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Hand movement restriction at the opening of child-resistant packaging: case study

Gabriel Henrique Cruz Bonfim[a], Danilo Corrêa Silva[a], Ana Laura Alves[a], Giselle Schmidt Alves Diaz Merino[b], Fausto Orsi Medola[a], Luis Carlos Paschoarelli[a]

[a]Universidade Estadual Paulista
[b]Universidade Federal de Santa Catarina
e-mails: gabrielhcbonfim@gmail.com; danilo@idemdesign.net; nalaudesign@gmail.com; gisellemerino@gmail.com; fausto.meloda@faac.unesp.br; paschoarelli@faac.unesp.br

Abstract: Child-Resistant Packages (CRPs) are very important to prevent children under five years old to access products that are hazardous to their health. However, the opening mechanisms end up hindering the use of such packages by adults, the elderly, and people with disabilities. The aim of this study was to analyze the influence of a movement-restriction glove by collecting the torque exerted in an attempt to open 3 different squeeze-and-turn CRPs. The study enrolled 10 subjects, divided equally between men and women. The subjects performed the task with and without the glove. The results showed that the moment of force when the subjects were wearing the glove was higher than that obtained without the use thereof. Besides, the cap with the largest diameter offered the best conditions for torque transmission.

Keywords: design, ergonomics, child-resistant packaging, disability simulation.

1. Introduction

Every day, many users interact with any type of packaging. These interactions are not always harmonious and usually cause some problems or even injury. Manufacturers are not always aware of the problems that consumers face when interacting with the packaging, and even when they are, it is common that they cannot resolve such problems. However, many difficulties can be minimized or even corrected if ergonomic aspects are considered and applied during the production of packaging.

Child-Resistant Packages (CRPs) are part of this scenario. Although they are designed to restrict the access of children to dangerous products, they end up being an obstacle to adults and the elderly due to their opening mechanism.

The existing test protocols for evaluation and validation of this type of package do not consider users with special needs, such as wheelchair users and people with limited range of hand movements, which are the most affected by the process of opening.

Currently, there are some attempts to generate empathy with those who have some physical limitations by developers and designers, in order to understand how the loss of dexterity can affect the ability to interact with a product (WALLER et al., 2015; CLARKSON et al., 2015).

Therefore, some devices can reduce the biomechanical capabilities of its users, causing them to become vulnerable to the difficulties experienced by people with special needs. The movement-restriction glove is one of these devices, and it is responsible for hindering the joint movements of the fingers of its user.

Thus, the aim of this study was to investigate the influence of wearing a movement- restriction glove in the transmission of torque force during the opening simulation of child-resistant packages.

2. Bibliographic review

2.1. Packages and interface problems with consumers

Packages often represent the first customer contact with a product. Oftentimes, they also represent the first obstacle to the use of the product, because they commonly have little information about their opening process or require extreme efforts, which increases the risk of embarrassment or injury. A study in supermarkets of the United Kingdom points out that about 54% of consumers have already hurt themselves with a package of food or beverages in recent years (WINDER et al., 2002).

Most accidents involving packages occur at the moment of opening (SPITLER et al., 2005). Part of these accidents are related to some opening instructions that are barely visible or absent, which may impede consumers to perform the opening and, in the midst of their frustration, they end up opting for the use of aggressive methods to do it, which increases the possibility of accidents (ZUNJIC, 2011).

The characteristics of user groups also influence this interaction, since some groups, such as women or the elderly have lower biomechanical capabilities. A common problem in opening the package is the inability to exert the forces necessary to break seals, twist caps or other devices. Consumer products, such as food and beverage, represent constant problems for disadvantaged users (WINDER et al., 2002).

It is common that these groups adopt opening strategies involving the use of tools or utensils for the opening. Older people know the risk of accidents and therefore they develop specific strategies to open packages in order to reduce the risk of injury (ZUNJIC, 2011).

