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Use of Medical Dental Sleep Appliance in the management of severe obstructive sleep apnoea: A case series

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ABSTRACT

Snoring and obstructive sleep apnoea are under-diagnosed and yet common in the adult population. One of the treatment options include mandibular repositioning appliance which is a noninvasive procedure. The primary objective of presenting the two case reports is to highlight the therapeutic efficacy of Medical Dental Sleep Appliance (MDSA) in the management of severe obstructive sleep apnoea both objectively and subjectively. The objective assessment was made by comparing base line AHI (apnoea–hypopnoea index) and AHI with appliance in situ which showed an improvement of 99% and 55%, respectively. The secondary objective is to provide an overview of clinical and laboratory steps in the fabrication of MDSA.

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1. Introduction

Obstructive sleep apnoea (OSA) is the most common sleep-related breathing disorder which is characterized by repetitive or partial closure of upper airway during sleep. Sleep disorders of the upper airway result from any condition or disease that causes its partial or complete obstruction when a patient assumes a supine position and goes to sleep. Common upper airway sleep disorders are: (a) snoring, (b) obstructive sleep apnoea, (c) sleep bruxism, and (d) upper airway resistance syndrome. Estimated prevalence of sleep disorder breathing (SDB) in urban Indian men is 19.5% (apnoea–hypopnoea index of 5 or more) and 7.5% (SDB with hypersomnolence) which is striking and may have major health implication in developing countries.[1] According to Wisconsin sleep cohort study, it affects 4% of males and 2% females.[2] It is a risk factor for various cardiovascular system (CV) diseases, increased vehicle accident rate, poor performance at work place, memory loss, and libido. The gold standard to diagnose a case of OSA is polysomnography (PSG) followed by dynamic MRI, CT scans, acoustic reflection test, and lateral cephalogram.[3] The management includes CPAP (continuous positive airway pressure) vide oral or nasal interface, maxillomandibular advancement surgery, palatouvulopharyngoplasty, midline glossectomy, hyoid suspension, and oral appliance.

Oral appliances are noninvasive and recommended treatment modality for mild to moderate and severe OSA cases who are not amenable to CPAP therapy and are not willing for surgery.[4] Currently available appliances not only produce incremental advancement which is self-adjustable, but also lateral movement of the mandible and ensure that the

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Table 1 – Objective assessment.

Events	Apnoeas		Hypopnoeas		Index AHI	
	Pre-treatment	Post treatment	Pre-treatment	Post treatment		
Case I	25	0	43	24	36.7	2
Case II	281	116	45	52	70	31.7

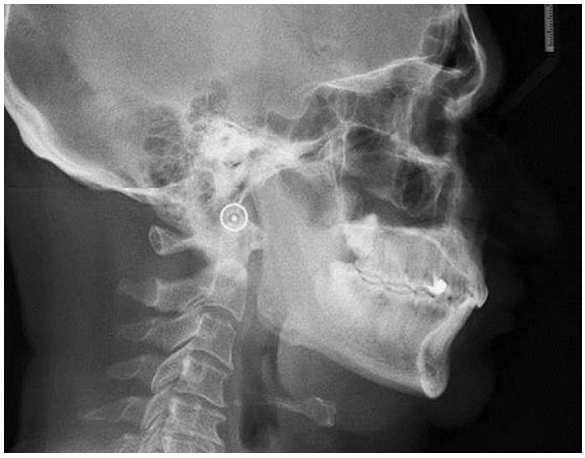


Fig. 1 – Lateral cephalogram of Case I at end expiration.

mandible is retained in the forwardly postured state during sleep.[5] In this case series, we would be highlighting the therapeutic efficacy of titratable mandibular advancement device (MAD) in the management of severe OSA cases.

2. Case reports

2.1. *Case I*

A 46-year-old male was referred from Department of Pulmonary and Sleep Medicine for craniofacial evaluation and feasibility of oral appliance therapy. He reported excessive snoring, excessive daytime sleepiness, gasping of air, and sleeping while driving for which he was taken off from vehicle duty. His PSG revealed Apnoea–Hypopnoea Index (AHI) of 36.7 events/hr (Table 1). His BMI was 30 and pre-treatment Epworth sleepiness scale (ESS) was 12. He had an airway grading of Mallampatti score III. He had sound dentition with 28 teeth. He had refused treatment with CPAP.

