between 0 and 180 degrees (Figure 67).

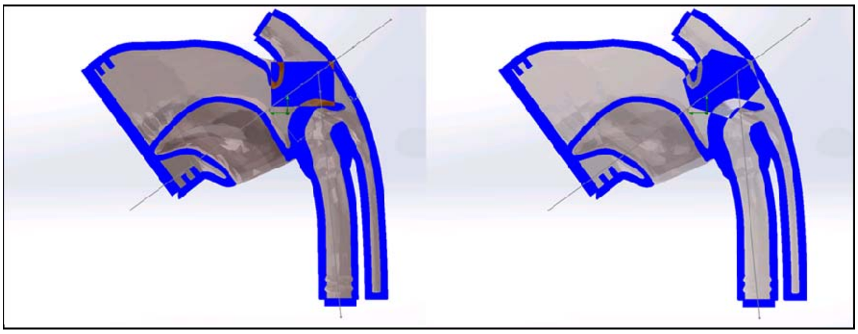


Figure 67. Polyhedrons placed in P3 (left: cube, right: regular dodecahedron)

5.3.4 Results of Airflow Simulation Analysis

(1) Effects of Shape

(a) Cube (regular hexahedron)

In the cube, airflow was found in all of the 36 positions (100%) between 0 and 180 degrees (Figure 68).

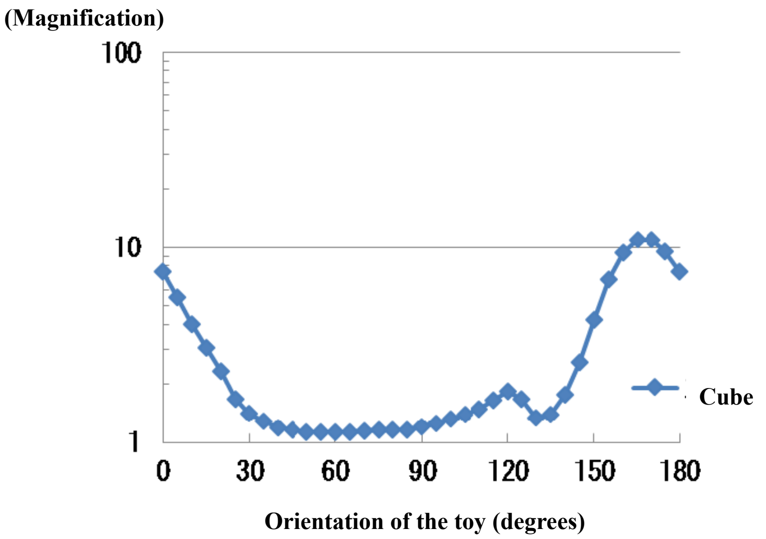


Figure 68. Suction pressure during obstruction by the cube (magnification ratio relative to the open state)

In addition, the magnification ratio of suction pressure[65] relative to the suction pressure in the open state was not more than 10 fold in almost all positions. It is

[65] The pressure necessary for suction at a suction flow rate set as an analysis condition.

highly possible that complete obstruction would be avoided even when a cube was lodged in the pharynx. A pathline diagram at 50 degrees with the smallest suction pressure is shown (Figure 69).

The results found that a cube was less likely to cause complete obstruction than a sphere, probably due to a large difference between the longest diagonal line and the shortest diagonal line of a cube. It is probable that a space was left even when the cube was lodged in the pharynx.[66]

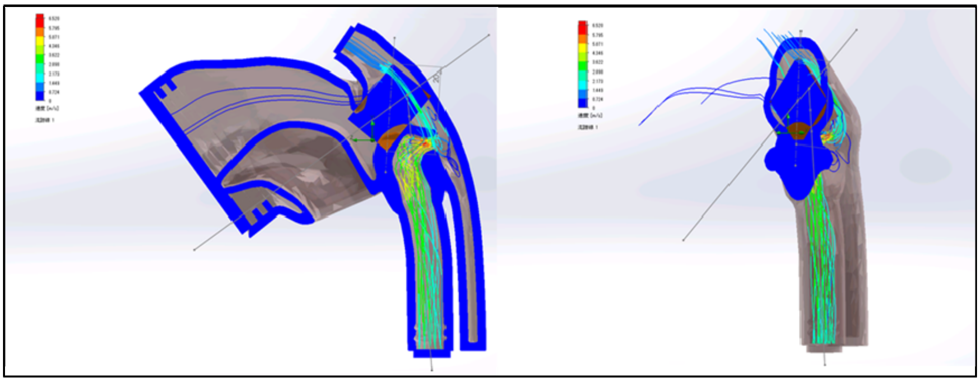


Figure 69. Pathline diagram in the orientation with the smallest suction pressure in the cube
(Left: cross section from the right side, right: coronal cross section)

(b) Regular dodecahedron

Airflow was found in 11 of the 36 points (31%) between 0 and 180 degrees. In addition, the magnification ratio of suction pressure relative to the suction pressure in the open state was not less than 60 fold in all positions except 1 position. The smallest suction pressure was 14-fold of the suction pressure in the open state (Figure 70). The regular dodecahedron is more likely to cause obstruction than the cube, because it was closer to a sphere than the cube.

[66] The results of the airway obstruction simulation analyses showed that the cube was assessed as posing a "high" risk of choking, due to differences in the methodology or purpose between these simulations; the airway obstruction simulation was to qualitatively assess choking risk and the airflow simulation was to quantitatively assess the degree of pharyngeal obstruction as measured by suction pressure.

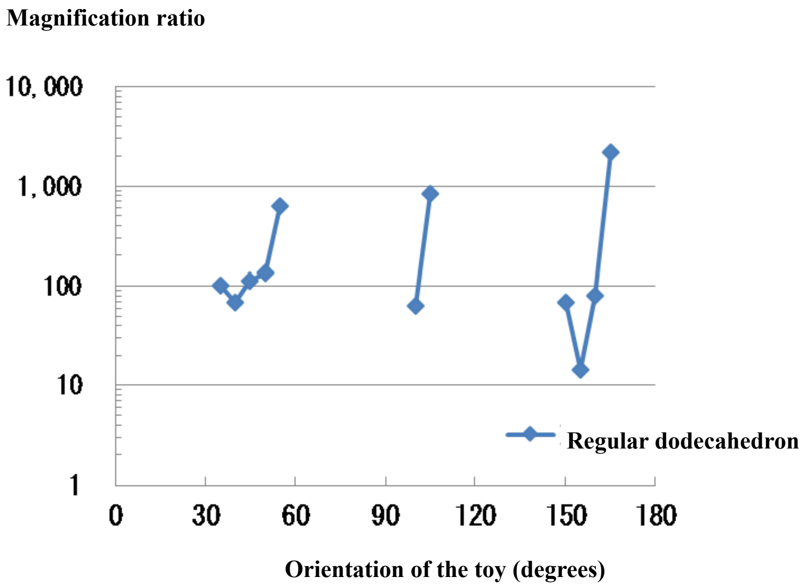


Figure 70. Suction pressure during obstruction by the regular dodecahedron (magnification ratio relative to the open state)

(2) Effects of the Twist of Making Holes

(a) Sphere without holes

First, a sphere 20 mm in diameter without holes was used to determine whether it caused complete obstruction in P1 to P3. The results showed that complete obstruction was not caused in P1 with airflow found only from the mouth at a suction pressure of 766.7 Pa.[67] This is probably due to the structure of the pharyngeal cavity characterized by being having a relatively large space, leaving small spaces even if a sphere is lodged in a relatively higher part of the pharyngeal cavity, such as P1. A pathline diagram in P1 shown in Figure 71 is provided.

[67] A unit of pressure. The condition in which force of 1 N (Newton) acts per 1 m^2.

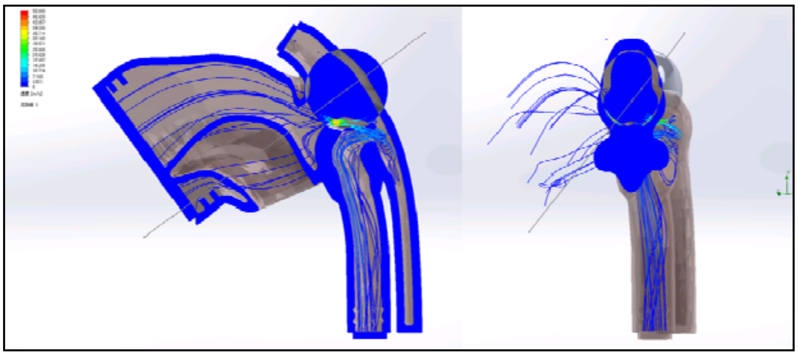


Figure 71. Results of the analysis of the ball without holes in P1
(Left: cross section from the right side, right: coronal cross section)

On the other hand, no inflow of air occurred due to complete obstruction of the pharynx in P2 (where the sphere was pushed into a lower part of the pharyngeal cavity) and P3 (where the center of the sphere was located near uvula). This is probably due to a narrower space near the epiglottis or below the uvula than that of the pharyngeal cavity. Therefore, analyses of spheres with holes were performed in P2 and P3.

(b) Spheres with holes located in P2

For either sphere with 3-mm holes or 4-mm holes, no inflow of air was found in any orientation analyzed. This was probably because the spheres were pushed down to obstruct the boundary between the larynx and esophagus, leading to the blockade of the passage of air from the pharyngeal cavity to the larynx. In addition, in an actual living body, it is probable that pharyngeal obstruction and laryngeal obstruction simultaneously occur due to additional obstruction of the laryngeal aperture caused by pressure on the epiglottis.

These results suggested that, when pushed down deep into the pharyngeal cavity, toys that caused pharyngeal obstruction might pose a high risk of causing complete obstruction of the respiratory tract regardless of the presence of holes in the toys (Figure 72).

It should be noted that spheres with 2-mm holes, which were smaller than 3-mm holes, were not analyzed, because no airflow might occur, as observed above.

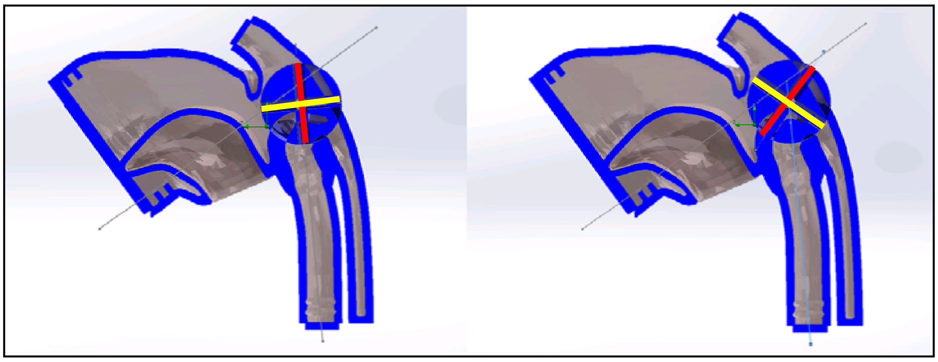


Figure 72. Results of the analysis of the sphere with 3-mm holes in P2 (left: initial position [0 degree], right: 60 degrees)

(c) Spheres with holes located in P3

An analysis of obstruction in P3 showed that airflow was observed in some orientations. Orientations with observed airflow included 9 of 18 points (50%) for 2-mm holes and 3-mm holes and 11 points (61%) for 4-mm holes. In addition, suction pressure varied with the hole size or sphere orientation, even in the presence of airflow.

Therefore, suction pressure was calculated as a measure for comparison of difficulty in suction to determine the magnification ratio relative to the suction pressure in the open state of 31.09 Pa.[68]

The results indicated that suction pressure was the lowest for 4-mm holes and less than 10-fold of the suction pressure in the open state in six orientations. Suction pressure for 3-mm holes was higher than that for 4-mm holes and not more than 20-fold of the suction pressure in the open state in six orientations. For 2-mm holes, suction pressure was not less than 50-fold of the suction pressure in the open state in all nine orientations with observed airflow (Figure 73).

[68] At the suction pressure of 3,109 Pa, suction is difficult, because suction of the same volume is impossible unless there is 100-fold of the suction pressure in the open state. A higher magnification ratio indicates more difficult suction and a higher risk of choking.

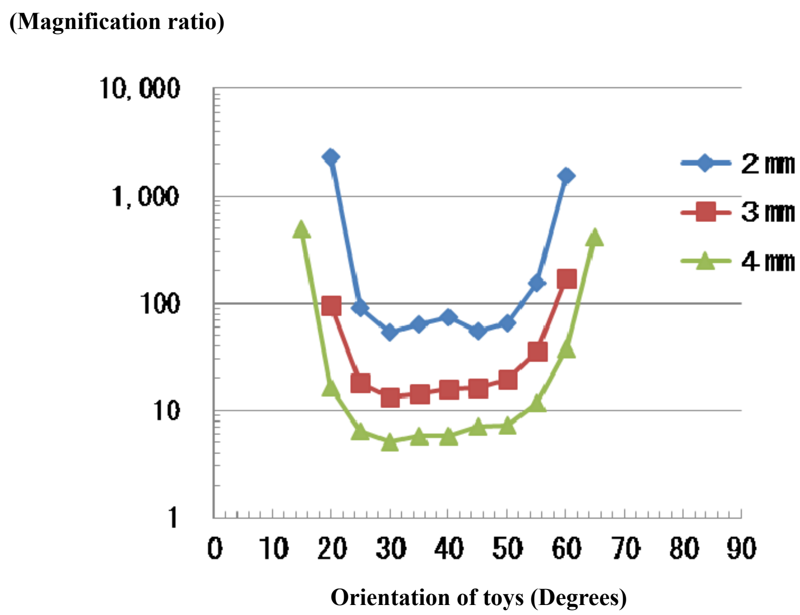


Figure 73. Suction pressure in P3 (magnification ratio relative to the open state)

These results indicated that respiration tended to be easier with an increase in hole size. It is probable that making as large holes as possible increases the potential for avoidance of complete obstruction of the pharyngeal cavity.

Next, a pathline of the analysis results in the orientation with the lowest suction pressure for each shape is provided (Figure 74). The results show that air flows through multiple holes that get crossed in the center, but not in a linear fashion. They indicate that making holes in one direction is less effective and making holes in multiple directions that get connected in the center to form multiple passages is required to avoid pharyngeal obstruction-type asphyxiation, because the pharynx is not a cylindrical tube standing upright.

