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Design, Fabrication and Functional Test of a Low Environmental Impact Personal Protective Element

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The use of masks as a Personal Protective Element (PPE) is necessary in various activities and circumstances. They are used to protect healthcare workers, chemical plant personnel, people in polluted cities, or in possible future pandemic scenarios similar to that of SARS-CoV-19, for which the World Health Organization (WHO) recommended their use. The widespread use of disposable masks has created an environmental problem due to the short useful time of those PPE made of polymeric nanofibers. The objective of this research is the design, fabrication and functional tests of a low environmental impact PPE which provides comfort and protection during long-time usage. In order to achieve that purpose, the existing face masks on the market were analyzed and their most important design requirements were determined. Those requirements were: usability, sustainability, comfort and safety. Then, the design was based on an iterative rapid prototyping and redesign methodology, through the usage of the software's Autodesk Inventor, Blender 3D, Marvelous Design and Autodesk Moldflow, that made possible the necessary 3D models and manufacture drawings to implement additive manufacture process as Fused Deposition Modelling (FDM) or Material Jetting (Poly Jet) and polymeric thermosets castings. Usability tests were applied on people from all backgrounds. The most suitable prototype was called VitaBulla Flex, and its principal comfort characteristic was flexibility. This reusable face mask was made of 30 shore D hardness silicone and high-efficiency interchangeable N95 filters. Finally, the prototype was tested according to EN 1827:1999 + A1:2009 standard, to determine the resistance to breathing during inhalation and exhalation, and filtration efficiency by penetration with paraffin oil. As a result, the VitaBulla Flex reach FMP 2 classification for resistance to breathing during inhalation and a and filtration efficiency of FMP 1.

1. Introduction

The humanity has faced pandemic scenarios through history, much of them have been respiratory disease as various kind of Influenza and SARS – CoV a, between others (Piret and Boivin, 2021), and we have to be ready for the next one. During the last pandemic declare in 2020, the WHO suggested the use of face masks "as part of a comprehensive strategy of measures to suppress transmission and save lives" (WHO, 2021). Since then, it was dictated that certified face masks as N95 or FFP2 respirators should be used (Gao et al, 2025) as standard to protect against very small particles with a size of 0,3 microns or larger, especially for health workers (Chu et al, 2020). Besides that, the tighter the facial fit of the mask, it means, no gaps for air entry and exit, the higher the barrier (Manomaipiboon et al, 2020). Even though, the efficacy of the use of a certified face mask alone has not been proved absolutely by itself (Loeb et al, 2009), its efficacy depends on different circumstances and contexts (MacIntyre et al, 2025). Only in the Colombian context, there were some barriers which made difficult to ensure the people COVID protection through the face masks. First, not everybody had access to a certified mask, either because the costs or its availability (DANE, 2021). Second, the single-use masks have a significant environmental impact, especially in oceanic ecosystems. All this due to the nano-polymeric fibres of which they are made, and which take longer than 450 years to degrade and are not able to be recycled. It is estimated that 129 billion face masks were used on average every month worldwide (Silva et al., 2020), and 1,56 billion of face masks ended up in the ocean (Bondaroff and Cooke., 2020). Then, it became imperative to develop a reusable and long-life face mask, to reduce the amount of waste resulting from the use of single use mask, as well as to provide an adequate protection.

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2. Materials and Methods

Figure 1 shows the diagram of the design methodology used. The design process consisted of iterative stages where feedback was key to develop the prototype that was subjected to the technical safety tests.

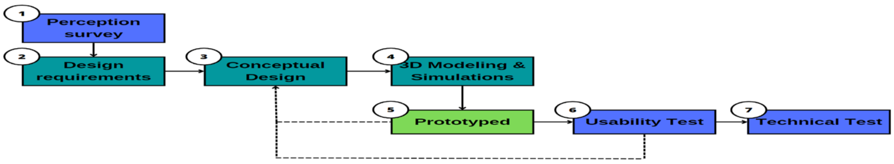


Figure 1: Iterative design methodology used to obtain and evaluate reusable mask prototypes.

Perception survey

Initially, a survey was taken by a sample of 238 people from the National University of Colombia. Participants were asked about their perception of the available PPE's on the market. The results showed that the PPE's considered the safest were neither comfortable nor sustainable. The main problems with the PPE's they used daily were also asked in the form of an open response, thus obtaining a large amount of important information for the design requirements.

