Crib Bumpers and the Infant Sleeping Environment: An Evaluation of the Scientific Evidence

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Executive Summary

Formal investigations into the safety of the infant sleeping environment by the Consumer Product Safety Commission (CPSC) have not identified bumper pads as a hazardous product or as a significant source of serious injury or death to sleeping infants (Wanna-Nakamura, 2010). Additionally, a recent review of epidemiological data and published scientific studies did not reveal any affirmative evidence of a causal link between crib bumpers and infant mortality (Schwartz, et al., submitted).

However, in an earlier article, Deaths and Injuries Attributed to Crib Bumper Pads (Thach et al., 2007), the authors raised concerns as to the safety and appropriateness of crib bumper pads as part of an infant sleep environment. The authors conclude, "this case series provides evidence that the risks from crib bumper pads or padded bassinettes (death) outweigh the possible benefits provided by such padding (minor bruises and contusions)… We conclude that bumpers should not be placed in cribs or bassinets."

Thach et al. (2007) has often been cited by others as scientific evidence that crib bumpers pose a serious risk of fatality to sleeping infants. For example, a team of researchers (Yeh, et al., 2011) publishing on injuries associated with cribs offered no independent analysis of infant fatalities associated with crib bumpers, nor did they present a specific analysis related to the potential for crib bumpers to mitigate injuries. Yet, citing Thach et al. (2007), they recommended that "the use of crib bumper pads is strongly discouraged because the possibility for serious injury, including suffocation and strangulation, greatly outweighs any minor injury they may prevent."

The conclusions of Thach et al. (2007) about the suffocation hazards posed by crib bumper pads remain in contrast to the scientific findings of others. Re-analyses of the Thach et al. (2007) data is ongoing, and preliminary examination of currently available portions of their data set has raised concerns about the validity of their findings and conclusions. For example, methodological problems are apparent in the criteria used to select the incidents included for analysis and in the analytical treatment of other potential contributors. Furthermore, an attempt to recreate the "injury analysis" presented by Thach et al. (2007) highlighted similar methodological and analytical concerns. A more thorough analysis of the injuries that occur to infant children within the crib demonstrates that crib bumpers could serve to mitigate the injury potential (e.g., lacerations, fractures) across a variety of the common accident modes (e.g., contact with railings, extremities caught between railings).

Background Information

Scientific literature, research, and data related to hazards and unsafe practices associated with infant sleep environments have investigated the possible relationship between crib bumpers and infant fatalities. However, the majority of these accounts do not provide evidence that crib bumpers present a significant hazard or risk. For example, neither recent nor historic reviews of national injury and fatality data performed by the Consumer Product Safety Commission (CPSC) have identified crib bumpers as a unique or identifiable source of serious injury or death to sleeping infants (Scheers et al., 2003; Chowdury, 2010, 2009a, 2009b; Wanna-Nakamura, 2010). For example, Wanna-Nakamura (2010) reviewed four databases maintained by CPSC (Injury and Potential Injury Incidents – IPII, Death Certificates – DTHS, In-Depth Investigations – INDP, and National Electronic Injury Surveillance System – NEISS) covering the period from January 1, 1990 to May 6, 2010 for incidents that reference the possible involvement of a bumper pad. In more than 10 years of data, 28 records referencing "bumper" and "pad" were identified and subjected to a further detailed review. This analysis stated that in the majority of the reports of the instances, there was "minimal" information. However in the majority of cases where there was some information upon which a review could be performed, it was evident that "the most significant risk factor appeared to be the fact that infants were in the prone position." Additionally this review highlighted that other factors, such as the presence of soft bedding including cushions and pillows, could have contributed to the deaths. Finally, the paper noted that one fatality was associated with an atypical usage of the crib bumper around a toddler bed and did not occur in a crib.

