Pressure Adaptive CPAP

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***Abstract* – The objective of this report is to research and present our findings on the continuous positive air pressure sleep apnea device and how it can be modified to increase the comfortability and therefore amount of adherence to those with obstructive sleep apnea. Quantified by the Sleep Apnea Resolution and Adherence Hybrid (SARAH) index. The system integrates a wrist-worn monitor which utilizes Heart Rate Variability (HRV) as a direct, real-time proxy for patient comfort and autonomic stress.**

I. Introduction

Obstructive Sleep Apnea (OSA) is a significant global health challenge which affects over 936 million people worldwide. OSA is a chronic sleeping disorder where the upper airways are caused to narrow and repeatedly collapse during sleep, often leading to pauses in breathing, reducing oxygen levels, and fragmenting sleep.[16] This condition is associated with multiple health risks, such as hypertension, strokes, and heart disease.

The current most effective non-surgical treatment for OSA is a Continuous Positive Airway Pressure (CPAP) therapy. A CPAP machine works by delivering a steady, pressurized stream of air through a mask which acts as a splint pushing the soft palate muscles to keep the airways open during sleep. This mechanism prevents the collapse of nasal passages and the pharynx, which in turn causes a reduction in snoring and breathing pauses, leading to improved sleep quality and overall better oxygen levels. Although millions of people would benefit from a CPAP, adherence is a critical challenge, with only 40-60% of patients using this device as prescribed. The primary cause of discomfort and low adherence comes from the sensation of "fighting the machine" and many patients report difficulty breathing out against a high continuous stream of pressure.[13]

Addressing this issue of adherence requires the shift of focus from simply eliminating apneas as a whole but by maximizing the adherence of the device to increase the actual effectiveness of the therapy in a patient's daily life. The

"Sleep Apnea Resolution and Adherence Hybrid" (SARAH) index quantifies the true burden of the disorder that integrates both therapy efficacy and real-world adherence data.[18]

This paper proposes a sensor-adaptive CPAP system designed to increase the user adherence by building a personalized algorithm that automatically adjusts the amount of air pressure to balance both efficacy and user comfort, maximizing the effectiveness of a CPAP machine.

II. Device Design

In order to address the low adherence (thus low real-life efficiency) problem, we propose an algorithm that dynamically balances two competing objectives: reducing discomfort caused by high pressure while maintaining sufficient pressure level to therapeutically treat OSA. The key idea is that optimal pressure is not a fixed value but rather a value decided and varied during the night of sleep and a patient-specific balancing strategy learnt over time. Through adjusting the balance based on each nights' feedback on adherence and efficiency, the algorithm develops personalized approaches according to each patient's comfort tolerance.

A. Data Collection

When a user is using the CPAP device, our algorithm constantly makes decisions of whether to increase or decrease the pressure. The decision is made based on several measurements collected.

1) Baseline Disease Severity: The patient's doctor would be responsible for setting two indexes: patient's OSA severity (scaling from 1 to 3, 3 representing most severe). This represents the level of patient's need for therapy.

2) Real-Time AHI: Actual AHI (Apnea-Hypopnea Index) calculated by apneas and hypopneas detected during usage. This represents whether the current pressure provides adequate treatment for the patient

3) Comfort Indicators: The algorithm also collects users' comfortability score. For our initial stage, it's solely determined by users' HRV (Heart Rate Variability) obtained from a wrist band. HRV score will be positively correlated with the comfortability score calculated. We also track the current pressure of CPAP.

4) Other Measurements: The doctor will set a baseline AHI indicating the user's default AHI when not wearing the

CPAP during sleep. We also need to collect users' total sleeping time and hours CPAP worn. These measurements are not directly used in the decision algorithm but are important for the learning algorithm.

B. Weighted Decision Factors

The algorithm sets three weighted factors for previously collected data to make pressure adjustments. This includes: w_severity (weight for baseline disease severity), w_AHI (weight for real-life AHI), and w_comfort (weight for comfortability score). These weights start with balanced values (0.33 each) but will be updated over time except for w_severity which is a fixed value unless updated by a physician.