Most of the consumers do not know the proper way to open the packages (WINDER et al., 2002). Many packages have some evidences of how users should grip them as the shape or different texture, which supposedly increases stability during handling. However, other packages do not exhibit such characteristics, which do not allow to visually identify where the grip must be performed or how to open the product (SILVA; PASCHOARELLI, 2014).

During the opening of packages with screw caps there are reports that a portion of consumers turn the container in the opposite direction to the opening (NORRIS et al., 2000). The package design aspects can provide evidence on how the opening must be performed. However, the packaging designer must know ergonomic and usability principles to recognize the difficulties that many consumers will face and possible steps that they will pass through to open some packages. In case of damage to the product, the consumer is not always guilty (ZUNJIC, 2011).

2.2. Child-Resistant Packages (CRP)

Child-Resistant Packages (CRPs) are designed to prevent children to access dangerous products. Their opening mechanism requires more than a movement to be performed to access the internal content, such as the push-down-and-turn and squeeze-and-turn packages. In general, it is common for medicine packages and toxic products to have safety devices on their caps (safety caps). The use of CRPs for medicines and household products is a way to limit the access of children to toxic substances (GORDON et al., 2004).

There is a variety of different mechanisms for opening commercially available CRPs (ZUNJIC, 2011). In addition, there is a wide variety of patents with different designs. In a quick search of patent databases using the term "child-resistant closures" more than 15,600 results were found for different patents related to CRPs.

Even so, in Brazil, recent data show that of the 23,123 cases of poisoning that occurred in children under 5 years old, 36.14% are caused by medicines, 23.2% by household cleaning products and 8.63% for industrial chemicals products (SISTEMA…, 2012). More than 35,000 children from 0 to 14 years old die every year as a result of unintentional poisoning. After the fall, poisoning is the leading cause of accidents in children aged from 0 to 4 years (OZANNE-SMITH, 2001).

In Brazil there is no complete statistics regarding intoxication. If it is taken into account the large territory of the country, the number of Toxicological Assistance Centers is little. Moreover, the operation of these centers is often poor, which does not produce regular statistical data. What is known is that poisoning accidents involving children happen mainly indoors. The poverty of most Brazilians makes difficult the existence of appropriate places where hazardous materials can be stored (BRASIL, 1999).

Toxic products of everyday use, such as household cleaning products, are commonly stored in easily accessible locations. As a result, accidents with children cause considerable damage not only to the families but also to the health system, which is overloaded with cases that could be avoided (BRASIL, 1999).

The CRPs became mandatory in the United States in the 1970s, precisely because of the large number of accidents caused by intoxication with children under 5 years old. For this reason, it was enacted the Poison Prevention Packaging Act. In Brazil, CRPs are not mandatory, but the Bill No. 4841/94 (BRASIL, 1999) determines the use of such packages for medicines and chemical products intended for domestic use which present a risk to health. However, this project is in the National Congress since 1994.

This project is based on other legislation, particularly on the United States' and Canada's, where the intoxication levels were reduced by up to 35% between 1969 and 1972 (RAMOS et al., 2005). The Brazilian Bill defines CRP as all packaging designed with the intention that a child under 5 years old cannot access its content and at the same time, it is not difficult to open by an adult. Another aspect is that this text prohibits price change in the price of products distributed in common packaging and/or in CRPs.

Despite their importance to the reduction of accidents with children under 5 years old, in many cases CRPs have presented certain accessibility issues, especially on prescribed medicines for seniors. With the difficulties experienced by these individuals in the opening process, they end up transferring the CRP content for a container easier to open, storing the medicine without the cap, or simply keeping the medicine in a bag or drawer (SPITLER et al., 2005), which not only annuls the protection of the package as it increases the risk of accidents.

The main difficulties for users at the moment of CRP's opening are: the lack of information, the existence of a large number of methods for opening, insufficient strength of the users, or the reduction of mental and physical abilities of individuals with advanced age (WINDER, 2009; ZUNJIC, 2011).

