Journal of Engineering and Applied Sciences 14 (1): 106-113, 2019
ISSN: 1816-949X

Reverse Innovative Design of Insole Shoe Orthotic for Diabetic Patient

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Abstract: All product innovations of manufacturing industry are now designed and developed using CAD (Computer-Aided Design) software. In the present study, geometry models of foot produced from the insole shoe orthotic product (ISO-product) corresponding to the contour of reliefs malformed legs due to illness (foot deformities) are described in detail in the form 3D mesh solid. In addition, the ISO-product can be made in a wide range of digital 3D design application such as foot iQube 3D scanning, 3D CAD PowerShape 2016, reverse engineering, CAE analysis and rapid prototyping/CNC machine. This study presents the stages of Reverse Engineering Design (RID) for a pair of ISO-product generated from the feet people suffering from the foot deformed. Initially, the scan to get a foot in the form of 3D meshes is presented in the STL file. A few feet of the Indonesian people by the age of fifty to mid-seventies and weight range of 50-80 kg and having foot deformities are obtained. A curved solid modeling-based on 3D surface and solid modeling of ISO-product is fitted to the contour of the scanned foot relief. The results can be a guide how to obtain the 3D surface and the solid model of the feet people with deformities for the subsequent analysis.

Key words: Computer-Aided Design (CAD), 3D-mesh solid model, a solid curved-based modeling, insole shoe orthotic product (ISO-product), deformities, Indonesian

INTRODUCTION

Design can be defined as a process involving creative thinking and problem solving. Design and knowledge can be strongly interrelated, recollected while the usage of knowledge is a straight forward in the practical design process (Ye *et al*., 2008; Perkins, 1986; McMahon and Browne, 1998; Foley *et al*., 1990; Ciobanu *et al*., 202). Moreover, product development can be started from physical to digital mock up and from 2D to 3D design. Here, the 3D CAD may involve a part of a completely digital development process including design and modeling (PowerShape, Art CAM, Toolmaker, Copy CAD, PS Mold maker and Ortho CAD), simulation and tooling (PowerMill, feature CAM, Art CAM, Ortho Mill) on Delcam software. On the other hand with the rapid advancement of 3D data acquisition tools, the Reverse Engineering (RE) technology has become significant in the product design community (Ye *et al*., 2008).

During this time, the engineering design of RE can be explored for designing or modifying the product of the existing products. Recently, the RE plays an important role in companies for engineering designs. Consequently, many researches of RE have been conducted in the area of product design such as (Ciobanu *et al*., 2012; Telfer and Woodburn, 2010; Anggoro *et al*., 2015; Xia, 2014; Babu and Thumbanga, 2011; Piperi *et al*., 2014). However, only limited studies have been focused on the development of the reverse innovative design for the orthotic shoe insoles. The main goal of the present work is to implement innovative methods of reverse design

Fig. 1: Traditional method for forming foot insoles (Uccioli and Giacomozzi, 2012)

