**Supplemental content to:**

Personalized ventilation masks for an optimized fit: a scoping review, by Pigmans et al.

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**eTable 1. PRISMA-ScR Checklist**

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

| **SECTION** | **ITEM** | **PRISMA-ScR CHECKLIST ITEM** | **REPORTED ON PAGE #** |
| --- | --- | --- | --- |
| **TITLE** | | | |
| Title | 1 | Identify the report as a scoping review. | 1 |
| **ABSTRACT** | | | |
| Structured summary | 2 | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives. | 3 |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach. | 3/4 |
| Objectives | 4 | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives. | 4 |
| **METHODS** | | | |
| Protocol and registration | 5 | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number. | 5 |
| Eligibility criteria | 6 | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale. | 5 |
| Information sources\* | 7 | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed. | 5 |
| Search | 8 | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated. | Supplement 6/7 |
| Selection of sources of evidence† | 9 | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review. | 6 |
| Data charting process‡ | 10 | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | 6 |
| Data items | 11 | List and define all variables for which data were sought and any assumptions and simplifications made. | 7 and Supplement 4/5 |
| Critical appraisal of individual sources of evidence§ | 12 | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate). | N/A |
| Synthesis of results | 13 | Describe the methods of handling and summarizing the data that were charted. | 7 |
| **RESULTS** | | | |
| Selection of sources of evidence | 14 | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram. | 7 and Figure 2 |
| Characteristics of sources of evidence | 15 | For each source of evidence, present characteristics for which data were charted and provide the citations. | 7 |
| Critical appraisal within sources of evidence | 16 | If done, present data on critical appraisal of included sources of evidence (see item 12). | N/A |
| Results of individual sources of evidence | 17 | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives. | Table 1 and Supplement 8-15 |
| Synthesis of results | 18 | Summarize and/or present the charting results as they relate to the review questions and objectives. | 7-11 |
| **DISCUSSION** | | | |
| Summary of evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | 10-14 |
| Limitations | 20 | Discuss the limitations of the scoping review process. | 14 |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | 15 |
| **FUNDING** | | | |
| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | 1 |

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

\* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O’Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting*.*

§The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 16 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. [doi: 10.7326/M18-0850](http://annals.org/aim/fullarticle/2700389/prisma-extension-scoping-reviews-prisma-scr-checklist-explanation).

**eTable 2.** Predefined domains with relevant sub-questions

A priori, we have identified five separate domains with a subset of relevant sub-questions:

|  |  |
| --- | --- |
| **Domain** | **Sub-questions** |
| ***Target population*** | * What type of patients (adult versus pediatric) have been targeted in this field? * In what setting (acute critical care versus long-term (home) ventilation)? * What is the evidence in terms of efficacy or effectiveness of using personalized NIV masks versus commercially available (off-the-shelf) masks in these target populations/settings (e.g. differences in acceptance and/or complications)? |
| ***Data acquisition technologies*** | * What type of technologies (e.g. 3D/CT scanning, imprinting) are being exploited? * What digital (post-)processing steps are being taken? * Have there been comparative studies in this field? * What are the differences (advantages/ disadvantages) between these technologies? * Are the used technologies CE-marked? |
| ***Mask design*** | * What type of mask designs (e.g. oronasal, total face, nasal) have been studied? * What structural designs (e.g. single or multiple components, including headgear or not) have been developed? * Have (open-source) (semi-)automated software platforms for customization been developed? * How are the mask designs tested for differences in pressure and/or leak, compared to conventional masks? |
| ***Material & Production Technologies*** | * What types of materials (e.g. silicone, clay, and plastics) have been exploited? * What type of production technologies (e.g. molding, 3D printing, extruding) for these materials have been investigated? * Have there been comparative studies in this field? * What are differences (advantages/disadvantages) between these materials/technologies (e.g. durability, reusability, or softness)? * Are the used materials compliant with the right ISO standards? |
| ***Working process*** | * Have there been (comparative) studies on the feasibility and logistical working process/flow (e.g. knowledge from personnel, duration between indication and availability) of personalizing NIV masks? * Have there been studies on production time and cost-effectiveness over the life cycle, from creation until disposal? * Are the services adopted into clinical practice or by a commercial company? |

