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## Effect of Pediatric Ear Infections on Postural Stability

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LOMA LINDA UNIVERSITY  
School of Allied Health Professions  
in conjunction with the  
Faculty of Graduate Studies

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Effect of Pediatric Ear Infections on Postural Stability

by

Ohud A. Sabir

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A Dissertation submitted in partial satisfaction of  
the requirements for the degree  
Doctor of Science in Physical Therapy

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December 2019

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Each person whose signature appears below certifies that this dissertation in his/her opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Science.

\_\_\_\_\_, Chairperson  
Eric Johnson, Professor of Physical Therapy

\_\_\_\_\_  
Noha Daher, Professor of Epidemiology and Biostatistics

\_\_\_\_\_  
Rhonda Nelson, Clinical Faculty of Physical Therapy

## ACKNOWLEDGMENTS

First I would like to thank Allah the almighty the greatest of all for the countless gifts and blessings he has given to me throughout my life and for the strength he provided me to reach this achievement successfully.

For my parents Adnan and Hayat, thank you is not enough for everything you gave me. I am here today because of you. You are the compass that was and continue to guide me. Your pleasure is my destination when I work and learn in this life. Thank you for your kind hearts that always pray for me and light my way. Thank you for your life that you gave me with unconditional love to be who I'm today. Thank you for everything I accomplished and for the love you patiently taught me how to give it to myself and the world around me. To my sister Nouf and my brothers Faisal and Rami thank you for being by my side encouraging me always.

To my husband Ammar Hafiz, my life companion, my soul love, and my classmate who shared this unique journey with me. Thank you for being a best friend. Thank you for your unconditional love and support. To my kids, my pure joy and happiness Omar, Amer, and Ibrahim who shared with me this long exhausting journey. I'm sorry for the days I was not fully present for you. Thank you for coloring my days with laughter and happiness. Thank you for all the unforgettable beautiful moments with you. Thank you for the strength your love gave me to achieve my goal.

I would like to express my special thanks and appreciation to my committee chair, Dr. Eric Johnson, thank you for your guidance, help, and support throughout my educational journey.

To my committee members, Dr. Noha Daher, thank you for giving me the skills through your effort and time to understand and learn from your expertise in statistics. Thank you for your love and support. Your assistance and knowledge made the outcome of this research successful. Dr. Rohnda Nelson, thank you for the significant valuable help that you provided me and to this study.

To my research team, Ammar Hafiz, Mitali Hudlikar, and Isha Sheth, you made the most challenging part during the data collection less stressful and enjoyable. Thank you so much for encouraging and supporting me.

To my friends, thank you for rich friendship that I hope will continue to grow for many years to come.

Finally, I would like to express my gratefulness to my sponsor, King Abdu-Aziz University for its financial support. My country Saudi Arabia for the great opportunity to continue my education.

To Loma Linda University, thank you for the wonderful and knowledgeable time I have spent in the university through the last several years.

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## **ABBREVIATIONS**

CMS	Chronic Motion Sensitivity
OME	Otitis Media with Effusion
SET	Stability Evaluation Test
CDP-IVR	Computerized Dynamic Posturography with Immersion Virtual Reality
PBS	Pediatric Balance Scale
CNS	Central Nervous System
COG	Center of Gravity
ES	Equilibrium Score
Hz	Hertz
SD	Standard Deviation
BMI	Body Mass Index
taMAX	theta maximum
taMIN	theta minimum
ICCs	Intra-class correlation coefficients

## ABSTRACT OF THE DISSERTATION

Effect of Pediatric Ear Infections on Postural Stability

by

Ohud A. Sabir

Doctor of Science, Graduate Program in Physical Therapy

Loma Linda University, December 2019

Dr. Eric Johnson, Chairperson

Ear infections in children often cause abnormal postural stability during the acute phase of the ear infection. However, the long-term effects of recurrent ear infections on postural stability have not been investigated. Postural stability is the foundation of many motor skills in early child development. Therefore, it is important to evaluate and treat postural instability problems in early childhood. The purpose of this study was to examine the effect of multiple ear infections on pediatric postural stability and visual over-reliance and to determine if computerized and non-computerized measurement tools could identify lasting postural instability in children with multiple ear infections and/or tympanostomy tubes prior to age five.

Forty children aged 10-12 years were divided into two groups (18 participants with history of tympanostomy tubes and/or 3 or more ear infections prior to age five and 22 participants without history of tympanostomy tubes and/or 0-2 ear infections prior to age five). Computerized and non-computerized postural stability was measured for all participants.

Postural stability was significantly worse in participants with history of tympanostomy tubes and/or 3 or more ear infections had decreased postural stability scores.

In Conclusion results suggest that children ages 10-12 with history of tympanostomy tubes and/or 3 or more ear infections prior to age five have decreased postural stability.

Both postural stability measures detected lasting effects of postural instability in children ages 10-12.

### **Key Words**

Ear infections, postural stability, tympanostomy tubes, vestibular system, balance

## CHAPTER ONE

### INTRODUCTION AND REVIEW OF THE LITERATURE

Postural stability is an essential motor skill developed in early childhood that allows children to interact with the environment.<sup>(Saxena, Rao, & Kumaran, 2014)</sup> Balance development starts at birth and continues until a child masters standing and walking by 18 months.<sup>(Condon & Cremin, 2014)</sup> The vestibular, visual, and proprioceptive systems are important elements of our postural stability control system.<sup>(Casselbrant, Villardo, & Mandel, 2008)</sup> When any of these three systems becomes impaired, postural stability is affected.<sup>(Casselbrant et al., 2008)</sup>

Otitis media with effusion (OME) is a common type of ear infections and it is related to postural instability and vestibular hypofunction in pediatrics.<sup>(Myers et al., 1999)</sup> Otitis media with effusion is defined as an infection with fluid in the middle ear, ranging from serous to thick and mucoid, and causing temporary reversible hearing loss.<sup>(Robb & Williamson, 2016; R. M. Rosenfeld et al., 2016; Williamson, 2011)</sup> Chronic OME has been considered as a main cause of balance impairments and vertigo in pediatrics.<sup>(Casselbrant et al., 2008; Gawron, Pospiech, & Orendorz-Fraczkowska, 2004)</sup>

It was reported by previous investigators approximately 25% of chronic OME episodes lasting more than three months negatively affect hearing, vestibular function, behavior, school performance, and quality of life (QOL).<sup>(R. M. Rosenfeld et al., 2016)</sup> The effect of OME on postural stability in children has been assessed by many investigators; however, none of these studies analyzed postural stability changes depending on the functional condition of middle ear.<sup>(Gawron et al., 2004)</sup>

Recent research shows that during recurrent OME episodes children have abnormal balance and vestibular hypofunction. <sup>(Casselbrant et al., 2000)</sup> Because OME is the most common disease in pediatrics, it is essential to examine their postural stability, vestibular system, and motor function during both the presence and absence of episodes to know if the child is at risk for these problems. <sup>(Casselbrant et al., 2000)</sup>

Robb and Williamson <sup>(Robb & Williamson, 2016)</sup> reported that there is a bimodal peak of incidence in children aged between two and five years old, with OME episodes resolving spontaneously within three months in approximately half of the cases. The structural complications in children with middle ear effusion are present in the tympanic membrane and ossicular chain of the ear. <sup>(van Cauwenberge, Watelet, & Dhooge, 1999)</sup> The impairment of middle ear pressure regulation and ventilation due to Eustachian tube obstruction leads to increase negative pressure in the middle ear. The angle and length of the Eustachian tube are more horizontal and shorter in infants than in adults. The angle observed to be constantly increased with age and become more vertical. However, the increase appears to be greater at three to four years old than in older age. <sup>(Takasaki et al., 2007)</sup>

Rosenfeld et al. <sup>(R. M. Rosenfeld et al., 2016)</sup> reported that 90% of children have OME before they are of school age and have, on average, one episode every year. This demonstrates how common this disease is in pediatrics which they now call an "occupational hazard of early childhood". <sup>(R. M. Rosenfeld et al., 2016)</sup>

Postural stability and balance are important components for purposeful and functional movement. <sup>(Saxena et al., 2014)</sup> The mechanism of how OME affects postural stability has been explained as subsequent changes in the ionic channels of the kinocilia and stereocilia by the transfer of ions through the semipermeable membrane gate which

affect balance.<sup>(Casselbrant et al., 2008)</sup> This transfer changes the arrangement of the endolymph via perilymph, and that can affect balance.<sup>(Casselbrant et al., 2008)</sup> Children learn by interacting with and exploring their environment.<sup>(Saxena et al., 2014)</sup>

Casselbrant et al.<sup>(Casselbrant, Redfern, Fall, Furman, & Mandel, 1998)</sup> suggested that children with OME who had vestibular hypofunction may solely rely upon the visual and proprioceptive systems to support postural stability. Postural sway in children with OME is greater than in children without OME when they respond to a visually moving object.<sup>(Casselbrant et al., 1998)</sup> To identify the importance of the vestibular system in managing OME in pediatrics further studies are needed.<sup>(Casselbrant et al., 1998)</sup>

Postural stability and the vestibular system in children with recurrent OME may or may not completely improve after the disease resolves.<sup>(Said, 2015)</sup> To avoid complications in the child's sensory integration, early intervention should be considered.<sup>(Said, 2015)</sup>

Current OME clinical practice guidelines strongly recommend tympanostomy tube insertion to manage children with OME lasting three months or longer.<sup>(Richard M Rosenfeld et al., 2016)</sup> This procedure involves surgical tube placement through a myringotomy incision to ventilate middle ear pressure.<sup>(Rosenfeld et al., 2013)</sup> It is the most common ambulatory surgery performed in the United States as 667,000 children younger than 15 years old undergo the surgery every year.<sup>(Rosenfeld et al., 2013)</sup>

Ear infections in children often cause abnormal postural stability. However, the long-term effects of recurrent ear infections on postural stability have not been investigated.



In pediatric physical therapy, examination of postural stability is important to know if the child is at risk for these problems in order to avoid balance problems as child ages.

(Casselbrant et al., 2000) Improved assessment and evaluation of pediatrics balance is necessary to avoid postural instability as adults. Many pediatrics postural stability measurement tools evaluated by researchers are used by physical therapist. However, none of the studies evaluated the effectiveness of these measurement tools regarding computerized and non-computerized outcomes.

Therefore, the study has two aims: first, to examine the effect of multiple ear infections on pediatric postural stability and visual over-reliance. Second, to determine if computerized and non-computerized measurement tools could identify lasting postural instability in children with multiple ear infections and/or tympanostomy tubes prior to age five.



***Fig. 1. Ear Infection (middle ear)***

## **Postural stability Assessment**

The Physical Activity Questionnaire for Children (PAQ-C) was used to assess the general activity level for the children. The PAQ-C was developed for elementary school-aged children ages 8-14 years, and is a nine-item questionnaire pertaining to recollection of the child's last seven days of physical activity. The total score was calculated by taking the mean of the 9 items. A score of one indicated a low physical activity, while a score of five indicated a high physical activity level for the child. (Kowalski, Crocker, & Donen, 2004) Voss et al. (Voss, Dean, Gardner, Duncombe, & Harris, 2017) reported that the PAQ-C is a valid and reliable tool used to assess physical activity level in elementary school-aged in healthy children.

Postural stability was measured using three different assessment tools. The Bertec Balance Advantage Dynamic Computerized Dynamic Posturography with Immersion Virtual Reality (CDP-IVR), Pediatric Balance Scale (PBS), and the NeuroCom® VSR™ SPORT Computerized Dynamic Posturography Stability Evaluation Test (SET).

