

A SCALABLE MASS CUSTOMISATION DESIGN PROCESS FOR 3D-PRINTED RESPIRATOR MASK TO COMBAT COVID-19

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4 Abstract:

Purpose: 3D printed custom-fit respirator mask has been proposed as a promising solution to
alleviate mask-related injuries and supply shortage during COVID-19. However, creating a
custom-fit CAD model for each mask is currently a manual process and thereby not scalable
for a pandemic crisis. This paper aims to develop a novel design process to reduce overall
design cost and time, thus enabling the mass customisation of 3D printed respirator masks.

Methodology: Four data acquisition methods were employed to collect 3D facial data from five volunteers. Geometric accuracy, equipment cost and acquisition time of each method were evaluated to identify the most suitable acquisition method for a pandemic crisis. Subsequently, a novel three-step design process was developed and scripted to generate respirator mask CAD models for each volunteer. Computational time was evaluated and geometric accuracy of the masks were evaluated via one-sided Hausdorff distance.

Findings: Respirator masks were successfully generated from all meshes, taking <2 minutes/mask for meshes of 50,000~100,000 vertices, and <4 minutes for meshes of ~500,000 vertices. The average geometric accuracy of the mask ranged from 0.3 mm to 1.35 mm, depending on acquisition method. The average geometric accuracy of mesh obtained from different acquisition methods ranged from 0.56 mm to 1.35 mm. A smart phone with a depth sensor was found to be the most appropriate acquisition method.

Originality: A novel and scalable mass customisation design process was presented, which can automatically generate CAD models of custom-fit respirator masks in a few minutes from a raw 3D facial mesh. Four acquisition methods, including the use of a statistical shape model, a smart phone with a depth sensor, a Light Stage, and a structured light scanner were compared; one method was recommended for use in a pandemic crisis considering equipment cost, acquisition time and geometric accuracy.

Practical implications: The proposed process can be adapted for other types of facial PPE
and wearables.

Keywords: COVID-19, Face mask, Design automation, Custom fit, Mass Customisation,
 Additive Manufacturing

1 Article Classification: Research paper

3 1. Introduction

In June, the World Health Organisation (WHO) affirmed the transmission of COVID-19 by asymptomatic or pre-symptomatic individuals based on growing evidence (WHO, 2020), health agencies worldwide have begun to adopt a change in stance to embracing a policy of encouraging or enforcing mask-wearing. This has created a huge strain on the global supply of respirator masks to frontline Healthcare Personnel (HCP) who are continuously faced with high patient numbers and the threat of infection. Increasingly, reusable respirators (e.g. elastomeric half-mask respirator commonly used in construction and manufacturing) have been proposed as an alternative to disposable respirators (e.g. FFP3 or N95) in a pandemic situation to address the problem of supply shortages (Pompeii et al., 2020). However, regardless of reusable or disposal respirators, studies have shown significant failure rates for mask-fitting of HCP ranging from 9.8% to 54%, largely attributable to a high variance of facial characteristics arising from demographic differences (Wilkinson et al., 2010, Yu et al., 2014). A previous respirator fit test study (n=6,160) has shown strong associations between the race of participants and differences in facial features, which resulted in statistically significant differences in fit test failure rates (Wilkinson et al., 2010). Hospitals with a multi-racial HCP population makeup can be particularly susceptible towards high fit test failure rates, thereby compromising on the availability of frontline deployable workforce and putting increased strains on the healthcare system in a public health emergency, such as the ongoing COVID-19 pandemic.

Apart from meeting high demands for respirators, it is equally important to ensure good fit and comfort for HCP, who often must don respiratory Personal Protective Equipment (PPE) for long periods on a regular basis. A recent study reported high incidence (97%) of skin damage related to enhanced infection-prevention measures, including prolonged wearing of respirators, especially over the nasal bridge and cheeks (Lan et al., 2020). High pressure at the skin/mask interface and long duration of mask wearing has been identified as key risk factors responsible for device-related pressure ulcers (Gefen et al., 2020). Such occupational hazards can put frontline HCP at greater risks of infection, undermine efficiencies and lead to loss of precious manpower in a pandemic. Custom fitting respirator masks to HCP would significantly reduce fit-failure rates, occurrences of skin damage and increase HCP comfort.

Rapid Prototyping Journal

Since the start of the COVID-19 pandemic, 3D printing has been utilized by makers, communities and institutions in various places to produce PPE locally to combat supply chain shortage (Novak and Loy, 2020a, Novak and Loy, 2020b, Wesemann et al., 2020). Various papers have been published to review and evaluate existing 3D printed PPE designs (Wesemann et al., 2020, Novak and Loy, 2020a, Novak and Loy, 2020b, Flanagan and Ballard, 2020, Clifton et al., 2020), and many introduced methods of PPE design and production, such as connectors for breathing devices (Cavallo et al., 2020, Greig et al., 2020), face shields (Flanagan and Ballard, 2020, Celik et al., 2020), and re-usable respirators (Provenzano et al., 2020, Greig et al., 2020, Swennen et al., 2020). These papers demonstrated the advantages of 3D printing in combating local supply chain shortage, and also pointed out limitations in the areas of design, manufacture and regulations to provide valuable insights for future 3D printed PPE design and production. However, a major benefit of 3D printing PPE was often overlooked; the ability to produce designs tailored to each individual, thus missing the potential to produce PPE with better fit and comfort for HCP. As supply chain gradually stabilises through the middle of 2020, it is important for us to look ahead and develop novel design strategies that can maximize the advantages of 3D printing to combat the long-term threat of COVID-19 and future health crises (Gates, 2020).

To date the key strategy employed for the design of PPE has been modularisation enabled by anthropometric sizing (classifying the anthropometric characteristics of a population into a few represented groups) (Hsiao, 2013). Modularisation does enable manufacturers to employ mass-production technology to offer products at minimal unit cost. However, modularisation does not enable true customisation for each individual, instead only a small amount of product variation is created. Some individuals will lie outside of the sizing architypes, as demonstrated by fit-test failure rates. As populations become increasingly biologically admixed due to globalisation, regular studies need be carried out to form accurately representative statistical models that reflect the composition changes in a population, making this method time consuming, labour intensive and economically prohibitive.