More recently, a systematic review of publicly available databases as well as published and unpublished reports related to infant mortality during sleep and the sleep environment (Schwartz, et al., submitted) found no association between bumper pads and SIDS/infant deaths. The available evidence led the authors to conclude that the presence of bumper pads does not increase the risk of infant mortality. For example, the researchers searched literature databases for controlled epidemiological studies that could inform this issue, and identified a potential 144 articles, of which twelve met inclusion criteria for detailed review. The authors noted that all of the available controlled epidemiological research failed to mention or report any relationship between crib bumpers and infant mortality. Furthermore, the authors cited a UK research program that specifically considered bumper pads in its investigation of sudden unexpected deaths in infancy and noted that the original study found no relationship between crib bumpers and infant mortality, stating that "there was a higher use of bumper pads among the (living) control infants."

Despite the above, one study (Thach et al., 2007) purports that the use of crib bumpers is dangerous and advises against their use. Thach et al. (2007) reviewed fatality data for the years 1985 through 2005 for infants under the age of two that reference bumper pads (utilizing the same CPSC databases as those considered by Wanna-Nakamura) and noted "27 cases of infant death involving bumper pads or similarly padded bassinets (4 of the 27 cases)." Based on the information available within these records, the authors classified these incidents into three accident scenarios, reporting that 11 cases were caused by an infant's face being pressed against a bumper pad, 13 cases were due to an infant being wedged between a crib bumper and another object, and three cases had occurred subsequent to a tie from the bumper pad becoming wrapped around an infant's neck. Additionally, the article describes a review of crib-related injury data (based on the NEISS database) for infants six months of age and younger for the years 2000 – 2004, reporting 25 injury records. However, the authors discount seven of the incidents stating "[t]he seven reported cases of limb fractures or closed head injury were likely not caused by

accidents." In summary, the authors report to have identified "a number of fatal accidental infant deaths directly attributable to crib bumper pads," concluding "[t]his case series provides evidence that the risks from crib bumper pads or padded bassinettes (death) outweigh the possible benefits provided by such padding (minor bruises and contusions)" and "bumpers should not be placed in cribs or bassinets." The opinions reached by Thach et al. (2007) stand in contrast to the data and analyses offered elsewhere in the scientific literature.

Reanalysis of Thach et al. (2007) Data

In order to assess the apparent discrepancies observed within the scientific literature, we attempted to re-analyze the data referenced within the 2007 Thach et al. paper. However, the original data on which Thach et al. (2007) based their review was not available; Dr. Thach reported that he could not locate his original data set. We performed a search of the same data sources using the same search terms cited in the article and attempted to identify the same records. To this end, we were able to find 22 of the 24 fatality records reported by Thach et al. (2007) to be related to infants having their face into or being wedged between a bumper and another object. At the time of this reanalysis, we did not have access to all the complete incident records maintained by the CPSC on all the records in question, but rather utilized the available information, including data within the electronic databases, CPSC incident records when available, and the information provided within the original Thach et al. (2007) article. Additionally, we duplicated the search for crib-related injuries within the NEISS database described, but, as discussed below, were unable to match the records or replicate the findings reported.

Our reanalysis has highlighted a number of methodological concerns related to original Thach et al. (2007) work. With respect to the fatality incidents reported, our reanalysis questions the inclusion criteria and the interpretation given in concluding that these individual incidents were "directly attributable to crib bumpers." None of the 24 incidents referenced by Thach et al. (2007) has sufficient evidence to support such a conclusion. Indeed, based on the data available at the time of this reanalysis, 22 of the 24 records (92%) are either unrelated to the issues raised by Thach et al. (2007) or contain at least one other factor that could account for the fatality. As described in Table 1 below, eleven of the records (46% of the data relied upon) were associated with an unrelated product or accident mode; seven incidents did not involve cribs or modern crib bumper pads. For example, one case involved a child that fell out of a crib and died subsequent to becoming wedged between the outside of a crib and a dresser, one case involved a child that is believed to have rolled out of "day bed" and interacted with a bumper pad hung around the open ends of this bed, and two cases referenced "plastic" bumper pads (which are no longer manufactured or sold).

