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Surgical glues: are they really adhesive?

Bertrand R.M. Perrin [a,*], Michel Dupeux [b], Piergiorgio Tozzi [a], Dominique Delay [a], Philippe Gersbach [a], Ludwig K. von Segesser [a]

[a] Department of Cardio-Vascular Surgery, CHUV, Lausanne, Switzerland
[b] SIMAP Lab. (Grenoble University/CNRS UMR 5266), Saint Martin d'Hères, France

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Abstract

Objective: The aim of this study is to create a standard test to approve the efficacy of a surgical sealant. An industrial test, the bulge-and-blister test, which is very convenient for measuring adhesion energy, is applied to the surgical field to quantify adhesion of bioadhesives. **Methods:** Samples were composed of two circular layers of equine pericardium glued by the surgical sealant studied. The sample was fixed to a support with an industrial glue. The support and the bottom layer were perforated in the centre to allow injection of pressurised water. Water was progressively introduced through the hole in the support and the bottom layer to create a blister with constant radius, increasing height and internal pressure during this first step. At a critical pressure, delamination started, the radius and height of the blister increased and the pressure decreased. At this point, the adhesion energy could be determined. The experimental parameters were measured with a pressure sensor and an optical profilometry device for deflection. **Results:** Adhesion testing was carried out in eight paired equine pericardium samples bonded with a Dermabond® cyanoacrylate glue. The average value of the practical adhesion energy is 2.3 J m^{-2} with a standard deviation of 1.5 J m^{-2}. **Conclusion:** Application of the bulge-and-blister test to the surgical field was achieved and allowed a quantification of adhesion of a surgical glue. Such information is essential to compare the different surgical glues presently available. The study of the impact of bonding conditions such as pressure, hygrometry or setting conditions will provide a better understanding of the characteristics of adhesion in the surgical field.

Keywords: Surgical glue; Bulge-and-blister test; Adhesion; Tissue joining; Cyanoacrylate

1. Introduction

Surgical adhesives are a very interesting and a promising area for development. A glue with strong adhesive properties in surgical conditions can be very useful. Some glues, such as Dermabond®, are used for skin suture. Surgical sealants are also developed for haemostasis. A third use of bioadhesives consists in closing gas and liquid leaks, such as air leaks from the lung [1].

Many different tissue sealants or haemostats have been developed over the past 30 years based on fibrin, cyanoacrylate, polyethylene glycol (PEG) [2], albumin-glutaraldehyde [3,4] or gelatin-resorcinal-formaldehyde (GRF). The cyanoacrylate tissue adhesives (Dermabond® and Liquidband®) are liquid monomers that polymerise on contact with tissue surfaces in an exothermic reaction, creating a flexible film that bonds the apposed wound edges [5]. A glue must be easy to use, safe and, above all, it must have good adhesion properties. This is a complex issue, different within each surgical specialty. However, the efficacy of a surgical glue can be summarised in two characteristics, adhesion and/or haemostasis.

Many clinical studies have been performed in surgical conditions to test these characteristics on different surgical sealants. To get approval by the FDA or to obtain the CE mark for surgical tissue adhesives, the material should meet the regulatory standards for safety and efficacy. Standards for biocompatibility are well established by the ISO 10993 norm. However, there is no equivalent standard test to approve the efficacy of a surgical sealant. Efficacy approvals are based on clinical studies without any quantitative standard or reproducibility of mechanical strength as the sealant is used in industrial tests. Only a few studies have attempted to quantify the adhesive properties of surgical glues [6–8]. The single shear-lap tensile test is the most common method used to determine adhesion of industrial structural adhesives. However, it has some basic drawbacks (detailed in Section 3), making its results strongly dependent on the size and quality of the specimens rather than on the intrinsic adhesion strength of the glue itself [9,10].

The aim of the present study is to quantify the adhesive properties of a surgical glue in an intrinsic and physically meaningful way by measuring the amount of mechanical energy needed to propagate a debonding crack along the

* Corresponding author. Address: Department of Cardio-Vascular Surgery, CHUV, rue du Bugnon 46, 1011 Lausanne, Switzerland. Tel.: +41 21 314 23 15; fax: +41 21 314 22 87.
E-mail address: Bertrand.Perrin@chuv.ch (B.R.M. Perrin).

