

*Original Article***Efficacy of a novel training food based on the process model of feeding for mastication and swallowing: A study among dysphagia patients**

Seiko Shibata, MD, DMSc,¹ Hitoshi Kagaya, MD, DMSc,¹ Shinichiro Tanaka, MD,¹
 Wataru Fujii, DDS, PhD,² Kazuharu Nakagawa, DDS, PhD,³ Koichiro Matsuo, DDS, PhD,³
 Kazumi Abe, MPHARM,⁴ Naoto Ishibashi, MPHARM,⁴ Yoko Inamoto, SLHT, DMSc,⁵
 Eiichi Saitoh, MD, DMSc¹

¹Department of Rehabilitation Medicine I, School of Medicine, Fujita Health University, Aichi, Japan

²Department of Dentistry, Fujita Health University Nanakuri Memorial Hospital, Mie, Japan

³Department of Dentistry, School of Medicine, Fujita Health University, Aichi, Japan

⁴Product Design Laboratory, Medical Foods Research Institute, OS-1 Division, Otsuka Pharmaceutical Factory, Inc., Tokushima, Japan

⁵Faculty of Rehabilitation, School of Health Science, Fujita Health University, Aichi, Japan

ABSTRACT

Shibata S, Kagaya H, Tanaka S, Fujii W, Nakagawa K, Matsuo K, Abe K, Ishibashi N, Inamoto Y, Saitoh E. Efficacy of a novel training food based on the process model of feeding for mastication and swallowing: A study among dysphagia patients. *Jpn J Compr Rehabil Sci* 2017; 8: 82–87.

Objective: Our goal was to verify the validity and safety of chew-swallow managing food (CSM) for dysphagia patients.

Methods: We conducted a study on 14 inpatients diagnosed with dysphagia and judged to be capable of ingesting pureed foods. We instructed each participant to ingest and freely swallow 4-g samples of CSM and pureed food. For each sample, we measured the number of chewing cycles, number of swallows, position of the leading edge of the bolus at the time of swallowing initiation, amount of residue in the oral cavity and pharynx, and occurrence of laryngeal penetration or aspiration.

Results: The number of chewing cycles was significantly higher for the CSM. The position of the leading edge of the bolus at the time of swallowing initiation was

primarily in the valleculae for both the CSM and pureed food, and the rate of laryngeal penetration did not significantly differ between the two test foods. There was a high rate of residue on the dorsum of tongue with the CSM and in the valleculae with the pureed food.

Conclusion: The CSM induced chewing in dysphagia patients, and the prevalence of penetration did not differ from the pureed food. Therefore, we concluded that the CSM could be used in chewing exercises with the same level of safety as the pureed food.

Key words: process model, chewing, swallowing, swallowing disorders, direct training

Introduction

Two types of approaches are widely used for treating dysphagia: direct swallowing training, in which the person ingests food to practice chewing and swallowing, and indirect swallowing therapy, which does not use food [1]. Indirect training avoids the risk of aspiration, and has proven to be effective for improving the swallowing motion by strengthening tongue squeezing and pharyngeal constriction. However, it does have a direct effect on the bolus condition during the actual swallowing motion. Direct training, on the other hand, can be more easily generalized to the swallowing motion. Therefore, to improve the swallowing function more efficiently, it is important to employ direct training in combination with indirect training in a safe manner.

Direct training usually begins with foods of a uniform consistency, such as pureed or jellied food. Since these foods do not require chewing, aspiration and food residue are minimized during the direct training.

Correspondence: Seiko Shibata, MD, DMSc
 Department of Rehabilitation Medicine I, School of
 Medicine, Fujita Health University, 1–98 Dengakugakubo,
 Kutsukake, Toyoake, Aichi 470–1192, Japan.
 E-mail: sshibata@fujita-hu.ac.jp

Accepted: June 9, 2017.

COI: This study was supported by a research grant from
 Otsuka Pharmaceutical Factory, Inc.