**eTable 3.** Questions to define gaps in knowledge

|  |  |
| --- | --- |
| **Domain** | **Sub-questions** |
| ***Target population*** | * Is the personalized mask tested for its population?\* |
| ***Data acquisition technologies*** | * Does the article mention the digital (post-)processing steps? * Does the article compare data acquisition technologies? * Are the used technologies CE-marked? |
| ***Mask design*** | * Does the study include a (open-source) (semi-)automated software platforms for customization? * Does the article mention headgear? * Have the mask designs been tested for differences in pressure and/or leak? * Have the mask designs been compared to conventional masks? |
| ***Material & Production Technologies*** | * Does the article compare materials? * Does the article compare production methods? * Are the used materials compliant with the right ISO standards? |
| ***Working process*** | * Does the article mention the feasibility and logistical working process/flow of personalizing NIV masks? * Does the article mention production time? * Does the article mention cost-effectiveness over the life cycle, from creation until disposal? |

A scoring (not addressed – minor focus – major focus) on five domains is given to the article regarding their contribution to evidence on producing personalized masks:

* Not addressed: zero questions answered
* Minor focus: one or two questions answered
* Major focus: three (or more) questions answered

\*For this category:

* Not addressed: bench study
* Minor focus: tested in healthy volunteers or a single patient
* Major focus: tested in patient group

**eText 1.** Search strategy logbook

**Name: Rosemijne Pigmans**

**Date: 02-05-2023**

**Purpose**: To write a scoping review

**Title:** Personalized ventilation masks for an optimized fit: a scoping review

**Research question(s):** see eTable 1 for a priori defined domains and (sub-)questions

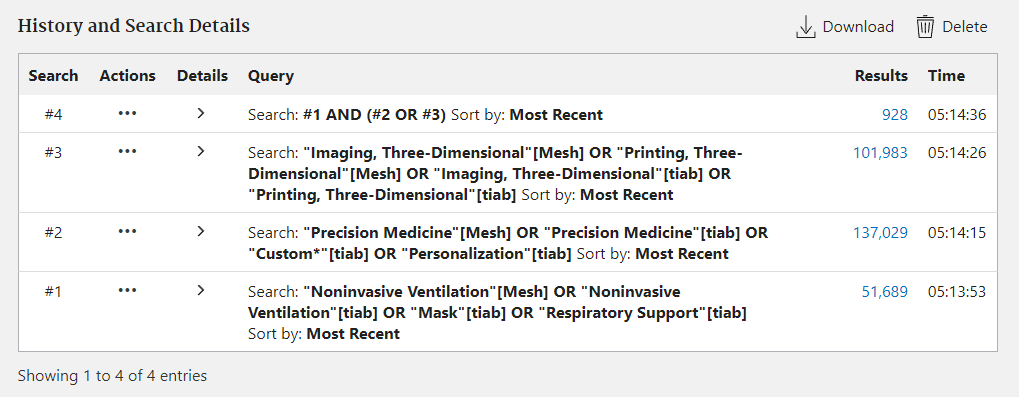
|  |
| --- |
| **Databases** |
| PubMed/MEDLINE |
| EMBASE |

**PubMed:** [PubMed (nih.gov)](https://pubmed.ncbi.nlm.nih.gov/) (n = 928)

|  |  |
| --- | --- |
| **MeSH database** | |
| Aspect 1: | "Noninvasive Ventilation"[Mesh] |
| Aspect 2: | "Precision Medicine"[Mesh] |
| Aspect 3: | "Imaging, Three-Dimensional"[Mesh] OR "Printing, Three-Dimensional"[Mesh] |

|  |  |
| --- | --- |
| **Tiab** |  |
| Aspect 1: | "Noninvasive Ventilation"[tiab] OR “Mask”[tiab] OR “Respiratory Support”[tiab] |
| Aspect 2: | "Precision Medicine"[tiab] OR “Custom\*”[tiab] OR “Personalization”[tiab] |
| Aspect 3: | "Imaging, Three-Dimensional"[tiab] OR "Printing, Three-Dimensional"[tiab] |

|  |  |
| --- | --- |
| **Combined** | |
| #1 | "Noninvasive Ventilation"[Mesh] OR "Noninvasive Ventilation"[tiab] OR “Mask”[tiab] OR “Respiratory Support”[tiab] |
| #2 | "Precision Medicine"[Mesh] OR "Precision Medicine"[tiab] OR “Custom\*”[tiab] OR “Personalization”[tiab] |
| #3 | "Imaging, Three-Dimensional"[Mesh] OR "Printing, Three-Dimensional"[Mesh] OR "Imaging, Three-Dimensional"[tiab] OR "Printing, Three-Dimensional"[tiab] |
| #4 | #1 AND (#2 OR #3) |

