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Description	

Development of a novel composite sensor for evaluating lip function

Running title: Lip function evaluating system

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Abstract

Objective To test the novel sensor for assessing lip function.

Methods The electromyographic (EMG) activity of the upper orbicularis oris muscle (OOM), lip-closing pressure (LP), and intraoral baro-pressure (IP) were simultaneously recorded in 20 healthy subjects (ten women and ten men) by using a novel composite sensor (CS). Subjects performed the lip-closure, blow, and suck tasks. EMG activity of upper and lower OOMs was recorded using conventional surface electrodes to evaluate the accuracy of CS electrodes. They also rated the user-friendliness of CS.

Results Integrated EMG signals recorded using CS and conventional electrodes from the upper OOM were highly correlated (in women: $r = 0.77 \pm 0.12$, in men: $r = 0.81 \pm 0.10$). The signal-to-noise (S/N) ratio with the CS was higher than that with the conventional electrodes. The mean LP during maximum lip closure, blowing, and sucking ranged between 2 and 6 kPa in women and between 5 and 7 kPa in men. Corresponding IPs in women were 0.0 ± 0.5, 3.2 ± 1.4, and -4.4 ± 2.6 kPa, and in men were -0.5 ± 1.4, 4.9 ± 1.8, and -5.6 ± 2.8 kPa, respectively. All subjects rated the recording technique as excellent or good.

Conclusion The CS was highly user-friendly and accurate in recording the EMG activity of the OOM, and could simultaneously measure the LP and IP. Therefore, it could be an effective tool for evaluating lip function.

Keywords: Lip function, Orbicular Oris muscle, EMG, intraoral baro-pressure, Lip closing pressure, composite sensor

Introduction

Oral health is important for maintaining general health among the elderly [1]. Indeed, a poor oral status strongly predicted the onset of adverse health outcomes, including mortality, among the community-dwelling elderly [2]. Prevention of oral frailty at an earlier stage is therefore essential for healthy aging. Consequently, diagnostic tools and criteria to accurately and easily evaluate oral function have to be developed [3]. Devices that separately evaluate jaw [4], tongue [5, 6], and facial functions [7] have already been developed.

In bedridden persons, the facial expression is an important aspect that should be monitored. The orbicularis oris muscle (OOM) plays a central role in expressing frailty. The OOM surrounds the mouth and is connected to the cheek muscle at the corner of the mouth. When this muscle is active, the lips are closed or sealed. The lips have several functions: they are involved in the expression of emotions [8], production of bilabial sounds [9], and maintenance of the intraoral baro-pressure (IP) that is positive when blowing and negative when sucking. During chewing and swallowing, the lips prevent the bolus from falling out of the oral cavity [10] and may even help direct the bolus posteriorly upon initiation of the oral swallowing phase. Therefore, the electromyographic (EMG) activity of the lip muscle has been studied, for instance, during water intake, using different tools [11]. In addition, several studies investigated the lip-closing function in the elderly and in young adults [12,13]. Tamura et al. [12] tested the relationship between the lip-closing function and aging during ingestion in 84 community-dwelling and 59 healthy young adults. They found that skilled movement of lip-closing might be compensated for by the labial pressure, and that subjects who experienced “choking on food” had poor labial pressure and lip movement, suggesting that the lip-closing function may play a role in the pharyngeal stage of swallowing. Baum and Bodner [13] examined 257 community-dwelling male and female subjects and reported a higher prevalence of lip-posture problems with increasing age.

Nakatsuka et al. developed a unique multidirectional lip-closing force measurement system that allowed recording the lip-closing force in eight directions [14]. Interestingly, lip-closing training could enhance the lip-closing force [15], and the lip-closing force correlated with the tactile sensation at the vermilion [16].

