Next-Generation Custom-Fit Reusable Respiratory Protective Device with Continuous Fit Monitoring – Part II: Continuous Fit Monitoring

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ABSTRACT

Filtering facepiece respirators (FFRs) are manufactured in discrete sizes, with some models being limited in accommodating the fit of some sex and race combinations. This study presents the development of a custom-fit respiratory protective device (RPD) which conforms to a user's facial features and flexes and moves with facial movements during use. Our design also integrates a pressure-sensing network, which continuously monitors fit and will alert the user when the fit is compromised.

In this Part II of the three-part series, we design and incorporate a continuous fit monitoring system in the RPD designed in Part I to enhance its role in protecting users from inhalation hazards in an effective manner during its use. The fit monitoring system comprises a fabric-based sensor network integrated into the RPD and an Android-based App designed to alert the user when the pressure at the faceseal falls below a given threshold established during the initial configuration of the RPD for the user. We also develop algorithms for the incorporation of the sensor slots and data buses into the custom-fit RPD using the Taxonomy of Landmarks defined in Part I. We enhance the structure developed in Part I to secure the sensor network during the use of the RPD. We develop algorithms for customizing a fastening hub to suit the head profiles of individuals to enable them to don the RPD quickly, easily, effectively, and in a repeatable manner. We demonstrate the successful application of the total design methodology by creating digital prototypes for three individuals with different facial profiles and make further advances to our goal of ensuring equitable respiratory protection for all including children, for whom RPDs are currently limited.

Keywords: Custom-fit respiratory protective device; continuous fit monitoring; fabric-based sensor network; head anthropometry; 3D digital scanning; protection; comfort; faceseal pressure; pressure injury; data analytics.

INTRODUCTION

In Part I of this three-part series, we established the need for continuous monitoring of the fit of the respiratory protective device to enhance its role in protecting users from inhalation hazards in an effective manner during its use (Park *et al.* 2024). The primary objective of the research reported in this paper is to design, develop, and incorporate a continuous fit monitoring system into the custom-fit RPD designed in Part I and enhance its design to secure the sensor network during the use of the RPD. Specifically, the goal is to develop a fabric-based sensor network and integrate it into the RPD for continuous fit monitoring. Yet another objective is to develop an algorithm for the placement of sensors in the RPD to monitor the pressure at the faceseal and detect any leakages that could compromise the protection afforded by the device. We also aim to develop a landmark-based algorithm for the design of a fastening hub to facilitate easy donning and doffing of the custom-fit RPD. Finally, we aim to demonstrate the successful application of the design methodology incorporating the Taxonomy of Landmarks defined in Part I by creating digital prototypes of custom-fit RPDs with continuous fit monitoring for three individuals with different facial profiles as a precursor to their physical realization and evaluation that will be discussed in Part III. In pursuing these aims, we hope to lay the foundation to facilitate equitable respiratory protection for all, including children.

Continuous Fit Monitoring

The primary purpose of continuous fit monitoring is to detect any changes in the fit of the RPD during use that could result in faceseal leakage and thereby adversely affect the degree of protection to the user. When using an RPD, the user, such as a physician, is talking with patients, smiling, and yawning after a long shift in the hospital. During this time, the user's facial profile changes. Some FFRs have a design with limited flexibility (e.g., duckbill, trifold) to move with changes in the facial profile and potentially cause leakages at the faceseal and compromise the fit of the RPD. To address this challenge, there is a need to monitor the fit of the RPD continuously.

The continuous fit monitoring system should measure the pressure at the faceseal, monitor any changes in the pressure that could case faceseal leakage and compromise the fit, and alert the user to adjust the RPD in real-time to ensure the degree of protection for which the RPD is designed. Since the monitoring system should be unobtrusive to the user, the sensor network for measuring the pressure at the faceseal should be integrated into the custom-fit RPD frame; it should stream the pressure data wirelessly for analysis resulting in recommendations for action by the user through an App on a smart connected device.

METHODS AND RESULTS

As the first step in the design of the continuous fit monitoring system, we investigated the potential points of failure leading to faceseal leakage caused by changes in the facial profile during use to determine the number of sensors and their locations around the faceseal to monitor fit in real-time. We did this by simulating the response of one National Institute for Occupational Safety and Health approved N95 FFR to changes in the facial profile from the natural state (neutral facial expression with mouth closed) to talking, to smiling, and to yawning. These four stages were chosen to simulate the changes that could occur to the facial profile, and potentially cause faceseal leakage, during the eight-step quantitative fit test (QNFT) protocol for fit testing using the PortaCount® Fit Tester in which the user is required to grimace, move the head side-to-side, bend up-and-down, and talk, among other activities (OSHA, 1998). A digital scanning system provided a powerful tool for carrying out this simulation study.

Digitization of Facial Profile Changes

Three subjects donned an N95 FFR (3M 1860, 1860S, 3M, St. Paul, MN, USA) and their outlines were traced on the faces using a lip liner. Their faces were then scanned using the 3dMD system (Temporal 3dMDface.t System, Atlanta, Georgia, USA). During scanning, the subjects went through the four stages of being natural (neutral facial expression with mouth closed), talking, smiling, and yawning. Following scanning, the four facial digital profiles for each subject were overlaid using the pronasale (0) as the origin. Figure 1(a) shows the changes in facial profiles for one of the subjects during the four stages: The red profile is the natural state, which is the baseline; the profile is in blue while talking, in green during smiling, and in orange during yawning. Figures 1(b-c) show the composite views for the other two subjects in the four states.

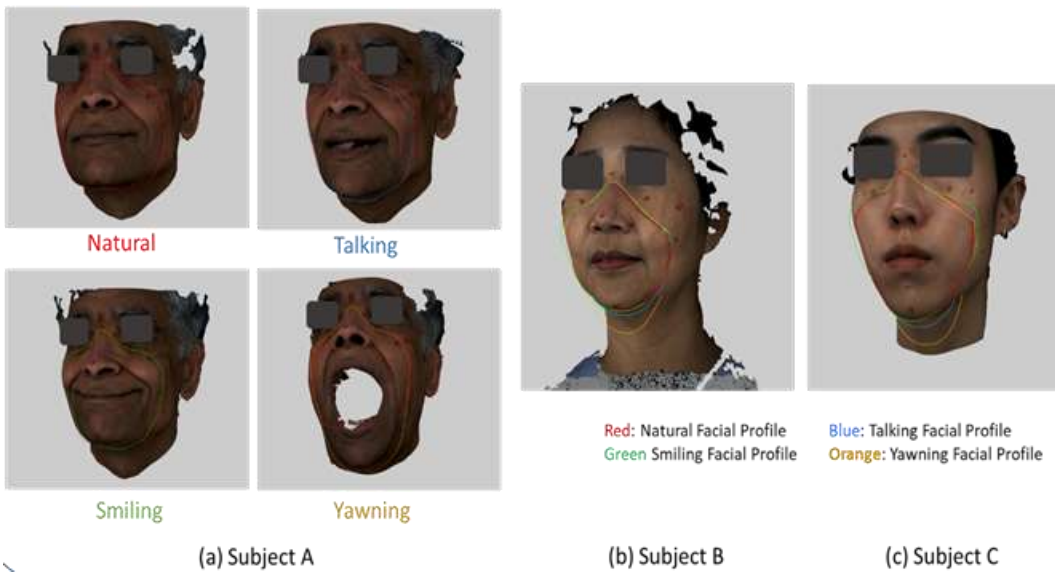


Figure 1. Facial profiles in four states for three subjects.

As seen in Figure 1, when the user yawns, the bottom of the FFR trace (shown in orange in the figure) is displaced way down from the natural position and could cause faceseal leakage since the FFR is rigid and will not flex with the change in the facial profile. Thus, the chin was chosen as a location for the placement of a sensor. Leakage around both sides of the nose bridge is a typical problem caused by the natural profile of the nose bridge making them ideal targets for the location of the sensors. Finally, the sides of the face present a large perimeter of the faceseal that must be monitored, making them additional locations for the placement of sensors. This choice of using five sensors and their locations was a good starting point for the development of an anthropometric landmark-based algorithm to determine the exact locations to meet the overarching objective of designing a custom-fit RPD with continuous fit monitoring for individuals with different facial profiles to ensure equitable respiratory protection for all.

