CHALLENGES AND CONTROVERSY OF THE CONSERVATIVE TREATMENT OF FOOT PATHOMECHANICS

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Conservative treatment of foot pathomechanics involves the use of foot orthoses and footwear as medical devices. They are designed to change the size and time evolution of reaction forces acting on the foot in order to allow a normal functioning and lowering the pathological loads on the structural components of the lower extremities during the gait cycle. Prescription and design of these devices represent a great challenge for professionals involved in these processes due to the large amount of knowledge from different fields which has to be very well assimilated in order to succeed in effectively managing the conservative treatment’s implementation. Although these devices are apparently simple, the positive results of their implementation generate controversy in many cases. For example, rocker sole reduces the pressure on the heads of the metatarso-phalangeal joints, reducing the risk of ulcers’ development. Meanwhile the patient’s postural stability is affected by increasing the risk of falls and injury. This situation creates a conflict for the specialist called to find a solution to balance these two contradictory effects of the same device. Therefore, the interdisciplinary team is justified in implementing the conservative treatment of the foot. This paper aims to do a review of challenges and controversies in the implementation of conservative treatment of the foot that specialists have to deal with. The article also demonstrates the complexity of the process of prescribing and designing these medical devices as opposed to their apparent simplicity.

Key words: medical device, controversies, conservative treatment.

INTRODUCTION

In the developed countries the conservative treatment of the foot pathomechanics is assumed by several professions from which two are specialized in foot and leg problems: podiatry and pedorthics. According to The Society of Chiropodists and Podiatrists from the UK, “podiatry (also known as chiropody) is the diagnosis and treatment by podiatrists (chiropodists) of diseases and other disorders of the feet. Podiatrists are highly skilled health professionals who have been trained to prevent, diagnose, treat and rehabilitate abnormal conditions of the feet and lower limbs. They also prevent and correct deformity, keep people mobile and active, relieve pain and treat infections.” [1]. At the same time, “pedorthics is the practice, pursuant to a written order/prescription when addressing a medical condition, of evaluating, treatment planning, patient managing, measuring, designing, fabricating, assembling, fitting, adjusting or servicing, necessary to accomplish the application of a pedorthic device for the prevention or amelioration of painful and/or disabling conditions of the foot and ankle” [2]. Conservative treatment of foot pathomechanics is based on the intense study of the biomechanics of musculoskeletal system by evaluating all the existing theoretical currents of thought. This occurs in the context of rapid changes in both theoretical concepts and technical systems that allow experimental investigations, which generates a feeling of uncertainty in terms of education system [3] as well as in relation to the decisions which have to be taken into a given clinical situation. Thus, according to Payne [3], a critical approach is necessary to all of the theoretical currents of thought which involves “the ability to weigh evidence, examine arguments, and construct rational bases for decisions and beliefs.” In a study made in The Netherlands on the comparison of foot orthoses made by podiatrists, pedorthists and orthotists regarding
plantar pressure reduction, [4] the authors conclude that within each discipline there was an extensive variation in construction of the orthoses and achieved peak pressure reductions. Thus, conservative treatment of foot pathomechanics is not a process of finding solutions to a mathematical equation, but a process of thinking poled by challenges and controversy.

CHALLENGES

In a reference paper, Benno Nigg [5] analyzes the evolution of concepts which was the base of the study of shoes and supporting surface influence on the impact forces and foot pronation in sports activities. He made an analysis of concepts of “cushioning” and “movement (or rearfoot) control” showing that, according to research of the moment, the relationship between impact forces, foot pronation and the risk of injuries during sports activities cannot be sufficiently explained by these concepts. Thus, in the cited article, a new paradigm – neuromechanical or preferred motion pathway paradigm – is proposed for the motion control of the movement and foot pronation. It is obvious that an understanding of this paradigm, which according to Nigg has to be further researched to be validated, generates a different strategy for prescription of footwear and foot orthoses, which is less accessible to the practitioner than the traditional strategies developed based on the traditional concepts.

Any conceptual framework that addresses the functionality of a normal or abnormal biomechanical system is characterized by parameters that define it and whose evolution is followed during a therapeutic process.

A biomechanical examination can generate the following categories of information:

- quantifiable information:
  o kinematic and kinetic parameters:
    ▪ angles, i.e. angles of flexion/extension of the knee and ankle, the angle of the rotation of the tibia, the angle of rearfoot with supporting surface or the shank, etc.
    ▪ distances, e.g. step size.
    ▪ range of movement - ROM, such as ROM of tibia rotation in the transverse plane, the navicular’s displacement in the sagittal plane, etc.
    ▪ velocities determined based on kinematic measurements,
    ▪ accelerations, determined based on velocities,
    ▪ pressure,
    ▪ forces,
    ▪ moments.
  o an information about muscle activity (muscle activation time, the intensity of muscular activity).

