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Research paper

# Are surgical masks manufactured from sterilisation wrap safe?

Sam E. Grigg<sup>a,\*</sup>, Andrea Zampiron<sup>d</sup>, Farzan Akbaridoust<sup>d,e</sup>,  
Dileep Chandran<sup>d</sup>, Natasha E. Holmes<sup>b</sup>, Paul D.R. Johnson<sup>b</sup>, Ivan Marusic<sup>d</sup>,  
Daryl Jones<sup>c</sup>

<sup>a</sup> Department of Medicine, Austin Hospital, Victoria, 3084, Australia

<sup>b</sup> Department of Infectious Diseases, Austin Hospital, Victoria, 3084, Australia

<sup>c</sup> Department of Intensive Care, Austin Hospital, Victoria, 3084, Australia

<sup>d</sup> Department of Mechanical Engineering, University of Melbourne, Victoria, 3010, Australia

<sup>e</sup> Department of Mechanical and Aerospace Engineering, Monash University, Victoria, 3800, Australia

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equipment

**Abstract** *Background:* Due to regional shortages some health services have proposed using surgical masks manufactured from sterilisation wrap. However, there has been little assessment of the safety of this practice. Therefore, we developed our own prototypes and evaluated whether they met regulatory standards.

*Methods:* Surgical mask prototypes were manufactured from two thickness grades of commercial sterilisation wrap. Safety was assessed in the context of regulatory standards. As it was not previously reported, we developed and performed differential pressure and synthetic blood penetration resistance experiments in accordance with official methodology.

*Results:* Bacterial filtration efficiency was comparable between sterilisation wrap and commercial surgical masks. Both prototypes met regulatory standards for synthetic blood resistance, whilst only our thinner mask fulfilled acceptable differential pressure ('breathability') thresholds.

*Conclusion:* Acceptable barrier and breathability properties can be achieved with surgical masks produced from sterilisation wrap. Therefore, this may be a reasonable method to supplement stock if required. Unless there are shortages mandating alternatives, health-care workers should always use approved personal protective equipment.

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\* Corresponding author. Austin Health, 145 Studley Rd, Heidelberg, 3084, VIC, Australia. Fax: +61 3 9496 6677.  
E-mail address: [Samuel.grigg@austin.org.au](mailto:Samuel.grigg@austin.org.au) (S.E. Grigg).

### Highlights

- During the COVID-19 pandemic there has been regional shortages in surgical masks.
- Some services have proposed using surgical masks manufactured from sterilisation wrap.
- There has been limited assessment of the safety of this practice.
- We developed prototypes and evaluated whether they met regulatory standards.
- Acceptable barrier and breathability properties were achieved.

## Introduction

The COVID-19 pandemic has placed critical pressure on health services to maintain access to personal protective equipment, in particular surgical masks [1]. The unprecedented crisis has seen regional shortages, which compromise the safety of frontline staff, and risk uncontrolled spread of infection. In response, there has been growing concern from healthcare workers that has seen the launch of campaigns such as *GetMePPE* in the United States, and *properPPE* in the United Kingdom [2,3]. Concerningly, low income countries are particularly affected [4].

Given the risk of ongoing inadequacy in the global supply chain, there is the need for practical and innovative solutions [5]. In this context, some centres have proposed manufacturing surgical masks from sterilisation wrap used to protect surgical instruments as a contingency plan [6]. The rationale for this method is that both products are made from similar non-woven polypropylene fabric formed from layers fused with spunbound meltblown spunbound processing. Commercial reports also show similar bacterial filtration efficiency. Further, this material is routinely stocked at hospitals, likely with decreased need at times of low elective surgical activity.

However, whilst it has been the focus of considerable public interest, there has been limited assessment of the safety of this practice. Therefore, we developed our own surgical mask prototypes from sterilisation wrap and performed tests to evaluate whether they met regulatory standards.

