

# EFFECTS OF LOCAL VIBRATION THERAPY ON LOWER LIMB'S SENSORIMOTOR CONTROL IN WORKERS SUFFERING FROM DIABETIC FOOT – STATE OF ARTS AND STUDY ON A NEW PREVENTION AND THERAPEUTIC SYSTEM.

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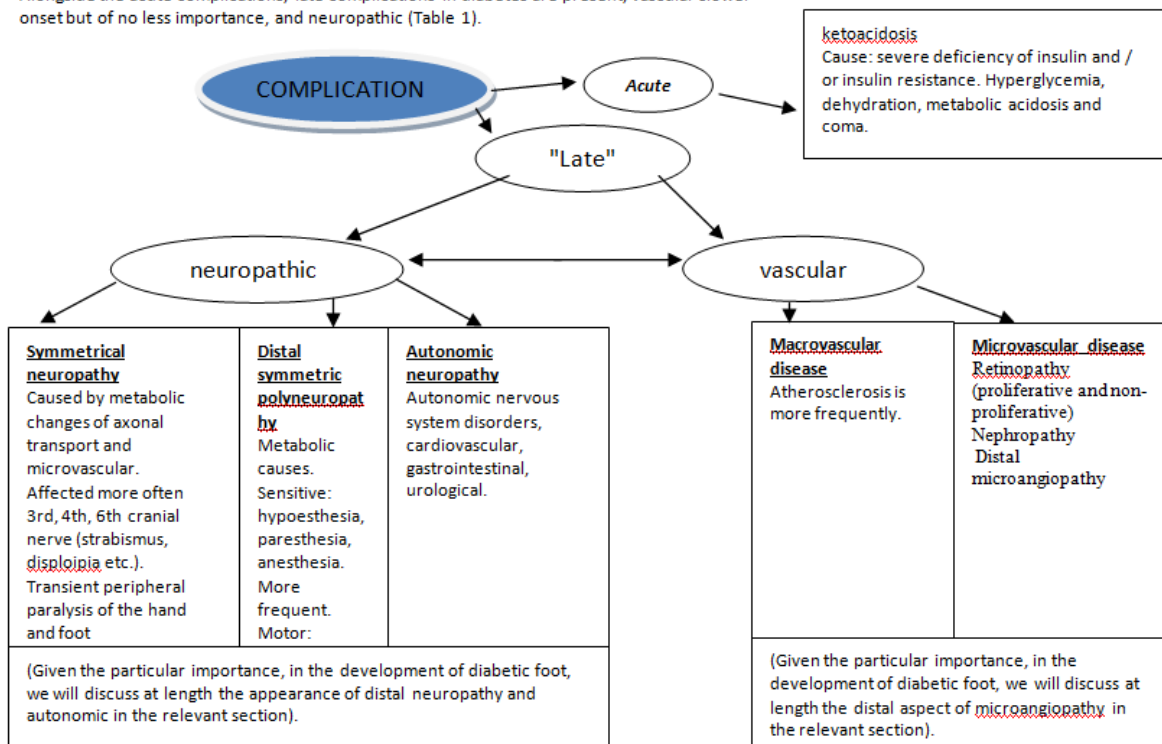
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## Abstract

