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New pressure ulcers dressings to alleviate human soft tissues: a finite element study

Nolwenn Fougeron[1], Nathanaël Connesson[1], Grégory Chagnon[1], Thierry Alonso[1], Laurent Pasquinet[2], Manuelle Bahuon[2], Eugénie Guillin[2], Antoine Perrier[1,3], Yohan Payan[1]

[1] Univ. Grenoble Alpes, CNRS, UMR 5525, VetAgro Sup, Grenoble INP, TIMC, 38000 Grenoble, France

[2] Urgo Research, Innovation & Development, 21300, Chenôve, France

[3] Service de Diabétologie, AP-HP, 75004 Paris, France

Corresponding author:

Nolwenn Fougeron

TIMC Biomeca

Univ. Grenoble Alpes, CNRS, UMR 5525

Pavillon Taillefer, Allée des Alpes 38700 La Tronche

E-mail: nolwenn.fougeron@univ-grenoble-alpes.fr

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Abstract

Pressure Ulcers (PU) are real burdens for patients in healthcare systems, affecting their quality of life. External devices such as prophylactic dressings may be used to prevent the onset of PU. A new type of dressing was designed to alleviate soft tissue under pressure, with the objective to prevent PU and to improve the healing conditions of category-1 and category-2 wounds. The mechanical interactions of this dressing with a generic model of human skin/hypodermal soft tissue was simulated using the Finite Element (FE) method. Different cases with intact skin tissues and injured tissues with a category-2 PU, with and without dressings in place, were modeled. The tissues were deformed under compressive load; internal strains were computed. The results showed a clear benefit from the use of the dressing to reduce the peak internal strains both in the intact and injured tissues models by 17 to 25 %, respectively. The intact soft tissues model was evaluated via sacral pressure measurements performed on one healthy volunteer. Results showed a good agreement between pressure measurements and estimations both with and without the dressing in place; particularly under the bony prominence and in surrounding tissues. As a conclusion, the importance of dressings to maintain a proper biochemical environment for the healing of PU is incontestable. Yet, new concepts of dressings may be developed to prevent the onset of PU, but also to provide local stress and strain reliefs and create mechanical conditions as less damaging as possible for the tissues.

Word count: 248

1. Introduction

In Europe and North America 7 to 23 % of patients in healthcare facilities develop Pressure Ulcers (PUs) with an increased risk for older patients, people with spinal cord injuries or comorbidities [1]. PUs have terrible consequences on the quality of life of patients including longer hospitalisation time, social isolation and pain.

PUs are localised wounds that propagate in the soft tissues after a detrimental external loading. Short time but intense load application is sufficient to cause tissue wounds while reduced loads applied for an extended period of time can also lead to PUs [2]. Pressure or shear loads applied at the skin level may lead to significant internal strains [3]. When these strains exceed the cell ability to deform, in most cases under bony prominence, this eventually leads to cell death and the development of PUs [4–6].

To reduce the prevalence of PUs, external medical devices are used to redirect external loads away from areas prone to PUs such as the sacrum or the heel. More particularly, dressings have been demonstrated to have a prophylactic effect [7,8]. Finite element (FE) modelling is a known tool to estimate internal tissue strains and stresses, since these quantities cannot be measured *in-vivo* [9]. Consequently, FE models have played a key role to assess the ability of dressings to alleviate soft tissues [10–13]. Most studies report a decrease of the strain energy density and stress in soft tissues, with various dressings [14] considering a supine position. This was also confirmed with head-of-bed elevation [15,16].

However, only few studies focusing on PUs compute the strains correlated to cell death in soft tissues [17] and none of the models proposed in the literature were evaluated with experimental data. Only one study shows the effect of dressings on tissues with a PU [18]. Yet, the used model accounted for a category-4 wound which is not representative of the majority of clinical cases.

Urgo RID is currently developing a new concept of dressing that can be used both to prevent PUs and to improve the healing process for PUs as deep as category-2 PU. To do so, the objective is to reduce the internal strains in the wound and in surrounding tissues. This study aims at developing a parametric FE model of the interaction between intact soft tissues, the Urgo RID dressing and the lying surface. This model was evaluated with regard to pressure estimations which were compared with experimental data. The parametric model was used to assess the prophylactic properties of the dressing and its ability to reduce tissues strains in the presence of a category-2 PU.

2. Materials and methods

2.1. Dressing model

2.1.1. Dressing description

The new Urgo RID (Urgo Research, Innovation & Development, Chenôve, France) dressing is an improved version of UrgoStart Plus Border® dressing, currently under study and development. The novelty of the dressing consists in adding a deformable and protective layer. This layer is made of alveoli that can be removed in a subject-specific manner in order to unload the wound and its surrounding tissues (Figure 1). To model the mechanical behavior of this new dressing, we proposed to build an FE model with two layers. A first component, referred as "dressing layer 2", was supposed to model the UrgoStart Plus Border® dressing which is in contact with the skin. In a first approximation this layer was approximated by a single material. The second component, the protective layer was modeled as a deformable layer glued with "dressing layer 2" and was referred as "dressing layer 1".