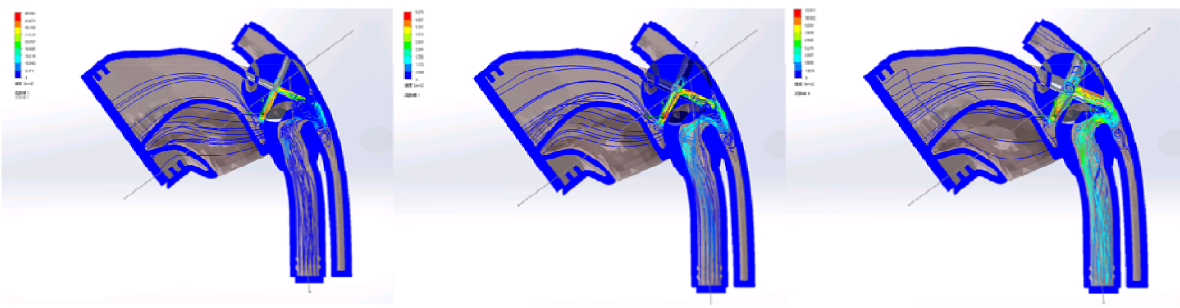


Figure 74. Pathline diagrams in the orientation with the lowest suction pressure in P3

(Left: 2-mm hole, mid: 3-mm hole, right: 4-mm hole)

In addition, the regular dodecahedron was characterized by inflow of all air from the nasal cavity without any inflow from the mouth. For example, the results of the analysis at 155 degrees with the lowest suction pressure are provided in a pathline diagram (Figure 75). Even if suction is blocked in a structural narrowed area between the soft palate and tongue, which is called the faucial isthmus, airway from the nasal cavity may be maintained at the back of the pharyngeal cavity with a relatively large space in a regular dodecahedron.

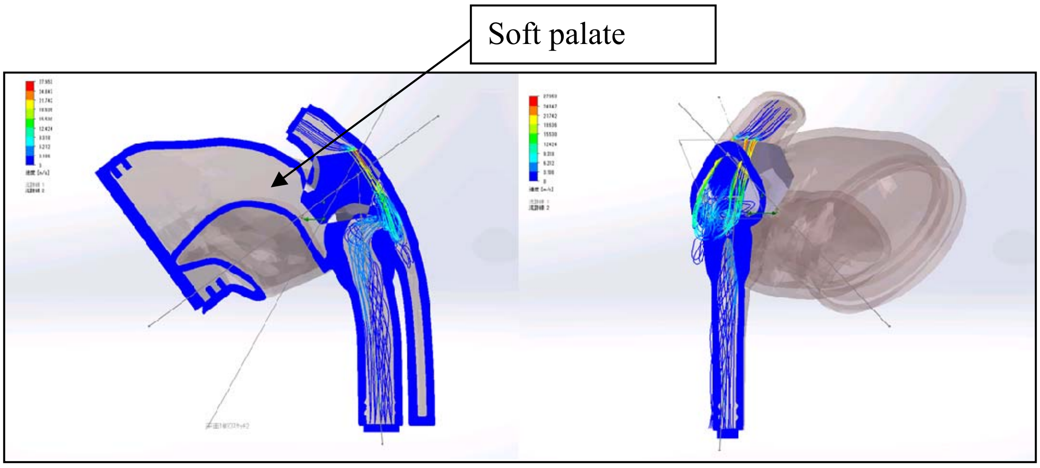


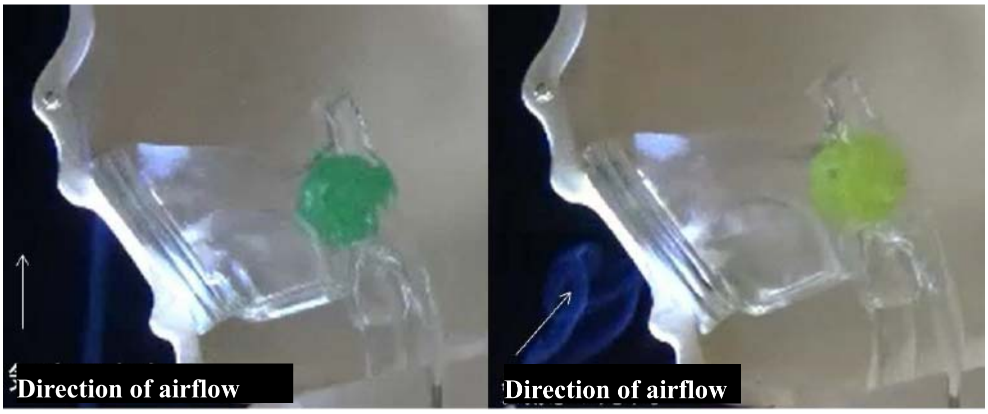
Figure 75. Pathline diagram in the orientation with the lowest suction pressure in the regular dodecahedron
(Left: cross section from the right side, right: coronal cross section)

5.3.5 Suction Experiment on Balls with Holes Using a Phantom Model

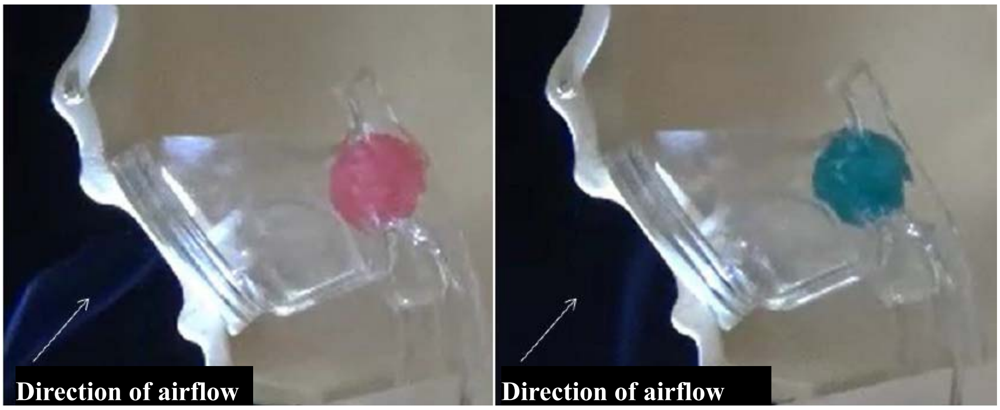
As with toy models used for airflow simulation, bouncing balls 20 mm in diameter with 2-mm, 3-mm, and 4-mm holes were actually created and were allowed to obstruct the pharynx of a phantom model[69] to perform an experiment for the presence of airflow.
To directly visualize airflow, incense smoke was used. Suction was performed from the side of an Ambu bag[70] of the phantom model and videos were shot to determine whether incense smoke brought close to the mouth was inhaled. The videos showed that no smoke was inhaled in the absence of holes, a small amount of smoke was inhaled in the presence of 2-mm holes, and smoke flowed in the direction of the mouth in the presence of 3-mm and 4-mm holes (Picture 7 and Picture 8). In addition, measurement

[69] A human body model reproducing the human body or body organs.
[70] A bag for medical use to deliver air (oxygen) through the mouth and nose in an emergency and other situations. An Ambu bag for children was used as the lung of the phantom model considering the expiratory volume of infants.

of wind speed at the tip of the mouth under the conditions found that wind speed was increased with the size of the holes (Table 15).



Picture 7. Images from the phantom experiment (left: ball without holes, right: ball with 2-mm holes)



Picture 8. Images from the phantom experiment (Left: ball with 3-mm holes, right: ball with 4-mm holes)

Table 15. Results of measurement of wind speed at the tip of the mouth

State of holes	Wind speed
Open	0.35 m/s
4 mm	0.24 m/s
3 mm	0.20 m/s
2 mm	0.13 m/s
Obstructed	0.02 m/s

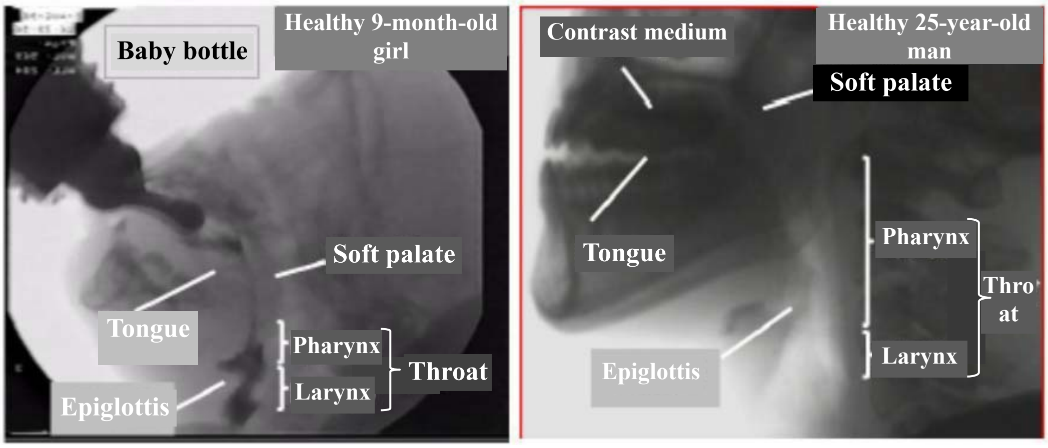
6. Discussion

Discussion was done in light of the results from questionnaire surveys and computer simulations.

6.1 Characteristics of Infants and Aspiration Accidents

6.1.1 Why do Objects Enter the Throat (Pharynx and Larynx) through the Mouth?

When a solid enters the mouth, adults first chew it to fluidize it. At the age of approximately six months to one year and six months, when the formation of four upper and lower front tooth is completed, infants cannot adequately chew food, because they have an incomplete set of teeth.
Swallowing movement is different between adults and infants. For example, the comparison of the movements during swallowing of liquid in a 9-month-old child (a healthy 9-month-old girl) and an adult (a healthy 25-year-old man) with available videofluoroscopic images of swallowing shows that the adult holds liquid in the mouth and then swallows it at a gulp, whereas the 9-month-old child holds liquid in the pharynx but not in the mouth and swallows it after a certain volume is held in the pharynx (Picture 9).



Picture 9. Videofluoroscopic images of swallowing (left: 9-month-old child[71], right: adult)

[71] Hiroyuki Haishima, et al. "Observation of swallowing movement in a nine-month-old child with an X-ray TV – comparison of swallowing between infants and adults" Japanese Journal of Dysphasia Rehabilitation, Vol.1 p33-44, 1997 (in Japanese)

Thus, infants have a short distance between the mouth and throat (pharynx and larynx) facilitating the entry of objects into the throat through the mouth due to a difference in swallowing movement and infants' anatomical characteristics of a flat and narrow pharyngeal space and the high position of the larynx (the larynx close to the nasal cavity). In addition, infants secrete much saliva, increasing the likelihood that objects put into the mouth may enter the pharynx without frictional resistance.

6.1.2 Why does an Object Lodge in (Obstruct) the Throat (Pharynx and Larynx)?

Voluntary movements such as ingesting and expelling something take place in the mouth, whereas involuntary movements take place in the pharynx and larynx, including swallowing, vomiting, and choking.

In infants, the size of the pharynx is smaller than the maximal mouth opening. Thus, objects entering the mouth are likely to be lodged in the throat without passing through the throat. In addition, infants have less well-developed muscles of the mouth and pharynx than adults and have a weak strength to ingest and expel something. Thus, they have difficulty in removing (swallowing and vomiting) an object on their own once it gets lodged in the throat.

6.2 Characteristics of Toys Likely to be Aspirated (Discussion Based on the Results from the Questionnaire Survey among Parents/Guardians)

The results from the questionnaire survey among parents/guardians found that aspiration accidents caused by toys frequently occurred in infants younger than three years, especially those aged between six months and one year and 6 months. This is probably related to the process of children's growth. Children are perceived to start weaning around the age of five to six months and complete it around the age of one year to one year and six months[72], which coincides with the time when they get more motivated to touch something on their own with development of their ability to move. In addition, infants have the characteristic that they "put anything in their mouth."

For the type of frequently aspirated toys, "marbles" was the most common response, followed by "bead-based toys" and "small balls." For the size, "6 to 10 mm" was the most common response, followed by "11 to 20 mm" and "0 to 5 mm." For the shape, "objects of the same size when viewed from any plane (such as spheres and cubes)" was the most common response, followed by "flat objects."

[72] Ministry of Health, Labour and Welfare "Breastfeeding and Weaning Guide" (March 14, 2007)

For the material, hard materials such as plastic were commonly used, probably related to the fact that most materials of commercially available toys are such materials.
For the color, the most common colors were blue and red. This may be related to the preference of infants for fundamental hues such as red, blue, and yellow[73] and the wide commercial availability of toys of these colors.
Finally, the results of the questionnaire survey among parents/guardians suggested that the products that were intended for children younger than three years, but were not more than approximately 30 mm in size[74] and did not appear to have their safety assured[75] were commercially available (Figure 36). It is thus possible that some toy-related enterprises design and manufacture products or specify and indicate the intended age without regard to standards for the safety of toys.

6.3 Discussion of the Computer Simulation

6.3.1 Classification and Characteristics of Choking by Area Obstructed by Toys

Choking can be classified into the pharyngeal obstruction-type and laryngeal obstruction-type according to the area in which foreign substances such as toys are lodged. Pharyngeal obstruction-type choking refers to the obstruction of the pharynx by a toy to interfere with breathing (Figure 76(a)). Laryngeal obstruction-type choking refers to the obstruction of the larynx by a toy that is lodged above the glottis (Figure 76(b)).

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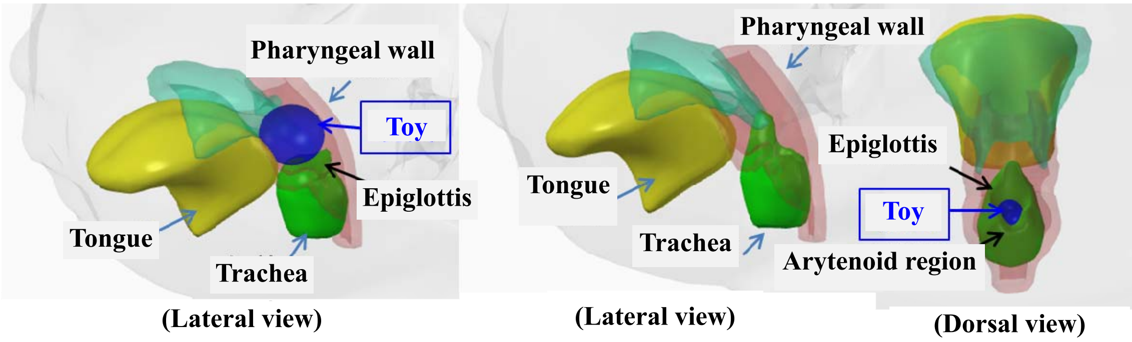
[73] Toshio Mori, Masumi Saito, Kyoko Kajiura. "Color features preferred by infants" (Major in Home and Life Sciences, Department of Home and Life Sciences, Faculty of Home Economics, Gifu Women's University, September 15, 2010).
[74] Values indicated considering safety based on ST Standard (See Section 3.3.3 (1)).
[75] Whether these toys bore the ST Mark is unknown.



