



# Exploring the Feasibility of Advanced Manufacturing for Mass Customization of Insoles in the Context of ESG

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## Abstract

With the growing demand from the diabetic population and the advancement of lower limb biomechanics, the need for customized insoles for diabetic foot care and lower limb biomechanics correction is rapidly increasing. This has led to a digital transformation in the insole manufacturing process to achieve mass customization. This includes subtractive manufacturing and additive manufacturing. However, the environmental and social impacts of these processes have not been thoroughly assessed. Therefore, this study aims to analyze the ESG (Environmental, Social, and Governance) performance of existing digital processes compared to TP (traditional processes) and identify factors conducive to achieving both mass customization and sustainability. The results indicate that while NC (Numerical Control process) and 3DP (3D printing processes) benefit from digitization by reducing processing time (NC: 69%, 3DP: 38% of the labor hour needed for TP as 100%) and increasing the reliability of process, but NC is limited by energy consumption (TP: 0.39, NC: 0.9, 3DP: 0.32kWh) and manual grinding techniques. In the other hand, traditional process generates the most waste (Waste Weight Percentage: TP: 94.36%, CNC: 87.15%, 3DP) and requires the most processing space. The FFF (fused filament fabrication) type 3DP drastically shortens labor hour and technical barriers, providing an opportunity to change the service model of customized insoles from at least two visits to potentially just one. This makes the 3DP has the best chance to achieve the need of mass customization and the goal of ESG during the digital transformation. Not only the ESG goals but also the metamaterial ability to bring a better function to the insoles. In the future, by the introducing smart material into 4D printing, which can adapt to variable factors and change their structural characteristics, has the potential to enable a single pair of insoles to meet various usage scenarios. Moreover, the concept of 4D printing combined with sensors can elevate the application of insoles from medical usage for preventing or treating illness to daily usage for predicting illness. This is a goal worth researching further to elevate worldwide healthiness.

**Keywords** Mass Customization · Customized Insole · 3D Printing · Digital Transformation · ESG

## 1 Introduction

According to a global market analysis report published by SkyQuest Technology Group in 2023, the global market size for orthopedic shoe insoles was approximately \$3.2 billion in 2021. It was estimated to expand at a compound annual growth rate (CAGR) of 6.4%, surpassing \$5.9 billion by 2030. On the other hand, medical orthopedic insoles were

expected to grow at a CAGR of 4.6%, exceeding \$3.9 billion by 2030 [1]. The continuous growth of the orthopedic insole market was primarily driven by the increasing foot care of diabetes patients and the advancement of lower limb biomechanical concepts.

The foot care need of diabetes patients is a primary application area for traditional customized insoles. Due to the risk of peripheral neuropathy and vascular complications in diabetes patients, the soles of their feet are susceptible to high-pressure areas that can lead to non-healing wounds and, in severe cases, amputations. According to the International Diabetes Federation (IDF) statistics in 2022, there are over 500 million people with diabetes worldwide, and it is estimated that by 2045, the global diabetic population will exceed 700 million [2]. With the increasing number of

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diabetes patients, the demand for foot care is also on the rise. Customized insoles that help distribute pressure evenly on the sole are crucial in addressing this issue [3–5].

In addition to the medical use for treating diabetic foot, customized insoles have another wide application in sports. As we know that maintaining good health through regular physical activity is a universally acknowledged healthcare concept. In the process of exercising, the most significant benefits are derived when effectively stimulating and enhancing cardiovascular function [6]. Therefore, activities that engage the lower extremities are the most popular choices for most people, whether it's running, walking, hiking, or strength training. These activities all involve the joints of the lower extremities. However, as individuals age, wear and tear and injuries to the lower extremity joints and spine can gradually occur, making it challenging to sustain physical activity habits. In some cases, individuals may require medical care as a result. Research in sports medicine and orthopedics has widely indicated a strong correlation between many spinal and lower limb injuries and the biomechanics of the feet [7]. Consequently, the medical field frequently employs insoles as a crucial tool in the treatment and prevention of biomechanical conditions in the spine and lower limbs [8, 9].

However, when users require customized insoles, it often involves a professional assessment to determine the necessary adjustments for creating customized insoles. Furthermore, most people usually only discover the need for customized insoles when they are already experiencing pain or medical issues. Therefore, the service for providing customized insoles is predominantly found in healthcare institutions.

In traditional processes, from molding to manufacturing, a significant amount of waste and pollution is generated. The manufacturing process is energy-intensive, and tasks like molding, positive mold adjustments, and insole pressing and grinding require a substantial and skilled labor force (Fig. 1), leading to process instability, low production, high costs, and poor labor conditions. This doesn't align with the global trend towards sustainability. The production of such customized insoles demands a high level of professional expertise and resource input, resulting in high prices and inconsistent quality. Sometimes, it requires repeat visits for adjustments. This makes it challenging to widely use customized insoles for the treatment or prevention of lower limb biomechanical diseases.

Hence, many companies and scholars have ventured into research on the advanced manufacturing to customized insole processes [10], attempting to address the aforementioned issues associated with traditional processes [11]. As illustrated in Fig. 2. From the assessment, measurement of the foot, and the design of the insole to the processing of materials, all steps can be conducted in a digital manner.

