The Effects of Programmed Cryotherapy and Continuous Passive Motion in Patients after Computer-Assisted Total Knee Arthroplasty: A prospective, randomized controlled trial

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Abstract
Background: Cryotherapy and continuous passive motion (CPM) are commonly used for conventional total knee arthroplasty (TKA) to reduce postoperative pain and increase of the range of motion (ROM). However, this postoperative nursing intervention remains elusive for patients undergoing computer-assisted total knee arthroplasty (CAS-TKA)
Methods: A prospective, randomized controlled trial with a purposive sampling method was utilized. Sixty patients scheduled for a unilateral CAS-TKA at a medical center were randomly assigned to the intervention group (n=30) and control group (n=30). The intervention group applied programmed cryotherapy and CPM within one hour while returning to the ward on the day of surgery, while the control group did not. Data were analyzed using mixed models to compare numeric rating scale (NRS) for pain, ROM, and swelling at postoperative day (POD) 4.
Results: There was no significant difference in the NRS score between the groups ( p = 0.168). The intervention group had significantly higher ROM than the control group (98 degrees vs. 91 degrees, p = 0.004) at POD 4. Although no significant difference in joint swelling was found between groups ( p = 0.157), the intervention group had lower mean joint swelling (32.2 cm) than the control group (33.9 cm).
Conclusions: Programmed cryotherapy and continuous passive motion can improve the range of motion after CAS-TKA. It should be incorporated into the daily nursing plan for patients undergoing CAS-TKA.

Background
Total knee arthroplasty (TKA) is an effective intervention in reducing pain and enhancing physical mobility for end-stage knee osteoarthritis [1]. Computer-assisted surgery (CAS) has shown to improve implant positioning, restore the mechanical axis, and provide better functional outcomes during TKA [2]. In CAS-TKA, several temporary pins are placed in the thigh and the upper tibia percutaneously through separate stab incisions. After the addition of these temporary pins, the early postoperative recovery is often hindered by significant pain, swelling, and stiffness [3]. The pain sensation and extremity swelling inhibit patients’ motivation for early mobilization, which results in prolonged
hospital stays, delayed functional recovery and negative psychological responses.

Pain has been defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage [4]. Therefore, adequate pain management and control of localized swelling and stiffness after TKA has become a priority because it is essential for improving patient satisfaction, prevention of complications, and enhancing quality of life by faster recovery. Systemic and local analgesics are the most common strategies for postoperative pain management in TKA [5]. However, patients might experience nausea, vomiting, constipation, or respiratory failure due to opioid-related side effects, subsequently refusing to mobilize and delaying the rehabilitation program [6].

In addition to pain control, cryotherapy and continuous passive motion (CPM) are commonly used for TKA patients as non-pharmacological methods to reduce the postoperative pain and swelling and to increase the amount of knee flexion [7]. The application of cryotherapy after TKA has been described extensively in the literature [7] and is part of standard care globally [8]. However, its benefits and value remain controversial due to the disparity in practice, such as differences in clinical protocols and the type of cryotherapy application [9]. Continuous passive motion is a motorized device, which passively moves the knee joint within a certain range of motion (ROM) to decrease analgesics requirements, reduce the incidence of deep vein thrombosis, and increase ROM [10]. But the effects of CPM remain contentious in the literature [11]. Although controversial, cryotherapy and CPM have been used extensively as part of the standard postoperative management protocol for TKA patients without knowing its cost-effectiveness. However, the value of combined therapy of cryotherapy and CPM remains uncertain and unclear following CAS-TKA.

The hypothesis of this study was the patients, who received programed cryotherapy and CPM, had experienced less postoperative pain, joint swelling, and increased ROM following CAS-TKA.

Materials And Methods
Study design
A prospective, randomized, single-blinded controlled trial (ClinicalTrials.gov identifier: NCT04136431) was conducted at a single, academic, teaching, and medical hospital. After approval by the
Institutional Review Board (IRB Number: 201102015B0), this study started to enroll the participants after obtaining written informed consent. All patients were enrolled by the Consolidated Standards of Reporting Trials.

Participants and setting
Patients undergoing primary CAS-TKA were assessed for eligibility from January 2017 to July 2017. Patients between 18 and 90 years of age who underwent primary, unilateral navigation-assisted TKA were included in this study. The exclusion criteria were as follows: (1) patients who underwent bilateral TKAs, unicompartmental TKA or revision TKA (2) patients who had to remove previous implants or history of high-tibial or distal femoral corrective osteotomy (3) patients who were unable to response the questionnaires.

