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Finite Element tissue strains computation to evaluate the mechanical protection provided by a new bi-layer dressing for heel pressure injuries.

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Abstract

Objective: In healthcare facilities, pressure injuries are a burden for medical staff since they not only result in longer care but also in increased risks of complications for the patients. Considering prevention, the aim is to hinder the propagation of the pressure ulcer and to speed up the healing time. Urgo RID recently developed a new bi-layer dressing to improve the healing of stage-2 and stage-3 heel pressure injuries. This study aims to numerically investigate the efficiency of this new bi-layer dressing to reduce strains around the pressure ulcer site.

Methods: Three finite element models based on the same heel dataset were designed to compare the Green-Lagrange compressive and maximal shear strains in models without a pressure ulcer, with a stage-2 and with a stage-3 pressure ulcer. Simulations with and without the dressing were computed. Analysis of the results was performed in terms of strain *clusters*, defined as volumes of tissues with high shear and compressive strains.

Results: The decrease of the peak and mean values of strains, between 0 % and 20 %, was small for the three models, but the reduction of the strain cluster volumes was important and up to 68 %.

Conclusion: The cluster analysis enables the quantitative comparison of finite element analysis robustly. Results suggest that the use of the new bi-layer dressing may reduce the strains around the pressure ulcer sites and that it could also be used in a prophylactic manner. Results should be extended to a larger cohort of participants.

Keywords (max 6): Dressing, Finite Element Modelling, Pressure injuries, Shear strains, Compressive strains

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Introduction

Pressure injuries are injuries of the soft tissues affecting about 15 % of patients in healthcare facilities and up to 27 % of the patients in intensive care units.^{1,2} Classified from stage-1 to stage-4, these injuries always result in an extended duration of care and an increased risk of complications.³ On average, 10 weeks are needed to treat stage-2 pressure injuries, the most common in healthcare facilities ⁴ that struggle to prevent the onset of these injuries.

The difficulties in the prevention of pressure injuries are most certainly linked to the multifactorial causes of these injuries which are physiological, biological and mechanical.⁵ Detrimental external pressure and shear loads applied to the tissue may lead to ischemia and then cell hypoxia, a decrease in nutrient supply and an increase of toxic wastes around the cells. This results in cell death which eventually leads to inflammation and the onset of oedema. From a mechanical point of view, excessive external loads may also result in mechanical damage to the cell membrane, eventually leading to cell death. Oedema and inflammation increase the mechanical stress applied to cells.⁵ As a result, pressure injuries can quickly develop to the most severe stages, this is the reason why prevention and treatment of the early stage of the injuries are recommended. The heel is one of the regions most affected by pressure injuries when people are lying in a supine position.⁶ The heel region is particularly vulnerable due to its geometry and the associated comorbidities such as immobile legs, diabetes or other peripheral vascular diseases.⁶ Unloading the tissues around the bony prominence is the first and most important intervention to prevent pressure injuries or offload to enable their healing process. Yet, permanent unloading is not guaranteed as it depends on the patient's condition, position preference and integrity of other weight-bearing areas. Medical devices can also be used to relieve the mechanical loads on the soft tissues under the bony prominences. More particularly, dressings have been demonstrated to have a prophylactic effect.⁸ This was supported by finite element analysis that showed a local reduction of the mechanical stresses and strains with the use of dressings.⁹⁻¹³ Yet, few studies investigated the mechanical impact of dressings on body regions with a pressure ulcer. Schwartz et al. 2019 modelled the sacrum region with a stage-4 pressure ulcer to evaluate multiple dressings.¹⁴ All tested dressings resulted in a decrease in the effective and maximal shear stresses around the pressure ulcer but the anisotropic dressing performed best. This study provided interesting insights into the mechanical impact of dressing on tissues surrounding a pressure ulcer, however, the

authors did not report internal strains such as the Green-Lagrange maximal shear strains that have been reported to be a potential mechanical biomarker to study the development of pressure injuries.¹⁵ The authors also chose to study stage-4 pressure injuries, with a depth up to the bone, but these pressure injuries are less common in the clinical routine than stage-2 or stage-3 pressure injuries. In a previous study, the new bi-layer dressing from Urgo RID has been shown to locally reduce the maximal shear strains around a stage-2 sacral pressure ulcer.¹³ Nevertheless, only the sacrum was studied and the authors chose to design a parametric model that may lack accuracy for the computation of the internal strains.

