International Journal of Pharmaceutics 368 (2009) 83–88

Contents lists available at ScienceDirect

International Journal of Pharmaceutics

journal homepage: www.elsevier.com/locate/ijpharm

Adherence performances of pressure sensitive adhesives on a model viscoelastic synthetic film: A tool for the understanding of adhesion on the human skin

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ARTICLE INFO

Article history:
Received 1 August 2008
Received in revised form
30 September 2008
Accepted 30 September 2008
Available online 17 October 2008

Keywords:
Peeling tests
Adhesion
Adherence
Rheological behavior
Human skin
Synthetic skin
Wound dressings

ABSTRACT

This work deals with the rheological behavior and adherence properties of pressure sensitive adhesive formulations dedicated to medical applications. We have developed a specific viscoelastic substrate which mimics adhesion on human skin to measure the adherence properties of PSAs when they are stuck on the human skin. By comparing peeling results of PSAs, dedicated to medical applications, stuck on human skin and on this viscoelastic substrate we show that this substrate, based on a blend of natural proteins, presents a better representation of the interactions occurring at the skin/adhesive interface than conventional substrates used for peel test (*i.e.* glass and steel).

1. Introduction

The adherence performances of soft adhesives depend on (i) the interfacial properties of the substrate (Gent and Schultz, 1972) and (ii) strongly on their rheological behavior (Gent and Petrich, 1969; Yarrusso, 2002; Derail et al., 1997; Benyahia et al., 1997). One can establish, as a first approximation, quantitative relationships between the rheological behavior measured in the linear domain and the adherence properties of soft adhesives such as hot melt (HM) or pressure sensitive adhesives (PSAs) (Derail et al., 1997; Benyahia et al., 1997; Gibert et al., 1999; Gower and Shanks, 2005). In the case where the structure of the polymer-base is well defined, it has been shown that the rheological behavior can be analytically described through concepts of molecular dynamics (Benallal et al., 1993; Gibert et al., 2003). This type of description has been successfully extended to the case of soft adhesive formulations (Derail et al., 1997, 2004; Gibert et al., 2003). The relationship between rheological behavior and peeling performances is quite clear when the adhesive is deposited on a non-deformable substrate which also presents a strong affinity with adhesive (high surface energy for the substrate) (Derail et al., 1997; Gower and Shanks, 2005; Marin and Derail, 2006). In the case where surface energy becomes lower (Marin and Derail, 2006) and/or in the case of flexible substrate (Kinloch et al., 1994; Williams, 1993; Chivers, 2001; Renvoise et al., 2007a), the picture becomes much more complex.

In the particular case of viscoelastic substrates, the adhesive properties (particularly the peeling behavior) depends strongly on the mechanical properties of the substrate as well as on the adhesion properties as shown by Chivers (2001) in the field of wound dressings. This author compares the peel force measured on different backing materials using calculations proposed by Kinloch et al. (1994) and Williams (1993). He shows that, within the elastic domain, one may determine the variations of the peeling force by taking into account the deformation of the substrate. In the same way, Renvoise et al. (2007a) compare the peel force measured for various adhesive formulations deposited on different substrates, in particular by using a synthetic film which is especially formulated in order to mimic the viscoelastic properties of the skin and described in Renvoise (2006) and Renvoise et al. (2007b). A similar model substrate has been also described in detail by Lir et al. (2007). This substrate has been clearly developed to mimic mechanical and interfacial properties of real skin using a simple process, and not biological properties which are out of the scope of adhesion performances studies. As a first approximation, this type of model

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doi:10.1016/j.ijpharm.2008.09.056

substrate is not relevant for pharmaceutical applications such as transdermal drug delivery for example.

Renvoise et al. (2007a) propose a "failure transition diagram" which allows end-users to predict the rupture mode depending on both the rheological behavior of the substrate and the adhesive. This diagram shows two important features. When the elastic moduli of the adhesive and the substrate are very different, the rheological behavior drives mainly adherence performances, in a predictable way. The model indicates on the contrary that the relationship becomes more complex when the rheological behaviors of the two parts of the assembly (adhesive and substrate) are very close.

