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# Validation of a novel diagnostic tool for decreased tongue pressure

Yoshiki Imamura<sup>1,2,3</sup>  | Najla Chebib<sup>1</sup> | Midori Ohta<sup>1,4</sup> |  
Regina Maria Schulte-Eickhoff<sup>5</sup> | Mustapha Mekki<sup>6</sup> | Martin Schimmel<sup>1,7</sup>  |  
Itsuka Arakawa<sup>7,8</sup>  | Christophe Graf<sup>5</sup> | Yuji Sato<sup>2</sup> | Frauke Müller<sup>1</sup>

<sup>1</sup>Division of Gerodontology and Removable Prosthodontics, University Clinics of Dental Medicine, University of Geneva, Geneva, Switzerland

<sup>2</sup>Department of Geriatric Dentistry, School of Dentistry, Showa University, Tokyo, Japan

<sup>3</sup>Yoshiki Imamura Meikai University, School of Dentistry, Division of Fixed Prosthodontics, Saitama, Japan

<sup>4</sup>Department of Removable Prosthodontics & Gerodontology, Tokyo Dental College, Tokyo, Japan

<sup>5</sup>Department of Rehabilitation and Geriatrics, University Hospitals Geneva, Geneva, Switzerland

<sup>6</sup>Division of Fixed Prosthodontics and Biomaterials, University Clinics of Dental Medicine, University of Geneva, Geneva, Switzerland

<sup>7</sup>Department of Reconstructive Dentistry and Gerodontology, School of Dental Medicine, University of Bern, Bern, Switzerland

<sup>8</sup>Comprehensive Dental Care, The Nippon Dental University Niigata Hospital, Niigata, Japan

## Correspondence

Yoshiki Imamura, Department of Geriatric Dentistry, School of Dentistry, Showa University, 2-1-1 KT-Bld 3F Kitasenzoku Ota Ward, Tokyo, Japan.  
Email: [imamu1201@dent.showa-u.ac.jp](mailto:imamu1201@dent.showa-u.ac.jp)

## Abstract

**Introduction:** Reduced tongue pressure may render eating and swallowing difficult. The purpose of this study was to investigate whether the tongue training device can also be used as a diagnostic device and whether its sensitivity and specificity are equal to the numerical tongue pressure measuring device.

**Material and Methods:** The target group is patients aged 70 years and over who are hospitalised for rehabilitation. Tongue pressure was measured by both, a tongue pressure measuring instrument and a tongue training tool. The diagnosis of the reduced tongue pressure was made with the tongue pressure measuring instrument and set the verified with the novel tongue training tool.

**Results:** Sixty-two participants were included in the study. Forty-five were classified by the tongue pressure measuring device and 53 by the tongue training device as 'low tongue pressure'. Spearman correlation confirmed a positive correlation between the tongue pressure measuring device and the tongue training device  $r_s = 0.800$ ,  $p = 0.01$  level (2-tailed). The tongue training device test identified sensitivity was 100%, and its specificity was 52.9%. The AUC of the ROC curve is 0.901.

**Conclusion:** The tongue training device seems a simple, safe and readily available alternative to the tongue pressure measuring device for the diagnosis of low tongue pressure, with an excellent sensitivity and very good specificity.

## KEYWORDS

geriatric patients, oral hypofunction, Peko-Panda, swallowing disorders, tongue pressure, TPM-01

## 1 | INTRODUCTION

Along with the demographic ageing of the world population, physical, mental and social frailty of elders is increasing in prevalence.<sup>1,2</sup>

The decline in oro-facial function is called 'Oral Frailty' for which the Japanese Society of Gerodontology (JSG) created a conceptual diagram divided into four stages based on seven parameters: oral hygiene, oral dryness, occlusal force, tongue-lip motor function,