Design requirements

The main source for the design requirements was the perception survey previously conducted. In addition, the design team added some important features to contribute to ease the environmental problem generated by single-use PPE. Finally, the design requirements were weighted in order of importance as follows: Safe (Biosafety), user acceptability (usability, appearance, ergonomic, low environmental impact), easy to clean, visibility, economical, freshness (ventilation) and ease to manufacture

Conceptual Design

In the conceptual design stage, the established design requirements were used. A market study (Benchmarking) was also carried out to analyse the proposed solutions for a reusable and comfortable PPE, the main problems to be solved and important factors to be considered were listed as follows:

- Exhalation valves: They generate a considerable particle spray zone (Verma et al, 2020), so their use should be avoided since an infected person can release potentially contaminated particles into the environment and disperse them with greater reach.
- Tightness and filtration efficiency: The gaps between a mask and the face dramatically affect filtration efficiency. For example, an N95 mask has a filtration efficiency of 99,9% for particle sizes greater than or equal to 300nm. However, the gaps between the mask and the face allow air to enter and exit without being filtered, so the filtration efficiency can drop to 12% (Konda, et al 2020). Therefore, generating an airtight seal between the mask and the face should be promoted.
- Reusable mask: They can reduce waste by 60% when they have interchangeable filters, while single-use devices can have a contribution to climate change of $1,5x10^9$ kg CO_2 eq. Reusable masks with interchangeable filters would have a contribution of $8x10^8$ kg CO_2 eq. (Goyena and Fallis, 2020).
- Material to be used (SEBS): It is a styrene-ethylene-butene-styrene thermoplastic elastomer widely used in medical devices because it is sterile, soft to skin contact, resistant to high temperatures and UV rays (sterilizable) and 100% recyclable. Additionally, it is compatible with other materials which leads to improve its mechanical and thermal properties, as well as the option of providing bactericidal properties to the material (Angel et al., 2013; Polymer Properties Database, n.d.-b).
- Interchangeable filters: The filtering material is the element with the shortest useful life in a mask with interchangeable filters; it should be changed every 69 hours of use (Goyena and Fallis, 2020).

Finally, ECOFLEX and DRAGON SKIN 30 silicone were used for the prototypes, Smooth-On silicones that provide mechanical properties like SEBS, but unlike SEBS, they set at room temperature with the mixture of component A and B and therefore facilitate fabrication at the prototyping stage.

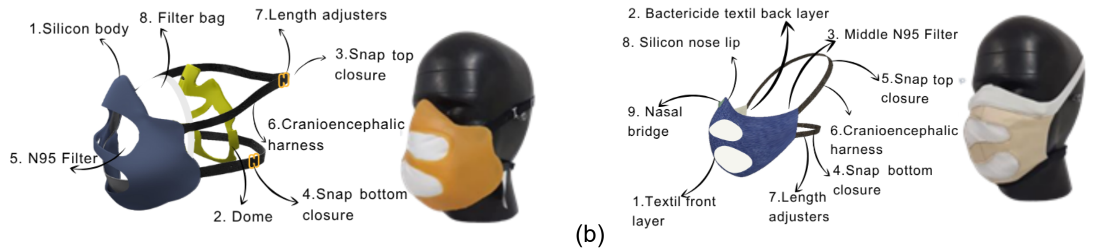
3D Modelling and Simulations

Autodesk Inventor and Blender 3D modelling software were used to generate design geometries, mainly for the handling of surfaces and Boolean operations to obtain the geometries of the molds used to cast silicone. The Ansys tool was used for the simulation of mechanical stresses. A finite element analysis was performed to reinforce the critical areas that could generate some tearing. It was found that the mechanical stresses are maximum when the user removes the mask, so the mechanical simulation focused on this case. The Autodesk

Moldflow and Ansys tools were used to design and simulate the pouring of the silicone into the mold and to define the feeding channels and vents to prevent filling difficulties and air entrapment.

Prototyped

The rapid prototyping stage consisted of different iterative activities that served as feedback to the final design. During the manufacturing process, different improvement opportunities for the resulting parts were observed. In this stage, fused deposition modelling (FDM) and stereolithography (SLA) were mainly used for the molds fabrications of the silicone parts for the VitaBulla Flex prototype. Tailoring patterns were also designed using Marvelous Designer for the VitaBulla Air textile parts. Two prototypes were manufactured, which are described below. VitaBulla Flex (Figure 2 (a)) is a long-life reusable face mask with interchangeable filters, mainly composed of silicone. Its geometry and flexibility allow an airtight face-mask seal, ensuring that all air inhaled and exhaled by the user flows through a single hole intended for that purpose and which will have a filter. The filter has an N95 efficiency and is protected by a pocket in bactericidal textile material, promoting longer filter life. The piece contains a dome that allows the filter to be fixed to the face mask and also generates a space between the respiratory tract and the face mask, giving a feeling of freshness to the user.



