

Dec 2nd, 9:00 AM - Dec 5th, 5:00 PM

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### Citation

Chakraborty, S., Loyens, D., Aston, J., Jain, H., Ornelas, M.D., and de Gouveia, R.H. (2025) Insights on designing a novel 99% biodegradable FFP2 BioMask through interdisciplinary applied research., in Chang, C.-Y., and Hsu, Y. (eds.), *IASDR 2025: Design Next*, 02-05 December, Taiwan. <https://doi.org/10.21606/iasdr.2025.748>

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# Insights on designing a novel 99% biodegradable FFP2 BioMask through interdisciplinary applied research.

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**Objective:** This research developed an environmentally sustainable alternative, called BioMask, to non-biodegradable polypropylene FFP2 masks, addressing the dual challenge of medical waste reduction and public health protection through interdisciplinary collaboration.

**Approach:** The study employed Research through Design (RtD) methodology integrating expertise from design, nanomaterial science, fibre engineering, and medicine within a 15-month applied research project. RtD facilitated concurrent product-process development by using iterative prototyping as a common language across disciplines, enabling real-time problem-solving rather than traditional sequential development. The interdisciplinary consortium developed a novel sandwich material consisting of an electrospun cellulose acetate nanofibre filtration layer combined with viscose and banana fabric substrates, utilising design thinking to bridge technical knowhow across the disciplines mentioned.

**Results:** The BioMask achieved key performance metrics that surpass conventional alternatives: 1. Filtration efficiency: 98.3% for 0.3-micron particles (vs. 65-94% for standard FFP2 masks) 2. Biodegradability: 100% decomposition in 83 days (vs. 0% for polypropylene masks) 3. Material composition: 99% biodegradable components 4. Technology readiness: Achieved Technology Readiness Level 4 (TRL) validated with a provisional Portuguese patent protection.

**Interdisciplinarity:** The collaborative approach revealed disciplinary synergies: nanomaterial scientists provided the core filtration technology, designers identified user-centred concerns and optimised



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morphology, fibre engineers ensured manufacturing feasibility, and medical professionals validated clinical applicability.

**Insights:** This interdisciplinary process model provides transferable insights and a replicable structure for addressing complex sustainability challenges in medical product development. The approach demonstrates design thinking serving as a bridge between disciplines, translating laboratory innovations into commercially viable, environmentally responsible solutions.

**Broader impact:** The output demonstrated a proof-of-concept utilizing nano material manufacturing with electrospinning and machine stitching the BioMask sandwich material achieving 25 functional prototypes, integrating banana fabric, cellulose acetate, and viscose. Future commercialization depends on scaling up manufacturing and achieving EN149 / FFP2 certification.

**Keywords:** *Sustainability; Biodegradable; Medical product design; Interdisciplinary research.*

## 1 The theoretical foundation

### 1.1 Disciplinarity, Interdisciplinarity and New Product Development

This research paper illustrates how translating a nanomaterial innovation into a medical product, through the formation of a startup, unfolds in the context of university-funded research projects. The subject of this article is the design and development of BioMask, executed over 15 months between 2022 and 2023.

BioMask is a 99% biodegradable banana fibre based medical grade FFP2 (filtering facepiece) mask, 98.3% efficient in capturing 0.3-micron particles, which has been recognised as a novel product, a claim justified by analysis of existing literature, patent search, and the award of a provisional patent protection by the Portuguese National Institute of Industrial Property (INPI) in June 2023.

The background against which this research is presented is interdisciplinarity and the associated complexities and opportunities that such collaborative product design and development presents.

In this paper, special attention will be given to how design makes an additional contribution by bridging critical thinking with creative thinking (Norman, 2022, in Muratovski) to overcome roadblocks in a project path within an interdisciplinary applied research project.

In the context of this research project, from the outset, the deployment of all the core disciplinary experts necessary to build a product of this nature was ensured, namely fibre engineering, nanomaterial science, design, medicine, project management, manufacturing, and finance. A culture and mentality of design from manufacturing (DfM), concurrent engineering, and getting it right the first time (Anderson, 2020) was embedded from the moment of grant approval, due to the realities of minimal budget allocation and a non-extendible project delivery timeline.

Existing literature (Anderson, 2020) presents the argument that when developing novel products, using existing processes conditions the product design to the existing limitations of manufacturing technologies. Therefore, under such scenarios, the product and the process must be developed and evolved concurrently, deploying “multi-functional” teams early into the project lifecycle to collectively imagine and confront predicted risks (advanced team participation model) associated with creating a novel product in a timely fashion (Anderson, 2020). Delaying the onset of participation (traditional team participation model) of all necessary disciplines lengthens the problem-solving time and inflates cost. On the contrary, anticipating the deployment of disciplines as

soon as possible promotes early and timely prediction of problems which may emerge on any project from the concept design to “official product release” (Anderson, 2020).

