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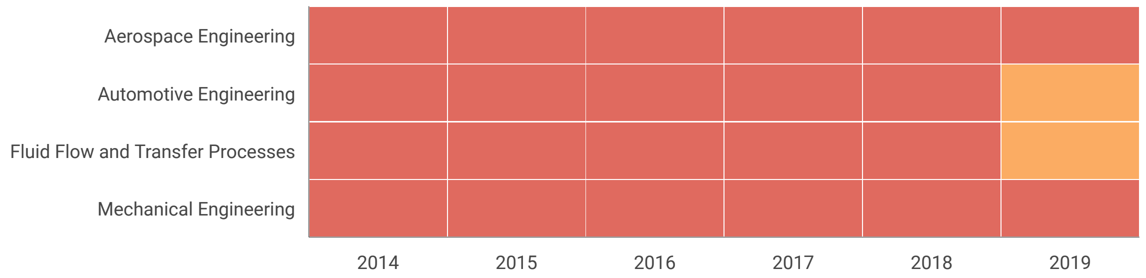

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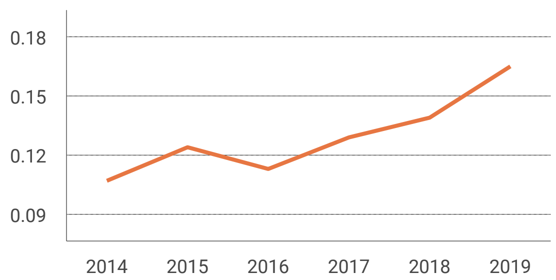

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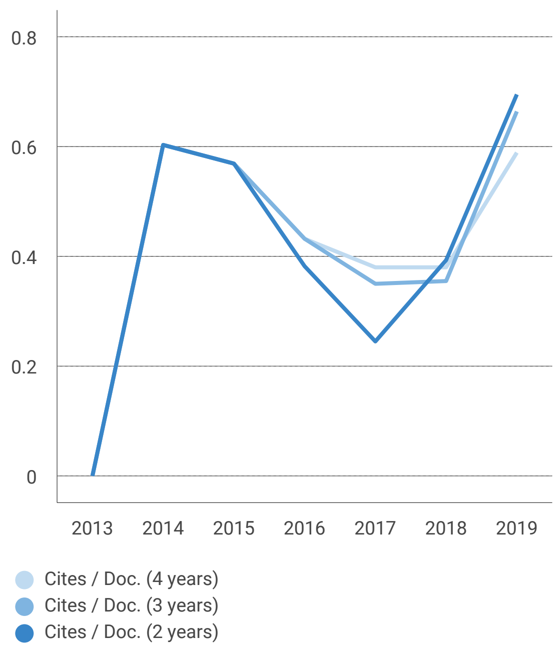

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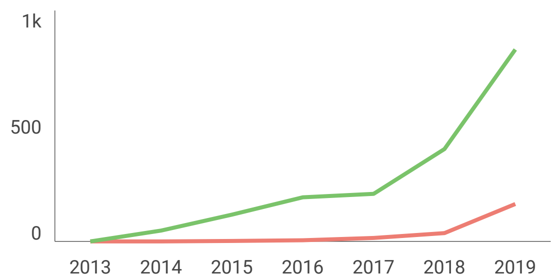

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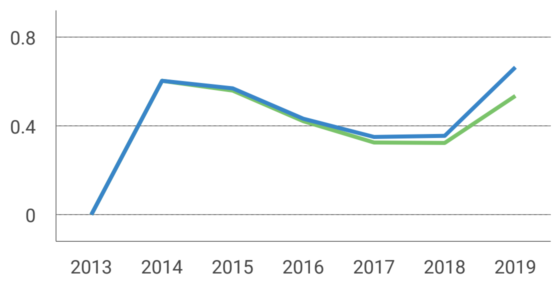

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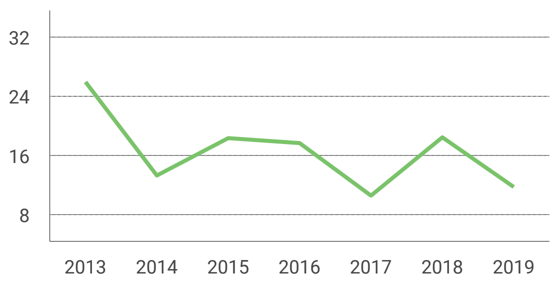

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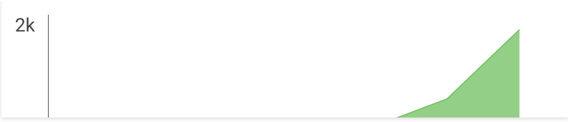

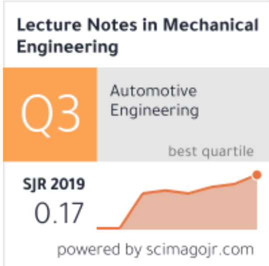

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ANKLE FOOT ORTHOTIC (AFO) FOR FOOT DEFORMITY PATIENTS - THE DESIGN AND MANUFACTURING OF SHOES ORTHOTIC

