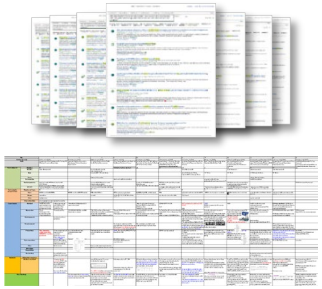
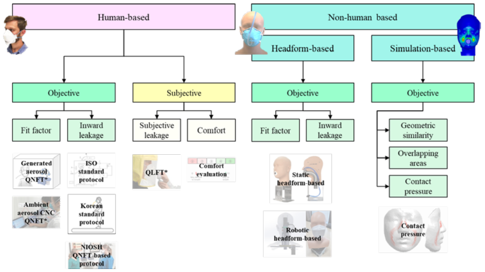
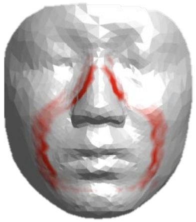
Fit Evaluation Methods for Filtering Facepiece Respirators

안면부 여과식 마스크의 밀착도 평가 방법 분석







최신아[1], 이아람[2], 김희은[2], 전은진[1], **유희천[1]**

[1] 포항공과대학교 산업경영공학과
[2]경북대학교 의류학과/장수생활과학연구소

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This work was funded by a grant from Ministry of Food and Drug Safety.

Contents

- **Introduction**
- **Method of Literature Review**
- **Results**
  - Human-Based Fit Evaluation
  - Non-Human Based Fit Evaluation
  - Comparison of Fit Evaluation Methods
- **Discussion**

Background

- An **effective fit evaluation method** for **filtering facepiece respirator (FFR)** is important to provide **proper protection for the wearer from harmful agents** in various situations.
- Various fit evaluation methods have been developed for the **design and certification stages of FFRs**

FFRs

Fit evaluation on FFRs

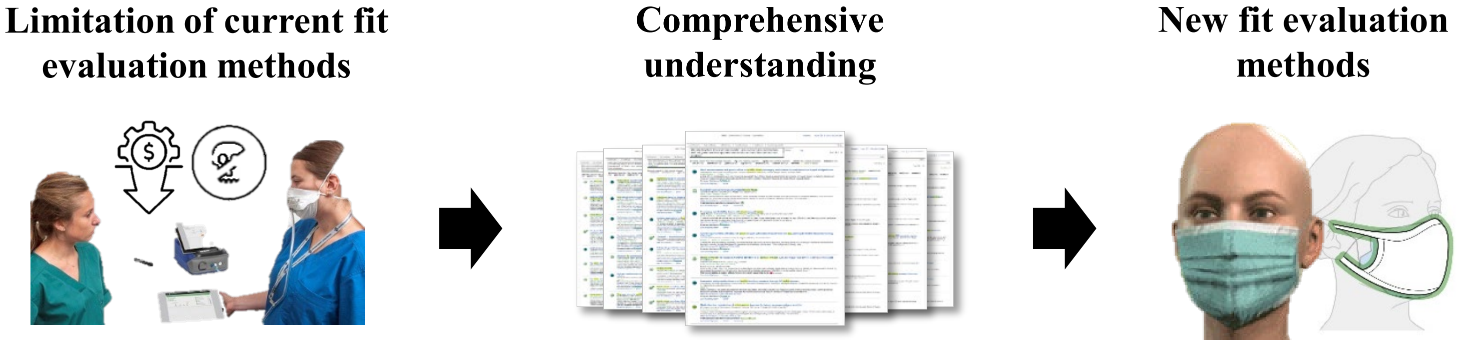
FFRs

Motivation of the Study

❑ A **new fit evaluation method** with more **adaptability** and **effectiveness** is needed

- ✓ Widely used **human-based fit evaluation** methods are limited in terms of **ethics**, **efficiency**, and **effectiveness**.
- ✓ **Non-human based fit evaluation** methods are still under development and struggling with verification issues.

→ A **comprehensive understanding** of fit evaluation methods for FFRs are need



Limitation of current fit evaluation methods

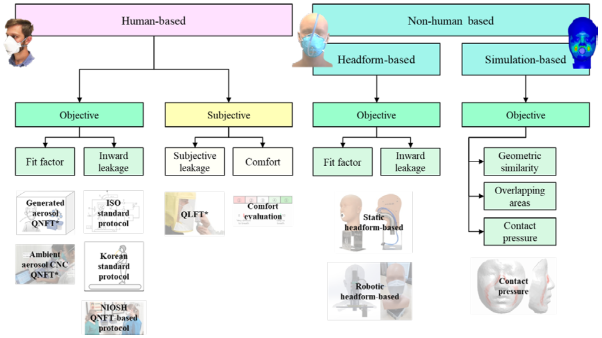
Comprehensive understanding

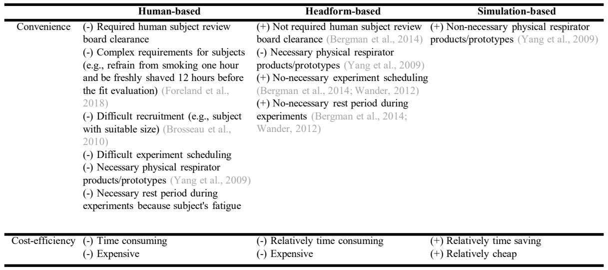
New fit evaluation methods

Objective of the Study

Identify features and research directions for fit evaluation methods of FFRs by literature review

1. **A comprehensive literature review on fit evaluation methods for FFRs**
    - Human-based fit evaluation
    - Non-human based fit evaluation
2. **Identification of research directions by comparative analysis**
    - Positive and negative features
    - Further research directions



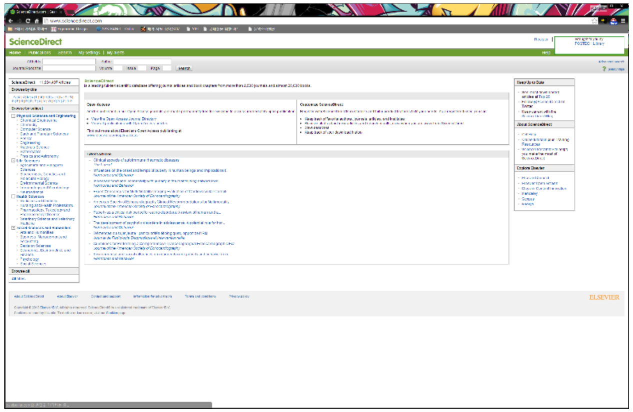


	Human-based	Headform-based	Simulation-based
Convenience	(-) Required human subject review board clearance (-) Complex requirements for subjects (e.g., refrain from smoking one hour and be freshly shaved 12 hours before the fit evaluation) (Foreland et al., 2018) (-) Difficult recruitment (e.g., subject with suitable size) (Brosseau et al., 2010) (-) Difficult experiment scheduling (-) Necessary physical respirator products/prototypes (Yang et al., 2009) (-) Necessary rest period during experiments because subject's fatigue	(+) Not required human subject review board clearance (Bergman et al., 2014) (-) Necessary physical respirator products/prototypes (Yang et al., 2009) (+) No-necessary experiment scheduling (Bergman et al., 2014; Wander, 2012) (+) No-necessary rest period during experiments (Bergman et al., 2014; Wander, 2012)	(+) Non-necessary physical respirator products/prototypes (Yang et al., 2009)
Cost-efficiency	(-) Time consuming (-) Expensive	(-) Relatively time consuming (-) Expensive	(+) Relatively time saving (+) Relatively cheap

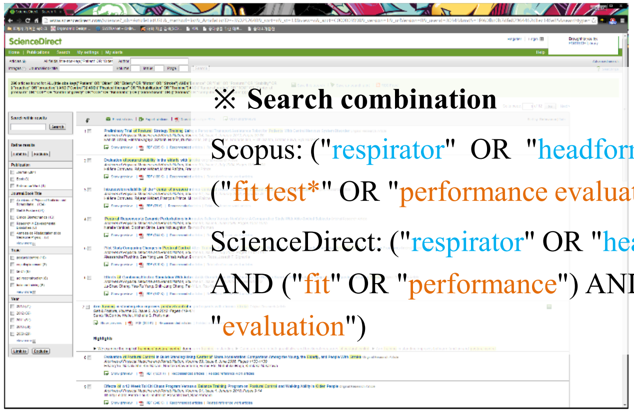
Literature Review: Search Method

- ☐ Source: Scopus & ScienceDirect database
- ☐ Search criteria: keyword, title, abstract
- ☐ Keywords:
  - ✓ Evaluation target: respirator, headform
  - ✓ Evaluation measure: fit, design, performance, evaluation/testing

Search site: Sciencedirect



Search result example



※ Search combination

Scopus: ("respirator" OR "headform") AND ("fit test*" OR "performance evaluation*")

ScienceDirect: ("respirator" OR "headform") AND ("fit" OR "performance") AND ("test" OR "evaluation")

