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Design and Validation of Biofeedback:
Increases Active Range of Motion of the Ankle

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Increasing Active Range of Motion of the Ankle

By

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Design and Validation of Biofeedback:
Increasing Active Range of Motion of the Ankle

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Stroke patients can have spastic paresis of the lower leg, impeding an ankle which hinders gait. A novel orthosis has been developed which counteracts this impediment to the ankle. It is expected that gait training will improve stroke patients' use of the orthosis by increasing their ankle dynamics. Gait training with biofeedback, which is based on physiological signal, has been shown to be effective for stroke patients. The main design requirement for the biofeedback is that it facilitates learning of an increased active range of motion of the ankle. To fulfill this requirement the biofeedback is based on the maximum angle in plantar- and dorsiflexion during the swing phase of the impeded leg. In this research, the biofeedback is validated on healthy participants with an impeded right ankle performing five gait trials. First an unimpeded reference trial was conducted capturing normal gait. After which the participant's ankle was impeded. During the initial impeded trial the participant got accustomed to the impediment during gait. Then two trials with feedback were conducted followed by a retention trial without feedback. During the retention trial the effects the biofeedback has on the ankle dynamics are determined. The outcome measures were chosen to validate whether the biofeedback facilitated learning of an increased active range of motion of the ankle. The outcome measures were the increase of active range of motion of the ankle from the initial impeded trial to the retention trial and the error quotient. The error quotient is a measure showing to what extent the angles making up the active range of motion during a trial were the same as during the reference trial. The active range of motion of the ankle of participants increased ($p < 0.001$) from the initial impeded trial to the retention trial. Moreover a significant decrease in the error quotient of participants was found between the initial impeded trial and the first feedback trial ($p = 0.033$), second feedback trial ($p = 0.013$) and retention trial ($p = 0.020$). Therefore, the biofeedback facilitated learning of an increased active range of motion of the ankle to participants. Further research is required to determine how to best adapt the biofeedback such that it is suitable for use by stroke patients in daily life.

1 Introduction

A stroke[1] causes damage to part of the brain, resulting in permanent disability that makes it difficult to perform everyday tasks such as walking [1]. Spastic paresis of the lower leg affects up to 20% of all stroke patients [2]. Spastic paresis causes an abnormal plantarflexed neutral orientation with increased joint stiffness. This is caused by increased muscle tone in the calf and limits daily functioning of stroke patients [3]. Stroke patients with a paretic leg can regain their ability to walk by learning a compensatory gait pattern.

Gait is what the periodic pattern of walking is called. The typical gait pattern of stroke patients with a spastic paresis of the lower leg is called a hemiparetic gait. During each gait cycle, the leg performs a weight-bearing stance period and a progressive swing period [4]. A depiction of the gait cycle is given in figure 1. Two events required for efficient gait are push-off and toe clearance [5]. During push-off, swing leg velocity is generated by increasing plantarflexion at the beginning of the swing phase. Toe clearance is achieved mid-swing when the foot swings forward under the hip and clears the ground. The "Active Range of Motion of the ankle" (ARoM) of the ankle occurs during the swing phase and is defined by the maximum plantarflexion angle, occurring close to push-off, and the maximum dorsiflexion angle, occurring close to toe clearance.

Whenever push-off or toe clearance is not achieved, compensations are incorporated into the gait pattern. Stroke patients with a paretic leg are hindered in achieving toe clearance by dorsiflexing their impeded ankle, making gait laborious. Achieving toe clearance is made

[1] A glossary and list of acronyms can be found on page 12

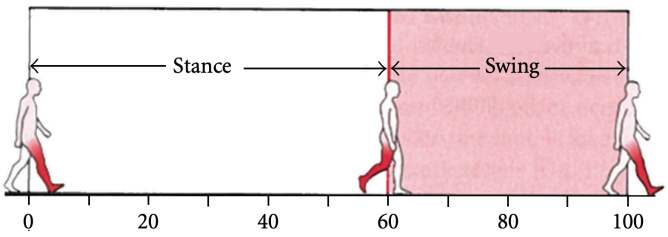

Figure 1: *Adapted from [6].* Simple representation of the gait cycle. The right leg (red) is the limb of interest. The stance period (white) is the first 60% of the cycle. The swing period (pink) is the remaining 40% of the cycle. Push-off occurs at 60% and toe clearance occurs at 80%. The active range of motion of the ankle is defined as the difference between the maximum plantarflexion and dorsiflexion angles during the swing period.

easier by keeping the foot of the paretic leg perpendicular to the lower leg using a rigid "Ankle-Foot Orthosis" (AFO). However, the stiffness of the rigid AFO diminishes push-off, which also leads to compensatory gait as less momentum is generated. Six months after stroke, the compensatory gait pattern has become ingrained [7] and recovery stagnates in a period called the chronic phase [8].

The compensatory gait pattern becomes ingrained because the control and execution of motor skills are impaired, making it difficult to learn new motor patterns [9]. In addition, stroke patients often have cognitive impairments and gait training is mentally demanding, making stroke patients easily overwhelmed [10, 11]. However, research has shown that stroke patients can reduce motor deficits by retraining motor patterns through repetitive motor tasks in the chronic phase [12, 13, 14].

After a stroke, motor learning with biofeedback is effective in improving gait and balance [12, 15]. Biofeedback is feedback that is based on physiological signals and provides insight into one's own physiological functioning [16]. The physiological signal can be a signal derived from any bodily function, such as a joint angle or blood oxygen level. The feedback parameter is the physiological signal on which biofeedback is based. The feedback parameter is compared to a reference signal to find the feedback score. The reference signal is derived from the same physiological quantity. The method of delivering the feedback parameter is called the feedback modality [16]. For example, the feedback parameter could be the angle of the knee joint and the feedback modality could be an audio cue. Biofeedback effectively delivers the intended information by choosing the appropriate feedback parameter and feedback modality.

Stroke patients may perceive biofeedback as overwhelming due to sensory and cognitive impairments [17]. Each stroke patient is unique in terms of the disabilities that they have and the severity of those disabilities. Therefore, additional patient-specific adjustments to the feedback design are required to ensure that stroke patient are not overwhelmed by the biofeedback [18]. This means that the biofeedback should be personalised for each stroke patient based on their disabilities. Therefore, the choice of feedback parameter and feedback modality determines whether biofeedback could be an effective rehabilitation tool for stroke patients during gait training.

The design of a novel "negative-stiffness Ankle-Foot Orthosis" (nAFO) aims to improve the gait pattern of stroke patients in the chronic phase with a spastic paresis by counteracting the increased passive stiffness of the ankle [19]. A depiction of the nAFO can be seen in figure 2. The nAFO negates the patient's increased joint stiffness using a spring-loaded hinge with an adjustable cam. Unlike a rigid AFO, the nAFO increases the sagittal range of motion of the paretic ankle during both passive manipulation and voluntary activation. Therefore, the researchers that made the nAFO hypothesised that the ARoM would be increased compared to hemiparetic gait with a rigid AFO. However, paretic stroke patients using the nAFO only marginally increased their ARoM compared to their ARoM with a rigid AFO.

While connected to a passive ankle manipulator [21] and wearing the nAFO, most stroke patients performed poorly in a tracking task based on their ankle angle. However, their performance improved significantly when they were provided with visual biofeedback based on the angle of their ankle joint. This finding led to

Figure 2: *Adapted from [20]. Left:* Negative-stiffness ankle-foot orthosis designed to compensate for increased joint stiffness in stroke patients with spastic paresis of the leg. The spring-loaded hinge with adjustable cam (yellow) connects the foot and brace sections (black). The in-shoe and calf cuff (beige) ensure user comfort. *Right:* Image of the orthosis in use.

the hypothesis that ARoM in hemiparetic gait with the nAFO could be increased through gait training using biofeedback.

