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Artificial Skin Model simulating dry and moist *in vivo* human skin friction and deformation behaviour

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Abstract

In vivo friction and indentation deformation experiments were carried out using the human volar forearm of a healthy 29 year old Caucasian woman and compared with various synthetic materials in order to select materials and develop a new moisture-sensitive artificial skin model (ASM). Analogous to human skin the final ASM comprised two different layers: a relatively stiff hydrophilic moisture-absorbing top layer representing the epidermis and a very soft under-layer representing the dermis and hypodermis. The friction and deformation behaviour of the new ASM was comparable to human skin when tested under dry and moist skin conditions. This development has potential for use as a test-bed in the development of devices that interact with the skin in a mechanical way.

1. Introduction

Skin substitutes are important for clinical use, for example in the management of acute burn injuries and for post burn reconstructions. However, they can also be used as models for experimental testing, for example of healthcare device-patient interfaces, cosmetic skin care devices, electric shavers, etc. In the development of such devices it is often desired to investigate the friction and deformation behaviour of the skin, since these can be important factors for the device function and the perceived comfort during use. Skin hydration is one of the main factors influencing the tribological behaviour of human skin. Moisture commonly increases the skin friction, as is experienced in everyday life, e.g. the friction experienced when sliding a moist finger on a touchscreen is much greater than when the finger is dry. In a very humid climate or under wet conditions, the skin becomes completely hydrated, and the friction has been found to be much higher than in dry sliding conditions [1 - 3]. Unfortunately, friction measurements of devices on human skin *in vivo* have several disadvantages. Such measurements often suffer from poor reproducibility due to person-to-person variability and involuntary human motions occurring during testing. Also, certain experiments are not possible to carry out *in vivo* because they are too damaging to the human tissue. Furthermore, the

necessary regulatory approval process for testing on human subjects can increase the development effort and lead-time required. For these reasons, many tribological studies on products involving human skin contact attempt to use mechanical skin equivalents. Synthetic skin substitutes are an alternative that have the potential provide objective and reproducible results within a reasonable time-frame [4].

There are many skin substitutes available commercially, each of which has been designed with specific purposes and skin characteristics in mind. Examples are: BiobraneTM, AlloDermTM, LaserSkinTM, IntegraTM, TissuFoilTM, MatriDermTM, EpidexTM, ApliGraftTM, Comp Cult SkinTM, DermaGraftTM, EpiCellTM, TransCyteTM, OrCel®, Hyalomatrix®, EpiDermTM, EpiSkinTM, Cultured Epidermal Autograft (CEA), Cultured Skin Substitutes (CSS). The majority of these were designed to be used in the testing of cosmetic products or for the treatment of skin wounds or burns and attempt predominantly to imitate the biological or histological properties of skin. The mechanical behaviour and textual similarity is often not taken into account [5].

Of the synthetic materials that have been suggested and/or used as mechanical skin substitutes [4, 6-24], silicone elastomers and polyurethanes are the most commonly employed materials. Some of these have also been used to simulate the tribological behaviour of human skin under dry conditions. For example, Silicone Skin L7350 is recommended by the Federation Internationale de Football Association (FIFA) for the determination of skin–surface friction of artificial football turf. A major disadvantage of these materials is that they are hydrophobic and unable to absorb sufficient moisture to effectively simulate skin friction behaviour under varying environmental conditions. Use of a material that does not absorb water in a moist environment can lead to the formation of a surface film that reduces the friction [4], whereas as mentioned above, human skin absorbs moisture and its friction increases with moisture content until saturated [1, 2]. Thus, although silicone elastomers may simulate human skin sufficiently well in the dry condition, they are not capable of simulating the behaviour of moist human skin. The Epidermal Skin Equivalent reported by Morales-Hurtado et al [24], which is based on a mixture of hydrophobic Polydimethyl Siloxane (PDMS) and hydrophilic Polyvinyl Alcohol (PVA) hydrogel, may show potential in this respect. Although the tribological behaviour was not reported, indentation tests showed that in a 25°C / 50% relative humidity environment the synthetic material had an elastic modulus of approximately 0.7 MPa, within the range reported in the literature for human skin in vivo, and that there was a small decrease to 0.5 MPa after the material had been immersed for 4 days in water.

In contrast to human skin, highly porous water-absorbing hydrophilic materials such as SynTissue® from SynDaverTM Labs tend to show a decrease in friction with water content [25]. This is likely due to fluid being squeezed out of the porous structure of the synthetic material, forming a lubricating surface layer [25]. Obviously, fluid cannot be squeezed out of the deeper layers of human skin under load due to the barrier function of the stratum corneum. It is necessary to take account of these phenomena in order to develop a skin substitute that simulates the friction behaviour of human skin in both dry and moist conditions.

Structurally, human skin is built up of a number of heterogeneous layers: a very thin upper epidermis layer, with the stratum corneum as a stiff outermost layer, a fibre-reinforced dermis layer and an extremely viscous and soft hypodermis layer. The different mechanical properties and individual thicknesses of these layers influence and determine the deformation behaviour of skin and through this, the friction behaviour is influenced [3]. A wide range of values for the elastic modulus and thickness of the various skin layers is reported in the literature [3, 25 – 31] and an overview is given in Table 1 [27].

Table 1. Elastic moduli and thickness of the different layers in human skin [27].

Skin layer, tissue		Elastic modulus, MPa	Thickness, mm
Stratum corneum	dry	500 (3.5 – 1000)	0.025 (0.01 – 0.04)
	wet	30 (10-50)	
	Viable epidermis	1.5	0.095 (0.04 – 0.15)
	Dermis	0.02 (8-35 kPa)	1.4 (0.8 – 2)
	Hypodermis	2×10^{-3}	0.8

The current study was aimed at developing an artificial skin model that was capable of mimicking in vivo human skin friction behaviour for both dry and moist skin conditions, and which had mechanical properties within the range expected of human skin. To simulate human skin it was decided that the artificial skin model should comprise two layers with very different mechanical properties: a very soft under-layer simulating the dermis and hypodermis, and a stiffer water-absorbing hydrophilic top layer simulating the epidermis.

2. Selection of Materials

2.1. Top layer representing epidermis

The uppermost layer of the epidermis (stratum corneum) in human skin absorbs water from the external environment. Skin hydration reduces the elasticity and stiffness of human skin (SC, epidermis) typically by one order of magnitude and this strongly influences the friction behaviour. Like human skin, silicone elastomers are viscoelastic materials and can be prepared so as to result in an effective elastic modulus in the range of a few MPa [32], as required for the top layer of the synthetic skin model. However, as mentioned previously, conventional silicone elastomers are hydrophobic and are not able to absorb water, which can lead to a friction behavior different to actual human skin in moist conditions [4]. Therefore, a new class of hydrophilic silicone rubber that absorbs water was used as the material for the top layer. These silicones are based on standard silicones but modified with strongly hydrophilic alpha-olefin sulfonate. Details on the hydrophilic silicone rubber can be found in patent US 20140113986 A1 and the preparation process adopted for the synthetic skin model is described in section 3.1.

