RESEARCH ARTICLE

A Novel Respiratory Control and Actuation System for Upper-Limb Prosthesis Users: Clinical Evaluation Study

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ABSTRACT The most widely-used active upper-limb (UL) prostheses worldwide are body-powered (BP), which is a two-century-old technology. Despite their affordability and functional benefits to users, these devices are prone to poor outcomes for many patients. Additionally, BP devices have witnessed limited improvements compared to their externally-powered counterparts. Literature indicates a strong need for appropriate prosthetic solutions for children and adolescents. Our previous work introduced a first-of-its-kind breathing-powered UL prosthesis ("Airbender") that can overcome several limitations of the current BP systems (e.g., restricted operation space, user discomfort caused by the harness to which the cables are attached). Users can regulate their breathing, and this controllable airflow is subsequently used to power a small (purpose-built and optimised) Tesla turbine that can accurately control the opening and closing of the prosthetic hand. The current work explores device usability in children and adolescents with a UL difference (n = 15). Further, we gathered feedback, suggestions, and satisfaction levels from the study participants and their parents on breathing as a modality of controlling a prosthetic device. The collected responses and study observations were subjected to qualitative and statistical analysis. This study showcases real-world testing of a breathing-powered prosthesis and proves that UL-deficient children and adolescents can indeed operate the device (i.e., volitionally open or close) with their breathing input. The perceived level of difficulty in opening or closing the device tended to be on the 'easy' side. We report generally favourable feedback obtained from participants and their parents. Additionally, design suggestions and satisfaction levels concerning different device attributes help us involve the key stakeholders in co-creating and proactively developing a robust product development roadmap. This work is aligned with creating a step-change in the potential BP prosthesis options for patients in the future, propelled by a need-led approach.

INDEX TERMS Adolescents, artificial limbs, body-powered prosthetics, breathing-powered device, children, clinical study, parents, tesla turbine, upper-limb prosthesis, usability study.

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I. INTRODUCTION

Congenital or acquired upper-limb (UL) differences result in substantial functional deficits and adversely impact a

child's quality of life (QOL), posing substantial functional, psychological, economic, and/or social implications for the entire family [1]. Worldwide estimates for congenital UL deficiency vary widely, ranging from 0.04–1 per 100 live births [2]. Whilst acquired UL amputations in children and adolescents can be due to a wide variety of aetiologies, with the primary cause usually being trauma [1], [3]. In general, children in need of a prosthetic aid are typically equipped with a passive device or a body-powered (BP) prosthesis. They are often meant to improve the functional performance of the young user. Yet, these prosthetic aids can also play a vital role in improving their gross motor development [4]. However, compared to adult users, the issue of affordable and appropriate prosthetics remains more pressing for children and adolescents, as many options are not suitable for use by younger individuals [5], [6], [7]. There has been little progress in developing new approaches for this user group, specifically concerning the power and control of BP devices. Traditional BP devices rely on a harness system for their control, which results in a severely limited or restrictive operational workspace [8], [9]. Furthermore, they usually require extensive fitting procedures from a high-skilled professional [10]. Unfortunately, current BP prostheses are also associated with higher device repair and maintenance rates than other device types [11], [12]. In addition, they often consist of cables and harnesses that many children and female users find uncomfortable or cumbersome [13], [14]. Children and adolescents using BP devices might experience prosthetic technologies very differently than adults due to their smaller size, constant growth, and psychosocial development. This is potentially reflected in high rejection rates and device abandonment for paediatric UL prosthesis users [15], [16], [17], [18]. Providing suitable active devices to children and adolescents has remained a priority for the field. Battraw et al. [7] outlined actions to translate technological advancements in adult UL prostheses that are yet to be leveraged for paediatric devices and proposed strategies to begin removing barriers to adoption. For example, ease-of-control and elimination of the harness altogether have remained a hope for BP device users [9], [14], [19]. Efforts have also been made to address the need for a purely mechanical device that does not require harnessing (e.g., "Self-Grasping Hand" [20], "Wilmer Elbow Control" [10], "Cyborg beast Hand" [21]), but these have their own inherent functional drawback(s). Nonetheless, BP prosthesis users' design priorities and needs have remained virtually unchanged for decades [9], [14], [18], [22], with little attention given to broadening the design choices. Efforts are still underway in the quest for a more appropriate or fit-for-purpose BP prosthesis for paediatric (and adult) users [6], [10], [23].

Especially, realising satisfactory levels of UL prosthesis control has remained a challenge [17]. Bongers et al. [24] highlight that muscles developed over evolution for a particular function are utilised for a different function whilst controlling a prosthetic device; hence, prosthetic control is non-intuitive. Thus, identifying novel, intuitive, and

non-invasive control options for UL prostheses has remained an ongoing topic of interest for researchers, academics, and clinicians alike [17], [25], [26]. Leveraging the respiratory pump (lungs) to create a novel control option was suggested at a conference in Oxford in 2016 (MEIbioeng'16) by Bergmann [27]. Research has recently been published that showed such a novel breathing-powered prosthetic device (Airbender) can help decouple aperture control from the control of the position of the prehensor in space [28]. However, this technical feasibility study involved limited user testing in demonstrating device operation. Usability research helps to ensure that products are designed, developed, and optimised to meet user needs. User testing studies provide feedback on device performance and perceived usability. The successful design of prosthetic devices is attributed to a research and development process that synergistically combines end-users with device developers [15]. Integrating patient desires into the prosthetic design has been noted as a crucial component of patient satisfaction and maximising the real-world impact of research and innovations [29]. Consequently, numerous studies have emphasised the need for co-creation to facilitate the translation of UL prosthetics research [30]. Though implemented in other fields for several decades, there is little published work reporting on the usability of prosthetic devices or the best design for conducting usability tests of prosthetic devices [31].

Despite low satisfaction levels of paediatric UL prosthesis users, many studies have relied extensively on parent's proxy reports, interviews, and/or questionnaire-based surveys to gauge their needs and priorities (e.g., [14], [32]). The reality of how UL differences and prosthetic technology affect an individual may be exceptionally subjective. To illustrate, Sheffler et al. [32] compared self-reports with parent proxy reports of function and QOL amongst children with limb differences; they found that parents underestimated their children's physical and social function and overestimated their comfort. Further, design priorities can vary substantially between adults and children, suggesting there are distinct requirements for paediatric users [14]. However, previous studies involving paediatric users in the development of prostheses have explored the design priorities of device users of all age groups, thereby combining the findings from adult and paediatric populations (e.g., [14], [18], [22]). This approach does not fully appreciate a child's needs and views as unique to an adult's. Children's prosthetic needs are distinct as they are not just small adults – one key difference is their cognitive development limits of what they can do with the prosthesis [33]. Hence, before fitting a device to a child, one should consider what they are physically and mentally capable of using. Nevertheless, very few studies have tried to capture the opinions of UL-deficient children and adolescents (e.g., [34]). Involving children at the design stage has resulted in products that truly met the children's needs [35], [36]; additionally, the authors suggested that the children's likes and dislikes that were revealed were contrary to the researchers' preconceived ideas about the children and would

have remained unknown without their participation. Furthermore, besides involving children and adolescents using UL prostheses, it still is essential to consult with other stakeholders (parents/carers and professionals), as they will have different levels of expertise, motivations, and/or engagement for using these devices [37], [38].