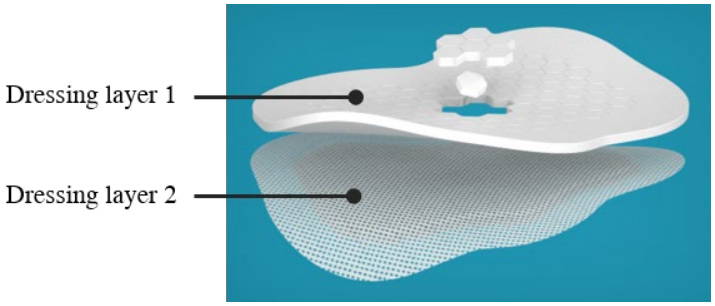

Figure 1: The new dressing design developed by Urgo RID

2.1.2. Mechanical tests and modeling of "dressing layer 1"

Compressive mechanical tests were performed on the "dressing layer 1" (Figure 2, right panel). Creep tests showed an increase by 12 % of the stretch ratio for a constant compressive force maintained for 30 min. "Dressing layer 1" was modelled as a compressible homogeneous isotropic material following an hyperelastic Blatz-Ko law [19]. Stretch ratio values were increased by 12 % to account for the creep resulting from the extended used of the dressing. The initial strain shear modulus, 1.00 kPa, was optimized using a curve fitting method with Matlab (Figure 2). "Dressing layer 1" was modelled as a hollow cylindrical layer with a radius of 125.0 mm, a central opening surface of 255.6 mm², larger than the PU surface, and a thickness of 5.2 mm. It was meshed in Ansys Mechanical APDL with 3 612 hexahedral elements (SOLID185).

2.1.3. Mechanical tests and modeling of "dressing layer 2"

Tensile mechanical tests were performed on specimens from the "dressing layer 2" cut at 0.0°, 22.5°, 45.0° and 90.0° according to the orientation of the dressing with the spine (Figure 2, left panel). These tests revealed the orthotropy of the dressing. Additional creep tests showed an increase by 16 % of the stretch ratio for a constant tension force maintained for 30 min. Thus, the "dressing layer 2" was modeled as a linear homogenous orthotropic material. Stretch ratio values were increased by 16 % to account for the creep resulting from the extended used of the dressing. Young moduli were optimized using a curve fitting method with Matlab. The resulting Young modulus in the principal direction, *i.e.* in the spine direction, was 4.40 MPa, whereas the secondary direction, orthogonal to the spine direction in the dressing plane, was 1.80 MPa. An FE inverse method based on compression tests performed on both dressing layers was used to assess the Young modulus in the transverse direction of the dressing which, eventually, was set to 0.03 MPa.

The Poisson coefficient was set to 0.25 according to literature data [15]. This "dressing layer 2" was modeled as a cylindrical layer with a radius of 125.0 mm and a thickness of 3.5 mm, and meshed in Ansys Mechanical APDL with 2 476 hexahedral elements (SOLID185).

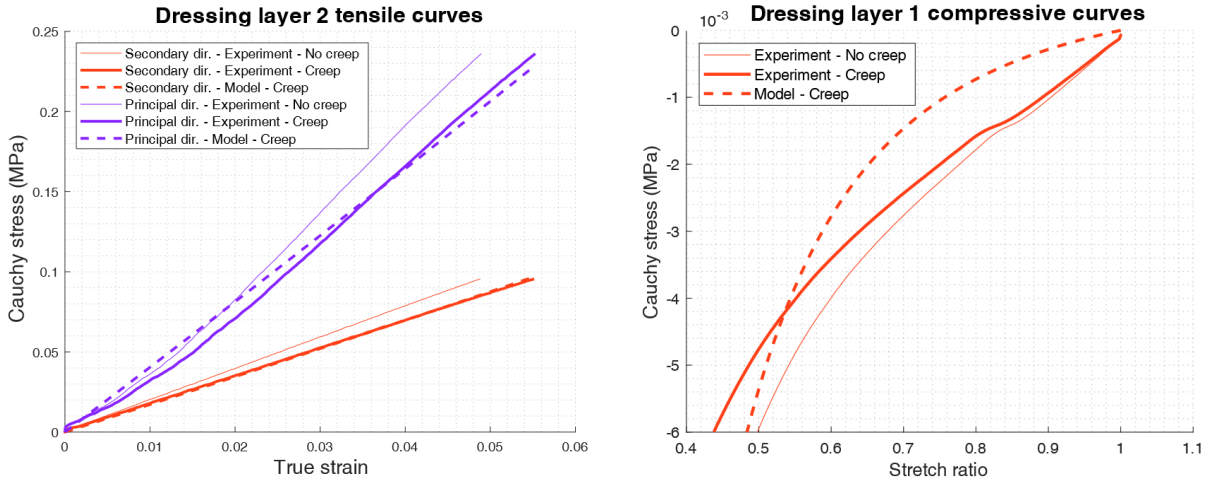

Figure 2: Material parameters optimization of the dressing layers. The optimization was processed after a correction by the creep ratio. (Left) "Dressing layer 2". (Right) "Dressing layer 1" hyperelastic response.

2.2. Soft tissues/dressing interaction

2.2.1. Modeling of the sacral area

This study focused on the dressing ability to i) prevent PU within intact soft tissues, and to ii) reduce further damage of injured tissues, with a category-2 PU, using parametric FE models. One healthy volunteer (male, 40 years old, 94 kg, 1.73 m) was included for the modeling and for the experimental setup (described in part 2.3.1). The volunteer gave his informed consent as required by the Helsinki declaration (1964). In both intact and injured tissues models, two cases of analysis were performed, without and with the dressing placed at the skin surface. In

both models the subject was simulated in a supine position on a mattress with linear elastic isotropic homogenous properties. The mattress height was set to 50 mm and its Young modulus to 230 kPa [19].

