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Squeeze Me if You Can: Variability in Force Requirements to Extract a Drop from Common Glaucoma Bottles

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Abstract

Purpose—To determine the force requirements to dispense a single drop from commonly prescribed brand and generic topical glaucoma medications and correlate these findings with pinch strength in a representative patient population.

Patients and Methods—Four bottles of each medication were tested: two in the vertical and two in the horizontal orientation. Bottles were housed in a customized force gauge apparatus designed to mimic ballpoint fingertip contact with a bottle tip. For all bottles, each of the first 10 dispensed drops was tested and then tests were performed in increments of 10 until the bottle was empty. For each tested drop, the maximum force and displacement were electronically measured. Concurrently, maximum pinch strength was measured on consecutive glaucoma patients.

Results—A total of 84 bottles from 21 bottle designs were tested. There was significant variability across the designs, with roughly a 7-fold (0.67–4.49 kilograms of force, kgf) and 4-fold (0.81–3.00 kgf) difference in force requirements in the vertical and horizontal positions, respectively. Of 53 enrolled patients in the glaucoma clinic, the mean pinch strength was 5.05 (range 1.23–10.4) and 4.82 (range 1.47–10.67) kgf for the right and left hands, respectively.

Conclusions—There is statistically significant variability in the force required to squeeze a drop from common glaucoma medications, and a representative sampling of clinic patients suggests that many likely struggle with the force requirements of several bottle designs. These data further support standardization of topical glaucoma drug delivery and design.

Keywords

glaucoma medication; pharmacology; pinch strength; eyedrop

Introduction

Glaucoma is the second leading cause of global blindness.¹ Although robust evidence demonstrates slowed progression with appropriate pharmacotherapy,^{1,2} reported compliance tends to hover around 70%.^{3–5} Investigators have implicated multiple reasons for poor adherence to glaucoma medications,⁶ with difficulty instilling drops playing a prominent role.⁷ A videotaped observation of glaucoma patients attempting to instill a single drop of liquid from a 2.5 or 15 mL eyedrop bottle found that only 31.0% and 21.9% of participants using the respective bottles were able to achieve the 3 criteria of installation into the eye, releasing only a single drop and no touching of the bottle to the eye or adnexa.⁸ A recent survey requesting patient input regarding ease of glaucoma bottle use found the most frequent patient suggestions revolved around bottle characteristics, particularly improving the capacity to easily and reliably dispense a single drop.⁹ Another patient survey revealed that one-third of patients reported running out of drops prior to the next refill due to bottle related mechanics such as “more than one drop comes out” or “size of drops is too large”.¹⁰

Despite the importance of bottle design in proper use of topical therapeutics, there exists no standardization of manufacture as it relates to drop instillation dynamics.^{11,12} In the only three published studies on the topic, investigators evaluated a small sample of ophthalmic medications and found a wide variation in the force required to deliver a single drop.^{13,14,15} We hypothesize that 1) the multitude of generic and brand glaucoma medications require significant variability in force required to dispense a single drop, 2) the force requirements differ based on the amount of solution remaining in the bottle, 3) the force requirements differ based on the angle the bottle is held and 4) the force requirement to dispense a drop in certain bottles will exceed some patients’ strength to squeeze them. This study was designed to determine the force requirements to deliver a single drop from each of the commonly prescribed brand and generic topical glaucoma bottles and correlate these findings with pinch strength in a representative glaucoma patient population.

Methods

Bottle Testing

The force and displacement required to dispense a single drop from various common glaucoma medications stored at room temperature were measured. All medications were purchased at cost from the University of Kentucky Research Pharmacy and represented available regional brand and generic medications. A force gauge apparatus consisting of a Mecmesin M500E Motorized Tension and Compression Test Stand, Mecmesin 100N Advanced Force Gauge (Mecmesin Corporation, Sterling, VA, USA) and custom grips and compressors were designed and calibrated by JA King & Company (Whitsett, NC, USA). The compressors were designed to mimic ballpoint fingertip contact with a bottle tip (Figure 1A).

For each medication, the bottle was housed in the apparatus and clamps were adjusted until the ballpoint compressors were located at mid bottle length. Bottles with a rectangular instead of round shape were compressed at their thinnest dimensions, as this represents the method most likely to be utilized by patients when instilling drops. The L-shaped

compression clamp was then adjusted until the force gauge sensor was centered on the crosshairs of the clamp at a 90-degree angle (Figure 1B).