Has been presented by

Paulus Wisnu Anggoro, Athanasius Bayuseno, J Jamari, Baju Bawono and Tonny Yuniarto

in

The 6th International Conference and Exhibition on Sustainable Energy and Advanced Materials

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Ubaidillah Sabino
Fitrian Imaduddin
Aditya Rio Prabowo *Editors*

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Editors

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Editors
Ubaidillah Sabino
Mechanical Engineering Program
Faculty of Engineering
Universitas Sebelas Maret
Surakarta, Central Java, Indonesia

Fitrian Imaduddin
Mechanical Engineering Program
Faculty of Engineering
Universitas Sebelas Maret
Surakarta, Central Java, Indonesia

Aditya Rio Prabowo
Mechanical Engineering Program
Faculty of Engineering
Universitas Sebelas Maret
Surakarta, Central Java, Indonesia

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Contents

Ankle Foot Orthotic (AFO) for Deformity Patients: The Design and Manufacturing of Shoes Orthotics

P. W. Anggoro, B. Bawono, T. Yuniarto, J. Jamari, and A. P. Bayuseno

Abstract A foot is a part of the human body that is crucial and functions when doing an activity of standing, walking, jumping, or running. When the body is on the move, a good footwear that is required to support weight is shoes. The design and manufacturing of shoes has currently experienced a very rapid development, to meet the needs of users. However, some people have an abnormal foot deformity so it tends to always get pain or uncomfortable while wearing shoes. These people obviously need special shoes with ankle foot orthosis (AFO). Research employing AFO reverse innovative design (RID) of the phase leg scanning, design, and manufacturing of shoes that fit the contour of the patient's foot is still rare in Indonesia. This process takes approximately 34–45 working days in the making of AFO with the traditional concept by simply following specific instructions from the physician or orthopedic, handmade, not precision, and comfortable use. The application of the Computer-Aided Reverse Engineering System (CARE System) is used to assist researchers to design and manufacture AFO which fits with the contour of the patient's foot. Curve base surface modeling (CBS-modeling) in RID methods was applied to obtain the optimal design of the insole and shoe last. The research output of shoe orthotics (insole, shoe lasts, and shoes) have been used and enjoyed by patients with diabetes very well. This technology is significantly more efficient than the manual process. The manufacturing process was shortened up to 64%.

Keywords AFO · CARE system · Base curve surface modeling · Foot deformities · RID

P. W. Anggoro (✉) · B. Bawono · T. Yuniarto
Department of Industrial Engineering, Faculty of Industrial Technology, University of Atma Jaya Yogyakarta, Jl. Babarsari 44, Yogyakarta 55281, Indonesia
e-mail: pauluswisnuanggoro@ymail.com

J. Jamari · A. P. Bayuseno
Department of Mechanical Engineering, University of Diponegoro, Jl. Prof. Soedarto, SH. Tembalang, Semarang 50275, Indonesia

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1 Introduction

A foot is part of the human body that serves to do a lot of activities, such as standing, walking, jumping, and running. When the body is on the move, a good footwear that is required to support the weight shoes. The design and manufacturing of footwear have developed very fast and rapidly. However, some people have a foot deformity that is not normal (deformity foot) as reported by Refs. [1–3]. Foot deformity can be classified as "significant or not" according to the condition of the patient's leg. Prior research (…)has suggested that significant deformity is closely related to the alignment of the foot mechanics related to aspects of normal shoes, namely heel, ball, and toe. If the conditions of the foot are not aligned or aligned with all of these aspects, the shoe design parameters will potentially cause friction, shear forces. Furthermore, due to such pressure on the foot, the user will feel pain or discomfort. This is what causes the foot to have a significant deformity. Foot deformities, especially in diabetic patients, can be shown in Fig. 1.

People with such disorders (see Fig. 1) tend to experience pain when using the shoes as footwear when moving. Shoes commonly do not last long because the friction between the foot with the shoe upper part tears the shoe material. Problems to find the right shape and size of the shoe that fits the dimensions of the patient's legs are also a major factor. In Indonesia, it is not easy to find costumized shoes for people with a foot deformity due to the lengthy duration of the shoe production. (AFO). Therefore, there is an urgent need to produce orthotic shoe, known as the

