**Usefulness of a new malodour-compound detection portable device in oral malodour diagnosis**

For figures, tables and references we refer the reader to the original paper.

1. Introduction

'Bad breath', 'malodour' and 'halitosis' are synonym terms used to describe the unpleasant smell in a person's breath. In 2003, the American Dental Association (ADA) concluded that up to 25% of the population suffers from chronic bad breath [[1](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib1)]. In most of the cases (90%), this unpleasant smell originates within the oral cavity as the result of the degradation of organic substrates by anaerobic bacteria [[2](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib2)]. It is only in this particular situation that the term 'oral malodour' correctly applies. The microbial activity produces a wide range of volatile compounds out of which sulfur-containing gases are the most extensively studied. Hydrogen sulphide (H2S) and methyl mercaptan (CH3SH) have been proposed as the main contributors to the unpleasant smell [[3](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib3), [4](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib4)].

Nowadays, the diagnosis of bad breath involves the subjective detection of the unpleasant smell (organoleptic rating), along with an objective recording of the odours compounds whenever possible. Despite its subjective nature, the organoleptic rating is still the diagnostic 'gold standard'. The human nose is the only 'sensor' able to detect 10 000 different odours [[5](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib5)]. Moreover, this method of evaluation is immediate, and reflects best how the patients' breath is perceived by others in their environments.

Gas chromatography is probably the most objective and repeatable method for the measurement of many volatile compounds [[4](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib4), [6](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib6)]. Unfortunately, however, its complexity and high cost make it unsuitable for routine analyses. Several 'sulphide monitors', such as the Halimeter® and the Breathtron™ and even a portable gas chromatograph, the OralChroma™, have been developed over the years. These devices allow the volatile sulfur compounds (VSCs) in breath samples to be quantified with more or less specificity.

A new portable gas detector called BB Checker® has recently been made available. This thin-coat tin dioxide semiconductor gas sensor is said to be capable of detecting several volatile compounds such as VSCs, hydrogen, ethanol, acetone, butyrate and ammonia. This device has been specially designed to make independent measurements of oral, exhaled and nasal air samples [[7](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib7)].

Our aim was to evaluate the usefulness of this new portable device in the diagnosis of oral malodour. To this end, the BB Checker® (Oral/Breath Gas Detector mBA-21) was compared with standard diagnostic tools in the examination of patients with bad breath complaints who attended a special halitosis consultation.

2. Materials and methods

2.1. Population

Data from 100 consecutive patients attending their first consultation at the halitosis clinic (University Hospitals KU Leuven) were considered for analysis (Approval Ethical Committee ML9381). Prior to the examination, patients received a letter including the following instructions: to refrain from eating garlic, onion or spicy food for two days before the appointment; to refrain from drinking alcohol or coffee, and from smoking during the 12 h period before the appointment; and to refrain from using chewing gum, mints, drops, scents or mouth rinses on the morning of the appointment. Tooth brushing with water and having breakfast were allowed in order to avoid confusion between breath malodour and morning bad breath. Upon arrival, patients were informed about the new device to be used in the study, and they were asked for their consent to doing so. All measurements were recorded between 8:30 and 11:30 in the morning, and at least 2 h after eating or drinking, and after oral hygiene. All patients were examined by the same breath specialist [[2](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib2)].

2.2. Diagnostic tools

Briefly, the breath samples were evaluated organoleptically and by means of two portable devices (Halimeter® and OralChroma™). The organoleptic evaluation preceded all other measurements, and was performed by a trained and calibrated judge, who assessed the samples using the 0–5 Rosenberg scale [[8](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib8)]. The evaluation included mouth and nose air samples, as well as tongue coating samples when present. The intra-oral examination included the assessment of the tongue coating's presence and extent [[6](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib6)], the level of oral hygiene according to Silness and Loë (1964) [[9](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib9)], and the pocket probing depth [[2](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib2)]. The full protocol has been described in detail before [[2](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib2)]. In time, the BB Checker® was added to the above routine clinical examination at the halitosis consultation. All devices were used according to the manufacturers' instructions, and data were electronically stored by means of dedicated software whenever possible.

The BB Checker® was used to analyse three sample types. On the one hand, oral and exhaled air samples were measured while keeping the sensor probe inside the patient's oral cavity for 15 s while he either held his breath or exhaled after a deep inhalation. Nasal air samples, on the other hand, were measured with the help of a nose adaptor placed in one of the patient's nostrils while he pressed his other nostril shut using one of his fingers. The sensor probe was covered with a disposable cardboard piece, which allowed us to directly insert the probe into the mouth of the different volunteers.

While the data from the other two portable devices were reported in parts per billion (ppb), the BB Checker® delivers arbitrary data called 'BB values' (BBVs) in a 0–100 range. According to the manufacturing company, this arbitrary scale follows the Weber–Fechner law, which states that 'the magnitude of a subjective sensation increases proportional to the log of the stimulus intensity' [[7](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib7)]. Even though values above 100 were recorded—as in 8/96 nasal air measurements—, these values were considered as '100' for the statistics. A zero calibration was always performed at the beginning of the day before using the device.

