A Single-Centre Feasibility Randomised Controlled Trial Comparing the Incidence of Asymptomatic and Symptomatic Deep Vein Thrombosis Between a Neuromuscular Electrostimulation Device and Thromboembolism Deterrent Stockings in Post-Operative Patients Recovering From Elective Total Hip Replacement Surgery

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ABSTRACT

Background: Total hip replacement is recognised as a major risk factor for deep vein thrombosis (DVT). The aim of this study was to investigate the feasibility of using a novel neuromuscular electrical stimulation device (NMES) for DVT prevention in patients recovering from elective hip replacement surgery.

Methods: Twenty-eight patients undergoing total hip replacement were randomised to receive postoperative treatment with either the NMES device or compression stockings continually from post-surgery until discharge (day 4). The primary outcome measure was the presence of symptomatic or asymptomatic DVT at 48 hours post-surgery and on the day of discharge from hip replacement surgery, as assessed by Duplex ultrasound. Secondary outcomes included hemodynamic responses to the devices, lower limb oedema, sit-to-stand and timed-up-and-go (TUG) scores, and hip range of motion.

Results: In the compression stockings group, two cases of asymptomatic DVT were identified by Duplex

ultrasound at 48 hours post-surgery. No cases were found in the NMES group. Patients in the NMES group demonstrated a general trend of a decrease in leg volume from post-surgery to discharge, whereas leg volume largely remained static for the compression stockings group. In addition, positive hemodynamic effects were found in favour of the NMES group in the non-operated leg. The change in TUG scores also favoured the NMES group (NMES: 150 ± 152%, compression stockings: 363 ± 257% (p=0.03)), whereas no differences in sit-to-stand scores or hip range of motion were observed.

Conclusions: This study supports the feasibility of NMES as an alternative mechanical prophylaxis worn in the postoperative phase until discharge and provides important findings for clinicians considering novel mechanical prophylaxis options.

BACKGROUND

Current guidelines from the American Academy of Orthopaedic Surgeons (AAOS) recommend pharmacologic agents and/or mechanical compressive devices to reduce venous thromboembolism (VTE) risk following orthopaedic surgery.[1] These guidelines are consistent with recommendations from the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK), which suggest pharmacologic interventions combined with anti-embolism stockings to reduce risk.[2] Whilst historical VTE rates post-joint replacement have been high,[3] they are decreasing with modern surgical techniques and Enhanced Recovery after Surgery (ERAS) programmes,[4] which encourage early mobilisation.[5] In large cohort series in the UK and Denmark, the need for chemoprophylaxis in low-risk patients on ERAS joint replacement pathways has been questioned.[4,6] Instead, independent use of mechanical devices and early mobilisation have been considered as attractive alternatives for prophylaxis against VTE events, as they do not increase bleeding complications or require pharmacologic prophylaxis at additional cost.[4]

The most commonly used mechanical prophylactics are Thromboembolism Deterrent Stockings (TEDS) and Intermittent Pneumatic Compression (IPC) devices. TEDS have been considered to be effective in diminishing the risk of DVT in hospitalised patients as a stand-alone intervention and even more when combined with another method of prophylaxis.[7] Despite the widely accepted use of IPC, the relative effectiveness of different types of IPC systems as prophylaxis against thrombosis after hip replacement surgery remains unclear.[8] In addition, these devices do not easily enable early and frequent mobilisation. Neuromuscular electrical stimulation (NMES) is an alternative prophylaxis that has been approved by NICE in cases where other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated.[9] NMES stimulates nerves to activate muscles. It has been shown to produce immediate, beneficial hemodynamic responses [10-13] and reduce the incidence of DVT.[14,15] Preliminary work concluded that NMES can increase microcirculatory blood flow of the thigh three-fold in healthy adults when compared to an IPC device.[16]

This study aimed to assess the feasibility of using NMES as a novel alternative to compression stockings in the prevention of Deep Vein Thrombosis (DVT) in patients recovering from elective hip replacement surgery.

METHODS

This was a single-centre, randomised, open-label study assessing the feasibility of using an NMES device (geko™ (T-2 or R-2), FirstKind Limited, Buckinghamshire, UK) compared to compression stockings (Saphena® anti-embolism stockings, H&R Healthcare Ltd. Hull, UK) in patients recovering from elective hip replacement surgery. All patients received chemoprophylaxis as per NICE guidelines.[2] Compression stockings were chosen as the comparator as they are used as standard care for the prevention of DVT in UK hospitals. Secondary objectives were to compare the levels of lower-limb oedema, muscle function, hip range of motion and hemodynamic responses to those with compression stockings, and following augmentation with NMES.

Full ethical approval was granted by the National Research Ethics Service (REC reference: 13/LO/0059, protocol number: FKD-TEDS-001, IRAS project ID: 117650). The study was conducted in accordance with the principles of the Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects) and in compliance with European Standard ISO 14155:2011 Clinical Investigations of Medical Devices for Human Subjects – Good Clinical Practice. It was registered on ClinicalTrials.gov (Identifier: NCT01935414) on 5th September 2013. This study is reported using the CONSORT 2010 checklist for the reporting of pilot and feasibility studies.[17]

This study followed a preceding trial,[18] but with a different device and additional outcome measures. This study repeated the original protocol but with a revised device that provides more stimulation levels. Ultrasound measurements were added to better understand the mechanism of the effect of NMES, and the feasibility of taking these scans was a key component of the study. It was originally planned as a multicentre trial, but was instead performed at a single site to assess the efficacy of the additional outcome measures; it may later be expanded to a multicentre trial.

