

CliniCum

The Magazine for Managers in the Hospital

expertise

Safety and hygiene of surgical gowns and surgical drapes

Introduction

Reusable surgical gowns and drapes have proven practical especially during dynamic operations where there are a lot of fluids involved. In two consensus statements^{1,2} and one expert opinion³ it was shown meticulously that reusable surgical gowns and drapes are highly functional but are also not very detrimental to the environment. If nothing else, time and money can also be saved with practically composed reusable sets.

In this expert opinion, only surgical gowns and drapes are meant by "surgical textiles" or "reusable textiles".

Safety of high-tech surgical gowns and drapes

Surgical textiles primarily have to guarantee the safety of patients and surgical staff. Here it is necessary – and also prescribed in EN 13795 –

- that they are resistant to germ penetration (wet and dry);
- that hardly any or no particles are released;
- that they have a high liquid barrier;
- that they have high sturdiness (wet and dry);
- that they – including over several hours – are comfortable to wear and are highly absorbent.*

* The last two requirements are laid down only as information in EN 13795. They are not mandatory.

From the perspective of surgery, the gowns and drapes used in operations have to form a germ barrier. Special forms of storage and necessary manipulations during an intervention (e.g. total hip endoprosthesis) require high tensile strength of the used drapes and good durability of the medical adhesive tapes. With operations involving a particularly large

amount of fluids it also has to be ensured that the drapes cannot become penetrated with blood.

It also needs to be ensured that surgical gowns and drapes are free of impurities and damage.

The following characteristics for assessing surgical textiles are required both with patient drapes and with surgical gowns:³

- Resistance against bacteria penetration – dry/wet
- Cleanness – microbiological
- Cleanness – particulate matter (foreign fibres)
- Barrier to prevent fluid passing through (test medium is water)
- Bursting strength – dry/wet
- Tensile strength – dry/wet

Now there are three studies overall on the use of disposable and reusable textiles in operations:

- a) SAFEC (Safety/Ecology/Economy in the O.R.) study (Feltgen M., Schmitt O., Werner HP. Hygiene & Medizin [Hygiene & Medicine], Suppl. 2, November 2000, p. 60 ff.)
- b) EDANA (European Disposable and Nonwoven Association) study (Werner HP., Feltgen M., Schmitt O. Hygiene & Medizin [Hygiene & Medicine], March 2001, p. 62 ff.)
- c) Life Cycle Assessment Comparing Laundered Surgical Gowns with Polypropylene Based Disposable Gowns. (Carre A. Report for the Australian Industry Group and the Textile Rental and Laundry Association (Victoria) by the Centre for Design at RMIT, 27 November 2008)

Only the SAFEC study contains Austrian results. The study proves that the requirements can be fulfilled if there is qualified processing of reusable medical devices and with corresponding materials and quality management. It was also



Administrative Director Norbert Grass, Lorenz Böhler Emergency Hospital of the Austrian Workers' Compensation Board AUVA, Vienna: "In Austria quality is also the main priority with surgical textiles. This is why reusable textiles are the first choice for Austrian hospitals – especially in dynamic operations where there are a lot of fluids involved."

able to be shown that reusable textiles have positive characteristics in terms of barrier properties, particle shedding and mechanical strength with exposure to moisture and exceed the normative standards.

The reusable surgical gowns and drapes consist of robust and high-performance materials. The innovative textiles (trilaminates and microfilament fabrics) clearly fulfil all normative requirements and are the reason for the high safety of the processable surgical textiles.

The EDANA study conducted in England, France and Wales comes to partly different results, and here it must be pointed out that a direct comparison between the EDANA study and the SAFEC study is not allowed because of the different framework conditions (type and number of examined parameters, scope, materials, processing method). In individual cases the specifically available products have to be objectively tested and compared.

Cost situation

In a study by Prof. DDr. Wilfried von Eiff from the Centre for Hospital Management in Münster from 2007 the costs of surgical drapes – reusable textiles and disposable textiles – were compared with each other as well as the costs per operation and the costs at the hospital level.⁴

At first glance the reusable providers are clearly above the costs of disposable products. But several differences have to be considered here, there is no direct comparability. The reason: in the von Eiff study it was discovered that reusable drapes are bigger than disposable drapes on average.