(a) (b)

Figure 2: Prototypes, parts and final products: (a) VitaBulla Flex and (b) VitaBulla Air

Table 1: Materials of prototypes

Classification	VitaBulla Flex	VitaBulla Air
Outside barrier	Silicon body: Ecoflex™ 00-30 (Smooth-On)	Cotton 23% - Polyester 73% - Spandex 4%
Inside barrier	Filter bag: 91 %Polyester 9% Lycra fabric Dome: polycarbonate	Bactericide textile: 91 %Poliester 9% Lycra fabric. Nose lip: Dragon Skin™ silicon
Filter	N95 Filter	N95 Filter

VitaBulla Air (Figure 2 (b)) is a reusable face mask in a three-layer bactericidal textile material. The external layer is rigid to preserve the geometry of the mask, the intermediate layer has the interchangeable N95 filter, and the internal layer is made of soft textile in contact with the skin. It has a silicone nasal bridge that reduces face-mask gaps to improve filtration efficiency. Its main quality is its low weight and breathability.

Final tests

Two tests were applied to the final prototypes: Usability Test and Technical Tests. The Usability test was divided into three main parts: intuitive use (with and without user manual); running (for 10 min at 6km/h); work simulation (20 min of activities to simulate normal working conditions). The latter two were carried out in accordance with the END144 standard, or its equivalent, EN1827. After these tests, a photographic record was taken of any marks left by the mask and questions were asked to the participants about the user's experience. The second test was carried out in a certified laboratory for such tests (AITEX, Alicante, Spain). Aitex assessed the breathing resistance and filtration efficiency according to EN 1827:1999 +A1 2009. According to this, the acceptable values for the respective efficiency classifications are shown in the Table 2.

Table 2: Breathing resistance test and Filtration efficiency (Resistance to penetration with paraffin oil): acceptable values according to EN 1827:1999 +A1 2009.

Classification	Inhalation (30 l/min)	Inhalation (95 l/min)	Exhalation (160 l/min)	Maximum penetration with paraffin oil (%)
FM P1	0,6	2,1	3,0	20
FM P2	0,7	2,4	3,0	6
FM P3	1,2	4,2	3,0	1

3. Results

3.1 Perception survey of PPEs available on the Colombian market

Following the premise that the motivation to protect oneself is related to the perceived efficiency of the prevention measure and the subjective cost of following the recommendation (efforts made, obstacles related also to comfort) (Cottin et al., 2016), the first result that the study got was related to the perception of EPP available on the Colombian market shown in the Figure 3. Four parameters were measured on 8 alternatives of PPEs: usability, sustainability, comfort and safety, parameters that appear to be mutually exclusive as can be seen in the results. Moreover, there is a misperception of security, not based on scientific studies, but rather spread by the media. As a result, devices with exhalation valves and the use of shield are perceived as safe, despite the fact that studies show the opposite (Verma et al, 2020).

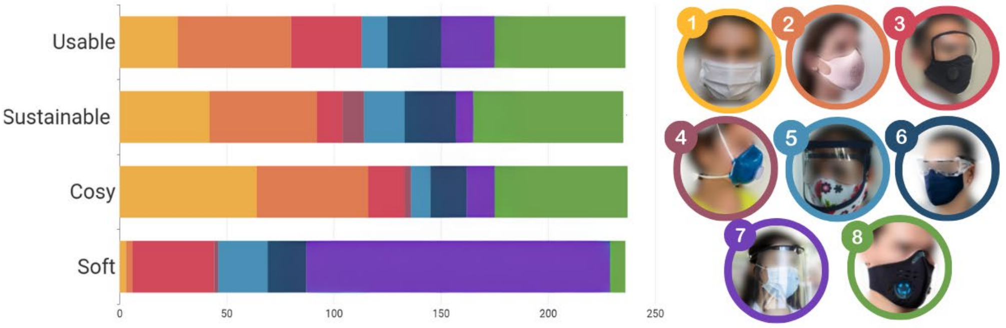


Figure 3: Perception of PPEs on the Colombian market, by selecting the preferable to each characteristic.

3.2 Usability Test

After the walk test and work simulation, the results were satisfactory according with the Figure 4. In both models there was no significant reddening, only superficial facial marks after prolonged use were observed. Those marks appeared on noses or cheeks after 20 min of usage, in the case of VitaBulla Flex, for VitaBulla Air, facial marks turned up after 10 min on nasal septum and nose tip. On the difficulty of breathing, it can be said that the one that had the most difficulty was the VitaBulla Air'. On the other hand, the comments about breathing with the VitaBulla Flex, were positives. General comments about both PPE's are shown in the Figure 5; VitaBulla Flex received good feedback for its comfort and freshness. Regarding the VitaBulla Air, the feedback about comfort was not too positive, the nose lip seemed to be rigid, the size of textile piece appeared not to be large enough to cover the full face of the user, and the inner layer constantly collapsed upon inhalation.

