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Quantifiying the Depth of Oral Sedation Using Bispectral Index Monitoring

John Flowers
Virginia Commonwealth University

QUANTIFYING THE DEPTH OF ORAL SEDATION USING BISPECTRAL INDEX MONITORING.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science at Virginia Commonwealth University.

by

JOHN ALAN FLOWERS
B.S. James Madison University, 2002
D.D.S. Virginia Commonwealth University, 2006

Director: TEGWYN H. BRICKHOUSE D.D.S., PH.D.
ASSISTANT PROFESSOR, DEPARTMENT OF PEDIATRIC DENTISTRY

Virginia Commonwealth University
Richmond, Virginia
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Abstract

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By John A. Flowers B.S., D.D.S

A thesis submitted in partial fulfillment of the requirements for the degree of Masters of Science at Virginia Commonwealth University.

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Major Director: Tegwyn H. Brickhouse, D.D.S.,Ph.D.
Department of Pediatric Dentistry

Purpose: To determine whether Bispectral Index Monitoring is an effective tool for quantifying sedation depth after the administration of oral drug regimens in children.

Methods: This retrospective study reviewed the charts of 75 children who received oral conscious sedation for dental treatment. Data collected from the chart included; 1) BIS values at 5 minute intervals and at five critical events: pre-operative, local anesthesia delivery, rubber dam placement (if utilized), during operative treatment, and postoperatively, 2) behavior ratings at the five critical events and an overall behavior

assessment, 3) treatment data, and 4) demographic data. Results: The mean BIS value for orally sedation children in this study was 84.53 (SD = 5.76). The mean overall sedation assessment was 2.04 (SD = 1.16). No significant correlation was found between BIS values and behavioral ratings.

Conclusion: The BIS monitor provided limited information regarding the depth of sedation in children undergoing oral sedation for dental treatment.

Introduction

Tooth decay is currently the most common chronic disease affecting children in the United States.[1] The disease affects approximately 60% of our nation's youth.[2] An estimated 51 million school hours are lost each year as a result of dental caries.[3] Children present with varying degrees of tooth decay, some requiring extensive dental rehabilitation. The chronological and developmental age of many of these patients necessitates the use of moderate sedation in order to provide dental treatment in a safe and controlled manner.[4]

Moderate sedation is defined by the American Academy of Pediatric Dentistry (AAPD) as "a drug induced depression of consciousness during which patients respond purposefully to verbal commands…" with "no interventions required to maintain a patent airway".[2] Moderate sedation has become an invaluable tool utilized by pediatric dentists to facilitate efficient, safe, and quality dental care to children, adolescents, and patients with special health care needs.

Patients under moderate sedation are able to respond to verbal commands and light tactile stimulation. For younger patients, age-appropriate behaviors such as crying, often occur and are expected. With moderate sedation, a patient's airway is stabilized without intervention and ventilation is adequate. Cardiovascular function is usually maintained without aid. The sedation of children may have serious risks associated with each procedure. These include hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment. With appropriate physiologic monitoring and observation by a person not directly involved with the procedure, these risks can be minimized and also allow for rapid diagnosis if complications should occur.[2, 5]

There are five main goals of sedation in the pediatric patient. These are: 1) to guard the patient's safety and welfare; 2) to minimize physical discomfort and pain; 3) to control anxiety, minimize psychological trauma, and maximize the potential for amnesia; 4) to control behavior and/or movement so as to allow the safe completion of the procedure; and 5) to return the patient to a state in which safe discharge from medical supervision is possible.[2] In order to comply with these guidelines, patients are physiologically monitored before, during, and after a procedure. The patient's oxygen saturation, heart rate, respiratory rate, and blood pressure are continuously monitored and recorded every five minutes to ensure the patient maintains optimal levels while sedated. While these monitors verify a patient's current physiological state, they do not indicate the depth of sedation that is induced by the drugs administered. In young children, too light of sedation will fall short of reducing anxiety and pain for the patient, while over sedation may result in serious effects such as respiratory depression. Clinicians have resorted to using subjective methods of patient reaction to verbal commands and painful stimuli to determine the level of sedation; however these measures are very challenging to determine in children.[6]

The success of dental treatment with the use of oral sedation can be measured with varying criteria such as the presence of adverse events and ratings of patient behavior. Some adverse events are minor and have little effect on the treatment being rendered. Yet other more severe adverse events can dramatically affect patient safety. Events such as upper airway obstruction, vomiting and laryngospasm leading to oxygen desaturation and respiratory compromise all increase the likelihood of medical emergencies and complications.[7-8] While current AAPD monitoring protocols help to identify and prevent adverse events, such monitoring does not offer a means to quantitatively measure the depth of sedation.

A device called the bispectral index monitor (BIS), has been used to quantitatively measure the level of sedation of a patient. This monitor, originally designed for general anesthesia cases to monitor awareness under sedation, may provide useful and relevant information in assessing the depths of conscious sedation procedures with children.

The Bispectral Index (BIS, *Aspect Medical Systems*©) monitor utilizes electroencephalogram signals to measure depth of sedation on a unitless scale from 0 to 100 (0=coma, 100=awake).[6] The index score correlates with the level of awareness in anesthetized/sedated patients. BIS values below 40 are defined as a "deep hypnotic state, values between 40 and 60 are observed during surgical (general) anesthesia, 60-70 during "deep sedation", and 70-100 in light/moderate sedation.[8,10] Non-medicated, awake patients have BIS values at or above 93.[11] A visual representation of this scale can be found in Figure 1.

The use of the BIS monitor has been shown to reduce the emergence time from general anesthesia, reduce the frequency of anesthetic agent dosing errors, and reduce costs of sedation procedures.[10, 13-14] In 2004, "the BIS monitor received an FDA approved indication for reducing the incidence of intraoperative awareness during general anesthesia (510(k) #K030267)."[11] In addition, several reports have documented the use of Bispectral index monitoring in dental offices, intensive care units, and outpatient surgery centers.[11]

The BIS was initially designed to evaluate the effect of anesthetic agents in the adult population and for years it was believed that the BIS was not useful in the pediatric population due to the fact that the neurophysiology of children is constantly changing and maturing.[6, 15-16] Recently, published reports have validated the use of BIS monitoring in pediatric patients and have also shown a significant association between BIS values and observed behaviors in orally sedated children.[16, 17]

A recent study done by Sadhasivam et al, designed to validate the use of the BIS monitor in children, concluded that the BIS monitor has many advantages over observational sedation scoring methods. The bispectral was determined to be objective, quantitative, free from observer bias, and easy to use.[18, 19] Sadhasivam's study used a wide array of sedative drugs and evaluated both invasive and noninvasive procedures.

