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Reliability of a new bite force device for measuring occlusal bite force in healthy dentate subjects

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ABSTRACT

Background: Bite force is a key indicator of masticatory function and oral health. While the GM-10 device is widely used for assessing bite force, its cost and complexity limit its routine clinical use. The Oramo-bf, a newer portable sensor, offers a more accessible alternative; however, it lacks validation against established systems.
Objective: To assess the validity and reliability of the Oramo-bf device compared to the GM-10 transducer in measuring bite force among healthy adults.
Methods: Twelve healthy, fully dentate adults (mean age 24.4 ± 3.9 years; 10 females) underwent bite force testing using both the GM-10 (strain-gauge) and Oramo-bf (capacitive) devices. Each participant performed three maximal voluntary bites per device, with standardized positioning and rest intervals. Mean values were computed per device and side. Paired t-tests, Pearson correlation, repeated-measures ANOVA, and intraclass correlation coefficients (ICC) were used to assess differences, consistency, and reliability. A Bland–Altman analysis was used to examine the agreement between the devices.
Results: Oramo-bf recorded significantly higher bite force values than GM-10 (mean difference = 221.8 N, p = 0.003), with poor correlation between devices (r = 0.255, p = 0.424). Test-retest reliability was excellent for Oramo-bf (ICC = 0.936) and moderate for GM-10 (ICC = 0.698). No significant intra-device variability was observed across repeated trials for either device (Oramo-bf: p = 0.711; GM-10: p = 0.118). The GM-10 exhibited greater within-subject variability. Bland–Altman analysis showed wide limits of agreement and a systematic bias, with GM-10 underestimating bite force relative to Oramo-bf.
Conclusion: Oramo-bf demonstrates excellent reliability and usability for bite force assessment but shows limited agreement with the GM-10. Further research is needed to evaluate sensor-specific performance and clinical applicability before substituting standard transducers in practice.
CLINICAL SIGNIFICANCE: Oramo-bf device showed higher reliability compared to GM-10. However, the poor agreement and systematic bias between GM-10 and Oramo-bf suggest that the two devices with different sensor technologies differ significantly in their ability to accurately assess the bite force of dentate subjects.

1. Introduction

The capacity to proficiently bite, chew, and grind food is defined as masticatory function. This function is of paramount importance in sustaining dietary consumption, digestion, and overall quality of life. Mastication is considered a key component of oral function, based on the force and coordination of the masticatory muscles, acting in conjunction with the teeth, temporomandibular joints, and central and peripheral control systems [1].

One of the few markers that are used to measure the execution of chewing, or mastication, is bite force. The bite force is recognized as a direct and objective parameter that reflects the strength and efficiency of the stomatognathic system [2]. A variety of factors, such as age, gender, periodontal status, dental occlusion, temporomandibular joint health,

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and neuromuscular coordination, affect bite force [3,4]. Therefore, bite force measurement is critical for not only clinical applications, such as monitoring prosthetic and orthodontic treatment, assessing implant success, but also for detecting temporomandibular joint disorders and oral hypofunction or dysfunction [5]. Oral dysfunction, particularly in older individuals, is characterized by a reduction in a range of oral skills, including tongue pressure, occlusal strength, chewing efficiency, and oral hygiene, and has recently come to the forefront [6].

Several different appliances have been developed for measuring bite force. These include strain-gauge transducers, piezoelectric sensors, and pressure-sensitive films. Of these, the GM-10 device, a widely accepted portable transducer based on strain gauges, has been used extensively in research and clinical settings due to its reliability and accuracy in recording occlusal force [7]. However, the GM-10 system requires technical handling and regular calibration, and is relatively expensive, which may limit its broader use in routine dental practice or large-scale community screening programs. However, a novel device utilizing a capacitive surface pressure distribution sensor (Oramo-bf, Sumitomo Riko Co., Ltd., Japan) has recently been introduced to overcome these limitations. This device utilizes SR (Smart Rubber) sensor technology to digitally quantify occlusal force in a rapid and user-friendly manner. The device was specifically designed for the screening of oral hypofunction, it is lightweight, portable, and easy to operate, making it a potentially suitable equipment for general practice, geriatric care, and preventive dentistry [8].

