



## Weighted Blanket Use as an Alternative to Protective Stabilization During Moderate Sedation

Mackensie McBeain, DDS<sup>1</sup> • Sydney Malone<sup>2</sup> • Robert S. Jones, DDS, PhD<sup>3</sup>

**Abstract:** ***Purpose:** The purpose of this retrospective cross-sectional study was to examine protective stabilization (PS) patterns before and after the availability of weighted blankets (WBs) as a behavioral guidance approach during in-office dental moderate sedation. **Methods:** A retrospective chart review evaluated pediatric patient sedation records after six-pound lead-free WBs were introduced into the dental clinic and compared clinical outcomes to a time before WBs were available. Multivariable logistic regression analyses assessed variables associated with the occurrence of PS use during a sedation visit. **Results:** PS (PS) usage decreased from 78.7 percent before to 32.8 percent after the availability of WBs during sedation visits (chi-square,  $P < 0.001$ ). Increase in age (adjusted odds ratio [OR] equals 0.69, 95 percent confidence interval [95% CI] equals 0.53 to 0.90,  $P = 0.006$ ) and WB use reduced PS management (adjusted OR equals 0.067, 95% CI equals 0.020 to 0.22,  $P < 0.001$ ). Body mass index, gender, treatment amount, and sedation regimen did not predict the occurrence of PS. The number of completed teeth treated was not found to be statistically different between cases managed with PS versus those managed without restraint. Children managed with PS but without WBs had statistically higher heart rate changes ( $20.26 \pm 23.17$ ) during treatment than children managed without restraint ( $8.12 \pm 15.15$ ). **Conclusions:** An increase in age and weighted blanket use was associated with a reduction in the occurrence of protective stabilization during moderate sedation dental visits at the university pediatric dental clinic. Clinical practice sedation protocols should consider weighted blanket use as an alternative to PS. (Pediatr Dent 2022;44(5):340-4) Received May 23, 2022 | Last Revision September 2, 2022 | Accepted September 3, 2022*

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Pediatric patient behavior can be managed with pharmacological treatment to minimize dental anxiety and uncooperative behavior.<sup>1</sup> Severely uncooperative and physically resistant behavior that impedes successful oral rehabilitation can be effectively managed through general anesthesia, given the full loss of consciousness.<sup>2-4</sup> Despite the weak evidence for sedation effectiveness with the use of various drug regimens, moderate (conscious) sedation continues to be utilized for the management of children.<sup>5-8</sup> For moderate sedation, behavior guidance efficacy is less predictable than general anesthesia. Due to the unpredictability of dental treatment using moderate sedation, sedation visits often utilize protective stabilization (PS) for behavioral guidance. PS is an advanced behavioral guidance technique. The overall use and acceptance of PS is over 50 percent for surveyed board-certified pediatric dentists.<sup>9</sup> For moderate sedation visits, studies in the United States (US) and Brazil demonstrate the prevalence of PS use to be 51 percent and 70 percent, respectively.<sup>10,11</sup> The American Academy of Pediatric Dentistry endorses PS use for limited treatment and for a sedated patient who needs "limited stabilization to help reduce untoward movements during treatment."<sup>9,12</sup>

Parental acceptability of PS, as a standalone behavioral guidance option, is well documented to be among the lowest accepted management techniques, alongside voice control.<sup>13</sup> This low acceptance is shared across racial and ethnic groups (African American, Asian, Caucasian, and Hispanic) in the US and is ranked behind minimal to moderate sedation.<sup>14</sup> It has been shown that parents are more accepting of PS if there is a prior usage of stabilization.<sup>14</sup> In the case of moderate sedation, children often have had previous PS. While the acceptance of PS coupled with moderate sedation techniques is not well characterized against other forms of behavior guidance options, parental satisfaction was found to be higher in cases where moderate sedation was used without the use of PS.<sup>10</sup> The majority of parents (75 percent) believe that PS should not be necessary during a sedation visit.<sup>15</sup>

The usage of weighted blankets (WBs) during dental moderate sedation is an unexplored behavior guidance technique in pediatric dentistry. There have been studies examining WBs, in the form of regular dental X-ray lead vests, used within a comprehensive adaptive sensory intervention, that involve additional auditory and visual stimulation.<sup>16-18</sup> This intervention, termed sensory adapted dental environment (SDE), was first applied to neurotypical developed children with dental anxiety undergoing routine dental cleaning.<sup>16</sup> Compared with traditional management, children managed with SDE were more relaxed based on behavioral and psychophysiological measures.<sup>16</sup> Outside of dentistry, occupational therapists report using WBs to address pediatric sleep disturbances, although the present level of evidence for effectiveness is inconclusive.<sup>19</sup> While the evidence for sleep improvement as a result of WBs is still emerging with current clinical trials, qualitative studies support high parental satisfaction with using WBs as a sleep aid in sleep-disturbed children.<sup>20</sup> Systematic reviews report no adverse events with their use at home.<sup>19</sup>

