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Adaptive FES Delivers Stimulation Amplitudes Based on Real-Time Gait Biomechanics

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ABSTRACT

Functional electrical stimulation (FES) is often used in post-stroke gait rehabilitation to decrease foot drop and increase forward propulsion. However, not all stroke survivors experience clinically meaningful improvements in gait function following training with FES. The purpose of this work was to develop and validate a novel adaptive FES (AFES) system to improve dorsiflexor and plantarflexor stimulation timing and iteratively adjust the stimulation amplitude at each stride based on measured gait biomechanics. Stimulation timing was determined by a series of bilateral footswitches. Stimulation amplitude was calculated based on measured dorsiflexion angle and peak propulsive force, where increased foot drop and decreased paretic propulsion resulted in increased stimulation amplitudes. Ten individuals with chronic post-stroke hemiparesis walked on an adaptive treadmill with adaptive FES for three two-minute trials. Stimulation was delivered at the correct time to the dorsiflexor muscles during 95% of strides, while stimulation was delivered to the plantarflexor muscles at the correct time during 84% of strides. Stimulation amplitudes were correctly calculated and delivered for all except two strides out of nearly 3000. The adaptive FES system responds to real-time gait biomechanics as intended, and further

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individualization to subject-specific impairments and rehabilitation goals may lead to improved rehabilitation outcomes.

INTRODUCTION

Stroke is one of the leading causes of disability in the United States, where someone has a stroke once every 40 seconds [1]. Stroke often leads to physical impairment, including hemiparesis, gait instability, and increased falls and mortality [1–3]. Hemiparesis can result in decreased forward propulsion in stroke survivors compared to unimpaired individuals. Decreased propulsion is linked to decreased walking speed [4], which is an indicator of poor mobility and a risk factor for falls and mortality [5]. Additionally, stroke survivors often experience foot drop due to hemiparesis, which increases the risk of falls and limits mobility [6].

Functional electrical stimulation (FES) is electrical impulses applied to the muscles to restore function, and is often used in post-stroke gait rehabilitation [3,6,7]. FES to the dorsiflexor (DF) muscles can decrease foot drop [6], while FES to the plantarflexor (PF) muscles can increase propulsive forces [8], thus addressing typical gait abnormalities post-stroke [2,4,9]. When used during walking trials, FES to the plantarflexors is applied during terminal stance to augment forward propulsion, while FES to the dorsiflexors is applied during swing phase to reduce foot drop [8,10–12]. FES delivery is typically triggered by a series of force sensors, or footswitches, placed on the soles of the feet to detect the phase of gait and determine the appropriate timing for stimulation [8,10–14]. However, these footswitches may trigger stimulation at the improper time; for example, when someone with foot drop strikes the ground with their

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toes instead of their heel, the footswitch configuration appears the same as during terminal stance, thus incorrectly triggering PF stimulation (Fig. 1). Additionally, FES protocols usually set the stimulation amplitudes at the beginning of the session, and they remain constant throughout the trial. However, gait and muscle activity change with activity and fatigue [15], so the amplitude of stimulation required to induce a given motor response at the beginning of the trial may not be constant for the entire trial, potentially decreasing the efficacy of the stimulation.

A few previous studies have developed FES protocols that use real-time measurements of dorsiflexion angle to iteratively update the amplitude of the DF stimulation [16–21]. These studies found improved peak dorsiflexion [16,19–21] and inversion/eversion [17,19] during swing phase as well as increased walking speed [18], However, these studies either only adjusted stimulation to the dorsiflexors [16,17,19–21] or based their adaptive stimulation adjustments on electromyography [18], which may not provide a direct measurement of propulsion.

The purpose of this work is to develop and validate an adaptive FES (AFES) system and protocol for post-stroke gait that will rectify the timing issues with current FES systems and iteratively adjust the stimulation amplitude to paretic DF and PF muscles at every stride. There are two tasks necessary to achieve this work:

(1) Develop an updated timing protocol that delivers stimulation with 95% temporal accuracy to the DF and PF muscles, focusing on ignoring forefoot strikes to minimize PF stimulation delivered during early stance.

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(2) Validate that the amplitude of DF and PF stimulation adjust proportionally to dorsiflexion angle error and peak propulsive force asymmetry, respectively, where increased error and asymmetry will increase the amplitude of the delivered stimulation at the next stride.

METHODS

Physical Equipment

A flowchart of the AFES system is presented in Fig. 2. A Digitimer DS8R stimulator is connected to a Digitimer D188 Remote Electrode Selector (Digitimer Ltd., Welwyn Garden City, England) that controls the stimulation to two sets of electrodes, one for the DF muscles and one for the PF muscles. A data acquisition (DAQ) board (USB-6341, National Instruments, Austin, TX, USA; 600 Hz) is connected to the stimulator to control amplitude and triggering, as well as to the remote electrode selector to control the selected set of electrodes. The DAQ also reads analog input data from a set of bilateral footswitches (Noraxon, Scottsdale, AZ, USA) on the heel and toe to determine the position of the feet throughout the gait cycle and trigger stimulation delivery at the correct time.

The laptop running the stimulation code is connected to an 8-camera motion capture system (Qualisys AB, Göteborg, Sweden; 100 Hz). Real-time data streaming sends six degree-of-freedom forces and moments from the instrumented treadmill (Bertec Corp., Columbus, OH, USA; 2000 Hz) as well as kinematic data from the marker set to the laptop for real-time calculation of peak forces and joint angles.

AFES Algorithm

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The AFES code, run in MATLAB (MathWorks, Natick, MA, USA), contains several subfunctions that run once, continuously, or when a certain event occurs to handle the different stimulation scenarios.

To set initial stimulation parameters, static stimulation trials are performed while the subject is stationary. First, the minimum stimulation limits are set to the sensory threshold of the subject, where the subject indicates they can first feel the stimulation. Then, the initial stimulation amplitudes are set by gradually increasing the amplitude until the desired motor response is achieved. The muscular response necessary for the DF stimulation is dorsiflexion to a neutral ankle angle while the subject is seated, and the muscular response for the PF stimulation is set while the subject is standing with most of the body weight on the nonparetic limb until the knee begins to flex and the heel begins to lift off the ground [8,16,22]. Following the initial stimulation amplitudes, the amplitude is again gradually increased to the pain threshold, where the subject indicates that the discomfort caused by the stimulation is no longer tolerable. The maximum stimulation limit is set to 5 mA below the pain threshold to ensure that the stimulation amplitude remains tolerable even if sensitivity increases with exercise [15]. For static stimulation trials, the stimulation is set to a 300-ms constant frequency train of 10 pulses at 30 Hz [8,13]. Additionally, the goal dorsiflexion angle is calculated as the dorsiflexion angle during quiet standing, which is approximately 90° [23].

