Clinical Study – Executive Summary

Anti-Snoring Device GOODNITE™

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Contents

Descriptive Information

Executing Location of Clinical Study

University ENT Clinic Mannheim
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Supervising Clinical Director for Study

Dr. Joachim T. Maurer

Study Supervisor for Nitetronic

Dr. Uwe Mehrmann, Nitetronic (Europe) GmbH

Manufacturer

Nitetronic (Europe) GmbH

Device Model

Goodnite 1st Generation by Nitetronic (OEM Brand: "Sissel Silencium")

Study Type

This study is an analysis on the effect of Goodnite on snoring duration and on arousal caused by the pillow activities.

Study Design

This study is a controlled clinical crossover study to objectify the effect on snoring of an anti-snoring pillow, which changes the head position when snoring is detected. Participants with the symptom "snoring" without significant OSAS diagnosis were chosen out of a larger selection of suitable candidates with the help of the Supervising Clinical Director of the University ENT Clinic at Mannheim. Two consecutive nights in the sleep laboratory were conducted, one night with inactive pillow and the second night with active pillow. All data were collected by PSG (Polysomnographie) and individual questionnaire.

Arms, Groups and Cohorts

The contents of this study are the snoring duration and arousals caused by the pillow-activities. The experiment is the usage of the pillow during two consecutive nights – one night inactivated and second night activated – with PSG reporting in the sleep laboratory in the University ENT Clinic at Mannheim.

Eligibility

Ages Eligible for Clinical Study

The test accepts any candidates over the age of 18 for inclusion.

Sexes Eligible for Clinical Study

There is no exclusion on the basis of sex. Both men and women were eligible

Inclusionary Criteria

The participants must be over the age of 18, have a BMI ≤ 30, have an exclusion of OSAS, prior use of PG or PSG, snoring and must be able to provide informed consent.

Exclusionary Criteria

There are no exclusionary criteria except BMI > 30, OSAS, no bed partner.

Purpose

Change in head position has a positive impact on snoring. This has led to the development of Goodnite as a uniquely device to minimalize snoring. A first empirical test with 157 patients sleeping on the anti-snoring pillow showed a reduction in snoring of 67% in average. Based on these results a controlled crossover study to objectify the effect on snoring and on arousals caused by pillow-action is performed.

Implementation

The nature of the clinical study is explained and documented with the approved patient pool by the physician in change in order to obtain informed consent.
The test begins with the selection of participants, the documenting of the patient pool´s previous PSG reports and the completion of a questionnaire prior to the introduction of Goodnite.
Goodnite has to be used by each involved user during two consecutive nights in the sleep laboratory – 1st inactive and the 2nd active. All PSG data were collected, including acoustic snoring and the Arousal Index.
After both nights the patients have used Goodnite in the sleep laboratory, a subsequent questionnaire will be completed by the participants that asks about their experiences.

Expectations of Clinical Results

Without the support offered by Goodnite, it is expected that user will snore continuously without any alteration. This is represented by a comparison between pre-test PSG report and inactive night PSG report.
By using Goodnite, it is expected, that user will snore significantly less and have an improvement of sleep quality. Furthermore it is expected, that there will be no increase of the Arousal Index caused by pillow-action.