Diabetes mellitus is a pathology constantly expanding worldwide and, along with its complications, is a major challenge for medicine. To understand the dimensions of this disease, we may refer to the data from the World Health Organization (1) (WHO) according to whom there are about 366 million people suffering from diabetes or pre diabetes worldwide, a number which is expected to grow inexorably as a result of population growth and aging, besides the high prevalence of obesity and overweight leading to changes in lifestyle. In Countries with a particularly high rate of growth (BRIC) Brazil, Russia, India, China the disease is forecasted to expand explosively. Type 2 diabetes is increasing in all westernized countries, although significant differences are noted among different ethnic groups. The genetic and ethnic basis which contributes to the different expression and the development of diabetes, namely its complications, are in the process of being understood. Recent studies have shown that people of Asian origin (India, Pakistan, and Bangladesh) tend, more than Caucasians, to have a higher incidence of diabetes, especially of type 2, characterized by a high resistance to the action of insulin. However the incidence of obesity, an important risk factor in the development of type 2 diabetes, is significantly lower in Asian Indians compared to Caucasians. Changes in lifestyle, more western and sedentary, are not completely useful to clarify this difference. The resistance to the action of insulin, on one hand, helps to understand the increased incidence and, on the other hand, it leaves open the debate on its causes. Moreover, as in Caucasians, the expression of serious complications such as microangiopathy, requires the presence of the genetic-biochemical alterations, so some changes in the expression of diabetes in the Asian regions may be related to factors scrambling gene, linked to colonialism. In fact, studies indicate a significant difference in the expression of diabetes and its complications (see fat distribution and microangiopathy) between Asian cities (Madras-Chennai) with long colonial presence, especially English, and campaigns. Diabetes is often undiagnosed or highlighted in the course of clinical trials or for the appearance of its dangerous complications. In particular, in this work, we stress the problems of the diabetic foot. In its various expressions such as neuropathic, vascular and mixed, and propose the preliminary results of a new therapeutic approach of this complication, so serious as well as so much misunderstood.

## COMPLICATIONS OF TYPE 2 DIABETES

Alongside the acute complications, late complications in diabetes are present, vascular slower onset but of no less importance, and neuropathic (Table 1).



In particular, our work focuses mainly on all the complications listed above, which alone or in combination give rise to the diabetic foot.

#### Definition of diabetic foot:

Plantar skin ulcers, and bone and joint deformities sometimes showy, (Charcot arthropathy) are the characteristic features of the diabetic foot, a major cause of morbidity and disability, which affects 15% of diabetics. The main predisposing factor are diabetic neuropathy, autonomic and motor-ways and the macro and micro vascular alterations.

#### Classification of diabetic foot

The alteration of the function of the distal peripheral nerves, is a focal point for the mechanisms give direct and induced charged to the diabetic foot. Recent studies (13), have suggested, a direct influence, of the increase glycemic, and the relative insulin deficiency, on the, mitochondrial energy production, and, on the cytoskeletal systems axonal transport (Kinesin-Dynein). It would explain, so, the primary involvement on nerve endings, sensory motor at various levels and especially autonomic system. This would be added the damage, given by microangiopathy vasa nervorum.

Depending on the cause that is the basis of the disease, there are three types of diabetic foot: neuropathic foot, Autonomic neuropathy foot and neuro-ischemic foot. The three forms can occur independently of each other, or overlap, summing the own detrimental effects. The co-presence of genetic factors, which are expressed in metabolic alterations, can, even in the presence of hyperglycemia minor or preclinical, create more damage, with release of free radicals and superoxide ions, creating, also in conditions of hypo vascularisation (on the basis macroangiopathic or autonomic) the conditions for the creation of an abnormal vascular tissue, known as microangiopathic, which due to its anatomic pathological characteristics and biochemical genetic alteration, can amplify exponentially the risks associated with diabetic foot, impairing also the benefits of revascularization, (making it, even, potentially counterproductive)

Depending on the progression of various pathological factors, their simultaneous presence, and the combination of genetic-metabolic cofactors, you will have various levels of suffering diabetic foot.

#### Classification system risk

Class	Description Risk	Frequency of checkup
0	sensory neuropathy absent	once a year
1	sensory neuropathy	once every 6 months
2	sensory neuropathy , signs of vascular disease device and / or foot deformities	once every 3 months
3	prior ulcer	once every 1-3 months

In India, the form more present is neuropathic, especially in rural areas, while in urban areas are more easily, always with low incidence of ischemic neuro mixed forms, which represent a high prevalence in the European area .

#### Neuropathic Foot

The sensorimotor polyneuropathy, and, autonomic neuropathy, as well as being , the most frequent forms of diabetic neuropathy, are also the ones responsible, for the onset of the "clinical picture" that characterizes the diabetic foot.