In addition to identifying the locations for the sensors to address the potential points for leakage around the faceseal, we considered the need to retain the sensors in their locations even as the facial profile changes. The curvy facial features, such as the lacrimal groove that is close to the nose, should not affect the performance, i.e., the responsiveness of the sensors.

As shown in Figure 2(a), sensors were placed on both sides of the nose bridge around the infraorbitale and zygomatic areas; sensors were placed symmetrically on either side of the face; and the fifth sensor was centrally located at the bottom of the frame near the chin. Thus, the sensors at these five locations around the faceseal will ensure continuous monitoring of the fit as the facial profile changes when the RPD is in use.

Figure 2(b) also shows the schematic of the fabric-based sensor network of the continuous fit monitoring system. It consists of five sensors (20 mm x 5 mm) distributed around the RPD frame. The signals from these sensors are carried by the conductive data buses to the signal processing module outside the frame. This sensor network is integrated into the RPD frame by creating the necessary slots and pathways to accommodate the sensors and the data buses, respectively.

We now discuss the development of the algorithms for the placement of the sensors and data buses of the continuous fit monitoring system in the RPD frame.

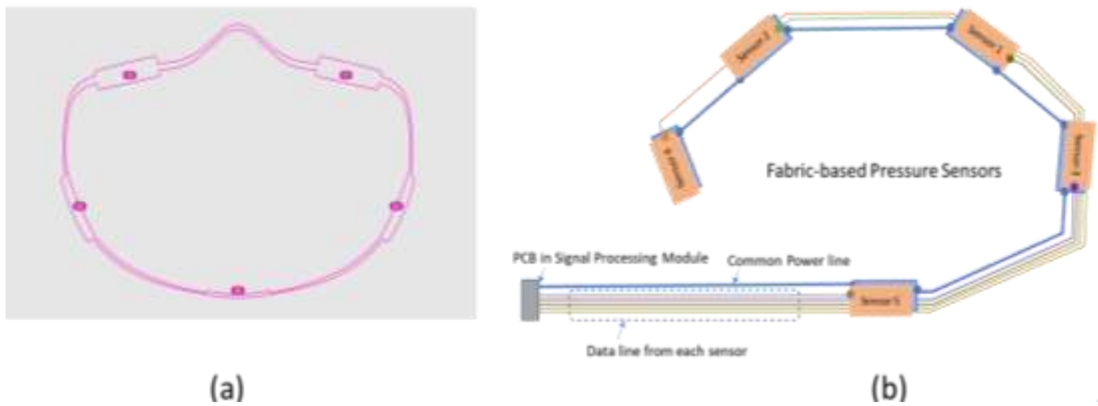
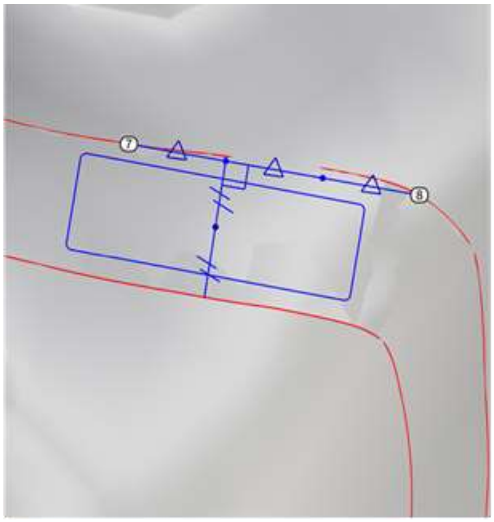


Figure 2. Continuous Fit Monitoring Sensor Network and Locations in RPD Frame. (a) Locations of sensor for the continuous fit monitoring system in RPD frame. (b) Schematic of continuous fit monitoring sensor network system.

Algorithms for the placement of Sensor Slots in the RPD Frame: Figure 3 shows the algorithms for locating the slots for sensors S1 through S5. The sensor slot was designed to be a 25 mm x 8 mm rectangle to accommodate the 20 mm x 5 mm sensor. We used the 2D mapping of the front face view to determine the locations for the slots for sensors S1 and S2 as shown in the algorithm in Figure 3(a).

We used the 2D mapping of the side face view to determine the location for the slots for sensors S3 and S4. As seen in the algorithm shown in Figure 3(b), the locations of the sensor slots are dependent on the facial profile, specifically the relative positions of the Derived Landmarks D2 and D3 from the Taxonomy of Landmarks (Park *et al.* 2024). Thus, the algorithm accommodates the range of facial profiles.

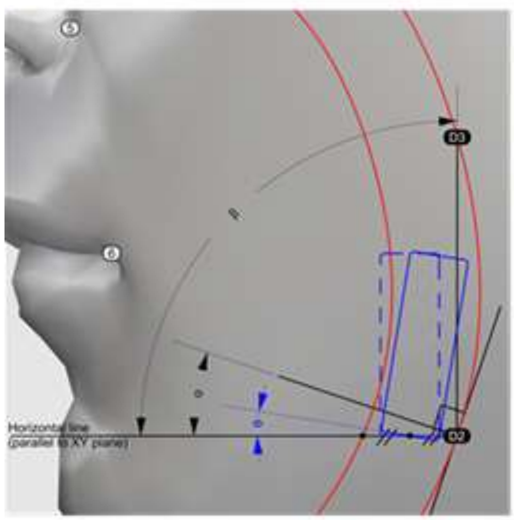
For the slot for sensor S5, on the front 2D mapping, we extend the principal longitudinal axis along the sagittal plane until it intersects with the frame contours in the perspective view. Figure 3(c) shows the algorithm for locating the slot for sensor S5. We used these algorithms to identify the locations of the sensor slots for the three subjects.



Algorithm for Location of Sensor Slots S1 (and S2)

- Draw a straight line between Infraorbitale (7) and Zygomatic (8).
- From the Infraorbitale, find the 1/3rd point on the 7-8 line.
- Draw a perpendicular at this 1/3rd point on the 7-8 line towards the inner and outer contours of the frame.
- Find the midpoint of this perpendicular line. It will be the center point of the slot for Sensor S1.
- Construct a 25mm x 8mm rectangle using the center point.
- Mirror the steps on the other side of the frame to locate the slot for Sensor S2.

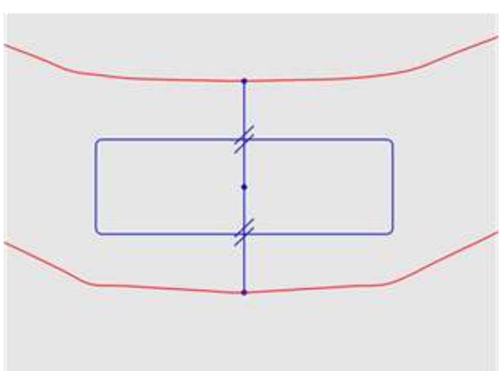
a)



Algorithm for Location of Sensor Slots S3 (and S4)

- From D2, construct a horizontal line in the X-Y plane until it intersects the inner frame contour.
- Find the midpoint of this line segment between the two contours.
- Construct a 25mm x 8mm rectangle using the midpoint as the bottom edge center in the vertical direction in the X-Y plane (shown in dotted line).
- Draw a straight line connecting D2 and D3.
- Construct a tangent at D2 and draw a perpendicular line at D2 on to the inner contour.
- Measure the angle **α** between the horizontal line and the perpendicular line at D2.
- Measure the angle **β** between the horizontal line at D2 and the D2-D3 line.
- Based on the values of **α and β, compute the** angle **θ** by which the rectangular sensor slot should be rotated.
  - If $\beta < 90^0$, $\theta = 0$
  - If $\beta = 90^0$, $\theta = ½\ \alpha$
  - If $\beta > 90^0$, $\theta = 0.9 * \alpha$

b)



Algorithm for Location of Sensor Slot S5

- At the bottom center of the frame, draw a vertical line connecting the two contours of the frame.
- Find the midpoint. It will be the center point for the bottom sensor S5.
- Construct a 25mm x 8mm rectangle with the midpoint as the center of the rectangle. That is the slot for sensor S5.

c)

Figure 3. Algorithm for location of slots for five sensors (S1 – S5). (**a) Sensors S1 and S2. (b) Sensors S3 and S4. (c) Sensor S5.**

From Frame Contour to Frame Surface: Accommodating the Fit Monitoring Sensor Network

Figure 4 shows the steps to create the surface to accommodate the sensor network from the initial frame contour derived from the Construction Landmarks in the Taxonomy of Landmarks discussed in Part I. Through multiple iterations during which we changed the frame width, we arrived at 12 mm as being the optimum surface width of the RPD frame to accommodate the sensor network. Figure 4 also shows the digital RPD Frame with the surface for one of the subjects.