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glued interface of interest (in joules per m^2) between representative biological tissues. The adhesion test used for this purpose is the so-called bulge-and-blister test, which has been developed by industrial engineering and is very convenient for measuring adhesion energy. First introduced by Dannenberg [11], this test proved to be applicable to varied systems including mineral, metallic or polymer materials [12–14]. It is appropriate to obtain a stable interfacial crack growth under a well-known mechanical loading mode for film/film or film/substrate geometry, which determines the interfacial crack propagation energy with the help of reliable and simple mechanical analyses, independent from the crack-initiation stage. Thus, delamination between two layers glued to each other can be analysed in a reliable and significant way, and this is the reason why the blister test has been chosen as the most relevant here.

2. Materials and methods

2.1. Principles of the bulge-and-blister test

In its principle, the test consists in applying a fluid pressure on one side of a freestanding film window through a hole in the film substrate. In this study, the film and substrate were two circular layers of equine pericardium glued by the surgical sealant to be tested. The sample was fixed to a flat aluminium support with high-strength industrial glue. The support and the bottom layer were perforated in the centre to allow the fluid injection (Fig. 1A). Eight paired calf

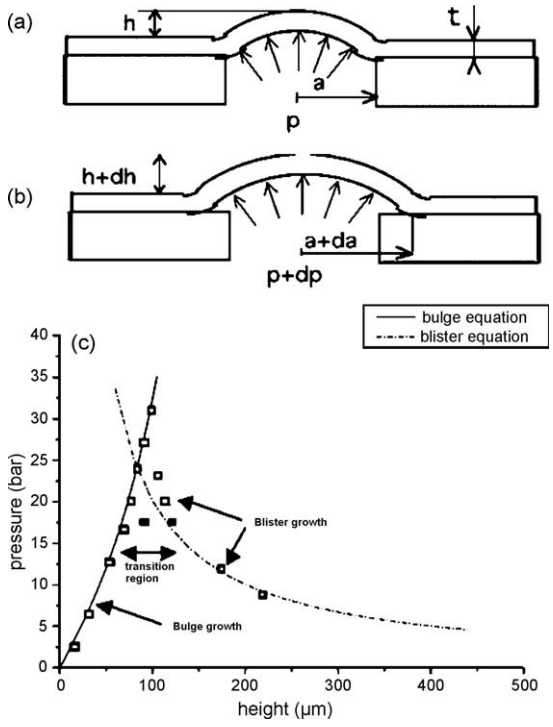

Fig. 1. (A) Bulge step for a membrane bonded to a substrate. (B) Blister step: an increment of the injected fluid volume causes the membrane to debond from the substrate. (C) Schematic of the pressure vs height data: the square dots represent possible experimental points compared to theoretical curves.

pericardium samples bonded with a Dermabond® cyanoacrylate glue were prepared to carry out the adhesion test.

As the name indicates, the bulge-and-blister test is divided in two steps. During the first part of the experiment (the bulge test), the fluid is progressively introduced through the hole in the substrate to cause an outward deflection of the freestanding membrane of the top layer. While injection proceeds, the resulting pressure p and the membrane deflection h follow an increasing curve, which can be analysed in terms of the mechanical properties of the membrane material; but, so far, the contour of the deflected membrane keeps its initial dimensions.

At a critical pressure value, delamination starts with an interfacial crack front propagating from the initial outline of the freestanding membrane (Fig. 1B). As soon as this blister step begins, the height and volume of the blister increases rapidly, thus causing a pressure decrease. The process of delamination between the two layers may begin unevenly due to the statistically variable crack-initiation conditions, which may also cause either under- or over-loading during the bulge to blister transition (Fig. 1C). However, the blister eventually becomes circular and stable as it progresses. When the top membrane behaves elastically, the stationary debonding rate is controlled by the injection rate and the p versus h curve follows a decreasing hyperbolic law

$$G_i = C \times p \times h, \tag{1}$$

where C is a numerical dimensionless constant, which varies slightly between 0.618 and 0.516 according to the residual stress value in the film, and G_i is the interfacial crack propagation energy [14] (Fig. 1C). To reach such a stable crack growth regime, first, the pressurising fluid must be incompressible (a liquid rather than a gas; distilled water was used in the present study); second, the pressurising system must be controlled through volumetric injection rather than pressure regulation.

