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Celon® radiofrequency thermo-ablative palatoplasty for snoring – a pilot study

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Abstract

A prospective non-randomized study was designed to investigate the effects of Celon® radio-frequency thermo-ablation (RFTA) of the soft palate in patients with snoring/mild obstructive sleep apnoea. Ten patients, fulfilling various inclusion/exclusion criteria, underwent single operator sub-mucosal RFTA palatoplasty as an office procedure. Two separate procedures six weeks apart involved each patient receiving six distinct sub-mucosal lesions on each visit. Questionnaires including visual analogue scales (VAS) were used to evaluate post-operative pain and subjective snoring (scored by patient/partner). Polysomnography (PSG) was performed pre-operation and three months following the second procedure. Using non-parametric statistical analysis, a significant reduction in VAS snoring was noted from initial levels to those scored at six and 16 weeks in nine of 10 patients ($p = 0.013$ and $p = 0.007$ respectively). (Five of these nine showed a greater than 50 per cent reduction in score). Objectively, six of 10 patients had a reduction in the apnoea-hypopnea Index between the two PSGs, (four of these six showed a greater than 50 per cent reduction) however, this was not statistically significant. Subjective assessment of the PSG snoring signal by the senior author showed eight of 10 patients had either a reduced or much reduced signal at four months. VAS pain confirmed both procedures are well tolerated with minimal analgesia requirements. Minor complaints of transient mild palatal swelling, dry throat, catarrh and referred otalgia were noted and one patient developed mucosal ulceration following both procedures that healed within three weeks. Swallowing and speech were unaffected. These results confirm similar findings using the Somnus® Unit, although the Celon® device provides additional advantages including inherent safety in a bipolar electrode tip, auto-stop energy application and reduced procedure time.

Key words: Snoring; Sleep Apnoea, Obstructive; Palate, Soft; Surgical Procedures, Operative; Treatment Outcome

Introduction

Sleep disordered breathing comprises a spectrum of sleep-related airway disruption ranging from primary snoring to obstructive sleep apnoea syndrome (OSAS).[1] OSAS ranges from mild to severe, dependent on the severity of airway obstruction, with potentially severe, systemic, cardiovascular and respiratory sequelae, a consequence of associated hypoxia, fragmented sleep and daytime dysfunction.[2]

Primary snoring is mainly a source of social disturbance resulting in marital disharmony and divorce, job loss and increased risk of road-traffic accident.[3,4] Chronic habitual snoring affects 24 per cent of men and 14 per cent of women[5] with partial obstruction and narrowing of the upper airway during sleep, often involving redundant tissue, resulting in increased resistance to airflow. The resulting vibratory turbulent airflow combined with the Bernoulli effect produces the noise of snoring in sleep.[6] The uvula and soft palate is reported to be the primary vibratory tissue in 70 per cent of cases.[7]

Medical treatment options for snoring include weight loss and exercise, cessation of alcohol and tobacco consumption, alteration in sleep position, as well as the use of various marketed nasal and dental splints. These are all very much dependent on patient compliance with long-term success typically not achieved in the majority. Various surgical treatment options have evolved over the last 40 years, some more controversial than others, each with their own inherent advantages and disadvantages. Uvulopalatopharyngoplasty (UPPP) was introduced in 1964 but popularized by Fujita in the early 80's.[8] Kamami introduced laser-assisted uvulopalatoplasty (LAUP) in the 80s as an alternative to UPPP that could be performed as an out-patient office procedure under local anaesthesia (LA).[9]

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TABLE I
STUDY CRITERIA

Inclusion	Exclusion
Symptomatic snorer seeking treatment	Moderate to Severe OSAS
Mild OSAS (AHI <20)	(AHI >20 excluding artefacts)
BMI <32	Morbid obesity (BMI >32)
ASA 1 or 2	Nasal Obstruction/Pathology
SNE Grade 1, 2 or 3 (Multilevel Inspiratory Obstruction but predominantly nasopharyngeal)	Tonsillar hypertrophy
18 years or older	ASA 3 or 4
Informed consent	Previous palatal/pharyngeal surgery
	Previous radiotherapy to head/neck
	Bleeding diatheses
	Speech/swallowing problems
	Maxillary/mandibular deficiency
	Neurological disorder
	Active URTI
	Unstable psychiatric disorder
	Age < 18

