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ORIGINAL ARTICLE

The biomechanical efficacy of a hydrogel-based dressing in preventing facial medical device-related pressure ulcers

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Abstract

Continuous positive airway pressure masks for breathing assistance are used widely during the coronavirus pandemic. Nonetheless, these masks endanger the viability of facial tissues even after a few hours because of the sustained tissue deformations and extreme microclimate conditions. The risk of developing such device-related pressure ulcers/injuries can be reduced through suitable cushioning materials at the mask-skin interface, to alleviate localised contact forces. Here, we determined the facial tissue loading state under an oral-nasal mask while using hydrogel-based dressing cuts (Paul Hartmann AG, Heidenheim, Germany) for prophylaxis, which is a new concept in prevention of device-related injuries. For this purpose, we measured the compressive mask-skin contact forces at the nasal bridge, cheeks, and chin with vs without these dressing cuts and fed these data to a finite element, adult head model. Model variants were developed to compare strain energy densities and effective stresses in skin and through the facial tissue depth, with vs without the dressing cuts. We found that the dry (new) dressing cuts reduced tissue exposures to loads (above the median loading level) by at least 30% at the nasal bridge and by up to 99% at the cheeks, across the tissue depth. These dressing cuts were further able to maintain at least 65% and 89% of their protective capacity under moisture at the nasal bridge and cheeks, respectively. The hydrogel-based dressings demonstrated protective efficacy at all the tested facial sites but performed the best at the nasal bridge and cheeks, which are at the greatest injury risk.

KEYWORDS

biomechanical model, computer finite element simulations, MDRPUs, pressure injury prophylaxis, prophylactic dressings

Key Messages

- CPAP masks are widely used during the COVID pandemic but may cause pressure ulcers
- suitable mask-skin interface materials reduce the device-related facial injury risk

- a hydrogel-based dressing was evaluated for this role using computer modelling
- the tested dressing demonstrated protective efficacy at all the facial sites
- the dressing performed the best at the most vulnerable nasal bridge and cheeks

1 | INTRODUCTION

Non-invasive ventilation masks (also known as oxygen masks) are commonly prescribed to patients with acute or chronic respiratory insufficiency, and their usage has become pivotal during the current COVID-19 pandemic, particularly for those presented with COVID-related acute respiratory distress syndrome.[1-4] The most recent clinical findings published in this regard suggest that delivery of continuous positive airway pressure (CPAP) by means of an oral-nasal mask can avoid intubation in almost half of the COVID patients who require respiratory support.[5,6] However, prolonged use of CPAP masks is known to endanger the viability of facial tissues as these soft tissues are subjected to sustained mechanical deformations caused by the tightening of the mask onto the skin, which further alters the microclimate conditions at and near the mask-skin contact sites.[2,7] Specifically, the mask applies compressive and shear forces to the facial skin along narrow contact regions, which generates compound tissue loads (consisting of compression, tension, and shear stresses) and results in localised stress concentrations at the skin and subdermally, that eventually cause cell and tissue damage.[2,8-11] Lack of biomechanical knowledge-driven guidance for healthcare professionals with regards to how to safely apply CPAP masks (which contributes to over-tightening of masks in the clinic), together with the generic mask designs that do not necessarily fit the contours of the individual face and use relatively stiff polymeric materials with respect to skin and subdermal fat, all contribute to the above-mentioned stress concentrations.[2,12] Specifically, in its classic work "transferring load to flesh", Murphy discussed the two imperative factors that intensify stress concentrations in skin when in contact with an object (including medical devices) and which may lead to skin breakdown (in the context of use of prostheses).[13] Namely, these factors are as follows: (i) Transition from high (device material) to low (soft tissue) stiffness and; (ii) geometrical irregularities of either the device surfaces or the skin topography.[13] Undoubtedly, CPAP masks meet both conditions. In addition, because the tissue stress concentrations also increase with a rise in the mask-skin contact pressures (which are, in turn, proportional to the contact forces), over-tightening the mask intensifies tissue stresses as well.

Medical device-related pressure ulcers (MDRPUs) form primarily because of the sustained mechanical loading and deformations of the skin and subcutaneous tissue layers between the applied device and any internal stiff anatomical structures, such as the nasal or zygomatic (cheek) bones under a CPAP mask. Nevertheless, the skin microclimate (including the temperature, humidity, and airflow near the skin surface) is critically important, although being an indirect MDRPU risk factor. Temperature and humidity are known to affect the structure and function of the skin, which alters the damage thresholds for the skin and underlying soft tissues of the affected individual. For example, increased temperature at the microclimate of the skin causes an increase of the trans-epidermal water loss (TEWL), which in turn promotes moisture accumulation on the skin, and, thereby, leads to loss of the cohesive strength of the stratum corneum.[7] Likewise, the stratum corneum hydration, which develops under relative humidity in excess of 60%, leads to swelling of corneocytes and the entire stratum corneum, as well as to abnormal changes in the micro-topography of the skin surface.[7] In the context of CPAP-related MDRPU prevention, the effects of humidity and temperature near the skin surface are inextricably linked to the concurrent soft tissue deformations, as the tissue tolerance to the sustained mechanical loading is compromised by either the elevated temperature or the high humidity, which occur concurrently within the space of a CPAP mask.

Recent work had shown that the incidence of hospital-acquired pressure ulcers (also known as pressure injuries) associated with medical devices may approach 40%, hence the currently widespread use of the concept and term MDRPUs, which are considered a stand-alone pressure ulcer category in many injury classification systems worldwide.[14] Among these hospital-acquired injuries, the ones caused by CPAP masks are common, which is not surprising, in view of the biomechanical considerations described above.[15] The specific facial locations at the greatest risk for CPAP-related injuries are known to be the nasal bridge and the cheeks.[16-18] Of note, CPAP masks are in clinical use since the 1980s, and their design evolved very little from the time when they were first invented by the Australian physician Dr. Colin Sullivan to treat severe sleep apnoea; while the volume of use of

CPAP masks increased rapidly in the last couple of years, because of the COVID pandemic, CPAP masks were long-known for their association with facial MDRPUs.[2,14-18] Specifically, Carron and colleagues[19] conducted a meta-analysis reviewing the complications of non-invasive ventilation and reported that nasal skin lesions (ie, erythema or ulcers) under a CPAP mask become more frequent with longer ventilation sessions; occur in 5% to 50% of the patients after a few hours, and in virtually 100% of the patients after continuous 48 hours of CPAP mask usage.

