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Innovative bulls eye drop applicator for self-instillation of eye drops

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ABSTRACT

Purpose: To report the role of Bulls eye drop applicator device in self-instillation of eye drops and in prevention of wastage of medicine.

Methods: A small pocket sized device "Bulls eye drop applicator" was developed, which is a simple, handy, mirror-based attachment which can be attached to any eye drop bottle to help in accurate self-instillation of the drops in the eye. The prototype of this device was tried in ten volunteer subjects (Group 1) and 15 patients (Group 2); they were asked to use lubricating eye drops (5 ml bottle) in one eye without the device (N) and in the other eye with the device (M). The numbers of attempts for the application of eye drops were noted and the residual eye drops in the returned bottles were measured for quantitative assessment.

Results: Ten volunteers and 11/15 patients completed the study. At the completion of the study, there were a total of 232 applications of eye drops in the Group 1 N (without device) and 1 M (with device). To achieve these 232 applications, there were 330 attempts without the device and 266 attempts of instillation were needed with the device ($P < 0.0001$). In Group 2, there were a total of 544 applications of eye drops; to achieve this, there were 879 attempts in Group 2 N and 685 attempts of instillation in Group 2 M ($p < 0.0001$). The cumulative quantity of residual drops in the returned bottles collected from Group 2 N was 5.1 ml and it was 19.7 ml in Group 2 M ($p = 0.001$).

Conclusions: The number of attempts of instillation reduced significantly with the use of the eye drop applicator device. The use of eye drops applicator device reduced the wastage of drops from 42.2% to 14.6% in Group 1 N Vs Group 1 M and saving of about 35.7 % in Group 2 M compared to Group 2 N.

1. Introduction

Management of many eye diseases depends on proper compliance of patients with the use of prescribed medication, which includes proper instillation of eye drops. The diseases include acute and chronic conditions including glaucoma, dry eyes and infectious keratitis which need long term use of topical eye drops [1,2]. Clinical outcome of any disease depends on proper and successful instillation of eye drops. Incorrect ways of putting drops may result in eye injury, abrasion, congestion of the eye, allergic skin reaction and also contamination of eye drops [3]. Self-instillation of eye drops is one of the challenging issues for patients. Correctly self-aiming the eye drops in the eye, without seeing own eye, is difficult for many patients [4]. Consequently, the drops often fall on the eyelids or on the face and so a person generally would request somebody else (spouse/family member or a friend) to put these eye drops in the eye. When no person/ family support is available to put the drops, then the patient may not be able to put the drops at the right time resulting in delay or missing on the correct schedule of medication. Also, self-instillation may result in spillage of drops resulting in wastage of precious medicine and increasing the cost to the patients [5,6].

The problem faced by patients in self-instillation of eye drops is well recognized in ophthalmic literature [3,7–9] and has been researched extensively specifically in glaucoma patients [1,2,10] as they need to use eye drops on long-term basis as compared to patients with other short term eye ailments. It has been shown that if the drops are not

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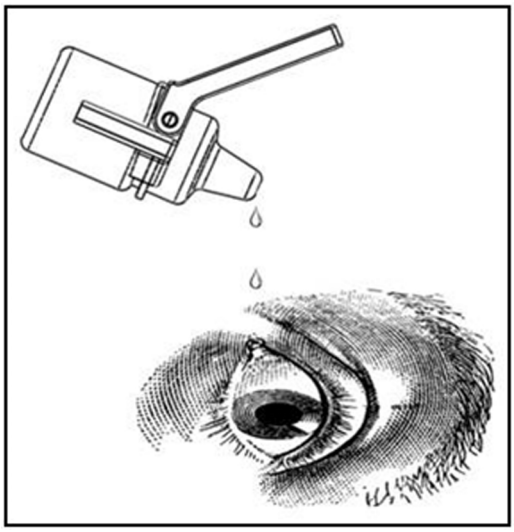

Fig. 1. Design and Concept of Bulls Eye Drop Applicator Device.

instilled properly, then the patients may have poor control of disease, leading to poor outcome and then may dropout from the treatment out of frustration [2].

Various devices and techniques have been designed and proposed which help in self-instillation of the eye drops by aiding in positioning of the eye drop bottle or in aiming of the eye drops into the palpebral aperture of the eye. Some of these devices include funnels, sprays, modified goggles with a hole in it for holding a bottle and mirrors [2,11–14].