Participants: Consecutive total hip replacement operations performed by a single surgeon at a private hospital were screened for the eligibility criteria listed in Table I. Recruitment was ongoing between February 2015 and November 2016 to match the funding window for this study.

Randomisation: After patients had given their informed consent, they were randomised into one of two treatment

arms, allocated via a sealed envelope system which was prepared by an independent Clinical Research Organisation. All patients received standard preoperative, perioperative and postoperative care for hip replacement surgery regimens (including the administration of anticoagulants as per NICE guidelines[2]). All patients were mobilised as soon as possible (either on the day of surgery or the first postoperative day). Patients were randomised to receive either the NMES device or compression stockings from post-surgery until discharge during recovery from surgery. Patients were required to wear either the NMES device or compression stockings continually for 48 hours post-surgery and then for a minimum of four hours per day until discharge. Because the NMES device and compression stockings are easily visually distinguishable, it was not possible to blind this study.

Interventions: The geko™ device (either the T-2 or R-2) (Firstkind Ltd, High Wycombe, United Kingdom) was used in this study. It is a small, disposable, self-adhesive, internally powered, neuromuscular stimulation device that is applied to the leg externally. Application to the posterior aspect of the knee enables integral electrodes to apply a stimulus to the common peroneal nerves, which branch from the sciatic nerve. These nerves control the contraction of several muscles in the lower leg. Contraction of the lower leg muscles increases blood flow from the lower limbs back to the heart, increasing venous return and local blood circulation, and helps to prevent venous thrombosis.[13] Participants randomised to receive electrical stimulation were fitted with either a geko™ T-2 device or R-2 device so that discernible dorsiflexion of the foot could be observed. The NMES device was changed daily in accordance with the manufacturer's instructions for use.[19]

The comparison devices were Saphena® anti-embolism stockings fitted in accordance with the manufacturer's instructions.[20] They have a pressure of 18 mmHg ± 20% administered to the ankle, 14mmHg ± 20% administered to the calf and 9mmHg ± 20% administered to the thigh. They were chosen for the comparator in this study as they are widely and routinely used within the National Health Service (NHS) in the UK for DVT prevention following hip replacement surgery.

Table I
Eligibility Criteria

Inclusion	Exclusion
1. Aged 18 years of age and over	1. Requires hip revision surgery
2. Free of significant abnormal findings as determined by medical history (specifically an absence of DVT or haematological disorders).	2. History or signs of previous deep or superficial vein thrombosis/pulmonary embolism.
3. Has not used any medications (prescribed or over-the-counter including herbal remedies) judged to be significant by the Principal Investigator during the ten (10) days preceding enrolment.	3. Evidence of asymptomatic DVT by Duplex ultrasound
4. Able to understand the Patient Information Sheet and willing to sign the written Informed Consent Form.	4. Peripheral arterial disease (ABPI < 0.8), varicose veins or lower limb ulceration or ischemia.
5. Able and willing to follow the protocol requirements.	5. Significant varicose veins, phlebitis or lower limb ulceration or ischemia. CEAP Grade 4-6. See Appendix 2
	6. Recent surgery within the last 3 months (such as abdominal, gynaecological, hip or knee replacement).
	7. Recent trauma to lower limb.
	8. Chronic Obesity (BMI Index >40kg/m2).
	9. Pregnancy.
	10. Significant history of following diseases I. Cardiovascular: Recent MI (< 6 months) II. Percutaneous Coronary Intervention (PCI) with stent (< 3 months for Bare Metal Stent (BMS) and < 12 months for Drug-Eluting Stent (DES) III. Moderate to severe CCF, uncontrolled AF IV. Neurological: Stroke, Hemiplegia/Paraplegia, Myopathies V. Significant dermatological conditions affecting lower limbs resulting in bro ken or inflamed skin particularly at the site where the device is to be fitted. VI. Clinically significant haematological conditions, e.g. coagulation disorders, sickle cell disease VII. Psychiatric disorders
	11. On LMWH/Heparin (Prophylactic/therapeutic doses) or warfarin, or warfarin stopped recently and replaced by LMWH/ Heparin
	12. Long-term steroid with dermatological changes
	13. A pulse rate of less than 40 beats/minute
	14. A sitting systolic blood pressure >180 and <100 mmHg and/or a sitting diastolic pressure of >100 mmHg.
	15. Any significant illness during the four (4) weeks preceding hip replacement surgery.
	16. Participation in any clinical study during the eight (8) weeks preceding the screening period
	17. For subjects randomised to the geko™ (T-2 or R-2) treatment arm, the devices do not work (e.g., do not respond to stimulation)

Table II
Baseline demographic and clinical characteristics

	NMES (Mean ± SD)	Compression stockings (Mean ± SD)	T-test or *Fisher's exact (p value)
Age (years)	68.50 ± 8.97	66.82 ± 10.03	0.67
Gender	9 (64%) female 5 (36%) male	7 (64%) female 4 (36% male	1.00*
BMI (kg/m^2)	28.64 ± 4.28	28.14 ± 4.96	0.79
Treated leg	Left side 8 (57%) Right side 6 (43%)	Left side 5 (45%) Right side 6 (55%)	0.70*