Importantly, the risk for developing MDRPUs and particularly CPAP mask-related injuries can be reduced by providing additional soft and flexible cushioning at the susceptible mask-face contact areas.[2] Such local cushioning directly addresses the biomechanical factors identified by Murphy[13] as described above, that is, it smoothens the stiffness gradient between the CPAP mask materials and the skin and also increases the contact area for transfer of the loads delivered by the mask, which results in redistribution and reduction in the intensities of the tissue stress concentrations. Prophylactic dressing pieces that are used as cushioners on facial skin in conjunction with CPAP masks are a well-known clinical practice in many care settings. Clinicians typically cut different wound dressing products in various shapes to match the individual face contours and place the dressing cuts at certain skin-mask contact regions, particularly on the nasal bridge, the cheeks, and the chin, albeit with generally limited research regarding the efficacy of this type of preventative intervention. Currently, the vast majority of published evidence for prophylactic efficacy against MDRPUs exists for *foam* dressings,[18] whereas dressings made of other materials, including hydrogels, received little or no attention, particularly from a biomechanical perspective. In this study, we aimed to investigate the biomechanical efficacy of a hydrogel-based dressing material in mitigating the sustained facial tissue stress concentrations associated with the use of a CPAP mask. Using an integrated experimental-computational approach, we determined here, for the first time, the performances of a hydrogel-based dressing in this preventative context, which adds important information to the literature with respect to alternative and advanced material technologies for prophylaxis of MDRPUs.

2 | METHODS

2.1 | Subjects

This study was conducted as a pilot arm of an ongoing MDRPU research project (details of the Ethical Approval are provided in Reference 2). Six healthy volunteers (three of whom were males) aged 27.8 ± 2.6 years (mean ± SD) were recruited and all have provided their informed consent. The subjects were not obese or underweight according to the World Health Organisation criteria. Exclusion criteria were respiratory obstructive disorders or diseases, craniofacial anomalies, facial trauma, scarring or burns, skin diseases, or malignancy.

2.2 | Experimental test protocol

The compressive contact forces measured at the nasal bridge, chin, and cheek locations in the above subject group (Figures 1,2) were used as input data for the finite element (FE) modelling framework (as described further below) to simulate the compression of the mask at these anatomical locations. To measure the compressive contact forces generated between a CPAP mask and facial skin at the nasal bridge, the chin, and the cheeks, which are the common facial sites for development of MDRPUs, we based our protocol on the previous work of Peko Cohen and colleagues.[2] A measurement apparatus utilising paper-thin force sensors (Force Sensing Resistors; Interlink Electronics, Camarillo, California) connected to a sampling board (Arduino Uno R3, Ivrea, Italy) and operated using a custom-made graphical user interface (Version 19_f01, National Instruments, Austin, Texas) was built and used for all the presently reported CPAP-skin contact force measurements. The working range of the above sensors is 0.2 to 20 N, their repeatability is ±2%, and the drift range is up to 5%/logarithmic time; these specifications make the aforementioned sensors suitable for the current biomechanical device-skin interaction studies.[2] Before acquiring force measurements on facial skin, a log(resistance)-log(mass) (Ω/g) sensor calibration was conducted using precision weights (100–400 g), considering the linearity of the sensors at their working range. The calibrated system was used to experimentally determine the local compressive contact forces applied by an oro-nasal, single-use, medium-size CPAP mask (AF531; Philips Respironics Inc., Murrysville, Pennsylvania) on the nasal bridge, cheeks, and chin, as depicted in Figure 1A. Readings were taken from each subject at two configurations, with vs without applying cuts of hydrogel-based dressings (HydroTac Transparent, manufactured by Paul Hartmann AG, Heidenheim, Germany) at the above anatomical sites, to measure the facial contact force alleviation associated with this clinical prophylactic intervention applying the hydrogel-based dressings. For the measurements acquired with the dressing cuts, the dressings were positioned along the contours of the CPAP mask (Figure 1A).