Reusable textiles are also better than the disposable products in terms of their tear and bursting strength. In the area of set composition there is also no direct comparability because the contents and quality of the sets vary from provider to provider. The set prices for single-use products cannot be used for working out total costs because generally there are additional costs for logistics, daily delivery, distribution in the hospital, storage and disposal of the surgical sets.

If all covering materials needed in an operation are taken into consideration when working out costs, reusable textiles tend to be more attractive economically. The following reasons support this finding:

- Disposable coverings are often applied in several layers.
- Disposable products do not cling to the patients so well because of their lower material weight.
- Disposable products are usually smaller than reusable textiles. This means additional drapes are often needed to weigh down the edges.

- The poor thermal insulation of disposable products often means additional materials are required.
- Defective disposable drapes (tensile strength!) have to be covered with additional drapes or replaced.

A decision to obtain surgical gowns and drapes based entirely on the price argument ignores risks such as the risk of infection for the patient. As an example von Eiff indicates total hip endoprosthesis in his study. This is an operation with a heavy mechanical load. If the disposable drapes used for covering "flutter", this multiplies the risk of infection for the patient. If the bond does not stick, additional material, time and (ultimately therefore also money) are needed to cover the patient again.

So if we compare disposable products with reusable textiles, these additional costs have to be included. In practice this does not usually happen though – here von Eiff speaks of a cost gap. But the fact is that surgical textiles are usually not purchased by those who are aware of these risks, such as the surgical staff. Instead it tends to be the hospital management which is responsible for purchasing. And here – in Germany this can already be seen very clearly – the price is the only factor taken into consideration.

In Austria the situation is different. At a round table meeting in 2008 it could be seen, for example, that Austrian hospital managers and doctors mainly choose reusable textiles. The price card is not played here. Instead quality is considered more important. Although economising is also given a lot of consideration in Austria, the thought of saving with surgical systems is not a priority because surgical gowns and drapes play a comparatively minor role in the overall costs of a hospital.



Chief Physician Univ.-Prof. Dr. Michael Hermann, Surgical Department, Empress Elisabeth Hospital, Vienna: "As well as safety, the wearing comfort of surgical textiles also plays a not inconsiderable role. Clothing which is permeable to water vapour improves the thermal comfort and enables safe work on the operating table."

Wearing comfort and resilience

Reusable surgical gowns and drapes have been used in operating theatres for around 20 years. The textiles need to provide an effective germ and particle barrier. Different materials are available which have to fulfil the following requirements:

1. Maximum protection for the patient, users and third parties
2. High microbiological and hygienic standard to prevent the risk of infection
3. Good wearing comfort of the clothing to maintain the high performance (breathability, temperature regulation)
4. Easy handling of the patient drapes

Two materials are mainly used in the production of reusable surgical gowns and drapes:

1. Microfilament fabrics
2. Textile laminates

Microfilament fabrics

These fabrics consist of very fine endless polyester fibres. A conductive carbon fibre is also always woven in. This guarantees permanent antistatic properties. These fabrics are very resistant to abrasion and tearing and release practically no particles. With a fluorocarbon finish these fabrics are also liquid-repellent and can be processed up to 80 times. The germ barrier (dry and wet) corresponds with the limits stipulated in EN 13795.

Textile laminates

With a textile laminate there is a membrane between the top and bottom layer. The membranes are designed so that neither bacteria nor viruses can penetrate the laminate when there is fluid involved. For water vapour molecules, the membranes are no barrier, however. Breathability is therefore guaranteed. Trilaminates are also liquid-tight with high pressure, and this plays an important role especially in dynamic operations where there are a lot of fluids (for example total hip endoprosthesis). There is a very effective germ barrier (dry and wet) with textile laminates.

Excursus: EN 13795 and its significance for surgical textiles

Surgical gowns and drapes are medical devices as per the Medical Devices Act according to the Austrian Federal Law Gazette 1996/657 and the Council Directive 93/42 EEC of 14 June 1993 concerning medical devices. This applies for disposable and reusable products. Medical devices can be marketed only after a conformity assessment procedure has been positively carried out. If reusable textiles are placed on the market repeatedly, the conformity assessment and CE marking have to be renewed every time they are processed. With Classification Class I "Sterile", there also has to be indication of the four-digit number of the notified body which checks the validated sterilisation process.