## **Computerized Dynamic Posturography**

The CDP-IVR measured static postural stability by calculating participants' center of gravity displacements under three conditions. (Palm, Lang, Strobel, Riesner, & Friemert, 2014) Condition 1 was a postural stability base-line measurement using a stable force-plate with eyes open. Condition 2 measured postural stability on a stable force-plate with eyes open and focusing on a virtual reality infinite tunnel. Condition 3 measured postural stability on an unstable force-plate with eyes closed. Each condition included three 20-second trials, and

the average of the three trials for each condition was calculated. The CDP-IVR calculates postural stability and generates an equilibrium score in the following manner: Signals from the participants' effort to maintain balance were sampled and analyzed at 1000 Hertz and the sway path was computed. The testing protocol calculates the sway path with equilibrium scores quantified by how well the participants' sway remains within the expected angular limits of stability during each testing condition. The following formula was used to calculate the equilibrium score: Equilibrium Score (ES)=  $([12.5 \text{ degrees} - (\text{taMAX} - \text{taMIN})] / 12.5 \text{ degrees}) * 100$ . The ES uses  $12.5^\circ$  as the normal limit of the anterior-posterior sway angle range, taMAX is theta maximum and taMIN is theta minimum. Sway angle was calculated as follows: Sway Angle =  $\arcsin(\text{COGy} / (.55 * h))$  where y=anterior-posterior sway axis and h=the participant's height in [cm or inches]. The inverse Sin of the center of gravity was divided by 55% of the subject's height. Participants exhibiting little sway achieve equilibrium scores near 100, while participants exhibiting more sway achieve equilibrium scores further away from 100.<sup>20</sup>

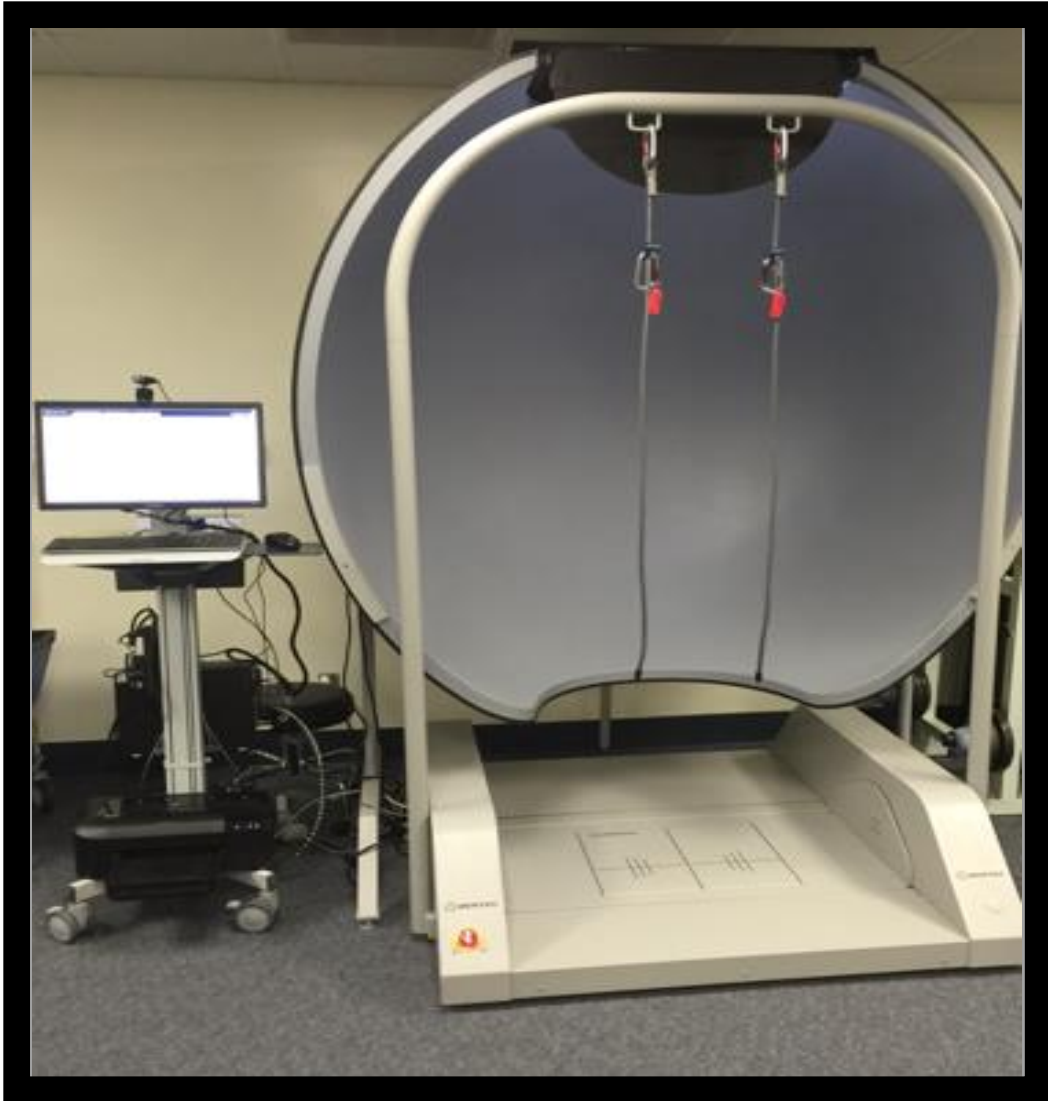
### **Pediatric Balance Scale**

The Pediatric Balance Scale (PBS) was used to assess balance in participants. The PBS is a non-computerized 14-item criterion-referenced tool that measures static and dynamic functional balance of daily activities in children.<sup>(AbilityLab, 2015; Franjoine, Darr, Held, Kott, & Young, 2010)</sup> The PBS tasks include items such as sit to stand, transfers, and turning 360 degrees.<sup>(AbilityLab, 2015; Franjoine et al., 2010)</sup> Sook-Hee Yi et al.<sup>(Yi, Hwang, Kim, & Kwon, 2012)</sup> reported that the PBS is a simple and valid tool that could be used in pediatric rehabilitation to

examine functional balance and predict motor capability and capacity. In addition, Chen et al. (Chen et al., 2013) reported that the PBS is a valid tool to examine functional balance in children with cerebral palsy. Franjoine et al. (Franjoine, Gunther, & Taylor, 2003) reported that the PBS is a reliable tool to assess balance in school-aged children with mild to moderate motor impairments.

### **Stability Evaluation Test**

Postural stability was also measured using SET. The SET has good to excellent reliability for postural stability measurement (ICC=.93; 95% CI: .88,.95) with significant practice effects ( $P<.05$ ). (Williams et al., 2017) Static postural stability was tested on a stable surface in three conditions. SET Condition 1 measured postural stability with narrow double limb stance on firm surface. SET Condition 2 measured postural stability with single limb stance on firm surface. SET Condition 3 measured postural stability with tandem (dominant foot behind) stance on firm surface. SET Condition 4 measured postural stability with narrow double limb stance on unstable surface. SET Condition 5 measured postural stability with single limb stance on unstable surface. SET Condition 6 measured postural stability with tandem (dominant foot behind) stance on unstable surface. In all conditions participants closed their eyes and placed their hands on their iliac crests. The SET protocol quantifies the center of gravity (COG) sway or postural stability as a weighted average of all six conditions.



***Fig. 2.*** Bertec™ Balance Computerized Dynamic Posturography with Immersion Virtual Reality (CDP-IVR).

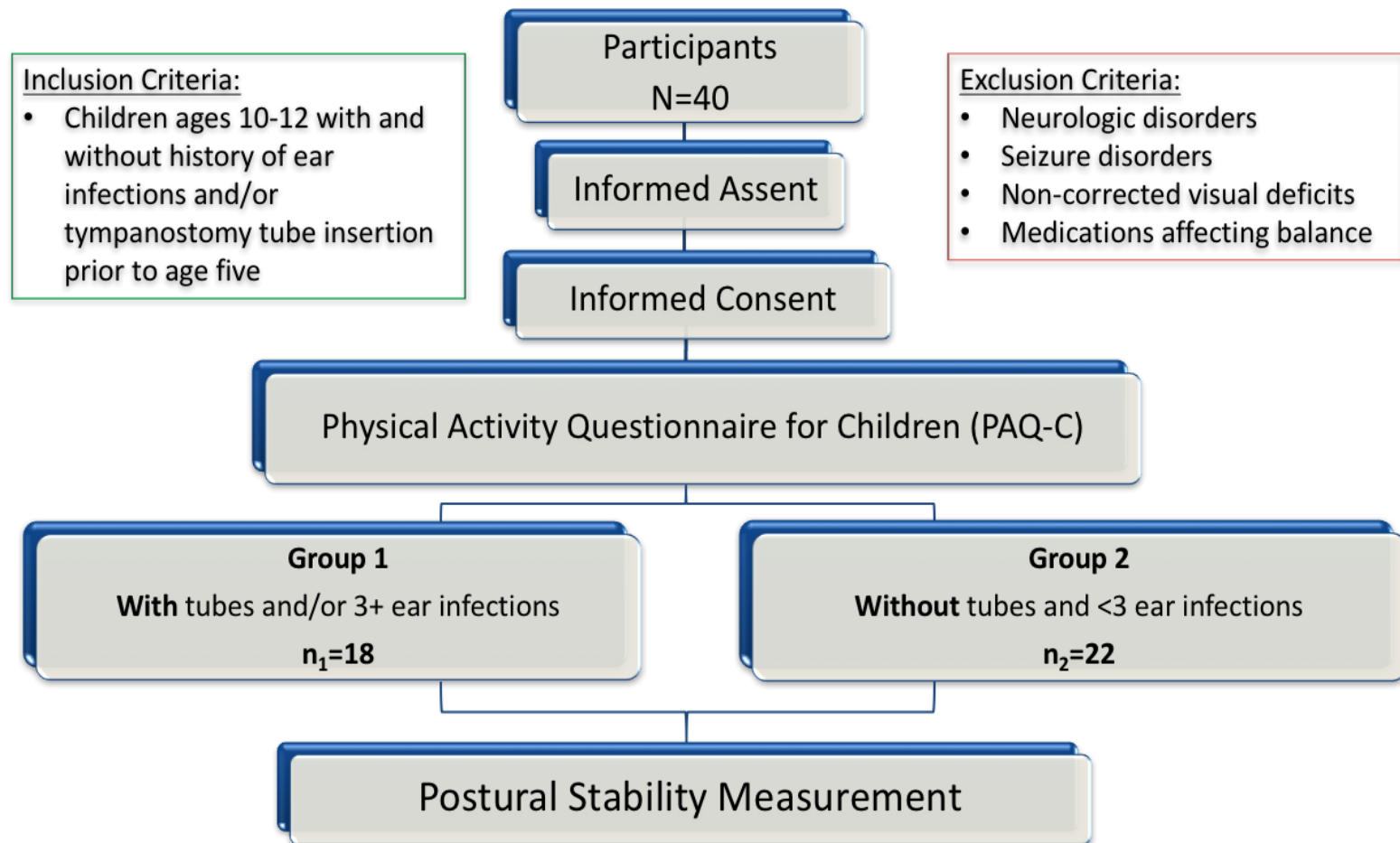


*Fig. 3.* (CDP-IVR) static baseline condition 1.