As Chivers (2001) recalls, the essential requirements for PSAs dedicated to medical applications are the need to stick firmly but also to be easily and cleanly removed. The first property may be quite easily obtained by addition of a tackifying resin to the polymer-base. In addition, tack properties must be controlled to avoid some damages on the skin when one removes the dressings for example. Finally, to obtain a clean and easy removal, one has also to take into account the evolution of cohesion of the adhesive during wearing time (absorption of liquids as sweat or secretions).

In this paper we will mainly deal with the case of peeling on human skin. The problem is highly complex particularly because the physiological properties of human skin depend on a large number of parameters such as gender, age, location on the body..., which makes comparative studies difficult to set up. In order to simplify the study of adherence performances of adhesives on human kin, we will focus on the synthetic substrate used by Renvoise et al. (2007a,b) and Renvoise (2006) which mimics the mechanical properties of an "average" human skin. We will compare the peeling properties of commercial adhesives dedicated to a particular medical application (stomae tool), these adhesives being stuck on the forearm of different subjects for characterizing *in vivo* behavior and also on the synthetic substrate for *in vitro* reference testing. We will comment also on the limitations of the model substrate. We will conclude by some comments on different ways to improve adhesives dedicated to medical application on the basis of this rheological approach.

2. Materials and methods

2.1. Adhesives

To compare the peeling properties on human skin and on a synthetic substrate prepared in the laboratory, we have used four different commercial adhesive formulations developed by the BBraun Medical OPM® Company. An important component of the adhesive formulation is the hydrocolloid. This type of filler allows the dressing to pump secretions around the wound as well as sweat, in order to maintain adhesion of the dressing. Regarding rheological properties, this filler plays the same role as a regular polymer filler component. The composition of the adhesives is reported in Table 1.

Table 1
Composition of adhesive formulations.

	Polyisobutylene content (%) (10^5 g mol^{-1} < M_w < 10^4 g mol^{-1})	Filler content (%)	Other components (%)
I1	34	54	12
I2	44	45	11
I3	37	52	11
I4	44	51	5

2.2. Substrates

We have performed peeling tests on various human subjects in order to determine an average of peeling force of adhesives stuck on human body. As described in the next part of this paper, the *in vivo* peeling tests took place with a special preparation of the skin to mimic the state of the skin around a chronic wound after peeling of wound dressings time after time.

In the same time, we have prepared a substitute of human skin to mimic average *in vivo* peeling behavior. This synthetic substrate is a 1-mm thick film made from a natural protein (gelatine from pig skin) formulated with additional components in order to reproduce the mechanical and surface properties of human skin. The main components added to gelatin allow in particular adjusting the interfacial energy (fat components) and the rheological behavior by reticulation of the proteins. We have prepared a modified aluminum surface by chemical abrasion as a negative mould of human skin. The solution of natural protein is deposited on this surface before reticulation. Fig. 1 contains pictures showing similar topographies between human skin and artificial substrate. Various changes in the formulation of the skin substitute allow getting a very broad range of Young's modulus values close to values reported in the literature for human skin (Jego et al., 2004). We have reported some relevant data on skin in Table 2. We have performed studies on one given specific composition which represents an "average natural skin" behavior (surface and bulk).

2.3. Surface energy measurement

A contact angle method has been used to measure the angle formed between three different liquids and the substitute, using

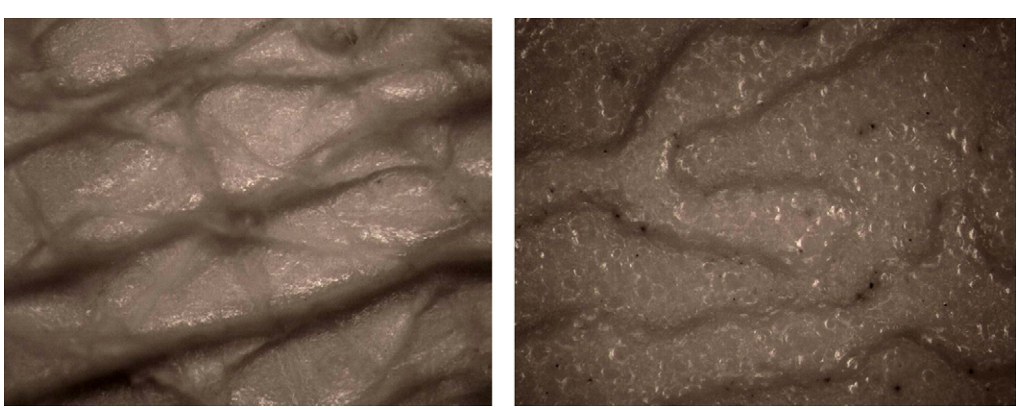

Fig. 1. Human skin (left) and synthetic film (right). The main surface parameters are given in Table 2.

