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Design Of a Novel Low-Cost 3D-Printed Respiratory Muscle Trainer for Post-Covid Rehabilitation for LMIC

Knulst AJ[12*], Adhikari R[1], Kandel D[1], Riggsbee J[1], Riggsbee SO[1], Dankelman J[2]

[1] INF Green Pastures Hospital and Rehabilitation Center, Pokhara, Nepal
[2] Department of Biomechanical Engineering, Delft University of Technology, Delft, The Netherlands

[*] Corresponding author: Arjan J Knulst (email: a.j.knulst@tudelft.nl)

Abstract

Respiratory muscle trainers (RMTs) are proven devices useful in improving the condition of patients after breathing-related conditions like COVID-19 or chronic obstructive pulmonary disease (COPD). These RMT devices are neither broadly available nor affordable in most low- and middle-income countries (LMIC). Therefore, the aim of the study was to design a low cost RMT. Requirements were formulated based on consultations with clinical staff. A 3D printed design was engineered and three prototypes were produced for evaluation. The most important requirement was to have a calibrated, adjustable expiratory pressure range of 0 to 80 cmH_2O in 10 cmH_2O increments. Three RMT devices were produced using a 3D printer in Nepal, and successfully assembled and tested on functionality. Material cost of the final design was USD 1.30 per device. Two different institutes were able to successfully print the model after minor printer-specific adaptations. The resulting design was made available online.This study showed that it is possible to design an effective, affordable RMT device using only a 3D printer, PETG filament, and a readily available spring. It allows for easy production in LMIC hospitals. Future research is required to further validate the clinical effectiveness of the novel device.

Keywords; *Respiratory muscle training, 3D printing, Low-cost medical devices, LMIC Pulmonary rehabilitation, Open-source hardware, Expiratory pressure, COVID-19 recovery.*

editor@best-lmic.org, www.best-lmic.org, Post Office BOX 00800-13975, Westlands, Nairobi, Kenya.

1. Introduction

Respiratory Muscle Trainer (RMT) devices are proven to be useful in improving the health of patients that have breathing-related conditions like COVID-19 infections, chronic obstructive pulmonary disease (COPD), post-stroke, or even voice and speech problems.[1–11] Various approaches exist, categorized into two groups: resistance-based and threshold-based devices.

For resistance-based training, spirometers are often used, where a patient's airflow keeps a ball afloat. For threshold-based devices, a valve opens to let air pass at a predefined pressure. A threshold-based RMT device is a calibrated valve that opens at a set pressure during expiration. These devices are similar to positive end-expiratory pressure valves on ventilators or some artificial manual breathing unit bags. Inside a threshold-based RMT device is a pre-loaded spring whose pre-load can be adjusted to obtain different pressure set-points. Our project focuses on threshold-based devices.

Among threshold-based devices are expiratory RMT devices and inspiratory devices. An Expiratory RMT device keeps a positive expiratory pressure during and at the end of expiration, thereby preventing alveoli from collapsing and training the expiratory muscles. An inspiratory RMT device keeps a negative inspiratory pressure during inspiration, thereby training the inspiratory muscles.

Required pressures can be created by breathing into a device that only opens at a certain set pressure. Pressure ranges of commercial devices vary between 30 and 100 cmH_2O expiratory or inspiratory pressure. During the course of treatment this pressure is gradually increased as the patient's condition improves.

COVID-19 infections brought many patients in LMICs that could benefit from using an RMT device to improve their physical condition and thus their quality of life. However, these RMT devices are not readily available in LMIC countries like Nepal. They are too expensive for the LMICs (approximately USD 50-75, excluding import tax and transport), where patients would have to purchase a device out-of-pocket. 17% of people in Nepal is living below the poverty line [12] and would not be able to afford such a device.

Therefore, the goal of this study is to design a low-cost, low-resource RMT device that can effectively create expiratory and inspiratory pressures to providing RMT training in Nepal. This article describes the design of such RMT device and provides the results of an initial evaluation.

2. Development of the RMT Prototype

The clinical requirements for the RMT device were obtained through semi-structured interviews with rehabilitation specialists and speech therapists in the hospital. These clinical requirements were translated into technical requirements. Design concepts were made based on these requirements and one design was selected and further detailed. This device was then prototyped and functionally tested. For sustainability in a low resource setting, the design needed to be made from locally available materials and local production means.