Figure 4: Marks that popped up after walk test and work simulation a) results of VitaBulla Flex model and (b) results of VitaBulla Air.

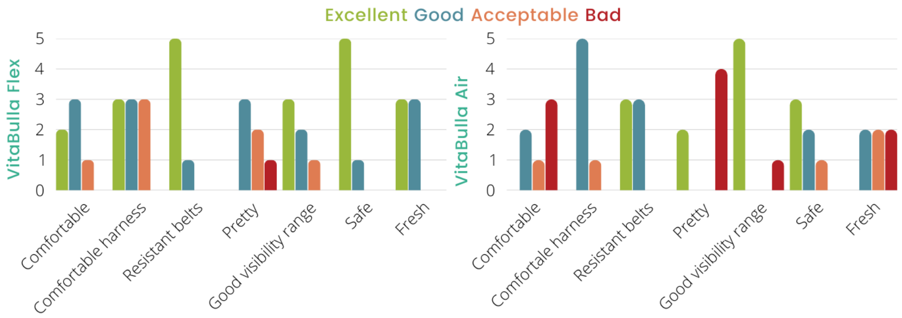


Figure 5: General perception about VitaBulla Flex (left) and VitaBulla Air (right) grading from 0 to 5 where 0 was Bad and 5 were Excellent.

3.3 Technical Test

Applying the methodology of 2.6., the results of breathing resistance test are shown in Table 2. According to the standard, VitaBulla Flex complies with the inhalation breathing resistance values up to the FMP2 classification. However, the exhalation resistance was not met for the minimum classification FMP1. VitaBulla Air meets the inhalation and exhalation breathing resistance values up to FMP3 classification.
In the case of paraffin oil penetration test, VitaBulla Flex, meets a FMP1 classification but VitaBulla Air, does not meet any classification (Table 3).

Table 2: Breathing resistance test results for VitaBulla Flex Prototype

	VitaBulla Flex			VitaBulla Air		
Sample	Inhalation (30 l/min)	Inhalation (95 l/min)	Exhalation (160 l/min)	Inhalation (30 l/min)	Inhalation (95 l/min)	Exhalation (160 l/min)
1	0,6	2,7	4,0	0,2	1,3	1,8
2	0,5	2,4	4,0	0,2	1,2	1,8
3	0,5	2,4	3,9	0,3	1,3	1,7

Table 3: Filtration efficiency (resistance to penetration with paraffin oil) for VitaBulla Flex

	Average penetration value (%)	
Sample	VitaBulla Flex	VitaBulla Air
1 (Paraffin oil penetration test for 3 min)	19,3	67,8
2 (Paraffin oil penetration test for 3 min)	19,5	68,7
3 (Exposure to 120 mg of paraffin oil)	More than 20	-

4. Conclusions

VitaBulla Flex achieved superior filtration efficiency compared to VitaBulla Air, despite using the same N95 filter, so we see how tightness plays a very important role in improving the safety level of PPE.
VitaBulla-Flex exceeded the inhalation breathing resistance values up to the FMP2 classification, however it did not pass the exhalation test for the minimum classification, to improve this value the most bio secure proposal would be to use a larger filter. By other hand, VitaBulla-Air passed the breathing resistance test in both inhalation and exhalation for even the FMP3 level, however the filtration efficiency failed to exceed the minimum FMP1 level despite the use of an N95 filter. This is largely because the tight seal of the device is not as efficient, so air can enter and exit to a large extent through the free areas between the face and the device, reducing the overall filtration efficiency. Therefore, the lip design should be reconsidered to improve results.
Given the results of the technical tests together with the usability and comfort tests, the aspects to be considered for the improvement of the final product are: Increasing the filtering area, improving the coupling system of the filters to improve the airtightness and finally, rethinking the design of the fastening system in a simpler and more intuitive way.
Assuming a reusable mask with a SEBS body and acrylic ring is used for approximately 1,000 hours with a single N95 filter (3M, 2023; NIOSH, 2018), it could replace an estimated 125 disposable masks based on an average use of 8 hours per unit (WHO, 2021; CDC, 2025). For shorter or longer usage scenarios (e.g., 500–1,500 hours), this range could extend from 63 to 188 disposable masks avoided. Considering that each surgical mask contributes about 20.5 g CO_2e (Li et al., 2023), this substitution could prevent roughly 2.6–3.9 kg of CO_2 emissions over the assumed lifespan. These figures are preliminary estimates; a complete life cycle assessment would require a more comprehensive analysis including manufacturing, transportation, cleaning, and end-of-life stages.

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