The existing limitations for customisation in modularised designs can be avoided with the use of 3D printing or Additive Manufacture (AM), which has negligible tooling costs associated with producing one-off items. This makes AM a cheaper alternative for the Mass Customisation (MC) of products as compared to existing mass-production technologies (e.g. injection moulding), as large costs incurred to alter any tools, moulds, processes due to product design moulding), as large costs incurred to alter any tools, moulds, processes due to product design

changes for each individual can now be minimised. Therefore, designers and companies can avoid employing anthropometric sizing-based design methodologies and move towards new mass-customisation methods. However, while AM creates a manufacturing route for customised products and the associated costs are likely to fall as the technology matures; a key barrier repeatedly noted in literature is a recursive labour-intensive design process to create Computer-Aided Design (CAD) models for each individual (Rogers et al., 2007, Pallari et al., 2010, Tuck et al., 2008, Salles and Gyi, 2012). Previous studies focused on demonstrating the feasibility of using AM technologies and comparing their performance with those fabricated through craft production (Rogers et al., 2007, Paterson et al., 2014, Schrank, 2011, Pallari et al., 2010) or mass production (Cheng and Chu, 2013, Salles and Gyi, 2013a, Salles and Gyi, 2013b, Tuck et al., 2008, Salles and Gyi, 2012). Swennen et. al. (Swennen et al., 2020) proposed using 3D printing to produce customised respirator masks when FFP2/3 masks are not available in a pandemic. However, the employed design process was predominantly manual and required expert knowledge in data acquisition (collect the body shape of an individual via a 3D scanning device), data manipulation (extract useful anthropometric data) and CAD modelling (adapt the geometry of a CAD model to the extracted anthropometric data). Salles and Gyi noted that the cost for employing a CAD specialist to create engineering drawings of custom-fit shoe insoles was the second highest among all costs, with fabrication cost being the first (Salles and Gyi, 2013a, Salles and Gyi, 2012). Studies have also shown that time taken from obtaining anthropometric 3-dimensional (3D) data to the creation of a single custom-fit CAD model in a manual design process can amount to approximately 20 - 30% of the overall production time (Salles and Gyi, 2013a, Tuck et al., 2008, Salles and Gyi, 2012). This labour-intensive and knowledge-driven design process adds unit cost and time to production, and therefore, in many instances makes MC economically unviable. To reduce the design process cost, labour wages could be lowered, but this appears unsustainable and intellectually unstimulating. Apart from cost, slight variations and errors may be introduced during a manual design process (Spallek and Krause, 2016), which will undermine the reproducibility of design features and thereby its intended functionalities. Alternatively, the development of smart processes to minimise manual interaction in a design process is an attractive option.

Significant advances have been made over the years to automate or simplify parts of the custom-fit design process. In recent years, statistical shape models of heads and faces have been used to predict 3D head and facial shapes from 1D anthropometric measurements, thereby removing the need of 3D scanners in the data acquisition step (Verwulgen et al., 2018, Lacko

et al., 2017, Chu et al., 2017, Chu et al., 2015). Advances in 3D scanning technologies have also brought about affordable handheld 3D scanners to make the acquisition process less cumbersome. However, the trade-offs between accuracies, time and costs across different data acquisition methods, including the use of a statistical shape model, has not been evaluated before. Significant advances have also been made for the CAD modelling step, particularly for medical device applications such as custom-fit hearing aids (Unal et al., 2008), splints and orthoses (Schrank, 2011, Paterson et al., 2014, Cazon et al., 2014). Most of these studies made use of Application Programming Interface (API) in commercial CAD packages to achieve automatic creation and modification of a CAD model by adjusting the values of a few parameters (e.g. dimensions) that define the model. APIs have been widely recognised as a key enabler of MC due to its flexibility in design modification (Fogliatto et al., 2012, Da Silveira et al., 2001). While these studies provided user-friendly co-design platforms to de-skill the CAD modelling process for non-engineering communities (e.g. medical community) and supported the increasing commercialisation of automated processes in certain industries, these processes can still take up to half an hour to create a single design as medical practitioners need to manually manipulate the raw scan and incorporate their clinical knowledge during the design process to ensure optimally designed devices for an individual (Cazon et al., 2014). However, in a pandemic crisis, the design of a custom-fit respirator mask for a HCP should involve as little manual work and time from a HCP as possible to maximize their time for patients and to meet demand for a larger population of HCP. To the best of the authors' knowledge, no study has demonstrated a scalable MC design strategy for 3D printed respirator masks before.

In this paper, we propose a scalable MC design process for a concept respirator mask design for 3D printing. We first evaluated the trade-offs between four acquisition methods by comparing their geometric accuracy, acquisition time and equipment costs to look for an appropriate acquisition method for a pandemic crisis. Then, we investigated the feasibility of automating the data manipulation and CAD modelling steps for creating a concept respirator mask. A novel three-step process has been developed to achieve automation. The process starts with a template fitting step which brings raw facial meshes into dense correspondence. Followed by a data extraction step which uses vertices on the fitted mesh as landmarks to identify and extract a region of interest on the face that the mask will be in contact with. Finally, a parametric CAD modelling step to generate custom-fit CAD model. The process was subsequently converted into scripts written in Fusion 360 API (Autodesk, Inc., USA) and MATLAB (MathWorks, Massachusetts, USA) to achieve automation at each step. Five

volunteers were recruited for the evaluation of the acquisition methods and the new design
 process.

2. Method

Five volunteers with varying age, gender, and ethnicity (summarised in Table I) were recruited
at Imperial College London (UK) in February 2020 following Protocol (19IC5167) approved
by Imperial College Research Ethics Committee. A 4 step process (Figure 1) was employed to
convert data of each volunteer into a custom-fit respirator:

- Data acquisition; facial geometry of each volunteer in the format of a digital 3D facial mesh was collected via four acquisition methods. Volunteers were asked to remain in a natural position and face in a neutral expression with mouth and eyes closed to minimize variation in results between different acquisition methods for the same volunteer.
 - 2. Template fitting; the shape of a template facial mesh was morphed or fitted to the shape of the input racial mesh.
 - 3. Region of Interest extraction; topographical data were identified and extracted from the fitted facial mesh.
- 4. CAD modelling; a custom-fit respirator mask CAD model was automatically generated
 from a Fusion 360 API script.

18 2.1 Data acquisition

Four different approaches to acquire 3D facial geometry were employed; one based on structured light reconstruction, one based on photometric-stereo, one that combines both, and one based on 3D reconstruction from a single 2-Dimensional (2D) image using a statistical shape model. With all the above methods, the resulting geometry is represented as a triangulated mesh. Table II provides a summary of the four acquisition methods, including details of equipment, software and output file. Figure 2 shows 3D meshes obtained from each method.

The first acquisition method is by reconstructing 3D facial geometry from a 2D image using a morphable model. 3D facial shape reconstruction from a 2D image is an ill-posed problem, but it is also a well-researched area in computer science as it is an interesting problem to solve. The seminal work by Blanz and Vetter (Blanz and Vetter, 1999) was the first to demonstrate that it is possible to synthesise a 3D face from a single 2D image with the use of a morphable model which contains a statistical shape model and a statistical texture model.

Page 7 of 38

Rapid Prototyping Journal

The morphable model provides a shape and a texture space that covers the variation in shape and texture of a group of similar faces. When given a 2D image, it searches through the space to generate a realistic 3D face that best matches the face in that 2D image. In this study, the publicly available morphable model, Large-scale Statistical Face Model (LSFM) developed by Booth et al. (Booth et al., 2018) was employed to generate 3D facial meshes. The LSFM was developed by learning the shape and texture space of 9,663 facial scans captured over a period of 4 months via a 3dMD[™] photometric-stereo capture device. The result of this learning was a morphable triangular mesh with 53,215 vertices, whose shape can be modified into different realistic 3D facial shapes with the input of 2D images. For each volunteer, a 2D "in-the-wild" image (image taken under no constraints in terms of lighting, background etc.) of his/her face in neutral expression was taken from an Apple Iphone 6s (Apple Inc., Cupertino, California, USA). This image was then loaded into the LSFM to alter the shape of the morphable mesh to match as closely as possible the shape and texture of the input image. The output of the LSFM will follow the mesh structure of the morphable mesh, which is a triangular mesh with 53,215 vertices. An example of the LSFM output mesh is shown in Figure 2 (a).

