



Introduction

Good inhaler technique is key for an effective inhalation treatment and reduction of critical inhaler errors. Recent publications show that treatment effects can be improved if inhalers are easy to use and support patients with pulmonary hypertension in their inhaler technique (1, 2). The aims of this study were the usability assessment of the soft mist inhaler (PFSI, Resyca®, Netherlands), evaluation of inhalation flow profiles with the resistance of the inhaler, and observation of ability to safely use the inhaler.

Aims

A formative human factors study was conducted in 15 patients with pulmonary hypertension, functional class II, III, or IV, thereof 3 patients with handling difficulties like scleroderma. User device interaction, inhaler flow profiles and use tasks were assessed for all patients. Patient satisfaction and user needs were assessed in qualitative interviews.

Methods

Different designs were investigated during this study; designs of the PFSI device with different dose release mechanisms (with the button release being the primary device used for usability assessment), and a design to investigate force required to turn the charge knob in a worst-case scenario. Figure 1 shows the PFSI device design, which was tested.



Figure 1: PFSI Soft Mist Inhaler

The 60-minute sessions followed the below structure as outlined in the protocol starting with an introduction and participant background and rapport building.

- Breathing measurements: Obtain a breathing profiles
- 5-minute break to allow participant recovery after breathing measurements
- Intuitive use: Work through use steps of assembly
- Simulated Use: Works through use steps inhalation, disassembly
- Actual use expectations: Feedback on using this device in real life
- Design comparisons: Explore different device designs

Table 1: Participant Demographics

Number of participants	15	
Age mean	55 years	
Age range	36 – 83 years	
Gender (n)	Male	1
	Female	14
Functional classes PAH	Class 2	5
	Class 3	7
	Class 4	4
Comorbid connective tissue disorder*	3	
Handedness (n)	Left	1
	Right	14

*Scleroderma / Systemic Sclerosis / Ehlers Danlos Syndrome

Results

Table 2: Breathing profile results

	Average Inspiratory Flow (L/min)	Peak Inspiratory Flow (L/min)	Inhalation Duration (sec)	Inhaled Volume (L)
Mean	14.3	16.2	6.0	1.3
10% Percentile	8.8	10.4	3.6	0.6
Median	13.5	15.6	6.8	1.3
90% Percentile	20.0	21.6	8.1	2.0