The project BioMask process model elaborated here presents an insight into how new product development (NPD) occurring in a university research scenario cannot frontload deployment of all human resources due to funding rules and therefore crosses boundaries between advanced and traditional team participation models.

## **1.2 Research through Design (RtD)**

Muratovski (2022) highlights the tendency to separate thinking (research) and making (design) activities within the current design profession, and the weakness that exposes contemporary design practitioners in the era of Industry 4.0, which ostensibly necessitates creative experts to be well-informed in both these specialist areas. While design academics operating in the university environment are often focused on thinking, this paper presents the inseparable link the two share through the illustrative example of an executed applied research project as a case study of Research through Design (RtD), where scientists from academia collaborate with commercial professionals and also participate robustly in the making. The actions of design and research are interlinked, where the relationship between building and thinking can be inverted in terms of priority depending on the activity being undertaken (Koskinen et al., 2011).

RtD is a type of scientific inquiry that leverages insights gained through design practice or product design activity to understand a complex issue or answer a research question (RQ) (Godin and Zahedi, 2014). RtD is entirely concerned with the end product being designed and doesn't stop at answering the RQ. Designers who operate in RtD act at the intersection of new materials experimentation, new products, and process model experimentation (Godin and Zahedi, 2014). RtD is also discussed as project-grounded research, practice-led research, and constructive design research (Koskinen et al, 2011).

The applied nature of the approach used by the authors to investigate the BioMask project emphasised the value of building and constructing as a means of demonstrating whether basic nanomaterial science research developed in a lab setting can be successfully applied in a real-world scenario. The posture of the design research undertaken in this project was therefore constructive and practice-led, with the building and thinking occurring in synergy and concurrently, while being set within the broader context of interdisciplinary collaborative science.

## **1.3 Project background and context**

The BioMask project addresses the challenges of pollution from non-biodegradable medical products and public health emergencies resulting from the COVID-19 pandemic (WHO, 2020). The widespread use of single-use FFP2 masks increased medical waste and plastic pollution (Ashworth, 2022). The current generation of FFP2 masks, made from non-biodegradable polypropylene (PP), has a particularly negative environmental impact (Vandiver, 2022); therefore, there is an urgent need to develop an alternative, biodegradable material that can replace PP in FFP2 masks (Prata et al., 2022).

In addition to the environmental challenges, the current design of FFP2 masks also presents several user-related issues. Variations in face topology, Menton-sellion length, Bizygomatic breadth (IOS,

2015), and facial hair growth are obstacles to ensuring an airtight gap leakage seal protection and breathability. Minor changes can have a significant impact on fit and function (Ipaki et al., 2022).

The BioMask project addressed these complex problems by translating knowledge from nanomaterial science, fibre engineering, product design, and medicine into an economically viable production model, ultimately forming a startup entity - The BioMask Company (TBC).

## **2 Problem setting**

### **2.1 Project incubation**

The project originated from a serendipitous interaction between the design scientists and the nanomaterial scientists coordinating this research. While the material was developed and existed within a lab setting, the design scientists connected its applicability towards the FFP2 medical mask product category. Thus, in the very first step, one can draw some insights into the roles of nanomaterial scientists and designers. While the nanomaterial invention provided the core technology, and no project would exist without it, the designers identified the beneficial applications of this core technology for the greater good.

This is how the problem definition, which eventually evolved into an RQ, originated. The question rotating in the minds of nanomaterial scientists and designers at this stage was: Can cellulose acetate (CA) nanomaterials be coupled with banana fibre to form a stable filtering sandwich material suitable for FFP2 mask applications, capable of capturing the COVID-19 pathogen?

### **2.2 Consortium construction**

The commercial partner was identified to fulfil the role of investing in the startup entity, The BioMask Company (TBC), and the academic partners were identified according to the disciplinary expertise needed to build the science, nominally, the Department of Art and Design of the University of Madeira and the Regional Agency for Development of Investigation, Technology and Innovation (ARDITI). The specialised product design, materials science, and engineering expertise were identified through subcontracting with Anchiale Technologies and ESAD-IDEA, an academic research unit, which filled in the knowledge that the startup entity and its academic partners could not provide through their existing human resources.

On the industry side, the motivation was to receive Transfer of Technology (ToT) from local academic and research institutions for a competitive advantage in the European (EU) marketplace. On the academic side, the motivation was to train academics to evolve from disciplinary experts into interdisciplinary experts, able to operate agilely and further develop into transdisciplinary or convergence experts (NCSU, 2020).

