STUDY ON THE EFFECTS OF THE RELAXSAN SOCK MEDICAL AID ON THE FEET OF DIABETIC, ATHLETIC AND HEALTHY SUBJECTS

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**INTRODUCTION**

The RelaxSan® sock, whose properties we analyzed, is made from a special seamless fabric, in silver and cotton thread, and has a particular characteristic: its "glove" form, or rather, its structure with individual inserts for each toe, just like gloves which are worn on the hands.

The study was carried out with enthusiasm, due to the innovativeness and typology of the product, and involved diabetic patients who were followed on an outpatient basis.

The main objective was to investigate the possibility of preventing the onset of inter-digital and circulatory problems for the diabetic subject. However, we also wanted to examine how to take advantage of the features of the
RelaxSan® Sock in order to guarantee maximum foot comfort when wearing athletic shoes.

Likewise, we wanted to extend our observations to healthy subjects who, while practicing normal lives, have suffered a series of age-specific foot problems due to the use of work shoes, or else deriving from intrinsic orthopaedic deformities.

**PROPERTIES OF THE RELAXSAN® SOCK**

The RelaxSan® Sock represents a typical example of textile advancement, designed to give the finished product a healthy connotation, which would otherwise be impossible with the use of single-yarn fabrics and with regular socks.

Finished textile products which are obtained through the use of advanced fabrics are generally called “braces”.

The bioavailability of a brace is not like that of its original single-yarn fabric, but is that of a fabric which is subjected to complex technological processes, during both the production and weaving phases.

This is how the medical devices are created, as required by the Italian Legislative Decree dated 24.2.97, which find prominent positions amongst our therapeutic instrumentation, both as preventive measures and as therapeutic supports, thereby opening the way for so-called "fabric therapy”.

In effect, the RelaxSan® Sock is a medical device which has been approved by the Ministry of Health and is recognized as Class I; due to its bioavailability, it is best employed as a brace for so-called "diabetic foot“, as it possesses features which render it quite suitable for this purpose.

First of all, it is seamless, so as to avoid any possibility of causing abrasion or irritation to the skin and to the toes.

Next is its construction, which is that of a glove, so that each toe has its own insert; this characteristic prevents friction between the toes and helps to prevent the formation of calluses and skin macerations due to excess sweating; mechanically as well, it tends to reduce toe conflicts.

The natural cotton fibre ensures both an anallergic effect and also allows for a constant foot temperature to be maintained, thereby providing a thermoregulatory effect.

The cotton fibres, which make up the fabric, have an internal cavity which helps to transport water.
Therefore, when in contact with the skin of the foot, the cotton absorbs the water contained within the perspiration and carries it outwards, thereby dissipating excess heat as well. During the winter, on the other hand, the fibre’s inner cavity acts as insulation against the cold. In this manner the foot remains dry in the summer, with minimal perspiration, and warm in the winter.

| ° “ glove “ shaped for the toes  
° seamless  
° natural cotton fibre  
° pure silver thread  
° absence of compression |
| Physical properties of the Relaxan Sock |

The silver thread was added in order to take advantage of the therapeutic and antibacterial properties which are characteristic of silver; these properties have been recognized, studied and approved for some time, especially for use in treating foot skin lesions. Tests performed regarding the use of silver for bacterial control have resulted positive in relation to

- Staphylococcus aureus
- Klebsiella pneumonia
- Pseudomonas aeruginosa
- Candida albicans
- E.Coli enterotoxin
From a practical perspective, the presence of silver in the fabric helps to neutralize foot odour by fighting the germs which cause it and neutralizes ammonia and denatured proteins. Silver also provides for an antibacterial effect which prevents the formation of inter-digital mucus.

After having been put on, the sock does not exert any compression on the arch, the foot or, especially, the ankle; for this reason there is no risk of the typical tourniquet effect, which could result in circulatory stagnation and the paralysis of the skin’s microcirculation.

These properties remain unaltered, even after numerous repeated washings: the only precaution which is required of the patient is to wear the sock properly, inserting each toe into its respective insert, just as he/she would do with a pair of gloves.

- Antibacterial and antimycotic effect
- Anallergic effect
- Neutralization of foot odour
- Foot temperature regulation
- Moisture transpiring effect
- Sanitizing effect
- Respects blood circulation
- Reduction of toe conflict

Health Properties of the Relaxan Sock

SURVEY OF DIABETIC PATIENTS

25 patients with diabetes were included in the survey, of whom

- 7 suffering from diabetic neuropathy and vasculopathy.
- 18 suffering from type II diabetes.
- 7 suffering from type I diabetes.
- 8 had suffered repeated foot ulcer episodes.

