The protective efficacy of surgical latex gloves against the risk of skin contamination: how well are the operators protected?

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Latex gloves are used by surgical staff to avoid exposure to patient body fluids, thus reducing the risk of contracting bloodborne viral diseases, such as hepatitis C and HIV. We studied the efficacy of the surgical barrier provided by latex gloves, before and after use in the operating theater. The electrical conductivity, insulation and mechanical resistance of glove latex were investigated, using routine supplies of surgical gloves. Latex structure was assessed by scanning electron microscopy and by mercury intrusion porosimetry. Latex is subject to hydration, a phenomenon associated in the laboratory with the loss of its electrical insulation properties. Such glove latex properties were found to be highly variable, with latex hydration times varying between 2 and more than 30 min. Rapidly hydrating gloves showed increased permeability to methylene blue, associated with higher levels of porosity. Thirty min of surgical use was associated with measurable hydration of glove latex and a statistically significant loss of electrical and mechanical resistance, with rupture load decreasing by 24%. Electronic control of the insulation properties of gloves during surgery permits early detection of hydration, and allows prompt correction by glove change, before the gloves lose their electrical and mechanical competence.

1. Introduction

The use of rubber gloves during surgical procedures was first introduced over a century ago, not so much for the prevention of surgical infection, but mostly as a means to protect the operators from the caustic effects of the antiseptics then used [1]. Today, the protective role of surgical gloving is once again becoming actual, but now the efficacy against biological, more than chemical aggression has become the issue. The growing prevalence of viral hepatitis forms and human immunodeficiency virus (HIV) seropositivity in the general population has led to a significant increase in the risk of infection among health care workers, especially those operating in the surgical sector. While the greatest risk of transmission of such viral pathogens lies in the accidental parenteral inoculation, the risk of seroconversion pursuant to direct skin or mucosal contact may have been underestimated. The risk of seroconversion following skin contact with infected body fluids has been estimated to amount to less than 10% of the risk on parenteral inoculation [2], but this mode of exposure appears to occur at least as frequently as accidental skin punctures.

Surgical glove breaching was the second most frequent type of exposure (after needle- stick injury) in a survey on more than 15,000 surgical procedures in Italy by Pietrabissa *et al*. [3]. In this survey, 21% of such glove failures remained undetected until the surgeon removed his gloves to discover blood stains on his skin. This sequence of exposure causes particular concern, since the intimate skin contact, the prolonged exposure time, the local occlusive condition provided by the glove latex and the possible presence of (micro)lesions and/or skin irritation, all presumably contribute to increase the risk of transdermal transmission of viral agents possibly present in the contaminating fluids. That this route may be an effective way of transmission was suggested by the survey of Ippolito *et al*. [4], who documented a small but

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measurable risk of HIV seroconversion after dermal and mucosal exposure to infected blood.

Wong *et al*. [5] surveyed 324 spinal surgery procedures and found that the surgical operators had an increased risk of blood contacts on intact skin, whereas there was no higher risk of penetrating injuries, as compared to other types of surgery. Sim and Dudley [6] had reported that surgeons' fingers were blood-stained in 20% of the operations lasting more than 2 h, even if no holes could be identified in the gloves. Brough *et al*. [7] found a 37.5% incidence of glove breaches in general surgery and only 39% of the breaches were recognized intra-operatively. Wright *et al*. [8] analyzed 249 cases of glove breaches among surgical staff. In 63% of the cases the glove failures were detected only upon removal of the gloves, with the observation of blood-stained skin.

The awareness of increased risk of exposure of surgical operators to patients' body fluids has led to concern over the protective efficacy of latex gloves used during surgical procedures. Standards set by the US Food and Drug Administration [9] allow a surprisingly high failure rate of 2.5% for surgical gloves in the water leakage test. Glove latex is a natural product and despite all industrial precautions and material quality control, an intrinsic level of variability in manufacture is hard to avoid, especially as regards hydration properties, permeability and porosity.

Several groups have investigated the penetration of viral and bacterial agents through latex gloves. Using *S. marcescens*, Korniewicz and Laughton [10] found 20% penetration of latex examination gloves, and Pickett *et al*. [11] found 35% penetration of dentistry gloves after usage. Bacteriophage was used by Korniewicz *et al*. [12], who showed 8% penetration through used latex examination gloves, whereas Hamann and Nelson [13] found 30% bacteriophage penetration in one brand of latex surgical gloves and 80% in another brand. It has been suggested that the rate of hydration of latex on immersion in water could be critical to facilitate viral passage through surgical gloves [14].