Typically, the person is instructed to hold the bolus in the mouth until the swallowing reflex is initiated. Then the person is expected to swallow the bolus all at once by propelling it into the pharynx. This swallowing process is described in a four-stage model, which is based on the action of discrete swallowing [2].

However, in the course of stepwise therapy, it is essential to shift from foods of a single consistency to foods that require chewing. Therefore, it is necessary to consider shifting from the four-stage swallowing model to the process model. The process model has been proposed to describe chewing and swallowing [3, 4]. The characteristic of this model is progress processing and stage II transport concurrently. In the processing stage, food inserted in the oral cavity is broken down by chewing and mixed with saliva, making it swallowable. In the oral propulsive stage, a swallowable portion of the ingested food is transported to the pharynx during chewing through the squeeze-back action of the tongue (stage II transport). Bolus formation in the chewing and swallowing process is performed in the valleculae during stage II transport [5, 6]. Furthermore, it is reported that the position of the bolus at the initiation of swallowing under stage II transport varies depending on the properties of the ingested food [7–9]. When the person is chewing and swallowing runny foods with low viscosity, or foods consisting of both liquid and solid pieces such as miso soup, the location of the bolus at the initiation of swallowing under stage II transport will be the hypopharynx. Therefore, those with more severe dysphagia will be at greater risk of aspiration.

Taking into consideration the importance of using standardized foods to ensure safe chewing and swallowing exercises, we developed a chew-swallow managing food (CSM). We designed the CSM to have an initial hardness that requires chewing, and thus induces stage II transport, and to transform in texture to a puree with chewing, thus enabling swallowing with a minimal risk of aspiration.

The aim of this study was to examine the validity and safety of the CSM as a training food for chewing and swallowing by comparing the swallowing motions of patients with dysphagia when ingesting CSM versus pureed food.

Subjects and Methods

The study protocol was approved by the institutional review board of Fujita Health University (Approval No. 13–289).

1. Participants

The participants consisted of 14 patients who required a videofluorographic examination of swallowing (VF) after suspecting dysphagia, and who were judged to be capable of swallowing pureed foods. Exclusion criteria were unstable physical status and insufficient

comprehension of verbal instructions. Prior to starting the study, we provided each participant, and in some cases, a family member, with an explanation of the study, and the participants provided their written informed consent.

The participants comprised eight men and six women, with a mean age of 74 ± 8.7 years. Regarding the primary diseases of the participants, five had suffered a stroke, two had a brain tumor, three had a neuromuscular disease, two had pharyngeal cancer, and two had a respiratory disease. Regarding the severity of their dysphagia as measured using the Dysphagia Severity Scale (DSS) [10, 11], one participant was classified under “food aspiration,” nine were classified under “water aspiration,” two under “occasional aspiration,” one under “oral problem,” and one under “minimum problem.” Regarding the participants’ dental condition, five had no molar occlusion and did not require dentures, four were using dentures, and five required dentures but were not using them.

2. Methods

We positioned the participants in the posture recommended for VF and conducted the videoendoscopic evaluation of swallowing (VE). We inserted a fiberscope of 3.6 mm in diameter (ENF Type P4, Olympus, Tokyo) into the nasal cavity, and positioned the tip of the endoscope at the level of the soft palate so that we could observe the entire pharyngeal cavity. We recorded the endoscopic images during the feeding process onto a mini digital video tape (mini-DV) player. To enable confirmation of the number of chewing and swallowing movements afterward, we recorded the participants eating the food and the VE images with another video camera and saved the images on a DVD.

For the test foods, we used 4 g of the CSM and 4 g of a commercial pureed product (*Nameraka yasai kabocha* [soft vegetable pumpkin], Kewpie, Tokyo), which falls under Category 4 of the Universal Design Food [12]. The participants were instructed to eat three samples of each food while the endoscope was inserted. The order in which the participants ingested these samples was randomized.

The properties of the test foods are shown in Table 1. We measured these properties using the method indicated in the Consumer Affairs Agency’s licensing standards for “Foods for special dietary uses” and “Foods for persons with dysphagia” [13].