The second acquisition method is via the use of a Light Stage capturing system for photometric-stereo reconstruction. Light Stage was first introduced by Debevec (Debevec, 2012) as a reflectance acquisition setup, and it can be used as a high-quality 3D facial geometry acquisition device (Kampouris et al., 2018, Ghosh et al., 2011, Lattas et al., 2019). It comprises of a room-spanning sphere, mounted with controllable lights that illuminate a subject and cameras that capture the subject from different known view-points. The Imperial College Multispectral Light Stage (Kampouris and Ghosh, 2018) was used in this study. A volunteer was asked to sit inside the sphere with eyes closed and in neutral expression. Images of the volunteer's face were captured in the Light Stage under a uniform illumination and base geometry of the subject's face was reconstructed from these images using the state-of-the-art Structure-from-Motion (SfM) COLMAP photometric-stereo algorithm (Schönberger et al., 2016, Schonberger and Frahm, 2016). A universal template (mean shape) created from the LSFM study was employed to align the reconstructed meshes: a landmark localisation method (Sagonas et al., 2013) was employed to automatically landmark 2D images rendered from the reconstructed mesh and projected 3D landmarks back into the reconstructed mesh; then rigidly align the reconstructed mesh to the mean shape of LSFM by calculating the transformation matrix using their respective facial landmarks. Finally, as the reconstructed mesh was in an arbitrary topology, the method of quadratic edge collapse decimation from MeshLab

(MeshLab, 2020) was employed to reduce the mesh to about 50,000 vertices. All final meshes
 are triangular mesh (Figure 2b) with an average file size of 5MB.

The third acquisition method combines structured light and RGB input, which are captured as an RGB + Depth video sequence from the TrueDepth camera in Apple Iphone X (Apple Inc., Cupertino, California, USA). It works by projecting a dotted infrared light pattern of 30,000 dots on a face while capturing their reflection. Bellus3D app (Face mode) was used for aligning captured frames and for merging the depth and RGB captures from each image into a single 3D triangular mesh. During capture, the volunteer is asked to hold the Iphone X in front of his face and turn his head from side to side, while maintaining a neutral expression with mouth closed. The mesh was then exported in *HD resolution* from the app. The resulting mesh (Figure 2c) has an average size of 10MB, containing about 100,000 vertices. Also, in contrast with the previous methods, it does not require the attendance of a scanning expert.

The fourth acquisition method is via the use of a structured-light based capturing system, Artec Space Spider from Artec 3D (Artec 3D, Luxembourg). It is a handheld 3D scanner that works by projecting pulsed blue light onto a person's face. As reported by the manufacturer, it has a 3D resolution up to 0.1mm and 3D point accuracy up to 0.05 mm. During data acquisition, a volunteer was seated on a movable chair with eyes and mouth closed, head in a natural position and face in a neutral expression, while an experienced technician moved the scanner from one side of the face to another in a steady pace to capture the entire face. Artec Studio 11 Professional software was used to receive and process data transmitted from the scanner and create 3D meshes. The average file size of one mesh is over 50MB, containing over 500,000 vertices, as shown in Figure 2 (d).

2.2 Template fitting

Once a scanned 3D facial mesh was obtained, it was fitted to a universal template facial mesh. This is a crucial step to remove heterogeneity across different raw facial meshes in terms of orientation, location, and mesh structure (vertex indexing and triangulation), thereby enabling the subsequent automatic extraction of topographical data from a large facial dataset. In this study, the template mesh used is the mean shape created from the LSFM. It is made of 53,215 vertices indexed in an orderly fashion in a regular triangular mesh structure, as shown in Figure 3. An algorithm was developed in MATLAB to achieve template fitting in a four-stage process:

Rapid Prototyping Journal

pre-processing, coarse rigid alignment, fine rigid alignment, and non-rigid alignment stage. These stages are highlighted in Figure 4 (a). Details of the algorithm are explained as follows.

The first operation in the pre-processing stage is to match the scale of the raw mesh to the template mesh by comparing the order of magnitude of each axes range. Once the mesh is scaled correctly, the vertices of the raw mesh are checked through to find the minimum values in x-, y-, and z-axis directions and compared with those of the template. The differences in the minimum values in each axis were used to translate the raw mesh to a position relatively close to the template mesh. Next, at the coarse alignment stage, an error minimization technique was employed to determine a rotation matrix which re-orientates the raw mesh to the same plane as that of the template mesh. 2D outlines of the raw mesh and the template mesh were projected onto the X-Y, X-Z, and Y-Z planes as shown in Figure 4 (b). Then, the raw mesh was incrementally rotated along the X, Y, and Z axis through its centroid while the area of overlapping between the raw mesh and the template mesh, as well as the area falling outside of the template mesh, were calculated. The rotation matrix that gave the maximum overlapping area and minimum area falling outside of the template mesh was used to perform rigid transformation of the raw mesh. Next, the raw mesh is translated onto the template by collocating the tip of the noses; the nose tip was identified in the raw mesh by assuming it to be the maxima in the z-axis. Stage 3 utilises Iterative Closest Point (ICP) algorithm (Besl and McKay, 1992) on the central facial area of the mesh (excluding ears, nose, neck) to rigidly align the two meshes further. Finally, stage 4 employs Non-rigid Iterative Closest Point algorithm (NICP) (Amberg et al., 2007) to morph the shape of the template mesh into the shape of the aligned raw mesh, by incrementally moving each vertex on the template mesh closer to their nearest neighbouring vertex on the aligned mesh.

The NICP is an essential step to bring all aligned meshes into dense correspondence with one another. Figure 5 shows an example of dense correspondence achieved between 2 aligned meshes: the shape of each aligned mesh was represented by a morphed template mesh or as called a fitted mesh after NICP. These fitted mesh will have the same number of vertices (n=53,215) and mesh structure as the template mesh. More importantly, every vertex on the fitted mesh carries a consistent anatomical meaning. For example, the vertex at the tip of the nose will always represent the tip of the nose, however its xyz coordinate values will change across different fitted meshes.

2.3 Extract Region of Interest

Dense correspondence achieved in the previous step is critical for enabling the automatic identification and extraction of facial topographical data, or the Region of Interest (ROI) on the face. This is because individual vertices can now be used consistently as facial landmarks to identify area on the face that needs to be extracted. Without dense correspondence, this step can only be achieved via manual visual inspection. An algorithm was written in MATLAB to identify ROI on the face where the mask is expected to be in direct contact with the face. Details of the algorithm are explained as follow.

