Introduction

Increased air pollution attributed to fine dust and yellow dust is considered to be a grave social issue in South Korea [1], and several risk assessment studies have been conducted on the population who are susceptible to the disease [2,3] to protect public health.

The average particulate matter (PM) 2.5 level in South Korea was 27.9 μg/m³, which was the highest level among the Organization for Economic Cooperation and Development (OECD) nations [4]. In comparison, the average PM2.5 concentration in OECD countries was approximately 13.9 μg/m³. The World Health Organization sets the guideline limit as 10 μg/m³ [5].

Industries are one of the largest emitters of several varieties of pollutants, and they PM10 emissions have increased by four times since 2000 mainly because of extensive consumption of fossil fuels. Furthermore, road transport is the largest contributor of NOx and CO emissions. Transboundary particles, specifically the fine particulates from the industrial sites in China and yellow sand dust from the deserts in China and Mongolia, significantly exacerbate PM concentrations in Korea. However, the precise amount of air pollutants from the two neighboring countries remains unclear [6].

The National Institute of Environmental Research reported [7] that the impact of fine dust and yellow dust on health can be evaluated through several body indicators, including pulmonary illnesses and functions. In addition, the report revealed that a higher level of pollutants was associated with an increased relative risk of hospitalization because of the onset of asthma [2,8].

Because the amount of fine dust in South Korea is comparatively higher than that of other OECD countries, the general population has demanded better management of the air quality to address the associated health risks. Accordingly, the Ministry of Environment has established air quality standards considering particulate matters (PM 2.5, 35 μg/m³ over 24 h, 15 μg/m³ on an annual basis), which have been in effect since 2018. Furthermore, the Ministry has imposed stricter regulations to control PM, by issuing alerts in cases when the PM concentrations exceeded the standard, and has recommended that the general population should wear respirators when necessary.
Similarly, the Ministry of Food and Drug Safety in Korea advised the public to wear respirators to protect themselves from infectious diseases, bad odors, exhaust gases, yellow sand dust, and PM. It has further implemented the Korean Filter system to certify respirators. In terms of the protection provided by the respirators, not only the filter performance but also the quality of fit specific to a user’s face is particularly important, regardless of its certification status, to protect users from hazardous and harmful substances in the air. Face seal leakage is a key factor in respiratory protection.

Traditionally the respiratory protective devices (RPDs) have been designed for industrial workers to protect from the hazardous substances associated with their workplaces. In comparison, however, RPDs for general public need to cover wide range of population including children and elderly. Despite this, respirator performance is being tested using head forms that are manufactured based on European facial dimensions. These head forms have different facial dimensions than those of the general public in South Korea.

Presently, there has been an increase in the need for new specifications for facial dimensions for the general public. Considering this, Han et al. [5] measured and classified the facial dimensions of Koreans and developed a half facepiece respirator for workers, and that could be applied to the Korean facial dimensions. Furthermore, Kim et al. [10] recently used three-dimensional (3D) anthropometry to develop PM masks for children and the general population. Seo et al. [11] classified the facial dimensions of children into three types through cluster analysis to provide basic data for respirator design. Three-dimensional anthropometry was particularly used to conduct facial measurements instead of traditional direct measurement and ensured a faster and easier measurement for children who cannot sit still for a long time during the process. The method also permitted repeated data measurement with fewer errors, along with measurement of curves in the face, which was not possible via the previous methods [12]. In Korea, Seo et al. [13] used a 3D scanner to measure the facial dimensions of 730 children and classified them into three different size groups. In China, Yanyan et al. [14] used a 3D scanning method to produce 3D digital head forms representing workers and developed five facial models (small, medium, large, long/narrow, and short/wide), which were used in the process of designing and testing the respirators for the Chinese population [15]. Since 1970, the United States (US) has used several means to develop head forms that represent the worker population. Cyberware 3D Rapid Digitizer [16] has been used to this end, and the variations in facial shape have been studied across four racial strata [17]. These studies have facilitated the development of respirators with adequate sizes for different wearers with advanced efficiency and performance [18].

