Increased Transcutaneous Oxygen Tension in the Skin Dorsum Over the Foot in Patients With Diabetic Foot Disease in Response to the Topical Use of an Emulsion of Hyperoxygenated Fatty Acids

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Abstract
The aim of this study was to examine changes in the skin over the feet of patients with diabetic foot syndrome after local application of a product containing hyperoxygenated fatty acids (HOFAs) by measuring transcutaneous oxygen. In 64 patients, transcutaneous oxygen pressure (TcPo2) was measured on days 0, 7, 30, 60, and 90 of the study. Foot skin dryness, shedding, and skin color were also assessed using a clinical score. The patients were grouped on the basis of initial levels of transcutaneous oxygen: group 1 comprised patients with TcPo2 >30 mm Hg and group 2 comprised patients with TcPo2 <30 mm Hg on the skin over the dorsum of the feet. Increases in local oxygenation values were observed at a local level in group 2 patients after 30 days of treatment. Skin trophism showed clinical improvement in all patients, and these observations may be attributed to improved local microcirculation.

Keywords
microcirculation, transcutaneous oxygen, diabetic foot disease, hyperoxygenated fatty acids

The prevalence of diabetic foot syndrome is estimated at between 1.3% and 4.8% of patients with diabetes mellitus. Approximately 15% of patients with diabetes develop a foot ulcer at some point during their lives, which can sometimes require amputation of the foot or leg, the risk of amputation being 15 times higher in diabetic patients compared with the nondiabetic population.

Diabetic neuropathy, peripheral vascular disease, and mechanical stress are involved in the pathogenesis of ulcerated diabetic foot. In addition, microcirculatory changes play an important role in the development of diabetic foot syndrome. Deterioration of the microcirculation in diabetic patients is another contributing factor to the onset of secondary complications in the lower limbs, such as ulceration and infection.

Approximately 50 years ago, Goldenberg et al. made the uncorroborated statement that the existence of occlusive changes to small caliber vessels was a sign of diabetic microangiopathy. Successive studies have shown this to be a functional rather than an occlusive disorder, characterized by diffuse capillary basement membrane thickening, which causes microvascular diffusion described as increased capillary permeability, and damage to the self-regulation of the blood flow and vascular tone, which causes dysfunction of the endothelium by affecting the transport and tissue metabolism mechanisms.

The most important structural changes in diabetic microcirculation have effects on the basal cell membrane thickening, which affects vascular permeability, changing the nutrient transport mechanisms and leukocyte function leading to changes in cutaneous trophism as well as nonspecific immune response. These conditions are more prominent in the lower limbs where hydrostatic pressure is greater and associated with poor metabolic control of diabetes.

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Another cause of microangiopathic changes affecting decreased blood flow is peripheral polyneuropathy,11 particularly autonomic involvement, which causes vasomotor changes leading to poor fluid distribution, which may in turn lead to functional ischemia. The interaction between neuropathy and the microcirculation is complex, and different studies have shown microcirculatory changes in cases of clinically mild neuropathy,12 and even in patients at high risk of developing diabetes.13

On the other hand, vasomotor function is altered in diabetic patients, especially related with underlying neuropathy, affecting the permeability of the endothelium, through self-synthesizing substances such as nitric oxide (NO), prosta cyclines, and prostaglandins (PG) and also the contraction of smooth muscular fibers, aggravating the local microcirculation in the foot.14,15

There are but few studies in the diagnostic and therapeutic field of microcirculatory in the diabetic foot, but it is known that a foot with dermal dystrophy, loss of elasticity, and skin shedding suffers a higher risk of injury.16

Transcutaneous oxygen pressure (TcPO2) is a diagnostic tool that has been used to assess the microcirculatory status at a local level. It measures the spread of oxygen through the skin. TcPO2 is directly dependent on blood flow and indirectly dependent on resistance to oxygen diffusion as well as oxygen consumed.17 This technique must be used in controlled conditions to be reproducible and accurate. It is dependent on the presence of edema, skin thickness, or other skin dysfunctions in the area of measurement.17

Hyperoxegenated fatty acid (HOFA)–based products have been reported to be clinically useful for preventing ulcers of other etiologies, particularly in pressure and venous ulcers.18,19 HOFA products are readily absorbed through the skin increasing cohesion among the corneocytes thereby limiting transepidermal water loss and skin scaling. HOFA products are precursors of the metabolic mediators of NO, arachidonic acid, and PG. They promote capillary vasodilatation as a hyperemic response to external and/or local lesions.20 The purpose of this study was to examine changes in TcPO2 values in patients with diabetic foot after local application of a product containing HOFA.

