DOR: 20.1001.1.27170314.2023.12.3.3.0

Research Paper

Analysis of Orthotic Insoles Manufacturing for Treating Flatfoot Using Smart Orthotic Insole in Comparison with Traditional Methods

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Received: January 3, 2023; Accepted: August 27, 2023

Abstract
In this research, the anomaly of flatfoot was initially introduced, followed by an examination of both traditional and new methods for designing and manufacturing orthotic insoles suitable for it. Regarding this matter, the design and construction of orthotic insoles using a stamp as a traditional method was introduced, and subsequently, the step-by-step elucidation of new methods, including foot scanning and the utilization of smart orthotic insoles in designing and manufacturing insoles suitable for flatfoot, was carried out. In both of these new methods, the design and construction of appropriate orthotic insoles involved the transfer of information obtained from the foot to relevant software and their subsequent processing. This research, while explaining the mentioned methods, described how to use engineering design software in designing and manufacturing orthotic insoles suitable for flatfoot. In conclusion, the results obtained from all three manufacturing methods were presented and compared to ascertain the advantages and disadvantages of each approach.

Keywords
Flatfoot, Smart Orthotic Insole, Foot Scanner, Stump, CNC

1. Introduction

The structure of the arches of the feet played a significant role in influencing the forces exerted on the feet during standing and walking. As a result, examining foot arches is of paramount importance in the field of biomechanics. Deformities or alterations in foot arches can lead to upper body injuries, premature fatigue, and lower limb and back pain, as well as musculoskeletal damage. Depending on the severity of these abnormalities, neglecting the geometric defects of the foot arches over time can have irreversible effects on individuals. To address issues related to foot arch geometry deformities, indirect therapeutic methods such as corrective exercises or the use of orthotic insoles can be employed. Additionally, improper walking or standing postures can also be addressed through the use of orthotic insoles and other rehabilitation methods [1].

Flatfoot, often referred to as pes planus, valgus foot pes planus, or simply fallen arches, is a common abnormality that can adversely affect an individual's health, safety, and efficiency. While flatfoot is a normal developmental state in young children and may persist into adulthood without noticeable symptoms, it can also occur due to various factors, including neuromuscular disorders, laxity syndromes, and other causes. Acquired flatfoot, characterized by the partial or complete flattening of the inner arch, can develop after skeletal maturity. Posterior tibialis tendon degeneration is a common cause of acquired flatfoot. Initially termed posterior tibial, it has recently been referred to as Adult-Acquired Flatfoot Deformity (AAFD) as it encompasses a range of soft tissue abnormalities in the posterior and plantar aspects of the foot [2].

Flatfoot can lead to uneven distribution of mechanical forces on the foot, which may be transferred to the upper extremities. Regarding the treatment of flatfoot through physiotherapy and orthotic interventions, there is a difference of opinion among practitioners [3]. Treatment approaches for flatfoot include exercises, corrective movements, weight reduction, immobilization, physiotherapy, and pharmacological treatments aimed at reducing pain and inflammation [4]. In severe cases, surgical interventions may be necessary [5]. Orthotic treatment options encompass the prescription of custom orthoses, prefabricated orthotic devices, arch supports, and orthotic insoles [6, 7]. Studies have indicated that individuals with flatfoot tend to shift their weight line towards the inside of the foot [8]. Furthermore, research in this field has shown that wearing orthotic insoles can reposition the weight line towards the center [9]. Previous studies have also revealed that wearing shoes and orthotic insoles can alter the center of pressure within the foot, subsequently affecting torque changes and forces applied to it [10]. Given that physical exercise can increase the levels of stress, strain, and shear forces applied to the lower extremities, using appropriate orthotic insoles during exercise is particularly crucial for individuals with flatfoot [11 and 12]. Consequently, the following section will provide a brief overview of studies conducted on various common orthotic insoles for treating flatfoot.

1.1 Simple Orthotic Insole

Sadeghi et al. [13] conducted an evaluation of 15 male athletes with flexible flatfoot, assessing the vertical and anterior-posterior ground reaction forces during walking in three conditions: barefoot, shoes without insoles, and shoes with custom orthotic insoles. Their findings indicated that, in individuals with flatfoot, the ground reaction forces when using custom orthotic insoles (designed and manufactured based on the individual's foot structure) significantly differed in both vertical and anterior-posterior directions compared to the barefoot condition and using shoes without insoles, especially during weight transfer onto the heel and foot lift-off from the ground. This study demonstrated that the control of pronation and eversion of the foot while walking using custom orthotic insoles can alter the pattern of ground reaction force distribution in both vertical and anterior-posterior directions compared to the barefoot condition. This suggests an impact of custom orthotic insoles on the force distribution pattern across the foot and, consequently, on other joints. Therefore, the study recommended investigating kinetic changes in joints following insole use.