In this regard, authors have developed and studied a mirror based medical device to help patients in self-instillation of the eye drops by direct visualization of the eye drop bottle's nozzle and palpebral aperture while instilling the eye drops (Fig. 1).

2. Methods

The medical device, that has been named "Bulls Eye drop applicator", comprises of an inbuilt mirror, attached at an adjustable angle to a clasp that clips on very easily to most of the eye drop bottles (Fig. 2 A, B and C) in such a way that user can see the image of the nozzle of the eye drop bottle and his eye simultaneously (Fig. 2 D) thereby making it easy and simple for any patient with an eye ailment to self-instill the eye drops in his eyes and also save on wastage of eye drops spilled outside the eye.

The prototype of this device (Fig. 2C) was tested in two groups. The Group 1 included ten volunteer subjects (6 males and 4 females), without any significant eye ailments and who had a refractive error (SE-spherical equivalent) ranging from +1.00 D to −3.00 D. Every subject was given two bottles of lubricating eye drops (Genteal Eye Drops, 5 ml bottle, Novartis India Limited, Mumbai, India), one bottle without the device and the other with the device attached, to be used 3–4 times in a day, in the right eye without the device (Group 1 N, N = normal instillation) and in the left eye with the device (Group 1 M, M = mirror device assisted instillation) for a period of one month or till the time when the drops in one of the bottles finished.

Group 2 included patients with minor ocular ailments such as mild dry eye, computer vision syndrome, allergic conjunctivitis or meibomitis for which they were routinely using lubricating eye drops. Group 2 included 15 patients (9 males and 6 females). Their refractive error (SE) ranged between +1.50 D to -4.00 D. In this group too, each subject was given two bottles of Genteal eye drops, one without the device and the other with the device attached. The same methodology was followed. They were also asked to use the lubricating drops in their own eyes without the device in the right eye (Group 2 N) and with the device in the left eye (Group 2 M) for a period of one month. To maintain the uniformity of the study, patients were asked to use eye drops without device in right eye and with the applicator device in the left eye, right and left hand preference was not considered while instilling the eye drops.

Each instillation event was counted as one application and the number of attempts needed to instill a drop in the eye with or without the applicator device was noted by the user in the data sheet provided to them. In addition, users in Group 2 were asked to return the used bottles (both without the mirror device and the one with the device) after one month or earlier whenever the drops in one of the bottles finished. The quantity of the residual eye drops in the returned bottles

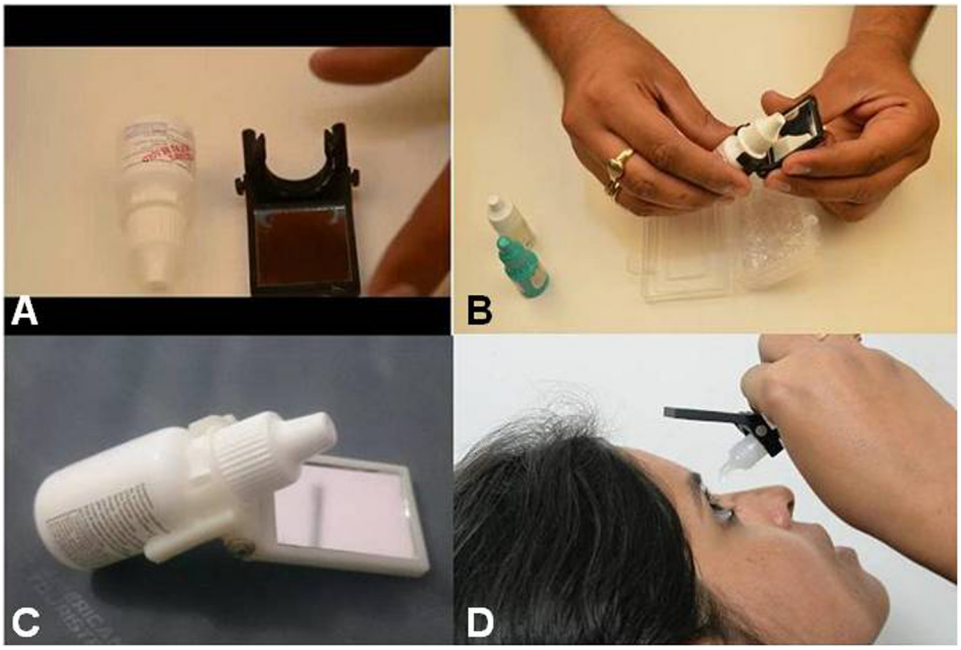

Fig. 2. (A) Prototype of the Bulls Eye drop Applicator Device. (B) Applicator device being attached to the eye drops bottle. (C) The applicator device clasped on to eye drops bottle (D) The device being used by the subject for self instillation of the eyedrops.

was measured with the help of a syringe. The difference between the attempts made for instillation without and with the mirror device was compared.