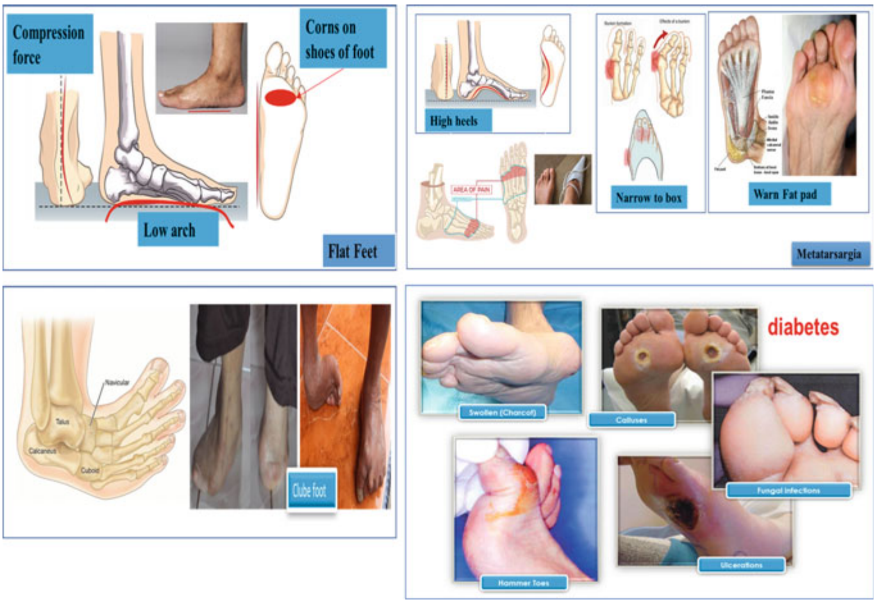


Fig. 1 Foot deformity in patients with foot deformity

Fig. 2 Foot diabetic patients **a** Feet diabetic patients with high risk scale. **b** Shoe upper tear due to friction with the swollen bone

ankle-foot orthosis (AFO). This type of shoe is designed specifically for people who have foot deformities, including patients with diabetes, club foot, flat foot, and high heel injury.

This research was conducted to address some complaints on prolonged pain, difficulty in choosing comfortable shoes, and the appearance of the second leg swollen bone of patients in Fig. 2a. This led to a short lifespan of shoes because the shoes are easily torn at upper section Fig. 2b. The number of AFO shoe-last makers and orthotic footwear industry in Ganjuran Bantul, Yogyakarta is limited. Most of the industries are still based on manual procedures, experiences, and follow the specific instructions given by a doctor or orthopedic. Consequently, the products may not be precise and inconvenient for the users. Moreover, this process requires a considerable amount of time. Normally, it takes around 35–45 working days to complete the process; from the diagnosis stage through the fabrication of AFO shoes.

AFO shoe is an equipment for footwear designed specifically to support the ankle and foot section during daily activities and help the healing process or the reduction of pain in patients with deformity during the rehabilitation process, as has been reported by Refs. [4]. Some researchers such as [4–6] introduced the methods of design and production of customized shoe insole orthotics utilizing digital technology surface capture, CAD/CAM, CNC, and adaptive manufacturing, but all these studies are still too broad and not integrated from the design phase through the manufacturing process and testing the product in patients. Some good research about orthotic shoes by Refs. [3, 7–13] in research explains that the manufacturing process AFO generally always use the technology of reverse engineering (RE), both conventional and non-conventional phases of the methodology. The orthotic shoes in this paper, according to [10], are included in the category of organic shapes, which refer to a complex foot relief with different contours for each foot. Therefore, both feet should be scanned in detail and separately.

That is why Reverse Innovative Design (RID) is the most appropriate RE procedure conducted in this research. The RID application can be done very well in an industrial or laboratory system when the system has a set of technologies that support the process. Automation of RID according to [14] is often called Computer Aided Reverse Engineering System (CARESystem).

In Indonesia, research that elaborated an integrated process of producing AFO shoes with CARESystem, which include design, manufacture, and product tests to users, is not much, as reported by Refs. [4, 15]. Previous studies demonstrated that the use of modern technology CARESystem significantly accelerated the design time and manufacturing of AFO shoes for patients with diabetes mellitus orthotics [3, 7–9, 11–13, 16–18] and other deformities. The detailed stages of CARESystem methodology for application in the process of design and manufacturing AFO can be shown in Fig. 4, while the flow charts in detail the methodology developed in this study are presented in Fig. 5.

In Indonesia, the use of commercial software to make shoe lasts is still uncommon. Mostly, shoe lasts and the prototypes for academic purposes are made with conventional technology or hand made. This study successfully demonstrated the product development of AFO (insole, outsole, shoe last and orthotic shoes) that are based on modern technology integrating 3D HandySCANN 700TM, PowerSHAPE 2016 CAD, CAM PowerMILL 2016 and 1020EV20A YCM CNC 3 axis. All of the existing infrastructures in this research are fully integrated with other tools during the study (Fig. 4a). This process has enabled to shift away from the manual production process of AFO shoes to the innovative production process that produces more precise and accurate shoes for the patient's feet. The stages used in this study to design orthotic shoes are described in detail are presented in Fig. 3.

RID-based AFO development [10] in this research was used to simplify the stages (see Fig. 3). and followed for the development of research in the years 2019–2022 in patients with clap foot, flat feet and diabetes due to amputation.

2 Context Problems and Methodology

This research was conducted to respond to the need for the development stages of design, manufacturing and fabrication AFO shoes on foot deformity patients, especially in patients with diabetes mellitus using modern technology in the field orthotic CARESystem. This technology is very necessary to lessen the design and manufacturing time of AFO orthotic shoes. AFO footwear product consists of four parts, namely: insole, outsole, shoe last and shoes upper. Those parts are shown in Fig. 4. The assembly of thesecomponents will form customized AFO shoes that can solve the concerns of patients and related industries.