2.1.1 Water uptake experiments

Two types of experiments were carried out in order to calculate the water uptake capacity of the hydrophilic silicone top layer. In both cases, samples of approximately 5x5 cm and $100 \pm 10 \mu\text{m}$ thickness were first dried in a vacuum oven at $70 \text{ }^\circ\text{C}$ ($<10 \text{ mbar}$) for 12 hours and immediately weighed. The percentage increase in weight was calculated as follows:

$$\text{Increase in wt. \%} = (\text{Wet Weight} - \text{Dry Weight}) * 100 / \text{Dry Weight}$$

The first experiment was carried out in a climatic room in moist conditions (80 %Rh and $28 \text{ }^\circ\text{C}$) in order to simulate a very humid environment. Mass changes were measured at different time periods, up to 24 hours.

A second experiment was carried out where the samples were immersed in distilled water at room temperature and mass changes were measured as a function of time, up to 24 hours. For these measurements, the immersed samples were removed at regular intervals and excess surface water was removed using absorbing paper before weighing. After weighing the samples were re-immersed in water.

The results of both experiments are shown in figure 1.

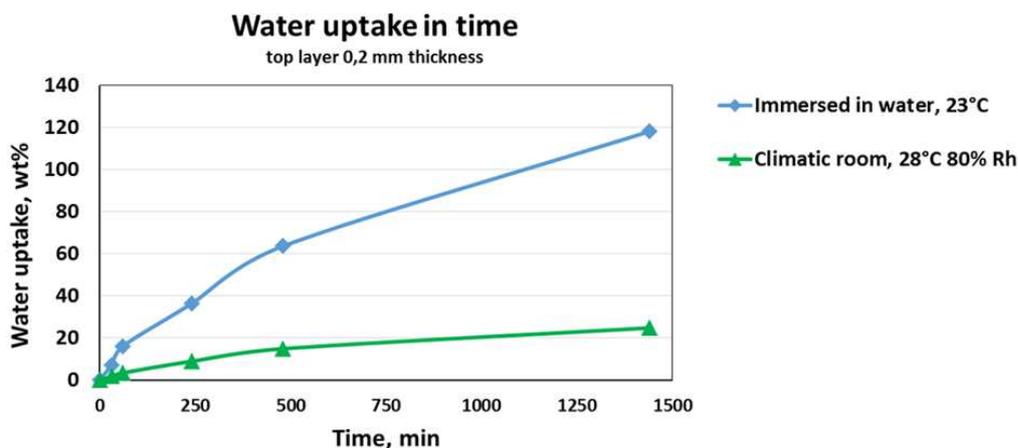


Fig. 1. Water uptake over time of the top layer made of hydrophilic silicone rubber.

The water capacity of the material was determined to be approximately 120 % after 24 h immersed in water and about 25 % after 24 h in a climatic room at $28 \text{ }^\circ\text{C}$ and 80 %RH, see figure 1. Figure 1 also shows that the water uptake of the hydrophilic silicone is still rising after 24 hrs, indicating that the material has not yet reached its saturation point.

For comparison, the hydration was also monitored using a Corneometer® which is based on a capacitance measurement and routinely used for assessing the hydration of human skin. Note that this method does not give an absolute value for the water content, however, this method allowed the absolute value of the water content in wt.% to be correlated with the hydration value given in arbitrary units (AU), see fig. 2.

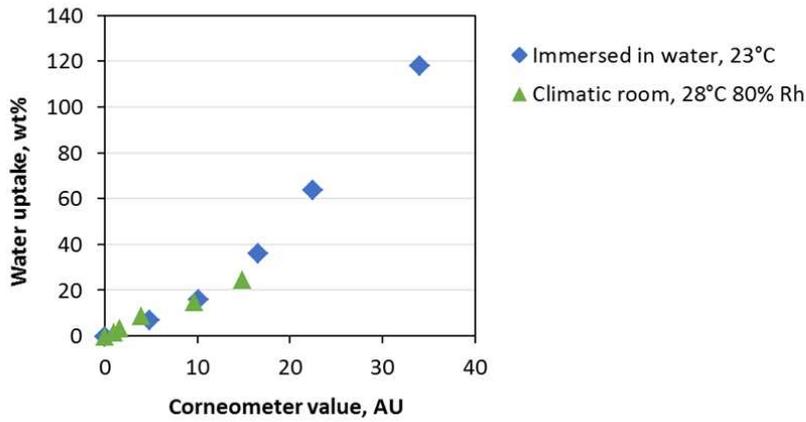


Fig. 2. Water uptake as measured using the Corneometer® over time (to 24 hrs) of the top layer made of hydrophilic silicone.

2.2. Material for the under-layer representing dermis and hypodermis

When devices interact mechanically with the human skin, the skin indentation depth during contact can easily be of the order of millimetres. In that case, the mechanical properties of the dermis and hypodermis determine the deformation behaviour of the whole skin [27, 30]. For this reason it is important to ensure that the deformation behaviour of the synthetic material used as the under-layer is similar to that of human skin. The force-displacement curve was measured on the forearm for indentation of a steel ball and compared to various commercially-available synthetic materials in order to select the most appropriate material simulating the dermis and hypodermis (i.e. the under-layer of the synthetic skin model). The characteristics of the materials tested are given in Table 2. As a reference for full skin, one material was a commercially available synthetic skin substitute from SynDaver™ Labs comprising three porous layers. A further three synthetic materials tested were potential under-layer materials. These were chosen to be non-porous and non-water absorbing, in order to avoid the possibility of water being squeezed out of the material when deformed during testing under moist conditions, which may affect the friction through formation of a surface film. In this way, analogous to human skin, the moisture content of the environment would affect only the top layer of the synthetic skin model.

Table 2. Characteristics of the tested materials.

