Acta Tecnología - International Scientific Journal about Technologies
Volume: 9 2023 Issue: 4 Pages: 109-114 ISSN 2453-675X

https://doi.org/10.22306/atec.v9i4.179 *Received: 25 July 2023; Revised: 12 Oct. 2023; Accepted: 11 Nov. 2023*

Technological process of design and production of facial burn mask

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Keywords: skin burns, facial mask, facial orthosis, 3D printing, 3D scanning.
Abstract: This article deals with the issue of the management of facial burn treatment using an orthotic device. Discusses the possibilities of using thermoplastic as a suitable material for the production of facial orthosis. It describes the methods of obtaining measurement data of the patient and the subsequent design and production of the orthotic aid using traditional and innovative methods. Subsequently, a model of the human face was obtained using the Artec Eva optical hand-held 3D scanner, which served as a basis for the design of the facial mask in the Meshmixer software. From the conclusions, it is clear that the process of manufacturing a burn mask using innovative methods brings many advantages, in terms of patient comfort and time-saving, compared to conventionally used procedures. After verifying this methodology and verifying the biocompatibility of the proposed material, it would be appropriate to put the methodology proposal into practice.

1 Introduction

Burns are one of the most common injuries in all age groups. Globally, according to the World Health Organization (WHO), approximately 180,000 people die from burns each year. They are mostly people from low to middle-income countries, where, statistically, the most burn victims are. Of this number, up to two-thirds are from Africa and the regions of Southeast Asia. This is also related to a higher level of education in the field of burns and knowledge of providing first aid in more developed countries, where the number of burn victims decreases every year thanks to the rapid development of medical facilities [1].

Scars are the long-term complication of burns to the face, head, neck, and other areas. Over time, these can significantly limit the mobility of some parts of the patient's body. The formation of a scar is associated with a contraction, which leads to a disturbance of the movement properties, especially of the lips (microstomia), or the eyelids. When such a scar occurs, the only option to restore the functionality of the tissue is to cut out the scar, which, however, creates a defect on the face. Therefore, the optimal solution is to eliminate the risk of these scars in the healing phase of the damaged tissue [2].

Hypertrophic and keloid scars are caused by deep burns, which we classify between the second and third degree. These scars need to be treated appropriately and taken care of so that they are as aesthetically and functionally acceptable for the patient as much as possible. In general, the deeper the burn and the longer the healing time, the more prone the damaged tissue is to excessive growth - hypertrophy. The scar does not become hypertrophic immediately after the healing of the burned area, but only during the first 3-6 months after the burn. After this time, hypertrophic scars tend to regress, meaning they flatten, soften, and become lighter in color and more elastic. The risk of developing a hypertrophic scar is higher in children and adolescents than in adults [2].

During the first to sixth month of healing, hypertrophic scars are pink, red, or purple, and their surface is raised. They are dry, tend to itch, and are sometimes even painful. Their structure is rigid, brittle, inflexible, and without elasticity. Stripes tend to form on their surface. Scars themselves deform, but they also deform the undamaged tissue around the scar. With more serious deformations, limited movement of the joints may also occur. Sometimes small blisters with clear contents or with blood form on the surface of the scar.

This can occur with mechanical damage to the scar or when the ducts of the sweat and sebaceous glands located under the scar are blocked [3].

In the period of one to three years after the burn, the scar becomes more flexible and pliable, which means that it is possible to shape it with different procedures.

In some cases, patients are forced to undergo reconstructive plastic surgery, where the damaged area is cut out. As far as non-invasive procedures are concerned, it is also customary to apply lubricate the scarred area, pressure massages, or splints [3].

Some scars tend to exceed the size of the original scar, which are keloid scars. These scars are coloured purple, are significantly raised, and do not tend to regress. The treatment of these types of scars is therefore much more difficult than the treatment of hypertrophic scars. Freshly formed scars must be protected from mechanical and chemical damage and adverse physical influences [2,3].

The goal of the research is to introduce the design of additively manufactured orthotic aids that are used for the treatment of burns, specifically burn masks that are made of transparent thermoplastic, individually based on a 3D scan (or cast) of the part of the patient's body.

