Why MDSA®?

The MDSA® offers patients;
- **the most effective**
- **robust**
- **easy to keep clean**

simple to use appliance available.

The MDSA® offers patients;
- **a safe**
- **comfortable**
- **extremely well tolerated**

treatment for snoring and mild to moderate OSA.

Mandibular Advancement Splints ("MAS"), (generically termed Oral Appliances) are approved by the Australia Dental Association as a safe and effective first line treatment for snoring, mild and moderate OSA and suitable for patients with severe OSA who are intolerant of ("CPAP").

The MDSA® has many unique patented features, which overcome many of the problems associated with other MAS;
- **made from patients own impressions**
- **easily titratable up to 14mm**
- **full lateral movement**

Most Patients attain immediate benefit from the MDSA®.
(Published patient acclimatisation period of 1-3 weeks not 5-40 weeks as published for other appliances).

The versatility of the MDSA® means that a wider cross section of patients can be treated.

Availability of the MDSA® is not restricted to expensive in house manufacture. Its unique design means that any Dentist or Dental Laboratory can manufacture an MDSA®.

Registered Design Patents,
Australia No. 144305 (2001), USA No. D450,850S (2001)
Australian Patent No. 770465 (2004)
USA Patent Pending
Awaiting USA FDA 510(k) Approval
International Trade Mark Registered
CE Mark/TGA Approved Exempt

Race Dental

Contact your M.D.S.A supplier today!

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Email : customersupport@racedental.com.au
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The MDSA® is easy for the patient to use...

< Upper plate

Place over top teeth

Press firmly in place

Ensure its comfortable with good retention

< Lower plate

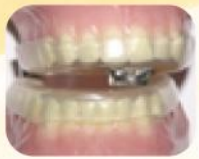
Place over bottom teeth

Press firmly in place

To engage push the bottom jaw forward and up

Full lateral movement minimises TMJ problems

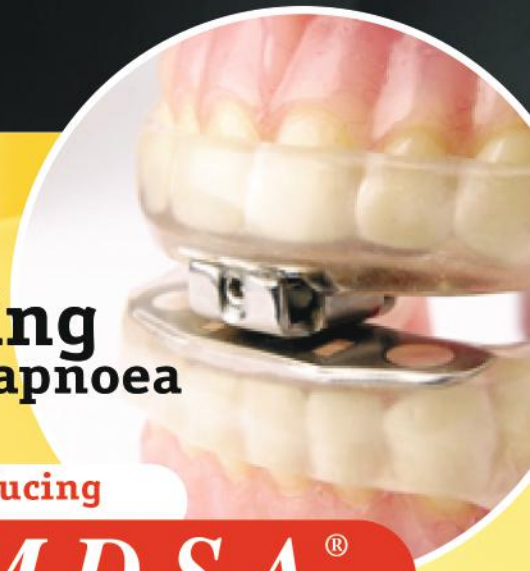
Use turn key to adjust



Titratable up to 14mm

published medical evidence confirms M.D.S.A.®

as the clinically proven alternative to CPAP for first line therapy in mild-moderate OSA



snoring & sleep apnoea

introducing

M.D.S.A.®

Titratable Medical Dental Sleep Appliances

Clinically proven, safe, effective, more compliant than CPAP in mild-moderate sleep apnoea.

Efficacy of Positive Airways Pressure and Oral Appliance in Mild to Moderate Obstructive Sleep Apnoea

Maree Barnes, R. Douglas McEvoy, Siobhan Banks, Natalie Tarquinio, Christopher G Murray, Norman Vowles, and Robert J Pierce
Am. J. Respir. Crit. Care Med. published 16 June 2004, online.
http://www.ajrccm.org/cgi/content/abstract/200311-15710Cv1?etoc

Abstract:
The efficacy of currently - recommended treatments is uncertain in patients with mild to moderate obstructive sleep apnoea (apnoea - hypopnea index 5-30). A group of 114 sleep clinic patients with apnoea-hypopnea index 5-30 have participated in a randomized controlled crossover trial of 3 months treatment with each of nasal continuous positive airways pressure, a mandibular advancement splint and a placebo tablet. Outcomes were sleep fragmentation and hypoxemia, daytime sleepiness, quality of life, neurobehavioral function and blood pressure.

Both active treatments improved sleep outcomes, but positive pressure had a greater effect.