2.2.2. Intact tissues model

The sacral area was modeled as one layer of dermis and one layer of adipose tissues. By means of ultrasound images collected onto the volunteer, the dermis thickness was set to 1.3 mm while the adipose tissue thickness was 13.3 mm under the bony prominence and 22.3 mm outside the bone. The bone boundary was modeled by a portion of sphere with a radius of curvature of 110.0 mm. A bony prominence, approximated by an elliptical surface, with a height of 5.2 mm, was added to the model (Figure 4). The length of the sacral area model was 250.0 mm, i.e. twice the dressing one, to reduce free boundary effect close to the dressing area. This geometry was meshed in Ansys Mechanical APDL using hexahedral linear elements (SOLID185) with a mixed pressure-displacement formulation. A mesh convergence study was performed on the displacement of the adipose tissues' nodes. Eventually, the complete mesh was composed of 15 936 elements (Figure 5, left panel).

The skin was modelled with an Isihara's et al. law [20] (equivalent to a Yeoh constitutive law with the parameter C_{30} equals to zero). Material parameters were optimized using a curve fitting method with Matlab from the experimental data of Ni Annaidh et al. [21] who did uniaxial tensile tests on skin samples collected in the sacral region (Table 1). The adipose tissue layer was modeled with a Yeoh law [22] and parameters were optimized according to the equibiaxial test data of Sommer et al.[23] (Table 1).

All incompressibility parameters were supposed equal and were computed from the formula provided in Mott et al. [24]:

(1) $D_1 = D_2 = D_3 = \frac{3(1-2\nu)}{2C_{10}(1+\nu)}$

With ν, the Poisson's ratio, set to 0.4999, to account for the nearly incompressibility of soft tissues.

	C_{10} (MPa)	C_{20} (MPa)	C_{30} (MPa)	D_1 (MPa^{-1})	D_2 (MPa^{-1})	D_3 (MPa^{-1})
Adipose tissue	$1.3\ 10^{-4}$	0.0	$12.2\ 10^{-3}$	1.6	1.6	1.6
Skin	$2.7\ 10^{-1}$	1.9	-	$7.5\ 10^{-4}$	$7.5\ 10^{-4}$	-

Table 1: Soft tissues material parameters.

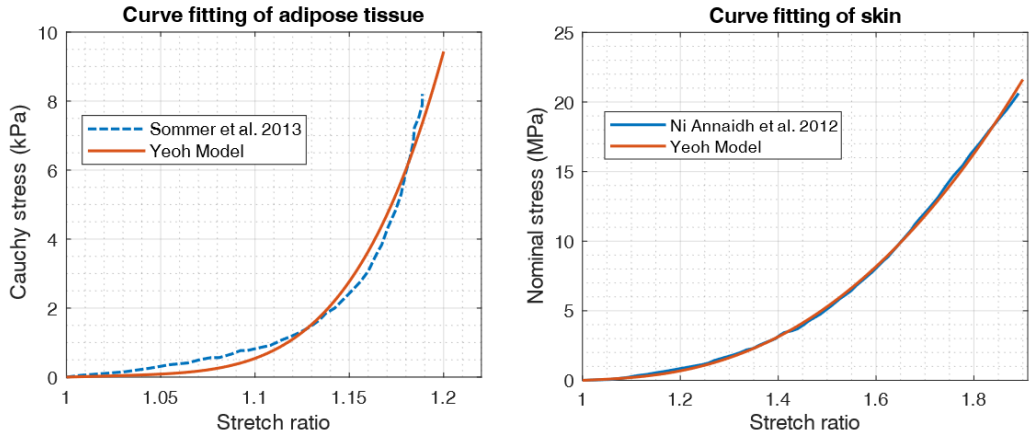

Figure 3: Optimization of the material parameters of the adipose tissue (left) and the skin (right)

2.2.3. Injured tissues model

A category-2 PU was added in a second parametric model considering that PU are described by circular shapes [25]. A 1.3 mm deep open wound was modeled by removing a cylinder of skin tissue at the center of the model with a radius of 13.0 mm (Figure 4). This geometry was also meshed using hexahedral linear elements (SOLID185) with a mixed pressure-displacement formulation. The resulting mesh was composed of 18 664 elements (Figure 5, right panel).

The soft tissues surrounding a PU are usually stiffer than healthy tissues [26]. Three areas were therefore defined both for the skin and the adipose tissues to account for this local stiffening. For both tissues, the C_{10} coefficient was multiplied by 1, 1.5 or 2 for the areas nearest to the wound [27] to define soft, medium and rigid material, respectively.