An overview is given of the current state of research on biofeedback in stroke patients, and in particular its use in increasing ankle dynamics in hemiparetic gait[2]. Gait retraining in stroke patients using biofeedback has been shown to improve gait symmetry, speed and stability [23, 24, 25]. Furthermore, ankle dynamics can be increased using biofeedback, as increased ground reaction force at push-off and increased ARoM have been achieved [26, 27, 28]. Most commonly, gait retraining for stroke patients using biofeedback involves visual feedback based on kinematic parameters that focus on joint angles during specific phases of the gait cycle [29]. A visual feedback modality is shown to be capable of increasing ARoM during gait rehabilitation of stroke patients [30]. The joint angles and phases of gait can be obtained using wearable devices like inertial measurement units or angle sensors, or both [31, 32]. This makes it possible to use this biofeedback in daily life. Other common biofeedback methods targets muscle activation, gait parameters or forces generated during a phase of gait [33]. In terms of update timing of the feedback, performance is best when the feedback is updated while the task is being performed [34]. However, concurrent feedback creates a dependency on the biofeedback that degrades task performance compared to baseline performance [35, 36]. Terminal feedback is updated after task completion and has the best long-term results without creating a dependency on the feedback [35]. In summary, gait retraining of stroke patients using terminal biofeedback is effective in improving gait parameters and increasing ankle dynamics in hemiparetic gait without creating a dependency on the biofeedback.

Based on the current state of research, it is considered possible to develop biofeedback that can be used to train stroke patients to increase ARoM during gait with the nAFO. In addition to improving gait by learning the participant to increase ARoM, the requirements for biofeedback, in order of priority, are that the feedback modality is suitable for stroke patients. Furthermore, in order to remain independent, stroke patients should not become dependent on biofeedback to walk properly. Moreover, the biofeedback should not be overwhelming for the stroke patient in order to increase compliance. Finally, the biofeedback should be applicable to everyday life to allow for implementation in daily activities.

The scope of this study is limited by using healthy participants, having a general design and using a controlled environment. These constraints allow for a controlled and repeatable experiment. The design requirements for the biofeedback are determined by applying these constraints to the requirements listed previously. In summary, the design requirements of biofeedback subjected to the studies constraints are:

1. Learns to increase active ankle range of motion
2. Feedback modality: suitable for stroke patients
3. Users do not become dependent on biofeedback
4. Feedback parameter: can be acquired in daily life

[2]The sources used in this paragraph were found in the unpublished literature review by Hogenboom et al. [22]

The aim of this paper is to develop and validate biofeedback that meets the design requirements listed above. Healthy participants with an impeded ankle will perform an experiment involving gait trials with and without feedback. The results from this experiment are used in the outcome measures to validate whether the biofeedback facilitated learning of an increased active range of motion of the ankle. The first outcome measure is the change in ARoM between the reference gait trial with normal gait and impeded gait trials. The second outcome measure quantifies the extent to which a participant has learned from the biofeedback. In this paper, the design and validation of the biofeedback and are presented.

2 Methods

The methods consist of a section on the design of the biofeedback and a section on the validation of the biofeedback. The biofeedback design is explained by outlining how the design requirements are fulfilled and displaying the feedback parameter and its design. To validate that the biofeedback meets the design requirements, an experiment with gait trials based on a single group design was conducted in a motion capture lab.

2.1 Design of the Biofeedback

The design of 'the biofeedback' aimed to fulfil the five design requirements based on the current state of research outlined in the introduction. Firstly, the facilitation of learning an increased ARoM was to be fulfilled by selecting a feedback parameter and a reference signal which would facilitate learning and increase the ARoM. Both the feedback parameter and reference signal were based on the angles that make up the ARoM. These angles are the maximum angles in plantarflexion and dorsiflexion during the swing phase. The reference signals were the average angles in dorsiflexion and plantarflexion that make up the ARoM during normal gait. The feedback parameters were the angles making up the ARoM of the last two completed swing phases during impeded gait. An increased ARoM was aimed to be fulfilled as the reference signal had a larger ARoM than the ARoM demonstrated when participants were initially impeded. Learning was aimed to be fulfilled as a worse feedback score was the result of the feedback parameters deviating from the reference signal in either plantarflexion or dorsiflexion. Therefore, complying with the feedback score was aimed to facilitate learning of an increased ARoM. Secondly, a visual feedback modality was chosen which aimed to fulfil the requirement for the feedback modality to be suitable for stroke patients. Thirdly, to ensure participants remained independent of the biofeedback, the timing of the biofeedback was chosen to be based on terminal feedback by updating the biofeedback after the swing phase. Fourthly, the ability to acquire the feedback parameter in daily life was aimed to be fulfilled by choosing the angles that make up the ARoM of a step as the feedback parameter. Therefore, all the design requirements of biofeedback were aimed to be fulfilled by using the angles that make up the ARoM of a step as the feedback parameter, the average angles that make up the ARoM of a step during unimpeded gait as a reference and a visual feedback modality.

2.1.1 Feedback Parameter

Determining the feedback parameter, which was the angles making up the ARoM of the last two steps, the maximum angles in plantar- and dorsiflexion during the last two swing phases had to be determined in real-time. The swing period was discerned in real-time by finding the latest period during which the speed of the heel of the impeding shoe was consecutively above 0.5 m/s. The maximum plantar- and dorsiflexion angle are found by determining the maximum and minimum ankle angles during the period the heel speed is above the 0.5 m/s-threshold.

The biofeedback was made more stable by reducing the variability in included steps through taking a two-step average of the feedback parameter angles and by excluding steps with missing or unlabelled mark-

ers. To minimise the variability between steps, only steps within 1.5 meters from the centre were included to minimise the effects of the participant turning and accelerating. It was found during initial tests that the biofeedback was more stable by taking a two-step average of the feedback parameter angles and by excluding all steps which were made in the turning areas, had markers missing steps or had unlabeled markers were excluded.

2.1.2 Feedback Design

The feedback design consisted of a feedback template using the angles that make up the ARoM of normal gait and the feedback score resulting from the feedback parameter. The feedback design consisted of a feedback template on top of which the feedback score was displayed. The feedback template was based on the average of the angles that make up the ARoM of normal gait. The feedback score resulted from the feedback parameters. Examples of the feedback template, feedback score and feedback design are shown in figure 3[3]. The top half relates the ARoM's dorsiflexion angle and the bottom half relates to the ARoM's plantarflexion angle.

[3]Appendix 5.1 gives an in depth description of the feedback design is given and multiple examples of how the feedback design changes with different feedback scores.

The feedback template consisted of a diagram based on the reference ARoM during normal gait and two pictograms depicting phases of gait. The centre of the green-shaded areas were the reference angles. The size of the colour-shaded area was determined as a fraction of the distance from the black 0°-line to the reference angle. The pictograms improved understanding of the feedback design by conveying the phase of gait that determined the feedback score in each section.

The angles of the feedback parameter were used as the feedback score, so the upper and lower sections represented the two-step average angle in dorsiflexion and plantarflexion of the last two steps, respectively. The colour of each section of the feedback score was determined by the coloured area in which the outer boundary of the feedback score was located. A textual instruction to improve the section's feedback score was given whenever that section of the feedback score was not green.

2.2 Validation of the Biofeedback

2.2.1 Experimental Design

An experiment based on a single group design was conducted involving normal and impeded gait trials with

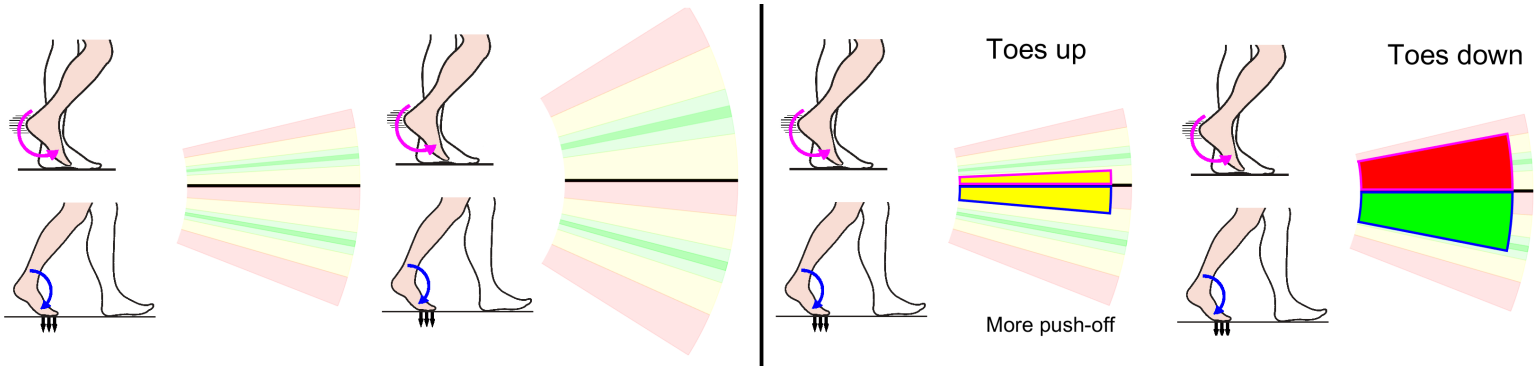

Figure 3: *The two left images* are examples of the feedback template with different reference angles. The centre of the green areas are the reference angles found in normal gait. The pictograms indicate in which phase of gait the upper and lower sections of the feedback score are determined. *The two right images* are examples of the feedback design. Both use the leftmost feedback template and have non-transparent coloured feedback scores based on the feedback parameter with accompanying instructions for improvement. The first example shows the result when both the maximum angle in dorsiflexion and plantarflexion are too small. The second example shows the result when the plantarflexion angle is correct but the dorsiflexion angle is too large.

