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SCIENTIFIC INVESTIGATIONS

Validation of Polyvinylidene Fluoride Impedance Sensor for Respiratory Event Classification during Polysomnography in Children

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Study Objectives: Polysomnography is the gold standard for diagnosis and characterization of severity of sleep-disordered breathing. Accuracy and reliability of the technology used are critical to the integrity of the study's interpretation. Strict criteria for obstructive sleep apnea in children are lacking and diagnosis often requires consideration of frequency of respiratory events in addition to other measures. Current American Academy of Sleep Medicine recommendations for pediatric patients includes use of respiratory inductance plethysmography (RIP) belts, whereas polyvinylidene fluoride (PVDF) belts are currently only acceptable for use in adults. We hypothesized that PVDF belts would be equally effective as RIP belts for detection of respiratory effort and events in children.

Methods: Children ages 2–17 y were recruited from a large pediatric tertiary referral center after obtaining consent for participation. Fifty subjects were recruited (average age, 7.8 y). Clinically relevant limits of agreement were predetermined to be a difference in total count of obstructive or central apneas or hypopneas of ± 5 events.

Results: Scoring of respiratory events was not significantly different by belt type based on Bland-Altman plots of total apnea-hypopnea index and obstructive apneas. Obstructive hypopneas scoring ranged beyond our clinical limit of agreement. Findings in obese subjects were consistent with the larger sample with the exception of an increase in outliers. Artifact amount was comparable (RIP 10.9% ± 22.5% and PVDF 10.5% ± 19.5%).

Conclusions: Based on these findings, PVDF belts appear to be as effective as RIP belts in detection of respiratory effort and events in children.

Commentary: A commentary on this article appears in this issue on page 159.

Keywords: obstructive sleep apnea, pediatrics, polysomnogram, respiratory monitoring, sleep-disordered breathing

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INTRODUCTION

Polysomnography is the gold standard for diagnosis of sleep-disordered breathing (SDB) and characterizing disease severity. In addition to careful history and physical examination, management of SDB often hinges on the interpretation of multiple measured respiratory parameters used during a polysomnogram (PSG). The accuracy and reliability of the technology used during a PSG are critical to the integrity of the study's interpretation.

Based on the update of American Academy of Sleep Medicine (AASM) Scoring Manual,[1] in children, identification of respiratory events such as apnea and/or hypopnea requires oronasal thermal airflow sensor, nasal pressure transducer, respiratory inductance plethysmography (RIP), and carbon dioxide partial pressure (pCO_2) monitoring. For evaluation of respiratory effort, esophageal manometry or dual thoracoabdominal RIP belts are recommended for use in children. Further, polyvinylidene fluoride dual thoracoabdominal belts (PVDFb) are also recommended sensors in detection of respiratory effort in adults, largely based on the work by Koo and colleagues demonstrating comparable detection of respiratory events of apnea and hypopnea with polyvinylidene fluoride (PVDF) versus RIP monitoring.[2] RIP technology has become the mainstay of respiratory event detection with widespread usage in polysomnography because of its noninvasive approach and accessibility in contrast to the decreased practicality and invasiveness of esophageal manometry. PVDF technology is already an incorporated technology in oronasal thermal airflow sensors recommended for use in both children and adults.[3] However, based on a lack of evidence for its use in pediatric polysomnography, PVDFb are not currently recommended for respiratory effort monitoring and event detection in children. PVDFb detect changes in impedance and are less position dependent compared to RIP belts (RIPb). RIPb require proper orientation to detect changes in cross-sectional areas during breathing to obtain accurate and interpretable information. RIPb require correct orientation, and

BRIEF SUMMARY

Current Knowledge/Study Rationale: Current American Academy of Sleep Medicine recommendations include use of respiratory inductance plethysmography belts (RIPb) for detection of respiratory events in children and adults, whereas use of polyvinylidene fluoride belts (PVDFb) is only recommended for adults. With advances in quality of technology, we aimed to determine if PVDFb would be as effective as RIPb in the pediatric population.

Study Impact: Our study directly compares traditional RIPb technology and PVDFb technology for respiratory effort sensing in pediatric patients.

their adjustment may interrupt the sleep of young patients and lead to interference in their natural sleep cycles and suboptimal study results. As PVDFb detect changes in electrical resistance without the polarity seen in RIPb positioning, PVDF may be a particularly attractive new technology for respiratory event sensors to be used in pediatric polysomnography.

