EFFECTIVENESS OF ACCOMMODATIVE INDIVIDUALIZED FOOT ORTHOSIS IN DECREASING OF PATHOLOGICAL PRESSURES ASSOCIATED WITH DEVELOPMENT OF PLANTAR ULCERATION

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Plantar ulcerations founded in case of feet with sensorial or motor neuropathies are some of major causes of foot amputation. Occurring and development of plantar ulcerations is determined by the loosing of sensitiveness and appearance of some higher, pathological pressure areas. In these situations, the pathological pressure areas are related with foot deformities, restriction of joint mobility as well as appearance and development of callosities. Relationship between development of plantar ulcerations and biomechanical condition of foot as well as technical solutions for decreasing the some areas pressures, are discussed in different articles in the medical area. Bringing the pathologic pressures on that limits which favours the healing process is a very important part of the neuropathic foot treatment. The technical solutions assume the use of foot functional / accommodative orthosis, having the cushion ability of the impact and friction area pressures as well as of special individualized footwear in the cases where the acquired deformities make the use of ordinary footwear impossible. This article presents a way for achieving the individualized accommodative foot orthosis, as well as the results obtained in order to decreasing the pathologic pressure at the ulceration site.

Key words: plantar ulcerations, foot orthosis.

INTRODUCTION

Many articles emphasize the purpose of using the foot orthosis as well as different ways to achieve them, and also the results in the plantar ulcerations treatment[4,5,6,13,14]. According Kevin Kirby, DPM: "A foot orthosis is an in-shoe medical device, which is designed to alter the magnitudes and temporal patterns of the reaction forces acting on the plantar aspect of the foot in order to allow more normal foot and lower extremity function and to decrease pathologic loading forces on the structural components of the foot and lower extremity during weightbearing activities"[12].

There are two types of orthosis: prefabricated orthosis and orthosis obtained on prescription basis. The orthosis obtained on prescription basis are made by capturing of the three-dimensional image foot plantar surface – foot cast – and they are individualized for each patient, for their design being used on the one hand the biomechanical parameters measured both with the nonweightbearing and weightbearing foot conditions, and on the other hand the information resulted from the biomechanical analysis of gait. The accommodative orthosis are prescription basis orthosis designed to change the size and shape of loads which act on the affected structures of weightbearing foot.

The prefabricated foot orthosis are achieved using some average size and shape surfaces, their execution doesn't need the use the three-dimensional foot surface and therefore, they aren't individualzated product[12].

The use of accommodative orthosis leads to a decrease of pressures between 30 and 55% on interested areas according to the specialized literature data[2,4,5,7]. The materials used to manufacturing of these orthosis are cover a wide hardness spectrum, starting from some very low hardness materials, 14 degree "0" Shore[2] to rigid devices made of stiff materials as polypropylene or polyethylene[4] or combinations between these. The most simple way to get the accommodative orthosis are based on bi-dimensional record of the foot plantar surface in orthostatism, the qualitative evaluation of pressure distribution and its correlation with the muscular and bone systems. The improved methods require the use of electronic systems for measuring pressure in their dynamics and correlation with three-dimensional foot surface captured through three-dimensional scanning devices or by taking casting techniques. If there is a consensus concerning the use of measuring system of pressure distribution in dynamics, capturing three-dimensional foot image raises many problems. In this respect, several articles states that individually orthosis have been used but not specify how they were made. Most authors use weightbearing casting method, by taking the cast with foam or three-dimensional foot scanning[4,13]. The main issues raised by these techniques is that the position of the foot while scanning or weightbearing casting couldn't be very well controlled, this fact leading to capture the information caused by the foot compensatory movements and translate them into orthosis construction. A method less used consist of taking mould with the foot in a nonweightbearing position with subtalar joint as close to the neutral position. This method requires a specialized technique of taking and modification of foot cast has the advantage of improved control of the constructive parameter orthosis[4].

CASE STUDY

The orthosis was made for a female patient, aged 60 years, weight 80 kg, having paralysis of the sciatic popliteal external nerve of 35 years old and diabetes revealed a month before. Ulceration is positioned among right proximal V metatarsal head of the right foot, (Figure 1) and is the result of wound infection caused by removal of callosity formed in the area [1].

The results of initial measurements made using the system of measuring pressure in footwear, have confirmed the existence of a range of high pressure reported in adjacent areas, between 150 and 205 kPa, with an average of 175.9 kPa calculated for a total of 26 walking cycles (Table 1).

Fig. 1. Ulceration positioning.