Re-Analysis of 24 Records Cited in Thach				
Unrelated Product/Accident Mode		**11**		**46%**
Not Crib/Crib Bumper		*7*		
Unrelated Accident Mode		*4*		
Confounding Factors		**11**		**46%**
Multiple Confounds		*6*		
	Other Items in Crib		*5*	
	Sick/Compromised Child		*2*	
	Crib/Mattress Problems		*2*	
	Prone Sleeping		*3*	
	Bumper Not Secured		*2*	
Single Confound		*5*		
	Other Items in Crib		*3*	
	Sick/Compromised Child		*2*	
No Detailed Information Available		**2**		**8%**
Total		**24**		**100%**

Table 1: Summary of fatality cases identified by Thach et al. 2007

Another eleven records have significant confounding factors. Confounding factors are conditions present in these cases that are unrelated to the crib bumper but could affect the outcome (death of the child). Over half of these 11 incidents have more than one confounding factor present. Therefore these confounding factors make conclusions regarding the causal role of the crib bumper unreliable. For example, the images below (Figure 1) taken from the in-depth investigation files where the presence of a crib bumper was mentioned, show a variety of other conditions in the environment that could affect the fatal outcome. Similar to the images below (Figure 1), eight of the eleven cases specifically reference objects being present in the crib that are known risks to the infant sleeping environment (e.g., blankets, pillows) while others reference highly atypical sleeping environments (e.g., crib with most its hardware missing and the substitution of a folded and wrapped blanket for a mattress). Four of the eleven incidents reference that the children involved had compromised respiratory health. Of the five records where only one confounding factor has been identified, four are cases in which the complete CPSC incident record

has not been made available for review and the only record available for the remaining case was a one-page death certificate. In general, the more details provided for the cases identified by Thach et al., the more tenuous any causal relationship between the crib bumper pad and the infant fatality appears.

The amount of information in the records for the remaining two incidents simply does not offer sufficient detail to support conclusive statements as to whether the crib bumper contributed to the incident. It should be noted that, based on the information available within the electronic database, a systematic review of sleep position could not be performed, but as observed by Wanna-Nakamura (2010) on a similar and partially overlapping set of data and from analysis of the available records received from the CPSC, a substantial number of the fatalities reviewed occurred to infants in a prone sleeping position.

Review of electronic database entries and the complete CPSC records available for the incidents referenced in the Thach et al. study provides additional details not included in the descriptions of the incidents provided in the published study. These additional details lead to questions regarding how the authors concluded a bumper pad was causal to the infant's death. For example, in one instance while an infant's face was described as being towards the bumper pad, information in the CPSC records described that the child was facing an area where an opening in the bumper pad existed, that the face was not covered by the bumper pad; the death was ruled SIDS. Other examples of details referenced in records but not provided in the narratives in Thach et al. include a child with a history of sleep apnea, a child's head being covered by a blanket, and a child being placed in an adult bed between two pillows and a bumper pad. Given the additional details available, it is unclear if or how this information was considered in the analysis by Thach et al. and why it was not included in the descriptions of the incidents. While we have yet to receive and review all the available information for the incidents underlying the original work of Thach et al., for those cases where we have been provided additional information, that information has lead to further questions regarding the inclusion criteria and conclusions presented.