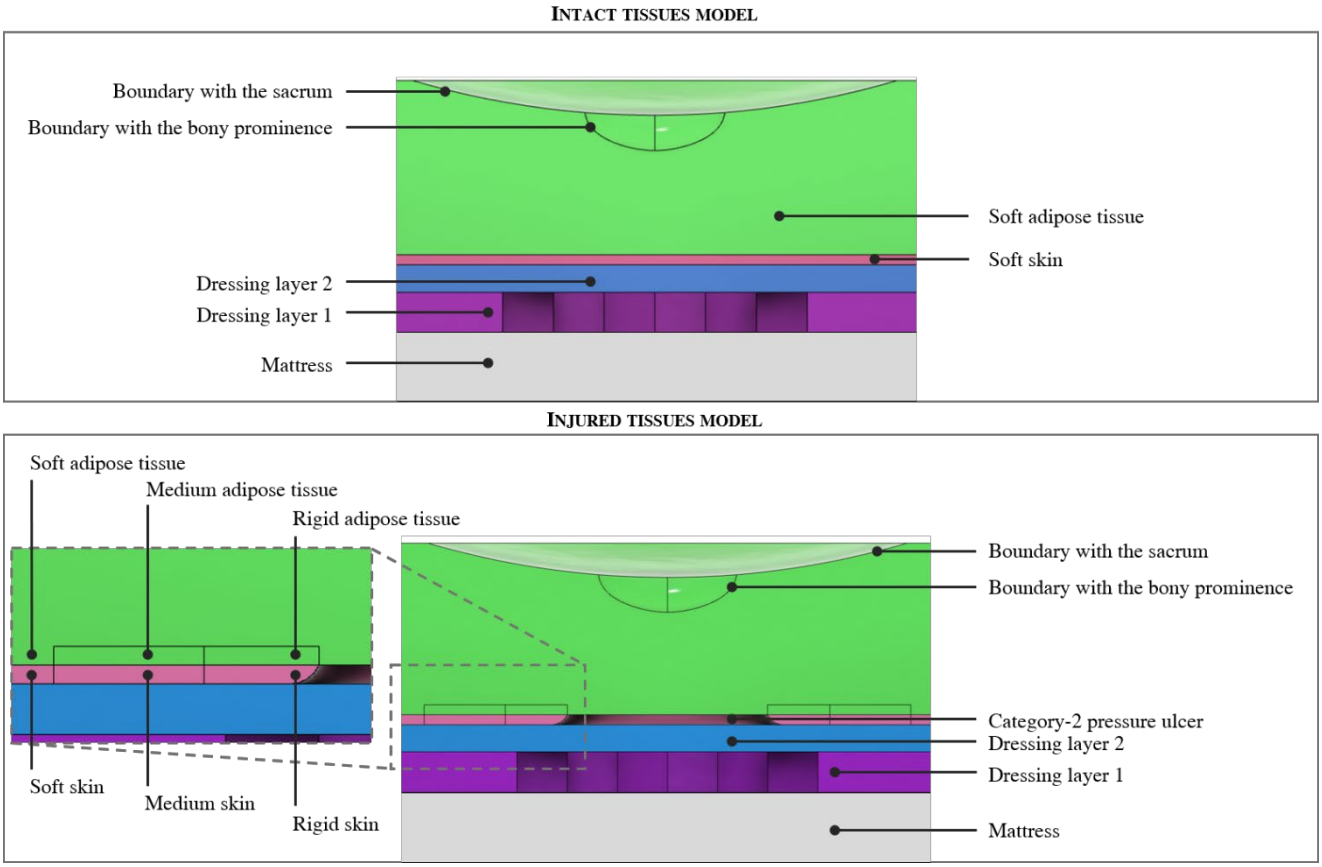

Figure 4: Models of the dressing/soft tissues coupling with intact (top) and injured soft-tissues (bottom).

2.2.4. Boundary conditions and loading

Nodes between skin and adipose tissue, skin and "dressing layer 2", and, between "dressing layer 2" and "dressing layer 1", were tied (Figure 5). Friction tests were performed to assess the coefficient of friction between the support and the dressing layer 2, set to 0.62. A coefficient of friction of 0.43 was set between the skin and the mattress [29].

A vertical force of 47 % of the subject body weight was simulated, to account for the weights of thighs, pelvis and abdomen body segments [28]. Considering the symmetry of the model, half of the resulting force, 217 N, was applied to a pilot node, located at the center of the bony prominence. All nodes at the boundary between the sacrum and the adipose tissues, in a radius of 68.5 mm, were tied in displacement with the pilot node. This radius was equal to half the distance between the sacroiliac crests measured on the sacrum 3D reconstruction of the volunteer (Figure 5). The bottom nodes of the mattress were fixed.