The ROI was determined by projecting a 2D egg shape parallel to the XY plane onto the 3D surface of the fitted mesh, Figure 6. A 2D parametric egg shape curve expressed in the following function was used to define the boundaries of the ROI:

 $x = ((c \times r) - (p \times r) \times \cos \theta) \times \sin \theta$ (1)

 $y = r \times \cos\theta \tag{2}$

where c is the circularity and p the pointiness of the egg shape. Together, c and p define the overall shape of the egg and their values were chosen as c = 1, and p = 0.4 such that the egg shape resembles the typical shape of commercially available respirator masks. The radius rdetermines the size of the egg. Two egg shapes were created with two radii to represent the outer and inner edge of the mask respectively. The <u>radius for the outer egg shape (r_{outer}) </u> was defined as the y-axis distance between the philtrum and the lower edge of the chin for the outer edge, Figure 6 (a); and the radius for the inner egg shape (r_{inner}) was 8 mm smaller for the inner edge, Figure 6 (b). The centre of the 2D egg was located at the philtrum xy coordinate and the z coordinate of the nose tip, Figure 6 (c). Vertices at the philtrum, chin and nose can be consistently identified across different faces because their indexing remain the same after the template fitting step, with only their xyz coordinates being altered. At this stage the 2D shape, size and location of the egg had been fully defined. Then, 100 points were evenly sampled on each egg shape and projected onto the fitted mesh surface. Their 3D coordinates were determined using a ray-triangle intersection operation. These projected points marked out the boundaries of ROI, shown as red and blue dots in Figure 6(d) and referenced vertices as coloured asterisks.

Page 11 of 38

2.4 Conceptual design and CAD API script

Figure 7 (a) shows the conceptual design of the respirator mask. The design was developed by taking into consideration of criteria outlined in international standards for respiratory protective devices and PPE (British Standards of BS EN 149-2001, and the European Union Regulation 2016/425), and taking inspirations from industrial half-mask respirators such as the 3MTM Half Facepiece Reusable Respirator 6200 (3M Company, Minnesota, USA) and popular design on open source CAD repository Thingiverse (lafactoria3d, 2020). The design of the mask was modularised to minimise the number of components that needs to be customised, while enabling easy disinfection, assembling and disassembling. It contains four components: shell (blue), filter house (green), cap (yellow) and connector (white). The shell is the main mask body, the *filter house* and *cap* secures an off-the-shelf filter material in place, and the connector is for straps.

All components were created parametrically in Autodesk Fusion 360. Parametric CAD models are built from successive addition of geometric entities (lines, curves etc.) and features (extrusion, revolve etc.) with defined rules and constraints (Saxena and Sahay, 2007). The geometry created later on in a modelling workflow is dependent on the geometry created earlier on. Therefore, given a carefully defined parametric CAD model, i.e. the dimensions for each entity and feature, and the geometric relations among them are fully defined, the final geometry of the CAD model can be easily modified by changing the values of a few parameters (e.g. dimensions). In this study, only the *shell* component will be in direct contact with the face, therefore its shape needed to be updated for each individual. The rest of the components are standardised, and their shapes remain unchanged for different individuals. To automatically update the shape of the shell component, a fully defined parametric model of the shell component was first manually created, then an API script was written to replicate the modelling workflow to achieve automation.

Essential modelling steps for creating the *shell* component are shown in Figure 7 (b-e). ROI was first imported into Fusion 360 and fitted with two splines as shown in Figure 7 (b). Then, the egg centre point extracted from the previous step was referenced as the centre to create a circular sketch for the filter, shown in Figure 7 (c). A Boundary-Representation (BREP) surface was created by lofting from the bigger spline to the smaller spline then to the circular sketch to form the main body of the *shell*, as shown in Figure 7 (d). This surface was the area on the mask that would be in direct contact with a face. Once a BREP surface was created, it was thickened by 1.5mm to form a solid body. The filter part of the shell was created by extruding
the circular sketch away from the face by 10mm, and adding a thread on the inner surface of
the extrusion. Finally, fillets were added on the edges of the entire model to form the final *shell*body, as shown in Figure 7 (e).

5 2.4 Evaluations

6 2.4.1 Evaluate geometric accuracy of raw meshes

Geometric accuracy of raw meshes for each volunteer were evaluated by calculating the Hausdorff distance (Aspert et al., 2002) between raw meshes obtained from the 2D image, the Light Stage, the Bellus3D app, and the 'ground truth' mesh obtained from the Artec Space Spider. Meshes generated from the Artec were used as the 'ground truth' as it has the highest reported 3D point accuracy, as well as the highest resolution (highest number of vertices per unit area). Hausdorff distance is a commonly employed metric for comparing the distance between two meshes in a 3D space. Its key advantage over a simple vertex to vertex Euclidean distance metric is its robustness in comparing meshes of different structure, which is the case in the present study.

Prior to carrying out the Hausdorff distance measurement, a few pre-processing steps were carried out. Raw meshes were first automatically aligned to the ground truth mesh in MATLAB using ICP algorithm that iteratively finds the optimal transformation matrix that best aligns a raw mesh to the ground truth mesh. Then, the aligned mesh was imported into mesh processing software Meshmixer (Autodesk, Inc., USA) to crop away noise and areas on the face that were not present in the ground truth mesh (e.g. back of the head, neck, etc.). This was to ensure that the maximum distance found between the two meshes would only be in the area that the two meshes overlap.

Once the meshes were aligned and cropped, they were imported into another mesh processing software MeshLab (MeshLab, 2020) and its in-built algorithm Metro (Cignoni et al., 1998) was used to calculate the one-sided Hausdorff distance from the aligned mesh to the ground truth. For each mesh, points on its vertices, edges, and faces were sampled (10 times more than the number of vertices on the raw mesh) and the distance from the sampled point to the closest point on the ground truth was measured. The computed distance values were saved as a colour-coded 3D distance heat map where identical regions with a low distance value between the two meshes were indicated in blue, areas in discrepancy were indicated in green,

yellow, and red with increasing distance value. The maximum of all distances for a single mesh,
 and the average distance in root mean square (RMS) were recorded for each mesh.

3 2.4.2 Evaluate geometric fitting of masks

For each volunteer, raw facial meshes obtained from the 2D image, Light Stage and Bellus3D
were loaded into the custom-written MATLAB code to perform template fitting and extract
ROI using a MacBook Pro (3.5 GHz Intel Core i7, 16 GB 2133 MHz LPDDR3, Intel Iris Plus
Graphics 650 1536 MB). Once the ROI was extracted, it was inputted into the custom-written
Fusion API script to generate a customised CAD model of the mask on the same laptop.
Computational time needed to extract ROI in MATLAB and subsequent time needed to create
a mask in Fusion API was recorded respectively for each mesh.

For each volunteer, geometric deviations from the masks (obtained from 2D image, Light Stage, and Bellus3D) to his/her corresponding ground truth facial mesh (obtained from the Artec) were measured to determine how closely the mask can match the face. For each mask, its surface that would be in direct contact with the face was first aligned to the ground truth in MATLAB using ICP algorithm. Then, points were sampled on that surface and one-sided Hausdorff distance was calculated from the mask to the ground truth in MeshLab. Similarly, a colour-coded 3D distance heat map, the maximum distance and the RMS distance were recorded for each mask.

19 2.4.3 Prototyping

Prototypes of the customised masks generated from Bellus3D meshes of the volunteers were fabricated via a desktop SLA printer (Form2, Formlabs, USA). The masks were manufactured from Formlabs Durable engineering resin (FLDUCL02, Formlabs, USA) using a layer height of 0.1 mm. Durable resin has Polypropylene-like strength and stiffness properties, with a postcured tensile modulus of 1 GPa and a flexural modulus of 0.66 GPa. Its soft and pliable nature adds comfort to the user, whilst maintaining its mechanical strength and ensuring an effective seal. To ensure the best surface finish for the mask sections in contact with skin, the masks were printed in an orientation with the valve opening horizontal to the printing bed. This ensured the support sections were always on the outer area of the mask. A support tip size of 0.4 mm was used to ensure surface defects were minimized, whilst ensuring a consistent print quality. Once printed, the basic finishing steps for VAT polymerization were followed (Redwood et al., 2017), including washing parts in IPA, drying and removal of supports before

curing. The parts were cured in a UV chamber for 60 minutes at 60 °C to reach their optimal
mechanical properties. Finally, areas where support was removed were sanded down to ensure
a smooth finish to the outer surface of the mask.

