgeons (ASES) elbow function subscale, in favor of CPM, at 6 weeks. The use of CPM decreased swelling and reduced the loss of flexion strength, flexion endurance, and grip strength on day 3, with no between-group differences thereafter.

Conclusions: Among patients undergoing arthroscopic release of elbow contracture, those who received CPM obtained a faster recovery and a greater range of motion at 1 year, with a higher chance of restoration of functional elbow motion than those who underwent routine PT.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Several rehabilitation protocols are used following surgical release of elbow contracture, including continuous passive motion (CPM), physical therapy (PT), splinting, or a combination of methods. However, there is a lack of high-level evidence to determine the optimal rehabilitation protocol for surgical release of elbow contracture[1,2]. Preclinical data have suggested that CPM might prevent joint stiffness better than either immobilization or intermittent motion due to an increase in the clearance of fluids from the joint and the periarticular tissues[3-5]. Based on these experimental results and the safety demonstrated over the early years of its clinical use[6], CPM has been used in our institution as the rehabilitation

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/G872).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/G873).

protocol of choice for surgical release of elbow contractures for almost 30 years, with satisfactory clinical results[7-10].

Although CPM has been in clinical use for decades, few clinical studies have compared CPM to other rehabilitation protocols[11-13] and we are not aware of any prospective randomized controlled trial (RCT) involving elbow contracture release that has evaluated its effectiveness and safety as compared with other methods. Therefore, we performed such a trial to evaluate CPM, as compared with PT, in patients who underwent arthroscopic release of elbow contractures, hypothesizing that CPM would be superior to PT with regard to the speed of recovery and elbow range of motion at 1 year.

Materials and Methods

Trial Design and Oversight

This was a prospective, single-blinded, single-center RCT (ClinicalTrials.gov Identifier: NCT01420887). The research protocol was approved by our institutional review board.

Trial Population

Patients were recruited from a consecutive series of patients who had been referred to 3 surgeons at our institution. The inclusion and exclusion criteria are shown in Table I. All patients provided written informed consent before the initiation of trial-specific procedures.

Randomization and Trial Procedures

Patients were randomly assigned, in a 1:1 ratio, to a rehabilitation protocol of either CPM or PT. Before randomization, patients were asked whether they had any preference for the treatment assignment. To eliminate the surgeon effect on the outcomes, 1 surgeon performed all of the procedures and remained blinded to group assignment until the end of surgery (see Appendix). Arthroscopic contracture release was performed in a standard fashion following a surgical technique that has been previously described in detail[14,15]. To prevent delayed-onset ulnar neuritis, the ulnar nerve was routinely decompressed[16]. Subcutaneous ulnar nerve transposition was only performed if ulnar neuropathy was present preoperatively.

After surgery, patients in the CPM group were admitted and received an indwelling axillary catheter for a continuous brachial plexus block for 48 hours. CPM was performed in the hospital for 3 days, and, on day 3, patients were discharged from the hospital with a home CPM program involving a standard protocol that took up to 4 weeks. Patients in the PT group were discharged on the day of surgery but were required to stay locally for 3 days if they lived out of town. Each day, those patients attended a supervised PT session with 1 of 4 physical therapists from our therapy department; these sessions involved a standard protocol and included training in home exercises. After 3 days, the patients were referred to a physiotherapist near their home, where they were to be seen 3 times a week for 4 weeks while continuing daily home exercises (see Appendix). Upon hospital discharge, all patients received a prescription for indomethacin for 21 days for prophylaxis against heterotopic ossification and an opioid medication for breakthrough pain.

Trial Outcomes

Data were collected preoperatively and at 6 weeks, 3 months, and 1 year postoperatively. There were 2 primary outcomes: rate of recovery and range of motion at 1 year. Rate of recovery was evaluated by measuring range of motion at 6 weeks and 3 months. Recovery of range of motion was measured in absolute degrees as well as in the percentage of lost motion recovered. The percentage of patients who achieved a functional arc of motion (extension to ≤30° and flexion to ≥130°)[17] at 1 year was also compared between groups. Key secondary outcomes included the scores on the American Shoulder and Elbow Surgeons (ASES) elbow assessment form, the Disabilities of the Arm, Shoulder and Hand (DASH) score, the Summary Outcome Determination (SOD) score, and the EuroQol-5 Dimension 3-Level (EQ-5D-3L) utility index at all time points. Other secondary outcomes included the forearm circumference, grip strength, and elbow flexion strength and flexion endurance compared with the unaffected arm, at all time points (an additional time point at day 3 after surgery was included for these outcomes) (see Appendix). At each visit, patients completed questionnaires that were used to calculate patient-reported outcome measure (PROM) scores. A trained evaluator who was blinded to group assignment and was not involved in the care of these patients measured the active range of motion with use of a goniometer (see Appendix); the measurements were rounded to the nearest 5° and then were recorded. The remaining physical examination measurements were performed by 1 of the 4 physical therapists, who had not been blinded to group assignment. Flexion strength and endurance were measured with use of a BTE (Baltimore Therapeutic Equipment) machine (see Appendix). Starting on the first postoperative day and continuing for 90 days in total, patients completed a daily diary in which they responded to questions related to pain, opioid consumption, compliance and satisfaction with postoperative treatment, and perceived recovery (see Appendix). All of the included patients completed the entire 90-day diary. Outcomes from patients' diaries were exploratory. For the secondary and exploratory outcomes, this trial was designed as a pilot study and should not be used to infer definitive treatment effects for these end points. Surgery-related adverse events and complications were documented. In addition, we defined an adverse event as a persistence or worsening of stiffness or pain resulting in additional treatment outside the trial.