Shojai et al. [14] conducted a study to investigate the major cause of foot pain, often related to plantar fasciitis (inflammation of the plantar fascia). The common treatment for this condition includes the use of orthotic insoles. Their study aimed to compare the effects of custom-made insoles created using a CAM-CAD system with conventional insoles on pain, daily activities, and quality of life in individuals with plantar fasciitis. They concluded that both custom-made insoles crafted using CAM-CAD technology and conventional insoles can effectively improve pain, symptoms, daily activities, sports and recreational activities, and overall quality of life in individuals with plantar fasciitis. Furthermore, there was no significant difference in their effects on the mentioned variables. Given the lack of substantial difference between the two types of insoles and their effectiveness in improving the mentioned variables in treating patients, this study recommended the use of both types of insoles in healthcare centers.

Heydari et al. [15] stated that one of the treatment methods for flexible flatfoot in children is the use of orthotic insoles. Their research aimed to investigate the short-term effects of using supportive arch insoles on balance and symptoms of flexible flatfoot in children in Tehran. They concluded that children with flexible flatfoot should be recommended to use supportive arch orthotic insoles to enhance their motor and balance performance, as well as to alleviate the symptoms associated with flatfoot.

Soltani et al. [16] concluded in their study that understanding the biomechanics of the foot is crucial for determining the specific needs of different gender groups (male and female). Based on the results obtained from the study comparing foot pressure variables between men and women, it appears that the structural effects of foot pressure distribution can be considered in the design of various manufactured products. For instance, these findings are highly applicable and practical in the production of shoes, orthotic insoles, and specialized sports footwear tailored for individuals. In another study, Karimkhani and Mirtalaie [17], through their work in designing and constructing orthotic insoles, observed a significant decrease in Von-Mises stress values during three loading phases in the analysis of orthotic insoles, ranging from 2 to 12 MPa. This finding suggests the effectiveness of orthotic insoles in alleviating the consequences of flatfoot, which can, to some extent, prevent injuries caused by foot forces and provide substantial assistance in rehabilitation.

1.2 Smart Orthotic Insoles

After examining orthotic insoles, there was a recognized need for an insole that could establish a more convenient link between diagnosis and treatment for individuals. This insole should serve as a comfortable and alternative method of treatment, accessible to both healthcare providers and patients. Erlin and et al. [18] demonstrated that measuring plantar pressure indicates foot functionality during walking and other functional activities. Analyzing the results of this study led to the evaluation of the health status of the feet of patients suffering from diabetes and peripheral neuropathy. Additionally, the information gathered from plantar pressure data can be valuable in identifying and managing musculoskeletal disorders.

Abdulrazak et al. [19] demonstrated that plantar pressure is a pressure field that operates between the foot and the supporting surface during daily movement activities. The information derived from their research indicated that pressure distribution is crucial for diagnosing lower limb issues, shoe design, sports biomechanics, injury prevention, and other applications. They delved into the characteristics of foot sensors, which, besides pressure measurement systems, are capable of detecting various foot problems. In their study, they discussed the strengths and limitations of conventional systems and proposed a wireless foot pressure system to accurately and reliably measure foot pressure distribution.

Farago et al. [20] demonstrated that walking is one of the most effective forms of human activity for achieving mobility. Their research showed that a wearable smart system can be used for monitoring and evaluating the biomechanical performance of the foot during walking. Their proposed solution assumes a relationship between foot pressure and the muscular activity of the lower limb during the stance phase of walking. Foot pressure is measured using a set of resistive pressure sensors placed on the insole of the shoe along the progression line of the body's center of gravity. To assess the muscular activity of the lower limb, electromyography of the tibialis anterior and gastrocnemius of the lower limb muscles is used in sequence. Based on this, during physiological walking, the interdependent relationship between foot pressure in the heel region with the activation of the tibialis anterior and foot pressure in the arch and toe region with the activation of the gastrocnemius is measured. Similarly, an evaluation of physiological walking is transformed into a reference walking pattern by comparing it with a walking pattern formulated based on the correlation of the calf muscle in the lower limb. The details of the system used in this study are illustrated in Figures 1 and 2.

