Vanderveken O.[1, 3], Boudewyns A.[1], Braem M.[2], Willemen M.[3], Okkerse W.[2], Verbraecken J.[3], Hamans E.[1], De Backer W.[3] and Van de Heyning P.[1]

Subjective assessment of the effect of a one-piece mandibular advancement device out of thermoplastic material on snoring and daytime sleepiness.

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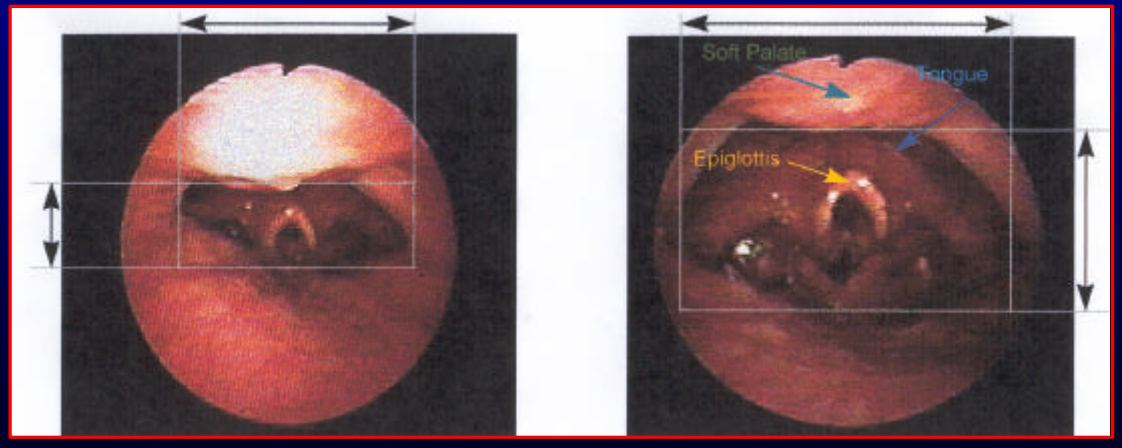
Mandibular advancement device (MAD)

- Enlargement of retroglossal space
  - Collapsibility of upper airway ↘
  - Cross-sectional dimension UA ↗



Mandibular advancement device (MAD)

- Popular alternative to control SRBD
- Habitual snorers or mild OSA
  +/- excessive daytime sleepiness (EDS)
- Moderate to Severe OSA
  - Intolerance / no compliance / refusal nCPAP
  - or as a temporarily alternative

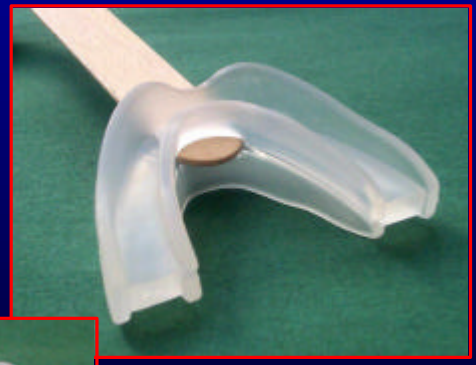
Standards of Practice Committee of the American Sleep Disorders Association. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. Sleep. 1995; 18(6): 511-3.

Mandibular advancement device (MAD)

- Various design
- Usually “custom-made”
  - Individually fabricated
  - Polymethyl-methacrylate
  - Potential disadvantages:
    - Costs
    - Time