Previous studies have identified the correlation between BIS levels and the COMFORT (Calmness, Movement, Facial Tension, Respiratory response, and Muscle Tone) scale in children.[20-21] In 2005, Twite et al. identified a significant correlation between the BIS and the COMFORT scale in pediatric intensive care unit patients. Patients in this study were intubated and mechanically ventilated throughout the study. The mean age of patients in this study was 10 months and 25% of the patients were under 6 months of age. Although significant correlation between the BIS and

COMFORT scale were found, it is difficult to assess the application of these results to the orally sedated pediatric patient in the dental setting. Patients who are intubated and mechanically ventilated are sedated to a much greater depth than orally sedated dental patients. Another consideration is that patient's in Twite's were much younger than most patients sedated for dental treatment.

The Richmond Agitation-Sedation Scale (RASS) and the Observers Assessment of Awareness/Sedation (OAA/S) have also been correlated with BIS readings in the adult population.[16, 22-23] In 2003, Ely et al. compared BIS readings to the Richmond Agitation-Sedation Scale (RASS) in 124 mechanically ventilated intensive care unit patients over the course of 382 days. This study found significant correlation ($r = 0.64$) between BIS values and RASS scores over a range of levels of arousal from alert to coma ($P<.001$).

In 1997, Glass et al. examined the relationships between BIS values and a parenterally sedated patient's ability to recall a specific picture or word. The response was measured by the Observers Assessment of Awareness/Sedation Scale. The examiners also compared the OAAS scale to plasma drug concentrations in the same patients. The authors concluded that BIS scores correlated ($r = 0.883$) significantly better than the measured drug concentrations and that bispectral index monitoring provided "an excellent prediction of the loss of consciousness".[23] There is still limited data that correlates BIS values with observational behavior scales in pediatric patients sedated using oral medications.[24]

In 2002, Religa et al sought to find an association between the use of the BIS monitor in pediatric patients undergoing oral conscious sedations for operative dental treatment and the behavior of the patient.[17] Their results showed that there was a significant association between observed patient behaviors and levels of sedation. They also concluded that the BIS monitor did not appear to be a more valid means of monitoring sedation depth than the current commonly accepted methods. However at the time of their study, there were no pediatric electrodes available to use, causing numerous problems in data collection. One limitation of the study was lack of a baseline BIS measurement for the patient. Religa suggested that “acquisition of baseline data in frightened children may not be possible but should be investigated in future studies involving the BIS monitor”. In a similar study by Overly et al. results showed that the BIS correlated well with a Visual Analog Scale (VAS) and the Observer’s Assessment and Alertness/Sedation Scale (OAA/S), an observational pediatric sedation scale in parenterally sedated patients.[16]

By knowing the patient’s BIS level, it may be possible to assess the depth of sedation of the patient and accurately predict the overall success and outcome of a sedation procedure both physiologically and with respect to behavior. “A reliable monitor of anesthetic depth should display a good correlation between the measured value and the physiologic response during surgery…”[12] Further studies are needed to prove the validity and success of the BIS monitor’s use in pediatric conscious sedations and how the BIS monitor may correlate, if at all, to a patient’s behavior and successful sedation outcomes.

Several indices have been used to describe patient behavior in oral conscious sedation; the Frankl Scale, the Ohio State Behavior Rating Scale, Ramsay and the Briekopf and Buttner Scales.[25-26] The modified version of the North Carolina Behavior Rating Scale (NCBRS) has been used to objectively assess the behavior of orally sedated pediatric patients in the dental setting.[27] In 2006, Sheroan et al. utilized the NCBRS to compare the effect of two different oral sedation drug regimens on pediatric dental patients. Although the authors found no significant difference in behavior between the two drug regimens, the NCBRS displayed a high degree of reliability between observers. This observational scale allows an observer to rate a patient on a scale of four descriptive criteria: (1) quiet, (2) annoyed, (3) upset, or (4) wild. Each of these values can be used to describe behaviors at specific events/times, as well as to gauge the overall behavior throughout the dental appointment. A "quiet" patient is described as one who is quiet and/or sleeping with only extraneous, inconsequential movements. These movements are minimal and do not affect the delivery of care. An "annoyed" patient is cooperative for treatment, but exhibits one or two undesirable behaviors. An undesirable behavior consists of crying, screaming, head movement, torso movement, and/or limb movements that deter from the delivery of safe, quality treatment. "Upset" patients are noticeably disturbed, with two to three of the undesirable behaviors present, making treatment difficult but possible. Lastly, a "wild" patient is extremely defiant with presence of all undesirable behaviors, making treatment extremely difficult or not possible (Table 1). Patients are evaluated at five critical events throughout the procedure. The first critical event, labeled "preoperative," is the time period between the placement of patient monitors until the delivery of local anesthesia. The second critical event is the delivery of local anesthesia. The third event is the placement of a rubber dam, if utilized, and specifically is the time point at which the rubber dam clamp is being placed on the tooth. The fourth event represents the "operative" period during which there is bur to tooth contact. The final critical event is termed "postoperative" and is the portion of the appointment that occurs between the end of treatment and removal of the patient from the operatory. (Table 1)

The purpose of this study was to quantify the level of sedation attained after the administration of oral sedative drug regimens using the Bispectral Index Monitor (BIS) and examine whether BIS values correspond to behavioral ratings during the procedure and overall sedation outcomes as measured by a modified version of the North Carolina Behavior Rating Scale.

Materials and Methods

Study Design

This was a retrospective chart review of seventy five patients who chose oral/moderate sedation for their dental treatment from the Department of Pediatric Dentistry at the Virginia Commonwealth University School of Dentistry. The inclusion criteria were all children who had received oral conscious sedation between November 1, 2007 and May 2008.

Patient Sample and Data Collection

Data collection was initiated at the chart level for patients receiving dental treatment under oral/moderate sedation between the specified dates. The list of variables extracted from the chart included a baseline bispectral index value (BIS) prior to the administration of oral drug regimens, and values every five minutes throughout the procedure. Subsequent BIS measurements and behavioral ratings were documented at the following critical events during the procedure: preoperative, delivery of local anesthesia as part of care, rubber dam placement (if utilized), during the operative procedure, and postoperative. The demographic data collected consisted of the child's ethnicity, sex, and age at the time of sedation appointment. Control variables collected were: the American Society of Anesthesiologists Classification of physical status (ASA), duration of treatment, number of sextants restored and type of dental treatment performed. A complete list of variables gathered can be found in Table 2. All data collection and analysis was performed within the confines of the VCU School of Dentistry Department of Pediatric Dentistry. Each patient was assigned a case number with no individual identifying information. Charts of both male and female patients were analyzed and the study was open to the charts of all ethnic groups. This study was approved for human subjects by the Virginia Commonwealth University Institutional Review Board.