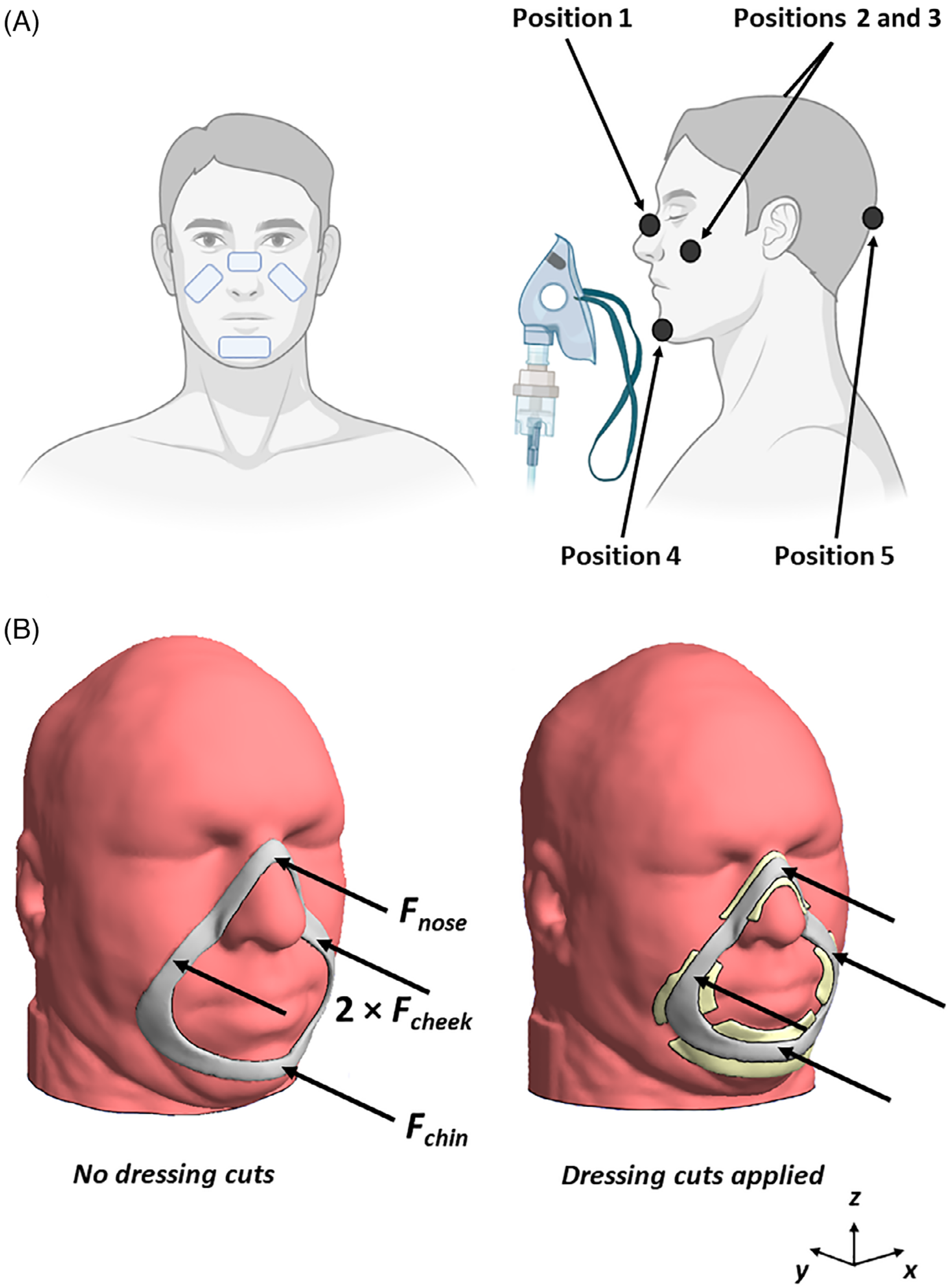

FIGURE 1 Determination of the contact forces generated by a continuous positive airway pressure (CPAP) mask on facial skin and their application in the computational modelling: A, Experimental measurements of the contact forces with the CPAP mask in five head sites, namely, the nasal bridge (Position #1), the two cheeks (Positions #2 and #3), the chin (Position #4), and the back of the head (Position #5). The latter sensor position was used to ensure a good fit of the CPAP mask for each subject. The contact forces were measured in Positions #1 to 4 with and without application of the hydrogel-based dressing cuts (as depicted in the left frame). B, Two corresponding computational finite element model variants were developed, with vs without the applied dressing cuts. The measured contact forces at the nasal bridge (F_{nose}), the cheeks (F_{cheek}), and the chin (F_{chin}) were used as force boundary conditions to simulate the strapping of the CPAP mask onto the head

Prior to each measurement session, subjects were allowed to fit the CPAP mask and acclimatise to it for 1 minute and then had approximately 5 minutes of a break period between measurements with vs without the dressing cuts. Based on preliminary testing, we chose the 1-minute acclimatisation duration as this time period was more than sufficient for subjects to identify and flag any discomfort or areas of poor fit (eg, related to misalignment of the mask), and also, because, from a tissue mechanics perspective, it is widely known that soft tissues typically reach the plateau region of their stress relaxation response within less than a minute, and so their stiffness stabilised shortly after the application of the CPAP mask. Contact force data were acquired continuously for 90 seconds after the real-time force-time plot had stabilised, indicating that the sensors were properly positioned. Contact force measurements were also acquired under the straps of the mask at the occipital scalp (Position 5 marked in Figure 1A) to determine the force levels generated under the straps after they were tensioned to an extent at which no more than two fingers could slide between the straps and the scalp, as per the clinical practice; this technique was also reported to result in the lowest level of perceived user discomfort on

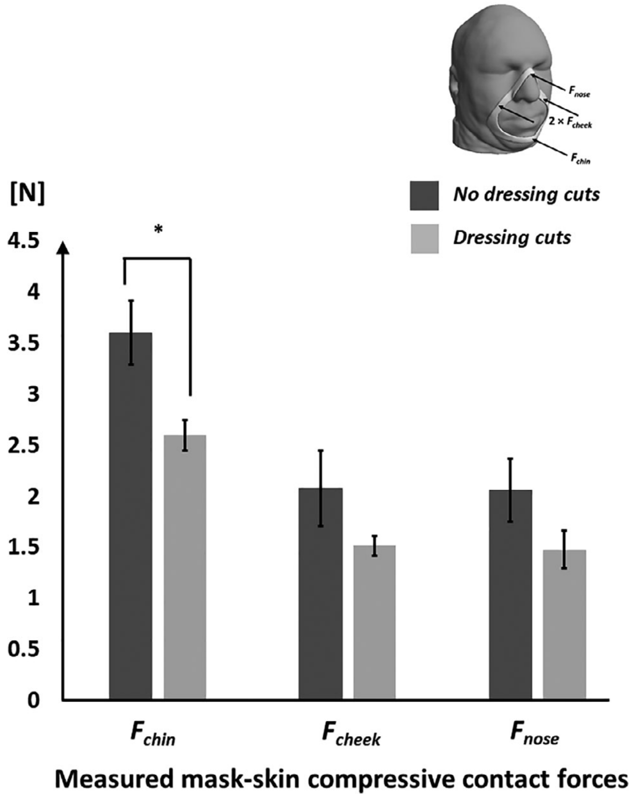

FIGURE 2 The contact force data measured in the subject group at the three facial sites of interest, with vs without the protection of the hydrogel-based dressing cuts. The error bars show the standard deviations (N = 6) and the asterisk is for $P < 0.05$

a visual analogue scale.[20] For this condition, the measured forces in Position #5 were approximately 2 N for each subject. For these conditions, the dressing cuts were positioned along the CPAP contours (as shown in Figure 1A) and the sensors were placed between the CPAP mask and the hydrogel-based dressings.