We hypothesize that compared to RIPb, detection of respiratory events with PVDFb will allow for improved pediatric polysomnography interpretation, through decrease in artifact and increase in respiratory event recognition.

METHODS

This study was approved by the Institutional Review Board at Ann & Robert H. Lurie Children's Hospital of Chicago. Informed consent and assent (when appropriate) was obtained for all subjects. Fifty subjects ages 2 through 17 y who were scheduled for routine nocturnal polysomnogram[4–7] were prospectively enrolled from September 2013 through February 2014, at the AASM-accredited Sleep Medicine Center at Ann & Robert H. Lurie Children's Hospital, a tertiary referral center. Non–English-speaking patients or those with chronic disease (such as recent major chest or abdominal surgery) that precluded safe participation were excluded.

In addition to routine monitors including conventional RIP belts (Protech, Murrysville Pennsylvania), PVDF belts (Dymedix Diagnostics, Shoreview Minnesota) were placed on the chest and abdomen of the child per manufacturers' guidelines. All PSGs were recorded and scored based on AASM criteria, using low-frequency filter (LFF)/high-frequency filter (HFF) settings of 0.3/35 Hz for all electroencephalography (EEG) and right and left electrooculography (EOG) leads, 0.3/70 Hz for the electrocardiography (ECG) leads, 10/100 Hz for electromyography (EMG) at the chin, intercostal, right leg and left leg, and snore microphone, and 0.1/15 Hz for pressure transducer air flow (PTAF), PVDF airflow nasal sensor, RIP belts, and PVDF belts. End-tidal pCO_2 and oxyhemoglobin saturation (SpO_2) were obtained via capnography and pulse oximetry. After clinical interpretation of the PSG occurred, two copies of an unscored, deidentified study were created with coded file names. Each deidentified study included a single set of chest and abdomen belts (RIPb or PVDFb).

Cadwell's Easy III acquisition software (version 3.14.2, Kennewick Washington) was used with expanded (patients age 3 y or older) and regular (patients younger than 3 y) montages, which included bilateral EEG leads of Fp1, Fp2, Fpz, F3, F4, C3, C4, Cz, T3, T4, P3, P4, Pz, O1, O2, M1, M2 and Fpz, M1, T3, C3, Cz, C4, T4, M2, Pz, O2, respectively, EOG, EMG (submentalis, anterior tibialis), ECG with heart rate, continuous end tidal carbon dioxide monitoring with waveform, oxygen saturation with plethysmography waveform, PTAF channel facilitated by Salter Laboratories oral/nasal cannula (Lake Forest Illinois), and PVDF air flow sensor (Dymedix Diagnostics). Sleep stage was determined by a registered polysomnographic technologist for each 30-sec epoch.

Scoring of respiratory events was performed by two board-certified sleep medicine physicians (DAL, IT) who were blinded to belt type (RIP or PVDF). Each scorer reviewed 33 studies, 8 of which were randomly selected for duplicate scoring to determine interscorer reliability based on percent concordance. Each study was scored for respiratory events according to the AASM recommended Respiratory Rules for Children.[7] The total number of respiratory events (central apnea, obstructive apnea, obstructive or central hypopnea), respective respiratory indices (central apnea index, obstructive apnea index, apnea-hypopnea index [AHI]), and diagnostic category (mild, moderate, or severe) were recorded. Prolonged expiratory apnea and post-sigh central apnea were excluded from analysis. Also, epochs with respiratory sensor artifact were counted and percentage of artifact based on total sleep time (TST) calculated. Epochs consisting of more than 50% artifact were counted as epochs of significant artifact that restricted interpretation for that time period.

In addition to respiratory measures, characteristics of the subjects were also entered into an Excel database and later exported to Statistical Package for Social Sciences (SPSS) software for further statistical analysis. Statistics included Pearson correlation for artifact by montage. Preliminary Pearson correlation was performed to determine strong correlation between the two montages using RIPb and PVDFb; however, formal Bland-Altman plots were constructed to better characterize the agreement between montages utilizing RIPb and PVDFb, identifying trend lines for 2 standard deviations (SD) from the mean bias for each plot. Designated limits of agreement based on clinical relevance were identified by our sleep medicine physicians to be a difference in total count of obstructive apneas, obstructive hypopneas, and/or central apneas of ± 5 events. Subgroup analysis of belt agreement in obese subjects was also performed for total AHI and central apneas.

