The reduction of muscle tone during sleep leads to a reduction in airway diameter, and therefore to a noticeable increase in airflow velocity during inspiration—and occasionally also during expiration. Above a critical speed threshold, local pressure variations occur at specific bottlenecks in the upper aero-digestive tract. Consequently, these lead to vibrations of the soft tissue and their resulting sounds. The most relevant anatomical structures that contribute to this are the palatal arch, the sides of the pharynx including the adenoids, the base of the tongue, and the epiglottis.

Snoring can therefore be classified as a commonly inspiratory but also expiratory sound associated with sleep, and takes place in the upper airway. Snoring is considered “disruptive” (cf. “primary” or “habitual”) if it occurs without quantitative evidence of airflow limitations (e.g. apnoea or hypopnoea) [9].

A multifactorial aetiopathology can be assumed. Important risk factors for the development of snoring have been identified to be nasal obstruction, male sex, age and excess weight [2, 6, 8]. Moreover, there is a direct association with alcohol and nicotine consumption.

Unlike obstructive sleep apnea (OSA), disruptive snoring is not considered a disease with medical danger to the affected person, according to the current state of scientific knowledge. For this reason, there is no need for medical treatment, according to latest expert opinion [14].

Nonetheless, subjects who snore present with relevant complaints. It is typical that the quality of life of the bed-partner, specifically, is reduced. Women with partners who snore often complain about sleep disorders, headaches in the morning, and fatigue during the day [15]. According to a study published in 2005, 55% of bedpartners of patients with sleep-related breathing disorders are disturbed almost every night, 40% sleep in another room at least once a week, 26% regularly use earplugs or sleeping pills, and 35% report at least intermittent relationship problems occurring due to the snoring [17].
The snorers themselves also show evidence of a reduced quality of life. There are signs of an association of snoring with the development of hoarseness, headaches, scary dreams, and poor sleep quality [3, 5, 12].

In summary, disruptive snoring is a phenomenon without direct impact on the morbidity and mortality of patients; however, it has significant potential to induce a high level of suffering for both the snorer and their personal and/or domestic environment, which quite often leads them to resort to medicinal services.

Numerous treatment options are available to treat disruptive snoring [14]. Amongst these, especially general measures like weight loss and alcohol and/or nicotine abstention are noteworthy. Possible instrument-based therapies are vests to prevent the supine position during sleep, diverse sleep position trainers, and mandibular advancement devices. When it comes to surgical treatment options, they primarily concern interventions at the soft palate and in the nasal septum and conchae. Thereby, one must bear in mind that there is little scientific data available to support general measures and positional treatment for snoring [14], and not all snorers prove suitable for mandibular advancement devices or surgical procedures. In addition, the short- and long-term consequences of these measures should be considered, particularly given that they are not medically necessary.

Furthermore, surgical procedures are not sustainably effective in all cases [14], and the treatment costs are usually not covered by health insurance. As a result, there is a demand for a non-invasive, affordable alternative treatment method.

**Muscle stimulation to treat snoring**

In two independent studies on the effectiveness of electrical muscle stimulation in OSA, it has already been shown that despite not bringing about a significant reduction of the Apnoea–Hypopnoea Index (AHI), it did lead to an improvement in snoring. The number of snoring periods within the training groups significantly decreased [11, 16]. Due to the lack of effectiveness in OSA, this alternative treatment was not pursued, and at present there are no data on its application to disruptive snoring.

Given this background, a CE-certificated stimulation device (SnooZeeal®, Snoozeal Limited, London, GB) was developed. It lies completely intraorally, and has been especially designed to treat patients with disruptive snoring. The mouthpiece is placed under the tongue, and the electrodes for muscle stimulation occur within set parameters.

Risk of electric or thermal damage is not expected with the present licensing parameters, given pre-defined device settings and their limited adjustability by patients.
Aims of the study

In this study, the hypothesis was put forward that electrical stimulation of the intraoral musculature with the newly developed intraoral stimulator improves snoring in the absence of OSA or presence of mild OSA.