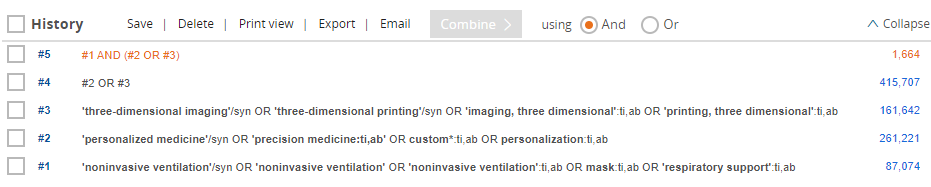


**EMBASE:** [Embase](https://www.embase.com/#advancedSearch/default) (n = 1664)

|  |  |
| --- | --- |
| **EMTREE database** | |
| Aspect 1: | ‘Noninvasive Ventilation’/syn |
| Aspect 2: | ‘Personalized Medicine’/syn |
| Aspect 3: | ‘Three-Dimensional imaging’/syn OR ‘Three-Dimensional printing’/syn |

|  |  |
| --- | --- |
| **Tiab** |  |
| Aspect 1: | 'noninvasive ventilation':ti,ab OR mask:ti,ab OR 'respiratory support':ti,ab |
| Aspect 2: | 'precision medicine:ti,ab' OR custom\*:ti,ab OR personalization:ti,ab |
| Aspect 3: | 'imaging, three dimensional':ti,ab OR 'printing, three dimensional':ti,ab |

|  |  |
| --- | --- |
| **Combined** | |
| #1 | 'noninvasive ventilation'/syn OR 'noninvasive ventilation':ti,ab OR mask:ti,ab OR 'respiratory support':ti,ab |
| #2 | 'personalized medicine'/syn OR 'precision medicine:ti,ab' OR custom\*:ti,ab OR personalization:ti,ab |
| #3 | 'three-dimensional imaging'/syn OR 'three-dimensional printing'/syn OR 'imaging, three dimensional':ti,ab OR 'printing, three dimensional':ti,ab |
| #4 | #2 OR #3 |
| #5 | #1 AND (#2 OR #3) |