2.3 | Computational modelling

Two comparable FE model variants were developed for visualisation and quantitative analyses of the potential differences in facial skin and underlying soft tissue stresses and strain energy density (SED) magnitudes while a CPAP mask is being used, with vs without the dressing cuts as tissue protectors (Figure 1B). Both of the FE model variants used the same adult head that was built using the visible human (male) project image database (head dimensions: 16.5 cm ear-to-ear and 21.5 cm occiput-to-forehead; head weight = 5 kg; Figure 1B) and which has been extensively applied and tested in previous research work of our group.[2] The anatomical features, the constitutive laws of the hard and soft tissue components, and the tissue mechanical properties fed into this computational head model are described in detail in our published work[2,21]–.[22] The head model variant that included the hydrogel-based dressing cuts beneath the CPAP mask (Figure 1B) considered the long-term elastic moduli of these dressings, which have been measured and reported elsewhere[23] and found to be 74.2 ± 15.9 and 21 ± 7.2 kPa in the dry (new) and moist (used) conditions of these specific dressings, respectively. The silicone pads of the CPAP mask were assigned a compressive elastic modulus of 119 kPa and a Poisson's ratio of 0.49,[24] consistent with our previous work on MDRPUs caused by CPAP masks.[1]

Using the FE modelling framework described above, we delivered the compressive forces measured at the nasal bridge, chin, and cheeks (Figure 2) to the corresponding regions of the CPAP mask in the two head model variants, after fixing the skull for all translations and rotations. The contact conditions between the CPAP mask and facial skin as well as the contacts between the mask and the dressing cuts were all set as “tie”. The two head model variants (with vs without the dressing cuts) were meshed using the Scan-IP module of Simpleware (Version 5.1, Synopsis, Mountain View, California) using tetrahedral elements. The simulations were computationally solved using the Pardiso FE solver (Version 2.5) and post-processed using PostView (Version 1.10.2), which are both modules of the FEBio FE software package (Version 1.10, University of Utah, Salt Lake City, Utah). The runtime of each head model configuration was in the range of 8 to 12 minutes, using a 64-bit Windows 7 based workstation with CPU comprising Intel Xeon R5645 2.40 GHz (2 processors) and 64 GB RAM.

For the purpose of quantitatively and systematically analysing the sustained exposure of facial soft tissues to the mechanical loads induced by the CPAP mask, we plotted the volumetric distributions of the effective (von Mises) stresses and SEDs in each anatomical site as histograms, consistent with our published computational modelling work concerning pressure ulcer/injury prevention.[25,26] We produced such tissue-exposure-to-loading histograms for facial tissues: (*i*) without the protection provided by the dressings, as a baseline condition; (*ii*) with new, straight-from-the-package dry hydrogel-based dressings (ie, considering the ‘dry’ dressing stiffness specified above); and (*iii*) with moist, used dressings (considering the aforementioned ‘moist’ dressing stiffness). These stress exposure histograms were produced separately for skin and for the entire soft tissue thickness at each facial location, henceforth termed “pooled soft tissues”, to isolate the superficial influence of the hydrogel-based dressings on skin from its protective effect throughout the tissue depth.[25,26] We further calculated the protective efficacy index (PEI), protective endurance (PEN), and prophylactic trade-off design parameter (PTODP), which are likewise described in detail in our published work.[25,26] In brief, the PEI, PEN, and PTODP parameters have been established to form a minimum dataset that characterises the protective biomechanical performances of a dressing material/technology used for prophylaxis of pressure ulcers/injuries, including MDRPUs. This minimum dataset* considers the biomechanical efficacy of a dressing used for prophylaxis when the dressing is new out of the package (using the PEI); in its used condition after absorbing moisture such as perspiration (given by the PEN) and when combining the two latter states in the normal lifecycle of a dressing (which is provided by the PTODP).[25,26]

3 | RESULTS

The descriptive statistics of the contact force values measured in the study group while wearing the CPAP mask are shown in Figure 2. The contact forces developed on

