Validation of Automatic CPAP Leak Algorithm*

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Abstract—**Obstructive Sleep Apnoea (OSA) is a prevalent disease. Reliable estimation of respiratory parameters by devices used to treat OSA is important for therapy initiation and maintenance. This is achieved by estimating patient flow in the presence of inadvertent leak from the total flow measured by the device. A method of validating the patient flow estimation of an Automatic Continuous Positive Airway Pressure (APAP) device is described. Novel techniques of a multi-composite simulant head and recorded patient flows are used. The APAP device tested was shown to reliably estimate patient flow across a range of therapy pressures, leak conditions and breath types.**

I. INTRODUCTION

Obstructive Sleep Apnoea (OSA) is a chronic condition, characterized by recurrent episodes of reduced or interrupted breathing caused by upper airway collapse during sleep, leading to intermittent hypoxemia and sleep fragmentation. OSA comprises a continuous spectrum of severity ranging from simple snoring and upper airway resistance through mild to severe symptomatic obstructive hypopnoea and apnoea. The prevalence of sleep disordered breathing in the adult population is 24% males and 9% for females. The prevalence of symptomatic OSA in the adult population has been estimated to be 4% in males and 2% in females [1]. These patients demonstrate behavioural and neuropsychological consequences to varying degrees.

Symptoms of OSA include the direct effects of sleep fragmentation such as excessive daytime sleepiness, intellectual deterioration and depression [2], plus a legion of less specific complaints including impotence, nocturia, fatigue and headache, although symptoms are absent in the majority [3]. More serious consequences include arterial systemic hypertension, arterial pulmonary hypertension and heart disease [4]. Recurrent episodes of intermittent hypoxemia and sleep fragmentation cause several physiological responses, including sympathetic activation, neurohumeral changes and inflammation, which are precursors for cardiovascular disease and diabetes. Obesity has been consistently identified as a major risk factor for OSA [5], but there is accumulating evidence of increased cardiovascular morbidity and mortality in OSA, independent of obesity [6]-[9].

Continuous Positive Airways Pressure (CPAP) acts as a pneumatic splint to prevent upper airway collapse, and is the most effective therapy for OSA. CPAP therapy is associated with improvements in quality of life, accidents, lower blood pressure and reduced risk of cardiovascular disease [6].

Positive Airway Pressure (PAP) devices for the treatment of OSA and non-invasive ventilators typically interface to the patient via a mask. Masks are designed to be close-fitting and to seal to the patient's face whilst PAP therapy is applied. However, this seal is not always maintained and leak may occur between the mask and the patients face due to the therapy pressure. These leaks are not uncommon and are a factor for consideration in any non-invasive PAP application [10].

ResMed's CPAP and Automatic Positive Airway Pressure (APAP) devices implement a Leak detection algorithm to facilitate computing of Patient Flow [12].The Patient Flow, and hence the Leak Flow provide information useful for the characterization of sleep disordered breathing, as well as in the development of a therapeutic intervention [11]. For example, Patient Flow may be used to identify inspiratory and expiratory phases, and to compute patient respiration information including: respiratory rate, ventilation, and Apnea Hypopnea Index (AHI). Autosetting CPAP, or APAP, may adjust the treatment pressure based on features of the Patient Flow [12]. Leak itself is used for patient management. High Leak is poorly tolerated and contributes to poor patient adherence to PAP therapy. Clinical intervention in cases of high Leak may improve patient adherence to PAP therapy [10].

Leak cannot be measured directly by existing PAP devices. It is derived from the Total Flow as measured by the PAP device. This Total Flow is the sum of: Patient Flow, Mask Diffuser Flow and Leak.

Given a recorded signal for Total Flow (given by the sensor flow in Fig.1), Leak may be estimated ex post-facto using filtering techniques. However, when determining real-time therapeutic interventions, it is beneficial if Patient Flow, given by the piston flow in Fig.1, may be determined instantaneously. In this scenario, when considering the Total Flow signal available to the PAP device, a sudden occurrence of Leak may appear similar to the start of inspiration of the patient.

This paper describes the validation of the leak detection algorithm, by comparing the estimated Patient Flow signal from a ResMed S9 Autoset APAP device, ResMed, Bella Vista, NSW Australia, to the measured Patient Flow, provided by a mechanical patient simulator. The comparison was made at two therapy pressures, across a range of four leak conditions and five breath morphologies.
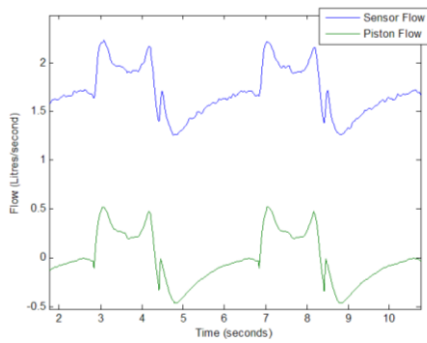
Figure 1.   Sensor (Total) Flow and Piston (Patient) Flow.