Materials and methods

Methods

In the bicentric prospective study (Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Essen, Germany; Nottingham University Hospital, Nottingham, United Kingdom), a total of 16 patients (body mass index [BMI] < 32) with snoring and mild sleep apnea (AHI < 15) were tested.

Initially, a medical history, ENT examination and out of center sleep testing was performed to exclude relevant sleep-related breathing disorders. The patients snored regularly for at least the last 6 months and did not suffer from an OSA requiring treatment (AHI < 15). Additionally, no serious nasal pathologies, e.g. a pronounced septal deviation, and Neck Surgery, University Hospital Essen, Germany; Nottingham University Hospital, Nottingham, United Kingdom), a total of 16 patients (body mass index [BMI] < 32) with snoring and mild sleep apnea (AHI < 15) were tested.

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The training frequency and duration was $2 \times 20 \text{ min}$ daily. During the treatment phase and up to 2 weeks after the end of the treatment (post-treatment phase, day 43–56), the snoring intensity was documented daily by the bedpartner according to a visual analogue scale (VAS: 0–10).

Patients with an AHI < 10 responded better to therapy. No unexpected events occurred. In the present pilot study, the first signs of the effectiveness of intraoral muscle stimulation in snoring patients were shown. In addition to a technical improvement of the stimulator, carrying out controlled trials and assessing potential influencing factors on the success of therapy are necessary.

Keywords

Pharyngeal muscles · Sleep related breathing disorder · Electric stimulation therapy · Sleep apnea syndrome · Muscle tonus
Original studies

Fig. 2. Graphical representation of the change in snoring VAS scores of all patients over the treatment period (average and standard deviation). Pre pre-treatment score week 1 and 2, TW treatment week scores week 5 and 6, Post post-treatment score week 1 and 2 post completion of treatment.

Fig. 3. Graphical representation of the change of the snoring scores of patients with an Apnea–Hypopnea Index (AHI) below 10/h (dark blue columns) and patients with an AHI 10 and above (light blue columns). Pre pre-treatment score, TW treatment week, Post post-treatment score.

Statistics

The data were tested using the Kolmogorov–Smirnov test for normal distribution (not normally distributed). Comparison of the values before and after the treatment was conducted using the Wilcoxon rank sum test.

Results

In total, 16 patients were included in the study. Three patients left the study due to technical problems with the device during the treatment.

Of the 13 remaining patients, 11 were male and 2 were female. The oldest patient was 59 years old, the youngest 25. On average, the patients’ age was 43.2±12.2 years. The BMI was on average 26.9±3.2 kg/m². In the study population, the mean AHI was 9.3 ± 4.6. The mean score of the Epworth Sleepiness Scale (ESS) was 7.4 ± 2.3. An overview of the epidemiological data of the research population is provided in Table 3.

The average snoring score was statistically significantly (p < 0.05) reduced from 5.6 ± 1.1 (baseline) to 3.2 ± 2.7 (af-
ter treatment), and remained stable up to 2 weeks after the treatment (3.3 ± 2.4). The snoring score was lowered on average by 44% by the end of the treatment phase. This effect was not weakened even 2 weeks after the end of the treatment (with an average reduction of the snoring score by 43%). With 7 patients (53.9%), a reduction of the snoring score of above 50% was noted. An overview of the snoring scores over time is shown in Fig. 2 and Table 4.

It was noteworthy that the patients with an AHI below 10 (n = 6) could benefit more markedly from the treatment. This relationship is shown in Fig. 3 and Table 4. Moreover, there was a negative correlation between the reduction percentage of the snore score and the AHI.

The patients reported a subjective feeling of electrical stimulation in the mouth during the training phase as a short “twitching” or “tingling”. No undesirable effects arose in the study group.

### Discussion

In various studies, it has already been shown that by training the upper breathing musculature by playing a wind instrument (didgeridoo; [10]) and corresponding oropharyngeal exercises [1, 4, 7], a moderate OSA can be alleviated. As demonstrated in the current meta-analysis, oropharyngeal exercises can reduce the AHl by 50% in adults, and consequently improve snoring [1]. It is suspected that these effects were caused by a change in oropharyngeal muscle tone. This is supported by observations that transcutaneous electrical stimulation appears to affect a noticeable increase in muscle strength and base muscle tone in paralysed or inactive limbs [13]. As the muscles of the pharynx and tongue, as well as the limbs, are skeletal muscles, an electrical or electromagnetic stimulation of the pharyngeal and tongue musculature can affect an increased muscle tone above the base tone during sleep, and therefore reduce the tendency for the pharynx to collapse and result in snoring.