**Fig. 4.** Stability Evaluation Test (SET)





*Fig. 5.* Diagram illustrating flow of participants and study procedure

## Summary

Chronic Motion sensitivity, according to the sensory conflict theory, results from faulty central nervous system (CNS) processing of visual, vestibular, or somatosensory inputs (Oman, 1990; Reason, 1978). The CNS processes sensory system inputs and drives motor system outputs to maintain postural and visual stability (Herdman & Clendaniel, 2014; Horak & Macpherson, 1996). During sensory system mismatch, particularly with improper vestibular function, postural and visual instability can result (Massion, 1998; Nashner et al., 1982; Ricci et al., 2010). Micro-synaptic changes in the vestibular nerve function occur after the age of forty; whereas vestibular receptor organs become more susceptible to degeneration after age 50. By the age of 60, the electrical conductivity velocity of the vestibular nerve begins to decline (Ricci et al., 2010). Postural stability is required for static conditions and dynamic conditions in response to applied or volitional perturbations (Prieto & Myklebust, 1993). Postural stability and the integrity of the various systems contributing to it, is commonly measured using computerized dynamic posturography (CDP) (Chaudhry et al., 2004; Prieto & Myklebust, 1993). Walking at alternating velocities places different demands on the control visual and postural stability including contributions of angular and linear vestibulo-ocular, vestibulocollic, vestibulospinal reflexes (Hirasaki et al., 1999). During head-turning motion, multisensory inputs systems are incorporated into cooperative actions resulting in the maintenance of postural stability (Schubert, 2019; Takahashi et al., 1997). Hirasaki et al. reported that walking produces linear and angular head perturbations (Hirasaki et al., 1999). Paloski et al. (Paloski et al., 2006) found that postural stability was worse during different head motion frequencies in healthy individuals. The coordination of head, trunk, and body movement is most coherent at walking velocities of 1.2–1.8 m/s and least consistent at walking

speeds outside that range <sup>(Hirasaki et al., 1999)</sup>. The compensatory mechanisms of the head pitch during slow, moderate, and fast walking is different <sup>(Hirasaki et al., 1999)</sup>. Cooperatively, these reflexes maintain head orientation and stability of gaze over a plethora of walking velocities. Significant frequency of head translation and rotation was limited to a narrow range of 1.4 Hz at 0.6 m/s to 2.5 Hz at 2.2 m/s <sup>(Hirasaki et al., 1999)</sup>.

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## **CHAPTER TWO**

### **EFFECT OF PEDIATRIC EAR INFECTIONS ON POSTURAL STABILITY**

Ohud A. Sabir<sup>1</sup>, Eric G. Johnson<sup>1\*</sup>, Ammar E. Hafiz<sup>1</sup>, Rhonda N. Nelson<sup>1</sup>, Mitali  
Hudlikar<sup>2</sup>, Isha Sheth<sup>2</sup>, Noha S. Daher<sup>2</sup>

\*Corresponding Author: Eric G. Johnson, Department of Physical Therapy, Loma Linda  
University, 24951 North Circle Drive, Nichol Hall A-712, Loma Linda, California 92350  
(909) 558-4632 ext. 47471, Fax (909) 558-0459, ejohnson@llu.edu

<sup>1</sup>Department of Physical Therapy, Loma Linda University, California, USA.

<sup>2</sup>Department of Allied Health Studies, Loma Linda University, California, USA.

### **Acknowledgments**

The authors thank Loma Linda University and King Abdul-Aziz University in Saudi  
Arabia for supporting this research.

## **Abstract**

### **Background**

Ear infections in children often cause abnormal postural stability. However, the long-term effects of recurrent ear infections on postural stability have not been investigated.

### **Purpose**

The purpose of this study was to examine the long-term effects of multiple ear infections on pediatric postural stability.

### **Methods**

Forty children aged 10-12 years were divided into two groups (18 participants with history of tympanostomy tubes and/or 3 or more ear infections prior to age five and 22 participants without history of tympanostomy tubes and/or 0-2 ear infections prior to age five). Computerized Stability Evaluation Test (SET) and non-computerized postural stability was measured for all participants.

### **Results**

A significant difference was found in median postural stability scores in the SET during tandem stance on unstable surface between the two groups (median (minimum, maximum) of 9.1 (1.4, 11.4) versus 5.8 (1.7, 12.8),  $p=0.04$ ). In addition, there was a significant difference in median Pediatric Balance Scale scores between participants with versus without ear infection (54 (47, 56) versus 56 (55, 56),  $p=0.001$ ).



## **Conclusions**

Results suggest that children ages 10-12 with history of tympanostomy tubes and/or 3 or more ear infections prior to age five have decreased postural stability.

**Key Words** Ear infections, postural stability, tympanostomy tubes, vestibular system

## **Introduction**

Otitis media with effusion (OME), or "glue ear", has been defined as a serous to thick fluid in the middle ear without acute infection symptoms that can cause temporary hearing loss.<sup>1-3</sup> Otitis media with effusion is considered a common cause of vestibular disturbance and movement disorganization in pediatrics.<sup>4</sup> However, there are a small number of studies on the relationship between vestibular hypofunction and OME in pediatrics.<sup>4</sup> Chronic OME has been identified as a principal cause of balance instabilities and vertigo in pediatrics.<sup>5,6</sup>

Rosenfeld et al.<sup>3</sup> suggested that the persistence of fluid in the middle ear, which comes from OME, might lead to reduced tympanic membrane mobility and negatively affect sound conduction. Approximately 25% of chronic OME episodes lasting more than three months negatively affect hearing, vestibular function, behavior, school performance, and quality of life (QOL).<sup>3</sup> The effect of OME on postural stability in children has been assessed by many investigators; however, none of these studies analyzed postural stability changes depending on the functional condition of middle ear.<sup>5</sup> Middle ear dysfunction includes partial or complete blockage of the Eustachian tube that contributes to chronic ear infections and failure to effectively regulate ear pressure.<sup>7</sup>

Recent research shows that during recurrent OME episodes children have abnormal balance and vestibular hypofunction.<sup>8</sup> Because OME is the most common

disease in pediatrics, it is essential to examine their postural stability, vestibular system, and motor function during both the presence and absence of episodes to know if the child is at risk for these problems.<sup>8</sup> The primary reason for parents of children with OME to consult an otolaryngologist is hearing loss, which is the most common complication of OME.<sup>9</sup> Williamson<sup>1</sup> determined that 91% of children between the ages of two months and two years will experience one episode of OME, and 52% of children will have bilateral middle ear effusion.<sup>1</sup> Risk factors that have been described in case-control studies include attendance at day care centers, children age six years and younger, exposure to second-hand smoking, repeated upper respiratory tract infections, and a significant number of siblings.<sup>1</sup>

Robb and Williamson<sup>2</sup> reported that there is a bimodal peak of incidence in children aged between two and five years old, with OME episodes resolving spontaneously within three months in approximately half of the cases. The vestibular, visual, and proprioceptive systems are the main components of our postural stability control system.<sup>6</sup> When one of the three postural stability systems becomes dysfunctional, vestibular compensatory efforts are increased.<sup>6</sup> The structural complications in children with middle ear effusion are present in the tympanic membrane and ossicular chain of the ear.<sup>10</sup> Reddy et al.<sup>11</sup> reported that the lack of Eustachian tube ventilation plays an important role in developing OME. Eustachian tube dysfunction (ETD) is the lack of ability of the Eustachian tube to sufficiently perform at the minimum one of its functions, which are ear protection, middle ear ventilation, and mucociliary clearance of the middle ear. The impairment of middle ear pressure regulation and ventilation due to Eustachian tube obstruction leads to increase negative pressure in the middle ear. The angle and length of

the Eustachian tube are more horizontal and shorter in infants than in adults. The angle observed to be constantly increased with age and become more vertical. However, the increase appears to be greater at three to four years old than in older age.<sup>12</sup> Takasaki et al.<sup>12</sup> reported that there was no statistical difference between the angle and length of the Eustachian tube in infants with and without OME.

Rosenfeld et al.<sup>3</sup> reported that 90% of children have OME before they are of school age and have, on average, one episode every year. This demonstrates how common this disease is in pediatrics which they now call an "occupational hazard of early childhood".<sup>3</sup>

Postural stability and balance are important components for purposeful and functional movement.<sup>13</sup> The mechanism of how OME affects postural stability has been explained as subsequent changes in the ionic channels of the kinocilia and stereocilia by the transfer of ions through the semipermeable membrane gate which affect balance.<sup>6</sup> This transfer changes the arrangement of the endolymph via perilymph, and that can affect balance.<sup>6</sup> Children learn by interacting with and exploring their environment.<sup>13</sup>

Casselbrant et al.<sup>14</sup> suggested that children with OME who had vestibular hypofunction may solely rely upon the visual and proprioceptive systems to support postural stability. Postural sway in children with OME is greater than in children without OME when they respond to a visually moving object.<sup>14</sup> To identify the importance of the vestibular system in managing OME in pediatrics further studies are needed.<sup>14</sup>

Postural stability and the vestibular system in children with recurrent OME may or may not completely improve after the disease resolves.<sup>9</sup> In order to avoid complications in the child's sensory integration, early intervention should be considered.<sup>9</sup>

Current OME clinical practice guidelines strongly recommend tympanostomy tube insertion to manage children with OME lasting three months or longer.<sup>15</sup> This procedure involves surgical tube placement through a myringotomy incision to ventilate middle ear pressure.<sup>16</sup> It is the most common ambulatory surgery performed in the United States as 667,000 children younger than 15 years old undergo the surgery every year.<sup>16</sup>

Our aims in this study were to examine the effect of multiple ear infections on pediatric postural stability and visual over-reliance. We hypothesized that postural stability would be worse in children with history of multiple ear infections compared to children without history of multiple ear infections. We also hypothesized that children with history of multiple ear infections would be more visually dependent for maintaining postural stability.

### **Methods**

Forty children aged 10-12 years with and without history of multiple ear infections and/or tympanostomy tubes prior to age five were recruited for this study from the local community. Based on parent self-report, participants were divided into two groups (18 participants with history of tympanostomy tubes and/or 3 or more ear infections prior to age five and 22 participants without history of tympanostomy tubes and 0-2 ear infections prior to age five). Participants were excluded if they have disorders of balance and gait, seizure disorders, non-corrected visual deficits, and/or medications affecting balance. Parents of all participants signed Loma Linda University's Institutional Review Board approved informed consent prior to study participation and then the children read and signed the informed assent.

The Physical Activity Questionnaire for Children (PAQ-C) was used to assess the general activity level for the children. The PAQ-C was developed for elementary school-aged children ages 8-14 years, and is a nine-item questionnaire pertaining to recollection of the child's last seven days of physical activity. The total score was calculated by taking the mean of the 9 items. A score of one indicated a low physical activity, while a score of five indicated a high physical activity level for the child.<sup>17</sup> Voss et al.<sup>18</sup> reported that the PAQ-C is a valid and reliable tool used to assess physical activity level in elementary school-aged in healthy children.

Postural stability was measured using three different assessment tools. The Bertec Balance Advantage Dynamic Computerized Dynamic Posturography with Immersion Virtual Reality (CDP-IVR), Pediatric Balance Scale (PBS), and the NeuroCom® VSR™ SPORT Computerized Dynamic Posturography Stability Evaluation Test (SET). The CDP-IVR measured static postural stability by calculating participants' center of gravity (COG) displacements under three conditions.<sup>19</sup> Condition 1 was a postural stability baseline measurement using a stable force-plate with eyes open. Condition 2 measured postural stability on a stable force-plate with eyes open and focusing on a virtual reality infinite tunnel. Condition 3 measured postural stability on an unstable force-plate with eyes closed. Each condition included three 20-second trials, and the average of the three trials for each condition was calculated. The CDP-IVR calculates postural stability and generates an equilibrium score in the following manner: Signals from the participants' effort to maintain balance were sampled and analyzed at 1000 Hertz and the sway path was computed. The testing protocol calculates the sway path with equilibrium scores quantified by how well the participants' sway remains within the expected angular limits

of stability during each testing condition. The following formula was used to calculate the equilibrium score: Equilibrium Score (ES)=  $([12.5 \text{ degrees} - (\text{taMAX} - \text{taMIN})] / 12.5 \text{ degrees}) * 100$ . The ES uses  $12.5^\circ$  as the normal limit of the anterior-posterior sway angle range, taMAX is theta maximum and taMIN is theta minimum. Sway angle was calculated as follows: Sway Angle =  $\arcsin(\text{COGy} / (.55 * h))$  where y=anterior-posterior sway axis and h=the participant's height in [cm or inches]. The inverse Sin of the center of gravity was divided by 55% of the subject's height. Participants exhibiting little sway achieve equilibrium scores near 100, while participants exhibiting more sway achieve equilibrium scores further away from 100.<sup>20</sup>

The Pediatric Balance Scale (PBS) was used to assess balance in participants. The PBS is a non-computerized 14-item criterion-referenced tool that measures static and dynamic functional balance of daily activities in children.<sup>20,21</sup> The PBS tasks include items such as sit to stand, transfers, and turning 360 degrees.<sup>20,21</sup> Sook-Hee Yi et al.<sup>22</sup> reported that the PBS is a simple and valid tool that could be used in pediatric rehabilitation to examine functional balance and predict motor capability and capacity. In addition, Chen et al.<sup>23</sup> reported that the PBS is a valid tool to examine functional balance in children with cerebral palsy. Franjoine et al.<sup>24</sup> reported that the PBS is a reliable tool to assess balance in school-aged children with mild to moderate motor impairments.