## Methods

### Prototype development

Two surgical mask prototypes were developed from H300 and H500 Halyard One-Step Sterilisation Wrap, which both contain two layers of material [7]. H300 and H500 refers to different grades of sterilisation wrap designed to correlate with tensile strength, and were chosen for practical reasons as they were the most common type stocked at our tertiary hospital. The masks were manufactured by a local textile company. A small metal strip was inserted into the top half of the mask permitting moulding around the nose. Fabric cable ties were stitched onto the sides to permit tying of the mask behind the head (Fig. 1).

## Compliance with standards and testing

We assessed whether surgical mask prototypes complied with official standards. There are different North American (ASTM F2100-19), European (EN 14683:2019) and Australian (AS 4381:2015) regulations that grade surgical masks (Table 1) [8–10]. Further details of the tests incorporated in these standards are described in Table 2.

Specifications and results of testing for commercial Halyard One-Step sterilisation wrap were initially obtained by directly contacting the manufacturer [7]. As results were lacking on two common tests (differential pressure, and synthetic blood resistance), we conducted experiments at the Walter Bassett Aerodynamics Laboratory at the University of Melbourne to evaluate these parameters.

### Differential pressure testing

The differential pressure test was designed in line with BS EN14683:2019 guidelines [9]. Five masks of each prototype were tested. Each mask was cut into six samples with all layers preserved. The samples were installed at the cross-



**Figure 1** Prototype of masks manufactured from sterilisation wrap.

**Table 1** Regulatory standard for surgical masks.

	North America ASTM F2100-19			Europe EN 14683:2019			Australia AS 4381:2015		
	Level 1	Level 2	Level 3	Type 1	Type II	Type IIR	Level 1	Level 2	Level 3
BFE%	≥ 95	≥ 98	≥ 98	≥ 95	≥ 98	≥ 98	≥ 95	≥ 98	≥ 98
PFE%	≥ 95	≥ 98	≥ 98	Not required	Not required	Not required	Not required	Not required	Not required
Fluid resistance	> 80 mmHg	> 120 mmHg	> 160 mmHg	Not required	Not required	> 120 mmHg	> 80 mmHg	> 120 mmHg	> 160 mmHg
Differential pressure (mm H <sub>2</sub> O/cm <sup>2</sup> )	< 5.0	< 6.0	< 6.0	< 40 Pa/cm <sup>2</sup>	< 40 Pa/cm <sup>2</sup>	< 60 Pa/cm <sup>2</sup>	< 4.0	< 5.0	< 5.0
Flammability	Class 1			See European Medical Directive 2007/47/EC			Class 1		

BFE: bacterial filtration efficiency, PFE: particulate filtration efficiency.

section of a circular pipe with a diameter of 25 mm. A flow rate of 8 L/min was established using compressed air. Two rotameters were used to measure flow rates at the inlet and outlet sections of the pipe to ensure no air leaks were present. Differential pressure ( $dP$ ) was measured with static pressure taps on the upstream and downstream side of the mask samples connected to a high accuracy differential pressure transducer (10 Torr 698A MKS Baratron with MKS type 270 signal conditioner). The surgical masks were not preconditioned, however the laboratory environment guaranteed quasi-constant temperature and relative humidity of  $19.5 \pm 0.5$  °C and  $45 \pm 5\%$ , respectively. The mean differential pressure value across all test specimens was calculated and used to determine compliance with standards.

