

Novel tactile bottle neck adaptor facilitates eye drop adherence in visually impaired patients

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ABSTRACT

Purpose To test the use of Ring-IT, a novel 3D tactile bottle neck adaptor in topical eye drop adherence in visually impaired patients.

Methods Bottle neck ring adaptors with either one, two or three protrusions with cube or sphere endings were designed. In phase 1, low vision was simulated in healthy subjects (n=20) with a 20/200 vision simulator; while in phase 2, visually impaired patients (n=26; 20/70 or worse) were recruited. Subjects were randomised to six combinations of varying protrusions and shapes on medication bottles and asked to identify these traits at different presentations. Responses and time to identify were recorded.

Results Phase 1: 98.3% of subjects correctly identified the number of protrusions. Mean time to identify was 4.5±6.1 s. Identification success for cube and sphere end pieces were 91.7% and 73.3%, with average time for identification of 9.9±7.6 and 10.9±9.0 s. In phase 2, 92.3% of subjects correctly identified the number of protrusions. Mean time to identify was 6.0±3.0 s. Identification success for cube and sphere end pieces were 78.2% and 74.4%; with average time for identification of 7.5±4.8 and 8.5±5.6 s, respectively.

Conclusions Ring-IT was identified with accuracy and speed by both low vision simulated subjects, and by patients with true limited visual capabilities. These tactile bottle neck ring adaptors can be used as an assistive low vision aid device and may increase eye drop regimen adherence in visually impaired patients.

INTRODUCTION

Over 3.2 million Americans aged 40 and above are noted to have some form of visual impairment, and at least 1 million of them are blind. The number of individuals with visual impairment and blindness in the USA is expected to double by 2050, largely due to the ageing of the US population.¹ The major causes of vision loss in older adults are macular degeneration, diabetic retinopathy, glaucoma and advanced cataracts.²⁻⁴ Glaucoma is the second leading cause of blindness in the USA and is largely treated with topical eyedrop medications; 50% of those with glaucoma need to use two or more ocular hypotensive

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Individuals with visual impairments face challenges in adhering to dosing frequency when managing multiple eye drop medication bottles.

WHAT THIS STUDY ADDS

⇒ This research introduces the innovative 3D tactile adaptor ring (Ring-IT), offering a promising solution to significantly improve topical eye drop adherence in patients with complex chronic treatment regimens.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The study holds breakthrough potential to catalyse a shift in clinical practice, providing a practical tool to enhance topical eye drop adherence in patients with visual impairment. This innovation could have a profound impact on both patient care and policy considerations.

agents and 73% of them require application of drops more than twice per day.⁵

Regardless of the aetiology, vision-related impairment can negatively affect proper adherence to medical therapy.⁶ Those with visual impairments struggle with reading medical information have difficulties distinguishing medical pills from one another and are more than twice as likely to need help in managing their medications.⁷ In a previous study of glaucoma patients, 18% of the drop nonadherence was attributed to difficulty reading instructions.⁸ Of note, the majority subjects in the study only had minor visual impairment. The proportion will likely be higher in visually impaired patients. Poor adherence to eye drop regimens by either over or underusing drops can cause worsening clinical symptoms both locally and systemically.⁹⁻¹¹

Colour-coded caps help patients to identify their eyedrops and is an industrial standard. However, colour does not convey additional



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information such as the usage frequency.¹² Patients with visual impairments must rely more heavily on senses other than vision to experience the world around them.¹³ Haptic perception produces detailed, durable, long-term memory representations.¹⁴ A recent survey found that patients with glaucoma favoured additional tactile information from the bottle to aid with drop instillation.¹⁵ Providing tactile information in drop bottles could improve adherence to medication regimens in visually impaired patients.

We present a novel 3D tactile adaptor Ring-IT with varied number of protrusions that may be utilised for representing dosing frequency of eye drops. These assistive aids may improve topical medication adherence in visually impaired patients.