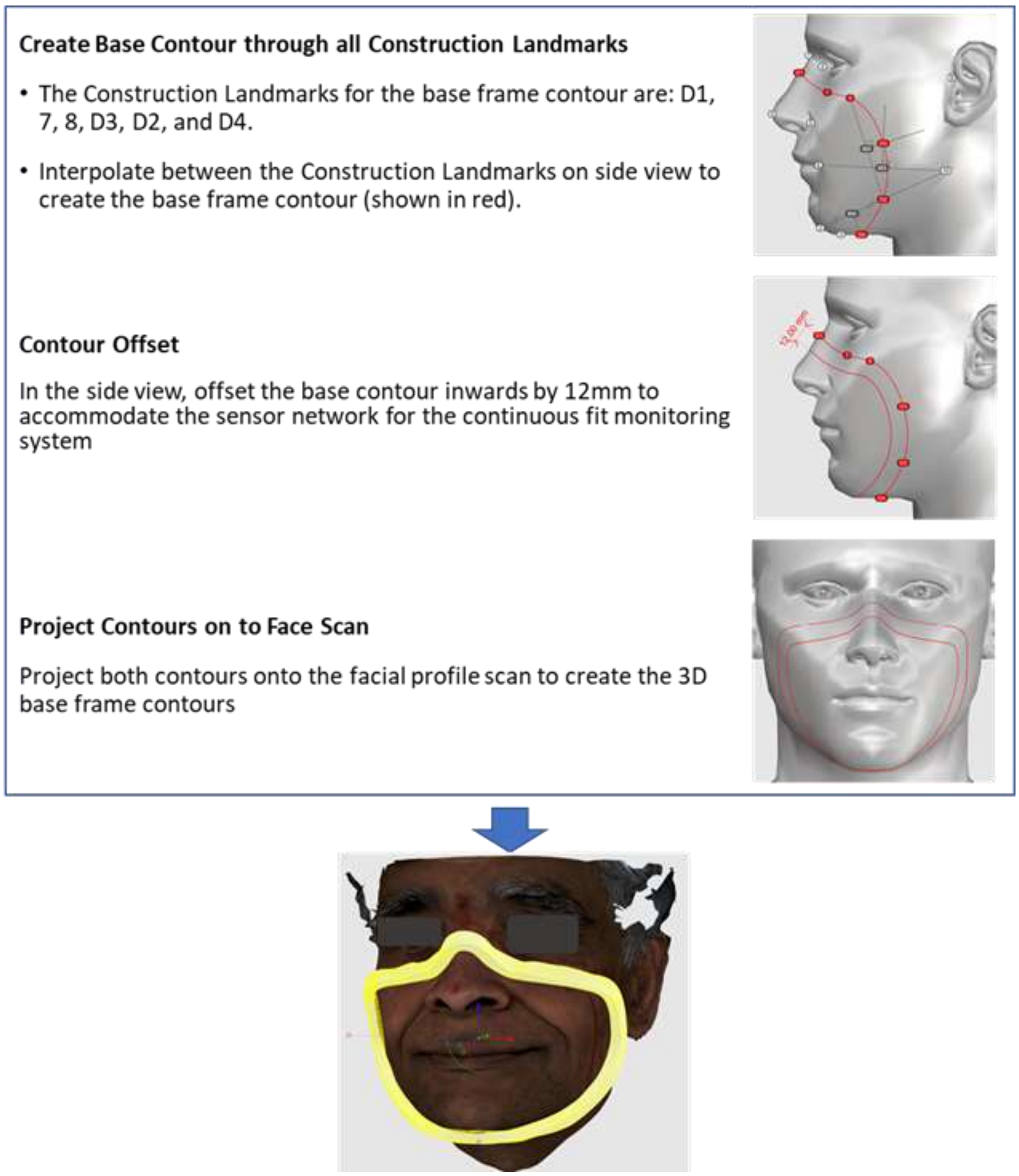


Figure 4. Steps to create the RPD frame with a 12 mm surface to accommodate the sensor network.

We applied the placement algorithms in Figure 3 to incorporate the sensor slots into the frame using the “3D to 2D to 3D” design methodology. We create the base surface for the sensor slots as shown in Figure 4. We construct the rectangular slots with a 25 mm length, 8 mm width, and 0.5 mm edge radius on the 2D mapping and then project them onto the frame base surface. As shown in Figure 5, for sensors S1 and S2, we sketch the rectangular shapes on the 2D front view mapping; for sensor S3 and sensor S4, we sketch the rectangular shapes on the 2D side view mapping; for sensor S5, we sketch the rectangular slot from the top view. We then created the path or conduit for the data buses that connect the five sensors in the network of the continuous fit monitoring system.

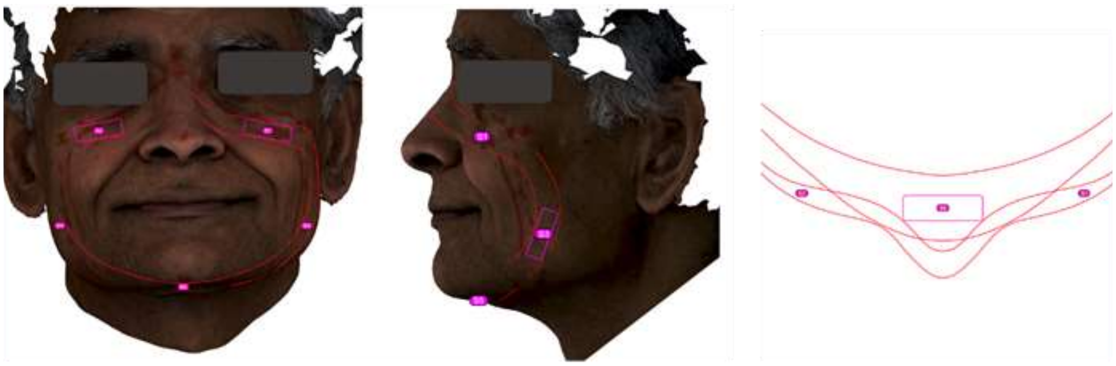


Figure 5. Locations of sensor slots on a subject's profile. (a) Front View: Sensor Slots for S1 and S2. (b) Right Side View: Sensor Slots for S3 and S4. (c) Top View: Sensor Slot for S5.

***Algorithm for incorporation of conduit for data buses in RPD Frame*:** We designed the conduit for carrying the data buses to be a 3 mm channel between the outer and inner contours of the frame that continuously connects all the sensor slots. We used the "Tween Curves" tool in the Rhino® software (Rhinoceros, 2021) to build the tween contour; this contour – the mid-line of the conduit – follows the basic contour of the frame throughout. We offset this tween contour on the outer and inner sides by 1.5 mm leading to a 3 mm-wide contour for the conduit. By cutting off the unwanted intersection parts of the sensor slot shapes and these contours, we obtain a complete silhouette contour of the combined sensor slots and data bus conduit. Figure 6 shows the realization of the data bus conduit in the RPD frame.

