In our previous study, we developed a walking support shoe with an elastomer-embedded flexible joint (EEFJ) to assist the function of tibialis anterior (TA) in initial stances (IC) and swing phases (SW). However, its usability and supporting effect have not been sufficiently evaluated. Therefore, in this study, we developed a dorsiflexion support unit (DSU) using the EEFJs with consideration on the usability for frail persons. Their needs were investigated in hearings at community centers. With reference to their comments, we proposed a three-phased scenario in which pre-/post-activities were considered as important factors of its product design of the DSU. We designed the DSU for better usability in the pre-/post-activities. Its basic function and mechanical properties were also investigated in experiments. According to the mechanical tests, the supporting torque was around 10% of the activation of TA in IC. In addition, the results of gait tests show reductions of ankle rotations by 17% and 11% in IC and SW, respectively, without significant increases of TA activations.

Keywords: ankle, gait support, flexible joint, dorsiflexion, gait analysis

1. Introduction

Life expectancy has increased over the past few decades. However, the difference between life expectancy and healthy life expectancy has been maintained at approximately 9 and 12 years for men and women, respectively (Fig. 1). From the viewpoints of both preservation and life support, adequate treatment for frail persons is very important in these periods. Frailty [1] is a common geriatric syndrome characterized by age-associated decline in physiological functions, leading to increased vulnerability for adverse health outcomes. The frailty syndrome may be a physiological precursor and etiological factor in disability due to its central features of weakness, decreased endurance, and slowed performance [2]. There is a growing consensus that markers of frailty included age-associated decline in lean body mass, strength, endurance, balance, walking performance, and low activity. Detecting frailty in primary care consultations can help improve care of the elderly, and walking speed may be an indicator that could facilitate the early diagnosis of frailty in primary care. Persons aged 75 and older with walking speed < 0.8 m/s are at particularly high risk of frailty [3]. Difficulty walking [4, 5] represents a significant barrier in daily file. A decrease in muscular volume due to aging is found more in the lower limbs than in the upper limbs; in particular, the gastrocnemius (GC)
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and tibialis anterior (TA) are considered major weakened muscles [6]. TA is the main muscle that activates dorsiflexion or decreases the dropping speed of the ankle joint. Its weakness causes a slapping foot at the initial contact (IC) of gait and energy-loss walking. It was proved that the foot dropping speeds in the IC were proportional to walking speeds in the natural gaits of healthy individuals [7]. Weakness in TA causes drop foot in swing phases (SW) and often dangerous stumbles. Falling prevention should be the most important function of walking support for frail individuals.

Gait training is a high priority in rehabilitation medicine. For patients with permanent movement disabilities in the ankles or who are in the middle of the recovery process, an ankle-foot orthosis (AFO) is used [8]. In general, AFOs are made of thermoplastic resin or metal frames, and do not have movable joints. Such fixed AFOs are effective in stabilizing the stance phase and in achieving clearance between the toe and ground, the shortness of which is a large contributor to dangerous falls.

To support ankle motion during walking, robotic AFOs have been developed with different types of actuators, such as pneumatic actuation systems [9–11], ball screw drive systems [12], DC motors and worm gears [13], series elastic actuators [14], and soft pneumatic helical actuators [15]. Tanaka et al. developed a robotic walking supporter, RE-Gait® [16], using a DC motor and a worm gear mechanism [13]. These devices successfully control dorsi and plantarflexion of the foot and improve the walking manner for individuals. The usage of semi-active elements is another effective approach for reducing the weight of devices. We developed the intelligently controllable ankle-foot orthosis (I-AFO) [17]. However, its rigid frame prevents the three-dimensional motion of the ankle joint. In addition, computers, batteries, and other components of control systems deteriorate compactness and robustness of these devices.

To solve these problems, we proposed a basic structure of an elastomer-embedded flexible joint (EEFJ, Fig. 2) [18], and applied it to AFOs [19] and shoe-type ankle supporters [20]. The EEFJ is a passive flexible joint composed of a C-shaped spring and an embedded elastomer. The mechanical properties can be adjusted by changing the shape, inner structure, and material of the embedded elastomer. The C-shaped spring flexed easily in dorsiflexion. In addition, the combination of the spring and embedded elastomer generates a higher torque for plantarflexion. Its non-linear property in the open-close directions can be used to support different manners of dorsiflexion, respectively, and works to prevent dangerous falling or decrease in the fear of falling. However, their usability and supporting effects have not been sufficiently evaluated.

