# Effectiveness of Neuromuscular Electrical Stimulation for Enhanced Recovery After Total Hip Replacement Surgery: A Randomized Controlled Trial

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#### Abstract

**Background:** The aim of this study was to investigate the feasibility of using a novel neuromuscular electrical stimulation (NMES) device for enhanced recovery after total hip replacement surgery. **Methods:** Sixty patients undergoing total hip replacement for osteoarthritis of the hip were randomized and divided into 2 groups: I group received postoperative treatment with the NMES device, and the other group did not receive NMES. The primary outcome measures were postoperative pain, lower limb swelling, and length of stay (LOS) postsurgery. Secondary outcomes included wound drainage at 24 hours and acceptability by the intervention of the device. **Results:** Data from 60 participants were analyzed (NMES (n = 30), control group (n = 30)). Patients in the NMES group demonstrated a general trend of beneficial postoperative pain, calf swelling, and average length of stay from postoperative to discharge. However, wound drainage largely remained static for both groups. The overall comfort rate of the device was 93.3%. **Conclusions:** The results of this study suggest that the geko<sup>TM</sup> NMES device is partly useful for enhanced recovery after total hip replacement surgery. In addition, the device should be considered tolerable and safe. A larger study is required with this device in the future to determine its effectiveness on compelling data.

#### **Keywords**

neuromuscular electrical stimulation, total hip replacement, rehabilitation

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#### Introduction

Total hip replacement (THR) is a frequently performed and highly successful surgical intervention for treating osteoarthritis of the hip.<sup>1</sup> The increasing numbers of patients undergoing THR, combined with the rapidly growing progress of surgical techniques and evidence-based treatment options, have put considerable pressure on surgeons and other health care professionals to produce excellent postoperative recovery, leading to lower mortality and morbidity as well as high patient satisfaction.<sup>2,3</sup> The current economic climate and the restricted health care budgets further necessitate a shorter hospital stay and lower costs on the health care system.<sup>4,5</sup> Clinical pathways and protocols introduced to achieve these goals include a variety of peri-operative interventions to fulfill patient expectations and achieve the desired out-comes.<sup>6</sup> However, some postoperative issues remain, and the main clinical reasons for delayed discharge following THR

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are pain, swelling and general weakness.<sup>7</sup> Immediate postoperative decreased muscle function or weakness is partly due to the onset of postoperative pain and swelling, which is widely accepted to increase the risk for complications.<sup>8</sup> Efforts to enhance recovery and reduce the length of stay after THR should focus on postoperative pain, swelling, and rapid recovery of muscle function.

Early physical therapy intervention yielded faster achievement of short-term functional outcomes. Neuromuscular electrical stimulation (NMES) is a promising treatment method to counteract muscle impairment in hip osteoarthritis and improve function to expedite recovery from joint replacement surgery.<sup>9</sup> Several studies have demonstrated that NMES, which stimulates nerves to activate the muscle, significantly improves blood flow in the veins.<sup>10-13</sup> Nonetheless, its application in clinical orthopedic practice is still limited, partly due to concerns regarding wound drainage and patient acceptability.<sup>13,14,9</sup>

#### Materials and Methods

In this study, we primarily investigated the use of NMES to reduce postoperative pain management, reduce limb swelling, and average hospital length of stay (LOS) postsurgery. The secondary investigation is to assess the NMES device, to test the effects of the wound drainage at 24 hours and acceptability by the intervention of the device.

Ethical standards: This was a single-center, randomized, open-label study assessing the feasibility of using an NMES device (geko<sup>™</sup>, FirstKind Limited, Buckinghamshire, UK) for enhanced recovery after THR. This study was approved by the Institutional Review Boards of our hospital and conducted according to the principles described in the Declaration of Helsinki. All participants or their family members signed the informed consent form.