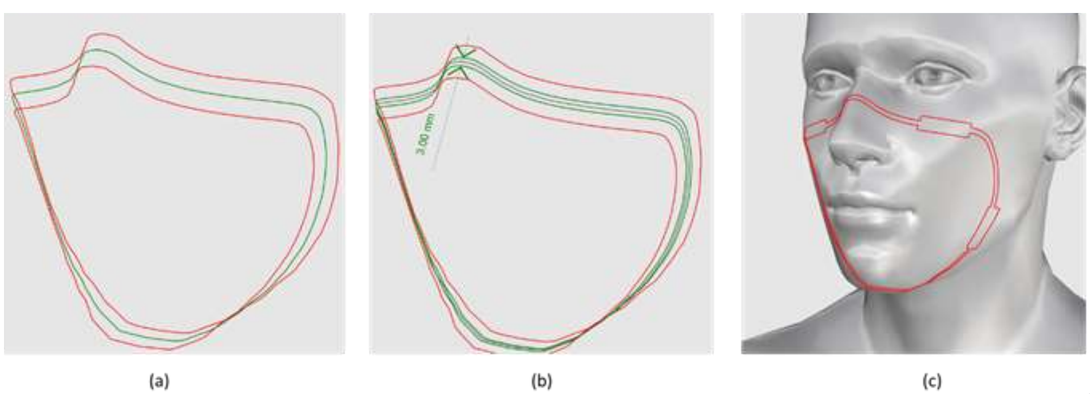
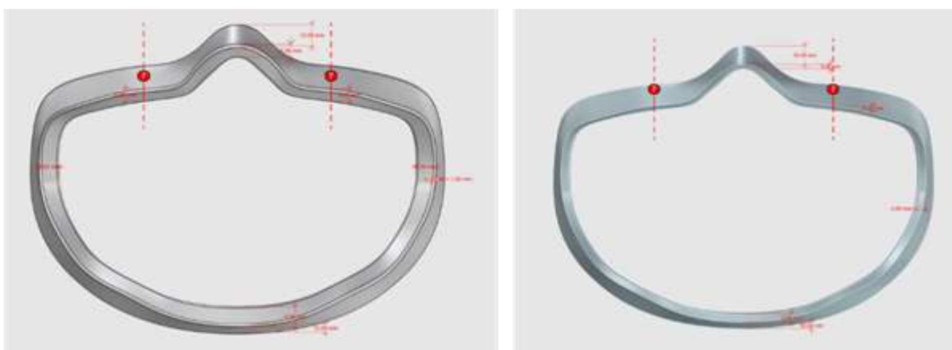


Figure 6. Realization of Data Bus Conduit in RPD frame. (a) Constructing the center contour of frame. (b) Creating the Data Bus contour. (c) Integrating the Sensor Slots and Data Bus Conduit.

The Need for a Two-Component Structure for the RPD Frame

The fabric-based sensor network for the continuous fit monitoring system must be held securely in the RPD frame during use. While the sensors must be close to the user's face to capture the changes in pressure at the faceseal with changes in facial profile during use, they (and the data buses) themselves should not come in contact with the user's face to prevent contamination during use. Therefore, we decided on a two-component structure for the RPD frame, viz., the Base Frame and the Covering Piece, respectively. The Base Frame and Covering Piece hold the sensor network embedded between them securely. The other side of the Base Frame is exposed to the outside; likewise, the other side of the Covering Piece, which is also smooth, is in contact with the user's face.

Figure 7 shows the profile and principal dimensions of the Base Frame and Covering Piece, respectively. The Base Frame has an overall thickness of 8 mm. To reduce the weight and footprint of the RPD around the nose bridge area, we gradually reduce the thickness of the Base Frame from 8 mm to 7mm from the infraorbitale (7) to the center of the nose bridge on either side. Likewise, we reduce the wall depth from 4 mm to 3 mm. The Covering Piece has an overall thickness of 4 mm. As in the case of the Base Frame, we gradually reduce the thickness of the Covering Piece from 4 mm to 3 mm between the infraorbitale (7) and the center of the nose bridge on either side. The outer surface width is 10 mm. Since the outer surface width of the Base Frame is 12 mm and the edge radius fillet is 1 mm, the Covering Piece fits snugly into the Base Frame.



(a) (b)

Figure 7. Digital prototypes of Base Frame and Covering Piece. (a) Base Frame outer surface (b) Covering Piece outer surface.

Figure 8 shows the inside views of the Base Frame and Covering Piece, respectively. The Covering Piece hosts the slots for the sensors and the data bus conduit. The Base Frame has the corresponding extrusions that mate with the Covering Piece with the sensor network embedded between them. The figure also shows the dimensions of the sensor slots, the extrusions, and the tolerance to accommodate the sensors and data buses while ensuring proper mating of the two pieces all around the frames.

Interlocking Mechanism for Base Frame and Covering Piece

While the slots for sensors and data buses in the Covering Piece and the corresponding extrusions in the Base Frame have been designed to hold them securely, the flexible nature of the materials used to produce them could cause them to separate during use. To avoid this separation, we designed an "interlocking mechanism" that holds the two components together using specially designed screw sets. The pegs in the screw set would pass through the holes designed in the Base Frame and Covering Piece, respectively, and be capped by screw caps. We designed the interlocking mechanism to serve another purpose, viz., provide the means to secure the filter in the RPD frame during its use. This functionality will help us realize the ability to use a filter of the desired filtration efficiency, discard it after use, and decontaminate the RPD frame. To ensure that the two components are held securely, we identified three locations for interlocking: one at the top center and one on either side of the frame. Figure 9 shows the algorithm for locating the three interlocking positions and the locations of the interlocking holes in the digital prototypes of the Base

Frame and Covering Piece, respectively. Figure 10 shows the design and dimensions of the screw peg and screw cap of the interlocking mechanism.

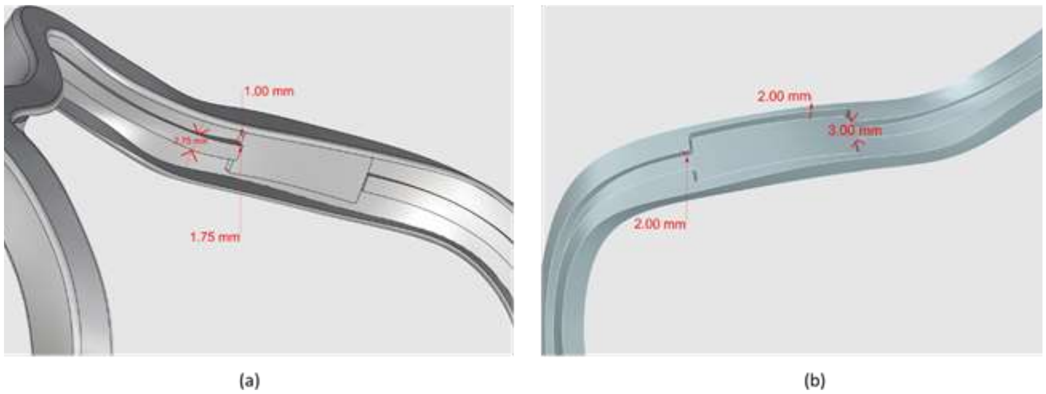


Figure 8. Close-ups of inside views of digital prototypes. (a) Base Frame (b) Covering Piece.