3. Results and Discussion

It is important to select an appropriate data acquisition method to ensure geometric accuracy of the raw mesh while balancing time and cost required to carry out data acquisition quickly and on a large scale in a pandemic crisis. The Hausdorff distance heat maps for facial meshes generated from the various acquisition methods compared with the Artec ground truth mesh for each volunteer are shown in Figure 8. The maximum and RMS distances are tabulated in Table III. The facial mesh reconstructed by the LSFM from 2D images gave the largest geometric discrepancy with RMS distances between 0.54 mm to 2.43 mm for the five volunteers, followed by those from the Light Stage with RMS distances between 0.35 mm to 1.29 mm. Meshes generated by the Bellus3D app using Apple TrueDepth camera gave the least geometric discrepancy with RMS distances between 0.35 mm to 0.91 mm.

Figure 8 (a) shows the distance map between the mesh obtained from a 2D image and the ground truth mesh obtained from the Artec Space Scanner for each volunteer. Large geometric discrepancies were observed in different regions of the face: up to 1.85 mm at the forehead in Volunteer 1, up to 8.55 mm on cheeks and chin of Volunteer 2, up to 3.58 mm on both sides of the nose in Volunteer 3, up to 5.51 mm on the chin of Volunteer 4, and up to 3.79 mm on the side of the nose in Volunteer 5. Large discrepancies were expected as data input was highly deficient where there could be partial occlusion of the shape, variance in pose and lighting conditions, and direct depth information was missing. Moreover, the reconstruction was restricted by both the linearity of the LSFM model and its training data.

Distance heat maps from the Light Stage meshes are shown in Figure 8 (b). Facial mesh of Volunteer 2 and 5 have the lowest geometric discrepancy in almost all regions of the face. The largest discrepancies were observed at the eye and eyebrow regions as a result of poor reconstruction for hair (eyebrows and eyelashes). Facial mesh of Volunteer 1, 3, and 4 had various degrees of geometric discrepancy on the chin, forehead and right side of the cheek with largest distance at 1.80 mm, 3.33 mm and 3.12 mm respectively. These discrepancies are likely caused by missing direct depth information during the data acquisition process since only 2D images with varying illumination conditions were used to infer depth information.

Page 15 of 38

Rapid Prototyping Journal

Facial data captured by the Apple TrueDepth camera produced the most geometrically accurate facial reconstruction for all five participants, Figure 8 (c). The TrueDepth camera was able to directly capture 3D depth information based on structured light principle (Salvi et al., 2004), which is considered one of the most reliable techniques for recovering the surface of objects. The regions on the face that gave the largest geometric discrepancies are at the eyes and eyebrow regions where the presence of hair can greatly affect reconstruction results. Nevertheless, these regions are outside the ROI of the mask, hence they will not affect the 'fit' of the mask.

Choosing an appropriate data acquisition approach is the first crucial step towards achieving mass customisation of a respirator mask. In a pandemic crisis, speed is essential for delivering customised PPE to HCP, whilst travel restrictions and social distancing are practiced globally. Given Table II, the fastest and most accessible data acquisition method among the four tested acquisition methods would be the single 'in-the-wild' 2D image where anyone with a phone equipped with a camera can do anywhere. However, results from Figure 8 (a) showed that 3D reconstruction from a single 2D image can be highly unreliable for different faces. On the other hand, reconstructions from the Bellus3D and Light Stage meshes were more accurate, resulting in an average RMS distance less than 1 mm, as shown in Table III. While both provided good geometric accuracy, it took only a few minutes by a volunteer to capture his facial data using an IPhone X (£629) and the Bellus3D app (£0.55 per exported mesh), at any location; while it took a specialist about half an hour to acquire the facial data of the same volunteer using the Light Stage capturing system (costs between £50,000 - £100,000), at a dedicated location. Clearly a phone equipped with a reliable depth sensor will be the most practical data acquisition method in the midst of a pandemic, as it is fast, reliable, and does not require additional manpower or cumbersome equipment. In this study, Apple TrueDepth camera was employed as it was readily available among the authors of this paper. Other options can also be explored such as the Samsung Galaxy S20 Ultra, Huawei P30 Pro, etc. While not all phones came equipped with a depth camera now, as depth sensor technology matures, it is likely that more and more phones will come with an in-built depth sensor in the future.

For each volunteer, regardless of the acquisition methods, a mask CAD model can be successfully generated. For example, for volunteer 1, CAD model of the masks can be successfully generated for facial mesh of volunteer 1 obtained through all four acquisition methods. Since mesh generated from different acquisition methods differ by the number of vertices and topologies, this demonstrated the robustness of our algorithm in handling meshes
 with different mesh structures.

Geometric deviation of the mask surface to the volunteer's face were measured and visualised as distance heat maps shown in Figure 9. All maximum and RMS distances were tabulated in Table IV. By comparing the heat maps of the masks with that of the facial meshes, it can be observed that geometric inaccuracies in facial meshes had been carried forward, resulting in masks having similar geometric deviations at similar locations on the face. For example, a large deviation of 8.55 mm was observed at the bridge of the nose in mask No.2, shown in Figure 9 (a); the same deviation was observed in the raw mesh generated from the 2D image of Volunteer 2. This showed that our design process can accurately reconstruct the ROI of a given facial mesh. How well a mask can fit onto its user depends largely on how accurate the acquired raw 3D facial mesh is.

Time taken to perform template fitting and ROI extraction in MATLAB and generate a customised CAD model in Fusion 360 were also tabulated in Table IV. Design time has been significantly reduced as a result of automation. Time taken for MATLAB to process a raw mesh generated from 2D image, Light Stage, Bellus3D and Artec was on average less than a minute and half. Time taken to process the Artec mesh was almost doubled at an average of three minutes and half. Longer time was needed because the Artec mesh consisted of an order of magnitude more vertices than the other meshes, which significantly slowed down the NICP process. Time needed to generate a mask from Fusion script was much shorter at an average 6~7 seconds. Overall, our process took less than two minutes if the number of vertices in the mesh is at ~50,000 (2D image and Light Stage) or ~100,000 (TrueDepth and Bellus3D). Even with a large number of vertices at ~500,000 (Artec), the overall computational time was less than four minutes per mask. This was a significant time saving as compared to those reported in literature which can take hours from acquiring data to generating a custom-fitted CAD model (Salles and Gyi, 2013a, Tuck et al., 2008). More importantly, further time reduction can be achieved with greater processing power and/or more efficient algorithm. The only manual work involved in this process was to trigger the MATLAB and Fusion scripts, which was done at the click of a button. Such time and labour savings make it feasible for mass customising respirator masks via AM as a quick response to equip HCP, who have failed the fit test, with a bespoke mask that fits them. Additionally, to provide an alternative for frontline HCP who are suffering from mask-related injuries due to prolonged usage and non-optimal fit.