Sedation Procedure

Patients included in the study required dental treatment under the current American Academy of Pediatric Dentistry (AAPD) guidelines for moderate sedation. Each patient followed current AAPD preoperative protocols for moderate sedation. The Bispectral Index Monitor (BIS) was used during the sedation appointment as part of routine monitoring. The BIS monitor was attached prior to administering the sedation medication to obtain a baseline score. Once a baseline value was obtained, the patient and parent/guardian waited in the operatory to allow time for the oral medications to be absorbed. A pediatric dentistry resident remained in the room to ensure safety while the medications took affect. Depending on the medication regimen used, this time period ranged from 20 to 60 minutes. At this time additional monitors consisting of a pulse oximeter, blood pressure cuff and precordial stethoscope were attached. Vital signs were continuously monitored and recorded every five minutes throughout the procedure. The BIS values were recorded at 5 minute intervals during the course of the procedure and documented at critical events during the operation period: preoperative, delivery of local anesthesia, rubber dam placement (if utilized), during the operative procedure, and postoperative. The values for the BIS and vitals signs were recorded by a monitor not involved in the dental treatment. The operator providing dental care was blinded to the BIS values during treatment. The patient was recovered in the operatory and released once appropriate discharge criteria were met. Following completion of the procedure the operator completed a modified version of the North Carolina Behavior Rating Scale on each sedation to assess the patient's behavior during the same critical events: preoperative, delivery of local anesthesia, rubber dam placement (if utilized), during the operative procedure, and postoperative. The observer rated each patient on a scale of four descriptive criteria: (1) quiet, (2) annoyed, (3) upset, or (4) wild (Table 1). Additionally, an overall assessment of the sedation outcome was recorded using ratings 1 through 4: 1) Satisfactory; 2) Moderately successful; 3) Mildly successful; and 4) Unsuccessful.

Statistical Analysis

The principle outcome variables were the overall scores of sedation behavior and behavior ratings at critical events. The main explanatory variables were the mean BIS value for the procedure and BIS values at critical events. The power analysis revealed that a 0.050 two-sided test of the null hypothesis that the Pearson correlation coefficient $r = 0$, will have > 80% power to detect an r of 0.33 when the sample size is 75. Descriptive statistics such as group means were calculated at critical events and for the overall mean BIS values. A repeated-measures mixed-model ANOVA was then used to compare the

BIS levels and behavioral ratings across the five events. A Pearson's correlation statistic was used to compare overall mean BIS values to the overall behavior rating. A reapeated-measures ANOVA with effects for behavior and critical event was completed to examine the association between the BIS scores and behavioral ratings. The statistical analysis was completed using SAS JMP Software Version 7.0.1 for Windows.[28]

Results

Of the seventy five charts reviewed for the study, 60% were female and 40% were male. Fifty-two percent of the patients were identified as African American, 32% Caucasian, and 15% Hispanic. The range of ages of patients treated under moderate sedation was 2-15 years (mean 5.39 years, SD = 2.43).

The mean duration time of sedation treatment was 36 minutes (SD = 23). In 61% of the sedations, two or more sextants received treatment. In seven sedations (9%), no treatment rendered due to behavior and the sedation aborted. Restorative procedures and extractions were the most common dental procedures performed. Restorative treatment was delivered in 76% of cases while extractions were performed in 32% of cases. Pulp therapy and surgical procedures occurred in 9% and 4% of sedations, respectively (Table 3). The drug regimens of chloral hydrate/ meperidine/ hydroxyzine (CH/M/H) or midazolam/ meperidine/ hydroxyzine (M/M/H) accounted for 69% of the sedation drug regimens used in these cases (Table 4).

BIS Values

The mean baseline BIS value obtained prior to the administration of oral medications was 94.55 (SD = 4.99) with a range from 71 to 98. The average BIS values after medication throughout the procedure was 84.53 with a SD of 5.76, with a range of

72 to 96. The mean baseline BIS value obtained prior to the administration of oral drug regimens was compared to the mean preoperative BIS value of 98.40 (SD = 8.31). The difference between these values was found to be significant (paired t-test = 8.07, $p<.0001$) (Table 5).

Figure 2 shows the BIS readings across time. A repeated measures regression model was used to indicate the time trend. Fitting a quadratic function to the BIS values, we see in Figure 2 (BIS across time) that the values decreased until approximately 45 minutes and then increased d ($F (2, 541) = 7.91$, $p = 0.0004$). Note that the number of observed values decreased considerably after one hour.

Mean BIS values at the critical events were as follows. Mean BIS value pre-operative was 84.27 (SD = 0.90). Mean BIS values for delivery of local anesthesia, rubber dam placement, and during operative treatment were 85.47 (SD = 0.99), 85.94 (SD = 1.54), and 82.99 (SD = 0.92), respectively. The mean post-operative BIS value was 85.51 (SD = 0.91). A repeated-measures mixed-model ANOVA was then used to compare the BIS level across the five events. BIS was not significantly different across the five events. The summary results are shown in Table 6 and Figure 3.

Behavioral Ratings

The behavioral ratings across the five events were as follows. The mean NCBRS ratings for pre-operative, delivery of local anesthesia, rubber dam placement, during operative treatment were 1.45 (SD 0.11), 1.92 (SD = 0.12), 1.92 (SD = 0.18), and 2.01 (SD = 0.12) respectively. The mean post-op NCBRS rating was 1.64 (SD = 0.11) and the mean overall NCBRS was 2.08 (SD = 1.21). These results can be seen in Table 7 and Figure 4. The NCBRS values were also compared across the five events and found to be different. Although nominally highest, the RD value is not significantly different than any other (by Tukey's HSD). Preoperative NCBRS values were found to be significantly lower than the values during the delivery of local anesthesia and during operative treatment. There were no other significant differences (Table 7 and Figure 4).

Correlations

The repeated measures ANOVA analysis with effects for behavior and critical events indicated that there was no significant difference between behavior ratings and the mean BIS, after accounting for event differences. As may be seen in the figure below, there is no relationship between BIS and the behavior ratings (p-value = 0.5456). After adjusting for event differences (p value=.0559) the estimated correlation between BIS and NCBRS across all five critical events was 0.108 (Figure 5).

The relationship between the overall mean BIS and the overall NCBRS was also not significant with a correlation of 0.043 and significance of probability equal to 0.7167 (Table 8).