Starting at 0 kilogram-force (kgf) and 0 millimeters (mm) displacement, the gauge was advanced in 0.1mm increments until a drop of liquid fell from the bottle. The force gauge was retracted to neutral displacement and force, and any residual liquid at the tip of the bottle was wiped clean. For each drop, the maximum force and displacement were electronically measured and recorded using Mecmesin Emperor Lite Force and Torque Data Acquisition Software (Mecmesin Corporation, Sterling, VA, USA). For all bottles, each of the first 10 drops were tested, and then tests were performed in increments of 10 (20th, 30th, 40th, etc.) until the bottle was empty. The final drop recorded represented the final incremental test, not the absolute number of drops in the bottle. For example, if a bottle emptied on drop 85, the last data point would be the 80th drop. For many bottles, the final drop consisted primarily of air bubbles and required significantly more force to expel than the remainder of the bottle. If encountered, these drops were not recorded; all incremental measurements required drops to observably consist of liquid only.

Four bottles of each medication were tested. Two bottles were tested in the vertical orientation with the bottle tip at 180 degrees and two bottles were tested in the near horizontal orientation with the bottle tip at 30 degrees. The vertical and horizontal orientations were the starting position for the bottle tip during each measurement, as compression of the bottle variably and slightly changed the tip position.

Pinch Strength

Consecutive glaucoma patients on a stable regimen of self-administered topical glaucoma medications were recruited from the University of Kentucky glaucoma clinics. After obtaining informed consent, maximum pinch grip strength (Jamar Digital Pinch Gauge, Sammons Preston, Bolingbrook, IL, USA) was measured. Per standard recommendations,¹⁶ participants were seated with the shoulder adducted, 90 degrees of elbow flexion, the wrist extended approximately 30 degrees and the forearm in a neutral position. Lateral pinch strength was measured three times on each hand, with the greatest value used for analysis. Patients also completed a short questionnaire detailing their medical and ocular history. The Human Subjects Division of the University of Kentucky Institutional Review Board gave approval for the clinical project and questionnaire.

Statistical Analysis

Descriptive statistics consisted of computing the mean and standard deviation of the force measurements across all drops and bottles tested for a given brand, size and position. Then, since each brand-size combination and position had different numbers of drops (Table 1), the mean force was computed across drops for each of the two bottles tested for a given brand, size and position. These force means were then analyzed using an analysis of variance (ANOVA) for a two-way design with 2 observations per cell. The two factors were position (horizontal and vertical) and brand-size (21 different combinations of brands and bottle sizes). The data were then re-analyzed using an ANOVA for a repeated measures design with the two factors listed above (between bottles factors) and the third factor (with bottle

factor) corresponding to the mean of the first 10% of the drops in the bottle, the mean of the middle 80% of the drops and the mean of the last 10% of the drops. Statistical significance was determined at the 0.05 level using two-tailed tests. All computations were performed on PC-SAS, Version 9.3 (SAS Institute Inc., Cary, NC, USA).

Results

Bottle Testing

Twenty-one bottle designs were tested (Table 1). Further reference to medications will include generic or brand name and bottle volume for identification. The mean number of drops per bottle and force for each medication (on a per drop basis) in the vertical and horizontal axis are listed in Table 2. Across all designs, the mean force ranged from 0.67–4.49 and 0.81–3.00 kilograms of force (kgf) in the vertical and horizontal positions, respectively. Three outliers are evident in this table: Timoptic 5mL, which has a large standard deviation in the horizontal position and Cosopt 10mL and Trusopt 10mL, which have larger standard deviations and mean forces for both the horizontal and vertical positions when compared to the remaining 18 brand-sizes. Homogeneity of variances required for the ANOVA analysis is not met when all 21 brand-sizes are included in the analysis.

Using all 21 brand-sizes, the two way ANOVA indicated a significant position by brand-size interaction among the means listed in Table 1 ($p < 0.001$). However, this was due to the three outliers, and in particular, for Cosopt 10mL, the mean vertical force was significantly larger than the horizontal ($p = 0.0193$). Eliminating the three outlier brand-sizes demonstrated no evidence of a two factor interaction ($p = 0.17$), but there was evidence of a main effect due to position ($p < 0.001$) with the mean for horizontal being larger than that for vertical. For medications with two or more bottle sizes (Combigan, Lumigan, Travaprost and Travatan Z), there was a significant difference in the estimated mean force among all the different bottle sizes (p all < 0.035) with the exception of Lumigan 5mL and 7.5mL. Among the medications with multiple bottle sizes, the larger bottle had a lower estimated mean force.