Statistical Analysis

For the primary outcome, we calculated that a sample of 50 patients would provide the trial with 80% power, at a 2-sided alpha level of 0.05, to detect a treatment difference of 10° (standard deviation, 12°) in the range of motion at 1 year. We chose the standard deviation for the sample size estimate from retrospective unpublished data on range-of-motion results after arthroscopic elbow contracture release in our institution. We added 20% more patients to account for potential loss to follow-up, resulting in a final enrollment goal of 60 patients. P value correction was made to address rounding in range-of-motion measurements according to the method recommended by Zdravkovic and Jost[18], and the p value that was considered to

TABLE I Complete Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Patients who are 13 years of age or older. • Patients who have a lack of elbow flexion and/or extension causing functional impairment that have been present for at least 6 months. • Patients who have failed to respond to nonoperative treatment. • Patients who are scheduled to undergo an arthroscopic capsulectomy or osteocapsular arthroplasty (OCA).	• Patients with contraindication to use of CPM or regional brachial plexus block, such as bleeding diathesis, use of anticoagulants, or severe restriction in shoulder range of movement. • Patients with progressive or recalcitrant neuropathy or neuritis • Patients with preexisting factors that might limit ability to completely participate in rehabilitation such as a neuromuscular or psychosocial condition. • Patients with progressive or recurrent contracture due to inflammatory disease such as rheumatoid arthritis, juvenile idiopathic arthritis, or chondrolysis. • Patients presenting with elbow joint infection or with a history of previous joint infection • Patients with altered anatomy that might limit elbow motion, independent of the condition being treated, such as dysplasia, malunion, osteonecrosis, and congenital deformity. • Patients in whom a reasonable restoration of motion and function cannot be expected. • Patients with inadequate postoperative regional anesthesia. • Patients with an intraoperative or postoperative complication that could affect outcome. • Patient with an injury or disease in the postoperative period that could affect elbow function. • Patients in whom is not possible to have a postoperative physical therapy appointment. • Patients in whom a substantial portion of the procedure is performed in an open manner.

indicate significance was set to 0.026 (see Appendix). This p value correction was only applied to outcomes evaluating mean differences in range of motion between groups. For the remaining outcomes, a p value of 0.05 was considered significant. The primary outcome analysis used a linear mixed model for repeated measures that accounted for the correlation among the range-of-motion measurements for the same patient and that adjusted for the range of motion and patient preference for treatment at baseline. Similar analyses were applied to the continuous secondary outcomes. Dichotomous secondary outcomes were compared between groups with use of Cochran-Mantel-Haenszel chi-square tests, controlling for the contracture severity at baseline. To address multiplicity across end points, secondary end points were assessed hierarchically; 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 are reported as point estimates with multiplicity-unadjusted 95% confidence intervals (CIs), without p values, from which no definite clinical inferences can be made. Similarly, exploratory analyses were not adjusted for multiplicity (see Appendix). Statistical analyses were performed with use of Stata, release 14 (StataCorp) and JMP, version 14.1.0 (SAS Institute).

Source of Funding

The trial was funded by the Mayo Foundation for Medical Education and Research. All authors had full access to the data, directed and supervised the data analyses, interpreted the data, and vouch for the accuracy and completeness of the data and for full reporting of adverse events.

Results

Patients

From December 2016 to April 2019, a total of 134 patients were screened and 81 patients met the eligibility criteria. Thirty-eight eligible patients (47%) had a preference for either CPM or PT before randomization. Of those patients, 17 still consented to randomization despite their preference and 21 declined to participate in the trial and opted for their treatment of choice. Thus, 60 patients underwent randomization, with 31 assigned to the CPM group and 29 assigned to the PT group. Five patients who met exclusion criteria after randomization and 4 patients who withdrew consent before surgery were excluded (see Appendix). A total of 51 patients were included, of whom 24 were assigned to CPM and 27 were assigned to PT (Fig. 1).

Baseline and procedure-related characteristics were similar between the 2 groups (Table II). All patients received

