

ORIGINAL ARTICLE

Effects of Pulsed Ultrasound with Low-Intensity on Recovery of Physical Impairments After Total Knee Arthroplasty: A Preliminary Quasi-Experimental Study

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ABSTRACT

Introduction: Total knee arthroplasty (TKA) commonly cause physical impairments, which necessitate physiotherapy post-operatively. Low-intensity pulsed ultrasound is an adjuvant treatment to conventional physiotherapy; however, its effects on TKA recovery require further investigation. The study aimed to ascertain the outcome of adding low-intensity pulsed ultrasound therapy into conventional physiotherapy on recovery from physical impairments after TKA. **Methods:** This assessor-blinded quasi-experimental study was conducted in a tertiary medical centre in Central Malaysia. Patients with TKA due to grade III and IV knee osteoarthritis (Kellgren-Lawrence grading system) were alternately allocated into either an experimental group (n=10) or a control group (n=10). Other than low-intensity pulsed ultrasound as received by the experimental group's participants, the two groups received the same amount and content of conventional physiotherapy. Participants' pain, knee swelling, active knee flexion range, and quadriceps strength were assessed at baseline, week 1 of the intervention, and the 1-week follow-up. The two interventions' effects were analysed using a mixed model ANOVA. **Results:** The pain score and knee swelling decreased ($P<0.05$), while the knee flexion range and quadriceps strength increased significantly ($P<0.001$) after both interventions. The experimental group had a significantly lower pain score [3.07(2.18) at visual analogue scale] and a greater active knee flexion range [80.48(26.42) degrees] compared to the control group [pain score=4.29(1.54); knee flexion=67.00(25.15) degrees] following the interventions. There were no significant interaction effects for all outcomes. **Conclusion:** The combination of low-intensity pulsed ultrasound into a conventional physiotherapy program demonstrated more promising results in pain alleviation and knee motion recovery following TKA.

Keywords: Pulsed ultrasound, Rehabilitation, Total knee arthroplasty

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INTRODUCTION

Projection of the use of total knee arthroplasty (TKA) in countries around the world has been estimated to increase (1-4). In Malaysia, TKA has been performed at several University Hospitals since 1980, and the procedure is readily accepted by the patients (5). Total knee arthroplasty is an option for patients with severe knee osteoarthritis (6) or an alternative intervention after the failure of conservative treatments (7).

Multidisciplinary care plans involving physiotherapy

at the acute phase after TKA could positively impact recovery after surgery and have been recommended for hospitals in Malaysia (8). Pain management is an important physiotherapy intervention at the acute phase that provides positive changes in function and activity after TKA (9). Low-intensity pulsed ultrasound is a treatment modality that can be used in acute management (10). Pulsed ultrasound acts as an inflammatory optimizer, which improves the efficiency of the process of an inflammatory response, thus increasing the effective progress of tissue healing to subsequent phases (10). Evidence shows that pulsed ultrasound with low-intensity is beneficial in relieving pain (11) and promoting cartilage repair in mild to moderate knee osteoarthritic patients (12). However, only three studies (13-15) have been published relating to the effects of ultrasound on recovery following TKA.

This shows that reports of the effect of pulsed ultrasound on the recovery from pain, knee swelling, limited knee range of motion, and quadriceps weakness after TKA are limited.

A single case study found that the pulsed ultrasound with low intensity helped improve knee flexion range of motion following TKA (13). However, in the study, the pulsed ultrasound therapy was started at 2 weeks after TKA, which was conducted in the order of placebo ultrasound therapy (3 days), ultrasound therapy (9 days), and placebo ultrasound therapy (3 days). Another study (14) showed that the addition of ultrasound with other treatments (hot pack, transcutaneous electrical nerve stimulation, and continuous passive movement) after TKA could improve the recovery from pain, wound, and limited range of motion. The researchers compared the ultrasound treatment with microcurrent treatment and concluded that both treatments were effective in improving the recovery following TKA. Pulsed ultrasound with low-intensity in TKA patients was demonstrated in a more recent study (15). The researchers found that the combination of this modality with cryotherapy helped relieve inflammation and improve the range of motion and joint function of post-TKA female patients better than low-intensity pulsed ultrasound or cryotherapy alone. No adverse events were reported in previous studies. All of the three studies assessed the effects of the pulsed ultrasound on the recovery of pain and/or knee range of motion after TKA. Until now, there has been no study that reported the effect of pulsed ultrasound with low-intensity on the recovery from all physical impairments, including knee swelling and quadriceps weakness following TKA.

