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THE USE OF A UNIVERSAL DESIGN METHODOLOGY FOR DEVELOPING CHILD-RESISTANT DRUG PACKAGING

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THE USE OF A UNIVERSAL DESIGN METHODOLOGY FOR DEVELOPING CHILD-RESISTANT DRUG PACKAGING

By

Claudio Javier de la Fuente

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ABSTRACT

THE USE OF A UNIVERSAL DESIGN METHODOLOGY
FOR DEVELOPING CHILD-RESISTANT DRUG PACKAGING

By

Claudio Javier de la Fuente

People with disabilities and older adults are significant consumers of prescription drugs. However, most testing protocols for child resistant (CR) packaging do not take these individuals into account. One example is the United States Consumer Products Safety Commission's (CPSC's) protocol that excludes people with any obvious disability from the "senior-friendly" test. Instead of forcing manufacturers to develop CR packages that people with difficulties can use, the government permits pharmacies to dispense drugs in non-CR packages upon request, and allows the manufacturers of over-the-counter medications to package one size in non-CR packages. This assumes that people with disabilities do not live with children, and thus limits their choices.

For this research, a user-centered methodology that follows the universal design principles, guidelines, and methods was crafted. Universal design is an approach that addresses the needs of the widest possible audience; by applying its principles to CR packaging, users with a wider range of abilities can be accommodated. Three working groups were at the core of this process: people with disabilities, older adults, and children. Four distinct areas (hand strength, hand-finger dexterity, hand anthropometrics, and cognitive abilities) have been identified that can be employed to defeat children while allowing adults easy entry to packages. This information has the potential to guide designers not only in design choices, but also in dimensional and force related decisions regarding CR package design.

For Ale, my beautiful super woman

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PREFACE

Different portions of this research have been presented in the following international conferences:

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ABBREVIATIONS

9-HPT	Nine-hole peg test
ASTM	American Society for Testing and Materials
CPSC	Consumer Product Safety Commission
CR	Child-resistant
CT	Continuous thread
HDPE	High density Polyethylene
Non-CR	Non child-resistant
OTC	Over-the-counter
PPPA	Poison Prevention Packaging Act
PP	Polypropylene
PS	Polystyrene

CHAPTER 1

INTRODUCTION

Drug packages protect and deliver prescription and over-the-counter (OTC) drugs, as well as communicate necessary warnings and directions to people so that the pharmaceuticals they contain within can be correctly used. Packages of all types reach every patient at some point during their care. This project addresses two major issues of concern to public health that are related to packaging design: patient compliance and child safety.

PATIENT COMPLIANCE

Textual, graphic, tactile, and even auditory cues on packages can contribute to enhance patient compliance. New and emerging packages are able to provide electronic feedback to healthcare providers and patients regarding the therapy [1]. Package design is increasingly seen, and used, as a way to enhance compliance by patients.

Patient behavior and ultimately, their compliance or noncompliance, is extremely complex. One simple reason why patients do not comply with drug treatment is that they encounter obstacles associated with the package [2]. For instance, patients that have difficulty opening packages, or cannot read dosage instructions and important warnings on package labels may show reduced rates of compliance [2-8]. Ineffective packaging and labeling can result in a number of possible types of medication error including wrong drug, wrong dose, wrong time of administration, dose omission, wrong patient, extra dose, and wrong route of administration [9].

Noncompliance affects individuals and families both financially and emotionally. Research indicates that 50%-70% of patients do not take prescribed medication properly, and suggests that as many as 125,000 people with treatable ailments die annually as a

result. Economically, patient noncompliance has been estimated to cost $100 billion per year in the United States [10].

As the population ages and becomes more infirm, the issue becomes more critical. The elderly are at greater risk for noncompliance than the general population [6, 11-14], and older consumers and people with disabilities have a higher per capita rate of consumption of both OTC and prescription drugs [13, 15-17]. Older people tend to consume more pharmaceuticals than younger people because they are more likely to have several, often chronic, disorders. On average, an older person takes four-five prescription drugs and two OTC drugs each day [18]. Further complicating the issue is the fact that older consumers are more likely to engage in poly-pharmacy [13, 16], and are also more likely to be experiencing mental, physical and perceptual problems [5, 13, 14, 19-24] that make adherence more difficult for them.

Woolley [16] indicates that people 65 and older are more likely to require multiple medications, both prescription and OTC. Consumers over age 50 used an estimated $41 billion in prescription drugs last year [1998]; twice the per capita consumption of the rest of the population. A study conducted at the University of Missouri Columbia's School of Nursing indicated that elderly subjects reported using almost twice as many OTC as prescription medications [17].

This is also true for the segment of the population afflicted with disabilities. The Disability Statistics Abstract Number 12, published by the US Department of Education and the National Institute on Disability Rehabilitation Research (NIDRR) indicates that medical spending of people with disabilities is four times as great as for people without disabilities [25]. The same report states that the average per capita expenditure of a citizen with a disability was $366/year for prescription drugs, as compared with $109/year for citizens who did not have disabilities. Given these facts, marginalized users such as elderly consumers and people with disabilities should be an integral part of the drug package design process.

CHILD SAFETY

At the same time that manufacturers must aid the access to packaged drugs for people with difficulties they must keep small children from accessing drug products. The United States Consumer Product Safety Commission (US CPSC) administers the Poison Prevention Packaging Act of 1970 (PPPA) in order to protect children from the inadvertent ingestion of dangerous household products, including pharmaceuticals. The number of childhood deaths that result from accidental ingestion has declined drastically since the implementation of the PPPA in 1970 [26].

Despite this reduction, many children are poisoned or have "near-misses" with medicines and household chemicals each year. The American Association of Poison Control Centers still reports that annually almost a million calls are made to poison control centers following unintentional exposure of children under five years to medicines and household chemicals. There is still an average of almost 50 deaths each year of children under five years of age who unintentionally swallow medicines and household chemicals [26]. The US CPSC lists misuse of child-resistant containers in the home (leaving the cap off, or transferring the medication to a non-child-resistant package) and the availability of both prescription and OTC drugs in non-child resistant (non-CR) packages as some of the reasons why poisonings still occur [26].

To compound the problems, children are becoming increasingly skillful at younger and younger ages, making it more difficult to prevent access to medications [27-29]. Today's toys and computers have improved kids' fine motor skills and made it easier for them to interpret symbols, like the common line-up-the-arrow method on many existing bottle caps [27]. This makes researching effective designs that allow marginalized populations access, yet maintain child-resistance, an increasingly critical area for investigation.

USABILITY OF DRUG PACKAGES

During the 60s and 70s, package designers were so focused on protecting children from poisoning that they frequently forgot to take into account the convenience of the person needing the medication. The effect was the exclusion of many seniors and people with disabilities. Even younger consumers frequently complained about issues of utility; hence, the many jokes and cartoons about "adult proof" packages.

During that era, adults between the ages of 18 to 45 were the specified subjects for the "senior friendly" portion of the US CPSC's test protocol. The end result was that packaging regulations were not really senior friendly. Therefore, the elderly frequently circumvented child-resistant features, and the expected protection level was not achieved. In 1986, the US CPSC conducted an ingestion study with the American Association of Poison Control Centers (AAPCC). The results indicated that many children were being poisoned by drugs that belonged to their grandparents [30]. Many of these incidents occurred because child-resistant packaging was not being used properly; the closures were loose or not properly closed. In other cases, the drugs were not in CR packages at all; they had been transferred to other packages [30].

It became necessary for the US CPSC to design a new test protocol and revise the regulations. In 1995 the US CPSC published new requirements for senior-friendly testing. As a result of this revision, the current protocol tests adults 50 to 70 years old to measure adult-use effectiveness of CR packages that contain pharmaceuticals. However, the current protocol allows testing firms to exclude people with overt or obvious disabilities and people that cannot open a non-CR screening package from the testing group (Figure 2.2).

Over the past four decades several studies have been published on the issue of CR packaging (Table 1.1) [31-50]. Several have shown that elderly people [34, 36, 40, 43, 47, 48, 51] and people with disabilities [35, 38, 44, 45] encounter a number of difficulties associated with the use of medical packages.

Table 1.1 – Previous studies on the subject of child-resistant packaging usability

First author	Year	Country	Article type	Subjects	Packages used	Comments
Arena [52]	1959	USA	Descriptive			Pointed out the need for safety closures for aspirin
Lane [41]	1971	USA	Testing	148 people (tested CR packages) 125 people (tested non-CR packages)	CR: Palm-'N'-Turn® (push down and turn) Non-CR: Pop top vials	Reported problems with the use of CR packaging and found poorer compliance in the group using CR vials
Mason [44]	1976	UK	Testing	200 patients with rheumatoid arthritis (age rage=15 to 77 years)	10 packages (lacked detailed descriptions)	People had difficulties opening at least five of the ten containers
McIntire [39]	1977	USA	Survey	636 phone samples		Found that 33% of the subjects over 60 and 14% of people under age 30 reported improper use of CR packages.
Myers [42]	1977	USA	Testing	100 subjects (average age= 41.2 years)	Brockway SafeRx® Snap Cap (align tabs)	83% experienced some kind of difficulty with the CR package
Lambert [45]	1978	UK	Testing	136 patients with rheumatic complaints	CR: Screw packs Non-CR: Blister packs	78 patients (57%) could not open the non-CR pack

(CONTINUED) Table 1.1 – Previous studies on the subject of child-resistant packaging usability

First author	Year	Country	Article type	Subjects	Packages used	Comments
Sherman [43]	1979	USA	Testing	120 older adults (average age=70 years)	Not reported	60% admitted having difficulty opening or closing CR medication containers
Khanderia [46]	1980	USA	Survey	330 senior citizens (ages were not reported)	Not reported	79% experienced problems with CR packages
Chambers [37]	1981	UK	Descriptive		Pop-Lok® (push tab and pull off cap) Snap-Safe® (align arrows) Clic-Loc® (push and turn)	Describes three popular CR designs in the UK
Kresel [49]	1982	USA	Testing	Children younger than 5 years	2 CR packages: Align arrows (Ø 44 mm) Push down and turn (Ø 23 mm)	Reported that children use teeth for opening. Suggested that larger containers are safer than smaller ones
Lisberg [35]	1983	UK	Testing	50 subjects w/ rheumatoid arthritis 50 "normal" control subjects	19 CR containers	Concluded that the dispensing of drugs in CR containers for rheumatic patients with hand involvement should be limited
Le Gallez [38]	1984	UK	Testing	99 patients with arthritis	12 packages	Gave recommendations for successful containers

(CONTINUED) Table 1.1 – Previous studies on the subject of child-resistant packaging usability

First author	Year	Country	Article type	Subjects	Packages used	Comments
Sherman [33]	1985	USA	Descriptive			Suggested testing of CR and tamper-resistant packaging on groups of "normal" elderly people and those with selected disabilities
Keram [34]	1988	USA	Testing	50 subjects over 60 years old	4 non-CR packages 6 CR packages	Over 30% could not open some of the CR designs but all participants could open all non-CR packages
Meyer [47]	1989	USA	Testing	93 older adults		Found that motor skills for opening and closing vials, and removing tablets were not related to cognitive status
Walburn [50]	1991	USA	Survey	1544 registered pharmacists		Surveyed the attitudes of pharmacists and older adults on the issue of CR packaging
Fleming [40]	1993	USA	Testing	100 elderly patients		Found that 40% experienced difficulties opening their medications bottles; 77% of which were stored in CR containers

(CONTINUED) Table 1.1 – Previous studies on the subject of child-resistant packaging usability

First author	Year	Country	Article type	Subjects	Packages used	Comments
Atkin [32]	1994	Australia	Testing	120 elderly patients		The study found that 78.3% were unable to open a container or break a scored tablet
Rahman [48]	2002	USA	Testing	42 women and 9 men over 60 years old	2 Non-CR packages: - Aerosol can - Trigger pump spray bottle 4 CR containers: - Squeeze sides while turning cap (Aleve®) - 2 sizes of a push down and turn design - Align arrows and push up cap (Meijer®)	Found relationship between grip and pinch strength and the ability to open some of the containers
Donaghy [36]	2003	UK	Testing	207 patients over 60 years old	Unspecified CR containers	Found that 43% were able to open the CR containers. After 80 years old this ability reduced dramatically: Age group / % able to open 60-69: 71.8 70-79: 52.0 80-89: 15.9 90+: 8.7

The first published material (1959) about CR packaging is a paper written by researchers from Durham, NC who indicated the need to use safety closures for aspirin [52]. In 1971, Lane *et al.* compared the use of a push-down-and-turn vial (Palm-'N'-Turn® manufactured by Reflex Co., Windsor, Ontario, Canada) with a standard non-CR pop top vial and found that the patients given CR containers experienced significantly greater difficulty in opening their containers than did patients given standard containers. Users of the CR container were significantly poorer in their compliance with prescribed dosage schedule. Finally, the authors were reluctant to recommend to the Department of Health that this safety closure be used in all municipal facilities [41]. McIntire *et al.* (1977) found that one-third of a group of patients over the age of 60 years were unable to reliably remove their tablets from CR containers [39]. Myers (1977) reported the problems that patients had with the use of a specific CR design (Brockway's SafeRx Snap Cap), a variation of the align-the-arrows-and-lift type. Eighty-three subjects out of 100 experienced some kind of difficulty. The average age of this population was 41.2 years old [42].

Sherman *et al.* (1979) reported the results of a survey of 120 community-residing elderly persons. Of those tested, 60% admitted to have difficulty opening or closing CR medication containers. This study also points out that, at that time, few people knew that they could ask for non CR packaging at the pharmacy [43]. Sherman *et al.* (1985) also examined the issue of tamper-resistant and CR packaging and its relationship to older adults and other adults who have mental, motor, and/or sensory disabilities [33].

Keram *et al.* (1988) tested six CR packages and four non-CR packages with a group of women and men over 60 year of age (n=50, average age=75.3 years). CR types included push and turn (two sizes), a blister pack, align arrows, align tab with notch, and reversible cap (depress tab and turn). Over 30% could not open some of the CR designs and all participants could open all non-CR packages [34].

Fleming *et al.* (1993) conducted a study with 100 elderly patients and found that 40% experienced difficulties opening their medications bottles; 77% of them were stored in CR containers [53]. Atkin *et al.* (1994) assessed the difficulties experienced by older people in opening and removing tablets from a range of commercial medication containers. The study found that 78.3% were unable to open a container or break a scored tablet [32].

Some of the studies investigated the issue of CR packaging in the hands of patients with rheumatoid arthritis. Mason *et al.* (1976) found that patients had considerable difficulty in opening at least five of the ten packages tested [44]. Lambert *et al.* (1979) tested both non-CR and CR packages; 78 out of 136 patients could not open the CR "screw pack" [45]. Lisberg *et al.* (1983) concluded that the dispensing of drugs for rheumatic patients in CR containers should be limited in those with hand involvement [35].

Finally, Donaghy *et al.* (2003) found that once patients reach the age of 80, their ability to open CR packaging and read medicine labels decreases dramatically [36]. Such difficulties may compromise patient compliance [2, 9, 39, 41] because people that have difficulties opening containers or reading directions are less likely to take their medication correctly [2-8, 41]. Radical rethinking of the design of drug containers will provide more suitable packaging, which in turn, will facilitate adherence to strict medical regimens.

Few studies examining the ease of use of CR drug packages have been published in the US since the protocol change took effect on January 21, 1998. Many of the current containers use operational principles that have been commercially available since the late 60's. For instance, the CR package studied by Lane *et al.* in 1971 [41], the Palm-'N'-Turn®, is very similar to one of the most popular current designs for prescriptions: the push-down-and-turn vial systems [54]. The effect of poorly-designed packaging ranges from inconvenience to dependence on others. Healthy, "average" people are inconven-

ienced when they have to seek better light to read opening directions, or require a gripping tool in order to effectively "push down and turn." The effects can be more than mere inconvenience for the disabled or elderly when they are moved to assisted living facilities because they are unable to adhere to medicine regimens.

Factors such as the aging of the population, the cultural shift to keep people with disabilities living as independently as possible, and the desire for convenience from all consumers make exploration of new designs for drug packages increasingly critical.

THE UNIVERSAL DESIGN APPROACH

American architect and designer Ron Mace first coined the term "universal design" in 1985. Mace defined the concept as "the design of all products and environments to be usable by people to the greatest extent possible without the need for adaptation or specialized design" [55]. Products that are designed universally reach the largest possible audience by going beyond the needs and abilities of "average, healthy" adults to include those with motor and sensory disabilities, children, and older adults. This can be viewed as a continuum of abilities from the most capable to the least capable. The goal is to include all levels of the continuum seamlessly.

Designs created with a focus on improving inclusion benefit all users, not just those that are having difficulties [55-57]. At some time during our lives, we all have problems with the spaces where we live or work, or the products we use. Age, illness, and accidents can make these problems more challenging. Universal design is the practice of considering these factors by designing as inclusively and equitably as possible, for people of any age or ability [55].

The movement has evolved in the 20 years since Mace coined the phrase and has achieved considerable recognition. The ideas have been widely applied in architecture, product design, and web design, but they have yet to be applied widely to packaging in the United States.

By applying the seven principles of universal design (Table 1.2) to packaging we can address the needs of people who are, at present, disadvantaged when designers do not consider them. If package designers do not begin considering marginalized users during the design process, it is likely more people will have difficulties in the future.

	The Seven Principles of Universal Design
1	**EQUITABLE USE** The design is useful and marketable to people with diverse abilities.
2	**FLEXIBILITY IN USE** The design accommodates a wide range of individual preferences and abilities.
3	**SIMPLE AND INTUITIVE** Use of the design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level.
4	**PERCEPTIBLE INFORMATION** The design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.
5	**TOLERANCE FOR ERROR** The design minimizes hazards and the adverse consequences of accidental or unintended actions.
6	**LOW PHYSICAL EFFORT** The design can be used efficiently and comfortably and with a minimum of fatigue.
7	**SIZE AND SPACE FOR APPROACH AND USE** Appropriate size and space is provided for approach, reach, manipulation, and use regardless of the user's body size, posture or mobility.
	* Copyright 1997 North Carolina State University The Center for Universal Design. Version 2.0 Raleigh, NC: North Carolina State

Table 1.2 – The seven principles of universal design

HYPOTHESIS

This research hypothesizes that by applying the concepts and methods of universal design to CR packaging, users with a wider range of abilities can be accommodated.

SPECIFIC AIMS

The project relies on the following four sequential specific aims:

Specific Aim #1

Characterize representative commercial drug packages from a usability and physical accessibility standpoint.

a) Subject representative drug packages to usability tests.

b) Characterize user's physical attributes

   i. Collection of anthropometrical data

   ii. Collection of physical strength data

   iii. Hand dexterity test

c) Correlate package design with user ability

Specific Aim #2

Characterize representative commercial drug packages regarding child resistance.

a) Subject representative commercial drug packages to test for child resistance based on the US CPSC protocol.

b) Characterize the physical attributes of the working group composed of children

   i. Collection of anthropometrical data

   ii. Collection of physical strength data

   iii. Hand dexterity

c) Correlate package design with child ability

Specific Aim #3

Develop universal design criteria for packaging based on data collected from the older adults and people with disabilities, as well as further discussions with these groups.

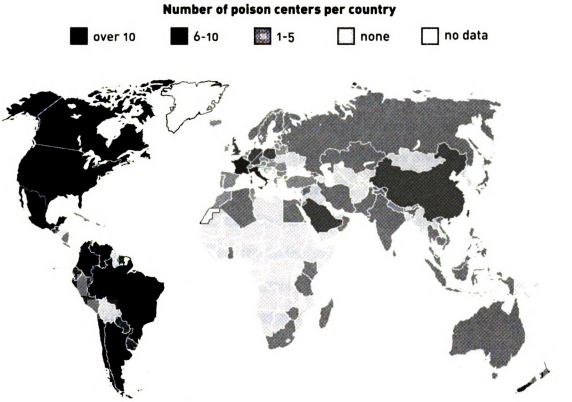
Specific Aim #4

Develop child-resistant design criteria based on the child data and discussion with a child development expert.

CHAPTER 2

CURRENT TEST PROTOCOLS FOR CHILD-RESISTANT PACKAGING

Poison control centers around the world provide treatment advice, record incidents, raise awareness, and promote prevention campaigns (Fig. 2.1). However, more than 35,000 children aged 0 to 14 years die every year as a result of unintentional poisoning. The use of child-resistant (CR) packaging for medicines and household products is one way to limit children's access to toxic substances [58].



Source: World Health Organization (2004)

Figure 2.1 – Number of poison centers in the world

This is one of the reasons why CR packaging is regulated by most of the governments throughout the world. Although each country or region has its own regulations, there is broad consensus among countries, and the essence of all regulations is quite similar. The main idea behind the different standards and regulations is that, for a package to be considered child-resistant, it must pass a two-part test protocol: a child test and a senior-adult test.

INTERNATIONAL REGULATIONS AND STANDARDS

Table 2.1 summarizes some of the current international standards for pharmaceutical products with respect to child resistance and senior friendliness. In these regulations there is a special distinction between non-reclosable and reclosable packages. Until fairly recently, the European position was that non-reclosable packages, such as blisters, are inherently child-resistant as long as they are opaque. A widely publicized incident in 2000, in which a child in the United Kingdom died after ingesting a massive amount of an iron-containing product contained in a non-reclosable, opaque package, inspired a change in regulation [59]. Now European countries have a standard for non-reclosable packages and another for reclosable packages. The United States and Australia regulate reclosable and non-reclosable packages with a single rule.

The international standard, ISO 8317:2004 "Child-resistant packaging – Requirements and testing procedures for reclosable packages", has been the reference for the European standard for reclosable packages (CEN EN 8317:2004), and hence for local standards such as the British, Italian, Spanish, and the German standards. This document is also followed by Japan and the countries of Mercosur (Argentina, Brazil, Paraguay, Uruguay, and Venezuela). In this standard, the International Standards Organization (ISO) specifies the requirements and test methods for reclosable packages designated as "resistant to opening" by children. These methods provide a measure of the ef-

fectiveness of the package in restricting access by children and cover the accessibility of adults between the ages of 50 and 70 [60].

Table 2.1 – Standards and regulations for senior-friendly child-resistant packaging for pharmaceuticals products

Country/Region	Local Organization	Standard for	
		Nonreclosable packaging	Reclosable packaging
International	International Standards Organization		ISO 8317:2004
European Union	European Committee for Standardization	CEN EN 14375:2003	CEN EN 8317:2004
United Kingdom	British Standards Institution	BS EN 14375:2003	BS EN ISO 8317:2004
Germany	Deutsches Institut für Normung	DIN EN 14375:2003	DIN EN ISO 8317:2004
Italy	Ente Nazionale Italiano di Unificazione	UNI EN 14375:2004	UNI EN ISO 8317:2005
Spain	Asociación Española de Normalización y Certificación	UNE EN 14375:2004	UNE EN ISO 8317:2005
Australia	Standards Australia	AS 1928:2001	AS 1928:2001
Japan	Japanese Standards Association		ISO 8317:2004
Argentina	Instituto Argentino de Normalización y Certificación		IRAM 3590
Canada	Canadian Standards Association	CSA Z76.2-00 (R2005)	CSA Z76.1-99 (R2003)
United States	Consumer Product Safety Commission	16 CFR 1700-1750	16 CFR 1700-1750

On the other hand, the European standard CEN EN 14375:2003 "Child-resistant non-reclosable packaging for pharmaceutical products – Requirements and testing procedures", has been adopted across Europe (United Kingdom, Germany, Italy, Spain, etc.) for testing non-reclosable pharmaceutical packages. Each European country has their

own standards organization responsible for issuing local standards; that is why, even though these countries adopted a common European standard, the prefixes for local standards are different (Table 2.1).

THE AMERICAN TEST PROTOCOL

The international and European standards are heavily inspired by the American regulation, which was the first regulation of its kind in the world. In the United States, the Consumer Product Safety Commission (US CPSC) administers the Poison Prevention Packaging Act of 1970 (PPPA), in order to protect children from the inadvertent ingestion of dangerous household products, including pharmaceuticals. The US CPSC protocol, which is found in the Code of Federal Regulations Title 16 Parts 1700-1750 [61], describes three tests (senior-adult test, younger-adult test, and child-test) that are used to test new CR package designs. The testing is carried out by testing agencies; companies hire them to test their packages before commercialization. An up-to-date list of testing firms can be found at the CPSC website [62]. The CPSC does not approve, certify, or endorse these firms.

Senior-adult test

The CR designs are first subjected to a test of senior friendliness (Fig. 2.2). One hundred people between the ages of 50 and 70 who do not have "obvious or overt physical or mental disabilities" [61] are eligible to be tested. Table 2.2 shows the distribution of gender and age of the test panel.

Participants test the package individually in well-lighted and distraction free areas. The presence of other participants or onlookers is not allowed. Each person is provided 5 minutes to try to open and close the package. If the participant is successful, he/she has to try to open and close a second package during 1 minute. If the person is

able to open and close the package during that period, the package gets a pass, if not the data is counted as a failure of the CR package being subjected to the protocol.

Table 2.2 – Test for senior friendliness, distribution of age and gender

Age range	Percentage of the test panel	Percentage by gender	
		Female	Male
50-54	25	68-72	32-28
55-59	25	70	30
60-70	50	70	30

If in the 5-minute period, the person was not able to open or close the package, she/he is given a 2-minute screening test (one minute for each screening package). This screening determines whether or not the participant is able to open packages that do not have CR features: a plastic snap closure and a continuous thread (CT) plastic closure. Each closure shall have a diameter of 28 mm ± 18% and the CT closure shall have been resecured 72 hours before testing at 10-inch pounds of torque. The containers for both closures shall be round plastic containers, in sizes of 2 ounce ± ½ ounce for the CT-type closure and 8 drams ± 4 drams for the snap-type closure. If the person successfully opens and closes both screening packages the participant continues with the 1-minute period testing the original CR package, otherwise the person is eliminated from testing and replaced with another participant.

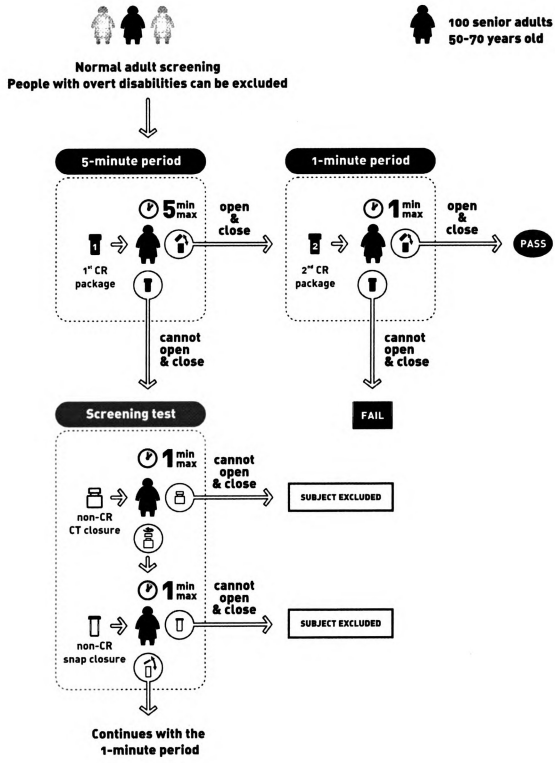


Figure 2.2 – Diagram of the US CPSC senior-adult test

The packages that have been opened and appear to be resecured by adults are tested by children according to the child-test procedures to determine if the packages have been properly resecured.

A package passes the senior adult test if the senior adult use effectiveness (SAUE) is at least 90%. The SAUE is the percentage of adults who both opened the package in the first 5-minute test period and opened and (if appropriate) properly closed the package in the 1-minute test period.

Younger-adult test

The younger-adult test was the earlier version of the current adult test. It was the only adult test before the revision of the regulation in 1995. However, in 1995 the commission concluded that products which must be packaged in metal packages with metal closures, or in aerosols, shall not be subject to the new senior-adult test and they shall be subject to existing younger-adult test. The Commission's technical staff believed that senior-friendly packaging for all products, including those in metal containers and in aerosol, could be produced eventually. At that time, the Commission assumed that any applications that use both a metal can and a metal closure would probably take the longest to develop and implement senior-friendly packaging. Today, in the year 2006, the younger–adult test still exists.

The younger-adult panel consists of 100 adults, age 18 to 45 inclusive, with no overt physical or mental handicaps, and 70% of whom are female. Every participant is given 5 minutes to complete the opening and, if appropriate, the resecuring process.

Child test

Child-resistant designs are also subjected to a test of child resistance (Fig. 2.3). This portion of the test is conducted with a panel of children between the ages of 42 and 51 months of age. One to four groups of 50 children are used as required under the se-

quential testing criteria (Table 2.3). Thirty percent of the children in each group should be 42-44 months of age, 40% should be 45-48 months of age, and 30% of the children in each group should be 49-51 months old. The difference between the number of boys and the number of girls in each age range should not exceed 10% of the number of children in that range.

Table 2.3 – Test for child resistance, sequential test pass/fail table

Test Panel	Cumulative number of children	Package openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1	50	0-3	4-10	11+	0-5	6-14	15+
2	100	4-10	11-18	19+	6-15	16-24	25+
3	150	11-18	19-25	26+	16-25	26-34	35+
4	200	19-30		31+	26-40		41+

Children are tested in pairs so that they feel more comfortable during the testing. The testing takes place in a well-lighted location that is familiar to the children and that is isolated from all distractions, usually a room in a kindergarten or childcare facility. The tester escorts the pair of children to the test area and she/he talks to the kids to make them feel at ease. The children are seated in such a way that there is no visual barrier between them and the tester.

Reclosable packages used in this test have been opened and properly resecured one time (or more if appropriate) by the testing agency (at least 72 hours prior to the beginning of the test) or other adult prior to testing (for instance, the packages resecured during the adult senior test). Each child is given a package for a 5-minute period and asked to try to open it (Fig. 2.3). After the 5-minute trial, if the children have not successfully opened the package, a tester will demonstrate how it is opened, and ask the children to try again for a second 5-minute period. Children are also told that they can

use their teeth if they wish. This is a difference with the international standard; at no time in the course of testing with the international standard does the demonstrator tell the children they can use their teeth.

A failure is indicated if a certain percentage of the test population accesses the medication inside the package during either of the two test periods. Pass/fail percentages are determined by a sequential table based on the results obtained from panels of 50 children (Table 2.3). For instance, a package fails if more than 41 children out of 200 (20%) gain access to the contents. The total number of children may vary from 50 to 200, according to the number of package openings obtained at each phase of testing.