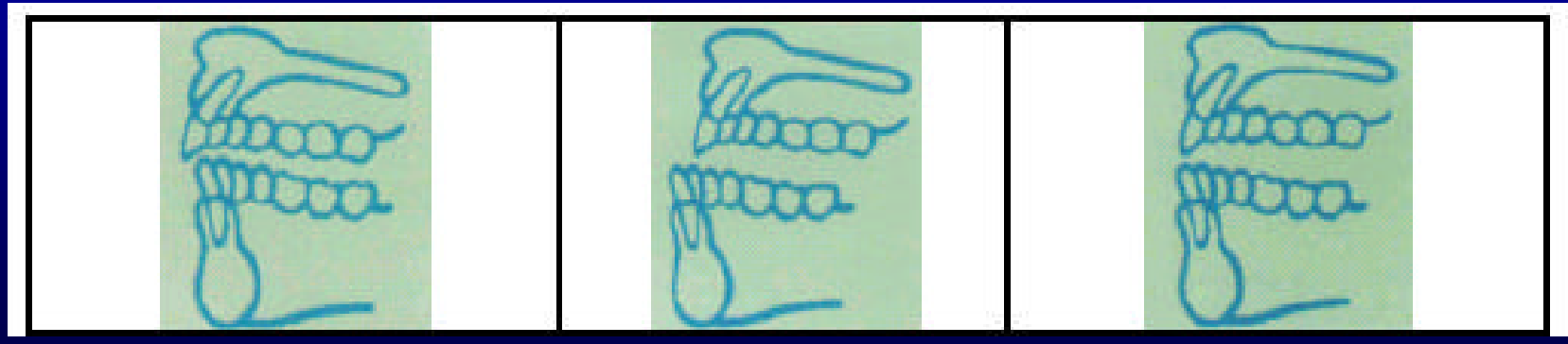
Somnoguard®

- MAD out of thermoplastic material
- Immediately intraorally adaptable
- ‘Boil-and-bite’ device
- Low cost appliance



Somnoguard®



normal position jaw maximal extension searched position halfway

O.M. Vanderveken, A.N. Boudewyns, M.J. Braem, W.A. De Backer & P.H. Van de Heyning
Prospective evaluation of a thermoplastic mandibular advancement device in 20 patients with sleep related breathing disorders. Eur Respir J 2002; 20 (suppl 38) : 103s

Aim of the present study

- Subjective evaluation of thermoplastic MAD for the control of daytime sleepiness and snoring
- Instruments:
  - **Daytime Sleepiness: Epworth Sleepiness Scale (ESS)**
  - **Snoring: Visual Analogue Scale (VAS)**

Epworth Sleepiness Scale (ESS) (0-24)

- Subjective daytime sleepiness evaluated by the ESS
- EDS defined as ESS score > 10

Johns MW. A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep. 1991; 14(6): 540-5.

Visual Analogue Scale (VAS) (0-10)

- Standard 10 cm visual analogue scale (VAS) to evaluate snoring during sleep assessed by the sleeping partner
- 0 (no snoring noise) - 10 (extreme noise-bedpartner leaves the room)
- Heavy snoring defined as VAS ≥ 7

Patients & Methods

- 36 heavy snorers
  (29 males; age 47.1±11.6 years (mean±SD); body mass index(BMI) 25.9±3.4 kg/m²; AHI 6.3±7.0)
- 1-month & 6-months follow-up visits
- End-point: follow-up after 0.8±0.4 y
- Responder = use of the device + important reduction in snoring (VAS≤3)

Statistical analysis

- Data presented as mean ± SEM
- Bonferroni method
- SPSS for Windows
- Statistical significance: $p < 0.05$