The sensorimotor polyneuropathy (30 - 39) involves mainly the lower limbs and is characterized by its progressive deterioration of disease. The sensory neuropathy, involves first the vibratory sensitivity, then peripheral nerve pathways of pain, and then and finally get to a state of complete anesthesia of the foot. The impairment , of the large caliber, sensitive fibers, leads to a

decrease of the proprioceptive sensitivity and tactile, while the impairment of those of small caliber reduces the pain and temperature sensation. These sensory disturbances depart from the toes and then gradually extend to the foot and leg. Often the loss of sensation (paresthesia, dysesthesia) is associated with pain (mainly at night). When diabetic neuropathy progresses the pain diminishes until it disappears while remaining the sensory deficit.

Motor neuropathy causes instead hypotonic and atrophy of the intrinsic muscles of the foot, leading to the development of deformities (Charcot arthropathy) such as bunions and clawed fingers, which can occur even before the onset of symptoms characteristic of diabetes. These deformities, not peculiar only of the diabetic neuropathy, are to be based potential injury. The skin that covers the metatarsal heads, in fact, becomes subject to increased pressure loads, ( that are not perceived by subjects if there is a loss of the perception of pain). This brings the subject to not implement those defenses (modification of the position of the foot during walking, (45) replacement footwear, diabetic foot care) that would normally be carried out by exposing it to the risk of developing an ulcer.

Autonomic neuropathy, in the lower limbs, is seen in the impairment of the sympathetic nervous system. This impairment leads to the onset of anhidrosis and impaired postural vasoconstriction. The first will lead to dry skin, making it vulnerable and predisposed to the development of fissures; the second will prepare, the individual, to the development of neuropathic edema. As mentioned autonomic neuropathy may, in the presence of other co-factors, result in dangerous microangiopathies

#### Ischemic diabetic foot: macro and microangiopathy.

The rapid degeneration, in the feet of diabetics, in ulcers and infections from a small lesion, is often supported by an alteration of the circulatory system, of the lower extremities, species charged to the arterial system (arterial disease). The arterial disease of the lower extremities, is the cause of the ischemic foot. Differentiates into macroangiopathy and microangiopathy.

For macroangiopathy phenomena, that starting from the alteration of the intimate inner, cause thrombus formation, mainly at the level of distal arteries (arteries tibialis anterior and posterior and popliteal.) (macroangiopathy). This peculiarity makes the situation more serious because these arteries, have less capacity to develop collateral circulation. In the presence of macroangiopathy, there is a decreases of perfusion pressure, and, it causes a misdistribution of the cutaneous microcirculation, as well as thrombotic phenomena in the capillaries. In this situation, the feet, not getting the proper blood supply, is in difficulty, to repair the damage of all tissues of the foot, and, of the skin, in particular. Then, the skin of a diabetic macroangiopathy foot, becomes thin, brittle, and extremely delicate and therefore more subject to traumas and injuries of any kind. The earliest sign of peripheral arterial occlusive disease is intermittent claudication, or, the onset of pain, after a certain number of steps, forcing to stop the walk; This usually subsides with rest, and is usually localized to the calf, and, in severe cases, may be present even at rest. The feet are pale (cyanotic marbling in more advanced cases), the skin is cold, and the nails take an irregular shape, with wrinkled surface.

- Diabetic Microangiopathy (9), is characterized by a reduced blood flow at the level of microcirculation, with alterations of the same, and a change in the skin tropism. Starting point, is the

malfunction of peripheral sympathetic and parasympathetic system, which causes an alteration, and, opening of thermoregulatory arteriovenous subcutaneous shunt, with decreasing