Type of material/skin	Characteristic
Human skin	Left inner hairless forearm of healthy 29 year old Caucasian female
SynDaver skin	Synthetic skin: SynTissue muscular tissue plate T-PLA-A-0010 from SynDaver™ Labs, consisting of adult skin, subcutaneous fat and skeletal muscle. The thicknesses for skin, fat and muscle were 1.0 mm, 5.0 mm and 5.0 mm respectively.
Silicone rubber	Elastosil® LR 3003/03 (Wacker™ Silicones, Germany), hardness 3 ShA, thickness 4.0 mm
Technogel®	Polyurethane gel patented by Bayer, thickness 4.0 mm
Polyurethane gel	Shore Durometer OOO Scale Polyurethane gel MPP-W43D from NorthstarPolymers™, hardness 19 ShOOO, thickness 4.0 mm

Preparation of materials for testing:

The human volar forearm in vivo was cleaned and prepared according to a standard procedure [25]. In the literature, tribological studies on human skin have focused mainly on hairless and shaved skin [3] and in order to enable comparisons with literature data, in this study the hairs on the forearm skin were gently shaved. However, although the effect of hairs on skin friction and deformation was not taken into consideration in this study, this remains an interesting question for future research. Prior to testing, the human skin of the subject's left forearm was cleaned using a non-degreasing soap and dried with a non-lint towel. The subject was then seated for approximately 30 minutes before testing to acclimatise in the laboratory environmental conditions (23 ± 2 °C, 38 ± 4 %RH). The SynTissue from SynDaver™ Labs was stored in distilled water at room temperature (23 °C). The material was tested in the fully hydrated condition, this being the normal state recommended by the supplier. Prior to testing the material was taken out of the distilled water and the excess surface moisture was removed from the surface using a non-lint towel. The non-water absorbing materials: silicone rubber from Wacker™, the Technogel® and the polyurethane gel from NorthstarPolymers™, were tested after acclimatization for 24 h in the laboratory environmental conditions (23 ± 2 °C, 38 ± 4 %RH).

Indentation measurements

Indentation tests were carried out using a CETR-UMT Tribometer on the inner forearm of a 29 years old Caucasian woman and compared to the commercial materials described in table 2, see fig. 3.

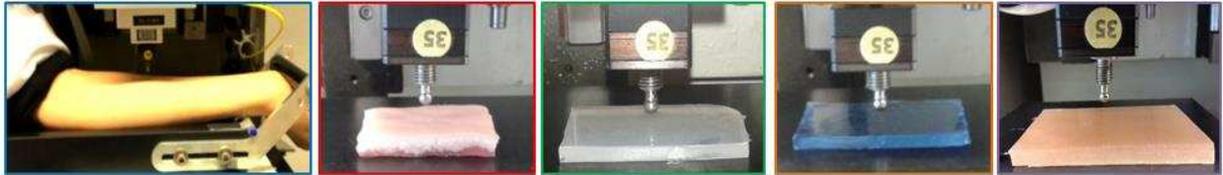


Fig. 3. All tested materials during indentation measurements: (starting from left) inner forearm of a 29 years old Caucasian woman, a commercial synthetic skin from SynDaver™ Labs, silicone rubber from Wacker™, Technogel® patented by Bayer and polyurethane gel from NorthstarPolymers™.

The test parameters used were as follows:

- Diameter of steel ball: 4 mm
- Load: 30, 20, 10 mN
- Loading speed: 0.5 mN/s
- Holding time at maximum load: 20 s
- Unloading speed: 0.5 mN/s
- 5 independent repeat tests

30 mN was selected as the maximum load in order to give an indentation depth large enough to minimize the influence of the epidermis on the deformation behaviour. 10 mN was chosen as a minimum load in order to minimize the influence from underlying tissue such as muscles and bones.

After applying a force at the maximum sample displacement the force was kept for 20 seconds and unloaded at a speed of 0.5 mN/s. All indentation tests were repeated five times for each tested material on five different locations.

Static indentation tests were used to determine the reduced elastic modulus, E_r , of the tested materials, where E_r is defined as $(1/E_r) = (1 - \nu_1^2)/E_1 + (1 - \nu_2^2)/E_2$. E_1 and E_2 refer here to the elastic moduli of the indenter tip and the indented material respectively, and ν_1 and ν_2 refer to the Poisson's ratio of these [30]. In this study, since E_1 (steel) $\gg E_2$ (skin, silicone rubber or polyurethane gel), it can be assumed that E_r is the reduced elastic modulus of the indented material, $(1/E_r) \approx (1 - \nu_2^2)/E_2$. For human skin and many viscoelastic materials, accurate values for Poisson's ratio are not known. For this reason it is more accurate to give the results of indentation experiments using the reduced elastic modulus, which can be obtained from the initial unloading slope of the load–displacement (P, h) curve [33, 34]:

$$E_r = \frac{\sqrt{\pi}}{2\sqrt{A}} S$$

where A is the contact surface and S is the normal contact stiffness which is the slope of the initial portion of the unloading curve, $S = (dP/dh)|_{P=P_{max}}$.

During indentation testing on human skin and synthetic materials, the tip displacement is not equal to the contact depth. At the vicinity of the tip, the surface can either sink-in or pile-up. In the current experiments, sink-in of the indenter was observed, see example in figure 4 for the synthetic skin model.

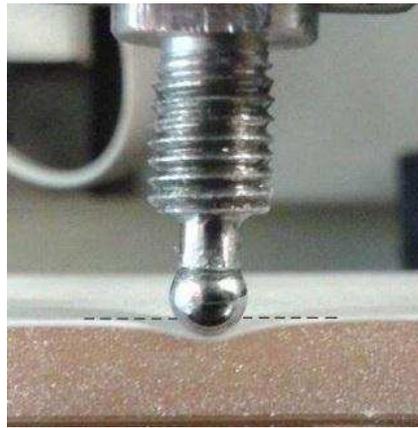


Fig. 4. The area of an indenter and a surface of a synthetic skin model during indentation test.

For this case, in order to calculate the contact surface A , the indentation depth h was replaced by the contact depth h_c . The contact surface A was calculated according to:

$$A = 2\pi R h_c$$

The indentation curves were analysed according to the method proposed by Oliver and Pharr [33, 34] in order to determine the reduced elastic modulus for all materials. This allowed comparison with in-vivo human skin values reported in the literature (Table 1).

The contact depth was established from the Oliver–Pharr model,

$$h_c = h - \epsilon P/S$$

where h is the measured displacement into the sample, P is the load [N], and ϵ is a geometric constant based on the indenter geometry; ϵ is 0.75 for a sphere [33, 34].

The sample load–displacement curves obtained from the tested materials are shown in Figs. 5-7 for the three loads used in the measurements. The reduced elastic modulus data are presented in Table 3.