Discussion

This study examined values from a Bispectral Index monitor that were recorded at specific time intervals as well as at key events during the sedation procedure compared to behavior ratings at critical events during the sedation procedures of children receiving dental treatment. This study differs from previous research by Overly and Religa in two areas. First, patients in the Overly study were treated under intravenous sedation in which medications were titrated to effect by the surgeon during the procedure based on the patients' "appearance of alertness and discomfort."[15] Our study sought to evaluate the effect of a single dose of medication administered orally. Second, Religa compared BIS readings with two observational behavior scales, a pre-operative scale, and a second scale used intra-operatively.[16] These scales classified a patient as either quiet, sleeping, crying only, or crying and struggling. The behavior oberservations in Religa's study were collected at the same five critical events used in this study; pre-operative, delivery of local anesthesia, rubber dam placement, during operative treatment, and post-operatively. Although the same events were used, no reference was made as to the relationship between the observed behaviors (quiet, sleeping, crying only, or crying and struggling) and the effect of the child's movement (NCBRS) on the dental treatment during the events.

The mean baseline BIS value obtained prior to the administration of oral medications in this sample was 94.55 (SD = 4.99) and ranged from 71-98. This mean value is consistent with the work by Johansen who found that non-medicated awake patients display BIS values at or above 93. As seen in Table 5, the mean baseline BIS values prior to medication was significantly higher than the mean preoperative BIS value after medication (p<.0001). As expected, the data show that orally sedated patients display BIS values which fall into the category of "light/moderate sedation. The mean BIS value observed in this study throughout treatment was 84.53 (SD = 5.76) regardless of the medication regimen used. This is consistent with previously published reports by Leeubbehusen and Religa for conscious/moderate sedation who found BIS values between 70 and 100 for moderately sedated patients.[16, 28] Mean BIS values were observed to decrease for the first 45 minutes following the initiation of treatment after which there was a steady rise in BIS values. The steady decrease could be due to the patient becoming less stimulated once oral tissues were locally anesthetized and/or due to increases in plasma drug concentrations over time. As the body begins to process and metabolize these medications resulting in a decrease in plasma concentrations, the level of sedation would also decrease resulting in a more alert/aware patient and higher BIS scores. This would help to explain the rise in BIS values after 45 minutes into treatment.

The mean BIS values at the critical events can be found in Table 6. Mean BIS values were found to be somewhat different across the five critical events. The data reveal that the highest BIS values during treatment occurred during placement of a rubber dam (85.94, SD = 1.54). This can be explained by the fact that this event is very stimulating to the patient and such stimulation can evoke an increase mental awareness and brain activity. The mean BIS value during the operative period was 82.99 (SD = 0.92). While it may be suspected that operative treatment would actually evoke the highest level of BIS activity, the proper use of local anesthesia, inhalation of nitrous oxide, and the inclusion of a narcotic (Meperidine) in the drug regimen all contribute to reduce oral sensitivity and in turn, reduce potential stimuli to the patient. Though the mean BIS values across the five critical events differed, they were borderline according to statistical significance ($p=0.0685$).

The mean behavioral (NCBRS) results across the five events can be seen in Table 7. The mean NCBRS ratings for pre-operative, delivery of local anesthesia, rubber dam placement, during operative treatment were 1.45 (SD 0.11), 1.92 (SD = 0.12), 1.92 (SD = 0.18), and 2.01 (SD = 0.12) respectively. This data shows that operative treatment resulted in the highest mean NCBRS rating. Analysis of the data revealed that preoperative NCBRS values were found to be significantly lower than the values during the delivery of local anesthesia and during operative treatment. There were no other significant differences. The mean overall NCBRS was 2.04 (SD = 1.16).

The cases reviewed in this study resulted in contradictory data regarding the operative event. Recall that this event had the lowest mean BIS score (82.99, SD = 0.92), but also displayed the highest mean behavior rating (2.01, SD = 0.12). The BIS values recorded during the operative period were not averaged across the event, but rather were recorded at a single point. It is possible that this value could have been recorded at the very instant the operative period began and thus might not reflect the true BIS scores over the entire event. In contrast, the behavior rating was based on a subjective assessment by the operator based on the patient's behavior across the operative period. Had a mean BIS score been recorded during this event, it is possible that the BIS values and behavior scores may have a stronger correlation.

A repeated-measures ANOVA analysis of BIS by behavioral rating found no relationship between the two. The correlation between the mean BIS and the overall behavior rating; (1) Satisfactory; 2) Moderately successful; 3) Mildly successful; and 4) Unsuccessful) was also not significant.

Limitations

A limitation of this study was that BIS values were not recorded during the time interval between baseline (the administration of oral medications) and the initiation of dental treatment. Were this data available, it may provide the practitioner with a very specific physiologic indicator of how long a particular drug regimen will take to reduce the patient's level of awareness. Such data could be used to determine the time of onset for particular medications or combinations and possibly be used to predict the overall success or failure of a sedation appointment.

Values from the Bispectral Index monitor were recorded at specific time intervals as well as at key events during the sedation procedure; pre-operative, delivery of local anesthesia, placement of a rubber dam, during operative treatment, and post-operatively. In this study, BIS values and behavior ratings were not recorded during the time period between the administration of oral medications and the beginning of treatment. A modified version of the North Carolina Behavior Rating Scale was also used to measure sedation behavior at critical events. When examining four of the five events; pre-operative, delivery of local anesthesia, placement of a rubber dam, and postoperative, one can see that each of these occurs within a relatively short period of time, perhaps thirty to sixty seconds. In contrast to this, the "operative" event takes course over a range of time lasting several minutes and in some cases over one hour. BIS values were not averaged across this time but rather were recorded at a single time point within the operative period that was randomly chosen by individual monitoring the sedation. It is therefore possible that the mean BIS value for the operative period reported in this study is not an accurate reflection of intraoperative sedation for orally sedated patients.

The work of Johansen et al. ascertained that the BIS monitor is not perpetually perfect and can be altered due to artifact from EMG activity and BIS sensor dislodgement with excessive movement by the patient. Moreover, significant electromyographic activity may be present in sedated patients, which could interfere with EEG signal acquisition and alter the BIS reading. EMG activity can be interpreted as waves showing high frequency, low amplitude, which raises the BIS number. At any given time if the BIS monitor reads high EMG activity, it is possible that the BIS number is artificially elevated as a result.[10] Luebbehusen found the most frequent sources of unreliable BIS data to be the result of artifact created by muscle activity of the patient's face, forehead and extraocular muscles. There is no way to control for this in orally sedated patients. Other factors that can contribute to either patient stimulation or artifact as measured by the BIS include dental handpieces, suction devices, and head movement by the operator. It is not possible to measure the effect these factors had on the recorded data.