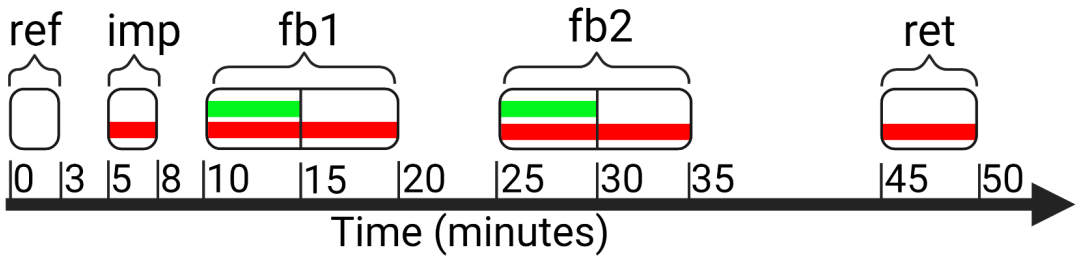

Figure 4: Experiment with five gait trials based on a single group design. The **red** stripe indicates impeded gait with an impeded ankle. The **green** stripe indicates gait with biofeedback. Firstly, normal gait was performed during a three minute reference trial (*ref*). Then, an impediment is imposed to the ankle. Secondly, the initial impeded trial (*imp*) is performed during 3 minutes. Thirdly, the first feedback trial (*fb1*) of 10 minutes was performed. Biofeedback was used for the first five minutes of this trial. Fourthly, this trial was repeated in the second feedback trial (*fb2*). Fifthly, after a ten minute break, the retention trial (*ret*) of five minutes is carried out.

and without feedback[4]. Breaks were taken between trials to ensure that fatigue did not affect performance. Figure 4 shows the experimental timeline. On arrival, participants gave informed consent and the experimental protocol and biofeedback were explained[5]. Furthermore, participants were instructed to walk up and down the centre of the walkway in their preferred gait and turn around in the turning areas while trying to achieve the best feedback score. A good score was explained to be when both sections of the biofeedback were green. The ARoM during normal gait was determined during the reference trial. Then, the participant accustomed their gait to ankle impediment. After which, the 2 impeded trials with biofeedback were conducted. Lastly, a retention trial without feedback was conducted.

2.2.2 Ankle Impeding Shoe

An 'impeding shoe' was used to unilaterally reduce participants' ARoM by impeding their right ankle[6]. An embedded frame was used to attach a gas spring to the impeding shoe. The gas spring was attached to the lower leg via a shin guard such that when the gas spring was fully extended the ankle was in 35° plantarflexion. At rest, the gas spring exerted a force of 80 N, a damping coefficient of $7 * 10^2$ Ns/m and the moment arm varied between 0.05 m and 0.15 m over the range of motion. Participants were affected differently by the impeding shoe as the moment arm was different in the same ankle orientation because of differences in lower leg length and shoe size. However, this was inconsequential as wearing the impeding shoe during initial tests resulted in a decreased ARoM.

Figure 5: Impeding shoe which decreases active ankle range of motion by applying a force (80N) to the shin and foot when retracted and by damping ($7 * 10^2$ Ns/m). The shin guard and embedded frame ensured that no excessive pressure was applied. The shoes and gas spring rod were interchangeable to ensure a personalised fit for each participant.

2.2.3 Set-up & Participants

The experimental set-up was a 6 meter long walkway with monitors at either end. Each turning area extended one meter from each monitor. Reflective markers were

[4] In appendix 6 a detailed description of the experiment protocol is given.

[5] The informed consent forms and biofeedback explanation can be found in appendices 8 & 5.2

[6] Device report of the impeding shoe in appendix 7

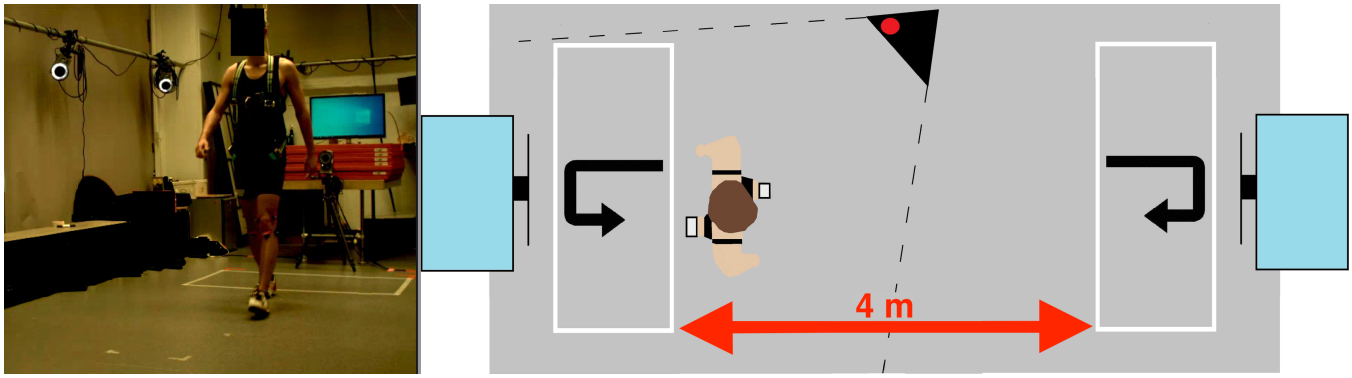

Figure 6: *Left:* Participant in the motion capture lab wearing experimental clothing, a safety harness and reflective markers. *Right:* An illustration of the experimental set-up. The triangle represents the camera that captured the image on the left. Monitors capable of displaying the biofeedback were placed at each end of the 6 meter walkway. The white boxes with the arrow are the turning areas. The distance between the turning areas is 4 meters.

tracked in the walkway using a motion capture system from Qualisys® consisted of two 24 Hz video cameras and twelve 100 Hz marker tracking cameras. Figure 6 contains an image and illustration of the motion capture lab.

Leardini et al's [37] static lower body marker model was used to track the body segments. This marker model contains 26 markers and can be seen in figure 7. The foot markers were placed directly on the impeding shoe. The position and label of each marker was determined in real-time by processing the marker position data using the Qualisys Track Manager® software program.

The sagittal ankle angle that was used to determine the feedback parameters and the outcome measures is shown in figure 7. The ankle angle signal used to determine the feedback parameters was derived using the real-time position data of the markers of the right lower leg and foot in Matlab® [38]. This ankle angle signal could not be calculated whenever a marker was missing or not labeled. During post-processing, an improved ankle angle signal was acquired from the motion capture analysis software 'Visual3D' Professional™. No documentation is provided how Visual3D is capable of calculating the ankle angle. However, a common method of reconstructing marker position is through interpolation [39]. The improved ankle angle signal from Visual3D was used to determine the results.

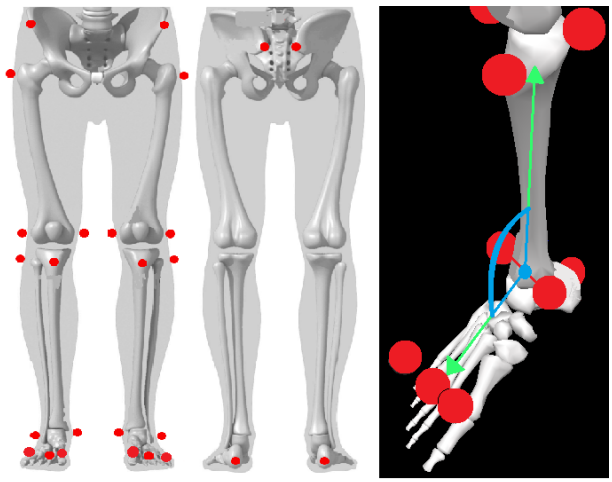

Figure 7: *Left:* Marker model from Leardini et al. [37]. The markers are shown as red dots. The foot markers were placed on the shoes. At least three markers are placed on each segment. *Right:* Ankle angle [38] (blue) used to determine the feedback parameter for biofeedback.