**eTable 4.** Target Population

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study** | **Target patients** | **Care setting** | **Test Environment** | **How tested** | **Outcome** |
| Artal et al., 2017\*1 | Adults  (Sleep disorder patients with CPAP treatment) | Chronic | At home | Mask effect was examined with questionnaires in 8 patients. | NQ: Personalized masks were well received |
| Bockstedte et al., 20222 | Children | Acute | N/A | Bench model. Fit visually examined on manikin | NQ: PM had a better fit than CM. |
| Borras-Novell et al., 20213 | Neonates | Acute | N/A | Bench model. Leak was examined in a leak-free-circuit. Fit was examined by leaving an ink impression on a manikin’s face. | Lower leak (64% vs 78% (no p-value reported)) and more facial contact points for the PM compared to CM |
| Carroll et al., 2014\*4 | Children  (Syndromic patient needing NIV) | Unknown | Unknown | Unknown | Unknown |
| Carroll et al., 2015\*5 | Children | Unknown | N/A | Bench model. On a facial model of a patient, the leak was measured in PM and two different CM for different weights that created a seal. | PM showed lower leak percentages than one CM (p<0.01), the other CM was similar (p = NS) |
| Chee et al., 2018\*6 | Adults  (OSA patients receiving CPAP) | Chronic | Unknown | Data on mask leak and nightly CPAP use was collected in patients. | Patients used their masks more and air leak seemed to be lower (NQ). |
| Cheng et al., 20157 | Adults  (OSA patients receiving CPAP) | Chronic | At home | Apnea-hypopnea index, leakage volume and comfort were collected in 40 patients, that were randomly assigned to either PM group or CM group. | PM showed more improvement of apnea-hypopnea index than CM (p<0.01). Leakage volume (32.8 vs 35.5 L/min) and comfort score were NS. |
| Duong et al., 20218 | Adults  (OSA patients receiving CPAP) | Chronic | Hospital  (healthy volunteers) | Leakage and comfort were evaluated in 6 healthy volunteers at different headgear tightness (100, 350, 600g) and CPAP pressures (4, 8, 12 cmH2O) | There were no differences in leakage and comfort between customized and conventional masks at CPAP level 4 and 8 cmH2O and at 100 and 350g tightness. At maximal tightness the custom mask had a lower leak (p<0.05): at 4 cmH2O compared to smallest size CM and at 8 and 12 cmH2O compared to middle size CM. |
| Hsu et al., 20159 | Adults  (OSA patients receiving CPAP) | Chronic | At home | Mask fit (headgear force, fit and comfort) was evaluated with a questionnaire in 40 patients. | No difference in comfort, but headgear force (r = .51) and the cushion fit (r = .62) were rated better (p<0.01) in PM. |
| Kamath et al., 202210 | Neonates | Acute | N/A | Bench model. Skin pressure and strap tension were measured for different CPAP pressures (4, 6, 8 and 10 cmH2O) and different positions on a face model of a patient. Both with and without the fitting component. | The fitting component reduced skin pressure (9.6-62%) and strap tension (16.0-56.6%). No p-value was presented |
| Lanza et al., 201911 | Neonates | Acute | N/A | Unknown | NQ: custom mask is well accepted by babies compared to commercial masks. |
| Ma et al., 202112 | Adults  (OSA patients receiving CPAP) | Chronic | Hospital  (healthy volunteers) | Mask fitting and comfort were scored in two healthy volunteers using a questionnaire, comparing conventional standard 3D printed mask and customized 3D printed masks.. | The 3D printed masks scored better on fit and comfort than conventional. But the personalized mask was not better than the standard 3D printed mask. No numerical results or p-value was presented |
| Martelly et al., 202113 | Adults  (Patients receiving nightly CPAP/NIV) | Chronic | Hospital  (healthy volunteers) | The CM and PM were tested for comfort (questionnaire) and air leak in five healthy volunteers. | The PM was similar in comfort (p = NS) and air leak (p = NS) compared to CM. Nevertheless, there were trends in favor of the PM. |
| Martin-Gonzalez et al., 202214 | Neonates | Unknown | Hospital | The PM was tested according to the vital signs and NIV parameters and local skin lesions. These values were collected in an infant in the incubator and in kangaroo position. | The PM showed a good fit and the oxygen supply could be reduced from 45% to 21%. No p-value was presented. PIP and PEEP could be lowered and desaturations and bradycardias were not present. There were disappearing red marks on the skin. |
| McLornan et al., 200815 | Adults  (OSA patients receiving CPAP) | Chronic | N/A | Unknown | Unknown |
| Nuzhny et al., 2023\*16 | Adults  (NIV users) | Chronic | At home | Unknown | NQ: Air leak decreased and comfort was improved. |
| Prehn et al., 201617 | Adults  (OSA patients receiving CPAP) | Chronic | N/A | Unknown | Unknown |
| Reddy et al., 201918 | Adults  (OSA patients receiving CPAP) | Chronic | At home | The personalized mask was tested on one patient for fit and comfort | NQ: Air leak decreased, a lower CPAP setting was sufficient and skin irritation decreased. |
| Shikama et al., 201819 | Adults  (Critically ill, receiving NIV) | Acute | Hospital  (healthy volunteers) | The effect of the fitting component was examined in an crossover RCT study in 20 healthy participants by measuring the presence of erythema, comfort and contact pressure. | The incidence of erythema (100% vs 75%, p<0.01), discomfort (p<0.01), contact pressure on the nasal bridge (32.3 vs 18.6 mmHg, p<0.01) and pressure distribution (71.6 vs 57.5%, p=0.01) )were reduced with the fitting components. The contact pressure at the chin (p<0.01) and the strap tension (105.0 vs 9.4 gf, p<0.01) were increased. |
| Tsuboi et al., 199920 | Adults | Chronic | Hospital | The PM was compared to prongs and a CM regarding blood gasses and leak volume for 10 patients. | The PM resulted in lower PaCO2 (5.56 vs 6.87 kPa), and higher ventilation pressure (30 vs 24 cmH2O, p<0.01) with fewer leaks (43 vs 90 mL/breath, p<0.01) were supported. |
| Willox et al., 202021 | Children | Chronic and acute | Hospital  (healthy volunteers) | The PM was tested in three adult volunteers. The air leakage and the force in headgear and on the face was measured. | The pressure and leak results show a correlation between higher loadings and reduced leak, and the PM with wound dressing had lower leaks than the CM. No numerical value or p-value was presented |
| Willox et al., 202122 | Children | Chronic and acute | Hospital  (healthy volunteers) | Unknown | Unknown |
| Wu et al., 201823 | Adults | Chronic | At home | Different designs of the PM were tested for comfort, leak, preference, recommendation and tolerance in a questionnaire for one patient. | The softer personalized cushions were more prone to leak and thin layers eventually started to leak over time. However, the comfort scored better in all personalized masks. No p-value was presented |

