Development of a Reusable Metal 3D-Printed Heat and Moisture Exchanger

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Introduction

Due to a less than optimal humidification performance and adherent use of small heat-and-moisture exchangers (HME), pulmonary complaints (such as coughing and excessive mucus production) remain prominent in patients who had a laryngectomy or patients with a tracheostomy. Although the development of higher performing HMEs without increasing its breathing resistance or size is essential for adherence and clinically relevant, this is challenging to achieve within the design of currently available HMEs.[1,2] Commercially available HMEs often consist of a plastic housing and polymer foam core coated with hygroscopic salt. These HMEs are intended as single-use disposable devices, with patients who had a laryngectomy using an average of 2 HMEs per day[3] because prolonged use and cleaning of these devices adversely affect their function.[4]

If an HME can be made reusable by using a material with a high total heat capacity (ie, the ability to store and release a lot of heat for the evaporation and condensation of water),[1] then this could potentially result in a higher-performing and cost-effective product and reduce the single-use plastic waste. Metals (including metal alloys) are durable and biocompatible, and some have a high heat capacity per volume (ie, the material's specific heat capacity per weight times its weight per volume).[5,6] The recent improvements in metal 3-dimensional (3D) printing now enable the development of a durable HME with a higher heat capacity than the current plastic HMEs. The high accuracy and printed mass density of the current metal 3D-printing technique,[5] together with computer-aided design, make it possible to increase the amount of metal within the available volume (increasing the HME's heat capacity) while enabling accurate optimization of other parameters, such as the HME's breathing resistance, shape, and contact surface. In this study, we designed and assessed 3D-printed all-metal HME prototypes to improve the humidification performance compared with commercially available disposable HMEs.

Methods

HME Prototypes

The designed metal HME prototypes have a monolithic design (Fig. 1): the HME's core and housing (without a speaking valve) are reduced to a single component with

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Key words: 3D printing; additive manufacturing; heat and moisture exchanger; total laryngectomy; pulmonary rehabilitation.

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Mobius 3D Technologies (Velsen-Noord, The Netherlands) has filed a patent application for the additive manufacturing of heat-and-moisture exchangers (P6105500NL). The authors have disclosed no other conflicts of interest.

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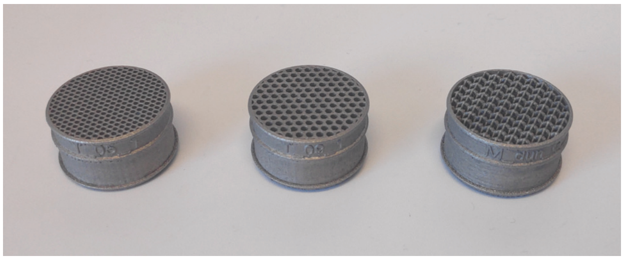

Fig. 1. Metal heat-and-moisture exchanger (HME) prototypes (without a speaking valve) 3D-printed from stainless steel (SS 316 L). Prototypes' exterior dimensions: height 13 mm, diameter 21 mm. From left to right: core design Tubes-1 (wall thickness between flow channels 0.2 ± 0.1 mm, flow channel diameter 1.0 ± 0.1 mm), Tubes-2 (wall thickness between flow channels 0.4 ± 0.1 mm, flow channel diameter 1.4 ± 0.1 mm), and Mesh (mesh wire diameter is 0.45 ± 0.1 mm, distance between mesh wires is 1.22 ± 0.1 mm).

exterior dimensions comparable with commercially available disposable HMEs. In this study, we used 3 different HME core designs: a core with a mesh structure ("Mesh") and 2 cores that consist of small parallel cylindrical flow channels of different sizes ("Tubes-1" and "Tubes-2"). The dimensions of the core designs can be found in Figure 1. The Tubes designs allow a larger amount of material (thus a higher heat capacity) within the available volume. The Mesh geometry is more similar to the foam core of the disposable HMEs. The core designs' dimensions were chosen such that the size and breathing resistance of the HME prototypes (without a speaking valve) were comparable with those of the Provox XtraFlow HME (Atos Medical, Malmö, Sweden [for the purpose of the study, also without its speaking valve]).[2] This HME is one of the most commonly used disposable HMEs and is considered to have an acceptable low breathing resistance by most patients who had a laryngectomy.[2]

The HME prototypes were manufactured from stainless steel (SS 316L) because of its high heat capacity per volume, excellent reliability in 3D-printing the intricate HME designs, and its biocompatibility, but it does have a high density (weight per volume).[5] The HME prototypes were manufactured by Mobius 3D Technologies (Velsen-Noord, The Netherlands) with a Concept Laser M2 Cusing Multi-Laser (GE Additive, Frankfurt, Germany [printing accuracy of ~0.05-0.1 mm]).