The European Norm 13795 "Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment" regulates the requirements for manufacturers and processors of disposable and reusable textiles in operating theatres. It also stipulates the necessary testing procedures for such products. Here it is clarified that the distributor, i.e. either the

- manufacturer of single-use products,
- provider of reusable textiles,
- manufacturer of reusable textiles with CE marking or
- hospitals with in-house production,

is responsible for fulfilling EN 13795. The distributor has to indicate the procedure with which the product is sterilised and how the user knows when the textile may no longer be used.

In its current version EN 13795 has three essential chapters:

1. General requirements for manufacturers, processors and products
2. The selection and development of test methods for measuring the identified product characteristics
3. Determination of limits for the qualification of surgical textiles as medical devices

Applicability of EN 13795

The objective of the norm and its context are comprehensibly and clearly defined. The area of application is also clearly defined by indicating what is handled in the norm – and what is not. The information to be provided by the manufacturer is clearly defined and can be checked well. The characteristics which are to be assessed are also precisely stipulated. The norm takes into consideration the central importance of the requirements for manufacture and processing and the requirements for testing.

The norm specifies the testing procedures and here it entrusts qualified institutes with checking fulfilment of the requirements for the surgical textiles. There is no precise information on the type of quality assurance and control.

In the norm the limits for the use requirements and performance levels are also specified. As well as the distributor's responsibility for fulfilling EN 13795 it is also incumbent on the user to fulfil the instructions of the norm by observing the directions for use.



Dr. Magda Diab-Elschahawi, Division of Hospital Hygiene, Vienna General Hospital AKH: "On account of the precise legal regulations and norms, reusable textiles provide a high degree of safety and infection-prophylaxis."

Requirements for the manufacture and processing of surgical textiles

1. Manufacturers must be able to prove that the requirements laid down in EN 13795 are fulfilled and that there is usability both with disposable products and with non-disposable products and also with reusable medical devices.
2. Validated procedures have to be used for manufacturing and processing methods.
3. The manufacturing and processing methods have to be determined and validated.
4. All manufacturing and processing steps have to be included in the validation.
5. The frequency of validation has to be determined during the validation procedure; it has to be determined again after all changes in the manufacture or processing which have a decisive influence on the product.
6. The decisive parameters for manufacturing and processing have to be determined, monitored and documented. The type and frequency of routine monitoring must be documented and the documents must be stored.
7. The results of the validation and the routine monitoring must be documented and the documents must be stored.
8. During the manufacture and processing, control must be maintained over the decontamination and disinfection processes and it must be ensured that the progress of sterilisation can be tracked.
9. It must be possible to prove that the properties of the materials were maintained during the manufacture and processing.

Test methods

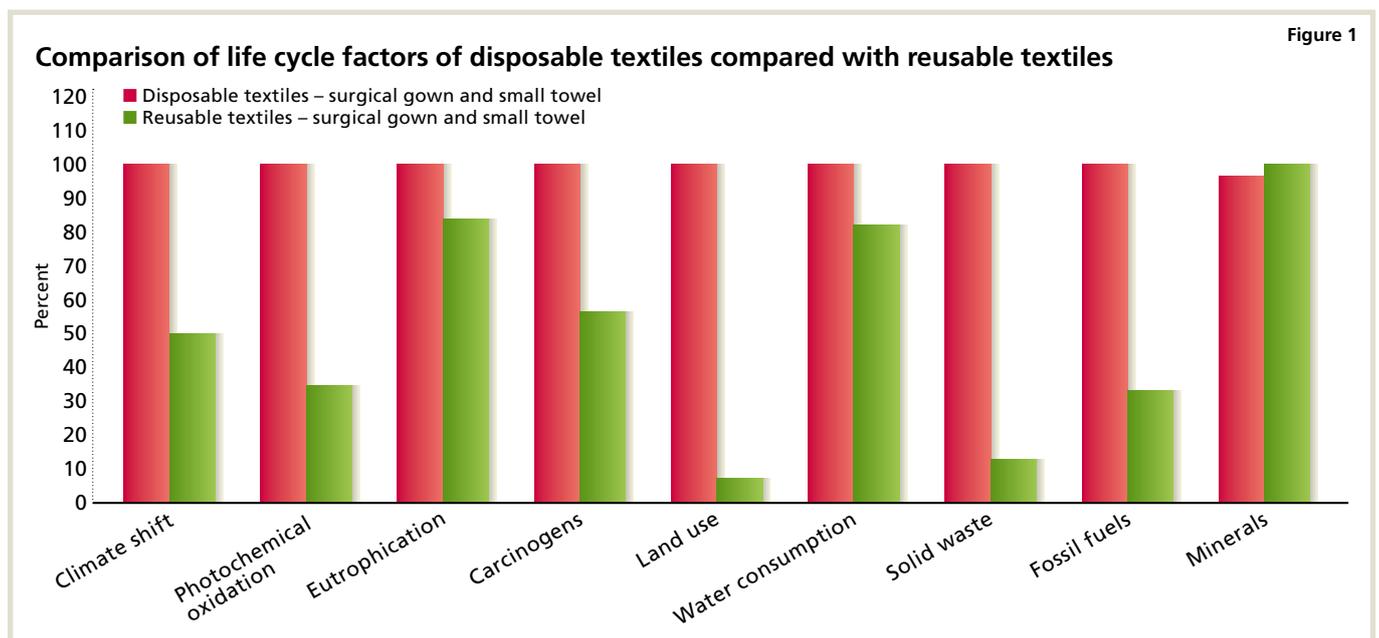
The test methods for assessing fulfilment of the requirements for surgical textiles attempt to simulate the conditions in operations and to directly measure the most important material properties.

