DUO: an innovative multidrug delivery system

Jacopo Allamprese, Michele Allamprese, Francesco Gelormini, Alessandro Rabiolo and Giuseppe Querques

Ther Adv Ophthalmol
2018, Vol. 10: 1–3
DOI: 10.1177/2515841418812061

Received: 16 July 2018; revised manuscript accepted: 12 October 2018

Correspondence to:
Giuseppe Querques
Department of Ophthalmology, University Vita-Salute, IRCCS Ospedale San Raffaele, Via Olgettina 60, Milan 20132, Italy.
giuseppe.querques@hotmail.it

Jacopo Allamprese
Department of Aerospace Science and Technology, Politecnico di Milano, University of Milan, Milan, Italy

Michele Allamprese
R BIO TRANSFER S.R.L, Albanella, Italy

Francesco Gelormini
Alessandro Rabiolo
Giuseppe Querques
Department of Ophthalmology, University Vita-Salute, IRCCS Ospedale San Raffaele, Milan, Italy

The ophthalmic market offers many different medications for numerous eye diseases. Several classes of active ingredients are used to treat ocular pathologies, and often patients are prescribed multiple topical medications. In the case of chronic diseases requiring a long-term treatment (i.e. glaucoma, dry eye syndrome, and chronic conjunctivitis), patients often instill more than one drug. The number of medications and the complexity of therapeutic regimen can be a major hurdle for compliance.[1] Two or more different kinds of active principles, and consequently more eye drop dispensers, make the therapeutic regimen complex.[2] The poor compliance can significantly affect the therapy success, and is regarded as a major cause of treatment failure in the glaucoma field.[2] Besides the patient compliance, multidrug therapy has a significant impact on the exposure to preservatives and on average therapy costs.[3]

In this letter, we present DUO (Patent No. 0001427873), an innovative double-chamber eye drop dispenser. DUO is a cost-effective and user-friendly device that can help patients to manage medication treatment in case of multidrug therapy. The main aim of the present invention is to provide a container for ophthalmic solutions, which allows rapid administration in sequence, reducing the number of instillations with different bottles, and considerably decreasing the timing of execution of such medical practice.

The device permits delivering the two ophthalmic solutions with delayed instillation, according to the doctor's instructions, with potential increase in patient compliance and cost-effectiveness. The two chambers are placed in a specular position inside a vane, contained in an elastic body. The two chambers have a semi-circular shape, same dimension, and each one is separated from the other with no direct communication. From each chamber, a pipeline originates and runs vertically and parallel to the other one reaching an opening at the top of the bottle. The DUO device is based on two analogous units (each one with its own reservoir, pipeline, and opening) operating in a parallel fashion (Figure 1). The instillation of the two different ophthalmic active principles takes place through a spring activated by pushing on two or more facilitating points, symmetrically placed on the body of the bottle in correspondence to the internal chambers. The TAP switch system at the top of the DUO system allows the instillation of either drugs preventing their simultaneous delivery and mixing.

DUO keeps the two active principles separated to maintain properties of individual drugs avoiding potential drawbacks of a container with a single chamber. Some couple of drugs, indeed, can be chemically immiscible, such as in the case of an aqueous base and a fatty base. Different substances may have different density coefficients, and this could not ensure the appropriate dosage with one element floating over the other one. The eye lotions might not mix to the desired degree, again causing uncertainties of dosage. Finally, the mixing may theoretically modify pharmacokinetic properties of the single component. DUO device overcomes the aforementioned limitations.