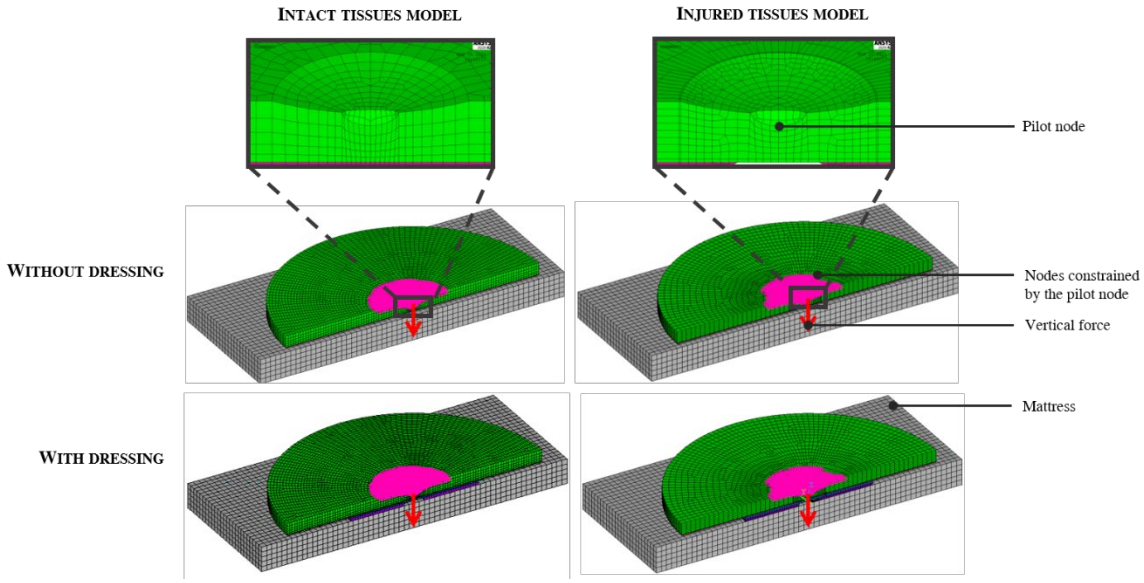

Figure 5: Models of the dressing interaction with intact (left) and injured (right) tissues. Pink areas represent the nodes tied to the pilot node.

2.3. Model validation

2.3.1. Experimental setup

The volunteer was wearing tights and laid in supine position on a rigid support, holding his legs up to exacerbate the loading on the sacrum to account for a worst-case scenario. A Tekscan 5250 pressure sensor (Tekscan, South Boston, USA) with 44x44 sensors was positioned between the rigid support and the sacral region. The calibration was performed according to the manufacturer protocol. The sensor could measure pressures up to 1 724 kPa with a 5 mm resolution. Three acquisitions of 30 s were recorded for all configurations. First measurements were performed without the dressing. Pressures were then measured with the dressing placed between the rigid support and the pressure sensor (Figure 6, left panel). For such a case, the alveoli located at the position of the previously measured peak pressure were removed.

2.3.2. Experimental setup model

The intact tissues model was used for the evaluation. Yet loads were adapted to the performed experiments (Figure 6, right panel). Since the experiment aimed to load solely the sacrum prominences, only nodes in a radius of 37 mm around center of the model were tied to the pilot node. Because of the symmetry in the model, half the forces measured during the experiments without and with the dressing, respectively 291 N and 245 N, were applied

to the pilot node as vertical forces. Considering the experimental setup, the subject was simulated as lying on a rigid support.

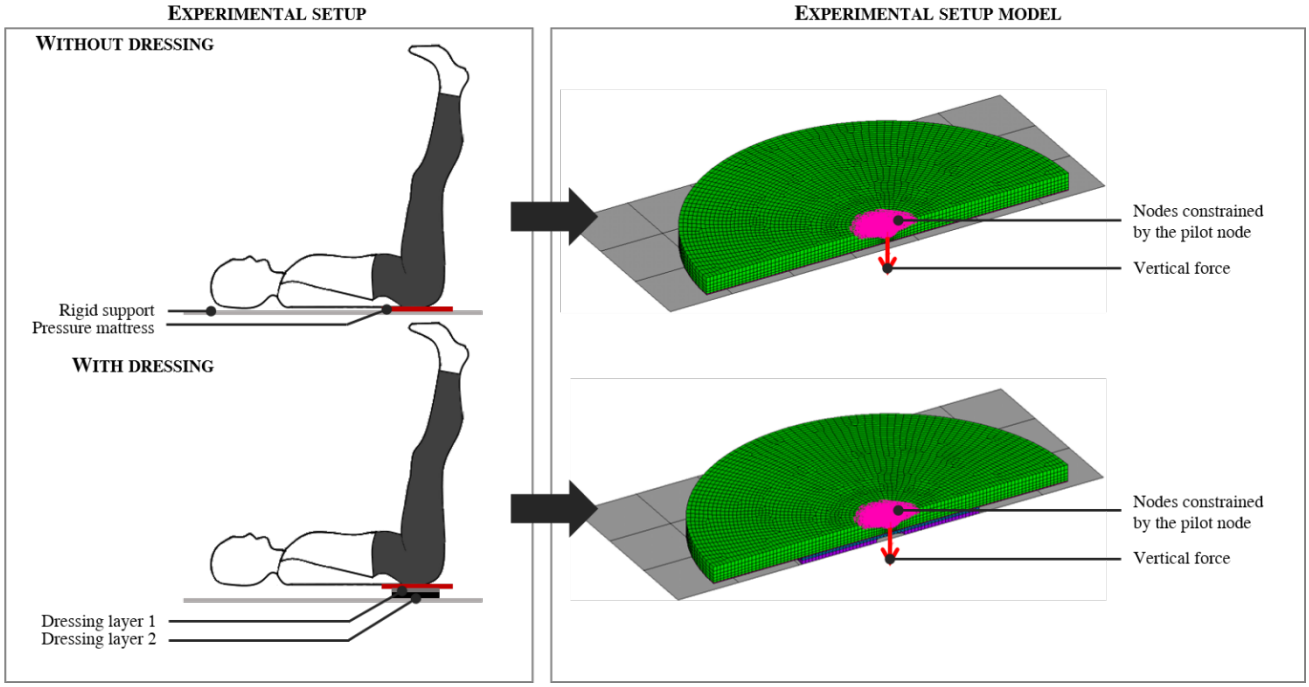

Figure 6: Experimental setup (left) and associated models (right) without (top) and with (bottom) the dressing. Pink areas represent the nodes tied to the pilot node. Pressure sensor and dressing thicknesses were exaggerated for illustration