All 13 participants were fully informed of the experimental procedures and were healthy adults (12 males, 1 female) of age 23 ± 3[7]. Participants wore a harness to prevent falls, as shown in figure 6. Participants were excluded if they had a physical condition that affected their gait.

[7]See appendix 8 for the informed consent forms and appendix 5.2 for the explanation of the feedback provided to participants.

2.2.4 Gait Cycle: Normalised Joint Angles

The joint angles were normalised over the gait cycles. The gait cycles were found based on the instances of heel strike of the foot wearing the impeding shoe. Heel strike was determined by the vertical velocity of the midfoot [40]. Toe clearance was determined by finding the local minimum in the vertical height of the fifth metatarsal head between toe-off and heel strike [41]. The joint angle signals were normalised from 0 to 100% over the gait cycle. The normalised joint angle signals were used to determine the mean and standard deviation of joint angles over the gait cycle.

2.2.5 Outcome Measures

The extent to which the biofeedback facilitated learning of an increased ARoM was assessed using the outcome measures. The increase in ARoM was assessed by determining the change in ARoM between impeded trials. The extent of learning was quantified by determining an error quotient for each impeded trial and comparing them.

Both outcome measures used the angles that make up the ARoM of each step. These angles were determined from the ankle angle signal acquired through Visual3D. By including only steps within 1.5 meters from the centre, the same steps were assessed as those used to generate the feedback score.

Change in Active Ankle Range of Motion

To assess whether gait training with biofeedback was able to increase the participants' ARoM, the change in average ARoM from the initial impeded trial to the retention trial was determined. Furthermore, the effect of the impeding shoe on the ARoM was determined by assessing the difference in ARoM between the reference trial and the initial impeded trial. Lastly, to ensure the ARoM was stable and no learning occurred at the end of the initial impeded trial the difference in ARoM between the first and second half of the initial impeded trial was determined.

Error Quotient

The extent to which learning occurred during gait training with the biofeedback was determined by comparing the error quotients of the impeded trials. The error quotient quantifies performance by comparing the average angles that make up the ARoM of the reference trial to the angles making up the ARoM of the impeded trials:

$$E_{q,it} = \frac{|d_{ref} - d_{it}| + |p_{ref} - p_{it}|}{d_{ref} + p_{ref}} \tag{1}$$

Equation 1 gives the error quotient E_q. The variables d and p denote the average maximum angle in dorsiflexion and plantarflexion during swing within a trial, respectively. The subscript *ref* denotes the reference trial and it denotes the impeded gait trial of interest. The higher the error quotient, the greater the difference between the angles of the reference and the impeded trial of interest. The extent of learning was quantified by comparing the error quotients within subjects between the impeded trials.

Statistical Analysis

Two-tailed one-sample t-tests ($p < 0.05$) were used to to compare the changes in ARoM for significance during the reference trial to the initial impeded trial, the first to the second half of the initial impeded trial and the initial impeded trial to the retention trial. The error quotient of the trials were tested for significance using repeated measures analysis of variance ($p < 0.05$) on the 4 impeded conditions for all participants. Mauchly's sphericity test is used to check whether the assumption of sphericity holds. The Greenhouse-Geisser correction is used in case of lack of sphericity. Pairwise comparisons of the conditions with reduced type 1 errors are made by using the Bonferroni correction [42].

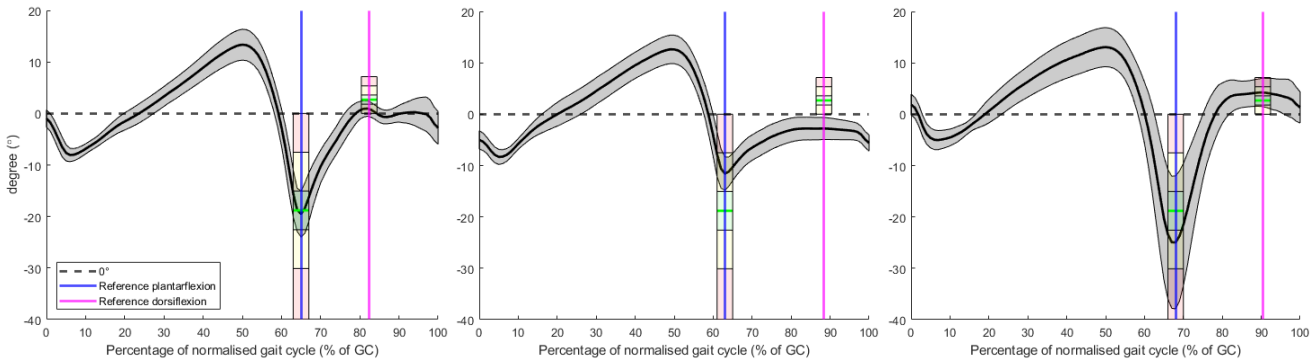

Figure 8: Normalised ankle angles over the gait cycle of one participant during the *Left:* reference trial, *Middle:* initial impeded trial and *Right:* retention trial. The thick black line is the average ankle angle with the standard deviation as outer bounds of the grey area. The blue and magenta vertical lines denote the moment with maximum plantarflexion and dorsiflexion, respectively. The coloured areas are a representation of the feedback template.

3 Results

Figures 8 and 9 are representative examples of how the biofeedback affected the ankle angles. Figure 8 demonstrates the effect of the impeding shoe and biofeedback through the participant's normalised ankle angle during the reference-, the initial impeded- and the retention trial. Figure 9 shows one participant's feedback parameters during the second feedback trial.

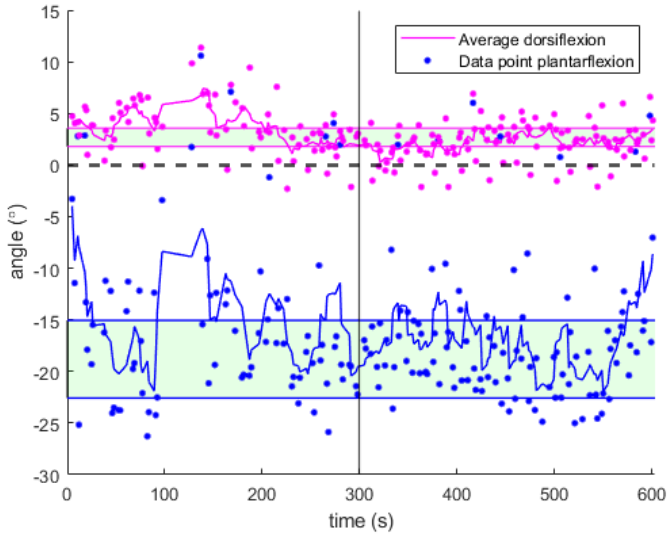

Figure 9: The feedback parameters' angles used during a participant's second feedback trial. The dorsiflexion angles and reference are in magenta. The plantarflexion angle and reference are in blue. The individual data points are shown as well as a moving average of six data points. The vertical black line indicates the time during the trial when the biofeedback was switched off.

3.1 Change in Active Ankle Range of Motion

The change in ARoM from the reference trial to impeded trials can be seen in figure 10. The ARoM during the first impeded trial is reduced ($p < 0.001$) compared to the reference trial. The ARoM was stable during the initial impeded trial as the average ARoM during the first and second half of the trial are not significantly different ($p = 0.051$). There is an increase ($p < 0.001$) in ARoM from the initial impeded- to the retention trial.