Despite the fact that, various types of head forms have been used to test respirator performance while considering different sizes and characteristics of respirator wearers in the USA and EU, the ISO 16900-5 [19] has stipulated five types of RPD head forms as international standards. Since 2016, the National Institute for Occupational Safety and Health (NIOSH) in the US has developed and studied robotic head forms that simulate human actions, such as facial movements and speech [20]. The NIOSH has developed a new robotic manikin head form (called an “advanced head form”) to facilitate the evaluation of respirator fit and respirator inward leakage, along with the study of factors including the penetration of particles through the filter and leakage in the area of the face seal. Advanced head form [20] may aid in process involved in respirator design and advance respirator certification and consensus standards. In addition, one recent study used the ISO breathing machine to perform leak test with a medium-sized head form [21]. The study by Kimjong-Kyu [22] assessed total inward leakage using head forms and a breathing machine, according to the respirator safety test method of Korea [23], emphasized that the test should be conducted on head forms instead of human participants, considering the fact that the test material (silver nanoparticles) raised safety concerns owing to its toxicity. Rengasamy and Eimer [24] assessed the efficiency and performance of RPDs using head forms and a breathing machine and not human participants. However, respirators in Korea continue to be tested using a head form that has been designed according to the facial dimension of European workers. This poses a considerable problem with regard to representativeness and performance validation because these respirators are used by all members of the general public, including children, adolescents, and adults, for protection against yellow dust and PM. The head forms used to test the performance of respirators must represent the facial diversities of the target population.

We aimed to (1) categorize the facial dimensions of the public aged between 7 and 69 years (covering children and the elderly) using a piece of 3D software, (2) build facial models representing the Korean general population, and (3) use 3D printing technology to develop and manufacture head forms to test the respirator performance.

2. Materials and methods

2.1. Participants

Facial dimensions of the Korean general population were acquired by using the report of the 6th 3D anthropometric survey of Koreans (Korean Agency for Technology and Standards, Size Korea. 2010—2013) [25]. The 3D scanning was used to acquire the 3D anthropometric data of 4,583 Koreans, aged between 7 and 69 years, while ensuring that the participants adopted the posture and head position according to the ISO 20685 guidelines [26].

Participants were recruited using a statistical method to determine the necessary number in accordance with ISO 15535 [27]. Table 1 shows the number of participants in each age group. Data of 4,583 participants (50.8% men, 49.2% women) were collected from 2010 to 2013. These participants were categorized according to their age as follows: 1,233 participants aged 7–13 years, 1,292 aged 14–19 years, 830 aged 20–39 years, and 1,228 aged 40–69 years.

An age interval of 1 year was set for participants aged between 7 and 19 years, and samples were collected considering their physical characteristics were classified by age group, and the minimum number of samples required for each group [28] was predetermined before analyzing the data.

| Age | No. of participants | Male | Female |
|-----|---------------------|------|--------|
| 7–13| 1,233               | 610  | 623    |
| 14–19| 1,292              | 676  | 616    |
| 20–39| 830                | 425  | 405    |
| 40–69| 1,228              | 618  | 610    |
| Total| 4,583              | 2,329| 2,254  |
| %   | 100                | 50.8 | 49.2   |
2.2. Data collection and clustering

Head and facial data were collected using an anthropometry database that was built in accordance with the standardized measurement protocols of the ISO 20685 [26], using a 3D anthropometry scanner. In the 6th 3D anthropometric survey of Koreans [25], the participants’ heads were automatically measured in 3D according to the items and methods in the ISO 7250 and ISO 8559 [29,30], and the head and face data displayed in Table 2 were collected as presented in Fig. 1. Among the 45 items, 44 were used to develop the head forms, the remaining one item was not considered because it was relatively ambiguous. Nose root–pronasale length (No.16) was excluded from the 45 face measurements because it was similar to that of the nose length (No.2); both parameters can be considered identical given their measurement locations.

From the 3D measurement data of 4,583 participants, 5–95% values were included, whereas particularly extreme values were excluded. Among the 5–95% values, 354 extreme cases were excluded for the following reasons: those having facial width <110 or ≥170 (317 cases) and those having facial length ≤71 or ≥140 (37 cases). The data were subsequently classified into several different facial size groups to develop and manufacture the head forms, as demonstrated in Fig. 2. A hierarchical cluster analysis was designed based on a multiple-phase cluster analysis; the number of clusters necessary to classify facial dimensions was determined and analyzed using a dendrogram with a Ward linkage [11,31]. The final clusters were determined using the k-means method [32].

