Impact of Geko Neuromuscular Stimulator on Preoperative Preparation in Ankle Fractures

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ABSTRACT

Objective: To explore the impact of the Geko neuromuscular stimulator on preoperative preparation in patients with ankle fractures. **Study Design:** Quasi-experiment study.

Place and Duration of the Study: Department of Foot and Ankle Surgery and Department of Orthopaedics, Beijing Tongren Hospital, Capital Medical University, Beijing, China, between December 2020 and 2021.

Methodology: This quasi-experiment study included patients with ankle fractures treated with Geko neuromuscular stimulator before surgical fixation. The primary outcome was limb swelling at 24, 48, and 72 hours (h) after admission, and the secondary outcomes were pain according to visual analogue scale (VAS) at 12, 24, and 48 hours after admission, preoperative waiting time, and comfort 4 and 72 h after admission.

Results: A total of 60 patients were included in the study; 30 in the conventional treatment group (mean age 41.16 \pm 2.01 years) and 30 in the Geko group (mean age 40.22 \pm 2.68 years). The limb swelling in patients was significantly different between the Geko and conventional treatment groups (p = 0.004). Besides, the swelling values at 48 (p < 0.001) and 72 (p < 0.001) hours were significantly lower than those at 24 hours. The pain in patients was significantly different between the Geko and conventional treatment groups (p = 0.001) and 48 (p < 0.001) hours are significantly lower than those at 24 hours. Comfort was significantly higher at 4 h (69.54 \pm 2.18 vs. 67.22 \pm 3.14, p = 0.002) and 72 h [(88.50 (84.00 - 94.00) vs. 82.14 \pm 3.08, p < 0.001)] after admission. The preoperative waiting time (3.52 \pm 1.8 vs. 5.15 \pm 2.1 hours, p = 0.002) was significantly shorter in the Geko group. **Conclusion:** The Geko neuromuscular stimulator is a useful option for preoperative preparation in patients with ankle fractures to reduce local swelling and pain and improve patients' comfort.

Key Words: Ankle fractures, Lower extremity, Neuromuscular stimulator, Peroneal nerve, Pain.

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INTRODUCTION

Ankle fractures are the most common intra-articular fractures with soft tissue damage. The ankle joint has the lowest position and the largest load-bearing capacity among the large joints. With increased longevity and the continuous development of urban transportation, the incidence of traffic accidents and fall injuries has risen. Consequently, the occurrence of ankle fractures has also gradually increased.^{1,2} The change of the load-bearing line in unstable ankle fractures usually demands internal fixation.³ However, accompanying soft tissue injury peaks at 24-72 h after ankle fractures, with varying degrees of local swelling delaying surgery or making it impossible.^{4,5}

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Rapid local swelling after fracture is caused by the rupture of capillaries and lymphatic vessels. The colloid osmotic pressure in the interstitial space increases and various stress-induced inflammatory factors increase vascular permeability, aggravating the extravasation of intravascular fluid into the muscle space.⁶ Moreover, with the vicious cycle of swelling and pain, serious consequences such as tension blisters, soft tissue necrosis, and compartment syndrome can occur, further delaying surgery.⁷ Some patients miss the optimal operation timing because they do not see a doctor immediately after injury. As a result, surgery can only be performed once the swelling has subsided.⁴ Although it was reported that the average recovery time of patients with early surgery and middle-late surgery after ankle fracture was the same, a too long preoperative waiting time increases the anxiety of the patients and the financial burden of hospital stay.^{5,8} As the optimal operation timing for ankle fractures is about 6-8 hours after injury, controlling swelling to reduce the pain and gain time for the operation has become a promising direction of research.