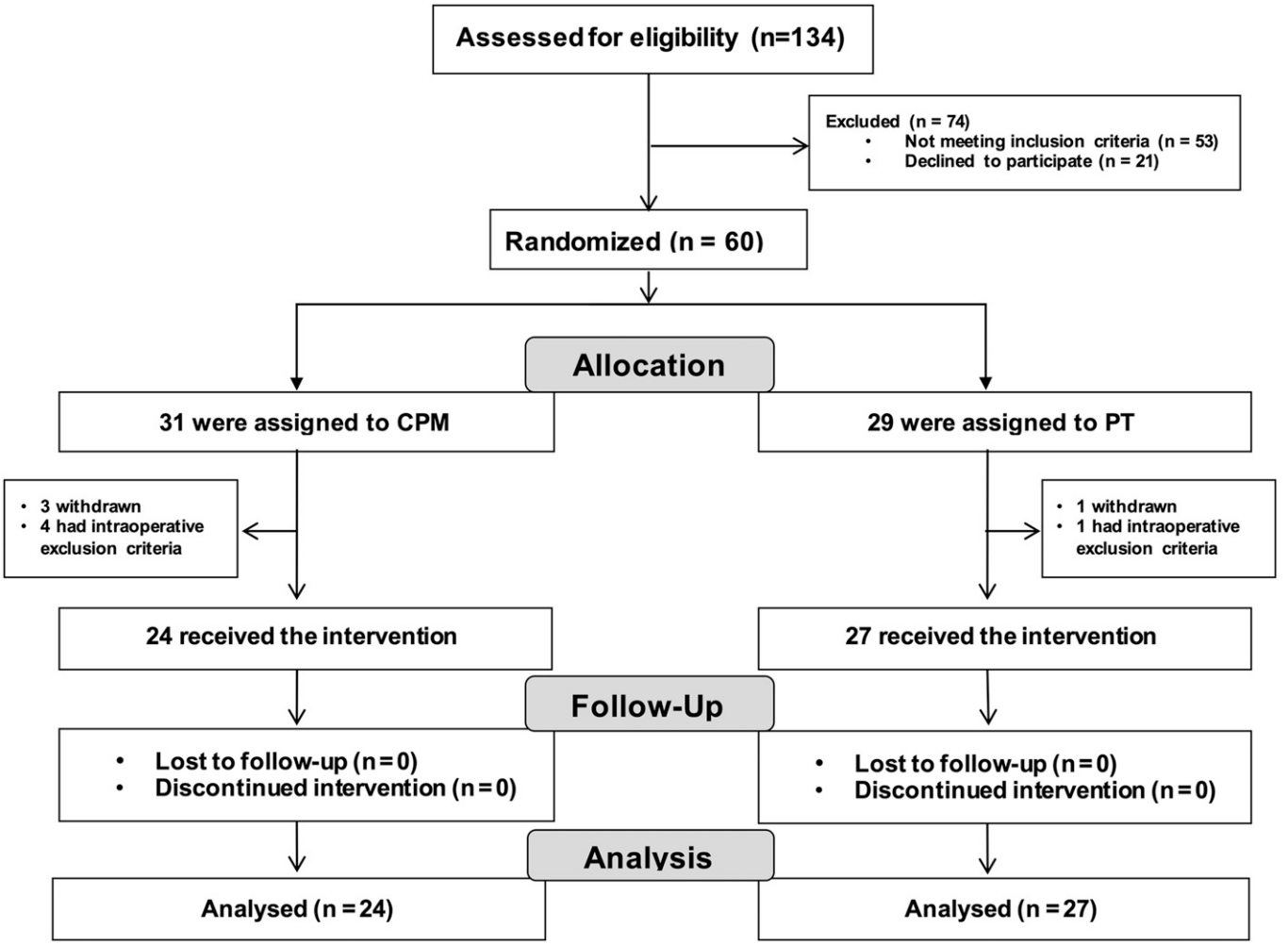

Fig. 1

Flow diagram for enrollment, randomization, and follow-up. (Reprinted with permission of Mayo Foundation for Medical Education and Research. All rights reserved.)

the intervention to which they were randomly assigned; of the 17 patients (33%) who had a preferred treatment before randomization, 9 were not assigned to their treatment of preference. Self-reported compliance was adequate in the 2 groups (see Appendix). There was no crossover between groups. No patients were lost to follow-up, and data regarding the primary and secondary outcomes were complete for 100% of the patients.

Primary Outcome and Range of Motion-Related Secondary Outcomes

CPM was superior to PT with regard to the rate of recovery as well as the final improvement in range of motion (Fig. 2). An estimated treatment difference of 9° in range of motion (95% CI, 3° to 16°; p = 0.007) was seen at 1 year. CPM was also superior to PT with regard to range of motion at 6 weeks and 3 months (Table III). The percentage of lost motion recovered from baseline to 1 year was 15% (95% CI, 3.3% to 25.9%; p = 0.01) higher in the CPM group than in the PT group (Table III). A functional range of motion at 1 year was observed in 16 (67%) of 24 patients in the CPM group, as compared with 10 (37%) of 27 patients in the PT group (risk ratio [RR] for functional range of motion, 1.62; 95% CI, 1.01 to 2.61; p = 0.04), a difference that was mainly driven by a higher gain in flexion in the CPM group than in the PT group (see Appendix). At 1 year, twice as many patients in the CPM group than the PT group had functional flexion (flexion to ≥130°) (75% vs. 37%; p = 0.001). The percentage of patients who had functional extension (extension to ≤30°) was similar in the 2 groups (87% vs. 81%; p = 0.72).

PROMs and Other Secondary Outcomes

The PROM scores were similar in the 2 groups at all time points, except for a difference in the ASES elbow function subscale, favoring CPM, at 6 weeks (Table III, Figs. 3-A through 3-E). The effects of CPM use, as compared with PT, in terms of flexion strength and endurance, grip strength, and forearm circumference indicate that CPM is beneficial during the early postoperative period (day 3), with no apparent effect at other time points (Figs. 4-A through 4-E).

TABLE II Demographic and Baseline Characteristics of the Patients and Operative Data*