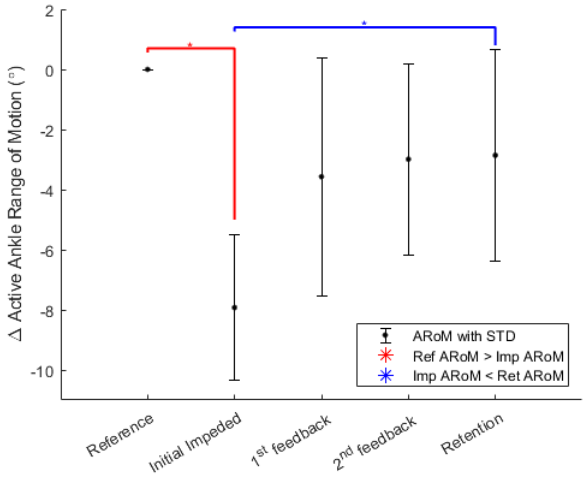

Figure 10: The average change between participants in active ankle range of motion with standard deviation (STD) from reference trial to impeded trials with standard deviation between participants. The reference trial is greater ($p < 0.001$) than the initial impeded trial. The initial impeded trial is smaller ($p < 0.001$) than the retention trial.

3.2 Error Quotient

Figure 11 shows the average error quotient for each impeded trial. One participant performed exceptionally poorly on the retention trial due to problems with the fit of the impeding shoe during that trial. This data point is therefore excluded from the results. The Greenhouse-Geisser correction had to be applied to assume sphericity, which is an assumption that is required to perform repeated measures analysis of variance, as Mauchly's sphericity test was significant ($p = 0.027$). By applying the Bonferroni correction type 1 errors were reduced. A learning effect is observed as the error quotients decreased from the initial impeded trial to the later impeded trials, as can be seen in figure 11.

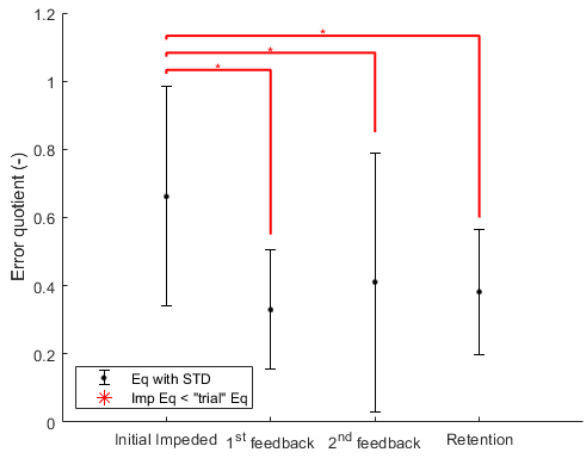

Figure 11: The average error quotient between participants with standard deviation (STD) during the impeded trials. The initial impeded trial is larger than the first feedback trial ($p = 0.033$), the second feedback trial ($p = 0.013$) and the retention trial ($p = 0.020$). No differences are found between the first feedback trial, second feedback trial and retention trial (all $p = 1.000$).

4 Discussion

The change of ARoM from the reference trial to the impeded trials and error quotients are used as outcome measures to determine whether the design requirement of facilitating learning of an increased ARoM is fulfilled. During the retention trial the plantarflexion angle was increased at push-off and the dorsiflexion angle was increased at toe clearance by the biofeedback as the ARoM increased and the error quotient decreases in later impeded trials. Furthermore, the participants remained independent as the biofeedback facilitated learning because the angles that make up the ARoM during the retention trial are closer to the angles that make up the ARoM during normal gait than during the first impeded trial because the error quotient was lower. This means that the participants did not become dependant on the biofeedback to retain the increased ARoM. Therefore, the design requirements of facilitating learning of an increased ARoM and keeping participants independent are fulfilled..

The biofeedback employed ankle angles as feedback parameters which are acquirable in daily life [31, 32] and a visual feedback modality which is used most with stroke patients [30]. However, a requirement to optimise the biofeedback's effectiveness for stroke patients, is the personalisation of the feedback modality or design, or both, based on the stroke patients disability.

The influence the biofeedback has on the gait pattern remains to be researched. A myriad of outcome measures exist to quantify gait patterns. However, a typical evaluation of gait with these outcome measures is complicated and the data interpretation is difficult [43]. To gain more insight, summary measures which represent the quality of gait in a single number can be used alongside the typical evaluation [44, 45]. In these summary measures the overall gait pattern is regarded causing insight into specific instances of gait to be lost. An outcome measure has been derived to quantify toe clearance [46, 47]. In future research, a specific summary measure could be developed which incorporates a toe clearance outcome measure and an outcome measure for push-off to give insight into compensation patterns while simplifying the analysis.

The impeding shoe altered every participant's gait pattern as ARoM is reduced with respect to the ARoM during normal gait. During the initial impeded trial, the participants gait pattern came to an equilibrium be-

fore reaching the end of the trial as the ARoM during the first and second half of the trial were not different. Which means that by using the impeding shoe during gait, participants ankle movement was similarly reduced as with stroke patients.

The biofeedback had periods where it failed to update, due to markers not being detected or the motion capture system mislabeling them. Marker movement on the shoes was found to be the cause for the failure in automatic marker identification. Additionally, these markers occasionally fell of the shoe. To address this, researchers in the past have used better marker placement by creating holes in the shoes [48].

Other influences on the methods included differences in the participants' endurance of the tibialis anterior and differences in task difficulty. Participants with a stronger tibialis anterior muscle experienced less impact from the impeding shoe as it was the only muscle that could counteract the force applied by the impeding shoe. The task difficulty was different as the reference angles, acquired during normal gait, each participant had to train towards was different. Both the difference in tibialis anterior endurance and task difficulty had an impact on the participants capability to improve their feedback score.

Employing the biofeedback on stroke patients wearing the nAFO looks to be promising as the biofeedback was able to increase ARoM of healthy participants. However, a better understanding is needed of whether stroke patients will be overwhelmed by biofeedback and how biofeedback can be integrated into daily life. A preliminary test with stroke patients is necessary to determine if the complexity of the biofeedback will be overwhelming for them. Additionally, the general design of the biofeedback does not allow for personalisation based on the specific disabilities of the stroke patient, which could contribute to its potential to overwhelm. Incorporating the biofeedback into daily life presents some challenges. The reference signal used in the study was acquired from gait in a controlled environment, but in daily life people exhibit many types of gait influenced by activities and the environment [49]. A more complex reference signal may be necessary to provide adequate feedback in these complex and varied everyday scenarios. Additionally, the visual design of the biofeedback may not be suitable for use in daily life, and other types of feedback modalities may need to be considered to make it more practical for daily use. Which means that further research is required before the biofeedback could effectively be employed in stroke patients' daily life.

In conclusion, the presented biofeedback facilitated learning of an increased ARoM, as evidenced by the increased ARoM and the improvement in the error quotient from the initial impeded trial to the retention trial. Based on the literature the visual feedback modality is suitable for stroke patients and the feedback parameter can be acquired in daily life. Further research is required to determine whether the biofeedback is overwhelming the stroke patients, in what way to personalise the biofeedback based on the specific disabilities of the stroke patient and how to incorporate the biofeedback into daily life.

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Acronyms

ARoM Active Range of Motion of the ankle
AFO Ankle-Foot Orthosis
nAFO negative-stiffness Ankle-Foot Orthosis
STD STandard Deviation

