Response to Reviewer 1

In this article, a soft monolithic haptic biofeedback device is introduced that has been developed through fused deposition modeling (FDM) 3D printer using Polyurethane. A validation study has been performed on 5 subjects to explore the effectiveness of the device. The results reveals the promising performance of the device, however, there are a few major requirements for this study to get accomplished:

We appreciate the reviewer on their time and effort and their constructive feedback to improve the quality of the manuscript. The manuscript has been amended according to the comments and suggestions provided, and further clarifications are made where necessary.

1. How the accuracy of stress analysis performed via FEM simulation is calculated? It is highly suggested that the authors study the performance of their final device (rather than using NinjaFlex data) under physical compression (uniaxial tensile testing) and validate their simulation results.

The authors appreciate the reviewer's suggestions. Such bellow actuators and many other structures were 3D printed using same material and method and tested in our previous studies (e.g. [Ref. 24, 25]) that Mooney-Rivlin hyperelastic material model estimates the behavior of the soft devices fabricated. The reviewer's suggestion is valid and more accurate material models can be utilized with further material characterizations such as uniaxial tensile testing where stress in the structure is in critical levels that the soft bellow actuators show minimal stress levels. Nevertheless, von-Misses stress criterium was used to investigate maximum stress occurred in the soft haptic actuator in comparison to the hyper elastic model obtained from experimental data. The authors are confident with the simulation results that experimental tests of such soft structures under cyclic loading for over 100,000 cycles achieved with no sign of rupture or fatigue.

The authors have also amended the manuscript in line with the reviewer's comments as below and the changes are highlighted in the manuscript in page 5.

"Several material models can be utilized to estimate a soft material, TPU Ninjaflex in this case, including linear and non-linear models with use of experimentally obtained material characterization data in tension and compression, uniaxially and biaxially, planar tension and equibiaxial tension. Among material models, Mooney–Rivlin and Ogden models are the most commonly used model hyperelastic material modelling. We utilized Aa 5-parameter Mooney-Rivlin hyperelastic material model was used for NinjaFlex that the material model was based on the experimental stress-strain data of NinjaFlex obtained experimentally [24, 25] which estimates material behavior with minimal experimental material data."

2. In the fabrication section, it is not clear where the sensory element is located in the device and how it has been integrated into the TPU body structure? Are they printed together? If not, how carbon black part is attached to TPU without delamination.

We appreciate the reviewer's comments on this matter that such insights enable us to improve the paper. Further clarifications have been added to the manuscript; changes highlighted can be found in page 4 starting from line 157.

"Sensory parts were 3D printed separately due to the fact that 3D printing transition from one nozzle to another creates printing strings lowering printing quality even though the 3D printer used is equipped with a double nozzle extruder. Rubber adhesive was used to bond the sensory parts to the soft haptic actuator; one part on the bellow and the other sensory part on the head. The authors were not observed any sign of delamination of sensory parts during the experimental tests."

3. The experiments are designed in two modes of static-standing and leaning in the direction of the target location. It would be nice to see what are the effects of motion artifacts on the device performance if the experiments includes a variety of movements in different directions rather than just one.

We agree with the reviewer that diverse range of motion artifacts on the device performance can be conducted to investigate performance of the soft haptic biofeedback device. This pilot study shows that use of only three soft actuators was capable of creating proprioceptive feedback to reduce swaying of the wearer in both sagittal frontal planes. COP results already included sway in any directions in the transverse plane and reports the device performance. Due to the ultimate goal of compactness, this study only utilized three soft haptic actuators. In addition, one of our target applications is falling motion detection and prevention using the proposed biofeedback system. Such experimental study was not considered to focus on our main contribution that is the proposed biofeedback system in this paper. We believe that such motions require further analysis and experiments with larger group of subjects with different ages and physical conditions, which may deviate the main focus of this paper. And more importantly further safety and ethical precautions should be administered. We aim to apply the proposed biofeedback system to different applications in our future studies.

In this paper, we focus on establishing a novel biofeedback system that is capable of providing CoP information to users in a safe manner thanks to the proposed soft robotic technology. For the sake of brevity and consistency, we evaluated the performance of the proposed biofeedback system using two different tasks: 1) Task 1: Keeping the CoP within a desired area to indicate improvement of postural balance and 2) Task 2: Moving the CoP to the desired location as stimuli provided substitution/augmentation of proprioceptive feedback. **While the second task included a CoP movement along only one direction (i.e., forward direction), subjects needed to move their CoP along different directions (i.e., forward, backward, right, left, and the different combinations of these directions such as left forward) in order to keep the CoP within the desired location**. This is illustrated for the reviewer in Figures a – d below. While Figure a shows how the CoP of a subject sways when biofeedback is not provided in the experiment, Figure b – d show different CoP movements with biofeedback. It is clear from these figures that the proposed biofeedback system enables us to control the CoP along different directions. Thus, we believe that the initial experimental results illustrated in this paper are highly promising and they show that proposed biofeedback system could be used to provide CoP information for various different motions. It must be noted that as a summary of results the last CoP results are illustrated in Figure 7 in the manuscript as illustrated below.

The whole manuscript has been revised and necessary changes have been made accordingly which are highlighted in the manuscript.

This pilot study is the first step for developing a low-cost, easily manufactured biofeedback device that can constitute robotic applications for human-machine/computer interfaces such as complementing robot-assisted rehabilitation devices.

