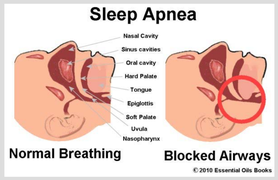
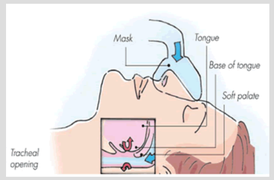
A Novel Device to Treat Obstructive Sleep Apnea (OSA)

Brent Han[1], Ethan Li[2], Dr. Jed Black[3]
Henry M. Gunn High School[1,2], Jazz Pharmaceuticals[3]

INTRODUCTION

Obstructive sleep apnea is a serious condition that can seriously degrade quality of sleep and, with it, quality of life. In obstructive sleep apnea, the muscles of the throat are not strong enough to hold the airway open during sleep, leading to the body not being able to get enough oxygen. This causes the sufferer to wake up in the middle of the night, preventing restful sleep.





The premier way of treating obstructive sleep apnea is CPAP, or Continuous Positive Airway Pressure. This method of treatment uses pressurized air to keep the airway open while allowing the patient to breathe. However, the mask used to direct air is unable to accommodate all facial sizes and structures, leading to leakage that dramatically lessens the effectiveness of treatment. This new device that we have developed is designed to alleviate that problem while being cheap, portable, easy to make and use, and disposable.

MATERIALS & METHODS

Materials

- Silicone
- Double sided tape
- Plastic
- Perforated sticky cloth
- Paper
- Silhouette Cameo cutting machine
- Envelopes
- Conventional CPAP masks

Methodology

Assembly Procedure

1. Cut out strips of double sided tape.
2. Back them on both sides with plastic.
3. Place into Silhouette machine and use programmed cut pattern.
4. Repeat with silicone.
5. Place cloth sticky side down onto paper and cut using cut pattern.
6. Reinsert tape and use shorter blade to cut only the plastic, avoiding cutting the tape.
7. Flip and repeat.
8. Peel plastic off tape and place carefully onto silicone.
9. Peel plastic off other side of tape and attach silicone onto cloth backing.
10. Seal into envelopes.

Trial Procedure

1. Have patients participating in trial sign consent forms.
2. Randomly distribute devices to sleep apnea patients.
3. Monitor quality of sleep and breathing with device.
4. Distribute conventional masks to other patients.
5. Monitor quality of sleep and breathing with masks.
6. Compare data gathered.

RESULTS

Pilot Trial Data--Distribution of Ratings

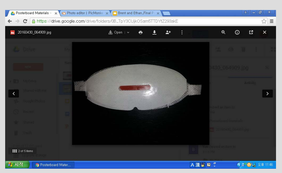
	1 (poor)	2	3 (fair)	4	5 (great)
Ease of device application?	--	1	1	1	5
Effectiveness of device to keep lips sealed?	1	1	3	1	--
Effectiveness of valve in device?	1	1	1	2	--
Adherence to skin during night	1	1	2	--	1
Ease of removal?	--	--	1	--	6
Sturdiness of Device?	--	3	2	1	--
Patient-reported device comfort ?	--	4	1	--	1
Breathing comfort?	--	4	1	--	1

Note: Pilot trial utilized early version of lip seal. See pics below for current version.

PGS Report Data Template

	Chin Strap	Natural Lip Seal Device
Duration of Use		
AHI		
Maximum mouth leak		
Average mouth leak		

Pictures of Materials Used



Lip Seal (back)
Lip Seal (front)

Chin Strap (side/profile view)

DISCUSSION

The pilot trial was conducted to assess the feasibility of the lip seal as a practical device. A prototype version of the current lip seal was used with 1 silicone puck in the center. Compared to the conventional CPAP chin strap, the lip seal had an advantage of being easy to apply and remove.

One issue that arose was the device's lack of stability, which was resolved by adding a second silicone puck over the first. Another issue was the device's inconsistent adherence to the skin, which was remedied by using stronger tape backing in the current design. As of now, the improved lip seal is ready for use in control trials that will take place in controlled environments (independent clinics).

SUMMARY / CONCLUSIONS

In conclusion, pilot data demonstrates that the lip seal offers greater minimization of air leakage and patient comfort as opposed to a conventional CPAP chin strap device.

Formal control trials will be conducted in two blocks with subgroups for a total of at twenty-fifty test subjects.. Each subject will act as their own experimental control by being given the choice to switch between the lip seal and the chin strap halfway through the night. The data gathered for each type of mouth covering will ascertain if the same difference in experience as seen in the pilot trial is consistently observed, and to what degree. All trials will be held randomly.

The ideal long-term goal is for this lip seal device to be mass-produced and used on a widespread scale.

ACKNOWLEDGEMENTS / REFERENCES

- Thank you to Dr. Jeong Choe for making all of this possible through coordinating, organizing, and generally going out of your way to help. It wouldn't have been possible without your support.
- Thank you to Dr. Jed Black for introducing us to this project and guiding us through it. Your insights and experience were invaluable.
- Thank you to Dr. Mehran Farid for assisting us in conducting the clinical trials. We greatly appreciate the time you sacrificed to help us make this project succeed.
- Thank you to the Journal of the American Academy of Sleep Medicine for providing valuable background information.