

## —原著—

## トレハロースタブレットの口腔保湿に対する効果の分析

川崎真依子<sup>1)</sup>, 鈴木亜夕帆<sup>2)</sup>, 坂井裕次<sup>3)</sup>, 相田美和<sup>4)</sup>, 五十嵐敦子<sup>5)</sup>, 渡邊智子<sup>2)</sup><sup>1)</sup>新潟大学大学院医歯学総合研究科 生体歯科補綴学分野<sup>2)</sup>千葉県立保健医療大学健康科学部栄養学科<sup>3)</sup>株式会社ブルボン製品開発部 海外製品開発課<sup>4)</sup>新潟大学大学院医歯学総合研究科 口腔生化学分野<sup>5)</sup>新潟大学歯学部 口腔生命福祉学科

## Analysis of Oral Moisturizing Effects of Trehalose Tablets

Maiko Kawasaki<sup>1)</sup>, Ayuho Suzuki<sup>2)</sup>, Yuji Sakai<sup>3)</sup>, Miwa Sohda<sup>4)</sup>, Atsuko Igarashi<sup>5)</sup>,  
Tomoko Watanabe<sup>2)</sup><sup>1)</sup> Divisions of Bio-Prosthetics, Niigata University Graduate School of Medical and Dental Sciences.<sup>2)</sup> Department of Nutrition Faculty of Health Science, Chiba Prefectural University of Health Sciences.<sup>3)</sup> Bourbon Corporation Product Development Center.<sup>4)</sup> Divisions of Biochemistry, Niigata University Graduate School of Medical and Dental Sciences.<sup>5)</sup> Department of Oral Health and Welfare, Faculty of Dentistry, Niigata University.

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**Abstract**

In recent years, the elderly population has been growing, and subsequently, the number of patients complaining of xerostomia symptoms has been increasing. In this study, we focused on the moisturizing effects of trehalose. We developed a trehalose tablet as a novel supplement for xerostomia and compared it to a sucrose tablet for verification of its moisturizing effects. A total of 72 healthy female subjects were randomly assigned to receive either the sucrose or trehalose tablet, followed by the other. Subjects received a 14-question survey soon after each tablet had dissolved completely in the mouth. For objective evaluation of the tablets, compression and solubility tests were performed. Based on sensory (subjective) evaluation, the trehalose tablets provided significantly more moisturization in the mouth and a sense of salivation than the sucrose tablets. Therefore, trehalose may confer a greater effect on moisturizing the mouth than sucrose. In addition, the trehalose tablets were about 2/3 as soft and dissolved 2 to 3 times more quickly than the sucrose tablets. These subjective and objective evaluations suggest that trehalose is a better supplement for maintaining oral moisture than sucrose, and may therefore be useful as a therapeutic supplement. The use of this convenient and safe therapeutic supplement could help improve the quality of life of elderly individuals who are suffering from xerostomia by allowing them to better enjoy meals and conversation.

**和文抄録**

近年、高齢者の急激な増加に伴い、口腔乾燥症の症状を訴える患者も増加の一途を辿っている。本研究では、トレハロースの保湿効果に着目し、口腔乾燥のための新しい治療補助食品として、トレハロースタブレットを開発した。保湿効果の比較の為に蔗糖のタブレットも同時に開発し、効果について主観的、客観的に検証を行った。実験には72名の健常な女性に参加して頂き、タブレットを試食して口腔内で完全に溶解して消失してから、その後14項目の

アンケート調査を実施した。また、タブレットの物性について客観的評価として、圧縮試験及び溶解度試験も合わせて実施した。主観的評価結果から、トレハロースが蔗糖と比較して、有意に口腔内の保湿に影響を与えている可能性が示された。また、客観的評価より、トレハロースタブレットは、蔗糖タブレットと比較して2/3程度軟らかく、口腔内で2~3倍早く溶解することが示された。これらの結果より、トレハロースタブレットは、口腔内の保湿に寄与することが示唆された。このことから、口腔内の乾燥で悩む高齢者に対しても効果が期待でき、食事や会話への楽しみ、QOLの向上へと繋げていく可能性が示唆された。

## Introduction

In recent years, the elderly population has been growing rapidly, and accordingly, the number of patients complaining of xerostomia symptoms has been increasing. Xerostomia is an oral disease in which decreased saliva production results in oral dryness, possibly as a result of adverse drug reactions, aging, decreased muscular strength, the effects of diseases such as Sjögren's syndrome, diabetes and stress.<sup>1)</sup>

Treatments for xerostomia have generally included mouthwashes, lozenges, oral ointments, artificial saliva and oral drugs. However, these treatments fail to alleviate xerostomia symptoms resulting from multiple factors in some elderly patients, causing much concern over the appropriate response.

Trehalose is a nonreducing sugar with two glucoses joined by an  $\alpha, \alpha$ -1,1-glucosidic bond that is not found in starch. Furthermore, trehalose has anti-cariogenic characteristics.<sup>2)</sup> With a sweetness 45% that of sugar, trehalose is more frequently being used in Japanese and Western confectionery and other types of cooking.<sup>3, 4)</sup> It can also be used to protect proteins and cells against drying and freezing by replacing water.<sup>5, 6)</sup> There has been a report that adding trehalose to bacteria<sup>7)</sup> or transferring trehalose synthase into human fibroblasts confers a tolerance to desiccation.<sup>8)</sup> Trehalose is therefore often used as a moisturizer in cosmetics and other products.<sup>9, 10)</sup>

In this study, we focused on the moisturizing effects of trehalose and developed a trehalose tablet as a new supplement for treatment of xerostomia. We concurrently developed a sucrose tablet for comparing and verifying various aspects of these moisturizing effects.

## Materials and Methods

### 1. Subjects

As xerostomia is a common ailment among women,

we enrolled 72 healthy female subjects with a mean age of  $30.28 \pm 7.87$  years. Informed consent was obtained from all subjects. Because this was a primary experiment, individuals who were currently suffering from dry mouth were excluded.

### 2. Methods

Subjects were randomly assigned with a number to determine the order of tablet sampling. The even-numbered subjects were first directed to take a sucrose tablet, followed by a trehalose tablet, while the odd-numbered subjects were first directed to have a trehalose tablet followed by a sucrose tablet. Subjects were blinded to the ingredients of the tablets and the order in which they were taken. The two samples were labeled "A" for sucrose and "B" for trehalose (Figure 1). Between sampling, subjects rested for 5 min and rinsed to exclude bias based on the order of sampling. To exclude the effects of differences in tablet dissolution time, subjects were asked to spit out the remaining portion of the tablets that had not dissolved in the mouth after 1 min. Subjects received a 14-question survey soon after the second tablet had dissolved completely in the mouth (Table 1). Questions 1-4 evaluated both tablets (sucrose or trehalose) with



A: Sucrose, B: Trehalose

Figure 1: Trehalose & Sucrose samples