2.3. Studies with CRPs

Since they became mandatory in the United States, the CRPs have been studied to assess their performance. Use issues are, usually, focused on the influence that the different security mechanisms play in the opening process, as well as users of different age groups respond to these mechanisms.

In a study conducted with outpatients aged from 22 to 87 years old, there were no significant differences between subjects who were able to open a CRP (87%) and the subjects who were able to open a conventional package (95%). However, many people have reported that the CRP was difficult to open and they ended up transferring its content to another container (LANE et al., 1971).

A survey in the United States found that 14% of subjects under 30 years old and 33% of those over 60 had difficulty in opening or used the CRPs incorrectly. The subjects reported that as a result of interaction problems with the package, they changed the container of the product; they left the cap opened; or they stopped using the product (MCINTIRE et al., 1977).

Other researchers evaluated two CRPs of the press-and-turn type and two of the squeeze-and-turn type. The results showed that the effect of age was statistically significant for all packages, and none of the containers was accessible by elderly (THIEN; ROGMANS, 1984).

In an evaluation with push-down-and-turn and squeeze-and-turn CRPs, it was observed that the difficulty of opening led individuals to: use scissors or other tool to cut the packages; transfer the product to another container; or not close the package again. The study also showed that 1 out of 5 individuals older than 75 years old cannot open certain CRPs (WARD et al., 2010).

Another study assessed the usability of two different CRPs with elderly subjects, in which the push-down-and-turn packaging seemed to be easier to open, but the level of satisfaction was higher for the squeeze-and-turn packaging (BONFIM; PASCHOARELLI, 2014).

Elderly and people with cognitive, physical and perceptual disabilities were the participants in a research that analyzed 8 CRPs with different opening systems. Overall, all packages received negative evaluation from the participants, but the lower scores were from the disabled subjects (BIX; DE LA FUENTE, 2012). Studies like this are valid, since the testing protocols for CRP's validation do not consider individuals with disabilities as part of the scope of the experiments (BIX et al., 2009).

Designing CRPs that comply with all safety requirements, preventing access of children, and ensuring accessibility to adults and the elderly is not an easy task. In the developed studies, it could be observed that the more complex the opening system, the greater the rejection of the public. However, the solution of the problem can be achieved by developing CRPs which are not physically and cognitively difficult to open (WINDER, 2009).

3. Material and methods

3.1. Ethical issues

This study was approved by the Ethics Committee in Research of the School of Sciences of UNESP-Bauru (Proc. 254413). Consequently a Consent and Informed Form (ICF) was established, in compliance with the Resolution 466/12-CNS-MS and the "Code of Ethics of Certified Ergonomist - Standard ERG BR 1002 – ABERGO".

3.2. Sample

This study had the participation of 10 subjects with a mean age of 30.8 years (s.d. 11.28), of which 50% were male and 50% were female. No subject reported the occurrence of musculoskeletal symptoms within twelve months prior to data collection.

3.3. Material

Three mouthwash packages with the squeeze-and-turn cap were selected (Figure 1). These packages have basically the same volume of liquid, however, their bodies and caps have different shapes.

The first package has a white cap with a conical frustum shape where the upper diameter is smaller than the lower; this cap also has grooves in all its surroundings, except in the tabs where it must be squeezed.

The second package also has a white cap with a conical frustum shape, but the upper diameter is larger than the lower; and the grooves are only in the regions where the cap should be squeezed.

The third package has an entirely black and cylindrical cap with grooves involving the entire outer region of the cap, except in the places that it should be squeezed.

All those packages were adapted to internally receive a Static Torque Screwdriver (STS - Mecmesin Ltd., UK - ST10-871-101) with a capacity of 10 N.m. This device is used to measure the torque forces during data collection and can be seen in Figure 2.

The STS was then connected to an Advanced Force Gauge (AFG 500N - Mecmesin Ltd., UK - Figure 3), maximum capacity 500N, accuracy 0.1%, which is used

Figure 1. Selected packages (the dimensions are in millimeters).

