1. Introduction

The recent development of functional materials, including smart textiles, has enabled the development of wearable biosignal measurement devices that are easy to handle and can be used on a daily basis, even by non-medical users. We focused on sleep disorders as a preliminary application for wearable devices, which are reported to be associated with or exacerbate other diseases, and must therefore be detected early and treated appropriately based on the usual sleep status of the patient. Periodic limb movement disorder (PLMD), which induces nocturnal awakening due to PLM while sleeping, is a sleep disorder that is thought to affect a considerable number of individuals. Since polysomnography (PSG), which needs time consuming hospitalization and forces a financial burden on the patient, is the only practical method for PLMD screening, some PLMD patients are supported to be remain undiagnosed and untreated.

In order to resolve this situation, we aim to develop a PLM home monitoring system that consists of fabric adapters and fabric electrodes that can detect PLMs based on surface electromyogram (SEMG) measurement, without disturbing the usual sleep of subject. We developed a prototype SEMG measurement system that combined ready-made stretchy socks and fabric electrodes that can be easily handled by the patients without any medical knowledge. This prototype can prevent measurement faults due to the slippage of measurement electrodes as the measurement electrodes are fixed by the pressure of the fabric adapter. We first evaluated the functional ability in voluntary movements by comparing the SEMG obtained with the prototype to that obtained using conventional electrodes. We then performed SEMG measurement while PLMs and confirmed that the prototype has the potential to discriminate PLMs from voluntary movements. The proposed socks-type SEMG measurement device is expected to be able to precisely quantify PLMs, even when handled by non-medical users in their home.

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polysomnography (PSG), which evaluates sleep itself from various perspectives using various biological indicators such as electroencephalography (EEG) and electromyography (EMG). Since most PLMs occur in the lower extremities [4], a practical assessment of PLMs using PSG including surface EMG (SEMG) of the bilateral tibialis anterior. All of the PLM epochs extracted from either tibialis anterior are evaluated to determine whether that PLM epoch forces patients to “wake” in the sleep stages, which are determined by EEG [4].

While PSG devices are the only medically approved PLM screening devices, PSG is burdensome to the patient from both financial and time perspectives. This may prevent some potential PLMD patients from being properly examined, and leave them undiagnosed and untreated. Although there are some screening devices without medical approval, PLMs are difficult to properly distinguish from voluntary movements with these devices because they only use an accelerometer to detect PLM [8]. Since acceleration around lower extremities may easily change, regardless of the movement pattern, it is fundamentally difficult to discriminate all PLM epochs from voluntary movements. Even after PSG, it is important to precisely evaluate PLMs at home so that appropriate medical treatment can be administered based on the severity of symptoms, as the frequency of PLMs varies from day to day.

The goal of our research is to develop a home screening device for PLMD that is easy to handle, even by non-medical patients. This device should precisely discriminate PLMs from voluntary movements without disturbing the usual sleep of the patient, even when the device is set up by a patient without medical knowledge; thus, the device itself should be designed based on both biomechanics and human interface perspectives. We herein report the development of a smart wearable sock prototype for a home monitoring system for PLM. The socks contain embedded e-textile measurement electrodes. In the present study, we evaluate its ability of the EMG measurements obtained with this prototype device to detect movements corresponding to PLMs.

2. Overview of PLMD

2.1 Symptoms and pathophysiology of PLMD and other related diseases

PLMD is characterized by nocturnal awakening caused by PLM while sleeping, and may cause daytime sleepiness because of a shortage of good sleep [4]. These symptoms are not unique to PLMD and have been reported in 80% of patients with restless leg syndrome/Willis-Ekbom Disease (RLS/WED) [4]. Since each PLM epoch temporarily oppresses the blood pressure, PLMD and RLS/WED with PLM while sleeping have been reported to induce other fatal diseases, such as cerebral infarction and myocardial infarction [5, 9]. While both PLMD and RLS/WED are suspected to be associated with A11 dopamine system dysfunction [10], the fundamental causes remain unclear and no radical treatments have been established. Thus, patients must undergo symptomatic treatment; this includes the administration of medications to suppress PLMs [4]. Furthermore, the severity of PLMs varies from day to day, even while on medication; thus, it is important to measure the PLMs on a daily basis in order to ensure appropriate symptomatic treatment.