In this work, the mechanical efficacy of the new bi-layer dressing developed by Urgo RID has been investigated by evaluating the relief of strains. Finite element models of the heel without a pressure ulcer, with a stage-2 pressure ulcer and with a stage-3 pressure ulcer were designed. For all models, two configurations, with and without the dressing, were compared by computing the strain clusters with a loading equivalent to the force applied on the foot while a patient is lying on a bed.^{16,17}

Materials and methods

Data collection

Data for this study were extracted from a previously published work. For more details, the reader is invited to refer to the paper of Trebbi et al. 2021.¹⁸ One healthy participant volunteered for this study (male, 40 years old, 94 kg, 1.73 m). The foot geometry was acquired with a proton density Magnetic Resonance Imaging (MRI) (Philips Achieva 3.0T dStream MRI system) in a supine position. The images were composed of 512 x 428 x 512 voxels with voxel sizes of 0.3125 mm x 0.375 mm x 0.3125 mm and were segmented using Amira (Amira Avizo 6.4, Thermos Fisher Scientific, Waltham, Massachusetts, United States) to reconstruct the geometries of the calcaneus, adipose tissues, Achille's tendon, muscle, skin and the remaining bones and tissue indiscriminately. The foot was kept in position with a made-to-measure cast to capture the undeformed configuration.

Finite element models of the heel

Geometry

Three distinct models were designed: (i) a reference model without a pressure ulcer, (ii) a model with a stage-2 pressure ulcer, and, (iii) a model with a stage-3 pressure ulcer as shown in Figure 1. The two models with pressure injuries were designed based on the reference model on which modifications on the geometry and the material properties were done as detailed later. The models included the skin, adipose tissues, and, muscles. All muscles were fused to consider only one complex entity named muscles. In order to reduce the computation time, the calcaneus and tissues and bones of the upper part of the foot were not included in the model but rather considered as a rigid boundary. The upper part, bones and soft tissues, of the foot was not modelled since these tissues are localized far from the rear face of the heel which is our region of interest and might have a neglectable impact on the results. Similarly, the metatarsi and toe regions were not included in the model since the focus here concerns the heel. All components were meshed using Hypermesh (Hypermesh 2021, Altair Engineering, Inc., Troy MI, USA) with linear tetrahedrons (SOLID285) with a mixed hydrostatic pressure-linear displacement formulation to avoid volumetric locking. The meshes were then imported in PyAnsys used as an interface for ANSYS MAPDL (ANSYS 2020 R2 software, ANSYS Inc., Cannonsburg, PA, USA).¹⁹ The mesh size was set according to a mesh convergence study on the reference model that lead to a mesh with 296,408 degrees of freedom and 263,071 elements.

No sliding was allowed between all tissue layers. The heel reference model was then rotated to account for the orientation of the foot when the participant is lying in a hospital bed without the MRI cast. Orientation of the foot while the participant was lying was measured. Consequently, the heel was rotated by 21 deg in abduction and 26 deg in dorsiflexion.