Figure 2. Static Torque Screwdriver (STS).

to indicate the torque values generated by the STS during the test.

The set composed by the packaging (body and cap), the STS and the AFG can be seen in Figure 4.

It was also used a movement-restriction glove (Cambridge Simulation Gloves - Figure 5) developed by the University of Cambridge in England. This glove consists of 5 plastic strips which limit the strength and range of motion of each of the fingers, in order to better understand how the loss of dexterity can affect the ability to interact with the products.

Figure 3. Advanced Force Gauge (AFG 500 - Mecmesin Ltd., UK).

As visible in Figure 5, the glove is fixed on the hand of the subject by Velcro® strips on the joints between the distal and middle phalanges. To reduce the influence of this aspect, when the subject was not wearing the glove, Velcro® strips were placed in the thumb and index finger (Figure 6) in order to generate the same interference caused by the glove.

For the measurement of hand force transmission before and after the test with the packages, it was used a digital dynamometer (Digi-II Digital Hand Dynamometer - Figure 7) with a maximum capacity of 1334N. The goal was to find out whether the realization of the proposed activity caused some sort of loss in the force transmission capacity of the subjects.

In addition to the materials mentioned above, it was also developed an identification protocol for collecting information such as name, date of birth, gender, laterality and possible recurrent musculoskeletal symptoms in upper limbs in the last year.

Figure 4. Set used for data collection.

Figure 5. Movement-restriction Glove (Cambridge Simulation Gloves).

3.4. Local of data collection

Data collection occurred in the Laboratory of Ergonomics and Interfaces (LEI), at the Univ. Estadual Paulista (UNESP - Bauru). This place is air-conditioned and well-lit.

3.5. Procedures

Each subject participated individually in the test. First, the objectives and procedures were explained to the subjects and, if they agreed to participate, they read and filled the ICF. Further, the participants completed the identification protocol.

At the end of this stage, the subject sat in a chair and with the right arm close to the body, holding the digital dynamometer with the right hand leaving an angle of approximately 90º between arm and forearm. So, it was requested for the participant to perform the maximum strength during a period of 4 seconds. Data was recorded and the subjects rested the upper limbs for 1 minute.

Figure 6. Velcro® strips positioned in the thumb and index finger of the right hand.

Figure 7. Digital hand dynamometer.

Then the researchers put the glove on the right hand of the subject (if the order indicated) and the first package was presented. With the left hand, the individual held the body of the package at the height of the stomach and positioned the index finger and thumb of the right hand on the squeeze locations of the cap (Figure 8), because this is the right way to open this type of packaging.

It was then requested for the subject to squeeze the package cap with the thumb and index finger and, at the same time, perform the maximum torque force counterclockwise for 4 seconds. After this procedure the glove was removed and it was given 1 minute of rest. At the end of that period, the Velcro® strips were placed on the thumb and index finger of the right hand. The same procedures were repeated with the second and third packages.

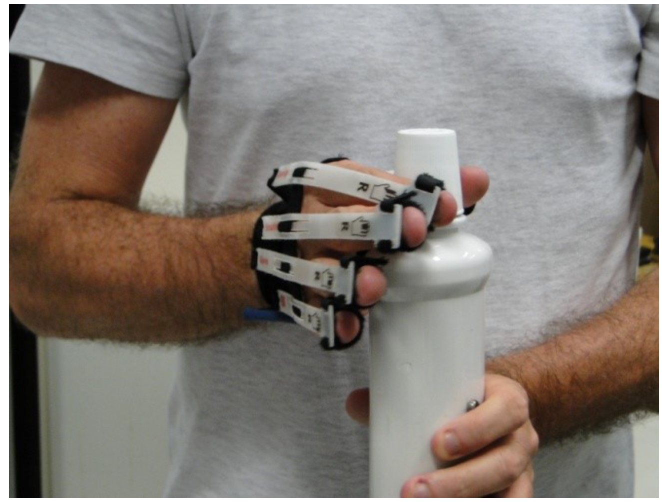

Figure 8. Position of hands on the package.