Figure 1.The model used by Farago et al. [20]

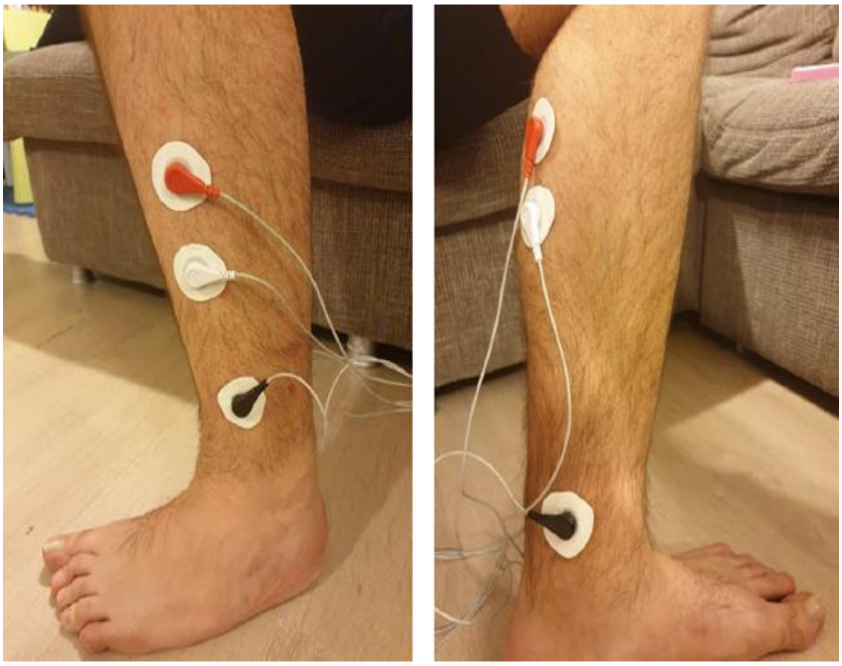

Figure 2. EMG-evaluable parts for muscles [20]

According to the literature review, the next step was to describe the procedure, followed by the methods of investigation. Three methods for examining and constructing orthotic insoles for flatfoot deformity were discussed and evaluated.

2. Methods of Constructing Orthotic Insoles in Individuals with Flatfoot

2.1 Traditional Method with Stamp

In this method, an individual with flatfoot deformity is examined. For this purpose, their foot was immersed in ink (stamped), and the image of their foot is then printed on paper, as depicted in Figure 3.

Figure 3. The image of the flat foot is covered with ink (stumped)

Subsequently, the scanned image of the foot was transferred to a computer, and using AutoCAD software, the outline of the insole is defined, as demonstrated in Figure 4. This technical blueprint was used for the precise fabrication of the insole.

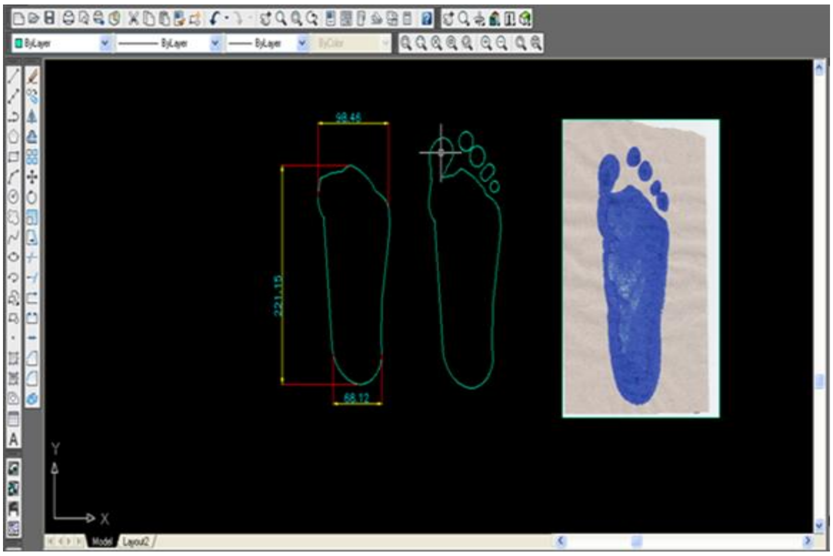

Figure 4. A view of a medical insole for a person with flat feet in AutoCAD software

The obtained blueprint was then transferred to CATIA software, with images presented in Figure 5.

