Three dimensional design, simulation and optimization of a novel, universal diabetic foot offloading orthosis

Chand Sukumar[1]**, K I Ramachandran**[2]

[1]Department of Electronics and Communication Engineering

[2]Centre for Computational Engineering and Networking (CEN)

Amrita School of Engineering, Coimbatore, Amrita Vishwa Vidyapeetham, Amrita University, India

chandsuku@gmail.com, ki_ram@cb.amrita.edu

Abstract. Leg amputation is a major consequence of aggregated foot ulceration in diabetic patients. A common sense based treatment approach for diabetic foot ulceration is foot offloading where the patient is required to wear a foot offloading orthosis during the entire treatment course. Removable walker is an excellent foot offloading modality compared to the golden standard solution - total contact cast and felt padding. Commercially available foot offloaders are generally customized with huge cost and less patient compliance. This work suggests an optimized 3D model of a new type light weight removable foot offloading orthosis for diabetic patients. The device has simple adjustable features which make this suitable for wide range of patients with weight of 35 to 74 kg and height of 137 to 180 cm. Foot plate of this orthosis is unisexual, with a size adjustability of (US size) 6 to 10. Materials like Aluminum alloy 6061-T6, Acrylonitrile Butadiene Styrene (ABS) and Polyurethane acted as the key player in reducing weight of the device to 0.804 kg. Static analysis of this device indicated that maximum stress developed in this device under a load of 1000 N is only 37.8 MPa, with a small deflection of 0.150 cm and factor of safety of 3.28, keeping the safety limits, whereas dynamic analysis results assures the load bearing capacity of this device. Thus, the proposed device can be safely used as an orthosis for offloading diabetic ulcerated foot.

1. Introduction

Diabetes mellitus (DM) is a chronic disease which is associated with the abnormalities in blood glucose level of body [1]. It has been estimated that, by 2030, the number of diabetic patients may shoot up to 366 million [2]. India, one of the major developing countries, is considered as the diabetic capital of World [3]. DM is well renowned for its short term and long term complications. Diabetic foot ulceration (DFU) is one among the major complication of long term DM for both type 1 and 2[4]. The life time risk of a diabetic foot ulceration development in a patient is 15 - 25% and also the frequency of ulcer occurrence is more in elder patients [5]. DFU is one of major reason for non traumatic lower leg amputation and it was found that 40% -70% of non traumatic lower leg amputation cases in hospitals are due to DFU [6]. About 40% of diabetic lower leg amputation can be avoided by giving special foot wound care. Delay in wound healing is one among the main issues related with diabetes mellitus and continuous mechanical stresses on the wound can seriously affect the healing process and period. So, the ideal treatment strategy is foot ulcer offloading (rebalancing

the weight exerted on the wound site to non wounded area, in a weight bearing condition) by means of an external set up [7].

The different offloading modalities includes complete bed rest, wheel chair, total contact cast (TCC), felted foams, insoles, healing shoe and removable cast/walker. Among these methods, even though TCC is considered to be the bench mark solution with a better wound healing rate than other modalities like half shoes, insoles, irremovable TCC and other removable walkers[8], it is less preferred by patients and podiatrists because it is irremovable, difficulty to monitor wound and needs experienced hands for patient application [6]. An online survey of offloading practices for diabetes related plantar neuropathic ulcers reported that the widely preferred foot offloading modality is felt padding followed by removable walker/cast [9]. The considerable option left for the ulcer treatment is using removable walker because felt padding can cause secondary foot ulcers even though it is effective in healing foot ulcer. Prefabricated walking brace or removable walker (examples like DH-Pressure Relief Walker, Aircast Pneumatic Walker- available in market), was found to be good in pressure reduction but they are expensive and less compliant, most of them were custom made. In India, a low income country, different low cost (<$1) offloading modalities have been developed, for instance, Mandakini [10], Samadhaan system [11], and Bohler iron cast [12], which uses only cheap materials. But, the clinical effectiveness of these devices in randomized trials was not reported. So, in India, there exists a need of a foot offloading orthosis which should be featured as removable, light weight, low cost, durability, easily fabricable, of universal design and user friendly.