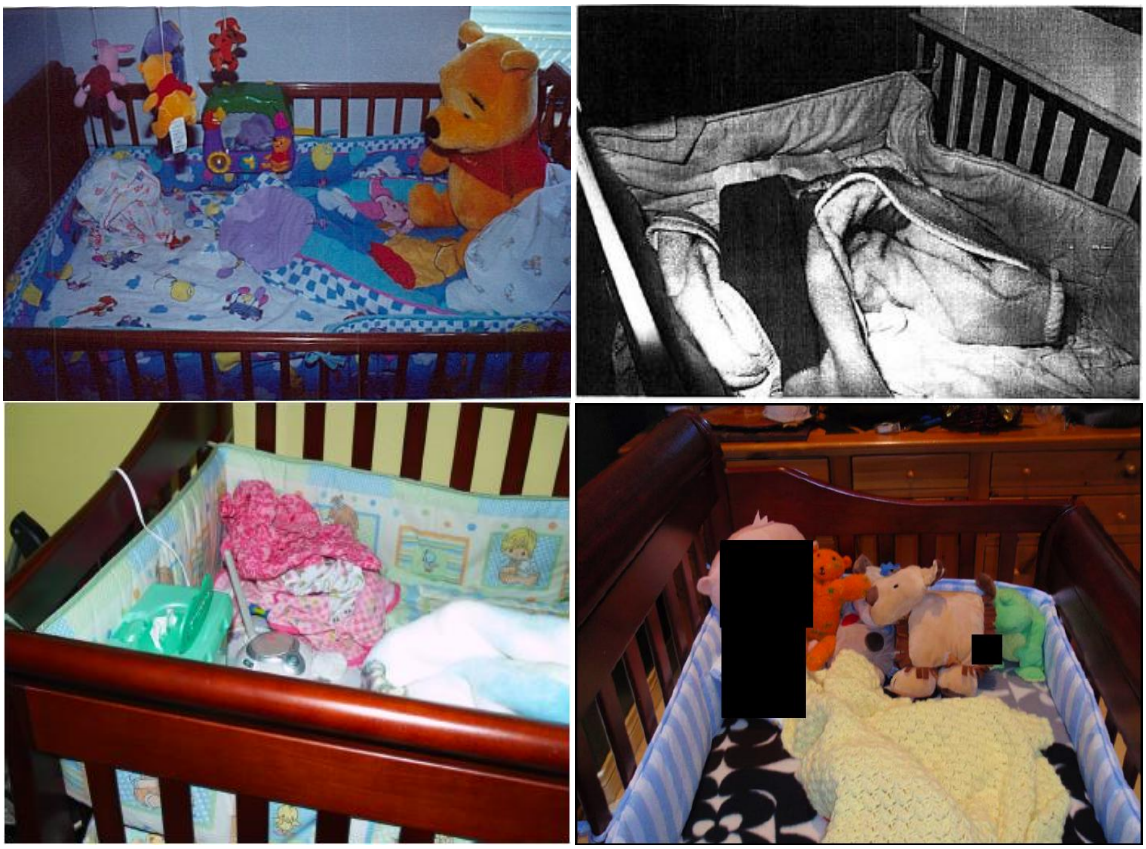

Figure 1: Four images depicting the presence of objects in and condition of sleep environments associated with infant fatalities. Note: the pictures in the top row are taken from records #3 and #13 from Thach et al. 2007.

With respect to the Thach et al. (2007) review of non-fatal injuries associated with cribs, we were unable to replicate the set of records or the findings presented in their paper. While the article states that "[t]here were 25 non-fatal crib injuries in the database," our attempt to duplicate the same search returned 272 records. It is unknown what method the authors used to select the subset of 25 records presented within the article. Regardless, of these 25 reported records, the authors' analysis dismisses the injuries that they deem "serious," by suggesting that the injuries were actually intentional; "such cases would immediately raise a pediatrician's suspicion of intentional injury." The authors' suspicion of parental intent and reticence to accept the available narrative data related to injuries is in contradiction to their acceptance and reliance on the same form of data reviewed for fatalities. The data considered and the analysis provided by Thach et al. (2007) cannot address questions as to the range of crib-related injuries experienced by children and whether the presence of a crib bumper may be a means of injury prevention.

Potential Injury Mitigation by Bumper Pads

We performed a new analysis of crib-related injury data in the NEISS database to address questions raised by Thach et al. (2007) as to whether bumper pads may be expected to mitigate injuries occurring to children within the cribs and if so, what types of injuries might they potentially mitigate. We utilized the most current five years of emergency room reported injury data available (2005 – 2009). Similar to the Thach et al. (2007) inclusion criteria for the review of fatality data, injury data for children under the age of two years old were included in the analysis. Injury records associated with crib products (excluding play yards, bassinets, and rails) were read and coded as to whether the available information allowed one to determine whether the injury occurred inside or outside the crib. For all records where it could be determined that the injury occurred inside the crib, two independent coders determined the child-crib interaction by which the accident occurred (the "accident mode"). Notably, among the "accident modes" were instances in which an injury was subsequent to a child hitting the interior of the crib, a child falling and contacting the interior of the crib, or a child's limb being between the crib railings.