Recent usability and co-creation studies involving UL prosthesis development have been undertaken mainly in high-income countries (HICs) for paediatric users [39], [40], [41], [42]. Nonetheless, studies documenting the development of appropriate prosthetic technologies are far more limited in low- to middle-income countries (LMICs) [23], [43], [44], [45]. Besides, these studies too have predominantly dealt with adult users, suggesting a strong need for device usability testing involving children and adolescents hailing from such often under-examined contexts through an inclusive approach [46]. Especially, the paucity of literature published about paediatric prosthetic and orthotic (P&O) care in the developing world has remained a persistent issue [47]. Ikeda et al. [48] noted a conspicuous lack of end-user involvement (either passively or actively) in the design process of P&O devices for low-resource settings. Further, Aranda-Jan et al. [49] reported that the literature regarding how medical devices for low-resource settings are designed is minimal. It has been argued that creating appropriate designs for LMICs is more challenging than for HICs due to cost, among other factors [50]. Biddiss and Chau [15] suggest that an increased emphasis on participatory research and consumer satisfaction is needed to ensure that future prosthetic designs can bridge the gap between the research lab and clinic as well as clinic and home. The present study aims to capture the initial stages of novel prosthetic device development that is iterative and systematic to reach a stage at which they can be placed on the market. Involving target users from this early stage is likely to ensure that the design agrees with the users' contexts, views, experiences, and expertise [36], [39].

Therefore, this study focuses on testing the usability of our breathing-powered technology with UL-deficient children and adolescents (target users). The current case series intends to address the following research questions: (1) Can target users operate a breathing-powered prosthesis? (2) How difficult do target users find the operation of a breathing-powered prosthesis? (3) Is there an association between peak expiratory flow rate (PEFR) and grip strength with perceived difficulty of device operation? Also, what are the typical grip strengths and PEFR of target users? and (4) What are target users' preliminary perceptions (patient-reported) and satisfaction levels of operating a breathing-powered system?

II. MATERIALS AND METHODS
A. ETHICS
This study was conducted per the Declaration of Helsinki and approved by the *Oxford Tropical Research Ethics Committee (OxTREC)* at the University of Oxford (OxTREC

Ref. No.: 61-19) and the *Institutional Ethics Committee (IEC)* at the St John's Medical College & Hospital, Bengaluru (IEC Ref. No.: 265/2019). It followed the guidelines published by the *International Society for Prosthetics and Orthotics (ISPO)* and the *Exceed Research Network (ERN)* for the ethical conduct of assistive technology research in LMICs [51]. Further ethics approval, study design, inclusion/exclusion criteria, and trial-related details can be found elsewhere.[1]

B. STUDY PARTICIPANTS AND SAMPLING STRATEGIES
Fifteen children and adolescents (seven boys and eight girls; mean ± SD age of 13.5 ± 2.1 years) with UL loss or absence were recruited through a combination of purposeful sampling and convenience sampling (see Table 1 for further details). The clinical team undertook subject recruitment from the group of patients currently treated at Mobility India – Rehabilitation Research & Training Centre, Bengaluru (and their affiliate/partner organisations in South India) as well as St John's Medical College & Hospital. The first six subjects were recruited from Mobility India, and the remaining nine subjects were from their partner organisations. One of Mobility India's staff physiotherapists performed a complete patient evaluation per their institutional guidelines, besides checking the patient's fitness/suitability before proceeding with the data capture procedure. All the volunteers were reimbursed for their participation time.

C. EQUIPMENT
Isometric grip strength was quantified (in kilograms [kg]; with an increment of 0.1 kg) using a handheld Jamar Plus+ Digital Hand Dynamometer (Sammons Preston, Rolyon, Bolingbrook, IL). In addition, we used a commercially-available Mini-Wright peak flow meter (Clement Clarke International Ltd., Essex, UK) [52] to measure PEFR (in litres per minute [L/min]; with an accuracy of 10 L/min).

Our previous work's methodology while designing the novel BP prosthetic hand "Airbender" [28] consisted of developing mathematical models and virtual prototypes to adequately describe the performance of the individual sub-systems of the prosthesis. The design process commenced with identifying a suitable turbine. The findings from the turbine design were then used to inform the transmission system design. Finally, the TD design was considered to accommodate the turbine and transmission assembly to provide the requisite prosthetic device functionality. Our virtual prototyping efforts were followed by making physical prototypes and subsequent preliminary real-world testing.

A Tesla turbine [53] was chosen, and the mass flow rate for the expected operating conditions was taken as 40 kg/h (approximately 550 Ls/min) – based on the maximum PEFR value corresponding to children [54], [55], as this would form the lower bound of the user population for use in our

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[1]**ISRCTN trial registry:** Testing a novel, affordable body-powered prosthetic arm for children (https://doi.org/10.1186/ISRCTN15596121)

prosthetics. Based on optimisations and virtual prototyping results, the input from the Tesla turbine to the gearing-based transmission system was 2.5 Nmm at 2500 RPM. A scan of the relevant literature on prosthetic hands for children revealed that the transmission's output requirements were 9.81 N (1 kg) of grip force and 1 s of open/close time. Evidently, the Tesla turbine produces excessive speed and insufficient torque to achieve desired prosthetic functionality.

Consequently, drive reductions were considered necessary to optimise output speed and torque to realise physiological speeds and grip strength. Hence, a transmission was designed using a series of meshing (simple and compound) spur gears and a worm drive at the last stage to obtain the required speed, torque, and self-locking. After optimising the Tesla turbine, the model outputs were inputted into a mathematical model of our transmission system to achieve the desired size, torque, RPM, and power for finger actuation. Finally, the output of this optimised virtual transmission model was used to accomplish the TD actuation. The 'Slow' gearbox helps transform the 2.5 Nmm at 2500 RPM input from the Tesla turbine rotor shaft to 1312 Nmm at 3.5 RPM output at the TD's final stage for actuation (total reduction = 720:1). The 'Slow' gearbox version resulted in a theoretical value of 10.93 N (1.11 kg) of grip force and 3.36 s of response time, used in user testing. Besides, we have designed another ('Fast') gearbox that transforms 2.5 Nmm at 2500 RPM input from the Tesla turbine rotor shaft to 409.9 Nmm at 11.1 RPM output at the TD's final stage for actuation (total reduction = 225:1). This results in a theoretical value of 3.42 N (0.35 kg) of grip force and 1.05 s of response time. However, the current study did not use this gearbox version for user testing. In-depth information about the prosthetic design can be found elsewhere [28]. See Supplementary Figures 1 and 2 for the turbine and gearbox schematics (Note: These figures are reproduced from [28]; Published under an open access Creative Common CC BY license).

