ISSN 214-453-2

A PROPOSED DESIGN FRAMEWORK FOR THE PROVISION OF APPROPRIATE FOOTWEAR FOR PEOPLE SUFFERING WITH DIABETICS

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ABSTRACT

A frequently referenced component in the prevention of diabetic foot problems is the use of therapeutic footwear. Thus, footwear should be designed to relieve pressure areas, reduce shock and shear forces and be able to accommodate foot deformities by supporting and stabilizing them. There is however lack of adequate knowledge about the role of footwear and multidisciplinary approach in the management of foot related problems among diabetic patients and health care providers. This study is the first of its kind to be done in Nigeria with an aim to develop a design framework that would help to identify appropriate footwear designs for people suffering with diabetes. The proposed design framework was developed based on information gathered through questionnaires and interview surveys of diabetic patients and medical doctors in Nigeria respectively. The design framework shows three step-by-step procedures for provision of appropriate footwear to people suffering with diabetes. Product Design Specification was also formulated to determine key elements that could be considered in the design and selection of appropriate materials for diabetic footwear manufacture. Three functional prototypes (footwear) were made and used to test various usability aspects of the product with the prospective users. It was concluded that the high rate of amputation reported amongst diabetic patients could be drastically reduced through effective use of the proposed design frame work. Finally, limitations of this work and areas that would require further research were also outlined.

Keywords: *Design Framework, Footwear, Diabetics, Foot Problems, and Nigeria.*

1.0 Introduction

The rising prevalence of diabetes worldwide will lead to an increasing prevalence of complications (Forlee 2010; Sheridan 2012) such as those of the lower extremities. The spectrum of foot problems actually varies in different regions of the world due to differences in socio-economic conditions, standards of foot care and quality of footwear. In Africa, diabetes is one of the leading health problems which has reached epidemic proportion in the continent over a decade ago. The incidence and prevalence rates of the disease in the continent are increasing and foot complications are rising parallel (Abbas and Archibald 2007). The International Diabetes Federation report (IDF 2013) has shown that Nigeria has the highest number (3 million), followed by South Africa (1.9 million), Ethiopia (1.4 million), and Kenya (769,000) .

According to Abbas and Archibald (2007), the reasons for poor outcomes of foot complications in Africa and in various less-developed countries include; lack of awareness of foot care issues among patients and health care providers alike, and lack of the concept of multidisciplinary approach. However, teams providing foot care and footwear are becoming much more multidisciplinary in nature.

The team approach is probably more beneficial to the successful treatment of the diabetic foot than almost any other problem physicians may encounter (Janisse and Janisse 2006). A multidisciplinary foot-care team is expected to advise on footwear provision and get the opinions of patients' satisfaction with footwear provision. A fully functioning multidisciplinary team can bring a wide range of expertise that could have a dramatic impact on the patient foot-care and well–being. Leese (2009) pointed out that two thirds (2/3) of diabetic patients wear poor-fitting footwear. However, he argued that footwear specially designed for diabetic patients could reduce re-ulceration rates by half .The patient should be motivated by the team to wear the recommended footwear, for it would be useless to provide bespoke footwear if the patient will never wear it or will not use it frequently (Tyrrell and arter 2009, Janisse and Janisse 2006).

The role perform by multidisciplinary teams in the treatment of diabetic foot problems has been shown (Tyrrell and Carter, 2009) to improve results and increase patient satisfaction with footwear. It is expected that each professional member of the team should bring his or her expertise for the overall well-being of the patient. To achieve this, all the professional members of the team should communicate well with one another in order to be able to develop an overall strategy. Nather, et al (2010) pointed out that multidisciplinary diabetic foot team would typically comprise of an orthopaedic surgeon, a vascular surgeon, infectious diseases specialist, endocrinologist, podiatrist, and a nurse. And some multidisciplinary teams have included shoemakers and orthotists to make special footwear and orthoses for patients to prevent foot ulcers and injuries.

