Current Advances and Gaps in Knowledge on Personalizing Masks for Noninvasive Respiratory Support

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Noninvasive respiratory support delivered through a face mask has become a cornerstone treatment for adults and children with acute or chronic respiratory failure. However, an imperfect mask fit by using commercially available interfaces is frequently encountered, which may result in patient discomfort and treatment inefficiency or failure. To overcome this challenge, over the past decade, increasing attention has been given to the development of personalized face masks, which are custom-made to address the specific facial dimensions of an individual patient. With this scoping review, we aim to provide a comprehensive overview of the current advances and gaps in knowledge with regard to the personalization masks for CPAP and NIV. We performed a systematic search of the literature and identified and summarized a total of 23 studies. Most studies included were involved in the development of nasal masks. Studies that targeted adult respiratory care mainly focused on chronic (home) ventilation and included some clinical testing in a relevant subject population. In contrast, pediatric studies focused mostly on respiratory support in the acute setting, whereas testing was limited to bench or case studies only. Most studies were positive with regard to the performance (ie, comfort, level of air leak, and mask pressure applied to the skin) of personalized masks in bench testing or in human, healthy or patient, subjects. Advances in the field of 3-dimensional scanning and soft material printing were identified, but important gaps in knowledge remain. In particular, more insight into cushion materials, headgear design, clinical feasibility, and cost-effectiveness is needed before definite recommendations can be made with regard to implementation of large-scale clinical programs that personalize noninvasive respiratory support masks for adults and children. *Key words: face mask; customization; 3D printing; noninvasive ventilation; continuous positive airway pressure; obstructive sleep apnea; intensive care; respiratory failure; home ventilation.* [Respir Care 2024;69(9):1201–1211. © 2024 Daedalus Enterprises]

Introduction

Noninvasive respiratory support, such as CPAP and non-invasive ventilation (NIV) is widely used for a variety of clinical indications associated with acute and chronic respiratory failure in children and adults.[1-3] Treatment with CPAP or NIV most commonly use either a nasal, oronasal, or total face mask as an interface to provide positive pressure to the respiratory system and, less commonly, a helmet.[4-7] A good fit with a seal between the mask and the patient's face, which minimizes overall air leak and skin pressure, and maximizing comfort, is essential to deliver the treatment effectively.[8-11] For noninvasive respiratory support in the acute setting of respiratory failure, mask fit can be a major challenge, especially in children and in the growing group of patients with atypical facial features (eg, in the context of syndromic craniofacial disorders) or with abnormal facial tonus (eg, in neuromuscular diseases).

For these groups, commercially available mass-produced masks often do not fit well. An inadequately fitting mask will frequently result in large air leaks and painful skin pressure points with ulcers and/or necrosis, which leads to discomfort and patient-ventilator asynchrony, thereby contributing to treatment failure.[8,10-13] For long-term treatment in the chronic setting, even small deficiencies in fitting and sizing may lead to discomfort over time, as mentioned by studies[14,15] in adults receiving CPAP for obstructive sleep apnea.[9] In addition, in children with home ventilation, a frequent complication caused by increased pressure delivered to the face by ill-fitted masks is disruption of normal growth, which leads to development of facial deformities.[16]

With the advent of novel technologies, in particular, 3-dimensional scanning and printing in the past decade, several groups have started research lines to customize or personalize masks for CPAP and NIV by addressing the specific, individual facial features of patients. Ultimately, by providing a better fit, personalized face masks may increase the success of noninvasive respiratory support.[17] These current studies have a typical workflow on which the personalization of masks is based, shown in Figure 1. The current knowledge on data acquisition, materials, and production methods can be useful for multiple applications of NIV. However, there is a paucity of information on the comparison of the currently used methods. Because expertise is rapidly growing, we believe that an overview of the research on personalized ventilation masks is valuable because it will facilitate progress in its research and development, which makes personalized ventilation masks globally available in the near future. The primary objective of this study was to identify advances and gaps in knowledge in the technologies and working process(es) of personalizing ventilation masks. The secondary objective was to review any potential evidence with regard to the clinical efficacy, clinical effectiveness, or cost-effectiveness of applying personalized ventilation masks compared with commercially available interfaces.