Materials and Methods

From March to September 2008, a prospective, longitudinal study was done to which the authors recruited 64 patients (see Table 1) attending the Diabetic Foot Clinic of the University Podiatry Clinic at the Complutense University in Madrid, Spain. The following were the inclusion criteria:

- patients with diabetes type 1 or 2
- patients 18 years old of both genders
- pharmacological treatment received did not affect recruitment
- patients without frank wounds at the time of inclusion in the study
- patients with diabetic neuropathy21 defined as insensitive to Semmes-Weinstein monofilaments (SW) in more than 4 of the 10 sites examined as shown in Figure 1 and with biothesiometer values >25 V
- those who agreed to and were capable of signing an informed consent
- those who were able to visit the clinic in keeping with its conditions and for the duration of the study.

Patients with an ankle brachial pressure index (ABPI) <0.5, with TcPO2 <20 mm Hg, with rest pain, with an absence of 2 distal pulses (at the dorsalis pedis and posterior tibial sites), with edema in lower limbs, and patients who were bedridden or had difficulty walking were excluded from the study. The data gathered on the details of their condition are shown in Table 2.

On the day the patients entered the study (day 0), TcPO2 measurements were made using the TCM400 measuring device (Radiometer, Copenhagen, Denmark) on the dorsal zone of the foot, by placing the reading electrode between the first and second metatarsals and recording the value in mm Hg after a stabilization period of 15 minutes. Patients were lying supine during the measurement.17,22 A control or reference value was taken on the chest, along the mid-clavicular line precisely between the second and third intercostal space.

The criteria used for dividing the patients were the TcPO2 values on day 0 of the study, classifying patients without microvascular dysfunctions as those with a TcPO2 value >30 mm Hg (group 1, n = 45) and patients with microvascular dysfunctions as those with a TcPO2 value between 20 and 30 mm Hg (group 2, n = 19).

Patients were treated with a HOFA-based emulsion product from the day of inclusion (Aloe barbadensis and Mimosa tenuiflora; Mepentol Leche BAMA-GEVE). Patients were instructed to apply the product to unbroken skin from the third middle of the leg to the tips of the toes, on both sides. The product was applied twice daily for the 90-day duration of the study.

The clinical variables gathered reflected the evolution of the microcirculation: skin dryness, skin shedding, and skin color. Skin shedding and dryness were observed on the plantar surface area of the foot and were recorded using a clinical scale divided into absent, moderate, intense, and very intense.

Skin color was classified as very pale, pale, normal, and mild rubor and scored using a validated system by
Table 1. General Characteristics of the Sample Included in the Study