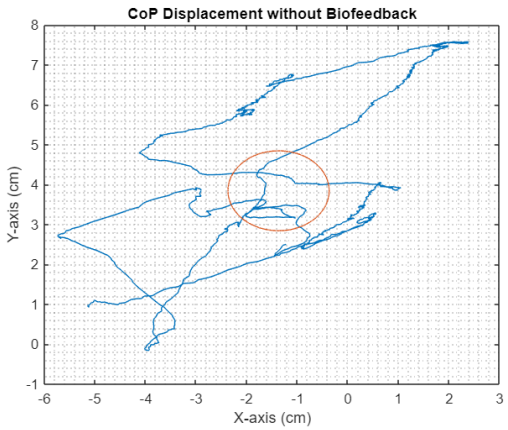


Figure a

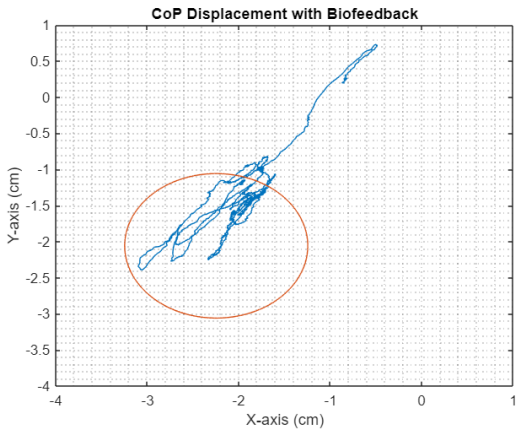


Figure b

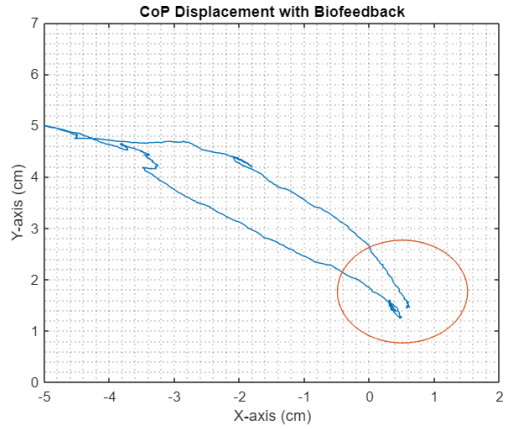


Figure c

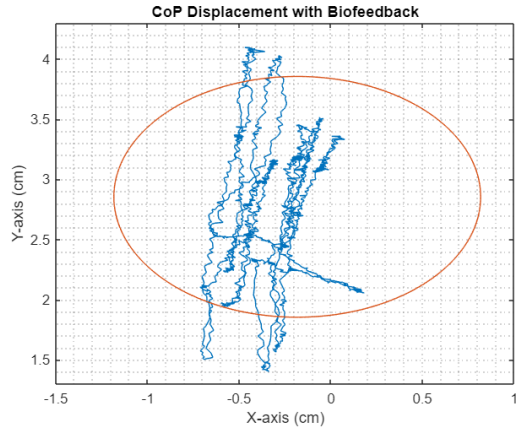


Figure d

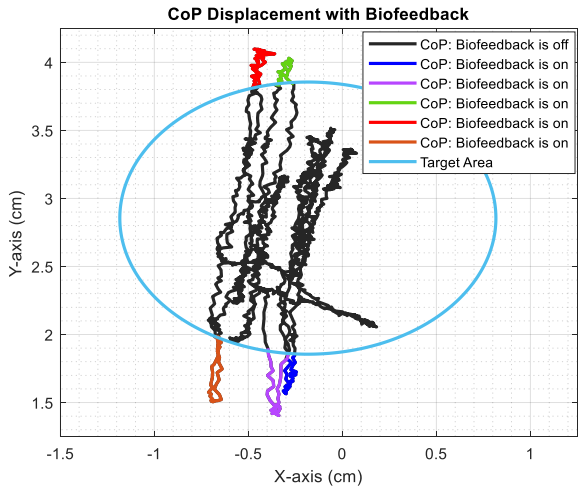


Figure 7. CoP displacement with biofeedback.

4. How would the device perform if the body sway in a direction different from the one indicated by the activation of each actuator?

In simplest manner, four regulators and correspondingly four actuators can be used to map stimuli/biofeedback to the CoP displacements along forward, backward, right, and left directions and their combinations; for instance right forward and left backward directions. While the forward leaning motion can be detected by activating the front actuator, right backward leaning motion can be detected by activating the right and back actuators. The pressure level represents the position of the CoP along each direction.

However, the compactness in mind, same tasks can be attained using three regulators/soft actuator combination. This is even more valid if another biofeedback device is being employed in the other lower limb. Below is activation combination(s) of the soft actuators in experiments.

Table 1

Sway Direction	Front Actuator	Back Actuator	Right Actuator
Forward	x		
Backward		x	
Right			x
Left	x	x	
Right Forward	x		x
Right Backward	x	x	
Left Forward	x	x	0.5Hz Square Signal
Left Backward	x	x	1Hz Square Signal

Table 1 shows that if the subject sways forward, backward, and right directions, only the front, back, and right actuators are activated in respect to the distance from their CoP position predetermined. However, when the subject sways left direction, the front and back actuators are activated as we don't use an actuator for the left direction. While the right backward and right forward motions can be similarly conducted as explained above, we need to use signals with different frequencies to distinguish the backward and forward motions in the left direction. As shown in this table, the motion of CoP can be described using different actuation methods.

Increasing the number of actuators would obviously makes it easier for the participants to adapt the system, however it would also increase the cost of the test setup, more importantly reduce the compactness. Therefore, there is a trade-off between the cost and ease of use in this experimental setup. The experimental results presented in the paper show that the performance of subject significantly improved using the biofeedback device with three regulators/actuators.

5. The results revealed that visual information (eyes being open) has almost no positive effect on the success rate, with or without using the biofeedback. This cannot be attributed to the performance of the device. More accurately designed experiments are suggested to explore why this was observed.

The authors appreciate on this point that results presented with bars in Figure 8 introduce confusions that effects of the soft haptic biofeedback with visual-feedback present (eyes being open). We have revised our figures and included test success values on top of the bars. Please see Figure 8 in the revised version of the paper.

In addition, to be consistent with the human balance experiments in the literature, we conducted our experiments in two conditions: 1) Eyes being opened, and 2) Eyes being closed. Please see the similar balance experiments in [Ref. 1 - 3]. In line with the literature, our experimental results show that subjects had better performance when they conducted experiments with open eyes as they have their visual feedback augmented with the soft haptic biofeedback. It should be noted that the authors intention was not to compare conditions of "eyes opened" and "eyes closed", instead to demonstrate efficacy of the biofeedback in both conditions.

The main aim of this pilot study was to compare the balance performance between with and without using the biofeedback whereas balance and proprioception were substituted and/or augmented. While presence of visual feedback (eyes being open), subjects show lower improvement of their balance as this is expected due to the participant criteria of healthy subjects with no sign of inability of keeping balance. However, with introduction of soft haptic biofeedback the subjects showed improvement on the CoP circumference, which is even more significant for proprioceptive feedback as subjects' accuracy of recalling and performing pre-tested body position with an object aiding the test. Some key results are presented in Figure 8 and we have revised the sub-figures to include the numerical success rates for an easier comparison. As previous studies suggested eyes being open and close can have effects on static balance [Ref 1-3], we studied the effects of biofeedback in both conditions. Our results presented in Figure 8 indicated that all 5 subjects improved their successful rates in balance upon using the biofeedback with 3% to 90% improvements in eyes being open condition and 5% to 78% improvements in eyes being closed conditions. Thus, necessary changes and amendments have been made in the manuscript and highlighted.

References

[Ref. 1] C. A. Reed, A. M. W. Chaudhari, L. C. Worthen-Chaudhari, K. E. Bigelow, and S. M. Monfort, "A new perspective on transient characteristics of quiet stance postural control," *PLOS ONE*, vol. 15, no. 8, p. e0237246, Aug. 2020, doi: 10.1371/journal.pone.0237246.

[Ref. 2] H. Luo *et al.*, "The Effect of Visual Stimuli on Stability and Complexity of Postural Control," *Frontiers in Neurology*, vol. 9, Feb. 2018, doi: 10.3389/fneur.2018.00048.

[Ref. 3] M. Schieppati, E. Tacchini, A. Nardone, J. Tarantola, and S. Corna, "Subjective perception of body sway," Journal of Neurology, Neurosurgery & Psychiatry, vol. 66, no. 3, pp. 313–322, Mar. 1999, doi: 10.1136/jnnp.66.3.313.

