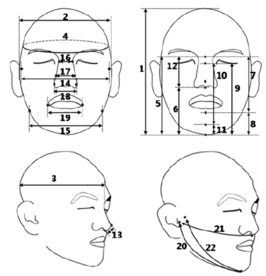
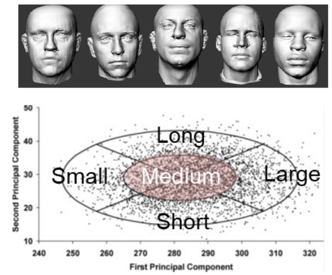
INDUSTRIAL AND MANAGEMENT ENGINEERING, POSTECH

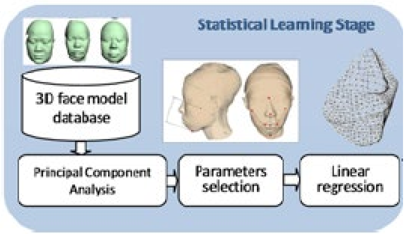
Ergonomic Design Technology Lab

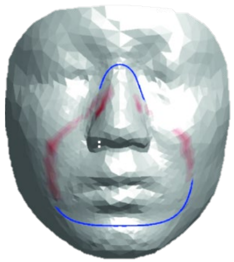
A Literature Review on Ergonomic Issues for Development of Non-Invasive Ventilation (NIV) Mask

비침습적 인공호흡기 마스크의 인간공학적 설계 및 평가 방법: 문헌 조사









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본 연구는 양산부산대학교병원 의생명융합연구소의 인큐베이팅 연구과제의 지원을 받아 수행된 결과입니다.

Global Contributor to Eco-Techno-Humanopia

Contents

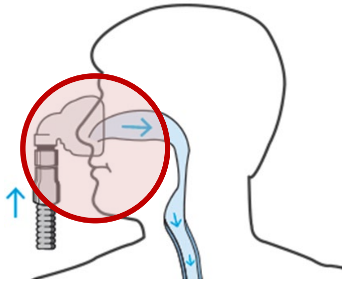
Non-Invasive Ventilation (NIV)

- The non-invasive ventilation (NIV) is a therapy to manage respiratory depression & respiratory failure.

Respiratory depression due to collapses airway during sleep

Respiratory failure due to neuromuscular disease

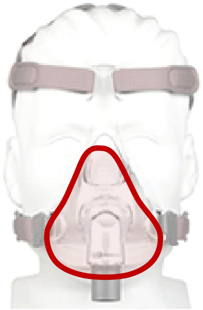
Non-Invasive ventilation Therapy



NIV Mask Interfaces

- NIV mask interface is divided by face coverage area.

Full-Face Mask



Oronasal Mask

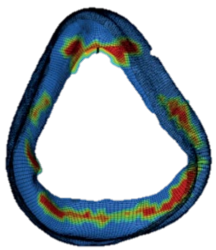
Nasal Mask

Oral mask

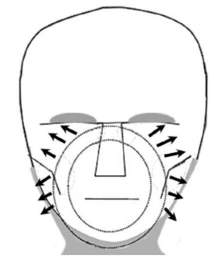
Mask Related Problems

- The **shape of NIV mask interface** is important for the **comfort and safety of patients**. **Excessive pressure** and **air leakage** caused by **improper fit** are the main reasons of NIV failure (5%-60% in critical patients).

Excessive pressure

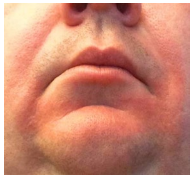


Air leakage

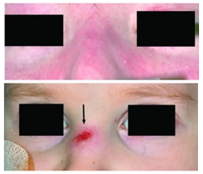


discomfort

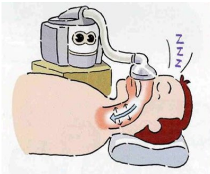
rash



skin damage

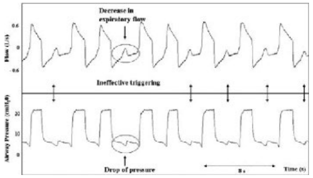


oronasal dryness & sleep disruption



conjunctivitis

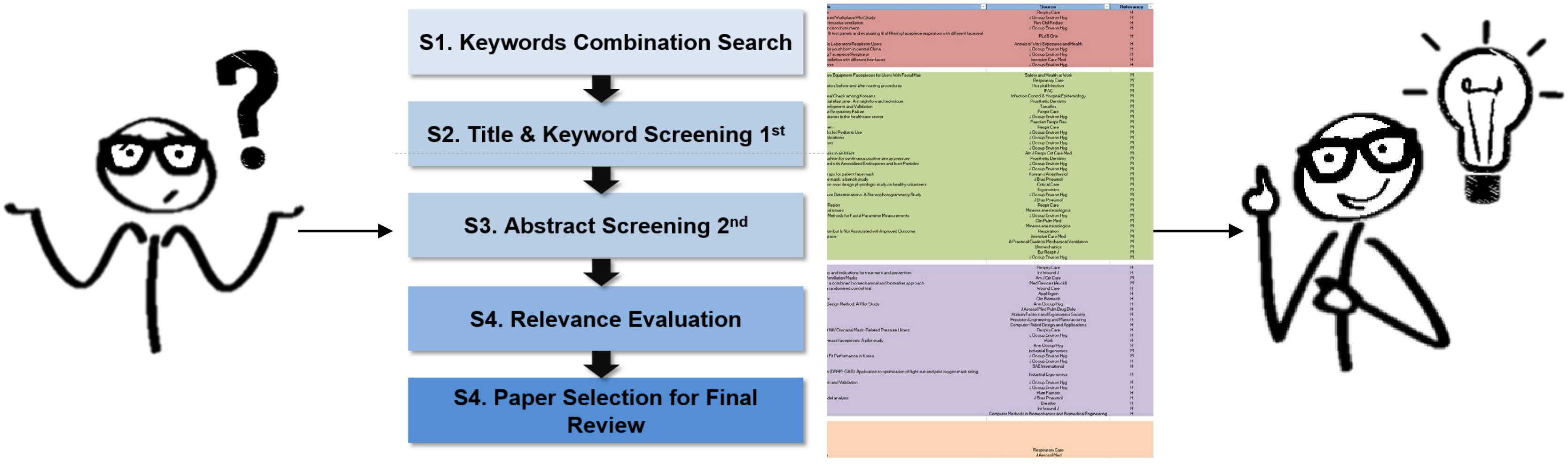
ventilation error



(BaHammam et al., 2017; Visscher et al., 2015; Barros et al., 2014)

