

Analysis of the Oral Muscle Training Device Gaumfit® in the Application at Primary Snoring

Kai-Olaf Henkel*

Clinic for Oral and Maxillofacial Surgery and Plastic Surgery, Federal Armed Forces Hospital Hamburg, Lesserstrasse 180, 22049 Hamburg, Germany

***Corresponding Author:** Kai-Olaf Henkel, Clinic for Oral and Maxillofacial Surgery and Plastic Surgery, Federal Armed Forces Hospital Hamburg, Lesserstrasse 180, 22049 Hamburg, Germany.

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Summary

Introduction: Snoring endangers the health and can lead to the emergence or worsening of existing diseases, such as high blood pressure and heart attack. There are numerous surgical and non-surgical treatment options for snoring and snoring apnea syndrome (SAS). All surgical and conservative treatments do not address the cause of snoring, only the symptom. Gaumfit® is the first device that treats 90% of the causes of snoring.

Aim: To verify that primary snoring improves when the oral musculature is trained by the Gaumfit® exercise device.

Method: In a retrospective analysis on 100 test persons (83 males and 17 females) the effectiveness of the innovative concept of Gaumfit® exercise device was analyzed. The subjects wore Gaumfit® for 3x10 minutes a day(!) and were interviewed after four weeks.

Results: Snoring was reduced in 94 out of 100 subjects. This represents a success rate of 94%. This finding is highly significant ($p=0.008$). It felt more rested in the morning 79% of Gaumfit® users. 94 subjects used Gaumfit® during the four weeks and rated the innovated therapy method with the predicate “good” (school grade 1.95).

Conclusion: The oral muscle training device Gaumfit® significantly strengthens the palatal and tongue muscles and is therefore suitable to alleviate primary snoring.

Keywords: Snoring; muscle development; isometric contraction; well-being

Introduction and research question

It is generally accepted that snoring endangers health. Thus, snoring can lead to the development or worsening of existing diseases, such as hypertension and myocardial infarction [1]. There are numerous surgical and non-surgical treatment options for snoring and snoring apnea syndrome (SAS). All surgical and conservative treatments do not address the cause of snoring, only the symptom. They only help to keep the airway open for the snorer during sleep and thereby secondarily prevent snoring. Henkel and Ahmed [2] demonstrated that snoring can be significantly reduced by the principle of isometric muscle building in the soft palate. Since the glossopharyngeal cleft space in snorers, especially in patients with sleep apnea syndrome (SAS), is further reduced by the tongue falling back, it makes sense to look for a way to improve the tongue position. The tongue is connected to the inside of the anterior mandible via the genioglossus muscle [3]. In snorers and patients with a SAS, this muscle is hypotonic. Therefore, the tongue falls towards the pharyngeal wall and constricts the glossopharyngeal space. With Gaumfit®, for the first time an exercise device is available which, in addition to building up the muscles in the soft palate area, also strengthens the genioglossus muscle, i.e. the tongue muscles. This counteracts the main causes of primary snoring, the loss of muscle tone in the soft palate and tongue. According to the German Society

for Sleep Medicine, this is the cause of snoring in 90% of all snorers [4]. Gaumfit® is a further development of the pharyngeal muscle trainer presented by Ahmed (2020) [5].

The aim of this work was to retrospectively analyze the innovative oral muscle trainer Gaumfit®. The efficacy and tolerability of Gaumfit® should be determined.

Material and method

Material

For the study was used the innovative oral muscle exercise device Gaumfit® (Pharmact GmbH Mannheim, Germany), which was shown in figure 1. It is made of a medical polyether amide block. This kind of medical plastic offers the highest quality and meet the stringent requirements of the medical applications such as minimally invasive devices (USP Class VI). In the investigation, the training device should be worn for three times about 10 minutes throughout the day. It should be noted that Gaumfit® is used exclusively during the day.

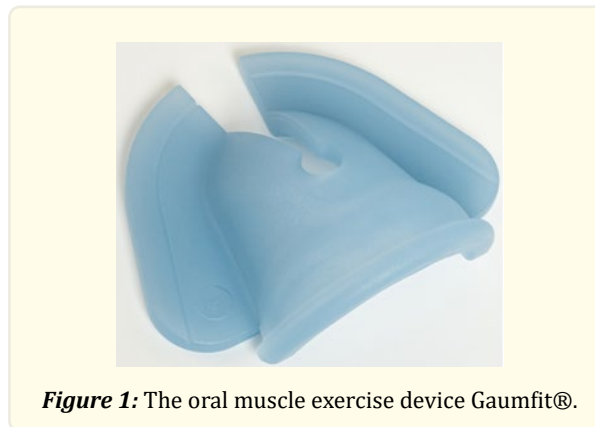


Figure 1: The oral muscle exercise device Gaumfit®.