To fully evaluate lip function, one must investigate not only the lip-closing force but also how the lip muscles contract and how they are involved in blowing/sucking by measuring the IP. Therefore, we developed a new device that allows simultaneous recording of these three parameters. The preliminary laboratory work involved (1) developing a small composite baro-pressure sensor that allowed recording the pharyngeal baro-pressure changes occurring during swallowing [17], oral baro-pressure changes during speech [18], and negative baro-pressure in the Donders space at rest [19], and (2) confirming that the EMG activity of the OOM could be recorded by placing the electrodes directly in contact with the lip mucosa, which is moistened with saliva and lacks the stratum corneum.

The aim of this study was to evaluate the accuracy and user-friendliness of the novel composite sensor (CS) by recording the activity of the OOM during maximum lip contraction, blowing, and sucking. The accuracy of CS recording was assessed by comparing the EMG signal recorded using the CS with that recorded using conventional surface electrodes attached to the skin over the upper and lower OOMs (u-OOM and l-OOM, respectively).

Materials and Methods

The study was performed in accordance with the Helsinki Declaration II and was conducted with approval of Ethic Committee of Tokyo Dental College. All subjects received verbal and written information about the study and gave written consent to participate. There is no conflict of interest declared.

Subjects and recording protocol

Ten healthy women (mean age, 25 ± 3.8 years) and ten men (mean age, 26 ± 4.6 years) participated in the study. To be included in the study, the subjects had to be healthy, have full dentition (except for the third molars), and have no history of motor abnormalities. Subjects who had difficulty in closing the lip, deleterious oral habits, and morphological abnormalities of the mandible were excluded.

The EMG activity of the OOM, lip-closing pressure (LP), and IP were recorded simultaneously by using the newly developed CS. After placing the CS between the lips, the subject was instructed to slightly hold the CS between the lips for 5-s (resting activity), to close the lips with maximum force, to blow (IP-positive task) and to suck (IP-negative task), and finally to rest for another 5-s. Activities were spaced by 2-min of rest and lasted for 20-s. Nevertheless, the subject was allowed to stop the activity before the 20-s target time in case of fatigue. The full sequence was repeated three times with a 2-min rest between sequences.

To evaluate the recording accuracy of the CS electrodes, the EMG activity of the u-OOM and l-OOM was simultaneously recorded using two surface electrodes. After cleaning the skin with alcohol, the two gel-type electrodes (Kendall-H124SG; Cardinal Health Inc., UK) were attached to the skin over the u-OOM and l-OOM in the direction of the muscle fibers. The inactive electrode of the CS was also used for this recording. All measurements were performed by one examiner, with the subjects sitting upright in a chair.

CS

The CS was designed to simultaneously register the activity of the u-OOM, force exerted by the lips, and intraoral baro-pressure. The CS consisted of a T-shaped polyimide film carrying EMG amplifiers, a baro-pressure sensor (MPL115A2; NXP Semiconductors, The Netherlands), and a force detector (FSR 402; Interlink Electronics, USA).

The OOM-EMG signal was recorded using two active electrolytic hard gold-plated films (area = 105 mm^2 each), arranged at the two extremities of a T-shaped polyimide film (width = 4 cm), and

an indifferent electrode (area = 49 mm^2), placed at the center of the reverse side of the T-arms. The contact force sensor and the baro-pressure sensor were placed on each side of the polyimide film (Fig. 1). The details of the baro-pressure sensor controller have been described by Hasegawa et al. [17] and Hiraki et al. [19] The signals were transmitted from the oral cavity along the polyimide film that was connected to laboratory-made amplifiers and a micro-CPU (H8/3694; Renesas Electronics Corporation, Japan) via a small connector. The micro-CPU carried 10-bit A/D converters and sent the signals to a PC via USB. The recorded signals could be monitored on the computer screen and logged in the comma-separated value format for further analyses. The CS was designed such that it could be disposable.

Data analysis

The signals, except for those of baro-pressure, were digitized using an A/D converter at a sampling rate of 333 Hz according to the speed of the baro-pressure sensor. After A/D conversion, the EMG signal was bandpass filtered (40-125 Hz), full rectified, and smoothed (time constant = 0.1 s).