II.   METHODS

Validation of the Leak detection algorithm is made difficult by the disruptive nature of direct Patient Flow measurements, requiring the attachment of one or more flow meters to the outlet of the patient's airway [13]. Additionally, techniques for directly measuring either Leak or Patient Flow will typically affect the nature of the leak behaviour being studied.

To overcome this limitation, a simulant head was developed to enable simulation of realistic leak behaviour [14]. The simulant head is a composite structure created by three dimensional manufacturing reproduction of medical imaging. There are four functional composites: facial skin, skull, nasal cartilage and sub-dermal facial tissue, see Fig.2. The simulant head has been demonstrated to exhibit both static and dynamic mask leak behaviours similar to a human subject with the same topology [14]. The simulant head features nostril and nasal passage analogues that plumb to a 22mm internal diameter tube to allow pneumatic coupling, for example to flow meters or patient simulators.

The experiment has been designed to be ignorant of the mechanism of the S9 AutoSet APAP's leak algorithm. The strategy is: endeavour to create a realistic leak; induce these leaks for a spectrum of realistic conditions; and compare measured simulated Patient Flow with the S9's estimated Patient Flow. The degree to which these are similar is equal to the effectiveness of the Leak algorithm.

Simulated Patient Flows were developed by an ASL5000 Adult/Neonatal Breathing Simulator, IngMar Medical, Ltd., Pittsburgh, PA USA. The ASL5000 Adult/Neonatal Breathing Simulator features a sliding-seal piston cylinder driven by a brushless motor drive servo controlled at 2 kHz to deliver user-specified flow profiles as well as compliant lung model simulation. ASL5000 flow measurement is calculated from piston position with a limit of reading of 3.10×10^{-5} Litres.
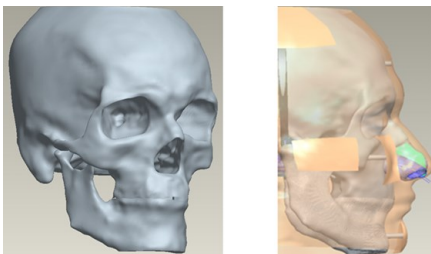

Figure 2.   Simulant head components.

The breathing simulator was connected to the pneumatic coupling of the simulant head. A ResMed Mirage Quattro mask was fitted to the simulant head, and connected via a standard tube to the APAP device. A computer was used to simultaneously record Patient Flow as reported by the APAP device and the Piston Flow of the Breathing Simulator via serial communications. The apparatus used in the experiment can be seen in Fig.3. The patient simulator was configured to execute a number of characteristic patient flow profiles at a breath rate of 15 breaths per minute. These were selected from clinical data recordings to represent a range of patient flows common to upper airway instability present in OSA. The five flow profiles, or Breath Morphologies, are termed: "Standard", "Chair-Shaped", "Reverse-Chair", "M-Shaped", and, "Flat" and are represented in Fig.4.
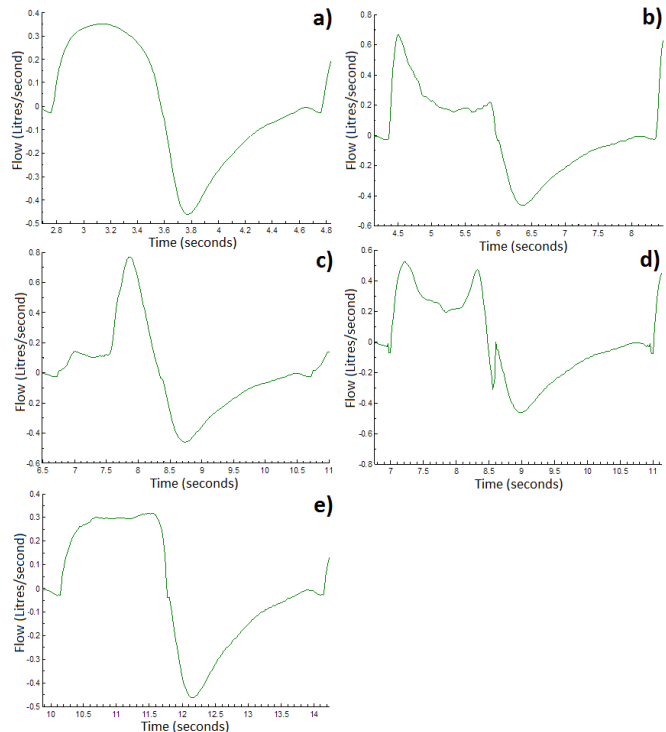

Figure 3.   Experiment apparatus.