RESULTS

Subjects included 18 girls and 32 boys, ages 2.5 through 17.7 y (mean age 7.8). No subjects were excluded from participation based on the presence of chronic conditions. Eight subjects had a history of previous adenoidectomy and/or tonsillectomy. Of our cohort, more than half of the subjects presented with underlying chronic or comorbid conditions, and many children had more than one chronic disease or congenital abnormality (**Table 1**). The most frequent comorbid conditions included obesity (40%, n = 20), asthma (20%, n = 10), developmental delay (8%, n = 4), and craniofacial anomalies (8%, n = 4).

Interscorer reliability was high based on calculated percent concordance (approximately 98%) for the randomly selected eight studies scored by both sleep medicine physicians' review.

Bland-Altman plots were constructed and limits of agreement based on 2 SD of the mean difference were added to the plots for total AHI, obstructive apneas, and obstructive hypopneas. No central hypopneas were scored. Subgroup analysis of total AHI and central apneas was performed for obese subjects. Mean bias (d), upper limit of agreement (mean bias +2 SD, lower limit of agreement (mean bias −2 SD), number of total subjects (n), and 95% confidence intervals for the limits of agreement of each Bland-Altman plot are listed in **Table 2**.

When looking at all included subjects in our sample, more than 95% of the data were contained within the limits of agreement (or within 2 SD of the mean) with relatively equal scatter on either side of the mean bias indicating no systematic bias between methods. The agreement between the montages using RIPb and PVDFb (demonstrated in **Figure 1**) for AHI is strong, with data tightly scattering on either side of the mean bias and contained within the limit of agreement by 2 SD and clinical criteria (less than ± 5). Outliers in AHI account for less than 5% of the data overall.

Figure 2 reveals similar results of total AHI determination and demonstrates a strong degree of agreement in obstructive apnea scoring between the two belt types (RIPb and PVDFb) for all study subjects. Evaluating obstructive hypopneas alone, the data demonstrate increased scatter beyond our clinically determined limit of agreement of greater than ± 5 events but still suggests no systematic bias between methods (**Figure 3**).

Subgroup analysis of total AHI in obese subjects did demonstrate a 95% confidence interval for the lower limit of agreement that crossed −5. In general the scatter is tightly surrounding the mean bias of −0.59 (± difference of 2 in AHI score) with the exception of the two outliers (accounting for 10% of the obese subgroup), which demonstrated an increase in AHI with PVDFb montage compared to with RIPb montage (**Figure 4**). Subgroup analysis of central apneas in the obese patients demonstrated outliers on either side of the limits of agreement by 2 SD criteria; however, they were not beyond our predetermined realm of clinically significant difference with scoring differences of ± 2 events. The scatter demonstrated in central apnea scoring in obesity does not favor one belt strongly over the other (**Figure 5**).

The amount of recorded artifact was comparable between the PVDFb and RIPb montages, with artifact accounting for 10.9% of TST using RIPb (± 22.5% SD) and 10.5% of TST using PVDFb (± 19.5% SD), (**Table 3**).

DISCUSSION

This study directly compares respiratory effort sensing using RIP and PVDF technology in the pediatric population. Pediatric patients span a wide range of weights, heights, and other anthropometric parameters, requiring technology that can adapt for this. Infants in particular have small body surface area for proper belt placement.

Bland-Altman analysis of belt performance in terms of respiratory effort overall demonstrated strong agreement without

Table 1—Comorbid or chronic conditions of study participants.

Comorbid or Chronic Conditions	Number of Patients (% of Cohort)
Obesity	20 (40)
Asthma	10 (20)
Craniofacial anomalies or midface hypoplasia	4 (8)
Developmental delay	4 (8)
Sickle cell disease	3 (6)
Known OSA	3 (6)
Hypotonia	3 (6)
Airway abnormality (tracheomalacia or subglottic stenosis)	2 (4)
Prematurity	2 (4)
Trisomy 21	2 (4)
Dysphagia	2 (4)
HTN	1 (2)
9p deletion	1 (2)
Seizure disorder	1 (2)
Precocious puberty	1 (2)
Achondroplasia	1 (2)
Spinal stenosis	1 (2)
Hypothyroidism	1 (2)
Schizoaffective disorder	1 (2)
Allergic rhinitis	1 (2)
ADHD	1 (2)
Scoliosis	1 (2)
IUGR	1 (2)
GERD	1 (2)
Hypoglycemia	1 (2)