Nather and Singh (2008) had since identified rejection of certain footwear due to cultural, cost and aesthetic

reasons as the major reason for lack of progress in the management of diabetic foot problems. Therefore, this present work was undertaken to investigate acceptable footwear for people suffering with diabetes and to design a framework that would help heath care providers and footwear designers/manufacturers to provide appropriate footwear for people suffering with diabetes.

2.0 Materials and Method

The design framework presented in this paper was developed based on information gathered through questionnaires and interview surveys of diabetic patients and medical doctors in Nigeria respectively. Overall, 180 questionnaires were given out to people living with diabetes and 164 were collected back, but 8 were rejected or excluded from the analysis because they were not properly filled. Therefore, 156 (75 male and 81 female) filled questionnaires were analysed (Table 1). In addition, 45 health care providers (clinicians) involved in the management of the diabetic foot and its complications were invited to participate in the study using structured interview questionnaire. During the research, a pilot survey was initially planned and conducted. Six doctors from three government hospitals were interviewed to validate the questionnaire. The pilot survey provided the researcher with valuable information that was used to plan and conduct the main survey successfully.

In addition to the above mentioned materials and tools, a pair of last was used to make the trial prototypes. The appropriate last as selected from a pool of different lasts at the footwear department of Nigerian Institute of Leather and Science Technology (NILEST), Zaria, Nigeria after consultations with the research supervisors and footwear designers/ technologists at the above mentioned Institute.

Twelve styles of footwear designs were initially developed based on certain features and information gathered from questionnaire and interview surveys among diabetic patients and medical doctors respectively. Recommendations given by previous authors on required features for diabetic footwear were also taken into account during the design of the footwear. The designs were presented to diabetic patients (n=43) to indicate their preferred footwear style using a questionnaire. Furthermore, the views of the respondents about the 12 styles were analysed and the top 3 most preferred footwear styles were developed into trial prototypes. Real prototypes which could be described as functional prototypes were made for this study and traditional methods of making footwear (sandals) were used to make the prototypes. To effectively evaluate the prototypes, a questionnaire was designed and used in conjunction with the prototypes.

The study was approved by the research ethics committee at the Ministry of Health, Kaduna State, Ahmadu Bello University Teaching Hospital, Zaria, Nigeria and De Montfort University, Leicester, UK. Participants at the beginning of the study were given information on the nature of the survey, the participants' right to withdraw from the study at any time and confidentiality of personal data provided. In order to maintain confidentiality, questionnaires were made anonymous.

3.0 Results and Discussion

3.1 Results

The findings from this research are outlined below.

Table 1 The outcome of the interview and questionnaire surveys in respect to type of footwear most often used by diabetic patients**.**

S/No.	Type of footwear used often by male (M) and female (F) subjects.		Findings from medical doctors (%)	Findings from diabetic patients (%)
1	Shoes	M	15	17
		F	11	13
2	Half-shoes	M	17	14
		F	18	15
3	Sandals	M	35	29
		F	24	19
4	Boots	M	05	01
		F	00	00
5	Slippers	M	26	37
		F	45	53
6	Sports shoes/	M	01	02
	Sneakers	F	01	00
7	Custom moulded	M	01	00
		F	01	00

Table 2. Product Design Specification (For clarity of the design and construction of the trial prototypes, a product design specification was developed as presented below).