2 Methodology

Burn treatment can be divided into the following categories:

- Medicinal treatment – cooling gels, topical ointments, pain relievers,
- Treatment using medical material – hydrophilic, gauze, elastic, biosynthetic, or pure cotton bandages, silicone patches,
- Treatment using an orthotic device – textile or plastic face mask,
- Skin transplantation – skin replacement with a skin graft,
- Implantation of biomaterials – e.g. Integra [4,5].

When treated with an orthotic device, these are orthoses that speed up the tissue healing process for patients after suffering a burn and also allow doctors to monitor the healing process without the patients having to take off the mask. They also serve as prevention against the formation of hypertrophic and keloid scars.

Currently, the conventional method of producing burn masks is by casting and then molding thermoplastic material over a patient model, which creates a replica of the contours of the patient's face.

2.1 Materials used for facial burn mask production

Choosing the right material is one of the most important parts of the medical device manufacturing process. Polymers in particular have many properties that can be used for medical applications. They are divided into three groups - thermoplastics, thermosets, and elastomers [6]. The most advantageous material for the production of a burn mask is a transparent thermoplastic. The advantage of thermoplastics is the possibility of producing the aid using additive manufacturing technology [7].

Also, its transparency ensures trouble-free monitoring of the condition of the damaged part of the body, without having to remove the device from the patient. Thermoplastics, which will be used as production material for facial masks, must be well tolerated by the human body. This factor is especially important from the point of view of higher susceptibility to infection after a burn. Among the thermoplastics that can be used for the production of facial masks are e.g. PLA (Polylactic acid), PP (Polypropylene), PE (Polyethylene), and PCL (Polycaprolactone).

Burn masks can also be made from thicker fabrics. These masks also apply pressure, but it is not possible to monitor the condition of the burn through them. However, these textile masks provide better breathability than thermoplastic masks. One of the usable textile materials is, for example, Sohatex. It is a highly elastic black material. It has a special spatial structure that ensures the skin's breathability. Its fibers help to keep the skin dry by transporting moisture away from the skin. For example, the use of elastic knitwear is also suitable, because this material can provide suitable circular compression [8].

Silon-STS (STS – Silicone Thermoplastic Splinting) is another optimal material for the production of facial burn masks. It is a product that combines the good formability of thermoplastic and the healing effects of silicone coating. It is a thermoplastic burn mask that is lined with silicone on the inside. The silicone sheets are used to treat scars. They act as a barrier against external, harmful influences. Silicone can mimic human skin and retain moisture in the body. It also prevents itching and redness of the skin during treatment. The silicone-lined burn mask also provides spot heating to adjust mask pressure [9].

2.2 Facial burn masks

There are also mass-produced orthotic aids for the treatment of burns – textile burn masks. However, they are less practical, as they are produced in only a few sizes and it is also not possible to monitor the condition of the skin through them.

HealthPartners (Minnesota, U.S.A.) offer a custom-made translucent face mask. This mask acts on the tissue with a slight pressure, which prevents the hypertrophy of the scars. Compression of the mask is achieved by strapping it to the back of the patient's head and securing it enough to exert slight pressure on the damaged tissue. The effectiveness of this facial mask depends on two factors: good coverage of the facial surface (the mask should follow all the folds and contours of the face) and adequate application of pressure on the scars. A big advantage of this facial mask is its transparency, thanks to which the doctor can monitor the compression areas of the mask for scars and modify the mask accordingly [10].

Scheck & Siress Prosthetics (Chicago, U.S.A.) also produce similar facial mask.

The plastic burn mask from this company has a layer of silicone applied on the inside for patient comfort and for the beneficial effects of silicone on wound healing. Jobskin (Nottingham, United Kingdom) also uses plastic facial mask to speed up the healing process after burns and to prevent the formation of keloid scars. Masks are made from high-temperature thermoplastic, which is covered with a layer of silicone. This combines the beneficial effect of silicone and the effect of moderate pressure by mask [11].

According to some studies, masks can be used after skin graft transplantation, or they can also be applied directly to the burned tissue if it is capable of regeneration [12]. Mass-produced burn masks include textile antimicrobial compression masks that use a pressure of approximately 15 to 25 mmHg to reduce capillary flow. This type of mask is globally one of the most widely used aids for regeneration after facial burns. Textile masks are produced in series, they are mostly available in sizes S, M, L, XL [13].

