SLEEP APNEA DEVICE

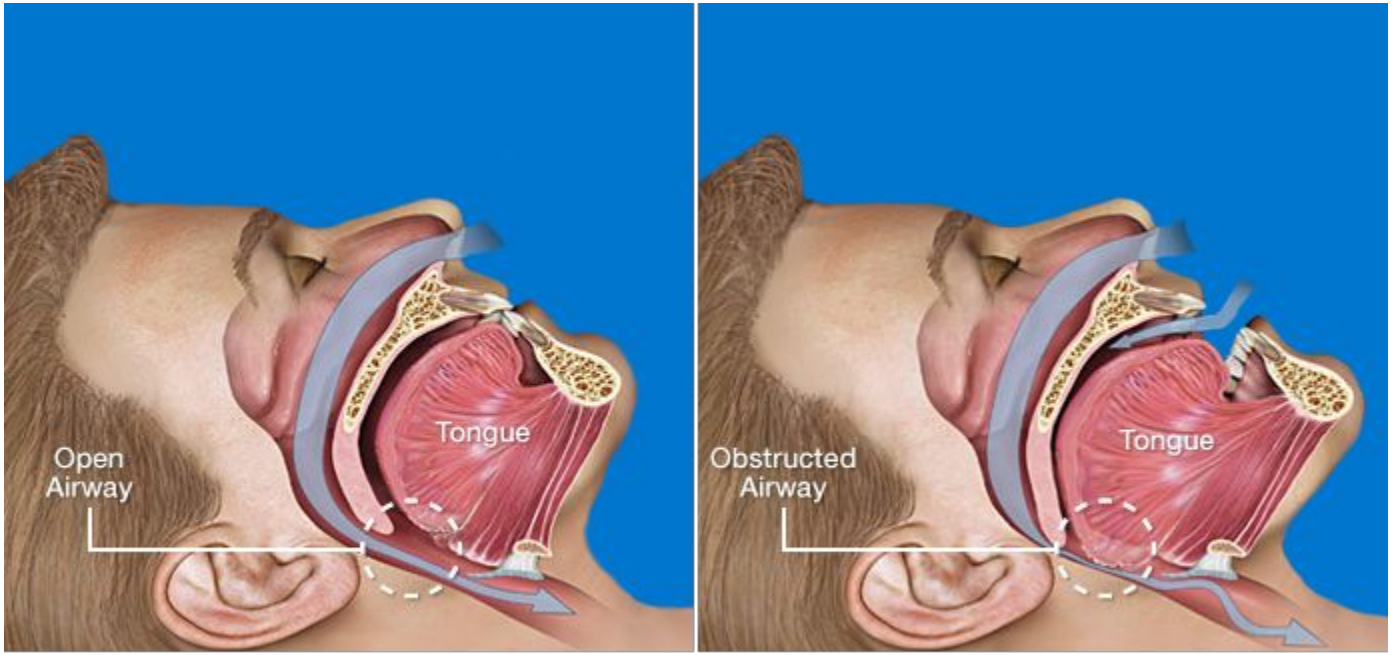
Section 1 - Team 3

Christina Chai, Kaleb Lovingier, Adrian Morales, Daphne Poon

Sponsor: Dr. Joon You, Praxis BioSciences, Inc.

Project Definition

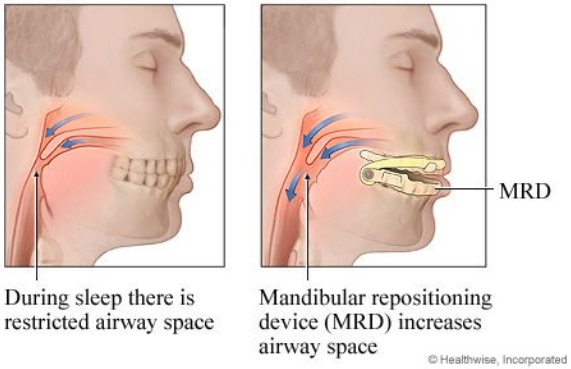
What is obstructive sleep apnea?



