

Clinical Study on efficacy of undergarments manufactured with medicated silk (DermaSilk®) in some gynaecological disease

MM Anceschi*, G Marcellini HG*

(Department of Gynaecological Science, Perinatology and Puericulture – University of Study Rome “La Sapienza”*

Preface

The itchiness, the tingle and the pain are symptoms that often are linked to the infections by candida, to vulvo-vaginitis and to other gynaecological inflammatory disease or on the other hand, they are a frequent reason of specialistic counselling.

The classical pharmacotherapy, by general and/or topical route, not always achieve the efficacy expected but, sometimes, it can bring forth numerous side-effects, included some phenomenons of sensibilization, that worsen the clinical picture itself.

The pudendas area is necessarily in contact with undergarments, that have different shape and faabrics' composition, and the local ecosystem can result altered owing to imbibition by hyperhidrosis, by accumulation of secretions and picking up, from the cotton fibers, in microbics charges that contribute to prolongation of the prognosis.

In fact, the cotton even though is the most widespread fabric used for the production of these garments, is a material that, because of its characteristic structure, may induce skin irritation^{2,3}; such structure is constituted by millions of rough short fibers (1-3 cm) with flat and irregular section that must extend and contract themselves with a spiral movement in order to absorb and give up the damp.

The silk fiber, instead, shows a structure very similar to the structure of the human hair (97 % proteins, 3 % fats and ceramids) and it is composed of a series of totally smooth and cilindric thread long more than 800 metres, that don't present irritating mechanical frictions and ensure an high resistance against the wear.

In particular the silk undergarment *DermaSilk®*, by the increase and the reduction of the diameter of the cilindric thread, have an high hygroscopic capacity to absorb the sweat (up to about 30 % of own weight without appearing wet).

Since time the industries are trying out the possibility to usage of textiles treated with up-to date tecniques of impregnation of the fabrics itself with sensors and/or chemical, pharmacological compounds that have leded to revolutionary results in military, aerospaceal and sports field.

A study, performed in Japan by Sugihara et al^{4,5}, has evaluated the effects from a silks' film vs traditional fabrics (cotton) on cutaneous injuries, has showed that, in the first case, the patients healed 7 days earlier.

OBJECT OF THE RESEARCH

The object of this work is to evaluate, through an observational study, the clinical efficacy of the use of undergarments, based on utilization of *DermaSilk®* with *ÆGIS Microbe Shield™*, in the gynaecological diseases of pudenda characterized by erythema and subjective troubles .

The silk vest DermaSilk® has an high hygroscopic capacity of absorption, such characteristic is very important, in the treatment of the cutaneous and mucocutaneous inflammatory diseases, because it helps to preserve the skin water balance by carrying out a softening and soothing action that can turn out of particular efficacy about the injuries of the female genital apparatus (vestibulitis, external herpetic lesions, bartholinitis, scar resolution of the birth, ecc). The same function is provided by its sweating property that concur, by decreasing the diaphoresis, to control the cutaneous temperature.

The antibacterial properties of Dermasilk result from the bond to the silk thread of a strong antibacterial, the compound ÆGIS: 3 (trimetoxysilil) propildimethyloctadecylammonium-chloride), a quaternary ammonium salt that carry out its microbicidal activity either for direct contact (physical action) with the micro-organism membrane or for ionic action. The spectrum of activity is highly broad, and it include bacteria fungus and micetes. The fact that such activity is not carried out by the diffusion of the compound in the textile but rather by the adhesion of the micro-organism to the compound bound to the silk fiber by a covalent bond, make the compound particularly appropriate to the treatment of all the microbial inflammatory diseases, located in the perineal area.

PATIENTS AND METHOD

We have recruited 94 women aged between 23 and 71 years (median age 41 years old) in a period of time extended for six months and started in November 2003. All the patients showed acute obstetrical/gynaecological diseases, of inflammatory sort such as chronic Vulvovaginitis with vulvar burning , Vulvar and Perineal herpetic lesions, Folliculitis, Vestibulitis, enucleation outcomes from the Bartolini's cystis and Urethritis.

To 47 patients (half of them was chosen with an alternate randomization) in addition to a standard pharmacological therapy, has been prescribed the use of panties manufactured with MICROAIR DermaSilk®, a pure form of silk made up entirely of fibroin) and medicated with ÆGIS Microbe Shield™ (GROUP A). All the subjects of this trial have been informed about the frequency and the procedure of clothings' wash.