#### Subject Selection

In the present study, 65 patients scheduled for elective THR were recruited. Following the implementation of the detailed inclusion and exclusion criteria (Table 1), the study included 60 patients who underwent THR, including the NMES group and a control group. The NMES group comprised 12 males and 18 females with a mean age of  $63.7 \pm 10.23$  years and a mean body mass index (BMI) of  $24.85 \pm 2.67$  kg/m<sup>2</sup>, and the control group comprised 9 males and 21 females with a mean age of  $58.4 \pm 12.97$  years and a mean BMI of  $25.46 \pm 3.64$  kg/m<sup>2</sup> (Table 2). They had undergone elective THR operations performed by the same senior surgeon at our

#### Table I. Details of Inclusion and Exclusion Criteria.

Inclusion criteria

- I. Men and women over the age of 35 and younger than 75 years
- 2. Free of significant abnormalfindings as determined by medical history
- 3. Primary cementless implant with THR
- 4. Central neuraxial anesthesia
- 5. Able to understand the patient information sheet and willing to sign the written informed consent form
- 6. Able and willing to follow the protocol requirements

Exclusion criteria

- I. Hip revision surgery or cemented implant with THR
- 2. General anesthesia
- 3. History or signs of previous deep vein thrombosis or asymptomatic DVT.
- 4. Peripheral arterial disease, varicose veins or lower limb ulceration
- 5. Recent surgery within the last 3 months (such as abdominal, ynaecological, trauma to lower limb)
- 6. Chronic obesity (BMI index >40 kg/m2)

7. Pregnancy

- 8. Significant history of following diseases
- 9. Cardiovascular: Recent MI (<6 months), or moderate to severe CCF, uncontrolled AF, with a pacemaker
- 10. Neurological: Stroke, Hemiplegia/Paraplegia, myopathies
- 11. Significant dermatological conditions affecting lower limbs resulting in broken or inflamed skin particularly at the site where the device is to befitted
- 12. Clinically significant haematological conditions ie coagulation disorders, sickle cell disease
- 13. Psychiatric disorders and cognitive deficits
- 14. Any significant illness during the 4 weeks preceding THR surgery
- 15. For NMES group, the devices do not work or do not respond to stimulation
- THR: Total Hip Replacement, DVT: Deep Vein Thrombosis; BMI: Body Mass Index; MI: Myocardial Infarction; CCF: Congestive Cardiac Failure; AF: Atrial Fibrillation; NMES: Neuromuscular Electrical Stimulation.

	NMES group (n = 30)	Control group (n = 30)	P Value*
Age (years)	53.1 ± 5.7	53.4 ± 5.5	.77
Sex	18 Female/12 Male	21 Female/9 Male	.56
BMI (kg/m2)	23.8 ± 3.7	22.3 ± 3.2	.66

Table 2. Baseline Demographic and Clinical Characteristics.

BMI: Body Mass Index; NMES: Neuromuscular Electrical Stimulation.

hospital. After participants or their family members gave their informed consent, the patient was randomly assigned to receive the NMES group (NMES group, n =30) or the control group (control group, n = 30). All participants followed the standard care pathway for THR. The only difference in treatment between the 2 groups was that during postsurgery, the NMES group patients were required to wear the NMES device for a minimum of 30 minutes each session, added up to 20 sessions over 5 days. Dr Zhao placed the device, and Dr Liu initiated the session. The session was terminated when 1. The skin where the device is to be installed appears to break or become inflamed; 2. The devices do not work or do not respond to stimulation; 3. The patients in the NMES group give a verbal categorical rating of unbearable. Because the NMES device is easily visually distinguishable, it was not possible to blind this study.

The geko<sup>TM</sup> NMES device was used for the study, which is small disposable, internally powered, and can be applied externally to the leg. The device is manufactured by Firstkind Ltd, High Wycombe, United Kingdom (27 mA, 1 Hz, pulse width 70-560 ms).<sup>15,16</sup> It is self-adhesive and applied to the outer/posterior aspect of the knee. This positioning enables integral electrodes to apply a stimulus to the common peroneal nerve, which branches from the sciatic nerve. These nerves control the contraction of several muscles in the lower leg so that discernible dorsiflexion of the foot can be observed. The stimulation of these nerves by the geko<sup>TM</sup> device causes the muscles to contract isometrically and will not affect the normal movement of the limb or mobility of the patient. Contraction of the lower leg muscles increases blood flow from the lower limbs back to the heart, thus increasing venous return-such as the common femoral vein, superficial femoral vein, popliteal vein, gastrocnemius veins, soleal veins, posterior tibial veins and peroneal veins-increasing local blood circulation, and helping prevent venous thrombosis. Furthermore, contracting the calf muscles increases lower limb blood flow to meet the metabolic demands of exercising skeletal muscles.<sup>11,17,18</sup> These devices were worn continually from postsurgery until Day 5. Following the manufacturer's instructions for use, the NMES devices were changed each day.

