

ORIGINAL ARTICLE

Aegis Mark II Study on Powered Air Purifying Innovation Respirator Efficiency Comparison: ASPIRE Study*

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ABSTRACT

Introduction. COVID-19, a respiratory droplet-transmitted disease, has claimed approximately 7 million lives worldwide, partly due to a shortage of Personal Protective Equipment (PPEs) needed for prompt patient care. This study was done to assess if the locally developed Aegis Mark II Powered Air Purifying Respirator (PAPR) can fill this need in terms of usability and filtration efficacy.

Methodology. The battery life was recorded in a controlled environment by running the PAPR continuously on low and high settings. To test usability, participants were allocated to three groups (commercial PAPR, Aegis Mark II, and Aegis Mark I), then participated in a clinical simulation while wearing the PAPR, and answered a questionnaire regarding their satisfaction with the PAPR. Filtration efficacies of the commercial PAPR and Aegis Mark II were compared in a controlled environment (acrylic box) by measuring the number of aerosolized NaCl particles inside the PAPR compared to outside the PAPR.

Results. The Aegis Mark II PAPR's 20,000mAh rechargeable Lithium battery pack lasted for a mean of 11 h and 34 min (SD 16 min), and 8 h and 34 min (SD 38 min), for low and high flow blower settings, respectively. The mean charging time was 2 h and 20 min (SD 19 min) using a Fast Cellphone Charger (2.4 Amps). Participants reported higher satisfaction with the Aegis Mark II compared to the commercial PAPR in terms of factors affecting residency and education use and communication effort (n = 30, overall mean = 7.86 ±1.81) (Table 1), comfort (n = 8.52, overall mean = 8.52 ±1.63), and PAPR care (n = 30, overall mean = 7.76 ±1.75). The mean particle counts inside the hood of the Aegis Mark II PAPR and Commercial PAPR showed that PM2.5 (5.7 and 6.2), and PM10 (6.2 and 6.6) values were within acceptable Ambient Air Quality Standards.

Conclusion. The locally developed Aegis Mark II PAPR displayed a high degree of protection comparable with commercial PAPRs. Its battery life was adequate. It was highly conducive to training and clinical work while being comfortable to use and maintain. It can provide a high degree of protection and alleviate the logistical strain during pandemics and public health emergencies.

Keywords. Aegis Mark II PAPR, filtration efficacy, user comfort and acceptance

INTRODUCTION

The COVID-19 pandemic has caused approximately 7 million reported deaths worldwide.1 The virus is transmitted through respiratory droplets between people in proximity indoors, placing healthcare workers at risk for infection.^{2,3} Personal protective equipment (PPE) were some of the most important means to protect healthcare workers. This massive demand led to a shortage of PPEs.^{4,5}

Respiratory protection programs worldwide have increasingly used reusable devices. These devices include loose-fitting powered air-purifying respirators (PAPRs) and elastomeric half mask respirators. Loose-fitting PAPRs are well-accepted and more comfortable but may influence communication and mobility. They provide a high degree of protection when measured in a simulated workplace.6

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**This study was performed at the Corazon Locsin Montelibano Memorial Regional Hospital (CLMMRH), in cooperation with the Department of Science and Technology and the Western Visayas Health Research and Development Consortium.*

It is important to understand how PAPR use affects employees' physical, psychological, psychomotor, cognitive, and visual abilities. PAPRs enhance compliance and reduce heart, lung, and heat stress by delivering ambient air into the user's breathing zone as opposed to non-powered respirators that require active air intake through a resistive filter.⁷ Loosefitting facepieces do not require fit testing, and improve communication.⁸

Protection factors indicate how safe a device is. Of these, the Assigned Protection Factor (APF) is the expected value when the respirator is used in the prescribed situation by a respiratory protection program. The Program Protection Factor (PPF) is the actual measurement in the workplace or in work simulations. The value of the protection factor for each commercially available filter or device is provided by the manufacturer.⁹⁻¹³

A PAPR is a PPE in which a battery-powered blower passes positive air flow through a filter to a hood. The filters are often P100 and high-efficiency particulate air (HEPA) filters, with efficiencies of more than 99%, and are considered more protective than N95 respirators. These PPEs are used when working closely with COVID-19 patients, especially during high risk aerosol-generating procedures.¹⁴⁻¹⁷ While there are several studies determining the efficiency and comfort of N95 respirators, studies on PAPR's are few.