Methods

Because of the broad scope of our study, and the new and variable research field, we considered a scoping review to be most suitable for our aim. The evidence synthesis methodology for this scoping review included a systematic search of the literature and was conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews. The PRISMA-ScR checklist is shown in eTable 1 (see the supplementary materials at http://www.rcjournal.com).[18]

Data Sources and Search Strategy

We searched the electronic databases PubMed/MEDLINE and Ovid EMBASE on May 2, 2023, by using search terms that relate to personalization of NIV masks. The complete and detailed search strategy by using index terms is reported in the predefined research protocol in eText 1 (see the supplementary materials at http://www.rcjournal.com). The reference lists of all included sources of evidence were screened for additional studies. There was no language restriction. Because the topic is related to recent developing technology, only articles published in the past 25 years were included. Abstracts could be included

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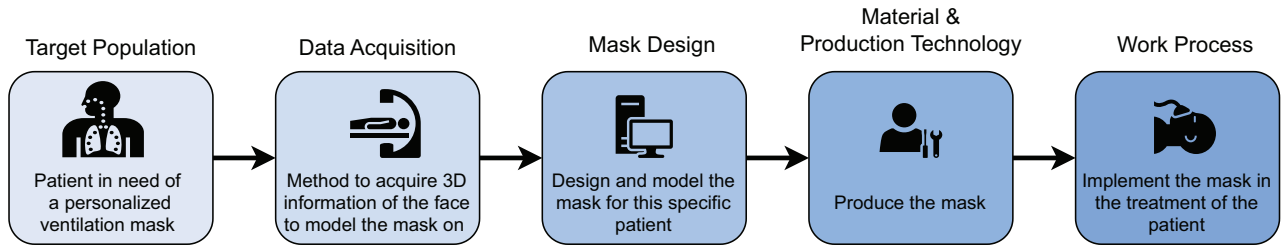
Fig. 1. A typical production workflow of personalization of noninvasive ventilation masks.

if sufficient relevant information was addressed. In addition, articles from design journals and patents on this topic were searched for additional information that might not be identifiable in the above-mentioned databases. For patents, the Google Patents database and European Patent Office were searched.

Study Selection

The citations were screened independently by 2 reviewers (RP and JS) on title and abstract, and discrepancies were resolved through discussion; when this failed, resolution was reached through arbitration by a third researcher (RB). Full-text articles were checked independently for eligibility. Eligible studies were those that report the development and/or production of fully or partially personalized ventilation masks indicated for patients (children and/or adults) who required acute or chronic respiratory support at home or at the hospital as well as studies that describe the testing of personalized masks. We considered both experimental and quasi-experimental study designs, including bench studies, modelling studies, methodologies, randomized controlled trials, non-randomized controlled trials, observational study designs, and case series/reports.

Outcome Measures

Studies were specifically searched, identified, and extracted against the background of 5 pre-defined outcome domains with a subset of relevant sub-questions, as fully reported in eTable 2 (see the supplementary materials at http://www.rcjournal.com). The 5 main domains with sub-questions were identified through extensive discussion with all the co-authors and the parent advisory board in an iterative process, and include the following: (1) target population, (2) data acquisition technologies, (3) mask design, (4) material and production technologies, and (5) working process.

Data Charting and Synthesis

Data charting was conducted by one researcher (RP) and independently checked by another (JS or RB) by using a data-charting form, which included study type, target population, data acquisition technologies, mask designs, material and production methods, and process feasibility. For the primary objective of this study, we organized and summarized the charted data described above as a qualitative synthesis through thematic analysis. The gaps in knowledge are shown by radar charting based on the scoring of each included study for minor or major focus on predefined research questions (see the supplementary materials at http://www.rcjournal.com). For the secondary objective, we organized the charted clinical data as a quantitative synthesis if deemed possible.

Results

The literature and patent database search resulted in 1,898 potentially relevant studies. After screening, 18 articles[8-11,19-32] and 5 abstracts[33-37] were included in this scoping review (Fig. 2). The studies originated in North America,[22,23,25,27,28,32-35,37] Europe,[9,11,19,20,26,31] Asia,[8,10,21,29,30] and South America.[24] With regard to study design, 5 case reports,[26,29,32,34,37] 8 experimental studies,[9,11,22,25,30,31,33,36] 4 bench studies,[19,20,23,35] 3 randomized controlled trials,[8,10,21] and 3 methodological studies[24,27,28] were included. The extracted data were presented according to our 5 pre-defined domains, with an overall summary in Table 1 and Figure 3. An overview of the gaps in knowledge as identified based on the domains is shown in Figure 4, whereof the classification of each article per domain is mentioned in Table 1. In roughly 7 studies, the domains of data acquisition[9,10,19,23,25,31] and mask design[9,10,11,22,23,25,30,32,36] were the major focus. Target population was a major focus in 5 studies,[8,21,30,33,36] of which 2 were abstracts.[33,36] For the domains material and production technology and working process, there were hardly any studies with these domains as a major focus.