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n = 64)</th>
<th>TcPO₂ ≥ 30 (n = 45)</th>
<th>TcPO₂ = 20-30 (n = 19)</th>
<th>PValue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean ± SEM)</td>
<td>65.5 ± 1.26</td>
<td>65.5 ± 1.52</td>
<td>65.3 ± 2.29</td>
<td>.90</td>
</tr>
<tr>
<td>Gender (n)</td>
<td>Male 44; female 20</td>
<td>Male 32; female 13</td>
<td>Male 12; female 7</td>
<td>.53</td>
</tr>
<tr>
<td>Type of diabetes (n)</td>
<td>Type 1 = 7; type 2 = 57</td>
<td>Type 1 = 7; type 2 = 57</td>
<td>Type 1 = 3; type 2 = 16</td>
<td>.21</td>
</tr>
<tr>
<td>Diabetes duration, years (mean ± SEM)</td>
<td>18.5 ± 1.5</td>
<td>17.3 ± 1.87</td>
<td>21.5 ± 2.58</td>
<td>.10</td>
</tr>
<tr>
<td>Glycated hemoglobin, % (mean ± SEM)</td>
<td>7.9 ± 1.4</td>
<td>7.9 ± 1.1</td>
<td>8.1 ± 1.8</td>
<td>.32</td>
</tr>
<tr>
<td>Treatment of the diabetes (n)</td>
<td>OHG = 21; insulin = 43</td>
<td>OHG = 30; insulin = 15</td>
<td>OHG = 5; insulin = 14</td>
<td>.66</td>
</tr>
<tr>
<td>History of ulcer and/or amputation (n)</td>
<td>28</td>
<td>22</td>
<td>6</td>
<td>.20</td>
</tr>
<tr>
<td>Smoking history (n)</td>
<td>9</td>
<td>7</td>
<td>2</td>
<td>.62</td>
</tr>
<tr>
<td>Ankle brachial index (mean ± SEM)</td>
<td>1.03 ± 0.03</td>
<td>1.05 ± 0.04</td>
<td>0.99 ± 0.05</td>
<td>.51</td>
</tr>
<tr>
<td>Artery's calcification</td>
<td>19</td>
<td>14</td>
<td>5</td>
<td>.66</td>
</tr>
<tr>
<td>TcPO₂ in reference site (chest; mean ± SEM)</td>
<td>51.8 ± 1.53</td>
<td>53.9 ± 1.87</td>
<td>46.8 ± 2.39</td>
<td>.019*</td>
</tr>
</tbody>
</table>

NOTES: TcPO₂ = transcutaneous oxygen pressure; SEM = standard error of the mean; OHG = oral hypoglycemics.

*Statistical significance P < .05

Figure 1. Location of 10 tested sites by Semmes Weinstein monofilament.

the same observer throughout the study.17-19 TcPO₂ measurements were repeated at 7, 30, 60, and 90 days after inclusion.

Data Analysis

Statistical analysis was carried out using the SPSS v15.0 software. Qualitative variables were described by absolute data and quantitative variables by mean, standard error of mean (SEM), and quartiles 25 and 75. The means were compared using the Wilcoxon test for related samples and the Mann–Whitney test for nonrelated samples. The association of qualitative variables was determined using the McNemar test. A probability level of $P < .05$ was set as the threshold for defining statistical significance.

Table 2. Complications Related to Diabetes Mellitus in the Study Population

<table>
<thead>
<tr>
<th>Complications of Diabetes</th>
<th>TcPO₂ ≥ 30 (n = 45)</th>
<th>TcPO₂ = 20-30 (n = 19)</th>
<th>PValue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiopathy</td>
<td>15</td>
<td>4</td>
<td>.32</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>12</td>
<td>9</td>
<td>.10</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>2</td>
<td>0</td>
<td>.35</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>25</td>
<td>14</td>
<td>.17</td>
</tr>
<tr>
<td>Hypertension</td>
<td>32</td>
<td>11</td>
<td>.30</td>
</tr>
<tr>
<td>Cardiovascular history</td>
<td>2</td>
<td>1</td>
<td>.88</td>
</tr>
</tbody>
</table>

Results

An increase in oxygen values at local level in patients who had TcPO2 values below 30 mmHg was observed at 30 days of treatment with the HOFA, continuing until the end of the study (Day 90). Patients with TcPO₂ >30 mm Hg (group 1) maintained their oxygenation levels with respect to baseline (day 0); any increases being not statistically significant (see Table 3 and Figure 2).

Improvement in cutaneous trophism was observed in both groups.

Skin color improved significantly in the majority of patients, showing improved local microcirculation (see Table 6).