S/No.	Parameters	Specifications
1	Product	Diabetic Footwear (Sandals).
2	Product user	The target users of the product are people living with diabetics in Nigeria and neighboring Africa countries.
3	Gender	Male and female
4	Age Group	Diabetic patients of age group 36- 65 years.
5	Materials selection or short listed materials	Upper Components**:** Good water permeability materials (mainly heavy leather for the upper and light leather or fabric for the lining). Insole: Multi-density Ethylene vinyl acetate (EVA) and, or Polyurethane (PU). Sole and Heel: Ethylene vinyl acetate (EVA) and, or Polyurethane (PU).
6	Construction	• Select an appropriate last, or make the required last (particularly if there is foot deformation) based on recorded measurements of the customer's feet. • Create the footwear style and the pattern pieces • Close the upper sections • Attach the insole component to the last • Pull down the prepared upper onto the last • Skive excess leather, add bottom filler and attach sole/ heel unit • Remove last and carry out quality checks on the finished product.
7	Special features	• No or low heel height • Functional fastening to minimize compaction of fore foot • Flexible soling with adequate cushioning properties • Firm sole, but not rigid • Very soft, minimal or seam-free full leather linings • Firm upper material • Highly comfortable footwear with high level breathability or good ventilation, long lasting cushioning and light weight footwear.
8	Comfort and Ergonomics	• To make the footwear comfortable for the wearer and to prevent the diabetic footwear from sliding around on the feet, the upper should be designed in such a way that it can be easily adjusted to fit. • The product should be designed ergonomically taken into consideration the fact that some diabetic patients can have problem with their sight and a significant number of them might have neuropathy or numbness. Therefore, the design should be simple in order to make it very easy for the customers to use.
9	Environment	The prospective product users would be people living with diabetics in Nigeria and probably, in other Africa countries. The weather in Nigeria is generally hot year-round. It is hot and dry most part of the year in the North and hot and humid in the South. The average temperatures are: 27-34^{o}c during the day and 23-27^{o}c at night.

Table 3 Outcome of fit and comfort assessment of the trial prototypes.

S/No.	Enquiry	Yes (%)	No (%)
1	Sandals go onto your feet easily.	86	14
2	The width of the footwear is alright.	84	16
3	The length is alright.	84	16
4	Comfortable with the top line.	86	14
5	The fastening aligned properly.	84	16
6	The depth of the Instep is alright.	92	08
7	No experience of new pain in any part of the feet.	95	05
8	The footwear is not too tight.	81	19
9	No experience of discomfort in any part of your feet.	81	19
10	Adjustment is not required in order to accommodate feet well.	76	24