<sup>1</sup>Dr. McBeain is an adjunct assistant professor; <sup>2</sup>Dr. Malone is a fourth year dental student; and <sup>3</sup>Dr. Jones is an associate professor, all in the Division of Pediatric Dentistry, Department of Surgical and Developmental Sciences, School of Dentistry, University of Minnesota, Minneapolis, Minn., USA.

Correspond with Dr. Jones at rsjones@umn.edu

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The purpose of this study was to determine if the availability and use of weighted blankets are associated with an overall reduction in the utilization of protective stabilization during moderate sedation visits. A retrospective review of moderate sedation visits at the University of Minnesota pediatric dental clinic examined PS patterns before and after the availability of WBs. Additional goals of the study were to assess patient and treatment-related factors associated with potential changes to restraint usage.

## Methods

Pediatric dental records of sedation visits at the University of Minnesota, Minneapolis, Minn., USA, between 2018 and 2019 and 2020 and 2021 were chosen for review after Institutional Review Board (IRB) approval. Inclusion criteria included dental visits that billed moderate sedation (CDT code D9248) between September 1 through the end of February. This six-month period represented the second half of the pediatric dental resident's sedation training experience. During this period, pediatric dental resident operators were well educated in office-based sedation protocols and familiar with behavior guidance techniques.

The specific years studied correspond to a time before and after WBs were available for use in routine and sedation-based operative care. An implementation science approach was undertaken where PS (medical immobilization) use during sedation visits was assessed during the years before and after the availability of WBs with self-holding straps (Dr.B.Essential, Flagstaff, Ari., USA). The purchased WBs were introduced to the residency program in August 2020 with a dedicated instruction for use presentation. The WBs were lead-free and weighed six pounds with the addition of 54 sealed plastic poly bags of micro-glass beads. These poly bags were stitched inside a polyurethane/nylon fabric (23 inches by 34 inches) with the addition of inner self-holding straps allowing children to voluntarily hold the blanket toward their body and self-engage in tactile sensory stimulation. Infection control between patients, as verified by clinic protocol, followed the manufacturer's recommended two-step disinfection, beginning with mild surface disinfection followed by biocidal disinfection wipe application (CaviWipes, Metrex Research, Romulus, Mich., USA).

All clinic charts that attempted treatment using moderate sedation were included in the analysis from September 1, 2020, through February 28, 2021, which represented the period after WB clinic introduction, and compared to a historic reference, September 1, 2018, through February 28, 2019. Demographic information was collected and included age, gender, weight, height, and calculated BMI. Insurance coverage and racial/ethnicity data were not collected. There were no changes to insurance acceptance for the clinic during the periods examined. Sedation medication type and local anesthesia dosage were recorded. In cases where more than one sedation medication was utilized, the combination of drugs was categorized into sedation regimen groups. Vital signs including heart rate (HR) and oxygen saturation, measured via pulse oximetry and recorded in real-time by the sedation monitoring resident during the treatment appointment, were collected.

Clinic charts collected oxygen saturation during appointments with an ordinal scoring measurement: at least 96 percent (score two), at least 92 but less than 96 percent (score one), and less than 92 percent (score zero). Level of consciousness (ordinal scoring), active stabilization use, and duration were transcribed from charts for analysis. For the 2020 to 2021 period, WB use and duration were also included. While real-time sedation

monitoring was recorded at five-minute intervals in chart documents, the review transcribed these vitals at 15-minute perioperative intervals up to 90 minutes after sedation medication administration, in addition to pre-/postoperative time points. Charts did not include systematic adverse event reporting, but a section for side effects and treatment notes were examined for descriptions of adverse events. Charts included records of resident sedation workups that consisted of initial treatment plans for the sedation visit. The extent of dental treatment and total treatment time was also used for analysis.