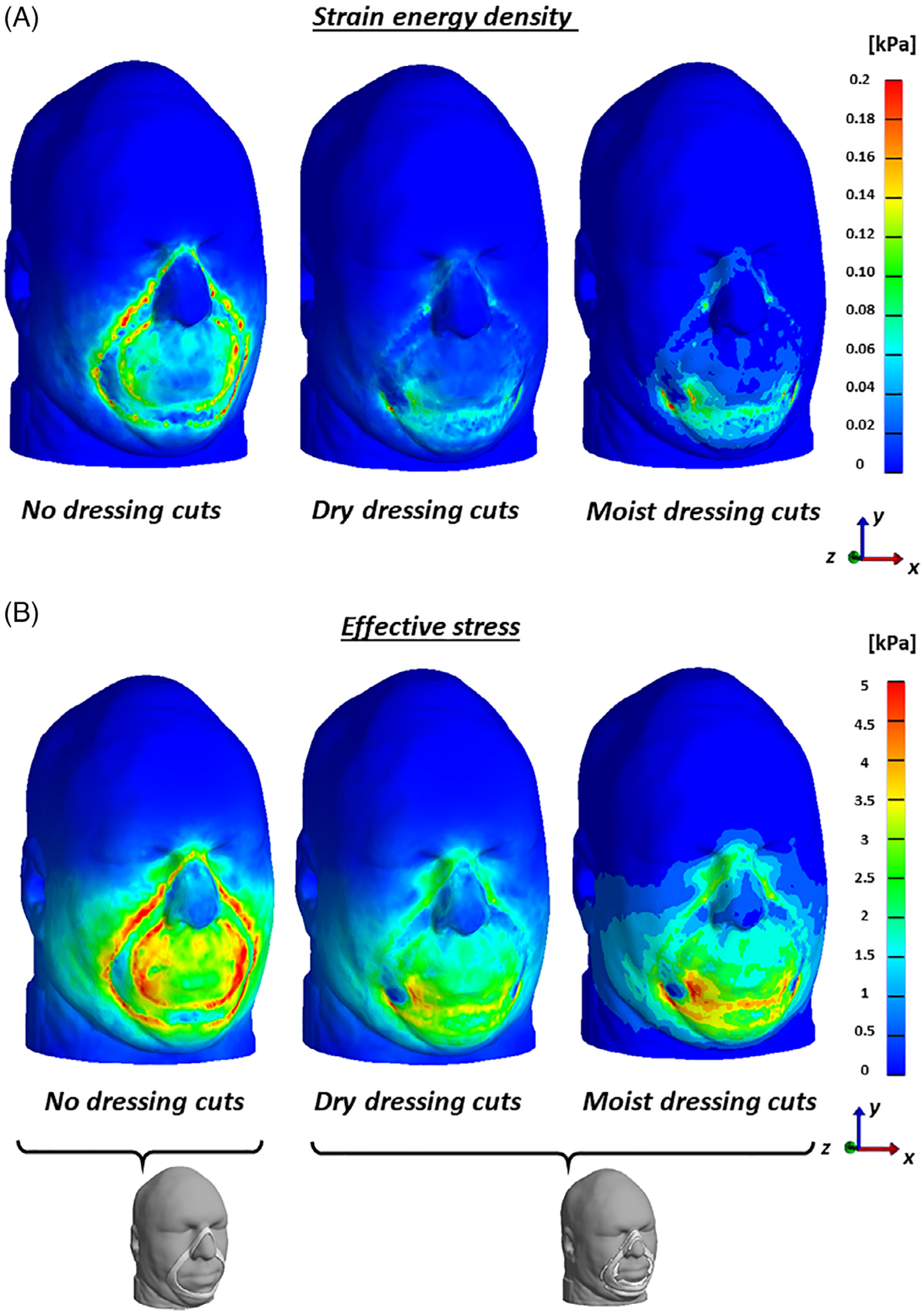

FIGURE 3 The distributions of facial tissue loads determined by means of the computational finite element modelling: A, Strain energy density (SED) and B, effective stresses in skin. Both the SED and effective stress data exhibit greater values for the “no dressing” case with respect to the ‘dressing’ cases, either in dry or moist conditions

the chin were approximately 1.7-fold greater than the forces that formed at the nasal bridge and the cheeks. The application of the hydrogel-based dressing cuts consistently lowered the contact forces at all the facial anatomical sites under investigation, to an extent of 27% to 28%, with a statistically significant difference ($P < 0.05$) at the chin and a marginal difference not meeting the significance level ($P < 0.1$) at the nasal bridge.

The distributions of SEDs and effective stresses on facial skin are shown in Figure 3, for the no-dressing, dry (new) dressing, and used (moist) dressing cut cases. The no-dressing model variant clearly demonstrated elevated SEDs and effective stresses along the contours of the CPAP mask (Figure 3; left column), which considerably dissipated when the hydrogel-based dressing cuts have been applied, with the new/dry dressings performing slightly better than the used/moist ones in alleviating the SEDs and stresses (Figure 3; centre and right columns, respectively). The protective effect of the hydrogel-based dressing cuts was the strongest on the cheeks and the nasal bridge, both at the skin (Figures 3,4) and subdermally (Figure 5).

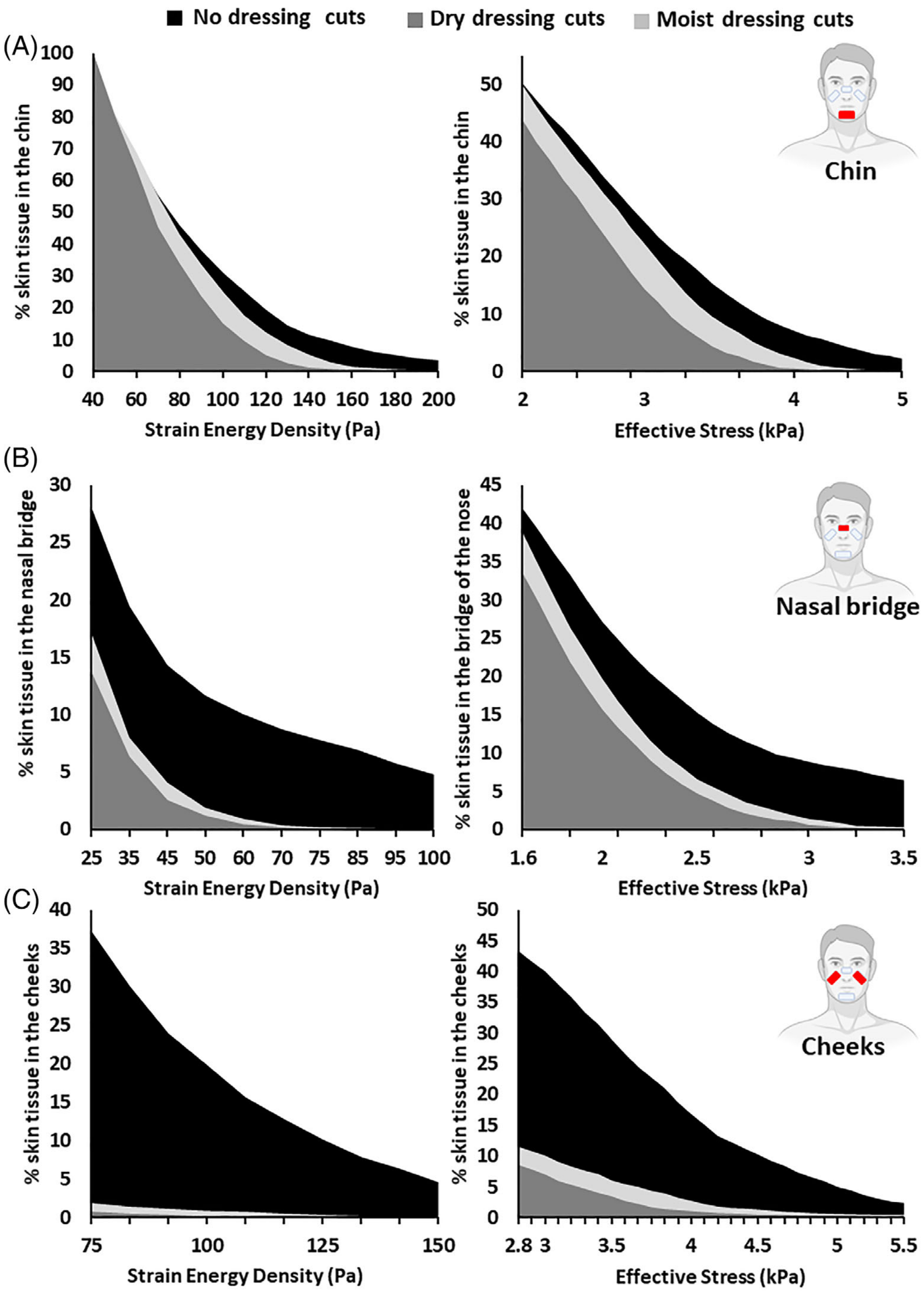

FIGURE 4 Model calculations of the exposure of facial skin (only) to strain energy density and effective stresses in the A, chin, B, nasal bridge, and C, cheeks, with vs without the protection of hydrogel-based dressing cuts in their dry and moist conditions