In summary, a novel BP prosthetic hand "Airbender" that relies on the user's respiratory system to power and control the terminal device (TD) is shown in Figure 1 [28]. Users can regulate their exhalation by forcing the diaphragm upward; the controllable airflow is subsequently used to power a small (custom-built and optimised) Tesla turbine [53], which helps achieve accurate control of the prosthetic TD via a bespoke gearing-based transmission system suitable for paediatric users. This prosthetic device can produce a grip force and response time typical of active prostheses used by paediatric users [28]. A flexible rubber tube connected to the device with a small nozzle/mouthpiece near the user's mouth helps them provide breathing input to actuate the Tesla turbine. The disposable nozzles were 3D-printed using PLACTIVE^{TM} antibacterial filaments. Key components of Airbender are additive-manufactured, allowing easier product adaption as the child grows. The friction-based locking ability at any position (achieved by the non-back-drivable worm drive in the transmission) and dual-input capability at the two nozzles for turbine actuation in both directions renders Airbender a

(a) Schematic of the device and its primary sub-systems.
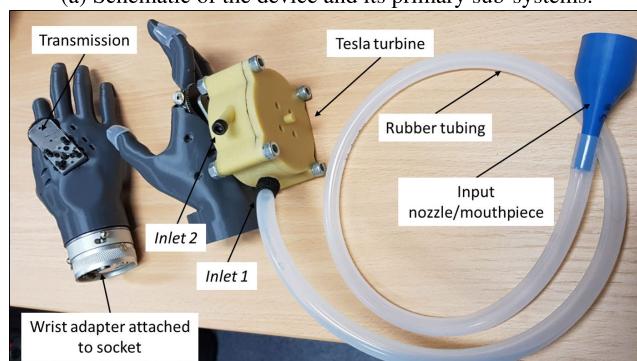
(b) Device prototype with the 'Slow' gearbox (transmission); Note: The image shows 'Inlet 1' connected to rubber tubing for device closing and 'Inlet 2' is closed with a rubber bung.

FIGURE 1. Breathing powered-prosthetic [28] assessed during usability trials.

hybrid voluntary *open-or-close* device. Therefore, there is no pre-determined rest position – the device is lockable in any position due to the worm drive. Both opening and closing of the TD happen with exhalation, with input to a different turbine inlet. It should be mentioned that the current device version only allows opening or closing at one time (based on which turbine inlet the rubber tube is connected to, with the other inlet closed with a tapered rubber bung [3D-printed using Thermoplastic Polyurethane or TPU]). So, for example, after the prosthetic device was fully opened, the tube and bung had to be swapped between the turbine inlets to allow the device's closing operation. This swapping was done by the researcher (VHN) during the user trials.

D. PROTOCOL

The study volunteers and their parents (or guardians) who participated in the usability trials were informed about the entire procedure before obtaining consent: (i) for participants aged 3–7 years, parents were required to sign the Informed Consent form on behalf of their child/ward; and (ii) for participants aged 8–17 years, besides parents signing the Informed Consent forms, both the parents and their child/ward were required to sign the Informed Assent forms. After obtaining consent, the following information was recorded using a custom-made data capture sheet: (i) anthropometric measurement (such as height, weight, residual limb length, etc.) through a standard weighing scale and cloth measuring tape;

(ii) participant demographics; and (iii) the handedness of the study participants (before and after amputation, for acquired cases) were quantified using the Edinburgh Handedness Inventory [56].

Hand grip strength is an indicator of general muscle strength. The grip strength was measured in a seated position using the handheld dynamometer per a standardised protocol [57]. The dynamometer handle was set to the second position as the standard position for measuring grip strength for all participants, as recommended [58]. Measurements were done with the intact/sound arm, and the elbow of the arm holding the dynamometer was placed against their side at 90° of flexion so that their forearm pointed forward with their thumb pointing upwards. The shoulder was adducted and neutrally rotated, and the forearm was held in a neutral position. After the subjects were positioned appropriately, three trials were performed with a 10-second break allowed between attempts; the best trial was used for the evaluation. The participant was encouraged to squeeze the dynamometer's handle as hard as possible with maximal isometric effort, maintain this for approximately three seconds, and then relax as recommended by the American Society of Hand Therapists [59]. All subjects were given words of encouragement by the study team in the subject's preferred language.

PEFR is considered a 'gold standard' physiological index for the functional status of the respiratory system and is defined as the maximum respiratory flow rate during forced expiration by an individual. The low-range peak flow meter (i.e., Mini-Wright AFS Low Range) was used for all participants with lower peak flow monitoring requirements (measuring range: 30–400 L/min). However, the Mini-Wright Standard (Adult) peak flow meter (measuring range: 60–880 L/min) was used for participants whose PEFR values crossed the upper limit of the low-range peak flow meter (i.e., 400 L/min). Three trials of PEFR were recorded, and the maximum value was considered. During the data capture, the participants were seated and encouraged to exhale as hard and fast as possible.

Device usability cannot be directly measured, as it is often evaluated by indirect measures or attributes, e.g., observing the user interacting with the device, user's impressions of device ease-of-use, and user reports of device satisfaction [31]. Most of the qualitative methods adopted in usability testing are sourced from ethnography and typically entail (i) participant observation, (ii) observation of live or video-recorded device use, and (iii) observations made by investigators of responses (both verbal and visual) made by participants during usability testing. Qualitative methods also include administering open-ended surveys, questionnaires, interviews, and focus groups [31]. A qualitative/descriptive usability testing was conducted using the proposed breathing-powered device [28] following methodological considerations from relevant literature [31]. The recommendations by Upper Limb Prosthetic Outcome Measures (ULPOM) Group [60], [61] (set within the World Health Organization (WHO) – International Classification of

FIGURE 2. Usability study demonstrating a study volunteer operating the breathing-powered prosthesis.

Functioning, Disability, and Health for Children and Youth [ICF–CY] framework, [62]) was adopted as a conceptual framework for device assessment. The choice of testing methods depended on the usability attributes that need to be evaluated but typically include (i) observations of the user's interaction with the device; (ii) the user's reports of satisfaction and assessment of the usability of specific device features; and (iii) collection of standardised usability metrics [31].

This observational and predominantly qualitative study explored how the user engages with the breathing-powered device and their view of breathing input as a prosthetic control option. Data capture started with a demonstration of device operation by the study investigator (VHN). The usability study involved 'bench testing' wherein the study volunteer did not don the prosthetic device. Instead, the (right-hand) device prototype (with the 'Slow' gearbox) was placed on a table (Figure 2). The volunteer, seated on a chair next to the table, exhaled forcefully into the rubber tube via a nozzle/mouthpiece placed in their mouth to actuate (open or close) the TD as instructed. The participant held the mouthpiece and rubber tube with their contralateral/intact hand. The rubber tube and the mouthpieces for breathing input to the device underwent strict hygiene requirements and sterilisation techniques, and the 3D-printed nozzles were disposed after use by each volunteer. After the tests, the subjects and their parents responded to a set of questions on a Likert scale and a few open-ended questions.