Requirements

Clinicians indicated that the RMT device will need:

- To be suitable for both inspiration and expiration use, but expiration use is expected to be the dominant way of use;
- An expiration pressure range at least adjustable from 0 to 40 cmH_2O (0 to

3,923 Pa), and preferably to 80 cmH_2O that can be calibrated within +/- 5 cmH_2O;

- A calibrated pressure setting, with at least 10 cmH_2O increments indication;
- lightweight, portable, and usable in different patient postures, weighting max 100 grams, and maximum dimension in any direction 15cm;
- material costs as low as possible, preferably less than USD 5.

Conceptual Design

The chosen conceptual design (Figure 1) has a pressure control valve. It consists of a spring that operates a valve plunger that seals on a valve seat. The preload of the spring can be changed, and as a result the pressure at which the valve plunger opens can be controlled. The body was designed such that it can be 3D printed using a food safe plastic. The device has two outlets on the body, one below the valve seat for expiration use, and one above the valve seat for inspiration use. The 3D design was done in SolidWorks 2023.

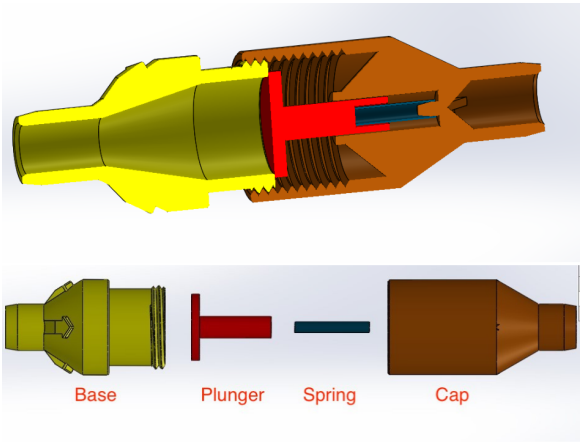

Figure 1. *Top panel: Cross-section of RMT device. Valve body (yellow), valve plunger (red), spring (dark blue), cap (brown). Left port can be used for expiration training, right port for inspiration training. By rotating the valve body with respect to the valve cap the preset threshold pressure changes. Bottom panel: Exploded view of RMT device with labeled parts.* [13]

Detailed Design

The spring is the basis of the design; all dimensions result from the spring selected. In Nepal springs cannot be ordered to specification; therefore, a spring needs to be found in the local market. A reliable and well-available source of springs are springs of pens. Various pen springs were evaluated on straightness, constant pitch and constant dimensions and compressible length. The selected spring was measured in more detail to obtain the spring characteristics to base the design on. A kitchen weighing scale (DM.3, range 0-600g, resolution 0.01g) and a digital caliper (INC-CO HDC01150) were used to determine the spring stiffness (k) by measuring the relation between compression force and length. The characteristics of the spring are provided in Table 1.

Table 1. *Measured spring properties*

Characteristic	Symbol	Value
Inner diameter [mm]	ID	3.30
Outer diameter [mm]	OD	4.15
Uncompressed length [mm]	L	28.11
Compressed length [mm]	L_c	13.11
Compression range [mm]	dL	15.00
Pitch [mm]	p	1.00
Wire diameter [mm]	d	0.33
Stiffness [N/mm]	k	0.2548

The valve orifice dimensions and valve plunger travel length followed from the measured spring characteristics. First, the maximum spring force (at maximum compression) was determined:

$$F_{max} = k \cdot dL = 0.2548 \times 15.00 = 3.82\,\mathrm{N} \quad (1)$$

Next, the corresponding orifice area and orifice diameter to obtain our target

maximum pressure (80 cmH_2O or 7845 Pa) at full compression of the spring were calculated:

$$A_{max} = \frac{F_{max}}{P_{max}} = \frac{3.82\ \text{N}}{7845\ \text{Pa}} = 4.87 \times 10^{-4}\ \text{m}^2 = 487.1\ \text{mm}^2 \quad (2)$$

$$D_{max} = \sqrt{\frac{4A_{max}}{\pi}} = 24.90\ \text{mm} \quad (3)$$

The valve body was designed around this orifice and plunger characteristics, taking into account production on the available 3D printer using food safe PETG filament. The valve was designed to have no soft sealing surfaces, but hard plastic to plastic sealing surfaces. Arrows on the device indicate the direction of flow for expiratory use. Total length of the device was 11 cm when fully screwed in. The device could be printed in 4:05h using 37.3 grams of material, resulting in a total material cost of USD 1.30 (NRs 147).