Characteristic	CPM Group (N = 24)	PT Group (N = 27)	All Patients (N = 51)
Age *(yr)*			
Mean and standard deviation	50 ± 11	47 ± 18	48 ± 15
Range	13-65	14-71	13-71
Sex *(no. of patients)*			
Male	21 (88%)	22 (81%)	43 (84%)
Female	3 (13%)	5 (19%)	8 (16%)
Elbow contracture etiology *(no. of patients)*			
Primary osteoarthritis	16 (67%)	13 (48%)	29 (57%)
Posttraumatic	6 (25%)	10 (37%)	16 (31%)
Inflammatory	2 (8%)	4 (15%)	6 (12%)
Preoperative arc of elbow motion *(deg)*			
Mean and standard deviation	83 ± 26	80 ± 16	82 ± 21
Range	5-110	50-115	5-115
Severity of elbow contracture† *(no. of patients)*			
Mild (arc >90°)	10 (42%)	7 (26%)	17 (33%)
Moderate (arc 61°-90°)	11 (46%)	18 (67%)	29 (57%)
Severe (arc 31°-60°)	1 (4%)	2 (7%)	3 (6%)
Very severe (arc ≤30°)	2 (8%)	0 (0%)	2 (4%)
History of previous surgery for elbow contracture *(no. of patients)*			
No	21 (88%)	21 (78%)	42 (82%)
Yes	3 (13%)	6 (22%)	9 (18%)
Ulnar nerve neuropathy *(no. of patients)*			
No	17 (71%)	16 (59%)	33 (65%)
Yes	7 (29%)	11 (41%)	18 (35%)
Heterotopic ossification *(no. of patients)*			
No	20 (83%)	24 (89%)	44 (86%)
Yes	4 (17%)	3 (11%)	7 (14%)
Operative data *(no. of patients)*			
Type of elbow contracture release			
Osteocapsular arthroplasty	23 (96%)	23 (85%)	46 (90%)
Capsular release (soft tissue only)	1 (4%)	4 (15%)	5 (10%)
Ulnar nerve management‡			
Limited decompression	20 (87%) of 23	21 (81%) 26	41 (84%) of 49
Subcutaneous transposition	3 (13%) of 23	5 (19%) of 26	8 (16%) of 49
Additional surgical procedures			
Removal of heterotopic ossification	4 (17%)	3 (11%)	7 (14%)
Radial head excision with or without interposition arthroplasty	0 (0%)	3 (11%)	3 (6%)
Hardware removal	0 (0%)	2 (7.4%)	2 (4%)
Other procedures§	1 (4%)	1 (4%)	2 (4%)
Tourniquet time *(min)*			
Mean and standard deviation	91 ± 29	90 ± 26	90 ± 27
Range	33-129	49-140	33-140

*The recruited patients were randomly assigned to receive continuous passive motion (CPM) or physical therapy (PT) as the rehabilitation protocol after arthroscopic contracture release of the elbow. There were no significant between-group differences in the demographic and clinical characteristics of the patients at baseline or in the procedure-related variables. †Severity of elbow contracture was determined according to the system of Mansat and Morrey[23]. ‡One patient in each group did not receive management of the ulnar nerve because they had previously undergone ulnar nerve transposition and did not have ulnar neuropathy symptoms at the initial assessment. The ulnar nerve transposition was performed prior to the contracture release in a separate prior surgical procedure in 7 patients and at the same time as contracture release in 1. §Other procedures included recontouring distal humeral osteotomy in 1 patient in the PT group and open removal of a medial forearm cyst with arthroscopic curettage of a cyst in the capitellum in 1 patient in the CPM group.

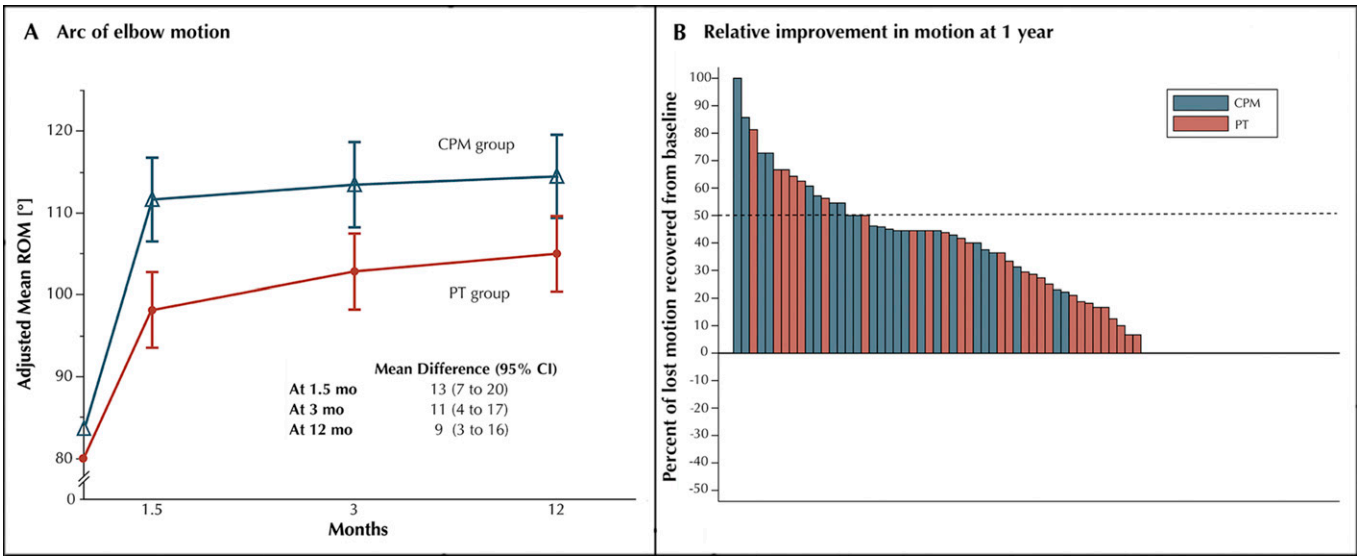

Fig. 2

Figs. 2-A and 2-B Range-of-motion (ROM)-related outcomes. **Fig. 2-A** Arc of elbow motion over the 12-month follow-up period. The data points at baseline represent the observed means in the CPM group and the PT group, whereas the data points on the plot lines represent the estimated means based on a mixed-effects model after adjustment for the baseline value and patient preference. The I-bars denote 95% CIs. **Fig. 2-B** Waterfall plot of the relative improvement in elbow motion expressed as the percentage of lost motion recovered at 1 year. Each vertical bar represents 1 patient. Bars above zero represent recovery of lost motion from baseline to 1 year, and the data are organized from the best result on the left side of the plot to the worst result on the right side. The dashed line denotes a recovery of at least 50% of the lost motion from baseline to 1 year, which was observed in 10 (42%) of 24 patients in the CPM group, as compared with 7 (26%) of 27 patients in the PT group. (Reprinted with permission of Mayo Foundation for Medical Education and Research. All rights reserved.)