Notwithstanding its increasing utilization in clinical contexts, the Oramo-bf has not yet undergone comprehensive validation in comparison with established devices, such as the GM-10. The cause for concern is the paucity of data on the measurement accuracy, reliability, and agreement with gold-standard transducers. Without proper validation, the clinical and research applications of the Oramo-bf remain ambiguous. As a result, it is crucial to assess its performance compared to the GM-10 to determine whether it can be used as a viable alternative in bite force measurement.

This study aims to validate the Oramo-bf biteforce meter by comparing its bite force measurements with those obtained using the GM-10 transducer in healthy adult participants. The study will evaluate not only the correlation but also the repeatability of the Oramo-bf to determine its suitability as a practical replacement for the GM-10 in clinical and research settings.

2. Materials and methods

This cross-sectional study was conducted at the Centre for Dental Medicine, University of Zurich, Switzerland. Participants were healthy, fully dentate individuals with normal oral function, no history of neuromuscular disorders, and clinically healthy dental and periodontal conditions. Exclusion criteria included individuals presenting with orofacial pain, those undergoing active orthodontic treatment, the presence of dental implants in the posterior region, and pregnancy. The Ethics Committee of the Canton of Zurich (KEK-Zurich) determined that this study did not require formal ethical approval (BASEC No Req-2025–00,480). All participants were enrolled only after receiving a thorough explanation of the study's objectives and providing verbal informed consent. Demographic and clinical information was collected for each participant, including age, gender, number of natural teeth, presence of oral pain, prior orthodontic treatment, and parafunctional habits such as bruxism.

All bite force measurements were conducted in a controlled clinical environment. Participants were seated comfortably in an upright position, with their head supported by the dental chair, and the median sagittal plane oriented perpendicular to the floor to standardize head posture.

Two assessment modalities were employed:

(1). Bite force measurement using a pressure transducer

(2). Occlusal force evaluation using a capacitive bite force sensor.

2.1. Measurement of bite force using a pressure transducer

Maximum bite force (MBF) was assessed using the GM-10 occlusal force gauge (Nagano Keiki Co., Ltd., Japan) (Fig. 1A), a digital hydraulic pressure system equipped with an 8.6 mm thick bite element. The device utilizes a vinyl-covered pressure sensor enclosed in a disposable polyethylene occlusal cap (17 mm wide, 5.4 mm high, 63.5 mm long), specifically designed for single-patient use to ensure hygiene and reliability during measurements.

Bilateral recordings were obtained beginning at the first molar region. Participants were instructed to bite down with maximum voluntary force, and each site was tested three times with a 30-second rest interval to prevent muscle fatigue. This process was repeated for the second molars and first and second premolars on both the left and right sides. Bite force values were displayed in Newtons (N) on the device's digital screen, and the mean of the three trials was calculated for each tooth position, which was then used for statistical analysis [9].

2.2. Assessment of occlusal force with the Oramo-bf device

The Oramo-bf (Sumitomo Riko Co., Ltd., Japan) (Fig. 1-B) is a portable, battery-operated occlusal force sensor designed for the rapid and non-invasive assessment of maximum occlusal force (MOF). Unlike conventional devices that rely on pressure-sensitive films, the Oramo-bf utilizes a capacitive-type sensor embedded in a thin, biocompatible sheet that is placed intraorally during measurement. When clenching