Primary outcome: The primary objective of the study was to determine the feasibility of the NMES device for preventing the formation of asymptomatic or symptomatic DVT compared to compression stockings following total hip replacement surgery. The primary outcome measure was DVT at 48 hours post-surgery and on the day of discharge from hip replacement surgery, as assessed by Duplex ultrasound. The common femoral vein, superficial femoral vein, popliteal vein, gastrocnemius veins, soleal veins, posterior tibial veins and peroneal veins were assessed for patency, compressibility and the presence or absence of flow. DVT, full venous thromboembolism, pulmonary embolism, stroke or deaths were also primary endpoints of the study. All ultrasound measurements were completed by an independent consultant radiologist according to a standardised technique.

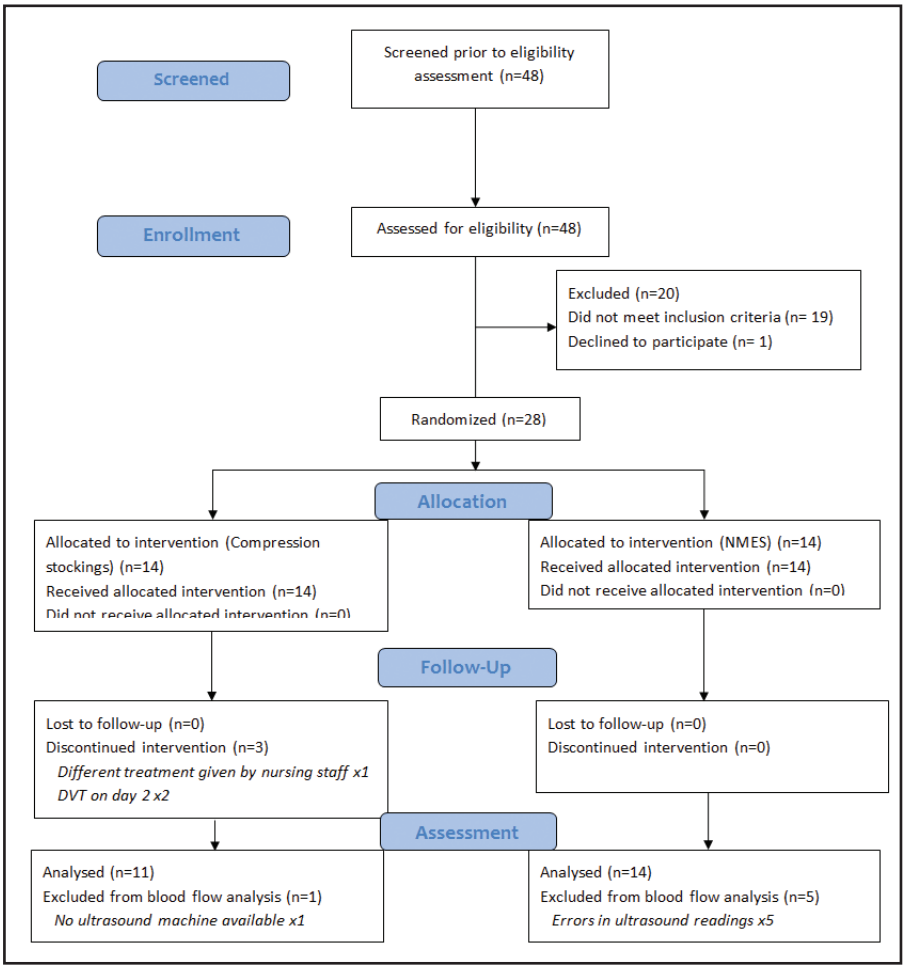

Figure 1. Patient flow

Secondary outcomes: Secondary outcome measures included oedema, functional measures (the five times sit-to-stand test, the three metre timed-up-and-go (TUG) test, hip range of motion (flexion and abduction, assessed using a goniometer)) and blood flow measurements when wearing the NMES device or compression stockings. Oedema was recorded by measuring leg circumference at the ankle, knee and thigh prior to and following surgery on the day of operation, at 24 hours post-surgery, on day two and between day three and discharge. Data gathered from these three measurements were used to calculate an approximation of leg volume based on a truncated cone model,[21] using the following formula:

$$\frac{L*((A^2)+(A*K)+2*(K^2)+(K*T)+(T^2))}{(24*pi)}$$

L = segment height; A = ankle circumference; K = knee circumference; T = thigh circumference.

On the second postoperative day, blood flow was measured by ultrasound with and without the NMES device or compression stockings to measure any change in blood flow attributed to the device. Differences in lower-limb blood flow whilst using the NMES device or compression stockings were evaluated using routine colour flow Duplex ultrasound of the superficial femoral vein and femoral artery. Blood flow measures included bilateral assessment of the diameter of the blood vessel, blood volume and blood flow velocity. These measurements were made in triplicate and monitored for quality and accuracy to ensure they did not vary by more than 20%.[22] All ultrasound measurements were monitored by an external independent radiologist. The blood flow measurements were first performed with the device in place and activated. Next, the devices were removed for a 30-minute "washout" period and the baseline blood flow measurements were performed. The devices were then refit as per protocol specification.

