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Comparative Evaluation of efficacy of PVAS device in measuring the variations in Pressure, Volume and Airflow Velocity during breathing in Skeletal Class II Horizontal and Vertical cases with those observed in Skeletal Class I

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Abstract

The respiration is a very important physiological process, which is essential to maintain not only the vital signs but also normal growth and development in growing individuals. It has been proved that the normal respiratory physiological process is affected in skeletal class II pattern. Any kind of upper airway obstruction is a significant risk factor for growth retardation in children. Abnormalities of the upper airway require prompt attention, since these often alter ventilatory patterns and gas exchange, particularly during sleep, when upper airway motor tone and ventilatory drive are diminished. Polysomnography, upper airway endoscopy , Radiological methods such as Lateral cephalogram, CT scans, and MRI are some of the most commonly used tools to assess the upper air way. But these techniques are mostly invasive and also expensive and cannot be used for longitudinal studies.

In this study, a cost-effective portable pressure, volume and velocity sensor-based respiratory measure device is designed i.e. PVAS Device . This device enables to measure the changes in breathing airway pressure , airflow volume and airflow velocity. The subject has to wear a facial mask with a unidirectional airflow valve attached to a digital manometer. This facial mask will collect the air passing through both mouth and nose to check for oro-nasal respiration. Patients will be divided in to 3 groups Skeletal Class I, Class II horizontal and Class II Vertical depending on the cephalometric evaluation and comparison will be done in between groups

Keywords: Airway Analysis, Breathing Airway Pressure, Breathing Airway Volume, Breathing Airway Velocity, Orthodontics

Introduction

The respiration is a very important physiological process, which is essential to maintain not only the vital signs but also normal growth and development in growing individuals. It has been proved that the normal respiratory physiological process is affected in skeletal class II pattern. Respiratory diseases such as asthma, bronchiectasis and obstructive sleep apnea (OSA), are widely prevalent in population. Upper airway obstruction is the most common cause of OSA. This upper airway obstruction is a significant risk factor for growth retardation in children. Abnormalities of the upper airway require prompt

attention, since these often alter ventilatory patterns and gas exchange, particularly during sleep, when upper airway motor tone and ventilatory drive are diminished. Polysomnography is used as a standard tool to establish the existence and severity of such disorders during sleep.[1]The preferred radiological or visual technique to evaluate the upper airway in children and a common technique in clinical practice is upper airway endoscopy that is used to evaluate both the anatomy and function of the airway, and is commonly performed under sedation or anesthesia. Radiological measures such as neck radiographs and cephalometry provide a static two-dimensional assessment of the airway.[2]The most advanced imaging techniques to evaluate upper airway characteristics are computed tomography (CT) and magnetic resonance imaging (MRI). Both provide a three-dimensional evaluation of the airway and surrounding tissues with very high precision. CT technology is hampered by its use of ionizing radiation, though cone-beam CT scans may reduce the radiation dose significantly.[3,4] According to a study conducted on diagnostic radiation exposure and cancer risk they concluded that these patients are more sensitive to radiation and have more years of life expectancy and therefore more years at risk of cancer occurrence.[5] Hence avoiding invasive and radiation exposure technique is needed and use of such techniques should be avoided.

Upper airway breathing pressure is not given due importance and is not measured in our routine day to day clinical examination. No such device is currently available to measure pressure, volume and velocity of breathing airflow. Only devices which are available measure the pulmonary pressure and are invasie hence not applicable in day to day clinical setting. Many studies have shown that the upper airway is reduced in skeletal class II cases as compared to skeletal class I but they require cephalometric or volumetric radiograhs for the diagnosis[14].

In this study, a cost-effective portable pressure, volume and velocity sensor-based respiratory measure device is designed i.e. *PVAS Device* . This device enables to measure the changes in breathing airway pressure , airflow volume and airflow velocity. The subject has to wear a facial mask with a unidirectional airflow valve attached to a digital manometer. This facial mask will collect the air passing through both mouth and nose to check for oro-nasal respiration.