Therefore, we designed a pair of dorsiflexion support unit (DSU) using the EEFJ to assist the function of the TA in IC and SW by considering the usability of frail users. We aimed to eliminate the fear of falling for frail users with dorsiflexion support function in IC and SW, and increase the chances of going out, and as a result, improve frailty. The needs of frail users were investigated in hearings at community centers. As an outcome, we proposed a three-phased scenario for product design in which pre- and post-activity was considered an important factor. We designed a DSU for better usability in the pre- and post-activity phases. Its basic functions and mechanical properties were investigated experimentally.

2. Conceptual Design of DSU

This section summarizes the results of interviews conducted with elderly people in two districts (A and B) in Kitsuki City, Oita Prefecture, Japan (Fig. 3), and discusses the attitudes of frail elderly people toward wearing shoes. In district A, there were 11 men and 11 women aged 70–90 years, and in district B, there were 11 women aged 71–84 years.

In response to the question, “What would you like to do if you could walk long distances?”, most of the respondents in district A answered “take a walk,” while most of the respondents in district B answered “travel.” When asked what kind of shoes they would like to have, most of the respondents in district A answered “shoes that can be worn while standing and have a good appearance,” while most of the respondents in district B answered “shoes that are light and have cushioning.” The results of the survey showed that the needs of the respondents differed depending on their physical abilities, even if they were of the same age. Mildly frail respondents wanted to walk long distances, such as on a trip, whereas severely frail respon-
Dorsiflexion Support Unit Using Elastomer Embedded Flexible Joint

Fig. 4. Three-phased scenario for product design (gait support unit in some daily scenes).

In response to the question, “Have you ever felt afraid when you were walking and what was the reason?,” the majority of the respondents in district A, where symptoms tend to be more severe, responded that they “trip over even on flat ground” and “usually take care not to fall.” This indicated that they were concerned about falling.

For the product design of the DSU with better usability, we propose a three-phased scenario as shown in Fig. 4. In this scenario, the design requirements are not only for main “activities,” e.g., walking, traveling, and so on, but also for ease of wearing and inconspicuousness when stored. For activities, it is better to make the unit adjustable for various activity levels according to the user’s physical abilities.

3. Measurements for Clearance Inside Both Feet

3.1. Method

Unexpected interference between the left and right foot deteriorates the supporting effect and causes discomfort and sometimes dangerous falling. The minimum clearances between the left and right foot for six healthy subjects (22–42 years old, Table 1) were measured to determine the maximum boss height of the inner structure of the unit. The subjects wore a pair of black socks on their feet with three optical markers on each foot. The optical markers were attached to a single foot of the subjects, in which one was attached to the malleolus medialis and the others on top of the foot (Fig. 5), to measure the three-dimensional positions with an IR-camera based motion capture system (Flex3, OptiTrack). Each subject was required to walk on a black carpet on a straight line of 1.8 m using two different walking styles: normal walk and sliding walk. The diameter of the optimal markers was 10 mm, and the distance from the human skin to the center of the marker was 20 mm. We directly measured the distance from both markers and added 50 mm to this value to calculate the clearance between the two feet.

3.2. Result

Table 2 presents the experimental results of the clearance tests. The left and right columns show the results of the normal and sliding walking, respectively.

3.3. Discussion

According to Table 2, the distances in sliding walking are relatively smaller than those in normal walking, because in sliding walking, each foot flies just a small height
Fig. 6. Basic structure of DSU (left side is left foot).

Fig. 7. Motion of DSU.

and the vertical distances become smaller. The average value during sliding walking was 68 mm. From this result, we determined that the maximum boss height of the inner structure of the unit was 25 mm for each side.

4. Development of DSU

4.1. Basic Structure

Figure 6 shows the basic structure of the DSU. The structure is composed of a main frame, cuff, heel holder, two connection pins, and elastomer cap. The main frame and heel holder are connected via pin joints on the inside and outside to create a single rotational axis (Fig. 7). This results in smooth dorsiflexion. The combination of the C-shaped curve of the main frame and elastomer cap constructs the EEFJ structure (Fig. 2), creates strong resistive torque to plantarflexion, and supports dorsiflexion of the ankle with their elastic properties. The main frame, made of carbon-fiber reinforced plastic with a 3D printer, connects the cuff and heel holder. The cuff holds the lower leg of the users, and the heel holder is tied with a shoe with tie bands. An elastomer cap is attached to the outside of the shoe and functions as an embedded elastomer with the curved part of the main frame. Embedded elastomers can be replaced with different spring constants to fit the user and ground conditions. The inner side of the main frame was 6 mm thick to prevent unexpected interference between the left and right feet.