MATERIAL AND METHODS

The study was approved by the institutional review board at the University of Texas Medical Branch and McGovern Medical School at UT Health Houston and was conducted in accordance with the tenets of the Helsinki Declaration. Subjects provided their written informed consent to participate in the study. Informed consent for research was obtained from all participants and the study is in accordance with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

Construction of Ring-IT tactile rings with sphere or cube ends

Ring-IT was designed using a 3D printed model of a rigid plastic ring clip, manufactured at Maker Health Space Medical Fabrication Laboratory at the University of Texas Medical Branch at Galveston. The prototype was designed using Polylactic acid, a polyester derived from renewable biomass sources such as fermented plant starch, including corn, cassava, sugarcane or sugar beet pulp. Future device manufacturing using plastic injection moulding can employ the use of similar renewable biomass sources.¹⁶ The diameter was chosen such that it can be attached to the standard eye drop bottles of 0.9 cm diameter neck. Each coloured clip had one, two or three individual distinct protrusions ending in sphere or cube shapes to correspond to the colour of the cap of the medication (figure 1). Ring-clip is designed to have an inner diameter of 12.5 cm, an outer diameter of 16 cm and a height of 1.5 cm. The ring is cut at 2 cm to form a semi-circle allowing it to be clipped onto the bottleneck. The ring clip fits most if not all prescription eyedrop bottles. Standard eye dropper bottles from Nalgene LDPE White Dropper Bottles that are similar in size and shape to commercially available eye dropper bottles were compatible with Ring-IT. The shapes on this novel invention were carefully designed to reduce the risk of self-harm.

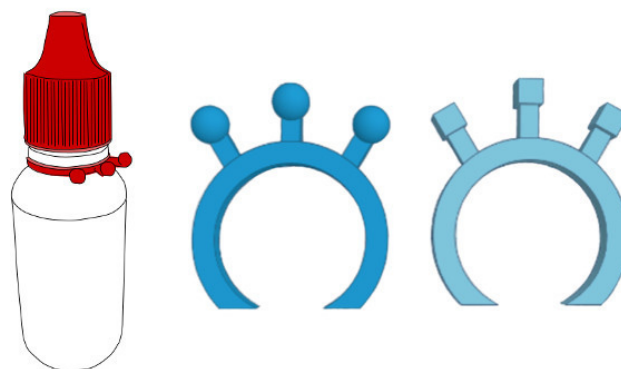


Figure 1 Ring-IT specific design that attaches to eye drop bottle neck with either cube or sphere ends.

Study design

We utilised a stratified random sampling procedure and conducted the study in two phases as described below.

Phase 1

Twenty healthy adults ages from 19 to 100 years of age were included in the study. Subjects with visual, cognitive or tactile losses were excluded. Subjects were asked to wear a low vision simulator that simulated 20/200 or worse visual acuity monocularly and binocularly when tested on Snellen acuity chart (Lowvisionsimulators.com).

Phase 2

Twenty-six visually impaired patients (29–90 years old) with a best-corrected visual acuity equal or worse than 20/70 or having central vision field loss of 20 degrees or less were recruited. Vision was verified by an ophthalmologist or an optometrist. Subjects with comorbidities that could potentially confound their ability to complete the assessments in this study (ie, advanced neuropathy of the hands, dementia or mental incapacity), and those with a history of prior non-compliance or the presence or history of psychiatric condition (including drug or alcohol addiction) were excluded.

We asked each subject to verbally identify the shape of the tactile label, and the number of tactile protrusions that simulated the frequency of treatment for that bottle. There were three possible dosing frequencies, and two shapes (cube and sphere) for each label. Each subject was randomised by random number generator to one of four preset groups of six combinations of varying protrusions, and shapes (table 1).

The set of six tactile-labelled bottles were introduced to each patient one bottle at a time. At first, each participant was asked to identify the number of protrusions on each bottle (1, 2 or 3), presented in the order listed in each preset group.

Once each participant had attempted to identify the frequency of protrusions on each of the six bottles, the same labelled bottles were presented in random order for a second time, at which point the subject was asked to

Table 1 Age range, gender (male: M, female: F), race, best-corrected visual acuity of the better eye, eye condition and comorbidities of the phase 2 participants are shown