Postural stability was also measured using SET. The SET has good to excellent reliability for postural stability measurement (ICC=.93; 95% CI: .88,.95) with significant practice effects ( $P < .05$ ).<sup>25</sup> Static postural stability was tested on a stable surface in three conditions. SET Condition 1 measured postural stability with narrow double limb stance on firm surface. SET Condition 2 measured postural stability with single limb stance on

firm surface. SET Condition 3 measured postural stability with tandem (dominant foot behind) stance on firm surface. SET Condition 4 measured postural stability with narrow double limb stance on unstable surface. SET Condition 5 measured postural stability with single limb stance on unstable surface. SET Condition 6 measured postural stability with tandem (dominant foot behind) stance on unstable surface. In all conditions participants closed their eyes and placed their hands on their iliac crests. The SET protocol quantifies the COG sway or postural stability as a weighted average of all six conditions.

### **Procedures**

Parents of all participants signed Loma Linda University's Institutional Review Board approved informed consent prior to study participation and then the children read and signed the informed assent. Participants then completed the PAQ-C. Before testing, participants removed shoes and socks followed by height and weight measurements. Participants donned a safety harness before postural stability was measured. Postural stability was measured using three different assessment tools. Postural stability was first measured using the CDP-IVR in three conditions: Condition 1 measured baseline postural stability using a stable force-plate with eyes open. Condition 2 measured postural stability on a stable force-plate with eyes open and focusing on a virtual reality infinite tunnel. Condition 3 measured postural stability on an unstable force-plate with eyes closed. Next, participant's postural stability was measured using the PBS test. Each item ranged from 0 (unable to perform) to 4 (able to perform the task without difficulty independently as instructed). Participants were given verbal and visual instructions for each item. One trial was given to each participant. A second trial was given if the participant was unable to understand verbal and visual instructions. Finally,

postural stability was measured using the SET, which measured static postural stability on a stable surface in six conditions including double limb stance, single limb stance, and tandem (dominant foot behind) stance. In each condition, participants closed their eyes and placed hands on their iliac crests. The same three conditions were repeated on a foam surface to test dynamic postural stability.

Data analysis was performed using Statistical Package for the Social Sciences SPSS version 24.0 (IBM Corp, Armonk, NY). A sample size of 42 subjects was estimated using an effect size ( $d=0.90$ ), a power of 0.80, and a level of significance set at 0.05. The general characteristics of the participants were summarized using means and standard deviations for quantitative variables, and counts and percentages for categorical variables. The frequency distribution of gender was compared between the two study groups using chi-square test. The normality of the continuous variables was examined using Shapiro-Wilk test and box plots. We compared mean age, BMI, and postural stability during conditions one, two, and three, double leg stance on stable and foam surfaces, single leg stance on stable and foam surfaces, and tandem stance on a stable surface using independent t-test. The distribution of postural stability during tandem stance on foam surface and PBS scores were not approximately normal, and thus Mann Whitney test was used to examine differences in median stability scores between the two groups. The level of significance was set at  $p \leq 0.05$ .



## **Results**

Forty children (20 males and 20 females) with mean age  $10.7 \pm 0.8$  years participated in this study. The study sample comprised of 18 children with a history of tympanostomy tubes and/or 3 or more ear infections and 22 children without history of tympanostomy tubes and/or 0-2 ear infections. The baseline characteristics were similar between the two groups ( $p > 0.05$ ). There was no significant difference in mean postural stability in CDP-IVR at baseline, during eyes open, eyes closed and in immersion virtual reality conditions. Also, no significant differences in mean postural stability in the SET during double leg stance on firm and unstable surfaces, single leg stance on firm and unstable surfaces, and tandem stance on a firm surface were observed ( $p > 0.05$ , Table 1).

A significant difference was found in median postural stability scores in the SET during tandem stance on unstable surface between the two groups (median (minimum, maximum) of 9.1 (1.4, 11.4) versus 5.8 (1.7, 12.8),  $p = 0.04$ ; Figure 1). In addition, there was a significant difference in median PBS scores between participants with versus without ear infection (54 (47, 56) versus 56 (55, 56),  $p = 0.001$ ; Figure 2).

## **Discussion**

The present study investigated the effect of pediatric ear infections, prior to age five, on chronic motion sensitivity in children aged 10-12 years with history of tympanostomy tubes and/or 3 or more ear infections versus those without history of tympanostomy tubes and/or 0-2 ear infections by using the CDP-IVR, SET, and PBS. Our results demonstrated that postural stability was worse in the group with history

of tympanostomy tubes and/or 3 or more ear infections during tandem stance and PBS scores.

Casselbrant et al.<sup>8</sup> reported that during recurrent OME episodes, children have abnormal balance and vestibular hypofunction. In addition, Van Cauwenberge et al.<sup>9</sup> reported that postural stability and the vestibular system in children with recurrent OME may or may not completely improve after the OME episode resolves. The present study results showed that the postural stability did not improve completely after resolution of OME.

Casselbrant et al.<sup>14</sup> suggested that children with OME and vestibular hypofunction might solely rely on the visual and proprioceptive systems to support postural stability. They used a posture platform with a visual surround (Equitest, NeuroCom, Inc) in three conditions: no visual scene movement, scene movement at 0.10 Hz, and scene movement at 0.25 Hz to test visual balance dependency. In the present study, there was no significant difference in mean postural stability during eyes closed or during the immersion virtual reality conditions. Our results suggest that children with OME don't over rely on their visual system to compensate for their abnormal postural stability. This could be related to the fact that all participants were active as measured by the PAQ-C. However, children with multiple ear infection history that have lower activity levels might present differently.<sup>26,27</sup>

The CDP-IVR measures static postural stability by calculating participants' center of gravity displacements under three conditions.<sup>19</sup> The SET measures postural stability as sway velocity in degrees per second across several different testing conditions.<sup>28</sup> There is a difference in the base of support between the CDP-IVR and the SET protocol, which

could be the reason for the different results between the SET and CDP-IVR.

The PBS is a valid, reliable, simple, and quick tool that can be used to assess a child's functional balance in less than 20 minutes.<sup>20,21</sup> The 14-items include tasks that are routinely performed by children throughout the day as part of their activities of daily living. It is easily scored and does not require special equipment compared to balance computerized tools, which are expensive and have more difficulties during the assessment. In this study, there was no significant difference in mean postural stability during eyes closed or during the immersion virtual reality condition.

This study has some limitations. The study sample included few participants with a history of tympanostomy tubes. Also, group assignment was based on self-report. In addition, blinding was not utilized during the PBS, which introduces the possibility of examiner bias. Future investigators should consider recruiting children with history of tympanostomy tubes, children with multiple ear infection history that have low activity levels, and having participants' parents supply medical records regarding history of tympanostomy tubes and ear infections. In addition, participants in both groups were physically active. Future research should consider recruiting participants with lower activity levels as physical activity level may positively impact postural stability in children with tubes and/or 3 or more ear infections prior to age five.

In conclusion, the results of this study suggest that children ages 10-12 with history of tympanostomy tubes and/or 3 or more ear infections prior to age five have decreased postural stability compared to children without history of tympanostomy tubes and/or 0-2 ear infections. The results suggest that postural stability impairments persist even after the resolution of the ear infections in early childhood.

**Table 1.** Mean (SD) of characteristics and outcomes by study group (N=40)

	Tubes and/or $\geq 3$ ear infections (n <sub>1</sub> =18)	No tubes and <3 ear infections (n <sub>2</sub> =22)	p-value (d)
Female, n (%)	11 (61.1)	9 (40.9)	0.17
Age (years)	10.5 (8.1)	10.9 (0.9)	0.17 (0.07)
BMI (kg/m <sup>2</sup> )	20.5 (4.9)	20.8 (4.8)	0.90 (0.06)
CDP-IVR Condition 1	89.7 (3.8)	89.4 (3.3)	0.74 (0.08)
CDP-IVR Condition 2	85.8 (5.5)	87.4 (3.5)	0.26 (0.35)
CDP-IVR Condition 3	29.9 (24.3)	31.2 (22.8)	0.87 (0.06)
SET Condition 1	0.9 (0.2)	0.8 (0.2)	0.40 (0.27)
SET Condition 4	2.1 (0.5)	2.2 (0.8)	0.65 (0.15)
SET Condition 2	4.3 (1.8)	3.9 (2.0)	0.59 (0.21)
SET Condition 5	6.3 (1.3)	5.9 (1.5)	0.46 (0.28)
SET Condition 3	3.0 (2.3)	2.8 (1.8)	0.76 (0.10)
SET Condition 6 <sup>**</sup>	9.1 (1.4, 11.4)	5.8 (1.7, 12.8)	0.04 <sup>*</sup> (0.56)
PAQ-C	3.2 (0.8)	3.1 (1.0)	0.58 (0.11)
PBS <sup>**</sup>	54 (47, 56)	56 (55, 56)	0.001 <sup>*</sup> (1.33)

Abbreviation: SD, Standard Deviation; BMI, Body Mass Index; PAQ-C, Physical Activity Questionnaire for Children; CDP-IVR, The Bertec Balance Advantage Dynamic Computerized Dynamic Posturography with Immersion Virtual Reality; CDP-IVR Condition 1: baseline using a stable force-plate, eyes open; CDP-IVR Condition 2: stable force-plate, eyes open, and focusing on a virtual reality infinite tunnel; CDP-IVR Condition 3: unstable force-plate, eyes closed; SET, Stability Evaluation Test; SET Condition 1: measured postural stability with narrow double limb stance on firm surface; SET Condition 2: measured postural stability with single limb stance on firm surface; SET Condition 3: measured postural stability with tandem (dominant foot behind) stance on firm surface; SET Condition 4: measured postural stability with narrow double limb stance on unstable surface; SET Condition 5: measured postural stability with single limb stance on unstable surface; SET Condition 6: measured postural stability with tandem (dominant foot behind) stance on unstable surface. In all conditions participants closed their eyes and placed their hands on their iliac crests; PBS, Pediatric Balance Scale