C. Decision Algorithm

There are two types of signals that tell the algorithm how to adjust the signal. Increase signal represents the factors that pushes for high pressure, and is calculated by the following formula:

$$Increase\_Signal = w\_severity \times severity + w\_AHI \times real\text{-}time\_AHI$$

Decrease signal represents the factors that pushes for lower pressure, calculated through:

$$Decrease\_Signal = w\_comfort \times comfort\_score$$

We then finally calculate adjustment score, which is modulated by the current pressure so that we are less likely to further increase the pressure when the pressure is already high:

$$Adjustment\_Score = (Increase\_Signal - Decrease\_Signal) / sqrt(Current\_Pressure)$$

A positive net score indicates increasing pressure and a negative net score indicates decreasing pressure. A net score with magnitude below a certain threshold will not induce change in pressure. The magnitude of the score also determines the rate of adjustment. For example, a higher positive score increases the pressure level more than a lower positive score.

```python
def Get_Pressure_Adjustment_Score(measurements, weights):
    '''
    Calculate a score indicating the algorithm's willingess to
    increase / decrease current CPAP pressure

    Args:
        measurements: dictionaries containing measurement values
        - 'baseline_AHI': baseline apnea-hypopnea index
        - 'detected_AHI': currently detected AHI
        - 'comfort_score': patient comfort score (obtained by HRV score)
        - 'current_pressure': current pressure level

    Returns:
        float: final adjustment score
    '''

    # Signals to increase pressure
    increase_signal = (
        weights['w_severity'] * measurements['baseline_AHI'] +
        weights['w_AHI'] * measurements['detected_AHI']
    )

    # Signal to decrease pressure
    decrease_signal = (
        weights['w_comfort'] * measurements['comfort_score']
    )

    # Net signal modulate by current pressure level
    raw_score = increase_signal - decrease_signal
    pressure_modulation = 1.0 / (measurements['current_pressure'] ** 0.5)
    final_score = raw_score * pressure_modulation

    return final_score
```

Fig. 1. Function used to calculate the score for pressure adjustment.

D. Learning Algorithm and Weight Update

Our algorithm learns and updates the weights according to each user in order to minimize the Sarah Index, which quantifies real-world treatment effectiveness by integrating both how well the pressure reduces apneas and how many hours the patient actually wears the device [18]. This is a more reliable criteria than simple AHI because it accounts for both adhesion and effectiveness. Note that the formula for calculating Sarah Index is:

$$SARAH\ Index = (Hours\ untreated / Total\ sleep\ hours) \times Baseline\ AHI + (Hours\ treated / Total\ sleep\ hours) \times On\text{-}CPAP\ AHI$$

```python
def Pressure_Adjust(score):
    """
    Convert score to actual pressure adjustment.

    Args:
        score: float, the calculated adjustment score

    Returns:
        int: value representing rate of pressure adjustment
            +2 = strong increase
            +1 = small increase
             0 = maintain current
            -2 = strong decrease
            -1 = small decrease
    """

    if score > 5.0:
        return +2
    elif score > 2.0:
        return +1
    elif score < -5.0:
        return -2
    elif score < -2.0:
        return -1
    else:
        return 0
```

Fig. 2. Function used to determine the rate of pressure adjustment from the score calculated by the previous function.

A lower Sarah Index indicates a higher efficiency of the CPAP treatment. By incorporating the Sarah Index to our algorithm, we can capture both efficacy and adherence of the treatment. After each night of usage (or a certain time period), the algorithm adjusts the weights based on two key signals: Sarah Index and CPAP Hours Worn. The decision logic is as follows:

TABLE 1

Decision Matrix For the Weight Update Algorithm

Sarah Index	**Hours Worn**	**Weight Update**
Increase	>5 hours	Increase w_AHI Decrease w_comfort
Increase	<5 hours	Decrease w_AHI Increase w_comfort
Decrease	Any	Keep current weights
Stable	Any	Try exploration

For the first case, the diagnosis of the reason for increasing Sarah Index is because the pressure is tolerable but insufficient. Thus, we need to make the algorithm more willing to increase the pressure by increasing w_AHI and decreasing w_comfort. For the second case, the pressure set for users is too uncomfortable so we want to prioritize more on comfort to enable the user to wear the mask longer. Thus, we need to decrease w_AHI and increase w_comfort.