This article presents an optimized 3D model of a novel universal foot offloading orthosis design, using finite element analysis (FEA) technique and material selection database in the 3D modeling, parametric and featuring software - SOLIDWORKS 2013. Selection of appropriate materials is a crucial step considered in the design and simulation of the foot offloading orthosis because of its direct effects on reducing the overall weight of the device, inducing strength and durability and also, in reducing the overall fabrication cost [13]. Different materials like High Density Polyethylene (HDPE), Acrylonitrile Butadiene Styrene (ABS) [14] and Aluminum alloy T6-6061[13] have been used successfully in the optimization including weight reduction process and Factor of Safety (FOS) analysis. Key factors like material availability, easiness in fabrication, material and production cost were taken into account while designing the orthosis. The proposed design consists of certain adjustable features which makes the design as an off-the-shelf design for wide range of patients, both men and women, ranging from height of 135 to 170 cm, weighing up to 75 kg. Unisexual foot plate accommodates a wide variety of patients with US foot size ranging from 6 to 10. In the following sections, methodology involved and results obtained are described in brief.

2. Methodology
2.1 Description of proposed foot offloading orthosis design
The proposed design is universal and unisexual in nature, which is an assembly of several parts like two height adjusting Aluminum alloy T6-6061 bars, two knee bars, two calf bands, rigid ankle joint and an adjustable foot plate. One of the significant advantage of this design is that the overall height of the device including the height required for foot offloading can be easily adjusted by sliding and fixing the adjustable bar and knee bar, using Metric 8 size screw and bolts. People with less lower leg height (below or equal to 28 cm) needs only the adjustable bars and one calf band and does not require knee bars. So, the weight of the device can be adjusted easily for patients with light and medium/heavy weight. Moreover, the size of the footplate can be increased or decreased easily with a simple adjusting mechanism, which does not affect the patient comfort and aesthetics of the foot plate. The length of the foot plate can be increased from 23 cm to 27 cm; so that women and men of different foot size (US size- men (6 to 10) and women (7 to 10)) [15] can use the device. The two calf bands consist of sliding slots, which makes the bands suitable for patients with different calf circumferences. These slots also will be helpful in attaching the bands with those two sidebars. The overall weight of device, excluding fasteners and inner lining is 0.80 kg.

2.2 Three dimensional modeling of the featured design

In this section, the design strategies involved in three dimensional modeling of all the parts of the proposed foot offloading orthosis will be discussed in brief. For designing those parts, anthropometric measurements have taken from 39 volunteers, including seventeen male and twenty two female of age ranging from 46 ± 28 and 42 ± 23 respectively. Oral consent was taken before the data collection. Table 1 shows the summary of anthropometric data collected. Standard methods have been followed in the anthropometric data collection step. A 3D modeling, parametric and feature based software- SOLIDWORKS 2013 has been used in this work for modeling and finite element analysis. Figure 1 shows the block diagram of the major steps involved in the proposed work.

Table 1. Summary of anthropometric data collected from 39 subjects.