Gaumfit consists of a dorsal effective area intended for training the soft palate. In the anterior section, which is adjacent to the hard palate, there is a gap (anterior effective area). This gap is tatted by the tongue, as a foreign body. As a result, the tongue is reflexively lifted and the tongue muscles, in particular the genioglossus muscle, are also exercised.

Methods

For the tests were performed on the group of 100 patients (83 men and 17 women) with an average age of 45, 5 years. The patients. The patients come from the practice for maxillofacial surgery Prof. Henkel at Hamburg. They were interviewed on a voluntary and anonymous basis retrospectively after four weeks of use via a questionnaire. The questionnaire asked the following questions:

- Has your snoring improved?
- Do you feel more rested in the morning?
- How would you rate the effectiveness of Gaumfit® in school grades from 1 to 6?

To answer the question whether snoring had improved, the change in snoring volume was asked. A rating from 1 to 4 were offered:

- 1: No change of snoring volume
- 2: Snoring volume has improved
- 3: Snoring volume has improved significantly
- 4: Snoring is no longer present.

In the second question, the patients were asked to subjectively rate the innovative myogenic snoring therapy using Gaumfit® for success. For this the patients were to assign school marks from 1 to 6. The mark 1 stands for very good and the mark 6 for insufficient.

With the third question, the patients were asked about the subjective sleep quality. A sign of good sleep quality is a patient who is rested and refreshed after sleeping. It was asked whether the patient is more rested in the morning or not. This question could only be answered with “yes” or “no”.

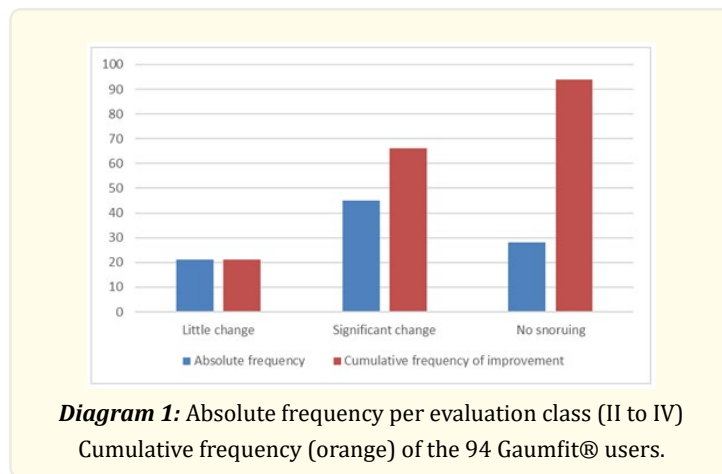
Statistical analysis was performed with regression analysis by using software: Stata Corp LLC, College Station Texas, USA [6].

Result

Results from this study regarding the change in snoring volume after four weeks of using Gaumfit® are shown in Table 1. Six subjects did not use Gaumfit® due to a strong gag reflex. The remaining 94 users reported a reduction in snoring volume. This finding is highly significant with $p = 0.008$. Thus, it can be assumed with a very high probability that the use of Gaumfit® positively influences snoring and a healthy sleep is achieved. Related to the total number of 100 test persons, a positive change of primary snoring was achieved in 94% (94/100). In 28% (28/100) of the users even a complete remission of snoring could be achieved (Diagram 1). Diagram 1 includes only those subjects who had used Gaumfit®, i.e. 94 subjects.

<i>Parameter</i>	<i>Class</i>	<i>Absolute frequency</i>	<i>Relative frequency</i>	<i>Cumulative frequency of improvement</i>
No Change	I	6	6%	0
Little Change	II	21	21%	21
Significant Change	III	45	45%	66
No Snoring	IV	28	28%	94

Table 1: Change in snoring volume after 4 weeks of application of Gaumfit®.