Figure 4.   Various breath profiles as measured by breathing simulator. a). Standard, b). Chair-Shaped, c). Reverse-Chair, d). M-Shaped, e). Flat

Measures of actual and estimated patient flow were recorded for these five Breath Morphologies, at both 6cmH2O and 12cmH2O of therapeutic pressure (CPAP), and for four different approximate leak conditions, nominally: no leak, 0.33Litres/second, 0.67Litres/second and 1.00Litres/second.

Prior to each test, the mask was adjusted so as to not seal well and leak the specified nominal leak flow. This was done at the CPAP therapy pressure to be tested and with no simulated patient flow so that Leak could be measured. Leak was induced by loosening the mask headgear. Once the required Leak was achieved, the apparatus were configured for the test and the recording made.

The Leak Flow is deemed "nominal" as within clinical application, and here, ideally mirrored in simulation, the leaking mask is an unstable arrangement. The Leak Flow may vary with small changes in Mask Pressure due to patient respiration. During each test, the APAP device-reported real-time Leak was monitored to ensure that it remained as required.

Each test condition was performed and recorded for 60 seconds. The key parameters of interest were the measured Piston Flow of the breathing simulator and the Patient Flow channel of the S9, representing the actual and estimated patient flows respectively.

III. RESULTS

The 60 seconds of each data recording was used for analysis. Patient Flow from the APAP device was recorded at 50Hz. Piston Flow from the Breathing Simulator was recorded at 128Hz and then down-sampled to 50Hz. The Root Mean Square Error (RMSE) of Piston Flow and S9 Patient Flow was calculated. An example of a section of the resulting flows may be seen in Fig.5.

The RMSE for each recorded session are reproduced in Fig.6 for each Breath Morphology and for each CPAP pressure. In all cases the RMSE is less than 0.0804Litres/second. No discernible trends in RMSE can be seen against Breath Morphology, CPAP Pressure or Leak Condition.
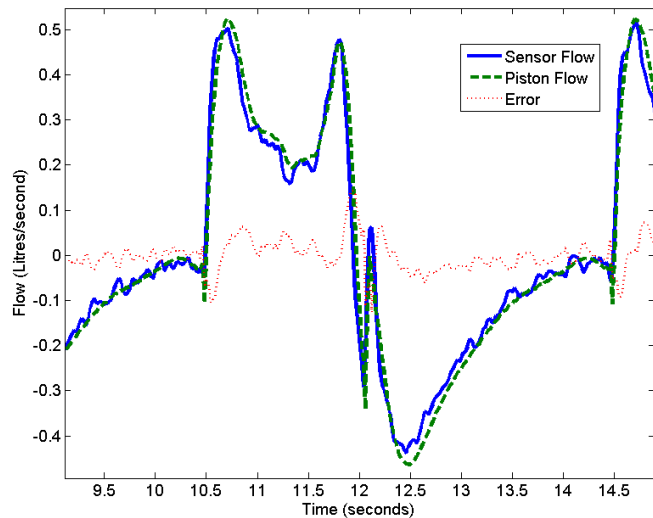

Figure 5.   Example of result: Measured (Piston) Flow, Estimated (Sensor) Flow and Error for an M-shaped breath, with 0.67Litres/second leak, 12cmH2O pressure.
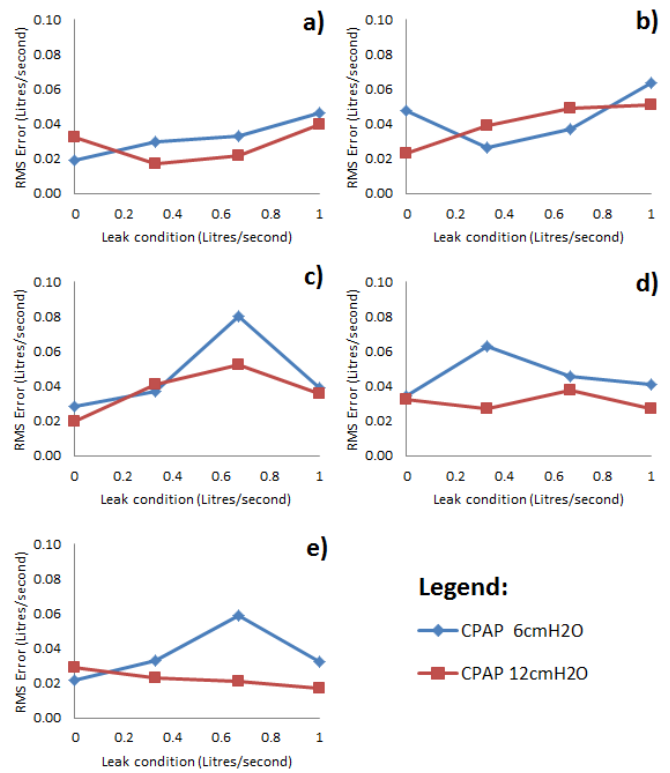