EN 13795 in practice

This European norm is a useful tool for checking the quality of the used surgical gowns and drapes. The norm also gives criteria for checking quality assurance during the processing method.

Environmental compatibility

Factors such as environmental pollution and climate change have become issues which also have to be taken increasingly into consideration in hospitals. In particular in the discussions about the use of reusable textiles or disposable textiles these points also need to be included in the decision for or against certain surgical textiles. In a project report published in November 2008 in Australia by Andrew Carre, director of the Life Cycle Assessment programme at the Royal Melbourne Institute of Technology, it was shown that the use of reusable textiles in surgery causes much less environmental pollution than the use of disposable textiles.⁵ In particular the more expensive manufacturing process and the associated environmental impact with the production of disposable textiles and also the necessary disposal of disposable textiles after a single use cause a high amount of environmental pollution (see figure 1).





Qualified Hospital Manager Franz Mannsberger, MBA, Department of Surgery, Innsbruck: "Reusable textiles are preferable to disposable products because they have greater tear and bursting strength and are also antistatic and hardly inflammable. Reusable products are also much easier to handle for the nursing staff."

The study attempted to record all possible environmental pollution arising with the delivery of a disposable or reusable textile set (surgical gown and small towel). Here it became apparent that reusable textiles cause much less environmental pollution than disposable textiles in the categories climate shift, photochemical oxidation, eutrophication (overfertilisation of waters via wastewater influx), carcinogens, land use, water consumption, solid waste and fossil fuels (see table 1).

The study in detail

The greater environmental pollution caused by disposable textiles is explained by the manufacturing process of each individual disposable set. The frequently necessary cleaning of reusable textiles (on average reusable textiles are used 127 times) represents less environmental pollution.

During the project work several possibilities were discovered for how the environmental pollution associated with the manufacture and use of disposable and reusable textiles could be further reduced:

- The extent of disposable components should be reduced.
- Optimised processing methods in all laundries.

The environmental pollution caused by disposable textiles could be reduced merely if these textiles were used several times, which – according to the Medical Device Ordinance – is prohibited in Austria. There were problems for the study author because for disposable surgical gowns – unlike reusable surgical gowns – there was little information available on environmental pollution. The data used therefore had to be extracted mostly from the results of industry surveys and from publicly available data on disposable gowns. A series of sensitivity analyses were therefore conducted in order to make the findings comprehensible and valid. In summary it must be said that in most of the observed categories reusable textiles are preferable to the disposable products because these are

shown to cause less environmental pollution than disposable textiles. The lower environmental pollution is mainly due to the repeated usability of reusable textiles because the environmental pollution caused by the manufacture can thus be regarded as relative. However, with disposable textiles the pollution caused by the manufacture arises fully with every use.