Over weeks of usage, this learning algorithm converges to patient-specific weights that minimize their individual SARAH Index - finding the optimal pressure balance between comfort and efficacy for that person. Patients who can tolerate high pressure will have a high w_AHI and patients who find high pressure intolerable will have high w_comfort. Instead of forcing all patients to adapt to high pressure and total apnea elimination, the algorithm makes the CPAP device adapt to the patients, thus improving real-world effectiveness through sustained patient adherence.

E. System Architecture

The proposed pressure-adaptive CPAP system signifies a transformative transition from conventional fixed-pressure therapy to an intelligent, patient-responsive framework that continuously enhances both therapeutic effectiveness and user comfort. The system has four parts that work together to give each person the best treatment for sleep apnea. These parts are a wrist-worn physiological monitoring band, a responsive pressure delivery system, a customizable mask interface, and a touchscreen controller that connects to the cloud.[1]

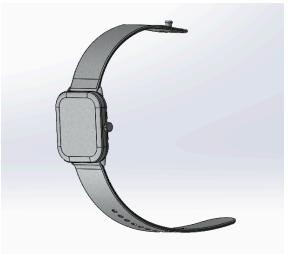

Fig. 3. Patient-sensing wearable CAD design

A low-profile wristband with photoplethysmography (PPG) sensors is used in the physiological monitoring component to continuously track heart rate variability (HRV) during sleep. With mean absolute errors for important time-domain parameters like SDNN (standard deviation of normal-to-normal intervals) and RMSSD (root mean square of successive differences) below 15 ms, contemporary PPG-based wearable sensors have shown respectable accuracy for HRV measurement during sleep. The wristband form factor was chosen based on data demonstrating that, in comparison to gold-standard electrocardiography, wrist-worn devices achieve the highest accuracy during sleep periods when motion artifacts are minimized, with correlation coefficients exceeding 0.95 for heart rate and above 0.85 for time-domain HRV metrics.[2]

In order to extract both time-domain and frequency-domain HRV parameters that function as proxies for autonomic nervous system activity, the device continuously samples cardiac intervals at a temporal resolution that is adequate. According to research, CPAP pressure levels have a direct impact on HRV patterns. High pressure causes sympathetic activation, which is reflected in decreased HRV and an elevated low-frequency to high-frequency (LF/HF) ratio. Before the patient feels uncomfortable or takes off the mask, the system can identify when pressure settings are causing autonomic stress by continuously monitoring these physiological signatures.[3]

The device's primary innovation is the pressure delivery subsystem, which uses a real-time adaptive algorithm to continuously modify airway pressure based on integrated physiological feedback instead of just apnea detection. This system uses comfort metrics from HRV analysis to proactively optimize pressure before patient intolerance develops, in contrast to traditional auto-titrating CPAP

(APAP) devices that react primarily to detected obstructive events and flow limitations.

A major advantage of the pressure adjustment mechanism is that it eliminates the lag time that is typically present when using conventional APAP devices. Conventional devices often take 2-3 respiratory cycles (10-15 seconds) to recognize an event and then make pressure adjustments. However, the device can anticipate when an event is about to occur using data from HRV fluctuation and sleep stage changes based on the patient's movement patterns, allowing for a much smoother transition in pressure adjustment, often in less than one respiratory cycle. Because of this rapid reaction time, it is particularly effective during the REM sleep phase when apneas are at their peak and the conventional devices have a lag time before making a pressure adjustment.

The mask system is designed to address one of the most important reasons why patients stop using CPAP: discomfort at the mask-skin interface. Therefore, the mask has many features that enhance comfort for the patient, based on collecting feedback in studies from patients who have listed pressure points, leaking air, and skin irritation as their main reasons for discontinuing CPAP use.