As illustrated, this principle has already been attempted to be used in treatment for OSA [11, 16]. Randerath et al. [11] included 67 patients with mild to severe OSA (AHl 10–40) in a randomised, placebo-controlled, double-blind study on electrical stimulation of the tongue musculature. The biphasic stimulation took place using an electrode positioned under the tongue, and a further electrode that was attached to the floor of the mouth from the outside. In this study, no effect was noticed on AHl; however, a significant effect on snoring was observed (the snoring episodes were lowered from 63.9 ± 23.1 episodes/h to 4.5 ± 31.2; p < 0.05). In the placebo group, this effect was not demonstrated.

A further study by Verse et al. [16] took place with 15 patients with OSA or Upper Airway Resistance Syndrome (UARS). These received transcutaneous electric stimulation via two conventional electrodes attached to the skin.

### Table 4 Overview of the results of the study with the formation of 2 groups (AHl below 10/h and AHl 10 or above)

| No | AHl | Score week 1 (Pre 1) | Score week 2 (Pre 2) | Mean Pre 1 + 2 | Score treatment week 5 (TW 5) | Score treatment week 6 (TW 6) | Score treatment week 5 + 6 | Mean TW 5 + 6 | Score after treatment week 1 | Score after treatment week 2 | Mean Post 1 + 2 |
|----|-----|---------------------|---------------------|---------------|---------------------------|-----------------------------|-----------------------------|--------------|-----------------------------|-----------------------------|------------------|
| 2  | 3.5 | 4.54                | 4.72                | 5.65          | 1.07                      | 0.99                        | 1.03                        | 0.89         | 1.05                        | 0.97                        |                  |
| 3  | 4.8 | 6.05                | 7.27                | 4.63          | 3.26                      | 3.17                        | 3.22                        | 3.66         | 3.21                        | 3.44                        |                  |
| 4  | 5.5 | 2.19                | 3.02                | 3.57          | 0.98                      | 0.78                        | 0.88                        | 1.12         | 0.85                        | 0.99                        |                  |
| 5  | 4.4 | 4.96                | 4.11                | 5.14          | 0.33                      | 1.15                        | 0.74                        | 0.65         | 2.1                         | 1.38                        |                  |
| 6  | 2.5 | 5.65                | 5.83                | 6.91          | 1.29                      | 3.71                        | 2.50                        | 0.49         | 0.13                        | 0.31                        |                  |
| 13 | 7.7 | 7.46                | 8.71                | 6.73          | 0.31                      | 0.43                        | 0.37                        | 0.49         | 0.13                        | 0.31                        |                  |
| Mean | 4.73 | 5.14 | 5.61 | 5.44 | 1.21 | 1.71 | 1.46 | 1.56 | 1.75 | 1.66 | |
| SD  | 1.63 | 1.61 | 1.92 | 1.16 | 0.99 | 1.26 | 1.03 | 1.16 | 1.16 | 1.11 | |
| 1  | 12.5 | 5.94 | 5.65 | 5.80 | 3.07 | 3.23 | 3.15 | 3.15 | 3.52 | 3.34 | |
| 7  | 13.1 | 7.10 | 6.75 | 4.66 | 1.97 | 1.41 | 1.69 | 1.24 | 2.16 | 1.70 | |
| 8  | 13.5 | 1.37 | 3.40 | 5.20 | 0.67 | 0.77 | 0.72 | 1.96 | 2.74 | 2.35 | |
| 9  | 13.5 | 7.79 | 8.24 | 6.52 | 7.79 | 8.27 | 8.03 | 7.41 | 8.03 | 7.72 | |
| 10 | 11.5 | 5.04 | 5.00 | 4.84 | 5.77 | 5.03 | 5.40 | 4.36 | 5.21 | 4.79 | |
| 11 | 14.1 | 4.59 | 4.73 | 6.20 | 5.56 | 6.17 | 5.87 | 5.69 | 5.12 | 5.41 | |
| 12 | 13.9 | 7.99 | 7.50 | 7.75 | 7.19 | 7.69 | 7.44 | 7.56 | 7.38 | 7.47 | |
| Mean | 13.14 | 5.69 | 5.90 | 5.85 | 4.57 | 4.65 | 4.61 | 4.48 | 4.88 | 4.68 | |
| SD  | 0.77 | 2.00 | 1.47 | 0.94 | 2.34 | 2.56 | 2.44 | 2.18 | 1.94 | 2.05 | |
| Mean All | 9.26 | 5.44 | 5.76 | 5.66 | 3.02 | 3.29 | 3.16 | 3.13 | 3.43 | 3.28 | |
| SD All | 4.38 | 1.93 | 1.75 | 1.10 | 2.58 | 2.63 | 2.58 | 2.38 | 2.32 | 2.33 | |