2.3. Processing for the 3D head form

Three head forms based on facial dimensions of the Korean population were developed and classified according to the cluster analysis by generating 3D images using a 3D software program (Design X; 3D Systems, USA). The “.stl” format file of the dummy head for 3D printing was used with help from a 3D expert (Fig. 3).

The sketch image for printing was completed in an “.stl” file format, and three head forms (Abs-m30; Stratasys, USA) were printed using a 3D printer (Fortus 450mc; Stratasys, USA). The three printed head forms were checked for the presence of cracks and sanded to ensure that their surfaces were smooth. Lastly, the surface was covered with a 2-mm thick human skin-like material. To ensure that it had attributes similar to that of real human skin, urethane rubber (60L[A], 60L[B]; Prototech, Korea) was used at a ratio of 100:33 and a hardness range of 10 shore to 30 shore to replicate the texture of human skin, in accordance with the head form finishing standards of the ISO 16900-5 [19]. The head forms were connected to a breathing machine via a tracheal tube (Tygon medical tubing; US Plastics, USA) that penetrated through the back of the head (Fig. 4).

2.4. Statistical analysis

The SPSS system, version 20.0 (SAS Institute Inc., USA) was used for statistical analysis of all data. Statistical significance was tested at $\alpha = 0.05$.

A t-test was used to determine the differences in age and gender with respect to facial length and width. Hierarchical clustering analysis was performed to roughly determine the number of clusters before analyzing the face sizes for each participant via k-means analysis. The k-means cluster analysis was used to categorize the clusters by size, by applying the squared Euclidean distance, and statistical significance was confirmed in the final clusters through analysis of variance ($p < 0.05$).

3. Results

3.1. Classification of facial dimensions

Before classifying the facial dimensions to produce standard head forms, face width and length were analyzed to identify gender and age differences.

Table 2

| No. | Measurement item                                      | No. | Measurement item                                      |
|-----|-------------------------------------------------------|-----|-------------------------------------------------------|
| 1   | Nose protrusion                                       | 24  | Menton: head protrusion horizontal breadth            |
| 2   | Nose length                                           | 25  | Sellarion: head protrusion horizontal breadth         |
| 3   | Head circumference                                     | 26  | Tragion: sellarion horizontal breadth                |
| 4   | Head vertical length                                  | 27  | Zygion head protrusion horizontal breadth (right)    |
| 5   | Head point: chin length                               | 28  | Zygion head protrusion horizontal breadth (left)      |
| 6   | Head point: bitragion (right)                         | 29  | Tragion: ectocanthus horizontal breadth              |
| 7   | Head point: bitragion (left)                          | 30  | Bitragion: lip length                                |
| 8   | Head point: lip length                                | 31  | Sellarion coronal arc                                |
| 9   | Head point: subnasale length                          | 32  | Bitragion coronal arc                                |
| 10  | Head point: pronasale length                          | 33  | Bitragion: chin arc                                  |
| 11  | Head point: nose root length                          | 34  | Bitragion: nose root Arc                             |
| 12  | Head point: intercanthal length                       | 35  | Bitragion: subnasale Arc                             |
| 13  | Face length                                           | 36  | Neck (left): bitragion coronal arc – neck (right)    |
| 14  | Head point: intercanthal length (right)               | 37  | Head breadth                                         |
| 15  | Head point: intercanthal length (left)                | 38  | Minimum frontal breadth                              |
| 16  | Nose root: pronasale length                           | 39  | Interpupillary breadth                               |
| 17  | Subnasale: chin length                                | 40  | Nasal root breadth                                   |
| 18  | Head length                                           | 41  | Maximum frontal breadth                              |
| 19  | Ectocanthus: head protrusion horizontal breadth (right)| 42  | Bizygomatic breadth                                  |
| 20  | Ectocanthus: head protrusion horizontal breadth (left) | 43  | Nose breadth                                         |
| 21  | Sellion: zygion horizontal breadth                    | 44  | Lip length                                           |
| 22  | Subnasale head protrusion horizontal breadth          | 45  | Bignomial breadth                                    |
| 23  | Lip: head protrusion horizontal breadth               |     |                                                       |
Data demonstrated that the faces of men were 3.0 mm wider than those of women, constituting a significant difference ($p < 0.000$) (Table 3). Comparing the means of the two age groups revealed that the faces of the participants aged between 20 and 69 years were 13.0 mm wider than those in the 7–19-year age group ($p < 0.000$). Table 3 demonstrates that the faces of men were 6.5
mm longer than those of women, constituting a significant difference \((p < 0.000)\). The face length of individuals in the 20–69-year age group demonstrated a mean difference of 10.3 mm, which was significantly greater than that of the other groups \((p < 0.000)\).