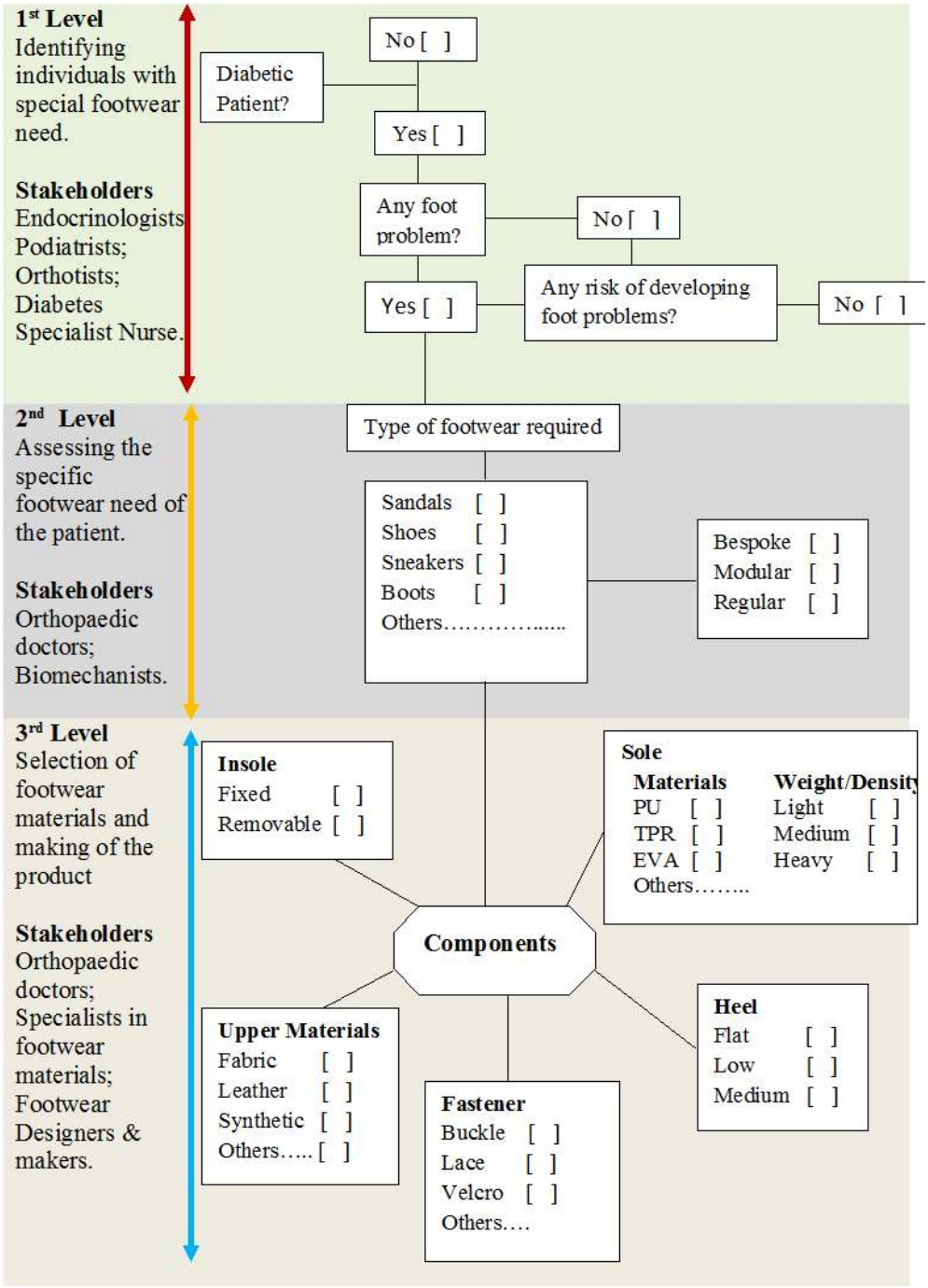

Fig. 1. Diabetic footwear design framework

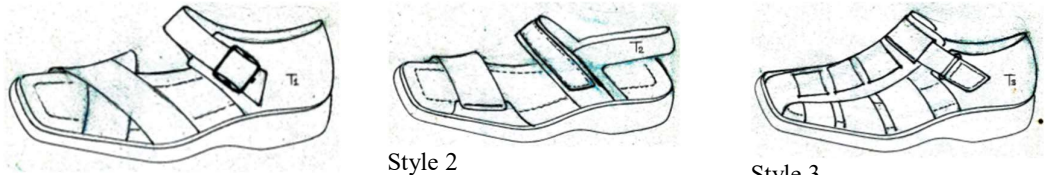

Fig. 2. Top 3 footwear styles developed into trial prototypes.

3.2 Discussion

I. Proposed Design Framework for Provision of Diabetic Footwear

The framework presented in figure 1 provides a concept which consists of identification of persons suffering with diabetes by clinicians, categorising them according to their foot care needs and recommendations about the specific type of footwear and footwear materials for each case. It is believed that clinicians and product developers can confidently use these tools to develop appropriate footwear for individual patients.

The framework shows three step-by-step procedures for provision of appropriate footwear to people suffering with diabetes. The first step involves identifying individuals with diabetes and categorising them into patients with foot problems or at high risk of developing foot problems. The second level of the framework deals with assessing the specific footwear needs of the patient, and selection of suitable footwear materials/ components to make the appropriate footwear is done at the third level.

Regarding the implementation of the design framework, wide spectrums of professionals are considered to be key stakeholders. Nevertheless, the main stakeholders at the first level include endocrinologists, podiatrists and diabetic specialist nurse. These have the responsibility of identifying diabetic patients with at risk foot or with foot problems like ulcer. Immediately someone with foot problems or at risk of developing foot problems is identified, it is recommended that other stakeholders, mainly orthopaedic surgeons, orthotists, and biomechanists should be involved at the second level of the framework. These professionals are expected to identify the nature of the patient's foot problem and the most appropriate type of footwear that could be recommended for the patient. For a very successful management of diabetic foot problems, it is advocated that a specialist in footwear materials, product developers, footwear designers and manufacturers should be given the opportunity to make their professional inputs at the 3rd level. To make the framework a complete cycle where there is proper flow of information from one level to another, the product designed and made for the patient at the 3rd level should be sent to the specialists at the 1st level to check for proper fitting. If there is need for amendments, the professionals at the 2nd and 3rd levels should be involved accordingly. It was noted that referral of cases from one professional to another or the involvement of the appropriate stakeholders at the early stage in the management of diabetic patients would go a long way to reduce foot ulcerations and amputations.