**\*** Abstract only

Continuous Positive Airway Pressure (CPAP); Non-Invasive Ventilation (NIV); Not quantified (NQ); Personalized mask (PM); Conventional mask (CM); Obstructive Sleep Apnea (OSA); Not significant (NS)

**eTable 5.** Data Acquisition

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Article** | **Type(s) of data acquisition** | **Advantages** | **Disadvantages** | **Digital (post-)processing steps** | **CE-marked** |
| Artal et al., 2017\*1 | Scan data | Unknown | Unknown | Unknown | Unknown |
| Bockstedte et al., 20222 | 3D scanners   1. Handheld – structured light   Intraoral scanner (Trios 3, 3Shape, A/S)   1. Portable – photogrammetry Facial scanner (3dmd Flex System) | 1. Intraoral:    * More affordable  * Often available in hospital * Portable  1. Facial:  * Frame selection * Whole face * Possibly portable | Intraoral:   * Sensitive to movement   Facial:   * More expensive | Reduce and trimm scan data  (Fushion 360) | Yes |
| Borras-Novell et al., 20213 | 3D scanner  Handheld – structured light Peel 2 CAD scanner (Peel 3d) | Handheld | Direct light into eyes for 1.5-2 min | Convert scan to STL format | Not mentioned on website 3D scanner |
| Carroll et al., 2014\*4 | 3D scanner  Structured light  Facial topographic 3D photography | Unknown | Unknown | Convert scan to STL format | Unknown |
| Carroll et al., 2015\*5 | CT | Unknown | Unknown | CT image to 3D model (Mimics Innovation Suite software) | Yes |
| Chee et al., 2018\*6 | 3D scanner  Stationary – structured light  Xbox Kinect | Freely available software | Unknown | Convert scan to STL format | No |
| Cheng et al., 20157 | 3D scanner  Unknown  M300, Logistic Technology Corp | * Easy to set up and use in the hospital * 10 minutes for scan | Unknown | Convert to 3D computer-aided design cast | Unknown |
| Duong et al., 20218 | 3D scanner  Stationary – photogrammetry  3dmdface System | Unknown | Unknown | Reduce and trim scan data  (Meshmixer) | Yes |
| Hsu et al., 20159 | 3D scanner  Unknown  M300, Logistic Technology Corp | * Lightweight (6kg) * Easy to install * Takes 0.5s to capture scan | Unknown | Convert scan to solid  (Geomagic Studio CAD toolbox (3D system Inc) | Unknown |
| Kamath et al., 202210 | CT  3D scanner   1. Handheld - Structured light   Artec Spider   1. Multi-image acquisition system – handheld   Sony   1. Photogrammetry – handheld  * Bellus 3D camera (infrared)   Iphonex with truedepth | Structured light scanning:   * Safe * Rapid acquisition * Affordable | CT:   * Radiation exposure * Segmentation * Coslty   Photogrammetry:   * Requires surface distinctions   Laser scanning:   * Eye protection required * Image degraded   Long acqusition time | Convert scan to solid  (Meshlad and Meshmixer) | Artec: Yes  Sony: Unknown  Bellus: Unknown  Iphone: Yes |
| Lanza et al., 201911 | Impression | Unknown | * Additional oxygen needed   Vital signs monitoring | N/A | N/A |
| Ma et al., 202112 | 3D scanner  Handheld – structured light  Creaform goscan 50 (Levis, CA) | 5 min acquisition for 30,000 triangles. | Fast scanning has difficulties scanning near the nose bridge and the eyelids | Convert scan into 3D mesh and remove nose and smooth artifacts  (VX-Elements software). | Yes |
| Martelly et al., 202113 | 3D scanner  Stationary - photogrammetry  four Logitech C270 web cameras on 180\* rail | * Low cost * Ease of implementation * Less post-processing steps compared to laser scanning (Vivid 91 3D digitizer) | Less accurate, but accurate enough for purpose | Stitch photos to create 3D image  (Recap Photo, Auto-Desk) | Yes |
| Martin-Gonzalez et al., 202214 | 3D scanner  Handheld – structured light  (Asorcad Engineering S.L.) | * No contact * No radiation | Sensitive for movement | Unknown | Unknown |
| McLornan et al., 200815 | Impression | Unknown | * Additional appointment * Laboratory expenses | N/A | N/A |
| Nuzhny et al., 2023\*16 | Unknown | Unknown | Unknown | Unknown | Unknown |
| Prehn et al., 201617 | Impression | Quicker than previous used impression method | Unknown | N/A | N/A |
| Reddy et al., 201918 | Impression | Unknown | Unknown | N/A | N/A |
| Shikama et al., 201819 | 3D scanner  Handheld – structured light  Eva, Artec 3D | * Can be applied in adults and children * No radiation * No need for sedation of critically ill | Unknown | Align face scan and mask | Yes |
| Tsuboi et al., 199920 | Impression | Unknown | Unknown | N/A | N/A |
| Willox et al., 202021 | 3D scanner   1. Stationary - photogrammetry   3dmd body scanner   1. Handheld - Structured light   Artec Spider | Static:  Fast (near instant) and accurate | Unknown | Unknown | Yes |
| Willox et al., 202122 | 3D scanner   1. Stationary - photogrammetry   3dmd body scanner   1. Handheld - Structured light   Artec EVA, Artec Spider and Artec Leo   1. Stationary - photogrammetry   (123D catch: smartphone and non-single lens reflex camera). | * Accurate * Handheld * More cost effective than static | Static camera is faster: 12 min total (<2 ms scanning) | Post-processing (in Artec Studio) work of 10–30 min depending on the quality and number of scans. | Yes |
| Wu et al., 201823 | MRI | Readily available in hospital | * Expensive   Claustrophobic | * Segment MRI (Materialize Mimics, Belgium) * Smooth data and make computer model * Save segmented surface as STL format * Imported to interactive computer program to make personalized mask | Yes |