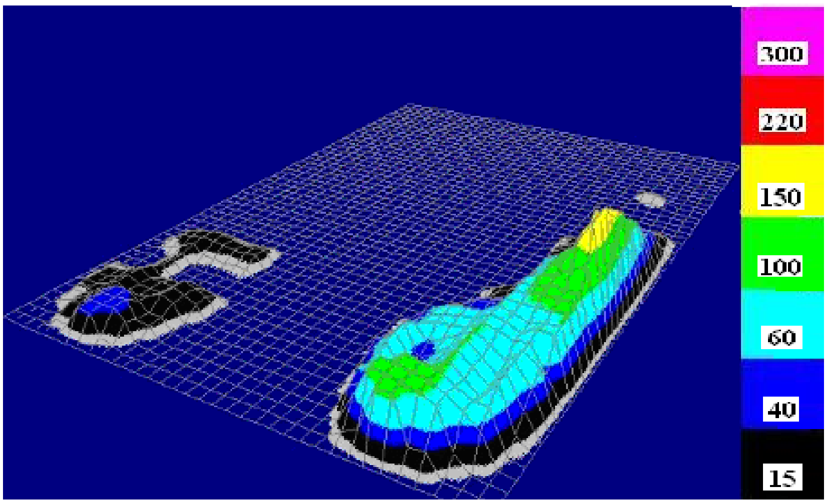

Fig. 2. Initial pressures analyses using Pedar of in/shoe pressure measuring system. Pressures are measured in kPa.

The shoes used in the initial measurement is shown in Figure 5. Due to the paralysis of external popliteal sciatic nerve the foot has deformed in time, getting the letter "C" shape, having the calcaneus positioned in 14° varus. This foot position and also the external popliteal sciatic nerve paralysis, which nerve is responsible for innervation of dorsiflexor foot muscles, encourages the development of unilateral stance phase of gait in a supinated position, thus creating the conditions for appearance of a high pressures on the proximal end of the V metatarsal and callosity forming in that area. Also, the pressure distribution analysis showed that in the support phase, the right foot comes in contact with the ground only in the proximal half area of plantar surface, while there is no pressures on forefoot in the contact phase, as shown in Figure 2. From the same image is seen that the propulsion of the right foot is not made at the forefoot level but at the midtarsal joint and rearfoot level, this fact leading to an apropulsive gait with a high energy consumption. In this case the therapeutic indication of orthosis had a complex and specific purpose of ensuring a redistribution of pressures on an area as large with consecutive decreasing pressures in the ulceration area and maintaining the foot in a position to facilitate a more efficiency propulsion for medical condition of patient[4,5,7,13, 16].

ORTHOSIS MANUFACTURE

After analyzing the problem and determining the orthosis role in the treatment it passing in the manufacture of orthosis. It involves going through the following steps: casting the foot, getting the negative cast, getting the positive cast, modifying the positive cast, thermoforming of assembly materials, processing all the materials to get the final form, finishing of orthosis, making the trial with the patient, orthosis readjust if necessary, dipense the orthosis and its indications of use.

For orthosis manufacture a non-weightbearing casting technique have been used with subtalor joint as close to neutral position while midtarsal joint is in a maximum pronation position[14]. Ulceration area was marked to be translated on positive cast. By the orthosis manufacture using this casting technique and balanced so that the bisecting line of calcaneus be brought as close to vertical, is made the induction of strong pronation forces on calcaneus in time of the contact and avoiding foot positioning in a inversion position so as to facilitate contact area as large. By supporting the foot in a correct as possible position during the phase of unilaterally support, redistributing of pressure on the as large contact area, the introduction of a pressure relief in the ulceration area and the use of some special materials to provide decreasing of forces during walking, it aims to achieve the desired objectives. The materials used were polyethylene foam of different densities – Pedilen ®, with the density of 41 degrees hardness Sh A having the role to keep the foot in the desired position and absorb impact forces and Plastazote ® with 20 degrees hardness Sh A having the role to absorb impact forces and to reduce friction forces between the foot and the orthosis[11]. It should be noted that both the hardness of materials and the thick of Plastazote layer ® 8 mm in accordance with Medical instructions code A5513 U.S., where these devices are regulated[13]. After cast balancing and making required modify-cations, the orthosis has been processed. During materials thermoforming it aimed to transfer the ulceration marks from the positive cast to the materials ensemble for a more accurate processing of the relief area under the ulceration. The edges of the relief area were marked at a distance of 6 mm round about ulceration (Figure 3). In agreement with the data from literature it was considered as the depth of the relief area to be 12 mm, so as due to compressibility of the materials used, the relief area to keep its efficiency as long as possible[4].

