A Manufacturable Indirect Calorimeter Disposable Mouthpiece with Medical Waste Minimization

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Abstract

The project aims to develop a manufacturable mouthpiece for Perth-based Medical Device Manufacturer, Metabolic Health Solutions (MHS) with considerations to reduce medical waste. ECAL™ developed by MHS measures metabolism with a single-use bacterial and viral mouthpiece filter. MHS currently uses non-biodegradable polypropylene mouthpieces from the UK, with high shipping costs and discontinuation risks. As MHS expands, these single-use mouthpieces will have a greater environmental impact. Project objectives include updating the specification for a custom mouthpiece; producing a manufacturable model; creating a specification for a biodegradable mouthpiece reporting on its feasibility and other waste reduction methods. A literature review on biodegradable materials informed the specifications. Industrial-compostable filtration media options exist, but home-compostable media are not yet feasible. Filter housing can be made from PHA biopolymer - suitable for injection molding and home-compostable. User requirements included unnoticeable resistivity to normal breathing and 99.9% bacterial and viral filtration efficiency. A flow model investigation using Ansys Fluent established optimized dimensions. A prototype was 3D-printed and tested to verify the predicted pressure drop model, which was accurate within 1Pa at 30L/min. Testing with other filter media showed potential for reducing mouthpiece diameter. Future work should verify or increase the detectability threshold of the current filter.

1. Introduction

Metabolic Health Solutions Pty Ltd (MHS) is a medical device start-up company that has developed a clinical indirect calorimeter (ECAL™). Researchers and clinicians use ECAL™ to accurately measure energy metabolism in order to optimise personalised treatments. The device measures metabolic markers in expired breath using a disposable mouthpiece that is connected via tubing to sensors in the ECAL™ device. The current mouthpiece is a single-use filter type, made of polypropylene (PP), and imported from overseas. As MHS is a start-up, the current volume of testing is not sufficient for the disposable mouthpieces to have a significant environmental impact. As MHS grows and ECAL™ becomes a reference diagnostic and management test, mouthpiece volumes will increase significantly, with the plastic waste produced increasingly problematic – contributing to landfill and other environmental concerns. MHS also wants to reduce dependency on the company that manufactures the current mouthpieces. This is because of price insecurity and the risk of product discontinuation. Shipping costs are also an issue as the mouthpieces occupy a large volume for their weight –

contributing extra costs as shipping defaults to pricing by volume. For these reasons, MHS would prefer to control the design and manufacture of the mouthpiece.

1.1 Project Objectives

The specific objectives of the project are as follows:

1. Update the specification and create a custom manufacturable plastic injection-moulded mouthpiece that will replace the current mouthpiece.
2. Create a specification for a biodegradable mouthpiece and conduct a feasibility study to determine whether it can be manufactured in an economically viable way.
3. Explore ways to further reduce the environmental impact of the mouthpiece.

1.2 Plastic Waste in Australia

Plastic waste causes significant environmental concerns due to a lack of biodegradation and the degradation of plastic parts into microplastics which end up in the environment, food, and the human body (O'Farrell et al., 2021). In Australia, the national plastic recycling rate is only 12.4% (from 2019-2020), and out of approximately 350 recycling plants nationally, only 10-20 take plastics that can be commercially composted into non-toxic breakdown products (O'Farrell et al., 2021). Plastics that reached landfill amounted to 85% (Cáceres Ruiz & Zaman, 2022). This suggests that if the mouthpiece is made from a recyclable or commercially compostable material, based on these statistics, a large proportion will not be recycled or decomposed, likely reaching landfill instead.

1.3 Mouthpiece Material

Potential materials for the mouthpiece are constrained by several factors. The material must be rigid for stability and must be stable in long-term storage so that during testing, each breath is sampled accurately. The mouthpiece material must be suitable for injection moulding to keep production cost-effective, and must be non-toxic and hypoallergenic for user safety. Environmental impact, cost-effectiveness, and availability within Australia are also key factors.