Discussion

The results obtained in this study show the application of HOFA was associated with improved tissue oxygenation in the skin over the foot in patients who had TcPO₂ varying between 20 and 30 mm Hg at the start. This increase was statistically significant at 30 days compared with the start of the treatment ($25.3 ± 0.7$ vs $43.8 ± 2.3$ mm Hg; $P < .001$). An increasing trend in tissue oxygen was observed from day 7 (see Figure 1). On days 60 and 90, measurements were similar to those on day 30, thus
Table 3. Evolution of the TcPo2 Values* Through Wilcoxon Test in the Group of Patients With Neuropathy and Low Tissue Oxygen Levels After Application of HOFA

<table>
<thead>
<tr>
<th>Measurement Date</th>
<th>TcPo2 ≥ 30 (n = 45; mm Hg)</th>
<th>PValue</th>
<th>TcPo2 = 20-30 (n = 19; mm Hg)</th>
<th>PValue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0</td>
<td>47 ± 1.3</td>
<td></td>
<td>25.3 ± 0.7</td>
<td></td>
</tr>
<tr>
<td>Day 7</td>
<td>44.3 ± 1.8</td>
<td>.325</td>
<td>36.5 ± 4.3</td>
<td>.055</td>
</tr>
<tr>
<td>Day 30</td>
<td>45 ± 1.6</td>
<td>.558</td>
<td>43.8 ± 2.3</td>
<td>&lt;.001⁹⁶</td>
</tr>
<tr>
<td>Day 60</td>
<td>46.2 ± 1.7</td>
<td>.950</td>
<td>45.2 ± 2.9</td>
<td>&lt;.001⁹⁶</td>
</tr>
<tr>
<td>Day 90</td>
<td>47 ± 1.6</td>
<td>.732</td>
<td>42.1 ± 3.5</td>
<td>.002⁹⁶</td>
</tr>
</tbody>
</table>

NOTES: TcPo2 = transcutaneous oxygen pressure; HOFA = hyperoxygenated fatty acid.
*All values are given as mean ± standard error of the mean.
⁹⁶Statistical significance between day 0 and days 7, 30, 60, and 90 (P < .05).

Figure 2. Improvement in oxygenation through study
CV = control values, measured in reference sites at the chest.

indicating that a normal oxygenation level was maintained in the patients.

In group 1, that is, in patients with normal TcPo2, oxygenation levels remained statistically unaltered throughout the study. The reference (control) values taken in the chest did not show vary statistically significantly throughout the study in either of the groups (group 1, 53.9 ± 1.86 vs 53.5 ± 1.87; group 2, 46.8 ± 2.39 vs 46.5 ± 2.30; P = .818, nonsignificant).

It was surprising that HOFA treatment was more effective in the group of patients with TcPo2 values <30 mm Hg, which demonstrates a potential therapeutic benefit in this category of patients, thus raising the following question: Can the microcirculation be modified?

There are but few references regarding locally applied products that improve local microcirculation in diabetic patients. Incandela et al²³ reported the results of applying a gel that increased microcirculation in patients with diabetes mellitus at 10 hours from application. The same product has been used by other authors of the same group with outcomes of increased oxygenation at 2 and 4 weeks of applying the gel,²⁴,²⁵ with respect to the control group, where an upward trend was seen at 1 week, as was the case in our study. These studies measured changes in the microcirculation using the laser Doppler technique. Although both techniques (TcPo2 and laser Doppler) may be used for determining the microvascular status in diabetic patients,²⁶ the laser Doppler technique measures changes in local blood flow. It cannot comment on how such perfusion is used by the tissues, that is, metabolic changes. The TcPo2 technique is a direct measure of tissue hypoxia and is influenced by metabolic changes. Changes in hypoxia levels associated with capillary microangiopathy may be measured using this technique.

Recent reports suggest the effect of light therapy to study improvement in microcirculation after exposure to light sources. These types of irradiation stimulate microcirculation at the local and systemic levels through a mechanism of enhancement of endothelium-dependent and endothelium-independent vasodilation, in which nitric oxide plays a major role.²⁷

Urokinase has been demonstrated to be effective in improving microcirculation in critical limb ischemia.²⁸ Although the clinical results were good, the authors did not explore the values of the microcirculatory status. Kalani et al²⁹ studied the effects of daltiparin on local tissue oxygenation in patients with diabetes, severe vascular disease, and foot ulcers. Again TcPo2 showed good reproducibility and validity in the determination of microcirculatory status in diabetic patients.

The variables that describe skin integrity, such as dryness, skin shedding, and skin color, showed an improvement in approximately 90% of the patients. The restitution of skin trophism is directly related to the patients’ improved microcirculation, which contributes to a decreased risk of suffering lesions.