Table 2
Young's modulus, interfacial energy and depth of the crevasses for human skin (Renvoise, 2006; Renvoise et al., 2007b) and synthetic film. The crevasses have been measured by profilometry.

	Young modulus [Pa]	γ_s (mN m^{-1})	Mean depth of the crevasses (μm)
Human skin of old man	–	–	91
Human skin of young man	–	–	36.3
Human skin prepared	2×10^4 to 1×10^8	25.3	–
Skin substitute	2×10^5 to 1×10^8	29	79.3

a DIGIDROP apparatus (GBX, Romans, France). The shape of the drop was recorded immediately after deposition of the droplet. The imaging system comprises a high speed CCD video camera for data acquisition and an image analysis software. Surface tension (γ_s) of the substitute is calculated using the Owens–Wendt method (Owens and Wendt, 1969).

2.4. Peeling experiments

The peel sample is made of an adhesive formulation applied to a non-woven backing layer. This backing material is considered as flexible layer and does not deform during the peeling experiments. Each strip is 1.5-cm wide, with a thickness of 1.5-mm. We have used two different methods to evaluate adherence properties:

(1) For *in vivo* experiments, the adhesive strips are applied to the prepared forearm of a subject, and left for a dwell time of 24 h. Peeling of the strip is made at fixed angle and peeling rate (180°, 150 mm min^{-1}). Temperature of the experiment is considered to be 33 °C, *i.e.* the average external human body temperature. The experiments have been performed on the forearm of four different subjects (Table 3). The forearm is placed on a mobile support and the layer is peeled at constant peeling rate with a cable attached on one side to the adhesive and to the mobile sleeper of the traction machine on the other side. We will discuss the specific preparation of the forearm of the subjects in the experimental part.
(2) For peeling on the skin substitute, what we will call *in vitro* experiments, the adhesive strip is stuck on the skin substitute, and left in a ventilated oven at 33 °C during 24 h. The sample is attached to a peeling system and tested in the same conditions as for the *in vivo* case. We have performed peeling experiments at various peeling angles. The angle value is given in each case.

2.5. Rheological experiments

To evaluate the rheological properties of the viscoelastic substrate and the adhesives, we have measured the variations of the complex shear modulus as a function of angular frequency at a reference temperature corresponding to the average temperature at the surface of human skin which is about 33 °C. We have used a rotational rheometer (RDAII, Rheometrics) in a parallel plates geometry. Measurements have been performed in the linear domain initially determined from a strain sweep.

Table 3
Characteristics of the different subjects.

Subject	Age (year)	Gender
S_1	25	Male
S_2	30	Female
S_3	23	Male
S_4	36	Female

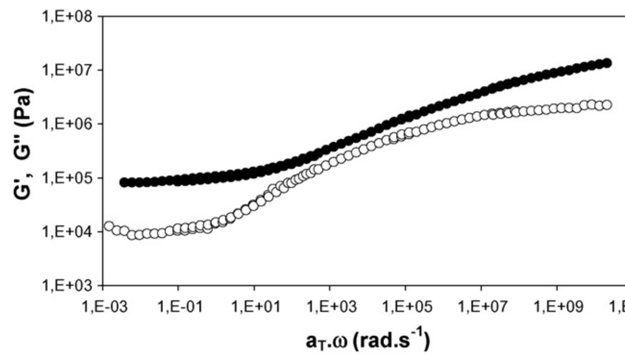

Fig. 2. Complex shear modulus of the synthetic film as a function of angular frequency at T_{ref} = 33 °C. (●) G', (○) G″.