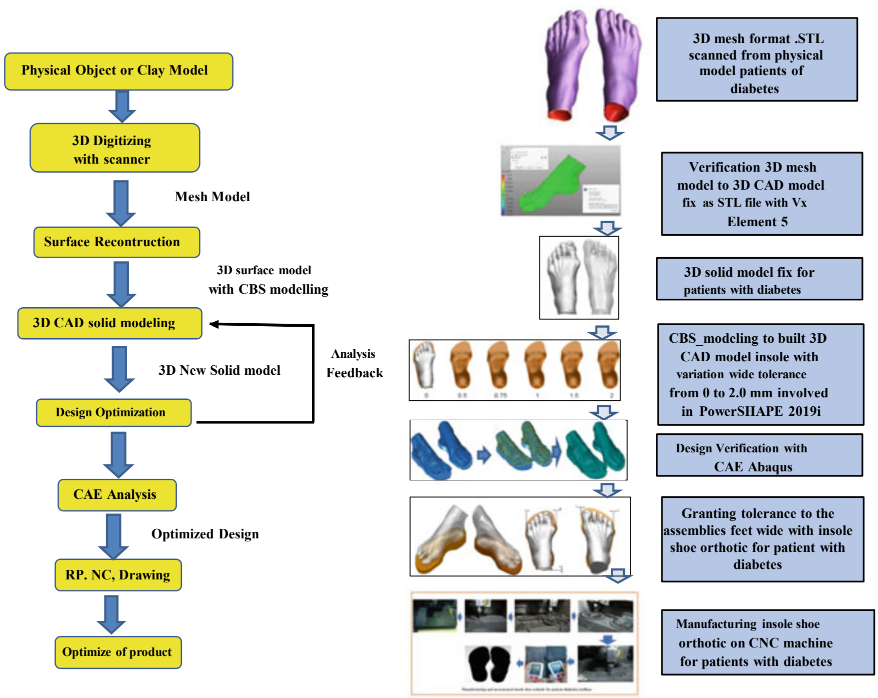
There were two diabetic patients, aged between 55–74 years old and weight between 60–70 kgs were selected as research subjects. These two patients had diabetes for more than 10 years and according to previous research [1, 2] both were included in the "high risk" scale category.

The purpose of this study is to produce customized orthotic shoe lasts for patients with high-risk diabetes mellitus using CARESystem (Fig. 4a). This modern technology, which included a set of 3D scanners, CAD, CAE, CAM, CNC, and RP was employed to design and manufacture the orthotic shoes.

There are two types of AFO shoes that were produced in this study, namely: AFO shoes type 1 and type 2. Type 1 is orthotic shoes with hand-made shoe lasts (Figs. 3b and 4b). The second type is shoes with AFO shoe last made with a CNC machine (Figs. 3c and 4c).

This project began with scanning the patient's foot using the Handyscan 3D image 700 to obtain the insole and outsole model in files with IGES format (Fig. 5a). Then, the scanning results were processed usingthe curve based surface modeling, as has been done successfully by Refs. [3, 7, 8, 10, 16, 17] (Figure 5b). The process of making this prototype conducted by researchers to verify the results of the size of the foot with the insole and shoe last that have been machined on CNC. The accuracy of each geometry has been done [7] with the result of an error on each foot measured dimension is less than 0.05 mm (Fig. 5c).

The process of manufacturing orthotic shoes insole on a CNC machine with EVA FOAM material as illustrated in Fig. 5d. Manufacturing output in the form insole with



(a)

Fig. 3 Flowchart method CARESystem AFO RID technology in patients with diabetes mellitus **a** RID AFO. **b** Conventional methods AFO. **c** Methods of shoes CARESystem AFO