A total of 1790 records resulting in 46,724 estimated injuries related to crib products were found over this five year period. The majority (66%) of injuries occurred outside the crib, while 17% occurred while the child was inside (Figure 2 A). The accident mode analysis of the inside-the-crib injuries revealed that the most common accident modes were the child falling or hitting the inside of the crib surface (31%) and getting caught between the crib rails (12%, Figure 2 B). By far the most common body part injured in the fall/hit accident mode was the head (87%, Figure 3). The majority (74%) of those head injuries could likely be classified as superficial (e.g., contusions and abrasions), however, even these injuries were of sufficient severity that the child was taken and examined at an emergency room. Almost one fifth (18%) of the "hit" and "fall" head injuries were categorized as "internal" including diagnoses of closed head injury. Crib bumpers have the potential to prevent or mitigate (lessen) the injuries that occur by contacting the crib inner surfaces. The padded surface of the bumper can distribute the contact load and reduce the head accelerations during the impact therefore reducing the risk of both superficial and more serious head injuries. The potential for injury prevention or mitigation will depend on a number of factors including the location of the impact relative to the bumper, the severity of the impact, the age of the child, and the bumper size and padding characteristics.

Not surprisingly, the extremities (arms and legs) were the most common (92%) body parts injured in accidents where an infant was caught between the crib rails (Figure 4). A substantial number of fracture/dislocation injuries occurred to the arms (58%) and legs (34%) in this accident mode. A crib bumper could potentially prevent these injuries by acting as a barrier and not allowing the extremity to pass between the crib rails. The prevention of limb entrapment will depend on several factors including the location of the limb relative to the bumper, age and capabilities of the child, and the method and quality of the bumper installation.

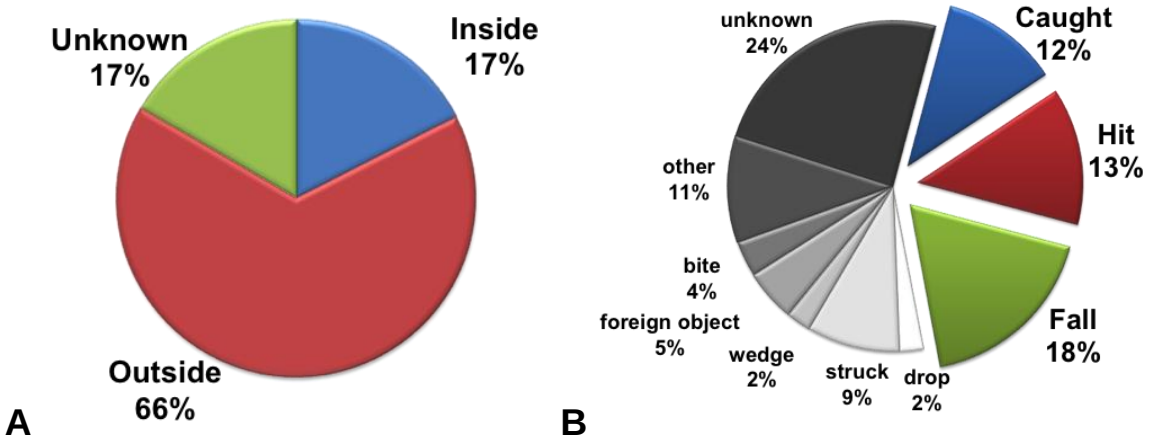

Figure 2: Distribution of crib-related injury based on (A) the location where the injury occurred, (B) mode of the accident where the injury occurred inside the crib