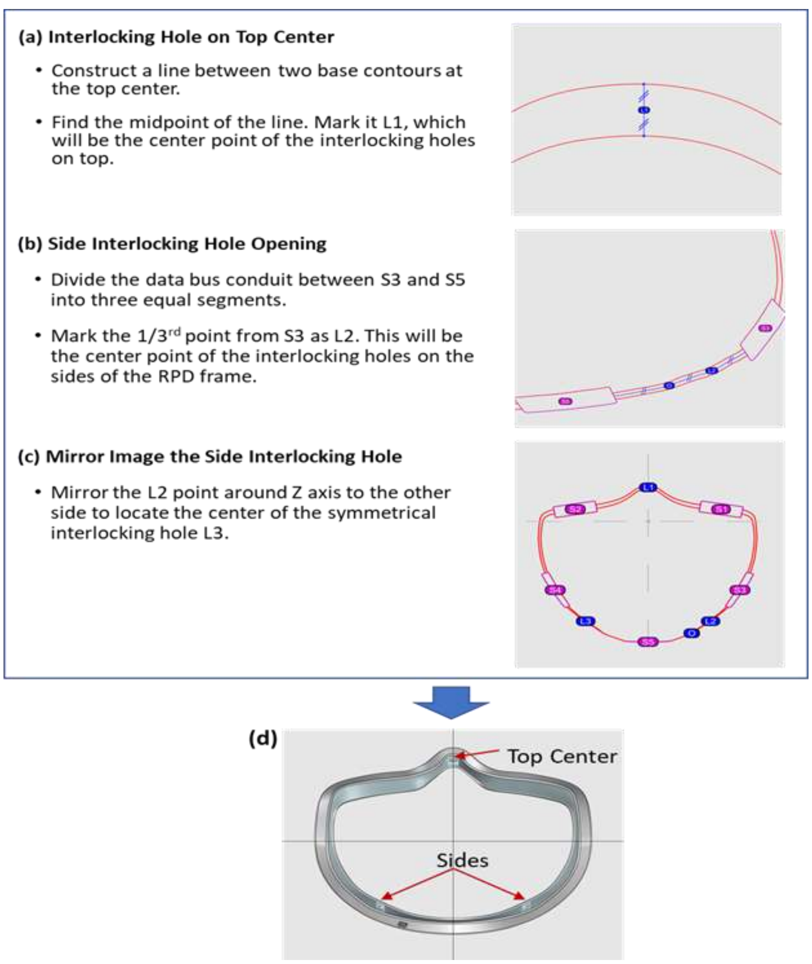


Figure 9. Determining the locations of the interlocking mechanisms. (a) Top Center opening (b) Side opening. (c) All three openings (d) Openings in the digital prototype.

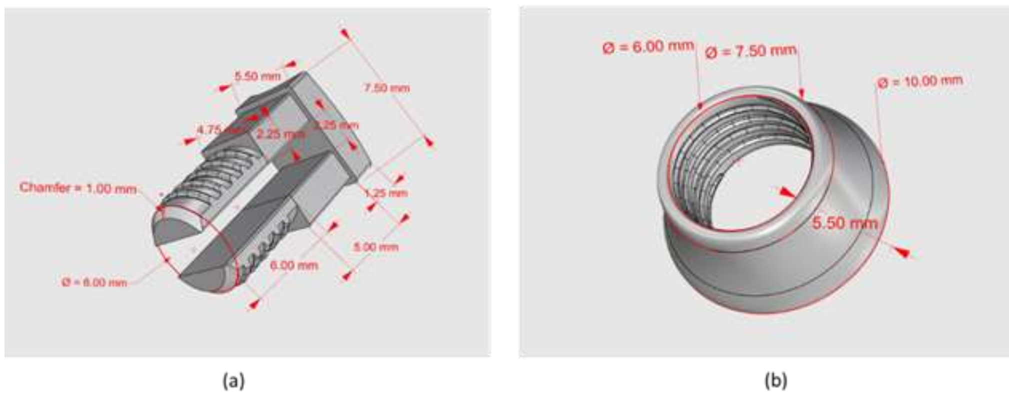


Figure 10. Design and dimensions of the Screw Peg and Cap. (a) Screw Peg. (b) Screw Cap.

Design of Fastening Hooks on Base Frame of RPD

To don the RPD, the user needs a fastening mechanism. Instead of the typical two straps in an FFR, we designed multiple fastening hooks (spaced at a 12 mm center-to-center distance) along the surface of the Base Frame between the zygomatic and jaw side point (D2). This will enable the user to choose specific hooks for fastening using straps to ensure an optimal fit. As shown in Figure 11, the profile of the hooks is a 10 mm square pipe-shape with 6 mm thickness to ensure that the hooks will be sturdy during use.

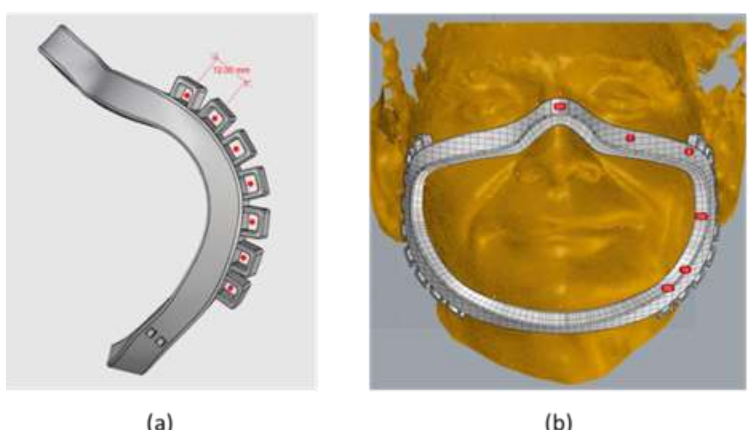


Figure 11. The multiple fastening hooks on the Base Frame. (a) The hooks are aligned along the frame. (b) The Base Frame on subject.

Digital Prototype of RPD

Figure 12 shows the final digital prototype of the RPD comprising the Base Frame, the Covering Piece, the interlocking screw pegs and caps, and filter with the desired degree of filtration. Figure 13 shows the digital prototypes on the three subjects.

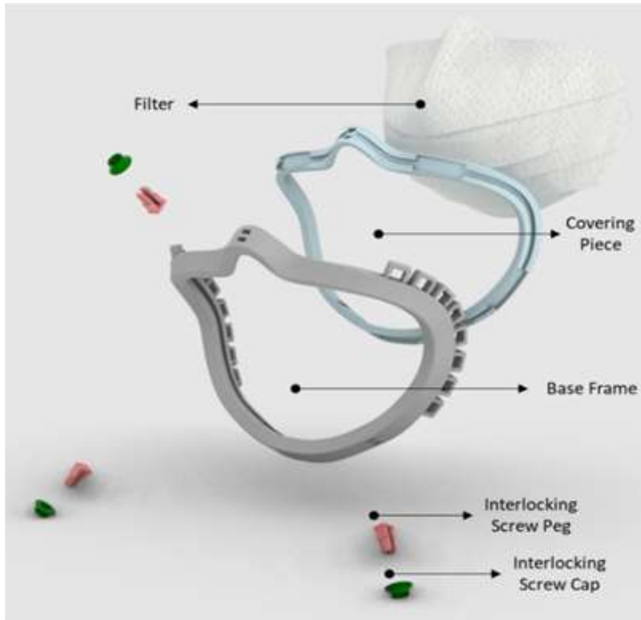


Figure 12. Final digital prototype: Base Frame, Covering Piece, Interlocking Screw Sets, and Filter.

Figure 13. Digital prototypes of custom-fit RPD Frames on three subjects.

Prototype of the Continuous Fit Monitoring System

Figure 14 shows the architecture of the continuous fit monitoring system integrated into the custom-fit RPD.