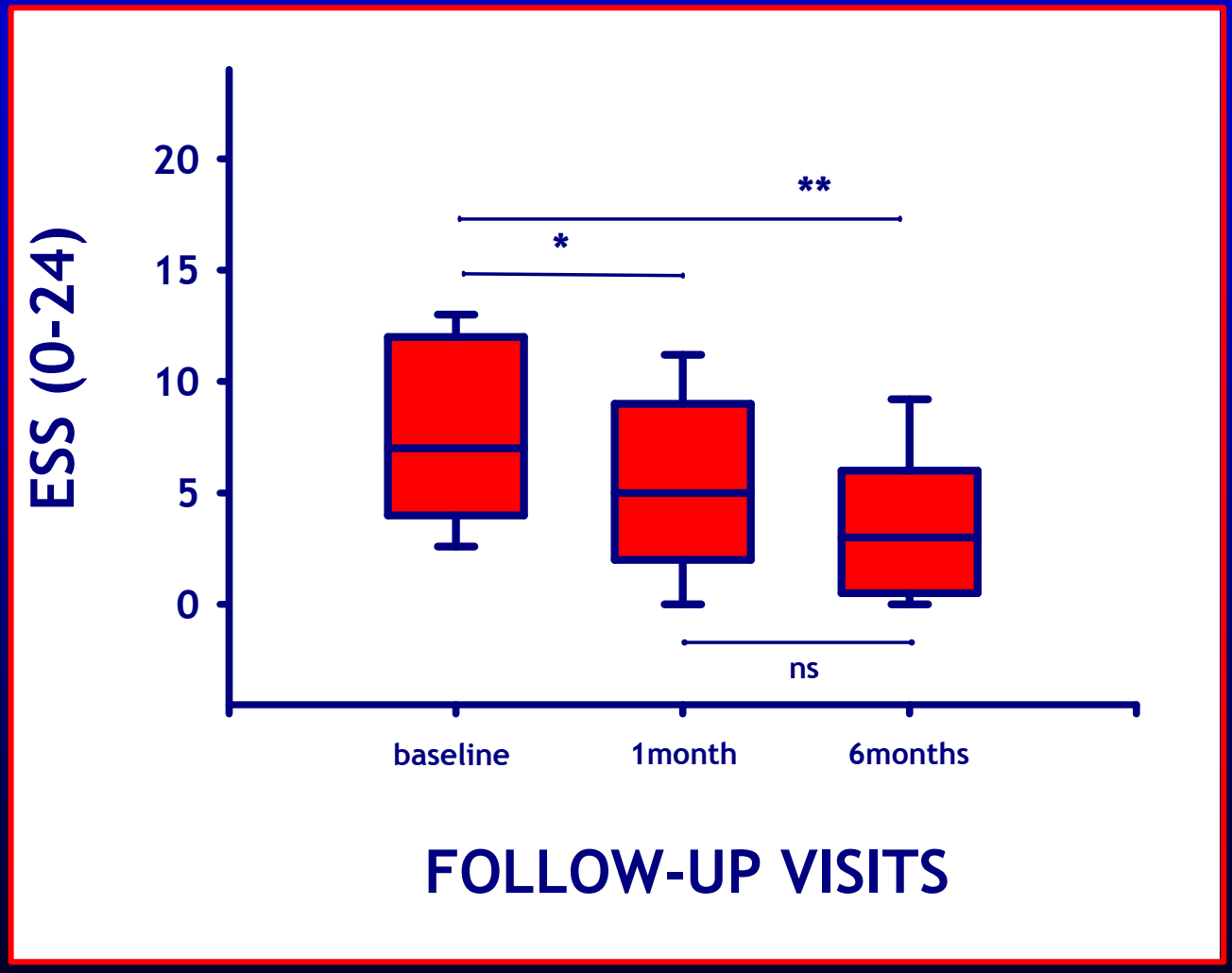
Subjective evaluation (n=36)

Daytime Sleepiness - Epworth Sleepiness Scale

- 9 patients reporting EDS at baseline
- Six out of 9: ESS ≤10/24 with MAD (67%)
- Statistically significant reduction in ESS at both follow-ups compared to baseline

baseline	7.4 ± 0.8
1month	5.3 ± 0.8
6months	4.1 ± 0.7

ESS values (n=36) before adaptation and at a 1-month and a 6-months follow-up; * p = 0.005; ** p < 0.001; ns = no significance