When separating drops into the first 10%, the middle 80% and the last 10% of drops available per bottle of medication, the force requirement was significantly greater in the last 10% than both the first 10% and middle 80% ($p < 0.0001$), but not between the first 10% and middle 80% ($p = 0.51$).

Pinch Strength

Fifty-three patients were enrolled (Table 3) with a mean age of 64.1 ± 16.2 (60% female). The mean pinch strength was 5.05 kgf (range 1.23–10.4) and 4.82 kgf (range 1.47–10.67) for the right and left hands, respectively. Women had a significantly lower maximum pinch strength ($p = 0.002$) compared to men. There was no significant association between pinch strength and age, race, other medical comorbidities, glaucoma diagnosis, number of glaucoma medications, self reported compliance, self-reported early bottle exhaustion, visual acuity or visual field mean deviation.

Discussion

This study was designed to evaluate the force required to squeeze a drop of medication from 21 commonly prescribed brand and generic glaucoma medications. We found significant variability across the designs with roughly a 7-fold and 4-fold difference in force requirements between the vertical and horizontal measurements, respectively. The force requirement did vary significantly based on the amount of solution remaining on the bottle, but there was no overall difference in force between the horizontal and vertical positions for most brand-sizes with the possible exception of Cosopt 10mL.

The results of the current study augment another recent publication utilizing a load cell amplifier to test the force required to extract the first three drops from 13 different latanoprost designs resting in the vertical position.¹⁴ The authors, Drew and Wolffsohn, found significant variability in force between designs, ranging from 6.4 Newtons to 23.4 Newtons (0.65 to 2.39 kgf). These results are similar to an earlier study evaluating the first drop from a variety of glaucoma medications using a static pressure transducer: the authors reported a range in force from 3.1 to 17.2 Newtons (0.32 to 1.75 kgf) across 15 glaucoma medications.¹³ A third study utilized a level apparatus with 50g weight increments to evaluate the first three drops from a variety of eyedrop bottles and found that the force ranged from 867 to 2267 grams (0.87 to 2.27 kgf) among the 14 glaucoma medications tested.¹⁵ The current study differed from the three previous reports in design and equipment, evaluating force requirements for all drops from each bottle and testing bottles in both a vertical and horizontal position. Although these studies employed four different experimental designs with diverse bottle types tested, each found significant variability in force requirements.

To better translate these findings to practical application, we also evaluated the pinch strength of representative glaucoma patients in our clinic. While there was a wide variability, 21 patients (40%) had a maximum R and L pinch strength less than that of the maximum mean bottle force recorded (4.49 kgf). Drew and Wolffsohn similarly evaluated the “comfortable” and “maximum” pressure 102 consecutive clinical patients could apply between their thumb and index fingers to an eye dropper attached to a pressure sensor. They found the comfortable squeeze averaged 25.9 Newtons with a range from 1.2–87.4 (2.64 kgf, range 0.12–8.90) and maximum squeeze was 64.8 Newtons, range 19.9–157.8 (6.61 kgf, range 2.03–16.10).¹⁴ Extrapolating to the current study, the mean patient would be outside the range of comfort when squeezing drops from three and six of the tested bottles in the vertical and horizontal positions, respectively. These data suggest a substantial number of patients may encounter difficulty manipulating some glaucoma bottle designs due simply to strength requirements, as indicated by prior patient surveys.^{9,10}

Despite the acknowledged problems with drop mechanics and the growing size of the industry, there exist no regulations or standardization of bottle manufacture as it relates to patient administration. Current criteria for standardization are centered around providing sterile products with containers that are not compromised by the polymers or additives interacting with the drug liquid.^{11,12} It may prove difficult to design an ideal eyedrop bottle, as there are many factors to consider.¹⁷ Design decisions must incorporate measures to

ensure a sterile product, but design flexibility coupled with limited regulation allows for the many different bottle types currently in use, some of which are proprietary and exclusive to the manufacturer. The variability of force requirements as a product of bottle design has potential clinical implications for glaucoma patients and warrants further review.