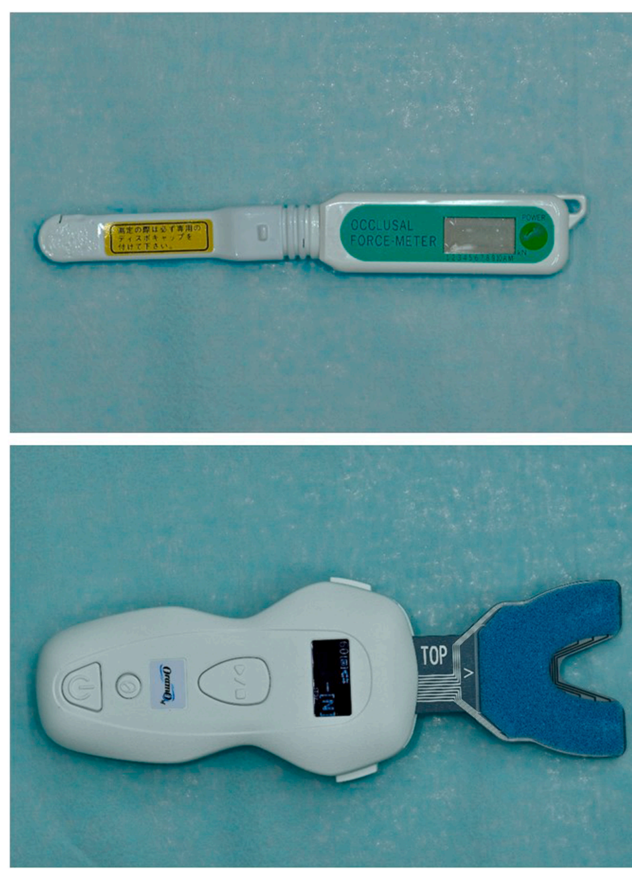

Fig. 1. Bite force measurement devices used in the study: (1-A) Bite force device using a pressure transducer (GM-10 occlusal force gauge, Nagano Keiki Co., Ltd., Japan), and (1-B) occlusal force device using a capacitive bite force sensor (Oramo-bf, Sumitomo Riko Co., Ltd., Japan).

occurs, the sensor detects changes in capacitance caused by applied pressure and converts these into real-time digital force values [10,11].

2.3. Standardized protocol for Oramo-bf measurements

The Oramo-bf measurements were performed using the same standardized participant posture as in the GM-10 testing protocol. With the participant in an upright seated position and the head properly supported, the sensor sheet was carefully placed between the dental arches. Participants were instructed to clench maximally for approximately three seconds. After the clenching task, the sensor sheet was removed, and the peak force value, displayed in Newtons (N), on the digital screen was recorded [10].

Each participant underwent three consecutive measurements, with short rest intervals between each trial to minimize the effects of fatigue. The mean value of the three recordings was computed and used further. The sensor sheet was used with a new disposable cover for each participant to ensure proper hygiene and infection control protocols.

2.4. Data analysis

Descriptive statistics were used to summarize bite force data. Paired *t*-test, Pearson correlation, and repeated-measures ANOVA were used for hypothesis testing. The reliability of the repeated measurements using each of the two devices was assessed using the intraclass correlation coefficient (ICC) and its 95 % confidence intervals, which represent the extent to which individuals' scores were consistent across the three test occasions, providing an estimate of the test reliability. A higher ICC value indicates greater reliability, meaning there is less variability in the measurements taken at the three different time points. The following cut-off points were used for interpreting ICC values: <0.5 – poor reliability, 0.5–0.75 – moderate reliability, 0.75–0.9 – good reliability, and >0.9 – excellent reliability.

Then, to assess systematic bias between the two devices, a Bland-Altman plot with multiple measurements (three consecutive tests) per subject was used to compare the measurements obtained by the GM-10 and Oramo-bf devices, with the GM-10 (mean of right and left measurements) serving as the reference method [12,13]. The differences between the two methods (X-axis) were plotted against the averages of the two methods (Y-axis). The IBM SPSS 23.0 and MedCalc 23.2.1 software programs were used for data analysis. The $p < 0.05$ was considered for statistical inferences.

3. Results

Twelve volunteers participated in this study, comprising 10 females, with ages ranging from 21 to 33 years (mean = 24.4; SD = 3.9). Table 1 summarizes the descriptive data on bite force measurements using the two devices. There was a significant difference in the GM-10 measurements between the right and left sides (mean difference = 94.3; p = 0.008), and the mean force was higher on the left side in 11 out of 12 subjects.

When using the GM-10 device, a moderate correlation was observed between measurements on the left and right sides ($r = 0.593$; $p = 0.042$). However, the overall GM-10 and Oramo-bf measurements did not correlate ($r = 0.255$; $p = 0.424$). Overall, the measurements obtained with the Oramo-bf device were significantly higher compared to those with the GM-10 (mean difference = 221.8; $p = 0.003$).

Table 1
Descriptive data of the bite force measurements, according to the device used.

Device / side		Mean (SD)	Min – Max	Range
GM-10	Right	311.7 (97.5)	191.0 – 545.7	354.7
	Left	405.9 (120.8)	273.3 – 612.3	339.0
	Overall	358.8 (97.6)	252.0 – 569.3	317.3
Oramo-bf		580.6 (208.6)	306.3 – 943.7	637.3

Fig. 2 shows the between-subject variations of measurements in the three consecutive tests for the two devices. No significant differences were found among the three tests for GM-10 ($p = 0.118$) and Oramo-bf ($p = 0.711$) devices. However, the variability in consecutive measurements, represented by the mean within-subject range of values (maximum-minimum), was higher for the GM-10 (117.3 ± 78.1) compared to the Oramo-bf device (86.1 ± 51.1).