Glossary

Active Range of Motion of the ankle: the range of motion during the swing phase of gait
Ankle-Foot Orthosis: a device designed to support the ankle and foot during walking
Ankle: the joint in between the foot and the lower leg the foot to the leg
Ailment: a health problem or illness
Biofeedback: feedback based on a physiological signal
Bonferroni correction: a statistical method used to control for Type I errors in multiple comparisons
Cam: a mechanical mechanism which converts rotary motion into linear motion
Compliance: the extent to which a participants follows the instructions of a feedback system
Chronic phase: period after the onset of stroke when recovery stagnates
Damping coefficient: a unit showing the damping force exerted for different speeds
Dorsiflexion: movement of the ankle joint that brings the foot closer to the lower leg
Disability: a physical or mental impairment that limits a person's ability to carry out normal daily activities
Feedback modality: the method by which feedback is delivered
Feedback parameter: the signal that is provided as feedback
Feedback, Concurrent: feedback delivered in real-time while the task is being performed
Feedback design: The workings of the feedback based on its design, feedback parameter and feedback modality
Feedback score: The likeness between the reference signal and the feedback parameter
Feedback, Terminal: feedback delivered after the task has been completed.
Gait: the manner of walking
Gait parameters: Gait parameters are quantitative measures that describe various aspects of a person's walking pattern
Gait phases: The sub-division of the stance and swing period in smaller periods.
Gait speed: The speed at which a person performs gait
Gait stability: The state of a person to maintain balance during gait
Gait symmetry: The similarity of a person's walking pattern on the right and left sides of the body
Greenhouse-Geisser correction: a statistical method used to adjust for the violation of sphericity assumption
Heel strike: the initial point of contact of the heel with the ground during gait
Hemiparetic: having weakness or paralysis on one side of the body due to a stroke or other neurological condition
Motion Capture lab: a laboratory equipped with motion capture equipment able to track movement using markers
Mauchly's sphericity test: a statistical test used to determine if the variance-covariance matrix of a set of variables is spherical
Plantarflexion: movement of the ankle joint that points the foot away from the leg
Push-off: the instance during the gait cycle when the foot pushes off the ground to start the swing phase
Range of Motion: the full extent of movement possible at a joint
Reflective marker: a small, spherical device attached to the skin to track movement in a motion capture lab
Spastic paresis: a condition characterized by increased muscle tone and joint stiffness
Sphericity assumption: equality of variances for the differences between pairs of observations within a group
Stroke: a sudden loss of brain function caused by a disruption of the blood supply to the brain
Toe clearance: the vertical distance between the ground and the foot during walking
Torque: a measure of a force's ability to rotate an object

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5 Appendix: The biofeedback design Feedback

5.1 Overview of biofeedback build up

In the following section the feedback design presented during the measurements will be explained. Starting with the feedback template, which consists of the pictograms, followed up by the feedback score. The pictograms and the black line are parts of the feedback template that do not change. Figure 8 shows these parts of the feedback template. The black line denotes the ankle angle at zero°. Originating from this line the push-off and toe clearance segments of the feedback score are drawn. The pictograms are used for better comprehension during which phase in the gait cycle the ankle angle is used to determine the feedback score. The top pictogram denotes the ankle angle at toe clearance while the bottom pictogram denotes the ankle angle at push-off. Each of the arrows in the pictograms has a unique colour which later facilitates easy recognition of the different ankle angles in the feedback score.

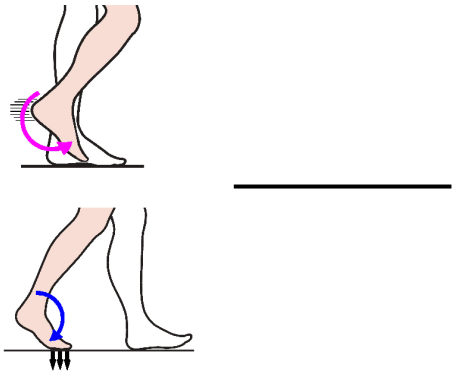

Figure 8: Parts of the feedback template that do not change. The black line denoting the 0° ankle angle, the magenta arrow in the pictogram in the top left denotes the ankle angle at toe clearance and the blue arrow in the pictogram in the bottom left denotes the ankle angle during push-off.

Originating from the black line a colour-shaded area is plotted which portrays the reference signal to the participant. Figure 9 shows these colour-shaded areas in three examples. The upper and lower dark green shaded area denotes what the ankle angle at toe clearance and push-off are during natural gait, respectively. The distance between these denote the ARoM during normal gait. Which means that the the colour-shaded areas changes size proportional the reference signal. Therefore, if the participant improves their ankle angle 1° with respect to the natural ankle angle this corresponds with a 1° improvement of that feedback score segment. Each colour-shaded area on the same side of the 0° line is equal in size. The size of each area is determined by the distance of the natural angles to the 0° line. It should be noted that the outer red-shaded areas actually have no bounds. In the upper segment, a choice was made to

exclude the red-shaded section closest to the 0° line because any angle above 0° is deemed as at least sufficient to achieve toe clearance. Which means that the bottom red-shaded section of toe clearance starts below the 0° line. Figure 9 shows three examples of different reference signals. As can be seen when comparing the different examples each colour-shaded area changes proportionally to the change in ARoM.

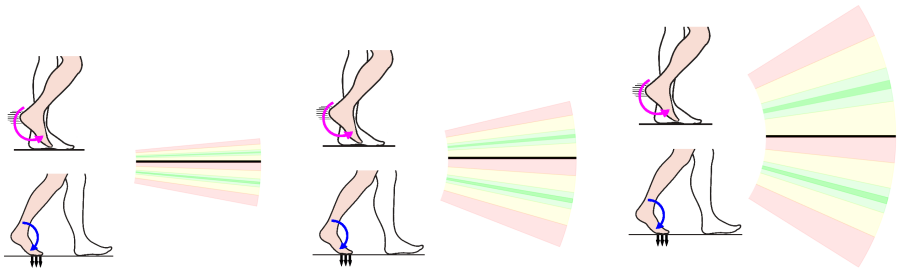

Figure 9: Three examples of the colour-shaded areas for three different reference signals. The natural ankle angles for push-off and toe clearance in the figure are respectively: *Left:* 5° plantarflexion 2° dorsiflexion, *Middle:* 10°plantarflexion 5°dorsiflexion, *Right:* 15°plantarflexion 12°dorsiflexion

On top of the colour-shaded areas the feedback score is plotted based on the last feedback parameters of the last 2 steps. Figure 10 shows an example of a feedback score where both angles are close to their reference angles. Both sections of the feedback score are green as their outer bounds lie in a green-shaded area. The borders of each section of the feedback score matches the colour depicted in the corresponding pictogram to improve comprehension what ankle angle determines the size of that section.

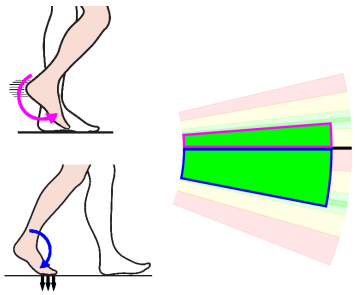

Figure 10: An example of the feedback score were both the push-off and toe clearance angles match their reference angles. Therefore, the different segments of the feedback score are green. The segments have a border colour corresponding with the arrow in their associated pictogram.

Whenever the push-off angle is not close to the reference angle the colour of the segment will change and a written instruction is given how to improve.

Figure 11 shows two examples of feedback scores when the push-off angle is not close to the reference.

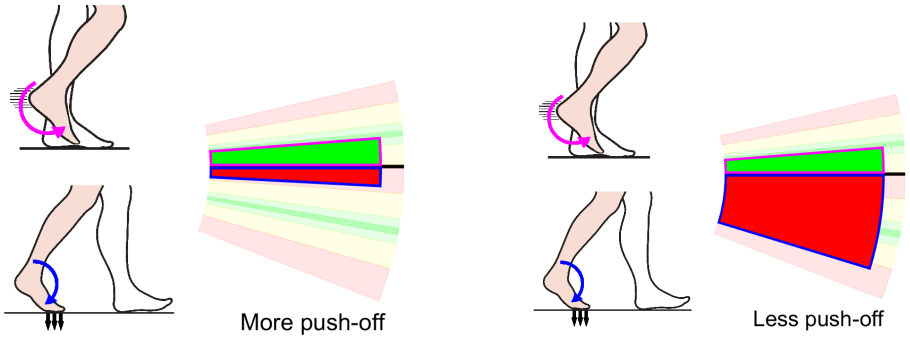

Figure 11: Examples of the feedback score when the natural push-off angle is close to the reference angle. *Left:* The push-off angle is too small with its outer border in a red-shaded area. Therefore, the participant is instructed "More push-off" and the segment is red. *Right:* The push-off angle is too big with its outer border in a red-shaded area. Therefore, the participant is instructed "Less push-off" and the segment is red.

Whenever the toe clearance angle is not close to the reference angle the colour of the segment will change and a written instruction is given how to improve. Figure 12 shows three examples of feedback scores when the push-off angle is not close to the reference. It is important to note that this segment can cross below the 0° line. When this occurs the border of the two section the striped line denotes that the red section overlaps the green section.