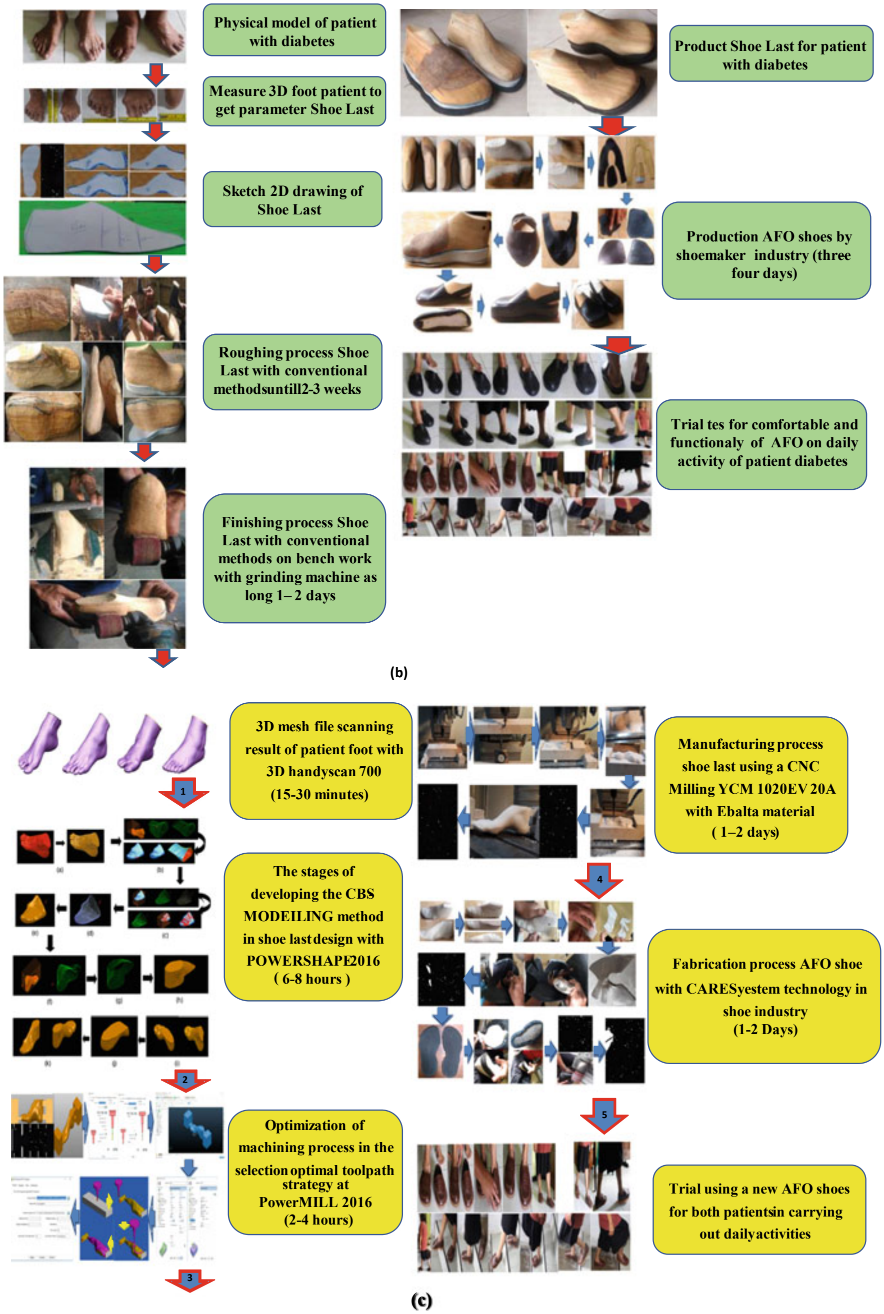
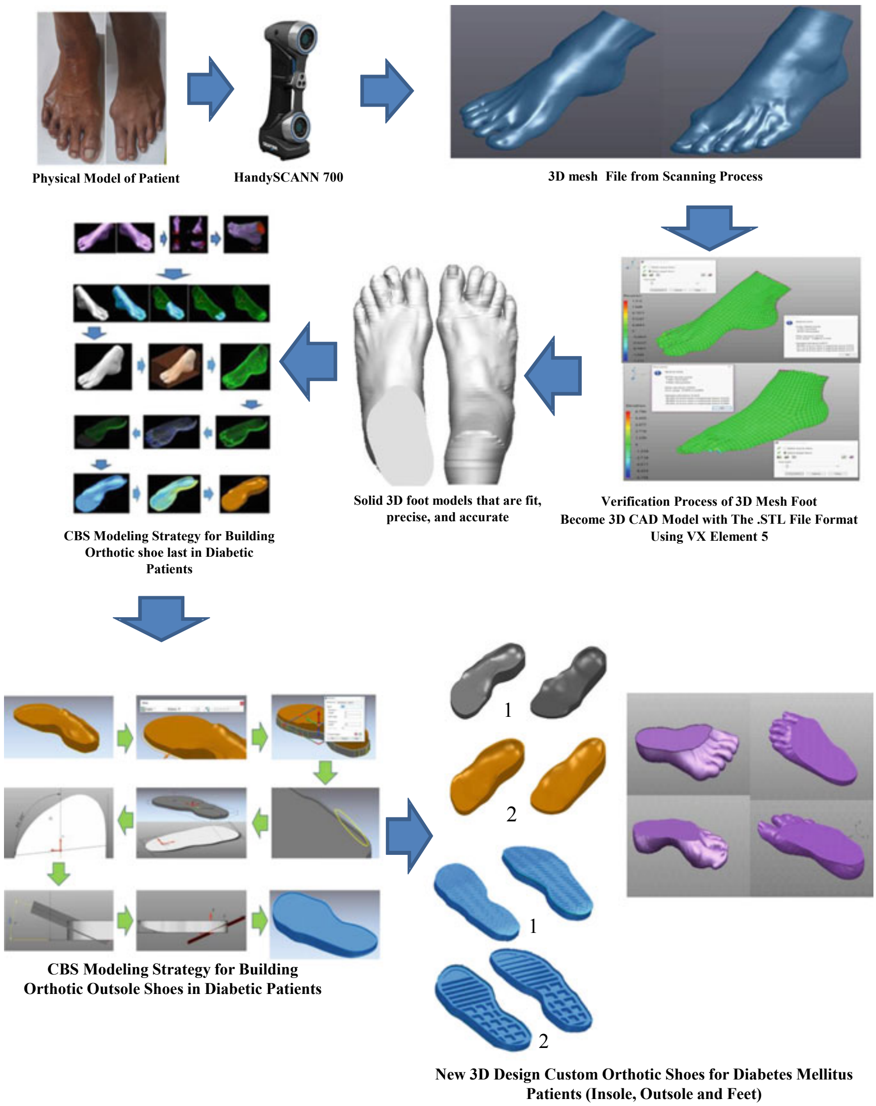