2.2. Preparation of the samples

Preparation of the samples is a very important and difficult part of the test. This step is essential to get a proper and stable de-cohesion providing measurable blisters. To simulate surgical conditions, it was necessary to use a biological material for the adhesive bond. To obtain reproducible conditions, we needed a standard material comparable for each sample, which was waterproof with enough strength and stiffness. Equine pericardial patches (Edwards, St-Jude) are designed for cardiac and vascular reconstruction and repair. Pericardial patches are fixed by glutaraldehyde to mitigate antigenicity and cytotoxicity and yield a biologically stable patch material. Pericardial patches are packaged in sterile water and 2% propylene oxide that, prior to shipment, undergoes a chemical conversion to 2% propylene glycol. The patches are available in 9 cm × 14 cm sizes with a thickness of 2 mm. Discs measuring 26 mm in diameter were cut from these patches.

The first pericardium layer was fixed to the aluminium sample holder with a commercial sealant Saderglue® and then pressed for 30 min to 12 h. This step was very important because this first layer was to act as the substrate and its interface with the aluminium sample holder had to be strong

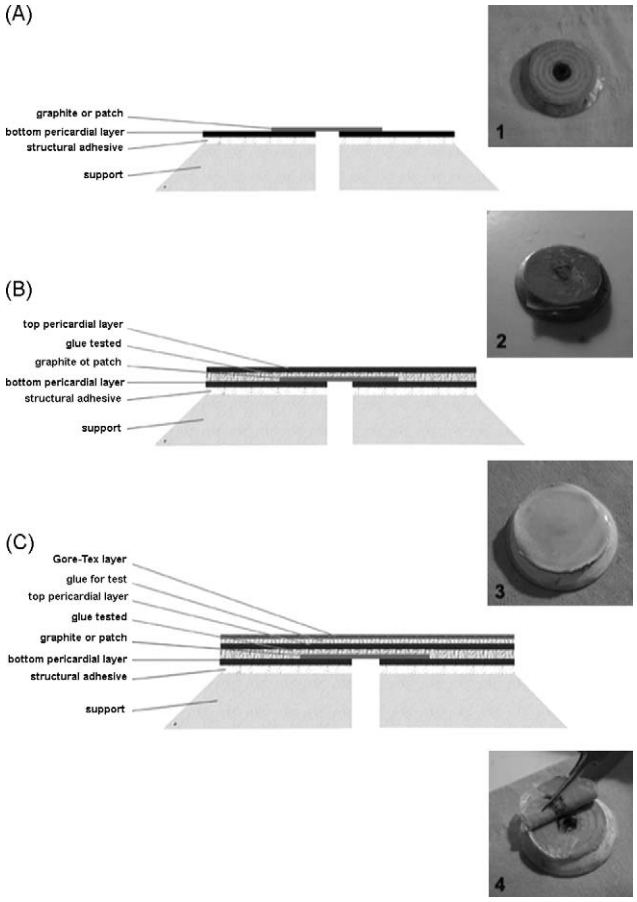

Fig. 2. Preparation of the samples. (A and 1) Unbounded zone with graphite or patch of Teflon, (B and 2) fixation of the top pericardial layer, (C and 3) fixation of the Gore-Tex layer, (4) delamination between the two pericardial layers.