Both procedures have proved effective in the short term, success rates varying from 70–95 per cent.[10–12] In the longer term however, results are less favourable.[13–15] Both procedures have the significant associated side-effects of post-operative pain and odynophagia, with the potential for various complications including haemorrhage, infection, nasal reflux/regurgitation and altered gustation.[16,17]

The search for simple, effective, inexpensive and well-tolerated surgical treatment in snoring is therefore on. In recent years, minimally invasive temperature-controlled radio-frequency tissue ablation (RFTA) has been investigated. Although initial studies of RFTA in the field of snoring used porcine models,[18] subsequent human studies revealed statistically significant snoring improvement when performed on chronic habitual/mild OSAS snorers.[19–22] Most of these and other published similar studies have utilized technology developed by Somnus® Medical Technologies, Inc. and have looked at short-term results: more recently it has been shown that medium to long-term results show a significant relapse rate.[23]

The authors introduce and investigate similar technology developed by Celon® AG Medical Instruments in a pilot study designed to investigate the results of Celon® RFTA in simple snorers/mild OSAS. Celon® proclaims additional benefits over its rival Somnus® unit, including inherent bipolar probe tip safety and a shorter procedure time.

Materials and methods

A prospective non-randomized study was carried out at the Royal National Throat Nose and Ear Hospital, London, on 10 patients diagnosed as chronic habitual snorers or mild OSAS having been referred to the sleep clinic for investigation and treatment of snoring. All patients gave informed consent and were fully aware of the nature of the study i.e. primarily to establish whether there is subjective/objective improvement in snoring, and secondly to identify associated side-effects or complications.

Included subjects underwent a complete history, physical and otolaryngological examination that included measurement of the Epworth Sleepiness Score (ESS), body mass index (BMI), collar size, Muller manoeuvre, full blood count and thyroid function tests, sleep nasendoscopy (SNE) and polysomnography (PSG). PSG at base line was used to exclude patients with moderate to severe OSAS for whom a surgical treatment option was deemed inappropriate. SNE was performed to determine the anatomical origin of each patient's snoring.[24] Patients graded 1 (palatal flutter) or 2 (naso-pharyngeal collapse ± palatal flutter) snorers at SNE were considered for the study, whilst those graded 3 (multilevel obstruction with collapse during inspiration) were included only if it was felt the snoring predominantly had a palatal/naso-pharyngeal origin. Further inclusion and exclusion criteria are as documented (Table I). The 10 patients chosen were consecutive patients fulfilling the study criteria. One patient, despite an apnoea-hypopnoea index (AHI) of 33 at baseline was included in the trial as there was some question over artefacts elevating the AHI on PSG. She had a BMI of 28, ESS 11/24 and SNE grade 2.

The patients received two Celon® RFTA treatments to the soft palate six weeks apart in the surgical day-care unit, each performed by a single operator (senior author). At baseline each patient with their partner recorded on a 10 point visual analogue scale (VAS), ranging from 0 to 10, (0 = no snoring, 10 = loudest possible snoring) their perceived subjective level of snoring (SnorVAS1). Local anaesthesia was provided by topical two per cent Xylocaine (seven sprays) to the palate followed by sub-mucosal infiltration using two per cent Xylocaine with one in 80 000 epinephrine. A radiofrequency generator, CelonLab *ENT* (Celon AG Medical Instruments, Berlin) with a hand-held disposable bipolar electrode probe for puncturing the soft palate, were used to produce sub-mucosal palatal lesions. Each electrode was supplied with an insulating cover that allowed exposure of only 1 cm of active electrode to avoid mucosal injury during treatment. Six palatal punctures were performed on each patient, the second procedure following six weeks after the first (Figure 1). The application time varied between four to six seconds per puncture, terminated by acoustic 'end-indication' and autostop facilitated by a thermistor and tissue impedance

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Punctum	Position of punctum	Power
1	15 mm above height of palatal arch	10 W
2	8-10 mm above puncture 1	10 W
3	5mm left, 4mm above puncture 1	13 W
4	5mm right, 4mm above puncture 1	13 W
5	8-10mm above puncture 3	13 W
6	8-10mm above puncture 4	13 W