Target Population

Of the 23 included studies, 14 focused on adults[8,9,10,21,22,25,27-30,32,33,36,37] and 9 focused on pediatric subjects.[11,19,20,23,24,26,31,34,35] For the adult studies, 13 studies designed a ventilation mask for chronic applications in adults,[8,9,21,22,25,27-30,32,33,36,37] mostly for obstructive sleep apnea.[8,9,21,22,27-29,32,36] Only one study focused

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          │                   │ No focus on noninvasive ventilation: 131           │
          │                   │ No focus on noninvasive ventilation mask: 110      │
          │                   │ No personalized ventilation mask: 49               │
          │                   │ Animal studies: 10                                 │
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          │                   │ No ventilation mask: 10                            │
          │                   │ Not personalized: 8                                │
          │                   │ Abstract with insufficient information: 4          │
          │                   │ Review: 2                                          │
          │                   │ Correspondence: 2                                  │
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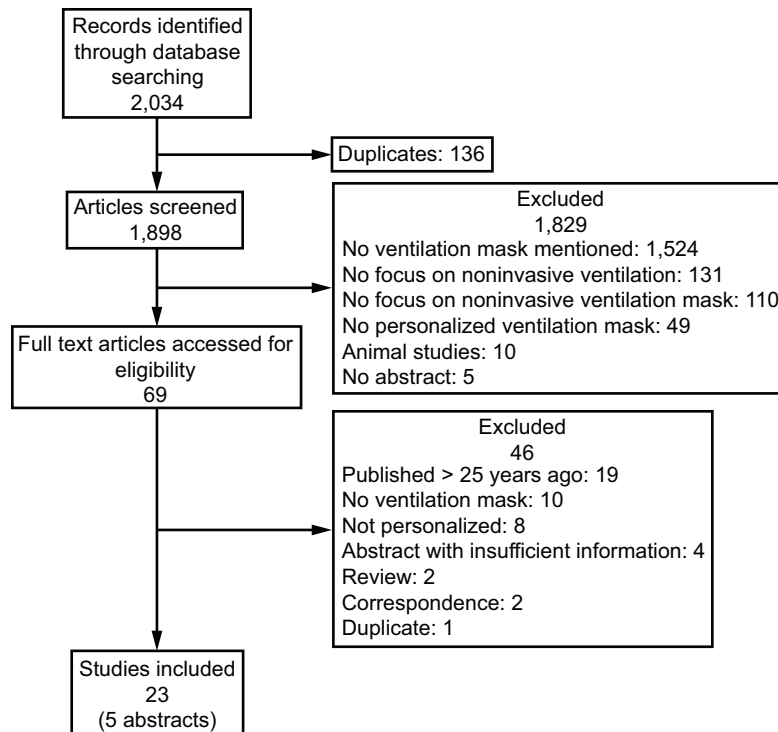
Fig. 2. Flow chart.

on application in the acute setting.[10] All adult studies tested their masks in human subjects, either in healthy volunteers,[9,10,22,25] patient cases,[27,30,35] or patient groups.[8,21,27,28,30,33,36] For the studies that focused on children, 4 designed masks especially for neonates.[20,23,24,26] The pediatric studies were more commonly centered around the application in acute respiratory failure.[11,20,23,24,26,31] However, testing for pediatric purposes only occurred in a bench setup,[19,20,23,35] in healthy adult subjects,[11,31] or in a single case.[26,34]

The masks were tested in various setups, frequently comparing with conventional masks. Some studies only examined subject comfort rating,[8,9,33] some examined only best fit based on skin pressure and/or air leakage,[11,20,23,25,29,30,35] and others tested both.[10,21,22,25,32,36] For the studies with children as the target population, all the studies reported positive results of the personalized interfaces, such as reduced air leak, reduced skin pressure, and/or improved comfort.[11,19,20,23,24,26,31,34,35] However, these results were not formally quantified and did not stem from studies that involved multiple pediatric subjects. For the studies with an adult target population, the same overall positive results were reported, which were often not quantified.[21,27-30,37] However, there were a few studies that showed improvement in subject comfort but no change in headgear force or air-leak volumes.[9,25,32] On the other hand, Hsu et al[8] showed no difference in subject comfort but did show a better rating in head-gear force and fit.

Only Duong et al[22] showed no improvement in air leakage and subject comfort compared with conventional masks.

Only 3 adult studies[8,21,30] included data on efficacy and effectiveness in patient groups, whereof, 2 studies referred to the same data set.[8,21] Hsu et al[8] and Cheng et al[21] showed a greater reduction in the apnea-hypopnea index for personalized masks ($P < .01$) and no difference in leak volume. Tsuboi et al[30] did find improved P_{aCO_2} values and lower leak volumes in personalized masks ($P < .01$). An overview of the target populations is shown in eTable 4 (see the supplementary materials at http://www.rcjournal.com). A quantitative analysis for clinical efficacy and effectiveness (secondary objective) was deemed not possible due to limited data from heterogenous studies.