Research Motivation

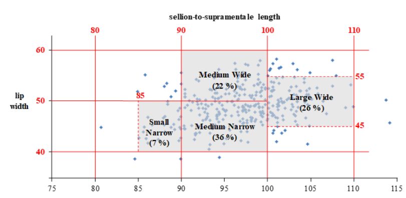
- Ergonomic studies of NIV mask development are needed to improve the fitness, solve the usability and safety problems of the NIV mask.
- Systematically organization of NIV mask development issues is needed.

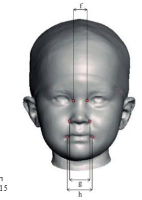


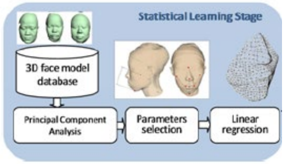
Objective of the Study

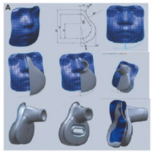
Systematically literature review on ergonomic issues for development of NIV mask

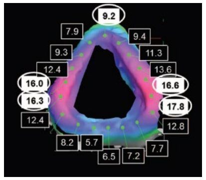
1. **Facial feature analysis**
   - Facial dimensions important to mask design
   - Measurement strategy
   - Sizing system
   - Generation of representative face models
2. **Mask interface design**
   - Shape design method
3. **Usability test**
   - Subjective and objective evaluation
   - Virtual fit testing

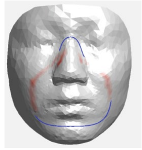












Literature Review: Search Method (1/3)

❑ Source

- www.scopus.com

❑ Scope

- Search title, abstract, or auto-specified keywords

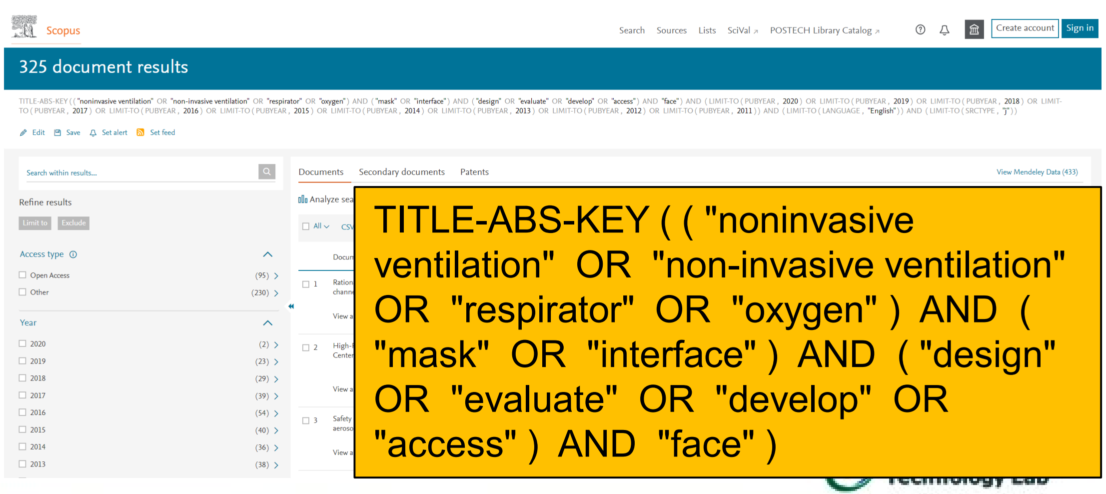
❑ Keywords

- Mask design and evaluation related: mask, interface, design, evaluate, noninvasive ventilation, respiratory, face

❑ Selection criteria

- Year: within 10 years
- Source type: journals
- Language: English

Keywords Combination Search



TITLE-ABS-KEY (("noninvasive ventilation" OR "non-invasive ventilation" OR "respirator" OR "oxygen") AND ("mask" OR "interface") AND ("design" OR "evaluate" OR "develop" OR "access") AND "face")

Literature Review: Screening Process (2/3)

❑ A total of **75** papers screened by title and abstract screening.

S1. Keywords Combination Search

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S2. Title & Keyword Screening 1st

↓

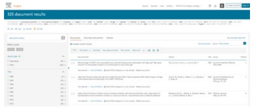
S3. Abstract Screening 2nd

↓

S4. Relevance Evaluation

↓

S4. Paper Selection for Final Review



325 papers

144 papers

91 papers

High: **22** papers, Medium: **44** papers, Low, **25** papers

22 (High) + **44** (Medium) + 9 (Additional) **75**

Literature Review: Paper List (3/3)

- After checking the full text of each of the screened papers, a total of 35 papers (high: 24 papers; medium: 11 papers) were lastly cited in the present study.

