This is to certify that the

thesis entitled

Downforce to Remove and Consumer Perceptions of
Type 1A Continuous Thread Child-Resistant Closures

presented by

Beth Emma Waggoner

has been accepted towards fulfillment
of the requirements for

M.S. degree in Packaging

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Date May 4, 1989

DOWNFORCE TO REMOVE AND CONSUMER PERCEPTIONS OF TYPE 1A CONTINUOUS THREAD CHILD-RESISTANT CLOSURES

By

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A THESIS

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree

MASTER OF SCIENCE

School of Packaging

1989

ABSTRACT

DOWNFORCE TO REMOVE AND CONSUMER PERCEPTIONS OF TYPE 1A CONTINUOUS THREAD CHILD-RESISTANT CLOSURES

By

Beth Emma Waggoner

Four similar child-resistant closures were evaluated to determine the level of downforce necessary for a successful removal. A minimum required downforce value was established by testing with an automated torque machine. Using an instrumented bottle the force actually exerted during a removal was measured. Subjects were asked perceptual questions regarding the openings.

Analysis of the minimum downforce data indicated differences between the four closures, with one at a lower required downforce than the others. The downforce measurements for subjects also showed that same closure as different by requiring a lower force.

Comments from the subjects indicated that the majority did not understand how to operate the child-resistant closures on the market, and several expressed negative feelings. Comparatively there were few instances during the testing

where the subjects couldn't remove the closures, and only seven times where the subjects did not generate the necessary minimum downforce.

DEDICATION

This thesis is dedicated to my mother Katherine Waggoner, for without her support it would never have been finished, and to the memory of two men who also made a difference; my father Wayne Waggoner, and my friend Joe Irvin.

ACKNOWLEDGEMENTS

I would like to thank my committee members for their time and input; Dr. Hugh Lockhart, Dr. Susan Selke, Dr. Bruce Harte, and Dr. Robert Wilkinson. My sincere thanks are extended to Dr. Gary Burgess for his assistance in designing and machining the instrumented bottle. I would also like to thank Dr. John Gill for his help in the statistical design and analysis of this research.

I would also like to express my gratitude to Dr. Julian Lee who spent many hours helping me understand what a statistical design and analysis was, and as a friend was never too busy when I had trouble.

Finally, the people whose friendship and caring made all the difference: Jan Toebe, Vandana Kohli, Lisa Hewartson, Mark Schroeder, Jim Konczal, Suresh Nagaraj, and a special thanks to Paul Singh.

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INTRODUCTION

This study was initiated to examine downforce requirements necessary to remove specific child-resistant closures using a machine measurement and human strength measurements. The closures tested fall under the classification of ASTM Continuous Thread Type 1A (ASTM, 1988), and are a style commonly referred to as "push and turn" closures. To remove one of these closures, a subject must exert a downforce and a torque at the same time, two dissimilar motions. If sufficient downforce is not applied, the closure will not be removed. For this study an assumption was made that the downforce, not the torque, is the inhibiting force to open these closures.

There are two main objectives of this study. The first is to establish the minimum downforce required to remove the closures by utilizing an automated torque testing machine. Secondly, to measure the downforce actually exerted by subjects when attempting to remove a closure. The subjects were also asked to answer questions regarding the removal attempt. The data was statistically analyzed looking for any effects due to the age group of the subject, the sex of the subject, the particular closure being manipulated, and any interactions among these variables.

It is hoped that information resulting from this study may be used to help evaluate downforce requirements for new and existing push and turn child-resistant closures.

LITERATURE REVIEW

History

Safety in the home has been and continues to remain a major issue among consumers today. Of the many accidents that occur in the home, one category involves accidental ingestions of poisonous products by young children. In 1969 the American Association of Poison Control Centers reported over 76,000 cases of accidental poisonings involving children under five years of age (Verhulst, 1970). Of these, almost 90% were associated with children three years of age and younger. These numbers include only cases reported to a poison control center. The actual figure has been estimated at seven to eight times higher. Statistics such as these helped push legislation that required child-resistant (CR) packaging on many potentially dangerous medicines and household products.

Child-resistant packages have existed for over 100 years (Sacharow, 1988). But it took until the early 1960's for the United States Government to become actively involved and seriously investigate the situation. Initially the attention was focused on changing the environment surrounding the child by modifying the actions of adults (Maisel, 1975). Informational programs and other forms of publicity were employed to try to educate adults on the dangers of accidental poisonings, and they urged the public to lock up potentially dangerous substances or at least place them out of reach of young children. These efforts were not very effective in reducing the level of poisonings (VanGieson, 1983). Young children are curious, and if something is misplaced or left within their reach they will often pick it up and put it in their mouth (Arena, 1970).

A new preventative viewpoint soon emerged. The focus changed from modifying the child's environment to modifying the problem ingestants themselves (Maisel, 1975). This could be accomplished in many ways including changing the formulation of a product, or changing the products' packaging. In late 1970, the Food and Drug Administration (FDA) organized a committee of representatives from industry and government to set guidelines for safer packaging (VanGieson, 1983). Five main points emerged:

1- a closure should be difficult for a child to open,
2- adults should be able to easily remove and resecure that same closure,
3- instructions on the operations of the package should be provided,
4- the package should still be able to protect the product contained within, and
5- a closure should only be called "child-resistant" if it passes designated protocol tests.

At the same time the guidelines were published, Congress passed the Poison Prevention Packaging Act of 1970, Public Law 91-601 (ASTM, 1970). This Act together with the Poison Prevention Packaging Regulations, provided a foundation to begin to reduce accidental poison ingestions among young children. Enforcement of the Act and Regulations was given to the FDA, which relinquished control to the Consumer Product Safety Commission (CPSC) in 1973. In the late 1970's the Environmental Protection Agency (EPA) was given the responsibility of child-resistant packaging for pesticides (VanGieson, 1983).

The law defined a carefully chosen new term "special packaging". Special packaging was "packaging that is 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" (Code of Federal Regulations, 1987). In other words, most children should not be able to open the package, but it was recognized that it is impossible to keep all children out of all packages.

The Regulations list substances that are required to have the special packaging, organized guidelines and requirements, and set up a testing protocol. The guidelines state that a product should not interfere with the normal operation of the package, and the package should be reusable if that was the intention of the design.

Testing Protocol

The testing protocol was defined as "the procedure for testing special packaging under specific conditions to determine if the packaging fulfills the standards...to be considered a poison prevention package" (Perritt, 1975). To be labeled as a child-resistant package at least 90% of the adults tested must be able to properly operate the package including opening and closing, and at least 85% of the children must not be able to obtain access to the package contents, even after a demonstration (Code of Federal Regulations, 1987).

Before undertaking a protocol test, the testing organization must be given a complete description of the package to be tested. Any package designed to contain pills may be filled with placebos to imitate an actual package found in the home. Any closures to be tested must first be manipulated by the tester to make sure they are functioning correctly (Press, 1970). Adults may test any number of packages, but children are only allowed to manipulate two packages (Perritt, 1975).

The protocol states that 200 children, half male and half female, aged 42 to 51 months are to be tested in groups of two. This allows for competition or teamwork, and gives the children a greater sense of security by having another child present. The testing is conducted in settings familiar to the children such as a school or daycare center.

When beginning the testing, both children are handed identical packages and allowed five minutes to attempt an opening (Press, 1970). It had been reported that many children appear to lose interest if the package isn't opened after three minutes, but this is not always the case (Perritt, 1975). If the package is not opened the child will be given a visual demonstration of the opening procedure, and if they haven't used their teeth yet, told they may try that. The children are given another five minutes to work, after which the packages are removed (Press, 1970).

The protocol also states that 100 adults, 70% of which are female, between the ages of 18 and 45 years must be tested (Code of Federal Regulations, 1987). Each adult is tested individually, and given five minutes to open and properly close the package. They receive only the printed instructions that appear on the package itself, no demonstration is performed. When testing is completed the packages are removed, and the data evaluated according to the guidelines previously mentioned.

Legislation Effects

In 1972 the first legislation took effect and required the use of child-resistant packages on specified products (MacArthur, 1988). In that year, fatalities among children under five years of age who accidentally ingested poisons dropped from 216 to 149 (Maisel, 1975). By 1984 it was reported that the use of child-resistant containers reduced the number of accidental poisonings by 50% (Thein and Rogmans, 1984). But a report from the American Association of Poison Control Centers stated that in 1985 there were still over 60,000 accidental prescription drug ingestions (Jacobson et al., 1989).

An investigation was initiated studying 2,015 incidents from nine poison control centers in 1986 (Sharma, 1987). It was reported that 17% of the ingestions involved a grandparent's medication, and 14% occurred in the grandparent's home. These findings are consistent with reports that many people, especially the elderly and also the handicapped, cannot properly operate the child-resistant packages (Rider et al., 1987). One study outlined in 1970 reported that of 281 women who mentioned having some degree of arthritis, 68% had experienced difficulties in opening child-resistant closures (Tainter, 1970). Often people cannot read or understand the opening and resecuring instructions printed on the packages. Other problems can occur to compound this situation. The packages themselves may be old and not functioning properly, or the users may be transferring the medication to another container.

A survey by the CPSC in 1976 reported that 70% of the households contacted for a survey told of frustrations when using child-resistant packaging (Sharma, 1987). Almost 20% had replaced the child-resistant closures with a non-child-resistant substitute. In 1987 Western Michigan University reported that many times people will transfer medication to a non-child-resistant container, disable the child-resistant feature on a package, or simply leave the container open (Western Michigan University, 1987). Many people are resentful of being forced to use child-resistant containers if they have no small children at home (Dana, 1975).

A study conducted at Michigan State University in 1987placed articles in several women's magazines and asked readers to send in comments and suggestions relating to their experiences with child-resistant packaging (Lockhart et al, 1988.). Almost 48% of the respondents listed problems with push and turn closures. They were not able to properly perform the two dissimilar motions, and could not easily remove the closures. Specific products were mentioned, and an investigation revealed many of the problems were occurring with Type 1A Continuous Thread Closures as classified by the American Society for Testing and Materials (ASTM, 1988). These closures have an inner and an outer shell that snap together. When a downforce is exerted on the outer cap it engages with the inner cap so that a torque can be applied to the inner cap to remove the closure. If insufficient downforce is maintained when applying the torque, the outer shell will ride over the inner shell, and the closure will not be removed. Some closure constructions are such that a clicking sound will be heard, and when this happens the consumer knows the removal attempt was not successful.

Human Strength Studies

Many attempts have been made to measure human strength and relate the findings to container openings. Two separate studies on this subject have concluded that it is possible to measure strength and relate it to containers, but it must be done experimentally for each package type (Sharma, 1970, Berns, 1981).

An early study conducted in 1971 by Dr. Wilton M. Krogman for the Closure Committee of the Glass Manufacturer Institute, measured what was called a "palm-push" force in children ages 3 to 6 years (Krogman, 1970). This measurement was defined as "the total force exerted when the palm of the hand is pressed or opposed to an object, and the object is pushed against". The measurements were made when a subject pushed on a button mounted on the side of a machine. A Jamar Hand Dynamometer mounted in the machine detected the force, which was then read in pounds pressure from an analog dial.

This same piece of equipment was utilized by Western Michigan University in 1987 (Sharma, 1987). Twenty-one children aged 30 to 65 months, and twenty-eight adults aged 61 to over 85 years were tested. Readings were taken using the subject's left and right palms. The data showed the children aged 41 months and above had a similar palm-push strength as the adults aged 71 and above, in the range of 30 pounds +/- 5 pounds. The subjects were also asked to open a push and turn closure. Both the adults and the children had difficulties with the packages.

