PERFORMANCE OF THE INVACARE TWILIGHT MASK- CLINICAL TRIAL RESULTS

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Introduction:

Continuous Positive Airway Pressure (CPAP) is an accepted means for non-invasive treatment of Obstructive Sleep Apnea (OSA). It provides breathing assistance for patients, through the use of masks, so that patients can maintain their airway, thus providing optimum oxygen saturation. Commercially, there are approximately 30 masks available for use with CPAP. CPAP is 95% effective for the treatment of OSA if the patient is compliant[1]. Factors that influence compliance are comfort, suitability, and cost[2]. It was with these considerations in mind that we evaluated the Invacare Twilight Mask**.** This mask uses a clear polycarbonate shell, dual walled silicone cushion, adjustable forehead support, and dual quick release clips. An initial clinical trial focusing on comfort and fit was conducted in 2002 utilizing experienced mask users. Those patient suggestions were incorporated into an upgraded design**,** which was again tested among a patient pool of experienced CPAP users. Feedback was gathered among these patients regarding the innovations added based on suggestions from the first clinical trial.

Method:

Institutional Review Board (IRB) approval for clinical trials was obtained. Positive Airway Pressure (PAP) therapy patients that met inclusion criteria were recruited, after informed consent, from a database of patients who have undergone treatment with CPAP for at least 6 months. 14 of 15 recruited patients completed the study, 1 was dropped due to failure to appear for follow-up appointments. Each participant was using PAP therapy ranging from 11 months to 3 years (mean 1.85 $\pm$ 0.70 years). Mean nightly PAP use was 7.10 $\pm$ 0.96 hours. Participants came to the sleep center where they completed a pre-trial questionnaire gauging their current level and duration of use and their perceptions of their current nasal mask**.** Participants were then fitted with the standard size study mask and given instruction on adjustment and use. Participants then took the mask home and used it for a 2-week period. At the end of the trial period, participants returned to the sleep center and completed a post-trial questionnaire about the study mask.

The questions asked required the participant to compare the study mask to their current mask, and focused on the forehead support and headgear, the silicone seal, the exhalation exhaust ports, the swivels, and the ease of assembly. These were grouped under four subheadings: 1) forehead support, 2) silicone seal, 3) mask shell, and 4) general. Within these subheadings, there were two types of questions asked. One type required "yes" and "no" responses only. The other type required responses that were answered along a weighted continuum. Analysis of these responses grouped answers into three classes: 1)

inferior to their current mask, 2) same as their current mask, and 3) superior to their current mask. For questions in which the majority of responses were in the "same as" category, the criteria being evaluated was considered to be similar to that offered by the patients' current masks. When the majority of responses were not in the "same as" category then the "same as" responses were dropped and the "inferior" and "superior" responses were compared.

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Results

Under the forehead support subheading, 100% of patients responded that the ability to adjust the forehead support was superior to other masks. 92% stated that disengaging and re-engaging the locking mechanism was also superior. 86% were able to adjust the forehead support for a comfortable fit so that air did not leak into their eyes.

Forehead Support	**Inferior**	**Superior**
Adjustment	0	11 (100%)
Disengage/Re-engage	1 (8%)	11 (92%)

	Yes	**No**
Air leaking into eyes	2 (14%)	12 (86%)

Interestingly, in the silicone seal subheading, only 14% remarked that the mask caused irritation on their nose. The reason that this finding was remarkable is that in all cases only the standard mask size was used, and, the study exclusion criteria did not disqualify participants based on nasal dimensions. Thus, it appears that this single mask size was able to meet the fit needs in over 80% of the cases. Also, 60% found the mechanism for removing and replacing the silicone seal to be easier to use than that on their current mask.

Silicone Seal	**Yes**	**No**
Nose irritation	2 (18%)	9 (82%)

	Inferior	**Superior**
Removing/Replacing	4 (40%)	6 (60%)

Within the mask shell subheading, 100% found movement of the large mask swivel was superior, while 92% answered similarly for movement of the smaller tubing swivel. 82% of the patients found the headgear clips superior to the clips on other masks.