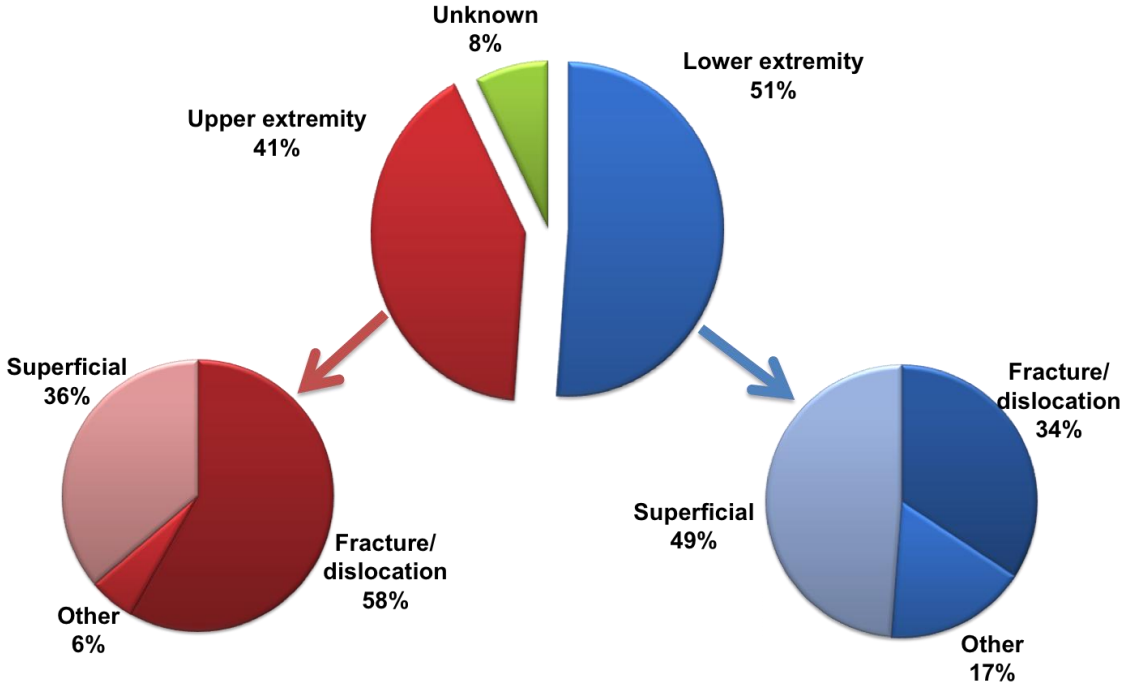

Figure 3: Distribution of the body region injuries and the types of head injuries in the "hit" and "fall" accident modes.

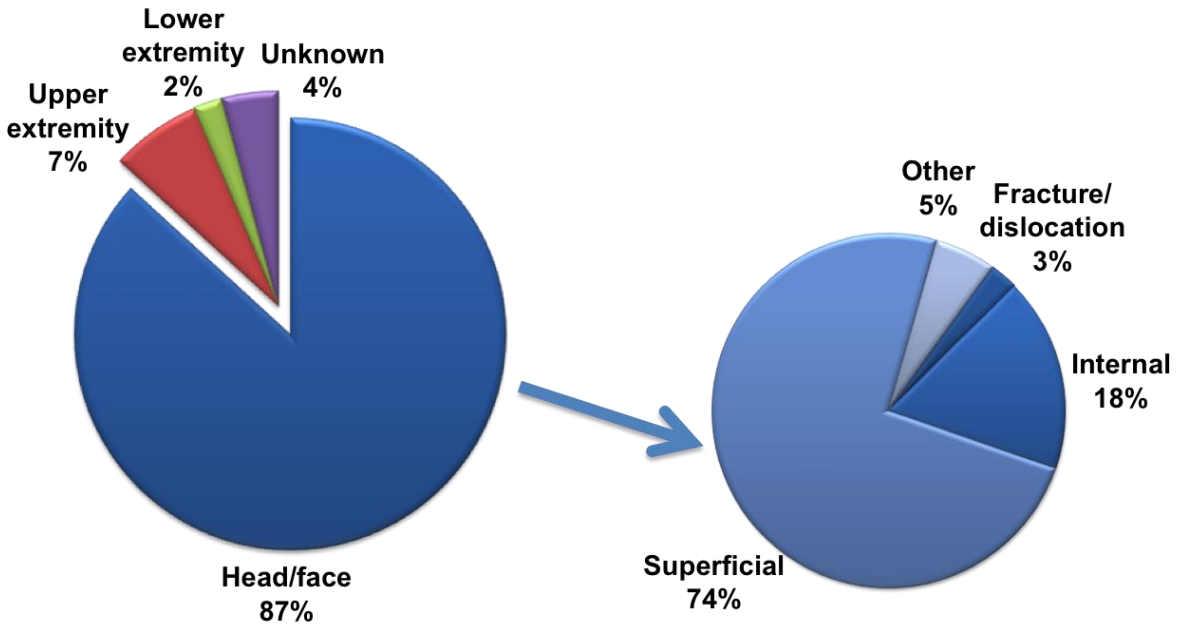

Figure 4: Distribution of the body region injuries and the type of extremity injuries in the "caught" accident mode.