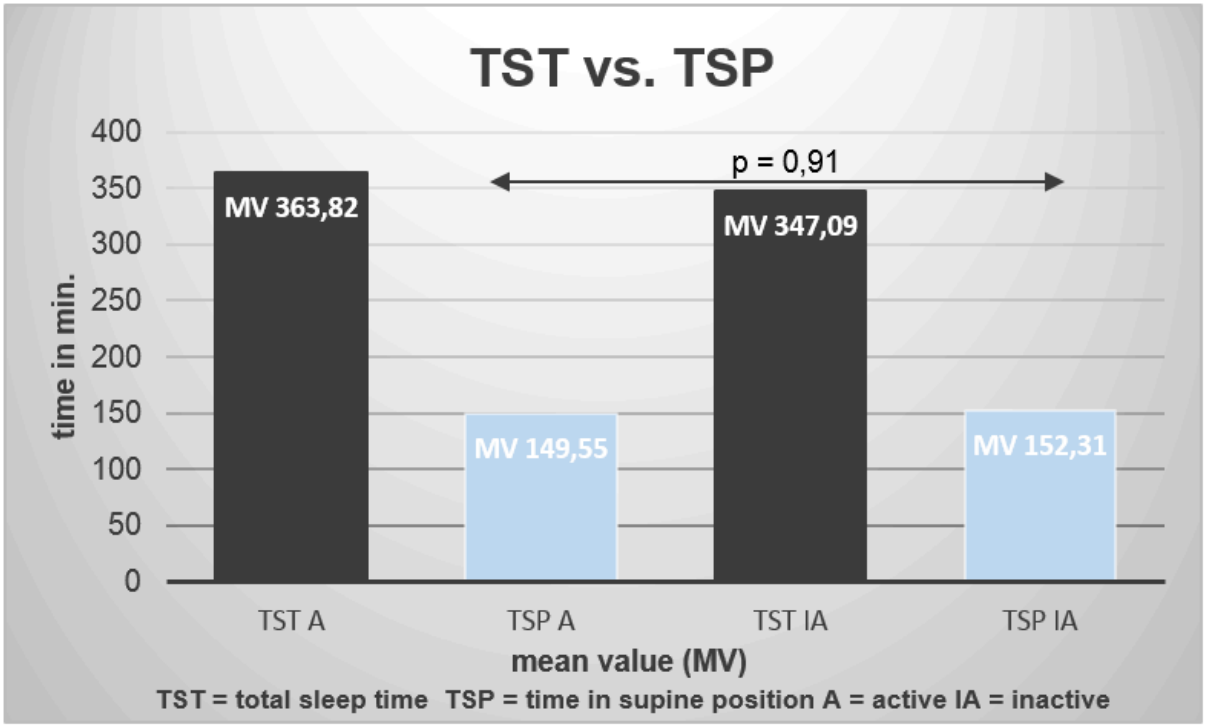
Graphical Data from Clinical Study

The clinical study includes 20 patients who completed the two consecutive, PSG controlled nights in the sleep laboratory.

Fig. 1

Sleep- and Breathing-related Parameters										
PSG active						PSG inactive				
	AHI	AHI-SP	RDI	RERAS	snoring-index	AHI	AHI-SP	RDI	RERAS	snoring-index
1	7	9,2	21,5	14,5	72,2	8,5	0	21,9	13,4	132,8
2	1,8	0	58,8	57	460,2	1,2	0,8	35,8	34,6	657,3
3	1,8	2,3	7,8	3,1	182,2	1,6	2	5,8	3,1	188,3
4	1,5	0	8,5	7	63,3	1,4	0,9	10,1	8,7	981,3
5	24,2	0	57,9	33,8	509,8	22,8	0	76,3	52,1	555,8
6	0,7	0	46,8	46,2	537,1	0,4	3,5	33	32,7	531,8
7	3,2	3,1	4,4	1,3	4,8	3	0	7,4	4,4	96,5
8	17,3	23,9	28	10,7	105,5	15,8	33,4	20,7	4,9	130,7
9	3,3	0	15,9	7,2	52,9	4	0	12,5	8,5	46,9
10	9,6	15	16,9	11	361,4	8	11,3	19	11	405,8
11	12,6	22,7	15,8	2	224,8	8,8	0	14,6	5,8	365,3
12	9,5	9,7	23	13,4	128,8	11,7	16,9	21,2	9,5	227,4
13	1,4	0,5	1,4	0	14,1	4,5	6	8	3,5	92,3
14	4,4	7,4	8	3,6	75,4	1,4	2,2	2,2	0,7	169
15	9,1	14,4	12,8	3,7	136,7	11,2	23,3	15,8	4,6	290,8
16	2,5	5,8	22	19,5	165,5	2,1	2,8	9,1	7	248,9
17	4,4	0	6,1	1,8	2	7	10,7	7,5	0,5	20,9
18	19	52,5	21,8	2,8	35,5	27,2	61,3	37,2	10	147,8
19	3,6	4,9	9,6	6	86,6	5,5	7,7	17,1	11,7	87,5
20	1,3	1	20,8	19,6	31,3	0,8	0	10,1	9,3	2
p-value	**0,5**	**0,8**	**0,6**	**0,5**	**0,03**					

Fig. 2



Analysis of Graphical Data

Sleep-related respiratory parameters (AHI, supine AHI, RDI, RERA) showed no significant change. The snoring index decreased significantly while using the pillow Goodnite in the active mode ($p < 0,03$) (Fig. 1). The snoring Index was determined using internal signal processing technologies of the PSG-system after manually adjusting snoring thresholds for each night by the aid of the PSG audio files. The time spent in supine position doesn´t change by pillow activity (Fig. 2).

Limitations

There are always limitations to conduct a study like this. The first of these is the small sample size of the participant cohort. It is always preferable to have a larger group with which to conduct clinical research. Secondly there are no pre-existing clinical studies on devices to change the head position to stop or minimize snoring. The shown effects cannot be compared to results of other studies or clinical trails.

Conclusion

With every single patient, a **significant reduction in snoring** duration was observed in PSG reports during the nights with pillow activity. The comparison of PSG reports shows that the active head position change leads to **no deterioration of the sleep- and breathing-related parameters**. There was **no increase in arousals or subjective sleep disturbances**. This implies that the head movements are gentle enough.

There is no significant change of the total sleep time (TST) spent in supine position with activated vs. non-activated pillow. This indicates that head rotation alone is responsible for the documented effects.

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