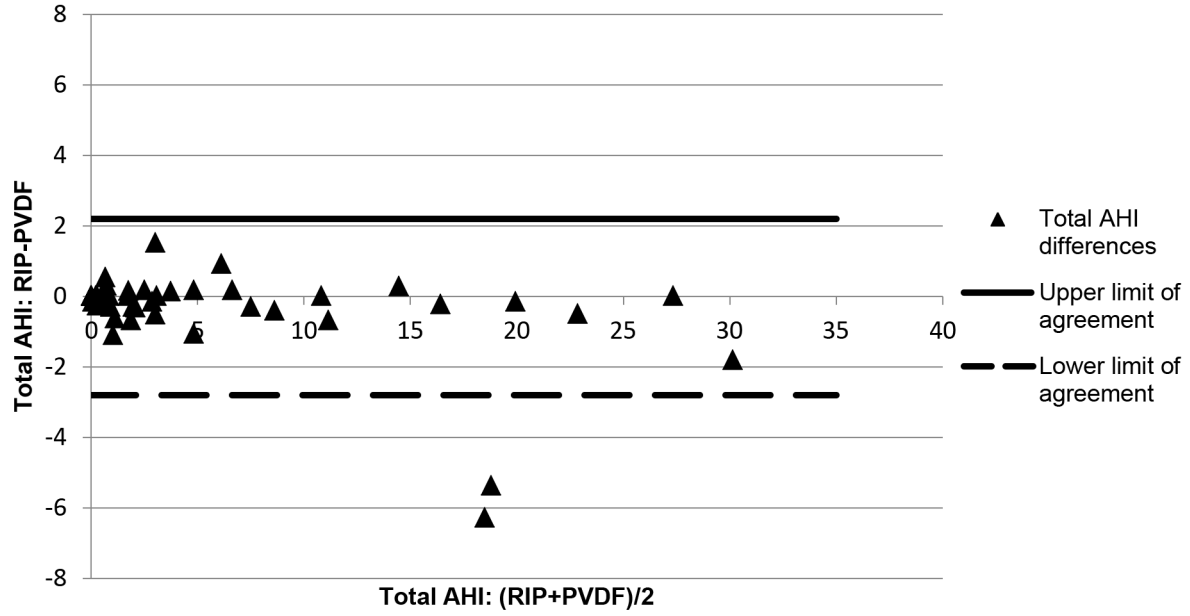
ADHD = attention deficit hyperactivity disorder, GERD = gastrointestinal reflux disease, HTN = hypertension, IUGR = intrauterine growth restriction, OSA = obstructive sleep apnea.

Table 2—Mean bias (d), upper limit of agreement (d + 2 SD), lower limit of agreement (d − 2 SD), number of total studies reviewed (total n = 50, obesity subgroup n = 20), and 95% confidence intervals for limits of agreement for Bland-Altman analysis

	Total AHI Differences	Obstructive Apneas Differences	Hypopneas Differences	Obesity Subgroup Total AHI Differences	Obesity Subgroup Central Apneas Differences
Mean bias (d)	−0.31	−0.16	−1.05	−0.59	−0.05
d + 2 SD	2.15	1.93	8.49	3.13	1.60
d − 2 SD	−2.77	−2.25	−10.60	−4.31	−1.70
Number of studies (n)	50.00	50.00	50.00	20.00	20.00
95% CI for lower limit	−3.37, −2.17	−2.76, −1.73	−12.94, −8.26	−5.75, −2.87	−2.34, −1.06
95% CI for upper limit	1.55, 2.75	1.42, 2.44	6.15, 10.83	1.69, 4.57	0.96, 2.24