After the food was placed in the mouth by the examiner using a spoon, the participant was instructed to eat the food freely. Participants were told to swallow 3 mL of water if any food residue was observed in the oral cavity or pharynx after swallowing.

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	3.4×10 ³
Cohesiveness	0.4	0.4	0.4	0.8
Adhesiveness (J/m ²)	1.8×10 ³	1.8×10 ³	1.5×10 ³	1.1×10 ³

* Shoushokuhyou Notification No. 277.

** Universal Design Food Concept.

3. Data acquisition

3.1 Number of swallows and chewing cycles

We defined the swallow as coinciding with the appearance of a white-out in the VE images. The VE administrator counted the number of times the participant swallowed until the participant indicated finishing eating the sample. The number of chewing cycles was measured by counting the number of vertical movements of the jawbone between the time of intake and the time of the first swallow. This measurement was performed by an examiner other than the VE administrator. We used the video images recorded on the external camera to corroborate the number of swallows and chewing cycles, if necessary.

3.2 Location of the leading edge of the bolus at swallowing initiation

Based on the VE images recorded by the VE administrator, we identified the locations of the leading edge of the bolus immediately before the first swallow. We classified these locations into the following: (1) oral cavity: VE images show that there was no premature spillage of the bolus into the pharynx; (2) tongue base to valleculae: VE images show that the leading edge reached the valleculae prior to swallowing; and (3) valleculae to pyriform sinus: VE images show that the leading edge passed the valleculae and reached the pyriform sinus.

3.3 Food residue and aspiration

An examiner, other than the VE administrator, evaluated the food residue in the oral cavity by direct observation and in the pharynx by VE images. Based on a previous study, we classified the degree of residue into four levels: (1) none, (2) trace, (3) less than half, and (4) half or more. The VE images were used to identify residue in the valleculae and pyriform sinus. The residues on the dorsum of the tongue and floor of the mouth were identified by direct observation after the final swallow in each trial.

Laryngeal penetration and aspiration were evaluated using the VE images and quantified with the Penetration-Aspiration Scale (PAS) [14].

4. Data analysis

We used a paired *t*-test to evaluate the differences in

the mean numbers of chewing cycles and swallows between the CSM and pureed food. We used the Wilcoxon signed-rank test to compare the differences in the amount of residue, location of the leading edge of the bolus at swallow initiation, and PAS scores. Statistical analyses were performed using IBM SPSS software version 23.0 (SPSS Inc., IBM, Armonk, NY, USA), with a statistical significance threshold of $p < 0.05$.

Results

With regard to the mean number of swallows (mean \pm standard deviation [SD]), there was no significant difference between the CSM and pureed food (2.4 ± 1.5 vs. 2.0 ± 1.0 , $p = 0.083$; see Figure 1A). The mean number of chewing cycles until the first swallow was significantly higher for the CSM than for pureed food (34.6 ± 18.2 vs. 6.5 ± 6.7 , $p < 0.001$; see Figure 1B).

There was no significant difference between the CSM and pureed food in terms of the location of the leading edge of the bolus at swallow initiation. The location in both cases was primarily in the valleculae to pyriform sinus (78.6% and 81.0%; see Table 2).

The amount of residue in the dorsum of the tongue and valleculae differed significantly between the CSM and pureed food ($p = 0.001$, $p = 0.047$; see Table 3).

The residue in the dorsum of the tongue was highest with the CSM, but this represented only trace residue in most cases.

The residue in the valleculae with the pureed food was Level 3 (less than half) in 23 of 42 cases (54.8%). With the CSM, two of the 42 cases (4.8%) had Level 4 (half or more) residue, but Levels 1 (none), 2 (trace), and 3 residues were similar with 11/42 cases (26.2%), 14/42 cases (33.3%) and 15/42 cases (35.7%), respectively.