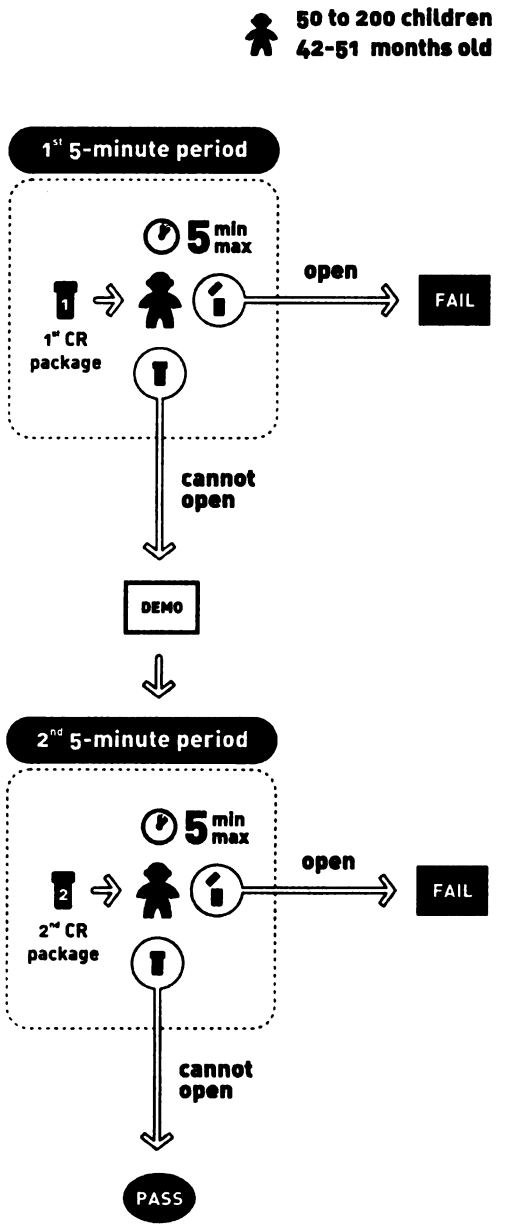


Figure 2.3 – Diagram of the US CPSC child test

TEST SUBJECTS: "NORMAL ADULTS"

The issue of CR packaging has gained the attention of several countries during the past decades. In Europe, there is an ongoing debate regarding child resistance aspects of the regulation, especially with the non-reclosable packages. There is less debate about the senior friendly portion of testing. In the United States there is debate about the number of openings for non-reclosable packages. Surprisingly, there is no discussion related to the discriminatory screening mechanisms of the adult test.

Despite the fact that people with disabilities represent a significant portion of the pharmaceutical consumer market, the US CPSC protocol for testing child-resistant packaging, which is required for most medications, excludes people with any obvious or overt disabilities from the senior friendly portion of the test. Under the section "Test Instructions for Senior Test", incise 1, the regulation states:

> *"No adult with a permanent or temporary illness, injury, or disability that would interfere with his/her effective participation shall be included in the test."*

In the same section, incise 2, the rule explains:

> *"Before beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test."*

A similar statement appears in European standard, CEN EN 14375:2003 "Child-resistant non-reclosable packaging for pharmaceutical products – Requirements and testing", in the section "5.3.3.1 Composition of Adult Test Group", this standard specifies:

> *"Persons with obvious physical disabilities that might affect manual dexterity shall not be approached and those unable to understand the written opening instructions discounted."*

Furthermore, in the international standard, ISO 8317:2004 "Child-resistant packaging – Requirements and testing procedures for reclosable packages", in the section "5.5.2 Composition of test group", the standard states:

> *"Persons with obvious physical handicaps which may affect manual dexterity shall not be approached and those unable to understand the instructions should be discounted."*

In the American case, the argument can be made that people with disabilities do have medication packages that are available to them. The PPPA indicates that consumers may request prescription drugs in non-CR containers, and OTC manufacturers may package one size of each of their products in a non-child-resistant container [63]. This assumes that people with disabilities are not living in environments where children are present, and, in the case of OTC drugs, limits their purchase choices. This approach to inclusion may have been appropriate at the time of the inception of the PPPA [64]. However, new trends are changing the society as we know it: the aging of the population [65], higher per capita consumption of pharmaceuticals [13, 15-17] by this vulnerable population, the cultural shift to keep people with disabilities living as independently as possible, and the desire for convenience in all consumers. Today more than ever before, it is necessary to include people with disabilities as test subjects so that new child-resistant designs are more inclusive.

CHAPTER 3

ADULT TESTING OF COMERCIALLY AVAILABLE DRUG PACKAGES

In order to characterize representative commercial drug packages from a usability standpoint (Specific aim 1.a), a set of tests was conducted with a working group of older adults and a working group of people with disabilities. Four child-resistant (CR) packages were tested according to the US CPSC senior-test protocol for CR packaging [61] and participants were asked to answer a survey about each package.

MATERIALS AND METHODS

Packages

Two CR vials and unit dose CR packages were tested. One of the vials was a 10-dram[1] 1-Clic® (Owens-Illinois Inc., Toledo, OH) vial and closure, ASTM type IIB (Fig. 3.1A). The other was a dram-13 size Screw-Loc® (Owens-Illinois Inc., Toledo, OH) vial and closure, ASTM type IIA (Fig. 3.1B). For the unit dose packages, one was a ShellPak® (MeadWestvaco Corp., Stamford, CT), ASTM type XIIIA (Fig. 3.1C) and the other was a typical CR blister package (Perrigo Co., Allegan, MI), ASTM type VIIIB (Fig. 3.1D).

Packages description

The **1-Clic® vial system** has a one-piece, plastic, reversible, lug-bayonet closure that can be used in a non-CR mode or in a CR mode. In the CR mode, the closure is opened by holding down a tab on the container labeled "HOLD" and simultaneously

[1] Dram is a unit of apothecary weight equal to an eighth of an ounce

turning the closure counterclockwise. One of the two lugs inside the closure fits into a bayonet attached to the tab on the container and the inner threads of the closure are screwed into the outer threads of the container, keeping the package closed. In the non-CR mode, the cap is reversed so that the closure is simply turned counterclockwise to open it. In this mode, the continuous threads on the outside of the closure are screwed into the inner threads on the container. The instructions on the closure are three counterclockwise arrows with the words "HOLD TAB DOWN TURN" (Fig. 3.2.A).

The **Screw-Loc® vial system** has a push-down-and-turn closure that is opened by pushing down on the closure and simultaneously turning it counterclockwise. The interior of the closure has square lugs that fit into the "L" shaped bayonets on the container neck, keeping the package closed. The instructions on the closure are two counterclockwise arrows with the words "PUSH & TURN" (Fig. 3.2.B).

The **ShellPak®** is a semi-rigid blister reclosable package. It consists of an outer high-impact, injection-molded Polystyrene shell containing a blister. The front of the blister card covers each tablet with a clear semi-rigid plastic film and the back of the blis-

Figure 3.1 – Child-resistant packages chosen for testing

ter is aluminum foil (non-CR). The CR feature of the package is opened by pressing a tab on the front of the outer shell, holding it down, and pulling a small, exposed portion of the blister card. A plastic hook inside the package prevents the blister card from being fully removed from the outer, plastic shell. Once the blister card is exposed, a tablet can be pushed through the foil. The manufacturer's instructions on the front of the outer plastic shell are "PRESS BUTTON WHILE PULLING OUT INNER BLISTER CARD" (Fig. 3.2.C).

The **CR Blister** is a semi-rigid non-reclosable, blister package. The one employed for this testing had six blister cavities, each containing a pair of pills. Every unit is covered with a molded clear semi-rigid plastic film. The CR feature of this package consists of the blister backing, which is composed of a tear-resistant paper/foil laminate. The package is opened by tearing along a series of perforations that separate the blisters from one another. A second set of perforations on one of the unit's corners allows the corner/tab to be removed by tearing it. The paper backing must first be peeled off and the pills are then pressed through the foil backing of the package.

Figure 3.2 – Printed directions for each CR package

The manufacturer's instructions on the front back cover of the card are: "1) TEAR TO REMOVE CORNER, 2) PEEL BACK PAPER, 3) PUSH THROUGH FOIL, USE SCISSORS IF NECESSARY" (Fig. 3.2.D).

Criteria for packages choice

The 1-Clic® and Screw-Loc® packaging systems were chosen for testing because of their popularity in the prescription drug market. Data provided through interviews with pharmacists (Table 3.1) and information provided by packaging manufacturers confirmed these packages to be among the most prevalent in the American prescription drug market [54, 66, 67]. Both types of packages are available in a variety of sizes (or drams). According to information provided by the manufacturer [66, 67] (See Appendix K – Personal communications), the dram-10 size of the 1-Clic® vials account for 77% of 1-Clic® sales, representing the largest seller for this type of container. The dram-13 Screw-Loc® vials account for the 43% of the sales of Screw-Loc® system, representing the largest selling size of the Screw-Loc® system. As such, these two packages are likely to be found at a pharmacy and the sizes chosen are typical.

Table 3.1 – CR packages for prescription drugs and pharmacy chains

Package	Manufacturer	ASTM Type	Pharmacy
1-Clic®	Owens-Illinois	IIB	Walgreen's MSU Olin Center[a] MSU Clinical Center[a]
Screw-Loc®	Owens-Illinois	IIA	Rite Aid Meijer Kroger
Friendly & Safe®	Kerr	IIA	CVS Sparrow Hospital[b]

[a] East Lansing, Michigan, USA
[b] Lansing, Michigan, USA

The two unit dose packaging systems were chosen for testing because they offer two different child resistant solutions: one based on a foil-backed blister encompassed in a hard plastic shell and a more traditional, peel-push blister. Therefore, both packages would challenge the user's physical and cognitive abilities in a different manner.

Screening test packages

Two non-CR packages were used for the screening test, as dictated by the protocol. One package was a 2-ounce square plastic bottle that had a plastic continuous thread (CT) closure with a bottle finish diameter of 28 mm (Fig. 3.3.A). It is important to note that the use of this package represents a slight deviation from the protocol, which dictates a round container. The package was closed 72 hours before testing with a torque of 10 inch-pounds using a Sure Torque automatic torque tester. The second package was a plastic dram-8 round vial with a plastic snap-type closure and a finish diameter of 28 mm (Fig. 3.3.B).

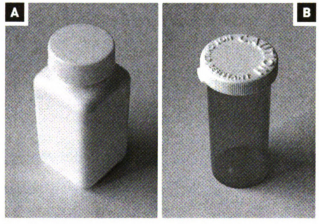


Figure 3.3 – Screening test packages

Adult panels

Participants were recruited for the two panels from the greater Lansing area (MI, USA). The project's approval for using human subjects is IRB # 05-454.

Working group A: People with disabilities

Subjects in working group A (n=10), people with disabilities, were 18 years old or older and had a variety of types of disabilities but at least partial use of one hand. The average age of this group was 52 years (s=14, min=31, max=73) and consisted of one male and nine females. People in this group reported to take, on average, 9 medications daily (s=8, min=1, max=24) (See Appendix A – Working groups composition).

Working group B: Older adults

Working group B (n=10), older adults, consisted of people 65 years old and older that had at least partial use of one hand. The average age of this group was 84 years (s=6, min=71, max=90) and consisted of two males and eight females. People in this group reported to take, on average, 7 medications daily (s=4, min=1, max=12) (See Appendix A – Working groups composition).

Testing procedure

The four packages were tested during two separate meetings with working groups A and B. Participants tested the packages individually in a well-lighted and distraction-free room. All testing was conducted in accordance with instructions of the US CPSC adult test protocol for CR packaging [61], with minor modifications. For example, each participant read and signed a consent form before participating but when participants were unable to read a researcher read the consent form aloud. In the US CPSC protocol participants that cannot read for any reason (forgot glasses, illiterate, visually impaired, etc.) are not allowed to participate in the test. Another deviation from the US CPSC pro-

tocol was that the use of tools was not allowed. For instance, even though the instructions for opening the CR blister suggest the use of scissors, participants could not use tools. Additionally, people with obvious or overt disabilities were test subjects, as compared with the US CPSC protocol, which would eliminate them from testing. Sessions were videotaped to obtain records which were used to confirm test times and inform design. Prior to the beginning of the test, information about the participants was recorded. The experiment, like the US protocol, was divided into three parts: a 5-minute period, a 1-minute period, and a screening test (See Appendix B – Adult test protocol).

5-minute period

During the initial phase of testing, the participants attempted to open and properly close a package for a maximum period of 5 minutes. Once the package had been opened and closed, opening time and time to close (if appropriate) were recorded. If the package was not opened, the time at which the participant gave up the test or, if the participant continued trying until time had elapsed was recorded.

1-minute period

Subjects that successfully opened the package during the 5 minute period, were tested a second time, the one minute portion of the test. During the one minute portion of the test, a CR package, identical to the one tested during the 5-minute period, was handed to the subject. Again, the time periods required to open and to close were recorded. If this was accomplished within the allotted 60 seconds, the CR package was recorded as a "pass" for that particular subject, if not, it was recorded as a failure.

Screening test

Subjects that could not successfully open the package during the 5-minute test period went to the screening test. The screening test consisted of two 1-minute periods

in which the participant tried to open and close two non-CR packages (described above). Subjects that opened and closed both the non-CR, screening packages continued testing with the 1-minute period. If a person did not open and close both screening packages, he/she did not proceed to the 1-minute period. In the US CPSC test participants who do not pass the screening test are excluded from the panel test; their results are not recorded and they are replaced with another test subject.

After testing each package, participants were asked if they agreed with the statement "This package is easy to use". The five possible answers to this question were "strongly disagree", "disagree", "neutral", "agree", and "strongly agree". Answers were translated into a numerical scale from zero (strongly disagree) to four (strongly agree) in order to calculate a subject's ease-of-use rating. Subjects also reported if they had used a package like the one just tested.

Observation of use

All the openability tests were video taped with a digital camcorder; those videos were used to gain understanding of the user needs.

Universal Design Performance Measures

Participants were asked to answer a survey after using each package. The Universal Design Performance Measures for Products [68] consists of a set of 29 statements, derived from the seven universal design principles (Table 1.1). The statements were tailored for drug packaging use and a scale from zero (strongly disagree) to four (strongly agree) was employed. Statements sparked participant's comments that were recorded as well. Researchers gained qualitative information about the usability of the four packages tested in the openability testing (See Appendix F – Universal Design Performance Measures).

Data analysis

A Pearson product-moment correlation was done between opening times and subject's ease-of-use ratings. Portney and Watkins's guidelines were used to interpret the association between the variables where correlations ranging from 0 to .25 indicate little to no relationship, .25 to .50 a fair degree of relationship, .50 to .75 a moderate to good correlation, and greater than .75 a good to excellent relationship [69].

RESULTS AND DISCUSSION

Openability

Openability results refer to the percentage and number of participants able to open a package. These results are shown in Table 3.2 together with average opening times. For both working groups, the 1-Clic® package was the most opened package. Ninety percent of all adult participants could open it during the 5-minute period, and all of the participants who passed the screening test did so during the following 1-minute period. The most difficult package for both groups to open was the CR blister package. During the 5-minute period, only 40% percent of participants in working group A and 30% of subjects of working group B were able to open it. Those percentages dropped to 10% and 13%, respectively, for the 1-minute period.

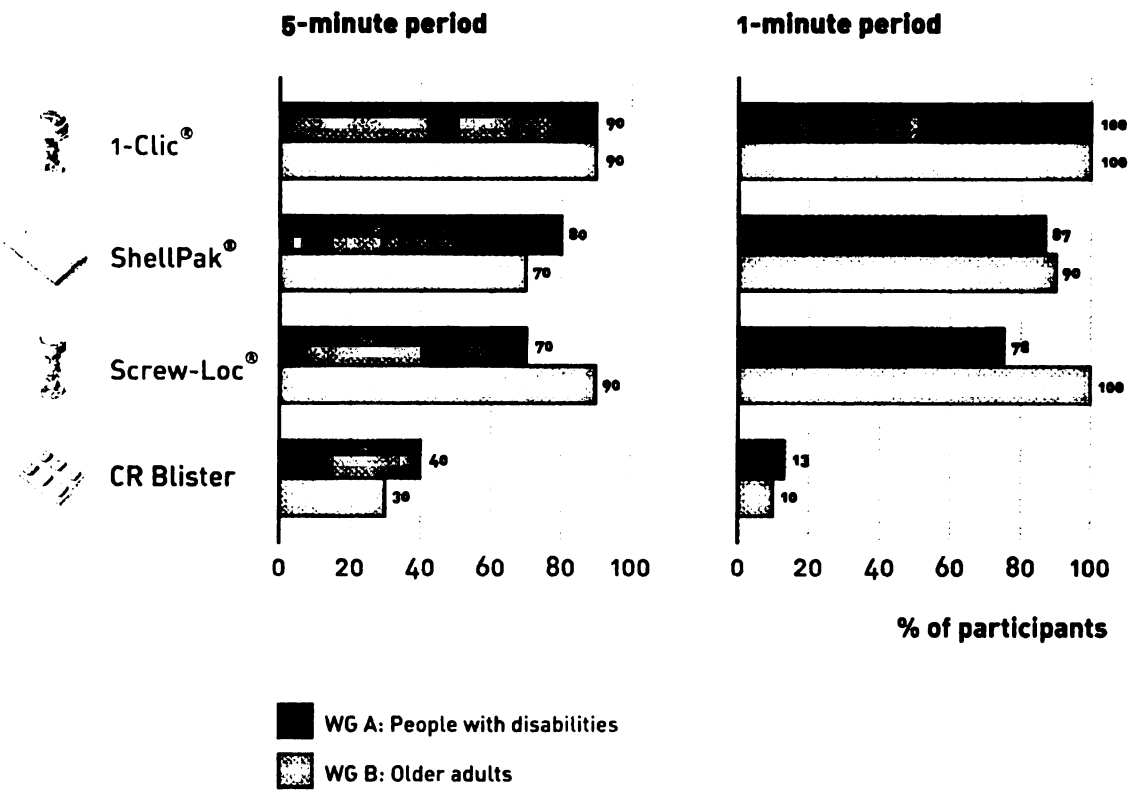


Figure 3.4 – Percentage of participants able to open the four CR packages

For working group B, older adults, the first place in openability was shared by two packages: 1-Clic® and Screw-Loc®. For both packages, 90% and 100% of the total participants could open them during the 5-minute and 1-minute period respectively.

Table 3.2 – Average opening times and number and percent of subjects able to open the four CR packages in both periods of time

Working group	Package type	5-minute period			1-minute period*		
		Opening time (seconds)	Number of subjects able to open the package		Opening time (seconds)	Number of subjects able to open the package	
A (n=10)	1-Clic®	26 ± 23	9	(90%)	12 ± 14	9	(100%)[a]
	ShellPak®	57 ± 28	8	(80%)	18 ± 12	7	(87%)[b]
	Screw-Loc®	8 ± 10	7	(70%)	5 ± 4	7	(78%)[a]
	CR Blister	153 ± 52	4	(40%)	50 ± 0	1	(13%)[b]
B (n=10)	1-Clic®	10 ± 8	9	(90%)	5 ± 3	10	(100%)
	ShellPak®	64 ± 38	7	(70%)	26 ± 16	9	(90%)
	Screw-Loc®	9 ± 6	9	(90%)	12 ± 14	10	(100%)
	CR Blister	98 ± 41	3	(30%)	54 ± 0	1	(10%)

* Only participants that passed the screening test
[a] : n=9 because 1 participants did not pass the screening test
[b] : n=8 because 2 participants did not pass the screening test

For both working groups, ShellPak® ranked second in both the five and one minute periods as the most opened package. In the 5-minute period it was opened by 80% of the subjects in group A and 70% of the people in group B. In the 1-minute period, those percentages increased to 87% and 90% respectively. This is possibly because participants became familiar with the package during the 5-minute period and, in the people with disability group, two participants did not pass the screening test.

Previous experience

Subjects of both working groups were very familiar with the Screw-Loc® package (95%, 19 subjects), followed by the CR blister (70%, 14 subjects), and the 1-Clic® (35%, 7 subjects). Very few participants had used a package like ShellPak® before (15%, 3 subjects) (Fig. 3.5).

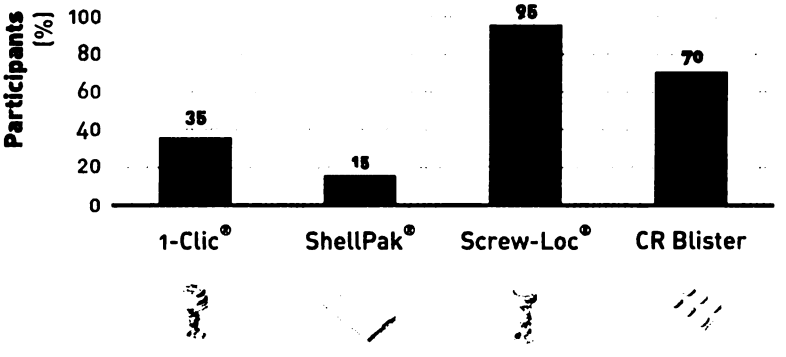


Figure 3.5 – Percentage of participants that reported to have used the package before.

Opening time

Table 3.3 summarizes average opening times for each of the four packages. Both working groups showed a similar pattern (Fig. 3.6), the Screw-Loc® and 1-Clic® are opened faster than ShellPak® and the CR blister. For both working groups Screw-Loc® was opened faster than the other three packages, 8 seconds (people with disabilities) and 9 seconds (older adults) on average, this could be because of the prevalence of the push-and-turn package (Fig. 3.5).

Table 3.3 – Average opening times in both periods and percentage of change between periods

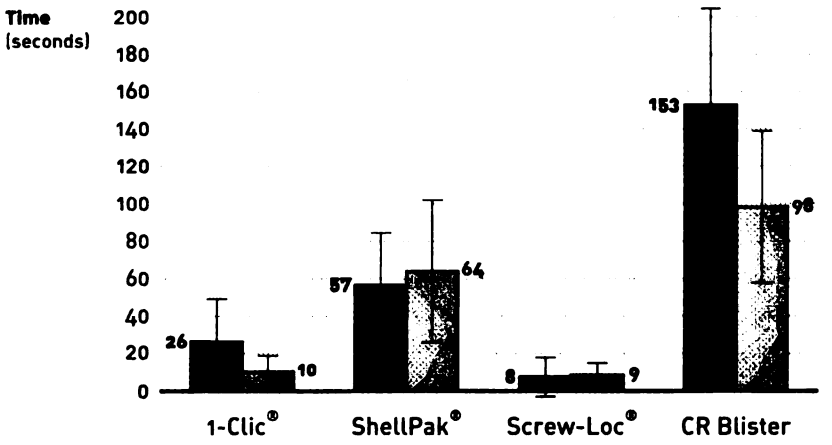
Working group	Package	Opening time (seconds)		Percentage of change between periods
		5-minute period	1-minute period*	
A (n=10)	1-Clic®	26 ± 23	12 ± 14	-54
	ShellPak®	57 ± 28	18 ± 12	-68
	Screw-Loc®	8 ± 10	5 ± 4	-38
	CR Blister	153 ± 52	50 ± 0 [a]	-67
B (n=10)	1-Clic®	10 ± 8	5 ± 3	-54
	ShellPak®	64 ± 38	26 ± 16	-60
	Screw-Loc®	9 ± 6	12 ± 14	+34
	CR Blister	98 ± 41	54 ± 0 [a]	-45

* Only participants that passed the screening test

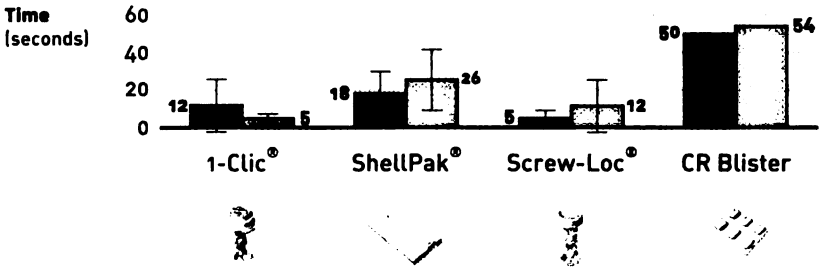
[a]: because only one participant opened it

In the 1-minute period times to open were reduced drastically, suggesting that familiarity with a package during the 5-minute period plays an important role in opening speed (Table 3.3, final column). The only exception was the Screw-Loc® (group B), which showed an increase of the average opening time of 34%. This was because three participants spent considerably more time (18, 34, and 39 seconds) than the other seven participants (2, 2, 3, 3, 4, 5, and 5 seconds)

5-minute period



1-minute period



People with disabilities

Older adults

Figure 3.6 – Average opening time for both working groups.

Ease-of-use rating

Table 3.4 and Figure 3.7 summarize the subject's ratings for each package. The rating scale goes from zero through four; the following list explains the meaning of each rating:

- Zero: "I STRONGLY DISAGREE that this package is easy to use"
- One: "I DISAGREE that this package is easy to use"
- Two: "I am NEUTRAL about considering that this package is easy to use"
- Three: "I AGREE that this package is easy to use"
- Four: "I STRONGLY AGREE that this package is easy to use"

For the purpose of this study, it was decided that a package should get more than two points in the mentioned scale to be considered easy to use. For both working groups, the 1-Clic® package got the best ratings (2.7 for people with disabilities and 3.6 for older adults). However, the lower rating for people with disabilities points to some usability problems.

Table 3.4 - Subject's average ease-of-use rating

Working group	Package	Subject's Ease-of-use Rating
A (n=10)	1-Clic®	2.7 ± 1.3
	ShellPak®	1.6 ± 1.6
	Screw-Loc®	1.2 ± 1.5
	CR Blister	0.3 ± 0.9
B (n=10)	1-Clic®	3.6 ± 0.5
	ShellPak®	1.3 ± 1.3
	Screw-Loc®	2.1 ± 1.3
	CR Blister	0.2 ± 0.4

For people with disabilities there were no other packages that obtained more than 2 points (besides 1-Clic®), the closest was ShellPak® with 1.6 points. For older adults, the Screw-Loc® obtained 2.1 points; this rating is very close to a neutral position about the statement "This package is easy to use". The CR blister obtained very poor ease-of-use ratings for both groups.

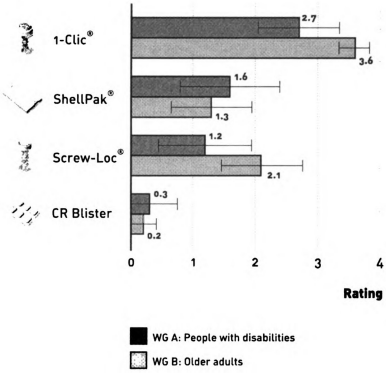


Figure 3.7 – Subject's ease-of-use rating calculated from the answers to the statement "This package is easy to use". Possible answers include: 0 = strongly disagree, 1 = disagree, 2 = neutral, 3 = agree, 4 = strongly agree

Opening time and ease-of-use rating

During all the 5-minute periods, from a total of 80 trials (20 subjects tried to open 4 packages), participants could not open a package on 24 occasions. As would be expected, these participants gave very low ratings to packages that were not successfully opened. Nineteen subjects rated them with zero, four subjects with a one, and one par-

ticipant with a three (a participant who later opened the package during the 1-minute period). A Pearson product-moment correlation was calculated between opening times during the 5-minute period of people who opened a package (n=56, 80 trials minus 24 failures) and subjects' ease-of-use ratings. A moderate correlation ($r = 0.57$, $p < 0.01$) between opening times and the subject's ease-of-use ratings is shown in Figure 3.8.

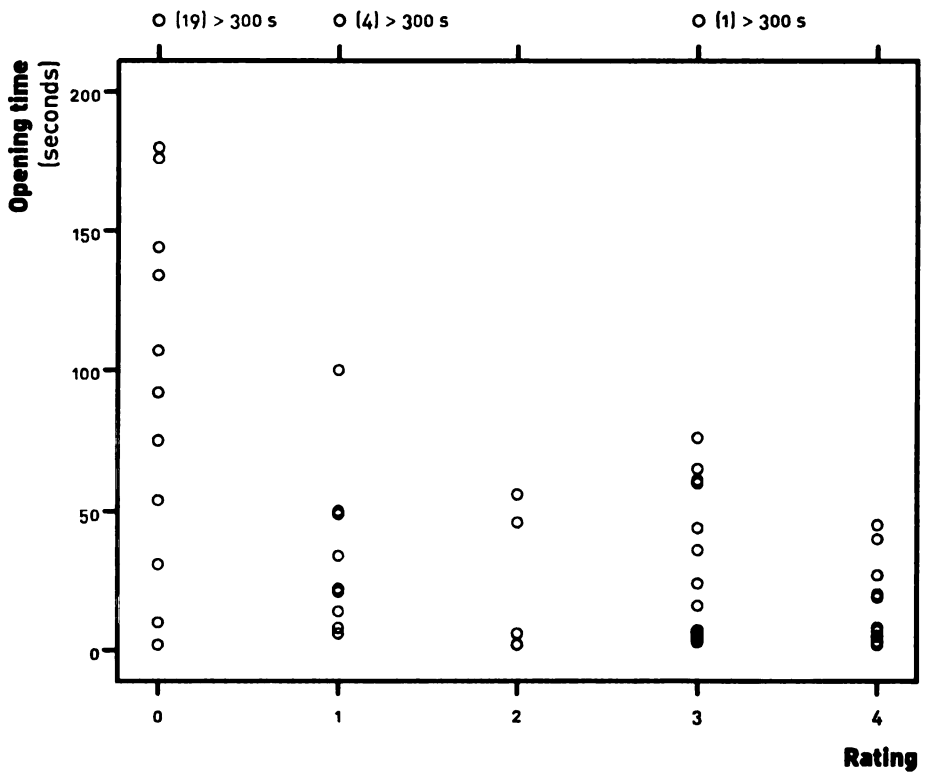


Figure 3.8 – Relationship between opening time and subject's ease-of-use rating for all adult participants.

However, despite low opening times for a given package, some subjects still rated that package low in terms of ease of use. A general trend is suggested: the longer a package takes to be opened the higher the probability of being rated low but, a fast opening time does not necessarily mean a good ease-of-use rating. A good example of this situation is the Screw-Loc®, which had the lowest opening times but a neutral to bad average

ease-of-use rating. A possible explanation of this situation is the pain in the hands reported by several participants when they do the push-down-and-turn operation. This is especially true for those participants who use pill organizers and need to open several vials periodically to refill them.