The symptoms of RLS/WED, including PLMs, are also known to occur in some patients without primary PLMD or RLS/WED, including healthy pregnant subjects, patients with other diseases such as iron deficiency, and hemodialysis patients (so-called secondary RLS/WED) [11, 12]. While secondary RLS/WED can be resolved by appropriately treating the main factors, both the sleep quality and daytime sleepiness may worsen until these main factors are completely resolved, and the late treatment of the main factors may increase the risk of cardiovascular disease, as it does in patients with primary PLMD or RLS/WED. Thus, it is meaningful to evaluate PLMs during sleep in patients who complain about their sleep quality or daytime sleepiness to clarify the relationship between the detected PLMs and their sleep.

2.2 PLM motor features and its scoring criteria in PSG

In the field of sleep medicine, PLMs are described as typically involving the extension of the big toe in combination with partial flexion of the ankle, the knee, and sometimes even the hip [4]. The extension of the big toe while PLM is quite similar to the Babinski reflex and is accompanied by the extension of other toes, besides the aforementioned parts, in some cases. According to both descriptions, PLMs involve the movement of at least the big toe and the ankle.

In practical PSG, PLMs are detected according to the PLM scoring criteria, which are based on SEMG
of the bilateral tibialis anterior, which is measured using two electrodes that are placed longitudinally to the bilateral tibialis anterior [13]. The diagnostic criteria for PLM, which were established by the American Academy of Sleep Medicine (AASM), define PLM as a series of ≥4 consecutive PLM epochs, each lasting from 0.5–10 s with 5–90 s intervals [13]. The severity of PLM is evaluated based on the PLM index (PLMI), which is calculated as the number of PLMs divided by the observation time in hours. In general, a PLMI of >5/h in children and >15/h in adults is considered abnormal. Since PLMs are sometimes a benign epiphenomenon [4], PSG is sometimes also used to determine whether PLMs cause events that affect sleep (i.e., nocturnal awakening).

2.3 Biomechanics of PLM motor features

With regard to biomechanics, the combinational deformation of both joints and multiple muscles results in body movement [14]; thus, the muscles associated with PLMs might be identified by investigating the PLM related joint action units and their agonists and synergists.

In the analysis of PLMs (as defined in sleep medicine [4]) from a biomechanical perspective [14, 15], the major PLMs occurring in the lower extremities were regarded as unique movements consisting of toe movements (at least one of the following: inversion, abduction, extension) or dorsiflexion of the ankle. Table 1 shows a list of muscles corresponding to the aforementioned movements that may also occur in PLMs. Note that the abduction of the big toe is more or less related to the flexion of the big toe, which is a converse movement to extension that occurs due to the muscles located around the abductor hallucis. Since involuntary movements, including PLMs, occur in a different way from voluntary movements, the combination of multiple SEMGs targeting PLM related muscles is considered to be useful for discriminating PLMs from voluntary movements.

3. Related Research

Conventional biosignal measurement such as electrocardiogram (ECG) and SEMG requires the appropriate placement of measurement electrodes on the target muscles as well as a body earth, based on biomechanics. It is therefore quite difficult for users without any medical knowledge to do this by themselves at home due to the psychological and physiological burdens.

Fabric biosignal measurement devices with e-textile electrodes are currently developed in order to resolve the issues associated with conventional electrodes [1, 2, 16]. The Nishijin electrode, an e-textile that was designed in order to tackle the aforementioned issues, using the traditional tsuzure technique and enables the creation of measurement electrodes, lead wires for the electrodes, and fabric adapters [17], and the development of a device with embedded Nishijin electrodes can reduce the total processing cost. The incorporation of fabric adapters into a belt or other clothing item that can easily be handled by non-medical users means that all the user must do is to wear the device on their body as they would wear any other item of clothing.