Conclusions

Investigations into sleep environments of infants consistently fail to identify crib bumpers as a unique or separate source of serious injury or death to sleeping infants. Studies focusing efforts on evaluating sleep-related hazards generally, and crib bumpers explicitly, similarly do not find crib bumpers to be a significant risk. One article, by Thach et al. (2007), presents contrasting findings, concluding that crib bumper pads pose significant suffocation hazards. However, methodological problems related to both the selection of incidents for inclusion and the analytical treatment of these data raise concerns as to the validity of the ultimate conclusions. Indeed, our reanalysis of the same fatality data leads to conclusions consistent with the majority of research on this matter. Furthermore, our attempt to recreate the "injury analysis" presented by Thach et al. (2007) again found methodological and analytical concerns. A more thorough analysis of the injuries that occur to infant children within the crib demonstrates that crib bumpers could serve to mitigate injury (e.g., lacerations, fractures) across a variety of the common accident modes (e.g., contact with railings, extremities caught between railings).

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Professional Background

Joseph B. Sala is a Senior Managing Scientist at Exponent and a member of the Human Factors Practice. He routinely addresses how the capabilities and limitations of people interact with the products, equipment, and systems in their environment, and how this interaction affects safety. Dr. Sala frequently uses large-scale databases (e.g., National Electronic Injury Surveillance System, National Fire Incident Reporting System) to analyze the frequency and patterns of accidents, identify patterns of unsafe behaviors, and measure risk.

Dr. Sala has performed a number of investigations into how the particular developmental abilities of children affect safe usage of products. He has performed research on child behavior and capabilities an applied this to product development. He has reviewed accident data, complaint records, product designs, and cognitive and physical developmental attributes of children in order to perform hazard assessments on a variety of products.

Dr. Sala received a Bachelor's Degree in psychology from and performed Honors research in psychology at Rutgers University. He holds a Ph.D. in experimental psychology from Johns Hopkins University and conducted post-doctoral research at Stanford University, with a focus in cognitive neuroscience. He has published papers and presented at conferences related to human factors issues, including visual information processing, brain functioning, and risk communication. He is a member of the Human Factors and Ergonomics Society, the Association for Psychological Science, Society for Neuroscience, and the Society for Risk Analysis.

Michael T. Prange is a Managing Engineer in Exponent's Biomechanics practice. He addresses issues involving human injury biomechanics and occupant kinematics to assess the severity and mechanism of injury incurred during traumatic events. He has expertise in human injury biomechanics, specializing in head and neck injury tolerance and pediatric biomechanics. His work includes analysis of injuries occurring in transportation accidents; incidents involving consumer products; and accidental and inflicted injury scenarios.

Pediatric injury biomechanics is a focus of his consulting practice and research. He has over a decade of experience addressing questions involving the unique aspects of pediatric biomechanics and injuries. He has investigated the injury mechanisms and kinematics of children during automotive transportation (vehicle seatbelts, child safety restraints, airbags), accidental falls, and child abuse. His research experience includes studies of pediatric traumatic brain injury, structural and failure properties of the pediatric neck and spine, child restraint systems, biomechanics of shaken baby syndrome and household falls, biological material testing of the mechanical properties of tissue, helmet protection, and computational models of injury prediction. He also has unique experience in the determination of pediatric head and neck structural properties and injury tolerances using pediatric cadaveric specimens.

He obtained his Ph.D. and M.S.E degrees in bioengineering from the University of Pennsylvania. He also holds a B.S. with honors in biological engineering from North Carolina State University. He is a member and past organizer for the Society of Automotive Engineers. He is a licensed Professional Engineering in the state of Pennsylvania.