

Lenzing PROFILEN® PTFE Fibers in Medical Textile Applications

Volker Biladt and Gallus Durz

Lenzing Plastics GmbH & Co KG, Werkstraße 2, 4860 Lenzing, Austria

Phone: +43 7672 701 3974, email: v.biladt@lenzing-plastics.com

Abstract

PTFE fibers are an absolute niche product in the global fiber industry. However over the years due to the outstanding and unique characteristics, PTFE fibers got well established in many technical applications. Lenzing Plastics together with its customers is continuously working to introduce PTFE fibers into new markets, where the outstanding performance can add value to textile products. One core target market is medical textiles, where Lenzing PROFILEN® PTFE fibers are successfully used in a few different product groups already. In this article the PTFE fiber and the characteristics relevant for medical applications will be introduced. Three product groups based on PTFE fibers will be described including the findings in clinical tests on the corresponding end products. Finally an outlook to future possible applications within the medical sector will be done.

Keywords: PTFE, fibre, decubitus

Introduction

The polymer PTFE (Polytetrafluorethylen) is an outstanding polymer regarding its performance in many ways. It shows a very broad temperature resistance from minus 200° C up to 280° C in permanent exposure. PTFE is also the polymer with the highest chemical resistance among all plastics due to the extremely strong bond between the carbon and the fluor atom. So it is considered as chemically inert. And the third key characteristic is its very low friction coefficient of around 0.1, in dry as well as in humid condition. Beside that it is totally UV resistant and completely hydrophobic. Normally such a number of great advantages are accompanied with some disadvantages; in case of PTFE

the disadvantage is the difficulty to produce fibres and filaments out of this polymer, as PTFE is not meltable. Nevertheless Lenzing Plastics GmbH was able to overcome this hurdle and is producing PTFE fibres and filaments now since more than 30 years, sold as Lenzing PROFILEN®. In the beginning the above mentioned key benefits of Lenzing PROFILEN® PTFE were mainly valued in the technical textiles industry, such as the field of filtration or compression packing. The use of PTFE fibres is absolutely necessary in applications where every other textile material is rapidly getting destroyed. Nevertheless over the years Lenzing Plastics explored new markets, where PTFE can add value to existing or

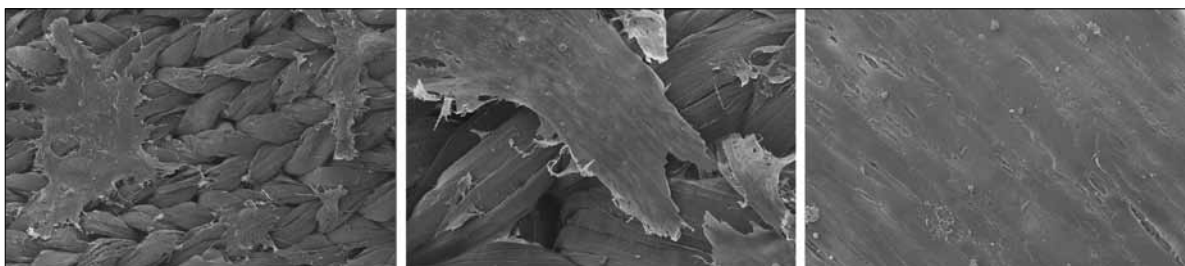


Figure 1. Biocompatibility - human cell growth on Lenzing PROFILEN® fabric (day 0 to 8). [1]

new products, one of those is the market of medical textiles and permanent implants. PTFE is nearly chemically inert and does not react with any substance, resulting in a very high biocompatibility of Lenzing PROFILEN® PTFE fibres (see Figure 1).

The low friction coefficient and the related low surface tension of PTFE bring two benefits in the medical surrounding: very low skin irritation when used in medical textiles outside the body and the “non-stick effect”. Due to this low surface tension and the slippery surface nothing is sticking on a PTFE fabric.

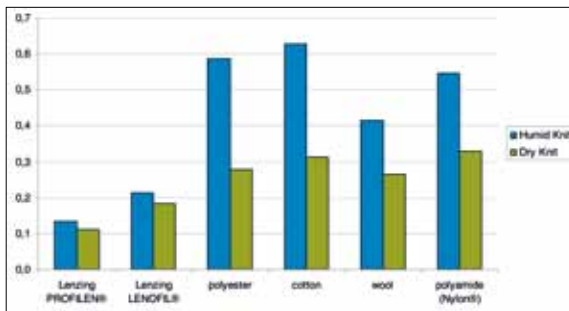


Figure 2. Coefficient of friction of different fibres. [2]

Additionally to those key advantages the strong hydrophobia of PTFE enables an efficient moisture management in a fabric and Lenzing PROFILEN® fibres are extremely durable in contact with the skin. Even many industrial washing cycles will not attack the fibre, as the high temperature window and the chemical resistance prevent the fibre from any damage.