Although there are no practical portable PLM screening devices using SEMG, a preliminary evaluation was performed to investigate the SEMG findings of the tibialis anterior using a SEMG measurement system with Nishijin electrodes. This study showed that the proposed device was indeed useful for SEMG measurement [18]. However, since various adjacent muscles, which correspond to different joint units, are present in the lower extremities [14, 15], a belt type fabric adapter is not yet sufficient for non-medical users; some measurement electrodes may be placed on different muscles near the target when preparing for measurement, or the device may slip off while sleeping. Thus, new types of smart PLM screening devices with different fabric adapters should be considered.

| Part      | Movement     | Agonist                                      |
|-----------|--------------|----------------------------------------------|
| ankle     | dorsiflexion | anterior tibialis                            |
|           |              | extensor digitorum longus                    |
|           |              | extensor hallucis longus                     |
|           |              | peroneus terius                             |
| toes      | extension    | extensor digitorum longus                    |
|           |              | extensor digitorum brevis                    |
|           | abduction    | abductor digit minimi                        |
|           |              | interossei dorsalis                          |
|           | adduction    | interossei plantares                         |
| big toe   | extension    | extensor hallucis longus                     |
|           |              | extensor digitorum brevis                    |
|           | abduction    | abductor hallucis                            |
|           | adduction    | adductor hallucis                            |
4. Proposed Method

4.1 Overview

PLM home monitoring devices that can easily be handled by non-medical users and which can appropriately measure SEMG to detect PLM, must meet the following three requirements: (a) they must obtain SEMG measurements from PLM related muscles, (b) they must be practical for the long-term SEMG measurement of those muscles during overnight sleep regardless of changes in the measurement conditions, (c) they must appropriately discriminate PLMs from voluntary movement based on measured SEMG.

In this paper, we propose a smart wearable sock with embedded electrodes that meets requirements (a) and (b). By using fabric electrodes with a sock-type fabric adapter, users do not have to consider the appropriate points for the measurement of SEMG of the target muscles. They simply need to wear the device, as they would normally wear socks. Socks have a back and forth direction and can be appropriately positioned by fitting the heel parts to the heel. Furthermore, a sock-type fabric adapter also prevents the measurement electrodes from slipping from the target muscle, regardless of changes in the measurement conditions (i.e., sweating). Even when multi-channel SEMG measurement is required to detect PLM discrimination, the fixation of all of the measurement electrodes to the fabric adapter, relieves the psychological and physiological burdens on the user that are associated with the use of conventional electrodes.

4.2 Prototyping

4.2.1 Target muscles

In order to appropriately discriminate PLMs from voluntary movements in the last step of the PLM screening system, we used multi-channel SEMG with multiple target muscles. Major PLMs may induce several different motor movements at a time, as shown in Table 1; thus, the detection of PLMs is based on SEMG of the tibialis anterior alone may result in the misdetection of PLMs.

According to the anatomical location of the PLM-related muscles, we set the tibialis anterior (Fig. 1) and abductor hallucis (Fig. 2) as the preliminary target muscles. These muscles are comparatively large outer muscles among candidate muscles shown in Table 1; thus for which SEMG, which requires the placement of two or more measurement electrodes on the target muscle alone with a few centimeters of space between the electrodes to prevent cross-talk from the adjacent muscles, can easily be performed. To perform SEMG for these two target muscles, we set the body earth to the inside of the ankle where few muscles are located and this can prevent crosstalk from the other muscles.

4.2.2 Implementation

The main problems when users without any medical knowledge use conventional electrodes are the following: (i) it is difficult to correctly place the electrodes on the target muscle; and (ii) it is difficult to stably perform SEMG measurement when either perspiration or body movements cause the slippage of electrodes. Furthermore, the measurement device should not to disturb the sleep of the user.