The 44 items were classified into three clusters after a hierarchical cluster analysis. Each item was analyzed using k-means cluster analysis and subsequently classified into three sizes: small, medium, and large (Table 4). Analysis of variance was conducted on these three cluster centroids and revealed significant differences among all items \((p < 0.001)\). The size differences of these three head forms are shown in Fig. 3.

### 3.2. Head forms for respirator performance testing

Sizes of the three head forms were determined as shown in Table 4. A 3D software program (Design X; 3D Systems, USA) was used to complete the design plan of the head forms (Fig. 3). Three Korean manikin head forms were printed using the Fortus 450mc (Stratasys, USA) as shown in Fig. 4. The facial area of the head forms that comes in contact with the respirator underwent a certain amount of finishing to ensure a skin-like texture. A tracheal tube was mounted in front of the mouth to connect the head form with a breathing machine [33].

### 4. Discussion

Standard head forms that are currently in use in Korea to test respirators have specifications that are identical to those used to test RPDs for industrial workers. In addition, respirator performance is being tested using head forms that were manufactured based on facial dimensions of European workers. Considering this, a previous study [9] suggested a measurement system that could conveniently produce the facial dimensions of Korean workers.

However, respirators for general public are worn by people of various age groups, including the children and elderly; therefore, there is a need for new standard head forms to test the performance of the respirators. Furthermore, it should consider variations in the facial dimensions along with the breathing capacities of its wearers.

#### 4.1. Comparison of facial dimensions

The standard Korean head form clusters that were classified in this study were compared with those of previous studies by dividing the participants into two age groups: preadults (7–19 years) and adults (20–69 years). The face widths and lengths of the individuals in the preadult and adult groups were 136.1 mm, 103.7 mm, and 149.1 mm, 114.0 mm, respectively. The two groups demonstrated significant differences between their face width sand lengths considering their age \((p < 0.000)\). In addition, the face
Facial dimensions by cluster