Applications for PTFE Fibers in Medical textiles

Over the last few years Lenzing Plastics was working to support customers in developments in many fields of medical applications and currently in the following areas Lenzing PROFILEN® PTFE fibres are used successfully:

- 1) Surgical sutures and yarns for permanent implants (heart valves)
Key benefits: excellent biocompatibility, softness, “non-stick effect”
- 2) Garments for patients suffering Psoriasis
Key benefits: low friction of fibre on the skin; “non stick effect”; perfect moisture management of fabric
- 2) Bed sheets for hospitals to prevent Decubitus / Pressure ulcer
Key benefits: low friction, perfect moisture management, “non-stick effect”

In all three applications clinical trials were done to prove the effect of PTFE in the respective surrounding

and all showed very positive results, which will be summarized in the following section.

Surgical Sutures and Yarns for Permanent Implants

Every medical device for permanent or partial implant constructed with Lenzing PROFILEN® yarns has to be certified and approved by regulatory affairs in the region it is meant to be sold in. Lenzing Plastics itself got certified with ISO 13485. So far there are no cases where Lenzing PROFILEN® yarns did not pass the evaluation and already several devices are sold regularly, starting from heart valves (class 3 implants) to relatively simple surgical sutures (sterilized yarn with a needle attached). This application is not the focus of this article, if you look for further details, please contact the author.

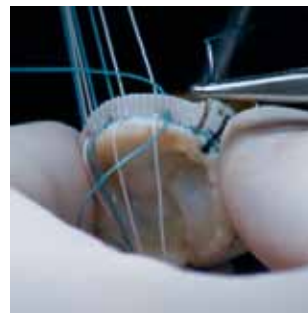


Figure 3. Surgical sutures.

Garments For Patients Suffering from Psoriasis

Psoriasis is a non-curable disease where actually 2-3% of world population (125 Million people) is suffering from. [3] Psoriasis is not a cosmetic problem; nearly 60% of the people with psoriasis reported their disease to be a large problem in their everyday life.[4] Just in the USA total direct and indirect health care costs of psoriasis for patients are calculated at USD 11.25 billion annually, with work loss accounting for 40 percent of the cost burden.[5] Current treatment is mainly creams to reduce the itching and prevent further damage of the skin as well as several pharmaceuticals. In order to offer a sustainable and long term solution, one of our customers developed a product line using 51 to 100% of Lenzing PROFILEN® PTFE fibres sold as TEPSON® in form of socks, underwear, shirts, sleeves and bed sheets.[6] TEPSON® garments are not a cure but an effective instrument that provides relief and an increased sense of wellbeing.

Depending on the product, PTFE fibers are blended in the knit structure with Elastan, Polyamide or cotton in the following product lines:

- Skin Bed: 67% PTFE fiber; 33% cotton
- Skin comfort: 51% PTFE fiber; 46% cotton; 3% Polyamide
- Skin Protector: 100% PTFE fiber
- Skin Active: 95% PTFE fiber, 5% Elastan

Table 1. Fabric comparison – permeability.

fabric type	Area weight g/m ²	Thickness mm	R(ct) m ² K/W	R(ct) Average	R(et) m ² Pa/W	R(et) Average
Skin bed 1	160,0000	0,1400	0,0180	0,0160	5,8383	5,5875
Skin bed 2			0,0151		5,4278	
Skin bed 3			0,0150		5,4964	
Skin comfort 1	230,0000	0,5800	0,0181	0,0158	3,0847	3,2078
Skin comfort 2			0,0148		3,2075	
Skin comfort 3			0,0144		3,3313	
Skin protector 1	160,0000	0,2600	0,0037	0,0031	0,8618	0,9300
Skin protector 2			0,0032		0,7069	
Skin protector 3			0,0024		1,2212	
Skin active 1	220,0000	0,3300	0,0040	0,0037	2,2185	2,2484
Skin active 2			0,0038		2,5327	
Skin active 3			0,0034		1,9939	

