Cost-effective Design Development of Medicated Footwear for Diabetic Patients

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Abstract—Diabetes is one of most common metabolic disease in world-wide. This common metabolic diseases has the risk of amputations including complexity of human body. The medicated footwear provides some attributes such as to reduce the foot ulceration and amputation risk and improves the blood circulation to the legs and feet. This paper is about the development of quality and cost effectiveness of medicated footwear for diabetic patients, which is dramatically decreasing the risk of foot troubles. It also covers the future work that can be done regarding the medicated-footwear development techniques for another amputation patient.

Keywords— Diabetes, ulcerations, consciousness, medicated footwear, quality enhancement, cost effectiveness.

I. INTRODUCTION

Diabetes is growing rapidly world-wide. The World Health Organization (WHO) estimates that in 2030 more than 334 millions of persons will suffer from diabetes [1]. Many complications is occurred due to the diabetic. Among one of the most relevant complication called “diabetic foot”. It often leads to amputation. Peripheral neuropathy, a loss of feeling in the extremities, renders these individuals unaware of sores that develop on their feet until the wound becomes infected. Then, because of other diabetes-related complications, the infection often defies healing and eventually leads to amputation. The main cause of foot ulceration in the adult neuropathy diabetic is thought to be the presence of abnormally high plantar pressures secondary to neuropathy. It is evident that reduction of amputations can be achieved if it is possible to effectively prevent the foot ulceration. Early diagnosis through a continuous foot monitoring can be applied.

As a person suffering from diabetes definitely need to consider using diabetic footwear, instead of conventional footwear. These types of footwear offer good feet support and they are more comfortable to wear than conventional footwear. These footwear are good to keep our foot healthy and maintain a good lifestyle. It is reported to studied of 60 patients, 30 were male, 30 female. Mean age was 62 years; mean duration of the disease was 17 years. Patients’ performance was: 77% adequate moisturizing, 88% proper washing and drying, 83% proper toe-nail cutting, 83% no cuticle trimming, 77% routine shoe inspection, 70% no use of pumice stones or similar abrasive objects, 95% no barefoot walking, but only 5 patients (8.7%) regularly wore the provided footwear. Providing all diabetic patient at risk or high risk for foot ulcer and amputations with adequate prevention would be a cost effective or even cost saving strategy [2].

Furthermore, A better understanding of the link between innovation and cost-effectiveness analysis is particularly important given the large role of technological change in the growth of health care spending. The cost effectiveness was analyzed in the standard export oriented footwear industry context [3]. For this reason, all concerned bodies and industrialists should come forward and take essential steps to set up the diabetic shoe manufacturing plant separately with reasonable cost for diabetic patients so that these shoes can play a vital role to reduce foot ulceration and other risks of diabetic patients. Moreover, diabetic patients also concerned about the difference between medicated and conventional footwear. By using the medicated footwear, it is enabled to high compliance of ulcer prevention and reduces the amputation risk.

But the best approach is to wear suitable personalized shoes that avoid the causes of ulceration. Despite needs, there is not a full user-centered footwear development due to the difficulty to simultaneously take into consideration multiple design aspects such as foot shape and biomechanics, materials performance for upper, insole and outsole, manufacturing methods. Diabetic shoe is specially designed shoes that feature extra and double depth, come equipped with a removable footbed and removable insole spacers and are finished with a smooth interior lining to reduce the risk of skin abrasions or blister. Moreover, market competition and fast technology change made performance a prerequisite for survival any organization. To cope with this, organizations look for maximising gains [4]. For this fact, cost of a product is most important to both manufacture & buyer. It is needed to keep a level of standard.

This paper is to bring the object into the adopted footwear design approach and development and for consciousness about diabetic foot troubles. Also it can enhance the quality & effectiveness of cost of footwear that can be mostly demanded for the diabetic holder.
II. METHODOLOGY

A. Material requirement

The materials that is required for the development of Medicated footwear:
Article Title: Medicated footwear.
Style: Slip on.
Last: Wooden.
Size: 41.
Upper Leather: Lamy black, Milled Softy type (thickness: 1.5mm).
Lining Leather: Goat leather (Brown), thickness: 1.0 mm.
Padding: Nylon Mesh Foam, thickness: 5mm.
Inter Lining: Knitted Fabrics.
Sole: Expanded EVA.
Insole: Cellulose Board.
In sock: Multi-Layer, EVA, Foam, Moulded EVA, Leather.
Toe Puff: TPR
Stiffener: TPR.
Adhesive: Latex, Water based PU/Rubber solution.