We developed a fabric SEMG measurement device that consisted of a stretchy sock-type fabric adapter and embedded fabric electrodes to resolve the aforementioned problems. As a prototype of the proposed device, we remodeled ready-made stretchy socks (Dr. Scholl, Medi-Qtto short socks for sleeping) by fixing Nishijin electrodes inside the socks. The circumference of the Nishijin electrodes was heat sealed using a fusible tape to prevent fraying (Fig. 3), and the electrodes were fixed to the fabric adapter using double-sided fusible tape. In addition, we
caulked the male part of a nickel hook so as to extract the measured SEMG signal by attaching an alligator clip that was connected to the measurement circuit. Fig. 4 shows a flattened overview of the prototype (inside out). Based on the anatomical location of the target muscles, the Nishijin electrodes were placed inside the fabric adapter so that they would be located near the muscle belly, where the SEMG measurements are clearest. We expect that the fabric adapter using ready-made stretchy socks can appropriately place the measurement electrodes on the surface of the target muscles and prevent slippage. Note that the material of the Nishijin electrode in this prototype is AGposs® (MITSUFUJI Corporation), which consists of silver coated nylon yarn [20]. It is well known that the size of electrode defines signal collection performance. The higher impedance of bigger electrode prevents signal collection. We set the size of electrodes around 1.3 cm², which is the one confirmed feasible in our previous study [1].

5. Experiment

As a preliminary evaluation of the prototype described in 4.2.2, we conducted the following two experiments. Note that all of the experimental data were measured from the first author with the informed consent agreement.

Exp.1- Two channel SEMGs during voluntary movement were compared between conventional electrodes and the prototype to confirm whether the SEMG of the target muscle measured by the prototype could appropriately detect the target movement. Since the target muscles of the prototype are the tibialis anterior and abductor hallucis, we set two types of voluntary movement as the target: dorsiflexion of the ankle, corresponding to the tibialis anterior (Fig. 5 [a]), and extension of the big toe, corresponding to abductor hallucis (Fig. 5 [b]). The interval between each voluntary movement was set as approximately 15 s.

Exp.2- We evaluated the potential of the prototype for PLM screening by measuring SEMGs from a PLMD diagnosed patient on a day when the test subject felt it was difficult to sleep due to severe PLM. In this experiment, we only measured the target muscles in the left leg based on the complaint of the test subject on that day.

5.1 Experimental conditions

5.1.1 Hardware settings

In order to suppress both the crosstalk from the nearby muscles in the SEMG comparison and the common-node noise, we used a double differential SEMG measurement circuit with the same body earth; the body earth of one SEMG measurement circuit was connected to the electrodes placed on the inside of the ankle, whereas the one on the other circuit was directly connected to the input of the body earth on aforementioned circuit. We also used a 50 Hz notch filter to prevent alternating current (AC) derived from power lines. SEMG was captured every

Fig. 3 Enlarged view of Nishijin electrode

Fig. 4 Lay flat overview of the prototype

Fig. 5 Target movements in Exp.1 [14]

Fig. 6 Overview of measurement point of target muscles using the prototype
1 ms using a USB-connected two-channel oscilloscope (EasySYNC Ltd., DS1M12).

5.1.2 SEMG measurement conditions
In both Exp. 1 and Exp. 2, the SEMG measurement electrodes were placed on the left lower leg shown as Fig. 6. We used conductive paste on the electrodes (Suzuken Co., Ltd., Kenz ECG cream) to reduce the effect of impedance between the skin and the electrodes, which may according to the skin condition.

In Exp. 1, we used Vitrode C electrodes (Nihon Kohden), which consist of a combination of conductive solid gel and soft cloth tape, as conventional electrodes. The Vitrode C electrodes were placed as shown in Fig. 7.

5.1.3 Data post-processing
Since measured SEMG may contain noise or artifacts due to the changeable measurement conditions, it is difficult to analyze the measured EMG obtained in these experiments as it is. We performed post-processing according to the following methods in order to reduce the effects of noise and artifacts: moving average filter, mean value subtraction (direct current removal), absolute value calculation, and peak envelope calculation. In Exp. 2, we also evaluated all of the detected movements by comparing them to the duration and intervals defined in the AASM criteria [13].