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tongue pressure, chewing function and swallowing function. Oral hypofunction is defined as a state when three or more signs are present.<sup>3</sup> Decreased tongue pressure refers to a condition where the pressure that can be generated between the tongue versus the palate is reduced owing to chronic functional decline of the tongue muscles.<sup>4,5</sup> As the condition progresses, mastication, food bolus formation and swallowing are impaired, which may impair digestion and absorption of nutrients and finally even lead to insufficient food intake to meet the amount of nutrition required.<sup>6-11</sup>

A variety of instruments are used in the oral function tests recommended by JSG to understand the state of deterioration of oral function. A tongue pressure inspection device (JMS tongue pressure measuring instrument, TPM-01, JMS Co., Ltd.) has been developed in Japan to easily obtain objective numerical evaluation of oral function.<sup>12,13</sup> The device measures the change in internal air pressure whilst crushing a balloon-shaped probe between the anterior part of the palate and the tongue using a maximum force as illustrated in Figure 1. The Peko-Panda tongue training device is made of rubber silicone. It consists of a handle and dome resembling a Panda's nose that snaps to a flat position when pushed at a given force. The device is placed in the mouth between the tongue and the anterior palate, and the patient crushes the Panda's nose with a maximum force. When the force is released, it snaps to its original shape by elasticity. There are four different Peko-Pandas with increasing levels of force required to crush the Panda's nose (S: 10 kPa: pink, MS: 15 kPa: purple, M: 20 kPa: green, H: 30 kPa: yellow). This training tool can be used by the patient himself and proved effective in improving

tongue function. The Peko-Panda was designed as a tongue training tool after low tongue pressure was diagnosed with TPM-01. The question arises if the Peko-Panda can also be used as diagnostic tool.

The aim of this study was to investigate whether the tongue training device (Peko-Panda) can be used as a diagnostic device for the evaluation of tongue pressure in the framework of the oral function evaluation and whether the sensitivity of this tool is equal to the tongue pressure measurement device (TPM-01). The null hypothesis to be tested was that there is no difference in sensitivity and specificity between the TPM-01 and the Peko-Panda as a diagnostic tool for low tongue pressure.

## 2 | MATERIAL AND METHODS

### 2.1 | Ethical approval

The protocol of a larger study on oral hypofunction and nutritional state in geriatric patients was approved by the Swiss Cantonal Ethics Committee (CCER 2019-01338). In this paper, only the results from the tongue pressure testing are reported.

### 2.2 | Participants

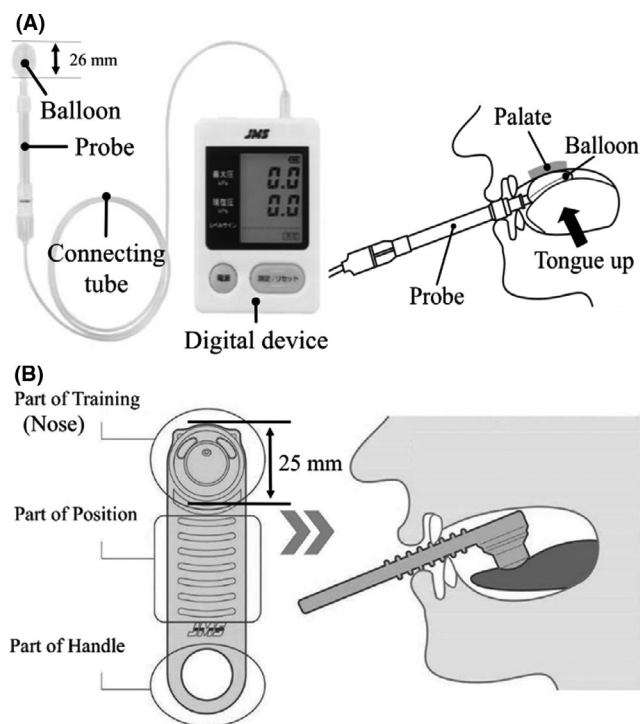
Patients admitted at the Loëx Hospital of the Geneva University Hospitals (HUG) between October 2019 and July 2020 were consecutively screened and included when meeting inclusion criteria, and written, informed consent was obtained. Inclusion criteria comprised the following:

- age 70 years or more,
- hospitalised in University Hospitals of Geneva (Loëx),
- ability to follow simple instructions and perform the tests,
- understand French,
- ability to answer the questionnaire,
- signing the consent form.