\* Abstract only

**eTable 6.** Mask Design

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study** | **Mask Type** | **Structural Design** | **Headgear** | **Customization Software** | **PM\*\* vs CM\*\*\*** |
| Artal et al., 2017\*1 | Nasal | Unknown | Unknown | Unknown | Yes |
| Bockstedte et al., 20222 | Nasal and oronasal | Single component | Unknown | Digital and semi-automated:  Editing parameters of basic mask design in Fushion 360 (Autodesk) | Yes |
| Borras-Novell et al., 20213 | Nasal | Single component | Unknown | Digital and non-automated:  Adapt standard mask model to follow facial contours in Mimics Medical 24.0 (Materialise) | Yes |
| Carroll et al., 2014\*4 | Nasal | Single component | Standard | Digital and non-automated :  Edit 3D drawing of a standard mask to match face contours | Unknown |
| Carroll et al., 2015\*5 | Unknown | Unknown | Unknown | Digital:  Subtract facial surface from generic mask form in Rhinoceros. Unknown if automated for more patients. | Yes |
| Chee et al., 2018\*6 | Fitting component | Additional silicone where needed | N/A | N/A | Yes |
| Cheng et al., 20157 | Nasal | Single component | Unknown | Digital and non-automated :  The mask outline was drawn on the face scan. Then a section of the cushion was designed and swept along the line to create an object. | Yes |
| Duong et al., 20218 | Nasal | A soft cushion with a rigid coupler piece | Standard | Digital and non-automated :  Point-wise matching the cushion design to the face scan in Fushion 360 (Autodesk). | Yes |
| Hsu et al., 20159 | Nasal | Single component | Unknown | Digital and non-automated:  The mask outline was drawn on the face scan. Then a section of the cushion was designed and swept along the line to create an object. | Yes |
| Kamath et al., 202210 | Fitting component | Single component | N/A | Digital:  Fushion 360 (Autodesk) and 3-matic (Materialise) was used for the development | Yes |
| Lanza et al., 201911 | Nasal | Single component | Unknown | Manual | Unknown |
| Ma et al., 202112 | Oronasal | Single component | Standard | Digital and non-automated:  A polyline across 12 chosen facial landmarks is made in SpaceClaim (Ansys). The mask height is chosen through patient preferences and a standard connection is used. | Yes |
| Martelly et al., 202113 | Oronasal | Customized cushion on a commercial mask | N/A | Digital and automated:  Interactive computer program was developed (C++). The shell contour of the standard mask is automatically placed on the face scan and the cushion is automatically generated. In four steps there is a possibility to adapt the mask size, planar placement and wall thickness, rotation, and/or tapering | Yes |
| Martin-Gonzalez et al., 202214 | Nasal | Single component | Unknown | Unknown | Yes |
| McLornan et al., 200815 | Prongs | Single component | Unknown | Manual | Unknown |
| Nuzhny et al., 2023\*16 | Nasal | Two components | Unknown | Unknown | Yes |
| Prehn et al., 201617 | Oronasal | Single component | Not needed | Manual | Unknown |
| Reddy et al., 201918 | Prongs | Single component | Unknown | Manual | Yes |
| Shikama et al., 201819 | Fitting component | Single component | N/A | Digital and non-automated:  The space between chin and mask was digitally filled in Geomagic Sculpt 3D (3D systems). | Yes |
| Tsuboi et al., 199920 | Nasal | Single component | Standard | Manual | Yes |
| Willox et al., 202021 | Oronasal | Single component with wound dressing | Developed | Unknown | Yes |
| Willox et al., 202122 | Unknown | Unknown | Unknown | Unknown | Unknown |
| Wu et al., 201823 | Oronasal | Customized cushion on a commercial mask with a rigid interface in between. | N/A | Digital and semi-automated:  Interactive computer program was developed (C++). The user can design outline of rigid interface, which is made 3D by projecting on face scan. According to this interface the cushion was made. | Yes |