At all of the patients we have provided a questionnaire containing a card for the semi-quantitative evaluation of "discomfort", fully similar to the pains' VAS (Visual Analogic Scale) (Tab.1), which was to fill in immediately and then after 7 days from the beginning of the treatment. The check-up, on average, has been carried out 14 days after the beginning of the treatment.

RESULTS

FIRST MEDICAL EXAMINATION

80 patients have give back the questionnaire filled out, 43 belonging to the treatment group and 37 to the control group. 7 patients in each group have been missed to follow-up.

At the time of the check-up the VAS means score is resulted to be 8.4 in the treatment group and 7.8 (NS) in the control group. 7 days after in the group A the means score was 2.4 vs 4.9 in the control group (Tab II).

AFTER 7 DAYS

After 7 days, among the 43 women belonging to the group A, 7 of them (15 %) showed itchiness, 10 (23.2 %) tingle, 9 itchiness and tingle (20.9 %), 5 (11.6 %) pain, 12 no symptoms (27.9 %).

In the control group, instead, the patients respectively showed: 11 of them (29.17 %) itchininess, 12 (32 %) tingle, 8 itchininess and tingle (21.6 %), (13.5 %) pain, no symptoms 1 (2.7) (Tab. III).

AFTER 14 DAYS

At the check-up after 14 days, we have can observe the healing of 37 women belonging to the group A (86 %) vs 18 (48.6 %) belonging to the group B ($p=0.002$) (Tab. IV).

As regards these last few patients (group B), the 21 women that still showed symptoms was thereby represented: 12 (59.4 %) showed a slight rubefaction more or less linked to the itchininess, 7 (31,2 %) a noticeable flush with tingle and the remaining 2 (9,4 %) maintained a serious clinical picture (pain).

DISCUSSION AND CONCLUSIONS

In this our preliminary experience, we have observed that the using of medicated garments is very effective in relieving the symptomatology and in producing an high percentage of healings on wet epithelial surfaces.

The patients have reported an instantaneous feeling of well-being in the early phase of application (first 2 hours).

Some patients, who have obtained such beneficial effects up to recovery, have decided, of their own free will, to put on it once again when the first symptoms of recidiva have arisen, showing in that way an excellent compliance of the product.

Some patients use the product as a general rule when they do a sport or gym activity.

The skin of females pudenda affected by inflammatory pathologies is very susceptible to many other factor as, for example, the mechanical action of friction from cotton undergarments which, moreover, promote the bacterial over-infections because they allow the harnessing of such microbes among its own irregular section fibres.

We have seen that, the silk, instead, because of its specific structure, doesn't produce neither this type of complications nor other type.

In fact, in our study, we had the possibility to show, with statistical significance, that the patients to whom it had been requested to put on silk undergarments, without sericin type MICROAIR Dermalilk® with ÆGIS MICROBE SHIELD™, have shown a more early resolution of pathological condition (about 10 days), at the same age and severity of disease, against to those (group B) that have put on cotton undergarments.

The benefits quickly arises (decrease of the itching symptom within an hour) because the reduction of the bacterial over-infection enable to the irritated/injured skin to recover, in short time, the own function of barrier.

Finally, we can affirm that the use of undergarment manufactured in MICROAIR Dermalilk® with ÆGIS Microbe Shield™ alleviates, within 12 hours from the putting on of the undergarment, the itchy-painful symptomatology and allows a more quick recovery from the inflammatory status.

