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Contents

Journal of Southeast Asian Orthopaedics
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Editorial

Greetings to our esteemed readers and contributors,

We are delighted to present Volume 48, Number 1 (January – June 2024) of the Journal of Southeast Asian Orthopedics (JseaOrtho). As a platform dedicated to advancing orthopaedic research and clinical practices, this edition encompasses many original articles and case report reflecting the diverse facets of orthopaedic endeavors.

In the dynamic landscape of orthopaedics, progress and advancements in various specialties are pivotal. Our commitment at JseaOrtho is to keep our readers abreast of these developments, serving as a conduit for the exchange of knowledge and experiences within the orthopaedic community.

This volume encapsulates the essence of our mission, offering insights into the latest research findings and clinical practices. From the safety and effectiveness of novel surgical techniques in pediatric cases to addressing challenges posed by the era of COVID-19, the articles featured herein contribute significantly to the evolving field of orthopaedics.

As editors, we recognize our responsibility to both readers and authors. We are dedicated to ensuring a fair and timely peer-review process, emphasizing the scientific validity of the information presented. Our goal is to maintain the high quality and regional relevance of JseaOrtho as a trusted source for orthopaedic research.

We extend our gratitude to the authors, reviewers, and readers who continue to contribute to the success of JseaOrtho. Your commitment and collaboration play a pivotal role in shaping the future of orthopaedics in the Southeast Asian region.

Thanainit Chotanaphuti, MD, FRCOST
Editor in chief, Journal of Southeast Asian Orthopaedics
Past President, the RCOST

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The Safety and Effectiveness of an In-Depth Esmarch Tourniquet Technique in Achieving Target Pressures for Pediatric Upper Extremity Surgery

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Purpose: This study aimed to determine the appropriate number of turns required for an Esmarch tourniquet, using commonly sized Esmarch bandages, to achieve a pressure target of at least 150 mm Hg during pediatric upper extremity surgery.
Methods: Twenty participants who underwent upper extremity surgery were included in the study. Two surgeons used 2- and 3-inch-sized Esmarch bandages to apply an Esmarch tourniquet to each participant's arm. The pressure and number of turns were recorded from the second to fifth turns. The pressure was measured using a pressure sensor device.
Results: At the third turn of both the 2- and 3-inch-sized Esmarch bandages, a 150 mm Hg pressure was achieved in all participants. Intra-observer reliability resulted was "good"; however, inter-observer revealed "poor" reliability.
Conclusions: The Esmarch tourniquet is an effective and safe method for creating a bloodless operative field for upper extremity surgery in pediatric patients. The results of this present study suggested the application of three turns of the 2- and 3-inch-sized Esmarch bandages.

Keywords: Esmarch, pressure, tourniquet, upper extremity surgery, children

Pneumatic tourniquets are widely used in upper extremity surgeries. However, a child's limb has unique characteristics for which a traditional pneumatic tourniquet is not suitable, including the relatively small limb size that may leave no space for the application of a pneumatic tourniquet. Furthermore, acute tapering of the extremities often results in distal sliding of the tourniquet[1].The standard tourniquet pressure recommended for surgery in the upper extremities of children ranges from 150 to 250 mm Hg[2]. The use of different methods, such as skin protection techniques and the availability of various commercial pneumatic tourniquet systems may result in variations in the applied pressure, often leading to higher pressures than necessary[3,4]. Currently, no specific studies have investigated the appropriate size and number of turns of the Esmarch tourniquet required to achieve the desired pressure in the upper extremities of children during surgery. This study aimed to determine the appropriate number of turns for commonly sized Esmarch bandages to

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achieve a pressure target for upper extremity surgery in children.

METHODS

This study was approved by the Institutional Review Board of our hospital (LH611050). Informed consent was obtained from the parents of all participants. Participants aged between 3 months and 5 years who underwent upper extremity surgery were included in the study. The exclusion criteria were as follows: pathology at the site where the tourniquet would be applied; an underlying disease of abnormal blood circulation; or a coagulopathy. Two orthopedic surgeons (a highly-experienced, specialized pediatric hand surgeon and a non-specialized, fellowship-trained hand surgeon) performed the procedures of the application of 2- and 3-inch-sized Esmarch bandages.

The Esmarch Bandage Torniquet Technique

All the participants were placed in a supine position, and they received general anesthesia. The load cell of a pressure sensor device (FlexiForce™, standard model A201, Piezoresistive Force Sensor, Tekscan, USA) was placed on the medial aspect of the arm (Fig. 1). The two surgeons used two Esmarch bandages. One was used to exsanguinate the upper extremity, and the other was used as a tourniquet to control the pressure. The first Esmarch bandage (2-inch-sized) was applied starting from the distal to proximal aspect of the forearm (Fig. 2), and the second Esmarch bandage was applied proximal to the elbow. Subsequently, the surgeons applied 2- and 3-inch-sized Esmarch bandage tourniquets (VBM Medizintechnik GmbH, München, Germany) to each participant's arm (2-inch-sized Esmarch bandage first) by pulling the Esmarch bandage and stretched it to match the width of the upper arm in the coronal plane, to distribute a standardized pressure (Figs. 2, 3). An open straight clamp was applied before the last turn. The clamp was closed after the final turn (Fig. 4). The pressure measurements at the second to fifth turns were recorded. The 2-inch-sized Esmarch bandage was released. After a 3-min pause, the entire procedure was repeated, and the 3-inch-sized Esmarch bandage was used in the same manner. The two surgeons performed the applications of the 2- and 3-inch-sized Esmarch bandages, independently of each

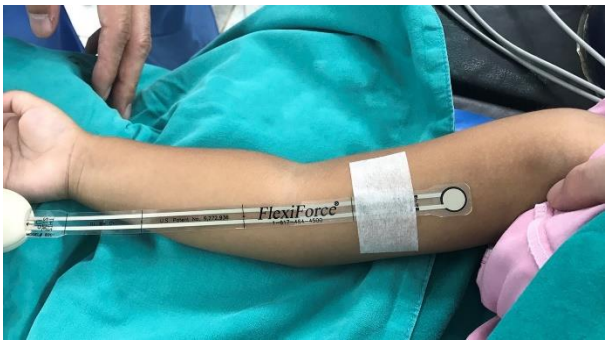

Fig. 1 The load cell is applied to the medial aspect of the arm.

Fig. 2 The surgeon gently pulls and stretches the Esmarch bandage to the width of the upper.

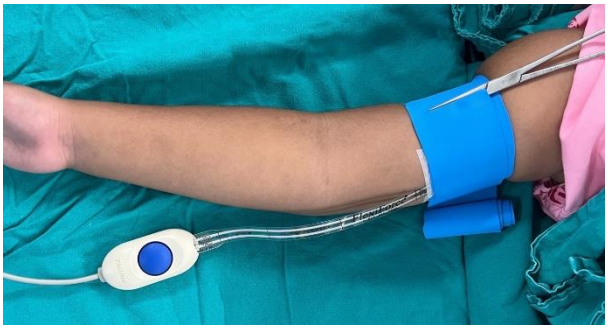

Fig. 3 The Esmarch bandage is applied.

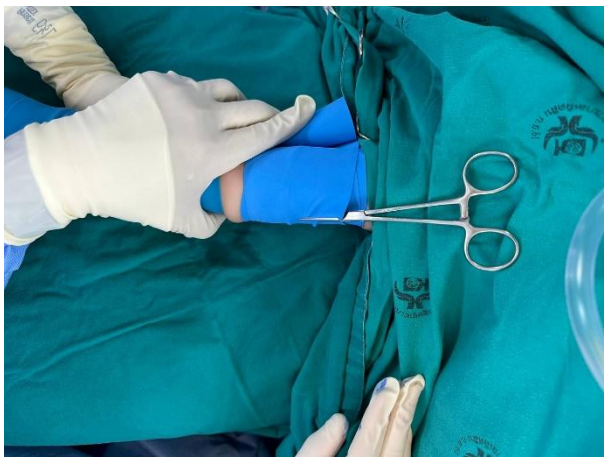

Fig. 4 A straight clamp is applied.

The average pressure of each turn of each sized bandage was measured and reported. A repeated measures analysis of variance (ANOVA) with post-hoc analysis was used to determine the difference between the measurements of pressure for each turn, with a p-value of less than 0.05 considered for significant significance. Intraclass correlation coefficient (ICC) was used for intra-observer (2-way random effects model; absolute agreement) and inter-observer (2-way mixed-effects model; absolute agreement) reliability.

RESULTS

Of the 20 participants that were included in the study, 9 were male and 11 were female patients. The average age of the participants was 29.2 months. For the 2-inch-sized Esmarch bandage, a pressure of 150 mm Hg was obtained at the third turn for both the surgeons in all participants (pediatric hand surgeon: mean= 185 mm Hg, SD= 13.4 mm Hg, range= 154–211 mm Hg; fellowship-trained hand surgeon: mean= 187 mm Hg, SD= 14.9 mm Hg, range= 152–213 mm Hg). Furthermore, for the 3-inch-sized Esmarch bandage, the target pressure of 150 mm Hg was obtained at the third turn for both the surgeons in all participants (pediatric hand surgeon: mean= 182 mm Hg, SD= 20 mm Hg, range= 136–216 mm Hg; fellowship-trained hand surgeon: mean= 190 mm Hg, SD= 21 mm Hg, range= 140–219 mm Hg; Table 1). Repeated measure ANOVA revealed a statistically significant difference in mostly all of the pressures between the 2- and 3-inch-sized Esmarch bandages for both surgeons. However, the pressures between the fourth and fifth turns of the 2-inch-sized Esmarch bandage that was applied by the pediatric hand surgeon (p= 0.06) and fellowship-trained hand surgeon (p= 0.44) did not reveal a statistically significant difference. Furthermore, no statistically significant differences were observed between the third and fourth turns (p= 0.82) and between the fourth and fifth turns (p= 0.32) for the 3-inch-sized Esmarch bandage that was applied by the fellowship-trained hand surgeon.

The intra-observer reliability revealed good agreement (ICC > 0.8) for both sizes, all turns, and both surgeons. In contrast, the inter-observer reliability revealed poor agreement (ICC < 0.5) for both sizes and all turns.

Table 1 Average pressures (mm Hg) of the 2- and 3-inch-sized Esmarch bandages; reported as mean (SD).

2-inch-sized Esmarch bandage	**Second Turn**	**Third Turn**	**Fourth Turn**	**Fifth Turn**
Pediatric hand surgeon	128 (18)	185 (13)	202 (24)	218 (26)
Fellowship-trained hand surgeon	138 (22)	187 (15)	205 (18)	215 (23)
3-inch-sized Esmarch bandage				
Pediatric hand surgeon	132 (20)	182 (20)	201 (24)	219 (28)
Fellowship-trained hand surgeon	133 (13)	190 (21)	199 (15)	212 (28)

DISCUSSION

Pneumatic tourniquets are commonly used in extremity surgeries by pediatric orthopedic surgeries. Previous studies have reported that a pressure approximately 100 mm Hg above the systolic blood pressure is considered to be the effective pressure for hemostasis[5]. However, most of these studies have been conducted on adults.

Currently, evidence for the proper use of tourniquets in children is limited. The standard tourniquet;t pressure used in children ranges from 150 to 250 mm Hg[2]. Lieberman et al. reported that the average pressure used in upper extremity surgeries in pediatric patients is 173.4 mm Hg (range= 155–190 mm Hg), and that the traditional pneumatic tourniquets do not fit the small-circumference extremities of pediatric patients less than 2-years-old[6]. Eidelman et al. reported that there is only a limited area on a pediatric patient's limb for the application of a tourniquet due to the small size of their extremities. In addition, acute tapering of a child's extremities often results in inadvertent distal sliding of the tourniquet[1]. The small size of the upper extremities probably results in the loss of tourniquet compression and causes blood leakage into the surgical field.

In 1993, Biehl et al. reported that the Esmarch tourniquet generated safe and reliable pressures during foot and ankle surgeries. The application of both the 3- and 4-inch-sized Esmarch bandages with three, circumferential, overlapping wraps has consistently resulted in a pressure that is within a safe range[7]. Regarding the use of an Esmarch tourniquet to achieve adequate hemostatsis during surgery, Abraham et al. recommended stretching the Esmarch bandage before wrapping each turn. The author observed that the pressure can increase at a rate of three to four times that of its initial pressure when the bandage is stretched after each wrap, rather than over the total length initially[8].

The present study demonstrated that three turns of the 2- and 3-inch-size Esmarch bandages generated the optimal pressure that could be consistently used as a tourniquet for upper extremity surgery in pediatric patients. Furthermore, we observed a good intra-observer reliability, although the inter-observer reliability was poor. This may attributed to the analysis method used (absolute agreement) and the variability among the surgeons. However, despite the lack of reliability between the surgeons, the effective pressure was obtained at the third turn for both sizes of the Esmarch bandages, for all the participants. At the third turn, the pressure did not exceed the recommended upper limit of 250 mm Hg in any of the participants.

A limitation of this study was its small sample size. Furthermore, the study revealed that a number of variable factors related to the pressure needs to be considered. The first is the difference between the physical pressures applied by individual surgeons. The second is the size and circumference of the pediatric patient's upper arm. The third is the brand and condition of the Esmarch bandage, which may affect its elasticity. A fourth factor is the variability in pressure that may result from the different technique used for stretching the bandage until the width of the bandage is equivalent to the width of the upper arm in the coronal plane. These variables affect the true value of the overall pressure achieved by individual surgeons. Further studies with larger sample sizes and involving more surgeons may be of benefit in refining further results.

CONCLUSIONS

The Esmarch tourniquet is an effective and safe procedure for creating a bloodless operative field for upper extremity surgery in pediatric patients. The results of this present study suggested the application of three turns of the 2- and 3-inch-sized Esmarch bandages to obtain an optimal pressure, which is considered to be between 150 and 250 mm Hg.

ACKNOWLEDGEMENTS

We would like to thank Pattarasak Rakchucheep for data collection.

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Effect of Transdermal Microneedle Patch Plus Nonsteroidal Anti-Inflammatory Drug in Knee Osteoarthritis: A Randomized, Double-Blind Study

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Purpose: No recent clinical study has shown the efficacy of transdermal microneedle patch (TDM) plus nonsteroidal antiinflammatory drug (NSAID) in early knee osteoarthritis (OA). This study aimed to determine the effect of TDM plus NSAID on synovial hypertrophy, knee pain, and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) score in osteoarthritic knees.

