UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

October 25, 2019

U.S. Consumer Product Safety Commission:

My team recently completed the final report of Solicitation Number: [redacted], titled *Biomechanical Analysis of Inclined Sleep Products – FINAL Report 09.18.2019*. We have noticed three errors that we wish to correct. **<u>Please note that none of these corrections change the results or conclusions of the study in any way.</u>**

<u>Errata:</u>

1. *Page 46:* Figure 25 was incorrectly copy/pasted into the document. The **figure caption and all discussion regarding the data in the figure was correct**, but the figure was the same as Figure 24. The correct figure has been inserted in the revised report. This changes no results or conclusions of the report.
2. *Page 52:* The word "in" was incorrect in the following phrase: "…are not the same when an incline **<u>in</u>** introduced." The word "in" was changed to "is" in the revised report. This changes no results or conclusions of the report.
3. *Page 67:* Citation Kuczmarski et. al (2002) was incorrectly formatted. The correct format has been used in the revised report. This changes no results or conclusions of the report.

We have provided for you a revised copy of the report with these errors corrected. Please let me know if you require any additional information. Thank you for understanding.

Sincerely,

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Biomechanical Analysis of Inclined Sleep Products – FINAL Report 09.18.2019

Consumer Product Safety Commission Solicitation Number: [redacted]

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Project Time Period: September 2018 to September 2019

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1. BACKGROUND

Since 1992, the American Academy of Pediatrics (AAP) has recommended that infants under the age of one should be placed for sleep on a flat and firm surface in the supine position to reduce the incidence of Sudden Infant Death Syndrome (SIDS). The rate of SIDS deaths has decreased by 70% since the National Institute of Child Health and Development (NICHD) "Safe-to-Sleep" campaign (formerly "Back-to-Sleep") was implemented in 1992.[1] However, some infants are currently placed to sleep in Inclined Sleep Products, designed to keep an infant supine at a 10 to 30 degree incline, and do not meet safe sleep guidelines set forth by the NICHD and AAP. Parents are advised to always use restraints in the products and to discontinue use once an infant has the ability to roll over. However, several infant deaths have been reported in Inclined Sleep Products with the deceased infants often found in the prone position, with suffocation as the apparent cause of death. It is, therefore, imperative to understand if the *design* of the Inclined Sleep Products contribute directly to an increased rate of infant deaths by either making it easier to roll from the supine to the prone position or making it more difficult to self-correct from the prone to the supine position when infants are prone in the product. It is hypothesized that an infant's body position on or within a product is related to the infant's ability to move, to perform a head lift, or to achieve a roll. Movement demands based on a product design or body position may have a direct relationship to an infant's risk of suffocation due to inability to maneuver into a safe breathing position.

The following studies were proposed to begin answering these questions:

1. An analysis of the **incident reports** related to Inclined Sleep Products to qualitatively assess trends, similarities, or differences in the incidents that may inform product safety,
2. A thorough **product analysis** of various Inclined Sleep Products within the product class to identify differences in design,
3. A non-invasive *in vivo* **biomechanics study** of infants 2-6 months of age to determine:
   (a) the strength and space requirements for infants to move their heads and/or roll from the supine to the prone position in Inclined Sleep Products compared to a Flat Sleep Product,
   (b) the strength and space requirements for infants to lift their heads and/or roll from the prone to the supine position in Inclined Sleep Products compared to a Flat Sleep Product.

The outcomes of this study will inform the Consumer Product Safety Commission (CPSC) on whether the designs of Inclined Sleep Products impact an infant's ability to move within the products, and if those designs directly impact safety or present a risk factor contributing to suffocation of an infant. Based on the results of the studies, if necessary, the current ASTM International standard will be reviewed to make recommendations to mitigate hazards from this class of products.

Summaries of the project team can be found in Appendix A. Summaries of the facilities and equipment used in this study can be found in Appendix B.

2. INCIDENT REPORT ANALYSIS

2.1 Incident Report Methods

The CPSC provided the research team with details of incidents involving Inclined Sleep Products. At the time of this report (July 2019), there were 91 separate incidents reported to or investigated by the CPSC involving an incident (hazard, injury, or death). Varying amounts of information were provided for each incident, including police reports, coroner reports, witness statements, photos, videos, and summaries of the event written by CPSC employees. The summaries written by the CPSC were not considered in this qualitative analysis.

Each incident was reviewed by two members of the research team, separately confirming details of the events. The following data was gathered from the reports and organized in a spreadsheet: date of incident, incident (hazard, injury, or death), manufacturer and model, city and state, infant demographics at time of incident (age, sex, race/ethnicity, height, weight), incident details (initial position, found position, time since last checked, found by, restraint used, soft goods found with infant, other items found with infant, room temperature, current medical conditions, usual sleeping position, other notes), birth and pregnancy details (pregnancy concerns, gestational age, maternal age, paternal age, Apgar Score, height, weight, previous medical history), coroner report details (medical findings, cause of death, manner of death, medical notes), conflicting details noted by the team, and other notes of interest.

The incidents were sorted into the following six categories with descriptions:

- *Supine-supine*: infant was placed in a supine position and found in a supine position.
- *Supine-prone*: infant was placed in a supine position and found in a prone or side-lying position.
- *Supine-other*: infant was placed in a supine position and found in a sitting position, was hanging from the product, or had fallen out of the product.
- *Prone-prone*: infant was placed in a prone position and found in a prone position.
- *Other circumstances*: external circumstances not related to the product caused the incident.
- *Not enough information*: reports do not have enough information to determine event; there were no witness statements, detailed description of the event, police report, hospital records, or medical records included in these incidents.

Because some incident reports were incomplete or contained conflicting details regarding initial and found positions, extra attention was given to these incidents to categorize them as accurately as possible. For instance, if autopsy or police investigative evidence supported that the found position was different than initially reported by the caregivers (i.e. location of lividity in autopsy reports), the categorization was based on an evaluation of all information available for that incident.

Descriptive qualitative analysis of each of these incident categories was provided, with the biomechanists and pediatric orthopaedists focusing on the movement-based incidents (*supine-prone, supine-other)*, and the biomechanists and pediatric pulmonologist focusing on the *supine-supine* and *prone-prone* categories. Student's t-tests (p=0.05) were used to compare average ages of infants who experienced *supine-supine* v. *supine-prone* events. Reference to specific product manufacturers or designs has been blinded from the main portion of this report, so companies are referred to as "Company A, Company B," etc. Similarly, the products are coded as "S01, S02," etc. The key for company and product codes can be found in Appendix C.

2.2 Incident Report Results

All 91 incidents were reviewed and sorted into the following categories described in section 2.4:

- ***Supine-supine****:* 38 [Company A (products S01 and S02); Company B (products S03 and S06)]. Of these, 33 were deaths, 4 were injuries, and 1 was a hazardous event.
- ***Supine-prone***: 25 [Company A (products S01 and S02); Company B (products S03 and S06); Company C (product S08)]. Of these, 21 were deaths and 4 were injuries.
- ***Supine-other***: 4 [Company A (product S01)]. Of these, 2 were injuries and 2 were hazardous events.
- ***Prone-prone:*** 3 [Company A (products S01 and S02)]. All 3 of these incidents were deaths.
- ***Other circumstances***: 2 [Company A (products S01 and S02)].
- ***Not enough information***: 19 [Company A (products S01 and S02)].

Detailed summaries of all incidents are provided in Appendix D.

The ***Other circumstances*** category included incidents where external circumstances not related to the product caused the event. Both cases were deaths. These two events are not under consideration as incidents that may have been caused by the inclined sleep products.

After eliminating the two incidents from the ***Other circumstances*** category, 89 events were left to analyze. Nineteen incidents were categorized as ***Not enough information***. If incidents did not contain police reports or interviews, medical records, descriptive information regarding the event, or autopsy/coroner's reports, they were considered in this ***Not enough information*** category. Two of these incidents (1 death, 1 injury) were reported to the CPSC or found via internet research but attempts by the CPSC for follow-up communication were unsuccessful. Of the remaining 17 events, 14 were deaths and 3 were injuries. Most of these incidents were reported to or discovered by the CPSC after the April 2019 voluntary recall of two companies' inclined sleep products. Therefore, many of the CPSC investigations are ongoing. It is expected that many of these events will eventually fall into either the ***supine-supine, supine-prone, supine-other,*** *or* ***prone-prone*** categories after in-depth investigations have been completed, but there is not enough information to be certain at the time of this report.

After excluding the 19 incidents from the ***Not enough information*** category, 70 events remained. The ***supine-supine, supine-prone, supine-other,*** *and* ***prone-prone*** events were considered the highest priority in analyzing and understanding the circumstances surrounding the events, therefore these categories were examined in more detail.

Figure 1 shows a map of the continental United States with pins placed at the locations of each ***supine-supine***, ***supine-prone, supine-other,*** *or* ***prone-prone*** incident, and colors indicate the event (blue-death; orange-injury; green-hazard). Events occurred in 29 states throughout the country.

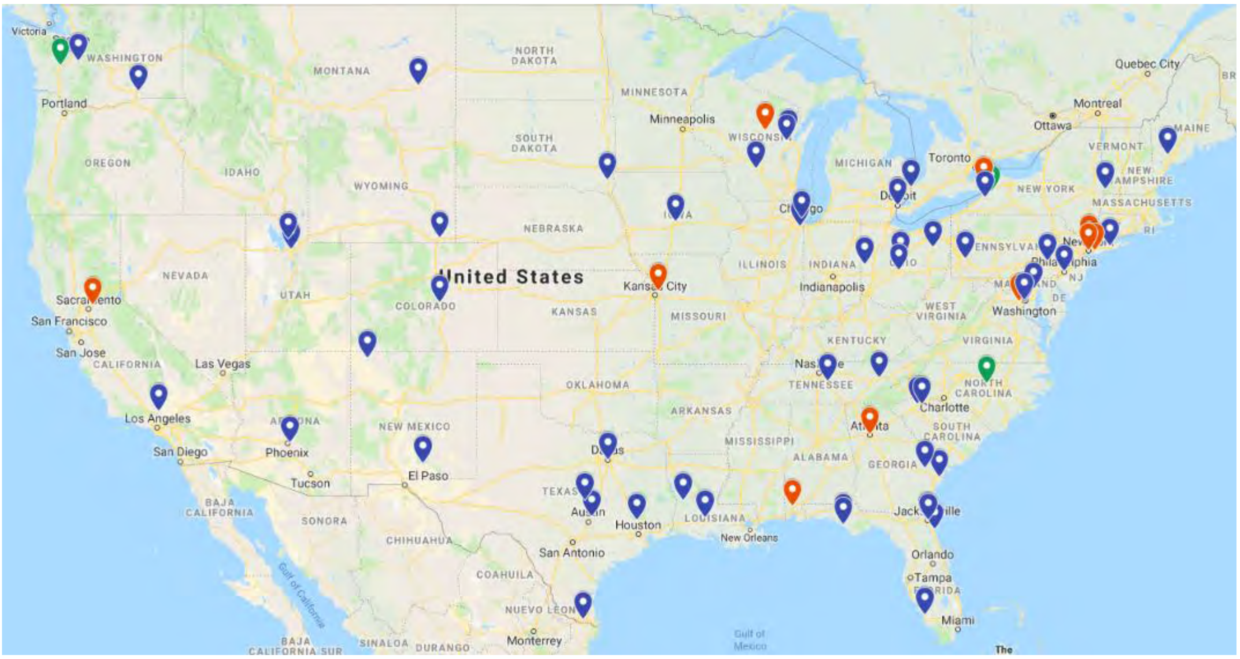


Figure 1. Map of the United States showing *supine-supine, supine-prone, prone-prone,* and *supine-other* incidents related to inclined sleep products reported to and investigated by the CPSC. Blue-death; orange-injury; green-hazard.

<u>Supine-Supine Events</u>

There were 38 ***<u>supine-supine</u>*** events reported and investigated between 2011 to 2019. Of these, 33 resulted in death, 4 resulted in injury, and 1 was a hazard. Events occurred in products from Companies A and B, with basic (S01 and S03) and deluxe (S02 and S06) versions of their inclined sleep products. Sex distribution was 20 males and 18 females. Racial/ethnicity distribution was 23 White, 5 Black, 3 Hispanic, and 7 Not Reported. The average age of the infants at the time of the event was 3.2±2.3 months (adjusted age 3.0±2.3 months). Six infants were reportedly born pre-term (<37 weeks gestation).

The incidents in which a death occurred when an infant was placed supine and found supine show a few notable trends. First, 10/33 (30%) of the deaths occurred in infants who were currently sick with colds, respiratory symptoms, or fevers. Upon further review, 4/33 (12%) of infant deaths occurred in infants with significant health problems or chronic health issues. Four reports indicated smoking in the home, and all of these were of infants who were currently sick or chronically ill. A pediatric pulmonologist determined that 4/33 (12%) of the deaths are likely attributed to health issues not necessarily caused by the sleeping position. While only a few incidents specifically indicated a "chin-to-chest" position, the deaths or injuries may have been related to either a chin-to-chest position that restricted airflow, and/or carbon dioxide rebreathing from contact or near-contact of the infants' faces to the sides of the products, a position that was commonly noted in the police reports in the in-depth investigations. However, no further analyses on these incidents nor on the chin-to-chest position were performed, so the impact of the chin-to-chest position in inclined sleep products is unknown. In addition, many of the reports indicate the parents utilized an inclined sleep product on the recommendation of a medical professional or friend to aid with either respiratory sickness or reflux, though this recommendation is not supported with evidence-based research. Of the infants who were not suffering from a chronic health condition or temporary illness at the time of the death, four were sick within the last month. 6/33 (18%) of infants who died were born premature. Two reports indicated the inclined sleep product was not the infant's regular sleeping surface, but most reports had missing information regarding normal sleeping position. Several infants were placed supine with their lower extremities swaddled and their upper extremities free to move. Twelve infants were reportedly not buckled into the product, while six were initially buckled, with many reports not listing the information. No significant trends were found regarding other demographic or situational data, partly due to incomplete reports across the many categories.

Positional asphyxiation is the most likely cause of death for most of the infants in the ***supine-supine*** group, particularly when considering most of the products were "deluxe" versions (S02 and S06) which feature very heavy padding with a pillow-like headrest. It is likely that infants' noses and mouths were too close to the side of the product, resulting in reduced airflow and carbon dioxide rebreathing, leading to their demise. This is further supported by the number of infants who had blood and/or mucus on their noses or mouths when they were found. Nasal hemorrhaging is associated with suffocation in infant deaths (Bercroft et al., 2001), and the presence of blood noted in these reports supports suffocation as the cause of death. However, no breathability analysis was conducted as a part of this study, so it cannot conclusively be stated that the material or design of the product promoted carbon dioxide rebreathing or suffocation based on the incident analyses.

Supine-Prone Events

There were 25 ***supine-prone*** events reported and investigated between 2010 and 2019. Of the 25 events, 21 resulted in death and 4 resulted in injury. Events occurred in products from Companies A, B, and C, with basic (S01 and S03) and deluxe (S02 and S06) inclined sleep products, and product S08 which was sold as a stand-alone sleep product in a larger set by Company C. Sex distribution was 15 males and 10 females. Racial and ethnicity distribution was 15 White, 2 Black, 1 Hispanic, 2 Other, and 5 Not Reported. The average age of the infants at the time of the event was 4.2±1.8 months (adjusted age 4.0±2.1 months), 1.0 months older than the age of infants who experienced supine-supine events ($p=0.081$). One infant was reportedly born pre-term (<37 weeks gestation).

Similar to the *supine-supine* incident analysis, the incidents in which a death occurred when an infant was placed supine and found prone show a few notable trends. First, 4/21 (19%) of the deaths occurred in infants who were currently sick with colds, respiratory symptoms (at least moderate congestion), or fevers. No deaths occurred in infants with significant health problems or chronic health issues. Of the infants who were not suffering from a temporary illness at the time of the death, three were sick within the last month, and five others had findings during the autopsy that indicated mild lung congestion. 1/21 (5%) of infants who died was born premature. A few reports specifically mentioned that the baby had never before rolled unassisted, but most investigations did not contain this information. Similarly, though many reports did not have the information, five parents indicated the inclined sleep product was not the infant's typical sleeping environment, with one mother stating the infant died the first time the product was used. Nine infants who died were reportedly not buckled into the product, while one was initially buckled, with eleven reports not listing the information. In many of the incidents, the babies were found with their faces in direct contact with the surface, the "pillow" portion, or the seat portion of the inclined sleep product. In the incident where the infant was reportedly initially buckled, it was noted that the caregiver found the infant with the feet in the seat portion of the inclined sleep product, in a "standing" type of prone-lying position within the product. No significant trends were found regarding other demographic or situational data, partly due to incomplete reports across the many categories.

In the United States, it is recommended that infants are put to sleep on their backs, partly based on previous research indicating prone sleeping results in lower oxygen saturation levels in babies (Galland et al., 2000), especially premature babies (Smith et al., 2010). Other peer-reviewed research indicates that at 4 months old, 40% of infants who sleep supine are able to roll (Jantz et al., 1997), with 80% of infants rolling prior to six months of age (Benjamin Neelon et al., 2016). One study reports the age of rolling from front-to-back-to-front is just under six months (Ertem et al., 2018). Once an infant is able to roll on his/her own, the risk of suffocation from prone sleeping may decrease as the infant has increased motor control and has a greater ability to reposition themselves to avoid suffocation. In fact, once an infant is able to roll from supine to prone and prone to supine unassisted, parents are told by the AAP to continue to place the infant to sleep on their backs until 1 year of age, but not to worry or reposition the baby back to supine if the baby rolls to prone on their own during sleep (Moon et al., 2016). This logic likely does not translate to the inclined sleep products because the environment is so different compared to a flat crib mattress. Additionally, other researchers report that the most common risk factor for sleep-related deaths in 4 to 12 month old infants is rolling into other objects in their sleep area such as crib bumpers or pillows (Colvin et al., 2014). This again raises concerns with the inclined sleep products, as the surface is not the same as a crib mattress and often features heavy padding similar to crib bumpers and headrests that are similar to small pillows.

The average age of the infants in these ***supine-prone*** incidents who experienced events of rolling from supine to prone in an inclined sleep product was 4.2 months (approximately 1.5 months less than average front-to-back-to-front rolling age, Ertem et al., 2018), and many of the reports include statements that the parents had never observed the infant roll on his/her own. It is likely that if an infant experiences a supine to prone roll for the first time in an inclined sleep product, that the baby is put in a position he/she has never before experienced: prone in a non-rigid, concave, and/or heavily padded inclined sleep product. The biomechanical analysis (Section 4) explores these ideas further.

Supine-Other Events

There were four ***supine-other*** events reported and investigated between 2011 and 2013. Two events were injuries and two were hazards. Events occurred in basic products (S01) from Company A. Sex distribution was two males and two females. Racial and ethnicity distribution was 1 White, 1 Other, and 2 Not Reported. The average age of the infants at the time of the events was 7.0±3.4 months. Restraints were reportedly used in three of the four events (75%). No information on prematurity or health was reported in these events.

These four ***supine-other*** incidents occurred in infants aged 5 months to 12 months, an older cohort than the other categories. In two incidents, caregivers reported that infants were able to climb out of the product, even when buckled into the harness. One infant was found sitting backwards in the product. In the remaining incident, the infant was found hanging from the product with her leg caught in the harness straps. These four incidents describe events in which babies have maneuvered within or out of the inclined sleep products, resulting in unintended and hazardous positions. A fall from the product to the floor presents a risk of injury for the infant. The incident describing the infant’s leg caught in the product presents a risk of serious injury if circulation is cut off for too long; pain and muscle damage are potential outcomes. These events highlight a unique set of risks that are likely specific for older infants who are able to significantly maneuver within or out of the inclined sleep products

Prone-Prone Events

There were three ***prone-prone*** events reported and investigated between 2013 and 2017. All three events resulted in deaths. Events occurred in products from Company A basic (S01) and deluxe (S02) inclined sleep products. All three infants were female. Racial and ethnicity distribution was 2 Black and 1 Hispanic. The average age of the infants at the time of the event was 2.3±2.1 months (adjusted age 1.9±2.3 months). One infant was reportedly born pre-term (<37 weeks gestation). At the time of the incidents, one infant was healthy, one was sick, and one was chronically ill. Two parents reported that no restraint was used. While instructions on inclined sleep products indicate that infants should be placed in the supine position, it is clear from these three incidents that those instructions are not always followed by caregivers. The biomechanical analysis (Section 4) will further explore the implications of the prone position in inclined sleep products.

Incident Report Summary

Ninety-one reported incidents of deaths, injuries, and hazards occurred in inclined sleep products from 2010 to 2019. Most incidents fell into two main categories: *supine-supine* and *supine-prone*. The *supine-supine* events occurred in younger infants (average 3.2 months), and many were currently sick, suffering from chronic conditions, or born prematurely. Many reportedly were found with their faces in contact with the sides of the product, and several had blood or mucus on their nose and mouth when they were found, suggesting suffocation as a cause of death. The *supine-prone* events occurred in older infants (average 4.2 months), and sickness, chronic conditions, and prematurity were less prevalent compared to the *supine-supine* events. The three-point harness was used in at least one *supine-prone* event and three of the four *supine-other* events, and many reports indicated that the infant had not been observed to roll alone prior to the incident.

3. PRODUCT ANALYSIS

3.1 Overview

The CPSC provided the research team with 14 different unassembled products that fell into the category of “Inclined Sleep Product.” Most products were frame-type products that were sold alone, but one product (S08) was sold as a part of a set of infant products. Each product was assembled by the research team according to the instructions and was thoroughly examined to ensure no product damage was present.

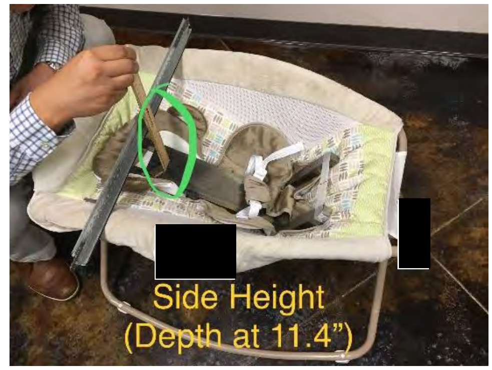
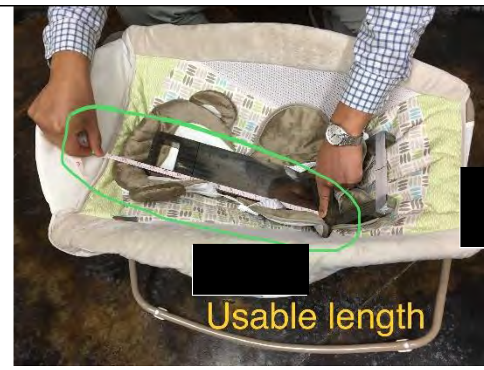
Each of the 14 inclined sleep products were analyzed and measured using methodology from ASTM F3118-17a: Standard Consumer Safety Specification for Infant Inclined Sleep Products. The research team also identified additional differences in products, and therefore added other measurements as needed. Below is a table of the Measurement, Procedure, and corresponding Photos used to obtain each measurement. A hinged weight gauge infant was also provided by the CPSC. The research team measured and analyzed it to ensure it met the appropriate dimensions prior to using it for measurements.

