

# CLINICAL TEST ON THE UTILIZATION OF A NEW FABRIC (TEXENERGY\*) FOR SOME FOOT CONDITIONS

## INTRODUCTION

In temperate countries, foot skin is usually in contact with leather, rubber or synthetic material shoes. The skin of some susceptible people may show a very troublesome symptom called hyperhidrosis: it is the hyperfunction of eccrine sweat-glands, a physiological mechanism that controls homeostasis, that is to say the thermoregulation of human body if environmental temperature or the temperature of a body part increases, as during physical exercise.

In some particular cases, hyperhidrosis can occur if there are endocrine or neurological illnesses, and very often, depending on the person, in relation to emotional reactions of fear and anxiety. In this case hyperhidrosis is defined as constitutional, it appears during youth, it is worsened by caffeine and nicotine intake and generally it persists in time, localizing mainly on hand palms, foot soles, armpits, on the face, nape of the neck, trunk and perianal region.

Hyperhidrosis involves a troublesome discomfort both for the person that suffers from it and for his/her social interpersonal relations, restricting the possibility to accomplish everyday activities. For what concerns the feet, hyperhidrosis involves an excessive maceration of the skin, due to a poor sweat evaporation, sometimes visible if you observe shoes. This maceration promotes bacterial and fungal infections, often combined with and made worse by the use of safety shoes, very tight for the workers that have to wear them: as a consequence, there is scaling of the horny layer, very often localized in interdigital spaces, and the development of unpleasant odours because of the presence in those spaces of coryneform bacteria which decompose the horny substance.

Although there are different therapeutical approaches, nothing can be considered with certainty effective and definitive, and each patient needs a personalized intervention program, often in relation to the attempts made previously.

Another condition frequently found is the presence of plantar hyperkeratosis, due to the thickening of the horny layer, as a protective reaction to a moderate rubbing or compression of the plantar skin: this condition usually occurs in overweight subjects or on some spots of the feet where the body weight exerts its pressure more intensely. In this case, some yellowish areas thicker than normal skin can be seen, which can also present cracks such as fissures or rhagades.

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\* TEXENERGY manufactured by GAFITEX, in cotton, polyamide and elastomer with copper, zinc and silicon yarns.

When hyperkeratosis is limited to hand palms or to foot soles, it is called tyloma or corn and it develops on spots where the skin undergoes a strong friction, for instance for the presence of rings, tight shoes (such as those used in some sports or worn for orthopaedic reasons) or wooden sandals.

## MATERIALS AND METHODS

The test was carried out on 100 subjects, 52 women and 48 men, aged between 18 and 72, some with dermatological foot problems, others without any foot pathology. For each subject a form was filed with his/her personal data, dermatological notes mainly about current or past foot problems, and data concerning the development of the test. Each subject underwent an accurate clinical check aiming at detecting any dermatological pathology of the feet; moreover, a laboratory analysis with a cultural examination was carried out to verify the possible presence of bacteria and/or fungi. Each person participating in the test was given samples of the TEXENERGY sock manufactured by GAFITEX, and he/she was advised to wear it at skin contact every day. Furthermore, each subject was requested not to change his/her habits, especially concerning the type of shoes worn and the foot hygiene. After 3 months of using the socks, each participant underwent a medical check that included an accurate clinical check of his/her feet, another laboratory analysis carried out only on those people who, during the first check, had shown a fungus and/or bacterium positivity. Every subject was also requested to report about the presence of side effects, if any, caused by the fact of wearing the socks, and to express his/her personal opinion about the effectiveness of the product. We divided the different cases into 3 groups:

- A) people suffering from hyperhidrosis with scaling in interdigital spaces and bad smelling feet;
- B) people suffering from plantar hyperkeratosis and people suffering from tylomas;
- C) people with healthy feet, regular gym-goers.