Cephalometric analysis (Fig. 1) revealed Class II (ANB 7°) skeletal bases with decreased superior airway (SAS = 7 mm) and posterior airway space (PAS = 8 mm) respectively (Table 2). He was treated with customized Medical Dental Sleep Appliance.

2.2. *Case II*

A 57-year-old male was referred by Department of Pulmonary and Sleep Medicine for craniofacial evaluation and feasibility of oral appliance therapy as he was uncomfortable with CPAP therapy. He reported with chief complaint of loud snoring, excessive daytime sleepiness, feeling of choking, restless sleep, loss of concentration, nocturnal oesophageal reflux, and change of personality. His PSG revealed AHI of 70 events/hr (Table 1). His BMI was 32 and pre-treatment ESS was 20. He had an airway grading of Mallampatti score IV. Cephalometric analysis revealed Class II (ANB 6°) skeletal bases with increased hyoid distance (21 mm), decreased superior, middle and posterior airway space (SAS), i.e., 10 mm, 7 mm and 8 mm respectively. Pre-treatment airway analysis and lateral cephalogram are shown in Table 2 and Fig. 2.

The patients were asked to wear it initially for few hours and gradually increase the wearing time. Improvement in snoring, excessive daytime sleepiness, and improvement in tiredness were evaluated following titration of the appliance. PSG/overnight sleep study was done at sleep clinic of the hospital with appliance in situ.

3. Results

3.1. *Case I*

Follow-up polysomnography that was performed 1 month after the insertion of the appliance revealed that his AHI decreased 36.7 to 2 events per hour of sleep with a mean SaO2 of 99% and ESS reduced from 12 to 2. The improvement in AHI was estimated to be 99% with gross reduction in total number

Table 2 – Cephalometric assessment (Airway Analysis).

Measurements	Normal	Case I		Case II	
		Pre-Rx	Post-Rx	Pre-Rx	Post-Rx
SNA (°)	82	84	84	88	88
SNB (°)	80	78	78	81	81
ANB (°)	2	6	2	7	7
SAS (mm)	15–20	7	14	10	17
MAS (mm)	9–11	8	10	7	9
PAS (mm)	9–11	8	9	8	8
MPH (hyoid distance) (mm)	15	17	14.6	21	14



Fig. 2 – Lateral cephalogram of Case II at end of expiration.

of apnoeic and hypopnoeic events. Post-treatment airway analysis and cephalogram are shown in Table 2 and Fig. 7.

3.2. *Case II*

Follow-up polysomnography that was performed 1 month after the insertion of the appliance revealed an AHI decrease from 70 to 31.7 events per hour of sleep with a mean SaO2 of 94% and ESS score reduced from 20 to 6. The improvement in AHI was estimated to be 55% with gross reduction in total number of apnoeic and hypopnoeic events. Post-treatment airway analysis and cephalogram are shown in Table 2 and Fig. 8.

4. Discussion

OSA is one of the commonest SDB disorders, yet grossly underdiagnosed. It is characterized by repetitive episodes of partial or complete obstruction of airway resulting in drop in oxygen saturation levels.[6,7] OSA syndrome affects 2–4% of adult population as per western.[8] According to Indian study, prevalence is 7.5% in urban Indian population.[9]

OSA patients are susceptible to compromised cardio-metabolic derangement like HTN (hypertension), hypoglycemia, hyperlipidemia, and behavioral deficits like excessive daytime sleepiness, altered mood state, and problem with memory consolidation.[10] The cases reported also had some of the presentation as described above. Obesity, increased neck circumference, craniofacial factors like maxillo-mandibular deficiency, increased hyoid distance, and increased Mallampatti scores (means of determining airway patency where assessment is made by asking the patient to fully open the mouth with tongue protruding: Score I: soft palate, uvula and pharyngeal wall are fully visible. Score II: pharyngeal wall is slightly visible and space between uvula and tongue is reduced. Score III: Uvula is partially obscured by tongue and pharyngeal wall not visible at all. Score IV: Uvula and part of soft palate obscured and pharyngeal wall not visible at all) have been well documented as risk factors.[11–13] Both the cases had class II skeletal bases, reduced posterior airway space, and increased hyoid distance.