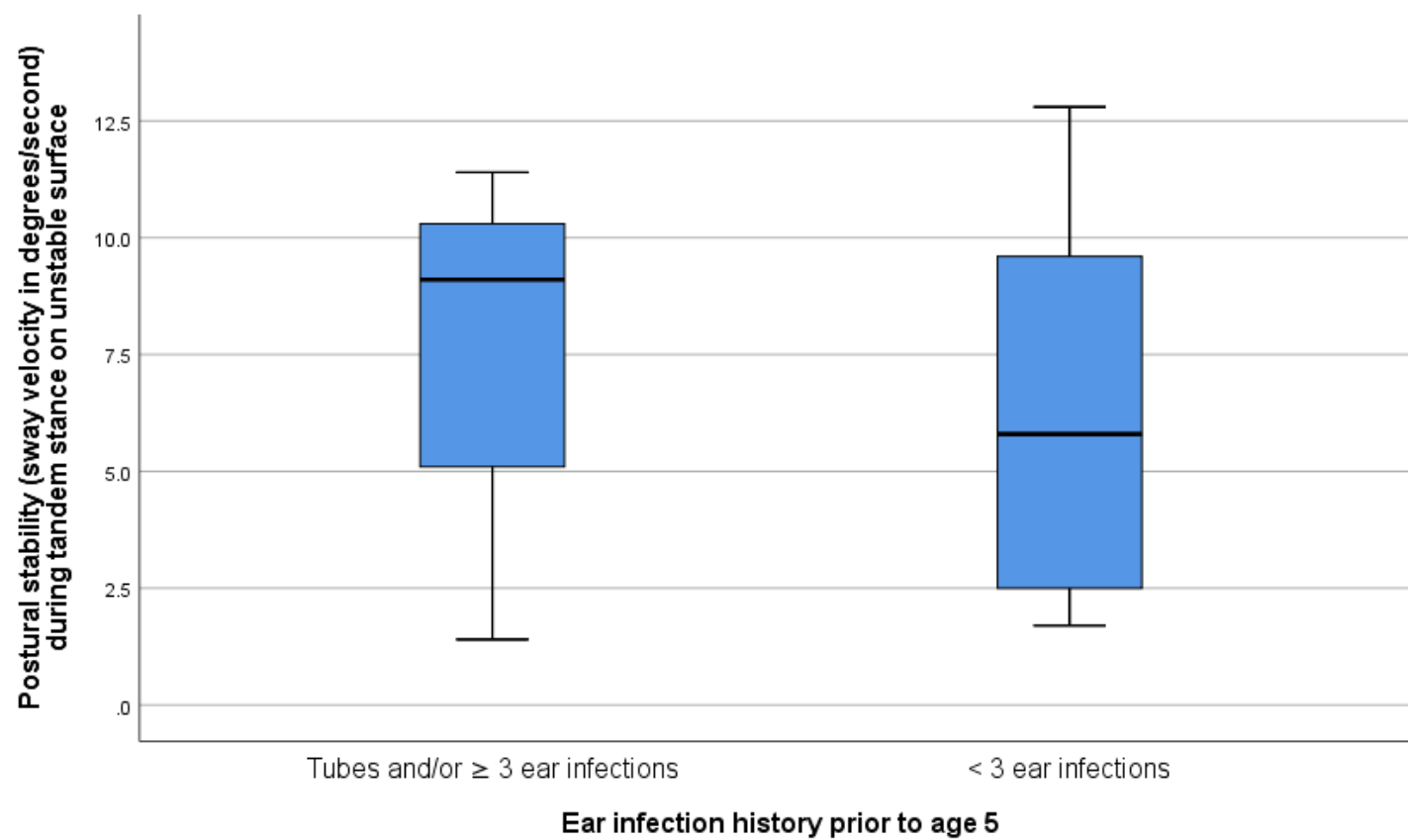
<sup>\*</sup>: p<0.05 <sup>\*\*</sup>: Results are reported as Median (Minimum, Maximum)

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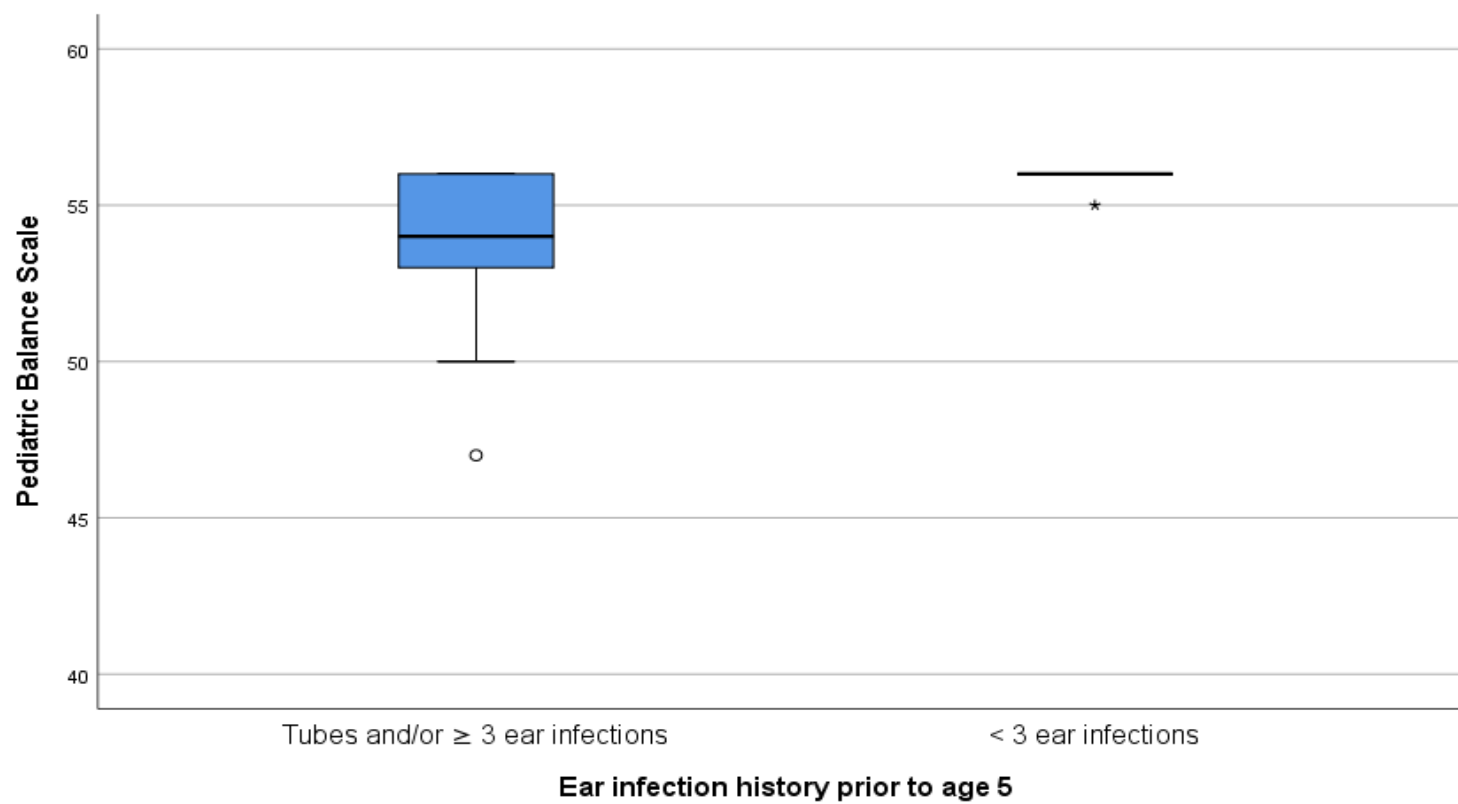
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**Fig. 6.** Postural stability scores during tandem stance on unstable surface by study group





**Fig. 7.** Pediatric Balance Scale score by study group

## **CHAPTER THREE**

### **COMPUTERIZED AND NON-COMPUTERIZED MEASURES FOR DETERMINING LASTING EFFECTS OF EARLY CHILDHOOD EAR INFECTIONS ON POSTURAL STABILITY**

Ohud A. Sabir<sup>1</sup>, Eric G. Johnson<sup>1\*</sup>, Ammar E. Hafiz<sup>1</sup>, Rhonda N. Nelson<sup>1</sup>, Mitali  
Hudlikar<sup>2</sup>, Isha Sheth<sup>2</sup>, Noha S. Daher<sup>2</sup>

\*Corresponding Author: Eric G. Johnson, Department of Physical Therapy, Loma Linda  
University, 24951 North Circle Drive, Nichol Hall A-712, Loma Linda, California 92350  
(909) 558-4632 ext. 47471, Fax (909) 558-0459, ejohnson@llu.edu

<sup>1</sup>Department of Physical Therapy, Loma Linda University, California, USA.

<sup>2</sup>Department of Allied Health Studies, Loma Linda University, California, USA.

## **Abstract**

### **Background**

Postural stability is the foundation of many motor skills in early child development. Therefore, it is important to evaluate and treat postural instability problems in early childhood.

### **Purpose**

The purpose of this study was to determine if computerized and non-computerized measurement tools could identify lasting postural instability in children with multiple ear infections and/or tympanostomy tubes prior to age five.

### **Methods**

Forty children aged 10-12 years were divided into two groups; 18 participants with a history of ear tubes and/or three or more ear infections and 22 participants without history of ear tubes and less than three ear infections prior to age five. Postural stability was measured using the Pediatric Balance Scale (PBS) and the NeuroCom<sup>®</sup> VSR™ SPORT Computerized Dynamic Posturography Stability Evaluation Test (SET) protocol.

### **Results**

A significant difference was found in median postural stability scores in the SET during tandem stance on unstable surface between participants with versus without ear infections (median [minimum, maximum] of 9.1 [1.4, 11.4] versus 5.8 [1.7, 12.8],  $p=0.04$ ). In addition, a significant difference in median PBS scores was detected during

tandem stance between the two groups (3 [0, 4] versus 4 [4, 4],  $p=0.001$ ). Also, there was a significant difference in median PBS scores during single limb stance (4 [0, 4] versus 4 [4, 4],  $p=0.037$ ). In all cases, the participants with a history of ear tubes and/or three or more ear infections had decreased postural stability scores.

### **Conclusions**

The results suggest that computerized and non-computerized postural stability measures detect lasting effects of postural instability in children ages 10-12 with a history of ear tubes and/or three or more ear infections prior to age five. Given the cost of computerized technology, the PBS is an affordable alternative for examining postural stability in children.

### **Key Words**

Postural stability, early childhood, vestibular system, ear infections

## **Introduction**

Postural stability is an essential motor skill developed in early childhood that allows children to interact with the environment.<sup>1</sup> Balance development starts at birth and continues until a child masters standing and walking by 18 months.<sup>2</sup> The vestibular, visual, and proprioceptive systems are important elements of our postural stability control system.<sup>3</sup> When any of these three systems becomes impaired, postural stability is affected.<sup>3</sup> In pediatric physical therapy, examination of postural stability is important for determining if the child is at risk for these problems in order to avoid balance problems as the child ages.<sup>4</sup>; The purpose of this study was to compare computerized and non-computerized postural stability measurement tools in children 10-12 years of age with history of ear tubes and/or three or more ear infections to children without a history of ear tubes and/or less than three ear infections prior to age five.

## **Methods**

Forty children aged 10-12 years with and without history of multiple ear infections and/or tympanostomy tubes prior to age five were recruited for this study from the local community. Based on parent self-report, participants were divided into two groups: 18 participants with history of tympanostomy tubes and/or three or more ear infections prior to age five and 22 participants without history of tympanostomy tubes and less than three ear infections prior to age five. Participants were excluded if they had neurologic disorders affecting balance and gait, seizure disorders, non-corrected visual deficits, and/or medications affecting balance. Parents of all participants signed Loma Linda

University's Institutional Review Board approved informed consent prior to study participation and then the children read and signed the informed assent.

The Physical Activity Questionnaire for Children (PAQ-C) was used to assess the general activity level for the children. The PAQ-C was developed for elementary school-aged children ages 8-14 years, and is a nine-item questionnaire pertaining to recollection of the child's last seven days of physical activity. The total score was calculated by taking the mean of the 9 items. A score of one indicated a low physical activity, while a score of five indicated a high physical activity level for the child.<sup>5</sup> Voss et al.<sup>6</sup> reported that the PAQ-C is a valid and reliable tool used to assess physical activity level in elementary school-aged in healthy children.

Postural stability was measured using the Pediatric Balance Scale (PBS) and NeuroCom<sup>®</sup> VSR<sup>™</sup> SPORT Computerized Dynamic Posturography Stability Evaluation Test (SET). The PBS is a non-computerized 14-item criterion-referenced tool that measures static and dynamic functional balance of daily activities in children.<sup>7,8</sup> The PBS tasks include items such as sit to stand, transfers, and turning 360 degrees.<sup>7,8</sup> The PBS is a simple and valid tool that can be used in pediatric rehabilitation to examine functional balance and predict motor capability and capacity.<sup>9,10,11</sup>

Postural stability was also measured using SET. The SET has good to excellent reliability for postural stability measurement.<sup>12</sup> Static postural stability was tested on a stable surface in six conditions including narrow double limb stance on firm surface, single limb stance on firm surface, tandem (dominant foot behind) stance on firm surface, narrow double limb stance on unstable surface, single limb stance on unstable surface, and tandem (dominant foot behind) stance on unstable surface. In all conditions

participants closed their eyes and placed their hands on their iliac crests. The SET protocol quantifies the participant's center of gravity (COG) sway as a weighted average of all six conditions.

