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Effect of enhanced recovery after surgery (ERAS) pathway on the postoperative outcomes of elbow arthrolysis: A randomized controlled trial

Haomin Cui[a,b,1], Ziyang Sun[a,b,1], Jihao Ruan[a,b], Yaling Yu[a], Cunyi Fan[a,b,*]

[a] Department of Orthopedics, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, Shanghai, China
[b] Department of Orthopedics, Shanghai Sixth People's Hospital East Affiliated to Shanghai University of Medicine & Health Sciences, Shanghai, China

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ABSTRACT

Background: Enhanced recovery after surgery (ERAS) protocols aim to improve perioperative outcomes and facilitate recovery for the patient through multimodal pathways. While implementation of ERAS has improved outcomes in numerous surgical specialties, benefits specific to elbow arthrolysis have not been investigated. The purpose of this study was to determine the effects of an evidence-based ERAS pathway on: (1) reducing pain intensity and postoperative complications compared to conventional care, and (2) improving range of motion (ROM) and function of the elbow after open arthrolysis.

Methods: A randomized controlled study was performed between September 2017 and January 2018. Fifty patients with post-traumatic stiff elbow scheduled for surgery were randomly divided into ERAS group (25 patients) and conventional care group (25 patients). Duration of surgery, pre- and post-surgery ROM, Mayo Elbow Performance Score (MEPS), and visual analog scale (VAS) pain scores at rest and in motion were measured postoperatively at 1 through 5 days, 6-weeks, and 6-months. Complications were recorded 6-months postoperatively.

Results: VAS pain score values at rest and in motion in the ERAS group were consistently significantly lower than those in the conventional care group at 1 through 5 postoperatively days ($P < 0.05$). At 6-weeks and 6-months after surgery, pain score values at rest and in motion were similar between the 2 groups ($P > 0.05$). ROM was consistently significantly better in the ERAS group compared with the conventional care group ($P < 0.05$). No significant differences in MEPS or complications were found between the 2 groups ($P > 0.05$).

Conclusion: ERAS pathway is feasible to implement in elbow arthrolysis and can result in clinically meaningful improvements in levels of pain (at rest and in motion) and ROM without an increase in the rate of postoperative complications.

1. Introduction

Elbow fracture, which is treated either conservatively or surgically, may develop a common complication known as post-traumatic stiff elbow [1,2]. Worldwide, up to 12% of patients with post-traumatic elbows end up with limited function, thus requiring operative release [1,3]. Open arthrolysis has demonstrated high efficacy in patients in whom conservative treatments or arthroscopic techniques have failed [4,5]. This is important considering that, in theory, a 50% reduction in elbow range of motion (ROM) leads to approximately 80% reduction of upper extremity function [6]. Multidisciplinary techniques have been developed for the treatment of elbow stiffness in recent years with the aim of restoring a pain-free and functional elbow [1,3–5,7,8]. However, the curative efficiency of open arthrolysis reported in different studies, such as the effects on improved ROM, functional status, and perioperative complications, have been inconsistent [4,8]. Rates of unsatisfactory outcomes up to 21% and postoperative elbow dysfunction up to 47% remain matters of concern and are seemingly uncorrelated to the advances in surgical techniques [9]. Cases of complex stiff elbow present formidable challenges to the surgeon, not only in the operating room, but also during perioperative management [5,10]. Nevertheless, the scientific perioperative protocol of elbow arthrolysis is still undefined and varies by surgeon and treatment center [1–4,8,10]. Therefore, we established an evidence-based clinical pathway to improve postoperative outcomes and standardize care for the surgical treatment of stiff elbow in order to report our findings and strengthen the literature around this topic.

Enhanced recovery after surgery (ERAS) is an evidence-based

* Corresponding author. Department of Orthopedics, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, 600 Yishan Road, Shanghai 200233, China.
E-mail address: cyfan@sjtu.edu.cn (C. Fan).
[1] Co-first authors: Haomin Cui and Ziyang Sun.

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multimodal protocol of perioperative care, pioneered by Henrik Kehlet in the 1990s in an effort to improve recovery after colorectal surgery [11]. Following their introduction, ERAS protocols have produce significant clinical and economic benefits in a range of orthopedic surgeries, especially for joint surgery including total knee, hip, and shoulder arthroplasty [12–15]. ERAS pathways represent the next step in the evolution of standardized care for orthopedics patients [14,16–18]. Although early evidence has shown that the ERAS pathway for orthopedics is promising, reports on specific ERAS programs for elbow arthrolysis are lacking. Given that post-traumatic elbow stiffness can be painful and intractable [2–4], the implementation of a customized ERAS pathway for elbow arthrolysis would be impactful.