B. Working flow diagram

![Flow Diagram of Developed Medicated Footwear](image)

III. DESIGN INNOVATION OF MEDICATED FOOTWEAR

The proposed design approach is based on an integrated product design framework for enabling the management of the whole life cycle of shoes for diabetic people. The approach is based on a set of integrated solidworks software systems. A diabetic patient needs at first specific analysis, in order to evaluate important bio-mechanical parameters (first MPJ motion & torque, plantar pressure, ankle Dorsiflexion, dorsal geometry, foot pronation, etc). This software is used to design the best shoe required to fit the specific needs. In order to measure above parameters, commercial solutions could be sufficiently integrated. Therefore, new measurements devices and the integration of already existing ones in portable systems are going to be investigated. These integrated systems mainly concern foot geometry and pressure acquisition during a complete gait cycle. In the case of insole design of medicated & conventional footwear, pressure & load distribution must be maintained. For this reason the following insole design geometry are shown below.

![Pressure Load distribution on insole into the same plane (In the case of conventional Footwear).](image)

![Pressure Load distribution on insole into the different regions. (In the case of medicated Footwear)](image)

In standing, the foot acts as a base for the body. Therefore, the larger the area in ground contact the more stable the person.

From the above Fig.2 illustrates narrow width of shoe and heel being worn, increased pressure on medial border of sole of foot, and instability as weight is unevenly spread. Fig.3 Medicated footwear insole increases the contact area which stimulates the total load divided around the forepart of...
the shoe [5]. The geometric views of diabetic shoes are shown below:

The three most important biomechanical mechanisms by which medicated footwear act can be summarized as follows: (i) uppers that protect and relieve stress on the dorsum, yet limit shear motion, (ii) a footbed that distributes load and relieves load on high-risk areas, and (iii) outsoles that restrict joint motion and alter load distribution [6]. The single most successful footwear modification yet identified is the rigid rockered or rollered outsole. A number of studies [7-8] have shown that reductions in plantar pressure of up to 50% are possible compared to similar shoes with non rigid soles. Surprisingly, clinical trials to confirm that this efficacy in plantar pressure reduction is reflected in ulcer prevention have not been attempted. Although the placement and design of the rocker certainly influence the amount of relief [9], almost any placement seems to provide some reduction in plantar pressure. Very little patient education is typically given, but wearers of rocker shoes should be encouraged to take short steps to ensure that they are in the toe-off phase of gait before the forward rocker surface contacts the ground and helps to prevent the foot ulceration. By using the medicated footwear, it is enabled to high compliance of ulcer prevention and reduces the amputation risk.

IV. COST EFFECTIVENESS ANALYSIS

When any new technologies are brought to life from costly R&D, consumer surplus may be a poor guide to inducing optimal R&D investments. Currently, CE analysis plays a vital role to satisfy the consumer demand with required attributes paying reasonable price. CE analysis also imply what sorts of accessories would be adopted for gaining feature. In this paper, CE analysis is interpreted on material which were used in this article and also try to control pricing. Here, the cost was calculated for one pair of medicated footwear in respect of export oriented industry context. Such as:

Table 1: Cost analysis of medicated footwear

<table>
<thead>
<tr>
<th>ARTICLE</th>
<th>COLOUR</th>
<th>YEAR/QUARTE R</th>
<th>MRP</th>
<th>COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic Shoe</td>
<td>Black</td>
<td>1500</td>
<td>100.0%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>White</td>
<td>1500</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PART NAME</th>
<th>MATERIALS SPECIFICATION</th>
<th>UNIT</th>
<th>PRICE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPPER</td>
<td>Leather Upper</td>
<td>Ekw</td>
<td>2.40</td>
<td>80.75</td>
</tr>
<tr>
<td></td>
<td>Flexible Leather</td>
<td>Ekw</td>
<td>2.40</td>
<td>80.75</td>
</tr>
<tr>
<td></td>
<td>Rocker Sole</td>
<td>Ekw</td>
<td>2.40</td>
<td>80.75</td>
</tr>
<tr>
<td></td>
<td>Toe Puff</td>
<td>Ekw</td>
<td>2.40</td>
<td>80.75</td>
</tr>
<tr>
<td></td>
<td>ADHESIVE</td>
<td>Neoprene Latex</td>
<td>Ekw</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>STAMPING FOIL, 20mm</td>
<td>STAMPING FOIL, 20mm</td>
<td>Ekw</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>SILVER PEN</td>
<td>SILVER PEN</td>
<td>Ekw</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>C. B. CASE</td>
<td>C. B. CASE</td>
<td>Ekw</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>GUM TAPE</td>
<td>GUM TAPE</td>
<td>Ekw</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>FEATURE TAG WITH PLASTIC PIN</td>
<td>FEATURE TAG WITH PLASTIC PIN</td>
<td>Ekw</td>
<td>0.30</td>
</tr>
</tbody>
</table>