The Project Manager (PM) was responsible for identifying the commercial elements of the consortium, while the Principal Investigator (PI) was responsible for identifying the scientific elements of the consortium.

### 3 Project Objectives

This activity fixed the mission statement of the project consortium.

#### 3.1 Lab research for a proof-of-concept product

The purpose of identifying the project objective is to establish the orientation for converting scientific knowledge into a tangible product, one that is measurable in terms of performance and quality.

In the case of BioMask, since no project would exist unless the material could be engineered and a commercial entity could manufacture it economically, the priority of defining the objectives was accorded to the nanomaterial scientists, the fibre engineers, and The BioMask Company promoter. The PI and PM filtered the discussion to make sure the identified objectives met the funding call requirements.

The project objectives centred around nanomaterial science, product design, and FFP2 mask production know-how.

*Sandwich Development:* The project created an environmentally sustainable, 100% biodegradable, four-layered sandwich material based on banana fabric as the outermost encapsulating layer, a cellulose acetate polymer nanomat 0.3-micron particle filtering layer deposited on a viscose substrate layer.

*Product Design:* Shape coding an optimised design for an FFP2 mask, achieving high user comfort and ease of donning and doffing. This was achieved by applying methods and tools, such as patents search, design criteria definition through project consortium group discussion, focus grouping, AHP - Analytical Hierarchy Process, design workshop, TOPSIS (Multi-criteria ranking and decision making model), anthropometric fit testing, stitch testing simulations, analogue prototyping, material volume optimisation, digital 3D modelling and 3D printing.

*Transfer of Technology (ToT):* The building of a medical products startup -The BioMask Company, Lda, and equipping it with the production knowhow needed for electrospinning, nanomaterial science, and sandwich material construction to produce FFP2 masks locally in the Autonomous Region of Madeira (RAM) thus bringing the nanomaterial and medical products sector to a peripheral European Union geography.

### 4 Project Constraints

This activity adjusted the degrees of freedom concerning the project mission.

#### 4.1 Defining the Constraints

The BioMask project was executed against the backdrop of three constraints: 1) funding call requirements (ToT through academic-industrial partnership); 2) budgetary limitations; 3) timeline defined through a hard, non-extendable deadline.

Understanding the constraints present in a research project from the outset is fundamental to crafting a well-structured activity task timeline and a human resources deployment map. Designer researchers, due to their inherent lack of dominance in financial, project management, materials

science, and technology domains, cannot, therefore, be the leaders when the task of identifying and enforcing constraints arises in an NPD research project of this nature.

Defining constraints was carried out by the PM, who was a strategic advisor often lacking scientific expertise, with core disciplinary experts from nanomaterials, fibre engineering, medicine, and design providing support roles.

## 5 Material Development

The material development was a specialist activity done only by nanomaterial scientists and fibre engineers in a lab setting. The output was a filtration nanomaterial formulation of cellulose acetate, combined with viscose and banana fibre layers, to achieve a stable sandwich structure. Success in this phase was crucial to the entire project. This phase was very disciplinary and marginally multidisciplinary, with no scope for interdisciplinarity to occur.

### 5.1 Nanofibre Science

Fibres made from biopolymers have the ability to act as an effective filter medium in face masks and FFP2 respirators. Nanofibre-based filtration media are the current trend in high-efficiency filtration, with several nanofibrous mats showing excellent filtration performance at low pressure drops.

The electrospinning process can be used to produce nanofiber-based filter media with diameters ranging from 50 to 500 nm (Figure 1). A large nanofibre web has a large surface area, which facilitates rapid adsorption of dust particles, microorganisms and hazardous molecules present in the atmosphere. Apart from a high specific surface area, small pore size and high porosity also contribute to the enhanced filtration performance and adsorption capabilities. Generally, the thickness of a nanofibre web is lower than 1  $\mu\text{m}$ . This low thickness of the web is responsible for high airflow permeability. However, it also leads to low mechanical strength. Thus, a porous substrate is required to support the nanofibre web. The low thickness of the nanofibre web and ultra-small diameter of the nanofibres provide materials with extremely high filtration efficiency, accompanied by a minimal increase in pressure drop.



Figure 1: Electrospinning and cellulose acetate manufacturing lab unit.

For developing an efficient filter media, three major parameters need to be closely monitored and controlled: 1) filtration efficiency, 2) pressure drop 3) filter life. While developing filters, it is generally observed that when an increment is made in one parameter, the other parameters are adversely affected. However, nanofibres have shown significant filtration efficiency and filter lifetimes with a minimal increase in pressure drop. Cellulose is a low-cost, eco-friendly and renewable material, thereby pushing its case for use in air filters. However, it has been reported that nanofibres made from cellulose have low particle capture and removal efficiency. This is primarily due to the lack of active functional or chemical groups in its structure. Thus, there was a need to identify potential cellulose derivatives for application in filter media. Amongst the cellulose derivatives, cellulose acetate (CA) has been deployed in gas separation applications for a long time. CA's ester functionality throughout the polymer chains and thermoplastic nature make it an ideal material for processing into functional fibres and films.

