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Design of Dental Mouth Prop

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Mouth props are widely used tools in clinical practice: from general dental practice to oral care in residential elderly care facilities. Mouth props are particularly useful for keeping the mouth open while administering oral care to persons in residential elderly care facilities who are unable to communicate with others. Currently, oral bites and such devices are used mainly as mouth props in such cases. However, patients who have difficulty communicating resist the insertion of the tools using their lips, which they often clench and defiantly refuse to open their mouths. On such occasions, medical personnel and caregivers must wait until the range of mouth opening is sufficient to insert a tool; this is a heavy burden for caregivers responsible for administering dental and oral care during house calls. To resolve these difficulties, we developed a mouth prop, which is easy to use by both medical personnel and caregivers, can be inserted through a smaller range of mouth opening, can open the mouth by the application of force via the tool after insertion, and can prevent injury inside the oral cavity.

1. Introduction

The world population has recently changed to a structure in which 20% of the population is more than 60 years old.(1) The population aged 65 and over in Japan is 28.9% of the total, making Japan the world's most rapidly aging society.(2) Along with the aging population, approximately 80% of people aged 75 years or older in Japan have two or more concomitant chronic diseases:

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about 60% of them have three or more.[3] Reportedly, about 20% of people aged 65 years or older are frail elderly people who are assisted by their family members and friends.[4] The maintenance of the oral hygiene of frail elderly people with multiple morbidities is a burden. The negative cycle of deterioration in health because of poor oral hygiene has persisted as a significant and difficult issue.[5,6]

In addition, the number of patients with dementia has doubled worldwide during the years 1990–2016. The number is estimated to have doubled every 20 years, presenting a major global healthcare issue.[7,8]

The incidence of dementia is known to increase because of oral-related diseases resulting from the deterioration of the oral environment. Many reports have described that the incidence and severity of dementia are higher in proportion to the loss of teeth.[9–13] Others have explained that the incidence of dementia increases with the rate of periodontal disease.[12–15] The cognitive ability also reportedly declines in proportion to the rate of increase of dental caries.[13] These reports also indicate that elderly people with dementia might often be adversely affected by tooth loss, periodontal disease, and dental caries when they require intervention in their oral environment.[16,17] Self-care is difficult because of the declining cognitive ability. Care by caregivers or family members as well as the education of caregivers in these matters are all needed.[15,18]

Nevertheless, the priority of oral care is lowered by family caregivers and medical personnel because of the resistance against care caused by a continued decline in cognitive ability, which may manifest itself in a refusal to open the mouth.[19] Care-resistant behaviors (CRBs) are experienced by most nurses during oral care at medical institutions. They pose major obstacles to care, and addressing them requires much time and effort.[20,21] A survey questionnaire was administered in Japan to nurses in wards into which many patients who need help with oral care had been admitted. About 30% reported difficulty in caring for patients who refused to open their mouths. The nurses expressed the need for a tool to open the mouth for tasks of administering care.[22]

Today there are mouth props such as versatile mouth gags and bite blocks for those who follow directions to open their mouths. However, opening the mouth is difficult to do without damaging the interior of the oral cavity when the patient cannot communicate or when the patient resists mouth opening. These tools are not applicable to cases of multiple tooth loss, which are often observed in dementia patients, or in cases involving a loosened tooth. Therefore, in a clinical environment, an oral bite or other device may be used to hold the mouth open with a tool made of material that does not damage the inside of the oral cavity when the mouth is opened. An important shortcoming of this method is that a physician must often wait a long time for a patient to open the mouth. A long wait is not amenable to situations in which the mouth must be opened immediately, such as when there is a risk of aspiration.

Although oral care becomes increasingly necessary as dementia advances, more CRBs can be expected to occur as dementia progresses. The deterioration of the state of oral hygiene because of heavier burdens of care is expected to engender further progression of dementia symptoms. To resolve the various inherent difficulties, a novel device is needed so that oral care may be carried out more simply and easily and to address needs for oral hygiene in elderly

people with a declining cognitive ability. For that reason, we have developed a mouth prop that does not damage the interior of the oral cavity. It does not damage gingival tissue and can be inserted easily. Moreover, it can open the mouth merely with the force exerted by a user.