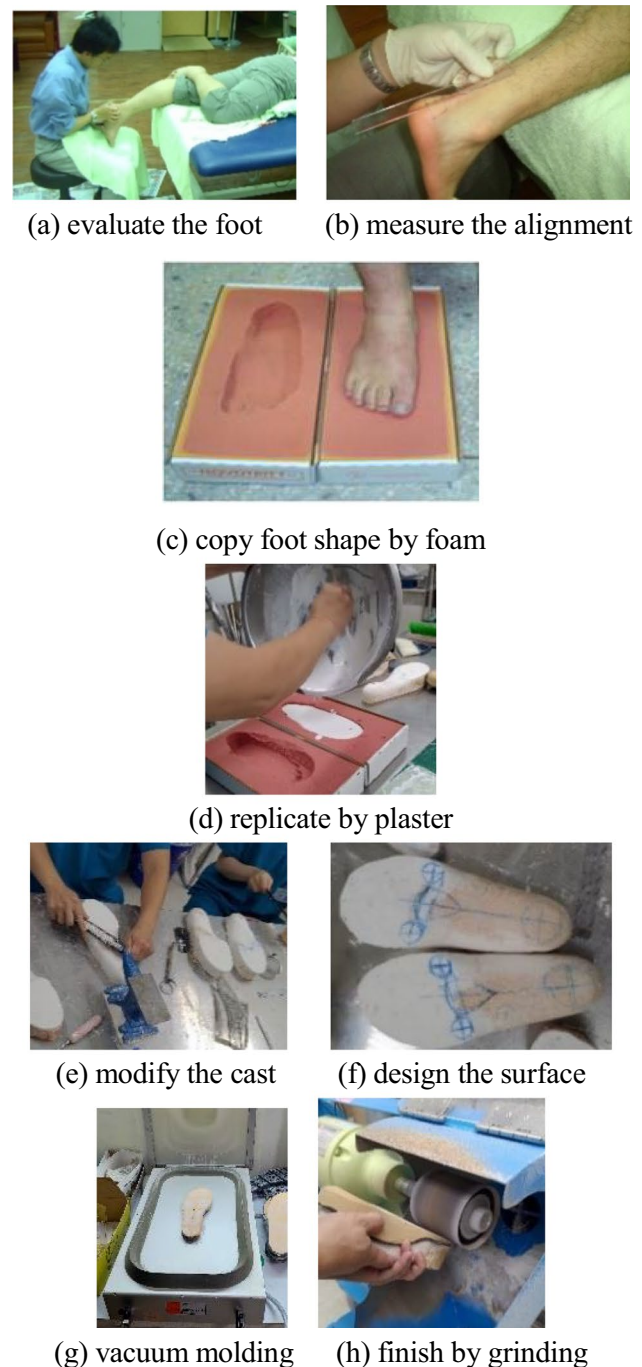
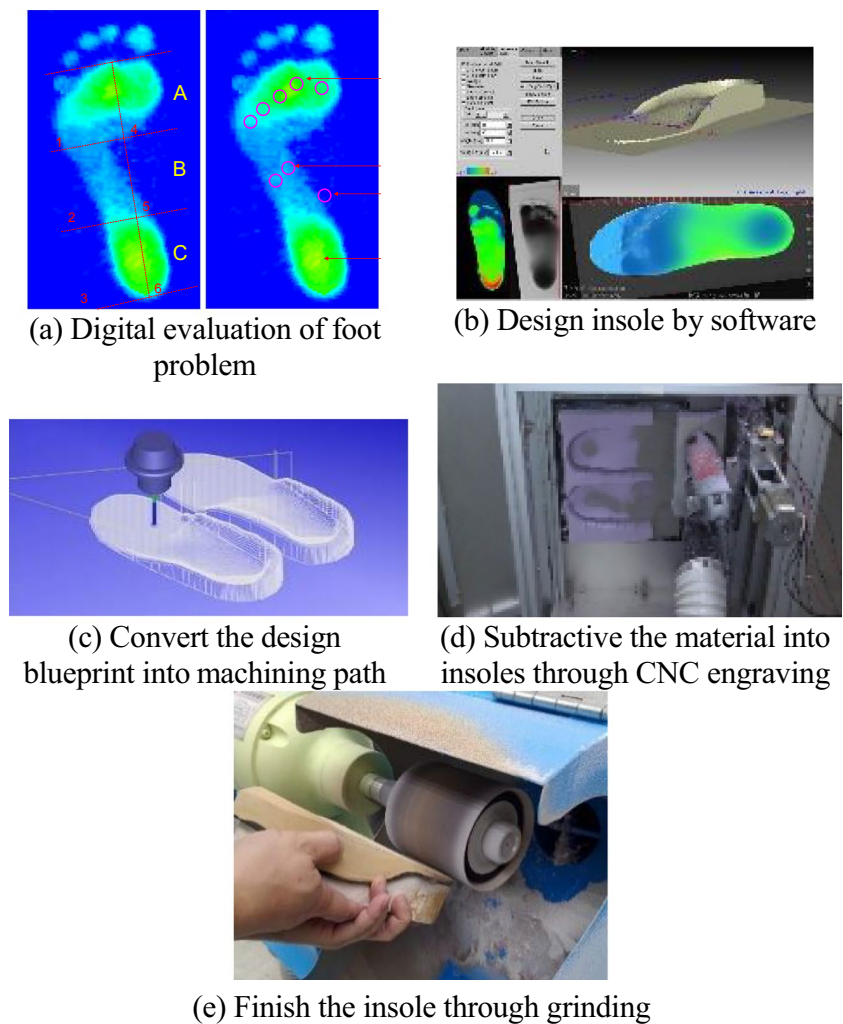


Fig. 1 Traditional process of customized insole manufacturing

Only the final adjustment and fine-tuning step require manual intervention.

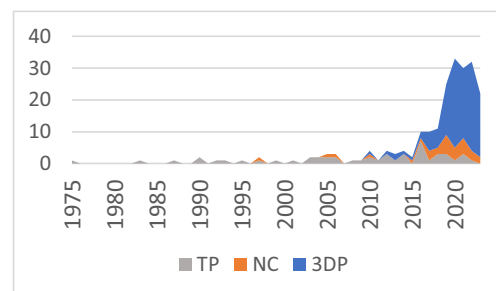
However, in embracing digital transformation, as governments and private enterprises worldwide are increasingly required to develop ESG-compliant business strategies to achieve balance across various sustainability indicators. New introduced technologies must face ESG-related audit criteria to gain effective market application. A study shows that digital

**Fig. 2** Digital process of customized insole through CNC engraving



transformation significantly enhances a company's ESG performance [12]. In labor-intensive industries like customized insoles, digital transformation can unlock greater service potential, making customized insole services more accessible for improving people's quality of life and disease prevention, thus saving substantial medical resources and social costs.

This study started by literature survey of manufacturing process of customized insoles and it is suggested the keywords “casting” or “plaster” together with “insole” can be used to represent conventional manufacturing process and “CNC” or “milling” together with “insole” as well as “3D printing” or “additive manufacturing” together with “insole” can be used to represent digital manufacturing process. The academic research quantities retrieved from the Scopus platform using (casting OR plaster) AND insole, (CNC OR milling) AND insole, and (3D printing) OR (additive manufacturing)) AND insole to search on 2023/11/28. The results of number of published papers in each year between 1975 to 2023 were presented in Fig. 3. It revealed explosive growth in



**Fig. 3** The number of researches by year in three different processes on Scopus

3D printing in the mid-2010s. Research related to plaster and CNC processes also shows a rising trend year by year. From these phenomena, it can be inferred that there is a trend in the digital transformation of customized insoles, accompanied by a growing demand for customized insoles each year.

Given this context, it becomes crucial to analyze the ESG performance of the digital transformation for customized insoles. Unfortunately, there is currently a lack of research related to the sustainability of digitalized processes for customized insoles, making it a worthwhile area for investigation.

This study has four purposes:

- To explore whether the insole manufacturing process can offer enhanced insole functionality through various forms of digital transformation.
- To analyze and compare the mainstream processes of existing customized insole production to identify those that are conducive to achieving mass customization while also meeting sustainability criteria in terms of ESG.
- To outline the technological, material, and process blueprints that are suitable for large-scale customized insole production while adhering to ESG principles based on the characteristics demanded by ESG, this entails elements such as energy efficiency, low carbon emissions, low labor intensity, waste reduction, and addressing inequality.
- To investigate the prospective technologies which can be used to achieve mass customization and also meet the ESG movement.

## 2 Review of Customized Insole Manufacturing

The digitization of customized insole manufacturing emerged in the 2010s [13]. With the proliferation of CAD/CAM, digitized manufacturing of insoles became practical [14]. The digitalization can be viewed in three aspects: measurement of the plantar surface, insole designing, and insole processing. The measurement of the plantar surface has evolved from the early method of directly stepping on a glass panel for scanning [13] to the use of handheld scanners directly scanning the plantar surface [15], until the emergence of reusable soft formers. In terms of replicating foot shapes, the methods have become increasingly capable of reproducing the performance behavior of feet stepping on natural soft ground [16].

Regarding insole design, there has been a progression from early use of only total-contact surface [17] for design to modularized corrective elements in the insole [18], making insole design more flexible.

Following is the insole processing aspect. In the early stages, due to the matured nature of CNC-related technologies and the advantageous pricing for market applications, digitized insole processing mostly employed subtractive manufacturing, using milling method. Currently, the subtractive manufacturing methods used in manufacturing

customized insoles continue to evolve. This evolution ranges from single-spindle to multi-spindle milling to achieve shorter machining time [16]. Furthermore, through the optimization of processing parameters, there has been a reduction in processing time and an improvement in the surface finish of the final product [19]. As of 2023, relevant research is still ongoing, indicating that digital manufacturing processes involving subtractive manufacturing methods are well-established and widely utilized.