PSG is the gold standard for diagnosing OSA.[14] It involves overnight sleep study with recording of ECG, EOG, EMG, body position change, oxygen saturation, snoring cycle, and generates apnoea index, hypopnoea index, and AHI. PSG provides the AHI scores which are an estimation of apnoea–hypopnoea episodes per hour of sleep. American academy of sleep medicine recommends the following criteria to grade OSA based on AHI into mild (5–15), moderate (15–30), and severe (>30 events/hr). The recommended sleep study is a level 1/type 1 standard attended PSG.[15] Both our patients underwent Type 1 PSG without and with appliance in situ. PSG was carried out for both diagnosis and ascertaining the therapeutic efficacy with MDSA.

ESS is the most commonly used subjective-based self-assessment.[16] The ESS is useful in identifying degrees of sleepiness with high test-retest reliability. The eight questionnaire of ESS questions the individual subject reporting of sleepiness in eight different situations on scale of 0–3. A score of more than 10–11 is found to be abnormal. In cases reported, ESS showed an improvement from 12 to 2 and 20 to 6 in Case I and Case II respectively. This is suggestive of a remarkable subjective improvement.

The management protocol includes behavioral modifications sleep position change and weight control by modification in lifestyle. Definite modalities include CPAP, surgery to enlarge upper airway, and oral appliance. Oral appliance treatment for OSA was reported way back in 1980s wherein a tongue retaining device was successfully used.[17] Subsequently, MAD was introduced for the management of OSA. MAD takes its origin from monobloc appliance which was introduced for Pierre Robin syndrome to hold the jaw forward in order to prevent asphyxia in an infant.[18]

Clinical procedure for the construction of appliance involves impression making, fabrication of study and working models, and recording of protrusive bite with George bite gauge. The bite was recorded at 60% of maximum protrusion (Fig. 3a, b). The working model along with bite was articulated. Durasoft 2.5 mm (thermoplastic sheet) was adapted on working model. The appliance components included a titratable screw in upper (faster component) and platform on the lower base (shelf) which was secured with autopolymerising resin (Figs. 4 and 5). The appliance was finished and delivered. The mandible had to position anteriorly to engage the lower plate with upper titratable hook (Fig. 6).

All MAD work by guiding the mandible forward during sleep, thereby increasing the space between posterior pharyngeal area and tongue. The MAD appliance acts by elevating the base of tongue, pulling the soft palate and tensing the palatoglossus muscle, stabilizing the lateral pharyngeal wall by applying tension to pterygomandibular raphe which is coupled to pharyngeal constrictors, and splaying the tonsillar arches.[19] An influential review in 1995 for OSA accompanied by practice parameters of American sleep disorder association signaled the entry of dentistry into sleep medicine. Adjustable titratable MAD became the predominant form of dental therapy for OSA in 1990s. Practice parameters for treatment of snoring and OSA with oral appliance endorsed by American Academy of Sleep Medicine have recommended oral appliance therapy for mild to moderate OSA and those who are not amenable to CPAP therapy or who fail to show any treatment response with CPAP therapy.[20]