### **Procedures**

Parents of all participants signed Loma Linda University's Institutional Review Board approved informed consent prior to study participation and then the children read and signed the informed assent. Participants then completed the PAQ-C. Before testing, participants removed shoes and socks followed by height and weight measurements. Participants donned a safety harness before postural stability was measured. Postural stability was measured using two different assessment tools. Postural stability was first measured using the PBS. Each item ranged from 0 (unable to perform) to 4 (able to perform the task without difficulty independently as instructed). Participants were given verbal and visual instructions for each item. One trial was given to each participant. A second trial was given if the participant was unable to understand verbal and visual instructions. Next, postural stability was measured using the SET, which measured static postural stability on a stable surface in six conditions including double limb stance, single limb stance, and tandem (dominant foot behind) stance. In each condition, participants closed their eyes and placed hands on their iliac crests. The same three conditions were repeated on a foam surface to test dynamic postural stability.

Data was analyzed using Statistical Package for the Social Sciences SPSS version 25.0 (IBM Corp, Armonk, NY). A sample size of 42 subjects was estimated using an effect size ( $d=0.90$ ), a power of 0.80, and a level of significance set at 0.05. The general characteristics of the participants were summarized using means and standard deviations

for quantitative variables, and frequency and percentages for categorical variables. We compared mean age and body mass index ( $\text{kg/m}^2$ ) (BMI) using independent t-test. Since the distribution of postural stability during tandem stance on foam surface, PBS scores during tandem stance and single limb stance were not approximately normal, Mann Whitney U test was used to examine differences in median stability and PBS scores between the two groups. The level of significance was set at  $p \leq 0.05$ .

## Results

Forty children (20 males and 20 females) with mean age  $10.7 \pm 0.8$  years participated in this study. The study sample comprised of 18 children with a history of tympanostomy tubes and/or three or more ear infections and 22 children without history of tympanostomy tubes and/or less than three ear infections. The baseline characteristics were similar between the two groups ( $p > 0.05$ ). ( $p > 0.05$ , Table 1).

**Table 2.** Mean (SD) of characteristics by study group (N=40)

	<b>Tubes and/or <math>\geq 3</math> ear infections (<math>n_1=18</math>)</b>	<b>No tubes and <math>&lt; 3</math> ear infections (<math>n_2=22</math>)</b>	<b>p-value (d)</b>
<b>Female, n (%)</b>	11 (61.1)	9 (40.9)	0.17
<b>Age (years)</b>	10.5 (8.1)	10.9 (0.9)	0.17 (0.07)
<b>BMI (<math>\text{kg/m}^2</math>)</b>	20.5 (4.9)	20.8 (4.8)	0.90 (0.06)

Abbreviations: SD, Standard Deviation; BMI, Body Mass Index

A significant difference was found in median postural stability scores in the SET during tandem stance on unstable surface between participants with versus without ear infections (median [minimum, maximum] of 9.1 [1.4, 11.4] versus 5.8 [1.7, 12.8],  $p = 0.04$ ; Figure 1 and Table 2). In addition, a significant difference in median PBS scores was detected during tandem stance between the two groups (3 [0, 4] versus 4 [4, 4],  $p =$

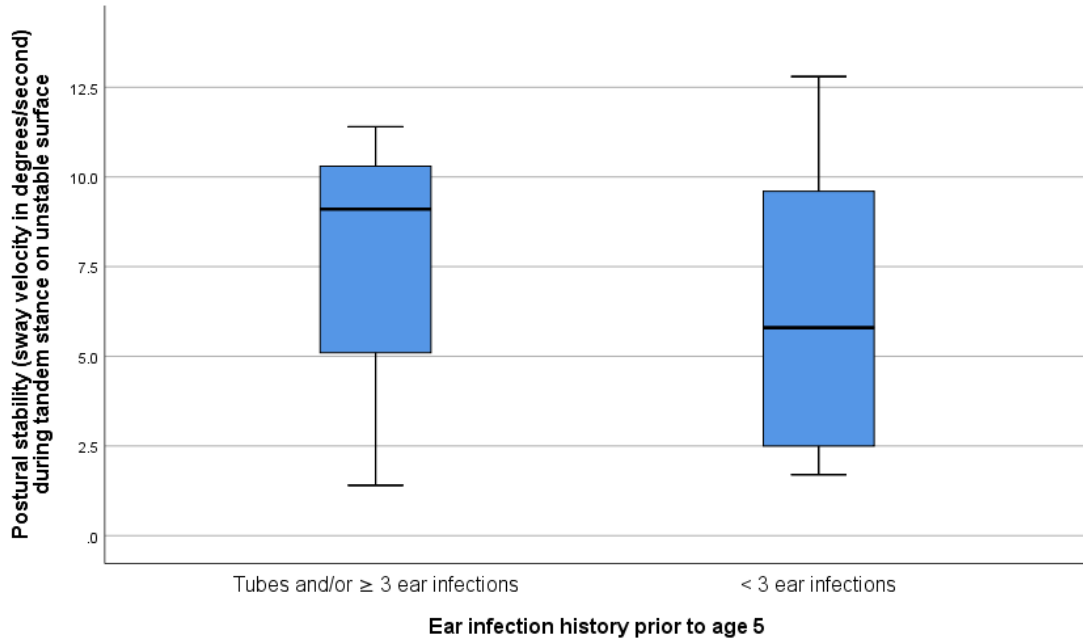


0.001; Figure 2 and Table 2). Also, there was a significant difference in median PBS scores during single limb stance (4 [0, 4] versus 4 [4, 4],  $p=0.037$ ; Figure 3 and Table 2).

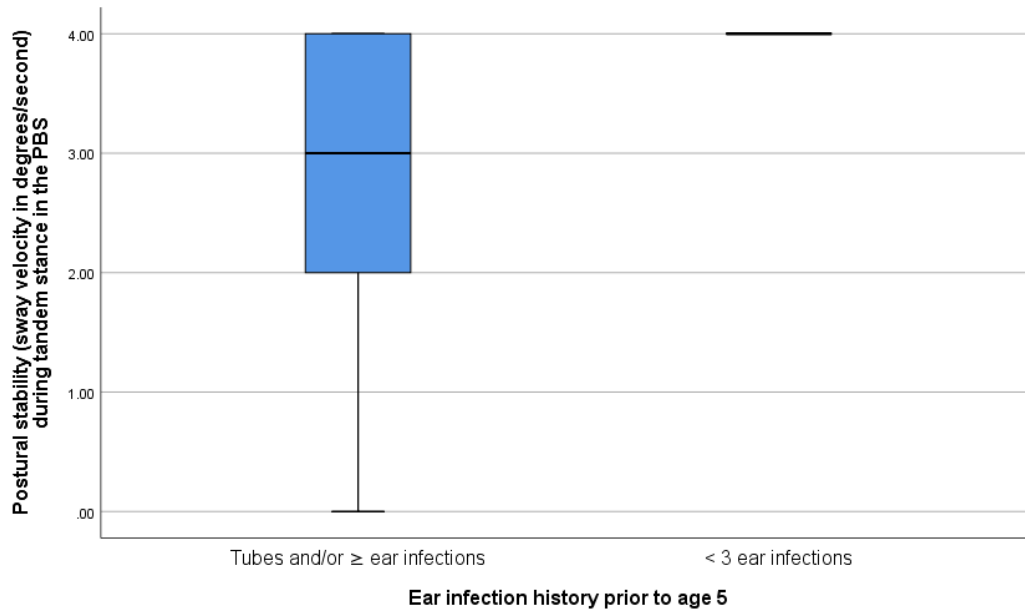
**Table 3.** Median (minimum, maximum) postural stability scores by study group (N=40)

	<b>Tubes and/or <math>\geq 3</math> ear infections (<math>n_1=18</math>)</b>	<b>No tubes and <math>&lt;3</math> ear infections (<math>n_2=22</math>)</b>	<b>p-value (<math>\eta^2</math>)</b>
<b>SET TLS</b>	9.1 (1.4, 11.4)	5.8 (1.7, 12.8)	0.041 (0.56)
<b>PBS SLS</b>	4(0,4)	4(4,4)	0.037 (0.26)
<b>PBS TLS</b>	3(0,4)	4(4,4)	0.001 (0.45)

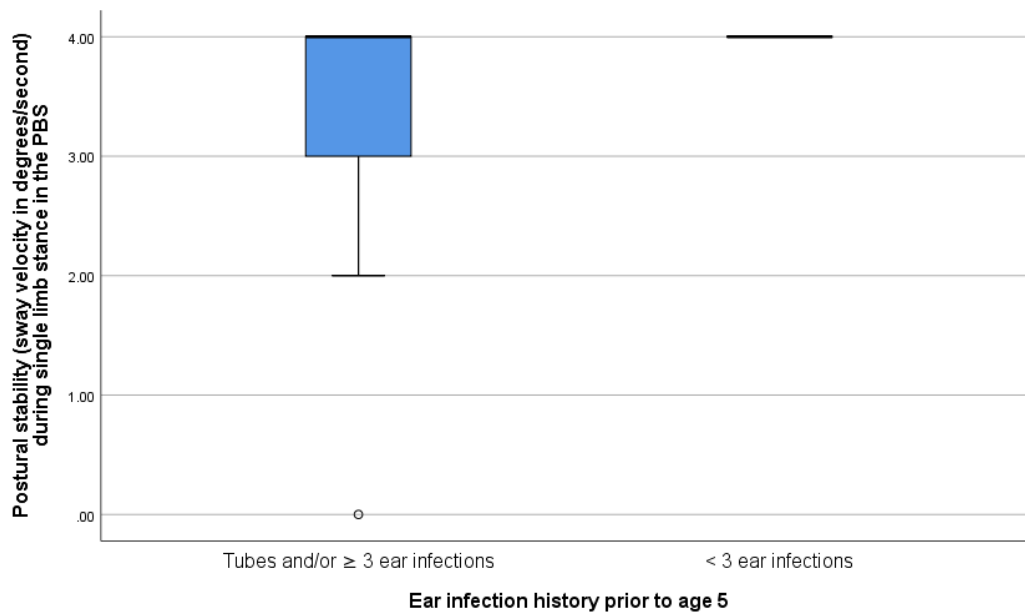
Abbreviations: SET, Stability Evaluation Test; PBS, Pediatric Balance Scale; SLS, Single Limb Stance; TLS, Tandem Limb Stance (dominant foot behind);  $\eta^2$ , Effect Size



**Fig. 8.** Postural stability scores during tandem stance on unstable surface by study group



**Fig. 9.** Pediatric Balance Scale scores during tandem stance by study group



**Fig. 10.** Pediatric Balance Scale scores during single limb stance by study group

## Discussion

The present study investigated the effectiveness of postural stability computerized versus non-computerized measurement tools in children aged 10-12 years with history of tympanostomy tubes and/or three or more ear infections versus those without history of tympanostomy tubes and less than three ear infections prior to age five by using the computerized SET and non-computerized PBS. Our results demonstrated that both the SET and PBS detected postural instability in the group with history of tympanostomy tubes and/or three or more ear infections during tandem stance in both measurement tools.

Casselbrant et al.<sup>4</sup> reported that during recurrent OME episodes, children have abnormal balance and vestibular hypofunction. In addition, Van Cauwenberge et al.<sup>13</sup> reported that postural stability and the vestibular system in children with recurrent OME may or may not completely improve after the OME episode resolves. The present study demonstrated that postural stability did not improve completely after resolution of OME.

The SET measures postural stability as sway velocity in degrees per second across several different testing conditions.<sup>14</sup> The PBS measures functional postural stability without special equipment such as computerized dynamic posturography, which is expensive and have more difficulties during the assessment.<sup>7,8</sup>

This study has some limitations. The study sample included few participants with a history of tympanostomy tubes. Also, group assignment was based on self-report. Future investigators should consider recruiting children with history of tympanostomy tubes, children with multiple ear infection history that have low activity levels, and

having participants' parents supply medical records for group assignment. In addition, there were no physical activity level differences between groups. Future research should consider recruiting participants with lower activity levels as physical activity level may positively impact postural stability in children with tubes and/or three or more ear infections prior to age five.