The onset and cessation of lip contraction were determined visually from the LP curve, i.e., the beginning and end corresponding to the point where the force began rising and returned to the rising level, respectively (Fig. 2). Thereafter, the computer calculated the area under the curve (integral) for each signal, i.e., the integrated LP (∫LP), integrated IP (∫IP), and integrated CS-EMG (∫CSE). In addition, the mean values and standard deviations (SDs) were calculated: (mCSE), (mLP), and (mIP).

To evaluate the accuracy of the OOM-EMG signal recorded using the CS (CSE), the correlation coefficients were calculated using the cross function of a software during the lip-closure tasks (1) between ∫u-OOM and ∫CSE, (2) between ∫l-OOM and ∫CSE, and (3) between ∫u-OOM and ∫l-OOM. The coefficients were compared statistically.

The time-series data were analyzed using a software application (Spike 2, version 9; Cambridge Electronic Design Limited, UK).

Usability of the CS

To evaluate the user-friendliness of the CS, each subject received a questionnaire with three questions. The first one was close-ended: “How is the CS in comparison to the conventional electrodes?”, while the second and third were open-ended questions: “Why did you prefer the device?” and “Do you have any comment about the CS?” Possible answers to the first question were: excellent (4 points), good (3 points), fair (2 points), and poor (1 point).

Statistical analysis

Data were first analyzed using conventional descriptive statistics, e.g., mean and SD. The differences in the correlation coefficient between the different ∫EMG signals were analyzed using

repeated-measures one-way ANOVA followed by Tukey's multiple-comparisons test. Differences in the setting time for conventional electrodes and CS were analyzed using the Mann-Whitney U test. A p-value < 0.05 was considered statistically significant. The statistical tests were performed using GraphPad Prism 6.0h (GraphPad Software, USA).

Results

Figure 2 shows an example of the signals recorded during the lip-closure task.

Usability of the CS

The total time (mean ± SD) for setting up the conventional electrodes was 123 ± 13 s in women and 111 ± 19 s in men. Also the total time for the CS was 10 ± 6 s ($p < 0.0001$) in women and 12 ± 3 s ($p < 0.0001$) in men (Fig. 3). The CS was rated very positively by the subjects (3.4 ± 0.6 in women and 4.2 ± 0.9 in men): all the subjects selected either "excellent" or "good" ratings. There were no significant differences in the values between the women and the men. In addition, most of the subjects appreciated the fact that the skin did not have to be scrubbed with alcohol, as this might cause skin inflammation. However, although the CS was overall well appreciated for its easy application, some subjects reported difficulties in positioning the sensor between the lips owing to its flat shape.

Evaluation of the accuracy of the CS-EMG signal

The ∫EMGs of the CSE and of the u-OOM were highly correlated ($r = 0.77 \pm 0.12$ in women, $r = 0.81 \pm 0.10$ in men), while the ∫EMGs of the CSE and l-OOM and those of the u-OOM and l-OOM were less correlated in women ($r = 0.62 \pm 0.18$ and $r = 0.66 \pm 0.17$, respectively) and in men ($r = 0.54 \pm 0.20$ and $r = 0.625 \pm 0.13$, respectively) (Fig. 4). Statistically significant differences were observed in the mean values between CSE and u-OOM, CSE and l-OOM ($p = 0.009$ in women, $p < 0.0001$ in men), as well as between CSE and u-OOM and between u-OOM and l-OOM ($p = 0.005$ in women, $p = 0.0004$ in men). The amplitude of the EMG signal recorded using the CS was 1.2 ± 0.4 times in women and 1.7 ± 0.3 times in men larger than that recorded using the conventional electrodes.

There were no significant differences in the values between the women and the men.