Exploratory Outcomes

Over the first 90 days, the use of CPM shortened the median time to perceive a normal or almost normal elbow, increased the percentage of days that the elbow was perceived as normal or almost normal, and reduced the percentage of days that the elbow prevented patients from performing work at normal or full capacity, as compared with PT. The results of the remaining exploratory outcomes, including daily pain scores and opioid consumption, appeared similar in the 2 groups (see Appendix). At day 90, the percentage of patients who would choose the same rehabilitation protocol again if they were to need the same procedure in the contralateral elbow was 78% in the CPM group as compared with 38% in the PT group.

Adverse Events

The percentage of patients who had at least 1 adverse event was similar in the 2 groups (Table IV). One patient in each group underwent revision of ulnar nerve decompression, neurolysis, and subcutaneous transposition for persistent ulnar nerve symptoms.

Discussion

In this single-center trial involving patients with posttraumatic and nontraumatic elbow contractures who underwent arthroscopic contracture release, the use of CPM resulted in faster and greater improvement in range of motion compared with PT. The average 9° benefit in range of motion in the CPM group as compared with the PT group is consistent with a medium-to-large standardized treatment benefit (Cohen d = 0.6) at 1 year[19]. However, the 95% CI around this estimate indicates that plausible results can range from little benefit (3°) of CPM over PT to a substantial difference (16°). To put into perspective this variation in the treatment effect, it is helpful to understand that CPM resulted in a 15% increase in the percentage of lost motion recovered at 1 year, indicating that the magnitude of the benefit of CPM depends on the severity of motion loss preoperatively; larger benefits may be expected with the use of CPM in patients having greater preoperative range of motion impairment.

A logical question to ask is whether or not the average difference in range of motion of 9° at 1 year is a clinically important difference. Since the minimal clinically important difference (MCID) for elbow motion after contracture release is not known, we must consider other factors that are known to be clinically important. CPM patients in this study recovered function faster, lost fewer days from work, and achieved a functional arc of elbow motion at 1 year twice as frequently as those treated with PT. As such, we conclude that CPM does result in a clinically important improvement in elbow motion and function.

While this trial was not powered to test an effect on PROMs, all of the PROM scores at 1 year and the trajectories of improvement over time appeared quite similar in the 2 groups, suggesting that CPM use had a marginal effect or no effect on PROMs. The reason for the absence of effect of CPM on PROMs, despite a greater improvement in range of motion, may be

TABLE III Primary and Key Secondary Outcomes*

Outcome	CPM Group (N = 24)	PT Group (N = 27)	Difference (95% CI)
Primary outcome			
Range of motion at 1 yr† *(deg)*	114 ± 2.6	105 ± 2.3	9 (3 to 16)
Secondary outcomes‡			
Range of motion at 6 wk *(deg)*	111 ± 2.6	98 ± 2.3	13 (7 to 20)
Range of motion at 3 mo *(deg)*	113 ± 2.6	102 ± 2.3	11 (4 to 17)
Percentage of lost motion recovered at 1 yr	51% ± 4.1%	36% ± 3.9%	15% (3.3% to 25.9%)
ASES elbow function subscore *(points)*			
6 wk	31.7 ± 1.1	27.7 ± 1.0	4.0 (1.0 to 7.0)
3 mo	32.3 ± 1.1	31.5 ± 1.0	0.8 (–2.3 to 3.9)
12 mo	30.5 ± 1.1	30.6 ± 1.0	–0.1 (–3.1 to 3.3)
ASES elbow pain subscore *(points)*			
6 wk	10.8 ± 1.7	13.7 ± 1.5	–2.9 (–7.4 to 1.6)
3 mo	6.1 ± 1.7	8.2 ± 1.5	–2.1 (–6.7 to 2.5)
12 mo	7.6 ± 2.1	13.7 ± 1.9	–6.0 (–11.7 to 1)
DASH score *(points)*			
6 wk	18.4 ± 2.1	21.0 ± 2.0	–2.6 (–8.6 to 3.3)
3 mo	13.1 ± 2.1	12.3 ± 2.0	0.8 (–5.3 to 6.8)
12 mo	11.7 ± 2.1	11.9 ± 2.0	–0.2 (–6.1 to 5.7)
SOD score *(points)*			
6 wk	6.1 ± 0.5	6.0 ± 0.5	0.1 (–1.4 to 1.7)
3 mo	7.1 ± 0.6	7.3 ± 0.5	–0.2 (–1.8 to 1.3)
12 mo	8.3 ± 0.6	7.2 ± 0.5	1.1 (–0.5 to 2.6)
EQ-5D-3L utility index			
6 wk	0.84 ± 0.02	0.84 ± 0.02	0.00 (–0.07 to 0.06)
3 mo	0.90 ± 0.02	0.86 ± 0.02	0.04 (–0.03 to 0.11)
12 mo	0.87 ± 0.03	0.87 ± 0.03	0.00 (–0.08 to 0.08)