3. Results

3.1. Pressure estimations

To account for the soft tissues conditioning during the trials, the mean pressures measured for the last acquisition of both experiments were used to validate the model. Pressure measurements without and with the dressing are shown in Figure 7. Peak pressures measured during the experiment were 218 kPa without the dressing and 126 kPa with the dressing. Peak pressures estimated by the FE model without the dressing was located at the center of the skin interface and was up to 217 kPa. With the model that includes the dressing, maximal pressures were estimated up to 147 kPa and were located at the level of opened alveoli boundary, while the simulated maximal pressure at the center of the model were equal to 102 kPa.

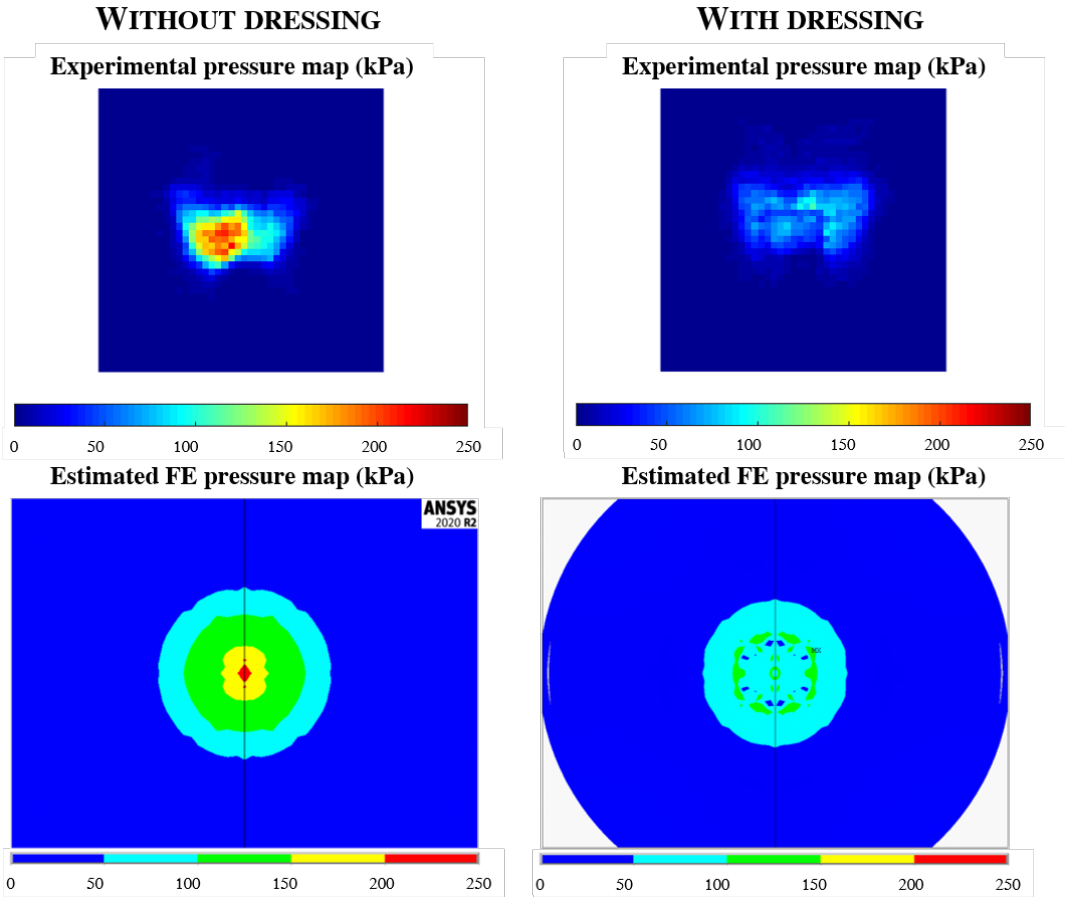

Figure 7: Pressure measurements (top) and estimations (bottom) obtained without (left) and with (right) dressing.

3.2. Internal strains with the intact tissues model

Green-Lagrange maximal shear strains are assumed to be a relevant numerical biomarker for PU prevention [4] and were computed from the simulations. The Region Of Interest (ROI) consisted of all soft tissues

elements included in a radius lower than 19.5 mm. This value included the soft tissues below the surface surrounding the bony prominence where strains should be as low as possible according to clinician experts. The dressing helped to decrease the internal strains in the ROI. The volumes of soft tissues above strains thresholds are presented in Figure 8. The peak strain in the ROI was estimated to 0.42 without dressing. This value decreased to 0.23 with the dressing.