2. Design of Dental Mouth Prop

The device developed in this study was designed with the following objectives in mind: (1) The tool can be inserted through a small mouth opening gap. (2) There is no risk of the tool being broken by the bite force of the patient or of fragments being swallowed. (3) The tool does not damage the interior of the oral cavity, even when the molar area is edentulous. (4) The mouth can be opened by a user applying reasonable force to the tool. (5) No excess force is applied inside the oral cavity. (6) The mouth can be held open. (7) The tool does not come off easily. It holds the molar area firmly even when the patient moves. The device consists mainly of two parts: the main part and the tip.

Autodesk Fusion 360 was used to design the main part of the mouth prop. A tool that uses a clamp mechanism was made to respond to requirements 4, 5, and 6 listed in the previous paragraph. The tip shape was designed to be thin when closed to respond to requirement 1 (Fig. 1).

The shape of the tip of the mouth prop was also designed using Autodesk Fusion 360. The mold was produced using a 3D printer. A silicone preparation was used to address requirement 2. The tip shape changes to enfold the gums when air is released so that the tool is useful when there are no teeth. By holding its position firmly by deformation, requirements 3 and 7 are satisfied (Fig. 2).

The main part of the tool consists of into three parts: the handle, the clamp mechanism, and the opening. The handle was designed with a 77-mm-long fixed part and a 54-mm-long action part. The clamp mechanism is at a maximum distance of 152 mm from the opening part. The opening part is 85 mm long and 5 mm thick at the tip in a closed state. It can be opened to a maximum distance of 61 mm. A circular motion of the handle is converted by the clamp mechanism into a linear motion. The opening part is connected to the clamp mechanism so that the linear motion is converted into a circular motion at point A. A stopper is built into the handle.

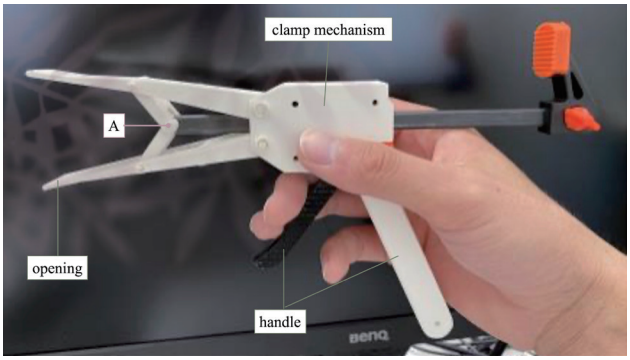
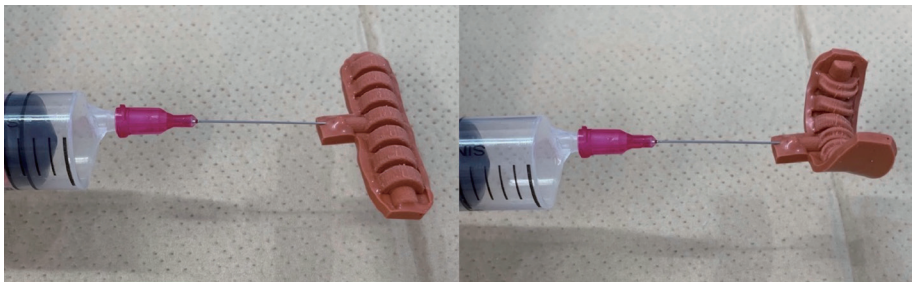


Fig. 1. (Color online) Prototype produced using a 3D printer.



(a) (b)

Fig. 2. (Color online) Silicone tip: (a) normal state and (b) under negative pressure.

The stopper is designed so that, when the handle is moved until it hits the stopper, the clamp moves 2 mm, opening the tip of the mouth prop by 4 mm.

The tip is 24 mm thick in the normal state, 55 mm wide, and 14 mm tall. The thickness of the top is 24 mm when the tip part is mounted on the main part, which is 27 mm less than the maximum thickness of the versatile mouth gag.

3. Manufacturing the Dental Mouth Prop

The handle of the main part of the prototype was prepared by Ultimaker Black Tough PLA, using Ultimaker 5S as a 3D printer. The ring and slide rail of a quick bar clamp (LFX-20-277; Kohnan Shoji Co., Ltd.) were moved to the clamp mechanism. The bracket was prepared by Ultimaker 5S using Ultimaker Black Tough PLA. The opening was machined from pieces of aluminum (Fig. 3).