*The values in the CPM group and PT group columns are given as the mean and the standard error. Means were 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 range of motion and patient preference for treatment at baseline were included as covariates. The patient was included in the model as a random effect. ASES = American Shoulder and Elbow Surgeons, DASH = Disabilities of the Arm, Shoulder and Hand, SOD = Summary Outcome Determination, and EQ-5D-3L = EuroQol-5 Dimension 3-Level. †P = 0.007 for the difference in the primary outcome. ‡P < 0.001 for the difference in range of motion at 6 weeks, p = 0.003 for the difference in range of motion at 3 months, p = 0.01 for the difference in the mean percentage of lost motion recovered at 1 year. P values for PROMs at 1 year did not reach significance, and therefore no further significance was inferred for the PROMs at other time points according to our fixed-sequence testing method for hierarchically ordered correlated multiple end points. PROMs are thus reported as point estimates with multiplicity-unadjusted 95% CIs, without p values, from which no definite clinical inferences can be made.

largely attributed to the known lack of correlation between range of motion and PROMs after contracture release of the elbow[20].

Our trial provides some insights into the beneficial effects of CPM use in the early postoperative period that are consistent with our clinical experience. Swelling, grip strength, flexion strength, and flexion endurance were all improved with CPM as compared with PT on day 3. These results are consistent with the findings of preclinical studies of CPM[3-5]. Decreased edema is likely related to speed of recovery. We suggest that these benefits of CPM use may be advantageous for patients for whom the least possible impact on elbow flexion strength and endurance over the early postoperative period is desired, such as athletes or manual laborers.

To our knowledge, this trial represents the first Level-I evidence comparing CPM and PT after contracture release of the elbow. The results of previous nonrandomized studies comparing CPM with PT after elbow contracture release have been contradictory[12,13], and comparison of the results of those studies with the results presented here may be limited because of differences in several methodological and clinical aspects.

The major strengths of this trial included (1) the broad eligibility criteria and the high percentage of eligible patients who agreed to participate, including those who had a clear treatment preference before randomization, which enhanced generalizability; (2) the high compliance with the assigned rehabilitation protocol, with 100% follow-up at all-time points; and (3) the evaluation of the primary outcome by a blinded independent evaluator. This trial also had limitations. First, it was not possible to conceal group assignment from patients, resulting in a potential source of bias as