The purpose of our investigation was to investigate the physical properties of regular supplies from different manufacturers of surgical gloves, by measuring the electrical insulation properties with an electronic barrier surveillance device, the rate of hydration, the permeability to methylene blue, the mechanical resistance on traction and fatigue, the biological resistance on incubation with heparinized blood, the porous volume by means of mercury vapor porosimetry, and morphology in scanning electron microscopy (SEM). Both new unused surgical glove supplies and gloves used in the operating theater were tested.

2. Materials and methods

Sterile surgical gloves, routinely available on the hospital products market, were obtained from several manufacturers (list supplied upon request). Gloves of thickness between 0.18 and 0.22 mm were used. The thickness was measured with a precision caliper in at least three different sites of the glove.

2.1. Electrical properties of glove latex

2.1.1. Dynamic: hydration test

The glove is filled with 400 ml saline solution and suspended in a beaker containing 1000 ml physiological saline. By means of immersed electrodes, a pulsed signal is applied between the interior and exterior of the glove. An electronic barrier monitoring device (ELPER, manufactured by Igea, Carpi, Italy) [15] is used to detect the flow of microcurrents down to a level of less than 10 nanoamperes (nA). This sensitivity is attainable since the device employs a pulsed electrical signal at 1600 Hz. A pulsed signal is crucial to avoid the polarization of the electrodes.

Initially, the values of current measured lie below 20 nA. With time, saline solution hydrates the latex, causing increased electrical conductivity. The current flowing through the glove latex increases up to 560 nA or more. The test parameters we used were:

- t_o (time zero): the moment the glove is suspended in the beaker
- t_i (time initial): the moment current at the intensity of 28 nA becomes detectable
- t_f (time final): the moment the current reaches 560 nA.

The duration of the test never exceeded 30 min. Fig. 1 shows a typical experimental set-up.

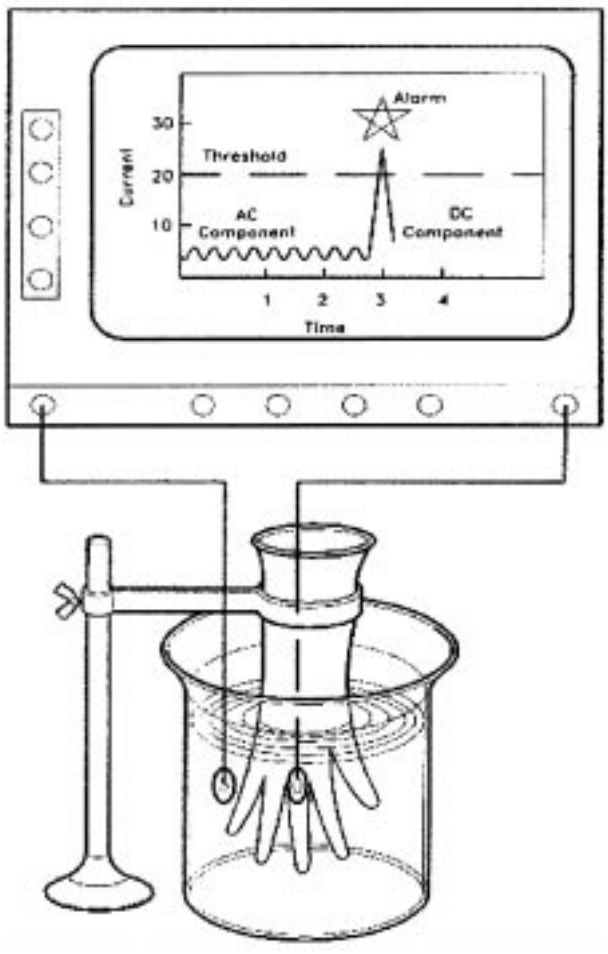


Figure 1 Experimental set-up showing the glove filled with saline and immersed in saline. One electrode is located within the glove and the other one in the surrounding solution.

The same device was also used in the operating room to evaluate barrier integrity during surgery. Surgeons were asked to change gloves when electrical conductivity between surgeon and patient exceeded the critical level of 560 nA, set for the electronic device to sound an alarm [15]. The glove latex properties were then investigated in the laboratory.

2.1.2. Static: electrical insulation

Latex specimens (3×5 cm) were taken from the back of the glove and placed between two copper electrodes to which an electric potential from 0 to 5000 V was applied. The maximum voltage value at which the latex still prevented the electrical discharge between the electrodes was recorded.

2.1.3. Scanning electron microscopy (SEM)

The glove specimens were carefully dried and cut into small segments of 0.5 cm × 0.25 cm. The specimens were then metallized with a gold film of 10 nm thickness at a temperature not exceeding 30 °C. They were fixed on specimen holders with silver paste and examined on a Philips 515 scanning electron microscope. Some of the specimens obtained directly from operating worn gloves were fixed in 4% paraformaldehyde phosphate buffer pH 7.4 prior to preparation for SEM observation.