No.	Author(s)	Year	Title	Source	Relevancy
1	Zhuang	2004	A Head and Face Anthropometric Survey of U.S. Respirator Users	Report (NIOSH)	H
2	Zhuang et al.	2008	A New Approach to Developing Digital 3-D Headforms	SAE International	H
3	Yu et al.	2011	Digital 3-D Headforms Representative of Chinese Workers	Ann Occup Hyg	H
4	Lee et al.	2012	Analysis of the Facial Anthropometric Data of Korean Pilots for Oxygen Mask Design	Human Factors and Ergonomics Society	H
5	Amirav et al.	2013	Design of Aerosol Face Masks for Children Using Computerized 3D Face Analysis	J Aerosol Med Pulm Drug Deliv	H
6	Lee et al.	2013	Development of a Design Methodology of Pilot Oxygen Mask Using 3D Facial Scan Data	Doctoral Dissertation	H
7	Lee et al.	2013	Ergonomic Design and Evaluation of a Pilot Oxygen Mask	Human Factors and Ergonomics Society	H
8	Lee et al.	2014	Ergonomic Design and Evaluation of a Pilot Oxygen Mask for Korea Air Force Pilots	3D Body Scanning Technologies	H
9	Barros et al.	2014	Facial pressure zones of an oronasal interface for noninvasive ventilation: a computer model analysis	J Bras Pneumol	H
10	Chu et al.	2015	Design Customization of Respiratory Mask based on 3D Face Anthropometric Data	Precision Engineering and Manufacturing	H
11	Visscher et al.	2015	Face Masks for Noninvasive Ventilation: Fit, Excess Skin Hydration, and Pressure Ulcers	Respiry Care	H
12	Luximon et al.	2016	A design and evaluation tool using 3D head templates	Computer-Aided Design and Applications	H
13	Lee et al.	2017	A Shape based Sizing System for Facial Wearable Product Design	Applied Human Factors and Ergonomics	H
14	Lee et al.	2017	Analysis Methods of the Variation of Facial Size and Shape Based on 3D Scan Images	Human Factors and Ergonomics Society	H
15	Lee et al.	2017	Comparison of a Semiautomatic Protocol Using Plastering and Three-Dimensional Scanning Techniques with the Direct Measurement Protocol for Hand Anthropometry	Human Factors and Ergonomics in Manufacturing & Service Industries	H
16	Manganyi et al.	2017	Quantitative Respirator Fit, Face Sizes, and Determinants of Fit in South African Diagnostic Laboratory Respirator Users	Annals of Work Exposures and Health	H
17	Lee et al.	2018	A 3D Anthropometric Sizing Analysis System Based on North American CAESAR 3D Scan Data for Design of Head Wearable Products	Computers & Industrial Engineering	H
18	Shikama et al.	2018	Development of Personalized Fitting Device With 3-Dimensional Solution for Prevention of NIV Oronasal Mask-Related Pressure Ulcers	Respiry Care	H
19	Lee et al.	2018	Ergonomic evaluation of pilot oxygen mask designs	Appl Ergon	H
20	Makowski et.al	2019	Application of 3D scanning and 3D printing for designing and fabricating customized half-mask facepieces: A pilot study	Work	H
21	Bader et al.	2019	Bioengineering considerations in the prevention of medical device-related pressure ulcers	Clin Biomech	H
22	Lee et al.	2019	Development of a distributed representative human model generation and analysis system (DRHM-GAS): Application to optimization of flight suit and pilot oxygen mask sizing systems	Industrial Ergonomics	H
23	Cohen et al.	2019	Dressings cut to shape alleviate facial tissue loads while using an oxygen mask	Int Wound J	H
24	Goto et al.	2019	Traditional and 3D scan extracted measurements of the heads and faces of Dutch children	International Journal of Industrial Ergonomics	H

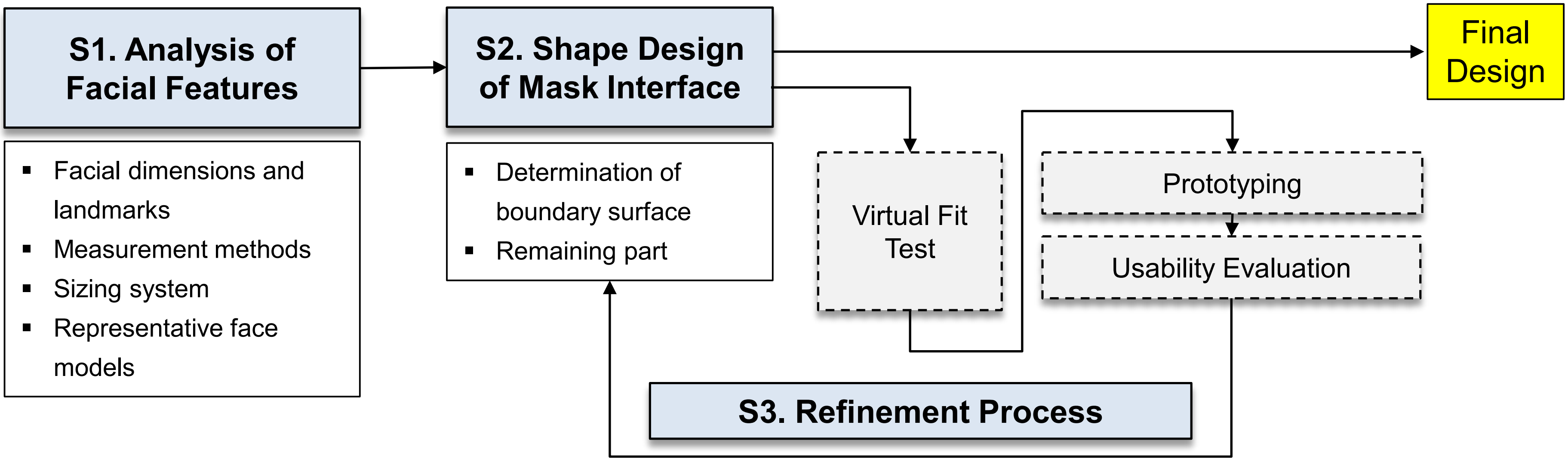
Literature Review: Paper List (3/3)

- After checking the full text of each of the screened papers, a total of 35 papers (high: 24 papers; medium: 11 papers) were lastly cited in the present study.