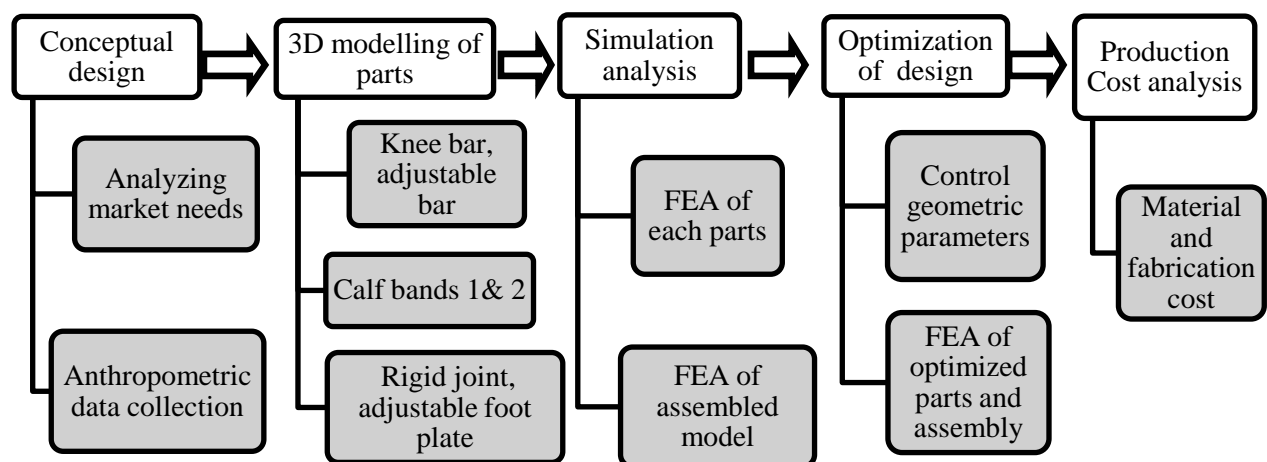|	Age in yrs	Weight (kg)	Height (cm)	Foot wear size (cm)	Lower leg height (cm)	CC1* (cm)	CC2 (cm)	CC3 (cm)	CC4 (cm)
Max.	74	74	180	27.1	44.1	41.5	44.75	26.25	41
Min.	18	35	137	23.7	27.5	26.5	27	41.25	26

* Calf Circumference

Figure 1. *Block diagram of the proposed method*

2.2.1 3D modeling of height adjustable bar.

For this modeling process, lengths of lower leg height of the volunteers have been taken using a measuring tape. Minimum and maximum lower leg height was found out as 27.5 and 44 cm respectively. So, a 3D model of adjustable bar with initial dimensions- length × width × thickness as 29 cm × 3 cm × 1 cm - was created using SOLIDWORKS 2013. The dimensions (width and thickness) have been optimized later based on maximum stress developed, maximum deflection occurred, factor of safety and weight of the part, using static finite element analysis. On the extruded model, a sliding adjustable feature was made in such a way that the position of calf bands and height of the device can be changed based on a Metric size 8 (M8) screw location.

2.2.2 3D modeling of knee bar.

Similar to the modeling of adjustable bar, the knee bar has been developed by considering the minimum and maximum value of lower leg height of the subjects. The initial dimensions considered

were length × width× thickness as 22 × 3 × 1 cm. After the optimization of the dimensions- width and thickness, final dimensions have been fixed. A long, centered slot had been made on the extruded model for the adjustable sliding mechanism.

2.2.3 3D modeling of calf bands.

Calf bands are designed using the anthropometric data collected (minimum and maximum value of circumference - below knee region, mid - calf region and lower calf regions. Two adjustable slots for each band were made in such a way that the radius and circumference of the band can be positioned according to the calf circumference of the patients. As the starting dimension, a thickness of 0.50 cm was considered for both the bands. Later it was replaced with the dimension optimization results.

2.2.4 3D modeling of adjustable foot plate and rigid joint.

Footwear size differs from patient to patient, so it is necessary to design an adjustable foot plate for accommodating a wide range of patients. A simple sliding mechanism is used in adjusting the length of the foot plate. The sliding mechanism is designed in such a way that the overall length of the device can be adjusted from 23.5 to 27.8 cm. For limiting the motion of ankle, a rigid joint was designed to attach the assembly of calf bands and bars to the foot plate. Thickness of the foot plate was varied from 5 to 3 cm for dimension optimization.