3.2 Measurement Procedures

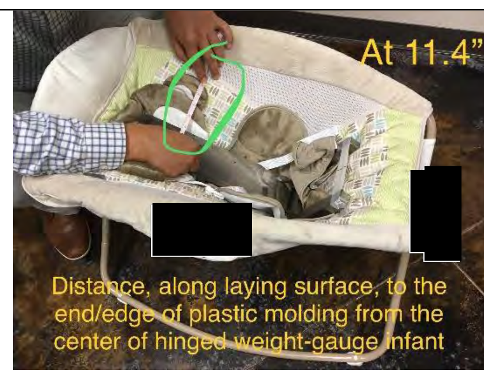
Table 1 details the measurements taken for each of the 14 inclined sleep products. Some products allowed for different incline settings, so measurements were taken at both the highest and the lowest settings.

Table 1: Measurements with detailed procedures and photos in a representative inclined sleep product.

<table>
<tr><th>Measurement</th><th>Procedure</th><th>Photos</th></tr>
<tr><td>Minimum Incline at Head</td><td>7.10* = Hinged weight gauge-infant centered in product with hinge centered over seat bight line, upper plate on seat back surface. Digital protractor placed (centered) on upper plate to measure top surface seat back angle relative to horizontal.</td><td rowspan="2">
</td></tr>
<tr><td>Maximum Incline at Head</td><td>7.11* = If applicable, repeated with manufacturer's recommended highest incline position</td></tr>
<tr><td>Minimum Incline at Thigh</td><td>Placed as above, for lower plate, to get thigh angle</td><td rowspan="2">
</td></tr>
<tr><td>Maximum Incline at Thigh</td><td>As above, repeated with manufacturer's recommended highest incline position</td></tr>
</table>

Side height (Depth at 11.4")	7.12* = Reference line made at 11.4" from hinge on upper plate. Center point of this reference mark also made. Straight edge with length greater than product width laid across product "rails"/"top", second straight edge placed vertically upwards from reference mark to ensure orthogonal measurement. Vertical distance (d) between underside of straight edge and the upper surface of the hinged weight gauge-infant measured with measuring tape. (Fig. 12, page 13)*	
Usable length (Hinge, to top of backing seam, where the head sits)	7.15* = Hinged weight gauge-infant centered in product with hinge centered over seat bight line, upper plate on seat back surface. Measured, using a tape measure, the distance from intersection of gage plates to top edge of head containment area (top seam above which the head cannot be positioned)	
Width at Shoulder (at 11.4")	Start of additional measurements. Straight edge with length greater than product width laid across product "rails"/"top", second straight edge placed vertically upwards from reference mark to ensure orthogonal measurement. Width of product at this point measured with tape measure	
Width at Hinge	As above, repeated at intersection of upper and lower plate (hinge)	

Width at Knee	As above, repeated at bottom of lower plate		
Maximum Width	Tape measure used to measure maximum width of product (excluding attachments such as electronics or mobile)		
Minimum Width	As above		

Minimum Incline (w/Rock)	Digital protractor placed (centered) on upper plate to measure top surface seat back angle relative to horizontal. Minimum incline w/rock was defined as the angle displayed on protractor with maximum rock/tilt towards head end	
Maximum Incline (w/Rock)	As above, with maximum tilt/rock towards foot end	
Curved / Thick Plastic Molding? (Y/N)	Whether the product had curved/thick plastic molding underneath the surface and/or seat	
Thin Plastic Molding? (Y/N)	As above, but whether the material was a thin deformable plastic	
Side Mesh? (Y/N)	Whether there was side mesh (3.1.9)*	
Plastic	For Reference line (11.4 from hinge), Hinge, and Bottom of lower plate, measurements made along the surface parallel to reference line. This measure is from the center line on the reference line to the "edge" of the plastic molding (if any)	

Solid	From the center line to the end/edge of the solid "fabric"	
Mesh	From the center line to the end/edge of the mesh (if any)	
End	From the center line to the end/edge of the product, i.e. up to the rail	

*These refer to Sections of ASTM F3118-17a: Standard Consumer Safety Specification for Infant Inclined Sleep Products

3.3 Measurement Results

All 14 inclined sleep products were evaluated, and all products exhibited no damage as received. After assembly, product S07 exhibited a slight lateral tilt, and if selected for further biomechanical evaluation, a different product of the exact same model would be purchased to ensure the tilt was not a result of mis-assembly or a manufacturing issue. However, all other results of the product analysis for product S07 would not have changed due to the lateral tilt, therefore the conclusions applicable to product S07 are valid.

Table 2 summarizes the measurements taken defining the design of the product. Products with a "–high" and "-low" row of measurements indicate that they had two incline settings at the head. Blanks (i.e. "x") for "maximum incline" at head or thigh indicates the product did not have an incline adjustable head portion. For products S05, S11 and S12 (i.e. the products with adjustable inclines), the maximum and minimum values are tabulated on the same row (high), and the row below has two blanks since the two values above are the minimum and maximum incline values of the product as a whole. When there is an "x" for min (or max) "incline w/ rock", that means the product does not rock.

Table 2. Sample measurements and characteristics

Sample	Minimum Incline @ Head (deg)	Maximum Incline @ Head (deg)	Thigh Angle @ Minimum Incline (deg)	Thigh Angle @ Maximum Incline (deg)	Side height (Depth at 11.4") (cm)	Usable length (Hinge, to top of backing seam/ head location) (cm)	Width at Shoulder (at 11.4") (cm)	Width at Hinge (cm)	Width at Knee (cm)	Maximum Width (cm)	Minimum Width (cm)	Minimum Incline (w/Rock) (deg)	Maximum Incline (w/Rock) (deg)	Curved / Thick Plastic Molding? (Y/N)	Thin Plastic molding? (Y/N)	Side Mesh? (Y/N)
S01	27.7	x	44.5	x	13.3	43.2	46.7	43.5	37.1	46.7	32.1	26.2	36.5	Y	N	Y
S02	24.4	x	51.7	x	14.0	45.1	47.3	16.8	38.7	51.8	32.4	23.0	31.7	Y	N	Y
S03	25.5	x	24.3	x	17.1	43.5	39.7	39.7	38.7	41.0	34.0	x	x	N	N	Y
S04	26.0	x	23.9	x	15.6	41.6	40.0	40.6	39.1	40.6	34.3	x	x	N	N	Y
S05-high	12.2	38.7	4.4	1.1	6.7	42.2	34.3	36.8	32.4	36.5	27.9	34.0	41.9	Y	N	Y
S05-low	x	x	x	x	20.0	39.4	30.2	35.6	32.4	x	x	10.7	18.3	x	x	x
S06	31.1	x	22.0	x	11.7	39.4	41.6	43.2	40.6	43.8	30.2	29.1	35.6	N	N	Y
S07	9.3	x	24.5	x	25.1	42.5	51.8	48.6	41.0	51.8	30.2	4.2	15.0	Y	N	Y
S08	31.3	x	38.2	x	3.8	43.5	42.9	40.6	35.2	41.9	18.4	29.8	36.4	N	N	N
S09	20.9	x	52.1	x	14.6	43.5	45.1	43.2	37.8	45.4	31.4	18.8	26.8	Y	N	Y
S10	25.7	x	52.6	x	13.7	44.5	44.5	43.2	38.1	44.5	31.1	24.7	30.0	Y	N	Y
S11-high	11.8	20.5	31.4	22.9	22.2	39.4	50.5	47.3	42.2	51.4	35.6	14.3	17.1	N	Y	Y
S11-low	x	x	x	x	21.9	40.0	49.8	48.9	42.2	x	x	20.3	22.4	x	x	x
S12-high	11.7	25.7	29.0	21.7	23.2	43.5	47.0	46.4	45.1	48.3	22.9	x	x	Y	N	Y
S12-low	x	x	x	x	26.0	43.5	47.3	46.0	43.5	x	x	x	x	x	x	x
S13	21.5	x	25.9	x	14.8	40.0	47.3	43.2	40.6	48.9	41.3	16.8	29.0	Y	N	Y
S14	16.9	x	44.2	x	11.4	44.1	48.3	48.6	43.2	48.9	38.1	10.8	20.6	Y	N	N

Table 3 summarizes the material makeup of the product surface. An "x" along the row for any measurement involving "Plastic", "Solid", "Mesh", and "End" indicates that, at the specific measurement location (11.4", hinge, or knee), the corresponding material is not present, so the first measurement written down is the first material that was available to measure. E.g., S08 has no plastic molding, no solid fabric after the lying surface fabric, and no mesh, and hence the only measurement written down is "End", which indicates a measurement made along the width of the product from the center of the hinged weight-gauge infant to the end (edge) of the product.

Table 4 is descriptive text regarding design and measurement of each product.

Table 3. Distance of different materials on samples from the center, at three locations

Sample	at 11.4"				at hinge				at knee			
	Plastic (cm)	Solid (cm)	Mesh (cm)	End (cm)	Plastic (cm)	Solid (cm)	Mesh (cm)	End (cm)	Plastic (cm)	Solid (cm)	Mesh (cm)	End (cm)
S01	15.2	16.5	22.2	29.2	12.7	14.0	30.8	39.1	x	13.0	21.3	27.9
S02	15.9	19.4	22.2	29.2	12.1	14.9	31.8	38.7	x	14.0	21.6	27.3
S03	x	12.1	24.1	29.2	x	11.1	x	39.4	x	12.7	x	34.9
S04	x	13.0	24.1	29.5	x	11.4	34.0	40.6	x	10.8	28.9	34.9
S05-high	15.2	17.1	20.3	28.9	16.5	20.3	x	34.3	x	x	x	25.4
S05-low	15.2	15.6	19.4	37.8	15.6	19.4	x	33.3	x	x	x	29.2
S06	x	12.1	21.0	27.3	x	10.8	34.6	41.3	x	10.5	29.8	36.2
S07	13.0	14.0	x	40.0	10.2	12.1	34.6	41.9	x	12.7	28.6	37.5
S08	x	x	x	23.5	x	x	x	28.9	x	x	x	21.0
S09	15.9	19.4	21.3	28.3	11.4	14.0	30.5	35.2	x	13.7	20.6	25.1
S10	14.6	19.1	21.0	27.6	10.8	13.7	30.8	35.9	x	14.0	20.3	25.7
S11-high	12.7	20.6	29.8	38.1	12.1	15.2	34.3	43.2	12.7	18.7	27.9	36.2
S11-low	13.3	21.0	30.5	38.7	12.7	15.6	34.9	42.9	12.7	19.1	26.7	34.9
S12-high	16.5	20.0	33.0	41.3	8.3	19.4	37.5	43.2	12.7	16.8	33.0	38.1
S12-low	15.2	18.1	32.4	41.3	10.2	19.1	37.5	43.2	15.9	16.5	33.0	38.1
S13	13.7	14.9	25.1	34.6	x	14.0	28.3	38.1	x	x	23.2	32.4
S14	12.7	23.5	x	30.2	x	28.6	x	34.0	x	19.1	x	26.0

Table 4. Sample measurement notes

Sample	Notes
S01	Additional Padded Head Rest. Plastic Molded Seat sewn in.
S02	Removable plastic molding. Removable head pillow. Removable body cushion. Built-in vibration electronics. Removable toy on harness. Solid headrest. Detachable top (all). Depth at hinge = 25.4 cm - Done because it seems deeper than the rest.
S03	Flaps to cover buttons. No plastic molding. No rocking motion. Mesh at head only.
S04	Removable full length cushion. Collapsible. Toy attached to harness. Attachable vibration electronics. Flaps on either end. Mesh only at head. Side flaps. Measurements done without cushion.
S05	Non-Rock Sitting Incline at head = 47.95°, at thigh = 3.2°. Sleeping incline at head = 21.25°, at thigh = 3.65°. All measurements performed with non-rocking stopper down. Removable head pillow. Difficult to assemble (Assembly instructions unclear). Sitting to sleeping incline shift very difficult. Rocker stopper increases incline for both positions. Thin/short mesh around head and torso. Different (cushion) material on side from bight line down. Product depth at head increases, which increases width of mesh. Removable toy mobile. Minimum width measured above top seam before mesh. Plastic molding is (Y) because it is wood/particle board backing (thin, solid), Aluminium frame, and Seat is plastic molding. At hinge, "Solid" measurement is to the Aluminium frame. "Child" (Hinged weight gage infant) shifted in the product when reclined from sitting to sleeping. Repositioned the best we could, hinge line aligned to seat seam (bight line). At 11.4" for sleeping setting, 19.4 cm is to a second material before mesh, and 37.8" is to end of mesh and this second material.
S06	Side mesh only at head. Flaps on either end. Detachable mobile with toy. Attachable vibration electronics. Detachable head pillow. "Mesh" measurements at hinge and knee are actually of second material.
S07	4.4° Lateral tilt towards the Electronic unit. Flat padded head rest. Head of baby (hinged weight gage infant) flush with the product. Plastic molded seat sewn in. Top removable.
S08	Measuring only the sleeper. Detachable head. Non-detachable head pillow. Embedded electronics under foot end. Fairly small product. No mesh. No plastic molding.
S09	Detachable top (all). Removable plastic molding. Solid head rest. Removable toy on harness.
S10	Detachable top (all). Removable plastic molding. Non-detachable head pillow. Detachable body cushion. Attachable electronics on rail.
S11	Dual folding mechanism (legs and top). Removable body cushion. 2 incline settings. Mobile embedded with toy. Fairly wide product (visually). Measurements done without body cushion.
S12	Standing product. Large base. Fairly heavy. 2 incline settings at head. Detachable body cushion. Attachable electronics on rail.
S13	Removable full length cushion. Collapsible. Mesh only up to just above the seat hinge (bight line). Hard plastic molding in two parts; there is a gap between the two parts at the seat bight line.
S14	Measuring only sleeper. Removable full length cushion, collapsible. No mesh. Has insertable thick plastic molding. Measurements from center to "Solid" Refers to measurement made to the edge of the cushion. Plastic molding ends above seat bight line.

As shown in the product analysis above, products in the Inclined Sleep Product class varied significantly in design. Inclined angles at the head ranged from 12° to 38°, while angles at the thigh ranged from 1° to 53°. Width of the products varied, where some were wider at the shoulders and narrower at the seat, while others exhibited a more consistent width throughout the entire length of the product. Some products rocked approximately 10° while others were stationary, and three products featured different incline settings. The surface of the product was one of the most obvious design differences, with some products featuring thick rigid plastic molding, others no plastic molding, and one with a semi-rigid thin plastic molding. Material selections in the products were just as broad and included thin padding, thick padding, or mesh, in a variety of combinations on the surface and sides of the products.

3.4 Product Selection Rationale

The project team had to select a portion of these inclined sleep products to include in the biomechanical testing, as time limitations prohibited inclusion of all products. Products were selected firstly if any adverse incidents had been reported to the CPSC. Company A's products represented most of the incidents (83), followed by Company B (7), and Company C (1).

The designs of Company A featured rigid plastic molding that conformed into the sides of the products and fell into two categories: basic (S01 and S09) and deluxe (S02 and S10), which featured a pillow or heavily-padded piece. S01 was selected to represent the basic version of Company A and S02 to represent the deluxe version of Company A because several incidents specifically noted these products.

Company B had products with no plastic molding and had basic (S03 and S04) and deluxe versions with padded pillows (S06) as well as a product that featured a maximum incline outside of the range of 10° to 30° (S05). S03 was chosen to represent the basic version of Company B and S06 to represent the deluxe version because incidents were reported in these products.

Company C had two products which were examined (S08 and S13). The incident occurred in product S08, and it was selected since this was the smallest product with an inclined surface made of a single material with no plastic molding or mesh. S13 was also chosen to be included in the biomechanical study because it had a unique design of plastic molding, with the molding split at the seat bight line.

There was room to include one final product in the biomechanical experiment, and a product that was the most different in design to the others and was manufactured by a different company was sought. This left products S07, S11, S12, and S14. Product S14 was received too late to include in testing. S07 and S12 both featured thick plastic molding, not unlike those from Company A, while product S11 had a unique thin plastic molding. S11 also exhibited near maximum product widths at all of the measurement points, making it different than many other products, so S11 from Company D was chosen as the final product.

The final list of products included in further product analysis and biomechanical testing were: S01, S02, S03, S06, S08, S11, and S13.

3.4 Contact Area Analysis

Overview

During the pilot testing of the Biomechanical Analysis experiment (section 4), pressure-mapping sensors [redacted]) were to be used to record the pressure imparted by infants' palms and forearm when lying prone on the inclined sleep products. The pressure-mapping technology consists of matrices of sensors embedded into elastic fabric mats that permit conformability to three-dimensional deformations and can accurately measure the total force and contact area on the interacting surface, even if heterogeneously loaded across the sensor. The particular sensors used in this study were equipped with 128 individual sensors in an 8 X 16 matrix, with an individual sensor area of 1 cm^2. However, it was observed that due to a combination of infants' inconsistent arm position during prone time, and the low amount of pressure registered even during proper contact with the sensors, this methodology was not reliable or feasible to control. Figure 2 demonstrates a mockup of this initial setup.

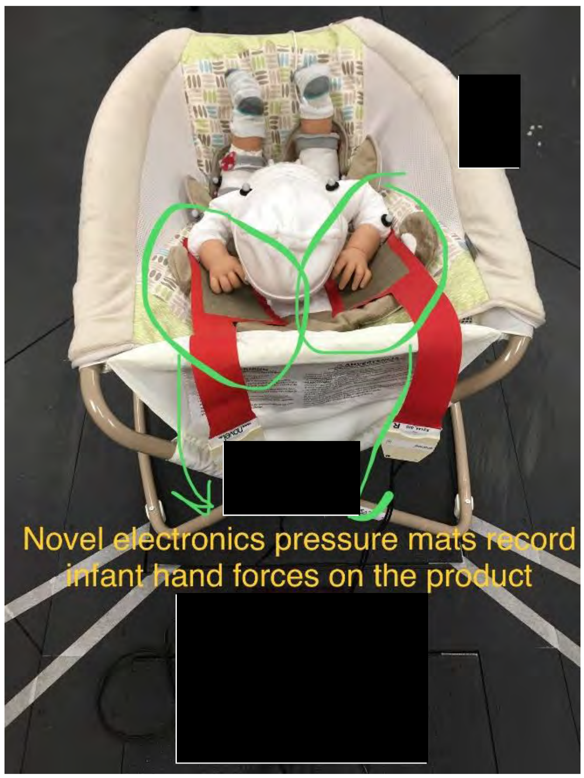


Figure 2. Mockup of prone palm and forearm pressure recording in one product.

Because of the problems with this initial idea, a more consistent methodology was developed to assess the magnitude and distribution of the pressure and contact area recorded on the sensors if a known weight were to be placed orthogonally on the sensors.

Experimental Design

A 2 kg weight was chosen for the controlled testing as it represents approximately 30% of the weight of an average 4-month old infant, a reasonable estimate of the weight a child must bear on their forearms or hands during prone positioning. The calibration weight was placed on a scale to verify its weight (Figure 3). The pressure-mapping sensor was placed on a flat, hard floor and the weight was placed on the sensor to collect the corresponding pressure and contact area readings. Five repetitions were made for each measurement, Figure 3 demonstrates the experimental setup.

Figure 3. Pressure-mapping sensor on floor with weight placed on top between tape.

During initial product testing with the pressure-mapping sensor, it was observed that the deformation of the sensor, as a result of the pliancy of the inclined sleep products, generated high pressure values when the sensor experienced too much deformation. These unreasonable values did not occur on the crib mattress surface, due to less deformation of the product. Since the magnitude of the values were unreasonable, the contact area experienced by the weight on each product was calculated and used as a measure of deformation.

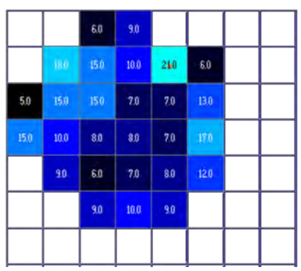


Figure 4. Contact area map of crib mattress product with minimal deformation.

A hinged weight-gauge infant (ASTM F3118-17a) was placed in each product, and the position of the top of the head was used as the indicator for placing the pressure-mapping sensor. Following this, the 2 kg weight was placed on the sensor and the product was tilted as needed so that the weight was sitting orthogonal to the sensor. Five repetitions were made for each measurement. The experimental setup is demonstrated on Figure 5.

Figure 5. Hinged weight-gauge infant and pressure-mapping sensor location determination (A), and 2 kg weight on pressure-mapping sensor on tilted product (B).

Data Analysis

The contact area was calculated as the number of active cells multiplied by the unit cell area (1 cm^2). The calculated contact area served as an estimation for the potential of the inclined surface to deform under a load. For example, when a weight is placed on the sensor on a hard surface, no deformation exists due to the rigidity of the surface, so the contact area reading from the pressure sensor is exactly the contact area of weight. Conversely, if a weight is place on a conforming surface, the sensor deforms with the product, enveloping the sensor such that more surface area of the weight is in contact with the sensor, resulting in a larger contact area reading. Therefore, the larger the contact area, the more deformation. All data analysis was conducted using MATLAB code.

Contact Area Results

Recorded contact area for all inclined sleep products are presented in Table 5 and Figure 6, where the products are categorized by the presence (and type) of plastic molding.

