

EVALUATION OF THE "CHIN-UP" STRIP

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Purpose: The purpose of this study was to evaluate the effectiveness of the Chin-up strip in patients with primary snoring and mild obstructive sleep apnea (OSA).

Methods: We recruited subjects from the Sleep Clinic at the University of Kentucky College of Medicine. Subjects had significant (>25% of time) snoring and/or mild OSA documented by overnight polysomnography (PSG). Baseline data included standard history and physical examination, Epworth Sleepiness scale (ESS), and standard PSG (Alice, Heathdyne). Data were analyzed by student T-test (hetero-scedastic). Patients underwent a repeat study while wearing the Chin-up strip and Breathe Right within 60 days of the original study.

Results: 3 of the patients had mild OSA. Their mean Respiratory Disturbance Index (RDI) was 17.8/hr baseline, and 2.3/hr with the strip. 66% of the patients reported subjective improvement in their quality of sleep with the strip.

| | Age(mean) | | 45.1 years 5/9 (55.0%) 4/9 (44.4%) 220.4 Ibs. | |
|---------------------------------------|---------------------------|-----------|--|-------------------------|
| | Male | Female | Weight (mean) | |
| | Baseline Study (n = 9) | | Chin-up Device (n = 9) | P value |
| BMI | 34.4 | | 34.2 | 0.480 |
| Sleep Efficiency (%) | 79.0 ± 13 | | 75.6 ± 14 | 0.312 |
| Stage 1 % Stage 2 % Stage 3/4 % REM % | 15.4 ± 14 | 41.0 ± 10 | 8.6 ± 6.0 12 16.1 ± 8.1 | 0.107 0.347 0.239 |
| % of total sleep time w/ snoring | 9.2 ± 6.9 45.9 + 14 | | 11.3 ± 8.1 29.3 + 14 | 0.280 0.035* |
| Total # of Arousals | 81.3 | | 74.3 | 0.395 |
| Epworth Sleep Scale (ESS) | 11.6 | | 9.8 | 0.272 |
| SaO2 lowest | 91.8 | | 92.6 | 0.367 |

Conclusions: Conclusion/Clinical Implication: We conclude that the Chin-up strip combined with Breathe Right nasal strip is an effective alternative treatment for primary snorer, as well as for mild OSA patients who are not surgical candidates or cannot tolerate CPAP.

U.S. Patents: 5640974 & 5690121 issued to Dale D. Miller.

EXPERT OPINION - Chin-Up Strips - CUS

11-27-01 - Opinion of Hospital Sleep Center Doctor:

The claims made by The Chin-Up Company for Chin-Up Strips are valid. By keeping the mouth closed, snoring is largely eliminated. Most snorers snore with an open mouth and only a very few individuals are able to snore loudly with a closed mouth. You can demonstrate this on yourself by attempting to simulate snoring with mouth open and closed. Snoring has both important medical as well as social consequences if left unmanaged.

Many snorers have what is known as socially unacceptable snoring disturbing their bed partners every night and if not corrected can lead to one of the bed partners leaving the bedroom, an action that can have dire consequences on one's marriage. Medical problems range from disrupted sleep and excessive daytime sleepiness to actually increasing one's risk for heart attack or stroke. There is new published evidence highlighting the possibility that snoring is not just a correlate of obstructive sleep apnea, but may actually cause sleep apnea. There are good reasons to attempt to curb snoring early on.

For those who have sleep apnea, prescribed CPAP therapy is the gold standard for sleep apnea management. CPAP users in the U.S. number in the hundreds of thousands. I estimate 50% tend to vent air or mouth breathe instead of nose breathe while sleeping with CPAP. The CUS, especially the Tan CUS appears to offer a reliable means of helping the CPAP patient maintain a closed mouth while sleeping with CPAP.

I could go on, but I think the message is clear, the CUS appears to be an effective, noninvasive and inexpensive means for helping one maintain a closed mouth while sleeping and eliminate snoring and attendant risk factors. CUS also assist CPAP users to maintain a closed mouth while sleeping so the prescribed positive air pressure does not escape through their open mouth instead of helping them maintain an open upper airway while they sleep.

At our sleep center we recommend CUS for snorers without sleep apnea and for those who mouth breathe while sleeping with CPAP. We advise CPAP users to wear the CUS while sleeping with CPAP. Many sleep centers across the country are also using the CUS as we are doing. Because snoring and sleep apnea and management of sleep apnea with CPAP is huge in terms of numbers of individuals affected, I believe the demand for CUS will correspondingly also be huge as it becomes more widely known just how effective this simple product is. The claims made for CUS by DMI are valid.

I should add that I am a supporter of the CUS product because I know what it can do first hand. My opinions are my own and I do not have a financial interest in DMI so my opinions are not biased by conflict of interest.

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