For the tip of the prototype, a mold for casting silicone was prepared by Ultimaker 5S using Ultimaker Black Tough PLA. The preparation protocol for silicone includes the following steps:
(1) Design the mold.
(2) Print using a 3D printer.
(3) Pour silicone into the mold.
(4) Degas in the mold (10 min) (vacuum desiccator VW: AS One Corp.).
(5) Allow silicone to solidify at a normal temperature for 6 h.
(6) Remove the object from the mold.

The following silicone preparations were used: HTV-2000 (Engraving Japan Corp.), Reline II ExtraExtraSoft (GC), EXAHIFLEX INJ (GC), and EXAHIFLEX RG (GC). Motions of the preparations in response to negative and positive pressures were examined (Fig. 4).

The motion was greatest in the order of HTV-2000, Reline II ExtraExtraSoft, EXAHIFLEX INJ, and EXAHIFLEX RG. The motion was confirmed to be greater under negative pressure than under positive pressure. EXAHIFLEX INJ was selected as the material for the model in this study on the basis of its motion and ease of processing. We decided to use negative pressure to induce motion.

A negative pressure device was prepared using a CHANCS385 diaphragm self-priming pump (Fig. 5). A tube was connected to the silicone tip to move it (Fig. 6).

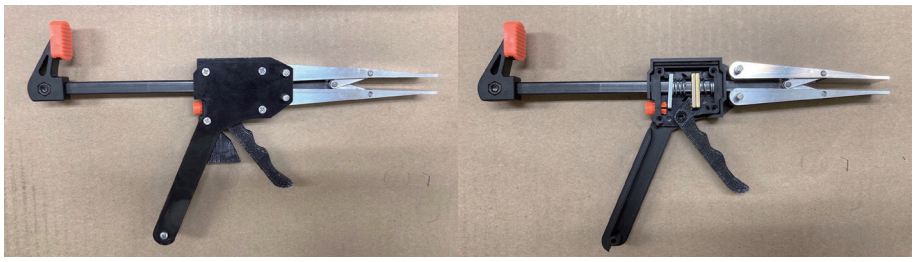


Fig. 3. (Color online) Main part of the prototype.

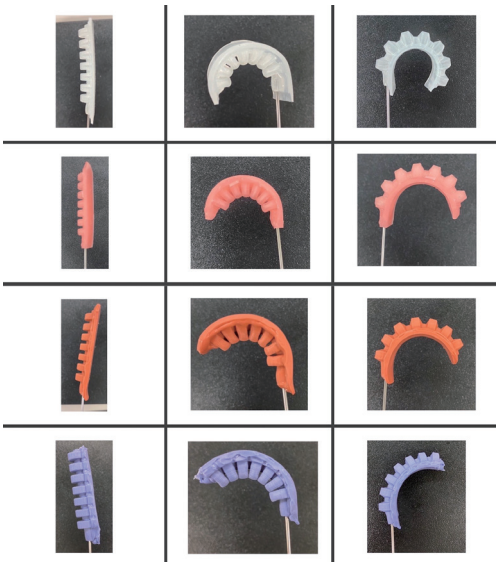


Fig. 4. (Color online) From the topdown: HTV-2000, Reline II ExtraExtraSoft, EXAHIFLEX INJ, and EXAHIFLEX RG [(a) normal state and under (b) negative and (c) positive pressures].

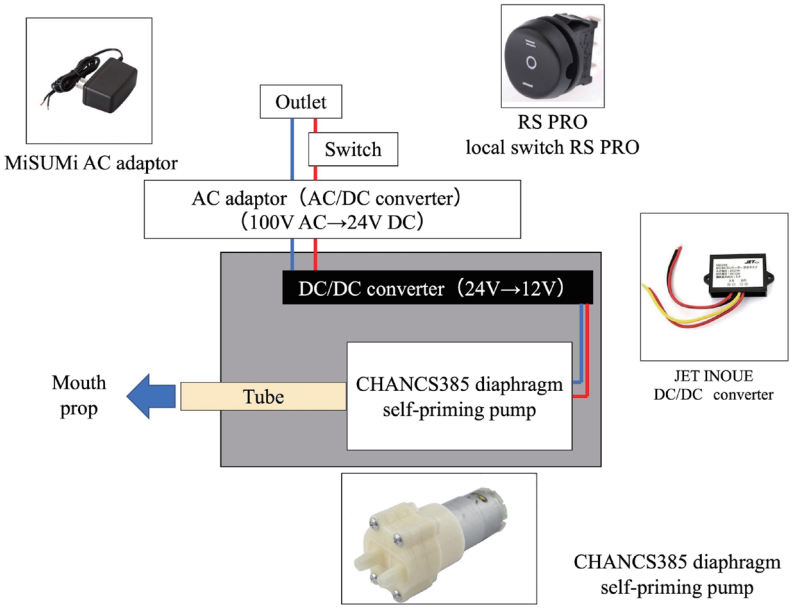


Fig. 5. (Color online) Negative pressure device.