Patients with tube/intravenous feeding, poorly controlled diabetes, with gastrointestinal diseases or symptoms (nausea, vomiting, diarrhoea, constipation) affecting oral intake were excluded. Patients taking an antimicrobial treatment at time of screening were excluded as well.

### 2.3 | The tongue pressure testing devices

Two different instruments were used to measure the tongue pressure. The tongue pressure measuring instrument (TPM-01, JMS Co., Ltd.) (Figure 1) consists from a flexible silicone balloon of 28 mm length and 18 mm diameter. This probe is connected via a thin air tube to a digital manometer. The instrument has previously been validated.<sup>12</sup> For testing the tongue pressure, the probe of the TPM-01,



**FIGURE 1** A: The TPM-01 tongue pressure measurement device (JMS Co. Ltd., Tokyo, Japan) B: The Peko-Panda tongue training device (JMS Co. Ltd., Tokyo, Japan)

the pressure receiving part (balloon part) is placed in the front part of the palate. The patient is asked to close the lips and to crush the balloon with the tongue against the palatal rugae for 7 s with maximum force. The highest of 3 measurements in kilo-Pascal [kPa] is defined as the maximum tongue pressure. Tongue pressure is considered low when the pressure obtained is less than 30 kPa. The measurement accuracy of TPM-01 is  $\pm 1$  kPa, when the set pressure value is 19.6 kPa and the pressurisation range is 0.0 to 80.0 kPa.

The alternative tongue pressure measuring device consists of a series of Peko-Panda instruments (Peko-Panda, JMS Co., Ltd.) (Figure 1). Peko-Panda is conceived as a tongue training device. The training part of Peko-Panda is placed on the tongue, and the positioning part is held by the teeth. After positioning the device, training is performed by pushing up the Panda's 'nose' with the tongue. Peko-Panda is set to the tongue pressure value based on TPM-01. The forces to 'snap' the Panda's noses are indicated by the manufacturer as S: pink: 10 kPa, MS: purple: 15 kPa, M: green: 20 kPa, H: yellow: 30 kPa, respectively.