Screening test

Eighty six percent (18) of the total number of participants (n=20) opened both types of screening packages (Fig. 3.3). In other words, two participants did not pass the screening test because they could not open the screening package with the CT closure. However, both successfully opened the snap-type closure. Both of these participants have muscular dystrophy. This fact was extremely useful because it helped researchers determine what people with muscular weakness and very limited hand dexterity can do regarding opening packages.

As suggested by previous studies with elderly populations [34, 53], the snap-type closure was found to be successful with all participants, even those with very limited hand dexterity. Winged-top containers have been suggested to help compliance in patients with mobility problems because they provide easy access to the medicines [53]. This is probably because it requires a simple motion and a small amount of force. However, some snap-type closures come off so easily that they are not useful for being carried in a purse.

Closability

Researchers evaluated the packages after each test to see if they were properly closed. In general, participants who were able to open a package were able to successfully close the package as well. The exception was one participant (group B, older adults) who could not resecure a Screw-Loc® package after the 5-minute and 1-minute periods.

Universal Design Performance Measures

The survey allowed the qualitative analysis of the 1-Clic®, Screw-Loc®, ShellPak® and CR blister packages from the perspective of the seven principles of UD and sparked user's comments about the packages. The following statements are comments of participants; they are identified by the group letter and participant number.

1-Clic®

1: Equitable use

"Once you know how to do it, it's easy" (A3)

"I can't use my index finger, need to use another finger. I made an adaptation" (N: to push down the tab) (A4)

"It's a nice alternative to the push and turn" (A5)

"It wasn't that difficult" (A8)

"I probably would use it" (B1)

"I like this concept very much" (B7)

"It's safe... adults can use it and it's impossible for kids to get in" (B9)

2: Flexibility in use

"It is not too bad because you can use it in a different way" (N: reversible cap) (A4)

"I keep one of these [packages] to refill it. I usually put the cap upside-down to avoid spilling it in my purse. The whole thing is more difficult with the other side" (A7)

"It depends on the strength of the person" (B9)

3: Simple and intuitive use

"If you can read it is simple. The most important features are the most obvious only if you can read" (A4)

"Tab language is hard to understand" (A5)

"I can tell the top from the bottom" (A8) (visually impaired)

"After you show me the tab" (B1)

4: Perceptible information

"Had to be sure I read the top because I didn't know how to do it" (A4)

"When it clicks you can tell the cap is secured... I can't see the directions but I was able to open it... I can make Braille labels for it" (A8) (visually impaired)

"I'm legally blind... the first time I had to have someone to show me how to open it" (A10)

"The instructions were not very clear" (B2)

5: Tolerance for error

"If you read the directions and the tab does not work, you are confused" (A4)

"When upside down I don't think I can make a mistake. This package does not make me focus" (A7)

"It is not complicated...eliminates spilling" (B3)

"The first time I used it required my attention" (B4)

"It is not going to spill out" (B7)

6: Low physical effort

"Some days it is hard to open this bottle" (A1)

"The number of bottles is important, when you have to open 10 or 12, repetitive motion is bad" (A7)

7: Size and space for approach and use

"Little bottles are harder. A little bit longer would be better" (A7)

"I didn't see the tab to begin with" (B1)

"I didn't see the tab clearly" (B3)

Screw-Loc®

1: Equitable use

"It's harder on my thumb. You have to exert a lot of pressure." (A4)

"I personally don't find this user friendly... Baby boomers getting older, taking a lot of pills..." (A7)

"I don't like these caps... are harder to get it open" (A8) (visually impaired)

"Twisting makes me spill the pills" (A10)

"Maybe someone can't coordinate" (B4)

"Others will have a hard time... It frustrated me" (B5)

"Other people have a better approach" (B6)

"It could be difficult for others... it's safe" (B9)

2: Flexibility in use

"Need both hands available." (A4)

"I can't get very quickly into it" (A8)

"I might struggle...spill them out in the bathroom... I'd put them in different package" (B5)

"I can use it once I get the hang of it...It takes some time to use it" (B1)

"I wouldn't carry it with me to dinner" (B9)

3: Simple and intuitive use

"Directions and design are not straightforward." (A5)

"It's simple if you have use of your hands" (A7)

"I expect it not to work because I have had problems" (A7)

"Once I read it, it helps to read" (B7)

"I didn't know about the button" (B9)

4: Perceptible information

"I can easily identify the directions but I can't follow them" (A3)

"Can't see the writing" (A7)

"I have to guess" (A10)

5: Tolerance for error

"If you can't open it will hurt you" (A-7)

"I can get it open but I'm afraid of holding it... It has to be in my lap... and I use a bag to avoid a spillage" (A10)

6: Low physical effort

"It's hard to push because I don't have any strength" (A5)

"This is the normal package I get from my pharmacy. I feel this package awkward. I can feel it in the center of my hand; I don't want to open 10 bottles like that. I just can't get the lid" (A7)

"My hands always hurt after using this... I have to rest after doing a couple" (A8)

"People might not have strong enough thumb" (B4)

"I pulled a muscle last week, it hurts to push and turn" (B5)

7: Size and space for approach and use

"I don't have a grip on this... need it to be taller!" (A6)

"This size is not that bad to handle. One size bigger, longer, would probably be easier" (A7)

ShellPak®

1: Equitable use

"This package is far better than the CR blister" (A1)

"Package does not explain that the inner foil does not come out separate from plastic" (A2)

"They [packages] should all be that easy" (A3)

"The interior pills are easy to get" (A5)

"I like the idea that you can slide it out, the button is not working" (A5)

"It's not too bad... it's doable but not easy... It's nice because the pills won't be all over the place... I don't hate this package" (A7)

"I don't like it at all... It's frustrating" (A10)

2: Flexibility in use

"I can use it, but it makes my thumbs hurt" (A4)

"It's not a perfect solution but.... I need a table to lay my hands on... I prefer the flip off cap that you can use with one hand... I prefer two steps... for instance, push then pull" (A7)

"I see myself with a medication holder with many of these [packages] in a box" (A7)

"I wouldn't want to have to carry it with me... it takes up a lot space" (A8)

"I'd be concern about spilling the pills... I have numbness in the hand and can't feel the pill" (A10)

"I have to use it over a table" (B5)

"If I work at it I can do it but it's inconvenient" (B6)

3: Simple and intuitive use

"Why do they make these? I wouldn't buy it" (A5)

"I didn't know if I was pushing hard enough" (A6)

"The button could be a hinge" (A7)

"You need to read directions twice" (B6)

"Doesn't work well" (B7)

4: Perceptible information

"I can understand the instructions pretty easily but the package is hard. I can't use it" (A6)

"The [light] reflection [in the foil] is bothering so I can't read [the instructions]" (A7)

"It's not easy to figure it out if you can't read the instructions... I can use my Braille labels on it" (A8) (visually impaired)

5: Tolerance for error

"If it were a drug that I need, it's dangerous" (A5)

6: Low physical effort

"I have to rest in between times and still can't do it" (A3)

"Pressing the button makes hurt my thumb, there pressure kills me. My left hand hurts, either pulling or pressing. I wouldn't want to repeat opening it frequently." (A4)

"The button is hard to push ... I can't do two things at the same time. My right hand hurts because I tried to do two movements... It could get frustrating" (A7)

"I need more finger strength... It works with repeated trials" (B6)

"I had to press really hard... using my thumbs is uncomfortable" (B10)

7: Size and space for approach and use

"For me, it would be good more space to grab it with my teeth on the end" (A3)

"The space for grabbing the blister card should be bigger" (A5)

"General size is good. The blister is hard to grab, the grabbing part is too small" (A6)

"General size is good to grab it... The area for pulling the blister could be bigger... The button is the most miserable part... Once it's open it's easy" (A7)

"It's too bulky... I'd rather a smaller package" (A8)

"General size is ok... I couldn't get the part for grabbing the blister card" (A10)

CR blister

1: Equitable use

"Corners of individual pills can't be separated" (A2)

"Very hard to open.... I'd use a pair of scissors" (A4)

"If I had the choice, I'd choose a bottle but they are not always available" (A4)

"It's too hard to open. Almost impossible" (A4)

"I can't use this package" (A6)

"I'm glad I don't get anything in this package. I'd ask the pharmacist to put the pills in a bottle" (A7)

"These things are horrible and ridiculous... frustrating" (A8)

"I get impatient and I think I'm the problem... I hope I was not desperate to take that pill" (A9)

"It's too small, too intricate" (A10)

"It's too safe" (B1)

"It's too safe... the box was easy not the blister [laugh]" (B2)

"Nobody is going to get a pill" (B7)

"Don't know anyone who can use it" (B8)

2: Flexibility in use

"I'd use a knife or I would not be trying" (A4)

"I'd use scissors to open this" (A6)

"I might take some scissors" (A7)

"I use Benadryl and I usually take the scissors... I took the pills out and put them in a vial" (A8) (visually impaired)

"I'd probably stick a knife" (A9)

"I'd open it with a knife" (B1)

"I wasn't able to use it" (B3)

"Perhaps if I have scissors" (B4)

"I'd use tools, scissors" (B5)

"I can cut it with scissors" (B10)

3: Simple and intuitive use

"I understand the directions but they don't work! Can see how to do it, but it doesn't work how I would be expect it to."

"I can understand the words, isn't possible most of the time" (A-4)

"It doesn't work for me. Even when you tear apart the corner it won't open up" (A7)

"It's very bad" (B1)

"I was looking at the other corner" (B2)

"It doesn't work the way it supposed to" (B4)

"It didn't function as it says... its purpose is to keep me out of it" (B5)

"Directions are Ok but they don't work" (B6)

"I read the directions but couldn't open" (B8)

"[I] understood directions but it didn't work" (B9)

"There has to be an easy way" (B10)

4: Perceptible information

"It's hard to read what's in there" (A7)

"The package makes absolutely no concession to anybody with any difficulty in seeing... it doesn't have any large printing on the little packages or on the back of the box... even for someone who just even wears bifocals... much less somebody who is legally blind....and can only see much up to right here and... it has unusual directions that you can't guess how to do it... the wording is very awkward" (A10)

"There is a big gap between directions and usage" (B5)

"I understand the directions just can't open it" (B7)

"It's hard to do though" (B10)

5: Tolerance for error

"If I use scissors I might cut myself" (Note: Participant can use only one hand) (A3)

"The plastic is too sharp. I could cut myself" (A7)

"It's too easy to cut yourself using this thing. It would be dangerous to use scissors" (A7)

"I could cut myself with scissors, or cut the pill... make a mess" (A8)

"I can't get it open" (A10)

"I couldn't peel the paper off... using scissors or a knife you could cut yourself" (B1)

"I can cut myself" (B4)

"I can wound myself using it" (B5)

"I can't overdose with it [laugh]" (B6)

"I lose my temper...it makes me unhappy" (B8)

6: Low physical effort

"The whole thing is a waste of time. It would be easy just to buy a bottle." (A1)

"It's making my finger hurt. It's too tough to break through. I have to stop trying" (A4)

"Frustration levels go up" (B5)

"You get mentally upset" (B6)

"I have to exert myself a lot" (B9)

7: Size and space for approach and use

"I couldn't use it" (A3)

"Anything larger would be better" (A6)

"It's too little" (the single unit with a couple of pills in it) (A7)

"Once you get the separate pack... the portion is too small... I can't do tiny stuff" (A10)

"Difficult but I opened them" (B9)

"For me, it's hard to grab tiny things" (B10)

Observation of use

The observation of the openability tests and the comments made by the users were synthesized in general and for each package. They take into account positive and negative issues.

In general

- For people with limited hand dexterity, sequential operating movements are easier than simultaneous operations.
- Spilling of contents on the floor and in the purse was recurrently indicated to be a concern. This problem has been reported in previous studies [41, 42]. Spilling of the contents onto the floor occurred when opening a container required too much strength so the actions are difficult to control. Spilling in the purse occurred when the cap popped out (e.g.: snap-type closure).
- A flip top lid that remains attached to the container would be appreciated.
- Very few participants used prescription drug vials to carry medications with them.
- Pill organizers were the only packaging participants could think of for helping compliance.
- Little pill boxes are often used when traveling or visiting.
- Directions on caps that are only embossed in the plastic were found hard to read.

1-Clic®

2: Flexibility in use

- The reversibility of the cap (CR and non-CR position) was well regarded by participants.

3: Simple and intuitive

- There were recurring problems with communicating what the tab is.

- Upon first impression, people tended to think this package was a push-down-and-turn vial.

4: Perceptible information

- There were problems identifying and locating the tab.
- Most participants thought the idea of the reversible cap was great but several people did not know about that feature until another person told them.

Screw-Loc®

1: Equitable use

- For people with disabilities and some older adults, the simultaneous operations complicate opening.
- For people who can only use one hand this package is impossible to open.

4: Perceptible information

- There was a participant who had trouble closing the Screw-Loc® package on two occasions. Participant thought the packages were secured. During the closing operation, both Shellpak® and 1-Clic® provide physical feedback and an audible cue, a click sound, while the Screw-Loc gives less than clear physical feedback to confirm resecuring.

6: Low physical effort

- For people with difficulties associated with the hands the Screw-Loc® requires too much force.

ShellPak®

3: Simple and intuitive

- People expected the blister card to separate completely from plastic shell.
- The word button in the directions confused people.
- Sometimes directions were hard for participants to find.

5: Tolerance for error

- If the participant opens the package with the button and directions facing up the blister card comes out with the pills facing down so that the user have to rotate the package 180 degrees to see the pills.

4: Perceptible information

- Most of the participants tended to use their nails to break the foil instead of pushing the pill through the plastic.
- The blister card system is good to keep track of the medications. Users can see if they took or not a specific pill.

6: Low physical effort

- Some participants thought the ShellPak® required too much force to pull the blister and to push the button.
- The foil on the back of the blister card was easy for participants to break.

7: Size and space for approach and use

- There was not enough space to grasp the blister card and pull it out.
- There was not adequate gripping surface to pull the blister card out.

CR Blister

The product comes in a glued folding carton. No participants had difficulty opening it.

1: Equitable use

- Most of the participants did not have the ability and strength required to open the blisters.

2: Flexibility in use

- The majority of participants would use a knife or scissors to open CR blister packages. This was not allowed during testing and very few participants were able to open the package.

3: Simple and intuitive

- Directions seemed to lack clarity, sometimes confusing users.

4: Perceptible information

- Directions are too small.

6: Low physical effort

- The CR blister requires too much precision pinching and grasping.

7: Size and space for approach and use

- It does not have enough space to grab and peel the backing.

CONCLUSIONS

- Opening time is related to a subjective user rating. However, it is not the only factor to explain user satisfaction.
- Even though few participants had used the 1-Clic® package before, it got a very good subject's ease-of-use rating from participants in working group B (older adults) and a fair rating from working group A (people with disabilities).
- The Screw-Loc® package had low opening times in both workings groups but it did not have good user ratings. This could be because people with disabilities had troubles opening it and the people who did open it thought it was not an easy task. The physical effort required by this package seems to be higher than the one demanded by the 1-Clic®.
- People with muscular weakness and very limited hand dexterity can easily open non-CR snap-type closures. All the participants were able to open the snap-type closure.
- It is likely that the CR blister used in this study would have never passed the US CPSC protocol if the testing did not allow the use of scissors.

CHAPTER 4

CHILD TESTING OF COMERCIALLY AVAILABLE DRUG PACKAGES

In order to characterize representative commercial drug packages regarding child resistance (Specific aim 2.a), an openability test was conducted with a working group of children. Four child-resistant (CR) packages were tested according to the US CPSC child test protocol for CR packaging [61].

MATERIALS AND METHODS

Packages

The same packages used in the adult testing were used with the child test (Chapter 2):

- A 10-dram 1-Clic® (Owens-Illinois Inc., Toledo, OH) vial and closure, ASTM type IIB (Fig. 3.1A),
- A 13-dram Screw-Loc® (Owens-Illinois Inc., Toledo, OH) vial and closure, ASTM type IIA (Fig. 3.1B).
- A ShellPak® (MeadWestvaco Corp., Stamford, CT), ASTM type XIIIA (Fig. 3.1C)
- CR blister package (Perrigo Co., Allegan, MI), ASTM type VIIIB (Fig. 3.1D).

Children panel

Participants were recruited from the Saginaw area (MI, USA). The project's approval for inclusion of human subjects is IRB # 05-454.

Working group C: Children

Subjects in working group C (n=8) consisted of children between 42 and 54 months old. The maximum age limit for the US CPSC is 51 months so the child panel for this study represents a more severe test of the package. Children included in this group had no physical or mental handicaps, injuries, or illness that would interfere with testing. The average age of this group was 47 months (SD=4.7, Min=41, Max=54) and consisted of three females and five males (See Appendix A – Working groups composition).

Testing procedure

The four packages were tested during two separate meetings. Children tested the packages in pairs in a well-lighted room that was familiar to them (Childcare facility Growing Years, Saginaw, MI). All testing was conducted in accordance with instructions of the US CPSC child test protocol for CR packaging [61]. The experiment was divided into two 5-minute periods. Each child was given a package for a 5-minute period and asked to try to open it. After the 5-minute trial, if the child had not successfully opened the package, a tester visually demonstrated how it is opened, and asked the child to try again for another 5 minutes. Children were also told that they could use their teeth if they wished (See appendix C – Child Test Protocol). All sessions were videotaped from behind a one-way mirror.

Task analysis

Task analysis was used to analyze video recordings. For each package, researchers identified common motions that the children employed (e.g. twist cap, pull blister out, hold, play, etc.) and calculated the percentage of time spent on each action during the first and the second 5-minute period.

RESULTS AND DISCUSSION

Openability testing

All CR packages were open by a child at least once (Figure 4.1). Screw-loc® was opened by four children (50%), ShellPak® was opened by 2 children (25%), and 1-Clic® and the CR blister were opened by 1 child (12.5%) each. It should be noted that the child that successfully opened the CR blister and the 1-Clic® opened all packages. Out of the eight openings, seven were after the visual demonstration. This finding suggests that the tester has an important impact on the final result of the test.

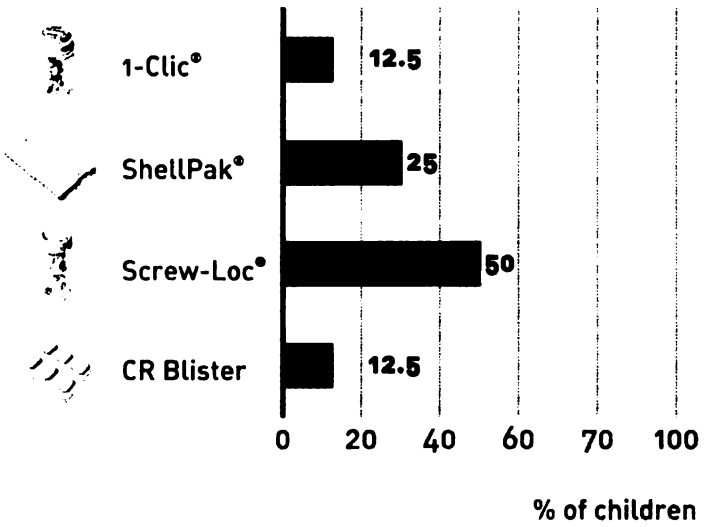


Figure 4.1 – Percentage of children who opened each CR packages

Task analysis

Different, typical actions were defined for every package. Eleven categories were defined for the 1-Clic® (Table 4.1), thirteen for the ShellPak® (Table 4.2), nine for the Screw-Loc® (Table 4.3), and ten categories for the CR blister (Table 4.4).

Table 4.1 – Typical child actions for 1-Clic®

Category	The child...
Nothing	is not touching the package
Plays	is playing with the package with no intention of opening
Rattles	is shaking the package
Uses teeth	tries to pull up the cap with his/her teeth
Hits container	hits the container against the floor, or with his/her hand
Hits cap	hits the cap against the floor, or with his/her hand
Pulls up cap	pulls up the cap
Pushes down cap	pushes down the cap
Manipulates tab	pushes, pulls or manipulates the tab
Twists cap	holds the cap and makes a twisting movement
Holds	holds the package in his/her hand. This comprises the time examining the package as well as the time holding the package without necessarily paying attention to it

Table 4.2 – Typical child actions for ShellPak®

Category	The child...
Nothing	is not touching the package
Plays	is playing with the package with no intention of opening
Rattles	is shaking the package
Peels foil	is trying to peel the foil off the blister
Manipulates blister (foil side)	is trying to puncture the foil side of the blister
Manipulates blister (plastic side)	is grasping the plastic blister and trying to open it by twisting, pulling or puncturing
Pulls blister and manipulates button	is pulling the blister and touching the button at the same time
Pulls blister with teeth	pulls the blister with the teeth while holding the plastic shell
Pulls blister	is holding the plastic shell with one hand and pulling the blister with the other
Tears shell apart	is trying to pull apart the opening of the plastic shell
Pulls up button	is pulling up the button, generally trying to insert his/her fingers under it
Pushes down button	is pressing down button
Holds	is holding the package in his/her hand. This comprises the time examining the package as well as the time holding the package without necessarily paying attention to it

Table 4.3 – Typical child actions for Screw-Loc®

Category	The child...
Nothing	is not touching the package
Plays	is playing with the package with no intention of opening
Rattles	is shaking the package
Uses teeth	is trying to pull up cap with his/her teeth
Hits cap	is hiting the cap against the floor, or with his/her hand
Pulls up cap	is pulling up the cap
Pushes down cap	is pushing down the cap
Twists cap	is holding the cap and making a twisting movement
Holds	is holding the package in his/her hand. This comprises the time examining the package as well as the time holding the package without necessarily paying attention to it

Table 4.4 – Typical child actions for CR blister®

Category	The child...
Nothing	is not touching the package
Plays	is playing with the package with no intention of opening
Pushes pill through plastic side	is pushing pill through the thermoformed plastic side to break foil
Uses teeth	is using teeth to peel foil, or to tear blister
Manipulates blister (foil side)	is trying to puncture the foil side of the blister
Manipulates blister (plastic side)	is grasping the plastic bubble and tries to open it
Tears through cut lines	is tearing through the pre-cut lines in blister
Bends	is bending the blister through perforated cutting lines
Peels foil	is trying to peel foil
Holds	is holding the package in his/her hand. This comprises the time examining the package as well as the time holding the package without necessarily paying attention to it

Elapsed time for each action was translated into a percentage of the total time period (5 minutes or less, if the package was opened). All percentages described below represent percentages of the total time across the eight children. The analysis of what kept children focused revealed different opening strategies and behavioral patterns for each package.

1-Clic®

Figure 4.2 offers a snapshot of a typical result for the 1-Clic® package. During the first 5-minute period most children tried to twist the cap for the majority of the time (41.8%). After the demonstration, the focus was on playing with the package (39.6%) and twisting the cap (23.6%).

During both periods, children spent small fractions of time in other actions (pushing down cap, pulling up cap, hitting cap and container, and using the teeth). The tab does not appear to catch the attention of the children; they probably did not see it or they did not know what to do with it. In the first 5-minute period children spent 0.5% of the time manipulating this tab and 1.7% doing so in the second period. This is an important observation, as understanding the function of this tab is a key to successfully opening the vial.

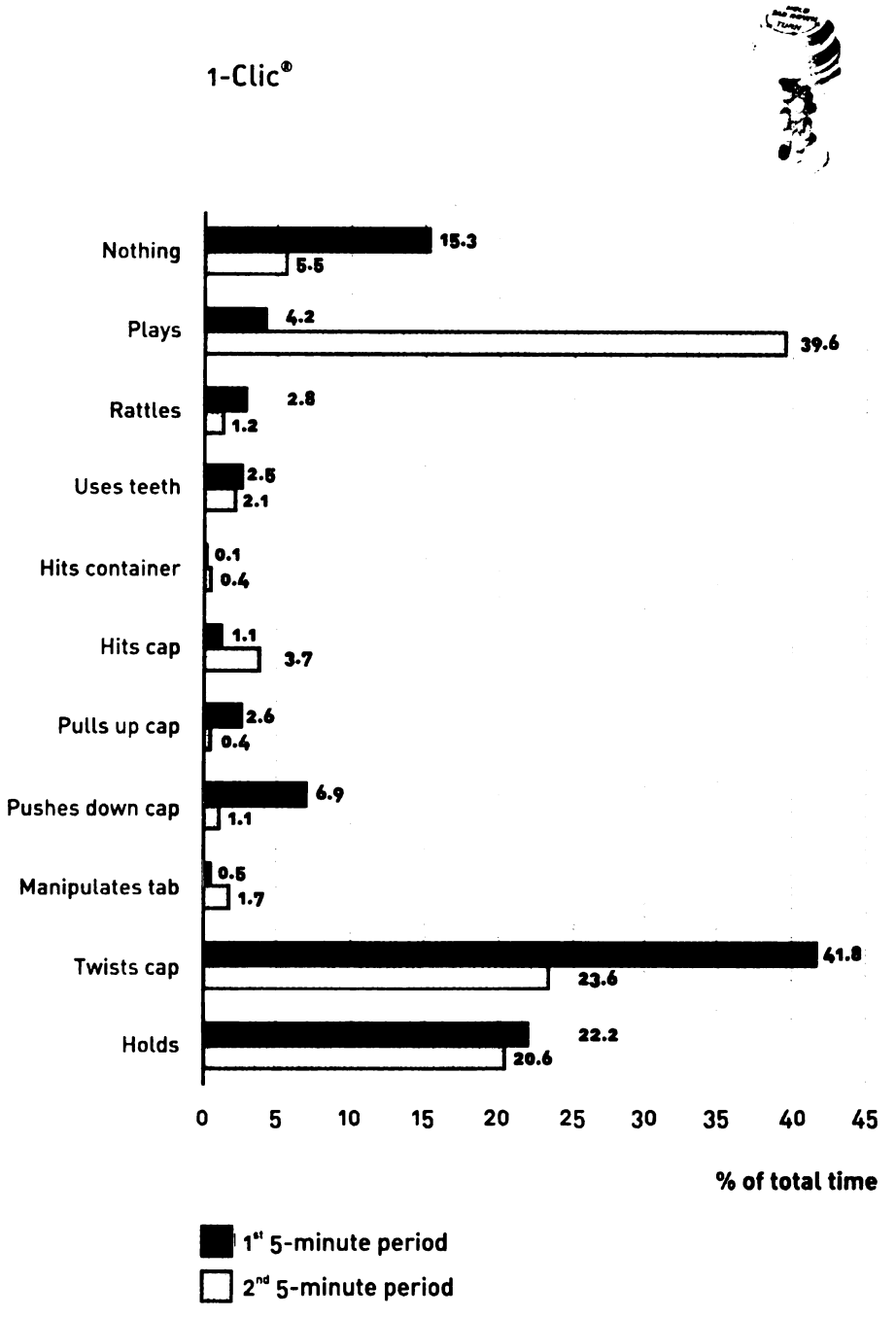


Figure 4.2 – Percentage of time spent on typical child actions for 1-Clic®

ShellPak®

Figure 4.3 describes the typical actions for the ShellPak® package. During the first 5-minute period children tried to pull up the button (or tab) (20% of the total time) and tried to pull out the blister card (19.6%). Another typical action was to try tearing apart both plastic shells (13.5% of the time).

After the demonstration, children were focused on pulling the blister out (27.7%). In this period, several children were successful in pulling the blister out. This can be observed on the typical actions in which children spent most of the time: manipulating the plastic side of inner blister (18.4%), pulling blister and manipulating the button (simultaneously) (8.4%), manipulating the foil side of the blister (4.1%), and trying to peel the foil (2.5%).

Four out of eight children gained access to the inner blister but even then, only two could get a pill out. The majority of children tested did not try to push the pill through the clear plastic to cause the breaking of the foil. The use of teeth did not appear in the first period but it appeared briefly (1.1%) in the second period.

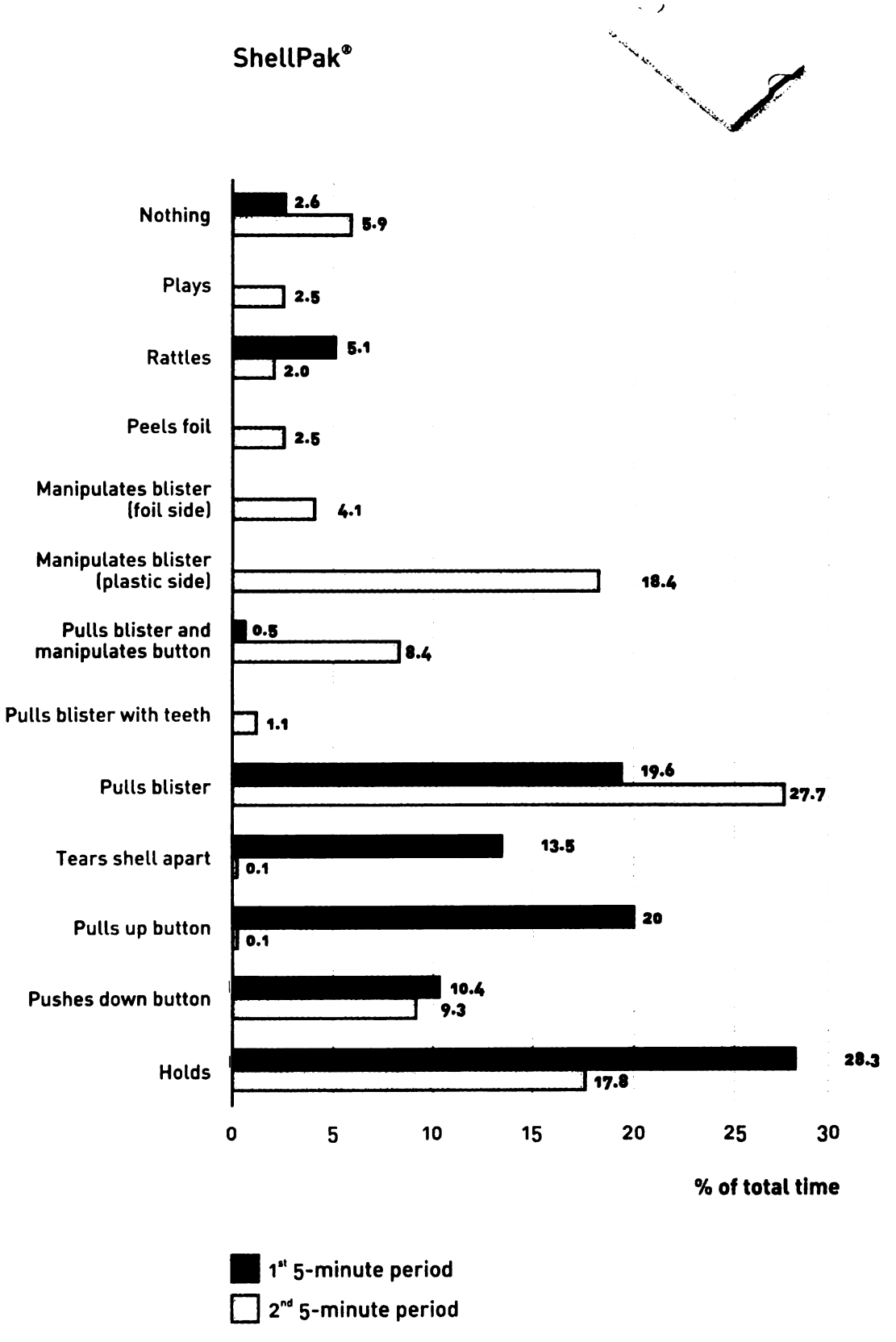


Figure 4.3 – Percentage of time spent on typical child actions for ShellPak®

Screw-Loc®

Figure 4.4 describes the typical actions for the ScrewLoc® package. This package resulted in a fewer number of typical actions. During the first 5-minute period children mostly tried to twist the cap (21.5%) and pull the cap up (10.5%). The third most common action in this period was the use of teeth (6%).