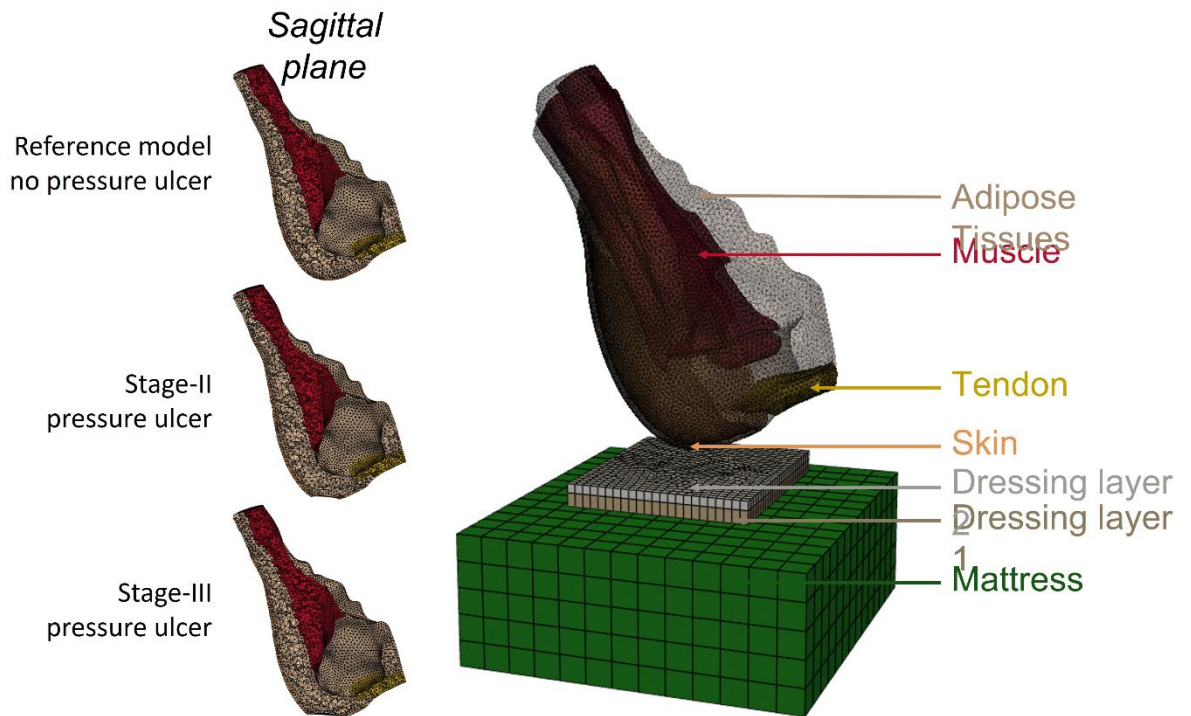


Figure1: Finite element models of the heel (a) without a pressure ulcer, (b) with a stage-2 pressure ulcer and (c) with a stage-3 pressure ulcer.

Material properties

The bone boundary was considered rigid. All soft tissues components were defined as non-linear hyperelastic, isotropic and homogeneous. Material parameters of the constitutive equations were computed using a curve fitting method from literature experimental data for tissues outside the injured area. Data from skin uniaxial tensile tests were used to compute the parameter for the skin layer modelled with the equation proposed by Isihara et al. 1951 (Equation 1).^{20,21} This model is equivalent to the one proposed by Yeoh, 1990 with the parameter C_{30} equal to zero (Equation 1). Compression tests performed on the fat pad of the heel were used to compute the material parameters of the 1st-order Ogden equation (Equation 2) used for the adipose tissues.^{22,23} Tensile test data obtained on tendon and muscle were used to compute the material parameters of the equation proposed by Yeoh, 1990 for Achille's tendon and the muscles in the

model respectively.^{24,25,22} The authors considered all tissues as nearly-incompressible with a Poisson's ratio of 0.4999. Constitutive equations are provided below:

$$(1) W = \sum_{i=1}^n C_{i0} (\bar{I}_1 - 3)^i + \sum_{l=1}^n \frac{1}{d} (J - 1)^{2l}$$

$$(2) W = \sum_{i=1}^n \frac{\mu_i}{\alpha_i} (\bar{\lambda}_1^{-\alpha_i} + \bar{\lambda}_2^{-\alpha_i} + \bar{\lambda}_3^{-\alpha_i} - 3) + \sum_{l=1}^n \frac{1}{d} (J - 1)^{2l}$$

$$(3) d = \frac{2}{\kappa}$$

With W the strain energy density function, C_{i0} , μ_i , α_i material parameters. The order n was equal to 1 for the Ogden constitutive law, 2 for the Isihara constitutive law and 3 for the Yeoh constitutive laws. The first deviatoric invariant of the right Cauchy-Green deformation tensor was denoted \bar{I}_1 and the principal stretches were denoted $\bar{\lambda}_1$, $\bar{\lambda}_2$ and $\bar{\lambda}_3$. The jacobian of the deformation gradient was noted J , d was the incompressibility parameter and κ the bulk modulus. Incompressibility parameters were computed based on Poisson's ratio value with the equation detailed in Mott et al. 2008. Material parameters are detailed in Table 1.²⁶

Material parameters	E_x (MPa)	E_y (MPa)	E_z (MPa)	μ (MPa)	α	C_{10} (MPa)	C_{20} (MPa)	C_{30} (MPa)
Adipose tissues	-	-	-	0.003	6.2	-	-	-
Skin	-	-	-	-	-	0.265	1.923	-
Tendon	-	-	-	-	-	9.654	1.897 10 ²	7.895 10 ⁴
Muscle	-	-	-	-	-	0.005	0.069	1.967
Dressing layer 1	-	-	-	0.001	-	-	-	-
Dressing layer 2	4.400	1.800	0.030	-	-	-	-	-
Mattress	0.430	0.430	0.430	-	-	-	-	-

Table 1: Material parameters of the reference finite element model (i.e., without a pressure ulcer).