There was no significant difference in the distribution of residue in the pyriform sinus. Twenty-four (57.1%) of 42 cases with CSM had Level 2 (trace) to Level 3 (less than half) residue in the pyriform sinus, compared to 25 (59.5%) of 42 cases with the pureed food. In addition, the rates for Level 1 (none) were 18/42 (42.9%) cases and 17/42 (40.5%) cases, respectively.

Regarding the PAS scores, none of the participants aspirated with either the CSM or the pureed food.

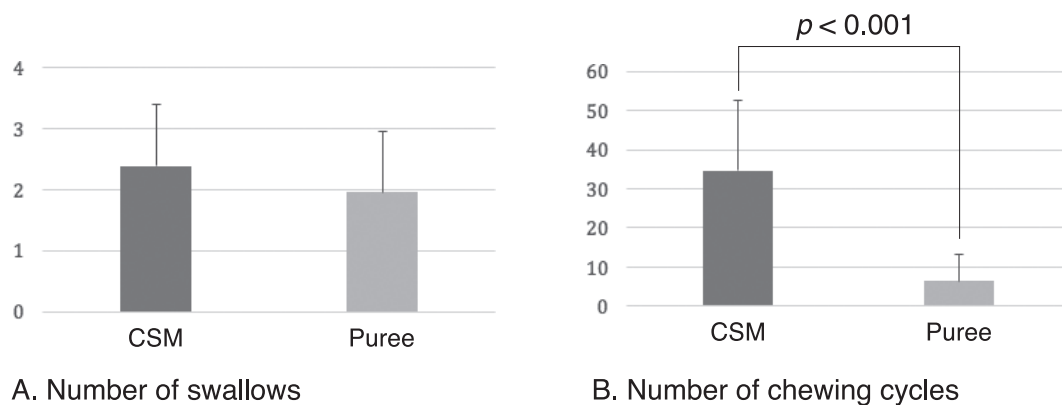


Figure 1. Number of chewing cycles and swallows.

A. Number of swallows until finishing the 4-g sample of CSM/puree.

B. Number of chewing cycles until the first swallow of the 4-g sample of CSM/puree.

Figures indicate the mean + standard deviation (SD). According to the Wilcoxon signed-rank test, the number of swallows did not vary significantly between the CSM and pureed food, but the number of chewing cycles was significantly higher with CSM ($p < 0.001$).

CSM, chew-swallow managing food.

Table 2. Location of the leading edge of the bolus for CSM and puree.

	CSM	Puree	Total
Oral cavity	1	3	4
Oropharynx-valleculae	33	34	67
Hypopharynx-pyriiformsinus	8	5	13
Total	42	42	84

$p=0.096$.

Wilcoxon signed-rank sum test.

Table 3. Post-swallow residue.

A. Dorsum of the tongue

	CSM	Puree	Total
Hal for more	0	0	0
Less than half	2	0	2
Trace	16	4	20
None	24	38	62
Total	42	42	84

$p=0.001$.

C. Valleculae

	CSM	Puree	Total
Hal for more	2	0	2
Less than half	15	23	38
Trace	14	16	30
None	11	3	14
Total	42	42	84

$p=0.047$.

B. Floor of the mouth

	CSM	Puree	Total
Hal for more	2	0	2
Less than half	1	0	1
Trace	2	1	3
None	37	41	78
Total	42	42	84

$p=0.066$.

D. Pyriiform sinus

	CSM	Puree	Total
Hal for more	0	0	0
Less than half	15	11	26
Trace	9	14	23
None	18	17	35
Total	42	42	84

$p=0.536$.

Wilcoxon signed-rank sum test.

Table 4. Penetration-aspiration scale.

	CSM	Puree	Total
1	40	38	78
2	0	0	0
3	0	2	2
4	1	1	2
5	1	1	2
6	0	0	0
7	0	0	0
8	0	0	0
Total	42	42	84

$p=0.751$.

Wilcoxon signed-rank sum test.

With the CSM, there were two cases of laryngeal penetration that reached the vocal folds, and with the pureed food, there were four cases of laryngeal penetration, two of which did not reach the vocal folds and two of which did ($p = 0.751$; see Table 4).