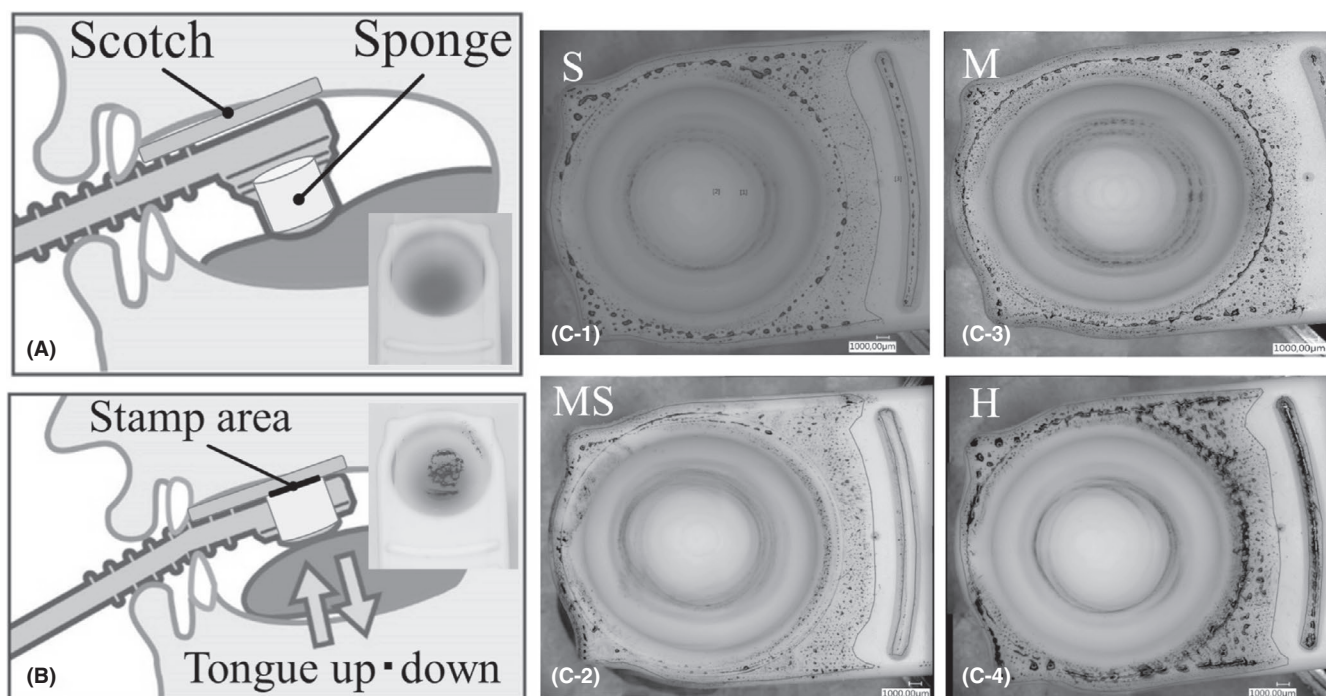
The training tool was modified for this study to fit its purpose as a simple and cost-efficient novel diagnostic tool. A plaque disclosing pellet (Paro plak-pellets, Paro Swiss) was placed inside the convex part of the Peko-Panda and a scotch tape sealed the upper surface (Figure 2A). The scotch tape is marked when the dome of the device had snapped successfully (Figure 2B). The mark provides an objective judgement as to whether or not the patient succeeded to push the panda's nose, indicating that the hardness of each Peko-Panda level has been cleared (Figure 2B). The modified Peko-Pandas were used in increasing order until the patient did no more manage to snap

the nose. The highest level of modified Peko-Panda force they were able to produce the colour mark was noted. Patients who cannot snap the yellow Peko-Panda with an estimated hardness of 30 kPa (H: yellow) are diagnosed with a 'low tongue pressure'.<sup>3</sup> The three lower force levels allow estimating the severeness of the low tongue pressure.

As a preliminary evaluation, the two instruments were compression tested and area calculated. The performance of two instruments was evaluated in a bench experiment using a universal testing machine AGX plus (Shimadzu Corporation) in compression mode coupled with a 500 Newtons force sensor. The TPM-01 balloon was compressed 5 times each until the pressure reached 4 levels (10 kPa, 20 kPa, 30 kPa, 40 kPa) (Figure 2C). The four types of Peko-Panda (S/MS/M/H) were compressed three times each until the nose snapped. The compressed area of the two instruments was measured. The surface area of the TPM-01 balloon was calculated after being measured with a precision measure. The area under pressure of Peko-Panda was measured by a calibrated digital microscope (VHX 5000–Keyence).

## 2.4 | Protocol

Participants were screened by the medical personnel (RS) of the geriatric ward for their inclusion and exclusion criteria. An information sheet was handed to the participant who had at least 24 h before signing the consent form. The examination was performed in the patient's room by two dentists (YI and MO) familiar with the



**FIGURE 2** Movement of modified Peko-Panda. A: The scotch tape on the top of nose of the Peko-Panda. B: The mark is made by the patient whilst snapping the Peko-Panda's nose. C: The effective surface of Peko-Panda's nose (S· MS· M· H) as measured and photographed with the digital microscope (VHX 5000–Keyence, Japan)

examination contents. Information on the patient's demographics, medical diagnoses and drug intake was retrieved from the medical record. A comprehensive battery of oral function testing were performed (oral hygiene, oral dryness, occlusal force, tongue-lip motor function, tongue pressure, chewing function and swallowing function). The instructions for the various tasks were supported by comic drawings with text bubbles, displayed to the participants on a tablet PC. The entire examination took on average 50 min per participant. This paper reports only the tongue pressure.