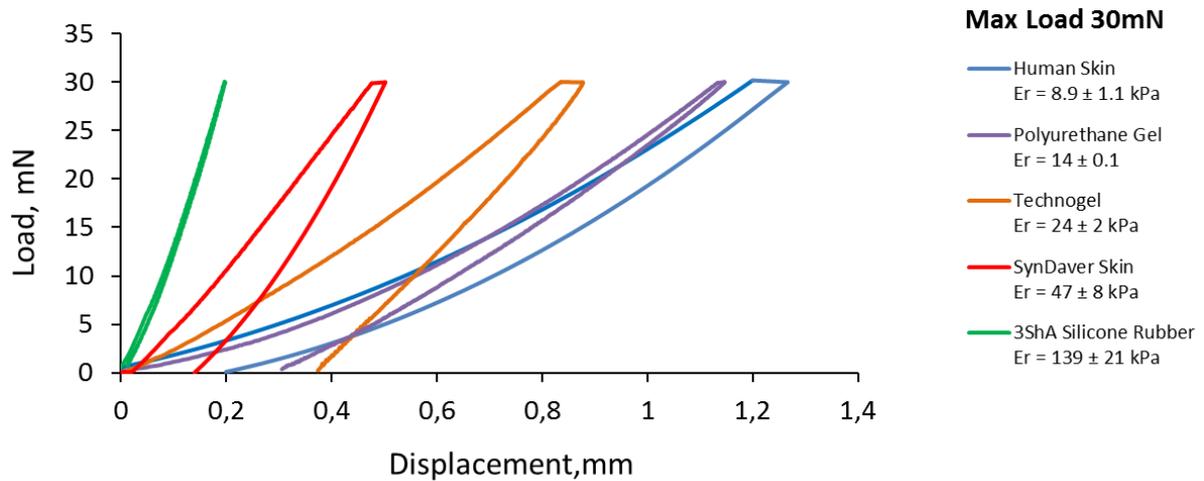


Fig. 5. Force-displacement curves on the silicone rubber from Wacker™, a commercial synthetic skin SynTissue from SynDaver™ Labs, Technogel® patented by Bayer, polyurethane gel from NorthstarPolymers™ and inner forearm of a 29 years old Caucasian for indentation of a 4mm steel ball. Max Load 30mN.

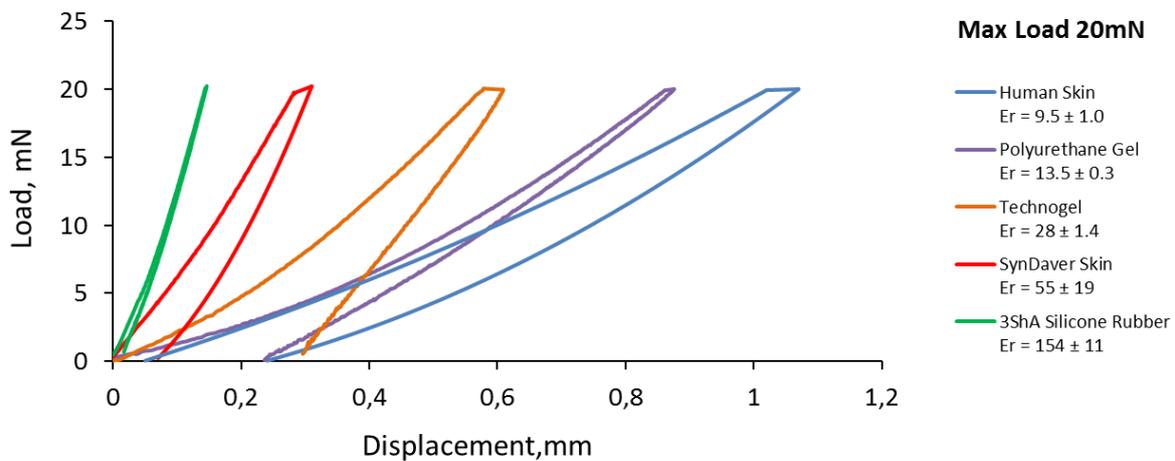


Fig. 6. Force-displacement curves on the silicone rubber from Wacker™, a commercial synthetic skin SynTissue from SynDaver™ Labs, Technogel® patented by Bayer, polyurethane gel from NorthstarPolymers™ and inner forearm of a 29 years old Caucasian for indentation of a 4mm steel ball. Max Load 20mN.

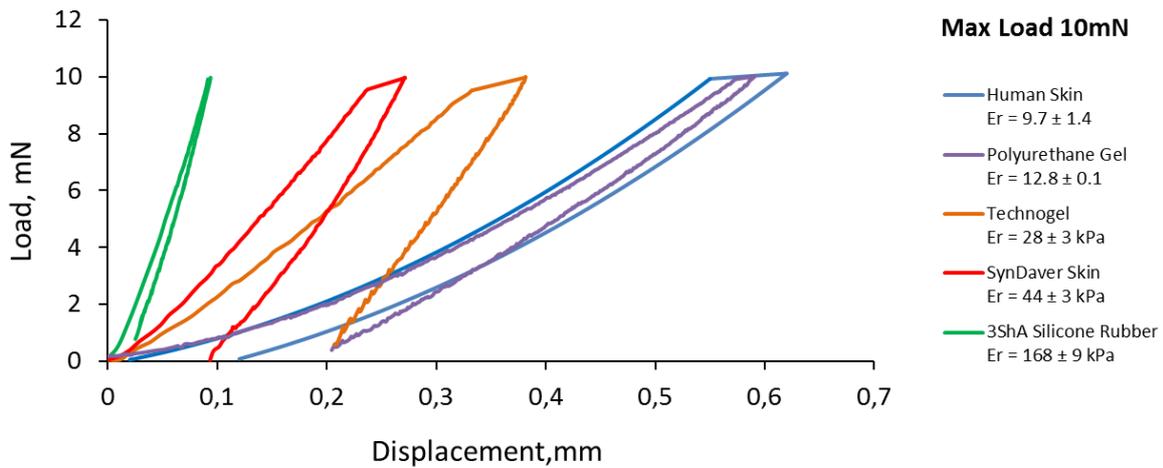


Fig. 7. Force-displacement curves on the silicone rubber from Wacker™, a commercial synthetic skin SynTissue from SynDaver™ Labs, Technogel® patented by Bayer, polyurethane gel from NorthstarPolymers™ and inner forearm of a 29 years old Caucasian for indentation of a 4mm steel ball. Max Load 10mN.

Table 3. The reduced elastic modulus of human skin and the synthetic materials obtained by indentation tests.

Max Load, mN	Material	*Reduced Elastic Modulus, kPa	*Standard Deviation, kPa
30	Human Skin	8.9	1.1
	Polyurethane Gel	14	0.1
	Technogel®	24	2
	SynDaver Skin	47	8
	Silicone Rubber	139	21
20	Human Skin	9.5	1.0
	Polyurethane Gel	13.5	0.3
	Technogel®	28	1.4
	SynDaver Skin	55	19
	Silicone Rubber	154	11
10	Human Skin	9.7	1.4
	Polyurethane Gel	12.8	0.1
	Technogel®	28	3
	SynDaver Skin	44	3
	Silicone Rubber	168	9

* For each material and each load range, five independent measurements were performed at different locations on the sample. The same sample was used for all measurements on a particular material.