Discussion

1. Efficacy of CSM as a training food for chewing and swallowing

We developed the CSM as a training food for use in direct training, particularly for inducing chewing and swallowing. In the case of conventional foods, the properties of the food may mean that it scatters in the pharynx during chewing, which can lead to aspiration. In addition, in the case of two-phase food, which consists of liquid and solid pieces, it is reported that the components with low viscosity are transported to the hypopharynx earlier [7–9]. Such conditions markedly increase the risk of aspiration in patients with dysphagia. Therefore, we designed the CSM to have two features: (1) an initial hardness that requires chewing and thus induces chewing, bolus formation, and transport of the bolus (stage II transport); and (2) the texture transforms with chewing to a pureed food such that it can be swallowed with a minimal risk of aspiration.

After testing the CSM on patients with chewing and swallowing difficulties, we found that the number of chewing cycles was significantly larger for the CSM than with the pureed food. The location of the bolus during the first swallow was in the valleculae in many cases for both the CSM and pureed food. The number of swallows was approximately two for both the CSM and pureed food, and there was no occurrence of aspiration with either test food. These findings suggest that when ingested by persons with dysphagia, CSM can recreate the series of motions involved in chewing and swallowing by appropriately inducing chewing, which in turn leads to bolus formation, bolus transport, and finally swallowing.

For both the CSM and pureed food, the amount of

bolus residue in the oral cavity and pharynx was within the range of Level 2 (trace) to Level 3 (less than half) residue, and there was no significant difference in the rate of residue in the pyriform sinus. This finding implies that the CSM has similar properties to pureed food immediately before swallowing, meaning that even patients with dysphagia, with their reduced pharyngeal constriction ability, can swallow it easily.

We did not observe any significant difference between the two test foods in terms of the rate of pharyngeal penetration. This finding suggests that the CSM does not excessively liquefy or congeal when chewed and mixed with saliva but rather has similar properties to pureed food.

2. Comparison between elderly participants who live at a residential facility and have no dysphagia and those with dysphagia

In the past, we conducted a similar study involving 23 elderly people (mean age: 83 ± 9 years) who were living in a residential facility, had no dysphagia, and ingested their food normally [15]. A comparison between the participants in the previous study and those in the present study revealed that both sets of participants exhibited significantly higher amounts of chewing with the CSM than with the pureed food. The results of the amount of residue were also the same for both sets of participants. Specifically, while there were differences in the amounts of residue in the dorsum of the tongue, valleculae, and pyriform sinus, these were all within the range of Level 2 to 3 (i.e., trace to less than half) for both the CSM and pureed food. However, among the participants in the previous study, the most common location (40.6%) of the leading edge of the bolus at swallowing initiation in the case of pureed food was the oral cavity, but among the participants in the present study, the equivalent location was the valleculae. Another difference was that compared to the participants in the previous study, the participants in the present study exhibited a higher number of chewing cycles for both the CSM and pureed food.

One possible reason why the location of the leading edge of the puree bolus at swallowing initiation tended to be the valleculae for patients with dysphagia might be that there was a greater rate of stage II transport and premature spillage of the bolus. Because they have reduced tongue function, patients with dysphagia experience difficulty with bolus formation and transportation of the bolus from the oral cavity to the pharynx [16–18]. Thus, unlike elderly people who retain their oral cavity functions, patients with dysphagia are unable to swallow the bolus whole while it is held in the oral cavity, and therefore, must transport the bolus several times. The latter would explain why the bolus reached as far as the valleculae at the time of swallowing initiation. On the other hand, an inability to keep the tongue in contact with the soft palate during chewing might explain the high rate of

premature spillage of the bolus in this group of patients.

3. Application of CSM

CSM can serve as a training food for chewing and swallowing, if the person who ingests it meets the following criteria: (1) must notice that there is a solid piece of food in their oral cavity and must have a sufficient level of consciousness to initiate chewing; (2) must have the ability to start chewing as instructed; and (3) must be able to do so without being in a reclined position, which would encourage premature spillage into the pharynx during chewing.