Mask Shell	**Inferior**	**Superior**
Large swivel	0	12 (100%)
Small tubing swivel	1 (8%)	11 (92%)
Headgear clips	2 (18%)	9 (82%)

Lastly, in the general subheading, 100% of the patients rated this mask to be quieter than the mask they typically use. 64% remarked that gas did not blow on their chest, and, in addition, 93% remarked that gas did not blow on their partner. 82% stated their overall impression of the mask was superior in quality and performance while 79% stated that they would consider using this mask.

General	**Inferior**	**Superior**
Noise	0	10 (100%)
Overall impression	2 (18%)	9 (82%)

	Yes	**No**
Gas blow on chest	5 (36%)	9 (64%)
Gas blow on partner	1 (7%)	13 (93%)
Consider using mask	11 (79%)	3 (21%)

Discussion

According to the latest U.S. Census Bureau, there are approximately 300 million Americans[3]. It has been estimated that 4% of all middle aged men, and 2% of all middle-aged women in America have Obstructive Sleep Apnea[4]. If left untreated, Sleep Apnea can have many adverse effects on our health, such as systemic and pulmonary hypertension. Therefore, the importance of treating this syndrome is evident.

CPAP is an accepted means for non-invasive treatment of OSA through the use of masks. There are approximately 20 companies that manufacture about 30 masks for commercial availability. This wide variety of mask options is a testament to varied anatomic differences and patient preferences that challenges the home medical equipment (HME) provider. In fact, it is common for an HME provider to provide a patient with several different masks in order to enhance compliance. Unfortunately, the added cost of using several masks is not reimbursed and must be borne by the provider.

Successful treatment of OSA with CPAP requires patient compliance. One of the most important factors influencing patient compliance is mask comfort[5]. The more comfortable the nasal mask, the less likely that sleep will be interrupted by discomfort[6].

Comfort can be assessed by fit and size of the mask. Inappropriate fit and size, leading to discomfort will occur if the mask interface is too close or too far from the face, or if the straps holding the mask to the head are too tight. Adverse events such as skin pain and irritation can result from inappropriate size and fit. This was reflected in the survey that asked patients if the mask caused any nose irritation. Although 18% answered yes, this could be due to the large size of their nasal anatomy. Nasal anatomy was not an exclusion criteria for participation in the study. Therefore, patients with large noses were

considered viable participants. Since 82% answered no to this question, it can be concluded that the mask has the potential to fit a large percentage of the population.

Many patients remarked that the ability to adjust the forehead support played a major role in producing a good fit. As one patient stated, "This mask…adjusted to my head better than my existing mask." In addition, 86% answered that they were able to adjust the pads so that air did not leak into their eyes, which is a contributing factor to discomfort.

Even though a mask may fit a patient well, another characteristic that concerns patients is the amount of disturbance that a nasal mask can cause on their bed partner. When asked about the noise emanating from the mask, the overwhelming response was that this mask design is quieter compared to other masks used. In addition, only 1 out 14 patients complained that gas blowing out of the exhaust ports disturbed their bed partner.

Another added feature that was commented on were the headgear clips. Although a few patients said "…they had to get used to [using them]," the overall majority of patients found them superior to the clips they have used on other masks. Some remarked that "…they are easy to use," and "…they are a vast improvement," and "it was better as I got used to it." Based on these remarks, success and acceptance of the headgear clips might improve with an introductory training and education session. An instructor can demonstrate the proper way to attach and re-attach the clips. In addition, the instructor can observe and correct any faulty technique. This should help to facilitate use at home as the patient becomes more familiar with this mechanism.

Overall, the impression of the majority of the participants is that this mask is superior to other masks used. Moreover, the majority of participants stated they would be willing to use this mask should it become commercially available.

Conclusion

Although this study was limited to 14 participants, when the results are combined with those of the initial trial with 23 participants, it becomes even more apparent that a high degree of patient acceptance favors this device. This mask seems to meet the comfort and fit requirements of a large portion of PAP users. Furthermore, the design seems to permit quiet, undisturbed sleep for most PAP users, and their bed partners**.** As a result, this nasal mask should become a valuable tool to aid in the promotion of patient compliance.

References

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