Table 5. Recorded measurements for all inclined sleep products and the crib mattress (at no incline)

Sample	Contact Area (cm^2)	Plastic Molding
Crib Mat	22.4 ± 1.7	No
S03	22.4 ± 2.2	No
S06	33.6 ± 0.9	No
S08	32.6 ± 0.5	No
S11	26.8 ± 1.8	Thin
S01	28.8 ± 0.4	Hard
S02	33.3 ± 1.9	Hard
S13	25.2 ± 0.5	Hard

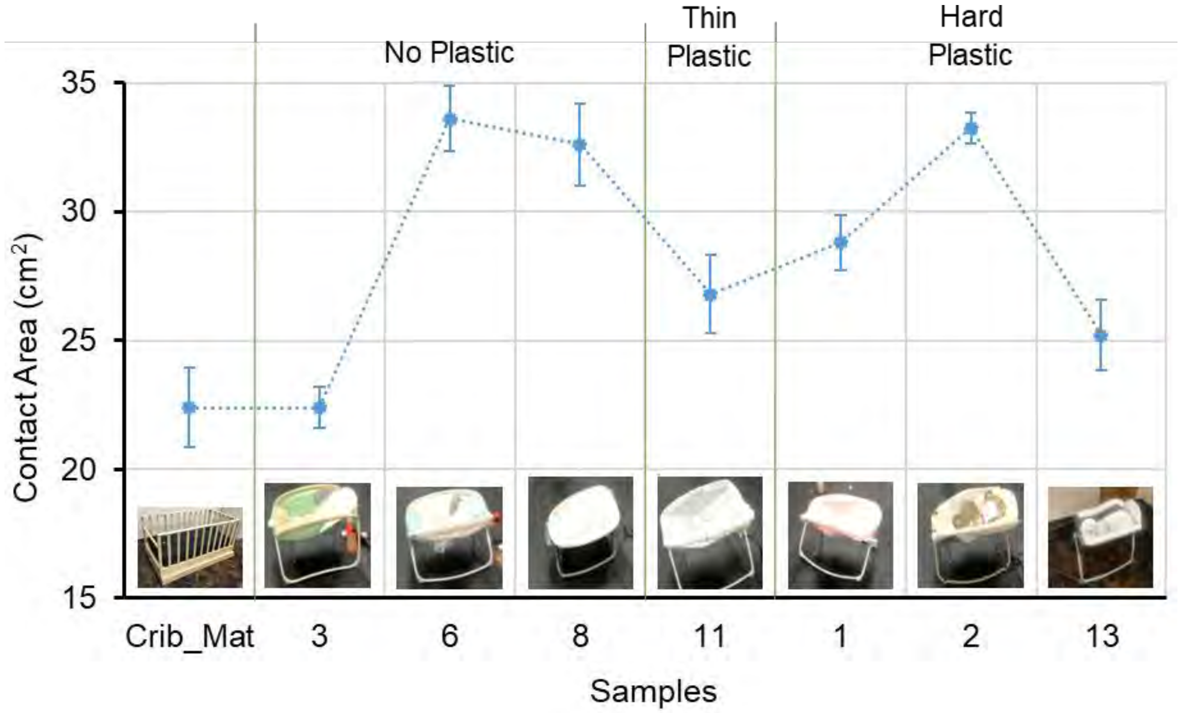


Figure 6. Calculated contact area for crib mattress and inclined sleep products.

Contact areas were highest in products S02, S06, and S08; all products that had a “pillow” or extra cushioning near the head. Product S03 featuring no plastic molding demonstrated contact area characteristics most similar to the crib mattress, and was markedly different from S06 and S08. The principle difference between S03 and both S06 and S08 was the absence of any additional heavy padding material on the product, which likely contributed to the findings.

The product with thin plastic molding, S11, demonstrated contact area characteristics similar to S03, S01, and S13. The slightly higher values demonstrated in S11 are likely due to the higher pliability of the plastic molding (vs. S13), and the presence of a flat full-length cushion on the product (vs. S03).

It is curious that, on average, products with solid plastic molding did not demonstrate significantly different force distribution characteristics compared to products with no plastic molding or thin plastic molding. On closer examination, it was observed that one aspect of this homogeneity is likely the presence of cushioning material near the head on some products. If the findings are examined without the products that have cushioning (i.e. S03 vs. S01 and S13), it is observed that S13’s contact area is closer to S03 than S01. One likely explanation for this may be that S13 has a flat solid plastic molding, while S01’s plastic molding is curved (concave), increasing its potential for a greater contact area as the product shape naturally envelopes the weight.

Beyond the classification criteria, one clear observation can be made of products that were “basic” and “deluxe” versions manufactured by the same company. Both in the case of Company A’s S01 (basic) and S02 (deluxe), and Company B’s S03 (basic) and S06 (deluxe), it is observed that the basic versions have a substantially lower contact area, indicating that the products’ high deformation potential due to extra cushioning may hamper infants’ ability to self-correct if they roll from supine to prone, presenting a safety hazard for babies.

4. BIOMECHANICAL TESTING

4.1 Overview

An *in vivo* experimental biomechanics study was designed to understand how babies move and use their muscles on inclined surfaces and in selected inclined sleep products.

Human Subjects Protections

The Institutional Review Board of the University of Arkansas for Medical Sciences approved this human subjects research study under protocol *228457: Biomechanical Evaluation of Infants in Inclined Sleep Products*. The study was advertised by word-of-mouth and flyers placed near the University of Arkansas for Medical Sciences in Little Rock, Arkansas. The legal guardians of infants enrolled in this study provided written parental permission and HIPAA agreement prior to testing. Testing took approximately two hours, and caregivers were modestly compensated for their time and effort.

Confidentiality

All caregivers signed a confidentiality agreement in which they agreed to not disclose any details about the testing or any products involved in the study. All branding of the products were covered by duct tape, and products were not referred to by name or company at any time during the experimental session.

Participants

A two-sample *a priori* power analysis performed on normalized mean electromyography (EMG) data collected in an ongoing study of healthy infants indicated a sample size of nine participants would be sufficient to produce significant results ($1-\beta = 0.8$; $\alpha = 0.05$). To exceed this minimum suggested sample size and to align with most human motion pilot study designs, ten infants (even gender distribution within 20%) ages two to six months were recruited for the study (Siddicky, 2019; Mannen, 2018). Efforts were made to represent the racial and ethnic make-up of the United States within the cohort (approximately 70% Caucasian, 20% Hispanic, 10% African American).

Inclusion criteria included:

- healthy infants born >37 weeks gestation,
- currently between 5 and 95 percentile height and weight for age according to the CDC (Kuczmarski et al, 2002),
- between the ages of 2.0 and 5.9 months on the date of testing.

Exclusion criteria included:

- infants born at low birth-weight (<5 lbs 8 oz),
- previous or current diagnosed orthopaedic or neurologic conditions,
- sickness or vaccinations within two-weeks of scheduled data collection.

After a pilot subject was tested (CPSC1 – not reported) to evaluate experimental design, ten additional subjects were enrolled in the study (Table 6). The average age was 4.2±1.2 months (range 2.3 to 5.5 months) and adjusted age (age – (40 weeks – gestational age at birth)) was 4.0±1.4 months (range 1.6 to 5.3 months) with an equal sex distribution and a racial distribution of 80% White, 10% Hispanic, 10% Black. Gestational age at birth was 38.6±1.0 (range 37 to 40 weeks). All babies were within the CDC 5 to 95 percentile for height and weight according to their age, were not considered low birth weight, and had not been sick or received vaccinations within two-weeks prior to testing. No infants had orthopaedic or neurological conditions.

Table 6. Infant participants' demographics.

Subject ID	Age (months)	Gestational Age (weeks)	Race/ Ethnicity	Sex (M/F)	Height (cm)	Weight (kg)
CPSC2	3.0	39	White	F	61.0	6.7
CPSC3	4.6	37	White	M	64.5	7.2
CPSC4	5.5	39	Black	M	69.9	8.1
CPSC5	2.6	38	White	M	61.0	6.7
CPSC6	5.5	39	White	F	67.3	7.6
CPSC7	4.9	39	White	M	64.8	7.5
CPSC8	2.3	37	White	F	53.3	4.9
CPSC9	5.1	40	White	F	61.3	7.4
CPSC10	4.2	39	Hispanic	M	61.0	6.0
CPSC11	5.2	39	White	F	54.6	5.2
Mean±SD	**4.2±1.2**	**38.6±1.0**	**8W/1B/1H**	**5M/5F**	**61.8±5.1**	**6.7±1.1**

<u>Experimental Conditions and Product Selection</u>

To test the effect of incline angle on motion and muscle activity, a custom-built inclining crib was designed and built for a 51.7" X 27.3" crib mattress ([redacted]). The inclining crib was manufactured using medium density fiberboard panels, plywood, whitewood studs, and pine-fir lumber (Figure 7). The crib enabled 0°, 10°, 20°, and 30° inclines which were chosen to represent the range of inclines (10° to 30°) of the product samples and span the allowable inclines detailed in ASTM F3118-17a.

Figure 7. Photos of the four incline settings of the inclining crib

The CPSC provided the research team with 14 unassembled samples of different inclined sleep products. Figure 8 depicts the products chosen to be included in experimentation. Based on a preliminary review of the Incident Reports (Section 3) and results of the Product Analysis (Section 2), seven inclined sleep products were chosen for testing: a basic version from Company A (S01), a deluxe version from Company A (S02), a basic version from Company B (S03), a deluxe version from Company B (S06), a product from Company C (S08), a product from Company D (S11), and a second product from Company C (S13). Detailed analysis of these products and rationale for selection can be found in Product Analysis (Section 2).

Figure 8. Photos of products used in the biomechanical analysis.
From left to right: S01, S02, S03, S06, S08, S11, S13.

During pilot testing, it was observed that the **30° crib incline did not allow for prone or supine lying without the infant sliding down the mattress** (Figure 9). After several attempts, it was determined that the infant was unable to maintain her position (supine and prone), and slid to the bottom of the crib, presenting a hazard for the infant participants. Therefore, the 30° incline crib mattress condition was excluded from all future testing, leaving three crib mattress conditions (0°, 10°, 20°) and seven inclined sleep products, totaling 10 product conditions.

Figure 9. Infant slips downward at 30° incline, presenting a hazard. Therefore, 30° was not included in future testing.

4.2 Experimental Design

Testing occurred at the HipKnee Arkansas Foundation human motion laboratory under the direction of the Principal Investigator. Height, weight, head circumference, birthdate, birth height and weight, gestational age at birth, and race/ethnicity were recorded.

Developmental Screening

No infants enrolled in the study had been diagnosed with any developmental delays at the time of testing. Caregivers were asked to complete an Ages and Stages Questionnaire corresponding with the age of their infant to assess developmental progress, with focus on the Fine Motor and Gross Motor portions of the test (Valleley and Roane, 2010; AAP, 2006). In addition, a pediatric psychologist, evaluated the movements of the infants via video of the biomechanical testing and provided a qualitative assessment of each infant's developmental age based on head control, bilateral kicking and arm movements, hands to midline, kicking or arm movement in response to being spoken to, reaching for items, and loss of newborn reflexes. No infants were excluded from testing or analysis based on the results of the developmental screenings.

Kinematics

Infant motion (kinematics) was recorded using marker-based motion capture. A set of 10 infrared cameras [redacted] tracked the position of 21 retro-reflective markers, positioned on specific body segments on the infant, at a sampling rate of 100 Hz. Figure 10 demonstrates the position of these markers, and a schematic of the data capture procedure. The motion capture system included a digital video camera which recorded video at a fixed location at 50 Hz. A [redacted] camera ([redacted]) mounted on a moveable tripod was used to record the entire data collection process.

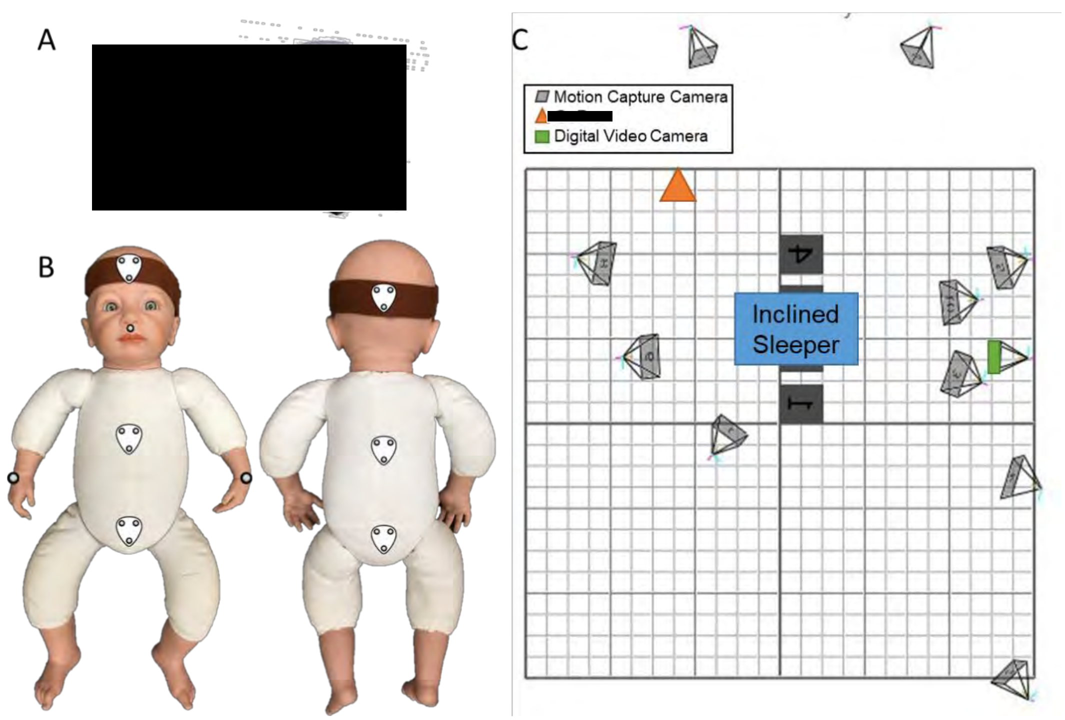


Figure 10. [redacted] Cameras (A), front and back view of marker location on infants (B), and schematic of camera positions during testing (C).

Muscle Activity

Infant muscle activity was recorded using surface electromyography (EMG). [redacted] wireless EMG sensors ([redacted]) were placed bilaterally on the cervical paraspinal, erector spinae, triceps, pectoralis major, and rectus abdominis muscles of infants. Muscle activity was recorded at 1000 Hz. To avoid possible motion obstructions from the connecting wires between the EMG sensor enclosure and the EMG electrode head, the sensor application sites (i.e. the torso and upper arm) were wrapped with soft cohesive self-adherent wrapping tape. Figure 11 demonstrates the [redacted] EMG sensors used in this study, and the anatomical placement locations of these electrodes. Pilot testing revealed that the pectoralis major EMGs were unable to remain in place during testing, so they were removed from the experiment.

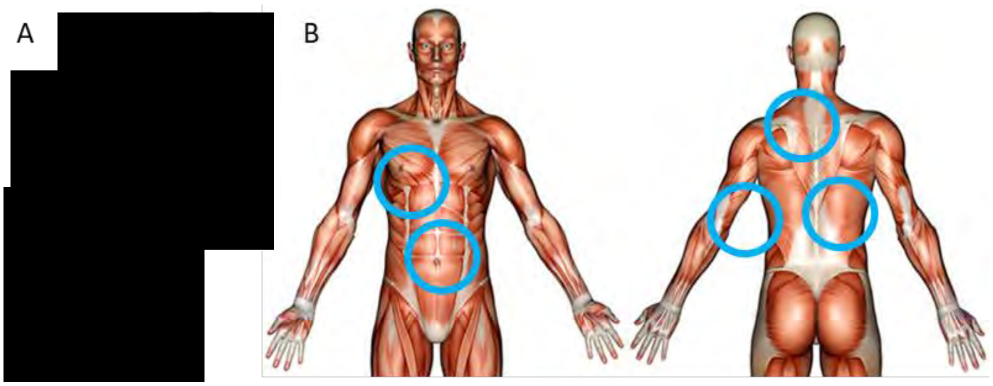


Figure 11. [redacted] electrodes (A), and EMG sensor placement locations (B).

Oxygen Saturation

Infants' oxygen saturation (SpO_2) while placed in each product was recorded using a commercial grade and a medical grade pulse oximeter. During pilot testing the commercial grade oximeter [redacted] was found to be inappropriate for continuous data logging capabilities because it was highly sensitive to leg movements, with slight movements generating a pop-up window that obscured the SpO_2 display. Therefore, the [redacted] was not used during testing.

The medical grade oximeter was the [redacted]. The onboard data logger recorded time-stamped SpO_2 data at 60 Hz (output at 1 Hz). Figure 12 demonstrates the experimental setup for the placement of the oximeter sensor on the infants' big toe. To avoid motion obstructions and sensor detachment, infants' feet were wrapped in soft cohesive self-adherent wrapping tape. Synchronization between SpO_2 data and the experiment data was maintained by time-syncing the oximeter's internal clock with the laboratory computer's internal clock and noting down the start time of each motion capture/EMG trial on the data collection sheet.

For safety of the testing subjects, a trial was ended if the SpO_2 reading was <95% for at least 5 seconds. To avoid instances of false readings or artifact, video footage of the infants was examined during postprocessing when the SpO_2 readings were <95% to understand the situation which may have led to the low reading.

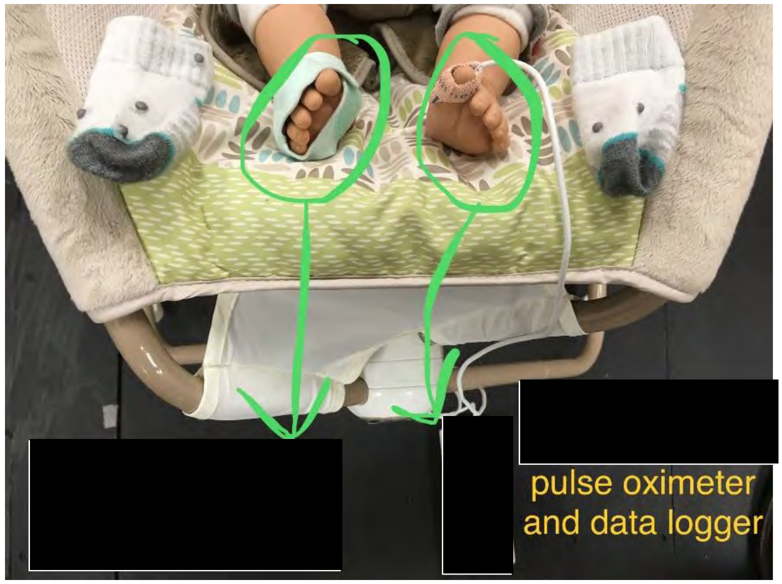


Figure 12. [redacted] SpO_2 sensors placed on the feet of an infant dummy.

Calibration

Calibration of the experimental equipment was conducted prior to each testing session to ensure measurements were accurate. EMG measurements from the prone and supine positions on the Flat Sleeping Surface in this study were compared to a previously collected healthy infant cohort which includes prone and supine positions to ensure reasonableness. If all data from a participant's testing session was found to be errant, the data would be excluded from the analysis and another participant would be recruited.

Testing Procedures

Infants were placed in a random order (Randomizer.org, Urbaniak and Plous, 2013) in each of the 10 testing conditions in both the supine and prone positions for at least 60 seconds (unless the oximeter data fell below 95%, in which case they were removed early to ensure safety, Figure 13). Testing data was considered usable if the infant completed 30 seconds of the task without significant crying or visible distress.

Figure 13. Infant testing setup for: Inclining crib at 0° supine (A), 0° prone (B), 10° supine (C), 10° prone (D), 20° supine (E), 20° prone (F), and an inclined sleep product with infant supine (G), and prone (H).

<u>Sensor Interference with Normal Movement</u>
It is understood that the laboratory environment differs from an infant's natural home environment. Previous studies have determined that small sensors do not interfere with the normal movement of infants (Trujillo-Priego and Smith, 2017). To further assess this concept, a pediatric psychologist qualitatively assessed video footage of the infants for 2 minutes without any sensors and during all testing conditions with the reflective markers and EMG sensors in place to determine if motion or movement of the limbs was hindered by the experimental equipment.

<u>Missing or Incomplete Data</u>
It was expected that not every infant enrolled in the study would successfully complete every activity, but that each infant would complete at least 70% of the planned conditions. By randomizing the order of activities, enough data from the cohort was collected for each condition to make a complete data set. If fewer than seven infants completed a single activity after the collection of ten participants, more subjects would be enrolled in the study.

<u>Data Storage and Reporting</u>
All raw and processed data was de-identified and stored in password-protected and HIPAA-approved secured storage space provided by the University of Arkansas for Medical Sciences.

4.3 Biomechanical Testing Data Analysis

Kinematics

The recorded marker data was used to calculate (1) angular orientation between adjacent body segments, (2) number of times the infants' trunks and necks were raised during prone time, (3) excursion of trunk and hand movements corresponding infants successfully rolling. Angular orientation between adjacent body segments was calculated by using the marker clusters on each body segment to define unit vector matrices forming the axes of local coordinate systems (LCS; Berthouze et al, 2011; Wilk et al., 2006). The element-wise dot product of the LCS unit vector matrices is equivalent to the 3D Cardan rotation matrix representing the relative orientation between the LCS of two adjacent body segments. This calculation is represented in the equation below:

$$R = \begin{bmatrix} c\alpha c\beta & c\alpha s\beta s\gamma - s\alpha c\gamma & c\alpha s\beta s\gamma + s\alpha s\gamma \\ s\alpha c\beta & s\alpha s\beta s\gamma + c\alpha c\gamma & s\alpha s\beta s\gamma - c\alpha s\gamma \\ -s\beta & c\beta s\gamma & c\beta c\gamma \end{bmatrix} = \begin{bmatrix} i.I & j.I & k.I \\ i.J & j.J & k.J \\ i.K & j.K & k.K \end{bmatrix}$$

where [i, j, k] = LCS of body segment 1, [I, J, K] = LCS of body segment 2, c = cosine, s = sine, and [α, β, γ] = rotational angles between the body segments.

Calculations were conducted via custom MATLAB code (MATLAB, Natick, MA). Angular profiles that included data for sagittal plane flexion/extension were calculated for the neck and torso (Figure 14).

