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Research Article

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Development of shoe insert for Diabetic Foot Ulcer Patients in case of Ethiopia

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Abstract

Foot ulcer is mainly developing due to diabetic disease. It is an open sore on the foot. The aim of this research is to develop polyurethane memory foam in sock/shoe insert in Ethiopia by replacing costly material silicon surfactant by locally available and affordable input materials castor oil as surfactant and tap water instead of distilled water for the diabetic foot ulcer patients. Under this research, it was able to prove the severity of foot ulcer in Ethiopia and enhance the high demand of orthotic appliance. Three memory foams in sock with different surfactant ratios were manufacture at AMAGA P.L.C foam factory, Bahir Dar Ethiopia using standard Polyols and diisocynates.

The shoe insert /in sock was prepared by using materials used in the factory to prepare polyurethane (PU) memory foam mattress with 5g, 9.5 g and 10.36g of castor oil surfactant amount as a new replaced material instead of costly silicon surfactant from the three the first (castor oil 5g is not form a foam and hence no further investigation is conducted on it). Physical properties such as thickness, density, hardness, compression set, water absorption and abrasion resistance of developed in sock were tested. Further the new developed in sock was compared with that of existed commercial polyurethane in sock and the SATRA standards. The new developed in sock has showed an equivalent mechanical property with the standard.

Key Words: Shoe Insert, Memory Foam; Foot Ulcer; Diabetic Patient; Polyurethane, Castor Oil.

Introduction

Foot ulcer is a term that references an open sore that forms on or near one or both of our feet. It may form on the bottom of the foot, the toes, and the top of the foot or even the lower region of the leg mainly caused by diabetic disease [2]. According to research result shows about 15% of diabetic patients develop foot ulcers in their lifetime enhancement [3]. Diabetic foot ulcer is becoming major concern of diabetic patients. People with a diabetic foot ulcer (DFU) have a 40% greater 10-year death rate than people with diabetes alone. Foot ulcer problems with diabetic patients account for up to 15% of healthcare resources in developed countries and 40% in developing countries and one in every six people with diabetes will develop ulcer [5].

Poverty and unhygienic conditions associated with foot ulceration are major factors contributing to development of the diabetic foot in developing countries like Ethiopia and for diabetic patients living at or below poverty line, the purchase of appropriate footwear (orthopedic footwear) might not be affordable, feasible or of high priority [1]. For diabetic foot ulcer patients and people who are overweight, extra pressure may be the cause of ongoing foot pain/ ulcer but by using /wearing orthopedic footwear appliance can be redistribute evenly and the development of ongoing foot pain/ ulceration development retards [4].

The, knees, and back are just some of the body parts that can be adversely affected by improper posture or gait. Orthotics can amend this by spreading the load uniformly around the feet, and then assure that they hit the ground perpendicularly, that is why it is so important that cushion memory foam shoe insert is a need to redistributes our pressure by absorbing shock. Inappropriate footwear and inappropriate insert can have a large share in contributing factor to the development of foot ulceration [8]. Researches implied, footwear with cushion shoe insert has been implemented to reduce pressure on the foot of diabetic patients [2].

Today Memory foam shoe inserts is available commercially at high cost and its source for foot ulcer purpose is import from developed Countries at high cost. This leads low access, and unable to be use by the low-income patients due to higher cost. Hence, replacement of castor oil surfactant and tap water in the place of silicon surfactant and distilled water had respectively better option. Polymer elastomers and foams are mostly use to fit the material properties of shoe appliances, like insole and in sock. Mainly ethylene vinyl acetate (EVA), polyurethane (PU) and rubber based materials are mostly used in footwear [8], [10]. PU foams and elastomers are demonstrated, as the best effective materials for shock absorption in footwear [6].

Different types of foam are available commercially at high cost. But the available materials are not scientifically characterized and optimized for application as in sock for foot ulcer patients treatment. PU viscoelastic cushion in sock will reduce the foot plantar pressure and give additional cushion support to the foot arches. Therefore, new PU memory foams were developed for application as shoe insert in therapeutic footwear for patients with diabetes. The developed materials were characterized for physical and mechanical properties and PU foam composition was also optimized for application as cushion in sock.

Materials and Methods

In this study the PU Memory Foam in sock was prepared by using standard polyols, HT, and isocyanates-toluene di isocyante (TDI), castor oil and methyl chloride were obtained from AMAGA, PLC. Bahir Dar bed foam manufacturing and Ethiopian Institute of Textile and Fashion Technology, Bahir Dar University, Bahir Dar Ethiopia. Other additive and auxiliary such as tin, thertialy cross linker; catalyst, inorganic filler and cell opener which are physicochemical and environmentally safe were used. The following chemicals specification present in Table1 were also derived from AMAGA, P.L.C. Bahir Dar bed foam manufacturing used for PU memory foam formation at different concentration of castor oil.