Time to achieve discharge criteria and device tolerability (measured on a Likert

Table III
Mean change in oedema from preop to discharge

Outcome measure	Time point	Operated leg			Non-operated leg		
		NMES (n=14)	Compression stockings (n=11)	Sig.	NMES (n=14)	Compression stockings (n=11)	Sig.
Mean change in ankle circumference from preop measurement (cm) (SD)	Postop	-0.11 (0.11)	0.23 (0.26)	0.22	-0.29 (0.19)	0.23 (0.30)	0.14
	PO day 1	-0.36 (0.18)	0.50 (0.20)	0.003	-0.75 (0.25)	0.14 (0.10)	0.005
	PO day 2	-0.36 (0.14)	0.41 (0.20)	0.003	-0.71 (0.16)	0.14 (0.10)	<0.001
	PO day 3	-0.21 (0.12)	0.41 (0.20)	0.009	-0.75 (0.20)	0.05 (0.14)	0.005
	Discharge	-0.21 (0.12)	0.45 (0.22)	0.01	-0.71 (0.19)	0.14 (0.10)	0.001
Mean change in knee circumference from preop measurement (cm) (SD)	Postop	-0.25 (0.22)	0.18 (0.18)	0.15	-0.21 (0.12)	-0.23 (0.26)	0.96
	PO day 1	-0.32 (0.20)	0.64 (0.15)	0.001	-0.50 (0.18)	0.00 (0.13)	0.04
	PO day 2	-0.32 (0.25)	0.77 (0.26)	0.006	-0.61 (0.20)	-0.14(0.14)	0.77
	PO day 3	-0.07 (0.30)	1.09 (0.26)	0.008	-0.61 (0.20)	-0.14 (0.11)	0.05
	Discharge	0.29 (0.36)	1.32 (0.33)	0.04	-0.61 (0.20)	-0.09 (0.11)	0.05
Mean change in thigh circumference from preop measurement (cm) (SD)	Postop	0.96 (0.21)	-0.05 (0.29)	0.01	0.32 (0.32)	-0.27 (0.33)	0.21
	PO day 1	0.54 (0.35)	1.00 (0.19)	0.28	0.11 (0.19)	0.27 (0.18)	0.53
	PO day 2	0.93 (0.43)	1.45 (0.30)	0.34	0.04 (0.21)	-0.09 (0.31)	0.73
	PO day 3	1.32 (0.51)	1.86 (0.39)	0.41	-0.11 (0.23)	0.09 (0.20)	0.52
	Discharge	1.11 (0.49)	1.91 (0.31)	0.19	-0.21 (0.22)	0.09 (0.25)	0.35
Mean change in leg volume from preop measurement (ml) (SD)	Postop	46.36 (47.80)	43.49 (58.12)	0.97	-20.58 (24.68)	-44.44 (61.10)	0.70
	PO day 1	-15.70 (62.44)	228.80 (35.80)	0.003	-144.59 (47.88)	35.39 (35.86)	0.02
	PO day 2	21.73 (81.22)	291.80 (63.61)	0.017	-137.31 (41.17)	-14.72 (42.42)	0.05
	PO day 3	102.45 (92.13)	379.80 (70.61)	0.028	-156.38 (39.99)	1.76 (35.36)	0.007
	Discharge	138.63 (92.72)	421.49 (71.18)	0.03	-163.82 (44.85)	7.36 (33.82)	0.001

scale, with 1 indicating no discomfort and 5 suggesting severe discomfort) were recorded at discharge, and adverse events were monitored throughout the duration of the study.

Sample Size: As this was a feasibility study, we did not consider a formal sample size calculation to be appropriate.[23] Recruitment was ongoing between February 2015 and November 2016 and closed when the funding stopped.

Statistical Methodology: Rates of DVT were compared at each time-point using descriptive statistics. Oedema and blood flow data were organised into the "operated" and "non-operated" legs for both groups. Independent sample T-tests were used to compare group differences in mean changes in oedema at each time point from baseline (preoperative) to discharge. Differences in approximate leg volume change, functional outcomes and blood flow measurements with and without the treatment devices in place were also compared using independent sample T-tests.

RESULTS

Successive patients were recruited between 25th February 2015 and 16th November 2016, and the follow-up of the final patient was completed on 19th November 2016. Twenty-eight patients scheduled for elective total hip replacements were enrolled into the study; three were withdrawn due to presence of asymptomatic DVT shown by Duplex ultrasound on postoperative day two (n=2) and a device-related error, where a ward nurse fitted an IPC device (n=1). The study groups were well-matched at baseline (Table II). The recruitment flowchart is presented in Fig. 1.

Incidence of deep vein thrombosis: Two patients in the compression stockings group were withdrawn from the study due to the presence of asymptomatic DVT shown by Duplex ultrasound on postoperative day two. DVT was not reported in the NMES study group at any time point.

Oedema: There were no significant differences between mean preoperative swelling measured before the application of the NMES device or compression stockings in the operated or non-operated leg at the ankle (p=0.50, 0.90), knee (p=0.40, 0.77), or thigh (p=0.31, 0.27), respectively. There were also no differences in approximate leg volume measured preoperatively in the operated or non-operated leg (p=0.40, 0.47). Furthermore, there were no significant differences in mean postoperative swelling, measured before the application of the NMES device or compression stockings, in either the operated or non-operated leg at the ankle (p=0.28, 0.65), knee (p=0.60, 0.75) or thigh (p=0.17, 0.19), respectively. Approximate leg volumes were also not significantly different in the operated or non-operated leg (p=0.42, 0.45).