Hand open and close operations were alternatively performed three times by the participant. After each operation, the subject was asked to rate the 'perceived difficulty' of operating (i.e., opening or closing, as applicable) on a Likert scale of 1–5 (1 = 'Very difficult,' 2 = 'Difficult,'

3 = 'Neither easy nor difficult,' 4 = 'Easy,' 5 = 'Very easy.'). During data capture, researcher-observed information on the subject's engagement and device operation was noted in real time. Besides, unstructured interviews captured participants' and their parents' feedback and suggestions for improvement after the usability tests. Finally, user response was sought on satisfaction levels of different design attributes (i.e., Colour, Shape, Noise, Appearance, Weight, Usefulness, Reliability, Comfort, and Overall) of the current version of the device on a Likert scale of 1–5 (1 = 'Very dissatisfied,' 2 = 'Dissatisfied,' 3 = 'Neither satisfied nor dissatisfied,' 4 = 'Satisfied,' 5 = 'Very satisfied.').

E. DATA COLLECTION

Data capture was conducted within the premises of Mobility India and their affiliate/partner organisations in South India. Data collection was undertaken per a standard protocol (alongside relevant institutional guidelines and COVID-19-related restrictions that were communicated to both ethics committees earlier) by a single *Good Clinical Practice (GCP)*-trained researcher (VHN) to avoid inter-rater repeatability issues. One of the clinical staff members at Mobility India acted as a translator and assisted with data collection with participants speaking local languages (barring fluent Kannada, Hindi and/or English). Relevant ethics application and protocol documents were translated into six local languages (Kannada, Hindi, Telugu, Tamil, Malayalam, and Marathi) as mandated by the ethics committees to facilitate data capture with participants and their parents/guardians who might not be proficient in English. These documents were provided to help the translator.

F. DATA ANALYSIS

All quantitative data analysis was conducted using Microsoft Excel 2016 and MATLAB® R2020b (Mathworks, Natick, MA, USA) software. Descriptive statistics (mean, standard deviation, range, frequency count, proportion, and percentage) were used to summarise the data. Scatter plots and Spearman's rank correlation (ρ) were used to check the association between grip strength and PEFR values with the perceived difficulty of device operation. Spearman's rank correlation coefficients were categorised similarly to Taylor [63], as "weak" ($\rho \leq 0.35$), "moderate" ($0.35 < \rho \leq 0.67$), "strong" ($0.67 < \rho \leq 0.90$), and "excellent" ($\rho > 0.90$). Statistical significance was detected at p < 0.05 for all relevant tests. All free-text entries were analysed qualitatively. The Likert scale for satisfaction levels was quantified by assigning the levels 'Very dissatisfied,' 'Dissatisfied,' 'Neither satisfied nor dissatisfied,' 'Satisfied,' and 'Very satisfied' a weighting of $-2, -1, 0, +1$, and $+2$, respectively, enabling the calculation of a weighted average.

III. RESULTS
A. STUDY POPULATION DEMOGRAPHICS
The summary of participant characteristics is provided in Table 1. The subjects belonged predominantly to rural and/or lower socioeconomic backgrounds. This study had seven male (46.7%) and eight female subjects (53.3%). Their mean ± SD age as of the date of final data capture of the trial is 13.5 ± 2.1 years (Range: 9.6–17.6 years). The subjects' mean ± SD height was 154.6 ± 13.7 cm (Range: 132.1–175.5 cm). Their mean ± SD weight was 44.0 ± 12.6 kg (Range: 25.6–70.0 kg). The participants' mean ± SD Body Mass Index (BMI) was 18.2 ± 3.9 kg/m^2 (Range: 14.1–26.6 kg/m^2).

There were four congenital (26.7%) and 11 acquired (73.3%) cases due to trauma caused by road traffic accidents, electric shock, etc. We found eight above-elbow (53.3%) and seven below-elbow (46.7%) cases of UL difference. Six (40%) and nine (60%) subjects had unilateral UL differences on the right and left sides, respectively; no bilateral cases were found. All congenital cases (n = 4) had their left side missing. All acquired cases were right-handed before amputation (n = 11), as indicated by a score of ≥ 9 of 10 on the preferred handedness inventory [56]. Further, transfer of dominance was noticed for all acquired cases who lost their dominant side (n = 6).

Among the 15 subjects, four currently use a prosthesis on a daily or occasional basis, two have entirely abandoned their device, and nine have no prior experience using a prosthesis. The two subjects who stopped using their device had a passive (Subject 'P01') and a BP device (Subject 'P06') fitted in the past. Among the current users, the three patients using a passive device have an above-elbow level of UL difference, and the one patient using a BP device has a below-elbow level of UL difference. Of those equipped with a prosthesis (n = 6), four subjects were fitted with a passive device, and two were fitted with a BP prosthesis. All six patients were fitted with a prosthesis that had an anthropomorphic TD. This study reports no instances of myoelectric devices, hook-shaped TDs, activity-specific TDs or ownership of multiple devices and/or TDs.

B. PEAK EXPIRATORY FLOW RATE AND GRIP STRENGTH
The mean ± SD PEFR value of 312.7 ± 97.2 L/min (Range: 150–500 L/min) was found for all subjects. For boys, the mean ± SD PEFR value was 368.6 ± 89.0 L/min (Range: 220–500 L/min). For girls, the mean ± SD PEFR value was 263.8 ± 75.2 L/min (Range: 150–370 L/min).

The mean ± SD grip strength of 20.1 ± 10.2 kg (Range: 2.3–43.0 kg) was observed for all the subjects. The mean ± SD grip strength for boys was 21.6 ± 14.3 kg (Range: 2.3–43.0 kg). For girls, the mean ± SD grip strength was 18.8 ± 3.5 kg (Range: 12.0–22.8 kg).

C. USABILITY STUDY
All subjects successfully performed three trials of device opening and closing with breathing input. Another key motivation was to understand whether target users find breathing input an acceptable modality for powering and controlling a UL prosthesis. All 15 participants and their family members liked the concept of using breathing to power and control a

TABLE 1. Characteristics of patients recruited in the study. Note: 'Hand' in the 'Terminal device type' column denotes an anthropomorphic terminal device. Handedness before upper-limb difference is 'Not applicable (-NA-)' for congenital cases.