For this study, an evidence-based, comprehensive ERAS clinical pathway for elbow arthrolysis was designed for use in our hospital, according to previous experience [4,19–22] and the ERAS® Society recommendations [23,24]. The randomized controlled trial was carried out with the aim to determine the effects of an evidence-based ERAS pathway compared to standard care on: pain intensity, elbow ROM, elbow function, and postoperative complications.

2. Methods and methods

2.1. Study design, study population, and randomization

A single-center, single-blinded randomized controlled study was conducted at our institution between September 2017 and January 2018 using patients who presented with post-traumatic elbow stiffness (defined as flexion of $< 120^{\circ}$ and loss of extension of $> 30^{\circ}$ [2]). The study was approved by the institutional ethics committee of Shanghai Sixth People's Hospital East Campus and was registered at Clinical Trials Registry (NO. ChiCTR1800016999).

The work has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.

Patients who presented at our institution after receiving open reduction with internal fixation (ORIF) or at least 12-months of conservative treatment including observation, physical therapy, and dynamic and progressive splinting protocols, without obtaining functional arc of motion, were considered for the study. Inclusion criteria included a post-traumatic stiff elbow indicated for open arthrolysis in patients older than 18-years. Exclusion criteria were prior history of burn injury or central nervous system injuries, nonunion or malunion of the elbow needing internal fixation, severe articular damage requiring joint arthroplasty, inflammatory arthritis (e.g. rheumatoid arthritis), elbow infection, or cognitive impairment. Before study enrollment, patients were recruited by research staff, who explained the study protocol and obtained informed written consent. Demographic data including age, sex, body mass index (BMI), diseased side, tobacco use, and disease duration, as well as preoperative clinical data including ROM, pain score, and MEPS, were recorded.

Between September 2017 and January 2018, 64 patients (64 elbows) with stiff elbow were enrolled. Three patients, one associated with craniocerebral injury and 2 with nonunion, were excluded. Four patients refused to participate in the study at the time of randomization. Hence, the total sample of 57 participants were randomized. Randomization was performed by an independent statistician. Participants were randomly allocated in a ratio of 1:1 to the ERAS group or to the conventional care group using a computer-generated digit table based on the permuted block randomization method using block size of 6 patients. After randomization, 3 patients (1 in the ERAS group and 2 in the conventional care group) refused the index surgical procedure because they declined to use the external fixation. In addition, 4 patients (2 in each group) dropped out because they needed additional procedures or were inoperable. Of the remaining patients, 25 received care per the ERAS pathway, and 25 received care per the conventional care pathway. No one was lost to follow-up. The flow chart of the study is presented in Fig. 1.

In spite of randomization, patients might discover which group they were assigned because of communication with each other during their hospital stay. In order to minimize this potential bias, participants from the same group stayed in the same inpatient ward, separate from the other group. Patient follow-up was conducted by a research staff to ensure strict accordance with the protocol.

2.2. Intervention

We develop an elbow arthrolysis-specific ERAS pathway for use at our institution. The ERAS and conventional care pathways are summarized in Table 1. Patients in each group received all elements of the corresponding protocol and follow-up was conducted by a researcher to ensure strict compliance. Details of each pathway were as follows:

(1) Elbow arthrolysis education class: This class was offered as an option in the conventional care pathway but was not mandatory. In the ERAS pathway, this educational class was compulsory. In addition, patients in the ERAS group received a checklist about their rehabilitation plan, daily mobilization exercises, and functional goals. Patients in the conventional care group did not receive these.
(2) Caretaker: A specific caretaker was required in the ERAS pathway but not in the conventional care pathway. The caretaker was asked to sign a contract declaring availability and ability to assist with the patient's postoperative exercise program for active and passive elbow ROM.
(3) Brachial plexus anesthesia: Only brachial plexus anesthesia was used in the ERAS pathway, whereas general anesthesia or brachial plexus anesthesia was used in conventional care pathway.
(4) Standardized surgical procedures: All patients had open arthrolysis performed by trained elbow surgeons on our team. Both groups had the same surgery procedures using a standardized evidence-based intervention approach [4,10,20,21,25]. The procedure included ulnar neurolysis and nerve anterior transposition combined with complete open release and hinged external fixation.
(5) Tranexamic acid utilization: Patients in the ERAS group received 1 g of tranexamic acid together with 100 ml of saline intravenously before skin incision, while patients in the conventional care group did not receive any anti-fibrinolytics.
(6) Postoperative oral analgesia: Patients in the conventional care group lacked a standard analgesic protocol. In the ERAS pathway, a standard regimen of oral analgesics (multimodal analgesia), containing acetaminophen and nonsteroidal anti-inflammatory drugs, combined with patient controlled intravenous analgesia (PCIA), was administered to every patient.
(7) Postoperative prophylaxis against heterotopic ossification (HO): In the conventional care group, celecoxib was administered to patients with preoperative radiographic evidence of HO. In the ERAS group, celecoxib was administered once daily for 6-weeks postoperatively as a standard regimen for every patient.
(8) Physical therapy: Physical therapy, specifically cryotherapy, was performed using the Cryo/Cuff system (Aircast Inc, CA, USA). Three sessions of cryotherapy were performed, 1 h/d for 3 days [26]. Patients in the conventional care group received cryotherapy on the first, second, and third day after surgery, while patients in the ERAS group received cryotherapy the day of surgery, as well as the first and second day after surgery.
(9) Functional exercises: In the conventional care group, no exercises were performed on the day of surgery and the first mobilization without a concrete scheme started on the first postoperative day. In the ERAS group, first mobilization was initiated on the day of surgery, after the effect of the anesthesia wore off. In addition, patients in the ERAS group received a standard exercise program including active and passive elbow flexion and extension movements based on the ROM documented during surgery. Patients did 30 cycles on the first postoperative day and increased by 30 cycles

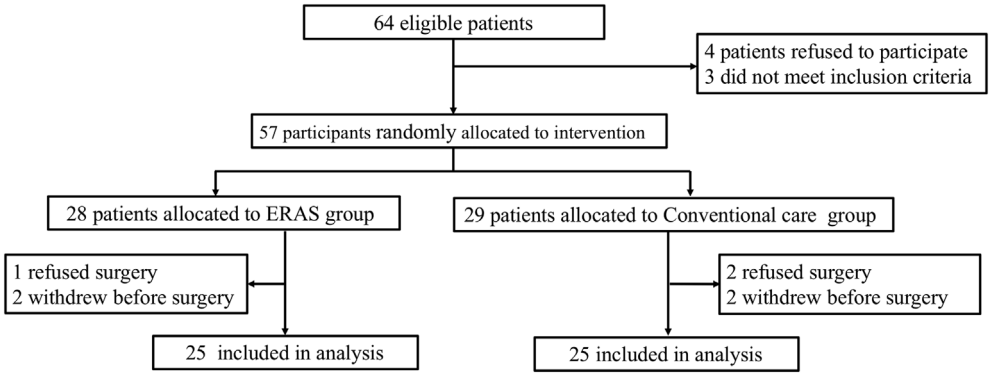

Fig. 1. Trial profile.

Table 1
Summary of ERAS pathway and conventional care pathway.

	ERAS Pathway	Conventional Care Pathway
Preoperative	Required elbow-arthrolysis education class; Identify postoperative care taker;	Optional elbow-arthrolysis education class; No identification of postoperative care taker;
Intraoperative	Brachial plexus anesthesia; Antibiotic prophylaxis; Tranexamic acid;	General anesthesia or brachial plexus anesthesia; Antibiotic prophylaxis; No anti-fibrinolytics;
POD 0	Multimodal analgesia: acetaminophen, NSAIDs, PCIA (low-dose opioids); Scheduled precaution of HO in every patient for 6 weeks, celecoxib; Physical therapy, cryotherapy, extend over 3 days; Mobilization;	No standardization of analgesics; Precaution of HO only in who preoperative have; No physical therapy; No mobilization;
POD 1	Flexion-extension exercises (reach at least 80% of intraoperative ROM), 30 cycles a day;	Encourage to mobilization (according to the intraoperative ROM) Physical therapy, cryotherapy, extend over 3 days;
POD 2	Flexion-extension exercises (reach at least 90% of intraoperative ROM), 60 cycles a day;	Encourage to more mobilization;
POD 3	Flexion-extension exercises (reach 100% of intraoperative ROM), 90 cycles a day;	Encourage to more mobilization;
POD 4	Flexion-extension exercises (reach 100% of intraoperative ROM), 120 cycles a day;	Encourage to more mobilization;
POD 5	Flexion-extension exercises (reach 100% of intraoperative ROM), 150 cycles a day;	Encourage to more mobilization;