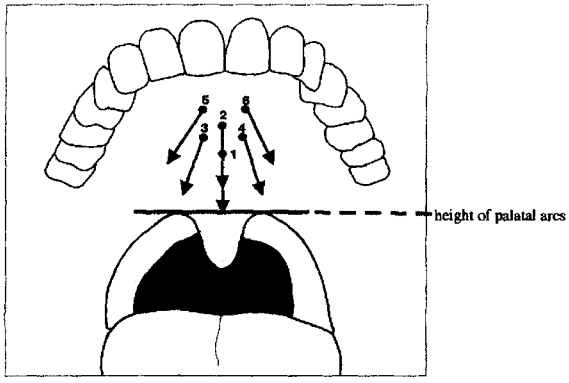

FIG. 1
Position of palatal punctures.

measurement at the probe tip. Energy delivery was terminated by the operator if any pain or blanching of mucosa occurred. The delivered energy at these power settings is 52–60 Joules per punctum. Following the procedure the patient was observed for 20 minutes prior to discharge home with simple, non-narcotic, analgesia (co-codamol). Antibiotics, steroids and non-steroidal anti-inflammatory drugs were not prescribed. For both procedures, visual analogue scores for pain (PainVAS), range 0 to 10, (0 = no pain, 10 = worst imaginable pain) were used to determine each patients subjective pain experience. Pain scores for the procedure itself, immediately post procedure, two hours, six hours, 12 hours post-procedure and then days two through to seven post-procedure were recorded. In addition, the patient noted the analgesia requirement during this period.

Clinical examination and assessment of the palate was performed at days three and 10 following each procedure to observe effects on speech and swallowing, as well as other complications.

VAS snoring by patient and partner (same person throughout study) was re-assessed at six weeks just prior to the second treatment (SnorVAS2) and then again at 16 weeks following the first procedure (SnorVAS3). A repeat PSG was performed at three months following the second procedure.

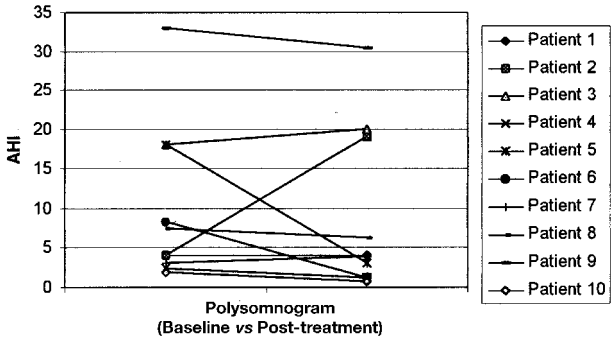

FIG. 2
Comparison of individual AHI at polysomnography.

Statistical analysis was performed on a personal computer using SPSS 8.0 SN statistics software. Pre-operative and post-operative means were compared using paired Student *t*-tests. Data are presented as mean ± SD, unless otherwise stated. Confidence intervals (CI) where given are at 95 per cent and relate to baseline mean/median values minus follow-up mean/median values. Where non-scalar evaluation was required, given the small sample size, non-parametric tests were performed (Wilcoxon Signed Ranks). A p-value <0.05 was significant.

Results

Ten patients were enrolled and all completed the study. Seven of the 10 were male and the mean sample age was 42.8 ± 11.2 years. The mean pre-treatment BMI was 28.1 ± 3.0 which did not significantly alter by four months post-treatment, 28.0 ± 2.8 (95 per cent CI = –0.43 to 0.63). The baseline mean ESS was 9.50 ± 3.27 which also did not significantly alter at four months post-treatment, 8.00 ± 4.08 (95 per cent CI = –0.61 to 3.61) ESS[25] is used clinically to provide a measure of the patient's general level of daytime sleepiness with scores on the whole increasing with the severity of OSAS: normal patients average scores are between two and 10.

Five of the 10 patients were classed on the basis of baseline PSG to be simple snorers (AHI <5). A further four patients were classed as mild OSAS (AHI 5–20). Despite an AHI of 33, the 10th patient was included in the study as this figure was felt to be artefact-related and too high; she otherwise met all the study inclusion/exclusion criteria. Polysomnographic data are summarized in Table II.