Table III presents the mean circumference measurements during the postoperative period until discharge relative to the preoperative values for both the NMES and compression stockings groups

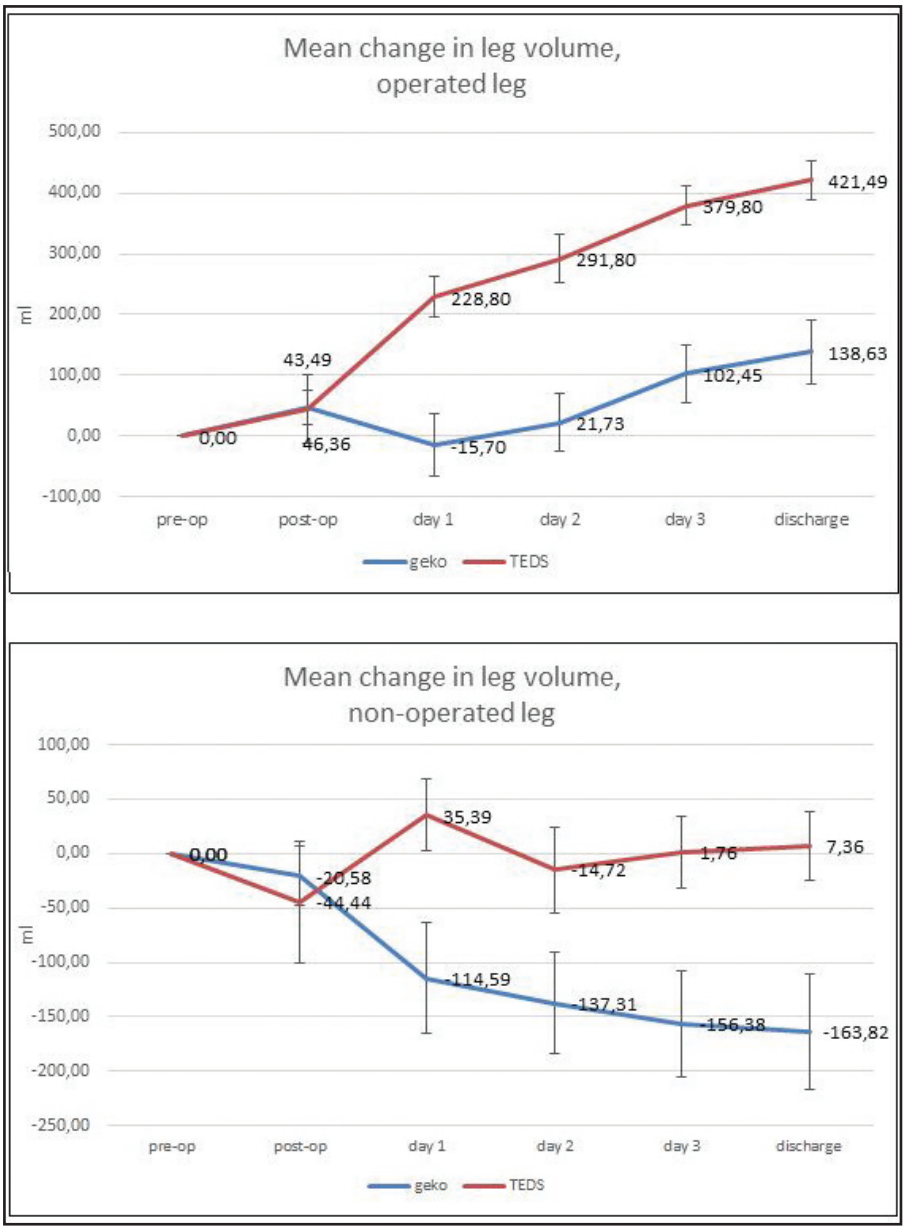

Figure 2. Mean change in leg volume in the operated (upper) and non-operated leg (lower).

in the operated and non-operated leg. Whilst ankle circumference decreased gradually over the postoperative period for the NMES group, patients using compression stockings demonstrated an increase in ankle circumference. Between-group differences in mean change were significant at all time points from postoperative day one until discharge.

The mean change in knee circumference of the non-operated leg demonstrates a similar trajectory to that of the ankle for both the NMES and compression stockings groups, but with group differences only significant at postoperative day one, day three and at discharge. For the operated side, much larger and more prolonged swelling is shown in the compression stockings group, given that knee circumference continued to increase from post-surgery to discharge. Significant between-group differences in mean change were observed at all time points from postoperative day one until discharge (Table III).

There were no significant changes between groups for thigh circumference from postoperative day one until hospital discharge for either the operated or non-operated leg (Table III). Thigh circumference on the non-operated side showed very little true change; however, the operated side demonstrated swelling over the days following surgery, and that in the compression stockings group was more severe than that in the NMES group.