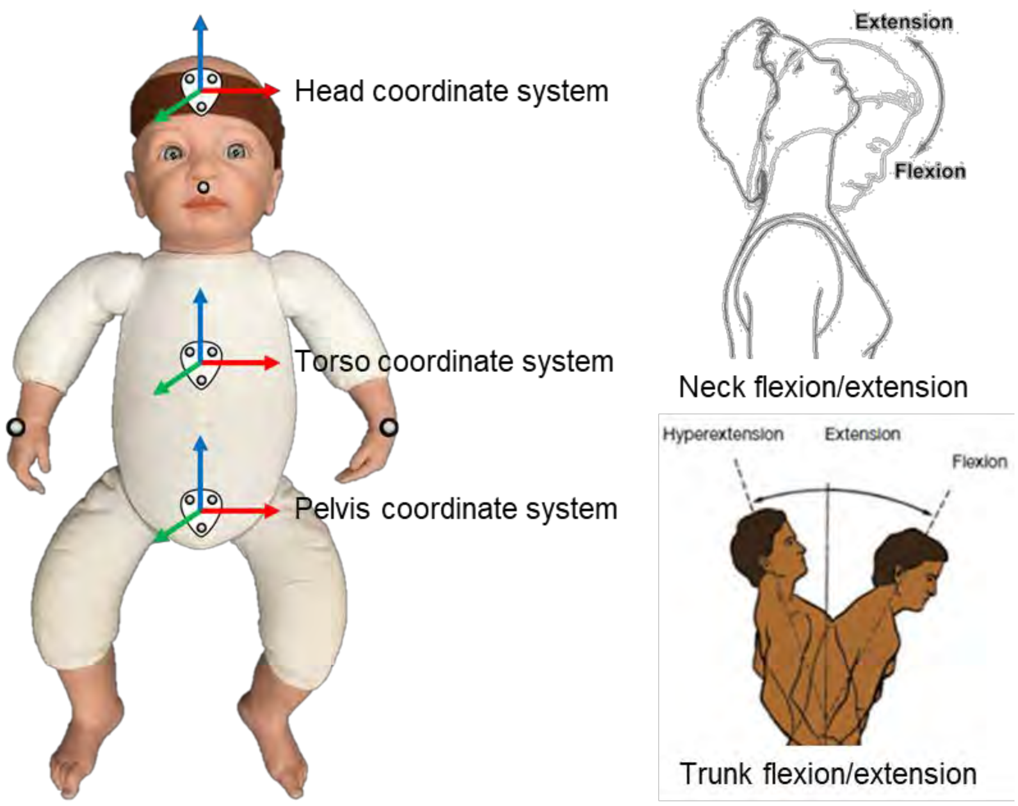


Figure 14. Infant body segment coordinate systems (L), and neck and trunk sagittal plane angles for which ranges of motion were calculated (R)

The neck flexion/extension angular profile was used in conjunction with a peak-finding algorithm to calculate the number of times infants raised their head in each inclined sleep product during the testing duration. The peak-finding algorithm swept through the angular profile data and isolated points in time where the angle value changed by 10° or more. Figure 15 demonstrates a neck extension angular profile with calculated data “peaks” corresponding to head raises.

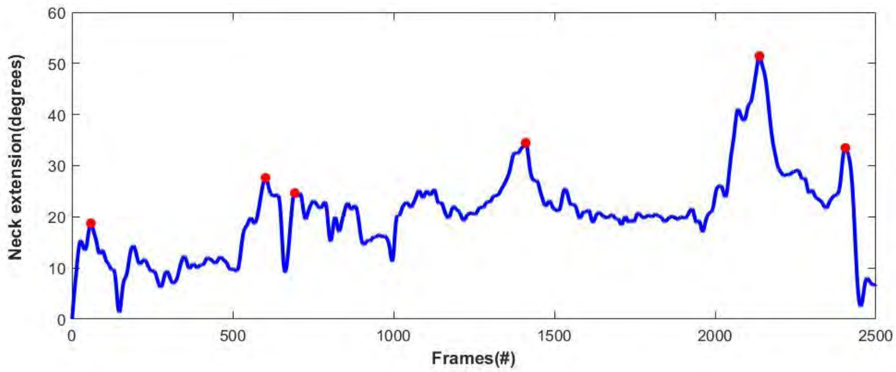


Figure 15. Calculated neck extension angle profile (blue), and data peaks as defined by peak-finder algorithm (red).

Results were compared to the corresponding crib mattress condition (either supine or prone), using paired t-tests (p=0.05), and trends were also noted (p=0.10). Pairwise comparisons were made for all crib mattress conditions.

<u>Muscle Activity</u>

Raw EMG waveforms were assessed for corrupted data using visual amplitude inspection and power spectral analysis (Boxtel, 2001), and such data (clipped amplitude, low power signal, and abnormal frequency pattern) was excluded from analysis. The raw EMG waveforms were band-pass filtered using a 4th order [redacted] filter between 35 Hz and 400 Hz, to reduce contamination from movement artefacts, electrocardiogram signals (Drake & Callaghan, 2006), and high frequency noise (Hermens et al., 1999). Additionally, to eliminate the effects of signal interference from nearby electronic sources, EMG waveforms were notch-filtered at 60 Hz using a 4th order [redacted] filter. EMG waveforms were then full-wave rectified, demeaned, and subjected to a low-pass 4th order [redacted] filter with a cutoff frequency of 50 Hz to obtain the EMG linear envelope (Hodges & Bui, 1996). The mean value of this linear envelope has been reported in the results. Results were compared to the corresponding 0° crib mattress condition (prone and supine, separately), using paired t-tests ($p<0.05$), and trends were also noted ($p<0.10$). Pairwise comparisons were also made for all prone and supine crib mattress incline angles, and for the prone and supine 0° crib mattress conditions. All data analysis was conducted using custom MATLAB code. All muscle groups were considered for prone conditions, and all muscle groups except the triceps were considered for the supine conditions since the arms were not in contact with the surface or product when babies were lying supine. Results are presented as normalized values to the crib mattress condition (supine or prone).

Space Required to Roll

Infant rolling data was extracted from an existing data set of healthy infants. Using the net excursion of a marker placed on the lateral epicondyle of the knee (Figure 16), the space required for infants to roll on a flat surface was estimated.

Figure 16. Infant rolling and location trajectory of lateral knee marker

The net excursion of the lateral knee marker was calculated in the transverse/horizontal plane as the resultant of the medial/lateral (x) and anterior/posterior (y) motion of the marker during the roll.

Oxygen Saturation

Retrospectively, SpO_2 data were extracted from the data logger, and the number of times infants registered a below 95% SpO_2 reading for each testing condition was tallied. Video footage was examined when SpO_2 <95% to help determine the cause of the reading.

4.4 Biomechanical Testing Results

All ten infants were able to complete at least 7/10 of the testing conditions, so all babies were included in the study. The qualitative video analysis to determine if the motion capture markers and the EMG sensors interfered with normal motion and movement revealed that sensors did not interfere with any arm or leg movement, agreeing with previously published research.(Trujillo-Priego and Smith, 2017) It was noted a few times during testing when a marker or sensor fell off, but the research team reattached it and testing resumed. Developmental screening, kinematic, EMG, and oxygen saturation results are presented below.

<u>Developmental Screening Results</u>
All 10 infants' caregivers completed the ASQ-3 questionnaire (3 1.0-2.9 months; 3 3.0-4.9 months; 4 5.0-6.9 months). ASQ-3 results indicated below average or delayed behavior for: Gross Motor 1/10 and Fine Motor 4/10. Video assessment revealed below average motor behavior in 4/10 infants. Because no babies had been previously diagnosed with developmental delays, all babies were included in the study.

4.4.1 Kinematic Results

Effect of Inclined Crib Mattress during Prone Positioning
No significant changes in sagittal plane range trunk or neck range of motion (ROM) were found (Figure 17). A significant trend toward an increased number of neck peaks was found for 20° as compared to 10° (p = 0.08). The inclined angles of the crib surfaces did not affect the number of neck and trunk angle peaks.

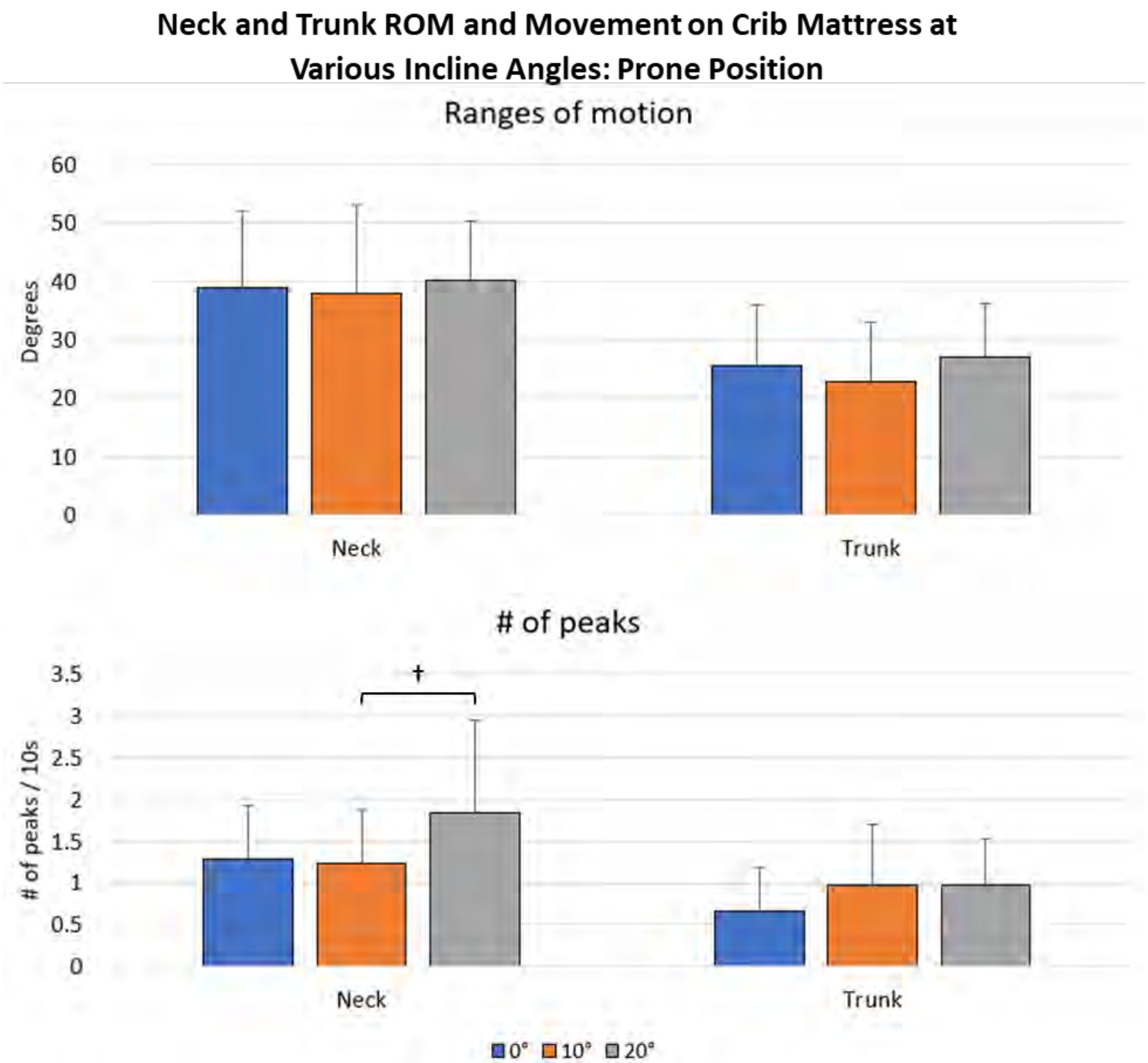


Figure 17. Effect of inclined crib mattress surface (0° vs. 10° vs. 20°) during prone positioning on (a) ranges of motion and (b) number of peaks [neck: number of times an infants raised heads relative to trunks; trunk: number of times infants raised trunks relative to pelvises]. †p<0.1.

Kinematic parameters during prone positioning were not sensitive to different inclined angles of the crib surfaces. Greater inclined angles (20°) may increase neck movement (the number of angle peaks) during prone positioning, meaning that infants may be lifting their heads more often at a 20° incline, but this did not reach statistical significance. The incline angle alone also does not appear to significantly impact trunk or neck range-of-motion during prone positioning.

Effect of Inclined Sleep Products during Prone Positioning

Although incline angle alone did not impact trunk or neck ROM, several inclined sleep products did (Figure 18). S03 resulted in increased neck ROMs as compared to the 0° crib mattress (p = 0.04). S03, S06, S08 increased trunk ROMs as compared to the 0° crib mattress (p = 0.03, p = 0.01, p = 0.04)

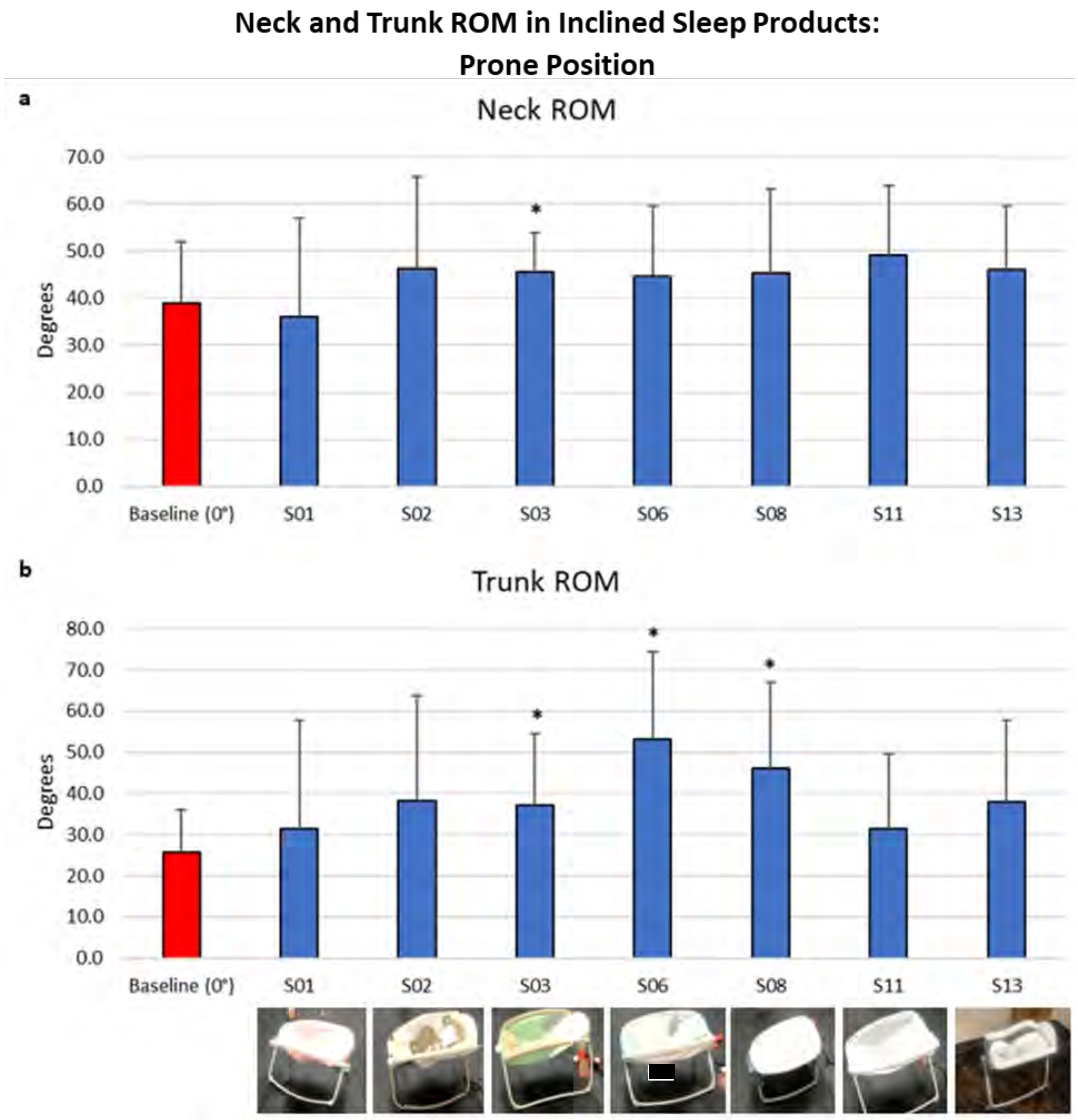


Figure 18. Effect of inclined sleep products during prone positioning on (a) neck and (b) trunk ranges of motion (ROM). *p<0.05 when compared to 0° crib mattress (Baseline).

S03, S06, and S08 are all products that do not have any plastic support underneath the surface (see Product Analysis section 3.3 for details). It appears that trunk and neck movement increases (up to 25°) during prone positioning in inclined sleep products without plastic support at the surface, which differs from the crib mattress incline results which showed no differences. The conformity of these particular products with no rigid support likely causes more movement as infants must work harder to position their bodies. The meaning of these kinematic results will be discussed in more detail after the EMG results are presented below (section 3.1.4).

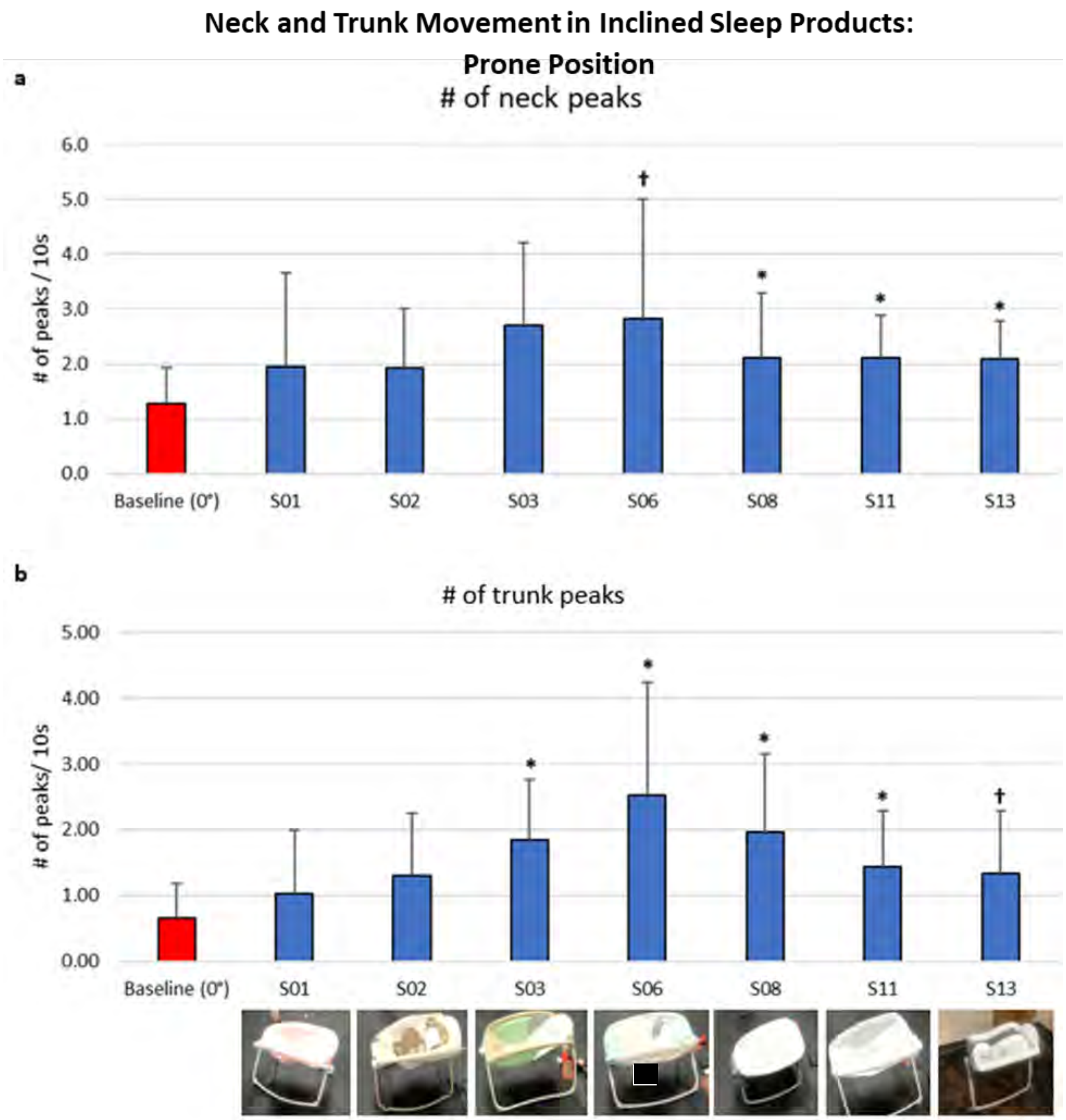


Figure 19. Effect of inclined sleep products during prone positioning on number of (a) neck and (b) trunk peaks [neck: number of times infants raised heads relative to trunks; trunk: number of times infants raised trunks relative to pelvises]. *p<0.05 and †p<0.1 when compared to 0° crib mattress (Baseline).

The number of trunk angle peaks was significantly increased for S8, S11, and S13 as compared to 0° (Figure 19, $p = 0.05$, $p = 0.02$, $p = 0.01$). Similarly, S03, S06, S08, and S11 showed an increased number of trunk angle peaks as compared to 0° ($p = 0.04$, $p = 0.01$, $p = 0.01$, $p = 0.02$).

These results tell a similar story as the ROM results: inclined sleep products result in different movement patterns during prone positioning compared to a flat crib mattress surface. Interestingly, products without any plastic surface support (S03, S06, and S08) caused babies to move more often as they worked against the pliant product to move their bodies compared to the firm and flat crib mattress. These peak results also show that products with a thin plastic surface (S11 and S13) also caused more movement. Only the products with a rigid plastic surface (S01 and S02) showed no difference in the number of times the babies lifted their trunk or neck compared to prone lying on a flat crib mattress. The meaning of these results will be discussed in more detail after EMG results are presented.

Effect of Inclined Crib Mattress during Supine Positioning

Neck ROM was significantly, though only slightly, increased for the 20° surface as compared to 0° surface (Figure 20, p=0.02) while no changes in trunk ROMs were found. Number of neck angle peaks were significantly increased when comparing 20° to 0° and 10° (p=0.02, p=0.01). No changes in trunk ROMs and number of trunk angle peaks were found.

