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Original Research

Comparison of electrically elicited quadriceps torque: burst modulated biphasic pulsed current (BMBPC) versus the Kneehab™ XP garment stimulator

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Purpose
Neuromuscular electrical stimulation (NMES) is the use of electrical current to generate muscle contractions for the purpose of increasing strength. Typically, discomfort limits the current amplitude tolerated and consequently how much force the recruited muscle produces, which influences strength adaptations. The purpose of this study was to compare the maximally tolerated knee extensor muscle torque produced by two neuromuscular electrical stimulation devices: the Vectra Genisys® stimulator delivering a burst modulated biphasic pulsed current (BMBPC) and the Kneehab™ XP (KH) garment sleeve that delivers a biphasic pulsed current (BPC).
Methods
For 28 abled bodied participants we compared the percent of the knee extensor maximal volitional isometric torque (%KEMVIT) produced by the BMBPC of the VG and BPC of the KH. This was determined by measuring the maximally tolerated electrically elicited muscle torque normalized to their KEMVIT.
Results
Our results showed a significant main effect for the devices on %KEMVIT. The BMBPC of the VG produced significantly greater %KEMVIT, 38.1 ± 14.9, than the BPC of the KH, 29.3 ± 9.9 (P =.001). A majority of the participants (23/28) described the BPC of KH as more comfortable than the BMBPC of the VG.
Clinical Implications
For eliciting maximum knee extensor torque, the VG clinical stimulator delivering BMBPC was more effective than the BPC of the KH garment stimulator. However, the KH was preferred by 23 of the 28 (82%) participants likely because of the lower muscle torques produced.

Keywords: Kneehab, Vectra Genysis, Neuromuscular Electrical Stimulation, Quadriceps Femoris Muscle

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1. Introduction

Neuromuscular electrical stimulation (NMES) is a clinical modality commonly used to treat muscle atrophy and promote neuromuscular re-education in order to increase strength. NMES stimulates peripheral motor neurons usually via electrodes placed on the skin to transcutaneously recruit muscle fibers.[1] NMES has often been used to increase the size and strength of the atrophied and weak quadriceps femoris muscle following ACL reconstruction and total knee arthroplasty.[2-5]

The electrically elicited muscle torque a person can tolerate from NMES is often limited by discomfort.[1,6,7] Medeiros et al.[8] compared the knee extensor muscle torque from four different types of NMES and while the maximum torque that was produced varied,

there was no difference in the discomfort reported at the maximum tolerated current intensities, suggesting that discomfort itself was the limiting factor and that different types of NMES affect discomfort. These findings are consistent with other reports that the electrical stimulation parameters of NMES can affect the torque produced at the maximum tolerable current amplitude a person is willing to tolerate.[1,6,9,10] It is desirable to produce the greatest electrically elicited muscle torques possible because there is a dose-response relationship between the electrically elicited muscle torques produced by NMES and subsequent increases in strength.[1,11-13]

One NMES waveform that has demonstrated the ability to evoke relatively high muscle torques at the maximal tolerated current intensity is the burst modulated biphasic pulsed current (BMBPC). This waveform is available on the Vectra Genysis® (DJO Global, LLC, Lewisville, TX) clinical stimulator under the VMS burst™ selection. Adams et al.[9] found that 1000-Hz BMBPC and 1000 Hz burst modulated alternating current to be more effective waveforms for maximizing knee extensor torque than 2500 Hz burst modulated alternating current, known clinically as Russian current. Bellew et al.[10] also found BMBPC utilizing a 1000 Hz carrier frequency produced significantly greater percent maximal knee extensor isometric muscle force than 2500 Hz carrier frequency BMBPC. Based on these findings the 1000 Hz carrier frequency BMBPC appears to be a highly effective, clinically available waveform to generate maximal electrically elicited knee extensor torque.