Quality of life, symptoms and subjective but not objective sleepiness improved to a similar degree with both treatments, however many of the improvements seen in the neuropsychological function and mood were no better then the placebo effect.

Some aspects of nocturnal blood pressure were improved with the splint but not with continuous positive airway pressure.

This study has shown that although both continuous positive airways pressure and mandibular advancement splint effectively treated sleep-disorder breathing and sleepiness, the expected response in neurobehavioral function was incomplete. This may be due to the splint having a lesser therapeutic effect, and the **continuous positive airways pressure being poorly tolerated and therefore used less in this patient group.**

(Products used; CPAP Resmed Australia. Oral Appliance MDSA® supplied by RJ & VK Bird Pty Ltd)

What the paper specifically states about the MDSA®

Patient Selection:
...patients were excluded if they did not have at least 2 teeth in the upper and lower jaws on both left and right sides to enable adequate retention of the MDSA®.

...only 5 patients out of 99 could not be fitted with an MDSA®.

Patient Fitting:
...The goal of the MDSA® advancement was maximum comfortable protrusion. At the initial fitting, the MDSA® was advanced maximally as tolerated by the subject. Subjects were reviewed weekly and the MDSA® advanced further. (wash in period for the MDSA®was 1-3 weeks). When no further advancement was possible, the screw was, sealed, advancement measured, and 3 month treatment period commenced.

...no subjects required an extra dental visit.

Patient Advancement:
...Mandibular advancement with the MDSA® was 10.3 ± 0.3mm. And ranged between 1-13mm. Seventy five percent of subjects required at least 70% of maximum possible protrusion.

Patient Acceptance:
...only one subject was unable to tolerate CPAP and **two were unable to use the MDSA®**

Effectiveness of the MDSA® design:
...There has been concern that vertical dimension opening of an oral appliance may result in posterior movement of the tongue and soft palate with consequent reduction of the posterior airway space and worsening of sleep disordered breathing. The AHI increase in uncontrolled oral appliance trials has attributed to a problem with the design of the oral appliance,

...however we found that significantly fewer subjects had an AHI increase with MDSA® than with placebo.

Treatment adherence:

	CPAP	MDSA®
Nights per week:	4.2 ± 0.3	5.3 ± 0.3
Hours per night:	3.6 ± 0.3	5.5 ± 0.3

...It has been proposed that effective CPAP treatment of OSA requires usage for at least 4hours per night on at least 70% nights. 43% of subjects treated with CPAP received adequate treatment, 71% with MDSA®.

...suggesting that the CPAP response extends to low usage levels.

Response to MDSA®:
...In addition to the primary analysis, we measured the improvement in sleep disordered breathing with the MDSA® using response definitions that have been used in similar studies. A complete response is defined as a reduction in the AHI to below 10, and partial response is a fall of at least 50% in the AHI but not below 10, with an improvement in symptoms; the remainder of subjects are classified as treatment failures. By this criteria 49.1% subjects had a complete response to the MDSA®, and a further 6.1% had a partial response. ***(55.2% in total).***

Quality of life:
...Both treatments (CPAP-MDSA®) were more effective than placebo in improving quality of life symptoms and subjective not objective sleepiness, **with neither treatment being better than the other.**

Blood Pressure:
...There was no response in blood pressure to CPAP, however MDSA® improved the nocturnal diastolic blood pressure and significantly increased the proportion of subjects with a normal night time dip in blood pressure.

...The blood pressure response to MDSA® was greater than that to CPAP, and raises the possibility that some aspects of CPAP treatment may mitigate against a lowering of blood pressure in the mild OSA severity range. To our knowledge, there have been no other published controlled trials of the effect on blood pressure of treating OSA subjects with CPAP, and none with an oral appliance.

Response in Mild Subjects:
...A planned *post hoc* analysis of 47 subjects with baseline AHI<15 was performed. Both CPAP ($p<0.01$) and MDSA® ($p<0.02$) were significantly better than placebo in improving sleep-disordered breathing (AHI and 4% desaturation rate).

...These mild OSA subjects had an improvement with both CPAP and MDSA® that was significantly better than placebo ($p\leq0.05$) in symptoms, ESS, FOSQ and sf36. **Neither treatment was superior to the other.**

...In this group 28% preferred CPAP, 41% preferred MDSA® and 31% preferred placebo.