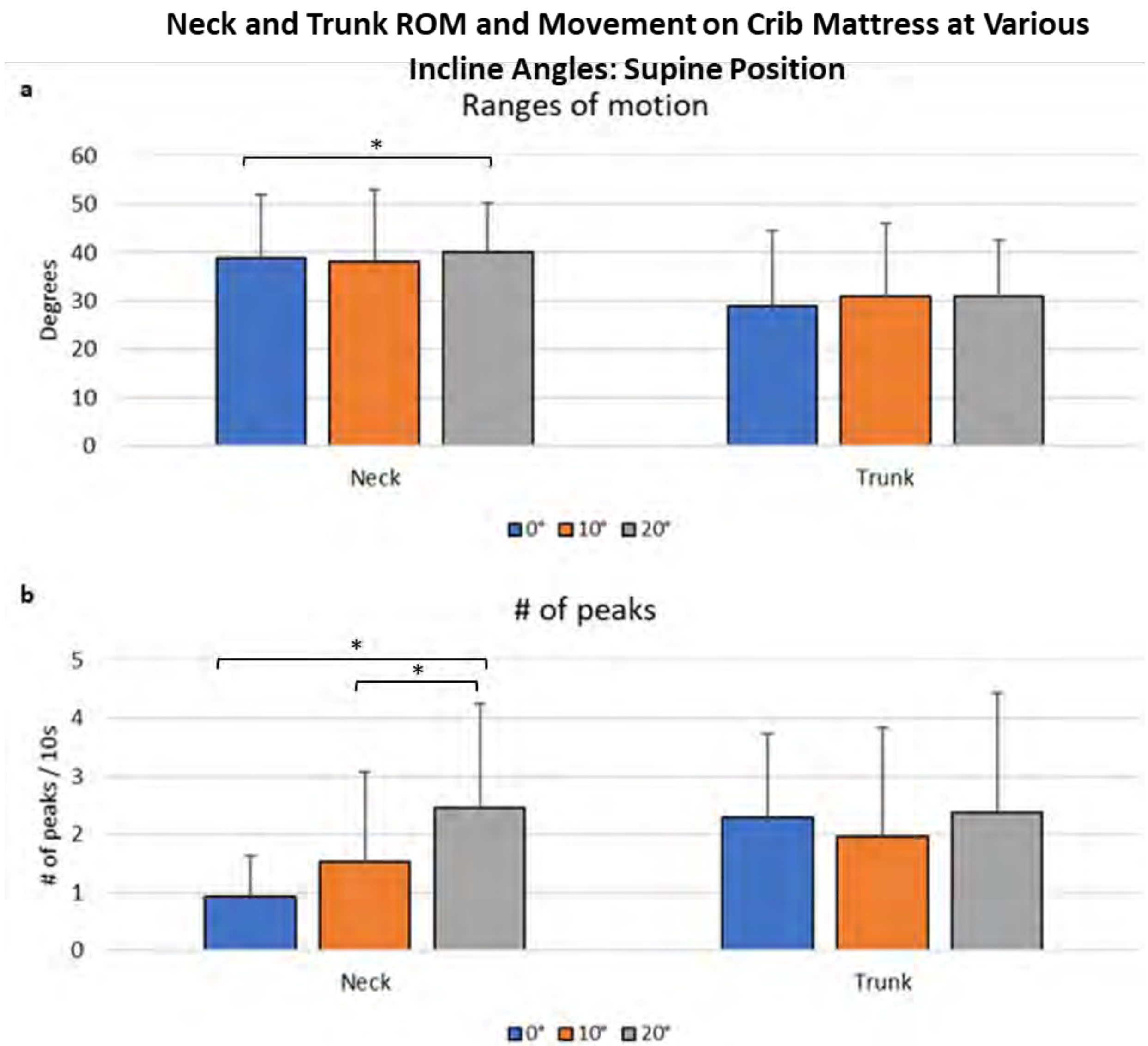


Figure 20. Effect of inclined crib mattress surface (0° vs. 10° vs. 20°) during supine positioning on (a) ranges of motion and (b) number of peaks [neck: number of times an infants raised their heads relative to their trunks; trunk: number of times infants raised their trunks relative to their pelvises]. * p<0.05.

Inclined surface angles slightly increased neck motion while trunk motion remained unchanged during the supine position. Babies lifted their heads 2.5 times more often at the 20° incline compared to the flat surface. These results will be discussed in detail in conjunction with the EMG results below.

Effect of Inclined Sleep Products during Supine Positioning

No significant differences in neck ROM were found (Figure 21). S01 and S02 resulted in decreased trunk ROMs as compared to 0° ($p=0.03$, $p=0.08$).

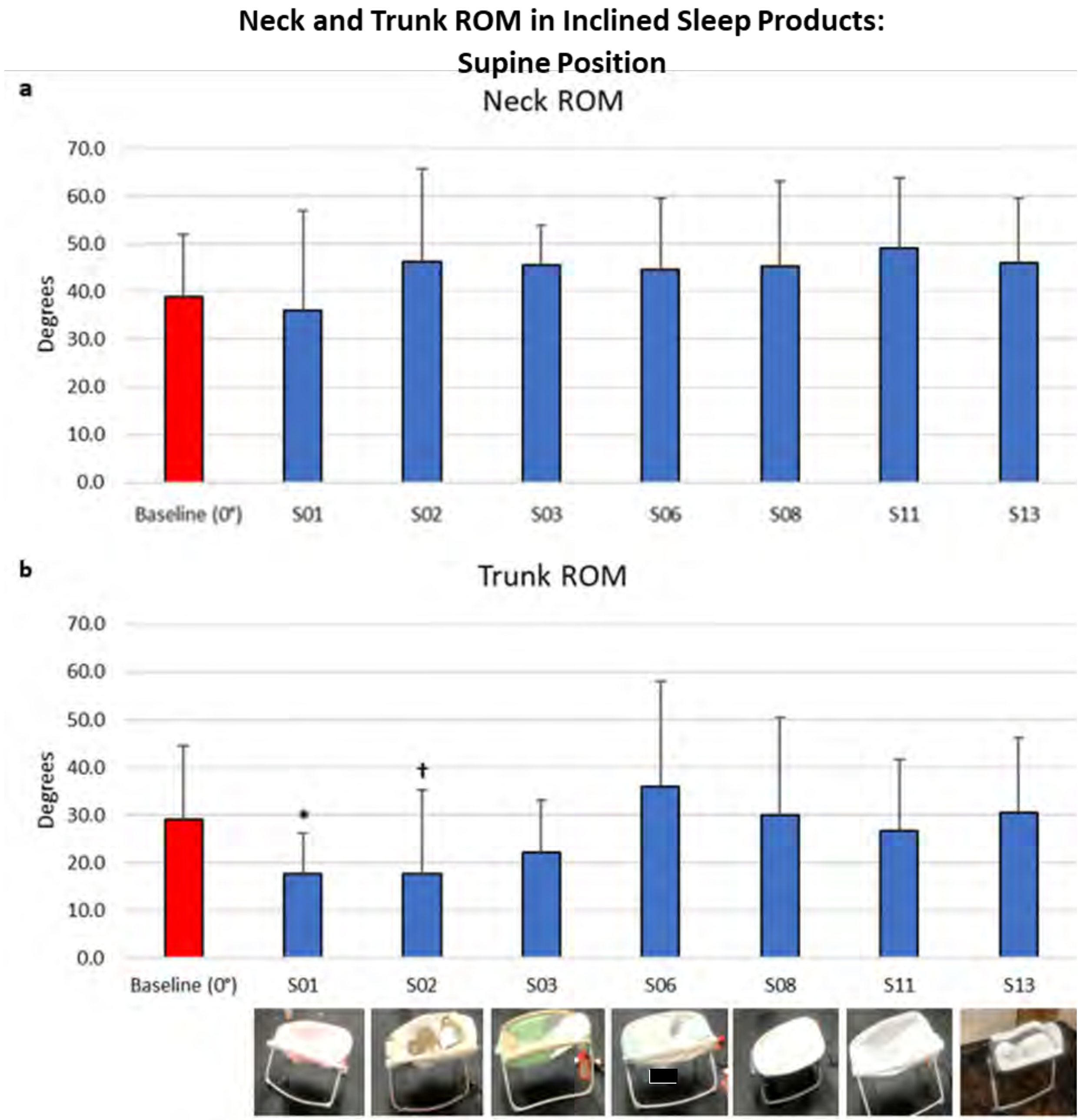


Figure 21. Effect of inclined sleep products during supine lying on (a) neck and (b) trunk ranges of motion (ROM). *$p<0.05$ and †$p<0.10$ when compared to 0° crib mattress (Baseline).

S01 and S02 showed decreased trunk motion as compared to 0° surface. These two products have a hard plastic surface, which may prevent babies from extending their trunks during supine lying, resulting in a lower range-of-motion.

No changes in the number of neck angle peaks were found (Figure 22). The number of trunk angle peaks was decreased up to 4 times for S02, S06, S11, and S13 (p = 0.06, p = 0.07, p = 0.01, p = 0.05)

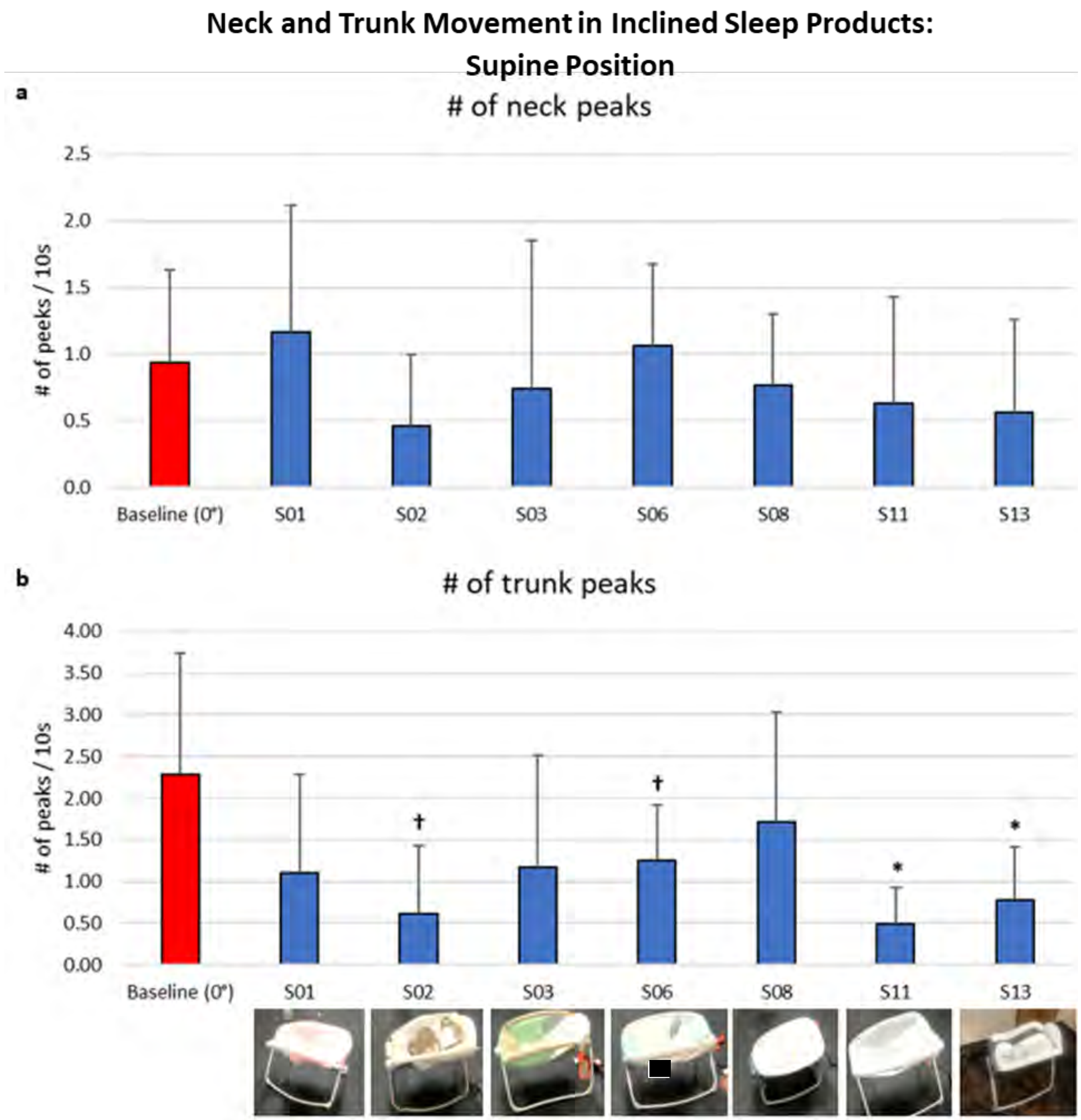


Figure 22. Effect of inclined sleep product during supine lying on (a) neck and (b) trunk peaks [neck: number of times an infants raised heads relative to trunks; trunk: number of times infants raised trunks relative to pelvises]. *$p<0.05$ and †$p<0.1$ when compared to 0° crib mattress (Baseline).

Contrary to the results of the crib mattress incline portion of this study, babies showed no difference in the number of times they lifted their heads in the inclined products but had significantly fewer trunk movements in the products during supine lying. This shows that something about the design of the inclined sleep products is preventing trunk motion during supine lying in a way that an inclined crib mattress surface does not. Decreased trunk movement was measured in all types of inclined sleep products (various angles, various plastic/ no plastic surfaces, various padding). One reason for this observation may be that when babies are positioned supine in the products, some conformity occurs (either due to no rigid plastic surface or due to heavy padding). The conformity causes an increased trunk flexion that does not occur on an inclined crib mattress surface. Because the babies are already in a flexed position, further flexion is more difficult to achieve and therefore they do not move as often. These results will be discussed in conjunction with the EMG results below.

4.4.2 EMG Results

Effect of Inclined Crib Mattress during Prone Positioning

The inclined crib mattress significantly impacted muscle activity of the infants (Figure 23, presented as normalized values). Erector spinae EMG activity was significantly decreased when comparing 10° and 20° to 0° ($p = 0.04$, $p = 0.01$, respectively). Cervical paraspinal EMG activity was significantly decreased for 20° as compared to 0° ($p = 0.02$). Abdominal muscle activity was significantly increased when comparing 10° and 20° to 0° ($p = 0.02$, $p = 0.01$) as well as when comparing 20° to 10° ($p = 0.04$). Triceps EMG activity was significantly decreased for 20° as compared to 0° ($p = 0.02$).

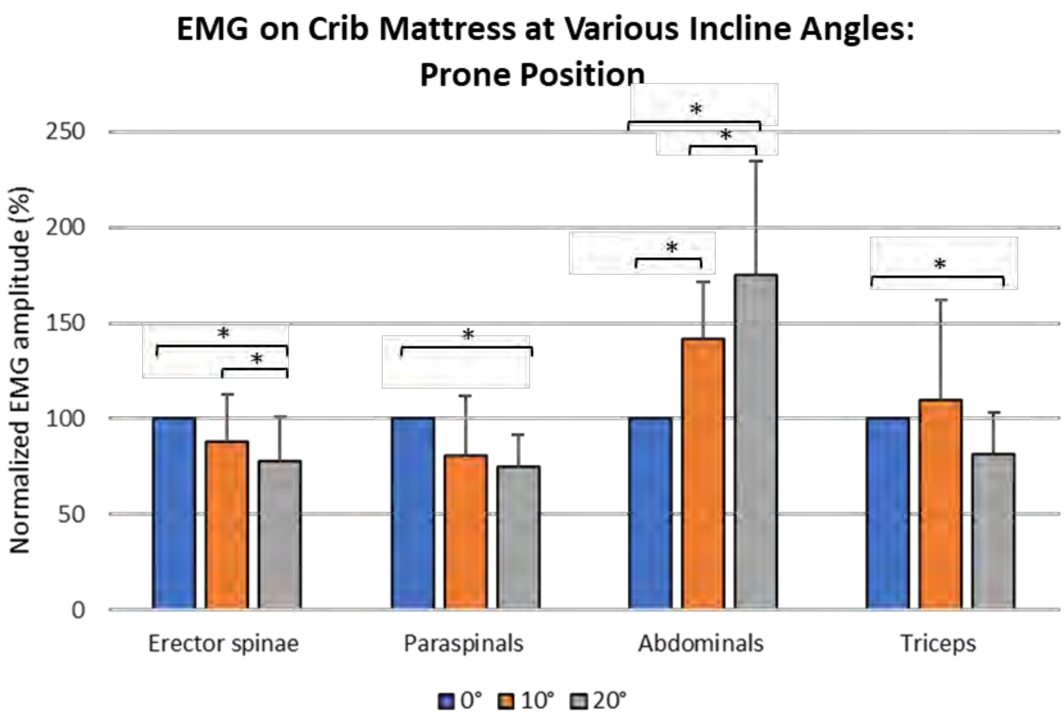


Figure 23. Effect of crib mattress surface at various inclines (0° vs. 10° vs. 20°) on EMG: erector spinae, cervical paraspinals, abdominals, and triceps during prone. *$p<0.05$.

These results indicate that inclined surfaces (especially 20°) require greater abdominal muscle activity while decreasing erector spinae, cervical paraspinal, and triceps muscle activities. In other words, to maintain a prone lying position, an infant must use and coordinate their muscles differently when on an inclined surface; babies must depend more on their abdominal muscles to maintain a lying position. In particular, the core muscles (abdominals) require 70% more activity to maintain a prone lying position, indicating that **muscle fatigue of the abdominals would occur more quickly at an incline compared to a flat surface**. Rather than depending on many muscles to maintain a prone position on a flat surface, the inclined surface increases the effort required of the core muscles. Postural adjustments and core muscle strength are closely related, so the role of abdominal muscles in changing position is critical and is impacted by incline angle.

When analyzed in conjunction with the kinematic results above, the narrative is supported; babies are not moving their heads or trunks more or less often in the prone position on an inclined crib mattress surface, yet the muscle activity profile is significantly different. Further, the decrease in neck and back muscle activity does not result in a decrease in neck or back movement, indicating that the abdominals must play a significant role in body movement during prone lying on an incline. Because the abdominal muscles are critical for body control and movement, it is likely that an incline makes it more difficult for infants to roll from prone to supine when compared to a flat surface due to the increased demand on their abdominal muscles to maintain a prone position.

Effect of Inclined Sleep Products during Prone Positioning
Erector spinae muscle activity was significantly decreased for S02, S03, and S08 as compared to 0° baseline (Figure 24, p = 0.007, p = 0.05, p = 0.005). Significant trends (i.e. p<0.1) toward decreased erector spinae muscle activity was found for S01 and S11. No significant changes and trends in cervical paraspinals were found.

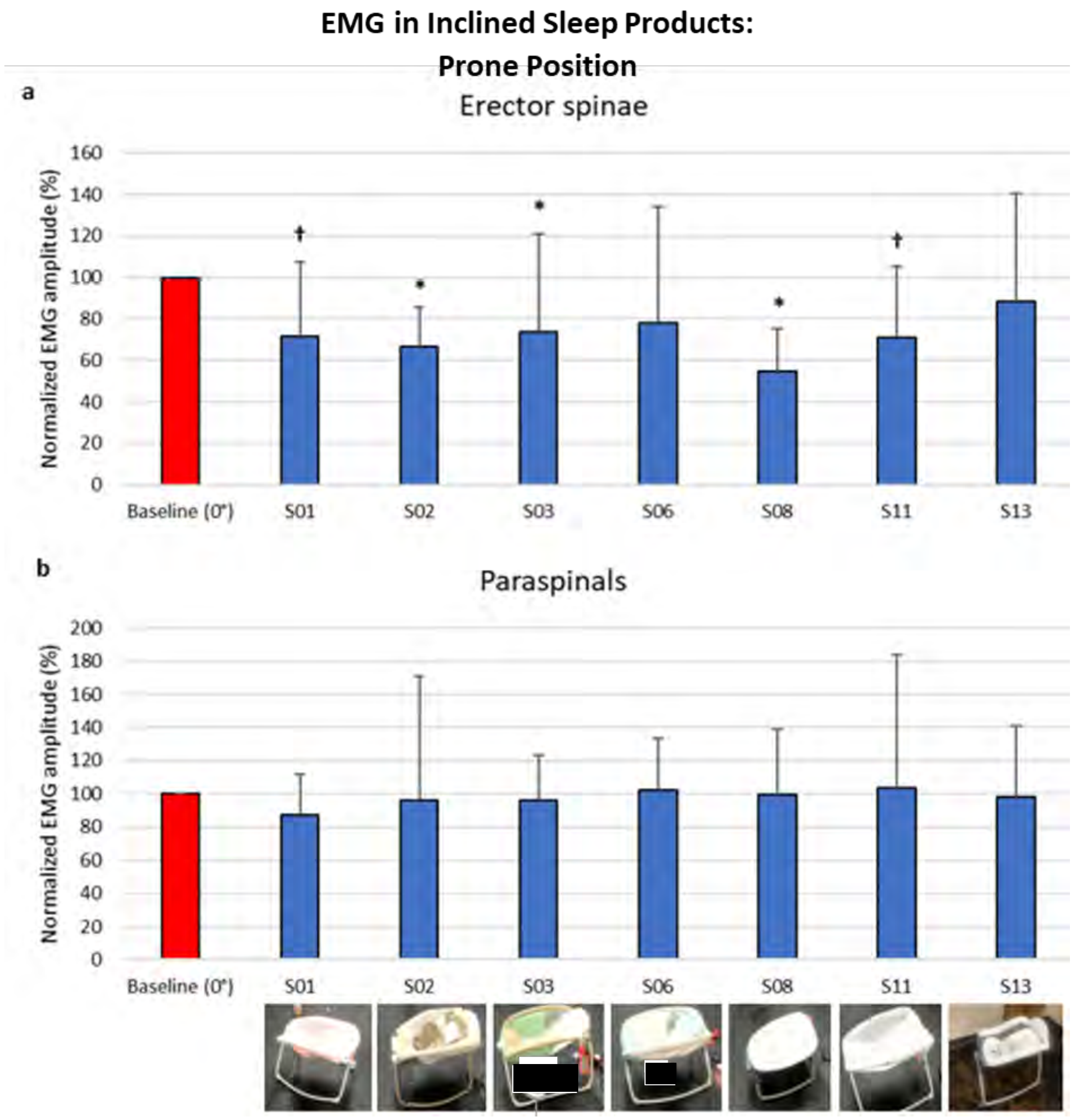


Figure 24. Effect of inclined sleep products during prone positioning on EMG activity of the (a) erector spinae and (b) cervical paraspinals. *p<0.05 and †p<0.10 when compared to 0° crib mattress (Baseline).

S01, S02, S03, S08, and S11 products resulted in decreased trunk extensor muscle activity during prone lying (as compared 0° crib mattress surface). S06 and S13 also showed decreased erector spinae activity but did not show significant changes due to high variability. These results agree with those of the 20° crib surface, showing less erector spinae muscle activity required to maintain a prone position. It is not surprising that the cervical paraspinal activity exhibited high variability. Observationally, babies rested their heads during prone tasks, while others appeared to move their heads continuously, resulting in high variability.

Abdominal EMG activity was increased for S02, S06, and S08 as compared to 0° baseline (Figure 25, p = 0.03, p = 0.01, p= 0.05). A significant trend for S03 (increased abdominal activity) was found (p = 0.08). No significant differences in triceps EMG were found.

