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A new anesthesia mask design

Yeni bir anestezi maskesi tasarımı

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A New Anesthesia Mask Design

Highlights

- *Analyzing problems through a user experience design approach.*
- *Reducing errors occurring in treatment processes*
- *Designing anesthesia masks to fit facial structures.*
- *Solving problems with a systematic design approach.*

Graphical Abstract

The general form design of the new anesthesia mask has a structure that allows stretching and comfortable sitting with an air cushion. In addition, the curves of the areas in contact with the cheek and chin reduce the rate of gas leakage, unlike standard designs. The areas of the face where the mask should fit were determined by taking into account the bone structures. The boundaries of the created structure are created so that the end point of the eye socket (orbita) lies between the cheekbones (os zygomaticum) and the jawbone (os mandibula). The anesthesia mask ultimately consists of six parts as seen in Figure.

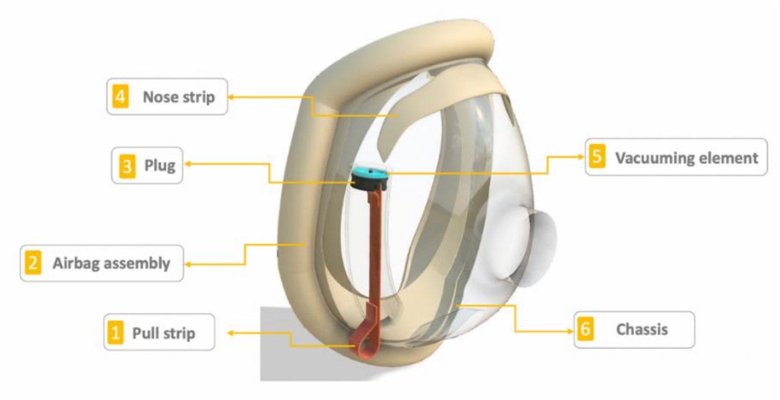

Figure . Components of the new anesthesia mask

Aim

This study aims to minimize air leakage by optimizing the compatibility of anesthesia masks with facial contours and to expedite treatment procedures in emergency scenarios.

Design & Methodology

User experience design method is a design approach that aims to develop positive user-product relationships and refers to processes that address usability problems. The affinity diagram prepared for the anesthesia ventilation mask. The use of anesthesia masks, also known as face masks, throughout the treatment process is outlined and shown in stages. This diagram provides detailed information about the role of masks in the treatment process, their applicability, usage scenarios and possible problems.

Originality

Unlike standard masks, the design emphasizes anatomical compatibility through drawings made on a 3D human model.

Findings

Through user experience analyses, it has been observed that most commercially available masks rely on 2D representations of the human face for sizing templates, resulting in designs that are overly simplistic compared to the complex geometry of the human face. Given that this issue can lead to prolonged treatment durations and the inability to administer proper therapies, the design process was advanced in line with these findings.

Conclusion

The design process has been completed so that it provides a more harmonious closure with the facial features and helps to reduce the errors that occur during the treatment process with the ergonomic grip of healthcare professionals.

Declaration of Ethical Standards

The author(s) of this article declare that the materials and methods used in this study do not require ethical committee permission and/or legal-special permission.

A New Anesthesia Mask Design

Araştırma Makalesi / Research Article

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ABSTRACT

Humanity has struggled with epidemics from the past to the present. All have similar problems, such as infection rates, prevention methods, and supply problems. Today, we are grappling with the problems we have witnessed during the COVID-19 pandemic. As part of this study, protective and therapeutic masks, which are the products that people of all ages and physical characteristics interact with most during the pandemic period, were examined. A conceptual design for an original anesthesia mask was developed based on the data obtained in this study, using the systematic design approach. User experience theories and applications were used to understand the interaction and reflect it in the new design. This stage is based on a systematic design approach. The optimum design option was then used to create a embodiment design for the mask. The materials and properties suitable for prototyping to be used by modelling in three dimensions in the computer environment were determined and prepared by the working functions of the system. By preparing the usage scenario of the product, the amount of air escape was reduced compared to that in the market. The design process has been completed so that it provides a more harmonious closure with the facial features and helps to reduce the errors that occur during the treatment process with the ergonomic grip of healthcare professionals.

Keywords: Epidemics, User experience design, Conceptual design, Mask

Yeni Bir Anestezi Maskesi Tasarımı

ÖZ

İnsanlık geçmişten günümüze salgın hastalıklarla mücadele etmiştir. Hepsinde enfeksiyon oranları, korunma yöntemleri ve tedarik sorunları gibi benzer sorunlar bulunmaktadır. Bugün de COVID-19 pandemisi sırasında tanık olduğumuz sorunlarla mücadele etmekteyiz. Bu çalışma kapsamında, pandemi döneminde her yaştan ve fiziksel özellikten insanın en çok etkileşimde bulunduğu ürünler olan koruyucu ve tedavi edici maskeler incelendi. Bu çalışmada elde edilen verilerden yola çıkılarak sistematik tasarım yaklaşımı kullanılarak özgün bir anestezi maskesi için kavramsal tasarım geliştirildi. Etkileşimi anlamak ve yeni tasarıma yansıtmak için kullanıcı deneyimi teorileri ve uygulamalarından yararlanılarak bu aşama sistematik tasarım yaklaşımına dayandırılmıştır. Optimum tasarım seçeneği daha sonra maske için bir somutlaştırma tasarımı oluşturmak için kullanılmıştır. Bilgisayar ortamında üç boyutlu olarak modellenerek kullanılacak prototiplemeye uygun malzemeler ve özellikleri belirlenmiş ve sistemin çalışma fonksiyonları ile hazırlanmıştır. Ürünün kullanım senaryosu hazırlanarak hava kaçış miktarı piyasadakine göre azaltıldı. Yüz hatları ile daha uyumlu bir kapanış sağlayacak ve sağlık çalışanlarının ergonomik tutuşu ile tedavi sürecinde oluşan hataların azaltılmasına yardımcı olacak şekilde tasarım süreci tamamlanmıştır.

Anahtar Kelimeler: Salgın hastalıklar, Kullanıcı deneyimi tasarımı, Kavramsal tasarım, Maske

1. INTRODUCTION

Throughout history, societies have faced numerous regional and global epidemics causing millions of deaths. Three major global epidemics include the plague of Justinian (6th-8th centuries AD), the recurring black plague (14th-19th centuries), and the worldwide spread of the Spanish flu after World War I. The Covid-19 virus, which was first detected in Wuhan, Hubei Province of China, was reported to the World Health Organization (WHO) on 31 December 2019 [1].

The pandemic has caused a global crisis, leading to economic and social uncertainty worldwide. Disruptions in production, transportation, and logistics, along with the impact of globalization, have constrained supply chains, causing shortages of essential consumer goods [1]. Generally, various aspects of life, particularly in the health sector, have experienced slowdowns, emphasizing the importance of timely access to basic necessities [2].

