Feasibility of Fabrication of transparent face orthoses by using 3D printing technology

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INTRODUCTION

Hypertrophic burn scars are the most common complication of a burn injury and can limit a survivor's ability to function as well as affect their body image. The use of external pressure as a non-invasive means of prevention and treatment of hypertrophic scars had been widely accepted.[1, 2] By the application of adequate pressure for a correct period of time, scares can be made softer and flatter. A transparent face orthosis (TFO), sometimes called a transparent facial mask, is widely used for facial burns treatment regarding the effectiveness of the TFO to minimize the hypertrophic scarring and maintaining the face contours against the deforming scars[3, 4]. TFO fabricated from an accurate pattern of the head eliminates many of the disadvantages of elastic garments. Furthermore, Groce et al found that although no significant difference in pressure under a TFO compared with a custom pressure garment, patients with facial scarring appear to accept the appearance of a TFO over the elastic hood because it is more socially acceptable as a result of the exposure of facial features in public.[5]

Generally, there are two methods of fabricating the facial mask that practiced by the occupational therapist in rehabilitation unit. First is the traditional method that involves a lot of processes and direct contact with the burned patient. The fabricating process included using dental alginate as a casting material, applying plaster bandages for reinforcement, filling liquid plaster for molding the mask, and using high-temperature thermoplastics to vacuum the mask mold.[6] This traditional method had to take several hours of labor-intensive and often discomfort to the patient. The latest technology for fabricating TFO is by using a 3D scanner that scans the facial area. The 3D scanner was used to provide the cloud data. The point of cloud data from the scanning process will be used to generate the mask using computer-aided design (CAD) software, and the part will be exported to a stereolitography or stl file for rapid prototyping process. This process improves the accuracy and fabrication on the concave or convex body area. Face mask built using this 3D scanner technology had been reported in a case study. It was proven that the accuracy and fitting of the mask are better than using the conventional method. [7] However, as 3D printing technology improves, more 3D printed methods are used to implement the project. In health care, three 3D printing processes: selective laser sintering (SLS), fused deposition modeling, and inkjet printing, have emerged and almost overtaken stereolithography in terms of frequency of use. The one of these, inkjet printing uses a print head that deposits thermally or mechanically droplets of “material ink” layer by layer to form the object. By virtue of its high resolution and low cost, inkjet printing is more available to the consumer market today, as an inexpensive go-to machine. Therefore, the purpose of this study was to investigate the feasibility of fabrication of TFO by use of non-contact structured light scanning with inkjet 3D printing technology. It was intended to provide a practical means of new fabrication technology for TFO.

METHOD

Participants

Fifteen able-bodied participants were recruited through posters in public spaces. Participants were included in the study if they met the following criteria: 20 years of age or older; did not have previous history of muscularskeletal or nerve injuries causing involuntary facial movements such as facial tics. If the participant appeared facial skin irritation after wearing mask, the participant was excluded. Participants were informed of the nature of the experiment and signed informed consent in accordance with the procedures approved by the Institutional Review Board of the Kaohsiung University Hospital prior to participation in the study. Afterwards, all participants were asked to go through the fabrication process by two methods. The order of fabrication process was assigned by the use of a computer-generated random number sequence.

Fabrication of TFO using traditional method

Participants were positioned in semi-reclined position on the hospital bed. The experienced occupational therapist performed the casting produces for all participants. The first step in making the mask, the participant's face was covered with dental alginate impression materials (Figure 1a) and reinforced with plaster bandages. Afterwards, the impression was removed from the patient's face. The inside of the impression duplicated the curves of the person's face. The face impression then was filled with liquid plaster. When the plaster dried, it formed a solid head. The total casting procedure took approximately 25 minutes for each participant, but the facial mold took approximately 72 hours to complete due to plaster mold drying time. Next, the therapist cleaned the plaster head and sanded it smooth. A sheet of transparent thermoplastic was then heated in an oven until the plastic was soft and pliable. The warm plastic sheet was then draped and completely pressed over the plaster head with a vacuum former. After the plastic cooled, the therapist cut openings in the mask for eyes, nose, mouth and ears, and attached elastic straps to the sides.

Figure1. Fabrication process: (a) casting facial mold with plaster; (b) casting facial mold with 3D printer.

Fabrication of TFO using 3D printing technology

Participants were positioned in semi-reclined position on the hospital bed. The three dimensional face image of participants was digitally scanned by a handheld scanner (iSense™ 3D-Scanner, 3D Systems, Inc, South Carolina, USA). The acquisition time was less than 1 minutes to complete the image. Afterwards, the imager was operated by Blender software package (www.blender.org). Extraneous data were trimmed from the scan. Then, any voids in the scanning data are filled by interpolation. Typically, a small amount of data smoothing was applied globally to the entire face. The finished 3D facial model was then exported to a stl file for use in 3D printing. An inkjet 3D printer (mBot Black Stone pluse, Armsource Inc, Kaohsiung, Taiwan) with the quality 0.2 mm layer resolution was used to make a face mold (Figure 1b). The printing process took between 24 and 32 hours depending on the size of face mold. Afterward, the following steps were the same as described above for traditional method including heating transparent thermoplastic, pressing over the face mold with a vacuum former, and cutting openings in the mask.