of superficial papillary dermal vasculature, and subsequent alteration of the inner membrane of the vessel and its permeability, impaired balance osmo-oncotic, impaired muscle function arteriolar with deposit of protein and fatty acids in the intimate arteriolar and increased production of extracellular matrix. The stimulus ischemic leads (in the presence of genetic conditions predisposing and blood glucose also not significantly disrupted), at the formation of new blood vessels, often without endothelium inside and thrombotic and vascular invalid in osmo-oncotic function, and, formations angiomatous. These formations neovascular altered, are themselves, elements predisposing state ulcerative skin, is its evolution, given the limited capacity to ensure proper blood supply from subcutaneous, both in depth, and was also to be an excellent substrate for settlement bacterial, and its proliferation often requiring alongside a proper antibiotic treatment, the deep and careful surgical curettage. The genetic-biochemical causes of the microangiopathy, not yet been established with certainty, Next to the alterations of the sympathetic system and the parasympathetic, is the phase one of lesion, the next step, Step Two, with the formation of new vascular pathological tissue, seems to be related, to the alteration of some biochemical mechanisms, associated with levels Glucose, also slightly higher than normal, may predispose the individual to getting this disease. The biochemical changes, including increased at flux through the polyol and hexosamine pathways, oxidative stress, AGE formation and protein kinase C (PKC) activation. The microvascular pathological tissue, is very sensitive to biochemical changes, and itself the source of the same biochemical alterations thus creating an exponential damage. It is important to remember that the blood sugar and AGE, critical cofactors in the genesis of microangiopathy, are strongly correlated with the alimentation. Along the limitation of high-sugar foods to rapid absorption (such as refined rice) will be severely limited. The modes of foods cooking (high temperatures and the presence of acids such as fries) greatly increase the nutritional intake of AGEs. (advanced glycation endproducts)

#### Neuroischaemic Foot

One foot defined, "neuro-ischemic", shows alterations, caused by both the neuropathy, which, of the arteriopathy obstructive macro and micro ischemic. Result of this combination, is the sum of the complications described above; as a result there will be a tendency to get injuries, and simultaneously a deficit in the ability to repair. The progression of these factors, combined with, to seemingly trivial errors, es. Abuse of shoes that are too narrow; The patient does not feel good pressure, and perceives tight shoes, as enveloping and protective, a poor and inadequate personal hygiene (removal of "do it yourself" to " calluses "and" hard skin ") and repeated micro injury, can foster with ischemia and infections, the evolution in gangrene with subsequent amputation.

In India are less present microvascular complications of the extremities, especially the rural population, but the habit of walking barefoot, poor sanitation, and limited health knowledge, can also lead to amputations

#### Vibration in medical therapy

Next to a bibliography, (7) in occupational medicine, showing the harmful effects of vibration on the human body, there is a 'clinical evidence, if these are used with the necessary precautions, and in compliance with the contraindications, can be used for therapeutic

purposes. One criticism that can be moved to the articles cited, is that they often take into account mainly the WBV (Whole Body Vibration), not considering the different degrees of absorption of vibrations of different tissues (skin, fat, muscle, bone, cartilage, connective etc. ) at different frequencies and amplitudes. This is why we feel safer and more specific in its action, stimulation with vibrations delivered locally, with specific frequencies, amplitudes and intensity.

Many studies have focused on muscle strength.

Bosco et al. (4) (1999-2000) assessed the concentration of hormones after treatment with WBV, at 26 Hz and found, an increase in growth hormone (GH) and a decrease, in testosterone and cortisol levels.

Loreto and colleagues (8) (2004) studied 10 healthy subjects to determine whether the 30 Hz WBV altered glucose and hormones in the blood, showing a transient decrease in blood sugar.

Roelants and colleagues (25) (2004) In a study of 24 weeks (with three times a week) compared the effects of WBV on muscle strength, as compared to a traditional physical training. WBV has led to an increase in strength and muscle mass comparable to the physical training.

Other studies, for us most relevant, have focused on the ability of the vibrations in producing a change in tissue blood flow.

Kerschman-Schindler (21) and colleagues (2000) have measured the variation of blood flow, in healthy subjects, following applications WBV (26 Hz), showing a significant increase in blood flow and a decrease in the resistance of the popliteal artery.

Maloney-Hinds (23) et al (2008) compared WBV with different frequencies (30 to 50 Hz) on blood flow. The frequencies of 50 Hz are preferred, as they have led to an increase in blood flow, with a more prolonged effect.

Lythgo et al (2009) (20) studying the effects of WBV, on the blood flow of the lower limbs, have shown that, the frequency between 10 and 30 Hz increases the speed of blood flow by 33%.

Bovenzi et al. (1999) (5) found a decrease in blood flow, in the fingers, as a result of exposure to vibration of 125Hz; same applies to vibration of 250 Hz and 310 Thompson et al. (2009).