Literature Review: Procedure

S1. Keywords 조합을 통한 journal paper 검색

Example: ("respirator" OR "headform") AND ("fit test*" OR "performance evaluation*")

731 건

S2. Title screening을 통한 1차 선별

273 건

S3. Abstract screening을 통한 2차 선별

131 건

S4. 입수된 full paper에 대한 관련도 평가

Classification of high, moderate, and low relevance

115 건

S5. 관련도에 따라 최종 review 대상 논문 선별

Additional paper in reference

Final review papers with high and moderate relevance

98 건

Results: Paper List (Example)

Appendix 참조

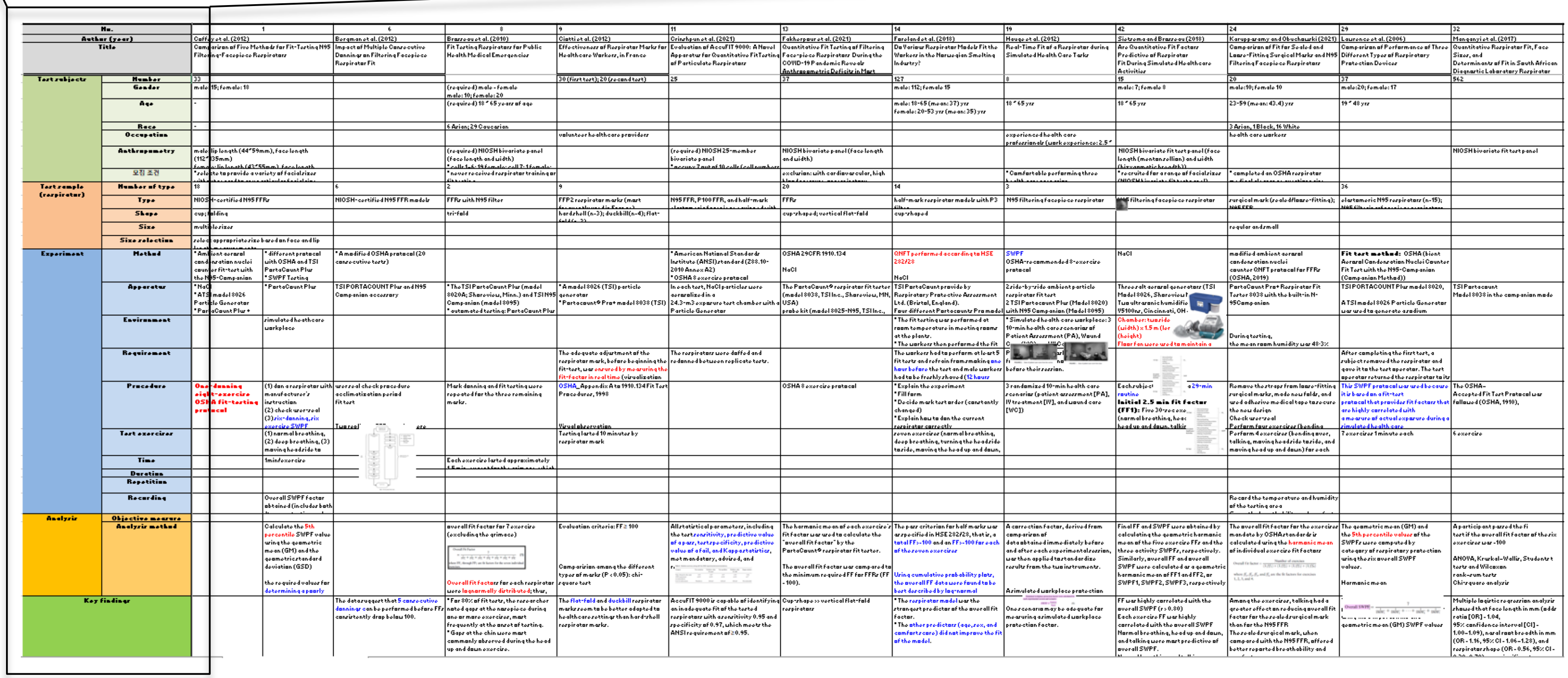
❑ 최종 선정 문헌 총 77편(관련도 상 46 편, 중 31편)

No.	Author(s)	Year	Title	Category	Relevancy
1	Rengasamy et al.	2014	Total Inward Leakage Measurement of Particulates for N95 Filtering Facepiece Respirators—A Comparison Study	TIL/IL	H
2	Han et al.	2005	Evaluation of Particulate Filtering Respirators Using Inward Leakage (IL) or Total Inward Leakage (TIL) Testing—Korean Experience	TIL/IL	H
3	Amy et al.	2020	Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE	Theory	H
4	Huh et al.	2018	Fit Characteristics of N95 Filtering Facepiece Respirators and the Accuracy of the User Seal Check among Koreans	Theory	H
5	McKay et al.	2018	Respirator Fit Test Methods – Are Faster Protocols Equivalent to OSHA?	Theory	H
6	Lam et al.	2016	Evaluation of the user seal check on gross leakage detection of 3 different designs of N95 filtering facepiece respirators	Theory	H
7	Landsittel et al	2014	Determining Sample Size and a Passing Criterion for Respirator Fit-Test Panels	Theory	H
8	Lam et al.	2011	Sensitivity and specificity of the user-seal-check in determining the fit of N95 respirators	Theory	H
9	Zhuang et al.	2008	Correlation Between Respirator Fit and Respirator Fit Test Panel Cells by Respirator Size	Theory	H
10	Han and Choi	2003	Facial Dimensions and Predictors of Fit for Half-Mask Respirators in Koreans	Theory	H
11	Sun et al.	2019	Real-time performance of filtering facepiece respirators at the workplace	SWPF	H
12	Sietsema and Brosseau	2018	Are quantitative fit factors predictive of respirator fit during simulated healthcare activities	SWPF	H
13	Zhuang et al.	2015	Respirator Performance against Nanoparticles under Simulated Workplace Activities	SWPF	H
14	Kim et al.	2015	Assessing Real-time Performances of N95 Respirators for Health Care Workers by Simulated Workplace Protection Factors	SWPF	H
15	Hauge et al.	2012	Real-Time Fit of a Respirator during Simulated Health Care Tasks	SWPF	H
16	Regli et al.	2021	The role of fit testing N95/FFP2/FFP3 masks: a narrative review	QNFT	H
17	Crinshpun et al.	2021	Evaluation of AccuFIT 9000: A Novel Apparatus for Quantitative Fit Testing of Particulate Respirators	QNFT	H
18	Fakherpour et al	2021	Quantitative fit testing of filtering face-piece respirators during the COVID-19 pandemic reveals anthropometric deficits in most respirators available in Iran	QNFT	H

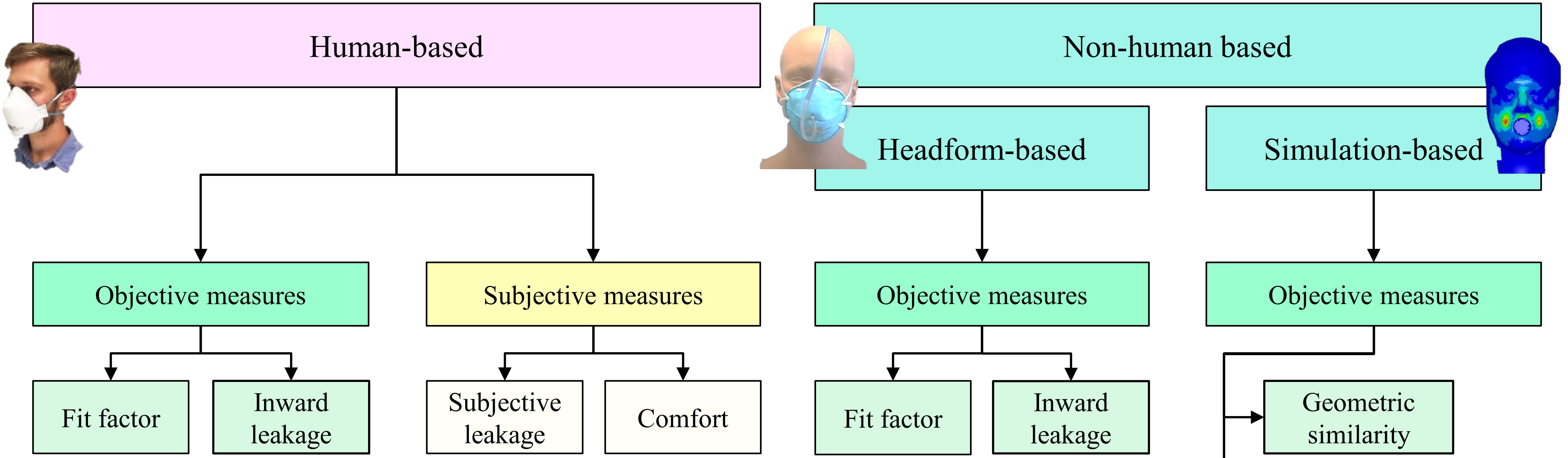
Results: Analysis Table

Test subjects							Test sample (respirator)				
Number	Gender	Age	Race	Occupation	Anthropometry	Recruitment conditions	Number of type	Type	Shape	Size	Size selection