The Kneehab™ XP Conductive Garment System (Theragen, LLC, Leesburg, VA) electrical stimulation device, which recently has become available in the United States, utilizes four electrodes within a battery-powered thigh sleeve garment that offers 6 preset stimulation programs with options for different stimulation frequencies and on/off times for repeated contractions. All of the programs utilize a biphasic pulsed current (BPC). Rather than using the unidirectional current flow that is typical of most NMES devices, the Kneehab (KH) uses a multipath current flow that is designed to alternate the location of the electrical current among 4 electrodes of varying sizes to reach a larger number of motor units with less discomfort.[6,7] It has been demonstrated that the KH can be an effective NMES device to produce muscle hypertrophy and improvements in knee extensor strength.[2,14,15] Furthermore, it has been suggested that the KH may be superior to traditional unidirectional NMES in producing higher muscle torques at the maximum tolerated current amplitude,[6,7] and better functional outcomes following ACL reconstruction surgery.[2] However, there has not been a study comparing muscle torques at the maximally tolerated current intensity between the BMBPC of the VG and the BPC of the KH. The purpose of this study was to compare the electrically elicited knee extensor muscle torques produced by the VG clinical stimulator delivering 1000 Hz BMBPC and the KH delivering BPC at the maximum current amplitude participants were willing to tolerate.

2. Materials and Methods

We recruited thirty participants from Husson University and the surrounding community. Participants with a history of cardiovascular disease, neurological disease, implanted electrical devices, or musculoskeletal dysfunctions of the right thigh or knee were excluded. All participants signed a written informed consent form. The Institutional Review Board of Husson University approved the study (#17PT03).

In this single blind, crossover design study, each participant underwent testing on the right leg with two NMES units. One unit was a Vectra Genisys® (VG) stimulator set to deliver the VMS burst™, a BMBPC with a carrier frequency of 1000 Hz, a phase duration of 400 microseconds, interphase and interpulse intervals of 100 microseconds, and a peak current output of 120 mA. The stimulation parameters of the VG stimulator were selected to closely match those of the KH program 6. Both stimulators delivered a biphasic square waveform for 6 seconds at a rate of 70 bursts (VG) or pulses per second (KH), via

2 channels. Ramp-up time was 1 second and ramp-down time was 0.5 seconds for both stimulators as well.

The VG utilized four round surface electrodes (Bodymed® Hudson, OH) with a diameter of 7.5 cms and a surface area of 44.2 cm^2 each for a total surface area of 176.7 cm^2. The electrodes for channel 2 were placed along the vastus medialis muscle. The distal electrode was positioned at 80% of the distance between the anterior superior iliac spine and the medial joint line of the knee, and the proximal electrode placed 15 cm above the distal. Channel 1 electrodes were placed along the vastus lateralis muscle; with the distal electrode positioned 2/3 of the distance between the anterior superior iliac spine and the lateral border of the patella, and the proximal electrode positioned 15 cm above the distal. The VG delivered the BMBPC as unidirectional current between the proximal and distal electrodes of each channel concurrently with a maximum current output of 120 mA (Figure 1).

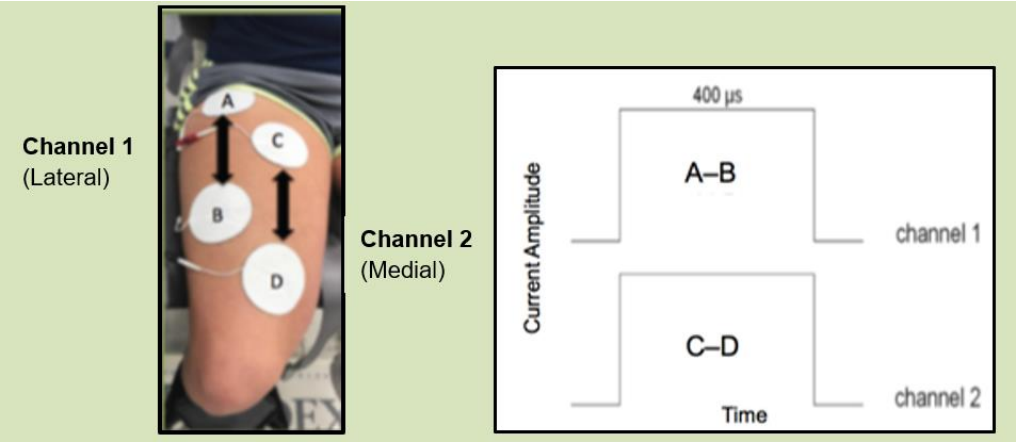

Figure 1. An image depicting the unidirectional pathway mechanism of the Vectra Genisys®.