In conclusion, the results suggest that computerized and non-computerized postural stability outcome measures detect lasting effects of postural instability in children ages 10-12 with a history of ear tubes and/or three or more ear infections prior to age five.

**Table 4.** Mean (SD) of characteristics and outcomes by study group (N=40)

	Tubes and/or $\geq 3$ ear infections (n <sub>1</sub> =18)	No tubes and <3 ear infections (n <sub>2</sub> =22)	p-value (d)
Female, n (%)	11 (61.1)	9 (40.9)	0.17
Age (years)	10.5 (8.1)	10.9 (0.9)	0.17 (0.07)
BMI (kg/m <sup>2</sup> )	20.5 (4.9)	20.8 (4.8)	0.90 (0.06)
SET Condition 1	0.9 (0.2)	0.8 (0.2)	0.40 (0.50)
SET Condition 4	2.1 (0.5)	2.2 (0.8)	0.65 (0.15)
SET Condition 2	4.3 (1.8)	3.9 (2.0)	0.59 (0.21)
SET Condition 5	6.3 (1.3)	5.9 (1.5)	0.46 (0.28)
SET Condition 3	3.0 (2.3)	2.8 (1.8)	0.76 (0.10)
SET Condition 6 <sup>**</sup>	9.1 (1.4, 11.4)	5.8 (1.7, 12.8)	0.04 <sup>*</sup> (0.56)
PAQ-C	3.2 (0.8)	3.1 (1.0)	0.58 (0.11)
PBS <sup>**</sup>	54 (47, 56)	56 (55, 56)	0.001 <sup>*</sup> (1.33)

Abbreviation: SD, Standard Deviation; BMI, Body Mass Index; PAQ-C, Physical Activity Questionnaire for Children; SET, Stability Evaluation Test; SET Condition 1: measured postural stability with narrow double limb stance on firm surface; SET Condition 2: measured postural stability with single limb stance on firm surface; SET Condition 3: measured postural stability with tandem (dominant foot behind) stance on firm surface; SET Condition 4: measured postural stability with narrow double limb stance on unstable surface; SET Condition 5: measured postural stability with single limb stance on unstable surface; SET Condition 6: measured postural stability with tandem (dominant foot behind) stance on unstable surface. In all conditions participants closed their eyes and placed their hands on their iliac crests; PBS, Pediatric Balance Scale

<sup>\*</sup>: p<0.05 <sup>\*\*</sup>: Results are reported as Median (Minimum, Maximum)

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## CHAPTER FOUR

### Discussion

The present study investigated the effect of pediatric ear infections, prior to age five, on chronic motion sensitivity in children aged 10-12 years with history of tympanostomy tubes and/or 3 or more ear infections versus those without history of tympanostomy tubes and/or 0-2 ear infections by using the CDP-IVR, SET, and PBS. This study was the first to our knowledge to evaluate postural stability after ear infections resolved. The results indicated that postural stability was worse in the group with history of tympanostomy tubes and/or 3 or more ear infections during tandem stance and PBS scores.

Casselbrant et al.<sup>(Casselbrant et al., 2000)</sup> reported that during recurrent OME episodes, children have postural instability and vestibular hypofunction. In addition, postural stability and the vestibular system in children with recurrent OME may or may not completely improve after the OME episode resolves.<sup>(Said, 2015)</sup> The present study results demonstrated that the postural stability did not improve completely after resolution of OME.

Casselbrant et al.<sup>(Casselbrant et al., 1998)</sup> suggested that children with OME and vestibular hypofunction might solely rely on the visual and proprioceptive systems to support postural stability. They used in the study a posture platform with a visual surround (Equitest, NeuroCom, Inc) in three conditions: no visual scene movement, scene movement at 0.10 Hz, and scene movement at 0.25 Hz to test visual balance dependency. In the present study, there was no significant difference in mean postural stability during eyes closed or during the immersion virtual reality conditions. Our results



suggest that children with OME don't over rely on their visual system to compensate for their abnormal postural stability. This could be related to the fact that all participants were active as measured by the PAQ-C. However, children with multiple ear infection history that have lower activity levels might present differently.<sup>(Alharbi et al., 2017; Gaikwad et al., 2018)</sup>

The CDP-IVR measures static postural stability by calculating participants' center of gravity displacements under three conditions.<sup>(Palm et al., 2014)</sup> The SET measures postural stability as sway velocity in degrees per second across several different testing conditions.<sup>(Al Mubarak et al., 2016)</sup> There is a difference in the base of support between the CDP-IVR and the SET protocol, which could be the reason for the different results between the SET and CDP-IVR.

The PBS is a valid, reliable, simple, and quick tool that can be used to assess a child's functional balance in less than 20 minutes.<sup>(AbilityLab, 2015; Franjoine et al., 2010)</sup> The 14-items include tasks that are routinely performed by children throughout the day as part of their activities of daily living. It is easily scored and does not require special equipment compared to balance computerized tools, which are expensive and have more difficulties during the assessment. In this study, there was no significant difference in mean postural stability during eyes closed or during the immersion virtual reality condition.

This study has some limitations. The study sample included few participants with a history of tympanostomy tubes. Also, group assignment was based on self-report. Future investigators should consider recruiting children with history of tympanostomy tubes, children with multiple ear infection history that have low activity levels, and

having participants' parents supply medical records for group assignment.

The present study investigated the effectiveness of postural stability computerized versus non-computerized measurement tools in children aged 10-12 years with history of tympanostomy tubes and/or 3 or more ear infections versus those without history of tympanostomy tubes and/or less than three ear infections prior to age five by using the SET, and PBS. Our results demonstrated that postural stability was worse in the group with history of tympanostomy tubes and/or 3 or more ear infections during tandem stance and PBS scores.

### **Conclusion**

Based on the current study children ages 10-12 with history of tympanostomy tubes and/or 3 or more ear infections prior to age five have decreased postural stability compared to children without history of tympanostomy tubes and/or 0-2 ear infections.

To help children, improve their postural stability after ear infections episodes resolves the results of the study encourage physical therapists to assess and treat postural stability problems in early childhood. Previous studies have shown that OME patients have balance problems during the acute phase of the OME.

Our study assumed, and the results showed, that balance problems continue as child ages. Future studies need to measure the effects of physical therapy intervention on pediatric postural stability and motion sensitivity to inform medical practitioner that they should consider referring pediatric patients for physical therapy after the OME has been resolved.

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## APPENDICES A

### *Physical Activity Questionnaire (Elementary School)*

Name: \_\_\_\_\_

Age: \_\_\_\_\_

Sex: M \_\_\_\_\_ F \_\_\_\_\_

Grade: \_\_\_\_\_

Teacher: \_\_\_\_\_

We are trying to find out about your level of physical activity from *the last 7 days* (in the last week). This includes sports or dance that make you sweat or make your legs feel tired, or games that make you breathe hard, like tag, skipping, running, climbing, and others.

**Remember:**

1. There are no right and wrong answers — this is not a test.
2. Please answer all the questions as honestly and accurately as you can — this is very important.

1. Physical activity in your spare time: Have you done any of the following activities in the past 7 days (last week)? If yes, how many times? (Mark only one circle per row.)

	No	1-2	3-4	5-6	7 times or more
Skipping .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rowing/canoeing .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In-line skating .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tag .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking for exercise .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bicycling .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Jogging or running .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Aerobics .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Swimming .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Baseball, softball .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dance .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Football .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Badminton .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Skateboarding .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Soccer .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Street hockey .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Volleyball .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Floor hockey .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Basketball .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ice skating .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cross-country skiing .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ice hockey/ringette .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other: .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
.....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. In the last 7 days, during your physical education (PE) classes, how often were you very active (playing hard, running, jumping, throwing)? (Check one only.)

- I don't do PE ..... ☐
- Hardly ever ..... ☐
- Sometimes ..... ☐
- Quite often ..... ☐
- Always ..... ☐

3. In the last 7 days, what did you do most of the time *at recess*? (Check one only.)

- Sat down (talking, reading, doing schoolwork)..... ☐
- Stood around or walked around ..... ☐
- Ran or played a little bit ..... ☐
- Ran around and played quite a bit ..... ☐
- Ran and played hard most of the time ..... ☐

4. In the last 7 days, what did you normally do *at lunch* (besides eating lunch)? (Check one only.)

- Sat down (talking, reading, doing schoolwork)..... ☐
- Stood around or walked around ..... ☐
- Ran or played a little bit ..... ☐
- Ran around and played quite a bit ..... ☐
- Ran and played hard most of the time ..... ☐

5. In the last 7 days, on how many days *right after school*, did you do sports, dance, or play games in which you were very active? (Check one only.)

- None ..... ☐
- 1 time last week ..... ☐
- 2 or 3 times last week ..... ☐
- 4 times last week ..... ☐
- 5 times last week ..... ☐

6. In the last 7 days, on how many *evenings* did you do sports, dance, or play games in which you were very active? (Check one only.)

- None ..... ☐
- 1 time last week ..... ☐
- 2 or 3 times last week ..... ☐
- 4 or 5 last week ..... ☐
- 6 or 7 times last week ..... ☐

7. On the last weekend, how many times did you do sports, dance, or play games in which you were very active? (Check one only.)

- None ..... ☐  
 1 time ..... ☐  
 2 — 3 times ..... ☐  
 4 — 5 times ..... ☐  
 6 or more times ..... ☐

8. Which *one* of the following describes you best for the last 7 days? Read *all five* statements before deciding on the *one* answer that describes you.

- A. All or most of my free time was spent doing things that involve little physical effort ..... ☐  
 B. I sometimes (1 — 2 times last week) did physical things in my free time (e.g. played sports, went running, swimming, bike riding, did aerobics) ..... ☐  
 C. I often (3 — 4 times last week) did physical things in my free time ..... ☐  
 D. I quite often (5 — 6 times last week) did physical things in my free time ..... ☐  
 E. I very often (7 or more times last week) did physical things in my free time ..... ☐

9. Mark how often you did physical activity (like playing sports, games, doing dance, or any other physical activity) for each day last week.

	None	Little bit	Medium	Often	Very often
Monday .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tuesday .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wednesday .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thursday .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Friday .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Saturday .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sunday .....	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Were you sick last week, or did anything prevent you from doing your normal physical activities? (Check one.)

- Yes ..... ☐  
 No ..... ☐

If Yes, what prevented you? \_\_\_\_\_



## APPENDICES B

### Pediatric Balance Scale

**Name:**

**Location:**

**Examiner:**

		<b>Date:</b>	<b>Date:</b>	<b>Date:</b>
		Score 0-4 (time- optional)	Score 0-4 (time- optional)	Score 0-4 (time- optional)
1.	<p>Sitting to standing “ Hold your arms up and stand up”</p> <p>4- able to stand without using hands and stabilize independently 3- able to stand independently using hands 2- able to stand using hands after several tries 1- needs minimal assist to stand or to stabilize 0- needs moderate or maximal assist to stand</p>			
2.	<p>Standing to sitting “Sit down slowly without using your hands”</p> <p>4- sits safely with minimal use of hands 3- controls descent by using hands 2- uses back of legs against chair to control descent 1- sits independently, but has uncontrolled descent 0- needs assistance to sit</p>			
3.	<p>Transfers</p> <p>4- able to transfer safely with minor use of hands 3- able to transfer safely; definite need of hands 2- able to transfer with verbal cuing and/or supervision (spotting) 1- needs one person to assist</p>			

	0- needs two people to assist or supervise (close guard) to be safe			
4.	<p>Standing unsupported</p> <p>4- able to stand safely 30 seconds</p> <p>3- able to stand 30 seconds with supervision (spotting)</p> <p>2- able to stand 15 seconds unsupported</p> <p>1- needs several tries to stand 10 seconds unsupported</p> <p>0- unable to stand 10 seconds unassisted</p>	(__ sec.)	(__ sec.)	(__ sec.)
5.	<p>Sitting unsupported</p> <p><b>“Sit with your arms folded on your chest for 30 seconds”</b></p> <p>4- able to sit safely and securely 30 seconds</p> <p>3- able to sit 30 seconds under supervision (spotting) or may require definite use of upper extremities to maintain sitting position</p> <p>2- able to sit 15 seconds</p> <p>1- able to sit 10 seconds</p> <p>0- unable to sit 10 seconds without support</p>	(__ sec.)	(__ sec.)	(__ sec.)
6.	<p>Standing with eyes closed</p> <p>“When I say close your eyes, I want you to stand still, close your eyes, and keep them closed until I say open”</p> <p>4- able to stand 10 seconds safely</p> <p>3- able to stand 10 seconds with supervision (spotting)</p> <p>2- able to stand 3 seconds</p> <p>1- unable to keep eyes closed 3 seconds but stays steady</p> <p>0- needs help to keep from falling</p>	(__ sec.)	(__ sec.)	(__ sec.)
7.	Standing with feet together	(__ sec.)	(__ sec.)	(__ sec.)