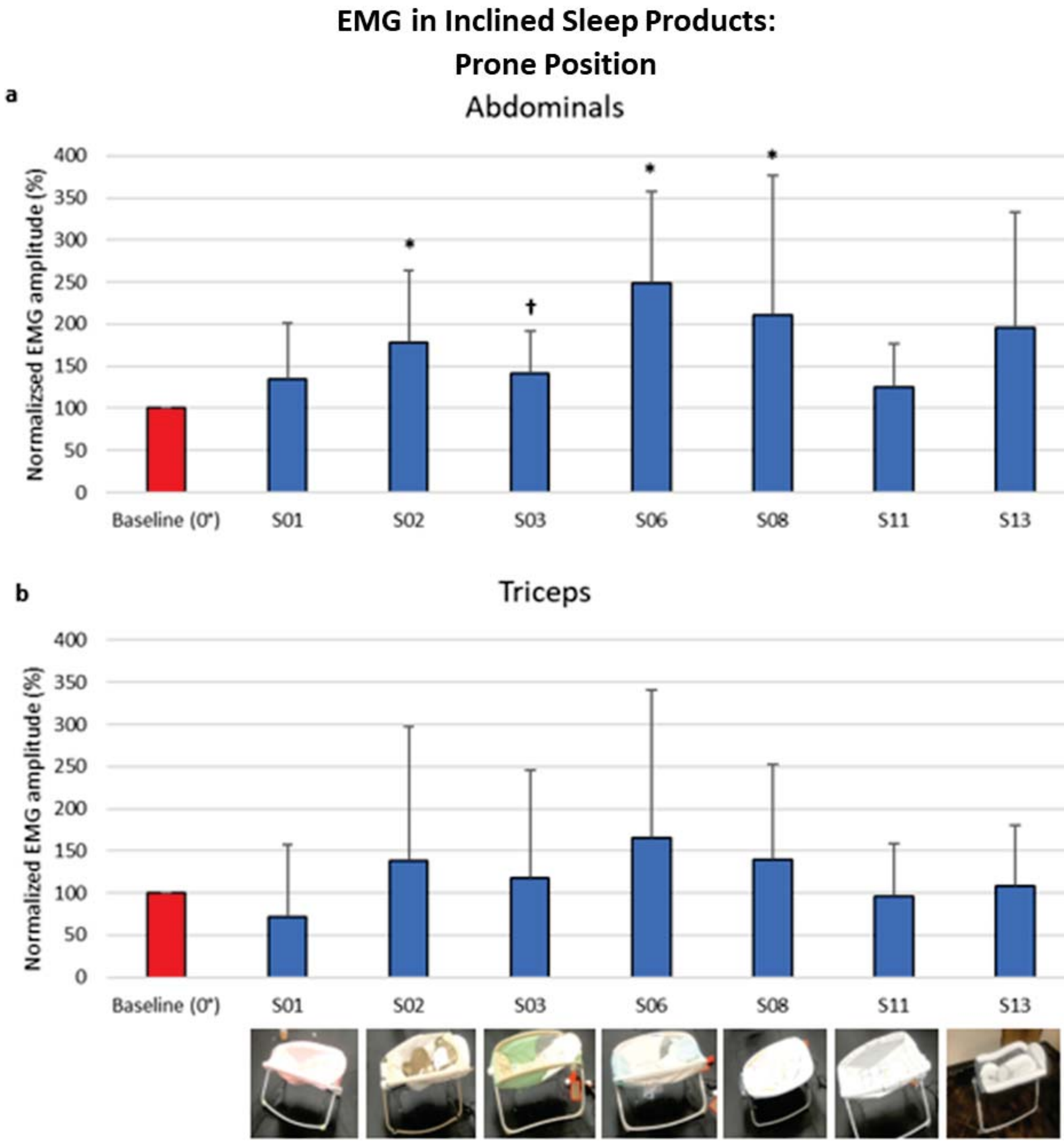


Figure 25. Effect of inclined sleep product during prone positioning on EMG activity of (a) abdominals and (b) triceps. *p<0.05 and †p<0.1 when compared to 0° crib mattress (Baseline).

Similar to the inclined crib mattress testing, infants used their abdominal muscles significantly more when lying prone in the inclined sleep products compared to the flat crib mattress surface. In particular, it was noted that products with the thickest padding (S02, S06, and S08) exhibited increases in abdominal muscle activity of 186%, 245% and 191%, respectively. **This suggests that the combination of incline angle and product design requires infants to use significantly more core effort (abdominal strength) to maintain a prone position compared to a flat surface.** If an infant rolls within an inclined sleep product, the product design of limited horizontal space and a non-rigid concave surface makes rolling prone to supine difficult or impossible. Therefore, infants attempt to maintain a safe prone posture, which the EMG results suggest places an increased demand on the core muscles.

Similar to the cervical paraspinal muscles, it is not surprising that the triceps muscle activity exhibited high variability. Observationally, some babies actively used their arms during prone positioning, while others appeared to utilize their legs to attempt repositioning, resulting in high variability. However, the consistent abdominal and erector spinae data indicate that babies rely on these muscle groups to reposition themselves regardless of variability in technique.

When considered with the kinematic results (section 3.1.3), back muscle activity decreases while the trunk motion actually increases, indicating that different muscles (abdominals) are being recruited to initiate movement during prone positioning in inclined sleep products, **presenting a significant hazard to babies if a roll from supine to prone in an inclined sleep product occurs**. Although babies may receive adequate practice in tummy time on a flat surface, a roll from supine to prone in an inclined sleep product would likely be the first time they have ever experienced a position that required muscles to work together in this particular way – with a significant need for abdominal strength. This situation would likely result in expedited muscle fatigue as the baby attempts to reposition and self-correct.

The role of abdominal muscles during breathing have been previously studied, though not on an inclined surface. In general, the contraction of the abdominal muscles, which normally play a role in breathing and are accessory muscles of respiration, stabilize the chest wall and push up on the abdominal contents, giving the diaphragm something to contract against, thus improving its function. Abdominal muscles are also expiratory accessory muscles that aid in forced expiration (exhalation) against obstructed airways (Campbell and Green, 1953; Martin and De Troyer, 1982). However, there is some evidence in infants that contraction of the abdominal muscles leads to decreased lung volume and hypoxic episodes (Boliver et al., 1995). So, an infant with increased abdominal muscle activity could have restricted rib cage expansion and low lung volumes or hypoxemia.

Effect of Inclined Crib Mattress during Supine Positioning
Erector spinae activity was increased for 20° as compared to 10° (Figure 26, p=0.04) though no changes were found when comparing 20° to 0°. For abdominals and cervical paraspinal muscles, there were no significant changes or trends across 0°, 10°, and 20° inclined surfaces.

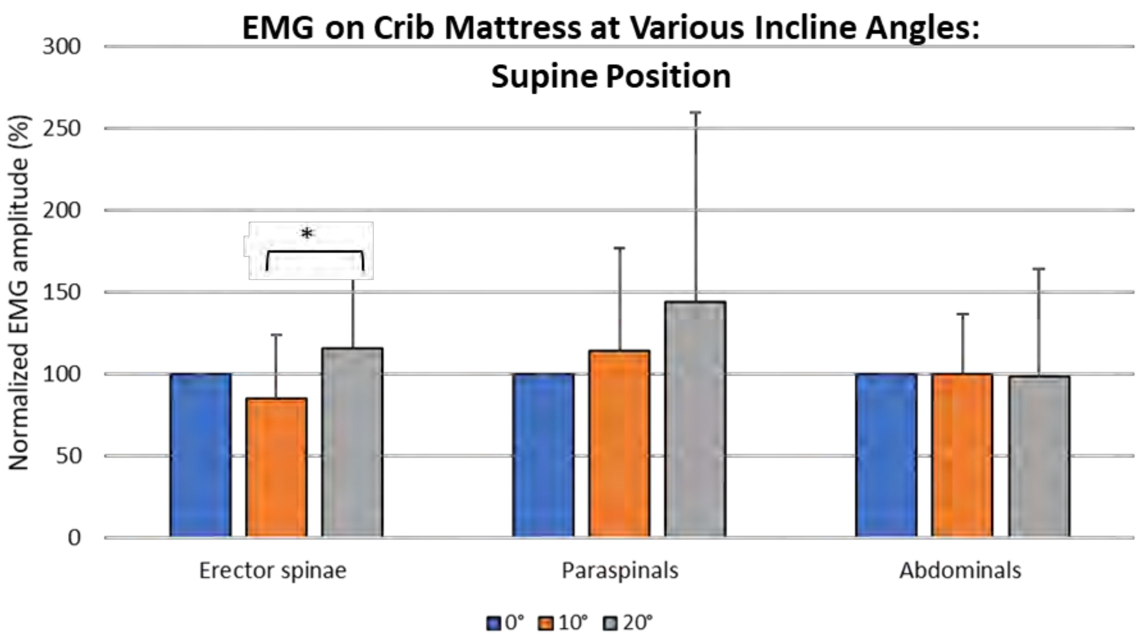


Figure 26. Effect of crib mattress at various incline angles (0° vs. 10° vs. 20°) during supine lying on EMG activity: erector spinae, cervical paraspinals, and abdominals. *p<0.05

Taken alone, these results suggest that an incline angle does not impact how infants are using their muscles during supine lying. However, when reviewed in conjunction with kinematic data (section 3.1.3), these EMG results become meaningful. The increased incline angle resulted in more neck motion, yet the EMG results mostly do not indicate an increase in muscle activity. Therefore, at an incline, it is easier for babies to move their heads in the supine position as compared to lying on a flat surface.

<u>Effect of Inclined Sleep Products during Supine Positioning</u>
Erector spinae EMG activity was significantly decreased for S06 as compared to 0°(baseline) (Figure 27, p=0.01). S02 also showed a significant trend toward decreased muscle activity when compared to 0° (p=0.07). Most inclined sleep product conditions tended to decrease erector spinae muscle activity when compared to 0°. No significant differences and trends in cervical paraspinal EMG were found.

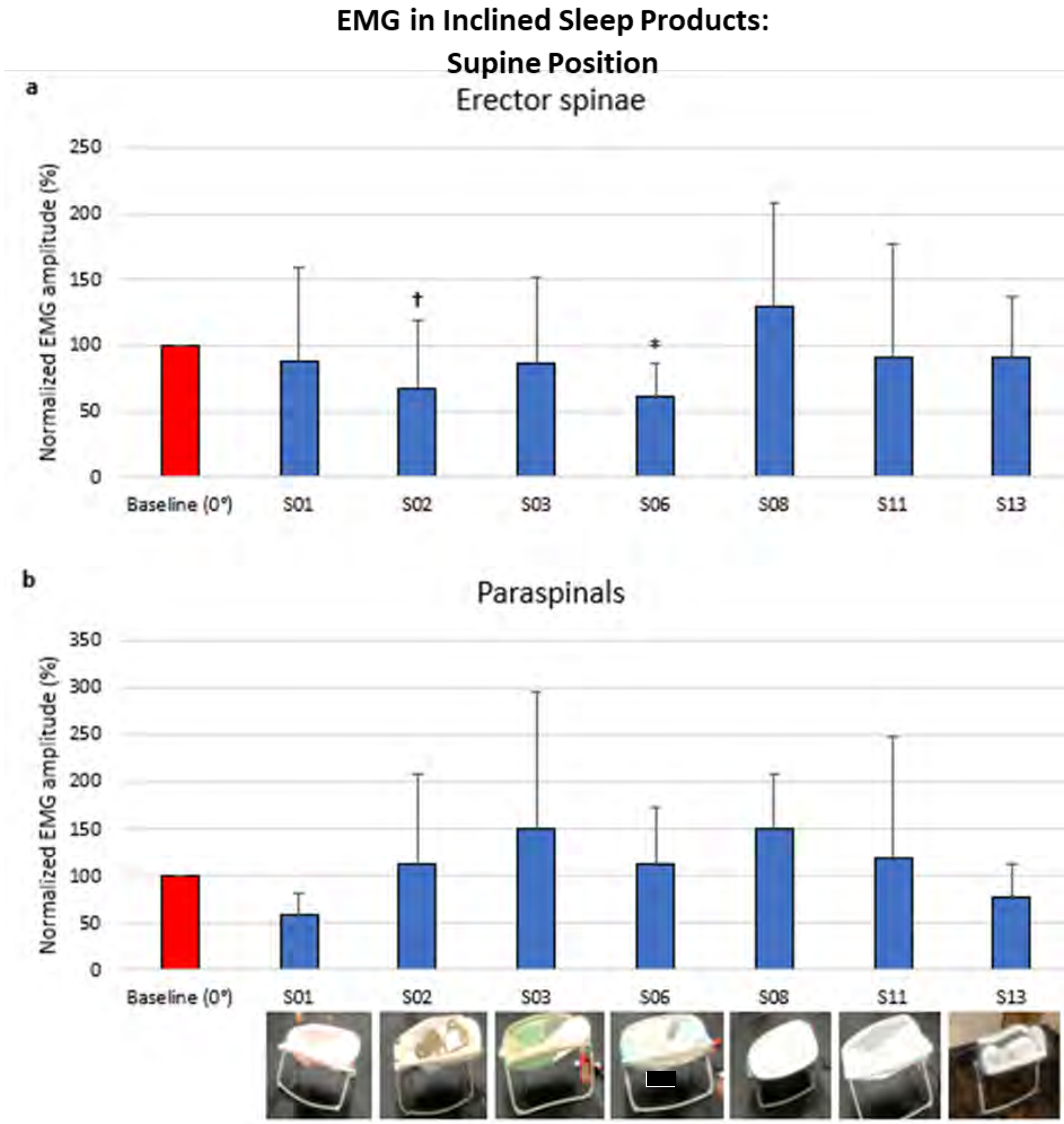


Figure 27. Effect of inclined sleep product during supine positioning on (a) erector spinae and (b) abdominals. * $p<0.05$ and †$p<0.1$ when compared to 0° crib mattress (Baseline).

Infants used their back muscles less during supine lying in products S02 and S06, two "deluxe" versions of products which exhibit significant padding. The heavy padding may conform to the infant during supine lying more than other products, resulting in a more flexed trunk which requires less muscle activity to maintain the position. It is also reasonable that the conforming products offer comfort to infants, resulting is less movement and muscle activity. Across all products, EMG activity was highly variable and not significantly different than the baseline 0° condition during supine lying for both erector spinae and paraspinal muscle groups. When considered with the results of the kinematic analysis (section 3.3.1), infants move their trunks less and use their back muscles less in some inclined sleep products.

No significant changes in abdominal EMG activity during supine lying was found (Figure 28). These results suggest that infants are not using their abdominal muscles differently when positioned supine in an inclined sleep product.

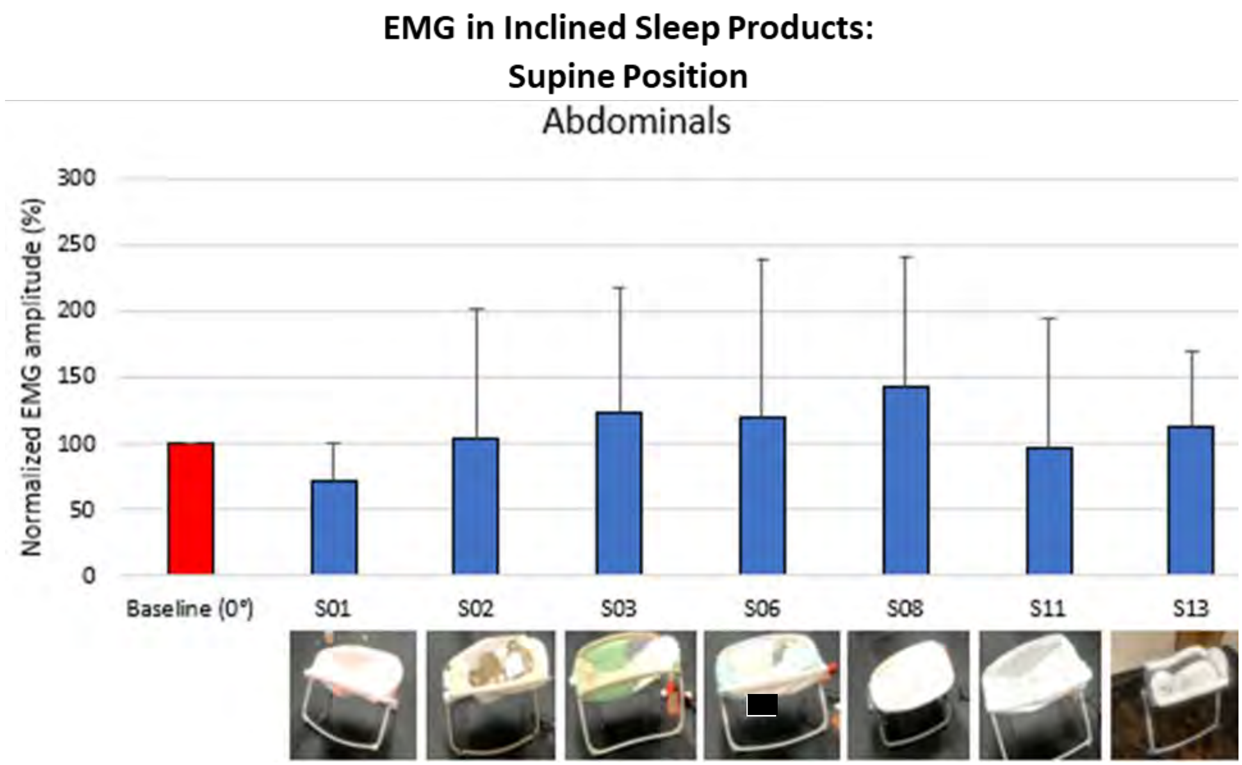


Figure 28. Effect of inclined sleep products during supine positioning on EMG activity of the abdominals.

While it is not fully understood how infants achieve a roll from supine to prone, the head represents a significantly higher percentage of total body weight in an infant compared to an adult. Therefore, head motion (in addition to other coordinated movements) likely plays a role in providing momentum and achieving a roll from supine to side-lying or supine to prone. The three incidents of supine to prone rolling that occurred on a flat surface during testing were analyzed, and it was found that the rolling mechanism was initiated by the fetal tuck (hip and trunk flexion) which requires a co-activation from the abdominal muscles and erector spinae as an agonist-antagonist pair. Because the conformity of the inclined sleep products naturally puts the infants in a more flexed hip and trunk position, it may be easier for infants to achieve the fetal tuck position to roll from supine to prone. Regardless if a roll from supine to prone is easier or more difficult to achieve on an inclined surface or in an inclined sleep product, it is fair to say that an inclined sleep product represents a different environment than a flat crib mattress or even a crib mattress at an incline. In particular, the most significant differences in supine lying occurred in the mostly heavily padded products (S02 and S06).

Prone v. Supine EMG Activity

EMG activity of the cervical paraspinals, erector spinae, and abdominal muscle groups were compared between prone and supine lying on a flat crib mattress. Results showed no difference between abdominal muscle activity in prone and supine lying, but 3 times more erector spinae ($p<0.001$) and 5 times more cervical paraspinal ($p=0.004$) muscle activity during prone lying compared to supine lying (Figure 29). In other words, while the abdominal effort may not change between prone and supine lying on a flat surface, the trunk extensor muscle groups (cervical paraspinals and erector spinae) are much more active in the prone position on a flat surface.

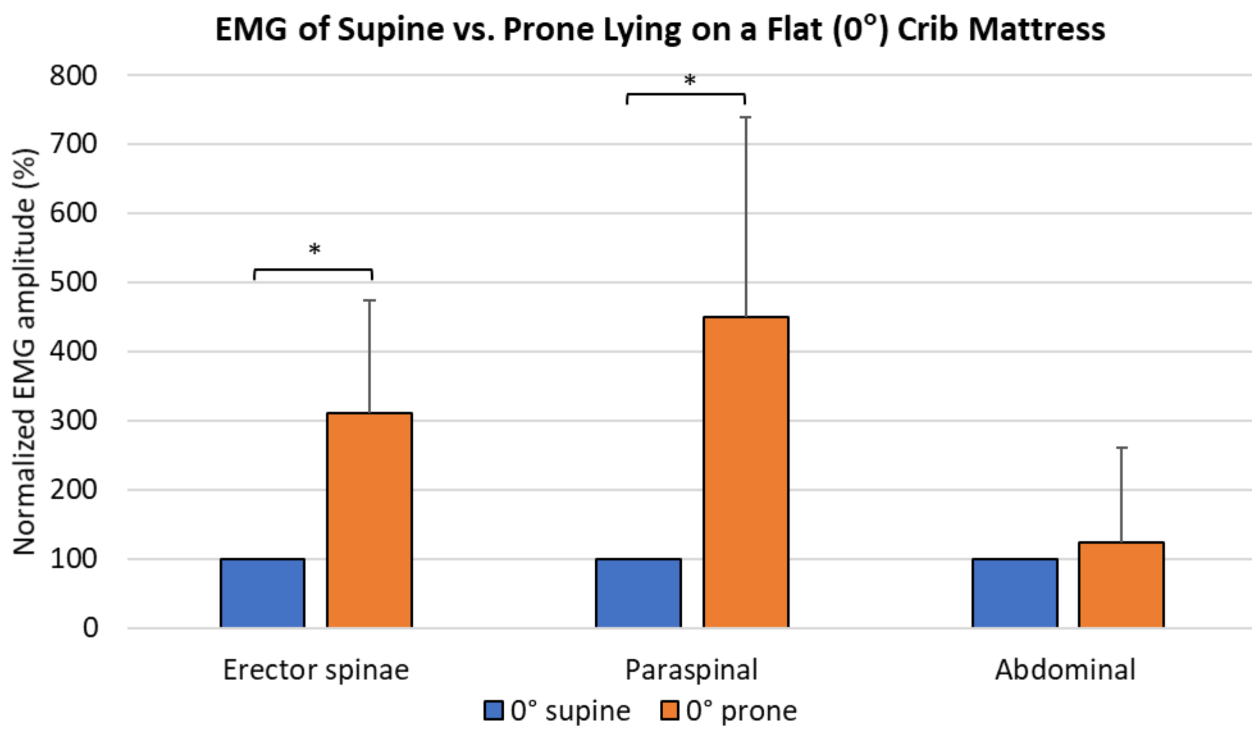


***Figure* 29.** EMG activity (erector spinae, paraspinal, and abdominals) during flat (0º) crib mattress supine compared to flat (0º) crib mattress prone lying, with EMG amplitudes normalized to the supine condition. *$p<0.05$.

When taken together with the results that show less extensor, more abdominal muscle activity, and more movement during inclined prone positioning compared to lying prone on a flat surface, it is clear that muscle synergies (i.e. how muscles work together) to achieve mobility and postural changes on a flat surface are not the same when an incline is introduced. The fact that abdominal muscle activity increased by nearly 250% in some inclined sleep products suggests that more effort than is ever needed for flat surface supine or prone lying is required when prone in an inclined sleep product (Figure 30). Positions that demand much more of muscles will also fatigue them more quickly, so if a baby experiences a roll, the baby is in a hazardous and unfamiliar position that requires efforts they have likely never experienced, presenting a risk factor that may contribute to suffocation if self-correction from prone to supine does not occur.