After assessing the foot care need of the patients by clinicians, it is recommended that patients with foot problems and those at high risk of developing foot problems should be referred to a foot care team (comprising different professionals including medical experts, designers, etc) who will investigate further about the foot care needs of each patient and give recommendations about the specific type of footwear and footwear materials for each case. From the survey, certain patients may require a special shoe last to be constructed to make the shoes in order to accommodate their deformed feet or to off-load areas of high pressure. The largest population of the patients would require footwear to be made on selected last but constructed with appropriate materials that will provide adequate protection and comfort for the patient's feet.

Note that the PDS (Table 2) is particularly linked to this design framework at the 3rd level. During the selection stage of footwear materials/ components, the product developer or manufacturer should refer to the PDS for the specific guidelines on appropriate footwear materials and ergonomic factors that must be taken into consideration during the design and manufacture of diabetic footwear. The PDS was found to be very useful in the selection of materials and designs for the prototypes.

In an attempt to meet the design requirements of diabetic footwear, the authors discovered that functional requirements or need of the diabetic foot should come first, and then structure requirements, and finally requirements of aesthetic appearance (Covington 2009; Harvey 1992).

II. Trial Prototypes

This research resulted in making functional prototypes that were used to test various usability aspects of the product with the prospective users. The trial prototypes were developed after a careful study of the problems from previous works, from the viewpoint of medical doctors and from the perspectives of diabetic patients. It was observed that most of the studies on diabetic and orthopaedic footwear were mostly based on clinical need and perspective, without an in-depth understanding of patients' expectations and perceptions of footwear. The literature has shown that two thirds (2/3) of diabetic patients wear poor-fitting footwear, but that shoes designed for people suffering with diabetes could reduce re-ulceration rates by half (Leese 2009).

Although Tyrrell and Carter (2009); Nathan and Singh (2008) pointed out that shoes, sneakers and bespoke footwear are the recommended types of footwear for at risk foot. However, financial constraints or limited economic resources forced most people suffering with diabetes in Nigeria to use cheap footwear regardless whether they provide the desired protection and comfort to them or not. For many patients price rather than quality is the major concern when buying footwear. The majority of the population lives in poverty and faces economic challenges.

In view of the above factors, sandals were considered as the most appropriate type of footwear to be developed as the prototypes. In addition, Sandals became the best choice on the basis that a well-designed sandal, constructed with appropriate materials would provide the desired protection and comfort to the wearer. Whereas a shoe will often put the foot under pressure by squeezing it, one of the advantages of wearing sandals is that they do not put the foot under pressure at all, and allow the foot to function normally (Erasmus and

Jorgensen 2008). More so, the cost of making a pair of sandal usually is not as high as shoes or sneakers. Another good point for choosing this type of footwear is due to the fact that they could provide enough room to comfortably fit swollen feet. Also, the rate of feet perspiration in this part of the world could be very high (Table 2) and the use of sandals are considered very appropriate as they provide good ventilation.

Therefore, after a careful survey on the most preferred and appropriate footwear for diabetic patients in Nigeria, three basic types of footwear (sandals) were produced and used to assess the acceptability of the products from prospective users. The idea behind the three designs (Fig.3) was to provide footwear that would give good instep support to the foot whereby preventing the foot from sliding forward to exert pressure on the metatarsal head of the foot. Other features critically considered in the design of the prototypes were comfort, ventilation and lightness of the footwear. This is in line with the general guidelines for provision of healthy footwear for diabetic foot (Davia et al. 2013; Steed, et al. 2008; Bus, et al. 2008; Vernon, et al. 2007).

III. Assessment of the Prototypes

Fit and comfort assessment of the prototypes presented in table 3 shows that up to 86% of those that participated in this research could wear the sandals easily. Over 80% reported that they were alright with the length and the width of the footwear. Similar percentage of the subjects also indicated that they were comfortable with the top line at the in-step. But it should be noted that up to 19% show that they experience some degree of discomfort when wearing the sandals. These were mainly patients that had swollen feet or some form of foot problems. Consequently, 24% reported that some form of adjustment to the footwear would be required in order to accommodate their feet well.