4.2. Main Frame

The main frame of the DSU was fabricated with carbon-fiber reinforced nylon resin (Markforged, Onyx) using a 3D-printer (Markforged, Mark Two). The filling rate was set to be 100% (solid). The mass of the main frame was 62 g, with a heel holder and two connection pins.

4.3. Elastomer Cap

We selected a pair of shoes with the BOA® Fit System on the outside of the shoe (left side of Fig. 8) and covered it with an elastomer cap to fix the embedded elastomer (right side of Fig. 8). The boss of the BOA® Fit System was utilized as fixing point of the embedded elastomer (Fig. 2). The elastomer cap is composed of a main part with flanges on both sides and an elastomer ring inside the granges. The elastomer cap covers the boss of the BOA® Fit System and adds elasticity to the boss. The outer side of the main frame was inserted into the flanges to avoid leaving the appropriate trajectory with ankle motions. The main body and elastomer ring of the cap were made of polylactic acid using a 3D printer and polybutadiene rubber, respectively. Its mass was 12–14 g depending on the shape and materials.

4.4. Cuff Design for Pre-/Post-Activity

Cuff parts that hold the calf of the users and transmit the supporting force are the most important and largest accessories (136 g). Its design directly affects the aesthetics of users and should be considered for better usability. For better usability of the pre-/post-activity in Fig. 4, we designed the cuff parts for the DSU, as shown in Fig. 9. It is composed of three parts: a main cuff, cushion, and fixing band. The fixing bands have a magnet on the outside and are attached to the opposite side of the DSU to stand alone. This function allows users to mount/unmount the DSU smoothly and creates a beautiful form at entrances.
5. Evaluation of Mechanical Properties for DSU

5.1. Method

To evaluate the supporting torque of the DSU, we prepared two types of elastomer caps with two different initial tilting angles: 0° (left of Fig. 10) and 30° (right of Fig. 10). Both caps are composed of a main part with flanges and an elastomer ring, as mentioned in Section 4.3. However, the shapes of the main part were arranged to obtain the above initial angles. The maximum plantarflexion angle at the IC during normal walking is approximately 10° [5]. Therefore, we measured the resistance torque around the ankle joint with a push-pull gauge at 10° plantarflexion (Fig. 11).

5.2. Result and Discussion

The resistance torque at 10° in plantarflexion with the 0° and 30° caps were 0.46 and 1.38 Nm, respectively. The resistance torque with eccentric contraction toward dorsiflexion at the IC was approximately 0.2 Nm/kgf [5] on natural walking. If the weight of the subject was 50 kgf, the resistance torque required at the IC was around 10 Nm. The supporting torque was 13.8% of user’s effort.

6. Gait Experiment

6.1. Method

Gait analysis was conducted for walking with and without the DSU (initial angle of 30°) to evaluate the assistive functions. For gait analysis, we used wireless EMG transducers (LP-WS, Logical Product, Inc.) and EMG sensors (LP-WS122, Logical Product, Inc.), wireless amplifiers for goniometers (PH-8010, Logical Product, Inc.), wireless data loggers (LP-WS1311, Logical Product, Inc.), and film-type force sensors (FlexiForce, NITTA). Fig. 12 shows the experimental setup. The force sensors were connected to a data logger to detect the contact condition between the foot and ground. Two switches were attached under the subject’s toe and one switch was attached under the heel. The EMG of the tibialis anterior (TA) muscle, and outer gastrocnemius (GC) muscles were measured using wireless EMG sensors. The sampling frequency was 1 kHz. A wireless goniometer was attached to the left ankle joint, and its angle was measured in the sagittal and frontal planes.

Nine healthy males (22–24 years old) were recruited for the gait analysis (Table 3). The subjects walked on a treadmill at 3 km/h for 5 min with and without the DSU. We recorded the EMGs, ankle angle, and contact conditions for 20 gait cycles. The subjects took enough rest between the no-DSU walk and the DSU-walk. Their heart-
Table 3. Information on subjects for gait experiments.