Although six of 10 patients had an objective decrease in AHI (Figure 2), and four of these a greater than 50 per cent decrease, this was not statistically significant using both the paired sample *t*-

TABLE II
POLYSOMNOGRAPH DATA AT BASELINE AND THREE MONTHS POST-SECOND TREATMENT

	Baseline		Post treatment			Significance
	Median	(Range)	Median	(Range)	95% CI	Wilcoxon Signed Rank
AHI	5.75	(1.8–33)	3.95	(0.7–30.4)	−4.34 to 6.48	None
Sleep Eff. (%)	86	(69–98)	89	(81–97)	−12.58 to 3.44	None
Mean O_2 Sat (%)	95	(94–97)	95	(91–96)	−0.99 to 1.56	None
Min O_2 Sat (%)	87	(82–89)	85	(81–92)	−1.77 to 4.17	None

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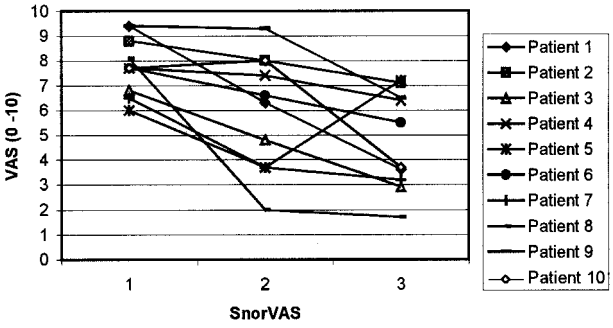

FIG. 3
Comparison of individual SnorVAS

test and Wilcoxon signed ranks test. No significant change was noted in either sleep efficiency (sleep eff.), mean oxygen saturation (mean O_2 sat) or the minimum oxygen saturation (min O_2 sat) between the two PSG's. Albeit a crude indicator, subjective assessment by the senior author of PSG snoring signal intensity as recorded by the microphone during the night, showed eight of 10 patients had a reduced or much reduced signal at the second PSG compared to the baseline.

Subjective baseline median snoring score (Snor VAS1) was 7.70 (range 6.0–9.4). Both at six weeks (median SnorVAS2 = 6.45 (range 2.0–9.3) and 16 weeks (median SnorVAS3 = 4.60 (range 1.7–7.2) following initial treatment there was significant reduction in snoring intensity as assessed by patient and partner ($p = 0.013$ and $p = 0.007$ respectively), using the non-parametric Wilcoxon signed ranks test. Nine of 10 patients reported a lower snoring score at six and 16 weeks compared to the baseline (Figure 3), with five of the 10 at 16 weeks showing a greater than 50 per cent reduction. Between six and 16 weeks post-initial treatment there was no further statistically significant improvement in the subjective snoring score (Figure 3).

Subjective assessment of pain (Table III), both during the procedure and at intervals post-procedure up to day seven, showed both treatments to be well tolerated and the median pain score (PainVAS) failed to rise above 3.9 on either occasion; maximal discomfort occurred between two hours and 48 hours post-procedure. The mean total number of days of required analgesia was not significantly different between the two treatments (3.50 ± 21.7 and 3.13 ± 2.10 days respectively). Similarly, the total number of required analgesic tablets did not significantly differ (14.20 ± 12.73 and 13.38 ± 12.34 tablets respectively). One patient misunderstood the instructions provided and proceeded to take the maximal amount of prescribed daily analgesia despite the absence of any discomfort. Only one other patient out of 10 required analgesia beyond day four.

There was minimal associated morbidity. All patients reported mild palatal swelling by the second post-operation day which had resolved by day four. Minor complaints of dry throat, catarrh and referred otalgia were noted but swallowing and speech were unaffected. One patient developed single puncture mucosal ulceration following both procedures that healed within three weeks, but required oral antibiotic prescription on each occasion at day seven post-operation.

TABLE III
MEDIAN PAIN VAS (RANGE) FOR FIRST AND SECOND TREATMENT

	Treatment 1		Treatment 2	
	Median	(Range)	Median	(Range)
Per-operative	1.4	(0.5–4.7)	0.8	(0.7–4.4)
Immediate Post-operative	0.65	(0–1.2)	0.9	(0.3–1.4)
2 Hours Post-operative	1.9	(0.4–5.4)	3.9	(0.5–6.1)
6 Hours Post-operative	2.1	(0.7–7.5)	3.1	(0.7–4.3)
12 Hours Post-operative	1.85	(0.6–9.6)	2.5	(0.7–5.4)
Day 2 Post-operative	1.7	(0.4–9.4)	1.6	(0.8–6.2)
Day 3 Post-operative	0.8	(0–9.1)	1.0	(0.1–5.3)
Day 4 Post-operative	0.85	(0–5.1)	0.9	(0–5.3)
Day 5 Post-operative	0.75	(0–5.8)	0.4	(0.2–4.9)
Day 6 Post-operative	0.4	(0–6)	0.3	(0–3)
Day 7 Post-operative	0.4	(0–7.2)	0.3	(0–2.5)

