QUANTIFYING HAND TORQUE FOR APPLICATION IN CHILD RESISTANT AND SENIOR FRIENDLY PACKAGING

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ABSTRACT

Child resistant packaging (CRP) is intended to restrict access of children aged 5 years or younger, but must not be too difficult for older adults to open. Over 70% of older adults use some form of medication, most of which are stored in CRP. The majority of commonly used child resistant packages require the user to grasp specific parts of the package or apply a specific amount of torque. Older adults, many of whom suffer from osteoarthritis of the upper limbs or other conditions, struggle to perform the fine motor skills required to open CRP. As a result, many adults choose to remove their medications from the CRP and place them in containers with fewer or no safety features. Medications are commonly stored in easy to reach locations, such as countertops or unlocked cabinets or purses, leaving children at a high risk of contact. Thus, there is a need for CRP that restricts children's abilities, but mitigates the struggles of adults. The goals of this work were to develop a testing system capable of accurately measuring an individual's torque generation on a cylindrical closure (similar to that of a standard bottle cap), determine the range of torque both older adults and young children could apply to a standard bottle cap, and evaluate the effectiveness of a newly designed CRP to reduce the torque generation of children. The new CRP design functioned by reducing the amount of functional surface area (FSA) the user had to grasp and open a continuous thread closure. A custom hand-held measuring system was created and used to obtain torque data from 24 adults (65 years or older) and 25 children (between four and six years old). Three variations in FSA (20%, 50%, 80%) and a control closure were tested. It was found that the adults applied significantly more torque than the children did for all tested closures. Based on published ranges of required torque for cap opening, the older adults were able to apply at least the minimum torque required to open all FSA variations, whereas the children were only able to open the control and marginally the 80% cap. Additionally, the largest differences in mean torque generation existed between the two groups for the 50% and 80% FSA variations. The new CRP design evaluated in this work was effective at restricting the access of children between four and six years old, while allowing older adults access to the package's contents. Optimization between 50% and 80% FSA would be ideal to create a truly child resistant and senior friendly CRP.

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INTRODUCTION

Children are curious and often intrigued by the things that the adults in their lives handle. This curiosity can lead to a child playing with packages that contain products that are toxic. Today, packages used to store many household substances, including medications, cosmetics, cleaning chemicals, fuels and other hazardous substances, are required to have closures that restrict the access of young children [1]. Nearly 70% of adults between the ages of 40- and 79-years old use at least one prescription medication, and one in five of those adults have five or more prescription medications [2]. Over-the-counter (OTC) medications are commonly used by adults of all ages, nearly 80% of all adults [3]. Almost all prescription medications and many OTC medications are required to be in child resistant packaging (CRP). Some of the most common re-closable packages used to store solid dose forms of medications are cylindrical bottles with various types of child resistant closures. While these packages are effective at restricting the access of young children, they often pose a challenge for older adults [4]. A closure system that restricts children and mitigates the struggle faced by older adults is therefore needed. The focus of this work was to develop a method and test the efficacy of a novel child resistant closure at restricting the access of young children *while* allowing older adults to easily access their medications.

CHAPTER 1: LITERATURE REVIEW

1.1 A brief history of the politics behind protective packaging

Poisons have been present in societies for hundreds of years, and despite a common understanding of the danger they present when used improperly or criminally, no laws or regulations were put in place until the 19th century. In the United States, the first law regulating the sale and packaging of dangerous substances was not passed until 1829. It required substances “usually denoted as poisonous” to be sold in irregularly shaped bottles and clearly labeled with the word poison in large text [5]. These substances included morphine and arsenic, which were commonly used for medicinal purposes, and others that were solely used as traditional poisons, such as prussic acid [5]. Further laws were put in place over the next several decades to enforce the licensure of pharmacists and apothecary shops in an attempt to regulate the sale of potentially dangerous substances. By the turn of the century, drugs were not the only dangerous substances found in the home. A new variety of cleaning products which contained chemicals that when ingested or mishandled resulted in serious injury or death had become commonplace. Over the next few decades, reports of childhood exposures or deaths due to accidental ingestion of these substances began to rise [6]. In 1927 the first piece of legislation intended to regulate the packaging of such substances was signed into law by President Calvin Coolidge. This act required a warning to be written in large text on top of a background of a plain, contrasting color. Over the next decade very little changed, childhood illnesses and other causes of death began to decrease, but deaths and injuries due to exposure to harmful substances remained the same.

In practice, pediatricians noticed that despite the advances made in medical care for common childhood illnesses, many children still presented with injuries or illness caused by exposure to harmful substances. Collectively, physicians began to advocate for stricter guidelines to be put in place regarding packaging and warning labels. They found that this danger was not limited to just the contents of cleaning supplies and other household chemicals, but also to OTC and prescription medications. In 1953, a survey of nearly 3,000 American Academy of Pediatrics members found that 49% of pediatric hospitalized cases were related to accidental poisonings [6]; furthermore, nearly half of all reported childhood exposures involved the ingestion of a harmful amount of medication [7], [8]. A study was conducted to compare the rate of accidental poisonings in the United States and Britain. It found that in the U.S., between 1949 and 1950, over one third of deaths in children under the age of four resulted from the accidental ingestion of a harmful amount of medication [9]. This same study reported that overdoses of aspirin, barbiturates, kerosene, lye, lead, and arsenic accounted for **two thirds** of all accidental poisoning deaths in children under five years old [9]. The results of these studies prompted the creation of the first poison control center in Chicago, Illinois. By 1960 there were over 300 centers across the country [6], [8], [10].

Urging from the American Academy of Pediatrics and the Food and Drug Administration pushed Congress to adopt stricter legislation. The Federal Hazardous Substances Labeling Act (FHSLA) was passed in July of 1960, requiring stricter labeling of household products that were deemed hazardous and contained toxic ingredients [11]. This law officially defined a hazardous substance as any substance or mixture that is “toxic, is corrosive, is an irritant, is a strong sensitizer, is flammable or combustible” and can cause harm or illness when handled in a typical or reasonable way [12]. It requires substances to be clearly labeled with explicit text that clearly states the name of the manufacturer, packer, distributor, or seller. Additionally, the common name of the hazardous substance and words such as “WARNING” or “CAUTION” must be present on the package and easy for the consumer to see. Despite this, many manufactures successfully ignored it and were able to avoid following all requirements of the FHSLA [13].

In October of 1976 the Toxic Substances Control Act (TSCA) was signed into law [14]. This act allowed the Environmental Protection Agency to identify and report dangerous chemicals currently in U.S. commerce. The information included in the reports advised the public on the production, use and any possible adverse effects of many chemicals. The chemicals included in the TSCA inventory were organics, inorganics, polymers, and other "chemical substances of unknown or variable composition" [15].

In 1961 a National Poison Prevention Week was signed into law by President John F. Kennedy. This educational program was in the third week of March and intended “to aid in bringing to the American people the dangers of accidental poisoning” (Public Law 87-319). Over the next several years almost every state adopted some form of a poison prevention activity.

Despite these efforts, simply educating the public did not significantly reduce the number of accidental poisonings in young children. Manufacturers, advocates, and governments began to explore other options, including the design of functional packaging capable of restricting the access of children to harmful products. Preliminary studies were completed during this time to determine the feasibility of protective packaging for medications and other harmful household substances [16], [17]. One such study was conducted in 1966 to explore the capabilities of child resistant packaging; it found that CRP reduced the number of accidental poisonings by 75% [18].

Based on studies such as the ones mentioned above, Congress signed into law the Poison Prevention Packaging Act (PPPA) in 1970. This act required many medications and hazardous substances to be stored in "special packaging". Special packaging are containers that are "designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time" [1]. Poisoning deaths in children under five years of age declined by 50% in the years after the enactment of the PPPA [19]–[21].

The United States Consumer Product Safety Commission (CPSC) was established in 1972 as an independent federal agency to regulate the manufacturing, distribution, and sale of consumer products [22]. Under the PPPA the CPSC was given authority to ensure the safety of products requiring CRP. Specifically, the CPSC has authority over the *packaging* of drugs, but it does not have authority over the actual contents [23]. The Food and Drug Agency (FDA) regulates the safety and effectiveness of all drugs prior to their release to the public, including the labeling of such products. It was in this area where the two agencies overlapped and had to divide their authorities, and to do this a Memorandum of Understanding was established in 1976 [24]. The jurisdiction of the FDA and CPSC was divided by how the product came in contact with a container and if 'migration' of a substance from the surface to the contents was possible. Even today the division between the two agencies is not firm and there are several instances when the jurisdictions of the two still overlap. For this reason, the regulation of drugs and their packaging remains a complicated challenge.

1.2 Recent Exposure Statistics

Emergency departments and poison control centers serve as the main resources for swift treatment of exposures and injuries [25], [26]. Caregivers or the injured seek immediate help when an accident occurs, and these locations can provide critical care in person or lifesaving instructions over the phone. The number of exposures is reported by these entities and can be used to gain a better understanding of the exposure rates, exposure products, and who is most at risk.

Today there are 55 poison control centers across the United States [27]. The National Poison Data System (NPDS) stores all de-identified data submitted by these centers. Poison control centers record and categorize the poison exposures by product. As of 2022, the five most common substances involved in exposures of children under five were household cleaning substances (10.3%), analgesics (pain medications) (9.54%), cosmetics/personal care products (9.49%), dietary supplements/herbals (6.65%), and foreign bodies/toys (6.61%) [28]. More than 77 million cases have been uploaded to the database so far and new cases are uploaded approximately every 4.72 minutes [28]. In 2020 over 2 million human poison exposure cases were reported to all poison control centers, and children under five years of age accounted for 41.7% of those exposures [29], see Figure 1.

With over 4,000 emergency departments across the United States, they serve as another valuable source for treating and reporting poison exposures. The Consumer Product Safety Commission operates an injury tracking system in partnership with hospitals across the country called the National Electronic Injury Surveillance System [10]. It collects data on consumer product-related injuries to monitor the safety of on the market products, including packaging. In 2022 almost 50,000 injures due to drug poisonings in children under five years old were treated in emergency departments [30]. Fifty percent of poison exposure calls involved the ingestion of OTC or prescription medications [31]. In children under six years, nearly 10,000 emergency department admissions due to unsupervised medication ingestion were reported from 2007 through 2011, and 75.4% of those cases involved children between the ages of one- and two-years old [31].

Despite the enactment of the PPPA and increased awareness of the danger medications and household chemicals pose to young children, staggering numbers of children are still at risk [32]. During an 8-month period, approximately 7,000 calls to poison control centers involving exposure of children aged five and under to solid dose medications, including both prescription and OTC medications, were made. Approximately 4,200 individuals, who called into a poison control center, agreed to take part in a study to examine where and how the child accessed the medication [33]. The findings revealed that the distribution between medication types was equally divided and 70% of the time the medication was intended for use by an adult. Over 30% of the time for all medications and more than 50% of the time for prescription medications in particular, the child accessed the medication *after it had been removed from the original child protective package* [33]. Reasons for the transfer of medication in this study included to remember to take, for easier travel and other unspecified reasons [33]. Among the most common reasons older adults transfer medications to easy to access containers is the difficulty to open CRP. This results in children being at a similar level of risk prior to the enactment of the PPPA over 50 years ago.

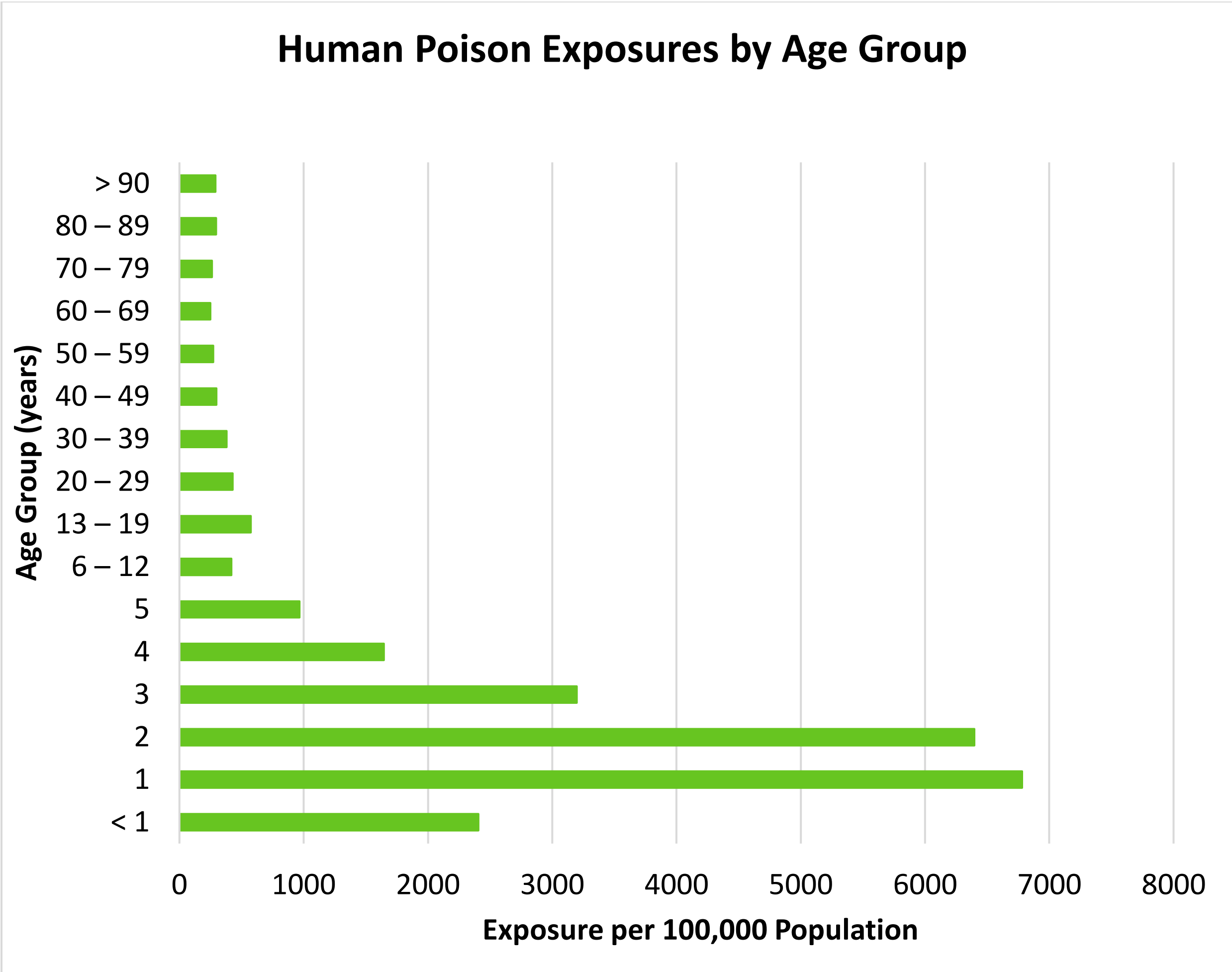

Figure 1. Human poison exposures by age groups (under one year old to over 90 years old) adjusted per 100,000 population in 2020 [29].