No.	Author(s)	Year	Title	Source	Relevancy
1	Ozsoy et al.	2009	Method selection in craniofacial measurements: Advantages and disadvantages of 3D digitization method	Cranio-Maxillofacial Surgery	M
2	Zhuang et al.	2010	Digital 3-D headforms with facial features representative of the current US workforce	J Occup Environ Hyg	M
3	Lee et al.	2013	Analysis of the facial measurements of Korean Air Force pilots for oxygen mask design	Ergonomics	M
4	Gutierrez et al.	2014	Designing an improved respirator for automotive painters	Industrial Ergonomics	M
5	Han et al.	2014	Development of Medium-size Half-mask Facepiece for Male Workers at a Shipyard and Its Fit Performance in Korea	J Occup Environ Hyg	M
6	Davidson et al.	2014	Performance Evaluation of Selected N95 Respirators and Surgical Masks When Challenged with Aerosolized Endospores and Inert Particles	J Occup Environ Hyg	M
7	Schallom et al.	2015	Pressure Ulcer Incidence In Patients Wearing Nasal-Oral Versus Full-Face Noninvasive Ventilation Masks	Am J Crit Care	M
8	Lee et al.	2016	Application of Massive 3D Head and Facial Scan Datasets in Ergonomic Head-Product Design	Digital Human	M
9	Worsley et al.	2016	Investigating the effects of strap tension during non-invasive ventilation mask application: a combined biomechanical and biomarker approach	Med Devices (Auckl)	M
10	Guha et al.	2016	Quantification of Leakage of Sub-Micron Aerosols through Surgical Masks and Facemasks for Pediatric Use	J Occup Environ Hyg	M
11	Hon et al.	2017	Comparison of qualitative and quantitative fit-testing results for three commonly used respirators in the healthcare sector	J Occup Environ Hyg	M

Ergonomic Mask Development: Overall Process

- Three ergonomic steps contribute to mask fit improvement
  1) Analysis of facial features
  2) Shape design of mask interface
  3) Refinement process by usability evaluation



S1. Anthropometric Analysis: Facial Dimensions & Landmarks

- 107 facial dimensions related to the design of a half-face mask were identified.
- 22 facial dimensions were selected for the oxygen mask design for Air Force pilots (Lee et al., 2013).

Facial dimensions and landmarks (*n*=22)

No.	Facial Dimensions	Importance
1	head height	L
2	head breadth	L
3	head length	L
4	head circumference	L
5	face length	H
6	lower-face length	M
7	sellion-to-supramentale length	M
8	supramentale-to-menton length	L
9	rhinion-to-menton length	M
10	rhinion-to-promentale length	H
11	promentale-to-menton length	L

No.	Facial Dimensions	Importance
12	nose length	M
13	nose protrusion	M
14	face width	M
15	chin width	L
16	nasal root breadth	H
17	maximum nasal bridge breadth	H
18	nose width	H
19	lip width	H
20	bitragion-menton arc	L
21	bitragion-subnasale arc	L
22	bizygomatic-menton arc	L

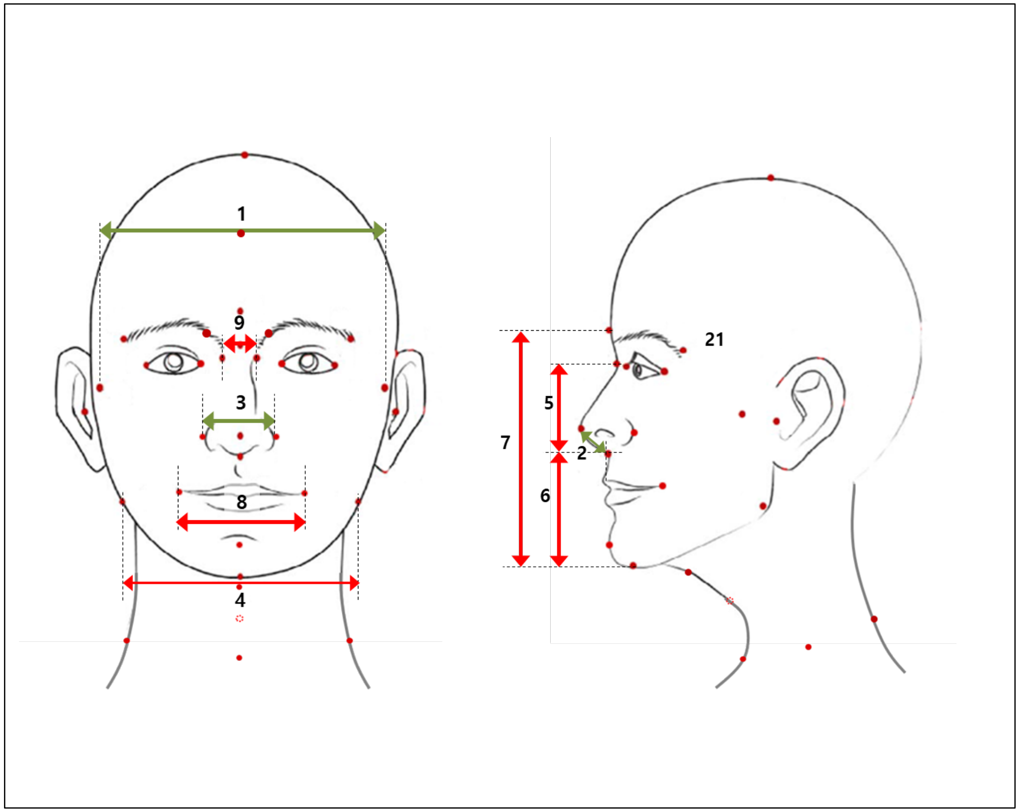
(L: low; M: medium; H: high)

S1. Anthropometric Analysis: Facial Dimensions & Landmarks

- 9 highly featured facial dimensions for half-face mask design were identified in the present study.

No.	Facial Dimension	Usage Rate
1	face width	100.0%
2	nose protrusion	100.0%
3	nose width	83.3%
4	chin width	66.7%
5	nose length	66.7%
6	lower face length	66.7%
7	face length	66.7%
8	lip width	50.0%
9	nasal root breadth	50%

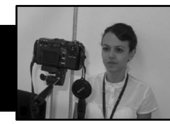
Facial dimensions and landmarks (*n*=9)



(Zhuang et al., 2008; Yu et al., 2012; Lee et al., 2013; Han et al.,2014; Gutierrez et al., 2014; Goto et al., 2015)

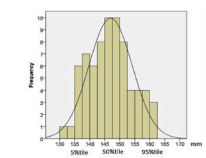
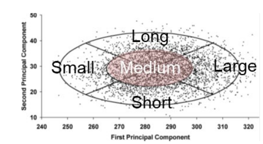
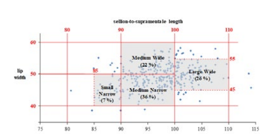
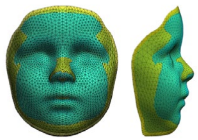
S1. Anthropometric Analysis: Measurement Methods

- **Direct measurement**, **photogrammetry**, and **3D scanning method** (3D-SM) are used for anthropometric analysis.
- Existing studies selected the measurement method by considering the accuracy, efficiency of measurement, time, and cost.