2.1.4. Evaluation of surface porosity of gloves

For each sample different images of the glove surface were recorded. Using several SEM images, a TESAK image analyzer was used to estimate the surface area of the glove covered by porosity, this being expressed as: porous area × 100/total area measured: surface porosity.

2.1.5. Mercury intrusion test

A mercury penetration porosimeter (Carlo Erba Porosimeter Series 200), with a linked macropores unit (Carlo Erba Macropores Unit 120) was used. This instrumental set-up measures the porosity of solid substances down to a diameter of 7.5 nm. Glove specimens of 0.3–0.5 g were used, obtained by cutting the gloves in small pieces of about 1 cm^2, for a total of 15–25 cm^2. This material was placed in a dilatometer, provided with a capillary calibrated at 3 mm diameter, in which a vacuum (1 Pa) was produced and then filled with distilled mercury. By increasing the pressure and simultaneously measuring the reduction of the level in the capillary, it is possible to gauge the volume of the pores as a function of the diameter. For the purposes of our study, we considered pores of diameter exceeding 0.1 μm.

2.1.6. Mechanical fatigue test

A 30 min sequence of repeated compression and decompression cycles was applied to the index finger of the gloves by pumping distilled water into it at a pressure of 0.2 kg/cm^2. Each compression bout lasted 5 s. Duration of the test was 30 min and the mechanical resistance of the fatigued latex was then measured.

2.1.7. Mechanical resistance test

Strips of latex 1 cm × 2.5 cm were fixed between two clamps, one of which was connected to a dynamometer. Traction was applied up to rupture load. The sensitivity of the system was ± 20 g. Traction tests were performed on five samples of latex always taken from the index area of the gloves.

2.1.8. Latex hydration volume

We weighed the gloves before and after hydration in order to measure the amount of liquid the latex was able to absorb. After hydration, the glove was placed in a vacuum to assess the possibility of extracting the liquid from the thickness of the latex.

2.1.9. Latex permeability

To verify whether the absorbed liquid could cross the thickness of the latex, the middle and index fingers of the glove were filled with a 2% solution of methylene blue (molecular weight 319.98) and immersed in a 100 ml beaker containing distilled water. At fixed intervals, 1 ml was removed. The sample removed was read on the 662 nm spectrophotometer to detect the presence of traces of the methylene blue stain.

2.1.10. Biological resistance test

Latex specimens were immersed in physiological saline (controls) or in heparinized venous blood and incubated at 37 °C for variable periods. After incubation, part of the specimens was observed with SEM and part was subjected to the mechanical resistance test.

2.1.11. Surgical use

In a series of 89 surgical procedures (hand microsurgery and orthopedic surgery) the ELPER device was used to monitor the integrity of the surgical barrier. In order to assess the combined effect of hydration and mechanical stress, the surgeon was provided with two sets of gloves. He donned the right glove from one set and the left glove from the other set; the corresponding left and right gloves being used as controls. In one series of procedures, the surgeon was required to replace gloves when the electronic device sounded the hydration alarm at 560 nA of current flow between surgeon and patient. In another series, the surgeon was required to change gloves after 30 min of use, as recommended by universal precautions practice [17]. The electric insulation, the porous volume and the mechanical resistance of both the unused control gloves and the used ones were tested.

3. Results

We studied the hydration times, electrical and mechanical properties of a series of commercial supplies of sterile surgical gloves. The first series of results refer to

the investigations performed in the laboratory on unused gloves, whereas the second series refers data obtained on gloves that had been used in the operating theater.

Different lots and different brands of surgical gloves from several suppliers, tested *in vitro* in the electrical test set-up yielded hydration times t_i and t_f for right and left gloves as shown in Table I. No significant variations between right and left gloves of the same brand was observed, where as a great variation between different suppliers was seen, with some supplies already being hydrated after only 2 min of immersion, against supplies lasting longer than the 30 min test time.

Hydrated gloves showed a measurable weight increase, highly significant after 24 h of imbibition (Table II). At time t_f when the latex has already lost its electrical resistance properties, the amount of fluid absorbed; is, however, still minimal, Indicating that just initial hydration of latex already impairs the electrical barrier properties.

On SEM examination it was seen that rapidly hydrating gloves showed a higher degree of porosity, as exemplified in Fig. 2a and b. The porous volume analysis by mercury intrusion, shown for 7 glove brands in Table III, indicated limited variability between right and left gloves of the same supplies, whereas a greater variability, of the order of $\pm 13\%$ was observed between supplies.