	4- able to place feet together independently and stand 30 seconds safely 3- able to place feet together independently and stand for 30 seconds with supervision (spotting) 2- able to place feet together independently but unable to hold for 30 seconds 1- needs help to attain position but able to stand 30 seconds with feet together 0- needs help to attain position and/or unable to hold for 30 seconds			
8.	Standing with one foot in front 4- able to place feet tandem independently and hold 30 seconds  3- able to place foot ahead of other independently and hold 30 seconds 2- able to take small step independently and hold 30 seconds, or required assistance to place foot in front, but can stand for 30 seconds 1- needs help to step, but can hold 15 seconds 0- loses balance while stepping or standing	(__ sec.)	(__ sec.)	(__ sec.)
9.	Standing on one foot 4- able to lift leg independently and hold 10 seconds  3- able to lift leg independently and hold 5-9 seconds 2- able to lift leg independently and hold 3-4 seconds 1- tries to lift leg; unable to hold 3 seconds but remains standing 0- unable to try or needs assist to prevent fall	(__ sec.)	(__ sec.)	(__ sec.)
10.	Turning 360 degrees “Turn completely around in a full circle, STOP, and then turn a full circle in the other direction”	(__ sec.)	(__ sec.)	(__ sec.)

	4- able to turn 360 degrees safely in 4 seconds or less each way 3- able to turn 360 degrees safely in one direction only in 4 seconds or less 2- able to turn 360 degrees safely but slowly 1- needs close supervision (spotting) or constant verbal cuing 0- needs assistance while turning			
11	Turning to look behind “ Follow this object as I move it. Keep watching it as I move it, but don’t move your feet.”  4- looks behind/over each shoulder; weight shifts include trunk rotation  3- looks behind/over one shoulder with trunk rotation 2- turns head to look to level of shoulders, no trunk rotation 1- needs supervision (spotting) when turning; the chin moves greater than half the distance to the shoulder 0- needs assistance to keep from losing balance or falling; movement of the chin is less than half the distance to the shoulder			
12	Retrieving object from floor 4- able to pick up chalk board eraser safely and easily 3- able to pick up eraser but needs supervision (spotting) 2- unable to pick up eraser but reaches 1-2 inches from eraser and keeps balance independently 1- unable to pick up eraser; needs spotting while attempting  0- unable to try, needs assist to keep from losing balance or falling			
13	Placing alternate foot on stool 4- stands independently and safely and completes 8	(__ sec.)	(__ sec.)	(__ sec.)

	steps in 20 seconds  3- able to stand independently and complete 8 steps >20 seconds 2- able to complete 4 steps without assistance, but requires close supervision (spotting) 1- able to complete 2 steps; needs minimal assistance 0- needs assistance to maintain balance or keep from falling, unable to try			
14	Reaching forward with outstretched arm “ Stretch out your fingers, make a fist, and reach forward as far as you can without moving your feet”  4- reaches forward confidently >10 inches  3- reaches forward >5 inches, safely 2- reaches forward >2 inches, safely 1- reaches forward but needs supervision (spotting) 0- loses balance while trying, requires external support	(__ in.)	(__ in.)	(__ in.)
TOTAL SCORE				

## APPENDICES C



### Research Opportunity



#### Effect of Ear Infections on Balance in Children

The Physical Therapy Department in the School of Allied Health Professions at Loma Linda University is conducting a Doctoral Student research project examining the potentially lasting effects of ear tubes/tubes on the physical and visual aspects of balance in children as they age.

### PARTICIPANTS ARE NEEDED

You may qualify to participate in this study if

- You are a healthy child **with** or **without** history of ear tube insertion before the age of five
- Your current age is between 10-12

You're eligible to participate if you don't have difficulty with walking, seizures, vision disorders, or current medications causing dizziness or imbalance. Then, your balance will be measured using a combination of non-invasive computerized machines, basic balance activities, and questionnaires.

Neither you nor your health insurance provider will be charged for the cost of any evaluation or treatment provided for the purposes of this study. After completing the assessment, you will receive a gift card as an expression of our thanks for your participation.

If you are interested in participating or would like to know more about the study, please contact

Eric Johnson at: 909-658-5223 or 909-558-4632 ext. 47471/email at [ejohnson@llu.edu](mailto:ejohnson@llu.edu)

## **APPENDICES D**

### **INFORMED CONSENT**

**TITLE:** **EFFECT OF EAR INFECTIONS ON BALANCE IN CHILDREN**

**SPONSOR:** **Department of Allied Health Studies, Loma Linda University**

**PRINCIPAL INVESTIGATOR:** Eric Glenn Johnson, DSc, PT, MS-HPed, NCS  
Professor, Physical Therapy Department  
Loma Linda University, Loma Linda CA  
School of Allied Health Professions  
Nichol Hall Room #A-712  
Phone: (909) 558-4632 Extension 47471  
Fax: (909) 558-0459  
Email Address: [ejohnson@llu.edu](mailto:ejohnson@llu.edu)

#### **1. WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to examine the effect of ear infections on balance in children. Your child is invited to participate because we need healthy children between 10-12 years of age in this research study who had ear tube insertion prior to age 5 and some who did not have ear tube insertion.

#### **2. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

Approximately 100 subjects will be recruited to participate in this study.

#### **3. HOW LONG WILL THE STUDY GO ON?**

The study requires one session. The session will be approximately 90 minutes in the research lab at Loma Linda University.

#### **4. HOW WILL I BE INVOLVED?**

Your child will be asked several questions to determine if they can be in this study. Your child's date of birth, height and weight will be recorded followed by these activities:

- Your child will complete the Physical Activity Questionnaire for Children (PAQ-C), then will be assigned into two groups (50 participants with history of ear tube insertion and 50 participants without history of ear tube insertion).

- Next, standing balance will be measured using a computerized machine. After that, standing balance will be measured using a non-computerized functional test. Finally, standing balance will be measured using another computerized machine.

## **5. WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?**

There is risk of falling and/or mild dizziness during standing balance testing. To minimize the risk of falling, your child will be wearing a safety harness and two researchers will be standing beside them at all times during testing. There is also a minimal risk that your identity will be made known.

## **6. WILL THERE BE ANY BENEFIT TO ME OR OTHERS?**

We hope to improve our understanding of standing balance and the effect of ear tube insertion on pediatric standing balance. Future research involving interventions for improving standing balance in children with history of ear tube insertion will be guided by our findings.

## **7. WHAT ARE MY RIGHTS AS A SUBJECT?**

Participation in this study is voluntary. Your decision whether or not your child should participate or terminate at any time will not affect your child present or future relationship with the Loma Linda University Department of Physical Therapy. You do not give up any legal rights by your child participating in this study.

## **8. WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?**

Your child is free to withdraw from this study at any time. If your child decides to withdraw from this study you should notify the research team immediately. The research team may also end your child's participation in this study if your child does not follow instructions or if your child's safety and welfare are at greater than minimal risk due to greater than mild dizziness during testing.

## **9. HOW WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?**

Efforts will be made to keep your child's personal information confidential, but we cannot guarantee absolute confidentiality. We will use a code name throughout the study for all recorded data so your child's actual name will not be used. Your child will not be identified by name in any publications describing the results of this study. Data in hard copy will be kept in a locked file cabinet in a locked office and electronic data will be password protected.



## **10. WHAT COSTS ARE INVOLVED?**

There is no cost to your child for participation in this study beyond the time involved to participate.

## **11. WILL I BE PAID TO PARTICIPATE IN THIS STUDY?**

You will receive a \$25 gift card on the day of data collection.

## **12. WHO DO I CALL IF I HAVE QUESTIONS?**

If you feel your child has been injured by taking part in this study, consult with a physician or call 911 if the situation is a medical emergency. No funds have been set aside nor any plans made to compensate you for time lost for work, disability, pain or other discomforts resulting from your participation in this research.

If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4674, e-mail [patientrelations@llu.edu](mailto:patientrelations@llu.edu) for information and assistance.

## **13. SUBJECT'S STATEMENT OF CONSENT**

I have read the contents of the consent form and have listened to the verbal explanation given by the investigators. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent that my child is a participant in this study. I have been given a copy of this consent form. Signing this consent document does not waive my rights nor does it release the investigators, institution, or sponsors from their responsibilities. I may call and leave a voice message for Eric Johnson, DSc during routine office hours at this number (909) 558-4632 ext. 47471 or e-mail him at [ejohnson@llu.edu](mailto:ejohnson@llu.edu), if I have additional questions and concerns.

I understand I will be given a copy of this consent form after signing it.

---

Parent or Legal Guardian's  
Signature

---

Printed Name of Parent or Legal  
Guardian's Signature

---

Date

**14. INVESTIGATOR'S STATEMENT**

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

---

Signature of Investigator

---

Printed Name of Investigator

---

Date

## **APPENDICES E**

### **Assent Form**

#### **Effect of Ear Infection on Balance in Children**

Would you like to help one of our physical therapy students learn more about balance problems? Ohud Sabir is studying the effect of ear tubes on children's standing balance to learn more about how to improve balance in children with poor balance.

You can help with the study by completing a short form called the Physical Activity Questionnaire for Children and letting the physical therapist and her helpers measure your standing balance with 3 different balance tests.

You might feel like falling and/or feel a dizzy during the balance testing. To prevent falling, you will be wearing a safety harness and 2 of my helpers will be standing beside you at all times during testing.

Do you have any questions about participating in this study? If you do, you can ask the person who gave you this form. If you want to participate, say "yes" to helping with the study for measuring your standing balance then sign on the line below.  
Thank you for thinking about this idea.

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---

Child's Signature

Date

## APPENDICES F

### AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION



## INSTITUTIONAL REVIEW BOARD Authorization for Use of Protected Health Information (PHI)

*Per 45 CFR §164.508(b)*

*RESEARCH PROTECTION PROGRAMS*

LOMA LINDA UNIVERSITY | Office of the Vice President of Research Affairs  
24887 Taylor Street, Suite 202 Loma Linda, CA 92350  
(909) 558-4531 (voice) / (909) 558-0131 (fax)/e-mail: [irb@llu.edu](mailto:irb@llu.edu)

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TITLE OF STUDY:	Effects of Chronic Motion Sensitivity on Vestibular Function, Balance, Strength, and Stress in Middle-Aged Adults
PRINCIPAL INVESTIGATOR:	Eric G. Johnson, DSc, PT, MS-HPed, NCS
Others who will use, collect, or share PHI:	Authorized Research Personnel

The student research study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered “Protected Health Information” (PHI) is needed to conduct this study and may include, but is not limited to name, birth date, phone number, e-mail, and a health questionnaire.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University. The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk. All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not be required to follow national and international “protected health information” (PHI) regulations such as the federal privacy rule. Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

This authorization does not expire and will continue indefinitely unless you notify the researchers that you wish to revoke it.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission; no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at 909-583-4966.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

---

I agree that my personal health information may be used for the study purposes described in this form.

_____ Signature of Patient or Patient's Legal Representative	_____ Date
_____ Printed Name of Legal Representative (if any)	_____ Representative's Authority to Act for Patient
_____ Signature of Investigator Obtaining Authorization	_____ Date