#### Procedure and Data Collection

This study used the NMES device in a randomized, controlled study.

Data were collected prior to surgery (Day 0), the first postoperative day (Day 1), the third postoperative day (Day 3), and the fifth postoperative day (Day 5). At each time point, adverse events and device deficiencies were monitored.

Postoperative pain was quantified through the visual analog scale (VAS) pain score (0 = no pain; 10 = worst pain) while moving on Days 1-3-5.<sup>19</sup> The NMES device was placed on an area that should not have been painful to the subject. Each subject responded to electrical stimulation to varying degrees, so the electrical stimulation was reduced to a lower intensity level that caused significant muscle contractions.<sup>20</sup>

Lower limb swelling was examined in the supine position by taking measures of the circumference of both the thigh (10 cm above the patella) and the calf (10 cm below the tibial tubercle) on Days 0-1-3-5.<sup>21</sup> The measurement position was marked with an indelible marker to ensure that measurements were continuously recorded on the same part of the lower limb, and the same staff member completed all measurements.

Length of stay (LOS) during postsurgery counts as the number of postoperative nights in the hospital until discharge. LOS was under the strictly functional discharge criteria (ability to get dressed independently, to get in and out of bed, to sit and rise from a chair/toilet, to be independent in personal care, to be mobile with a walker/ crutches, and to walk >70 m with crutches under full weight-bearing). In addition, sufficient postoperative pain treatment (VAS <3 on activity) and discharge acceptance were defined as the days until a patient was ready for discharge.<sup>7</sup>

Wound drainage was quantified through the negative pressure drainage device. According to the postoperative protocol, mobilization started as soon as peripheral sensory and motor skills were approved, usually 4-6 h after surgery. After removing the drains postoperatively at 24 h,<sup>22,23</sup> full weight-bearing and range of motion were allowed. Starting on postoperative Day 1, the first walking exercises with crutches began under physiotherapeutic supervision, including mobilization of the hip and muscle strengthening.

Before discharge, the patients in the NMES group were asked to complete a short verbal questionnaire. They were asked to give a verbal categorical rating of the NMES treatment as 'very comfortable', 'comfortable', 'bearable' or 'unbearable'. Acceptability by the intervention of the device was recorded on a completed short verbal interview detailing their experience with the NMES treatment.<sup>24,25</sup>

#### Statistical Analysis

All statistical analyses were performed with Prism 8 (GraphPad Software Inc). Descriptive statistics were used to describe the cohorts and their demographics. Categorical variables were analyzed using chi-square statistical analyses, while continuous data were analyzed using independent t test. The significance level was set at P < .05.

#### Results

#### Postoperative Pain

Table 3 shows the postoperative pain data. Figure 1 shows the 2 groups' mean postoperative pain during Days 1 to 5. There was a significant difference between the 2 groups of pain on Day 1 and Day 3 after the operation during mobilization (P < .05, respectively). There was no significant difference between the 2 groups regarding pain values at Day 5 postoperatively.

#### Lower Limb Swelling

Table 3 shows the swelling data. There was no significant difference in the mean swelling measured before THR surgery (Day 0) between the 2 groups in thigh circumference or calf circumference (P > .05). Between-group

Table 3. Postoperative Pain and Thigh Circumference/Calf Circumference.

		NMES Group	Control Group	
		Mean ± SD		P value*
Postoperative pain	Day I	2.93 ± 1.57	4.17 ± 1.91	.0118*
	Day 3	2.43 ± 1.14	3.23 ± 1.07	.004***
	Day 5	1.93 ± .78	2.2 ± .61	.103
Thigh circumference (cm)	Day 0	45.22 ± 5.27	47.6 ± 5.53	.096
5	Day I	45.28 ± 5.14	47.93 ± 5.52	.062
	Day 3	45.47 ± 5.29	48.25 ± 5.42	.055
	Day 5	46.33 ± 5.34	48.94 ± 5.46	.079
Calf circumference (cm)	Day 0	35.73 ± 2.97	36.04 ± 2.81	.717
	, Day I	36.03 ± 3.05	37.48 ± 2.81	.094
	Day 3	36.39 ± 2.94	38.11 ± 2.82	.049*
	Day 5	36.78 ± 2.96	38.49 ± 2.77	.049*



Figure 1. Postoperative pain of 2 groups.