Regarding additive manufacturing, even the first 3D printing technology was developed in 1984, but it starts widely applied to customized insoles after 2013 when the material and machines reached the sweet point. Among the seven major categories of 3D printing processes listed in ISO/ASTM 52900:2021: MEX (Material Extrusion), PBF (Powder Bed Fusion), MJT (Material Jetting), VPP (Vat Photopolymerization), BJT (Binder Jetting), DED (Directed Energy Deposition), and SHL (Sheet Lamination), the most frequently mentioned methods for producing customized insoles by material and process are those in the MEX category, such as FFF (Fused Filament Fabrication), PBF category, such as SLS (Selective Laser Sintering), and VPP category, such as SLA (Stereo Lithography Apparatus).

In the above three 3D printing methods suitable for producing customized insoles, this study conducted a review of literature that has used these processes within the past decade. As mentioned in the introduction, the future demand for customized insoles has two main purposes: correction of lower limb biomechanics and care for diabetic feet. Regarding the correction of lower limb biomechanics, the FFF manufacturing method for customized insoles can improve the VAS (Visual Analogue Scale) index of plantar pain in flat feet [20]. The improvement in the arch height and ankle joint mobility in flat feet was also found [21]. Concerning diabetic feet, research showed that FFF-customized insoles can effectively distribute plantar pressure to reduce the probability of ulcers [22]. For different populations, customized insoles need to reduce the peak plantar pressure during walking. The peak plantar pressure during walking were reduced in varying degrees with FFF-printed insoles, for example, a reduction from 218 to 109 kPa was observed in specific area [20, 22–27]. Most of these studies used TPU (Thermoplastic polyurethane) filament as the 3D printing material, and a few cases used PLA (Polylactic acid) [27].

In terms of SLS processing, it found that SLS-customized insoles can reduce the peak plantar pressure in normal walking by 30% [28]. However, research on SLS applied to diabetic feet has not appeared, and all studies on SLS applied to customized insoles use nylon powder as the printing material. This may be related to the higher hardness of the SLS process's final product. In addition, unlike FFF, which is mostly used for general walking and medical purposes, SLS processing has appeared in the field of athletes, possibly

due to the thinner and more rigid characteristics of SLS-produced items, making them easier to fit into the smaller space of athletic shoes.

As for the SLA process, there is a lack of relevant research in clinical applications and sports science. Although SLA produced insoles showed similar pressure relief performance compared with foot care pressure relief insoles [29]. However, there is limited additional research on SLA applied to foot care or sports science, indicating that the SLA process has not yet become widely used.

In addition, the introduction of Smart Material in 4D printing technology possesses the characteristic of changing the physical features of the finished product in response to environmental stimuli. Among them, the automatic change in hardness of the finished product in response to changes in temperature and external pressure can be greatly beneficial for addressing different situations encountered during the use of insoles. For example, the varying cushioning requirements between high-impact sports and everyday walking activities. The ability of insoles to adapt to the pressure behavior of the feet during movement and automatically change their hardness is a particularly appealing feature. Ren et al. utilized carbon black and PLA materials for 4D printing, creating active therapeutic insoles with shape memory properties that can adjust hardness according to foot pressure. Although the brittleness of PLA material may still need verification for suitability in daily use, the study indeed provides a promising research direction [30]. In the extended application of 4D printing, sustainable soft actuators (SSAs) are also worth noting. Benefiting from the evolution of additive manufacturing technology, SSAs can change shape actively or passively in different contexts according to user needs. If such technology could be applied to customized insoles, it could adjust the volume and shape of the insole based on the user's shoe shape or the degree of foot swelling, which is a highly anticipated application [31].

Furthermore, Kim, H. G. et al. proposed the use of TPU for 3D printing, creating metamaterials with gyroid structures and applying a surface coating of carbon nanotubes to develop insoles with pressure sensing functionality. This technology has approached practical application in terms of its applicability [32]. Meanwhile, Chaima Fekiri et al. directly utilized 3D printing to fabricate pressure-sensitive products using carbon nanotubes. Apart from exhibiting high sensitivity to pressure, these products also demonstrated excellent tolerance to cyclic pressure variations and showed good response and recovery times. They are highly suitable for producing customized insoles capable of sensing pressure to detect user gait pressure behavior [33].

Another noteworthy application is the use of 3D printing to produce metamaterials. Di Gao et al. conducted dynamic compression tests on 3D-printed structures of NPR CCF (Negative Poisson's Ratio Convex-Concave Foams) with

isotropic characteristics, and observed their mechanical energy absorption and deformation patterns. The results indicate that compared to traditional foam of the same size, this type of metamaterial exhibits a longer elastic range during compression, suggesting better shock absorption capability of the material [34]. If applied to insoles, for example, it could enhance their shock absorption performance and durability.

Matthew Sin-hang Leung et al. proposed the use of 3D-printed expansion structures for potential relief in diabetic heel pressure. Through finite element analysis, the expansion structures, compared to traditional PU material insoles, could effectively reduce the maximum contact force on the heel by approximately 10% and decrease the average pressure by approximately 14% [35]. However, their minimum unit still requires a thickness of 4.2 mm to function, posing significant challenges for applications beyond the heel area of the insole.

G Rico-Baeza et al. further compared the displacements and Von Mises stresses during walking between two different structures, triply periodic minimal surfaces (TPMS) and body-centered cubic (BCC) using FFF. They found that TPMS, with its cellular structure, exhibited better stress resistance and higher deformation compared to the lattice structure of BCC [36]. These characteristics will be crucial considerations for future applications in the production of custom-made insoles using 3D printing. In addition to manufacturing techniques, predicting whether the final product can meet individual functional requirements before production is a crucial step, especially for highly personalized and high-value-added products like customized insoles. To address this, Wesley R. Jerin et al. introduced the concept of design of experiments (DOE) and multi-objective optimization. By employing design simulation steps, they can preemptively predict the mechanical characteristics of the final product to ensure user satisfaction. This not only enhances customer satisfaction but also improves material utilization, which is particularly advantageous for cost control in mass customization [37].

From the literature review, it can be observed that the current 3D printing processes for customized insoles mostly use FFF and SLS processes, each with its advantages. SLS, compared to the FFF process, can print unsupported or more complex metamaterial shape without the need for additional support structures. Its compatibility with the structure of the shoe body is also more extensive [28]. However, the FFF process has cost advantages in terms of both machinery and materials (mostly using TPU), while the current SLS processing machinery is still quite expensive and requires post-processing steps, resulting in a significantly higher product price [38].

FFF has the advantages of relatively low equipment and material costs, and it is fast in processing. Moreover, its

precision is sufficient for customized insoles [23]. Therefore, many researchers and businesses use FFF for customized insole production, and use TPU as the major material.

In summary, the two well-discussed technologies for applying to the production of customized insoles using additive manufacturing techniques are FFF and SLS. The summary of the factors highly relevant to ESG when these two types of technologies are applied to the production of customized insoles were showed in Table 1. It is worth mentioning that the huge difference on the build cycle between both leads to that FFF can be manufactured on-demand, whereas SLS, mostly requires batch production. This difference directly affects the suitable business models for each. FFF is suitable for local manufacturing, while SLS is suitable for batch production in centralized factories.

Additionally, there is a significant difference in energy consumption between the two. FFF only requires heating the filament at the extruder and maintaining the temperature of the build platform for insole printing, while SLS requires maintaining the temperature of the entire chamber and powder, and consumes considerable energy due to laser pulse. SLS equipment used for manufacturing customized insoles typically consumes over 1500 W-hours, while FFF machines are mostly within 300 W-hours.

Regarding the weight of processing waste, both are comparable, which is advantageous for water environments and waste disposal. The materials used in both technologies, including TPU, PLA, and Nylon, are recyclable, contributing to meeting the demands of a circular economy.