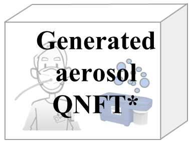
Experiment										Analysis		Key findings
Method	Apparatus	Environment	Requirement	Procedure	Test exercises	Time	Duration	Repetition	Recording	Objective measure	Analysis method	

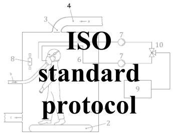


Literature Review Results: Summary



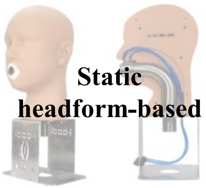
- Geometric similarity
- Overlapping areas
- Contact pressure


Generated aerosol QNFT*

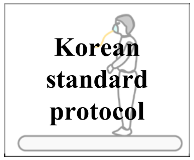

ISO standard protocol

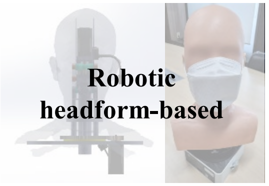

QLFT*

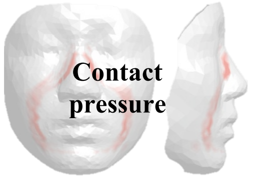

Comfort evaluation


Static headform-based


Ambient aerosol CNC QNFT


Korean standard protocol


Robotic headform-based


Contact pressure


NIOSH QNFT-based protocol

* QNFT: quantitative fit testing; QLFT: qualitative fit testing

Human-Based Fit Evaluation: General Requirements (1/2)

❑ 평가 인원

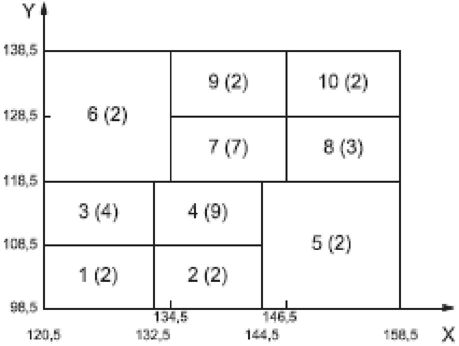
- ✓ 8명 ~ 1,271명 (median: 30)
- ✓ 최소 인원: 10명(식약처), 최소 15명(ISO, NIOSH)

❑ 모집 조건

- ✓ 얼굴 치수
  - ➢ NIOSH bivariate panel: 얼굴 길이(face length), 얼굴 너비(face width)

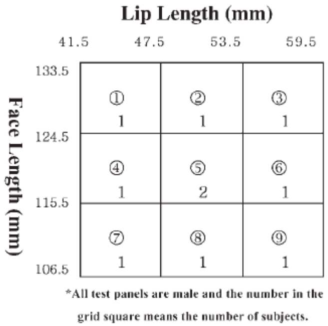
    (note) 기타 bivariate panel: 얼굴 길이(face length), 입 너비(lip width)
  - ➢ NIOSH PCA panel: 10개 얼굴 치수

Bivariate panel



Zhuang et al. (2007)

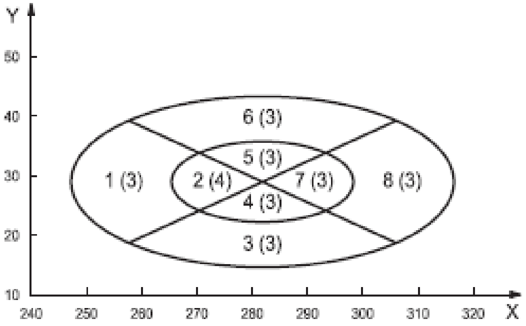
Bivariate panel



*All test panels are male and the number in the grid square means the number of subjects.

Han et al. (2014)

PCA panel



Zhuang et al. (2007)

Human-Based Fit Evaluation: General Requirements (2/2)

□ 모집 조건

- ✓ 건강 상태: 심혈관계 질환, 고혈압, 천식, 폐렴, 호흡기 질환이 없는 사람(ISO 16975-3)
- ✓ 얼굴 특징: 얼굴에 흉터가 없어야 함(ISO 16975-3)
- ✓ 성별: 남:여 비율 1:1 (Brosseau et al., 2010)
- ✓ 연령: 성인(18 ~ 65세)

□ 실험 참여 요구 사항

- ✓ 누설이 발생하지 않는 얼굴 상태 제공(ISO 16975-3, 수염이 있는 남성의 경우 면도 필요)
- ✓ 흡연자의 경우 평가 전 30분 금연 후 진행
- ✓ 평가 대상 호흡기의 올바른 착용과 사용 방법 숙지

Human-Based Fit Evaluation: Subjective Methods

☐ 밀착감 평가

✓ QLFT(qualitative fit testing): 에어로졸 노출에 따른 주관적 평가로 운동 상황에서의 호흡 평가 (OSHA; NIOSH)

☐ 착용감 평가

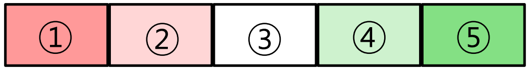
✓ 착용감 평가 척도: 1~5점 (1-매우 불편; 5-매우 편안) (Foreland et al., 2018)

✓ 통기성 및 착용감 평가 척도: 시각적 평가 척도0~10점 (0-호흡이 어려움, 10-호흡이 쉬움; 0-착용감 매우 불편, 10- 착용감 매우 편안)

QLFT 방법 예시

3M, Saint Paul: MN, USA(OSHA; NIOSH)

착용감 평가 척도 예시



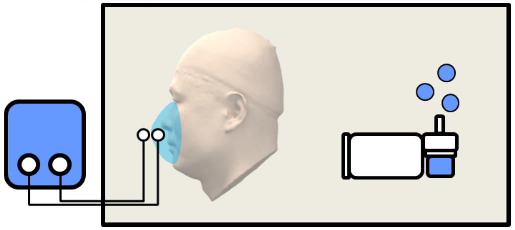
시각적 평가 척도 예시

(Karuppasamy & Obuchowski, 2021)

Human-Based Fit Evaluation: Objective Method – Fit Factor (1/2)

❑ 호흡기 내부 및 외부의 에어로졸 농도를 측정을 통한 정량적 적합성 평가

- ✓ **에어로졸 생성을 통한 QNFT :** 테스트 챔버에서 생성된 에어로졸 사용
- ✓ **대기중 에어로졸을 활용한 CNC QNFT:** 테스트 주변 에어로졸을 사용

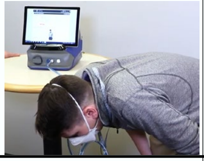
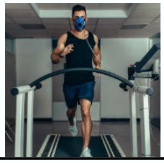
종류	Generated aerosol QNFT	Ambient aerosol CNC QNFT
시험 물질	▪ 인공 생성 에어로졸(e.g., NaCl)	▪ 대기중에 분포하는 에어로졸
도구	 Particle Generator 8026 (TSI, Shoreview, MN, USA)	 Respirator Fit Tester 8038 with/without N-95 Companion (TSI, Shoreview: MN, USA)  AccuFIT9000® (AccuTec-HIS,Tulsa: OK, USA)
시험 환경 (평가 챔버)	▪ 안정상태 실험 농도 (variation < 10%) ▪ 상대습도 (NaCl): ≤ 50% 	
측정 항목	▪ Overall FF*≥ 100 ▪ Overall FF ≥ 100, 각 FF ≥ 100	$(Overall\ fit\ factor = \dfrac{N}{1/FF_1 + \cdots + 1/FF_N}\quad FF = C_{out}/C_{in})$

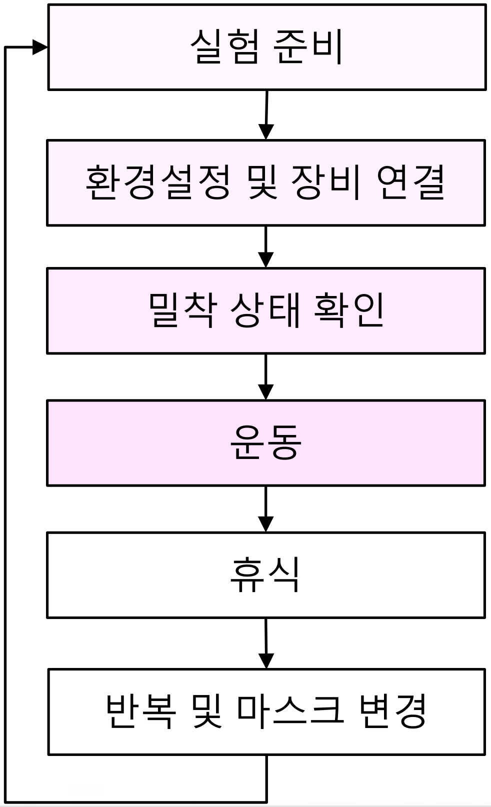
* QNFT: quantitative fit testing; CNC: condensation nuclei counter; FF: fit factor