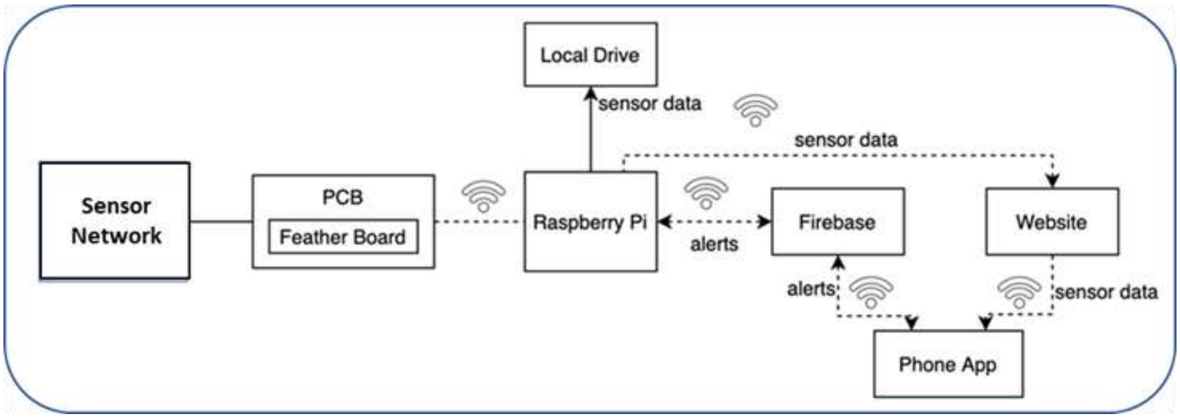


Figure 14. Architecture of the Continuous Fit Monitoring System.

As shown in the figure, the system architecture consists of the following technology building blocks:

- Sensor Network integrated into RPD Frame;
- Printed Circuit Board (PCB) with a Featherboard® assembled on top;
- Raspberry Pi®;
- Local Drive (internal to Pi and/or USB key);
- Firebase® (a Cloud database from Google);
- App on Android Tablet / Phone;
- Website for remote access of data.

The fabric-based sensor network consists of five pressure sensors integrated into the RPD frame (Figure 2). The architecture is flexible so that the number of sensors can be changed if necessary. Each sensor has its own power line and a common data line, all of which are housed in the data bus conduit in the frame. They are drawn through the data bus conduit opening in the frame and connected to the six pins on the printed circuit board (PCB), which is outside the frame. We designed the PCB with five P-channel Metal Oxide Silicon Field Effect Transistors (Toshiba 2024) to obtain analog signals from the sensors in the network and digitize them, i.e., perform the analog-to-digital conversion (ADC) through the ADC chips integrated into the PCB. The Featherboard® (Adafruit, 2021) mounted on the PCB is responsible for powering the PCB, establishing communication with the Raspberry Pi. It is also responsible for receiving and transmitting the ADC values from the sensor network to the Raspberry Pi for further processing.

The Raspberry Pi receives sensor data (ADC value) from the Featherboard and saves it on the local drive, which can be the Pi's internal storage or an external USB drive plugged into the Pi. The Pi analyzes the sensor network data to generate "Alerts" when the RPD is no longer "fitting" the user based on set baseline thresholds of pressure. In practice, this baseline will be set during the very first donning or calibration phase of the custom-fit RPD for the user. The Alerts are sent to Firebase® (a cloud database from Google). The Raspberry Pi also sends the sensor network data to a website host for remote visualization.

As shown in the architecture in Figure 14, Firebase stores the "active alerts" generated by the system when the RPD is no longer properly fitting the user and "confirmed alerts," i.e., those that were corrected by the user by adjusting the RPD. The user information associated with the RPD frame is also stored in Firebase. We developed an Android-based App, which displays a real-time "heat map" of the pressures as ADC values in the sensor network around the faceseal. The App has a feature to convert the pressure value shown in ADC to lb/in^2. The App retrieves the active alerts from Firebase and prompts the user to adjust the RPD when the pressure value falls below a set threshold that could potentially cause faceseal leakage. Following adjustments by the user, when the baseline parameters are restored the alert is automatically moved to “history of alerts” and the monitoring cycle continues (the details are presented in Part III of this series of papers). The heat map is also displayed on a website and can be viewed in other locations by accessing the site. This feature will enable remote monitoring of individuals working in hazardous environments, those participating in research studies, and when evaluating the performance of new designs of RPDs on users unobtrusively during their development.

Figure 15 shows the various technology building blocks (PCB, Featherboard, antenna, sensor network) and the assembled system for continuous fit monitoring.

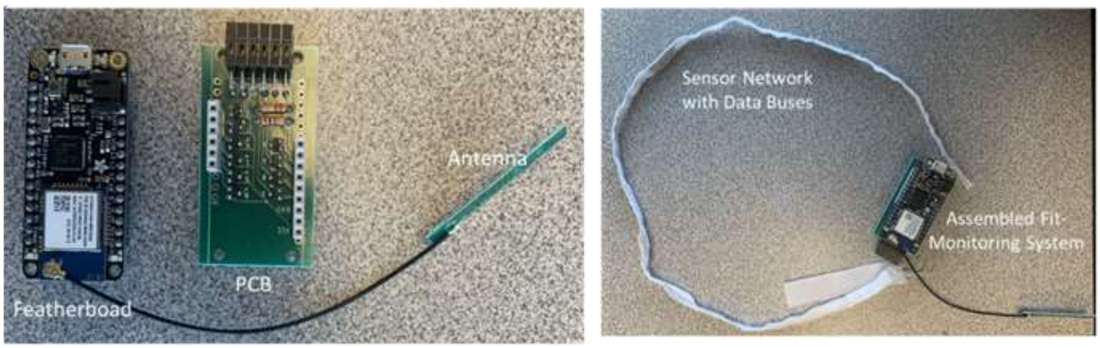


Figure 15. Continuous Real-Time Fit Monitoring System: Technology building blocks and assembled system.

Characterization of Sensor Network Performance*:* We conducted a series of benchtop tests to characterize the performance of the sensor network in the continuous fit monitoring system. According to Roberge *et al.* (2012), the force on the faceseal of a donned N95 respirator ranges from 2.018 to 5.937N (0.2-0.6 kgf). Based on this, we increased the load on the individual sensors from zero to 0.5kg, which corresponds to no pressure to 49.02 kPa (7.11 lb/in^2). . The system recorded the corresponding ADC value. As seen in the change in ADC values in Figure 16, the sensor network is responsive to small changes in the applied load. It should be noted that while the response trend for all the sensors is similar, the specific values for all the sensors are not identical; this is due to the inherent property of the sensor material. Since the sensors are independent and the change in the pressure is computed for each sensor independently, this small variation seen in ADC values will not affect the performance of the continuous fit monitoring system. These results demonstrate the sensitivity and resolution of the sensor network, which are important for detecting even minor changes in pressure at the faceseal during RPD use.

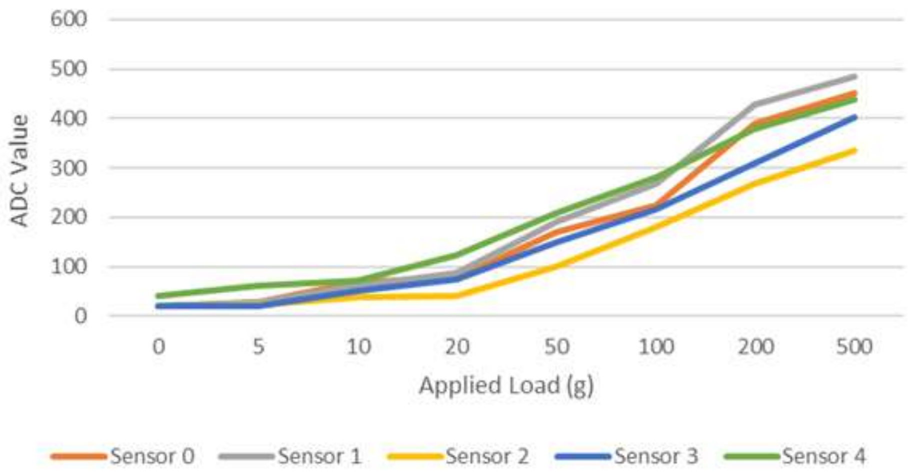


Figure 16. Sensitivity of the Sensor Network in the Continuous Fit Monitoring System to applied load.