One of the main differences between the two is the need of inert gas, SLS usually needs inert gas to prevent powder materials from oxidizing or burning at high temperatures. Inert gas, such as nitrogen for Nylon printing, is typically used to fill the build chamber of an SLS machine, replacing the oxygen in the air, thus reducing the risk of material oxidation. The other difference between the two is the post-processing requirements. After printing, FFF typically requires moderate modifications to the semi-finished product before use, while SLS semi-finished products mostly require

post-processing such as cleaning the powder in the hollow structure, as well as surface sandblasting treatments, often result in post-processing times for SLS mostly measured in hours, making it significantly longer compared to FFF processes.

In this regard, it is evident that FFF and SLS each have their suitable business models, with FFF being more flexible in one-visit insole mass customization.

### 3 Customized Insole Production Processes to ESG Indicators

This study evaluated two aspects of the customized insole production processes: a. system integrity and b. the relative performance of each process with regarding to ESG indicators. The essence of ESG is to assess the differences in operational models within the same industry. Therefore, ESG scoring is conducted by item-by-item comparison, and the details were explained in this section. Firstly, the reasons for selecting various processes in this study were described in the next paragraph.

#### 3.1 Selection of Processes

Before meeting the sustainable ESG requirements, the advanced manufacturing mass customization in insoles should also retain the advantages of the existing traditional manual customized insole production process to ensure the industry can smoothly transition to a more sustainable direction. The traditional process, especially the thermoplastic customized insole production process proposed in 1967 at the University of California's Biomechanics Laboratory, is widely adopted. This process includes features such as a customized 3/4 plantar surface, rigid arch support, and heel cup design for stable biomechanical utility [39]. In the early days, methods to replicate the plantar surface often involved using plaster bandages wrapped around the foot, waiting for about 10 min for the plaster to harden to obtain a negative mold of the plantar surface. Then, a positive mold was obtained through casting to produce the insole. Some practices used a foam box to replicate the plantar surface and create a mold, with subsequent processing methods mostly similar. This study used this process as a benchmark to compare the digital insole production process in terms of ESG performance.

This study used the traditional plaster mold production process mentioned above as the representative of traditional processes (referred to as TP) and compared it with two existing advanced manufacturing processes: CNC engraving (referred to as NC) and 3D printing (referred to as 3DP). As these two processes are highly digitized and quite mature but adopt entirely different manufacturing principles and

**Table 1** Comparison of 3D printing methods for customized insole production

	FFF	SLS
Material	TPU, PLA	Nylon
Build Cycle (hr)	~ 1	~ 20
Timeliness	on request	in batch
Energy Consumption (watt-hours)	~ 300	> 1500
Waste	near-zero-waste	near-zero-waste
Recyclable material	yes	yes
Inert Gas	no required	required
Post processing time (hr)	0.1	4

processing workflows, they are suitable for analysis and comparison as representatives of digital processes.

### 3.2 Selection of Market

Due to Taiwan's advantages in having a matured national healthcare system and rapid digital technology development, the customized insole production process in Taiwan features a diverse and mature service ecosystem and business models. Therefore, it is highly suitable to serve as a representative market for this study.

### 3.3 Selection of Processes Representing Various Domains

Due to Taiwan's advantages in having a matured national healthcare system and rapid digital technology development, the customized insole production process in Taiwan features a diverse and mature service ecosystem and business models. Therefore, it is highly suitable to serve as a representative market for this study.

**TP** As traditional processes are primarily retained within the assistive device manufacturing units in hospitals, an institution with an assistive resource center was selected for analysis. In this study, the Department of Assistive Resources at Taoyuan General Hospital was chosen as the representative. This department was established in 2003, is ISO50001,9001,14001,27001,14064,45001 certified [40], and the customized insole production process shown in Fig. 4 is executed by licensed physical therapists and orthopedic prosthetists. They have established standard operating procedures and are highly suitable as the subject of this study.

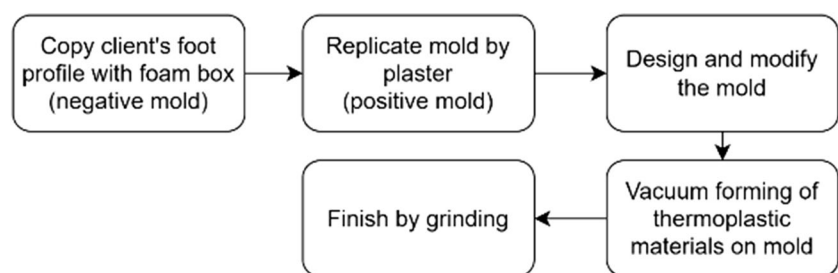
**NC** Since many hospitals without assistive centers outsource the production of customized insoles, most of the business is undertaken by assistive companies on behalf of hospitals. Therefore, for this process, a well-established orthopedic prosthetic company with NC digital processes was chosen as the representative. Cheng Chuan Prosthetics & Orthotics CO., Ltd. was founded in 1993 and obtained CGMP national certification in 2005. They handle the assistive production business for many hospitals in Taiwan and have developed standard operating procedures (Fig. 5) and a mature business model, making them highly suitable as the representative for the NC process.

**3DP** Research related to the 3D printing process for insoles began to appear in larger numbers around 2013. Among them, the processing method that utilizes Fused Deposition Modeling (FDM) and uses TPU as the material for 3D printing is more widespread. The advantages of the FDM process, such as the relatively small processing environment required and the absence of noise and dust pollution, have enabled this process to be used directly in clinical service settings. Therefore, clinical units with the aforementioned 3D printing technology were chosen as the research subjects for this process. Move & Treat Physical Therapy Clinic, established in 2018, began using the NC digital process and introduced the 3D printing process in 2019. They are familiar with digital processes and have established standard operating procedures (Fig. 6), making them highly suitable for this study.

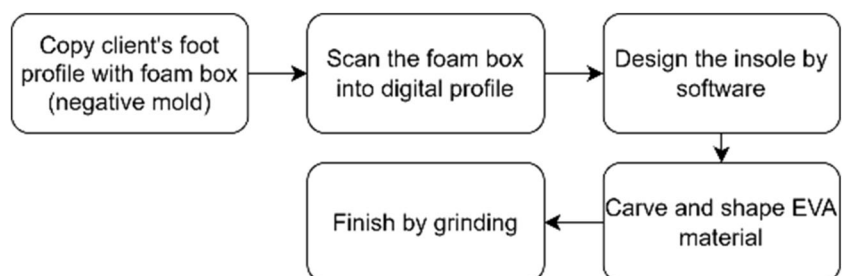
As the technology used by Move & Treat Physical Therapy Clinic, the following provides a detailed description of its technical specifications:

Due to the need to adjust only the extrusion speed and layer thickness, and by using different patterns, it is possible

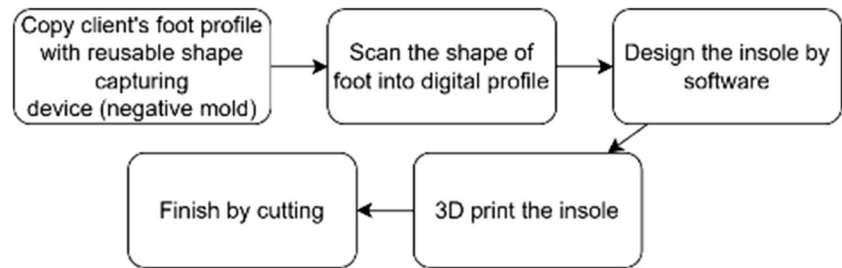
**Fig. 4** The work flow of the TP process