Human-Based Fit Evaluation: Objective Method – Fit Factor (2/2)

- ❑ **평가 절차:** 실험 준비, 환경설정 및 장비 연결, 마스크 밀착 상태 확인, 운동, 휴식의 절차로 진행
- ❑ **총 소요시간:** 35분 (Sietsema and Brosseau, 2016)

밀착도 평가 사용 도구 및 동작 내용

	맨몸 평가	트레드밀 사용	특정 상황 수행
종류			
운동	(1) 정상 호흡 (2) 심호흡 (3) 고개 옆으로 돌리기 (4) 고개 위아래로 움직이기 (5) 말하기 (6) 얼굴찡그리기 (7) 상체 숙이기 (8) 정상 호흡	걷기 (5.6km/h)	예시: (1) 정상호흡 (2) 심폐소생술 (3) 초음파 시험 (4) 병원 침구 준비
반복횟수	4 ~ 8	1	4
개별 운동시간	0.5~ 1.4 min/exercise (얼굴찡그리기는 0.3~0.4 min)	-	0.5 ~2 min
총 운동시간	3 ~ 10 min	-	6 min



실험 준비

환경설정 및 장비 연결

밀착 상태 확인

운동

휴식

반복 및 마스크 변경

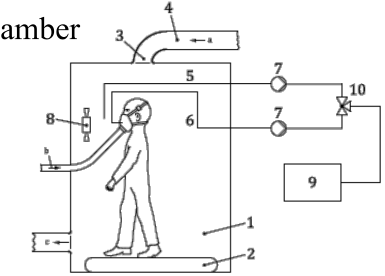
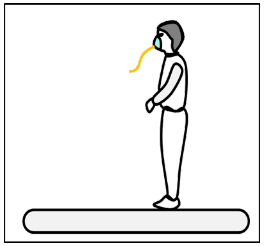
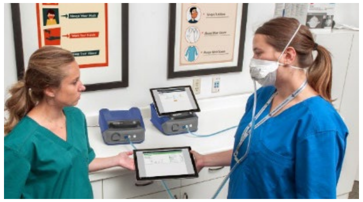
- 평가 요구사항 확인
- 마스크 사이즈 선택
- 착용 설명 및 연습

- 2 ~ 10 min

- 3회 ~ 6회 반복
- 평가 마스크 변경

Human-Based Fit Evaluation: Objective Method – Inward Leakage (1/3)

❑ 호흡기 내부와 외부의 **에어로졸 입자 농도** 차이와 **들숨과 날숨의 총 소요 시간**을 이용하여 누설율 평가

종류	ISO 표준기반	한국 표준 기반	NIOSH FF testing 기반
에어로졸	▪ NaCl	▪ NaCl	▪ NaCl
시험환경	▪ Test chamber 	▪ Test chamber 	▪ Test room/chamber 
측정항목	▪ 호흡 기구 내부/외부 농도 (C_2/C_1) ▪ 건조공기유량 (D) ▪ 호흡 기구 계면의 샘플 유량 (S) $TIL(\%) = 1.6.\left[\frac{C_2}{C_1}\right] \times [\frac{S+D}{S}] \times 100$	▪ 호흡 기구 내부/외부 농도 (C_2/C_1) ▪ 들숨/날숨의 총 지속시간(T_{in}/T_{ex}) $TIL(\%) = \frac{C_2}{C_1} \times \frac{T_{in} + Tex}{T_{in}} \times 100$	▪ 호흡 기구 내부/외부 농도 (C_2/C_1) $TIL = \frac{100\%}{FF} = \frac{C_2}{C_1}$
운동종류	▪ 트레드밀 시험 (5.5 km/h)	▪ 트레드밀 시험 (6 km/h)	▪ 도구사용하지 않는 시험

(ISO 16900-1 2019, KR MFDS 2019, NIOSH)

Human-Based Fit Evaluation: Objective Method – Inward Leakage (2/3)

- **측정 장비:** 시험물질, 시험물질 생성기, 평가 챔버, 실험 장비 및 측정 시스템
- **측정 환경:** 온도(16°C ~ 32°C), 습도(50±30% RH), 공기 청정도, 주변 환경 조정

측정 시스템

온도: 16 °C ~ 32 °C
습도: (50 ± 30) % RH

측정 장비

- 입자 측정

Particle counter

(PortaCount® Pro+)

Flame photometer

(SFP Services, Type 1250)

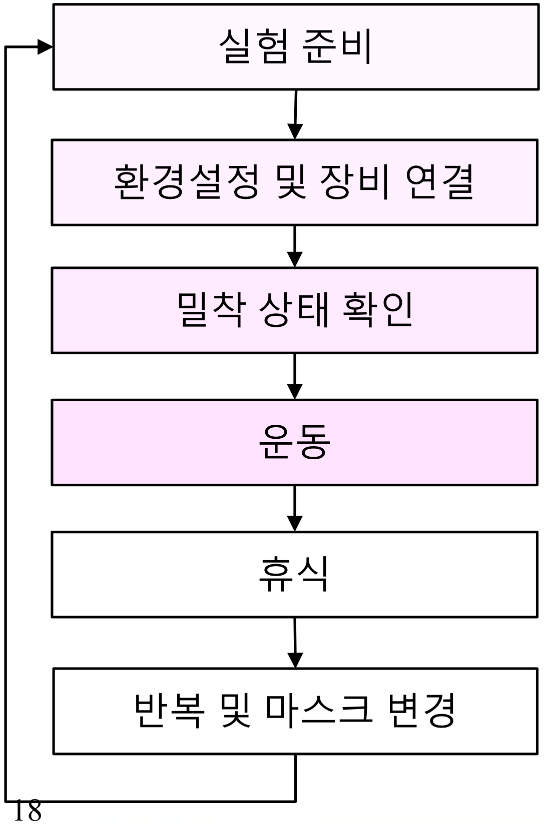
- 들숨과 날숨의 총 지속시간 측정
  호흡 측정 센서

Human-Based Fit Evaluation: Objective Method – Inward Leakage (3/3)

- 누설율 평가 절차는 밀착도 평가 절차와 동일
- 총 소요시간: 40분 (Zhang et al., 2016)

누설율 평가 사용 도구 및 동작 내용

	트레드밀 사용	평가도구 미사용
종류		
운동	(1) 머리 움직임 또는 말하기 없이 걷기 (2) 머리 좌우로 움직이기 (3) 머리 위아래로 움직이기 (4) 문장을 읽고 암송하기 (5) 머리 움직임 없이 걷기	(1) 정상 호흡 (2) 심호흡 (3) 고개 옆으로 돌리기 (4) 고개 위아래로 움직이기 (5) 말하기 (6) 얼굴찡그리기 (7) 상체 숙이기 (8) 정상 호흡
반복횟수	▪ 5 ~ 10	▪ 4 ~ 8
개별 운동시간	▪ 2 min/exercise	▪ 30s or 50s/exercise
총 운동 시간	▪ 10 ~ 19 min	▪ Around 4 min



실험 준비

환경설정 및 장비 연결

밀착 상태 확인

운동

휴식

반복 및 마스크 변경

- 평가 요구사항 확인
- 마스크 사이즈 선택
- 착용 설명 및 연습

- 2 ~ 10 min

- 3회 ~ 6회 반복
- 평가 마스크 변경

Headform-Based Fit Evaluation: Headform Type

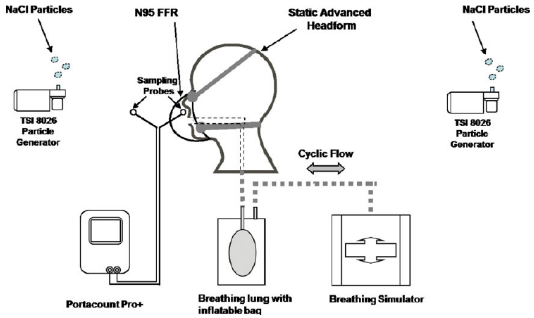
❑ 정적 로보틱 헤드폼 기반 평가

- ✓ 호흡 속도, 호흡 빈도의 설정에 따라 맞음새 요인(FF), 누설율(TIL), 내부 누출(IL) 측면에서 적합성 평가

❑ 로보틱 헤드폼 기반 평가

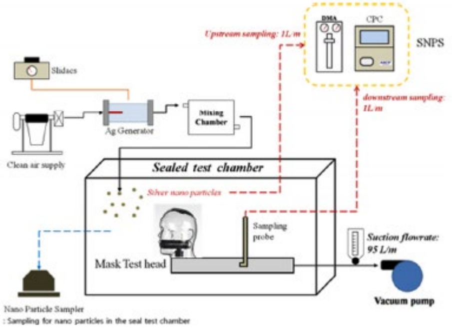
- ✓ 인간대상 평가 시 수행되는 동작 구현
- ✓ 개발 및 평가 방법은 개발 완료되었으나 평가 결과는 발표되지 않았음