Materials and Methods

Phase 1: The PVAS Device will be validated for safety and accuracy for measuring pressure, volume and airflow velocity during breathing in comparison with values obtained from polysomnography technique.

Piloting the device (5 samples each group)

Piloting will be done for deriving the sample size and also estimating the range of normalcy and variation.

Phase 2 : An observational & analytical study will be conducted on patients reporting to the Dept of Orthodontics, SPDC to measure the breathing pressure, volume and airflow velocity using *PVAS Device* after getting approval from the institutional ethical committee. Each patient or their guardian will be providing written informed consent to participate. All patients in age group of 18 to 40 years of age will be considered for inclusion. Patients will be further divided in to 3 groups (Skeletal Class I , Skeletal Class II horizontal and Skeletal Class II Vertical) Selected patients will be asked to gargle with warm saline water and sprayed with Oxymetazoline Hydrochloride (Otrivin) Nasal spray to remove any kind of mucus in nose and throat, which may cause obstruction and give biased reading. Patients will then be seated in relaxed position with their back upright and head in Natural Head Position (NHP). Ambu silicon face mask attached to manometer will be placed covering patients nose and mouth and patient will be asked to breathe in and out normally with out any additional efforts for a period of 60 seconds or 1 minute. Average breathing Pressure, Volume and Airflow velocity for a period of 1 minute will be calculated with values taken at regular interval of 5 seconds. Any complications during the procedure shall also be noted. The data shall be collected for 20 pateints in each group.

Study Type: Observational Analytical Study

Research approach: Quantitative approach

Study Participants: Cases reporting to Dept of Orthodontics, SPDC for Orthodontic treatment and willing to particiapte in study.

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Sample size: Sample size is calculated according to the average number of pateints reporting to the Dept of Orthdontics , SPDC for duration of study and considering the inclusion and exclusion criteria

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$$n = \frac{(\sigma 1^2 + \sigma 2^2/\kappa)\,(z\ 1\text{-}\alpha/2 + z\ 1\text{-}\beta/2)^2}{\Delta}$$

Confidence Interval (2-sided) 95%

Power 80%

	Group 1	Group 2	Difference*
Mean	27.73	25.8	1.93
Standard deviation	2.31	1.75	
Variance	5.3361	3.0625	
Sample size per group 18			
*Difference between the means			

Considering above formula 18x3 (groups) = 54 Minimum sample size

To round off sample size: 60 patients

Inclusion Criteria

1. Willingness to participate in the study with informed consent
2. No previous history of any orthodontic treatment
3. Patients with skeletal Class I
4. Patients with skeletal Class II Horizontal
5. Patients with skeletal Class II Vertical
6. Age group between 18 to 40 years.
7. ANB, FMPA, Mandibular plane angle Stiner's Analysis, Down's Analysis, Witt's appraisal, Beta Angle and saddle angle will be evaluated to differentiate patients in skeletal pattern.

Exclusion Criteria

1. Patients with any kind of syndrome or systemic disease
2. Patients with any kind of facial asymmetry
3. Patients with any kind of nasal deformity and deviated nasal septum
4. Patients with cough and cold at time of evaluation
5. Patients with history of COVID 19
6. Patients with history of asthma or any kind of breathing disorder
7. Patients having known history of adenoids or enlarged tonsils