Several different drug regimens were used in this selection of patients (Table 4). The two most common regimens were chloral hydrate/ meperidine/ hydroxyzine (CH/M/H) and midazolam/ meperidine/ hydroxyzine (M/M/H), which were utilized in 69% of the cases. An area of future research could be to determine if different oral drug regimens used in pediatric dentistry produce differences in BIS values. There were no significant correlations between BIS values and behavior ratings for any period of dental treatment. There is a possibility that BIS scores and or behavior ratings may differ according to drug regimen but this study did not have a sufficient sample size to test for these differences.

Conclusions

This study examined the relationship between bispectral index (BIS) values and behavioral ratings for orally sedated pediatric dental patients. This data suggests that while the BIS monitor has a well documented ability to assess the level of awareness in sedated patients, it did not display a significant correlation with observed behaviors as scored by the North Carolina Behavior Rating Scale (NCBRS). The BIS monitor provided limited information regarding the depth of sedation in children undergoing oral sedation for dental treatment.

Literature Cited

Literature Cited

1. Filstrup SL, Briskie D, da Fonseca M, Lawrence L, Wandera A, Inglehart MR. Early Childhood Caries and Quality of Life: Child and Parent Perspectives. Pediatric Dentistry 25:5, p. 431-440, 2003.

2. American Academy of Pediatric Dentistry. Guideline on Monitoring and Management of Pediatric Patients During and After Sedations for Diagnostic and Therapeutic Procedures. Pediatric Dentistry. 29:7, p.134-151, 2007-08.

3. U.S. Department of Health and Human Services. *Oral Health in America. A Report of the Surgeon General.* Rockville, MD: National Institutes of Health. (Available at http://www.nidcr.nih.gov/sgr/execsumm.htm.) (2000).

4. American Academy of Pediatric Dentistry. Guideline on Behavior Guidance for the Pediatric Dental Patient. Pediatric Dentistry 29:7, p.115-124, 2007-08.

5. Litman RS, Kottra JA, Berkowitz RJ, Ward DS. Upper Airway Obstruction During Midazolam/Nitrous Oxide Sedation in Children with Enlarged Tonsils. Pediatric Dentistry 20:5, p. 318-320, 1998.

6. Agrawal D, Feldman HA, Krauss B, Walzman ML. Bispectral Index Monitoring Quantifies Depth of Sedation During Emergency Department Procedural Sedation and Analgesia in Children. Annals of Emergency Medicine. 43(2):247-55, Feb 2004.

7. Leelataweedwud P, Vann WF. Adverse Events and Outcomes of Conscious Sedation for Pediatric Patients. Journal of the American Dental Association. 132:1531-1539, 2001.

8. Cote CJ, Notterman, DA, Karl HW, Weinberg JA, McCloskey C. Adverse Sedation Events in Pediatrics: A Critical Incident Analysis of Contributing Factors. Pediatrics Vol. 105 No. 4, p. 805-814, 2000.

9. Gan TJ, Glass PS, Windsor A et al. Bispectral Index Monitoring Allows Faster Emergence and Improvd Recovery from Propofol, Alfentanil, and Nitrous Oxide Anesthesia. BIS Utility Study Group. Anesthesiology. 87 p. 808-815, 1997.

10. Luebbehusen ML. Bispectral Index Monitoring: No Longer Used Only in the OR, Bispectral Index Monitoring Can Now Be Used to Help Ensure That a Patient is Sedated Safely and Effectively. Technology Today. RN 68:50-56, 2005.

11. Johansen JW. Update on Bispectral Index Monitoring. Best Practice & Research Clinical Anesthesiology 20:81-89, 2006.

12. Chen X, Tang J, White PF, Wender RH, Ma H, Sloninsky A, Kariger R. A Comparison of Patient State Index and Bispectral Index Values During The Perioperative Period. Anes. Analg 95:1669-1674, 2002.

13. Messieha ZS, Ananda RC, Hoffman WE, Punwani IC, Koenig HM. Bispectral Index (BIS) monitoring reduces time to discharge in children requiring intramuscular sedation and general anesthesia for outpatient dental rehabilitation. Pediatric Dentistry 26:256-260, 2004.

14. Bonhomme V, Hans P. Monitoring depth of anesthesia: is it worth the effort? European Journal of Anaesthesiology 21:423-428, 2004.

15. Hsia SH, Wu CT, Wang HS, Yan DC, Chen SC. The Use of Bispectral Index to Monitor Unconcious Children. Pediatric Neurology. 31(1):20-3 2004.

16. Overly FL, Wright RO, Connor FA, Jay GD, Linakis, JG. Bispectral Analysis During Deep Sedation of Pediatric Oral Surgery Patients. Journal of Oral & Maxillofacial Surgery 63(2):215-9, 2005.

17. Religa ZC, Wilson S, Ganzberg SI, Casamassimo PS. Association Between Bispectral Analysis and Level of Conscious Sedation of Pediatric Dental Patients. Pediatric Dentistry 24(3) p. 221-6 2002.

18. Sadhasivam S, Ganesh A, Robison A, Kaye R, Watcha MF. Validation of the Bispectral Index Monitor for Measuring the Depth of Sedation in Children. Anesth Analg 102;(2) p. 383-388, 2006.

19. Motas D, McDermott NB, Vansickle T, Friesen RH. Depth of Conciousness and Deep Sedation attained in Children as Administered by Nonaneaesthesiologiests in a Children's Hospital. Pediatric Anesthesia 14:256-260, 2004.

20. Crain N, Slonim A, Pollac MM. Assessing sedation in the pediatric intensive care unit by using BIS and the COMFORT scale. Pediatric Critical Care Medicine 3:11-14, 2002.

21. Twite MD, BChir MB, Zuk J, Gralla J, Friesen R. Correlation of the Bispectral Index Monitor with the COMFORT Scale in the Pediatric Intensive Care Unit. Pediatric Critical Care Medicine 6:648-653, 2005.

22. Ely EW, Truman B, Shintani A, Thomason JWW, Wheeler AP, Gordon S, Francis J, Speroff T, Gautam S, Margolin R, Sessler CN, Ditus RS, Bernard GR. Monitoring Sedation Status Over Time in ICU Patients. Journal of the American Medical Association. Vol 289. p. 2983-2912, 2003.

23. Glass Ps, Bloom M, Kearse L et al. Bistpectral Analysis Measures Sedation and Memory Effects of Propofol Midazolam, Isoflurane, and Alfentanil in Healthy Volunteers. Anesthesiology 86:836-847, 1997.

24. McDermott NB, VanSickle T, Motas D et al. Validation of the Bispectral Index Monitor During Conscious and Deep Sedation in Children. Anesth Analg 97:39, 2003.