This study follows the hypothesis that the combination of low-intensity pulsed ultrasound with other interventions could yield better outcomes on recovery following TKA. Therefore, this preliminary study aimed to ascertain the effects of low-intensity pulsed ultrasound in addition to conventional physiotherapy on the recovery from physical impairments (pain, swelling, limited knee range of motion, and quadriceps weakness) in patients following TKA.

MATERIALS AND METHODS

Study design and setting

This assessor-blinded quasi-experimental study was conducted in the Universiti Kebangsaan Malaysia Medical Centre (UKMMC), Kuala Lumpur. Ethical approval was granted by the Research Ethics Committee of the UKMMC (NN-2018-111). This preliminary study was conducted between July 2018 and July 2019 at orthopaedic wards and the physiotherapy unit of the medical centre. The Transparent Reporting of Evaluations with Non-randomized Designs statement was used as a guide in preparing this manuscript.

Participants

Participants with grade III and IV knee osteoarthritis (Kellgren-Lawrence grading system) who were scheduled for TKA surgery, aged between 50 and 80 years and able to walk with or without walking aids, ascend and descend stairs were recruited. Potential participants were excluded if they have known contraindications to pulsed ultrasound (e.g., had malignancy or bleeding at the treated area and deep vein thrombosis). Those who had a limitation in physical function due to the coexisting or a history of diseases (e.g., old lower limb fractures, neurological diseases, and other musculoskeletal problems) and TKA complication(s) (e.g., myocardial infarction, infection, septic arthritis, and neurological deficit) were also excluded. During the TKA procedure, all recruited participants were given intravenous tranexamic acid (1 gram) before the inflation of tourniquet. This was to reduce blood loss after TKA surgery.

Recruitment of the participants

Screening for eligibility, a verbal invitation, and distribution of an information sheet and informed consent form were conducted two days prior to the surgery. At postoperative day two, eligible participants who gave written informed consent were alternately allocated into either an experimental group or a control group. A research assistant who was blinded to the intervention groups performed the allocation process. The first participant was allocated to one of the groups at random using sealed envelopes, and then the next participant was allocated to the other. The process continued in that manner until all participants were allocated. Socio-demographic (age, gender, and race) and anthropometric (weight, height, and body mass index) data of the participants were recorded. The information on the pre-operative knee flexion range, degree of varus/valgus deformity, and Kellgren-Lawrence classification of radiograph for the participants' knee were also recorded. The knee radiograph was graded by the senior consultant orthopaedic surgeon who performs the surgery, which was based on the Kellgren-Lawrence grading system (16).

Interventions

The experimental and control groups received conventional physiotherapy. The experimental group also received low-intensity pulsed ultrasound as an adjunct to conventional physiotherapy. Each group was treated by a different physiotherapist.

Pulsed ultrasound with low-intensity (GYMNA Pulson 330, Netherlands) was administered for treating participants in the experimental group. The pulsed ultrasound application was set for 5 minutes with the use of 3-MHz frequency, a pulse ratio of 1:4 (20% duty cycle), and 0.2-W/cm² intensity. The ultrasound head was applied to the treated area with the use of ultrasound

gel (MyMedic gel) as the conducting medium. The treated area was the medial part of the knee, covering areas of 1 cm from the medial border. The application of low-intensity pulsed ultrasound was started on day 2 after the surgery. This intervention was conducted for 3 weeks (four times for the first-week post-TKA and once a week for a further 2 weeks).