1.3 Packaging

1.3.1 Child Resistant Packaging

Child resistant packages must follow all requirements set by the PPPA in design and function. According to Subchapter E of the PPPA, a CRP is determined to be effective if 85% of 200 children under the age of five could not open the container within five minutes, and after the 5-minute mark 80% of the 200 children should still not be able to access the contents (16 CFR Part 1700) [34]. In 1996 the guidelines were adjusted, now stating that within 10 minutes, not more than 20% of children under the age of five should be able to open a CRP after watching a demonstration of how to open the package by an adult. Of the adults tested 90% should be able to open the same package within 10 minutes of their first try. This change was made due to the large number of older adults who struggled to gain access to their medications [35].

Over 32 different substances are required to be in special packaging. These include substances such as aspirin (including medications containing aspirin), controlled drugs, prescription drugs, iron containing drugs, ibuprofen, acetaminophen, dietary supplements containing iron, mouth wash, sodium and/or potassium hydroxide, and turpentine [1]. There are some exceptions within the PPPA for certain forms of the aforementioned drugs, including powdered unflavored aspirin, effervescent aspirin, powered iron preparations, effervescent acetaminophen and others in specific dosages and preparations. There are two additional exceptions to the PPPA. First, OTC or household substances intended for use by the elderly or persons with disabilities who may have difficulty opening CRP can be sold in single size packages that are clearly labeled with a warning that states: “this package is for homes without young children”. The second exception allows a person, or the prescribing physician, to request a prescription medication from the pharmacist in non-CRP [36].

1.3.2 Commonly used CRP

There are 13 official types of CRP recognized by the CPSC and published by the American Society for Testing and Materials. Six of these are categorized as re-closable packages, three as non-re-closable, two are labeled as dispensers and the remaining kinds are boxes or trays and aerosol containers. Re-closable packaging refers to closures that have built-in mechanisms to store the contents in the original container. Strip and blister packages are non-re-closable. These packages require pinching force of the thumb and forefinger to force medication out of the package. Blister packages' effectiveness as CRP is debated [37], [38]. Hender & Balit investigated over 300 accidental exposures to solid dose medications and found that nearly 60% of the exposures to medications were in blister packs. While another study found that the usage of blister packs significantly reduced the instance of iron poisoning in children under six years old [39].

Re-closable package closures include continuous thread-on closures, lug-style closures, snap-fit closures, and press-on closures [40]–[42]. The focus of this work is on re-closable packages with continuous thread closures. The two most common types of re-closable child resistant packaging systems are the ‘push and turn’ and the ‘squeeze and turn’ packages [43]. They utilize a continuous-thread closure to open or close the bottle. The push and turn requires the user to first apply a compression force to the top of the cap and a simultaneous twisting force. The squeeze and turn requires a pinch/grip force on the cap and a simultaneous twisting force. Both mechanisms require the user to apply two different kinds of force simultaneously (Figure 2). This can pose a challenge for older adults.

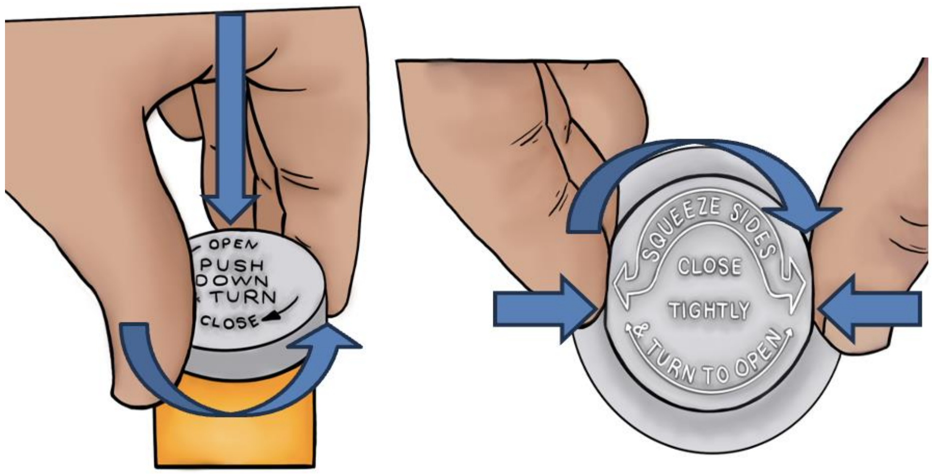

Figure 2. Common CRPs and the forces required to open them. The push and turn closure (left) requires simultaneous compression and twisting forces. The squeeze-and-turn closure requires simultaneous pinch and twisting forces (right).

1.3.3 Removal torque

Continuous thread closures can be opened by a simple twisting force, or a torque. Specifically, application and removal torque are measurements, typically recorded in Newton meters (N-m) or inch-pounds (in-lbs), of the torque required to open or close a threaded closure [44]. Data indicates that after package handling and time, the removal torque 24 hours after application is 40% to 60% of applied force [45]. For a plastic bottle with a 38mm neck, the application toque ranges from 1.92-2.93 N-m (17-26 in-lbs) and the corresponding range of removal torque is 0.79-1.81 N-m (7-16 in-lbs) [45]–[47].

1.3.4 Accessibility of CRP

Osteoarthritis (OA) is a common joint disease that frequently affects one or more joints in the hand and wrist [48], [49]. It is present in 80% of adults over the age of 55 [50]. Further, 13% of men and 26% of women over the age of 70 have symptomatic OA of a hand or wrist joint [51]. Symptoms include pain, stiffness, inflammation and deformities of the hand and wrist joints. Fine motor skills and dexterity when manipulating small items can be reduced, which impacts an individual’s ability to complete activities of daily living [52]. Specifically, pinch strength and thumb mobility can be decreased which affect the ability to open medication package closures [53]–[55]. Many CRPs rely on the ability of the user to apply a significant amount of both a grip and torque force. For older adults with reduced strength due to OA or other hand impairments, this can pose a real challenge.

CRPs, occasionally referred to as tamper resistant packaging, can not only limit the access of children under the age of five, but can also impede the access of the elderly. Testing procedures do not adequately test if a package is accessible for older adults or those with mobility, mental and/or sensory disorders [56]–[58]. The current guidelines require the older adults tested to be between the ages of 50 and 70 years old and “should have no obvious or overt physical or mental disability” [34]. By excluding adults over the age of 70, these testing procedures fail to test a large and growing portion of the world’s population. In the United States, the life expectancy of adults in 2021 was between 73 and 79 years old (for males and females respectfully) and by 2050, it is expected to rise to an average age of 85.6 years old [59], [60]. As the country's population ages, it is important that the procedures used to evaluate new CRP designs include a wide range of participants above the age of 65 years old as well as children under five [61]. Studies have indicated that adults over 60 have difficulties opening CRP and may transfer medications to other containers or even leave them open entirely to avoid the daily struggle [4], [57], [62]–[64].

One study asked grandparents between the ages of 50 and 80 about how they store their medication. This poll found that 29% of the adults surveyed admitted to transferring their prescription medications to other types of containers [65]. Additionally, 80% of those polled said that they don’t change where they keep their medication when grandchildren come to visit their house (usual places of storage found in this poll included in a cabinet (61%), on a table or countertop (18%), in a purse or bag (7%) or other locations (15%)) [65]. It is important that new child resistant packages are developed to accommodate older adults and help reduce the need to transfer medications.

1.4 Hand-package interactions

To open or close a continuous thread closure, such as the CRP types described previously, consumers must be able to apply multiple, and sometimes contrasting, forces. The user must tightly grip the cap and also apply the required application or removal torque of the package. There are six measurements of strength used to summarize the ability of adults to open packages, these include finger push strength, pinch-pull strength, hand grip strength, wrist twisting strength, opening strength, and push and pull strength [66], [67]. The two key measurements used in evaluating one's ability to open a continuous thread closure are hand grip strength and wrist twisting strength, or torque generation. The torque exerted on a cylindrical handle or package is reliant on the strength of grip, the coefficient of limiting friction between the hand and a cylindrical object and the diameter of that object [68].

The human grip force is dependent on the force applied by the fingers and the palm of the hand. The strength of a grip was defined by Pheasent and O'Neil (1975) as the sum of the components of those forces and normal to the surface of a cylindrical handle. This definition is still the standard used to calculate grip strength today. Individual finger strength contributes to the overall strength of the grip; the pointer and middle fingers make up a combined 60% of all the fingers' contribution to grip strength [69]. Grip force has been evaluated by researchers using a variety of existing devices such as strain gauges, grip dynamometers, and pinch gauges [70], [71]. The grip measurements obtained with these devices cannot be applied to situations involving cylindrical packaging because the geometry of the devices and the orientation of the grip is not similar to all real-world applications. Studies have found that the geometry of the test device is directly related to the strength measurement [66], [72]. Thus, the measurement devices used to evaluate torque generation for closure packages needs to resemble the package as closely as possible.

1.5 User interaction studies involving adults

There is handful of studies that have evaluated the ability of older adults to generate torque. The literature reported the range of torque application produced by older adults, aged 60 and older, on caps 20 mm to 50 mm diameter ranged from 1.64 to 2.43 N-m [72]–[76]. Another study included a wider adult age group, different cap geometries and larger cap sizes [72]. It found that as cap diameter height increased, so did the torque.

1.6 The gap in user interaction studies involving children

Child resistant packaging is intended to reduce access of children under the age of five; therefore, studies on human grip and torque generation must include participants under the age of five or they are not applicable to CRP. Many studies have focused on the upper extremity strength of children aged over five years old [77]–[82], or were focused solely on grip strength and wrist flexion in fixed postures [83], [84].

Much of the research done to evaluate upper extremity strength in children cannot be linked to torque generation for cylindrical package opening or closing. Reference values for hand-held dynamometry and isometric muscle torque generation of the upper and lower extremities have been evaluated. Decostre *et al*. collected wrist flexion and extension values when the subject's forearm was horizontal to the ground and fixed in place [83]. The results of this study cannot be applied to medication package opening because the posture used did not accurately simulate how a child would naturally attempt to open a closure, nor did it allow a child to use the full strength of their arm. Häger-Ross & Rösblad utilized a grip dynometer to gather grip strength data in children 4-16 years old [84]. Grip strength is only one component used to estimate a person's ability to open a package and cannot be used alone to judge a child's ability to open CRP.

The results of studies such as these can be used to inform child resistant package designs but are not useful in evaluating the real-world capabilities of children opening cylindrical closure systems. When trying to access the contents of a medicine bottle or cylindrical closures, children do not typically sit still or use only the hand and wrist to generate torque. Reference values taken from fixed postures or using a tool that isolates the forces of the hand, do not accurately reflect how much force a determined child could apply when trying to open something they don't typically have access to.

Two studies focused on torque generated by the hand and wrist and included children under the age of five. Rohles et al collected torque data on 400 children (200 boys and 200 girls) aged four to five years old. They tested closures with a variety of diameters, the largest being 123 mm and the smallest 27 mm. Cap diameter was found to play a significant role in torque generation. The results of this study found the mean torque on a 40 mm cap of males to be 0.99 and for females to be 0.91 N-m [85]. The testing apparatus in this study did not resemble a medicine bottle and could not be picked up while a torque was applied. This limits the results of the study because the participants could not hold it in their hands or interact with the package as they would at home. The work done by Bonfirm el al. utilized three different squeeze and turn packages and two specified grips (bi-digital or tri-digital) to collect maximum torque generation of 100 children (aged three to 17) and adults (aged 18 to 60 plus). In this work, it was found that adults' torque generation with both grip types was significantly greater than that of children aged three to five years old. Additionally, of the two grip choices used, the children could produce significantly less torque with the grip utilizing only two fingers [73]. This study indicates that a closure that limits the grip choices available to children and the functional surface area available could effectively reduce a child's ability to open a package with little impact to an adult's ability. In this work, the participants were instructed to hold the bottle near their abdomen and to use specific grips. This is useful to understand the strength differences of adults and children with the bi-digital and tri-digital grips, but it forces the participants to remain in a posture or use grips that are not most comfortable or effective for their hand size or strength. Allowing participants to choose their own posture and grip types provides a more accurate measurement of how much strength they could apply to a package closure at home.