25. Torres-Pérez J, Tapia-Garcia I, Rosales-Berber MA, Hernandez-Sierra JF, Pozos-Guillén Ade J. Comparison of three conscious sedation regimens for pediatric dental patients. Journal of Clinical Pediatric Dentistry 31(3):183-186, 2007.

26. Wan K, Jing Q, Zhao JZEvaluation of Oral Midazolam as Conscious Sedation for Pediatric Patients in Oral Restoration. Chinese Medical Science Journal. 21(3):163-166, 2006.

27. Sheroan, MM, Dilley DC, Lucas WJ, Vann WF. A Prospective Study of 2 Sedation Regimens in Children: Chloral Hydrate, Meperidine, and Hydroxyzine Versus Midazolam, Meperidine and Hydroxyzine. Anes. Prog 53:83-90 2006.

28. SAS software version 7.0.1, JMP Software, Cary NC.

Table 1. Modified North Carolina Behavior Rating Scale (NCBRS) and Critical Evnts

Rating	*Behavior Criteria*
1	**Quiet-** patient quiet and/or sleeping with only extraneous, inconsequential movements
2	**Annoyed-** patient cooperative for treatment, but with one or two of the undesirable behaviors*
3	**Upset-** patient noticeably disturbed, with two to three undesirable behaviors* present, making treatment difficult but possible
4	**Wild-** patient extremely defiant with presence of all undesirable behaviors,* making treatment extremely difficult
	***An undesirable behavior consists of crying, screaming, head movement, torso movement, hand or foot movement at critical events.**
Critical Events	***Description***
Preoperative	Monitors being attached to topical anesthetic application
Local anesthetic delivery	Topical placement to rubber dam clamp placement
Rubber dam placement	Clamp placement to bur penetrating tooth
Operative	Bur penetrating tooth to rubber dam removal
Postoperative	Rubber dam removal to removal of child from the operatory

Table 2. Variables Collected from Patient Charts.

Variable	Parameter
Age	Years
Sex	Male or Female
Race	African American, Asian, Hispanic, Caucasian, Other.
Weight	Kilograms (kg)
ASA Status	I, II, III, IV, V, VI
Medications Used and Dosage	Chloral Hydrate, Meperidine, Hydroxizine, Midazolam, Halcion, Diazepam; mg/kg
BIS Values at 5 minute intervals	0-100
BIS Values at key events	0-100
North Carolina Behavior Rating Scale	See Table 1
Critical Events	See Table 1
Overall mean BIS	0-100
Overall mean NCBRS	0-100
Procedure Duration	Minutes
N Sextants Treated	1, 2, 3, 4, 5, 6,
Type of treatment	Restorative, extractions, pulp therapy, surgical treatment

Table 3. Patient Characteristics.

Characteristic		N	Percent
Sex			
	F	45	60
	M	30	40
Race			
	AA	39	52
	C	24	32
	H	11	15
Age			
	Mean	5.39	
	SD	2.43	
	Range	2 to 15	
	N	75	
ASA			
	1	64	85
	2	11	15
Interventions			
Procedure Duration			
	Mean	35.74	
	SD	22.88	
	Range	5 to 120	
	N	75	
		N	Percent
N Sextants			
	0	7	9
	1	22	30
	2	21	28
	3	13	18
	4	9	12
	5	2	3
Restorative			
	N	18	24
	Y	57	76
Extractions			
	N	51	68
	Y	24	32
PulpTx			
	N	68	91
	Y	7	9
SurgTx			
	N	72	96
	Y	3	4

Table 4. Frequencies of drug regimens.

Med Combos	**Count**	**Prob**
Chloral hydrate/ meperidine/ hydroxyzine	27	36%
Meperidine/ hydroxyzine/ midazolam	25	33%
Hydroxyzine/ midazolam	16	21%
Hydroxyzine/ triazolam	3	4%
Other	4	6%
Total	75	1

Other sedation regimens included diazepam only, diazepam/ meperidine/ hydroxyzine, or hydroxyzine only.

Table 5. Comparison of Baseline BIS values with Preoperative BIS values.

			BIS			
Event	n	Mean	SD	95%	CI	Range
Baseline	66	94.55	4.99	93.92	95.77	71 to 98
PreOp	70	84.4	8.31	82.42	86.38	63 to 98
Change	64	-9.7	9.62	-7.3	-12.11	

Paired t-test = 8.07, p<.0001

Table 6. Repeated Measures of BIS Scores

		BIS			
Event	n	LS Mean	SE	95%	CI
PreOp	70	84.27	0.90	82.50	86.04
Local	55	85.47	0.99	83.52	87.42
RD	19	85.94	1.54	82.9	88.97
OP	66	82.99	0.92	81.18	84.81
PostOp	69	85.51	0.91	83.72	87.29

F (4, 210.9) = 2.22 p-value = 0.0685

Table 7. Behavior Rating Scale Across Events.

		NCBRS			
Event	n	LS Mean	SE	95%	CI
PreOp	70	1.45	0.11	1.23	1.68
Local	55	1.92	0.12	1.68	2.16
RD	19	1.92	0.18	1.56	2.27
OP	66	2.01	0.12	1.78	2.23
PostOp	69	1.64	0.11	1.41	1.86

$F\ (4, 198.8) = 7.95$ p-value = $<.0001$

Table 8. Correlation between BIS and North Carolina Behavior Rating Scale

Variable	Mean	Std Dev	Correlation	Signif. Prob	Number
NCBRS	2.04	1.16	0.043	0.7167	75
BIS	84.53	5.76			

Figure 1. Bispectral Index Scale.

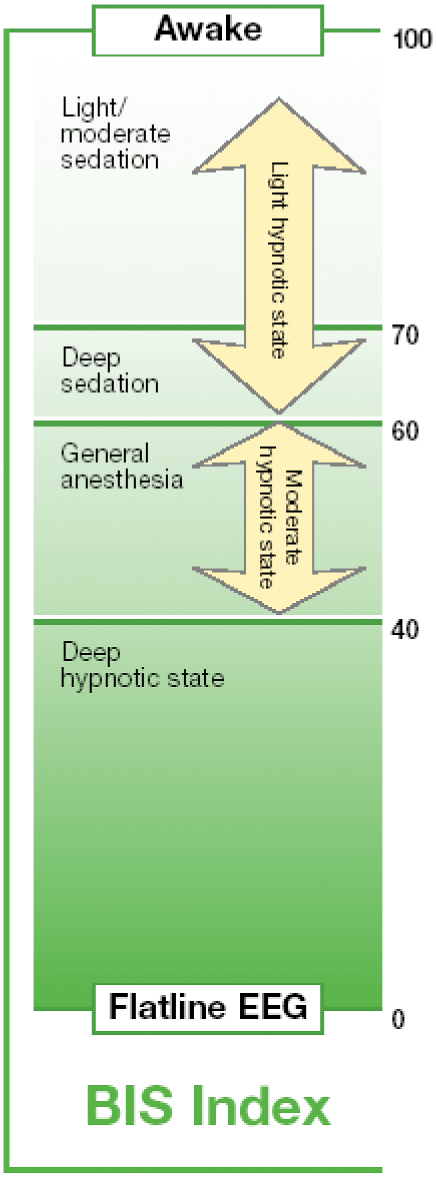


Image courtesy of Luebbehusen, 2005.