2.3. Data analysis

The Spearman's rank correlation was used to assess the agreement of the different devices with respect to the organoleptic score (OLS), considered to be the gold standard. The Mann–Whitney U test was used to assess the differences between the groups. Correction for simultaneous hypothesis testing (Bonferroni's correction) was applied when needed. The sensitivity, specificity, positive and negative predictive values for each device were calculated using the manufacturers' thresholds. Additionally, a 107 ppb threshold previously established by our group was used for the Halimeter® [[10](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib10)]. A receiver-operating characteristics (ROC) curve was built to establish the optimal sensitivity and specificity combination value for each of the three measurements recorded with the BB Checker®.

3. Results

Our final data base consisted of 96 patients (47 female; mean age 40.1 years) in general good health (table [1](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100t1)). Four cases of malodour with suspected extra-oral origin were excluded from the analysis. A total of 14 subjects were smokers, and 25 were diagnosed with gingivitis or periodontitis. 'Obvious malodour' (OLS ≥ 2) was diagnosed in 61 patients (64%). The presence of tongue coating alone (37/61) or in combination with periodontal disease (16/61) was the major cause of oral malodour (86.9%). Gingivitis and/or periodontitis were detected without the concomitant presence of tongue coating in seven patients (11.5%). One patient suffered from oral malodour as the result of extremely poor oral hygiene. The main characteristics of both groups are shown in table [1](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100t1). Although no effort was made to keep any balances, no statistically significant differences were observed for the age, gender or number of smokers in each group.

Table 1. Main characteristics of patients with and without obvious oral malodour. Since data were not normally distributed, median, upper and lower quartiles are presented (median, UQ, LQ) for some variables.

The correlations between the OLS and the data from the three devices are shown in table [2](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100t2). Whereas the OLS correlated well (*p* < 0.001) with the Halimeter® and the OralChroma™ (H2S, CH3SH, tVSC) data, the correlation with the BB Checker® values was extremely weak and statistically not significant. Within the BB Checker® data, a good correlation was observed between the exhaled and the nasal air samples.

Table 2. Spearman's correlation between the OLS (gold standard) and the BB Checker® (new device) with other breath parameters.

Table [3](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100t3) shows the compatibility between the three devices and the gold standard when using the manufacturers' thresholds. Both the OralChroma™ and the Halimeter® showed a very good sensitivity (±74%) and a very good specificity (>88%). For the BB Checker®, the sensitivity for all the measurements was below 40%, while the specificity varied between 71 and 91%. Even when considering an OLS ≥ 3 to be 'obvious malodour' as in a previous report (see discussion), no improvements were observed in the outcomes. Neither the exclusion of the smoker subjects from the database (see discussion) rendered any improvements, except for an increase in the sensitivity of the nasal air measurements. In order to establish the optimal sensitivity and specificity combination value for each of the three measurements taken with the BB Checker®, a ROC curve was built. The resulting thresholds were lower than the one proposed by the manufacturer. Similar values were obtained for the exhaled and nasal air samples. The threshold for the oral air samples was extremely low (14 BBV). Regardless of the sample type, the sensitivity and the specificity values did not exceed the 50% (table [3](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100t3)).

Table 3. Sensitivity, specificity, positive, and negative predictive values for the three devices when an OLS ≥ 2 was considered to be 'obvious halitosis'.

The BBVs for the exhaled and nasal air samples were significantly higher than for the oral air samples (*p* < 0.05), and correlated very well with each other (*R* = 0.93, *p* < 0.001). The correlation with the oral air samples was significant but less obvious.

4. Discussion

In the last ten years, the growing interest of the scientific community in halitosis has led not only to a better understanding of its aetiology and therapy, but also to the development of several chair-side devices that make the objective evaluation of breath air possible. There already exists evidence in support of some of these devices, as well as data reporting on their limitations [[11](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib11)–[16](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib16)]. However, no such information is available for the BB Checker® yet.

Objective measurements are crucial in halitosis clinics in order to reinforce the cases of pseudo-halitosis diagnoses. Pseudo-halitosis patients are convinced of suffering from bad breath even though there is no evidence of malodour. These patients represent up to 25% of the population visiting the halitosis clinics [[2](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib2), [17](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib17)], and become a real challenge to the practitioners. In patients with diagnosed oral malodour, objective measurements are used not only for monitoring their treatment outcomes, but also as motivation to gain their commitment to the treatment suggested.

Over the past year, patients attending their first consultation at our bad breath clinic were evaluated not only by means of our standard protocol, but also with a recently launched chair-side breath test: the BB Checker®. This device was easy to use, and none of the volunteers experienced any discomfort during the examination. The total measurement time was relatively short—less than 8 min for the three evaluations—, and in line with the running time of the OralChroma™ and the Halimeter® (duplicate measurements).