In addition to testing of the prototypes with patients, the footwear were presented to medical doctors (mainly orthopaedic doctors and endocrinologists) at the Ahmadu Bello University Teaching Hospital, Zaria for critism and expert feedback. The doctors gave convincing statements that the prototypes will meet the needs of their patients, particularly those at risk of developing ulcers and other foot problems. Overall, a very positive feedback was received from the medical doctors about the designs, styles and materials used for the construction of the footwear.

Furthermore, footwear technologists' and designers' at Nigerian Institute of Leather and Science Technology, Zaria and industry base footwear technologists' views about the designs and construction were sought. The footwear experts expressed optimism that the products would meet the required parameters in terms of technical, aesthetic, comfort and fitting specifications.

IV. The need for a multidisciplinary approach.

It is clear that the management of diabetic foot complications needs a multidisciplinary approach because diabetic foot problems are multifaceted. The role played by such teams in regards to foot care has proven to decrease amputation rates among diabetics and increase their satisfaction with footwear. Therefore, practitioners treating people with diabetes advocate that each team member must understand the principles and practice of comprehensive foot care, including the prescription of appropriate footwear (Mclnnes 2011; Tyrrell and Carter 2009; Noble-Bell and Forbes 2008). In this study, doctors involved in the treatment of diabetic foot complications also expressed the need for active involvement of all professional members in the early stage of the treatment in order to improve results. A point to note on this issue is the unfortunate situation that the multidisciplinary approach to addressing diabetic foot problems is yet to be understood and practiced in Nigeria. To make the point clear, a comment made by a medical doctor (Usman, 2013) during the interview survey is given thus:

> *Diabetic foot ulcers/ sepsis is the common cause of non-traumatic cause of amputation of human limbs worldwide and Nigeria has a great burden of diabetic mellitus. There is paucity of multidisciplinary approach to diabetics with orthopaedics being the least consulted until very late in the management. Thus there is need for early referral to orthopaedics and the need for orthopaedic surgeon to rise to the challenge to prevent this depressive event and not just to amputate a limb.*

In summary, the multidisciplinary foot care team is seen as the most effective way to provide patient education and to manage foot problems (Ellis, et al. 2010; Nather et al. 2010). However, health care providers involved in the treatment of diabetic patients would need further and continued education of the role footwear plays in the management of diabetic foot problems and/or prescription of diabetic footwear.

4.0 Limitations of this work

Even though it could be argued that this research was carried out at different hospitals in Northern Nigeria that admit patients from different regions of the country and employ the services of professionals trained at universities across the country and from overseas, still, generalizations of the findings of this study should be made with caution. In addition, even though all the respondents and interviewees were diabetic patients and qualified practitioners (medical doctors) respectively, there is a lack of perspective of other health professionals like orthotist, podiatrist, nurses etc. For a complete view of the role of diabetic footwear in the prevention of diabetic foot complications, their opinions should be included.

Another weakness of this study is the sample size for both the interview and questionnaire surveys. To improve the reliability of the results, involvement of more subjects is recommended.

5.0 Conclusion

This paper has shown that there is urgent need for collaboration across a number of disciplines including designers, engineers, clinicians, biomechanics, footwear technologists, etc to be fully involved to make footwear that could benefit a wide range of diabetic patients.

The information provided in this paper demonstrates that development of appropriate footwear for people suffering with diabetes requires so many considerations including footwear style or design, fitting/ comfort factors, cultural and environmental issues. This study indicates that sandals are well accepted by potential users in Nigeria, especially in the Northern Region.

We conclude that with increased awareness of the role of footwear in the prevention and management of diabetic foot problems along with expertise in the design of appropriate footwear using the proposed design framework, it is believed that the high rate of amputation reported amongst diabetic patients would be drastically reduced.

Whereas probably the most important area to research in the developed world would be usability of diabetic footwear; in the developing world, the problem is first and foremost the matter of awareness and education about diabetic foot complications and the role of footwear in the management of foot problems or for the maintenance of good foot health.

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