2.3 Material selection

The crucial step involved in the designing process of foot offloading orthosis is the material selection. It can control various factors like strength bearing capability of the device, weight of the device, fabrication cost and durability. There are different materials including metals, polymers, and polymer - composite materials are being widely using in various biomedical applications. For developing a light weight orthotic device, one of the commonly used materials is Aluminum alloy 6061-T6. It is an easily machinable and weldable material with good finishing characteristics and high yield strength of 275MPa and density of 2700 kg/m^3[16]; used in manufacturing many consumer durable products like cycle frame, rivets, aircraft body parts, camera lenses, brake components and so on[17]. Thus, for a light weight foot offloading orthosis, it is appropriate to consider this material for parts like knee bars, adjustable bars and the rigid joint parts. Since, foot is not allowed to touch the ground, it is mandatory to use materials with high yield strength, so Aluminum alloy 6061-T6 can be considered for developing the light weight orthosis.

 Calf bands are the significant parts of the proposed design, where most of the load or weight of the person is going to apply. A thorough material screening was conducted based on factors like biocompatibility, part dimensions, tensile strength, maximum load applied, medical application, chemical resistance, fabrication process and cost involved and based on the screening results, two polymers were selected, namely High Density Polyethylene grade (HDPE)[18] and Acrylonitrile Butadiene Styrene (ABS)[19] of yield strengths 25 MPa and 30 MPa respectively. Density of ABS (1020 kg/m^3)is higher than HDPE (955 kg/m^3). Optimization of dimensions and finalization of ideal material for calf bands of the proposed design was done using the results of Finite element analysis. For adjustable foot plate and inserting plug, 2 materials ABS and Polyurethane (PU) were compared and optimized the dimensions of foot plate.

2.4 Finite element analysis (FEA) and optimization of the different parts of model

Finite element analysis is an integrated, numerical analysis tool which is helpful in finding out the behavior of a complex system or structure in accordance with the applied load. SolidWorks Premium 2013 package has been used here for FE static and dynamic analysis studies. In the static analysis process, for a gradually increasing load with uniform distribution and unidirectional, various factors like von Mises stress, maximum deflection or displacement occurred, strain developed on the system, and factor of safety can be studied. Software assumes that all the materials used in the model obey Hooks law and it does not allow changing the boundary conditions after the meshing process. Initial and damping forces will be eliminated during the simulation process due to very less accelerations and velocities.

Von Mises stress analysis study was conducted in this work, with a compressive force of 1000 N. An equivalent stress formed was obtained using the eq. (1), without any directional component and it was compared with the yield strength of the material to predict whether this component is safe or not.

$$\sigma_v = \left[0.5\left[\left(\sigma_x - \sigma_y\right)^2 + \left(\sigma_y - \sigma_z\right)^2 + (\sigma_z - \sigma_x)^2 + 6\left(\tau_{xy}^2 + \tau_{yz}^2 + \tau_{zx}^2\right)\right]\right]^{\frac{1}{2}} \quad (1)$$

where σ_v is the von Mises stress resulted and σ_x, σ_y and σ_z are the principal stress induced in x, y and z directions when a body is applied with an external load. τ_{xy}, τ_{yz} and τ_{zx} are the corresponding shear stress values generated. A displacement or deflection will occur after the development of resulted stress and in this work, resultant deflection had been observed. Factor of safety study is another design criterion, which is obtained by considering the yield strength of the material and von Mises stress [20].

Based on the analysis results - stress developed, maximum deflection, factor of safety and weight, geometric dimensions of the parts like calf bands, adjustable bars and knee bars have been optimized. The minimum allowable factor of safety considered, with an applied load of 1000 N, to be as 3 for calf bands and 4 for both metal uprights. For optimizing geometric parameters, dimensions like width and thickness have been controlled, keeping length (for adjustable and knee bars) and radius (for calf bands) as constant.

After dimension optimization, dynamic analysis study of the models had been conducted using SolidWorks package. For this real time analysis, a muscloskeletal modeling biomechanical software, OpenSim [21] has been used to obtain the dynamic data. An OpenSim gait model 2354 with a weight of 74 kg has been simulated with normal walking speed, for 10 minute. Displacement data of leg shank was exported into the SolidWorks simulation and von Mises stress developed were noticed.

2.5 Production cost analysis

Many factors such as availability of material with necessary mechanical and physical properties and production cost are needed to be considered before manufacturing any product. So, an overall expenditure involved in developing the proposed device was tabulated after dimension optimization and market study.