(a) Pharyngeal obstruction-type choking

Shape: Sphere Diameter: 15 mm
Hardness: Rigid
Friction coefficient: 0.05 Restitution coefficient: 0.03

(b) Laryngeal obstruction-type choking

Shape: Sphere Diameter: 6 mm Hardness: Rigid
Friction coefficient: 0.05 Restitution coefficient: 1.0

Figure 76. Pharyngeal obstruction-type choking and laryngeal obstruction-type choking

The results of the simulation analysis found that pharyngeal obstruction-type choking commonly presented with not only obstruction of the pharyngeal cavity by a toy but also obstruction of the laryngeal aperture with downward pressure on the epiglottis from above by the toy. The pharyngeal cavity and laryngeal cavity are simultaneously blocked, resulting in short time in respiratory arrest. It is highly probable that there is a very high risk of asphyxiation.

In laryngeal obstruction-type choking, a toy is present in the larynx but the epiglottis does not cover the laryngeal aperture, which remains open. The laryngeal cavity is not a simple tube or cylinder in shape, but has folds with its opening being not vertically oriented. In addition, it is highly probable that it is difficult to expel a toy entering the larynx with cough reflex because infants have a poor strength to expel foreign matter. However, because the laryngeal aperture and pharynx are open, it is probable that breathing is possible to some extent if there is space left in the larynx, making the degree of seriousness lower than that in pharyngeal obstruction-type choking, although the risk of asphyxiation remains high.

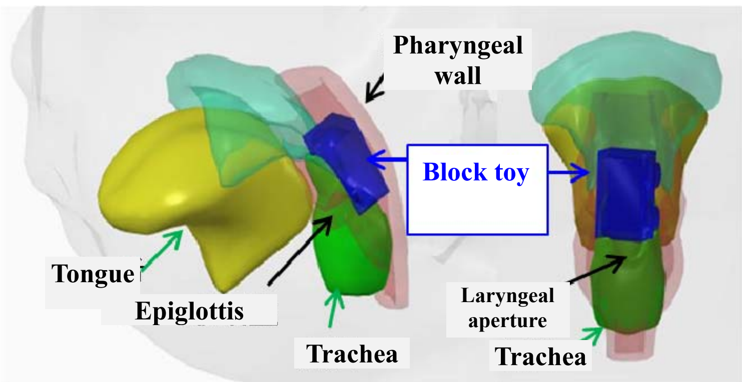
6.3.2 Shape of Toys Showing High Risk of Choking

The sphere showed “high” and “intermediate” risk of choking in 9 and 1, respectively, of a total of 10 sessions of simulation performed under multiple conditions, indicating that the sphere showed high risk of choking under the conditions analyzed. In the case of the sphere, relatively large objects caused pharyngeal obstruction-type choking and small objects entered the larynx to cause laryngeal obstruction-type choking.

Because infants have much saliva in their mouth, toys are likely to slip into the pharynx. In addition, because the tongue is horizontal in the mouth (tongue body) and represents an almost vertical slope (tongue root) on the pharynx, spherical toys are likely to drop down into the pharynx. In addition, the shape of the pharyngeal cavity is crescentic in shape during breathing. When food coming in from the mouth enters the pharynx during swallowing, the pharyngeal cavity takes a sphere-like shape because of a dimple made in the center of the tongue root. After food enters the pharynx, the cavity is closed, squeezed anteriorly and laterally. Thus, the sphere is a shape that fits into the pharyngeal cavity and is therefore likely to lodge in the pharynx and block the pharyngeal cavity once entering the pharynx. Even when an attempt is made to expel a spherical object into the mouth, the object is hampered by the soft palate on the upper side and by bulges located on the lateral pharyngeal walls (palatine tonsils) on the sides and therefore remains in the pharynx for a long time, probably leading to serious disease.

The results from the simulation analysis showed that the rugby ball shape and peanut shape, as well as spherical objects such as balls, caused pharyngeal obstruction-type choking when they were large in size and laryngeal obstruction-type choking when they were small in size.

On the other hand, the cuboid, cube, or block toy did not cause complete obstruction of the pharyngeal cavity, because some space was left in the pharyngeal cavity; however, they blocked the laryngeal aperture by applying downward pressure to the epiglottis from above (Figure 77).



Shape: Block toy
Hardness: Rigid
Friction coefficient: 0.05
Restitution coefficient: 0.03

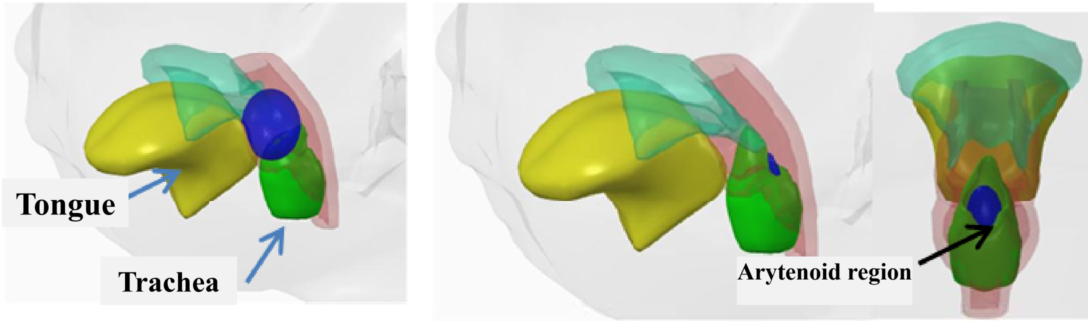
Figure 77. Example of pressure on the epiglottis exerted by the toy block

Next, the airway simulation and experiment on airflow using the phantom model determined whether modifications to the shape of toys could ensure an open airway. It is

highly probable that objects having a shape closer to the sphere are associated with greater difficulty in maintaining an open airway and higher risk of choking.
If holes are made in the sphere to prevent asphyxiation, holes in a single direction are not enough because the pharynx is not a cylindrical tube standing upright. It is somewhat likely that holes in multiple directions getting connected at the center position help to prevent asphyxiation, depending on the position in which the toy lodges. In this case, it is probable that larger holes are associated with higher likelihood of freedom from obstruction and lower suction pressure, thereby facilitating breathing.

6.3.3 Size of Toys Showing High Risk of Choking

The space of the pharynx is larger than that of the larynx. Therefore, it is highly probable that toys obstructing the pharynx are larger in size than toys obstructing the larynx.
The results of the simulation analysis showed that the spheres having a diameter ranging from 15 to 20 mm obstructed the pharyngeal cavity. For a smaller sphere 10 mm in diameter, breathing was possible under certain conditions. For the sphere 6 mm in diameter, it is probable that breathing is difficult due to obstruction of the laryngeal cavity, although some space is left in the pharynx.
For the hemisphere, a diameter of 20 mm showed "high" risk of choking, because the pharyngeal cavity was almost completely obstructed and downward pressure on the epiglottis caused obstruction of the laryngeal aperture, although changes in orientation made some space in the laryngeal aperture in some cases. For a diameter of 15 mm, it is probable that breathing is possible because larger space was left in the pharyngeal cavity, less pressure was exerted on the larynx, and the laryngeal aperture was kept open.
For the rugby ball shape, a size with a minor diameter of 14 mm caused the laryngeal cavity to be almost completely obstructed and the laryngeal aperture to be semi-obstructed by the epiglottis on which downward pressure was exerted (Figure 78(a)). The peanut shape, cuboid, cube, or block toy lodged in the pharynx with some space left in the pharyngeal cavity, but applied pressure to the epiglottis to cause obstruction of the laryngeal aperture when they had a major diameter or diagonal line length of at least 15 mm.



(a) Pharyngeal obstruction

Shape: Rugby ball shape
Minor diameter: 14 mm
Hardness: Rigid
Friction coefficient: 0.05
Restitution coefficient: 0.03

(b) Laryngeal obstruction

Shape: Rugby ball shape
Minor diameter: 7 mm Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate, 0.8 for below the pharynx

Figure 78. Pharyngeal and laryngeal obstructions

The results showed that all the shapes subjected to the simulation, except the block shape and marble-shaped toy, posed a high risk of pharyngeal obstruction-type choking, which refers to complete or almost complete obstruction of the pharyngeal cavity. In particular, the spherical objects having a diameter of at least 15 mm completely obstructed the pharyngeal cavity, accompanied by obstruction of the laryngeal aperture.
On the other hand, the sphere 6 mm in diameter, peanut shape, and block toy were found to pose a high risk of laryngeal obstruction-type choking, which refers to complete or almost complete obstruction caused by the obstruction of the laryngeal aperture by toys rather than pressure on the epiglottis from above.
Therefore, it is probably that even toys of a size that cannot obstruct the pharynx pose a high risk of choking by obstructing the laryngeal cavity.

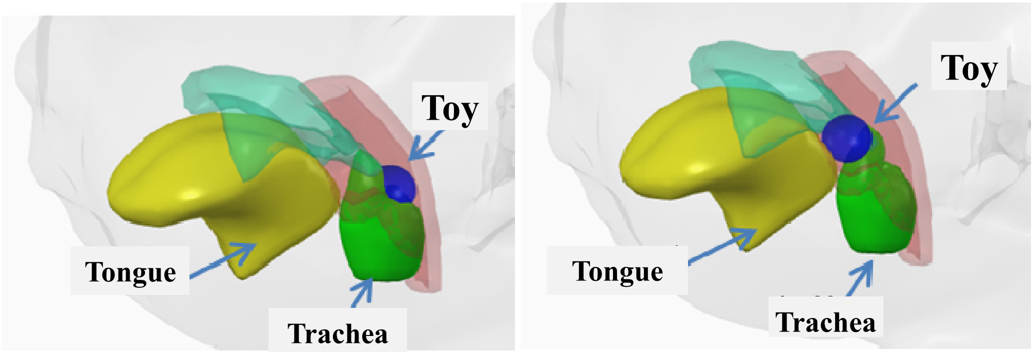
6.3.4 Coefficients of Friction and Restitution of Toys

The coefficient of friction is a coefficient that describes the slipperiness of a toy on the mucosal surface of the tongue or pharynx. Coefficients of friction of toys on mucosal surfaces in infants have not been known to be investigated or reported by other institutions and are also difficult to actually measure. Since infants secrete much saliva, it is probable that coefficients of friction are low, which means that slipperiness is high. Therefore, "notably slippery conditions" and "slippery conditions" were used. More specifically, with a standard coefficient of friction of 0.05 in the tongue, palate, and the other positions below the pharynx, the following two simulations were performed: one with a coefficient of friction of 0.1 of toys located in the tongue or palate under the assumption of “slippery conditions” and the other with a coefficient of friction of 0.2 of toys located below the pharynx under the assumption of “notably slippery conditions.”

The coefficient of restitution is a coefficient that describes how much a toy bounces back from a living body. As with a coefficient of friction, coefficients of restitution have not been known to be investigated or reported by other institutions and were also difficult to actually measure. With reference to values from experiments using the porcine tongue mucosa, the following two simulations were performed: one with a coefficient of restitution of 0.03 in the tongue, palate, and the other located below the pharynx and the other with a coefficient of restitution of 0.03 in the tongue and palate and a coefficient of restitution of 0.8, indicating a greater degree of bounce, below the pharynx.

The results of the above simulation analyses showed that the sphere 10 mm in diameter entered the laryngeal cavity to cause laryngeal obstruction-type choking under conditions of a coefficient of friction of 0.05 and a coefficient of restitution of 1.0 (Figure 79(a)), but stayed in the epiglottis valley[76] and showed only “intermediate” risk of choking under conditions of a higher coefficient of friction of (0.1 for the tongue and palate and 0.2 for the positions below the pharynx) and a lower coefficient of restitution (0.03 for the tongue and palate and 0.8 for the positions below the pharynx) (Figure 79(b)).

[76] The boundary between the tongue root and epiglottis and named after its form of V-shaped valley.



(a) Toy located in the laryngeal cavity

(b) Toy staying in the epiglottis valley

Shape: Sphere Minor diameter: 10 mm Hardness: Rigid Friction coefficient: 0.05 Restitution coefficient: 1.0

Shape: Sphere Minor diameter: 10 mm Hardness: Rigid Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx Restitution coefficient: 0.03 for the tongue/palate, 0.8 for the positions below the pharynx

Figure 79. Comparisons of different coefficients of friction and coefficients of restitution

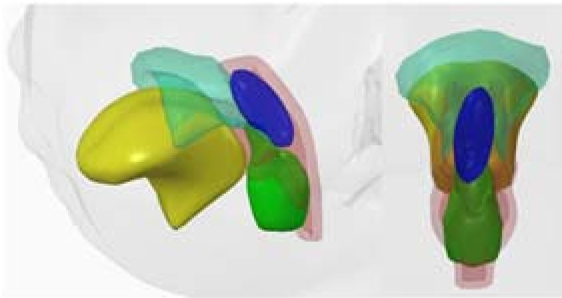
According to the results of this simulation analyses, it is possible that the coefficient of friction or coefficient of restitution of a toy affects the movement of the toy from the pharynx toward the larynx, as well as its slipperiness from the mouth to the pharynx.

6.3.5 Hardness of Toys

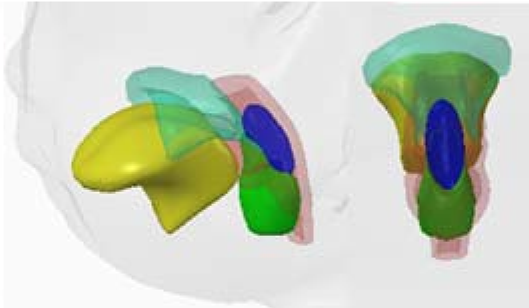
To determine the effects of the hardness of toys, simulations were performed to analyze choking risk at different levels of elasticity. The Young's modulus of elastic bodies was 20 kPa.

The results showed that the movement of toys remained unchanged with no change in choking risk for any of the sphere, peanut shape, and cube subjected to simulation at different levels of elasticity (Figure 80(a) and (b)).

This means that the results of the simulation analyses cannot identify the possibility of differences in choking risk among levels of elasticity of toys.