5.2 Results
5.2.1 Exp. 1
The processed SEMG envelopes of the tibialis anterior and abductor hallucis measured by the prototype and Vitrode C electrodes are shown in Fig. 8 and 9. The black dashed line shown in Fig. 8 and 9 indicates detected movements. The processed SEMG of the tibialis anterior in Fig. 8 and the abductor hallucis in Fig. 9 show that they were activated due to voluntary movements, whereas the abductor hallucis (Fig. 8) was comparatively stable, as was the tibialis anterior (Fig. 9). These comparisons of the processed SEMG of the two muscles between two different movements suggested that the prototype can appropriately measure the target movements.

5.2.2 Exp. 2
Fig. 10 shows the processed SEMGs of the tibialis anterior and abductor hallucis in PLMs during sleep. In this experiment, we confirmed that there were no voluntary movements and that only PLMs were observed according to the main complaint of the patients. The black dashed line in Fig. 10 indicates the detected PLM epochs that satisfied the AASM criteria for PLM detection based on both the duration and the interval [13], suggesting that the detected movements were more likely to be PLMs than similar voluntary movements. The comparison of the
processed EMGs between two muscles showed that most of the peaks that were considered to represent PLMs occurred synchronously; few epochs were observed in the abductor hallucis alone.

6. Discussion

The results of Exp. 1 showed that the prototype can perform SEMG measurements as well as conventional electrodes and that the measured SEMGs were sufficient for discriminating target movements such as dorsiflexion of the ankle (Fig. 8) and extension of the big toe (Fig. 9). Since the SEMG measurements using the prototype and the conventional system (using Vitrode C electrodes) were performed independently in Exp. 1, the validity of the measured amplitude itself was not evaluated. However, the amplitude of the processed SEMG measured by the prototype was still sufficient to discriminate the target movement, even though the values differed from the ones obtained by using the Vitrode C electrodes. Furthermore, the results of Exp. 2 implied that the prototype can discriminate PLMs based on the measured SEMGs of the tibialis anterior and abductor hallucis; the processed SEMGs showed that they were both activated at roughly the same time, unlike the voluntary movements shown in Fig. 8 and 9. Even though this experiment only investigated SEMG without any of the biosignals measured in practical PSG that physicians use to distinguish malignant PLMs from other voluntary or involuntary movements, the main complaint of this patient described was difficulty in falling asleep due to severe PLMs; thus, the detected epochs were considered to be probable PLMs. According to those results, this prototype, which used a combination of ready-made stretchy socks and fabric Nishijin electrodes, has potential to appropriate SEMG measurements that allow for the detection of PLMs.

The main advantage of the prototype over conventional electrodes is that it can be used by non-medical users. Since all of the measurement electrodes are fixed to the stretchy socks, the user...
does not have to know the exact position of the target muscles or the appropriate measurement position; they simply need to wear the prototype as they wear a normal pair of socks. The sock itself has back and forth direction, so that all the user has to do is to fix the heel of the sock to their heel. Furthermore, the prototype fixes measurement electrodes at the appropriate position with the pressure of the fabric adapters alone. Fig. 11 shows the mark of electrode after SEMG measurement by the prototype. Mark of electrode clearly remained on the skin and no mark of sliding is appeared. This feature makes the prototype comparatively robust with regard to changeable measurement conditions including body movements and perspiration. Since conventional electrodes with conductive gel fixes measurement electrodes by using the tape or adhesive gel, which may slide or slip off from the target muscles due to the user’s sweat. When using the combination of fabric electrodes and fabric adapters for SEMG measurement, both can absorb sweat, and wet fabric electrodes measure SEMG more easily than dry fabric electrodes due to reduced impedance.

