

An evaluation of a Mask with Dynamic Support Technology

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Abstract

This whitepaper outlines feedback gathered in a sponsored evaluation of Fisher & Paykel Healthcare (F&P) on a mask with Dynamic Support Technology™ (DST). Feedback was gathered from experienced positive airway pressure (PAP) therapy users with obstructive sleep apnea (OSA) (n = 126) and Durable Medical Equipment providers (DMEs) (n = 55). DMEs were asked to provide the mask with Dynamic Support Technology to patients currently facing mask issues or interested in trying something new. In the OSA user sample, 75% of respondents rated mask leak as a major problem with their previous mask. By comparison, when asked about their mask with DST, 95% of OSA users found their DST mask did not cause leak. From the DME respondents, 93% rated the performance of the mask with DST as a 4 or 5 on a scale of 1 (poor) to 5 (great).

Background

In an assessment of patient reviews across leading online sleep apnea equipment providers, the number one issue reported by full-face mask users was leak.¹ Mask leaks can lead to undesirable side effects including noise, drying of eyes and nasal/oral mucosa, nasal congestion, and rhinitis.² Consequently, mask leak is closely linked with patient preference. A cross-over study by Teo et al. showed that patients reported a higher preference towards mask types less prone to leak, rating them as better fitting and more comfortable.³ In line with this, mask leak has been shown to be an independent predictor of compliance to PAP(Positive Airway Pressure) therapy.⁴ Overall, one third of full-face mask users undergoing PAP therapy report issues with mask leak. Leaks not only impact comfort but also the effectiveness of PAP therapy, where the pressure response of the PAP machine can be reduced by up to 56% in the presence of an air leak of 30 L/min.⁵ With such a large proportion of OSA (Obstructive Sleep Apnea) patients experiencing mask leak, masks must be designed to be well fitting, stable, and able to withstand movement while also ensuring a comfortable and effective seal.

At Fisher & Paykel Healthcare (F&P), our mission is to do what is best for patients and solve common problems of our PAP therapy users by incorporating innovative features into our designs.

Dynamic Support Technology™ (DST) is the term used to describe how the stability bar works in conjunction with the RollFit™ seal to provide stability while allowing the seal to adjust dynamically to patient movements (Figure 1). This technology is designed to reduce the likelihood of the mask dislodging so an effective seal can be maintained throughout the night, even if the patient is tossing and turning.⁶

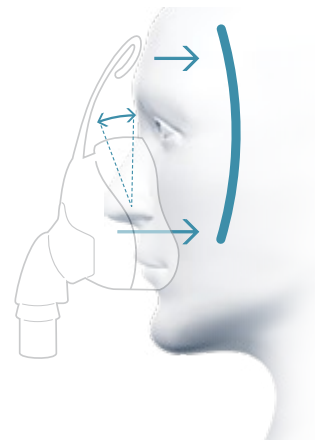


Figure 1. Dynamic Support Technology with Stability Bar and RollFit seal

Dynamic Support Technology Evaluation

The F&P Dynamic Support Technology evaluation began in July 2019, with the goal being to provide patients with a total package that can support them with issues around leak in full-face PAP masks. DST trial kits, containing a F&P Simplus™ full-face mask (Figure 2) as well as marketing collateral explaining the benefits of DST, were supplied to Durable Medical Equipment providers (DMEs) in the United States of America. DMEs were asked to provide the DST kits to their patients currently facing mask issues or interested in trying something new. A survey gathered feedback from patients and DMEs on mask performance and fitting.



Figure 2. F&P Simplus full-face mask with Dynamic Support technology.

Key findings

DMEs

To date, responses have been gathered from 55 DMEs. These respondents were predominantly respiratory therapists (62%) but also included nurse practitioners (5%), technicians (4%), managers (9%), and DME owners (20%). Results showed that 93% of DMEs rated the performance of the DST kit as a 4 or 5 on a scale of 1 to 5 (Figure 3) and 94% said they would consider using DST masks as their preferred product going forward (47% “Yes”, 47% “Maybe”). When asked for more general feedback on the DST mask kits, positive responses reflected on comfort, lack of leak, fit, and performance. Some areas that DMEs were unsure about included the style (stability bar) and over-the-nose seal.

DME performance rating of DST kit

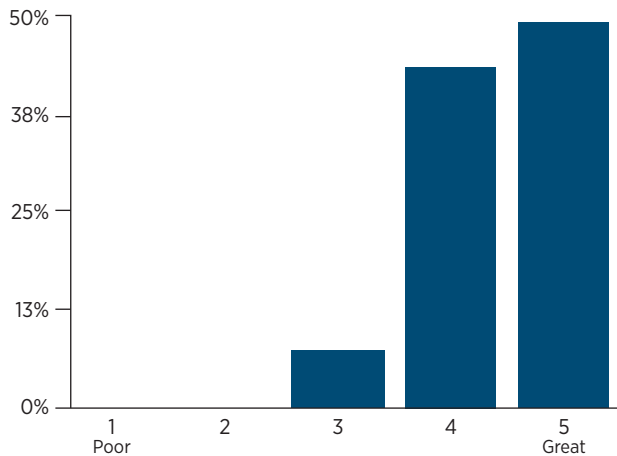


Figure 3. Feedback from 55 DMEs on “Overall performance rating of DST kit” on a scale of 1 (poor) to 5 (great).

Patients

To date, responses have been gathered from 132 patients. Of these, 126 participants were full-face mask users; the remaining six were nasal mask users and thus excluded from the analysis. Feedback was gathered from participants on their previous mask as well as their

experience with the DST mask after 1 to 6 weeks’ use of the DST mask. When asked about their previous mask, 75% of participants said that leak was a major issue (Figure 4A). When asked whether they experienced discomfort with their previous mask, mask dislodging/instability was a major issue (reported by 59%), followed by complaints including facial marks (22%), noise (17%), and pressure around nose (19%) (Figure 5A).