Care taker: Pre-identified caregiver that attests to availability upon discharge of patient; ERAS: Enhanced Recovery After Surgery.
HO: Heterotopic Ossification; POD: Postoperative Day; NSAIDS: Non-Steroidal Anti-inflammatory Drugs; PCIA: patient controlled intravenous analgesia.

per day until they reached 150 cycles per day.

2.3. Outcomes

The primary outcome evaluated was pain in motion, as measured by the VAS, which ranges from 0 to 10 [26]. The pain VAS score was rated using a 100 mm horizontal scale, for which 0 mm represented no pain and 100 mm represented extreme pain. Data points were collected postoperatively at first, second, third, fourth, and fifth day, at 6-weeks, and 6-months. Data were gathered in person during patient's in-hospital stay and outpatient follow-up.

Secondary outcomes included pain VAS at rest the day after surgery, ROM, drain time, the MEPS, and postoperative complications. Duration of surgery and ROM during surgery were recorded. Average normal ROM of the elbow is approximately 0°–145° of flexion and extension but individual difference may be quite considerable [1]. Drainage tubes were removed postoperatively if the volume of 2 drainages were < 50 ml and drain time was recorded. According to previous studies [2,22,27], postoperative complications after elbow arthrolysis include formation of heterotopic ossification, new onset or exacerbation of ulnar nerve symptoms, and repeat elbow stiffness. The 2 groups were followed up for 6-months after surgery. The MEPS, which included elbow pain (45 points), elbow motion (20 points), elbow stability (10 points), and elbow function (25 points), was used to evaluate elbow function and quality of life, where 0 to 59 indicated a poor result, 60 to 74 indicated a fair result, 75 to 89 indicated a good result, and 90 to 100 indicated an excellent result [28].

2.4. Study size and statistical analysis

The calculation of sample size was conducted according to the primary outcome (pain VAS in motion) using Statistics Analysis System software (version 9.0, SAS Institute Inc., Iowa, IA, USA). The calculation was based on our previous study describing a mean VAS on the first postoperative day equal to 7.7 (standard deviation, 2.1) after open arthrolysis [26]. We calculated that a minimum of 46 patients (23 in each group) would be required for this trial in order to achieve clinically important result of a 2 point mean decrease in the VAS score using a two-sided test at 5% significance level and 90% power [29].

Statistical tests were selected on the distribution and type of data. The normality of the distribution of the variables was evaluated using the Kolmogorov-Smirnov test. Fisher's exact or the chi-squared test was used to analyze categorical variables. An independent or paired *t*-test was used for normally distributed variables, and the nonparametric Mann-Whitney *U* test or Wilcoxon's signed-rank test was performed to compare continuous variables. The mean was reported for normally distributed data, and the median was reported when nonparametric testing was necessary. A two-sided P value of < 0.05 was considered significant. All statistical analyses were performed using GraphPad Prism (version 7.0, GraphPad Software, San Diego, CA, USA).

3. Results

Patient characteristics and preoperative elbow functional data are shown in Table 2. Preoperative pain scores at rest and in motion are shown in Figs. 2 and 3. There was no difference between study groups regarding age, sex, BMI, diseased side, tobacco use, disease duration,

Table 2
Demographic data and preoperative data.

	Conventional care group (n = 25)	ERAS group (n = 25)	*P* value
Age, years	40.88 ± 11.95	36.68 ± 10.63	0.190
Male, n (%)	15 (60%)	18 (72%)	0.551
BMI, kg/m^2	21.68 ± 1.84	22.20 ± 1.82	0.367
Diseased side (Right/Left)	20/5	22/3	0.702
Tobacco use, n (%)	12 (48%)	10 (40%)	0.776
Disease duration, months	16.00 ± 5.24	15.68 ± 5.07	0.904
Preoperative HO, n (%)	15 (60%)	19 (76%)	0.364
Preoperative elbow ORIF, n (%)	18 (72%)	22 (88%)	0.289
Preoperative pain at rest, points	0.48 ± 0.65	0.64 ± 0.70	0.456
Preoperative pain on motion, points	1.44 ± 1.08	1.00 ± 0.96	0.130
Preoperative ROM, °	61.60 ± 24.40	66.20 ± 19.16	0.747
Preoperative MEPS, points	68.40 ± 6.57	66.00 ± 5.59	0.190

ERAS, Enhanced Recovery After Surgery; BMI, Body Mass Index; HO, Heterotopic Ossification; ORIF, Open Reduction Internal Fixation.