A rehabilitation program for TKA at the medical centre (17) was adopted as the conventional physiotherapy in this study. The conventional physiotherapy was also based on evidence showing that the combination of strengthening, stretching (18), and functional training in an exercise program could produce a better outcome of post-TKA recovery (19-21). Both groups received conventional physiotherapy interventions four times in the first-week post-TKA and once a week for a further 2 weeks.

The participants and the treating physiotherapists were not blinded to the group interventions. All participants were instructed to do home exercises (17) two times per day through the 3-week trial. The participants were provided with an exercise diary to record their home exercise program. Participants were also reminded to do the home exercises once per week via a telephone call. Each participant's progress and the occurrence of potential adverse effects related to the exercises were also monitored, which included cramps and muscle soreness.

Measures

This study assessed the outcomes on physical impairments, namely pain, knee swelling, active range of knee motion, and strength of quadriceps muscles. The participants were assessed at baseline, at week 1 of the intervention, and 1-week follow-up. The baseline assessments of the physical impairments were performed at postoperative day 2 prior to the participants' group allocation. The baseline assessments were conducted once the drainage tubes were removed, and patient-controlled analgesia was omitted. All measurements were conducted and recorded by a trained physiotherapist who was blinded to the information about the participants' group allocation. The baseline measurements of the participants were only made accessible after the post-intervention assessments were completed.

Pain

A 10-cm visual analogue scale (VAS) was used to assess pain. This scale uses the term "no pain" at 0 cm and "unbearable pain" at 10 cm. The VAS is an assessment tool for pain with good validity and reliability for usage among patients with TKA (22).

Knee swelling

Knee swelling was ascertained by measuring knee circumference using a measuring tape. The area at 1 cm from the superior pole of the patella was palpated

and marked. Then, the measurement of the knee circumference at 1 cm from this marked area was recorded. This measuring knee swelling approach has been shown to be reliable in post-TKA patients (23) and used in previous studies (18, 24, 25).

Knee range of motion

A standard long-arm goniometer was used to measure the active knee flexion of the participants. The participants were asked to lie supine on a bed and do knee flexion by actively sliding their heels. The maximal active knee flexion done by the participants was measured. The measurement of active knee range of motion using a goniometer has been shown to have good reliability on acute patients (26) and outpatients after TKA (23).

Quadriceps strength

Quadriceps strength was measured isometrically using a hand-held dynamometer. The participants' position was in supine lying while the untested leg was positioned in hip and knee flexion, and the foot lay flat on the bed. The tested leg was positioned in 30° knee flexion with support by a rolled towel under the knee. The participants were asked to push against the dynamometer force pad placed proximal to the ankle joint. This test was performed two times (a 5-second hold for each trial) with a 30-second rest interval. The higher peak force achieved between the two trials was used, and it was recorded in kilogram force (27). Previous studies (24, 27) have used this method to measure patients' quadriceps strength after TKA.

Data analysis

An intention-to-treat analysis was used whereby all the patients recruited in this study were included in the outcome analysis. Statistical Package for the Social Sciences (SPSS) 20.0 software (IBM Corp., Armonk, NY) was used by the researcher to analyse the data. The sociodemographic and anthropometric data were analysed using descriptive statistics. All of the information and the baseline measures of all outcomes were compared between the two groups. An independent t-test was used for continuous data, and Fisher's exact test was used for the categorical data. Besides, the Mann-Whitney U test was used for data that were not normally distributed. A mixed model analysis of variance was performed to test this preliminary study's main objective, which is the effects of the interventions in terms of time, group, and interactions. A significance level of less than 0.05 was set for all statistical tests. Interpretation of the effect sizes of the outcomes for time, group, and interactions was based on Cohen's *f*, which were described as small ($f = 0.1$), medium ($f = 0.25$), and large ($f = 0.4$) effect sizes.

RESULTS

Twenty patients with TKA agreed to participate and were allocated into either experimental ($n=10$) or

control groups (n=10) (Figure 1). The characteristics of the participants have been described in Table I. All participants have varus deformity. The participants' characteristics, pre-operative knee flexion range, degree of varus deformity, Kellgren-Lawrence classification of radiograph, and baseline measures of pain, swelling, active knee flexion, and quadriceps strength were comparable between the groups (Table I).