Another study conducted by the CPSC and presented in 1985 evaluated the ability of 700 adults to open child-resistant packages, and additionally measured removal force values for several child-resistant packages (Rider et al., 1987). The subject's ages ranged from 18 to 75 years. Three types of child-resistant closures were tested, a snap cap, lug-style closure, and push and turn closure, the style which was also used in this research. This closure was applied at two application torques, 10 in-lbs and 20 in-lbs, hereafter referred to as AT=10, and AT=20.

The subjects were asked to open a container, and the times to open and success rates were recorded. Overall, the push and turn closure (AT=20) was rated last. Eighty-nine percent of adults aged 18 to 45 years could open and properly reclose the container, but this dropped to less than 50% of the adults aged 71 to 75 years. These same closures were removed using a piece of equipment specially designed by the CPSC. This equipment simultaneously measures the downforce to open, and the removal torque. This testing was conducted by CPSC operators. Again the push and turn (AT=20) ranked last, requiring between 17.2 and 22.5 pounds for removal.

Although the previous work yielded important information about human strength and the ability of adults to open child-resistant packages, no study has been found that directly measures the downforce a subject exerts when removing a CR closure.

Machine Minimum Downforce Measurements

ASTM D3471-82 describes a test method to determine the "top-load-to-engage", or minimum downforce value to engage the removal lugs on a Type 1A child-resistant closure (ASTM, 1988). To conduct the test, representative closures are applied to bottles which are placed in a torque measuring device. Weight is applied to the closure until a specific removal torque value can be reached by rotating the closure. This test method requires an operator to manipulate the closure during the test by rotating the closure, and by manually placing weights on a weight collar. For this research, the concept of "top-load-to engage" was used to devise a modification of the ASTM Standard Method.

An automated torque testing machine was used to determine the minimum downforce to remove the test closures. The machine was calibrated with dead weights according to the manufacturers instructions before undertaking any testing. An operator runs the machine through an interfacing computer keyboard, therefore eliminating any operator variability. The force values were input in the system in one pound increments starting at a value below the suspected minimum downforce as determined by preliminary testing. A value was considered to be the minimum downforce if the force caused the two pieces of the closure to engage, and the machine to remove the closure. The resulting removal torque was shown by the machine, but a torque value did not determine a minimum downforce value as dictated in the ASTM standard. For a description of the operation see the Materials and Methods section.

MATERIALS AND EXPERIMENTAL METHODS

Materials

Closures/Bottles

Four different 38 mm child-resistant closures were utilized in this study. They are considered type IA according to ASTM D3475-83 (ASTM, 1988). All four were molded from polypropylene in a two-piece push-and-turn style, but each had a different inner structure, and they were supplied by four different manufacturers. The caps tested were:

Van Blarcom Saf-Cap 1

Sunbeam FG "H" Series

Kerr CR1

Owens-Illinois Clic-Loc II.

The liners used in the closures were of a similar pulp/aluminum foil/saran coated material.

The Van Blarcom Saf-Cap 1 samples were obtained from Van Blarcom Closures, Inc. in Brooklyn, NY. The Saf-Cap 1 had a liner retaining ring built into the inner shell to hold the liner in place.

The Sunbeam FG "H" Series closures were obtained from Sunbeam Plastics Corporation in Evansville, IN. This liner was glued into place.

The Kerr CR1 closures were obtained from the Kerr Glass Manufacturing Corporation in Lancaster, PA. The liner had a lubricating finish of microcrystalline wax,and was glued into place.

Lastly, the Owens-Illinois Clic-Loc II was obtained from Owens-Illinois, Inc. in Toledo, OH. A lubricating film of microcrystalline wax was applied to the liner which was glued into place.

Hereafter the closures will be referred to as number one through number four, but the identity of each will not be specified. This was done due to the funding requirements of the research, and the cooperative nature of the suppliers involved.

All four closures operate in similar fashion during application and removal. They are composed of a separate inner cap and outer shell which snap together. They all have a positive-on feature which, through a series of lugs, springs, or another systems, automatically connects the two shells to allow for easy securing when a clockwize torque is applied. To perform a removal, it is necessary to apply a downforce and counterclockwize torque. This motion is referred to as simultaneous dissimilar motion. The downforce acts to engage the inner and outer pieces of the closure, allowing the two pieces to move as one when a torque is applied, which allows closure removal. If the downforce is not sufficient, or not kept at the correct level, the two pieces will separate, and the outer shell will slide over the inner cap resulting in a non-removal situation.

The bottles used in this study were obtained from the UpJohn Company in Kalamazoo, MI. They were molded from high-density polyethylene containing titanium dioxide and zinc stearate. They had a nominal capacity of 130 ml, a finish size of 38mm, and were square in shape.

Instrumented Bottle

An instrumented bottle was designed to use with human subject testing. A block of wood was worked into the shape of a bottle, and cut into two pieces. An Omega DS-350 force transducer was mounted between the blocks, and four stabilizer bars placed at the corners to prevent relative rotation of the two wooden pieces (Figure 1). A test bottle was cut apart, and the lower section placed over the bottom block. To operate the instrumented bottle, a closure was applied to a test bottle, and the bottle cut to a specified height. The top section of the bottle containing the closure was then placed over the top wooden block. The bottle was handed to a subject who was asked to remove the closure by mimicing an actual opening situation. When a subject applied a downforce to the top section of the instrumented bottle, the force transducer would detect the force and relay it through an Omega DP-350 digital pressure indicator to a Linseis L6012 strip chart recorder. The pressure indicator and strip chart recorder were calibrated using dead weights to record force, in tenths of a pound, used by the subject when

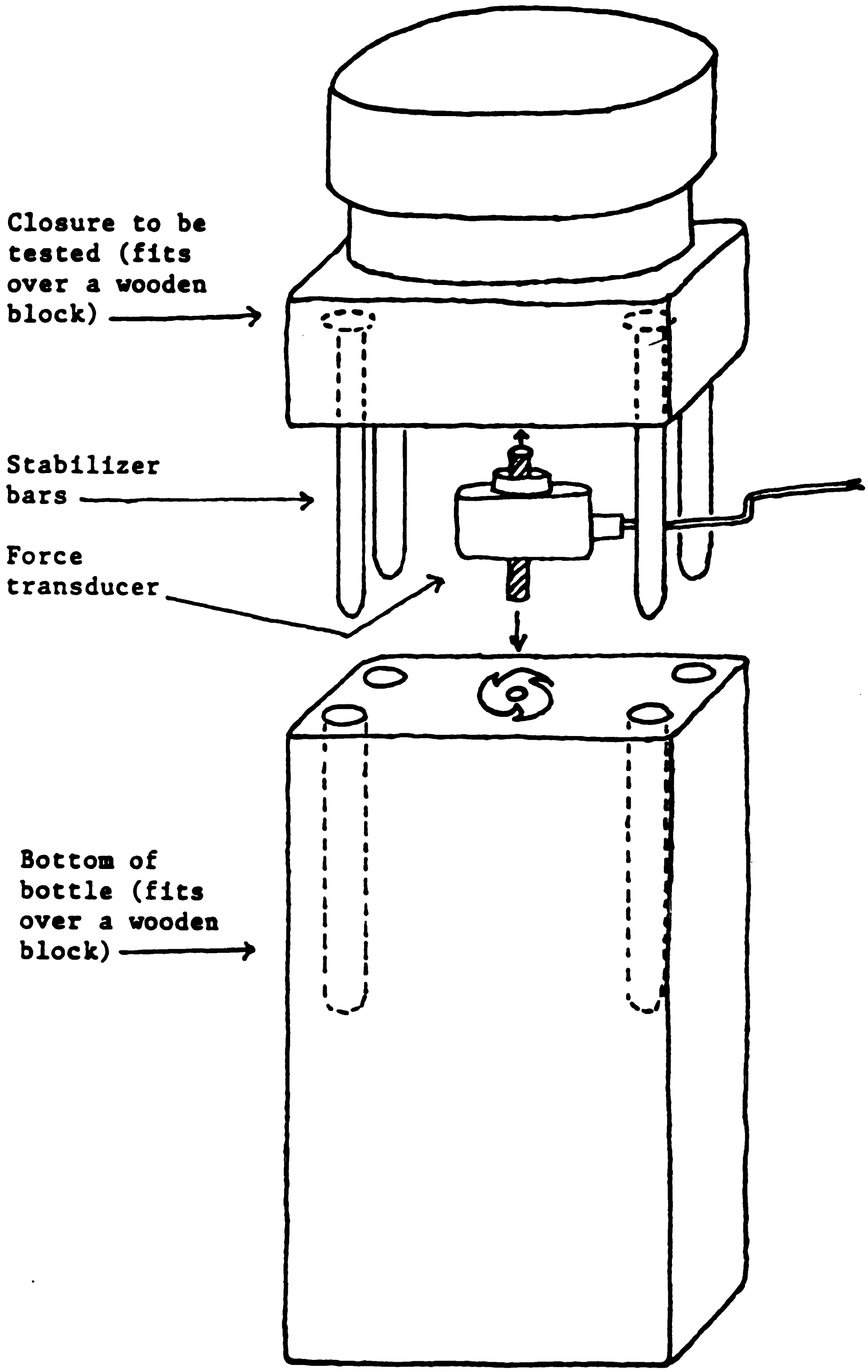

Figure 1. Sketch of the instrumented bottle used in the human subject testing (not drawn to scale).

opening the closure. This gave a hard copy of data to be used for evaluation purposes. The recorder chart was operated at a speed of 12 inches per minute.

Auto-Torque Tester

An automated torque testing machine was received on loan from Automated Dynamics Corporation. This machine interfaced with an IBM XT computer and an Epson LX-800 Series printer. The Auto-Torque was capable of applying and removing push-and-turn child-resistant closures. It generated tables and graphs from these tests. An operator would input dimensional information into a file which was later recalled to perform a test.

Before conducting any testing, the Auto-Torque was calibrated to read to one/one-hundreth of a pound according to the manufacturers instructions.

To conduct an application of a closure, the operator places the closure on the bottle and turns it until the first resistance is felt. This positions the closure properly so the machine can apply a torque. The bottle is then set on a plate inside the Auto-Torque. The operator recalls the dimensional information from the computer memory for the specific bottle and closure. In the application mode, the computer asks for an application torque and downforce. After both of those variables are entered, a set of four jaws on the plate closes upon the bottle to hold it securely in place. Next an upper plate descends, stopping just short of the top of the closure. An upper set of three jaws on this plate closes upon the closure and the machine applies the specified downforce. The upper plate and the jaws rotate, and applies the specified torque. When the proper torque value is reached, the upper jaws stop rotating, and open to release the closure. The upper plate rises, and the lower jaws open to release the bottle. The operator removes the bottle and by a slight manipulation of the closure, can tell that the application was successful. The computer then plots a graph showing the torque and downforce changes during the application as a function of time. It also prints the highest torque value reached during the application.

To conduct a removal, the bottle is once again placed on the plate, and the dimensional information again recalled. The operator chooses the removal test command, and is asked to specify a removal downforce value. The lower jaws close around the bottle, and upper jaws move into position. The Auto-Torque applies the downforce, and begins the removal rotation. If the downforce is sufficient to allow the two shells of the closure to engage, the torque from the machine allows removal of the closure. If the downforce is not large enough to keep the two parts engaged, the torque will not remove the closure, and the outer cap would slide over the inner cap. If this occurs, the operator can repeat the test, but increase the downforce value in increments of one pound. This procedure is repeated until the closure is removed. The downforce applied at the time the closure was removed is called the minimum downforce to remove.