## 2.5 | Statistical analysis

The sample size was calculated G\*Power 3.1.9.2 (Institute of Experimental Psychology, Heinrich Heine University)<sup>14</sup> based on the relation between oral function (tongue pressure) and nutritional state. According to Matsuo's study<sup>15</sup> comparing oral function (tongue pressure) in 84 malnourished patients and 173 normal patients, the average tongue pressure of malnourished patients is 16.7 N (SD 8.1) and the tongue pressure of normal patients is 25.3 N (SD 10.2). The effect amount was medium. The sample size was calculated by G-Power using the calculated effect amount  $d = 0.50$ . The required total sample size was calculated to be 54. Also, according to Maxwell,<sup>16</sup> using a method corresponding to the effect size of Cohen,<sup>17</sup> Medium:  $N = 52 + p$ . Since the number of explanatory variables in this research is 3,  $n = 55$ . ( $n$ : number of samples required,  $p$ : number of explanatory variables). Therefore, the sample size in this study was determined to be 60.

Normal distribution of the data was verified by means of Kolmogorov-Smirnov normality test. Two-tailed  $t$  tests was used to analyse the effect of age and sex on the tongue pressure from the two groups (Peko-Panda and TPM-01). We also examined whether there is a correlation between TPM-01 and Peko-Panda using the Spearman's correlation test.

Sensitivity (% participants are correctly identified as presenting with low tongue pressure) and specificity (% participants are correctly identified as not presenting with low tongue pressure) are expressed as percentages. SPSS version 26 (IBM) was used for the statistical analysis, and the statistical significance level was  $p = 0.05$ .

## 3 | RESULTS

### 3.1 | Participants

Participants were recruited from the consecutively admitted patients of the Loëx Hospital. From this patient pool, 249 patients were screened for inclusion and exclusion criteria. Finally, 66 eligible participants were included, signed the informed consent and 62 completed the present experiments. The mean age was  $82.3 \pm 9.1$  years and 62.9% of the patients were female. The demographic characteristics of the included patients and the reasons for their hospitalisation are presented in Table 1.

### 3.2 | Tongue pressure

As a result of the preliminary evaluation of TPM-01, it was calculated that the approximate curve is  $y = 0.6693x$  and the area under pressure is  $669.3 \text{ mm}^2$ . After the TPM-01 balloon was measured, the predicted surface area was calculated to be  $643.0 \text{ mm}^2$ . From the surface area calculated from the approximate curve and the balloon calculation, the calculated surface area error was 3.9%. As a result of the preliminary evaluation of Peko-Panda, the area under pressure was calculated by a digital microscope to be  $605 \text{ mm}^2$ . Based on this value, the pressure was calculated after compression with a universal tester. The S of Peko-Panda was 9.81 kPa, the MS was 14.00 kPa, the M was 19.89 kPa, and the H was 30.57 kPa (Table 2). The pressure announced by the manufacturer is 10 kPa for S, 15 kPa for MS, 20 kPa for M, and 30 kPa for H.

The TPM-01 revealed an average tongue pressure of  $24.2 \pm 9.1$  kPa. It was 24.7 kPa for men, and 23.9 kPa for women (n.s.). As measured by TPM-01, 45 patients (72.6%) were categorised as having 'low tongue pressure (less than 30 kPa)' (Table 3). When measuring the tongue pressure with the Peko-Panda, 9 patients managed to snap the Panda's nose with the pink (10 kPa), 11 patients with the purple (15 kPa), 27 patients with the green (20 kPa) and 9 patients with the yellow (30 kPa) Peko-Panda.

As measured by means of the Peko-Pandas, 53 (19 men and 34 women) participants (85.5%) were categorised as having 'low tongue pressure'. The statistical analysis revealed no significant difference in tongue force between gender, when using either the TPM-01 or the Peko-Pandas (Table 3). From the 26 patients aged 70–79 years, nine were diagnosed with low tongue pressure. From the 25 patients in their 80s, eight presented with a low tongue pressure. Amongst the 11 patients aged 90 years or more, no participant presented with low tongue pressure. Spearman correlation confirmed a positive correlation between TPM-01 and Peko-Panda  $r_s = 0.800$ ,  $p = 0.01$  level (2-tailed).