AHl Apnea–Hypopnoea Index, SD standard deviation, Pre pre-treatment score week 1 and 2, TW treatment week scores week 5 and 6, Post post-treatment score week 1 and 2 post completion of treatment.
(ECG-electrodes), which were positioned submentally. Rather than objective breathing parameters, in this study clear improvements were detected in subjective evaluations of snoring by the bedpartners. On average, a decrease from $7.0 \pm 2.2$ to $3.4 \pm 2.0$ points on theVAS was claimed ($p = 0.005$).

Also, in the present pilot study there were indications of effectiveness of introral muscle stimulations of patients with snoring, in relation to the bedpartners’ stated subjective snoring intensity. As already shown in the results section, especially patients with an AHI below 10 ($n = 6$) could benefit from the treatment. These patients’ snoring score decreased on average by 68%. The patients with an AHI of 10 and above ($n = 7$), in contrast, only benefitted minimally from the treatment, although the small sample size of this subpopulation cannot allow for reliable conclusions to be drawn. This is somewhat inconsistent with the results of the aforementioned studies on electrical stimulation of patients with OSA for whom a significant decline in snoring was also established.

Compliance with ethical guidelines

Conflict of interest. B. Stuck has received financial support for research, as well as consulting and advisory fees from the following companies: Aspire Medical, Fisher & Paykel Healthcare, Celon AG Medical Instruments, Olympus, Sutter Medizintechnik, Neurwirth Medical Products, Philips Healthcare, Helnenn & Lowenstein, Aaloo GmbH, Tomed Dr. Toussaint GmbH, MEDA Pharma GmbH, Inspire Medical, INT Medical, PCI Biotech, Atos Medical and SnooZeal Ltd. He is scientific advisor to the company SnooZeal Limited. A. Samea has received consulting and advisory fees from the following companies: Medtronic, Olympus, Cook Medical and SnooZeal and is on the Board of the SnooZeal Limited. A. Samea has received consulting and advisory fees from the following companies: Medtronic, Olympus, Cook Medical and SnooZeal and is on the Board of SnooZeal Limited. A. Samea has received consulting and advisory fees from the following companies: Medtronic, Olympus, Cook Medical and SnooZeal and is on the Board of SnooZeal Limited. A. Samea has received consulting and advisory fees from the following companies: Medtronic, Olympus, Cook Medical and SnooZeal and is on the Board of SnooZeal Limited. A. Samea has received consulting and advisory fees from the following companies: Medtronic, Olympus, Cook Medical and SnooZeal and is on the Board of SnooZeal Limited. A. Samea has received consulting and advisory fees from the following companies: Medtronic, Olympus, Cook Medical and SnooZeal and is on the Board of SnooZeal Limited. A. Samea has received consulting and advisory fees from the following companies: Medtronic, Olympus, Cook Medical and SnooZeal and is on the Board of SnooZeal Limited.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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Practical conclusion

- The presented treatment with a newly developed device for introral muscle stimulation has the potential to be effective particularly in the treatment of disruptive snoring.
- Further prospective studies with larger groups and a controlled design are in preparation to investigate the value of this procedure more thoroughly.

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