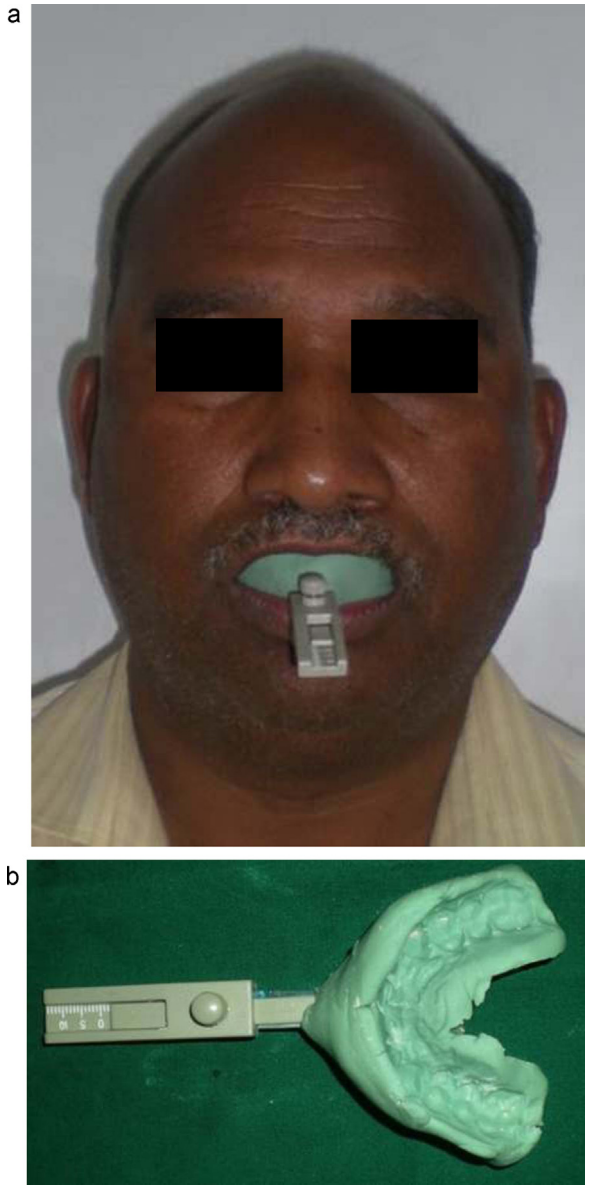


Fig. 3 – (a) Bite recording with George bite gauge. (b) Impression obtained from George bite gauge.

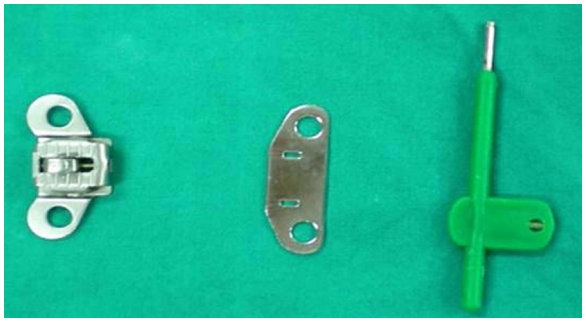


Fig. 4 – Component of MDSA. (a) Titratable screw (faster component). (b) Lower stainless steel platform. (c) Allen key for titrating/adjusting the screw.



Fig. 5 – MDSA view of upper and lower components.



Fig. 6 – Intraoral view of MDSA.

Adjustable/titratable MAD is preferred due to the fact that the titration or incremental advancement of mandible can be done which is more or less similar to titration of CPAP and the best possible treatment outcome can be established by optimizing the spatial position of mandible. There are various FDI approved titratable/adjustable MAD like Thorton adjustable positioner, Somnomed, PMA, etc.[5] In all these cases, the initial bite is recorded at 50–60% of total protrusion and gradually advanced with the help of adjustable screws. In our case, we used MDSA system which has titratable screw (faster component) with flat platform (shelf) in lower arch. The appliance design facilitates lateral movement of mandible in sleep. This appliance requires periodontally sound dentition, adequate protrusive movement, and interincisal opening. One of the authors in his experience put forward the criteria for predicting the success of oral appliance therapy (OAT) which encompasses[20]:

(a) PSG diagnosed OSA.
(b) BMI less than 30 kg/m^2.
(c) Dentally fit.
(d) Stanford morphometric model ≥70 with predominant contribution from craniofacial factors. Any two of cephalometric reading (increased ANB with decreased SNB, decrease posterior airway space, increased hyoid distance). Reported cases also had decreased PAS, increased ANB and increased hyoid distance which may have contributed to successful OAT (Oral appliance therapy). Literature cites

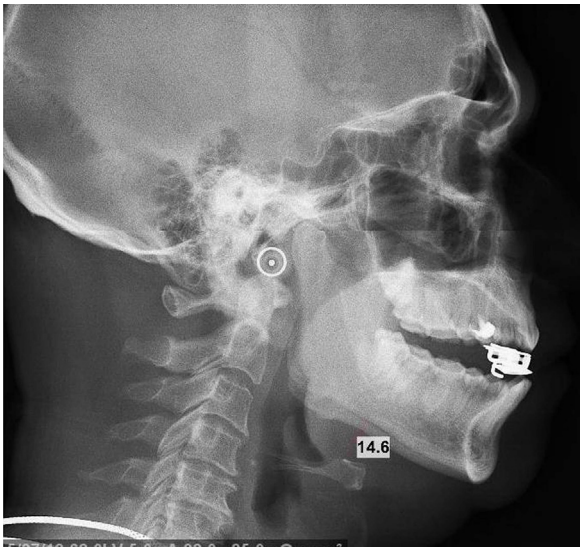


Fig. 7 – Post-lateral cephalogram of Case I at end of expiration.



Fig. 8 – Post-lateral cephalogram of Case II at end of expiration.