Anonymised participant ID	Sex	Age (in Years & months)	Height (in cm)	Weight (in kg)	Upper-limb (UL) difference			User status?	Prosthesis type	Terminal device type	Handedness		Max. grip strength (in kg)	Peak flow rate (in L/min)
					Aetiology	Level	Side				before UL difference	after UL difference		
'P01'	Male	17 Y 7 Mo	175.5	44.2	Traumatic	Above-elbow	Right	Past user	Body-powered	Hand	Right	Left	43.0	500
'P02'	Male	12 Y 10 Mo	162.0	69.9	Congenital	Above-elbow	Left	Current user	Passive	Hand	-NA-	Right	9.1	350
'P03'	Female	11 Y 10 Mo	145.0	33.7	Congenital	Below-elbow	Left	Never used one	-NA-	-NA-	-NA-	Right	22.8	240
'P04'	Female	9 Y 7 Mo	138.0	28.8	Traumatic	Above-elbow	Right	Current user	Passive	Hand	Right	Left	14.8	150
'P05'	Male	15 Y 9 Mo	169.0	45.9	Congenital	Below-elbow	Left	Current user	Body-powered	Hand	-NA-	Right	2.3	420
'P06'	Female	16 Y 8 Mo	165.1	38.6	Traumatic	Above-elbow	Left	Past user	Passive	Hand	Right	Right	22.6	370
'P07'	Female	12 Y 10 Mo	157.5	52.3	Congenital	Below-elbow	Left	Never used one	-NA-	-NA-	-NA-	Right	20	250
'P08'	Female	13 Y 1 Mo	144.8	32.3	Traumatic	Below-elbow	Right	Never used one	-NA-	-NA-	Right	Left	19.2	290
'P09'	Male	15 Y 7 Mo	172.7	70.0	Traumatic	Below-elbow	Left	Never used one	-NA-	-NA-	Right	Right	41.0	450
'P10'	Male	12 Y 9 Mo	144.8	50.7	Traumatic	Above-elbow	Left	Never used one	-NA-	-NA-	Right	Right	15.4	220
'P11'	Male	11 Y 7 Mo	132.1	36.5	Traumatic	Below-elbow	Left	Never used one	-NA-	-NA-	Right	Right	16.8	290
'P12'	Female	14 Y 5 Mo	165.1	45.3	Traumatic	Above-elbow	Left	Current user	Passive	Hand	Right	Right	19.9	350
'P13'	Male	14 Y 1 Mo	162.6	45.0	Traumatic	Above-elbow	Right	Never used one	-NA-	-NA-	Right	Left	23.4	350
'P14'	Female	11 Y 9 Mo	134.6	25.6	Traumatic	Below-elbow	Right	Never used one	-NA-	-NA-	Right	Left	12.0	160
'P15'	Female	12 Y 5 Mo	149.9	40.8	Traumatic	Above-elbow	Right	Never used one	-NA-	-NA-	Right	Left	19.1	300

prosthetic hand. The subjects provided feedback on a Likert scale of 1–5 (1 = 'Very difficult,' 2 = 'Difficult,' 3 = 'Neither easy nor difficult,' 4 = 'Easy,' 5 = 'Very easy.') for the perceived ease of difficulty for each device open or close activity. For the operation difficulty/ease reported by the user, we found the range to be 2–5, and the median value was 5.

No statistically significant correlation coefficients (ρ) were found between the patient's perceived difficulty with device operation and their PEFR and grip strength values. However, we report a strong correlation between the subject's age and PEFR ($p < 0.05$). Further, a strong correlation was found between the subject's height and PEFR value ($p < 0.05$). See Supplementary Figure 3 for relevant scatter plots.

The summary of the open-ended data (researcher-observed and patient-reported) and Likert-scale responses for satisfaction on different aspects of device features are provided as Supplementary Table 1. This supplementary table also includes feedback and design suggestions from study participants and their family members. Moreover, additional trial-related images (Supplementary Figures 4 and 5) and videos (Supplementary Videos 1–4) can be found in the supplemental materials. The researcher-observed information focused on user engagement, ability to open or close the device, e.g., the approximate number of breaths taken for the device operation. All patients expressed that they liked the concept and reported that the experiments and interaction with the device were fun, simple, and seemed like a game. In addition, the family member(s) broadly liked the concept and were happy for their child/ward to use a breathing-powered prosthesis. Besides, current or past device users mentioned liking the breathing-powered device over their passive or BP prosthesis for better comfort and function. All the volunteers said it is easy to learn to operate the breathing-powered device. Seven subjects were happy to use the device without feeling conscious/shy in public or social settings; three subjects said they would feel conscious/shy using a breathing-powered device during social interactions but would be happy to use it regardless. The remaining five subjects said they would feel conscious/shy using a breathing-powered device in a public or social setting but did not explicitly decline the possibility of using it – two of these subjects said they could see using it at home but not in public settings.

The participants and their family members also provided Likert-scale responses on the design attributes of the device's current version. Generally, the subjects were satisfied with most of the device attributes (Figure 3a). However, this figure masks the inter-subject variability in satisfaction levels across the various attributes (Figure 3b). The satisfaction levels of the different participants were very subjective and varied immensely. Finally, the study participant and their family member(s) provided design suggestions, e.g., (i) the need for anthropomorphic TD; (ii) the need for turbine and gearbox mechanism to be concealed; (iii) the need for the device colour and size to match that of the intact hand; (iv) lightweight design; (v) all fingers to be actuated; (vi) requirement of the contralateral arm to be free; (vii) better cosmesis; and (viii) silent operation.
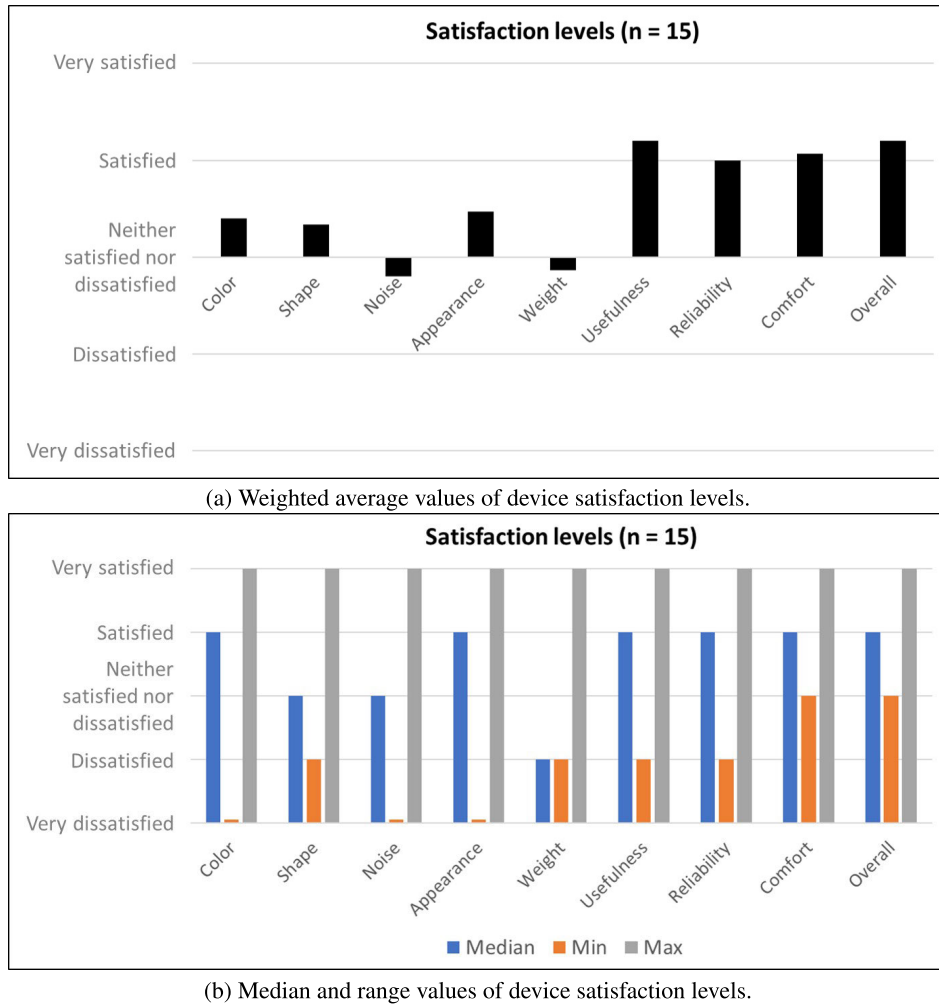
IV. DISCUSSION