When the mechanical resistance of non-hydrated (new) gloves and hydrated (t_f) gloves was tested, no significant differences in strength between right and left gloves and non- hydrated and hydrated gloves were recorded (Table IV).

Rapidly hydrating latex gloves however show different methylene blue permeability from slowly hydrating gloves, as shown in Fig. 3. The methylene blue permeability is positively correlated with hydration time t_f and increases significantly if the glove is subjected to the mechanical fatigue test (data not shown).

Rapidly hydrating gloves also show a prevalence of larger pore sizes on mercury porosimetry, as shown in Fig. 4, and an inverse correlation between hydration time t_i and t_f and latex porous volume was found $(r = -0.75; p < 0.0001)$.

In a series of 12 glove brands, an inverse correlation between the porous volume by mercury porosimetry and mechanical resistance was found (see Fig. 5).

The mechanical resistance of six different glove brands was not significantly modified after the mechanical fatigue test, nor did the incubation of three different brands for 24 h in heparinized blood impair their mechanical properties. SEM images of the latex surface of such incubated gloves (Fig. 6a and b), however, suggested some degree of modification of the material appearance.

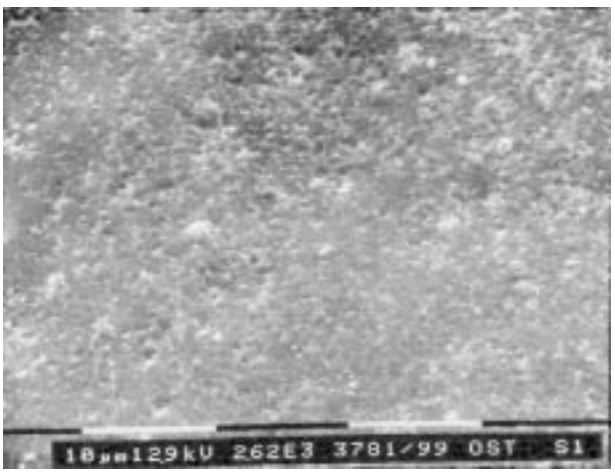
The following series of data refer to gloves used in the operating theater. The electric insulation properties of these gloves were tested in the laboratory, including also the *in vitro* hydration of control gloves. Fig. 7 shows that

TABLE I Hydration times of surgical gloves in minutes

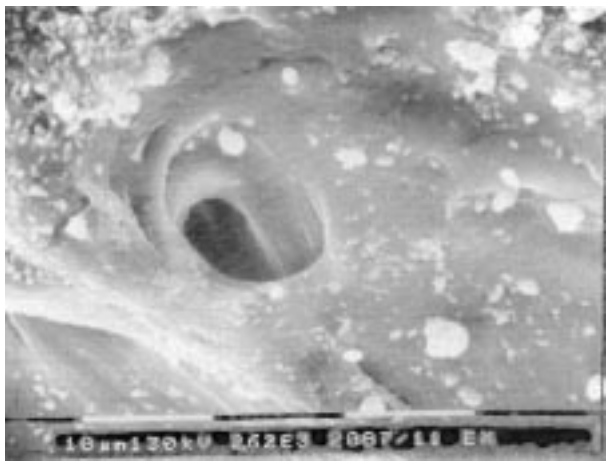
Manufacturer	Lot no.	t_i		t_f	
		Right	Left	Right	Left
1	HED3A7	0.1	0.1	1.3	2.3
1	HIP3B9	1	0.1	3	2
2	BL216	2.4	10.1	9	> 30
3	720400N	9	8.4	15.1	14.3
4	708663N	9	8.3	16	13.2
5	002073039F	8.1	7.1	19	18.2
6	92–183	18.3	19.4	> 30	> 30
9	9D1504	5	8	7	10
13	108011	3	0.1	12	7
	$p <$	n.s.		n.s.	

TABLE II Increase in weight of gloves following hydration in physiological saline

Manufacturer	Glove weight (g)		
	Initial	Δ at t_f	Δ after 24 h hydration
1	10.0506	+ 0.0076	+ 0.7089
1	11.1434	+ 0.0388	+ 0.6412
2	10.8898	+ 0.0564	+ 0.5266
2	9.4050	+ 0.1112	+ 0.6651
Mean	10.3722 ± 0.7	+ 0.0535 ± 0.043	+ 0.63545 ± 0.077
	$p <$	n.s.	0.0001



(a)



(b)

Figure 2 SEM of latex glove specimens showing different degrees of porosity (magnification × 2600). (a): surface view of a latex glove not hydrated after 30 min, (b): surface view of a latex glove hydrated after 1 min.