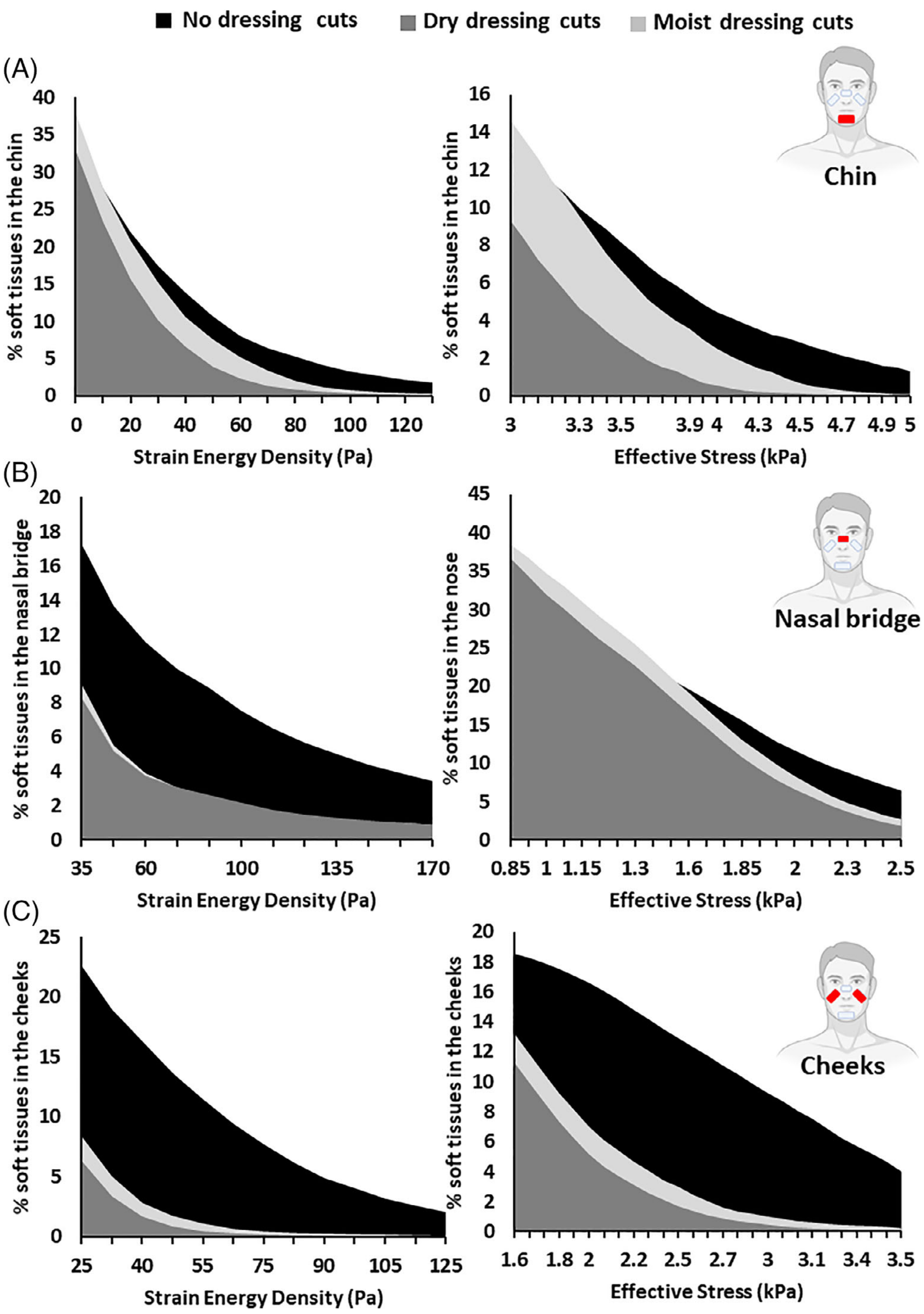

FIGURE 5 Model calculations of the exposure of facial skin and subcutaneous fat ("pooled soft tissues") to strain energy density and effective stresses in the A, chin, B, nasal bridge, and C, cheeks, with vs without the protection of hydrogel-based dressing cuts in their dry and moist conditions

For facial skin, the PEI of the hydrogel-based dressing was the greatest at the cheeks, followed by the nasal bridge, regardless of the (dry/moist) state of the dressing cuts (Table 1). For the entire facial soft tissue depth (the "pooled soft tissues"), the PEI of the hydrogel-based dressing still maximised at the cheeks; however, the PEI data calculated using SEDs vs effective stresses were inconclusive with regards to whether the dressing cuts protect more at the nasal bridge or at the chin (Table 1). Regardless, the PEI data demonstrated that the dry (straight from the package) hydrogel-based dressing cuts always reduced the exposure to sustained loads in facial soft tissues (above the median loading level) under the CPAP mask, by at least 30% (at the nasal bridge) and up to 99% (at the cheeks), irrespectively of the selected scalar loading measure (ie, SEDs or effective stresses), or the depth of the facial tissue (skin or subdermally). Consistent with the above, the maximum PEN values were obtained for the cheeks and the nasal bridge, where the hydrogel-based dressing cuts were able to maintain at

TABLE 1 The protective efficacy index (PEI), protective endurance (PEN), and prophylactic trade-off design parameter (PTODP) for the hydrogel-based dressing cuts at their dry and moist states. The aforementioned three parameters were calculated by means of the computational finite element modelling framework, separately for the strain energy density (SED) and the effective stress outcome measures