The level of civilization is determined by the value placed on human life and nature. Medical intervention, as well as protection from accidents and dangers, are essential. Achieving effective healthcare relies on advanced equipment and well-trained personnel, making the healthcare sector an early adopter of cutting-edge scientific and technological advancements [3]. Healthcare equipment should best meet the needs of patients and healthcare providers, emphasizing user experience design over traditional methods that focus on functionality and cost-effectiveness. This user-centered approach is particularly valuable in designing anesthesia ventilation masks, where diverse and conflicting expectations from both patients and healthcare personnel need to be addressed [4, 5]

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Anesthesia ventilation masks are crucial tools for pre and post-surgery intensive care. Their functionality and ease of use significantly impact patient treatment. Applying user experience design to these devices can enhance patient health and healthcare professionals' satisfaction and efficiency. Unlike other design methods, user experience design prioritizes user interests and expectations, directly improving the user experience with anesthesia ventilation masks, ultimately enhancing patient care quality and healthcare efficiency. Without user-centered design, complex medical devices like anesthesia masks can lead to misuse, workflow disruptions, and incorrect applications, potentially resulting in irreversible negative consequences.

This study examined user experiences with anesthesia masks available on the market and utilized interest diagrams to analyze different experience types and models. It also investigated treatment methods commonly used during epidemics to gather valuable insights for enhancing patient and healthcare professional experiences. Based on this analysis, a conceptual design for a new anesthesia mask was developed, encompassing shape design, function design, material selection for manufacturing, prototyping with 3D printers, and creation of use-case scenarios. The objective was to design a product that addresses identified issues and offers practical solutions for both patients and healthcare professionals.

Conceptual design plays a vital role in achieving an ideal design. However, during the early stages, complex user relationships can lead to superficial and incomplete problem analysis and requirement lists. To address this issue, this study incorporated the user experience design method into the conceptual design process, ensuring accurate and comprehensive user needs assessment. Relationship diagrams were employed to systematically and comprehensively analyze various user experiences with existing commercial anesthesia masks. This information served as the foundation for the conceptual design, resulting in the development of design concepts. Subsequent steps included detailed analysis, use case scenario creation, design shaping, and prototyping. Through this user-centered and systematic approach, a product addressing identified problems and meeting the needs of both patients and healthcare personnel was achieved. This study illustrates the effectiveness of the user experience design method in enhancing ventilation mask development within the healthcare sector and provides insight into its integration. It also offers an evaluation of the current practice and potential advancements in anesthesia ventilation mask design.

Azeloğlu and Alper (2019) [6] employed a conceptual design approach to create a unique medical product that simultaneously engages multiple muscle groups and supports physical therapy, distinguishing it from conventional medical devices. Bitkina, Kim, and Park (2020) [7] conducted a comprehensive study encompassing 88 resources related to healthcare and medical device designs, exploring various user experience design methodologies, their merits, and drawbacks, contributing to the advancement of research in health and medicine. Kessler and his team (2021) [8] established a task-based usability study for an online intervention program targeting individuals with voice problems, promoting the adoption of user experience design to enhance the healthcare field. In a recent development, Sümbül, Böğrek, and Tunçer (2023) [9] embraced a conceptual design approach to create an innovative combined bed and bed control system for intensive care units, facilitating treatment for individuals with limited mobility.

This article focuses on the problems arising from epidemic diseases, their socioeconomic impact, and their interaction with current products. The objective is to create an innovative product design that provides solutions to these challenges. First, interest diagrams were created using user experience design to understand the relationship between the product and the user. Subsequently, research was conducted to address emerging information needs. Utilizing the gathered data and information, a detailed embodiment design was achieved through computer-aided design technologies. These masks, initially designed based on 2D templates, have been further developed to accommodate the complex geometry of the human face. Additionally, improvements were made to enhance usability and ensure airtightness. The practicality of this new anesthesia mask was demonstrated through usage scenarios. This study aims to design an innovative anesthesia mask that aligns more closely with facial anatomy, enhances ergonomics, and minimizes air leakage by employing a user experience design approach. The absence of existing studies in the literature that integrate form modification and prioritize user experience in anesthesia mask design highlights the novelty of this research. Developed through systematic design processes, this mask represents a significant advancement toward the creation of more effective and user-centered designs in the healthcare sector.

2. MATERIAL and METHOD

The process of integrating user experience design into the systematic design approach is illustrated in Figure 1. It initiates with problem identification and analysis, generating a list of user-centered needs using the user experience design method. In the conceptual design phase, design concepts aligning with these needs are developed, and the optimal one is selected. Subsequently, the chosen design concept is refined through shaping design, making it more concrete and explicit. At this point, a second user experience design iteration is conducted, leading to design adjustments in line with user expectations. The design process concludes when the set criteria are met. This approach is adaptable and iterative, allowing for revisits to prior design stages if necessary. Further details on each stage are outlined in subsequent steps.

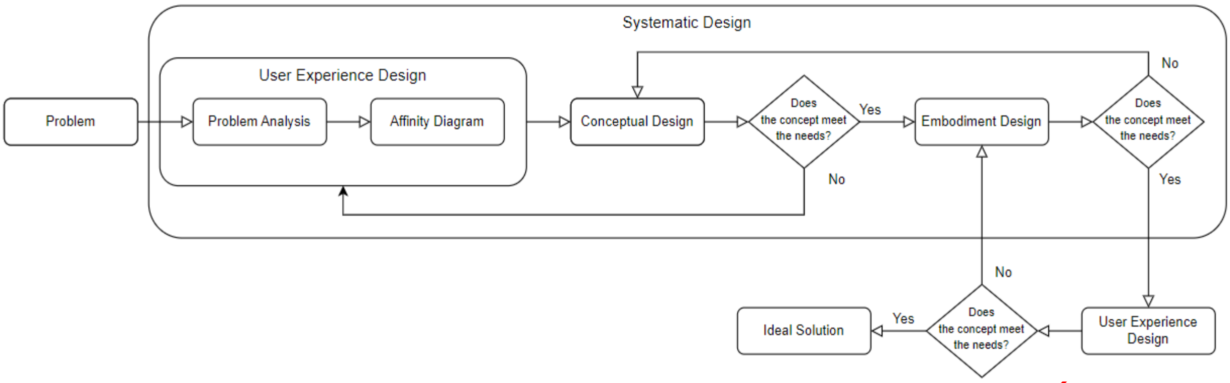

Figure 1. Process flowchart for systematic design with user experience design

2.1. User Experience Design

In addition to theoretical knowledge, knowledge obtained through senses such as hearing, sight, touch, taste and smell at certain times and places is called experience [10]. Space and time may be factors that influence, restrict and shape experiences to a certain extent. Here, the concept of time can be very important in shaping the felt senses, as it is formed by the interaction between the inner and outer world. Experiences can occur consciously, semi-consciously and unconsciously and can also change the user's feelings and thoughts [11].

User experience design method is a design approach that aims to develop positive user-product relationships and refers to processes that address usability problems [12, 13]. Essentially, this method aims to improve the user experience positively by highlighting human needs and values. In this process, work begins by collecting cause-effect related data that promotes positive results for the user [14]. Then; The process continues with the determination of factors such as visual, aesthetic, pleasure, stimulation and personal development and ends with the accumulation and application of a certain knowledge / experience [15].