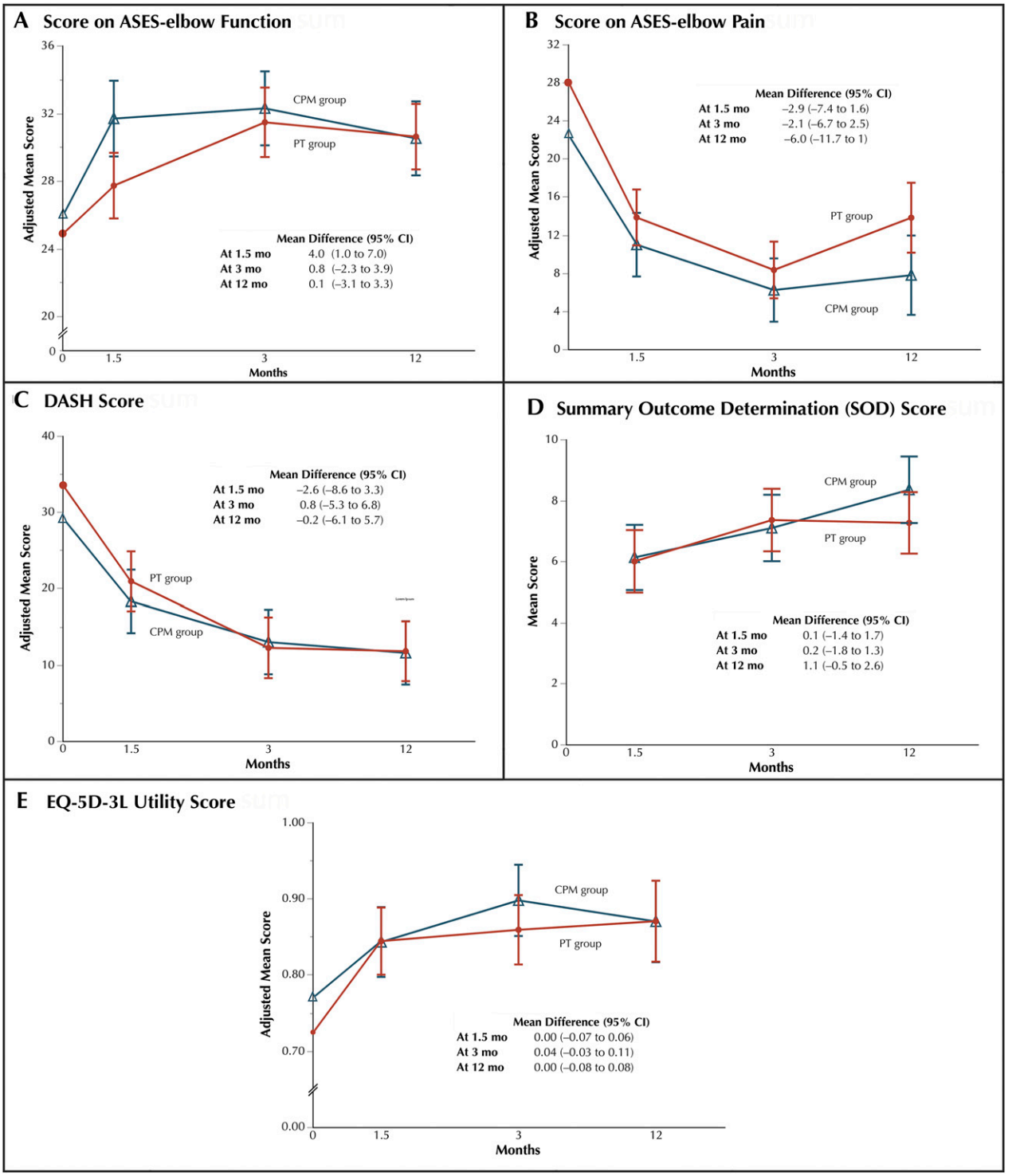

Fig. 3

Figs. 3-A through 3-E PROM scores over the 12-month follow-up period. The data points at baseline represent the observed means in the CPM group and the PT group, whereas the data points on the plot lines represent the estimated means based on a mixed-effects model after adjustment for the baseline value. The I-bars denote 95% CIs. **Fig. 3-A** Scores on the ASES elbow function subscale range from 0 to 36, with higher scores indicating better function. **Fig. 3-B** Scores on the ASES elbow pain subscale range from 0 to 50, with higher scores indicating worse pain. **Fig. 3-C** Scores on the DASH questionnaire range from 0 to 100, with higher scores indicating worse disability. **Fig. 3-D** Scores on SOD score range from −10 (death) to 10 (normal elbow); this score is only collected postoperatively. **Fig. 3-E** Scores on the EQ-5D-3L were converted into utility scores based on normative data; these utility scores range from 0 (death) to 1 (maximum health).

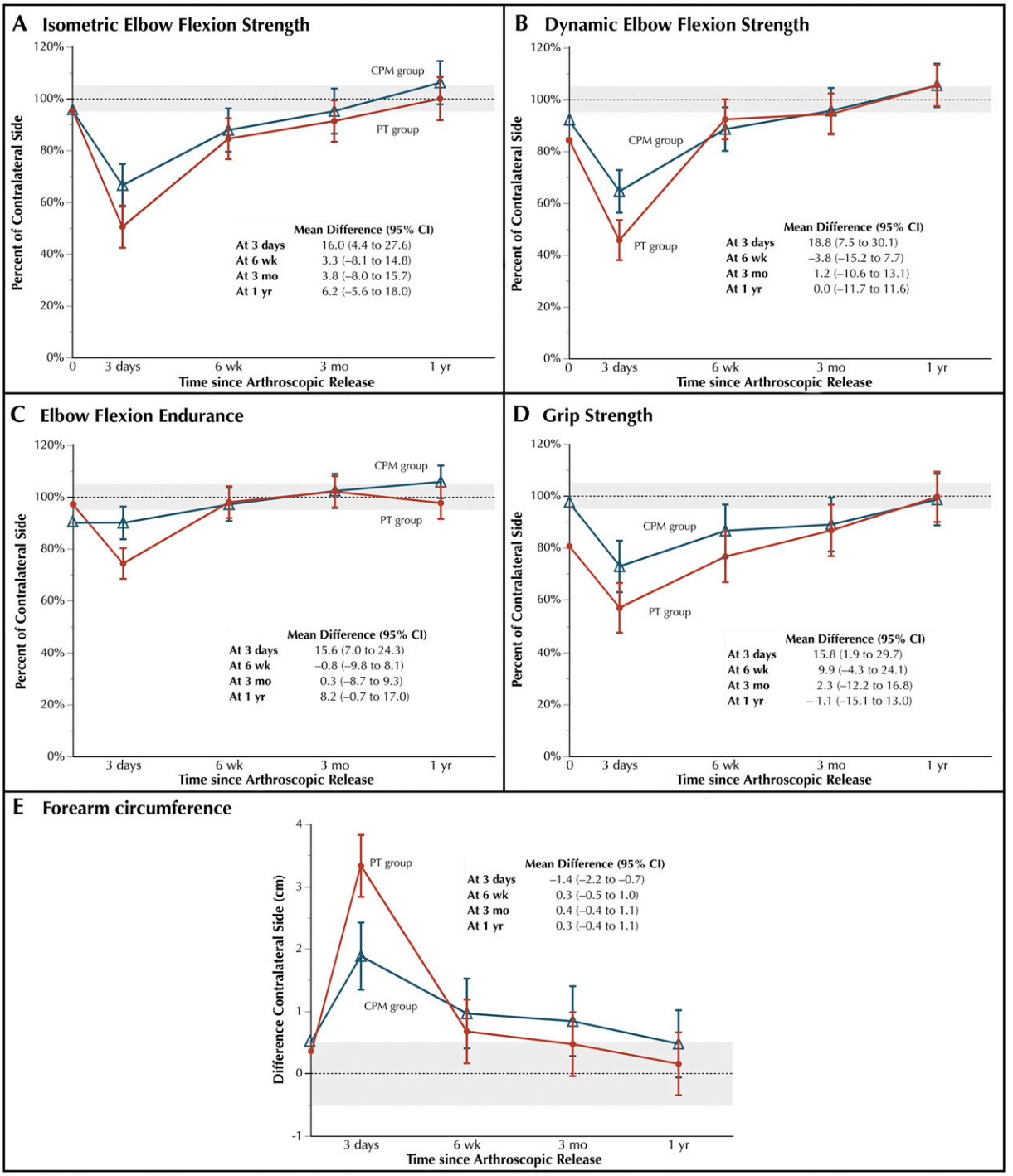

Fig. 4

Figs. 4-A through 4-E Other secondary outcomes over the 12-month period. At baseline, the data points represent the observed means in the CPM group and the PT group, whereas the data points on the plot lines represent the estimated means based on a mixed-effects model after adjustment for the baseline value. The I-bars denote 95% CIs. Strength is expressed as a percentage of the contralateral arm, whereas circumference is expressed as the difference from the contralateral arm. Shadowed areas represent strength within ±5% or circumference within ±0.5 cm of the contralateral arm. The drop in the isometric flexion strength (**Fig. 4-A**), dynamic flexion strength (**Fig. 4-B**), flexion endurance (**Fig. 4-C**), and grip strength (**Fig. 4-D**) observed at day 3 in both groups appeared to be lower in the CPM group than in the PT group. **Fig. 4-E** The forearm circumference was used as a measure of postoperative swelling. Reduced forearm circumference in the CPM group at day 3 suggests decreased edema and likely relates to more rapid speed of recovery. No differences between groups were apparent at other time points.