3. Experimental results and discussion

3.1. Rheological properties of the substitute

The values of the mechanical properties of human skin obtained from *in vitro* tests may vary within a very large range because the quality of human skin is highly variable depending on age, gender and location on the human body. Hence the Young's modulus of human epidermis lies in a broad range of values from 0.02 MPa up to 80 MPa (Jego et al., 2004). We have confirmed this range of values using uniaxial tension tests performed on abdominal pork skin which is considered as a good substitute of human skin. In terms of elastic shear modulus, one can expect values ranging from 1×10^3 Pa to about 6×10^3 Pa (Jego et al., 2004). The rheological behavior of the synthetic substrates used in the present study is presented in Fig. 2. We recall that it is possible to get a comprehensive range of rheological signatures by playing on the components of the formulation.

3.2. Surface properties of the substitute

Various authors have evaluated the surface energy of human skin following different methods (Ginn et al., 1968; Schott, 1971; El-Shimi and Goddard, 1974; El Khyat et al., 1996; Maillard-Salin et al., 2000). One can notice that the skin is often prepared before measurement by solvent washing. We have reported some data in Table 4. The surface tension of the substitute, namely 29 mN m^{-1},

Table 4
Surface parameters for different types of preparation of human skin (Jego et al., 2004; Owens and Wendt, 1969; Ginn et al., 1968; Schott, 1971; El-Shimi and Goddard, 1974) and skin substitute.

Substrate	Surface energy, γ_s (mN m^{-1})	Dispersive component, γ^d (mN m^{-1})	Polar component, γ^p (mN m^{-1})
Human skin	38.9	29.6	9.3
Human skin prepared	25.3	22.8	2.5
Substitute	29.0	26.9	2.1

is mainly composed of a dispersive part. These results are in agreement with the data given in the literature. The substitute will hence give a better representation of the surface forces developed between an adhesive and natural skin, as compared with usual substrates used in peel testing such as glass (ca 80 mN m^{-1}) or steel (ca 500 mN m^{-1}).

3.3. Preparation of the skin of the subjects before peeling experiments

In a series of experiments, Bothwell (1970) has measured the peeling force of a piece of adhesive stuck on the back of the subjects. Each piece of adhesive was applied during 24 h on the back of each subject and subsequently peeled. The same experiment has been repeated day after day at the same location on the skin. Bothwell reports that in the first days the peeling force increases. After about 10 days the peeling force tends towards a limiting value which depends on the subject. The skin seems to adapt itself against the aggressive procedure of peeling by modifying the complex structure of the stratum corneum layers. On the basis of these experiments we have prepared the skin of the subjects in order to get a significant *in vivo* adhesion value for the adhesives under study.

We have selected the forearm of various subjects to perform *in vivo* peeling tests. We stick first the adhesive strip and we perform the peeling experiment after a dwell time of 24 h. The tested location is then cleaned with alcohol, dried and a new strip of adhesive is applied on the same location for a dwell time of 24 h. The strip is then peeled again and the process is repeated during 10 days. The results have been reported in Fig. 3. According to the subject, one can notice that (i) the rate of increase of peeling force is highly variable and (ii) the maximum peeling force is reached for different number of peeling experiments. As a conclusion, one can consider that the limiting value for the peeling force is reached after about 8 days whatever the subject. So, in all reported *in vivo* experiments, the forearm of all subjects has been prepared by applying a strip for a dwell time of 24 h, with a peeling rate of 150 mm min^{-1}. This procedure will be repeated 10 times before measuring the given values of peeling force.

3.4. Peeling behavior of the synthetic substrate according to human experiments

For pressure sensitive adhesive tapes, typical value of "real life" removal rates from skin ranges from 100 mm min^{-1} to