Models with pressure injuries

Some models were designed to account for the presence of a pressure ulcer in stage-2 or stage-3. Averaged dimensions of heel pressure injuries were collected among URGO RID clinician experts. A total of 370 European nurses in healthcare facilities answered a poll to provide quantitative data on pressure injuries. The mean dimensions over the 892 stage-2 and 546 stage-3 measured pressure injuries were used to design the pressure injuries of both stages. Modification of the reference model geometry was done to

define the injury area for each model with a pressure ulcer. The injury areas were defined according to the following procedure:

- 1) Design a sphere with a radius of 30 mm.
- 2) Manually position the sphere below the apex of the heel in the reconstructed foot geometry.
- 3) Translate the sphere in the normal direction of the skin by 3 mm for stage-2 pressure ulcer or by 5 mm for a stage-3 pressure ulcer.
- 4) Perform a Boolean operation between the sphere and the heel model.

This corresponded to stage-2 pressure injuries 3 mm deep with an approximate diameter of 20 mm. The stage-3 pressure injury was 5 mm deep with an approximate diameter of 23 mm.

Material properties were also altered by the presence of pressure injuries to account for the stiffening of the tissues in the injury area.^{27,28} Considering models with a pressure ulcer, three regions were therefore defined: (i) the soft region, with the same behaviour as for the reference model tissues, (ii) the intermediate region, with a medium stiffening of the tissues, and (iii) the rigid region with an important stiffening of the tissues. The rigid region was defined as all tissues around the pressure ulcer within a distance of 5 mm. The intermediate region was defined as all tissues around the rigid region within a distance of 5 mm. The remaining tissues were in the soft region. Material parameters, C_{10} for the skin and μ for the adipose tissues, in the intermediate region, were multiplied by 1.5, while these parameters were multiplied by 2 in the rigid region.

Finite element model of the dressing

The dressing was composed of two layers and was a modified version of the UgroStart Plus Border dressing designed by Urgo RID (Urgo Research, Innovation & Development, Chenôve, France) ~~as shown in Figure 2~~. In the new design,¹³ a protective and deformable layer was added. The layer was referred to as dressing layer 1. Dressing layer 1 was composed of honeycombed alveoli made of a compressible material. Alveoli under and around the bone prominence, or the pressure injuries, were removed to locally relieve part of the load applied to the tissues. The second layer, dressing layer 2, is similar to the UgroStart Plus Border dressing which is composed of several components. This layer was designed to be in contact with the skin and was glued to dressing layer 1. In this finite element approach, both dressing layers were modelled as homogenous. Dressing layer 1 was modelled with a compressible, isotropic material with the

equation proposed by Blatz-Ko.²⁹ Dressing layer 2 was modelled with a linear elastic orthotropic material. Material parameters are provided in Table 1. For more detail about the characterization of the mechanical behaviour of both dressing layers, the reader may refer to the previous study of Fougeron et al. 2022.¹³

Boundary conditions and loading

Mattress support

A mattress of thickness 50 mm was added to all models to act as a hospital bed. The mattress was meshed with 910 linear hexahedrons (SOLID185) in PyAnsys.¹⁹ The mattress was modelled with a linear elastic constitutive behaviour with a Young's modulus of 430 kPa and a Poisson's ratio of 0.3.³⁰ The coefficient of friction between the skin and the mattress was defined according to the literature and set to 0.43.³¹ The static coefficient of friction between dressing layer 1 and the mattress was measured experimentally and set to 0.62 in the models.¹³

Finite element analyses

Models with the dressing needed a preliminary phase to compute the prestress in the tissues and the dressing after the positioning of the dressing on the heel as shown in Figure 2. The bone refers to the barycenter of the bone boundary subsequently. The position of the barycenter was computed as the sum of the position of all nodes at the boundary with a weight equals to one for each node divided by the number of nodes. This preliminary phase was composed of three steps. During the first step, a downward displacement of 15 mm was applied to the bone while the dressing border nodes were fixed in position. This step was performed to ensure that contact has been established between the skin and the dressing before the second step. During the second step, the bone position was fixed while all constraints on the degrees of freedom of the dressing node were removed to apply a force of 0.15 N in the normal direction at each node of the upper surface of the dressing, that should be in contact with the skin.¹² This value was arbitrarily set to ensure that all the surface of the dressing was in contact with the skin to activate the tie constraint. Eventually, the forces applied on the dressing nodes were discarded and the position of all nodes in the model was saved to define the initial state of the second analysis phase.