It is noteworthy that, both the order of the packaging and the test order (with or without the movement-restriction glove) were randomized to each individual.

Finally, the subject sat back on a chair and performed the maximum force in the digital dynamometer for 4 seconds.

3.6. Data analysis

Data was tabulated in spreadsheets, where mean and standard deviation were calculated.

Statistical analysis was based on the verification of normality of data sets, according to the Shapiro-Wilk test and homogeneity, according to the Levene test. Parametric tests were applied (Student t test) in the cases with normality **and** homogeneity, the absence of normality **or** homogeneity involved the application of non-parametric tests (Mann-Whittney or Wilcoxon).

4. Results

4.1. General

Of all the participating subjects, only 20% were left-handed and none had severe musculoskeletal symptom in recent years.

Data analysis relating to torque being performed with and without the use of the movement-restriction glove for each package can be seen in Figure 9.

As observed in Figure 9, data indicates that the torque exerted on the package with the use of the restriction glove was subtly higher than the values obtained without the use of the glove (for each package considered individually). However, there were no significant differences between these values.

When the differences between the forces applied in the different models of packaging were analyzed, it was noted that there were significant differences only between the packages 1 and 2 in the attempt with the glove (p = 0.0063); and between packages 2 and 3 in the attempt without the golve (p = 0.0301).

It was also possible to observe that the package 2 favored the application of torque forces. This was true for both with and without the use of the glove.

4.2. Male subjects

Regarding the male subjects, the average age was 38 years old (s.d. 10.77) and only one subject of this gender was left-handed. Torque forces exerted by the subjects of this group in each package and in each situation are shown in Figure 10.

For the men who participated in the study, the package 2 provided the best conditions for application of torque force. Both the force exerted with the glove and the force exerted without the glove were higher for this package.

It is also possible to note that the torque force transmitted when wearing the glove was subtly greater than the force exerted without the glove for each package individually. However, none of these differences were significant.

Statistical differences were only found between the packages 1 and 3 in the attempt without wearing the glove (p = 0.0210); and between packages 2 and 3 also without the glove (p = 0.0303). This shows that the package 3 offers the worst conditions for the transmission of opening force to the group of men without wearing the glove.

4.3. Female subjects

In the case of female subjects, the mean age was 23.6 years old (s.d. 6.39), and only one subject of this group was left-handed. Torque forces exerted by the women in each package and in each situation are shown in Figure 11.

It was noted that, when the packages were considered individually, the torque transmitted with the use of the