Methods: A randomized, controlled, double-blind trial was conducted. One hundred participants, aged 40–70 years, with painful knee OA and radiographic nonstructural changes were randomly assigned into two groups to undergo TDM plus NSAID (ketorolac 30 mg) or TDM (placebo) at the medial joint line of the knee twice (once weekly). The synovial thickness was measured using ultrasonography at pretreatment, weeks 1, 2, and 4. The visual analog scale (VAS) for pain, WOMAC score, and adverse events (AEs) were also recorded.

Results: The TDM plus NSAID group demonstrated a significant reduction in synovial thickness and VAS at weeks 2 and 4 compared with the placebo group ($P<0.05$). At week 4, the mean synovial thickness reduction was 1.1 and 0.3 mm, and the mean VAS reduction was 3.2 and 1.7 for the TDM plus NSAID and placebo groups, respectively. The mean WOMAC scores at week 4 were significantly reduced (5.7 and 0.9 for the TDM plus NSAID and placebo groups, respectively). No complication and treatment-related AEs occurred.

Conclusions: TDM plus NSAID significantly reduced synovitis and improved the pain score in knee OA after 2 weeks. The WOMAC score improved at week 4 without any AEs.

Thai Clinical Trials Registry (TCTR), TCTR identification number is TCTR20200613001.

Keywords: microneedle patch, knee osteoarthritis, synovitis, transdermal patch, NSAID

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Osteoarthritis (OA) is a common chronic joint disease that causes joint pain and disability. OA has recently been described as a whole-joint disease involving articular cartilage degradation, subchondral bone thickening, ligament degeneration, joint capsule hypertrophy, and synovial inflammation[1].

In early-stage knee OA, pain is the most prominent symptom. Nonsteroidal antiinflamma-

tory drugs (NSAIDs) keep on the mainstay of pharmacological management. Their use is strongly recommended along with the standard guidelines to control pain and inflammation[2]. Ketolorac is one of the NSAIDs that can be given through intraarticular, -muscular, and -venous injections as well as transdermal routes[3,4].

Transdermal microneedle patch (TDM) is a noninvasive choice of drug administration. It gives a more stable drug plasma concentration than oral and sublingual routes.[5] Regarding the mechanism of action, TDM pierces the stratum corneum, usually reaching a depth of 50–900 μm below the skin surface. A substantial benefit of this approach is its penetration range does not reach blood vessels or nerve fibers within the skin. Hence, it is painless, does not cause bleeding, and is unlikely to allow communicable disease transmission. Another key benefit of using TDM compared to the oral route is its ability to bypass the gastrointestinal tract and, thus, eliminate the first-pass metabolism. In addition, TDM is easy to terminate if complications occur. The systemic efficacy of TDM has been proven and used for many purposes, such as vaccination and hormonal therapy. Local controlled TDM is also used for cosmetic purposes[5,6].

Kellgren and Lawrence have provided a guide to radiographic imaging and grading for clinical diagnosis and treatment monitoring of OA. However, radiographic evidence of OA is a potential late sign indicating irreversible joint damage has already occurred[7]. Ultrasonography can detect synovial hypertrophy, the pathological hallmark of early-stage knee OA. Ultrasonography has been widely studied in synovitis monitoring, although the reliability of ultrasonography is operator-dependent. In a previous study, Termtanun et al.[8] found that the more advanced the knee OA stage, the higher the synovial hypertrophy prevalence. As the disease progresses, the knee structure decays, and the symptoms worsen. Synovial thickness was observed with moderate to good interobserver reliability. The overall prevalence of synovial thickness with a 2 mm cut-off value correlated well with the Kellgren-Lawrence (KL) classification. The prevalence of synovial hypertrophy with a 2 mm cut-off value, correlated with KL grade 2, was 70.8% and was statistically significant. In this study, the cut-off value in early knee OA (<2 mm) was the considerable thickness of synovial hypertrophy, relieving synovitis after treatment.

This study aimed to compare the differences in pain relief, satisfaction, and synovial thickness between patients with knee OA receiving a TDM plus ketorolac and those receiving a placebo.

METHODS

This study was approved by the participants and hospital ethics committee (RTA IRB No. R220h/62). All participants provided informed consent. The study design was a double-blind, blocked, randomized controlled trial (RCT). A nurse randomly assigned medication envelopes to patients. Sequentially numbered sealed opaque envelopes were used to ensure allocation concealment. Patients aged 40–70 years with primary knee OA KL classification grade I–II were randomized into two groups. Group 1 included 50 participants receiving TDM plus ketorolac, and group 2 comprised 50 participants receiving TDM without medication (placebo group). Patients had to be able to identify a predominantly painful (index) knee, defined as a score of 4 on the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire. Participants with inflammatory and septic arthritis, skin infection, liver and renal insufficiencies, and who underwent intraarticular hyaluronic acid and steroid injections within 6 and 3 months, respectively, were excluded from the study. Baseline radiography on the affected knee was done in standing AP and lateral views.

[Blinded for review] designed solid microneedles using the following parameters: needle height of 600 μm, fabricated in 15 × 15 needle arrays, and individually shaped as half-pyramids for ease of fabrication (Fig. 1). They were approved by the related government authority through a biological evaluation for medical devices.

The patients were arranged in a supine position on the examination table, with the knee flexed but relaxed at 90 degrees (Fig. 2). All patients were applied TDM patch at the midpoint between

the inferior pole patella and tibial tubercle, shifted to the medial about two fingerbreadths at the joint line level. Solid microneedles were applied with an insertion force of about 10 Newton until skin imprints occurred (Fig. 1). Ketorolac 30 mg/ml was dripped onto the pad and covered the imprint. The TDM patch was peeled off after 6 h and reapplied at 1-week intervals.

The patients were followed up at weeks 1, 2, and 4 and completed the VAS, modified WOMAC (Thai version), and ultrasonography to measure synovial thickness in every appointment.

The synovial thickness was measured using ultrasound (GE Healthcare model LOGIQ® e), with midline scanning technique, preset: musculoskeletal-knee in B-mode, and a 12L-RS wide band linear probe (12 MHz). The patients were set in a supine position on the examination table, with the knee kept flexed but relaxed at 30 degrees (Fig. 3). The midline scanning technique was done by vertically applying the linear probe just proximal to the superior pole of the patella.

Vital signs, body weight, and temperature were recorded at each visit. Adverse event (AE) was recorded throughout the study and for 30 days after study termination. AE intensity was rated by the investigator according to the Common Terminology Criteria for Adverse Events.

Statistical analysis

The Statistical Package for the Social Sciences software version 22.0 (SPSS, IBM Crop, Armonk, New York.) was used for analysis. Descriptive parameters were presented as mean ± standard deviation. The paired sample T-test and two-way repeated measurement were used for comparison between groups. Sample size calculation was based on demonstrating the superiority of TDM plus ketorolac to placebo in relation to the primary efficacy endpoint, using a one-sided superiority test with $\alpha = 0.05$ and $\beta = 0.2$. A P-value of <0.05 was considered significant. Adverse events were evaluated according to the chi-square method.

The primary endpoints were the change in VAS, WOMAC score, and synovial thickness in the 4th week.

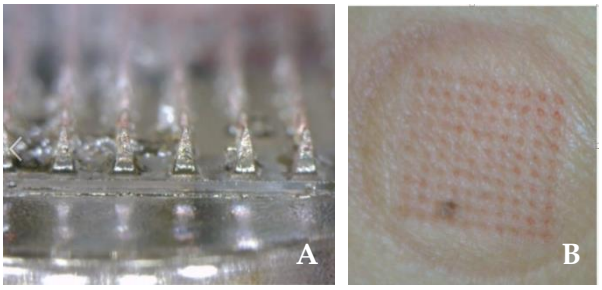

Fig. 1A Side view of solid microneedles and Fig. 1B skin after microneedle application.

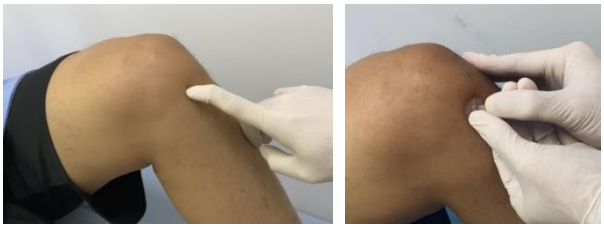

Fig. 2 Transdermal microneedle patch application at the medial joint line of the knee in 90-degree flexion.

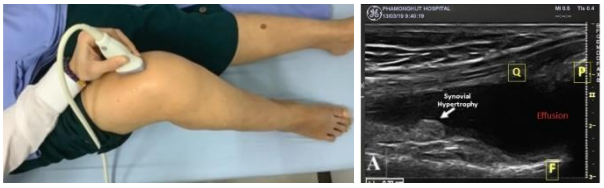

Fig. 3 Ultrasound measurement of synovial thickening. Q, quadriceps tendon; P, patellar bone; F, femoral condyle.

RESULTS

The mean age of patients in the TDM plus ketorolac group was 67.4 ± 7.4 years (40 women and 10 men). In the placebo group, the mean age of patients was 63.9 ± 8.4 years (35 women and 15 men). The prevalence of patients with body mass index >25 kg/m^2 was 56% and 60% in the TDM plus ketorolac and the placebo groups, respectively.

The mean VAS was 4.6 ± 1.4 in the TDM with ketorolac group and 3.8 ± 0.9 in the placebo group. The mean WOMAC score was 9.0 ± 5.3 in the TDM with ketorolac group and 6.6 ± 4.1 in the placebo group. The mean initial synovial thickness was 2.9 ± 1.1 mm in the TDM with ketorolac group and 2.9 ± 0.7 mm in the placebo group. Patient demographics and population baseline characteristics were balanced between groups (Table 1).

Table 1 Demographic data.

Parameter	TDM + ketorolac (N=50)	Placebo (N=50)	P-value
Age	67.4 ± 7.4	63.9 ± 8.4	0.225
Sex Female (N, %)	40 (80%)	35 (70%)	0.344
BMI < 25 (N, %)	22 (44%)	20 (40%)	0.317
BMI > 25 (N, %)	28 (56%)	30 (60%)	0.193
Synovial thickness (mm)	2.9 ± 1.1	2.9 ± 0.7	0.927
VAS (score)	4.6 ± 1.4	3.8 ± 0.9	0.099
WOMAC (score)	9.0	6.6	0.183

BMI, body mass index; VAS, visual analog score; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

Table 2 Comparison of mean synovial thickness, Western Ontario and McMaster Universities Arthritis Index score, and pain visual analog score between the transdermal microneedle patch plus ketorolac and the placebo groups.

Synovial thickness	TDM + ketorolac	Placebo	P-value
Pre-treatment	2.9	2.9	0.927
1st week	2.0	3.0	0.869
2nd week	1.8	2.7	0.014
4th week	1.8	2.6	0.004
WOMAC score	**TDM + ketorolac**	**Placebo**	**P-value**
Pre-treatment	9.0	6.6	0.183
1st week	5.6	6.0	0.713
2nd week	3.9	5.8	0.073
4th week	3.3	5.7	0.013
Pain VAS	**TDM + ketorolac**	**Placebo**	**P-value**
Pre-treatment	4.6	3.8	0.927
1st week	2.7	2.8	0.916
2nd week	1.9	2.6	0.014
4th week	1.4	2.1	0.037

The mean synovial thickness in the TDM plus ketorolac group was 2.9 mm at baseline and 2.0 mm, 1.8 mm, and 1.8 mm at 1st, 2nd, and 4th week, respectively. The mean synovial thickness in the placebo group was 2.9 mm at baseline and 3.0 mm, 2.7 mm, and 2.6 mm in the 1st, 2nd, and 4th weeks, respectively. The mean synovial thickening in the TDM plus ketorolac group showed a significant decrease in the 2nd and 4th weeks (P<0.05) (Table 2).

The mean synovial thickness reduction in the TDM plus ketorolac and placebo groups were 1.1 mm and 0.2 mm in 2nd week and 1.1 mm and 0.3 mm in 4th week, respectively (Fig. 4).

The mean WOMAC score in the TDM plus ketorolac group was 9.0 at baseline and 5.6, 3.9, and 3.3 in the 1st, 2nd, and 4th weeks, respectively. The mean WOMAC score in the placebo group was 6.6 at baseline and 6.0, 5.8, and 5.7 in the 1st, 2nd, and 4th weeks, respectively. The mean WOMAC score reduction in the TDM with ketorolac group significantly decreased in the 4th week (P<0.05) (Table 2). The mean WOMAC score reductions in the TDM plus ketorolac and placebo groups were 5.7 and 0.9 in the 4th week, respectively (Fig. 5).

The mean pain VAS in the TDM plus ketorolac group were 4.6 at baseline and 2.7, 1.9,

and 1.4 in the 1st, 2nd, and 4th weeks, respectively. The mean pain VAS in the placebo group were 3.8 at baseline and 2.8, 2.6, and 2.1 in the 1st, 2nd, and 4th weeks, respectively. The mean pain VAS in the TDM plus ketorolac group significantly decreased in the 2nd and 4th week compared with the placebo group (P<0.05) (Table 2). Mean pain VAS reduction in the TDM plus ketorolac and placebo groups were 2.7 and 1.2 in the 2nd week and 3.2 and 1.7 in the 4th week, respectively (Fig. 6).

During the four weeks, no complications and treatment-related adverse events were reported, such as skin irritation, injection site pain, and superficial skin infection.

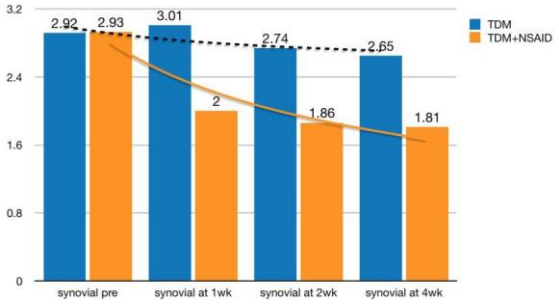

Fig. 4 Mean synovial thickness in TDM plus ketorolac and placebo groups at baseline, 1st, 2nd, and 4th week. TDM, transdermal microneedle patch; TDM+NSAID, transdermal microneedle patch plus nonsteroidal anti-inflammatory drug.