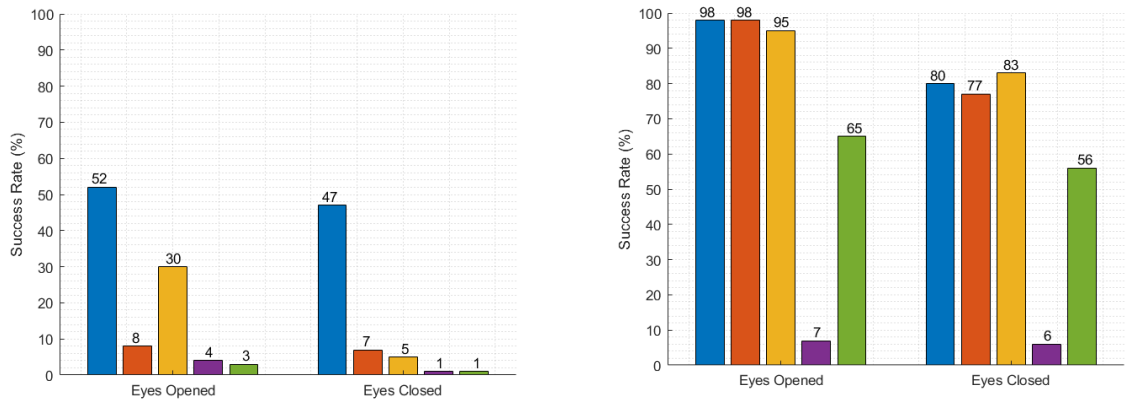


Figure 8 - The success rate of static standing experiment with 5-subjects.

6. The user study has been performed only on 5 subjects and that is when one of them (participant 4) does not show any positive success rate% to the biofeedback device. It is highly suggested that the authors perform the experiments with a larger group of subjects specifically from a variety of ages including elderly subjects as they are the main target group and the ultimate market and probably will impose unintentional swayings that would help to evaluate the real performance of the device.

The reviewer suggests a sound point on performance investigations of such a device to show its efficacy on improving balance and proprioception. With preliminary investigations of the soft haptic device developed and demonstrated in this study, our sampling criteria includes adults between age 18-65 with no limitations of ethnicity and background. The authors are also aware of the target groups of subjects in particular elderly subjects which also brings further safety requirements and professional support due to the ethics policy guidelines. The

authors certainly plan to expand this study to larger group of subjects with more diversity thus confidence rates can be investigated.

We would like to stress that this study is a "*pilot study*" investigating on the effectiveness of the proposed soft haptic biofeedback device with limited number of stimuli points applied by the soft actuators with major intention to conduct a thorough experimental study with more diverse movements with wider spectrum and larger number of participants. In addition, as highlighted as part of another ongoing project of ours on robot-assisted rehabilitation device development, we would like to combine the soft haptic biofeedback device as substitute/augmentation of loss of sensory functions while the rehabilitation robot can provide assistance for loss of motor functions. The primary objective of this study was to demonstrate novelty of the soft haptic biofeedback device with its compactness-in-mind development. Thus, we tested the device with a small group of participants with diverse criteria to attest that the soft haptic biofeedback can be utilized in more thorough experimental tests with larger group of participants and in more diverse robotic applications such as a robot-assisted rehabilitation device based on soft robotics concepts. In this study, participation criteria is to be aged between 18 to 65, had no known orthopedic or neurological deficits and/or balance disorders, were able to maintain static standing and/or sitting balance, and were able to communicate clearly.

To reflect the motives of this study, the title of this manuscript is now revised to "**Novel Soft Haptic Biofeedback – Pilot Study on Postural Balance and Proprioception.**
The whole manuscript has been revised and necessary changes have been made accordingly which are highlighted in the manuscript.

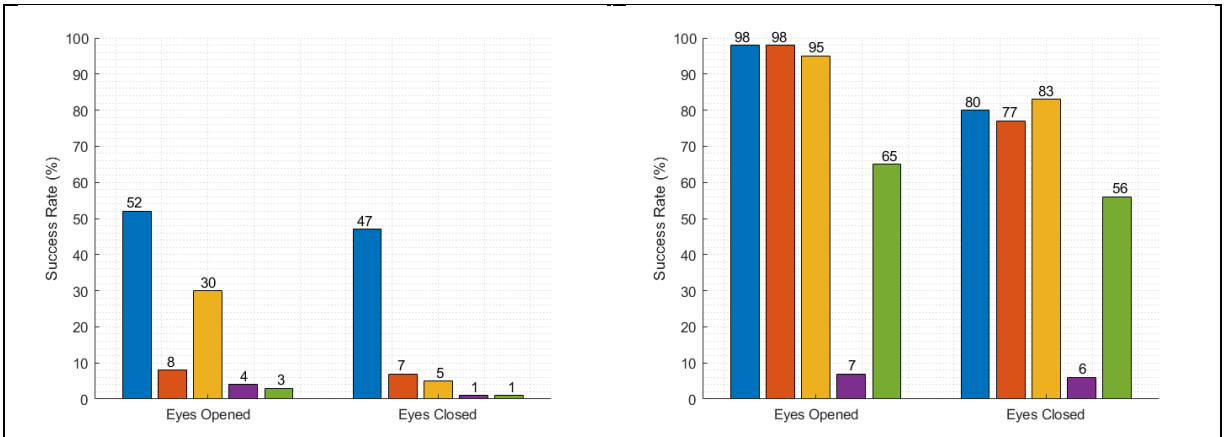


Figure 8 - The success rate of static standing experiment with 5-subjects.

Test results in Figure 8 clearly shows that the soft haptic biofeedback was effective to provide tactile feedback for improving balance by stimulating/augmenting proprioceptive sensation in all 5 subjects.

sensors

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Article

Novel Soft Haptic Biofeedback – Pilot Study on Postural Balance and Proprioception+

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+ This paper is an extended version of our paper published in D. Singh, C. Tawk, R. Mutlu, E. Sariyildiz, and G. Alici, "A 3D Printed Soft Robotic Monolithic Unit for Haptic Feedback Devices," *in 2019 IEEE/ASME International Conference on Advanced Intelligent Mechatronics (AIM)*, pp. 388-393, 2019.

Abstract: Sensory feedback is critical in propriception and balance to orchestrate muscles to perform targeted motion(s). Biofeedback plays a significant role substituting such sensory data when sensory functions of an individual is reduced or lost such as neurological disorders including stroke causing loss of sensory and motor functions requires compensation of both motor and sensory functions. Biofeedback substitution can be in the form of several means; mechanical, electrical, chemical and or combination. This study proposes a soft monolithic haptic biofeedback device prototyped and pilot-tests were conducted with healthy participants that balance and proprioception of the wearer were improved with applied mechanical stimuli on the lower limb(s). The soft monolithic haptic biofeedback device has been developed and manufactured using fused deposition modelling (FDM) that employs soft and flexible materials with low elastic moduli. Experimental results the pilot-tests show that the soft haptic device can effectively improve balance of the wearer as much as can provide substitute proprioceptive feedback which are critical elements in robotic rehabilitation.

Keywords: Soft Haptic; Biofeedback; Proprioception; Soft Sensor; 3D Printing

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1. Introduction

Sensory feedback is critical in propriception to orchestrate muscles to perform targeted motion(s). Sensory feedback gains even further significance in rehabilitation of neurological disorders such as stroke as a worldwide health problem requiring compensation of motor and sensory functions which may be augmented by biofeedback devices [1]. Brain regions devoted to sensory and motor functions are affected during stroke resulting in the loss of many neurons critical for feedback movement control. This results in reducing a person's sense of their limbs and their capacity for muscular force production along with spasticity, an increase in the resistance of a muscle(s) to lengthening [2, 3]. Neurological rehabilitation largely involves extensive physio- and occupational therapy interventions that aim to re-establish functional sensory and motor

pathways in the brain, thereby restoring mobility, functional use of limbs, reducing impairment and disability [4].