(a) Peanut shape (rigid body)



(b) Peanut shape (elastic body)

Minor diameter: 10 mm Major diameter: 23 mm
Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate 0.8 for the positions below the pharynx

Minor diameter: 10 mm Major diameter: 23 mm
Hardness: Elastic (Young's modulus of 20 kPa)
Friction coefficient: 0.1 for the tongue/palate 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate 0.8 for the positions below the pharynx

Figure 80. Comparison of different levels of hardness of the peanut shape

6.3.6 Guide of Toys Causing Choking (Summary)

The results of the simulation analyses under different conditions of the shape, size, coefficient of friction, coefficient of restitution, and elasticity of toys can be summarized as follows:

All the shapes subjected to simulation, that is, the sphere, hemisphere, ellipse, cuboid, cube, and block toy, completely or almost completely obstructed the pharyngeal or laryngeal cavity and were found to pose a high risk of choking. For the size of toys, large objects caused pharyngeal obstruction-type choking and even small objects caused laryngeal obstruction-type choking, depending on the shape. For the sphere, for example, a diameter of 6 to 20 mm caused choking.

Although the result of the simulation analyses in a nine-month-old child cannot be generalized to children at other ages in months because of potential changes in depth or width of the mouth or pharynx with growth, it is highly probable that the size of toys affects choking risk.

6.3.7 Results of a Simulation Analysis on the Case Filed

For the pacifier-shaped toy described in the case filed (Figure 81), an airway obstruction simulation was performed. It should be noted that the simulation is not a reproductive experiment of the accident.

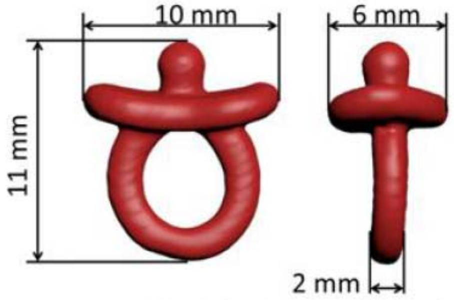
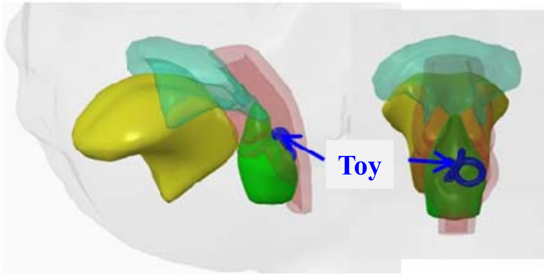


Figure 81. Shape model of the pacifier-shaped mode

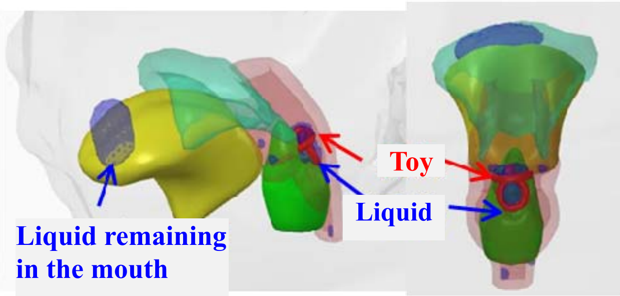
First, simulations were performed under multiple conditions, assuming aspiration of the pacifier-shaped toy alone. The results showed that, regardless of the orientation of the relevant toy, some models stayed in the hypopharynx or entered the larynx, but could not be considered to cause pharyngeal or laryngeal obstruction. It is probable that respiratory arrest is not caused in a short time (Figure 82(a)).

Next, because the statement “While eating baby food, a 9-month-old boy suddenly turned pale and gradually got exhausted” was included in the filing, ingestion of the relevant toy along with viscous liquid was simulated. The results showed that the toy with liquid getting entangled around it stopped in the oropharynx (epiglottis valley). In this case, because the epiglottis was in rest position, the laryngeal aperture was open, and the pharyngeal cavity and the laryngeal cavity were both kept open, breathing was possible and choking risk was not high.

As described earlier, when an object is present in the pharynx, an attempt is made to expel it into the mouth or swallowing is repeated to ingest it. Both movements are reflex, but not voluntary. Because infants have a weak strength to expel something, the process from the condition after the first swallowing to the second swallowing movement was simulated, assuming that swallowing was repeated. The results showed that the toy with liquid moved to the laryngeal aperture. The disc part of the pacifier got into contact with the reverse side of the epiglottis and the ring part of the pacifier with liquid was located in the larynx. The hollow part of the ring was filled with liquid and the entire toy almost completely blocked the laryngeal aperture, posing a risk of laryngeal obstruction-type choking (Figure 82(b)).



(a) After swallowing the toy alone



(b) After the first swallowing of a mixture of the toy and liquid followed by the second swallowing

Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate, 0.8 for the positions below the pharynx

Hardness: Rigid
Friction coefficient: 0.1 for the tongue/palate, 0.2 for the positions below the pharynx
Restitution coefficient: 0.03 for the tongue/palate, 0.8 for the positions below the pharynx
Viscosity of liquid: 100 mPa･s (equivalent to condensed milk)

Figure 82. Choking caused by the pacifier-shaped toy

When infants have an adequately strong power to exhale, it is somewhat likely that they can cough to dissipate and remove the liquid. On the other hand, because infants have much saliva, which is more viscous than water, saliva might have gotten entangled in the toy when it poured into the pharynx. Because the toy was not easy to remove from the larynx or hypopharynx with the infant’s power to expel something, it is possible that hypoxia progressed with time.

The results of the simulation analyses suggest that toys of sizes and shapes that are unlikely to independently cause pharyngeal or laryngeal obstruction may cause choking with viscous liquid, etc. when entering the mouth and lodging in the pharynx or larynx.

6.4 Current Situation of Sharing of Information on Accidents

The questionnaire survey among parents/guardians and data on emergency transportation showed that a certain number of swallowing accidents due to toys occurred even when they might not lead to airway obstruction. On the other hand, the results of the questionnaire survey among toy-related enterprises showed that only a few toy-related enterprises obtained information on the occurrence of swallowing accidents.

For accident information data banks, only two cases of airway obstruction accidents due to toys have been registered over a period of eight years, highlighting that information on aspiration or airway obstruction accidents occurring at home is not shared among concerned parties, including administrative bodies.

6.5 Awareness of Parents/Guardians in Buying Toys

"Interest of children" was the most common response to the question about what parents/guardians placed importance on when buying toys, provided by 73% of parents/guardians, followed by "safety" (64%) and "price" (37%). Older parents/guardians tended to place greater importance on safety when buying toys.

Also, in determining the safety of toys, parents/guardians tended to place greater importance on the size or shape of toys rather than marks or precautionary statements for safety indicated on products, regardless of age.

In response to the question about the awareness of marks for safety, such as the ST Mark, approximately 50% of parents/guardians had seen such marks but did not know their meaning. On the other hand, parents/guardians who had seen the ST Mark and also knew its meaning were asked whether the presence or absence of the ST Mark contributed to their decision of whether to buy the toy. The results showed that approximately 75% of parents/guardians responded "Yes" or "Maybe yes." It is therefore probable that the ST Mark played a certain role as a determinant to select and buy safe toys in parents/guardians who had an understanding of the meaning of the ST Mark.

Approximately 80% of parents/guardians responded that they "checked" or "maybe checked" the intended age for toys. Among them, at least 60% of parents/guardians responded that they "bought" or "maybe bought" toys even when they had children at home who were under the intended age for the toys. The reasons for buying such toys included high priority given to raising the level of children or interest of children. It is possible that the intended age may not be understood by parents/guardians even if it has been established considering children's development or safety.

6.6 Actions in Case of Swallowing Accidents

All respondents to the questionnaire survey (2,164 respondents) were asked about possible actions to be taken in case that their children experienced accidental ingestion or aspiration. The results showed that the most commonly given responses included "patting the child's back," "putting the finger into the child's mouth," and "turning the child upside down," consistent with the actions taken by individuals who encountered actual swallowing accidents.

The results found that the "back blow maneuver" or "Heimlich (abdominal thrust) maneuver," which are recommended actions to be taken in case of airway obstruction in life-saving training or maternal and child health handbooks, were not pervasive in home settings.

7. Conclusion

The questionnaire survey among parents/guardians to determine what age groups of children experience aspiration and what types of toys were aspirated demonstrated that such accidents frequently occurred in infants younger than three years, especially those aged between six months and one year and six months. In addition, "marbles" was the most common type of toys, followed by "bead-based toys" and "small balls." For the size, "6 to 10 mm" was the most common, followed by "11 to 20 mm" and "0 to 5 mm." For the shape, "objects of the same size when viewed from any plane (such as spheres and cubes)" was the most common, followed by "flat objects."

It is probable that the behavioral characteristic of "putting anything in the mouth," observed especially in infants, also contributes to aspiration of toys. In addition, physical characteristics of infants, such as the size of the pharynx smaller than the maximal mouth opening, the mouth close to the throat, much saliva, and inadequate ability to expel (swallow/vomit) something that lodges in the throat on their own, also may prompt an aspirated toy to lodge in the throat (pharynx/larynx) to cause airway obstruction.

To elucidate the mechanism of such airway obstruction due to toys, as well as to gain insights into the size or shape of toys that caused airway obstruction, the airway obstruction simulation and airflow simulation analyses were performed using the CT images and videofluoroscopic images of swallowing from a nine-month-old child.

These analyses showed that all the shapes, that is, the sphere, hemisphere, ellipse, cuboid, cube, and block toy, caused complete airway obstruction and posed a high risk of choking. The rugby ball shape and peanut shape, as well as the sphere, caused pharyngeal obstruction-type choking when they were large in size and laryngeal obstruction-type choking when they were small in size. On the other hand, the cuboid, cube, and block toy did not cause complete obstruction of the pharyngeal cavity, because some space was left in the pharyngeal cavity; however, they blocked the laryngeal aperture by applying downward pressure to the epiglottis from above.

In addition, these simulations also suggested that toys that were unlikely to cause obstruction of airway (pharynx/larynx) based on their size or shape may stay in the pharynx or larynx together with liquid to cause airway obstruction and therefore asphyxiation when they entered the pharynx or larynx, mixed with viscous liquid.

The questionnaire survey among parents/guardians suggested that some toy-related enterprises may design and manufacture toys or specify and indicate the intended age without regard to standards for the safety of toys, even though toys familiar to infants may obstruct the airway to cause asphyxiation. It is also possible that parents/guardians do not fully understand that intended ages are determined with regard to the development of children and safety aspects.

It was also found that the "back blow maneuver" and "Heimlich (abdominal thrust) maneuver," actions to be taken in case of accidents, were not pervasive in home settings, although they are recommended in maternal and child health handbooks or local life-saving training sessions are held.

In addition, it was found that a certain number of accidents of aspiration of toys occurred, while information on accidents was not shared among toy-related enterprises and administrative bodies.

8. Measures to Prevent Recurrence

The behavioral characteristic of “putting anything in the mouth” is observed in infants. In addition, physical characteristics, such as the size of the pharynx smaller than the maximal mouth opening, the mouth close to the throat, much saliva, and inadequate ability to expel (swallow/vomit) something that lodges in the throat on their own, are also observed.
As described in Section 7 “Conclusion,” it is not unlikely that toys familiar to children cause aspiration and therefore a serious accident of choking in light of these behavioral and physical characteristics observed in infants.
The Investigation Commission feels that it is important and the role of administrative bodies, toy-related enterprises, and parents/guardians to create an environment in which children can play with toys safely and happily, because playing with toys is an important experience for children and small toys also have roles in contributing to the development of hands of children and satisfying their curiosity.
It is important for all parties involved with children to first understand characteristics of infants and then recognize characteristics of toys potentially causing aspiration or choking and risks of accidents.
This report described characteristics of infants and also showed that the airway obstructions simulation performed based on the results of the questionnaire surveys provided insights into the shape or size of toys that are considered to pose a high risk of choking and also demonstrated that even toys with a low risk of choking might pose an increased risk of choking when mixed with viscous liquid, etc.
Based on these investigation results, measures expected to be effective in preventing of recurrence of accidents are summarized below.

8.1 Measures in Design, Manufacture, and Sales

8.1.1 Awareness of the Size and Shape that Possibly Cause Airway Obstruction

The questionnaire survey among parents/guardians showed that “marbles” were the type of toy with the highest incident of aspiration accidents, followed by “bead-based toys” and “small balls.” For the size, “6 to 10 mm” was the most common, followed by “11 to 20 mm” and “0 to 5 mm.” For the shape, “objects of the same size when viewed from any plane (such as spheres and cubes)” was the most common response, followed by "flat objects."

The airway obstruction simulation analyses in a nine-month-old child to verify how these toys lead to airway obstruction showed that the shapes of the sphere, hemisphere, ellipse, cuboid, and cube completely obstructed the airway to cause choking. The rugby ball shape and peanut shape, as well as the sphere, caused pharyngeal obstruction-type choking when they were large in size and laryngeal obstruction-type choking when they were small in size. On the other hand, the cuboid, cube, and block toy did not cause complete obstruction of the pharyngeal cavity, because some space was left in the pharyngeal cavity; however, they blocked the laryngeal aperture by applying downward pressure to the epiglottis from above.

In the light of behavioral and physical characteristics of infants, toy-related enterprises need to design, manufacture, and sell toys with reference to the results of these investigations of the size or shape of toys.

8.1.2 Determination of Intended Ages considering Safety Aspects

The questionnaire surveys among parents/guardians indicated that approximately 80% of parents/guardians check intended ages when buying toys. It is probable that an intended age indicated on a toy is an important factor for consumers to determine whether to buy the toy.

Therefore, it is necessary that intended ages should be determined and indicated based on standards or international standards for safety of toys, including the ST Standard.

In addition, the surveys showed that toys that are approximately 30 mm or larger in size tend to be aspirated by children under three years (Figure 19). Most such toys were intended for children over three years, but some of them were intended for children under three years. It is possible that toys that do not meet ST Standard, etc.[77] caused accidents (Figure 36).

To prevent the occurrence of these accidents, it is important to design, manufacture, and sell products considering standards or international standards for safety of toys, including the ST Standard.

8.1.3 Further Efforts to Ensure Safety

The Injury Alert presented an accident case in which a two-year-old child aspirated a toy 35 mm in diameter (diameter in the center: 35 mm, tip part of the object which

[77] Whether the relevant toys carried the ST Mark is unknown.

could be divided into two pieces with a hook and loop fastener) and died about several months later. The relevant toy did not carry the ST Mark; however, if product tests had been performed in accordance with ST Standard, the test using the test template for "small parts" (cylinder) would have applied and the relevant toy had the shape and size that conformed to the test. It is thus possible that this accident might have been prevented if the relevant toy had been designed to conform not only to the small parts test, but also to the small balls test as a proactive approach by the toy-related enterprise or if the toy had been subjected to a test with Accidental Ingestion Checker or other tests.[78]

In addition, it is somewhat likely that choking accidents might be prevented by designing toys with the assumption that they may be thrown by children and broken into small pieces, even if such a design is considered unnecessary considering intended ages.