After the demonstration, the most typical action was to push down the cap (15.6%), action that in the first period only registered a 0.1%. Pulling up the cap remained at the same percentage level (8.9%) as prior to the demonstration and twisting the cap decreased more than a half to 9.5%. The use of teeth slightly increased to 8.2%.

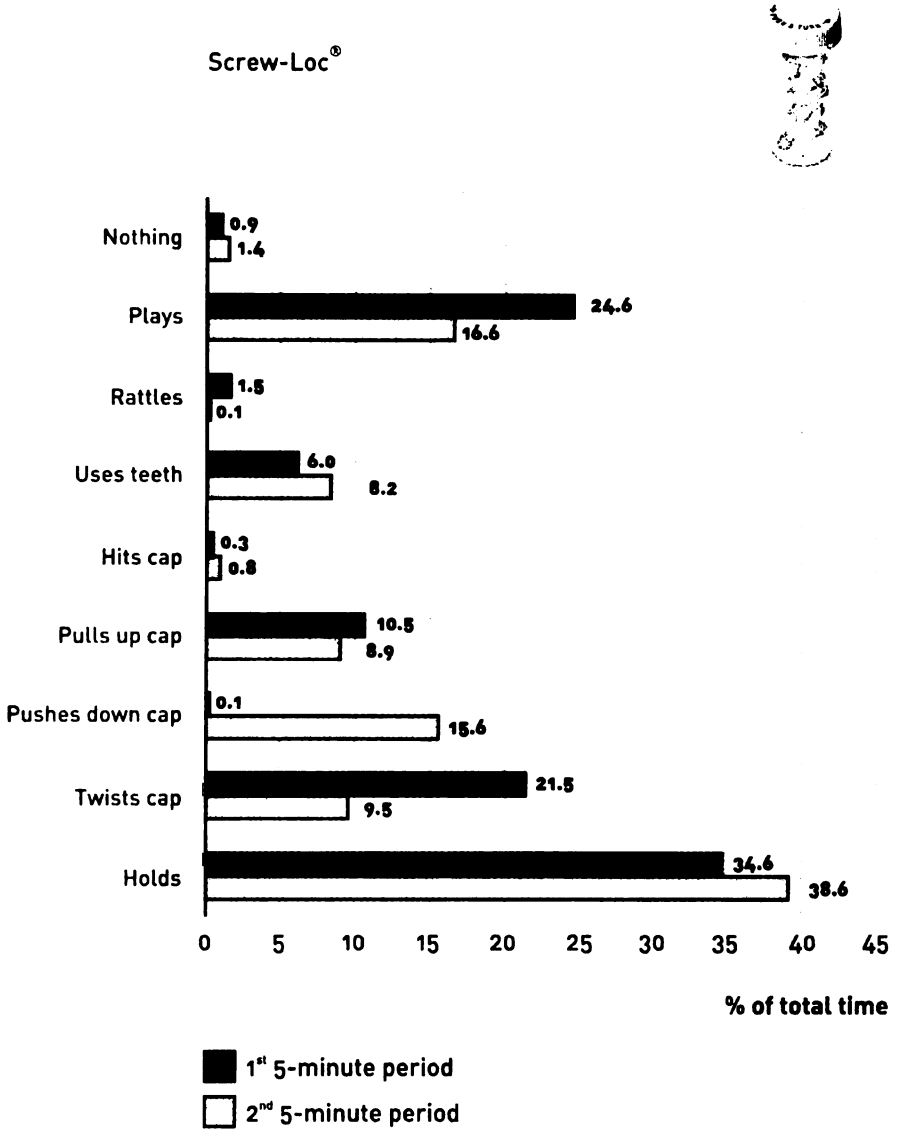


Figure 4.4 – Percentage of time spent on typical child actions for Screw-Loc®

CR blister

Figure 4.5 depicts a typical test of the CR blister package. During the first 5-minute period, children tore the package apart at the perforations between individual units (12.5%); all children did so. This represents a real danger because these units could be swallowed by a child (the individual unit measures 32 mm by 28 mm). Other common actions included manipulating blisters on the plastic side (8.4%), using teeth (7.6%), bending the blister (4.5%), and trying to peel the foil (4.5%).

During the second test period, children mostly tried to peel the backing of the blister (15.7%) and the manipulation of the blister on the plastic side decreased (from 8.4% to 1.5%). Pushing the pill from the plastic side increased from 0.2% to 2%.

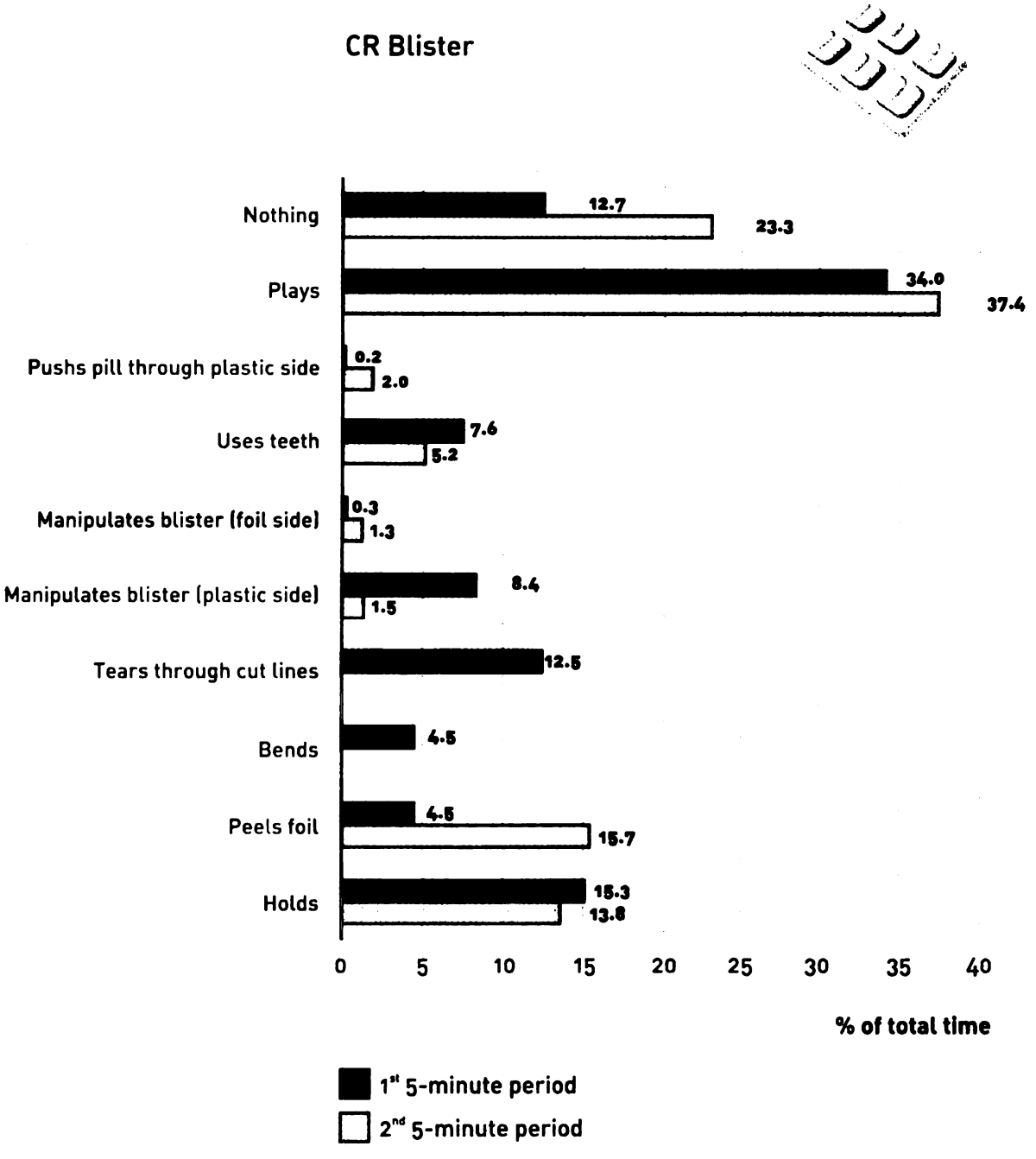


Figure 4.5 – Percentage of time spent on typical child actions for CR blister

Boredom index

The time spent on the actions labeled "nothing" and "play" could be a measure of how bored a child was with a given package (a boredom index). A tedious package is a desirable thing for child resistance. It is a good thing that children are not engaged and focused on actions that could result in an opening. Table 4.5 summarizes boredom indexes for the four packages during both test periods. For instance, in the period in which most of the openings occurred (second 5-minute period), the packages with higher indexes resulted in fewer openings (Fig. 4.6).

Table 4.5 – Percentage of time spent on the actions "nothing" and "play" for both testing periods and overall

Package	Percentage of total time		
	1st 5-minute period	2nd 5-minute period	Overall
1-Clic®	19.2	45.1	31.4
ShellPak®	2.6	8.4	5.4
Screw-Loc®	25.5	18	22.5
CR Blister	46.7	60.7	53.6

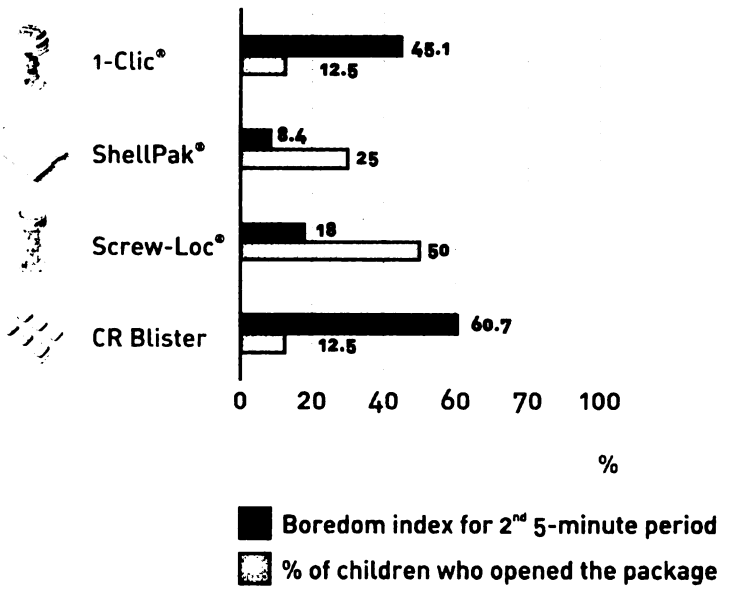


Figure 4.6 – Relationship between boredom index and percentage of children who opened the package

CONCLUSIONS

- It is interesting to see how the visual demonstration of the tester in between the two 5-minute periods changed the attempts of the children and the opening strategies they employed.
- Since children seem to reproduce the tester's hand movements to try to open the package, packages requiring subtle hand movements might have a greater chance to pass the child test. In those cases, it would be difficult for the children to imitate the tester.
- The time children spent playing with the package and doing nothing with the package could be taken as a measure of children boredom, termed "boredom index". Future research could relate this index to child resistant efficacy.

CHAPTER 5

CHARACTERIZATION OF ADULTS AND CHILDREN

In order to characterize users' physical attributes (Specific aims 1.b and 2.b), all participants' hands were evaluated for three aspects: strength, dexterity, and anthropometrics. Table 5.1 summarizes the variables measured.

Table 5.1 – Dimensions and variables measured for user characterization

Attribute	Variable
Strength	Grip strength
	Tip (two-point) pinch strength
	Key (lateral) pinch strength
	Palmar (three-jaw chuck) pinch strength
	Wrist strength
	Bilateral palm-to-palm squeeze strength
Dexterity	Nine-hole peg test
Anthropometrics	Finger and hand dimensions
	Functional grip diameter
	Hand grip span TI1 (thumb-index finger's first phalanx)
	Hand grip span TI2 (thumb-index finger's second phalanx)

MATERIALS AND METHODS

Subjects

All participants were tested: working group A (people with disabilities, n=10), working group B (older adults, n=10), and working group C (children, n=8).

Equipment and methods for hand strength evaluation

Grip strength

Grip strength was evaluated with a Jamar® hydraulic dynamometer (0-200 lb, Sammons Preston Inc., Chicago, IL, USA) set at the second position (Fig. 5.1). The dynamometer was lightly held around the readout dial by the examiner to prevent inadvertent dropping [70].

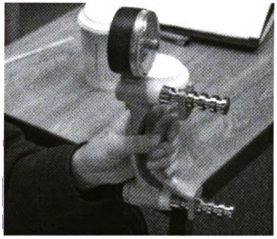


Figure 5.1 – Jamar® dynamometer.

Pinch strength

Pinch strength was evaluated using a B&L® pinch gauge (0-60 lb, B&L Engineering, Tustin, CA, USA). It measures finger prehension force in pounds. The pinch meter was always held by the examiner at the distal end to prevent dropping [70]. To measure tip pinch, the meter was grasped with the tips of thumb and index finger (Fig 5.2.T). To measure key pinch strength, the gauge was positioned between the pad of the thumb and the radial side of the index finger's second phalanx (Fig. 5.2.K). For palmar pinch strength, the gauge was grasped between the pads of the thumb, index finger, and middle finger (Fig. 5.2.P) [71].

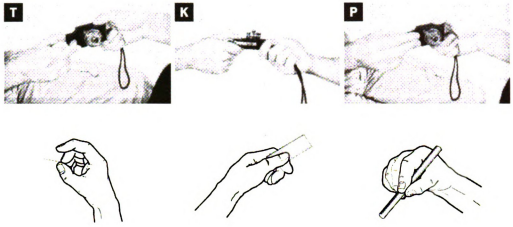


Figure 5.2 – Pinch strength.
T) Tip pinch, K) Key pinch, P) Palmar pinch

Wrist strength

Wrist strength was evaluated with a Baseline® wrist dynamometer (0-200 lb, Sammons Preston Inc., Chicago, IL, USA) (Fig. 5.3). This device measures the force required to twist an object; the fitting used in this study was a plastic doorknob. Participants were asked to hold the instrument at its base at approximately chest level and twist the knob clockwise as much as they could with the hand at test.

Figure 5.3 – Wrist dynamometer.

Bilateral palm-to-palm squeeze strength

Bilateral palm-to-palm squeeze strength was measured with a Baseline® pneumatic bulb dynamometer (0-200 lb, Sammons Preston Inc., Chicago, IL, USA). Participants were asked to bend their elbows and put their forearms at shoulder level with their palms facing each other. The bulb of the dynamometer was placed in between the participant's palms and then the examiner asked him/her to push palms together using as much strength as possible (Fig. 5.4).

Figure 5.4 – Position for bilateral palm-to-palm squeeze strength.

Hand dominance was determined before each evaluation by asking adult participants for the hand used for writing and asking children to draw a circle. This information was recorded for all participants. Grip strength was tested first, followed by palmar pinch, key pinch, tip pinch, and wrist strength. Grip and pinch measurements were made in accordance with the American Society of Hand Therapists (ASHT) standards, with elbow flexed at 90°, the forearm in a neutral position of pronation/supination, and the wrist in the neutral position [70]. The standard procedure was only modified with some participants of working group A because of the different types of disabilities they had. For all strength measurements three consecutive determinations were performed while alternating dominant and nondominant hand. There was no distinction of hand dominance for bilateral palm-to-palm squeeze strength since the test required the use of both

hands simultaneously. The mean of the three measurements was used as the outcome for this study.

Equipment and method for hand dexterity evaluation

Nine-hole Peg Test

The Nine-Hole Peg Test (9-HPT) (Fig. 5.5) measures fine motor dexterity in terms of the number of seconds (i.e., completion time) the subject takes to place nine pegs in a pegboard and then remove them [72]. It is commonly used by occupational therapists as a quick measurement of fine motor finger dexterity [72-74].

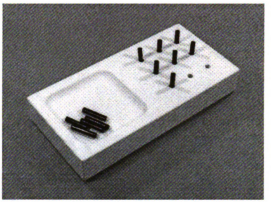


Figure 5.5 – Nine-hole Peg Test.

Based on information published by Mathiowetz [6], the 9-HPT consists of a rectangular board, 254 mm by 127 mm (10 in by 5 in) with nine holes and a shallow container to hold the pegs. The holes are spaced 32 mm (1 ¼ in) apart measured center to center, each hole is 13 mm deep and is drilled with a 7.1 mm (9/32 in) drill bit. The nine wooden pegs are 5.4 mm (¼ in) in diameter and 32 mm (1 ¼ in) in length. Wade [75] suggested different dimensions for the 9-HPT. Since normative data was collected and published by Mathiowetz, the pegboard and the pegs used in this study were built in accordance with his suggested standards [73]. However, we modified the shallow container, designing it to be more stable and to be incorporated to the board, and corners and interior edges of the tray were rounded to avoid pegs getting stuck during testing. After sanding, a coat of enamel air spray paint was applied to the board and pegs (for a detailed drawing see Appendix H – Nine-hole peg test specifications).

The dominant hand was tested first, followed by the non-dominant hand until each hand was tested twice. For subjects that only had the use of one hand, their useful hand was tested twice. For all subjects, the first trial served as an acclimation period; the final time on their second trial (for each hand) was recorded as the completion time (in seconds). Standard instructions [73] were provided prior to testing each subject. A stopwatch was started by the examiner as soon as the subject touched the first peg and stopped when the last peg hit the container.

Equipment and methods for hand anthropometrics

Fingers and hand dimensions

A photographic method used by previous studies was employed to characterize the anthropometrics of each subjects [76, 77]. A folding camera holder was designed and developed for taking pictures of subjects' hands. It consists of an articulated arm with a flat base. A 10 mm square grid is printed on the base. The top of the foldable arm has a digital camera (Canon PowerShot SD500) mounted to a fixed distance from the board (Fig. 5.6).

Figure 5.6 – Folding camera holder

Every participant was asked to place their hand on the grid, spreading their fingers (if possible). Three different pictures were taken: palm down, palm up, and hand closed with the thumb parallel to the lens. Each of these pictures was taken for each of the users' hands (Fig. 5.7).

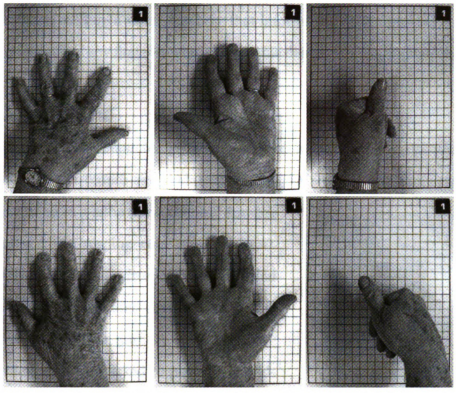


Figure 5.7 – Typical set of six pictures taken for each participant.

Using CorelDraw for Windows [78], a software for graphics, these pictures were scaled and parts of the hand measured. The length of each digit was measured from the crease at the base of the phalanges to the tip of the finger (excluding the nail) (Fig 5.8.a). The maximum width of each digit was measured across the widest part of the finger (Fig 5.8.b). Hand width was measured between metacarpal II to metacarpal V (at the knuckles) (Fig. 5.8.c).

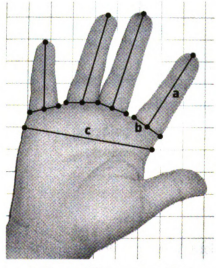


Figure 5.8 – A picture of a child's hand and its associated measurements.

This method was chosen because of its flexibility and velocity to collect data. Pictures of the hand built up a visual database that informs the design process and eventually the dimensions of any finger can be known if the design process requires it.

Functional grip diameter

Functional grip diameter is defined as the maximum diameter that can be grasped between the thumb and middle finger [76]. A wooden grasping cone was designed and turned in a lathe (for a detailed drawing see Appendix I – Grasping cone specifications). The cone varies in diameter from 20 to 80 mm and it has attached a coordinated scale (in mm). The cone slope angle is 6° (Fig. 5.9).

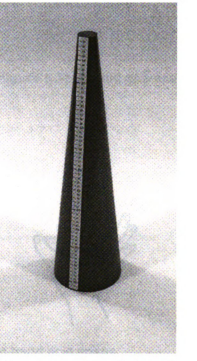


Figure 5.9 – Thumb-finger grasping cone.

Participants were asked to place their middle finger and thumb around the conical cylinder so that the finger and thumb ends are in contact (Fig. 5.11.a). They were asked to slide their finger and thumb down the cone until they just start to separate. The diameter at which this occurred was read off the recorded scale on the side of the cone and recorded. The measurement was repeated three times with each hand for each subject.

Hand grip spans

Hand grip span was measured using a flat wooden triangular plate 15 mm thick, varying in width between zero and 215 mm, and marked with lines across the plate at 1 mm intervals (Fig. 5.9). The participants were asked to place the palm of their hand onto the face of the triangular surface, and grip the edges at the maximum possible width con-

sistent with a usable grip. The width at which the finger and thumb contacted the edge of the surface is recorded using the scale marked on the surface. This procedure was repeated three times and the whole procedure repeated with the other hand. Hands were alternated after each measurement was recorded. Researchers recorded the hand grip span between thumb and index finger's first phalanx (Fig. 5.11.b) and the hand grip span between thumb and index finger's second phalanx (Fig. 5.11.c).

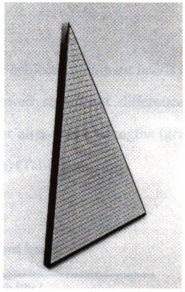


Figure 5.10 – Hand grip span gage.

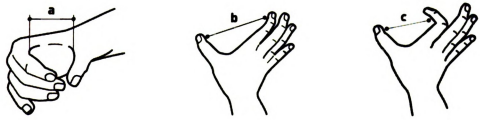


Figure 5.11 – Functional grip diameter and the two hand grip spans.

Data analysis

Data were analyzed with SPSS for Windows software version 14.0 [79]. One-way analyses of variance (ANOVAs) were performed on the three working groups to examine potential differences in grip strength, pinch (tip, key, and palmar), bilateral palm-to-palm squeeze, hand-finger dexterity, and hand anthropometrics (functional grip, length of index finger, hand grip spans, and hand width) (See Appendix K – Statistical Analysis).

RESULTS AND DISCUSSION

Hand strength

A summary of all average strength measurements for subjects' dominant hands is shown in Table 5.2. A one-way ANOVA on groups showed significant differences (α=0.05) between the group of older adults and children for all average strengths (grip strength, pinch strength, and bilateral palm-to-palm squeeze) (Table 5.3).

Table 5.2 – Average strength for dominant hand.

Strength type	Average strength (lbs)		
	Working group A	Working group B	Working group C
Grip	33.00 [a] ± 22.03	43.50 [a] ± 11.23	13.75 [b] ± 3.38
Tip pinch	5.07 [a] ± 4.34	8.20 [b] ± 2.99	3.08 [a] ± 1.18
Key pinch	8.03 [a] ± 5.71	11.27 [b] ± 5.34	4.92 [a] ± 1.44
Palmar pinch	7.03 [a] ± 5.99	11.33 [b] ± 4.31	4.67 [a] ± 1.27
Wrist	62.67 [a] ± 62.25	43.67 [a] ± 29.65	ND*
Bilateral squeeze	2.56 [a] ± 2.64	5.73 [b] ± 3.72	1.83 [a] ± 1.94

[a,b]: Identical letters indicate groups with no significant difference ($p \leq 0.05$)
*ND: not determined. Wrist strength of working group C was below the detection limit of the dynamometer utilized.

The group of people with disabilities showed only significant differences with children on average grip strength. The only significant difference between older adults and people with disabilities was on bilateral palm-to-palm squeeze.

Table 5.3 – Statistical significance and p-values for hand strength between working groups A (people with disabilities), B (older adults), and C (children).

Strength type (Dominant hand)	Comparison between working groups					
	A vs. B		A vs. C		B vs. C	
	S*	p	S*	p	S*	p
Grip	N	.135	Y	.013	Y	.000
Tip pinch	N	.087	N	.117	Y	.003
Key pinch	N	.239	N	.137	Y	.013
Palmar pinch	N	.109	N	.169	Y	.006
Bilateral palm-to-palm squeeze	Y	.025	N	.611	Y	.009

*: Statistical significance (Y=yes, N=no)
* Mean difference is significant at α=0.05

Grip strength

On average, dominant hand grip strength was slightly higher than the nondominant hand for the three working groups (Fig. 5.12). Older adults were stronger than people with disabilities, children were the weakest group. The two adult groups (A and B) had significantly different grip strengths than the children (α=0.05). However, some participants in group A (people with disabilities) were as weak as the children. People with disabilities showed a high variability in their average grip strength, this is certainly related to the fact that this group consisted of people with different types of disabilities ranging from memory loss to muscular dystrophy.

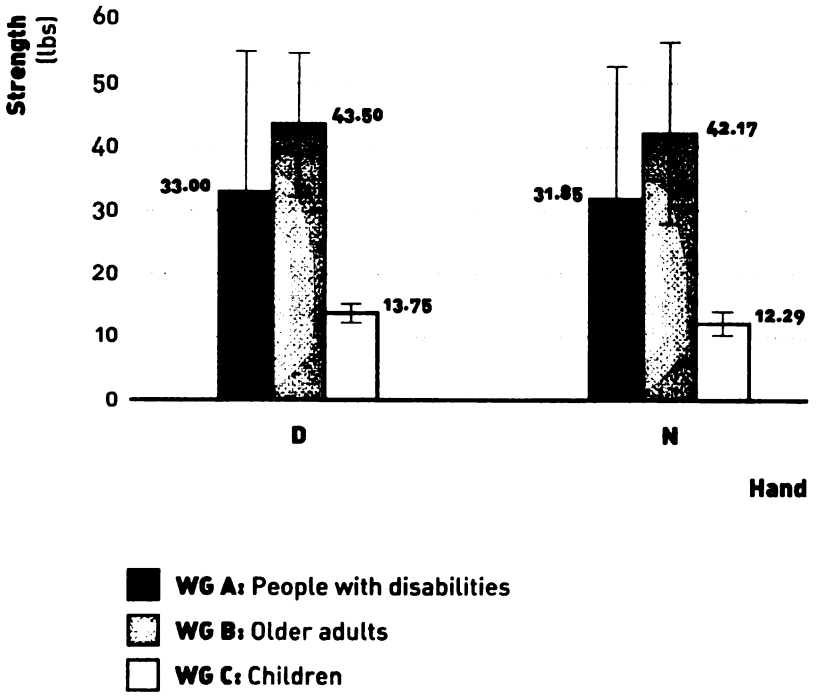


Figure 5.12 - Average grip strength
(D = Dominant, N = Nondominant)

Data of the three working groups were compared with normative data. Figure 5.13 is a compilation of grip strength for dominant hand from three previous studies [80-82] regarding gripping force and its relation with age, gender, and dominant hand. Data for the children between 3 and 5 is from Lee-Valkov *et al.* [82], data for people between 6 and 19 year old is from Mathiowetz *et al.* [80], and data for adults between 25 and 85 years old is from a model developed by Voorbij *et al.* [81] (See Appendix J – Normative data for grip strength). As indicated in Figure 5.13, measurements of the three working groups are in good agreement with the normative data. Children and older adults are at the extremes of the curve, people with disabilities are scattered somewhat below the female normative curve. The normative curve shows that aging has a degenerative effect on hand function, hand and finger strength decline. The peak grip strength force occurs between 25-35 years.