**Fig. 5** The work flow of the NC process



**Fig. 6** The work flow of the 3DP process

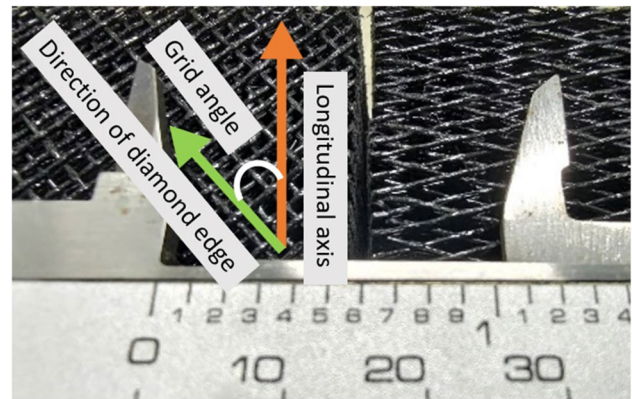


**Table 2** Printing parameters

Machine specifications	Single extrusion head
Extrusion head heating temperature	245°C
Platform temperature	75°C
Layer thickness	0.3 mm
Nozzle size	0.6 mm
Material Specifications	TPU material with Shore hardness of 90A, filament diameter of 1.75 mm

to meet the requirements for different levels of rigidity and hardness. Therefore, only one extrusion head is needed for printing. As for the extrusion temperature set at 245°C, which is significantly higher than the typical TPU temperature of 220°C, it is intended to improve material flowability to accelerate manufacturing speed. At the same time, it ensures sufficient bonding of each layer of material at higher feed rate to withstand the pressure and shear forces experienced during use of the insoles. The temperature of the processing platform is set at 75°C to ensure the adhesive on the building plate. The layer thickness is related to the size of the nozzle. Generally, the layer thickness is suggested to be less than a half of the diameter of the nozzle. The process adopts a larger diameter 0.6 mm of the nozzle to achieve faster feed rate and 0.3 mm of the layer thickness which will help shorten the time of printing process. Due to the lower precision required for the insoles and the need to adhere a skin-friendly layer to the sole contact surface, the impact of using a larger nozzle and thick layer thickness on user perception is negligible. This choice offers a possibility of obtaining customized insoles in a single visit. Finally, the selection of materials is crucial. The process uses a softer TPU material with a Shore hardness of 90A to meet the support strength required for the insoles at faster feed rate (Table 2).

The use of a staggered hollow structure allows the insole to keep stiffness and cushioning property in the same time. Additionally, different grid angles related to the longitudinal axis (Fig. 7) are utilized to create varying axial flexural resistance for different insole purposes. For instance, when arranging diamond-shaped grids parallel to the longitudinal



**Fig. 7** The close-up view of the different grid angles related to the longitudinal axis and the interlace between layers to generate the staggered hollow structure

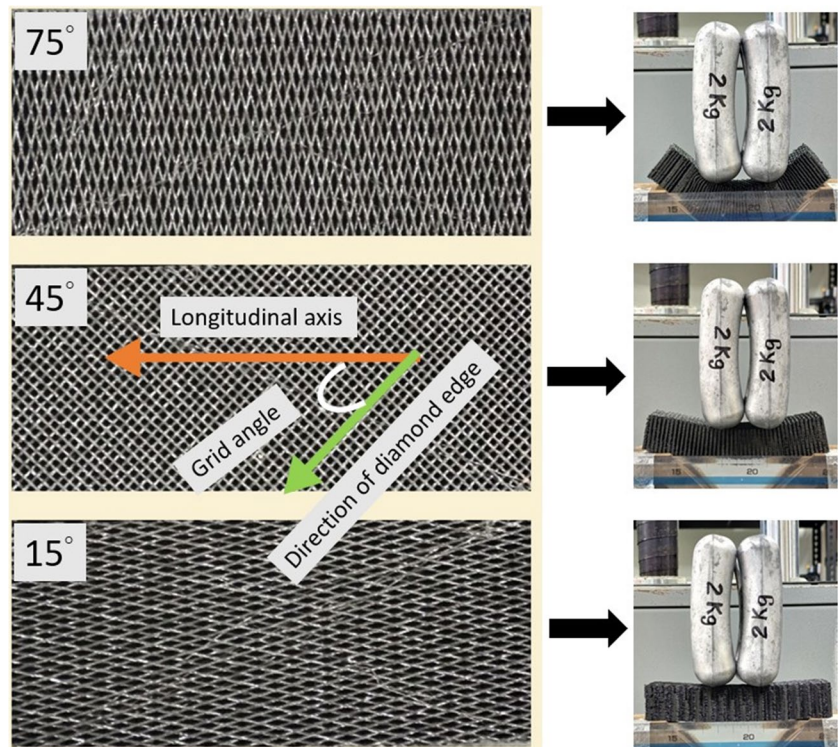
axis of the insole, a larger acute angle between the diamond edge and the longitudinal axis (grid angle) of the insole can minimize flexural resistance among the longitudinal axis and provide better lateral support during movement, making it particularly suitable for vigorous physical activities. On the other hand, a smaller grid angle, offer higher flexural resistance and more evenly distributed support in different directions, making them suitable for daily use (Fig. 8).

To create a customized insole that effectively improves lower limb biomechanics, foot pressure distribution, and joint alignment, the system must be capable of accurately measuring the individual's foot contour. Subsequently, it should analyze the mechanical characteristics based on the foot contour and lower limb joint alignment. Then, the system should produce the insole, incorporating suitable biomechanical components as determined by the analysis, to achieve the desired biomechanical performance. Therefore, this study uses the three phases of "Measuring", "Designing", and "Manufacturing" to analyze existing customized insole processes. The following explains the significance of these three components:

**Measuring** This phase involves the examination of the individual's foot structure, including measuring the foot's unique contours, lower limb biomechanics, and joint alignment.



**Fig. 8** The different angle between the diamond edges and the longitudinal axis from 75°, 45°, and 15° provide variable flexibility by given the same vertical bending force on the samples with dimension of 4" \*2" \*1" in size



**Designing** After measuring the individual's foot, the system must analyze the data and match it with appropriate biomechanical components. This includes selecting the right materials, support structures, or adjustments to enhance the biomechanical benefits.

**Manufacturing** This phase focuses on the physical production of the customized insole, using the analyzed data to guide the fabrication process and create the insole with the intended biomechanical properties.

This section assessed whether each process can meet the service requirements of customized insoles in the three major phases. It will also summarize the service blueprint and key technologies for each process. The analysis in this section did not involve a comparison between processes. Instead, it breaks down the processes and technologies to facilitate the assembly of a process blueprint and corresponding key technologies that are most favorable for achieving the goal of mass customization, especially after conducting ESG analysis.

### 3.4 ESG Analysis Within the Context of Process Applications

Since there are numerous sub-items within the three aspects of ESG [41], but the selection and definition of

the items were various depends on the purpose of evaluation [42], and due to limitations related to data collection that may involve proprietary information of various institutions, this study chose the specific items that can be directly compared in the customized insole production process for analysis in the sub-items of ESG. The selected items as show in Table 3 included 2 environmental, 4 social and 2 governance sub-items those can mostly accentuate the disparity of the ESG performance between 3 processes. The environmental sub-items included energy consumption and waste weight percentage. The social sub-items included labor hours and work noise which represent the manufacturing side, and other 2 sub-items were product quality and consumer right which represent the consumer side. At the last, the risk management and inventory management which affect the extendibility of the customized insole service, were considered as the governance sub-items. Following were the details of each item.