In all of the applications performed, the application torque used was 19 in-lbs (United States Pharmacopeia, 1985). No information was available on actual application downforces used in industry, and 10 pounds was chosen as a standard.

Additional Equipment

An Owens-Illinois Spring Torque Tester was used during the human subject testing to resecure some of the closures. It was not convenient to resecure the numbered closures between test subjects using the Auto-Torque, so they were reapplied to 19 in-lbs on the Owens-Illinois Torque Tester. The torque tester used has been calibrated according to the ASTM standard method D3474-80 (ASTM, 1988).

Additionally, the Auto-Torque malfunctioned during the time the human subject testing was being conducted, so a portion of the closures to be used with the instrumented bottle were applied with this tester. This was feasible for this testing, as a study presented in 1988 showed no statistically significant differences between using the Auto-Torque and an Owens-Illinois Spring Torque Meter (Automated Dynamics Corporation, 1988).

Experimental Methods

Auto-Torque Tester

It was recognized that it would be impractical to try to apply closures immediately before removal by human subjects because of the time required for application and because of scheduling requirements for machine use and subject interview times. Therefore, a time interval was determined over which the removal torques for the closure systems would not change from day to day. So, before beginning any testing, an optimal time period between application and removal was determined. A short torque degradation study was conducted over a six day period. Removal torque was measured at time zero (immediate removal) and after 4, 5, and 6 days. An assumption was made that if the torque was not changing rapidly over a time period neither would the associated downforce value. After analyzing the torque data, a time period of five days was chosen. After five days the removal torque had changed relative to time zero, but not when comparing to four or six days.

All closures, whether to be removed by machine or by subjects, were set up to be applied on the Auto-Torque. This would remove any possible operator variability. Part way through the subject testing the machine malfunctioned, so the last few closures were applied using the Owens-Illinois Spring Torque Tester. To keep operator variability at a minimum, only one operator performed the applications.

Sixteen of each of the four closures were tested. The applications were performed over a four day period. After storage for five days the closures were removed using an estimation of the minimum downforce required to open each closure. It was decided to begin testing at two pounds below the lowest recorded downforce value for each closure determined from previous testing. This was done to insure that no closure would be removed on the first removal attempt. The exception was closure 2. Previous testing showed the removal force to be close to 2 pounds. The machine operates in increments of 1 pound, and so the testing was started using a downforce of 1 pound. The resulting minimum downforces for each closure were:

Closure 1	6 pounds
Closure 2	1 pound
Closure 3	6 pounds
Closure 4	4 pounds

The differences in the forces are due to the different inner structures of the closures. The downforce required depended on whether the closure had a spring system that had to be compressed, lugs to be pushed into a slot, or another method of mating the two pieces.

Preliminary Work - Human Subject Testing

This study was designed to look at four different adult age groups: 25-45, 46-55, 56-65, and 66-85 years. It was felt that starting at age 25 many subjects would have small children in their home, or friends visiting with young children. At ages up through 85, the subjects may have grandchildren visiting. Within each group, four men and four women were tested. To qualify as a valid test subject, the person had to be living in a non-institutionalized setting, and have the ability to self-administer medication. Volunteers were located through local advertising, and a local Kiwanis Club.

Before testing, the way in which people grip bottles and closures was studied. This was done by handing a random group of people a bottle/closure system, and observing how the bottle and closure was held. Several variations were found and these were coded and later listed on every subject's questionnaire (Appendix A, Tables 1-4). Two main closure grips were found, one using the fingers and thumb in some variation of a pincher grip, and another where the palm of the hand is applied to the top and around the circumference of the top panel. Six main bottle grips were used. A subject could place the bottle on the table surface and lean to open, or place the bottle against their leg and push. The bottom of the bottle could rest on a subject's palm. The subject could place all four fingers around the bottle, or place the little finger, or ring and little finger underneath for support.

A questionnaire was developed for the purpose of obtaining information about subject's perceptions of useability of closures (Appendix B). The first page was used for basic demographic information, and to determine if a subject was familiar with the closures being tested. To help clarify this, samples of all four closures were applied to bottles, which were placed in front of the subject for viewing. On the second page subject's were asked about the ease of opening of all four closures, which has been coded as the Scaling question (Meilgaard, 1987). A line for each closure ran horizontally on the page. The left end point was labelled "Very Easy to Open" and the right end point was labelled "Very Hard to Open". The subject would open a closure, and then placed a slash along the line indicating his opinion of the opening. The distance between the left end point and the slash mark was measured to the nearest 0.1 inch, and this data was recorded for later analysis.

On the third page subject's were asked about how well they liked each closure, which has been coded as the Acceptance question. Each closure was removed separately, and the response immediately marked on a separate scale. For this test, a nine point scale was used which ran from "Extremely Well Liked" to "Extremely Dislike". The subject would place an "X" in a box next to the correct response. Each box was later assigned a number from one to nine, a one corresponding to "Extremely Well Liked" and a nine corresponding to "Extremely Dislike".

The fourth page asked the subject to order the four closures from one through four in comparison with each other according to their overall Preference. The closures were placed side by side, and the subject based his decision on a direct comparison. They were allowed to manipulate the closures if desired, but were not allowed to look at their scoring on the previous two pages.

The final page was never given to the subject. On that sheet the experimenter listed the hand positions the subject used during the removal attempts, and the order in which the closures were opened.

Testing Procedure

Upon arrival, the subject was ushered individually into a designated room and given a place to sit at a table. The rooms chosen were relatively small in size, and free from distractions. The subject was handed the first page of the questionnaire, and asked to take a moment to complete the page. Every subject was assigned a number to insure confidentiality. This number was placed on all the pages used by the subject. A sample of each of the four closures was placed on the table to show what types of closures they would remove.

When finished, the subject was taken to another table where the equipment was set up, and given a choice of sitting or standing. They were instructed that they would be asked to open four different closures and rate these on three different scales. They would also be opening the same four closures using an instrumented bottle to obtain a force measurement.

A sample of each closure had been applied to bottles using the Owens-Illinois Spring Torque Tester at an application torque of 19 in-lbs. These four bottles were marked using a numerical code to distinguish the closure styles.
All four bottles were placed in a brown kraft bag. Pages two and three of the questionnaire; Scaling and Acceptance questions; were placed side by side in front of the subject. The subject was instructed to choose one bottle from the bag, note the code number on both pages, and

remove the closure. They were reminded that they could stand or sit, and that they were free to try to remove the closure in any way they wanted. After a removal, whether successful or not, the subject ranked the closure on both scales. Next, the same closure style was placed on the instrumented bottle and given to the subject. The strip chart recorder was turned on, and the subject asked to remove the closure. When finished, the subject was asked to choose another bottle from the bag, and repeat the procedure until all four had been tested.

Lastly, the four closures and bottles were again placed in front of the subject along with the fourth page of the questionnaire. The subject was asked to compare the closures side by side, and rank them on the Preference scale of one through four, one being the closure they preferred the most overall, four being the closure they least preferred overall. The subject was told to reclose and reopen the containers as desired to help in the rankings. They were not allowed to look at their previous responses from the Acceptance and Scaling questions.

When the subject finished, they were shown the inner structures of all four closures, and informed about how the downforce operated to connect the two pieces and allow for removal.

ANALYSIS OF DATA

The data was analyzed using several different techniques.

Machine Minimum Downforce Measurements

The machine minimum downforce measurements were set up in a completely randomized design. The data from the testing can be found in Table 5.

A One-Way Analysis of Variance was performed on the machine downforce data (Table 6). The calculation revealed a highly significant difference between the downforce values for the four closures at a confidence level of 99.9%. This analysis showed a difference, but did not tell which closures were different from each other. Tukey's Honestly Significant Difference Test (Tukey's Test) was performed on the data to reveal which closures were different from each other (Table 7). Tukey's showed that there was no significant difference between closures 1 and 3, and closures 1 and 4.

Table 5. Data from the Machine Minimum Downforce Measurements from the Auto-Torque testing.

Downforce (lbs)

Sample Number	Closure # 1	2	3	4
1	10	1	10	8
2	9	1	8	8
3	9	1	12	7
4	9	1	9	8
5	8	1	9	9
6	8	1	12	8
7	8	1	7	8
8	7	1	8	6
9	7	1	9	6
10	10	1	8	8
11	8	2	9	9
12	7	1	7	8
13	10	1	9	7
14	8	1	9	8
15	7	1	10	6
16	8	1	10	9
$\bar{X}$	8.38	1.06	9.13	7.69
s	1.09	0.25	1.45	1.01

Table 6. One-way Analysis of Variance for the Machine Minimum Downforce Measurements.

Source of Variation	df	F-Value
Total	63	
Treatment (downforce)	3	200.95**
Error	60	

**significant at alpha = 0.01

Table 7. Tukey's Test for the Machine Minimum Downforce Measurements, looking for differences between individual closures.

Closure #	Mean (pounds)	Ranked Order
3	9.13	A
1	8.38	AB
4	7.69	B
2	1.06	C

alpha = 0.05

But there was a significant difference between closures 3 and 4, and between closure 2 and closures 1, 3, and 4. Closure 2 had the lowest minimum downforce reported at a mean value of 1.06 pounds, followed by closure 4 at 7.69 pounds, closure 1 at 8.38 pounds, and lastly closure 3 at 9.13 pounds.

Human Subject Testing

Fourty-one subjects were tested, but the data from only the first eight (four male and four female) in each age group was used in the analysis (Appendix C, Table 8). The additional subjects were tested to assure there would be 32 sets of usable data. There were no problems encountered during the testing, and the raw data from all 41 subjects, for all the questions, can be found in Appendix D, Tables 9-12.

The human subject data was evaluated by using two different techniques. The data from the Acceptance and Scaling questions, and from the Subject Downforce Measurements was analyzed by a Split-Plot Analysis of Variance of a completely randomized design. This experimental design is capable of handling factorial treatments. For this research, there are two factors in the main plot (age and sex), and one factor in the subplot (closure type). Calculating a Split-Plot Analysis of Variance is similar to a One-Way Analysis of Variance, but there are two resulting error terms, one from the main plot and one from the subplot. Four age groups and the two sexes were tested, creating eight possible factorial combinations, or treatments. These eight treatments were tested randomly, subjects of a certain age and sex were not tested in any set order. For each subject, all four closures were also tested randomly by having the subject select one at a time from a bag.

The data from the Preference question was evaluated by using Friedman's Two-Way Analysis of Variance. Friedman's test is used to examine sample data that has been ranked on an ordinal scale (Siegel, 1956). It helps determine whether the differences between the samples indicate that they are from one population, or different populations.

There were instances where subjects were not able to successfully remove the closures being tested. This data was still used in all of the calculations. This was done because the testing was set up to get consumer perceptions and a measure of what forces will be exerted to try to remove a closure. Obviously there are many instances at home where a closure cannot be easily removed. It was felt that the maximum force exerted, whether from a successful removal or not, was a measure of what the subject was capable of generating, and this was viable information to including in the data analysis.

The age groups have been listed using a code number to represent each group. Age group 1 is the subjects whose ages fall in the range of 25 to 45 years old, age group 2 is the subjects whose ages run from 46 to 55 years, group 3 runs from 56 to 65 years, and lastly, group 4 runs from 66 to 85.