A total of sixty-eight patients who underwent CAS-TKA were enrolled. Among them, seven patients declined to participate. One patient was excluded due to consciousness disturbance after returning the ward and unable to answer questions listed in the questionnaires. Therefore, 60 participants were randomly allocated to the intervention group (n = 30) and the control group (n = 30). All patients completed the analysis before discharge (Fig. 1).

Randomization
The randomization was performed by the research staff using a parallel, 1 to 1 allocation method. A computer-generated randomization schedule was generated to assign participants to the intervention group by using a block size of 8 (1:1 ratio). The randomization occurred on the day of surgery using an opaque, sealed envelope, pre-labeled method.

Surgical technique
All patients received a unilateral primary CAS-TKA by a single experienced surgeon. A pneumatic tourniquet was inflated to 300 mmHg pressure before the incision and deflated at the end of surgery after skin closure. The navigation system was Vector Vision (BrainLab, Heimstetten, Germany) and all TKAs were cemented using the same prosthesis (NexGen Legacy posterior-stabilized prosthesis; Zimmer Inc., Warsaw, IN, USA). There was no local infiltration of the local anesthetic in the knee joint. A suction drain was inserted before wound closure and removed on postoperative day (POD) 1. All surgical wounds, including the stab incisions for the insertion of temporary pins, were closed with
interrupted skin stitches. All patients received aspirin as venous thromboembolism prophylaxis for 14 days. Multimodal pain management (acetaminophen, cyclooxygenase-2 inhibitors drugs, and tramadol/acetaminophen combination tablets [Ultracet®] were applied for all patients.

**Intervention group**
In the intervention group, the systematic nursing intervention was implemented for the patients. The intervention group started to use a CPM machine and applied programed cryotherapy intermittently within one hour while returning to the ward on the day of surgery. The CPM machine was set to move from 0 degrees of extension to 60 degrees of flexion. The application of programed cryotherapy was continued for 20 minutes and then stopped for 30 minutes. The programed cryotherapy with the cryotherapy pack was replaced every four hours. From POD 1 to the day of discharge, the application of CPM and cryotherapy were conducted as the ward routine practice. The participants were blinded after assignment.

**Control group**
For the control group, a routine nursing procedure was conducted, but the CPM device and cryotherapy were not applied on the day of surgery. The patients started CPM from 0 degrees of extension to 60 degrees of flexion and received cryotherapy on POD 1. However, the application of cryotherapy was not programed, which meant the frequency and intervals of cryotherapy were not specified and determined by the patients or caregivers.

**Data collection**
The patients, outcome investigator, and statistician were blinded. Because of the different frequency of the replacement of the programed cryotherapy on POD 1, it was impossible to blind the surgeon and the floor nursing staff. The following participant characteristics (age, sex, body mass index, religion and education), surgical variables (surgical experience, anesthesia method, wound length), the drainage amount, and the use of patient-controlled analgesia were collected.

**Primary and secondary outcomes**
A numeric rating scale (NRS) with 0–10 points [12] was the primary outcome of interest in this study. It was evaluated when 0 is no pain and 10 the worst imaginable pain. The secondary outcome included the short-form McGill Pain Questionnaire (SF-MPQ), ROM and the swelling status of the
extremity. The SF-MPQ has been used to describe pain, feeling, memory, and influence in 15 pain situations [13]. The SF-MPQ has been validated to have a high correlation coefficient with long-form MPQ. A universal goniometer was used to measure ROM of the knee joints. The measurement of the thigh circumference was performed 15 cm proximal to the superior pole of the patella with a measurement tape, meanwhile 15 cm distal to the inferior pole of the patella for the calf circumference. Both thigh and calf circumference were compared to the normal contralateral leg to determine the amount of postoperative swelling. The above measurement was conducted at POD 1 and POD 4 or until the patients were discharged. All the patients completed the outcome evaluation by a research assistant.