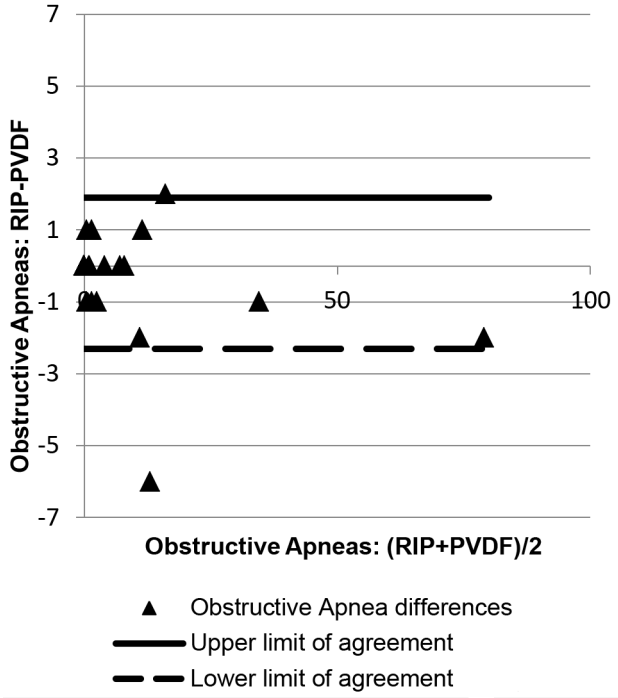
AHI = apnea-hypopnea index, CI = confidence interval, SD = standard deviation.

Figure 1—Bland-Altman plot illustrating the extent of agreement in total apnea-hypopnea index (AHI) by montage, respiratory inductance plethysmography (RIP) versus polyvinylidene fluoride (PVDF) belts.



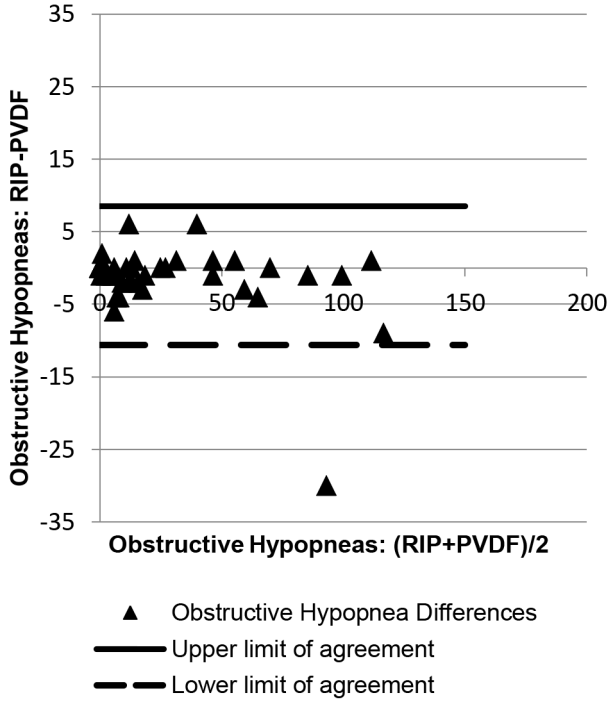
For total AHI, the mean bias (and 95% confidence interval) was −0.31 (−0.66, 0.04), the lower limit (mean bias − 2 standard deviations) was −2.77 (−3.37, −2.17), and the upper limit (mean bias + 2 standard deviations) was 2.15 (1.55, 2.75).

Figure 2—Bland-Altman plot illustrating the extent of agreement in obstructive apnea detection by montage, respiratory inductance plethysmography (RIP) versus polyvinylidene fluoride (PVDF) belts.



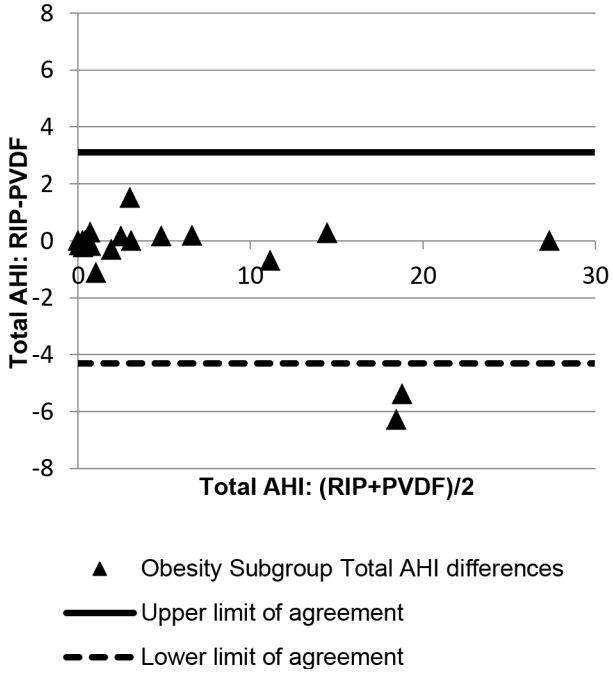
For obstructive apnea, the mean bias (and 95% confidence interval) was −0.16 (−0.45, 0.14), the lower limit (mean bias − 2 standard deviations) was −2.25 (−2.76, −1.73), and the upper limit (mean bias + 2 standard deviations) was 1.93 (1.42, 2.44).