3. Results and discussion

Three dimensional modelling is the preliminary work to be done after the conceptual understanding of device. Figure 2 shows the entire assembled model of proposed model, marked with various device parts.
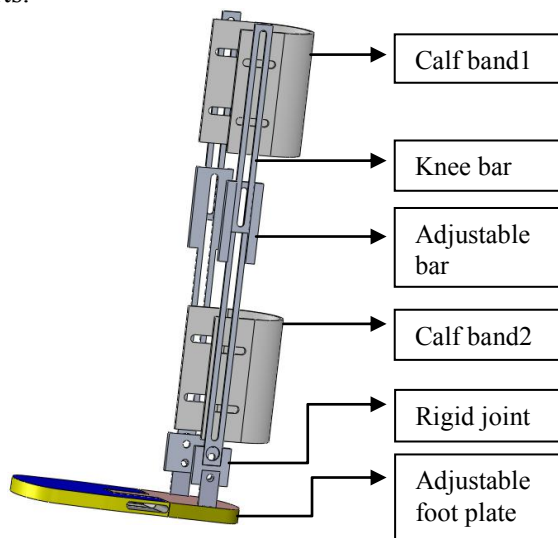

Figure 2. Entire assembly model of proposed foot offloading orthosis with different parts such as calf bands, adjustable and knee bars, rigid joint and adjustable foot plate.

Simulation analysis, using appropriate materials, is a significant step in structural designing process where the design engineers can easily analysis the structural part fault. After modelling, static analysis study of the parts was conducted by applying a uniform force and observed the maximum von Mises stress, resultant deflection, factor of safety and weight of the part. For all parts, a compressive load of

1000 N was applied, keeping zero loading condition at the lower side of parts. It was observed that with the initial dimension conditions, the parts can withstand the load applied to it. So, dimension optimization was carried out to obtain ideal geometric parameters for parts, until the factor of safety reached below 3. For both calf bands, ABS and HDPE materials have been used in the optimization process and found that ABS bands are comparatively better than HDPE, with lesser deflection and von Mises stress. Since ABS material is denser than HDPE, weight of ABS band is slightly higher. Table 2 shows the dimension optimization strategy adopted for calf bands. The optimized geometric parameter – thickness, for calf band 1 and 2 was 0.40 cm because it was observed that for values less than 0.40 cm, factor of safety resulted was less than 3. From Table 2, it was well understood that the von Mises stress and deflection of ABS bands, with 0.40 cm thickness, are lesser than HDPE. So, material chosen for calf bands 1 and 2 was ABS, even though ABS bands are heavier and rigid than HDPE bands.

For adjustable and knee bar, width and thickness was controlled to optimize the dimensions, keeping the part length fixed. Optimization of bar dimensions is shown in Table 3. The finalized dimensions of knee bar are 22×2×0.30 cm where these dimensions satisfy the factor of safety needed. Similarly, for adjustable bar, with a length of 30 cm, width and thickness was optimized as 2 and 0.30 cm respectively. After finalizing the dimensions, optimized parts including knee bar, adjustable bar, calf bands and rigid joint have been assembled and applied 1000 N load compressive load to the top portion. In simulation analysis, it was assumed that the foot offloading orthosis is bearing the entire load of 1000 N. The maximum stress acquired in this worst condition is 37.75 MPa with a minimum deflection of 0.15 cm and factor of safety of 3.28.