For the best use of orthosis and taking into account the foot deforming, a personalized deep footwear given in Figure 4 was made[9,16]. The personalized deep footwear is generally produced by foot cast or by modifying an existing last depending on the measured foot sizes. In this case, shoes were made based on measurements done by foot scanning using three-dimensional scanner INFOOT. The deep footwear allows interchangeability of accommodative or functional foot orthosis and ensures a very good dimensional correspondence with the foot. In normal conditions the personalized accommodative orthosis decreases the space inside the normal footwear, thus making their use impossible. Taking into account the feet particularities, shoes were designed with a large opening so that the foot can easily be placed in shoes, and has a locking system with adjustable bars and Velcro system.

Fig. 3. Verification of relief area and of cast position in relation to orthosis.

Fig. 4. The personalized deep footwear.

RESULTS

Aesthetics of personalized footwear, completely different from the usual footwear is caused the patient to refuse the test with the personalized shoes. Because the shoes worn and accepted by the patient (Figure 6) was 5 numbers greater size – 41 instead of 36 – but it allowed the use of accommodative personalized orthosis and doing determinations. Determinations were carried out using the Pedar system, for in-shoe pressures measuring[7,8], in two situations:

– in patient shoes with footwear original prefabricated insole (Figures 7 and 8),

– inside the patient shoes with personalized accommodative orthosis (Figures 9 and 10).

The results and also initial evaluation results are presented in Table 1.

The results centralized in Table 1 shows that when we use personalized accommodative orthosis it registers a decreasing of 108.9 kPa, representing 61.9% of pressure in the ulceration area confronted by the initial situation and a decreasing of 118.4 kPa representing 63.8% confronted by the case of use the original prefabricated insoles of footwear. Maximum value of personalized accommodative orthosis in the ulceration area is less by 110 kPa, representing 53.6% confronted by the initial situation and also with a value of 145 kPa representing 60.41% confronted by the situation of using prefabricated insole. Also, when we used prefabricated insoles it has been noticed an average growth of the pressure from the ulceration area, of 9.5 kPa, representing 5.4% and as well as a maximum value increasing of 35 kPa, representing 17% confronted by the initial situation.

Table 1

The minimum, maximum, average of maximum pressure and standard deviation measured in the ulceration area in three situations: initially, with prefabricated insoles, with the personalized accommodative orthosis for the right foot

Maximum pressure in ulceration area	Initial [kPa]	Prefabricated insole [kPa]	Personalized accommodative orthosis [kPa]
Average value	175.9	185.4	67.0
Standard deviation	14.9	35.7	13.5
Minimum Value	150	103	50
Maximum Value	205	240	95

Fig. 5. Patient's footwear used in initially assess.

Fig. 6. Patient's footwear used in finally assess.

Table 2

The minimum, maximum and average of maximum contact area and standard deviation measured in three situations: initially, with prefabricated insoles, with accommodative orhosis personalized for the right foot

Maximum contact surface	**Initially [cm^2]**	**Prefabricated insole [cm^2]**	**Personalized accommodative orhosis [cm^2]**
Average value	69.9	84.2	113.6
Standard deviation	4.7	3.7	2.2
Minimum value	59.1	73.2	108.0
Maximum value	78.9	94.1	118.1

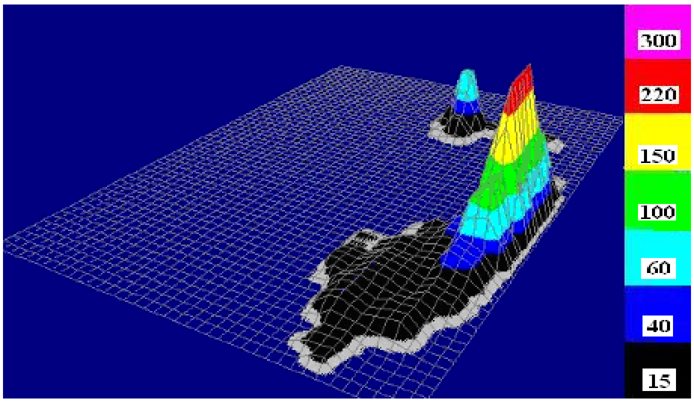

Fig. 7. Qualitative analysis of the pressure distribution with prefabricated insoles.Pressures are measured in kPa.

Fig. 8. Prefabricated insoles.

Analysis of maximum contact surface in the 26 walk cycles reveals a significant increase of the maximum contact surface. Thus in case of prefabricated insole the maximum contact area increases by an average value of 14.3 cm^2, representing 20.4% compared to the initial situation while the personalized accommodative orthosis causes an increase of the maximum area average value of 43.7 cm^2 representing 62.5% of the initial situation. The personalized accommodative orthosis also causes an increase of the average value of maximum contact surface with 29.4 cm^2, representing 34.9% of the situation of using of prefabricated insole (Table 2).