TABLE IV Summary of Adverse Events

Adverse Events	CPM Group (N = 24)	PT Group (N = 27)
No. of patients with at least 1 event	4 (17%)	4 (15%)
No. of events (event rate)	5 (0.21)	4 (0.15)
Adverse events *(no. of events)*		
Delayed-onset ulnar neuritis*		
No further surgery performed	1	1
Further surgery performed	1	1
Other neuritis†	1	1
Persistent intra-articular pain requiring corticosteroid injection	1	1
Block failure†	1	NA

*The 4 cases of delayed-onset ulnar neuritis (DOUN) corresponded to 2 patients (1 in each group) with nonprogressive DOUN who did not require further treatment and 2 patients (1 in each group) with slowly progressive DOUN who required further surgery involving ulnar nerve transposition at 6 months (PT group) and 12 months (CPM group) after the index procedure. No cases of rapidly progressive DOUN were observed, and no deterioration of range of motion due to ulnar neuritis was observed in any case[16]. †Other neuritis included a posterior antebrachial cutaneous nerve neuritis in 1 patient in the CPM group who only had sensory symptoms that improved over time without the need for further treatment and a radial nerve neuritis in 1 patient in the PT group who had pain with no sensorimotor symptoms that improved after a perineural corticosteroid injection. ‡One patient in the CPM group had a failure of the brachial plexus block at day 2 that require an additional single shot block. NA = not applicable.

patients with clear treatment preferences were included[21]. However, patients' treatment preferences were elicited before randomization, and the analyses were adjusted accordingly[22]. Second, despite randomization, some baseline, non-significant differences between the groups were noted in terms of range of motion and PROM scores. However, analyses were adjusted for baseline values. Third, our trial was conducted in a single center that may have had more experience with the use of CPM than others, and all of the procedures were performed by a single surgeon with vast experience in arthroscopic elbow contracture release. While these factors increased the internal validity of our study, they limit the generalizability of the results, and our findings may not be reproducible by other surgeons or in different clinical contexts. The expertise of different surgeons and centers with the procedure and rehabilitation protocols may result in clustering at the surgeon and hospital levels. However, this study aimed to compare CPM and PT at the individual level, and not at the level of clusters such as surgeons or hospitals. A further multicenter study including different surgeons at different centers is needed to evaluate the effect of those clusters in the results. Fourth, this trial compared the 2 rehabilitation protocols as independent interventions and therefore the results cannot be generalized to cases in which both interventions are used concurrently. Fifth, this trial was powered in a bivariate estimate and thus we could not, given the final sample size, evaluate potentially important differences, in relevant subgroups, of the interactions between surgical or clinical variables. As an example, 3 adolescent patients (13 to 14 years of age) who met all of the inclusion criteria and none of the exclusion criteria were included. Although their preoperative and postoperative arcs of motion (mean, 75° and 107°, respectively) did not differ from the adults (mean, 82° and 108°, respectively), the group was too small to perform statistical analysis. Based on our experience, it is our impression that the outcome of arthroscopic contracture release of the elbow is more dependent on the etiology and severity of the contracture than on the age of the patient. Stans et al. reported that the results of open elbow contracture release in the pediatric population were inferior in the presence of altered articular anatomy that can limit motion[10]. Such altered anatomy was one of the exclusion criteria in our trial. Finally, despite patients being given a standard protocol for CPM or PT after hospital discharge, there was some variability in the interventions, such as variable durations of CPM machine usage and different centers for the supervised PT sessions. However, this trial was planned as a pragmatic trial that aimed to assess the effectiveness of these interventions in a real-world setting.

In conclusion, the benefits of CPM use, as compared with PT, after arthroscopic release of elbow contracture at 1 year are a greater range of motion, a higher percentage of lost motion recovered, and a higher probability of a functional range of motion, especially functional flexion. CPM also resulted in higher patient satisfaction with the postoperative treatment, faster recovery (as manifested by less swelling and greater elbow strength and endurance at 3 days), and a greater range of motion and patient-reported function at 6 weeks. However, the benefits, especially in terms of range of motion, may be dependent on the severity of the contracture and may be more evident in moderate and severe contractures. Based on these findings, we propose that CPM should be indicated for patients with moderate to severe contractures (especially those with a lack of flexion), patients who need rapid recovery, or patients for whom a small difference in range of motion is important. These results, especially those concerning the secondary and exploratory outcomes for which this trial was

conceived as a pilot study, should be replicated in a larger multicenter study involving different surgeons at different locations with possibly more clinical and sociodemographic variation in the population. The evidence of superiority of CPM provided by this trial may serve as a basis to decrease barriers to insurance approval of this intervention but also for further studies to evaluate the feasibility of an outpatient CPM protocol given the advent of improved anesthesia control and outpatient care.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/G874). ■

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