		PEI [%]			
Skin		**Dry**	**Moist**	**PEN [%]**	**PTODP [%]**
Chin	SED	73.4	47.5	64.7	3486.5
	Effective stress	42.9	21.2	49.4	909.5
Nasal bridge	SED	86.7	81.7	94.2	7083.4
	Effective stress	61.0	50.4	82.6	3074.4
Cheeks	SED	98.7	95.5	96.7	9425.9
	Effective stress	97.1	92.1	94.9	8942.9
		PEI [%]			
Pooled soft tissues		**Dry**	**Moist**	**PEN [%]**	**PTODP [%]**
Chin	SED	46.3	24.5	52.9	1134.4
	Effective stress	67.1	28.1	41.9	1885.5
Nasal bridge	SED	72.6	72.5	99.9	5263.5
	Effective stress	29.8	19.3	64.8	575.1
Cheeks	SED	91.3	85.4	93.5	7797.0
	Effective stress	79.9	71.4	89.4	5704.9

least 89% and 65% of their protective capacity under moisture conditions at the cheeks and nasal bridge locations, respectively, and again regardless of the loading measure and tissue depth (Table 1). The highest PTODP values were obtained for the cheeks, which indicates that the hydrogel-based dressings maximised their capacity to remain effective at these facial sites from a dry to a moist time course and usage cycle (Table 1). Overall, the hydrogel-based dressings exhibited considerable biomechanical protective efficacy at all the tested facial sites and at either the dry (new) or moist (used) dressing states, but performed the best at the cheeks and the nasal bridge locations.

4 | DISCUSSION

The mass of published work for prophylactic efficacy against MDRPUs is for foam dressings,[18] hence we aimed here to use a modelling and biomechanical analysis method that we had already established and reported in the literature[2] for evaluating the potential biomechanical efficacy of a non-foam, specifically, a hydrogel-based dressing, in protecting from facial MDRPUs associated with the use of a CPAP mask. The importance of the current work is, therefore, in the expansion of the prophylactic dressing concept beyond foam-based dressings and testing of this concept using an already established methodology,[2] which is novel in the aspect of thinking beyond the "foam paradigm" when considering suitable (or candidate new) materials for the prophylaxis of MDRPUs.

Non-invasive ventilation by means of CPAP therapy is indicated in patients with acute and chronic respiratory failure. Facial tissue injuries caused by CPAP masks already a few hours after application of the mask affect between one-tenth and one-third of the CPAP users and are associated with the sustained tissue deformations caused by tightening of the mask to the head and the extreme microclimate conditions, exposing the skin under the mask to a near-100% humidity.[16,17,19,27-30] Cushioning elements in CPAP masks are typically included for comfort, as an integral part of the mask or as disposables. These are usually made out of silicone for comfort, but the silicone may cause skin sensitivity for some patients, particularly those with a silicone allergy; another common problem with silicone cushioning is that it may wear out from consistent use or change its mechanical properties over time. There are also cushioning elements made of gels, foams, or memory foams; however, the stiffness-matching (or modulus-matching) between all these cushion element types and human facial skin (eg, expressed as the ratio of the long-term elastic modulus of the cushioning element to the long-term elastic modulus of the skin), is not reported by manufacturers and is not transparent to purchasing decision-makers or to the clinicians who prescribe CPAP masks to their patients.

In the present study, we used a custom-made, multiple-force-sensor measurement system to determine the compressive forces applied by a CPAP mask upon facial skin at the nasal bridge, cheeks, and chin and the reduction in these force values because of the application of hydrogel-based dressing cuts (Figure 1A). Furthermore, we developed three comparable anatomically-realistic FE model variants of an adult head wearing the CPAP mask without the protective dressings vs with the dressing cuts applied at the aforementioned facial sites in their dry (new) and moist (used) conditions (Figure 1B). These three computer model variants facilitated quantitative and methodological analyses of facial tissue exposure to the sustained loading induced by the CPAP mask, either at the skin surface or while considering the subdermal influence, where tissues were protected by the dressing cuts vs being left unprotected.

We found that the application of the hydrogel-based dressing cuts was effective in consistently reducing the magnitudes of the facial skin contact forces while wearing the CPAP mask, by a quarter to a third of the baseline force levels, which is substantial (Figure 2). Noteworthy, the compressive forces measured between the CPAP mask and the facial skin were statistically significantly alleviated because of the application of the hydrogel-based dressing cuts at the chin, but there was no statistical significance for the nasal bridge or cheek locations (Figure 2), which is consistent with our earlier published work.[2] This may be associated with the foam cushioning elements embedded in the design of the CPAP mask, which are likely able to relieve some of the mask-skin contact pressures in addition to the contributions of the hydrogel-based dressing cuts. Nevertheless, the 27% to 28% lower force levels at the nasal bridge and cheeks that were achieved with the use of the dressing cuts, despite not being statistically significant per se (Figure 2), are associated with substantially more considerable reductions in the internal, localised tissue strain/stress levels at these facial sites (Figures 3-5 and Table 1), which could be expected given the amplifying effect that the rigidity and curvatures of the nasal and zygomatic bone surfaces have on the internal tissue stress concentrations. The FE modelling further showed that the protective effect of the hydrogel-based dressing cuts was most dominant on the cheeks and the nasal bridge, on the skin surface, and at the depth of the facial tissues (Figures 3-5). As could be expected, the dressing cuts provided their best protective effect when being new (straight from the package), in which case the hydrogel-based dressings had the optimal stiffness-matching (modulus-matching) with skin at all the anatomical facial sites that have been investigated here.[23]