Figure 2: BIS across time

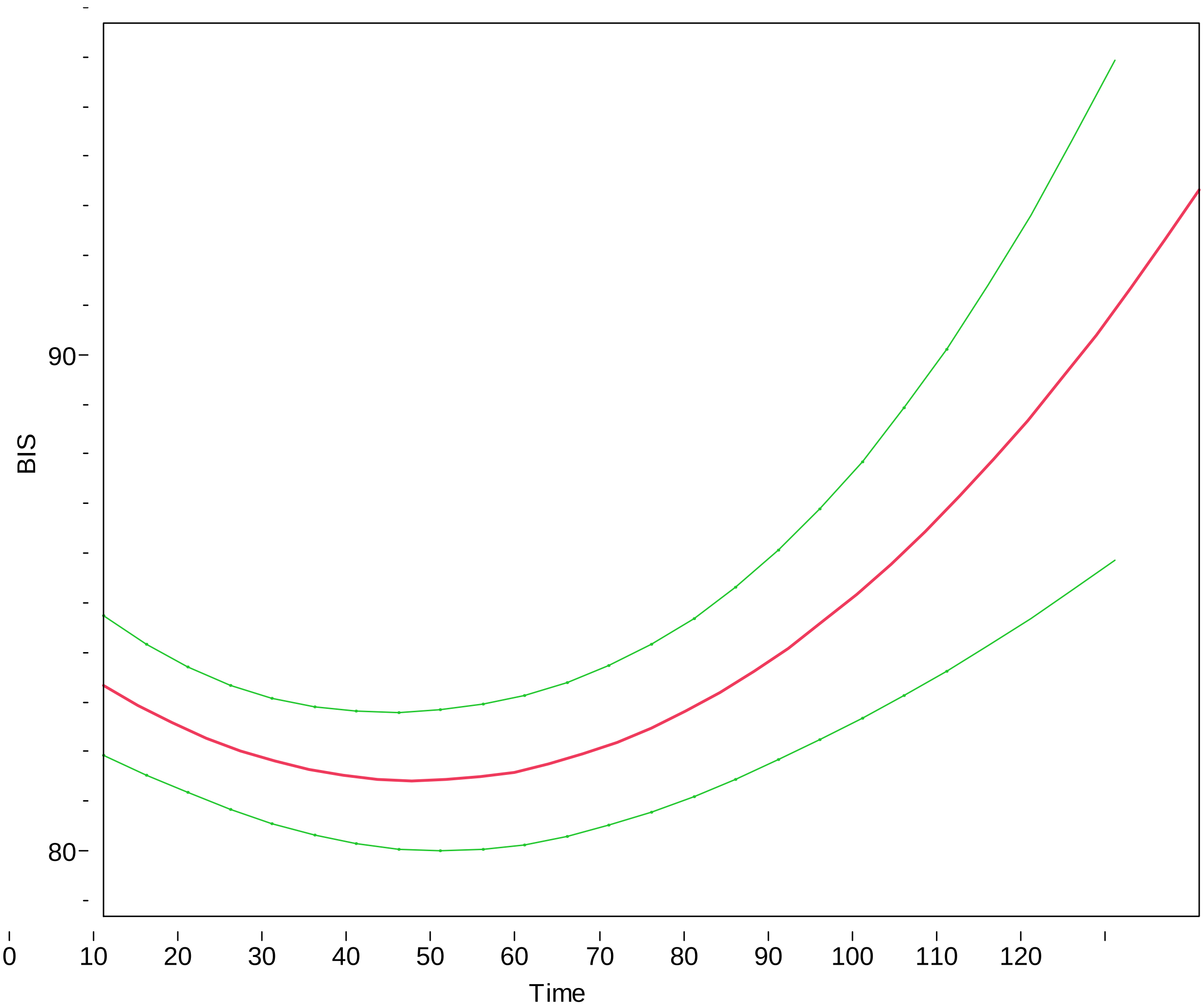


Figure 3: BIS across events

LS Means Plot

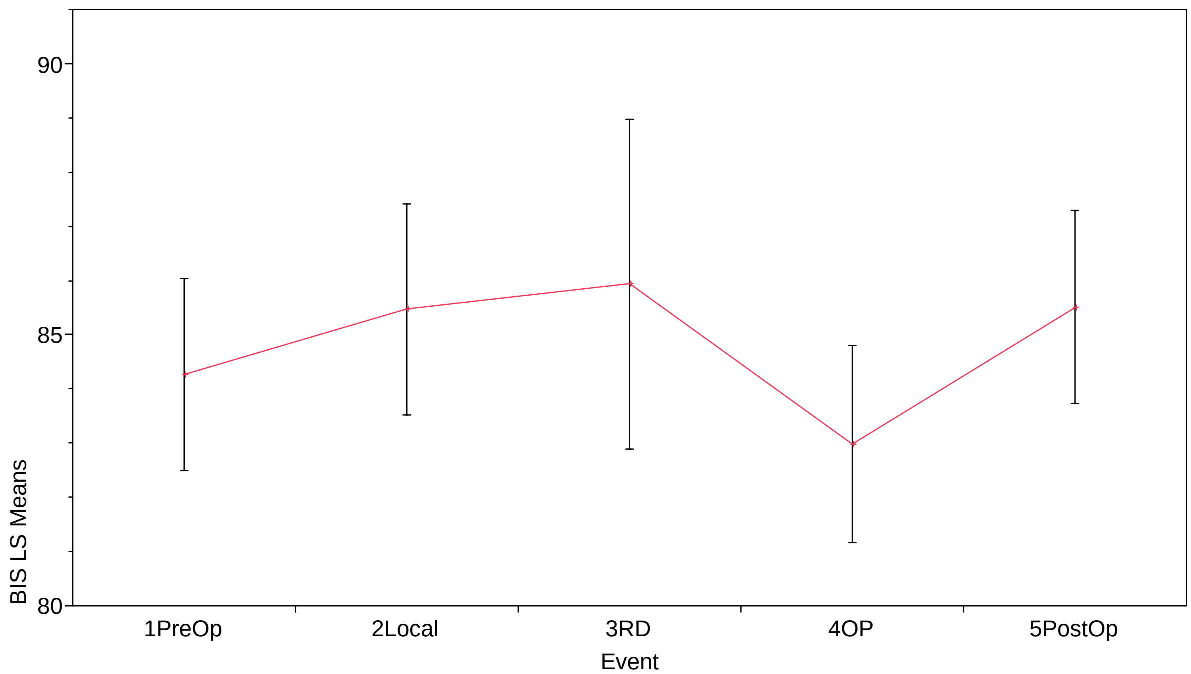


Figure 4. NCBRS Means Across Events.