50% reduction in AHI as criteria for successful treatment. In our case, we had reduction of 90% and 55% which indicates successful treatment.

Evidence with respect to therapeutic efficacy of MAD has shown significant improvement in objective sleep measurement, AHI, arousal index, arterial oxygenation, and snoring. Significant improvements were seen in subjective, objective measurements, quality of life, and BP. Studies have shown that CPAP and MAD have similar improvement in cardiovascular outcome and inflammatory markers.[21–23]

Side effects are common, and the most frequently reported include temporomandibular joint (TMJ) pain, myofascial pain, tooth pain, salivation, TMJ sounds, dry mouth, gum irritation, and morning after occlusal changes.[24–27] In both cases, MDSA was associated with mild, temporary subjective side effects mainly during the first month. Most of these side effects are minor and well tolerated and tend to be resolved in a short period. However, objective side effects such as tooth movement, skeletal changes, and occlusal alteration have also been reported.[25] Temporomandibular disorders (TMD) have been associated with the use of MAD, and this disorder is one of the exclusion criteria for many clinical studies.[28,29] The majority of studies used the Helkimo Index or signs and symptoms to assess TMD. TMD are a cluster of heterogeneous disorders of the masticatory muscles and TMJs.[30] The myogenous and arthrogenous disorders may be further subclassified into myofascial and arthrogenous pain, disk displacements, and degenerative joint disease as the most common conditions.

5. Conclusion

Titratable MAD has been considered one of the first line of treatment in mild, moderate, and severe OSA cases not amenable to CPAP therapy. The case series highlights successful management with MDSA wherein more than 50% of AHI reductions have been achieved and gross improvement on subjective parameters. In addition to following the recommended inclusion criteria for OAT for OSA, we have incorporated additional inputs for case selection which may have contributed to successful management of severe OSA with titratable MAD.

REFERENCES

1. Udwadia ZF, Doshi AV, Lonkar SG, Singh CI. Prevalence of sleep-disordered breathing and sleep in middle aged urban Indian men. *Am J Respir Crit Care Med*. 2004;169:168–173.
2. Bailey DR, Attanasio R. Dentistry's role in the management of sleep disorders. Recognition and management. *Dent Clin North Am*. 2001;45:619–630.
3. AARC-APT (American Association of Respiratory Care-Association of Polysomnography Technologists) clinical practice guideline. Polysomnography. *Respir Care*. 1995;40:1336.
4. American Sleep Disorder Association report. Practice parameters for the treatments of snoring and obstructive sleep apnea with oral devices. *Sleep*. 1995;18:511–513.
5. Johal A. A review of the use of mandibular advancement appliances in sleeps disordered breathing. *Dent Update*. 2008;35:230–235.
6. Bradley TD, Floras JS. Obstructive sleep apnoea and its cardiovascular consequences. *Lancet*. 2009;373:82–93.
7. Phillipson EA. Sleep apnea – a major public health problem. *N Engl J Med*. 1993;328:1271–1273.
8. Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. *Am J Respir Crit Care Med*. 2002;165:1217–1239.
9. Udwadia ZF, Doshi AV, Lonkar SG, Singh CI. Prevalence of sleep disordered breathing and sleep apnoea in middle aged urban Indian men. *Am J Respir Crit Care Med*. 2004;169:168–173.
10. Phillips CL, Wong K. Long term consequences of obstructive sleep apnea. In: Lavigne GJ, Cistulli PA, Smith MT, eds. In: *Sleep Medicine for Dentists – A practical Overview* 1st ed. Quintessence Publishing; 2009:47–52.
11. Guilleminault C, Quo SD. Sleep-disordered breathing. A view at the beginning of the new Millennium. *Dent Clin North Am*. 2001;45:643–656.