This study has several limitations. The experimental design was novel, and although objective and automated in measurements, it has not been independently verified. While 4 bottles from 21 different designs were tested, they still represent a small sampling of all available brand and generic ophthalmic medications. The bottles were stored and tested at room temperature. One study found increased force requirements for bottles refrigerated at 6°C for 24 hours.¹⁴ A relatively small sample size was used to test pinch strength.

In conclusion, this study found a statistically significant variability in the force required to squeeze a drop from common glaucoma medications. The force increased as more drops were expelled, but did not vary significantly when the bottle was held at either a horizontal or vertical position. A representative sampling of clinic patients suggests that many patients likely struggle with the force requirements of several bottle designs. There are many factors limiting patient compliance with topical therapy, but this under-recognized issue should compel future changes and standardization of topical glaucoma drug delivery and design.

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Figure 1.

Force Gauge Apparatus. A force gauge apparatus consisting of a Mecmesin M500E Motorized Tension and Compression Test Stand, Mecmesin 100N Advanced Force Gauge and custom grips and compressors were designed and calibrated by JA King & Company.

Figure 1A: The compressors were designed to mimic ballpoint fingertip contact with a bottle tip. **Figure 1B:** For each medication, the bottle was housed in the apparatus and clamps were adjusted until the ballpoint compressors were located at mid bottle length. The L-shaped compression clamp was then adjusted until the force gauge sensor was centered on the crosshairs of the clamp at a 90-degree angle.

Glaucoma Eyedrop Bottles Tested.

Table 1

Medication Name	Concentration	Volume	Manufacturer
Alphagan P (Brimonidine tartrate)	0.15%	10mL	Allergan Inc. (Irvine, CA)
Azopt (Brimonidine)	1%	10mL	Alcon Laboratories, Inc. (Fort Worth, TX)
Brimonidine tartrate	0.20%	10mL	Bausch & Lomb Inc. (Tampa, FL)
Combigan (Brimonidine Tartrate/Timolol Maleate)	0.2%, 0.5%	5mL	Allergan Inc. (Irvine, CA)
Combigan (Brimonidine Tartrate/Timolol Maleate)	0.2%, 0.5%	10mL	Allergan Inc. (Irvine, CA)
Cosopt (Dorzolamide Hydrochloride/Timolol Maleate)	22.3mg/mL, 6.8mg/mL	10mL	Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Inc. (Whitehouse Station, NJ)
Dorzolamide Hydrochloride	2%	10mL	Bausch & Lomb Inc. (Tampa, FL)
Dorzolamide Hydrochloride/Timolol Maleate	22.3mg/mL, 6.8mg/mL	10mL	Bausch & Lomb Inc. (Tampa, FL)
Latanoprost	0.01%	2.5mL	Alcon Laboratories (Fort Worth, TX) for Sandoz Inc. (Princeton, NJ)
Lumigan (Bimatoprost)	0.01%	2.5mL	Allergan Inc. (Irvine, CA)
Lumigan (Bimatoprost)	0.01%	5mL	Allergan Inc. (Irvine, CA)
Lumigan (Bimatoprost)	0.01%	7.5mL	Allergan Inc. (Irvine, CA)
Simbrinza (Brinzolamide/Brimonidine Tartrate)	1%, 0.2%	8mL	Alcon Laboratories, Inc. (Fort Worth, TX)
Travaprost	0.004%	2.5mL	Par Pharmaceutical Cos, Inc. (Spring Valley, NY)
Travaprost	0.004%	5mL	Par Pharmaceutical Cos, Inc. (Spring Valley, NY)
Travatan Z (Travaprost)	0.004%	2.5mL	Alcon Laboratories, Inc. (Fort Worth, TX)
Travatan Z (Travaprost)	0.004%	5mL	Alcon Laboratories, Inc. (Fort Worth, TX)
Trusopt (Dorzolamide Hydrochloride)	2%	10mL	Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Inc. (Whitehouse Station, NJ)
Timolol Maleate	0.50%	5mL	Alcon Laboratories (Fort Worth, TX) for Sandoz Inc. (Princeton, NJ)
Timoptic (Timolol Maleate)	0.50%	5mL	Valeant Ophthalmics, division of Valeant Pharmaceuticals North America LLC (Bridgewater, NJ)
Xalatan (Latanoprost)	0.01%	2.5mL	Pharmacia and Upjohn Co., a division of Pfizer, Inc. (NY, NY)

Table 2

Mean number of drops per bottle and force for each medication in the vertical and horizontal axis.