Sets

Another important aspect in the decision between disposable and reusable textiles is the question of the type and composition of sets. Today work is generally done with already composed sets for certain interventions because this can save time. This concerns both logistics and also the operation control. A direct comparison between identically named disposable and reusable sets for a specific intervention is not possible, though, because the sets are too inherently different. The reason why comparability is possible only to a limited extent is shown by the example of a total endoprosthesis of the hip and the surgical textiles necessary here (see table 2).

This table shows that the set contents are also different with sets of disposable and reusable providers with the same name. The quality of the products contained in the sets also varies. The sets contain the products which meet an assumed quality standard. This does not mean that every set contains exactly those products which can cover a certain operation entirely. Then there is also the fact that further materials do not have to be added only with disposable sets – see Stockinette – the operation blocking times also play a significant role. The cleaning takes longer if disposable products are used because the absorbency of these products cannot be compared with that of reusable products.

Table 1

Environmental pollution with the manufacture and use of disposable textiles compared with reusable textiles

Type of pollution	Factor*	Unit	Disposable set	Reusable set
Climate shift	20	Balloons	20.6	10.1
Photochemical oxidation	125511	Passenger car journey (m)	572.5	198.0
Eutrophication	80283	Grey water (l)	44.5	37.1
Carcinogens	76	Arsenic (kg)	0.000001	0.000001
Land use	0.5	Football grounds	0.000012	0.000001
Water consumption	100	Buckets	1.4	1.1
Solid waste	1	Waste (kg)	0.34	0.04
Fossil fuels	0.007	Household energy days	0.014	0.005
Minerals	0.007	Household energy days	0.00001	0.00001



Director Dr. Stefan Meusburger, MSc, Regional Health Authority of the Province of Upper Austria, Linz: "Keeping up hygiene in operations means acting responsibly – for patients and for employees. And if we include the effect on the environment in decisions then we act responsibly for all of us. In operations we have the choice. We use the functional advantages of reusable textiles and also send a small but important signal that we are moving away from the throwaway society."

Summary

In recent years reusable surgical gowns and drapes have proven safe, economical and - as a current study shows - environmentally friendly. Reusable textiles are resilient and of the highest quality. They require low logistical effort and are rated positively by the users, especially in terms of wearing comfort and temperature stability. In highly dynamic operations with a lot of fluids escaping it is especially the high tear and bursting strength, the good liquid absorption and germ barrier effect which mean reusable surgical gowns and drapes are preferred. ■

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Table 2

Comparison of reusable and disposable textile sets with total hip endoprosthesis⁶

Contents	Reusable		Disposable	
	Number	Size	Number	Size
Reinforced instrument table cover	2	79x160	1	77x145
Side table cover	1	147x200	1	150x190
U-drape	1	230x250	1	200x260
Drapes	1	281x167	1	175x300
	1	146x180	1	150x190
			1	90x150
			1	75x90
Surgical tape			3	9x49
Towels			4	19x25
Stockinette	1	Medium		
Standard surgical gown	2		2	
High-performance surgical gown	2		2	

■ **Imprint** Publisher: Medizin Medien Austria GmbH DVR No.: 0753211 **Publisher's and editor's address:** Wiedner Hauptstraße 120-124, 1050 Vienna, tel.: 01/546 00-0, fax: ext. 730, e-mail: medizin@medizin-medien.at **Managing Director:** Thomas Zembacher **Responsible for content:** Dr. Magda Diab-Elschahawi, Verw.-Dir. Norbert Grass, Prim. Univ.-Prof. Dr. Michael Hermann, Dipl.-KH-Bw. Franz Mannsberger, MBA, Dir. Dr. Stefan Meusburger, MSc **Medical writer:** Sabine Fisch **Translation:** Smile Translations **Project responsibility:** Mag. Andrea Budin **Art direction:** Karl J. Kuba **Layout and DTP:** Johannes Spandl **Printing:** Friedrich VDV, 4020 Linz **Print run:** 2,000. Reprinting in whole or in part is permitted only with the express written consent of Medizin Medien Austria GmbH. All rights reserved, in particular the right of reproduction and distribution and also translation. No part of the work may be reproduced in any form (photocopy, microfilm or any other procedure) or stored, processed, duplicated, used or distributed using electronic systems without the written consent of the publisher.

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