| Classification | Cluster (centroid) | F | Sig.** |
|----------------|-------------------|---|--------|
|                | 1                 | 2 | 3     |
| 1              | 8.3               | 11.0 | 13.3 | 146.1 | <0.001 |
| 2              | 41.7              | 49.4 | 53.8 | 256.6 | <0.001 |
| 3              | 539.2             | 568.6 | 598.3 | 81.3 | <0.001 |
| 4              | 198.7             | 220.7 | 234.6 | 189.4 | <0.001 |
| 5              | 177.2             | 193.1 | 208.2 | 167.8 | <0.001 |
| 6              | 126.7             | 133.8 | 137.5 | 114.4 | <0.001 |
| 7              | 116.0             | 131.0 | 137.5 | 55.6 | <0.001 |
| 8              | 174.0             | 186.2 | 194.7 | 204.2 | <0.001 |
| 9              | 147.0             | 186.2 | 194.7 | 204.4 | <0.001 |
| 10             | 137.5             | 147.4 | 155.6 | 143.8 | <0.001 |
| 11             | 104.0             | 115.2 | 122.3 | 206.3 | <0.001 |
| 12             | 93.3              | 109.1 | 120.0 | 242.9 | <0.001 |
| 13             | 906.0             | 104.0 | 120.2 | 208.4 | <0.001 |
| 14             | 113.5             | 118.4 | 123.8 | 91.4 | <0.001 |
| 15             | 114.9             | 121.9 | 169.0 | 943.6 | <0.001 |
| 16             | —                 | — | — | — | — |
| 17             | 45.5              | 55.1 | 62.4 | 172.1 | <0.001 |
| 18             | 181.3             | 189.3 | 199.1 | 138.5 | <0.001 |
| 19             | 89.0              | 117.0 | 172.3 | 402.2 | <0.001 |
| 20             | 153.0             | 173.6 | 199.0 | 158.0 | <0.001 |
| 21             | 83.1              | 93.1 | 114.5 | 132.0 | <0.001 |
| 22             | 177.7             | 196.9 | 206.6 | 317.0 | <0.001 |
| 23             | 185.5             | 194.5 | 200.6 | 96.6 | <0.001 |
| 24             | 153.5             | 167.7 | 180.7 | 301.9 | <0.001 |
| 25             | 162.0             | 183.1 | 187.4 | 1115.8 | <0.001 |
| 26             | 78.1              | 87.1 | 94.5 | 199.9 | <0.001 |
| 27             | 68.0              | 88.1 | 98.2 | 140.0 | <0.001 |
| 28             | 69.0              | 88.4 | 98.2 | 144.9 | <0.001 |
| 29             | 71.0              | 89.0 | 103.0 | 56.5 | <0.001 |
| 30             | 98.5              | 129.0 | 166.0 | 122.6 | <0.001 |
| 31             | 290.2             | 309.0 | 386.4 | 518.8 | <0.001 |
| 32             | 345.7             | 366.7 | 382.5 | 130.5 | <0.001 |
| 33             | 277.1             | 320.2 | 384.0 | 119.9 | <0.001 |
| 34             | 245.3             | 277.7 | 326.0 | 127.9 | <0.001 |
| 35             | 256.4             | 285.6 | 348.5 | 109.0 | <0.001 |
| 36             | 558.3             | 604.8 | 634.1 | 176.4 | <0.001 |
| 37             | 145.9             | 158.5 | 168.5 | 160.8 | <0.001 |
| 38             | 83.4              | 91.5 | 102.4 | 282.3 | <0.001 |
| 39             | 56.0              | 66.5 | 70.7 | 251.1 | <0.001 |
| 40             | 31.1              | 34.8 | 44.4 | 940.5 | <0.001 |
| 41             | 131.1             | 146.1 | 163.2 | 147.8 | <0.001 |
| 42             | 127.1             | 143.2 | 149.1 | 98.0 | <0.001 |
| 43             | 32.2              | 34.6 | 37.6 | 154.6 | <0.001 |
| 44             | 40.0              | 47.2 | 56.4 | 260.9 | <0.001 |
| 45             | 105.1             | 115.1 | 128.0 | 183.8 | <0.001 |

**Significant at α = 0.05.

Bold values represent in row "13 - Face length" and row "42 - Face width"; F, F-value by clustering.
different ethnicities and races [39], particularly in children. Considering this, we classified several participants in the preadult (7–19 years) group and investigated changes in their facial dimensions. Fig. 5 demonstrates that the results showed a significant degree of change with regard to face width and length between the participants aged 13 and 14 years, which was attributed to growth. Fig. 6 shows that the facial dimensions of preadults between 14 and 19 years were different from those of participants younger than 13 years. The 14–19-year-old group was then reclassified, and their facial dimensions were compared to those of adults, revealing similarities to the facial dimensions of adults aged 20–69 years. Moreover, Fig. 7 reveals that the medium and large clusters of the 7–19-year group were in close proximity to the adult group. These two clusters demonstrate that the preadults (14–19 years of age) had facial parameters similar to that of adults. Adolescents in the 14 + age group demonstrated a face size similar to that of adults (Fig. 6). Most individuals in the 14 + age group were classified into the medium or large cluster. Both the medium and large clusters in the 7–14-year age group, along with the small cluster in adults, corresponded to the medium head form model.

Accordingly, most participants in the 7–19-year age group were represented with a medium head form model, while those with a relatively small face were represented with a small head form model (Fig. 7).

Age-based cluster classification is presented in Fig. 7. The small clusters in the 7–19-year age group were in close proximity to those with the small head form (blue +) cluster, whereas the medium and large clusters in the 7–19-year age group and the small cluster in the 20–69-year age group were in close proximity to the medium head form (red +) cluster. Lastly, the medium and large clusters in the 20–69-year age group were in close proximity to the large head form (black +) cluster. Several children (aged ≤13 years) and adolescents showed smaller facial dimensions than adults and were represented by the small head form.