3D Printing

The final design was prepared for printing on a Prusa i3 mk3s printer equipped with a standard 0.4mm nozzle and a smooth polyetherimide (PEI) sheet print bed, using Prusament polyethylene terephthalate glycol (PETG) filament. All parts were positioned on the print bed as indicated in Figure 2 using PrusaSlicer 2.5.1 software. For obtaining smooth valve seat sealing surfaces those parts were positioned with any sealing surface on the smooth print bed. The print layer height was set to 0.20mm, XY separation between object and support material was set to 1mm to improve removal of support material without damaging the threaded outer surface. All other settings were kept default. Support was only enforced on the overhanging material present in the base part (Figure 2).

Figure 3 shows the printed parts of the device. All 3 prototypes were assembled without any difficulties after slight post-processing using a heat gun and fine sand paper. Care was taken not to post-process the valve seat sealing surfaces, as scratches could deteriorate sealing performance.

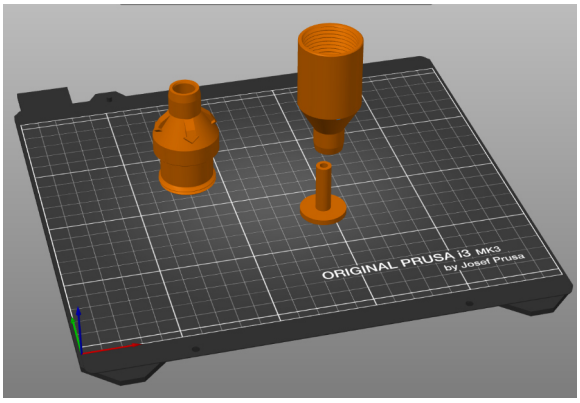

Figure 2. *3D parts positioned on the print bed in the slicer program where support was only enforced on the left part.*

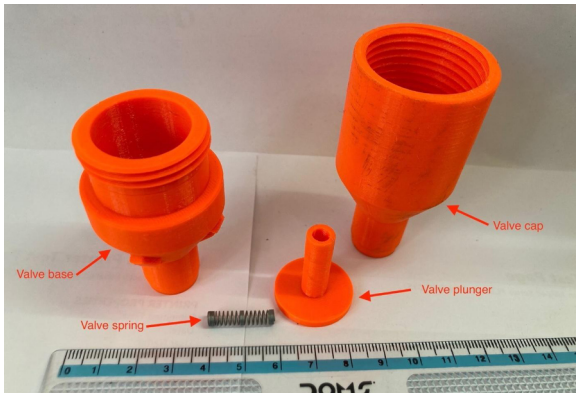

Figure 3. *Labeled parts of the printed RMT device, showing the valve base, valve spring, valve plunger, and valve cap.*

3. Functional Tests and Calibration

The device was tested by connecting both a small air pump (Hailea ACO-318) and pressure measurement device to the RMT prototype using a T-piece. A U-shaped water-filled tube was used as a pressure measurement device as other pressure measurement methods for this range were not available. The difference in height of the water level in both legs of the U measured the pressure in cmH_2O. This method was also used to calibrate the valve for expiratory use. The calibrated pressure setting was marked on the body of the device, ranging from 0 to 80 cmH_2O in increments of 10 cmH_2O. These

calibration markings were to be used by clinicians to have an indication of the pressure that was set as well as to give instructions to the operator of the device. The device was tested on functionality, e.g.: if the valve remained closed until the set pressure, and opened when the set pressure was exceeding across the full intended range.

The design allowed adjustment of the pressure at which the valve opens, and that an expiratory pressure could be controlled between 0 and 80 (+/- 5) cmH_2O. The inspiratory pressure could be influenced as well, from opening at low to at high negative pressure; however, the range was not measured as no source for steady suction was available at the time.