### Synthetic blood penetration resistance testing

The synthetic blood penetration test was developed in accordance with the ASTM F1862 protocol [11]. 25H300 and 29H500 masks were tested. The synthetic blood was prepared by mixing distilled water (0.78 l), Acrysol G111E thickening agent (40.0 g) and red dye (8.0 g). The specific gravity of the resulting mixture was 1.00 (measured with a hydrometer) and the surface tension was 60.5 dyn/cm (measured via the capillary rise method), which satisfied the ASTM F1862 conditions. 2 mL of synthetic blood was spurted through a 1.27 cm long 18-gauge stainless steel cannula. The dispensing system could accurately deliver the flow at velocities of 450, 550 and 635 cm/s, corresponding to pressure values inside the cannula of 80, 120 and 160 mmHg, respectively. The complete masks were installed on a specimen holder 30.5 cm from the cannula outlet. Pleats were stretched when mounting the prototype so that the testing area contained a single layer of the mask. A target plate with a 3/16-inch diameter hole was placed between the cannula and the mask to ensure the fluid stream hit the desired area. Blood penetration was visually assessed within 10 s. The test was considered passed if the blood did not penetrate through to the inner layer. The masks were initially tested at the highest pressure of 160 mmHg, with plans to sequentially downgrade to lower pressures if three or more samples failed. The masks were not preconditioned. During all tests the laboratory had a stable temperature of  $17.5 \pm 0.5$  °C and a relative humidity of  $51 \pm 1\%$ . The Acceptable Quality Level (AQL) of 4.0% mandated in the ASTM F1862 protocol would require that 32 masks be tested and that 29 of the 32 masks pass.

## Results

### Standardised testing

Results of standardised testing on sterilisation wrap and mask prototypes are summarised in Table 3.

Bacterial filtration efficiency and flammability specifications were provided for Halyard One-Step sterilisation wrap by the commercial manufacturer.

Differential pressure results from our own experiment are shown in Fig. 2. The prototype made from the thinner H300 Halyard One-Step wrap met regulations (mean = 4.98

**Table 2** Standardised tests used in surgical mask grading and regulations.

Test	Methods
Bacterial filtration efficiency ( <i>ASTM F2101, EN 14683</i> )	Measures the effectiveness of a mask to filter bacteria. The test is conducted using aerosol droplets containing <i>Staphylococcus aureus</i> as the challenge organism with a mean particle size of $3.0 \pm 0.3 \mu\text{m}$ .
Particulate filtration efficiency <sup>a</sup> ( <i>ASTM F2299</i> )	Evaluates the filtration efficiency of particles $0.1 \mu\text{m}$ in size. The challenge material used consists of latex aerosol spheres in a controlled airflow chamber
Fluid/synthetic blood penetration resistance ( <i>ASTM F1862, ISO22609</i> )	2 mL of synthetic blood is spurted through a small cannula onto the surface of the face mask, and the inside is observed for penetration. It can be evaluated at three different velocities corresponding to a human blood pressure of 80, 120, and 160 mm Hg.
Differential pressure (Delta P) - 'Breathability' ( <i>EN 14683</i> )	Determines the facemask's resistance to airflow. A controlled flow of air is driven through the mask, and the pressure before and after is measured. The difference in pressure is divided by the surface (in $\text{cm}^2$ ) of the sample. A lower breathing resistance indicates a better comfort level for the user. The mean of all tested samples is reported.
Flammability ( <i>16 CFR Part 1610</i> )	Exposes the face mask material to a flame and measures the time required for the flame to proceed up the material a distance of 127 mm (5 inches). Class 1 means the material exhibits normal flammability and is acceptable for use in clothing.

<sup>a</sup> Note the PFE is not considered a measure of *respirator* performance. For masks to be classified as N95 respirators, they must undergo a different filtration test guided by the U.S. National Institute for Occupational Safety and Health (NIOSH).

**Table 3** Standardised testing in sterilisation wrap mask prototypes.

Test	Halyard One-Step Sterilisation Wrap <sup>a</sup>
Bacterial filtration efficiency	<b>H100:</b> 98.9% <b>H200:</b> 99.7% <b>H300:</b> 99.9% <b>H400:</b> 99.9% <b>H500:</b> 99.9%
Particulate filtration efficiency	Not measured in line with ASTM F2299 standards.
Differential pressure	H300 mean: $4.98 \text{ mmHg}/\text{cm}^2$ <sup>b</sup> H500 mean: $7.87 \text{ mmHg}/\text{cm}^2$ <sup>b</sup>
Fluid/Splash resistance	160 mmHg
Flammability	<b>H100–H500:</b> Class 1

<sup>a</sup> H100-H500 refers to different grades designed to correlate with tensile strength.