Based on the above findings, the design methodology, which includes the algorithms to define a “standard” method for customization and subsequent refinement during each iteration, has led to digital prototypes of all the components of the RPD customized to the facial profiles of three individuals. The design and successful development of the fabric-based sensor network has demonstrated the realization of another key technology building block of the custom-fit RPD.

The Fastening Hub

The user’s role is critical in ensuring an optimal fit of the RPD because it affects both the user’s comfort and potential leakage at the faceseal. In addition to the elastic properties of the straps, the pressure exerted (both in magnitude and direction) at the faceseal depends on how the straps are positioned (e.g., distance and angle) on the wearer’s face and head. In practice, the straps may not always be in the same position each time the user dons the FFR. As a result, the pressure, and consequently the fit, could vary and affect the degree of protection for the user. Furthermore, unlike in an elastomeric half-mask respirator (EHMR), there is no provision in the FFR to “adjust” the force exerted by it based on the wearer’s facial profile and/or head size. In short, it is challenging for the user to place the straps in the ideal positions that will effectively balance comfort and protection. Therefore, there is a need for a mechanism to ensure that the user dons the RPD quickly, easily, effectively, and in a repeatable manner.

The concept of the Fastening Hub: We propose a hub that brings together the straps from the fastening hooks distributed on the sides of the RPD. It is placed on the user’s head. The straps are adjustable to enable the user to customize the force (pressure) exerted and thereby optimize the fit and comfort. The number of fastening hooks in the hub, the number of straps, and the best attachment points will be customized for each individual during the initial issue of the RPD when the user undergoes a QNFT to establish the baseline pressures that will ensure the proper fit of the RPD. A calibration scale built into the straps enables the user to position the straps quickly, which will be critical when access to respiratory protection is needed at short notice. The hub preserves the orientations and positions of the individual straps from the fastening hooks on the RPD frame to ensure uniform fit around the face during every use. Figure 17 shows the initial concept of the Fastening Hub with hooks into which straps with size adjustment clips are connected.

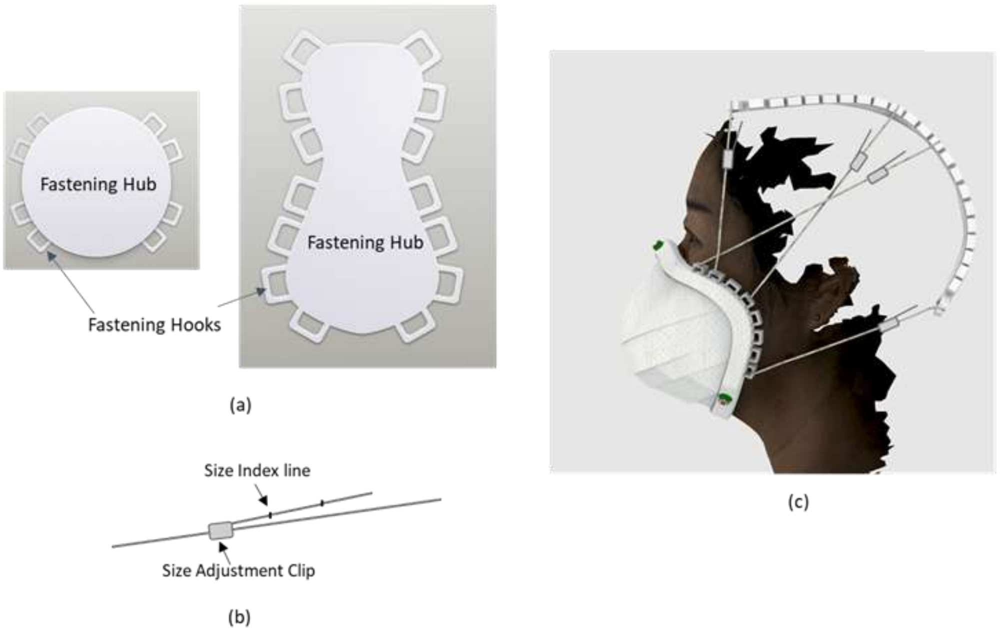


Figure 17. Concept of a Fastening Hub for enhancing fit and comfort of RPDs. (a) Design concepts for Fastening Hub. (b) Size-adjustable fastening strap. (c) Fastening Hub on Subject B using size-adjustable straps.

Algorithm for customizing the Fastening Hub for the individual: We developed algorithms to facilitate customization of the hub to fit the individual. The 3D scanning data acquired to create the RPD frame captures only the front ear-to-ear surface of the head. Since the Fastening Hub will rest on the top and back of the head, the facial landmarks used for creating the RPD Frame are not useful for creating the Fastening Hub. Therefore, based on a review of the head anthropometry literature, we chose the following landmarks as the starting set:

- Vertex (VT) - Top of the head (Lee *et al.*, 2018)
- Occiput (OP) - The most posterior point at the back of the head at the same vertical level to glabella (Lee *et al.*, 2018)
- Inion (IN) - The posterior-inferior protuberance point of the back of the head (Lee *et al.*, 2018).

We developed the steps to locate these points on the facial scan data through physical measurements. The Vertex is on the top of the head approximately parallel in vertical line with the Tragion. We located the Vertex by visual inspection and confirmed by palpation. We then measured the straight-cut distance from Tragion to Vertex and marked this point on the 3D scan data. Figure 18 (a) shows the location of the Vertex using this method for Subject B.

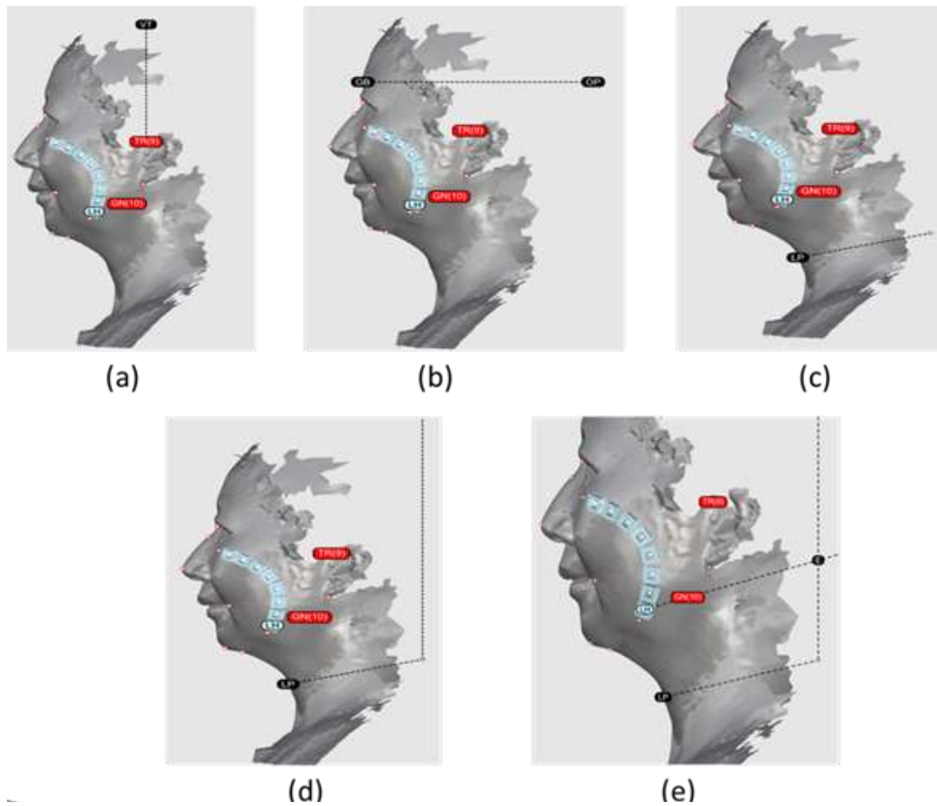


Figure 18. The steps to design the hub on the facial scan data of Subject B. (a) Locating the Vertex (b) Locating the Occiput (c-e) Locating the Hub End Point.