Tab. I

Questionnaire administered to the patients

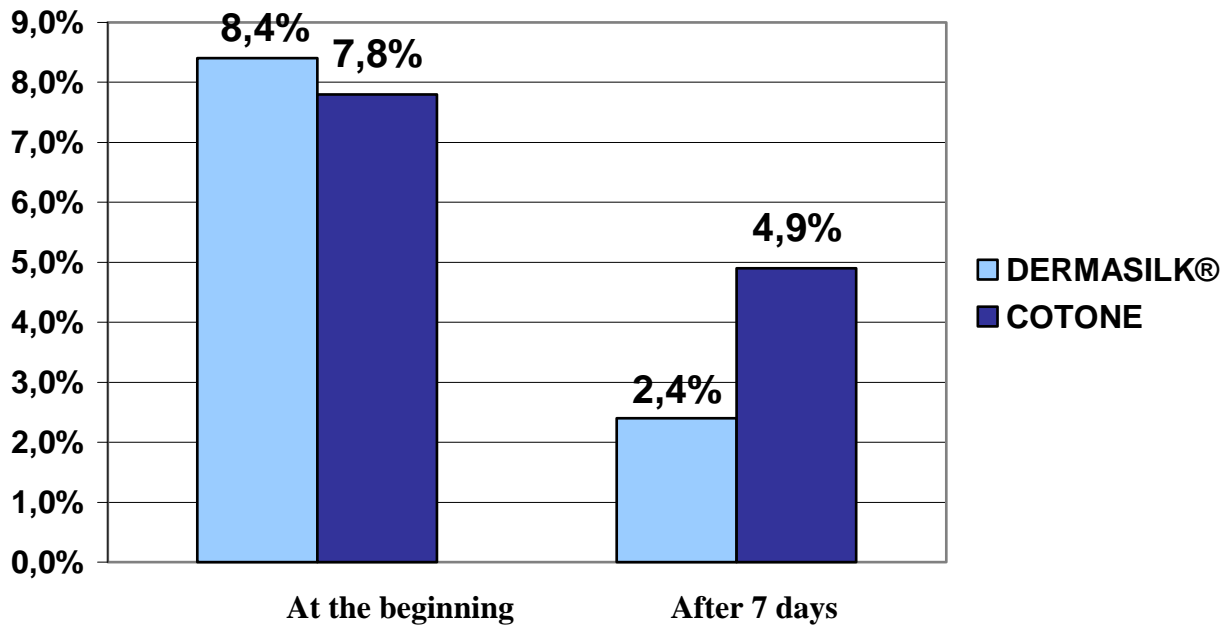
If you should give a score to the “discomfort” (trouble and/or irritability) from 0 to 10 as represented by the line under displayed, what number should you sign when the discomfort is the maximum of the intensity?

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
itchiness/trouble tingle/intolerance pain/intolerability

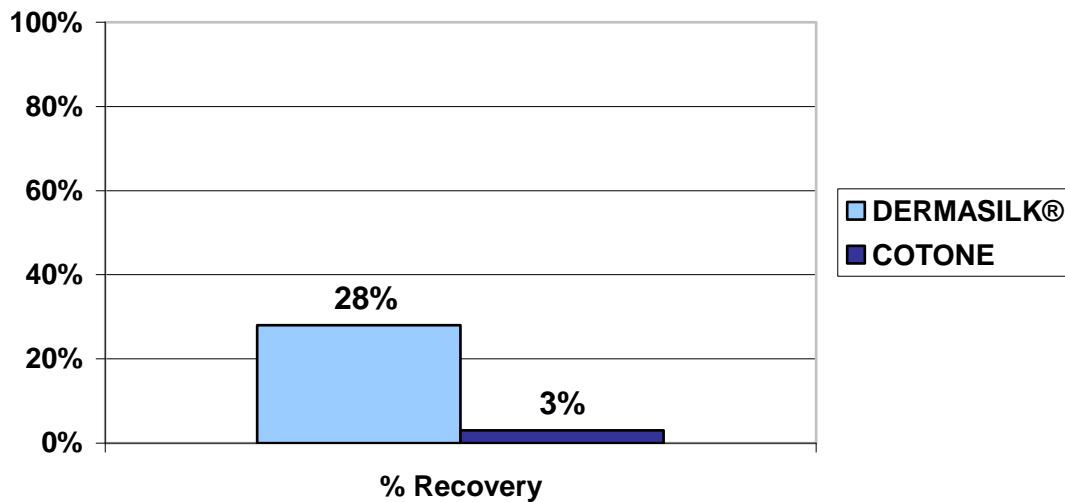
And what number should you sign after having put on the undergarment?