Discussion

Similar to diathermy, RFTA technology entails the patient being part of a circuit, with a radio-frequency generator and a disposable hand-piece. For operation however, RFTA utilizes a much lower voltage (80V *vs* 800V) and power levels (2–10 Watts *vs* 100 Watts) compared to diathermy. This results in lower tissue temperatures of typically 60–90°C (cf. 750–900°C with diathermy), the intention being to cause thermal injury and tissue coagulation in targeted tissue at the probe tip. Over a few weeks, subsequently, there is corporeal resorption of the coagulated tissue and scar formation with a tendency to fibrose and stiffen the treated tissue. The technology has been applied successfully in a number of other medical fields, including cardiology to treat Wolf-Parkinson-White syndrome and urology to treat benign prostatic hyperplasia.[26,27]

Most of the published studies to date have utilized technology developed by Somnus® and although these have shown promising early results, in the medium to long-term there appears to be a significant relapse rate. In this pilot study similar technology marketed by Celon AG® was introduced and investigated. Similar to the Somnus® device it allows sub-mucosal targeted thermal energy application under LA as an office procedure, however with much reduced application times, averaging 3–8 seconds per puncture compared to 120–180 seconds with Somnus®. The authors' experience was a much reduced and shorter procedure time, in contrast to the Somnus® unit, which typically required 20 minutes or more per patient for energy application through multiple punctures. The energy per puncture with the Celon® probe is 50–70 J, unlike the Somnus device which is 700–1000 J. Both the Celon® and Somnus® generators have similar power (9–14 W and 10–12 W respectively) and both operate at similar frequencies (470 Hz and 465 Hz respectively). The Celon® probe needle has a larger diameter of 1.3 mm (cf. 0.8 mm). The Somnus® unit has a higher energy input and is monopolar, exposing the entire body of the patient, whereas

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the Celon® unit has inherent innovative bipolar tip safety. This ensures that only tissue in the immediate vicinity of the probe tip, which has a bipolar arrangement of electrodes in the needle, is exposed to the radio-frequency current. This removes some of the risks linked to the process and the need for a neutral electrode is lost, eliminating the risk of burns and allowing patients with cardiac pacemakers to be treated. Further safety is provided by acoustic feedback and an auto-stop power control, whereas the Somnus® unit relies on the operator visualizing the temperature and impedance signal. The authors also found that the simplicity of the Celon® unit's design made for easier handling by the surgeon.

The results of this pilot study compare favourably with early results seen using Somnus® RFTA palatoplasty in simple snorers/mild OSAS. The subjective snoring score shows a statistically significant reduction at six weeks post-initial procedure, which is maintained at four months. The authors acknowledge, however, that given the absence of a control group, not all the observed reduction in snoring score may be attributable to this treatment as 'regression to the mean' may play some part. Furthermore, the authors have sought to find evidence for objective improvement in snoring on the basis of PSG, although fully aware that there is no widespread agreement on what constitutes a useful outcome measure to assess success in reducing snoring.[23,28,29] Although no statistically significant improvement was noted in PSG parameters, subjective assessment by the senior author of snoring signal intensity on microphone recording, showed reduced signal in eight of 10 patients at the second PSG relative to the baseline. Standardization of PSG microphone recording and the use of sound analysis software packages, currently being developed to allow statistical comparison of digital acoustic recordings, is an area of research showing strong promise[30–32] and our department is currently exploring this further.

This study revealed minimal morbidity and high patient acceptability, the patients requiring minimal analgesia and under little inconvenience, returning to work either the same day, or the day thereafter. The Celon® unit therefore compares well with the Somnus® unit and affords advantages over older surgical methods in avoidance of general anaesthesia and in-patient admission. The more significant effects of haemorrhage, infection, debilitating pain, naso-pharyngeal regurgitation and altered speech are also avoided.

Further larger and randomized prospective clinical trials, followed through to the medium and long-term, are required to substantiate the preliminary findings of this pilot study.

Acknowledgement

The authors are grateful to Mr C. Georgalas for providing statistical assistance in the analysis of results.

- **This is a prospective study of the effects of radiofrequency palatoplasty on patients with snoring**
- **The results presented are of 10 patients, each of whom was evaluated after two treatments of an interval of six weeks**
- **The subjects studied were snoring or had minor obstructive sleep apnoea**
- **The study is a preliminary report and is thus of limited value: no control group data are included and the length of follow up of patient treated was short**

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