The current mouthpiece housing is made from PP which is a thermoplastic, non-biodegradable, injection-moulded polymer commonly used for applications where the part must be rigid, tough, heat-resistant and chemically durable (Farotti & Natalini, 2018). Potential biodegradable polymers are compared in table 1. The most promising option to replace PP was found to be PHA as it is biobased and has multiple enzymes that can degrade it in marine and soil environments (table 1). The filtration media, which is the part that blocks pathogens entering the ECAL™ machine and protects the patient, is also made from spun PP fibres. The bacterial and viral filtration efficiencies of the current mouthpiece is 99.9% according to PB Technical Report 016 conducted by Dr C John Littleton (2021). While there have been studies that have tried to make biodegradable filter media, currently only commercially compostable options exist (Choi et al., 2021; Flachs et al., 2024)

1.4 Mouthpiece Design

Key specifications for the mouthpiece design encompass accurate sampling requirements and client safety. The design should be suitable for injection moulding, increase packability and decrease materials used to minimise costs and maximise efficiency. Airflow through the mouthpiece must be optimised so that the resistivity of the filter does not impede normal breathing. Within a breath cycle, peak inhalation and exhalation values can reach almost as high as 40L/min at rest depending on the size of the person and if they have any respiratory conditions (Bates et al., 2019). The normal threshold for detection of inspiratory breathing resistance is approximately 60 Pa/L/sec (Gottfried et al., 1978; Roberge et al., 2013). As MHS measures normal breathing, any noticeable resistance would affect the results. For the new mouthpiece design, a resistivity of 60 Pa/L/sec at 45L/min should be sufficient to maintain breathability requirements as this considers a margin of error for peak inhalation and exhalation at-rest.

Polymer	Biodegradability – Mechanism of Degradation	Degradation	Melting Point (ºC), Tensile Strength (MPa), Elongation at break (%)	Ref
PP	Nonbiodegradable, recyclable	-	160-176, 26-41, 15-700	1
PHA [P(3HB)]	Wide range of degrading micro-organisms in soil and marine environments	Commercial composting: 1-4 months. Ocean biodegradation: 1-6 months. Weight of injection-moulded P(3HB) 330 ± 25 mg, D=10 mm decreased by 38% in 160 days in seawater.	180, 43, 5	2
PCL	Structural similarity to cutins (plant-based polymers) – degrades via marine bacteria, cutinases and lipases	Commercial composting: 4-6 weeks. Ocean biodegradation: 6 weeks. PCL in soil composting reached 20% carbon mineralisation in 90 days.	56-65, 4-785, 20-1000	3
PLA	Biodiversity of PLA-degrading microbial strains is limited, only commercial composting viable.	Commercial composting: 6-9 weeks. Ocean biodegradation: > 1.5 years. PLA under 50ºC composting conditions reached full degradation in 269 days.	120-170, 53-70,10-100	4

P(3HB), poly(3-hydroxybutanoic acid). 1. (Suzuki et al., 2021) 2. (Rosenboom et al., 2022; Suzuki et al., 2021) 3. (Nevoralová et al., 2020; Rosenboom et al., 2022; Suzuki et al., 2021) 4. (Al Hosni et al., 2019; Mouhoubi et al., 2022; Rosenboom et al., 2022; Suzuki et al., 2021)

Table 1 Comparison of biopolymer properties to PP.

1.5 Computational Fluid Dynamics (CFD) Studies on Respiratory Filters

While CFD has been used to model air flow through electret filters, porous filters in pipes, and the respiratory system under various conditions, there is a gap in available literature on air flow through a bacterial and viral filter in a spirometry or ventilation respiratory filter housing (Bates et al., 2019; Fuyan et al., 2019) . As MHS's respiratory filter requirements are unique, there is not a specific model that optimises pressure drop and filter sizing for this application.

2. Design Approach

2.1 Filter Dimensions CFD Modelling Investigation

To determine minimum mouthpiece filter dimensions to optimise costs and reduce plastic material, Ansys Workbench 2024 R1 (v.24.1) 'Fluent' was used to model flow through simplified filters of varying dimensions using filter media property values obtained from Western Australian manufacturer electret filter media data (SureGuard® 'HyperGuard®' "TEC200GM", *Bird Healthcare*, Australia) data inputs. The effect on pressure drop of varying filter media diameter, filter media enclosure height, expansion height, and flow rate were investigated and an elliptical inlet was subsequently modelled to determine the effects of a mouthpiece inlet. A prototype was then created using optimised shape dimensions with a smaller diameter to validate the model and obtain the effects of other filter media that did not have the data inputs required for modelling. These filters were TECHNOSTAT® '90 PLUS' and '150 PLUS' (*Superior Felt & Filtration,* IL, USA).