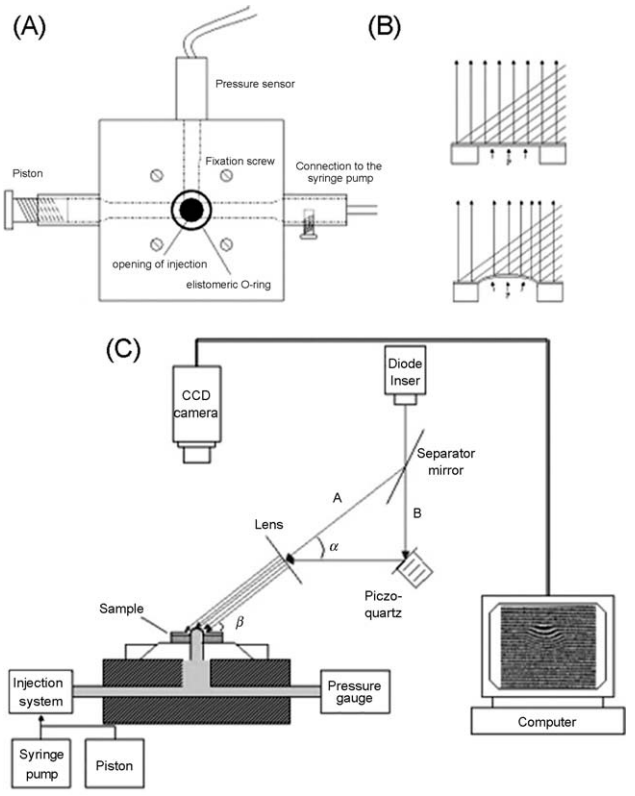

Fig. 3. Illustration of the test set-up. (A) Pressurizing block (top view), (B) principles of fringe projection profilometry, (C) complete set-up.

enough to avoid infiltration of the pressurised water. A hole was cut in the centre of the layer with a punch, corresponding to the 3-mm injection hole in the sample holder. A 6-mm unbonded zone was prepared with graphite in the centre of the support, around the hole (Figs. 2A and 1), or with a patch of thin Teflon or polyethylene. This central patch or zone with graphite excluded most of the glue from the injection hole in the centre of the support, thus clearing it for correct water injection. This contaminated zone was also a starter zone for the delamination because adhesion of any glue is weaker on graphite or Teflon. At this stage, the glue to be studied was applied on the first layer around the contamination zone or the patch of Teflon. The second pericardium layer was then fixed and pressed on the first layer (Figs. 2B and 2). The tested glue was left to set under the desired conditions of temperature and duration. During the injection, the water pressure caused the debonded part of the top layer to bulge. Wet pericardial layer has weak elastic properties so that the high deflection and the steep slopes of the resulting blister might disturb further optical measurements. To prevent this and increase the overall stiffness of the top layer, an extra thin layer of Gore-Tex (0.1 mm thick, with a very small bending resistance but high tensile stiffness) was glued with the same surgical sealant as studied on the top of the second pericardial layer (Figs. 2C and 3). At the end of the experiment, we could check that the delamination occurred between the two pericardial layers (Figs. 2 and 4).

We only tested Dermabond®, a cyanoacrylate glue, for this preliminary part of the study. This glue is one that is most widely used in surgical practice and easy to conserve. It is one of the least expensive and simple to use.

2.3. Description of the test setup

After preparation, the sample was fixed on a pressurising block filled with distilled water. A micrometric screw piston and a syringe pump were used to inject water towards the specimen, while the internal pressure was measured thanks to a piezoelectric sensor (Fig. 3A). The height and contour of the bulging part of the top layer was determined with help of a fringe projection system. A set of parallel interference fringes was produced from a laser beam and projected on the specimen in oblique incidence. A CCD camera was fixed over the apparatus and gave top views of the sample illuminated by the laser fringes.

These images were digitalised by a computer and analysed by a software (Fringe Analysis 2.5®) [15,16]. Fringes were projected on the sample with a certain angle. When the sample is flat, the fringes observed by the camera in normal view are parallel and equidistant. When the bulge deforms the sample surface, fringes are shifted laterally and became non-equidistant (Figs. 3B and 4A). The software compared fringes of the sample with the bulge to the flat sample of reference and deduced a phase image (Fig. 4B) from which the geometry of the observed surface can be calculated. The

