A prospective randomised comparative clinical trial: Laser Assisted Uvulopalatoplasty versus Radiofrequency Procut Palatoplasty for snoring and obstructive sleep apnoea

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Our Aim

- To compare a new technique of RF Procut palatoplasty against an older one of LAUP
- To set-up a randomised comparative trial
  Generates high level of evidence
- To address patient satisfaction & acceptability
Prospective Randomised Clinical Study

- Ethical Committee Approval – Interim Stats
- 50 patients with snoring and mild OSA
- Palatal snorers
- Patients were randomly assigned into 2 groups 25 in each group
  - LAUP v/s RF Procut Palatoplasty
- Investigator blinded
- Both procedures conducted under GA

Inclusion and exclusion criteria

- Age < 65
- BMI up to 33
- Investigations
  - Sleep Nasendoscopy
    - grade 1 & 2
  - Sleep study
  - Simple Snorer
- OSA - AHI < 30
- BMI > 33
- Age above 65
- AHI > 30
- Poor general condition
- Coagulopathy
- Mentally or psychologically unfit
- SNE = Excessive Lat Pharyngeal Wall Collapse
Sleep Nasendoscopic Grading

- Grade I
  Palatal flutter
- Grade II
  Palatal flutter & Nasopharyngeal collapse
- Grade III
  Multi Segmental Obstruction on inspiration
- Grade IV
  Multigemental on inspiration & expiration
- Grade V
  Retraction of tongue base & epiglottis

Pringle M B & Croft C B 1993
Breakdown of 2300 Sleep Nasoendoscopies

Demographics

**LAUP Group**
- **Sex** Male 18: Female 7
- **Age**
  - Median 47 years
  - Range 28 - 65
- **BMI**
  - Preop (20 – 33)
  - postop (20 – 33)

**RF Group**
- **Sex** Male 16 : Female 9
- **Age**
  - Median 42 years
  - Range 31 - 64
- **BMI**
  - Preop (21 – 33)
  - Postop (20 – 34)
Basic Principle of RFITT

- Cylindrical electrode
- Low current density is generated
- The tissue is heated up to the coagulation 60°C
- Ultimately necrosis and a scar formation occurs
- Stiffening and volumetric reduction of tissue

Bipolar Radio-frequency Group

**Celon Lab Generator**
- Energy control
- Acoustic feedback
- Auto stop signal

**Pro-sleep plus Probe**
- Bipolar Probe
- 4-8 seconds/puncture
- 10 Applications -10 Watts setting

**ProCut Needle 1.2 mm**
Sharp cutting 25 Watts
Celon Procut Needles & Forceps

Interstitial Radiofrequency

- 10 Applications
- 4 Median
- 6 lateral
- 10 watts = 60J each
RF Procure Palatoplasty

Healing

immediately post op

pre op

3 weeks post op

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LAUP

- Kotecha Technique (Eur Arch Otorhino 2006, 263: 152-155)
  - Co² laser - Microscope mounted
  - 10 Watts
- Boyls Davis Gag
  - Tongue piece with suction
- Wet Swabs for
  - skin exposed area
  - naso/ Oro pharynx
LAUP Posto Healing

Pre Op 3 weeks post op

Summary of Statistical Analysis

- Analysis of Each Individual Treatment
- Two Group Comparison
  - Paired Sample t test
- Repeated Measures ANOVA
- Tests of Within Subjects Effects
- Pair-wise Comparison
- Adjustments for Multiple Comparisons - Bonferroni
**MEAN - Pain with swallowing**

<table>
<thead>
<tr>
<th></th>
<th>LAUP</th>
<th>Celon</th>
</tr>
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<tbody>
<tr>
<td>Day 1</td>
<td>5.12</td>
<td>5.03</td>
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<tr>
<td>Day 7</td>
<td>5.54</td>
<td>4.29</td>
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No Statistical Significance between the two groups

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**Mean - Epworth Sleepiness Score**

![Epworth Sleepiness Score Chart](chart.png)

- **Before**
- **After**

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<tr>
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<th>ESS LAUP</th>
<th>ESS Celon</th>
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<tbody>
<tr>
<td></td>
<td>Before</td>
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Mean VAS of Snoring

![Graph showing Mean VAS of Snoring over time for LAUP and Celon Procut.]

**LAUP Versus RF Palatoplasty**

**Paired T Test**

- **VAS Snoring at 12 month**
  - Slightly significant difference
  - $t=2.169$, $df=48$, $p<0.05$
  - Snoring is statistically significantly better with **LAUP**
Sleep Study Analysis

Mean AHI Before and After LAUP & RF procut

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<tr>
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<tbody>
<tr>
<td>LAUP</td>
<td>12.832</td>
<td>11.62</td>
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<tr>
<td>Celon Procut</td>
<td>8.91</td>
<td>8.89</td>
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Complications / Undesirable effect

- Celon procut group
  Ulceration - two patients
  Superficial Needle?
  Delayed healing
  3 weeks - one patient

- LAUP group
  Mild sensation of discomfort in the throat
  With 3 patients

Patient Satisfaction

LAUP

- Better 56%
- Much Better 36%
- Same 4%
- Worse 0%
In Conclusion

- Snoring improved in both groups
- LAUP is to give slightly better results
- Healing duration comparable
- With time some snoring would recur
- Patients in RF group will require further treatment sooner
- Pain is slightly less with Celon Procut
- Long term f/U
- Larger sample size is recommended
I love you Alexandria

Hesham K Khalil