The Geko neuromuscular stimulator uses a patented technology to stimulate the common peroneal nerve of the lower limbs and promote blood circulation.⁹ The painless electrical impulses delivered by Geko activate the calf muscle pump through stimulation.¹⁰ The contraction of these muscles prompts the foot to move forward and outward to simulate walking, increasing the patient's blood flow rate compared with rest.¹¹ After 3 years of research at Queen Mary University of Cambridge, UK, the efficacy of neuromuscular electrical stimulation in activating the calf muscle pump to increase blood circulation was verified, and the electrical muscle stimulation was well tolerated, highly effective, and improved pain levels and ankle pain.¹² Previous research was mostly focused on the application of Geko in the management of venous leg ulcers and other wounds;¹³⁻¹⁵ accelerating the subsidence of swelling after ankle fracture is another potential clinical application.

It was hypothesised that electrical stimulation of the lower limbs using the Geko neuromuscular stimulator could promote blood circulation and accelerate the subsidence of swelling after ankle fracture, thus shortening the waiting time for surgery. Therefore, this study aimed to explore the impact of the Geko neuromuscular stimulator on preoperative preparation in patients with ankle fractures.

METHODOLOGY

This quasi-experiment study included patients with ankle fractures admitted to the Department of Foot and Ankle Surgery and Department of Orthopaedics, Beijing Tongren Hospital, Capital Medical University, Beijing, China, between December 2020 and 2021. The inclusion criteria were: Unilaterally closed ankle fractures planned for elective surgery, hospitalisation within 24 hours after trauma, and aged between 18-60 years, with normal cognitive function, and willing to collaborate in the study. The exclusion criteria were open fracture or underlying systemic diseases such as diabetes and heart disease or other conditions that could potentially interfere with the study results.

This research was approved by the Review Board of the Beijing Tongren Hospital, and written informed consent was obtained from all participating patients. The patients were divided into the Geko group and the conventional treatment group according to the orders of admission. The patients in both groups received conventional treatment and nursing. They were given 20% mannitol 125 ml intravenously twice a day. Manipulative reduction of the fracture site was attempted, followed by wearing the jig to achieve the purpose of immobilising the fracture site. The affected limb was elevated above the level of the heart, and the patients were instructed to perform knee flexion and extension exercises and quadriceps flexion and extension exercises three times a day for 15 minutes each time, as long as the patients were not fatigued. In addition, the patients in the Geko group wore the Geko neuromuscular stimulator after admission. According to the patient's tolerance, the 5-7 grades of treatment were chosen to induce muscle contraction of the lower leg without discomfort. The treatment was applied for 3 hours per session, twice a day, with an interval of about 8-10 hours between each session.

The primary outcome of this study was limb swelling at 24, 48, and 72 hours (h) after admission. The secondary outcomes included pain according to visual analogue scale (VAS) at 12, 24, and 48 h after admission, preoperative waiting time, and comfort. Limb swelling was defined as the swelling of the affected limb, measured and calculated at 24, 48, and 72 h after admission. The swelling value was calculated by measuring the circumference of the swollen part of the affected limb in relation to the healthy limb, that was, measuring the circumference of the inner ankle tip. The swelling value was measured as the circumference difference between the affected limb and healthy limb.⁷ Pain was evaluated by VAS at 12, 24, and 48 h after admission. The patients made marks according to their feelings or the degree of influence on sleep to indicate the degree of pain.¹⁶

Preoperative waiting time was recorded (the number of days between hospitalisation and operation day). The comfort scale score was evaluated within 4 h of admission and 72 h after admission. Kolcaba's Comfort Status Scale (GCQ) was used for evaluation.¹⁷ The baseline demographic characteristics were also collected, including age, gender, education level, and body mass index (BMI).

Statistical method SPSS 19.0 software (IBM, Armonk, NY, USA) was used for statistical analysis. Continuous variables were assessed for normality using the Shapiro-Wilk test. For variables with a normal distribution, means \pm standard deviations (SD) were presented, and intergroup comparisons were conducted using independent samples t-test. For non-normally distributed data, the median (range) was reported, and intergroup comparisons were performed using the Mann-Whitney U test. The categorical data were presented as n (%) and analysed using the Chi-squares test or Fisher's exact test. A generalised estimating equation was used for analysing limb swelling and pain. A two-sided p < 0.05 was considered statistically significant.