CA-based nanofibres have proven filtration efficiency, liquid permeability, high hydrophilicity, high water absorption capacity and biodegradability. Additionally, it has good water stability and high solubility in organic solvents. It exhibits significantly high filtration selectivity for low-level organic compounds. They are known for their high tensile strength, modulus and flexibility. The best part about CA nanofibres is their tunability. Its properties can be engineered to capture selective contaminants through chemical group functionalizations. Their biocompatibility, non-toxicity, and biodegradability make them promising candidates for use in the development of filter media for FFP2 respirators.

## **5.2 Sandwich Structure Development**

The first step in developing the BioMask sandwich structure was the creation of electrospun CA nanofibres, which would serve as the primary filter medium. For the preparation of these nanofibres, the CA polymer solution was pushed through a needle to commence the electrospinning process. The electrospun nanofibres were collected on a spun lace nonwoven viscose support fabric mounted on an aluminium collector plate. The nanofibre deposition time, temperature, and relative humidity were 2 hours, 25°C, and 65%, respectively. The prepared CA nanofibre mat was sandwiched between two surface-treated woven banana fabrics. This completed the development of the BioMask sandwich structure.

## **5.3 Filtration performance, washability and biodegradability**

Filtration efficiency and pressure drop were evaluated for BioMask and other commercially available FFP2/N95 respirators to gauge the relative filtration performance of BioMask. BioMask had the highest  $PM_{0.3}$  filtration efficiency of 97.85 %, compared with other commercially available FFP2/N95 respirators [65.48 % for Aroza N95, 65.60 % for JO-300, 94.34 % for 3M 8210 and 89.03 % for Venus V4400]. The pressure drop value for BioMask was found to be 76.89 Pa, which was comparable to the pressure drop values of other commercially available FFP2/N95 respirators [67.54 Pa for Aroza N95, 64.59 Pa for JO-300, 66.73 Pa for 3M 8210 and 103.21 Pa for Venus V4400]. Traditionally, higher filtration efficiencies are associated with higher pressure drop values. However, in the case of BioMask, a high  $PM_{0.3}$  filtration efficiency of 97.85 % didn't correspond to a significantly high-pressure drop value [due to the slip flow effect of air in BioMask CA nanofibre mat]. This implied the relatively higher filtration performance of the BioMask [high filtration efficiency and low-pressure drop] compared to the other commercially available N95/FFP2 respirators (Refer to Figures 1 and 2).

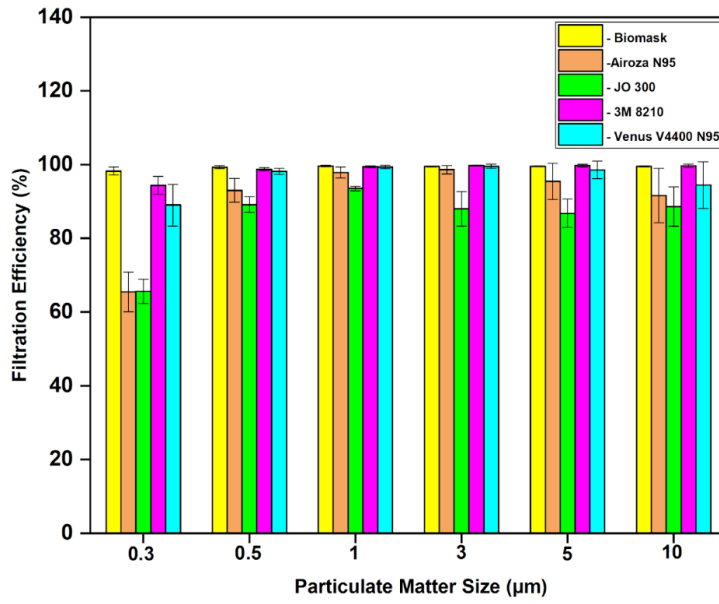


Figure 2: Filtration efficiency comparison of BioMask and other commercially available FFP2 / N95 medical facepiece masks