1.7 Research goals, objectives and hypotheses

Throughout this literature review I explored the history and the current state of CRP. Additionally, the benefits and challenges of these closures were discussed. The two most common re-closable CRPs, the push and turn and squeeze and turn designs, reduce both children's *and* older adults' access to medications by requiring a simultaneous, contrasting force application. CRP can effectively reduce the access of children under the age of five years old *when used correctly*; however, adults over the age of 65 years commonly have osteoarthritis of the wrist or hand, or other conditions, and as a result struggle to open many kinds of CRP. To avoid the struggles faced when accessing the contents within CRP, many older adults choose to leave the packages open or transfer the contents of the packages to non-CRP. Bypassing the child resistant mechanisms in medication packages leaves young children at risk.

A CRP that reduces the access of children while still allowing older adults to easily access their medications is therefore needed. A novel CRP that utilizes the cognitive and physical differences of an adult and a child to restrict access was designed by a Dr. Wilson, a graduate of the MSU School of Packaging, and evaluated through this work. The four main objectives of this work were to:

- Design a system that accurately measures an individual's ability to generate torque on a specific cylindrical closure.
- Determine the effectiveness of a novel CRP to reduce the torque generation of children, by quantifying the torque generation of adults over the age of 65 and children between the ages of four and six years old.
- Evaluate the impact of age and functional surface area on torque generation.
- Provide a recommendation for the percentage of functional surface area that optimizes adult torque generation and minimizes torque generation of children.

The hypothesis of this work was that the adults would be able to operate and open the novel CRP with more limited surface area and apply enough torque to open the bottle; while, children between four and six years of age would be unable to apply a sufficient amount of torque to the same closure.

CHAPTER 2: MATERIALS AND METHODS

2.1 Overall Experimental Approach

The experimental approach used to accomplish the objectives of this study had three main blocks. The first step was to create the measurement system. This system required a small and versatile torque sensor that could be used in an easy to handle apparatus. The next step was to collect data from a total of 50 participants in two groups, those over the age of 65 and those between four and six years old. The final block of the experiment was to synthesize the data and complete statistical analyses.

2.2 Torque Data

For this study, a specialized device was created to look similar to a medication bottle and to allow participants to interact with it while collecting torque data. As part of the system, a torque sensor designed and manufactured by Loadstar Sensors (Fremont, California) was chosen for use in this study. The RST1 torque sensor, Figure 3, can measure torque applied or experienced by an object in both the clockwise and counterclockwise directions. It has four threaded holes on each end for mounting. The sensor had the capacity to measure torque up to 60 N-m. A focused range of calibration was conducted for highest accuracy between 0 and 20 N-m. A calibration certificate was included with the sensor, stating it had been calibrated to the standards of the National Institute of Standards and Technology.

Figure 3. 60 Nm capacity RST1 torque sensor.

The RST1 torque sensor was coupled with a capacitive interface to transfer analog data from the sensor to a digital output. The DI-1000U (Loadstar Sensors, Fremont, California) was a signal conditioner and 24-bit digitizer recommended for use with the RST1 sensor. It regulated the power, read the frequency signal, applied calibration values to the signal and created a digital output of the forces. It was connected to a PC via USB. The digital output was read and recorded by the SensorVUE software (Loadstar Sensors, Fremont, California). It can display, log and plot all sensor data. Data capture rate was selected with this software. Several steps were conducted so that the device was usable for this closure assessment.

2.3 Verification of RST1 Accuracy

Verification of the torque sensor's accuracy and calibration was performed prior to participant data collection. A specialized testing system was created as part of this project. The first step was to design it in AutoDesk Inventor. The system was comprised of two aluminum plates (plate A and plate B), Figure 4. Both plates had four 5 mm holes in the center arranged to match the pattern of the threaded holes on the RST1 sensor. Plate B had two additional holes, diameter of 25 mm, evenly spaced on either side of the mounting holes. The distance from the center of the plate to the center of both additional holes was 78.7 mm. Both plates were fabricated in the Mechanical Teaching Laboratory on Michigan State University's campus by the author.

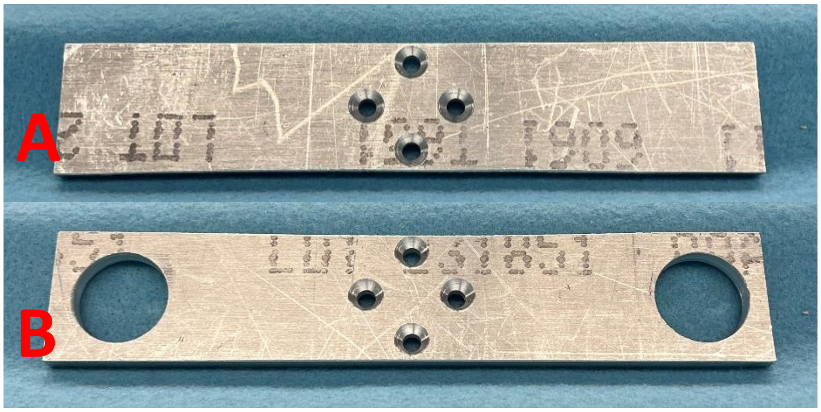

Figure 4. Plate A (top) and plate B (bottom) used to verify the accuracy and calibration of RST1 sensor.

The sensor was secured to each plate with 10-32 flat head zinc-plated steel machine screws. Plate A was clamped to additional supports and then securely fastened to a table top with C-clamps. The main body of the sensor and the side that was attached to Plate B was positioned over the edge of the tabletop, seen in Figure 5. Weights were hung off the right side of Plate B using a light weight rope. The weights applied were 1.11, 2.22, 3.34, 4.45, 5.56, 6.67, 7.78, 13.34, 22.24, and 44.48 Newtons. Once a weight was secured on the plate and still, the measured torque value was recorded. This process was repeated for each weight increment.

Results from the test were logged to CSV files at a data rate of one Hz. The value output by the sensor was then compared to a value calculated using the equation for the computation of torque based on a force acting at a distance shown below (1).

$$Torque\ = F * r\ \sin(\theta) \tag{1}$$

Where *F* was the force applied, *r* was the distance from the pivot point to the application of the force (the length of the moment arm), and ɵ was the angle at which the force was applied (angle between the force vector and moment arm). The values used for *r* and ɵ were 0.079 m and 90 degrees, respectively. The values of *F* corresponded the weight applied for each trial. This process was repeated two times on different days to ensure the accuracy of the method and sensor. Results of the verification can be seen in later in this document. All calculated values matched the values given by the sensor. This verified the sensors accuracy.

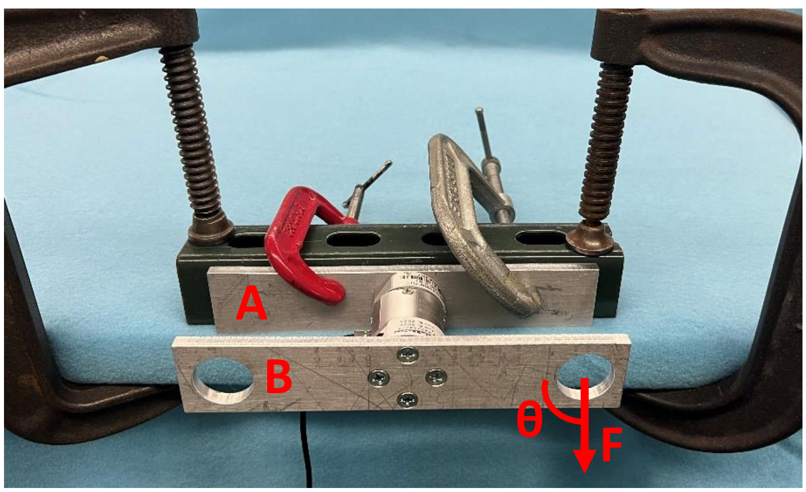

Figure 5. Torque sensor with plates A and B secured to table top for verification test. Weights were hung from either of the larger holes on plate B to create a torque. Weights hung on the left hole created a torque in the counter-clockwise direction, and weights hung on the right hole create a clockwise rotation. The direction and angle of force are indicated in the image.

2.4 'Bridge-cap' Design and Function

The novel cap used in this research was developed by Datashapes, LLC., Okemos, Michigan and was labeled as a 'bridge cap'. This design utilized a two-part system including an inner cap and an outer cap, seen in Figure 6. The inner cap could be screwed onto a medicine bottle as a typical thread-on closure. The outer cap snapped on overtop of the inner cap and spun freely in a groove of the inner cap.

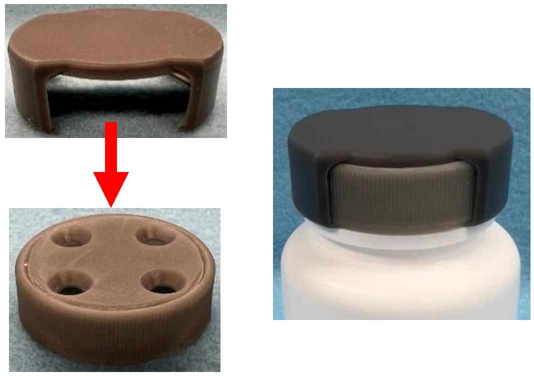

Figure 6. The "Bridge-cap" system.

The outer cap covered the entire top and a portion of the surface area along the side of the inner cap. There were two cutaway spaces of the outer cap that allowed the user to grip the inner cap. Three variations of the outer cap were used in participant testing. The amount of functional surface area of the inner cap that was exposed by the cutaways in the outer cap varied between each lid. The variations were labeled based on the amount of grip space, or functional surface area, available. The three sizes included 20%, 50%, and 80% functional surface area. A 100% functional surface treatment was tested as well (standard cap). The 100% treatment was referred to as the control and was the inner cap with no outer cap on top. All of the outer caps used for participant testing were 3D printed at Datashapes LLC., seen in Figure 7.

Figure 7. Three variations of outer cap showing the varying size of cutaways. Varying amount of functional surface area of the inner cap available to be gripped and a torque applied to.

The theory behind the 'bridge-cap' design was that the outer cap would interrupt the ability of smaller hands to grip the inner cap and apply enough torque to open the bottle. When a twisting force was applied to just the outer cap, no torque was applied to the inner cap and it would not become unscrewed. To apply torque to the inner cap and open the closure, the user must grip within the gaps of the outer cap. This design utilizes the different hand size, grip choices and intellectual differences between children and older adults to restrict the access of young children.

2.5 Testing System and Inner Cap Modifications

One challenge of this work was the design of the testing system. It was required to house the sensor and resemble a medicine bottle in shape, approximate weight, and height. The medicine bottle used as a model for this was a white HDPE (Alpha Packaging) 120 cc capacity bottle with a 38-millimeter neck diameter and 400 style neck finish. Considerations were taken to not mirror the bottle so precisely that it could encourage younger participants to be comfortable playing with or opening similar packages at home (e.g. no labels, not plastic, not exact shape). The device was also required to fully accommodate the 'bridge-cap' and allow participants to handle it in the same fashion as they would in a real-life scenario. To achieve both of these goals the following steps were taken.

The size of the inner and outer caps were the most important factors in determining the best way to utilize the RST1 sensor and collect accurate torque data. 3D models created in Autodesk Inventor of the inner cap and all outer caps were used in the development of the test system. The model of the inner cap was closely examined to evaluate the inner dimensions of the lid.

Several attachment methods were explored to determine the best way to attach the inner cap to the top of the sensor. The inner cap needed to sit securely on the top of the sensor and allow room for the outer cap to spin freely. Attempts to drill holes in the inner cap to match the mounting holes on the sensor were made, but the material was not strong enough to remain structurally sound. To avoid tampering with the material strength of the inner cap, modifications were made and a new 3D model in Autodesk Inventor was developed. These changes included the addition of four holes matching those of the sensor in size and location. The final version of the inner cap was 3D printed, seen in Figure 8.

Figure 8. Final 3D printed inner (control) cap used during human trials.

The next challenge to create a system that resembled a medicine bottle was accommodating the size and weight of the sensor. The RST1 sensor was 50.8 mm in height and 37.6 mm in diameter. The model medicine bottle was 97.8 mm in height. The inner diameter of the inner cap was 36.1 mm. To accommodate all of these dimensional requirements, spacers were needed to increase the height of the system and to ensure that the inner cap could be securely attached. A bottom spacer 38.2 mm in height was designed. This spacer was attached to the bottom of the RST1 sensor. Its main purpose was to increase the height of the system. A top spacer 14 mm in height and 34 mm in diameter was also designed. This spacer was placed on the top of the sensor and the inner cap was secured to the sensor over it. The diameter of this spacer was purposely smaller than both the diameter of the sensor and the inner cap. This was done so that the spacer could sit snugly inside of the inner cap and allow both to attach tightly to the end of the torque sensor. The top and bottom spacers had four 5 mm holes matching the pattern of the torque sensor. Both spacers were manufactured by the author out of aluminum.

Two iterations of the system used to house the RST1 sensor were considered. Both designs included the previously described spacers. The first design was a table top version; it was designed to be used while attached to a table and could not be held. The sensor was secured to the bottom spacer and an aluminum plate. This plate was then clamped to the table. The second design was handheld and was more similar to a medicine bottle to hold and apply torque to. A cylinder with dimensions similar to the model medicine bottle was created in

Autodesk Inventor It was then 3D printed. The bottom spacer and the sensor were secured to the bottom of the bottle. Both designs can be seen in Figure 9.