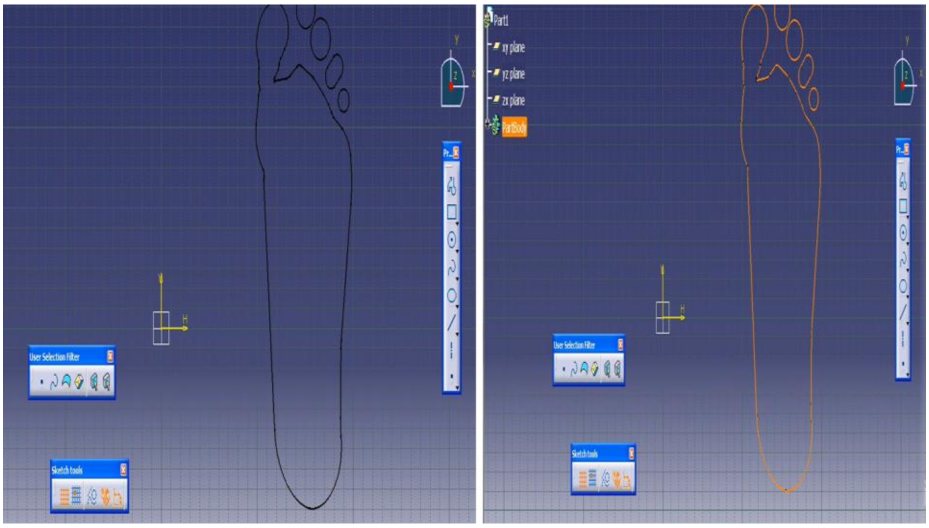

Figure 5. Transferring the designed insole from AutoCAD software to CATIA software

The required volume was determined using CATIA software, as illustrated in Figure 6. Based on this volume, finite element analysis and the orthotic insole manufacturing process can be carried out.

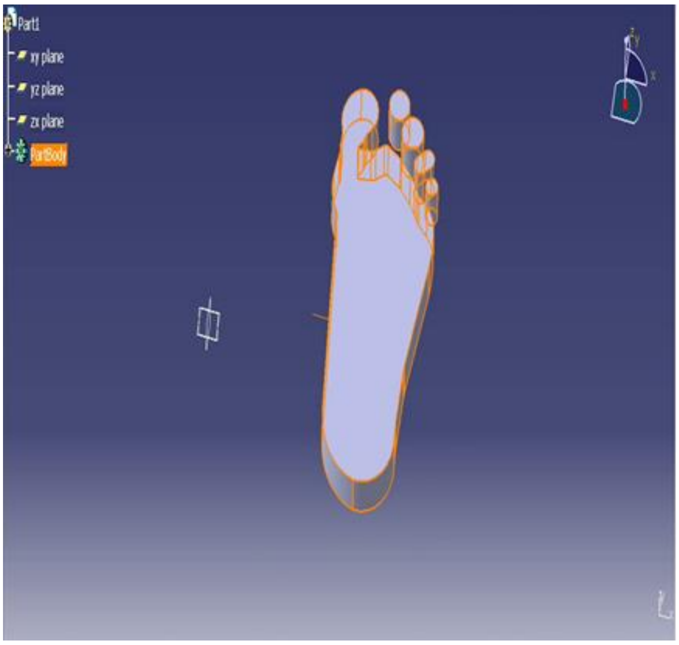

Figure 6. Creating a volume in the CATIA software for construction and checking the finite element if needed

A flowchart summarizing the execution of this process, which involves the design and fabrication of orthotic insoles using the traditional method, is depicted in Figure 7.