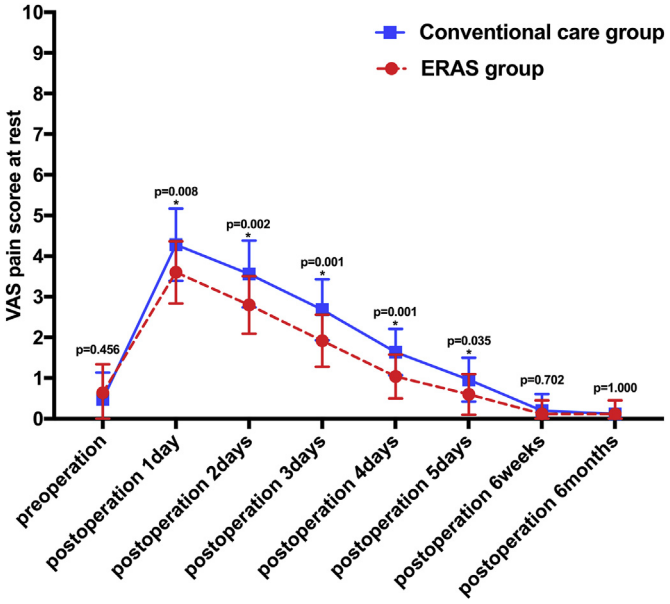

Fig. 2. Graph of the mean pain score [visual analog scale (VAS)] at rest preoperatively, from postoperative days 1 through 5, at 6weeks, and 6-months.

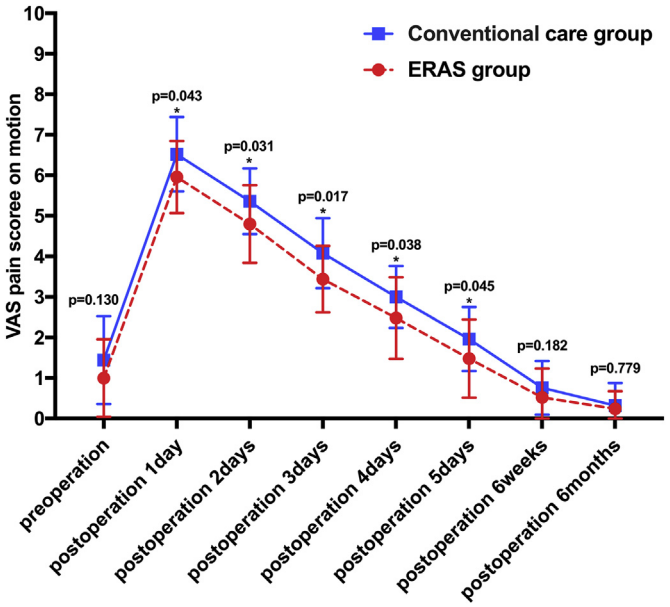

Fig. 3. Graph of the mean pain score[(visual analog scale (VAS)] in motion preoperatively, from postoperative days 1 through 5, at 6-weeks and 6-months.

previous ORIF, preoperative HO, preoperative MEPS, preoperative ROM, preoperative VAS at rest, or preoperative VAS in motion.

Intraoperative data are shown in Table 3. No statistically significant difference was noted with regard to the duration of surgery (conventional care: 128.60 ± 12.54 min *versus* ERAS: 130.00 ± 11.37 min) and gained ROM during surgery between the 2 groups (conventional care: 122.80 ± 3.84 min *versus* ERAS: 124.40 ± 5.07 min).