The overall volume change shows a similar pattern to the individual measurements in the non-operated leg, with patients in the NMES group demonstrating a general trend of leg volume decreasing from post-surgery to discharge, whereas for patients in the compression stockings group, leg volume largely remained static (Fig. 2 upper). Similarly, the measurements from the operated leg show a substantial and continuing increase in leg volume with compression stockings, but not with the NMES device (Fig. 2 lower).

Blood flow: Differences in blood flow measurements were significant in favour of the NMES group in the non-operated leg for the changes in mean venous velocity (NMES: 0.21cm/s ± 0.77, TEDS: -1.75cm/s ± 1.73 (p=0.01)), peak venous velocity (NMES: 2.37cm/s ± 3.89, TEDS: -3.58 ± 7.38 (p=0.04)) and venous volume flow (NMES: 43.38 ± 157.01, TEDS: -101.80 ± 157.64 (p=0.04)) (Table IV). No significant differences were observed in changes in the operated leg; however, while use of the NMES device significantly increased peak venous velocity in the operated leg (p=0.006), the compression stockings did not (Fig. 3 upper). Patients using the NMES device also experienced a significant increase in mean venous velocity (p=0.02), whereas no effect was observed for the compression stockings group (Fig. 3 lower).

Patients in the NMES group demonstrated a significant increase in venous volume flow (p<0.001), whereas no significant effect was observed with compression stockings. In many cases, the stockings appeared to reduce venous flow, therefore yielding very large error bars (Fig. 4). These large variances make it difficult to establish an effect, and mask any differences when compared to NMES.

Functional outcome measures: There were no differences in sit-to-stand scores at pre-surgery or discharge, or in the percentage change between patients receiving treatment with compression stockings or NMES. At pre-surgery, there were no differences in TUG scores between groups; however, at discharge, the compression stockings group took significantly longer to complete the test than the patients using electrical stimulation (NMES: 30.43 ± 13.54 seconds, TEDS: 51.45 ± 17.84 seconds (p=0.004)).

Table IV
Between-group comparison on the effect of the device on blood flow measurements (with/without)

	Operated leg			Non-operated leg		
	NMES (n=9)	Compression stockings (n=10)	Sig.	NMES (n=9)	Compression stockings (n=10)	Sig.
Mean effect on peak arterial velocity (cm/s) (SD)	6.79 (15.29)	-5.76 (18.93)	0.13	1.48 (14.10)	-61.49 (106.22)	0.10
Mean effect on mean arterial velocity (cm/s) (SD)	0.91 (2.36)	-0.80 (6.26)	0.45	0.66 ± 2.81	-0.85 (2.84)	0.26
Mean effect on arterial diameter (mm) (SD)	-0.01 (0.03)	0.01 (0.03)	0.20	-0.05 ± 0.18	0.02 (0.04)	0.30
Mean effect on mean arterial volume flow (cm/s) (SD)	17.19 (116.03)	0.00 (193.77)	0.82	-7.56 ± 145.75	-25.70 (157.57)	0.80
Mean effect on peak venous velocity (cm/s) (SD)	12.70 (11.58)	4.46 (10.6)	0.12	2.37 ± 3.89	-3.58 (7.38)	0.04
Mean effect on mean venous velocity (cm/s) (SD)	4.98 (5.78)	2.60 (5.90)	0.39	0.21 ± 0.77	-1.75 (1.73)	0.01
Mean effect on venous diameter (mm) (SD)	0.10 (0.23)	0.02 (0.13)	0.37	-0.01 ± 0.10	0.06 (0.11)	0.15
Mean effect on venous volume flow (cm/s) (SD)	323.67 (196.50)	132.73 (459.29)	0.26	43.38 ± 157.01	-101.80 (157.64)	0.04

There was also a significant difference in percentage change between groups, with time taken to complete the test increasing by 150 ± 152% for the electrical stimulation group and by 363 ± 257% for the compression stockings group, from pre-surgery to discharge (p=0.03) (Table V).

There were no differences in hip flexion or abduction scores at pre-surgery or discharge, or in the percentage change between patients receiving treatment with compression stockings or electrical stimulation. There were also no between-group differences for time to meet discharge goals or device tolerability scores. No adverse events were reported during this study.

DISCUSSION

Traditionally, VTE prevention strategies in total hip replacement surgery include a combination of pharmacologic agents and/or mechanical compressive devices. These recommendations have been based on randomised studies with long length of stays and without consideration of the use of ERAS protocols that incorporate early mobilisation.[6] Recent articles have provided a counterpoint for these traditional strategies by highlighting comparable VTE rates following early mobilisation and mechanical prophylaxis within an ERAS pathway to chemical prophylaxis for all patients.[4] The 90-day incidence of symptomatic VTE in fast-track pathways has been reported to be 0.40% and 0.41% in patients with a length of stay of five days or less using in-hospital-only thromboprophylaxis.[6,24] This study supports the feasibility of NMES as an alternative mechanical prophylaxis worn in the postoperative phase until discharge and provides important findings, albeit in a small sample, for clinicians considering novel mechanical prophylaxis options.

Whilst this study was not sufficiently powered to draw certain conclusions regarding which intervention is most effective, it is noted that both cases of asymptomatic DVT identified on postoperative day two through ultrasound were in the compression stockings group. Neither of these cases had clinical symptoms; the patients were provided with the appropriate chemoprophylaxis treatment and removed from the study. The inclusion of asymptomatic DVT as an outcome measure provides important results when investigating the efficiency of mechanical prophylactics. However, the limited availability of a radiologist/sonographer at 48-hours post-surgery and at discharge created some difficulty with recruitment for the study.