2.1. Statistical analysis

The statistical analysis was performed using Origin v7.0 (OriginLab Corporation, Northampton, MA, USA). Chi-square test was used to compare the proportions between the two groups, 1 N & 1 M and 2 N & 2 M. The data on quantity of residual eye drops were checked for the normality of distribution by Shapiro-Wilk test. Since the data were not distributed normally, Wilcoxon signed-rank test was applied to compare between with and without device in the patient groups. A p-value of < 0.05 was considered statistically significant.

3. Results

All the 10 volunteers in Group 1 completed the study. At the completion of the study, there were a total of 232 applications of eye drops in each eye in the Group 1 N and 1 M. To achieve these 232 applications, there were 330 attempts without the applicator device and only 266 attempts of instillation with the device were needed. Table 1 shows the number of attempts made for instillation in Group1. In the Group 1 N, self-instillation of eye drops in first attempt could be achieved only 154/232 times (66.38 %) and in Group 1 M, the same goal was achieved 85 % times (198/232 attempts) in single attempt. The difference between these two proportions was statistically significant ($p < 0.0001$).

Eleven out of the fifteen assigned patients completed the study in Group 2. In this Group (2 N & 2 M), there were a total of 544 applications of eye drops. To achieve these 544 applications, there were 879 attempts without the applicator device in Group 2 N and 685 attempts with the device in Group 2 M. In Group 2 N, self-instillation of eye drops, in first attempt, could be achieved only 286/544 times (52.6 %) and in Group 2 M the same goal was achieved 425/544 times (78.1 %) in one attempt. The difference was statistically significant ($p < 0.0001$). Table 2 shows the number of attempts in the Group 2.

In Group 2, eighteen used bottles (of 5 ml quantity each) were returned by the patients at the end of the study (9 without the device, Group 2 N and 9 with the device, Group 2 M). The median quantity of residual eye drops in 9 bottles in Group 2 N was 0 ml (Inter-Quartile Range - IQR, 0 ml–1.5 ml) while in Group 2 M, it was 2.8 ml in Group 2 M (IQR, 1.5 ml–3.0 ml). Group 2 M had a significantly ($p = 0.001$) higher quantity of residual eye drops than Group 2 N. (Table 3).

4. Discussion

Administration of eye drops is very crucial for management and treatment of chronic eye diseases such as glaucoma, infectious keratitis, dry eyes and after cataract or any other surgeries [2,3]. The problem faced by patients in self instillation of eye drops is well recognized in ophthalmic literature. Tsai et al. have reported that 82 % of Glaucoma patients self-administered the eye drops [2]. Only 16.3 % used a mirror for this purpose and the most common location of the mirror used was bedroom (46.8 %), followed by the bathroom (23.4 %) and kitchen (16.1 %).

In a study done in 141 patients by Kass et al., 48.1 % patients dispensed more than one drop for one application, thereby wasting approximately 50 % medication in the process of self-instillation of eye drops. In another study by Sayner et al. conducted in 279 glaucoma patients, only 51 % patients used only a single drop while self instilling the eye drops in their eyes, whereas rest of the patients had to use more than one drop. Many researchers have tried to address this problem and have proposed the use of instillation aids that have been designed to help patients in instilling the eye drops in their eyes by improving the aim, grip of the eye drop bottle or assisting in positioning of the eye drops bottle over the orbit [4,6,15–20].

Easidrop (Quoteforce, UK) was one of the earlier device introduced to aid in self instillation of the eye drops by the patients. This would attach to a conventional eye drop bottle, sit within the orbit, and assist in aiming while keeping the tip of the bottle clear of the eye. Winfield et al. [21] observed 30 patients instilling an eye drop into one eye using both a standard bottle and Easidrop. With the standard bottle, only 20 % of the patients were able to instil a drop on the first attempt. This was in comparison to 87 % percent instilling a drop on the first attempt with Easidrop.