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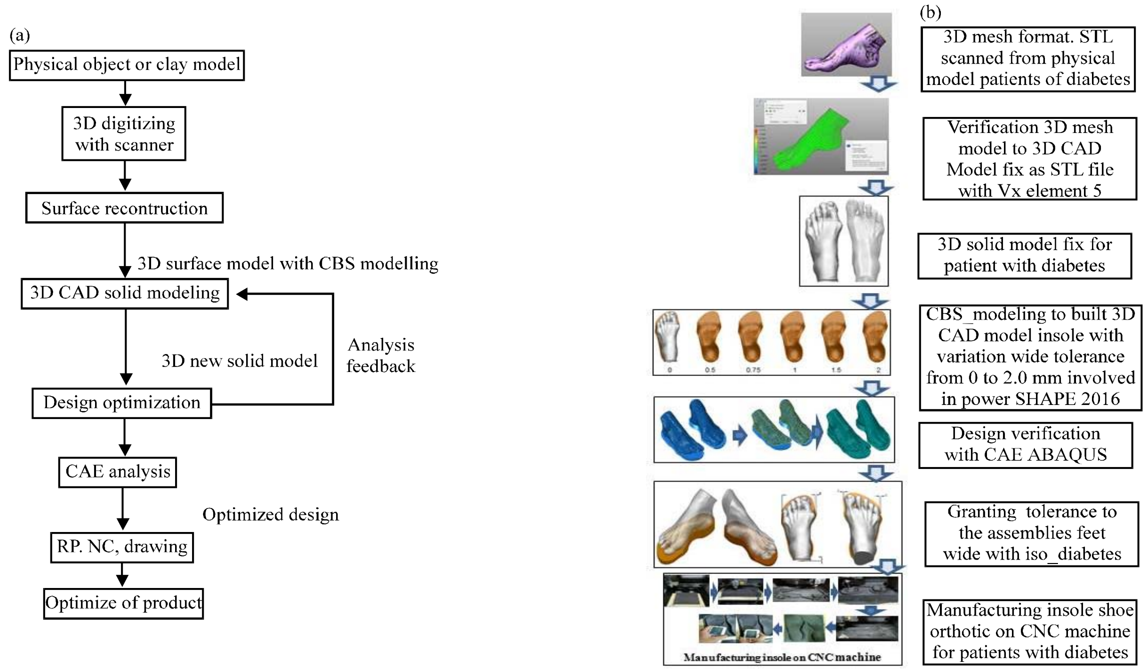

Fig. 2a): An illustration for RID methodology (Ye *et al*., 2008 b); RID of insole shoe orthotic for patients with diabetes

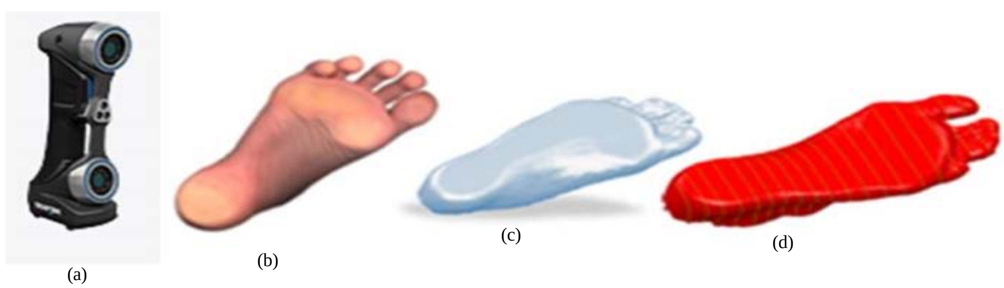

Fig. 3: Process scanning the foot: a) Handyscan 700TM; b) View output foot on scanning and c) 3D mesh foot from scan d) 3D mesh curve of the countour foot

(RID) which is similar to the researcher of Ye *et al*. (2008) for designing the orthotic shoe insoles. The RID method developed in the study involves the process of scanning the human foot for the verification stage of the design using ABAQUS® 6.13. The developed method is quit significant to analyze a tribology parameter of the ISO product in the foot surface which undergoing interaction and friction as the use of products. The results of the analysis can be used for the determination of the parameters in the design and development of the alternative iso_diabetes.

MATERIALS AND METHODS

Generally, the method of designing insole prosthesis was quite conventional in which a skilled operator is required and their steps were also time consuming (Ciobanu *et al*., 2012; Xia, 2014) as shown in Fig. 1. In this case, the final alignment of the prosthesis was performed using visual gait analysis and patient feedback. In the present method, the methodology of product design using RID is shown in Fig. 2 and 3. In this way, the design of insole uses a scanned foot to make a CAD model for subsequent CAE analysis. In this study, the application of Reverse Design (RID) in case of the orthotic shoe insole devoted only on stages, started from the foot scan process using laser scanning Handy SCAN 700™ to the verification of 3D solid models using ABAQUS 6.13. In detail, overall process.

RESULTS AND DISCUSSION

In this study, two patients with diabetes are taken as an object. The characteristics of two patients are in detail shown in Table 1 and Fig. 5 while the risk classes of diabetes are shown in Table 2.