2.1.1. Analysis of problems

A method based on market/user research, design, prototyping, user testing and repetition of these steps is followed to design and improve a product or service in accordance with user needs and expectations. In the first stage of this process, the usage area, user interaction and possible problems encountered are determined. Ventilation masks used in hospital environments and emergency situations are equipment used to provide safe oxygenation. These types of masks, which are used by healthcare personnel especially in the initial phase of anesthesia, known as induction, are actively used in emergency medicine clinics, intensive care environments and respiratory therapy. These masks generally maintain the patient's safe and efficient breathing in cases where the patient's natural breathing is weakened or stopped completely, either voluntarily (such as surgical operations and intensive care) or involuntarily (such as sudden loss of consciousness, shortness of breath) [16]. These masks, placed on the patient's face by a healthcare professional, provide oxygen gas flow to the lungs at the appropriate pressure and amount from a specific source (such as an oxygen cylinder, mechanical ventilator, anesthesia machine). In medical sources, this process is called “Noninvasive ventilation (NIV)” [17].

Mechanical ventilation involves supporting the breathing of patients with inadequate lung functions by providing a gas mixture (O2, nitrogen oxide (N2O) and isoflurance) under a controlled pressure [18]. This method is critical in meeting the oxygen needs of patients with limited natural breathing ability. In particular, the Covid-19 pandemic has proven the vital importance of mechanical ventilation in intensive care units and accelerated technological developments in this field. Mechanical ventilation is frequently used in situations such as oxygen deficiency, respiratory difficulty/insufficiency, diagnosis and treatment processes, surgical interventions and when airway safety is at risk.

Ventilators generally have two different operating principles, invasive and non-invasive, depending on the air supply method. While the term "invasive" generally refers to methods that require surgical procedures that disrupt tissue integrity; "non-invasive" indicates the preservation of body integrity. Invasive ventilation is used quite frequently in operating rooms, intensive care and emergency medicine clinics. Non-invasive mechanical ventilation, on the other hand, is widely used in critical care settings such as emergency departments and intensive care units. Non-invasive ventilation is a technique used in patients who are conscious, have sufficient lung capacity, and have coughing and swallowing reflexes [17]. This process is carried out in harmony with the selected anesthesia mask [19]. Here, in addition to ensuring absolute compatibility between the device and the equipment, it is also necessary to minimize the incompatibilities between the equipment and the patient. Additionally, according to Kebapçı's study conducted in intensive care units, attempting any airway intervention without adequate personal protective equipment poses a significant risk of infection for healthcare personnel [20]. NIV masks; It should include features such as being suitable for the patient's facial anatomy, fully covering the airway passages (mouth and nose), being flexible, not damaging the skin, and being easy to manipulate [21]. According to the studies conducted by Saltürk et al. at Süreyyapaşa Chest

Diseases and Thoracic Surgery Training and Research Hospital, in the 22-bed Respiratory Intensive Care Unit with 258 patients receiving NIV; in these masks or their use, excessive air leakage, soft tissue damage, dry mouth and nose, irritation, claustrophobia, and pain are the most common problems [22].To overcome such problems during effective mask ventilation, methods such as the use of auxiliary personnel and pressurized mechanical ventilation are used [16]. Additionally, ventilation problems may occur with patient-related masks. The most famous of these is the anomalies known as difficult intubation and evaluated with the mallampati scale. Kandemir et al. identified these challenges through studies conducted on individuals aged 18 to 70, classified as group 1-2 according to the American Society of Anesthesiologists (ASA) criteria. In general, anatomical factors such as short or muscular neck structure, limited neck movements, limited mouth opening, as well as hormonal reasons, foreign bodies, cleft palate, cleft lip and tumors cause this difficulty [23]. Techniques such as adjusting the head and neck position, applying pressure to the thyroid or neck cartilage, and retracting the tongue can be used to solve the difficult intubation problem. In cases where these techniques are inadequate, alternative medical interventions may be required [24, 25].

2.2. Affinity Diagram

A “relationship diagram (or affinity diagram)” is a tool used to organize and relate data obtained in various ways. It enables a clearer determination of customer wants and needs. The relationship diagram used in the second stage of the user experience design method examines a problem from different angles and provides collection, sorting and analysis of relevant ideas and information. This diagram can be used by individuals and groups to better design user experience [26]. The relationship diagram is an effective tool for quality user research and understanding user feedback. The affinity diagram prepared for the anesthesia ventilation mask can be seen in Figure 2. Here, the use of commercially available anesthesia masks, also known as face masks, throughout the treatment process is outlined and shown in stages. This diagram provides detailed information about the role of masks in the treatment process, their applicability, usage scenarios and possible problems. According to this diagram, the importance of masks in the treatment process and the priority issues to be considered during this process are determined. Figure 2 also shows the effects and benefits of anesthesia ventilation masks in the treatment of COVID-19.

From the perspective of user experience design, the application process of standard anesthesia masks was evaluated in a multidimensional way for both human users and healthcare personnel. In this context, studies were carried out on 1:1 scale models of 8-10 year old children and adults in the Model Laboratory of Istanbul Health and Technology University. Anesthesia technicians observed the application of standard anesthesia masks in detail and analyzed these problems (Figure 3).

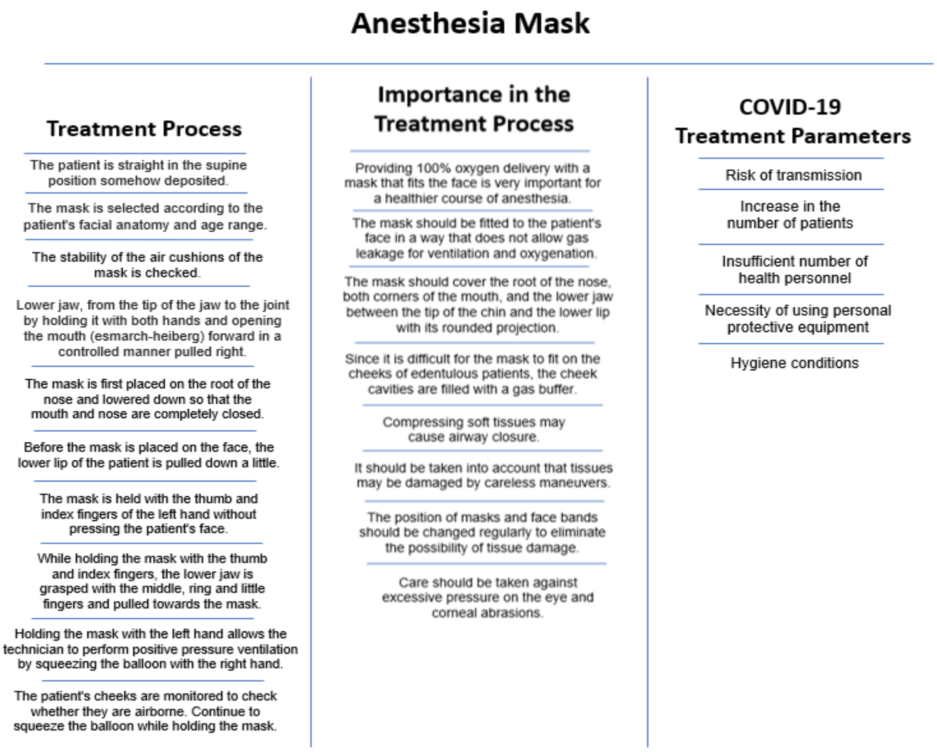

Figure 2. Process chart

Figure 3. Testing the use of the standard anesthesia mask on models a- Does not fit the patient's face b- Excessive pressure on the eye c- Lack of a form to guide medical personnel / difficulty in treatment