Biofeedback plays a significant clinical role in the rehabilitation process of patients with reduced sensory feedback [5]. Various feedback methods are used in the process such as auditory, visual and tactile systems, and combination(s) of those systems. These feedback means can improve the sensing ability of the patients about the kinematics, kinetics and muscular activities of their affected body parts [5] by compensating for the loss of sensory information previously delivered through the proprioceptive system. Multiple studies suggest that neurological rehabilitation such as stroke should consist of intensive and multisensory task-related training [6, 7]. Various forms of haptic feedback, including mechanical, electrical and vibrational systems, have been demonstrated to enhance the utility of sensory feedback for patients with proprioceptive dysfunction or loss [8]. Many of the haptic feedback studies examine the use of vibrotactile stimulation by employing commercially available, miniature and lightweight vibration motors that can easily and directly be placed onto the skin of a patient [9]. Although these mechatronic systems are advocated as non-invasive and low-cost feedback systems due to the fact that the components used in these systems are easily-accesible in the commercial market, their development is complicated, and they require complex and sophisticated control algorithms.

The field of soft robotics has gained a great amount of interest due to the numerous advantages it has in comparison to the conventional robotics field. This rapidly growing research field combines expertise from various disciplines including materials science, mechanical engineering, electrical engineering, control engineering, chemistry, physics, computer science, biology, medicine and many others [10]. Soft robotic systems have many interesting advantages such as such as adaptability, conformability, agility, high compliance [11, 12]. In addition, these systems can operate for very long periods of time without failure since they are made of highly elastic and deformable materials which in general operates quite under the rate stress levels in the material [13]. More importantly, soft robotic systems can safely interact with humans and operate in highly dynamic environments [14]. The realization of robotic systems with high biomimicry remains the focus of soft roboticists. One way to achieve this aim is to fully exploit the material properties involved in the fabrication of soft robotic devices. Primarily, the use of materials with low elastic moduli has effectively led soft robots to mimic their natural counterparts with hyper-deformations and minimal structural stress [15]. Conventional robotic systems are made of stiff and rigid components are ideal for precise and repetitive tasks that require high forces and fast movements, however, their safety is questionalble to operate alongside humans due to their rigidity, speed of operation, thus physical impact in case of any collision with a human. In addition, the manufacturing and development of such systems require complex machining, laborious assembly processes and incorporation of multiple physical sensors [16].

Among various examples of the soft robots with prime inspiration from movements of their natural counterparts, soft robotic systems can serve as biofeedback devices that can non-invasively be placed on the human body communicating useful information to substitute and/or augment our sensory system. Soft, wearable and pneumatically actuated haptic feedback systems in this matter have great potential as haptic feedback devices since they are great candidates for a safe human-machine/computer interaction due to their softness and compliance [10, 17]. Abd et al. demonstrated a soft haptic armband that can be used as a feedback system when operating with a robotic hand [18]. The tactile data obtained from the robotic hand was delivered back to the user to enhance the teleoperation experience. The soft haptic armband was fabricated using silicone rubber that was molded and cast using conventional techniques to produce soft pneumatic chambers that inflate when activated. Zhao et al. developed a soft haptic communicator with dielectric elastomer actuators, which is capable of delivering indentation force as low as 0.6 N against skin of a wearer's arm at the lowest operating frequency [19]. We have

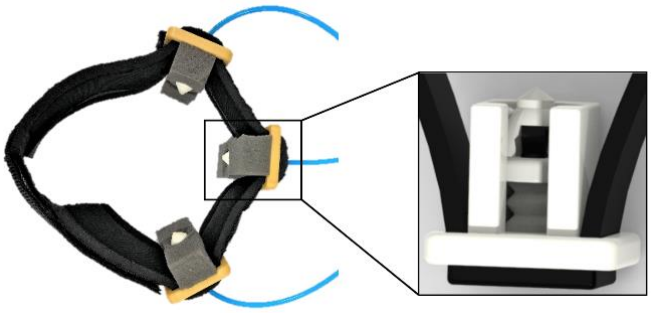


Figure 1. Soft haptic biofeedback system with three units with a padded Velcro strap.

developed an alternative soft haptic biofeedback device integrated with force sensing capability that employs the same actuation as the soft haptic device used by Zhao et al. to assess its efficacy for inducing biofedback of the wearer [20]. Our soft haptic device is actuated pneumatically while sensing pressure applied onto the skin of the wearer from the fully 3D printed soft force sensor operating as resistive sensor.

Conventional manufacturing methods limit the potential use of soft robotic devices due to imposing many constraints such as geometry, size and shape on pneumatic actuators. These limitations can be alleviated using additive manufacturing techniques (i.e. 3D printing) to produce soft robots with complex shapes and geometries based on computer-aided design (CAD) models of actuation [21] and sensing systems [22]. In this study, we prototyped a soft haptic biofeedback device comprising three units of soft



Figure 2. 3D printed Soft Haptic Biofeedback system: From left, custom housing, the soft bellow pneumatic actuator, the compliant head and an interchangeable tip.

bellow actuators which was fully 3D printed using a low-cost and open-source fused deposition modeling (FDM) 3D printer using a commercially available soft and flexible thermoplastic poly(urethane) (TPU). The soft bellow pneumatic actuator that generates a linear stroke upon activation was designed and implemented as in the actuation unit. Modular compliant tips on the head of the unit were designed with various shapes to assess the comfort and sensation levels of subjects when the bellow-actuator is activated using a positive pressure to push the tip of the unit against the skin of the user. Among several modular compliant tips, the pointy tip, as shown in Fig. 2, was found to be the most effective for stimulation and biofeedback while more round and flat tips distribute pressure, thus lose their effectiveness. The CAD model and the fabricated soft haptic biofeedback device proposed and the unit proposed in this study are shown in Fig. 1.

The major contribution of this study is prototyping a soft biofeedback device utilizing multiple monolithic and soft haptic units integrated with a soft Velcro strap that can be directly fabricated using a low-cost 3D printing technology. The soft haptic biofeedback device presented in this work can be benefit for various robotic applications as human-robot/computer-interactions. Robot-assisted rehabilitation is also one of the areas that requires biofeedback device(s) to step towards a more comprehensive rehabilitation compansating motor and sensory function loss. The soft haptic biofeedback device

prototyped in this study as shown in Fig. 1 is quite compact in size, and it can generate high force outputs with great potential to augment propriception in human-robot/computer interactions and/or compansate reduced proprioception in neurological rehabilitation. In this study, we propose a soft haptic biofeedback system that comprises three of the soft haptic units which were 3D printed from TPU material using the FDM type additive manufacturing. Soft bellow type soft actuators have been designed with minimal wall thickness. Biofeedback is provided by the device inflating and pressing onto skin of wearer's lower limb, activating cutaneous receptors in the skin. The soft haptic biofeedback units have modular tips with various shapes that enable comfort and sensation levels of subjects to be assessed and optimized. This study conducts a pilot investigation on the effectiveness of the soft haptic biofeedback device with participating healthy subjects for their balance and proprioception and reports the device performance in these pilot tests whereas experiments with a larger group of subjects will be conducted with wider spectrum of participant criteria including healthy as much as subjects with a loss/reduced sensory function by administering further safety protocols in our future studies. The soft haptic biofeedback system was operated with a center of pressure (CoP) measurement device equipped with force sensitive resistors (FSR) as force sensing components in order to obtain the CoP information of the subject which will help to evaluate the subject's posture and balance information. The pilot study is also investigates on the proprioception of the subject upon postural balance tests enquiring the subject to recall their body position in different conditions.