The CDC has allowed respirator manufacturers to produce equivalent new classes of PAPR to protect the front lines as soon as possible.18 Innovation has driven the use of 3D printed materials and arthroplasty helmets repurposed as PPEs.19 The ultra-portable low-cost improvised powered airpurifying respirator, novel reusable respirators, Bubble-PAPR, and Novel 3D printable powered air purifying respirator were encouraged.²⁰⁻²³

The Aegis Mark II PAPR is an improvement from the Aegis Mark I prototype. The current study assessed the Aegis Mark II PAPR's battery power, user acceptance, user comfort, and filtration efficacy.

MethodOLOGY

This laboratory controlled non-interventional study was conducted at the Corazon Locsin Montelibano Memorial Regional Hospital, a Tertiary Hospital, in Lacson St., Bacolod City, Negros Occidental, Philippines, in cooperation with the Department of Science and Technology Region VI and the Western Visayas Health Research and Development Consortium. Ethics approval was granted by the Western Visayas Research and Development Consortium Research Ethics Committee.

The following parameters were tested: battery life in a controlled environment at high and low blower power settings; mechanical and material construct of hood, blower unit, strength of hose and coupling, non-collapsibility, ability of the hose to resist kinking, and detachable coupling (CFR_42 CFR Part 84);²⁴ filtration efficacy using NaCl particulate $(CVB-APR-STP-0081-508);²⁵$ and users' acceptance, communication and comfort (CVB-APR-STP-0089-508).26

Participants were surgery and anesthesia residents, scrub nurses, and nurse assists who signed the informed consent, and were completely vaccinated. The study excluded those who are non-surgical/cutting and non-anesthesia residents, and ward nurses, and those who refused consent. Participants with pulmonary disease, cardiac disease, uncontrolled hypertension, claustrophobia, and facial abnormalities that prevent good fit were excluded. The study allowed participants to opt out. Participants who experienced mechanical failures were also excluded. Participants were randomly allocated to one of three groups: commercial PAPR (COLEMATE PAPR CM-200), Aegis Mark I, and Aegis Mark II.

Clinical simulation was performed inside a surgical theater with participants wearing their assigned PAPR for at least three hours. They simulated their respective job roles during a regular operation, including but not limited to transferring the patient, operating surgical equipment, postoperative care, etc.

Participants then answered a questionnaire which measured the study variables (clinical performance, communication, comfort and PAPR care) on a 10-point Likert scale (1-2 not satisfied, 3-4 slightly satisfied, 5-6 neutral, 7-8 very satisfied, and 9-10 extremely satisfied). The parameters included were factors affecting (Appendix 1):

- residency training and education (visual field, fogging, inside lighting/less shadowing, and noise)
- clinical performance (movement restrictions, weight distribution, and ambulation)
- communication effort (voice modulation and less muffling of voice)
- comfort (ease of donning, ease of doffing, ease of operation, and ease of monitoring)
- PAPR care (ease of storage, handling, size, durability of material during cleaning, material disassembly, time required to disinfect, time required for drying)

The Aegis Mark II's filtration efficacy was compared against the commercial PAPR's in a controlled environment. An adult size mannequin wearing the PAPR was placed in an acrylic box where a 0.9 NaCl solution was aerosolized (using a nebulizer) into airborne NaCl particles. Two particle counters (Temtop M2000C Air Quality Monitor for PM2.5 PM10 Particles) (one inside the PAPR hood, the other outside the PAPR hood but inside the acrylic box) measured the number of aerosol particles. The following set-ups were tested:

A: (Aegis Mark II) Nebulizer Off/PAPR Off

B: (Commercial PAPR) Nebulizer Off/PAPR Off

- C: (Aegis Mark II) Nebulizer On/PAPR Off
- D: (Commercial PAPR) Nebulizer On/PAPR Off
- E: (Aegis Mark II) Nebulizer On/PAPR On
- F: (Commercial PAPR) Nebulizer On/PAPR On

Efficacy was measured by dividing the number of particles inside the PAPR by those outside the PAPR. The differences between these setups were then analyzed.

Aegis Mark II PAPR System

The Aegis Mark II has two main parts: the blower/power unit and the hood assembly with tubing (Figures 1-3). This system can deliver 245 liters of filtered air per minute, well above the 115-170 lpm basic requirement. The centrifugal fan is housed in an airtight container with intake and output manifolds. The two intake manifolds hold the two filters. The filters are in-

Figure 1. Blower unit.

line bacterial/viral breathing circuit filters used in anesthesia and ventilator machines. These filters were chosen due to the following reasons: these are already certified for medical use with an APF of 25 (as stated by the manufacturer); these can be easily and safely replaced because the filter membranes are enclosed in a plastic that prevent direct contact; and these are supplied by the hospital. The output manifold connects with the hood's tubing. The fan is supplied by a 20,000 mAh lithium-ion battery. The blower unit, battery, and charger are housed in an integrated pack with a total weight of 1.8 kg. The hood assembly is constructed from a double layer of waterproof nylon fabric. The tubing is a corrugated 40 mm plastic tube, with a maximum length of 1100 mm and a diameter of 40 mm.