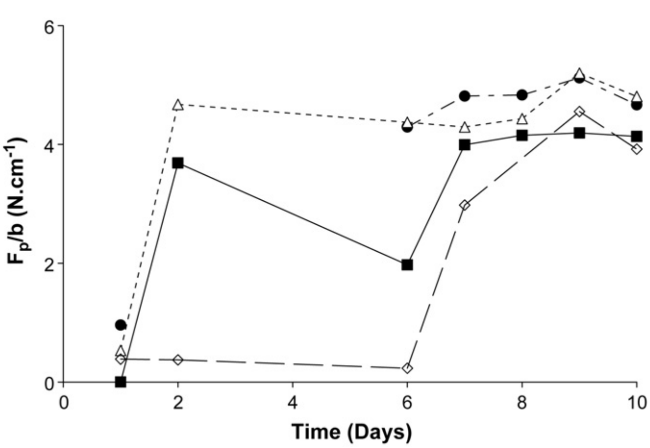

Fig. 3. Normalized peeling force of tapes removed and reapplied daily for 10 days on four subjects. (●) S_1, (■) S_2, (△) S_3, (◊) S_4.

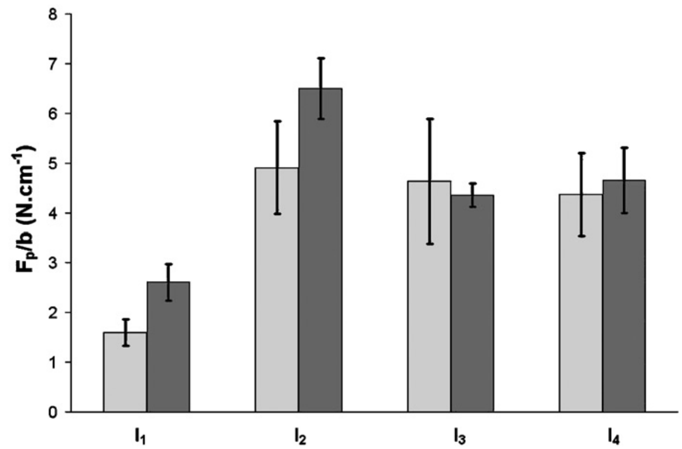

Fig. 4. Comparison of the normalized peeling force for four different adhesives (Table 1) removed from the forearm of four subjects (grey) and from the substitute (black). Peeling rate is 150 mm min^{-1}. T = 33 °C.

200 mm min^{-1} (Internal Data, in press). With the adhesives used in the present paper, cohesive failure occurs, leaving a sticky film on the skin corresponding to large peel force values.

We have used the four different adhesive formulations described in Table 1 and performed *in vivo* and *in vitro* peeling experiments. These peeling tests have been carried out at a peeling rate of 150 mm min^{-1} and a temperature of 33 °C in the aim to be close to the real case. In the case of *in vivo* experiments, the forearm of the subject has been prepared as described previously. This type of natural substrate which is peeled a repeated number of times can be considered as representing the case of the behavior of natural skin around a chronic wound.

As shown in Fig. 4, the level of peeling forces obtained when peeling on the substitute is quite close to what is obtained on natural skin. The ranking of each adhesive formulation is the same in both cases. Each value corresponds to an average of three peeling experiments performed in the same conditions for each subject.

It is important to notice at this stage of the study that one can consider that all the present peeling experiments are performed in dry conditions. The subject was forbidden to have physical activities such as sport and had to protect his forearm when he was washing himself. The wearing time on the forearm was short in these experiments and we have never observed a high de-cohesion of the adhesive as in the case of real applications.

Finally, the effect of diffusion of sweat within the adhesive during the wearing time on human body is obviously a key parameter to really control the behavior of the adhesive. We have performed experiments to evaluate the change in rheological behavior of the adhesive after a wetting time in conditions similar to human body. The results are described elsewhere and out of the scope of the present paper (Derail et al., 2008).

3.5. Effect of the peeling rate on peeling force on the synthetic substrate and on real skin

We have evaluated at last the range of peeling rates where the observed behavior is similar for human skin and the synthetic substrate. Different modes of failure can be observed when one performs peeling experiments on high energy rigid substrates at different peeling rates (Derail et al., 1997; Renvoise et al., 2007a). Usually, the fracture propagates within the adhesive layer (cohesive failure) at very low peeling rates. At higher peeling rates, one observes interfacial failure at different locations depending on the peeling rates and the type of the substrates. At intermediate peeling rates one observes a rubberlike failure, then a stick-slip unstable behavior at higher peel rates and finally a glassy fracture at very high peel rates. The stick-slip fracture is the image of the rubber to glass transition domain of the adhesive (Gibert et al., 1999; Marin and Derail, 2006) and precedes the glassy domain where the adhesive is brittle and the peeling force becomes negligible.