Age range	Gender	Race	Best-corrected visual acuity	Eye condition (AMD, glaucoma, etc)	Comorbidities
55–60	M	African American	20/100	Glaucoma	Well-controlled DM, denies neuropathy
60–65	F	White	NLP OU	Radiation-induced optic nerve damage	None
50–55	F	Asian	20/80	Retinitis pigmentosa	None
70–75	M	White	20/320	Glaucoma	Unspecified neuropathy; history of TIAs
80–85	M	White	20/80	Glaucoma, ARMD	None
50–55	F	African American	20/800	Retinitis pigmentosa	None
65–70	M	African American	HM	End-stage glaucoma	DM2, HLD
40–45	M	Hispanic	20/400	Retinal detachment, glaucoma, cataract	DM2, ETOH abuse, HLD
25–30	F	White	20/400	Optic atrophy OU unknown aetiology	Migraine
90–95	M	White	20/100	ARMD	None
60–65	F	African American	20/400	AMD, Sjogren's syndrome	Sjogren's syndrome, arthritis from Sjogren's syndrome
85–90	M	White	20/200	ARMD, wet macular degeneration	None
50–55	M	White	20/250	Diabetic retinopathy	DM
50–55	F	White	BLP	Optic atrophy OU, car accident.	Impaired speech
35–40	F	Hispanic	20/250	Diabetic retinopathy, macular oedema	DM, truncal obesity, RSV, bacterial infection foot
55–60	F	African American	20/100	POAG	Encephalitis
45–50	M	White	20/200	Ischaemic optic neuropathy	None
60–65	M	African American	20/80	Diabetic retinopathy, macular oedema	DM
85–90	F	African American	20/160	Macular hole OS pseudo macular hole OD	Neuropathy of the hands from trauma
85–90	M	African American	20/100	ARMD, retinoschisis, retinal cyst	Retinoschisis, retinal cyst
45–50	M	Hispanic	CF @ 6"	Neuro myelitis optica	Multiple sclerosis
65–70	F	White	20/100	Dry AMD	None
85–90	F	Hispanic	20/70	OD, CRVO, CMV, OS status post corneal transplant	None
65–70	M	African American	20/100	RP, macular oedema	None
55–60	F	Hispanic	20/400 OU	Diabetic macular oedema	DM, seizures
75–80	F	African American	HM OU	Glaucoma, corneal transplant complications	None

ARMD, Age-related macular degeneration; BLP, Bare light perception; DM, Diabetes mellitus; ETOH, Ethyl alcohol; HLD, Hyperlipidemia; NLP, No light perception; OD, Oculus Dexter - right eye; OS, Oculus Sinister - left eye; OU, Oculus Uterque - both eyes; POAG, Primary open angle glaucoma; TIA, Transient ischaemic attack.

evaluate the shape of the protrusions of each tactile label (cube or sphere). Time and accuracy to completion for each variable of identification (frequency of protrusions and shape) was measured with a stopwatch and recorded. In phase 2 subjects, a subjective assessment regarding patient satisfaction with device and interest in using it to manage medications, if clinically available, was recorded.

RESULTS

In the first phase, 20 healthy adults (24–82 years of age) with no visual comorbidities, or cognitive and tactile losses, were recruited after cross examination; 80% of the subjects were females.

In phase 2, 26 subjects were enrolled (mean age: 63.2 years) with equal number of men and women, and a slight predisposition of African Americans and Whites

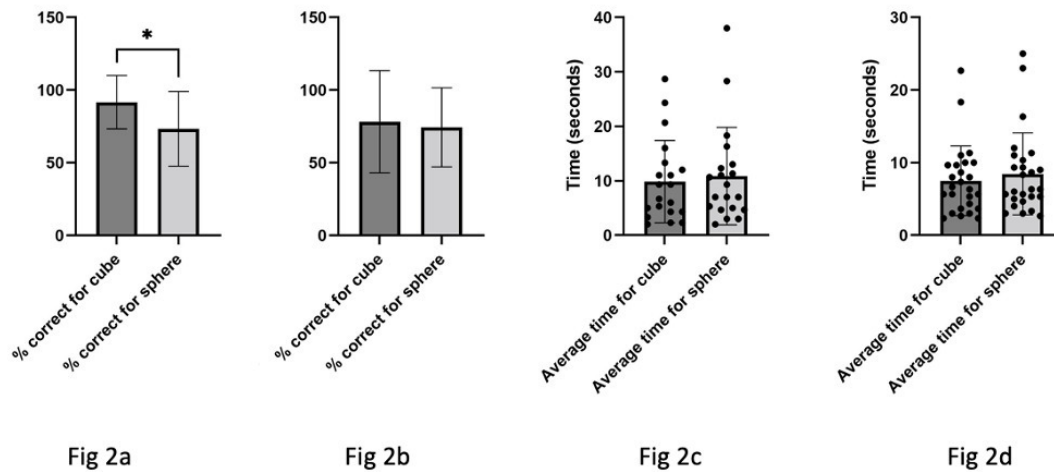


Figure 2 Percentage of shapes identified in phase 1 (figure 2a) and phase 2 (figure 2b) and time taken to identify shapes in phases 1 (figure 2c) and 2 (figure 2d) are shown. SD bars are depicted in all figures. Mann Whitney test was used to compare data across groups with* showing $p=0.0072$ for significance.

in the cohort. The main eye conditions present in the cohort were glaucoma and age-related macular degeneration (AMD). Most common comorbidity present in selected patients was diabetes mellitus (DM). A summary of demographics for phase 2 is listed in table 1. Per the subjective survey, 88.5% ($n=23$) of patients in phase 2 were satisfied with device use and expressed interest in using it to manage medications if available.