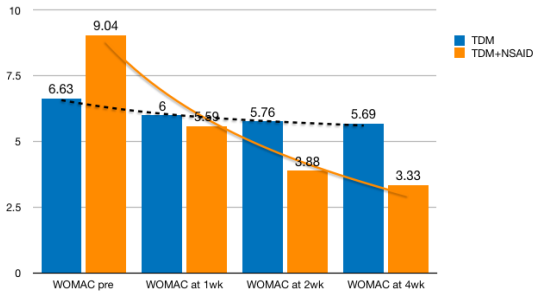

Fig. 5 Mean WOMAC score in TDM plus ketorolac and placebo groups at baseline, 1st, 2nd, and 4th week. WOMAC, Western Ontario and McMaster Universities Arthritis Index; TDM, transdermal microneedle patch; TDM+NSAID, transdermal microneedle patch plus nonsteroidal anti-inflammatory drug.

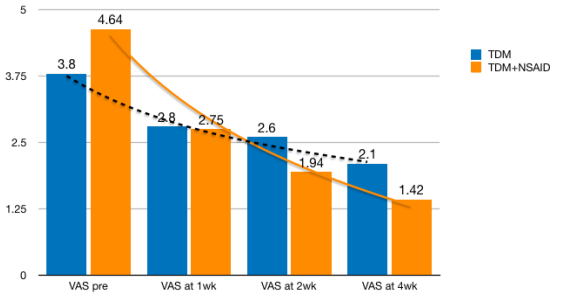

Fig. 6 Mean VAS in TDM plus ketorolac and placebo groups at baseline, 1st, 2nd, and 4th week. VAS; Visual analog score; TDM, transdermal microneedle patch; TDM+NSAID, transdermal microneedle patch plus nonsteroidal anti-inflammatory drug.

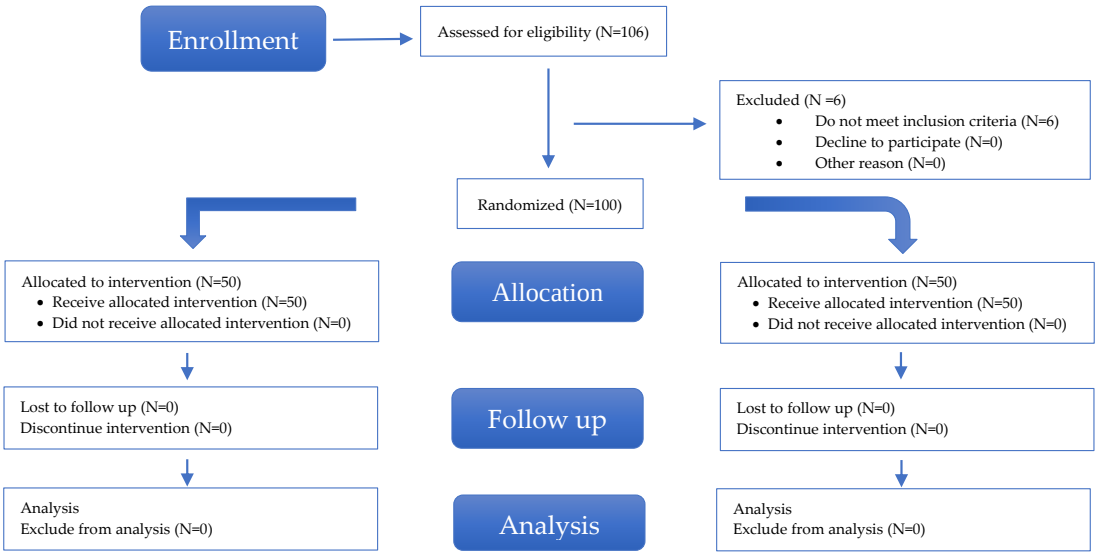

Fig. 7 Consolidated Standards of Reporting Trials 2010 flow diagram.

DISCUSSION

The patients in the TDM plus ketorolac group had a significant clinical improvement from the 2nd week to the last follow-up. No patients were lost to follow-up. The efficacy of TDM plus ketorolac 30 mg was statistically superior to the placebo in the 2nd and 4th week ($P<0.05$) in relieving knee OA pain and synovial thickness. Physical function and joint stiffness improvements throughout the 4-week study were better in the TDM plus ketorolac group than in the placebo group. No serious complications were found in both groups.

The metaanalysis by Lin *et al*. included 13 RCTs comparing the effects of topical NSAIDs with those of placebo or oral NSAIDs in 1983 patients with OA, mainly of the knee or hand, treated for up to 4 weeks[9]. The effects were calculated based on the pain, function, and stiffness. Topical NSAIDs were found to be significantly superior to placebo in terms of pain relief and functional improvement in the first 2 weeks of treatment. The global recognition of the critical role of topical NSAIDs in managing osteoarthritic pain is reflected in the increasing number of international societies and clinical practice guideline committees recommending them as an early treatment option[10-14].

This study showed that TDM plus ketorolac significantly reduced 1.1 mm of mean synovial thickness and led to a 40% reduction in VAS after the 2nd week. The mean decrease in the WOMAC score was 63% from baseline, statistically significant at 4 weeks.

There were some limitations in our study. First, the initial VAS and WOMAC scores were lower in the placebo group than in the TDM plus ketorolac group, although they were not statistically significant. Second, the ultrasonography of synovial thickness used to evaluate the antiinflammatory effect was an indirect method instead of measuring the intraarticular inflammatory cytokines, interleukin (IL)-1 or IL-6, and C-reactive protein. Third, the follow-up period was only 4 weeks. The short follow-up period reflected the efficacy of the single treatment and avoided the influence of other procedures. However, it did not provide information on the possible long-term effects of TDM. Finally, the intraarticular drug level after injection was unknown.

Given the advantages of minimal invasion and easy operation, microneedle therapy represents a promising alternative strategy for treating early knee OA, potentially improving pain and physical function.

CONCLUSIONS

This study showed that TDM plus Ketorolac improved pain, satisfactory score, and inflammation in patients with early knee OA (KL classification I–II). TDM plus ketorolac can be used for noninvasive treatment in knee OA. Further prospective controlled trials are necessary for confirm a longterm efficacy.

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Comparing Clinical Outcomes of Early and Elective Reconstruction in Patients with Anterior Cruciate Ligament Tears

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Purpose: The optimal time of treatment for anterior cruciate ligament tears remains controversial. Two times are early (< 6 weeks) and elective (≥ 6 weeks) reconstruction. This retrospective study tested the hypothesis that clinical outcomes are similar between the two time groups for anterior cruciate ligament reconstruction.

Methods: A total of 61 patients were included in this study. Thirty and 31 patients were in the early and elective reconstruction groups, respectively. The collected patient data included a preoperative and 2-year postoperative range of motion, visual analog scale scores, anterior stability tests, and clinical knee scores.

Results: There were no significant differences in the 2-year postoperative range of motion, visual analog scale scores, or anterior stability tests. The Lysholm and International Knee Documentation Committee knee evaluation form scores were significantly higher in the early reconstruction group than in the elective reconstruction group.

Conclusions: Early anterior cruciate ligament reconstruction is a more effective clinical knee score than elective reconstruction in treating anterior cruciate ligament tears.

Keywords: early reconstruction, elective reconstruction, anterior cruciate ligament reconstruction, anterior cruciate ligament tears

Anterior cruciate ligament tears are the most common sports injuries and the timing of anterior cruciate ligament reconstruction determines the clinical outcomes and complications[1].

The effects of the timing of anterior cruciate ligament reconstruction on postoperative knee function and clinical outcomes remain controversial. Early reconstruction may reduce postoperative complications in patients with anterior cruciate ligament tears[2], whereas elective reconstruction can decrease knee fibrosis and improve clinical results[3]. However, elective reconstruction may be associated with reduced strength and muscle atrophy, which prevents early rehabilitation[4]. Some reviews have suggested early reconstruction benefits patients with anterior cruciate ligament tears. In a prospective randomized clinical trial by Reijman et al.[5], 165 participants with anterior cruciate ligament tears were included; compared with elective reconstruction, early reconstruction was associated with improved movement ability and knee function at the 2-year follow-up. However, no review has considered whether early or elective reconstruction should be performed to

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treat anterior cruciate ligament tears. Therefore, this review aims to synthesize the latest research comparing the outcomes of early and elective reconstruction to help orthopedists and patients make decisions regarding the time of reconstruction.

The purpose of this study was to retrospectively compare the clinical outcomes of early and elective reconstruction and to determine whether reconstruction of anterior cruciate ligament tears improves knee joint stability.

METHODS

Our hospital annually has 20–30 patients with anterior cruciate ligament tears. We conducted a retrospective cohort review of patients diagnosed with anterior cruciate ligament tears between 2007 and 2021 based on physical examination and magnetic resonance imaging (MRI). The sample size was determined according to Bartz's (1999) central limit theorem with 30 patients per group. In the elective reconstruction group, we matched the subject selection for an equal number of patients. The inclusion criteria were as follows: associated meniscal tears, chondral defects, grade I medial collateral ligament injuries, normal alignment, normal contralateral knee, and willingness to participate in the prescribed physical therapy program. The exclusion criteria were as follows: the presence of fractures, associated medial collateral ligament injuries of grades II–III, overall erosion of the cartilage, and revision. Five patients were lost during follow-up, leaving 61 patients enrolled in our study.

Surgical Technique

All surgical procedures were performed by a single surgeon. In all cases, the autologous hamstring tendon was harvested from the ipsilateral knee joint. Both semitendinosus and gracilis tendons were harvested. The graft tendon was fixed to the femoral side using an EndoButton loop. The graft tendon was fixed to the tibia using bioabsorbable interference screws.

All patients with isolated anterior cruciate ligament tears underwent the same postoperative physical therapy program. For the first 3 weeks postoperatively, the patients were limited to partial weight-bearing with a crutch. After 3 months, the patients were able to start jogging. Six months postoperatively, the patients were allowed to participate freely in sports activities. In cases of meniscal or cartilage injury, range of motion (ROM) exercise was restricted for 3 weeks, and weight-bearing was restricted for 6 weeks.

All the tests were performed by the same participant. All preoperative assessments were performed 1 day before surgery. MRI was used when indications for surgery were uncertain. The postoperative assessment was performed 2 years post-surgery. The preoperative and postoperative results were compared. The mean ROM of the knee joints were objectively evaluated. The subjective evaluation consisted of the visual analog scale (VAS), Lysholm, and International Knee Documentation Committee (IKDC) Knee Evaluation Form scores. The anterior tibial-femoral translation was measured using the anterior drawer, Lachman, and pivot-shift tests.

Descriptive statistics were calculated for all data categories. The chi-squared test was used to compare categorical variables. An independent sample Student's t-test was used to compare continuous variables between groups. *P*-values < 0.05 were considered statistically significant.

RESULTS

The 61 patients in the study had an average age of 26.8 years (range 18–50 years). Patients were divided into two groups based on time to operation: the early reconstruction group (< 6 weeks) of 30 patients and elective reconstruction group (≥ 6 weeks) of 31 patients. All patients were followed up for more than 2 years after hospital discharge. The average follow-up was 28.1 months (range, 24–40 months). The demographic data are shown in Table 1.

Preoperatively, the mean ROM was 130.6° ± 16.2° in the early reconstruction group and 131.5° ± 17.1° in the elective reconstruction group. Postoperatively, the ROM values were 143.8° ± 8.7° and 142.9° ± 7.3°, respectively; the difference was not statistically different ($P = 0.662$). There were no cases of limitation of ROM at the final follow-up.

Table 1 Patient demographics.

	Early reconstruction group (n = 30)	Elective reconstruction group (n = 31)	*P*-value
Sex (M/F)	27:3	26:5	0.478
Age (years) (SD)	27.4 (2.8)	26.5 (2.9)	0.222
Injury time to operation (weeks) (SD) (range)	4.1 (1.5) (3.1–5.8)	8.1 (2.8) (6.0–11.8)	< 0.001
Meniscus injury (%)	21 (70%)	23 (74.1%)	0.714
Chondral defect (%)	5 (16.6%)	7 (22.5%)	0.526
Follow-up (months) (SD)	27.9 (3.1)	28.5 (3.2)	0.460

Preoperatively, the VAS scores were 4.6 ± 1.8 in the early reconstruction group and 4.4 ± 1.6 in the elective reconstruction group. Postoperatively, the figures were 1.6 ± 0.5 and 1.7 ± 0.6, respectively, with no significant difference between the groups. Preoperatively, the Lysholm scores were 69.6 ± 8.6 in the early reconstruction group and 68.2 ± 8.5 in the elective reconstruction group. Postoperatively, they were 88.5 ± 6.6 and 84.6 ± 6.4, respectively. The Lysholm scores were significantly higher in the early reconstruction group than in the elective reconstruction group ($P = 0.022$). Finally, preoperatively, the IKDC Subjective Knee Evaluation Form scores were 68.4 ± 7.9 in the early reconstruction group and 67.3 ± 7.8 in the elective reconstruction group. Postoperatively, they were 87.5 ± 6.3 and 83.7 ± 5.8, respectively. The IKDC Subjective Knee Evaluation Form scores were significantly higher in the early reconstruction group than in the elective reconstruction group ($P = 0.017$) (Table 2).

Table 2 Clinical Scores.

	Early reconstruction group (n = 30)	Elective reconstruction group (n = 31)	*P*-value
VAS score			
Preoperative	4.6 ± 1.8	4.4 ± 1.6	0.647
Last follow-up	1.6 ± 0.5	1.7 ± 0.6	0.483
Lysholm score			
Preoperative	69.6 ± 8.6	68.2 ± 8.5	0.525
Last follow-up	88.5 ± 6.6	84.6 ± 6.4	0.022
IKDC subjective knee evaluation form score			
Preoperative	68.4 ± 7.9	67.3 ± 7.8	0.586
Last follow-up	87.5 ± 6.3	83.7 ± 5.8	0.017

Preoperatively, the anterior drawer test was positive for everyone in both groups. Postoperatively, the anterior drawer test was negative in 27 cases (90%) in early reconstruction and 26 cases (83.8%) in elective reconstruction group. There were no cases of 2+ or worse and no significant differences between the groups. Preoperatively, the Lachman test was positive for everyone in both groups. Postoperatively, the Lachman test was negative in 27 cases (90%) in the early reconstruction group and 25 cases (80.6%) in elective reconstruction group. There were no cases of 2+ or worse. There were no significant differences between the groups. Preoperatively, the pivot-shift test was positive for everyone in both groups. Postoperatively, the pivot-shift test was negative in 26 cases (86.6%) and 25 cases (80.6%). There were no cases of 2+ or worse and no significant differences between the groups. (Table 3)

Table 3 Results of Anterior Stability Test.