Breathing Resistance and Humidification Performance

The institutional review board of the Netherlands Cancer Institute - Antoni van Leeuwenhoek (Amsterdam, The Netherlands) reviewed and approved this study (registration IRBd22-330). The HME's breathing resistance was measured by performing pressure drop measurements with a digital pressure indicator (DPI 705, BHGE Druck, Houston, Texas) at 30, 60, and 90 L/min in correspondence to ISO 9360–2:2001.[7] The humidification performance of the HME prototypes was determined with water exchange measurements. Each of the 3 HME prototypes was measured once within 1 month after production. The 3 prototypes were measured 4 times 1 year after production to assess performance over time. The water exchange data were collected and normalized as described by Leemans et al.[2] In summary, a healthy volunteer (ML, female, 30 years old) breathed through a spirometer setup, with an HME prototype placed on the other side of the spirometer (Flowhead MLT300, AD Instruments, Oxfordshire, United Kingdom).

The volunteer breathed with a fixed rectangular breathing pattern at a tidal volume of 1 L and flow of 0.33 L/s. After initial conditioning of the prototype, a sequence of 15 weight measurements was conducted, alternating at the end of inhalation and exhalation, to determine the prototype's water exchange. The prototype's weight was measured with a microbalance (Sartorius MC210p, Göttingen, Germany). During the measurement sequence, the ambient room humidity and temperature were recorded by a humidity sensor (Testo BV, Almere, The Netherlands). At the start and the end of a measurement sequence, the volunteer's temperature was measured with an electronic ear thermometer (Braun WelchAllyn, Kaz, Marlborough, Massachusetts). The data were normalized to the reference ambient humidity of 5 mg/L and reference humidity at the tracheal side of the HME of 32 mg/L as described by Leemans et al.[2]

Results

An overview of the breathing resistance (pressure drop), humidification performance (water exchange), weight, heat capacity per volume, and contact surface of the stainless steel HME prototypes is shown in Table 1. The breathing resistance of the HME prototypes is in a similar range as the breathing resistance of the Provox XtraFlow HME (without a speaking valve). All core designs have a humidification performance that is higher than the Provox XtraFlow HME. The HME prototypes are much heavier than the disposable HMEs, even though they have similar exterior dimensions, due to the high density of stainless steel. Tubes-2 is much heavier than the Mesh but had a similar performance, breathing resistance, and contact surface. Tubes-1 had the highest performance and contact surface, and the lowest breathing resistance of all 3 core designs but is heavier than the Mesh design. Over time since production, a slight decrease in humidification performance of the HME prototypes was observed (Table 1, the water exchange of the HMEs less than 1 month versus 1 year since production).[2,8,9]

Discussion

This study shows that the 3D-printed stainless steel HME prototypes have a higher humidification performance

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Table 1. Overview of the Breathing Resistance (pressure drop), Normalized Humidification Performance (water exchange), Weight, Heat Capacity per Volume (the material's specific heat capacity times its density) and Approximate Contact Surface

HME			Pressure Drop, cm H_2O			Water Exchange (SD), mg*	Weight, g	Heat Capacity per Volume, J/K/cm³†	Approximate Contact Surface, cm²
HME Type/Material	HME Design/ Configuration	Time Since Production	30 L/min	60 L/min	90 L/min	Tidal volume = 1 L; flow = 0.33 L/s; $AH_{amb\text{-}ref} = 5$ mg/L and $AH_{ts} = 32$ mg/L			
Metal HME prototype: stainless steel	Tubes-1	<1 month; 1 y	0.28	0.72	1.32	9.61 (–); 7.42 (0.51)	19.0	4.0	130
Metal HME prototype: stainless steel	Tubes-2	<1 month; 1 y	0.28	1.02	2.12	7.15 (–); 6.09 (0.55)	22.0	4.0	78
Metal HME prototype: stainless steel	Mesh	<1 month; 1 y	0.40	1.29	2.60	7.39 (–); 6.61 (0.55)	12.0	4.0	84
Disposable HME: polyurethane foam core, coated with hygroscopic salt (calcium chloride)	XF core in a straight cylindrical plastic cassette without a speaking valve‡		0.27‡	0.95‡	2.00‡	4.91 (0.35)‡	2.5§	3.7‖	Unknown

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* The water exchange values that would be observed in patients who had a laryngectomy will be slightly higher than these values measured by a healthy volunteer because the tube of the spirometer set up also acts as an HME (from Reference 2).