Two steps were defined for the second analysis phase. The bone was fixed in position and an upward displacement of 5 mm and 20 mm was applied to the bottom nodes of the mattress to ensure contact

with either the dressing or the skin depending on the model. During the second step, the nodes of the bottom of the mattress were fixed while the constraint on the vertical position of the bone was removed. A vertical force equivalent to 6 % of the body weight of a participant of 94 kg was applied to the bone. Concerning the models without dressing, only the second phase of the analysis was performed.³²

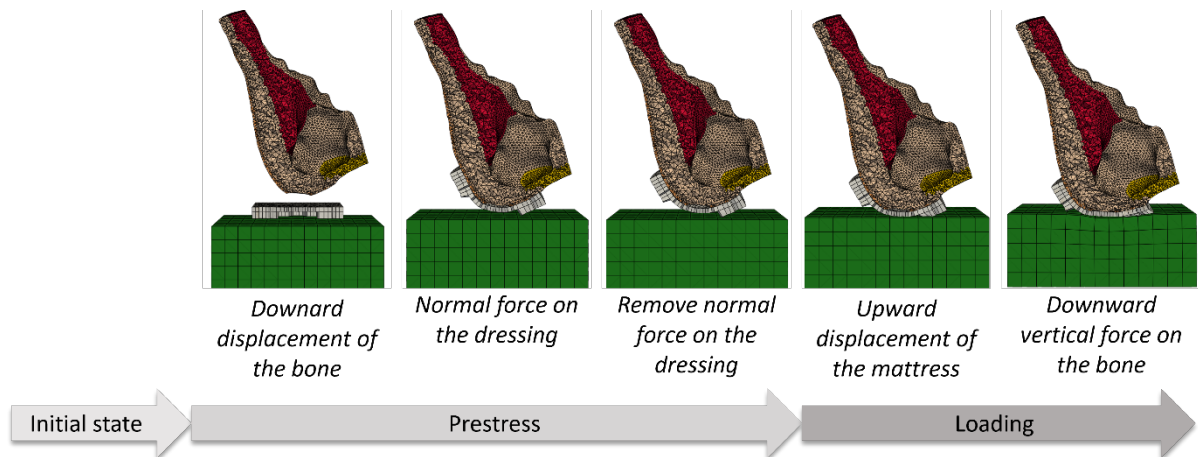


Figure 2: Analysis steps for the models with a dressing. The same boundary conditions were applied for all models whether there was or was not a pressure ulcer.

Eventually, analyses were conducted with PyAnsys,¹⁹ in quasi-static and with an implicit scheme. Results were post-processed to extract computed data for each model. The strain analyses were conducted in agreement with the study of Macron et al. 2019.¹⁶ Strain clusters were defined as the volume of tissues with high maximal shear strain, E_{shear} , and high compressive strains, E_{comp} , both with the Green-Lagrange formulation since these quantities of interest were previously correlated with the onset of pressure injuries.¹⁵ In the current study, clusters were defined as the union of the adjacent elements with both E_{shear} above or equal to 75 % and E_{comp} above or equal to 30 %. A threshold value of E_{comp} of 45 % has been recommended in the literature, yet on this particular model a value of 45 % was not enough for discriminating the models.^{15,16} The volume of each cluster, in the undeformed configuration, was computed to assess the main clusters in all models. Mean and maximal values of E_{shear} and E_{comp} were also computed for each cluster.

Results

Strain clusters are presented in Figure 3 and the characteristics of the clusters are given in Table 2. Only strain statistics of the clusters with the highest volumes in each model were computed since secondary clusters were at minimum 22 times smaller than the main cluster. The use of the dressing allowed for a reduction of the volume of the clusters by 55, 68 and 58 % in the reference model, stage-2 pressure ulcer model and stage-3 pressure ulcer model respectively. A small decrease in the maximal and mean values of E_{shear} was noticed while no impact was noted on E_{comp} .

Models	Reference (no pressure ulcer)		Stage-2 pressure ulcer		Stage-3 pressure ulcer	
	No	Yes	No	Yes	No	Yes
Volume (mm ³)	2471	1101	1541	489	1110	464
Maximal E_{shear} (%)	206	126	127	117	137	131
Mean E_{shear} (%)	91	86	91	87	89	84
Maximal E_{comp} (%)	44	43	45	41	42	43
Mean E_{comp} (%)	34	33	33	33	36	34

Table 2: Characteristics of the main cluster in all models, with and without the use of the dressing. The main cluster is defined as the cluster with the highest volume.