From the above table, the final cost of medicated footwear was reasonable which satisfy the target group and also attainable purchasing capability. Accessories and other materials were collected from our local suppliers. Design technique and fabrication procedure followed from export oriented industry. For that reason, the prime cost of product development was not so high. Most of the factory of medicated footwear producer of our country was not adopt appropriate technique and fabrication process which are helpful for gaining medicated attributes. In practice, the supplied raw materials were available in our country in respect of geographic and religious perspective. In addition, labor cost is the major distinguishing matter in respect of other country. The current product seems appropriate for stimulating the effects of prevention on long term cost associated with foot ulcer and amputation. This study approach can be used for future cost-effectiveness or cost utility analysis of diabetic
foot ulcer prevention when new technology will be available. Under the study, these design development would be cost-effective or cost-saving in all other patient with diabetes. All diabetic patients at risk or high risk for foot ulcer and amputations with the recommended approach would be cost effective. The recommended designed to promote greater usefulness in case of cost and achieving attributes.

V. RESULTS AND DISCUSSION

Now-a-days Diabetic patients are increasing day by day. It is not possible to cure diabetic completely with Medicare. But, from the research of Medical science & scientific aspect of footwear manufacturing, it is seen that the medicated footwear holding some features which strongly reduces to some extent of diabetes and also control foot ulceration and amputation risks and other disorder. For this reason, it is needed to develop the medicated footwear. In previous studies, it is seen that developed medicated footwear are most costly. As a result, a range of diabetic people are far away from the existing services. According to this consideration, the cost of footwear is the significant factor to obtain services. So, the price of medicated footwear to keep at a standard level of purchase. In these studies, it is tried to accumulate the treatment of diabetic patients by using medicated footwear with the proper cost effectiveness. From the above view of diabetic shoe design by solidworks, new medicated footwear development concept is achieved. The fabrication of different components & material selection process help to develop the modified medicated footwear that is beneficial to diabetic patients.

A pretty good advantage is obtained from medicated footwear rather than the normal footwear for the diabetic patients. The following features added to the medicated that will differ from normal footwear and it is much more beneficial for diabetic Patients more than normal Footwear.

The medicated footwear conforms to the contours of the foot, enhancing comfort of the diabetic patients. There are also seamless lining, made of soft fabric, and padded with foam, provide excellent protection of the foot. The only diabetic prefab orthotic with rear foot support that offers an arch filler and long lasting support of the diabetic patients. The cushioning sole, with a true toe Spring design, softens the step, and helps propel foot forward and extra-depth design offers a loose fit and freedom for toe movement & hidden depth design offers the appearance of regular depth shoes.

VI. CONCLUSIONS

Medicated footwear has been used for decades as one of many strategies to prevent reulceration in patients with diabetes and foot risk factors. The findings of several studies reporting statistically significant protective effects from medicated footwear may have been influenced by several design issues.

Literature overview shows that there is a need of dedicated systems to support the development of shoes for people with diabetes and on the contrary, there are not available technologies to effectively overcome all problems implied in footwear customization, flexibility, rapidly and quality. So all industrialists and entrepreneur should come forward and take essential steps to develop the definite technology that will be accelerated the much production of medicated footwear. Also this definite technology will help the diabetic patients to reduce the different foot troubles such as ulceration, amputation risk etc.

A general framework based on a KB system for managing the whole shoes development cycle is defined. It sets the basis for innovating the whole process from design to manufacturing and retailing. The paper is focused on the description of the adopted approach to the preliminary results about the implementation of the solidworks based platform for customized shoes design.

A medicated footwear service can produce significant improvements in mobility and is a valuable adjuvant to be helpful of a programme of care for diabetic people. For the consciousness of the reduction of diabetes, it is needed to develop a innovative medicated footwear & the cost of footwear should be kept with a standard level for customizations.

VII FUTURE DEVELOPMENT OF MEDICATED FOOTWEAR

The development of Medicated footwear is very important for the diabetic patients. In summary, the process of design innovation and development of medicated footwear for people with diabetes is still in a preliminary stage. There is a widespread clinical opinion that footwear can provide primary and secondary prevention of ulceration, but the scientific literature is difficult to interpret because the appropriateness and effectiveness of most footwear used in such studies was not established fully. More research are required for enhancing the development & cost effectiveness of medicated footwear for diabetic patients.

It is hope that the near future will be seen the more widespread use of medicated footwear that has some ‘intelligence’ in that on-board systems will be available to monitor certain features of the foot-ground interface and
either adapt the properties of the shoe to mitigate undesirable conditions [10-12]. The extra quality and more design innovation can be improved in the medicated footwear by using the basement of this work.

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