The 94 test persons who had used Gaumfit® evaluated the success of the application of Gaumfit® with an average value of 1.95, i.e. expressed in school grades with “good”. The distribution of the grades was 12 times school grade 3; 65 times school grade 2 and 17 times school grade 1 (see diagram 2). The six patients who did not wear Gaumfit® were not questioned.

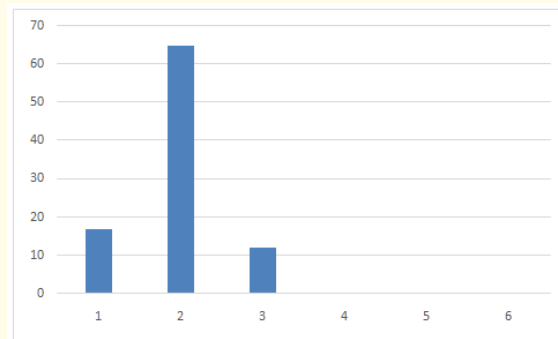


Diagram 2: Distribution of school grades four weeks after wearing Gaumfit® (Note: School grades 4 to 6 were not used by patients).

In the morning, 74 patients felt more rested compared to the start of the study. Based on the 94 patients who had used Gaumfit, this is a rate of 94% success (Diagram 3).



Diagram 3: Change in sleep quality four weeks after wearing Gaumfit®.

Discussion

A retrospective patient survey is basically suitable for answering scientific questions. The particular advantage is the speed with which the study can be conducted.

The volume of primary snoring is mainly determined by the tone of the muscles in the area of the soft palate and the tongue muscles. In about 80% of all snorers, the cause is decreased tone of the muscles of the soft palate and pharyngeal walls [7]. In another 10%, the lack of tone of the tongue muscles is a cause or leads to an increase in the snoring sound. The tested oral muscle trainer (Gaumfit®) significantly strengthens the muscles of the soft palate and tongue. This reaches 90% of all primary snorers. With the result that the subjectively perceived volume of snoring was significantly reduced within four weeks. This led to a significant improvement in primary snoring. In 28% of the test subjects (28/100), snoring was no longer evident after four weeks. This result is better than the result published by Ahmed (2020) with a customized muscle exercise device, which acts only in the soft palate region [5].

In the current therapy of primary snoring, mandibular advancement splint (MAS) or less frequently positive pressure ventilation is the main treatment [8]. Two-rail systems are usually used as MAS for the therapy of sleep-related breathing disorders. These systems rest on the upper jaw and push the lower jaw forward and aim to open the hypopharynx. They are worn during the night and are considered very uncomfortable by patients. The success rate of these systems is about 60%. The success rate of Gaumfit® in relation to

the total population was 94%. Of the subjects who had actually used Gaumfit®, all patients (94/94 subjects) reported an improvement (reduction) in snoring volume. Thus, Gaumfit® is superior to conventional MAS splint systems already after four weeks of wearing three times about 10 minutes per day.

The MAS splint and positive pressure ventilation only treat the symptom and not the cause of primary snoring. In contrast to the mentioned therapies, Gaumfit® is the only measure that is able to significantly treat the cause of primary snoring. This can be seen, among other things, in the reduction of snoring volume. Ahmed [5] proved that the subjectively assessed snoring volume is suitable to determine the severity of primary snoring. Thus, the focus on snoring volume in the present study is suitable to evaluate the efficacy of Gaumfit®.

The principle of action of Gaumfit® is based on the isometric contraction of the palatal muscles during the swallowing act and a strengthening of the tongue muscles. The effectiveness of muscle building through isometric contraction has been proven many times [9] and is used, for example, in high-performance sports [10]. Anatomically, the soft palate consists only of muscles surrounded by a mucosa [7]. In addition, Gaumfit® also strengthens the genioglossus muscle. This desired effect results from the activation of the tip of the tongue. When wearing Gaumfit®, the tip of the tongue constantly scans the anterior gap of Gaumfit®. This additionally strengthens the genioglossus muscle. This results in a better anterior tongue position in the mouth and an enlargement of the glossopharyngeal gap, which improves airflow in the oropharynx. The result is more restful sleep.

Conclusion

The oral muscle trainer Gaumfit® significantly strengthens the palatal and tongue muscles and is therefore suitable to alleviate primary snoring.

Conflict of Interest Statement

The study was conducted without any financial contribution or influence from Pharmact GmbH Mannheim, Germany or other industry influence.

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