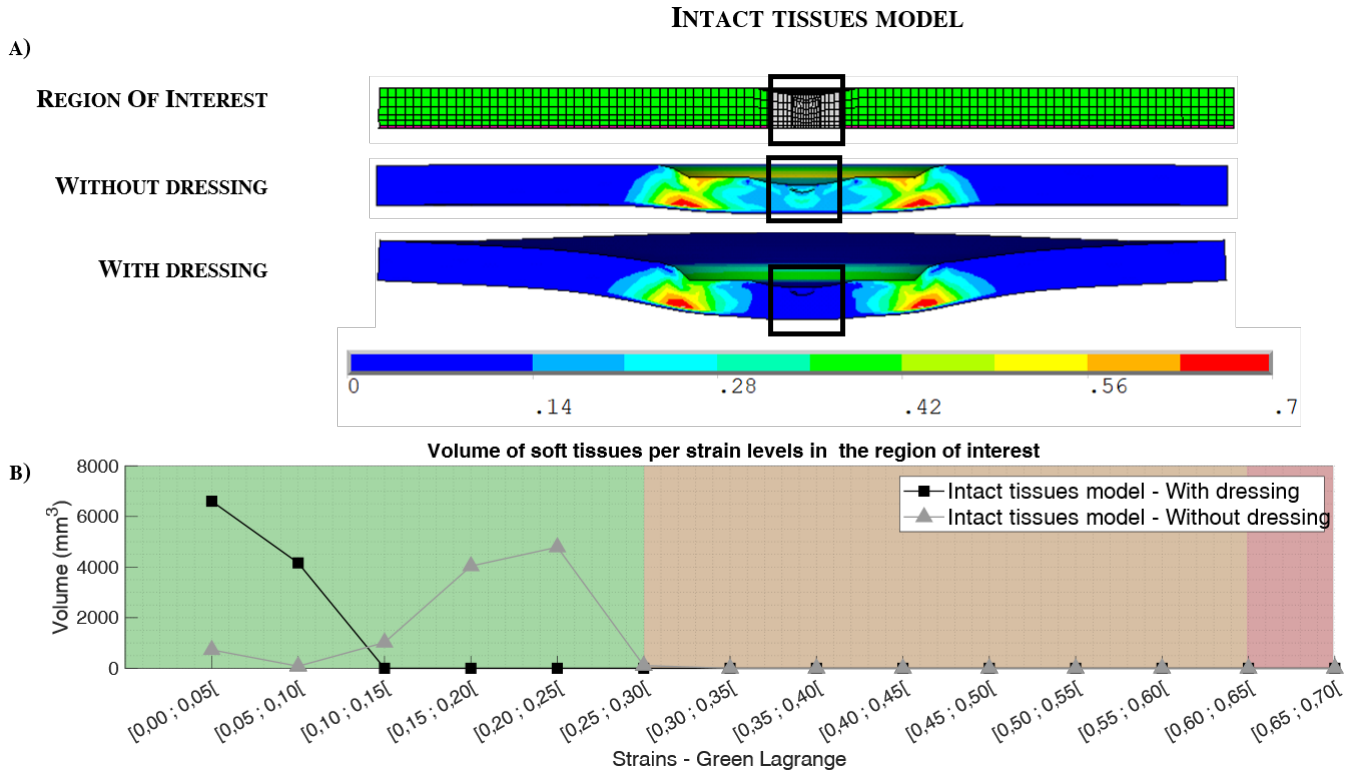

Figure 8: A) Strains in the sagittal plane. The dark square circled the ROI. B) Volume of soft tissues in ranges of strains for the intact tissues model without (grey triangles) and with the dressing (black squares) in the ROI. Green, orange and red regions are safe, potentially injurious and injurious domains of strains respectively [4].

3.3. Internal strains with the injured tissues model

Assuming a category-2 PU developed, the dressing was also able to reduce the internal strains (Figure 9) in the ROI. The peak strain was estimated to 0.43 without dressing, and decreased to 0.30 with the dressing.