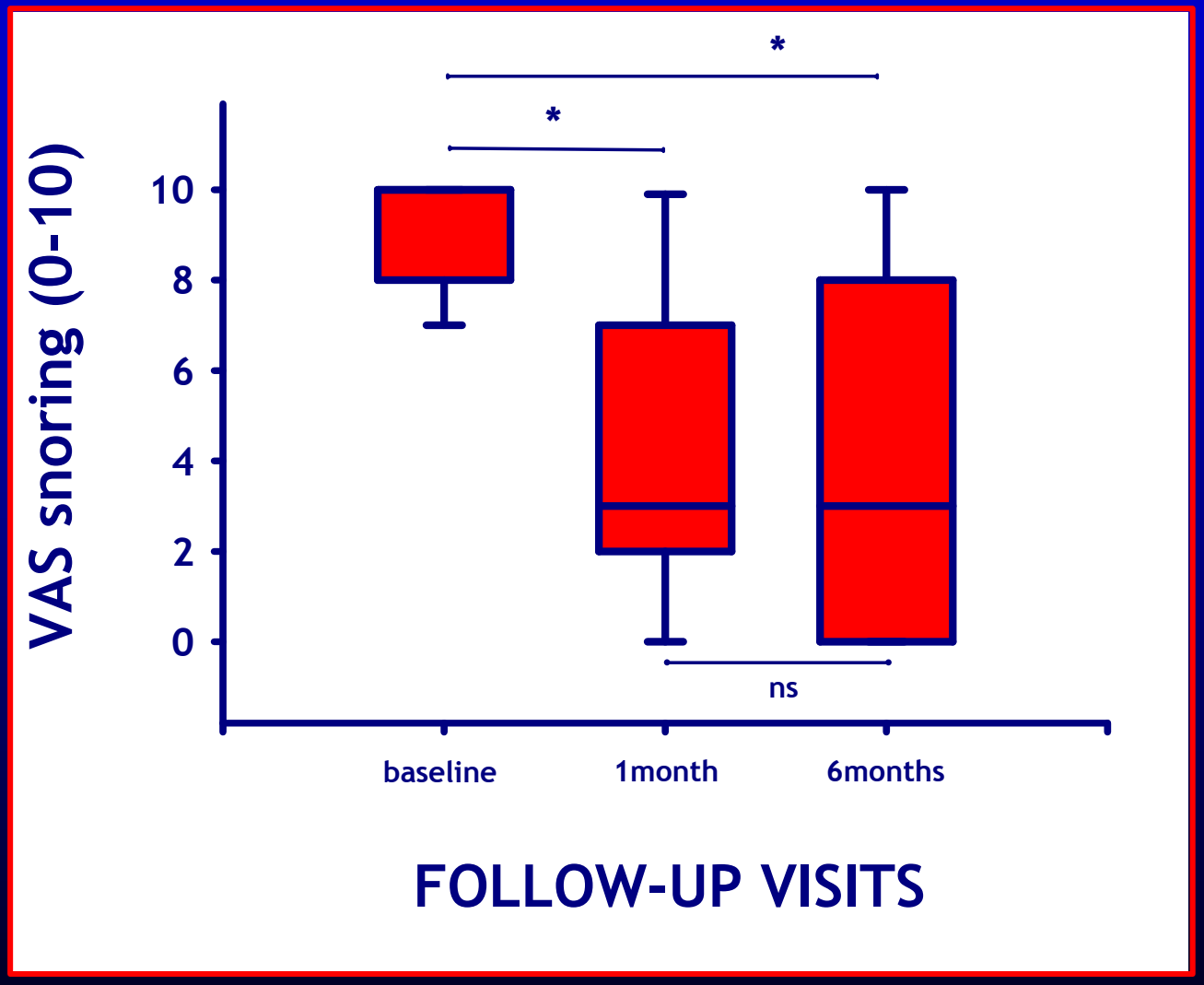
Subjective evaluation (n=36)