2.2 Porous Zone Inputs

Porous zones were used to simulate filter media, requiring at least three points of flow rate and pressure drop data for a particular filter media. The Ansys porous zone model uses inverse permeability, $1/\alpha$ and an inertial resistance factor, C_2 to calculate a momentum source term:

$$S_i = -\left(\frac{\mu}{\alpha} v_i + C_2 \frac{1}{2} \rho |v| v_i\right) \tag{1}$$

Where S_i is the source term for the ith momentum equation, $|v|$ is the magnitude of the velocity, μ is air viscosity and ρ is air density (ANSYS, Inc, 2024). Flow rate and filter data were plotted in Microsoft Excel. A polynomial line of best fit was used to obtain coefficients which could be used to calculate $1/\alpha$ and C_2. The inertial coefficient is calculated from the square term, m_1 and inverse permeability is calculated from the linear term, m_2 from equations 2 and 3:

$$m_1 = C_2 \frac{1}{2} \rho \Delta n \tag{2}$$

$$m_2 = \frac{\mu}{\alpha} \Delta n \tag{3}$$

Where Δn is the thickness of the filter media (ANSYS, Inc, 2024).

2.3 Experimental Design

To test the prototype, the design was 3D printed in PLA fibre with an adaptor for the outlet that fit into a pump connection adaptor and with tappings on either side of the filter for pressure drop sampling. A Bird Healthcare electret filter was cut to size to fit into the prototype. The TECHNOSTAT® '90 PLUS' and '150 PLUS' (*Superior Felt & Filtration,* IL, USA) were also cut to size and tested. Flow rates at 10, 15, 20, 25 and 30L/min were obtained for the Bird Healthcare filter media and 30L/min flow rates were obtained for the '90 PLUS' and '150 PLUS' filter media using a QuickTake30 sample pump (*Active Environmental Solutions*, Australia). Pressure across the filter was measured using a differential pressure instrument (Testo 420DP, *TechRentals*, Australia). A line of best fit through the experimental values was used to estimate the pressure drop for higher flow rates.

3. Results & Discussion

3.1 Experimental Results

The experimental results were reasonably well predicted by the simulation of the prototype using the Bird filter inputs. The Bird simulation predicted a pressure drop of 101.89Pa at 45L/min and the value obtained from the experiment was 101.64Pa – a percentage error of 0.25%. Comparing the predicted pressure drop values obtained from the Bird filter and the experimental results at 30L/min, both overestimated pressure drop but the Bird filter values were a better predictor than the experimental values (experimental prediction = 64.12Pa, Bird prediction = 61.11Pa, actual result = 60.54Pa). This may be due to the error associated with the experimental values as the instruments used for measurement with the Bird filter values may have been more accurate. At 30L/min, the '150 PLUS' filter media in the prototypical model housing had a pressure drop of 76.2Pa (SD = 1.96) but the '90 PLUS' had a pressure drop of 41.56Pa (SD = 2.86). This could suggest that the '90 PLUS' filter may be below the 60 Pa detectability threshold at 45L/min. While manufacturer flow rate and pressure drop data was not able to be provided for the '90 PLUS' filter media, its particle, bacterial and viral filtration efficiency are greater than required and this filter media at $90g/m^2$ is less material than the Bird $200g/m^2$ counterpart which could be another way to reduce plastic content in the filter media.

4. Conclusions & Future Work

Based on experimental results, the model was updated to form a manufacturable model. Compared to MHS's previous custom model and the current PB filter, the proposed design with a lighter filter media (such as the '90 PLUS' filter media) would reduce the diameter and height of the model, cutting down on material volume. As the simulations were a good predictor for the pressure drop in the mouthpiece, the models can be used to test other filters and adjust the design as needed. If the design can be made in PHA with a less dense electret filter, this would significantly reduce non-biodegradable plastic waste contributed by MHS to landfill, reducing environmental impact. Even if PHA is not an economically viable option and the mouthpiece and filter are still made from PP, the plastic waste associated with the filter that MHS uses would be decreased due to the decrease in plastic volume, even if only slightly. Future work that could further inform inputs to the model would include testing the PB and old custom designs experimentally to see if these filters are below the detectability threshold, or to see if the threshold can be raised, allowing for an even smaller mouthpiece diameter. Testing thinner filter media that have acceptable filtration levels could also be considered.

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