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Redesign of Foot Rehabilitation Products-Correction of Thumb Valgus and the Comfort and Hygiene of Wearable Assistive Technology

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Abstract: The foot is one of the organs that people use almost every day of their lives, and every human foot may suffer from some minor deformity. This project analyses one of the most common deformities of the foot, the bunion, and analyses the different occupations and lifestyle habits of different patients with this deformity and improves the existing rehabilitative corrective devices. In addition, the project investigated the comfort of the user with the wearable assistive technology. By analysing the sweaty areas of the foot, I used sweat sensing devices to control the ventilation system of the product and investigated different porous structures of the generative design as the foot support material to solve the problems of stuffiness and lack of ease of cleaning when wearing the wearable assistive technology for a long period of time, which brought the users a breathable and more hygienic wearing environment.

1. Introduction

People's walking habits are very different, people wear different shoes, do different professions, and the foot as the body's main support organs in different habits of life will appear a little deformed. Hallux valgus (HV) is a foot deformity with the main symptoms being lateral deviation of the first phalanx and medial deviation of the first metatarsal [1]. HV affects approximately 19% of the population worldwide. The prevalence varies significantly by region, with relatively high prevalence in Asia and Oceania [2]. HV is a deformity that not only causes foot pain and difficulty in walking, but also affects overall posture and balance. The symptoms of HV can significantly affect foot health, leading to gait disorders and foot pain, and increasing the risk of falls [3].

1.1 Hallux valgus effects on body posture

The effects of Hallux valgus (HV) on posture may not be obvious in everyday activities, however HV has a serious impact on the balance of the body's skeleton, and suffering from HV for a long period of time may affect the posture of the pelvis. While the effects of HV on one's skeletal structure may not be visually apparent by observing everyday activities such as walking or running, however, a relatively static, slow-motion movement can reveal the effects of HV on posture, and ballet is a straightforward example of how HV can affect posture. For the ballerinas, their feet are often under extreme stress. HV is a common foot deformity affecting many ballet dancers, and a study by Seki et al. showed a correlation between the extent of bunions and the kinematic characteristics of some of the basic techniques performed by ballet dancers. In specific, the greater the angle of the bunion, the greater the degree of posterior tilt of the pelvis during the flexion movement [4]. In that case, people with HV have a certain tilt of the pelvis that affects the skeleton and posture of the person.

1.2 Causes of the hallux valgus (HV)

There are some inherent predisposing factors to HV, such as flat feet, polio, cerebral palsy or Achilles tendon contracture. But inappropriate footwear is a major external cause of developing HV [5]. There is a high prevalence of HV in women and older adults. The prevalence of HV in adults between the ages of 18 and 65 is 23 %, and this rate rises to 35.7 % in those over 65 years of age [6].In addition, the prevalence among women is about 30 % compared to 13 % among men. This is because women will wear high heels more often as compared to men. Among women, the prevalence of HV among women who wear high heels is 25.25 % as compared to 10.87 % of women who wear flat shoes. This also implies that the risk of developing HV in women who wear high heels is 2.77 times higher than in women who wear flat shoes [7]. To sum up, high heels are one of the extrinsic factors that cause the formation of HV and may increase its severity. This is because high heels increase the pressure on the forefoot, which leads to the formation of HV. This is an indirect indication that inappropriate shoes are the main cause of HV development.

1.3 Treatment: Non-surgical methods

One of the most effective ways of treating HV has always been the use of bunion orthotics. By repositioning the Big Toe, the bunion orthosis reduces the pain by relieving the local mechanical irritation and joint deformity. In addition, minimalist footwear interventions have also had a positive effect on improving foot function in patients with HV. By wearing minimalist footwear for a long period of time, the intervention reduced stress loads on the metatarsal bones by improving the alignment and flexibility of the first metatarsophalangeal joint [8]. In order to prove the effectiveness of conservative treatment methods, Muh. Syaiful Akbar et al. studied 22 teachers and staff with HV in public primary schools in Kemangkon district, who were treated with the intervention of an over-pronation orthosis. The study found that the use of toe valgus orthoses significantly reduced toe valgus pain ($p = 0.000$, $p < 0.05$), which validated the effectiveness of the orthoses [9]. Moreover, according to Kulkarni and Patil, it was found that corrective exercises for bunion deformity combined with mobilisation and stretching were more effective in reducing the angle of valgus, relieving pain, and improving the functional performance of the foot and ankle compared to toe separation and short foot exercises [10]. This study also demonstrates the effectiveness of conservative treatment methods.