The other NMES unit was the Kneehab™ XP Conductive Garment System that utilizes a multipath system with biphasic square pulsed current with phase durations of 100-400 µsec with a maximum current output of 70 mA. Stimulator parameters were set by selecting program 6 which consisted of electrical stimulation of 70 pulses per second, a ramp-up time of 1 second and a ramp-down time of .5 second. We used the manual trigger function to allow for the 6-second contractions as the program uses 10-second contractions with 50 second rests. The KH generates multiple dynamically changing pathways within single pulses, with a temporal shift between pairs of electrodes for the first channel utilizing electrodes A–C and A–D for the first 300 µs followed by A–B for the last 100 µs of each pulse (400 µs total) and for channel 2, 100 µs pulses between electrodes D-A, D-B and D-C.[6,16] A pictorial representation of the KH waveform is shown in Figure 2. Adhered to the inner surface of the KH sleeve are four reusable adhesive hydrogel electrodes having surface areas of 194 cm^2, 83 cm^2, 74 cm^2 and 66 cm^2 respectively for a total area of 417 cm^2.[2,15] Figure 3 shows a participant with the KH in place. We fitted each participant for the KH cuff during a preliminary meeting. We adjusted the electrode placement within the garment to accommodate the length and girth of the thigh as per the instructions accompanying the device.

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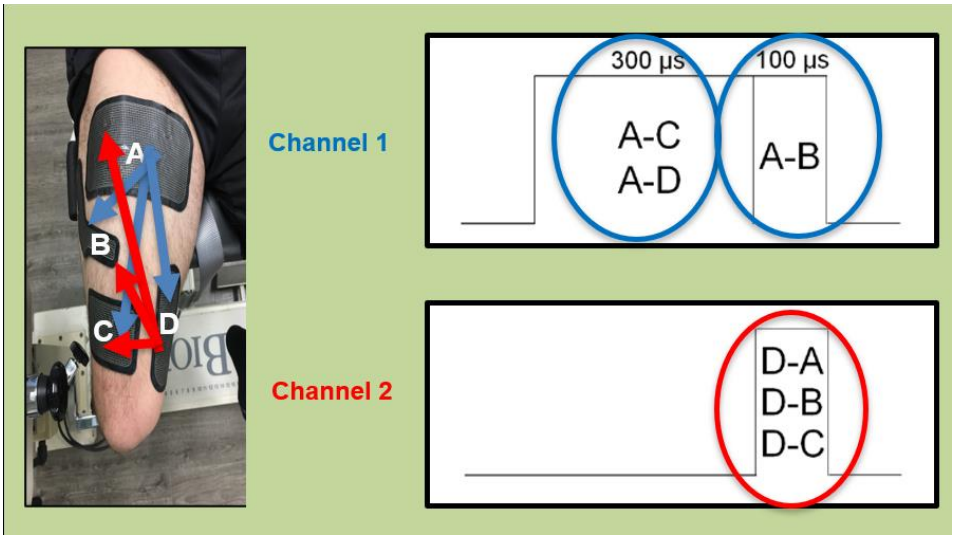

Figure 2. An image depicting the multipath system of the Kneehab™

Figure 3. Kneehab™ XP Conductive Garment System in place

Prior to testing, we recorded the participants' height, weight, and blood pressure. Participants then warmed up on a cycle ergometer for 5 minutes. Next, we positioned the participants in a Biodex electromechanical dynamometer to measure right knee extension muscle torque. Participants sat on the dynamometer with the knee flexed to 90 degrees, and we secured a pad to the anterior distal aspect of the lower leg approximately one inch superior to the ankle malleoli. We aligned the axis of rotation of the dynamometer lever arm with the lateral epicondyle of the femur. To determine the knee extensor maximum voluntary isometric torque (KEMVIT) participants performed a minimum of 3 maximal voluntary isometric contractions with verbal encouragement and 60 seconds of rest between each trial. If the peak torque produced during the third trial was more than 5% greater than the first two trials, participants continued to perform additional trials until the peak torque did not increase by more than 5% compared to the previous trials. The maximum peak torque produced during the contractions was used to normalize the peak

torque generated during the two NMES test conditions as a percentage of knee extensor maximal voluntary isometric torque (% KEMVIT). Following KEMVIT testing, based on a predetermined schedule of alternating conditions either the KH was donned, or four surface electrodes were placed over the quadriceps muscles of the anterior thigh for the VG.

We informed participants that the goal of the study was to measure how much torque their thigh muscles could produce with the two stimulators. During the stimulation, we instructed participants to "relax and let the stimulation make your muscle contract." An 11-point (0-10) numeric pain rating scale, where 0 represented "no pain" and 10 represented the "worst pain imaginable" was used. After each 6-second contraction we asked participants for a pain rating. We stopped testing when participants reached either their maximum acceptable pain level, or reported a 7 on the pain rating scale (which participants were aware would end the testing) or the stimulator reached its maximum output.