### 3.3 | Sensitivity and specificity

In order to measure the diagnostic accuracy of Peko-Panda, sensitivity (true positive rate) and specificity (true negative rate) with regard to the diagnosis from the TPM-01 test were calculated. Sensitivity is the percentage of people with low tongue pressure who were actually diagnosed with low tongue pressure by the Peko-Panda test. The specificity (true negative rate) is the percentage of those who had their normal tongue pressure confirmed by the Peko-Panda test. JSG defines low tongue pressure below 30 kPa. If the cut-off value is less than 30 kPa, the Peko-Panda test identified sensitivity of Peko-Panda was 100%, and the specificity was 52.9%. If the cut-off value was less than 20 kPa, Peko-Panda had a sensitivity of 89.5% and a specificity of 79.1%. If the cut-off value was less than 15 kPa, Peko-Panda had a sensitivity of 72.7% and a specificity of 86.3%. If the cut-off value was less than 10 kPa, Peko-Panda had a sensitivity of 66.7% and a specificity of 93.2%.



The ROC curve of Peko-Panda is shown in Figure 3, and the AUC (area under the curve) was 0.901. The optimum cut-off value is calculated by defining the Cut-off-point as the minimum distance from the upper left corner of the ROC curve. The coordinates of that point were (0.578, 1). If the cut-off value was less than 20 kPa, Peko-Panda's AUC was 0.878. If the cut-off value was less than 15 kPa, the Peko-Panda AUC was 0.902. If the cut-off value was less than 10 kPa, Peko-Panda's AUC was 0.876.

**TABLE 1** Demographic characteristics of the included patients and the reasons for their hospitalisation

	Years $\pm$ SD	N (%)
Sex		
Male		23 (37.1)
Female		39 (62.9)
Age	82.3 $\pm$ 9.1	
Reason for hospitalisation		
Waiting for LTC placement		17 (27.4)
Fracture		19 (30.6)
Physical rehabilitation due to weakness		7 (11.3)
Poor physical condition		3 (4.8)
Heart disease		4 (6.5)
Lower back pain		4 (6.5)
Cognitive impairment		1 (1.6)
Other		7 (11.3)

**TABLE 2** Verification of the pressure required to snap the Peko Panda's nose at the four pre-defined levels. Three measurements were averaged per hardness level

Manufacturer notation [kPa]	Peko-Panda			
	S	MS	M	H
	10	15	20	30
Average [kPa]	9.81	14.00	19.89	30.57
SD	0.67	1.14	1.64	2.32

**TABLE 3** Prevalence of diagnosis of tongue pressure, as diagnosed with the TPM-01 and the Peko-Panda

	Low tongue pressure			Normal tongue pressure			Sex
	Mean $\pm$ SD	Median	N (%)	Mean $\pm$ SD	Median	N (%)	
TPM-01			45 (72.6)			17 (27.4)	>.05
Male			17 (27.4)			6 (9.7)	
Female			28 (45.2)			11 (17.7)	
Age	82.6 $\pm$ 6.5	82.0		81.7 $\pm$ 7.0	81.0		>.05
Peko-Panda			53 (85.5)			9 (14.5)	
Male			19 (30.6)			4 (6.5)	
Female			34 (54.8)			5 (8.1)	
Age	82.2 $\pm$ 6.7	82.0		82.9 $\pm$ 7.0	81.0		

## 4 | DISCUSSION

Our recorded tongue pressures are in accordance with the values reported by Matsuo et al.<sup>15</sup> Neither TPM-01 nor Peko-Panda showed significant differences in age and sex. This may be due to the very high age of the study cohort. Utanohara et al.<sup>13</sup> confirmed that gender differences disappear between genders beyond the age of 60 years. For revealing the age-effect, a larger range of ages would have been necessary. However, the cohort was not designed to for detecting an age effect, as only geriatric patients were included. The main purpose was to validate the Peko-Panda as a diagnostic instrument for detecting low tongue pressure in a purely geriatric population.