Acceptance Question

A Split-Plot experimental design was utilized to set up and evaluate the data from the Acceptance question. The data can be found in Table 13. This question is used to ask the subjects about their like or dislike of the

Table 13. Data from the Acceptance question of the human subject testing.*

Age	Sex	Closure # 1	2	3	4
35	M	4	4	5	3
35	M	3	2	7	4
35	M	3	6	3	5
35	M	6	2	4	3
35	F	6	2	8	6
35	F	8	7	2	2
35	F	2	2	4	8
35	F	2	2	2	3
50	M	2	2	5	5
50	M	2	2	2	2
50	M	5	2	2	4
50	M	3	2	1	3
50	F	4	2	7	5
50	F	6	3	4	7
50	F	4	1	2	6
50	F	2	3	2	2
60	M	6	4	7	7
60	M	6	3	5	6
60	M	4	3	4	5
60	M	7	2	2	2
60	F	6	4	3	7
60	F	6	8	9	7
60	F	3	2	3	3
60	F	8	3	7	2
70	M	5	7	3	7
70	M	5**	4	7	6
70	M	6	2	8	4
70	M	2	1	2	1
70	F	3	1	9**	9**
70	F	3	2	1	3
70	F	7**	3	8**	8
70	F	3	1	9**	9**

*The choices run from one to nine. A "1" is "Extemely well liked" to a "9" being "Extremely dislike".

**Subject was not able to remove the closure from the test bottle.

closure removal. A value of "1" means the closure removal was "Extremely well liked", a "5" means the removal was "Neither liked nor disliked", up to a "9" meaning the removal was "Extremely dislike".

The results from the analysis of variance are shown in Table 14. There was an effect due to the age groups tested, and to the closure type. An effect due to the interaction of sex and closure type was noted, but further analysis of this was not possible. To determine any differences between the individual age groups for the Acceptance question (combining the closures into one group as a whole), a Tukey's Test was performed on the data (Table 15). It was found that there was no statistically significant difference between any of the age groups. This can be explained because Tukey's is a very stringent test, and the mean values were just not far apart enough to yield any statistically significant differences between them. A lower value for the Acceptance question means that the subject liked the closure better. The group 2 mean was 3.0, followed by group 1 at 3.88, group 3 at 4.47, and lastly group 4 at 4.81. The values of 3 to roughly 5, puts the responses in the range of "Moderately

Table 14. Split-Plot Analysis of Variance performed on the data from the Acceptance question of the human subject testing.

Source of Variation	df	F-Value
Total	127	
Main Plot	17	
Age	3	3.26**
Sex	1	0.31
Age x Sex	3	1.35
Error 1	24	
Sub Plot	31	
Closures	3	6.73***
Age x Closures	9	1.08
Sex x Closures	3	2.60*
Age x Sex x Closures	9	1.30
Error 2	72	

*significant at alpha = 0.10
**significant at alpha = 0.05
***significant at alpha = 0.01

Table 15. Tukey's Test performed on the Acceptance question data of the human subject testing, looking for differences between the age groups.

Age Group	Mean (units)	Ranked Order
4	4.81	A
3	4.47	A
1	3.88	A
2	3.00	A

alpha = 0.05

Table 16. Tukey's Test performed on the Acceptance question data of the human subject testing, looking for differences between the individual closures.

Closure #	Mean (units)	Ranked Order
3	4.91	A
4	4.66	A
1	3.31	B
2	3.28	B

alpha = 0.05

liked" to "Neither liked nor disliked".

An effect due to the closure tested was noted from the Acceptance analysis. Tukey's Test was used to look for the differences between the individual closures (Table 16). It was found that the means for closures 1 and 2 were significantly different from the means of closures 3 and 4. This indicates that closures 1 and 2 were liked better than closures 3 and 4. The means for closure 1 and 2 were very close, at 3.31 and 3.28 respectively; followed by closure 4 at 4.66 and closure 3 at 4.91.

Scaling Question

The Scaling question was used to obtain information about whether a subject thought the closure removals were easy or difficult. A subject places a slash along a six inch line corresponding to the ease of opening. The left end point was labeled "Very easy to open" and the right end point labeled "Very hard to open". The distance from the slash mark to the left end point was measured and recorded. The data can be found in Table 17.

Table 17. Data from the Scaling question of the human subject testing, in units of 1/10".*

Age	Sex	Closure # 1	2	3	4
35	M	0.8	0.8	1.3	0.9
35	M	0.9	0.5	3.1	1.9
35	M	1.7	0.3	2.0	0.9
35	M	3.9	2.1	3.7	5.4
35	F	2.9	0.5	4.6	3.2
35	F	6.0	5.0	0.7	0.7
35	F	1.1	0.4	2.1	5.1
35	F	0.5	0.4	0.5	0.8
50	M	1.4	1.5	1.9	1.8
50	M	1.1	0.8	1.1	0.8
50	M	1.4	0.3	0.2	1.2
50	M	3.3	2.3	3.1	3.4
50	F	2.2	0.8	3.9	2.5
50	F	4.3	1.6	4.4	5.0
50	F	3.0	0.4	0.9	5.4
50	F	1.3	0.5	1.4	0.6
60	M	3.4	2.8	4.9	4.8
60	M	5.1	2.8	3.7	5.1
60	M	1.8	0.7	1.1	1.2
60	M	4.7	0.8	0.9	1.1
60	F	2.9	1.3	0.8	3.6
60	F	3.7	4.5	5.1	3.9
60	F	0.8	0.4	1.0	1.0
60	F	4.9	0.7	3.8	0.3
70	M	1.5	3.1	0.3	2.9
70	M	3.4**	2.2	4.4	3.9
70	M	3.4	1.2	5.3	2.5
70	M	1.3	0.3	1.3	0.4
70	F	1.1	0.7	5.1**	5.0**
70	F	0.5	0.3	0.3	0.3
70	F	4.7**	1.3	4.8**	5.5
70	F	1.7	0.1	5.7**	5.7**

*The scale runs from 0.1" to 6.0". A 0.1" is "Very easy to open" to a 6.0" which is "Very hard to open".

**Subject was not able to remove the closure from the test bottle.

The Split-Plot Analysis of Variance performed on the Scaling question data showed an effect due to the closure type tested and a slight effect due to the interaction of sex and closure type (Table 18). Tukey's Test was utilized to determine which of the closures were different from each other (Table 19). There was no significant difference noted between closures 1, 3, and 4, but closure 2 was different than the other three. The mean value for closure 2 was lower than the others at a level of 1.30", followed by closure 1 at 2.16", closure 3 at 2.64 ", and lastly closure 4 at 2.79". A lower scaling value shows that the subject felt the closure was easier to open. This evaluation indicates that the subjects felt closure 2 was easier to remove than the other closures. The exact reasons again are not evident, but it may be partially due to the inner construction of closure 2 as compared to the other closures. An explanation of the inner constructions is provided later in this section.

Again, as in the Acceptance question, an interaction was noted between the sex of the subject and the closure type tested, but it was not possible to analyze the interaction to determine which sex /closure effect differed.

Table 18. Split-Plot Analysis of Variance performed on the data from the Scaling question of the human subject testing.

Source of Variation	df	F-Value
Total	127	
Main Plot	17	
Age	3	1.21
Sex	1	0.00
Age x Sex	3	0.52
Error 1	24	
Sub Plot	31	
Closures	3	10.21***
Age x Closures	9	0.97
Sex x Closures	3	2.48*
Age x Sex x Closures	9	1.25
Error 2	72	

*significant at alpha = 0.10
**significant at alpha = 0.05
***significant at alpha = 0.01

Table 19. Tukey's Test performed on the Scaling question data of the human subject testing, looking for differences between the individual closures.

Closure #	Mean (1/10")	Ranked Order
4	2.79	A
3	2.64	A
1	2.16	A
2	1.30	B

alpha = 0.05

Subject Downforce Measurements

The Subject Downforce Measurements were taken to gather information about what level of forces are exerted to try to remove a closure. The data can be found in Table 20. The Split-Plot Analysis of Variance showed a slight effect due to the subject age group, and an effect on downforce due the type of closure involved (Table 21).

Tukey's Test on the effect of age group on downforce showed no significant differences between any of the age groups (Table 22). The mean downforce for age group 2 (46-55 years) was the lowest at 14.21 pounds, followed by group 1 (25-45 years) at 17.26 pounds, group 4 (66-85 years) at 17.88 pounds, and lastly group 3 (56-65 years) at 22.47 pounds).

Tukey's was utilized to determine which closure was different (Table 23). Tukey's Test showed that closures 1, 3, and 4 were not significantly different from each other, but closure 2 was different from all of them. Closure 2 had a lower mean downforce value at 14.26 pounds, and it can be said that the subjects used less

Table 20. Data from the Subject Downforce Measurements in units of pounds.

Age	Sex	Closure #			
		1	2	3	4
35	M	16.9	11.2	21.3	13.4
35	M	21.2	13.3	15.5	17.8
35	M	19.6	6.0	22.6	15.0
35	M	22.0	13.0	11.0	14.4
35	F	30.0	23.4	42.1	27.0
35	F	20.3	17.5	23.2	13.4
35	F	16.6	12.5	15.6	16.1
35	F	15.5	9.6	17.2	18.2
50	M	21.8	12.7	10.1	23.7
50	M	17.3	12.3	8.6	19.1
50	M	12.4	5.5	13.3	6.6
50	M	7.6	8.5	14.9	13.5
50	F	9.5	9.4	19.6	16.1
50	F	26.4	18.1	21.1	21.9
50	F	13.3	9.4	13.4	16.5
50	F	18.4	4.2	16.6	12.9
60	M	14.3	12.5	19.0	19.5
60	M	42.3	21.4	43.8	23.6
60	M	25.2	25.4	24.7	15.9
60	M	12.6	17.8	18.5	15.5
60	F	29.4	26.4	25.3	36.5
60	F	36.4	36.5	46.8	24.9
60	F	18.9	18.3	21.2	17.6
60	F	17.2	15.9	15.8	20.6
70	M	36.2	32.4	23.9	33.1
70	M	11.9*	5.6	24.1	17.0
70	M	23.1	14.6	28.6	21.7
70	M	15.7	9.6	15.5	9.7
70	F	16.1	17.0	13.6*	21.2
70	F	22.5	20.5	25.4	22.4
70	F	11.1	9.5	9.6*	11.4
70	F	14.5*	14.7	10.4*	9.5*

*Subject was not able to remove the closure from the instrumented bottle.

Table 21. Split-Plot Analysis of Variance performed on the data from the Subject Downforce Measurements of the human subject testing.

Source of Variation	df	F-Value
Total	127	
Main Plot	17	
Age	3	2.36*
Sex	1	0.43
Age x Sex	3	0.90
Error 1	24	
Sub Plot	31	
Closures	3	9.17***
Age x Closures	9	0.55
Sex x Closures	3	0.70
Age x Sex x Closures	9	0.70
Error 2	72	

*significant at alpha = 0.10
**significant at alpha = 0.05
***significant at alpha = 0.01

Table 22. Tukey's Test performed on the Subject Downforce Measurement data of the human subject testing, looking for differences between the age groups.

Age Group	Mean (pounds)	Ranked Order
3	22.47	A
4	17.88	A
1	17.26	A
2	14.21	A

alpha = 0.05

Table 23. Tukey's Test performed on the Subject Downforce Measurement data, looking for differences between the individual closures.