Table 1: Quantity of Raw Materials for Three Pair of In Sock / Shoe Inserts Sample Production

Component		Sample -1	Sample-2	Sample -3
No.	ingredients used	Weight (g)	Weight (g)	Weight (g)
1	Polyols HT,762	93.3	93.3	93.3
2	Tap water	2*2.6	2*2.6	2*2.6
3	Castor oïl surfactant	5	9.5	10.36
4	Tertiary Amine Catalyst	1.7	1.7	1.7
5	Tin Catalyst	1.37	1.37	1.37
6	Cross linkers	8.4	8.4	8.4
7	Isocynates, TDI	75.5	75.5	75.5
8	Auxiliary blowing agents	4.7	4.7	4.7
Total consumption	----------	199.67g	199.67g	200.5g

Experimental Procedure for Foam Manufacturing

In this research work the PU memory foam in sock samples were developed using the following procedural steps.

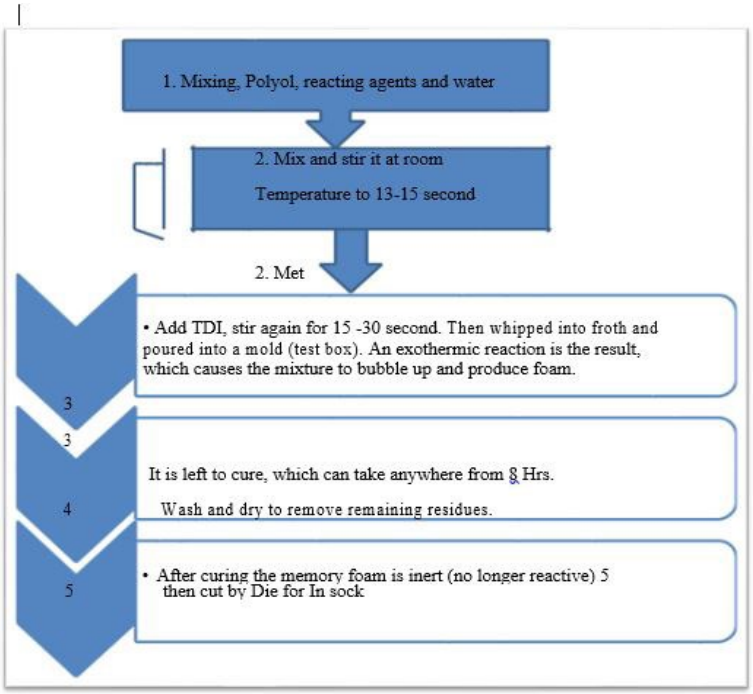

Figure 1: PU Memory Foam in Sock Sample-Manufacturing Steps

According to Figure: 1 Polyol, reacting agents and tap water were mixed, and stirrer at 30oC temperature for 14 seconds. Isocyanates-toluene Di Isocyante (TDI) was added and again stirrer for 15 seconds to make sure the reactant was well reacted. After all, the product was whipped into froth and poured into a mold (test box). An exothermic reaction was resulted which caused the mixture to bubble up and produce foam. The final product foam was no longer reactive (cured) and stored for 8 hours and then the foam was cut by die for next application.

Physiochemical Characterization

Type of foams with varying density and cushion ability were developed by varying the concentration of surfactant (castor oil). The developed foams were characterized for thickness (mm), density (g/cc) hardness (mg/L), water absorption (%) compression set (%) abrasion resistance and pressure redistributing properties of the in sock were.

Plantar Pressure Distribution Test

The plantar pressure reduction and distribution properties of the developed insert/in sock, foam was measured using carbon copy pressure measurement system, and then related with that of ethyl vinyl acetate (EVA) in sock/ shoe insert which was conducted at Leather Industry development institute (LIDI) and Ethiopian institute of textile and Fashion Technology (EiTEX) research laboratory with ELETTROTECNIC A.B.C machine at 7 bar pressure and were analyzed the materials effect on the foam.

Result and Discussion

The physiomechanical properties of the PU memory foam are discussed based on the data presented in Table 1& 2. It has shown that the initial formulation of PU memory foam in (sample 1) is not foam but as a thick liquid this is due to very low amount (5g) of castor oil as a surfactant is used due to this no further study is done on it and (sample 2) is not suitable for application as cushion in sock / shoe insert for Diabetic foot ulcer due to low hardness, density and low compassion but sample three shows a very good properties.

Density: By taking similar thickness of PU memory foam in sock and size. The density test resulted of samples are presented in Table 1. The test result value for sample 2 was 0.194 g/cm3and 0.22g/cm3 for sample 3.