Sedation appointment data were summarized using the number of patients who had no restraint (free/none), PS, and self-holding strap WBs. Chi-square tests were used for the categorical data. Logistical regression analysis examined variables associated with the occurrence of PS during a sedation visit. A two-step approach was used. Univariable logistic regression analyses were first modeled separately for age, BMI, gender, number of treatment planned teeth, sedation regimens, and WB use. The unweighted odds ratio (ORs), 95 percent confidence intervals (95% CIs) for the ORs, and *P*-values were summarized for preliminary analysis. In the second step, a multivariable logistic regression model was used where all variables were entered into the model followed by sequential removal of non-significant variables. The backward elimination procedure removed variables in the model if the associated significance level was greater than *P*=0.15. Adjusted ORs were calculated with the multivariable model for all significant variables (*P*<0.05) that predicted the occurrence of PS. Analysis of variance and pairwise comparison (Tukey-Kramer) were used to compare outcome variables (treatment duration, number of teeth completed, and heart rate changes from baseline) between behavioral guidance techniques (free/no restraint, PS, and weighted blanket).

For heart rate changes, level of consciousness was used to select interactive children (scores greater than zero, with zero meaning non-responsive to verbal commands) with the behavioral guidance technique comparison to adjust for any profound sedation effects. Data analysis was performed using MedCalc 20.027 software (MedCalc Software Ltd, Ostend, Belgium).

## Results

Descriptive statistics regarding the total number of children who were seen for sedation visits between 2018 and 2019 and between 2020 and 2021 periods are shown in Table 1. The data includes the total number of children who were managed with PS, WBs, or the absence of the aforementioned techniques (free/none). PS was utilized in 78.7 percent of all (*N* equals 61) sedation visits examined during the 2018 to 2019 period, with the remainder of the visits being children managed free from

Table 1. DESCRIPTIVE ANALYSIS OF SEDATION VISITS AND BEHAVIORAL GUIDANCE

Variable	2018-2019	2020-2021	<i>P</i> -value*
Sedation visits	61	64	
Free/none	13	19	0.29
Weighted blanket (WB)	**	24†	
Protective stabilization (PS)	48	21	<0.001‡

\* *P*-values obtained by chi-square test.

\*\* Weighted blanket implemented in 2020.

† 28 WBs cases were attempted, with four converting to and included in PS.

‡ PS versus absence of PS (free+WBs) between periods.

**Table 2. UNIVARIABLE AND MULTIVARIABLE LOGISTIC REGRESSION MODELS TO PREDICT THE OCCURRENCE OF PROTECTIVE STABILIZATION USE DURING SEDATION VISIT**

Variable	Odds ratio (95% CI)*	P-value**	Adjusted odds ratio (95% CI)	P-value†
Age	0.75 (0.60-0.95)	0.015	0.69 (0.53-0.90)	0.006
BMI	1.01 (1.00-1.02)	0.15		
Gender	1.17 (0.58-2.37)	0.66		
Teeth (#) planned	0.92 (0.76-1.12)	0.41		
sedation regimen	1.01 (0.81-1.27)	0.91		
Weighted blanket	0.082 (0.026-0.26)	<0.001	0.067 (0.020-0.22)	<0.001

\* CI=confidence interval.  
 \*\* Univariable logistic regression analysis.  
 † Multivariable logistic regression analysis.

**Table 3. COMPARISON OF BEHAVIORAL GUIDANCE OPTIONS WITH TREATMENT OUTCOME VARIABLES (MEAN±STANDARD DEVIATION)**

Variable	Free/none	Weighted blanket (WB)	Protective stabilization (PS)	P-value*
Age (years)	7.4±2.0**	6.5±1.7	6.3±1.4**	0.006
Treatment duration (min)	42.03±22.71	41.9±18.1	49.8±19.6	0.11
Teeth (#) completed	4.44±2.46	4.1±1.4	4.0±1.6	0.47
Heart rate change (beats/min)†	8.12±15.15**	11.8±19.2	20.3±23.2**	0.037

\* P-values obtained by analysis of variance.  
 \*\* Different P<0.05, Tukey-Kramer pairwise comparison.  
 † Heart rate change from baseline at 30-minute treatment time point; analysis did not include cases completed before 30 minutes (free=4, WBs=0, PS=3) and measurements not recorded at baseline or at 30 minutes (free=3, WBs=0, PS=11).

passive restraint. Use of PS decreased to 32.8 percent of all (N equals 64) sedation visits during the 2020 to 2021 period, with the remainder of the visits being children who managed with WBs (37.5 percent) or who were free of restraint (29.7 percent). Chi-square analysis rejected the null hypothesis that PS use was no different between the periods studied. A clarification of this analysis (Table 1) is that 28 patients were initially managed with WBs between 2020 and 2021, with only four of the 28 WB cases (14 percent) converting to PS management. These four cases were included in the PS category. A total of 24 children (37.5 percent) were exclusively managed throughout the entire visit with WBs.