Once the initial stimulation value and upper and lower limits are set, the dynamic stimulation trials begin. During dynamic stimulation trials, footswitch states are constantly monitored and used to determine if stimulation should be delivered. For DF

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stimulation, only current footswitch states are used to determine stimulation delivery. None of the paretic footswitches and any of the nonparetic footswitches should be on, indicating the paretic leg is in swing phase. For PF stimulation, both current and previous footswitch states are used to determine stimulation delivery. The previous footswitch state must include a paretic footswitch, indicating that the paretic leg is past initial contact and moving into terminal stance. Additionally, the paretic toe footswitch must be on. Finally, either the nonparetic heel or both nonparetic footswitches may be on, but are not required, as this allows the system to account for variable post-stroke gait patterns. The additional condition of the previous paretic footswitch state restricts the time when PF stimulation can be delivered to avoid stimulating the plantarflexors during a forefoot strike, which is common in individuals with foot drop (Fig. 1).

While the footswitches are constantly being monitored, real-time kinematic and kinetic data are streamed from the motion capture system to the laptop running the AFES code. Dorsiflexion angle error (DF_{Err}, Eq. (1)) is calculated as the percent difference between the measured peak dorsiflexion angle (DF_{Peak}) and the previously determined neutral goal dorsiflexion angle (DF_{Goal}):

$$DF_{Err} = \frac{DF_{Peak} - DF_{Goal}}{DF_{Goal}} \tag{1}$$

The “peak” dorsiflexion angle is the dorsiflexion angle at initial contact, which captures the effect of foot drop, as many individuals with stroke strike the ground with the forefoot instead of with the heel [23–26].

Then, the next (k+1) value of DF stimulation (DF, Eq. (2)) is calculated by adding the current (k) value to a change value, which is the maximum stimulation amplitude

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(DF_{Max}) weighted by the dorsiflexion angle error. Increases in dorsiflexion angle error result in increases in stimulation, which directly counteracts the increased error to promote healthy gait. For dorsiflexion angle errors smaller than 2%, the stimulation amplitude does not change, as this approximates healthy gait variability [23]. The calculated stimulation amplitude is decreased to remove the discontinuity around this threshold.

$$DF_{k+1} = DF_k + (DF_{Err} \times DF_{Max}) - (sign(DF_{Err}) \times 0.02 \times DF_{Max}) \quad (2)$$

To preserve subject safety and comfort, the stimulation amplitude is not permitted to change more than one quarter of the range between the minimum and maximum stimulation limits.

A similar procedure is used for the PF stimulation calculations. First, paretic and nonparetic peak anterior ground reaction forces (AGRF) are calculated as the maximum anterior-posterior ground reaction force. Then, peak AGRF asymmetry ($AGRF_{Asym}$, Eq. (3)) is calculated as the difference between the nonparetic ($AGRF_{NP}$) and paretic ($AGRF_P$) peak AGRF values divided by the sum. This form of symmetry index was chosen because it provides both positive and negative asymmetry values while avoiding bias [27], which will be used to increase and decrease the stimulation amplitude, respectively.

$$AGRF_{Asym} = \frac{AGRF_{NP} - AGRF_P}{AGRF_{NP} + AGRF_P} \quad (3)$$

Then, the next (k+1) value of PF stimulation (PF, Eq. (4)) is calculated by adding the current (k) value to a change value, which is the maximum stimulation amplitude (PF_{Max}) weighted by the peak AGRF asymmetry. Increases in peak AGRF asymmetry

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result in increases in stimulation, which directly counteracts the increased asymmetry to promote healthy gait. For peak AGRF asymmetries smaller than 5%, the stimulation amplitude does not change, as this approximates healthy gait variability [28,29]. The calculated stimulation amplitude is decreased to remove the discontinuity around this threshold.

$$PF_{k+1} = PF_k + \left(AGRF_{Asym} \times PF_{Max}\right) - \left(sign(AGRF_{Asym}) \times 0.05 \times PF_{Max}\right) \quad (4)$$

Following stimulation amplitude calculation, the same restriction on the change in amplitude is imposed as in the DF stimulation to maintain participant safety and comfort.

For both DF and PF stimulation, large values of angle error and asymmetry result in increased stimulation amplitude to correct for the larger asymmetry or error at the next stride. Additionally, smaller values of angle error and asymmetry result in smaller increases in stimulation amplitude. If the measured dorsiflexion angle is more dorsiflexed than the goal angle or if the paretic peak AGRF is larger than the nonparetic peak AGRF, the dorsiflexion angle error or peak AGRF asymmetry values will be negative, resulting in decreased stimulation amplitude. In this case, the current stimulation amplitude is more than is required to achieve the desired motor response, so to preserve participant comfort and minimize fatigue, the stimulation amplitude is decreased proportionally.

The stimulation delivered during the dynamic stimulation trials is a variable frequency train of 3 pulses at 200 Hz followed by 10 pulses at 30 Hz, as this pattern has

been found to reduce fatigue while maintaining motor response [8,13]. The pulse width is 200 µs and the phase is monophasic.

AFES System Validation

To ensure that the AFES system functions as intended, 10 individuals with chronic stroke (4 M, 6 F; 65 ± 5 years; 1.67 ± 0.07 m; 83.60 ± 9.61 kg; 88 ± 65 months post-stroke) were recruited through the University of Delaware's Stroke Registry database. There were three restrictions on level of function for participation in this study: participants needed to be able to walk continuously at their self-selected pace for six minutes, have passive ankle dorsiflexion to at least neutral, and have passive hip extension to at least 5°. Other inclusion and exclusion criteria were the same as in Ray et al. [10]. The study was approved by the University of Delaware's Institutional Review Board (IRB #1993248-3) and participants provided informed consent.

Participants were outfitted with 16 retroreflective markers on each leg for use with the motion capture system, eight of which were on anatomic landmarks and eight of which were on rigid tracking shells on the thigh and shank segments [30]. FES electrodes (Axelgaard Manufacturing Co., Fallbrook, CA, USA) were placed on the tibialis anterior and medial gastrocnemius [8], and minimum, initial, and maximum stimulation amplitudes were set as described previously. Footswitches were placed bilaterally on the heel and toe to control the timing of the stimulation [8,13].

Participants walked on the instrumented split-belt treadmill at their self-selected speed in the adaptive mode, where belt speed changed in real time based on user propulsive force, step length, and position [10,30]. Subjects wore a harness to prevent

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falling that provided no bodyweight support and were permitted to use the handrails with a "light touch" to maintain balance. Subjects were given up to five minutes of familiarization with the adaptive treadmill and up to two minutes of familiarization with the AFES system while walking at their comfortable pace. Once participants had achieved their desired speed and verbally indicated they could maintain that speed for two minutes, the stimulation was started. Stimulation amplitudes changed at each stride as described previously (Eqs. 2 and 4) and were recorded. Each participant performed three two-minute trials where stimulation amplitudes changed adaptively for the entire two-minute period [22]. Kinematic and kinetic data were recorded from the motion capture system.