Effects of the interventions on recovery from pain

A significant time ($F_{(2,36)}=3.93, P<0.05$) (Table II) and

Table II: Changes in pain, knee swelling, active knee flexion and quadriceps strength of participants (N=20) from baseline to week 1 of interventions and 1-week follow-up

Outcome	Mean (SD)			P-value	Effect size (f)
	Baseline	Week 1	1-week follow-up		
Pain	4.25 (2.36)	3.95 (1.70)	2.84 (1.56)	0.029*	0.47
Knee swelling (cm)	45.73 (5.38)	46.35 (6.35)	44.99 (5.93)	0.029*	0.47
Active knee flexion (°)	47.90 (20.36)	77.20 (19.57)	96.12 (11.59)	0.000**	1.74
Quadriceps strength (kgf)	3.40 (1.32)	4.90 (2.07)	7.01 (2.65)	0.000**	1.10

f = Cohen's f
 *Significant difference within-group ($P<0.05$).
 ** Significant difference within-group ($P<0.001$).

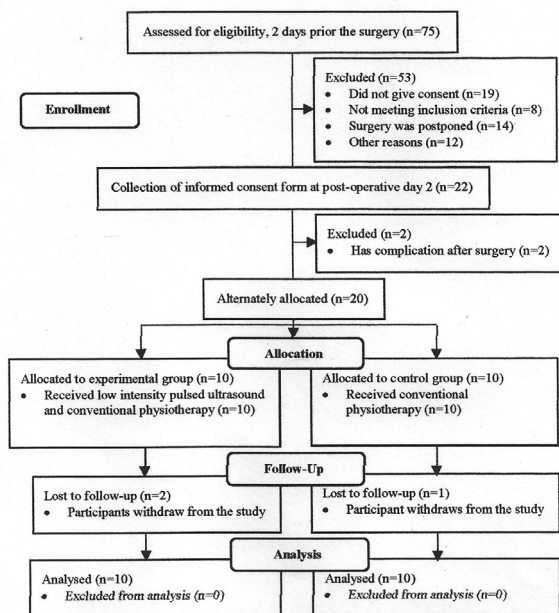


Figure 1: Flow chart of the study

group ($F_{(1,18)}=5.16, P<0.05$) (Table III) effects were shown for pain intensity. The effect sizes for time and group effects were both large ($f>0.4$). The pain score of the participants in the experimental group was significantly lower [mean(SD)=3.07(2.18)] than in the control group [mean(SD)=4.29(1.54)]. However, no significant time-group interaction ($F_{(2,36)}=0.71, P>0.05$) existed (Table IV).

Effects of the interventions on recovery from knee swelling

Changes in knee swelling showed a significant effect of time ($F_{(2,36)}=3.90, P<0.05$), with a large effect size ($f=0.47$) (Table II). However, no significant group ($F_{(1,18)}=0.01, P>0.05$) (Table III) and interaction effects ($F_{(2,36)}=0.11, P>0.05$) (Table IV) were reported.

Table I: Comparison participants' characteristics and baseline outcome measures between experimental group (n=10) and control group (n=10)

