Combination Therapy

Conflict of Interest Disclosure

Ronald S. Prehn, ThM, DDS

1. I do not have any potential conflicts of interest to disclose. OR

2. I wish to disclose the following potential conflicts of interest:

<table>
<thead>
<tr>
<th>Type of Potential Conflict</th>
<th>Details of Potential Conflict</th>
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<tbody>
<tr>
<td>Grant/Research Support</td>
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<tr>
<td>Consultant</td>
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<td>Speaker's Bureau</td>
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<tr>
<td>Financial support</td>
<td></td>
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<tr>
<td>Other</td>
<td>President of Fusion Sleep Solutions, LLC</td>
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3. The material presented in this lecture has no relationship with any of these potential conflicts. OR

4. The material presented in this lecture has a relationship with one or more of these potential conflicts, and the following objective references are provided, support for this lecture:

"To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science."

— Albert Einstein
A Story for Dentistry
Problem:

Constant Volume ventilators set at 45 cmw !!!

“Lyon mask”
(made by Respiratory Therapists)

“I determined that not only could I improve the mask she brought in, but improve the whole technology using dental techniques”

W. Keith Thornton, DDS

Dorothy
Deborah

“One of the biggest issues was the breathing while taking the impressions.”

- Body paralyzed except for two toes.
- On a ventilator.
- Had OSA.
"We think we have problems! If the lady doesn't come up with solutions, then you might as well be dead!"
What is Combination Therapy?

Combination Therapy

Combination Therapy

Custom Face Mask™

TAP-PAP nasal pillows

Custom Face Mask

Custom Face Mask
Combination Therapy: It is a combination of two therapies.

One: CPAP therapy
Two: Oral Appliance Therapy (OAT).

Combination Therapy: It is a combination of two therapies.

Working with a Sleep MD
CPAP (Continuous Positive Airway Pressure) - Sleep MD

OAT (Oral Appliance Therapy) - Sleep Dentist

CPAP Satisfaction and side effects

- A Review by the Positive Airway Pressure Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine
  - Long list of side effects
  - CPAP interface: satisfaction and side effects
    - No difference in type or brand of interface, long list of side effects.
    - “the majority of patients consider the use of the CPAP interface disturbing…”
      - Bachour, Vitikainen, Virkkula, Maasilta; CPAP interface: satisfaction and side effects; Sleep Breath (2013) 17:667-672

Treatment efficacy: how well an intervention works under ideal controlled circumstances

Treatment effectiveness: how well an intervention performs in uncontrolled real world condition
When treatment usage as a portion of the total sleep time is considered:

- While CPAP has a higher efficacy than OAT...
- OAT has a higher effectiveness than CPAP


Objective Evaluation of Severity

- And patient preference

American Academy of Sleep Medicine


Oral Appliance - moves the jaw forward

1. Therapy more effective
2. Increase risks of side effects
**Question:**

What to do when monotherapy fails?

**Prehn Definition of Combination Therapy**

It is a CPAP interface to the nose or mouth or both, that either is in conjunction with a MAS or one that connects the CPAP hose directly to an oral appliance that features mandibular stabilization.

**CT features:**

- Superior stability due to being connected to the skull base via the dentition.
- Excellent compliance and satisfaction because of the lack of straps and leakage.
REQUIRES:

the proper diagnosis and treatment by a Dentist trained in OAT.

OAT Failure
Positive Airway Pressure: Problems

CPAP Failure

I don't think so!