Data and Statistical Analysis

Kinetic data were filtered with a fourth-order low-pass Butterworth filter with a cutoff frequency of 30 Hz [10,22]. Heel strike and toe-off times were determined based on when the vertical ground reaction force on each treadmill belt increased or decreased beyond a threshold of 20 N, respectively [31].

AFES Timing

To verify that the stimulation was delivered at the correct times during the gait cycle, the paretic leg kinetic data was segmented into individual gait cycles based on heel strike and toe-off. Then, each gait cycle was further divided into early stance, late stance, and swing phase. Early stance was when the anterior-posterior ground reaction force was negative, indicating braking, while late stance was when the anterior-posterior ground reaction force was positive, indicating the propulsive phase of stance.

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Swing phase was between toe-off and the following heel strike. The number of gait cycles that should have had stimulation was counted. Then, each gait cycle was examined to determine if and when stimulation was delivered within a 200 frame (0.1 second) buffer of each phase of gait. This buffer was implemented to account for differences between force plate and footswitch data as well as any lag in stimulation delivery.

Stimulation timing was categorized into four groups for both DF and PF stimulation: correct, missing, multiple instances, or incorrect. Correct stimulation delivery occurs if stimulation is delivered only at the correct time in the gait cycle (i.e., in swing phase for DF stimulation and terminal stance for PF stimulation). Gait cycles are classified as missing if no DF or PF stimulation is delivered during that gait cycle. If stimulation is delivered at both the correct and incorrect time in the gait cycle, then the gait cycle is classified as having multiple instances of stimulation (e.g., DF stimulation delivery in both terminal stance and swing phase or PF stimulation delivery in in both early stance and terminal stance). Finally, if stimulation is only delivered at the incorrect time, then the gait cycle was classified as having incorrect stimulation. Dorsiflexor stimulation during early stance was not included in this classification because many strides had residual DF stimulation during early stance while the system responded to initial contact to turn off the stimulation. Plantarflexor stimulation during swing phase was not classified as many strides had residual PF stimulation during early swing phase while the system responded to toe-off to turn off the stimulation. Finally, the number of strides with correct, missing, multiple instances, and incorrect stimulation were counted

and reported as percentages of the total number of gait cycles that should have had stimulation, which were then averaged across trials and subjects.

To further examine the timing of the stimulation and describe the latency of the system, the temporal delay between when the footswitches indicated stimulation should be delivered and when stimulation was actually delivered was calculated [31]. First, ideal stimulation onset and offset times were determined during each stride based on the recorded footswitch conditions. Then, the actual stimulation onset and offset times were determined during each stride based on when the stimulation was delivered. For each onset and offset time, the difference in seconds between ideal and actual stimulation delivery was calculated, where a positive difference indicates that the actual stimulation delivery was later, or delayed, relative to the ideal time, while a negative difference indicates that the actual stimulation delivery was early, or preceded the ideal time. This delay for each stimulation onset and offset was averaged across gait cycles, trials, and participants. All values are presented as mean ± standard deviation.

AFES Amplitude

To verify that the calculated and delivered stimulation amplitudes were correct based on the corresponding gait parameters, the dorsiflexion angle error or peak AGRF asymmetry were plotted against the change in stimulation amplitude from one stride to the next. Larger angle error and asymmetry were expected to result in larger changes in stimulation amplitude (Eqs. 2 and 4), and changes in stimulation amplitude were categorized based on stride-by-stride system performance (Fig. 3). The number of

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strides with each type of behavior were counted and presented as a percentage of the total number of strides. All values are presented as mean ± standard deviation.

RESULTS

One trial from each of three subjects was excluded from the analysis because the subjects were not able to complete the trial with the set stimulation limits. The following results include the remaining 27 two-minute walking trials.

AFES Timing

The AFES system delivered DF stimulation at the correct time to 95.83% of the strides, and zero strides were missing DF stimulation (Table 1). The remaining 4.17 ± 12.97% of strides had DF stimulation delivered at both the correct and incorrect times, indicating that relatively few strides had DF stimulation delivered twice. PF stimulation was delivered at the correct time in the gait cycle during 84.17 ± 25.35% of strides but was missing in 9.45 ± 22.37% of strides (Table 1). For 6.37 ± 11.42% of strides, stimulation was delivered during multiple instances (i.e., once incorrectly in early stance and once correctly in terminal stance). Finally, no strides received PF stimulation at only the incorrect time.

The difference in seconds between stimulation onset or offset and the footswitch conditions necessary for stimulation delivery was always positive, indicating that there was a slight delay in stimulation delivery (Table 1). DF stimulation onset had the longest delay at 68.17 ± 13.21 ms, while PF stimulation offset had the shortest delay at 33.30 ± 7.43 ms. In general, stimulation onset was longer than stimulation offset for

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both DF and PF stimulation, and PF stimulation was faster than DF stimulation for both onset and offset.

AFES Amplitude

All DF stimulation amplitudes were correctly calculated and delivered according to Eq. (2) (Table 2). Data from a single trial from a representative subject are shown in Fig. 3. On average, nearly 50% of strides fell into the "repeatedly hit limit" category, while 25.98 ± 0.28% of strides had small DF angle error and therefore no change in stimulation amplitude. Only 15.88 ± 0.12% of strides had a linear change in DF stimulation amplitude, while approximately 1% of strides had a smaller change in amplitude than calculated due to hitting the minimum or maximum stimulation amplitude limit. A total of 8.15 ± 0.21% of strides had no calculation performed due to marker dropout, and therefore no change in stimulation amplitude.

PF stimulation was delivered at the correct amplitude during 99.94% of strides (Table 2). Most strides, specifically 61.52 ± 0.35%, were strides where the stimulation repeatedly hit the minimum or maximum amplitude and therefore did not change between strides. An additional 23.97 ± 0.25% of strides had small peak AGRF asymmetry, so the stimulation amplitude again did not change from one stride to the next. Approximately 10% of strides fell into the linear region, where the stimulation amplitude was calculated using the peak AGRF asymmetry and Eq. (4). For less than five percent of strides, the stimulation amplitude changed, but not as much as calculated, as the calculated amplitude exceeded either the minimum or maximum limit, so the delivered amplitude was set to the limit. Next, 0.08 ± 0.00% of all strides were unable to

have updated PF stimulation amplitudes due to a lack of force plate data and defaulted to no change in stimulation amplitude. Finally, all strides had correctly calculated DF stimulation amplitudes, while only 0.06% of strides had incorrect PF stimulation amplitudes, indicating that amplitudes are correctly calculated and delivered for the vast majority of gait cycles.