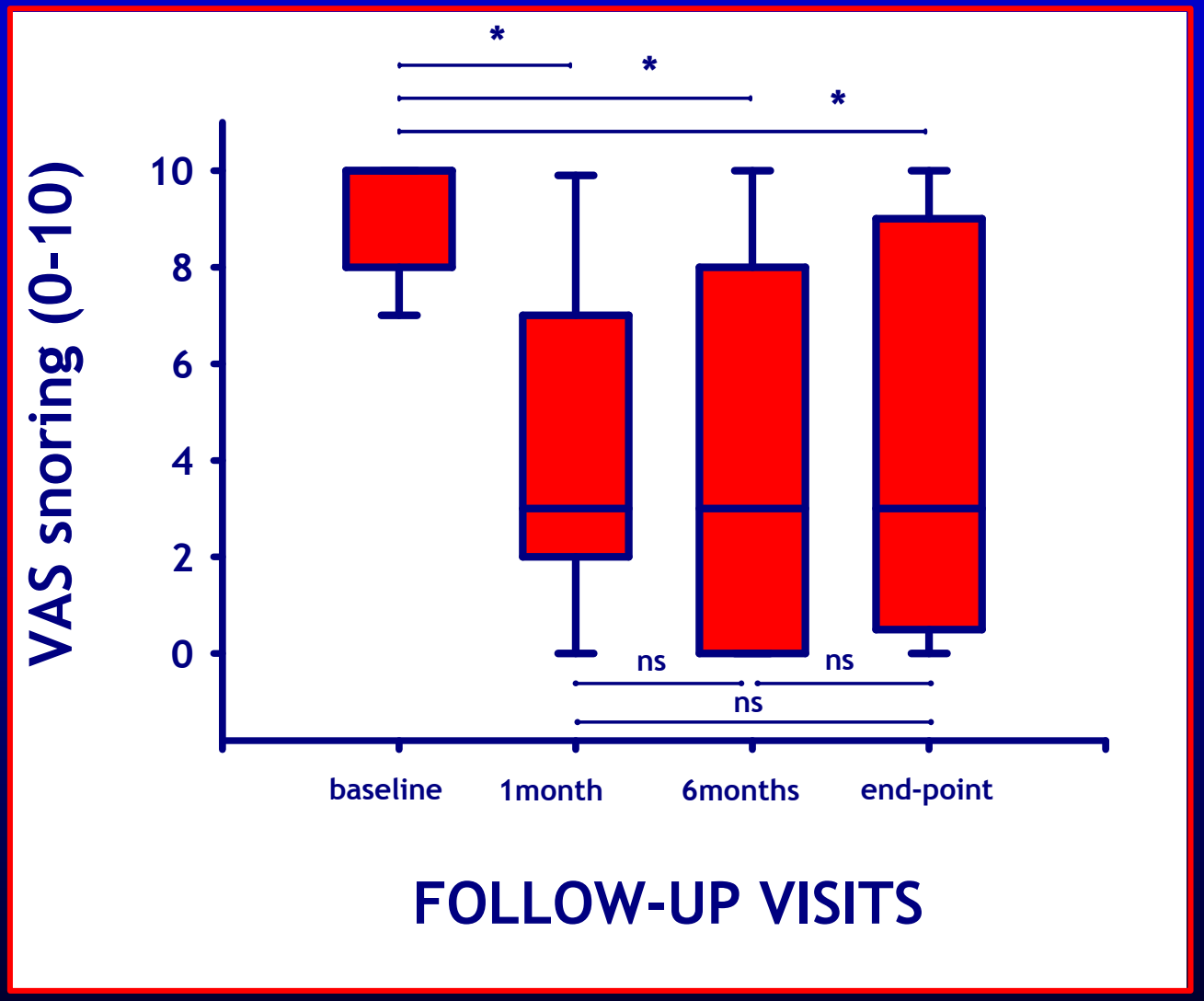
Snoring - Visual Analogue Scale

- At end-point follow-up (0.8±0.4 y): 56% responder rate
- Statistically significant reduction in VAS at both follow-ups compared to baseline

baseline	9.0 ± 0.2
1month	4.1 ± 0.6
6months	4.2 ± 0.6

VAS values (n=36) before adaptation and at a 1-month and a 6-months follow-up; * p < 0.001; ns = no significance




*
*
*
VAS snoring (0-10)
10
8
6
4
2
0
ns
ns
ns
baseline
1month
6months
end-point
FOLLOW-UP VISITS