Table 1 shows the fine details, listed in order of priority, extracted from the general information provided in the previous table. Here, the entire problem is divided into subheadings, the important/priority ones are determined and the necessary analyzes are made for their solutions. For example, it has been stated that the problem of the first row mask being incompatible with the patient's facial anatomy will cause errors in situations requiring sudden intervention. Another problem (problem 5) is the necessity of having masks of various sizes during the intervention to the patient. It is also stated in the table that this problem may cause loss of time and incompatible matches in choosing the correct mask size.

Table 1. Problems&Analysis chart

No	Problems	Analysis
1	Failure to fit the patient's face properly (Figure 3a)	Non-procedural mask application error during sudden intervention
2	In one-handed intervention technique; loading multiple functions	Multitasking the hand with both holding the mask and pulling back the chin
3	Wear caused by excessive pressure on the eye (Figure 3b)	Non-procedural mask application error during sudden intervention
4	Practice of mask strengthening exercises by healthcare professionals (Figure 3c)	They need constant practice in order to gain the correct mask holding skills
5	During the intervation, several sizes of masks should be kept	Symptoms that may occur with the loss of time between mask size mismatch and change in patient's requiring urgent intervention
6	Patients with beard, mustache and without teeth	Incompatibility of patient's with different facial anatomies with standard masks
7	Those with a body mass index of 26 kg/m^2	Incompatibility of patient's with different facial anatomies with standard masks

Figure 4 identifies the key categories that address the seven issues identified in the previous figure. These categories, including ergonomics, gripping/locking suitability for facial anatomy/universal use and material selection, are important criteria determined to create the ideal mask design.

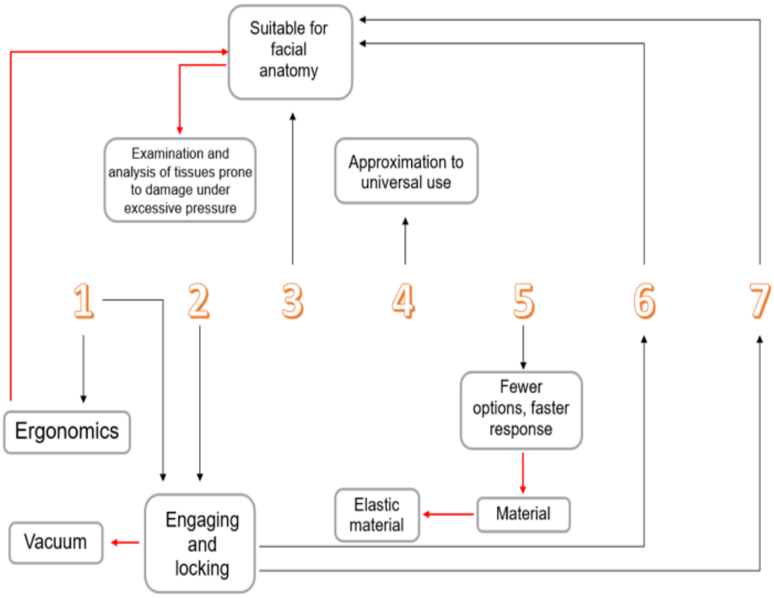

Figure 4. Solution methods chart

As shown in Figure 4, problems such as ergonomic errors, insufficient grip and balance difficulties may prevent the mask from fitting properly on the patient's face. In order to perform the procedure correctly in situations where it is necessary to hold the mask with one hand; In addition to the knowledge and experience of healthcare personnel and using holding techniques, choosing the appropriate mask is also important. Another problem, possible tissue damage due to excessive pressure applied to the eye, can cause problems in facial anatomy. Various preventive measures can be taken based on such problems and associated analysis. In such cases, medical personnel try to minimize negative effects. However, examining the size and shape differences between standard mask sizes can provide faster and more effective intervention with fewer options. Important findings obtained from relationship diagrams, suggested solutions, analyses, improvements and applications are given in Table 2. Thus, the problem analysis and needs determination required for the conceptual design process were carried out with user experience design.

Table 2. Conclusion of Affinity Diagrams

Solution	Analysis	Progress	Implementation
Suitable for facial anatomy	Ergonomic causes	Examination of different face types	Matching for similar face types or addressing a specific problem
	Review similar solutions	Using nose wire-like form for sealing in surgical masks	Placing the wire in the nose while giving the CE position during the sudden intervention
Engaging and locking	Investigation of vacuum methods	Harmonizing these methods with form and the human body	Simulating the method to be adapted
Approximation to universal use	Fixation to facilitate one-handed intervention	Indirectly investigating grip, locking and material options	Reducing complications related to the skill of the healthcare professional during treatment
Material	Detailed material scanning in selected problems in order to process certain parameters in the most efficient way	Analysis and examinations for the elastic region in contact with the patient's face Matching the right material with the right production technique	Meeting the requirements in other items by harmonizing the obtained data with the form
Decrease options	Ability to prevent waste of time in 6 standardized options	Reducing dimensional differences between them using fewer options	Providing faster access to the right choice with fewer options for intervention

The findings from the interest diagrams are synthesized and presented through charts, consolidating proposed solutions, analyses, developments, and applications. This method facilitates the gathering of technical data necessary for analysis and the initiation of the conceptual design process.

2.3. Understanding Facial Anthropometry

Anthropometry is the branch of science that deals with the physical properties and analysis of the human body, such as size, shape, strength and working capacity. Frequently used to identify user-product relationships [27]. Anthropometry involves direct measurements of facial soft tissue dimensions. However, these measurements can yield diverse results due to potential errors caused by compression and stretching of the tissues. To minimize inaccuracies, percent skin reader lines, which indicate changes in skin elasticity angles (Figure 5), can be used as a reference during surgical procedures [28].

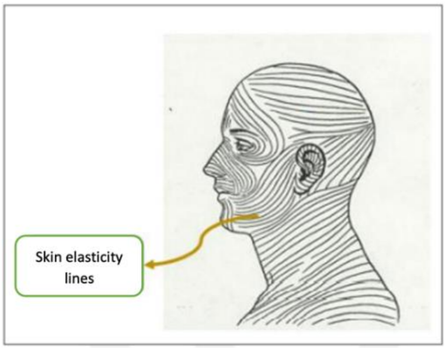

Figure 5. Skin Elasticity Lines

To overcome the challenges of manual measurement, Ma, Munguia, Hyde, and Drinnan (2018) [29] utilized reverse engineering techniques on 20 volunteers to create a 3D model of the human face (Figure 6). They employed a handheld 3D scanning device with a sensitivity of 0.1 mm. The objective was to gain a broader understanding of commercially available masks by analyzing them from a 2D measurement perspective and ultimately contribute to design advancements.