DISCUSSION

The purpose of this study was to develop and validate a novel adaptive FES system to improve upon existing FES systems, particularly by updating the timing algorithm and changing the stimulation amplitude iteratively at each stride. The timing algorithm used in the AFES system delivered stimulation to the DF muscles correctly for 95% of strides and did not miss any strides, but delivered additional stimulation at incorrect times for approximately 4% of strides across all trials and subjects. Stimulation to the PF muscles was delivered at the correct time to 84% of strides and missed nearly 10% of strides, with approximately 6% of strides receiving stimulation at the incorrect time. Additionally, the AFES system responded to various real-time scenarios and correctly adjusted the stimulation amplitude for all except two of nearly 3000 strides. The success of the new timing and amplitude functions indicates that the AFES system functions as intended.

AFES Timing

The first task was to develop a novel timing algorithm to deliver stimulation with 95% temporal accuracy, with a focus on removing errant PF stimulation delivery during initial contact. Overall, this task was achieved successfully, as indicated by the large

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percentage of strides with correct PF stimulation delivery and the small percentages with no stimulation, multiple instances of stimulation, or incorrect PF stimulation delivery. With 84% of strides having correctly delivered PF stimulation and 95% of strides having correctly delivered DF stimulation, the AFES system can correctly detect terminal stance and swing phase most of the time, although the DF stimulation is delivered with considerably higher accuracy. While no strides were missing DF stimulation, 9.45% of strides were missing PF stimulation, suggesting that the DF stimulation timing algorithm may be more robust than the PF stimulation timing algorithm and that further updates to the PF footswitch conditions may be needed to account for variable post-stroke gait patterns to accurately detect terminal stance. Only 6% of strides had multiple instances of PF stimulation delivery during both early and terminal stance and 4.17% of strides had multiple instances of DF stimulation delivery during terminal stance and swing phase. Again, the DF stimulation timing algorithm performs slightly better, but both muscle groups received stimulation at the incorrect time in the gait cycle relatively few times, indicating that the stimulation timing algorithms perform well overall. For both PF and DF stimulation, no strides had stimulation delivered only at the incorrect time, further supporting the high level of performance. When PF or DF stimulation were delivered at the incorrect time, the footswitches briefly indicated that stimulation should be delivered, when in actuality, it was not the appropriate time in the gait cycle. In some cases, the sensitivity of the footswitches may have been too high, such that minor shifts in weight distribution caused changes in footswitch configurations and erroneous stimulation delivery. While

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adjusting the footswitch sensitivity is a possible solution, it may be difficult to find a balance between too sensitive and not sensitive enough, such that the footswitches register only gait events that are truly occurring.

The large percentage of strides with correctly timed stimulation suggest that the AFES system can deliver stimulation to two muscle groups with a high degree of temporal accuracy across a variety of post-stroke gait patterns, which are typically heterogeneous [32–34]. The system delivered DF stimulation correctly to 95.83% of strides, while 84.17% of strides received correct PF stimulation. This difference is likely due to difficulty placing the footswitches to appropriately detect terminal stance. Most participants received acceptable PF stimulation with the paretic heel and toe footswitches placed laterally, but a few participants benefitted from the paretic heel or toe footswitches being placed medially. In two subjects, adjusting the footswitch placement led to improved PF stimulation delivery in subsequent trials. However, as gait changes over time and as individuals post-stroke fatigue, the same footswitch configuration may not work for consecutive gait cycles or walking trials. To ensure stimulation delivery at every stride, it is important to monitor the footswitches during walking trials and adjust their placement as necessary. With these two issues caused by the footswitches, future FES systems may pursue additional improvements to the timing algorithm, such as inertial measurement units [35] or using solely the ground reaction forces. Removing the need for the footswitches in stimulation systems may improve the stimulation timing.

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To our knowledge, this is the first paper to evaluate the correctness of stimulation timing relative to subsections of the gait cycle. Prior work with similar AFES systems has evaluated the effect of variable stimulation amplitudes on dorsiflexion angle, but has not validated the gait event detection or stimulation timing [16]. Chen et al. (2018b) [36] developed a speed-adaptive DF stimulator system to decrease stimulation onset times during faster walking, but they did not evaluate the timing of the stimulation relative to the gait cycle. Chen et al. (2018a) [20] also developed an intensity- and duration-adaptive DF stimulator to iteratively update the stimulation amplitude, but again did not evaluate the stimulation onset and offset times relative to the gait cycle. Similarly, Chen et al. (2010) tested an EMG-based adaptive FES system for both DF and PF stimulation but did not validate the timing of stimulation delivery [18].

The delay in footswitch response was shorter than 70 ms for all scenarios. In general, turning the stimulation on took longer than turning the stimulation off. This is likely because turning the stimulation on required writing an array of data points for the variable frequency train, which is considerably more data than the single data point that was required to turn the stimulation off. Turning on the DF stimulation took the longest, at 68.17 ± 13.21 ms, almost 20 ms longer than turning on the PF stimulation. When a stride includes both PF and DF stimulation, the offset of PF stimulation and the onset of DF stimulation are sequential, with minimal time without stimulation in between, as terminal stance transitions rapidly into swing phase. In this case, the time to turn on the DF stimulation must also include the time to turn off the PF stimulation, as well as a brief period of no stimulation to ensure participant safety and comfort. However, the PF

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stimulation onset occurs after a relatively long period without stimulation, as no stimulation is delivered during early stance. Therefore, the increased duration of DF stimulation onset relative to PF stimulation onset makes sense.

Furthermore, the delay in stimulation onset and offset is within the range of values seen in the literature. The speed-adaptive system seen in Chen et al. (2018b) [36] had a delay between footswitch conditions and stimulation delivery between 260 ms and 360 ms. Skelly et al. developed an algorithm to detect heel strike and toe-off within 12% of the gait cycle, which is approximately 120 ms assuming a 1-second gait cycle [14,23,37]. The gait detection algorithm used in this paper is capable of both detecting gait events and delivering stimulation in approximately half the time suggested in Skelly et al. and considerably faster than that found in Chen et al. (2018b) Additionally, real-time gait detection algorithms specific to FES are suggested to be able to detect events and deliver stimulation in 50 ms to allow enough time for the stimulation to take effect [38]. Again, the AFES system was capable of detecting gait events and controlling the stimulator in a maximum of 68 ms, which is comparable to the recommended value, with only DF stimulation onset being longer than 50 ms. Because of the speed with which the AFES system can respond to real-time gait events, the AFES system may be well-suited for use in post-stroke gait rehabilitation to optimize the timing and duration of FES delivery.

AFES Amplitude

The second task was to validate that DF and PF stimulation amplitudes change proportionally to measured dorsiflexion angle error and peak AGRF asymmetry.

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Stimulation to both the DF and PF muscles was delivered at the correct amplitude for nearly all strides, thus indicating success at achieving the second task and that the AFES system works as intended. For both muscle groups, approximately 25% of strides had small DF angle error or small peak AGRF asymmetry and therefore no change in stimulation amplitude. These values suggest that either the subjects were capable of achieving a neutral dorsiflexion angle or symmetric peak AGRFs on their own or that the stimulation was successfully assisting them in achieving healthy gait patterns. Small dorsiflexion angle error values, small peak AGRF asymmetry values, and the resulting zero change in stimulation amplitude suggest that individuals post-stroke may be able to achieve healthy levels of dorsiflexion [23] and peak propulsive force asymmetry [28,29] with the AFES system.