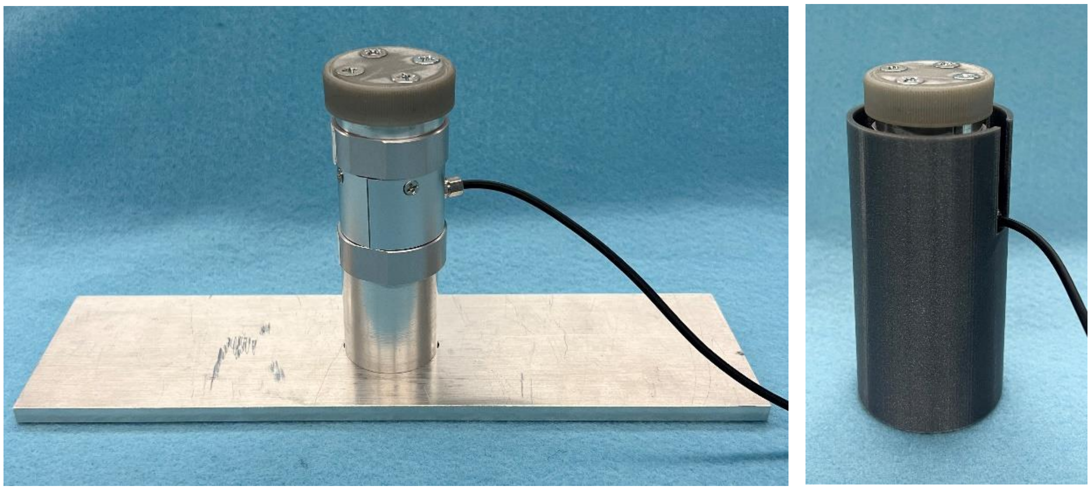

Figure 9. Prototypes of testing systems, table top (left) and hand-held (right), with control cap on top.

Both iterations were prototyped and tested to determine which was more suited to the proposed testing procedure. The criteria used to evaluate both designs included: ease of use and similarity to a real-life situation. Based on conversations with medication users and their experience with the device; it was determined that applying torque to the hand-held design felt more natural than applying torque to the table top version. Another consideration was the need for this device to be easy for children to hold on to and apply torque to. For these reasons, the hand-held design was chosen for use in the study. It better met the requirements for a bottle-like design and more accurately replicated how people would interact with the 'bridge-cap' in their day to day life. Final modifications were made to the spacers and the 3D printed 'bottle'. A 16 mm core from each spacer was removed to help reduce their overall weight. The height of the 'bottle' was shortened to 94 mm to allow participants to better grasp the lid. The final testing system can be seen in Figure 10.

Figure 10. **Final design of hand-held testing system with control cap secured on top.**

2.6 Experimental Procedure

This study was approved by Michigan State University's Institutional Review Board (IRB) (MSU Study ID STUDY00006846). Fifty participants were approved by the IRB and recruited in two groups, an adult group and a child group. All adults who participated in this study were required to be aged 65 or older and manage their own medications at home. Additional requirements included being willing to provide information about their current abilities to open packages and have their own transportation to campus. All children participating in this study were required to be over the age of four and under the age of six at the time of their participation. Additionally, all children were required to have no physical impairments that could have impacted their ability to open or close packaging, be able to verbally agree to participate and have transportation to campus. Consent of the child group required a parent or guardian's signature and verbal agreement from the child. All children were also required to be accompanied by a parent or guardian for the duration of the testing.

Participants for both groups were recruited from the East Lansing and surrounding areas. Flyers for both groups were posted on and around Michigan State University's campus. Flyers for the child group were shared with and distributed by local preschools and daycares to the classes of children within the eligible age for participation. The adult flyer was distributed to retired faculty and alumni of the university. Recruitment for both groups was also done through the Michigan State University Family Listserv. Additionally, participants who were interested were given copies of the IRB approved flyers to distribute to family and friends. All participants received a cash incentive of $50 for participating.

Testing took place at the Biomechanical Design Research Laboratory in the Engineering Building at Michigan State University, East Lansing, MI. Researchers provided all participants with a verbal explanation of the testing process and the goal of the work. The IRB approved consent form was verbally reviewed with all participants and the parents or guardians of the child group. Adult participants were provided with an IRB approved consent which they were asked to review and sign. Parents and guardians of the child participants were given a copy of the consent to review and sign. A copy of the consent form was offered to all participants or parents/guardians to keep for their own records. Additionally, the CDC's Up and Away Tip Sheet and Up and Away Brochure were provided to all parents and guardians. All participants who consented to testing were assigned a subject number (A1, A2 or B1, B2 etc.) and were given a demographic questionnaire to complete. Participants self-identified or parents/guardians identified the following demographic information: gender, age, ethnicity and handedness. Demographic questionnaires were labeled via subject number and made no reference to participants' identities. Videos and photographs were not taken of participants in either group, as they were not approved by the IRB.

Participants in the adult group were informed that testing would take approximately 30 minutes and no more than one hour. Participants and the parents/guardians in the child group were informed that testing would take approximately 30 minutes. Both groups were asked to perform the same tasks. Upon arrival the adult participants were offered to take a seat in an office chair; the child participants were offered to sit on a carpet square on the ground or in an office chair. A researcher briefly described what was to be done during the testing. Specifically, the participants were asked to twist a series of four caps, repeating each cap twice for a total of eight trials, to the best of their ability by exerting as much force as they could without injuring themselves. A researcher briefly explained how the 'bridge-cap' worked and explained that the inner cap (light gray) would not move or come off but the outer cap (dark gray) would spin freely.

All participants were encouraged to try and twist the inner lid once in the opening direction (counter-clockwise), once in the closing direction (clockwise), and then repeat for a total of four twists in each trial. The child participants were often reminded that the cap wouldn't come off and encouraged to continue twisting. All participants applied the four twists in a trial approximately 30 seconds long before having a one-minute long break. During the break, a researcher removed and applied the next treatment. All eight trials were randomized, ensuring that all four treatments were completed in each half of the testing, using a random number generator in MATLAB. Figure 11 illustrates the MALAB code used to randomize the trials for all participants. Table 1 contains an example of the tables used to organize the randomized trial orders for participants in both the adult and child groups.

```
clc;

n=4;
p=randperm(n);
q={'20%', '50%',
'80%','Control'
    }; %#ok<COMNC>

for i=1:n
    j=p(i);
    order{i}=q{j}; %#ok<SAGROW>
end

% celldisp(order')
order;
writecell(order','data.dat')
type data.dat
```

Figure 11. MATLAB code used to generate the random trial orders for all participants.

Table 1. Example of the tables used to organize the randomized trials for participant 3 in both age groups. All participants have a table similar table that is unique to their subject number and order of treatments.

Adult - Group A			Child - Group B		
Participant #	FSA/Cap	Trial #	Participant #	FSA/Cap	Trial #
3	50%	1	3	50%	1
3	80%	2	3	Control	2
3	Control	3	3	20%	3
3	20%	4	3	80%	4
3	80%	5	3	80%	5
3	20%	6	3	20%	6
3	50%	7	3	50%	7
3	Control	8	3	Control	8

At the end of the testing, a debrief script, that encouraged them to not interact with any similar looking packages at home, was read to all children.

2.7 Data Collection

The data were recorded by the Sensor Vue software and logged to a CSV file. Data were recorded in pounds-force per inch (later converted to N-m in Microsoft Excel) at a rate of 50 Hz. All CSV files were resaved to .xlsx format. Torque applied in the counter clockwise (opening direction) was recorded by the sensor as a negative value. Torque applied in the clockwise (closing direction) was recorded by the sensor as a positive value.

CHAPTER 3: DATA ANALYSIS

3.1 Adult Group - Data Synthesis

All adults completed two trials with each closure and twisted twice in each direction during both trials. The eight trials were completed by all participants in a random order and therefore all of the file names were unique. To analyze and graph all trials of one participant at one time, an automated MATLAB code was written. The folder containing all participant files was first accessed using the *cd* function. All files in that folder which began with the specified participant's number were copied into a list format. This list was then used to access all eight files, and the *readmatrix* function was used to pull the torque and time data columns from each excel file. A *for* loop was then used to create a figure containing eight plots (one per trial). Within the *for* loop, was eight *if* statements that created each plot and correctly labeled it according to each participant's unique order of trials. This code was modified slightly and also used in the analysis of the child group's data. Figure 12 contains portions of the code.

```
%% Creates a list with all file names associated with a specific participant
cd 'Adults - Group A xls files'\
list = dir('*A1_*'); %% Change this every participant
filenames = {list.name};
…

%%Creates one figure with 8 tiles, each tile containing one trial's time
versus torque graph%%

trial_orders = readcell("trial_orders");

for participant = 1 %% Change this every participant

t = tiledlayout(2,4);
t.Padding = 'compact';
t.TileSpacing = 'compact';
title(t,'Participant A1')%% Change this every participant
%All plots in N-m
%tile 1
    plot1 = 2;
    trial1 = trial_orders{plot1,participant};
    %% Repeated if statements to properly label all graphs.
    if (trial1 == 20)
        nexttile
        plot(D01Time,D01Torque,'b')
        title('Trial 1 (20%)')
        xlabel('Time(secs)')
        ylabel('Torque (N-m)')
        set(gca, 'FontSize',14)
    elseif (trial1 == 50)
```

Figure 12. Portions of the MATLAB code used to create a figure containing all eight plots showcasing a participant's eight trials. This code was fully automated for the both data sets and only needed to be modified in four places between participants.

An example of what an adult's eight trials looked like when graphed can be seen in Figure 13. The data for most adults looked similar to what is seen in the figure below. The clear pattern of twists in the closing and then opening directions (or vice versa), allowed the maximum (or minimum) value achieved each twist to be easily obtained using the MATLAB function *ginput*. With this function, the author could click on either side of a peak or valley and the following lines of code would output the maximum or minimum value between the locations of two clicks. The code was written so that *ginput* would expect eight clicks in total, two on either side of four peaks and valleys.

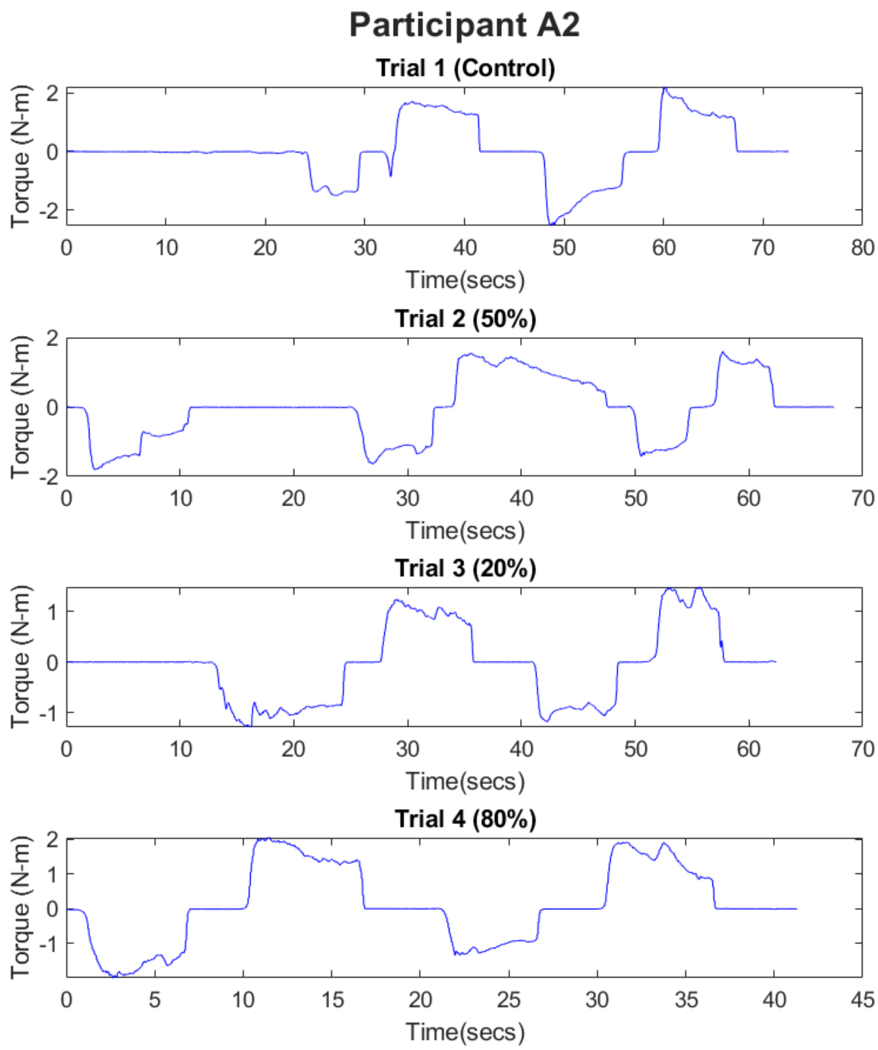

Figure 13. The graphs of the first four trials for one adult participant. The peaks represent twists in the closing direction and the valleys are twists in the opening direction. All values were recorded and graphed N-m.

Each adult had eight values associated with each FSA variation, four in the opening direction and four in the closing direction across the two trials.

3.2 Child Group - Data Synthesis

All children completed two trials with each cap and were encouraged to twist twice in each direction during both trials. After inspection of the data and the research experience of seeing the children conduct the trials, it was concluded that few children successfully completed two isolated twists in each direction. Instead, it was more commonly observed that when the children were attempting to grasp the lid, they did not have a good grip on the inner cap and therefore did not apply torque in a clear open/close pattern like the adults. Examples of a child who did not have isolated twists and one who did, can be seen in Figure 14 and Figure 15 respectively. To best capture the abilities of the children, four peaks in each direction within each trial were identified and the maximum (or minimum) values were determined using the MATLAB code described above.