Data Acquisition

Two different data acquisition techniques were used: a mechanical face impression and 3-dimensional scanning. Five studies[24,27-30] used impression methods to obtain face contours. The majority of studies (17) used a form of 3-dimensional photography and/or scanning,[8-11,19-23,25,26,31-36] with 3 studies that used data derived from a magnetic resonance imaging scanner[32] or computed tomography scanner[23,35] and one study used an unknown method.[33] The other 13 studies[8-11,19-23,25,26,31,34,36] examined a variety of 3-dimensional scan modalities based on light: handheld

Table 1. Overview of Scoping Review Findings: Baseline Characteristics

Study, Year	Study Design	Target Population	Data Acquisition	Mask Design	Material	Production Technology	Working Process
Artal et al,[33] 2017*	Experimental	Chronic: adults (sleep disorder patients with CPAP treatment)[†]	3D scanning[‡]	Nasal[§]	Unknown[§]	3D printing mold and casting	Unknown[‡]
Bockstedte et al,[19] 2022	Bench	Acute: children[‡]	3D scanning[†]	Nasal and oronasal[§]	Silicone[‡]	3D printing mold and silicone casting	Design: semi-automated; production: semi-automated and in-house production; time: <12 h[§]
Borras-Novell et al,[20] 2022	Bench	Acute: neonates[‡]	3D scanning[§]	Nasal[§]	Silicone[§]	3D printing mask	Design: manual; production: automated; time: 6 h[§]
Carroll et al,[34] 2014*	Case	Children (syndromic patient needing NIV)[§]	3D photograph[§]	Nasal[§]	Silicone[§]	3D printing mold and silicone casting	Unknown[‡]
Carroll et al,[35] 2015*	Bench	Children[‡]	CT[§]	Unknown[§]	Silicone[§]	3D printing mold and silicone casting	Unknown[‡]
Chee et al,[36] 2018*	Experimental	Chronic: adults (patients with OSA receiving CPAP)[†]	3D scanning[§]	Fitting component[†]	Silicone[§]	Fill gaps between face and mask	Production: manual[§]
Cheng et al,[21] 2015	RCT	Chronic: adults (patients with OSA receiving CPAP)[†]	3D scanning[‡]	Nasal[§]	Silicone[‡]	CNC mold and silicone casting	Design: manual; production: semi-automated; time: <1 wk[§]
Duong et al,[22] 2021	Experimental	Chronic: adults (patients with OSA receiving CPAP)[§]	3D photograph[§]	Nasal[†]	Cushion: silicone; coupler: resin[§]	Cushion: 3D printing mold and silicone casting; coupler: 3D printed	Design: manual; production: semi-automated[‡]
Hsu et al,[8] 2015	RCT	Chronic: adults (patients with OSA receiving CPAP)[†]	3D scanning[§]	Nasal[§]	Silicone[‡]	CNC mold and silicone casting	Design: manual; production: semi-automated; time: <12 h[§]
Kamath et al,[23] 2022	Bench	Acute: neonates[‡]	3D scanning[†]	Fitting component[†]	Silicone[§]	3D printing mold and casting silicone	Design: manual; production: manual; time: 6 h[§]
Lanza et al,[24] 2019	Methodology	Acute: neonates[‡]	Impression[‡]	Nasal[§]	Silicone[§]	Producing mold and casting silicone	Design: manual; production: manual; time: >72 h[§]
Ma et al,[9] 2021	Experimental	Chronic: adults (patients with OSA receiving CPAP)[§]	3D scanning[†]	Oronasal[§]	PLA[‡]	3D printing	Design: semi-automated; production: automated; time: >4-6 h[§]
Martelly et al,[25] 2021	Experimental	Chronic: adults (patients receiving nightly CPAP/NIV)[§]	3D photograph[†]	Oronasal[†]	Silicone[§]	3D printing mold and silicone casting to replace original cushion	Design: semi-automated; production: manual[§]

(Continued)