1.4 Treatment: Surgical approach

Surgical treatment of HV is more effective in specific professions. When correcting the 3D deformity characteristic of HV, the rotation of the first metatarsal is a key point in the comprehensive treatment of HV [11]. This is especially necessary for professional athletes who depend on their kinematic performance. Surgical intervention can be effective in recovering both freedom of body function and pain reduction in case of failure of conservative treatments [12]. However, after the surgery, the patient will still need to wear a rehabilitative foot brace to recover. Whether it's through an orthotic or a surgical procedure, patients can't do without a wearable fixator.

In that case, it is crucial to analyse both treatments together, therefore I would like to design a device that is also compatible with post-surgical rehabilitation.

2. Disadvantages of existing orthoses and wearable assistive technology

With the development of wearable assistive technology, there have been solutions for a variety of disabilities, such as different types of prosthetics and wearable devices. The user groups I work with have full feet, so I cannot design a single mechanical orthosis for the user, but instead I have to take into consideration of the reaction that the foot brings to the user. People are not cold machines with durable mechanisms, and although the human body is a magnificent piece of engineering, the skin is always going to be the outermost fragile layer of the human body. In particular, the skin on the feet is associated with a number of health problems such as pain, skin irritation and fungal effects. Prolonged use of wearable assistive technology increases the risk of skin irritation. Skin temperature control within the prosthetic sleeve is a key issue. High temperatures with moisture can lead to skin irritation, abrasion and even infection, which affect the comfort and use of the prosthesis [13]. Moreover, the design of existing liners and prostheses on the market does not consider how to maintain hygiene, for instance, by how the user should replace the liner with a new one and wash the product to maintain a hygienic and healthy wearing environment. To sum up, it is essential for wearable devices designed for the foot to be designed for a breathable wearing environment.

Thermal discomfort due to sweating is a common problem amongst lower limb prosthesis wearers. Thermal discomfort not only causes discomfort to the user, but is also associated with excessive sweating, skin damage caused by humid environments and friction. These problems are particularly acute due to the impermeable characteristics of prosthetic devices with warm, humid environments. Many prosthesis wearers experience discomfort on a regular basis, with the incidence of sweating and feeling uncomfortable due to heat exceeding 50 % [14]. Not only does this discomfort cause uneasiness, but it can also lead to problems such as increasing sweating and skin damage. As a result, how to correct the HV while solving the impermeable nature of wearable assistive technology is an essential direction for my further research.

3. Design of a Novel Solution

The design of the orthos is has two main functions. The first one is to have a flexible aligner to prevent bunion, and the second one is to turn on the ventilation system in the mid sole through the sweat sensing device, so that the user can have a refreshingly comfortable wearing environment. In my design, I used a porous structure for the insole, which allows air to circulate and creates a breathable wearing environment, and this structure also helps the user to maintain and clean the insole for a more hygienic wearing environment.

3.1 Conceptualisation

In the initial stages of the design, I made some design sketches, which provided me with a general understanding of the structure of existing foot rehabilitation products. In this process I was able to get a blueprint of the structure of existing foot rehabilitation products. I wanted to make sure that the design had a fixation that would hold the thumb and foot in place. Below in the Figure 1 is my idea of a ventilation system with a fan driven by a motor and operated by a sweat sensor. In order to get a clear conceptualization faster, I used cardboard to make a prototype based on the size of my foot. I tested the model and found that it wasn't very sturdy, and I had to resize it to hold the Arduino inside.

Figure 1: Design Sketch

3.2 Design and Arduino prototyping progress

According to Williams' research, tackling the problem of thermal discomfort requires not only technological innovations, but also psychological and situational considerations. A concept of "regaining control" was proposed to psychologically alleviate thermal discomfort. This concept can be incorporated into prosthesis design by using "on-demand" thermal discomfort relief techniques rather than traditional "always on" solutions [14]. In my design, the sweat would be the key controller, with the product sensing the user's perspiration and switching on the cooling fan to keep the user's feet comfortable and dry. In the process of researching the Arduino and coding, I have found that a humidity sensing device may be one of the more subtle ways to represent the subtle data. If the fan turns on when the humidity reaches a set position, this may be the most important goal I want to achieve, but the humidity sensing device needs to be used in a well-sealed environment, which means that the user's feet need to be in an unventilated environment in order to triggering the sensor, which seems to be the contrary of my original intention, then I find a device that can sense the liquid, and when the sensor panel is put on the soles of the feet, it can acutely sense the humidity and the pressure of the liquid, which can be detected when the user is sweating. By placing this sensor on the bottom of the foot, the user's sweat level can be accurately monitored, and the cooling system can be switched on without interfering with the user's daily activities, but also avoiding the need to use the sensor in a sealed environment. The design logic of this set of devices is straightforward, when there is any liquid on the sensor panel, it will trigger the motor to drive the fan ventilation system, and when the sweat completely vanishes, the ventilation system will be shut down. Meanwhile, I also directly tested the sensitivity of the sensor panel to sweat, I used a paper towel with a bit of water to simulate a human sweating scenario and found that even this change is very subtle, it will also make the ventilation system on. Moving on to the 3D modelling process, I considered the location of where the panel should be installed. The study by Anna M. West et al. found that the highest level of sweat rate was around the inner ankle area while the lowest was around the toes [15]. Due to the curved structure of the inner ankle and arch, sweat will eventually be distributed under the arch of the foot, so I designed the device to be placed under the arch of the foot, and in this way the sensor could detect sweat without constantly rubbing against the bottom of the user's foot, which would interfere with their daily activities. I printed several models to test and modify the dimensions and then I had the tricky problem of making the product more breathable so that air could circulate through the product and reach the user's feet.