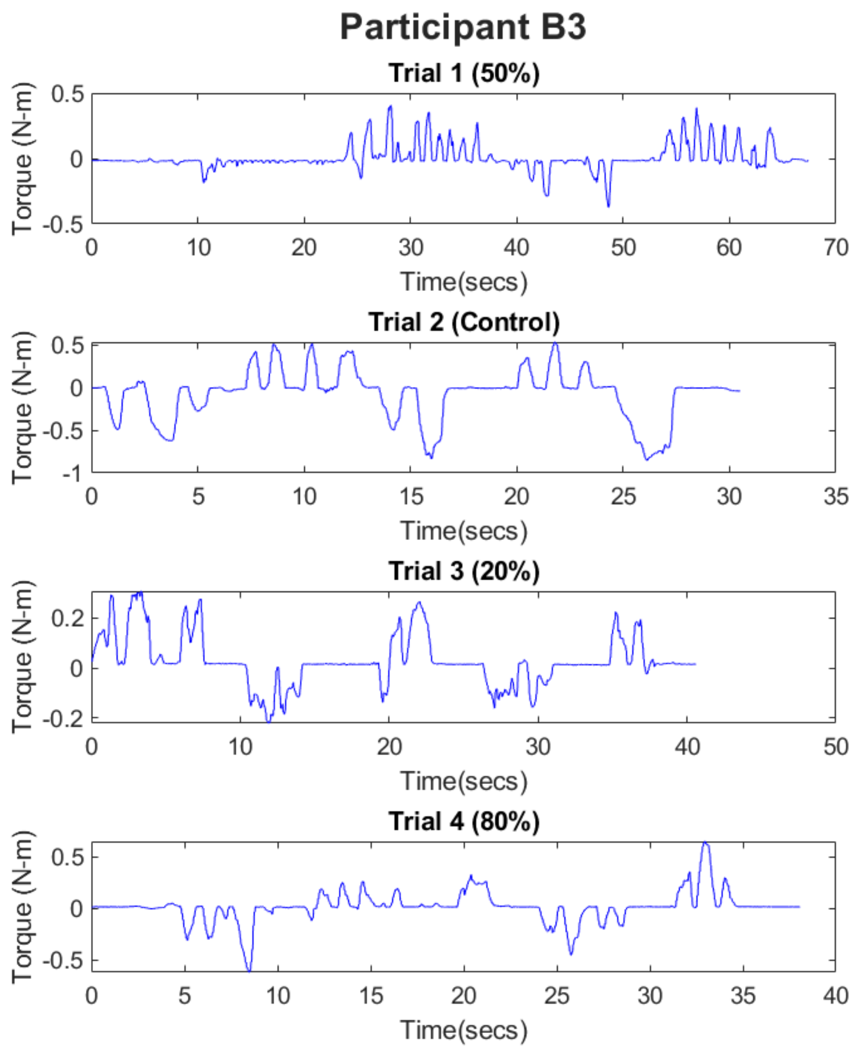

Figure 14. The graphs of the first four trials for child participant 3. The peaks represent twists in the closing direction and the valleys are twists in the opening direction. All values are graphed in N-m. This participant was 49 months old (four years one months) and is a good representation of how many of the children's graphs looked.

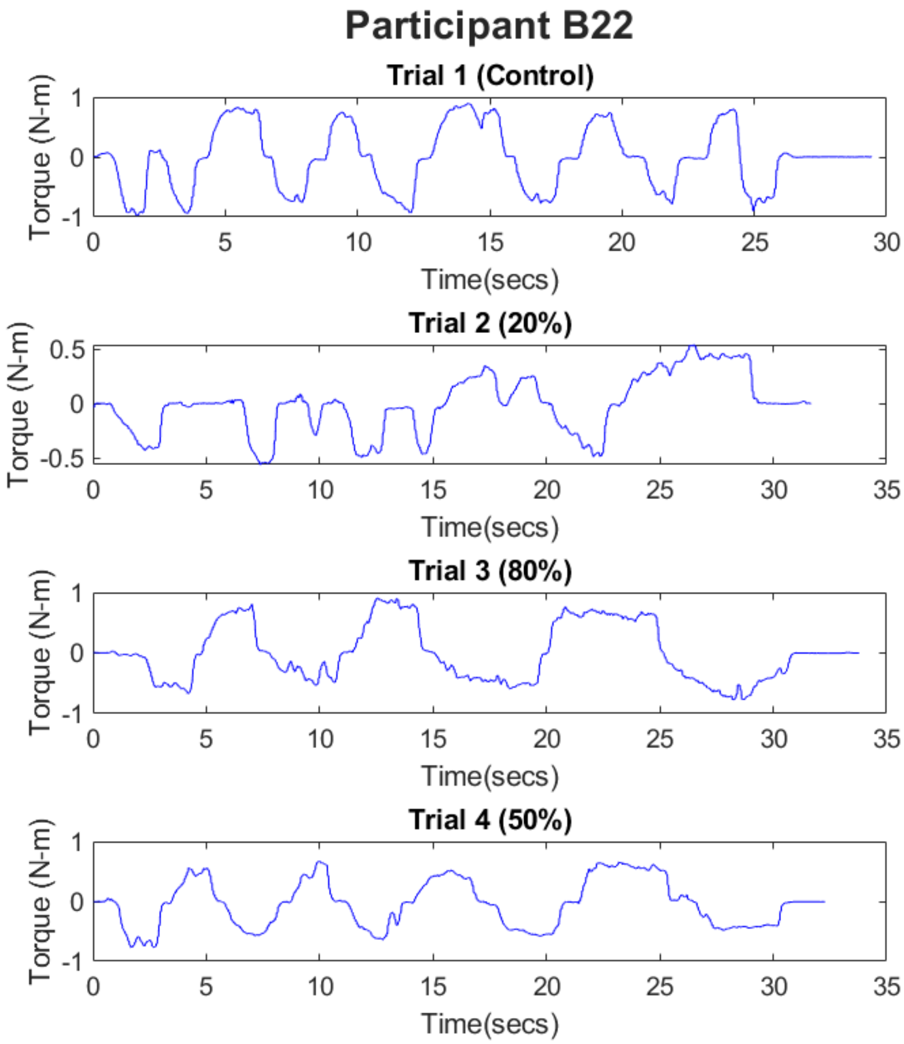

Figure 15. The graphs of the first four trials for child participant 22. The peaks represent twists in the opening direction and the valleys twists in the closing direction. All values are graphed in N-m. This participant was 63 months old (five years three months) and is a representation of the few participants in this group who had clear peaks and valleys were twisting was applied.

3.3 Data Sets Used in Statistical Analysis

The majority adult participants had two isolated attempts to apply torque to the sensor in each direction in each trial, as seen in Figure 13. The peak values from all four attempts in either direction were found. Those four values were averaged and used in subsequent analyses. The average of their attempts was chosen because an average would best represent what an adult over the age of 65 may be able to apply to the cap on an ordinary day. The goal of a *senior friendly* lid can only be met if the average senior can apply enough torque to open it, even when not at their maximum strength.

The children's attempts in each trial were not as isolated as the adults'; therefore, as many as eight attempts in either direction were identified and the peak values found. The values used in the child group's data set was made up of the maximum torque applied in any trial. The maximum value was chosen because a CRP must to keep children out, and to do this the amount of torque that children could apply when trying their best and at their strongest was what needed to be considered.

3.4 Statistical Analysis

The data sets discussed above were first analyzed to determine if there were any outliers. To do this the boxplot method was used, and the outliers were identified by using the interquartile range (IQR) rule. This rule states that if a value is 1.5*IQR above the third quartile or below the first quartile, then it is a statistically significant outlier [86]. SAS/STAT software Version 9.4 (SAS Institute Inc., Cary NC) was used to plot and identify the outliers. The outliers in each group were identified via this approach.

A two-way repeated measures ANOVA was performed to compare the effect of age and functional surface area on the amount of torque applied. The independent variables were the torque direction, age group and functional surface area. The dependent variable was the amount of torque applied to each closure. The end goal of this analysis was to identify if the effects of the independent variables were statistically significant and with what amount of functional surface area there was the greatest difference between the means of the adults and children. To determine significance all p-values were compared to $\alpha=0.05$.

CHAPTER 4: RESULTS

4.1 Torque Sensor Verification Results

The verification testing to confirm the calibration of the sensor was completed 3 times on 2 different days. The values output by the sensor were compared to the calculated torque value. The results of the verification test can be seen in Figure 16.

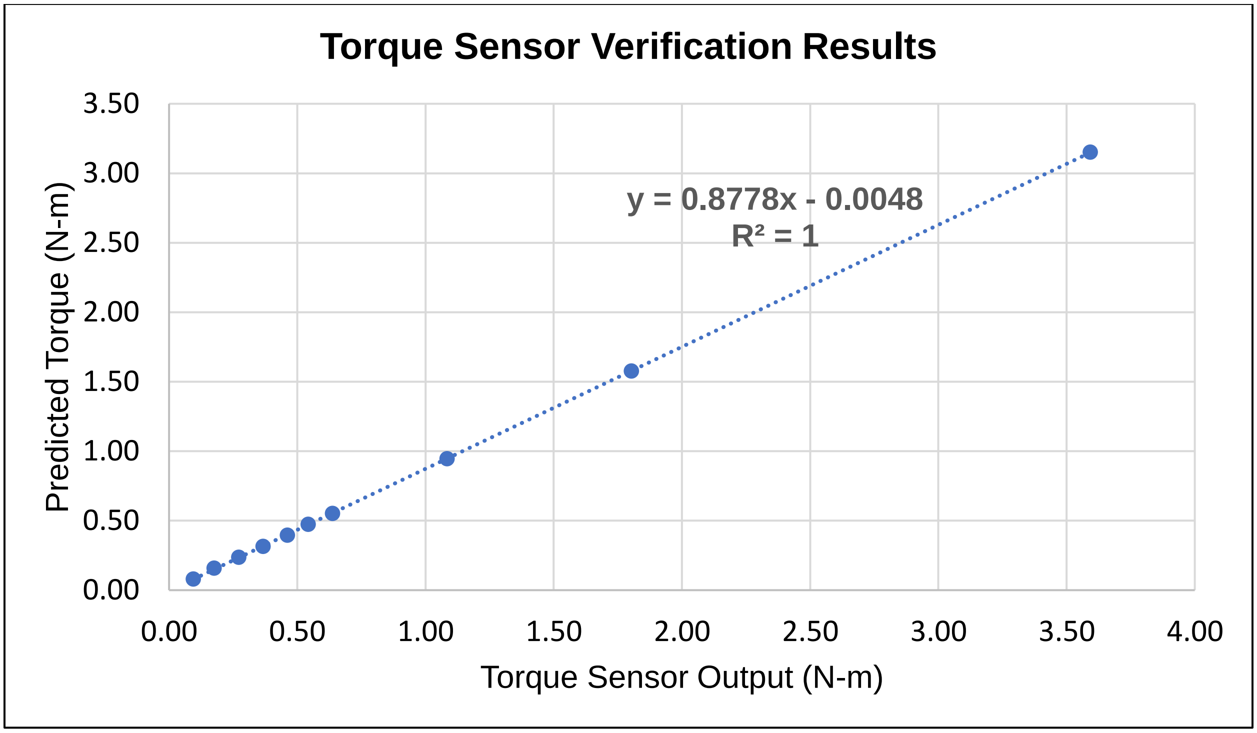

Figure 16. Results of verification testing completed twice prior to participant testing. Weights applied to the sensor were allowed to sit for a few moments before being removed and the next applied. The torque value output by the sensor was recorded and then compared to the calculated values.

4.2 Participant Demographics

In total 50 participants were recruited for this study. The first participant, an 85-year-old female, was designated a pilot participant and was not included in the subsequent analyses. A total of 49 participants completed all tasks and filled out the demographic questionnaire. The participants were divided into two groups, an adult group and a child group. The adult group contained 24 participants and the child group contained 25 participants. Table 2 presents the breakdown of the two groups by gender, age, and handedness.

Table 2. Research participants breakdown by age, gender and handedness.

	Adults	Children
Average Age (+/- SD)	70.08(+/- 5.41) years	58.04 (+/- 7.36) months
Male	10	9
Female	14	16
Left Handed	3	2
Right Handed	21	23

Figure 17 and Figure 18 present the distribution of ages of the participants in each group. The children were divided in into an under five group, a transitional age group, and an over five group. The adult group was divided by five-year increments.

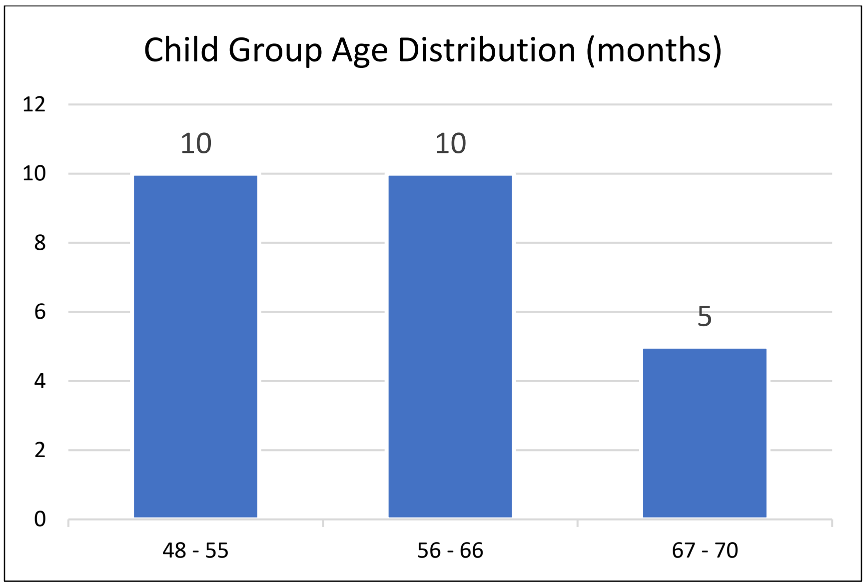

Figure 17. Child group age distribution divided into 3 groups: 48-55 months (4 years to 4 years 7 months), 56-66 months (4 years 8 months to 5 years 6 months), and 67-70 months (5 years 7 months to 5 years 10 months).