Medication	Vertical			Horizontal		
	mean # drops	mean (SD)	range	mean # drops	mean (SD)	range
Xalatan 2.5mL	90	0.9 (0.05)	0.36–1.36	75	1.06 (0.20)	0.71–1.38
Latanoprost 2.5mL	70	1.50 (0.23)	1.13–1.78	65	1.36 (0.20)	0.96–1.85
Travatan Z 2.5mL	75	1.65 (0.37)	1.04–2.47	100	1.77 (0.37)	1.21–3.32
Travaprost 2.5mL	70	1.59 (0.36)	0.98–2.17	65	1.75 (0.26)	1.23–2.11
Lumigan 2.5mL	95	1.47 (0.33)	0.95–2.78	70	1.62 (0.30)	1.16–2.85
Travatan Z 5mL	150	1.14 (0.15)	0.85–1.44	190	1.63 (0.64)	0.86–4.29
Travaprost 5mL	145	1.13 (0.17)	0.84–1.38	145	1.27 (0.31)	0.87–2.47
Lumigan 5mL	195	0.67 (0.11)	0.47–0.91	155	0.91 (0.19)	0.65–1.81
Timolol 5mL	160	1.78 (0.4)	1.18–2.49	150	1.63 (0.07)	1.02–2.3
Timoptic 5mL	210	1.81 (0.63)	0.77–3.38	145	2.33 (2.78)	1.01–12.78
Combigan 5mL	165	0.92 (0.35)	0.59–1.89	145	1.05 (0.21)	0.71–1.78
Lumigan 7.5mL	295	0.69 (0.12)	0.51–1.25	230	0.88 (0.23)	0.6–2.03
Simbrinza 8mL	195	0.97 (0.10)	0.77–1.16	210	1.31 (0.12)	1.08–1.87
Alphagan P 10mL	215	1.16 (0.10)	0.95–1.41	225	1.31 (0.20)	0.93–1.73
Brimonidine 10mL	310	0.88 (0.15)	0.68–1.4	275	1.03 (0.16)	0.7–1.38
Combigan 10mL	290	0.8 (0.10)	0.62–0.97	310	0.81 (0.22)	0.53–1.59
Cosopt 10mL	320	4.49 (1.48)	1.77–9.71	225	2.53 (1.40)	1.28–9.55
Dorz-Timolol 10mL	325	1.25 (0.19)	0.8–1.81	295	0.97 (0.13)	0.75–1.31
Azopt 10mL	290	1.51 (0.19)	1.19–2.02	295	1.45 (0.37)	0.97–2.26
Trusopt 10mL	325	3.30 (0.96)	1.34–5.34	215	3.00 (1.16)	1.54–6.77
Dorzolamide 10mL	325	1.09 (0.15)	0.78–1.39	310	0.93 (0.14)	0.58–1.43

kgf = kilograms of force; SD = standard deviation; mL = milliliters.

Table 3

Patient Demographics, Grip Strength and Pinch Strength.

		N = 53
Age		64.1±16.2
Sex	Male	21 (40%)
	Female	32 (60%)
Race	Caucasian	43 (81%)
	African American	10 (19%)
Grip Strength *	R	27.88±14.1
	L	26.41±13.9
Pinch Strength *	R	5.05±2.1
	L	4.82±2.1
Glaucoma Diagnosis	POAG	21 (40%)
	NTG	7 (13%)
	CACG	3 (6%)
	AACG	1 (2%)
	Uveitic	1 (2%)
	PDG	1 (2%)
	Traumatic	2 (4%)
	CMG	2 (4%)
	Other	4 (8%)
	Glaucoma Suspect	8 (16%)
Medical Comorbidities	OA Hand	10 (19%)
	RA Hand	7 (13%)
	Carpal Tunnel	9 (17%)
	Tremor	1 (2%)
	CVA	2 (4%)
	Trigger Finger	1 (2%)

R = right hand; L = left hand; POAG = Primary Open Angle Glaucoma; NTG = Normal Tension Glaucoma; CACG = Chronic Angle Closure Glaucoma; AACG = Acute Angle Closure Glaucoma; PDG = Pigment Dispersion Glaucoma; CMG = Combined Mechanism Glaucoma; OA = Osteoarthritis; RA = Rheumatoid Arthritis; CVA = Cerebral Vascular Accident.

* measured in kilograms of force.