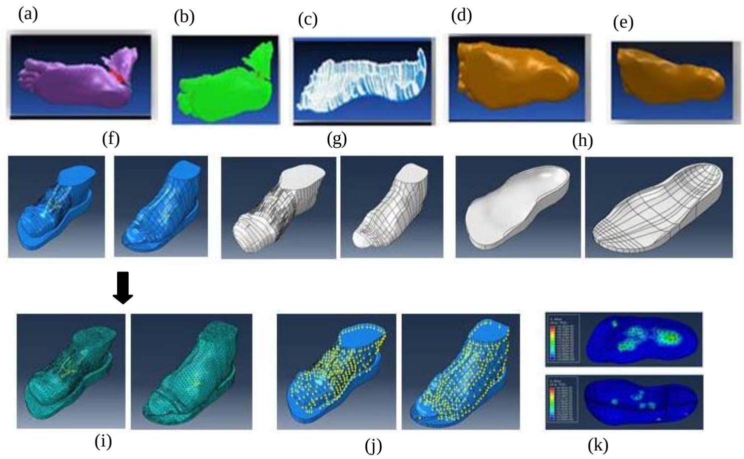

Fig. 4: RE insole shoe orthotic modeling: a) Mesh importing and preprocess; b) Rewiring; c) Repoint; d) 3D surface modeling; e) 3D solid modeling; f) 3D iso_diabetes for right and left foot; g) 3D indenter for right and left foot; h) Assembly 3D indenter foot and insole in CAE ABAQUS 6.13; i) 3D mesh asembly FE; j) Job analysis FE with various pressure and k) Output analysis von misses stress for iso_diabetes

Table 1: Data of the patient.

Name	Old (years)	Gender	Weight (kg)
Mrs. A	57	Female	50
Mrs. B	75	Female	72

Table 1 and 2 and Fig. 5 present the division of the type of diabetes based on the ranking of the class (Anggoro *et al*., 2015) the two patients in the subject of this study can be categorized as diabetic patients with high-risk because of the photo foot and a visual display can be seen in the section marked red in Fig. 6. Where the emerging bone spurs resulting in the patient discomfort when using normal shoes or sandals.

The process of scanning foot in two patients was performed by attaching a small black sticker as a sensor in some parts of the surface contour of the foot in order to read properly and the resulting 3D mesh has an image resolution approaching 0.05 mm and 0.03 mm accuracy approaching. Output scanning process can be shown in Fig. 7.

The foot scanning results can be seen in Fig. 5 on 3D foot scans in 3D mesh with .STL file format. Actually, this type of file can be quickly processed into 3D solid orthothic when using software such as Orthomodel, Orthema etc. In this study, the use of software CAD PowerShape 2016 in changing the patient's leg into a 3D mesh 3D solid modeling foot and shoe orthotic insole was carried out.

Based on the three scenarios of RE modeling strategy that has been described by Ye (Anggoro *et al*., 2015), Two strategy major of RE modeling (automatic freeform surface modeling and featured-based parametric solid modeling) was applied because it cannot form a 3D solid fit the contour of the foot scanning.

Fig. 5: Foot of diabetic patients and output 3D Handyscan 700 TM

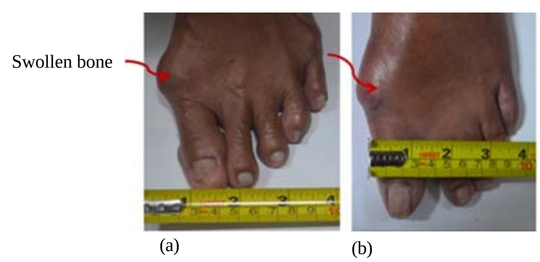

Fig. 6: The shape of foot: a) Patient 1 and b) Patient 2

Strategy Base Curve Surface modeling (CBS_modeling) was selected and applied in the implementation of this RID. CBS-modeling was chosen because foot contour curves may include section curves and boundary curves and the roommates. Gives advantage to the editing process so the curve formed curves may be generated into the perfect shoe insole surface. The time required in the establishment of the curve is short by using features creating of an oblique curve in PowerShape 2016. It produces the insole curve that automatically fits the scanned contours of the foot.