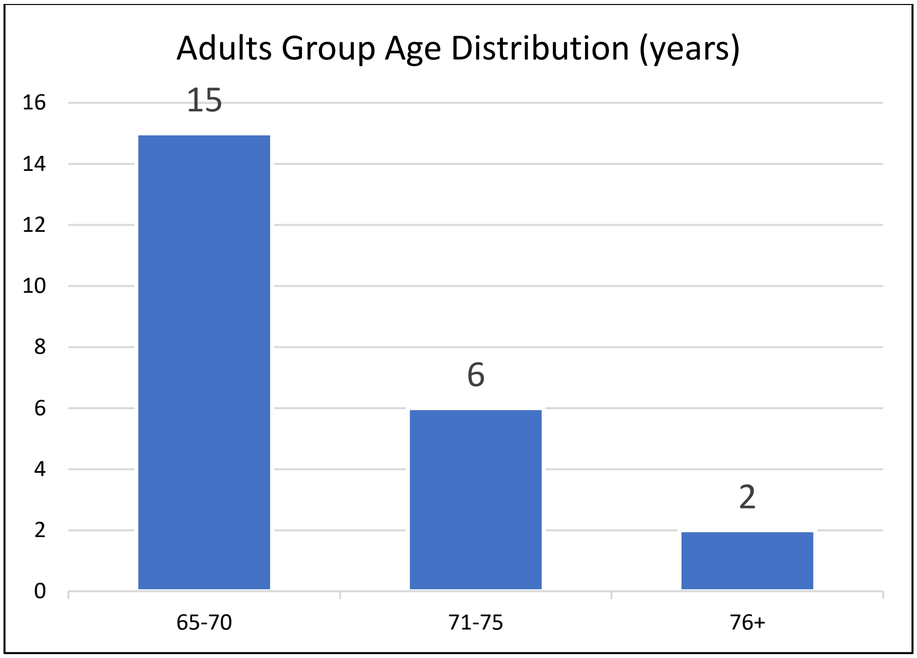

Figure 18. Adult group age distribution divided into 3 groups (years).

Table 3 presents the ethnicity groups identified by the participants (or their guardians) and their respective frequencies across all 49 participants.

Table 3. Research participants breakdown by self-identified ethnicity.

Ethnicity	Adults	Children
White	22	13
Spanish	1	0
Mixed (bi-racial)	1	2
Asian	0	9
Non-Hispanic/Latino	0	1

4.3 Outlier Identification and Removal

The outliers in the child group were identified first. The circles outside of the standard deviation bars represent the outliers, seen in Figure 19. The plots correspond to each FSA variation tested, 20%, 50%, 80% and 100%. The boxplot data were printed in a table and the corresponding values identified.

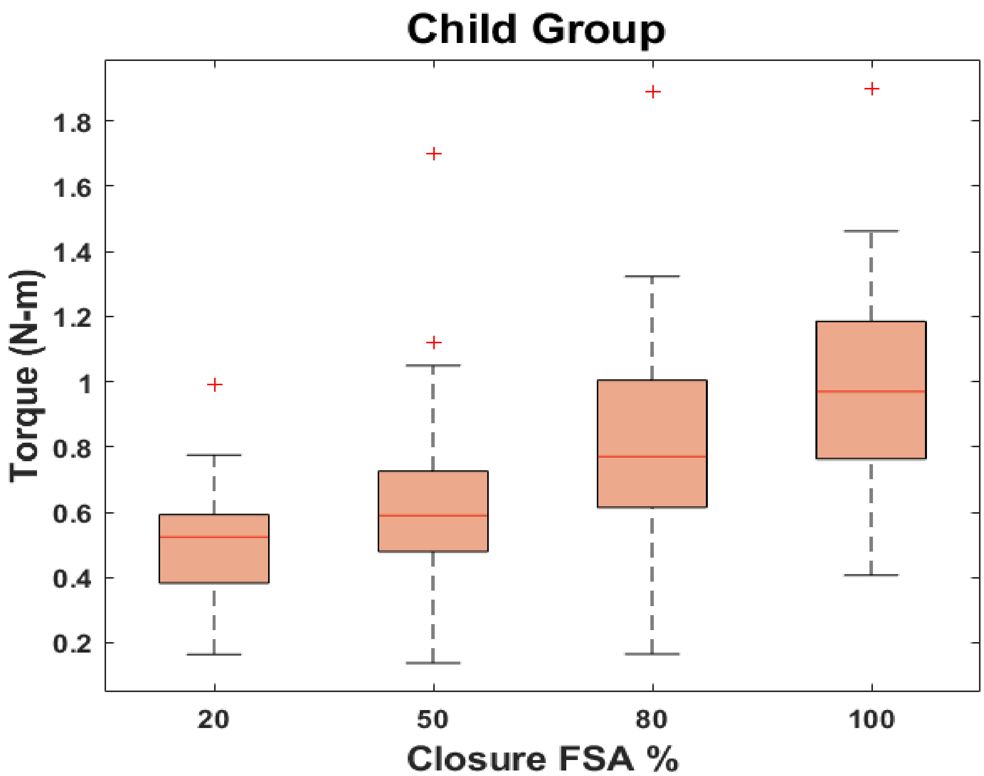

Figure 19. Boxplots used to identify the outliers within the child group. The dots outside of the standard deviation bars represent the outliers.

Participant B15 was consistently an outlier in all trials. Their maximum torque achieved in all trials was outside of the standard deviation and well above the average participant. This participant was removed from the data set prior to completing further statistical analysis. The same procedure described for the detection of outliers in the child group was followed with the adults. Figure 20 contains the boxplots used to identify the outliers in the adult group.

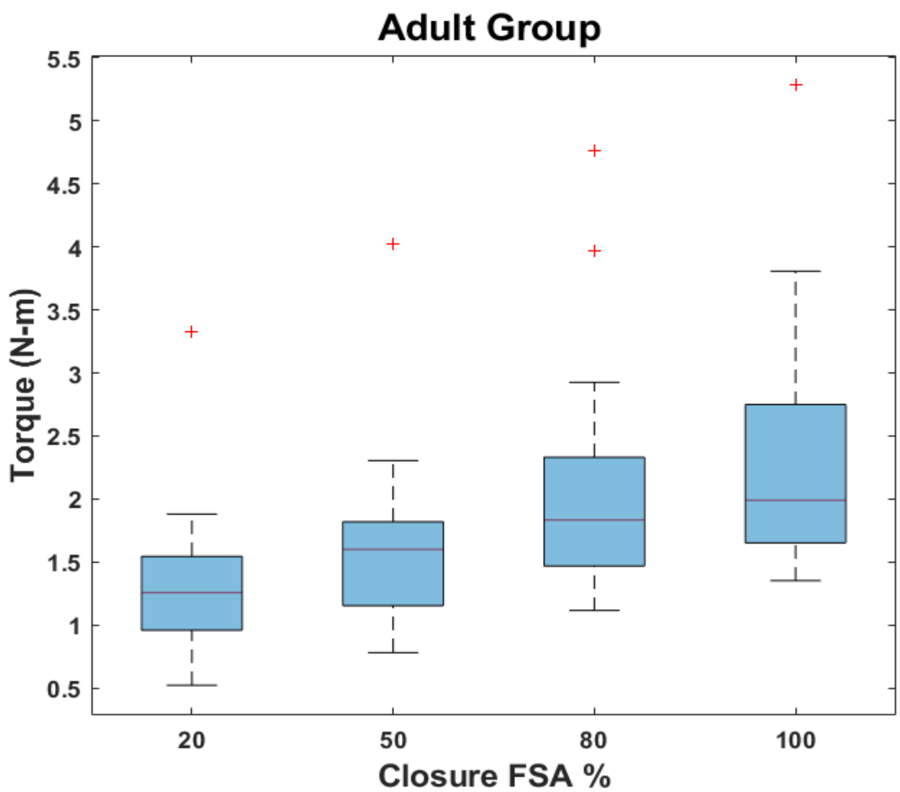

Figure 20. Boxplots used to identify the outliers within the adult group. The dots outside of the standard deviation bars represent the outliers.

Participant A6 was consistently an outlier in all trials. Their maximum torque achieved in all trials was outside of the standard deviation and well above the average participant. For this reason, this participant was removed from the data set prior to completing statistical analysis.

4.4 Opening vs Closing Direction

The magnitude of torque production of all participants with all tested closures was compared between the opening and closing directions, and it was found that there was no significant difference between torque applied in either direction (p=0.144). The same comparison was made within each of the two groups. For the adult group, it was found that there was a significant difference (p=0.004) between the torque produced in the opening direction compared to the torque produced in the closing direction. While there was a statistically significant difference, the difference in the average torque applied to all caps between the opening and closing direction was small in magnitude, only 0.126 N-m. For the child group, it was found that was no significant difference (p=0.824) between the magnitude of torque produced in either the opening or closing direction.

4.4 Data sets used in subsequent analysis

The data presented in Table 4 and Table 5 were used in all statistical analyses performed. Both data tables have the previously identified outliers removed. All values are in N-m and are torque applications applied in the opening direction.

Table 4. The average torque application across 4 twists in the opening direction of 23 adults (outlier A6 removed).

	Torque Generated (N-m)			
FSA:	20%	50%	80%	100%
Participant #				
1	1.54	1.77	2.44	2.95
2	1.27	1.75	1.76	1.84
3	1.13	0.97	1.20	1.36
4	0.97	1.38	1.57	1.58
5	1.18	1.47	1.83	1.90
7	1.78	2.30	3.97	3.81
8	1.31	1.44	1.94	1.95
9	1.08	1.18	1.47	1.44
10	1.62	1.71	1.97	1.98
11	1.19	1.58	1.77	1.75
12	0.62	0.84	1.11	1.36
13	1.48	1.98	2.12	2.28
14	1.24	1.62	2.10	2.12
15	0.92	1.03	1.47	1.35
16	1.77	2.03	2.92	3.27
17	1.55	1.90	2.73	3.23
18	0.67	1.13	1.46	2.08
19	1.34	1.77	1.67	2.68
20	1.36	1.87	2.22	2.68
21	0.81	1.31	1.84	2.00
22	1.88	1.66	2.88	2.82
23	0.52	0.78	1.29	1.57
24	0.95	1.08	1.45	1.72

Table 5. The maximum torque application across 4 twists in the opening direction of children (outlier B15 removed).

	Torque Generated (N-m)			
FSA:	20%	50%	80%	100%
Participant #				
1	0.39	0.59	0.65	0.97
2	0.16	0.49	0.80	0.86
3	0.43	0.42	0.62	0.85
4	0.18	0.20	0.52	0.59
5	0.76	1.12	0.95	1.30
6	0.18	0.14	0.17	0.41
7	0.35	0.43	0.61	0.72
8	0.48	0.54	0.54	1.24
9	0.65	0.67	1.00	1.17
10	0.56	0.72	1.29	1.29
11	0.77	0.72	1.10	1.01
12	0.42	0.34	0.48	0.54
13	0.32	0.17	0.57	0.48
14	0.35	0.64	0.72	0.78
16	0.53	0.51	0.72	1.02
17	0.53	0.81	0.95	1.18
18	0.46	0.53	0.62	0.91
19	0.57	0.54	1.00	0.94
20	0.56	0.56	0.73	0.63
21	0.54	0.74	1.32	1.46
22	0.56	0.77	0.77	0.97
23	0.52	0.69	0.90	1.07
24	0.66	0.68	1.05	1.20
25	0.67	1.05	1.01	0.99

4.5 Adult Group Data Tables

The average opening and closing torque values across adult participants can be seen in Table 6.

Table 6. The average torque application across the adults in the opening and closing directions. Each participant completed 2 trials with each closure, the average of each individual trial is seen in columns labeled 'Trial 1' and 'Trial 2'. Columns labeled 'Both Trials' contain the average and standard deviation of all 4 attempts for each lid. The opening values are presented as negative numbers because this was how the RST1 sensor distinguished between twisting directions.

N-m (St. Dev.)	Opening			Closing		
FSA	Trial 1	Trial 2	Both Trials	Trial 1	Trial 2	Both Trials
100%	-2.18 (.74)	-2.14 (0.72)	-2.16 (0.73)	1.87 (.66)	1.94 (0.69)	1.91 (0.68)
80%	-2.02 (0.79)	-1.91 (0.63)	-1.96 (0.71)	1.83 (.77)	1.74 (0.64)	1.78 (0.70)
50%	-1.52 (0.46)	-1.49 (0.44)	-1.50 (0.45)	1.47 (0.47)	1.51 (0.56)	1.49 (0.52)
20%	-1.25 (0.43)	-1.20 (0.38)	-1.22 (0.40)	1.22 (0.51)	1.23 (0.38)	1.22 (0.44)

The range of torque application across all adult participants' attempts can be seen in Table 7. These values represent the absolute maximum and minimum torque value that the adult participants could achieve with each variation of the 'bridge-cap' system.

Table 7. The absolute minimum and maximum of all attempts in each direction (across both trials of each lid) for adults.