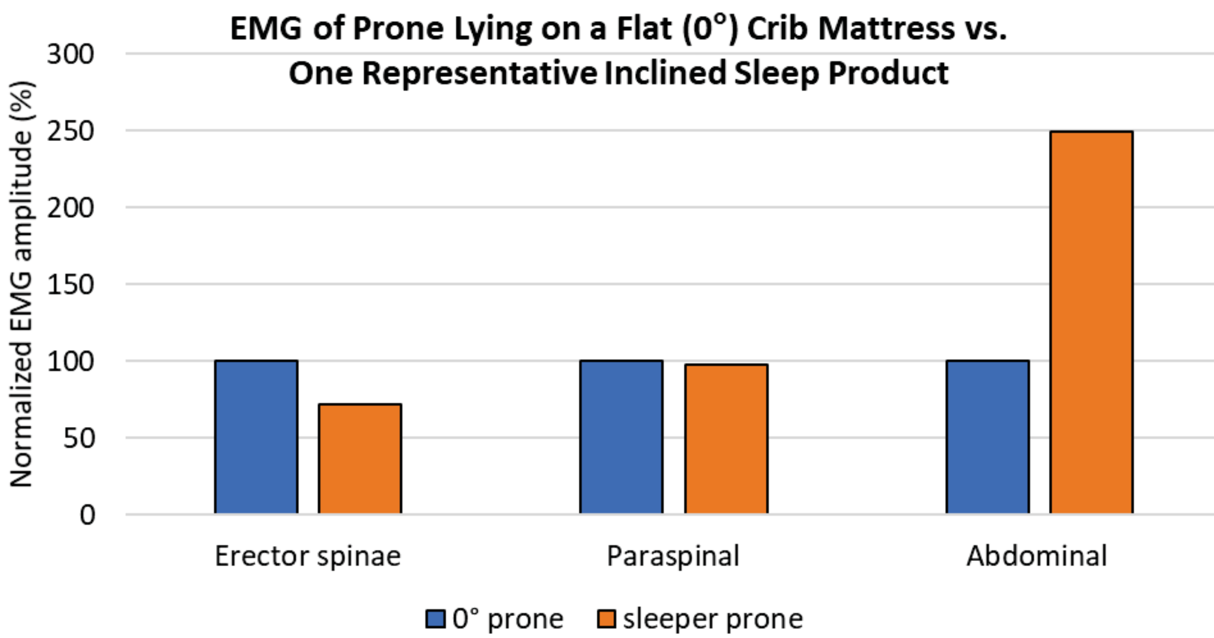


Figure 30: EMG activity (erector spinae, paraspinal, and abdominals) during flat (0º) crib mattress prone lying (blue) and with one representative inclined sleep product during prone lying (orange).

4.4.3 Space Required to Roll

Our dataset contained three full supine-prone rolls with visible marker data. All these rolls occurred on the flat crib mattress and were initiated by the fetal tuck (hip flexion) which drove trunk rotation after the lateral knee contacted the surface. Therefore, the excursion of the lateral knee marker was used to define the horizontal space of a roll. The mean space required to roll (at the knee) was 47.1 cm (range: 27.9 cm – 63.6 cm). However, the product analysis (Section 3.3) confirms that every inclined sleep product analyzed had a knee width less than 47.1 cm.

While in theory, a product narrower than the average space required for a roll on a flat surface should reduce or eliminate the ability of an infant to roll, as evidenced in the 33 incident reports of supine to prone rolls in Section 2, other factors are at play that allow infants to roll even though the width of many of the products appear to be prohibitive. Inclined sleep products have added factors of pliancy, concavity, and inclined surfaces, all of which may reduce the horizontal space required to achieve a supine to prone roll. In addition, every inclined sleep product is different, so space required to roll likely varies between products.

The infants who rolled on the flat surface had a mean knee-to-knee distance (infant's body size at knee) of 21.5 cm (range: 18.5 – 27.0 cm) while lying supine, prior to initiating the roll. Based on the mean space required to roll on the flat surface (47.1 cm), the distance from the outer knee to the side of a flat product should not exceed 12.8 cm if rolling is to be avoided.

If the goal is to avoid any supine to prone rolling in an inclined sleep product, the distance from the lateral aspect of the knee to the side of the product should be minimized when the infant is lying supine. However, due to the range of designs of inclined sleep products (conformity, pliancy, and incline angle) which likely all have an impact on space required to roll, it is difficult to state a width that will prevent rolling in this diverse product class.

4.4.4 Oxygen Saturation Results

The number of trials that each baby experienced a drop in oxygen saturation (SpO_2) <95% during the 60 second testing conditions were tallied. Nine of ten babies experienced at least one SpO_2 event during testing. No babies experienced problems in any supine-lying condition.

There were 18 total prone-lying trials that ended early due to SpO_2 readings of <95% (Table 7). Upon video analysis, in each instance where SpO_2 readings of <95% were found, the baby's face appeared to be in contact with the surface of the product, both on the crib mattress and in the inclined sleep products (Figure 31). Product S06 (deluxe version of Company B) resulted in four babies experiencing SpO_2 readings of <95%. S06 has no plastic molding, a plush thick pillow, and the largest incline angle at the head portion of the product. Product S13 (Company C) was the next highest with 3 babies experiencing SpO_2 readings of <95%. S13 has a rigid plastic molding that is split into two parts, making the product unstable if a force is applied to the surface. Products S01 and S02 (basic and deluxe versions from Company A) and S03 (basic version from Company B) each had 2 babies experience SpO_2 readings of <95%. One infant experienced SpO_2 readings of <95% in each of the other testing conditions (0°, 10°, 20° crib mattress; inclined sleep products S08 and S11). S08 features a low incline with low side heights and a uniform thick plush material. S11 is the widest of all products examined and has a thin plastic molding on the bottom surface.

Table 7. Number of events (SpO_2<95%) for prone lying on crib mattress and inclined sleep product conditions for each participant (CPSC 2 through CPSC 11).

	0°	10°	20°	S01	S02	S03	S06	S08	S11	S13
CPSC2	√	√		√		√				
CPSC 3				√			√	√		
CPSC 4					√					
CPSC 5					√	√	√			
CPSC 6							√			
CPSC 7										
CPSC 8							√			√
CPSC 9										
CPSC 10			√							√
CPSC 11									√	√
Total	1	1	1	2	2	2	4	1	1	3

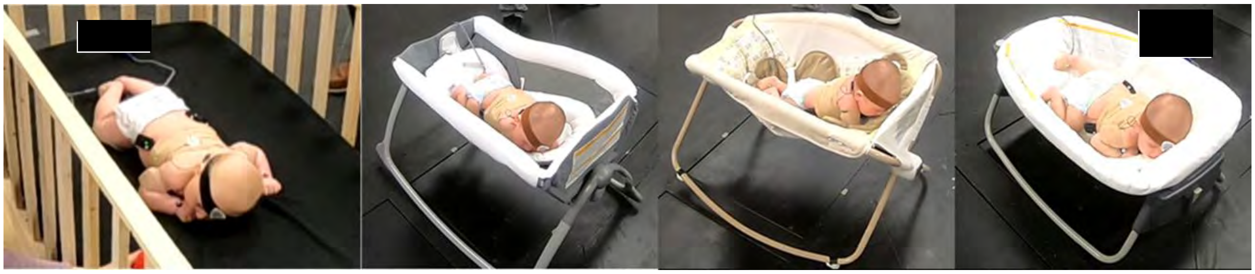


Figure 31: Examples of infants' faces in contact with crib mattress and inclined sleep product surfaces prior to low SpO_2 events from left to right: crib mattress, S13, S02, and S08.

When considering all crib conditions v. all inclined sleep product conditions, oxygen saturation concerns were found in 10% of crib mattress trials compared to 21% of inclined sleep product trials. In other words, **babies were more than twice as likely to experience SpO_2 readings of <95% while lying prone in an inclined sleep product compared to prone on a crib mattress.** The differences between a crib mattress and an inclined sleep product are vast and include more space to maneuver, no fabric materials on the sides of the product, little conformity with force application, and a flat product design featuring no concavity. These main differences likely contribute to fewer SpO_2 incidents in the crib mattress conditions compared to the inclined sleep product conditions.

Although no previous research has been done regarding the impact of inclined surfaces on breathing, these results agree with previous literature looking at prone compared to supine lying on a flat surface. Galland et al. (2000) compared the response of 3-month-old infants to asphyxia in the prone vs. supine position in quiet vs. active sleep. Three-month-old infants responded to asphyxia equally well in prone vs. supine position during quiet sleep. However, during active sleep (REM equivalent in infants), 3-month-old infants had a poorer (reduced) ventilatory sensitivity to asphyxia in the prone position compared to the supine position. This suggests that 3-month-old infants sleeping prone, in active sleep, would likely respond less to an asphyxia challenge compared to infants the same age in the supine position. This is particularly meaningful when considering that most of the incidents in the inclined sleep products occurred during naptime or overnight sleeping, when babies were less awake and possibly even experiencing active sleep.

It is critical to remember that the low oxygen saturation events in this study occurred within 60 seconds of being placed prone in each condition. Therefore, dangerous and fatal oxygen saturation levels could be reached in babies who roll from supine to prone in an inclined sleep product in a short amount of time.

Analyzing the results of this oxygen saturation portion of the study, in conjunction with the biomechanical analysis which showed differences in how muscles must work together to achieve a prone lying position with an increased demand on the core muscles in inclined sleep products, it is clear that **prone lying in a product in the class of Inclined Sleep Products evaluated in this study is a dangerous position that puts an infant's life at risk**, likely within only a few minutes after the roll occurs. These results also have implications for caregivers who may place infants to sleep prone within an inclined sleep product (as evidenced by three of the deaths from the incident analysis); prone positioning in an inclined sleep product, whether due to the infant rolling from supine to prone or due to the caregiver placing the infant prone in the product, is not safe for infants.

4.5 Study Limitations

This study is not without limitations. Infant biomechanics is grossly understudied compared to older children and adults. For that reason, established methodology for infant biomechanical studies is scarce. The project team has developed methods to analyze infant position and muscle activity by adapting widely accepted methodology for use in an infant population (Siddicky, 2019; Mannen, 2018). Specifically, the trunk-neck-head angular changes were analyzed to avoid the limitation of finding exact anatomical locations on which to place retroreflective markers. Exact placement of these markers is crucial to achieve high fidelity estimates of body segment kinematics, and the necessary landmarks are not always fully developed in infants. The method of using local coordinate systems on each body segment used in this study avoids the errors of lack of anatomical landmarks in babies and has been used in the spinal biomechanical analyses of children (Wilk et al., 2006).

Furthermore, there are inherent limitations in using surface electromyography (EMG) sensors on adults or children. While fine-wire EMG is more accurate, it is invasive and hence not feasible in a study on healthy infants. Surface EMG is used widely in older child and adult biomechanical studies, so similar methods and smaller EMG sensors were used to account for the infant population. One criticism of EMG technology is crosstalk between muscle groups. Since paired analyses were performed and were not specifically interested in one muscle but rather muscle groups, the results of this study accurately explain muscle use in various conditions. While other muscle groups may be important in achieving a roll, the experimental limitations did not allow for all muscles to be analyzed, and muscle groups were chosen based on preliminary data in the laboratory and knowledge of the field.

Oximetry technology is not without error. For this study, a medical grade handheld device commonly used in hospitals to detect oxygen saturation levels was used. Each event was examined to determine if the infant’s face was in contact with a surface or if the reading was possibly false. In all 18 events, the infant’s face was observed to be contacting a surface, giving confidence in the results.

Enrolling and testing enough participants for a biomechanical study can be challenging, particularly when considering the critical and expedited timeline for this study. The power analysis was based on EMG data from a previous study, and more subjects were tested than was suggested by the power analysis for achieving sufficient power to detect a significant difference in muscle activity between conditions. While the data showed several significant differences, especially between 0° and 20° crib mattress positions and between 0° crib mattress and inclined sleep products, a larger sample size may give more statistically significant evidence in other comparisons.

Though necessary for high-tech biomechanical testing, the laboratory environment is not the same as a home environment, but efforts were made to keep the temperature warm and the ambiance calm in the laboratory. Challenges of fussiness, crying, and sleeping were overcome by encouraging the caregiver to take an active role in the experiment. Data was included for analysis in this study if the baby was awake and not crying. Caregivers were given unlimited time to calm, feed, or change their infant’s diapers to help testing go as smoothly as possible and to replicate a home environment. Experimental constraints also limited the time of testing to 60 seconds per condition, which is less time that infants would spend in these products in a home environment. The fact that biomechanical changes and differences in oxygen saturation levels were seen in this short period of time shows that even short amounts of time in inclined sleep products impacts an infant’s ability to move and breathe.

Our testing was conducted on infants who were awake and not recently sleeping. This of course differs from the conditions reported to the CPSC where most infants were put into the inclined sleep products for a nap or for overnight sleep, so those infants were likely sleepier than the infants in the current study. An infant who is not wide awake may have less focus and energy to expend compared to the wide-awake infants in this study. So, while the muscle use and motion may be similar, it is likely that infants who find themselves in a compromised position in an inclined sleep product during a nap or overnight sleep may not have enough energy or alertness to achieve self-correction and may succumb to suffocation earlier or more easily than infants who are fully awake.

4.6 Summary of Biomechanical Analysis

An *in vivo* biomechanical study utilizing motion capture and EMG to evaluate the impact of an inclined crib mattress and inclined sleep products on an infant's ability to move and use their muscles to achieve movement was conducted.

Table 8 summarizes the main findings of the biomechanical study on incline angle of a crib mattress. During prone positioning, an increase in crib mattress incline angle resulted in a decrease in neck and back muscle activity and an increase in abdominal and triceps muscle activity, completely altering the normal muscle synergies that babies use to achieve a prone position when compared to the flat surface. Fewer changes were observed during supine positioning, with the most significant difference being an increase in head motion without the corresponding increase in muscle activity, indicating that the incline makes it easier for babies to lift and move their heads.

Table 8. Summary of EMG and Kinematic Results for Inclined Crib Mattress . Wide orange arrows indicate $p<0.05$ and narrow blue arrows indicate $p<0.10$.

During prone position			
Parameters	**0° vs. 10°**	**10° vs. 20°**	**0° vs. 20°**
Erector spinae	-	↓	↓
Cervical paraspinals	-	-	↓
Abdominals	↑	↑	↑
Triceps	-	-	↑
Neck ROM	-	-	-
Trunk ROM	-	-	-
# of neck peaks	-	↑ (narrow blue)	-
# of trunk peaks	-	-	-
During Supine position			
Erector spinae	-	↑	-
Cervical paraspinals	-	-	-
Abdominals	-	-	-
Neck ROM	-	-	↑
Trunk ROM	-	-	-
# of neck peaks	-	↑	↑
# of trunk peaks	-	-	-

Table 9 summarizes the main findings of the biomechanical study of the inclined sleep products. In general, babies moved their trunks more and more often while positioned prone in products with little or no hard plastic support surface. They also required more abdominal effort and less erector spinae effort to maintain a prone position. During supine lying, products with a hard or semi-rigid plastic support surface decreased trunk motion, and erector spinae muscle activity was significantly lower for products with heavy padding.

Table 9. Summary of EMG and kinematic parameters of each inclined sleep product when compared to 0° surface (baseline). Wide orange arrows indicate $p<0.05$ and narrow blue arrows indicate $p<0.10$.

During prone position							
Parameters	S01	S02	S03	S06	S08	S11	S13
Erector spinae	↓	⬇	⬇	-	⬇	↓	-
Cervical paraspinals	-	-	-	-	-	-	-
Abdominals	-	⬆	↑	⬆	⬆	-	-
Triceps	-	-	-	-	-	-	-
Neck ROM	-	-	⬆	-	-	-	-
Trunk ROM	-	-	⬆	⬆	⬆	-	-
# of neck peaks	-	-	-	↑	⬆	⬆	⬆
# of trunk peaks	-	-	⬆	⬆	⬆	⬆	↑
During supine position							
Erector spinae	-	↓	-	⬇	-	-	-
Cervical paraspinals	-	-	-	-	-	-	-
Abdominals	-	-	-	-	-	-	-
Neck ROM	-	-	-	-	-	-	-
Trunk ROM	⬇	↓	-	-	-	-	-
# of neck peaks	-	-	-	-	-	-	-
# of trunk peaks	-	↓	-	↓	-	⬇	⬇

The **key findings** of the biomechanics study are:

1. Inclined surfaces and inclined sleep products resulted in significantly higher muscle activity of the trunk core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant finds themselves prone in an inclined sleep product.

2. Muscle synergies (i.e how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine to prone in an inclined sleep product, it is likely the first time the baby has experienced the position of lying prone within an inclined sleep product and the demands the position requires of the muscles.

3. Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.

4. Prone lying in the inclined sleep product puts infants at higher risk of suffocation as evidenced by oxygen saturation results.

5. Some evidence was found that supports the idea that the inclined sleep products allow the babies to roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.

6. If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.

5. SUMMARY OF FINDINGS

5.1 Overall Results

The overall goal of this study was to inform the CPSC on whether the designs of Inclined Sleep Products impact an infant's ability to move within the products, and whether those designs directly impact safety or present a risk factor contributing to suffocation of an infant.

To meet this goal, the following studies were conducted:
1. An analysis of the incident reports related to Inclined Sleep Products to qualitatively assess trends, similarities, or differences in the incidents that may inform product safety.
2. A thorough product analysis of various Inclined Sleep Products within the product class to identify differences in design.
3. A non-invasive *in vivo* biomechanics study of infants 2-6 months of age to determine:
   (a) the strength and space requirements for infants to move their heads and/or roll from the supine to the prone position in Inclined Sleep Products compared to a Flat Sleep Product,
   (b) the strength and space requirements for infants to lift their heads and/or roll from the prone to the supine position in Inclined Sleep Products compared to a Flat Sleep Product.

Based on the results of the biomechanical testing, product analysis, and incident report analysis, **none of the Inclined Sleep Products that were tested and evaluated as a part of this study are safe for infant sleep.**

Ninety-one incidents (death, injury, hazard) were reported in inclined sleep products between 2010 and 2019. The majority of the incidents with adequate information supplied in the reports to analyze the events were supine-supine (53%) or supine-prone (35%) events. The supine-supine incidents occurred in younger infants (average 3.2 months), while supine-prone incidents occurred in older infants (average 4.2 months). Many supine-supine deaths occurred in infants who were currently sick, chronically ill, or born premature. Because these infants have higher mortality rates compared to healthy babies, for most incidents, it cannot be confirmed if the event was related to the condition or the product design. However, many reports indicate the infant was found with his/her face contacting the side of the inclined sleep product and that mucus or blood was found on the infant's face, suggesting suffocation was the cause of death. In combination with the product analysis which showed the sides were made of heavy padding or a combination of padding and plastic, it is likely that suffocation in the side of the product contributed to the deaths or injuries of these infants. Future work should consider the materials used on the product sides to reduce the risk of carbon dioxide rebreathing.

The current warning on inclined sleep products suggests that parents should stop using the product once the infant can roll, but the results of this study suggest that the first observed infant roll can occur in the product and can result in a fatal suffocation event evidenced by data within the incident reports. Further supporting that idea are results from the biomechanical analysis. During supine lying within an inclined sleep product, babies moved their trunks less and exhibited less erector spinae muscle activity, likely due to a combination of conformity of the products and the lack of rigidity as quantified in the product analysis. During supine lying, babies' trunks are more flexed solely due to the product design. Coupled with the lack of a rigid surface to move against in many of the inclined sleep products, babies are exposed to a much different environment than a crib mattress or even a crib mattress on a similar incline. The flexed trunk position in combination with flexed hips due to the design of the seat portion of the inclined sleep products puts babies closer to the fetal tuck position that is often used to achieve a supine to prone roll when compared to a flat or inclined crib mattress. This is further supported because the average age of infants who experienced supine-prone events analyzed in the incident reports was slightly less than the average age of rolling, suggesting that babies who died or were injured in inclined sleep products may have been able to roll more easily in the inclined sleep products than on a flat rigid surface. It is likely a combination of all of these factors that allow babies to roll supine to prone in inclined sleep products, despite the narrow width of the products that may otherwise prohibit rolling.

In the prone position within an inclined sleep product (whether from a roll from supine to prone or from being initially placed prone), infants are required to use their muscles differently and move their body in unusual and unfamiliar ways simply to maintain the prone posture and lift their heads to breathe. In particular, the demands of the core muscles are likely some of the highest that they have ever been exposed to, resulting in increased fatigue rates as the infant tries to self-correct. It is likely that in incidents where babies were found deceased in the prone position, that a roll occurred, and after some amount of struggling, the baby was fatigued and could no longer move into a position to prevent suffocation. This is further supported by the product analysis, which showed inclined sleep products have more deformation with force application compared to a crib mattress, resulting in a pliant surface that distributes force differently than a rigid surface. Therefore, when infants attempt to self-correct in inclined sleep products, their movements are less effective compared to a more rigid surface. Additionally, the oxygen saturation events from the biomechanics analysis indicated that infants in this study experienced <95% SpO_2 twice as often when lying prone in inclined sleep products compared to lying prone on a crib mattress. The combination of incline angle, rigidity of the surface, curvature of the surface, and material selection of a plastic surface with padding all contribute to an increased risk of suffocation if infants are positioned prone in an inclined sleep product. The unfamiliar movement requirements coupled with a product design that does not allow for the same force distribution of a flat crib mattress results in a situation in which infants may be unable to self-correct.

While there were differences in the product designs and the biomechanical results of infants within the products, no product that was examined in this study was found to be safe for infant sleep. **All products in the class of Inclined Sleep Products that were tested and evaluated in this study are unsafe for infants.** If this product class remains, ASTM F3118-17a should be rewritten and implemented as a mandatory standard to mitigate hazards posed by and prevent future incidents with Inclined Sleep Products.

5.2 Future Considerations

1. Future analysis should seek to understand if 15 degrees is a suitable angle for an inclined sleeping surface, or if movement and muscle activity are significantly different at this angle compared to a flat surface. The research team recommended testing 10 more infants in a biomechanical study at various inclined angles (0, 5, 10, 15, 20) to more specifically identify a safe incline angle for infant sleep.
2. CO_2 rebreathing, or breathability of the products, should be quantitatively assessed. The project team recommends utilizing the model by Maltese et al. (2019) (Figure 27) to understand how material selection and product design may impact CO_2 rebreathing, and the likelihood of suffocation. As noted in several of the supine-supine incidents, suffocation appeared to have occurred without significant movement within the product. This may be attributed partly to product design. In the same way that infants are not recommended to stay in a car seat for extended amounts of time, a breathability study may further quantify the time that is safe for babies to remain in an inclined sleep product.