Table 1. Continued

Study, Year	Study Design	Target Population	Data Acquisition	Mask Design	Material	Production Technology	Working Process
Martín-Gónzález et al,[26] 2022	Case	Neonates[§]	3D scanning[‡]	Nasal[§]	Elastic photopolymer[§]	3D printing	Design: semi-automated; production: semi-automated[§]
McLornan et al,[27] 2008	Methodology	Chronic: adults (patients with OSA receiving CPAP)[§]	Impression[‡]	Prongs[‡]	Silicone[‡]	Producing mold and casting silicone	Design: manual; production: manual[‡]
Nuzhny et al,[37] 2023[*]	Case	Chronic: adults (users of NIV)[§]	Unknown[‡]	Nasal[‡]	Silicone[‡]	3D printing	Unknown[‡]
Prehn and Colquitt,[28] 2016	Methodology	Chronic: adults (patients with OSA receiving CPAP)[‡]	Impression[‡]	Oronasal[‡]	Unknown[‡]	Unknown	Unknown[‡]
Reddy et al,[29] 2019	Case	Chronic: adults (patients with OSA receiving CPAP)[§]	Impression[‡]	Prongs[‡]	Silicone[‡]	Producing mold and casting silicone	Design: manual; production: manual[‡]
Shikama et al,[10] 2018	Crossover RCT	Acute: adults (critically ill, receiving NIV)[§]	3D scanning[†]	Fitting component[†]	Silicone[‡]	3D printing mold and silicone casting	Design: manual; production: semi-automated; time: >6 h[§]
Tsuboi et al,[30] 1999	Experimental	Chronic: adults[†]	Impression[‡]	Nasal[†]	Resin[‡]	Mask formed on impression	Design: manual; production: manual; time: 3 h[§]
Willox et al,[11] 2020	Experimental	Chronic and acute: children[§]	3D scanning[§]	Oronasal[†]	Polyamide and wound dressing[§]	3D printing mask and manually placing wound dressing	Production: semi-automated; time: <2 wk[†]
Willox et al,[31] 2021	Experimental	Chronic and acute: children[§]	3D scanning[†]	Unknown[‡]	Unknown[‡]	Unknown	Unknown[‡]
Wu et al,[32] 2018	Case	Chronic: adults[§]	MRI[§]	Oronasal[†]	Cushion: silicone; mask frame: resin[§]	Cushion: 3D printing mold and silicone casting; coupler: 3D printed	Design: semi-automated; production semi-automated; time: >5 h[§]

The scoring system for the focus indication is shown in Supplementary eTable 2 (see the supplementary materials at http://www.rcjournal.com).
* Abstract.
† Major focus.
‡ Not addressed.
§ Minor focus.
3D = 3-dimensional
NIV = noninvasive ventilation
CT = computed tomography
OSA = obstructed sleep apnea
RCT = randomized controlled trial
CNC = computer numerical control
PLA = polylactic acid
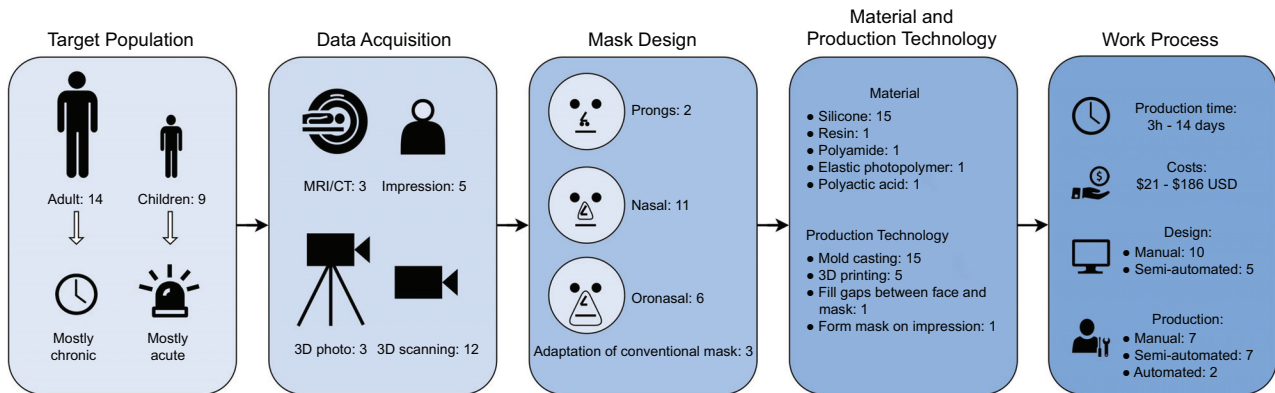MRI = magnetic resonance imaging

Fig. 3. An overview of the number of studies identified and main results in this scoping review per pre-defined outcome domain.
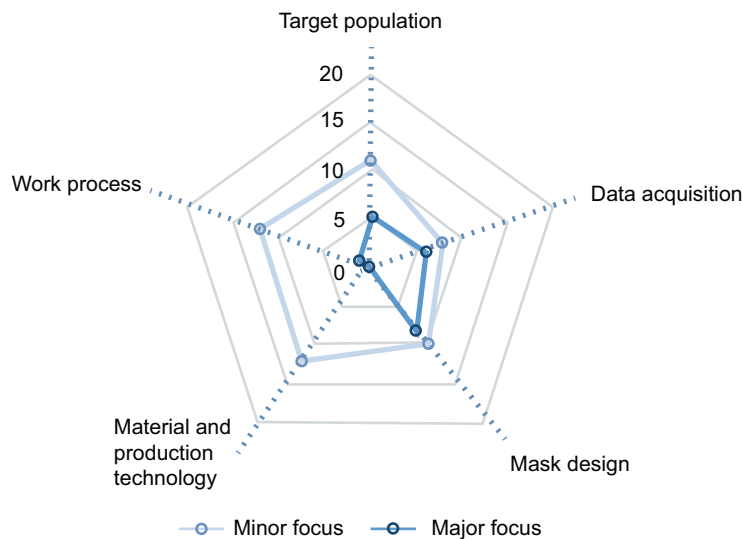

