DermaSilk® Briefs in Vulvar Lichen Sclerosus: An Adjuvant Tool

Antonietta D’Antuono¹, Sara Bellavista¹, Francesca Negosanti¹, Stefania Zauli¹, Elena Baldi², e Annalisa Patrizi¹

¹Dipartimento di Medicina Interna, Geriatria e Nefrologia, Sezione di Dermatologia, Ospedale San'Orsola-Malpighi, Università di Bologna; e ²Dipartimento di Medicina e Salute Pubblica, Università di Bologna, Bologna, Italia

STUDY OBJECTIVE

To evaluate whether DermaSilk briefs, made of pure silk fibroin with a permanent antimicrobial treatment, could be an adjuvant tool in the management of vulvar lichen sclerosus (LS).

MATERIALI e METODI

- Randomized double-blind study comparing DermaSilk versus placebo cotton briefs
- Patients recruited: 42 women (median age 51.5 years) affected by lichen sclerosus from 6 months to 12 years before consultation (mean duration = 2.8 years)
- 21 patients wore Dermasilk briefs (DS group)
- 21 patients wore cotton briefs (CT group)

Both groups were also treated with standard topic corticosteroid (clobetasol propionate 0.05% ointment) and vitamin E moisturizer.

For each patient, an evaluation of objective genital signs and subjective symptoms typical of LS was recorded, after 1 month and after 6 months from the beginning of the study.
RESULTS

After 6 months, all the patients reported a partial or total improvement in the subjective symptoms and in the objective signs.
- In the patients of DS group the improvement was better and faster in the symptoms of itching (Fischer exact test, p<0.05), skin irritation, burning sensation and pain (Fischer exact test, p<0.0001), as showed in the below graphics and in the following table.
- As the objective examination is concerned, the more significant difference between DS group and CT group, was seen in the erythema (Fischer exact test, p<0.05). During the six months study, in the DS group patients with erythema passed from 21 to 9, while in the CT group they passed from 21 to 19.

The graphics show the decrease of total score of the severity of itching, burning, pain in DS group and CT group.
In grey the effects of standard treatment in addition to cotton briefs, in green the improvement due to DermaSilk underwear.

* Graphics from the Poster presentation of the study - 84° National Congress SIDeMaST, Florence 10-13 June 2009
### Comparison - DermaSilk® versus Cotton

**Number of patients which still report the initial symptoms at the end of the study**

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>DS GROUP</th>
<th>CT GROUP</th>
<th>P (Fischer test)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of patients at baseline</td>
<td>Number of patients after 6 months</td>
<td>Number of patients at baseline</td>
</tr>
<tr>
<td><strong>ITCHING</strong></td>
<td>13</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td><strong>PAIN</strong></td>
<td>20</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td><strong>BURNING</strong></td>
<td>21</td>
<td>9</td>
<td>21</td>
</tr>
<tr>
<td><strong>DYSPAREUNIA</strong></td>
<td>20</td>
<td>9</td>
<td>16</td>
</tr>
<tr>
<td><strong>ERYTHEMA</strong></td>
<td>21</td>
<td>9</td>
<td>21</td>
</tr>
</tbody>
</table>

### CONCLUSIONS

“In this study, DermaSilk fabric seemed to be a useful adjuvant tool to topical treatment in producing a better and more rapid control of symptoms in patients with LS. DermaSilk works by minimizing skin and mucosal irritation often induced by other fabrics made of rougher fibers and by maintaining a stable water and temperature balance thanks to its hygroscopic and heat-regulation properties. It is these properties that qualify it to be considered a suitable adjunct in the management of LS.”