2.3 Obtaining measurement data

To design a burn mask, it is necessary to obtain the dimensions of the entire facial part of the subject´s head. The model should accurately copy the contours of the face region and also capture detailed areas such as folds around the nose, chin, and supraorbital arches, as the goal of this mask is to make the patient's face as close as possible to its original state before the burn.

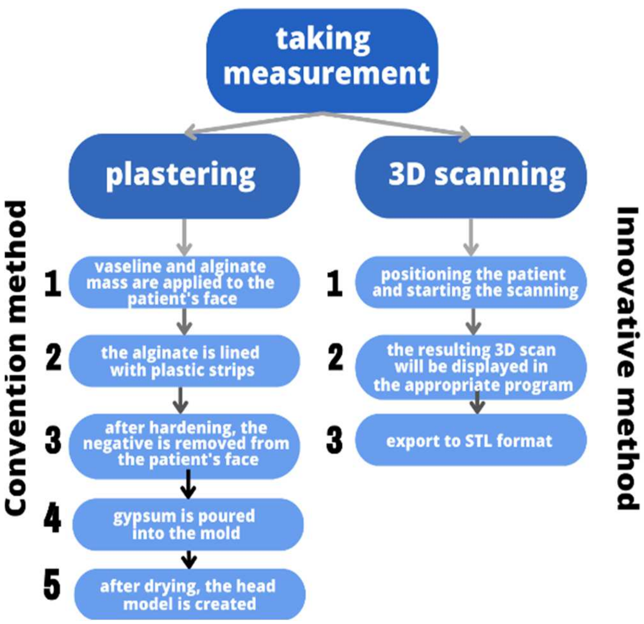

Figure 1 Methods of taking measurements for the production of a burn mask

2.3.1 Conventional method of acquiring measurement data

This traditional method consists in covering the wounds with plaster, which is time consuming and physically exhausting for the health worker and painful and uncomfortable for the burn patient. Sometimes it is necessary to give anesthesia to the patient during this process. This method produces a lot of waste and often injures the health worker [14].

The advantage of acquiring measurement data with traditional plastering is mainly the low price and the requirements for only basic equipment. There is also no need for special training of health workers. With such plastering, the health worker can influence the patient's soft tissues with his strength and thus get a more accurate model. This is especially useful in the hair area, whereby by pressing the hair to the head, a more detailed model of the skull can be obtained. However, in some cases, the action of the health worker's power can lead to the deformation of the tissue, which will give distorted results. This occurs especially in cases where measurements are taken in places with soft, pliable tissue [14].

The procedure consists in applying an alginate mass, which hardens over time and serves as a mold for making a cast on the patient's face [10,15].

2.3.2 Innovative method of acquiring measurement data

The manual 3D scanning process offers several advantages over traditional contact measurement. This method is completely painless for the patient, non-invasive, and there is no risk of transferring bacteria, as there is no contact with the patient's burned face. In addition, this method is also very fast, physically easy, and clean for an experienced worker. The resulting 3D scan of the patient's face provides detailed contours of the face, which is not always possible to obtain with a plaster cast.

The main disadvantage of 3D manual scanning is the higher price of this device [16].

2.4 Production technologies

There are several ways of produce the facial burn mask itself. When choosing a suitable production technology, the material from which the mask is being made, is mainly taken into account.

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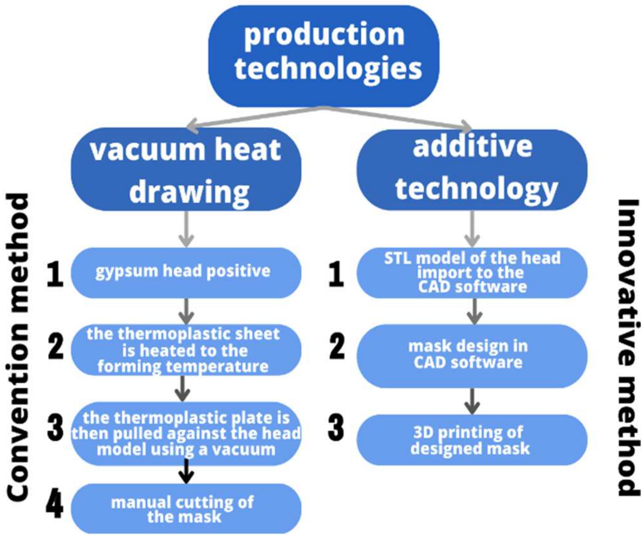

Figure 2 Burn mask production technologies

2.4.1 Conventional method of burn mask production

This method involves vacuum forming or deep drawing of thermoplastics. Vacuum forming is one version of thermoforming. The principle is that the thermoplastic sheet is heated to the forming temperature. It is placed in the device together with a mold model of the facial part of the subject's head. The heated thermoplastic is then pressed against the model using a vacuum. One of the disadvantages of this molding method is the occasional formation of bubbles on the inside of the plastic, which reduces the quality of the product. There is also a risk of overheating the material, which results in the formation of bands around the mold [17].