Fig. 4. Distribution (radar chart) of research questions addressed by all included studies (23) as either major or minor focuses (see the supplementary materials at http://www.rcjournal.com for scoring per domain) to identify gaps in knowledge.

scanners used multi-image acquisition,[23] laser scanning,[25] or structured light scanning[9-11,19,20,23,26,31,34,36] and stationary scanners used photogrammetry.[11,19,22,23,25,31] Three studies compared scanning methods.[19,23,31] They concluded that photogrammetry is the quickest (<1 s) and less sensitive to patient movement. Nevertheless, handheld scanners based on structured light were chosen as the best option, being affordable, safe, and more convenient. Both handheld and stationary scan methods require post-processing, which could take from seconds up to a few minutes, depending on the scanner, accompanying software and scan quality.[8-10,19-23,25,31,34,36] The quality depends on various factors such as patient movement, lighting conditions, scanner settings, and time constraints. Most study post-processing steps included trimming the scan and converting it to a STL format.

With regard to the CE-marking (Conformité Européenne) of the used data acquisition techniques, the medical scanners and stationary scanners were always CE-marked. For the

handheld scanners, the GoScan 50 (Creaform, Levis, Canada) and Artec 3-dimensional scanners (Artec Eva, Spider, and Leo; Artec 3D, Senningerberg Niederanven, Luxembourg) were found to be CE-marked. The other used handheld scanners were not CE-marked or could not be found online. A detailed overview of the findings with regard to data acquisition can be found in eTable 5 (see the supplementary materials at http://www.rcjournal.com).

Mask Design

Six studies designed an oronasal mask,[9,11,19,25,28,32] 11 designed a nasal mask,[8,19-22,24,26,30,33,34,37] 2 designed nasal prongs,[27,29] and 3 studies designed a fitting component applied to conventional masks.[10,23,36] The structural design in most studies involved a single component for the entire mask, prongs, or fitting component.[8-11,19-21,23,24,26-30,34] In 3 studies,[31,33,35] the structural design was unknown. Two

studies designed a nasal mask that consisted of 2 components: Duong et al[22] designed a soft cushion with a rigid coupler to connect the cushion to the tubing system, and Nuzhny et al[37] designed a nasal mask with nose clips. Moreover, Wu et al[32] and Martelly et al[25] designed a personalized cushion that replaced the original cushion of a conventional mask. Chee et al[36] manually added silicone to a commercial mask to fill existing air gaps in patients. The headgear used was mentioned in 5 studies,[9,11,22,30,34] whereof, in one study, the researchers developed their own headgear[11] and the other studies used commercial headgear. No information was given on the connection to the masks.

The customization of the masks was done digitally, except for the study by Chee et al[36] and the studies that used impression data acquisition.[24,27-30] Five studies[11,26,31,33,37] did not mention their customization methods. Eight studies used a non-automated method, in which they manually drew the outline of the mask on the face,[8,9,21,35] or digitally morphed a basic mask to fit the face.[10,20,22,34] Two studies used a semi-automated approach: Bockstedte et al[19] used commercially available software and made an interchangeable basic mask design that involved patient-specific parameters, and Wu et al[32] developed a semi-automatic software for cushion modelling by which the user can edit a standard outline (based on size), which is then automatically made into a 3-dimensional cushion. A detailed overview is shown in eTable 6 (see the supplementary materials at http://www.rcjournal.com).

Material and Production Technology

The production technologies used in the included studies to make personalized masks can be divided into 2 categories: (1) fabricating a mold and casting (a part of) the mask with a chosen material, or (2) 3-dimensional printing (a part of) the mask. Only Chee et al[36] and Tsuboi et al[30] used other methods because they manually formed the material into its form. The first method was chosen in most studies.[8,10,19,21-25,27,29,32-35] The molds were 3-dimensional printed, except for the study of Cheng et al,[21] which used computer numerical control. In 2 studies, the mold-producing method was not mentioned.[27,29] When using this method, silicone was always chosen as the mask material. Duong et al[22] and Wu et al[32] used a design in which personalized cushion and a coupler were fabricated. Both studies used the first method to produce the cushion and 3-dimensional printed the coupler. The second method was chosen in more recent studies (2020 and later).[9,11,20,26,37] For this method, rigid materials,[9,11] soft resins,[26] and silicone[20,37] were used. The articles that used hard materials or resin mentioned that the cushioning should be improved, which is achieved by the silicone printers. A detailed overview is shown in eTable 7 (see the supplementary materials at http://www.rcjournal.com).