Dimension	Direct Measurement 	Photogrammetry 	3D Scanning 
Accuracy	▪ Less accurate on soft tissue ✓ Posture error; ✓ Measurer's mistake ▪ Higher accuracy for stiff head area with hair than 3D-SM	▪ Less accurate ✓ Camera lens distortion ✓ parallax and perspective	▪ Higher accuracy on soft skin-related measurement ▪ Landmark mistake without palpation
Efficiency	Low	Low	High
Post Processing (Time demanding)	-	Normal	Large
Cost	Low	Low	High
Measurement Limitation	-	Inapplicable for the measurement of thickness, depth, and circumference dimensions	-
Availability of Post Measurement	Inapplicable	Applicable	Available

S1. Anthropometric Analysis: Sizing System (1/2)

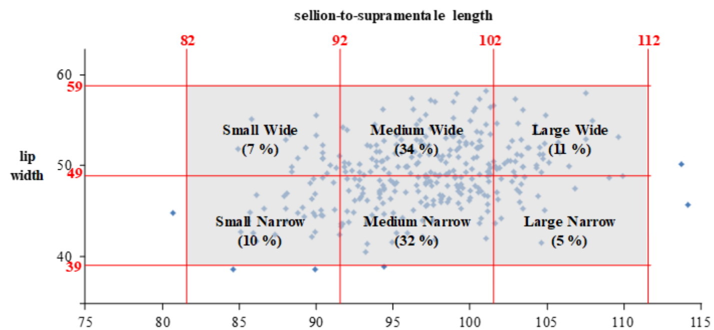
- A sizing system is generated based on target accommodation percentage and key facial dimensions.
- In recent, shape-based sizing system is generated by machine learning technique.

Consideration	Paper	Dataset	Dimensions	Method	Accommodation Percentage (rate)	X-Category-sizing system	
Variation of **size**	Luximon et al., 2016	144 Chinese adults Age 18-30	Head width	Percentile (5^{th} %tile, 50^{th} %tile, 95^{th} %tile)	100%	**6** (2 genders× small/medium/large)	
	Zhuang et al., 2008	1013 U.S.	10 dimensions (PCA)	PCA	95% (50%: medium; around 11% for rest categories)	**5** (small/ medium/ large/ short/ long)	
	Lee et al., 2013	336 KAF pilots	18 dimensions (PCA)	Grid method	90%	**4** (small narrow/ medium wide/ medium narrow/ large wide)	
Variation of size + **shape**	Lee et al., 2017	302 Dutch children Age 0.5-6	Edge vector in template registered faces	Machine learning clustering (Self-Organizing Map)	100%	**4** (two shape-based clusters × two sizes)	

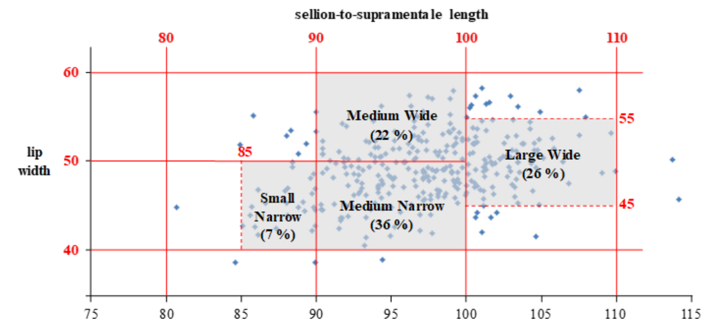
S1. Anthropometric Analysis: Sizing System (2/2)

- A conventional sizing system can be generated by a decision masking process
  1) Selection of target population
  2) Selection of key anthropometric dimensions
  3) Statistics for sizing system generation
  4) Accommodation percentage
  5) Number of sizing categories
  6) Tolerance and manufacturing cost

Grid Method



Initial sizing system (accommodation percentage = 98%)



Final sizing system (accommodation percentage = 90%)

S1. Anthropometric Analysis: Sizing System (2/2)

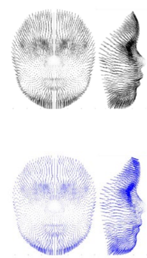
- PCA-based sizing system has still a lack of consideration about body shape.
- Generation of shape-based sizing system is developed by machine learning clustering method.

Shape-based sizing system

Two shape categories

Two sizing categories

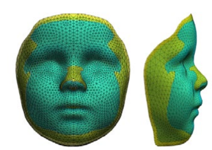
Template-registered face → Self-organizing map (SOM) →



→ Short (< mean face length)

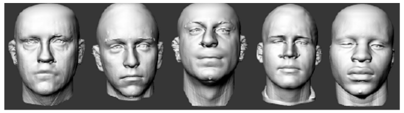
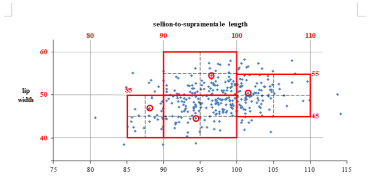
→ Long (> mean face length)

→ 4 type faces

Consideration	Paper	Dataset	Dimensions	Method	Accommodation Percentage	X-Category-sizing system	
Variation of size + **shape**	Lee et al., 2017	302 Dutch children Age 0.5-6	Edge vector in template registered faces	Machine learning clustering (Self-Organizing Map)	100%	**4** (two **shape-based clusters** × two sizes)	

S1. Anthropometric Analysis: Representative Face Models (1/2)

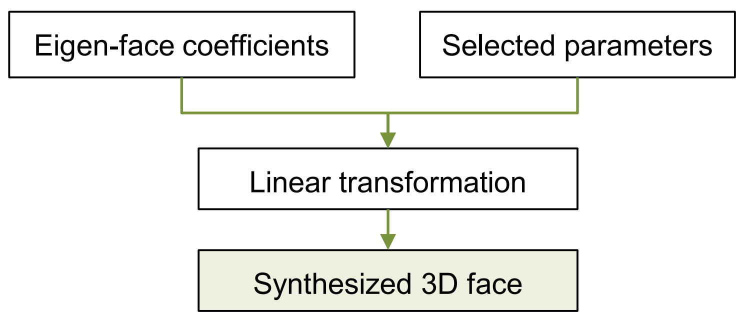
- Representative Face Models (RFMs) are generated based on the mean/medium values of key dimensions.
- 3D RFMs from sizing categories are used for facial mask designs and virtual fitting.