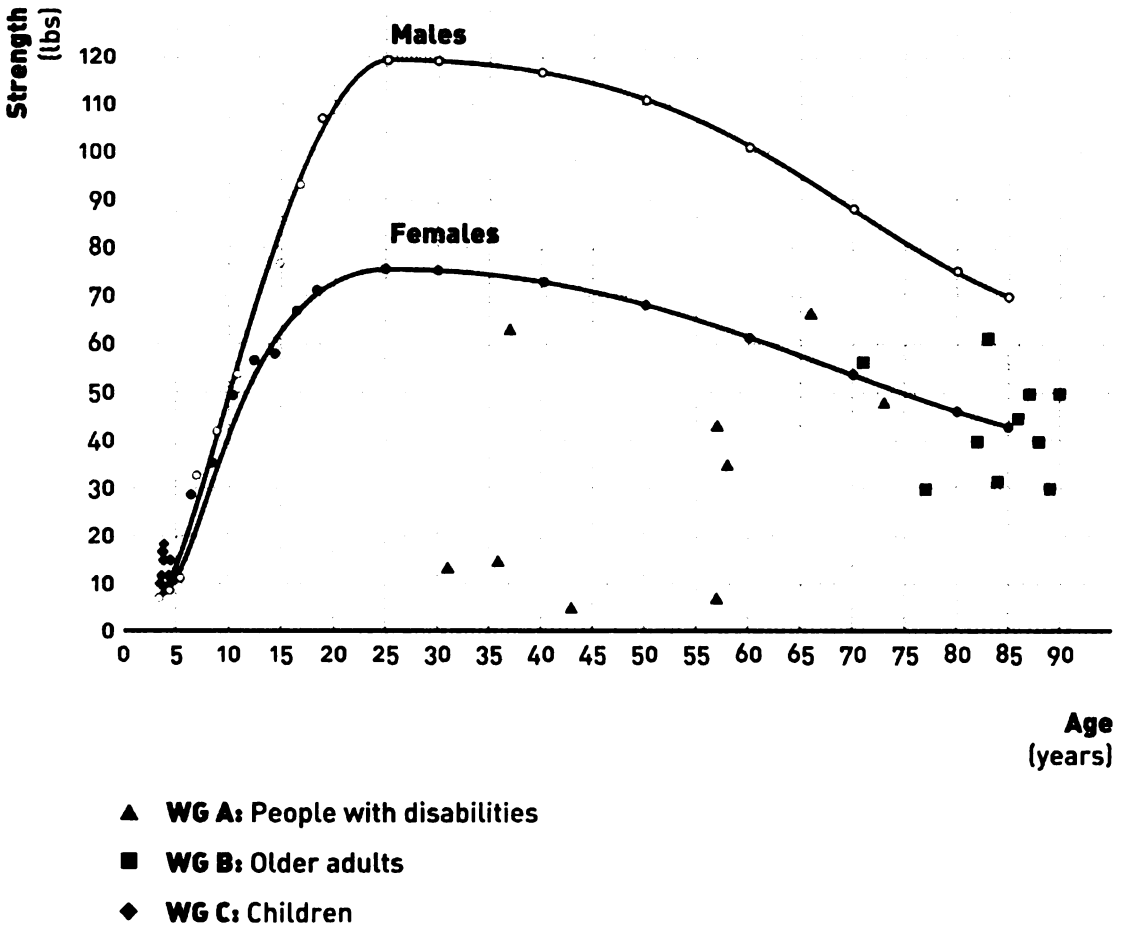


Figure 5.13 – Comparison between normative data and average hand grip strength of the three working groups (dominant hand).
Normative data from Lee-Valkov (2003), Mathiowetz (1986), and Voorbij (2001)

Pinch strength

Tables 5.4 through 5.6 show the results for pinch strength measurements (Fig. 5.14). Tip pinch, key pinch, and palmar pinch strengths showed significant differences between group B (older adults) and group C (children) (α=0.05). No significant differences were found between group A (people with disabilities) and children. No clear hand dominance was found across the three groups when it came to pinch strength.

Table 5.4 - Average tip pinch strength.

Working group	Tip pinch strength (lbs)	
	D	N
A	$5.07^{a} \pm 4.34$	5.15 ± 3.96
B	$8.20^{b} \pm 2.99$	8.73 ± 3.54
C	$3.08^{a} \pm 1.18$	3.25 ± 1.15

Table 5.5 – Average key pinch strength.

Working group	Key pinch strength (lbs)	
	D	N
A	$8.03^{a} \pm 5.71$	8.59 ± 3.96
B	$11.27^{b} \pm 5.34$	11.40 ± 4.46
C	$4.92^{a} \pm 1.44$	4.92 ± 1.86

Table 5.6 – Average palmar pinch strength.

Working group	Palmar pinch strength (lbs)	
	D	N
A	$7.03^{a} \pm 5.99$	6.70 ± 4.88
B	$11.33^{b} \pm 4.31$	11.80 ± 4.15
C	$4.67^{a} \pm 1.27$	4.00 ± 1.32

D = Dominant hand, N = Nondominant

^{a,b}: Identical letters indicate groups with no significant difference ($p \leq 0.05$)

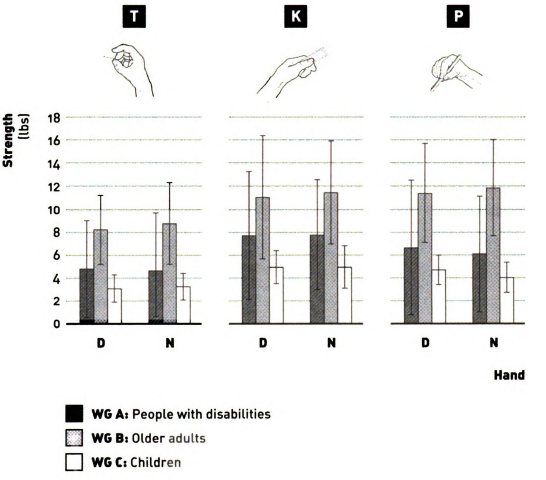


Figure 5.14 – Average pinch strength.
T) Tip pinch, K) Key pinch, P) Palmar pinch
(D=Dominant, N=Nondominant)

Wrist strength

Wrist strength measurements for the three working groups are shown in Figure 5.15 and Table 5.7. Average dominant hand values were slightly higher than average nondominant hand in both adult groups. The group of children registered wrist strengths below 15 lbs (minimum detection level of the dynamometer utilized). A T-test was done using data gathered from groups A and B, no significant difference was found. On average, people with disabilities had higher wrist strength than older adults but when looking at individual values the high variability of the data made any generalization impossible. It is suggested to repeat the measurements with a more sensitive device.

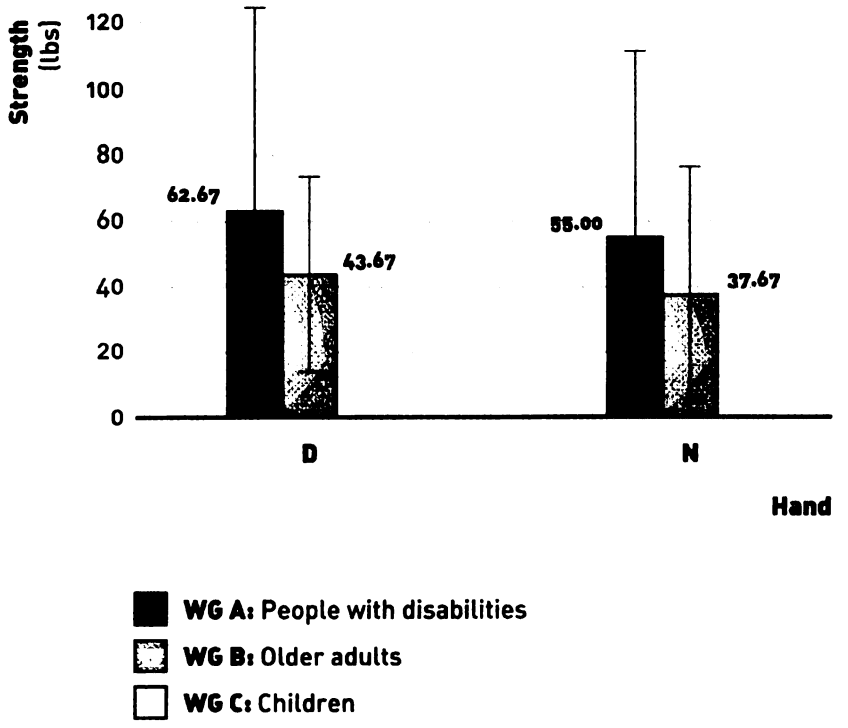


Figure 5.15 – Average wrist strength.
Wrist strength of working group C was below the detection limit ofthe dynamometer utilized (15 lbs).
(D=Dominant, N=Nondominant)

Table 5.7 – Wrist strength.

Working group	Wrist strength (lbs)	
	D	N
A	62.67[a] ± 62.25	55.00 ± 56.35
B	43.67[a] ± 29.65	37.67 ± 38.30
C	ND*	ND*

D = Dominant hand, N = Nondominant hand
[a]: Identical letters indicate groups with no significant difference ($p \leq 0.05$)
* ND: not determined. Wrist strength of working group C was below the detection limit of the dynamometer utilized (15 lbs).

Bilateral palm-to-palm squeeze strength

Average values and standard deviations for bilateral palm-to-palm squeeze strength are shown in Table 5.8 and Figure 5.16. The group of older adults was significantly stronger than groups B and C. No significance difference was found between the groups of children and people with disabilities.

Table 5.8 – Bilateral palm-to-palm squeeze strength.

Working group	Strength (lbs)
A	2.56[a] ± 2.64
B	5.73[b] ± 3.72
C	1.83[a] 1.94

[a,b]: Identical letters indicate groups with no significant difference ($p \leq 0.05$)

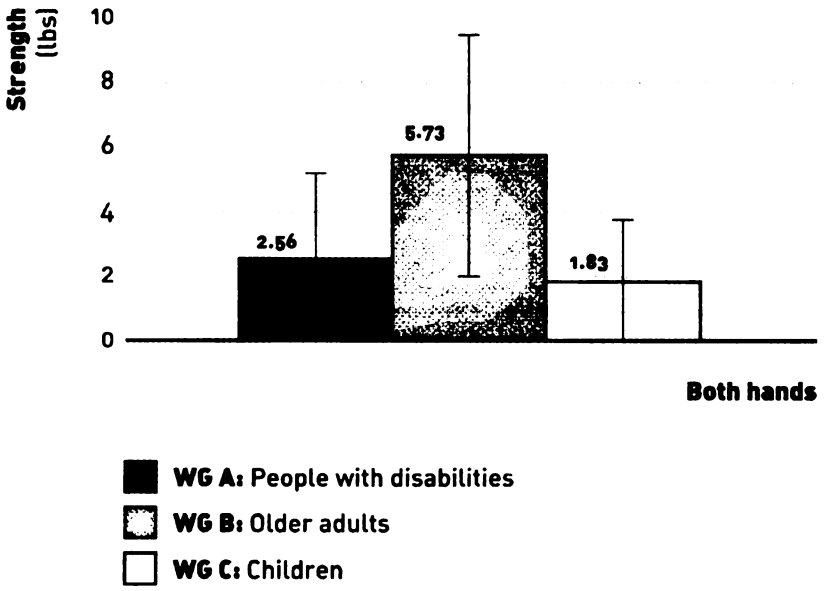


Figure 5.16 – Average bilateral palm-to-palm squeeze.

Hand-finger dexterity

A summary of average completion times on the Nine-hole peg test is presented in Table 5.9. A significant difference was found in readings taken from the nondominant hand when people with disabilities and older adults were compared. There were no other significant differences between the three groups (Table 5.10) when an overall analysis was performed. This is probably because of the high intra group variability of the dexterity scores.

Table 5.9 – Average completion time on the Nine-hole peg test

Working group	Average completion time (seconds)	
	Dominant hand	Nondominant hand
A	52.56 [a] ± 42.13	69.78 [a] ± 62.19
B	28.90 [a] ± 10.62	29.40 [b] ± 6.62
C	52.75 [a] ± 12.28	52.75 [a] ± 19.29

[a,b]: Identical letters indicate groups with no significant difference ($p \leq 0.05$)

Table 5.10 – Statistical significance and p-values for hand-finger dexterity between working groups A (people with disabilities), B (older adults), and C (children).

Hand	Comparison between working groups					
	A vs. B		A vs. C		B vs. C	
	S*	p	S*	p	S*	p
Dominant	N	.060	N	.988	N	.065
Nondominant	Y	.028	N	.361	N	.203

*: Statistical significance (Y=yes, N=no)
* Mean difference is significant at $\alpha = 0.05$

The Nine-hole peg test has been shown to be sensitive to change in adults with neuromuscular and musculoeskeletal disorders, and to correlate with daily tasks requiring dexterity [72, 73, 83]. For example, occupational therapists use normative dexterity scores to measure improvement in rehabilitation programs. Moreover, previous findings support this test as an effective screening tool for fine motor dexterity of school-age children [74].

Data from the three working groups were compared with normative data (Figure 5.17). The dotted curve represents normal dexterity scores for males and the solid curve represents the scores for females. The lower the values on the y-axis (time in seconds), the more dexterous the subjects are. On average, females tend to be slightly more dexterous than males. Here again, the normative curve shows that aging has a degenerative effect on hand function, hand and finger strength decline. The best dexterity scores occur in subjects between 20-25 years.

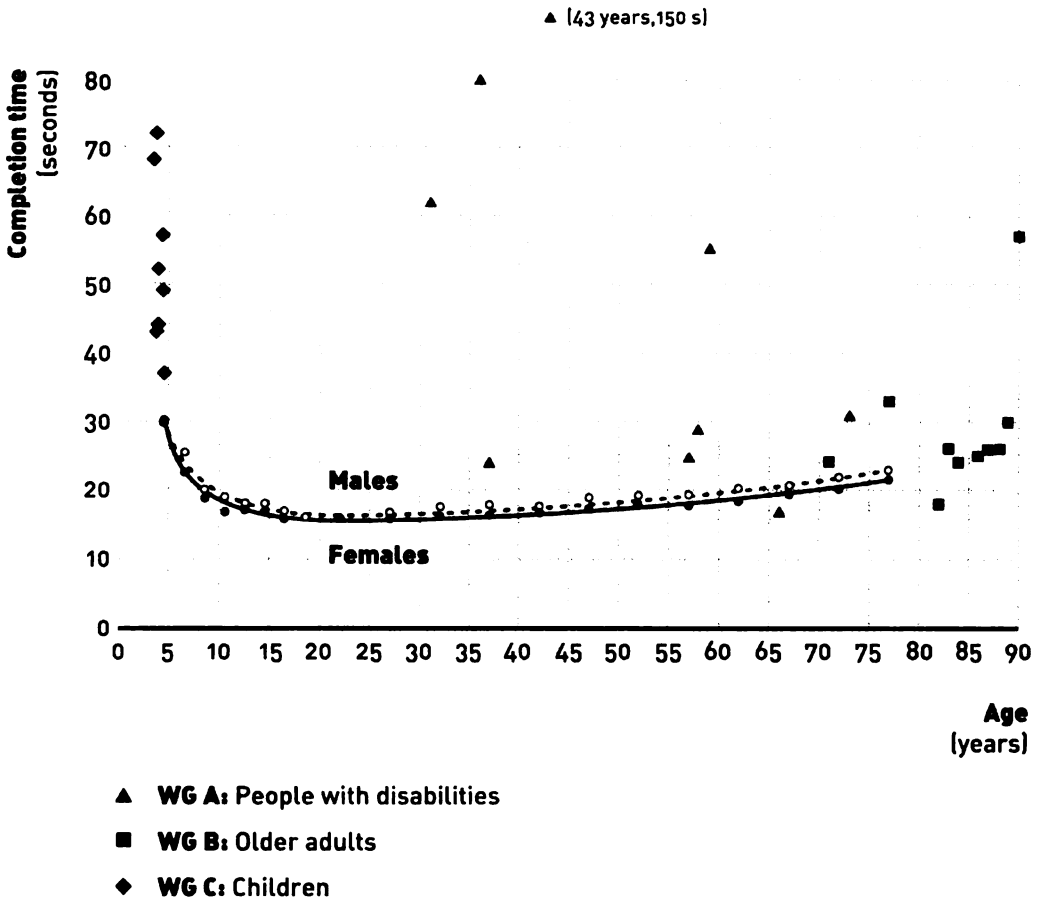


Figure 5.17 – Completion times on the Nine-hole peg test for dominant hand. Comparison of normative data with average completion times for the three groups. Normative data from Poole (2005) and Mathiowetz (1985)

Normative data for subjects between 4.5 years to 18.5 years old are from Poole *et al.* [84] and data for people between 22 years and 77 years old are from Mathiowetz *et al.*[73]. It is interesting to point out that there are no normative data for children younger than 4.5 years. It is known that between the ages of 3 and 5, children experience rapid gains in manipulative skills, finger dexterity, and tool use [85]. We can corroborate this phenomenon with the dexterity scores for working group C (children) that appear to be a continuation of the normal curve with a high slope.

Dexterity scores for working group B, older adults, also show very good agreement with cited normative data. Their values appear to continue the trend line. Dexterity values for working group A, people with disabilities, are scattered above the normal curves, as would be expected.

Hand anthropometrics

Table 5.11 shows a summary of all dominant hand anthropometrics measured for the three working groups. Dominant and nondominant hands did not show significant differences, as would be expected. Figure 5.18 summarizes average dimensions and standard deviations for functional grip diameter and hand grip spans (TI1 and TI2), for dominant and nondominant hand.

Table 5.11 – Average dimension for dominant hand

Hand characteristic	Average dimension (mm)		
	Working Group A	Working Group B	Working group C
Functional grip	37.70 [a] ± 8.49	43.67 [b] ± 3.72	25.54 [c] ± 1.38
Hand grip span TI1	82.83 [a] ± 27.03	104.17 [b] ± 13.90	58.75 [c] ± 7.84
Hand grip span TI2	73.33 [a] ± 14.41	78.00 [a] ± 15.57	33.54 [b] ± 11.56
Index finger's length	65.60 [a] ± 7.76	71.06 [a] ± 6.94	42.76 [b] ± 4.46
Hand width	86.74 [a] ± 6.73	91.73 [a] ± 8.82	61.70 [b] ± 3.11

[a,b]: Identical letters indicate groups with no significant difference ($p \leq 0.05$)

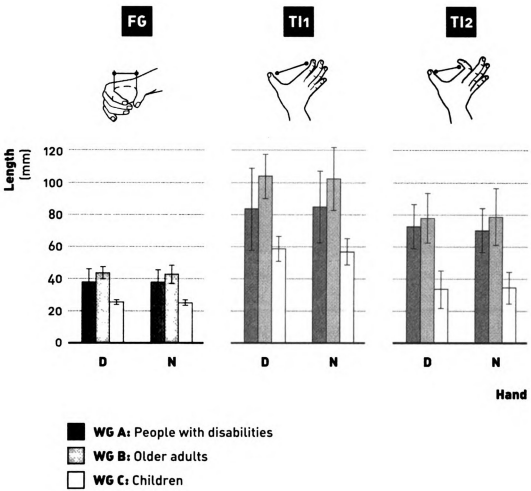


Figure 5.18 – Hand grips.
FG) Functional grip diameter, TI1) Hand grip span, TI2) Hand grip span (D=dominant, N=nondominant)

A one-way ANOVA examining differences in hand anthropometrics between groups showed significant differences between the three groups for both functional grip and hand grip span A (thumb-index finger's first phalanx). Additionally, significant differences were found between the group of older adults and the group of children, and between the group of people with disabilities and children, for all hand characteristics measured (Table 5.12).

Table 5.12 – Statistical significance and p-values for anthropometrics of the hand between working groups A (people with disabilities), B (older adults), and C (children).

Hand characteristic	Comparison between working groups					
	A vs. B		A vs. C		B vs. C	
	S*	p	S*	p	S*	p
Functional grip	Y	.014	Y	.000	Y	.000
Hand grip span TI1	Y	.019	Y	.013	Y	.000
Hand grip span TI2	N	.461	Y	.000	Y	.000
Index finger's length	N	.080	Y	.000	Y	.000
Hand width	N	.117	Y	.000	Y	.000

*: Statistical significance (Y=yes, N=no)
* Mean difference is significant at $\alpha = 0.05$

Data of the three working groups for functional grip diameter (dominant hand) were compared against data from a public database for infants, children, and youths to age 18 [86] (Fig. 5.19). The change in size of functional grip diameter with age is shown in figure 5.19. Curves for the 5^{th}, 50^{th}, and 95^{th} percentiles of children between 3 months and 12.5 years old have been plotted. As an example, the line at 36.1 mm represents the functional grip size for 95^{th} of children 5 years old and it could be taken as a safe divider for the purposes of this study. It can be seen how most of the adult participants are above this line. However, it must be noted that 5 participants with disabilities had a very small functional grip and were below the divider line.

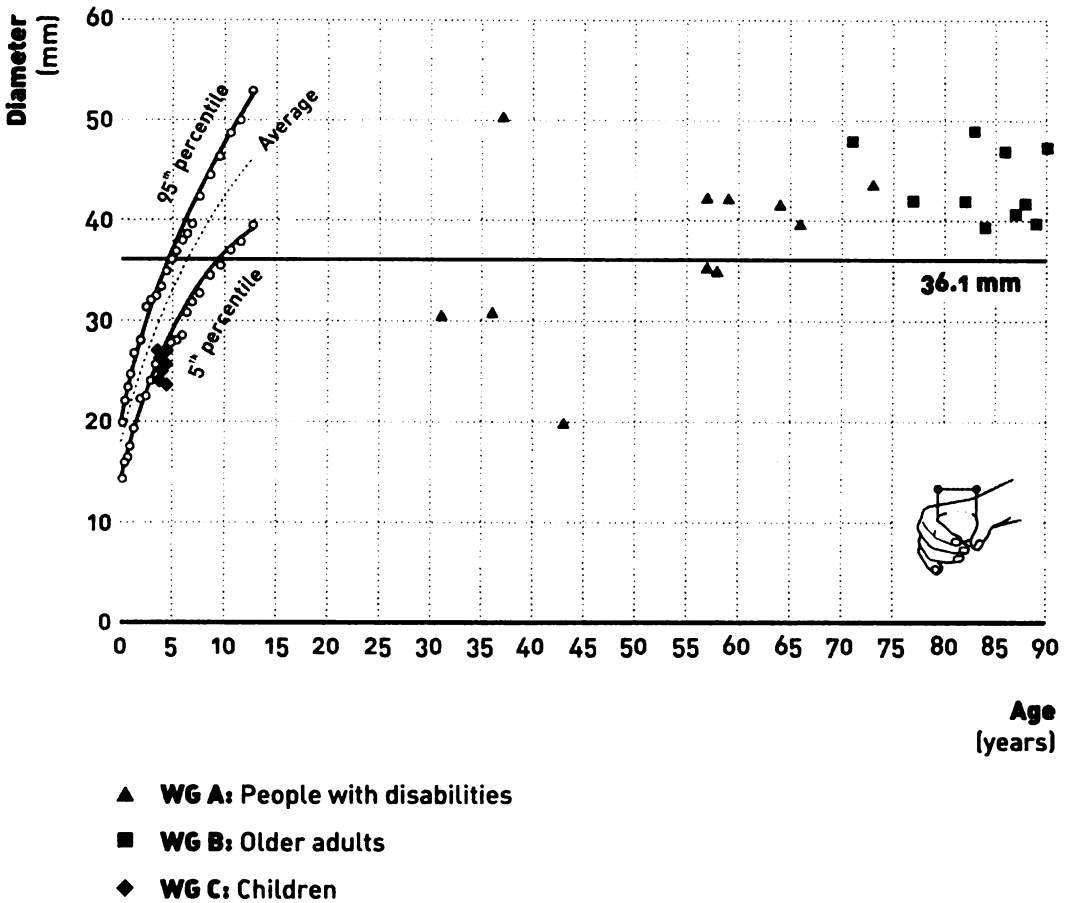


Figure 5.19 – Functional grip diameter (dominant hand) vs. age. Comparison between working groups and 5th and 95th percentiles for infants and children. The 36.1 mm line represents the 95th percentile for children 5 years old. Normative data from Snyder, RG *et al.* (1977) [86]

Figure 5.20 shows how length of the index finger (dominant hand) changes with age. The length of the index finger of working groups A, B, and C was contrasted against normative data [86]. Curves for the 5th, 50th, and 95th percentiles of children between 2.8 and 18.3 years old have been plotted. As an example, the line at 52 mm represents the length of the index for the 95th of children 5 years old and it could be taken as a safe divider for the purposes of this study. All adult participants are above this line.

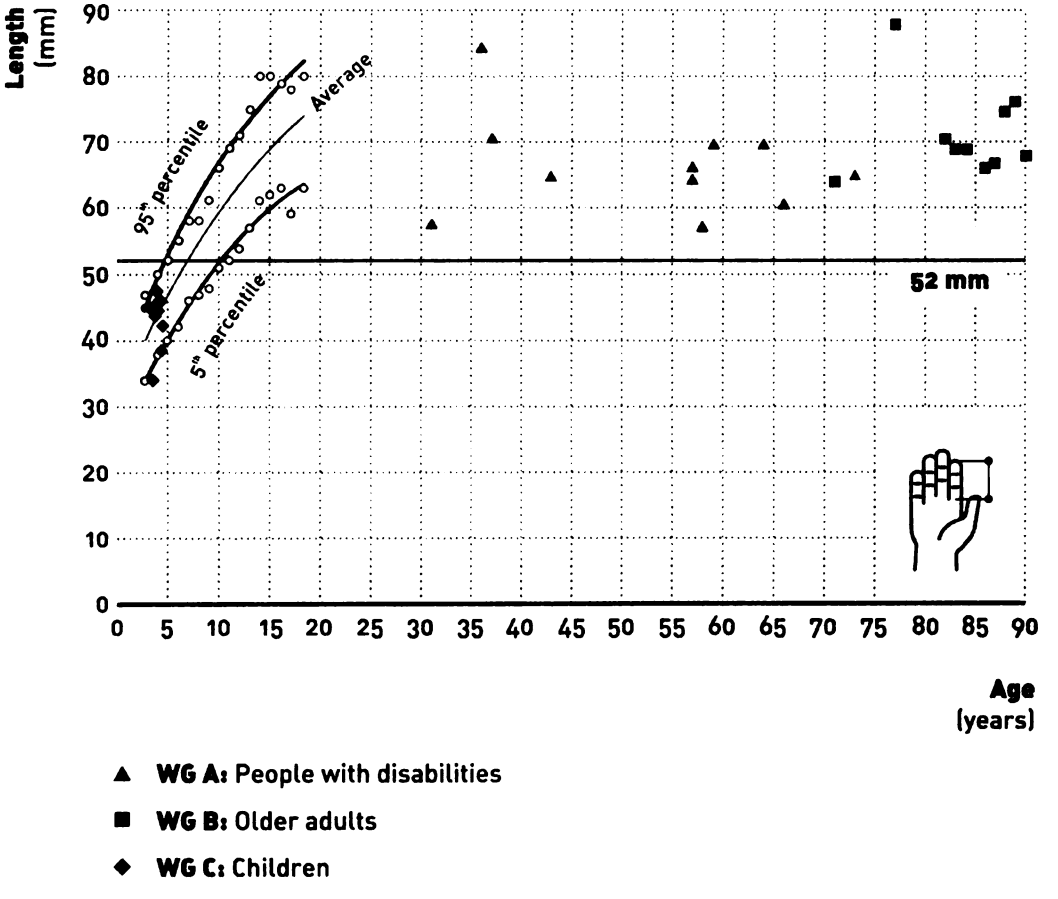


Figure 5.20 – Length of the index finger (dominant hand) vs. age. Comparison between working groups and the 5th and 95th percentiles for infants, children, and youths. The 52 mm line represents the 95th percentile for children 5 years old. Normative data from Snyder, RG *et al.* (1977) [86]

Figure 5.21 shows how hand width (dominant hand) changes with age. Normative data from two reports are shown [86]. Curves for the 5th, 50th (average), and 95th percentiles of infants, children, and youths have been plotted. The normative curves cover an age range from 1 month old through 18 years old. The line at 70 mm represents the hand width of the 1st percentile for adult females [87] and it could be taken as a safe divider for the purposes of this study. All participants are above this line.

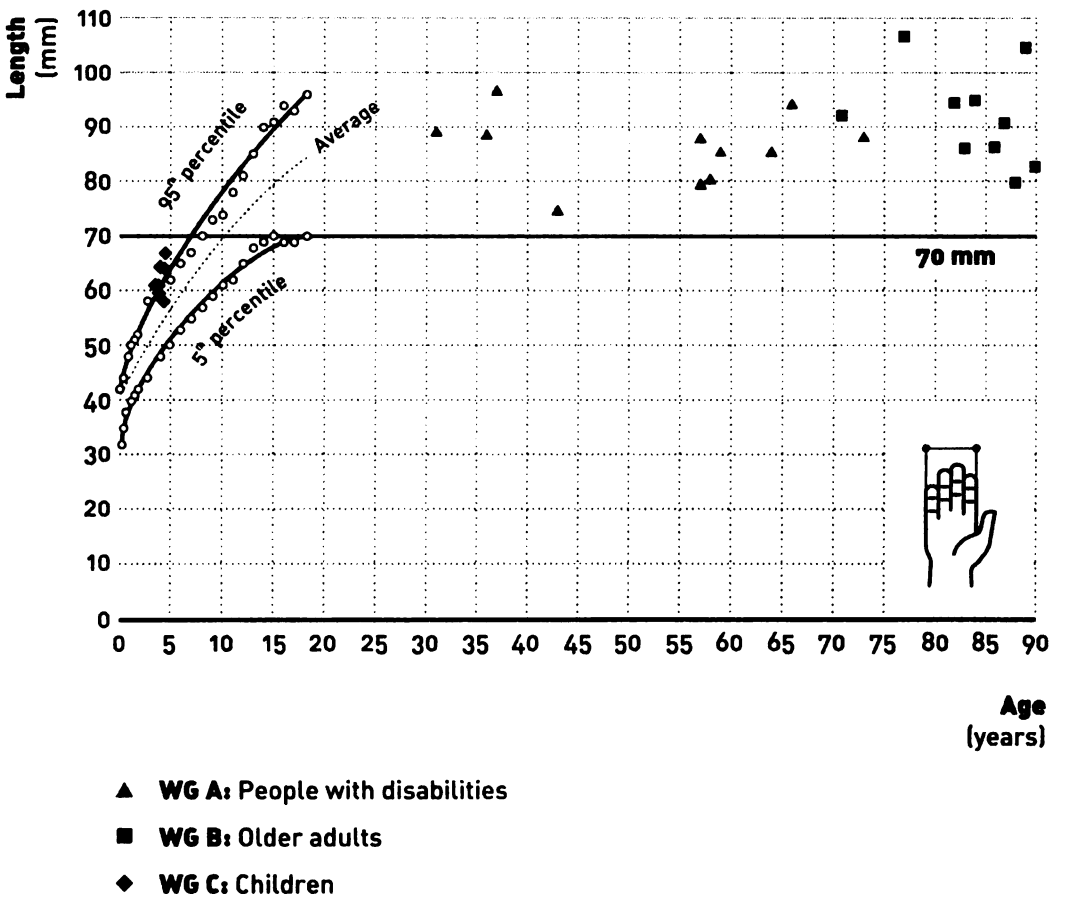


Figure 5.21 – Hand width (dominant hand) vs. age.
Comparison between working groups and 5th and 95th percentiles for infants, children, and youths. The 70 mm line represents the 1st percentile for female adults. Normative data from Snyder, RG *et al.* (1977) [86] and Gordon, CC *et al.* (1989) [87]

CONCLUSIONS

Hand strength

- Significant difference in grip strength was found between adults (working group A and B) and children (working group C).
- Significant difference in tip, key, and palmar pinches, and bilateral palm-to-palm squeeze were found between older adults (working group B) and children (working group C.
- No significant difference was found between people with disabilities (working group A) and children (working group C) for all the other strength measurements but grip strength.
- The group of older adults (working group B) was significantly stronger than group A and C on bilateral palm-to-palm squeeze strength.