Variable	Median (IQR) ^a / Frequency (%) ^b / Mean (SD) ^c		U	t	df	P value _{d, e, f}
	Experimental group (n=10)	Control group (n=10)				
Age (year) ^a	67.00 (19)	68.00 (6)	48.50			0.912 ^d
Gender ^b						0.628 ^e
Female	8 (80)	6 (60)				
Male	2 (20)	4 (40)				
Race ^b						0.582 ^e
Malay	9 (90)	7 (70)				
Others	1 (10)	3 (30)				
Kellgren-Lawrence classification of radiograph ^b						0.474 ^e
Grade III	0 (0)	2 (20)				
Grade IV	10 (100)	8 (80)				
Body weight (kg) ^c	75.81 (12.02)	73.67 (18.72)		0.304	18	0.764 ^f
Height (m) ^c	1.56 (0.08)	1.58 (0.10)		- 0.650	18	0.524 ^f
Body mass index (kg/m ²) ^c	31.91 (6.73)	29.45 (7.26)		0.786	18	0.442 ^f
Pre-operative knee flexion range ^c	102 (11.35)	99 (5.68)		0.747	13.235	0.468 ^f
Degree of varus deformity ^c	7.50 (2.59)	5.40 (2.40)		1.88	18	0.076 ^f
Pain ^c	4.00 (2.94)	4.50 (1.72)		- 0.464	18	0.648 ^f
Knee swelling (cm) ^c	45.70 (3.37)	45.75 (7.05)		- 0.020	18	0.984 ^f
Active knee flexion ^c	53.00 (17.19)	42.80 (22.84)		1.128	18	0.274 ^f
Quadriceps strength (kgf) ^c	3.56 (1.22)	3.24 (1.47)		0.530	18	0.603 ^f

^aMedian (IQR);^bFrequency (%);^c Mean (SD);^d Mann-Whitney U test; ^e Fisher's exact test; ^f Independent t-test

Table III: Comparisons of pain, knee swelling, active knee flexion and quadriceps strength between experimental group (n=10) and control group (n=10)

Outcome	Mean (SD)		P-value	Effect size (f)
	Experimental group	Control group		
Pain	3.07 (2.18)	4.29 (1.54)	0.036*	0.54
Knee swelling (cm)	45.56 (4.30)	45.82 (7.11)	0.922	0.03
Active knee flexion (°)	80.48 (26.42)	67.00 (25.15)	0.017*	0.62
Quadriceps strength (kgf)	5.60 (2.52)	4.60 (2.50)	0.151	0.35

f = Cohen's f

*Significant difference between-group ($P < 0.05$).

Effects on recovery of knee flexion following interventions

Active knee flexion showed a significant time effect ($F_{(2,36)}=54.30$, $P < 0.001$) after both interventions (Table II). A significant effect of group was shown ($F_{(1,18)}=6.94$, $P < 0.05$) in which the active knee flexion range in the experimental group was significantly greater [mean(SD)=80.48(26.42)] than the control group [mean(SD)=67.00(25.15)]. The effect sizes for time ($f=1.74$) and group effects ($f=0.62$) were both large. However, a significant interaction between time and group could not be found ($F_{(2,36)}=0.20$, $P > 0.05$) (Table IV).

Effects of the interventions on recovery from quadriceps weakness

A significant main effect for time is shown for quadriceps strength following the interventions ($F_{(2,36)}=21.69$, $P < 0.001$), with a large effect size of $f=1.10$ (Table II). However, no significant group ($F_{(1,18)}=2.25$, $P > 0.05$) (Table III) and interactions effect ($F_{(2,36)}=0.66$, $P > 0.05$) (Table IV) was observed.

DISCUSSION

This preliminary study found that a combination of low-intensity pulsed ultrasound and conventional physiotherapy at the acute short-term postoperative recovery phase produces more positive outcomes on the recovery from physical impairments following TKA. The results indicate that the combined intervention

is more promising than conventional physiotherapy alone in post-TKA pain alleviation and recovery of active knee flexion range. In this study, the two groups were comparable in characteristics. They received the same amount and content of physiotherapy with the exception of the low-intensity pulsed ultrasound, which was provided only to the experimental group. Therefore, the difference in performance between the two groups post-therapy can be regarded as due to the effect of the low-intensity pulsed ultrasound.