Type One – DUAL Therapy
Combining Two Therapies
Type One – DUAL Therapy
CPAP Combined with MAS

- Achieves mandibular stabilization
- Easy to implement into a General Dental Practice

- No special training
- No management of CPAP (MD controls)
- Cost, insurance and chair time is a known and constant variable

Improved Outcome of Full Mask CPAP Treatment with Mandibular Stabilization Using A Dental Appliance
Jerald H. Simmons, MD

10 patients (one drop out)
1. Failed Full Face Mask
2. Able to fabricate Snore Free (boil and bite)
3. Recognized improvement with MAS
6 Question survey before and after

Statistical improvement with combination (P < 0.001)
Type Two – INTEGRATED Therapy
Integrating Two Therapies

CPAP Connect Directly to MAS

• No straps

• Mandibular advancement not necessary, although advised

• Need special training with device

• Be familiar with CPAP Therapy

• Need to stock parts
• Difficult to implement into General Dental practice
• Chair time varies-staff frustrations
• Insurance is unknown and not appropriate
Who gets a Fusion Custom Mask?

Combination Therapy - Integrated Therapy

75 patients on combination therapy with a Custom Face Mask
Most often CPAP intolerant
CPAP intolerant patients had higher CPAP pressures than others in study
CPAP pressures were reduced
Long term compliance (10yrs)
Long term cost less than stock mask


Combination Therapy - Integrated Therapy

Conclusion: “The application of the CFM is for patients with more severe OSA and is well tolerated with improved compliance.

The CFM should be considered when other therapeutic methods of treating OSA have failed or when CPAP or the CPAP mask are intolerable to the patient.”

Study of 75 patients who had received a Fusion Custom Mask at my Dental Sleep Center 2009-2012

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Study of 75 patients who had received a Fusion Custom Mask at my Dental Sleep Center 2009-2012

Type II interfaces are a CLASS II Medical Device

Two Things to Know...

United States Patent and Trademark Office
An Agency of the Department of Commerce

Dr. Keith Thornton
Inventor
Patent Holder
Two styles of CPAP interfaces

**TAP - PAP CS Nasal Pillows**

- Fusion Custom Mask

- Monoblock

**TAP - PAP nasal pillow** (Chairside)

**Custom Face Mask** (lab fabricated)

- Simple to do chairside
- Fully adjustable
- Optional head set for hose
- Works best CPAP under 15cm H2O
Fusion Custom Mask

Phase one - Chairside

1. Fusion Monoblock
2. Screw on TAP post

2. Thermacryl upper and lower, slightly protruded

Phase two - Chairside

3. Take face impression

Validated superior compliance and satisfaction
Can tolerate high pressures
Can modify airflow to nose or mouth or both
Adjustable
Can lower CPAP pressure

Who gets a Fusion Custom Mask?
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*Journal of Dental Sleep Medicine, In Print*

### When to consider Combination Therapy

- Dual Therapy:
  - Unable to achieve therapeutic goals with OAT alone
  - Unable to manage side effects while advancing mandible with OAT
  - CPAP required but intolerant
  - MD requires CPAP for patient and needs mandible stable (leakage)
Integrated Therapy:

- OSA severe and CPAP intolerant
- CPAP pressures are high
- Significant comorbidities
- Unable to achieve goals with Dual Therapy
- Patient preference

Rickey H.
Age 40
BMI 40
RDI 70
AHI 43
PSO₂ 66%
BPAP 26/20

“Honey... The Sleep Lab called”
Medical discharge from Navy
24 hr Oxygen
Organ failure
Polypharmacy
Too sick for surgery
BiPAP not working

We Tried Type 1 CT!
Mandibular Advancement: 11mm
Maxillary Advancement: 16mm

60% Genioglossus reduction

Hope...
Ease of mind
Able to address his other issues now.
Future of Combination Therapy

Type one DUAL THERAPY can be implemented today in any Dental Sleep aspect of General Practice.

- Dentists and Sleep Physicians need more awareness of benefit
- Need more research validation

Type two INTERGRATED THERAPY should be done in a more advanced Dental Sleep Practice.

- Learn and practice
- Establish relationship with MD
- More development
- More research validation
- Profit issues

Final Considerations

- Consider Dual Therapy now for your OAT failures
- Consider learning Integrated Therapy if you desire to treat the more challenging cases
- Consider using this combination therapy to build bridges to your MD referrals