LP and IP

Figure 5A and B depict the LPs and IPs averaged over both groups. The mLPs (mean ± SD) in the women were 6.0 ± 3.8 kPa for the lip-closure task, 2.8 ± 1.5 kPa for the blow task, and 4.4 ± 1.9 kPa for the suck task. The mLP was higher in the blow task than in the other two tasks ($p = 0.012$ between the lip-closure and blow tasks and $p = 0.031$ between the lip-closure and suck

tasks). The mLPs in the men were 7.0 ± 3.2 kPa for the lip-closure task, 5.5 ± 3.1 kPa for the blow task, and 5.2 ± 3.1 kPa for the suck task. The differences among the three tasks in the men did not reach statistical significance ($p > 0.05$). A significant difference was observed between the women and men only in the blow task ($p = 0.0185$).

The mIPs in the women were 0.0 ± 0.5 kPa for the lip-closure task, 3.2 ± 1.4 kPa for the blow task, and -4.4 ± 2.6 kPa for the suck task. Statistically significant differences were observed between the lip-closure and blow tasks ($p = 0.0004$), between the lip-closure and suck tasks ($p = 0.0017$), and between the blow and suck tasks ($p = 0.0002$). The mIPs in the men were -0.5 ± 1.4 kPa for the lip-closure task, 4.9 ± 1.8 kPa for the blow task, and -5.6 ± 2.8 kPa for the suck task. Statistically significant differences were observed between the lip-closure and blow tasks ($p < 0.0001$), between the lip-closure and suck tasks ($p = 0.0017$), and between the blow and suck tasks ($p < 0.0001$). A significant difference was observed between the women and men only in the blow task ($p = 0.0185$).

Discussion

The present study evaluated the value of a CS as a practical tool to assess lip function and to obtain normative values for lip EMG activity, i.e., the LP and IP, during maximum lip closure, sucking, and blowing in young women and men.

Value of the CS

All the subjects rated the CS as “excellent” or “good,” indicating that it was well accepted. As expected, the CS proved very user-friendly and easier to use than the conventional EMG technique, because several manipulations, such as the burdensome scrubbing of the skin to reduce its impedance, determination of electrode position, preparation of the electrodes, and their fixation on the skin, were not necessary. Notably, some subjects had difficulty positioning the CS between the lips. Thus, for practical use, a guide may have to be provided with the CS, showing the subjects how to position it between the lips. The user-friendliness of the CS may make it suitable for evaluating lip activity in the elderly or in nursing homes.

Evaluation of the CS for EMG recording

As the CS was simply held between the lips, it was necessary to evaluate whether it correctly recorded the EMG signal from the u-OOM. Our results indicted a high degree of correlation between the integrated EMG signal of the u-OOM recorded using the CS electrodes and that recorded using the conventional electrodes during maximum lip contraction (Fig. 4), indicating that the CS electrodes accurately recorded u-OOM activity. Of course, the CS can also be used to

record l-OOM activity just by turning it around; however, a disadvantage is the inability of the CS to record the activity of the two muscles simultaneously. Nevertheless, a new version of the CS with two active electrodes placed on both sides of the polyimide film could be designed to address this limitation. Further studies could show if the CS can also be used to record the activity of other perioral muscles, such as the buccinator, even though keeping the CS in place may be difficult.

The CS electrodes delivered on average a slightly higher signal amplitude than did the conventional ones, even though the conventional electrodes had a three-times-larger skin contact area than did the CS and the S/N ratio of the surface electrode could be higher with a larger electrode [20]. The observation that the CS electrodes delivered on average higher signal amplitude (i.e. S/N ratio) is likely because the CS electrodes were placed in contact with the lip vermillion/lip mucosa, which lack the stratum corneum and are moistened with saliva, likely resulting in lower impedance. In fact, Nomura [21] succeeded in recording motor units from the l-OOM by means of a bipolar silver ball electrode in contact with the lower lip mucosa.