Postoperative pain levels are shown in Figs. 2 and 3. At the first (conventional care: 4.28 ± 0.89 *versus* ERAS: 3.60 ± 0.76), second (conventional care: 3.56 ± 0.82 *versus* ERAS: 2.80 ± 0.71), third (conventional care: 2.68 ± 0.75 *versus* ERAS: 1.92 ± 0.64), fourth (conventional care: 1.64 ± 0.57 *versus* ERAS: 1.04 ± 0.54), and fifth (conventional care: 0.96 ± 0.54 *versus* ERAS: 0.60 ± 0.50) day after surgery, VAS pain score values at rest in the ERAS group were significantly lower than those in the conventional care group ($P < 0.05$ at all test points) (Fig. 2). Compared to conventional care, VAS pain score values in motion at the first (conventional care: 6.52 ± 0.92 *versus* ERAS: 5.96 ± 0.89), second (conventional care: 5.36 ± 0.81 *versus* ERAS: 4.80 ± 0.96), third (conventional care: 4.08 ± 0.86 *versus* ERAS: 3.44 ± 0.82), fourth (conventional care: 3.00 ± 0.76 *versus* ERAS: 2.48 ± 1.01), and fifth (conventional care: 1.96 ± 0.80 *versus* ERAS: 1.48 ± 0.96) day after surgery were significantly lower (Fig. 3). Six weeks and 6-months after surgery, pain score values at rest (conventional care: 0.12 ± 0.33 *versus* ERAS: 0.12 ± 0.33) and in motion (conventional care: 0.32 ± 0.56 *versus* ERAS: 0.24 ± 0.44) were low and similar between the 2 groups.

Postoperative ROM are shown in Fig. 4. Significantly better ($P < 0.05$ at all test points) ROM was found in the ERAS group compared with the conventional care group at postoperative day one (conventional care: 93.60° ± 7.97° *versus* ERAS: 99.80° ± 8.72°), day 2 (conventional care: 104.92° ± 8.47° *versus* ERAS: 111.12° ± 7.74°), day 3 (conventional care: 112.60° ± 8.68° *versus* ERAS: 117.80° ± 7.37°), day 4 (conventional care: 115.68° ± 7.35° *versus* ERAS: 120.16° ± 6.01°), day 5 (conventional care: 117.40° ± 6.63° *versus* ERAS: 121.16° ± 5.98°), 6-weeks (conventional care: 119.80° ± 6.99° *versus* ERAS: 123.16° ± 6.43°), and 6-months (conventional care: 120.20° ± 6.99° *versus* ERAS: 123.76° ± 6.81°).

Postoperative data are shown in Table 3. The mean drain time was significantly lower ($p = 0.005$) in the ERAS group (4.24 ± 0.80 days) than in the conventional care group (3.60 ± 0.71 days). At postoperative 6-months follow-up, ROM in the ERAS group (123.76° ± 6.81°) were significantly better ($p = 0.018$) than that in the conventional care group (120.20° ± 7.00°). However, functional outcome scores with the MEPS showed no difference at postoperative 6-months (conventional care: 90.40 ± 5.76 *versus* ERAS: 91.40 ± 6.70).

At 6-months after index procedures, no significant differences were found in postoperative complications between 2 groups (Table 3). As shown in Tables 3 and 9 of 50 patients (18%) developed postoperative complications. Five patients developed new onset or exacerbation of

Table 3
Intraoperative data and Postoperative data.

	Conventional care group (n = 25)	ERAS group (n = 25)	*P* value
Intraoperative data			
Duration of surgery, minutes	128.60 ± 12.54	130.00 ± 11.37	0.654
Gained ROM during surgery, °	122.80 ± 3.84	124.40 ± 5.07	0.104
Drain time, days	4.24 ± 0.80	3.60 ± 0.71	0.005*
Clinical outcomes at 6 months after surgery			
ROM, °	120.20 ± 7.00	123.76 ± 6.81	0.018*
VAS at rest, points	0.12 ± 0.33	0.12 ± 0.33	1.000
VAS on motion, points	0.32 ± 0.56	0.24 ± 0.44	0.779
MEPS, points	90.40 ± 5.76	91.40 ± 6.70	0.610
Total complications, n (%)	5 (20%)	4 (16%)	1.000
New onset or exacerbation of ulnar nerve symptoms, n	2	3	
Heterotopic ossification, n	2	1	
Repeat elbow stiffness, n	1	0	

ERAS, Enhanced Recovery After Surgery; ROM, Range of Motion; MEPS, Mayo Elbow Performance Score; VAS, Visual Analog Scale.
*p < 0.05 for the comparison between the two groups.