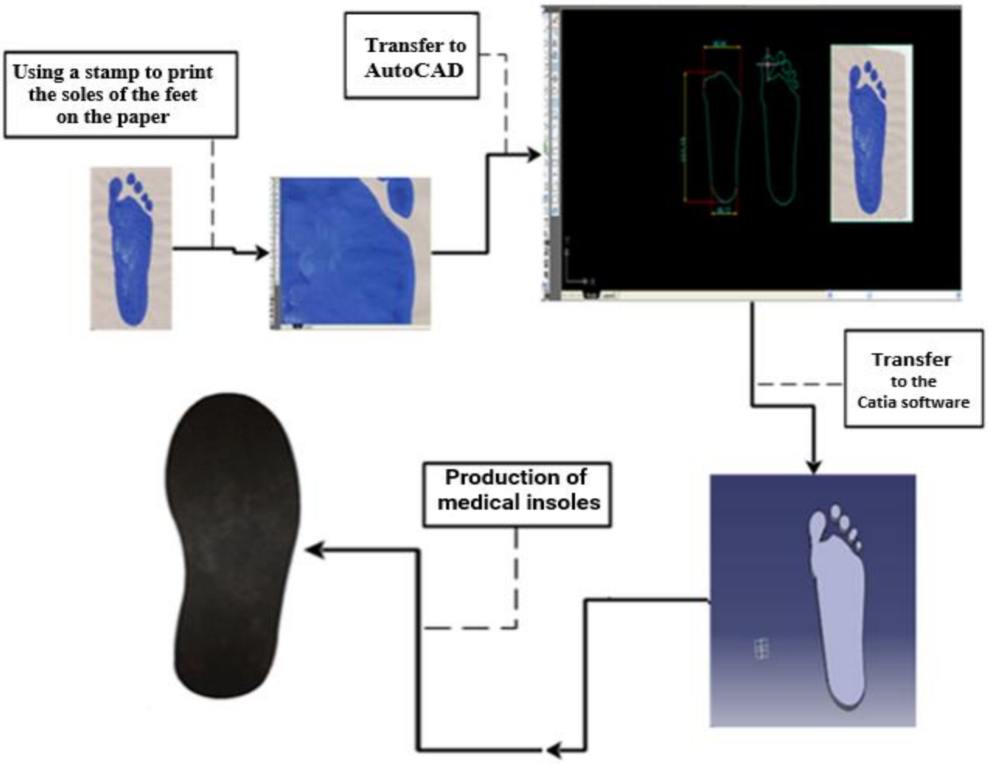

Figure 7. How to make a medical insole in the traditional method with a stump

2.2 Scanner-Based Method for Orthotic Insole Fabrication

According to research [17], the foot of an individual with flatfoot deformity was scanned, and the scan data was then transferred to the "design insole" software. With the assistance of this software, a suitable orthotic insole was designed for the individual under examination based on the geometry of their foot.

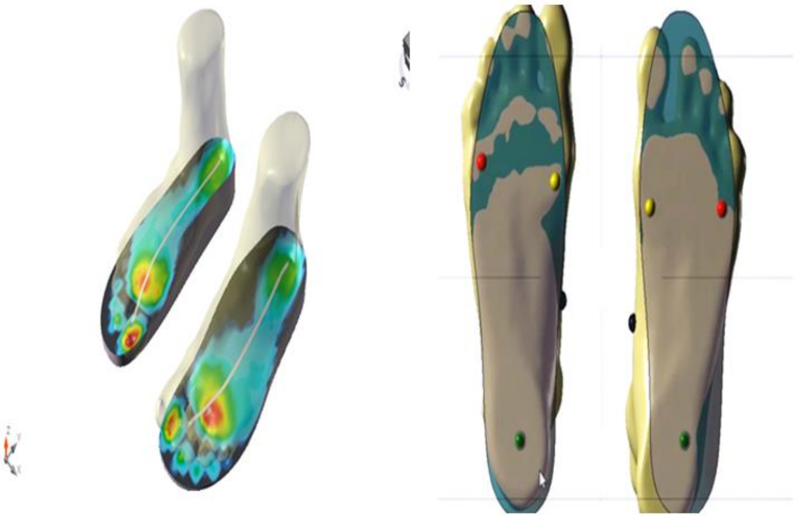

Figure 8. Data transfer for insole design software, for subsequent modifications to make medical insoles

An illustration of the orthotic insole design using this software is shown in Figures 8 and 9.

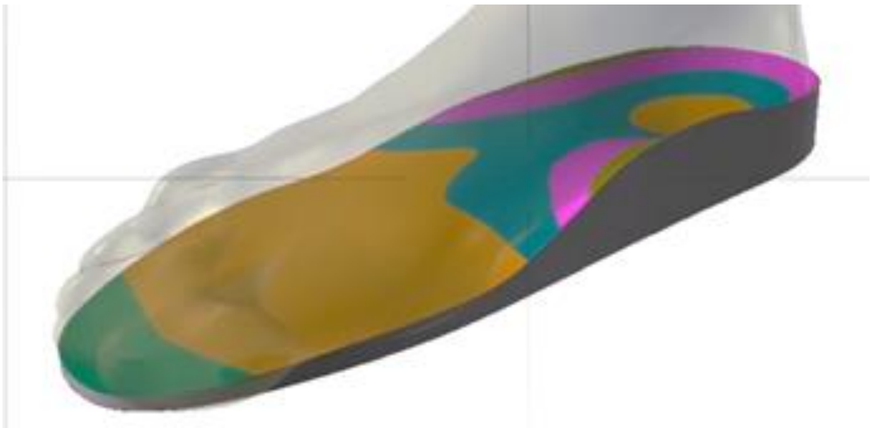

Figure 9. Preparing the sole for making and synchronizing it with the soles of the feet

A summary of the design and fabrication process of the orthotic insole using the scanner and the related software is given in Figure 10.