Table 2 summarizes the univariable logistic regression analyses assessing variables associated with the occurrence of PS use during a sedation visit. Using an initial threshold of P<0.15, age and the use of WB were significantly associated with the occurrence of PS. The univariable analyses were used to screen for variables in the multivariable logistic regression model (Table 2). An increase in the age of a child reduced the occurrence of PS in the multivariable model (adjusted odds ratio [OR] equals 0.69, 95% CI equals 0.53 to 0.90, P=0.006). The use of a

WB also reduced PS management (adjusted OR equals 0.067, 95% CI equals 0.020 to 0.22, P<0.001). Chart analysis identified six main sedation regimens (single/multidrug) used in the pediatric dental clinic that incorporated midazolam (alone/multi), meperidine (multi), dexmedetomidine (multi), and hydroxyzine (multi). The type of sedation regimen, along with variables such as BMI, gender, and the number of teeth initially treatment planned, were not associated with predicting the occurrence of PS (medical immobilization). The Hosmer and Lemeshow goodness-of-fit test indicated a sufficient fit (P=0.77) for the logistic regression model.

Children who were managed free (none) of any restraint were older (7.40±1.96 years old [mean±standard deviation]) than those requiring PS (6.28±1.38 years old). A pairwise comparison (Tukey-Kramer test) between those groups indicated statistical significance (P<0.05), with no differences found between those two management options and children managed with WBs (6.52±1.68 years old). Table 3 summarizes a comparison of outcome variables and the behavioral guidance options of using free/none, WBs, and PS. Treatment duration and the number of teeth completed during the sedation visit did not differ between the three behavioral guidance techniques. For HR assessment, level of consciousness data were used to control for sedative effects. Two cases out of the 125 cases had children who were not interactive with verbal commands and, thus, were not included in the analysis comparing heart rate changes between the three behavioral guidance techniques. In the remaining cases for assessing HR change 30 minutes after treatment was initiated, the analysis did not include cases that were completed before 30 minutes (free equals four, WBs equal zero, PS equals three) or in cases where there was an absence of measurements at baseline or at 30 minutes (free equals three, WBs equals zero, PS equals 11).

The absence of measurements was associated with behavior notes indicating uncooperative behavior for free, WB, and PS-managed visits. For those children whose heart rates were recorded, children who required PS had a statistically (P<0.05) higher heart rate change from baseline (20.26±23.17 beats per minute) versus those children who were freely managed (8.12±15.15 beats per minute). Children who were managed with WBs had a heart rate change of 11.83±19.16 beats per minute from baseline, but this was not found to be significantly different than HR changes observed with children managed with PS or free of any intervention. The choice of sedation regimens did not influence (data not shown) heart rate (P=0.11). For all 125 sedation cases, there were no time intervals transcribed at 15-minute intervals where there was oxygen desaturation below 96 percent.

**Discussion**

This retrospective evaluation of moderate sedation visits at the University of Minnesota pediatric dental clinic determined that PS patterns decreased after the availability of WBs. This investigation examined WB use within the context of a comprehensive behavioral guidance plan for children requiring moderate sedation. Medical imaging studies have shown that WBs can positively contribute to multi-technique intervention protocols that attempt to limit patient movement.<sup>21</sup> Children managed with moderate sedation are often managed in the University of Minnesota pediatric dental clinic with the assistance of numerous supplemental behavioral guidance techniques, such as tell-show-do, positive reinforcement, and voice control; however,

chart notes were not able to reconstruct the full breadth of various supplemental interventions. In terms of supplemental sensory interventions, aspects of SDE were applied to normal sedation protocols, such as light dimming; others, such as color light projection, had not been used due to potential counter-productive effects in sedated children where medications can cause visual disturbances.<sup>22</sup>

When comparing the level of evidence between the current study and SDE interventions, a few points need clarification. SDE interventions have undergone prospective clinical trials to demonstrate SDE's positive behavioral guidance effects in neurotypical developed children and children living with autism.<sup>16,18</sup> While the prospective trial evidence is rigorous in those studies, the SDE intervention has been studied during routine dental cleaning and not during restorative procedures. There are real-world challenges to investigating WB efficacy in the US during restorative operative procedures and comparing efficacy to PS. The addition of moderate sedation to those procedures increases the difficulty of performing prospective trials. First, since the use of PS is not a voluntary method, the ethics of randomization is influenced. Second, the findings of the present study brings to question past practices of highly frequent PS use during sedation. After the availability of WBs, providers in the present study were able to manage substantially fewer children with PS, and only 14 percent of WB cases converted to PS. The amount of treatment accomplished was equivalent between WBs and PS. Third, moderate sedation drugs/regimens, except for oral midazolam alone, are used "off-label" in terms of FDA regulation. IRB authorization of any future prospective trial studying WBs during sedation would be extremely difficult without the prior approval of an investigator new drug application for each of the sedation regimens employed. Any prospective trial would have to involve a more targeted assessment of WBs with specific drug regimens or instead examine routine restorative care with nitrous oxide-only sedation.