For further comparison of the prototype with the conventional electrodes, we conducted a secondary use evaluation of the prototype after washing. We washed the prototype according to the “E method” described in JIS L 1096:2010 [21]. Note that our washing test was a preliminary one and only used the procedure of the “E method” test without using any special equipment. Furthermore, since the prototype absorbed all specific water described in [21], we used 1,500 ml of water, which is 5 times as the amount of water described and enough for the prototype to be fully soaked. The conditions of this washing test are shown in Table 2. After washing, we measured SEMGs of the abductor hallucis and tibialis anterior under the same conditions described in Exp. 1. Fig. 12 shows the processed SEMG envelope during voluntary dorsiflexion of the ankle, and Fig. 13 shows the one during voluntary extension of the big toe. In both Figs. 12 and 13, the measured SEMG amplitude was sufficient for movement detection despite differing from the ones shown in Fig. 8 (a) and Fig. 9 (a). These results indicate that the fabric electrodes used in this prototype were washable and could be reused, unlike conventional electrodes, which are normally disposable.

An ideal home screening device for PLM should be easy for non-medical users to use at home and should be able to measure SEMG of the target muscle throughout the entire sleep period without disturbing the user; the measurement electrodes should obtain stable SEMG of the target muscle throughout the night, regardless of the body movement of user such as rolling over or the friction between the bed cover and the device. Furthermore, the entire device, including the lead wires and the measurement circuit

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| Phase       | Water Temperature | Detail                                      |
|-------------|-------------------|---------------------------------------------|
| Washing     | 37.4℃             | 15 min with 1,500 ml of water               |
| Rinsing 1   | 36.9±0.71℃        | 3 times                                     |
| Rinsing 2   | 38.5℃             | 5 min with 1,500 ml of water               |
| Dewatering  |                   | 1 min with a commercial washing machine    |
| Drying      |                   | Placed flat until dry out                  |

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Fig. 12 Processed SEMG envelope in the secondary use test during voluntary dorsiflexion of the ankle
Black dashed line: Detected movements

Fig. 13 Processed SEMG envelope in the secondary use test during voluntary extension of the big toe
Black dashed line: Detected movements
must not disturb the sleep of the user by preventing natural voluntary movements and PLMs while sleeping. Since the prototype we developed in this time must additionally connect the lead wires to the measurement circuit, these wires may disturb the body movements or induce measurement faults if they become entwined around the lower leg of the user. Thus, we expect that the fabric PLM screening device, which consists of fabric adapters, embedded e-textile electrodes and lead wires that are closely connected to a small measurement circuit satisfy all of the aforementioned requirements. For greater ease of use, the sock-type measurement device should prevent slippage and twists, which disturb appropriate measurement, by using printed instructions or ribbed fabric. Since the measurement electrodes must be fixed to the muscle belly of the tibialis anterior longitudinally, the fabric adapter is expected to employ an instruction indicator, which enables non-medical users to fix electrodes on the appropriate measurement position around the shin. For further practical use, multi-channel SEMG measurement in each target muscle is expected to be effective for reducing the effects of measurement faults or inappropriate measurement settings, which normally occur during sleep. By setting multi-channel SEMG measurement electrodes, we can increase the precision of SEMG of the target muscles. This may even enable the automatic selection of appropriate SEMG when the current channel seems unstable.

7. Conclusion

We aim to develop a PLM home monitoring system using e-textile SEMG measurements that can be easily handled by the patients without any medical knowledge to facilitate the early detection and appropriate treatment of PLMD, which induces nocturnal awakening by PLMs during sleeping and may induce daytime sleepiness due to the shortage of good sleep. In this paper, we described our development of a prototype SEMG measurement system that combines ready-made stretchy socks and fabric electrodes; the prototype is easy to handle, even by the non-medical users. This prototype also can prevent measurement faults due to the slippage of measurement electrodes by fixing the measurement electrodes using the pressure of a fabric adapter.

We confirmed the functional ability of the prototype by comparing the SEMGs of the tibialis anterior and abductor hallucis obtained by the prototype and by a system using conventional electrodes during target movements; these muscles are thought to be related to PLMs. The results of the experiments showed that the SEMGs obtained by the prototype were sufficient for discriminating the target movements, and this suggested that the prototype has potential to discriminate PLMs from voluntary movements based on the SEMGs. We expect that the proposed sock-type SEMG measurement device with a fabric adapter and fabric electrodes will be able to precisely quantify PLMs, even when the device is handled by non-medical users at home.

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