The facial locations that are at the greatest risk for CPAP-related injuries are the nasal bridge and cheeks[16]–[18] Peña Otero and colleagues comparatively assessed the efficacy of several therapeutic strategies (namely, application of a solution of hyper-oxygenated fatty acids, adhesive thin dressings, and adhesive foam dressings) to prevent the development of CPAP-related facial injuries in critically-ill hospitalised patients.[17] They found that approximately 49% of their total patient population (N = 152) developed such CPAP-related facial injuries, with the nasal bridge being the anatomical site that was most frequently affected, followed by the cheeks, whereas only a single patient in their study group (1/152) developed a chin injury. This can be explained by anatomical factors including a lower soft tissue mass over the nasal and cheek bony prominences, as well as lower perfusion at these sites with respect to the chin.[2,16] Hence, despite that the chin may be subjected to greater compressive forces by the CPAP mask (Figure 2), it is less susceptible to a CPAP-related injury with respect to the nasal bridge or the cheeks, very likely because the skull is flatter at the chin and the soft tissues are typically thicker and more vascularised there.[2] Accordingly, the nasal bridge and the cheeks are the less tolerable sites to sustained cell and tissue deformations and require the highest level of protection during non-invasive ventilation. The hydrogel-based dressings that were investigated here provided the best protection at the nasal bridge and cheeks, both at the skin surface and into the facial tissue depth, which is consistent with the above-described epidemiology, pathophysiology, and the biomechanics of CPAP-related facial injuries. The biomechanical efficacy of the hydrogel-based dressings in achieving facial protection should be attributed to its stiffness-matching (modulus-matching) with skin,[23,31] as well as to its conformability to fit the curved facial contours at the at-risk (nasal bridge and cheek) sites.

As with any modelling work, several limitations and assumptions must be acknowledged. First, we did not ventilate our subjects while acquiring the contact force measurements, because of ethical reasons; however, the air pressure in a CPAP mask must not compromise the sealing (ie, it is not expected that the mask would detach from the face during actual ventilation) and hence a potential influence of an active ventilation on the measured force levels is expected to be negligible. While the subjects in this work were not ventilated, we carefully followed the protocol and conclusions of Worsley and colleagues.[20] They found a statistically significant increase in subject-reported discomfort from an “optimal strap tension” state (that they had defined as tensioning the straps to not more than a level at which two stacked fingers could be slid between the straps and the skin, and which was the technique of the current study), to higher strap tension levels. Accordingly, and for ethical reasons, this protocol by Worsley et al[20] was used to minimise any potential discomfort to our subjects. Nevertheless, it should be considered that with the onset of even a microscale tissue injury leading to inflammation, inflammatory oedema may develop, and swell and stiffen the tissues locally, which would increase the intensity of the contact forces and the internal tissue stresses,[2,32] and potentially, the discomfort experienced by the CPAP user. In relation to the above point, all the FE calculations of the tissue strain/stress states (as detailed in Figures 3-5 and Table 1) were made under the assumption that the CPAP mask had been adequately fitted onto the face, ie, the computational simulations did not account for the fitting or alignment phase, during which the mask may move over the facial skin as a result of the clinician's attempts to achieve the best fit. Second, the results of the present study were obtained in a natural head position, which is the standardised and reproducible position of the head in an upright posture. In other body positions that may be required for clinical purposes where the head is not upright, gravity may potentially affect the mask-skin contact forces, implying that the current results cannot be directly generalised to all body positions; other positions should therefore be considered in future investigations. Third, with regards to the anatomical and biomechanical features of the head that were studied, we did not consider fragile skin conditions (as would be expected, for example, in geriatric patients, or in those who suffered a previous facial skin breakdown), or the presence of scars or other skin lesions that may compromise the mechanical tolerance or influence the stiffness properties of the skin. Likewise, we did not consider maxillofacial pathologies that may affect the loading state of facial tissues during CPAP ventilation. Lastly, in this regard, our work has focused on adults and cannot be extrapolated to paediatric patients, because the head structure of infants and toddlers differs from that of adults in proportions, tissue composition, and mechanical properties,[33] and thus a study relevant to paediatric settings should be conducted separately.

As for generalisability of the current findings to the adult male population, the male cadaver used by the National Library of Medicine (NLM) to create the "Visible Human" male database, of which the head part of the body was used here, is of a 38-year-old person.[34] The bodyweight of the donor at the time of death was 90 kg (199 lb) and his height was 180 cm (71 in.), yielding a body mass index (BMI) of 27.8, which is mildly overweight.[34] While this NLM donor was approximately 10 years older than our subjects, his body characteristics are reasonably close to those of our study participants, who were, likewise, not obese or underweight (as per the World Health Organisation criteria). The facial tissues of the NLM subject may be slightly swollen because of the freezing process that the cadaver underwent,[34] which may be a potential limitation, but currently there is no feasible substitute for this detailed anatomical scan of the human head, which was also used in many of our published research works,[2,21,35-37] and hence had been thoroughly characterised from a biomechanical and tissue mechanics perspectives.

To conclude, the present study had demonstrated that the hydrogel-based dressings tested here are advantageous for the prevention of MDRPUs from a bioengineering standpoint, as they were able to reduce the compressive forces applied by the CPAP mask by a quarter to a third with respect to the no-dressing condition (Figure 2). Moreover, the dry (new) hydrogel-based dressing cuts reduced the localised CPAP-induced exposure to sustained facial tissue loads (above the median loading level) by at least 30% at the nasal bridge and by up to 99% at the cheeks, irrespectively of the method of biomechanical calculation or the tissue depth (Table 1). In terms of endurance, the hydrogel-based dressing cuts were able to maintain at least 65% and 89% of their protective capacity under moisture conditions at the nasal bridge and cheek locations, respectively, again, regardless of the calculation method or tissue depth (Table 1). For the latter facial location, the hydrogel-based dressings maximised their effectiveness throughout a simulated dry-to-moist usage cycle (Table 1). Overall, the hydrogel-based dressings demonstrated protective efficacy at all the tested facial sites and at either the dry (new) or moist (used) dressing states but performed the best at the nasal bridge and cheek locations, which are at the greatest injury risk. Accordingly, we conclude that from a biomechanical perspective, the presently investigated hydrogel-based dressings are appropriate for prophylactic use to prevent MDRPUs under CPAP masks; clinical trials should now be conducted to confirm the current findings in different relevant care settings.

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ENDNOTE

* The minimum dataset of the PEI, PEN and PTODP parameters that characterises the protective biomechanical performances of prophylactic devices was proposed in our previously published work, e.g., in,[25,26] but still requires wider adoption by the industry and implementation by regulatory bodies, which may be achieved in the course of the work of the Prophylactic Dressing Standards Initiative (PDSI, npiap.com/page/PDSI) – a global venture steered by the EPUAP and the NPIAP which the senior author AG is currently leading with an international team of experts.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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