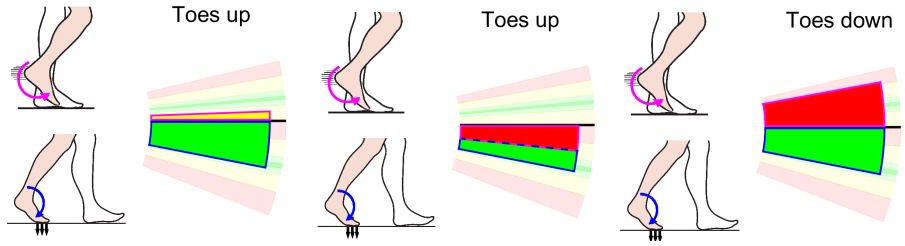

Figure 12: Three examples of feedback score's when the natural toe clearance angle is not close to its reference. *Left:* The toe clearance angle is too small. Therefore, the participant is instructed "Toes up". *Middle:* The toe clearance is to small and below 0° DF. Therefore the red area goes below the 0° line. The participant is still instructed "Less Push-off". *Right:* The toe clearance angle is too big. Therefore, the participant is instructed "Toes down".

.

All combinations and variations on the above mentioned examples are pos-

sible as a feedback score. Figure 13 shows a possible variation in which both the push-off and toe clearance angle are not close to their reference angles.

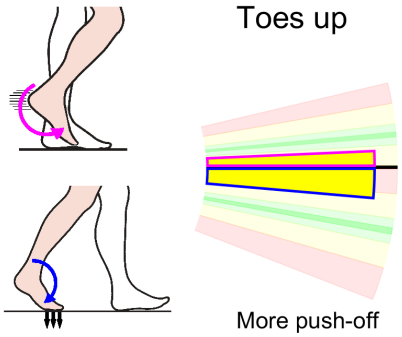

Figure 13: An example of a feedback score where both angles are not close to their reference angles. Both areas are yellow as their outer bounds lie in the yellow-shaded areas. The written instructions help the participant to comprehend what actions to take to improve the respective segments of the feedback score.

5.2 Explanation of feedback provided to participants

Each participant is provided with an explanation of the feedback to ensure understanding. A description of the explanation is outlined below.

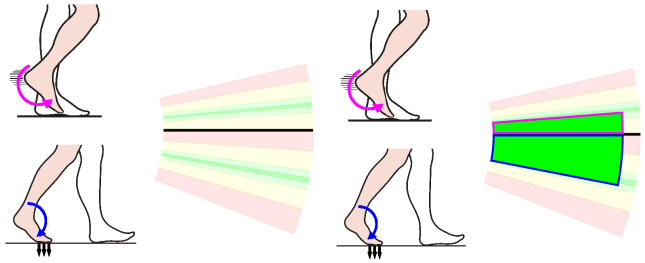

Figure 14: Images used to explain pictograms and the feedback score

The images in figure 14 are shown to the participant. Firstly, the moment of toe clearance and push-off are explained using the pictograms. Secondly, it is explained that the black line represents the ankle angle at 0°. Thirdly, it is explained that the dark green areas are the ankle angles to reach for during push-off and toe clearance. After which, the participants attention is drawn to the right feedback design of figure 14. Fourthly, the two segments of the feedback score that each segment has the same border colour as the arrow in to the corresponding pictogram. Fifthly, it is explained that the segment size of the feedback score is directly proportional with the magnitude of the ankle angle at the corresponding moment of gait.

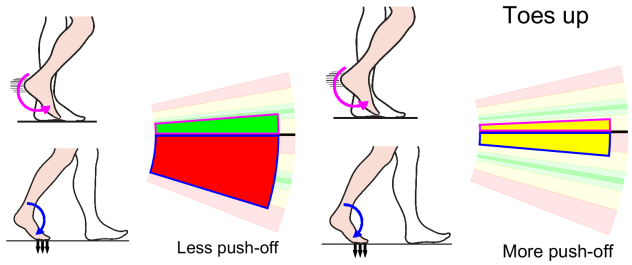

Figure 15: Images used to explain the colour of the feedback score and instructions

Then the images in figure 15 are shown to the participant. Both images are used to demonstrate that the colour of each feedback score segment depend on which colour-shaded area the outer border of that segment is. Furthermore, it is explained that whenever a feedback score segment is not green a written instruction will tell the participant how to improve that segment. Finally, it is made clear that the colour-shaded area presented to the participant might look different to the one shown during the instruction.

6 Appendix: Experimental protocol

Lab preparation
The lab is prepared for the measurements as followed. Two 32-inch monitors are set up at eye-height at either end of the 6-meter walkway which are used to display the biofeedback. One meter from each end of the walkway a line is drawn using masking tape. Next to the monitors located on the same side of the room the two normal camera are positioned at waist height. It is ensured that the placed objects are not blocking the field of view of the 12 marker camera, no reflection are created by the placed objects and the cameras remain in focus. Reflection are removed by changing the position of the objects or by taping over any reflective surface. If a reflection can not be removed physically it is removed in Qualisys Track Manager® using a software mask. The L-wand, which defines the origin, is placed in the exact center of the 6 meter walkway. After which, the T-wand is used to calibrate the entire walkway by waving it through the entire space using small circular motions during a period of 200 seconds. The wands are stored out of sight of the cameras.
Participant preparation
The participant arrives, is talked through the informed consent form, signs it, is asked whether they have any physical ailments influencing their gait and is made aware that they can ask any question at any time. This is followed up by a brief explanation of the feedback design. The participant changes into tight sports clothes behind a folding screen. Followed by the safety harness and the device shoes without the gas spring. The 26 markers are placed onto the participant according to Leardini et al's method [**?**]. If leg hair does not allow the marker to stick the hair is shaven off. Marker visibility is ensured by keeping clothes and the harness from covering the markers. Marker attachment on the shoes is guaranteed by attaching them with extra tape.
Measurement preparation
A measurement of the participant making some relative segment movement is done on the origin for 20 seconds. The researcher uses this measurement to train the AIM algorithm. If the fill level of all marker does not approach 100% this training is repeated until it does. After which, the participant is asked to keep their ankle in line with a right angle for a measurement of 10 seconds. The researcher runs the RS.m script during the measurement and saves the value of the neutral ankle angle. It is important to stop the script before Qualisys Track Manager® stops measuring or Matlab® will crash. Potentially, causing loss of data. The participant is asked to move to either end of the walkway behind the taped line. The clip is attached to the harness and it is checked whether the adjustment is correct. The participant is instructed to walk like they normally would and are asked to rotated completely behind the taped lines before starting to walk back again. The measurement takes 180 seconds. The researcher runs the RS.m script during the measurement to collect the average toe clearance angle and average push-off angle which will be used as the reference signal for the feedback. Participants with a natural toe clearance angle of less than 0° are deemed to have an unnatural gait and are excluded from the study. After

the measurement the reference signal is saved. While the participant is seated, the researcher helps the participant don the shinguard, tightening the straps such that no relative movement is possible while causing no discomfort to the participant. An obtuse angle is used to determine the rest angle of the ankle. The appropriate size connecting rod chosen and connected based on this ankle angle. The participant is asked to move their foot to dorsiflexion and to check for any discomforts. These are alleviated by changing the adjustment. The harness of the participant is clipped in and is asked to walk for a period of 180 seconds. After this the participant takes a break of 2 minutes.

Measurements

The participant is asked to walk with feedback and perform as well as possible for 600 seconds. The participant is again informed about being able to ask any question. The FB.m script is run during the measurement. During the first 300 seconds of the measurement, which is seen as the 1st learning trial, the feedback figure is shown to the participant on the two monitors. Any questions by the participant about how the feedback works are answered by the researcher to ensure clear understanding of what is shown. For the remaining 300 seconds, which is seen as the 1st retention session, the feedback figure is not shown to the participant. After the measurements is finished the FB-array is saved. The participant is asked to rest for 5 minutes while seated. The same measurement containing a learning- and retention session are repeated. After which, the FB-array is saved. The participant is asked to take a 10 minute break The final measurement contains a single retention session of 300 seconds. Thus, without the feedback figure. After which, the FB-array is saved.

Wrapping up

The participant is alleviated of all experimental equipment. After the participant has left all data is backed-up, the lab is cleaned and prepared for the next measurement.

7 Appendix: Impeding Shoe Device Report

Delft University of Technology
INSPECTION REPORT FOR DEVICES TO BE USED IN CONNECTION WITH HUMAN SUBJECT RESEARCH

This report should be completed for every experimental device that is to be used in interaction with humans and that is not CE certified or used in a setting where the CE certification no longer applies[1].

The first part of the report has to be completed by the researcher and/or a responsible technician.