(a) (b) (c) (d)

Fig. 7: Scanning process: a) Attachment of the hologram on the feet of diabetic patients; b) The scanning process with the Handyscan 700 TM at the patient's leg

Table 2: Risk classes

0	Low	Patient with normal protective sensation
1	Medium	Loss of protective sensation, without foot deformities and without history of foot ulceration or previous amputation
2	High	Loss of protective sensation, without foot deformities and but without history of foot ulceration or previous amputation
3	Very high	Loss of protective sensation, without foot deformities and with history of foot ulceration or previous amputation

Table 3: Standard wide tolerance for iso_diabetes

No.	1	2	3	4	5
Tolerance (mm)	0.50	0.75	1	1.50	2

With the method of CBS-surface modeling and smart features in PowerShape 2016, 3D surface can be formed only using curves that have been created. The results of RE is a variation of a special insoleshoeorthotic diabetes (iso_diabetes) for differently providing a wide tolerance dimensions. RE stage of the process can be presented in Fig. 8.

RID process that has been conducted by researchers passed through several stages, namely, imports to enter the files to be processed in the form 3D mesh. STL, oblique process to create a wireframe that form the shape of the foot patient original foot, organize and summarize wire, wireframe reconstruction that have been made to form insole become more concise, repoint reconstitute the composition point on the wireframe, wire support create additional lines to assist in the generation of surface insole, surfacing generation process surface insole of a 3D wireframe foot, surface editing to organize and improve surface 3D insole so that there are no surface is deformed and changing the processes convert 3D solid surface into a 3D solid iso, diabetes form that can be processed in the next stage. Based on Fig. 8, it can be observed that the processes of making variations iso, diabetes are performed by providing a wide tolerance on each side of the insole. The result in detail can be seen in Fig. 9a, b.

The next step is being taken insole models that have gained solid construction. In the stage of optimization of the required sample insole and a few variations of the design to obtain the best optimization results for it once formed a solid insole scale process is done, the process is carried out to obtain a variation of the size of the insole. Steps being taken to process scale, namely, getting the initial size information insole, this is done by measuring the insole with the help feature on PowerShape 2016, i.e., dimensioning. The size that is obtained is as a basis for determining the value of the magnification of the feature scale. Value enlargement in this paper using the equation:

$$\text{Enlargement} = \frac{\text{Initial size (A, B, C)+Gap size}}{\text{Initial size (A, B, C)}}$$

where, the initial size of the formula is the original size insole with width tolerance size using Table 2 and 3. In detail, Table 4: Dimensional Scale iso_diabetes for patient 1 and patient 2, the value of width tolerance on iso_diabetes is determined by the values of in Table 4. Wide selection tolerance to design a very small iso_diabetes >5 mm wide surface under on each foot patient according to investigators has been very decent. Because it is designed iso_diabetes really matches the contour of the surface of the edge of the foot patient. Expected wide tolerance that late this set later when the patient touches the surface of iso_diabetes really fit with legs that seemed comfortable when used later (Fig. 9-14).

Having obtained the kind of model iso_diabetes magnification scale is then performed on the initial model with a wide tolerance of zero became the new model with a wide tolerance of 0, 0.5, 0.75, 1.0, 1.5 and 2.0 mm in each of the left and right of the surface of the soles of the feet of the two patients. The results of the wide variation in the gap further iso_diabetes design can be seen in Fig. 9 and 10.

Table 4: Dimensional Scale iso_diabetes for patient 1 and patient 2

	Left foot for patient 1			Reft foot for patient 2		
	Dimension			Dimension		
Tolerance (mm)	Left of ISO (A)	Wide of ISO (B)	High of ISO (C)	Left of ISO (A)	Wide of ISO (B)	High of ISO (C)
0.00	223.103	95.373	21.807	225.724	92.128	23.500
0.50	223.603	95.873	22.307	226.224	92.628	24.000
0.75	223.853	96.123	22.557	226.474	92.878	24.250
1.00	224.103	96.373	22.807	226.724	93.128	24.500
1.50	224.603	96.873	23.307	227.224	93.628	25.000
2.00	225.103	97.373	23.807	227.734	94.128	25.500
0.00	240.967	98.006	25.000	243.638	98.784	25.500
0.50	241.467	98.506	25.500	244.138	99.284	25.750
0.75	241.717	98.756	25.750	245.391	99.534	26.750
1.00	241.967	99.006	26.000	245.638	99.784	26.000
1.50	242.467	99.506	26.500	245.838	100.284	26.500
2.00	242.976	100.006	27.000	246.138	100.784	27.000