Fig. 4. Pressure-adaptive CPAP system design

Unlike traditional silicone, the mask cushion is made from a medical-grade memory foam (thermoplastic elastomer-based UltraSoft foam). Memory foam CPAP masks have been validated in clinical studies; specifically, clinical studies of memory foam CPAP masks showed that 90% of the study participants found memory foams to be more comfortable than silicones and significantly decreased their facial marks after overnight usage of this material. Unlike rigid silicones which cannot adapt to varying facial contours and beard patterns as well as the foam cushion, the softer foam cushion provides a better fit reducing the incidence of leakage and enabling their patients to achieve effective CPAP therapy with a lower amount of pressure on the mask.

The system targets specific quantitative performance benchmarks validated against clinical sleep medicine standards. The pressure delivery range spans 4-20 cm H_2O with 0.5 cm H_2O resolution, covering the therapeutic needs of mild to severe OSA cases. Pressure adjustment velocity is constrained to maximum rates of 3 cm H_2O per minute to avoid abrupt changes that trigger arousals, with smoother 0.5 cm H_2O increments preferred during stable periods.

The HRV monitoring system samples inter-beat intervals with 4ms temporal resolution (250 Hz effective sampling rate), sufficient for accurate calculation of time-domain and frequency-domain HRV parameters. Power consumption targets for the wristband are ≤50mW average draw to enable 7-day battery life from a 200mAh lithium polymer cell, comparable to commercial fitness trackers.

Data latency from HRV measurement through pressure adjustment implementation is constrained to <2 seconds total, comprising <500ms for PPG signal processing, <500ms for wireless transmission, <500ms for algorithm computation, and <500ms for motor response, ensuring near-instantaneous adaptation to physiological changes.[5]

The proposed system addresses three fundamental limitations of existing CPAP technology that have remained largely unchanged for two decades despite poor adherence rates. First, it directly measures and optimizes for patient comfort through physiological monitoring rather than inferring comfort solely from usage patterns post-hoc. Second, it implements true personalization by learning individual patient tolerance thresholds and adapting to their unique physiological responses rather than applying population-averaged algorithms. Third, it generates large-scale datasets linking comfort metrics to adherence outcomes that can drive continuous improvement through machine learning.

The primary focus of fixed-pressure CPAP machines as well as the more recent APAP machines have been to optimize their ability to eliminate apneas, without taking into account any comfort factor in their controls and algorithms. Research studies continue to show that the adherence rates for patients using CPAP machines have stabilised at between 40-60% over the past two decades, in spite of major advances in technology related to masks and humidifiers. The discrepancy between clinical efficacy (which is exceptional in treating apnoea) and actual real-world effectiveness (which is restricted as a result of discontinuation) is responsible for this adherence crisis.

III. Key Challenges

Implementation is one of the most significant challenges for the pressure adaptive CPAP technology from development to regulatory approval and clinical validation. Given that there is a moderate risk in the use of the technology and that the regular CPAP is already categorized as a class II or moderate risk medical device, it is a reasonable assumption that the pressure adaptive technology will fall under the same classification [6], [22], [23].

At best the development alone of the device is estimated to cost a minimum of $500,000 USD and 18 months of time. This time and cost is mainly a result of a lengthy design verification process and a need for multiple prototypes. In order to partially mitigate the cost and time associated with device development modular prototyping is vital, but will still require early funding through investments [6].

Another key implementation challenge is integration with various CPAP brands and telehealth platforms which will require extensive testing for mechanical and digital compatibility especially since current CPAP technologies are usually not designed for integration with third parties [4]. Most CPAP devices restrict external control to manufacturer clinician platforms. The most feasible mitigation strategy for integration would be engineered external addons which would remove CPAP firmware modifying requirements. If however, this approach proves challenging we will consider either licensing the technology to CPAP manufacturers or bringing our own CPAP device to market.

The next major implementation barrier is attaining regulatory approval specifically for the pressure adaptive algorithm technology used in the CPAP. FDA approval is necessary because CPAP devices affect airway pressure which poses safety risks, and as such the adaptive algorithm must reliably demonstrate safe operation by reverting to the fail safe default pressure used in ordinary CPAP devices in the case of a weak or interrupted signal from the HRV monitoring wristband [6], [22]. One main mitigation strategy is consulting with regulatory consultants early on in the development process in order to reduce the time delays that might occur while seeking FDA approval, which is already estimated at 18 to 24 months [6].