In order to evaluate the performance of the new device, data from 96 consecutive volunteers with different degrees of oral malodour were analysed looking for correlations between the BB Checker® measurements and the gold standard OLS on the one hand, and between the BB Checker values and the results from the other commonly applied portable devices (Halimeter® and OralChroma™) on the other hand.

Unfortunately, as far as the oral and exhaled samples were concerned, no correlation could be demonstrated between the BB Checker® and the OLS, the Halimeter® or the OralChroma™ values. Yet, very good correlations were observed between the OLS and the levels of sulfur from the Halimeter® and the OralChroma™ data, both for the mouth air and tongue coating samples (correlation coefficient between 0.60 and 0.66), which is in line with previous reports [[6](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib6), [10](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib10), [11](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib11)].

In this study, while the BB Checker® showed a good specificity (>70%), the sensitivity observed turned out to be extremely low (<40%). Hanada *et al* (2003) have already reported that the sensitivity of tin dioxide to VSCs is too low to be used as detector in an oral malodour analyser [[14](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib14)]. In the only publication available on the BB Checker®, Tamaki *et al* (2011) calculated a sensitivity and a specificity above 80% using a screening level of 50 and 60 BBV for the oral and the exhaled air samples, respectively [[7](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib7)]. For the data base under analysis in this manuscript, the cut-off values obtained from the ROC curves were much lower (<40 BBV), and the best sensitivity and specificity combination values, regardless of the sample type, did not exceed the 50%. In order to compare our results with those of Tamaki *et al* [[7](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib7)], the different threshold calculations were repeated considering an OLS equal or higher to 3 as indicative of 'obvious malodour'. Unfortunately, the criteria change did not render any improvements in the test outcomes (data not shown). The carbon monoxide interference in the smokers' air samples was also considered. Carbon monoxide was expected to cause unexpectedly high BBVs, with the concomitant detriment in the specificity of the measurements due to the false positive results. The analysis was then repeated excluding the 14 smokers. Yet, no major improvements were observed (data not shown).

While Tamaki *et al* [[7](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib7)] have reported higher values for the oral and exhaled air samples than for the nasal air samples, the opposite was observed for our data base, where the oral air sample values were significantly lower. The reason why our exhaled and nasal air values are higher than our oral air values could be the greater amount of air in contact with the sensor probe while the patient exhales the air—through the nose or mouth—in comparison with the air content in the oral cavity during the passive measurement. In the case of the BB Checker®, the sensor probe is in contact with the air sample at all times, contrary to what happens in the case of the other devices, where the air is collected by means of a pump or a syringe before it can reach the detector. It is also interesting to note that, even though the authors state that the air composition from the oral and exhaled samples may differ [[18](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib18)], both measurements have been proposed as indicators of morning bad breath. Surprisingly enough, regardless of the malodour presence and its possible cause, the oral, exhaled and nasal air sample results from more than 80% of the patients enrolled in this study showed a similar trend (62.5% showed BBV ≤ 50; and another 20%, BBV > 50).

The oral malodour characteristic smell seems to result from a combination of multiple compounds [[19](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib19)]. It has already been reported that no pure odour alone resembles the typical smell of breath malodour [[20](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib20)]. Since most of the devices in use today have been designed to detect only the presence of VSCs, the BB Checker®'s ability to detect non-sulfur compounds as well seemed very interesting. Unfortunately, however, nothing is known about the sensor's sensitivity to the different 'reductive gases', nor whether their individual contributions are expected to change for the different sample types. Even though the relationship between these particular compounds and halitosis exceed the scope of this work, some considerations can be made. To the best of our knowledge, there exists only one publication exploring the presence of ammonia in breath malodour [[21](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib21)]. This compound has been proposed for the monitoring of kidney function [[22](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib22)]. The detection of H2 in breath is used to diagnose several functional gastrointestinal disorders—like carbohydrate malabsorption and small intestinal bacterial overgrowth—, and some of the test false positive results are caused by oral bacterial flora [[23](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib23)]. Acetone is present in everyone's breath. Its concentration increases when fasting or in the case of uncontrolled diabetes [[24](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib24)].

Finally we would like to emphasize the marked difference between our patient population with 'obvious malodour' and the small volunteer group with 'morning bad breath' from Tamaki *et al*'s work [[7](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib7)]. 'Morning bad breath' is a transient condition, caused by a decreased salivary flow during the night, which easily disappears when having breakfast and taking standard oral hygiene measures [[25](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib25)]. The aetiology of oral malodour, however, is different. In the majority of the cases, oral malodour can be attributed to the presence of tongue coating, gingivitis or periodontitis [[2](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib2)]. Since both conditions are the result of an increased concentration of odoriferous compounds in the breath, morning bad breath has served as a model in most research dealing with oral malodour management [[26](http://iopscience.iop.org/1752-7163/7/4/046005/article#jbr485100bib26)].

In summary, although the new device was 'operator and patient friendly', thus favouring its use in a clinical setting; our work does not provide evidence for the real usefulness of the BB Checker® in the diagnosis of oral malodour.