Cube and sphere-ended protrusions

In phases 1 and 2, 91.67% (figure 2a) and 78.21% (figure 2b) of patients correctly identified cube-shaped protrusions, respectively. In parallel, 73.33% (figure 2a) and 74.36% (figure 2b) correctly identified sphere shaped protrusions in those phases, respectively.

The average time taken to identify cube protrusions was 9.87 ± 7.56 s (figure 2c) and 7.50 ± 4.78 s (figure 2d) in phases 1 and 2, respectively, while the average time taken to identify sphere protrusions was 8.46 ± 5.64 s (figure 2c) and 10.87 ± 8.96 s (figure 2d) in phases 1 and 2, respectively.

Number of protrusions

All subjects correctly identified the number of protrusions when one or two protrusions were presented, and 95.00% subjects identified the three protrusions in phase 1 (figure 3a). However, 94.23%, 98.08% and 84.62% of subjects correctly identified one, two and three protrusions, respectively in phase 2 (figure 3b).

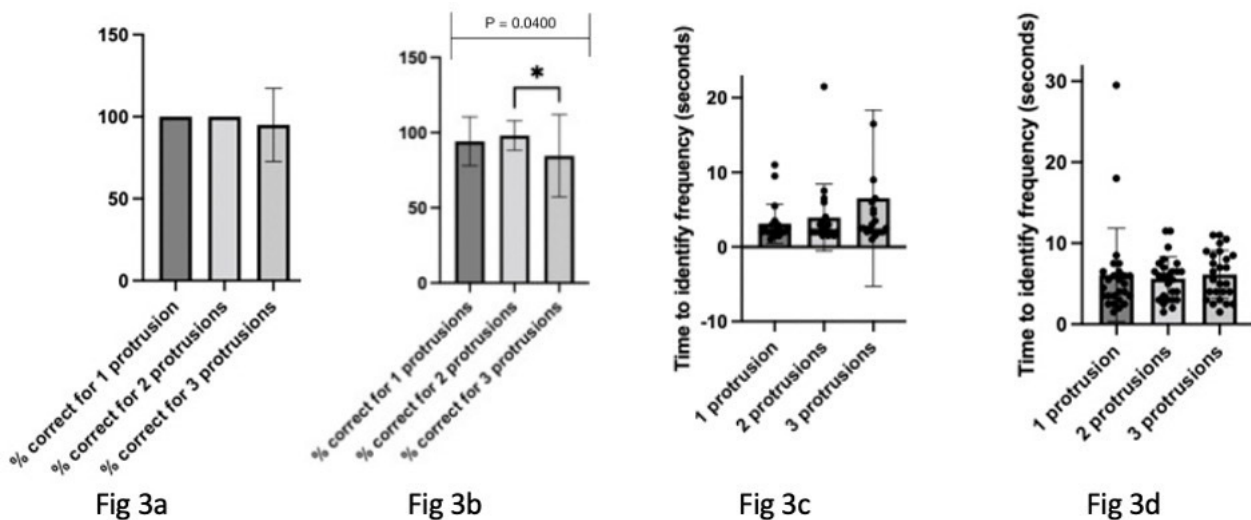


Figure 3 Percentage of protrusion frequency identified in phase 1 (figure 3a) and phase 2 (figure 3b) are shown. Figure 3c and figure 3d show the time taken to identify the protrusions. SD bars are depicted with * showing $p=0.0439$ (Mann Whitney test). Significance was found across groups using one-way ANOVA in figure 3b. ANOVA, analysis of variance.

The average time taken to identify the number of protrusions in phase 1 was 3.13 ± 2.63 , 3.93 ± 4.48 and 6.55 ± 11.83 s for one, two and three protrusions, respectively. The average time taken to correctly identify the number of protrusions in phase 2 was 6.10 ± 2.02 , 5.63 ± 2.68 and 6.15 ± 2.95 s for one, two and three protrusions, respectively.