A fourth major implementation barrier is clinical validation proving an increase in adherence through both pilot and large scale clinical trials. At best, pilots and large scale clinical trials for a class II medical device will cost hundreds of thousands of dollars [7]. In order to help mitigate clinical trial costs partnerships with sleep centers is a commonly used field strategy [26].

A final implementation barrier is a necessity for a technical support team for troubleshooting, setting up, and monitoring of the HRV and CPAP system especially when telehealth platform integration is included. Operational costs will at minimum cost hundreds of thousands of dollars annually even in a small 5 person team and will need to be scaled up depending on scale of the device [9], [24]. An effective mitigation strategy which would reduce but not eliminate the support team burden would be the use of Generative A.I. as a decision support tool in diagnostics.

Finally despite all of the major initial development costs, manufacturing of the HRV monitoring wristband will have a low production cost around $17 similar to that of a Fitbit Flex and other HRV monitoring wearable wristbands [8], [25]. As such, the wristband could have a low burden on the consumer but will require significant loans and investment for development.

IV. Ethical issues

One of the biggest ethical concerns in the technology is medical data privacy. The system collects and stores protected health information, whose wireless transfer increases privacy leak concerns. In order to mitigate the risk, compliance with the HIPAA Security Rule is necessary, for example end-to-end encryption and HIPAA-compliant cloud based storage [2]. Additionally, in order to reduce user concern over long term data storage, configurable data auto deletion, for example 30 or 60 days, would increase user autonomy, promote risk awareness and reduce overall risk while balancing clinical and research needs. These mitigation methods are both feasible and effective, however the risk for cyberattacks can never be fully eliminated and as such is still a genuine concern.

Another major ethical concern is the environmental impact of manufacturing the HRV monitoring wristband. Typically substances like silicone, which is not biodegradable, are used in wearable wristbands producing polymer waste [15], [28]. A great ecofriendly alternative to silicone is thermoplastic elastomers (TPE) which is already commonly used in many wearable wristbands. The use of TPE's has the potential to have a positive environmental impact by reducing carbon emissions, recyclability, and its ability to incorporate already used polymers into its initial creation [1]. Given that TPE's are already used in the industry, this ethical improvement's adoption is feasible. Additionally, some research has been conducted into specific TPE's which are biodegradable and could be used in the future [29].

A third ethical issue is cost accessibility given the high initial development cost. System and device affordability is vital for equitable access across all income levels. Luckily, the low predicted manufacturing cost of the HRV monitoring wristband at around $17 USD compared to that of the entire CPAP with prices ranging from $500 to $1000 USD will facilitate widespread adoption [3], [8]. However, the investors may push for higher prices given the expensive initial development cost. Therefore, maintaining transparency with the investors about the need to keep consumer cost low is necessary to support ethical and equitable access.

A final ethical issue is user safety concerns. Because of the inherent risk of the airway pressure adaptive technology, in order to mitigate risk, it is necessary for the algorithm to default to a safe pressure in accordance with FDA regulations [4], [22].

V. Generative AI

To evaluate whether generative artificial intelligence could independently propose a meaningful improvement to the pressure adaptive CPAP system, we used a large language model that was prompted with the same technical problem addressed in this project. The goal was to assess how the AI solution compared to our group's proposed design using the

Final Project Paper Rubric as the evaluation framework. The AI prompt we used was “Design an improved CPAP system for obstructive sleep apnea that increases patient adherence while maintaining therapeutic efficacy. Propose a technical design improvement or a new system architecture. Justify your design choices using quantitative or physiological reasoning where possible. Consider patient comfort, sensing modalities, control algorithms, and real world usability constraints.” We used the OpenAI GPT 5.2 model [30].