Page 17 of 38

Rapid Prototyping Journal

All *shell* components of the mask generated from Bellus3D meshes successfully fabricated are shown in Figure <u>10</u> (a). Significant differences in shapes and sizes can be observed in these masks, due to the variation in facial shape and characteristic of each volunteer. On average it took 8 hours and 40 mL of resin to fabricate a single *shell* component, and 4 hours and 25 mL of resin to fabricate the three standard components (*connector, filter house, cap*). Figure <u>10</u> (b) shows the complete concept respirator mask after assembling the four components. Figure <u>10</u> (c) shows one of the volunteers wearing his mask.

Overall, the proposed mass customisation design process can eliminate three manual tasks needed in a conventional design customisation process to achieve automation, as shown in Figure 11. Firstly, a raw facial mesh needs to be post-processed to remove holes and defects caused by occlusions, movements during capture and the presence of hair. By fitting a raw mesh to a template mesh, the fitted mesh will inherit the clean and complete mesh structure of that template mesh. Hence, noise was minimised and holes were eliminated. Secondly, ROI on the face needs to be identified and reverse engineered in a CAD environment to form a mask surface that will be in direct contact with the face. It is challenging to identify ROI automatically for different faces as there are few facial features that can be used consistently across different faces as reference points. It is possible to make use of the RGB values in a coloured mesh and leveraging on existing facial landmarking algorithms to identify key facial features on a face for ROI extraction. However, variation in pose, lighting, facial expression, and facial features can lead to significant errors in landmarking accuracy (Celiktutan et al., 2013, Johnston and de Chazal, 2018), therefore it remains a challenging approach. In this case, a design engineer is still needed to conduct manual inspection on every facial mesh to identify ROI. In our approach, a rigorous template fitting process via successive rigid and non-rigid alignment steps was used to bring fitted meshes into dense correspondence, all vertices inherit anatomical meaning of the template and can be used as reference landmarks, thereby making the ROI identification and extraction process more reliable and robust across different faces. Finally, the manual CAD modelling process was automated via API script as ROI were used as parametric inputs to update the mask geometry. In the present study, a manual step is needed to trigger the Fusion 360 API script, because Fusion 360 does not support external triggering. Going forward, practitioners can explore other parametric CAD packages that can be readily triggered externally to create a fully automated design pipeline.

> While the study has introduced a novel and scalable design process that supports the MC of 3D printed respirator masks to combat COVID-19 and future public health crises, concerted efforts are still needed from policy makers, manufacturers, and the 3D printing community to make MC of custom-fit 3D printed respirator masks a real alternative. A big hurdle to overcome is the lack of specific regulatory guidance on the design and manufacture of 3D printed customfit respirator mask, as evidenced by the lack of directives for 3D printed custom-fit PPE in the European Union (EU) Regulation (EU) 2016/425. Even though the US Food and Drug Administration has published Technical Considerations for Additive Manufactured Medical Devices to guide the design and manufacture of 3D printed medical devices (Food and Administration, 2017), and directed readers to the General Principles of Software Validation if software were to be used for automating parts of an AM process (Food and Administration, 2002); there's no guidance specifically for PPE. Policy makers should look into the development of detailed regulations specifically for the design and manufacture of 3D printed PPE, including different sub-types of respirator masks (e.g. medical and non-medical), as the certification processes for these respirator sub-types are different (Pecchia et al., 2020). Lessons can be learnt from guidance for AM medical implants and orthotics, where process validation has been emphasised for quality assurance. Apart from the lack of regulatory guidance, manufacturers of respirator masks should work with designers, engineers and scientist to conduct rigorous design iterations to select and incorporate an appropriate filter material to ensure that the mask meets the filtering criteria of an N95 mask or equivalent. Appropriate cleaning and disinfection protocols should also be developed considering the material properties of the printed mask; lessons can be learnt from existing studies for re-usable elastomeric half-mask respirators (Lawrence et al., 2017, Bessesen et al., 2015, Subhash et al., 2014).

> One limitation to the present study is the small sample size, which does not carry statistical significance for a large population. Nevertheless, the facial characteristics of the five volunteers are significantly different, mainly as a result of differences in age, gender and ethnicity (Table I). Hence the results have demonstrated the potential of our method for handling different facial shapes and characteristics. Future study is underway to recruit more number of participants to obtain a larger sample size to further validate the process.

Another limitation to the study is the lack of quantitative or qualitative fit testing of the
 fabricated masks to validate how well the physical prototype can fit onto its user. Nevertheless,

the Hausdorff distance heat maps have shown good results computationally. Future work
should be carried out to conduct more rigorous fit testing, such as Quantitative Fit Testing and
Qualitative Fit testing to evaluate the printed masks.

4 4. Conclusion

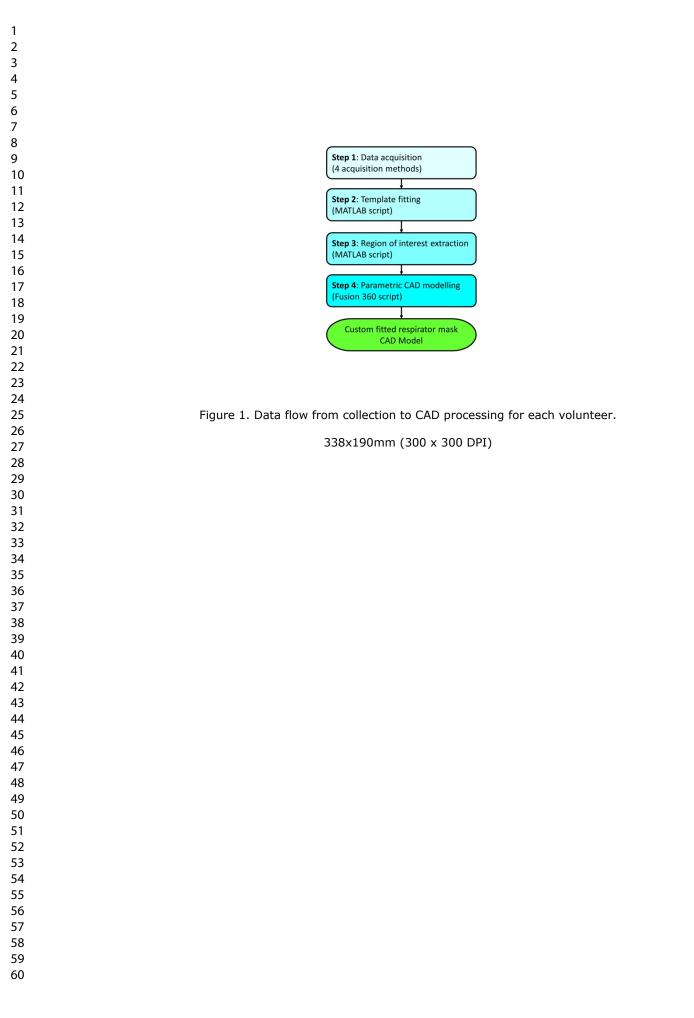
We have proposed a novel and scalable design process for the mass customisation of 3D printed respirator masks to combat COVID-19. Four different data acquisition methods were evaluated against geometric accuracies, cost and time considerations, where the one using a smart phone depth sensor was deemed the most appropriate for MC of respirator mask in a pandemic crisis. Subsequently, a three-step design process was proposed and scripted to enable automatic generation of a custom-fit respirator mask CAD model from the input of a raw 3D facial mesh, which took on average a minute and half for one mask. These results have implied that the new design process is a promising route towards future respirator mask and PPE mass customisation in a more time- and cost-efficient manner.