The correlation coefficients between the three consecutive tests showed a significant correlation for GM-10 ($r > 0.919<0.739$; $p < 0.001$) and Oramo-bf ($r > 0.953<0.0.978$). Reliability analysis revealed ICC measures of 0.698 (0.502–0.842) and 0.936 (0.843–0.980) for the GM-10 and Oramo-bf devices, respectively. The interpretation of data revealed moderate reliability for GM-10 and excellent reliability for Oramo-bf, suggesting that Oramo-bf provides higher consistency across consecutive measurements.

Finally, the Bland-Altman plot was produced, revealing a reasonable discrepancy between the two devices (Fig. 3). A mean difference of −221.8 (95 % CI = −645.4 – 201.7) suggests a systematic bias between the devices, in which the GM-10 tends to underestimate the bite force compared to Oramo-bf, and the wide limits of agreement suggest poor agreement between the methods. Moreover, since the differences between the methods tend to decrease as the average measurements increase, a proportional bias seems to occur.

4. Discussion

This study focused on the comparability between two devices for measuring bite force based on two distinct technologies: a pressure transducer and a capacitive bite force sensor. Findings showed that the Oramo-bf device performed better concerning intra-subject reliability across repeated measurements. Conversely, there was poor agreement and systematic bias between the two devices, suggesting that they can't be used interchangeably within the purposed of this study.

Overall, oral functioning can be assessed using a variety of methods and instruments, including pressure-sensitive devices that measure tongue and lip force, bite and occlusal force, and chewing efficiency [14]. Selecting bite force as a proxy of proper oral health and as an indicator of treatment efficacy may be a suitable strategy for clinicians. However, measuring bite force is not always straightforward and requires specialized equipment and procedures, especially when dealing with subjects with disabilities, poor dental status, or specific medical conditions. Furthermore, although several have been used to directly measure bite force, including biting fork, strain gauge transducers, quartz and foil transducers, pressurized rubber tube,

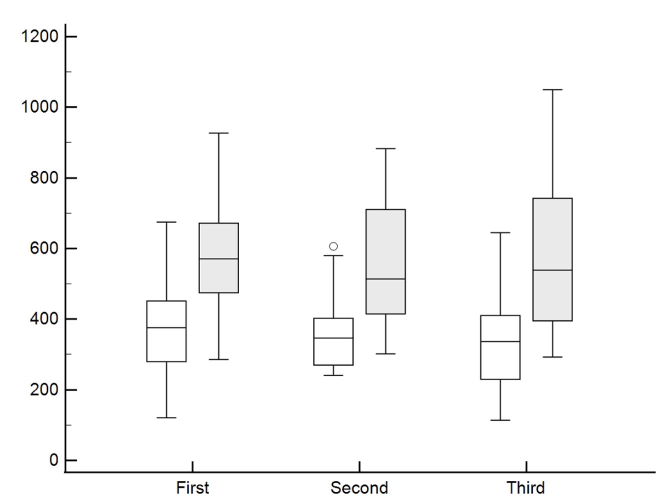

Fig. 2. Distribution of bite force measurements according to the consecutive test and devices – GM-10 (white) and Oramo-bf (grey).

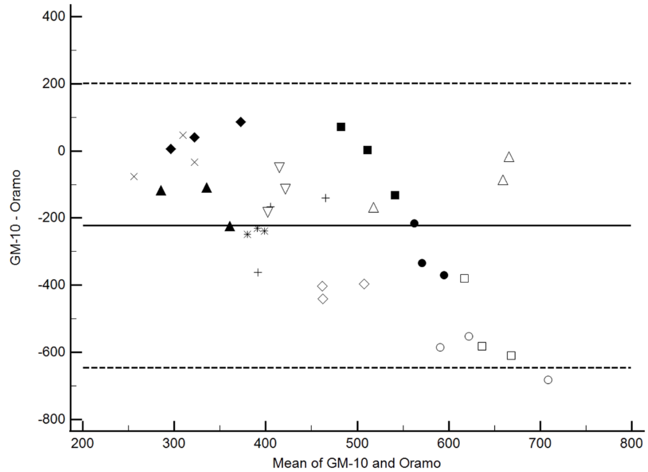

Fig. 3. Bland-Altman plot for multiple measurements per subject. Each subject is represented by the different markers. Horizontal line represents the mean difference, and the dotted lines represent the limits of agreement (±1.96 SD) between the two methods.