LP

Since the position of the dental arch is determined by the interplay of the forces exerted by the cheek, lip, and tongue [22], the lip-closing force/pressure has been studied extensively. The LPs recorded in this study were higher in men than in women. This agrees with previous findings [3, 23]. Tsuga et al. [3] reported LPs of approximately 10 and 5 kPa in a group of male and female subjects, respectively, by using a balloon probe. The last values lay approximately in the range recorded using the CS in our study. Ueki et al. [23] recorded a lip-closing force of 12.7 ± 1.1 N in healthy adult women (age = 29.5 ± 4.9 years) and 15.0 ± 1.8 N in healthy adult men (age = 25.4 ± 7.9 years) by using a lip holder device (Lip De Cum, Cosmos Inst. Co. LTD, Japan) [23]. Notably, lip-closing forces were also recorded using the same device in a sample of elderly subjects (age = 80.7 ± 7.4 years) [24], and the findings indicated that lip force decreased with age. A direct comparison of the values recorded in these two studies with those registered in our study was impossible because forces were reported in different units (N vs kPa). Moreover, Tsuga et al. [3] suggested the importance of measuring the lip-closing force for quantitatively evaluating oral function. Indeed, they found a significant association between the LP during maximum lip contraction and verbal diadochokinesis, i.e., the /pa/ articulation rate. Oral diadochokinesis is a well-accepted method to assess oral function. During this test, subjects are asked to repeat the syllables /pa/, /ta/, and /ka/ as fast and as steadily as possible [25].

IP

IP measurements have been performed in studies on jaw posture, swallowing, sound production, and playing wind instruments. These studies reported a wide range of IPs that varied between -5 and 25 kPa, depending on the performed oral tasks. For instance, a negative IP (-0.5 kPa) occurs in the Donders space with the mandible at rest [19]; swallowing is accompanied by a biphasic baro-pressure variation with two sequential peaks, varying between 10 and 15 kPa depending on food viscosity [17]; and during the production of the stop consonant /k/, IPs of 2.5, 0.7, and 1.6 kPa occur at the center of the “Ah” line, at the incisive papilla, and at the mid-pharynx, respectively [18]. The IP during sound production is lower than that during swallowing [17-19]. Lastly, IPs higher than the systolic pressure (about 17 kPa) have also been reported. Trumpet players may produce during blowing IPs as high as 25 kPa [26]. In the present study, the mean IPs in the women were 0.0 ± 0.5, 3.2 ± 1.4, and -4.4 ± 2.6 kPa during the lip-closure, blow, and suck tasks, respectively. The corresponding values in the men were -0.5 ± 1.4, 4.9 ± 1.8, and -5.6 ± 2.8 kPa, respectively. The mean values recorded during the three tasks were higher in men than in women; however, the differences were statistically significant only in the blow task. The values obtained during blowing were in the range of those produced during sound production.

During sucking, the baro-pressure was negative. The mean values recorded in this study were in the range of those recorded using a manometer in the vestibular interocclusal space (-4.9 kPa) reported by Engelke et al [27]. The mean IP during the lip-closure task was near zero, with a large variation from -1.3 to +1.5 kPa. This large variation may be because some subjects may have more difficulty in performing the lip-closing task than do the others. Therefore, these subjects may have produced maximum lip contraction by combining the contraction of the OOM with the production of a negative IP. Indeed, studies have shown that the ability to produce a negative IP increases the pressure exerted by the lips on an oral screen when sucking [28].

Conclusion

The CS could simultaneously record the EMG activity of the u-OOM, LP, and IP, and could therefore become an effective tool for evaluating lip function in epidemiological studies and/or for enhancing evidence-based decision-making in nursing home care.

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Figure Legends

Fig. 1: The composite sensor and electromyography (EMG) electrodes.

A: Structure of the composite sensor

The composite sensor is constructed using an EMG electrode, a lip-closing force sensor, and an intraoral pressure sensor on a T-shaped polyimide film.

B: The setting

The wing of the composite sensor is gripped simply by using the lips. Conventional electrodes are set on the upper and lower orbicularis oris muscles.