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
itchiness/trouble tingle/intolerance pain/intolerability

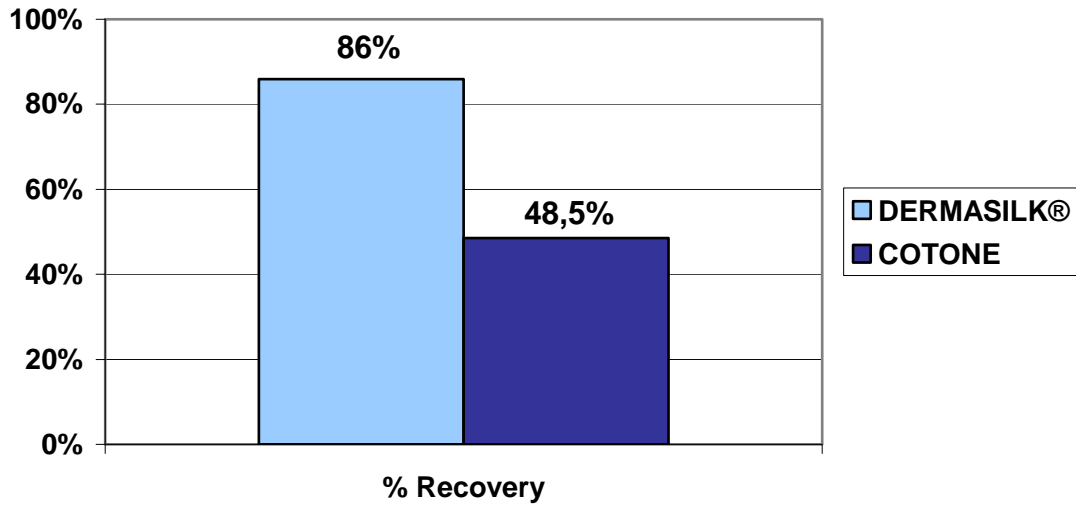
Tab. II: Average values of “discomfort” VAS (Visual Analogic Scale) at the beginning and after 7 days of treatment and use of Dermasilk® underwear compared with cotton



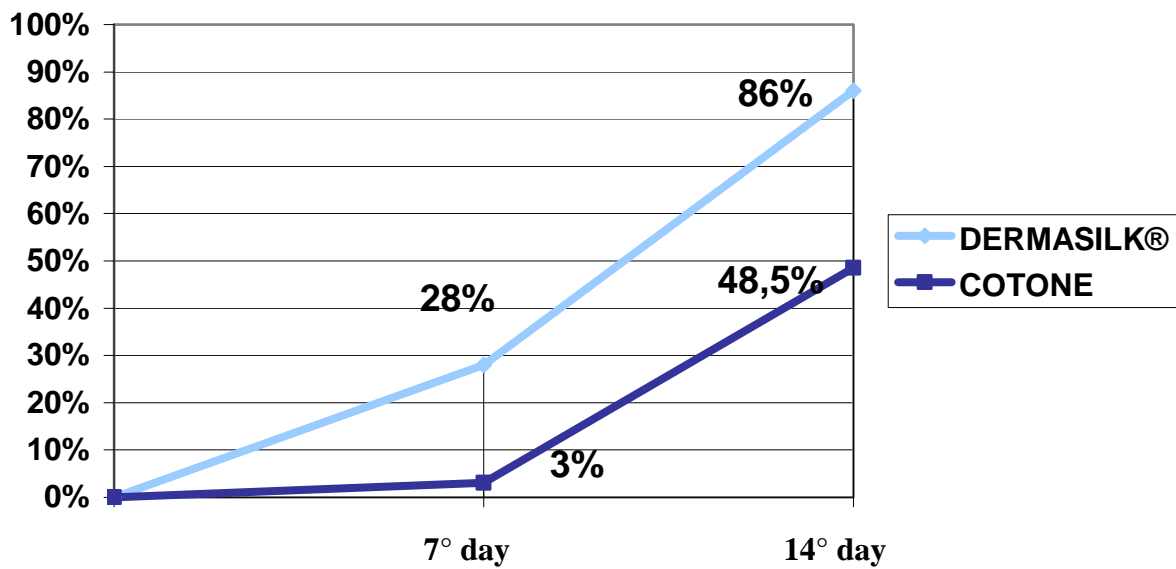
Tab. III Percentage of full recovery after 7 days



Tab. IV Percentage of full recovery after 14 days (p = 0.002)



Tab. V: Progress of recovery using Dermasilk® underwear versus cotton.



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