Figure 2. Change in calf circumference.



Figure 3. Change in thigh circumference.

differences in the mean change in calf circumference were significant at all time points postoperatively (Days 3-5) (Figure 2). However, the change in thigh circumference in the 2 groups showed very little significance (Days 1-3-5) (Figure 3). The overall lower limb volume change showed a general increasing trend in both groups, but the NMES group showed a smaller increase.

#### Length of Stay Postsurgery

There was a significant difference between the 2 LOS groups. The mean LOS was  $6.9 \pm 1.8$  for the NMES group and  $8.6 \pm 2.0$  for the control group (P = .002) (Figure 4).

#### Wound Drainage at 24 hours

There was no significant difference between the 2 groups. The mean wound drainage at 24 h was  $339.8 \pm 149.1$  mL in the NMES group and  $335.6 \pm 161.7$  mL in the control group (P = .711) (Figure 5).

#### Acceptability

During the application of NMES, 5 patients in the NMES group described the use of the device as 'very comfortable', 23 as 'comfortable' and 2 as 'bearable', and no 1 described it as 'unbearable.' The overall comfort rate was 93.3% (Table 4).

#### Discussion

The aim of this study was to investigate the feasibility of using a novel neuromuscular electrical stimulation (NMES) device for enhanced recovery after total hip replacement surgery. While the sample size was small, the



Figure 4. Length of stay at post-surgery.



Figure 5. Wound drainage at 24 hours.

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fact that this was a single surgeon series within the same hospital means that a high degree of pathway and treatment standardization was possible. This is an important factor when assessing outcomes such as LOS, which may have multifactorial contributing factors. A significant general risk factor for joint disease is age, as the prevalence of hip arthritis increases with age.<sup>1</sup> In the study by Schrader,<sup>26</sup> they found that 67.3% of total hip arthroplasty (THA) were implanted in patients aged 60-79 years. This is congruent with our results.

The NMES device provided a potential clinical benefit of helping to enhance recovery after surgery. THA is ranked 11th among the most painful surgical procedures.<sup>27</sup> The key factor for patient satisfaction is pain, measured using a visual or numerical scale. In a clinical situation, volumetric measurements are valuable for monitoring the severity of edema after surgery.<sup>28</sup> While the gold standard for volumetry is the waterdisplacement method, it is not always suitable for patients in the postoperative period. Here, we reported the circumference change (both the thigh and the calf) in measurements (conducted by 1 assessor) to ensure the reliability of the results. Pain and swelling delayed discharge following THR. Immediate postoperative decreased muscle function or weakness is partly due to the formation of postoperative pain and swelling, which widely accepted to increase the risk for is complications,<sup>8,29</sup> The current economic climate and the restricted health care budgets further necessitate a shorter hospital stay and lower costs on the health care system.<sup>4,5</sup> This may call for reconsideration regarding instant access to physiotherapy and further improvement of analgesia and detumescence. Therefore, early rehabilitation is important.<sup>28</sup> NMES can be better used for enhanced recovery in the postoperative period following THR surgery. The NMES theories of analgesia and detumescence may include 1. Stimulating the release of endogenous analgesic substances, such as enkephalins and endorphins (an opioid-like neurotransmitter)<sup>30</sup> and 2. Prolonging the period of capillary opening prior to occlusion, keeping the peripheral circulation open and promoting extracellular fluid exchange.<sup>31,32</sup>

In our experience, the early postoperative period is particularly challenging for patients for socioprofessional reintegration. Our results on postoperative pain showed

	Verbal Questionnaire	Count	Percentage, %
NMES group (n = 30)	Very comfortable	5	16.7
	Comfortable	23	76.7
	Bearable	2	6.6
	Unbearable	0	0

improvement in the NMES group before 5 days. They showed no significant difference between the 2 groups regarding pain values at Day 5 postoperatively. The ge-ko<sup>TM</sup> NMES device provided a benefit for postoperative pain management to enhance recovery early after surgery. The reason for the 2 groups showing no significance after 5 days may be that patients improved in walking ease and diminution of joint motion pain during the intervention of gait training.