On similar lines, Eyedrop (Vanguard Design, Sao Paulo, Brazil) is a plastic device that sits on the orbit into which a bottle is inserted. The design of the device helps patients to keep their eyes open, improve aim, and decrease tip contamination. This device was studied in a group of 32 participants that included a mix of both glaucoma patients and healthy volunteers. 78.6 % of the inexperienced users and 66.7 % of the experienced users found this device useful as compared to eye drops instillation without the device [22].

Salyani and Birt studied the effect that an inverted, funnel shaped, eye drop guide (Merck Frosst Canada, Que´bec, Canada) had on self-administration. This device was designed to attach to the top of an eye

Table 1
Results of Bulls Eye Drop Applicator Device in Group 1 (Volunteer Subjects, n = 10).

	Group1 N (without device)	Group 1 M (with device)	P value
Total applications	232	232	
Total attempts	330	266	< 0.0001
One attempt	154 (66.4 %)	198 (85.4 %)	< 0.0001
Two attempts	58 (25.0 %)	34 (14.6 %)	0.0074
Three attempts	20 (8.6 %)	0	< 0.0001
Wastage	42.20 %	14.60 %	< 0.0001

Table 2
Results of Bulls Eye Drop Applicator Device in Group 2 (Patients subset, n = 11).

	Group 2 N (without device)	Group 2 M (with device)	P value
Total applications	544	544	
Total attempts	879	685	< 0.0001
One attempt	286 (52.6 %)	425 (78.1 %)	< 0.0001
Two attempts	195 (35.8 %)	98 (18.0 %)	< 0.0001
Three attempts	50 (9.2 %)	20 (3.7 %)	0.0003
Four attempts	12 (2.2 %)	1 (0.2 %)	0.0052
Fifth attempt	1(0.2 %)	0	0.3200
Wastage	61.6 %	25.9 %	< 0.0001

Table 3
Quantity of residual eye drops in the bottles returned by 9 patients at the end of the study in Group 2.

Patient number	Residual drops in Group 2 N (without device)	Residual drops in Group 2 M (with device)	P value
1	0 ml	2.5 ml	
2	0.2 ml	3 ml	
3	1.5 ml	2.8 ml	
4	1.5 ml	3 ml	
5	0 ml	0.5 ml	
6	1.9 ml	3 ml	
7	0 ml	1.5 ml	
8	0 ml	3 ml	
9	0 ml	0.4 ml	
Cumulative Quantity of Residual Eye drops	5.1 ml	19.7 ml	0.001

drop bottle, sit within the margins of the orbit, and keep the eyelids open to accurately deliver drops into the eye. Of the 93 patients who completed the study, 74 % of the patients found using standard eye drops easier and more preferable compared with using the aid, and 71 % did not want to continue using the device [10].

As compared to the other devices which essentially help in mechanically positioning the eye drop bottle over the eye, the "mirror-hat device" is a magnifying mirror attached to a brimmed hat intended to aid in drop administration for better visualization of the eye drop and the bottle's nozzle while instillation of the eye drop. This was designed by a long-time eye drop user, Mr John Beck. Its use was studied by Strungaru et al. in thirty patients who were asked to place a drop in each of their eyes both with and without the use of the hat fitted with a concave mirror [16]. Of all the patients studied, 86.7 % stated that they could see the drop they were applying, while using the device while 40 % patients could see the drops even without the device. Half the patients in the study reported that they liked the device, and 46.7 % wanted to keep using it.

Charles E. Letocha in his 1985 paper described a method, conceived by Charles Nicholas, whereby an angled mirror was affixed, at an obtuse angle (about 125°), to a wall above the patient's eye so as to enable the patient to see his or her eye while looking upwards to instil the eye drop [15]. In the same paper, he also mentioned about an aiming device named I-SIGHT developed by Edgar Astrove [15,19]. This was essentially a portable mirror made of vacuum-metalized polyester film, one end of which contained an adhesive to which the bottle of the eye drops could be affixed. The mirror was angled at approximately 45° and was adjustable to suit the patient.

On somewhat similar lines, Sharma et al. have described the use of a Drop applicator strip (FDC Limited, New Delhi, India) in 72 glaucoma patients who were on chronic topical therapy. The strip is made of paper with a reflecting surface made of aluminium foil with markings. It consists of an adhesive tape that is to be peeled and stuck with the eye drop bottle. The tip of the bottle has to be aligned with the pink dot and has to be placed horizontally over the eye. The patient has to focus on the pink dot on the strip and gently squeeze a drop. The authors noted that the mean number of drops instilled to get 1 drop into the eye decreased from 2 ± 0.95 to 1.56 ± 0.78 when the drop application strip was used.