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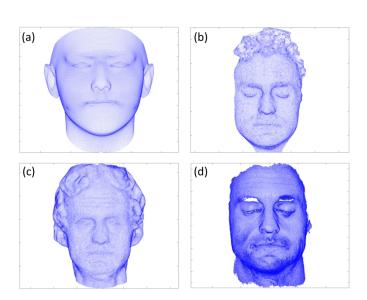


Figure 2. 3D facial mesh obtained via various acquisition methods. (a) LSFM reconstruction from a 2D image, (b) Light Stage, (c) Bellus3D using Apple TrueDepth camera, (d) Artec Space Spider.

338x190mm (300 x 300 DPI)

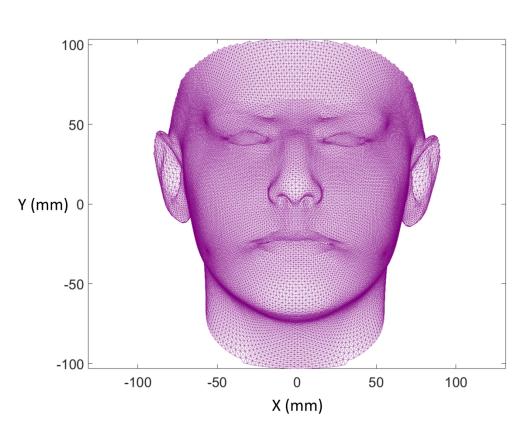


Figure 3. Universal template facial mesh.

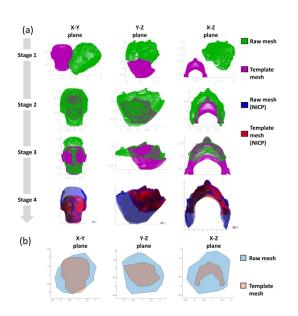


Figure 4. Template fitting process. (a) four stages of template fitting: 1. pre-processing, 2. coarse rigid alignment, 3. fine rigid alignment, and 4. non-rigid alignment stage, (b) error minimization in coarse alignment stage 2.

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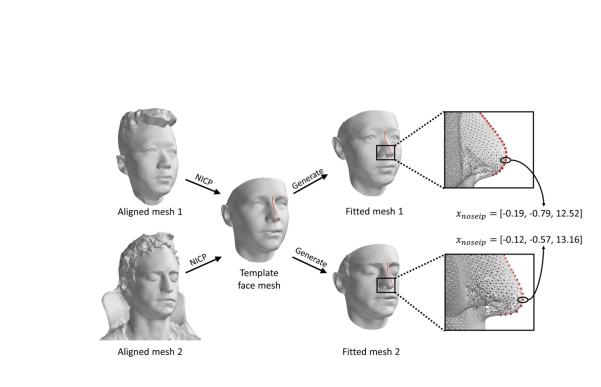


Figure 5. Create dense correspondence via NICP algorithm.

338x190mm (150 x 150 DPI)

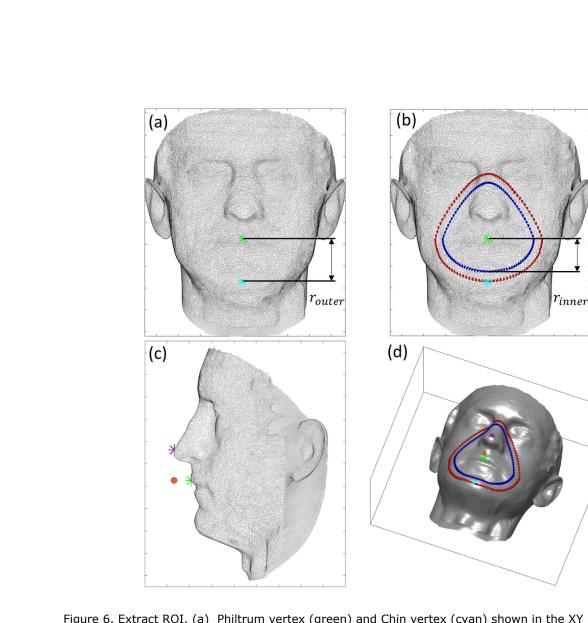
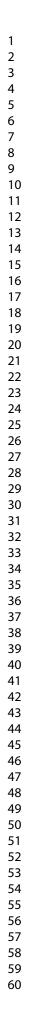


Figure 6. Extract ROI. (a) Philtrum vertex (green) and Chin vertex (cyan) shown in the XY plane, (b) inner (blue) and outer (red) mask edge points, (c) Philtrum vertex (green), Nose tip vertex (purple) and centre location (orange) shown in the YZ plane, (d) 3D view of referenced vertices (asterisks) and extracted data (dots).



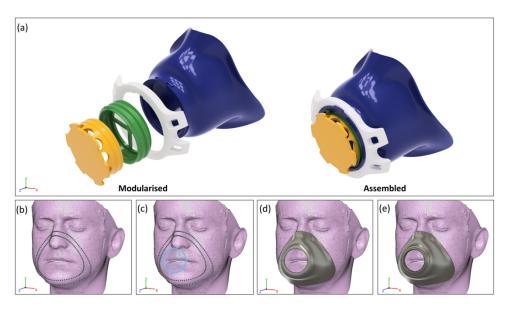


Figure 7. Mask conceptual design and CAD modelling workflow. (a) mask being modularised into four components, (b) splines fitted to ROI, (c) egg centre point used to create the sketch for filter house, (d) loft to create the entire mask body, (e) the final shell design.

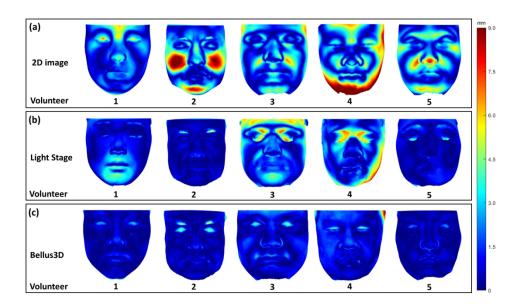


Figure 8. Hausdorff distance heat maps of raw meshes compared with Artec ground truth mesh for Volunteer 1-5. For meshes generated by (a) LSFM from a 2D image, (b) Light Stage, (c) the Bellus3D app.

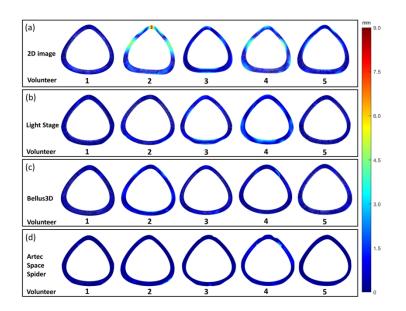
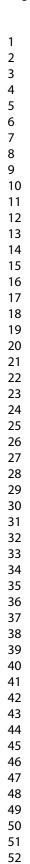


Figure 9. Distance heat maps of mask surface compared with Artec ground truth mesh for Volunteer 1-5. For masks generated from (a) 2D image mesh, (b) Light Stage mesh, (c) Bellus3D mesh, (d) Artec mesh.