Working Process

The production time of producing a personalized mask was noted to range from 3 h to 14 d.[8,11,19-21,23,30,36] Of these studies, 75% mentioned a production time < 24 h[8,19,20,23,30,36] and the other 25% of the studies[11,21] needed more than a day. In many studies, the duration was only mentioned for specific parts of the production process[9,10,24,27,29,31,32] or not at all.[22,25,26,28,33-35,37] Moreover, the costs for a personalized mask ranged from $21 to $186 per mask.[8,11,20,21,30,36] Most studies did not mention the production costs but frequently explained that the costs of personalized masks can be reduced when the production process is automated and/or located in house.[8,20,21,24,27] The cost-effectiveness is not mentioned in these studies. No study tested the feasibility of the workflow in a clinical setting. A detailed overview is shown in eTable 8c (see the supplementary materials at http://www.rcjournal.com).

Discussion

In this scoping review, we identified 23 studies that investigated personalization of noninvasive respiratory support masks, of which 10 studies[9,11,19,20,22,23,25,26,31,37] were published in the past 3 years, which indicates a rapidly growing research field. Whereas most studies were positive with regard to the performance (ie, comfort, air leak, and pressure applied to the skin) of personalized masks in bench testing, healthy or patient, subjects, we found only 3 studies[8,21,30] that formally investigated clinical efficacy and no studies on clinical- or cost-effectiveness compared with conventional commercial masks. Recent advances in data acquisition by 3-dimensional scanning and printing were identified, but important gaps in knowledge that encompass the entire design and clinical implementation process remain. For each thematic domain, this resulted in the following findings:

1. Target population: studies focused either on adult chronic (home) respiratory support, or pediatric acute respiratory failure. For both populations, mask personalization seems promising.

2. Data acquisition: 3-dimensional scanning (handheld or static) is the most accurate, quick, and cost-effective.

3. Mask design: most studies designed nasal masks, but automated or semi-automated modelling software is limited. Moreover, research into optimal mask fixation is lacking.

4. Material and production technology: mold casting of silicone is most commonly used. However, 3-dimensional printing for soft materials, including silicones, for personalized masks is an emerging methodology.

5. Working process: currently reported mask production processes range widely in costs and dedicated time.

Increased patient discomfort and ventilation difficulties due to suboptimal fit of commercially available masks are well-recognized complications during noninvasive respiratory support throughout pediatric and adult respiratory care fields.[8-13,38] Strategies and new technologies that personalize masks may therefore provide a valuable solution for this current unmet medical need. Although we indeed identified studies that address this challenge in adult chronic (home) respiratory support, limited research was conducted by focusing on the acute setting for this age group. Vice versa, pediatric studies focused mostly on acute respiratory failure. This reflects the notion that, especially in children, acute NIV failure, which may occur in up to 53% of patients,[39] can be assigned at least partly to ill-fitting masks.[40]

Few studies compared different data acquisition methods,[19,23,31] but, collectively, they identify 3-dimensional scanning as the most accurate, quick, and cost-effective option to date. Evidently, 3-dimensional scanning also holds an advantage over the use of computed tomography radiation. For mobile patients, a static 3-dimensional scanner can be advised because this setup acquires data quickly (<1 ms) and is less influenced by movement. However, static scanners are expensive and require calibration, considerable space for the setup, and hospital attendance of a patient. For immobile patients, handheld 3-dimensional scanners are advised because they can be used at the bedside or at home and remain relatively fast (1-10 min) and accurate. Currently, a few CE-certified handheld 3-dimensional scanners exist, and all have software to trim and improve scans if necessary. Nevertheless, we found no studies that formally tested the feasibility of using a handheld 3-dimensional scanner for data acquisition of immobile patients treated in an acute respiratory failure setting.

