

## **Controlled Velumount Study**

Position of the oral device (Gaumenspange) Velumount for Rhonchopathy and Obstructive Sleep Apnoea (OSA)

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### **Summary**

**Introduction:** The Velumount Method was developed and patented by A. Wyss from Bern (Switzerland) for the treatment of snoring and obstructive sleep apnoea (OSA). The principle consists of an external stinging of the retro palatal area and an ante flexion of the velum palatinum. The target of the presented work is the scientific evaluation of the success of the Velumount Method.

**Method:** During May 2007 - May 2008, 37 patients were evaluated with and without the Velumount. With a nocturnal polysomnography of the upper airways combined with a respiratory polygraphy the Apnoea-Hypopnoea-Index (AHI), the average Oesophagus pressure (Pes) and the percentage distribution of obstructions in the retro-palatal and retro-lingual were defined. With the aid of a questionnaire, the snoring index (1-10) as well as day tiredness with the Epworth Sleepiness Scale (ESS) was established.

**Results:** With Velumount a reduction was achieved for the snoring index from average 8.3 (SD+/-3.4) to 3.7 (SD+/-2.5), the point scale in ESS from average 8.2 (SD+/-4.3) to 3.9 (SD+/-3.4) and the Pes from average 15 cmH<sub>2</sub>O (SD+/-6.8) to 11.4 cmH<sub>2</sub>O (SD+/-6.6). The AHI by n=22 OSA patients without Velumount was as an average of 23.6 (SD+/-10.6) and reduced with the Velumount to an average of 14.0 (SD+/-12.9). All changes were highly significant (Wilcoxon test: p<0.001). With a snoring index of  $\leq 3$  socially classified as not disturbing, the response rate was 65%. Regarding the AHI and using the Sher criteria (AHI  $\leq 20$ /h and reduction compared to starting value around 50%) the result is a 55% response rate. A normalisation of a raised Pes (Pes  $\leq 10$  cmH<sub>2</sub>O) resulted in 41%. The retro-palate obstructive AHI Value had a predictive value with regard to overall improvement of AHI (Spearman r=0.46; p=0.004).

**Conclusion:** The Velumount Method is effective for snoring and OSA and the nocturnal Polysomnography of the upper airways validates the expectation of a therapy success.