gnathodynamometer, pressure-sensitive sheet, and force sensing resistors [15], factors like the subject's dental status, the measurement environment, and the type of device used can affect the accuracy and reliability of the results. Furthermore, the lack of a systematic comparison of different devices, considering their advantages and disadvantages, makes it challenging to select a device that suits the specific aims of recording bite force for research or clinical purposes.

The Occlusal Force Meter™ GM10, which can measure bite force on individual teeth, has been extensively used for research purposes [16]. The method enables the simple, fast, and reproducible measurement of occlusal force in the first molar by biting with the maximum possible jaw-closing force [17]. However, this device is no longer manufactured and has not been available to researchers or dentists in the European region [17]. Therefore, due to the need to develop and validate a new measuring device for the evaluation of occlusal force, new devices such as the Dental Prescale II (GC Corporate Center, Tokyo) and Oramo-bf has been introduced in clinical studies [10] aiming at providing reliable measurements in clinical studies and for practicing dentists to measure occlusal force in everyday clinical practice.

On the other hand, the Oramo-bf is also a compact and easy-to-use device that operates on three AAA batteries and is suitable for both clinical and non-clinical settings [15]. While it provides only a single peak force value per measurement without mapping occlusal contact areas, it is widely used in Japan for insurance-covered evaluations [8, 18], particularly for diagnosing oral hypofunction in elderly individuals. Despite its limitations in spatial resolution [18], the Oramo-bf offers a practical and reliable alternative for screening and monitoring bite force capacity in diverse populations.

Shortly after this device was developed, it was used in a large survey of community-dwelling older adults in Japan [11], aiming to establish age- and sex-standard values using a capacitive-type pressure-mapping sensor, and its concurrent validity of the OFMD against a pressure-sensitive sheet (Dental Prescale II). A high diagnostic accuracy was found, and concurrent validity was demonstrated, suggesting that this device has the potential to be a user-friendly tool for OF measurements and exhibits a high predictive value for the diagnosis of components of oral hypofunction, particularly low occlusal force and a limited number of natural teeth, in both clinical and epidemiological settings [11]. The Oramo-bf device was considered a suitable and objective method of assessing oral function and providing helpful information to explore the link between oral and systemic health, as well as to evaluate the risks of nutritional, physical, and cognitive problems by defining low or abnormal values of oral function according to sex and different age strata [11]. Moreover, the Oramo-bf device was also successfully utilized in a recent study examining the relationship between dietary variety and masticatory behaviors among community-dwelling older adults [18].

Bite force is a valuable indicator for treatment planning, as the magnitude of bite force has been inversely related to proprioception. A significant increase in bite force is observed in patients with endodontically treated teeth compared to their vital teeth. Similarly, when implants are used in patients with an elevated bite force, an increase in the number and diameter of implants, as well as occlusions with reduced occlusal tables buccolingually and lighter contacts, may be recommended [19]. Therefore, exploring the magnitude and load of an individual's bite force can assist in designing dental treatments, along with other standard risk assessment criteria related to occlusion and oral function.

5. Conclusion

Within the limits of this study, Oramo-bf device showed higher intra-subject reliability across repeated measurements. The poor agreement and systematic bias between GM-10 and Oramo-bf suggest that the two devices differ significantly in their ability to assess the bite force of dentate subjects. Further studies are needed to assess the comparative accuracy of the two devices and the effect of different sensor technologies and point of force application on detecting and measuring the force applied during a bite.

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CRediT authorship contribution statement

Qareen Fatima Hashmi: Investigation, Methodology, Validation, Writing – original draft. **Charlotte Rinderknecht:** Conceptualization, Investigation, Methodology, Writing – original draft. **Claudio Rodrigues Leles:** Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing. **Murali Srinivasan:** Conceptualization, Data curation, Methodology, Project administration, Resources, Validation, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare no conflicts of interest

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