\* Abstract only

**eTable 7.** Material and Production Technology

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study** | **Mask Material** | **ISO standards** | **Production Technology** | **Comparative** |
| Artal et al., 2017\*1 | Unknown | Unknown | 3D printing mold and casting | 2 versions of nasal mask were compared |
| Bockstedte et al., 20222 | Silicone  SF45 (Silikonfabrik) | Not skinsafe | 3D printing mold and silicone casting | No |
| Borras-Novell et al., 20213 | Silicone  AMSil Silbione 24501-50 TRS A-B (AMSil) | Skin safe† | 3D printing | No |
| Carroll et al., 2014\*4 | Silicone | Medical grade‡ | 3D printing mold and silicone casting | No |
| Carroll et al., 2015\*5 | Silicone | Medical grade‡ | 3D printing mold and silicone casting | Yes, several shores, but no results shown |
| Chee et al., 2018\*6 | Silicone  Ecoflex 10 (Smooth-on) | Skin safe† | Fill gaps between face and mask | No |
| Cheng et al., 20157 | Silicone | Unknown | CNC mold and silicone casting | No |
| Duong et al., 20218 | Cushion: Silicone, Dragon Skin 30 (Smooth-on)  Coupler: resin | Skinsafe† | Cushion: 3D printing mold and silicone casting  Coupler: 3D printed | No |
| Hsu et al., 20159 | Silicone  no.1310 (Shin-Etsu Chemical Co.) | Biocompatible‡ | CNC mold and silicone casting | No |
| Kamath et al., 202210 | Silicone  Ecoflex (Smooth-on) | Skin safe† | Producing mold and casting silicone | Yes, several shores but no results shown |
| Lanza et al., 201911 | Silicone  RTV A-2000 (Factor II) | Biocompatible‡ | Producing mold and casting silicone | No |
| Ma et al., 202112 | PLA | Unknown | 3D printing | No |
| Martelly et al., 202113 | Silicone  Platinum cure, Dragon Skin 10 (Smooth-on) | Skin safe  ISO 109993-10 | 3D printing mold and silicone casting to replace original cushion | No |
| Martin-Gonzalez et al., 202214 | Elastic photopolymer, shore 50 | Medical resin‡ | 3D printing | No |
| McLornan et al., 200815 | Silicone  A-2000 (Factor II) | Unknown | Producing mold and casting silicone | No |
| Nuzhny et al., 2023\*16 | Silicone | Unknown | 3D printing | No |
| Prehn et al., 201617 | Unknown | Unknown | Unknown | No |
| Reddy et al., 201918 | Silicone | Unknown | Producing mold and casting silicone | No |
| Shikama et al., 201819 | Silicone  Duplicone (SHOFU) | Unknown | 3D printing mold and silicone casting | No |
| Tsuboi et al., 199920 | Resin  Ostron 2 (GC Co) | Unknown | Mask formed on impression | No |
| Willox et al., 202021 | Polyamide and wound dressing | Medical grade‡ | 3D printing mask and manually adding wound dressing | No, there were iterations on measuring process but not comparative |
| Willox et al., 202122 | Unknown | Unknown | Unknown | No |
| Wu et al., 201823 | Cushion: Silicone  Platinum-cure, Dragon Skin 10 (Smooth-on)    Coupler: resin  Clear resin (Formlabs) | Skin-safe  ISO 10993-10 | Cushion: 3D printing mold and silicone casting  Coupler: 3D printed | Yes:  10 different kinds of silicone layers were tested - difference in silicone thickness - rigid interface following the contour of the face, or only the silicone layer following the contour - rough silicone edges to prevent mask movement |