Test	Early reconstruction group (n = 30)		Elective reconstruction group (n = 31)		*P*-value (Distribution at last follow-up)
	Preoperative	Last follow-up	Preoperative	Last follow-up	
Anterior drawer					0.478
—	0	27	0	26	
1+	5	3	5	5	
2+	19	0	22	0	
3+	6	0	4	0	
Lachman					0.303
—	0	27	0	25	
1+	4	3	6	6	
2+	21	0	21	0	
3+	5	0	4	0	
Pivot shift					0.525
—	0	26	0	25	
1+	5	4	4	6	
2+	20	0	22	0	
3+	5	0	5	0	

There were 30 cases (49.18%) of medial meniscal tears: 14 (46.6%) in the early reconstruction group and 16 (51.6%) in the elective reconstruction group. There were no significant differences between the groups. There were 24 cases (39.3%) of lateral meniscal tears: 11 (36.6%) in the early reconstruction group and 13 (43.3%) in the elective reconstruction group, with no significant differences between the groups. There were 12 cases (19.67%) of cartilage injury: 5 (16.6%) in the early reconstruction group and 7 (22.5%) in the elective reconstruction group. There were no significant differences between the groups. (Table 4). There were no significant differences in the meniscal tear patterns between the groups (Table 5). Patients with meniscal tears underwent meniscectomy or meniscal repair. Cartilage injury of International Cartilage Repair Society grade IV with an area of > 1 cm^2 surrounded by normal cartilage were treated using microfracture, and cases with overall erosion of the cartilage were excluded from the study. Meniscectomy was performed in three (10%) of the 14 patients with medial meniscal tears in the early reconstruction group, and meniscal repair was performed in the remaining 11 (36.6%). Meniscectomy was also performed in two (6.4%) of the 16 patients with medial meniscal tears in the elective reconstruction group, and meniscal repair was performed in the remaining 14 patients (45.1%). There were no significant differences between the groups. Meniscectomy was performed in two (6.6%) of the 11 cases of lateral meniscal tears in the early reconstruction group, and meniscal repair was performed in the remaining nine (30%). Meniscectomy was also performed in three (9.6%) of the 13 cases of lateral meniscal tears in the elective reconstruction group, and meniscal repair was performed in the remaining 10 cases (32.2%). There were no significant differences between the groups. Microfracture was performed in two (6.6%) of the five cases of chondral defects in the early reconstruction group and two (6.4%) of the seven cases of chondral defects in the elective reconstruction group. There were no significant differences between the groups. (Table 6)

There were five cases with limited ROM of the joint postoperatively: two patients in the early reconstruction group and three in the elective reconstruction group. In these five cases, physical therapy was administered postoperatively for 3 months. Two years after surgery, there were no cases with limited ROM or infection.

Table 4 Combined Injuries.

	Early reconstruction group (n = 30)	Elective reconstruction group (n = 31)	*P*-value
Medial meniscus	14 (46.6%)	16 (51.6%)	0.699
Lateral meniscus	11 (36.6%)	13 (43.3%)	0.673
Chondral defect	5 (16.6%)	7 (22.5%)	0.526

Table 5 Patterns of meniscal tears.

	Early reconstruction group (n = 25)	Elective reconstruction group (n = 29)	*P*-value
Vertical	6	8	
Oblique	4	6	
Radial	6	5	0.915
Horizontal	5	7	
Complex	4	3	

Table 6 Treatment of Combined Injuries.

	Early reconstruction group (n = 30)	Elective reconstruction group (n = 31)	*P*-value
Medial meniscus			
Meniscectomy	3 (10%)	2 (6.4%)	0.613
Repair	11 (36.6%)	14 (45.1%)	0.500
Lateral meniscus			
Meniscectomy	2 (6.6%)	3 (9.6%)	0.668
Repair	9 (30%)	10 (32.2%)	0.829
Chondral defect			
Microfracture	2 (6.6%)	2 (6.4%)	0.972
Observation	3 (10%)	5 (16.1%)	0.478

DISCUSSION

The current review found no significant differences in operative time, range of motion, knee stability, Tegner score, IKDC rating scale, or complications between early and elective reconstructions. Early reconstruction was better than elective reconstruction in terms of the Lysholm score at 2 years[6]. These results will help orthopedic surgeons and patients with anterior cruciate ligament tears to decide between early and elective reconstruction. Our review may be used to reduce anxiety in patients awaiting surgery for anterior cruciate ligament tears because the differences in outcomes between the two groups are clear.

The timing of reconstruction is an important factor in determining the postoperative outcomes[6]. Although many reviews have studied the effects of reconstruction timing on patient outcomes, optimal timing remains controversial. Currently, there are no definitions for early or elective reconstruction, and various reviews have used their own time cutoffs to define early and elective reconstructions. For example, in a study by Barenius et al.[7] early reconstruction was defined as an injury-to-operative time of < 5 months, and reconstruction at > 5 months was defined as elective reconstruction. In a study by Fithian et al.[8] early reconstruction was defined as an operation

performed within 3 months. In addition, other studies[5,9,12,13,14] defined injury-to-surgery times ranging from 8 days to 10 weeks. Such a large difference could have led to considerable heterogeneity in the conclusions of this study. Therefore, we redefined early reconstruction as an injury-to-surgery time within 6 weeks to minimize the overlap among the different definitions and make our conclusion more standardized and reliable. This definition has been used in some reports[5,9]. A definition of early reconstruction should be established in the future as it will reduce the noticeable heterogeneity in reporting.

Although many reviews have studied the improved knee function after reconstruction in patients with anterior cruciate ligament tears, the effect of reconstruction timing on functional improvement is unclear. Hunter et al.[10] divided 185 patients into four subgroups based on injury-to-operation and concluded no significant differences in flexion and extension in the subgroups at any time. However, few reviews have attempted to define optimal reconstruction timing. Most reviews have focused on comparing early and elective reconstruction. Some reviews conducted before the 21st century[11] reported that patients with anterior cruciate ligament tears can achieve better joint stability and less movement limitation after elective reconstruction than after early reconstruction. However, other reviews have reported that early reconstruction is better clinical outcomes[12]. These differences may be due to differences in the rehabilitation protocols. Effective modern early rehabilitation after reconstruction plays an important role in improving functional outcomes. Furthermore, we speculate that preoperative physiotherapy in the elective reconstruction group would be useful for improving clinical outcomes. Deabate et al.[13] found that early reconstruction provides similar good functional outcomes as elective reconstruction without increasing the risk of complications, such as range of motion limitation and arthrofibrosis. However, the follow-up periods in the included studies were heterogeneous, and long-term outcomes were lacking. To reduce heterogeneity, the results of the included studies were stratified by follow-up period.

We found no significant differences in postoperative range of motion, visual analog scale score, anterior drawer test, Lachman test, or pivot-shift test. The Lysholm and IKDC knee evaluation form scores were significantly higher in the early reconstruction group than in the elective reconstruction group. This differs from the results of Smith et al.[14] and Deabate et al.[13] These differences may be attributed to the inclusion of different items of interest in the different scoring systems.

The current review found no significant differences between early and elective reconstruction, such as anterior cruciate ligament retear and infection, and the rates of these complications were consistent with those reported in the literature[15]. This suggests that the timing of the operation has little effect on surgical complications.

This study had several limitations. This was a retrospective study; therefore, there was a potential for selection bias. In some cases, detailed information was not available. In these cases, we recorded the total clinical scores rather than the scores for individual factors. Therefore, we may not have been able to draw conclusions based on the results of this study. Finally, the follow-up period of 2 years may be short to conclude long-term outcomes; to improve this study in terms of clinical outcomes and rate of complications, we plan to extend the follow-up duration to 5 years.

CONCLUSIONS

Early anterior cruciate ligament reconstruction is a more effective clinical knee score than elective reconstruction for treating anterior cruciate ligament tears.

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Functional Outcome of Vojta Therapy as A Postoperative Protocol for Surgically Treated Patients with Cerebral Palsy

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Purpose: To evaluate the efficacy of postoperative Vojta therapy in children with cerebral palsy (CP) who have undergone orthopedic surgical interventions for lower limb deformities.
Methods: We conducted a prospective case series on children with ambulatory CP aged 3 to 15, indicated for orthopedic surgical interventions (contracture release and deformity correction) between January 2020 and December 2022. One month following these interventions, all patients were scheduled for Vojta therapy sessions. Ambulation capability was evaluated using video gait analysis, an expanded timed get-up-and-go (ETGUG) test, and a 6-minute walk test (6MWT) at 2, 4, and 6 months postoperatively. A multivariable multilevel linear regression analysis was employed to demonstrate the adjusted effect of Vojta therapy during the postoperative period.
Results: A total of eleven eligible children with CP were included. Of these, seven were boys (63.6%) with a mean age of 6.3 ± 3.1. The majority of patients were classified as gross motor function classification system (GMFCS) level I (45.4%). We observed a significant improvement in ETGUG (-14.1 sec, p = 0.011), 6MWT (6.3 m, p = 0.014), cadence (2.1 step/min, p = 0.033), and stride time (-0.1 sec, p = 0.027) after being adjusted by baseline function, age, and GMFCS level during the follow-up period. Sub-group analyses revealed no significant difference between patients with GMFCS I and those with GMFCS II to III.
Conclusions: This study demonstrated a significant ambulation capability improvement in surgically treated patients with CP who underwent postoperative Vojta therapy.

Keywords: cerebral palsy, orthopedic surgical intervention, Vojta therapy, 6MWT, ETGUG, gait analysis

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Cerebral palsy (CP) is a nonprogressive brain pathology in an immature brain, resulting in developmental musculoskeletal disorders, such as abnormal muscle tone, articular contracture, and movement imbalances.(1) This disease often requires surgical treatment as a multidisciplinary treatment plan that aims to improve the affected child's movement level according to their maximal ambulatory capability.(2) Orthopedic surgical intervention is a multidisciplinary treatment modality

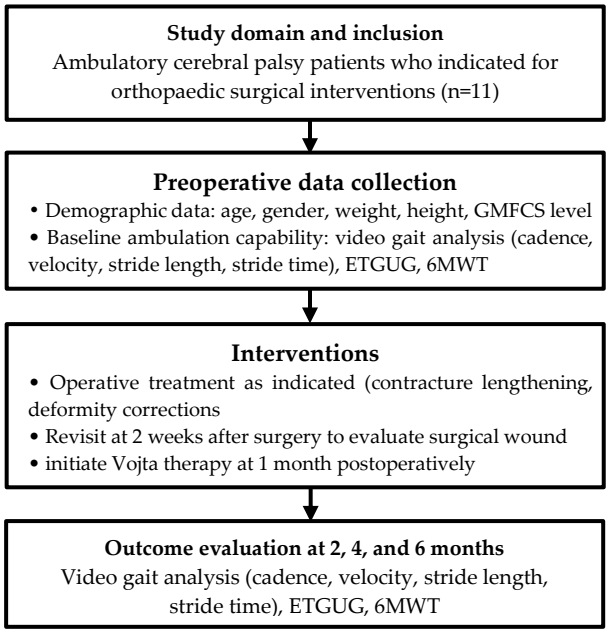
for children with CP that can be categorized into soft-tissue procedure, skeletal reconstruction, and salvage procedure.[3] In addition to operative treatment, a proper physical therapy program with or without orthosis is necessary as an initial conservative treatment or postoperative maintenance procedure.[4]

Vojta therapy is a dynamic neuromuscular physical therapy method that relies on developmental kinesiology and reflex locomotion.[5] Theoretically, the philosophy is based on a thorough kinesiological examination of the newborn. According to Vojta principles, the lack of coordination in the muscles of children with CP results from delayed postural development. Vojta's theory posits that the movement patterns are inherently stored in the central nervous system (CNS) and can be re-called with proper stimulation[6] Consequently, the reflex locomotion pattern of Vojta therapy offers an opportunity to activate dormant motor functions within the CNS. This method can be applied to patients with central nervous and musculoskeletal disorders such as CP, infantile postural asymmetry, and stroke.[7] Several studies have demonstrated the capacity of Vojta therapy to enhance motor function and improve gait patterns.[5,6,8]

However, patients with limb deformities, such as those with CP who have multiple joint contractures, might not fully benefit from Vojta therapy due to bone and joint abnormalities.[5] Their problems consist of structural deformities and movement disorders that must be addressed and require both operative treatment and proper physical therapy. Accordingly, this study aimed to elucidate the functional outcome of post-operative Vojta therapy in surgical patients with CP.

MATERIALS AND METHODS

We conducted a prospective case series of consecutive patients with CP and lower limb deformities between January 2020 and December 2022. The hospital ethics committee approved the study protocol. We included ambulatory patients with CP aged 3–15 y who had lower limb deformities and were indicated for orthopedic surgical procedures. All included patients and their caregivers were allowed to communicate and underwent functional outcome assessments. Patients with severe comorbidities, e.g., uncontrolled seizure, heart disease, severe osteopenia, and bleeding disorder, were excluded (Figure 1).



*ETGUG, Expanded get-up-and-go-test; 6MWT, 6 minutes walk test

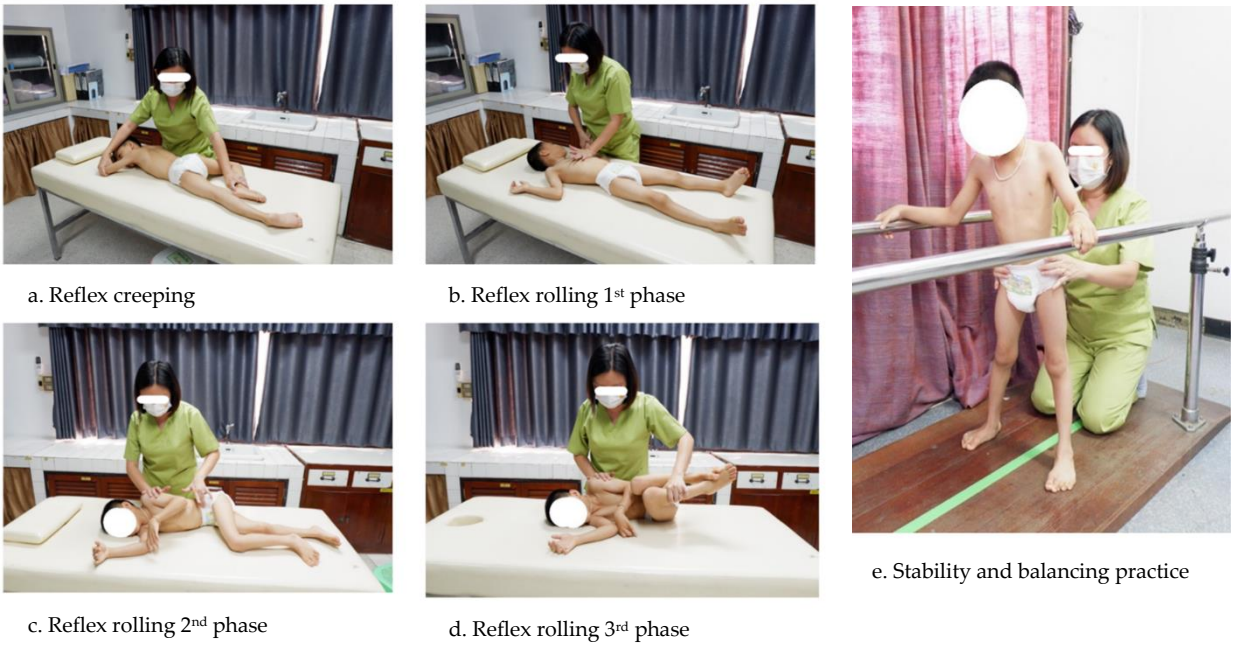
Fig. 1. Study flow diagram of eligible patients.

