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Original Article

Efficacy of a novel training food based on the process model of feeding for mastication and swallowing — A preliminary study in elderly individuals living at a residential facility —

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ABSTRACT
Nakagawa K, Matsuo K, Shibata S, Inamoto Y, Ito Y, Abe K, Ishibashi N, Fujii W, Saitoh E. Efficacy of a novel training food based on the process model of feeding for mastication and swallowing — a preliminary study in elderly individuals living at a residential facility —. Jpn J Compr Rehabil Sci 2014; 5: 72−78.
Purpose: We examined the validity and safety of a newly developed chew-swallow managing food (CSM) as a training material for chewing and swallowing.
Methods: Twenty-three elderly individuals (mean age: 82.8 ± 8.6 years) who followed a regular diet at a residential facility were enrolled in this study. The subjects ate 4 g each of CSM and puree 3 times while bolus transport and swallowing were recorded with a fiberoptic endoscope. For each trial, the number of chewing and swallowing movements was counted. We also identified the location of the leading edge of the food at swallow initiation, the amount of food residue in the oral cavity and pharynx, and the incidence of aspiration. The differences in measurements between CSM and puree trials were then compared statistically.
Results: With the CSM, the number of chewing and swallowing movements was significantly higher than that with puree and the leading edge of the food was deeper in the pharynx at swallow initiation. There were no significant differences in food residue or aspiration between the 2 foods.
Conclusion: Our findings suggest that CSM has an initial consistency that requires chewing but changes to a texture equivalent to puree at the time of swallowing. We are currently planning to verify the safety and efficacy of CSM in individuals with dysphagia.
Key words: process model of feeding, mastication, swallowing, dysphagia, direct therapy

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Introduction

As oropharyngeal dysphagia increases the risk of malnutrition and serious respiratory complications [1, 2], food modification corresponding to the severity of dysphagia promotes safe oral intake and prevents aspiration pneumonia [3]. Classifications of texture-modified dysphagia diets have recently been released by the Japanese Society of Dysphagia Rehabilitation [4]. The definition of texture-modified foods and liquids has also been compared among several countries to establish standardized international terminology [5].

Texture-modified food for severely dysphagic patients has a uniform consistency that can be swallowed as a single bolus. The design of such food is typically based on the four-stage sequential model of command swallowing of liquid, wherein mastication and its related tongue motion is not necessary [6]. In command swallowing, the bolus is held on the dorsal surface of the tongue and then propelled into the esophagus through the pharynx.

Texture-modified food for mild dysphagia, on the other hand, requires the ability to chew [4]. To eat this category of food, the material must be processed from ingestion to swallowing based on the process model of feeding [7]. Briefly, the ingested food is broken down by the masticatory movements of the jaw and mixed with saliva. The triturated food is then placed on the tongue surface, propelled into the oropharynx or valleculae by a backward squeezing tongue motion, and remains there until swallowing [8].

Direct therapies for severe dysphagia usually begin with foods of a single consistency, such as pureed or jellied food, and progress to food with a texture needing mastication as the eating function of the patient improves. However, single-consistency foods and mild dysphagic diets have considerable discrepancies in the movement of food while feeding; purees or jellies are suitable for swallowing a bolus, but not for the process of chewing, propulsion, and eventual swallowing. Meanwhile, some specific chewing exercises using chewing gum wrapped in gauze or hard dried squid have been proposed, but the target of these movements is only the motion of chewing and not the tongue rotation or backward tongue squeezing also involved in swallowing. Therefore, we hypothesized that if training food designed according to the process model of feeding were used from an early stage of direct therapy, the treatment would possibly have high transference to the actual eating process and lead to more rapid improvement of masticatory and swallowing functions. Based on this conjecture, we invented the novel chew-swallow managing food (CSM). We intended CSM to have an initial consistency and hardness that would require chewing but could be propelled to the oropharynx as a bolus and collected in the valleculae with a texture equivalent to pureed food at the time of swallowing.

The aim of this preliminary study was to examine the validity and safety of CSM as a training food for chewing and swallowing. Using community-dwelling elderly subjects with no dysphagia, we compared several characteristics of the feeding process for CSM and pureed food.

Methods

This study's protocol was approved by the institutional review board of Fujita Health University (Approval No. 13−289).