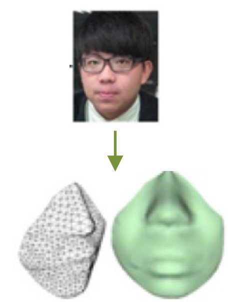
Paper	X-Category-sizing System	Representative Model Determination Method	
Zhuang et al. (2010)	**5** (small/ medium/ large/ short/ long)	▪ 5 subjects of each size category that are the closest to the computed means of the 10 dimensions ▪ Construct the averaged model (Polyworks)	
Lee et al.(2013)	**4** (small narrow/ medium wide/ medium narrow/ large wide)	Smallest weighted sum of Euclidean distance (WSED) based on the mean and medium values	

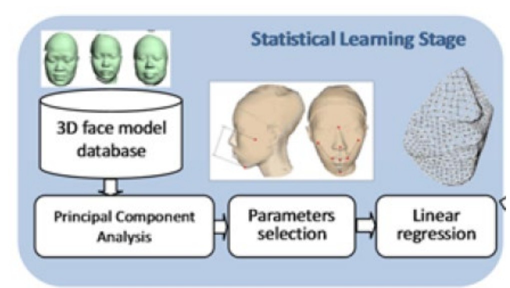
S1. Anthropometric Analysis: Customized Face Model (2/2)

- In recent, customized face model (CFM) instead of RFM is generated for personalized mask interface design using machine learning technique.

Generation of customized face model

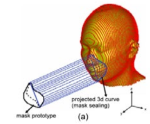
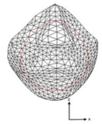
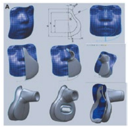
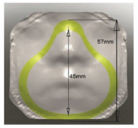
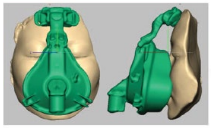
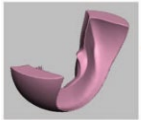
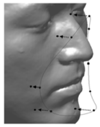
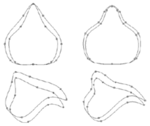




Paper	Customized Face Model	
Chu et al. (2015)	Machine learning based method ▪ Identify relevant parameters by AdaBoost ▪ Correlation between parameters were estimated using PCA and linear regression	

S2. Design Method: Mask Design (1/2)

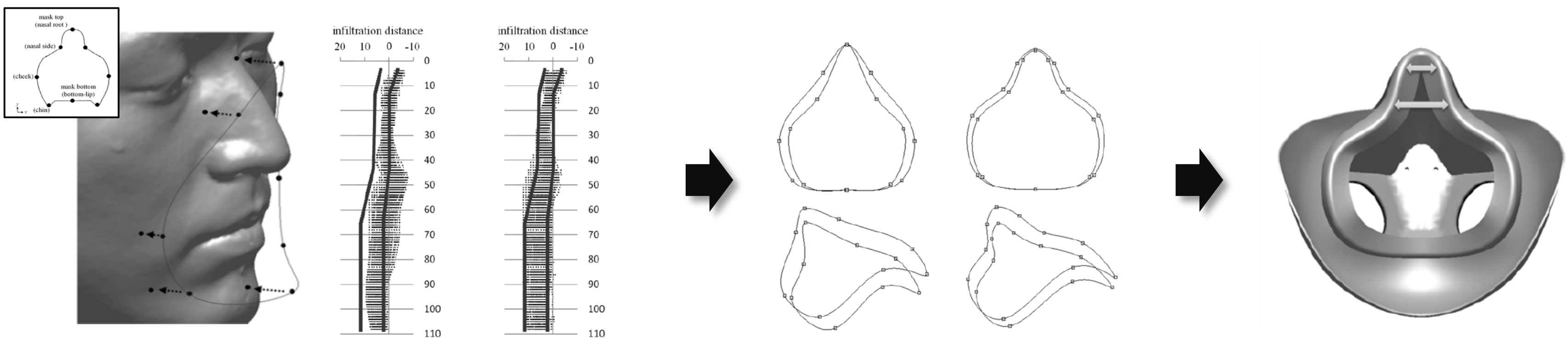
- **Boundary surface of facial contact area** is considered with **high priority** for mask design and virtual fitting evaluation.

Paper	Tool	Method	
Chu et al. (2015)	CAD	**Traced curve** was generated on the face model by 3D projection	 
Luximon et al. (2015)	Solidworks	Tracing of **3D spline** on the head template	 
Amirav et al. (2015)	Solidworks	Hand draw according to the face contour	 
Shikama et al. (2018)	Geomagic Sculpt 3D software	Subtract **contact surface** from the face and mask models	 
Makowski et al. (2018)	Geomagic Freeform Plus software with haptic device	Draw based on the face models	 
Lee et al. (2013)	Rhino 3D modeler	Generate new boundary by projection the existing design landmarks	 

S2. Design Method: Mask Design (2/2)

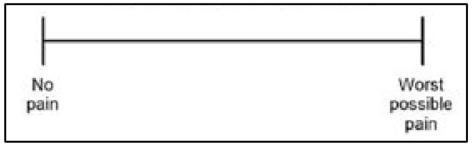
- Boundary surface can be generated and adjusted based on the shape of face models

Boundary adjustment progress



S3. Design Refinement by Subjective Evaluation (1/2)

- **Likert scale** and **visual analog scale (VAS)** were used to measure **subjective satisfaction** (e.g., comfort/discomfort, overall satisfaction, and adequacy of fitness) in mask design evaluation.