After obtaining informed consent, patient demographic data including age, sex, diagnosis, gross motor function classification system (GMFCS) level, and specific deformities were collected at the first visit. In addition, preoperative video gait analysis was recorded. All patients underwent single-event multilevel (SEML) surgeries as required (soft-tissue and skeletal reconstruction). The surgical site was reevaluated for surgical wound pain, cast time, and fracture union. Vojta therapy protocol was prescribed for all patients one month after surgery. Follow-up visits were scheduled for treatment outcome assessment at 2, 4, and 6 months postoperatively.

Video gait analysis

Video gait analysis, walking distance cadence, speed, stride length, stride time, expanded timed get-up-and-go test (ETGUG),[9] and six-minute walk test (6MWT)[10] were evaluated at the initial and follow-up visits. In this study, we used a lengthy 20-meter walking path to record patient

motion and measure various parameters. The recording setup included two cameras: a digital camera mounted on a tripod at the final walkway and a mobile camera moving horizontally alongside the patient to capture close-up views of their steps for subsequent re-evaluation. These videos were recorded to ensure measurement accuracy. We used the recorded videos to validate distance, walk duration, and step count. It was noted that some patients, particularly those classified as GMFCS 3, required walking assistance such as a roller walker or cane due to their pathology and pre-surgery deformities, making independent walking a challenge.



a. Reflex creeping

b. Reflex rolling 1st phase

c. Reflex rolling 2nd phase

d. Reflex rolling 3rd phase

e. Stability and balancing practice

Fig. 2. Vojta therapy and standing balance practice protocol. a) Reflex creeping, b) reflex rolling (1st phase), c), reflex rolling (2nd phase), d) reflex rolling (3rd phase), and e) stability and balancing practice**.**

Vojta therapy protocol

Vojta therapy protocol is a 40-minute physical therapy session that involves reflex creeping and reflex rolling stimulation (Figure 2a-e). Specific areas of the patient's skin were targeted for locomotion reflex stimulation. The techniques included reflex creeping (hip maximal flexion and overhanging) and reflex rolling (1st, 2nd, 3rd phase position), tailored to individual patients' deformities.[11] Subsequently, we assessed the patient's motor function and movement readiness.[11] The protocol was repeated twice a day and 1–2 days a week as appropriate. Patients without surgical complications or pain, and those capable of movement, were encouraged to engage in early ambulation.

Statistical analysis

All statistical analyses were performed using STATA 16 (StataCorp LLC, College Station, TX). Statistical significance was set at $p < 0.05$. Data distribution was assessed using the Shapiro-Wilk test. Normally distributed continuous parameters were expressed as mean ± SD while non-normally distributed continuous parameters were presented as median and interquartile range (IQR). Categorical data were represented by counts and percentages. Repeated outcome measurements were analyzed using multivariable multilevel linear regression analysis that considers the correlation between each follow-up information and individual patient baseline (random intercept). In addition, we compared the differences in combined Vojta therapy and surgical interventions between patients with GMFCS I and others.

Table 1 Individual demographic data of each patient.

Patient No.	Age (years)	Weight (kg)	Height (cm)	Sex	Baseline [a]GMFCS	Involvement	Pathology	Surgical procedure	Vojta therapy session per week	Vojta therapy session at 2, 4, and 6 months (hours)
1[b]	3	10	87	Male	3	Quadriplegia	• Hip adductor contracture • Knee flexion contracture • Equinus deformity	• Hip adductor release • Hamstring release • Gastrocnemius recession	4	(30 h/31 h/29 h)
2[b]	8	34	116	Male	3	Hemiplegia	• Motor weakness • Equinovarus deformity	• Tibialis posterior transfer • Percutaneous TAL • Gastrocnemius recession	4	(32 h/30 h/28 h)
3[b]	4	13	91	Female	2	Spastic diplegia	• Knee flexion contracture • Equinus deformity	• Gastrocnemius recession	4	(32 h/29 h/28 h)
4	7	32	127	Male	1	Monoplegia	• Knee flexion contracture • Equinus deformity	• Hamstring release • Gastrocnemius recession	2	(30 h/31 h/29 h)
5	6	15	100	Male	1	Spastic diplegia	• Hip adductor contracture • Knee flexion contracture • Equinus deformity	• Hip adductor tenotomy • Hamstring release • TAL	2	(16 h/14 h/14 h)
6	4	15	109	Female	1	Hemiplegia	• Equinovarus deformity	• Spilt tibialis anterior transfer • Plantar fascia release • Gastrocnemius recession	2	(16 h/14 h/14 h)
7[b]	11	26	138	Male	3	Quadriplegia	• Hip adductor contracture • Knee flexion contracture • Pes planus deformity	• Hip adductor release • Hamstring release • percutaneous TAL • Calcaneocuboid distraction	2	(16 h/15 h/15 h)
8[b]	8	20	105	Female	3	Paraplegia	• Excessive femoral anteversion • Pes planus deformity	• Femoral derotation osteotomy • Lateral calcaneal lengthening	4	(32 h/32 h/32 h)
9[b]	4	14	91	Male	2	Spastic diplegia	• Hip adductor contracture • Knee flexion contracture • Equinus deformity	• Hip adductor release • Hamstring release • Gastrocnemius recession	2	(15 h/14 h/13 h)
10	13	42	141	Female	1	Hemiplegia	• Knee flexion contracture • Equinus deformity	• Percutaneous TAL • Gastrocnemius recession	1	(8 h/6 h/6 h)
11	8	20	126	Male	1	Spastic diplegia	• Equinus deformity	• Gastrocnemius recession	2	(16 h/15 h/14 h)

[a]GMFCS: Gross motor function classification system, [b]Patients using gait aids

RESULTS

Eleven patients with CP were enrolled in the study. The demographic information of each participant is provided in Table 1 and summarized in Table 2. The median age with IQR of the included patients was 6.5(4–8) years. There was no postoperative surgical complication in any patient.

We observed an improvement in 6MWT, ETGUG, cadence, velocity, stride length, and stride time at six months postoperatively. There was a gradual improvement in 6MWT, ETGUG, speed, and cadence at four months and six months following corrective musculoskeletal surgery and postoperative Vojta therapy (Figure 3). After being adjusted by baseline gait parameters, age, and GMFCS level, multivariable multilevel linear regression analysis demonstrated that all outcome measurements significantly improved during the postoperative six months (Table 3).

Table 2 Demographic summary of included patients.

Demographic information	
Age (years) [Median (IQR)]	6.5 (4–8)
Weight (kg) [Median (IQR)]	20 (14–32)
Height (cm) [Median (IQR)]	109 (91–127)
Sex [n (%)]	
Male	7 (63.6)
Female	4 (36.4)
GMFCS[a] level [n (%)]	
I	5 (45.4)
II	2 (18.2)
III	4 (36.4)

Table 3 Differential effects of combined Vojta therapy and orthopedic surgical interventions on outcome measurements at each increasing postoperative month (adjusted for preoperative function, age, and aGMFCS level).

Outcome measurement	**change in outcome (per month)**	**standard error**	**95% confident interval**	***p*-value**
[b]6MWT (m)	6.3	2.6	1.2 – 11.3	0.014
[c]ETGUG (sec)	-14.1	5.5	-24.9 – -3.2	0.011
Cadence (step/min)	2.1	1.0	0.2 – 4.0	0.033
Velocity (m/sec)	0.02	0.007	0.003 – 0.03	0.016
[d]SL (m)	0.006	0.003	0.0003 – 0.01	0.040
[e]ST (sec)	-0.1	0.03	-0.13 – -0.008	0.027

[a]GMFCS: Gross motor function classification system, [b]6MWT: six-minute walk test, [c]ETGUG: expanded timed get-up-and-go test, [d]SL: Stride length, [e]ST: Stride time

Table 4 Outcome difference in the combined effects of Vojta therapy and orthopedic surgical interventions on outcome measurements between children with CP and GMFCS level I, II, or III.

Outcome measurement	**Mean differences**	**standard error**	**95% confident interval**	***p*-value**
[b]6MWT (m)	4.3	3.7	-3 – 11.6	0.249
[c]ETGUG (sec)	-0.8	7.7	-15.9 – 14.4	0.919
Cadence (step/min)	0.5	1.1	-1.7 – 2.6	0.676
Velocity (m/sec)	0.01	0.01	-0.0 – 0.03	0.257
[d]SL (m)	0.004	<0.1	-0.004 – 0.13	0.348
[e]ST (sec)	-0.001	0.03	-0.07 – 0.06	0.961

[a]6MWT: six-minute walk test, [b]ETGUG: expanded timed get-up-and-go test, [c]SL: Stride length, [d]ST: Stride time

Table 5 Outcome difference in the combined effects of Vojta therapy and orthopedic surgical interventions on outcome measurements between the 2nd and 4th months.

Outcome measurement	Mean differences	standard error	95% confident interval	*p*-value
[b]6MWT (m)	22.3	5.1	1.2 – 32.5	0.000
[c]ETGUG (sec)	-49.5	21.1	-90.8 – -8.2	0.019
Cadence (step/min)	5.2	2.6	0.13 – 10.3	0.044
Velocity (m/sec)	0.06	0.015	0.032 – 0.09	0.000
[d]SL (m)	0.032	0.009	0.013 – 0.05	0.001
[e]ST (sec)	-0.12	0.06	-0.24 – -0.01	0.031

[a]6MWT: six-minute walk test, [b]ETGUG: expanded timed get-up-and-go test, [c]SL: Stride length, [d]ST: Stride time

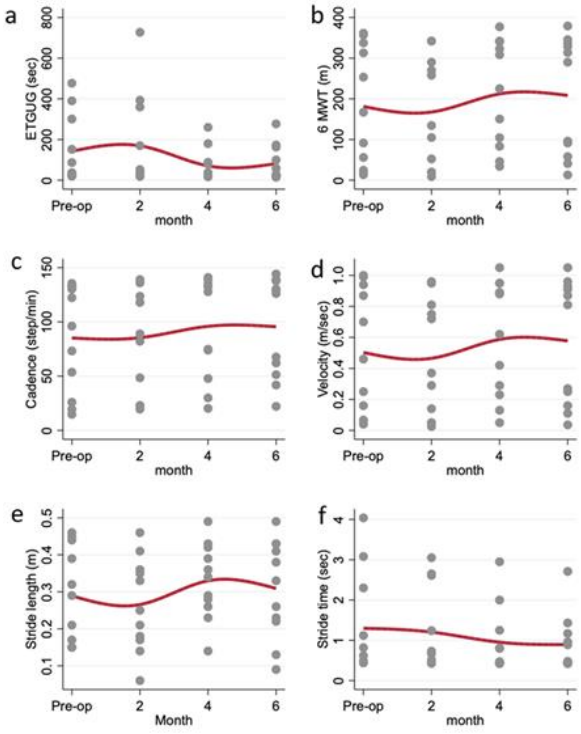


Fig. 3. Mean and standard deviation of ambulation capability in preoperative measurement and during the postoperative period, encompassing a) expanded timed get-up-and-go test (ETGUG), b) six-minute walk test (6MWT), c) cadence, d) velocity, e) stride length, and f) stride time.

In addition, when comparing patients classified as GMFCS level I and higher, no statistically significant differences were found in all interesting outcomes (Table 4). We postulated that the 1st and 2nd months post-surgery represented a period of improvement due to the corrective effects of the surgical procedure. Consequently, we compared the results between the 2nd and 4th months, speculating that the effectiveness of Vojta therapy might manifest during this period. Notably, all parameters showed significant improvement during this period (Table 5).

DISCUSSION

In CP cases, muscle or joint contracture are common deformities that hinder movement and can lead to disuse muscle atrophy. These deformities may progress, resulting in fixed conditions such as hip dislocation.

Surgical musculoskeletal procedures can improve skeletal alignment, joint motion, and joint stability in patients with CP. These improvements effect ambulation capability and physical function, thereby improving the GMFCS level.[12-17] Besides surgical treatment, patients with CP might present with various clinical conditions that require multimodal approaches to enhance their functional capacity, including physiotherapy. Muscle weakness and spasticity in patients with CP contribute to restricted gait function. Physiotherapy aims to improve optimal gait performance by increasing muscle strength. In addition to traditional physical therapy protocol, Vojta therapy aims to restimulate the alternative movement programs embedded in the brains of children with CP. Consequently, the neurophysiological programming from Vojta therapy could improve automatic coordination of the body's position, with

a change in the position of the center of gravity, as is common with each movement.[18] Thus, Vojta therapy is a physical therapy specifically designed for CP, which could improve the functional outcome of this condition.[7]

Various physiotherapy methods highlight the benefits of physical therapy in addressing infantile postural asymmetry. Concordant with previous studies, our findings emphasize the benefits of Vojta therapy in operatively treated children with CP. Several studies have demonstrated that Vojta physiotherapy can significantly improve a child's daily functional motor skills, gait pattern, GMFM-88, and locomotor stage.[5,8,19,20] We believe that applying Vojta principles, which involve repetitive reflex locomotion and reflex creeping to activate the stored "normal movement" in the brain, could contribute to functional recovery and improved movement in patients with CP.