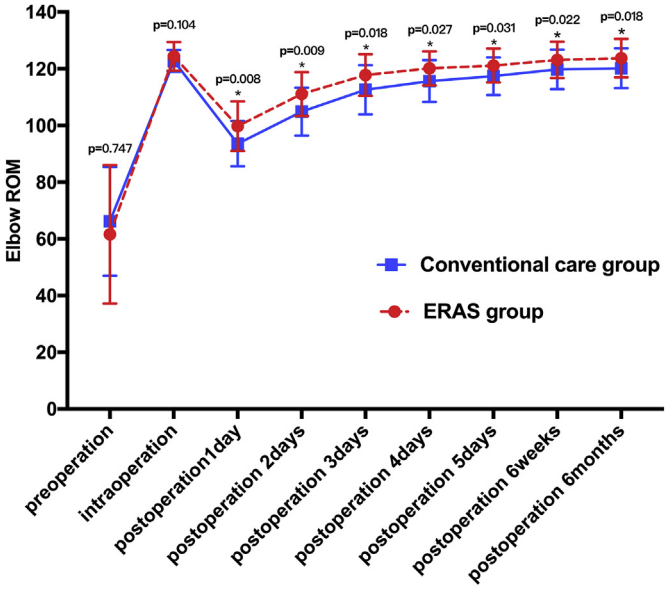

Fig. 4. Graph of the mean preoperative, intraoperative and postoperative range of motion.

ulnar nerve symptoms postoperatively, including 3 patients in the ERAS group and 2 patients in the conventional care group. All of the complications resolved spontaneously within 4–8 weeks. There were no other reported complications, such as elbow instability or peri-elbow refracture. Two patients in the conventional care group and one patient in the ERAS group developed HO in the extraarticular region of the elbow, which had no effect on the elbow motion. One patient in the conventional care group developed repeat soft-tissue contracture (ROM < 100°) and underwent re-operation for elbow release.

4. Discussion

In this developing health care environment, improving surgical outcomes while reducing postoperative pain should be the primary goal of any health care delivery system [30,31]. Several treatment details involving elbow arthrolysis have been described previously in the literature, but few involve an established clinical pathway to meet the special requirements of open arthrolysis for post-traumatic elbow stiffness [7,8,10]. This study showed that a comprehensive ERAS program for elbow arthrolysis improved patient recovery by reducing early postoperative pain. This study also showed less drain time and improved functional ROM in the ERAS group. The results from this trial demonstrate that multiple evidence-based improvements to the tradition pathway have a positive impact on its efficacy.

Before implementation of the ERAS pathway, our conventional care protocol contained several treatment modalities including optional elbow arthrolysis education class, oral analgesics, and postoperative rehabilitation. This protocol was effective, but there have been no recent improvements to reduce postoperative pain or improve elbow ROM at our institution in several years. Recent studies have shown that the key principles to enhance recovery are optimal pain control and acceleration of functional recovery [32]. Increased postoperative pain has been shown to be a risk factor for long-term pain, patient dissatisfaction, and reduced quality of life [7,26]. Moreover, pain is a predominant complaint in the early stage after elbow arthrolysis and affects postoperative functional exercise [33]. Multimodal analgesia is currently identified as the main analgesic method to control acute postoperative pain in the ERAS pathway [12]. An efficient pathway spans from pre-operation to post-discharge follow-up. Although postoperatively multimodal analgesia was a crucial proportion of the comprehensive ERAS pathway, multidisciplinary collaboration among ERAS programs, such as preoperative education, anesthesia management, and application of tranexamic acid, may have pain-relieving effects directly or indirectly. Preoperative education has been extremely useful in relieving anxiety and emotional stress, improving pain, or facilitating functional recovery for hip or knee replacement [14,34]. In light of this evidence, as well as to establish achievable goals for the index treatment, we set up nursing consultation center to deliver patient-centered care to patients and families in the ERAS group.