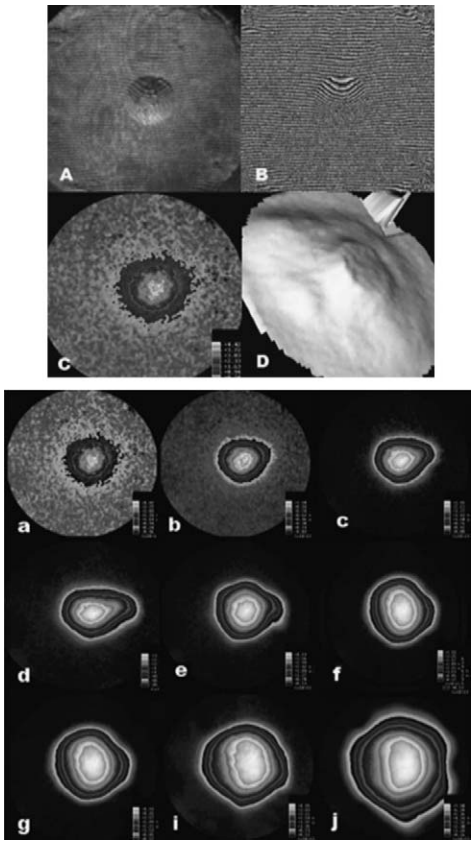

Fig. 4. (A) Real image; (B) phase image of bulge A; (C) 2D image altitude map; (D) 3D image. (a–i) Illustration of experiment no. 9; (a–d) constitution of the bulge; (e–j) constitution of the blister.

software was also able to create a map of the specimen surface with level curves (Fig. 4C) or 3D images (Fig. 4D). Thus, the height (±5 μm accuracy) and lateral contour and dimensions (±0.5 mm accuracy) of the bulge could be determined at any step of the test.

3. Results

An example of the experiment is illustrated in Figs. 5 and 4A–I and Table 1. The experiment started with the progressive introduction of water through the hole in the support and the bottom layer to create the bulge. Illustrations A–D in Fig. 4 show the growth of the bulge. The first bulge contour is circular and in the next four images

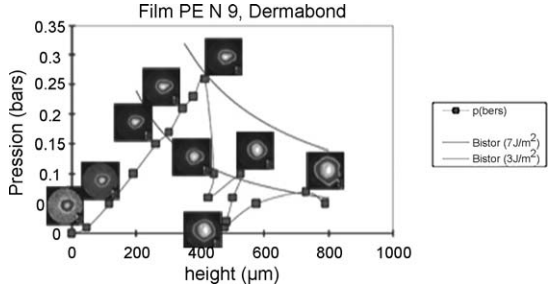

Fig. 5. Experiment no. 9, illustration on *p* vs *h* curve.

Table 1
Experiment no. 9, heights and pressures.

Measurements	*h* (μm)	*p* (bar)	Image 1
1	0	0	
2	47	0.01	a
3	117	0.05	b
4	191	0.1	
5	261	0.15	c
6	302	0.17	
7	344	0.21	d
8	378	0.23	
9	413	0.26	e
10	442	0.1	f
11	424	0.06	
12	525	0.1	g
13	501	0.06	
14	480	0.02	
15	473	0.01	h
16	573	0.05	
17	727	0.07	I
18	787	0.05	

the bulge is seen to become irregular in its upper right side. Sometimes, because of irregularities of adhesion close to the central initiation zone, the bulge could be asymmetrical. During this first step introducing the liquid, the bulge took its initial contour before delamination. Pressure *p* and the membrane deflection *h* followed an increasing curve. The illustrations F–I in Fig. 4 illustrate the constitution of the blister with the lateral enlargement of the debonded area. Between illustrations e and f (Fig. 4), the blister becomes more circular. This evolution was in relation to an increase of the blister deflection *h* and volume, and a consequent decrease of the pressure *p* (measure 9, $p = 0.26$ bar; $h = 413$ μm; measure 10, $p = 0.10$ bar; $h = 442$ μm). This is also well illustrated in Fig. 5. After a long ascending curve, the *p* versus *h* curve drops suddenly in association to delamination demonstrated by the enlargement of the blister. The pressure decrease stopped spontaneously and matched with measure 11. Then, the pressure was increased again by means of the injection piston. A second delamination was observed after measure 12 (Fig. 5), and illustrated by a new enlargement of the blister between illustrations g and h (Fig. 5). A last delamination occurred at measure 17. The complete delamination of the sample in this experiment occurred in three successive steps. The *p* versus *h* curve did not follow a regular decreasing hyperbolic law as presented previously in Fig. 1C but each delamination critical point – characterised by a sudden decrease in pressure – corresponds to a hyperbolic curve matching with a given value of interfacial crack propagation energy. In this experiment, we observed that the first delamination matched with an interfacial crack propagation energy of 7 J m^{-2}, and the last two delaminations with an interfacial crack propagation energy of 3 J m^{-2}, with a fitting incertitude about 0.1 J m^{-2} for each of these values.