Nearly 50% of strides had DF stimulation amplitudes that were repeatedly at the minimum or maximum value, while approximately 60% of strides had PF stimulation repeatedly at the limit. These proportions indicate that the stimulation amplitudes were remaining constant at the minimum or maximum limit for a large part of each trial. Stimulation at the minimum value indicates that subjects were able to achieve DF angles greater than neutral or paretic peak AGRF larger than nonparetic peak AGRF and therefore did not need the assistance of the stimulation. Amplitudes at the maximum value indicate persistent foot drop and peak AGRF asymmetry that the allowable levels of stimulation were not able to rectify. There were 11 trials at the DF minimum and 7 trials at the PF minimum, while there were 12 trials at the DF maximum and 17 trials at the PF maximum. Because more trials had stimulation repeatedly at the DF minimum

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than at the PF minimum, subjects were more able to reach and exceed the DF goal angle than the peak AGRF asymmetry goal. In most cases, a single subject either reached the maximum or the minimum for all trials, although three subjects had stimulation in multiple categories across their trials. Three trials for both DF and PF stimulation had continuously variable stimulation amplitudes throughout, indicating that the subject had some level of impairment but that the stimulation could help them achieve healthy gait patterns within the set limits.

Only 15% of strides had a linear change in DF stimulation amplitude relative to the previous stride, while 10% had a linear change in PF stimulation amplitude. While the AFES system is able to respond to real-time gait variations within trials and across subjects, reaching the minimum or maximum value within a short walking trial suggests that the AFES system may benefit from further individualization to maintain continuously variable stimulation amplitudes for the entire trial for all subjects. Some level of task-relevant variability promotes motor learning [39] and can even indicate healthy gait [40], suggesting that variable stimulation amplitudes may be beneficial over constant stimulation amplitudes. The AFES system used a simple linear equation to adjust stimulation amplitudes, but a more complex nonlinear equation may prevent the stimulation from reaching and remaining at the maximum or minimum values so quickly. Additionally, weighting factors could be used to modify the change in stimulation amplitude between consecutive strides. Individualizing these weighting factors to each participant may also increase the number of strides and subjects in the dynamic linear change region. Furthermore, adjusting the goal dorsiflexion angle and

peak AGRF asymmetry to each subject may increase the time spent in the linear region. For example, this AFES system used a neutral DF angle and perfect peak AGRF symmetry as indicators of healthy gait patterns. However, for individuals with more significant impairments, these goals may be unattainable even with the maximum allowable stimulation levels. Adjusting the goals to some level of improvement but not as far as unimpaired levels may further customize the AFES system and allow for more dynamic changes in stimulation amplitude.

A relatively small proportion of strides, approximately 1% for the DF stimulation and 5% for the PF stimulation, had changes in amplitude but not as large as calculated. This situation occurred when the stimulation amplitude was reaching either the minimum or maximum limit. As previously discussed, once the amplitude reached the minimum or maximum, it often remained there for the rest of the trial. In some cases, the amplitude would fluctuate away from the limit at later strides, but in most cases, it remained at the limit, which explains why the percentage of strides where the stimulation initially reached the limit is comparatively small. The difference in proportions between DF and PF stimulation amplitudes in this category is most likely due to individual subject variation in impairment level for dorsiflexion and paretic propulsion.

Additionally, there were very few cases where updated DF and PF stimulation amplitudes were not calculated due to marker dropout or poor force data streaming. In these cases, the stimulation amplitude was kept the same as the previous stride. Real-time marker labeling was done using an automatic identification of markers (AIM)

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model in Qualisys. For some of the earlier subjects, the AIM model was not as robust and therefore was not able to fully identify all markers. However, as additional subjects participated and more data was added to the AIM model, this issue occurred less frequently in later subjects. With more data continually being added to the AIM model, this issue is expected to decrease in frequency as the AFES system continues to be used.

Finally, there were very few strides with incorrect stimulation amplitudes—only two strides from one trial for one subject had incorrect PF amplitudes, while no DF amplitudes were incorrect. On rare occasions, the stimulation system may lag and fail to update stimulation amplitudes. In these cases, the stimulation amplitude from the previous stride is used to ensure consistency and that the stimulation remains at a reasonable level. While it is not ideal that the system may lag, once the system recovers, it returns to delivering dynamic stimulation amplitudes for the remainder of the trial. Furthermore, the system rarely lags, as only two strides out of nearly 3000 had incorrect stimulation amplitudes due to this issue, so the overall effect of any lagging is minor.

Two previous adaptive FES systems analyzed the performance of their respective systems in a stride-by-stride method, and they found that the initial stimulation amplitude and error between measured and goal dorsiflexion angle decreased as the trial progressed [16] and that dorsiflexion improved with the use of their adaptive stimulators [20]. However, Jiang et al.'s initial intensity was the maximum allowable intensity, so it makes sense that the stimulation amplitude continually decreased until reaching steady state [16]. Both Jiang et al. and Chen et al. (2018a) found that stimulation amplitudes increased or decreased based on the measured dorsiflexion

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angles [16,20]. Jiang et al. and Chen et al. (2018a) both only targeted dorsiflexion with their adaptive FES systems, while this system and the adaptive system presented in Chen et al (2010) targeted both DF and PF stimulation. However, Chen et al. (2010) did not present results about the amplitude adjustments used in their study. They did find that walking speed, stride length, and ankle range of motion improved after 12 weeks of gait training with their adaptive FES system [18]. These systems and the AFES system presented in this work all resulted in variable stimulation amplitudes proportional to the desired gait biomechanics, suggesting that this type of adaptive system could respond to real-time variations in post-stroke gait and be beneficial for rehabilitation.

Strengths

The main strength of this study and the AFES system is that the stimulation amplitude changes based on measured gait biomechanics. Most existing FES systems maintain a constant stimulation amplitude throughout [8,12,22,41] and are therefore unable to react to changes in gait due to fatigue or changes in muscle properties. Because the variable stimulation amplitudes were based on each subject's gait mechanics at each stride, the AFES system presented in this work represents a customized FES protocol. Customized rehabilitation technologies typically show increased benefits over standardized protocols, including human-in-the-loop systems [42–44], suggesting that this customized AFES system may be beneficial in rehabilitation.

An additional strength of this work is that the AFES system delivers adaptive stimulation to two muscle groups. Previous studies focused only on adaptive stimulation

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to the DF muscles to prevent foot drop [16,17,19], but PF weakness is commonly seen in post-stroke gait and rehabilitating propulsion is important for functional outcomes and community ambulation [4,11,45]. The few studies that have included adaptive PF stimulation have based their stimulation amplitudes on electromyography data, which, while important, can be confounded by FES signals and may have limited association with functional outcomes like walking speed [46,47].