**정적 헤드폼 기반
밀착도 평가**



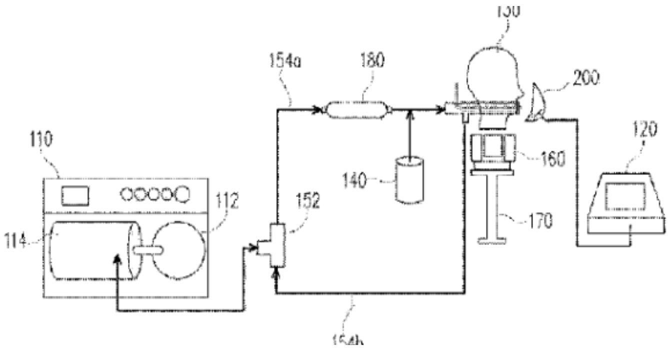
(Bergman et al., 2015)

**정적 헤드폼 기반
누설율 평가**



(김종규, 2016)

**로보틱 헤드폼
밀착도 평가**



(CN 103100156 A)

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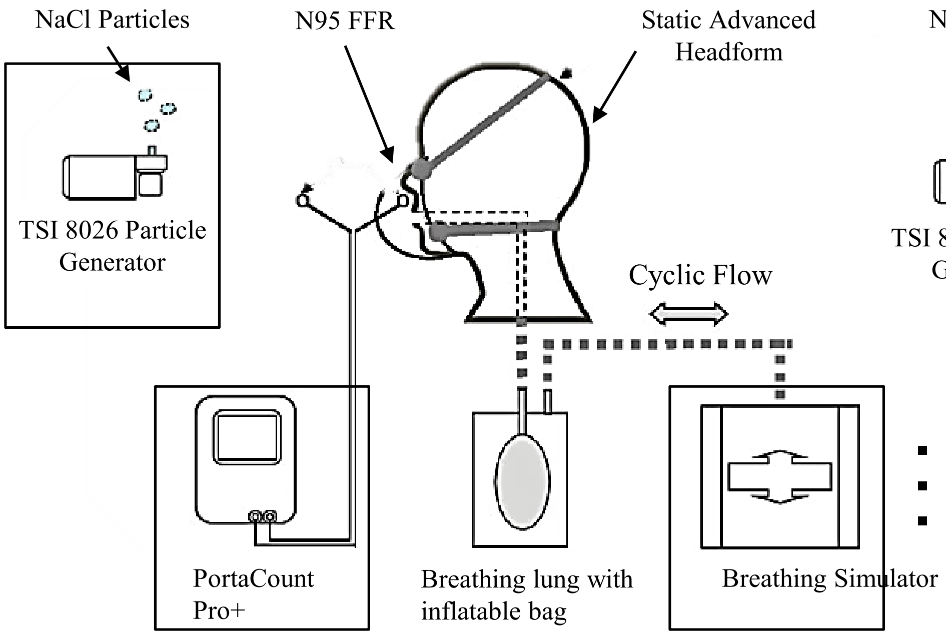
* FF: fit factor; TIL: total inward leakage; IL: inward leakage

Static Headform-Based Fit Evaluation: Fit Factor

- □ 에어로졸 생성 방법 이용하여 2가지 호흡(정상 호흡, 심호흡)시의 전체 밀착도 평가
- □ 환경 및 장비: NaCl 에어로졸 생성기(Model 8026, TSI Inc., Shoreview: MN, USA)

  밀착도 측정(TSI PortaCount Pro+ Model 8038, TSI Inc., Shoreview: MN, USA)

실험 환경 및 장비



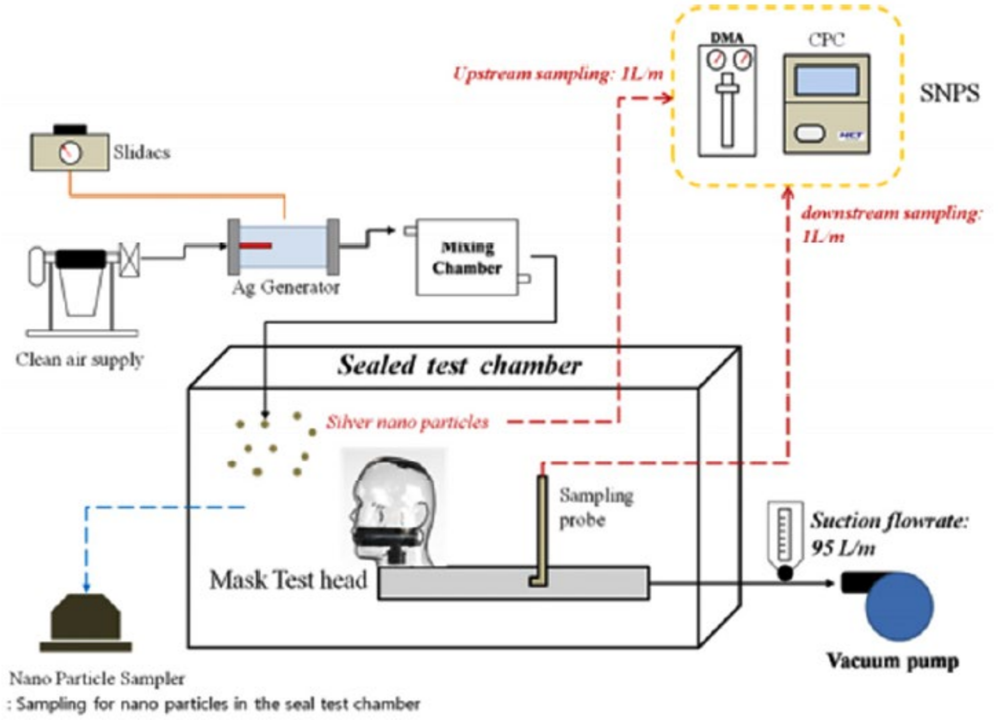
- ▪ 호흡 시뮬레이터 (Koken Ltd, Tokyo, Japan)
- ▪ 정상 호흡과 심호흡 2종류의 호흡 실행
- ▪ 2 min/exercise

(Bergman et al., 2015)

Static Headform-Based Fit Evaluation: Inward Leakage

- 정적 헤드폼과 인공폐를 이용하여 평균 50 L/min 유량을 흡입한 조건에서 챔버내의 공기를 흡입하여 **마스크를 통과하였을때 은나노 입자수의 농도를 측정**하여 평가

누설율 평가 환경 및 장비



(김종규, 2016)

Robotic Headform-Based Fit Evaluation (1/2)

- 로보틱 헤드폼(NIOSH medium size)의 외피에 인체 피부 두께 (19~22세 백인 남성) 적용하여 제작(Wander et al., 2012).
- 목 관절 구조를 파악하여 얼굴을 움직이는 **3개 동작 구동**이 가능하도록 제작
  - ✓ 구동 동작: 좌/우로 돌리기, 위/아래로 움직이기, 말하기
- **인간의 머리와 로보틱 헤드폼**의 **기능적 측면**의 유사성을 검증할 수 있는 연구 및 검증은 현재 진행중

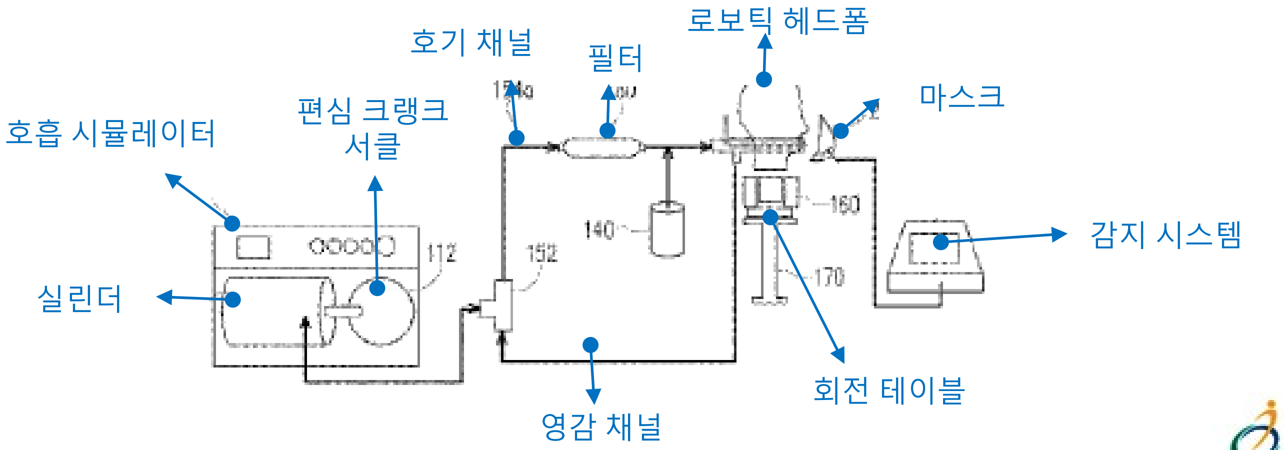
로봇틱 헤드폼 개발

(Wander et al., 2012)