The patients were aged between 69 and 84 years old. Patients with open foot sores were excluded from the survey. Patients who were taken into consideration had had the disease for at least 10 years and were considered "at risk" for the onset of trophic foot ulcers, according to the recently proposed definition of "diabetic foot" formulated by the diabetic foot Study Group, namely:
“A foot with anatomical and functional alterations caused by occlusive peripheral arteriopathy and/or by diabetic neuropathy. This surpasses the definition established according to the WHO criteria as a ‘condition of infection, ulceration and/or destruction of underlying tissues, associated with neurological abnormalities and with various degrees of lower limb peripheral vascular disease’, and therefore is intended to extend the new definition of "diabetic foot" to all diabetics who, in the absence of ulcers, are nevertheless considered to be at ulcerative risk”

The classification which distinguishes the lesions (Wagner) also considers this condition by defining it as grade 0, and as such to be kept under observation and prevention.

The group of diabetic patients analyzed included:

- One patient with allergies to metals, with consequent skin cracking and hyper-reactivity with the formation of pustules and vesicles.
- One patient who, using a corn ointment, caused a neglected inter-digital lesion between the 4th and 5th toes, with subsequent formation of fibrin and prevention of healing.

<table>
<thead>
<tr>
<th>class</th>
<th>Anatomical-functional alteration</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Non-ulceration, presence of eventual deformities, edema, cellulite</td>
</tr>
<tr>
<td>1</td>
<td>Superficial ulcer</td>
</tr>
<tr>
<td>2</td>
<td>Deep ulcer down to the tendon, at the articular capsule down to the bone, without infection</td>
</tr>
<tr>
<td>3</td>
<td>Deep ulcer with abscess, osteomyelitis, septic arthritis</td>
</tr>
<tr>
<td>4</td>
<td>Localized gangrene on the fingers or the heel</td>
</tr>
<tr>
<td>5</td>
<td>Gangrene of the entire foot or a significant portion</td>
</tr>
</tbody>
</table>

Classification according to Wagner
The diabetic patients examined possessed the following foot abnormalities:

- Inter-digital callosities at risk of infection.
- Inter-digital friction.
- Toe overlapping resulting in skin maceration.
- Amputations with overloading problems affecting the other parts of the foot.
- Digital conflict resulting from thickened or hypertrophic toenails.
- Burning sensations and cold and/or hot feet (neuropathy framework).
- Inter-digital maceration and cracking resulting from poor hygiene.
- Retraction of hammer-toes (neuropathy framework).
- Feet sensitive to the minimum formation of callosities (vasculopathy framework).
- Problems linked to orthopaedic toe deformities (hallux valgus).

All of these issues, in a framework of diabetic neuropathy, with the consequent reduction in sensitivity associated with vascular disease, represent typical cases of "diabetic foot" at risk of ulceration. Therefore, even the slightest abrasion, given the concomitant presence of arterial insufficiency, could become infected and result in a lesion.

In this context, we decided to refer these patients to a fabric-therapy type treatment: The patients were provided with two pairs of RelaxSan® Socks and, after having been explained how to put them on properly, were asked to wear them instead of their normal socks.

There was no initial refusal, especially since the RelaxSan® Sock looks like an ordinary sock when worn; in fact, it is quite similar even with regards to colour, fabric thickness and height upon the ankle.

The fabric-therapy with RelaxSan® lasted for six months and the patients were asked to report back once a month in order for the results to be evaluated.

The topics of observation included

- Avoidance of toe overlapping.
- Reduction in perspiration.
- Reduction in inter-digital maceration.
- Appearance of ulcerations, even in poor hygienic conditions.
- Sensitivity of the skin to friction with the footwear.
- Protection of the skin against the mechanical action of the shoe.
- Presence of microbiologically toxic agents.
- Appearance of mechanical lesions resulting from digital conflict.
- Formation of inter-digital callosities.
- Consistency of inter-digital callosities.
Another 20 people, between the ages of 9 and 45, were taken under observation, including at least 10 of whom regularly participate in traumatic sports activities (such as running and/or football) and two of whom perform at competitive levels and have had insulin-dependent juvenile diabetes for at least 15 years.

Some healthy people who did not show any signs of complications resulting from diabetes, especially of a podiatric nature, were also inserted into the framework.