The results of this study, where PS decreased from 78.7 percent to 32.8 percent, appear generalizable to moderate sedation outside of the university clinic since the choice of sedation regimens did not predict PS usage. One of the main sedation regimens (N equals 48) used was oral (PO) meperidine and hydroxyzine combined with either PO or intranasal (IN) midazolam. Another combination involved PO midazolam with IN dexmedetomidine (N equals 10). While intranasal dexmedetomidine may cause bradycardia, the effects have been shown in other studies to be transient.<sup>23</sup> This may explain why the heart rate changes from baseline to 30 minutes into treatment between the six sedation regimens were not found to be statistically different. Sedation medications illicit a wide response in children, which contributes to the difficulty in assessing sedation efficacy between medication types and sedation regimens.<sup>2</sup>

The study results suggest that the six-pound WBs did not affect patient oxygen concentrations, as measured by pulse oximetry, during sedations where the majority of cases had supplemental oxygen with nitrous oxide. While these results are suggestive of the safety of WBs, additional information, such as more precise pulse oximetry examination (five-minute intervals) and ventilation rate measured through capnography, was not available for analysis. Capnography was not routinely used during moderate sedation in the studied clinic. Vital sign data also demonstrated that some children managed with WBs had elevated, but not statistically different, heart rates when compared to children managed with free/no intervention. While

heart rate changes can be viewed as a proxy for distressed behavior, the analysis does have limitations since PS or WB use may influence the magnitude of stress and heart rate changes.

The relaxing effects of WB-induced pressure are an area of interest in medical-based studies, which examines the hypothesis that deep pressure can affect a superficial C-tactile afferent system that mediates pleasantness.<sup>24</sup> Future studies that examine heart rate differences between free/none and WBs need to consider the small mean difference in beats per minute (3.71, Table 3) with children managed by each intervention and their large standard deviations. The sample size needed for a future moderate sedation-based study between heart rate changes seen in free versus WBs, which would examine the relaxing/calming effects, would be 342 patients in each of the two behavior groups, based on a power calculation that considers type I (0.05) and type II (0.2, one-power) error.

The results of this study indicate that more investigation into the behavior guidance of WBs is warranted. The current study did not assess how effective WBs were at reducing the movement of children during moderate sedation. Future examinations of patient movement with and without the adjunct use of sedation medications are required and potentially helpful in the field. The current investigation has limitations as a retrospective chart analysis that is subject to bias and is inferior to a prospective design. Future studies, especially those examining WB use during routine operative procedures, can adopt a randomized clinical trial design. Future work is also needed to assess the long-term durability of this brand of WBs with an inner component of separate sealed pouches. Future studies should also directly assess the prevalence of children using inner self-holding straps to voluntarily hold the blanket toward their body and self-engage in tactile sensory stimulation. For the present study, while providers were educated about the inner straps of the WBs and instructing children to use them, the chart notes did not include details on the child's usage of the inner strap of the WBs. While parental acceptance of PS has been measured in previous studies to be low,<sup>13,14</sup> future studies should also address parental acceptance and patient fear, comfort, and acceptance of WB use during moderate sedation.

Despite the need for future studies, the present study suggests that the high usage of PS during moderate sedation visits requires re-evaluation. Given the new availability of WBs in the marketplace and parental adoption of these devices for even at-home use,<sup>25</sup> clinicians should consider WBs as a preemptive behavioral guidance option in children undergoing moderate sedation.

## Conclusions

Based on this study's results, the following conclusions can be made:

1. Increase in age and weighted blanket use was associated with a reduction in the use of protective stabilization during moderate sedation dental visits at the pediatric dental clinic of the University of Minnesota, Minneapolis, Minn., USA.
2. Management by WBs was highly accepted by patients, and only rarely was more definitive PS necessary.
3. Additional randomized controlled trials are needed to assess the efficacy of behavioral guidance with WBs; however, clinical practice sedation protocols should consider weighted blanket use as an alternative to PS.



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