We increased the amount of current delivered in 10 mA increments for the VG (range 0 to 120 mA) and 10-unit increments for the KH (0 – 99 corresponding to a range of 0 to 70 mA) from contraction to contraction. Due to the way both of the stimulator's work, the intensity could only be increased when the current was flowing. Consequently, the stimulation intensity was increased to the next target value during a brief contraction, and then stopped for approximately a 60-second rest followed by delivery of a stimulation train for the full 6 seconds. Consequently, each brief intensity-setting train alternated with a full 6-second train from which the peak torque was recorded. We delivered the stimulation trains manually approximately every minute.

We then tested the other stimulator following a 5-minute rest period. During the testing, participants were blinded with respect to their muscle torque output. Following testing of the second stimulator, participants rested for 5 minutes and then performed the KEMVIT testing again. We asked participants to report perceived differences in comfort between the two devices.

Analysis was completed in Microsoft Office Excel 2016 and IBM SPSS (Statistical Package for the Social Sciences v. 24.0, IBM Corporation, Armonk, NY 10504). We set the level of significance for all analyses at $P < 0.05$. We used an analysis of variance (ANOVA) for crossover studies to analyze the electrically elicited isometric quadriceps torque produced at the maximum tolerated current amplitude, expressed as a percentage of maximal voluntary isometric torque, %KEMVIT. The factors in this model included participants, condition (BMBPC of the VG or BPC of the KH), and period (order of application: first or second). We used a paired t-test to compare the pre-KEMVIT to post-KEMVIT.

3. Results

Thirty participants completed the study. Many of the participants were students in a Doctor of Physical Therapy program who had prior exposure to electrical stimulation. Other participants were students in other programs or members of the community who had little or no prior exposure to electrical stimulation. All testing was done in a single session, there was no prior session to familiarize the participants with the NMES. We did not record the training status of the participants or ask them to avoid strenuous activity for some period of time prior to testing. We excluded two participants due to poor tolerance of NMES; therefore, we analyzed data for 28 participants (15 males, 13 females). The mean age of all participants was 23.6 years old with a range from 21 to 41 years old.

Concerning our primary dependent variable of %KEMVIT, an ANOVA for crossover studies yielded a significant effect, $P = 0.001$, for condition (BMBPC or KH), but no significant effect, $P = 0.582$, for period (device administered first or second). On average, the BMBPC yielded significantly greater %KEMVIT, mean = 38.1 ± 14.9, than the KH, mean = 29.3 ± 9.9. The effect of device on %KEMVIT is illustrated in Figure 4. A paired t-test revealed the pre-KEMVIT was significantly greater than the post-KEMVIT ($P < 0.001$). On

average, the pre-KEMVIT was 250.5 ± 33.2 Newton meters and the post-KEMVIT was 206.1 ± 25.6 Newton meters (Figure 5).