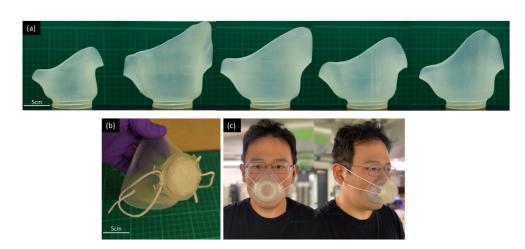
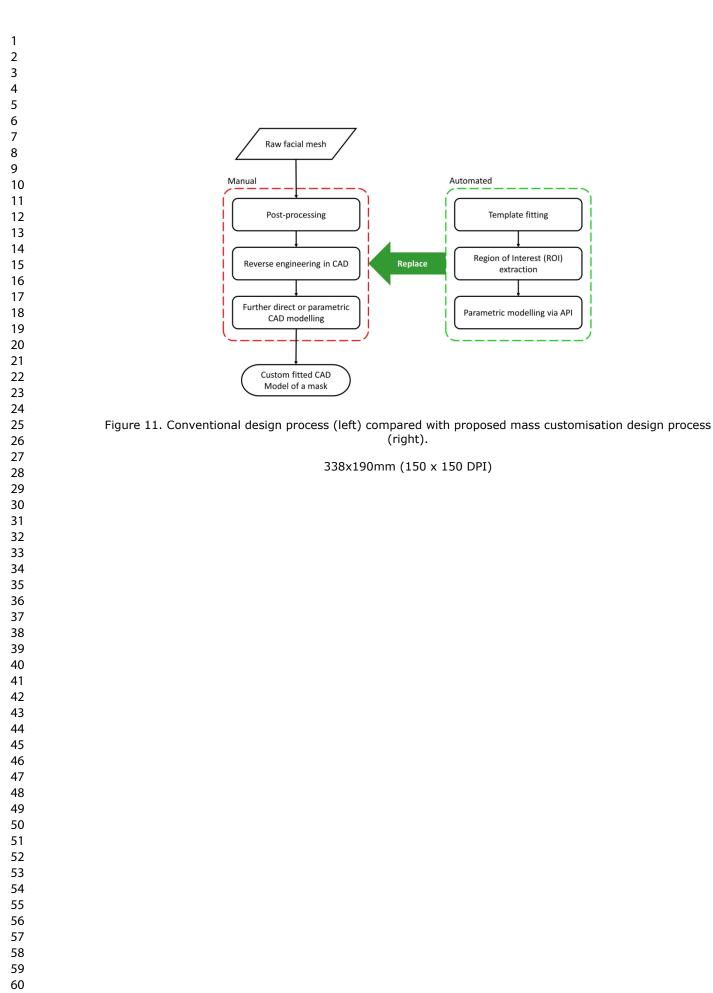


Figure 10. Masks fabricated via an SLA printer. (a) from left to right: customised mask for volunteer 1 to 5, (b) an example of a mask assembly, (c) A volunteer wearing his custom-fit respirator mask.



Volunteer	Age	Gender	Height (cm)	Weight (kg)	Body Mass Index (kg/m²)	Ethnicity
1	27	Female	158	50	20.03	Asian, Chinese;
2	35	Male	183	76	22.69	White, English / Welsh / Scottish / Northern Irish / Britis
3	27	Male	181	85	25.95	White, Any other White background;
4	32	Male	178	100	31.56	Asian, any other Asia background;
5	26	Male	171	63	21.55	Asian, any other Asia

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Table II. Details of the four acquisition methods

Acquisition method	Equipment	Equipment parameters	Equipment cost	Acquisition Time (minute)	Software/ Algorithm	Software cost	File format	File size	Number of vertices
RECONSTRUCTIO N FROM A 2D IMAGE USING A MORPHABLE MODEL	Iphone 6s, back-facing camera	12 megapixel, f/2.2 aperture	£249	< 1 minute	Large-scale Statistical Face Model	Free	OBJ	~5MB	53,215
PHOTOMETRIC- STEREO RECONSTRUCTIO N	Imperial College Multispectral Light Stage: - 336 white and RGB Philips Colour Kinetics - 9 Canon EOS800D	9x 24megapixel (portrait) DSLR cameras combined into 1x 24 megapixel (landscape), 3fps capturing speed, f/11, ISO 200	£50,000~ £100,000	10~15 minutes	COLMAP, MeshLab	Free	OBJ	~5MB	Up to 50,000
RGB + DEPTH VIDEO SEQUENCE	Apple Iphone X TrueDepth camera	7 megapixel, f/2.2 aperture, backside illumination sensor, Retina Flash	£629	1~2 minutes	Bellus3D app	£0.55/exported mesh	OBJ	~10MB	~100,000
STRUCTURED- LIGHT	Artec 3D Space Spider handheld scanner	Geometry tracking mode, 15 fps scanning speed	£18,641	20~30 minutes	Artec Studio 11 Professional software	Free	OBJ	~50MB	~500,000

Rapid Prototyping Journal

	Maxi	mum distance	(mm)	RM	MS distance (m	m)
Volunteer	2D Image	Light Stage	Bellus3D	2D Image	Light Stage	Bellus3D
1	1.85	1.80	1.41	0.54	0.35	0.35
2	8.55	5.31	2.86	2.43	0.72	0.91
3	3.58	3.33	1.86	1.03	1.02	0.55
4	5.51	3.12	3.00	1.76	1.29	0.55
5	3.79	1.29	1.79	1.01	0.37	0.46
Average	4.66	2.97	2.18	1.35	0.75	0.56
					1.29 0.37 0.75	

	Т	ime for MATL		Time for Fusio	on (min:sec)			
Volunteer	2D Image	Light Stage	Bellus3D	Artec	2D Image	Light Stage	Bellus3D	Artec
1	01:17	01:21	01:27	03:34	00:07	00:07	00:06	00:07
2	01:18	01:20	01:41	03:43	00:06	00:07	00:07	00:07
3	01:21	01:22	01:27	03:24	00:06	00:07	00:06	00:06
4	01:16	01:17	01:26	03:30	00:07	00:07	00:06	00:07
5	01:20	01:22	01:21	03:05	00:06	00:07	00:06	00:06
Average	01:18	01:20	01:28	03:27	00:06	00:06	00:06	00:07
		Maximum dist	ance (mm)			RMS distar	nce (mm)	
Volunteer	2D Image	Light Stage	Bellus3D	Artec	2D Image	Light Stage	Bellus3D	Artec
1	1.85	1.80	1.41	1.58	0.54	0.35	0.35	0.18
2	8.55	5.31	2.86	3.36	2.43	0.72	0.91	0.49
3	3.58	3.33	1.86 🥌	1.63	1.03	1.02	0.55	0.27
4	5.51	3.12	3.00	2.80	1.76	1.29	0.55	0.35
5	3.79	1.29	1.79	1.66	1.01	0.37	0.46	0.21
Average	4.66	2.97	2.18	2.21	1.35	0.75	0.56	0.30
							urn	

Table IV. Computational time and geometric accuracy of the masks