TABLE III Porous volume for right and left gloves

Manufacturer	Porous volume, cm^3/g of latex	
	Right glove	Left glove
1	0.03463	0.03564
2	0.03207	0.03219
3	0.03939	0.03983
4	0.03431	0.03536
5	0.03127	0.03054
6	0.03366	0.03267
9	0.03073	0.03143
$p <$		n.s.

TABLE IV Mechanical resistance of right and left gloves from the same lots (rupture load in g)

Manufacturer	Lot no.	Non-hydrated gloves		Hydrated gloves	
		Right	Left	Right	Left
1	HED3A7	999	1249	1493	1005
2	BL216	1350	1220	1031	1158
3	720400N	1200	1230	1201	1031
4	708670N	1039	1959	N.T.	N.T.
4	708663N	N.T.	N.T.	905	1014
5	02073039F	1595	1810	1302	1320
6	92–183	705	740	695	699
14	209201	1695	1833	N.T.	N.T.
$p <$			n.s.		n.s.
				n.s.	

N.T. = not tested

unused control gloves displayed an insulation exceeding 5 kV, whereas the electrical resistance of *in vitro* hydrated gloves failed at a voltage of 3.5 kV and gloves hydrated during surgical use already failed at 2.5 kV (means of five glove specimens for each value).

The mechanical resistance of gloves changed after an average of 30 min of surgical use was significantly reduced (1056 ± 245 g rupture load for used gloves *vs* 1377 ± 326 g for control gloves, $p < 0.002$), as shown in Table V, whereas the gloves changed in the operating theater when prompted by the electronic device, indicating latex hydration, were still mechanically competent, since the difference in rupture load (1107 ± 246 g *vs* 1247 ± 374 g) was not statistically significant (Table VI). Fig. 8 shows that gloves changed after an average 30 min of surgical use have a mean rupture strength impairment, as compared to matched control gloves, of -24%, compared to only -11% for the gloves changed on prompts from the electronic monitoring device. This implies that the safety margin of the electronic monitoring procedure compares favorably with the margin provided by the universal precautions rule of changing gloves after 30 min of use.

SEM observation of the gloves used in surgery (Fig. 9a and b) showed the presence of microlesions within the thickness of the latex, which were not observed in unused control gloves. Closer observation of the used surgical glove specimens (Fig. 10a and b) showed the presence of numerous corpuscolate bodies, evidently originating from the patient body fluids. It was incidentally found that the porous volume of such glove latex was lower than in unused control gloves (data not shown). This was conceivably caused by blood corpuscolate matter clogging the latex pores.

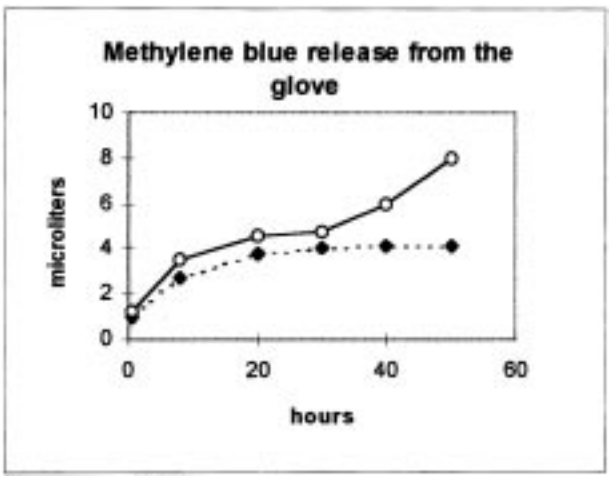


Figure 3 Methylene blue release from latex gloves after 48 h. Solid line: glove with a hydration time (t_f) of 14 min. Dashed lined: glove with a t_f longer than 30 min.

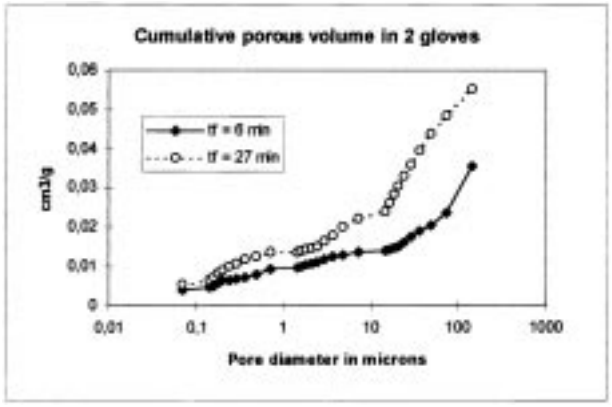


Figure 4 Distribution of pore size in two glove brands with different hydration times: 6 min (solid line), and 27 min (dashed line). The shorter the hydration time, the larger the porous volume by mercury porosimetry.