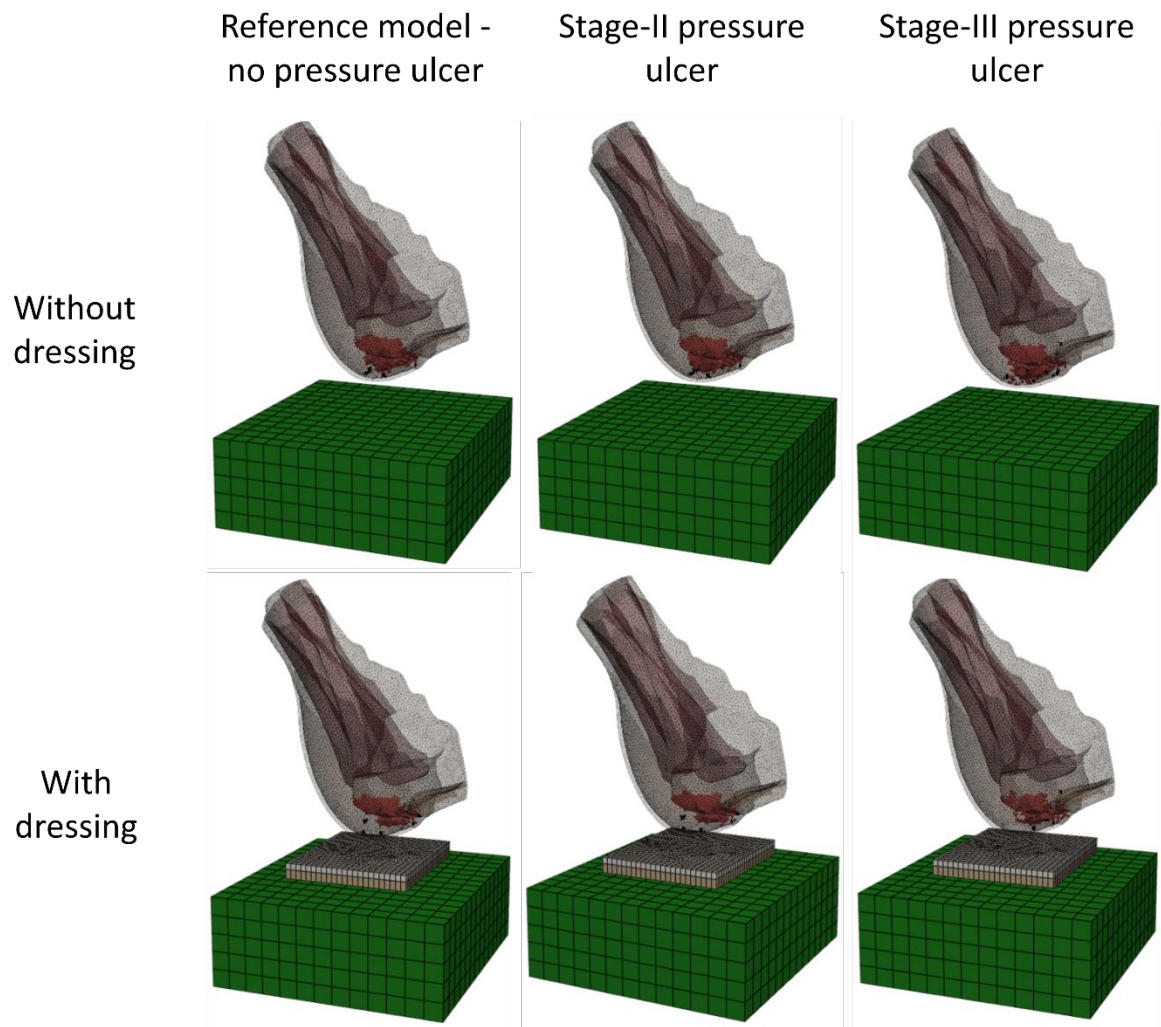


Figure 3: Strains cluster at the end of the analysis in all models. The main cluster is shown in pink. Remaining clusters are shown in black.

Maximal shear strains were still more discriminant than the compressive strains between models and are plotted in Figure 4.