Hand-finger dexterity

- No significant difference in dexterity scores for dominant hand was found between groups.

Hand anthropometrics

- A comparison between working groups revealed clear differences of hand dimensions (index finger's length, hand width, functional grip diameter, and both hand grip spans). The two adult working groups have consistently bigger hand dimensions than working group of children.

CHAPTER 6

USER INSIGHTS

One of the objectives of this study was to develop universal design criteria for packaging (Specific aim 3). Consequently, the user's point of view about prescription drug products was collected through three means: focus groups, observation of use, and a Universal Design Performance Measures survey.

MATERIALS AND METHODS

Focus groups

Two separate focus groups were conducted to get a sense of how people with disabilities and older adults were using drug packages and to gain understanding of the needs that these groups have with regard to drug packaging. Six participants from working group A (people with disabilities) and 8 participants from working group B (older adults) participated; these participants are the same that tested the packages reported in Chapter 3 and participated in the user characterization reported in Chapter 5.

The moderator guide used to run the meetings included questions about CR packaging, point of purchase (pharmacy, online pharmacy, etc.), openability, general use, storage, on-the-go situations, labeling, and compliance. Each section has allotted an estimated time and the entire meeting duration was 100 minutes (Table 6.1) (See Appendix G – Moderator guide for focus groups). Guidelines from previous studies on how to run focus groups for new product development were taken into account [88-90], especially when participants are elderly people and people with disabilities [91] . The meetings were video recorded with a digital camcorder connected to a high fidelity omni directional microphone to capture the conversation and facilitate the transcription process.

Table 6.1 – Topics and allotted time for focus groups.

Topic	Allotted time (minutes)
Introduction	5
Warm up	5
At the pharmacy	15
Openability	20
General use	15
Labeling	15
Compliance	15
Conclusion	10

Packages

Eight CR packages were used in an activity-based task during the focus groups (Fig 6.4 through Fig. 6.11). Each package was identified by a letter (Table 6.2).

Table 6.2 – CR Packages used in the focus groups.

Id.	Operating principle for opening	Description	ASTM Type
A	Line-up arrows and push cap off	An HDPE bottle with cap (Tylenol® Extra Strength, 24 caplets)	IIIA
B	Push down while turning cap	8½-dram PP vial with a PP closure (Friendly and Safe®, Kerr)	IIA
C	Squeeze sides below cap	Pop-Top®, Phillips Rx, LLC	IIIE
D	Squeeze tabs and turn cap	Safety Squease®, Aleve®, 24 tables	IM
E	Push down while turning cap	HDPE round bottle with HDPE cap Ø 43 mm	IA
F	Squeeze sides while turning cap	Square HDPE bottle (Caremark, 90 tablets)	IB
G	Push tab while lifting lid	HDPE round bottle with HDPE cap Ø 40 mm	IIID
H	Remove corner, peel back paper, and push through foil	CR blister package, Perrigo Co.	VIIIB

Five 10-dram 1-Clic® packages and five 13-dram ScrewLoc® packages were used during the focus groups when discussing the labeling topic. Each package had a standard prescription label in black and white that was 81 mm wide and 52 mm tall (Fig. 6.2). Additionally, two color stickers (Fig. 6.1), 40 mm wide and 10 mm tall. The stickers were actual warnings used at Olin Health Center Pharmacy (Michigan State University, East Lansing, MI) and were identified by a number.

Figure 6.1 – Warning stickers. Text color/background color (actual size).

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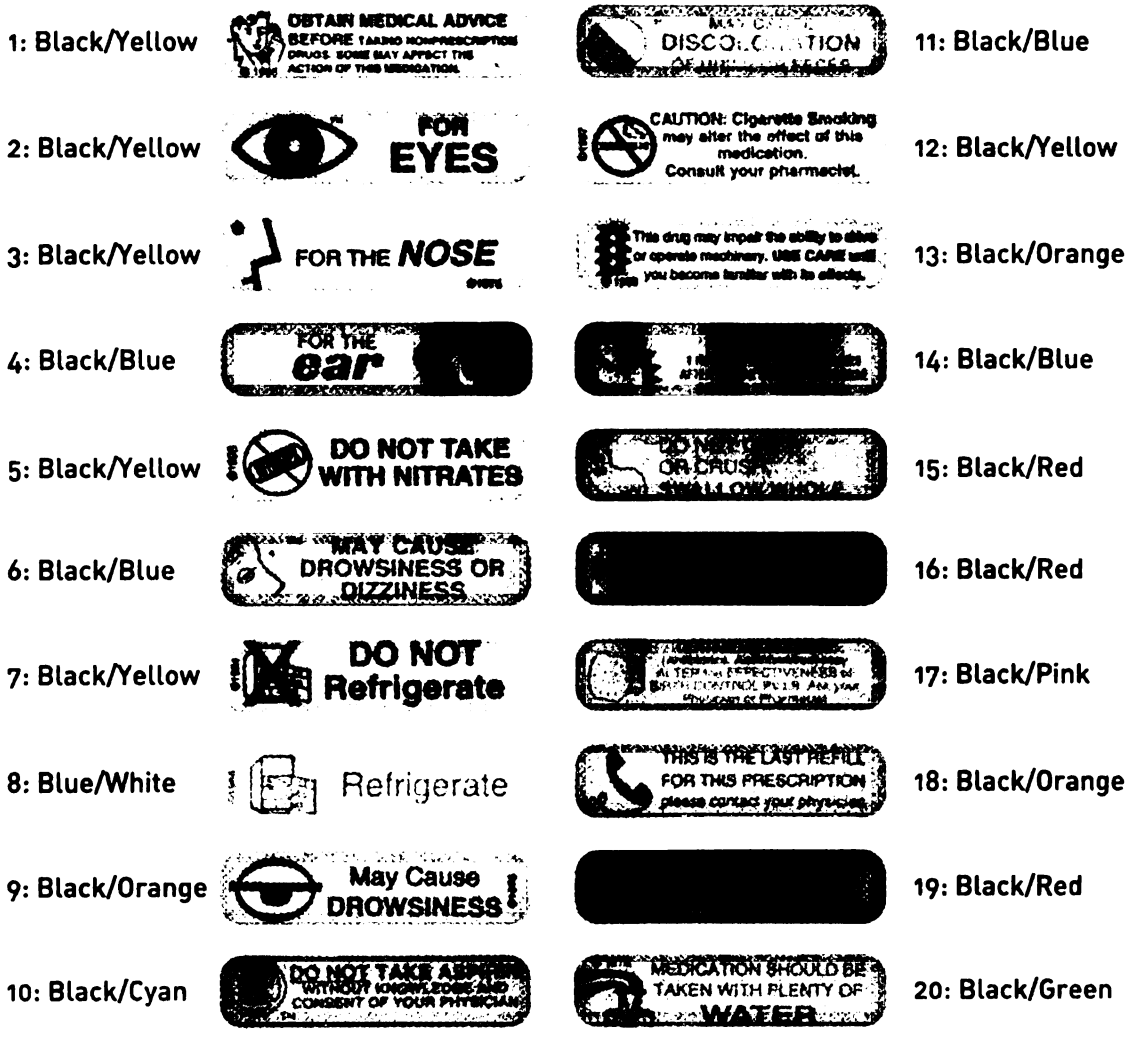


Figure 6.1 – Warning stickers. Text color/background color (actual size).

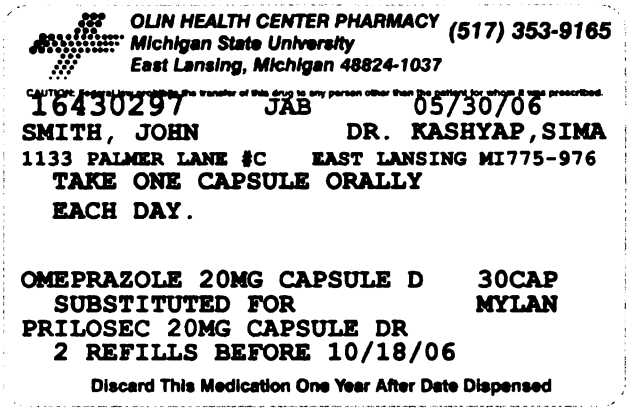


Figure 6.2 – Prescription label (actual size).

RESULTS AND DISCUSSION

The following report is organized by topics and includes input from both focus groups:

At the pharmacy

- Most people purchased their medication in supermarkets (Kroger, Meijer, Wal-Mart) or pharmacies (Apothecary Shop); three participants also used mail orders (Medco). One of them uses Medco because of her health insurance requirements.
- A participant said that Medco is legally not allowed to send non CR packages by mail.
- When asked about the meaning of CR, one of them joked that it means "children can get into it but adults cannot", and all others nodded in agreement.
- Supermarkets are preferred because of convenience (some of them also deliver), and also because they are cheaper.
- In the people with disabilities group, free delivery is something very valued.
- There was no clear agreement on which package they liked best.
- Pop-off lid and 1-Clic® were mentioned several times (1-Clic® is not identified by its name and used in the non-CR mode).
- The only male in the group preferred the push-and-turn, but he also mentioned that once in a while it didn't close back correctly. Another participant mentioned she preferred the push-and-turn because she can use her palm to exert the force.

- Regular screw cap (non-CR continuous thread) is mentioned because it avoids spilling.
- Participants did not like blister packaging with the combination backing (CR blister).
- Bigger containers are thought to be easier to open and smaller ones are difficult.
- Two people mentioned they disliked the line-up arrows because the arrows are difficult to see and it requires good finger strength; other didn't like the squeeze-sides-and-turn.
- Some participants ask for non-CR packages in the pharmacy, one participant does not like the snap-type closure because it comes off too easily in the purse.
- A participant with very limited hand dexterity and little hand strength prefers "Ziploc® baggy kind of thing" because they are easy for her. The zipper-type of closure is something she can do with no problem.
- One participant would prefer non CR but forgets to ask the pharmacy.
- "Old people should not get child proof containers."
- "My company sends me the drugs in a CR container and includes the non-CR one in the package."
- "Once I get the package open, I never close it again."
- "If I forget to tell them that I want the non child-resistant cap, I have a horrible time to get them off."
- One participant really likes the ShellPak® because it keeps the pills clean and organized but she has to take two dozens of pills daily so she cannot really use it.

Openability

The participants were given eight different CR packages (marked A through H) and asked to rate the packages. These ratings were converted to a scale from zero (hardest to open) to four (easiest to open). Figure 6.3 summarizes average ratings and standard deviation for both working groups.

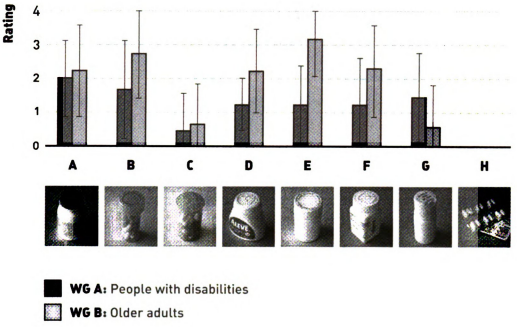


Figure 6.3 – Package ratings.
(4=easiest to open, 0=hardest to open)
*** All participants rated package H with zero**

In general, there was no agreement on openability. This is reflected in the fact that all packages received the worst rating from at least one participant and another participant would rate the same package rightly. People with disabilities tended to rate the packages lower than participants in the older adults group. For working group B, the best rated package was A (line-up arrows and push off cap), and for working group A, package E (large push and turn bottle) was rated highest. Package A was the only one that received the highest rating for both groups.

Package A (Fig. 6.4): Most people liked it, but a participant mentioned that aligning the arrows is difficult because it is hard to see them. Another participant pointed out that a significant amount of strength is needed to pop up the cap and her thumb is not that strong. For a blind participant it was difficult to tell the alignment of the arrows.

Figure 6.4 – Package A. Line-up arrows and push cap off.

Package B (Fig. 6.5): Half of the participants liked it. The ones that disliked it mentioned the difficulties in pushing down. That it is too small, and that pills tend to spill out while opening it.

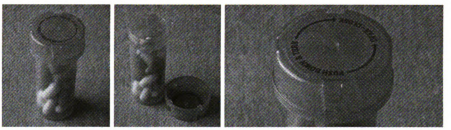


Figure 6.5 – Package B. Push down while turning cap.

Package C (Fig. 6.6): Most participants disliked it. They mention the instructions are very hard to read because the letters are just embossed, with little contrast (no color contrast). Other participants mentioned that they could not pinch it hard enough. The visually impaired participant could not get it open.

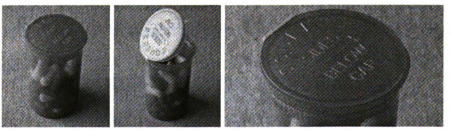


Figure 6.6 – Package C. Squeeze sides below cap.

Package D (Fig. 6.7): Most participants indicated a moderate response. The main criticism is that is too small. A participant with little sense of feeling in her fingertips found it very hard to open. A visually impaired participant could not tell how to open it. When another participant explained to her how to do it she was able to do so.

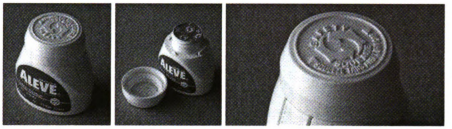


Figure 6.7 – Package D. Squeeze tabs and turn cap.

Package E (Fig. 6.8): Most participants responded favorably. They mentioned the fact that it is larger than most other packages as the reason why it is easy to open (ease of grasping). One participant found it difficult to open any package that is push-and-turn.

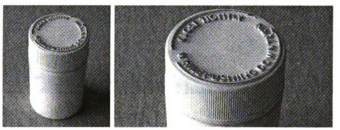


Figure 6.8 – Package E. Push down while turning cap.

Package F (Fig. 6.9): Participants indicated trouble reading directions (also embossed letters, lack of contrast). As a result they found it difficult to locate the proper area to squeeze.

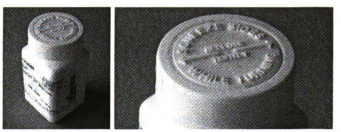


Figure 6.9 – Package F. Squeeze sides while turning.

Package G (Fig. 6.10): Most participants disliked this package. Many could not open it, indicating instructions were not clear. People who figured out how to open it thought it was easy to use.

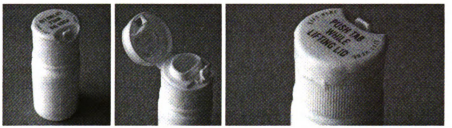


Figure 6.10 – Package G. Push tab while lifting lid.

Package H (Fig. 6.11): The worst rated package. None of the participants could open the CR blister without scissors. All of them rated it with a zero (hardest to open).

Figure 6.11 – Package H. Remove corner, peel back paper, and push through foil.

General use

- Most participants (12 out of 14) transfer part of their medications, once a week, to a pill organizer or daily dispensers, and keep the original package in the closet, in the cabinet, on the countertop, or in a basket or tray. Some places to keep the original packages medications are: on top of the microwave, a box in the living room, a plastic basket on top of the fridge, and in a Ziploc® plastic bag on the couch.
- One participant reported getting medications in the mail and then waiting for her son to open them for her. After that she keeps them in a pill organizer.

- Most of participants find pills organizers very useful and helpful in reminding them to take the medications.
- One participant complained about the lids of pill organizers because the action of pushing up makes her thumb hurt. Another complained about the size of the compartments, indicating they are too small and the pills within are hard to grasp.
- Two participants do not like pill organizers because they cannot recognize the pills so they keep them in their original vials.
- During trips, participants indicated they use weekly pill organizers (more than one if they are gone for more than a week), or a pillbox if it is only overnight or shorter.
- One participant reported using seven pill organizers, one for each day.
- Most female participants reported carrying their medications in the purse.
- Several participants who carried medications with them reported using little containers or pill boxes.
- When people have to carry their medications with them, in the older adults group, not a single participant reported taking their medicines in the original container packaging. In the people with disabilities group, two participants who do not like pill organizers put their vials in a plastic bag and the whole thing in a purse.

Labeling

- Participants can only read part of the labels; they need a magnifying glass for the smaller print.
- One participant would like to have the text of the labels in columns because long lines in a round vial are harder to read.
- Some participants like symbols and color warnings.
- All participants agreed they pay attention to the warnings.
- Participants preferred larger diagrams and symbols, and large print. However, many of them find the symbols hard to interpret by themselves.

- Good color contrast and larger print were mentioned several times as things that would help them pay more attention to warnings.
- Black letters on yellow or white background are the preferred contrasts. Other background colors were indicated to be more challenging. Black text on pink background and black on blue were considered as poor contrast.
- A visually impaired participant puts Braille labels on big vials and the smaller vials she gets from the pharmacy inside the bigger containers.
- The elements people considered important to the label were: the name of the drug, the phone number of the pharmacy, name of the doctor, the number of refills left, and the number of pills to take.
- Some participants think the information on the labels is not helpful and they rely on what the doctor says (when to take the medication, how many pills, etc.).

Compliance

- All participants reported to follow always the directions on the labels.
- All participants indicated that they have forgotten to take their medications at some point, generally as random occurrences.
- Participants agreed that if they do not see the pill organizer it is likely that will forget to take the medication.
- One of the participants usually misses her supper time medications and takes it the following morning.
- One member of the focus group indicated that she tends to forget her medication when she goes out visiting or for dinner.
- Participants felt that associating the medication intake with a meal makes it easier to remember.
- No one present could think of a package that would aid compliance except for pill organizers.

Conclusion

At the end of the meetings, participants were asked the following question:

> *"Imagine that you could talk with a drug packaging manufacturer, what would you say to him/her?"*

- "Cheaper medication for everybody who needs them."
- "Manufacturers should talk to a group like us and perhaps some other specialty groups to get some input. I don't know who designed some of these. I don't think there is any interaction there, between the consumer and the manufacturer."
- "The emphasis has been on child proof for some containers, but for older people with arthritis they pose a problem."
- Higher contrast printing and larger bold print would be better, also easier opening.
- "I think they should make it all as the flip top."
- "I like to put those ones upside down [pointing to a 1-Clic® package] but my pharmacy doesn't have those... then I can switch to a pharmacy were I can get those caps but I don't get free delivery... and I can't go and pick them up so I have to turn around my priorities, my delivery is more important to me but it would be really neat if there were some options... my assumption is that the reason there is no options is because the cost is probably a little bit more so the pharmacy is going to give you the cheapest thing they can get."

CHAPTER 7

UNIVERSAL DESIGN CRITERIA FOR CHILD-RESISTANT PACKAGING

CONCLUSIONS

Traditional considerations [41] for designing child-resistant packaging included the following:

- The mechanics of operation should not be so interesting as to attract the attention of the child and encourage attempts to open.
- It should not be difficult for large numbers of adults to open.
- The effort to open should not cause spilling of the contents in the process.
- The difficulty of opening should not encourage users to leave containers open or discourage the taking of medication according to the prescribed dosage schedule.
- It should not be difficult to close and there should be some positive indication that the closing has been sufficient to engage the safety action.

In Chapter 4 it was shown that the CR packages tested attracted children's attention in different manners and that attraction could be related to effective package openings. Chapter 3 and 6 show that the vast majority of the two adult groups, especially the group of people with disabilities, were not satisfied with the usability of commercially available CR packages. One plausible explanation is that the operating principles of these packages are based on a combination of cognitive skills, physical strength, and hand-finger dexterity. Some of the packages relied too much on physical strength and hand-finger dexterity and for participants with arthritis and hand disabilities this posed a problem.

The driving force in a universal design process is the search for abilities that most users have. For instance, a key finding of this study is that all adult participants were

able to open a snap-type closure. Even people with muscular weakness and very limited hand dexterity could easily open the non-CR snap-type closures. A huge challenge arises when children must be excluded from use.

This study explored four aspects involved in CR package usability with people with disabilities, older adults, and children: hand strength, hand-finger dexterity, hand anthropometrics, and cognitive abilities. The statistical analysis showed different levels of significant differences between groups (Table 7.1) that could be used for design strategies.

Table 7.1 – Statistical significance and p-values for hand strength, hand-finger dexterity, and anthropometrical characteristics between working groups A (people with disabilities), B (older adults), and C (children).

Variable (Dominant hand)	Comparison between working groups					
	A vs. B		A vs. C		B vs. C	
	S [a]	p	S [a]	p	S [a]	p
Grip	N	.135	Y	.013	Y	.000
Tip pinch	N	.087	N	.117	Y	.003
Key pinch	N	.239	N	.137	Y	.013
Palmar pinch	N	.109	N	.169	Y	.006
Wrist strength	N	.409	ND [b]		ND [b]	
Bilateral palm-to-palm squeeze	Y	.025	N	.611	Y	.009
Hand-finger dexterity	N	.060	N	.988	N	.065
Functional grip diameter	Y	.014	Y	.000	Y	.000
Hand grip span TI1	Y	.019	Y	.013	Y	.000
Hand grip span TI2	N	.461	Y	.000	Y	.000
Index finger's length	N	.080	Y	.000	Y	.000
Hand width	N	.117	Y	.000	Y	.000

[a]: Statistical significance (Y=yes, N=no)
[b] ND: not determined.
Mean difference is significant at α=0.05

Hand strength

The sizes of the hand and fingers are related to pinch strength and hand strength [92]. However, this does not hold true for adults with hand disabilities and older adults. The aging process affects the ability to control submaximal pinch force and maintain a steady precision pinch posture. Manual speed, and hand sensation decline as well [93]. Of all strength measurements evaluated in this study, only grip strength was significantly different between the two adult groups (A and B) and the group of children (C). Older adults did have significant differences in pinch strength (tip, key, and palmar) when compared with the children's group. In order to include people with disabilities a CR package design should not base its operating principle on the use of pinch strength. Children will tend to compensate for their lack of strength with the use of teeth. Younger children more often use their teeth to open containers while older children use their hands [49]. Designs considerations for defeating the use of teeth include: minimizing protrusions, providing smooth surfaces, elimination of gaps that offer space to pry, and use of sturdy durable construction.

Hand-finger dexterity

Dexterity has been defined as the "manual ability that requires rapid coordination of gross or fine voluntary movements based on a certain number of capacities, which developed through learning, training, and experience" [94]. Gross and fine motor dexterity have been differentiated, as the gross movement involves coordination of arm and hand and the fine motor movement involves the wrist and fingers [95]. Fine motor or finger dexterity has been further defined as "the ability to make rapid, skillful, and controlled manipulative movements of smalls objects, using primarily the fingers" [96].

Children between the ages of 3 and 5 have rapid gains in manipulative skills, finger dexterity, and tool use [85]. The younger the child, the less dexterous he/she is. By the age of 4, child dexterity scores are really close to scores of people 80 and older. In

addition, older adults and people with disabilities represent a population with a broad range of hand-finger dexterity. Hand-finger dexterity seems to be inappropriate as the main factor to include adults and exclude children (Figure 6.3).

Hand anthropometrics

For all hand dimensions measured, the two adult groups were significantly different from the children. The differences in size between adults and young children provide a unique opportunity to include one and exclude the others.

These findings are related to conclusions from previous studies that have suggested that larger CR containers have better child resistance properties than small ones [49]. For very young children, large containers are more difficult to open than small containers [97]. On the other hand, large containers are generally easier to open for adults than small containers [34, 35].

Dimensional analysis can be used for design optimization. The application of this concept has not been exploited by companies and it is unexplored territory. The challenge will be to make it practical and economical.

Cognition

Cognitive abilities of adults and children have similarities and differences. For instance, when presented with a vial-container system all the children in working group C immediately recognized cap (the interface for opening) and the container (the interface for griping). However, children did not seem to have a clear understanding of "mechanical causality", for example, when pushing a tab down to unlock a mechanism while turning a cap. In the same situation, adults tended to not to read instructions. To understand the working principle of the CR package, they seemed to rely on a previous experiences with a similar package and on what the package communicates through shape, color and configuration (for instance: "If it is a round vial with a cap, then I have to push and

turn"). When this strategy did not work adults focused on reading instructions more carefully. It is a common belief that two motions (consecutively or simultaneously) are inherently child-resistant [98]. People with difficulties in the hands preferred the two consecutive motions approach.

In order to include people with disabilities, the possible pathways lead to prioritize anthropometrics and cognitive abilities over hand-finger dexterity and hand-strength since some participants of working group A (people with disabilities) showed hand-finger dexterity and physical strength levels comparable to those found in working group C (children). If the level of strength and dexterity demanded by a package design increases, people with disabilities and older adults with hand impairment, might be excluded as users.

Interesting findings of this research include the fact that the vast majority of the participants of groups A (people with disabilities) and B (older adults) could successfully open the screening packages required by the protocol. All participants live independently and are consumers of prescription drugs. They would have been excluded from testing according to the US CPSC protocol for senior testing. Four distinct areas (hand strength, hand-finger dexterity, hand anthropometrics, and cognitive abilities) have been identified that can be employed to defeat children while allowing older adults easy entry. This information will guide designers not only in design choices, but also in dimensional and force related decisions regarding CR package design.

RECOMMENDATIONS FOR FUTURE RESEARCH

- A project aimed to develop new child-resistant designs for prescription drugs based on the findings of this study. It is strongly advised to involve as partners a pharmacy chain and a packaging manufacturer.

- In order to generalize the findings of this study, a similar research could be conducted using a larger number of older adults, people with disabilities, and children. It is advised to conduct only the testing of CR packages and collect data for user characterization, focus groups can be conducted until reaching the saturation level (the point in which no new information is gathered from the participants).

- There is little known about child-package interaction. Studies aimed to link child development concepts and child's package usability are advised. These could include research on cognitive skills and physical abilities and their relationship with package use.

- A study aimed to correlate the boredom index to child resistant efficacy. It is recommended to use one camera per child instead of one camera per pair of children. This will result in a more detailed picture of children's actions.

- It would be interesting to study subjective user ratings for packages and their relationship with other factors involved in packaging usability. In this research we explored some of these relationships (i.e. previous experience, grip strength, and opening time).

- Printed elements on prescription drug packages should be studied in detail. Most of current labels for prescription drugs do not highlight important information and use fine print. Some of the warning labels used in this research had poor contrast, confus-

ing symbols, and fine print. A research project aimed to quantify the extent of these problems is advised.

- Participants on both working groups were eager to collaborate on studies focused on other type of packages (e.g.: soup cans, cereal boxes, soda bottles, flexible packaging, etc.). Focus group sessions with groups of consumers have the potential of unveiling problems with other types packaging.

APPENDICES

APPENDIX A

Working groups composition

WORKING GROUPS COMPOSITION

Working group A: People with disabilities

Subj. #	Gender	Age	Dexterity	Daily Meds.	Children at home	Visiting children	Uses wheel-chair
1	F	58	R	11	-	-	-
2	F	37	R	4	-	-	-
3	F	73	L	8	-	Yes	Yes
4	F	66	R	4	-	-	-
5	F	43	R	2	Yes	Yes	Yes
6	M	36	R	2	Yes	Yes	Yes
7	F	57	R	24	-	Yes	Yes
8	F	31	R	9	Yes	-	-
9	F	57	R	1	-	-	-
10	F	59	R	20	-	Yes	Yes

Description of disabilities

Subj. #	Disabilities	Associated difficulties
1	Severe arthritis	When opening packaging feels pain in the thumb and wrist areas
2	Tardive dyskinesia	Involuntary movements of the hands
3	Stroke	Can use only left hand
4	Osteoarthritis	Feels pain in the fingers and thumbs
5	Muscular dystrophy	Muscular weakness
6	Muscular dystrophy	Muscular weakness
7	Rheumatoid arthritis, peripheral neuropathy, asthma, diabetes, sarcoi-dosis	Problems with almost every daily activity
8	Visually impaired, arthri-	Problems opening and identifying packages
9	Memory loss	Problems opening and identifying packages
10	MS Tardive dyskenesia	Very limited manually dexterity

Working group B: Older adults

#	Gender	Age (years)	Dexterity	Daily Meds.	Children at home	Visiting children	Pathology
1	F	87	R	12	-	Yes	Arthritis
2	M	90	R	6	-	Yes	Tremor
3	F	86	R	1	-	-	No feeling on finger tips
4	M	84	R	5	-	Yes	Arthritis
5	F	71	L	2	-	-	Weakness on hands
6	F	82	R	10	-	Yes	Osteoporosis & arthritis
7	F	88	R	5	-	Yes	Osteo-arthritis
8	F	89	R	10	-	Yes	-
9	M	83	R	10	-	Yes	Heart problems
10	F	77	R	12	-	Yes	Osteo-arthritis

Working group C: Children

Subj. #	Gender	Age (months)	Dexterity
1	M	52	R
2	F	52	R
3	M	47	R
4	M	54	R
5	F	44	R
6	M	42	R
7	F	46	R
8	M	45	R

APPENDIX B

Adult test protocol

ADULT TEST PROTOCOL

DESCRIPTION OF TEST

We are testing child-resistant packages to determine if they can be opened and properly close by an adult. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested, we are testing the package, not you.

1) I will give you a package and ask you to read the instructions and open and properly close the package.

2) I will then give you an identical package, and ask you to open and properly close it.

3) I may ask you to open some other types of packages

4) I will ask you whether you think the child-resistant package was easy or hard to use

TEST
5-minute test period

1) "I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP."

2) The first package is handed

3) "PLEASE OPEN THIS PACKAGE ACCORDING TO THE INSTRUCTIONS ON THE CAP AND EMPTY THE PILLS INTO THIS CONTAINER"

4) Stopwatch is started

5) When the participant opens the package stop the stopwatch, record the time and say:
"PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP"
Stopwatch is started.

6) If the participant does not open the package and stops trying say:
"ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?"
If the participant indicates she/he is finished proceed to the Screening Test

1-minute test period

1) The second package is handed

2) "THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP AND EMPTY THE PILLS INTO THIS CONTAINER"

3) Stopwatch is started.

4) When the participant opens the package stop the stopwatch, record the time to open and say:
"PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP".
Stopwatch is started. Stop it when the participant closes the package. Record the time to close.

5) If the participant does not open the package and stops trying say:
"ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?"

6) If the participant indicates he/she is finished or cannot open the package and does not wish to continue trying, this is counted as a failure of the 1-minute test.