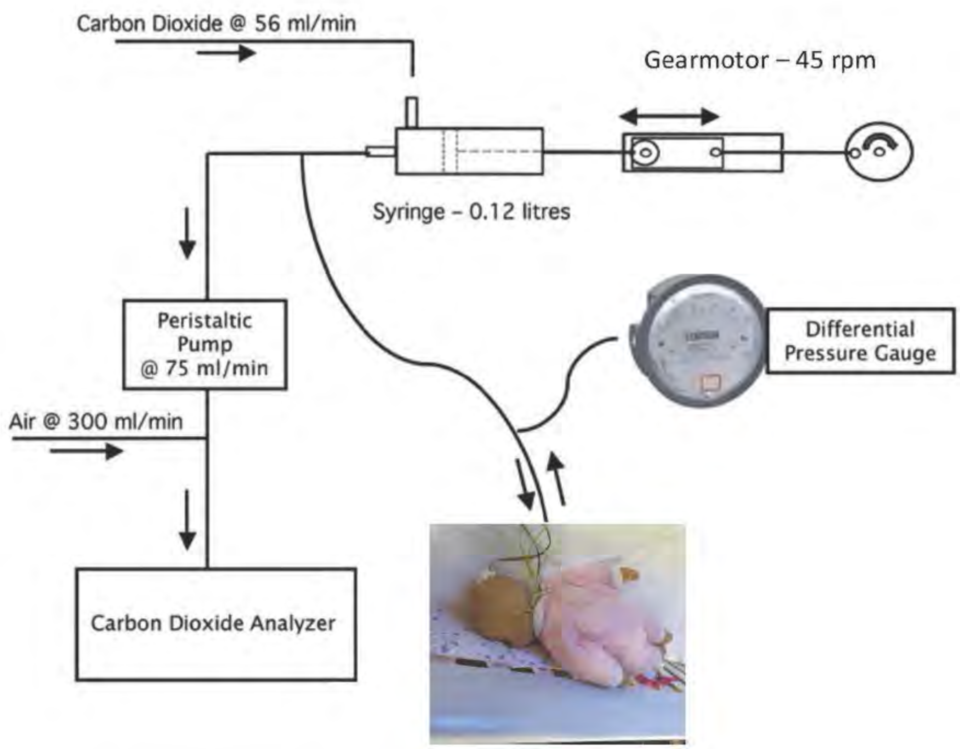


Figure 31. Infant CO_2 rebreathing setup used by Maltese and Leshner (Maltese et al., 2019)

3. A similar study should be conducted to evaluate the safety of seated products for infants by understanding how babies use their muscles to move within the confines of other common infant products.

6. ASTM RECOMMENDATIONS

With the findings of the biomechanical study, the product analysis, and the incident report analysis, the team reviewed, analyzed, and interpreted the safety and design of specific Inclined Sleep Products. The project team examined other Inclined Sleep Products per the CPSC's requests to determine whether the design specifications in ASTM F3118-17a are appropriate to prevent accidental deaths. **The team believes that no inclined sleep products that were examined as a part of this study are currently safe for infant sleep. The product category should be completely eliminated, or the ASTM standard significantly modified to ensure a safe environment and mitigate risk.**

When analyzing specific design considerations, particular attention was paid to the following: seatback incline angle, surface guidelines, minimum side barrier height and material, and maximum width. Specifically, the following are addressed: (a) the safety or hazard presented by a 30-degree incline, (b) the characteristics of Inclined Sleep Products that may diminish respiration and ways to minimize the hazard, and (c) recommendations to improve the ASTM standard to minimize injuries and deaths in Inclined Sleep Products.

6.1 Incline Angle

30-Degree Incline Does Not Allow for a Lying Posture

Based on the results of the biomechanical study, it was revealed that a 30-degree angle should not be considered a lying position for an infant. Infants could not maintain a lying posture at the 30-degree crib mattress incline and began to slide off the mattress. For this reason, 30-degrees is too steep of an incline for a lying or sleeping product.

20-Degree Incline Puts Infants at Risk for Muscle Fatigue

Based on the results of the biomechanical study, the 20-degree mattress incline resulted in significantly different muscle activity for the infants compared to the zero-degree incline surface. The increased demand on the abdominal muscles could lead to increased fatigue and suffocation if an infant is unable to reposition themselves after a roll from supine to prone occurs.

10-Degree Incline May Not Significantly Impact Infant Motion or Muscle Activity

Based on the results of the biomechanical study, fewer differences in muscle activity or lying posture were revealed at a 10-degree mattress incline compared to the zero-incline surface. 10 degrees is likely a safe incline for sleep on a crib mattress type of surface.

Inclines Between 10- and 20-Degrees Should Be More Thoroughly Studied

The experimental design of this study did not examine the angles between 10- and 20-degrees, so future work should focus on understanding which, if any, angles between 10- and 20-degrees may be safe for infant sleep.

> ***Recommendation:*** An incline angle of 10-degrees is likely safe for an infant Inclined Sleep Product, and an incline of 20-degrees or greater is not safe. In order to determine if angles between 10- and 20-degrees are safe, additional biomechanical testing is required.

6.2 Surface

Lying Surface Rigidity should be Standardized

The results of the biomechanical testing revealed that infants moved differently when lying prone in Inclined Sleep Products compared to an inclined crib mattress. This difference is likely due in part to the lack of surface rigidity of the Inclined Sleep Products. The product analysis revealed varying designs for the lying surface (hard plastic, malleable plastic, or no plastic with little to heavy padding). Regardless of the rigidity of the underlying plastic surface, the added padding of many of the Inclined Sleep Products resulted in a highly compliant surface, which could result in the inability of infants who have rolled to self-correct as they are unable to apply the force required to lift their head to breathe or perform a roll. It is also important to recognize that the biomechanical testing in this study was done with awake and alert infants; it is likely that infants who are recently aroused from a deep sleep may not have the same amount of effort to expend as fully awake infants, further decreasing the likelihood of self-correction if a roll occurs. For these reasons, specific recommendations for the surface rigidity of the Inclined Sleep Product need to be formulated. In the worst-case scenario, when infants are unable to self-correct after a roll and are lying prone on the product, the maximum allowable deformation of the Inclined Sleep Product surface should not exceed one-half of the infant's head radius. According to the WHO Child Growth Standard (WHO, 2006), a 5th percentile newborn's weight and head circumference are 2.6 kg and 32.2 cm respectively (male and female values averaged). Considering that an infant's head is 25% of the total body weight, the head weight of the 5th percentile newborn is 0.64 kg. From the head circumference measurement, one-half of the head radius of the 5th percentile newborn is 2.6 cm. The maximum allowable deformation on the Inclined Sleep Product surface should be 2.6 cm (1 inch) when a 0.64 kg (1.4 lb.) weight (i.e. a 6.25 N load) is placed on the surface. In order to obtain more robust parameters for the ASTM standard, future work on product surface deformation analyses are recommended.

Lying Surface Shape should be Flat

Product analysis of some of the Inclined Sleep Products revealed that the sleeping surface is either not flat or not flat with added weight. Concave curvature either in the back or the seat portion of the product increases the suffocation risk for babies who have experienced a roll, as the surface envelopes their face, increasing the risk for rebreathing and suffocation if self-correction is not achieved. Therefore, the surface of the Inclined Sleep Product should be flat with no curvature to the surface either with or without added doll weight. It would be beneficial to adapt a flatness test in the Inclined Sleep Products ASTM standard similar to the flatness test currently in the Bassinets and Cradles standard (F2194-16e1; Section 6.7).

Surface Material should be Standardized

The incident report analysis revealed that many of the infant deaths occurred in products with heavy plush padding on the surface of the products (S02 and S06). There were also differences in material of the sides of the products, varying from heavy plush to lightweight mesh. The surface of the Inclined Sleep Products should meet the standard used for Crib Mattresses (ASTM F2933-19). Therefore, recommendations for the surface material of the Inclined Sleep Products need to be formulated. In that regard, carbon dioxide rebreathing analyses are recommended to inform material recommendations for the sides of the Inclined Sleep Products. (Paluszynska et al., 2004; Carleton et al, 1998)

Surface Width should Prevent Supine to Prone Rolling

If all other recommendations regarding the surface are implemented, the concern of suffocation due to a roll from supine to prone will be significantly minimized. However, if the goal is for supine to prone rolling to be completely prevented, the product width should be minimized based on preliminary data from a flat crib mattress rolling.

Recommendation: The surface of the Inclined Sleep Product should have a minimum rigidity, should exhibit no curvature, and should meet material recommendations to minimize rebreathing. If roll prevention is still a concern, the maximum product width should minimize the distance from the lateral knee to the side of the product during supine lying.

6.3 Sides

Material and Height Minimum of the Sides should be Further Studied

Our study did not quantitatively evaluate safety of materials used for the sides of the Inclined Sleep Products. However, the products evaluated exhibited vastly different side materials. While a breathable side material is necessary, future work should focus specifically on carbon dioxide rebreathing of various materials or material combinations to quantify the level of breathability required for safety. This study also did not provide data to guide the heights of the sides of the product to avoid falling, so future work is required to define the minimum safe height.

Recommendation: Additional research should be done to understand the minimum height of the sides of the Inclined Sleep Product. Additional research is required to clearly define the threshold of carbon dioxide rebreathing to inform safe product design.

6.4 Warnings for Use

Caregivers of Infants Who are Sick, Chronically Ill, or were Born Prematurely Should Exercise Additional Caution when Using Inclined Sleep Products

The incident report analysis revealed that several of the supine-supine deaths occurred with infants who had chronic conditions, were experiencing sickness, or were born premature. Because these are risk factors for increased rates of infant mortality, it cannot be confirmed if the inclined sleep product contributed to the incidents for these vulnerable infants. One likely explanation for these incidents is that babies who already had a risk factor for increased mortality experienced suffocation in the sides of the products as many of their faces were found in contact or close contact with the product. A safe sleeping product may be even more important for infants who have previous risk factors for infant mortality. Additional research should be made into crafting and implementing warnings for inclined sleep products and other products regarding infants with sickness, chronic illness, or prematurity.

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Appendix A: STUDY TEAM

Principal Investigator:
Dr. Erin Mannen has a Ph.D. in mechanical engineering from the University of Kansas and specializes in biomechanics with over ten years of research experience in the field. As Principal Investigator, she was responsible for oversight of the entire project. Dr. Mannen led the design of the biomechanics experiment, oversaw data collections, managed data analysis, interpreted results, prepared reports, conducted meetings, ensured data quality, and managed all aspects of the project. Dr. Mannen has also served as Principal Investigator on similar projects studying biomechanics of infants in various infant products.

Co-Investigators:
Dr. John Carroll is a medical doctor specializing in pediatric pulmonology. He is a graduate of the University of Texas Southwestern Medical School, completed Pediatrics residency at the State University of New York, Upstate Medical Center, and completed Pediatric Pulmonology fellowship at the University of Arizona and McGill University. Dr. Carroll is board certified in Pediatrics and Pediatric Pulmonology and is currently an investigator on several NIH-supported projects. As a Clinical Co-Investigator, Dr. Carroll provided clinical guidance on experimental design and data interpretation, focusing on the respiratory aspects of the project. He provided analysis on the supine-supine incidents to help determine if external factors may have caused the events. Dr. Carroll has extensive experience in pediatric pulmonary clinical research.

Dr. David Bumpass is a board-certified orthopaedic surgeon specializing in pediatric spine. He is a graduate of the University of Virginia School of Medicine and completed his orthopaedic and spine surgery training at Washington University in St. Louis. He specializes in complex pediatric spinal deformity surgery. As a Clinical Co-Investigator, Dr. Bumpass provided clinical insight into experimental design and data interpretation, focusing on understanding an infant's ability to move based on typical motor development milestones. Dr. Bumpass's familiarity with biomechanics research allowed him to help interpret the results of the biomechanical studies from a clinical perspective.

Dr. Brien Rabenhorst is a board-certified pediatric orthopaedic surgeon specializing in pediatric hip development. He is a graduate of Louisiana State University School of Medicine. He completed an orthopaedic residency at Texas Tech Health Science Center, and a pediatric orthopaedic fellowship at the Children's Hospital of Colorado. As a Clinical Co-Investigator, Dr. Rabenhorst contributed to the experimental design and data interpretation, focusing on the strength and coordination required of infants to move from compromised positions. Dr. Rabenhorst's familiarity with biomechanics research allowed him to help interpret the results of the biomechanical studies from a clinical perspective.

Dr. Brandi Whitaker is a psychologist working extensively over the past seven in the areas of psychological assessment and treatment of infants and young children. She earned her Ph.D. in the Psychology from Washington State University and completed a Post-Doctoral Fellowship in Pediatric Psychology. As a Co-Investigator, Dr. Whitaker provided guidance on proper selection of a developmental measure for the subjects. She led the effort in analyzing and interpreting the developmental data and offered interpretation of the results from a developmental perspective.

Dr. Junsig Wang is a postdoctoral fellow specializing in infant biomechanics. He earned his Ph.D. in Kinesiology from Iowa State University where he specialized in biomechanical research involving human motion data collection and analysis and completed further training as a postdoctoral fellow in the Department of Orthopaedics at the University of Arizona. Dr. Wang carried out the experimental testing, data analysis, data processing, quality control, and report preparation.

Dr. Safeer Siddicky is a postdoctoral fellow specializing in infant biomechanics. He earned his Ph.D. in Engineering and Biomedical Informatics from the University of Missouri-Kansas City, where he specialized in biomechanical research involving human motion data collection and analysis. Dr. Siddicky provided technical support through IRB adherence, data collections, data processing, data analysis, and assisted with report preparation and data quality control.

Organizational Structure:
The multi-disciplinary project team consists of investigators with doctoral degrees in mechanical engineering and kinesiology specializing in biomechanics and psychology specializing in pediatrics, and medical doctors in the fields of pediatric pulmonology and pediatric orthopaedics. This team had the technical ability to carefully design and execute the work and interpreted the results from both an engineering and a medical viewpoint.

Dr. Mannen met with the CPSC regularly (every 2-4 weeks) to give updates on the progress of the project. The entire team met as needed throughout the project timeframe to meet goals and discuss outcomes.

Appendix B: FACILITIES AND EQUIPMENT

Laboratory: The HipKnee Arkansas motion laboratory at which testing will take place is equipped with state-of-the art validated experimental equipment costing over $250,000. Service contracts are in place to ensure all equipment is calibrated and functional.

Environment: UAMS is a research and teaching institution, fostering this collaborative team of engineers, researchers, and clinicians in a variety of specialties. As faculty, both research and clinical, we are encouraged and expected to participate in translational, meaningful projects. We are supported by a team of professionals in the UAMS Office of Research and Sponsored Programs to aid in the administrative requirements of a government contract.

IT: UAMS has a team of professionals to handle all technical issues that may arise relating to internet connectivity, computers, telephones, video-conferencing, email, and HIPAA-secured cloud storage space.

Office Space: The PI and Co-Investigators have their own computers and private offices. Members of the Project Support Team each has their own personal workspace and computer. There are private meeting rooms available to use as needed.

Appendix C: [redacted] [CONFIDENTIAL]

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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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Appendix D: Incident Report Summary

Data is summarized from all 91 incidents investigated by the CPSC related to inclined sleep products occurring from 2010 to May 2019. Data is separated into incident types: *supine-supine, supine-prone, supine-other, prone-prone, other circumstances,* and *not enough information.* The tables include:

- [redacted]
- Incident Date: date of the incident,
- Age (months): age of the infant at the time of the incident,
- Death/Injury/Hazard: type of incident,
- Restraint Use (Y/N/UNK): indicates if the buckle was used in the product prior to the incident [Y=yes; N=no; UNK=unknown],
- Healthy/Sick/Chronic/UNK: indicates if the state of health of the infant at the time of the incident [healthy, sick (includes colds, fevers, respiratory congestion), chronic (includes serious health issues such as sickle cell), UNK=unknown],
- Premature <37 weeks (Y/N/UNK): indicates if the infant was born prematurely (<37 weeks gestational age) [Y=yes; N=no; UNK=unknown].

Table D1: Supine-Supine Incidents (2011 to 2018)

[redacted]	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/Chronic/UNK	Premature <37 weeks (Y/N/UNK)
	09/23/11	3.3	Death	N	Sick	Y
	10/01/11	2.0	Injury	UNK	UNK	UNK
	01/21/13	1.0	Injury	UNK	UNK	UNK
	10/19/13	2.5	Death	UNK	Sick	N
	10/14/14	4.0	Hazard	Y	UNK	UNK
	11/07/14	3.3	Death	N	Healthy	Y
	12/23/14	2.1	Death	Y	Healthy	UNK
	04/13/15	1.1	Death	UNK	Sick	N
	05/16/15	1.5	Death	Y	Healthy	N
	05/25/15	0.2	Injury	UNK	UNK	UNK
	09/23/15	4.2	Death	N	Sick	UNK
	09/24/15	3.7	Death	UNK	Healthy	UNK
	09/26/15	8.7	Death	UNK	UNK	UNK
	10/27/15	2.6	Death	N	Healthy	UNK
	04/21/16	0.2	Death	Y	Healthy	UNK
	09/09/16	4.0	Death	N	Sick	N
	09/11/16	2.3	Injury	Y	UNK	UNK
	12/08/16	5.0	Death	UNK	Sick	UNK
	01/05/17	4.8	Death	UNK	Sick	UNK
	05/05/17	0.5	Death	UNK	Sick	N
	06/11/17	10.1	Death	N	Chronic	UNK
	07/31/17	3.3	Death	Y	Chronic	N
	08/01/17	3.4	Death	UNK	Healthy	Y
	09/15/17	1.2	Death	UNK	Sick	UNK
	12/23/17	2.8	Death	UNK	Healthy	UNK
	01/12/18	6.1	Death	N	Healthy	UNK
	03/10/18	4.5	Death	Y	Healthy	N
	03/14/18	3.1	Death	UNK	Healthy	Y
	03/21/18	1.7	Death	N	Healthy	N
	04/01/18	0.3	Death	N	Healthy	N
	04/24/18	5.1	Death	N	Chronic	UNK
	07/08/18	5.1	Death	UNK	Healthy	N
	08/15/18	1.3	Death	UNK	Healthy	UNK
	09/21/18	3.0	Death	UNK	Chronic	N
	10/20/18	4.3	Death	Y	Healthy	N
	11/15/18	1.3	Death	UNK	Sick	Y
	12/04/18	2.7	Death	N	Healthy	N
	03/01/19	7.0	Death	N	Healthy	Y

Table D2: Supine-Prone Incidents (2010 to 2019)

	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/ Chronic/UNK	Premature <37 weeks (Y/N/UNK)
[redacted]	11/08/10	3.2	Death	UNK	Healthy	UNK
	06/03/13	2.8	Death	N	Healthy	N
	06/19/14	8.7	Death	UNK	UNK	N
	07/25/14	1.6	Injury	N	Healthy	UNK
	02/22/15	6.8	Death	UNK	Sick	Y
	08/10/15	4.0	Death	UNK	Healthy	UNK
	09/23/15	3.0	Death	N	Healthy	N
	12/14/15	3.0	Death	UNK	Healthy	UNK
	07/16/16	3.3	Death	UNK	Healthy	UNK
	09/16/16	3.0	Death	N	Healthy	N
	11/26/16	4.0	Injury	UNK	UNK	UNK
	12/04/16	1.0	Injury	Y	Healthy	UNK
	04/17/17	2.9	Death	UNK	UNK	UNK
	06/12/17	1.9	Death	UNK	Healthy	N
	06/15/17	5.3	Death	N	Healthy	UNK
	07/17/17	4.0	Injury	Y	UNK	UNK
	09/03/17	4.8	Death	N	Healthy	UNK
	12/22/17	5.4	Death	Y	Healthy	N
	01/06/18	6.0	Death	UNK	Sick	UNK
	01/11/18	4.1	Death	N	Healthy	N
	04/10/18	4.8	Death	N	Healthy	N
	04/25/18	5.9	Death	N	Healthy	UNK
	12/13/18	6.9	Death	N	Sick	N
	03/26/19	3.0	Death	UNK	Sick	UNK
	05/02/19	5.4	Death	UNK	UNK	N

Table D3: Supine-Other Incidents (2011 to 2013)

	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/C hronic/UNK	Premature <37 weeks (Y/N/UNK)
[redacted]	09/04/11	5.0	Hazard	Y	UNK	UNK
	09/08/12	5.0	Injury	Y	UNK	UNK
	04/19/13	12.0	Hazard	Y	UNK	UNK
	06/17/13	6.0	Injury	UNK	UNK	UNK

Table D4: Prone-Prone Incidents (2013 to 2017)

	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/C hronic/UNK	Premature <37 weeks (Y/N/UNK)
[redacted]	02/27/13	2.0	Death	N	Healthy	N
	04/17/17	4.5	Death	UNK	Chronic	Y
	07/03/17	0.3	Death	N	Sick	N

Table D5: Other Circumstances (2016 to 2018)

	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/C hronic/UNK	Premature <37 weeks (Y/N/UNK)
[redacted]	08/26/16	2.2	Death	UNK	Healthy	UNK
	03/16/18	3.0	Injury	Y	Healthy	N

Table D6: Not Enough Information (2014 to 2019)

[redacted]	Incident Date	Age (months)	Death/Injury /Hazard	Restraint Use (Y/N/UNK)	Healthy/Sick/Chronic/UNK	Premature <37 weeks (Y/N/UNK)
	12/01/14	1.6	Injury	N	Healthy	UNK
	12/16/14	7.6	Death	UNK	Healthy	UNK
	01/25/15	4.2	Death	UNK	UNK	UNK
	04/18/15	4.0	Injury	UNK	UNK	UNK
	08/31/16	UNK	Death	UNK	UNK	UNK
	10/17/16	1.0	Injury	UNK	UNK	UNK
	11/19/16	1.7	Death	UNK	UNK	UNK
	02/27/18	3.0	Death	UNK	UNK	UNK
	04/18/18	UNK	Death	UNK	UNK	UNK
	07/08/18	5.0	Death	UNK	UNK	UNK
	09/28/18	2.8	Death	UNK	UNK	UNK
	10/27/18	4.4	Death	UNK	UNK	UNK
	01/02/19	2.3	Death	UNK	UNK	UNK
	02/10/19	3.2	Death	UNK	UNK	UNK
	02/20/19	3.1	Death	UNK	UNK	UNK
	03/02/19	3.4	Death	UNK	UNK	UNK
	03/21/19	1.2	Death	Y	Healthy	UNK
	04/09/19	2.9	Death	UNK	UNK	UNK
	05/13/19	UNK	Death	UNK	UNK	UNK