A. STUDY POPULATION DEMOGRAPHICS

In contrast to our study, generally high male-to-female ratios have been found—particularly for acquired cases due to trauma—in children and adolescents [1]. Additionally, studies have reported congenital cases to be more frequent than acquired causes in children and adolescents across different contexts [18], [64], [65] than found here. The prevalence of paediatric traumatic amputations was found to be the highest in three regions: South Asia, North Africa and the Middle East, and East Asia [3], suggesting a need for suitable prosthetic service provision in these regions. We found an almost equal number of above-elbow and below-elbow cases, although the below-elbow level is the most common for adults and children (e.g., [18], [64]). Among those with congenital UL absence, a high female-to-male ratio and left-side bias are observable, similar to earlier studies [11], [64], [66]. As found in our study, change of dominance [67] is typical in acquired cases who lose their dominant side. Typically, for a unilateral UL prosthesis user, it has been widely reported that the device offers only a supplementary role and often ends up acting as the 'non-dominant' side that supports the intact arm in bimanual tasks [22], [67].

Usability research typically requires a small cohort of test subjects for product assessment and highlighting the scope for improvements, e.g., it has been suggested that 80% of usability problems are detected by the first 4–5 subjects who use the device; the most severe usability issues are likely to be identified by the first few subjects [68]. The sampling strategy adopted in our work helps maximise the understanding of wide-ranging usability concerns with the breathing-powered system that a highly heterogeneous—and less prevalent, for those with specific characteristics—UL-deficient population (e.g., novice vs experienced users, male vs female users, past users vs current users vs non-users, above-elbow vs below-elbow levels, unilateral vs bilateral users) might have.

Many subjects are reported to use more than one (type of) prosthesis in affluent economies [69], [70]. In such settings, multiple or identical prostheses may serve the purpose of "backup" for service and breakdowns, whereas different prosthesis types and TDs have distinct functional advantages and may supplement each other. It was argued that successful unilateral UL-different paediatric users might choose multiple prostheses based on function and that frequently the most functional prosthesis selected in the long term is the simplest in design [69]. In the past, a need has been expressed for offering a variety of prosthetic options for unilateral UL-deficient paediatric population to help with activities of daily living [69], [70]. Further, the provision of various prosthetic designs over the children's growing years was also associated with improved prosthetic outcomes [5]. However, our study found no instances of multiple devices and/or TDs, often characteristic of low-income settings.

(a) Weighted average values of device satisfaction levels.

(b) Median and range values of device satisfaction levels.

FIGURE 3. Satisfaction levels across different device attributes (n = 15).

There is immense variability between and within countries regarding how children and adolescents with UL differences are treated, based on different funding, family support, and therapy resources [71]. Due to the complexity and high cost of these prostheses, they are generally not accessible to most children from low-income, uninsured families or developing countries. In low-income settings, there is a tendency not to fit children with prosthetics until adulthood. Most children are fitted with either a passive prosthesis or a BP voluntary closing TD as their first active prosthesis [65], [72], given the durability and affordability of these options. More sophisticated or myoelectric devices are rarely provided to the skeletally immature due to cost and weight constraints. The data presented in our work is consistent with the evidence that BP and passive devices have traditionally dominated the UL prosthetic segment in India [12], [18], [73] and elsewhere [74]. Adults more commonly use BP hooks than children, who tend to select anthropomorphic TDs [14]. Similarly, earlier studies in India [18], [73] found that most users favoured cosmesis and chose an anthropomorphic TD.

Affordability and awareness issues have resulted in non-wearers and past-wearers of prosthetic devices [19], [23], [47]. Besides, a lack of function and comfort were crucial reasons for prosthetic rejection by many non-wearers [75]. Unilateral UL-deficient individuals who have opted not to wear a prosthesis usually consider themselves functional and independent. Nevertheless, choosing not to wear a prosthesis has likely been made with a dearth of information and resources. The study of non-wearers suggests that UL-deficient individuals are unfamiliar with available technology, have not received state-of-the-art care, or have been given information on non-prosthetic options [19]. Notably, Melendez and LeBlanc [19] argue that there is an "invisible" population of people with UL differences who never wore or no longer wear a prosthesis and so are not involved in the usual prosthetic service networks; these people traditionally have not been included as a source of information on desires and needs of those with a UL-difference. Notably, in low-income settings, studies have found that parents of limb-deficient children were not interested in prosthetic management due

to economic reasons or a lack of awareness [47]. Only six out of 15 subjects in our study had been fitted with a device or were using a device currently. The four current users (i.e., three passive and one BP device) used their device daily, although their daily wear and functional use rates varied widely, as noted in a similar study [39]. A lack of appropriately designed prosthetics for the paediatric population in India has been expressed for decades (e.g., [76]). The remaining nine trialled patients did not have a device fitted or were not provided with a device at all. These findings perhaps highlight affordability issues, awareness issues, and/or lack of suitable paediatric prosthetic options in India, as also noted by one of the study authors (SGM; Clinical Prosthetist and Orthotist at Mobility India).

Individuals with unilateral congenital or acquired UL difference usually resort to one-handedness [77], and they have been found to have a higher chance of developing spine abnormalities. Other physical impacts of UL loss or absence on a child may include postural problems, back pain [78], and overuse syndrome from increased workload for the contralateral/intact arm and adopting compensatory movement strategies. Being able to use both ULs through the use of a UL prosthesis promotes symmetrical muscle development and the development of a straight spinal column [77]. These potential ramifications further underscore improving access to affordable and suitable prosthetic options for the paediatric population in their growing years across different geographical and socioeconomic contexts.

