

AAO Foundation Final Report Form (a/o 6/30/2018)

- Is this an example of your very best work, in that it provides sufficient explanation and justification, and is something otherwise worthy of publication? (We do publish the Final Report on our website, so this does need to be complete and polished.)
- Does this Final Report provide the level of detail, etc. that you would expect, if you were the reviewer?

Type of Award: Biomedical Research Award

Name(s) of Principal Investigator(s): Maria Therese S. Galang-Boquiren

Co-Investigators: Bharati Prasad, Rutger Stache, Grace Viana, David Carley

Institution: University of Illinois at Chicago

Title of Project: Oral Appliance and Pharmacological Agents in the Treatment of Sleep Apnea: A Pilot Clinical Study

Period of AAOF Support: 07-01-16 to 07-11-19

Amount of Funding: \$30,000

Summary/Abstract:

Hypothesis: Augmentation of a mandibular advancement oral appliance (OA) by pharmacotherapy (ondansetron + fluoxetine) will increase therapeutic efficacy in moderate to severe obstructive sleep apnea (OSA) patients.

Methods: Twenty-one subjects met inclusion criteria and were enrolled. Subjects with moderate-severe OSA were treated with a TAP3 Elite® OA plus placebo medication for two weeks, followed by a combination regimen of ondansetron (24 mg/day) and fluoxetine (10 mg/day) with continued use of the OA for four weeks.

Results: Ten subjects (7 male and 3 female, BMI 38.54±3.4) completed the study. AHI OA + Medications (18.02±4.3) was lower than the AHI baseline (32.96±3.19). Sleep efficiency and oxygen desaturation indices improved. Subjective (ESS) and objective (PVT) daytime sleepiness showed improvement. Mean total airway volume at end inspiration increased by 28.1% with OA compared to without OA. Minimum cross sectional area (CSA) increased by 43.2% with OA compared to without OA.

Conclusions: Combination of pharmacotherapy and oral appliance may be a viable option in treating patients with moderate to severe OSA.

Detailed results and inferences:

If the work has been published please attach a pdf of manuscript (PDF OF MANUSCRIPT THAT WE ARE PREPARING FOR SUBMISSION IS ATTACHED.)

Respond to the following questions:

1. Were the original, specific aims of the proposal realized?

Yes, the original specific aims of the project were fulfilled.

2. Were the results published?

A preliminary abstract has been published in the Sleep Medicine Journal. A manuscript has been submitted to the AAO for competition and is being prepared for submission to the AJODO.

a. If so, cite reference/s for publication/s including titles, dates, author or co-authors, journal, issue and page numbers

Oral Appliance and Pharmacologic Agents in Treatment of Sleep Apnea. Stache R, Prasad B, Viana G, Galang-Boquiren MT. Sleep Medicine. Vol 42, Supplement 1, 2019.

b. Was AAOF support acknowledged?

Yes, AAOF support was acknowledged in the poster upon presentation. As we submit our manuscript for publication, AAOF support will also be included.

c. If not, are there plans to publish? If not, why not? *N/A*

3. Have the results of this proposal been presented?

Yes

a. If so, list titles, author or co-authors of these presentation/s, year and locations

It was presented as a poster at the American Academy of Sleep Medicine Annual Meeting in San Antonio, TX earlier this year (June, 2019).

Title: Oral Appliance and Pharmacologic Agents in Treatment of Sleep Apnea

Authors: Stache R, Prasad B, Viana G, Galang-Boquiren MT.

b. Was AAOF support acknowledged?

Yes.

c. If not, are there plans to do so? If not, why not? *N/A*

4. To what extent have you used, or how do you intend to use, AAOF funding to further your career?

I am grateful for the support of the American Association of Orthodontists Foundation. It has been instrumental in allowing me to pursue my passion for interdisciplinary clinical science. The Biomedical Research Award from the AAOF has allowed me to collaborate with professionals in the field of medicine and nursing specifically in the field of sleep medicine which is one of the most relevant medical specialties to our field. The results we have obtained from this study will be utilized as preliminary data for applications to fund future larger scale trials.

Accounting for Project; i.e., any leftover funds, etc.

Please see attached accounting document. In summary: Total Amount Spent: \$29,866.84;
Leftover funding: \$133.16