In the study by Wainwright,<sup>33</sup> they found that the NMES device significantly treated postoperative edema of the calf end of the thigh that occurs following THR. But in our study, our results on lower limb swelling show that the geko<sup>TM</sup> NMES device is conducive to decreasing calf swelling but is ineffective in the thigh. However, considering the circumference changes reported and the steps to ensure reliability (same assessor and marked points of measurement), it is highly likely that the differences reported are accurate. The situation may be because the geko<sup>TM</sup> NMES device applies a stimulus to the common peroneal nerve, which controls the contraction of several muscles in the calf without the contraction of muscles in the thigh.

We demonstrated that NMES enhances analgesia and detumescence. On the 1 hand, patients can get up, walk with walking aids indoors, get dressed, and do personal hygiene completely independently as early as possible. On the other hand, this relieves the burden on the nursing staff. Our results on LOS show that using NMES encourages mobilization and thus improves muscular strength and the achievement of discharge criteria early.

The augmentative effect of the gekoTM device on microcirculation, both in terms of flow and pulsatility.<sup>34</sup> Contraction of the lower leg muscles increases blood flow from the lower limbs back to the heart, thus increasing venous return and local blood circulation.<sup>11</sup> Previous studies have been concerned with increasing wound drainage.<sup>10,14</sup> The present study shows no significant difference in wound drainage between the 2 groups. To our knowledge, this is the first study assessing wound drainage with NMES physiotherapy in THR patients.

In a previous study, the application of NMES had to be discontinued, as patients could not tolerate the 'stinging' sensation associated with the stimulus.<sup>35</sup> Discomfort has been identified as a limiting factor in the use of surface NMES. Lyons et al<sup>36</sup> concluded that smaller electrodes were found to be more comfortable. The GekoTM NMES device is light and small. Self-adherent integral electrodes are applied to the posterior-lateral aspect of the knee to apply a stimulus transdermally to the common peroneal nerve. The device, coupled with its disposable battery-operated characteristics, means that mobility and comfort

are maintained throughout its usage period. According to our research, more than 93% of patients in the NMES group described the use of the device as 'very comfortable' or 'comfortable' during the application of NMES. No 1 described the use of the device as 'unbearable.' This may prove the acceptability of NMES to patients. The geko<sup>TM</sup> NMES device is safe and robust enough to use in the clinical setting. No adverse events occurred during the protocol or were reported to us afterward.

A clear limitation of this study is its small sample size. Only primary cementless implants with THR under central neuraxial anesthesia were considered. Further studies should be conducted with a larger sample size and more implants under other anesthesia conditions to enable statistical analysis. At the same time, because the NMES device is easily visually distinguishable and the muscles contract significantly during electrical stimulation, it was not possible to blind and placebo this study.

Doheny and associates showed that 1 must increase electrode size on obese or overweight subjects to maintain the efficacy of electric stimulation.<sup>37</sup> As mentioned, all subjects in the study used the same size electrode, even with a wide range of BMIs, which would alter the efficacy of the NMES for each subject.

Furthermore, the long-term clinical effects of NMES have yet to be evaluated. The reported recovery course is restricted in the hospital. Therefore, possible external influencing factors on pain and swelling in the postoperative period, eg, family, daily routine, work and sports, could not be considered.

We also noticed that the original stimulation intensity gradually increased with the increase in the number of electrical stimulations. With NMES, the device needed to increase the stimulation intensity to achieve the same stimulation effect. The geko<sup>TM</sup> NMES device is effective in reducing swelling and pain. Benefitting from its small size and ease of operation, the device could reduce dependency on medical professionals, as it can be used in a home environment. However, the maintenance and repair of the device also need to be considered. Randomized controlled group analysis to use the geko<sup>TM</sup> NMES device for a long time after discharge should be performed in the future. To date, and to our knowledge, none has been published.

### Conclusion

The results of this study suggest that the geko<sup>TM</sup> NMES device is partly useful for enhanced recovery after total hip replacement surgery. In addition, the device should be considered tolerable and safe. A larger study is required with this device in the future to determine its effectiveness on compelling data.

#### **Declaration of Conflicting Interests**

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