Unfortunately, it was not possible to fully avoid the influence of the epidermis on the deformation behaviour of human skin in all measurements. From the results presented in table 3 it is possible to observe a small increase of the reduced elastic modulus with decreasing applied load (9.7 ± 1.4 , 9.5 ± 1.0 , 8.9 ± 1.1 kPa for applied loads of 10, 20, 30 mN respectively). With lower forces the much stiffer upper epidermis layer has a greater influence on the global mechanical response of the skin, leading to an increase in the reduced elastic modulus. The results obtained for the polyurethane gel show an opposite effect. The reduced elastic modulus decreases with decreasing load (12.8 ± 0.1 , 13.5 ± 0.3 , 14 ± 0.1 kPa for applied loads of 10, 20, 30 mN respectively). This may be attributed to a small influence of the stiff steel support table on which the sample was placed. To avoid this problem in future research it would be beneficial to perform indentation measurements on isolated samples of human dermis and hypodermis in vitro, and to then compare to the synthetic materials.

The results shown in figures 5-7 clearly showed that the polyurethane gel from NorthstarPolymersTM was the most appropriate material to be used for the under-layer of the synthetic skin model, which will be referred to as Artificial Skin Model (ASM). Of all the materials tested, the indentation behaviour of this material was closest to that of the human volar forearm for all of the applied loads: 30, 20, 10 mN. Furthermore, a comparison of the data presented in Table 3 with the mechanical properties of the different layers of human skin (Table 1) shows that the elastic modulus of the polyurethane gel from NorthstarPolymersTM lies within the range of 2- 35 kPa required in order to represent the dermis and hypodermis.

3. Preparation of the Artificial Skin Model (ASM)

3.1. Preparation of the top layer

A commercial silicone elastomer Elastosil LR 3004/40 (Wacker Silicones, Germany) was used as the silicone precursor material and modified with a commercial sodium alpha-olefin sulfonate (Bioterge® AS-90 beads) from Stepan Company (Northfield, Illinois, United States). Details on the processing method of the hydrophilic silicone rubber are given in patent: US 20140113986 A1. Following modification, the silicone mixture was cast into an aluminium mould with a cavity of 100 ± 10 microns depth. In the literature, there is various evidence suggesting that the contact shape and surface texture of human skin have a strong effect on the coefficient of friction [4, 7, 30]. For this reason, the top layer of the synthetic skin model was provided with a texture similar to that of human skin. An elastomer-based mould-making material (Alja-Safe® Breeze) was used to make a negative replica of the human skin texture from the forearm. The replica was subsequently pressed against the top surface of the silicone sample, see fig. 8.

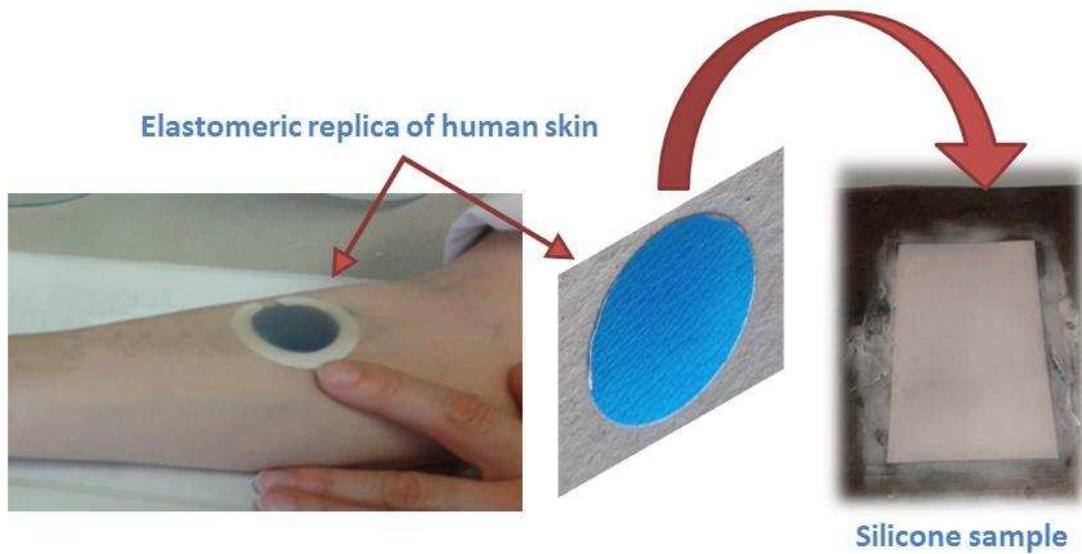


Fig. 8. Process of producing a similar texture to that of human skin on the top surface of the hydrophilic silicone layer.

The hydrophilic silicone was cured by heating in two stages: 1 h at 80 °C followed by 1 h at 140 °C. An image of the final cured top layer is shown in figure 9.



Fig. 9. The top layer representing the epidermis, made of hydrophilic silicone rubber.

3.2. Preparation of the under-layer and fixation to the top layer

The NorthstarPolymers™ polyurethane gel system selected for the under-layer consists of two components: part-A polyisocyanate prepolymer extended with polyether polyol, and part-B curing agent based on a blend of polyether polyols. The polyurethane gel material is formulated in such a way that it is possible to control the hardness of the product simply by changing the mixing ratio of the part-A and part-B components. Generally, increasing the part-B ratio will give softer products. For our application a very high mixing ratio of part-B was chosen (part-A: 1 = part-B: 6.1) in order to obtain a very soft gel. 61 g of the part-B component was degassed in vacuum in order to avoid bubbles in the final product.

The necessary amount of part-A (10 g) was poured into a plastic container and mixed together with part-B using a steel stirring rod for at least one minute. To obtain a life-like skin colour a

few drops of a pigment (SilTone light skin) were then added and mixed again. The hydrophilic silicone top-layer was placed on the bottom of a PTFE mould and the polyurethane gel mixture was poured on top of this layer in the mould, see fig. 10.