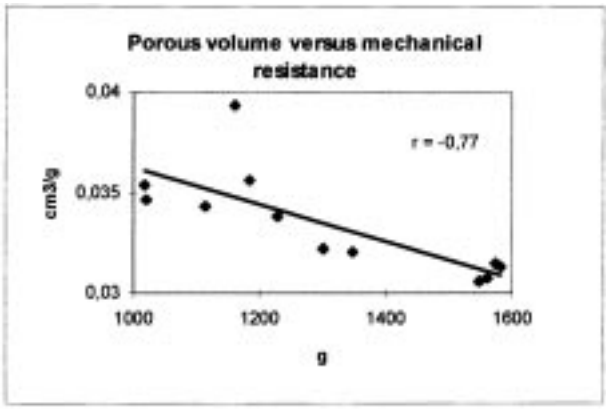
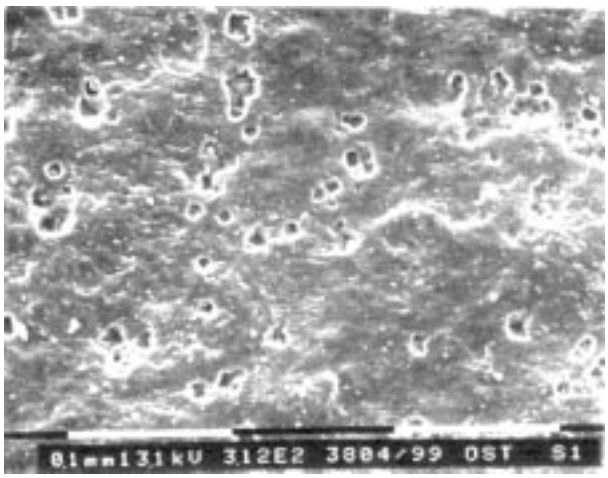


Figure 5 Linear correlation analysis between latex porous volume and mechanical resistance (rupture load in g) of 12 glove brands.

(a)



(b)

Figure 6 SEM of glove latex surface (a) before incubation and (b) following incubation at 37 °C in heparinized blood.

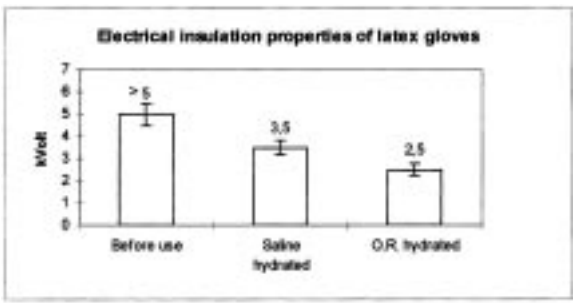


Figure 7 Electrical insulation properties of latex gloves hydrated in the laboratory or on surgical use (O.R.).

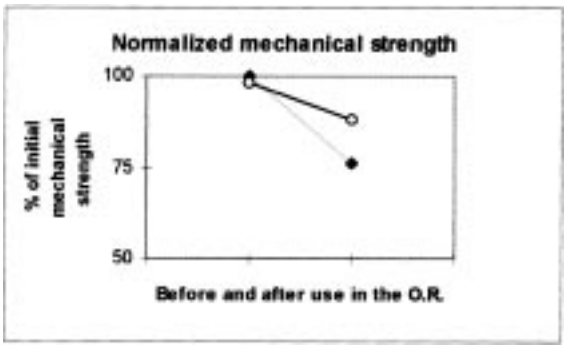


Figure 8 Mechanical resistance (rupture load, normalized to 100) of gloves used in the operating room (O.R.). Solid line: gloves changed on hydration alarm. Dashed line: gloves changed after 30 min surgical use.

TABLE V Mechanical resistance of gloves changed in the operating room (OR) after 30 min surgical use (rupture load in g)

Test no.	Control glove	OR glove	Difference	t_f (min)	Actual surgical use (min)
1-left	1614	1395	− 219	21	23
2-left	1915	1386	− 529	19	40
3-left	1099	670	− 429	13	29
4-left	931	911	− 20	No alarm	35
5-right	1460	895	− 565	21	23
6-right	1866	1495	− 371	13	29
7-right	1101	959	− 142	No alarm	35
8-right	1446	1064	− 382	19	40
9-right	1025	1035	+ 10	6	42
10-left	1159	886	− 273	6	42
11-right	1316	949	− 367	15	35
12-left	1602	1036	− 566	15	35
Mean	1377 ± 326	1056 ± 245	−321 ± 197		
$p <$		0.002			