To facilitate the differentiation of model features, the obtained models were categorized into three sections: the upper, middle, and lower sections. The data from the 20 volunteers are presented in Table 3, with a deviation of approximately ± 3 mm observed for all dimensions [29].

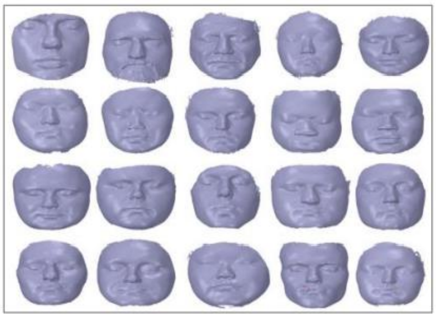

Figure 6. 20 volunteers to create a 3D model of the human face [29].

Table 3. Average facial measurements obtained from models [29].

Item	Dimension (mm)
The distance between eyes (eyelid)	26.26
The distance between eyes (Centre of eyes)	72.94
Width of eye	45.26
The distance between double cheeks	84.14
Eyebrow to Eye	27.48
Width of mouth	67.94
Height of mouth	23.36
Bottom of the nose to Upper Lip	16.25

3. EMBODIMENT DESIGN

The results and needs obtained in the previous section formed the basis for conceptual design, which is the second stage of the systematic design approach. According to this list of needs, design variants were created with a process that first diverges and then converges. Firstly, the general working structure and sub-functions of the product were determined with the function diagram [30]. This diagram can provide a holistic view of the design and make it easier to approach the ideal solution. Then, solution suggestions meeting these sub-functions were brought together in a morphological matrix. After some evaluation and elimination of the design options obtained, the ideal design concept was determined. Fast intervention, ease of use and application efficiency are the main expectations for the new anesthesia mask. The ideal design concept prioritizes user requests and ensures manufacturability, cost-effectiveness and reliability. Conceptual design aims to reach the most ideal design that can be adapted to developing technologies by determining simple, clear and reliable solutions, taking into account patient needs and other boundary conditions [31].

3.1. Embodiment Design Process

Decisions such as determining the final dimensions for the ideal design option determined at the conceptual design stage, creating the construction structure, determining production methods, and material selection are made in the shaping design. It is aimed to achieve the targeted functions under production and cost constraints. Apart from these, ease of use and ergonomics are among the important design criteria.

Necessary anatomical and atropomimetic features must be determined to model the ventilation mask in accordance with the face form. Geometric problems related to the anatomical structure should be solved with a new design. In order to prevent gas leaks from the mask during ventilation, the lower surface of the mask must be fully compatible with the nose curve and cheek cavity. However, most anesthesia masks do not have a distinct geometric shape for the nose. Standard masks typically have a bottom section designed as a flat surface parallel to the tissue. The air cushions surrounding this lower surface flex according to the shape of the face and ensure full integration. The protrusions on the cheeks and chin contribute to this function with some stretching.

The general form design of the new anesthesia mask has a structure that allows stretching and comfortable sitting with an air cushion. In addition, the curves of the areas in contact with the cheek and chin reduce the rate of gas leakage, unlike standard designs. In the mask design, anatomical harmony was highlighted with drawings made on a 3D human model. The areas of the face where the mask should fit were determined by taking into account the bone structures. The boundaries of the created structure are created so that the end point of the eye socket (orbita) lies between the cheekbones (os zygomaticum) and the jawbone (os mandibula) (Figure 7).

In addition, these limits are determined parallel to the stress lines that show changes in skin elasticity angles. In addition, guide curves were used to combine the geometries that correspond to the lower and upper planes, which determine the boundaries where the mask will contact, and to create solid models. These curves are designed to be combined into optimal palm and finger positions for healthcare professionals during interventions. The mask, designed according to the facial contours of a specific human model, was also tested on two human models with different contours (Figure 7). In order to test the compatibility of the observations made in the computer environment, a prototype was printed from polylactic acid (PLA) material with a 3D printer.

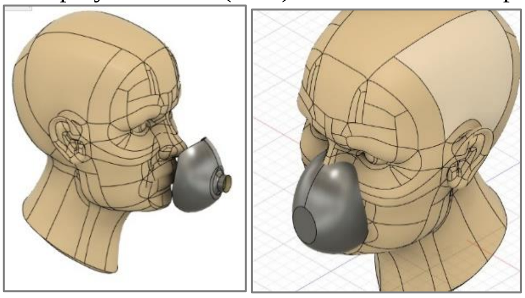

Figure 7. Adapting the mask to the contours of the human face

The compatibility of this prototype with the human face and its comparison with the standard mask was tested on 1:1 scale models in the Model Laboratory of Istanbul Health and Technology University as in the user experience design section (Figure 8).

According to these tests, geometric incompatibilities were observed in the chin and nose areas. Concave structures in these regions caused unwanted gaps. It should not be forgotten that the new mask that addresses this problem is adaptable to different facial contours. For this reason, nasal wires typically used with paper/cloth masks have been integrated into the silicone-based anesthesia mask. Thus, the manual pressure applied during the application eliminated the air leakage in the nose and chin area by stretching the airbag and nose band.

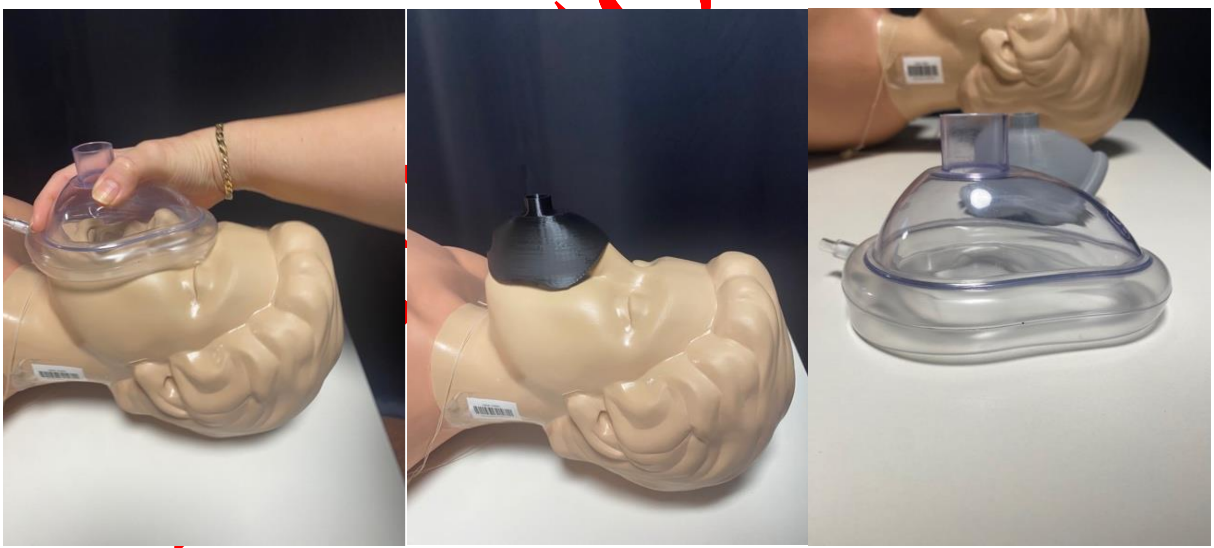

Figure 8. Human face was tested on 1:1 scale models and compare with the standard mask

