Using quality by design to optimize hydrogel semi-solid sheet masks for enhanced skin barrier: *in vitro* and *in vivo* studies

Poster ID 404

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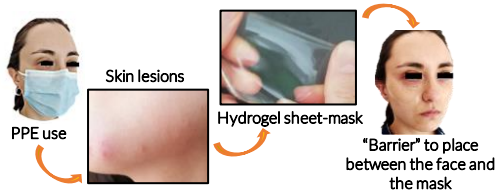
Introduction:

The coronavirus SARS-CoV-2 which is responsible for the COVID-19 pandemic has led to the general use of personal protective equipment (PPE) [1]. The prolonged and continuous use of PPEs exerts sustained pressure, tension forces, friction, and increases the local humidity and temperature, which may originate skin lesions [2]. A possible way to prevent such lesions is to incorporate a "barrier" between the skin and the PPE. This work aimed to develop and test the efficacy of a low-cost and easy to produce **hydrogel sheet-mask** to be placed between the PPE mask and the facial area where pressure is more concentrated. This polymeric film-forming system might increase Health Care Professionals skin health and personal wellbeing without compromising the protective function of PPEs.



Materials & Methods:

The polymeric film-forming system is a gelatin-based hydrogel, containing **biodegradable and eco-friendly ingredients**, **namely polyvinyl alcohol, silica, betaine and glycerin to enhance physical properties** of the hydrogel sheet-mask

1st Step – DOE and Risk Assessment

- ✓ Quality Target Product Profile (QTPP) Critical Quality Attributes (CQA) definition
- ✓ Formula optimization using MODDE® Software: Two-level Fractional Factorial Design Resolution V+

2nd Step – *In vitro* Characterization

- ✓ Gelation Temperature
- ✓ Elasticity
- ✓ Adhesiveness
- ✓ Tribology – Lubricant Properties

Malvern Kinexus Lab+ Rheometer (Malvern Instruments, Malvern, UK)

Geometries Used:
- Plate–plate geometry
- Three-ball-on-plate tribometer geometry

3rd Step – *In vivo* Studies

Biometric Parameters evaluated:

- ✓ Skin surface hydration – Corneometer® (Courage & Khazaka+, Germany)
- ✓ Facial temperature Measurement– FLIR® (FLIR Systems, Danderyd, Sweden)

Conclusions:

The resilient physical properties of the developed hydrogel sheet-mask and the attenuation of the physiological alterations in the facial area during its use are good indicators that this polymeric film-forming system can prevent skin lesions caused by the prolonged and continuous use of PPE.

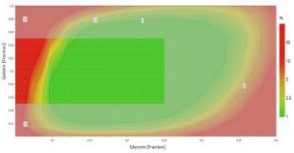
References:

[1] Zhang B, Zhai R, Ma L.. J Eur Acad Dermatology Venereol. 2020;34(9):e434–5.

[2] Graça A, Martins AM, Ribeiro HM, Marto JM.. J Dermatol. 2022;(April):1–13.

Results & Discussion:

DOE and Risk Assessment



Formula composition **optimized using DoE** and QbD tools

Figure 1. Plot evidence the Design Space for hydrogel sheet-mask.

In vitro Characterization

Table 2 - Compression test and respective values of elasticity and adhesiveness measurements (mean±SD, n=3).

	Elasticity (mm)	Adhesiveness (N)
Hydrogel Sheet-Mask	0.81 ± 0.08	0.24 ± 0.03
Gelatin Film	0.54 ± 0.06	0.11 ± 0.03

Hydrogel sheet-mask presents **a higher and complete elastic recovery** and **more adhesiveness** than a film with gelatin alone

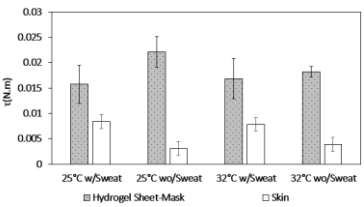


Figure 2. Friction of hydrogel sheet-mask and pig skin (mean±SD, n=3).

Friction values of the hydrogel sheet-mask comparable to skin were higher important to function as protective stiff layer, distributing stresses over an extended area and avoid misplacement of the mask

In vivo Studies

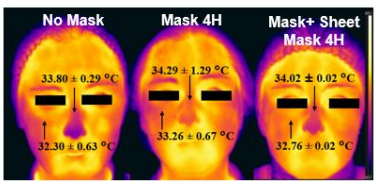


Figure 3. Infrared images of facial skin temperature distributions associated with the use of a FFP2.

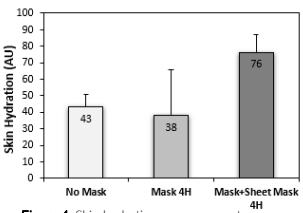


Figure 4. Skin hydration measurements.

Results show a **decrease of the facial temperature** and an **increase of skin hydration values**, indicating an **attenuation of the measured physiological alterations and skin hydration promotion** in the facial area from the hydrogel sheet-mask use.

Acknowledgements:

Funded by the Fundação para a Ciência e Tecnologia, Portugal (UIDB/04138/2020 and UIDP/04138/2020 to iMed.ULisboa, CEECINST/00145/2018 to J.Marto and fellowship 2020.10138.BD to A. Graça).