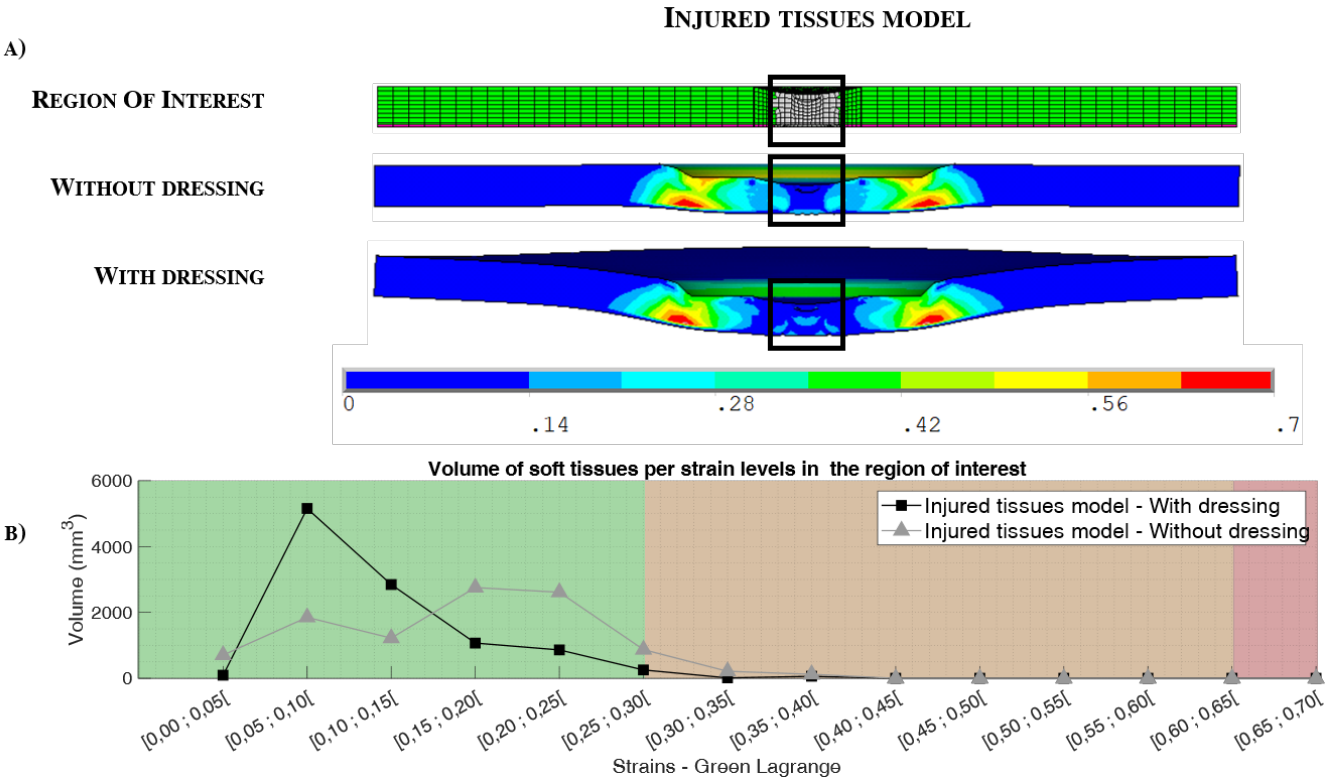

Figure 9: A) Strains in the sagittal plane. The dark square circled the ROI. B) Volume of soft tissues in ranges of strains for the injured tissues model without (grey triangles) and with the dressing (black squares) in the ROI. Green, orange and red regions are safe, potentially injurious and injurious domains of strains respectively [4].

4. Discussion

This study focused on a new approach based on a parametric model of the sacral area, interacting with a new dressing developed by Urgo RID, to investigate internal strains in the context of PU prevention. Thus, the FE method was used to model intact and injured tissues. To evaluate the model, one volunteer participated to measurements of pressures at the interface between the sacral region and the dressing, in a worst-case scenario. These measures were compared to the pressure estimated with the model.

FE estimations of the pressure showed a good agreement with measurements with and without the dressing. Yet estimated peak pressures, up to 217 kPa, revealed an overloading of the tissues during the experiment. This was performed on purpose to account for the worst-case scenario. In fact, clinical pressures as measured at the interface with the sacral areas do not exceed 15 kPa [30,31]. Peak pressure estimations were close to the measured pressure with an error up to 24 kPa. Errors may be explained by numerical geometrical non-linearities at the dressing boundary and also by the resolution of the pressure sensor, that may not capture local extrema. Internal strains were also estimated with and without the dressing. Loadings was modified to assess clinically relevant internal strains. As expected, the presence of the dressing resulted in a decrease of the soft tissues strains in intact tissues surrounding the bony prominence. The reduction of the peak strain by 45 %, highlighted the prophylactic effect of the dressing like in other literature studies [7,14,18,32]. Yet, this study focuses on a new dressing based on the combination with a honeycombed deformable layer. Considering injured soft tissues with a category-2 PU, results showed a decrease of the internal strains surrounding the PU with a reduction of the peak strain by 30 %. To our knowledge, this study is the first attempt to numerically investigate the ability of a dressing to reduce strains of category-2 sacral PU. A similar attempt was proposed for category-4 PU [18] and showed also a benefit of the dressings on the internal stresses. Direct comparison between both models was not possible since, in the present study, soft tissues were modelled between the bone and the wound bottom. To our knowledge, no other literature studies provided internal strains data in the human sacral area when lying on a rigid surface.

Some limitations may impact these findings. The parametric approach involved a simplification of the geometry that may lack accuracy to estimate isolated stress/strain concentration areas. Some parameters of the models had to be defined arbitrarily since they could not be measured such as the Poisson's ratio for soft tissues. A preliminary study revealed that this coefficient could be set between 0.4999 and 0.499 to account for a soft tissues' volume change from 2 % to 18 % respectively. The impact of this parameter on the results of the simulation clearly indicates that further investigation should be conducted to evaluate its value. It is however important to

mention that the efficacy of the dressing is still satisfying if the Poisson's ratio is changed to 0.499. In addition, the duration of the loading was not investigated [33]. The time parameter may, however, be implemented in further work since tissues and dressings may have viscoelastic properties. The time parameter may also be modelled to consider the biochemical and biophysical phenomenon that were not studied here such as the inflammation or ischemia [3]. Further work may also focus on the implementation of clinical parameters such as the head-of-bed elevation and the use of a mattress to assess the efficacy of the dressing in a clinical environment [12] but also extend this work to more subjects to account for geometrical but also material properties discrepancies in different populations. Finally, this model provided results applicable to category-2 PU and may not be extended to deeper wounds as this should involve further developments.

Eventually, this study highlights the potential of a new dressing which may benefit the PU healing process an also act as a prophylactic device with the implementation of a FE model. The FE method allows scientists, industry partners and clinicians, to assess data such as the internal strains that cannot be measured *in vivo* but are still fundamental to evaluate the risk of development of a PU.

5. Acknowledgement

This study was supported by Urgo RID.

6. Conflict of interest

7. References

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