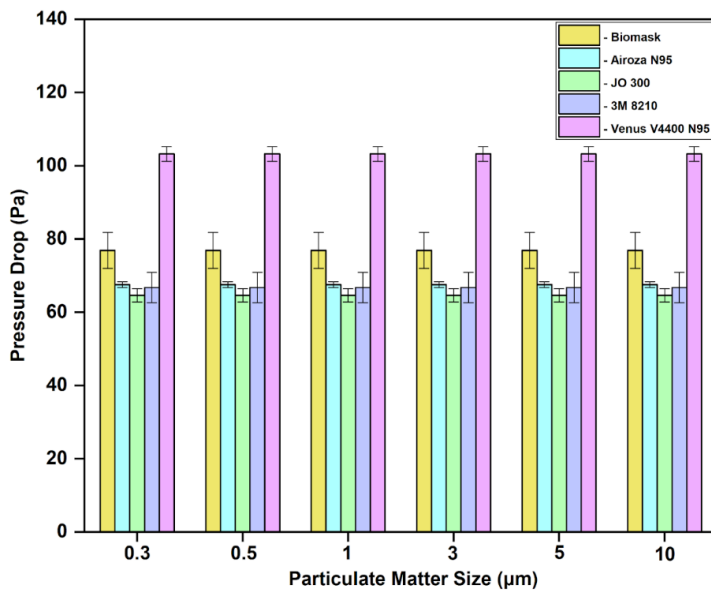


Figure 3: Pressure drop comparison of BioMask and other commercially available FFP2 / N95 medical facepiece masks

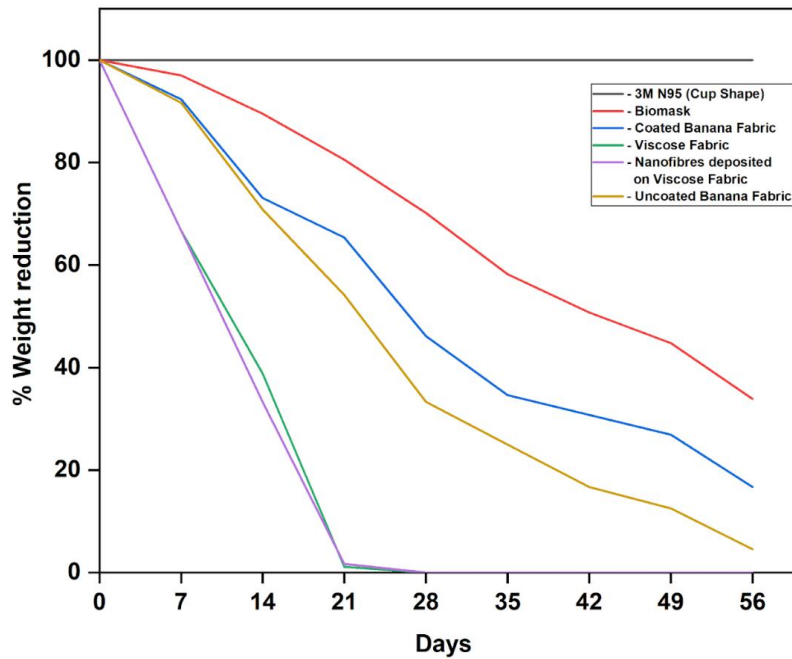


Figure 4: Quantitative Biodegradability observations of (i) 3M N95 mask, (ii) BioMask, (iii) Gum rosin coated banana woven fabric, (iv) Uncoated banana woven fabric, (v) CA Nanofibres deposited on Spunlace Nonwoven Viscose Fabric, (vi) Spunlace Nonwoven Viscose Fabric

Referring to Figure 4, no weight reduction was observed for the 3M N95 mask, indicating 0% biodegradation, after 56 days of study. When followed over the same period, a 66.15% weight reduction was observed for BioMask, suggesting a 66.15% degradation. This was mainly due to the presence of biodegradable materials in the BioMask [banana fabric, cellulose acetate nanofibres and viscose spunlace non-woven fabric]. 83.33 % and 95.45 % biodegradability [weight reduction] was observed for gum rosin coated banana woven fabric and uncoated banana woven fabric when studied for 56 days. CA Nanofibres deposited on spunlace nonwoven viscose fabric showed 100 % weight reduction in 28 days. The above observations indicate the nature and rate of biodegradation of individual constituents of the BioMask. Thus, the BioMask sandwich structure, without the metal nose clip and fabric glue in the final assembly, is a 100 % biodegradable FFP2 mask. Based on the extrapolation of the above trend, the 100% biodegradation of the BioMask can be achieved in 83 days (approximately 11 weeks).

The table 1 below summarises all the data above in a ready reckoner format.

Table 1. Summary of BioMask performance criteria for 0.3-micron target particle size

FFP2 face mask	Filtration efficiency for PM 0.3 (%)	Pressure drop (Pa)	Biodegradation time (days)
Airoza N95	65.48	67.54	Not biodegradable
JO 300	65.60	64.59	Not biodegradable
Venus V4400 N95	89.03	103.21	Not biodegradable
3M 8210	94.34	66.73	Not biodegradable
BioMask	97.85	76.89	83

## 6 Product Design

The design experts led the product design activity, with regular interaction from fibre engineering and nanomaterial science experts to overcome any doubts and roadblocks regarding material behaviour and limitations. In contrast, the designers manipulated the mask morphology. The medical experts were involved in episodic consultations when a targeted design issue had to be resolved.