Figure 9. Testing the mask on different human models

3.2. Functional Design

In this section, the designs were focused on fulfilling the mask's functions, considering the previously determined general form. A study was conducted on the use of felt to achieve conformity with the face shape and ensure full coverage, which is a crucial aspect in form design. These felt elements, commonly known as dust seals in the market, are typically employed in hydraulic cylinders, where their outer surfaces play a significant role in sealing [32]. To ensure the desired performance of the felt's outer surface, it was taken into account when designing the form of the anesthesia mask. An interface form was added to the model, specifically for the airbag and the part that comes into contact with the face. A notch-shape was included above, aligning with the nose area. Additionally, an inward fold was incorporated, following the working logic of the felts, to minimize air escape (Figure). This fold creates a structure that supports the airflow towards the inner surface when themask is fully fitted. Parallel lines were added to facilitate the integration of this fold on the outer surface with the face. To achieve this, the protruding structure of the felt is folded inward, resulting in a narrower contact area.

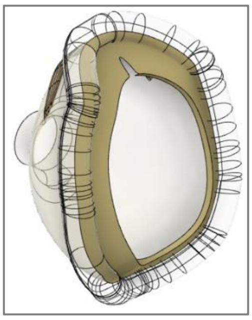

Figure 10. Adding crimp to prevent air escape

A vacuum mechanism has been developed to make the mask fully compatible with the face and to prevent air leaks from the mask [33]. This system aims to provide a better fit between the mask and the face. Here, it is provided by an attachment placed on the mask to remove the air in the breathing circuit (mask, hose and ventilator). This add-on includes a silicone valve to create an alternative air outlet path. Figure 11 shows the combination of parts 1 and 3, the mask surface geometry that effectively prevents leakage. Additionally, part 4 creates a convenient mounting interface for the valve.

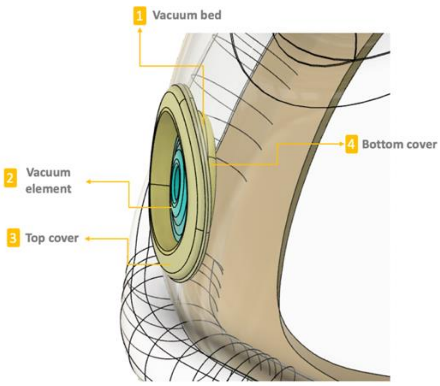

Figure 11. Sealant components

On the other hand, for this system to work, the depth on the inner surface of the mask must increase. For this reason, the mask form was changed and the vacuuming mechanism was moved to the side surface of the mask. Another innovation is the addition of the pneumatic system that controls the pressure, seen in Figure 12, to the mask. This allows sufficient air suction to effectively secure the mask to the airway passages. Figure 13 shows the injector movement required for this vacuum system to operate. By moving the orange part shown in the figure from position a to position b, vacuum is created in the mask.

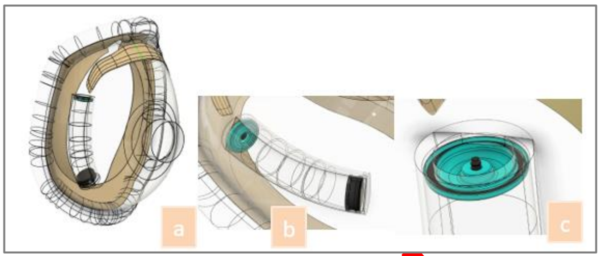

Figure 12. a- Curved form in the side plane of the mask to evacuate air, b- Curved form horizontal view, c-Sealing element between curved form and mask to prevent air leakage

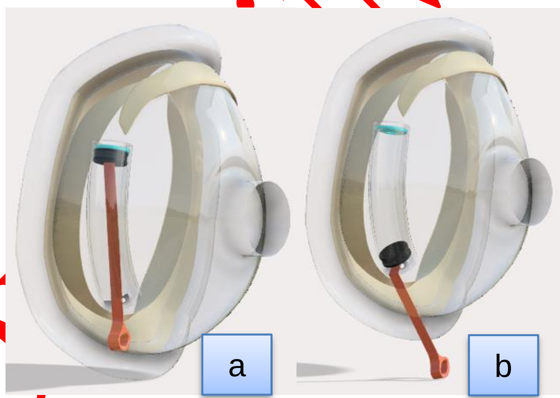

Figure 13. a- Tow strap in normal position, b- Pull strap in use

In the embodiment design section; according to the air leakage flow rate calculation derived from the Bernoulli equation, changes were made with the data that as A (area) decreases, the leakage also decreases (1). In this way, open areas were reduced by aiming for optimum closure with the new form.

$$Q_{\text{leak}} = C_d \cdot A \cdot \sqrt{\frac{2\Delta P}{\rho}} \tag{1}$$

Cd: Discharge coefficient (usually 0.6-0.9)
A: Leakage area (m²)
ΔP: Pressure difference (Pa)
ρ: Density of air (kg/m³)

3.3. Design for Production

Design for production is a design approach that enables products to be manufactured easier and faster and optimizes the production process for this purpose. In this context; manufacturing operations are reduced and simplified, tolerances and runs are reduced, special equipment and molds are avoided, parts numbers are reduced and their shapes are simplified, and excessive/unnecessary work/operations are avoided. Thus, the total production cost can be reduced. Below, the extensive changes made to the anesthesia ventilation mask design for production are explained. The anesthesia mask ultimately consists of six parts as seen in Figure 12. It is planned to use elastic silicone elastomers as the general production material [34]. With a wall thickness of 2 mm, the material will allow the desired stretching and will be able to maintain its shape during the intervention of healthcare personnel during application. This wall thickness meets the required stretch parameters of up to 20% during application and maintains the material's tear resistance [35]. Tension band number 1 works together with sealing plug number 3. These two components provide ease of assembly with the plug-in mechanism. After the plug is installed on the main body, it is fixed with a tensioning strip. The channel on the plug, with the opening at the edge, simplifies both the manufacturing process and assembly. A significant challenge during the transition from prototyping to mass production involved deformation during demolding. This issue can be mitigated by reducing molding tolerances to ±0.1 mm and utilizing high-precision CNC machinery.

The airbag group indicated by number 2 plays a vital role in meeting user experience requirements. The air cushion increases conformity to facial contours and contributes to overall comfort. These airbags are combined with the main mask body by tight fit, eliminating sizing problems in injection molding [36]. This unit is a thermoplastic elastomer material commonly used in standard anesthesia masks. The softness and flexibility of this material helps the mask perform the required function [37]. The nose strip numbered 4 is silicone elastomer supported by steel wire. Finally, sealing element number 5 is purchased ready-made and mounted on the main body. In the selection of this element, materials with low VOC (volatile organic compound) emissions were prioritized, emphasizing environmental sustainability.