Table 2. Dimension optimization of calf bands 1 and 2 using ABS and HDPE materials

| Part name | Thickness (cm) | HDPE | | | | ABS | | | |
		von Mises stress (MPa)	Deflection (cm)	Factor of safety	Weight (kg)	von Mises stress (MPa)	Deflection (cm)	Factor of safety	Weight (kg)
Calf band1	0.60	5.028	0.0195	4.86	0.173	5.001	0.0121	5.99	0.185
	0.50	7.165	0.0235	3.49	0.141	4.991	0.0121	4.22	0.151
	0.40	9.060	0.0296	2.76	0.112	7.152	0.0159	3.34	0.120
Calf band 2	0.60	5.092	0.0206	4.911	0.163	5.085	0.0105	5.89	0.171
	0.50	6.602	0.0256	3.792	0.135	6.611	0.0131	4.54	0.144
	0.40	8.256	0.0335	3.034	0.107	8.262	0.0171	3.63	0.114

Table 3. Dimension optimization of adjustable bar and knee bar with 6061-T6

Part name	Width (cm)	Thickness (cm)	von Mises stress (MPa)	Deflection (cm)	Factor of safety	Weight (kg)
		0.70	20.901	0.00385	13.16	0.073
	2.50	0.60	24.840	0.00443	11.07	0.062
		0.50	30.632	0.00532	8.98	0.051
Knee bar						
	2.00	0.40	54.125	0.00694	5.08	0.029
		0.30	66.510	0.00927	4.14	0.022
Adjustable bar		0.40	47.161	0.132	5.81	0.072
	2.00	0.30	66.233	0.143	4.15	0.057

Models - calf band 1 and knee bar, calf band2 and adjustable bars were assembled after dimension optimization and dynamic analysis of the assemblies were implemented. Maximum stress developed in assembly 1 was 194.1 MPa and assembly 2 was 97.8 MPa. Figure 4 shows the analysis results of both assemblies.

Another important part of this proposed design is the adjustable foot plate through which the force exerted by the patient is distributed. So, static analysis of foot plate with compressive load of 1000 N had been studied and compared the efficiency of ABS and PU as a foot plate. Table 4 shows the optimization of foot plate. Since the foot plate need to be light weight and flexible, Polyurethane material has been finalized as the base material. Thickness was finalized to be 4 cm so the weight of the foot plate was below 0.50kg.

Table 4. Dimension optimization of adjustable foot plate using ABS and PU material

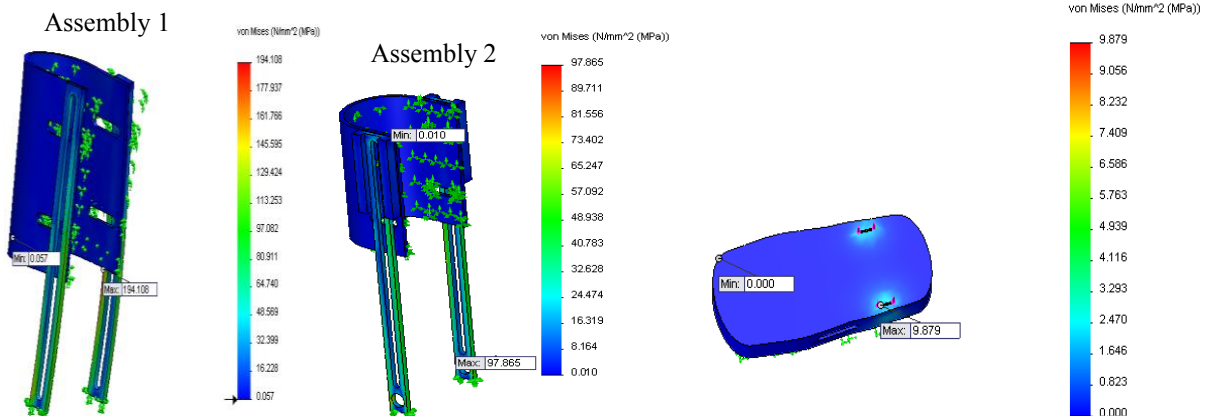| Part name	Thickness (cm)	ABS				PU			
		von Mises stress (MPa)	Deflection (cm)	Factor of safety	Weight (kg)	von Mises stress (MPa)	Deflection (cm)	Factor of safety	Weight (kg)
Foot plate	5.0	8.983	0.0195	3.34	1.270	9.879	0.0630	3.07	0.507
	4.0	9.202	0.0235	3.26	1.007	9.979	0.0689	3.04	0.402
	3.0	9.657	0.0296	3.11	0.745	10.440	0.0725	2.91	0.297