As an example, *in vivo* testing has been performed on the prepared forearm of one of the subjects (female, 36 years old, S_4) at peeling rates ranging from 10 mm min^{-1} to 1000 mm min^{-1} out of the range of typical peeling rates for the present application (stomae tool). We have kept the peel angle constant (180°). Temperature is still considered to be 33 °C at the surface of human skin. One can see in Fig. 5 that the force increases with increasing peeling rate at low peel rates. One obtains there a cohesive failure: a sticky film is left on the skin. As the removal rate increases, we then find a transition region where the failure propagates in a mixed mode, a combination of cohesive and interfacial failure: the range of this domain extends from 750 mm min^{-1} to 850 mm min^{-1}. Up to this range, the failure propagates between the adhesive and the skin, such as an interfacial fracture mode: no sticky film is left on the skin after peeling.

For the *in vitro* method on the substitute, we have used the same adhesive formulation at the same peeling rates range. The results are compared with the values obtained for natural skin (Fig. 5): one can notice that peeling force values obtained on the skin substitute vary in the same range as for *in vivo* case. One can observe in particular that the same mode of failure as well as the same level of peeling forces as for human skin are obtained for peeling rate varying from 10 mm min^{-1} to 400 mm min^{-1}. In the case of the skin substitute, the transition between cohesive and interfacial fracture is located at higher peeling rates and not reported here. These different transition rates can be explained by some differences on surface energy values (Marin and Derail, 2006) or in deformation of the substrates (Renvoise et al., 2007a). Nevertheless, one can recall that the usual range of removal rates encountered by a patient when removing wound dressings is about 100–200 mm min^{-1}. So, as a first approximation, one may consider that the proposed skin substitute is a reasonable candidate to represent human skin behavior for a wide range of laboratory studies, particularly in the range of deformation rates corresponding to the application studied here.

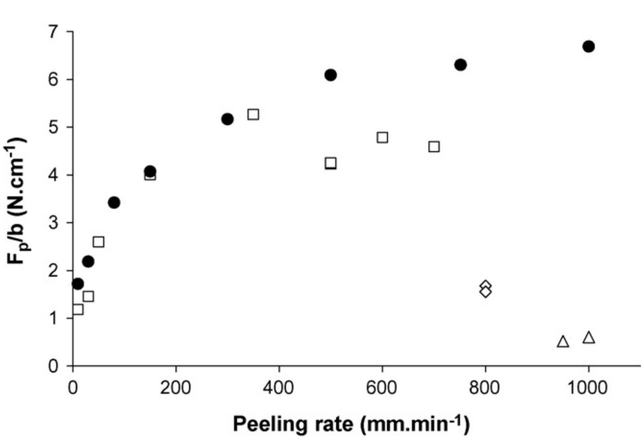

Fig. 5. Normalized peeling force vs. peeling rate for tapes removed from the forearm of one subject and from the substitute. T = 33 °C. (□) cohesive failure for *in vivo* peeling, (◇) mixte failure for *in vivo* peeling, (△) interfacial failure for *in vivo* peeling, (●) cohesive failure for *in vitro* peeling.