Furthermore, making as large holes as possible in multiple directions may be an effective twist for avoiding airway obstruction and subsequent asphyxiation if a toy enters the throat (pharynx and larynx).

Based on these findings, toy-related enterprises should consider further safety improvement, including twists to test methods and twists to products.

8.1.4 Dissemination of Meanings of Toy Safety Labels

Toy-related enterprises need to widely and accurately communicate the meanings of intended ages and safety labels such as the ST Mark to consumers such as parents/guardians. In buying a toy, consumers should check information contained in its labeling to determine whether their child reaches its intended age and refrain from buying the toy if the child does not reach the intended age.

8.2 Sharing of Accident Risks and Preventive Measures

8.2.1 Awareness of the Risk of Accidents

It is probable that detailed knowledge of administrative bodies, toy-related enterprises, consumers, etc. about behavioral and physical characteristics of infants and

[78] The manufacturer related to the relevant accident case states that, after this accident, the manufacturer makes independent further efforts to ensure safety, including designing products to conform to standards or international standards for safety of toys such as the ST Standard, using Accidental Ingestion Checker concomitantly during product tests, and avoiding shapes that potentially fit entirely in the throat, such as the sphere.

characteristics of toys that potentially cause aspiration or choking might make them aware of the risk of accidents, leading to prevention of accidents. Widespread use of the movie titled “Protection of children from choking accidents” to illustrate these characteristics and the papercraft “Model of the infant’s mouth and throat” to simulate the mouth, pharynx, larynx, and trachea by parties involved is effective in promoting awareness of the risk of accidents and preventing accidents.

8.2.2 Method of Storing Toys

The Injury Alert presented cases in which toys of older children caused choking accidents in younger children such as infants and the results of the questionnaire survey among parents/guardians showed that toys of older children caused many cases of aspiration accidents (Figure 13).

Based on these findings, it is necessary that consumers should check the reach of younger children and make efforts, especially for objects 6 to 20 mm in size which may cause choking, including keeping them out of reach of such children.

8.2.3 Prevention of Serious Disease

In case of choking, cerebral disorder occurs 5 minutes after respiratory arrest and brain death is caused at 15 minutes. Thus, serious disease develops in a short time after occurrence of choking, therefore raising a need for prompt intervention. It is necessary that consumers should learn actions to be taken in case of choking from experts at their local fire departments or local Japan Red Cross Society branches to be able to take appropriate actions (back blow maneuver, chest thrust maneuver, and Heimlich maneuver) immediately.

8.3 Collection and Sharing of Information on Accidents

The current questionnaire surveys indicated that a certain number of aspiration accidents due to toys occurred, whereas only a limited number of toy-related enterprises have obtained information on such accidents.

In addition, several relevant administrative bodies collect information on aspiration accidents due to toys along with other information, but the number of cases of accidents as suggested by the results of the questionnaire surveys is not reached. In addition, such cases do not provide detailed information, including the situations in case of accidents and the size or shape of toys responsible for accidents.

To ensure that administrative bodies, toy-related enterprises, and consumers take specific recurrence preventive measures to prevent recurrence of accidents, it is crucial to collect and accumulate detailed accident information on situations in which aspiration accidents have occurred and types of toys that have caused accidents and share such information among parties involved.

Possible information on accidents include the age of children in months, type, size, shape, and intended age for a toy with which the accident occurred, conformity to standards for safety of toys such as ST Standard, storage of the toy, owner of the toy, and actions taken, as well as medical data in the event that CT images, etc. have been taken in medical institutions. This information can be used by administrative bodies to implement various measures to prevent recurrence, by enterprises to design, manufacture, and sell safer toys, and by parents/guardians and other consumers to make a decision in buying or storing toys.

For these reasons, it is necessary to share information on accidents as shown above among relevant administrative bodies or toy-related enterprises in case of airway obstruction accidents or aspiration accidents. It is therefore important that relevant administrative bodies develop a system for collecting and accumulating information and also that the whole society is aware of the usefulness of such information and enterprises becoming aware of accidents, medical institutions providing treatment, and parents/guardians of infants suffering accidents report such information.

9. Opinions

To prevent recurrence of accidents, it is necessary that all parties involved with children, including administrative bodies, toy-related enterprises, and consumers, have and share an understanding of the risk of accidents. First, it is important for the parties involved to understand the behavioral characteristic of "putting anything in the mouth" observed in infants and physical characteristics, such as the size of the pharynx smaller than the maximal mouth opening, the mouth close to the throat, much saliva, and inadequate ability to expel (swallow/vomit) something that lodges in the throat on their own and it is a possible role of administrative bodies to disseminate these characteristics.

The Investigation Commission took this occasion to produce the movie titled "Protection of children from choking accidents" and papercraft "Model of the infant's mouth and throat" to provide parties involved with a detailed and clear description of the above-mentioned behavioral characteristic and physical characteristics of infants and the characteristics of toys that potentially cause aspiration or choking. Wide availability of these materials for parties involved may contribute to prevention of airway obstruction accidents due to toys in children.

9.1 Opinions for the Minister of Economy, Trade and Industry

(1) Dissemination of the Risk of Accidents

The Ministry of Economy, Trade and Industry should encourage toy-related enterprises to understand the behavioral characteristics of infants, structure of the mouth or characteristics of swallowing, and characteristics of toys that potentially cause aspiration or choking in order to manufacture or sell safe toys. To that end, the Ministry should continuously and widely disseminate the behavioral or physical characteristics of infants to toy-related enterprises by reference to this report and the Investigation Commission-produced movie titled "Protection of children from choking accidents" and papercraft "Model of the infant's mouth and throat."

(2) Design, Manufacture, and Sales of Safe Toys

(a) The Ministry of Economy, Trade and Industry should encourage toy-related enterprises to ensure that intended ages should be determined and indicated based on standards or international standards for safety of toys, including ST Standard. In addition, the Ministry should verify the effectiveness of the encouragement and should consider further measures if adequate effectiveness is not achieved.

(b) The Ministry of Economy, Trade and Industry should make efforts to ensure that safe toys are designed, manufactured, and sold by asking toy-related enterprises to implement the following efforts:

i) For toys intended for children under three years that are in shapes classified as the sphere, such as the sphere, hemisphere, or ellipse, further safety improvement should be considered by making approaches such as using combinations of various test methods, such as a combination of the "small parts" test and the "small balls" test, designing toys with the assumption that they may be broken into small pieces even if such a design is considered unnecessary considering intended ages, and making as large holes as possible in multiple directions for avoiding airway obstruction and subsequent asphyxiation if a toy enters the throat (pharynx and larynx).

ii) The meanings of intended ages and safety labels such as the ST Mark should be communicated to consumers clearly and accurately.

9.2 Opinions for the Director General of the Consumer Affairs Agency

(1) Dissemination of the Risk of Accidents

The Director General of the Consumer Affairs Agency, as a control tower for prevention of accidents in children, should work with the Cabinet Office, Fire and Disaster Management Agency, Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and other appropriate organizations to continuously and widely disseminate the risk of accidents to consumers so that consumers can gain a detailed understanding of the behavioral and physical characteristics of infants, characteristics of toys that potentially cause aspiration or choking, or the risk of accidents by reference to the Investigation Commission-produced movie titled "Protection of children from choking accidents" and papercraft "Model of the infant's mouth and throat" and other materials.

(2) Efforts to Disseminate Accident Preventive Measures

The Consumer Affairs Agency should make efforts leading to specific actions of consumers to prevent accidents, including dissemination of the accident preventive measures to consumers:

(a) Since even toys of sizes and shapes that are unlikely to cause choking may cause choking when mixed with viscous liquid, etc., consumers should check whether foreign substances such as toys are present in the mouth before giving children baby food or milk.

(b) Before buying toys, consumers should check the intended age for them and should refrain from buying them for children who do not reach the intended ages. After buying toys, consumers should check the reach of younger children in advance and keep the above-mentioned toys, especially objects 6 to 20 mm in size, out of the reach of younger children.

(3) Collection and Sharing of Information toward Safety Improvement

The Consumer Affairs Agency should ensure that other administrative bodies, toy-related enterprises, and consumers collect and accumulate and widely share among parties involved information including the age of children in months, type, size, shape, and intended age for a toy with which an accident occurred, conformity to standards or international standards for the safety of toys such as ST Standard, store of the toy, owner of the toy, and action taken so that they can gain a detailed understanding of situations in which accidents such as aspiration and choking have occurred and types of toys that have caused accidents and take specific actions required to prevent recurrence of accidents. In addition, it is desirable to collect and accumulate medical images such as CT images to the extent possible.

(4) Dissemination for Preventing Serious Disease

The Consumer Affairs Agency should work with the Fire and Disaster Management Agency to encourage consumers to learn appropriate actions to be taken in case of airway obstruction (back blow maneuver, chest thrust maneuver, and Heimlich maneuver) from experts at their local fire departments or local Japan Red Cross Society branches.

Reference

Table of Contents

1. About this Reference

This reference details the methods for performing airway obstruction simulations and airflow simulations using Swallow Vision® and describes the development of a phantom (human body model), papercraft "model of the infant's mouth and throat," and movie titled as "Protection of children from choking accidents."

2. Airway Obstruction Simulation

Airway obstruction simulations were performed using Swallow Vision® to determine the mechanism by which toys cause airway obstruction accidents and the likelihood of choking among different shapes or sizes of toys.

2.1 Preliminary Study about using Swallow Vision®

Swallow Vision® is a swallowing simulator developed for elucidating the mechanisms of swallowing and aspiration. The simulator has been validated after the modeling of morphologies of the mouth, pharynx, larynx, esophagus, etc. based on CT images for medical use[1] and the modeling of swallowing movement based on videofluoroscopic images of swallowing or four-dimensional CT images.

The airway obstruction simulations required prior confirmation that Swallow Vision® could be used. For this confirmation, simulations were performed using living body models and foreign matter models.

The results showed that a foreign matter model having a frustoconical shape, a height of 23 mm, a major diameter of 21 mm, a minor diameter of 17 mm, and a Young's modulus[2] of 20 kPa obstructed the pharynx (pharyngeal obstruction-type choking, Figure 1b).

A foreign matter model having an elliptical shape, a short diameter of 5.6 mm, a long diameter of 13 mm, and a Young's modulus of 20 kPa entered the esophagus (Figure 1a).

A foreign matter model having a short diameter of 13.5 mm, a long diameter of 32.5

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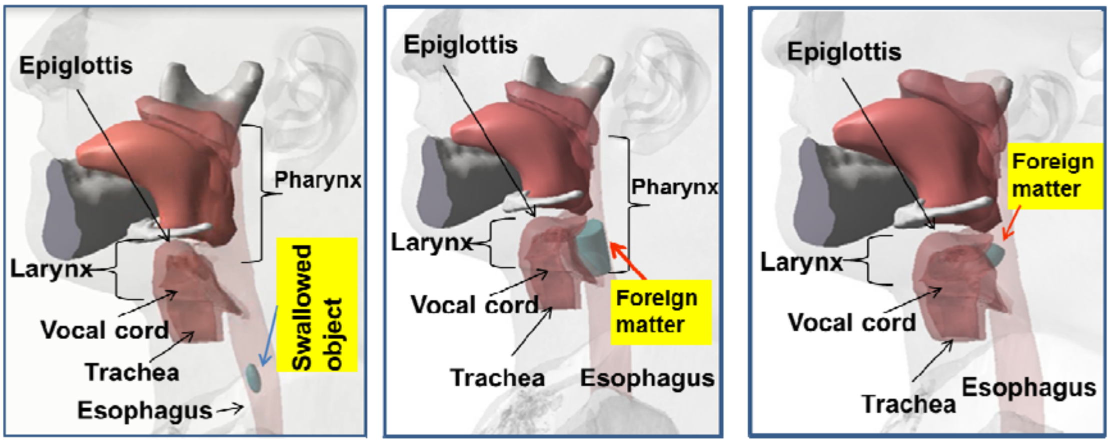
[1] CT images for medical use were used with the approval of Institutional Ethics Review Committee of Musashino Red Cross Hospital.

[2] A ratio of tensile or compressive stress to distortion in the direction of the stress (stretch or shrinkage per unit length) in a solid. A constant specific to a substance. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

mm, and a Young' modulus of 20 kPa obstructed the larynx (larynx obstruction-type choking, Figure 1c).



(a) Swallowing

(b) Pharyngeal obstruction-type choking

(c) Laryngeal obstruction-type choking

Figure 1. Swallowing and choking shown by Swallow Vision®[3]

The above simulations confirmed that Swallow Vision® could be used for elucidating the mechanism of airway obstruction.

2.2 Overview of the Procedure for Performing Airway Obstruction Simulations

Airway obstruction simulations involve numerical models of the living body and toys. Numerical models of the living body were created based on CT images of the head and neck of a 9-month-old boy without swallowing disorder and videofluoroscopic images of swallowing of a 9-month-old girl, because these images were available. Numerical models of toys were created to reflect features of shape, size, hardness, coefficient of friction, coefficient of restitution. Those features were chosen based on results from a questionnaire survey on parents/guardians and reported cases in "Injury Alert,". A total of 48 sessions of airway obstruction simulation, as listed below, were performed using these toy models and the living body model. The results of simulation analysis were finally visualized in a three-dimensional way on a computer.

(a) Sphere: 10 sessions

[3] The thyroid/cricoid cartilages are not shown and the larynx is semi-transparent with its inside shown.