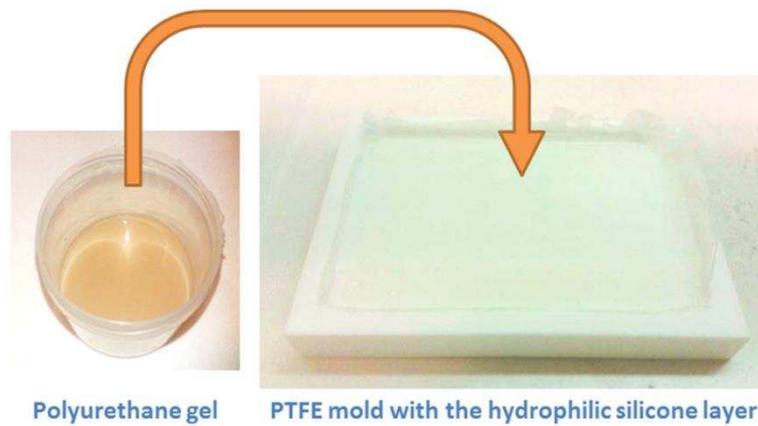


Fig. 10. Process of pouring the polyurethane gel on the top of the hydrophilic silicone layer.

After curing at ambient room conditions, preferably overnight, the thickness of the bottom layer so produced was 2.8 ± 0.2 mm. The adhesion between the top-layer and under-layer was found to be sufficient for all further testing. Because of the stickiness of the under-layer it was necessary to cover it, after curing, with a protective layer in order to facilitate handling. A commercial silicone elastomer Elastosil LR 3004/40 (Wacker Silicones, Germany) was used for this purpose. The protective layer with a thickness of 100 ± 10 microns was pressed by hand onto the polyurethane under-layer in the PTFE mould, see fig. 11.

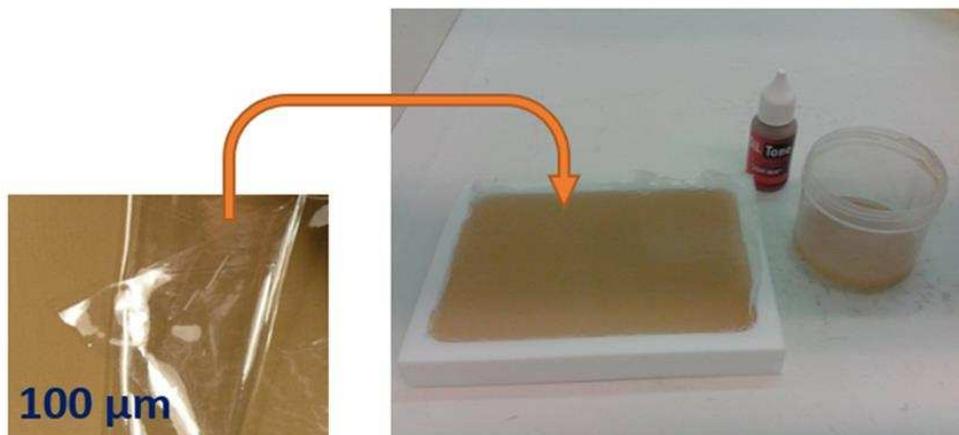


Fig. 11. Process of joining the protective layer onto the underside of the synthetic skin model.

Generally, it was found that it was possible to demould the ASM after about 5 to 6 hours. At this point the polyurethane gel was cured sufficiently that it was possible to handle it as a solid piece. However, further curing accompanied by a gradual increase in hardness occurred over a period of approximately 7 days.

Finally, because the uncovered surfaces of the polyurethane gel are very sticky, a small amount of talcum powder was carefully placed on the side-surfaces to facilitate handling without affecting the friction behaviour of the top surface of the synthetic skin model. An image of the final composite ASM is given in figure 12.



Fig. 12. Complete Artificial Skin Model.

4. Characterization of the complete synthetic skin model and comparison to human skin

4.1 Preparation of materials for testing

Prior to each friction and indentation test the human skin in vivo (volar forearm) and ASM were preconditioned to produce nominally “dry” and “moist” skin hydration states.

For the “dry” condition, the human skin of the subject’s left forearm was cleansed using a non-degreasing soap and dried with a non-lint towel. The subject was then seated for approximately 30 minutes in an environmental chamber set at 23 °C, 37 % relative humidity to allow the skin to acclimatise. To achieve the “dry” state of the ASM, the material was first dried in vacuum (15 hours at 30 °C) and then left for approximately 24 hours before testing to acclimatise in the same environmental chamber set at 23 °C, 37 % relative humidity.

To achieve the “moist” human skin hydration condition, the forearm was cleaned using warm water and wrapped in transparent plastic (kitchen) foil for 30 minutes immediately prior to testing. For the ASM “moist” conditions, the material was left for 24 hours in an environmental chamber under pre-stabilised conditions of 28 °C, 80 % relative humidity.

From the point of view of developing a useful synthetic mechanical skin model, the most important was to ensure that the difference in hydration values for the dry and moist conditions tested was sufficient to observe changes in friction and deformation behaviour that are similar to that of human skin. Nevertheless, it is interesting to compare the actual hydration of the ASM and human skin for the dry and moist states and a Corneometer® CM 825 was used to investigate this.

The Corneometer® gives a measurement value in Arbitrary Units (AU) ranging from 0 (extremely low) to 130 (extremely high). Commonly, for human skin, a value <30 AU is

considered to indicate very dry skin, 30-40 AU dry skin, normally hydrated skin 40-66 AU and hydrated skin >67 AU [36]. The results are shown in Table 4 and show, for the human skin, that the values obtained for the dry and moist conditions were within the ranges considered very dry to dry and normally hydrated to hydrated skin respectively.

Table 4. Corneometer® hydration values measured for the ASM and human skin.

Skin	Corneometer® hydration value [AU]	
	Dry condition	Moist condition
Human volar forearm	28-33	60-73
Artificial Skin Model	0	21-30

For the ASM, the Corneometer® values obtained were much lower, even though the values for the moist condition (21-30 AU) are indicative of a 50-100 wt.% water uptake, see figure 2. For comparison, normally hydrated human skin Stratum corneum, which has a Corneometer® value of approximately 40-66 AU, has been shown to have an actual water content of 30-50% of its dry weight [37, 38]. Thus it appears that the relationship between the Corneometer® value measured and the actual hydration of the uppermost skin layer is not the same for the human skin and ASM materials.

The Corneometer® is based on a capacitance measurement. Because the dielectric constant of water is more than 10 times higher than that of the human skin material itself, the capacitance of the water dominates the measurement [36]. The dielectric constant of silicone rubber is reported to be within the range 3-10 [39]. As with human skin, this is significantly less than water at about 80 and it can therefore be expected that the capacitance of the water within the silicone elastomer top-layer of the ASM when hydrated again dominates the measurement.