Before implementation of the ERAS pathway, general anesthesia or brachial plexus anesthesia were both optional according to the anesthetic specialists or opinions of the patients at our center. However, previous research associated the use of general anesthesia with an 8.5-fold increased risk of moderate to severe postoperative pain [35] and a 2.5-fold increased risk of persistent postsurgical pain for arthroplasty [36]. These data provide additional motivation to use brachial plexus anesthesia for patients in order to relieve postoperative pain and avoid the side-effects of general anesthesia. This study showed better pain control in the ERAS group from postoperative day 1 through 5, both at rest and in motion. These results are the consequence of multidisciplinary collaboration among all departments involved in the care of open arthrolysis patients. From our results, pain relief and standardized plans for postoperative rehabilitation was associated with increased early postoperative elbow joint mobilization, which plays an important role in maintaining the degree of ROM gained during elbow arthrolysis [8,10]. In our center, rehabilitation in the ERAS group was initiated on the day of surgery, and the functional exercise plan was goal-oriented for each day. It is encouraging that the significant improvements in elbow ROM at any point did not coincide with an increase in elbow instability and ulnar nerve palsies, a trend that has been

reported in some studies [3,37].

It is notable that the MEPS, which indicates elbow function, did not show a difference between groups at postoperative 6-months, even though ROM in the ERAS group (123.76° ± 6.81°) was significantly higher than in the conventional care group (120.20° ± 7.00°). This result may be attributed to the evaluation system of MEPS which might not be as useful as other scoring systems for evaluating the effects of the ERAS pathway, such as Disabilities of the Arm, Shoulder and Hand (DASH) scores.

In addition, blood management strategy is also crucial to the success of an ERAS program implementation [14], where a previous study has shown that minimizing blood loss may be good for joint ROM [38]. Tranexamic acid has demonstrated both clinical- and cost-efficacy during orthopedic surgery, especially in joint replacement. Although research on efficacy is on-going [13,14]. Reduced blood loss following elbow surgery can also reduce the risk of infection, hematoma, and HO formation [39]. Thus, tranexamic acid was an important part in the ERAS protocol. According to the results, it showed to be effective in maintaining low drainage time as a measure of blood loss.

There are multiple elements used in the ERAS protocol that may have contributed to successful outcomes; however, it is still unknown which element is the most valuable. This is a common limitation of other studies that evaluate comprehensive changes to established clinical practice [11,13]. Recent studies of other surgeries have shown that high compliance may improve outcomes, and supervising compliance has been an important element in ERAS implementation [40,41]. Therefore, maintaining the protocol is one key to the success of an ERAS pathway [12,14]. Although drawing specific cause-effect conclusions with our data is not possible, the outcomes are promising. Other institutions treating elbow arthrolysis may not be able to implement the ERAS changes precisely as outlined in this research, but improvements in outcomes can likely be made with similar institution-specific updates.

Our study has some limitations to consider. Firstly, we included only patients with post-traumatic elbow stiffness undergoing open arthrolysis in this trial. Further research is required to investigate the use of an ERAS in patients with more preoperative comorbidities or non-traumatic elbow stiffness. Secondly, due to the single-center nature of this study, our findings should be judiciously considered in the clinical settings of other hospitals. Despite these limitations, the present study is meaningful in that it is the first randomized trial that developed and evaluated the impact of an ERAS on patients undergoing elbow arthrolysis.

5. Conclusion

In conclusion, an evidence-based comprehensive ERAS pathway is feasible in open arthrolysis, acceptable for elbow stiffness patients, and showed detectable improved levels of pain (at rest and in motion), and elbow ROM in patients when compared with a conventional care pathway. Larger, multi-center studies should be conducted to validate our findings. In addition, future research might also assess the hospital stay and hospitalization costs, because of shorter length of stay and effected cost savings are major advantages of ERAS protocols.

Ethical approval

This research was approved by the institutional ethics committee of Shanghai Sixth People's Hospital East Campus and was registered at Clinical Trials Registry (ChiCTR1800016999).

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Conflicts of interest

The authors have no conflicts of interest or financial ties to disclose.

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CRediT authorship contribution statement

Haomin Cui: Conceptualization, Data curation, Investigation, Writing - original draft, Writing - review & editing. **Ziyang Sun:** Conceptualization, Data curation, Investigation, Writing - review & editing. **Jihao Ruan:** Investigation, Methodology, Writing - review & editing. **Yaling Yu:** Methodology, Writing - review & editing. **Cunyi Fan:** Conceptualization, Writing - review & editing, Project administration, Supervision, Resources.

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Appendix A. Supplementary data

Supplementary data to this chapter can be found online at https://doi.org/10.1016/j.ijsu.2019.06.010.

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