2. Soft Haptic System with Soft Force Sensor

Two soft and flexible commercially available materials were used to fabricate the soft haptic unit. The first material which is a TPU known as NinjaFlex (NinjaTek, USA) was used to 3D print the soft pneumatic bellow and the soft sensor base and tip as shown in Fig. 2 and Fig. 3.a. The second material, which is a conductive black filament based on Carbon Black (Creative Tools, Sweden), was used to 3D print the sensor parts. The complete 3D printed monolithic unit was printed using a low-cost and open-source FDM 3D printer (FlashForge Inventor, FlashForge Corporation). Sensory parts were 3D printed separately due to the fact that 3D printing transition from one nozzle to another creates printing strings lowering printing quality even though the 3D printer used is equipped with a double nozzle extruder. Rubber adhesive was used to bond the sensory parts to the soft haptic actuator; one part on the bellow and the other sensory part on the head. The authors were not observed any sign of delamination of sensory parts during the experimental tests.

2.1 Developing the Soft Haptic System

The computer-aided-design (CAD) models were designed and modeled using Creo Parametric 2.0 (PTC Inc.). The CAD models were sliced using a commercially available slicer known as Simplify3D (Simplify3D LLC, OH). The printing parameters were adjusted based on recent studies about 3D printing soft pneumatic actuators and sensors using FDM 3D printing [23]. The parameters were adjusted to obtain airtight pneumatic bellow actuators. A positive-pressure pneumatic pump (Chicago Air HUSH50) and Festo air-pressure regulators were used to actuate the soft haptic unit(s). The soft haptic units were secured in custom housings 3D printed from PLA using the same 3D printer. The assembly of the soft haptic biofeedback device for balance and proprioception was completed with three haptic actuators integrated with a soft Velcro strap.

2.2. Finite Element Modelling

Finite Element modeling was performed on a single actuator to predict its performance in terms of blocked force, stress analysis and deformation. ANSYS Mechanical (ANSYS Workbench 19.1) was used to perform the FEM simulations. Several

material models can be utilized to estimate a soft material, TPU Ninjaflex in this case, including linear and non-linear models with use of experimentally obtained material characterization data in tension and compression, uniaxially and biaxially, planar tension and equibiaxial tension. Among material models, Mooney–Rivlin and Ogden models are the most commonly used model hyperelastic material modelling. We utilized a 5-parameter Mooney-Rivlin hyperelastic material model for NinjaFlex that the material model was based on the experimental stress-strain data of NinjaFlex obtained experimentally [24, 25] which estimates material behavior with minimal experimental material data. The assembly was meshed using higher order tetrahedral elements. A Fixed Support boundary condition was imposed on the base of the bellow actuator and a Displacement Support boundary condition of 9.62 mm was imposed on the tip of the sensor. Contact pairs were defined between the different walls that touch upon activation.

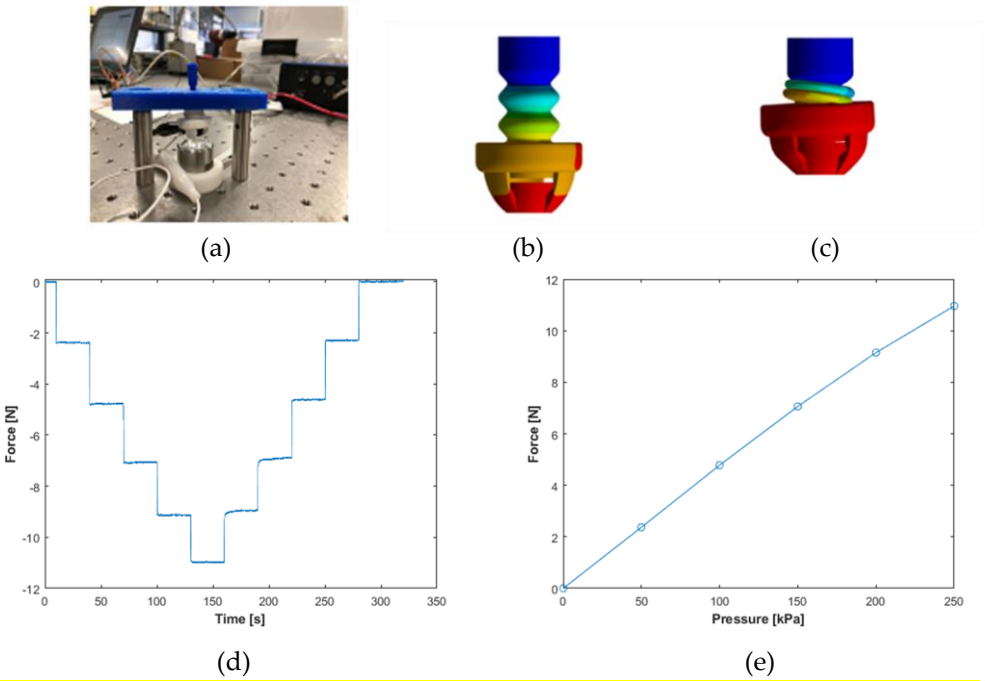


Figure 3. Blocked force measurement experimental setup and FEA comparison: (a) Haptic unit measuring blocked force with 6-axis force sensor, (b) FEM simulations in default state, (c) deformed state when a 9.62 mm displacement input is applied, (d) the soft haptic biofeedback device was subjected to variable pressure values of 50, 100, 150, 200 and 250kPa where the measured blocked forces in the transient, and (e) steady-state mode.

The FEM simulations estimated the blocked force of the soft haptic unit accurately. Fig. 3 shows the experimental and FEM unloaded states and deformed states for the soft haptic unit. The FEM blocked force obtained is 9.93 N which is 7.02% less than the experimental blocked force obtained of 10.68 N. The main reason of this acceptable difference is that FEM simulations were performed by considering that the soft haptic unit was made of NinjaFlex only. In addition, the geometry of one of the contact surfaces between the actuator and the sensor was simplified by modelling it as flat surface compared to the elliptical surface in the physical prototype.

2.3. 3D Printing

The primary objective of this study was to develop a single fully 3D printable soft monolithic haptic unit with conformal capabilities. However, multiple steps were required in manufacturing due to the limitations imposed by using multiple materials (i.e. NinjaFlex and Carbon Black) in 3D printing.

The parts were 3D printed with 100% infill. It is noted that rafts/supports should not be used for printing the parts to avoid any post-processing. Rafts/supports also reduce the quality of the surfaces of the 3D printed parts. Furthermore, the strong bonding that occur between the main parts and the rafts/supports makes their removal process very challenging. These criteria have been considered during the design of the soft haptic unit.

This problem diminishes the physical properties of the printed parts and affects their effective elastic properties. The main reason for printing the tip separately was to test different tips to ensure that the haptic unit provides the desired comfort levels. The base and the tip were fabricated using NinjaFlex and Carbon black was used for the sensory element. The actuator was activated using positive pressure where the load was transferred via the ring and pillars (Fig. 2). This load is then transferred to the tip that produces mechanical stimuli to the wearer.