Adhesion testing was carried out successfully on eight paired equine pericardium samples bonded with Dermabond® cyanoacrylate glue (Table 2). For example, photographs 2–4 show *post mortem* that the crack has propagated at the interface between the two layers. For some of these specimens, it has been possible to obtain several successive

Table 2
Adhesion energies (G) of 18 delaminations on eight samples.

	Experiments							
	PERI 4	PERI 5	PERI 7	PERI 8	PERI 9	PERI 10	PERI 12	PERI 13
Reticulation time	1 h	1 h	17 h	17 h	17 h	20 min	12 h	1 h
G_1 (J m^{-2})	3	1.8	1.8	1.8	7	1	0.9	1
G_2 (J m^{-2})				3	3	1	0.9	0.9
G_3 (J m^{-2})					3	1	0.9	0.9
G_4 (J m^{-2})							1	

propagation steps after repeated decrease of the internal pressure and re-injecting water. Mean reticulation time between the two pericardial layers was 8125 h (ranging from 20 min to 17 h). Adhesion energy was estimated in 18 delaminations, with five delaminations at 0.9 J m^{-2} (28%), five delaminations at 1 J m^{-2} (28%), three delaminations at 1.8 J m^{-2} (17%), four delaminations at 3 J m^{-2} (22%) and one delamination at 7 J m^{-2} (5%) (Table 2).

4. Discussion

We adapted the bulge-and-blister test to measure the practical adhesion energy of surgical glues on specially designed samples of two equine pericardium layers bonded together with the glue of interest. This test allowed a way of quantifying the adhesion energy of the glued bond.

4.1. Specific experimental features

4.1.1. Homogeneity of the bonded surfaces

Adhesion between two surfaces glued is rarely homogeneous. This aspect of adhesion is desired but difficult to obtain. It requires complete homogeneous thicknesses of the layers, surfaces of adhesion without any cracks or local contamination and uniform quality of the glue and conditions of adhesion. The application of the glue must be identical and various elements such as compression, duration and temperature for the reticulation must be optimised to obtain the optimal adhesion everywhere on the bonded surface. Slight variations of such parameters are likely to explain most of the dispersion of our results, which occurs even on a given specimen when several successive debonds have been obtained. However, in this series of results, it has not been possible to find any clear correlation between the measured energy and the reticulation duration.

4.1.2. Crack-initiation energy

The highest among our experimental energy values (7 J m^{-2}) was measured only once out of the 18 results. Since it was the first debonding of the specimen PERI 9, it was probably due to unwanted penetration of glue in the injection port during the preparation of this specimen, thus making the first crack initiation more difficult. As a consequence, if these first experiments are included, the average value of the practical adhesion energy is about 2.3 J m^{-2} (with a standard deviation about 1.5 J m^{-2}). If the delamination with the highly questionable value of 7 J m^{-2} is excluded, then the average value is 1.6 J m^{-2} (with a standard deviation about 1.1 J m^{-2}).

4.1.3. Visco-elastic behaviour of the biological support and subcritical propagation of the interfacial crack

At the end of the water injection, we observed a spontaneous decrease of the pressure without any delamination. Such relaxation is related to the visco-elastic behaviour of the pericardium, which is typical with biological tissues. Different and more complex theoretical approaches could account for this behaviour. Another option would be to use a high-density liquid, instead of water, to reduce the impregnation of the pericardial layers.

Another phenomenon observed at the end of the water injection was an increase of the delamination even when the pressure is very low. This characteristic is known as a subcritical propagation. The way to exclude this artefact is to take the propagation energy value into account at the beginning of each delamination step.

The actual discrepancy should be restricted in the future with further development of the methodology (improvement in the preparation of samples to obtain a continuous and circular delamination) and correction of artefacts. This topic needs to be fully detailed in a separate article.