Interestingly, we found that most studies designed personalized nasal masks. This type of mask may be a first choice in chronic respiratory failure (eg, home CPAP or NIV) but often is not sufficient for acute respiratory support due to air leaks from the mouth.[41,42] Additional interest in the production of other mask types, including oronasal and total face masks, therefore, is warranted. All studies reported designs by using conventional mask forms, while personalizing the cushion areas that come into contact with the face. No studies described alternative or more novel designs, such as those specifically sparing the nose bridge, which is the most sensitive area for skin pressure injuries.[43] In this light, it is interesting to note a recent randomized controlled trial among adults with acute hypercapnic respiratory failure, which showed a decrease in skin pressure ulcers by an under-the-nose NIV mask.[44] However, this mask also led to increased unwanted air leaks, reducing the enthusiasm for this type of design.[44] Another big influence on mask fitting is headgear usage. Differences between the number and placing of fixation points and the use of caps or straps could influence the fit.[45,46] However, most studies included in this review did not mention specific mask or they used commercially available headgear. As such, further research into this particular aspect is warranted.

Automation of the modelling and production process of personalized masks will be extremely important for feasibility in clinical practice.[8,11,19-21,24,25,27] Unfortunately, we found very limited information on the development of semi-automatic software, without the need to draw mask contours manually, for this purpose.[32] Such software could decrease the production time, limit the need for specialized technical personnel, and standardize mask quality. The research field might thus benefit from further development of open-source software aimed at personalizing ventilation masks, possibly by using built-in sizing charts for all ages. Furthermore, materials and production methods should be further investigated. Mold casting of silicone, a widely available, soft material with skin-safe ISO (International Organization for Standardization) standards, is often chosen to form a mask. This is rational because silicone is mostly used in commercial masks as the cushioning material. Nevertheless, in the production of personalized masks, this method requires substantial manual labor, time, and costs. However, no study compared different silicone shores to find the optimal cushioning material. Recently, 3-dimensional printing for soft materials, including silicones, for personalized masks is emerging.[20,26,37] This novel technology also introduces new materials, such as printable elastomers,[47] although the number of printable biocompatible soft materials is currently limited. In addition, these materials are not always compatible with standard 3-dimensional printers,[20,26,37] let alone those commonly available to hospitals for in-house printing beyond research purposes. A willingness of materials manufacturers to undertake biocompatibility testing for skin contact would enable these techniques to move forward more quickly for inclusion into clinically viable products.

Currently reported mask production processes range widely in costs and dedicated time. This can be explained by the differences between in-house production versus outsourcing, manual labor versus automation, and mask design. Some production prices were as low as $20-$40. However, it should be noted that such prices may not always include specific costs for labor and equipment. Conventional masks can vary from $20 up, but not limited, to $100. Therefore, it is believed that producing personalized ventilation masks can be cost-effective. When depending on the specific application, choices should be made to achieve the optimal balance between production time and costs.

Besides the costs and time for mask production alone, the important aspects of the entire process implementation should be mentioned. Currently, the use of 3-dimensional scanners is growing in multiple medical fields.[48] Moreover, 3-dimensional printers are also increasingly used in the standard clinical practice of multiple disciplines and departments of health care.[49] For in-house production, hospitals could greatly benefit from this growing technology if a

dedicated unit would provide 3-dimensional scanning and 3-dimensional printing expertise for multiple departments. This way, the expertise of biomedical engineers, clinicians, and technicians can be combined to implement new 3-dimensional techniques in the hospital.[50] Nevertheless, the implementation of these techniques remains fairly costly and will not be feasible for every hospital, particularly, those outside the academic environment. Therefore, it is imperative that future studies should focus on the cost-effectiveness of the entire production process. In addition, although included studies of this scoping review mainly focused on the proof-of-concept to personalize masks, there is a paucity of data on their clinical effectiveness in various patient groups. Therefore, further clinical research is of utter importance to stimulate the field of NIV mask personalization and for efficient implementation as a medical device in the standard clinical respiratory care.[51]

Strengths and Limitations

A strength of this research was that we followed the normal systematic review methodology[18] and predefined certain thematic domains with relevant sub-questions to identify advances and gaps in knowledge. To the best of our knowledge, this is the first full overview of current methodologies and outcome studies on personalization of noninvasive respiratory support interfaces. However, as per the methods of a scoping review, no recommendations on clinical practice can yet be made and no quality assessment of included studies was performed. Although the current research outlook is promising, studies on clinical efficacy and clinical- and cost-effectiveness were scarce, hampering any quantitative analysis.

Summary

This scoping review provides an overview of the relatively new and promising field of personalization of noninvasive respiratory support masks, with the intent to provide a resource for investigators in the field and an impetus for future research. Advances in the field of 3-dimensional scanning and soft material printing were identified, but important gaps in knowledge remain. In particular, additional insight into cushion materials, headgear design, clinical feasibility, and cost-effectiveness is needed before definite recommendations can be made with regard to implementation of large-scale clinical programs that personalize masks for treatment in adults and children with acute or chronic respiratory failure. Our work may serve as an impetus to further research efforts that encompass the entire workflow on noninvasive respiratory support mask personalization.

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