Fig. 3 (continued)

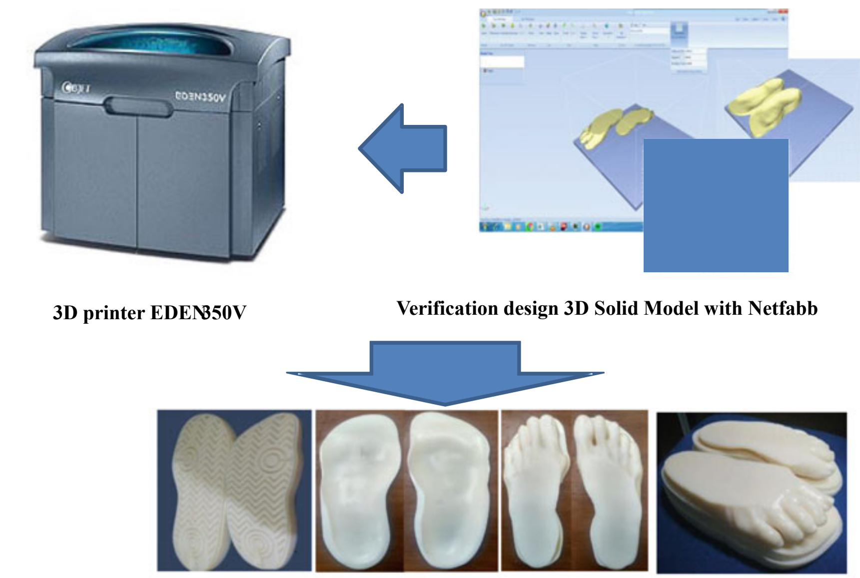
Fig. 4 **a** Architectural design and manufacturing shoes CARESystem based AFO. **b** Footwear AFO type 1. **c** Footwear AFO type 2

surface roughness up to the maximum set a maximum price of fewer than 10 μm. For the shoe last that was hand-made, it is a necessary outsole product made from Polyurethan (PU). This outsole was processed using CNC machine YCM 1020EV20a (Fig. 4a and Fig. 5e). After the shoe last footwear was completed, the manufacturing process was carried out on a custom AFO shoe industry in the area Ganjuran Bantul, Yogyakarta, Indonesia (Fig. 5f). The research procedures is described in detail in Fig. 5.



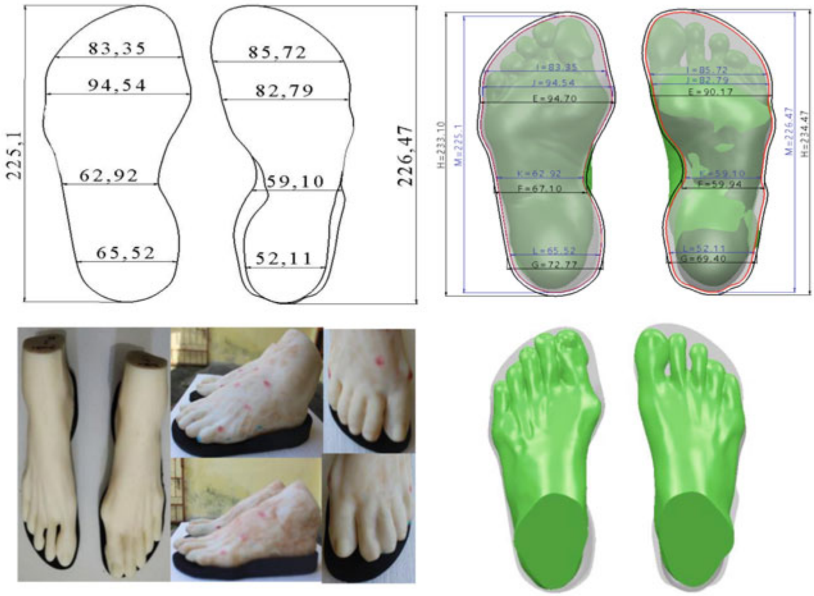
(a)

Fig. 5 Stages of methodology research **a** CBS-modeling to get a 3D CAD model of the insole, outsole, and shoe last with PowerSHAPE CAD. **b** Manufacturing prototype insole, outsole patient's legs and shoe orthotics using EDEN 350. **c** Verification of 3D CAD feet, insole, outsole and foot prototype 3D printer engine results. **d** Manufacturing orthotic shoe insole in CNC machine Rolland models MDX 40R. **e** Manufacturing and shoe last shoe outsole orthotic in CNC machine. **f** Fabrication AFO in shoe industry, Ganjuran, Bantul, Yogyakarta