Closure #	Mean (pounds)	Ranked Order
3	19.75	A
1	19.54	A
4	18.26	A
2	14.26	B

alpha = 0.05

downforce to try to remove this closure type as compared to the others. Closure 4 had a mean value of 18.26 pounds, followed by closure 1 at 19.54 pounds, and closure 3 at 19.75 pounds.

Preference Question

The Preference question was utilized to obtain a ranking of the closures based on overall preference. The closures were placed in the order of 1 through 4, a "1" meaning the closure was the most preferred overall to a "4" used for the closure least preferred overall. The experimental design allowed for ties, which occurred four times. The data can be found in Table 24.

The data was analyzed using Friedman's Two-Way Analysis of Variance. This technique is used to calculate two values; R_j and Xr^2. The R_j value is found by summing the data for each of the closures. If all four closures are from the same population the R_j values will be similar, and the ranking of the closures just a matter of chance. If the closures are from different populations the R_j values will

Table 24. Data from the Preference (ranking) question of the human subject testing.

Age	Sex	Closure # 1	2	3	4
35	M	1	2	3	4
35	M	2	1	4	3
35	M	2	4	1	3
35	M	4	1	3	2
35	F	2	1	4	3
35	F	4	3	2	1
35	F	3	1	2	4
35	F	2	1	4	3
50	M	2	1	3	3
50	M	4	1	2	3
50	M	3	1	4	2
50	M	1	2	4	3
50	F	4	1	3	2
50	F	4	1	3	2
50	F	2	1	3	4
50	F	2	3	1	4
60	M	4	1	3	2
60	M	2	3	1	4
60	M	4	1	2	3
60	M	2	2	2	4
60	F	3	2	1	4
60	F	4	1	3	2
60	F	4	1	3	2
60	F	4	2	3	1
70	M	4	2	1	3
70	M	2*	1	4	3
70	M	3	1	4	2
70	M	3	3	4	1
70	F	1	2	3*	4*
70	F	4	2	2	2
70	F	2*	1	3*	4
70	F	2	1	4*	4*

*Subject was not able to remove the closure from the test bottle.

be different. The Xr^2 value is used in comparison with a chi square table, using k-1 degrees of freedom, to test whether the R_j values differ significantly.

The Friedman's Two Way Analysis of Variance was first calculated separating the male and female subjects to test for an effect due to sex (Table 25). Both groups showed a significant difference at a high level of confidence, the males at 98% and females at 99.9%. This signifies that both sexes felt that there was a significant difference between the closures when ranked by overall preference, and that this difference was not due to chance.

Looking at the calculated R_j for males and females, closures 1, 3, and 4 have very similar values. Closure 2 has an R_j that is almost half of the other closures. This appears to be the closure that the males and females felt was different from the other closures. Closure 2 was the most preferred overall by males and females, and there were no apparent differences noted between the other three closures for this question.

Table 25. Friedman's Two-Way Analysis of Variance by Ranks performed on the Preference question data to look for an effect due to sex.*

Closure #	Male	Female
	R_j	R_j
1	43	43
2	26	22
3	46.5	46.5
4	44.5	48.5
Xr^2	10.03	16.78
Confidence Level**	98%	99.9%

*The male and female data was calculated separately to determine if an effect due to sex group was evident. Each sex group contained 16 subjects.

**This was determined by comparison with a chi square table according to the Friedman's test.

Friedman's test was also used to check for any effects due to the age groups tested (Table 26). Because there was such a high level of agreement between the male and female subjects, the sexes were combined into one group in each age category. When looking at the Xr^2 values from this calculation, all four age groups, at a confidence level of 90%, agree there is a significant difference between the closures. Only age group 2, ages 46-55, showed a higher level of confidence at 95%. This indicates that all the age groups noticed a significant difference between the closures for overall preference, and this was not due to chance.

The R_j for closures 1, 3, and 4 were in the same range for all the age groups, but closure 2 was lower. All the age groups noted a significant difference among the closures, and this was due to closure 2. Closure 2 was the most preferred overall, and with the highest confidence among the age group of 46-55 year olds.

Table 26. Friedman's Two-Way Analysis of Variance by Ranks performed on the Preference question data to look at a possible age group effect.

	Age Groups*			
Closure #	1	2	3	4
	R_j	R_j	R_j	R_j
1	19	22	24	21
2	13	11	12	12
3	25	23.5	20	24.5
4	23	23.5	24	22.5
Xr^2	6.3	8.21	7.2	6.86
Confidence Level**	90%	95%	90%	90%

*The age group data was calculated separately to determine if an effect due to age was evident. Each age group contained eight subjects, four male and four female. Group 1 contained subjects aged 25-45 years, group 2 was ages 46-55 years, group 3 was 56-65 years, and group 4 was ages 66-85 years.

**This was determined by comparison with a chi square table according to the Friedman's test.

General Trends

Although it is not possible to correlate the subject downforce measurements to the machine minimum downforce values due to different sample sizes, and a need to repeat the experiment several times to validate such a comparison, some general trends can be seen from the data. Tukey's Test on the subject downforce measurements (Table 23) shows closure 2 is different from the others, and has a lower mean downforce value. The subjects used less downforce when removing this closure as compared to the others. Tukey's Test on the machine minimum downforce readings (Table 7) also showed closure 2 as different from the others, and at a much lower mean value. A general trend can be noted that both the subjects and the machine testing revealed closure 2 as requiring the lowest amount of downforce for a removal.

This may be due to the inner construction of that closure. Closure 2 has a series of over 50 small angled ribs on the outside wall of the inner shell, and the same angled ribs on the inside wall of the outer shell (Figure 2). Exerting a downforce causes these ribs to fit together and

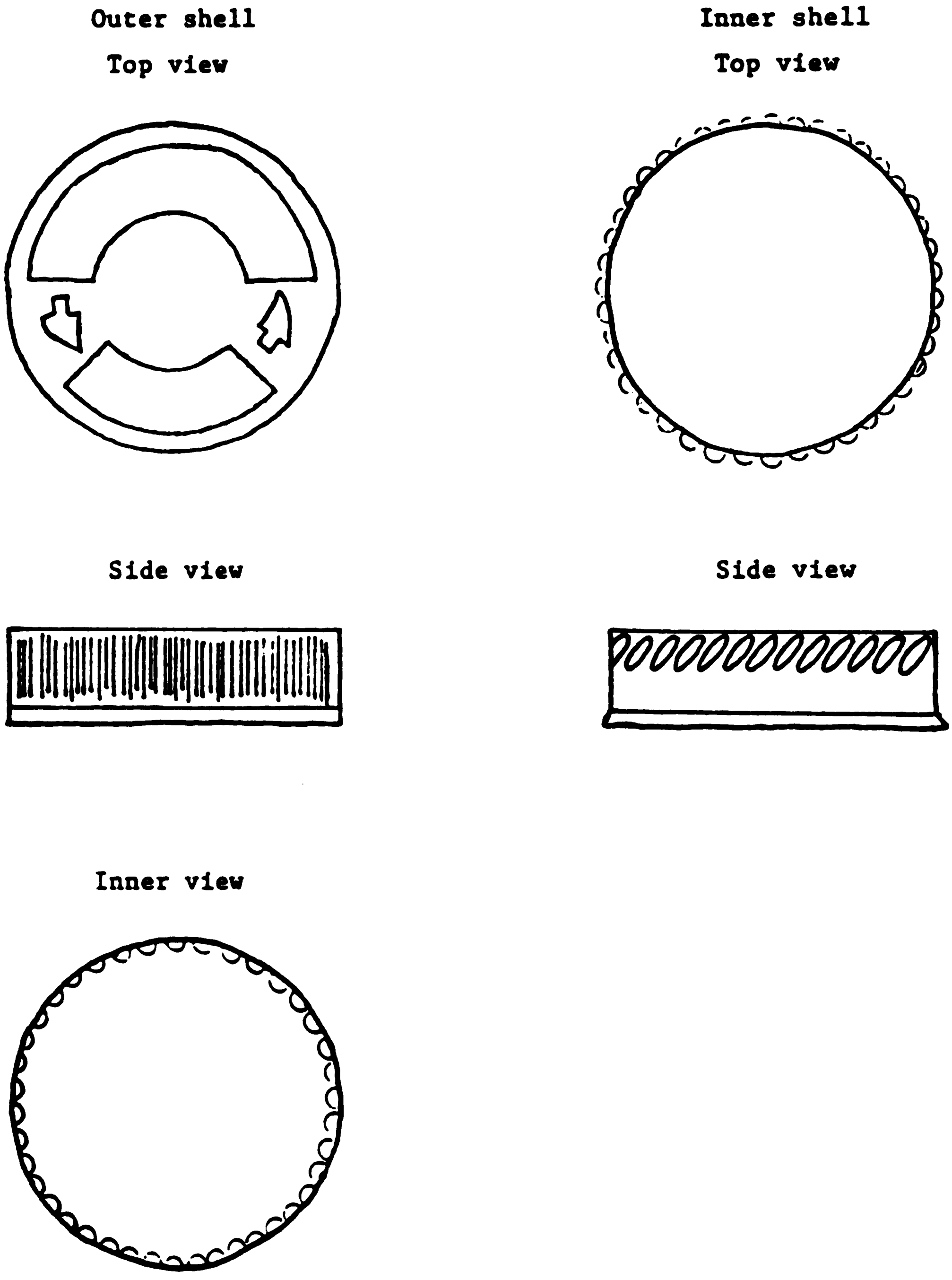

Figure 2. Inner construction of closure 2 (not drawn to scale).

allows a torque to be applied for a removal. Comparing this construction; closure 1 has six projections on the inside of the top of the outer shell that connect with slots on the top of the inner shell when a downforce is exerted (Figure 3). Six springs are also found on the inside of the outer shell that connect with six slots on the outside of the inner shell. The springs and slots connect for a positive on, but the resistance of the springs must also be overcome to connect the projections for the removal. The downforce must be sufficient to keep the protrusions engaged in the slots. If the downforce is not sufficient or not maintained at the correct level the protrusions will not stay engaged, and will slip out of the slot. Closure 3 has 12 oblong ridges on the inside of the outer shell that fit into 12 slots on the top of the inner shell (Figure 4). If the downforce is not sufficient or maintained, the ridges will not stay in the slots, and the outer shell will ride over the inner shell. Closure 4 has eight angled projections on the inside wall of the outer shell that mesh with eight ridges on the outside wall of the inner shell (Figure 5). Again, if the downforce is not sufficient, the projections and ridges will not mesh, and the outer shell will ride over the