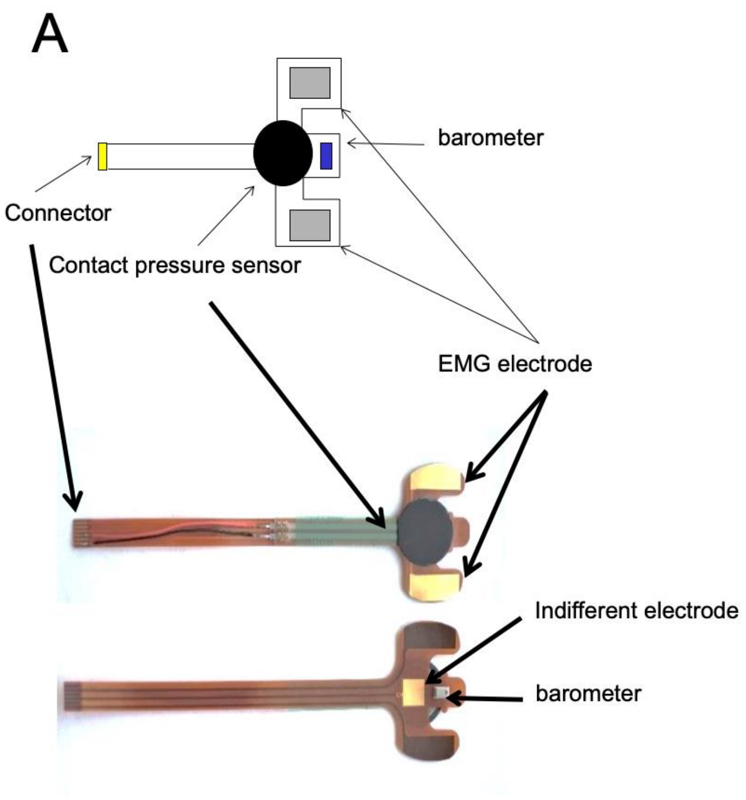

Fig. 2: Example of a recording during the lip-closure task.

Eight channels of analog data are shown in time sequence. The two vertical dotted lines indicate the onset and cessation of the lip-closure task. LP: lip pressure (kPa); ∫u-OOM: integrated upper orbicularis oris muscle activity; ∫CSE: integrated composite sensor output; ∫l-OOM: integrated lower orbicularis oris muscle activity; u-OOM: raw electromyographic (EMG) signal of upper orbicularis oris muscle activity (mV); CSE: raw EMG signal of the composite sensor (mV); l-OOM: raw EMG signal of lower orbicularis oris muscle activity (mV); IP: intraoral pressure (kPa).