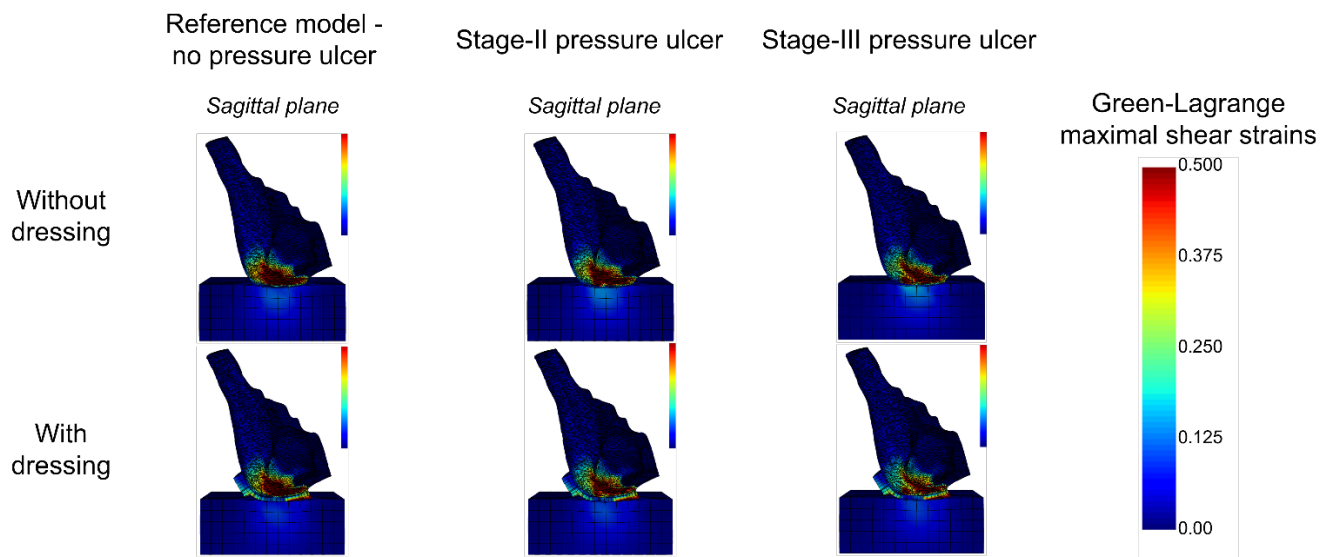


Figure 4: Maximal shear strains, according to the definition of Green-Lagrange, in all models in the sagittal plane.

Discussion

The healing of pressure injuries is a challenging task in healthcare facilities. Not only the healing is not guaranteed, but even cases of successful healing require several weeks to be achieved.⁴ New medical devices are designed to improve and ease such healing process. By changing some design features, dressings that were originally used to provide a safe biological environment around the pressure ulcer could also be used to help the healing process in mechanical terms. Based on the rationale that high maximal shear and compressive strains may lead to the onset of pressure injuries,¹⁵ the authors also supposed that high maximal shear and compressive strains may hinder the healing of pressure injuries. The new bi-layer dressing developed by Urgo RID was designed with the aim to improve the healing of stage-2 and stage-3 pressure injuries. In this study, the ability of this new bi-layer dressing to relieve maximal shear and compressive strains was investigated on finite element models of the heel without pressure ulcer, with a stage-2 pressure ulcer and with a stage-3 pressure ulcer.

The current study shows that the use of dressing allows for the reduction of the strains around the pressure ulcer considering stage-2 and stage-3 pressure injuries. As shown in the current study, the dressing allows for a reduction of the strains under the bony prominence when there is no pressure ulcer. A cluster analysis was performed to compare models robustly but also to avoid comparing local maxima in strains that may occur due to numerical errors. Even though changes in mean maximal shear strains were small and changes in peak and mean compressive strains were negligible, the volume of tissues above the strain thresholds decrease by 55 % in the model without pressure ulcer, by 68 % in the model with a stage-2 pressure ulcer, and by 58 % in the model with a stage-3 pressure ulcer, when the dressing was used. The decrease of the peak maximal shear strains was between 6 % for the model with a stage-3 pressure ulcer to 20 % for the models without a pressure ulcer. The maximal shear strains were highly above the damaging thresholds that were identified on rat hindlimbs while the compressive strains were slightly below the thresholds.¹⁵ However, the authors themselves declared that such thresholds were not absolute but should be personalized. As a result, the thresholds of the current study were used relatively to compare the models in between them but do not account for a limit between healthy and damaged tissues.

Research regarding pressure injuries of the heel in bedridden patients is limited.³³ Literature studies reported investigations on the impact on the mechanical responses of soft tissues of diabetes,³⁴ foot

orientation,³⁴⁻³⁷ calcaneus shape,^{38,39} mattress stiffness,^{9,30,35-37} mattress angles,³⁶ and dressings.^{9,10,34} Some studies published strain values using various definitions: Von Mises strain, Effective Green-Lagrange strain, Maximal shear strain or Lagrange strain. When available, strains were computed with the Green-Lagrange definition to simplify the comparison between studies and with the study of Ceelen et al. 2018.¹⁵ Literature studies reported maximal compressive strains between 54 % and 81 %, ³⁵ and maximal shear strains between 15 % and 60 %.^{9,35-37} The values in the current studies are above the ones presented in previous work. Yet, direct comparison is tedious to achieve. Model geometry, material and boundary conditions varied in all studies. The material parameters are among the most significant factors in the mechanical response of soft tissues, but the range of values proposed in previous works is wide. The material properties were usually extracted from literature values without evaluation of the resulting tissues' mechanical response, which is a huge limit from previous works since material parameters are known to be participant-specific.⁴⁰ In this study, the material parameters were evaluated using digital volume correlation on MRI acquisitions in an unpublished work to ensure that the chosen material parameters were appropriate for our participant data. On the other hand, the vertical force applied to the bone was equivalent to 6 % of the participant's body weight based on anthropomorphic data whereas this force was as low as 1 % of the body weight in some studies which lead to a reduction of the strain estimation.³⁶ In addition, the stiffness of the mattress used in the current study was amongst the highest values in the literature. This stiffness was based on the work of Lee et al. 2017 but clinically available mattresses exhibit a wide range of stiffnesses and behaviours.^{30,41}