The changes to the sudomotor system are related to microvascularity problems, as well as the tendency for these patients to present anhydrosis, which makes them more vulnerable to sustaining foot injuries.³⁰ The advantage of applying a product that combines restoration of skin integrity with increased local oxygenation is that it guarantees greater
Table 4. Evolution of Skin Shedding Throughout the Study

<table>
<thead>
<tr>
<th>Skin Shedding</th>
<th>Absent</th>
<th>Moderate</th>
<th>Intense</th>
<th>Very Intense</th>
<th>PValue$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>G1</td>
<td>G2</td>
<td>G1</td>
<td>G2</td>
<td>G1</td>
</tr>
<tr>
<td>Day 0</td>
<td>28</td>
<td>10</td>
<td>16</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Day 7</td>
<td>40</td>
<td>13</td>
<td>4</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Day 30</td>
<td>40</td>
<td>14</td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Day 60</td>
<td>41</td>
<td>17</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Day 90</td>
<td>43</td>
<td>16</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

NOTES: G1 = patients with TcPo$_2$ > 30 mm Hg; G2 = patients with TcPo$_2$ < 30 mm Hg; HOFA = hyperoxygenated fatty acid.

$^a$It can be seen that 1 week after treatment with HOFA lotion, 53 patients stopped suffering from skin shedding.

$^b$McNemar’s test was used for statistics analysis. The significance difference was calculated between days 7, 30, 60, and 90 and day 0.

Table 5. Changes of Skin Dryness With Respect to the Baseline Values

<table>
<thead>
<tr>
<th>Skin Dryness</th>
<th>Absent</th>
<th>Moderate</th>
<th>Intense</th>
<th>Very Intense</th>
<th>PValue$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>G1</td>
<td>G2</td>
<td>G1</td>
<td>G2</td>
<td>G1</td>
</tr>
<tr>
<td>Day 0</td>
<td>17</td>
<td>8</td>
<td>22</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Day 7</td>
<td>32</td>
<td>14</td>
<td>9</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Day 30</td>
<td>41</td>
<td>15</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Day 60</td>
<td>40</td>
<td>14</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Day 90</td>
<td>43</td>
<td>15</td>
<td>2</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

NOTES: G1 = patients with TcPo$_2$ > 30 mm Hg; G2 = patients with TcPo$_2$ < 30 mm Hg; HOFA = hyperoxygenated fatty acid.

$^a$It was seen that at 30 days using the HOFA emulsion, 56% patients had hydrated skin.

$^b$McNemar’s test was used for statistics analysis. The significance difference was calculated between days 7, 30, 60, and 90 and day 0.

Table 6. Evolution of Skin Color Throughout the Study

<table>
<thead>
<tr>
<th>Skin Color</th>
<th>Very Pale</th>
<th>Pale</th>
<th>Normal</th>
<th>Mild Rubor</th>
<th>PValue$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>G1</td>
<td>G2</td>
<td>G1</td>
<td>G2</td>
<td>G1</td>
</tr>
<tr>
<td>Day 0</td>
<td>—</td>
<td>—</td>
<td>12</td>
<td>4</td>
<td>24</td>
</tr>
<tr>
<td>Day 7</td>
<td>—</td>
<td>—</td>
<td>9</td>
<td>3</td>
<td>33</td>
</tr>
<tr>
<td>Day 30</td>
<td>—</td>
<td>—</td>
<td>5</td>
<td>1</td>
<td>36</td>
</tr>
<tr>
<td>Day 60</td>
<td>—</td>
<td>—</td>
<td>2</td>
<td>1</td>
<td>41</td>
</tr>
<tr>
<td>Day 90</td>
<td>—</td>
<td>—</td>
<td>3</td>
<td>1</td>
<td>39</td>
</tr>
</tbody>
</table>

NOTES: G1 = patients with TcPo$_2$ > 30 mm Hg; G2 = patients with TcPo$_2$ < 30 mm Hg; HOFA = hyperoxygenated fatty acid.

$^a$Most patients showed normal skin color (53) at 30 days of treatment with an HOFA emulsion.