1. Subjects

The participants were elderly individuals who lived at a residential facility. Inclusion criteria were a regular diet and no history of dysphagia or aspiration pneumonia. Exclusion criteria were unstable physical status, structural abnormality of the oral cavity or pharynx, insufficient comprehension of instructions, food allergies, and no occlusion of the molars. The participants provided written informed consent in advance of the study. If a subject had cognitive impairment, consent was obtained from both the individual and a family member.

A total of 23 subjects (mean age: 82.8 ± 8.6 years; 13 men and 10 women) were enrolled in the study. Their primary diagnosis was dementia (n = 13, 57%), cerebrovascular disease (n = 6, 26%), neuromuscular disease (n = 3, 13%), and heart disease (n = 1, 4%).

2. Materials and Methods

2-1. Development of CSM

The concept of CSM was to have an initial hardness requiring chewing that could later be propelled to the oropharynx as a bolus and collected in the valleculae with a texture equivalent to puree at the time of swallowing.

We first established the hardness of CSM. The lower limit was set at 2.0×10^4 N/m^2, which was the upper limit of the Standard Regulations III for foods for patients with swallowing difficulties released by the Consumer Affairs Agency. We considered this to be the minimum hardness to require chewing [9]. The upper limit of the hardness of CSM was set at 5.0×10^4 N/m^2, which was the limit at which food could be broken up using the gums without teeth as stipulated in the Universal Design Food Concept Guidelines (UD2) [10].

We confirmed in sensory evaluations of trial foods that a sufficient number of chewing cycles could be acquired with the established hardness limits. A target range was not set for adhesiveness or cohesiveness

Table 1. Characteristics of CSM and pureed food.

Texture	CSM*			Puree**
	Brown sugar lump	Stock	Soy sauce	
Hardness (N/m^2)	4.2×10^4	3.9×10^4	3.7×10^4	2.6×10^3
Cohesiveness	0.4	0.4	0.4	0.8
Adhesiveness (J/m^3)	1.8×10^3	1.8×10^3	1.5×10^3	7.9×10^2

* Shoshokuhyo Notification No. 277.
** Universal Design Food Concept.

since we did not consider them to greatly influence chewing performance. The CSM was manufactured by Otsuka Pharmaceutical Factory, Inc., in compliance with national food sanitation laws. The physical properties of CSM are shown in Table 1.

2-2. Data Acquisition

Each participant was seated comfortably upright in a chair. Videoendoscopic examination of swallowing (VE) was performed to observe the transport of food through the pharynx, timing of swallowing, and pharyngeal residue. These events were recorded on a digital video (DV). A fiberoptic endoscope (3.6 mm in diameter, ENF TYPE P4, Olympus, Tokyo, Japan) was inserted through the right nostril of the subject and the tip of the endoscope was positioned behind the soft palate to allow observation of the pharyngeal cavity. We recorded the subjects eating the food and the VE images with a video camera and saved the images on a DVD (Fig. 1).

We prepared 4 g each of CSM and puree as test foods. Participants were instructed to eat both foods 3 times while the endoscope was inserted. After the food was placed into the mouth by the caregiver, the subjects were instructed to eat the food normally. The eating order of the samples in each trial was randomized. Participants were told to swallow 3 mL of water if food residue was observed in the oral cavity or pharynx after swallowing.

2-3. Data Reduction

2-3-1. Number of swallows and chewing cycles

Swallowing was defined as the timing of “white-out” in VE images and was counted for each test food. The number of chewing cycles was considered to be the number of cycles until the first swallow following food intake. The number of chewing cycles was counted on video images recorded from the external camera (Fig. 1).

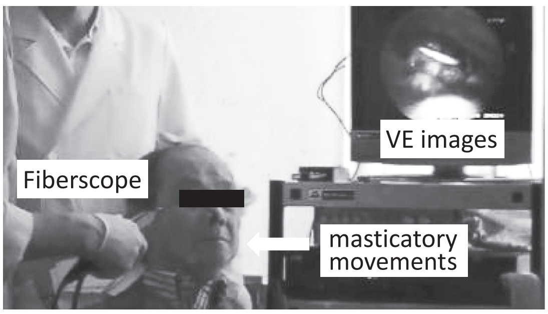

Figure 1. Subject eating a test food and video images from an endoscope were recorded simultaneously by a digital video camera. We counted the number of chewing cycles from ingestion to the first swallow using these images.