Statistical analysis
The sample size and Cohen’s effect size were calculated with the G*Power software package (version 3.1.4). The effect size f was interpreted as: f = 0.10 small effect, f = 0.25 medium effect, f = 0.40 large effect. The collected data were coded with numbers and input to computer software. According to the research purpose and variable characteristics, IBM SPSS Statistics for Windows (version 22.0; IBM Corp., Armonk, NY, USA) was used for information analysis. The statistical methods included descriptive statistics and deductive statistics. Descriptive statistics involved: (1) frequency and percentage, including category and ordinary variables of basic features of the investigated subjects, such as gender, education background, religious belief, and past surgical experience; and (2) mean value and standard deviation, including the equal-interval variables of basic features such as sex, education background, religious belief, operation experience, and anesthesia. Also, the scale score was described before and after measures. Deductive statistics included the independent t-test and Chi-square test before measures, as well as the homogeneity test of basic features in the intervention group and control group. An independent t-test was conducted to compare the pretest difference between the two groups, and a t-test of the samples was conducted to compare changes in the pretest and post-intervention groups. ANCOVA (analysis of covariance) was used to compare pain after the treatment, as well as differences in the posttest scores of knee flexion and knee swelling. A p-value < 0.05 was considered significantly different.
Results
The majority of the patients were Taoists and Buddhists. Among the 73.7% had operation experience, 93.3% had used general anesthetics. The average wound length was 14.2 ± 1.6 cm, and the average volume of the drainage tube was 116 ± 59 ml. Of the subjects, 52 patients (86.7%) did not use pain controllers. There was no significant difference in patients’ demographic data, surgical experience, anesthesia method, wound length, drainage amount, and the pain controller. Although there was not significantly different, the use of patient-controlled analgesia was reduced gradually in the intervention group (Table 1).

Table 1
Demographic data between the two groups

| Demographics          | All (N = 60) | Intervention group (n = 30) | Control group (n = 30) | p value |
|-----------------------|-------------|----------------------------|------------------------|---------|
| Age, year (SD)        |             |                            |                        |         |
| 40–50 years           | 2 (3.3)     | 1 (3.3)                    | 1 (3.3)                | .694    |
| 51–60 years           | 11 (18.3)   | 7 (23.3)                   | 4 (13.3)               |         |
| 61–70 years           | 21 (35.0)   | 10 (33.3)                  | 11 (36.7)              |         |
| 71–80 years           | 25 (41.7)   | 11 (36.7)                  | 14 (46.7)              |         |
| 81–90 years           | 1 (1.7)     | 1 (3.3)                    | 0 (0.0)                |         |
| Sex, n (%)            |             |                            |                        | .519    |
| Male                  | 12 (20.0)   | 7 (23.3)                   | 5 (16.7)               |         |
| Female                | 48 (80.0)   | 23 (76.7)                  | 25 (83.3)              |         |
| Religion, n (%)       |             |                            |                        | .511    |
| No religion           | 7 (11.7)    | 5 (16.7)                   | 2 (6.7)                |         |
| Taoism                | 24 (40.0)   | 13 (43.3)                  | 11 (36.7)              |         |
| Buddhism              | 24 (40.0)   | 9 (30.0)                   | 15 (50.0)              |         |
| Christian             | 3 (5.0)     | 2 (6.7)                    | 1 (3.3)                |         |
| Others                | 2 (3.3)     | 1 (3.3)                    | 1 (3.3)                |         |
| Education, n (%)      |             |                            |                        | .911    |
| Un literate           | 25 (41.7)   | 13 (43.3)                  | 12 (40.0)              |         |
| Elementary school     | 10 (33.3)   | 10 (33.3)                  | 10 (33.3)              |         |
| Middle school         | 7 (11.7)    | 3 (10.0)                   | 4 (13.3)               |         |
| High school           | 4 (6.7)     | 2 (6.7)                    | 2 (6.7)                |         |
| Specialist            | 2 (3.3)     | 1 (3.3)                    | 1 (3.3)                |         |
| Above university      | 1 (1.7)     | 1 (3.3)                    | 0 (0.0)                |         |
| Surgical experience, n (%) | 2 (3.3) | 1 (3.3) | 1 (3.3) | .911 |
| No                    | 15 (25.0)   | 7 (23.3)                   | 8 (26.7)               |         |
| Yes                   | 44 (73.7)   | 23 (76.7)                  | 21 (70.0)              |         |
| Missing value         | 1 (1.7)     | 0 (0.0)                    | 1 (3.3)                | .301    |
| Anesthesia, n (%)     |             |                            |                        |         |
| General               | 56 (93.3)   | 27 (90.0)                  | 29 (96.7)              |         |
| Regional              | 4 (6.7)     | 3 (10.0)                   | 1 (3.3)                |         |
| Wound length, cm (SD) | 14.2 (1.6)  | 13.9 (1.2)                 | 14.5 (1.8)             | .136    |
| Drainage amount, ml (SD) | 116 (59) | 122 (66) | 109 (52) | .387 |
| Patient-controlled analgesia, n (%) | 8 (13.3) | 3 (10.0) | 5 (16.7) | .448 |
| The time of analgesics injection | | | | |
| POD 1                 | 1.0 (0.7)   | 0.9 (0.6)                  | 1.2 (0.8)              | .098    |
| POD 2                 | 0.4 (0.6)   | 0.3 (0.5)                  | 0.5 (0.6)              | .064    |
| POD 3                 | 0.1 (0.3)   | 0.03 (0.2)                 | 0.2 (0.4)              | .090    |
| POD: postoperative day; SD, standard deviation |