Compared to other devices, the device used in this study is very light in weight, small, handy and portable. It uses an intuitively simple design, whereby a polymethyl methacrylate (PMMA) mirror is fixed at an adjustable angle to a plastic clasp which can be attached to any eye drops dispensing bottle. It can also be detached vey easily and therefore can be used any number of times to multiple eye drop bottles. The adjustable slant of the mirror helps the patient to have a clear and simultaneous view of the images of the nozzle of the eye drops' bottle as well as his or her eye, even when the quantity of eye drops decreases in the bottle after continuous use, by simple changing the angle of the mirror.

In Group 1 (Table 1,volunteer subjects), there were a total of 330 attempts for 232 application of eye drops in the eye in which the applicator device was not used, which is equal to 42.2 % wasted attempts and the eye drops. Whereas, there were only 266 attempts for the same number (232) of application of eye drops in the other eye of the patient with the applicator device leading to only 14.6 % wasted attempts and eye drops. This amounts to a saving of about 27.6 % (42.2-14.6) when the mirror based applicator device was used.

In Group 2 (Table 2, patients), there were a total of 879 attempts for 544 application of eye drops in the eye where applicator device was not used, which is equal to 61.6 % wasted attempts and the eye drops. Whereas there were only 685 attempts for the same (544) number of applications of eye drops in the other eye of the patient with the applicator device which amounted to 25.9 % wasted attempts and eye drops. This is equivalent to about 35.7 % saving of eye drops (61.6-25.9) when the mirror applicator device was used.

When the residual quantity of eye drops was measured in the 18 returned bottles (each being a 5 ml bottle, 9 without the device and 9 with the device) by the nine patients after the study, there were cumulative 5.1 ml residual drops in the bottles without the applicator device compared to 19.7 ml residual drops in the bottles with the applicator device. This indicated 32.4 % saving of eye drops when the mirror applicator device was used.

Eye drops is a multimillion dollar industry the world over and the average cost of an eye drop bottle ranges from approximately Rs 50 to Rs 700 in India. A 5 ml eye drops bottle on an average contains approximately 100 drops of which approximately 40–60 % would go waste in the process of self-instillation of eye drops in one's eyes [23,24]. Even on a conservative estimate, the present invention would save approximately 25 % of drops and if one takes a very conservative figure of Rs 100 for an eye drop bottle, this would mean a saving of about Rs 25 (25 %) for every eye drop bottle. So the total savings for the patients would be huge both in terms of effort as well as money saved and even complications such as allergic contact dermatitis noted with certain drugs could be avoided and also compliance of the patients with the use of the eye drops, will improve.

The possible limitation of this study could be that in the present prototype, the authors have used a plain mirror for visualization purpose which may not work for people who have high hypermetropic refractive error or presbyopia. The authors believe that substituting a convex mirror will be able to address this problem by magnifying the image.

In summary, the use of the Bulls Eye Drops applicator made it very simple for all the subjects to self-instill the eye drops in their eyes and also saved on the number of attempts needed to instill the eye drops. It's usage reduced the wastage of eye drops from 42.2% to 14.6% in Group 1 N Vs Group 1 M and saving of about 35.7 % in Group 2 M compared to Group 2 N. This device is small, handy, detachable, easy to carry and can be used on multiple eye drops bottles and came across as very useful in helping the patients in saving the time, effort and money spent in the process of self-instilling the eye drops.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.clae.2019.11.010.

References

[1] S.A. Davis, B. Sleath, D.M. Carpenter, S.J. Blalock, K.W. Muir, D.L. Budenz, Drop instillation and glaucoma, Curr Opin Ophthalmol 29 (2018) 171–177, https://doi.org/10.1097/ICU.0000000000000451.

[2] T. Tsai, A.L. Robin, J.P. Smith 3rd, An evaluation of how glaucoma patients use topical medications: a pilot study, Trans Am Ophthalmol Soc 105 (2007) 29–33 discussion -5.

[3] J.A. An, O. Kasner, D.A. Samek, V. Levesque, Evaluation of eyedrop administration by inexperienced patients after cataract surgery, J Cataract Refract Surg 40 (2014) 1857–1861, https://doi.org/10.1016/j.jcrs.2014.02.037.