Similarly, whilst the hemodynamic response of mechanical prophylactics is important to evaluate their potential role in DVT prevention, data collection was difficult due to the limited availability of both the ultrasound machine and radiologist. Previous work has demonstrated an increase in microcirculatory blood flow of the thigh when comparing NMES to IPC.[13,16] Here, our results show a positive hemodynamic effect in favour of the NMES group when compared to those receiving postoperative care with compression stockings in the non-operated leg. Interestingly, no differences were observed between groups in blood flow

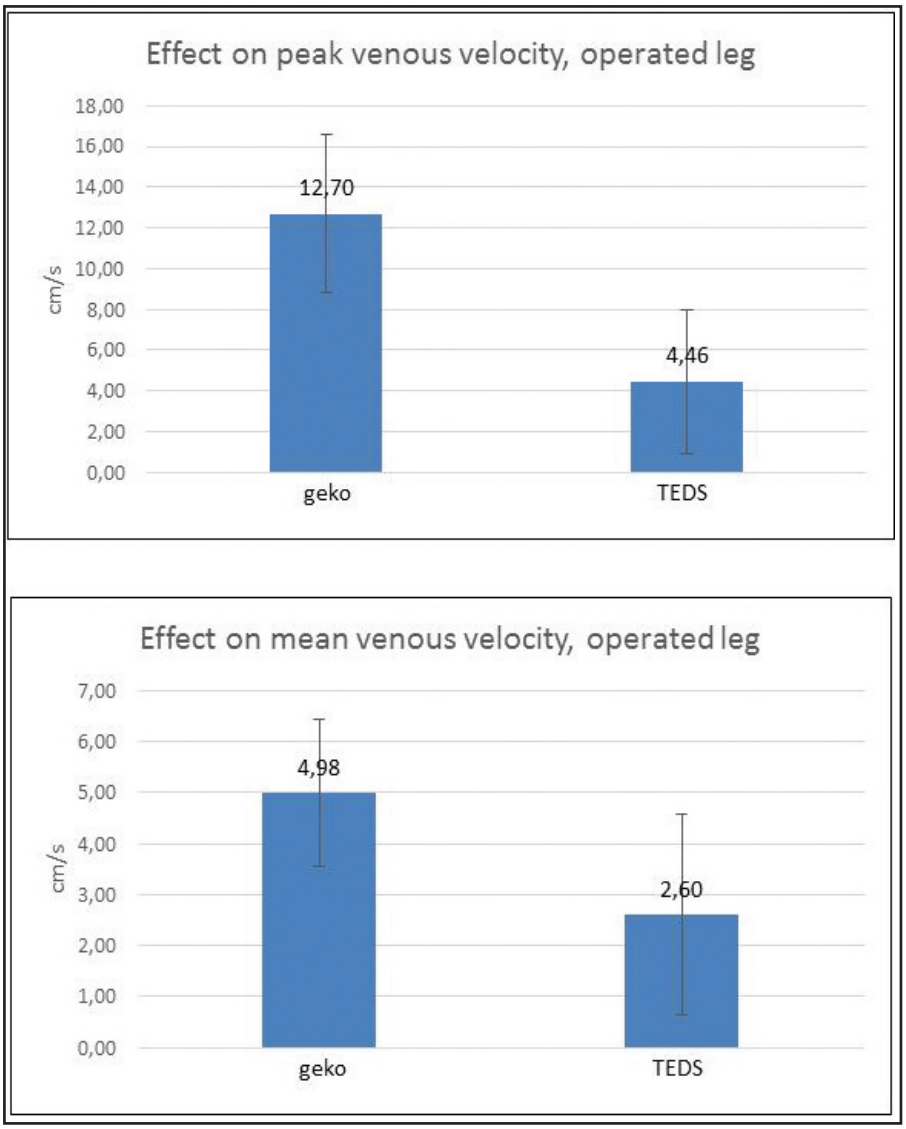

Figure 3: Effect of intervention on peak venous velocity (upper) and mean venous velocity (lower) in the operated leg.