B. PEAK EXPIRATORY FLOW RATE

The PEFR is an effort-dependent parameter emerging from the large airways within about 100–120 ms of the start of the forced expiration, and it remains at its peak for $\sim$10 ms [79]. Unfortunately, there is scant research on understanding the lung function or PEFR of adults and paediatrics with UL differences (e.g., [80]). Product development up to the current version of the breathing-powered device [28] was based on optimisations and virtual prototyping results as well as relevant literature on the non-disabled paediatric population [54], [55]. Therefore, the values gathered in this study help better contextualise a breathing-powered device and define operational requirements for a potential user. The PEFR values reported here can help drive further design optimisations (of the turbine and gearbox). Furthermore, PEFR values can also help inform a patient's suitability to use a breathing-powered device (i.e., understanding the minimum lung function required for someone to be deemed suitable for using the Airbender device); although this warrants a separate dedicated study. If necessary, such patients can be recommended exercises to increase lung function/PEFR capacity and, thereby, suitability for a breathing-powered prosthesis. It will also be worthwhile to see how the user's lung function changes with time after using Airbender. Notably, due to the requirement of breathing input for device actuation, our proposed prosthesis is contraindicated for those with a

history of breathing difficulties, e.g., asthma, chronic cough, pneumonia, and other lung diseases.

PEFR depends mainly on the strength of the respiratory muscles apart from the age, gender, height, and weight of the subjects. Typical PEFR values in children have been found to correlate best with height; with increasing age, larger differences occur between the sexes [81], [82]. We found a strong correlation between the subject's age and PEFR value ($p < 0.05$). Also, a strong correlation was found between the subject's height and PEFR ($p < 0.05$). Shaperman et al. [13], [83] showed that children with a congenital UL deficiency had lower strength in their deficient and their sound arm than non-disabled children ($\sim$1.5–2 times lower). Therefore, our breathing-powered device can offer a new option for people with less muscle force (e.g., children, older people, and those with a higher level of UL loss or absence) who might be unable to operate traditional BP prostheses. Low socioeconomic status is one of the factors that has been linked to adversely affecting PEFR [84]. Various environmental factors also influence PEFR during childhood, e.g., level of physical activity [84]. Furthermore, it was found that both age and BMI independently affect the PEFR in Indian populations, but age's effect on PEFR is much more significant than BMI [85]. It will be interesting to compare the BMI of UL-deficient children with that of typically-developing children [85] and its relation with PEFR. The PEFR values reported in our study (involving subjects predominantly from rural and/or lower socioeconomic backgrounds) broadly lie within the normative range reported in previous studies of the non-disabled paediatric population in India, albeit with some exceptions [54], [55].

C. GRIP STRENGTH

Some evidence shows that grip strength tends to reflect an individual's overall strength [86]. Besides, grip strength also informs regarding muscle mass, physical function, and health status [86]. Therefore, it would be valuable to explore grip strength values for the UL-deficient population as this could have implications for prosthetic prescription and patient suitability for a particular device, e.g., a traditional BP prosthesis. The grip strength values reported in our study broadly lie within the reference values reported for non-disabled children and adolescents from India and elsewhere [87], [88]. It will be compelling to explore the difference in grip strength between prosthetic users and non-users. Non-users are likely to have a higher grip strength on the intact side since more infrequent usage (if at all) of prosthetic arms might lead to a higher reliance on the intact hand. Therefore, comparing the grip strength of UL-deficient individuals to age-matched normative values longitudinally might be a novel way of understanding device use and wear rates as well as prosthetic outcomes in a real-world scenario.

D. USABILITY STUDY

Our usability trials demonstrate the feasibility of UL-deficient children and adolescents using their respiratory system to

power and control the proposed breathing-powered prosthetic system. Notably, operating this device did not require meaningful training time. With basic instructions, the users could directly operate the device due to the comprehensive responsiveness to a simple, intuitive, and controllable input. Reducing or even (almost) eliminating training times will positively influence user acceptance rates and provide a worthy directionality for what can be achieved with novel prosthetic designs. It is argued [33] that ''any prosthesis has to be usable very quickly, even if the true refined control takes a little longer; further, a simple hand and skilful guidance can be more effective''.

The Likert-scale responses for the perceived difficulty of operation indicate the users could actuate the breathing-powered device easily. In terms of the association between PEFR and perceived difficulty of operation, the values indicate the lack of range among user responses. Further, the users liked the concept and found our device generally easy to use. There is a lack of correlation between perceived difficulty and PEFR or grip strength values; it possibly indicates that the (younger) subjects are happy enough to use the device even if they have lower PEFR values. The range of (whole and/or partial) breaths the volunteers took to open or close the device was 1–7. This observation could be attributed to an individual's PEFR capacities (usually correlated with one's height, age, gender, etc.) or personal preferences, wherein some subjects might prefer deep/long breaths and others might adopt successive short/partial breaths for the device operation.

The eight children and adolescents who said they would feel conscious/shy using a breathing-powered device during social interactions comprised either female subjects and/or male subjects above the age of 15 years. In earlier studies, women have commented on their frustration when trying to find appropriately-gendered prostheses [15]. Adolescent subjects have been found to prefer myoelectric prosthesis with an anthropomorphic TD over the conventional BP limbs for better appearance [89]. Several paediatric studies have found a marked decrease in prosthesis wear with age [5], [64], [90], which could be linked to a shift in functional needs, from motor skills necessary for play and exploration, to cognitive skills exacting less extensive hand use [90]. In addition, Vasluian et al. [34] found that for UL-deficient children and adolescents, prostheses appeared particularly important for social integration but much less so for functionality.

At this stage, participants identified several device characteristics that they would like to see improved: colour, shape, noise, appearance, and weight, as also found elsewhere [39]. In addition, participants and their parents provided feedback on the design and suggestions for improvement. These design suggestions and satisfaction levels help prepare the scope for improvement for the breathing-powered device. Our findings agree with previous work [16], [75] that UL prostheses for children and adolescents need to be lighter, more comfortable, more practical, and more attractive. Furthermore, the older and/or female subjects who stated that they would feel conscious/shy using a breathing-powered prosthesis in public or social settings help us understand the target segment that might be more receptive to the novel device. The participants sought an appropriately-sized device that matched their skin colour and was life-like. The Tesla turbine is situated exterior on the dorsal side and requires miniaturisation – subjects requested the 'motor' (i.e., the Tesla turbine) to be hidden. The future version will aim to integrate the turbine into the palm of the TD. Some subjects were dissatisfied with the noise made during turbine spinning and gearbox actuation; however, others liked this aspect as they found it provided feedback about the device's operational status. There is scope for improving device appearance, which can be addressed with design changes (via turbine and transmission miniaturisation) and offering colour options and TD sizes matched to the intact hand. The subjects were dissatisfied with the weight. We intend to miniaturise the sub-systems and conceal them within the palm cavity, thereby improving cosmesis and reducing the weight substantially. The current TD prototype (i.e., the full system including the Tesla turbine, gearbox, and 3D-printed hand) weighs 429 grams, with the wrist adaptor weighing an additional 137 grams. The users found that operating the device with breathing input on a short-term basis in a lab setting was comfortable. This, however, does not cover the comfort aspects when the user would don the device via their socket and during long-term/prolonged use, which merits a dedicated study in the future. Satisfaction levels were high for usefulness, reliability, and comfort. Most of these favourable responses are reflected in the overall satisfaction score.