Statistical analysis was done using Microsoft Excel and SPSS (v.26, IBM). Descriptive statistics (mean and standard deviation) were used to summarize battery power supply, filtration efficacy, and participant questionnaire answers. Kruskall-Wallis H-test was used to determine if there were significant differences in the responses among those who tested the Commercial PAPR, Aegis Mark I, and Aegis Mark II. Furthermore, Mann-Whitney U-Test was used to determine which two groups showed significant differences. Welch's One-way Analysis of Variance was used for comparing filtration efficacy for Aegis Mark II and the commercial type since the homogeneity of variances requirement for the F-test using One-way ANOVA was violated (Levene's tests for all dependent variables returned *p*<0.05). Consequently, the Games-Howell Post Hoc test was used to identify significant differences among the set-ups for each dependent variable.

Figure 2. Surgical hood. Direction of airflow shown by the arrows. **Figure 3.** Hood and blower unit when worn.

Results

The Aegis Mark II PAPR rechargeable lithium battery pack required a mean total charging time of 2 h and 20 min (SD 19 min), while the mean service time was 11 h and 34 min (SD 16 min), and 8 h and 34 min (SD 38 min), in low and high flow blower setting, respectively.

Its materials and construction were durable; the hoses and coupling were non-collapsible, non-kinking, and detachable. A total of 50 participants were recruited. Ten participants were allocated to the commercial PAPR and Aegis Mark I groups, while 30 participants were allocated to the Aegis Mark II group. No participant experienced mechanical failure.

Most of the participants were very satisfied with the Aegis Mark II on factors affecting residency and education use and

communication effort (n = 30, overall mean = 7.86 \pm 1.81) (Table 1), comfort (n = 8.52, overall mean = 8.52 ± 1.63), and PAPR care ($n = 30$, overall mean = 7.76 \pm 1.75) (Table 2). These all differed significantly from satisfaction with the commercial PAPR (Table 3).

The Aegis Mark II PAPR and commercial PAPR both showed significant decreases in the particle counts on PM2.5 and PM10 particle size counts when compared with environmental baseline data where the nebulizer is off (Setup E vs A, and Setup F vs B, respectively). Both PAPRs also show significant differences when compared with setups when the nebulizer is on (Setup E vs C, and Setup F vs D, respectively). The mean particle counts inside the user's breathing zone of both PAPRs (Setup E and F) showed that PM2.5 (5.7 and 6.2), and PM10 (6.2 and 6.6) values were within acceptable Ambient Air Quality Standards (Tables 4 and 5).

Table 2. Comfort and Aegis II PAPR Care

Discussion

The National Institute for Occupational Safety and Health (NIOSH) suggested that the battery must operate for a minimum period of four hours. The airflow level or battery status generally should be checked prior to use, after four hours, and every two hours thereafter. The battery performance depends on the battery capacity, air‐purifying components used, and the environment.²⁷ The average battery life of Aegis Mark II is 11 h and 34 min, (SD 16 min), and 8 h and 34 min, (SD 38 min) in low and high blower settings, respectively. providing an adequate use-time with approximately 2 h and 20 min charging time. The user can also monitor battery levels using the indicators, and extend use by connecting the charger continuously.

The study instructed the use of N95 mask inside the hood to maintain the user's protection during donning and doffing. Using an N95 mask concurrently with a loose-fitting PAPR has multiplicative protection.28 The Program Protection Factor (PPF) provided by a loose-fitting PAPR exceeds its original Assigned Protection Factor (APF) of 25,²⁹ and provides 150%

Table 3. Results of the tests for significant differences in the responses to the questionnaire

* Difference is significant at α = 0.05

more protection than just an N95 mask (APF of 10).¹⁸ This study found that the filtration efficacy of the Aegis Mark II PAPR was comparable with the commercial PAPR, thanks to its two certified anesthesia machine breathing circuit filters with 99.99% filtration efficacy (APF of 25)^{2,6,9} The mean particle counts inside the hood or the user's breathing zone between PAPRs were within acceptable Ambient Air Quality Standards. Both groups showed a significant decrease of particle counts once the PAPR was turned on. In the NIOSH standards, the filtration efficiency of the device is measured by challenging the device with sodium chloride particles having a diameter in the most penetrating particle size range for the filter media made between filters supplied by different manufacturers.30-33 However, in the absence of any other recommendations, it may be considered appropriate to use a breathing system filter that has a filtration efficiency of at least 95% when challenged with sodium chloride particles in the most penetrating particle size range to prevent the air-borne transmission of microbes.34-36