(b) Hemisphere: 7 sessions

(c) Ellipse[4]: 7 sessions (3 sessions in a rugby ball shape and 4 sessions in a peanut shape)

(d) Cuboid: 2 sessions

(e) Cube: 6 sessions

(f) Block toy: 3 sessions

(g) Marble shape: 5 sessions

(h) Pacifier-shaped toy: 8 sessions

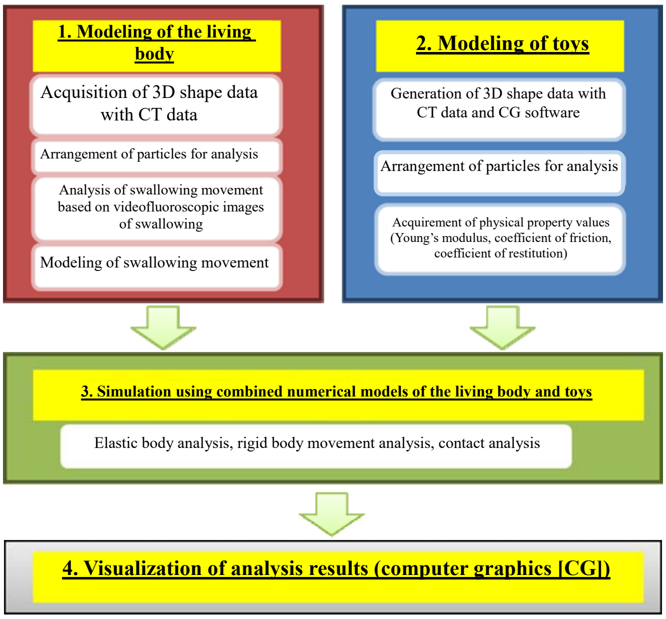


Figure 2. Process of airway obstruction simulation

2.2.1 Creation of Numerical Models of the Living Body

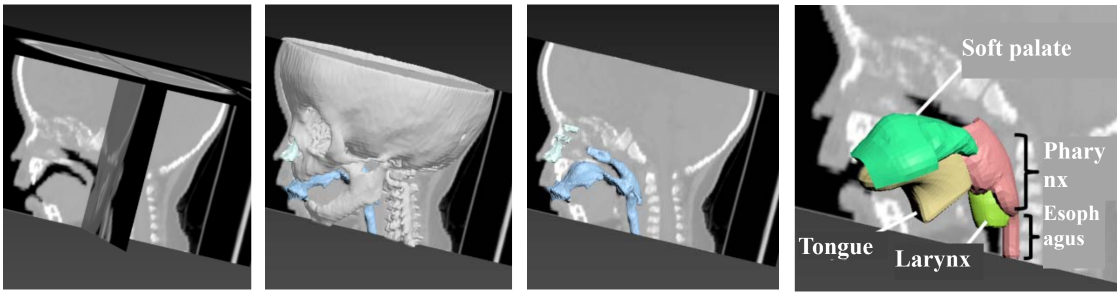
The process of creating numerical models of the living body consists of the following four steps: acquisition of three-dimensional shape data from CT images at rest, arrangement of particles for analysis from three-dimensional shape data, analysis of swallowing movement based on videofluoroscopic images of swallowing, and creation of models of swallowing movement.

(1) Acquisition of Three-dimensional Shape Data from an Infant at Rest

[4] The rugby ball shape and peanut shape are different in the length of the minor axis. The minor axis of the rugby ball shape is longer than that of the peanut shape.

All organs involved in swallowing were constructed in a three-dimensional manner based on CT images of the head and neck of a 9-month-old body.

The CT images of the head and neck were subjected to threshold processing for CT values[5] to automatically identify bones and spaces, with insufficient areas arranged with additional anatomical knowledge. The bones and spaces were used as markers to visualize soft tissues, including the thyroid cartilage, cricoid cartilage, tongue, and soft palate. This operation provided three-dimensional shape data on swallowing-related organs in the 9-month-old body at rest (Figure 3).



(a) CT image

(b) 3D construction of bones

(c) 3D construction of spaces

(d) 3D construction of organs (magnified)

Figure 3. Method of creating surface geometries of organs based on CT images from a 9-month-old child

Three-dimensional shape data were output in a Standard Triangulated Language (STL) format, in which surfaces of organs[6] were represented as sets of triangles. They were used as the initial shapes at the start of swallowing.

(2) Arrangement of Particles for Analysis on Three-dimensional Shape Data

Calculation methods for numerical simulation include mesh and particle methods. A mesh method is more excellent in analyses of small deformations such as deformations of metal, while particle methods are better for analyses of large

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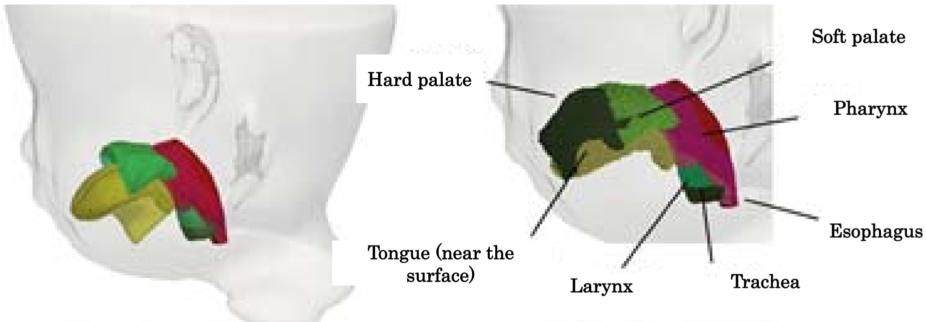
[5] In CT, the density of tissues is expressed as CT values, which are relative values. CT values are based on water (CT value of 0) and air (CT value of 100) and the CT value of bones is approximately at least 300. Therefore, threshold processing for CT values allows relatively easy automatic identification of bones and air.

[6] Three techniques for representing solids on a computer are wireframe, surface, and solid. The technique for representing only the surface using surfaces with the inside hollowed up is called surface and is suitable for representing complex geometries. It is used for a wide range of purposes, including design of the body of a car.

deformations such as those of rubber. A particle method was selected for airway obstruction simulations, because soft tissues of the living body from the mouth to the pharynx undergo large deformation during swallowing.

Particles for analysis using the particle method were arranged in a three-dimensional grid pattern within the region of the three-dimensional shape data at the start of swallowing (Figure 4). A total of 114,215 particles (each with a diameter of 0.6 mm) were arranged in the shape model for the 9-month-old child with consideration of accuracy and cost of calculation.



(a) Surface meshes and particles represented

(b) Magnified view (only particles represented)

Figure 4. Shape models for simulation created based on CT images

(3) Analysis of Swallowing Movement

An optimal examination of swallowing is a fluoroscopic examination that takes X-ray images of the actual process of swallowing of X-ray contrast medium (videofluoroscopy of swallowing). This examination is a standard method for clinical diagnosis of swallowing disorder and may also be used for research if it meets requirements. At the same time, cases of videofluoroscopy of swallowing in healthy infants have been rarely reported due to concerns of radiation exposure; however, a videofluoroscopic image showing that a 9-month-old child (a 9-month-old healthy girl)[7] swallowed liquid[8] was available and therefore used.

An analysis of this videofluoroscopic image of swallowing indicated that the

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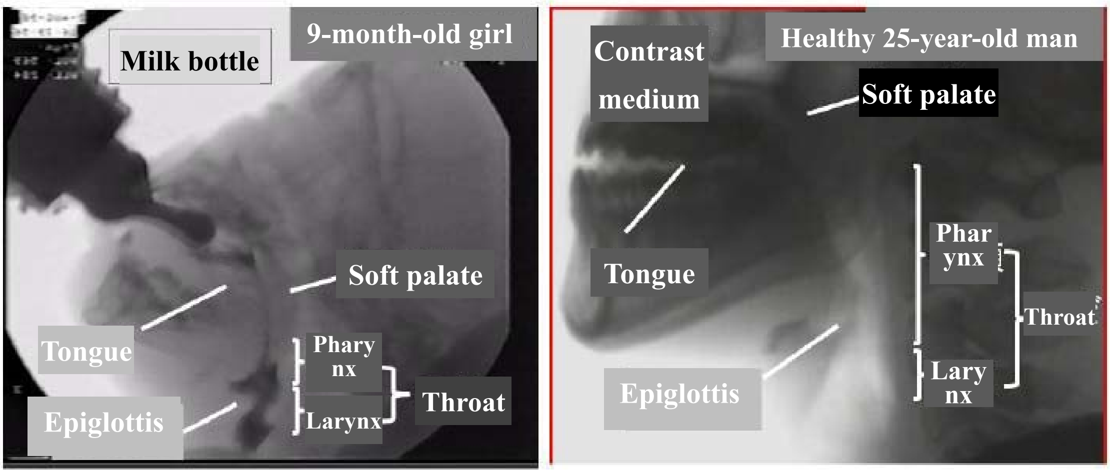
[7] It is likely that there are few gender-related differences in growth between males and females aged nine months.

[8] Hiroyuki Haishima, et al. "Observation of swallowing movement in a nine-month-old child with an X-ray TV – comparison of swallowing between infants and adults" Japanese Journal of Dysphasia Rehabilitation, Vol.1 p33-44, 1997 (in Japanese)

swallowing movement in the 9-month-old child was characterized as follows:
(a) She held liquid in the hypopharynx but not in the mouth.
(b) Swallowing movement was initiated when a certain volume of liquid was held in the hypopharynx.
This confirmed that swallowing movement was initiated in a 9-month-old child after a food bolus was held, whereas swallowing movement is initiated in an adult (a healthy 25-year-old man) before the food bolus enters the pharynx (Picture 1). The analysis of the videofluoroscopic images of swallowing confirmed that the timing of the initiation of swallowing movement was different between a 9-month-old child and an adult.



Picture 1. Videofluoroscopic images of swallowing (left: 9-month-old child, right: an adult)

Subsequently, the movements of the organs after the initiation of swallowing movement were analyzed. The results showed that the direction and timing of the movement of the organ related to swallowing, such as the tongue, soft palate, pharyngeal wall, and epiglottis, that is, the pattern of swallowing movement, was the same between the 9-month-old child and the adult.[9]

(4) Creation of the Model of Swallowing Movement

Based on the analysis of swallowing movement, the movement pattern was modeled using the same method as conventional Swallow Vision®. More specifically,

[9] Because the existing movement model in Swallow Vision® is based on the swallowing pattern of a healthy adult, it was confirmed that the movement model incorporated in Swallow Vision® was available for airway obstruction simulation in an infant.

swallowing movement was reproduced by forcibly displacing the regions with active movements, such as muscles, represented by particles arranged in the living body model (forced displacement) with time. Other regions of the living body were defined as elastic bodies like rubber and were allowed to passively move on with forcibly displaced regions.

2.2.2 Creation of Numerical Models of Toys

(1) Selection of Toys

Based on the results from the questionnaire survey conducted among parents/guardians by the Investigation Commission, objects that were of the same size when viewed from any angle, such as spheres and cubes, flat objects, and elongated objects such as cuboids, with which aspiration occurred more commonly, were selected as shapes of toy models. In addition, a pacifier-shaped toy, consistent with the case filed, was also selected. For the sphere, sphere-like shapes such as hemisphere and ellipse were also chosen.
The sizes ranging from 6 to 20 mm were selected based on the results of the above questionnaire survey and reported cases in Injury Alert.
Two different types of materials, rigid and elastic bodies, were selected.

(2) Measurement of Shapes and Sizes

For the sphere, hemisphere, ellipse, cuboid, or cube, the diameter, major diameter, or minor diameter was measured. For the pacifier-shaped toy with a complex shape, data on the shape and size were acquired by imaging with an industrial CT device.

(3) Young's Modulus

A Young's modulus of toys was used as a measure of hardness. A total of three types of indenters pressed into samples for measurement, two spherical indenters (φ20 mm, φ1 mm) and a plate indenter, were used, depending on the hardness and shape of samples. The Young's modulus measuring instrument SOFTMEASURE HG-1003 SL (Horiuchi Electronics) was used for measurement.
The instrument was secured to a stand with a sample placed directly below the instrument. Spherical samples or samples that became unstable depending on

orientation were held with clay and measured (Figure 5). In doing so, it was made sure that the plasticity of clay did not affect measurements.

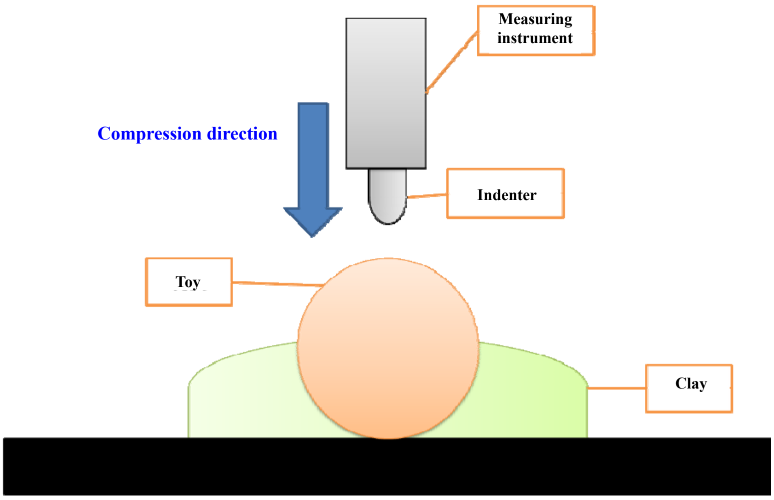


Figure 5. Method of measurement of the Young's modulus (image)

Since this instrument measures Young's moduli based on the load and displacement between a sphere and a plane, samples with a plane were measured using a spherical indenter and spherical samples were measured using a flat indenter. Soft samples were measured at a compression rate of 2 mm/sec. The maximum load selected was 1 N or 2 N, a standard load. For extremely soft samples, however, smaller load values were selected to prevent invagination of indenters from interfering with measurement.

It should be noted that published nominal values were used for hard samples (glass, plastic), because this instrument was not suitable for measuring hard samples with only small displacements.

(4) Measurement of Coefficient of Friction

Coefficient of friction, which is a measure for the status of the interface between a living body and a toy, was measured ex vivo due to extreme difficulty in performing experiments in the mouth or pharynx.

Hydrophilic polyvinyl alcohol (hereinafter referred to as "hydrophilic PVA"), which has similar physical properties to mucosa of the living body, was taken out from preservative solution and weighed in an adequately wet state. A sample was then placed on hydrophilic PVA, which, in turn, was sloped, and the angle at which the toy started to move was recorded. The coefficient of friction can be expressed as follows: $\mu = \tan\theta$, where μ is the coefficient of friction and θ is the angle of slope (Figure 6).

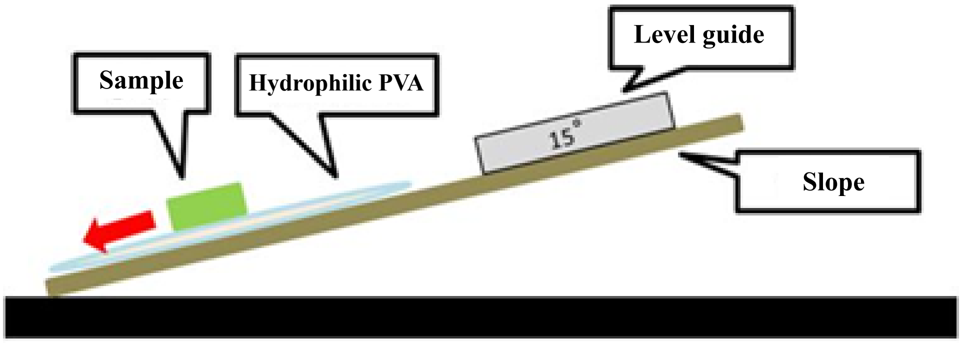


Figure 6. Method of measurement of the coefficient of friction

Measurement was repeated in triplicate for each sample and measurement results were represented as means of three replicates. Spherical samples were measured with two or more samples connected to prevent them from rolling. When a single toy potentially had two or more planes with different coefficients of friction, all of the planes were measured.