(N-m)	Opening		Closing	
FSA	Minimum	Maximum	Minimum	Maximum
100%	-0.93	-4.08	0.71	3.76
80%	-0.88	-4.56	0.50	4.00
50%	-0.70	-3.18	0.43	3.34
20%	-0.44	-2.45	0.35	2.52

4.6 Child Group Data Tables

The average opening and closing torque values across all child participants can be seen in Table 8. The maximum attempt of each child was used in the creation of this table.

Table 8. The average torque application across the child group in the opening and closing directions. The opening values are presented as negatives numbers because this was how the RST1 sensor distinguished between twisting direction.

N-m (St. Dev.)	Opening direction			Closing direction		
FSA	Trial 1	Trial 2	Both Trials	Trial 1	Trial 2	Both Trials
100%	-0.88 (0.30)	-0.79 (0.26)	-0.84 (0.29)	0.85 (0.24)	0.82 (0.28)	0.83 (0.26)
80%	-0.70 (0.30)	-0.67 (0.28)	-0.69 (0.29)	0.61 (0.26)	0.67 (0.30)	0.64 (0.28)
50%	-0.54 (0.24)	-0.52 (0.21)	-0.53 (0.22)	0.50(0.23)	0.50 (0.25)	0.50 (0.23)
20%	-0.42 (0.18)	-0.43 (0.16)	-0.42 (0.17)	0.46 (0.18)	0.42 (0.23)	0.44 (0.21)

The range of torque application across the child participants' attempts can be seen in Table 9. These values represent that absolute maximum and minimum torque value that the child group achieved with each FSA variation.

Table 9. The absolute minimum and maximum torque values of the child group.

(N-m)	Opening direction		Closing direction	
FSA	Minimum	Maximum	Minimum	Maximum
100%	-0.02	-1.09	0.22	1.69
80%	-0.03	-1.00	0.06	1.14
50%	-0.07	-0.75	0.07	1.04
20%	-0.05	-0.57	0.08	1.07

4.8 Impact of the Outer cap

The percent difference between the control and each of the three outer caps was determined. For the adult group, the peak torque with the control was compared to the average of all attempts, 2.16 N-m. For the child group, the peak torque with the control cap was compared to the average of the maximum torque achieved by each participant, 0.94 N-m. The percent decrease of peak torque with each cap can be seen in Table 10 below.

Table 10. For both the adult and child groups, the average torque production on the 20%, 50%, and 80% FSAs, alongside the percent difference between the outer caps and the 100% FSA closure.

N-m	Children		Adults	
FSA	Average of the maximum achieved	% Reduced from 100% FSA	Average of all attempts	% Reduced from 100% FSA
80%	0.80	14.89 %	1.96	9.25 %
50%	0.59	37.23 %	1.50	30.56 %
20%	0.48	48.90 %	1.22	43.52 %

4.9 Comparison of adult and child groups

A two-way repeated measures ANOVA was used to determine the effect of age, FSA and the interaction between age and FSA on the amount of torque applied to the four different variations. A p-value of 0.05 was used to evaluated significance. The first factor in this analysis was age, whether a participant was included in the adult or child group. The repeated measures were the four variations of FSA tested. The adult population applied significantly more torque to all FSA variations compared to the children ($p<0.0001$) with a mean torque difference of 1.12 N-m.

The change in torque application as a function of FSA was also examined. Across both age groups, torque application changed as a result of functional surface area (p-value < 0.0001). Consecutive FSA changes across all participants were compared first (e.g., 20% to 50% FSA, but not 20% to 80% FSA). The most significant difference was found between 50% and 80% FSA variations ($p<0.0001$) with a mean difference of 0.34 N-m. Comparisons of 20% FSA to 50% and 80% to 100% FSA both resulted in significant differences, with p-values equal to 0.009 and 0.016 respectively. After consecutive FSA variations were compared, non-consecutive FSA changes were compared (e.g., 20% FSA to 80%). All non-consecutive FSA comparisons resulted in significant differences (all p-values < 0.0001). Because both age and FSA significantly affected torque, it was important to compare the impact of FSA on each individual age group. When evaluating only the child group there was a significant difference found between 50% and 80% FSA (p-value<0.001) and between 80% and 100% FSA (p-value = 0.01). There was no significant difference found in this group between the torque application with 20% and 50% FSA (p-value = 0.116). When evaluating only the adult group there was a significant difference found between the 20% and 50% and between 50% and 80% FSA variations (p-values 0.004 and <0.0001 respectively). There was no significant difference between 80% and 100% FSA (p-value = 0.051) found in this group.

Next the age factor for each FSA was examined across all participants. This analysis found that the two age groups were significantly different from each other with each FSA variation with a p-value <0.0001. The graph below, in Figure 21, illustrates this relationship.

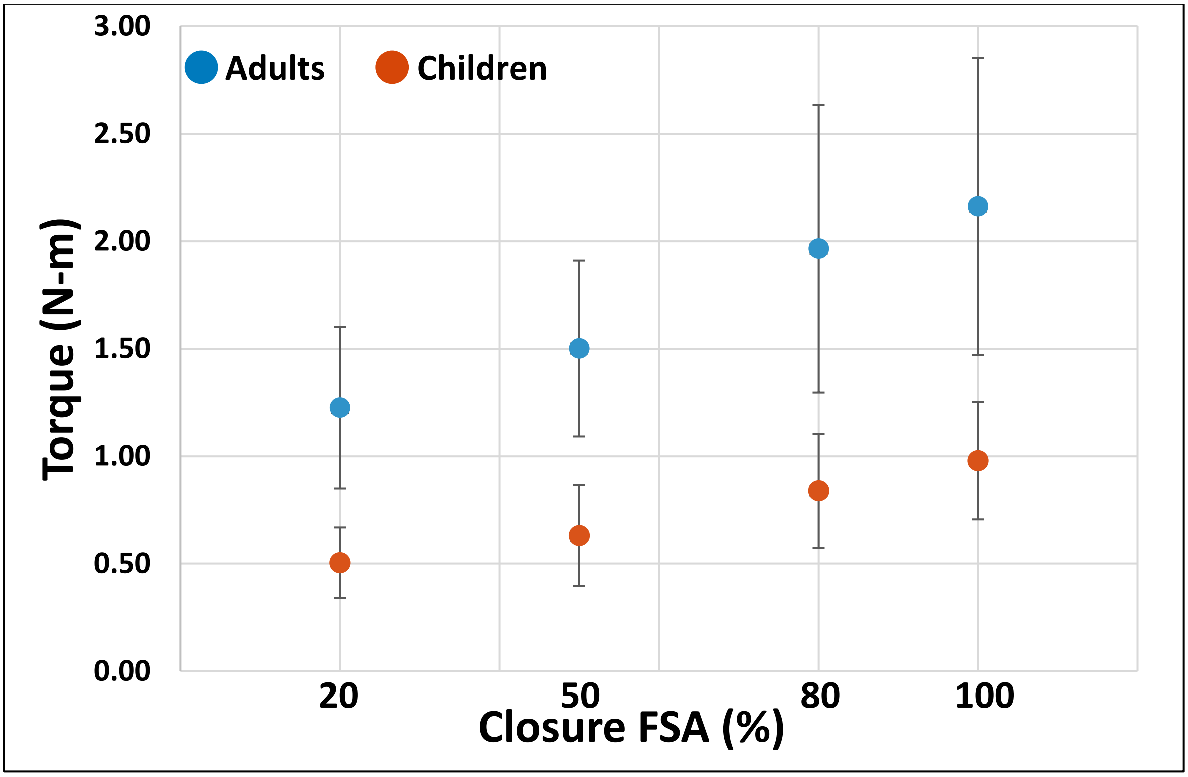

Figure 21. Mean difference between the adult and child groups. Error bars were created using the standard deviation of each group.

Tukey's Studentized Range test was used to determine between which FSA variations the adult and child groups had a significant difference. It was also used to determine at which FSA the difference was the largest. This test found that for all four FSA variations there was a significant difference in the torque application between the two age groups, all p-values <0.0001. The mean difference between the two groups and the respective confidence intervals for each FSA can be seen in Table 11. As the amount of functional surface area increased, the mean difference between the FSAs increased. The largest mean difference between the adult and child groups was with the control closure.

Table 11. Result of Tukey's Studentized Range Test; the p-values, the mean difference between the two groups and the respective confidence intervals.

FSA Available	P-value	Mean difference (N-m)	95% Confidence Interval (lower bound – upper bound)
100%	< 0.0001	1.22	0.91 – 1.53
80%	< 0.0001	1.17	0.87 – 1.47
50%	< 0.0001	0.92	0.72 – 1.11
20%	< 0.0001	0.74	0.57 – 0.91

The two groups were further analyzed to determine the difference in ability using a linked boxplot. The range of ability in both groups was large, so a more detailed analysis between the two groups was completed. First all adults and all children were plotted, Figure 22. The values analyzed from this graph and the differences between the adult and child groups' quartile values can be seen in Table 12.

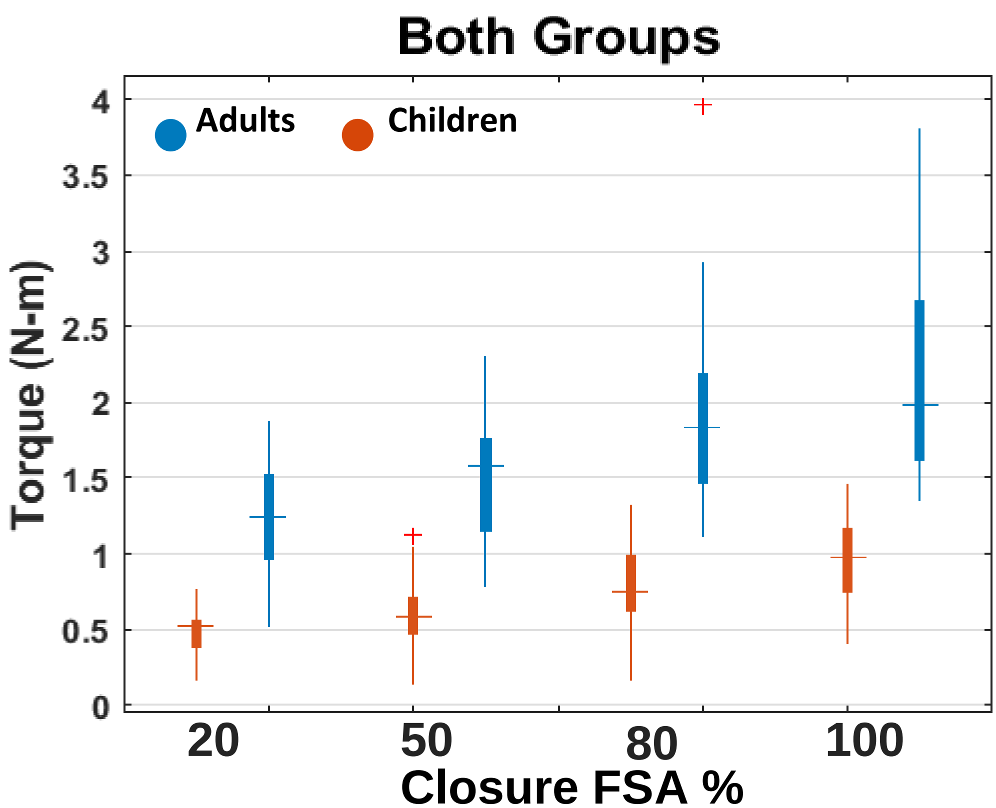

Figure 22. Boxplots all adults and all children.

From examination of the values in Table 12, it was found that when comparing the quartile values of the two groups the trend seen between the mean differences of the groups was not there. The differences between the quartile values were smaller than the observed mean differences, but they provide a more detailed look at the range in abilities of the two groups. The difference between the adult group's quartile 1 value and the child group's quartile 3 value was largest at the 80% FSA with a value of 0.47 N-m. The difference between the adult group's quartile 1 value and the child group's maximum value was again largest at the 80% FSA with a value of 0.15 N-m.

Table 12. The data values, pulled from Figure 21, used to determine the difference in torque application between all children and all adults. [Q1=first quartile value, Q3=third quartile value]

(N-m)	Adults	Children	Difference from A_Q1 to C_Q3	Difference from A_Q1 to the child data max
		20% FSA		
Q1	0.95		0.39	0.18
data max		0.77		
Q3		0.56		
mean		0.48		
		50% FSA		
Q1	1.13		0.41	0.08
data max		1.05		
Q3		0.72		
mean		0.59		
		80% FSA		
Q1	1.47		0.47	0.15
data max		1.32		
Q3		1.00		
mean		0.79		
		100% FSA		
Q1	1.58		0.41	0.12
data max		1.46		
Q3		1.17		
mean		0.94		

Next, the same analysis was completed with a refined population of children. A refinement of the age groups of children was conducted because child resistant caps are intended to restrict children under 5 years of age, and the fastest period of childhood development occurs between the ages of zero and six years old [87]. Between three and four and a half years old, children are learning impulse control and how to take part in group play. By the age of four, children begin to learn opposites[88]. Around five to six years old, children learn to follow simple instructions and other adult social skills [89]. For these reasons, an analysis was completed with only children aged four to five years old.

The under 5 years of age sub-group contained 14 children and was compared with the adults. The boxplots of both groups can be seen in Figure 23. The values analyzed in this graph and the differences between the quartile data can be seen in Table 13.