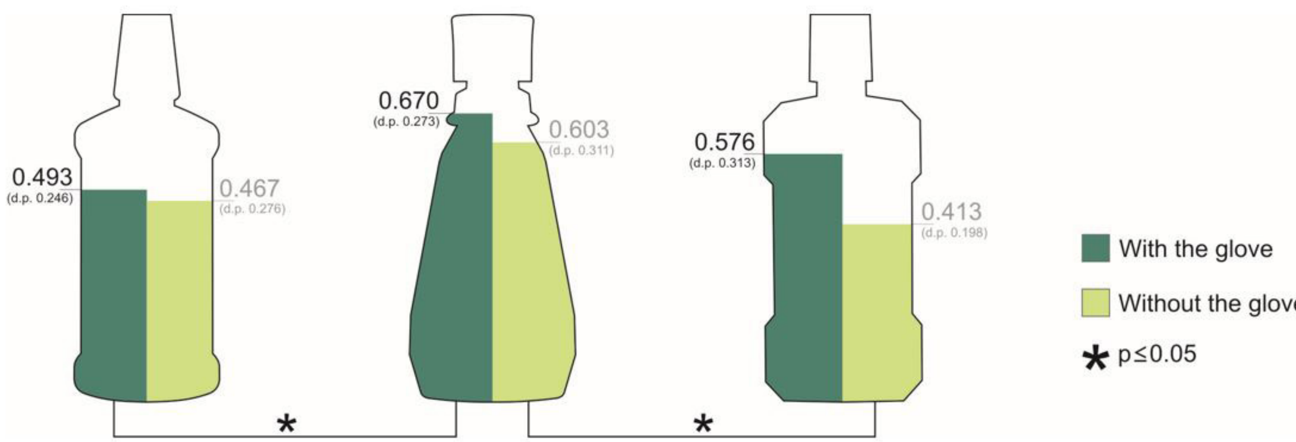

Figure 9. Overall result of the torque forces applied on packages (values are presented in N.m).

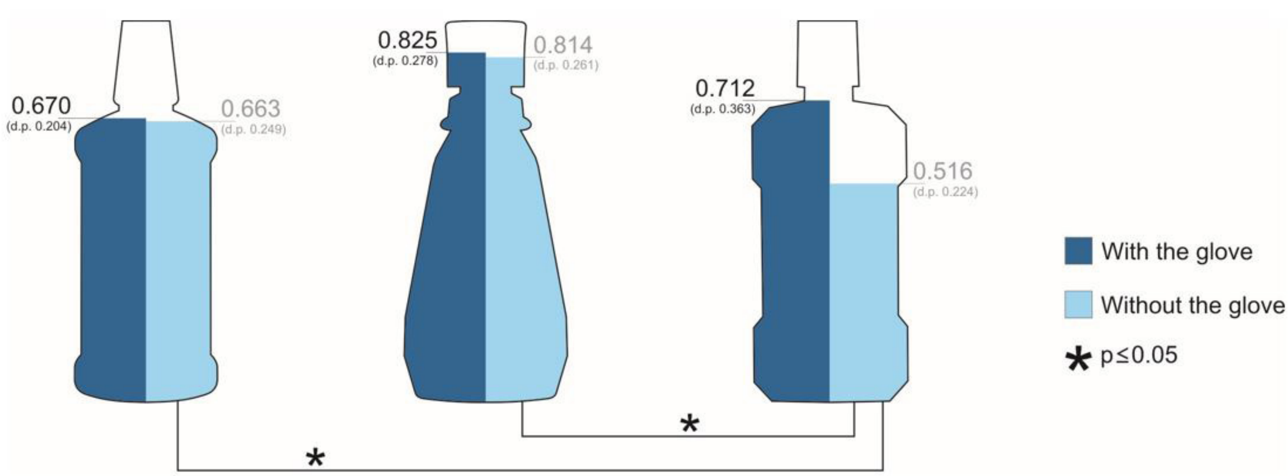

Figure 10. Result of torque forces applied by the male subjects (values are presented in N.m).

movement-restriction glove was, in all cases, subtly higher than the torque transmitted without the glove. However these values did not differ significantly.

For this group, statistical differences were observed between the packages 1 and 2 in the opening attempt with the glove ($p = 0.0209$); and between the packages 1 and 3 also with the glove ($p = 0.0464$). This indicates that the package 1 is the worst for the transmission of opening force considering the use of the movement-restriction glove for female subjects.

It was also noted that when comparing the torque transmission with the glove and the attempt without the glove, the highest values were found in the package 2.

Overall, the package 1 had the lowest values for women and it can be considered the worst packaging for torque transmission to the female subjects.

4.4. Male vs. female

When comparing the attempts between genders, it was found that in all cases, the torque force exerted by men was higher than women. However, significant differences were found only for the package 1, both the attempt with the glove and the attempt without the glove; and also for the package 2, only without the movement-restriction glove.

4.5. Manual prehension forces

Before and after the interaction with the packages, manual prehension forces of the subjects were collected to verify whether the activities were causing a change in the force transmission capacity of the participants. The prehension force values before and after the interaction with the packages are shown in Figure 12.