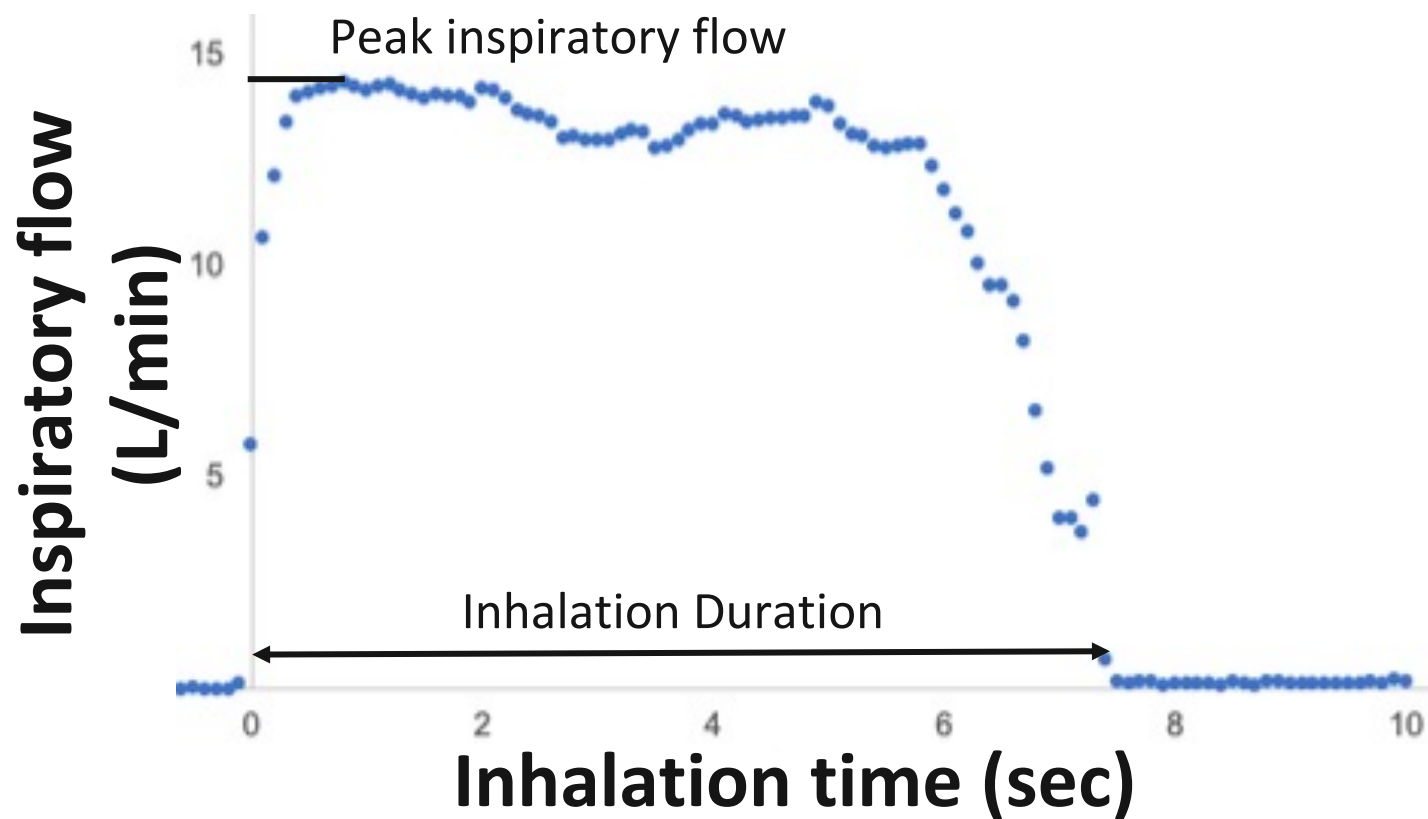


Figure 2: Typical flow profile from PAH patient during inhalation

87% of patients rated the inhalation treatment with several breaths and performing of required use steps as comfortable. 73% assembled the device correctly with instructions for use.

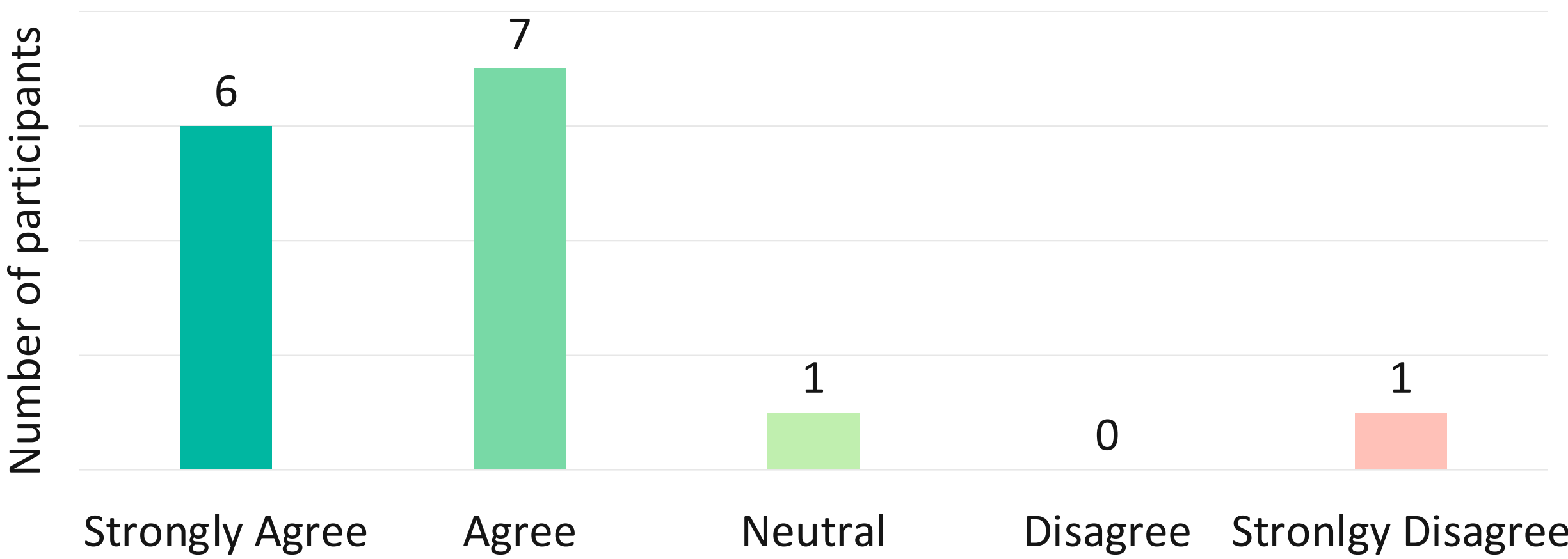


Figure 3: Responses on question ‘I feel comfortable performing the use steps of this device’