3. Biofeedback Device for Balance Improvement

3.1 Developing Pressure Control Unit

In the development of the biofeedback system, a pressure control unit was used to adjust the mechanical stimuli on the thigh. The proposed pressure control unit comprises MATLAB Simulink Real-Time, Humusoft MF644 Data Acquisition Card, Festo air-pressure regulators, and Chicago Air HUSH50 air compressor.

Before biofeedback was provided in experiments, the pressure regulation system was calibrated to determine the upper and lower bounds of the CoP of participants. The calibration process is composed of two steps that take 100 seconds in total. First, the participant is asked to step on the custom force plate and remain static with eyes opened, looking forward, feet together, and hands alongside the body. While the participant keeps this stance for 70 seconds, the participants' CoP data is recorded to be used for locating the initial position of the participant's CoP. the initial position of the CoP is used as a reference when tracking actual CoP throughout the experiment. Since the initial CoP varies for each subject, it is crucial to repeat this process before initiating the experiment. Recorded data is split into 5 data sets. The initial CoP point is determined by taking the average of these five datasets. The second step is used for locating the expected maximum distances between the initial CoP point and the points that the participant can reach without balance loss. The participant is instructed to lean forward, backward, left, and right with eyes opened, looking forward, feet together, and hands alongside the body. This process takes 30 seconds. At the end of the second step, maximum recorded CoP values are set to be the furthest points that the participant's CoP can reach.

After completing the crucial calibration step, biofeedback was provided to participants in the experiments. The actual positions of the CoP of participants were calculated by using a custom-made force plate in experiments. This is explained in the next section in detail. By using the actual position of the CoP and initial calibration, biofeedback was provided through a control algorithm illustrated in Fig. 4 to improve the performance of different tasks such as static standing and reaching a location. This process was repeated until the test ended or was terminated by the subject.

3.2 Developing Custom Force Plate to Measure CoP

A custom force plate was developed by utilizing Force Sensitive Resistor (FSR) sensors instrumented with voltage divider to measure their response. The FSRs were

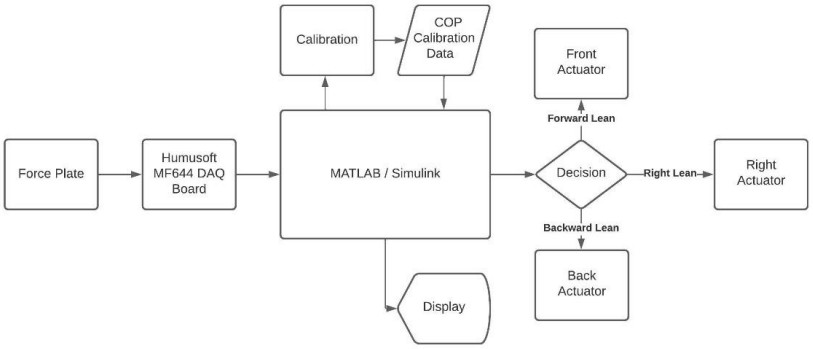


Figure 4. A flowchart that represents the control algorithm of the proposed biofeedback system.

strategically placed between two acrylic plates laser cut in the shape of sole of human foot, and secured on a 10 mm thick anodized Aluminum plate. The Centre of pressure of a participant is calculated using Eq. 1 and Eq. 2 as described in [26].

$$X_{CoP} = \frac{\sum_i^4 C_i^x F_i}{C_{total}^x F_{total}} \quad (1)$$

$$Y_{CoP} = \frac{\sum_i^4 C_i^y F_i}{C_{total}^y F_{total}} \quad (2)$$

In these equations, X_{COP} and Y_{COP} represent the projection coordinates of the participant's CoP on the force plate's planar surface. The medial–lateral direction is represented as X_{COP} coordinate and the anterior–posterior direction is represented as Y_{COP} coordinate of the CoP. C_{total}^x and C_{total}^y represent the distances between the force resistors placed underneath the acrylic plates. C_i^x and C_i^y represent the instantaneous distances that are calculated in reference to the CoP. While F_i represents the instantaneous force values measured by the force resistors, F_{total} is the sum of the measured forces.

4. Experiments

4.1 Experimental Procedure

To validate the performance of the proposed biofeedback device, we conducted experiments with 5 subjects. One subject is illustrated standing on the force plate with the soft haptic biofeedback device system strapped around his tibia in Fig. 5. Participants were aged 18 years old and over, had no known orthopaedic or neurological deficits and/or balance disorders, were able to maintain static standing and/or sitting balance, and were able to communicate clearly. All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the National Statement on Ethical Conduct in Research Involving Humans, and the protocol was approved by the Human Research Ethics Committee at the University of Wollongong (HREC Ethics Number 2019/423).

This study involved two major parts:

Part A: The pressure threshold of the soft haptic biofeedback system was tested on each subject. This was undertaken using the soft haptic biofeedback system during static standing, with eyes opened, looking forward, feet together, and hands alongside the body, and pressure input was gradually increased. This part of the study provides the minimum perceived pressure sensation and maximum pressure level that is comfortable for the

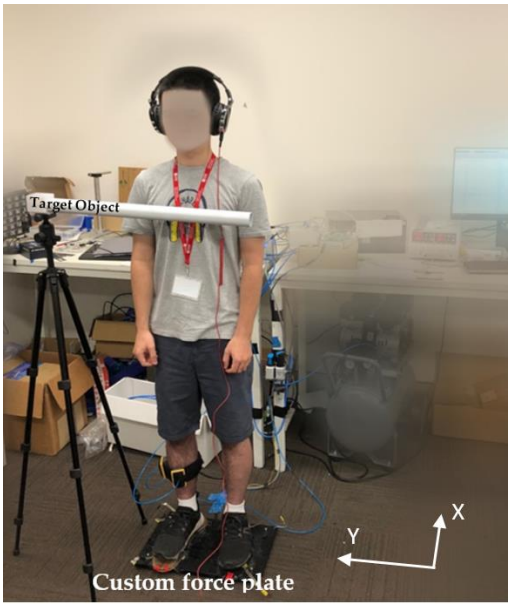


Figure 5. Participant on the custom built force plate.

subject. This was then used to determine the pressure limits to ensure the device did not cause discomfort to the subject. If this approach did not eliminate discomfort, the experiment was to be terminated.

Balance sensors wee also calibrated in this part of the study; asking the subject to perform various movements (i.e. perform body sway movements in the direction indicated by activation of each actuator) while static standing, with eyes opened, looking forward, feet together, and hands alongside the body and same exercise with eyes closed.

The soft haptic biofeedback device was strapped to the subject. Location of the device was determined based on the subject's perception; large muscular area such as thigh muscles might be difficult to feel pressure input which would require higher pressure levels, on the other hand, lean muscular area such as forearm or tibia may provide better sensation. This was determined during the calibration phase to the study. Then, the subject was given a three (3) minute practice period to get familiar with the soft haptic biofeedback system; for instance the subject was asked to tilt their body towards left/right and forward/backward to observe how the soft haptic biofeedback system provides an amplitude of pressure feedback onto their skin depending on the amount of tilting of their body.

Part B: On completion of Part A, the subject proceeded with performance of actual tests of the soft haptic biofeedback system for balance:

Test 1: The subject remained static standing, with eyes opened, looking forward, feet together, and hands alongside the body with no biofeedback. The subject standed in this position for 5 minutes.