Another strength of the AFES system is the ease with which the amplitude adjustment equations can be customized to better reflect individual rehabilitation goals. While the existing equations are simple and target only two gait parameters that are common in post-stroke gait, other gait parameters that may be more relevant to each person can easily be substituted into the equations to provide a more customized stimulation system.

Limitations

The primary limitation of this study is the reduced frequency of data available to the AFES system. The motion capture system records kinematic data at 100 Hz, but the AFES system could only read data at approximately 12.5 Hz to account for the additional time needed to process each frame of data before reading the next. While this does reduce the precision of kinematic and kinetic measures calculated in real time, this reduction in frequency was necessary to ensure continued real-time function of the system. Moreover, this reduced frequency did not impair the AFES system's ability to detect changes in dorsiflexion angle or propulsive force, as changes in both gait measurements were detected and the stimulation amplitude was changed accordingly.

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Therefore, the reduced frequency of data acquisition is not believed to have impacted the results.

Additionally, the AFES system does not run in true real time, as changes in stimulation calculated at one stride are implemented at the next stride. This is due to processing and hardware limitations, as the system could not detect changes in gait at each frame of data and adjust the stimulation amplitude correspondingly. Other adaptive FES systems [19] follow this same paradigm, and improvements to the system to make it truly real-time provide a clear avenue for future work and advancement of real-time adaptive FES.

Finally, the AFES system is currently only able to be used in a motion capture lab because of the required connections to an instrumented treadmill and motion capture system. This setup is likely not feasible for most rehabilitation programs due to the high cost of motion capture equipment and expertise required to run the system. Further work on the development of this system could include using inertial measurement units to measure DF angle and detect gait events and in-shoe force sensors to measure propulsive force [17,19,48,49], which would enhance portability and promote usage during activities of daily living to further improve mobility of individuals post-stroke.

CONCLUSIONS

In summary, the novel AFES system performed well in all trials with highly variable gait patterns in individuals post-stroke. Stimulation was delivered correctly during most gait cycles to both the DF and PF muscles, with only a few strides missing stimulation or having incorrectly timed stimulation delivery. Stimulation amplitudes

changed proportionally to the measured real-time gait biomechanics and stimulation was delivered with minimal latency, allowing for maximal effect. While this system uses a fairly simple equation to control stimulation amplitudes, the opportunity for further customization to different impairments, rehabilitation goals, and gait patterns makes the AFES system a promising new tool for post-stroke gait rehabilitation.

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NOMENCLATURE

AFES	Adaptive functional electrical stimulation
AGRF	Anterior ground reaction force
$AGRF_{Asym}$	Peak anterior-posterior ground reaction force asymmetry
$AGRF_{NP}$	Maximum anterior-posterior ground reaction force for the nonparetic leg
$AGRF_{P}$	Maximum anterior-posterior ground reaction force for the paretic leg
DAQ	Data acquisition

DF	Dorsiflexor
DF_{Err}	Dorsiflexion angle error
DF_{Goal}	Goal (neutral) dorsiflexion angle, defined during quiet standing
DF_{k}	Dorsiflexor stimulation amplitude at current stride
DF_{k+1}	Dorsiflexor stimulation amplitude at next stride
DF_{Max}	Maximum dorsiflexor stimulation amplitude
FES	Functional electrical stimulation
PF	Plantarflexor
PF_{k}	Plantarflexor stimulation amplitude at current stride
PF_{k+1}	Plantarflexor stimulation amplitude at next stride
PF_{Max}	Maximum plantarflexor stimulation amplitude

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Fig. Captions List

Fig. 1 Position of the paretic (black) and nonparetic (white) legs and feet during initial contact with the forefoot (top left) and terminal stance (top right) and the corresponding footswitch status (bottom, black = on). Identical footswitch states during initial contact and terminal stance may cause erroneous stimulation delivery to the plantarflexors at initial contact.

Fig. 2 Flowchart of the AFES system. Real-time kinematic and kinetic data are sent from the motion capture system to an independent laptop running the custom AFES code in MATLAB. Simultaneously, footswitch data are sent to the laptop via a data acquisition (DAQ) board. The kinematic and kinetic data are used to calculate updated stimulation amplitudes at each stride. The footswitch data are used to determine when stimulation should be delivered. The laptop sends signals to the stimulator and remote electrode selector via the DAQ to trigger stimulation, select the DF or PF electrode, and set the stimulation amplitude.

Fig. 3 Measured gait metric and the resultant change in stimulation amplitude. (A) Dorsiflexion angle error and the resultant change in DF stimulation amplitude for a representative subject. (B) Peak AGRF asymmetry and the resultant change in PF stimulation for a representative subject. Changes in stimulation amplitude were categorized into one of six groups: (1) small error or asymmetry (circles), (2) repeated strides at minimum or maximum

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limit (pluses), (3) linear change in stimulation (squares), (4) first stride at minimum or maximum limit or hit change threshold (triangles), (5) no calculated error or asymmetry (diamonds, points at the origin, although this subject does not have any), and (6) incorrect amplitude (stars, none for this subject). Groups 1-4 indicate correct stimulation amplitudes responding to various real-time gait biomechanics, while group 5 covers marker dropout or system lags where there is no real-time motion or force data. Group 6 is a catch-all for incorrect system behavior.

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Table Caption List

Table 1 Timing data for DF and PF stimulation. The percentage of strides (group mean ± standard deviation) with correct, missing, multiple instances, or incorrect stimulation timing is presented in the first four rows. The delay in milliseconds (group mean ± standard deviation) between the corresponding footswitch condition and stimulation onset or offset is presented in the final two rows.

Table 2 Percentage of strides (group mean ± standard deviation) in each trial in each category of amplitude calculation