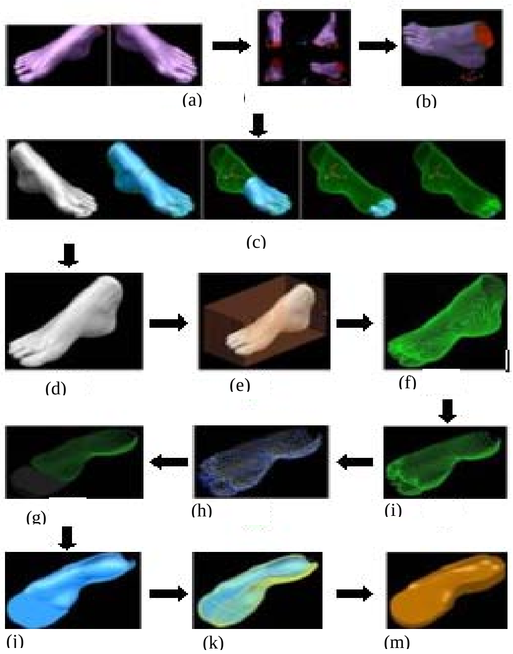

Fig. 8: CBS-modeling iso_diabetes involved in PowerShape 2016: a) Mesh importing and pre processes; b) Rewiring; c) Repoint, built and verification 3D surface to solid foot with solid doctor; d) 3D solid model foot from mesh; e) Oblique processing; f) Foot wireframe; g) Wire support; h) Repoint wireframe curve; i) Wire reconstruction; j) Surface generating; k) Surface curve editing and l) 3D solid iso_diabetes

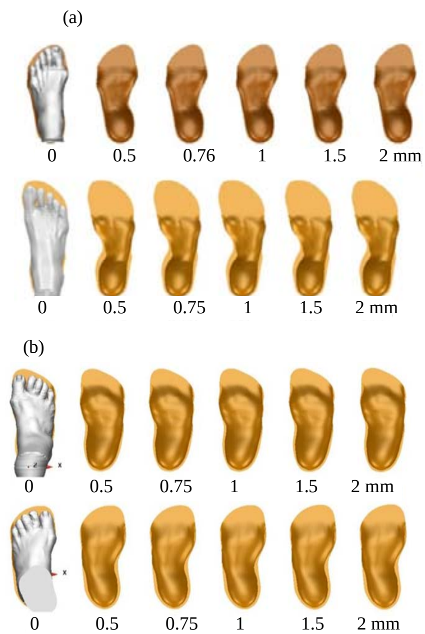

Fig. 9: Top view of 3D Model iso_diabetes with variation wide tolerance from 0-2.0 mm: a) Patient 1and b) Patient 2

Based on Fig. 9, performed the design optimization process to select iso_diabetes with the help CAE to obtain the value of the pressure distribution von misses stress smallest. This implies that when the indenter foot is contacted with varying load on each leg it will be seen in the simulation clearly in the wide gap how that actually has the smallest area von miss stress. In this condition it will have design iso_diabetes. Based on Fig. 9a, b the wide tolerance 0 can be modeled by FE contact mechanics between the legs as the indenter and iso_diabetes with EVA rubber foam material. FE with 6:13 ABAQUS results showed that the value of von misses smallest for patient No. 1 exists in the wide tolerance 1.5 mm and No. 2 patient there in the wide tolerance 2.0 mm. It is based because of the wide tolerance that von misses stress values obtained for each patient showed the lowest price. Wide gap on this new model can be considered as optimal from optimal iso_diabetes which can be said to be continued to the next stage. Some researcher's CAD design also provides tolerance foot wide gap is small, <5 mm (Anggoro *et al*.,