12. Lowe AA, Fleetham JA, Adachi S, Ryan CF. Cephalometric and computed tomographic predictors of obstructive sleep apnea severity. *Am J Orthod Dentofacial Orthop*. 1995;107: 589–595.
13. Jayan B, Prasad BNB, Atul K. The role of cephalometric analysis in obese and nonobese urban Indian adults with obstructive sleep apnea syndrome: a pilot study. *Indian J Sleep Med*. 2007;22:59–63.
14. Attanasio R, Bailey RD. Sleep assessment/studies. In: Attanasio R, Bailey RD, eds. In: *Dental Management of Sleep Disorders* 1st ed. Wiley Blackwell Publication; 2010:113–127.
15. Sleep related breathing disorders in adults; Recommendations for syndrome definition and measurement techniques in clinical research, the report of American Academy of Sleep Medicine Task Force. *Sleep*. 1999;22:667–689.
16. Johns MW. A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep*. 1991;14:540–545.
17. Cartwright RD, Samelson CF. The effects of a non-surgical treatment for obstructive sleep apnea: the tongue-retaining device. *J Am Med Assoc*. 1982;248:705–709.
18. Robin P. Glossoptosis due to atresia and hypotrophy of the mandible. *Am J Dis Child*. 1934;48:541–547.
19. Mohsenin N, Mostofi MT, Mohsenin V. The role of oral appliances in treating OSA. *J Am Dent Assoc*. 2003;134:442–449.
20. Jayan B, Prasad BNB, Kharbanda OP, Bhattacharya D. Therapeutic efficacy of Thornton adjustable positioner in the management of patients with severe obstructive sleep apnea: a pilot study. *Indian J Sleep Med*. 2008;33:97–101.
21. Lim J, Lasserson TJ, Fleetham J, Wright JJ. Oral appliances for obstructive apnoea. *Cochrane Database Syst Rev*. 2006; CD004435.
22. Gostopoulos H, Kelly JJ, Cistulli PA. Oral appliance therapy reduces blood pressure in obstructive sleep apnea: a randomized controlled trial. *Sleep*. 2004;27:934–941.
23. Itzhaki S, Dorchin H, Clark G, Lavie L, Lavie P, Pillar G. The effects of one year treatment with a Herbst mandibular advancement splint on obstructive sleep apnea, oxidative stress, and endothelial function. *Chest*. 2007;131:740–749.
24. Shadaba A, Battagel JM, Owa A, Croft CB, Kotecha BT. Evaluation of the Herbst mandibular advancement splint in the management of patients with sleep-related breathing disorders. *Clin Otolaryngol Allied Sci*. 2000;25:404–412.
25. Fritsch KM, Iseli A, Russi EW, Bloch KE. Side effects of mandibular advancement devices for sleep apnea treatment. *Am J Respir Crit Care Med*. 2001;164:813–818.
26. Almeida FR, Lowe AA, Tsuiki S, et al. Long-term compliance and side effects of oral appliances used for the treatment of snoring and obstructive sleep apnea syndrome. *J Clin Sleep Med*. 2005;1:143–152.
27. Marklund M, Franklin KA. Long-term effects of mandibular repositioning appliances on symptoms of sleep apnoea. *J Sleep Res*. 2007;16:414–420.
28. Fransson AM, Tegelberg A, Johansson A, Wenneberg B. Influence on the masticatory system in treatment of obstructive sleep apnea and snoring with a mandibular protruding device: a 2-year follow-up. *Am J Orthod Dentofacial Orthop*. 2004;126:687–693.
29. Battagel JM, Kotecha B. Dental side-effects of mandibular advancement splint wear in patients who snore. *Clin Otolaryngol*. 2005;30:149–156.
30. Tegelberg A, Wilhelmsson B, Walker-Engstrom ML, et al. Effects and adverse events of a dental appliance for treatment of obstructive sleep apnoea. *Swed Dent J*. 1999;23:117–126.

29th Annual Convocation and Awards Ceremony of PFA India section:

The 29th Annual Convocation and Awards Ceremony of the Pierre Fauchard Academy, India section will be held at 9.00 am on Sunday December 20, 2015 at Nehru Centre Discovery of India, Dr. Annie Beasant Road, Worli, Mumbai-400018 (Tel. No; 24964676-80).

The registration shall start at 09.00 am, the Annual General Body Meeting at 09.30 am, to be followed by the Second Maj. Gen. Kartar Singh Oration at 10.00 am. After Refreshments, the 29th Annual Convocation and Awards Ceremony of PFA India section will be held at 12.00 noon.

Further details regarding the Convocation and the Oration shall be intimated later.

Maj. Gen. Dr. Kartar Singh Fund:

The PFA India Section has started Maj. Gen. Dr. Kartar Singh Fund in honour of Late Maj. Gen. Dr. Kartar Singh. Fellows are requested to contribute generously by sending their contribution as a cheque / DD, drawn in favour of Pierre Fauchard Academy to the Secretary.