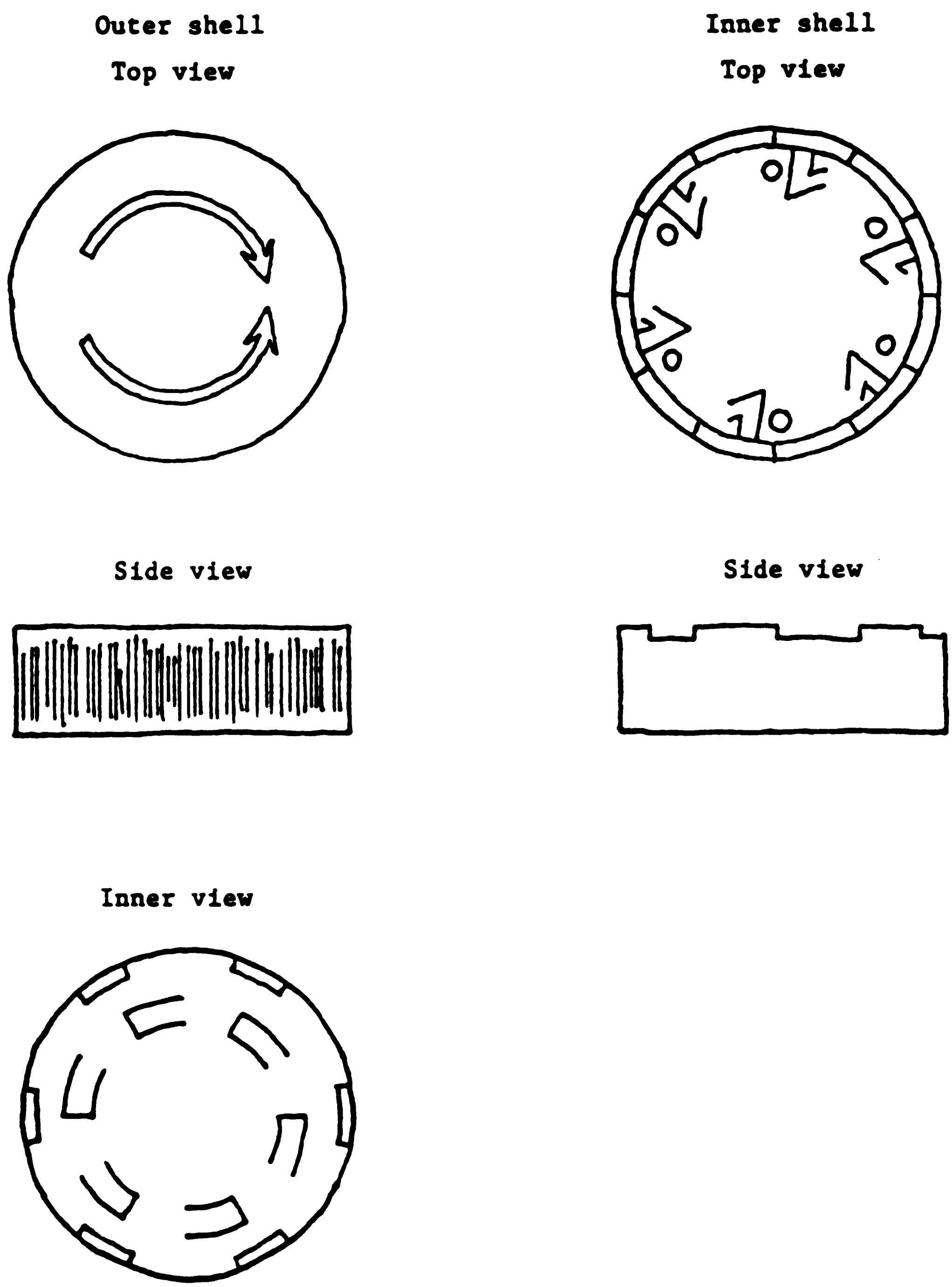

Figure 3. Inner construction of closure 1 (not drawn to scale).

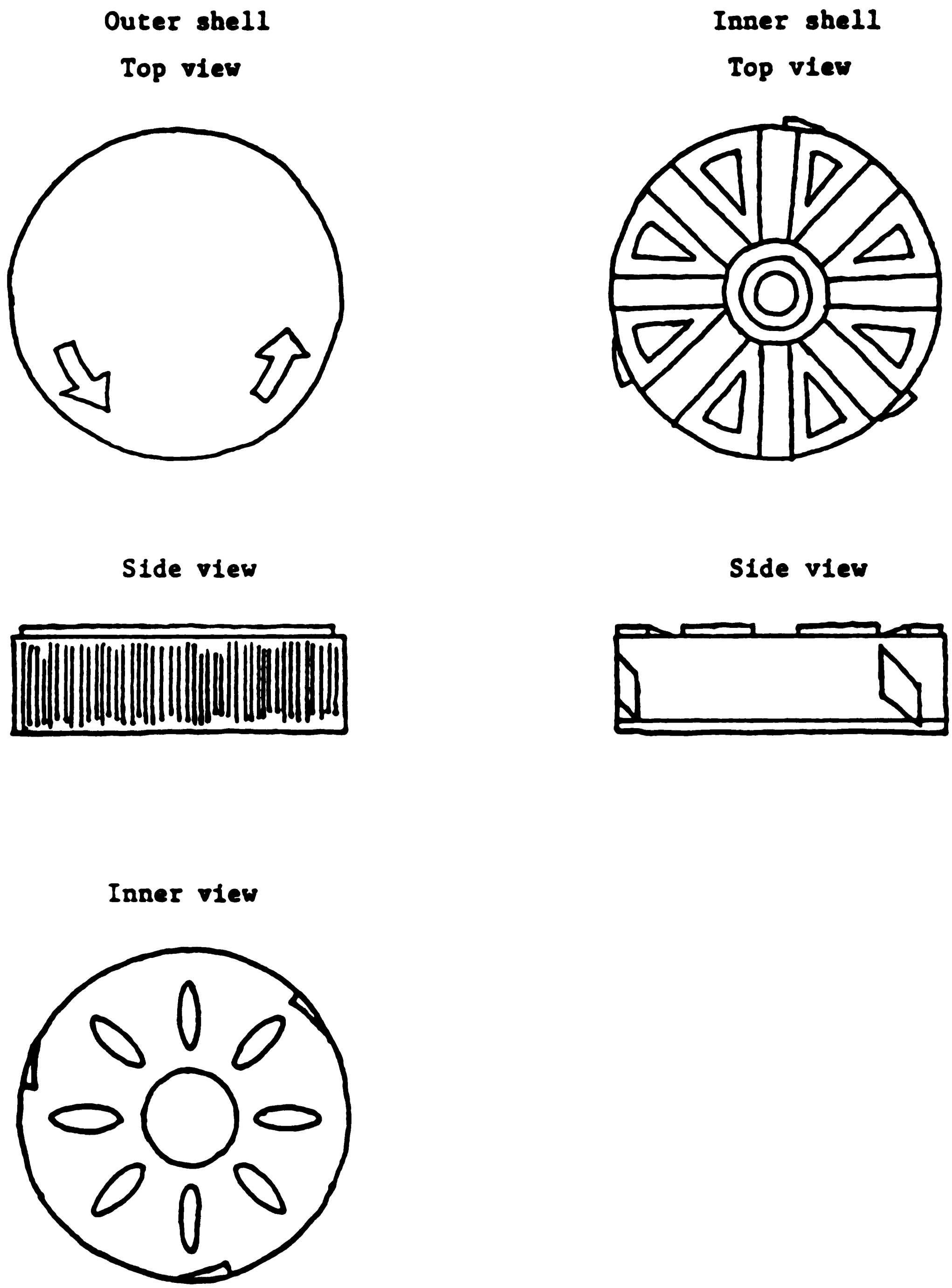

Figure 4. Inner construction of closure 3 (not drawn to scale).

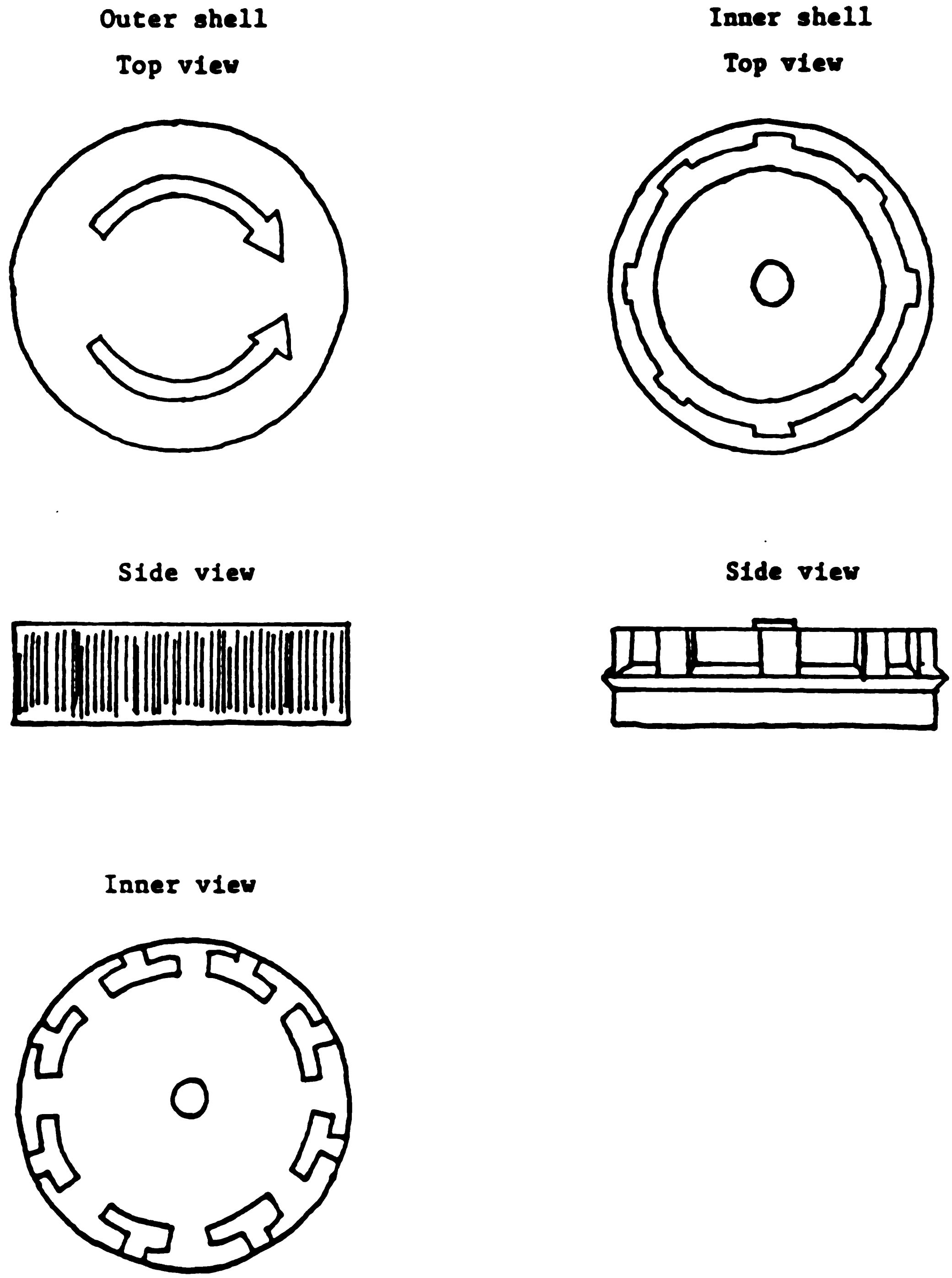

Figure 5. Inner construction of closure 4 (not drawn to scale).

inner shell.

The number of points of connection within the inner and outer shell may also contribute to the ability of subjects to remove these closures. If the subject does not have the required level of downforce, and there are only six possible points of connection, he or she will have to apply a torque and turn the closure farther if the first attempt was unsuccessful to try another connection than if the closure has over 50 possible connection points. This can cause fatigue and frustration if several attempts must be made.

Dimensional clearances and tolerances can be a factor that will hinder the engagements of the two shells. If a ridge is to be engaged into a slot, and the size of the slot is very close to the size of the ridge, a successful connection can be difficult to make and keep the parts together. Friction between hard materials and softer materials can wear down edges and this can be enough to prevent engagement.