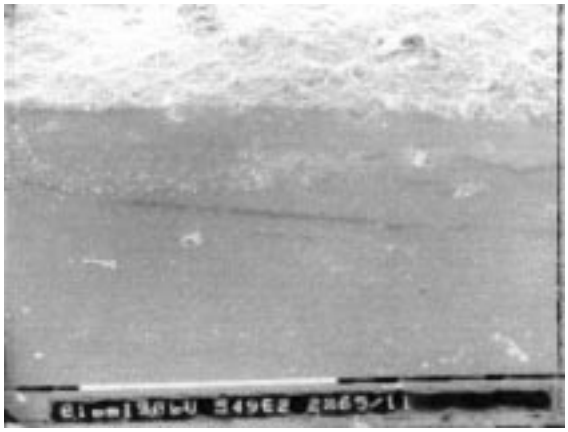
TABLE VI Mechanical resistance of gloves changed in the operating room (OR) when electronic monitoring signaled latex hydration (rupture load in g)

Test no.	Control glove	OR glove	Difference	t_f (min)
1-left	1604	1454	− 150	9
2-left	1487	1179	− 308	10
3-left	1001	1127	+ 126	11
4-left	1000	970	− 30	No alarm
5-right	1747	1665	− 82	9
6-right	1970	1247	− 723	10
7-right	858	833	− 25	11
8-right	998	982	− 16	No alarm
9-right	988	882	− 106	5
10-left	822	1028	+ 206	5
11-right	1204	1010	− 196	7
12-left	1291	916	− 375	7
Mean	1247 ± 374	1107 ± 246	−139 ± 245	
$p <$		n.s.		

4. Discussion

We have evaluated the mechanical and electrical properties of surgical gloves in the laboratory, as well as after use in the operating room. Our data indicate that such properties vary considerably from manufacturer to manufacturer and even from lot to lot, which is hardly surprising, considering that latex is a material of biological origin with an intrinsic level of variability. We have shown that glove latex is a porous material, and that a high level of porosity is associated with rapidly deteriorating mechanical and electrical properties of the gloves.

Moreover, the porosity of the glove absorbs *in vivo* the biological fluids of patients, and owing to this and to the mechanical stress to which the glove is subjected during surgical use, its electrical and mechanical qualities deteriorate more or less rapidly. In particular, the loss of the electrical insulation property exposes the surgical operator to the risk of shock from electric scalpels. The progressive loss of mechanical strength during use increases the probability that the glove will tear and cause contamination of the operator's skin with the patient's body fluids.



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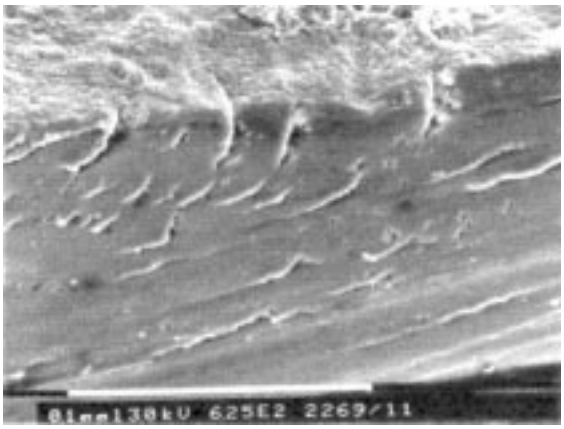
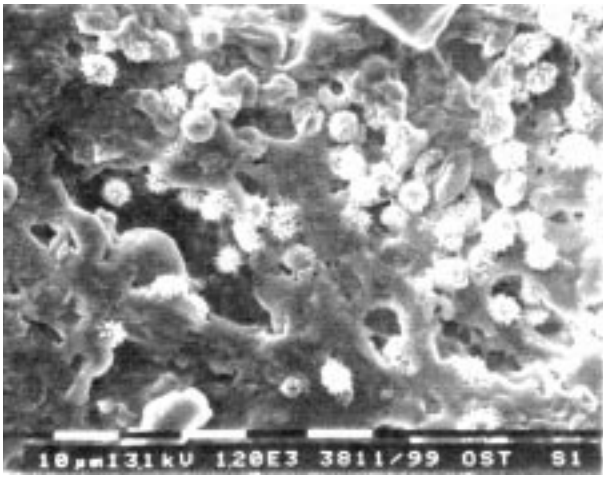


(b)

Figure 9 SEM of the thickness of latex gloves. (a): control glove (× 550). (b): glove after surgical use (hip surgery) for 30 min (× 625). Several fatigue lesions are seen after use in the operating room.