Robotic Headform-Based Fit Evaluation (2/2)

- ❑ **로보틱 헤드폼, 호흡 시뮬레이터, 감지 시스템** 이용하여 마스크의 **밀착도 평가**
- ❑ 로보틱 헤드폼 **5가지 동작**을 수행하여 평가
  - ✓ 머리 정지
  - ✓ 좌/우로 돌리기
  - ✓ 위/아래로 기울이기
  - ✓ 앞/뒤로 기울이기
  - ✓ 좌/우로 기울이기

로봇틱 헤드폼 기반 평가 환경 및 장비

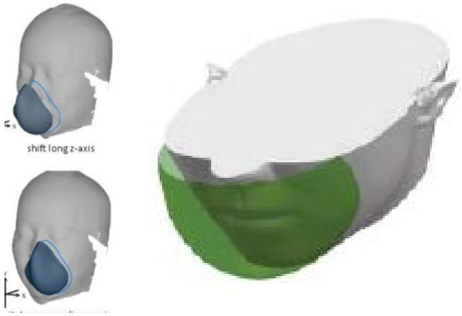


(중국 특허 CN 103100156 A)

Simulation-Based Fit Evaluation

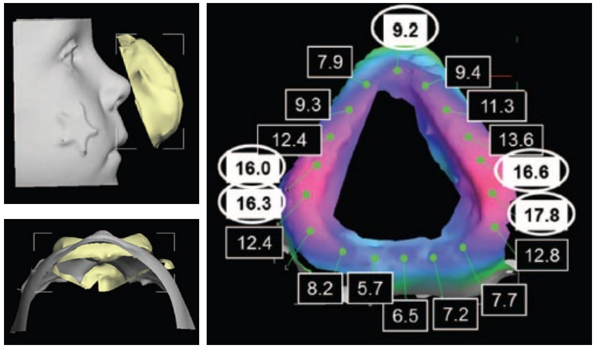
- Evaluate fit of FFRs in the simulated virtual environment by investigating measures such as **geometric similarity**, **overlapping areas**, and **contact pressure** between **digital face models** and **respirators**.

Geometric similarity



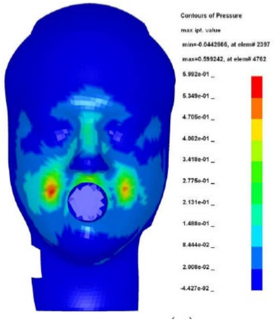
(Chu et al., 2015)

Overlap areas



(Visscher et al., 2015)

Contact pressure

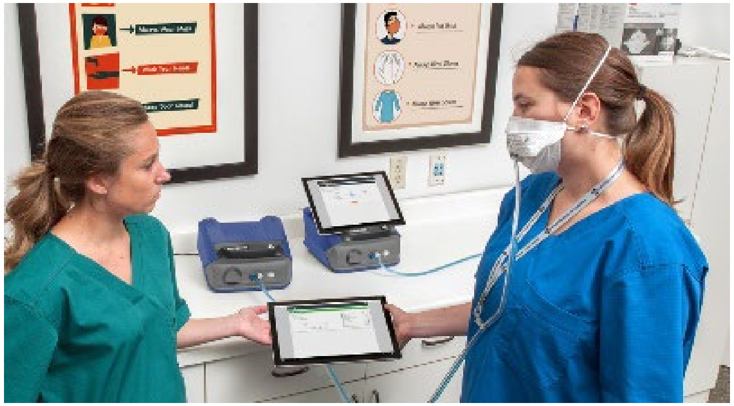


(Yang et al., 2009)

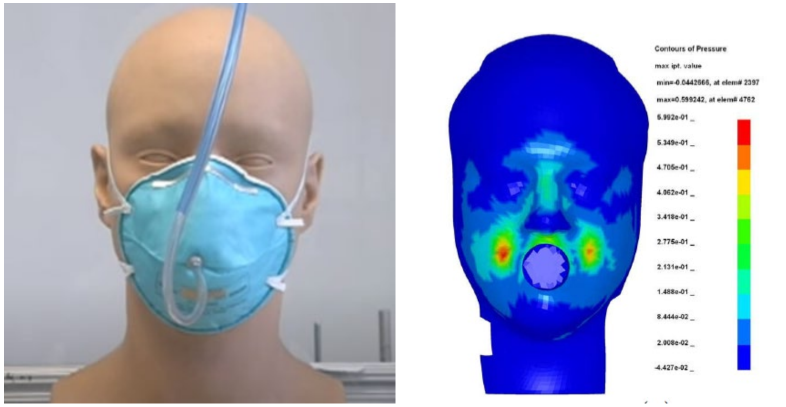
Comparison of Fit Evaluation Methods

- The **positive and negative features** of the **human-based** and **non-human-based** fit evaluation methods were compared in terms of **convenience**, **cost-effectiveness**, **representativeness**, and **applications**.

Human-based fit evaluation



Non-human based fit evaluation



Comparison of Fit Evaluation Methods

- ☐ **Convenience: non-human based** (simulation > headform) > **human-based**
- ☐ **Cost-efficiency: non-human based** (simulation > headform) > **human-based**

	Human-based	**Headform-based**	**Simulation-based**
Convenience	(-) Required human subject review board clearance (-) Complex requirements for subjects (e.g., refrain from smoking one hour and be freshly shaved 12 hours before the fit evaluation) (Foreland et al., 2018) (-) Difficult recruitment (e.g., subject with suitable size) (Brosseau et al., 2010) (-) Difficult experiment scheduling (-) Necessary physical respirator products/prototypes (Yang et al., 2009) (-) Necessary rest period during experiments because subject's fatigue	(+) Not required human subject review board clearance (Bergman et al., 2014) (-) Necessary physical respirator products/prototypes (Yang et al., 2009) (+) No-necessary experiment scheduling (Bergman et al., 2014; Wander, 2012) (+) No-necessary rest period during experiments (Bergman et al., 2014; Wander, 2012)	(+) Non-necessary physical respirator products/prototypes (Yang et al., 2009)
Cost-efficiency	(-) Time consuming (-) Expensive	(-) Relatively time consuming (-) Expensive	(+) Relatively time saving (+) Relatively cheap

Comparison of Fit Evaluation Methods

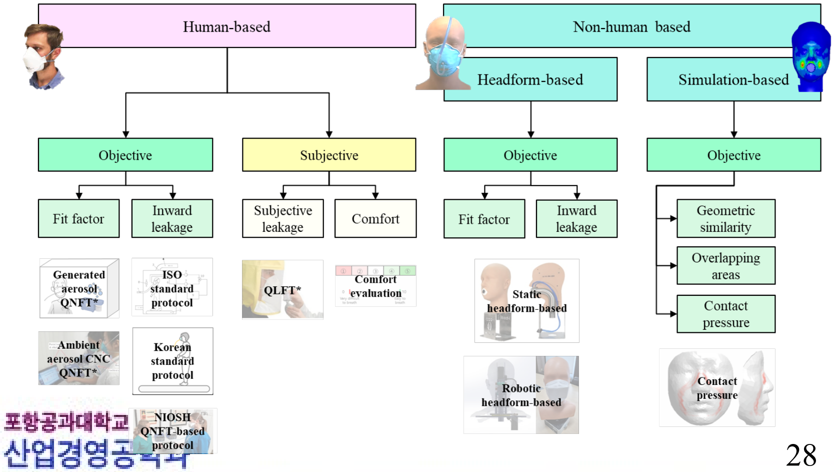
- ❑ **Representativeness:** **non-human based** (simulation ≈ headform) ≈ **human-based**
- ❑ **Application:** **non-human based** (simulation > headform) > **human-based**

	Human-based	**Headform-based**	**Simulation-based**
Representa-tiveness	(+) Experiment with realistic human facial features (Bergman et a., 2015; Bergman et al., 2014; Richardson et al., 2007) (+) Use realistic human movement in experimental environment to represent real world activities or experiment with practical activities in workplace/real world conditions (-) Can only use non-hazardous aerosols (Bergman et al., 2015)	(+) Can use headform that represent facial diversities of the target population (+) Can preliminarily simulate some of human facial texture and head/facial dynamic movements (Bergman et al., 2014; Richardson et al., 2007) (-) Need to verify human facial texture and head/facial dynamic movement properties (+) Enable experiment with more accurately representative aerosols such as hazardous (e.g., silver nano-particles, pathogenic microorganisms and industrial aerosols) and higher challenge concentrations (Seo et al., 2020; Bergman et al., 2015; Bergman et al., 2014; He et al., 2014)	(+) Can use head model that represent facial diversities of the target population (+) Can preliminarily simulate human facial texture and head/facial dynamic movements (Lei et al., 2014) (-) Need to verify actual physical (real-world) properties
Application	(-) Only evaluate the overall fit (Yang et al., 2009)	(-) Only evaluate the overall fit (Yang et al., 2009)	(+) Provide feedback of the location of unfit (Yang et al., 2009)

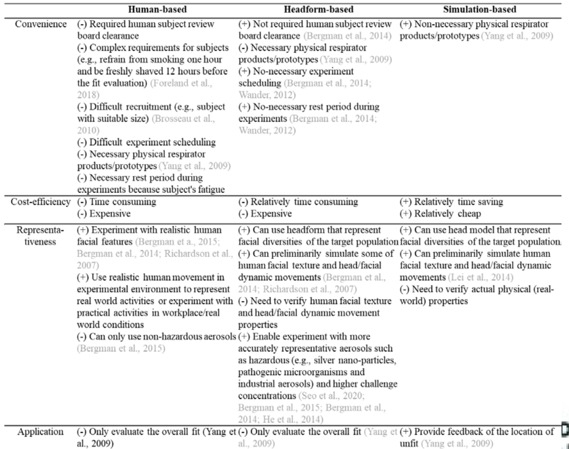
Discussion (1/2)

- ❑ A comprehensive knowledge of human-based and non-human based fit evaluation methods were organized in terms of **subject**, **apparatus**, **environment**, **requirement**, **protocol** and **analysis**.
- ❑ The **positive and negative features** of the human-based and non-human-based fit evaluation methods were compared in terms of convenience, cost-effectiveness, representativeness, and applications.