The Occiput is parallel to or at about the same level as the Glabella. To identify it, we measured the head circumference through the Glabella and Occiput and computed the diameter, which is the head depth. To confirm the use of this method to identify the Occiput, we measured the Nasion-Occiput distance and found it to be equal to the head diameter for the three subjects. Figure 18 (b) shows the use of this method for identifying the Occiput for Subject B.

We planned to use the Inion, the third landmark in the initial set, to locate the bottom or end point of the Fastening Hub. However, it was challenging to identify the Inion due to the lack of ready reference points. By utilizing the fact that the bottom-most fastening strap from the RPD frame must go below the ear to the bottom-most hook on the Fastening Hub, we used the Gonion as a reference point to locate the end (or bottom) point of the hub. We measured the neck circumference starting from the Larynx and used the diameter to estimate the neck depth. As shown in Figure 18 (c, d, e), we constructed a vertical line at the neck depth point, drew a line from the last hook on the RPD frame to the Gonion, and extended it until it intersected the vertical line. The intersection point is the end point of the Fastening Hub as shown in the figure, which we term the Hub End Point.

We used this algorithm to construct the profile of the back of the head for the three subjects, which defines the profile of the Fastening Hub. Figure 19 shows the base contours for the Fastening Hubs for the three subjects by interpolating through the Vertex, Occiput, and Hub End Point.

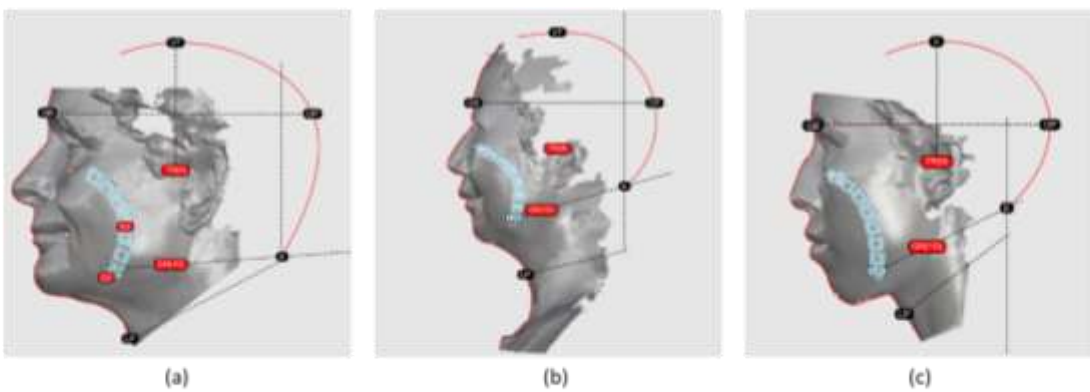


Figure 19. The base contours of the Fastening Hub for the three subjects.

Reducing the weight of the Fastening Hub using the Voronoi Tessellation: To reduce the weight of the Fastening Hub and to prevent any heat or sweat build-up under it during use, we transform the solid hub surface in Figure 19 into a Voronoi Tessellation (D'Agostino *et al.*, 2019). In this process, cells are cut out from the solid surface while preserving the integrity of the structure. Using Rhino® with Grasshopper plugin, we programmed a randomly generated Voronoi cutout pattern on the hub.

To ensure that the edges with hooks were not cut out, a 5 mm margin was maintained on the sides of the hub. We generated tessellation patterns by changing the counts, sizes, and offset percentages of the cells. Figure 20 shows two different pattern outcomes, one with 80 counts plus 70% offset and another with 20 counts plus 70% offset.

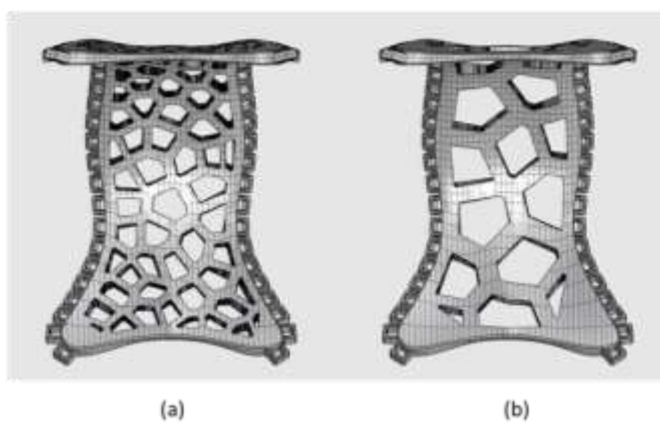


Figure 20. Fastening Hub Design with Different Voronoi Tessellations. (a) 80 counts plus 70% offset. (b) 20 counts plus 70% offset.

We chose the latter since it was airier and lighter than the former, thereby making it comfortable for the user and more economical to produce since it will require less material and shorter time. To arrive at the optimal design, in addition to the role of materials, the effect of design parameters (e.g., number and patterns of tessellations) on the durability of the hub will be studied by subjecting the hub to cyclical loading to simulate its typical use with the RPD. This will be an area of future research.

We used this algorithm for customizing the Fastening Hub to create digital prototypes successfully for the three subjects with different head profiles.

DISCUSSION

As was the case in Part I, the final set of algorithms for the placement of the sensors and the design of the fastening hub were based on landmarks associated with three individuals: two females and one male. The same iterative cycle was followed to arrive at the algorithms that were applied to the three individuals successfully.

As discussed earlier, the QNFT protocol was used as a guide to determine the placement of sensors in areas with higher chance of faceseal leakage. Accordingly, the number of sensors incorporated was five. These choices were made to demonstrate the feasibility of developing algorithms based on facial landmarks that could be applied to incorporate a continuous fit monitoring sensor network successfully into the RPD. The number and locations of the sensors can be refined based on extensive testing of the current system to identify and alert the user to faceseal leakages. As envisioned in practice, the baseline pressure values at the faceseal that ensure proper fit of the RPD for the user will be established during the QNFT at the time of issuance of the RPD. The changes in these baseline values will be processed by the algorithm and drive the generation of alerts to the user. Since the focus of the research presented here was on developing novel technology using a structured design methodology that harnessed the taxonomy of landmarks to create custom-fit RPDs for individuals with different facial profiles, such calibration and formal assessment of the continuous fit monitoring system on human subjects were not carried out; they will be the subject of future research. Likewise, starting with the current configuration, optimizing the number of sensors and their placement in the faceseal will be the subject of future research. Also, factors associated with conformity assessment were not considered in the study. For example, the number of straps, the materials used to make the straps, and the size-adjustable straps with scale are novel. Finally, the use of wireless technology and the App bring new dimensions and associated challenges with the integration of new technology into existing respiratory protection practices, which could potentially affect the cognitive load on the user.

CONCLUSIONS

We have designed and developed a continuous fit monitoring system successfully for a custom-fit RPD to enhance its role in protecting users from inhalation hazards in an effective manner during its use. We have developed algorithms for the incorporation of the sensor slots and data buses into the custom-fit RPD and enhanced its structure to secure the sensor network during the use of the RPD. We have developed algorithms for customizing a fastening hub to suit the head profiles of individuals to enable them to don the RPD quickly, easily, effectively, and in a repeatable manner. The resulting architecture of the custom-fit RPD comprises the technology building blocks of a Base Frame, a Covering Piece, a Fastening Hub, and a Continuous Fit Monitoring System. We have demonstrated the sensitivity of the fabric-based sensor network to changes in the applied load at the faceseal, which is at the heart of the continuous fit monitoring system integrated into the RPD. We have also successfully demonstrated the application of the total design methodology based on the Taxonomy of Landmarks by creating digital prototypes for three individuals with different facial profiles and set the stage for the realization of physical prototypes and their evaluation in Part III of this series. Thus, we have made further advances to our goal of ensuring equitable respiratory protection for all including children, for whom RPDs are currently limited.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health, Centers for Disease Control

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ATTRIBUTION

N95 is a certification mark of the U.S. Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.

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