Evidence of the efficacy of the SNX Mandibular Advancement Device

Publication in advance of main study - investigation of mean protrusion of SNX device -

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1. The Problem

Mandibular Advancement Devices are now being used increasingly in Germany to treat obstructive snoring and obstructive sleep apnoea. A wide variety of studies have shown them to be effective (Kushida et al. 2006, Peter et al. 2007) though models vary. However, 2 disadvantages have become apparent in the use of these devices so far. One is that the existing models are relatively large and can be unpleasant to wear as a result. The other is that most are very inflexible and therefore do not permit such actions as adequate swallowing movements and speaking. These and other problems with existing models led to the development of the SNX device examined here. This newly developed oral device protrudes the lower jaw. In the present study we aim to establish whether it is able to reduce snoring and improve apnoea-hypopnoea and oxygen saturation.

2. Method

2.1 Sample

This publication, in advance of the full study, is based on the evaluation of results from 15 patients. When they made contact with us all these patients complained of snoring with or without night-time cessations of breathing. Two were women and 13 were men. Their ages ranged from 31 to 67 years, mean age 55.5 years. Their mean Body Mass Index (BMI) was 26.2.

2.2 Design / Measurement method

Cardiorespiratory polygraphy was carried out before the start of treatment to discover the severity of the problem. The SNX device was then fitted and a further measurement was made. The data were appraised by a somnologist and the apnoea-hypopnoea index (AHI), oxygen desaturation index (ODI) and percentage of snoring in the total evaluation time were then calculated.

2.3 Statistics

The normal descriptive statistics (mean, standard deviation etc.) were calculated and the following non-parametric and parametric tests were used: Wilcoxon test, paired-sample T test, Spearman correlation.

3. Results

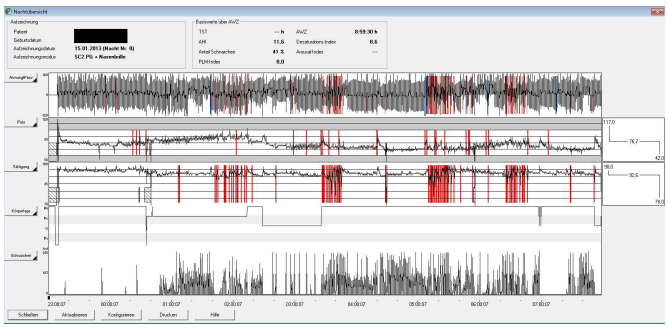

Figure 1. A recording made without the SNX device.

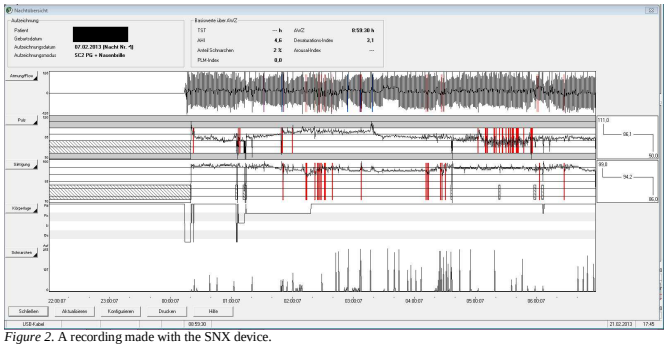

Figure 2. A recording made with the SNX device.

The results of cardiorespiratory polygraphy are shown here to illustrate the procedure for testing the efficacy of the SNX device. Figure 1 shows the results, validated by expert rating, without the SNX device (DD) and Figure 2 shows results with the device (SNXa). It can clearly be seen that breathing pauses, oxygen desaturation and snoring were all reduced.

Snoring percentage, AHI and ODI improved significantly when the SNX device was used (see Figure 3). Mean snoring percentage fell from 31.8% to 13.2%, mean AHI fell from 20.8 to 5.8 and mean ODI fell from 13.0 to 3.8. The improvement was found to be clearly significant in all three cases on both the tests used. Significance levels on the Wilcoxon test were between p = 0.001 and p = 0.004 while those on the paired-samples T test were between p = 0.001 and p = 0.002.

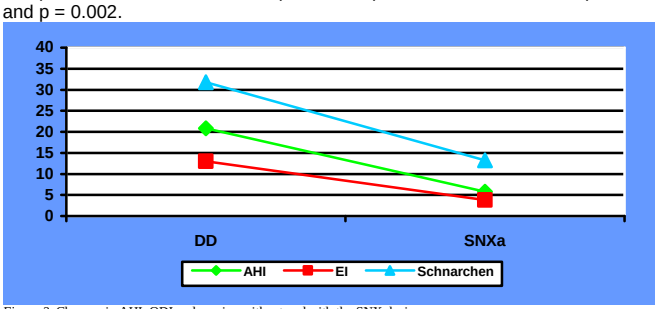

Figure 3. Changes in AHI, ODI and snoring without and with the SNX device.

The mean protrusion was 5.83 mm. The recording made with the SNX device also revealed a significant correlation (r = 0.686, p = 0.020) between BMI and snoring.

4. Discussion

These results confirm that the SNX device can bring improvements in both obstructive snoring and obstructive sleep apnoea. They also show that more obese patients continued to snore more than less obese patients, a finding that needs to be investigated more closely in the main study. If this association is confirmed it could prove helpful to use greater protrusion distances in more obese patients from the start in future. The degree of protrusion used here was a first (test) setting for each patient. When the SNX device is used for treatment in the main study, it will be individually adjusted again depending on the results of the first cardiorespiratory polygraphy recording made with the device in place. It can therefore be assumed that the recordings planned for the main study will reveal further improvements in the relevant indices and thus confirm the therapeutic efficacy of the SNX device. This procedure will also allow measurement of the mean degree of protrusion giving optimal results.

Literature:

Kushida CA, Morgenthaler TI, Littner MR et al (2006) *Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005.* Sleep 29:240-243.

Peter H, Penzel T, Peter JH (2007) *Enzyklopädie der Schlafmedizin.* Springer, Berlin Heidelberg New York Tokio.

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