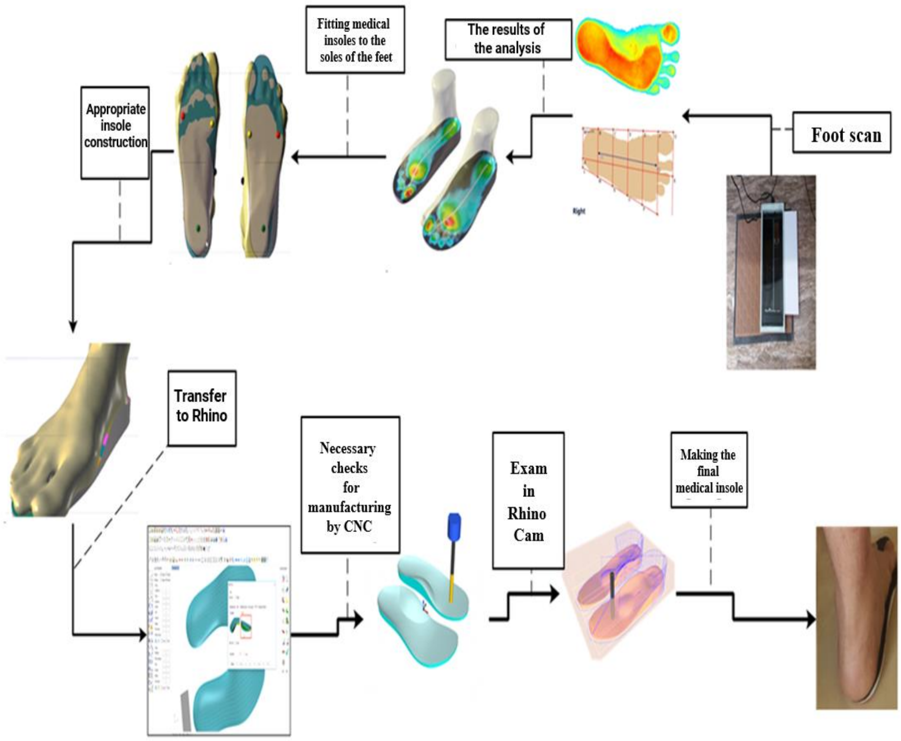

Figure 10. The general design of making medical insoles using a sole scanner

Furthermore, the algorithm used to implement this fabrication method is displayed in Figure 11.

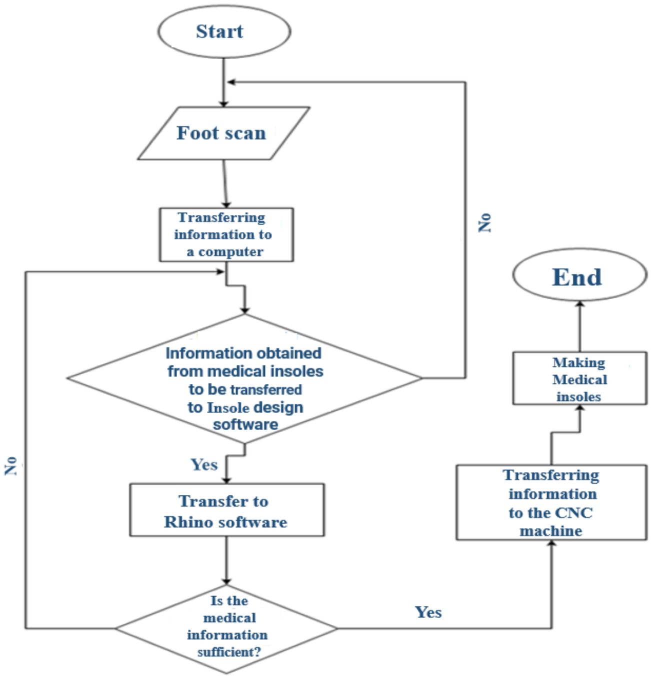

Figure 11. Overview process of medical insole design with 3D scanner

2.3 Orthotic Insole Fabrication Method Using Smart Orthotic Insole Device

Another method for designing and fabricating orthotic insoles involved using a smart orthotic insole device. The smart insole was placed inside the shoes of the individual, and the individual went about their normal walking. During this process, the orthotic insole recorded the necessary information from the person's foot and sent it to a computer for storage and processing. The design and fabrication of the orthotic insole were based on this collected data. In both of the aforementioned methods, there was a possibility of error in the design process due to the individuals' hesitation to place their foot correctly on the ground. This hesitation could lead to improper registration of the foot's geometry and could impact the effectiveness of the design and fabrication process. However, the smart orthotic insole was present during various movements and regular walking, gradually alleviating the individuals' fear over time. Consequently, measurement errors were minimized. The execution diagram of this process is illustrated in Figure 12.