From these studies, we can highlight that the answers circulatory application of vibrations, depend primarily on the frequency and extent of these, and as already highlighted in occupational medicine, frequencies are too high can cause serious damage.

#### Effects of local vibration.

"Vibrations local stimulation" are typically limited, to individual areas of the body, to individual muscles, groups of muscles synergistic or individual joints, and turn out to be different in their effects on the organism, and an essential role is played by the physical characteristics of 'wave used during application.

Even for the local vibrations, we have studies on muscle strength and the hormone concentration, and, on the proprioception though they are much less numerous than those on the vibrations to the whole body.

Capicikova (6) and coll. (2006) have shown, as a local vibration, focused on both soleus muscles of the legs, produces the effect a change in the center of the posture. Therefore they have shown the effect of local vibratory stimulation, as proprioceptive stimulation, which configures the balance of the whole body. The conclusion is that, the application of local vibrations, can be used in medical practice to modulate the muscular activity by means of a stimulus proprioceptive.

#### Vibration effects in diabetics .

Studies so far examined were conducted in healthy subjects. Studies concerning the application of vibration and their effects on diabetics, however, were less numerous.

Maloney-Hinds (25) et al. (2009) have studied the variation of the concentration of nitric oxide and blood flow, upon application of vibrations at a frequency equal to 50 Hz, in both healthy subjects and in subjects suffering from diabetes mellitus type 2. They have shown that there is a significant increase of blood flow in both groups (461% in healthy subjects, 223% in diabetic subjects) and the rate of production of nitric oxide, (258% in healthy subjects, 177% in

diabetic subjects) that remains high Also in the 30 minutes following application.

## MATERIALS AND METHODS

Evaluation Foot -diabetes : The patient's selection

All patients were of working age, and held with different activities and responsibilities, sedentary work, not stressful, with possibility to get up and move around at will. Ages of 50 and 65, men, all the diabetic disease was diagnosed two years ago. In good glycemic control (and in any case with HbA1c  $\leq$  6.5%) and adherent to the therapy (insulin glargine more biguanide (metformin)). They all had hypoesthesia, not perceived by them. All declared, coming from different centers, to have had an interview with the diabetologist, who had visited and trained to glucose monitoring, and advised of the potential risks, and pathology, and therapy, but in fact only 50% had been properly informed of the possible risks, out of the foot at the time of 'inclusion in the test.

Enrollment parameters to test were.

- 1) Patient compliance and absolute willingness on the part of the employer.
- 2) No changes in skin and subcutaneous tissue at the point of application EVM
- 3) No smoking and adhering to medication and diet
- 4) No comorbidity
- 5) No evidence of microangiopathy
- 6) negative for arterial thrombotic formations

As for the clinical testing the parameters are:

- 1) Positive test results of monofilament 10 Gr (three points out of six)
- 2) Negativity to vibration test with value  $\leq$  20 volts
- 3) ABI  $>$  1
- 4) TcPO<sub>2</sub>  $>$  to 60
- 5) TCPCO  $\leq$  to 40

Of the initial twenty-two patients, all men, randomly divided the two groups, weighing his age, one group was subjected to a physical activity with low impact (calisthenics), three times a week for an hour and half to two months. The second group always three times a week, and without contact with the first group, has been subjected to a physical activity equivalent to the first group (for an hour), and for half an hour at the treatment with Vibrations provided locally with apparatus EVM. All the patients, the control group and group EVM, were assessed at the same times, either by Gait Analysis, for the evaluation of the process, both as regards the aspects for diabetes scare. The cups, for the provision of the vibrations were placed on areas of intact skin and properly vascularized and innervated to prevent possible injury. The goal is to assess the effect on proprioception of the affected limb and its blood supply. The objective is to evaluate the effect on proprioception of the affected limb and its contribution to sanguine. La knowledge, in-depth and up to date, the mechanisms underlying the disease process, and knowledge of the equipment, allowed us to make this experiment safely.

Premise that article will be reported only the values of the ten patients of "Local vibration", not having, the control group, reported significant changes. We also had to remove two subjects, one for work, and one for a "diet non-compliance".