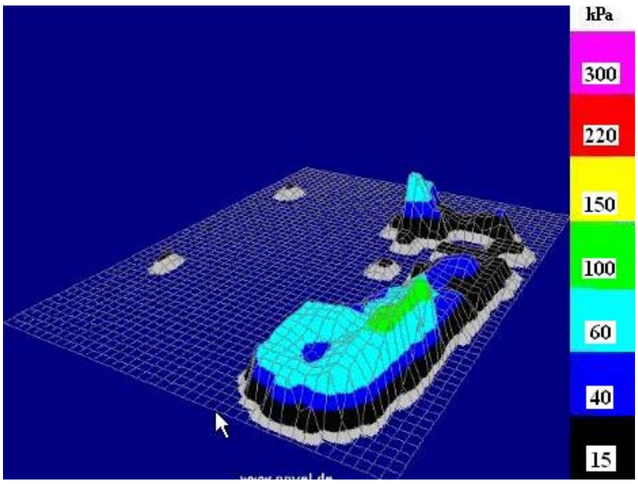

Fig. 9. Qualitative analysis of the pressure distribution with personalized accommodative orhtosis.

Fig. 10. Personalized accommodative orthosis.

The study of dynamic pressure distribution based on in-shoe pressure analysis Pedar System, shows a rearfoot strike in the contact phase of gait, a maximum load on lateral side of plantar surface, corresponding to the ulceration area, and a minimum pressure in the forefoot area. A subject with paralysis of the sciatic popliteal external nerve should present a steppage gait which has a forefoot strike in the contact phase of the gait, with maximum pressure on the forefoot and minimum pressure on the rearfoot. It is possible for the subject to achieve a modified gait pattern and pressure distribution because of the long history of paralysis and other associate neurological disease, a neurological reassessment being necessary in this case. To a detailed analysis of the structural modification of the foot joint which modified the foot architecture, an imagistic assessment (RX, MRI) would be helpful.

Using of prefabricated insoles leads to increasing the maximum contact area which also leads on overall to reduction of total pressure exerted on the foot. However, the main aim – to decrease pressures in the ulceration area – is not achieved, moreover in this case the effect is opposite to the desirable one due to the increasing of pressure in the ulceration area by 17% compared to the initial situation. The accommodative orthosis achieves their proposed goals by increasing the maximum contact surface both from the initial situation and from the situation of using prefabricated insole, while producing a significant reduction in pressure in the ulceration area of 61.9 kPa, respectively 63.8% from the two cases. This is due both of materials and technology: the design and execution on foot cast and placing pressure relief in the ulceration area. Although this orthosis tries to control in certain limits the movement and the leg position during walking, it should be kept in mind that the materials are compressible so that, in time, the effect of reducing pressure in ulceration area will be reduced. This implies the need for regular monitoring and reassessment of constructive form and also the orthosis efficiency[3,6]. Orthosis can be restored, if the effect of reducing pressures is increasing three / four times a year[5].

CONCLUSIONS

The personalized accommodative orthosis can significantly reduce the pressures in ulceration area having such a major contribution in the plan of treatment. Using in-shoe pressures measuring devices and measurements carried out in dynamics is costly way in a financial point of view but particularly useful in assessing both the foot pathomecanics and results of using the accommodative orthosis. There are a lot of materials and technical possibilities to obtain the accommodative orthosis.

The non-weightbearing foot casting technique is more difficult to run from other techniques and consequently it increases the time of execution. However the results may be significantly improved by using this technique. It is useful to continue the research on how the type of manufacturing process influences the results of orthosis using for the foot.

Is also showed that prefabricated insoles may have a negative effect on ulceration treatment by increases of pressures in the ulceration area, even if overall, they increase the surface contact area of the foot with a support area. Another important aspect is to use deep footwear that allows accommodation of the accommodative foot orthoses. The researches should continue in at least two directions: improving the aesthetic appearance without neglecting their functional respect and educating the patients on the beneficial results on the medical condition achieved by their wearing, which involves the acceptance of some compromises in terms of aesthetics. It also periodically checks after release of the accommodative orthoses is a necessity considering that the materials used are losing their properties of pressures discharge and control of their position because of their compressibility.

The complex researches for the use of foot orthosis yet started in Romania, but increasing the number of cases with a potential ulcerations issue and the need to prevent the lower level member amputation, require further investigation as to improve prescription and objective evaluation of the results of using foot orthosis. These can be done only in a multidisciplinary team that set out the diagnosis, to formulate the correct prescription, to follow and evaluate the results of the treatment [1,10,15].

Note:

– The system is Pedar belongs to the Politechnical University of Bucharest, Center for Research and Development for Mechatronics .

– 3D digitizing system belongs to ICPI – Leather and Footwear Research Institute, Bucharest.

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