Use of DermaSilk® briefs in recurrent vulvovaginal candidosis:
safety and effectiveness

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OBJECTIVE OF THE STUDY
Compare DermaSilk® underwear in pure silk protein with placebo cotton underwear, to see whether the use of
DermaSilk may be a useful additional tool in the treatment of Recurrent Vulvovaginal Thrush (RVVT).

- **Double blind randomised study DermaSilk briefs vs placebo briefs in pure cotton**
- **Patients enrolled:** 96 women (mean age, 30.25 years) suffering from Recurrent Vulvovaginal Thrush, for 1 to 6 years, mean 2.4 years.
- **48 patients used DermaSilk briefs** (DS group)
- **48 patients used cotton briefs** (CT group)

The randomised double blind study involved 96 women (mean age 30.25) with a long history of RVVT (from 1
to 6 years, mean 2.4 years) who did not respond completely to the antimycotic therapy administered orally. In
the six months prior to the start of the study they had already been treated with standard antimycotic therapy
but continued to present relapses and vulvar irritation.

At the time of recruiting, the suitable patients presented an episode of acute VVT, a positive vaginal culture for
Candida and a level 3 of severity of vaginitis as described by Sobel et al. This system for measuring the
severity of the symptoms evaluates the symptoms (itching, irritation and burning) and the objective signs
(erythema, oedema and skin wounds or fissuring).
The severity of each sign and symptom was classified on a scale from 0 (absent) to 3 (severe).
In each patient bacterial vaginosis was excluded thanks to a measurement of the pH and a microscope
examination with Gram staining.

Abstract written by Alpretec Srl
The yeast cultures indicated Candida Albicans in 82 patients and Candida Non Albicans in 14 (6 in the DermaSilk Group and 8 in the Cotton Group).

The mean duration of recurrent VVT and the incidence of the symptoms and the objective signs were not statistically different between the two groups, even though burning and dyspareunia were slightly more frequent in the DermaSilk group.

One group was told to use cotton underwear (CT) and the other group DermaSilk® underwear (DS). Both groups were treated with Fluconazole (150 mg once a week) for six months.

Each patient was given a sealed envelope containing 3 pairs of DermaSilk briefs or 3 pairs of cotton briefs. Each envelope was identified with a progressive number; the correspondence between the number on the envelope and its content was communicated by the manufacturer of the briefs only at the end of the study.

The patients were asked to wear these briefs, night and day, throughout the duration of the study. During check-ups, after 1, 3 and 6 months, the cultures for Candida were repeated and the measurements of the symptoms and of the objective signs. A score of 3 with a positive culture was considered a relapse.

RESULTS
No patient reported any collateral effects. Both groups showed a similar reduction of symptoms and of objective signs during the first month, but after 3 months a difference began to appear in favour of the DermaSilk group as regards itching, burning and erythema.

In the sixth month the patients in the DS group showed a significant decrease of itching, erythema (Fischer exact test p<0.0001) and burning (Fischer exact test p<0.05) in comparison with the patients in the CT group.
Most of the patients in the DS group (32/48, 66.7%) had no relapses or had only one, whereas in the CT group most (29/48, 60.5%) confirmed 2 or more relapses, as before recruiting.

The results show that at the end of the study no patient in the DermaSilk group suffered any longer from either itching or erythema, while in the Cotton group 50% continued to suffer from itching and 75% from erythema.

At the end of the study in both groups no other symptoms (burning and vulvar irritation) or objective signs (oedema and fissuring) were present in any patient.

The number of relapses in the study is higher than in other reports, but it must be stressed that our patients suffered from a particularly persistent form of RVVT and had had 4 or more episodes of VVT during the previous year, treated with a long-term antimycotic therapy.