Finally, it should be noted that in all except seven cases, the subjects tested were able to exert the maximum amount of downforce necessary to remove the closures as required according to the Auto-Torque tester. The results from the testing showed closure 1 required a maximum of 10 pounds for a machine removal, while the subjects used up to 42.3 pounds, with an average of 19.54 pounds. Closure 2 had a maximum machine downforce of 2 pounds, while the subjects used up to 36.5 pounds, with an average of 14.26 pounds. Closure 3 required a machine maximum downforce of 12 pounds, while the subjects used up to 46.8 pounds, with an average of 19.75 pounds. Finally closure 4 required a maximum of 9 pounds for the machine removal, but the subjects used up to 36.5 pounds, with an average of 18.26 pounds.

Comments of Test Participants

Most of the subjects tested did not understand how the closures operated, and did not realize they were trying to connect two shells when pushing on the closure. Many specified that they disliked all push and turn closures, but they realized that child-resistant closures performed a necessary function in homes with young children. Others said they would leave the containers open, or put their medication in another package they could open easier. Overall, much dissatisfaction with child-resistant closures was noted.

CONCLUSIONS

The results from the analysis of the data allow several conclusions to be made. The Machine Minimum Downforce Measurements revealed differences between three of the four closures, with closure 2 significantly having the lowest downforce value overall. The Acceptance and Scaling questions, and the Subject Downforce Measurements all indicated an effect due to closure type tested. For the Acceptance question, closure 1 and 2 had significantly lower mean values, which indicates they were liked better. Again closure 2 had the lowest mean value of the two. The Scaling question showed closure 2 as different from the others, at a mean value significantly lower. This indicates that the subjects thought closure 2 was easier to open. Additionally, the Subject Downforce Measurements revealed closure 2 as different, with a mean value significantly lower. This shows the subjects used less downforce to remove that closure.

For the Preference question, Friedman's analysis also showed closure 2 as lower than the others, with no significant effect due to sex or age group. Closure 2 was ranked as being preferred more overall.

Examining these results indicate that closure 2 was rated as better than any of the other closures. This may be due to the inner construction as described in the Analysis of Data section. It should be noted that this testing was performed with new closures, wear and tear and other factors may significantly change the results.

It should also be noted that as a general trend, the majority of the subjects were all able to generate the maximum necessary downforce to remove the closures as determined by the machine testing. This indicates that downforce alone may not be the inhibiting factor in the closure removals.

RECOMMENDATIONS

This study can be a starting point for further research. The bottles and closures tested were new, and had never been manipulated prior to the testing. It can be assumed that normal wear and tear will affect the closures. And although the Poison Prevention Packaging Regulations (Code of Federal Regulations, 1987) state that the product should not interfere with the special packaging, often cough syrups or other sticky liquids can spill onto the bottle finish area and interrupt the normal operation of the closure.

The level of torque used to apply the closure may also affect the downforce and removal torque necessary for a successful removal. This can be important, as the level of torque applied at the manufacturing site is assumed to differ from that applied by a consumer who is reclosing the container after usage.

A variation of this study would be to have subjects open the closures and record the downforce to open, show the subject the inner workings of the two shells and explain how downforce operates to connect the shells, and have them then remove another closure. This may help indicate if educating consumers about the closures will have an effect on their behavior when attempting a removal.

In this study children were not utilized for any of the testing, and it may be desirable to do so in the future. The closures require two dissimilar motions to achieve a successful opening, and although children can perform these motions independently, they do not usually have the cognitive and/or motor ability to perform both motions simultaneously. But information could still be gathered as to the relative strength a child would exert for an opening.

Lastly, it is recommended that more research be performed on the instrumented bottle itself. The model used for this testing was machined by hand by a relatively inexperienced person. A more efficient design, or perhaps one with closer tolerances to the closures may yield results with an even better degree of accuracy.

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APPENDICES

APPENDIX A

Appendix A

Table 1. Subject's bottle* and closure** grips used when removing closure #1.

Subject #	Test Bottle*** Closure	Test Bottle*** Bottle	Instrumented Bottle**** Closure	Instrumented Bottle**** Bottle
1	F	T	F	T
2	F	T	F	T
3	P	T	P	T
4	F	1	F	1
5	F	1	F	1
6	F	T	F	T
7	M	1	M	T
8	F	1	F	1
9	F	T	F	1
10	F	1	F	1
11	P	T	P	T
12	F	1	F	1
13	F	1	F	1
14	F	T	F	T
15	F	1	F	1
16	F	T	F	T
17	P	0	P	0
18	F	1	F	1
19	P	T	P	T
20	P	T	P	T
21	P	2	P	1
22	P	T	P	T
23	P	T	P	T
24	P	1	P	1
25	P	T	P	T
26	P	1	P	1
27	P	T	P	T
28	P	T	P	T
29	P	0	P	0
30	P	1	P	1

Table 1. continued

Subject #	Test Bottle Closure	Test Bottle Bottle	Instrumented Bottle Closure	Instrumented Bottle Bottle
31	P	1	P	1
32	P	1	P	1
33	P	1	P	1
34	P	1	P	1
35	P	T	P	T
36	P	1	P	1
37	F	1	F	1
38	P	1	P	T
39	P	T	P	T
40	P	1	P	1
41	P	1	P	1

*Bottle grips coding:
- T - Bottle placed on table
- L - Bottle placed against leg
- 0 - All four fingers grasp bottle, no fingers underneath for support
- 1 - One finger under bottle for support
- 2 - Two fingers under bottle for support

**Closure grip coding:
- F - Fingers grasp closure in a form of a pincher grip
- P - Palm of hand is applied to top of closure
- M - Multiple grips were used by the subject

***Test Bottle: This closure/bottle system was used for the subject when answering the Acceptance, Scaling, and Preference Questions.

****Instrumented Bottle: This closure/bottle system was used to measure downforces exerted by subjects.

Table 2. Subject's bottle* and closure** grips used when removing closure #2.

Subject #	Test Bottle*** Closure	Bottle	Instrumented Bottle**** Closure	Bottle
1	F	T	F	T
2	F	T	F	T
3	P	T	P	T
4	F	1	F	1
5	F	1	F	1
6	F	T	F	T
7	M	1	M	T
8	M	0	M	0
9	F	1	F	1
10	F	1	F	1
11	P	T	P	T
12	F	1	F	1
13	F	1	F	1
14	F	T	F	T
15	F	1	F	1
16	F	T	F	T
17	P	1	P	1
18	F	1	P	1
19	P	T	P	T
20	P	1	P	1
21	P	1	P	1
22	P	T	P	T
23	P	T	P	T
24	P	1	P	1
25	P	T	P	T
26	P	1	P	1
27	P	T	P	T
28	P	T	P	T
29	P	0	P	0
30	P	1	P	1
31	P	1	P	1
32	P	1	P	1
33	P	1	P	1
34	P	1	P	1
35	P	T	P	T

Table 2. continued

Subject #	Test Bottle Closure	Bottle	Instrumented Bottle Closure	Bottle
36	P	1	P	1
37	P	1	P	1
38	P	T	P	T
39	P	L	P	L
40	P	1	P	1
41	P	1	P	1

*Bottle grips coding: T - Bottle placed on table
L - Bottle placed against leg
0 - All four fingers grasp bottle, no fingers underneath for support
1 - One finger under bottle for support
2 - Two fingers under bottle for support

**Closure grip coding: F - Fingers grasp closure in a form of a pincher grip
P - Palm of hand is applied to top of closure
M - Multiple grips were used by the subject

***Test Bottle: This closure/bottle system was used for the subject when answering the Acceptance, Scaling, and Preference Questions.

****Instrumented Bottle: This closure/bottle system was used to measure downforces exerted by subjects.

Table 3. Subject's bottle* and closure** grips used when removing closure #3.

Subject #	Test Bottle***		Instrumented Bottle****	
	Closure	Bottle	Closure	Bottle
1	F	T	F	T
2	F	T	F	T
3	P	T	P	T
4	F	1	F	1
5	F	1	F	1
6	F	T	F	T
7	M	1	M	T
8	F	1	F	1
9	F	T	F	1
10	F	1	F	1
11	P	T	P	T
12	F	1	F	1
13	F	1	F	1
14	F	T	F	T
15	F	1	F	1
16	F	T	F	T
17	P	0	P	0
18	F	2	F	1
19	P	T	P	T
20	P	1	P	1
21	P	1	F	0
22	P	T	P	T
23	P	T	P	T
24	P	1	P	1
25	P	T	P	T
26	P	1	P	1
27	P	T	P	1
28	P	T	P	T
29	P	0	P	0
30	P	1	P	1
31	P	1	P	1
32	P	1	P	1
33	P	1	P	1
34	P	1	P	1
35	P	T	P	T

Table 3. continued

Subject #	Test Bottle Closure	Test Bottle Bottle	Instrumented Bottle Closure	Instrumented Bottle Bottle
36	P	1	P	1
37	F	1	F	1
38	P	1	P	1
39	P	L	P	L
40	P	1	P	1
41	P	1	P	1

*Bottle grips coding:
- T - Bottle placed on table
- L - Bottle placed against leg
- 0 - All four fingers grasp bottle, no fingers underneath for support
- 1 - One finger under bottle for support
- 2 - Two fingers under bottle for support

**Closure grip coding:
- F - Fingers grasp closure in a form of a pincher grip
- P - Palm of hand is applied to top of closure
- M - Multiple grips were used by the subject

***Test Bottle: This closure/bottle system was used for the subject when answering the Acceptance, Scaling, and Preference Questions.

****Instrumented Bottle: This closure/bottle system was used to measure downforces exerted by subjects.

Table 4. Subject's bottle* and closure** grips used when removing closure #4.

Subject #	Test Bottle***		Instrumented Bottle****	
	Closure	Bottle	Closure	Bottle
1	F	T	F	T
2	F	T	F	T
3	P	T	P	T
4	F	1	F	1
5	F	1	F	1
6	F	T	F	T
7	M	1	M	T
8	F	1	F	1
9	F	T	F	1
10	P	1	F	1
11	P	T	P	T
12	F	1	F	1
13	F	0	F	0
14	F	T	F	T
15	F	1	F	1
16	F	T	F	T
17	P	1	P	1
18	P	1	P	1
19	F	T	F	T
20	P	T	P	T
21	P	0	P	2
22	P	T	P	T
23	P	T	P	T
24	P	1	P	1
25	P	T	P	T
26	P	1	P	1
27	P	T	P	1
28	P	T	P	T
29	P	0	P	0
30	P	1	P	1
31	P	1	P	1
32	P	1	P	1
33	P	T	P	T
34	P	1	P	1
35	P	T	P	T

Table 4. continued

Subject #	Test Bottle Closure	Test Bottle Bottle	Instrumented Bottle Closure	Instrumented Bottle Bottle
36	P	1	P	1
37	F	1	F	1
38	P	1	P	T
39	P	L	P	T
40	P	1	P	1
41	P	1	P	1

*Bottle grips coding:
T - Bottle placed on table
L - Bottle placed against leg
0 - All four fingers grasp bottle, no fingers underneath for support
1 - One finger under bottle for support
2 - Two fingers under bottle for support

**Closure grip coding:
F - Fingers grasp closure in a form of a pincher grip
P - Palm of hand is applied to top of closure
M - Multiple grips were used by the subject

***Test Bottle: This closure/bottle system was used for the subject when answering the Acceptance, Scaling, and Preference Questions.