Another variant of mask production by drawing is a deep drawing of thermoplastics using a vacuum. In this case, the processed plaster model is placed on a stretching ring with a vacuum outlet. The thermoplastic is attached to the stretching hoop and can be heated in the oven. After heating, the thermoplastic hoop is stretched to the positive. It is necessary to focus on the even distribution of forces in the hands. After hardening and cooling, the facial mask is removed from the positive and sanded [18].

2.4.2 Innovative method of burn mask production

The advantage of using innovative methods such as additive manufacturing (3D printing) is the production of the mask exactly according to the digital design with high surface accuracy, the application of special shapes and patterns, normally complicated or impossible to produce by conventional methods, and rapid production. Additive manufacturing of the mask significantly reduces the amount of time and also the material, which would be otherwise used to make a model of the face mask or would be cut off during the final shaping of the mask into the desired shape.

This entire process is eliminated when using additive manufacturing technology for burn mask production.

Another advantage is that there is no need to cut holes for the eyes, mouth, and nose in the mask, as they can be designed directly in the software. It is also possible to print the device with a porous structure to prevent sweating and other skin problems caused by insufficient ventilation.

The disadvantage is the initial high price of the device, either of the 3D printer itself or the material used, but it is more efficient from a time point of view, which means a reduction in the number of standard hours required for the production of the mask. In additive manufacturing, a certain amount of expertise is also important, which is not very common. Also, it is not possible to use all available materials in 3D printing that would be suitable for a burn orthotic device such as Silon-STS. While traditional silicone cannot be directly printed using conventional 3D printers, some alternative materials and techniques can replicate some of its properties, such as TPU (Thermoplastic Polyurethane), some soft resins or thermoplastic polymers with additives to achieve a similar level of flexibility and softness.

The procedure is to first insert a 3D model of the subject´s head into the CAD (Computer Aided Design) software. The model will be adjusted and the orthotic aid will be designed directly in the software. It is separated from the head model in the software and can then be produced using the FDM (Fused Deposition Modeling), SLA (Stereolithography), or SLS (Selective Laser Sintering) technology. Material suitable for 3D printing of an orthotic device is, for example, PA (nylon), PU (polyurethane), or PLA [19].

2.5 *Facial burn mask design*

One of the proposals to simplify the design and production process of a facial burn mask starts with scanning the patient's face. After obtaining a 3D model of the head with an adequate 3D scanner, such as Artec Eva 3D scanner (Artec 3D, Luxembourg, Luxembourg), the mask was modelled in the appropriate CAD software Meshmixer (Autodesk, San Rafael, California, USA). First of all, it is important to mark the area of the face that the mask should cover. The mask should not extend below the supraorbital arch, as the compression applied to this area could cause pain for the patient. The mask covers the entire surface of the face, i.e. from the hairline to the bottom of the sledge, except the eyes, mouth, and nose. Lateral openings in the area of the sphenoid bone and under the cheekbone were modelled in the program for the placement of Velcro straps. After the exact marking of the surface, it is necessary to set the required thickness and smooth the corresponding edges. The thickness of the model was set to 1.8 mm. The standard range of mask thickness is between 1 and 3 mm, depending on the required level of stiffness or flexibility.

If necessary, the mask can be aligned with the original 3D scan of the face to verify the accuracy of the mask model. The resulting model is exported in STL (Standard

Triangle Language) format, which is suitable for additive manufacturing.

This method of designing a burn mask was relatively quick (less than 1 hour), with minimal subject involvement. The final quality of the actual mask depends on the selected material and the chosen additive manufacturing technology.