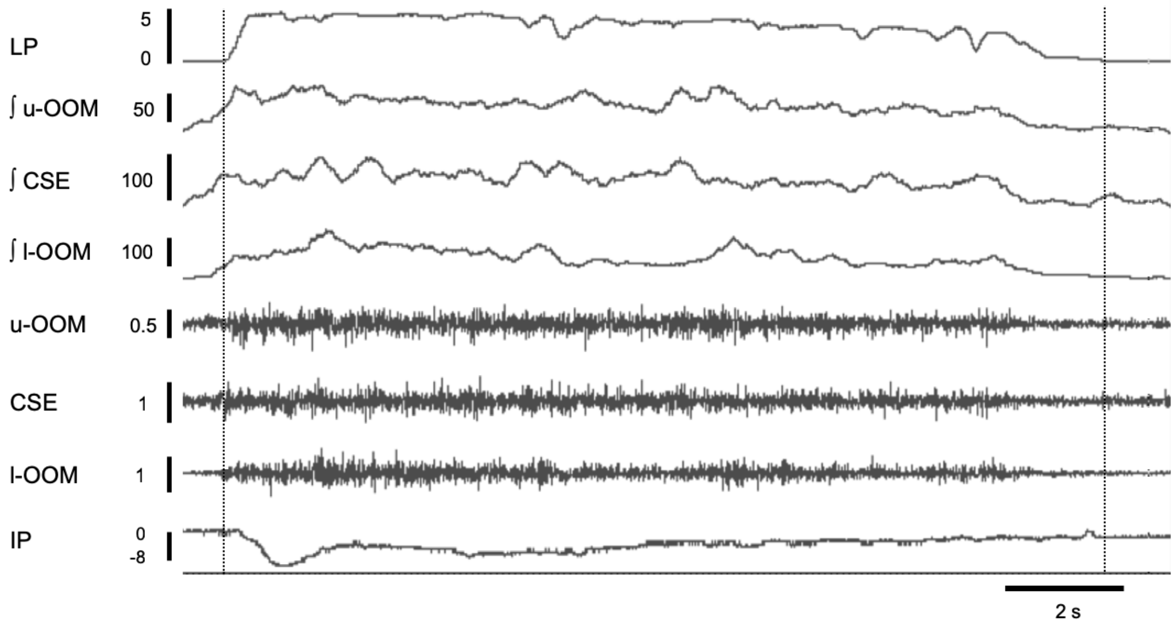

Fig. 3: Comparison of the time taken to attach the two conventional surface electrodes and to place the composite sensor.

CE: conventional electrode; CS: composite sensor. A significant difference is observed on analysis using the Mann-Whitney U test (**** $p \leq 0.0001$).

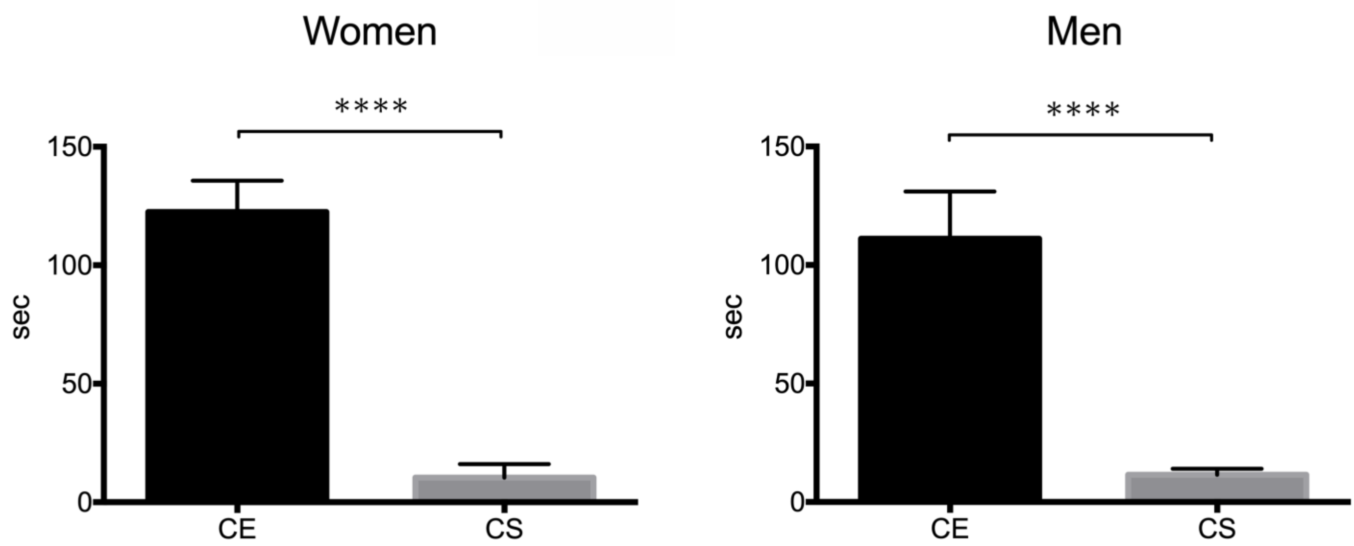

Fig. 4: Relationships between the integrated electromyographic signals (∫EMGs) of different electrodes.