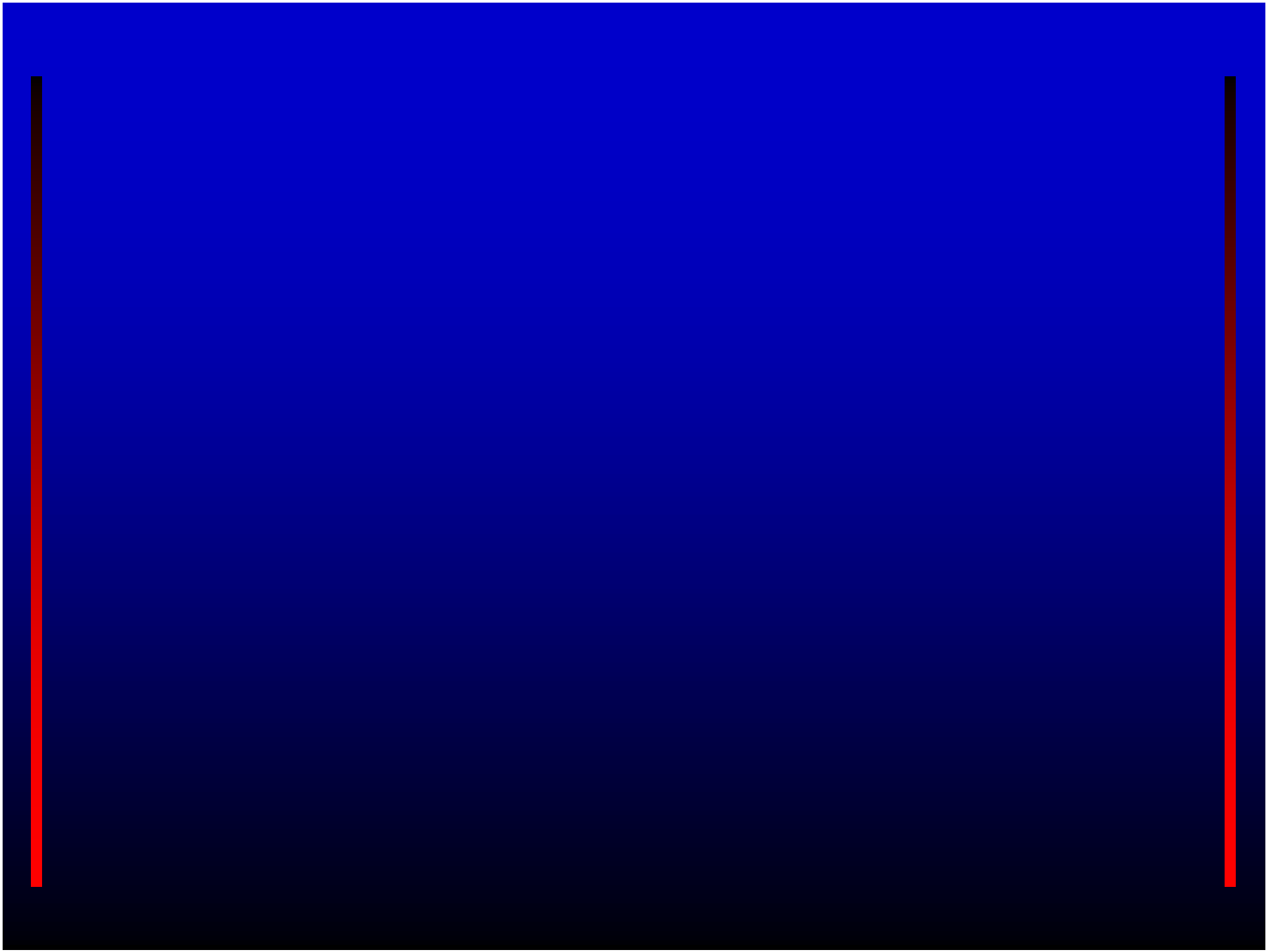
Conclusions

- Significant reduction of subjective snoring and daytime sleepiness in heavy snorers and mild OSA
- Cost-effective & valuable treatment for heavy snoring +/- EDS

Considerations for future study

- Screening of candidates for custom-made MAD with thermoplastic MAD ?
  - Further evaluation of the immediately adaptable technique
  - Studies that compare custom-made & thermoplastic devices

Schönhofer B, Hochban W, Vieregge HJ, Brunig H, Kohler D. Immediate intraoral adaptation of mandibular advancing appliances of thermoplastic material for the treatment of obstructive sleep apnea. Respiration. 2000; 67(1): 83-8.



Pilot study (n=20)

- 20 heavy snorers
  (15 males; age 46.8±12.1 years (mean±SD); body mass index(BMI) 26.7±3.5 kg/m^2; AHI 5.5±4.6)
- efficacy, feasibility, side effects and compliance of Somnoguard®
- 1-month & 6-months follow-up visits