Then, the safety officer (Heath, Security and Environment advisor) of the faculty responsible for the device has to inspect the device and fill in the second part of this form. An actual list of safety-officers is provided on this webpage.

Note that in addition to this, all experiments that involve human subjects have to be approved by the Human Research Ethics Committee of TU Delft. Information on ethics topics, including the application process, is provided on the HREC website.

Device identification (name, location): Ankle joint characteristic altering device

Configurations inspected[2]: Different rod lengths and different shoe sizes.

Type of experiment to be carried out on the device:[3] Walking with visual feedback

Name(s) of applicants(s): Winfred Mugge, Lennart Zielstra

Job title(s) of applicants(s): Assistant professor, Student (Lennart)

(Please note that the inspection report should be filled in by a TU Delft employee. In case of a BSc/MSc thesis project, the responsible supervisor has to fill in and sign the inspection report.)

Date: 14/09/2022

Signature(s):

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1 Modified, altered, used for a purpose not reasonably foreseen in the CE certification

2 If the devices can be used in multiple configurations, otherwise insert NA

3 e.g. driving, flying, VR navigation, physical exercise, ...

Setup summary

The device includes a gas spring (80 Newton) which pushes the foot away from the shin. This creates a new ankle joint characteristic. The pressure on the shin is made comfortable by applying the force to a industry standard shin guard. Similarly, the pressure on the foot is distributed by applying the gas spring force to a stirrup-like frame which is integrated into a shoe. This frame is made inhouse using an aluminum flat bar (3mm x 30mm). Different parts of the flat bar are connected using nuts and bolts (M4). The integrity of the frame was tested by applying a large force directly to the top (75 kg). To prevent the frame from turning forward, as a result of the moment created by the gas spring, a beam is attached from the stirrup to the section of the sole under the heel. The frame is embedded into the shoe such that there is no direct contact between the frame and the foot.

Multiple configurations of the device exist to ensure a good fit for all participants. To be able to accommodate for different shoesizes the frame can be integrated into shoes of different sizes. The length of the rod connected to the gas spring can be adjusted using a connector piece, this ensures the correct distance between the shin and foot.

During the experiment participants are instructed to walk as natural as possible. Training and measurement sessions are alternated. The control group must improve their gait by themselves. The feedback group is provided with visual feedback to aid them in their training sessions.

Figure 1. Depiction of the device. On the left the device can be seen when worn. On the right the device can be seen separately.

More elaborate descriptions should be added as an appendix (see below).

Risk checklist

Please fill in the following checklist and consider these hazards that are typically present in many research setups. If a hazard is present, please describe how it is dealt with.

Also, mention any other hazards that are present.

Hazard type	Present	Hazard source	Mitigation measures
Mechanical (sharp edges, moving equipment, etc.)	Yes	A gas spring is attached and pushes the foot away from the shin	The pressure on the shin is applied on directly to a padded shinguard. The pressure on the foot is dispersed by applying the pressure to a frame which is attached to a shoe. This shoe applies the downward pressure in a large area.
Electrical	No		
Structural failure	No		
Touch Temperature	No		
Electromagnetic radiation	No		
Ionizing radiation	No		
(Near-)optical radiation (lasers, IR-, UV-, bright visible light sources)	No		
Noise exposure	No		
Materials (flammability, offgassing, etc.)	No		
Chemical processes	No		
Fall risk	Yes	The device pushes the foot down which could lead to the participant tripping when attempting to clear the ground during walking.	A safety harness is worn whenever the device is used which catches the participant in the event of a fall.
Other:			
Other:			
Other:			

Appendices

Here, more elaborate depiction of the function of the device is given. Below the device can be be seen when fully extended and retracted. The device is designed in such a way that the force exerted on the foot and shin causes no discomfort to the user.


The shinguard is hold into place by multiple straps which are attached to the calf of the user. An extra cushion is placed into the shinguard to ensure pressure distribution.


The stirrup part of the frame is integrated into the between the sole and the inlay sole. The rearward facing part of the frame is embedded into the sole. Therefore, the foot is never in direct contact with the frame. Spacers are placed in between the frame and the shoe to prevent the frame from sliding.




The length of the rod can be adjusted by replacing the upper treaded wire with one of a different length. The frame can attached to a different shoe therefore accommodating for different foot lengths.

Device inspection

(to be filled in by the AMA advisor of the corresponding faculty)

Name: Erwin van Rijn

Faculty: L&L

The device and its surroundings described above have been inspected. During this inspection I could not detect any extraordinary risks.

(Briefly describe what components have been inspected and to what extent (i.e. visually, mechanical testing, measurements for electrical safety etc.)

De schoen en werking.

Date: 14 September

Signature:

Inspection valid until[4]: 13 September 2023.

Note: changes to the device or set-up, or use of the device for an experiment type that it was not inspected for require a renewed inspection

4 Indicate validity of the inspection, with a maximum of 3 years

8 Appendix: Informed Consent Form

You are being invited to participate in a research study titled "Improving altered gait using visual biofeedback". You have received this invitation at least 2 weeks prior to your scheduled experiment date. This study is being done by Winfred Mugge, Eveline Grootendorst and Lennart Zielstra from the TU Delft.

The purpose of this research study is to find out to what extent acquisition of a proper walking pattern is improved by providing participants with visual biofeedback after imposing an alternate walking pattern. This research will take you approximately 120 minutes to complete. The data will be used for understanding how feedback influences the learning process and will be published in a paper. On arrival you are asked to change into clothes provided by us for the duration of the experiment. If preferred, you can also bring your own tight-fitting shorts and shirt. Then we will attach reflective markers to you which are necessary for data acquisition. If hair around the knee prevents markers placed there from sticking, we will remove some hair. After this we will ask you to perform multiple walking trials to capture motion data and normal video. After an initial natural walking trial you will be asked to wear a shoe-and-shin-guard device which will temporarily alter your gait, and another set of walking trials will be performed. During these trials the visual feedback is turned on alternately. As your gait is slightly altered there is a risk of tripping. Therefore, you are asked to wear a safety harness during the entire experiment which will catch you if you fall.

To the best of our ability the data collected during your experiment trial will remain confidential. We will minimize any risks by ensuring a safe data storage, cropping out the upper body part from video and destroying the informed consent forms containing personal data after the project. All data is anonymised and saved in a secured drive. None of the personal data collected will be identifiable to you as a person by anonymising the data. This is done by saving your name and participant number separately from the rest of the data in an encrypted file.

Your participation in this study is entirely voluntary and you can withdraw at any time. If you withdraw from the study the data collected during your experiment trial will be deleted. You are free to ask any question at any point.

Contact details corresponding researcher: l.j.zielstra@student.tudelft.nl
Contact details responsible researcher: w.mugge@tudelft.nl

PLEASE TICK THE APPROPRIATE BOXES	Yes
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION	
1. I have read and understood the study information dated 14/09/2022, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	☐
3. I understand that taking part in the study involves: • Changing into tight sports clothes (shorts and shirt) • Getting reflective markers attached to me • Being recorded by video cameras and motion capture system • Having my gait temporarily be altered by a device	☐
4. I understand that I will not be compensated for my participation.	☐
5. I understand that the study will end at 30/02/2023	☐
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)	

PLEASE TICK THE APPROPRIATE BOXES	Yes
6. I understand that taking part in the study involves the risk of falling. I understand that these will be mitigated by wearing a safety harness which catches me when I fall.	☐
7. I understand that the following steps are taken to mitigate the risks of a data breach: All data is anonymised and saved in a secured drive. None of the personal data collected will be identifiable to me as a person by anonymising the data. This is done by saving my name and participant number separately from the rest of the data in an encrypted file. Also in any of video footage collected the upper part of the body is cropped out before saving.	☐
8. I understand that the (identifiable) personal data I provide will be destroyed at the latest one month after publishing the results.	☐
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION	
9. I understand and give permission that after the research study the de-identified information I provide will be used for presentations and publications.	☐
D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE	
10. I give permission for the de-identified marker data gathered during this experiment that I provide to be archived in TU Delft OneDrive repository so it can be used for future research and learning.	☐

Signatures

_____	_____	_____
Name of participant [printed]	Signature	Date

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____	_____	_____
Researcher name [printed]	Signature	Date

Study contact details for further information:

Lennart Zielstra, +31648486944, l.j.zielstra@student.tudelft.nl