To prove the effect of the TEPSO[®] fabric containing Lenzing PROFILEN[®] PTFE fibres the following clinical tests were conducted: pilot study, palmoplantar psoriasis study and pustular palmoplantar psoriasis study. In all three studies patients were randomly equipped with garments (socks) either out of the TEPSO[®] product line or similar products out of 100% cotton. With a quality of life judgement by the patients based on visual analogue scale (VAS) and a global assessment by a physician both products were evaluated after a period of 4 weeks of testing. In all three clinical studies with a total of 52 patients there was a clear statistical significance for the improvement of patient's global satisfaction as well as positive assessment by the physician.[7]

Furthermore a study of the thermo physiological comfort on TEPSO[®] fabrics by means of a skin model apparatus [8] was conducted as shown in Table 1. These results show clearly that the fabrics containing more PTFE fiber have a higher thermal conductivity, visible in the thermal resistance (R(ct)) values of Skin protector and Skin active sample, composed by, respectively, 100% and 95% PTFE fiber. They have a negligible thermal resistance, which is a very important point as it allows the fabric to very quickly absorb and dissipate the body heat. The thermal resistance slightly increases in that samples cotton is present in the blend (Skin bed and Skin comfort). The same tendency can be seen in the values of Evaporative resistance (R(et)). The samples tested are all very breathable, as all show a R(et) < 6 m²Pa/W, so based on categorization of the Hohenstein institute they are considered "extremely breathable" fabrics. Again Skin protector and Skin active with their high content of PTFE fibers have the lowest Evaporative resistance, probably a result of the hydrophobic PTFE fibers. The excellent hydrophobia allows a better water vapour crossing through the fabric,

whereas the samples containing cotton show a slight increase of resistance caused by the high absorption capacity of cotton.

As conclusion it can be said, that the analysis of the different fabrics highlighted two very important features for garments for Psoriasis patients:

- 1) The fabrics offer a high thermal conductivity that permits to gather and dissipate very quickly the body heat, which fosters the body temperature regulation.
- 2) The excellent breathability facilitates the body sweat removal, maintaining the body always dry and in comfort conditions.



Figure 4. TEPSO[®] garment for Psoriasis.

Bed Sheets for Decubitus / Pressure Ulcer Prevention

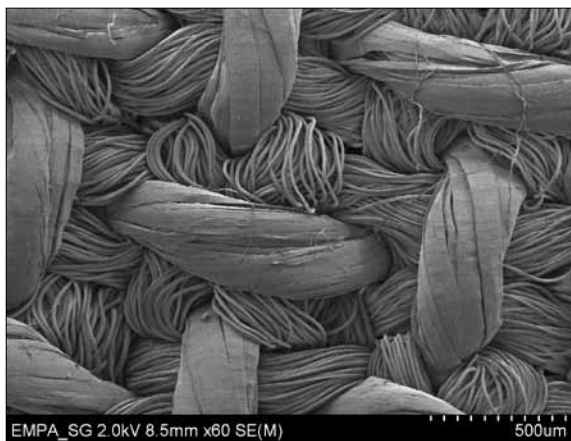
Decubitus or pressure ulcers, also known as bedsores, are localized injuries to the skin and/ or underlying tissue as a result, beside other influencing factors, of pressure in combination with shear and/or friction. Especially in hospitals treating immobile patients this is a major challenge for nursing staff taking a lot of actions to prevent. According to the US Agency for Healthcare Research and Quality the hospital costs related to pressure ulcer were USD 11 billion in 2006. As it is also a mayor cost factor, medical technology has recognized the problem. There are many approaches to

increasing the comfort of those at risk of developing pressure ulcers. But some of these methods are not sufficiently effective, while others – such as mattresses with changing areas of pressure – are still very expensive.

Therefore the Swiss company Schöller Medical AG developed together with Swiss EMPA and the Swiss paraplegic centre bed sheets that reduce friction and enhance the wellbeing of patients. Core component of this fabric are Lenzing PROFILEN® yarns. The new fabric was tested extensively in the lab scale to show the better friction behaviour compared to standard hospital bed sheets against a skin model (Figure 5).