2-3-2. Location of the leading edge of the bolus at swallow initiation

The location of the leading edge of the bolus immediately before the first swallow was identified in VE images and classified into 5 areas based on a previous study [11]: 1) oral cavity, the area where the food was not observed in VE images; 2) oropharynx, the area where the leading edge was observed in VE images but had not reached the base of the epiglottis; 3) valleculae, the area where the leading edge had reached the base of the epiglottis but not entered the hypopharynx; 4) hypopharynx, the area where the leading edge had entered the hypopharynx but not reached the bottom of the piriform sinus; and 5) piriform sinus, the area where the leading edge had reached the bottom of the piriform sinus.

2-3-3. Food residue and aspiration

We quantitatively classified food residue in the oral cavity and pharynx into 4 levels based on a previous study [12]: 1) none; 2) punctuate/trace; 3) less than half; and 4) half or more. With regard to the oral cavity, residue was evaluated by direct observation of the dorsum of the tongue and the floor of the mouth after the final swallow for each trial. For the pharyngeal cavity, residue on the valleculae and piriform sinus was evaluated in VE images just after the first and last swallows.

Pharyngeal penetration and aspiration were evaluated in VE images using the Penetration-Aspiration Scale (PAS) [13]. The PAS is an 8-point scale based on the depth of penetration of food in the lower airway (1, no laryngeal penetration; 2−5, laryngeal penetration; 6−8, aspiration).

2-4. Data Analysis

The Wilcoxon test was used to compare differences in the number of chewing cycles and swallows as well as the location of the leading edge of the bolus at swallow initiation between CSM and puree. Comparisons of residues were performed using the chi-square test, and the Wilcoxon test was employed for assessment of PAS scores. The critical value for rejecting the null hypothesis was $p < 0.05$. Statistical analyses were performed using SPSS version 21.0 software (SPSS Inc., IBM).

Results

Recordings of all trials of both CSM and puree for all subjects were obtained. As a result, 138 trials were included in the analysis. The mean (±SD) number of swallows was significantly higher with CSM than with puree (1.49 ± 0.63 vs. 1.23 ± 0.46, $p = 0.004$) (Fig. 2A). The mean number of chewing cycles until the first swallow was also significantly increased with CSM (16.9 ± 10.1 vs. 2.30 ± 2.07, $p < 0.001$) (Fig. 2B).

With the puree, the location of the leading edge of the food at swallow initiation was primarily in the oral cavity (28/69 subjects, 40.6%), followed by the oropharynx (23.2%), valleculae (21.7%), and hypopharynx or piriform sinus (14.5%) (Fig. 3). In contrast, with the CSM, the leading edge of the bolus at swallow initiation was typically observed in the valleculae in 39.1% of subjects, followed by the oral cavity (24.6%) and the hypopharynx or piriform sinus (20.2%). The location of the leading edge of the food at swallow initiation was significantly deeper in the pharynx with CSM than with puree ($p = 0.003$).

The amount of residue on the dorsum of the tongue and the floor of the mouth after the last swallow was comparable between CSM and puree. The amount of residue in the valleculae or piriform sinus was also similar for the 2 test foods for the first and last swallows (Fig. 4A, B).

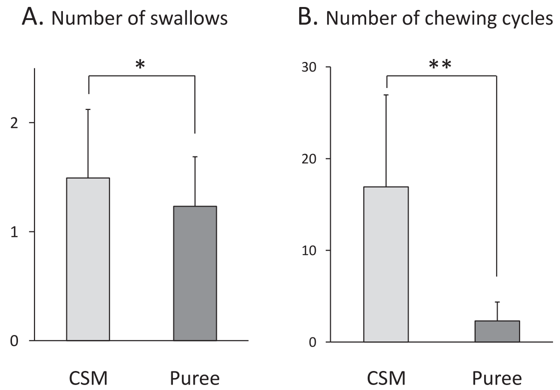

Figure 2. (A) The mean (± SD) number of swallowing and (B) chewing cycles to the first swallow for CSM and puree. Both the number of chewing cycles and swallowing were significantly increased with CSM (*$p = 0.004$ for swallowing and **$p < 0.001$ for chewing).