Users of the Aegis Mark II were on average very satisfied with the PAPR's performance in factors affecting user training, user clinical performance, user communication, user comfort, and PAPR care variables, compared to the commercial PAPR. Since design features can affect utilization and acceptance, clinical simulation is a better measure of APF. In addition,

Table 4. PM2.5 Particle Count Assessment on the different testing set-up: differences in particles counts between two set-ups at a time

Set-up 1	Set-up 2					
	A	в		D		
Α		$5.2667*$	$-22.2667*$	$-15.2000*$	7.6000*	7.1000*
В	$-5.2667*$	---	$-27.5333*$	$-20.4667*$	2.3333*	1.8333
C	22.2667*	27.5333*	$- - -$	7.0667	29.8667*	29.3667*
D	15.2000*	20.4667*	-7.0667	---	22.8000*	22.3000*
E	$-7.6000*$	$-2.3333*$	$-29.8667*$	$-22.8000*$	---	-0.5000
F	$-7.1000*$	-1.8333	$-29.3667*$	$-22.3000*$	0.5000	

Notes:

1) Filtration Efficacy Setup:

A: (Aegis Mark II) Nebulizer Off/PAPR Off

B: (Commercial PAPR) Nebulizer Off/PAPR Off

C: (Aegis Mark II) Nebulizer On/PAPR Off

D: (Commercial PAPR) Nebulizer On/PAPR Off

E: (Aegis Mark II) Nebulizer On/PAPR On

F: (Commercial PAPR) Nebulizer On/PAPR On

2) Each entry represents the difference in particle counts between Set-up 1 and Set-up 2; e.g., the difference in particle counts

between A ((Aegis Mark II) Nebulizer Off/PAPR Off) and B ((Commercial PAPR) Nebulizer Off/PAPR Off), that is, A – B = 5.2667 3) Asterisk (*) means that the difference is significant at $α = 0.05$

4) The comparison of the PM2.5 particle counts on the different filtration efficacy set-up showed that there is a significant decrease of the particle counts in the groups $C - E$ (29.8667*) and groups $D - F$ (22.3000*).

Table 5. PM10 Particle Count Assessment on the different testing set-up: differences in particles counts between two set-ups at a time

Notes:

1) Filtration Efficacy Set-up:

A: (Aegis Mark II) Nebulizer Off/PAPR Off

B: (Commercial PAPR) Nebulizer Off/PAPR Off

C: (Aegis Mark II) Nebulizer On/PAPR Off

D: (Commercial PAPR) Nebulizer On/PAPR Off

E: (Aegis Mark II) Nebulizer On/PAPR On

F: (Commercial PAPR) Nebulizer On/PAPR On

2) Each entry represents the difference in particle counts between Set-up 1 and Set-up 2; e.g., the difference in particle counts between A ((Aegis Mark II) Nebulizer Off/PAPR Off) and B ((Commercial PAPR) Nebulizer Off/PAPR Off), that is, A – B = 8.1333

3) Asterisk (*) means that the difference is significant at α = 0.05

4) The comparison of the particle counts on the PM10 different filtration efficacy set-up showed that there is a significant decrease of the particle counts in the groups $C - E$, (48.4333*) and groups $D - F$, (37.6667*).

users are diverse and have differing respiratory demands.⁸ The Aegis Mark II's filters, durability, and long battery life offered reliability and inspired confidence among the users. The visual field, clinical performance, communication, and comfort were on par with the published literature.^{28,37,38} In contrast, N95 respirators resist air intake and retain heat and moisture, causing heat stress; these factors can reduce focus on the critical tasks. The adequate and cooling air flow rate, wide visual field, and clear communication helps the user perform clinical duties.39-44 PAPRs have become indispensable during infectious disease outbreaks. $40,45-48$

Conclusion

The locally developed Aegis Mark II PAPR displayed a high degree of protection comparable with commercial PAPRs by using 99.99% filtration efficacy bacterial and viral filters. It is highly conducive to training and clinical work while being comfortable to use and maintain. Materials are more durable and can withstand repeated use and disinfection procedures. The high level of user satisfaction and acceptance can lead to a higher user's compliance. The Aegis Mark II may prevent the spread of infection to healthcare workers, reduce physiologic stress, and reduce the healthcare sector's financial burden.

Statement of Authorship

All authors certified fulfillment of ICMJE authorship criteria.

Authors Disclosure

The authors declared no conflict of interest.

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Appendix

Questionnaire Form

Questionnaire: Likert scale 1-10 (1-2- not satisfied, 3-4 slightly satisfied, 5-6 neutral, 7-8 very satisfied, 9-10 extremely satisfied).

Check box according to your response.