Some limitations are worth noting to discuss this work. Indeed, the participant database was composed of only one healthy participant. Consequently, this work only provides the first insights into the mechanical interaction between the soft tissues of the heel region and the new bi-layer dressing. Although the pressure injuries were considered in the model by removing soft tissues under the bony prominence and by locally altering the material properties, a model of a participant at risk of a pressure ulcer may differ from one healthy participant. People suffering from obesity, diabetes, malnutrition, or foot deformities may have significantly different tissue thicknesses, bone shapes and material parameters. Furthermore, the soft tissues' material parameters in this study were not participant-specific. Even though the chosen properties were evaluated with experimental data, the boundary conditions were different than in the current study. Regarding the material parameters, soft tissues were modelled as full solid with a high value of Poisson's

ratio compared to other studies. This value was set according to the recommendation of Bonet and Wood to define soft tissues as nearly incompressible. Previous work showed the high impact of the Poisson's ratio on the strain's computation.⁴² To better account for the tissue deformations and fluid exchanges during the loading of soft tissues, bi-phasic porous modelling may be used.⁴³ This approach could also allow us to account for the ischemic process that leads to the onset of pressure injuries which was ignored in the current study. Considering the material properties of the soft tissues additional work should be conducted to also account for the time-dependent response of the tissues to external loads. However, this complexifies the model by adding several a priori unknown material parameters for which data are tedious to find in the literature or obtain experimentally. The mattress was also simplified and modelled with a linear elastic behaviour which does not account for the large deformation response. As a first approach only vertical load on a flat mattress was investigated. Additional work is necessary to also study the impact of the shear forces on the computation of the strains. Indeed, even low shear forces could be potentially damaging to the tissues.¹⁸ The geometry of the pressure ulcer was simplified even though the proposed model approach agreed with the recommendations of clinical experts in the field. Pressure injuries may have a lot of different shapes, such as cavities or open wounds, with spherical, ellipsoidal, or random volumes. All these shape variations may lead to changes in the mode of loading of the tissues and thus in different strain distributions. However, this will be mitigated with the future inclusion of more participants.

Despite these limitations, the results suggested that pressure ulcer dressings can be designed to relieve the strains in the soft tissues not only in a prophylactic approach but also when a stage-2 or stage-3 pressure ulcer is present. Further investigations should be performed to define which of these mechanical data, the local peak strains, the volume of the strain's clusters, or a combination of both, are more relevant to evaluate the efficiency of pressure ulcer dressings. These results still need to be extended to a larger cohort.

Implication for practice

Dressings are usually used to provide a safe biological and physiological environment around the pressure ulcer to help the healing of the wound. However, apart from the biological and physiological causes to pressure injuries, external mechanical loads are also damaging to the tissues. The new generation of dressing designs may thus not only consider the biological and physiological paths to healing pressure injuries but also the relief of mechanical loads. Unloading the tissues will always be the best solution to treat pressure injuries. Yet the use of dressings may be temporally helpful while this unloading is not possible. For unavoidable temporary local loading of the pressure injury area, dressings, if designed with this purpose, may help to reduce the external loads applied on the weakened area. In the case of the new bi-layer dressing presented in this study, a detailed protocol is proposed to choose the alveoli to remove in the compressible layer in order to relieve the underlying soft tissues and reduce the strains. To support this work, further studies should be conducted including participants from several target populations. Comparison with different dressing technologies should also be performed to evaluate the best solution for various populations or boundary conditions.

Conclusion

Some studies have demonstrated the ability of dressing to prevent pressure injuries mechanically speaking. However, few studies investigated the mechanical impact of dressings after the onset of the pressure injury. Concerning stage-2 and stage-3 pressure injuries, which are the most common in clinics, the new bi-layer dressing presented in this study allowed for the reduction the strains surrounding the wound. Even though strain peak values remained high even after using the dressing, the volume of soft tissues above the damage thresholds was decreased in all scenarios.

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