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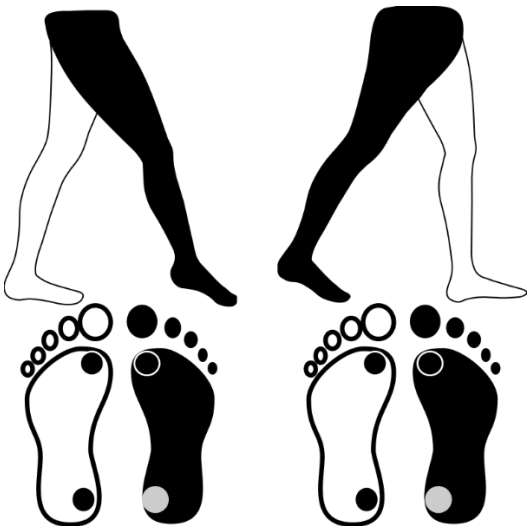
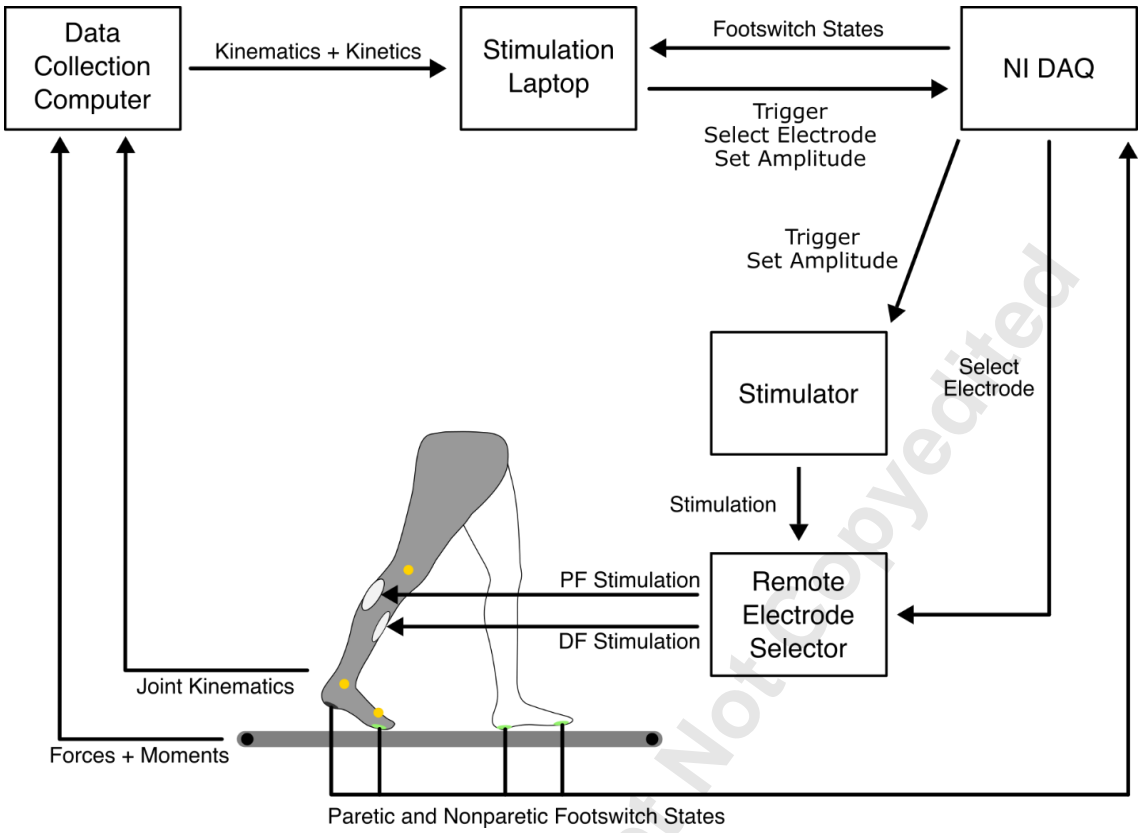
Fig.s





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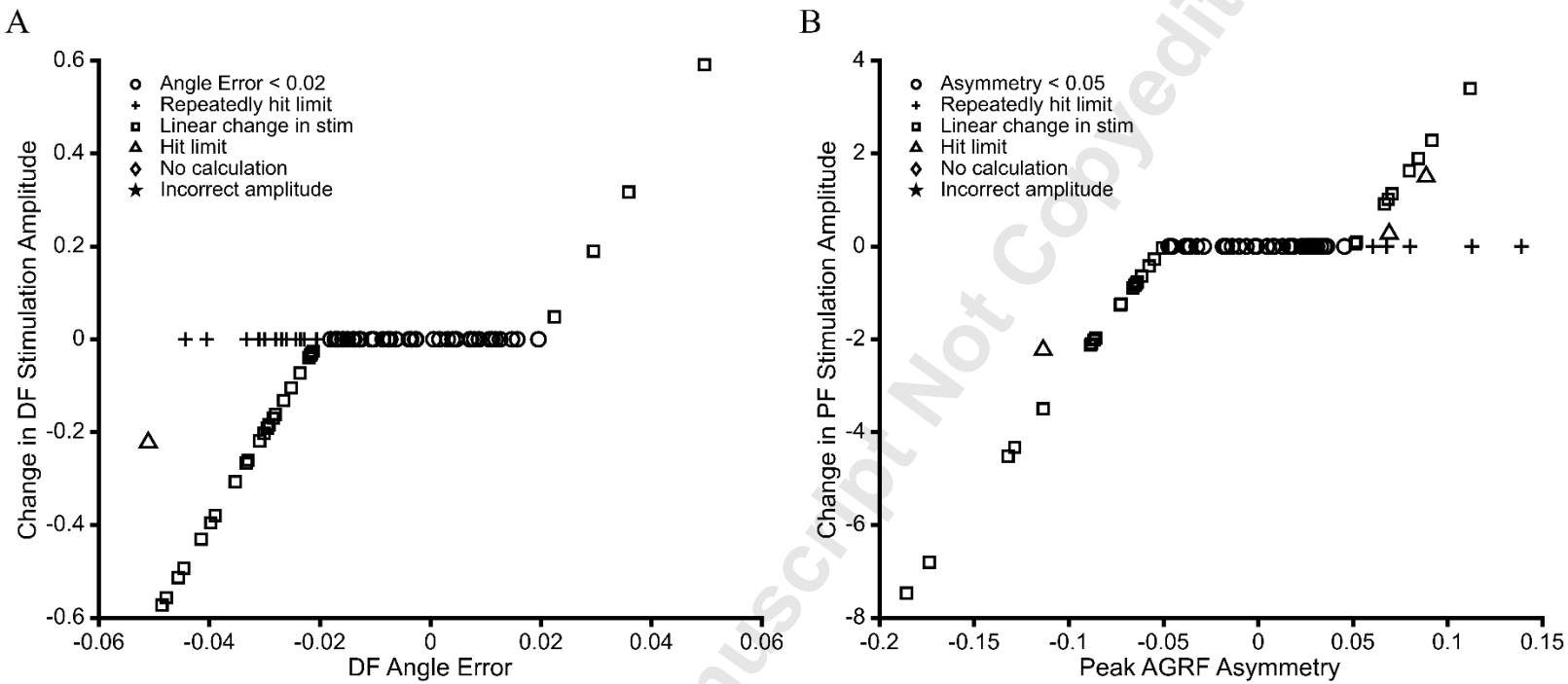

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Tables

	DF Stimulation	PF Stimulation
Correct (%)	95.83 ± 12.97	84.17 ± 25.35
Missing (%)	0.00 ± 0.00	9.45 ± 22.37
Multiple (%)	4.17 ± 12.97	6.37 ± 11.42
Incorrect (%)	0.00 ± 0.00	0.00 ± 0.00
On Delay (ms)	68.17 ± 13.21	48.69 ± 8.79
Off Delay (ms)	35.00 ± 7.58	33.30 ± 7.43

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	DF Stimulation	PF Stimulation
Small Asymmetry or Error (%)	25.98 ± 0.28	23.97 ± 0.25
Repeatedly Hit Limit (%)	49.03 ± 0.35	61.52 ± 0.35
Linear Change in Stim (%)	15.88 ± 0.12	10.12 ± 0.11
Hit Limit (%)	0.95 ± 0.01	4.26 ± 0.04
No Calculation (%)	8.15 ± 0.21	0.08 ± 0.00
Incorrect Amplitude (%)	0.00 ± 0.00	0.06 ± 0.00

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Editor's Checklist

This checklist is specific for the Journal of Medical Devices, in addition to the general author's checklist for all ASME journals. The completed checklist must be submitted as Supporting Information.