[4] I. Davies, A.M. Williams, K.W. Muir, Aids for eye drop administration, Surv Ophthalmol 62 (2017) 332–345, https://doi.org/10.1016/j.survophthal.2016.12.009.

[5] N. Kawai-Tsuboi, M. Kawai, Y. Minami, A. Yoshida, A study of the association between patterns of eye drop prescription and medication usage in glaucoma subjects, J Glaucoma 24 (2015) 202–206, https://doi.org/10.1097/IJG.0b013e31829e1b8b.

[6] M.A. Kass, E. Hodapp, M. Gordon, A.E. Kolker, I. Goldberg, Patient administration

of eyedrops: observation. Part II, Ann Ophthalmol 14 (1982) 889–893.
[7] M.I. Freeman, Instillation of eyedrops, Am J Ophthalmol 88 (1979) 273.
[8] G.M. Sheldon, Self-administration of eyedrops, Ophthalmic Surg 18 (1987) 393–394.
[9] J.S. Tennant, Instillation of eyedrops, Am J Ophthalmol 87 (1979) 104–105.
[10] A. Salyani, C. Birt, Evaluation of an eye drop guide to aid self-administration by patients experienced with topical use of glaucoma medication, Can J Ophthalmol 40 (2005) 170–174, https://doi.org/10.1016/S0008-4182(05)80028-6.
[11] M.I. Freeman, A method for delivery of ocular medications, Ophthalmology 86 (1979) 1202.
[12] R. Ritch, K.N. Jamal, R. Gurses-Ozden, J.M. Liebmann, An improved technique of eye drop self-administration for patients with limited vision, Am J Ophthalmol 135 (2003) 530–533.
[13] D.O. Gebhardt, Self-administration of eye drops. a patient's view, Am J Ophthalmol 136 (2003) 778 author reply.
[14] J.E. Lebensohn, Letter: The eyedrop, Am J Ophthalmol 77 (1974) 600–602.
[15] C.E. Letocha, Methods for self-administration of eyedrops, Ann Ophthalmol 17 (1985) 768–769.
[16] M.H. Strungaru, J. Peck, E.C. Compeau, G.E. Trope, Y.M. Buys, Mirror-hat device as a drop delivery aid: a pilot study, Can J Ophthalmol 49 (2014) 333–338, https://doi.org/10.1016/j.jcjo.2014.04.012.
[17] R. Sharma, D. Singhal, A. Shashni, E. Agarwal, M. Wadhwani, T. Dada, Comparison of eye drop instillation before and after use of drop application strips in Glaucoma patients on chronic topical therapy, J Glaucoma 25 (2016) e438–40, https://doi.org/10.1097/IJG.0000000000000342.
[18] B.F. Gomes, M. Lordello, L.F. Celli, M.R. Santhiago, H.V. Moraes, Comparison of eyedrop instillation technique with and without a delivery device in inexperienced patients, Eur J Ophthalmol 26 (2016) 594–597, https://doi.org/10.5301/ejo.5000797.
[19] R. Ritch, E. Astrove, A positioning aid for eyedrop administration, Ophthalmology 89 (1982) 284–285.
[20] R. Sayner, D.M. Carpenter, A.L. Robin, S.J. Blalock, K.W. Muir, M. Vitko, et al., How glaucoma patient characteristics, self-efficacy and patient-provider communication are associated with eye drop technique, Int J Pharm Pract 24 (2016) 78–85, https://doi.org/10.1111/ijpp.12215.
[21] A.J. Winfield, D. Jessiman, A. Williams, L. Esakowitz, A study of the causes of non-compliance by patients prescribed eyedrops, Br J Ophthalmol 74 (1990) 477–480, https://doi.org/10.1136/bjo.74.8.477.
[22] D.M. Junqueira, F.S. Lopes, F.C. de Souza, S. Dorairaj, T.S. Prata, Evaluation of the efficacy and safety of a new device for eye drops instillation in patients with glaucoma, Clin Ophthalmol 9 (2015) 367–371, https://doi.org/10.2147/OPTH.S78743.
[23] L. Van Santvliet, A. Ludwig, Determinants of eye drop size, Surv Ophthalmol 49 (2004) 197–213, https://doi.org/10.1016/j.survophthal.2003.12.009.
[24] Z. Sklubalova, Z. Zatloukal, Study of eye drops dispensing and dose variability by using plastic dropper tips, Drug Dev Ind Pharm 32 (2006) 197–205, https://doi.org/10.1080/03639040500466130.