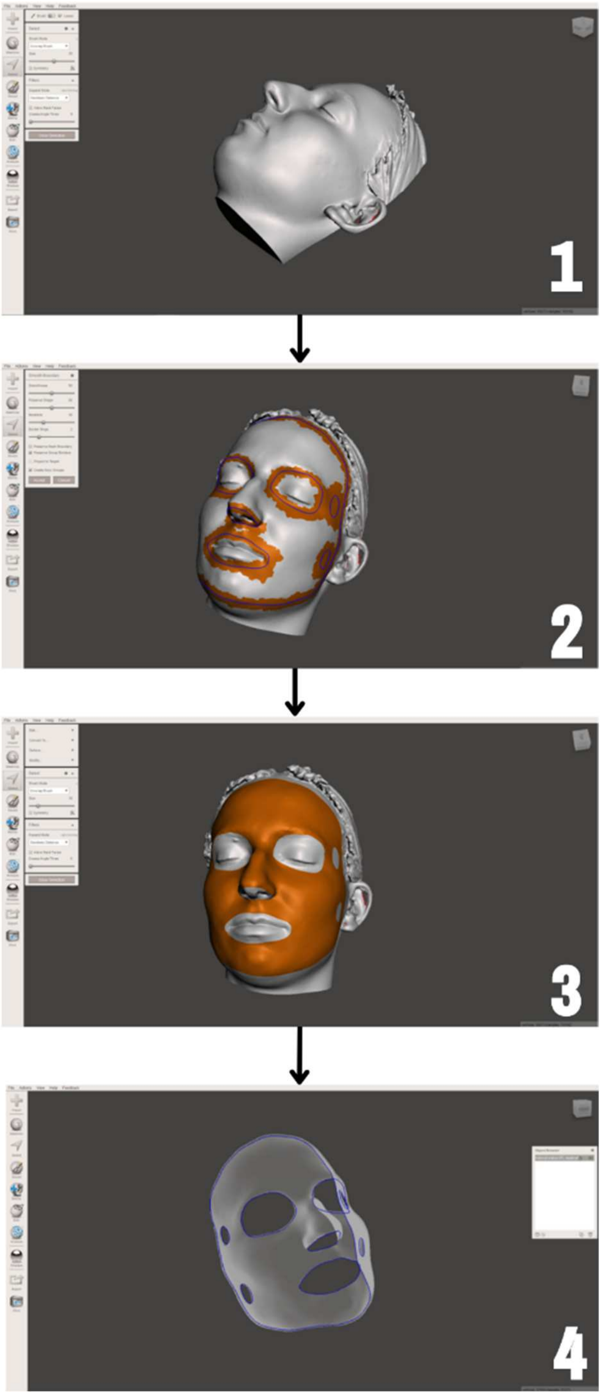

Figure 3 Illustration of facial mask modelling (Meshmixer software)

3 Discussion and conclusions

As part of the study, various methods of manufacturing a burn facial mask and also of taking the subject´s measurement data were presented. A conventional and innovative method of producing a burn mask was described. The conventional method of production has been used in the healthcare industry for many years, and therefore it is necessary to come up with a solution that would increase the comfort of the patient and make the work easier for the health workers. Based on this, the innovative possibilities that modern technologies offer us were highlighted.

By using a 3D scanner, measurement data were obtained for the design of the medical device. The freely available CAD software Meshmixer was used for editing 3D models and for the actual design of the burn mask. This innovative procedure allows the mask design that copies the topography of the subject´s face with high surface accuracy.

Additive manufacturing and 3D scanning greatly simplify the complicated process of manual burn mask production, with a great advantage, which is the non-contact and pain-free process for the patient. The mask model made using the described methodology is suitable for additive manufacturing. PA, PU, or PLA materials were selected as materials suitable for the production of this medical device. These materials are biocompatible and are used in orthotics development, but it is necessary to verify their suitability for burn wound treatment.

Future research will include the design and additive manufacturing of a mask for a specific patient with a facial burn. The research will also focus on material possibilities in orthotherapy for facial burn treatment.

Acknowledgement

This work was supported by the Slovak Research and Development Agency under contract No. APVV-19-0290. This work was supported by the Slovak Research and Development Agency under contract No. APVV-22-0340. This research was supported by project KEGA 044TUKE-4/2022 Implementation of progressive technologies in prosthetics and orthotics education and support integration with practice. This research was supported by project VEGA 1/0599/22 Design and biomechanical analysis of personalized instruments for arthroscopic applications.

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Review process

Single-blind peer review process.