Figure 3. Dynamic analysis results of two assemblies. Assembly 1- calf band1 and 2 knee bars, Assembly 2- calf band2 and 2 adjustable bars

Figure 4. von Mises stress plot of adjustable foot plate with a load of 1000N

From a manufacturer point of view, to approve any mechanical design, it is necessary that the von Mises stress developed in a system during a worst case situation should be less than the yield strength of the materials used. The proposed work produced satisfactory analysis results for all parts in the 1000 N load environment. This situation can be considered as a worst case because in this case it is assumed that entire weight of a 100 kg person is applying on one leg. Also, the dynamic analysis results assure the capability of this device to withstand the load applied by a 74kg person. Weight of the entire device excluding all silicon linings, screws and velcro bands is 0.80 kg, which was controlled by the dimension optimization process. Factor of safety and weight are the parameters which depends upon each other, i.e. if weight is more, factor of safety will also be more. But it can result in the wastage of material and so optimization of dimension should be done in order to ensure proper weight and good factor of safety. The design engineer should consider the current market state by studying the material availability and its production cost. Table 5, 6, 7 shows the overall expense of

production cost including the material and fabrication cost for different parts of the orthosis. For the estimation purpose, rapid prototyping method was chosen for the fabrication of calf bands. The overall production cost including VAT tax was found to be Rs. 15150/-. For mass production, the cost will be reduced further more.

Table 5. Overall expenditure for fabricating the metal uprights and rigid joint

Part name	Dimensions (cm)	Quantity (No.s)	Material	Material rate (Rs)	Fabrication cost (Rs)
Knee bar	22×2×0.3	2	Alu. 6061 T6	100	750
Adjustable bar	30×2×0.3	2	Alu. 6061 T6	218	1000
Rigid joint	10×4×0.3	2	Alu. 6061 T6	74	510
Total amount*:				392	2260

Table 6. Total expenditure for the fabrication of the two calf bands

Part name	Volume (cc)	Quantity (No.s)	Material	Material rate (Rs)	Fabrication cost (Rs)
Calf band1	131.09	1	ABS	2752	2522
Calfband2	114.71	1	ABS	2408	2317
Total amount*:				5140	4839

Table 7. Total cost including material and fabrication of foot plate

Part name	Sheet dimension (cm)	Quantity (No.s)	Material	Material rate (Rs)	Fabrication cost (Rs)
Foot plate	25×13×3	1	PU	500	2000
Total amount*:				500	2000

*including VAT

This work proposes a novel universal, unisexual design of diabetic foot offloading orthosis with optimized dimensions, minimum weight and satisfactory factor of safety.

Conclusion

As there is rise in the prevalence rate of foot ulceration in diabetic patients globally, it is wise to develop a patient compliant foot offloading orthosis. The proposed design can be considered as universally designed foot offloading orthosis with less weight (< 1kg) and several adjustable features. It can be used for patients with weight less than 74kg and height in between 137 to 180 cm. The designed foot plate can be adjusted for patients of US foot size - male between 7 and 10 and female 6 to 10. Simple mechanisms are used in this design for height, calf circumference and foot size adjustments. So, this design can replace the commercially available customized foot offloading orthosis. Materials selected after simulation analysis reduced the weight of the device considerably. Before fixing the materials, a thorough analysis study was conducted and it was found out that ABS

material is comparatively better than HDPE for fabricating calf bands. For the foot section, main material used was ABS, which can withstand the maximum load excreted on the device with minimum deflection. The assembled model including calf bands, knee and adjustable bars, rigid joint results a factor of safety of 3.28 which crosses the minimum safety limit requirement. To develop this device, different fabrication techniques like extrusion and machining for aluminium bars and rapid prototyping or injection modelling for calf bands and foot plate can be considered. Cost of fabrication for a single prototype will be more comparing to mass production. Strength of material testing including tensile test, hardness test and fatigue test can be used in future to validate the developed device.

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