Paper	Mask	Indicators	Method	Criteria
Schallom et al. (2015)	Half-face mask Full-face mask	Comfort levels	**5-point Likert scale**	▪ 1=comfortable with the NIV mask; ▪ 2=mild discomfort but will continue with the mask; ▪ 3=moderate discomfort but will continue with the mask ▪ 4=severe discomfort with the mask ▪ 5=very severe discomfort and need to discontinue use of the mask
Worsley et al. (2016)	Half-face mask	Discomfort	10-point **visual analog scale**	
Luximon et al. (2016)	Half-face mask	Overall satisfaction	7-point Likert scale questionnaire	▪ 1=extremely unsatisfied ▪ 4=neutral ▪ 7= extremely satisfied
		Regional fit (Adequacy of fitness)		▪ 1=extremely tight ▪ 4=neutral ▪ 7=extremely loose

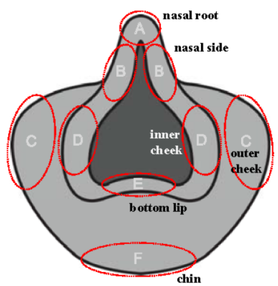
S3. Design Refinement by Subjective Evaluation (2/2)

- Fit assessment questionnaire in terms of discomfort level, leakage and overall satisfaction with different scales were developed.

Examples of subjective satisfaction evaluation questionnaire

Oxygen Mask Usability Evaluation	Evaluation Mask	☐ Existing Mask ☐ Revised Mask

1. Check (√) how much you feel discomfort by facial area.

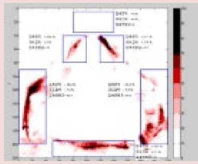
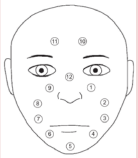
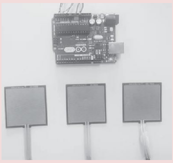
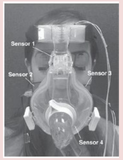
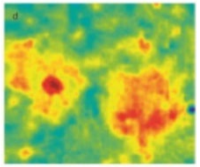
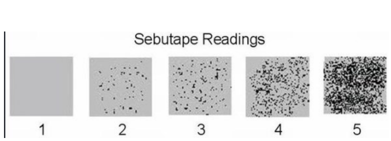


Facial area	no discomfort	rare discomfort	somewhat discomfort	slight discomfort	moderate discomfort	quite discomfort	very discomfort	extreme discomfort
	0	1	2	3	4	5	6	7
A: nasal root	☐	☐	☐	☐	☐	☐	☐	☐
B: nasal side	☐	☐	☐	☐	☐	☐	☐	☐
C: outer cheek	☐	☐	☐	☐	☐	☐	☐	☐
D: inner cheek	☐	☐	☐	☐	☐	☐	☐	☐
E: bottom lip	☐	☐	☐	☐	☐	☐	☐	☐
F: chin	☐	☐	☐	☐	☐	☐	☐	☐
overall discomfort	☐	☐	☐	☐	☐	☐	☐	☐

Paper	Mask	Indicators	Method	Criteria
Lee et al.(2013)	Pilot oxygen mask (half-face mask)	Discomfort level caused by contact pressure	Fit assessment questionnaire (7-point scale)	▪ 0=no discomfort, 1=rarely discomfort ▪ 4=moderate discomfort, 7= extreme discomfort
		Oxygen leakage		▪ 0=no leakage, 1=rare leakage, 4=moderate leakage, 7= extreme leakage
		Overall satisfaction		▪ -3=very unsatisfied ▪ 0=neutral ▪ 3=very satisfied

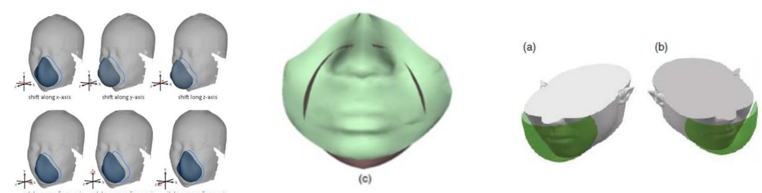
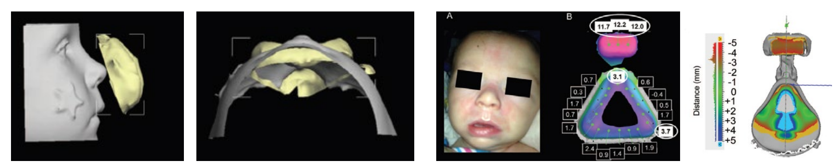
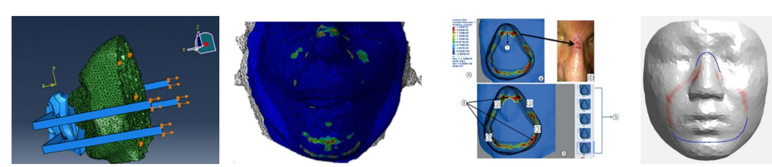
S3. Design Refinement by Objective Evaluation

- Quantitative fitness was measured by objective measures such as **air leakage, pressure, skin condition,** and **inflammatory biomarker**.

Paper	Method	Apparatus	Analysis	Result
Davidson et al., 2013; Guha et al., 2016; Hon et al., 2017; Manganyi et al., 2017;	**Air leakage detection**	TSI Portacount Model 8038	▪ Aerosol concentrations outside and inside the respirator	
Lee et al., 2018	**Pressure measurement**	Prescale™ pressure indicating film (Fujifilm Co., Japan) Scanner	▪ Intensity of the color → level of contact pressure	 
Shikama et al., 2018; Cohen et al., 2019		Sensor, 0.2mm (Flexi Force, Japan)	▪ The distribution of proportion among the 12 sensors ▪ A smaller value → a more even redistribution of contact pressure on the face	  
Shikama et al., (2018); Visscher et al., 2015	**Skin condition**	Nikon D-90 camera	▪ Red (a*) image as percentage of red pixels above the mean plus 1 SD $(\mu + \sigma)$ threshold ▪ Large percentage → the presence and degree of skin compromise	
Worsley et al., 2016	**Inflammatory biomarkers**	Sebutape (CuDerm, USA)	▪ Inflammatory cytokine, IL-1α ▪ IL-1α increase → high pressure and shear	 

S3. Design Refinement by Virtual Fit Testing (1/2)

- Virtual fit testing offers quick validation with low cost and less time consuming, and avoids the potential harm to the participants in experimental evaluation.