### 6.1 Extracting FFP2 Mask Design Criteria

The design researchers initiated the product design activity with a literature review, an examination of prevailing design standards, and the collection of inputs from experts in design and medicine within the consortium. Through these tasks, a set of preliminary design criteria was established and categorised into aesthetic and functional criteria.

In the following step, the proposed criteria underwent rigorous deliberation, validation and ranking through a focus group of eight medical doctors and nurses active in COVID-19 duty, both in Portugal and India, to balance cultural and geographical variation.

Next, a SAATY questionnaire placing the qualified criteria ( $n=8$ ) into 28 comparative pairs ( $n \times (n-2) / 2$ ) was disseminated to the same group of medical experts. The results of this SAATY questionnaire were processed using the Analytic Hierarchy Process (AHP) model (Sindhu et al, 2017). This model processed the SAATY questionnaires into a weighted ranking list of the 8 criteria, thereby enabling the designers to prioritise the form generation activity towards the top three criteria. The focus on trimming the final priority to three criteria was made to assist the product designers in focusing their form generation activity.

*Table 2: Design criteria ranked through AHP*

S. no	Parameter	Weightage
1	Compatible with glasses/eye protection	0.23
2	Adjustability	0.23
3	Sizing	0.18
4	Comfort	0.14
5	Surface Geometry	0.11
6	Flexibility	0.06
7	Speed of Deployment	0.03
8	Stackability	0.02

## 6.2 Concept Design

Following the extraction and ranking of the design criteria, a four-day intensive design workshop (32 hours) was conducted. This step led to an increase in general entropy in the NPD and also encouraged maximum participation from all BioMask project disciplines, thereby promoting interdisciplinary operations.

This facilitated a convergence of multidisciplinary expertise within the consortium, including designers, doctors, nanomaterial engineers, fibre engineers, and representatives from the TBC Startup entity. The aim was to foster a collaborative atmosphere for designing and refining FFP2 mask concepts. Through brainstorming, sketching, paper prototyping, and iterative feedback, as well as form exploration, three final concept designs were agreed upon (Figure 5).



Figure 5: Paper prototyping and final concepts

Three low-fidelity paper prototypes were constructed based on the agreed-upon concept forms, which were derived from the three existing typologies of morphologies in the FFP2 mask category: the three-piece (Type 1), duckbill (Type 2), and vertical fold (Type 3) types.

Each of the three prototypes was then constructed in three sizes - small, medium, and large (IOS, 2015), which were derived by benchmarking against the menton-sellion length and bizygomatic breadth of the European population recorded in anthropometric specifications. The medium size was calibrated to match the existing size of commercial FFP2 masks, while the small size was 10% smaller and the large size was 10% larger.

Even though radically new morphologies were explored, medical products are a highly regulated category, and the EN149 certification regime highly dictated the formal possibilities for guaranteeing an airtight fit. The medical doctors in the consortium advised against deviating too much from codified and established morphologies currently commercially available.

These prototypes were then subjected to a fit test performed by eleven non-expert participants (six females and five males) to evaluate the three concepts for each of the three sizes across the eight design criteria outlined in Table 2. The non-expert testers evaluated the concept performance qualitatively in terms of high, medium, and low for each of the eight design criteria.

This data was captured in questionnaires and fed into a TOPSIS evaluation model (Sindhu et al, 2017) (figure 6).



Figure 6: AHP model (left); TOPSIS model(right)

This technique facilitated the generation of scores for each prototype, reflecting the degree to which each mask satisfied the established design criteria. This scoring system enabled a hierarchical ranking of the prototypes.

The top-scoring proposals were three-piece (type 1) and duckbill (type 2) in medium (m) size and were thus considered for further development.

Through a consortium discussion involving all the disciplinary experts, the three-piece (type 1) concept was eliminated from further development due to the complexity of manufacturing.

### 6.3 Detail Design

This step represented a reduction in entropy, similar to the material development activity, which involved only the participation of product design experts. Once the product design experts had resolved a solution, they presented it for a broader discussion among the other disciplines. The intention of this step was to convert the final concept paper prototype into a simulated fabric prototype approximating the texture and mechanics of the BioMask sandwich material.

The duckbill (type 2) size medium (M) concept was constructed in simulation fabric to evaluate the behaviour of the mechanical structure of the morphology in fabric compared to paper. As a result of this simulation, the decision to add a 3D printed "T-piece" to stabilise the nose cone and the adjustment clip for altering the head strap tension was established. Several tests were conducted using cotton canvas, which exhibited similar mechanical properties to the sandwich material (Figure 7).