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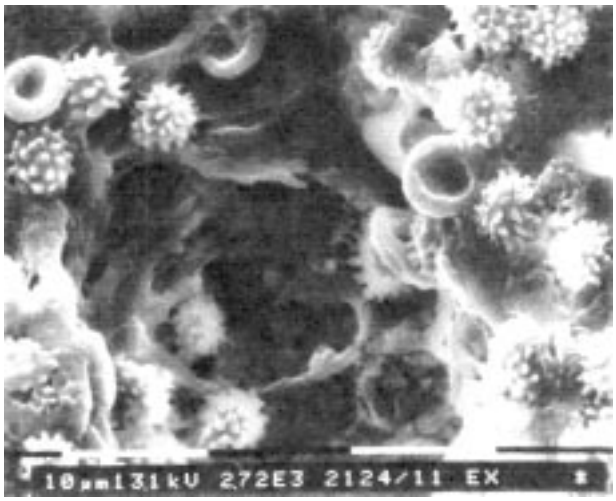

(b)

Figure 10 SEM of latex surface of glove used in the operating room. (a): × 1200; (b): × 2700. Diffuse presence of patient blood–derived corpuscles.

Our investigation for the first time used an instrumental physical approach to the assessment of functional properties of surgical gloves. Our data provide a quantitative basis for the assessment of surgical glove quality, thus setting possible new criteria for the cost-benefit analysis of this essential surgical adjunct.

Hydration can be effectively monitored in the operating theater by electronic monitoring of surgical barrier efficiency. This strategy appears to be much more reliable than changing surgical gloves every 30 min, as recommended by universal precautions [17]. Indeed, not only may the surgical operator replace a good glove with a perforated one (0.2% of surgical gloves may already be perforated at the outset [16]), but he/she may put on a glove with sub-optimal latex properties. Our study clearly shows that all latex gloves present a level of porosity the extent of which cannot be predicted without complex instrumental procedures; we observed an extreme variability not only among the different brands, but also within a single lot from the same producer.

In our experience, the hydration times found in the laboratory will reliably predict the behavior of the gloves in the operating room. As regards the mechanical properties of latex, while *in vitro* hydration in our conditions did not appear to modify these properties, significant loss of strength was associated with the hydration by body fluids during surgery, thus progressively increasing the probability of glove breaching, even on minor accidents. Even though the *in vitro* incubation of latex with heparinized blood did not significantly alter its physical properties, it may be that *in-vivo* biological activities present in blood contribute to the break-down of the physical properties.

Hydration in the operating room is due, on the inside of the glove, to perspiration from the surgeon's hand and, on the outside, to contact with the patient's blood. Particularly abundant perspiration by the surgeon may lead to hydration of the latex in a few minutes. The normal quality tests of the gloves are unable to detect the properties of latex structure in sufficient detail [16–18], and we feel it is significant that in our investigation the physical properties (mechanical resistance and electrical insulation) of the gloves were shown to be impaired quite quickly.

It is therefore useful to apply the electrical test system to detect the moment the physical properties of the glove show critical impairment, allowing the operator to

change gloves in time, before reaching the stage of actual breaching risk. Our data show that in the operating room, at the moment of hydration signaled by the alarm, the mechanical properties of the hydrated gloves were still satisfactory. If on the other hand the phenomenon of hydration is disregarded during surgery, increased fluid imbibition, with further diminution of the electrical insulation properties will follow [19] and, ultimately, impaired mechanical properties will increase the risk of tearing and unprotected skin exposure.

The importance of avoiding skin contamination by the patient's biological fluids is especially relevant for the hands and fingers, which are subject to frequent irritation an/or (micro)lesions connected with routine scrubbing procedures before surgery [20, 21]. Even though the risk of injury due to penetrating surgical tools is not affected by the electronic monitoring of the efficiency of the glove barrier, the use of such a system will ensure immediate alert when the gloves lose their insulating function, and when breaches, even of minimal entity, occur. This will prevent the risk of occult skin contamination by the patient's blood [15, 22–25]. The alerts are therefore particularly precious to avoid the often reported finding of blood stains on the fingers on removing surgical gloves.

Although latex hydration has been suggested by some researchers as a factor favoring viral passage [14], we agree that it does not appear to involve the immediate risk of transmission of pathogenic agents through the thickness of the latex [16, 26, 27]; nonetheless, hydration should certainly be taken into consideration as a factor associated with the rapid decline of the physical quality of latex.

Our data can be taken to confirm that while the intact latex glove represents an effective barrier, one must bear in mind the fragility of this barrier in the face of the combined action of mechanical, thermal and biological stress due to infiltration of body fluids during use in the operating room. On-line electronic monitoring of the properties of the gloves, in light of the data here reported, would appear more reliable and precise than the standard precautions currently recommended. The results of our investigation should be carefully considered by surgical operators, who will realize the importance of the rational quality selection of gloves used in surgery, as well as the need for careful monitoring of the continuous efficacy of the surgical barrier, of which gloves represent the first-line defense.

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