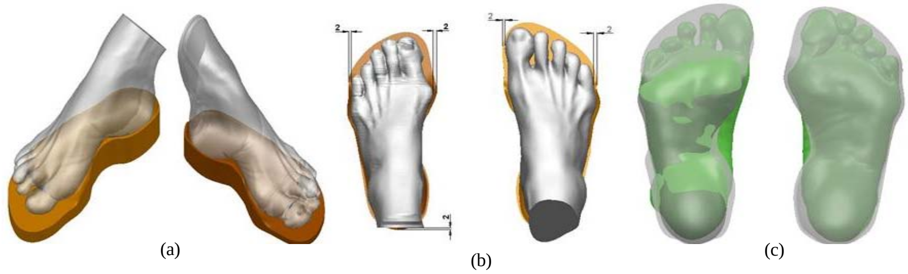

Fig. 10: Granting tolerance to the assemblies feet wide with iso_diabetes: a) Isometric view; b) Top view and c) Bottom

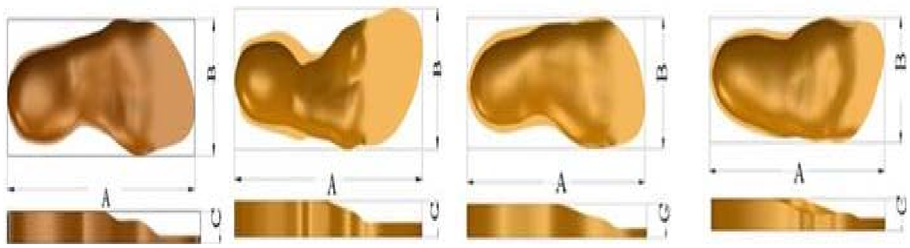

Fig. 11: Dimensional Scale iso_diabetes for patient 1 and patient 2

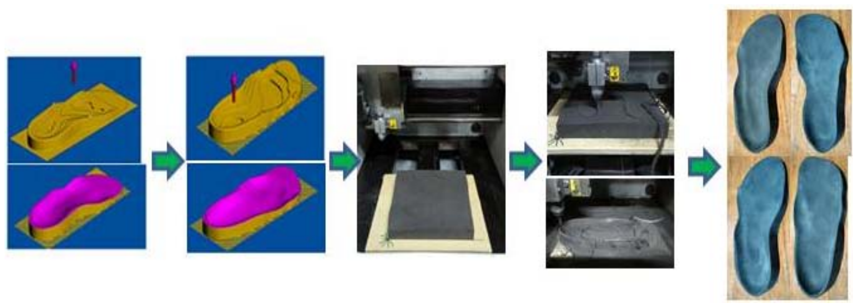

Fig. 12: Manufacturing left and right iso_diabetes for patient 1 and 2 on CNC machine

2015; Perkins, 1986; Ye *et al*., 2008). Value enlargement sought is in three sizes, namely insole length (A), width (B) and height (C). With features on PowerShape 2016 scale, gradually entered magnification value by locking other measure. Results iso_diabetes scale of five different sizes shown in Table 5 and Fig. 11. The final stage of this process iso_diabetes RID is a subtractive process technology manufactured using CNC machines Rolland modela MDX 40R and CAM Software PowerMill 2016 and PowerShape 2015 R2. Strategy finishing raster machining 45^0 and finishing steps and shallow selected and used to obtain the desired processing time. End of the workmanship can be shown in Table 5 and Fig. 12 and Fig. 13.

The result of this research is a pair iso_diabetes for each patient listed in Fig. 13. Both have been tried in two patients as shown in Fig. 14. It shows that the profile shape and relief of iso_diabetes is in conformity with the contour of the soles of their feet. Based on survey, the patient does not feel pain during the second pressing of their feet when hitting the surface of this iso_diabetes. Results of surface machining also can meet the patient's

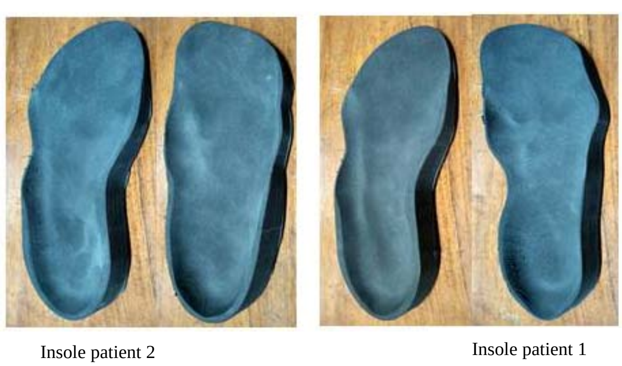

Fig. 13: Product iso_diabetes for patient 1 and 2

Table 5: Manufacturing left and right iso_diabetes for patient 1 and 2 on CNC machine