<table>
<thead>
<tr>
<th>Sub.</th>
<th>Height [cm]</th>
<th>Weight [kg]</th>
<th>Size of shoes [cm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>183</td>
<td>72</td>
<td>27.5</td>
</tr>
<tr>
<td>B</td>
<td>175</td>
<td>68</td>
<td>27.5</td>
</tr>
<tr>
<td>C</td>
<td>173</td>
<td>65</td>
<td>26.5</td>
</tr>
<tr>
<td>D</td>
<td>161</td>
<td>63</td>
<td>26.5</td>
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<tr>
<td>E</td>
<td>174</td>
<td>85</td>
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<td>F</td>
<td>177</td>
<td>70</td>
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<tr>
<td>G</td>
<td>165</td>
<td>60</td>
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</tr>
<tr>
<td>H</td>
<td>167</td>
<td>57</td>
<td>26.5</td>
</tr>
<tr>
<td>I</td>
<td>165</td>
<td>49</td>
<td>25.0</td>
</tr>
</tbody>
</table>

Beat rates were measured before and after the experiments using a fingertip pulse oximeter (ChoiceMMed) to check whether the rest was sufficient or not.

This experiment was approved by the Ethical Board of Faculty of Science and Technology, Oita University.

6.2. Results

The gait conditions: initial contact (IC), foot flat (FF), heel off (HO), and toe off (TO) were assessed with these signal conditions. The measured values for the 20 steps in each condition were averaged, and their distributions for the subjects are shown in Figs. 13–15. Muscle activation was normalized to maximum voluntary contraction (MVC). The range of ankle motion (ROM) was calculated from the differences between the maximum and minimum angles for each duration. Signed rank paired tests were conducted for each group, and star marks were attached to the groups with significant differences ($p < 0.05$).

6.3. Discussions

According to the EMG of the TA and GC muscles, there were no significant differences in any of the gait phases. These results indicate that DSU does not disturb walking in healthy users. On the other hand, the ROM with the DSU in the IC-FF and SW phases was significantly smaller than that without the DSU. As a result, the DSU successfully reduced the ankle rotations by 17% and 11% in IC and SW, respectively, without an increase in the TA and GC activation. The SW results indicate that the DSU effectively assists dorsiflexion of the ankle in SW and improves the clearance between the tiptoe and the ground. However, the effect of IC-FF is not clear.

Figures 16 and 17 show the distributions of the ROM and GC activities for subject B, whereas Figs. 18 and 19 show those for subject C. Mann-Whitney U tests were conducted for each group and star marks were attached to the groups with significant differences ($p < 0.05$). Although B and C had similar physical properties (see Table 3), their responses were different. In particular, the GC activity in HO-TO, which generates a propelling
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Fig. 16. Distribution of ROMs of ankle for subject B.

Fig. 17. Distribution of muscle activations of GC for subject B.

Fig. 18. Distribution of ROMs of ankle for subject C.

Fig. 19. Distribution of muscle activations of GC for subject C.

force, significantly increased with DSU for B, whereas it decreased for C. This implies that the mechanical properties of the DSU, for example, elasticity of the elastomer ring and initial tilting angle of the main frame, should be adjusted based on the walking manner of users.

As reported in [21], the ankle angle and resistive torque at the moment of the IC are important for the stability and energy efficiency of walking. There have been many types of robotic AFOs with automatically adjustable functions [22]. However, their large size and complexity limit their feasibility in daily use. Although some simple adjustable mechanisms for these functions have also been developed for AFO [23], our device has an advantage in its usability and adjustability.

Optimization of the elasticity and tilting angle for individuals must be performed in the future. Additional gait tests should be conducted to ensure a supporting effect in frail individuals.

7. Conclusions

In this study, we proposed an elastomer-embedded flexible joint, EEFJ, which is composed of C-shaped flexible joints and embedded elastomers, applied to dorsiflexion support unit (DSU). The conceptual design and basic structure are presented in this study. The results of mechanical tests showed that the resistance torque at 10° in plantarflexion with the 30° caps was 1.38 Nm, which was 13.8% of user’s effort. In addition, gait analysis was conducted for walking with and without DSU (initial angle of 30°) to evaluate its assistive functions. The results of gait tests showed reductions in ankle rotations by 17% and 11% in IC and SW, respectively, without significant increases in TA activation.

We believe that eliminating the fear of falling will increase the chances of going out, and as a result improve frailty. The optimization of the elasticity and tilting angle for individuals must be performed in the future.
Acknowledgments

This research was partially supported by the Innovative Science and Technology Initiative for Security, ATLQ, Japan (JP19H04596), JKA through its promotion funds from KEIRIN RACE, and JSPS Grant-in-Aid for Scientific Research of Japan (JP19H04503).

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