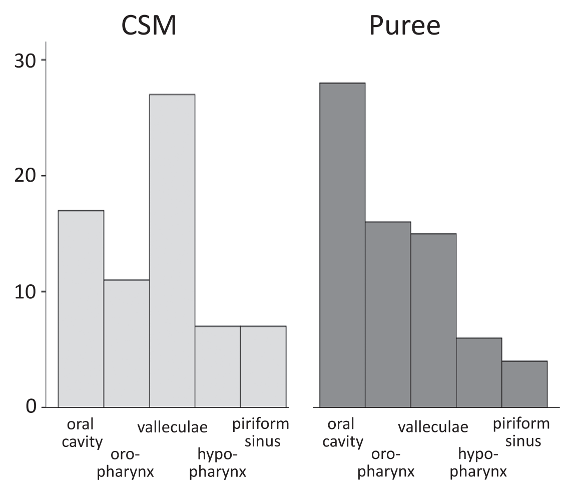

Figure 3. Location of the leading edge of the food for CSM and puree. With puree, the food was mainly held in the oral cavity, but with CSM, the food was primarily kept in the valleculae ($p = 0.003$).

Neither aspiration nor penetration was observed in over 95% of trials, and there was no significant difference in PAS scores between the CSM and puree groups ($p = 0.083$, Fig. 5). No subject aspirated the test foods.

Discussion

1. Development of CSM

We hypothesized that performing swallowing movements based on the process model of feeding [7] in direct therapy would improve dysphagia more rapidly. However, conventional food requiring chewing sometimes scatters in the pharynx due to low cohesiveness or enters the hypopharynx before swallow initiation from low adhesiveness [14]. Such conditions markedly increase the risk of aspiration in patients with dysphagia.

Our CSM was designed to have an initial hardness that required chewing but could easily be propelled to the oropharynx (i.e., stage II transport) and collected in the valleculae with a texture equivalent to puree at the time of swallowing. The texture of the CSM was based on the criteria for foods for patients with swallowing difficulties issued by the Consumer Affairs Agency, which determines the ease of swallowing certain foods by dysphagic patients, and the Universal Design Food Concept of the Japan Care Food Conference that defines masticatory strength [9,10]. The upper limit in Standard Regulations III for foods for patients with swallowing difficulties (2.0×10^4 N/m^2) is equal to the level of soft pureed or jellied food. This was set as the lower limit of CSM hardness. The upper limit of the hardness of CSM was 5.0×10^4 N/m^2, which could be broken up using the gums without teeth as stipulated in the Universal Design Food Concept (UD2). We found that CSM needed noticeably more chewing than pureed food, suggesting that it possessed our intended hardness.

When food is chewed and mixed with saliva, its hardness decreases while its adhesiveness and cohesiveness increase [15,16]. We aimed for the texture of the CSM at the time of bolus transport to fall within the range of Standard Regulations I to II for foods for patients with swallowing difficulties, which was equal to jelly or mousse, after chewing [9]. At the same time, we ensured that the bolus would not be too thin following mixture with saliva and that its cohesiveness would be such that the food did not scatter in the pharynx. We observed that the residue in the oral cavity and pharynx and the depth of aspiration did not significantly differ between the CSM and puree. This indicated that excessive liquefaction or decline in cohesiveness did not occur after the change in CSM texture by chewing and transport.

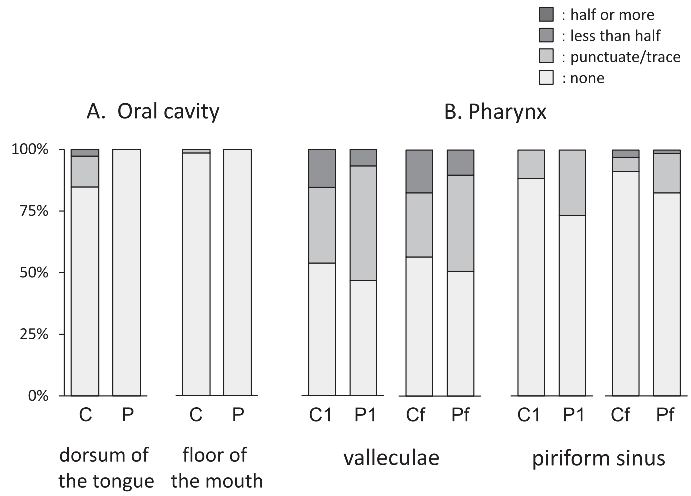

Figure 4. Post-swallowing residue in the (A) oral cavity and (B) pharynx. 1, residue after the first swallow; f, residue after the last swallow. There was no significant difference in the amount of residue in the oral cavity or pharynx between CSM and puree trials.