Non-Obstructed Airway

Obstructed Airway

Current Solutions



Mandibular Advancement Device (MAD/MRD)

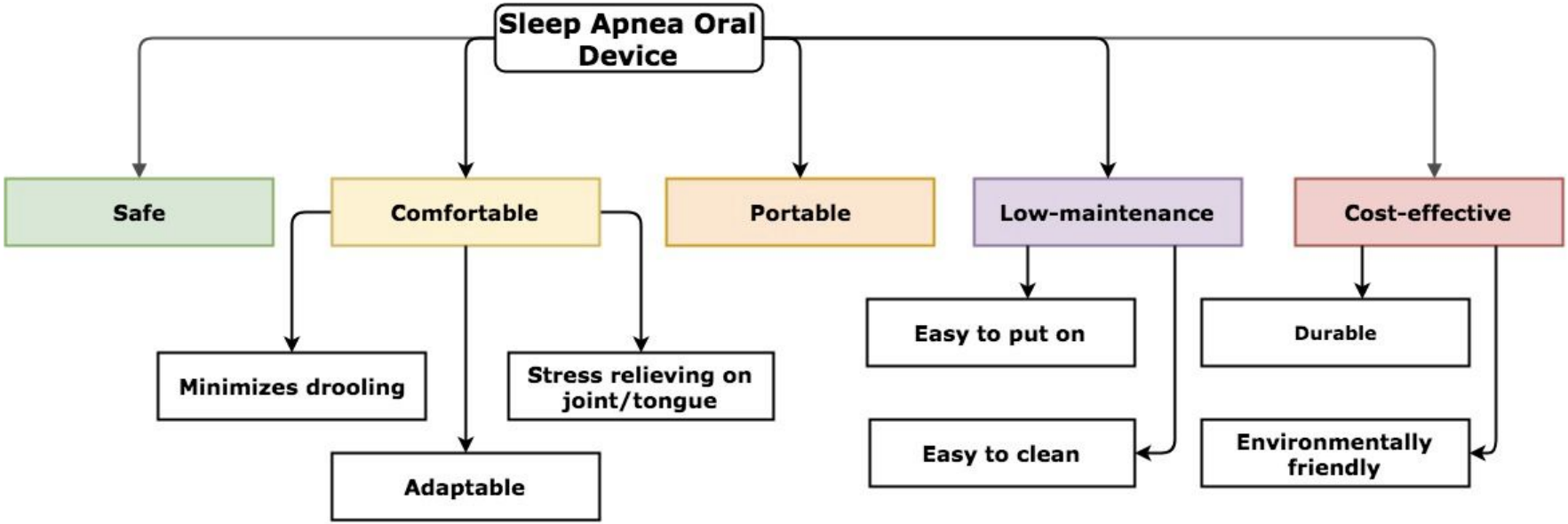
Tongue Retaining Device (TRD)

Continuous Positive Airway Pressure Machine (CPAP)

Revised Problem Statement

“The objective of this project will be to design a device that will open the airway for middle aged and older adults without causing the user discomfort or long term damage.”

Objectives


Sleep Apnea Oral Device
Safe
Comfortable
Portable
Low-maintenance
Cost-effective
Minimizes drooling
Stress relieving on joint/tongue
Adaptable
Easy to put on
Easy to clean
Durable
Environmentally friendly

Pairwise Comparison Chart

	Safe	Comfortable	Portable	Low-Maintenance	Cost-Effective	Total
Safe	X	1	1	1	1	**4**
Comfortable	0	X	1	1	1	**3**
Portable	0	0	X	1	1	**2**
Low-Maintenance	0	0	0	X	1	**1**
Cost-Effective	0	0	0	0	X	**0**

**Note: a higher score under 'total' column indicates higher priority*

Constraints

- *The prototype must be able to be produced under $125.*
- *The device must have no sharp parts.*
- *The device must not have loosely secured parts.*
- *The device must be non-toxic, as defined by the FDA.*

Functions

- *Opens Airway:* The device must be able to open up the user's airway to allow them to breathe during sleep.
- *Positions Itself Properly:* The device must be able to stay properly positioned on the user—resisting shifts to dysfunctional positions, or becoming dislodged from the user completely.