This type of examination involves the use of instruments to obtain biomechanical parameters.

- descriptive information: the type of normal or pathological gait, describing the compensatory movements, etc. This type of examination is made in the observational analysis of gait.

It is important to note that a method of assessment does not exclude another one. Thus, the parameters provided by instrumental analysis must be interpreted in relation to the medical and technical knowledge related to etiology of the injury.

For example, analyzing how different types of compensatory elements placed in the shoes influence the legs kinematics and kinetics while running, Mundermann et al. [6]
evaluate no less than 15 kinematic and kinetic parameters and their evolution during the stance phase of the gait. The article concludes that different types of compensatory elements placed in the shoes influence the kinematic and kinetic parameters of running. This is important when analyzing the type of conservative therapeutic interventions which have to be implemented in order to reduce the risk of injury during sports activities.

Successful implementation of a conservative treatment of foot pathomechanics can not ignore the patient’s subjective perception of disease [7, 8] and the study of the evolution of the quality of life through the implementation of the treatment [9]. In the equation of the treatment this is achieved by introducing new variables. Studying the relationship between the rearfoot frontal plane motion of 22 subjects presenting excessive rearfoot pronation and reducing the symptoms with conservative treatment with foot orthoses, Zammit and Payne conclude that, although the foot orthoses have a small but statistically significant effect on the movement, this effect is not correlated with the improvement of the quality of life as it is measured by two scales – pain and functionality – of FHSQ (Foot Health Status Questionnaire). The study concludes that the effectiveness of the medical device has to be studied in relation to other variables than those of the control of movement concepts of classical theory.

From those which were written above we can consider that there is a significant challenge for the specialist when he has to make a choice of the dependent and independent variables whose correlation has to be studied in order to demonstrate the effectiveness of the device and improve the efficiency of conservative treatment of foot pathomechanics.

CONTROVERSY

A meta-analysis is “a statistical summary of the numerical results of several studies that have dealt with the same problem” placing itself in terms of level of scientific evidence on one of the highest level of scientific evidence [11]. It is not the goal of this paper to make a meta-analysis of the papers which deal with the aspects of how the decision of selecting the independent and dependent variables which characterize the evolution of conservative treatment of foot pathomechanics is achieved. The purpose of this paper is to underline that, viewed from different angles, applying the same principle can lead to different results.

Pressure Relieving with Rocker Sole

There are different ways to redistribute and reduce the high pressures from the foot-supporting surface interface in order to avoid the ulceration’s development in the case of diabetic foot. One of the most used is the rocker sole (Figure 1). The conclusion of a study on the influence of rocker sole on plantar pressures in neuropathic feet, where 10 subjects aged between 44 and 78 years were included, with an average of 63 years was that “the most effective way to offload the forefoot of patients with neuropathic feet is through the use of the rocker sole principle” [12]. These positive results were demonstrated through the use of an in-shoe pressure system, which shows a reduction of pressure in the center of the heel and under the metatarsophalangeal heads between 35-65%. Looking from another perspective, which is that of very well documented postural instability in people with diabetic neuropathy, Albright and Woodhull-Smith [13] studied the effect of two types of rocker sole (forefoot rocker sole and negative) and a
pair control shoe on the potential of imbalance, based on the fact that people with diabetic neuropathy shows a high risk of falls and injury.

![Anterior-posterior rocker sole](image)

**Figure 1. Anteroposterior rocker sole**

The study was conducted on 20 young subjects, aged between 22 and 25 years, his conclusion being that there are justified concerns that footwear with rocker bottom sole modifications to accommodate an insensate foot may increase the risk of falls. Thus, in opposition to the first study using as variable the plantar pressure in the rocker sole shoes and proving its usefulness in preventing ulcers, the second study uses as variables the sway for center of pressure (COP) and center of mass (COM) showing that the rocker sole can increase the risk of falling and injuries. In this case we have a situation where the same therapeutic device – rocker sole – can produce two antagonistic effects, one beneficial and one which increases the risk for injuries. The specialist has to consider both effects and has to balance the therapeutic solution that he chooses.