The solution generated by ChatGPT focused on improving existing auto titrating CPAP systems by refining airflow based sensing and control algorithms. The AI proposed using enhanced flow limitation detection, snoring pattern analysis, and gradual pressure ramping to improve patient comfort while maintaining apnea suppression. Comfort was treated indirectly through smoother pressure transitions and user adjustable settings rather than through the physiological measurement. Overall, the AI approach used software on top of current CPAP architectures and it prioritizes ease of implementation and compatibility with existing devices.

Compared to the AI generated solution, our proposed system addresses adherence more directly by incorporating real time physiological feedback through heart rate variability monitoring. While the ChatGPT design is highly reactive and event driven, our system proactively adjusts pressure based on autonomic stress signals that correlate with discomfort and mask intolerance. Additionally, our use of the SARAH Index balances efficacy and adherence rather than just optimizing apnea reduction. Based on the rubric, the AI generated solution would be graded in the Fair range, corresponding to approximately 70 to 80 percent, since it proposes a reasonable but incremental design improvement that lacks direct comfort sensing, quantitative personalization, and deeper consideration of earlier described ethical challenges.

VI. Conclusion

Both traditional CPAPs and newer technologies such as automated titrating CPAP systems are clinically proven to reduce the occurrence of apneic episodes in patients through physiological mechanisms. However, they do not adequately address issues of comfort, personalization and adaptability, which is why patient use is still very low even though these technologies have been available for many years. By integrating a wrist-worn heart rate variability (HRV) sensor with a proprietary algorithm that optimises airway pressure on an individual’s behalf based on measured HRV, we propose that a CPAP system can become a two-way exchange of information between the patient and their CPAP machine, enabling it to become a patient-responsive therapy platform rather than simply a device that generates airflow at a set pressure [4].

When combined with the use of the SARAH Index to guide our work, we believe that this model provides a new way to define success for the CPAP [4]. Instead of measuring success only by apneic episodes eliminated, we will measure how much patients are benefitting from CPAP therapy by looking at both the number of apneic episodes suppressed AND the number of hours CPAP was used. The objective of this shift is to allow for continued optimization of airway pressure settings that favor long-term periods of comfortable use, rather than maximally eliminating apneic episodes at the expense of removing the mask or stopping the use of the CPAP altogether. This approach provides a mechanism through which the CPAP system can continuously learn about the balance point for each patient's level of comfort versus their level of efficacy with respect to CPAP therapy, thereby facilitating improved adherence.

The next critical step in this clinical project will involve conducting a small cohort feasibility study to assess the clinical efficacy of the technology and how it is used by patients in realistic, yet limited, controlled settings [10]. This study will primarily assess adherence rates each night for a specific number of hours, measured by each patient using standardized questionnaires at baseline and at six months after the initial implementation of the device. In addition, there will be an objective assessment of the number of awakenings that the patient had during the night and how many times the patient removed their CPAP mask from their face, measured compared to their baseline CPAP use. Collectively, these data will provide evidence that the use of HRV for determining CPAP adaptation pressure has a clinical effect on improving CPAP use under real-world conditions, thus supporting the conduct of larger trials while mitigating the overall risk of harm.

Using the extensive, multimodal dataset created by the HRV metrics, the patient pressure trajectories, SARAH scores, and patient usage patterns created during this study could potentially be used to develop machine learning-based algorithms that allow for a wider range of more complex clinical decisions to be made, compared to traditional rule-based controllers [10]. Such algorithms would allow the system to detect trends in CPAP use patterns across many different clinical scenarios while still adhering to the required safety measures and fail-safe defaults set forth by regulatory bodies and healthcare practitioners.

It will be necessary for future trials to rigorously test this device on a wide variety of different patient populations by looking at the complete range of factors typically associated with the success of CPAP therapy: including an individual's comorbidities, body shape, sleep position, and known phenotypes for CPAP intolerance [10]. This would provide assurance that personalization is maintained for a robust group of patients and not just for "ideal" (i.e., most compliant) users. As a result, future efforts should focus on developing the trials for under-served communities, continually enhance the methods for evaluating comfort and patient adherence, and align all levels of regulation, ethics, and cost for pressure-adaptive CPAP therapy to transform this promising concept into a clinically validated, readily accessible treatment option that will have long-term sustainability in the real world.

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