Screening test

1) A package with CT-closure is handed

2) Tester say:
"PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE"

3) Record time to open and time to close separately

4) A package with Snap-closure is handed

5) Tester say:
"PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE"

APPENDIX C

Child test protocol

CHILD TEST PROTOCOL

DESCRIPTION OF TEST

- Escort to children to a quiet area, and ask them to sit on a carpet square on the floor.
- Give each child a package.
- Ask the children:

"PLEASE TRY TO OPEN THIS FOR ME"

- Watch the children very carefully for 5 minutes.
- Minimize conversation with the child.
- If he/she stops, try encouraging him/her to continue trying.
- Take the package from the child immediately in the event that it is opened
- In the event that the package is not opened in 5 minutes, open the package in front of the child and say:

"WATCH ME OPEN MY PACKAGE"

- Give them a second 5 minute period to try to open the package saying:

"NOW YOU TRY TO OPEN YOUR PACKAGES"

- If they haven't used their teeth during the first 5 minutes, the tester shall say:

"YOU CAN USE YOUR TEETH IF YOU WANT TO"

- Thank the children for helping us, and indicate:

"I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN"

"NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."

- Escort the children back to their classroom

APPENDIX D

Data recording sheets for adult test and child test

Adult Test – Data Recording Sheet

Participant #	
Package Name	
Place	

5-minute period

Package code	Time to			Time Over	Comments
	Open	m	s	☐	
	Close	m	s	☐	
	Total	m	s	☐	

1-minute period

Package code	Time to			Time Over	comments
	Open	m	s	☐	
	Close	m	s	☐	
	Total	m	s	☐	

Screening test

CT package	Time to			Time Over	comments
	Open	m	s	☐	
	Close	m	s	☐	
	Total	m	s	☐	
Snap closure package	Time to			Time Over	comments
	Open	m	s	☐	
	Close	m	s	☐	
	Total	m	s	☐	

1 Have you use a package like this before? ☐ YES ☐ NO

2 This package is easy to use

☐	☐	☐	☐	☐
Strongly disagree	Disagree	Neutral	Agree	Strongly agree

Child Test – Data Recording Sheet

Seated on the RIGHT

Participant #

Package Name

1st 5-minute period

Opening time				Time Over ☐
Comments				

2nd 5-minute period

Opening time Time Over ☐

Comments

Seated on the LEFT

Participant #

Package Name

1st 5-minute period

Opening time				Time Over ☐
Comments				

2nd 5-minute period

Opening time Time Over ☐

Comments

APPENDIX E

Data recording sheets for adult and child characterizations

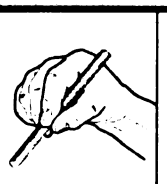
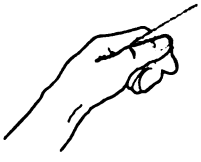
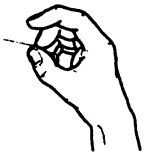
Physical Ability – Data Recording Sheet

Participant #	
Place	

Grip strength				9-HPT		
Left Hand		Right Hand				
Trial #	Strength (lbs)	Trial #	Strength (lbs)	Trial #	Time	
					LH	RH
1		1		1		
2		2		2		
3		3				

Wrist strength				Push strength	
Left Hand Right hand is holding the dynamometer		Right Hand Left hand is holding the dynamometer			
Trial #	Strength (lbs)	Trial #	Strength (lbs)	Trial #	Strength (lbs)
1		1		1	
2		2		2	
3		3		3	

Pinch strength

 Three fingered		 Lateral		 Tip	
Trial #	Strength (lbs)	Trial #	Strength (lbs)	Trial #	Strength (lbs)
	LH RH		LH RH		LH RH
1		1		1	
2		2		2	
3		3		3	

Anthropometrical Data – Data Recording Sheet

Participant #	
Place	
Dominant hand	

Take pictures	
Left Hand (up & down)	Right Hand (up & down)

Thumb/middle finger inside diameter			
Left Hand		Right Hand	
Trial #	Dimension	Trial #	Dimension
1		1	
2		2	
3		3	

Thumb/index first phalangeal joint			
Left Hand		Right Hand	
Trial #	Dimension	Trial #	Dimension
1		1	
2		2	
3		3	

Thumb/index second phalangeal joint			
Left Hand		Right Hand	
Trial #	Dimension	Trial #	Dimension
1		1	
2		2	
3		3	

APPENDIX F

Universal Design Performance Measures

Package Evaluation

1/7

Participant #

Package

Place

Please mark with X if you agree or disagree with the following statements.

			Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1	**Equitable Use**		☐				☐
	A	This package is as usable for me as it is for anyone else	☐	☐	☐	☐	☐
	B	Using this package makes me feel segregated or stigmatized	☐	☐	☐	☐	☐
	C	This package gives me needed security, and safety	☐	☐	☐	☐	☐
	D	The design of this package appeals to me	☐	☐	☐	☐	☐
	Comments						
	A						
	B						
	C						
	D						

Please mark with X if you agree or disagree with the following statements.

			Strongly disagree	Disagree	Neutral	Agree	Strongly agree
2	Flexibility in Use		☐				☐
	A	I can use this package in whatever way is effective for me	☐	☐	☐	☐	☐
	B	I can use this package with either my right or left hand alone	☐	☐	☐	☐	☐
	C	I can use this package precisely and accurately	☐	☐	☐	☐	☐
	D	I can use this package in any place	☐	☐	☐	☐	☐
	Comments						
	A						
	B						
	C						
	D						

Please mark with X if you agree or disagree with the following statements.

			Strongly disagree	Disagree	Neutral	Agree	Strongly agree
3	Simple and Intuitive Use		☐				☐
	A	This package is as simple and straightforward as it can be	☐	☐	☐	☐	☐
	B	This package works just like I expect it to work	☐	☐	☐	☐	☐
	C	I understand the language used in this package	☐	☐	☐	☐	☐
	D	The most important features of this package are the most obvious	☐	☐	☐	☐	☐
	E	This package lets me know that I'm using it the right way					
	Comments						
	A						
	B						
	C						
	D						
	E						

Package Evaluation

Please mark with X if you agree or disagree with the following statements.

			Strongly disagree	Disagree	Neutral	Agree	Strongly agree
4	**Perceptible Information**		☐				☐
	A	I can use this package without hearing	☐	☐	☐	☐	☐
	B	I can use this package without over-exerting sight	☐	☐	☐	☐	☐
	C	I can use this package without seeing	☐	☐	☐	☐	☐
	D	I can easily identify the features of this package to use directions	☐	☐	☐	☐	☐
	E	I can use this package with the aids, devices, or techniques that I use					
	Comments						
	A						
	B						
	C						
	D						
	E						

Package Evaluation

Please mark with X if you agree or disagree with the following statements.

			Strongly disagree	Disagree	Neutral	Agree	Strongly agree
5		**Tolerance for Error**	☐				☐
	A	The package features I use most are the easiest to reach	☐	☐	☐	☐	☐
	B	This package protects me from potential hazards	☐	☐	☐	☐	☐
	C	If I make a mistake, it won't cause damage or hurt me	☐	☐	☐	☐	☐
	D	This package forces me to pay attention	☐	☐	☐	☐	☐
	Comments						
	A						
	B						
	C						
	D						

Package Evaluation

Please mark with X if you agree or disagree with the following statements.

			Strongly disagree	Disagree	Neutral	Agree	Strongly agree
6	Low Physical Effort		☐				☐
	A	I can use this package comfortably, without awkward movements or uncomfortable postures	☐	☐	☐	☐	☐
	B	I can use this package without over-exerting myself	☐	☐	☐	☐	☐
	C	I can use this package without having to repeat any motion enough to cause fatigue or	☐	☐	☐	☐	☐
	D	I have to rest after using this package	☐	☐	☐	☐	☐
	Comments						
	A						
	B						
	C						
	D						

			Strongly disagree	Disagree	Neutral	Agree	Strongly agree
7		**Size and Space for Approach and Use**	☐				☐
	A	It's easy for me to see all the important elements of this package from any position	☐	☐	☐	☐	☐
	B	It's easy for me to reach all the important elements of this package from any position (such as standing or	☐	☐	☐	☐	☐
	C	This package fits my hand size	☐	☐	☐	☐	☐
	D	There is enough space for me to use this package with the devices or assistance that I need	☐	☐	☐	☐	☐
	Comments						
	A						
	B						
	C						
	D						

APPENDIX G

Moderator guide for focus groups

FOCUS GROUPS MODERATOR GUIDE

GOALS

We are trying

1) To get a sense of how people with disabilities and older adults are using drug packages
2) To gain understanding of the needs that these groups have with regard to drug packaging.

Note

- Goals are only for the moderator, they are not intended to be told to the participants
- Time allotted for each section is as follows:

Section	Minutes
Intro	5
Warm up	5
At the pharmacy	15
Openability	20
General use	15
Labeling	15
Compliance	15
Conclusion	10
Total	100

INTRODUCTION (5 minutes)

Hello everyone. My name is Javier. Welcome to our focus group discussion. A focus group is just a group of people who get together to a talk about a specific topic. The group talks for about an hour until all the questions are answered and everybody has said what they want to say.

I'll be your moderator today and with me are other members of the team, Audrey and Laura; they will be taking notes and taking care of the cameras. Today we are going to talk about issues related to prescription drug packages. I have to confess that I am not expert in this topic; I don't know much about it. My job will be to lead the discussion and make sure that everybody gets a chance to talk. Basically, I am here to find out what you think, to listen your opinions.

We want everyone to feel comfortable talking about their ideas and opinions so let's set up some rules for our discussion:

1 – There are no right or wrong answers here.

2 – Everything you have to say is very important for us.

3 – Feel free to disagree or agree with other's opinions. We expect people to have different opinions

4 – Please try not to interrupt each other.

5 – I might skip over you if have talked a lot or I might call on you if you haven't talked at all. My goal is to try to get everyone to talk.

Ok. Whatever is said in this room will only be used for research purposes and presentations in conferences. We will be videotaping this talk so we don't forget what was said. Even though you are being videotaped, nothing that you say will be connected with your name.

Any questions? All right, let's get started!

I. **WARM-UP** (5 minutes)

1. I'd like to begin by having each of you tell us your name, and...
2. Where do you buy your prescriptions?
   a. Why do you buy your prescriptions there?

II. **AT THE PHARMACY** (15 minutes)

1. What comes to your mind when you hear the phrase "child-resistant" packaging?

   PROBES

   a. Are you familiar with the term "child-resistant packaging"?
   b. What about with "childproof packaging"?
   c. Could you describe the type of package that you usually get?
   d. Do you ask for non-child-resistant caps?
   e. Do you know that you can ask for non-child-resistant caps?

2. (KEY) Could you describe the type of package that you prefer the most for your prescriptions?

   PROBES

   a. What do you like about ...
      - Blisters / unit dose packaging
      - Vials
      - Bottles
   b. What don't you like about them?

III. **OPENABILITY** (20 minutes)

(Set the samples on the table and pass a handout for each participant. See activity page at the end of this document)

1. ACTIVITY: Please rank them from the easiest to the hardest to open.
2. (KEY) Please comment on the package and its ability to be opened by you.

   PROBES

   a. What made it easy to open?
   b. What made it difficult to open?

c. What recommendations would you make to manufacturers who are designing pill packages?

IV. GENERAL USE / STORAGE / ON-THE-GO (15 minutes)

1. (KEY) After you have purchased your prescriptions, you return to your home, what do you do next with them?

   PROBES

   a. Where do you keep them?
   b. Do you transfer the pills to another container?

2. (KEY) How do you manage your medications?

   PROBES

   a. Do you use pills organizers? How many? Why that many?
   b. Describe your pill organizer. What does it look like? Shape? Depth? Lid?
   c. What are the benefits of pill organizers?
   d. Are there any barriers/problems with using pill organizers?
   e. How do you transfer the pills to it? When? Where?

3. (KEY) Try to remember an experience you have had when you were traveling (going to work, going to visit a friend, etc.) and carrying medicines with you. Please describe the experience and highlight anything memorable about the experience. For example, any problems you had or anything that made it particularly easy to do.

   PROBES

   a. Where do you carry them? (A purse, a bag, etc.)
   b. What type of package?
   c. How many medications did you carry?
   d. Where were you going when you did this? (Traveling, to work, etc.)
   e. How often does this happen?

V. **LABELING** (15 minutes)

(We have a sample for every participant; every sample has a label and two different warnings. Each warning has a number for identification.)

1. I want you to look at your sample package. How do you feel about the label?

   PROBES

   a. Can you read it?
   b. Is the font clear? Is the size of print easily read?
   c. What information is important to you?
   d. Is important information highlighted for you?
   e. Do you think that you could easily follow the directions?

2. (KEY) What would improve the label for you?

3. How do you feel about these warnings?

   PROBES

   a. Is the warning effective?
   b. Would you pay attention to the warning?
   c. Can you tell what the symbol means?
   d. Can you read the text that accompanies it?

VI. **COMPLIANCE** (15 minutes)

1. Do you always follow the directions on the package? I mean the directions in the label and the warnings.

   PROBES

   a. Do you read them?
   b. What are situations when you might not follow the directions on a pill package?
   c. Are you concerned when you do not follow directions?

2. Could you tell me of a time you forgot to take a pill?

   PROBES

   a. Please describe the situation

b. Was that pill important?

c. Why do you think you forgot?

3. (KEY) Could you describe a package that helps you to keep track of your medications?

PROBES

a. What about a package feature that helps you to do so?

VII. **CONCLUSION** (10 minutes)

1. (KEY) Imagine that you could talk with a drug packaging manufacturer, what would you say to him/her?

Thank you very much for participating in our focus groups! Your input will help us to improve drug packages. Have a good evening!

Name: _____

Place: _____

ACTIVITY

1. Could you please rank these packages from the easiest to the hardest to open? Each package has a letter on the bottom, put a number to each package from 0 to 7 (0=easiest to open / 7=hardest to open)

a	_____	e	_____
b	_____	f	_____
c	_____	g	_____
d	_____	h	_____

APPENDIX H

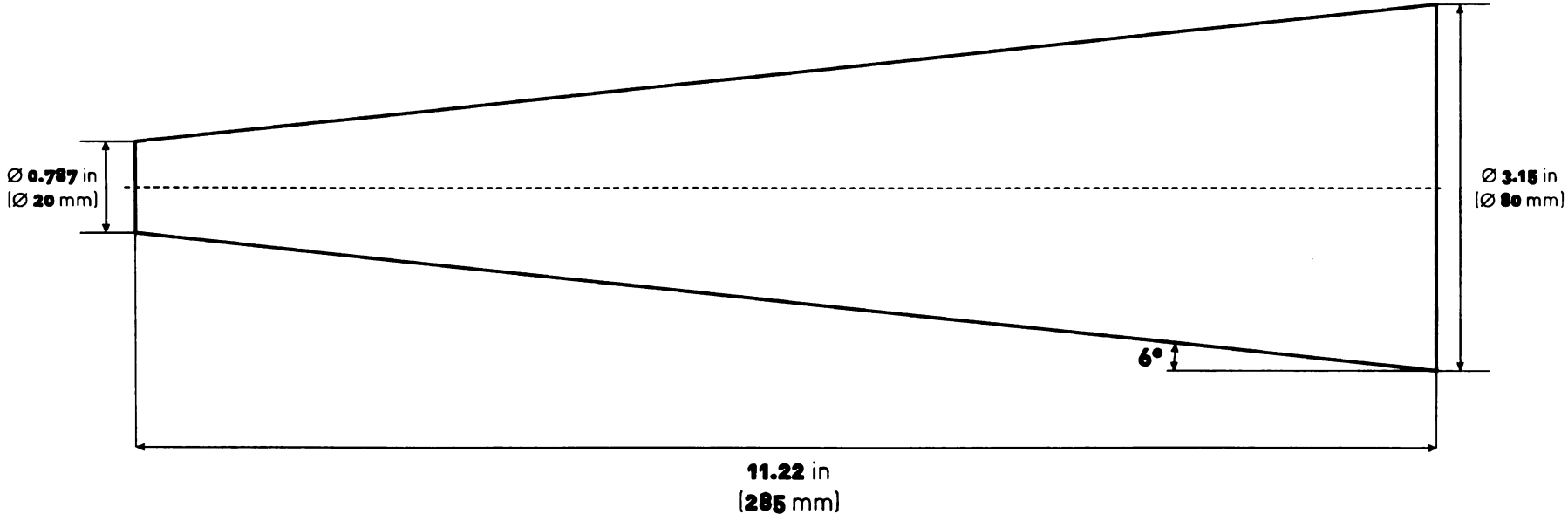
Nine-hole peg test specifications

PEG
1.25 in
(32 mm)
Ø 0.25 in
(6.4 mm)
BOARD
1.25 in
(32 mm)
0.2 in
(12 mm)
0.1 in
(6 mm)
section A-A
9 holes x
Ø 9/32 in
(7.1 mm)
5 in
(127 mm)
1.25 in
(31.75 mm)
1.25 in
(31.75 mm)
1.25 in
(31.75 mm)
A
A
1.25 in
(32 mm)
1.25 in
(32 mm)
1.25 in
(32 mm)
10 in
(254 mm)
3.94 in
(100 mm)
0.53 in
(13.5 mm)
3.94 in
(100 mm)
0.53 in
(13.5 mm)
top view

APPENDIX I

Grasping cone specifications

THUMB-FINGER GRASPING CONE



APPENDIX J

Normative data for grip strength

NORMATIVE DATA FOR GRIP STRENGTH

Data for subjects between 3 through 85 years old

Source	Age (Years)	Force (lbs)			
		Nondominant hand		Dominant hand	
		Male	Female	Male	Female
Lee-Valkov (2003)	3.0	6.1	6.1	6.5	6.5
	4.0	7.6	7.6	7.8	7.8
	5.0	10.0	10.0	10.8	10.8
Mathiowetz (1986)	6.5	30.7	27.1	32.5	28.6
	8.5	39.0	33.0	41.9	35.3
	10.5	48.4	45.2	53.9	49.7
	12.5	55.4	50.9	58.7	56.8
	14.5	64.4	49.3	77.3	58.1
	16.5	78.5	56.9	94.0	67.3
	18.5	93.0	61.7	108.0	71.6
Estimated point	21.0	106.0	66.5	117.0	75.0
Voorbij (2001)	25.0	113.4	69.9	120.7	76.2
	30.0	113.0	69.3	120.3	75.6
	40.0	111.1	67.0	117.9	73.2
	50.0	105.8	62.7	112.1	68.5
	60.0	96.0	56.6	101.9	61.5
	70.0	83.4	49.7	88.7	53.6
	80.0	71.9	43.5	75.8	46.2
	85.0	67.4	40.9	70.3	43.1

Equations for people between 25 and 85 years

Voorbij *et al.* conducted a study with 750 young and elderly, male and female subjects and determined that the variation of force per age can be described with the following general non-linear equation:

$$y = a + \frac{b}{1 + \left(\frac{x}{c}\right)^d}$$

Where:

y = force [N]

x = age [years]

a = transition height

b = transition center

c = shape controller

d = shape controller

Table A.1 shows the values for a, b, c, and d for gripping force of the left and right hand for men and women.

Table A.1 – Coefficients for gripping force curves

Sex	Hand	Coefficients			
		a	*b*	*c*	*d*
Women	Nondominant	114.92	197.96	72.50	4.24
	Dominant	113.22	227.64	73.29	4.35
Men	Nondominant	222.90	282.14	71.26	5.58
	Dominant	196.19	342.19	74.59	5.07

APPENDIX K

Personal communications

Personal communication with O-I (1/2)

Javier,

Attached is the info I gathered for your request. We do not have any reports on this, but we do have the experience of our sales force. O-I's push down and turn vial package is called Screw-Loc.

You can visit our web-site at www.o-i.com for pictures and more detailed information regarding O-I child-resistant packages.

Hope this helps. Good luck with your research project.

Brian Brozell
Advanced Design Engineer
O-I Closure & Specialty Products
419-247-7962 Phone
419-247-7672 Fax
[redacted]@us.o-i.com

----- Forwarded by Brian Brozell/User/O-I on 09/13/2005 08:20 AM -----
Patrick J O'Connell/User/O-I
To
Brian Brozell/User/O-I@O-I
09/12/2005 03:12
cc
Joseph Cutcher/User/O-I@O-I,
Raj Krishna/User/O-I@O-I,
William Negrini/User/O-I@O-I

Subject
Re: Fw: CR packaging(Document link: Brian Brozell)

Brian
Largest chain (Walgreens) uses 1clic reversible vial package.
Largest vial usage is traditional "Push Down & Turn" package.

Patrick J. O'Connell
Vice President, Sales & Marketing
Owens-Illinois Prescription Products
419-247-8524-office

Brian Brozell/User/O-I 09/12/2005 02:53 PM
To
Patrick J O'Connell/User/O-I@O-I,
William Negrini/User/O-I@O-I
cc
Joseph Cutcher/User/O-I@O-I,
Raj Krishna/User/O-I@O-I
Subject Fw: CR packaging

Pat and Bill,

Can you answer this gentleman's question regarding the most popular child-resistant packages on the market?
Thanks,

Brian
----- Forwarded by Brian Brozell/User/O-I on 09/12/2005 02:50 PM -----

"Javier de la Fuente" cjd@msu.edu
To [redacted]@us.o-i.com
09/09/2005 06:31
cc
PM
Subject
CR packaging

Dear Brian,

I hope everything is going well for you. This is Javier from Michigan State University and I am working in a research project with Dr. Laura Bix at The School of Packaging. I found your contact information at CSPC's website.

We are trying to identify the most popular (or best selling) child-resistant closures/packages (particularly for prescription drugs). We were hoping that your company has some kind of report, statistics or information in this matter. Could you please give us some advice?

Your help is very much appreciated. Thank you very much.

Kind regards,

Javier de la Fuente, IDSA
Research Assistant
School of Packaging
Michigan State University
East Lansing, MI 48824, US
Ph +1 (517) 432 9975
Fx +1 (517) 353 8999

Personal communication with O-I (2/2)

Javier,
See the attached for the information you are looking for. Feel free to contact Craig directly with any additional questions you may have. He is our lead salesman for our Prescription Products division. We would like to see your research when you are done if it wouldn't be a problem.

Brian Brozell
Advanced Design Engineer
O-I Closure & Specialty Products
[redacted]@us.o-i.com
567-336-7962 Phone
567-336-8010 Fax

----- Forwarded by Brian Brozell/User/O-I on 03/27/2006 09:56 AM -----

Craig P Moskowitz/User/O-I
To Brian Brozell/User/O-I@O-I
03/27/2006 09:31 AM
cc Patrick J O'Connell/User/O-I@O-I
Subject
Re: Fw: Screw-Loc and 1-Clic
(Document link: Brian Brozell)

Brian,

I am very interested in the two pharmacies Javier had mentioned. Please feel free to share my contact information as the commercial contact for Rx.

Owens-Illinois Screw-Loc:% product line vial sales (traditional push and turn)
6 dram 1%
8.5 dram 28%
13 dram 43%
16 dram 12%
20 dram 2%
30 dram 6%
40 dram 7%
60 dram 2%
COMPLETE Screw-Loc LINE = 18 TOTAL SKU's (vials 8 + child resistant
closures 5 + non child resistant closures 5)

Owens-Illinois dual purpose 1-Clic % product line vial sales (1-Clic is both child resistant and non child resistant)
10 dram 77%
13 dram 3%
16 dram 2%
20 dram 10%
30 dram 5%
40 dram 2%
60 dram 1%
COMPLETE 1-Clic LINE = 10 TOTAL SKU's (vials 7 + closures 3)

Craig Moskowitz

Owens-Illinois Prescription Products
One Seagate 29 LDP
Toledo, Ohio 43666
Ph (419) 247-8529

Brian Brozell/User/O-I 03/27/2006 08:59 AM I
To
Craig P Moskowitz/User/O-I@O-I,
Patrick J O'Connell/User/O-I@O-I
Subject Fw: Screw-Loc and 1-Clic

Craig and Pat,
Could either of you tell me the most popular sizes for Screw-Loc and
1-Clic?
Thanks!

Brian
----- Forwarded by Brian Brozell/User/O-I on 03/27/2006 08:59 AM -----

"Javier de la Fuente" cjd@msu.edu
To [redacted]@us.o-i.com
03/27/2006 08:56 AM
Subject Screw-Loc and 1-Clic

Dear Brian,

This is Javier from Michigan State University, again bothering you. Six months ago you kindly suggested me two vial models from O-I as the "most popular" (the Screw-Loc and the 1-Clic). This information has been extremely useful for the project. Now, I need to buy some samples for it and I was wondering if you could tell me which is/are the most popular size/s for these two models. I am trying to gather the same info from two pharmacies here in town as well. Thank you VERY much for all your help.
Kind regards,

Javier

Javier de la Fuente, IDSA
Research assistant
School of Packaging
Michigan State University
East Lansing, MI 48824, US
Ph +1 (517) 432 9975
Fx +1 (517) 353 8999

APPENDIX L

Statistical analysis

Hand strength

One-way
ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Grip strength	Between Groups	3981.110	2	1990.555	8.630	.001
	Within Groups	5766.548	25	230.662		
	Total	9747.658	27			
Key Pinch	Between Groups	179.296	2	89.648	3.578	.043
	Within Groups	626.441	25	25.058		
	Total	805.737	27			
Tip pinch	Between Groups	117.022	2	58.511	5.483	.011
	Within Groups	266.795	25	10.672		
	Total	383.817	27			
Palmar pinch	Between Groups	199.390	2	99.695	4.485	.022
	Within Groups	555.657	25	22.226		
	Total	755.046	27			

Post Hoc Tests
Multiple Comparisons
LSD

Dependent Variable	(I) Factor1	(J) Factor1	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Grip strength	1	2	-10.50200	6.79208	.135	-24.4906	3.4866
		3	19.24775(*)	7.20409	.013	4.4106	34.0849
	2	1	10.50200	6.79208	.135	-3.4866	24.4906
		3	29.74975(*)	7.20409	.000	14.9126	44.5869
	3	1	-19.24775(*)	7.20409	.013	-34.0849	-4.4106
		2	-29.74975(*)	7.20409	.000	-44.5869	-14.9126
Key Pinch	1	2	-2.69800	2.23864	.239	-7.3086	1.9126
		3	3.65175	2.37444	.137	-1.2385	8.5420
	2	1	2.69800	2.23864	.239	-1.9126	7.3086
		3	6.34975(*)	2.37444	.013	1.4595	11.2400
	3	1	-3.65175	2.37444	.137	-8.5420	1.2385
		2	-6.34975(*)	2.37444	.013	-11.2400	-1.4595
Tip pinch	1	2	-2.60000	1.46095	.087	-5.6089	.4089
		3	2.51625	1.54957	.117	-.6751	5.7076
	2	1	2.60000	1.46095	.087	-.4089	5.6089
		3	5.11625(*)	1.54957	.003	1.9249	8.3076
	3	1	-2.51625	1.54957	.117	-5.7076	.6751
		2	-5.11625(*)	1.54957	.003	-8.3076	-1.9249
Palmar pinch	1	2	-3.50000	2.10838	.109	-7.8423	.8423
		3	3.16675	2.23627	.169	-1.4389	7.7724
	2	1	3.50000	2.10838	.109	-.8423	7.8423
		3	6.66675(*)	2.23627	.006	2.0611	11.2724
	3	1	-3.16675	2.23627	.169	-7.7724	1.4389
		2	-6.66675(*)	2.23627	.006	-11.2724	-2.0611

* The mean difference is significant at the .05 level.

Wrist strength

T-Test
Group Statistics

	Factor3	N	Mean	Std. Deviation	Std. Error Mean
Wrist strength	1	10	62.6660	64.36914	20.35531
	2	10	43.6670	29.95877	9.47380

Independent Samples Test

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean Diff.	Std. Error Diff.	95% Confidence Interval of the Difference	
								Lower	Upper
Equal variances assumed	16.493	.001	.846	18	.409	18.99900	22.45198	-28.17086	66.16886
Equal variances not assumed			.846	12.724	.413	18.99900	22.45198	-29.61259	67.61059

Bilateral palm-to-palm squeeze

One-way
ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	80.206	2	40.103	4.800	.018
Within Groups	200.513	24	8.355		
Total	280.719	26			

Post Hoc Tests
Multiple Comparisons
Dependent Variable: Squeeze
LSD

(I) Factor4	(J) Factor4	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1	2	-3.17933(*)	1.32807	.025	-5.9203	-.4383
	3	.72292	1.40451	.611	-2.1758	3.6217
2	1	3.17933(*)	1.32807	.025	.4383	5.9203
	3	3.90225(*)	1.37106	.009	1.0725	6.7320
3	1	-.72292	1.40451	.611	-3.6217	2.1758
	2	-3.90225(*)	1.37106	.009	-6.7320	-1.0725

* The mean difference is significant at the .05 level.

Hand-finger dexterity

Oneway
ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
9-HPT Completion time - DH	Between Groups	3550.785	2	1775.393	2.618	.094
	Within Groups	16272.622	24	678.026		
	Total	19823.407	26			
9-HPT Completion time - NH	Between Groups	7823.211	2	3911.606	2.766	.083
	Within Groups	33943.456	24	1414.311		
	Total	41766.667	26			

Post Hoc Tests
Multiple Comparisons
LSD

Dependent Variable	(I) Factor2	(J) Factor2	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
9-HPT Completion time - DH	1	2	23.65556	11.96406	.060	-1.0371	48.3482
		3	-.19444	12.65265	.988	-26.3082	25.9193
	2	1	-23.65556	11.96406	.060	-48.3482	1.0371
		3	-23.85000	12.35135	.065	-49.3419	1.6419
	3	1	.19444	12.65265	.988	-25.9193	26.3082
		2	23.85000	12.35135	.065	-1.6419	49.3419
9-HPT Completion time - NH	1	2	40.37778(*)	17.27937	.028	4.7149	76.0406
		3	17.02778	18.27387	.361	-20.6876	54.7432
	2	1	-40.37778(*)	17.27937	.028	-76.0406	-4.7149
		3	-23.35000	17.83872	.203	-60.1673	13.4673
	3	1	-17.02778	18.27387	.361	-54.7432	20.6876
		2	23.35000	17.83872	.203	-13.4673	60.1673

* The mean difference is significant at the .05 level.