Paper	Indicator	Method	
Chu et al., 2015; Luximon et al., 2016	**Geometric Similarity**	▪ Calculate the space between the mask boundary and its projected contour on the face model ▪ Visual evaluation by drag-and-drop and semi-transparent state operations	
Visscher et al., 2015; Shikama et al., 2018	**Distance**	Calculate the distance between mask and face models	
Barros et al., 2014; Bader et al., 2019; Lee et al., 2019	**Pressure**	Finite element modeling (FEM) Finite element analysis (FEA)	

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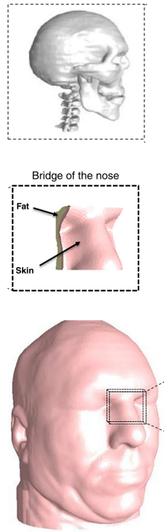
S3. Design Refinement by Virtual Fit Testing (2/2)

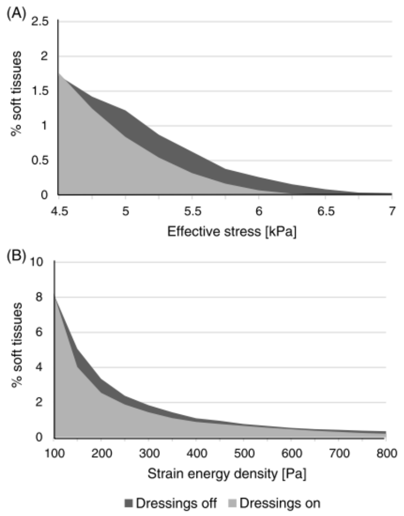
❑ Anatomical properties are applied to FE models.

Mechanical properties and element data

Model component	Shear modulus (MPa)	Bulk modulus (MPa)	Elastic modulus (MPa)	Poisson's ratio	Number of mesh elements
Skin[a]	0.031900	3.1794	-	-	125 826
Fat[b,c]	0.000286	0.0285	-	-	342 692
Skull[d]	-	-	6483.6	0.495	159 528
Vertebrae[e]	-	-	10 000	0.29	37 253
Ventilation mask	-	-	0.12	0.49	13 700
Mepilex Lite dressings cut-to-shape	-	-	0.02675	0.258	16 490

Paper	Indicator	Method
Cohen et al., 2019	Effective stress	➢ Computational modelling (FE modeling) ➢ Tissue with mechanical property (from animal study)

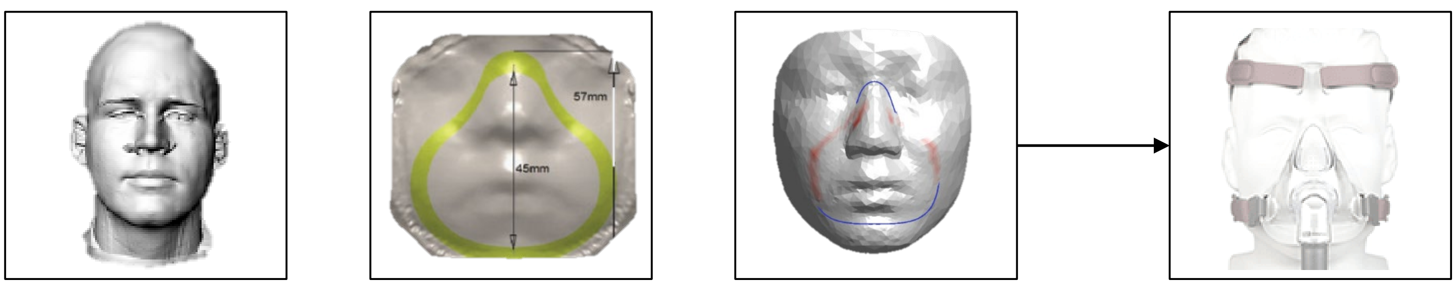




Discussion (1/2)

- The issues organized in 3 categories should be considered for better fit NIV mask
  - Key facial dimensions, measurement strategies, sizing methods and representative models
  - Shape design method
  - Virtual testing, subjective evaluation and objective evaluation methods

Mask Development Process

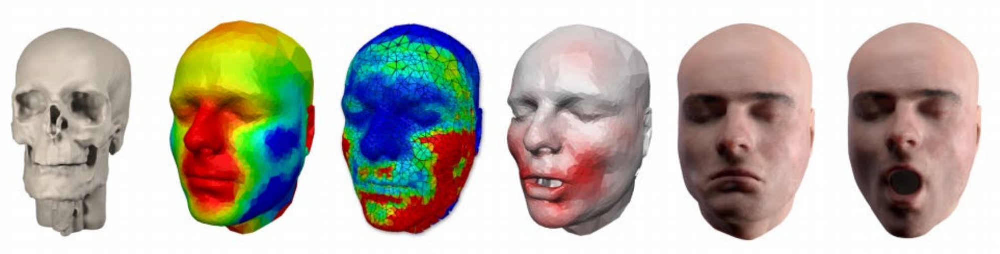


Facial feature analysis | Mask interface design | Usability test | Better fit NIV mask

Discussion (2/2)

- The importance of representative face models can decrease in ergonomic design and virtual fit testing.
- A customized mask is necessary to be developed for the safety and effectiveness of NIV treatment.
  - An ergonomic design algorithm that identifies an optimal NIV mask design
  - An ergonomic design tuning (adapter) algorithms
  - An ergonomic selection algorithm
- Digital face model with human anatomy features need to be apply to virtual fit testing.

Examples of Deformable Digital Face Model (Kadlecek and Kavan., 2019)



경청해 주셔서 감사합니다.

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