<sup>b</sup> Experiments performed at University of Melbourne designed to replicate regulatory methodology.

$\text{mmHg}/\text{cm}^2$ ), whilst the thicker H500 prototype did not (mean =  $7.87 \text{ mmHg}/\text{cm}^2$ ).

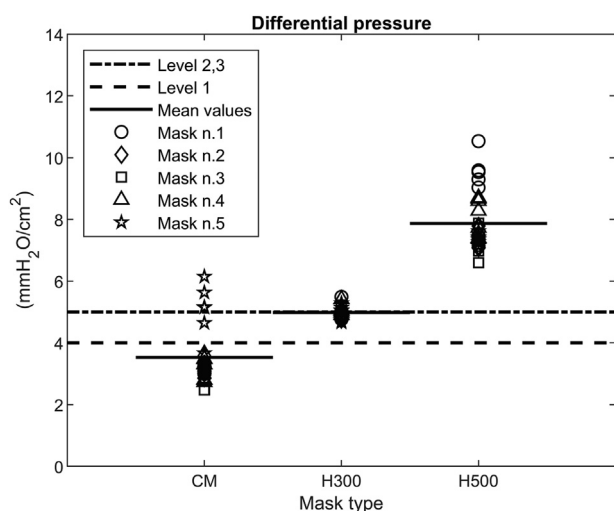
In the synthetic blood penetration test, all prototypes (25 masks from H300 wrap, and 29 from H500 wrap) passed at the highest-pressure threshold of 160 mmHg. Complete raw data is available in the supplementary material.

## Discussion

In the context of uncertain supply chains, the current COVID-19 pandemic risks regional and periodic shortages of surgical masks, especially as some hospitals in areas of wide-spread community transmission adopt a policy of universal masking for all staff. Therefore, to ensure the safety of healthcare workers and patients, contingency plans are required.

In this report, we assessed the feasibility of manufacturing surgical masks from sterilisation wrap and tested the safety of a prototype against the necessary standards. Whilst there is slight variation in North American, European and Australian grading, they all rely on similar protocolised tests. Based on data from the commercial manufacturer Halyard and our own experiments, our prototypes fulfilled requirements for bacterial filtration efficiency, flammability, and synthetic blood penetration resistance. The thinner H300 mask met differential pressure standards, whilst the thicker H500 design did not. The clinical implications of this are uncertain, as the process by which exact regulatory thresholds were determined is not publicly described. Lastly, ASTM F2999 Particulate Filtration Efficiency was not performed or reported elsewhere, although notably this is not required in Australian nor European regulations [12].

Collectively, these results suggest surgical masks produced from sterilisation wrap may offer a similar level of barrier protection to droplets, can be used in clinical scenarios with risk of high velocity fluid exposure, and (for the thinner prototype) have adequate breathability.



**Figure 2** Results of differential pressure testing in two prototypes. Five masks of each prototype were tested (n1–n5) with 6 samples from each. CM = commercial Level 2 grade mask. H300 = masks made from H300 Quick-Step sterilisation wrap. H500 = masks made from H500 Quick-Step sterilisation wrap. Level 1, 2 and 3 correspond to the different thresholds used in Australian surgical mask grading regulations (AS 4381:2015).