4.3. Korean head forms

The three head forms developed in the present study were similar or relatively shorter than the corresponding dimensions. Previous studies [30,35] have reported that the head forms of the 5 facial types with medium (140.0 mm), long/narrow (140.0 mm), and short/wide (141.0 mm) face widths were similar to medium head forms in Koreans aged 7–69 years. However, the large head forms described in the present study were similar to or slightly larger than those of the previous studies. Facial widths of small, medium, and large head forms were 127.1 mm, 143.2 mm, and 149.1 mm, respectively. Facial length of the large Korean head form was 120.2 mm, which was similar to that of medium (119.0 mm) head forms; however, the face lengths in the small and medium head forms were 90.6 and 104.0 mm, respectively, which were shorter than those in the previous studies [34,40].

Although United States and China have classified the head forms into five types, the present study classified the Korean faces into three types. The five head forms developed by United States and China were based on facial features without considering age and gender. In this study, although observed the facial dimensions of Koreans varied by age and gender (Table 3), we included all the participants in clustering analysis so as to determine head form models that could be used to test respirators, regardless of the age or gender of users.

Three-dimensional images were created using the cluster centroid of each item. The procedure was previously introduced by Seo et al. [13], and Lii et al. [31]. Standard head forms were produced using a 3D printer based on the pertinent 3D images.
The head forms produced in this study were based on the standards that represent the facial dimensions of the Korean population and can be used to evaluate respirator performance. Hierarchical clustering was associated with the development of three head form models; in addition, there were significant differences between these clusters. Therefore, these three models are significantly distinct from each other considering the face size of the participants (Table 4).

The large head form, representing particularly larger facial dimensions, must be used to test respirators for adults. Meanwhile, medium head forms are suitable for testing respirators in adults with small facial dimension or adolescents, and small head forms are ideal for testing respirators in children with small facial dimensions.

International standard head forms, based on previous studies, were used to evaluate the performance of respirators designed for adults. The head forms designed by us can specifically be used to test the respirator performance of those worn by Koreans, including children. However, our study has some limitations. None of the head forms have been produced for children, and even the present study does not provide sufficient evidence regarding the small head form being useful for testing respirators worn by children. Furthermore, no RPD head forms have been produced for respirator performance tests in Korea, suggesting that the results of present study were limited because of the absence of an appropriate reference data. Previous studies have reported differences in facial size of the participants according to their countries. Unfortunately, there are no standard head form dimensions for children and adolescents, and there have been no previous studies that have compared Korean head form sizes. However, Seo et al [11,13] classified facial sizes of children, which could be used as a basis for head form production.

Here, we demonstrated differences in facial size between countries and ethnicities, along with differences of the same between adults and children. Considering this, it is evident that there is a need for head forms that account for the facial sizes of those wearing respirators. Therefore, performance testing standards for the respirators worn by Koreans must be improved.

In this regard, it is important that researchers produce head forms that represent the facial dimensions of the Korean population. According to a report by the National Institute of Environmental Research [3], respiratory systems of children were more vulnerable to the harmful effects of yellow dust and PM, and respirators are worn by a large population to protect them, including children and the elderly. Therefore, the present study is highly significant because it proposes head forms for respirator performance tests based on the facial dimensions of Korean citizens.

5. Conclusion

In conclusion, standard head forms for respirator performance tests must be produced considering the differences in the facial
dimensions of the wearers. Particularly, considering that respirators are worn by the general public of all ages, it is imperative to include head forms for both adults and children.

Head forms to evaluate respirator performance were also connected to a breathing machine to simulate human breathing, and a tracheal tube of the same specification must be inserted into the three head forms, in accordance with the ISO 16900-5 guidelines [19]. Furthermore, the skin texture of the head forms compiled with material specifications and finishing standards.

Head forms with texture similar to that of human skin were designed using 3D anthropometry; small, medium, and large faces were created considering the same. Accordingly, introduction of skin texture to simulate human participants in the respirator performance tests and the fabrication of head forms by connecting them to breathing machines could be considered as the strengths of this study. This study has significant implications because of the fact that it has developed the first Korean standard head forms to evaluate respirators.

Conflicts of interest

All authors declare that there are no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.shaw.2019.12.008.

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