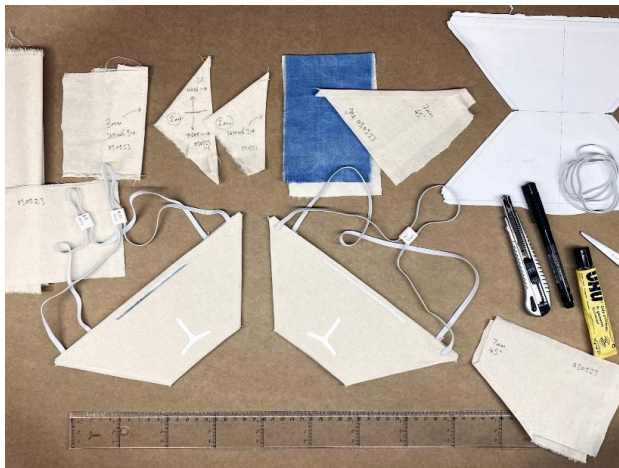


Figure 7 BioMask prototype with simulated material and refined morphology, including nose t-piece and metal nose clip

### 6.4 Testing and Refining

At this stage, it was essential to evaluate the final concept's morphology and sizing by the consortium's design experts and validate it through anthropometric standards (Figure 8). The final concept was thus cross-checked using the ISO/TS 16976-2:2015(E) standards.

1. Published anthropometric data (IOS, 2015). Menton-Sellion Length, the vertical distance between the bridge of the nose to the underside of the chin / Male 50th percentile 123 mm / Female 50th percentile 113 mm.
2. Human head, face and neck dimension data conforming to the 50th and 90th percentiles for males and females. This range was established to guarantee that a single size will fit both males and females in a statistically significant percentage.

The final prototypes were developed using CAD and precision-cut using a laser machine. These samples were fit tested within the consortium, and as a result, they fit well on both male and female users. For the purposes of the project (proof of concept), it was sufficient to produce a working prototype that would comfortably fit the majority of users in the healthcare community.



*Figure 8 Human head size variation evaluation and 3D printed accessories development, including a removable metal nose clip.*

In concluding this stage, a stabilised final solution resulted from eight weeks of constant iteration conducted by the product design researchers, nanomaterial scientists, medical doctors and fibre engineering elements of the consortium. Product design researchers proposed adding 3D printed accessory elements, including a nose “t-piece” and an adjustment clip, along with two head straps made from biodegradable elastic material to stabilise the mask's mechanical structure. The suggestion to add a quick adjustment clip arrived from the medicine experts in the consortium. It was essential to evaluate the possible polymers for developing 3D-printed accessories; finally, PLA was used to preserve the biodegradability rating of the final product.

For a controlled series production run, the BioMask prototypes needed to use a nonbiodegradable fabric glue in addition to stitching (Figure 9) to achieve an airtight sandwich assembly, which reduced the biodegradability rating of the final product to 99%, approximately calculated by surface area of glue footprint in comparison to the entire product assembly.

The input from nanomaterial scientists was critical to designers in resolving these issues.



*Figure 9 Stitching test showing various stitch patterns exploration suitable for application on the BioMask sandwich material.*

## 6.5 Final prototype and end-user testing

The final prototype was constructed using the complete BioMask sandwich material. It featured three variants of the final BioMask design: a single head strap with no T-piece, a single strap with a T-piece, and a twin head strap with a T-piece variant.

These variants were tested by three medical doctors from the consortium, who simulated the end user, thereby applying a second-order understanding of the end users' expectations and deployment scenario. The testing was conducted across surgery, pathology labs, and first-contact primary care clinical settings to validate the BioMask's final pre-production prototype (Figure 10).

The R-Comfi FFP2 mask testing protocol was deployed to the doctors who evaluated each prototype variant against queries arranged in three categories: 1) discomfort, 2) general user experience 3) function. Twenty-one factors impacting mask comfort, such as claustrophobia, difficulty breathing, and dry eyes, were evaluated in terms of their degree of intensity - never, occasionally, and continuously.



*Figure 10: Clinical testing and evaluating the variants of the final prototype in a primary care first contact health centre setting.*

The design methodology presented here encourages a systematic approach to arriving at a final design proposal from a fuzzy initial state, characterised by high entropy due to data input from multiple disciplines. FFP2 masks are a product category whose design criteria are not well understood scientifically and technically by designers, end-users, or healthcare professionals. Therefore, this methodology aimed to identify the elements that impact the generation of a mask design and counteract individual biases by incorporating feedback and weighted analysis across multiple disciplines.