By comparison, when asked whether the DST mask caused leaks, 95% of patients said no (Figure 4B). When asked whether discomfort was experienced with the DST mask, 83% said it did not cause discomfort. The frequency of discomfort complaints reduced dramatically following use of the DST mask. Dislodging/instability was reported by just 5% of patients; the frequency of complaints around facial marks (2%), noise (4%), and pressure around nose (3%) were reduced as well (Figure 5B).

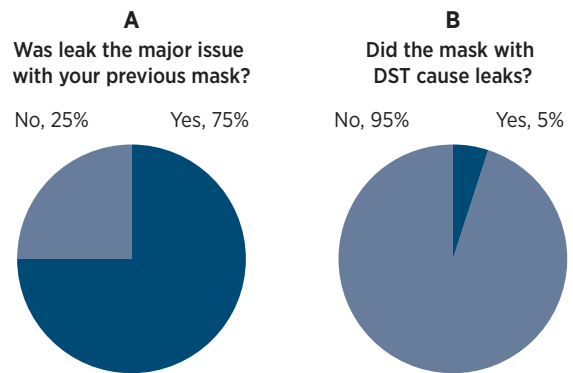
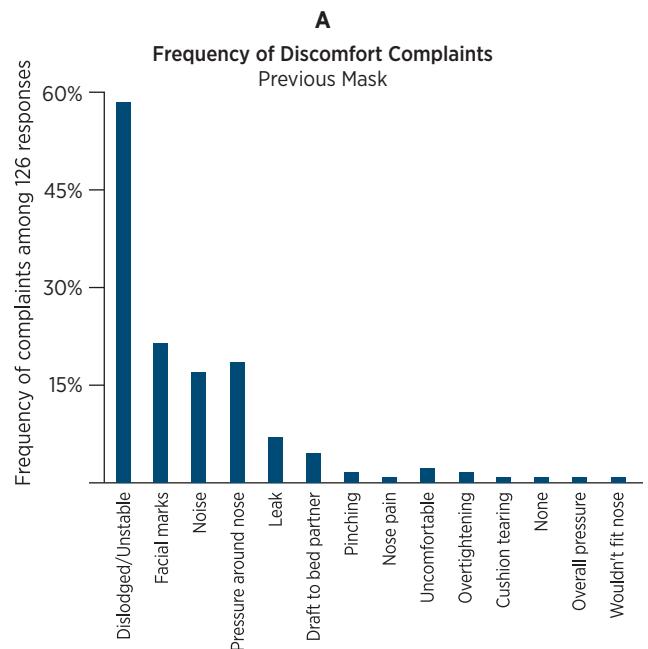


Figure 4. Leak comparison between patients’ previous mask and DST mask. (A) Feedback from 126 patients on the question “Was leak the major issue with previous mask?” (B) Feedback from 126 patients on the question “Did the DST mask cause leaks?”



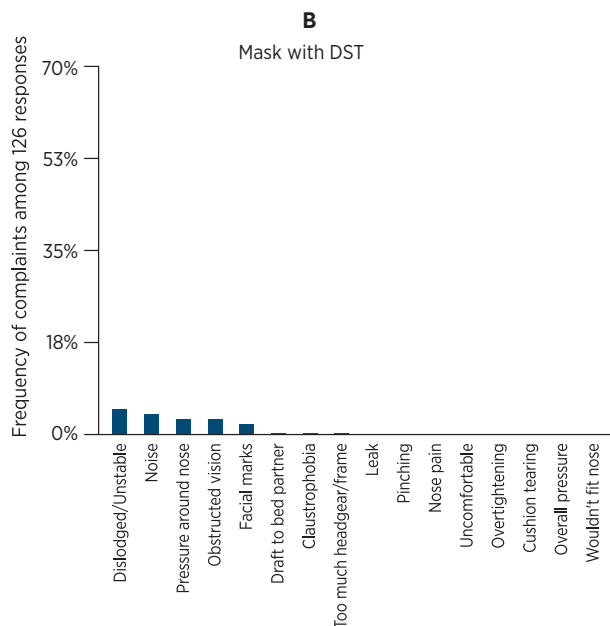


Figure 5. Frequency of discomfort complaints comparison between patients' previous mask and DST mask. (A) Feedback from 126 patients on discomfort complaint categories for previous mask. (B) Feedback from 126 patients on discomfort complaint categories for DST mask.

When asked to compare the DST mask with their previous mask, 91% said the DST mask performed better (6% said "no change in performance"; 3% said "previous

mask"). On completion of the survey, 94% of patients were still using the DST mask rather than their previous mask, further highlighting a preference for the DST mask within this patient group. Patients were given the option to provide additional written feedback around the DST mask. The themes of these responses focused on the lack of leaks, comfort, stability, and ability to hold pressure.

Conclusions

Patient feedback showed that DST masks had lower levels of leak and a lower frequency of discomfort complaints compared with patients' previous masks. DST masks were well-received among DMEs as well, with the majority considering it as a preferred product going forward. Overall, the DST evaluation and assessment has shown that masks with Dynamic Support technology may be a good option for patients struggling with issues around mask leak and discomfort.

Dynamic Support technology is being incorporated across a range of F&P CPAP masks, including our recently released full-face mask, F&P Vitera™, and nasal mask, F&P Eson™ 2. With these products, we aim to support our patients by providing effective therapy delivery in comfortable, dynamic, and high-performing masks.

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References:

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6. 31 out of 41 participants rated the sealing performance of the mask as "good" or "very good". Internal validation study conducted by Fisher & Paykel Healthcare on 41 participants in United States of America 2017.