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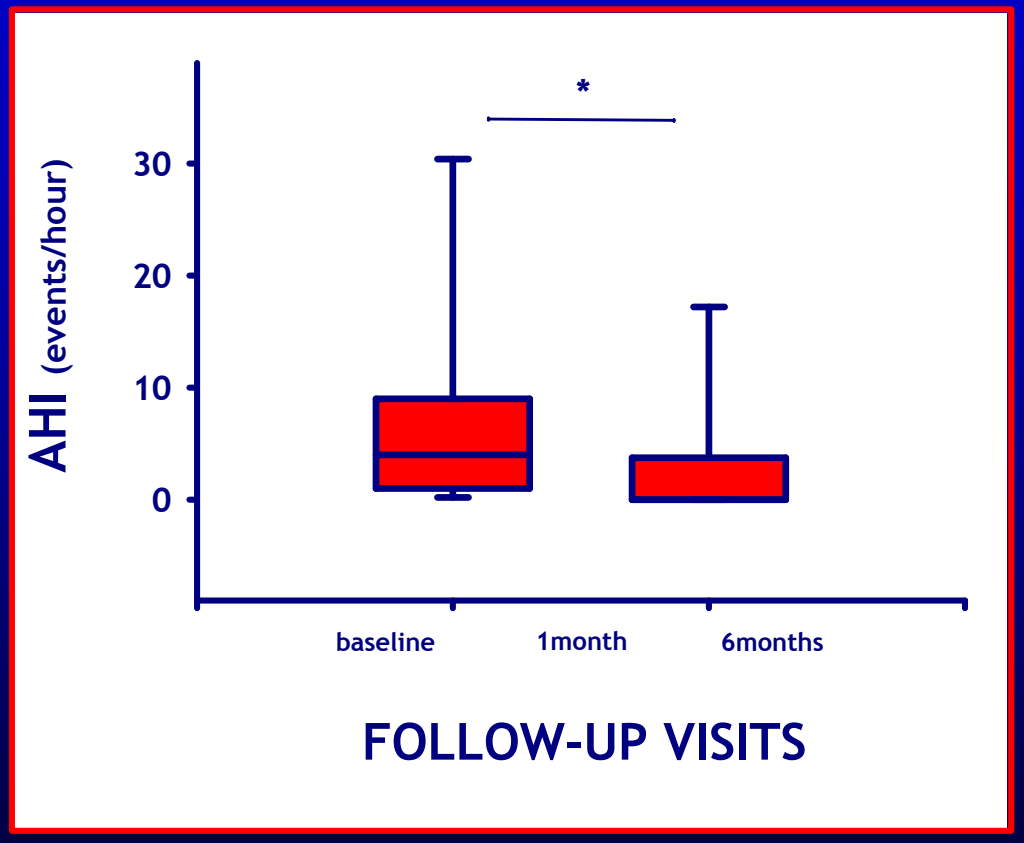
Polygraphy results without (baseline) and with (1 month) MAD; * p = 0.001 (n=17); Wilcoxon Signed Ranks test



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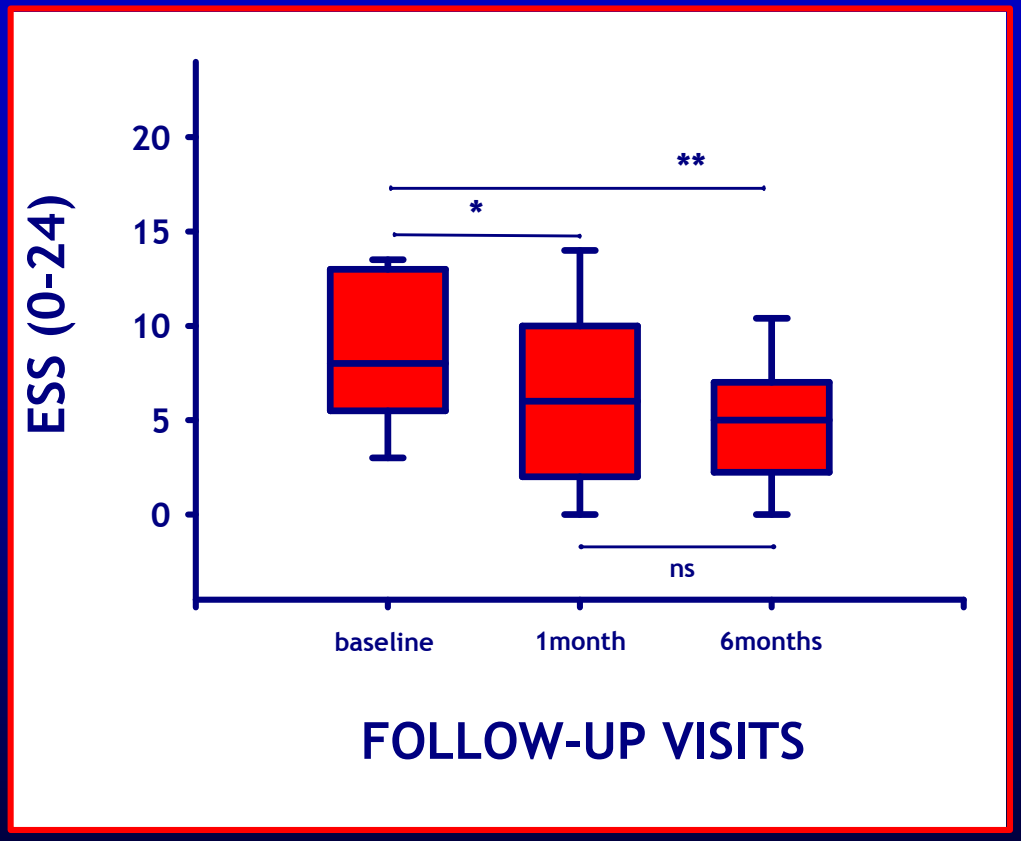
Subjective daytime sleepiness values (n=20) before adaptation and at the 1-month and 6-months follow-up visits; * p = 0.036; ** p = 0.033; ns = no significance