In this study, we observed a significant improvement in all parameters of instrumental gait analysis, including velocity, cadence, stride length, and stride time. It is worth noting that these parameters initially showed a decline in the first two months after surgery. This can be attributed to the fact that most patients started postoperative physiotherapy after immobilization. As a result, prolonged immobilization time often caused disuse muscle atrophy. Therefore, besides correcting deformities, it is essential to incorporate muscle-strengthening exercises and Vojta therapy post-surgery.

Furthermore, patients' functional outcomes, as assessed by the 6MWT and ETGUG, gradually improved during the follow-up period. The findings from the 6MWT and ETGUG revealed that patients with CP who received surgical treatment and underwent Vojta therapy exhibited improved ambulation abilities, as demonstrated by greater distances covered in shorter periods. Additionally, there was a slight but noticeable enhancement in patients' stride length and duration with each gait cycle. Although these improvements may seem minimal, they can become significantly more pronounced when multiplied by the patient's increased cadence and speed. A more extended follow-up period might elucidate the cumulative benefits of Vojta therapy. Moreover, our findings also demonstrate similar benefits between those with mild severity (GMFCS I) and moderate severity (GMFCS II and III). As a result, the combination of operative treatment and Vojta therapy could improve the functional level in both mild and moderate-severity patients with CP.

This study has several strengths. To the best of our knowledge, it is the first prospective study to evaluate the efficacy of postoperative Vojta therapy on gait analysis and functional outcome in surgical patients with CP. The therapy was performed by two Vojta therapy-certified practitioners. Furthermore, the use of comprehensive outcome measures, including video gait analysis, expanded timed get-up-and-go test (ETGUG), and 6-minute walk test (6MWT), offers a thorough evaluation of ambulation capabilities.

However, our study also had some limitations. First, the sample size was small. Second, this study could not determine the efficacy of intervention due to the lack of a control group. Finally, we could not differentiate the effect of Vojta therapy from surgical treatment since only one patient group underwent both interventions. Nevertheless, it is one of the few studies demonstrating the results of Vojta therapy on patients with CP; therefore, our findings remain relevant to the field. Future studies may incorporate a larger sample size and multicenter trials, an appropriate control group with propensity score matching, proper differentiation between intervention effects, and longitudinal follow-up to determine long-term effects.

CONCLUSIONS

While recognizing the aforementioned limitations, this study provides evidence of noteworthy improvements in ambulation capabilities among surgically treated patients with CP after postoperative Vojta therapy. Our findings underscore the potential of Vojta therapy as a valuable alternative to postoperative physical therapy in individuals with CP, enhancing ambulation and overall functional outcomes in this patient population.

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Orthopedic Treatment in the Era of COVID-19: Perspectives from a National Survey in Thailand

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Purpose: The coronavirus disease 2019 (COVID-19) pandemic has affected the management of patients with non-emergent orthopedic conditions, resulting in postponed surgical intervention(s) and changes in hospital services. Specific guidelines have been issued for emergency orthopedic cases; however, no definitive guidelines have been proposed for the management of elective or non-urgent conditions during the pandemic. As such, physicians have been obliged to make decisions based on their judgment. This study aimed to analyze data regarding changes in general orthopedic practices during the pandemic, especially those pertaining to surgery, clinical procedures, follow-up periods, referrals, and protective equipment.

Methods: This study investigated the impact of the COVID-19 pandemic on the management of non-urgent orthopedic conditions by outpatient orthopedists. A questionnaire was developed and shared with nationwide orthopedic social media groups and through e-mails.

Results Of the 200 orthopedic surgeons invited to participate, 129 (64.5%) responded. Results revealed that 65.9% of the surgeons preferred conservative treatment to surgery among patients with the appropriate indications. Additionally, follow-up periods were extended in 69.0% of patients, and 70.5% were prescribed more medication. The N-95 mask and home delivery system for medications were the two most desirable protective equipment and innovations that surgeons needed (79.1% and 69.8% of respondents, respectively).

Conclusions: The COVID-19 pandemic has led to changes in general orthopedic practices in outpatient clinics, such as a preference for more conservative treatment than surgery, extension of appointment periods, prescription of medicine for a longer period, and use of drug delivery to patients' homes.

Keywords: COVID-19, orthopedic, surgery, treatment

The coronavirus disease 2019 (COVID-19) pandemic has had a significant impact on the management of general orthopedic patients, particularly for non-emergency or non-urgent cases, requests for postponement of surgical intervention(s), and switching to nonoperative management. In response, many hospitals have altered their services to comply with public health policies. In 2020, policies regarding insurance and compensation for medical personnel, telemedicine, and patient home care were implemented[1]. Moreover, specific guidelines have been issued for emergency or urgent orthopedic and hand patients requiring surgical treatment[2]. Clough et al. reported a reduc-

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tion in the incidence of postsurgical COVID-19 after elective surgery by limiting the number of visitors and regularly screening doctors, medical personnel, and patients for the disease[3]. Furthermore, Lockey et al. argued that postponing elective surgery was not unethical, and identified urgent and necessary surgeries based on the principles of medical ethics, including autonomy, non-maleficence, beneficence, and justice. Their medical and moral framework classified patients into three groups: those who could postpone surgery without permanent residual pathology; those who could postpone without loss of cost and the operation could be performed later; and those who volunteered to postpone the operation[4]. Despite the pandemic, patients still require elective surgery and prefer admission to avoid crowded outpatient surgical centers. A policy to decrease unnecessary interactions and reduce the number of patients at the hospital has been reported to minimize patient concerns regarding the fear of acquiring COVID-19[5].

This study aimed to determine and report the impact of the COVID-19 pandemic on orthopedic surgeons managing general non-urgent orthopedic conditions in outpatient departments. The survey investigated surgeons' decision-making regarding performing procedures in the office, follow-up appointment period, patient referral decisions, and equipment for outpatient care that can be used routinely in the outpatient department.

METHODS

The survey instrument used in this study was collaboratively developed by all authors and underwent a thorough review process. The questionnaire consisted of 5 sections: decision-making regarding surgery; clinical procedures; follow-up periods; patient referral; and protective measures. The first section examined the decision to perform surgery during the pandemic along with factors that influenced the decision to postpone surgery, which remains a controversial topic[4]. The second section focused on the trend of performing close-contact procedures in the clinic during the peak pandemic period, given the potential risk for COVID-19 transmission in crowded outpatient settings. The third and fourth sections explored physicians' decisions regarding follow-up periods and patient referrals, with some providers opting to extend follow-up periods or refer patients to avoid crowded waiting rooms. The final section of the questionnaire sought to identify the protective measures that the respondents deemed necessary. Participants were instructed to assume that they were dealing with a non-urgent orthopedic condition, such as carpal tunnel syndrome, without progressive neurological deficits or non-progressive painful knee osteoarthritis during the peak of the COVID-19 pandemic period. This study was exempt from ethics committee review. The questionnaire, presented in *Google Docs* format with a link, was disseminated nationwide to orthopedic social media groups and via email to 200 practicing orthopedic surgeons in public health administration, universities, and private practice settings. To prevent duplication, all potential respondents were required to log into their accounts before completing the questionnaire. The questionnaire comprised binary questions to which participants responded anonymously by indicating their preferences. Of the 200 orthopedic surgeons who completed the questionnaire, 129 responded, corresponding to a response rate of 64.5%. Descriptive statistics were used to analyze the data, which are reported as percentages.

RESULTS

In terms of the decision to treat non-urgent orthopedic conditions during the COVID-19 pandemic, results of this study demonstrated that the majority of general orthopedists preferred conservative treatment over surgery among patients with the appropriate indication(s) (65.9%). However, the use of alternative medicines was not a popular option among the respondents. Regarding the type of procedure preferred by surgeons, 58.1% preferred fewer contact procedures to direct patient contact. Among those who spent less time with each patient (44.2%), 69.0% extended the follow-up period, and 70.5% prescribed a longer period of medication.

In terms of equipment and innovation required at the outpatient clinic, the N-95 mask and

home delivery system for medication were the top 2 most desirable items preferred by 79.1% and 69.8%, respectively, of the responding surgeons. In contrast, 47.3% of the respondents preferred telemedicine. The complete survey results are summarized in Table 1.

Table 1 Questionnaire Results.

Questions	Response	
	Yes	No
Indication for treatment		
Prefer conservative	85 (65.9)	44 (34.1)
Prefer alternative medicine	40 (31.0)	89 (69.0)
Procedure		
Prefer local/joint injection	71 (55.0)	58 (45.0)
Avoid close contact	75 (58.1)	54 (41.9)
Less time with the patient each visit	57 (44.2)	72 (55.8)
Follow-up periods		
Longer appointment period	89 (69.0)	40 (31.0)
Add more medicine supply for patients each visit	91 (70.5)	38 (29.5)
Prefer discharge from service	44 (34.1)	85 (65.9)
Refer the patient	35 (27.1)	96 (74.4)
Equipment for outpatient care		
Essential equipment in		
- N95 mask	102 (79.1)	27 (20.9)
- Face shield	65 (50.4)	64 (49.6)
- Personal protective equipment	42 (32.6)	88 (68.2)
- Screening table partition	66 (51.2)	63 (48.8)
Telemedicine	61 (47.3)	68 (52.7)
Drug(s) delivery to home	90 (69.8)	39 (30.2)

Data presented as n (%)

DISCUSSION

During the COVID-19 pandemic, general orthopedic practice in non-emergency settings has been affected by prolonged follow-up periods, increased conservative management, and a shift toward local injections or alternative treatment instead of surgery. To prevent infection, doctors were provided with N95 masks, face shields, personal protective equipment (PPE), and screening table partitions for use in the outpatient departments. Telemedicine and drug delivery to home services were encouraged during follow-up. These changes affected not only the patients, but also the surgeons. In this article, we describe the protocols implemented during the pandemic and how they affected personal practice in general orthopedic outpatient departments.

Results of our study revealed that surgeons preferred non-contact and conservative methods and avoided close contact practice and surgery. Additionally, the clinical follow-up interval was prolonged during the pandemic. While conservative treatment is preferred not only in Thailand but also in other countries, delayed elective surgery, such as increased pain and deformity, has also been reported[6]. The results reported herein indicate that 68.2% of the respondents tended to extend appointment intervals for follow-up, and 70.5% of the respondents preferred to prescribe medicine for a longer time per visit.

In this study, approximately 47.3% of respondents used telemedicine, and 69.8% preferred delivering home medication services. The low rate of telemedicine usage may be due to the

Personal Data Protection Act (PDPA), which was ambiguous during the pandemic in our country. A lack of knowledge and scarce support for telemedicine technology led to more than one-half of the surgeons not preferring to use telemedicine, fearing personal data leakage, especially for patients in remote areas. The study raised concerns about the small number of surgeons preferring telemedicine despite their preference for prolonging conservative treatment and follow-up time. Telemedicine has proven to be effective in terms of clinical care and rehabilitation, and provides high-quality care and cost-effective satisfaction[7–10]. To prepare for unpredictable situations, such as a pandemic, telemedicine should be improved, with education for the public, and implemented in the healthcare system.

Regarding innovative equipment for outpatient care, most surgeons needed N95 type masks, which made it easier for them to contact patients when performing physical examinations than other equipment, such as screening table partitions or face shields. Only one-third of surgeons required PPE while in close contact with patients. Surgeons rarely referred the patient. Thus, appropriate PPE that meets this demand should reach the patient care team in a limited-resource situation. Resources should be prepared and allocated to the appropriate units or users for unpredictable future pandemics.

The current investigation was a questionnaire survey study conducted through emails and public social media groups, with a good response rate (64.5%) to the questionnaire. However, this may be a limitation of this study because some surgeons' responses may have been missing, particularly those who practiced in rural areas where Internet communication is difficult. Additionally, the study could not identify a group of surgeons from different sectors, such as the public health administration, university, and private practice, who may have had different policies in their hospitals. Each hospital's policies can influence the practices of orthopedists during a pandemic. The scarcity of information regarding the hospital sector could limit generalizability. As such, the inclusion of such information for the hospital sector in future studies could provide clearer results and yield more insights.

CONCLUSIONS

In conclusion, the COVID-19 pandemic caused changes in some general orthopedic outpatient practices, such as more conservative treatment with less conservative procedures than surgery, and more extended appointment periods by providing more medicine or using drug delivery services to patients' homes. These practices can be adapted to standard practice after the situation is clarified, in which case an analysis of costs and benefits for patients would yield more specific results. Telemedicine may help surgeons in general practice in the future.

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Hip Capsular Repair Affect on Joint Laxity in Total Hip Arthroplasty

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Purpose: Loss of tissue tension around the hip is a cause of hip dislocation. The shuck test is a simple intraoperative test for soft tissue tension. This study evaluated the soft tissue tightness around the hip joint after capsule repair and compared the joint tension resulting from different capsule repair approaches.

Methods: Fifty-three patients underwent a non-cemented total hip replacement using image-free computer-assisted surgery. The patients were divided into the posterior and the anterolateral approach groups. After the hip was reduce, a computer navigation plan was devise to restore proper leg length. The shuck test was applied to determine the soft tissue tension before and after capsule repair. The leg length was recorded after hip reduction and the shuck test. Data from the computer navigation were collected for analysis.

Results The results of this study showed that after the shuck test, the leg length increased by up to 5.98±1.75 mm. (6.73±1.64 mm. and 5.26±1.56 mm for the posterior and anterolateral approach, respectively). After capsule repaire, the leg was shortened by 4.78±1.31 mm. (5.42±1.10 mm. and 4.15±1.20 mm for posterior and anterolateral approach, respectively). The study found that the leg shortening from the posterior approach was significantly higher than the anterolateral approach (p-value <0.001). There were no hip dislocations in this series.

Conclusions: Hip capsule repair improves the soft tissue tension around the hip joint. This helps reduce the risk of hip dislocation. Hip capsule repair using a posterior approach has a better outcome.

Keywords: Arthroplasty, capsule, Hip dislocation, Computer assisted surgery

A total hip replacement is the most efficient treatment for primary or secondary severe osteoarthritis. It relieves the pain associated with arthritis and allows for faster recovery. Hip replacement patients can work and resume routine activities. However, the post-procedural hip arthroplasty, may result in a Leg Length Discrepancy (LLD)[1-4] and/or Dislocation[5-8].