EVM.

The EVM is an apparatus, for physical therapy, designed for the administration of vibratory energy muscle, by compression-decompression ambient air. It looks like a mobile, topped by a control console. In the upper part of the rear panel, they are located fourteen pneumatic connectors, for as many pressure pipes connecting to the applicators in the cup, which transmit the mechanical vibration (transducers) to the human body. These vibrations are generated from 'EVM, through a compression \ decompression (within a range of  $\pm$  400mBar), of the columns of air

present inside the tubes, and, then applied to the body surface of the patient, thanks to one or more of fourteen transducers cup available, each with its own seal. The transducers establish a mechanical connection to the skin causing a shift in the same synchronous compressive \ decompression amplitude + \ - 3 mm to +/- 400 millibars; these transducers are attached to the areas treated, using elastic bands. The maximum frequency that can be delivered is 300Hz (therapeutically lower at around 30 Hz) on a sine waveform. Via console, the device is set in delivery times, frequencies, any breaks, and change frequencies specified time frame; also it allows you to store a customized therapy for each patient. Regarding contraindications therapeutic worth of machinery, of course, all those typical of the physical means to be applied on the outer surface of the body (and that may cause heating endogenous and repeated micro trauma of sensitive structures), so avoid using in the presence of, vascular disease in problem areas (such as varicose veins, thrombophlebitis, bleeding, arterial disease), as well as if there are inflammations in place, or skin lesions evident. Obvious exclusion of the application of neoplasms and in the presence of alterations in heart rate eg arrhythmias and atrial and ventricular fibrillation. In the presence of synthetic means use should be carefully evaluated. As for the carriers of active implantable means (eg. Pacemakers), although there is (in the case EVM) generation of direct electric currents and / or induced, directly provided on the patient, one must evaluate the opportunity of treatment, in addition to what has already been indicated above, also according to the degree of EMC immunity, of the device implanted, being the generator, even if shielded, capable of generating a weak electromagnetic field. The machine, in compliance with international standards, is produced by J & S Ltd. and distributed by Endomedica

Parameters of administration EVM.

Based on the studies in the literature, it was decided to use for this study, local vibration. Also on the theoretical basis, as described above, it has been taken into consideration three frequencies: 120 Hz, for the stimulation of the corpuscles of Pacini and spindles; 80 Hz, for the stimulation of the Golgi tendon organs; 50 Hz, the frequency in the literature that proves to be the best for the variation of blood flow, leading to vasodilation without a subsequent paradoxical vasoconstriction. The allocation of the frequency of 120 Hz has never been applied distally (foot and hand) is in close proximity to bony ledges, for the risk of a focus of its effects, as reported in literature (5). To prevent adaptation of the receptors, it was determined every 5 minutes to vary the frequency, in the course of the application, according to a sequence from the highest to the lowest. The application time was thus 15 minutes for each session. The sessions were carried out three times a week for two consecutive weeks.

GAIT ANALYSIS.

In this experimental work, it has been, for the functional evaluation, used an analysis system, able to provide with good precision information about the step, and, posture, during ambulation. A digital camera connected to a PC via port fire-ware instructed to store the video tracks, was positioned at a calibrated distance, and, always the same with respect to the path dedicated to the path of the subjects concerned. This course was delimited by special lines of demarcation, to obtain of the video tracks as homogeneous as possible, for the various patients. Behind the route it has been placed against a white background, to obtain a greater focusing of the camera on the subject under consideration. On the ground and in the background were placed markers, (colored tape) useful, the calibration phase of the software, which are translated such landmarks in space coordinates, in centimeters (accuracy +/- 3mm). For the entities in question are then applied markers, made from adhesive material colored / reflective, about the size of 1 cm x 1 cm, so as to obtain, with reasonable accuracy the displacement of the body segments concerned, than the involved joints from ' analysis

For both limbs were placed markers in the following anatomical landmarks:

- Projection skin of the greater trochanter
- Projection skin of the head of the fibula
- Projection cutaneous fibular malleolus
- Projection skin of the lateral portion of the head of the fifth metatarsal