**Hardness of Materials Used in Medical Devices for Diabetes**

Hardness of different materials of the foot orthoses or insoles differs a lot, as there are not clear standards on which to base the decisions for selecting them. According to Medicare claims code, A5513: “for diabetics only, multiple density insert, custom molded from model of patient’s foot, total contact with patient’s foot, including arch, base layer minimum of 3/16 inch (4.76 mm) material of shore A 35 durometer or higher, including arch filler and other shaping material, custom” [14]. Birke et al. [15] studied the effect of reducing the plantar pressure from risk areas of the foot in the case of using the same material – Poron – with seven different hardnesses (14, 17, 22, 27, 32, 40 and 55 shore “O”) of the material and with a thickness of ¼ inch (6.3 mm) for high-risk patients. A 36-39% reduction of pressure in areas considered, supports the use of medium-Poron material hardness, shore “O” durometers 22-32, (approximately 15-25 shore A 23), which includes the current standard formulation shore “O” durometers 22 (approximately 15 shore A 23), for fabricating orthoses in high-risk diabetic patients. According to the authors, this study does not support the use of harder materials for heavy subjects for the purpose of pressure reduction. Opposite to this approach, the efficient use of hard materials (Subortholen, thickness 4 mm) is successfully used in treatment of a patient, 60 years old, with diabetes for 24 years and type I for 17 years presenting ulceration and in the other case of a 63 year-old patient with Hansen’s disease with ulcerations too. The study shows that the rigid-relief orthosis “has been clinically shown to be an effective, adjuvant modality in preventing recurrent plantar ulcers”. Related to the material hardness and thickness studies show that both thick (16-27 mm) and soft (Shore A15) materials for insoles had a negative effect on static and dynamic balance performance [18].
Plantar Pressure Redistributing Principle

Pressure redistribution principle at the foot-support surface interface is the basic principle in the treatment of foot ulcerations in diabetic neuropathy. The principle represents the base for the construction of accommodative foot orthoses, therapeutic footwear and other devices such as TCC (total contact cast). In an analysis of articles regarding the effectiveness of pressure relieving interventions, the number of randomized controlled trials treating the subject of the prevention or treatment of diabetic foot ulcers is small (only four RCTs that satisfied the criteria for inclusion from the study) [19]. The author’s conclusion is that there is a limited level of evidence for the effectiveness of insoles, therapeutic footwear and treatment of diabetic ulcers and the TCC. However, there is a rich literature that supports the principle of plantar pressure redistribution in the treatment of ulcers and of the reulceration [4, 12, 14, 15, 20]. Pressure redistribution principle involves building a device to reduce pressure in the points of high risk such as those of the metatarsophalangeal heads, through high-risk points pressure relief and increase of the total surface contact area. Different types of conservative interventions demonstrate a 35-65% reduction of the pressure in the considered points. According to Goonetilleke, “the ideal pressure distribution between the human body and any surface of a given application has yet to be defined” [21]. The relationship between pressure distribution over a larger area and the comfort-discomfort/pain phase transition is analyzed through the spatial summation theory (SST) which states that simultaneous stimulation of many sensory receptors is required to arouse stimulation. To exemplify the application of this theory, the author gives the example of shoes designed to achieve a great comfort through conforming to the morphology of the foot and generating a uniform distribution of the pressure at the foot-insole interface. The transition from the comfort phase to that of discomfort/pain will occur when, due to the activity, the pressure on each sensor from the skin of the foot will increase due to foot’s deformation and increased volume. Discomfort occurs due to a greater number of skin receptors/sensors stimulated by a larger contact area. Because the indications for pressure relieving devices are that they have to be worn continuously for a long period [22], relationship between comfort/discomfort phase change and efficacy of conservative treatment should be considered. The fact that, despite the medical indications, relieving/redistributing pressure devices are not used more than 25% of the prescribed time [22], leading to inefficiency of conservative treatment, could be explained through ergonomic principles of spatial summation of theory.

CONCLUSIONS

The complex process of diagnosis of a foot pathomechanics and that of the prescription and implementation of a conservative treatment using medical devices represents a challenge for the involved specialist.

As challenges we can note:
- proper application of theoretical concepts to practical clinical situations,
- evaluating the effectiveness of the conservative treatment by appropriate selection of dependent and independent variables that characterize the pathology, medical device technical characteristics, the interaction between device and patient and patient-subjective sensation perceived regarding the evolution of treatment.

The controversies appear because of the continuous development of the theoretical concepts regarding the functioning of normal and abnormal foot and lower extremities.
and because of the increased number of techniques and instruments used in validation of these theoretical concepts. The same therapeutic intervention could have opposite effects when it is viewed from different approaches. Because of multitude of theoretical concepts, variables, techniques and instruments used in the study of the effectiveness of the conservative treatment of foot pathomechanics often is difficult to compare results of different studies. It is the specialist’s duty to form a wider horizon through a critical view on all challenges and controversial aspects of this treatment. In this way the patient can receive the best treatment for his problem.

REFERENCES