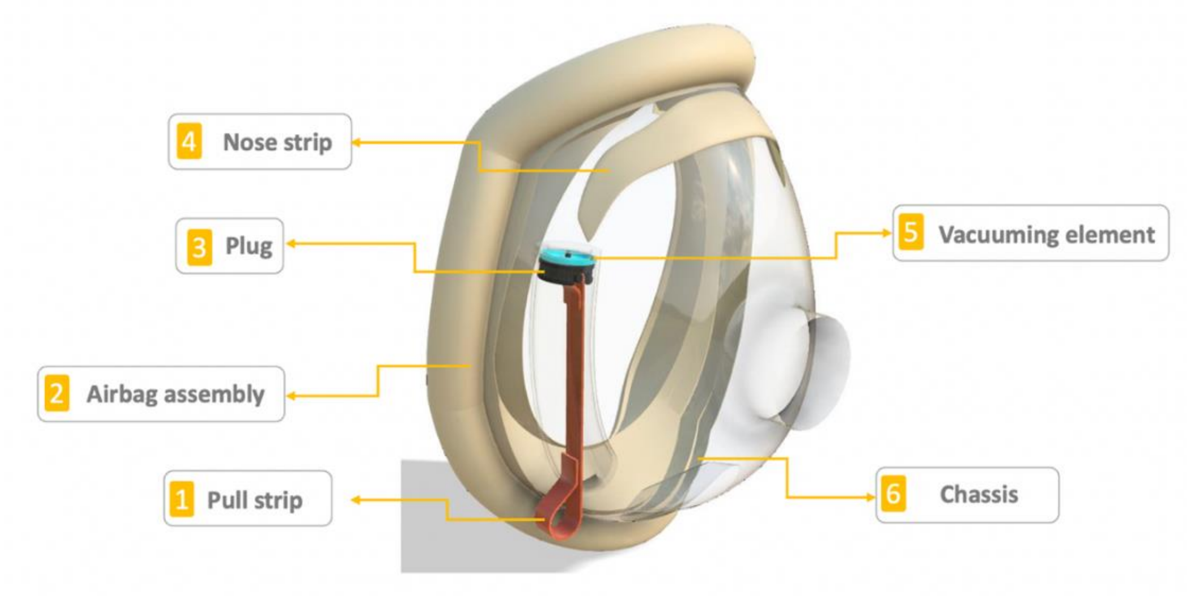

Figure 14. Components of the new anesthesia mask

3.4. Creating the User Scenario

A user scenario is a visual diagram that explains how to use the product in a manner accessible to most individuals. It helps designers identify specific issues and develop solutions that prioritize the user experience [38]. All the stages depicted in Figure 15 should be carried out within healthcare institutions and by healthcare professionals.

The prototype of the newly designed mask was evaluated through usage scenarios conducted on a model. In the prototype, the PLA material failed to provide the flexibility of medical silicone typically used in standard masks. It is desired that the air cushion section of the mask, when produced with the intended material, matches the dimensions of a standard mask. Due to the inability to achieve the required flexibility in the prototype, analyses related to air leakage and the placement of the nose strip could not be performed. This was attributed to the inability to position the plug in the channel where vacuuming is intended to occur. With this prototype, it was observed that solutions were only achieved for the first and third most critical issues identified in Table 1 during the user experience analysis. The first issue, ensuring proper fit to the patient's face, was resolved by designing the form to align with the complex three-dimensional contours of the human face, allowing the surface to follow the curved facial features harmoniously. Additionally, the third issue, which involved excessive pressure on the eyes, was addressed by reshaping the protruding edge into an upward-extended form (Figure 16).