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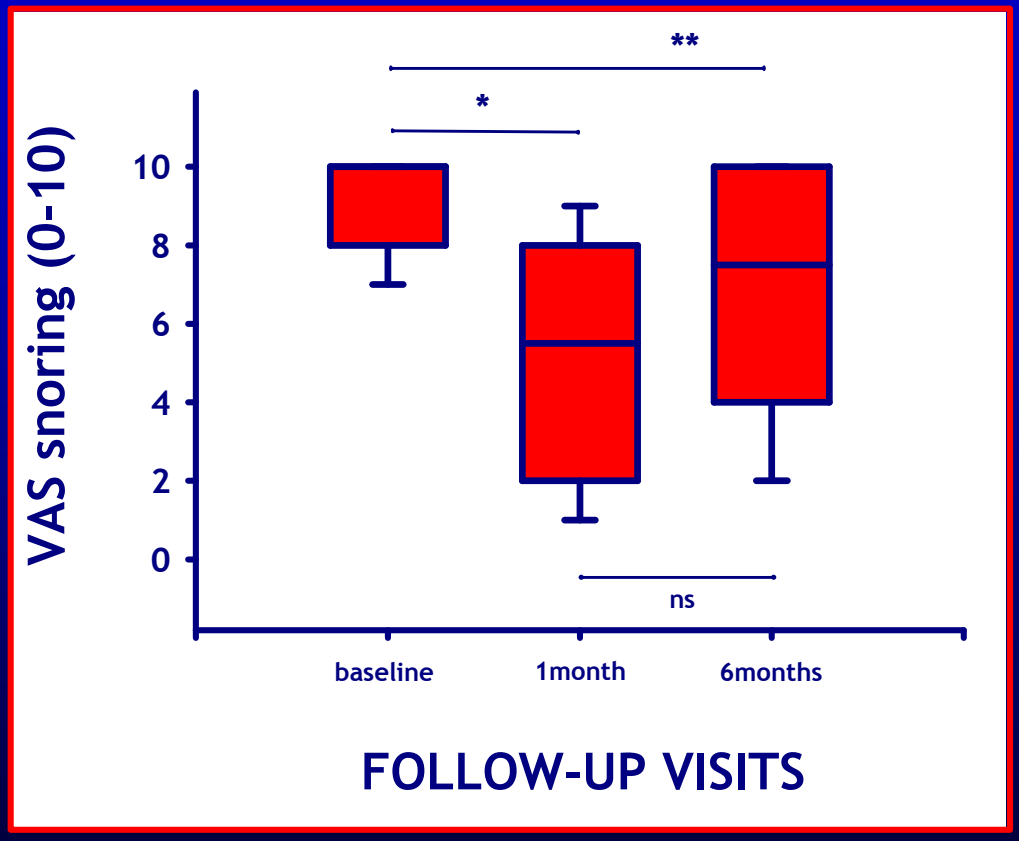
Subjective snoring values (n=20) before adaptation and at the 1-month and the 6-months follow-up visits; * p < 0.001; ** p = 0.025; ns = no significance



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Pilot study (n=20)

- 65% success rate on AHI
  (success = reduction AHI of at least 50 %)
- Significant reduction of subjective snoring and daytime sleepiness
- Rather high compliance rate
- No severe side effects

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