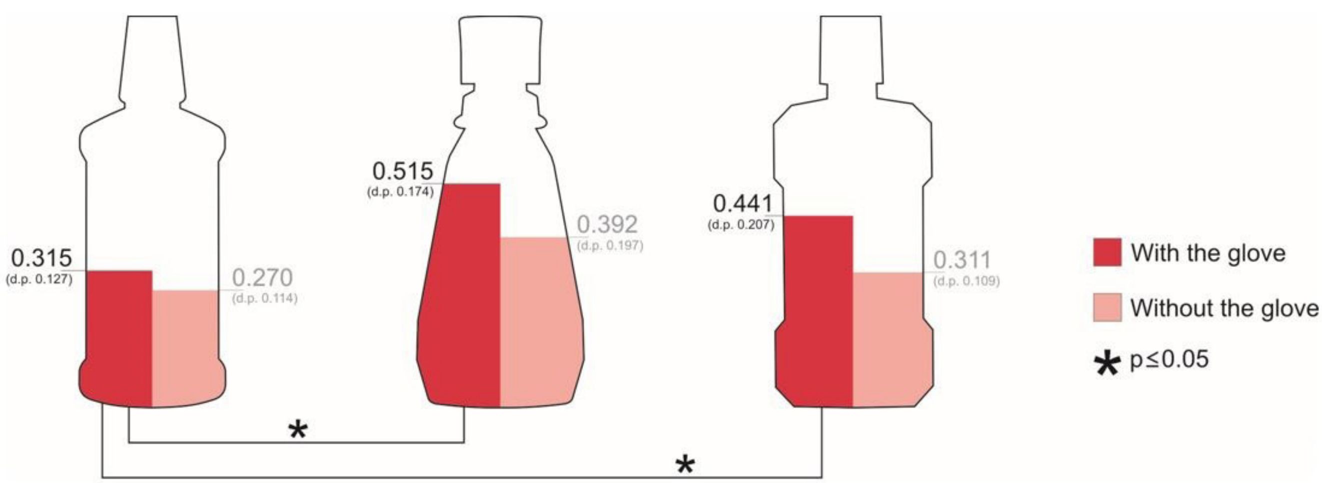

Figure 11. Result of torque forces applied by the female subjects (values are presented in N.m).

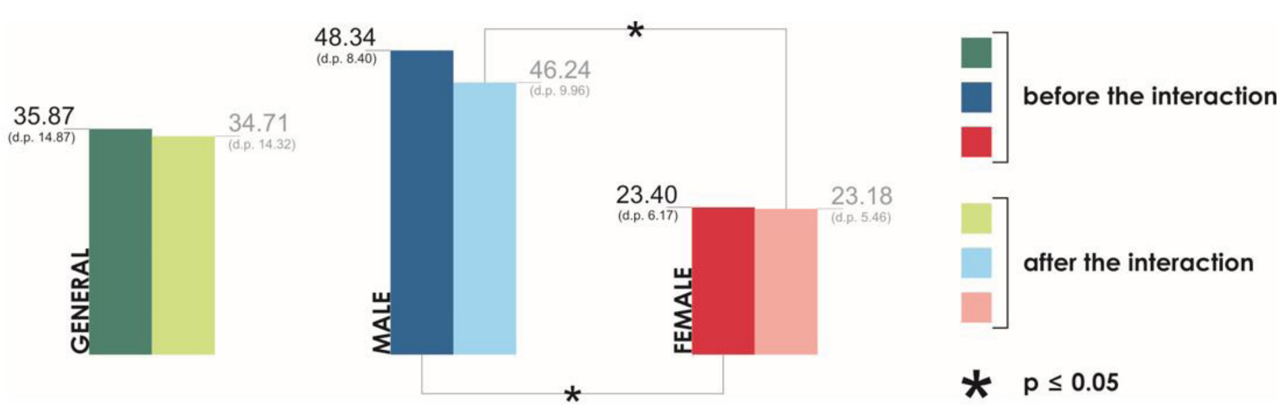

Figure 12. Results of manual prehension forces with the dynamometer (values are presented in N.m).