The first group represented 35% of the participants. During a local objective check, scaling in one or more interdigital spaces and/or on foot soles was detected. According to the seriousness of symptoms, the subjects were divided into three groups:

- 1) hyperhidrosis slight degree (40%)
- 2) hyperhidrosis medium degree (35%)
- 3) hyperhidrosis high degree (25%)

After 3 months, the same people who had undergone the medical check reported not to have had any side effect due to the use of the socks, they subjectively declared to have noted a clear improvement or the disappearance of hyperhidrosis and, as a consequence, of bad smelling feet as well. During a clinical check, we noted a reduction in scaling both in interdigital spaces and on foot soles. As a consequence, the three sub-groups of the beginning were divided as follows on the basis of the clinical check:

- 1) no symptoms (55%)
- 2) hyperhidrosis slight degree (35%)
- 3) hyperhidrosis medium degree (10%)

The results of the laboratory analysis carried out during the first and second check are shown below (table 1).

Table 1: results of the mycological examination carried out during the first and second check on subjects suffering from hyperhidrosis.

1st CHECK		2nd CHECK	
NEGATIVE CULTURAL EXAMINATION	7	NEGATIVE CULTURAL EXAMINATION	13
Trichophyton rubrum	5	Trichophyton rubrum	4
Trichophyton mentagrophytes	8	Trichophyton mentagrophytes	8
Bacteria	6	Bacteria	1

It can be deduced from these data that no significant changes in the number of isolated fungi were found during the second check; during the first check, the cultural examination had shown the presence of bacteria in 6 subjects, number that went down to 1 during the second check.

The second group represented 20% of the participants. During a local objective check, hyperkeratosis and rhagadiform lesions were detected, especially on heels, and tylomas. During the second check, the participants said to have noticed a clear reduction of callosities, which made walking easier to them as well. These subjective data were confirmed by the clinical check as well. The laboratory analysis carried out only on 8 subjects clinically suspected to suffer from dry tinea pedis had the results shown below (table 2).

Table 2: results of the mycological examination carried out during the first and second check on subjects suffering from hyperkeratosis.

1st CHECK		2nd CHECK	
NEGATIVE CULTURAL EXAMINATION	5	NEGATIVE CULTURAL EXAMINATION	6
Trichophyton rubrum	2	Trichophyton rubrum	1
Trichophyton mentagrophytes	1	Trichophyton mentagrophytes	1
Bacteria	0	Bacteria	0

For this second group of patients as well, it can be deduced that the results of the laboratory analysis did not change significantly during the second check.

The third group represented 45% of the participants. During the first check, the local objective check had shown that these people had perfectly healthy feet. The same people underwent a medical check three months later and they still had feet without any mycotic, microbial and viral infection. The results of the laboratory analysis carried out both during the first and second check, that took place three months later, were all negative.

## CONCLUSIONS

The test carried out about the use of the TEXENERGY sock manufactured by GAFITEX did not show any irritant effect caused by the device under examination. The test leads to deduce that this device can prove itself to be a valid support in the symptomatic therapy of hyperhidrosis: our data show that at the second check, carried out three months after the first, 55% of the participants did not show clinically any sign of hyperhidrosis, 35% still suffered from hyperhidrosis of slight degree and 10% from hyperhidrosis of medium degree.

Moreover, also the subjects who had plantar hyperkeratosis, rhagadiform lesions and tylomas, representing 20% of the participants in the test, during the second check reported to have noticed a reduction of callosities and of hyperkeratosis, and they remarked that they could walk more easily, a subjective remark that was confirmed by the objective clinical check as well.

As to the prevention of infectious symptoms of the feet, we did not notice any infection in the participants in the test who were regular gym-goers or who practised sports activities such as football, basketball etc., people who are by definition exposed to the risk of catching infections because of the communal use of sports facilities and equipments. However, our data refer to too short an observation time span and to too limited a group of people and, as a consequence, they would require a further confirmation, only for this last group.

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**AUTHENTICATION OF THE STUDY**

The undersigned, Dr. Marisa Mosca, in charge of the evaluation, declare on her own responsibility that the test was carried out according to the principles of good clinical practice and of the Helsinki Declaration (1989).

All the documents concerning this study will be kept on our files for three years.

This study consists of 7 pages, apart from this one, numbered from 1 to 7.

Dott.ssa Marisa Mosca

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