There was no significant difference in the NRS score between groups (p = 0.168). As shown in Table 2,
SF-MPQ showed no significant difference in 15 pain situations of the tested patients between the two groups ($p > 0.05$). The average pain intensity of all the tested patients was lower than 2 points, indicating there was no serious pain (Table 2).

| Pain description | All (N = 60) | Intervention group (n = 30) | Control group (n = 30) | $p$ value |
|------------------|-------------|-----------------------------|------------------------|-----------|
| Throbbing        | 1.00        | 0.90                        | 1.10                   | 0.92      |
|                  | 0.94        | 0.96                        | 0.92                   | 0.33      |
| Sudden           | 0.45        | 0.57                        | 0.33                   | 1.00      |
| sharp            | 0.83        | 1.04                        | 0.55                   | 0.55      |
| Stabbing         | 0.43        | 0.57                        | 0.30                   | 0.60      |
| Lancinating      | 0.27        | 0.20                        | 0.33                   | 0.76      |
| Spastic          | 0.20        | 0.20                        | 0.20                   | 0.55      |
| Gnaing           | 0.22        | 0.56                        | 0.30                   | 0.58      |
| Burning          | 0.10        | 0.07                        | 0.27                   | 0.58      |
| Soreness         | 0.93        | 0.73                        | 1.13                   | 1.01      |
| Heavy            | 1.33        | 1.27                        | 1.40                   | 1.04      |
| feeling          | 1.05        | 1.08                        | 1.04                   | 1.04      |
| Pain upon        | 0.10        | 0.07                        | 0.37                   | 0.43      |
| touching         | 0.40        | 0.37                        | 0.13                   | 0.37      |
| Tearing          | 0.13        | 0.07                        | 0.20                   | 0.55      |
| Exhausted        | 0.87        | 0.67                        | 1.03                   | 1.01      |
| Unbearable       | 0.60        | 0.57                        | 0.63                   | 0.76      |
| Fear             | 0.37        | 0.50                        | 0.23                   | 0.57      |
| Tortured         | 0.32        | 0.37                        | 0.27                   | 0.52      |
|                  | 0.65        | 0.76                        | 0.27                   | 0.52      |

Table 2: The short-form McGill pain questionnaire between the intervention group and control group

As shown in Table 3, the average ROM of the intervention group was significantly higher than the control group (98 degrees vs. 91 degrees, $p = 0.004$) at POD 4. Although no significant difference in joint swelling was found between groups ($p = 0.157$), the intervention group had lower mean joint swelling (32.2 cm) than the control group (33.9 cm).

Table 3: Comparison the degrees of range of motion after interventions in the pre-test (postoperative day 1) and post-test (postoperative day 4)

| Group         | Pre-test | Post-test |
|---------------|----------|-----------|
|               | Mean     | SD        |
| Intervention  | 65       | 14.1      |
| (degrees)     |          |           |
| Control       | 56       | 11.6      |
| (degrees)     |          |           |

Discussion

In past studies, CPM devices and cryotherapy have been applied to patients undergoing TKA with different intervention effects. However, no literature has discussed the effect of combined CPM with programmed cryotherapy in patients following CAS-TKA. The findings showed that the intervention effect on ROM had significant differences, while the effect on pain and knee joint swelling had no
significant difference.