Figure 3—Bland-Altman plot illustrating the extent of agreement in obstructive hypopnea detection by montage, respiratory inductance plethysmography (RIP) versus polyvinylidene fluoride (PVDF) belts.



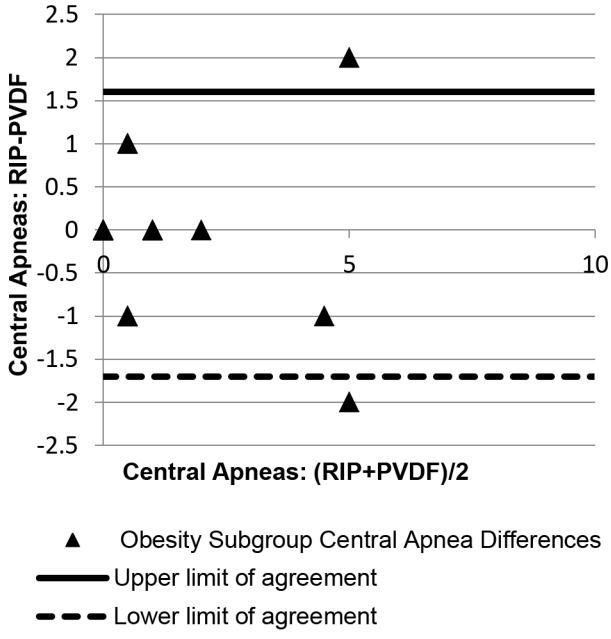
For obstructive hypopneas, the mean bias (and 95% confidence interval) was −1.05 (−2.40, 0.30), the lower limit (mean bias − 2 standard deviations) was −10.6 (−12.94, −8.26), and the upper limit (mean bias + 2 standard deviations) was 8.49 (6.15, 10.83).

Figure 4—Obesity Subgroup Bland-Altman Analysis demonstrating the extent of agreement in total apnea-hypopnea index (AHI) by montage, respiratory inductance plethysmography (RIP) versus polyvinylidene fluoride (PVDF) belts.



For total AHI in obese subjects, the mean bias (and 95% CI) was −0.59 (−1.42, 0.24), the lower limit (mean bias − 2 standard deviations) was −4.31 (−5.75, −2.87), and the upper limit (mean bias + 2 standard deviations) was 3.13 (1.69, 4.57).

Figure 5—Obesity Subgroup Bland-Altman Analysis demonstrating the extent of agreement in central apnea detection by montage, respiratory inductance plethysmography (RIP) versus polyvinylidene fluoride (PVDF) belts.



For central apneas in obese subjects, the mean bias (and 95% CI) was −0.05 (−0.42, 0.32), the lower limit (mean bias − 2 standard deviations) was −1.70 (−2.34, −1.06), and the upper limit (mean bias + 2 standard deviations) was 1.60 (0.96, 2.24).

significant systematic bias. However, there was wider scatter of the data for the scoring of obstructive hypopneas overall in either direction (revealing no systematic bias), and weaker agreement was demonstrated as five comparisons crossed our clinical threshold of importance of ± 5 events. Hypopneas are often difficult events to score[1] and belt type may not simplify that process for sleep medicine physicians. The subgroup analysis of PSG scoring agreement in obese subjects was comparable to that seen in the larger sample, with the exception of wider limits of agreement by the 2 SD criteria and increase in outliers. Given the small sample size of the obesity subgroup, a larger sample in the future may help demonstrate whether or not systematic bias would be present in that population.

Parents of infants and developmentally delayed children often find polysomnographic testing to be distressing as their children may not sleep well, even with the least disruption possible during testing. As volitional study participation and cooperation in pediatric polysomnographic testing is challenging, obtaining valid results with proper belt function is essential in avoiding repeated studies.