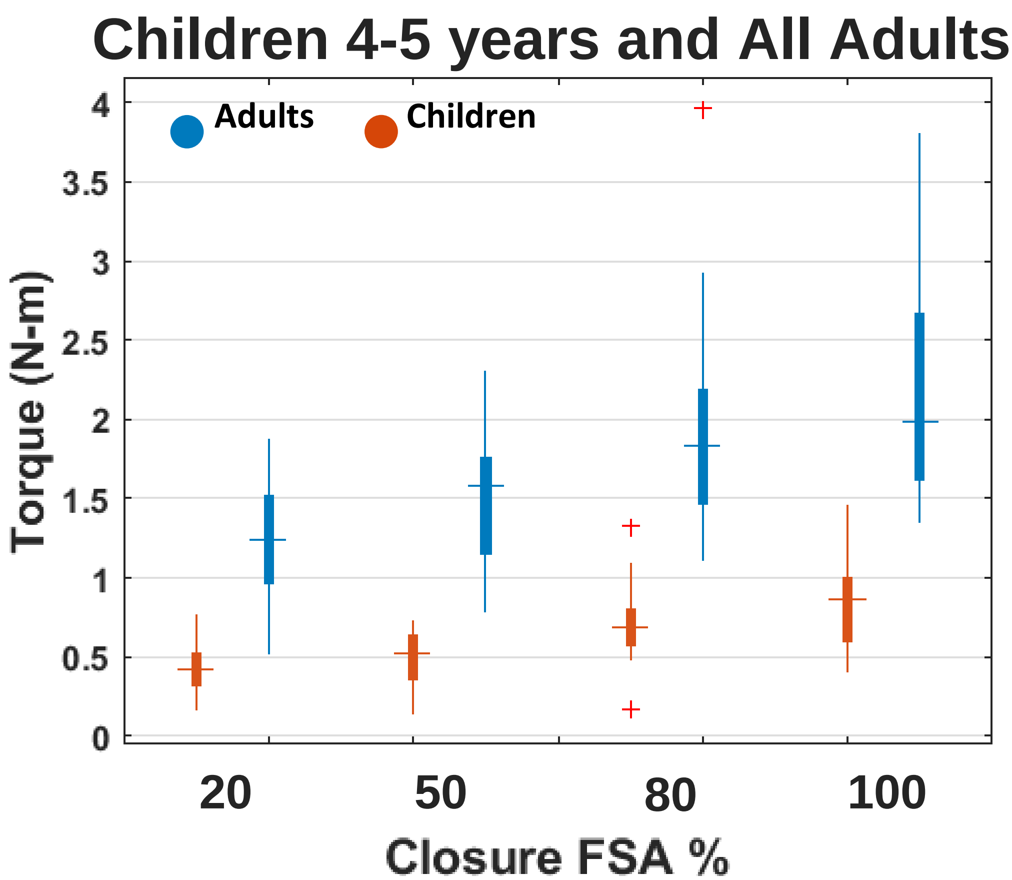

Figure 23. Boxplots all adults and children aged 4 to 5 years old.

In Table 13, when comparing the quartile values of the adult group and a subset of the children, the same trend was found as discussed above. The difference between the adult group's quartile 1 value and the child group's quartile 3 value, was largest at 80% FSA with a value of 0.67 N-m. The difference between the adult group's quartile 1 value and the child group's maximum value was again largest at 80% FSA with a value of 0.37 N-m.

Table 13. The data values, pulled from Figure 22, used to determine the difference in torque application between children aged 4-5 years and all adults. [Q1=first quartile value, Q3=third quartile value]

(N-m)	Adults	Children	Difference from A_Q1 to C_Q3	Difference from A_Q1 to the child data max
20% FSA				
Q1	0.95		0.42	0.18
data max		0.77		
Q3		0.53		
mean		0.41		
50% FSA				
Q1	1.13		0.49	0.39
data max		0.74		
Q3		0.64		
mean		0.48		
80% FSA				
Q1	1.47		0.67	0.37
data max		1.10		
Q3		0.80		
mean		0.71		
100% FSA				
Q1	1.58		0.57	0.12
data max		1.46		
Q3		1.01		
mean		0.83		

CHAPTER 5: DISCUSSION LIMITATIONS, AND CONCLUSIONS

5.1 Impact of the Direction of Torque

During all trials, all participants in both age groups were asked to apply torque to the sensor in both the opening and closing directions. When all participant data were evaluated as one group, there was no significant difference found between the magnitude of torque applied in the opening direction versus the closing direction. Within just the adult group, it was found that the difference between the average torque values in the opening and closing directions was statistically significant, and the average torque value for the adult group was larger in the opening direction. There was no significant difference between the twisting directions in the child group, and the average torque values of both directions were equal. For these reasons, all following discussion points were made only considering the opening torque.

5.2 Magnitude of Torque

This study determined the magnitude of torque application of children and older adults on three variations of a novel child resistant medicine bottle cap through the development and utilization of a custom torque measurement system. Current child resistant closures can be difficult for older adults to open, and as a result, many adults transfer their medications to non-child resistant containers or leave the closure entirely unfastened. A new CRP that can prevent children from gaining access while still allowing older adults to access their medications with less struggle is needed. One key step to understanding if a CRP meets this goal was to understand the abilities of the users, specifically the ability to apply torque to a cap.

The average torque application of both groups on each of the four tested FSA variations were compared to the industry standard to determine if either group was capable of opening the closure. As previously discussed, the removal torque of a 38 mm closure ranges from 0.79 to 1.81 N-m. The average value across the adult group for the control cap and all three limited FSA closures were within or exceeded this range. This result confirmed that the older adult population could likely gain access to the contents of a container that utilizes any of the tested closures. The average maximum torque application produced by the child group was within this range only with the 80% FSA and 100% FSA closures (0.80 and 0.94 N-m respectively). This indicates that children in this age group could not grip and apply enough torque to a CRP that severely limits their ability to grasp the inner cap, but they are strong enough to apply torque to and open packages that are not child-resistant or that have a large amount of FSA.

An important metric to judge the validity of the data gathered with the custom measurement system designed in this study was to compare the results to previously completed research. For the adult group, there was a limited amount of data for comparison. In many published studies, the range of torque application produced by older adults, aged 60 and older, on similarly sized caps (20 mm to 50 mm diameter) ranged from 1.64 to 2.43 N-m [72]–[75]. In the work involving the 'bride-cap', it was found that the adult group could on average apply 2.16 N-m of torque to the control 40 mm closure. Given the similarity in results, it can be concluded that the method in which the data was collected in this work was successful in capturing the ability of adults over the age of 65. Few studies with similar data on the torque abilities of children could be found. A study published over 35 years ago collected torque data of 400 children aged four to five years old. The results of this study found the mean torque on a 40 mm cap of males and females to be similar to the results of our work with the control cap (40 mm) of children aged four [85]. In the work completed by Rohles *et al*., the mean torque was significantly reduced between a 40- and 27-mm cap and cap diameter was found to play a significant role in torque generation [85]. The results of this study support the mean torque values of children found here.

It is important to note that child resistant packages are intended to restrict access of children *under* five years of age [1]. A subgroup of children, containing only those between the ages of four and five years old, was thus created and found to have lower torque values on the control cap than the children over the age of five. Additionally, when compared to the industry standard removal torque, the children in this group could not apply sufficient opening torque to any of the limited FSA variations to remove it. This demonstrates that the outer cap is effective at reducing the ability of children under five years of age to apply torque.

5.3 Impact of Functional Surface Area and Age

The two independent variables in this analysis greatly impacted the magnitude of torque generated by all participants. The difference in age played a significant role in the ability to generate torque, and the reduction in functional surface area limited the torque generated by both groups. It was found that for all three outer caps and the control lid there was a significant difference in the mean torque application between the two age groups. The mean difference in magnitude of torque values between the groups was a valuable metric because it illustrated how the abilities of the adults and children differed.

The impact of the available functional surface area provided by each outer cap can best be understood when comparing each cap to the control closure. The percent of torque reduction from the 100% FSA to the three test closures provided a clearer picture of how the abilities of both groups were impacted. Between the 20% and 50% FSA variations, both groups were similarly impacted by the reduction in surface area. This suggested that an outer cap below 50% would not reduce the children's ability *and* also maximize the ability of the older adults. Instead, it would likely pose a similar challenge to both groups and not meet its original goal of being a "senior friendly" CRP. With the 50% FSA outer cap, the abilities of both groups were again similarly reduced; however, when comparing the change between the 50% and 80% closure for both groups, the reduction in ability for the child group is lower than the reduction of the adults' ability. This suggests that a closure within this range could be effective at reducing the ability of children and maximizing the ability of adults. The percent reduction in torque generation with the 80% FSA closure was minimal for both groups. A closure with FSA above 80% would be ineffective at restricting access of children under 5 years old as it behaved like the 100% control.

When evaluating the child group's data, it was found that the magnitudes of torque applied to 20% FSA and to 50% FSA were not significantly different. The magnitude between the same FSA variations for the adult data was found to be significantly different, but realistically the difference between the two was only 0.3 N-m. Additionally, as the functional surface area (20% to 100%) increased so did the mean difference between the adults and children. The smallest difference existed between the two groups at 20% FSA, and given that the difference between 20% and 50% is not impactful for either group, it was concluded that FSA in this range would not be the ideal outer cap size.

5.4 Final Design Considerations

While the mean difference between the two groups was significant, it was important to consider the range of abilities in both groups. The standard deviation of the two groups overlapped for all of the tested closures. This meant that the strongest child could apply more torque to the closures than the weakest adult. Because the goal of this work was to advise the design process of a senior friendly and child resistant closure, more in-depth comparisons were made between the two groups. The first quartile value of the adult group was chosen to use in comparisons because it represented the torque a weaker adult was able to produce. The third quartile value of the child group was chosen to use in comparisons because it represented the torque a stronger or more determined child could produce on any given day. A second value of the children's data used was the maximum. This was used to quantify the difference between the weaker adults and the absolute strongest child. The differences between the adult first quartile value and the two values of the child group were largest at 80% FSA. This comparison was repeated for a subgroup of children between the ages of 4 and 5 years old. Within this subgroup, it was found that the largest difference between the previously described values was again with 80% FSA. The difference between the same values with the 50% and 100% FSA variations for each comparison previously discussed were nearly equal. Given the adults could apply nearly 40% more torque to the 50% FSA than the children could, it was concluded that a closure with FSA between 50% and 80% would maintain a sufficient gap in ability between the age groups.

When comparing across the FSA variations (20% to 50%, 50% to 80%, and 80% to 100%) the most significant change was between the 50% and 80% FSA for both age groups, as discussed above. This change in torque was most impactful in the child group. Furthermore, it was identified that the children could apply just enough torque to the 80% FSA to open it. Thus, it was recommended that an outer cap that would best maximize the abilities of adults and minimize the ability of children would be within 50-80% FSA. Additionally, a smaller outer cap would lower the amount of material required for manufacturing and consequently reduce production costs and the impacts to the environment.

5.4 The 'Human' Factor

The limited amount of FSA in the three variations of the outer cap created a physical barrier for the participants to grasp the inner cap and apply a torque. The amount of area exposed and the average hand-size of adults and children are two factors that were used to evaluate what amount of was is ideal. The average adult woman's thumb ranges from 18.4 to 20.6 mm in breadth at the proximal interphalangeal joint. The average adult male's thumb breadth at the same joint ranges from 20.6 to 24 mm [90], [91]. The average thumb breadth of children between three and six years old ranges from 13.4 to 16.25 mm [91], [92]. Thumb breadth is a good indicator of an individual's hand size. Torque generation is dependent on grip strength, the coefficient of friction between the hand and object, and the object's diameter [68]. Based on this definition, it can be assumed that a larger hand would result in a greater amount of torque as a larger hand would have a greater contact area with the inner cap. The 20% FSA outer cap only allowed about 18 mm of the inner cap to be grasped. A larger adult thumb would likely struggle to maintain good contact with the inner cap at this FSA. This was seen in the data wherein the adults applied significantly less torque to the 20% FSA compared to the control (43% less). The amount of FSA exposed with the 50% and 80% outer caps would allow all participants to have a better grasp on the inner cap. For the adults, the greater surface area and larger hand size resulted in a larger increase of torque application between the two lids than that of the children.

5.5 Limitations

This study tested the magnitude of torque children between the ages of four and six years old and adults over the age of 65 could apply to three variations of an outer cap and a control 38-mm closure. There were a few areas that limited the scope of this work. Firstly, child resistant packages, as defined by the PPPA, are required to be difficult for children under the age of 5 to open. While most of the children who participated in this study were under five, a larger group of young children, including some under the age of 4, would be ideal to fully understand the ability of this closure system to reduce children’s access. This, however, would be difficult to accomplish as children younger than four would likely struggle to complete the assigned task due to lower attention spans and inability to follow specific instruction. The second limitation of this study was this the scope of the data collected. For future studies, it would be beneficial to also collect hand size data and to record the grip styles used by all participants. Both of these data sets could provide additional insights into the finding of this work as well as serving as comparisons to other work. The third area that limited the scope of this work was the inclusion criteria used for to gather the participants in the adult group. The participants in this group were required to be over 65 years old and handle their own medications, but there was no requirement for upper limb deformities or disabilities. A future study focused on adults with significant osteoarthritis of the hand or wrist could yield different magnitudes of torque and a better representation the abilities of older adults.

5.6 Conclusions

In summary, the results of this work found that the difference in torque application in the opening and closing directions to be negligible. This allowed analysis to be focused on the opening, or removal, torque. Optimization of the amount of functional surface area between 50% and 80% FSA would create an outer cap that meets the goal of a child resistant and senior friendly lid. An outer cap closer to 50% functional surface area would best reduce the torque generated by children, while having a negligible impact on the ability of older adults. Additionally, an outer cap exposing closer to 50% FSA would lower the amount of material required for manufacturing and consequently reduce production costs and the impacts to the environment.

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