**Energy Consumption** The total energy used in the production process was measured in kilowatt-hours (kWh). This measure focuses on energy efficiency and its direct impact on the environment.

**Waste Weight Percentage** The percentage of the weight of waste generated during the manufacturing process was measured in percentage by weight. This measure reflects

**Table 3** Selected ESG items and the comparable factors of each item

Item	Comparable factor
Energy Consumption (kWh):	kWh
Waste Weight	WT%
Labor Hours	Min
Work Noise	dB
Product Quality (Durable Lifetime)	Year
Consumer Rights (Waiting Time in days)	Day
Risk Management (Training Time for Operators)	Month
Inventory Management (Warehouse and Processing Area)	Square meter

the efficient use of resources and the environmental impact of waste disposal.

**Labor Hours** The total time spent on labor during the process was recorded in minutes. This measure considered the labor intensity of the process, which affects costs, pricing, and sustainability in the context of an aging workforce.

**Work Noise** The noise level in the working environment, measured in decibels (dB), is important for assessing the health and well-being of workers and its impact on the process's development.

**Product Quality (Durable Lifetime)** The durability of the customized insole directly affects the frequency of repurchase and reflects the environmental and social costs associated with frequent replacements.

**Consumer Rights (Waiting Time)** The waiting time for consumers to receive their customized insoles is critical. Longer waiting times negatively impact consumers and may lead to higher medical costs and reduced willingness to use the service, affecting the industry's sustainability.

**Risk Management (Training Time for Operators)** The time required for training operators was assessed. Longer training times represent increased costs and pose a systematic risk, hindering the widespread adoption of mass customization.

**Inventory Management (Warehouse and Processing Area)** The space required for processing and storing materials impacts fixed operating costs. Larger space requirements are less favorable for achieving mass customization and meet the ESG demand in the same time.

### 3.5 ESG Evaluation Method

A total of eight evaluation items were considered for comparison, including 2 environmental items, 4 social items, and 2 governance items. The ESG performance of the three

processes were comparatively scored based on the relative scale using point allocation way (with each item totaling 6 points) [41]. The best performer received 3 points, the second-best received 2 points, and the lowest performer received 1 point. If there was a tie within a specific item, the remaining points would be shared."

## 4 Results


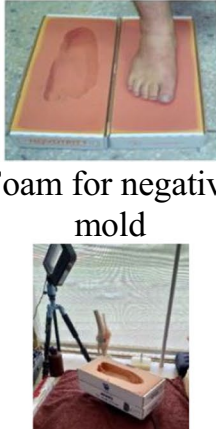


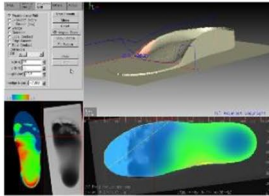
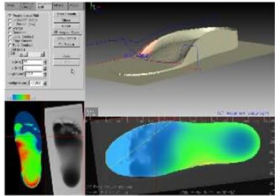
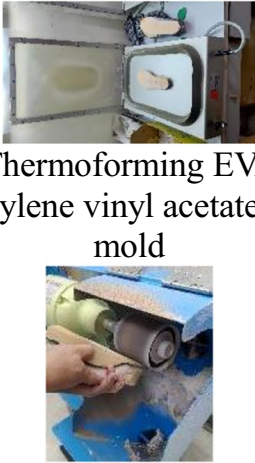

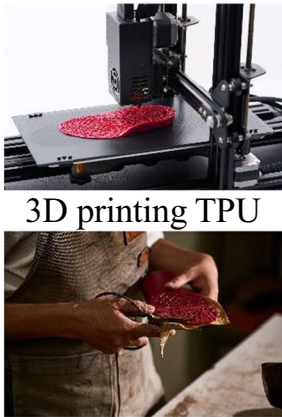
This section begins by presenting Table 4 outlining the comprehensiveness of the three processes in this study. It could be observed that the TP process lacks digital elements in all three phases, while the NC process utilizes digital tools in all three phases of production. The 3DP process has a degree of digitization like the NC process but eliminates the need for the final detailed manual grinding step used in the NC process.

The performance of the three processes in the eight set ESG evaluation criteria in this study were detailed next. All relevant data is presented in Table 5.

**Energy Consumption** The calculation method for energy consumption involved multiplying the rated power (kW) of each device by the usage time (hour) to calculate the electricity consumption, presented in units of kWh. It can be observed that in the TP process, electrical equipment is used in the heating, vacuum pressing, and grinding steps, while in the NC process, power is required in the scanning, design, cutting, and grinding steps. Finally, in the 3DP process, electricity is only needed in the scanning, design, and printing steps. The result showed that TP and 3DP processes have the similar energy consumption, and NC process has the highest level of energy consumption (TP:0.39, NC:0.90, 3DP:0.32).

**Waste Weight Percentage** This study calculated the percentage of waste generated during the manufacturing process relative to the weight of the raw materials. A higher percentage indicates more waste. Among the three processes, the TP process involves the extensive use of plaster and foam boxes to replicate the positive mold, resulting in a

**Table 4** The integrity of customized insole manufacturing process in this study

	TP	NC	3DP
Measuring	 <p>Foam for negative mold and Replicate into positive mold by plaster</p>	 <p>Foam for negative mold Scan for digital mold</p>	 <p>Reusable shape capturing device for negative mold, and scan for digital mold</p>
Designing	 <p>Manually modify positive mold</p>	 <p>Digital Design</p>	 <p>Digital Design</p>
Manufacturing	 <p>Thermoforming EVA (ethylene vinyl acetate) on mold Finish by grinding</p>	 <p>CNC milling EVA material Finish by grinding</p>	 <p>3D printing TPU Finish by cutting</p>

significant amount of waste. This not only adds weight but also occupies a considerable amount of space. Additionally, due to potential reprocessing needs, the positive molds used cannot be immediately discarded after use; they need to be retained for a certain period before disposal. The storage and

disposal of positive molds have become a challenging issue. It is evident that the 3DP process has a significant difference in waste percentage compared to the other two (TP:94.36%, NC:87.15%, 3DP:4.9%), showcasing a natural advantage of 3DP process in terms of waste generation.

**Table 5** The raw data of the ESG assessment in each process

	TP		NC		3DP	
Energy Consumption (kWh)	Heating	0.14	Scanning	0.01	Scanning	0.01
	Vacuuming	0.01	Designing	0.03	Designing	0.01
	Grinding	0.24	Milling	0.7	Printing	0.30
			Grinding	0.16		
	Total=0.39		Total=0.90		Total=0.32	
Waste Weight Percentage (wt%)	94.36%		87.15%		4.9%	
Labor Hours (min)	Measuring	15	Measuring	15	Measuring	10
	Designing	15	Designing	10	Designing	10
	Assembling	15	Grinding	20	Cutting	5
	Grinding	20				
		Total=65		Total=45		Total=25
Workplace Noise (dB)	85		85		59	
Product Quality (Durable Lifetime in years)	2		2		2	
Consumer Rights (Waiting Time in days)	7~21		7		0~7	
Risk Management (Training Time for operators in months)	2		2		1	
Inventory Management (Warehouse and Processing Area in square meters)	Warehouse	25	Warehouse	5	Warehouse	2
	Processing	20	Processing	10	Processing	2
		Total=45		Total=15		Total=4

**Labor Hours** The impact of digitization on the customization of insoles can be observed in this item. The higher the degree of digitization, the fewer labor hours are required. Compared to the TP process, the NC process requires only 69% of the labor hour needed for TP processing, while the 3DP process takes only 38% of the labor hour required for TP processing. Especially in the design and production processes, for example, in the TP process, the design and production (assembling and grinding) processes require 50 min, while in the 3DP process, where both design and production processes are digitized, and no subsequent grinding steps are needed, the labor hours for design and production processes significantly decrease to 15 min.