Process	Toolpath strategy	Tooling design	Time machining (h, min, sec)
Roughing of left foot for patient 1	Model area clearance	cutter: end mill dia 6 mm Spindle speed: 15.000 rpm Feed rate: 1.500 mm/min Plunge rate: 3000 mm/sec Step over: 4.5 mm Step down: 2 mm	00.23.55
Finishing of left foot for patient 1	Raster finishing 45	cutter: ballnose dia 6mm Spindle speed: 14.000 rpm Feed rate: 900 mm/min Plunge rate: 3000 mm/sec Step over: 0.3 mm Step down: 0.25 mm	01.00.45
Roughing of right foot for patient 1	Model area clearance	cutter: end mill dia 6mm Spindle speed: 15.000 rpm Feed rate: 1500 mm/min Plunge rate: 3000 mm/sec Step over: 4.5 mm Step down: 2.0 mm	00.25.55
Finishing of right foot for patient 1	Raster finishing 45	cutter: ballnose dia 6mm Spindle speed: 14.000 rpm Feed rate: 900 mm/min Plunge rate: 3000 mm/sec Step over: 0.3 mm Step down: 0.25 mm	00.59.27
Roughing of left foot for patient 2	Model area clearance	cutter: end mill dia 6 mm Spindle speed: 15.000 rpm Feed rate: 2000 mm/min Plunge rate: 3000 mm/sec Step over: 5.0 mm Step down: 3 mm	00.21.50
Finishing of left foot for patient 2	Raster finishing 45	cutter: ballnose dia 6mm Spindle speed: 15.000 rpm Feed rate: 2000 mm/min Plunge rate: 3000 mm/sec Step over: 0.3 mm Step down: 0.25 mm	01.20.45
Roughing of right foot for patient 2	Model area clearance	cutter: end mill dia 6mm Spindle speed: 15.000 rpm Feed rate: 2000 mm/min Plunge rate: 3000 mm/sec Step over: 4.5 mm Step down: 5.0 mm	00.35.45
Finishing of right foot for patient 2	Raster finishing 45	cutter: ballnose dia 6 mm Spindle speed: 15.000 rpm Feed rate: 1000 mm/min Plunge rate: 3000 mm/sec Step over: 0.3 mm Step down: 0.25 mm	01.13.25

(a) (b

Fig. 14: Trial iso_diabetes: a) Patient 1 and b) Patient 2

request. However, for future research, the research should be done focusing on aspects of comfort and quality of products when used in their everyday activities.

CONCLUSION

In the present researcher the steps in creating the 3D Model of the deformed foot were presented. In conclusion, the subtractive manufacturing technologies with CNC machines high speed machining type of medium can be the best choice in the process of manufacturing product iso_diabetes with raw materials such as rubber EVA foam rubber and can be directly assembly in normal shoes or shoe outsole. The strategy CBS modeling in CAD PowerShape 2016 provided very well, precision and meticulous 3D solid of normal feet and iso_diabetes. The process design optimization with CAE ABAQUS 6.13 and the optimization of manufacturing with CAM Autodesk PowerMill 2016 and machine Rolland Modella MDX 40R can be done. Iso_diabetes produced can be accepted by both patients so in term of comfort, the use of the product when patients perform activities of daily living (walking, sitting and standing).

ACKNOWLEDGEMENTS

We would like to gratefully thank you for: Stefani as Managing Director and Head of Engineer PT. Trimitra Wisesa Abadi, V. Aryono as Chairman of the Department of Industrial Engineering and Laboratory Production Process, Industrial Engineering Program, Faculty of Industrial Technology, University of Atma Jaya Yogyakarta and Tribology Laboratory of the Department of Mechanical Engineering, University of Diponegoro in Semarang that already provide full support in the form of infrastructure support CAD, CAM, CAE and CNC during the design and manufacturing process as well as the writing of this study iso_diabetes.

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