After positive technical test results, a risk assessment was done using a Failure Mode and Effect Analysis (FMEA) that covered risks in the design, production process, and clinical use. The risk was assessed to be very low (highest Risk score < 80), and safe for clinical use in a research setting. The clinical outcome of a case study was documented earlier [13] and showed positive results on patient respiratory performance.

The design was shared with the biomedical department of United Mission to Nepal hospital, Tansen, Nepal, and with the Global Health Informatics Institute, Lilongwe, Malawi. Both locations were tried to 3D print the device on their printer. Some fine-tuning of the 3D model and of printing settings were needed to achieve a working device. Both managed to produce a working device. Finally, the device was made available online for further dissemination.[14]

4. Discussion

A design was developed and fabricated for a low-cost RMT device using 3D printing. The functional test of the RMT device showed that the design is able to perform according to the designed and required expiratory pressure set points across the full range of 0 to 80 cmH_2O.

The earlier reported improvement of the condition of a patient [13] suggests that it is possible to construct a functioning RMT device that seems clinically effective for only USD 1.30 using a 3D printer and a spring. To measure the clinical outcome of using this device a larger and well-designed study needs to be set up. Potentially, this device can improve the lives of many patients suffering from post-COVID ventilation problems, as well as other breathing related diseases like COPD.

Pressure measurement and calibration of the device was done using limited resources, because a suitable pressure sensor was not available. The U-shaped water tube was accurate enough to measure the expiratory pressure with a 0.5 cmH_2O resolution. The calibration markings on the device were relatively thick lines, reducing the accuracy of setting a desired pressure. However, clinicians did not require accurate calibration; the role of calibration marks is mainly for following up on patient's progress and for communicating a correct pressure setting of the device.

A future study could assess the functionality as inspiratory trainer. However, as the effective valve area will be slightly larger when using the valve as an inspiratory device, and as there is no good sealing at the threaded connection between valve body and valve cap, the expiratory pressure calibration will not be valid for inspiratory use. Devices would need to be calibrated either for expiratory or inspiratory use or have a double scale for both inspiratory and expiratory use.

For inspiratory use the device might require more thorough cleaning to ensure no particles will be inhaled during use. Further evaluation on suitability for inspiratory use would be required.

As with any manufacturing method, each method or machine has its own limitations. In case of 3D printing, different printers, slicing software, filament materials, environmental factors like temperature and humidity, and printing settings can affect dimensional accuracy of the parts. These inaccuracies can block parts from fitting together or give too much clearance and reduce smooth movement of parts as a result. In this study the 3 prototypes could be assembled without any issues; the design had sufficient clearance to produce a reliable device repeatedly. When using different printers or different materials the design might need fine-tuning to achieve the same functional performance. This was also demonstrated by the successful printing attempts done by the Global Health Informatics Institute, Lilongwe, Malawi and by the biomedical department of United Mission to Nepal, Tansen, Nepal. The fine-tuning indicates that some engineering knowledge and skill is required to adapt printing settings and even 3D model dimensions. It also means some future design optimization might be beneficial for easier printing.

5. Conclusion

This study showed that it is possible to design and produce a 3D printed RMT device, suitable for expiratory and inspiratory use, with a pressure range of 0 to 80 cmH_2O that costs only USD 1.30 and needs no more resources than a 3D printer, 37.3g of PETG filament and a spring. It allows for easy production in any LMIC hospital that has access to a 3D printer. The design was shared online for further dissemination.[14] After achieving positive results in a case study,[13] now a more thorough clinical study is required to validate the clinical effectiveness of the novel device.

Authors' Contributions

JR and SOR identified the need for a low cost RMT device and provided the clinical requirements for the device specifications. AJK designed the device and performed all verification tests. RA performed production and calibration of the various test series. DK, JR, SOR gave feedback on the design from a doctors' and from a patient's perspective. JD provided the budget for 3D printing capacity at the hospital. AJK wrote the draft manuscript, made the design accessible through printables.com, and oversaw the entire project. All coauthors provided input to the manuscript and have reviewed and approved the final version.

Declaration of Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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