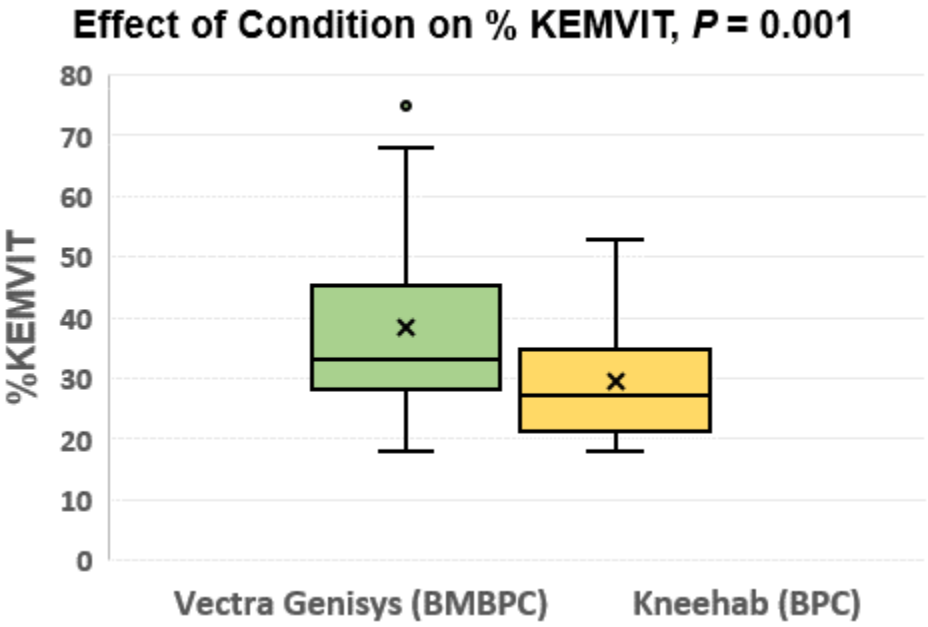

Figure 4. Effect of stimulation device on %KEVMIT

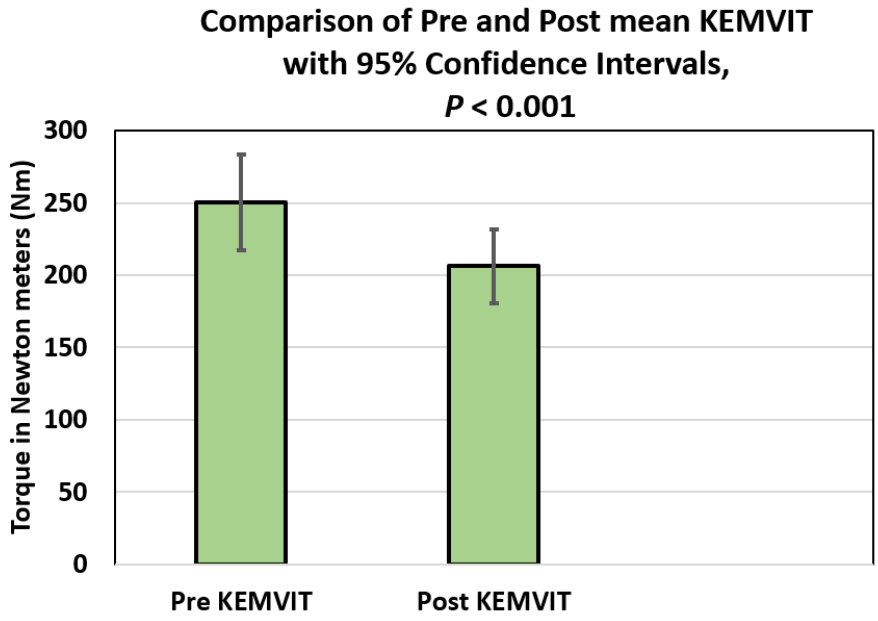

Figure 5. Comparison of pre and post stimulation KEMVITs

All participants (28/28) reached their maximum pain tolerance with the BMBPC delivered by the VG prior to reaching the maximum current output of the device. Only 4 participants reached their maximum tolerance using the KH, while the remaining 24 participants reached the maximum current output of the device first. Consequently, the pain ratings when testing was terminated were compared using a paired t-test. The pain

ratings for the KH were significantly lower (5.1 ± 1.2) than those of the BMBPC delivered by the VG (7.0 ± 0.2, $P < 0.001$). Twenty-three participants reported favoring the KH, 1 participant favored the BMBPC, and 4 participants stated no preference for either device. All 4 participants who reached their maximum tolerated current amplitude with both the VG and the KH reported preferring the KH.

4. Discussion

Our purpose in conducting this study was to compare the electrically elicited knee extensor muscle torques at the maximal level of discomfort participants were willing to tolerate between the 1000 Hz BMBPC of the VG and the BPC of the KH. We were not able to make this comparison because the KH lacked the ability to deliver sufficient current to reach 24 of the 28 participants' maximum tolerated current, whereas the BMBPC of the VG was able to reach all participants' maximum tolerated current. Consequently, while the comparison was between the maximum electrically elicited knee extensor torque produced by the two NMES stimulators this was always limited by discomfort for the BMBPC of the VG but was only the case for the BPC of the KH for 4 participants, with the other 24 limited by the KH current output. This finding is demonstrated by the significantly lower pain ratings reported in response to the BPC of the KH as compared to the BMBPC of the VG.