Despite dislocation occurring less frequently, with an incidence of about 3.5%, regardless of the type of surgery[9], it has the greatest impact on the patient's daily life. Theoretically, anterior capsule surgery loses less muscle mass and stability than posterior capsule surgery but is more complicated, resulting in more operative time and increased intraoperative blood loss[10,11]. However, a comparative study in terms of length of hospital stay, use after surgery, pain, hip implant place-

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ment, and complications, including post-operative hip implant dislocation, found no difference[12,13]. The type of surgery chosen depends on the experience and familiarity of the surgeon and the suitability of each patient.

Of all the factors that affect dislocation, the relaxation of the hip capsule tension or the capsule not being repaired[14] was the most frequently found, followed by malposition from the safe zone of the acetabular cup. LLD, the most frequent post-operative complication, can be prevented by prudent planning or by using an assistant in the form of Computer Assisted-Navigation approaches for total hip arthroplasty (CAS)[15] to ensure accurate and precise surgery[16-18].

The "shuck" test"[19-22] is commonly used to evaluate the tension of the hip capsule intra-operatively as it helps a surgeon reconsider the relaxation of the hip joint by adapting the length of the implant or repairing the hip muscle and capsule to reduce the risk of post-operative dislocation[14]. Computer-assisted hip replacements ensure accurate leg length calculation, leading to proper tissue tension around the hip joint[23]. Two suture methods, soft tissue-to-soft tissue, and soft tissue-to-bone, were used for both the anterior and posterior capsules. Studies have found that posterior capsule soft tissue-to-bone repair results in fewer dislocations than soft tissue-to-soft tissue repair or no repair[24-26], and the same result was found in anterior capsule repair[27]. When the posterior approach was compared to the anterior approach regarding treatment outcomes and post-operative complications, there were no significant differences[12,13]. No studies could conclusively conclude that hip capsule repair affects the tension of the post-operative hip capsule.

This study aimed to evaluate the tension of the closed post-operative hip capsule and to compare the anterior and posterior surgical approaches.

Research question

- To study the change in joint tension after the hip capsule was closed.

- To study the differences in joint tension between the anterolateral and posterolateral approaches after the hip capsule was closed.

MATERIALS AND METHODS

A prospective study of 53 hip arthroplasty patients treated at our hospital between April 2016 and January 2021 was carried out. Of these, 27 were treated with the anterolateral approach, and 26 were treated with the posterolateral approach. Patients with chronic joint inflammation, ligament laxity, and previous hip joint trauma with capsular tears were excluded.

Computer-assisted surgery – Total hip arthroplasty (CAS-THA) software: The hip arthroplasty program

All surgery in this study was aided by Computer Assisted-Navigation, i.e., OrthoPilot THA PRO Ver. 3.2 (B. Braun Aesculap Thailand) (Fig 1).

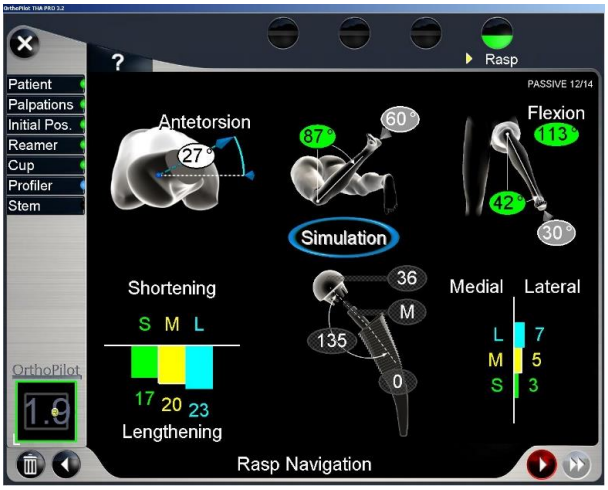

Fig. 1 The hip arthroplasty program: OrthoPilot® Hip Suite THA Pro 3.2.

Total hip arthroplasty surgical procedure

A cementless prosthesis was applied to each patient placed in a semi-lateral decubitus position for the anterolateral approach and in the lateral decubitus position for the posterolateral approach under spinal block. The surgical procedure for total hip arthroplasty (THA) was as follows:

1. Leg length was measured on x-ray images before surgery to ensure minimal post-operative LLD (Fig 2).

2. A skin incision was then made either anterolaterally or posterolaterally.

3. The hip capsule was identified and incised along the length of the femoral neck from the acetabulum to the intertrochanteric line.

4. CAS-THA was performed, and the femoral head was removed from the acetabulum.

5. The acetabulum was assessed, and the hip center was identified and recorded.

6. The femoral neck was cut, the femoral stem size and type (standard or offset) were selected, and the optimal head diameter and neck length could be chosen with the help of the CAS-THA system.

7. The femoral stem and head were then inserted according to the plan devised by the CAS-THA system, and the hip was repositioned. The landmarks that were palpated for referencing were again assessed so that the change in leg length and offset were calculated and displayed, and the data were collected (result 1).

8. The leg was then placed in traction (20 kg) with the shuck test[28]. The leg length, without the capsule closure, was measured with the CAS-THA program. The data were again collected (result 2).

9. Hip capsule closure was performed[29]. The leg was again placed in traction (20 kg) with the shuck test. The leg length was measured with the CAS-THA program. The data were collected (result 3) (Fig 4).

10. Each patient was assessed for instability and range of motion (ROM) [30] before the incision was closed.

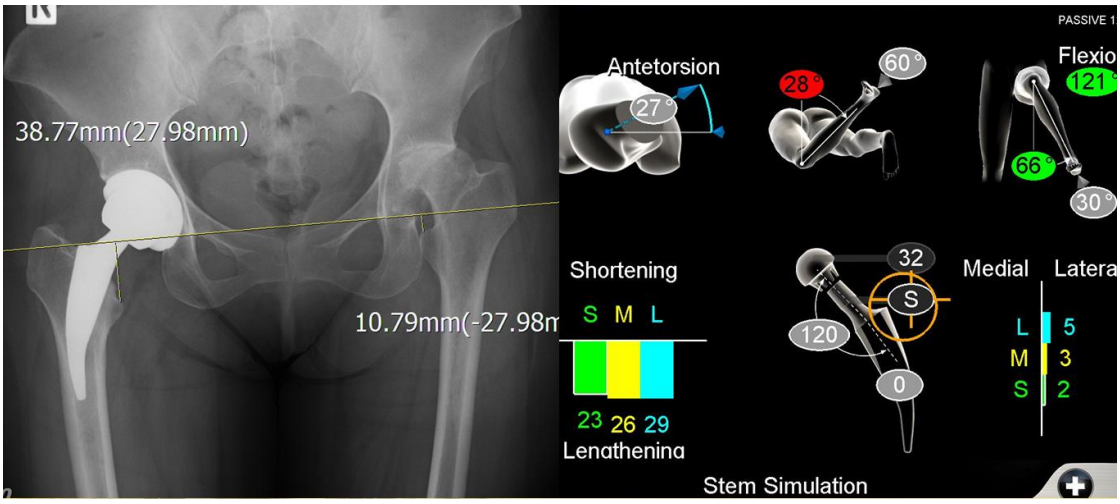

Fig. 2 Assessment of pre-operative leg length (left) was performed with computer-assisted evaluation (right).

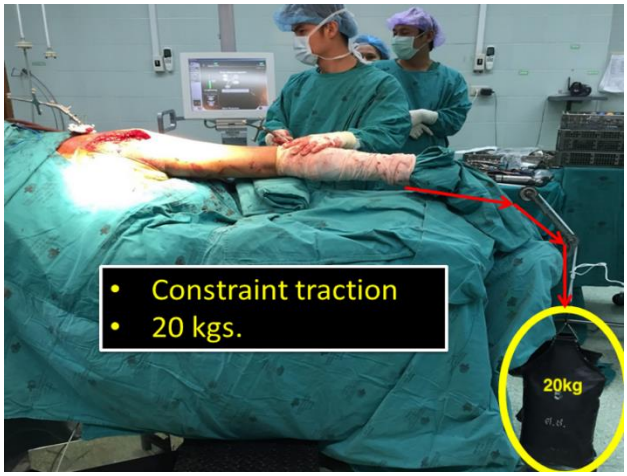

Fig. 3 The leg was stretched under 20 kg traction with the shuck test[28].

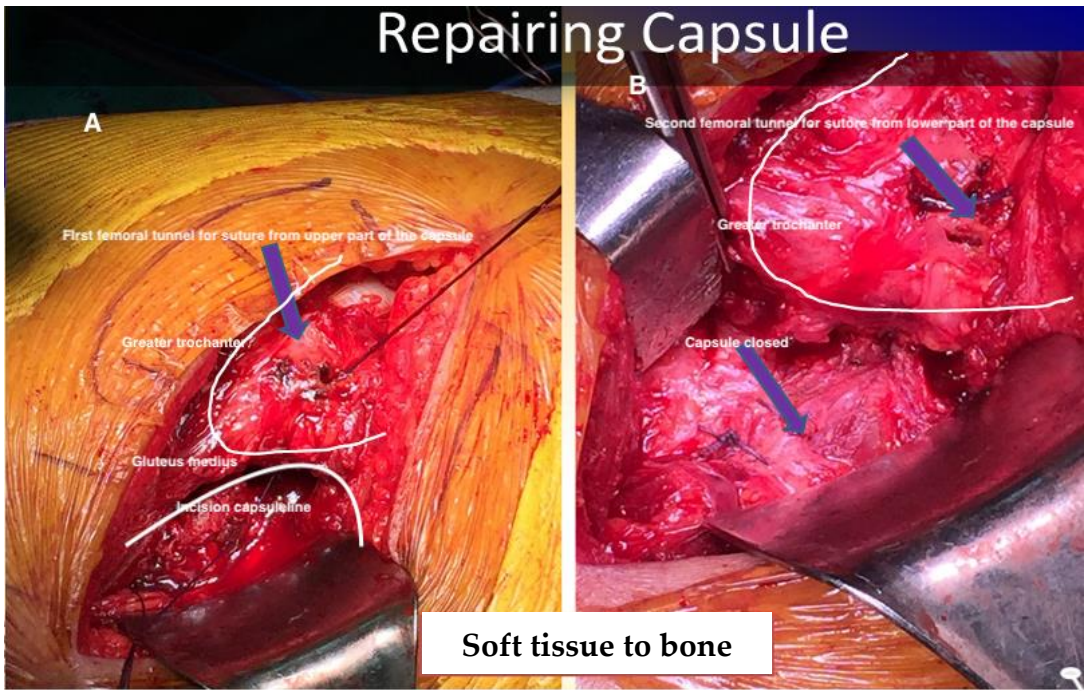

Fig. 4 (A) Suture from the upper part of the hip capsule passing to the femoral tunnel (B) Hip capsule closed with a suture from the lower part of the capsule, passed through the femoral tunnel, and tightened with a suture from the upper part[29].

Statistical analysis

- All analyses were performed using the statistical program SPSS 17.0 (IBM, Armonk, MY, USA). Comparison of repeated measures of leg length (Post-operative, Tele, and at Close of capsule) between the two groups was made using the repeated measures ANOVA.

- A student's t-test was used to compare changes in leg length between the anterior and posterior approaches. A p-value of < 0.05 was set for statistical significance.

RESULTS

Demographics data

The study included 53 patients (68% male) with a mean age of 51.5 (range, 40–59) (table 1). There were no hip dislocations in this cohort.

Leg length in patients undergoing total hip replacement

The mean leg length after reduction was 13.38+5.07 mm, after the shuck test 19.36+5.72 mm, and after capsule closure 14.58+5.66 mm, as illustrated in Table 2.

Table 1 Baseline characteristics (n=53).

Characteristics	Case (n)	Percent
Sex		
Male	35	66.0
Female	18	33.9
Age (year)		
<40	6	11.3
40-49	18	34.0
50-59	18	34.0
60-69	8	15.1
70+	3	5.7
Mean±SD	51.5±10	
Side		
Left	28	52.8
Right	25	47.2

Table 2 Leg-length of post operation, Shuck and Close capsule (n=53).

Length of leg	Mean	SD	Min	Max
Post-operation (mm.)	13.38	5.07	3	23
Shuck (mm.)	19.36	5.72	9	30
Close capsule (mm.)	14.58	5.66	2	26

The change in leg length during the Shuck test before capsule closure was 5.98+1.75 mm, and after capsule closure, it was 4.77+1.31 mm, as illustrated in Table 3.

Comparison of leg length between groups

The outcomes of the shuck test demonstrated that the leg length without capsule closure increased significantly (p<0.001) compared to before it was stretched. The length after capsule closure reduced significantly (p<0.001) compared to the Shuck test without capsule closure (fig 5).

Comparison of changes in leg length between the anterolateral and posterolateral approaches

The posterolateral and anterolateral approaches were compared. The results of the Shuck test (Tele-Post operation) showed that the intra-operative leg length in the posterolateral approach increased significantly (p=0.002). After capsule closure, it decreased significantly (p<0.001) compared to the anterolateral approach.

There was no difference in post-operative leg length after capsule closure between the two approaches (p=0.668), which implies that the loss of tension in the posterolateral approach was recovered after capsule repair, resulting in no difference in post-operative leg length, as illustrated in Table 4.

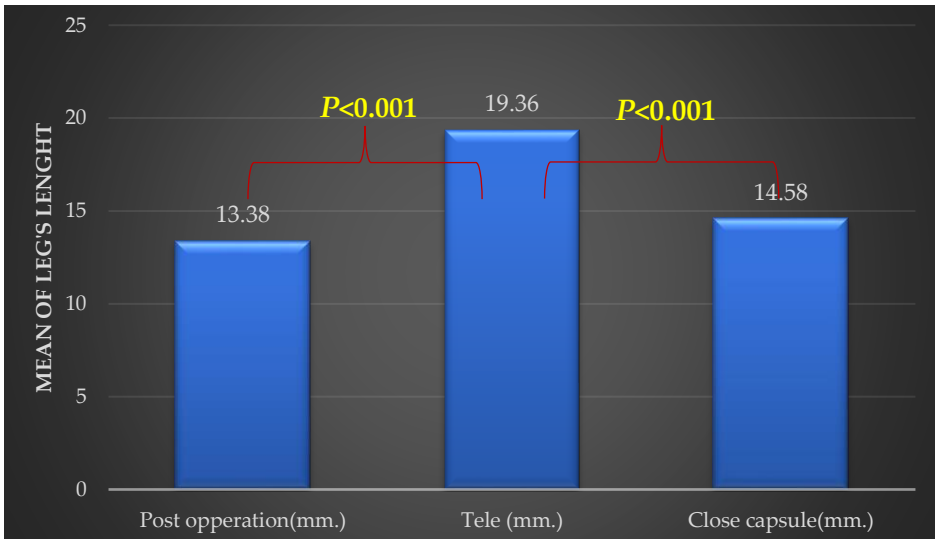

Fig. 5 Leg length Post-operation, during the shuck test, and after capsule closure: P-value from Repeated Measures ANOVA.