Figure 2 shows the prototype testing.

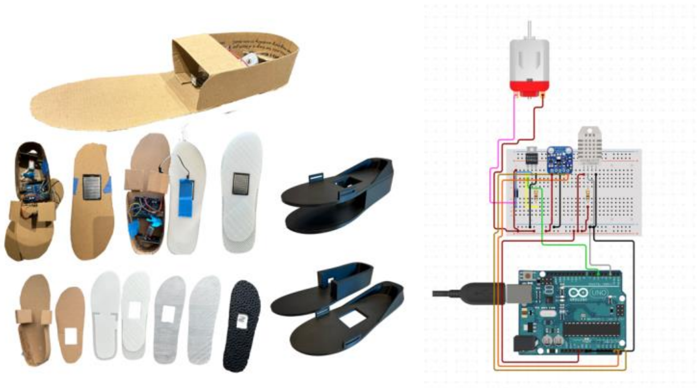

Figure 2: 3D model testing: Cardboard prototype, 3D print models, and Arduino set up.

3.3 Material Suitability Testing: breathable structure and material

Xiang et al. developed a self-assembly method based on block copolymer for the synthesis of porous materials with a sequential continuous structure. The structure of these porous materials is conducive to improving the effective mass diffusion within the materials [16]. Such porous-like structures can effectively apply forces uniformly, and if used as the insole portion of a product can support the HV patient's body uniformly, as shown in Figure 3. In addition, such a structure also has a protective effect on the skin, and a breathable soft stress sensor based on liquid metal foam has been proposed in the study of Xu et al. The innovative material and structural design of this porous structure provides high sensitivity and stretchability while avoiding skin irritation [17]. Although physics and chemistry are not one of my main research fields, such porous structures should be applied to the bottom of the orthotic device I am designing as a support for the foot, which would allow air flow to make the skin accessible and at the same time spread the person's weight evenly.

During the modelling process, I thought that generative design would help me to design this porous type of structure. The CAD programme I used included Autodesk Meshmixer to generate a hexagonal pedicle and for the insole. Besides, I used NTopology to generate a breathable and firm insole section. By combining both of the design outcomes, I was able to create an insole with a breathable and firm structure that would allow the skin to come into contact with the air while spreading the weight evenly. I tested the product in a comprehensive use case, and the product is lightweight and also has a breathable user experience, as shown in Figure 4.

3.3.1 Porous structures and product rendering

Figure 3: Porous structures and product rendering.

3.3.2 Final product

Figure 4: Final product testing.

4. Conclusions

This study focuses on the correction of hallux valgus and the comfort and hygiene of wearable assistive technologies, successfully designing a novel orthosis that integrates corrective functionality and comfort through analysis and improvement of existing foot rehabilitation products.

In terms of hallux valgus correction, the research deeply analysed the impact of this deformity on body posture and its causes, confirming the effectiveness of orthoses in non-surgical treatments. By integrating the needs of post-surgical rehabilitation, a device compatible with both conservative and surgical pathways was designed. The flexible aligner achieves effective correction of hallux valgus, offering patients more comprehensive treatment options. For improvements in the comfort and hygiene of wearable assistive technologies, the study utilised sweat-sensing devices to control a ventilation system based on analysis of foot sweating areas, combined with generative-designed porous structures as foot support materials. This successfully addresses the stuffiness and cleaning difficulties of existing products during long-term wear, creating a breathable and hygienic wearing environment. Prototype testing and material suitability assessments show that the design accurately detects user sweating and activates the ventilation system in a timely manner, while the porous materials ensure air circulation and wearing comfort alongside effective support.

This study provides new ideas and directions for the design of foot rehabilitation products. Its achievements are expected to bring better treatment experiences and rehabilitation outcomes for hallux valgus patients, while also expanding the application of wearable assistive technologies in the field of foot health.

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