Prototype product of Orthotic Shoes with the assembly part

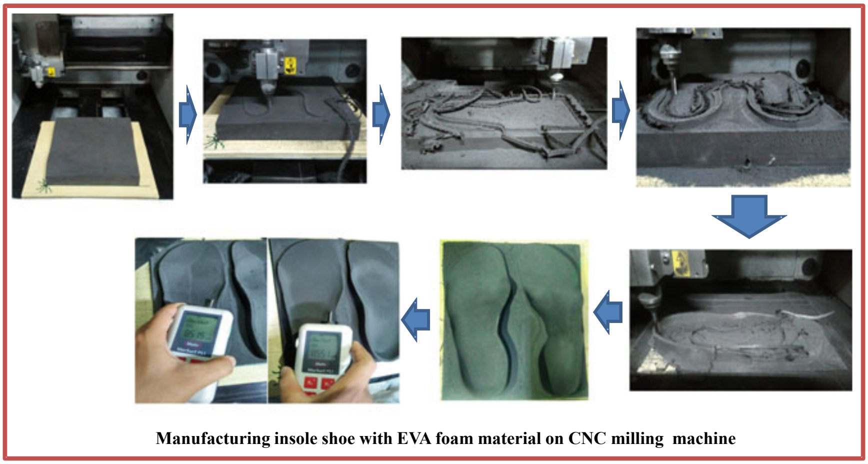
(b)



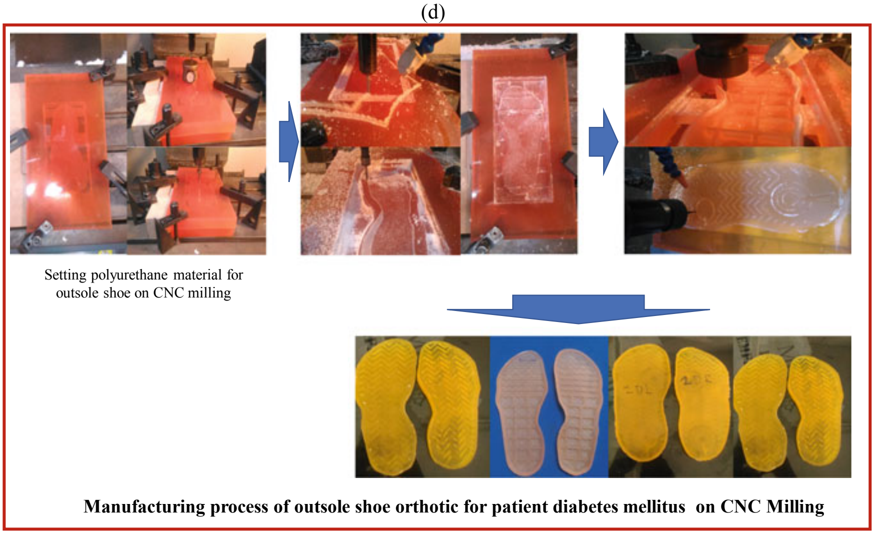
Prototype and 3D CAD Feet Models from 3D printer

(c)

Fig. 5 (continued)



(d)



(e)

Fig. 5 (continued)

(f)

Fig. 5 (continued)

3 Result and Discussion

This paper describes the design, manufacturing and fabrication technology CARESystem of orthotic shoes (See Fig. 4). These shoes were specially made for two high-risk diabetic patients [1, 2] with foot deformities (see Fig. 1). Both patients were women. The condition of the patients' feet with their usual footwear is presented in Fig. 2. It can be seen that the footwear is rapidly destroyed by the growth of the patients' bones in both swollen feet. Consequently, the upper parts of the shoes can be easily torn and the shoes will not last long. For patients from the middle and lower economic class, this situation is very disturbing.

The reverse innovative design (RID) of shoe insoles and shoe lasts were performed successfully with the stages described in Fig. 3. The sequence has also been successfully undertaken by Refs. [7, 10, 19, 20]. The RID results demonstrated that the shoe insoles designed and manufactured on CNC machines were really precise, accurate and comfortable to be used by both patients. The error measurement results between 3D CAD insole, prototype and product insole with the patient's feet are 0.2 mm [7, 8, 21].

Figure 3b shows the total time to make manual AFO shoe last is 210 h, while the AFO shoe processing timeusing the CARESystem technology is for 134 h. The detailed explanation of the work of the two types of shoes is presented in Table 1.

Tabel 1 Compare time production and percentage improvement (%) of AFO shoes

No	Description	Shoe last manual (hours)	Shoe last CARESystem (hours)
1	Scanning process	8	1
2	Design Insole shoes	2	18
3	Design shoe last		
	a. Roughing process shoe last	144	0
	b. Finishing process shoe last	32	0
	c. CBS modeling of shoe last	0	24
	d. Optimazation with CAM software	0	8
	e. Setting material shoe last on CNC machine	0	9
	f. Manufacturing process of shoe last on CNC machine	0	50
	g. Manufacturing AFO shoes on small enterprice industry	24	24
5	Time production total	210	134
6	Procentase Improvement (%)	63.57	

Table 1 indicates that there is a time reduction in the shoe manufacturing process using the AFO CARESystem by 63.57% or about 64% faster compared to manual methods. In addition to the lack of precision in terms of size, the hand-made production of larger shoe lasts, approximately 5–8 mm in size, from the physical model of the patient's feet took longer timenearly 3–5 weeks. This time will multiply if the deformity forms are more complicated, such as for patients with club foot, flat foot, or high heel injury. This current finding was consistent with previous research [5, 6, 8, 9].