However, our findings only pertain to surgical masks, and not N95 respirators, which are certified by the US National Institute for Occupational Safety and Health (NIOSH) [13]. They are designed to offer a higher level of protection against airborne particles, and current World Health Organisation guidelines recommend restricting their use for aerosol generating procedures [14]. When producing masks from sterilisation wrap was first proposed by the University of Florida Department of Anaesthesia as part of their ‘Mask Alternate’ initiative, numerous reports claimed it offered a filtration rate more effective than N95 respirators [6,15]. These statements were falsely extrapolated from bacterial filtration efficiency, which is not used to certify respirators, and therefore cannot be used as justification to manufacture N95 prototypes. In comparison to surgical masks, a different metric of filtration is assessed by NIOSH. Uncharged NaCl aerosol particles with an aerodynamic mass median diameter of 0.3  $\mu\text{m}$  are sent through the filter at a flow rate of 85l/min. *Lammers et al.* subjected Halyard H600 sterilisation wrap to this test and found filtration efficiencies of 64.5% and 78.3% through one and two layers respectively [16]. Three further studies have reported on sub-micron filtration in their prototypes. *Long et al.* detail a filtration efficiency of 96.5% with two layers of H500 wrap [17]. *Meijer et al.* claim a filtration efficiency of 93.8% through three layers of Halyard H300, whilst *Walawalkar et al.* report an efficiency of 92.1% through two layers [18,19]. However, their methods differ considerably to those outlined in NIOSH regulations with variation in particle size, type, flow rates, and particulate counters. This explains the heterogeneity in results and limits direct comparison to N95 specifications. Further, prototypes would need undergo specific fit testing in order to provide appropriate protection. Consequently, the current data

assessing NIOSH standards does not justify the use of sterilisation wrap to make N95 respirator alternatives.

There are certain limitations to our report. We used a specific brand and strength of sterilisation wrap for our prototypes, and therefore results are not necessarily generalisable to masks developed from different commercial wraps, or by a different manufacturer. Further, whilst our methodology for differential pressure and synthetic blood resistance testing was designed to closely replicate ASTM F1862 and BS EN 14683:2019 protocols respectively, we were not able to precondition our specimens, thus resulting in a slightly lower temperature and relative humidity than indicated.

Despite these caveats, we believe this report offers practical guidance for clinicians and policy makers in areas of need. Our surgical mask prototypes provide proof of concept, and our assessment in the context of regulatory standards indicates acceptable barrier and breathability properties can be achieved. Although unlikely to fully meet demand in isolation, these findings suggest manufacturing surgical masks from sterilisation wrap is a reasonable method to supplement stock if required. Further research could investigate the potential re-use of masks by evaluating the relevant tests following re-processing and disinfection. Notably, sterilisation wrap is routinely used in hospitals, and at the time of major outbreaks, elective surgical activity is likely to be low, thereby facilitating increased availability for mask production. Nevertheless, unless there are shortages mandating alternatives, health-care workers should always use approved personal protective equipment.

## Ethics

Ethics approval was not required for this study.

## Authorship statement

**Dr Sam E. Grigg:** conceptualisation, methodology, formal analysis, project administration, writing (original draft).

**Dr Andrea Zampiron:** methodology, investigation, formal analysis, writing (review and editing).

**Dr Farzan Akbaridoust:** methodology, investigation, writing (review and editing).

**Dr Dileep Chandran:** methodology, investigation, writing (review and editing).

**Dr Natasha E. Holmes:** conceptualisation, supervision, writing (review and editing).

**Professor Paul D.R. Johnson:** conceptualisation, supervision, writing (review and editing).

**Professor Ivan Marusic:** methodology, investigation, formal analysis, writing (review and editing), supervision.

**Associate Professor Daryl Jones:** conceptualisation, methodology, supervision, writing (review and editing).

## Conflict of interest

SEG, PDRJ, NEH, AZ, FA, DC, IM and DJ have no conflicts of interest to disclose.

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University of Melbourne Department of Mechanical Engineering provided funding for the ingredients used to prepare the synthetic blood mixture.

## Provenance and peer review

Not commissioned; externally peer reviewed.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.idh.2020.11.001>.

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