The sensitivity of the modified Peko-Panda was very high, yet the specificity was much lower, so the null-hypothesis of the study cannot be rejected for the sensitivity but can be rejected for the specificity.

The ROC curve of Peko-Panda was calculated with TPM-01 as the diagnostic tool and 30 kPa as the cut-off value. The high AUC (area under the curve) confirmed that the Peko-Panda is a useful alternative tool. The optimum cut-off value is calculated by defining the minimum distance from the upper left corner of the ROC curve. This coordinate indicates that the optimal cut-off value for Peko-Panda is 20 kPa, confirming a very high sensitivity with only very few true positive diagnoses being overlooked. The AUC of the ROC curve remained high at all cut-off values. This suggests that Peko-Panda has a high diagnostic value in each hardness level.

The Peko-Panda is a simple and cost-efficient device that can be used as a diagnostic tool within the context of a geriatric assessment of oral function. An added advantage is that it can be subsequently used for training the tongue, where necessary. Training incompetent tongue pressure, and hence improving swallowing function, may be contributing to preventing aspiration pneumonia, one of the most prevalent causes of death in elders.<sup>18</sup> The advantages for using the modified Peko-Panda in comparison with the gold standard TPM-01 are its low cost, re-usability and last but not least its playfulness. It instantly rewards the patient and provides a welcome success-event when the Peko-Panda snaps. No electronics or batteries are required, rendering the Peko-Panda an environmentally friendly