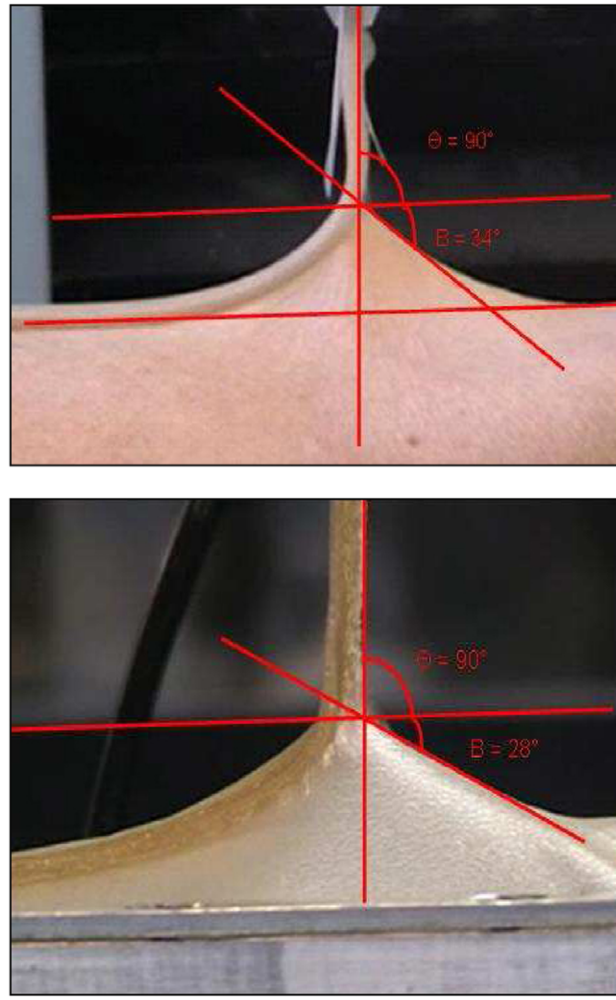

Fig. 6. Comparison between the deformation of the skin substitute and human skin. Peeling experiments parameters are the same.

These comments are in agreement with these presented by Lir et al. (2007). It is important to recall that the synthetic substrate has been prepared here for a specific application and family of adhesive formulations. To generalize the relevance of this synthetic substrate (at higher peeling rates for example), one must recall that it is possible to play on its composition (Renvoise, 2006; Renvoise et al., 2007b; Lir et al., 2007) according to the adhesives tested.

We have studied the behavior of the synthetic substrate on a larger range of peeling rate by the application of the time–temperature equivalence on the synthetic substrate. As this method is evidently not applicable on human skin, we have not reported here the results which can be found in Renvoise et al. (2007a).

At last, we have performed peeling experiments at a peeling angle of 90° and a peeling rate of 150 mm min^{-1}, in order to obtain a better visualization of the deformation of the substrate upon peeling. These conditions correspond to the same type of behavior for the skin substitute and human skin; they are also relevant of real conditions for the removal of wound dressings on human body. One can clearly observe in Fig. 6 similar deformations of the human skin and skin substitute confirming that the synthetic film described here can be considered as an interesting alternative of substrates usually used to study adhesion on human body with respect to mechanical and interfacial properties.

4. Conclusions

The surface properties and mechanical behavior of human skin depend on its location on the human body. These properties govern to a large extent the adherence performances of an adhesive patch stuck on human skin. We have proposed to use a synthetic substrate which mimics human skin in order to explore adhesion properties of wound dressings. We confirm that the substitute can be considered as a model skin by performing different peeling experiments with industrial pressure sensitive adhesives: (i) *in vivo* experiments on natural skin of different subjects which yield an "average" value of peeling force and (ii) *in vitro* tests on the skin substitute. We have confirmed that human skin must be prepared if one wishes to have a stationary peeling behavior. The peeling behavior of commercial adhesives has been measured on such prepared human skin and on the synthetic film. The data on both substrates is quite similar in the peeling rate domain relevant of the practical application. We obtain also similar results for the peeling force. We have also noticed that some differences may appear at higher peeling rate, regarding in particular the mode of failure. This last observation is in agreement with a previous study made on the same type of adhesive/substrate. We have shown in that case that the mode of failure depends on both the rheological behavior of the adhesive and the rheological behavior of the substrate. When the peeling rate changes, the rheological behavior of the layers changes and, as a consequence, the mode of failure can be different.

As a final remark, one may recall that adhesives used for applications on human skin must absorb liquids such as sweat, secretions... The rheological properties of the adhesive depend on the nature and quantity of liquids absorbed during the wearing time. Hence when a patient removes an adhesive, the deformation of the adhesive, as well as the mode of failure and the level of peeling force, depends strongly on the quantity of liquid adsorbed. This point will be described in a subsequent paper in which we will describe an original tool for the measurement of the rheological properties of an adhesive in wet conditions.

Acknowledgement

The authors are grateful to the Conseil Régional d'Aquitaine (fonds FEDER) for financial support of this study.

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