4. Limitations of this study

The results of this study demonstrated that the CSM successfully induces chewing, and its texture after chewing is transformed so that it can be swallowed as safely as pureed food. However, the results do not clarify the severity levels of dysphagia for which CSM-based chewing exercises can be applied effectively.

Chewing involves the synchronized motions of the jaw and tongue, including trituration. Since we could not visually confirm the synchronized motions of the jaw and tongue, we relied on the visual assessment of the vertical movement of the jawbone to measure the number of chewing cycles.

Acknowledgments

I would like to thank the members of the Department of Rehabilitation, Fujita Health University who cooperated with the research needed to complete this study.

References

- Logemann JA. Evaluation and treatment of swallowing disorders. 2nd ed. Austin Texas: Pro-Ed; 1998.
- Dodds WJ, Stewart ET, Logemann JA. Physiology and radiology of the normal oral and pharyngeal phases of swallowing. *AJR Am J Roentgenol* 1990; 154: 953–63.
- Palmer JB, Rudin NJ, Lara G, Crompton AW. Coordination of mastication and swallowing. *Dysphagia* 1992; 7: 187–200.
- Hiiemae KM, Palmer JB. Food transport and bolus formation during complete feeding sequences on foods of different initial consistency. *Dysphagia* 1999; 14: 31–42.
- Palmer JB. Bolus aggregation in the oropharynx does not depend on gravity. *Arch Phys Med Rehabil* 1998; 79: 691–6.
- Matsuo K, Saitoh E, Takeda S, Baba M, Fujii W, Onogi K, et al. Effects of gravity and chewing on bolus position at swallow onset. *Jpn J Dysphagia Rehabil* 2002; 6: 65–72. Japanese.
- 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.
- Takeda S, Saitoh E, Matsuo K, Baba M, Fujii W, Palmer JB. Influence of chewing on food transport and swallowing. *Jpn J Rehabil Med* 2002; 39: 322–30. Japanese.
- Kang SH, Kim D, Seo K, Seo JH. Usefulness of video fluoroscopic swallow study with mixed consistency food for patients with stroke or other brain injuries. *J Korean Med Sci* 2011; 26: 425–30.
- Baba M, Saitoh E. Indication of dysphagia rehabilitation. *Rinsho Reha* 2000; 9: 857–63. Japanese.
- Ozaki K, Kagaya H, Yokoyama M, Saitoh E, Okada S, Gonzalez-Fernandez M, et al. The risk of penetration or aspiration during videofluoroscopic examination of swallowing varies depending on food types. *Tohoku J Exp Med* 2010; 220: 41–6.
- Japan Care Food Conference. Available from: <http://www.udf.jp/about/table.html> (cited 2014 April). Japanese.
- Shoushokuhyou Notification, No. 277, June 23, 2011, Food Labeling Division, Consumer Affairs Agency, Government of Japan. Japanese.
- Rosenbek JC, Robbins JA, Roecker EB, Coyle JL, Wood JL. A penetration-aspiration scale. *Dysphagia* 1996; 11: 93–8.
- Nakagawa K, Matsuo K, Shibata S, Inamoto Y, Ito Y, Abe K, et al. 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: 72–8.
- Clark HM, Henson PA, Barber WD, Stierwalt JA, Sherrill M. Relationships among subjective and objective measures of tongue strength and oral phase swallowing impairments. *Am J Speech Lang Pathol* 2003; 12: 40–50.
- Pouderoux P, Kahrilas PJ. Deglutitive tongue force modulation by volition, volume, and viscosity in humans. *Gastroenterology* 1995; 108: 1418–26.
- Lee JH, Kim HS, Yun DH, Chon J, Han YJ, Yoo SD, et al. The relationship between tongue pressure and oral dysphagia in stroke patients. *Ann Rehabil Med* 2016; 40: 620–8.