Figure 6.   RMSE for various breath morphology for all leak conditions and CPAP pressures. a). Standard, b). Chair-Shaped, c). Reverse-Chair, d). M-Shaped, e). Flat

IV. DISCUSSION

The lack of apparent trends in the RMSE across: therapy pressure, leak condition and breath morphology indicates no immediately obvious systematic deviation in the leak algorithm on these bases.

After considering the histogram of RSME, Fig.7, the data associated with the outlier of 0.0804Litres/second was examined and a systematic timing offset between the signals was observed. This offset is attributed to technical error rather than an aspect of the leak algorithm. This could be investigated by repeating the method.

To indicate the practical significance of the RMSE value, a number of clinical parameters are calculated and presented, Table 1, for the measured and estimated patient flows of a representative example, RSME of 0.0374Litres/second, along with percentage error with respect to the measured flow.
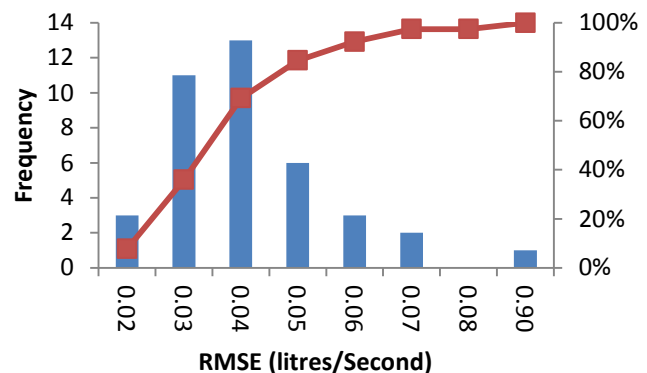

Figure 7.   Histogram of RMSE

Table 1. Clinical parameters of Respiratory Flow from Measured and Estimated Flow, for the M-shaped, 12cmH20 0.67Litres/second case

Clinical Parameter	Patient Flow	Estimated Flow	Percentage Error
Mean Abs. Flow (Litres/second)	0.230	0.218	-4.9%
Mean Peak Insp. Flow (Litres/second)	0.524	0.506	-3.3%
Mean Tidal Volume (millilitres)	0.447	0.403	-9.8%
Mean Curvature Index[a]	0.208	0.225	8.2%

a. As described in [12]

Mean Absolute Flow, Mean Peak Inspiratory Flow and Mean Tidal Volume represent clinically relevant measurements derived from respiratory flow. Mean Curvature Index[12] is a non-linear relation of respiratory flow designed to indicate the patency of the upper airway.

Table 1 indicates that the APAP device under investigation is accurate in estimating the respiratory flow, as well as flow-based clinically relevant parameters, for the test conditions described. The errors in the clinical parameters are low. It is possible that some error may be due to a systematic timing offset introduced by the method and observed in at least one case. Further investigation may improve the method.

The American Society for Testing and Materials (ATSM) Ventilator standard [15] requires machine indicators to be accurate within ±10% tested in the absence of leak. The results demonstrate this accuracy for the machine-indicated flow in the presence of significant leak.

Previous studies have investigated the effects of leak on APAP performance [16]-[18]. In these studies, the leak was introduced by opening a valve in the experimental circuit. The valve represents an approximation of the mask leak. Clinically, the behaviour of mask leak is dynamic, and the seal created by the mask can be broken and/or sealed within a breath. The intent of the simulant head is to improve the realism of the simulated mask leak.

V. CONCLUSION

A modern APAP device was shown to reliably separate the total flow measured into estimated Patient Flow and inadvertent Leak Flow. The RMSE between the estimated Patient Flow and the flow programmed by a lung simulator was low and of the order of the flow measurement accuracy. The Leak Flow was created using a realistic simulant head and a commercially available mask. Patient Flow estimation was repeatable across a range of leak, mask pressure and breath morphologies normally encountered during sleep-disordered breathing. Limitations of this study are those of any bench test which does not account for patient movement, which may induce rapid changes in leak, tidal volume and respiratory rate. Future work will investigate the performance of leak algorithms used by ventilation devices where rapid instantaneous changes in mask pressure are encountered during the presence of leak.

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