(5) Measurement of Coefficient of Restitution

Coefficient of restitution is a measure for the relationship between a sample and a living body when the sample collides with the living body at high speed. Due to difficulty in performing measurement in the mouth or pharynx, a 10-mm thick slice of the tongue of a pig, which is similar to that of a human, was placed on an aluminum tray and dropped from a height of approximately 150 mm while imaged with a high-speed camera. Imaging speeds of 1000 fps[10] and 250 fps were used. The experiment was repeated twice or more for each sample and performed in different orientations for samples other than spherical samples.

(6) Modeling of Toys

Three-dimensional shape data (in the STL format) of the sphere, hemisphere, ellipse

[10] Stands for frames per second. A unit that indicates smoothness of a motion picture and describes how many times per one second images or screens were updated. For example, a motion picture at 1000 fps consists of 1000 still images per one second and is played by switching images at intervals of 0.001 seconds.

(rugby ball shape and peanut shape), cuboid, cube, block toy, and marble shape were generated based on measured values on CG software. Particles for simulation analysis were arranged along a curved surface of toys, not in a three-dimensional grid pattern, for toys with the curved surface to improve the reproducibility of the surface of toys.

For the pacifier-shaped toy, in contrast, CT scans were taken and the CT data were used to obtain three-dimensional shape data for efficiency. Particles were arranged within this area in a three-dimensional grid pattern.

The number of particles arranged depended on the size of toys; for example, a total of 18,950 particles were arranged for a sphere with a diameter of 20 mm.

The density of toys was 1.0×10^3 kg/m^3 and the coefficient of friction ranged from 0.05 to 0.2, as determined by measured values.

2.2.3 Simulation Analysis Using the Particle Method

This simulation analyzed the motion of particles representing the living body and toys using the particle method. An overview of the simulation analysis using the particle method is provided below.

In the simulation analysis using the particle method, the living body was defined as an elastic body that became deformed when subjected to external force (Mooney-Rivlin hyperelastic body[11]), like rubber. When a part of the living body actively moves during movement, other parts are passively moved or deformed under pushing or pulling force. In addition, viscous force is added to provide a more stable analysis. Swallow Vision® uses this method for the modeling of swallowing movement. The same method was used for this simulation.

In contrast, hard toys that underwent only negligible small deformation when subjected to force from the living body, such as plastic toys, were defined as rigid bodies. Handling such toys as rigid bodies without respect to deformation reduces the time required for analysis. Other soft toys were handled as elastic bodies.

Toy models are moved by gravity and contact force from the living body. Contact force consists of normal force[12] and frictional force, which are applied to both the living body and a toy at the contact point between the living body and the toy. The magnitude of

[11] A hyperelastic body model that was devised based on the extension ratio from a phenomenalistic viewpoint and is used to simulate rubber or soft tissues of a living body.

[12] A force that acts on the surface of an object to interfere with its movement. A component perpendicular to movement is normal force and a component parallel to movement is typically frictional force. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

frictional force is determined by the magnitude of normal force and coefficient of friction.
A detailed description of the simulation analysis using the particle method is provided below.

(1) Particle Method

The particle method is a type of the Lagrange method in which calculation points are moved with movement or deformation of objects. Swallow Vision® uses the moving particle simulation (MPS) method, a type of the particle method. The MPS method is a method in which governing equations are discretized by using inter-particle interaction models corresponding to differential operators.
For the purpose of this analysis, the infant's human body was defined as an elastic body (Mooney-Rivlin hyperelastic body) and toys were defined as elastic or rigid bodies. Toy models, analytes of interest, were also divided into groups of fine particles and the movement of each particle was simulated over time.

(2) Analysis of Elastic Bodies

The movement of each particle defined as an elastic body was analyzed using the following equation of motion:

$$\rho \frac{\partial \mathbf{v}}{\partial t} = \mathbf{f}_{\text{elastic}} + \mathbf{f}_{\text{artificial}} + \mathbf{f}_{\text{viscous}} + \mathbf{f}_{\text{contact}}$$

where ρ is the density and $\mathbf{v}$ is the velocity vector. The terms on the right side of the equation are the elastic force, artificial potential force, viscous force, and contact force with other structures (human body or toys), respectively. The elastic force, artificial potential force, and viscous force are all internal forces, whereas the contact force (as described later) is an external force.
In this simulation, the Hamiltonian MPS method[13] was used for analysis of elastic force. Elastic force is a restoring force that acts to restore deformation exerted inside a deformed elastic body to return the elastic body to its original shape. In this method, the governing equation of an elastic body

[13] An expanded version of the MPS method to make it applicable to non-linear elastic bodies, which are elastic bodies in which deformation does not bear a proportionate relationship to stress.

$$\rho \frac{\partial \mathbf{v}}{\partial t} = -\frac{\partial W}{\partial \mathbf{x}}$$

is transformed to formulate the elastic force per unit volume with the following equation:

$$\mathbf{f}_{i,\mathrm{elastic}} = \rho \frac{\partial \mathbf{v}}{\partial t} = \sum_{j \neq i} (\mathbf{F}_i \mathbf{S}_i \mathbf{A}_i^{-1} \mathbf{r}_{ij}^0 + \mathbf{F}_j \mathbf{S}_j \mathbf{A}_j^{-1} \mathbf{r}_{ij}^0) w_{ij}^0$$

$$\mathbf{F}_i = \left[\sum_j \mathbf{r}_{ij} \otimes \mathbf{r}_{ij}^0 w_{ij}^0 \right] \mathbf{A}_i^{-1}$$

$$\mathbf{A}_i = \sum_j \mathbf{r}_{ij}^0 \otimes \mathbf{r}_{ij}^0 \, w_{ij}^0$$

where W is the strain energy function, $\mathbf{r}$ is the relative position vector, $\mathbf{F}$ is the deformation gradient tensor[14], and w is the weight function for MPS method, and the superscript 0 represents the status at the initial point.

In this simulation, the Mooney-Rivlin model given by the following equation was applied as a dynamic model:

$$W = C_1^{\mathrm{MR}}(\tilde{I}_1 - 3) + C_2^{\mathrm{MR}}(\tilde{I}_2 - 3) + D_1(J-1)^2$$

where C_1^{MR}, C_2^{MR}, and D_1 are the material constants[15], J is the third invariant[16] (percent volume change), and $\tilde{I}_1$ and $\tilde{I}_2$ are the reduction invariants of the right Cauchy-Green deformation tensor.

In addition, a supplementary force to suppress specific displacement modes or vibrations with the Hamiltonian MPS method (artificial potential force) and a viscous force similar to that used to decrease the particle velocity to stabilize calculation in fluid analysis based on the MPS method were defined by the following equations:

[14] When there are two vector quantities and the component of one vector is expressed as the linear form of the other vector component, an overall quantity for connection between them is called gradient deformation tensor. Stresses or strains inside a solid are expressed as tensors. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

[15] Constants or physical property values to describe properties of materials.

[16] An invariant is a scalar quantity that is associated with vectors or dyadic tensors and is not affected by changes in coordinates. (Compiled by Japan Association for Nonlinear CAE and written by Takashi Kyoya, "Continuum Mechanics", Morikita Publishing, 2008)

$$\mathbf{f}_{i,\text{artificial}} = \sum_j \left(C_i^{\text{art}} (\mathbf{r}_{ij} - \mathbf{F}_i \mathbf{r}_{ij}^0) + C_j^{\text{art}} (\mathbf{r}_{ij} - \mathbf{F}_j \mathbf{r}_{ij}^0) \right) w_{ij}^0$$

$$C_i^{\text{art}} = \frac{\hat{E}_i d}{\sum_j \left| \mathbf{r}_{ij}^0 \right|^2 w_{ij}^0}$$

$$\mathbf{f}_{i,\text{viscous}} = \rho \nu^{\text{ela}} \frac{2d}{\lambda n^0} \sum_j (\mathbf{v}_j - \mathbf{v}_i) w_{ij}^0$$

where *Ei* is the coefficient of a supplementary artificial potential power determined based on a Young's modulus of an object, *d* is the space dimensionality, and λ and n^0 are the constants for the MPS method.

(3) Analysis of Rigid Bodies

Because rigid bodies are objects that do not deform, the movement of each particle was not calculated, but the translational movement[17] and rotational movement of the gravity center position of a rigid body as a whole was calculated. The momentum **P** and the angular momentum [18]**L** of a rigid body are described by the following equations:

$$\mathbf{P} = M\mathbf{v}$$

$$\frac{d\mathbf{P}}{dt} = \mathbf{F}$$

$$\mathbf{L} = \mathbf{I}\boldsymbol{\omega}$$

$$\frac{d\mathbf{L}}{dt} = \boldsymbol{\tau}$$

[17] Movements of place systems or rigid bodies that consist only of the same parallel translation at each place without rotation or deformation. Arbitrary movements of rigid bodies can be divided into translational and rotational movements. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

[18] Moment of momentum regarding a certain point. For rigid bodies, its magnitude is expressed as the product of the moment of inertia around the axis of rotation and the angular velocity. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

where M is the mass of the rigid body, $\mathbf{v}$ is the translational velocity of the rigid body, $\mathbf{F}$ is the external force applied to the rigid body, $\mathbf{I}$ is the inertial tensor, $\boldsymbol{\omega}$ is the angular velocity[19], and $\boldsymbol{\tau}$ is the torque produced by the external force applied to the rigid body.[20] Since the rigid body is expressed as a group of particles, the external force $\mathbf{F}$ and torque $\boldsymbol{\tau}$ can be determined based on the external force applied to the particles that compose the rigid body.

(4) Contact Analysis

Contact force consists of normal force and frictional force, which are generated by contact between a wall surface of a living body and food bolus or between a wall surface and another wall surface of a living body.

Contact analysis using the conventional particle method involves an issue that exposure of a wall to force causes particles to get stuck among wall particles, resulting in the eruption of asperities on the wall surface. A solution to this issue is the metaball method in which a group of spheres with a concentration distribution is defined and a wall surface is defined by a certain threshold. This study applied a method that involves smoothing of a wall surface expressed by particles using the metaball method. However, in the contact analysis, elastic body particles were handled as spheres for stabilizing the analysis.

In addition, mucosal surfaces of the tongue or pharynx are highly elastic and soft, and therefore less repulsive. On the other hand, the less repulsive nature is not easy to simulate in a contact analysis. A penalty method that uses only springs allows a relatively stable analysis, but the coefficient of restitution is set only to 1 and cannot be adjusted. On the other hand, a penalty method that uses springs and bumpers involves spring and bumper coefficients given in a trial-and-error approach.[21] In addition, an impulse-based method, in which calculations are made based on conservation of momentum and coefficient of restitution, may involve unstable analyses or sneaking-through in contact with multiple objects. Thus, although any method has good and bad points, this simulation used a penalty method using springs in combination with an impulse-based method to simulate a less repulsive nature in a

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[19] Angle of rotation of an object undergoing circular motion per unit time. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

[20] The magnitude of the ability of rotating an object. ("Kojien" 6th edition, edited by Izuru Shinmura, Iwanami Shoten, 2008)

[21] Running simulations with varying values assigned to the spring and bumper coefficients to check for consistency with actual phenomena.

simplified manner.

(5) Parameters Used for Analyses

Numerical simulations often handle soft tissues of a human body as incompressible non-linear elastic bodies. Therefore, this simulation defined a human body as a Mooney-Rivlin hyperelastic body. In addition, the compressibility factor D_1 of 1 [MPa] was selected to control changes in volume. A ratio of material constants of Mooney-Rivlin hyperelastic bodies as soft tissues of the human body (C_1^{MR} and C_2^{MR}), a C_1^{MR}/C_2^{MR} ratio, is often set to 1. This simulation also used this ratio to determine the C_1^{MR} and C_2^{MR} values based on the Young's moduli of the organs.

The measurement of Young's moduli of internal organs such as the mouth and pharynx is difficult for ethical reasons and the measurement of physical properties of soft tissues during swallowing is also extremely difficult for technical reasons, with no reported cases identified. This simulation used physical properties during speech and literature values from numerical simulations of speech as references.

There has been no report in which the coefficient of friction of the tongue or pharynx was quantitatively measured and actual measurement in infants is further difficult. At the same time, because infants appear to secrete much saliva, resulting in a small coefficient of friction, a coefficient of friction ranging from 0.05 to 0.2 was selected (Table 1).

The time step Δt of 2.5×10^{-6}[s] and initial interparticle distance l_0 of 0.6×10^{-3} [m] were used.

Table 1. Specifications of analysis and analysis time

Analytical parameters	
Time step Δt[s]	**2.5×10^{-6}**
Initial interparticle distance l_0 [m]	**0.6×10^{-3}**
Number of particles	
Living body (9-month-old boy model)	**114,215**
Foreign substance (20-mm ball)	**18,950**

Number of simultaneous calculations	**Calculation time**
One analysis (parallel calculation)	**20 hours**
Six analyses (simultaneously)	**85 hours (one analysis)**

Intel core i7-3970X (6 core HT)

Physical properties of a living body		
Density [kg/m^3]		**1.0×10^3**
Young's modulus [Pa]	**Tongue**	**2×10^4**
	Soft palate and pharynx	**1×10^4**
	Larynx	**4×10^3**
	Epiglottis	**2×10^5**
Compressibility factor D_1 [Pa]		**1×10^6**

Foreign substance (toy)	
Density [kg/m^3]	**1.0×10^3**
Young's modulus	**None (rigid body)**
Coefficient of friction	**0.05, 0.1, 0.2**

2.2.4 Presentation of Analysis Results

Although the movements of a living body and toys are presented as groups of particles in the particle method, the surfaces of the living body and toys were presented using a three-dimensional CG to enhance visibility in this simulation.

More specifically, the geometries of a living body and toys at the start of swallowing were expressed with multiple triangles based on three-dimensional shape data (in the STL format). The geometries of the living body and toys were reconstructed at each time during swallowing movement by moving each vertex of these triangles in association with the movements of particles obtained from analysis.

The conventional Swallow Vision® used radial basis function (RBF) interpolation to associate particles for analysis with each vertex of triangles for presentation of geometries. The RBF interpolation is a widely used method for generating a smooth function in a space with RBF functions based on point group data as input values.

However, in this simulation, it was difficult to apply the RBF interpolation, because of a high spatial resolution for analysis and a large number of particles. Therefore, Koshizuka's method[22], rather than the RBF interpolation, was applied. This method is a method in which a weight function used for analysis by the particle method is used to move the vertices of three-dimensional shape data representing the initial shape of an object. In this simulation, a unique change was made to adjust a parameter called radius of influence, as appropriate, in order to ensure that the vertices of three-dimensional shape data were not outside the radius of influence of particles.