****Instrumented Bottle: This closure/bottle system was used to measure downforces exerted by subjects.

APPENDIX B

APPENDIX B

Human Subject Questionnaire

Date _____________ Page 1

Subject # ________

CHILD RESISTANT PACKAGE TESTING

I am studying problems that adults have when opening certain child resistant packages. You will be asked to open four containers, and to fill out a short questionnaire.

This test should take about 15 minutes. You are free to end the test at any time. You are free to not answer any of the questions, and to ask if you need a clarification at any time.

Your identity will be kept in strict confidence. The data from this test will be used to identify problems with push and turn child resistant closures.

Thank you for your cooperation and participation.

Age /__/ 25-45 /__/ 46-55 /__/ 56-65 /__/ 65-75 /__/ 76+

Sex /__/ M /__/ F

Right Handed /__/ Left Handed /__/

Do you believe you have any physical limitations which may make these packages difficult for you to open or close?

Are you familar with this kind of push and turn child resistant packages?

Yes /__/ No /__/

If yes, which products or product types have you used that have this child resistant feature incorporated into the package?

/__/ Antifreeze or other automotive products

/__/ Vitamins or diet suppliments

/__/ Cleaning products

/__/ Herbicides

/__/ Prescription drugs

/__/ Pain relievers

/__/ Other , please specify ____

DATA SHEET Page 2

Date _______________

Subject # __________

We are studying four different aspects of child resistant closures, using four different test closures that have been labeled "514", "127", "285", and "329" for identification purposes. Please choose one from the bag and open and close it, then rate it on the scales on pages 2 and 3. When you have finished, I will have you remove the same closure one more time with a different bottle. I will then have you choose another sample from the bag, and continue until all have been tested.

Please rate each test sample, immediately after opening, by placing a mark on the line corresponding to the ease of opening.

EASE OF OPENING

Closure #	Scale	
	Very easy to open	Very hard to open
--------	|—————————————————|	
--------	|—————————————————|	
--------	|—————————————————|	
--------	|—————————————————|	

DATA SHEET Page 3

Date ____________

Subject # ________

Please rate each test closure, immediately after opening, on how well you liked it.

HOW WELL YOU LIKED EACH CLOSURE

Closure _____

Extremely well liked	/__/
Liked very much	/__/
Moderately liked	/__/
Slightly liked	/__/
Neither liked nor disliked	/__/
Slightly dislike	/__/
Moderately dislike	/__/
Dislike very much	/__/
Extremely dislike	/__/

Closure _____

Extremely well liked	/__/
Liked very much	/__/
Moderately liked	/__/
Slightly liked	/__/
Neither liked nor disliked	/__/
Slightly dislike	/__/
Moderately dislike	/__/
Dislike very much	/__/
Extremely dislike	/__/

Closure _____

Extremely well liked	/__/
Liked very much	/__/
Moderately liked	/__/
Slightly liked	/__/
Neither liked nor dislike	/__/
Slightly dislike	/__/
Moderately dislike	/__/
Dislike very much	/__/
Extremely dislike	/__/

Closure _____

Extremely well liked	/__/
Liked very much	/__/
Moderately liked	/__/
Slightly liked	/__/
Neither liked nor dislike	/__/
Slightly dislike	/__/
Moderately dislike	/__/
Dislike very much	/__/
Extremely dislike	/__/

DATA SHEET Page 4

Date ____________

Subject # _______

RANKING

Please compare the four closures by opening them, and then placing them in the order of which one you prefer overall, to the one you least prefer overall. Place the number of the closure you prefer overall next to the #1 space, and continue, placing the closure number you least preferred on the #4 space.

Preferred closure #1 ____________

#2 ____________

#3 ____________

#4 ____________

DATA SHEET

Date _____________

Subject # ________

Closure	Force reading (a)	(b)	Chart Reading	Hand Position	Comments
--------	------	------	------	---------	-------------------------
					-------------------------
--------	------	------	------	--------	--------------------------
					--------------------------
--------	------	------	------	--------	--------------------------
					--------------------------
--------	------	------	------	--------	--------------------------
					--------------------------

(a) initial force reading
(b) maximum force reading

APPENDIX C

Appendix C

Table 8. Subjects listed by age group and sex.

Subject #	Age Group*	Sex
1	4	F
2	3	F
3	3	F
4	3	M
5	4	M
6	4	F
7	1	F
8	1	F
9	1	F
10	1	F
11	3	F
12	1	M
13	2	M
14	1	M
15	3	M
16	1	M
17	3	F
18	1	M
19**	1	F
20	2	M
21	2	F
22**	3	F
23	3	M
24	2	M
25	3	M
26**	3	F
27	2	F
28**	3	F
29**	3	M
30**	3	M

Table 8. continued

Subject #	Age Group	Sex
31**	3	F
32	2	F
33**	1	F
34	4	M
35	4	F
36	2	F
37	2	M
38	4	F
39	4	M
40	4	M
41**	4	F

*Age Groups : 1 - ages 25-45
2 - ages 46-55
3 - ages 56-65
4 - ages 66-85

**The data from these subjects was not used in the data analysis, these were tested as alternates in case problems were encountered.

APPENDIX D

Appendix D

Table 9. Raw data from the Acceptance Question.

Subject #	Closure # 1	2	3	4
1	3	2	1	3
2	3	2	3	3
3	6	8	9	7
4	4	3	4	5
5	5	7	3	7
6	3	1	9	9
7	6	2	8	6
8	8	7	2	2
9	2	2	2	3
10	2	2	4	8
11	6	4	3	7
12	3	2	7	4
13	3	2	1	3
14	6	2	4	3
15	6	4	7	7
16	4	4	5	3
17	8	3	7	2
18	3	6	3	5
19	2	3	4	2
20	2	2	5	5
21	4	1	2	6
22	2	6	3	9
23	6	3	5	6
24	2	2	2	2
25	7	2	2	2
26	2	6	4	3
27	4	2	7	5
28	8	2	7	6
29	4	3	5	3
30	4	3	3	5
31	9	2	9	2
32	6	4	5	7
33	1	1	3	1
34	5	4	7	6
35	7	3	8	8

Table 9. continued

Subject #	Closure # 1	2	3	4
36	2	3	2	2
37	5	2	2	4
38	3	1	9	9
39	6	2	8	4
40	2	1	2	1
41	7	7	9	4

Table 10. Raw data from the Scaling Question (1/10").

Subject #	Closure # 1	2	3	4
1	0.5	0.3	0.3	0.3
2	0.8	0.4	1.0	1.0
3	3.7	4.5	5.1	3.9
4	1.8	0.7	1.1	1.2
5	1.5	3.1	0.3	2.9
6	1.1	0.7	5.1	5.0
7	2.9	0.5	4.6	3.2
8	6.0	5.0	0.7	0.7
9	0.5	0.4	0.5	0.8
10	1.1	0.4	2.1	5.1
11	2.9	1.3	0.8	3.6
12	0.9	0.5	3.1	1.9
13	3.3	2.3	3.1	3.4
14	3.9	2.1	3.7	5.4
15	3.4	2.8	4.9	4.8
16	0.8	0.8	1.3	0.9
17	4.9	0.7	3.8	0.3
18	1.7	0.3	2.0	0.9
19	1.2	2.1	4.1	1.2
20	1.4	1.5	1.9	1.8
21	3.0	0.4	0.9	5.4
22	0.4	3.8	0.9	5.7
23	5.1	2.8	3.7	5.1
24	1.1	0.8	1.1	0.8
25	4.7	0.8	0.9	1.1
26	0.6	0.1	0.9	1.2
27	2.2	0.8	3.9	2.5
28	5.6	0.5	4.7	3.8
29	2.6	1.3	3.4	2.8
30	1.7	1.5	1.5	2.8
31	5.7	0.1	5.8	0.1
32	4.3	1.6	4.4	5.0
33	0.1	0.1	3.1	0.1
34	3.4	2.2	4.4	3.9
35	4.7	1.3	4.8	5.5

Table 10. continued

Subject #	Closure # 1	2	3	4
36	1.3	0.5	1.4	0.6
37	1.4	0.3	0.2	1.2
38	1.7	0.1	5.7	5.7
39	3.4	1.2	5.3	2.5
40	1.3	0.3	1.3	0.4
41	4.5	4.5	5.7	3.1

Table 11. Raw data from the Preference Question.

Subject #	Closure # 1	2	3	4
1	4	2	2	2
2	4	1	3	2
3	4	1	3	2
4	4	1	2	3
5	4	2	1	3
6	1	2	3	4
7	2	1	4	3
8	4	3	2	1
9	2	1	4	3
10	2	1	3	4
11	3	2	1	4
12	2	1	4	3
13	1	2	4	3
14	4	1	3	2
15	4	1	3	2
16	1	2	3	4
17	4	2	3	1
18	2	4	1	3
19	3	2	4	1
20	2	1	3	3
21	2	1	3	4
22	2	1	3	4
23	2	3	1	4
24	4	1	2	3
25	2	2	2	4
26	3	1	4	2
27	4	1	3	2
28	3	1	2	4
29	4	1	3	2
30	4	1	2	3
31	3	1	4	2
32	4	1	3	2
33	2	1	4	3
34	2	1	4	3
35	2	1	3	4

Table 11. continued

Subject #	Closure # 1	2	3	4
36	2	3	1	4
37	3	1	4	2
38	2	1	4	4
39	3	1	4	2
40	3	2	4	1
41	2	3	4	1

Table 12. Raw data from the Subject Downforce Measurements (lbs).

Subject #	Closure # 1	2	3	4
1	22.5	20.5	25.4	22.4
2	18.9	18.3	21.2	17.6
3	36.4	36.5	46.8	24.9
4	25.2	25.4	24.7	15.9
5	36.2	32.4	23.9	33.1
6	16.1	17.0	13.6	21.1
7	30.0	23.4	42.1	27.0
8	20.3	17.5	23.2	13.4
9	15.5	9.6	17.2	18.2
10	16.6	12.5	15.6	16.1
11	29.4	26.4	25.3	36.5
12	21.2	13.3	15.5	17.8
13	7.6	8.5	14.9	13.5
14	22.0	13.0	11.0	14.4
15	14.3	12.5	19.0	19.5
16	16.9	11.2	21.3	13.4
17	17.2	15.9	15.8	20.6
18	19.6	6.0	22.6	15.0
19	18.2	20.6	34.1	23.9
20	21.8	12.7	10.1	23.7
21	13.3	9.4	13.4	16.5
22	19.6	14.5	16.9	23.2
23	42.3	21.4	43.8	23.6
24	17.3	12.3	8.6	19.1
25	12.6	17.8	18.5	15.5
26	17.0	15.1	18.6	14.1
27	9.5	9.4	19.6	16.1
28	29.6	19.4	31.5	39.4
29	21.6	9.0	13.4	12.9
30	14.2	25.1	23.6	8.0
31	4.1	8.0	12.0	12.5
32	26.4	18.1	21.1	21.9
33	24.4	12.9	23.6	19.1
34	11.9	5.6	24.1	17.0
35	11.1	9.5	9.6	11.4

Table 12. continued

Subject #	Closure # 1	2	3	4
36	18.4	4.2	16.6	12.9
37	12.4	5.5	13.3	6.6
38	14.5	14.7	10.4	9.5
39	23.1	14.6	28.6	21.7
40	15.7	9.6	15.5	9.7
41	17.9	17.6	15.2	25.9