Test 2: The subject remained static standing, with eyes closed, looking forward, feet together, and hands alongside the body with no biofeedback. The subject standed in this position for 5 minutes.

Test 3: The subject remained static standing, with eyes closed, looking forward, feet together, and hands alongside the body with biofeedback. The subject standed in this position for 5 minutes.

Test 4: The subject remained static standing, with eyes opened, looking forward, feet together, and hands alongside the body with biofeedback. The subject standed in this position for 5 minutes.

Test 5: The subject remained static standing, with eyes opened, looking forward, feet together, and hands alongside the body with no biofeedback. Then, the subject was asked to reach a target location/object location fixed by leaning their trunk as illustrated in Fig.

5. The subject repeated this task 3 times. The target/object was removed and the subject was instructed to reach the same target location/object location by leaning their trunk.

Test 6: The subject remained static standing, with eyes opened, looking forward, feet together, and hands alongside the body with biofeedback. Then, the subject was asked to reach a target location/object location fixed by leaning their trunk. The subject repeated this task 3 times. The target/object was removed and the subject was asked to reach the same target location/object location by leaning their trunk with presence of biofeedback provided depending on the amount of tilting of their body.

4.2Experimental Results

The static standing experiments as first part of the pilot study, i.e., Test 1, Test 2, Test 3 and Test 4. Figure 6 illustrates the displacement of the CoP of a subject when biofeedback was not provided and the subject was asked to remain steady by keeping their CoP fixed (i.e., within the blue circle shown in Figures 5 and 6) for 5-mins with closed eyes. While the blue circle represents the desired area for the CoP, the orange curve represents the actual position of the CoP of the subject. As shown in these figures, we observed large CoP movements and the subject could not keep their CoP within the desired area most of the time during the experiment. The subject was not aware of this large CoP movement due to the lack of biofeedback.

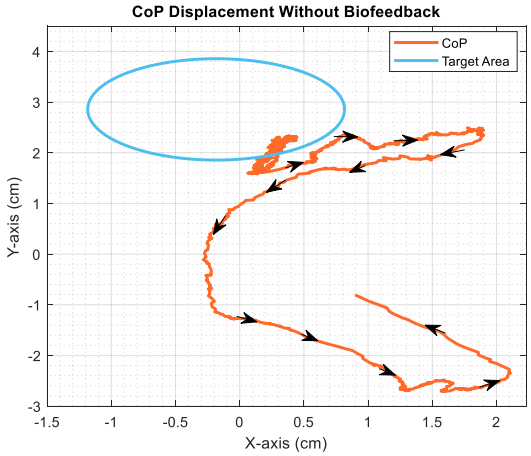


Figure 6. CoP displacement without biofeedback.

Figure 7 illustrates the same experiment when biofeedback was provided to the subject. While the black curve represents the actual position of the CoP within the desired area, the red, green, brown, purple, and blue curves represent the actual CoP position

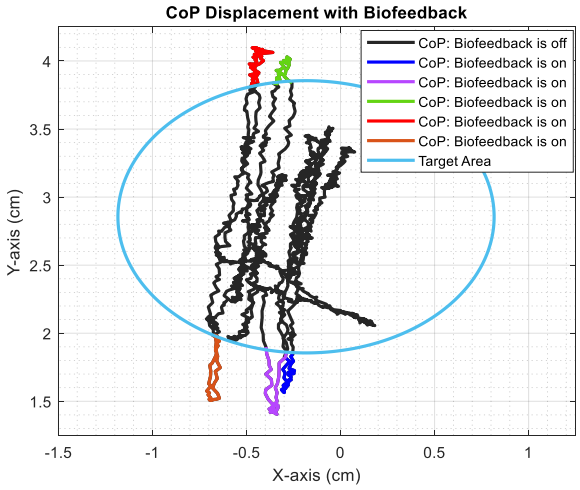


Figure 7. CoP displacement with biofeedback.

outside the desired circular area where the biofeedback system was activated. As shown in this figure, the subject could immediately respond and move their CoP into the desired area using the proposed biofeedback system. The CoP of the subject stayed inside the desired area most of the time during experiment.

To verify the performance of the biofeedback system, we repeated this experiment with 5 subjects. The result of these experiments are outlined in Figure 8. The success rate is calculated by considering the time over which the CoP of a subject stayed within the desired circular area as a proportion of the total trial time. As shown in Figure 8, the proposed biofeedback system improved the participants' ability to remain within the target circle about the CoP, thus participants' balance was improved with the provided biofeedback.

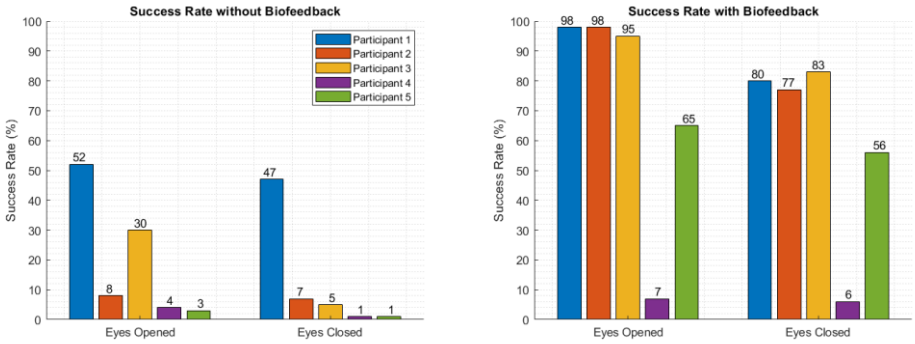


Figure 8. The success rate of static standing experiment with 5-subjects.

The second major part of the experiments assesses the subject's ability to recall their body position by employing a target object to reach by leaning forward, i.e., Test 5 and Test 6. This is asssed by utilizing the CoP data collected during the Test 5 and Test 6. It is noted that the desired location of the CoP is different for each subject due to biomechanical differences such as height and body mass index. Figure 9 illustrates the displacements of the CoP of two subjects along Y-axis when they attempted to reach the target object location by leaning forward. Despite some differences, this figure clearly shows that the proposed biofeedback system allows subjects to locate their CoP to a desired location.

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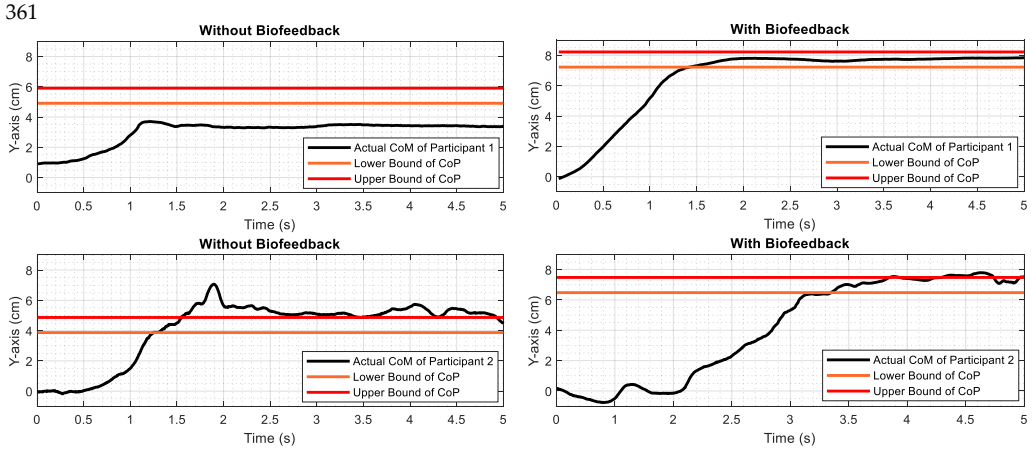


Figure 9. Reaching a desired CoP location experiments of two subjects.