Questionnaire

After completing fabrication of TFO by using two methods, the participants were asked to wear the TFO which were made from either the traditional plaster mold or 3D printed mold for one hour. The wearing session between two TFOs was one week apart to minimize problems with recall over a more extended time interval. The sequential order of the wearing was assigned by a random number generator. After one-hour wearing, the subjects filled out a subjective questionnaire asking about comfort and identifying the presence of physical discomfort in the regions of the face (Figure 2). Perceptions of TFO fitting comfort were measured by a visual analog scale of 10cm in length. The scale ranged from extreme discomfort (0cm) on the left to extreme comfort on the right (10cm).[8] Subjects were asked to place an "X" on the visual analog scale to represent their level of comfort with each region of face for each TFO.

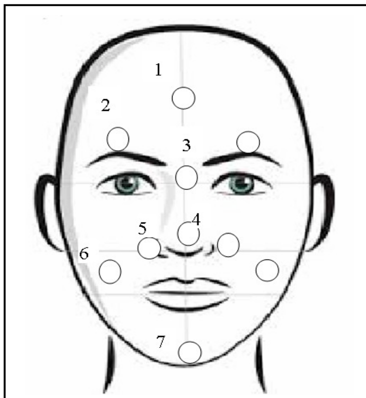

Figure 2. The facial regions

Statistical analyses

Descriptive statistics were used to describe the presence of physical discomfort in the regions of the face. A Wilcoxon Signed Rank Test was used to look for significant differences of comfort level between TFO made from the traditional plaster mold versus 3D printed mold. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp, Armonk, NY, USA). The level of significance was set to 0.05.

RESULT

There were statistically significant differences in reported comfort levels between plaster mold casting and 3D printed mold for casting TFO. Participants with 3D printed mold felt much more comfortable during the fabrication process ($p<0.01$). In term of comfortable fit with TFO, there are no significant differences ($p=0.57$). The comfort of the participants with 3D printed model ranged from 2.1 to 8.7; the range from 1.8 to 7.9 with traditional plaster mold. The presence of self-reported physical discomfort across seven facial regions was presented in Table 1. Most participants with 3D printed mold reported experiencing discomfort in the root of nose (93%). 40% participants reported discomfort in supraorbital ridge, 20% participants reported in forehead region, and 7% participants reported in chin. On the other hand, 53% participants with traditional plaster mold reported experiencing discomfort in the root of nose, 33% participants reported in forehead region, 20% participants reported in supraorbital ridge and chin region. No severe complaints such as stinging, itching, and irritation on facial skin were reported by any participant after wearing TFO for 1 hours.

Table 1. The presence of self-reported physical discomfort across facial regions

n=15	Forehead	Supraorbital ridge	Root of nose	Tip of nose	Wing of the nose	Zygoma	Chin
3D printed mold	3/15 (20%)	6/15 (40%)	14/15 (93%)	0/15 (0%)	0/15 (0%)	0/15 (0%)	1/15 (7%)
Traditional plaster mold.	5/15 (33%)	3/15 (20%)	8/15 (53%)	0/15 (0%)	0/15 (0%)	0/15 (0%)	3/15 (20%)

DISCUSSION

Our results found that the non-contact structured light scanning with inkjet 3D printing technology is feasible to fabricate TFO. No difference was noticed between wearing TFO fabricated by 3D printed mold and traditional plaster mold. The use of 3D scanning systems has gained popularity in recent years. The handheld scanner rotated 360° around the participant's head and captured 3D models of the facial profile and contour. By using this scanning process, there was no direct contact with the participant involve in the process which was different from the previous traditional method that mostly painful to the participant. As shown by our results, participants felt much comfort during the fabrication process. Furthermore, the scanning process took just a few minutes. This significantly reduced the amount of time and resources devoted to each step. The noncontact nature of the3D scanner combined with the speed of shape acquisition eliminated most of the drawbacks of traditional fabrication.

From the results, the root of nose was clearly the most discomfort regions reported by participants with 3D printed model. Although the handheld scanner used in this study claimed resolutions as high as 0.5mm and an accuracy of up to 4mm, our 3D printed model might result in poor accuracy in particular region of facial contour. Through structured light technology by 3D scanner, highlight bridge of nose (usually between eyebrow) might shade down the sides of the nose. Therefore, it might not be able to capture all details in the concavity of the nasal root. It was suggested that softening of a bony nose contour should be done carefully by the CAD software to create facial model. Besides, 3D scanners are gaining accuracy and speed each year. The technology is making significant improvements to make this tool the most reliable possible to get a perfect 3D model. Therefore, it can be expected that more handheld scanners will deliver a very high level of feature accuracy in near years.

3D scanners and printers are gaining accuracy and speed each year. 3D printing technology has great potential to improve the quality of life of people with disabilities by providing options for highly customized and affordable assistive devices for daily living activities. The advantages of non-contact scanning with inkjet 3D printing technology for TFO fabrication include decreased time involved by therapists, an easily transportable imager, and imaging software that is user friendly and requires minimal training. The facial contour can be captured quickly and accurately without discomfort to the patient. Overall, it appears to be a less anxiety-provoking, less painful, simpler, and more efficient process than conventional methods.

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