The differences in the correlation coefficients of ∫EMGs in women were analyzed using repeated-measures one-way ANOVA followed by Tukey's multiple-comparisons test. Statistically significant differences are observed between u-OOM and CSE, l-OOM and CSE, u-OOM and CSE, and u-OOM and l-OOM (** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$). u-OOM: upper orbicularis oris muscle; CSE: composite sensor EMG; l-OOM: lower orbicularis oris muscle.

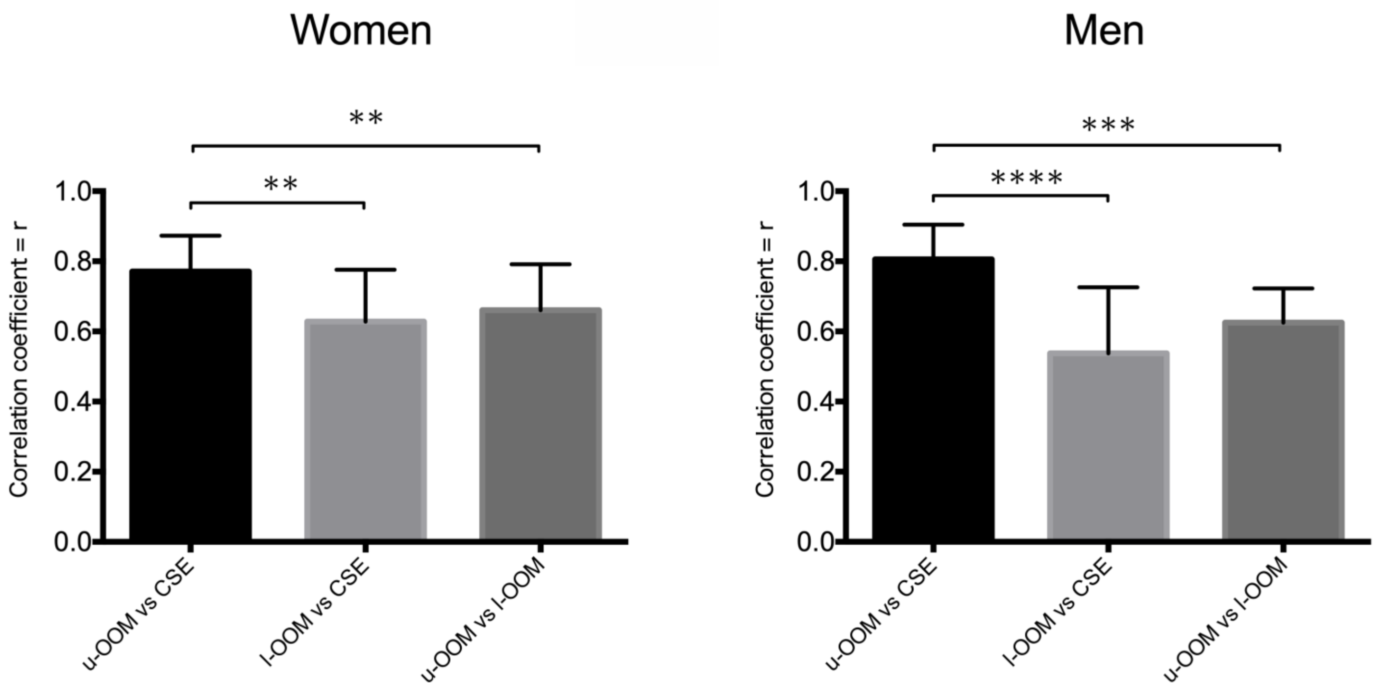

Fig. 5: Comparison of the mean values of the lip-closing pressures (left) and intraoral baro-pressures (right) in the three tasks. The lip-closing pressures and intraoral pressures were averaged over both groups. Statistically significant differences between the lip-closure and blow tasks, in mean lip-closing pressure between the lip-closure and suck tasks (A), and in mean intraoral baro-pressure among the three tasks (B) (* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$).