Functions	**Means***				
Opens Airway	Inflating/ deflating balloon	Hinges	Mouth device that pulls jaw forward	Plastic tongue device	Tongue depressor
Positions Itself Properly	Strap across back of head	Suction	Snap over dental arches	Mold to teeth	Straps across ears (like a mask)

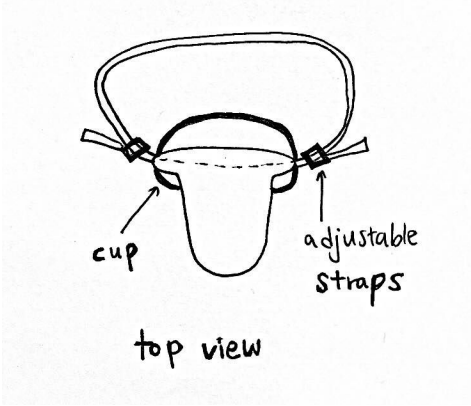
**Not the full list of means*

Choosing a Design

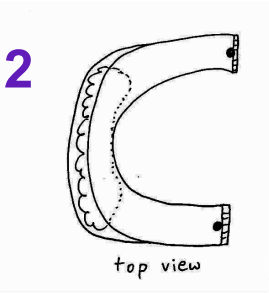
Design Alternatives

1. Strapped TRD
2. Absorbent Tissue
3. TRD + MAD
4. Strapped Balloon
5. Tongue Slit Device

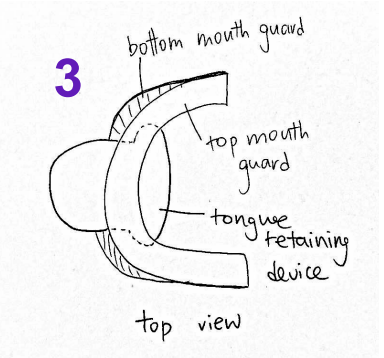
1



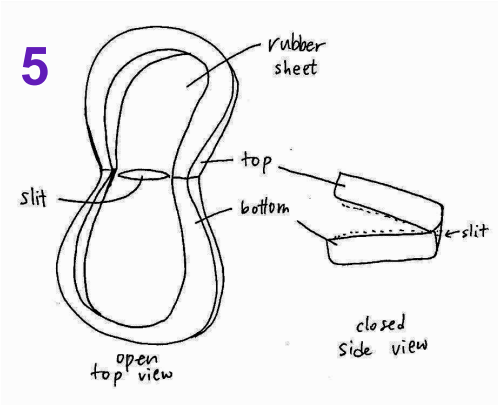
2



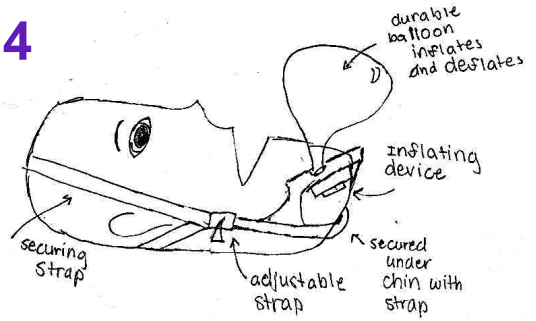
3



5



4



BEST OF CLASS	**1: Strapped TRD**	**2: Absorbent tissue**	**3: TRD + MAD**	**4: Strapped Balloon**	**5: Tongue Slit Device**
C: Must not have loosely secured parts	✓	✓	✓	✓	✓
C: The prototype must be able to be produced under $125	✓	✓	✓	✓	✓
C: Must be non-toxic	✓	✓	✓	✓	✓
C: Must not have sharp parts	✓	✓	✓	✓	✓
O: Safe	5	3	2	4	1
O: Comfortable	5	3	3	1	3
O: Portable	1	4	1	5	1
O: Low-Maintenance	1	5	1	4	1
O: Cost-Effective	3	4	1	5	1