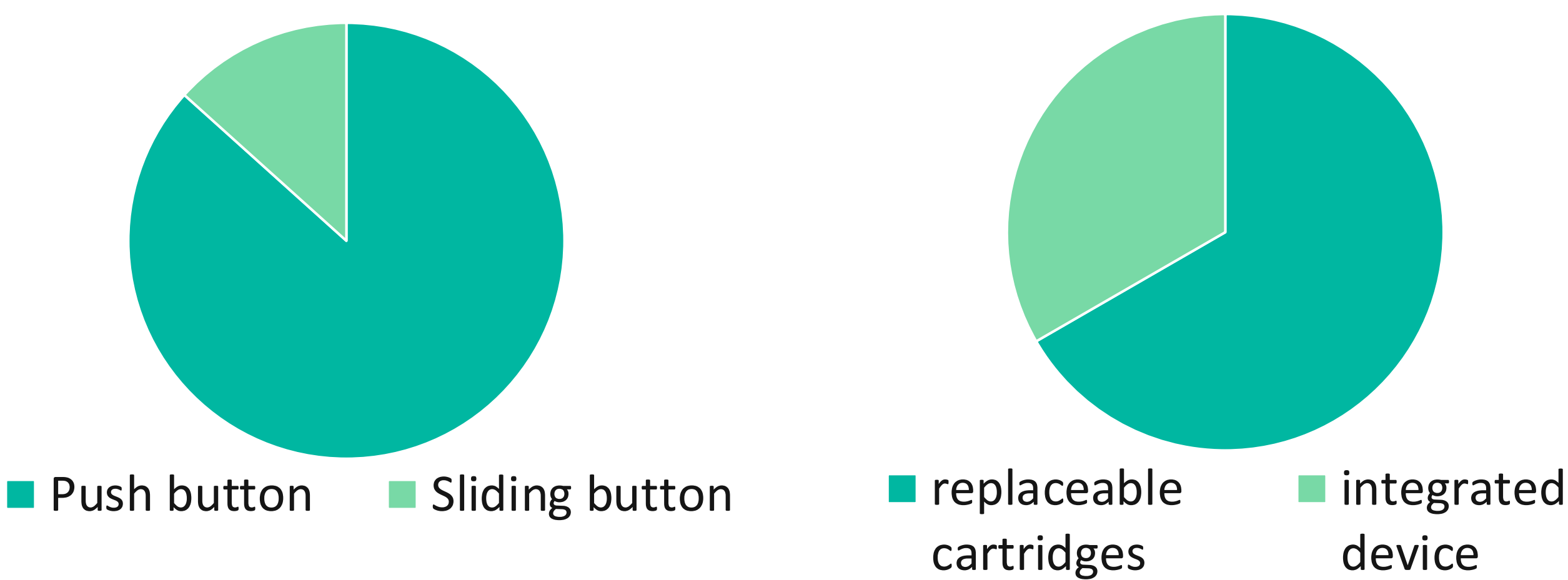


Figure 4: Design preferences of participants.

Preference of actuation button (left) and preference related to a multi-use device with replaceable cartridges vs integrated device (right)

Conclusion

Results from this human factors study show that patients with PAH of functional class 2 to 4 comfortably inhaled slow and deep with the high resistance soft mist inhaler. All patients were able to inhale with an inhalation duration of 3.6 seconds. Median inhalation duration was 6.8 seconds, median inhaled volume was 1.3 L and median flow rate was 13.5 L/min.

The intuitive device design supported patients of different functional classes including patients with comorbid tissue disorder in applying steps to good inhalation technique, while informing further design improvements.

References

- Gessler T, Ghofrani HA, Held M, Klose H, Leuchte H, Olschewski H, Rosenkranz S, Fels L, Li N, Ren D, Kaiser A, Schultze-Mosgau MH, Müllinger B, Rohde B, Seeger W. The safety and pharmacokinetics of rapid iloprost aerosol delivery via the BREELIB nebulizer in pulmonary arterial hypertension. Pulm Circ. 2017 Apr-Jun;7(2):505-513.
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