The present AFO products have significantly cut down the production time. With the technology, the orthotic shoes can be completed 64% faster than the hand-made production. [9]. Both patients admitted that the geometry quality and comfort had no significant difference between the traditional and innovative processes. However, in terms of the model and shape of shoes, the two patients agreed that the innovative products with the modern technology produced orthotic shoes that met the patients' expectations. Therefore, CARE System that use of CAD technology (PowerSHAPE2016) to design development and manufacture orthotic shoes is definitely feasible and can be recommended for further processing in the shoe industry.

The application of CARE System technology as shown in Figs. 4 and 5 has succeeded in proving that the technology is fast, precise, and accurate in the stages of design, manufacturing and fabrication of AFO shoes for diabetic patients, particularly patients with foot deformities. This study [9, 21] also has successfully demonstrated that the technology made the shoe production time 64% faster than the hand-made orthotic shoes as presented in Fig. 4 (c) and Tabel 1. This finding is important for

AFO shoe designers to produce AFO shoes that are convenient, accurate, precise, and faster. These results show an increase of 24% compared with other research [6]

Our research output is a pair of custom orthotic (insole, shoe last and upper shoe) shoes for diabetic patients designed using existing CAD software that have been tested and used every day by two patients and have been shown to be tested in an orthotic laboratory (PT. Pratama Sentra Rehabilitasi, Jakarta, Indonesia). Both the development process of this technology (traditional and CARESystem) have also been carried out to obtain a significant influence on the concerns experienced by both patients with diabetes mellitus during this time.

Figure 2 illustrated the two types of shoes AFO with the CARE System. Both types of AFO shoes have been used by the patients with diabetes for less than eight months. They feel comfortable in the shoes. The AFO shoes type 1 in Fig. 4b is not an artistic form [7], giving rise to the complaint in two patients but successfully repaired with the making shoe last (Fig. 4c) with CNC machines according to the shape of shoes in general, as already reported by Refs. [8, 9] and is able to provide comfort for the patient. Regarding the geometry quality and shape, the shoes have already met both DM patients [3].

To examine the quality of the AFO shoes, both patients were asked to wear and perform daily activities such as sitting, standing about 5 min, walking slowly, walking fast and walking on the stairs. Running was not performed considering the age of the patients. The patients wore the shoes about 2–5 min. The test was conducted slowly, smoothly and both patients said that they were very comfortable in using these AFO shoes (Fig. 5). The present finding supports other researchers [11].

Meanwhile, the use of optimum cutting parameters in the CNC milling machine including spindle speed, feed rate, step over, depth of cut, toolpath strategy to determine the type of design and the right materials, EVA foam, have also successfully been produced by previous researchers [8, 11, 18, 22]. The machining parameters can be used as a reference for the shoe industry or laboratory to use CNC machines in the process of shoe last and the insole made of EVA Foam.

The current findings can be developed to solve the case design, manufacture and fabrication of orthotic shoes for patients with other deformities (club foot, flat feet, and other types of diabetes feet problem). Future research can produce innovative findings to speed up and improve the quality of the AFO shoe design process for DM patients.

4 Conclusion

The applications of CARESystem technology based on RID successfully improved the design and fabrication stages of AFO shoes specifically for DM patients with high-risk scale. AFO shoe insoles offer an exact surface contour, dimensional accuracy, and precision appropriate for patient's feet. and a good comfort level to reduce the pain. In the future, CARESystem can be used to design and fabrication of various AFO shoes types of patients such as club foot, flat feet, high heel syndrome, metatarsalgia and disability amputation due to diabetes.

The design ofinsole, outsole and shoe orthotics with existing CAD software has been tested in patients and has been tested in the orthotic laboratory. The process of the technology (traditional and CARESystem) has been carried out to address the concerns experienced by both patients with diabetes mellitus. The patients participating in this study felt very satisfied and comfortable with the products after wearing for about six months.

AFO new product trials in both patients have shown savings of working time on average, for the entire production process AFO approximately 64%. Both patients admitted geometry quality and comfort no significant difference with traditional and innovative processes. But in terms of the model and the shape of shoes, two patients agreed that innovative processes with CARESystem (see Fig. 3c and Fig. 4c) AFO was able to produce shoes that fit with the expectations of the patient so that the use of CAD technology (PowerSHAPE2016) in design development and manufacturing of shoe orthotics a decent design process and can be recommended for further processing in the shoe industry.

Collaborative research has been conducted by researchers together with a team from SIBAD UNDIP Group Research. This collaborationwill lead to the establishment of MoU and MoA between Diponegoro University with other universities and the private sector which has been a partner in the implementation of research inbiomedical engineering,

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