DUO may be potentially applied to all the situations where an ophthalmologist prescribes two or more different bottles. In the field of glaucoma, the device allows the combination of two intraocular pressure (IOP)-lowering medications or an IOP-lowering medication with artificial tears. Ocular surface disease is a well-known complication of ocular hypotensive medications, and patients are often prescribed lubricants.[4] Although there are no studies in this regard, it is possible to hypothesize that the instillation in rapid succession of an

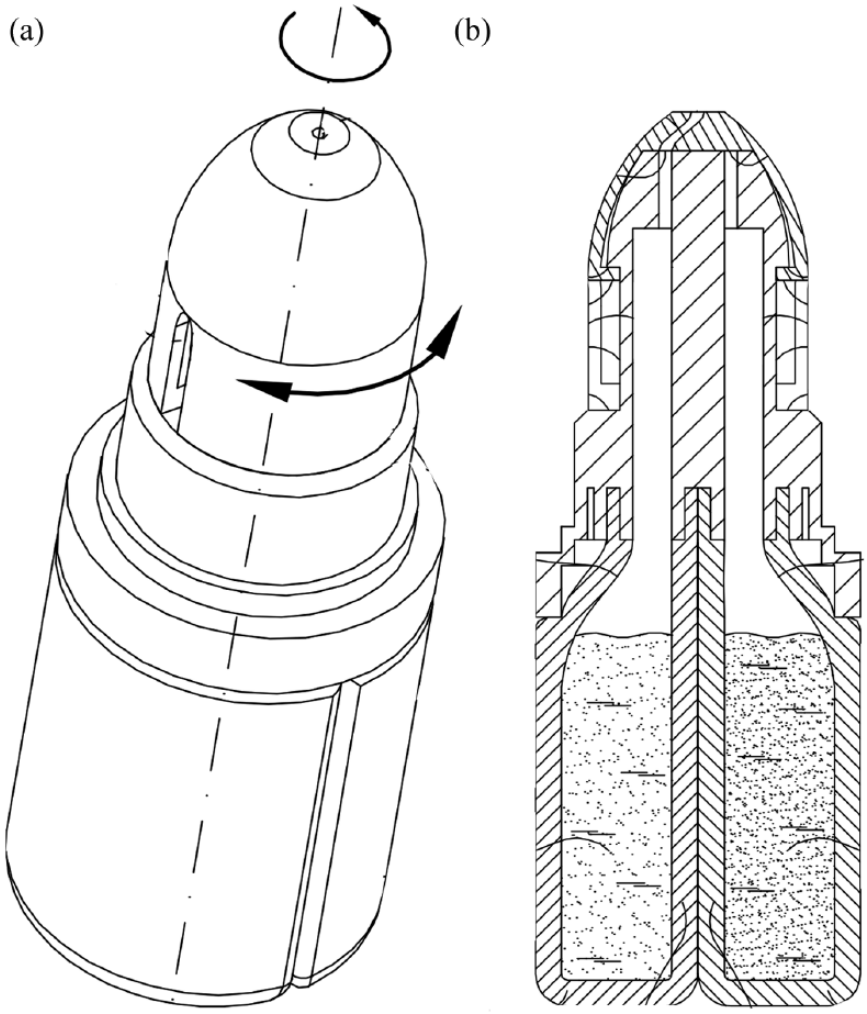

Figure 1. Technical drawings of the (a) outer and (b) inner views of the Duo device. The device contains two separate, analogous units made of a reservoir, pipelines, and opening. The TAP switch system at the top of the bottle allows the selection of one of the two units.

artificial tear and an active principle may dilute the latter, potentially reducing its therapeutic efficacy. Nevertheless, the TAP switch system allows the patient to manage the elapsing time of the administration of the two active principles.

In conclusion, DUO is a novel device which can simplify patients' therapeutic regimen, potentially increasing the compliance and the quality of life. DUO has also a social impact since it may potentially reduce the therapy costs.

Conflict of interest statement

The authors have no proprietary interest in the materials used in this study. MA, AR and FG have no disclosures. GQ is consultant for Alimera Sciences, Allergan Inc., Bayer Schering-Pharma, Fidia-Sooft, Heidelberg, KHB, Lumithera, Novartis, Roche, Sandoz, Topcon, and Zeiss. JA detains the patent No. 0001427873 for DUO device.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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