The use of pulsed ultrasound with low-intensity in relieving pain was shown in a previous study, but it was conducted among patients with knee osteoarthritis who undergo conservative treatment (11). To date, the effects of pulsed ultrasound on recovery following TKA have been reported in only three studies (13-15), and not all of their results were parallel with ours. A single case study by Shomoto, Okazaki and Kanai (13) showed that the use of low-intensity pulsed ultrasound at two weeks after TKA helps improve knee flexion range of motion but did not significantly help in pain reduction. These present study findings showed that the combination of low-intensity pulsed ultrasound and conventional physiotherapy helped improve short-term postoperative recovery of knee flexion range and relieved pain. These findings are consistent with those of Cho et al. (14), which indicated that ultrasound improved pain reduction and range of motion after TKA. Another previous study examined the effect of using pulsed ultrasound at a low-intensity and cryotherapy on post-TKA recovery and reported that inflammation was reduced, range of motion was increased, and joint function was improved significantly after the intervention (15). The reduction of inflammation might result from the intervention used in the present study, which has helped reduce pain among the patients. This observation is in line with Garrett and Walters (28), who stated that acute postoperative pain after TKA surgery is caused by surgical trauma and inflammatory response.

A study by Cho et al. (14) found a significant time-group interaction for the recovery from pain and knee flexion range limitation. Those results differ from the present study, where no interaction effect was found. The study by Cho et al. (14) used ultrasound with high-intensity, which might explain the differences in the findings. The present study results support the finding of the study by

Table IV: Changes in pain, knee swelling, active knee flexion and quadriceps strength from baseline to week 1 of interventions and 1-week follow-up between experimental group (n=10) and control group (n=10)

Outcome	Mean (SD)		Mean (SD)		Mean (SD)		P-value	Effect size (f)
	Baseline		Week 1		1-week follow-up			
	Experimental (n=10)	Control (n=10)	Experimental (n=10)	Control (n=10)	Experimental (n=10)	Control (n=10)		
Pain	4.00 (2.94)	4.50 (1.72)	3.20 (1.48)	4.70 (1.64)	2.00 (1.49)	3.67 (1.16)	0.500	0.20
Knee swelling (cm)	45.70 (3.37)	45.75 (7.05)	46.10 (4.98)	46.60 (7.75)	44.88 (4.75)	45.11 (7.19)	0.898	0.08
Active knee flexion (°)	53.00 (17.19)	42.80 (22.84)	84.30 (19.56)	70.10 (17.70)	104.13 (9.74)	88.11 (6.81)	0.757	0.11
Quadriceps strength (kgf)	3.56 (1.22)	3.24 (1.47)	5.68 (2.18)	4.11 (1.71)	7.56 (2.29)	6.46 (2.98)	0.473	0.19

f = Cohen's f

Kang et al. (15) in which no time-group interaction was found.

This study showed that knee swelling decreased, and quadriceps strength increased significantly after both interventions. However, this study was unable to demonstrate a significant group difference and a significant time-group interaction for knee swelling and quadriceps strength. This finding may be due to the small sample size, which has less impact on the result. None of the previous studies determined the effects of pulsed ultrasound with low-intensity on these outcomes among patients with TKA; as such, a comparison of these results could not be made. Knee swelling and quadriceps weakness are considered important physical impairments that should be evaluated at an early stage after TKA. It is because evidence has shown that postoperative knee swelling leads to considerable quadriceps weakness and causes decreased functional outcomes in patients after TKA (24, 29).

This study's strength is that we determined the effects of low-intensity pulsed ultrasound on all the important post-TKA physical impairments: pain, knee swelling, knee range of motion limitation, and quadriceps weakness. Literature has pointed out that these are the main post-TKA consequences that affect the recovery of post-TKA functional ability (24, 29, 30). This study results suggest a pulsed ultrasound with low-intensity as a possible adjunct modality to acute physiotherapy to improve the outcomes at the early stage and enhance recovery following TKA.

The main limitation of this study was the difficulty in performing randomisation of subjects because of the absence of a sampling pool; hence, selecting a quasi-experiment and not randomised controlled trial as the study design. This has lowered the quality of the evidence yielded from the study. Further, being a preliminary study with a small sample size of 20, the findings of this study are subjected to external validity issues and need to be cautiously interpreted. Recruitment of at least 32 participants to obtain a study power of 80% for the actual or original study could overcome this validity issue.

CONCLUSION

A combination of low-intensity pulsed ultrasound with conventional physiotherapy seems to provide better progression on the short-term postoperative recovery from pain and knee flexion range following TKA. Further studies with a larger sample size are warranted to confirm these findings.

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