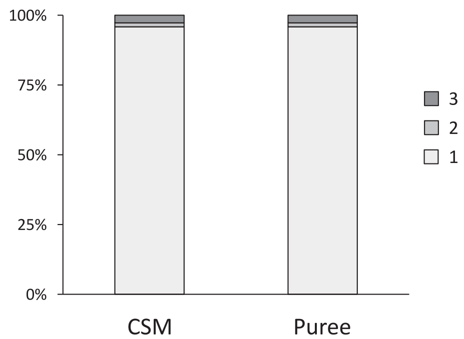

Figure 5. Penetration-Aspiration Scale (PAS).
No aspiration was observed for either CSM or puree, but laryngeal penetration was witnessed in three subjects. 1: no laryngeal penetration, 2: laryngeal penetration, remains above the vocal folds, and is ejected from the airway, 3: laryngeal penetration, remains above the vocal folds, and is not ejected from the airway.

2. Efficacy of CSM as a Training Food for Chewing and Swallowing

The mechanism of food transport from ingestion to swallowing is different for CSM and puree. Pureed food is swallowed based on the four-stage sequential model [6]: the ingested puree is held in the mouth and then propelled to the esophagus through the pharynx. Because of its texture, it is swallowed as a bolus after a relatively little amount of chewing. In contrast, CSM has a texture that requires chewing performance. With CSM, the process from ingestion to swallowing follows the process model of feeding that includes mastication, stage II transport, and swallowing [7]. Accordingly, the number of chewing cycles increases significantly and swallowing occurs after the masticated food is collected and gradually propelled to the pharynx, resulting in a greater number of swallows compared with pureed food. As expected, the amount of chewing and swallowing movements was significantly higher for CSM than puree in our cohort. One of our main requirements for CSM was transference and actual mastication and swallowing. Our observed increases in the number of chewing and subsequent swallowing movements suggest that CSM could be used as a training food for dysphagic individuals.

The leading edge of the food at swallow initiation was located deeper in the pharynx with CSM than with pureed food. In our study, the leading edge of the puree was primarily in the oral cavity. However, the leading edge of the CSM at swallow initiation was more frequently in the oropharynx or valleculae, likely because of oro-pharyngeal stage II transport during mastication. These findings suggest that eating CSM increases the number of chewing cycles and produces more oro-pharyngeal stage II transport, with the clinical implication that direct training using CSM targets the entire process of mastication and swallowing.

Transference is a key focus in swallowing therapies, for which several muscle augmentation exercises have been reported as effective in indirect treatments [17,18]. Since maintaining a minimum level of muscle strength in the oral cavity and pharynx is crucial to develop mastication and swallowing ability, muscle augmentation exercises are recognized as important regimens for patients with dysphagia. However, the transference of indirect exercises to actual swallowing activities is relatively low, and so it is difficult to enhance swallowing function by these exercises only [19]. Thus, transference is important in direct swallowing therapies. Food with one consistency, such as pureed or jellied food, is a suitable starting material for direct swallowing therapy. Regimens using these foods are good for restoration of "swallowing", but are less effective for "eating (mastication and swallowing)" since they do not provoke mastication. In this study, CSM required mastication and oropharyngeal food transport, suggesting that it could improve both mastication and swallowing in dysphagic patients.

3. Safety of CSM as a Training Food for Mastication and Swallowing

Post-swallow residue is influenced by oral and pharyngeal function as well as by food properties. High food adhesiveness increases the risk of pharyngeal residue due to its stickiness, while low cohesiveness raises the risk of oral residue and aspiration due to its low rheological characteristics. In the present study, there were no significant differences in the amount of residue in the oral cavity or pharynx between CSM and puree trials. PAS scores were almost identical for both test foods, and no aspiration was observed. Since the participants in this preliminary study were elderly individuals following a regular diet, the safety of CSM for dysphagic patients could not be precisely determined. However, our findings indicate a possible efficacy of CSM as a training food for mastication and swallowing with a low risk of residue and aspiration.

Lastly, the location of the leading edge of the food before swallowing is also significantly affected by masticatory performance and food properties [14]. The leading edge traveled more deeply into the pharynx with CSM than with puree, and even reached the piriform sinus before swallowing in seven subjects with CSM. Such deep penetration of food into the hypopharynx during chewing may increase the risk of aspiration in dysphagic individuals with weak airway protection. However, CSM does not share food properties with low viscosity two-phase food [14]. The number and duration of chewing may have been extended in subjects with low masticatory performance in our study. With longer masticatory duration, the bolus could have more frequently reached the hypopharynx. This suggests that it is necessary to carefully monitor patients with low masticatory performance in future clinical studies of CSM.