Prototyping

Stage 1 Prototype

Design 5a: **Tongue Slit Device**

Side View

Back View

Front View

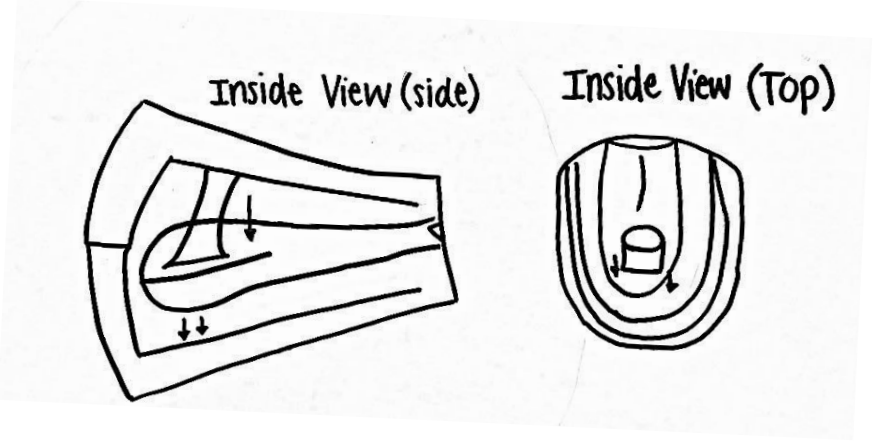
Stage 1 Testing Results

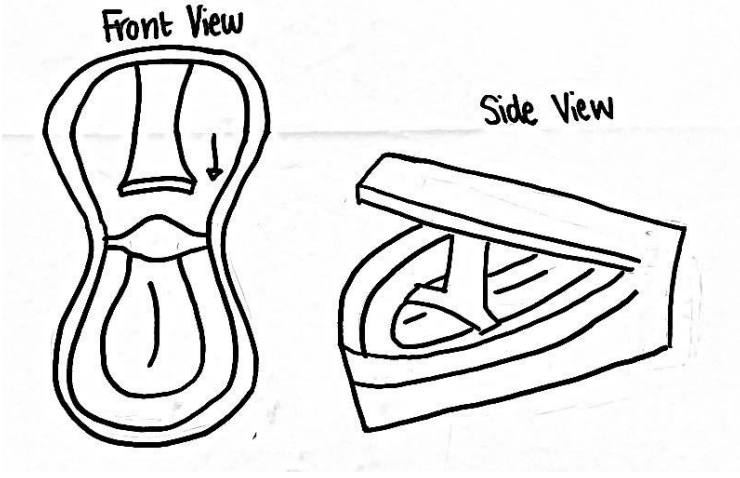
Pros	Cons
+ Pulled jaw forward + Elastic bands allowed for opening/closing of device	- Bulky - Uncomfortable over tongue - If broken, pieces would separate - Plastic used was too weak

Stage 2 Prototypes

Design Variations Tested

- Combinations of different sized mouthguards
- Tongue depressor (as pictured below)





Prototype Variations

Variation 1: Youth + Youth

- Two youth mouthguards
- Plastic wrap with slit

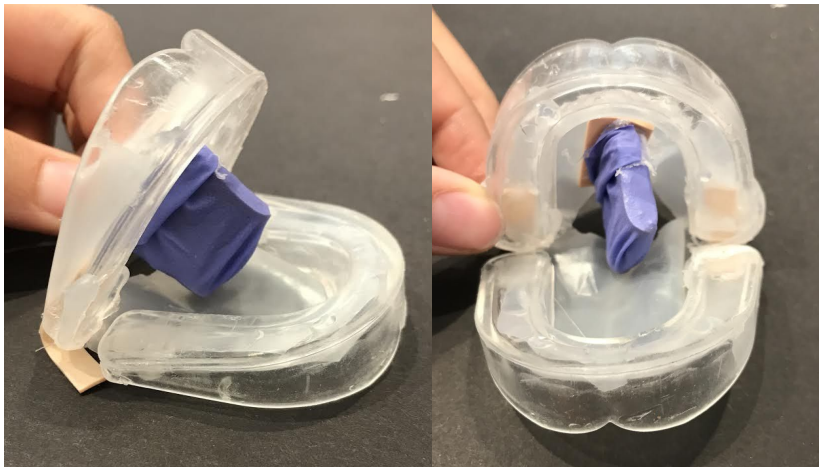
Variation 2: Youth + Adult

- Youth mouthguard on top, adult mouthguard on bottom
- Plastic wrap with slit

Prototype Variations (cont.)