PVDF has been shown to demonstrate strong piezoelectricity to induce a dipole moment and can be manufactured into thin films. When the film is stretched, the molecular chains orient under tension. Unlike other piezoelectric sensors and

Table 3—Comparison of percent artifact by montage.

	Mean ± SD	Median	Correlation
RIP	10.9% ± 22.5%	1.0%	−0.076 (NS)
PVDF	10.5% ± 19.5%	3.3%	

NS = not significant; PVDF = polyvinylidene fluoride; RIP = respiratory inductance plethysmography; SD = standard deviation.

strain gauges, PVDF compresses instead of expands (and expands instead of compresses when exposed to the same electrical field), making its stability a desirable feature.[8] It should be noted that this is not the first application of PVDF technology in pediatric polysomnography. PVDF airflow sensors are a recommended modality for monitoring of airflow in both adult and pediatric patients according to the update of The AASM Manual for the Scoring of Sleep and Associated Events.[1] However, this application of PVDF technology in respiratory effort sensing belts was not recommended at the time of that publication.

Polysomnographic study of children poses some challenges that are distinct from those seen in adults. Classification of severity of SDB is more conservative in pediatric patients than in adults.[7,9] Pediatric PSG scoring classifies greater severity of SDB based on frequency of events than scoring based on the

adult recommendations for the same frequency of events. Unlike in adults, obstructive events are rare in children[1] (highlighting the importance of equipment accuracy for result validity and reproducibility).

Classification of disease severity should not be limited to AHI scoring, and treatment thresholds remain controversial.[7,9–13] However, the recent American Academy of Pediatrics (AAP) Clinical Practice Guideline for pediatric obstructive sleep apnea diagnosis and management[7] discusses considering pharmacotherapy in residual SDB that is designated as mild based on AHI cutoff. Our results emphasize the point that caution should be used in interpreting PSG results in its contribution to disease severity classification in clinical practice.

Contrary to our hypothesis that less artifact would be detected using PVDFb than with the use of RIPb, quantity of artifact was not statistically different. Although the amount of recorded artifact was comparable, it did not always occur in overlapping periods for PVDFb and RIPb, suggesting perhaps subtle differences in each belt's susceptibility to artifact and signal disturbance.

Limitations to our study were identified. Many of our subjects had relatively mild SDB, which may have skewed our results due to fewer apnea or hypopnea events for analysis. Outliers existed between the two belt types. Nonetheless, they were not associated with poor technical quality or signaling uses. Additionally, our study was not designed to look at how often the registered polysomnographic technologist interrupted testing to reposition PVDF versus RIP belts. Our center does not use summation belt effort data as a surrogate for airflow, and thus belt summation data were not analyzed in this study. In the pediatric population it would be helpful to look at belt agreement in a larger sample of subjects with skeletal deformities because our study was limited in number of such individuals. Furthermore, overall this was a small cohort comparing relatively new equipment and we are unable to comment on whether either belt type would more likely become damaged or unusable overtime. A difference in cost and durability may be present. Analysis of price differential and durability was beyond the scope of this project but may be an important consideration in employing various methodologies in the sleep laboratory.

CONCLUSIONS

Our study demonstrated that PVDFb appeared to be as effective as the currently recommended RIPb in detection of respiratory effort and events in children. Further, the quantity of artifact was comparable between PVDFb and RIPb. Therefore, when used in conjunction with additional standard polysomnographic monitoring equipment, PVDFb can be considered acceptable sensors for pediatric use.

ABBREVIATIONS

AASM, American Academy of Sleep Medicine
ADHD, attention deficit hyperactivity disorder
AHI, apnea-hypopnea index
CI, confidence interval
ECG, electrocardiography
EEG, electroencephalography
EMG, electromyography
EOG, electrooculography
GERD, gastrointestinal reflux disease
HFF, high-frequency filter
HTN, hypertension
IUGR, intrauterine growth restriction
LFF, low-frequency filter
OSA, obstructive sleep apnea
pCO_2, carbon dioxide partial pressure
PSG, polysomnogram
PTAF, pressure transducer air flow
PVDF, polyvinylidene fluoride
PVDFb, polyvinylidene fluoride belts
RIP, respiratory inductance plethysmography
RIPb, respiratory inductance plethysmography belts
SD, standard deviation
SDB, sleep-disordered breathing
SpO_2, oxyhemoglobin saturation
TST, total sleep time

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DISCLOSURE STATEMENT

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