After completing the standard trial procedure, some subjects were selected randomly and asked to try grasping small (3D-printed) objects already placed on the table with the TD's proximal part held by their intact hand (see supplemental videos). All the subjects could easily open or close the device, but most of them could not grasp the object (which necessitated a 'tip grip' or 'cylindrical grip'). It was noticed that the subjects could not plan the grasp aperture indicating the need for training and acclimatisation. More importantly, this could also be partially because the TD was held in their contralateral hand and not attached to their socket. Finally, after the trial completion (for two subjects) at the end of the day, the study team noticed water collection in the Tesla turbine due to condensation of moisture-laden breaths. The turbine was opened and cleaned with disinfectant and allowed to dry overnight to address this issue.

We showcase the value of involving children and parents while developing novel prosthetic technology. The study participants engaged fully and shared unique insights, which are challenging to capture solely with literature review and other conventional techniques. UL-deficient children and adolescents were enabled to express their views on matters that affect them, allowing them to exert more control and recognising them as equally able to impart insightful knowledge and experience [39]. Participants also described having fun while testing the Airbender prosthesis and found it game-like, which supports our understanding of play as an essential

requirement for the paediatric population [40], [91]. Play is also recognised as a central occupation of childhood, and integral to children's development [92].

The findings and responses captured through this descriptive usability testing will help drive the following stages of device development. The next steps would consist of clinically validating the device (attached to the patient's socket, allowing donning and doffing) by selecting a set of (subjective and objective) outcome measures. The function can be tested by exploring the accuracy of the patient's control of a TD, dexterity, grasp, and speed. Due consideration will be provided to have cross-sectional and longitudinal time perspectives for different stages of future trials. This study would also open up opportunities for dedicated workshops for engagement with different stakeholders (i.e., UL-deficient children and adolescents across different age groups, parents, service providers, etc.) to explore the various design attributes to develop the scope for device improvement and to understand the context of use in a more nuanced manner [36].

V. STUDY LIMITATIONS

The use of purposeful and/or convenience sampling, rather than a random selection of subjects from a representative group, could have introduced bias by selecting subjects who may not be fully representative of the broader population. Due to the small sample size (n = 15), responses and (PEFR and grip strength) measurements of all subjects have been combined; justifiably, these generalisations were carried out as the total number of patients when classified into different categories (such as wearers vs non-wearers, age groups, height, sex, etc.) would have led to very small numbers in each of the categories disallowing any meaningful comparisons. Even though the authors intended to include participants aged 3–17, the age range of participants we could finally recruit for the study is 9.6–17.6 years. Hence, our study lacks representation and views of younger children and toddlers with UL difference and their parents [6], [13]. Besides, the participants were predominantly from rural and/or low-resource settings. It will be beneficial to undertake a similar (comparative) study in an HIC setting and include children from a younger age group.

An unequal proportion of prosthesis (current or past) wearers and non-wearers may have introduced some bias into our findings since the experience of current or past prosthesis use might help a subject better articulate and assess our proposed device with a 'comparative lens.' Besides, the TD was placed on the table and not attached to the user's socket, which might influence some aspects of satisfaction levels. The user-reported responses are specific to the current stage of the device prototype, which is self-classified at a *Technology Readiness Level (TRL) 4 or 5*, as defined by the European Commission [93] (i.e., *TRL 4* – 'Technology validated in lab'; *TRL 5* – 'Technology validated in relevant environment [industrially relevant environment in the case of key enabling technologies]'). The user feedback will be crucial in driving design changes to realise the next device iterations

and TRL milestones (eventually realising *TRL 9* – 'Actual system proven in operational environment [competitive manufacturing in the case of key enabling technologies]'). One of the main limitations of the current device is the lack of optimisation in extracting power from the Tesla turbine. While careful consideration was taken in the turbine's design to optimise its performance, there is still considerable room for improvement (to make the device more anthropomorphic, less noisy, less bulky, cosmetic-pleasing, etc.).

VI. RECOMMENDATIONS FOR FUTURE WORK

Our previous study [28] has highlighted the potential product development roadmap for the breathing-powered prosthesis. Hence, apart from further device development and associated clinical trials—and based on our experience and findings from the current usability study—our novel device warrants numerous avenues for exploration and scrutiny in the short term to ready the device for seeking requisite regulatory approvals, design for scale, and market launch. First, it would be helpful to understand the type of feedback the breathing-powered prosthesis offers to the user (e.g., visual, auditory) and to explore avenues to include suitable feedback mechanisms. Second, the effect of the ambient temperature and humidity on water collection in the Tesla Turbine after a brief period of device operation should be investigated, which could help implement ways to make the device use more hygienic and user-friendly. Third, the link between the level of UL difference and pulmonary function is yet to be well understood. Hence, it will be helpful to know if a decrease in skeletal muscles on the UL-different side also causes loss of respiratory muscle mass and strength, thus leading to impaired/reduced pulmonary function. Besides, little is known about the association between hand grip strength and pulmonary function in the UL-different population. Fourth, a breathing tube/mouthpiece positioning system, bi-directional turbine input system, as well as bespoke device fitting and training regime (for pre- and post-prosthetic fitment aspects, e.g., patient suitability) specific to a child-sized Airbender device needs to be developed. Fifth, our study predominantly considers the below-elbow level of UL differences; however, the device would also appeal to those with more proximal levels of UL loss or absence. The level of UL differences is not directly related to achieving device functionality for the breathing-powered prosthesis, which is an advantage of our device. It is acknowledged that people with different levels of UL differences will have different needs, which need to be covered in a future study concerning our device. Finally, the eventual aim for this "reverse innovation" [94], [95] would be to be first deployed in LMICs, before exploring adoption in HICs and other contexts.

VII. CONCLUSION

This is the first clinical usability study demonstrating the real-world applicability of a breathing-powered UL prosthesis. Further, the demonstration with 15 paediatric volunteers shows the potential functionality of the proposed concept.

This device provides a step-change in how BP prostheses have been designed and offers new possibilities to those with a UL difference. It is among the first genuinely new design approach for the power and control of BP prosthetics since the emergence of a cable-driven system over two centuries ago. In addition, this is one of the few studies dealing with usability testing of paediatric UL prostheses in an LMIC setting. We report that UL-deficient children and adolescents can easily open and close the novel TD with breathing input. Furthermore, the subjects and parents have expressed interest in using the proposed prosthetic device. This novel way of powering and controlling the device allows it to compete with the traditional (Bowden) cable-driven BP devices while simultaneously overcoming several limitations of a cable-driven approach.

AUTHOR CONTRIBUTIONS

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CONFLICTS OF INTERESTS

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