Once applied markers, capable of being easily detected by the camera, it has been required to patients, to be placed in the starting position, placing the beads on the colored line drawn on the ground, to the left with respect to the camera, and, starting ambulation in the direction of the finish line on the right side of the shooting range. The same process, and was performed by the patient from right to left, of the shooting range, in such a way as to have information from both the limbs, and therefore evaluate possible asymmetries. At this point, collecting the video track, ends the phase that is involved actively in the patient, and, begins the phase of computerized analysis of the way by means of software Skillspector (v 1.3.2), developed by Video4coach. This software proceeds to a frame by frame analysis of the movement. The program can provide a dynamic two-dimensional representation of the body of the analyzed subject, by means of a representation stick (in segments); a sort of skeleton representative of the motion of the patient. However, over the graphic representation, aid in the interpretation of the movement, and, in the identification of a distinct change of pace, this system Gait analysis provides some important quantitative information concerning: stride length and speed of the various body segments, in relation to landmarks examined.

#### FINAL RESULTS

At the end of treatment, we have been repeat the assessments carried out before treatment in order to quantify the effects of therapy; these were then repeated at follow-up after 15 days to assess the maintenance or the possible dispersion of the results obtained.

#### VISIT Foot -diabetes OUTPUT

##### Windsor index (ABI)

- Foot right: from data we can see a rise in the index of Windsor in 6 of 10 patients. Of the remaining 4: 3 subjects showed an ABI unchanged, while only 1 patient shows a slight decrease.
- Foot Left: also as regards the left limb we have the values of ABI that increase in 6 patients out of 10. In the remaining 4 this value remains unchanged.

##### Transcutaneous oxygen pressure (TcPO<sub>2</sub>)

- Foot right: the evaluation of transcutaneous oxygen pressure (TcPO<sub>2</sub>) comes out, in 50% of cases, higher values; in patients 7 and 8, however, the TcPO<sub>2</sub> remains unchanged, while there is a decrease (albeit minimal) of the patients in the values 1, 5 and 9.
- Left Foot: the right hind limb data see grow to 6 the number of patients who showed an increase in TcPO<sub>2</sub>. The remaining four patients did not show alterations of this value.

##### Pressure transcutaneous CO<sub>2</sub> (TcPCO<sub>2</sub>)

- Foot dx: as regards the pressure transcutaneous carbon dioxide (TcPCO<sub>2</sub>) the data are rather mixed; In fact, if on one side 4 of the 10 subjects examined reported a decrease of this value (which is very significant in the patient 2), on the other patients 3 show an increase of TcPCO<sub>2</sub> albeit minimal. For the remaining 3 the situation is unchanged.
- Left Foot: in this case the picture that comes out is very similar to the previous one. They remain always 4 subjects in which there is a decrease of TcPO<sub>2</sub>, while increases by one the number of those who reported a decrease. There are two cases in which there is no variation.

##### VPT and test monofilament

As regards the values of VPT (Vibration Perception Threshold), and, data from the testing of the monofilament, is not recorded no significant change, if not in a single case, (which has no importance from the statistical point of view), or for the right limb nor to the left.

All patients, to the control at 15 days, have shown, for the part "laboratory tests" a substantial return to the pretreatment data.

#### GAIT ANALYSIS

##### Average Speed of Foot

- Foot right: the values in the table there is a substantial homogeneity of the data. In fact, as regards the parameter considered (Average Speed of Foot), to control post-treatment there is an increase of the values in 100% of cases. The speed variations, oscillate from lower values, (2.5 - 3.0 cm / s), to values rather important, as in the case of the patient 1 in which there is an increase equal to 9.9 cm / s. At follow-up, after two weeks, from the end to therapy, there was a general continuation of the results obtained at the end of the treatment cycle, with minimal variations between -1.1 (cm / s) and +0, 8 (cm / s).

- Foot Left: as regards the left limb is no effective compliance with the values of the contralateral limb. The data in fact do not present significant changes, except in patient 3 that control post-treatment showed a slight decrease (from 29.4 to 38.6 cm / s); but this has to follow up returns roughly in line with the figures recorded in the first evaluation. For the remaining data in this case too, at follow-up, the situation remains the same, with only very minor changes, which are in line, with the right limb.