Anthropometrics

Oneway
ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Functional grip	Between Groups	1472.976	2	736.488	23.186	.000
	Within Groups	794.108	25	31.764		
	Total	2267.084	27			
Index finger length	Between Groups	3885.037	2	1942.518	43.587	.000
	Within Groups	1114.164	25	44.567		
	Total	4999.200	27			
Hand width	Between Groups	4458.053	2	2229.027	47.424	.000
	Within Groups	1175.047	25	47.002		
	Total	5633.101	27			
Grip Span A	Between Groups	9176.139	2	4588.070	12.728	.000
	Within Groups	9011.583	25	360.463		
	Total	18187.722	27			

Post Hoc Tests
Multiple Comparisons
LSD

Dependent Variable	(I) Factor1	(J) Factor1	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Functional grip	1	2	-6.63400(*)	2.52049	.014	-11.8250	-1.4430
		3	11.49050(*)	2.67338	.000	5.9846	16.9964
	2	1	6.63400(*)	2.52049	.014	1.4430	11.8250
		3	18.12450(*)	2.67338	.000	12.6186	23.6304
	3	1	-11.49050(*)	2.67338	.000	-16.9964	-5.9846
		2	-18.12450(*)	2.67338	.000	-23.6304	-12.6186
Index finger length	1	2	-5.45700	2.98552	.080	-11.6058	.6918
		3	22.84150(*)	3.16662	.000	16.3197	29.3633
	2	1	5.45700	2.98552	.080	-.6918	11.6058
		3	28.29850(*)	3.16662	.000	21.7767	34.8203
	3	1	-22.84150(*)	3.16662	.000	-29.3633	-16.3197
		2	-28.29850(*)	3.16662	.000	-34.8203	-21.7767
Hand width	1	2	-4.98400	3.06600	.117	-11.2986	1.3306
		3	25.04750(*)	3.25199	.000	18.3499	31.7451
	2	1	4.98400	3.06600	.117	-1.3306	11.2986
		3	30.03150(*)	3.25199	.000	23.3339	36.7291
	3	1	-25.04750(*)	3.25199	.000	-31.7451	-18.3499
		2	-30.03150(*)	3.25199	.000	-36.7291	-23.3339
Grip Span A	1	2	-21.33300(*)	8.49074	.019	-38.8200	-3.8460
		3	24.08425(*)	9.00579	.013	5.5365	42.6320
	2	1	21.33300(*)	8.49074	.019	3.8460	38.8200
		3	45.41725(*)	9.00579	.000	26.8695	63.9650
	3	1	-24.08425(*)	9.00579	.013	-42.6320	-5.5365
		2	-45.41725(*)	9.00579	.000	-63.9650	-26.8695

* The mean difference is significant at the .05 level.

Grip span B

Oneway
ANOVA
Grip Span B

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	10117.856	2	5058.928	25.508	.000
Within Groups	4759.847	24	198.327		
Total	14877.703	26			

Post Hoc Tests
Multiple Comparisons
Dependent Variable: Grip Span B
LSD

(I) Factor2	(J) Factor2	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1	2	-4.85322	6.47063	.461	-18.2079	8.5015
	3	39.60528(*)	6.84304	.000	25.4819	53.7286
2	1	4.85322	6.47063	.461	-8.5015	18.2079
	3	44.45850(*)	6.68009	.000	30.6715	58.2455
3	1	-39.60528(*)	6.84304	.000	-53.7286	-25.4819
	2	-44.45850(*)	6.68009	.000	-58.2455	-30.6715

* The mean difference is significant at the .05 level.

APPENDIX M

Raw data

RAW DATA

Adult test

#: Participant number
P: Passed screening test
NP: did not passed screening

Adult test / Working group A / 1-Clic®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	40	1	-	-	-	2	2	-	-	-	1	4
2	8	1	-	-	-	8	1	-	-	1	-	1
3	65	27	-	-	P	31	1	-	-	-	1	3
4	6	2	-	-	-	1	1	-	-	-	1	3
5	-	-	1	-	NP	-	-	-	-	1	-	0
6	46	2	-	-	-	40	3	-	-	-	1	2
7	16	7	-	-	-	3	5	-	-	1	-	3
8	7	5	-	-	-	12	5	-	-	-	1	4
9	44	9	-	-	-	9	3	-	-	-	1	3
10	3	5	-	-	-	2	2	-	-	-	1	4

Adult test / Working group A / Screw-Loc®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	2	2	-	-	-	2	2	-	-	1		2
2	2	1	-	-	-	2	1	-	-	1		0
3	-	-	1	-	P	-	-	1	-		1	0
4	2	1	-	-	-	2	2	-	-	1		2
5	-	-	1	-	NP	-	-	-	-	1		0
6	-	-	1	-	P	-	-	-	1	1		0
7	31	31	-	-	-	14	36	-	-	1		0
8	6	3	-	-	-	5	1	-	-	1		1
9	5	3	-	-	-	3	2	-	-	1		4
10	5	2	-	-	-	5	2	-	-	1		3

Adult test / Working group A / ShellPak®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	45	2	-	-	-	11	2	-	-	-	1	4
2	100	10	-	-	-	13	4	-	-	-	1	1
3	27	3	-	-	-	20	3	-	-	1	-	4
4	21	2	-	-	-	6	2	-	-	-	1	1
5	-	-	1	-	NP	-	-	-	-	-	1	0
6	-	-	1	-	NP	-	-	-	-	-	1	0
7	56	9	-	-	-	-	-	-	1	-	1	2
8	50	4	-	-	-	21	2	-	-	-	1	1
9	61	2	-	-	-	13	6	-	-	-	1	3
10	92	2	-	-	-	42	2	-	-	-	1	0

Adult test / Working group A / CR Blister®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	-	-	1	-	P	-	-	-	1	1	-	0
2	-	-	1	-	P	-	-	-	1	1	-	0
3	176	-	-	-	-	-	-	-	1	1	-	0
4	75	-	-	-	-	-	-	1	-	1	-	0
5	-	-	1	-	NP	-	-	-	-	1	-	0
6	-	-	1	-	NP	-	-	-	-	1	-	0
7	180	-	-	-	-	-	-	-	1	-	1	0
8	-	-	-	1	P	-	-	-	1	1	-	0
9	180	-	-	-	P	50	-	-	-	-	1	3
10	-	-	-	1	P	-	-	-	1	-	1	0

Adult test / Working group B / 1-Clic®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	-	-	1	-	P	5	3				1	3
2	7	4	-	-	-	4	4				1	3
3	8	2	-	-	-	9	3				1	4
4	19	6	-	-	-	5	8				1	4
5	4	2	-	-	-	2	2			1		3
6	5	4	-	-	-	4	3			1		4
7	20	2	-	-	-	4	3				1	4
8	3	2	-	-	-	4	2			1		4
9	2	2	-	-	-	1	1			1		4
10	24	3	-	-	-	9	3				1	3

Adult test / Working group B / Screw-Loc®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	3	2	-	-	-	3	2	-	-	1	-	3
2	7	2	-	-	-	4	8	-	-	1	-	3
3	10	Didn't secure	-	-	P	39	Didn't secure	-	-	1	-	0
4	-	-	1	-	P	34	24	-	-	1	-	1
5	6	2	-	-	-	2	2	-	-	1	-	2
6	14	4	-	-	-	5	5	-	-	1	-	1
7	6	2	-	-	-	5	3	-	-	1	-	3
8	7	6	-	-	-	2	2	-	-	1	-	3
9	2	2	-	-	-	3	2	-	-	1	-	4
10	22	2	-	-	-	18	2	-	-	1	-	1

Adult test / Working group B / ShellPak®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	49	2			-	13	6			1		1
2	-	-	1		P	-	-	1			1	0
3	144	20			-	25	3				1	0
4	60	2			-	40	4				1	3
5	49	4			-	14	2			1		1
6	-	-	1		P	55	4				1	1
7	34	2			-	19	2				1	1
8	76	3			-	15	2				1	3
9	36	4			-	7	2				1	3
10	-	-	1		P	42	2				1	0

Adult test / Working group B / CR Blister®

#	5-minute period Time (seconds)				Screening test	1-minute-period Time (seconds)				Used before?		Rating (0-4)
	Open	Close	Gave up	Time Over		Open	Close	Gave up	Time Over	Y	N	
1	-	-	1		P	-	-		1		1	0
2	-	-	1		P	-	-		1		1	0
3	-	-	1		P	-	-		1	1		0
4	-	-	1		P	-	-		1	1		0
5	54	-			-	54	-	-	-	1		0
6	-	-	1		P	-	-	1	-		1	1
7	-	-	1		P	-	-	1	-	1		1
8	-	-	1		P	-	-		1	1		0
9	134	-	-		P	-	-		1	1		0
10	107	-	-		-	-	-		1	1		0

Child test

#: Participant number

Child test / Working group C / 1-Clic®

#	First 5-minute period Time (seconds)		Second 5-minute period Time (seconds)	
	Time to Open	Time Over	Time to Open	Time Over
1	-	1	-	1
2	-	1	4	-
3	-	1	-	1
4	-	1	-	1
5	-	1	-	1
6	-	1	-	1
7	-	1	-	1
8	-	1	-	1

Child test / Working group C / ScrewLoc®

#	First 5-minute period Time (seconds)		Second 5-minute period Time (seconds)	
	Time to Open	Time Over	Time to Open	Time Over
1	-	1	41	-
2	-	1	160	-
3	-	1	-	1
4	170	-	-	1
5	-	1	25	-
6	-	1	-	1
7	-	1	-	1
8	-	1	-	1

Child test / Working group C / ShellPak®

#	First 5-minute period Time (seconds)		Second 5-minute period Time (seconds)	
	Time to Open	Time Over	Time to Open	Time Over
1	-	1	-	1
2	-	1	247	-
3	-	1	-	1
4	-	1	-	1
5	-	1	131	-
6	-	1	-	1
7	-	1	-	1
8	-	1	-	1

Child test / Working group C / CR Blister®

#	First 5-minute period Time (seconds)		Second 5-minute period Time (seconds)	
	Time to Open	Time Over	Time to Open	Time Over
1	-	1	-	1
2	-	1	251	-
3	-	1	-	1
4	-	1	-	1
5	-	1	-	1
6	-	1	-	1
7	-	1	-	1
8	-	1	-	1

RAW DATA

User characterization
Working group A

#	Grip Strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	25	20	15	20.00	5.00	40	30	35	35.00	5.00
2	55	55	45	51.67	5.77	60	65	65	63.33	2.89
3	-	-	-	-	-	45	50	50	48.33	2.89
4	70	65	65	66.67	2.89	60	70	70	66.67	5.77
5	5	5	5	5.00	0	5	5	5	5.00	0
6	10	15	15	13.33	2.89	15	15	15	15.00	0
7	20	10	10	13.33	5.77	10	10	0	6.67	5.77
8	50	45	45	46.67	2.89	10	20	10	13.33	5.77
9	45	50	45	46.67	2.89	40	45	45	43.33	2.89
10	30	20	20	23.33	5.77	30	35	35	33.33	2.89

#	Wrist Strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	100	90	90	93.33	5.77	30	30	25	28.33	2.89
2	100	90	90	93.33	5.77	130	130	130	130.00	0
3	-	-	-	-	-	120	110	130	120.00	10.00
4	90	100	100	96.67	5.77	110	120	130	120.00	10.00
5	0	0	0	0	0	0	0	0	0	0
6	15	15	15	15.00	0	15	20	20	18.33	2.89
7	15	0	0	5.00	8.66	0	0	0	0	0
8	30	40	15	28.33	12.58	15	20	15	16.67	2.89
9	160	160	170	163.33	5.77	170	170	170	170.00	0
10	0	0	0	0	0	20	20	30	23.33	5.77

#	Palmar pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	6	6	4	5.33	1.15	8	6	2	5.33	3.06
2	14	14	14	14.00	-	16	16	16	16.00	0
3	-	-	-	-	-	12	14	14	13.33	1.15
4	8	10	10	9.33	1.15	10	12	12	11.33	1.15
5	-	-	-	-	-	0	0	0	0	0
6	1	2	2	1.67	0.58	2	1	2	1.67	0.58
7	2	2	2	2.00	0	0	0	0	0	0
8	14	12	12	12.67	1.15	2	4	2	2.67	1.15
9	10	10	10	10.00	0	14	14	14	14.00	0
10	6	4	6	10.00	0	6	6	6	14.00	0

#	Key pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	6	8	10	8.00	2.00	6	4	2	4.00	2.00
2	12	12	10	11.33	1.15	14	14	14	14.00	0
3	-	-	-	-	-	14	12	12	12.67	1.15
4	12	10	12	11.33	1.15	16	16	14	15.33	1.15
5	2	2	2	2.00	-	2	2	2	2.00	0
6	2	2	2	2.00	-	2	2	1	1.67	0.58
7	10	6	6	7.33	2.31	2	0	0	0.67	1.15
8	12	12	12	12.00	0	6	6	6	6.00	0
9	14	14	14	14.00	0	14	16	14	14.67	1.15
10	8	10	10	14.00	0	8	10	10	14.67	1.15

#	Tip pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	4	4	4	4.00	-	2	6	4	4.00	2.00
2	10	10	10	10.00	-	12	10	10	10.67	1.15
3	-	-	-	-	-	12	8	8	9.33	2.31
4	6	6	8	6.67	1.15	12	10	8	10.00	2.00
5	1	1	0	0.67	0.58	1	1	0	0.67	0.58
6	2	0	1	1.00	1.00	1	1	0	0.67	0.58
7	0	0	0	0.00	0	0	0	0	0.00	0
8	10	10	10	10.00	0	2	0	4	2.00	2.00
9	10	8	10	9.33	1.15	10	10	8	9.33	1.15
10	4	6	4	9.33	1.15	4	4	4	9.33	1.15

#	Bilateral palm-to-palm squeeze (lbs)				
	1	2	3	Mean	SD
1	5	4	4	4.17	0.76
2	2	3	2	2.33	0.58
3	-	-	-	-	-
4	6	6	6	5.67	0.29
5	0	0	0	0	0
6	0	0	0	0	0
7	0	0	0	0	0
8	0	0	0	0	0
9	7	6	7	6.67	0.58
10	6	3	5	4.17	1.53

#	Nine-hole peg test scores (seconds)			
	Nondominant hand		Dominant hand	
	Trial 1	Trial 2	Trial 1	Trial 2
1	30	29	30	29
2	31	27	26	24
3	-	-	22	31
4	20	19	18	17
5	-	190	-	150
6	58	61	80	80
7	-	160	-	-
8	80	60	66	62
9	27	26	26	25
10	56	56	56	55

#	Functional grip diameter (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	34	33	33	33.33	0.58	35	35	35	35.00	0
2	52	52	52	52.00	0	50	50	51	50.33	0.58
3	-	-	-	-	-	43	43	45	43.67	1.15
4	40	39	38	39.00	1.00	40	40	39	39.67	0.58
5	25	25	25	25.00	0	20	20	20	20.00	0
6	32	32	32	32.00	0	30	31	32	31.00	1.00
7	-	-	-	-	-	36	35	35	35.33	0.58
8	35	33	32	33.33	1.53	30	31	31	30.67	0.58
9	41	43	43	42.33	1.15	42	43	42	42.33	0.58
10	45	46	46	42.33	1.15	46	45	44	42.33	0.58

#	Hand grip span TI1 (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	80	80	80	80.00	0	75	75	75	75.00	0
2	120	115	115	116.67	2.89	105	105	110	106.67	2.89
3	-	-	-	-	-	100	100	100	100.00	0
4	95	100	95	96.67	2.89	95	95	95	95.00	0
5	75	75	70	73.33	2.89	80	75	80	78.33	2.89
6	50	50	55	51.67	2.89	55	55	55	55.00	0
7	45	45	45	45.00	0	20	20	20	20.00	0
8	90	85	90	88.33	2.89	90	85	90	88.33	2.89
9	100	100	110	103.33	5.77	95	95	95	95.00	0
10	95	100	115	103.33	5.77	120	115	110	115.00	0

#	Hand grip span TI2 (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	65	65	60	63.33	2.89	60	55	50	55.00	5.00
2	90	90	90	90.00	-	85	85	80	83.33	2.89
3	-	-	-	-	-	90	85	85	86.67	2.89
4	80	85	85	83.33	2.89	75	80	75	76.67	2.89
5	45	45	45	45.00	-	45	45	40	43.33	2.89
6	70	70	65	68.33	2.89	75	70	70	71.67	2.89
7	55	55	50	53.33	2.89	-	-	-	-	-
8	80	80	75	78.33	2.89	80	85	90	85.00	5.00
9	80	80	85	81.67	2.89	75	80	80	78.33	2.89
10	80	75	70	81.67	2.89	80	80	80	78.33	2.89

#	Dimension for dominant hand (mm)	
	Index finger length	Hand width
1	57.39	80.66
2	70.71	97.01
3	65.03	88.35
4	60.63	94.32
5	64.89	74.87
6	84.50	88.82
7	64.54	79.59
8	57.67	86.36
9	66.05	89.22
10	64.58	88.25

Working group B

#	Grip Strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	45	40	40	41.67	2.89	50	50	50	50.00	0
2	75	70	80	75.00	5.00	50	50	50	50.00	0
3	50	50	55	51.67	2.89	40	45	50	45.00	5.00
4	20	35	20	25.00	8.66	30	30	35	31.67	2.89
5	50	50	55	51.67	2.89	50	60	60	56.67	5.77
6	40	40	40	40.00	0	30	45	45	40.00	8.66
7	35	30	35	33.33	2.89	40	40	40	40.00	0
8	30	25	30	28.33	2.89	30	30	30	30.00	0
9	40	40	40	40.00	0	60	60	65	61.67	2.89
10	35	35	35	35.00	0	30	30	30	30.00	0

#	Wrist Strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	50	60	60	56.67	5.77	50	60	60	56.67	5.77
2	110	100	90	100.00	10.00	50	60	60	56.67	5.77
3	10	0	10	6.67	5.77	30	40	30	33.33	5.77
4	0	0	0	0	0	0	10	30	13.33	15.28
5	60	70	60	63.33	5.77	70	70	60	66.67	5.77
6	0	0	0	0	0	40	20	30	30.00	10.00
7	10	30	20	20.00	10.00	40	30	30	33.33	5.77
8	40	30	30	33.33	5.77	40	30	50	40.00	10.00
9	100	100	90	96.67	5.77	110	110	100	106.67	5.77
10	0	0	0	0	0	0	0	0	0	0

#	Palmar pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	8	12	10	10.00	2.00	12	12	12	12.00	0
2	16	14	14	14.67	1.15	8	10	10	9.33	1.15
3	14	16	18	16.00	2.00	16	16	16	16.00	0
4	12	10	10	10.67	1.15	8	8	8	8.00	0
5	16	14	14	14.67	1.15	16	16	16	16.00	0
6	8	8	10	8.67	1.15	8	8	10	8.67	1.15
7	10	10	10	10.00	0	10	10	10	10.00	0
8	6	6	6	6.00	0	6	6	6	6.00	0
9	18	20	20	19.33	1.15	16	20	22	19.33	3.06
10	8	8	8	8.00	-	8	8	8	8.00	0

#	Key pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	10	10	10	10.00	0	14	10	12	12.00	2.00
2	16	16	16	16.00	0	12	12	10	11.33	1.15
3	10	12	12	11.33	1.15	12	12	10	11.33	1.15
4	8	8	8	8.00	0	12	10	12	11.33	1.15
5	14	14	14	14.00	0	14	16	16	15.33	1.15
6	8	8	8	8.00	0	6	8	8	7.33	1.15
7	8	10	10	9.33	1.15	10	8	8	8.67	1.15
8	6	6	6	6.00	0	6	6	8	6.67	1.15
9	20	22	22	21.33	1.15	24	24	24	24.00	0
10	12	8	10	10.00	2.00	6	4	4	4.67	1.15

#	Tip pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	6	8	6	6.67	1.15	8	8	8	8.00	0
2	14	12	14	13.33	1.15	10	8	10	9.33	1.15
3	8	12	8	9.33	2.31	10	10	10	10.00	0
4	10	8	6	8.00	2.00	6	6	6	6.00	0
5	12	12	12	12.00	0	10	8	8	8.67	1.15
6	6	6	6	6.00	0	6	8	8	7.33	1.15
7	8	10	10	9.33	1.15	8	8	10	8.67	1.15
8	4	4	4	4.00	0	4	4	4	4.00	0
9	14	14	14	14.00	0	14	16	14	14.67	1.15
10	6	4	4	4.67	1.15	4	8	4	5.33	2.31

#	Bilateral palm-to-palm squeeze (lbs)				
	1	2	3	Mean	SD
1	3.0	3.0	3.5	3.17	0.29
2	6.5	7.0	8.0	7.17	0.76
3	10.0	10.0	10.0	10.00	0
4	3.5	3.0	3.0	3.17	0.29
5	8.0	12.0	12.0	10.67	2.31
6	2.0	2.0	2.0	2.00	0
7	6.0	7.0	10.0	7.67	2.08
8	0	0	0.5	0.17	0.29
9	12.0	7.5	8.0	9.17	2.47
10	2.5	4.0	6.0	4.17	1.76

#	Nine-hole peg test scores (seconds)			
	Nondominant hand		Dominant hand	
	Trial 1	Trial 2	Trial 1	Trial 2
1	29	28	26	26
2	47	44	112	57
3	33	32	25	25
4	32	29	26	24
5	19	23	27	24
6	21	23	23	18
7	29	32	26	26
8	24	21	26	30
9	29	29	31	26
10	34	33	30	33

#	Functional grip diameter (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	35	38	36	36.33	1.53	39	42	41	40.67	1.53
2	47	47	48	47.33	0.58	46	48	48	47.33	1.15
3	46	46	50	47.33	2.31	46	46	49	47.00	1.73
4	32	32	34	32.67	1.15	40	39	39	39.33	0.58
5	48	47	48	47.67	0.58	48	48	48	48.00	0
6	45	43	44	44.00	1.00	42	42	42	42.00	0
7	43	44	44	43.67	0.58	40	42	43	41.67	1.53
8	36	38	39	37.67	1.53	41	38	40	39.67	1.53
9	50	50	52	50.67	1.15	48	49	50	49.00	1.00
10	40	40	40	40.00	0	42	42	42	42.00	0

#	Hand grip span TI1 (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	95	95	95	95.00	0	90	95	100	95.00	5.00
2	120	125	125	123.33	2.89	110	105	110	108.33	2.89
3	60	95	100	85.00	21.79	80	90	95	88.33	7.64
4	70	75	75	73.33	2.89	90	90	90	90.00	0
5	110	115	115	113.33	2.89	120	115	120	118.33	2.89
6	105	105	105	105.00	0	115	110	110	111.67	2.89
7	120	130	130	126.67	5.77	110	110	105	108.33	2.89
8	90	95	90	91.67	2.89	95	100	100	98.33	2.89
9	125	125	130	126.67	2.89	130	130	135	131.67	2.89
10	85	85	85	85.00	0	90	90	95	91.67	2.89

#	Hand grip span TI2 (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	75	75	75	75.00	0	70	70	75	71.67	2.89
2	85	90	85	86.67	2.89	75	85	90	83.33	7.64
3	65	70	70	68.33	2.89	50	70	65	61.67	10.41
4	55	50	50	51.67	2.89	65	65	65	65.00	0
5	95	95	95	95.00	0	100	100	105	101.67	2.89
6	85	90	85	86.67	2.89	80	70	70	73.33	5.77
7	95	100	100	98.33	2.89	95	100	95	96.67	2.89
8	55	55	60	56.67	2.89	60	55	65	60.00	5.00
9	105	105	105	105.00	0	95	95	100	96.67	2.89
10	65	65	65	65.00	0	70	70	70	70.00	0

#	Dimension for dominant hand (mm)	
	Index finger length	Hand width
1	63.90	92.19
2	87.73	106.54
3	70.30	94.33
4	68.73	85.87
5	68.77	94.83
6	65.95	86.08
7	66.66	90.60
8	74.53	79.75
9	76.12	104.65
10	67.87	82.45

#	Hand grip span TI2 (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	75	75	75	75.00	0	70	70	75	71.67	2.89
2	85	90	85	86.67	2.89	75	85	90	83.33	7.64
3	65	70	70	68.33	2.89	50	70	65	61.67	10.41
4	55	50	50	51.67	2.89	65	65	65	65.00	0
5	95	95	95	95.00	0	100	100	105	101.67	2.89
6	85	90	85	86.67	2.89	80	70	70	73.33	5.77
7	95	100	100	98.33	2.89	95	100	95	96.67	2.89
8	55	55	60	56.67	2.89	60	55	65	60.00	5.00
9	105	105	105	105.00	0	95	95	100	96.67	2.89
10	65	65	65	65.00	0	70	70	70	70.00	0

#	Dimension for dominant hand (mm)	
	Index finger length	Hand width
1	63.90	92.19
2	87.73	106.54
3	70.30	94.33
4	68.73	85.87
5	68.77	94.83
6	65.95	86.08
7	66.66	90.60
8	74.53	79.75
9	76.12	104.65
10	67.87	82.45

Working group C

#	Grip Strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	10	15	10	11.67	2.89	10	15	10	11.67	2.89
2	10	10	10	10.00	0	15	10	10	11.67	2.89
3	20	20	20	20.00	0	20	20	15	18.33	2.89
4	10	10	15	11.67	2.89	15	15	15	15.00	0
5	10	10	10	10.00	0	15	10	10	11.67	2.89
6	10	10	10	10.00	0	10	10	10	10.00	0
7	10	10	10	10.00	0	15	15	15	15.00	0
8	15	15	15	15.00	0	15	15	20	16.67	2.89

#	Wrist Strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	0	0	0	-	-	0	0	0	-	-
2	0	0	0	-	-	0	0	0	-	-
3	0	0	0	-	-	0	0	0	-	-
4	0	0	0	-	-	0	0	0	-	-
5	0	0	0	-	-	0	0	0	-	-
6	0	0	0	-	-	0	0	0	-	-
7	0	0	0	-	-	0	0	0	-	-
8	0	0	0	-	-	0	0	0	-	-

* All measurements were below 15 lbs.

#	Palmar pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	4	4	4	4.00	0	4	4	2	3.33	1.15
2	4	2	4	3.33	1.15	4	6	6	5.33	1.15
3	6	6	6	6.00	0	6	6	6	6.00	0
4	2	2	4	2.67	1.15	4	4	4	4.00	0
5	2	4	4	3.33	1.15	4	6	4	4.67	1.15
6	4	4	4	4.00	0	6	4	4	4.67	1.15
7	2	4	4	3.33	1.15	4	2	6	4.00	2.00
8	6	4	6	5.33	1.15	6	6	4	5.33	1.15

#	Key pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	4	4	4	4.00	0	4.00	4.00	4.00	4.00	0
2	4	2	4	3.33	1.15	4.00	2.00	4.00	3.33	1.15
3	8	10	6	8.00	2.00	8.00	6.00	8.00	7.33	1.15
4	4	6	6	5.33	1.15	4.00	4.00	6.00	4.67	1.15
5	4	6	6	5.33	1.15	6.00	6.00	6.00	6.00	0
6	4	4	4	4.00	0	4.00	4.00	4.00	4.00	0
7	4	4	2	3.33	1.15	4.00	4.00	4.00	4.00	0
8	8	6	4	6.00	2.00	6.00	6.00	6.00	6.00	0

#	Tip pinch strength (lbs)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	2	4	4	3.33	1.15	2	2	4	2.67	1.15
2	2	4	2	2.67	1.15	2	4	4	3.33	1.15
3	4	6	4	4.67	1.15	4	6	4	4.67	1.15
4	4	2	4	3.33	1.15	2	2	2	2.00	0
5	2	4	4	3.33	1.15	4	4	2	3.33	1.15
6	2	2	2	2.00	0	2	2	2	2.00	0
7	4	2	2	2.67	1.15	2	2	4	2.67	1.15
8	4	4	4	4.00	0	4	4	4	4.00	0

#	Bilateral palm-to-palm squeeze (lbs)				
	1	2	3	Mean	SD
1	0	4.0	3.0	2.33	2.08
2	2.0	2.0	1.0	1.67	0.58
3	4.0	0	2.0	2.00	2.00
4	4.5	3.0	4.0	3.83	0.76
5	6.0	4.0	4.0	4.67	1.15
6	0	0.5	0	0.17	0.29
7	0	0	0	0	0
8	0	0	0	0	0

#	Nine-hole peg test scores (seconds)			
	Nondominant hand		Dominant hand	
	Trial 1	Trial 2	Trial 1	Trial 2
1	39	50	29	57
2	33	36	50	49
3	35	42	48	52
4	40	34	39	37
5	50	55	52	72
6	67	95	50	68
7	61	50	31	44
8	61	60	46	43

#	Functional grip diameter (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	26	26	28	26.67	1.15	25	26	26	25.67	0.58
2	23	23	22	22.67	0.58	23	24	24	23.67	0.58
3	25	23	24	24.00	1.00	24	25	26	25.00	1.00
4	24	26	26	25.33	1.15	28	27	26	27.00	1.00
5	24	25	27	25.33	1.53	26	26	27	26.33	0.58
6	26	26	26	26.00	0	27	27	27	27.00	0
7	27	28	28	27.67	0.58	25	25	27	25.67	1.15
8	24	24	24	24.00	0	25	24	23	24.00	1.00

#	Hand grip span Tl1 (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	65	60	60	61.67	2.89	70	55	65	63.33	7.64
2	50	45	50	48.33	2.89	45	50	55	50.00	5.00
3	50	55	55	53.33	2.89	60	65	55	60.00	5.00
4	60	65	65	63.33	2.89	70	65	60	65.00	5.00
5	55	50	50	51.67	2.89	65	55	55	58.33	5.77
6	45	50	50	48.33	2.89	50	55	50	51.67	2.89
7	55	75	70	66.67	10.41	50	65	75	63.33	12.58
8	60	55	70	61.67	7.64	50	60	65	58.33	7.64

#	Hand grip span TI2 (mm)									
	Nondominant hand					Dominant hand				
	1	2	3	Mean	SD	1	2	3	Mean	SD
1	40	40	45	41.67	2.89	45	30	35	36.67	7.64
2	40	40	40	40.00	0	45	45	40	43.33	2.89
3	30	35	30	31.67	2.89	25	30	30	28.33	2.89
4	45	50	45	46.67	2.89	45	55	40	46.67	7.64
5	25	25	25	25.00	0	25	20	20	21.67	2.89
6	20	25	20	21.67	2.89	20	20	20	20.00	0
7	45	45	45	45.00	0	55	40	45	46.67	7.64
8	25	25	25	25.00	0	30	25	20	25.00	5.00

#	Dimension for dominant hand (mm)	
	Index finger length	Hand width
1	45.97	64.18
2	38.45	58.02
3	44.50	64.34
4	42.28	66.84
5	45.40	59.52
6	34.07	60.97
7	47.58	58.75
8	43.81	60.96

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