RESULTS

A total of 82 patients were screened. Of them, eight patients with open fractures, six patients with non-surgical treatment options, and eight patients with underlying diseases such as diabetes and heart disease were excluded. Therefore, 60 patients were finally included. Thirty were in the Geko group (mean age 40.22 ± 2.68 years), and 30 were in the conventional treatment group (mean age 41.16 ± 2.01 years). No patients in either group dropped out, and all patients completed the study as planned. They were comparable in baseline characteristics between groups (Table I).

The limb swelling in patients was significantly different between the Geko and conventional treatment groups (p = 0.004). Besides, the swelling values at 48 (p < 0.001) and 72 (p < 0.001) hours were significantly lower than those at 24 hours (Table II).

The pain in patients was significantly different between the Geko and conventional treatment groups (p = 0.007). Besides, the pain values at 24 (p < 0.001) and 48 (p < 0.001) hours were significantly lower than those at 12 hours (Table II).

Preoperative waiting time was also significantly shorter in the Geko group ($3.52 \pm 1.8 \text{ vs.} 5.15 \pm 2.1 \text{ days}$, p = 0.002). The comfort scores were significantly higher in the Geko group 24 h ($69.54 \pm 2.18 \text{ vs.} 67.22 \pm 3.14$, p = 0.002) and 72 h ($88.50 (84.00-94.00) \text{ vs.} 82.14 \pm 3.08$, p < 0.001) after admission (Table II). No adverse reactions occurred in all patients.

Characteristics	Geko group (n = 30)	Conventional group (n = 30)	p *	
Age	40.20 ± 2.68	41.13 ± 2.01	0.133	
Gender			0.787	
Male	19 (63.33)	20 (66.67)		
Female	11 (36.67)	10 (33.33)		
Education			0.622	
Primary school	2 (6.67)	1 (3.33)		
Junior high school	4 (13.33)	6 (20.00)		
Senior high school	15 (50.00)	16 (53.33)		
College or above	9 (30.00)	7 (23.33)		
Body mass index	23.96 ± 2.41	24.08 ± 3.01	0.865	

Data were presented as mean ± SD or n (%). * The p-values were obtained through independent sample t-test, Chi-squared test, or Fisher's exact test.

DISCUSSION

This study found that swelling and pain in patients with ankle fractures after admission were significantly reduced in the Geko group compared with the conventional treatment group, and the patients in the Geko group had higher comfort scale scores and shorter preoperative waiting times. To the authors' knowledge, it is the first prospective study to access the application of the Geko neuromuscular stimulator in ankle fractures and report promising findings, suggesting that the device might be potentially used in future clinical practice for preoperative preparation in patients with ankle fractures.

The Geko neuromuscular stimulator uses the "muscle pump" principle by stimulating the common peroneal nerve in the calf, causing the calf muscles to contract and pump blood back to the heart. Therefore, it is actively discussed whether neuromuscular stimulation can reduce swelling by promoting the venous circulation of blood and lymph. In particular, Xiong et al. reported that neuromuscular electrical stimulation used for the prevention of deep venous thrombosis could effectively reduce knee swelling of lower extremities after anterior cruciate ligament (ACL) reconstruction.¹⁸ A randomised controlled trial by Wainwright et al. also demonstrated statistically significant improvements in swelling reduction, as measured by fluid displacement after ankle sprain.¹⁹ Electrical nerve stimulation of the common peroneal nerve by the Geko device was successfully used to treat refractory, multifactorial leg oedema,²⁰ as well as in a number of rehabilitation settings and patient groups, for treatment of both upper and lower limb oedema.¹¹ In this study, the primary outcome was limb swelling, which was significantly less prominent at 24, 48, and 72 h after admission in those patients who wore the Geko device, confirming the results of the previous studies.