##### Stride length

- Foot right: for what concerns the second parameter examined through Gait Analysis (stride length), shows the following results: 7 out of 10 patients showed an increase in the amplitude of the pitch, or the distance between two consecutive supports of the same heel; variations ranging from a minimum of 2.8 cm (patient 6), to a maximum of 15,3 cm (patient 2). In the remaining three patients there is instead a decrease, albeit minimal, of the values, which reaches the maximum excursion into the patient 1 in which the step length decreases by 6 cm. At follow-up, the picture remains largely unchanged, with respect to the assessment after treatment; data changes are included in values ranging from 0.9 cm (paziente7) and 1.7 cm (patient 3).

- Left Foot: examining data on the left limb, the results are always positive in 8 of 10 patients. The progression of this parameter goes from the minimum value of 2.5 cm of the patient 8 to 7.6 cm of the patient 4. Instead in patients 3 and 7 which do not show improvements in this measurement, the situation remains virtually unchanged with physiological fluctuations values that do not exceed 13 mm. Even in this case to the control after two weeks the scenario remains roughly the same: the oscillations of the values in this case ranging from -3.3 cm to +1.2 cm of the patient 9 of the patient 7.

#### CONCLUSIONS

##### Vascularization

Treatment with local vibration therapy showed a significant effect, as regards the spraying, and tissue oxygenation. The improvement in the Index of Windsor (ABI), the TcPO<sub>2</sub> and TcPCO<sub>2</sub> in zones exposed to vibration, most likely, is associated to the increase in circulating nitric oxide in the periphery (25) (Maloney-Hinds et al, 2009). The variation of these parameters is in fact due to an increase of the blood flow in the distal consequent vasodilation action of this molecule on peripheral vessels. (Is more important use this system whit attention on macrovascular disease and in present of advanced microvascular disease.) On the contrary, the failure of variation results in the tests of monofilament and VPT is, presumably, the result of an insufficient sensitivity of these evaluations, rather than ineffective action of therapy.

##### PROPRIOCEPTION

Even in this evaluation, the results were more than satisfactory, positively oriented toward all items proposed. In all patients examined, in fact, it was found a more or less distinct difference, compared to the initial assessment. The positive effect of vibration therapy, on proprioception, which is apparent from the data of the study, which is already anticipated by (7) Capacikova et al. (2006), is

comparable, rather than to the improvement of vascular patients, the action of the vibrations on the different receptors: Pacinian corpuscles, Golgi bodies, muscle tendon reflex, Meissner corpuscles and muscle spindles. Note, also, that the effects most relevant and satisfactory, have been seen in subjects in which the symptoms appeared in the later stages. It is confirmed, therefore, that the application of vibrations premises may be used in the rehabilitation practice to modulate the muscle activity and improve proprioception.

#### WALKING

The analysis of the results, concludes with the taking into consideration of the findings by analyzing gait; Once again, the results obtained, they direct us to an outlook cautiously optimistic. The increase of the average speed of the foot and stride length, in fact, involved, with the due differences, all subjects examined. Presumably, these results, are closely related with the improvement of the proprioceptive sensibility, which predisposes the patient to improve the dynamics of the step, increasing the duration of the "rest phase", which, in this way allows more oscillation of the suspended (greater stride length) and increasing the sense of security of the person causing it to accelerate its average pace (average speed increase of the foot).

In conclusion, since the first results, we collect, they are positively oriented towards all targets proposed, as the first pilot study, regarding the rehabilitation of the lower vibrational, suffering from complications of neuropathy and to prevent macro and microvascular diabetic albeit characterized by a small sample, which is not a significant statistical significance, bodes well regarding future studies. The clinical confirmation obtained after the first few applications suggests that the local vibration therapy, for ease of application, the non-invasiveness and the relative absence of contraindications, can represent an innovative rehabilitation methods, to be included within the traditional protocol of treatment a problem so widespread, and, which is difficult to manage the diabetic foot. In particular it was improved performance in the workplace of the examinees, which have increased their level of activity and participation in working life and everyday .

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