$^b$McNemar’s test was used for statistics analysis. The significance difference was calculated between days 7, 30, 60, and 90 and day 0.

efficacy in secondary prevention of wounds in this type of patients. None of the patients in our study suffered lesions in the follow-up.

Microcirculatory changes in diabetic foot are functional based on current thinking. Further research in this field, based on randomized controlled efficacy studies, is needed to study the potential of this therapy in the treatment and prevention of the microangiopathy of diabetic foot.

Declaration of Conflicting Interests
The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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References


Bios

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J. P. Sánchez-Rios, DPM, MSc, received his doctor in podiatric medicine degree in 2003 and master's in science degree in 2008. He is a podiatry physician at the Diabetic Foot Unit of the Complutense University Clinic. His role in the study was to
record clinical data, clinical settings of the patients, and to input data in SPSS.

E. García-Morales, DPM, PhD, received her doctor in podiatric medicine (2003) and PhD (2007) degrees from Complutense University, Madrid, Spain. She is a professor of clinical podiatry at Podiatry University School of Complutense University since 2007. She is also a podiatry physician at Diabetic Foot Unit of the Complutense University Clinic. Her role in the study was to record clinical data, clinical settings of the patients, and statistical analysis in SPSS.

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T. Segovia-Gómez, RN, obtained her nursing degree in 1968 from the Autonoma University of Madrid. She is the supervisor of the Multidisciplinary Chronics Ulcer Unit at the University Hospital “Puerta de Hierro” in Madrid. She is a member of the Board of Directors of GNEAUPP (member of EWMA). Her role in the study was to record clinical data and clinical settings of the patients.
INCREMENTO: La afectación microvascular del Pie Diabético produce una alteración funcional a nivel local que incide en la respuesta inmunitaria y reparadora del paciente, y lo expone al padecimiento de úlceras. Mepentol® Leche, una emulsión a base de ácidos grasos hiperoxigenados (AGHO), favorece la vasodilatación capilar y contribuyen a la regeneración de la piel, pudiendo mejorar la microcirculación en estos pacientes.

OBJETIVO: Evaluar el aumento de la microcirculación sanguínea mediante la medición de la presión transcutánea de oxígeno, demostrando un incremento de los valores de oxigenación transcutánea en el pie de pacientes a riesgo de Pie Diabético, después de la aplicación local de Mepentol® Leche.

MATERIAL Y MÉTODO: Estudio analítico prospectivo de seguimiento longitudinal en el que se incluyen 64 pacientes con afectación neuropática (TcPO₂>30 mmHg) y neuroisquémica (TcPO₂ entre 20-30 mmHg), a los que se les aplicó Mepentol® Leche dos veces al día durante 3 meses. El estado microvascular de los pacientes se estableció mediante la medición de la presión transcutánea de oxígeno (TcPO₂) en el día 0, 7, 30, 60 y 90 del estudio. También se registraron la evolución de la sequedad, descamación y coloración de la piel.

RESULTADOS: Mepentol® Leche aumenta los valores de oxigenación a nivel local en los pacientes neuroisquémicos de forma significativa a los 30 días de tratamiento, consiguiendo que este grupo alcance valores de TcPO₂ de normalidad, y manteniéndolos hasta la finalización del estudio (TcPO₂ día 0: 24,8 +/- 3,6 mmHg, TcPO₂ día 30: 43,2 +/- 10 mmHg; p=0,001, TcPO₂ Día 90: 42,2 +/- 15,7 mmHg; p=0,037). Los pacientes neuropáticos mantuvieron estables sus niveles de TcPO₂ con respecto a su nivel basal (TcPO₂ día 0: 46,3 +/- 8,5 mmHg vs TcPO₂ día 90: 46,7 +/- 7,5 mmHg; p=0,064). La sequedad y descamación de la piel mejoraron significativamente a los 7 días de tratamiento (p=0,001). La coloración de la piel recuperó su normalidad a los 30 días de tratamiento con respecto a la situación basal (p=0,005).

CONCLUSIONES: La aplicación de Mepentol® Leche produjo una mejora de la oxigenación local del pie de los pacientes a riesgo de Pie Diabético. El trofismo cutáneo mejoró clínicamente en estos pacientes al incrementar la microcirculación sanguínea.