Conclusion

With our novel training food for mastication and swallowing, CSM, the number of mastication and swallowing movements increased significantly and oropharyngeal stage II transport occurred more frequently than with pureed food. In contrast, the level of residue and laryngeal penetration did not differ between CSM and puree. These findings imply that CSM is an appropriate mastication and swallowing training food that provokes mastication with the safety of pureed food. Future trials are being planned to verify the efficacy of CSM in individuals with dysphagia.

References

1. Poisson P, Laffond T, Campos S, Dupuis V, Bourdel-Marchasson I. Relationships between oral health, dysphagia and undernutrition in hospitalised elderly patients. Gerodontology. 2014.
2. Serra-Prat M, Palomera M, Gomez C, Sar-Shalom D, Saiz A, Montoya JG, et al. Oropharyngeal dysphagia as a risk factor for malnutrition and lower respiratory tract infection in independently living older persons: a population-based prospective study. Age Ageing 2012; 41: 376−81.
3. Robbins J, Gensler G, Hind J, Logemann JA, Lindblad AS, Brandt D, et al. Comparison of 2 interventions for liquid aspiration on pneumonia incidence: a randomized trial. Ann Intern Med 2008; 148: 509−18.
4. Fujitani J, Uyama R, Ogoshi H, Kayashita J, Kojo A, Takahashi K, et al. Classification of type food for dysphagia patients by the Japanese Society of Dysphagia Rehabilitation 2013. Jpn J Dysphagia Rehabil 2013; 17: 255−67. Japanese.
5. Cichero JA, Steele C, Duivestein J, Clave P, Chen J, Kayashita J, et al. The need for international terminology and definitions for texture-modified foods and thickened liquids used in dysphagia management: foundations of a global initiative. Curr Phys Med Rehabil Rep 2013; 1: 280−91.
6. Logemann JA. Evaluation and treatment of swallowing disorders. 2nd ed. Austin Texas: Pro-Ed; 1998.
7. Palmer JB, Rudin NJ, Lara G, Crompton AW. Coordination of mastication and swallowing. Dysphagia 1992; 7: 187−200.
8. Hiiemae KM, Palmer JB. Food transport and bolus formation during complete feeding sequences on foods of different initial consistency. Dysphagia 1999; 14: 31−42.
9. Shoushokuhyou Notification, (No. 277, June 23, 2011, Food Labeling Division, Consumer Affairs Agency. Government of Lapan. Japanese.
10. Japan Care Food Conference. Available from: http://www.udf.jp/about/table.html (cited 2014 April). Japanese.
11. Matsuo K, Kawase S, Wakimoto N, Iwatani K, Masuda Y, Ogasawara T. Effect of viscosity on food transport and swallow initiation during eating of two-phase food in normal young adults: a pilot study. Dysphagia 2013; 28: 63−8.
12. Yokoyama M, Okada S, Baba M, Saitoh E, Shigeta R, Suzuki M, et al. A new jelly —type food for dysphagia patients —study on its usage in direct therapy. Jpn J Dysphagia Rehabil 2005; 9: 186−94. Japanese.
13. Rosenbek JC, Robbins JA, Roecker EB, Coyle JL, Wood JL. A penetration-aspiration scale. Dysphagia 1996; 11: 93−8.
14. Saitoh E, Shibata S, Matsuo K, Baba M, Fujii W, Palmer JB. Chewing and food consistency: effects on bolus

transport and swallow initiation. Dysphagia 2007; 22: 100−7.
15. Shiozawa K, Kohyama K, Yanagisawa K: Relationship between physical properties of a food bolus and initiation of swallowing. Jpn J Oral Biol 2003; 45: 59−63.
16. Shiozawa K, Kohyama K: Effects of addition of water on masticatory behavior and the mecanical properties of the food bolus. J Oral Biosci 2011; 53: 148−157.
17. Shaker R, Easterling C, Kern M, Nitschke T, Massey B, Daniels S, et al. Rehabilitation of swallowing by exercise in tube-fed patients with pharyngeal dysphagia secondary to abnormal UES opening. Gastroenterology 2002; 122: 1314−21.
18. Robbins J, Kays SA, Gangnon RE, Hind JA, Hewitt AL, Gentry LR, et al. The effects of lingual exercise in stroke patients with dysphagia. Arch Phys Med Rehabil 2007; 88: 150−8.
19. Young WB. Transfer of strength and power training to sports performance. Int J Sports Physiol Perform 2006; 1: 74−83.