The subjects displayed typical problems with regards to the mechanical action footwear upon the foot: Some showed signs of persistent athlete’s foot, inflated-vesicle dermatomycosis or psoriasis of the sole of the foot.

Even for this group of patients it was deemed appropriate and advisable to initiate a fabric-therapy treatment with RelaxSan® Socks, since all of the subjects were required to wear rigid, work-safety shoes for long periods of time and required proper footwear control.

In particular, it was felt that these patients might benefit from a fabric-therapy treatment with the RelaxSan® Sock, thereby taking advantage of:

- The thermo-regulating and perspiration-transporting effect of its cotton fibres.
- The antibacterial and antimycotic action of the silver threading.
- The glove effect upon the toes.

Therefore, this group of patients also began the experiment for a period of six months, with short visits every 1-2 months, and were provided with two pairs of RelaxSan® Socks, after having been explained how to put them on properly, toe by toe, in such a way so as to avoid problems linked to improper wear.
After some initial concerns, the patients worked with enthusiasm and expressed both interest and dedication. The results gathered were decisively positive from a clinical point of view, both with regards to the use of the sock for diabetic foot, as well as with regards to its use with the athletic and healthy subjects.

The subjects with diabetic foot required repeated checks and greater care which, in some cases, even required the cooperation of family members in order to put the sock on properly.

The healthy and athletic subjects even began using the socks habitually and, in some cases, even changed their personal looks in order to wear them in place of their traditional nylon socks.

It was observed that, in the case of diabetic foot, the RelaxSan® Sock was particularly useful in preventing foot ulcerations, especially since it allowed the subjects greater control over situations, which are typical of neuropathy, related to pain reduction (i.e. a trivial lesion between the toes or the simple rubbing of a toe nail against a nearby toe) and above all eliminated all situations resulting from disease, failing eyesight or poor hygiene in elderly subjects.

In the 10 athletic and healthy subjects, we noted a significant reduction in all of their problems in relation to:

- Contrast with the footwear with mechanical trauma.
- Painful ingrown toenails.
- Inter-digital maceration (athlete’s foot).
- Foul-smelling perspiration (bromidrosis).
- Formation of vesicles and abrasions resulting from football footwear.
- Friction of the big toe with the 1st and 2nd toe in dance shoes, with pain during movement upon the tips.
- Reduction in the sensation of cold feet.

The diabetic subjects who regularly play football reported a remarkable feeling of protection from the shoe which, by its nature, is very narrow; the same sensation was also felt when the foot hit the ball. Likewise, these subjects reported a reduction in inter-digital perspiration and itchy cracking.

One subject who runs regularly reported the same results, but expressed slight difficulty in wearing the sock for prolonged periods of running (5 hours).
Wherever there were symptoms of itching resulting from dermatological conditions, good control of the disease over time was reported. In the presence of inter-digital callosity, these phenomena were observed to have decreased and to have maintained their "hardness", without becoming soft.

Even the patient with skin cracking and hyper-reactivity, with the formation of pustules and vesicles resulting from an allergy to metals, found wearing the RelaxSan® Socks beneficial as they kept the skin at the right level of humidity, thereby preventing cracks from developing into a painful state of dryness and flaking. Likewise, even the subject with inter-digital lesions resulting from the use of a corn ointment reported significant pain reduction after the mechanical cruentation of the fibrin.

The football players in particular experienced many benefits from wearing the RelaxSan® Socks, both for protection from the mechanical aggressiveness of the footwear as well as for the contrasts of play, but above all for protecting the tips of the toes against the cold during matches and on cold days in which they had previously had the "painful" experience of erythema pernio (chilblains).

Within the framework of the study, only one person stopped using the socks, claiming that they took too long to put on, while another complained that during the winter their toes felt cold.

Elderly patients found some difficulty in putting the socks on by themselves, due to difficulties in bending or else due to failing eyesight: hence the recommendation that for elderly diabetic patients at serious risk of ulceration, RelaxSan® Socks should be worn under the supervision of a relative, or of whomever cares for the patient, in order to be able to take advantage of all of the typical benefits that this new medical aid has to offer. We would like to add that the RelaxSan® Sock can be used both in summer as well as in winter, as it offers remarkable thermoregulation characteristics, and can therefore effectively become the natural brace for diabetic foot.

After having verified how the use of a textile brace, such as the RelaxSan® Sock, has its own therapeutic rationale which contributes to preventing and mitigating foot damage which would otherwise threaten the health and autonomy of the patient, we can conclude that we are enthusiastic about the results obtained in all of the fields of application.