4.1.4. Comparison between surgical and industrial glues adhesion energies

To our knowledge, no other practical adhesion energy values for surgical glues are available in scientific literature. So, our results can only be compared to the adhesion energies obtained with structural adhesives on industrial materials, which usually range from some tens to hundreds of J m^{-2} [10]. This first set of results provides an average about 1.6 J m^{-2} $\pm$ 1.1 J m^{-2}, which is a very small value with regard to the practical adhesion energy values of industrial adhesives on metallic, polymer or ceramic-glued joints. For instance, adhesion energies for common adhesive tapes on a polymer surface are in the range of a few J m^{-2}, while assemblies of polymer parts with domestic glues can hold several 10 J m^{-2} and industrial joints between structural metal parts with a technical adhesive may reach several 100 J m^{-2}. Indeed, in practical surgery, the efficiency of a surgical glue alone on a wound or cut to be closed is rather small, due to surgical conditions such as contamination by blood and fat, or possibly the limited strength of biological tissues themselves. For example, it is not unimaginable to get sufficient adhesion to join a vascular prosthesis to an artery without a traditional suture. More experiments and observations of the fractured surfaces are necessary to decide which is the physical or chemical limiting process at the microscopic scale for the crack propagation and the practical toughness of the surgical glue bonds.

4.1.5. Interests of the bulge-and-blister test (compared to other adhesion tests)

As mentioned in Section 1, a few papers are available concerning the adhesive strength of surgical glues, and all of them rely on tensile tests either of sutured joints or of the single shear-lap glued specimens [6—8]. Among the more than 200 tests available to measure adhesion [9,10,17,18], the shear-lap test is widely used in industry to evaluate adhesion. It is well standardised and seems easy to perform and analyse at first sight; however, the shear-lap tensile test does not provide very accurate and reproducible results, neither on industrial nor on surgical bonds. Measurements have to be performed at least four or five times to obtain a reliable average of the adhesion strength, with a large uncertainty. In case of highly inhomogeneous interfaces, as on a sample with porcine skin [6,8] this dispersion is increased. Indeed, even if it allows fruitful comparative studies, this test does not really quantify the intrinsic adhesive properties, because its results mix together both the crack-initiation resistance and the crack propagation strength. The crack initiation at the edges of the specimen is a decisive step which controls the maximum strength experimental value, and depends strongly on the dimensions and quality of the specimens. Because the crack initiation needs a maximum strength (superior to the crack propagation), the fracture is generally rather sudden and unstable, which makes it impossible to know the exact applied stress at each stage of the fracture process.

In comparison, the bulge-and-blister test is free from all these disadvantages, and well described from the mechanical point of view, at least for industrial elasto-plastic materials [11—14]. So, we chose the bulge-and-blister test for this study because it allows continuous determination of the critical energy of the crack propagation. The progressive delamination can be followed, monitored and recorded step by step which provides a better understanding of the phenomenon. The reproducibility and accuracy of the results is only dependent on the homogeneity and intrinsic reproducibility of the specimens.

4.1.6. Interests of the study and future developments

Even if it seems important to pay special attention to prepare reproducible and homogeneous glued specimens, the bulge-and-blister test appears to be promising in quantifying the intrinsic adhesive properties of two biological layers glued with any type of surgical sealant. Such information and data are essential to compare and improve the various surgical glues presently available. Study of the impact of various bonding conditions such as normal pressure during setting, hygrometry, time of reticulation of the glue, nature of the debonding liquid and the tissue impregnation liquid will provide better understanding of the adhesion phenomenon. With an experimental procedure including variation of these parameters, the bulge-and-blister test will be more appropriate to evaluate the effectiveness of sealants in the surgical field. This test is essential to understand adhesion and will provide ways to improve its efficacy. The association of the test with clinical evaluation will give a complete report of the effectiveness of surgical glues.

The incredible evolution of industrial adhesion during the past decades has been performed principally thanks to the study of the adhered surfaces. Industrial glues achieved spectacular advances with the understanding of adhesion properties through specific tests and studies. The main progress has been made by studying the chemical characteristics of the surface to be bonded, together with the mechanical aspects of adhesion [17,18]. Biological surfaces are also better known now and this could be an interesting starting point for the development of surgical glues. In that respect, a standard and reliable test such as the bulge-and-blister test is essential to understanding factors governing adhesion. A large number of animals such as the Gecko use natural adhesion. Recently, considerable efforts have been devoted towards the understanding of adhesion mechanisms in nature in order to develop new concepts for adhesion and new synthetic glues [19]. Such promising ideas can be useful also for medical research, for surgical glues, for anti-adhesive surface treatments or else for the adhesion of special coatings on biological or biocompatible materials [20].

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