The conclusion of these experiments was that the textile composed of PTFE fibers showed a factor of three lower friction coefficient than normal hospital bed sheets under both dry and wet conditions when tested in vitro against a mechanical skin model. By absorbing and distributing interfacial water within the textile structure, the prototype also exhibited beneficial water transport properties during mechanical contacts. The observed properties suggest that the textile is a promising candidate for a skin protective hospital bed sheet which might be applied for the prevention of decubitus.[9]

Later on a clinical study on 20 patients was conducted, all with a sub acute spinal cord injury during the last period of the in-patient rehabilitation. Summarized the new bed sheet was favoured to the conventional one by patients and physiological skin examinations showed certain tendencies that underline the positive effects of the new bed sheet.[10, 11] Currently some hospitals specialized on paraplegic patients are equipped with the bed sheets to also get some long term data on a big number of patients. In the relevant group of physicians and textile specialists the new product was received very positively and even presented in the Swiss television as important innovation within the medical technology. In June 2013 the product received the “TECHTEXTIL INNOVATION AWARD”.



Conclusions

The above three market areas with their clinical studies show clearly the positive impact of PTFE for medical textiles in certain areas. The low friction as well as the absolute hydrophobia of the fiber proved especially in the last two applications to be valuable in a fabric used to protect the human skin.

Additional to that there are R&D projects in the field of wound dressings containing PTFE yarns. Beside the other mentioned benefits the “non-stick effect” can lead here to a faster healing as recovering skin will not be damaged during exchange of wound dressing.

Lenzing Plastics with its specialized PTFE multifilament yarns is continuing to work hard to support customers who are developing or already selling products in this very promising but also challenging area of medical textiles.

Acknowledgement

We would like to thank Lenzi Egisto s.p.a./ Prato, owner of Tepso brand as well as Schöller Medical AG/ Sevelen for their efforts and their perseverance on working with PTFE fibers in their projects described in this article.

References

- [1] Mark Test conducted by: University of Siena, Dipartimento di Medicina clinica e scienze immunologiche, Sezione di Scienze dermatologiche, Prof. Fimiani.
- [2] Test done by Lenzing Plastics GmbH on round knitted fabric.
- [3] Source: National Psoriasis Foundation, Portland, OR / USA.
- [4] Stern RS, Nijsten T, Feldman SR, Margolis DJ, Rolstad T. Psoriasis is common, carries a substan-

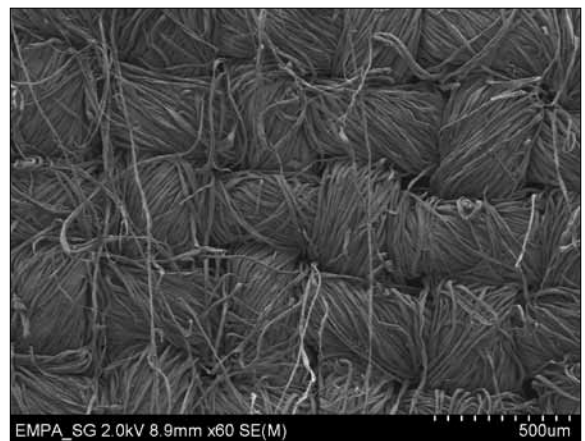


Figure 5. SA scanning electron microscope (SEM) image of the new bed linen showing the dot-matrix like structure (PTFE on the surface) in comparison with a standard cotton bed sheet currently used in hospitals.

- tial burden even when not extensive, and is associated with widespread treatment dissatisfaction. *J Investig Dermatol Symp Proc.* 2004 Mar; 9(2):136-9.
- [5] Fowler JF, Duh MS, Rovba L, Buteau S, Pinheiro L, Lobo F, Sung J, Doyle JJ, Swensen A, Mallett DA, Kosicki G. The impact of psoriasis on health care costs and patient work loss. *J Am Acad Dermatol.* 2008 Nov; 59(5):772-80.
- [6] See also www.tepso.com
- [7] Studies conducted by Centro Studi Gised, Bergamo / IT and University of Siena / IT, Dipartimento di Medicina clinica e scienze immunologiche, Sezione di Scienze dermatologiche, Prof. Fimiani.
- [8] Study conducted by Next Technology Tecnotessile – Societa Nazionale die Ricerca r.l.; Prato/ IT.
- [9] Conclusion: „Medical textiles with low friction for decubitus prevention“ – *Tribology International* 46 (2012) 208 - 214.
- [10] CTI Project No: 10609.1 PFLS-LS: Does a low friction bed sheet optimize the skin, resistance and physiology and reduce the risk for pressure ulcer? A. Scheel-Sailer, A. Frotzler, G. Müller, G.-M. Rotaru, S. Annaheim, P. Kellenberger, S. Derler (Swiss Paraplegic Center, Empa – Swiss Federal Laboratories for Materials Science and Technology St. Gallen, Schoeller Textil AG).
- [11] See also: <http://www.empa.ch/plugin/template/empa/1321/125698/---/l=2>