\* Abstract only

† no corresponding ISO standards found

‡ as mentioned by article only

Computer numerical control (CNC); Polyactic acid (PLA)

**eTable 8.** Working Process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study** | **Feasibility Working flow** | **Production time** | **Cost-effectiveness** | **Commercial vs Public** |
| Artal et al., 2017\*1 | The scanning process was accepted by clinical personnel. | Unknown | Unknown | Commercial |
| Bockstedte et al., 20222 | Their method is automated as much as possible, to optimize the process of in house production. | Nasal mask:   * 6h 2m with 1h30m hands on time * 9h with 33m hands on time   Oronasal mask:   * 8h 46m with 1h 46m hands on time * 16h 40m with 47m hands on time | Unknown | Public |
| Borras-Novell et al., 20213 | Unknown | 6h   * 10m scanning * 2h mask design * 3h printing | $88 USD (€80,-)  Four times higher than conventional mask. Costs can be reduced by atomization and in house production. | Public |
| Carroll et al., 2014\*4 | Unknown | Unknown | Unknown | Public |
| Carroll et al., 2015\*5 | Unknown | Unknown | Unknown | Public |
| Chee et al., 2018\*6 | Unknown | 4h | $22 USD ($30 CAD) | Public |
| Cheng et al., 20157 | Unknown | < 1 week   * 10m scanning * <1 week of production | Unknown | Public |
| Duong et al., 20218 | Unknown | Unknown | Unknown | Public |
| Hsu et al., 20159 | Unknown | 13h   * 5h labor * 6h30m CNC * 30m silicone curing | $21.45 USD (when producing a minimum of five masks)   NOTE: study in Taiwan, hourly labor rates are $6.67 | Public |
| Kamath et al., 202210 | Unknown | 6h | low cost | Public |
| Lanza et al., 201911 | Unknown | Unknown   * 72h silicone curing * 5m release * 10m disinfection | Unknown | Public |
| Ma et al., 202112 | Unkown | Unknown   * 5m scanning * 4-6h printing | Unknown | Public |
| Martelly et al., 202113 | The interface-generation software allows for easy customization of the mask by the patient or the physician. The molding and casting process were standardized to ensure consistent mask quality. | Unknown | Unknown | Public |
| Martin-Gonzalez et al., 202214 | Unknown | Unknown | Unknown | Public |
| McLornan et al., 200815 | The impression method is less feasible as it needs an additional patient appointment. | Unknown   * 2h silicone curing | Unknown | Public |
| Nuzhny et al., 2023\*16 | Unknown | Unknown | Unknown | Public |
| Prehn et al., 201617 | Unknown | Unknown | Unknown | Commercial |
| Reddy et al., 201918 | Unknown | Unknown   * 24h silicone curing | Unknown | Public |
| Shikama et al., 201819 | Unknown | Unknown   * 5h mold printing * 30m silicone curing | Unknown | Public |
| Tsuboi et al., 199920 | Unknown | 3h | $30 USD  Usable for 18 months | Public |
| Willox et al., 202021 | 3D scanning patients is feasible, for further research the following aspects should be taken into account:   * Timings * Staff requirements * Feasibility of access to the location of the scanner * Hair covering * Scan should be made in neutral face position | 10-14 days   * 4h processing scan data * 10-14 days sending file to be printed | $155-$186 USD (£123-£147) for oronasal adults mask  $38 USD (£30) for infant nasal mask. | Public |
| Willox et al., 202122 | Unknown | Unknown   * 30m scanning | Unknown | Public |
| Wu et al., 201823 | Unknown | Unknown   * 5h printing interface | 5$ USD for printing interface | Public |

\* Abstract only

**References** eTable 4 – 8

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