If the density is below standard requirements the shoe insert will compressed and sticky during use and if it is too high, it consume more material and become costly and less comfort. Material with higher density the higher the load bearing capacity, this implies that the sample 3 has remarkable load bearing capacity and support. Therefore, the replacement of materials silicon surfactant by castor oil surfactant and distilled water by tap water shows a positive effect in this particular property

Table2: Physical Test Results of PU Memory Foams]

No.	Properties	Obtained value			
		Sample 2	Sample 3	Commercial insert	SATRA standard
1	Density (g/cc)	0.194	0.22	0.253	0.2-0.3
2	Hardness (mg/L)	19.25	21.09	5-7	17-22
3	Thickness (mm)	11	11.5	8	13-14
4	Abrasion resistance (%)	2.98	2.62	6.9	-
5	Compression (%)	3.82	4.2	6.1	5
6	Water absorption (%)	63	52.5	39	30

Hardness: The mean value of hardness was shown is 19.25 % of the new developed PU memory foam in sock of sample 2 and 21.09 for sample 3 is obtained within the standard range in SATRA test method, and greater than that of existing PU foam in sock. The failing of the test result below standard requirement leads the product strength somewhat poor. On the other side, if this property is above standard it will be less flexible. The only difference between in sample 2 and 3 is due to using of different amount of surfactant (castor oil). Therefore, this research finding fulfills standard requirement.

Thickness: The recipe of the chemicals/materials including the new surfactant material, castor oil and tap water is formulated based on SATRA standards and Amaga foam factory in Ethiopia materials to produce 11mm foam in sock thickness and then manufactured it. Mean thickness of sample 2 and 3 are uniform. Therefore, research result shows it is possible to manufacture these products with uniform thickness.

Compression Set: Elastic properties of the in sock were conducted for both sample 2 and 3 each in average is 3.82%, which is within standard requirement. In case of sample 2 is 4.2% which is also between the standard but its value is greater than that of sample 1.Its commercial insert value is 6.1, which is not fit with standard requirements, this shows that just commercial in sock is not good for diabetic foot ulcer patients foot ulcer treatment due to lower elastic property than that of standards. This leads the product to have lower comfort particularly in this property because orthopedic shoe appliance need to be more flexible and comfort for foot ulcer patients and with good compression set has good comfort.

Abrasion Test: The purpose of testing of this property is to know its resistance to abrasion because during wearing the in sock will rub between our feet and the shoe sole/insole, so it needs to have

very good abrasion resistance. To know this property, the experimental test in abrasion resistance of normal PU foam and that of the newly developed foam in sock were conducted. From these as result shown the PU memory foam in sock abrasion resistance resulted is very good that commercial foam because it has less amount of weight loses due to abrasion than that of normal PU foam. This implies that the newly developed memory foam in sock abrasion property.

Pressure Redistribution Test of the Shoe Insert

The pressure reduction and distribution properties of the developed shoe insert was measured at leather industry development institute (LIDI) Addis Ababa, Ethiopia. The ethyl vinyl acetate, (EVA) and the newly developed memory foam shoe insert carbon test results is presented in Figure 2.

Figure 2: Comparison of (A) Carbon Copy Test Result of Eva and (B) Memory Foam Shoe Insert

The contact area (points) of carbon on in sock were almost the same but, the figure of test results of memory foam shoe insert slightly greater than that of EVA shoe insert, this implies that, our foot contact to shoe insert during wear is also higher. Therefore, if the contact area is higher it reduces our body pressure and redistributes it to the ground in addition the insert can retard the pain of the ulcer by increasing contact areas of our feet.

Conclusion

Foot ulcer is an open sore on the bottom of our feet mainly caused by diabetic disease. Therapeutic shoe with appliance (in socks) like PU memory foam in sock plays a great role in retarding foot ulcer. In this study the insert is developed with 5g, 9.5 g and 10.36g of castor oil surfactant. The in sock with 10.36g of castor amount has shown better physical and comfort properties and that of which with 5g castor oil quantity were unable to be foam but it remains as a thick liquid. Generally the in sock is produced, at low cost by including less cost and locally available surfactant materials (castor oil) instead of costly silicon surfactant and tap water instead of distilled water. In the field test at Adina's hospital, Bahir Dar Ethiopia implies a very good comfort, and pressure reduction ability.

Over all, from the result of the research the insert has good futurity for foot ulcer patients and can solve limited access problem by affordable price.

Abbreviation

EVA: ethyl vinyl acetate; PU: Polyurethane; P.L.C: private limited company; SATRA: South African Telecommunications Regulatory Authority; LIDI: leather Industry development Institute; TDI: toluene Di –Isocyante; MM: millimeter/CC: gram per centimeter cubic ;G/CM3: gram per centimeter; G/L: gram per liter; HT; specific code polyurethane

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Author's Contribution

Awoke Fenta Wodag: Conceptualization the idea, Methodology, Data analysis, writing the first draft preparation, Visualization, Investigation, Final reviewing, and editing.
Adane Adugna Ayalew: Reviewing the manuscript formats, paper fonts and structure

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Availability of Data and Materials

All the datasets are available from corresponding author if required.

Ethics Approval and Consent to Participate.

All the participants, from Adinas Hospital patients in Bahir Dar, Ethiopia, are asked and had showed their voluntariness' (consent) prior to their participation and then the products are checked on them.

Consent for Publication

Not applicable.

Conflict of Interest

It is declared that they have not conflict of interest.

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