**Workplace Noise** The primary difference lies in whether a grinding machine is needed in the production process. Both TP and NC processes require the use of high-power grinding and dust collection equipment, resulting in higher noise levels (85 dB). While these noise levels comply with local labor regulations, they limit the widespread adoption of the processes. In contrast, 3DP only produces equipment operation sounds during printing, with a sound level of 59 dB, similar to the ambient background noise, posing minimal auditory burden on on-site personnel.

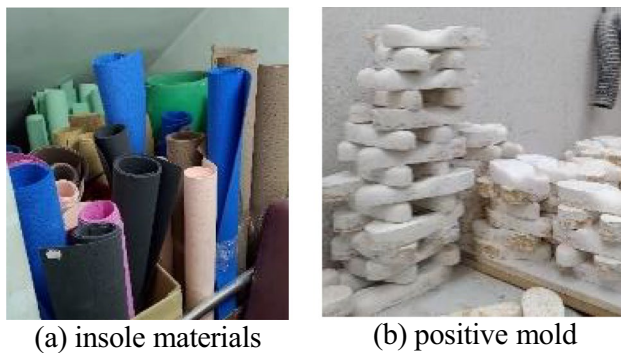
**Product Quality (Durable Lifetime)** The service life of the products is the same for all three processes.

**Consumer Rights (Waiting Time)** The direct impact of digitization on customer waiting time can still be observed. The

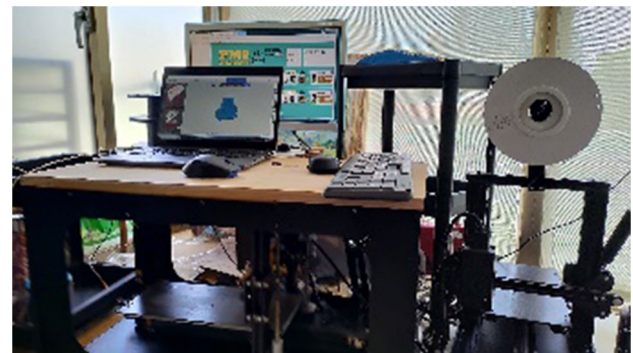
higher the degree of digitization, the shorter the labor hours required, and consequently, the shorter the customer's waiting time. In the TP process, it might take up to 21 days to receive the insoles, while in the NC process, it takes 7 days. However, in the 3DP process, customers can receive their insoles on the same day, demonstrating the direct impact of digitization on product delivery times.

**Risk Management (Training Time for Operators)** With knowing the longer the training hours required for tasks that demand experience in the process, the greater the risk for companies facing an aging labor market. As both TP and NC processes involve manual grinding techniques that require a delicate touch and experience to ensure the safety and the quality of the products, a longer training period (both two months) is needed to become proficient in these tasks. In contrast, thanks to its fully digitized process, 3DP requires only one month for operators to become familiar with software and the setup and operation of the printing machine, significantly reducing the training threshold for process operations.

**Inventory Management (Warehouse and Processing Area)** Among the three processes, the TP process requires the largest space, with the most significant space occupied by various materials and positive molds. Due to differences in storage conditions for materials and gypsum, both need to be stored in separate independent spaces (Fig. 9). Additionally, considering the operational space for various processing tools, the space required for the TP process is



**Fig. 9** Separated storage spaces in TP process



**Fig. 11** Tabletop equipment in 3DP process

significantly larger than the other two, and the NC process requires operational space for CNC and grinding tool leads to a larger space than the 3DP process (Fig. 10). On the other hand, the equipment used in the 3DP process is all tabletop equipment, occupying a small footprint and easy to move (Fig. 11). Moreover, the production materials are TPU filaments, which are easy to store. Therefore, the 3DP process has the most flexible space requirements among the three.

Assessing the ESG items based on the various contents listed in Table 4 and obtaining the results presented in Table 5, it is evident that, across the three major aspects, the 3DP process has the highest scores. Interestingly, despite the NC process having a higher level of digitization compared to the TP process, its scores are comparable to those of the TP process. Further analysis was provided in the discussion section.

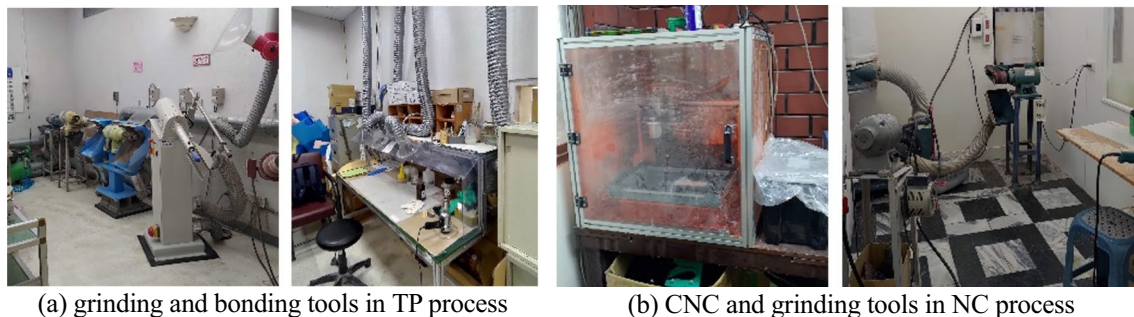
## 5 Discussion on Process

### 5.1 Measuring Phase

TP and NC processes involve disposable sampling with foam boxes or plaster molds. After use, the foam boxes and plaster

can only be discarded as waste, and the disposal process can create dust and pollution, which is not in line with sustainability goals. However, there is existing literature that uses optical scanning to avoid waste generation. Although optical scanning can avoid waste generation, many of these methods involve either barefoot scanning [43] or having the individual step on a transparent glass plate for scanning [44]. Barefoot scanning can lead to issues where the obtained foot shape has an excessively high arch, which does not accurately represent the foot's shape and can lead to discomfort for the insole user, affecting its effectiveness. On the other hand, the method of stepping on a glass plate for scanning can deform the soft tissues of the foot when compressed against the glass surface, leading to inaccuracies. For example, the most deformable area of the foot under pressure is often the heel's fat pad, and this region is vulnerable to injury when walking and standing. If the shape of the heel's bottom bowl-like curvature is not accurately preserved during the scanning, the protective effect of the insole on the heel's fat pad will be compromised.

This is one of the key reasons why many processes still use foam and plaster mold methods. The reusable shape capturing device used in 3DP process can address both sustainability goals and biomechanical effectiveness. There are also insole brands that use a silicone gel bladder with



**Fig. 10** Operational spaces in TP and NC proces

a vacuum pump as a foot shape capturing device to create thermoplastic insoles for customers. However, this method does not convert the obtained foot shape into digital data. If a similar principle can be used in combination with commonly available optical scanning equipment to create digital models, it would be possible to balance sustainability and biomechanical effectiveness.

## 5.2 Designing Phase

As different processes serve different target groups, the design details of insoles vary, but there are three common design elements: total contact design of the plantar surface, lower limb biomechanical correction, and local pressure relief design.