† From References 6, 8, 9.

‡ Pressure drop and water exchange measurements of the Provox XtraFlow HME configuration are from Reference 2.

§ The XF core inside its normal commercially available plastic cassette with a speaking valve has a total weight of 1.5 g. The relative heat capacity per volume and the relative weight per volume of aluminum alloy compared with stainless steel are of a factor of 0.61 and 0.34, respectively (from References 6 and 9). By using this information, we can calculate that the highest performing HME prototype Tubes-1 made from aluminum alloy and with the same water exchange performance as the disposable HME would theoretically weigh 7 g ([19 g *0.34]*[4.91 mg/{7.42 mg *0.61}]). This aluminum prototype with lowered performance (*theoretically weighing 7 g*) would lead to a weight reduction of *approximately a factor of three* compared with the stainless steel prototype (*weighing 19 g*).

‖ The XF core has the average heat capacity per volume property of the polyurethane foam core and hygroscopic salt solution that covers the core.

HME = heat-and-moisture exchanger

$AH_{amb\text{-}ref}$ = reference ambient absolute humidity

AH_{ts} = reference absolute humidity at the tracheal side of the HME

XF = Provox XtraFlow HME

SD = standard deviation

AH = absolute humidity

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(water exchange) at a similar acceptable low breathing resistance (pressure drop) compared with a commercially available disposable HME of a similar size. The humidification performance did slightly decrease over time, possibly due to oxidation.[10] The comparison between the different core designs showed that a higher weight and thus higher total heat capacity did not necessarily lead to a higher humidification performance. This indicates that, although heat capacity is an important factor in determining humidification performance,[1] contact surface and geometry also play a role, and humidification optimization requires the consideration of all these factors during the computer-aided design process.

With fixed restricted exterior dimensions of the HME and low breathing resistance, a fixed volume is available for the core material. In disposable HMEs, the available volume is filled suboptimally with an irregularly shaped foam core formed by uncontrolled expansion.[11] Accurate 3D-printing of the polymer material currently used in disposable HMEs for medical devices is not possible. Using 3D-printing technology for metals makes it possible to use the whole available volume accurately and optimally and to increase the amount of material, thereby increasing the HME's humidification performance while controlling the HME's breathing resistance and shape.

Metals have been used in the past in parts of the HME design for patients who are ambulant[12,13] but, as far as we know, these current HME prototypes are the first single-component all-metal HMEs. The prototypes were made from stainless steel (SS 316L), a material that has excellent reliability in 3D-printing and is widely used in cost-effective, short-term implants and filters.[5] Because the humidification performance of these stainless steel HMEs does not rely on a hygroscopic salt coating,[1] it is possible to clean and reuse them multiple times, with minimal loss of function. The repeated cleaning procedure of the metal HME (which can be performed by patients with an off-the-shelf ultrasonic cleaning device and dental tablets) satisfies the AAMI TIR 30 acceptance criteria[14] for reusable medical devices for at least 30 cleaning cycles.

Because patients who have a laryngectomy discard an average of 2 HMEs per day,[3] introducing a cost-effective reusable metal HME, depending on the product lifespan and production costs (outside the scope of this study), could potentially lead to a reduction of single-use plastic waste and health-care costs. The stainless steel prototypes, however, are heavier than the plastic disposable HMEs. By using an aluminum alloy, although less suitable for 3D-printing of small structures, and by sacrificing the performance gain, a weight reduction of a factor of three could be achieved (Table 1, see Table footnote §). Clinical long-term assessment of the reusable metal HME, with the addition of a speaking valve, to assess patient adherence, acceptance, and preference (eg, with regard to the reusable metal HME's weight and cleaning procedure) should be the next step.

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