The measurement depth of the Corneometer® in human skin is reported to be of the order of 10-20 μm [36]. The silicone elastomer top-layer of the ASM has a thickness of approximately 100 μm and it is therefore reasonable to assume that the Corneometer® measurement retrieves information only from this top-layer; the polyurethane under-layer is unlikely to contribute to the measurement. However, human Stratum corneum can have a thickness of between 10 and 40 μm , see table 1, and in the current case (forearm of 29 year old female) it is likely that the Stratum corneum is at the lower limit of this range. This means that the Corneometer® values obtained for the human skin are likely to be influenced by the generally much higher water content of the skin layers immediately beneath the Stratum corneum barrier, leading to a higher measurement value than would otherwise be obtained from the Stratum corneum alone. This phenomenon may explain the higher Corneometer® hydration values measured for human skin compared to the ASM (see Table 4).

4.2 Friction behaviour

Friction measurements were carried out using a CETR-UMT Tribometer on human skin in vivo (volar forearm) and the ASM, under the “dry” and “moist” skin hydration conditions described in section 4.1, see figure 13. In these tests, a steel ball was rubbed with a constant applied normal load and speed in a linear reciprocating manner over the skin surface and the tangential friction force was recorded continuously. The instantaneous Coefficient of Friction (COF) was calculated from these results:

$$\text{COF} = F_F / F_N$$

Where: F_F = absolute value of the friction force [N] at any given time during the test, and F_N = normal force [N] at the same time during the test.

The test parameters used were as follows:

- Diameter of steel ball: 4 mm
- Load: 30 mN
- Stroke: 10 mm (reciprocating)
- Speed: 0.5 mm/s
- 5 cycles (100s test time)
- 5 independent repeat measurements

Note that in this initial study, which focuses primarily on developing a synthetic skin material that simulates the effect of the skin hydration conditions on the friction, only one normal load (30 mN) was investigated. Further research is required in order to investigate how well the ASM reproduces the well-known load dependency of human skin friction [2,3].

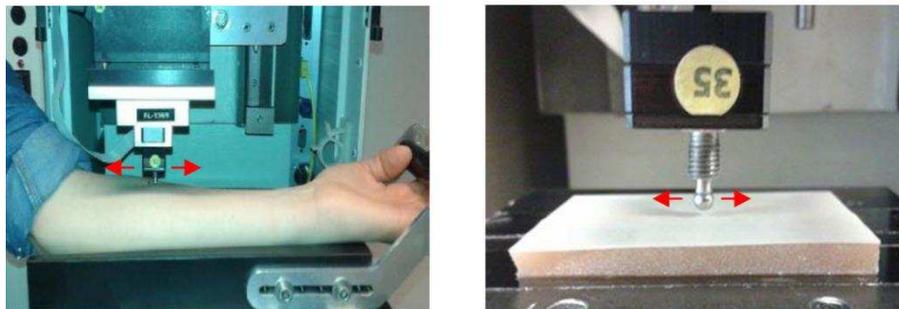


Fig. 13. Friction tests on human skin in vivo (left) and the ASM (right).

Fig. 14 shows the average COF values with standard deviation (5 independent measurements) of the human skin and ASM in dry and moist conditions. Clearly, the average COF values in dry and moist conditions are very similar for the human skin and ASM. The higher COF in the moist case can be attributed to a greater adhesion friction as discussed in e.g. Hendriks and Franklin 2010 [1] and Adams et al 2007 [2] and is related to a reduction in the stiffness of the uppermost layer, leading to a greater contact area of the steel ball on the material surface.

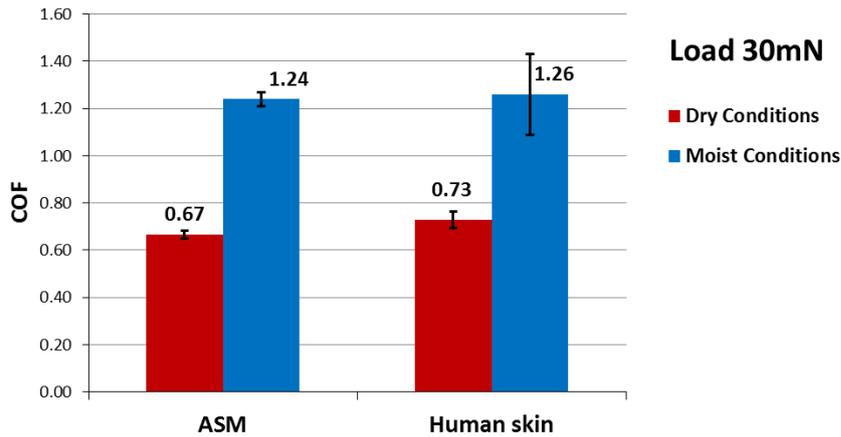


Fig. 14. Comparison of COF (coefficient of friction) of ASM and human skin in dry and moist skin conditions at 30mN load.

Figures 15 and 16 show examples of the typical friction behaviour measured over time for the human skin and ASM respectively. In these plots, the COF is shown as negative for the half of each reciprocating cycle because of the reverse in direction of the friction force at these times. Note the greater stability of the friction behaviour of the ASM over time (Figure 16), which is a clear advantage for use as a test-bed for testing skin-contact applications.

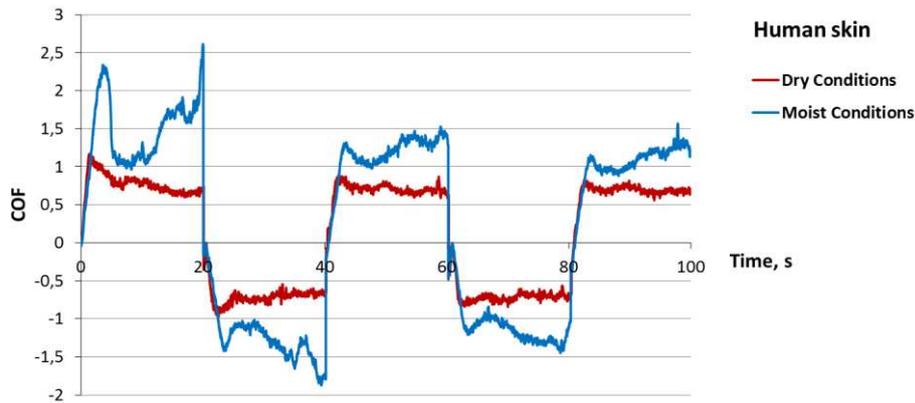


Fig. 15. Friction behaviour of human skin in dry and moist conditions at 30mN load.



Fig. 16. Friction behaviour of ASM in dry and moist conditions at 30mN load.

4.3 Deformation behaviour

The CETR-UMT was also used to perform indentation tests on the human skin in vivo (volar forearm) and the synthetic skin model, under the same “dry” and “moist” skin hydration conditions described previously. Experimental details of the indentation test method are given in section 2.2 and details on the preparation of the materials for these measurements are given in section 4.1.