A 3D digital model was only developed at this stage, demonstrating that sometimes an NPD process can work with some steps in reverse. This approach guides product form development through analogue methods and tools, including sketching, drawing, iterative prototyping, user testing, and collective reflection, followed by computational virtual modelling to conclude.

## 7 Conclusions and Insights

BioMask intersects the scientific areas of fibre engineering, nanomaterial science, design, and medicine. The core mission of this project was the transformation of the CA nanomaterial based 100% biodegradable sandwich structure into an FFP2 grade filtering facepiece mask, offering two benefits to the local society: 1) reducing single use medical waste; 2) provide local availability of this critical PPE (Personal Protective Equipment) to the local public health authority. The startup entity, The BioMask Company (TBC), received a fully equipped nanomaterial lab and know-how to manufacture a medical-grade product in the ultra-peripheral European geography of the Madeira

Island archipelago. Thus, the project fulfilled all the primary requisites necessary to classify the research as translational (NCSU, 2020). A working prototype (Figure 11) realised up to Technology Readiness Level 4 - TRL (Tomaschek et al., 2016), manufactured in a pilot production run of twenty-five pieces in a clean room, was evidenced at the project conclusion, thereby completing the ToT from academia to local industry as anticipated.

The NPD process presented here was the BioMask process model executed to achieve a new product innovation (NPI) evidenced by the award of provisional Portuguese patent protection N<sup>o</sup> PT118742A “Biodegradable multilayer filter, protective face mask including the similar and associated uses” by The Portuguese National Institute of Industrial Property (INPI) in June 2023. A final patent could not be achieved at the moment of writing this paper. The product has not yet been certified to EN149 as of the time of writing; however, the filtration efficiency and biodegradability have been recorded at 98.3% for 0.3-micron particles and 100% biodegradation in 11 weeks, respectively, under controlled laboratory conditions performed independently in India and in Portugal.

Designing a medical product presents challenges distinct from those of appliances and household equipment, due to the highly regulated and restrictive operating environment. The various activities and the steps elaborated in the BioMask process model highlighted the role and posture of each discipline within each activity. Designers are not technically capable of handling material science, scientific equipment, and a lab scenario unlike the fibre engineers and nanomaterial scientists. Unlike designers, these disciplines instead are dominant in their respective scientific areas but lack the empathy and interest to perceive the difficulties and expectations of other stakeholders participating in a common mission or RQ. The medicine discipline, being the end users, offer valuable insights into the reality of the product usage scenarios and therefore contribute with creative inputs on product development and morphological issues. The scenario and equipment in which a medical product is deployed are not easily accessible; hence, the participation of medical experts gives invaluable inputs, such as how a doctor manipulates a mask to extract the packaging or discard the item after exposure to an infectious patient.

The designers are the most capable communicators (soft skills) among all these disciplines. What they lack in technical depth (hard skill), they compensate for through abductive thinking (soft skill) often times by posing simple suggestions to address deep technical roadblocks. In BioMask, their “scientific innocence” at times resolved fibre engineering issues.



Figure 11: Final prototype pilot production in a cleanroom setting

BioMask was a problem-solving, outward-looking project (Muratovski et al., 2022). The project drew upon the principles of translational research (Gani, 2023). The project's research strategy represented the collective vision of product designers, communication designers, nanomaterial scientists, fibre engineers, and medical doctors, each bringing their unique expertise into the project's planning and implementation. It was noted during this project that encouraging engineering and medicine experts to contribute to designerly issues was easier than engaging designers to participate in engineering and technology issues.

In conclusion, the profile of a designer is well-suited for leadership positions that require soft skills, as the role of a PI often involves communication, conflict resolution, and the ability to understand highly technical problems from a different disciplinary perspective. Although when an activity requires hard skills, such as great specialised technical depth and scientific expertise, design cannot contribute at the same level as engineering and medicine. Due to the nature and intensity of interdisciplinary research work, as in the case of the BioMask project, where disciplinary boundaries are blurred, definitely by the end of the project the experts involved transcended interdisciplinarity towards transdisciplinary or convergence (NCSU, 2020) and were confident in giving suggestions beyond their core disciplinary expertise of either fibre engineering, nanomaterial science, design and medicine.

This insight may yield further discussions upon deeper investigation and cross-checking experiences of PIs and PMs in other research projects involving interdisciplinarity.

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**Acknowledgements:** This research was funded by FEDER - Fundo Europeu de Desenvolvimento Regional, under the project reference M1420-01-0247-FEDER-000052, and the publication costs through FCT - Fundação para a Ciência e a Tecnologia, I-P-, under project reference UID/05237/2025 of ESAD.IDEA - Associação para a Promoção da Investigação em Design e Arte.