DISCUSSION

Using eyedrops more or less than prescribed can be detrimental in visually impaired patients and can worsen their clinical outcomes both locally and systematically.^{17–19} The current industrial standard coloured bottle top relays information to differentiate medications but fails to provide dosing frequency. We present a novel tactile aid Ring-IT with 3D protrusions that can be applied to the bottle neck to facilitate adherence to dosing regimens of topical eye drops. This device is an efficient, low-cost visual aid device that can be easily attachable to eye drop bottles and can be applied by any healthcare provider and used in the clinical setting. Its use can be personalised and modified depending on the doctor's and patient's preferences. In this pilot study, we report that tactile 3D ring adaptors with varying number of protrusions relayed information of dosing frequency with high accuracy and speed in visually impaired patients. Subjects with simulated or real visual impairment were able to correctly identify the shape and number of protrusions attached to the bottle neck quickly. Simulated subjects were more successful in identifying cube protrusions that relayed sharper sensations. Visually impaired subjects correctly identified the shapes of the protrusions at comparable rates. Simulated volunteers were younger than those with visual impairment, and the difference between groups might be explained by a decline in the main sensory modalities such as touch and sensation in older individuals.²⁰ Therefore, we propose using cube-shaped ends on the tactile protrusions.

Ring-IT low vision tactile bottle neck adaptors can help low vision patients and perhaps even those who are well sighted. We know that visually impaired individuals, the elderly, individuals with low literacy levels and those that use multiple eye drops are at the highest risk to fail to adhere to their prescribed treatment plans.^{18 19 21–24} Incorrect use of eye drops at home, or even at nursing care facilities, are also common mainly due to the lack of reading capabilities of the bottle labels or error in remembering the topical drop frequency. This device boosts patient compliance where incorrect eye drop frequency usage can impact treatment effectiveness, minimising risks of overdosing and underdosing. This is particularly beneficial for complex treatment plans, where multiple daily applications of topical eyedrop medications are common.

Poor adherence to glaucoma treatment is a significant problem.^{25–27} Glaucoma patients are often given more than one type of topical medication with different dosing frequency to control their intraocular pressures.

Coloured bottle tops convey information on the type of medication bottle, but not on the dosing frequency.²⁸ The likelihood of misidentifying medication characteristics using such a model varies greatly among different patient populations. Those displaying higher vision loss and colour vision loss are associated with higher rates of medication misidentification. Solely relying on coloured bottle tops is not enough to assure compliance with correct treatment regimen in visually impaired patients.²⁹ Attaching an additional 3D tactile device like Ring-IT will help in compliance of drop regimen. This device is designed to enhance medication management in chronic long-term treatments and is not intended for short term hourly use. Ring-IT is easy to apply and can be removed if the drop regimen changes. The device can also be recycled in patients with chronic treatments, where it can be transferred from one bottle to the next during the refilling process. In addition, the plastic protrusions can also be tailored with ease by snapping the prongs if drop therapy is switched from three to two or one time only. In addition, Ring-IT is low cost, light weight and carries minimum risk to patients. Attaching an additional descriptor that can be used to relay more information, such as a bottle neck adaptor Ring-IT, may prove to be very beneficial in improving treatment regimen adherence, especially in low vision patients.

There are a few limitations in this study. First, this is a small sample size of patients. However, this study aims to be a proof of concept that these novel tactile attachments can be easily and accurately identified by low vision patients. Second, this study cannot prove that there is increased compliance with the tactile ring adaptor. For this purpose, we hypothesise that with increased ease of use of the eye drops would help to increase compliance. Additionally, the improved identification of eye drop bottles with the ring adaptor can possibly alleviate stress associated with using the eye drops. Further studies need to be performed to assess the improved adherence of eye drops using this tactile adaptor. Finally, while we did not add a formal survey questionnaire for patient feedback. However, informally every participant stated on the ease and safe application of the Ring-IT device. In addition, they added that this will definitely help them to adhere to the treatment regimen.

In summary, we present a novel tactile 3D bottle ring adaptor Ring-IT and its efficacy of improving patient identification of the type and frequency of eye drop therapy in low vision patients. It is an efficient, low-cost device that can be easily attached to eye drop bottles and allows for tactile determination of dose frequency.

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Patient consent for publication Not required.

Ethics approval This study involves human participants and was approved by Institutional review board at the University of Texas Medical Branch. Reference number: 20-0087 Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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