Variation 3: Youth + Youth + Rubber Depressor

- Two youth mouthguards
- Plastic wrap with slit
- Layered tongue depressors wrapped with nitrile rubber



Variation 4: Youth + Youth + Popsicle Stick

- Two youth mouthguards
- Popsicle stick attached to the top half
- Presses down on top of tongue when mouth closed

Stage 2 Testing Results

+ PROS - CONS

Variation	Observations
1: Youth + Youth	+ Kept the tongue forward - Plastic sheet was uncomfortable at times
2: Youth + Adult	- Triggered gag reflex - Uncomfortable due to large size
3: Youth + Youth + Rubber Depressor	+ Depressor was comfortable - Mouthguard was popping off of teeth - Tongue easily slid back into throat
4: Youth + Youth + Popsicle Stick	+ Greater surface area of contact - Pressure lessened when jaw moved - Popsicle stick obstructs tongue; hard to slide in

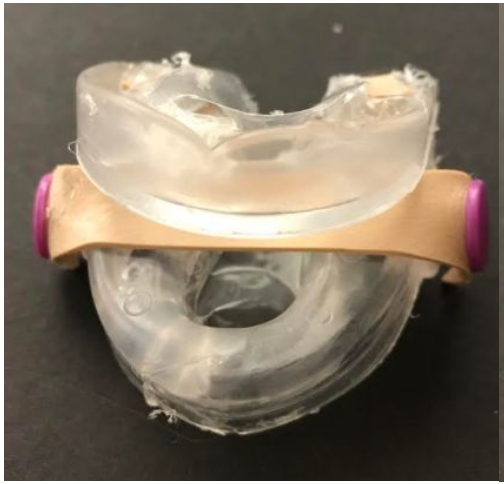
Improvements

- From the results, we decided that we needed to:
  - Use two youth manufactured mouthguards for all future prototypes
  - Reduce the thickness of mouthguards
  - Use a depressor that clamps down the tongue

Stage 3 Prototypes

- Flap-like depressor with snaps buttons that connect
- Buttons on inside of the mouth guard and on depressor
- Sandwiches the tongue

- Elastic strap across the bottom half of the mouthguard with snaps on the side
- Tongue goes over the rubber band at an angle



Stage 3 Testing Results

+ PROS - CONS

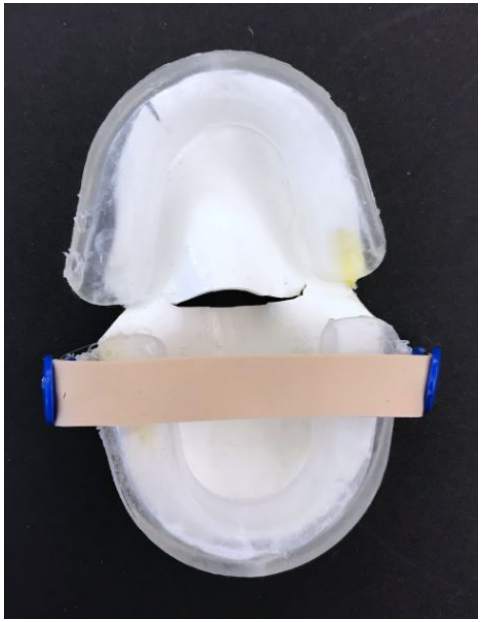
Variation	Observations
Flap Depressor Device	+ Easy to put on + Flap depresses tongue in place - Snaps are a choking hazard - Flap did apply pressure but not enough
Elastic Band Slit Device	+ Easy to slip the tongue past band + Tongue pulled forward, vertical + Tension prevents tongue from receding - Elastic band could break

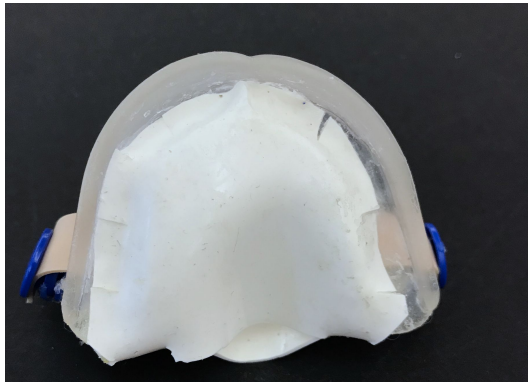
Final Prototype

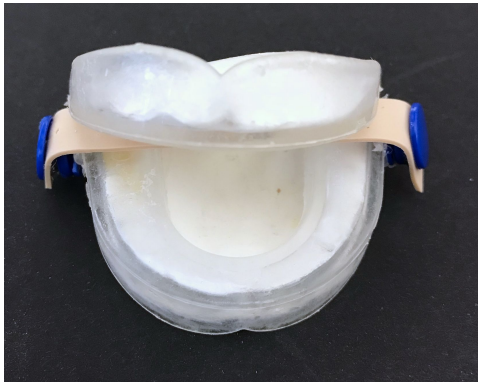
Elastic Band Slit Device

Changes:

- Rubber sheet with slits
- Removed elastic bands

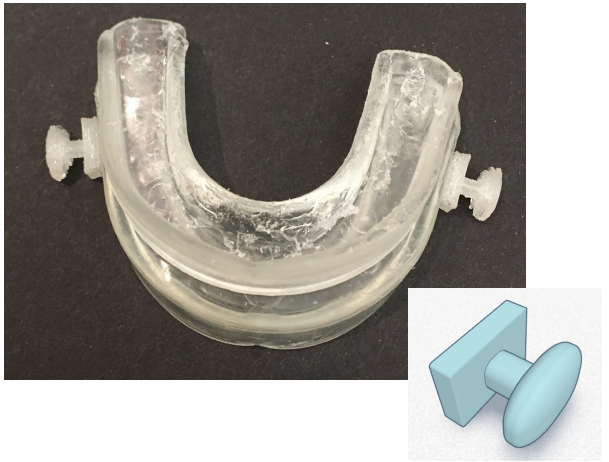




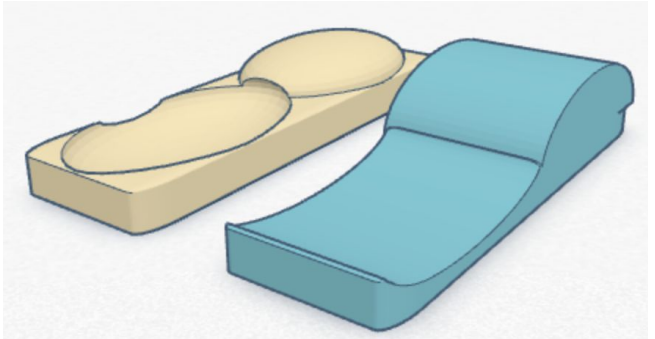


Recommendations

Problems we ran into:



- Lack of resources and manufacturing equipment
  - Adhesive was not optimal
  - Injection molding into a singular device not possible
  - Silicone tubes in place of elastic bands



Further Recommendations:

- Ensure material is resistant to saliva
- Buy textured material with larger μ for use in depressor/strap
- Explore different geometries of tongue depressors

Conclusion

- We picked the best design alternatives and from there, made multiple variations
  - Different sized mouthguards
  - Different depressors
  - Different ways to attach depressor (straps, buttons, etc.)
- Our final prototype ended up costing ~$2.75
- It satisfies all our constraints and objectives

Acknowledgements

Joon You, Ph.D

Professor Little

Professor Orwin

Professor Krauss

Professor Furuya

Professor Zorman

HMC Shop Proctors

HMC Makerspace

References

- Dym, Clive L., et al. Engineering Design: A Project-Based Introduction. Wiley, 2014.
- FRITSCH , KARSTEN M, et al. “Side Effects of Mandibular Advancement Devices for Sleep Apnea Treatment” *American Journal of Respiratory and Critical Care Medicine*, 1 Sept. 2001, www.atsjournals.org/doi/full/10.1164/ajrccm.164.5.2003078.
- Peters, Brandon.”CPAP Side Effects: What Commonly Occurs with Sleep Apnea Therapy?”*Verywell Health*, 9 Nov. 2017, www.verywell.com/cpap-therapy-what-are-the-side-effects-3015024.
- Peters, Brandon. “Stick Out the Tongue: Using a Mouthpiece to Treat Snoring and Apnea.” *Verywell Health*, 6 Nov. 2017, www.verywell.com/tongue-stabilizing-device-for-treating-sleep-apnea-3015243.
- “Sleep Apnea.” Mayo Clinic, Mayo Foundation for Medical Education and Research, 9 Mar. 2018, www.mayoclinic.org/diseases-conditions/sleep-apnea/symptoms-causes/syc-20377631.
- “What Is a CPAP Machine and How Does It Work?” Sleep Resolutions, 2 May 2018, www.sleepresolutions.com/blog/what-is-a-cpap-machine-how-does-cpap-work.