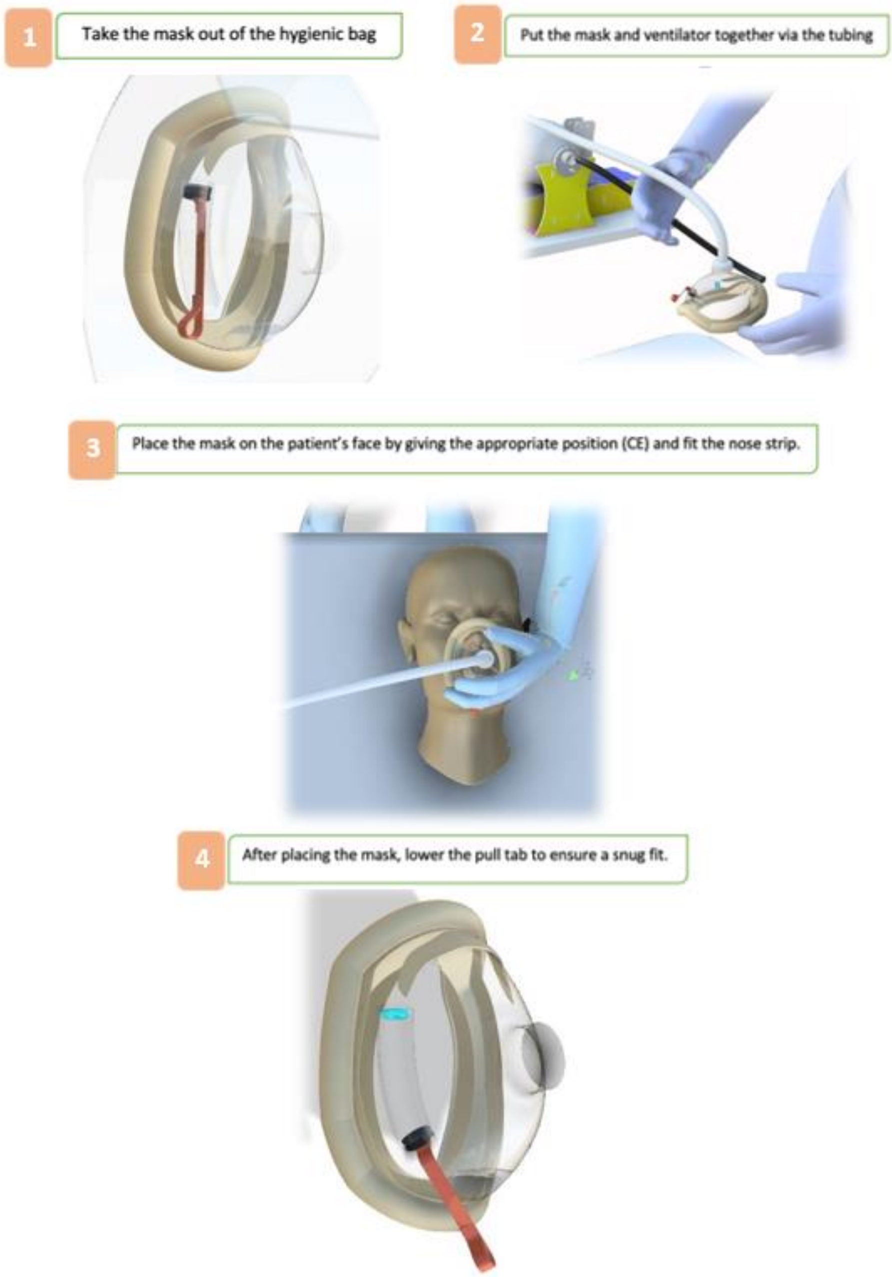

Figure 15. Detailed treatment views for the usage scenario

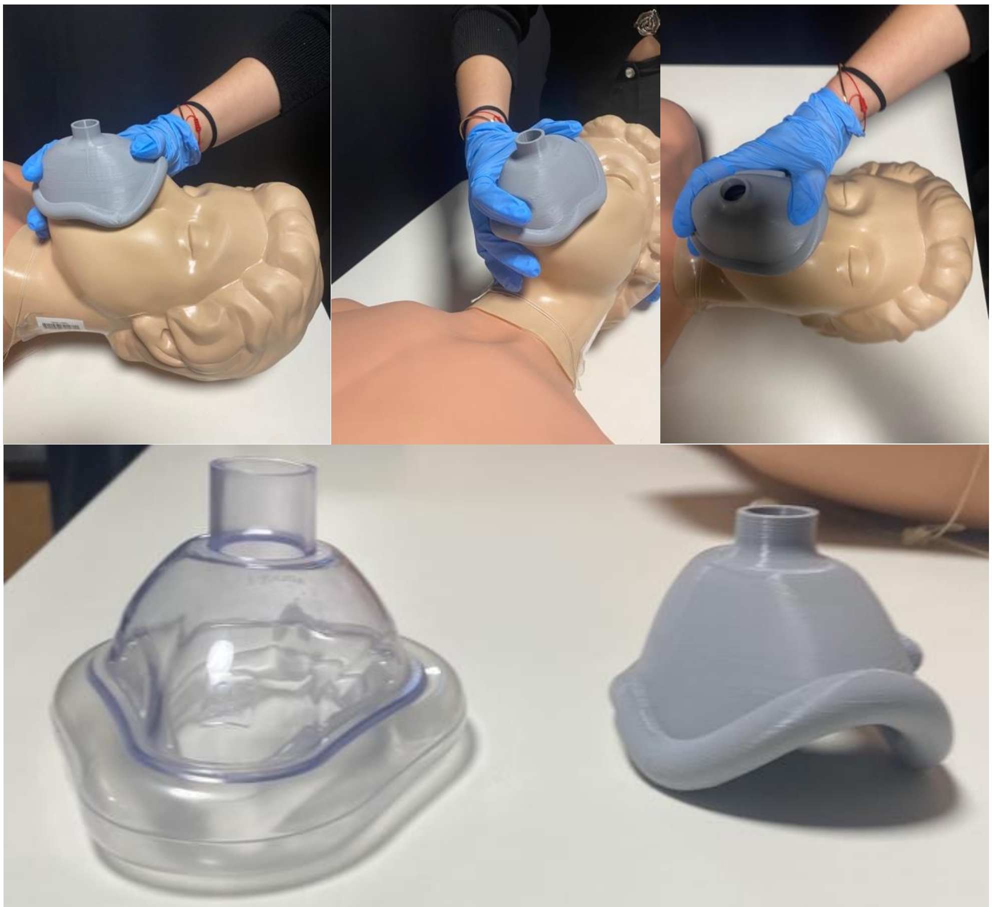

Figure 16. Prototype design and use case

4. RESULT AND DISCUSSION

This study focused on designing a new mask for epidemic diseases by analyzing both protective and therapeutic masks as part of a master's thesis. Common issues encountered during epidemics include limited access to therapeutic materials, shortages in personal protective equipment, insufficient healthcare personnel, and challenging working conditions. Therefore, alongside successful patient treatment, facilitating treatment methods and ensuring patient and healthcare personnel comfort were considered as crucial factors.

To comprehend user interaction with masks, a thorough examination of user experience design was conducted. Affinity diagrams were created to organize information gathered from the healthcare field and facilitate the transition from theory to practical user experience design. The findings were processed in these diagrams, resulting in clear solutions. Moreover, these diagrams highlighted crucial factors, prompting further research in related areas. Consequently, detailed investigations were conducted on intubation, mask treatment processes during the COVID-19 epidemic, and mask ventilation procedures, gathering essential design information from literature sources. This comprehensive approach allowed a clear understanding of the requirements, desires, and needs of both healthcare personnel and patients before delving into the conceptual design phase.

Optimal solutions were developed based on the conceptual design. Embodiment design was employed, starting with user-driven forms and computer-based modeling experiments on various facial features. The initial form underwent changes to align with the system's operating principles, resulting in positive design outcomes. Fundamental modifications were made to ensure the required functionality, while dividing the main assembly group into subgroups facilitated the production process and brought internal solutions. Each change in this stage improved the design and enhanced its functionality. Upon completing the design changes, the model was finalized. The subsequent step involved explaining the treatment process through diagrams and visuals, demonstrating the unique improvements compared to standard masks with realistic computer-generated views. This study outlines the stages of designing a new anesthesia mask, which differs from existing market options that perceive the human face as 2D and offer simplistic designs. The product's user-friendly nature and technological solutions set it apart from competitors, effectively meeting the expectations of the target user group.

Although various test methods are available to assess air leakage, obtaining completely accurate and realistic data from prototypes remains challenging. Laboratory measurements, while providing preliminary insights, are typically conducted under controlled and idealized conditions that may not fully reflect real-world scenarios. Techniques such as soapy water tests, pressure drop analysis, or ultrasonic detection serve as baseline methods to evaluate the sealing performance of prototypes. However, the actual performance of the mask, particularly its adaptability to diverse facial anatomies, can only be rigorously assessed through experimental studies conducted on the final product. To achieve this, advanced manufacturing techniques must be employed to produce the final version of the mask, which should then undergo testing under conditions that simulate real-world usage. Furthermore, experimental investigations involving participants with varying facial features are essential for generating comprehensive and reliable data on the mask's sealing performance. Such extensive studies, however, necessitate a long-term research framework and a significantly larger cohort of subjects. Therefore, it can be concluded that an accurate and thorough evaluation of air leakage is achievable only through detailed and prolonged investigations using the finalized product.

Integration of user experience design into the conceptual design phase enables consideration of user needs,expectations and usage experiences in the early stages of the design process. This integration promotes a user-centered approach from the beginning of the design process, producing user-friendly, functional and effective results. In addition, this methodology enables the detection of user experience problems and potential solutions before the final stages of the product development process. Thus, a more economical and faster design and production process can be carried out. Another important aspect of this study is that it has a great user potential since the design is made directly on 3D human models. Thus, a new anesthesia mask can be designed that is different from existing market options.

DECLARATION OF ETHICAL STANDARDS

The author(s) of this article declare that the materials and methods used in this study do not require ethical committee permission and/or legal-special permission.

AUTHORS' CONTRIBUTIONS

Cansu KARDAŞ: Optimized the processes and realized the design and presented the results.

Hüseyin Rıza BÖRKLÜ: Completed the writing process of the article.

Nurullah YÜKSEL: Optimized the processes and ensured that the design process progressed correctly.

CONFLICT OF INTEREST

There is no conflict of interest in this study.

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