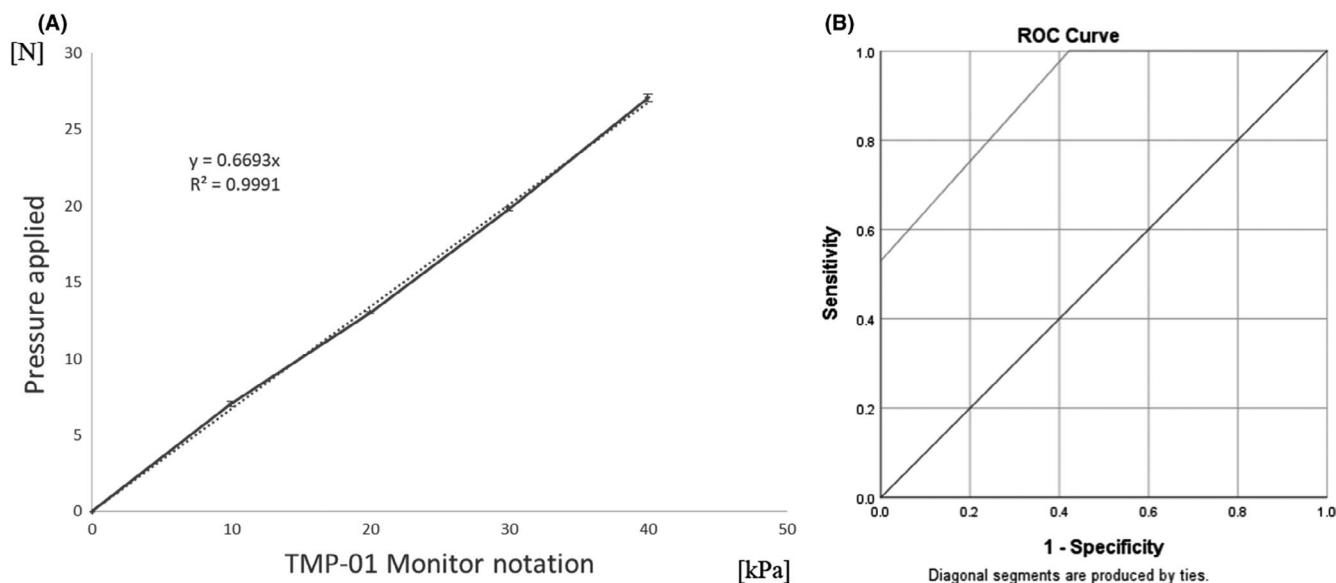


FIGURE 3 A: Force Calibration of TPM-01. B: ROC curve of Peko-Panda

device. An important advantage is that it is too big to swallow and presents therefore no risk of aspiration; it is a safe device that the patient can use at home without supervision. It can be re-used multiple times in the same patient and allows to monitor therapy results over time. However, the modified Peko-Panda also presents a disadvantage. It does not provide a continuous reading but indicates the tongue pressure only on 4 levels. Furthermore, the verification of the success may not as easy, if used in the unmodified standard version. Marking with Paro-paper helps, but needs preparation. However, the modified Peko-Panda proved to be a valuable tool to diagnose low tongue pressure. The high sensitivity indicates a 'safe' diagnosis, as no low tongue pressure was left undiagnosed. However, the specificity of 52.9% may introduce a small percentage of positive diagnoses, where the condition is not present. At any rate, prescribing exercises for the tongue, where it may not necessarily be needed has no negative side effects and the associated cost in terms of finances, time and effort are low. In short, Peko-Panda could be used as a good test to detect low tongue pressure in the general population.

A simple test, not requiring sophisticated apparatus, lowers the threshold to include the testing of tongue pressure into the geriatric assessment, as it is performed for example at admission to a geriatric ward. The novel testing method by using the modified Peko-Panda device is simple to perform, the devices could be easily available in any clinical setting. The proposed modification by adding ink and a scotch tape to verify if the Peko-Panda has snapped could be performed in a few minutes, without any extensive training of the medical personnel.

One of the shortcomings of the study is that only 22% of the eligible participants agreed to participate. Often refusal was based on the already busy schedule during the rehabilitation stay in the Hospital, or some did not see a benefit in participation, as no financial compensation was offered. The most obvious reason for refusal was physical weakness and fatigue. Since the currently reported

experiments were part of a larger study, patients had to be sufficiently fit to undergo the complete test-battery. Hence it is likely that the frailest patients, who would have fulfilled the criteria for low tongue pressure, would not participate.

Age is expected to be one of the factors that goes along with a decrease of tongue pressure.<sup>5</sup> The loss of lean muscle mass with age is well documented in the literature, even for the masseter muscle, which loses around 40% of its cross-sectional area with age.<sup>19</sup> However, the loss of muscle mass is particularly pronounced in muscle groups that are under-used. The loss of teeth for example, which is associated with complete denture wearing, represents an under-use of the masseter muscle, and a corresponding significantly larger loss in cross-sectional area has been reported. Re-training by restoring the dentition with implant reconstructions, and hence improving the chewing activity, may be a beneficial exercise for re-gaining muscle mass.<sup>20</sup>

## 5 | CONCLUSION

In conclusion, the modified Peko-Panda seems a simple, safe and readily available alternative to the TPM-01 device for the diagnosis of low tongue pressure, with an excellent sensitivity and very good specificity. Its low cost, playful application and ready availability may facilitate including this novel diagnostic tool in a geriatric assessment.

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## CONFLICT OF INTERESTS

The authors have no conflict of interests to declare.

## AUTHOR CONTRIBUTION

Yoshiki Imamura initiated the study together with FraukeMuller and Midori Ohta and Najla Chebib, Yuji Sato, Martin Schimmel and Itsuka Arakawa, and conceptualised and designed the study, collected and analysed data, and drafted and revised the manuscript; Christophe Graf, Regina Maria Schulte-Eickhoff, contributed to data collection and analysis during the systematic search; Mustapha Mekki contributed to data collection and instrument accuracy research.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

## ORCID

Yoshiki Imamura  <https://orcid.org/0000-0003-1545-4120>

Martin Schimmel  <https://orcid.org/0000-0001-9700-5534>

Itsuka Arakawa  <https://orcid.org/0000-0003-2168-1469>

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