In addition, the Geko electrical stimulation was previously shown to increase blood circulation successfully in the calf muscle and improve pain levels in patients with leg ulcers,¹⁵ after ACL reconstruction,¹⁸ and anterior knee pain.²¹ Still, a review reported insufficient and inconclusive evidence for the usage of neuromuscular stimulation in patients with patellofemoral pain syndrome.²² In this study, the pain at each time point after admission was less prominent in patients who used the Geko device compared to the patients who received only conventional treatment. As a result, the reduction of pain improved the comfort of the patients, suggesting that the application of Geko could help relieve tension and anxiety and improve the overall medical experience. Moreover, during treatment, patients and their family members could intuitively see the rhythmic contraction of the muscles and feel the effect of the treatment so that they could cooperate with the treatment with more confidence and enthusiasm.

The inflammatory factors released after trauma and tissue compression can aggravate swelling, further delaying surgery.⁴ As neuromuscular electrical stimulation can prevent venous stasis,⁹ it was hypothesised that the promotion of blood circulation after ankle fracture could shorten the waiting time before surgery, shorten hospital stay, and decrease medical expenses. Zhao *et al.* reported that the Geko device enhanced recovery and demonstrated a general trend for shortening the length of hospital stay after total hip replacement surgery.¹⁷ This study confirmed that the application of the Geko neuromuscular stimulation device could effectively shorten the preoperative waiting time, suggesting potential benefits for preoperative preparation in patients with ankle fractures.

There are some limitations in this study. First, this study only studied preoperative patients with closed ankle fractures, limiting generalisability. Second, it was a single-centric study, and the applicability of the results should be considered with caution. Besides, the patients were not blinded, which might have resulted in additional bias and interference with the placebo effect. Third, the post hoc power analysis revealed a power of 64.5% (α = 0.05, effect size = 0.25, n = 60), indicating that the statistical efficiency might have not been sufficient using the sample size. Finally, the Geko neuromuscular stimulator device stimulates the common peroneal nerve in the calf to induce contraction of the calf muscles; whether the contracted muscle adversely affects the wound has not been established, and there was no conclusive evidence that Geko can be used in patients with open ankle fractures and in patients with ankle surgery. In future studies, the scope of the study will be expanded to further confirm the applicability of Gekoneuromuscular stimulator.

Table II: Comparison of the outcomes between the conventional treatment group and the Geko stimulation group.

Characteristics	Geko group (n = 30)	Conventional group (n = 30)	p-value	P _{Time}	PInteraction
Limb swelling			< 0.004 [#]	< 0.001	< 0.001
24 h	3.84 ± 1.1	4.28 ± 1.2			
48 h	2.98 ± 0.8	3.500 (2.60 - 5.70)	< 0.001*		
72 h	2.01 ± 0.6	3.46±0.9	< 0.001*		
VAS			0.007	< 0.001	0.047
12 h	6.00 (5.00 - 6.00)	6.00 (5.00 - 7.00)			
24 h	5.00 (4.00 - 6.00)	5.00 (5.00 - 6.00)	< 0.001*		
48 h	3.00 (3.00 - 4.00)	4.00 (3.00 - 4.00)	< 0.001*		
Preoperative waiting time (hours)	3.52 ± 1.8	5.15 ± 2.1	0.002#		
Comfort scale					
4 h	69.54 ± 2.18	67.22 ± 3.14	0.001#		
72 h	88.50 (84.00 - 94.00)	82.14 ± 3.08	< 0.001#		

Data were presented as mean ± SD or median (range). *vs. 24 or 12 h. *p in independent-sample t-test or Mann-Whitney U test.

CONCLUSION

The Geko neuromuscular stimulator is a useful option for preoperative preparation in patients with ankle fractures to reduce swelling and improve patients' comfort.

ETHICAL APPROVAL:

This work has been carried out in accordance with the Declaration of Helsinki (2000) of the World Medical Association. This study was approved by Beijing Tongren Hospital, Capital Medical University (Approval no. TREC2017-27. R1).

PATIENTS' CONSENT:

All patients provided written informed consent.

COMPETING INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

XZ, YD: Carried out the studies.

- YL: Collected data.
- XZ: Drafted the manuscript.

ZN: Performed the statistical analysis and participated in designing.

XZ, ZZ, WW: Participated in the acquisition, analysis and interpretation of data, and drafted the manuscript.

All authors approved the final version of the manuscript to be published.

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