Table 3 Change of leg's length.

Change of leg-length	Mean	SD	Min	Max
Shuck-Post operation (mm.)	5.98	1.75	3	11
Shuck-Close capsule	4.78	1.31	2	7

Table 4 Comparison change of leg's length between Anterior and Posterior's operation.

Length of leg	Anterior		Posterior		p-value
	Mean±SD	Min-Max	Mean±SD	Min-Max	
Tele-Post operation (mm.)	5.26±1.56	3-9	6.73±1.64	4-11	0.002*
Tele-Close capsule (mm.)	4.15±1.20	2-7	5.42±1.10	3-7	<0.001*
Close capsule-Post operation (mm.)	1.11±1.45	(-3)-4	1.31±1.85	(-3)-4	0.668

DISCUSSION

In this study, the Shuck test, which involves lower limb traction, showed the relaxation of the hip capsule and an increase in post-operative leg length of 5.98±1.75 mm. The hip capsule became more constrictive after capsule closure, which resulted in a decrease in post-operative leg length of 4.77±1.31 mm on the Shuck test. The post-operative leg length with capsule closure was evaluated by digital software, which provided greater validity than previous studies. The factors associated with a hip dislocation, such as alignment of the acetabulum cup, neck length, caput-collum-diaphyseal (CCD) angle of the stem, offset, and hip tension, were assessed using the CAS-THA system. There was a significant decrease in hip joint stability before capsule repair, with a statistically significant increase in joint after capsule repair.

The closed capsule leg length in the posterolateral approach decreased significantly ($p < 0.001$) compared to the anterolateral approach. There was more relaxation of the hip capsule in patients undergoing the posterolateral approach, as shown by the LLD, which increased by 6.73±1.64 mm in the posterolateral group and by 5.26±1.56 mm in the anterolateral group. This could be treated with capsule closure. This is in keeping with previous studies, which found that soft tissue-to-bone repair in the posterior hip joint capsules resulted in dislocation occurring less often than soft tissue-to-soft tissue repair or non-repair[24-26]. The same result was seen in anterior capsule repair[27]. The current study has shown that capsule closer from both sides resulted in a decrease in post-operative leg length from 5.26±1.56 mm to 1.11±1.45 mm for the anterolateral approach and from 6.73±1.64 mm to 1.31±1.85 mm for the posterolateral approach which implies an increase in tension of about 20% both sides. In a situation where there is an LLD with loss of some tension, repairing the capsule is the one option that can solve this problem without comprising the other factors that are associated with hip dislocation, such as alignment of acetabulum cup, neck length, CCD angle of stem, and offset.

Dislocation caused by the relaxation of hip capsule tension has been found in several previous studies. Capsule closure improving hip capsule tension has been shown in this study to reduce the possibility of dislocation, and a study by Agarwal S showed that the use of computer navigation resulted in a lower revision rate for dislocation in the CAS-THA cohort. The cumulative percentage revision for dislocation at ten years was 0.4 for navigation (or CAS) compared with 0.8% for non-assisted THAs, and in the five component combinations most commonly used with navigation, the rate of all-cause revision was significantly lower when these components were navigated compared with non-navigated, the cumulative percent revision at ten years for these five prostheses combined was 2.4% for the navigated group compared to 4.2% for the non-navigated THA[30].

CONCLUSIONS

- Post-operative closure of the hip capsule results in increased tension on both sides of the hip and can diminish post-operative dislocation[24, 25].

- The change in hip tension after capsule closure was greater in the posterolateral approach group than in the anterolateral approach group.

- Post-operative capsule closure should be applied to every total hip replacement patient, especially when using the posterolateral approach.

- The use of computer-assisted navigation influences the validity and accuracy of this study and differentiates it from previous research.

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Acute Pseudoseptic Arthritis after Intra-Articular Sodium Hyaluronate Injection: A Case Report and Literature Review

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Purpose: This report describes the case of 59-year-old woman with right medial compartment knee osteoarthritis (OA) who experienced an unusual adverse reaction to intra-articular sodium hyaluronate injection.

Methods: The patient received an intra-articular sodium hyaluronate injection for treatment of knee OA. Ten days after injection, she experienced severe pain in her right knee wherein laboratory test results showed inflammatory profiles that could not rule out septic arthritis. Joint lavage was performed, after which the patient was monitored for any changes in her symptoms or laboratory test results.

Results: The patient experienced severe pain in her right knee after intra-articular sodium hyaluronate injection. Additionally, laboratory test results showed inflammatory profiles that could not rule out septic arthritis. One month after joint lavage, the patient's symptoms resolved, and her laboratory test results returned to normal range.

Conclusions: An inflammatory flare could occur as an adverse effect of intra-articular sodium hyaluronate injection, mimicking septic arthritis. Importantly, both physicians and patients should be aware of this potential reaction, particularly, patients should report any unusual symptoms to their healthcare provider.

Keywords: Knee osteoarthritis, sodium hyaluronate injection, pseudoseptic arthritis

A 59-year-old female public officer presented with a history of right knee osteoarthritis (Kellgren-Lawrence grade II). While walking, she felt continuous pain, leading to limited mobility. She received only oral medication, without undergoing any injections. However, upon this presentation, she was injected with 3 ml of 1,4-butanediol diglycidyl ether (BDDE)-crosslinked sodium hyaluronate (Hyruan One®), which was carried out in a sterile setting. Following injection, the patient was able to move freely without knee swelling.

Ten days after the intra-articular injection of Hyruan One®, she presented to the emergency room with significant limping, low-grade fever, and acute monoarthritis of the knee. Due to her intense pain and limited knee range of motion, a knee aspiration was performed to test for any potential joint infections. Fluid analysis showed white blood cell (WBC) count of 197,000 cell/mm3 (neutrophil: 91%). Moreover, blood test results revealed erythrocyte sedimentation rate (ESR), 52

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mm/h; C-reactive protein (CRP), 59 mg/dL; and uric acid, 2.5 mg/dL. Since the WBC count was quite elevated, septic arthritis could not be ruled out. Therefore, the surgeon decided to perform arthrotomy for debridement. The intraoperative findings showed 40 ml of clear yellow fluid without pus. The articular cartilage was intact without significant chondrolysis.

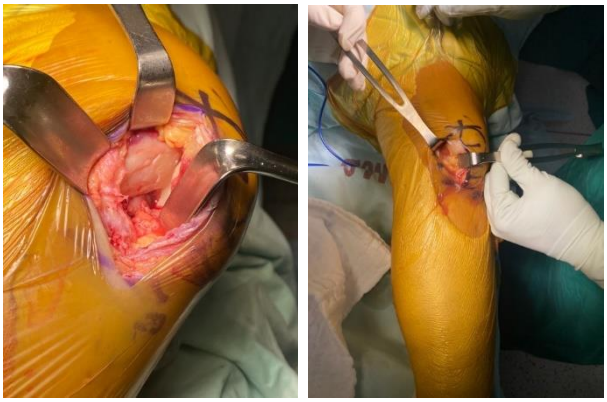

Fig. 1 Intraoperative findings of right knee arthrotomy show neither pus discharge nor significant chondrolysis.

After surgery, the patient received intravenous cefazolin. Thereafter, synovial fluid and tissue analyses indicated negative results of Gram staining and bacterial culture. Furthermore, polymerase chain reaction testing for tuberculosis showed negative results. After obtaining negative culture results and consulting with an infectious disease specialist, we immediately discontinued the antibiotic treatment. The duration of the intravenous antibiotic treatment was less than 10 days. After receiving supportive care, the knee pain and edema quickly subsided within 3 days postoperatively. Only five days after admission, although the ESR level was still elevated at 57 mm/h, the CRP level decreased to 13 mg/dL. The patient was discharged and treated with non-steroidal anti-inflammatory drugs (NSAIDs) and knee rehabilitation. We did not prescribe any oral antibiotics or steroids for home medication. Three weeks following the onset of inflammation, from the initial visit to the follow-up at the outpatient department, the inflammation gradually improved. Additionally, all laboratory test values returned to normal range.

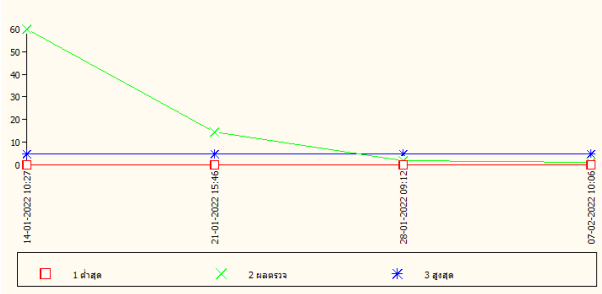

Fig. 2 CRP trend.

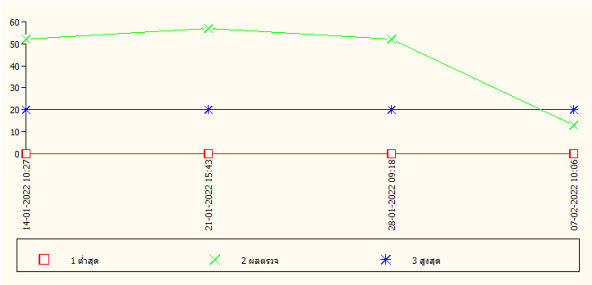

Fig. 2 ESR trend.

DISCUSSION

The use of intra-articular injections of hyaluronic acid (HA) for the treatment of osteoarthritic pain was recommended according to the American College of Rheumatology guidelines for the treatment of osteoarthritis of the knee, published in September 2000. It has been proven that HA injection as viscosupplementation was a remarkably successful non-surgical treatment of knee osteoarthritis. In general, HA injection has been shown to be very safe[1,2]. Compared with other knee joint injections, such as steroid injections, infection was incredibly rare. According to the Korean registry[3], there were approximately 3 in 100,000 cases of infection following HA injection of the knee. However, since HA injections into the knee joints have gained growing popularity nowadays, improving infectious conditions surveillance is mandatory.

Acute local skin reaction has been reported to be the most frequent HA injection side effect that could occur in 11% of knee injections according to Puttick et al. However, there have been reports of patients with acute pseudoseptic arthritis after

HA injection, causing acute inflammation of the knee with swelling, redness, and warmth. Inflammatory markers such as ESR, CRP could elevate in patients with acute pseudoseptic arthritis, which mimicking infection. However, in our case, the findings of the knee joint fluid analysis revealed no infection or crystals. In addition, the symptoms could spontaneously resolve after receiving conservative care with NSAIDs and other anti-inflammatory drugs. The drugs that have been reported to cause such reactions included: Hylan G-F 20 (Synvisc®), which is an elastoviscous high-molecular-weight fluid containing hylan A and hylan B polymers extracted from chicken combs. Hylans are derivatives of hyaluronan (sodium hyaluronate). Hylan G-F 20 is unique in that the hyaluronan is chemically crosslinked. Hyaluronan is a long-chain polymer containing repeating disaccharide units of Na-glucuronate-N-acetylglucosamine, as indicated in another report of sodium hyaluronan (Ostenil®)[4,5].

Table 1 summarizes the clinical and demographic features of cases of acute septic and pseudoseptic arthritis after HA injection reported in the literature. Of note, although several incidences of aseptic arthritis after HA injection have been documented as in the article by Goldberg et al.,[6] none involved Hyruan One®.

Table 1 Review of studies regarding agents used and clinical data.

Study	Patients	Agent	Clinical data
Puttick et al. [1]	6 in 28 knees	hylan	24 h after injection: pain, warmth, and swelling
Leopold et al. [2]	6 in 19 knees	hylan GF-20 (Synvisc)	within 6 to 36 h after injection: acute mono-arthritis
Bernadeau et al. [8]	2 case reports	hylan GF-20 (Synvisc)	2, 4 h after injection: pain, fever with local inflammation signs
Pullman-Mooar et al.	8 cases report	hylan GF-20 (Synvisc)	within 12 to 48 h after injection: local swelling, high fluid WBC count
Idrissi et al. [4]	1 case report	sodium hyaluronan (Ostenil®)	6 days after injection: acute mono-arthritis, major functional impotence, and fever
Ross et al. [5]	1 case report	sodium hyaluronan (Ostenil®)	8 days after injection: acute mono-arthritis, purulent fluid without crystal

Abbreviation: WBC, white blood cell.

The patient's symptoms were strikingly comparable to those in individuals previously identified, including knee pain and edema after injection of synthetic knee joint fluid. The distinction was that the onset in this case was 10 days after injection, which was delayed compared with other cases: typically occurred 3–4 days after injection. The product is 1,4-butanediol diglycidyl ether (BDDE)-crosslinked sodium hyaluronate (Hyruan One®, LG Chem, South Korea), which has never been reported to cause such a reaction. The product is widely used in many areas such as dermal fillers, a vitreous humor substitute, and viscosupplementation for the knee. More than 50 studies including more than 9,000 patients have been conducted since the first BDDE crosslinked HA dermal filler for cosmetic application was introduced in 1996, reporting on the safety and tolerability of this product[7] Based on the information available so far and the patient's follow-up, there is currently no evidence of any infection found. Therefore, the current working diagnosis is acute pseudoseptic arthritis.

The mechanism underlying this condition remains unclear. A study by Bernadeau et al. suggested that this condition may have been caused by an immune sensitization phenomenon during HA degradation. Inflammation was caused by pro-inflammatory cytokines being activated by interaction with CD44 receptors[8]. Another study reported that the leukocyte count in arthroscopic fluid could range between 3,150 and 103,000/ mm3.[9] This could be confused with septic arthritis of the knee, leading to different treatments.

CONCLUSIONS

Based on the findings of this case, it is the first known example of acute pseudoseptic arthritis due to Hyruan One® viscosupplementation. It may be necessary to further study on how such substances could induce inflammatory reactions with their onset being slower compared with similar agents. In addition to encouraging the physicians and personnel involved know about this condition, our report emphasizes how crucial sterile injection is. Physical examination, blood tests, and synovial fluid results that are compatible with this condition should be carefully interpreted to distinguish this condition from acute septic arthritis and give proper treatment. However, patients should always be informed that there might be a risk of infection before receiving an intra-articular injection, despite the extremely low probability.

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