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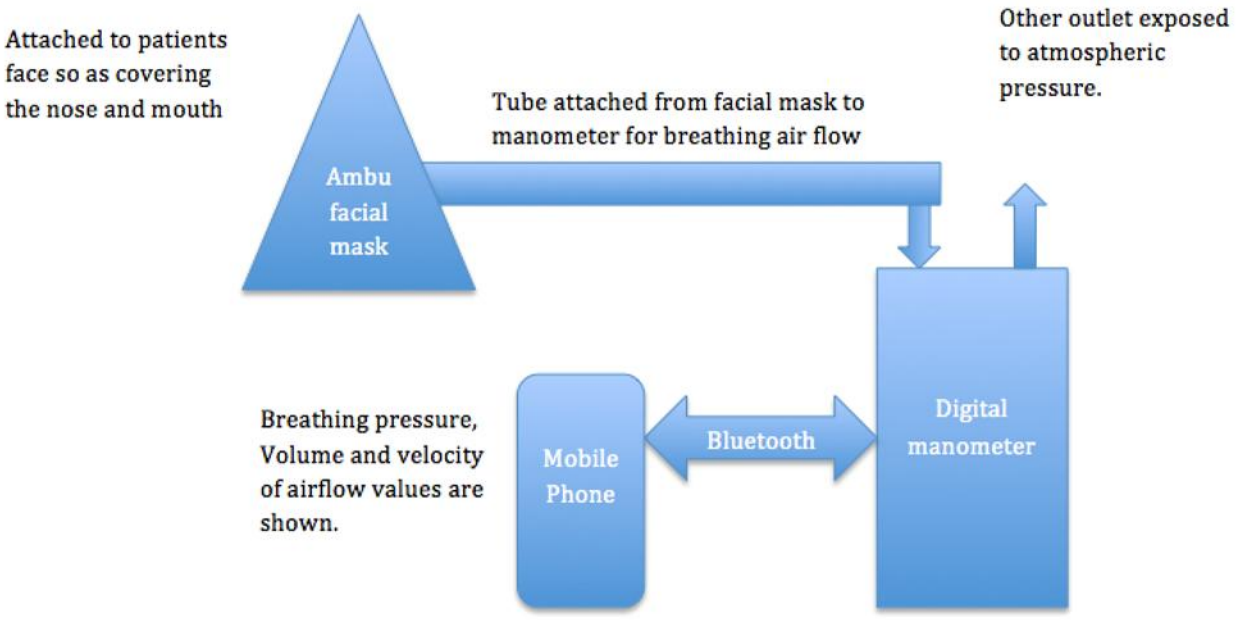
Description of the PVAS Device (Blue Print)



Expected Results

The study findings shall be unique as there is not similar study found in the literature which has studied the breathing pressure, volume and airflow velocity in patients with Skeletal Class I, Class II (Horizontal) and Class II (Vertical). This new *PVAS Device* can be used as non invasive, portable and user friendly device which can be used in our day to day clinic setting to measure the breathing pressure, volume and airflow velocity. This can be used to indirectly assess the constriction/ obstruction of upper airway. *PVAS Device* will contribute to enhance and promote the quality of diagnosis and care provided to the patients.

After screening the patients through cephalometric examination and clinical examination and considering inclusion and exclusion they will be divided in to 3 groups. Skeletal Class I (N=20) Skeletal Class II Horizontal (N=20) and Skeletal Class II Vertical (N= 20). They will be evaluated for breathing pressure, volume and airflow velocity by *PVAS Device*. Comparison of the values obtained will be done for patients having Skeletal Class I with Skeletal Class II Horizontal.

Skeletal Class I with Skeletal Class II Vertical and Skeletal Class II Horizontal with Skeletal Class II Vertical. Correlation of outcome will be done pressure to volume, pressure to airflow velocity, volume and airflow velocity and the results will be calculated. The statistical analysis shall be based on the objectives of the study. Descriptive Statistics shall be used for describing the population with percentage, standard deviation and mean scores. The obtained values will be subjected to statistical analysis according to paired "t" test (2 tailed). Prevalence value will be calculated according to SPSS software.

Conclusion / Future scope

1. New *PVAS Device* will serve as an essential non invasive diagnostic aid in day to day clinical setting to determine the breathing pressure, volume and airflow velocity of patients and indirectly help to assess any kind of obstruction or constriction in the upper airway.
2. This device can be used to study new parameters with respect to breathing pressure, volume and airflow velocity in patients with Cleft lip and palate.
3. PVAS Device can be used to assess the age related changes in upper air way constriction /

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soft tissue hardness and improve the quality of life of patients suffering from breathing disorders like OSA.

4. This device can be used to assess the changes in upper airway volume due to orthognathic surgeries and functional appliances

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