Based on the indentation tests, the calculated average and standard deviation values (five independent measurements) for the reduced Elastic Modulus of the ASM and human skin measured are presented in fig. 17. For the human skin, the measured Elastic Modulus is within the lower range of that expected for the dermis (8-35 kPa) based on values reported in the literature, see table 1. As expected, the moist human skin showed a lower Elastic Modulus compared to the dry state and this can be attributed to the influence of the increased hydration of the Stratum corneum in the moist case. The ASM showed a similar behaviour, the water uptake within the top-layer of the ASM causing a reduction in its stiffness.

For both dry and moist conditions, the reduced Elastic Modulus of the ASM material was greater than that measured on the human skin. This can be attributed to the influence of the stiffer top-layer, since in the tests carried out on the polyurethane gel under-layer at the same load of 30 mN (see section 2.2 and figure 5) the measured Elastic Modulus was very similar to that of the human skin. Nevertheless, at 30-35 kPa the measured Elastic Modulus of the complete ASM was still within the range expected for human skin dermis, 8-35 kPa, see Table 1.

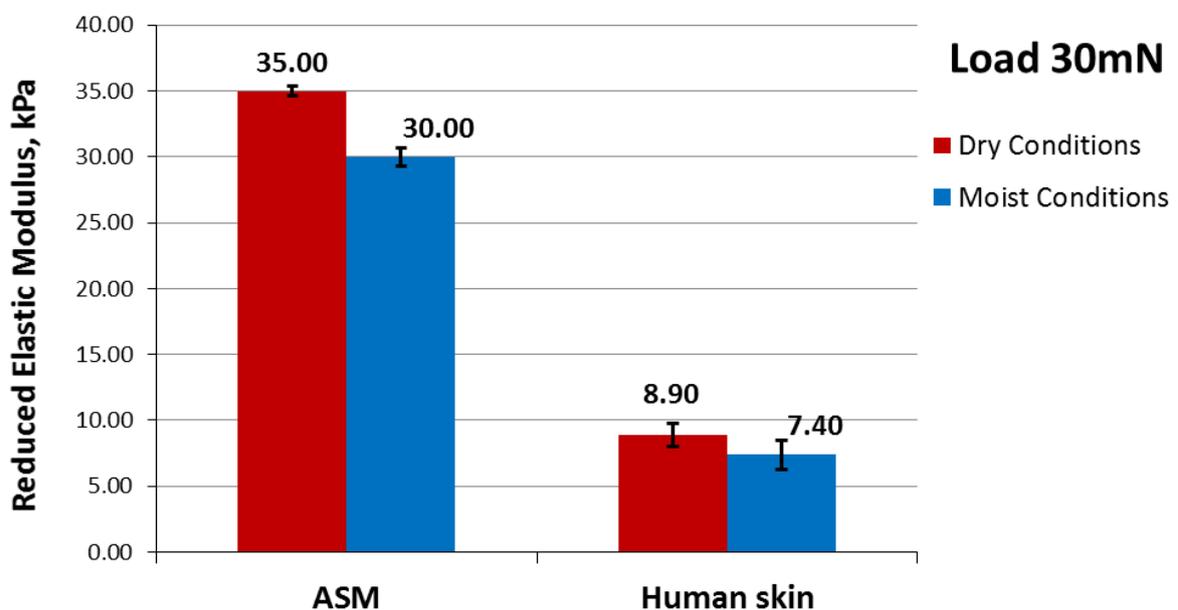


Fig. 17. Reduced Elastic Modulus of the ASM and human skin measured from indentation experiments for dry and moist skin conditions.

4. Study limitations and future work

From a practical perspective of using the Artificial Skin Model as a test-bed in the development of skin-contact devices, a serious limitation of the ASM described here is the time required to hydrate the hydrophilic silicone rubber top layer to a sufficient degree that the hydration is comparable to that of fully hydrated human skin. The required hydration time of the ASM is related primarily to the permeability and thickness of the top layer and a shorter hydration time can be expected for a thinner top layer. Further research should focus on investigating the effect of the thickness of the top-layer on the rate of water uptake through the methods of water immersion and subjection to a high humidity environment. The study should also consider the practical limitations imposed on the minimum thickness by the manufacturing process and the effect of the top layer thickness on the durability of the ASM.

In order to be fully accepted as a skin substitute, the properties and behaviour of the ASM need to be investigated in greater detail and compared to human skin. In the current study, only one normal load and only two hydration conditions were included in the investigation of the friction coefficient and elastic behaviour of the complete ASM. Systematic investigation of the load dependency of the friction coefficient is required, as well as of the moisture-dependency of the friction and elastic properties for a greater range of hydration conditions. A further limitation of the current study is that only the deformation in the normal direction (vertical to the skin surface) has so far been investigated. The lateral skin deformation behaviour (parallel to the skin surface) also requires study, including measurement of the lateral skin stiffness as described by Kwiatkowska et al [28].

Regarding wear behaviour, the ASM clearly lacks the structural complexity of human skin and is unlikely to exhibit the same wear mechanisms that occur when dead cells are removed from human stratum corneum. Nevertheless, it would be beneficial to investigate how closely the ASM is able to simulate the rate at which human stratum corneum is removed as a result of mild abrasion. This may enable the usability of the material to be extended, for example to enable the efficacy of mechanical skin exfoliation devices to be evaluated or other skin abrasion processes to be simulated. Investigation of the wear and durability is also necessary in order to gauge at what point the ASM material needs to be replaced after use in a friction test. In that case, in addition to studying the wear rate and wear mechanisms, the friction behaviour of the ASM as a function of sliding time should be investigated and compared to human skin.

5. Summary and Conclusions

A new Artificial Skin Model (ASM) has been developed comprising two different layers: a very soft under-layer simulating the dermis and hypodermis, and a stiffer hydrophilic top-layer simulating the epidermis, which was provided with a surface texture similar to that of human skin via a skin replica from the forearm. For the top-layer a new class of hydrophilic silicone that absorbs water has been used. The under-layer layer was chosen to give approximately the same force-displacement characteristic as a human forearm and an elastic modulus within the range expected for human skin based on properties reported in the literature. A very soft polyurethane gel was selected for this layer.

The ASM was developed for application as a test bed in the development of devices that interact with the skin in a mechanical way. The friction behaviour under dry and moist environmental

conditions was shown to be very similar to that of human skin, showing a similar increase in friction when the environmental conditions were changed from dry to moist. The deformation (indentation) behaviour of the ASM, as characterized by its Elastic Modulus (in the range of a few kPa), was also shown to be within the range expected for human skin dermis.

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