The study indicated that pain intensity is a concern in TKA patients [14]. In this paper, the research results showed that constructive systematic nursing measures have significantly different effects on pain intensity after TKA. The literature indicated that patients who undergo computer-navigated surgery do not suffer from a serious loss of blood or pain because intramedullary nailing of the femur is not required for CAS-TKA [15]. The findings showed that the use of CPM devices can relieve pain intensity after surgery and that it is an appropriate rehabilitation exercise for alleviating pain. This finding was similar to the studies by Pozzi et al. [16]. Overall, of the 15 types of pain, the respondents in the two groups mainly experienced throbbing pain, and a heavy feeling after CAS-TKA and the effective evaluation was dominated by feeling exhausted. The mean value of these three items had the highest score, ranging from 1 to 2. Given the results after CAS-TKA, health education should be enhanced to feel the nature of pain and teach the patients how to alleviate their pain and solve their physiologic discomfort. Interventions should be implemented for the three items to solve clinical problems.

CPM effect focuses on immediate use after surgery and not the amount of time needed for CPM [10]. In this study, the CPM intervention time was the operation day, and the length of use did not empathize. CPM can relieve pain intensity if it is instituted as early as possible. This finding was the same as the results in the literature. Pain intensity was alleviated on the fourth day after the operation. The result of the immediate use of CPM in our study was similar to the result of Pozzi et al. [16]. Cryotherapy can have the effect of pain relief [17]. It is also one of the common methods to relieve pain after surgery. In this study, nursing interventions included CPM use time and the cryotherapy construction process. The intervention group and the control group received both nursing interventions after surgery. It is necessary to establish one set of standard cryotherapy processes, ensure a uniform guidance mode, and monitor the effect of CPM intervention time. Many studies have separately discussed the effect of CPM and cryotherapy, but no studies have combined the two. In clinical manifestation and practice, the combination should be addressed after the revision of the research design. The effect of constructive systematic nursing interventions on ROM reached a
significant difference. Early rehabilitation effect has demonstrated a better knee joint motion and performance [18]. These results were the same as the effect on ROM in this study. This study focused on early interventions of CPM and the resultant effect was different when CPM was used on the same day after CAS-TKA.

To sum up, constructive systematic nursing interventions have a significant effect on ROM. The effect of the constructive systematic nursing intervention on swelling showed no significant differences. Literature has demonstrated that the use of cryotherapy has a better effect on the wound swelling in TKA patients [19]. The results of pre-test swelling and post-test swelling of the two groups showed that the knee joint swelling of the intervention group was smaller on the first day and the fourth day than the control group, with a swelling difference of 1.82 centimeters. Theoretically, cryotherapy can reduce the excitability of free nerve ending and peripheral nerves, thereby indirectly reducing tissue edema and increasing the pain threshold to reduce pain intensity [19, 20].

Limitations
Due to limitations of the research framework and number of samples, the intervention effect on pain intensity and ROM had significant differences, while the effect on knee joint swelling had no significant difference. The study, measures, and subjects of this study knew which patients were distributed to the intervention group and the control group. In addition, this was not the first time some subjects had undergone TKA, and they knew that CPM would be used on the first day after operation instead of the same day of operation. Thus, the subjects may have been prone to the Hawthorne effect. If a subject was randomly distributed to the intervention group, he/she must be informed of the group, and receive instruction. The external validity may, therefore, have been affected. The study was conducted in a hospital center in southern Taiwan. The samples were limited to the southern area, and the number of samples was smaller. The characteristics of the patients may be different from other places in Taiwan. Therefore, extrapolation is not recommended. However, the analysis found that the measurement tools were not sensitive and the measurement scope for joint swelling was not clear. It is suggested that PQRST evaluation can be used in clinical practice to evaluate the pain of TKA patients, which can be considered during the evaluation of the intervention.
Conclusion
Programmed cryotherapy and continuous passive motion can improve range of motion after CAS-TKA. The establishment of this application should be incorporated into the daily nursing plan.

Abbreviations
TKA: Total knee arthroplasty; CAS: Computer-assisted surgery; CPM: Continuous passive motion; ROM: range of motion; POD: Postoperative day; NRS: Numeric rating scale; SF-MPQ: Short-form McGill Pain Questionnaire.

Declarations

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Authors’ contributions
MCC and FCK were involved in conception, design of the study and manuscript drafting. MCC and CCL collected and analyzed the data together. JYK and FCK supervised the version to be published. All authors read and approved the final manuscript.

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Availability of data and materials
Not applicable.

Ethics approval and consent to participate
Ethical approval was given by Chang Gung Medical Foundation. All patients signed the written informed consent.

Consent for publication

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All of the authors have consent to publish this research.

**Competing interests**

All the authors declared that they have no competing interests.

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Figures
Figure 1

The CONSORT flowchart showing enrollment and exclusion of patients through the trial.