(a) (b)

Fig. 6. (Color online) Silicone tip connected to the negative pressure device: (a) normal state and (b) under negative pressure.

4. Results and Discussion

An experiment was conducted using a dental model (ANA-3003-UL-JCP-D-28; Nissin). Seven dentists with different lengths of clinical experience were asked to use the device on the dental model. They then evaluated the device via a questionnaire.

The items on the questionnaire were as follows.

Question 1: Was the handle easy to move?
Question 2: Was the force needed to move the handle appropriate?
Question 3: Were the time and number of pushes on the handle required for opening the mouth appropriate?
Question 4: Was the force withstood by the locking function of the clamping mechanism appropriate?
Question 5: Was the release of the locking mechanism easy to use?
Question 6: Was the size of the tip of the prototype appropriate for clinical practice?
Question 7: Was it possible to hold the tool stably while opening the mouth?

The seven items were evaluated on five levels from 1 to 5: 5 was chosen when the respondent judged that it was sufficiently useful for practical application, 3 when it was acceptable for use, and 1 when it could not be used. Table 1 presents responses to the evaluation questionnaire.

The examination of the findings revealed the following information:

Question 1 (Was the handle easy to move?) showed that the shape of the handle was generally good; however, a better shape is desired because a square part of the handle is uncomfortable.

Question 2 (Was the force needed to move the handle appropriate?) yielded good responses. A respondent who answered that it was acceptable wanted the tool to move with less momentum.

Question 3 (Were the time and number of pushes on the handle required for opening the mouth appropriate?) elicited good responses. A respondent who answered that they were acceptable wanted more pushes with less maximum opening per push.

Question 4 (Was the force needed for the locking mechanism appropriate?) generally showed good results. It was difficult to evaluate whether the tool could endure the strong bite force of an actual patient because a model was used in this test.

Table 1
Questionnaire for the mouth prop.

Evaluation item	Evaluation							
	A	B	C	D	E	F	G	Mean
Question 1	5	3	5	5	5	3	5	4.4
Question 2	5	3	5	5	5	5	5	4.7
Question 3	5	3	5	5	5	5	5	4.7
Question 4	5	5	5	4	5	5	2	4.4
Question 5	5	5	5	5	5	3	4	4.6
Question 6	5	5	2	4	2	2	2	3.1
Question 7	5	5	5	5	5	2	4	4.4

Question 5 (Was the release of the locking mechanism easy to use?) generally showed good results.

Question 6 (Was the size of the tip of the prototype appropriate for clinical practice?) indicated that the size was in the acceptable range, but a smaller size would be needed for use with some patients.

Question 7 (Was it possible to hold the tool held stably when opening the mouth?) generally showed good results. One respondent wanted an increase in holding pressure.

These results show that the performance of the body of the prototype is sufficient for use. The use of a smaller tip was suggested. Therefore, the shape of the tip needs to be developed further.

5. Conclusions

We developed a device that can be inserted easily into and taken out of the oral cavity, and can be used to open the mouth without damage. To date, only thick devices have had a suitable shape to hold the teeth at the tip; other devices without a shape sufficient to hold teeth have demonstrated a lower holding capacity. Our device is thin enough to be inserted into the oral cavity and can then change its shape to hold teeth by changing the shape of the silicone at the tip using negatively pressurized air. Results of the evaluation of the mechanism of the main part and the holding performance of silicone were good. However, the comments indicated that a smaller silicone part was desirable. We are planning future improvements to yield a smaller size and a higher holding capacity by changing the pattern of the silicone shape and the structure of the tip. In the questionnaire completed by dentists, a concern was expressed about possible damage to the instrument and strain on the temporomandibular joint (TMJ) due to high forces. This suggests that control is a necessary element to make the instrument safe for anyone to use. In the future, we plan to improve the device by incorporating a pressure sensor so that it can only operate below a certain pressure level, thereby avoiding damage to the device and strain on the TMJ. We also plan to mechanize the mouth prop to control the amount of opening, the opening pressure, and the air pressure; with these improvements, the device could function as a new training device for patients with opening disorders.

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