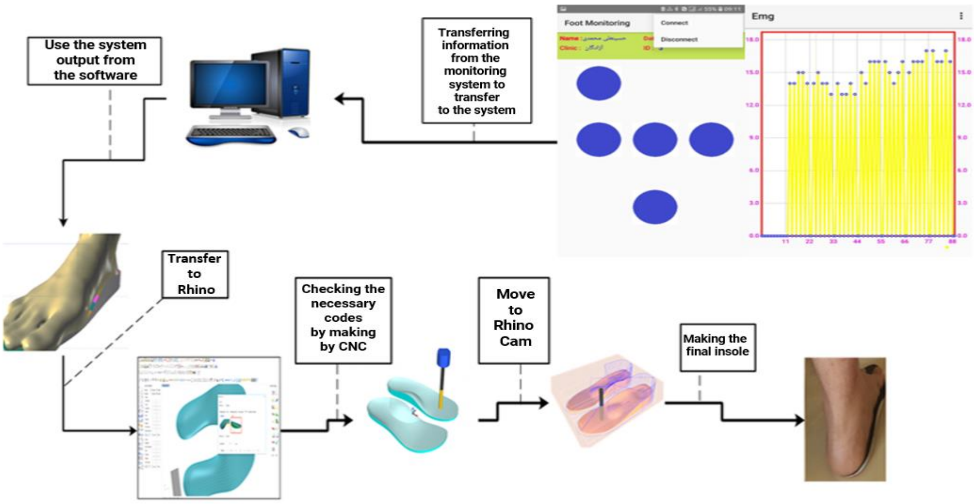

Figure 12. The general plan of make medical insoles using smart medical insoles for the soles of the feet

Furthermore, the algorithm utilized in the design and fabrication of the orthotic insole through this method is depicted in Figure 13 as a flowchart.

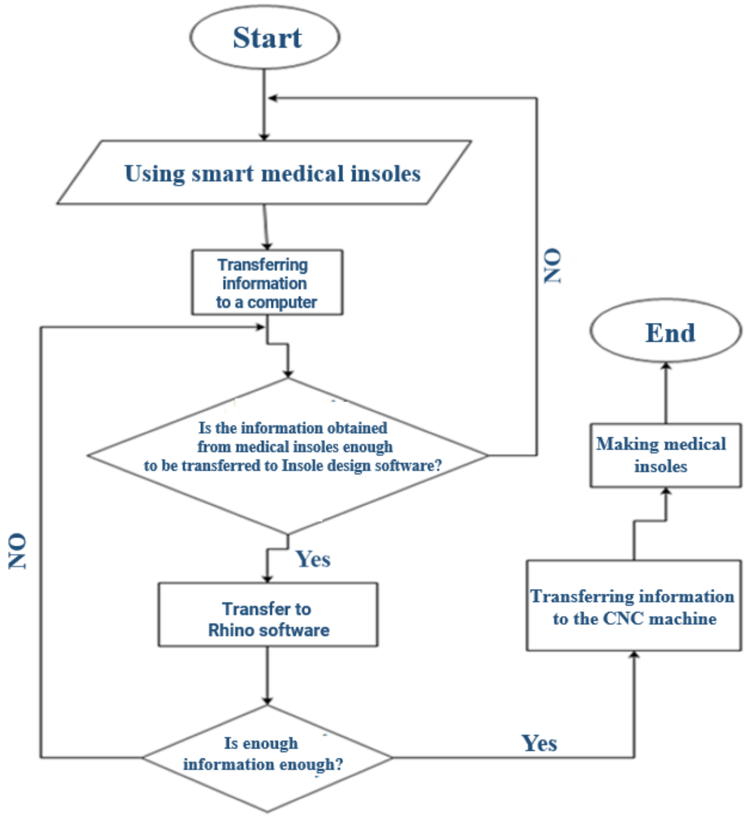

Figure 13. Overview process of medical insole design with smart medical insoles for subjects with flat feet

As observed from the algorithms of the two recent methods, after the relevant foot data was collected from the 3D scanner or the smart insole, the Insole Design software was employed to generate a customized orthotic insole for the individual. The fabrication was then executed using CAD/CAM technology. Alongside appropriate measurement systems and dependable CNC machines for milling the orthotic insole, the specialized and tailored insole design software played a critical role in expediting the process and achieving more accurate designs. The advantage of this software over its competitors lay in its provision of all the necessary tools required by an orthopedic technician for designing an orthotic insole. The diagram of this software's operation is presented in Figure 14.