Among these three elements, the full-contact design of the footbed surface is typically used in all three processes. This is because full-surface contact helps effectively distribute foot pressure, providing the best comfort for insole users. For diabetes patients, this is an essential design element. For users who require lower limb biomechanical correction insoles, total contact surfaces enhance comfort, but the design of biomechanical correction insoles has a decisive impact on the correction of lower limb biomechanics. It's like wearing glasses: full-surface contact is like the frame, affecting user comfort and willingness to wear, while biomechanical correction insoles are like the lenses, providing crucial correction effects. Lastly, the design of local pressure relief is essential for addressing foot pain or diabetic foot ulcers. If a process can incorporate these three design elements, it is more likely to meet the majority of insole correction needs.

## 5.3 Manufacturing Phase

In the two digital manufacturing processes for insoles, NC cutting generates significant noise and dust, with a material utilization rate of only about 13%, leading to a substantial amount of waste. Additionally, the energy consumption during the processing is quite high. These characteristics clearly show that NC cutting is less likely to meet sustainability and mass customization goals. On the other hand, 3DP is more aligned with the objectives of sustainability and mass customization. Furthermore, in all three processes, individuals typically need to make at least two visits to the clinic (the first for measurement and shaping, and the second for receiving and trying on the insoles) to obtain custom-made insoles. The carbon footprint generated by transportation is quite significant. A study showed that the environmental impact of customized insole sales processes accounts for 61% of the entire customized insole production process [45]. Among these impacts, customer return visits contribute the most to environmental consequences. Therefore, it is crucial to

find ways for customers to obtain custom-made insoles in a single visit, and 3DP processes can often achieve this goal in about an hour, making them highly promising in this regard.

Moreover, thanks to the research on metamaterials mentioned earlier, 3DP has the potential to significantly enhance adaptability and durability in human biomechanics. It can also reduce the frequency of replacing insoles due to damage. Consequently, this could further decrease the long-term labor and resource consumption required.

As for the type of 3D printing technology applied, FFF is more suitable for meeting single-visit demand than SLS. This is because its short build cycle, and the finished products require very few post-processing steps to complete. Although FFF may not offer as smoothness exterior of insole as SLS, but for the demand of customized insoles, the level of smoothness in FFF finished products is already sufficient to meet the biomechanical correction requirements.

## 6 Discussion on ESG

In the three aspects of ESG, the performance of 3DP is the best, while the total scores of TP and NC processes are comparable. Details are as follows:

### 6.1 Environmental Aspect

In this subcategory, both the TP and NC processes scored lower than the 3DP process. The main reason for this is that the TP process generates a significant amount of waste due to the use of plaster for replicating the foot's positive mold, requiring additional space and costs for storage and disposal. Thus, it scored lower in the waste category compared to the other two processes. The NC process, on the other hand, uses high-speed cutting for extended processing times, resulting in high energy consumption due to the high-speed rotating tool heads and the need for powerful grinding equipment to refine the product's appearance after cutting, making it the most energy-consuming of the three processes. It's worth noting that TP's energy consumption is on par with 3DP. Therefore, if TP's waste generation can be further reduced through digitization, the TP process still has a chance to be competitive with 3DP in the environmental category.

### 6.2 Social Aspect

The three processes exhibit significant differences in labor hours, which are also reflected in the waiting time for consumers. The key factor here is the level of digitization in design and manufacturing. Processes with higher digitization significantly reduce the need for labor, thus substantially

shortening lead times. This characteristic underscores the necessity of digital transformation in the industry to address the global trends of an aging population and labor force shrinkage.

The level of work-related noise within the processes has a considerable impact on their popularization. This is mainly due to whether high-noise grinding and dust collection equipment is needed in the final stages of production. In this aspect, it can be seen that the 3DP process, which allows for simple cutting and delivery after printing, eliminates the need for high-noise grinding processes and equipment, making it highly favorable for popularization. As for the product's service life, there are no significant differences among the three processes.

### 6.3 Governance Aspect

In terms of ESG information transparency, all three processes do not disclose ESG-related risk assessments, goals, and financial information, so there are no significant differences among them in this aspect. regarding the training time for process operators, all three processes require operators to be familiar with the measurement and design procedures. However, TP and NC both require skilled grinding techniques to operate grinding equipment, leading to longer training times. Longer training times signify that the process is more sensitive to workforce mobility and skill levels, which can introduce more limitations on the widespread adoption and stability of the process. This is less favorable considering the labor force shrinkage trend. Also, the safety issues raised due to the operation of the high-speed rotating machinery.

In the category of space management, TP requires more space due to the need for handling plaster foot molds. The storage and production space for plaster materials are significantly larger compared to the other two processes. In the case of NC, the digitalization of measurement and manufacturing methods eliminates the need for plaster disposal space, but the cutting and grinding steps both require separate workspace to prevent dust and noise pollution.

As for the 3DP process, 3D printers are typically desktop-sized, stackable, and the finished products do not require grinding equipment. They can be trimmed manually and then delivered. Therefore, the 3DP process occupies the smallest space and has a significant advantage in terms of spatial requirements, making it the most favorable for popularization.

## 7 Conclusions

The results of this study clearly showed that digital transformation has a significant impact on the customized insole manufacturing process across all three aspects of ESG. The

advantages of 3D printing in reducing environmental impact are evident. Additionally, during the research process, it was found that 3D printing's extremely short delivery times reduce the number of times customers need to visit a physical store. This not only reduces carbon emissions associated with customer travel but also increases the willingness of the general public to use customized insoles.

This opens up another business model for the proliferation of customized insoles, making them more accessible and aiding in the prevention of lower limb biomechanical diseases and complications of diabetic foot at an earlier stage for the general public. However, the TP process, due to its plaster mold-based analog 3D data, offers precision and reproducibility in representing the contour of the foot that remains unmatched, particularly in cases involving amputated feet or wounded feet. Hence, during the digital transformation, there is still value in retaining the TP process, especially for such specialized applications. However, when it comes to the adjustment of lower limb biomechanics for broader purposes, digital processes have an absolute advantage, and 3D printing processes are best suited to meet the needs of the majority when it comes to accessibility. According to the study, the FFF type 3D printing technology is suggested for this application, as it best aligns with operational models considering ESG performance. Through the design of different processing pathways, the metamaterial properties generated can expand its applications in sports biomechanics contexts.

Additionally, since customized insoles are used in various contexts with different biomechanical and kinetic demands, users often need to adjust the insole hardness based on the specific application scenario. In light of this, the application of 4D printing, especially technologies capable of automatically adjusting hardness, is well-suited to address this issue. Consequently, users would only need one pair of insoles to meet various sports demands. However, further information on the technical details and their relevance to biomechanics is still required for their application in clinical and sports science fields. Finally, the concept of 4D printing to bring energy harvesting capability to insoles can be used to capture the signals of using and elevate the application of insoles beyond corrective biomechanics or pressure dispersion, typical of medical devices aimed at preventing and treating diseases. Instead, they can become everyday items capable of predicting illnesses and widely used in various contexts. Therefore, it is worthwhile to continue researching in this area in the future.

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**Authors' Contributions** Conceptualization, data collection, data curation, manuscript preparation, editing and analysis: Jung Cheng and Jia-Chang Wang; conceptualization, validation, supervision, and funding acquisition: Jia-Chang Wang.

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**Data Availability** The data underlying this article are available in the article (The raw data of the ESG assessment in each process are collected by the authors of this article, same to pictures).

## Declarations

**Ethics Approval** The submitted work is original and have not been published elsewhere in any form or language.

**Consent to Participate** Verbal informed consent was obtained prior to the interview.

**Consent for Publication** Additional informed consent was obtained from all individual participants as listed in the acknowledgement is included in this article.

**Conflicts of Interest/Competing Interests** Author Jung Cheng is the founder of Move & Treat Physical Therapy Clinic. The authors declare that they have no other conflict of interest.

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