3. Airflow Simulation

One possible method to prevent asphyxiation even under the condition of obstruction by a toy is giving the shape of a toy twists, including making holes in a toy to establish an air passage. Therefore, simulations were performed to determine whether such twists avoided asphyxiation.

3.1 Creation of Shape Data of the Living Body and Toys

The shape data of a living body was created using shape data from the 9-month-old child used for airway obstruction simulation. Analytical calculation was performed

[22] Seiichi Koshizuka "Particle method simulation – Introduction to physically-based CG" (in Japanese) Baifukan, 2008.

using SOLIDWORKS FlowSimulation® (hereinafter referred to as "FlowSimulation®") provided with the 3D CAD software SolidWorks.
First, the shape data were converted to the STL file format and the number of meshes was reduced down to 5% of the original data for reading with FlowSimulation® (with a total number of meshes[23] of 13,502), with care to keep shapes from being too rough.
Next, the shape data were simplified to simulate pharyngeal obstruction-type choking. More specifically, the epiglottis was inverted to place a choking object at the back of the soft palate and above the epiglottis, the vocal cords within the larynx were omitted to establish a passage of airflow, and the area leading to the nasal cavity was kept open. Among the openings, the terminals on the side of the mouth and on the side of the nasal cavity were defined as inflow and the terminal on the side of the trachea was defined as outflow (Figure 7).

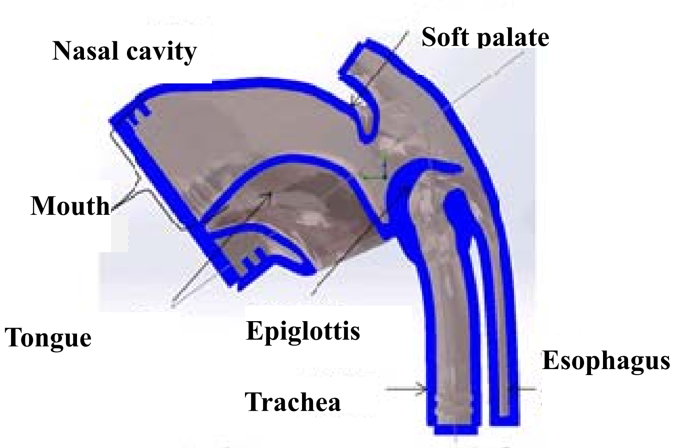

Figure 7. Shape data from a 9-month-old child (cross section from the right side)

In addition, the shape data of toys were also created on FlowSimulation®.

3.2 Setting of Analysis Conditions

FlowSimulation® involves setting the inflow surface and outflow surface. The openings in the mouth and nasal cavity were set as the inflow surfaces and had a defined environmental pressure (101,325 Pa). The opening on the side of trachea was set as the outflow surface and had a defined outflow volume flow rate of 80 mL/s[24] (Figure 8).

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[23] Airflow simulations require quantification of phantom models (i.e., giving coordinates etc. to represent the models on a computer). The standard procedure is segmentalizing shapes into meshes, with the total number of segments being defined as the total number of meshes.

[24] Outflow volume flow rate was set based on a body weight. Based on the average standard body weight of a 9-month-old boy, a model for the living body's shape, of 8.9 kg and with reference to a tidal volume

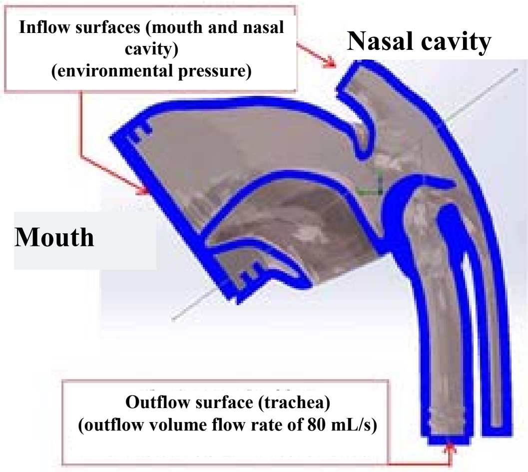

Figure 8. Setting of the inflow surfaces and outflow surface

In addition, analysis calculation was performed with consideration of gravity (Y: -9.81 m/s^2).

FlowSimulation® involves setting the conditions for ending analytical calculation (goals), consisting of surface goals for the entire calculation domain and surface goals for the inflow and outflow surfaces. In this analysis, static pressure, total pressure, mass flow rate, and velocity were set for the global goals and static pressure, total pressure, volume flow rate, and velocity were set for the surface goals for each of the three surfaces, that is, the surfaces in the mouth and nasal cavity selected as the inflow surfaces and the surface in the trachea selected as the outflow surface. It should be noted that mass flow rate was included in the global goals in FlowSimulation® to confirm that the mass of gas was maintained throughout the entire calculation domain.

4. Fabrication of a Phantom (Human Model)

4.1 Purposes of Fabrication of a Phantom

Models simulating the human body or body organs are called phantoms. CT images from the 9-month-old child were used to fabricate a phantom that simulated the outer surfaces of the head and the chest-abdomen and the internal organs ranging from the mouth through the pharynx down to the lungs as faithfully as possible. The purposes of

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of 80 mL in an individual weighing 9 kg according to Radford's nomogram (Radford, Edward P. "Ventilation standards for use in artificial respiration." Journal of Applied Physiology 7.4 (1955): 451-460.), the outflow volume flow rate was set assuming that one inspiration takes one second.

the fabrication are shown below:

(a) To visualize where a toy is lodged to cause choking to serve as an aid in getting an understanding of choking.
(b) To provide a clear description of actions to be taken in case of choking.
(c) To visually illustrate by an example twists to be given to toys to avoid choking.
(d) To produce toys having a structure that allows avoidance of choking and to test their effectiveness.[25]

4.2 Design

First, the face was fabricated to establish a whole profile and the mouth, pharynx, larynx, esophagus, trachea, and lung were then fabricated. The left half of the face had a detachable structure so that the mouth, pharynx, and larynx were directly visible from the outside. Details are provided below.
To facilitate an understanding of where a toy was lodged among the internal spaces of the pharynx and larynx, the walls of the spaces of the mouth, pharynx, larynx, esophagus, and trachea were made transparent.
To provide a clear description of actions to be taken in case of choking, the head and neck, as well as the shoulder, chest, and abdomen, were fabricated and the inner cavity of the chest was provided with the trachea and lung. An Ambu bag[26] for children for medical use was used as the lung with consideration of the expiratory volume of infants.
For the fabrication of the phantom, CT images of the head and neck from the 9-month-old child used for the creation of simulations were used as fundamental data.
Because morphological information of the chest-abdomen was not included in the CT images of the head and neck, it was newly generated and the ratio of the chest-abdomen to the head and neck visualized on CT was checked to ensure that the image of an infant was not disrupted (software used: Geomagic® Freeform®).
Next, the facial appearance of the base shape was deformed to avoid identification of the individual. After that, the left half of the facial appearance was designed to be detachable so that the relevant organs were directly visible.
Among the transparent organs, the pharynx, larynx, esophagus, and trachea were created based on the CT images. The mouth, which also served as a passage for

[25] More specifically, a suction experiment with bouncing balls with holes of different sizes was performed to determine the effect of holes.
[26] A bag for medical use to deliver air (oxygen) through the mouth and nose in an emergency and other situations.

inserting a toy into the pharynx, was gotten into an open state that was deemed medically appropriate based on a trajectory of mandibular movement during mouth opening estimated from the jaw joint of the base shape.
Finally, the phantom was designed to exemplify toy choking by omitting unnecessary parts such as bones, cartilages, and vocal cords, closing the lower end of the esophagus, and diminishing in size the outer margin of the epiglottis to allow inversion (Figure 9).

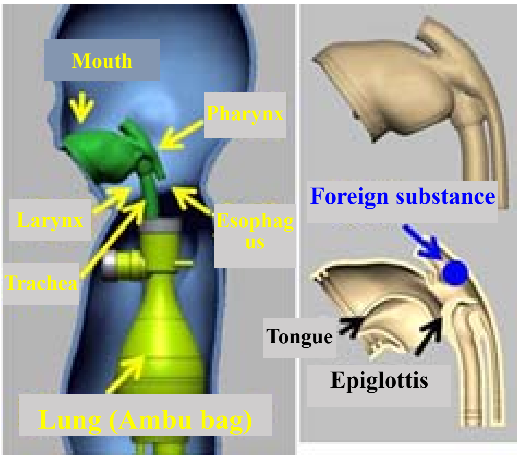
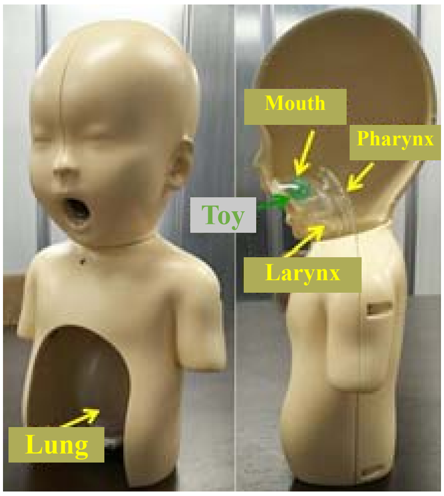


Figure 9. Overall cross-section of the phantom (left) and major relevant organs (right)

4.3 Method of Fabrication

The external surfaces of the head and neck and the chest and abdomen were made of nylon powder and fabricated by a lamination technique for 3D printer modeling. A 3D printer was used to produce resin molds of the mouth, pharynx, larynx, and esophagus and silicone was poured into them to make the models of these organs. These models were hollow, with their walls made of transparent silicone.
The size of the phantom is 140 mm in width, 190 mm in height, and 160 mm in depth for the head and face (in the open state) and 230 mm in width, 220 mm in height, and 110 mm in depth for the chest and abdomen (Picture 2).



Picture 2. Appearance of the phantom and cross section of the head and neck

4.4 Confirmation of Whether Toys can be Discharged

A bouncing ball was lodged in the pharynx and the back blow, chest compression, and Heimlich (abdominal thrust) maneuvers were performed. It was visually confirmed how the bouncing ball was pushed out into the mouth.

5. Production of Papercrafts

The location, size, and structure of the mouth, pharynx, larynx, trachea, and esophagus are not easy to understand. Therefore, the Investigation Commission first performed the airway obstruction simulation and fabricated the phantom to visualize the relevant organs and their movements. The Commission then produced a papercraft (a paper-based model) that was less expensive and expected to become widely used, because it believed that actually touching the model with hands would lead to realizing the location and size and developing a deeper understanding.
By actually assembling the model with our hands, we can realize the size and structure of the mouth, pharynx, larynx, trachea, and esophagus of an infant.

5.1 Design

The contour of the face and neck and the mouth, pharynx, larynx, esophagus, and trachea were designed so that they were of the actual size in a 9-month-old child when

assembled. The spaces of the mouth and pharynx were designed to be directly visible and the pharynx was designed so that a ball approximately 15 mm in diameter could be lodged in it. The mouth was in an open state so that a ball could be inserted through the mouth to obstruct the space of the pharynx.
To enhance the potential for wide availability, the papercraft was made of A4 construction paper and the assembly illustration was made printable on A4 plain paper.

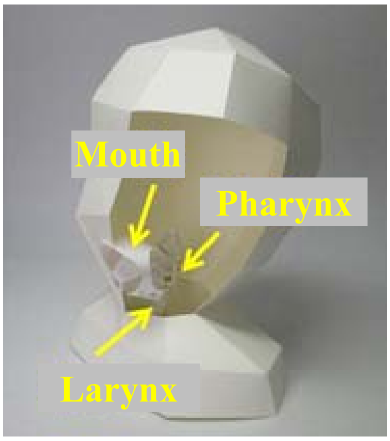
5.2 Method of Production

Based on three-dimensional shape data from the 9-month-old child used for phantom fabrication, a simplified three-dimensional model for the papercraft was made (software used: 3DCG software "Metasequoia®") and a development drawing was made based on the data (software for creating development drawings "Pepakura Designer®").
To allow assembly to be completed in a short time and in view of ease of assembly and ease of understanding of the structure while maintaining accuracy, the three-dimensional model for the papercraft was designed as follows.
The left one-fourth of the face was left open to make the internal organs directly visible while ensuring the stability of the head as a model. The internal organs of the mouth, pharynx, larynx, and esophagus were created, with the mouth containing the tongue, the pharynx containing the soft palate, and the larynx containing the epiglottis. The left half of the mouth was cut out in a circle to make the spaces of the tongue and mouth directly visible. The left one-fourth of the pharyngeal wall was similarly cut out in a crescentic form to make the epiglottis and the inside of the pharynx directly visible. To incorporate the internal organs in the head, notches were made to insert and fix the organs[27] (Picture 3).
The development drawing contained margins to paste up for assembly and numbers for confirming positions to glue together.

5.3 Time Required for Production

When a total of ten individuals, including healthcare professionals and students, assembled the papercraft experimentally, the time required for assembly was approximately one hour. It was confirmed that this papercraft produced based on actual data was useful for realizing the actual size and also helped to understand the structure.

[27] See the attachments Assembly Illustration for "Model of the infant's mouth and throat," the Model of the infant's mouth and throat, Assembly Illustration for "Model of the infant's head," and the Model of the infant's head.



(a) Overview of the papercraft


(b) Mouth, pharynx, and larynx components

Picture 3. Final image of the papercraft

6. Movie Production

The Investigation Commission produced a movie titled “Protection of children from choking accidents,” which included the results of the airway obstruction simulation as the main content. This movie tells that choking accidents are common accidents that can occur in households and contains examples of choking symptoms and descriptions of actions to be taken and preventive measures.

In this movie, a four-member family consisting of the father, mother, older brother, and younger brother appears in an environment in which airway obstruction accidents due to toys are assumed to occur in children and the younger brother aspirates and chokes on a toy when he is playing with it. The scene in which the siblings are playing with toys is live action. Shape data of the phantom was used to provide a description of the structure of related organs and the movies obtained from the airway obstruction simulation analysis were used for illustrating choking accidents by example.

For illustrating choking accidents by example, realistic computer graphics (CG) that met medical requirements were produced.

For actions to be taken at home in case of choking accidents (basic life support), the movie was used to show how a toy blocking the pharynx was brought to the mouth with the back blow maneuver, chest thrust maneuver, and Heimlich maneuver applied to the phantom.

Preventive measures, including keeping small objects 4 cm or smaller in size out of reach of children and learning actions to be taken in case of choking in case of emergency were presented.