General

- ☑ The main text should be organized with the following main headings/sections: Abstract, Introduction, Methods, Results, Discussion (this may be combined together with the Results section as Results and Discussion), and Conclusions.
- ☑ If a manuscript is focused on developing a new method, most of the info on the new method should be included in the Results section.
- ☑ Subheadings are strongly encouraged under Methods, Results, and Discussion sections.
- ☑ All acronyms should be spelled out at their first appearance except in the manuscript title.
- ☑ All figures (and their panels for multi-panel figure), tables, and equations should be numbered in the same order as their appearance in the manuscript. For example, Fig. 1B must be mentioned after Fig. 1A in the manuscript.
- ☑ Cite papers published in this journal when appropriate
- ☑ No more than 10 figures in the main manuscript, although there is no limit on the number of figures in the Supplementary Materials
- ☑ No more than 2 Tables (except for review papers) in the main manuscript, although there is no limit on the number of tables in the Supplementary Materials.
- ☑ Ensure smooth transitions from sentence to sentence and from paragraph to paragraph.

Title (no more than ~25 words)

- ☑ The title is essentially a shorter version of the Abstract and focused on the most novel/unique/significant. methods and results reported in this work for its aimed applications, in terms of addressing the remaining challenges in the field.
- ☑ Acronyms may be used in title, but must be spelled out in the Abstract at first appearance.

Abstract (no more than ~250 words)

- ☑ The Abstract is a concise summary of the whole paper including Introduction, Methods, Results, Discussion, and Conclusions.
- ☑ No references should be cited in the Abstract.
- ☑ In one paragraph with no subheading
- ☑ The abstract should include information on:
  - ☑ What the major biomedical problem/disease relevant to this work is
  - ☑ What has been done and what challenge(s) remain that are to be addressed in this work
  - ☑ What the unique/new methods are for addressing the challenge(s) in this work
  - ☑ How well the challenge(s) can be addressed in this work (i.e., important results)
  - ☑ What the broad significance of this study is in one last sentence.
- ☑ Keywords (5-10) that are not in the title should be given.

Introduction (no more than ~1000 words)

- ☑ This is essentially the expanded version of the info for Abstract (except the last bullet point on broad significance) mentioned above.
- ☑ References must be cited to support any important statement regarding work published in the literature.
- ☑ No subheadings in this section
- ☑ Introduction should have more than one paragraph.

Methods

- ☑ All methods must be described in detail to the extent that they can be repeated by others, to ensure repeatability.
- ☑ Subheadings are used in this section to guide the reader.
- ☒ This work does not involve human subjects (or procuring human tissue from human subjects).
- ☑ This work involves human subjects (or procuring human tissue from human subjects):
  - ☑ A statement is given to inform that the human study was approved/exempted by a specific ethics committee in your institution.
  - ☑ In the above statement, the full name of the ethics committee is given followed by an acronym in parentheses (e.g., Institutional Review Board (IRB), etc.).
  - ☑ The approval/exempt # of the human study specific for this work is provided.

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- ☑ This work does not involve animal study.
- ☒ This work involves animal study:
  - ☒ A statement is given to inform that the animal study was approved/exempted by a specific ethics committee in your institution.
  - ☒ In the above statement, the full name of the ethics committee is given followed by an acronym in parentheses (e.g., Institutional Animal Care and Use Committee (IACUC), etc.).
  - ☒ The approval/exempt # of the animal study specific for this work is provided.
- ☑ A last section with the subheading "Statistical Analysis" is included to summarize the methods used for statistical analysis and the criteria used for being statistically significant, better, higher, etc., to ensure scientific rigor.
- ☒ No section on Statistical Analysis is included. Please justify briefly:

Results

- ☑ Subheadings are used to guide the reader.
- ☑ To ensure scientific rigor, all quantitative results are presented either as plots with error bars (standard deviation (SD)) in figures (preferred) or as mean +/- SD in tables. Standard error of mean (SEM) may be used. It should be made clear in the manuscript whether SD or SEM is used.
- ☑ The number (n) of independent experiments/animals/human subjects/tissue samples, etc., should be given in the figure or table caption, to ensure scientific rigor.
- ☑ Figures
  - ☑ A scale bar must be given for either each image or each group of images with the same scale bar in each figure.
  - ☑ The scale-bar size is either labeled clearly above each scale bar in the figure or described clearly in the figure caption.
  - ☑ The number of figures should match approximately with the number of subheadings in this section.
  - ☑ Plots, images, or sketches from the same experimental study or supporting the same point (e.g., given as subheadings in this section) should be consolidated into a multi-panel figure.
  - ☑ In captions of multi-panel figures, a brief overall summary of the figure in approximately one line is given before describing the different panels in the figure. This overall summary can be similar to the subheading if the number of figures follow the number of subheadings in this section.
  - ☑ All symbols/labels in a figure are explained in either the figure or its caption.
  - ☑ No figure (either in part or as a whole) of this paper is published elsewhere already.
  - ☑ Any component that is published already elsewhere must have permission, which must be made clear per the party who owns the copyright. The evidence showing permission was obtained must be submitted as Supporting Information.
- ☑ All figures (e.g., Fig. 1), all panels in multi-panel figures (e.g., Fig. 2g), and all tables (e.g., Table 1) must be cited in order.
- ☑ All claims of significant difference are supported by statistical analysis, to ensure scientific rigor.

Discussion (may be combined with the Results section)

- ☑ Minimize repeating things already stated in the Results section
- ☑ References must be cited to support any important statement regarding work published in the literature.
- ☑ Subheadings may be used but are not required.

Conclusions

- ☑ This section should summarize the major methods and results and conclude with a sentence on the broad significance of the methods and results.
- ☑ No references should be cited.
- ☑ In one paragraph with no subheading

Table of contents (TOC) graphic

- ☑ An original (i.e., made by the authors), color (if possible), and simple but informative TOC graphic is provided.
- ☑ The TOC graphic is a structure, graph, drawing, photograph, scheme, or combination of the aforementioned with minimal text.
- ☑ The TOC graphic can help capture the reader's attention and give readers a quick visual impression of the essence of the manuscript, when displayed with the paper title and abstract on the journal website.
- ☑ The TOC graphic is submitted as an image file.