Summary of fit evaluation methods



Positive and negative features of fit evaluation methods

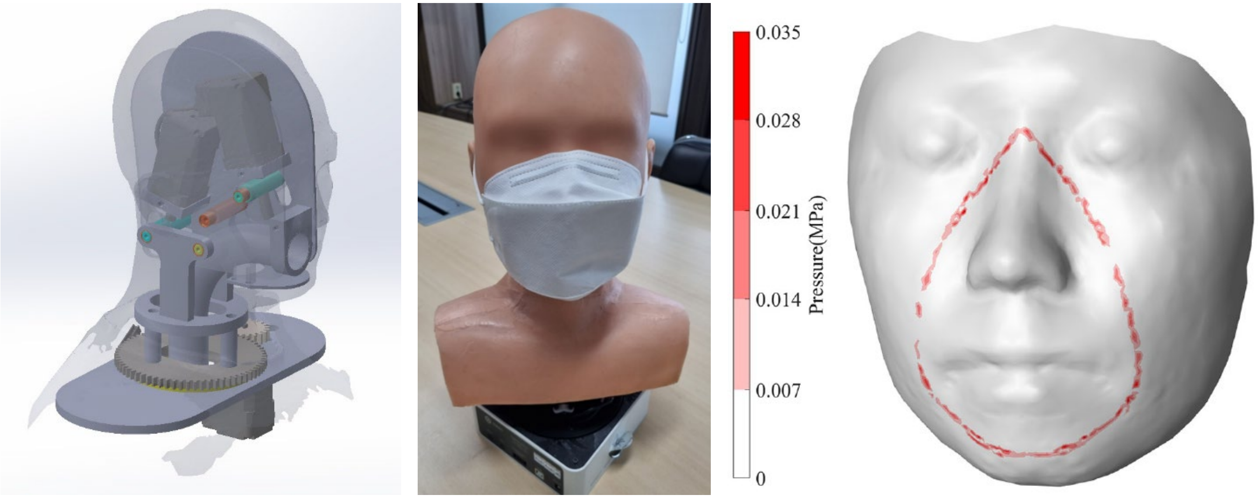


	Human-based	Headform-based	Simulation-based
Convenience	(-) Required human subject review board clearance (-) Complex requirements for subjects (e.g., refrain from smoking one hour and be freshly shaved 12 hours before the fit evaluation) (Foreland et al., 2018) (-) Difficult recruitment (e.g., subject with suitable size) (Brosseau et al., 2010) (-) Difficult experiment scheduling (-) Necessary physical respirator products/prototypes (Yang et al., 2009) (-) Necessary rest period during experiments because subject's fatigue	(+) Not required human subject review board clearance (Bergman et al., 2014) (-) Necessary physical respirator products/prototypes (Yang et al., 2009) (+) No-necessary experiment scheduling (Bergman et al., 2014; Wander, 2012) (+) No-necessary rest period during experiments (Bergman et al., 2014; Wander, 2012)	(+) Non-necessary physical respirator products/prototypes (Yang et al., 2009)
Cost-efficiency	(-) Time consuming (-) Expensive	(-) Relatively time consuming (-) Expensive	(+) Relatively time saving (+) Relatively cheap
Representa-tiveness	(+) Experiment with realistic human facial features (Bergman et a., 2015; Bergman et al., 2014; Richardson et al., 2007) (+) Use realistic human movement in experimental environment to represent real world activities or experiment with practical activities in workplace/real world conditions (-) Can only use non-hazardous aerosols (Bergman et al., 2015)	(+) Can use headform that represent facial diversities of the target population (+) Can preliminarily simulate some of human facial texture and head/facial dynamic movements (Bergman et al., 2014; Richardson et al., 2007) (-) Need to verify human facial texture and head/facial dynamic movement properties (+) Enable experiment with more accurately representative aerosols such as hazardous (e.g., silver nano-particles, pathogenic microorganisms and industrial aerosols) and higher challenge concentrations (Seo et al., 2020; Bergman et al., 2015; Bergman et al., 2014; He et al., 2014)	(+) Can use head model that represent facial diversities of the target population. (+) Can preliminarily simulate human facial texture and head/facial dynamic movements (Lei et al., 2014) (-) Need to verify actual physical (real-world) properties
Application	(-) Only evaluate the overall fit (Yang et al., 2009)	(-) Only evaluate the overall fit (Yang et al., 2009)	(+) Provide feedback of the location of unfit (Yang et al., 2009)

Discussion (2/2)

- **Non-human based fit evaluation methods** trends to be developed and apply in practice instead of human-based methods, but the **effectiveness** of non-human-based methods need to be further **verified**.

Non-human based fit evaluation method development

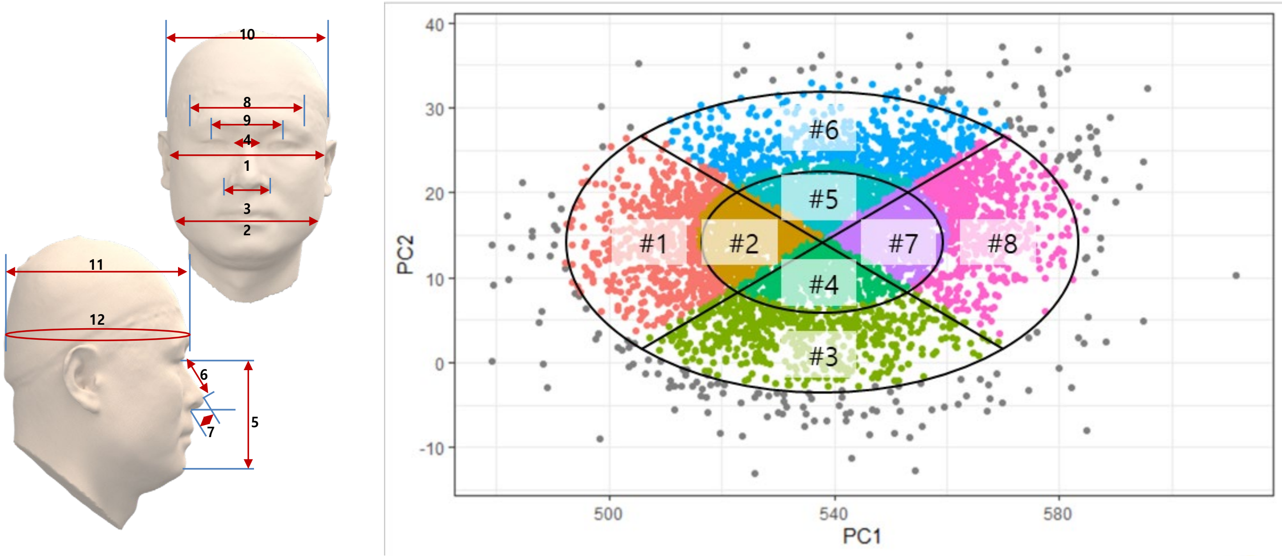


Future Work

☐ **Non-human-based fit methods** needs to be improved by providing **adequate representativeness** and **accurate partial feedback of unfit**.

- ✓ Represent realistic human using representative headform/3D models
- ✓ Simulate real-world using conditions by applying dynamic movement and toxic environment

Korean representative headform development



Q & A

경청해 주셔서 감사합니다.

This work was funded by a grant from Ministry of Food and Drug Safety.