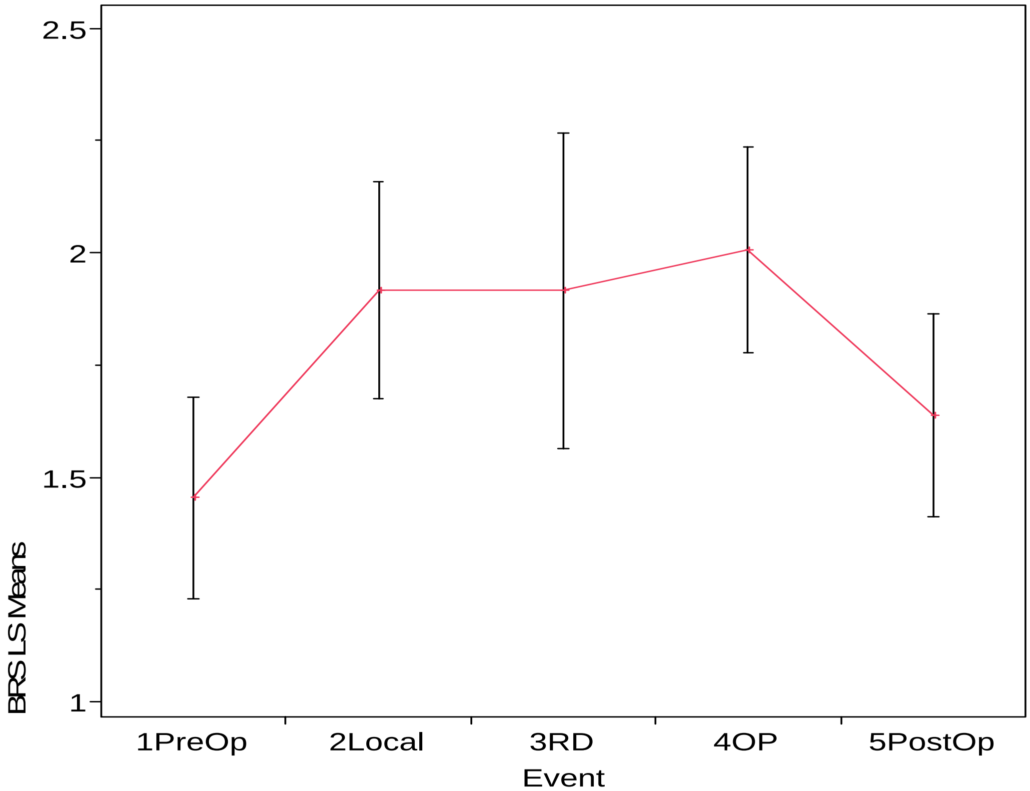
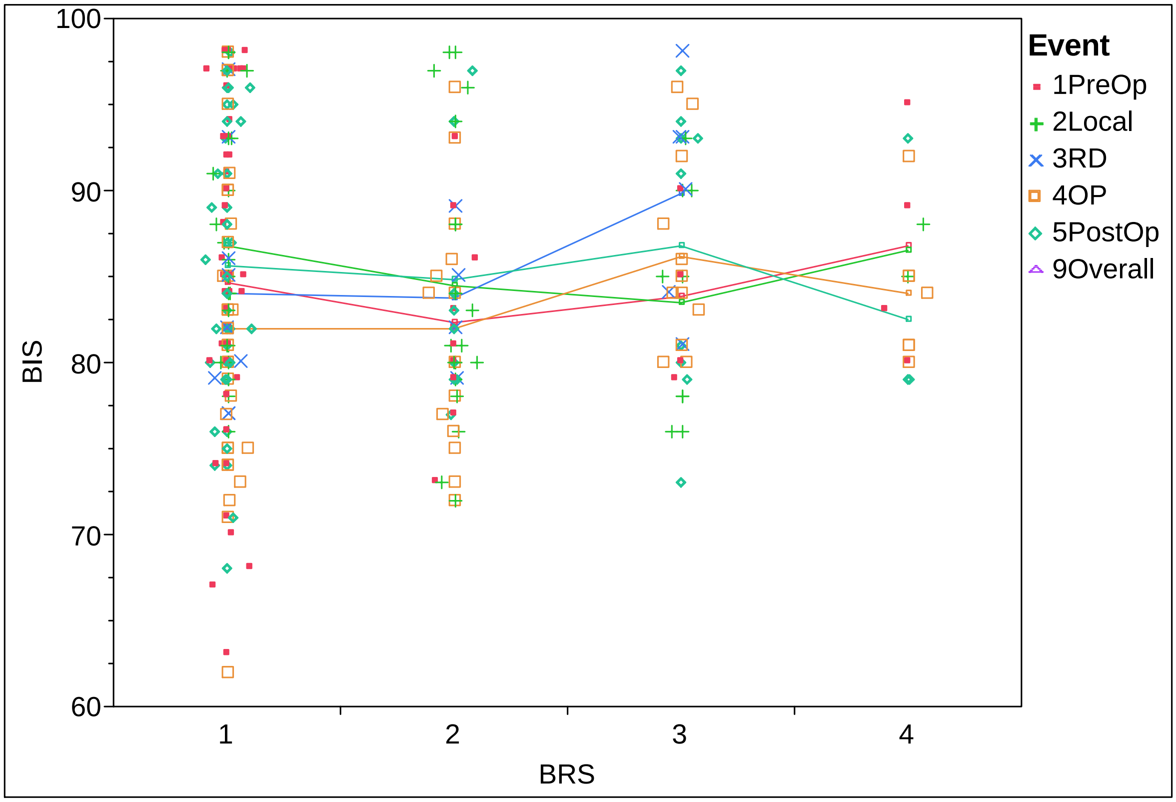


Figure 5. Oneway Analysis of BIS By North Carolina Behavior Rating Scale



VITA

John A. Flowers was born October 2, 1979 in Albuquerque, New Mexico. He graduated Hickory High School in Chesapeake, Virginia in June, 1998. He graduated James Madison University in 2002 earning a Bachelor of Science degree. Dr. Flowers graduated Magna Cum Laude from the Virginia Commonwealth University School of Dentistry in 2006.