Our primary finding was that the BMBPC of the VG produced significantly greater electrically elicited knee extensor muscle torque than the BPC of the KH. This observation is in contrast to work by Maffiuletti, Vivodtzev, Minetto, and Place[6] and Morf, Wellauer, Casartelli and Maffiuletti[7] that demonstrated the multipath system of the KH stimulator was capable of producing greater knee extensor muscle torque than what they termed conventional NMES using unidirectional electrical stimulation. However, importantly, in both of those studies the KH was modified to be able to deliver a maximum current of 200 mA rather than the 70 mA of the commercially available KH unit used in this study. Maffiuletti, Vivodtzev, Minetto, and Place[6] reported the average maximum tolerated current amplitude with the KH was 92 ± 25 mA which is consistent with our observations that 70 mA is not enough current to reach the maximum tolerated level of discomfort for most persons with the KH. Another factor that may have contributed to the limited ability of the KH to reach participants' maximum tolerated current amplitude was a lower phase charge. At 70 mA the phase charge for the BMBPC of the VG was 28 μC per channel or 56 μC in total (Figure 1). At the same current output of 70mA for the BPC of the KH the phase charge for channel one was 21 μC for the first 300 μsec and 7 μC for the last 100 μsec while for channel 2 it was 7 μC for 100 μsec corresponding temporally with the final 100 μsec of channel 1 (Figure 2). Therefore, the total phase charge of the KH for both channels was 35 μC. This lower phase charge may have resulted in the recruitment of fewer motor units at a given current output level and therefore compromised the muscle torque produced.[17]

The only other study that compared the KH to a traditional unidirectional stimulator (Polystim, Biomedical Research Ltd., Galway, Ireland) is difficult to compare to this study due to significant methodological differences. Feil, Newell, Minogue, and Paessler[2] compared the unidirectional Polystim to the multipath KH as an adjunct to a standard rehabilitation therapy program following ACL reconstruction surgery. The electrical stimulation was superimposed on volitional isometric contractions during 3, 20-minute training sessions 5 days per week. Following 12 weeks of training the KH group as compared to the Polystim group and a control group that did not receive NMES produced greater gains in the strength of knee extensor muscles and greater improvements in multiple markers of functional improvement.[2] Of note, both the Polystim and KH were limited to a maximum current output of 70 mA.

Twenty-three out of 28 of the participants (82%) from the present study favored the BPC of the KH sleeve garment delivering multipath electrical stimulation in regards to comfort as compared to the BMBPC of the VG. This observation is not surprising given that only 4 of the participants reached their maximum tolerated current amplitude with the KH. However, the 4 participants that reached their maximum tolerated current amplitude with the BPC of the KH all reported a preference for that condition as compared to the BMBPC of the VG. Consequently, this study may support previous findings that multipath electrical stimulation is perceived as more comfortable than conventional unidirectional NMES.[6,7] Unfortunately, since the KH output was in arbitrary units of 0-99 and not in current amplitude we can't say if these participants tolerated more current with the multipath BPC of the KH or the BMBPC of the VG, although 3 of 4 actually had higher torque outputs from the BPC of the KH at the maximum tolerated current level. Another possible explanation for people finding the KH more comfortable is that the surface area of the electrodes of the KH were considerably greater than those used to deliver the BMBPC with the VG (417 cm^2 vs. 176.72 cm^2). Therefore, at any given current level the current density would have been lower for the KH, which is associated with less discomfort.[11]

The findings from this study may inform clinicians when making decisions regarding which NMES device to purchase or use as a strengthening adjunct during patient rehabilitation. Producing the greatest NMES elicited torque possible should be the goal in order to maximize the patients' strength gains.[1,11-13] Our observations suggest that the VG delivering 1000Hz BMBPC is a superior stimulator as compared to the KH for achieving this goal due to the limited current output of the KH.

This study is not without limitations. The design of the study to test both conditions during the same testing session was probably not ideal. Although there was no effect of period detected, the fact that the post testing KEMVITs were reduced indicates that the muscle force producing capacity was likely reduced by muscle fatigue in the course of the testing. This may have resulted in lower %KEMVITs than would have been produced otherwise. The participants in this study largely consisted of young, able-bodied college students. It may be the case that if the participants were older or recovering from knee injuries, and therefore likely to be relatively weak, the limited current output of the KH would be less of a limitation for recruiting a relatively high percentage of the force-generating capacity of their muscles.

5. Clinical Implications

In conclusion, for eliciting maximum knee extensor torque, the BMBPC delivered by the VG clinical stimulator was more effective than the KH garment stimulator. Although the KH was preferred by the majority of participants based on level of comfort, this was likely due to the lower muscle torques that were produced by the KH as participants reached the maximum current output level of the KH stimulator before reaching the maximum discomfort they were willing to tolerate. Therefore, clinicians need to be wary that when using the KH for patient populations, particularly relatively strong patient populations such as athletes, that the KH may compromise the efficacy of NMES strengthening.

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