Appendix

Appendix: Paper List (H)

- 최종 선정 문헌 총 77편(관련도 상 46 편, 중 31편)

No.	Author(s)	Year	Title	Category	Relevancy
19	Karuppasamy and Obuchowski	2021	Comparison of Fit for Sealed and Loose-Fitting Surgical Masks and N95 Filtering Facepiece Respirators	QNFT	H
20	Rollings	2020	FFP3 respirator face fit testing – what is it all about?	QNFT	H
21	Foreland et al.	2018	Do Various Respirator Models Fit the Workers in the Norwegian Smelting Industry?	QNFT	H
22	Manganyi et al.	2017	Quantitative Respirator Fit, Face Sizes, and Determinants of Fit in South African Diagnostic Laboratory Respirator Users	QNFT	H
23	Zhuang et al.	2017	Recommended test methods and pass/fail criteria for a respirator fit capability test of half-mask air-purifying respirators	QNFT	H
23	Zhuang et al.	2017	Recommended test methods and pass/fail criteria for a respirator fit capability test of half-mask air-purifying respirators	QNFT	H
24	Or et al.	2016	A novel approach to fit testing the N95 respirator in real time in a clinical setting	QNFT	H
25	Sietsema and Brosseau	2016	Comparison of Two Quantitative Fit-Test Methods Using N95 Filtering Facepiece Respirators	QNFT	H
26	Lawrence et al.	2014	Comparison of Performance of Three Different Types of Respiratory Protection Devices	QNFT	H
27	Yu et al.	2014	Fitting Characteristics of N95 Filtering-Facepiece Respirators Used Widely in China	QNFT	H
28	Bergman et al.	2012	Impact of multiple consecutive donnings on filtering facepiece respirator fit	QNFT	H
29	Coffey et al.	2012	Comparison of Five Methods for Fit-Testing N95 Filtering-Facepiece Respirators	QNFT	H
30	Ciotti et al.	2012	Effectiveness of respirator masks for healthcare workers, in France	QNFT	H
31	Park et al.	2011	Fit Test for N95 Filtering Facepiece Respirators and KF94 Masks for Healthcare Workers: a Prospective Single-center Simulation Study	QNFT	H
32	Spies et al.	2011	Respirator fit of a medium mask on a group of South Africans: a cross-sectional study	QNFT	H
33	Brosseau	2010	Fit Testing Respirators for Public Health Medical Emergencies	QNFT	H
34	McMahon et al.	2008	Implementing fit testing for N95 filtering facepiece respirators: Practical information from a large cohort of hospital workers	QNFT	H

Appendix: Paper List (H)

- ☐ 최종 선정 문헌 총 77편(관련도 상 46 편, 중 31편)

No.	Author(s)	Year	Title	Category	Relevancy
35	Sreenath et al.	2001	A Modified Protocol for Quantitative Fit Testing Using the PortaCount ®	QNFT	H
36	Fakherpour et al	2019	Feasibility of replacing homemade solutions by commercial products for qualitative fit testing of particulate respirators: a mixed effect logistic regression study	QLFT	H
37	Seo et al.	2020	Development of Korean Head forms for Respirator Performance Testing	Manikin	H
38	Pacitto et al.	2019	Effectiveness of commercial face masks to reduce personal PM exposure	Manikin	H
39	Yao et al.	2019	Impact of structural features on dynamic breathing resistance of healthcare face mask	Manikin	H
40	Bergman et al.	2017	Development of a Manikin-Based Performance Evaluation Method for Loose-Fitting Powered Air-Purifying Respirators	Manikin	H
41	Kim	2016	Filtration efficiency and Manikin-based Total Inward Leakage Study of Particle Filtering Mask Challenged with Silver Nanoparticles	Manikin	H
42	Bergman et al.	2015	Correlation of Respirator Fit Measured on Human Subjects and a Static Advanced Headform	Manikin	H
43	Bergman et al.	2014	Development of an Advanced Respirator Fit-Test Headform	Manikin	H
44	He et al.	2014	Effects of Breathing Frequency and Flow Rate on the Total Inward Leakage of an Elastomeric Half-Mask Donned on an Advanced Manikin Headform	Manikin	H
45	Rengasamy et al.	2014	A Quantitative Assessment of the Total Inward Leakage of NaCl Aerosol Representing Submicron-Size Bioaerosol Through N95 Filtering Facepiece Respirators and Surgical Masks	Manikin	H
46	Wander et al.	2012	Humanlike Articulate Robotic Headform to Replace Human Volunteers in Respirator Fit Testing	Manikin	H

Appendix: Paper List (M)

❑ 최종 선정 문헌 총 77편(관련도 상 46 편, 중 31편)

No.	Author(s)	Year	Title	Category	Relevancy
47	Rengasamy et al.	2018	A comparison of total inward leakage measured using sodium chloride (NaCl) and corn oil aerosol methods for air-purifying respirators	TIL/IL	M
48	Zhang et al.	2016	Temporal changes in filtering-facepiece respirator fit	TIL/IL	M
49	Zhang et al.	2015	Inward Leakage Variability between Respirator Fit Test Panels – Part I. Deterministic Approach	TIL/IL	M
50	Zhang et al.	2011	Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering Facepiece Respirator Fit: Part I – Pilot Study	TIL/IL	M
51	Kelly et al.	2021	Comparing the fit of N95, KN95, surgical, and cloth face masks and assessing the accuracy of fit checking	Theory	M
52	Stemen et al.	2021	Frame to Improve the Fit of N95 Filtering Face Mask Respirators	Theory	M
53	Trehan et al.	2021	Comparing the quantitative fit-testing results of halfmask respirators with various skin barriers in a crossover study design: a pilot study	Theory	M
54	Singh et al.	2020	Under-mask beard cover (Singh Thattha technique) for donning respirator masks in COVID-19 patient care	Theory	M
55	Sandaradura et al.	2019	A close shave? Performance of P2/N95 respirators in health care workers with facial hair: results of the BEARDS (Adequate Respiratory DefenceS) study	Theory	M
56	Suen et al.	2019	Comparing mask fit and usability of traditional and nanofibre N95 filtering facepiece respirators before and after nursing procedures	Theory	M
57	Viscusi et al.	2019	Evaluation of the Benefit of the User Seal Check on N95 Filtering Facepiece Respirator Fit	Theory	M
58	Vuma et al.	2019	The Effect on Fit of Multiple Consecutive Donning and Doffing of N95 Filtering Facepiece Respirators	Theory	M
59	Rembialkowski et al.	2017	Impact of Time and Assisted Donning on Respirator Fit	Theory	M
60	Roberge et al.	2015	Effect of Pregnancy Upon Facial Anthropometrics and Respirator Fit Testing	Theory	M
61	Niezgoda et al.	2013	Flat Fold and Cup-Shaped N95 Filtering Facepiece Respirator Face Seal Area and Pressure Determinations: A Stereophotogrammetry Study	Theory	M
62	Danyluk et al.	2011	Health Care Workers and Respiratory Protection: Is the User Seal Check a Surrogate for Respirator Fit-Testing?	Theory	M

Appendix: Paper List (M)

❑ 최종 선정 문헌 총 77편(관련도 상 46 편, 중 31편)

No.	Author(s)	Year	Title	Category	Relevancy
63	Reponen et al.	2011	Effect of Fit Testing on the Protection Offered by N95 Filtering Facepiece Respirators Against Fine Particles in a Laboratory Setting	Theory	M
64	Oestenstad et al.	2007	The Effect of Gender and Respirator Brand on the Association of Respirator Fit with Facial Dimensions	Theory	M
65	Campbell et al.	2005	Reducing Respirator Fit Test Errors: A Multi-Donning Approach	Theory	M
66	Derrick et al.	2005	Predictive value of the user seal check in determining half-face respirator fit	Theory	M
67	Zhang et al.	2000	The Relationship between the Filtering Facepiece Respirator Fit and the Facial Anthropometric Dimensions Among Chinese People	Theory	M
68	Elmashae et al.	2017	Performance of Two Respiratory Protective Devices Used by Home-Attending Health-Care Workers (A Pilot Study)	SWPF	M
69	Robertson and Ramsdale	2021	Audit of qualitative fit testing for FFP3 respirators	QNFT	M
70	Clapp et al.	2020	Evaluation of Cloth Masks and Modified Procedure Masks as Personal Protective Equipment for the Public During the COVID-19 Pandemic	QNFT	M
71	Kim et al.	2016	Physiologic and fit factor profiles of N95 and P100 filtering facepiece respirators for use in hot, humid environments	QNFT	M
72	Colton	2001	Respirator Fit Testing: Choosing the Best Method	QNFT	M
73	Pan et al.	2021	Assessment of Use and Fit of Face Masks Among Individuals in Public During the COVID-19 Pandemic in China	QLFT	M
74	Wardhan et al	2020	Does a Modified Adhesive Respirator Improve the Face Seal for Health Care Workers Who Previously Failed a Fit Test?: A Pilot Study During the Coronavirus Disease 2019 Pandemic	QLFT	M
75	He et al.	2013	Manikin-Based Performance Evaluation of Elastomeric Respirators Against Combustion Particles	Manikin	M
76	Davidson et al.	2013	Performance Evaluation of Selected N95 Respirators and Surgical Masks When Challenged with Aerosolized Endospores and Inert Particles	Manikin	M
77	Balazy et al.	2006	Manikin-Based Performance Evaluation of N95 Filtering-Facepiece Respirators Challenged with Nanoparticles	Manikin	M