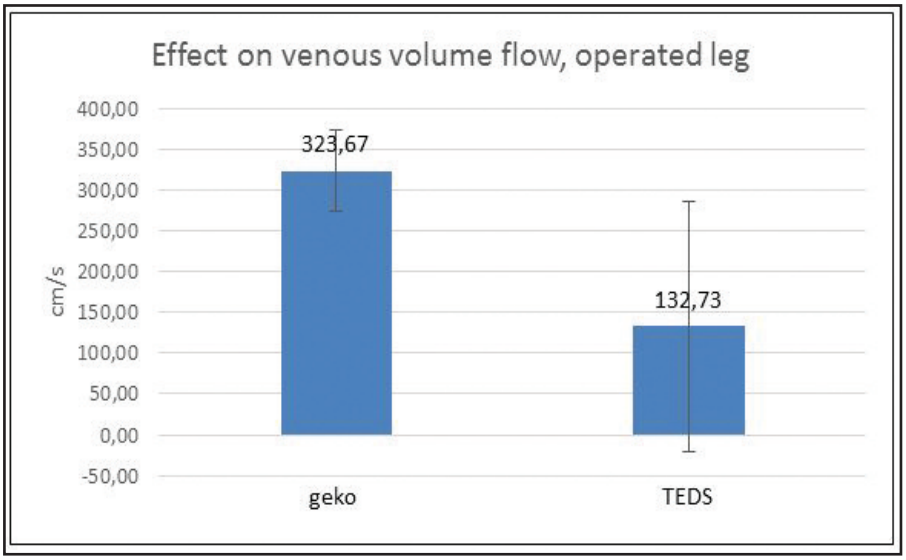

Figure 4: Effect of intervention on venous volume flow in the operated leg

measurements of the operated leg, although significant changes in peak venous velocity and mean venous velocity were observed in the NMES group when using the device.

In a clinical situation, volumetric measurements are valuable for monitoring the severity of oedema after surgery.[21] Whilst the gold standard for volumetry is the water-displacement method, it is not always suitable for patients in the postoperative period. Here, we reported the percentage change in measurements (conducted by one assessor) to ensure reliability of the results. Our findings are consistent with our previous investigation,[18] suggesting that NMES can be better than compression stockings at reducing oedema in the postoperative period following hip replacement surgery. In the non-operated leg, this was shown as a progressive reduction in circumference and volume in the days following surgery, whereas circumference and volume in the compression stockings group largely remained static. In the operated leg, patients in the NMES group tended to show a static lower-limb circumference and volume, whereas these values progressively increased in the compression stockings group.

In our previous work, we theorised that reducing oedema may encourage mobilisation and thus facilitate early functional recovery and achievement of discharge criteria.[18] To establish whether reduced oedema in this context may be of clinical significance, this feasibility study included functional outcome measures. Patients in the NMES group performed better than those in the compression stockings group in both the sit-to-stand and TUG test in terms of percentage change from pre-surgery to discharge, although this was only significant for the TUG test. Given our small sample size, it is not possible to indicate whether the reduction in oedema has a noticeable effect on patient function at discharge. However, all participants were able to complete the functional outcome measures at time of discharge from hospital, supporting the feasibility of including these measures in larger investigations.

LIMITATIONS

A clear limitation of this study is its small sample size. We encountered difficulty with recruitment due to the limit-

Table V
Functional outcome measures

	Time point	NMES (n=14)	Compression stockings (n=11)	Sig.
Sit-to-stand (seconds)	Preoperative	16.36 ± 5.50	17.27 ± 4.41	0.65
	Discharge	26.57 ± 11.21	29.45 ± 7.95	0.46
	Change	10.21 ± 10.12	12.18 ± 9.34	0.62
	% Change	68 ± 72	83 ± 71	0.61
Timed Up and Go (seconds)	Preoperative	15.43 ± 14.19	13.0 ± 4.67	0.56
	Discharge	30.43 ± 13.54	51.45 ± 17.84	0.004
	Change	15.00 ± 15.92	38.45 ± 19.55	0.004
	% Change	150 ± 152	363 ± 257	0.03
Hip Flexion (degrees)	Preoperative	78.21 ± 12.03	75.91 ± 12.00	0.64
	Discharge	72.86 ± 11.22	74.55 ± 8.20	0.67
	Change	-5.36 ± 15.99	-1.36 ± 11.85	0.48
	% Change	-5 ± 21	0.01 ± 16	0.54
Hip Abduction (degrees)	Preoperative	18.21 ± 4.64	17.73 ± 5.18	0.81
	Discharge	20.71 ± 3.31	20.00 ± 6.32	0.74
	Change	2.50 ± 5.10	2.27 ± 8.17	0.94
	% Change	23 ± 44	22 ± 54	0.96
Time to meet discharge criteria (days)	Discharge	2.86 ± 0.66	3.00 ± 0.77	0.63
Patient tolerability	Discharge	1.86 ± 0.36	2.00 ± 0.45	0.40

ed availability of both the ultrasound machine and radiologist. Whilst our findings may warrant further investigation of NMES as a mechanical prophylaxis, future similar trials may face a similar difficulty. As this study was performed at one site and by the same surgeon as in our previous investigation,[18] we cannot report increased external validity or generalisability. However, as these findings are consistent with our original results, the internal validity is strengthened.

CONCLUSION

Research suggests that traditional thromboprophylaxis techniques following hip replacement surgery may be outdated in the context of ERAS and fast-track pathways. The independent use of mechanical devices and early mobilisation has been proposed as an alternative mechanism for the prevention of VTE events. This study supports the feasibility of NMES as an alternative mechanical prophylaxis in the postoperative phase until discharge and provides important findings for clinicians considering novel mechanical prophylaxis options. STI

AUTHORS' DISCLOSURES

TW and RM have received grant/research support from FirstKind Limited (Buckinghamshire, UK) and are major shareholders of Healthdecoded Limited (Broadstone, UK). Healthdecoded Ltd has previously performed consultancy activities for Firstkind Ltd., which manufactures the geko device. There is potential in the future for Healthdecoded Ltd to be provided with an option to buy shares in Sky Medical Technology (parent company of Firstkind Ltd). The funding source did not play a role in the data collection, analysis, or interpretation, or in writing of the manuscript. LB declares that she has no conflicts of interest.

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