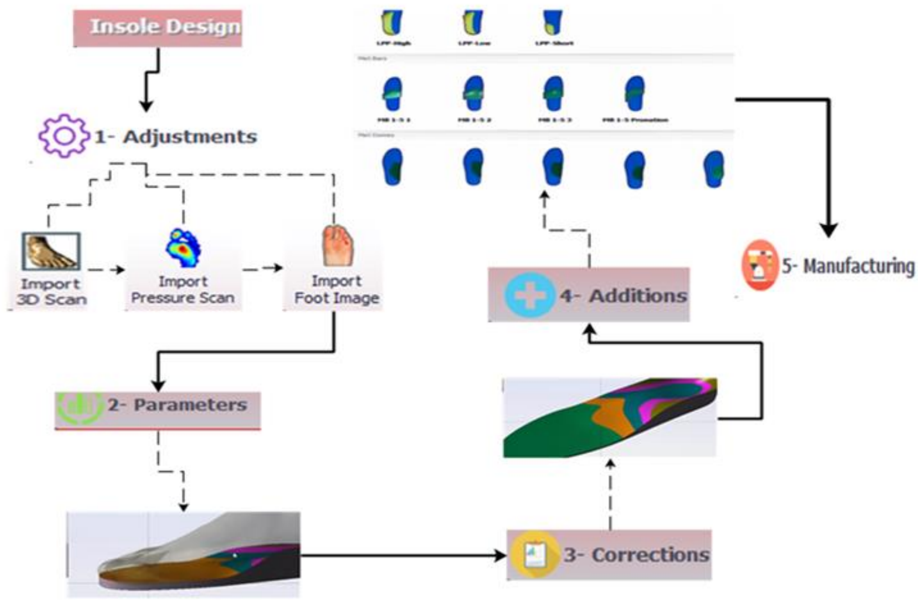

Figure 14. The steps of making a smart medical insole in the Insole Design software

3. Comparison of Fabrication Time in Orthotic Insole Manufacturing Methods

In the preceding sections, three methods applicable to the design and fabrication of orthotic insoles, along with their pros and cons, were explained. It was also established that the method based on using smart insoles is more precise compared to the other methods. To provide further comparison among these methods, the fabrication times of orthotic insoles using these approaches were measured and compared. The chart depicting this comparison is presented in Figure 15. As observed, a considerable amount of time was required for manufacturing orthotic insoles using the stamp method, whereas the fabrication process was faster with the use of smart insoles and 3D scanners. According to this chart, creating an orthotic insole using the stamp method took around 11 days, while using a 3D scanner took approximately 9 days. The fabrication time for a smart insole was approximately 7 days, which was shorter compared to the other two methods. This reduction in fabrication time, coupled with the increased precision associated with this technology, justified the economic rationale for utilizing this method in orthotic insole design and manufacturing.

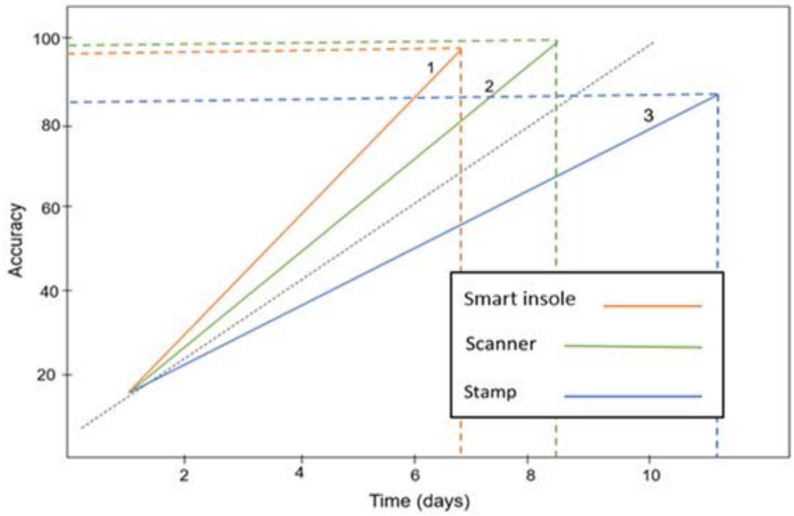

Figure 15. The time spent making medical insoles using the mentioned manufacturing methods

4. Conclusion

This research introduced various methods for designing and manufacturing orthotic insoles, along with the advantages and disadvantages of each method. Subsequently, the time required for designing and producing orthotic insoles was determined for each method, and the results were compared. Given that neglecting foot issues and not addressing them can lead to harm to all tissues and the skeletal system, a method capable of quickly creating orthotic insoles and providing them to the wearer is crucial for preventing subsequent harm more rapidly. As observed from the results, the traditional stamp-based method takes more time to manufacture compared to other methods. Due to its inefficiency and the substantial time consumed by the process based on this method, it is preferable to adopt a more advanced approach for insole production. This advanced method revolves around using information acquired from smart orthotic insoles. Compared to the traditional stamp-based and scanning-based methods, the smart orthotic insole approach collects accurate and real-time information about the subject's foot condition due to its continuous presence during regular movements and activities. Consequently, the insole designed based on this data is highly precise. Moreover, this method significantly reduces the manufacturing time for orthotic insoles. Hence, among the available methods, the smart orthotic insole approach emerges as the most optimal. It not only ensures precision but also expedites the manufacturing process, making it the ideal choice for orthotic insole design and production.

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