We repeated the reaching a desired location/object location experiment with 5-subjects. The success rate was calculated by considering the time which the CoP of a subject stayed within the target object location as a proportion of total trial time. As illustrated in Figure 10, the success rate of reaching the target location was higher when biofeedback was provided to the subjects.

4.3 Discussion

This study is organised to conduct a pilot investigation on the effects of soft haptic biofeedback device on the postural balance control and proprioception of the wearer. The pilot tests were conducted with participants aged 18 years old and over, had no known orthopaedic or neurological deficits and/or balance disorders, were able to maintain static standing and/or sitting balance, and were able to communicate clearly. Before biofeedback was provided in the experiments, the pressure regulation system was calibrated to determine the upper and lower bounds of the CoP of participants. The calibration process is composed of two steps that take 100 seconds. First, the participant is asked to step on the custom force plate and remain static with eyes opened, looking forward, feet together, and hands alongside the body. While the participant keeps this stance for 70 seconds, the participants' CoP data is recorded to locate the initial position of the participant's CoP. The initial position of the CoP is used as a reference when tracking actual CoP throughout the experiment. Since the initial CoP varies for each subject, it is crucial to repeat this process before initiating the experiment. Recorded data is split into 5 data sets. The initial CoP point is determined by taking the average of these five datasets. The second step is used for locating the expected maximum distances between the initial CoP point and the points that the participant can reach without balance loss. The participant is instructed to lean forward, backward, left, and right with eyes opened, looking forward, feet together, and hands alongside the body. This process takes 30 seconds. At the end of the second step, maximum recorded CoP values are set to be the furthest points that the participant's CoP can reach.

After completing the crucial calibration step, biofeedback was provided to participants in the experiments. The actual positions of the CoP of participants were calculated by using a custom-made force plate in experiments. This is explained in the next section in detail. Using the actual position of the CoP and initial calibration, biofeedback was provided through a control algorithm illustrated in Fig. 4 to improve the performance of different tasks such as static standing and reaching a location. This process was repeated until the test ended or was terminated by the subject.

The ultimate intention of the soft haptic biofeedback device is to employ in more thorough human-robot/computer interactions, such as rehabilitation activities of individuals who have limited proprioception and poor balance control, such as

individuals with sensorimotor dysfunction. In this study, we have demonstrated that a soft haptic biofeedback device, actuated with positively pressurized bellow-like soft chambers, is safe and hihgly compatible in utilization within human-computer interactions, effective in reducing CoP deviation during standing and voluntary movement, and substituting (when the wearer's eyes closed) / augmenting (when the wearer's eyes opened) proprioceptive feedback.

In Part A of this pilot study, experiments were focused on maintaining balance, operationalised as Center of Pressure (CoP), during steady-standing. Results presented in Figures 6 and 7 clearly indicate that when participants closed their eyes, they showed higher performance (smaller CoP deviation) if they were assisted by the soft biofeedback to remain in their target CoP area compared to their performance when the biofeedback was not present. We also demonstrated that even when visual information was available (i.e. the wearer's eyes being open), wearers' performance was lower than their performance with the soft biofeedback during eyes closed tests, as illustrated in Figure 8. This result is perhaps surprising since visual feedback is the dominant form of sensory

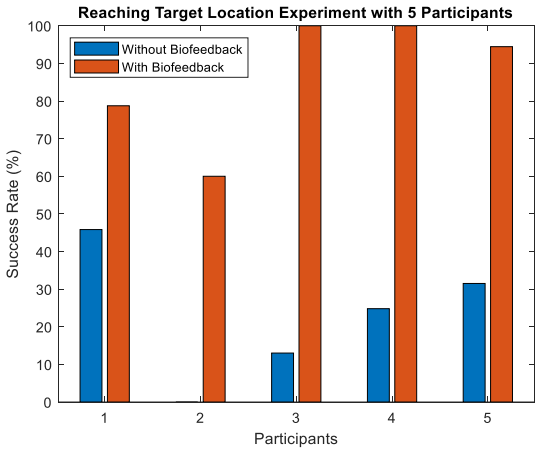


Figure 10. The success rate of reaching a target location experiment with 5-subjects.

feedback by which humans guide their movements, although the lack of visual cues related to the target CoP region in this study likely explains the result. It does, however, also emphasise the effectiveness of providing a source of information related to CoP position for balance regulation, as this information must usually be calculated by the central nervous system indirectly.

In Part B of the pilot study, participants were asked to reach a target body position by leaning their trunk as illustrated in Figure 5 to investigate propriceptive feedback. While each subject repeated this task 3 times, the target/object was removed and they were inquired to reach the same target object location by leaning forward. As per data collection, the subject was not informed how to lean their body; for instance either move their trunk or lean from their ankles. With presence of the soft biofeedback monitored by their CoP position, participants were able to move to the target location more quickly and accurately compared to their attempts with no biofeedback was provided – this was reflected by higher success rates during movements with biofeedback as shown in Figure 10.

5. Conclusion

In this paper, a pilot study of a novel soft haptic biofeedback device has been conducrted to assess its effectiveness on improving the balance and prioception of the wearer through a non-invasive soft biofeedback stimuli. The device was developed according to the principles of soft robotics with use of soft bellow-type-actuators, actuated with positive pressure to create mechanical stimulation of sensory receptors in the skin of the wearer. the pilot investigation of the effects of soft haptic biofeedback on substitution

and/or augmentation of sensory functions associated with postural balance and proprioception of the wearer is outlined in which centre of pressure excursions during standing and voluntary body movements were assessed in five neurologically healthy participants. The results from these experimental studies show that participants were performed in higher success rates in maintaining their balance and recalling their body posture more accurately to a target when a soft biofeedback is present which was mapped with correspondiong CoP axes.

Future studies will focus on testing our soft haptic biofeedback device within thorough investigations of larger group of healthy participants, wider spectrum of participation criteria with inclusion of subjects with limited sensory functions, and in the context of more diverse movements. Further, the authors will extend this studies intergrating with a robot-assited rehabilitation device to complement motor and sensory function loss withing our undergoing projects.

Author Contributions:

Mert Aydin and Rahim Mutlu have equal contributions to this study: while Mert Aydin and Rahim Mutlu conducted experiments and Mert Aydin analysed the data, Rahim Mutlu designed the soft biofeedback device with Dilpreet Singh; Dilpreet Singh also helped with experimental setup; Emre Sariyildiz helped with building experimental setup and data analysis; Robyn Coman, Elizabeth Mayland, Jonathan Shemmell helped providing biomechanical insights to the design of the experimental procedure and ethics application; and Winson Lee helped with analysis.

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Institutional Review Board Statement: The study was conducted with the guidelines approved by the Health and Medical Human Research Ethics Committee UOW.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding authors.

Conflicts of Interest: The authors declare no conflict of interest.

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