It is noted that, in general, there was no significant difference between the forces applied before and after the interaction with the packages. However, when considering genders, it is possible to observe that the forces applied by men were significantly higher than the forces applied by women ($p = 0.0007$ before the interaction, and $p = 0.0090$ after the interaction).

5. Discussion

A number of ergonomic factors are involved in the opening of child-resistant packages, the present study analyzed some biomechanical aspects (torque transmission and manual prehension forces) involved in the interaction with squeeze-and-turn caps, jointly with the hand movement restriction.

By the results, it was concluded that the package 2 provided the best conditions for the opening, which can be explained by the fact that it had the cap with the largest diameter, corroborating with other studies which showed that devices with larger diameters allow the application of higher torque forces (KONG et al., 2007; KONG; LOWE, 2005a, b; CRAWFORD; WANIBE; NAYAK, 2002).

Another explanation for the fact that the subjects could transmit higher forces in the attempt to open the package 2, was that the grooves of this cap were exactly in the places of contact with the thumb and index finger at the moment of opening. This provided greater friction between the fingers and the cap and prevented the slippage thereof, which is in agreement with other authors who have studied the friction of the fingers on different types of surfaces (BONFIM; PASCHOARELLI, 2014; DERLER et al., 2009; TOMLINSON et al., 2009; LEWIS et al., 2007).

This study also found significant differences between the forces exerted by the male subjects compared to female, showing the strength of men is higher than women, as shown by other authors (SHINOHARA et al., 2003; IMRHAN, 2003; KIM; KIM, 2000; CAMPOS et al., 2010; CAMPOS; PASCHOARELLI, 2013).

One of the most interesting findings in this study was that the torque force exerted with the movement-restriction glove was greater than the force exerted without the glove, which contradicted the expectations of the authors.

However, other researchers have studied the reason of the squeeze-and-turn packages being uncomfortable to open, and they found that "a small increase in required force at the finger tips to produce the 'turn' motion results in a large increase in joint interface stresses and hence a likely increase in pain and/or discomfort" during the opening process (YOXALL et al., 2013).

Thus, it is possible that the movement restriction glove served to support the fingers of individuals during the opening process, which caused a relief in the tension of joints, reducing discomfort and allowing greater torque force transmission.

This study also found that the interaction of proposed tasks with and without the use of the movement-restriction glove did not affect the prehension force of the subjects after the tests.

6. Conclusion

This study evaluated the torque force transmission with and without the use of a movement restriction glove in three packages of mouthwashes with squeeze-and-turn caps, which were different in shapes and sizes to verify if the use of the glove generates some influence on the biomechanical process of opening of such products.

The results showed that the package 2 provided the best conditions for torque transmission, because of its larger diameter cap and also because the grooves of this cap were in the local of squeezing.

One of the results showed that the use of the glove allowed subjects to exert higher force to open the packages. This indicates that the glove does not interfere with the movements of the wrist and arm, but only restricted the movements of the fingers, as explained by the producer.

Therefore, it is suggested that additional usability studies involving the use of the movement-restriction glove on real CRPs (with no adaptation) be developed. Such studies may identify how the opening process is influenced by the use of the glove in both task accomplishment and the time spent on opening and closing activities. Furthermore, they can provide a greater awareness relative to people who have reduced hand movements.

It is also suggested that future studies shall use other equipments such as Pinch Gauge® to assess how the glove reduces the bidigital prehension force of the thumb and index finger (both are directly involved in the task). The use of the dynamometer with and without the use of the glove can also facilitate the evaluation of the restriction level generated by the glove.

It is important to note that the principles of the Ergonomic Design should be respected when designing everyday product packages, since the focus should be the user. Thus, the design of CRPs should take into account the real capabilities of users (young people, adults and the elderly) and should also be concerned with nonusers (children), ensuring access of those who really need the product and preventing access of children.

7. Acknowledgements

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