A User-Preference Study on an Ophthalmic Injection Device to facilitate Microliter Dosing for Intravitreal Injections

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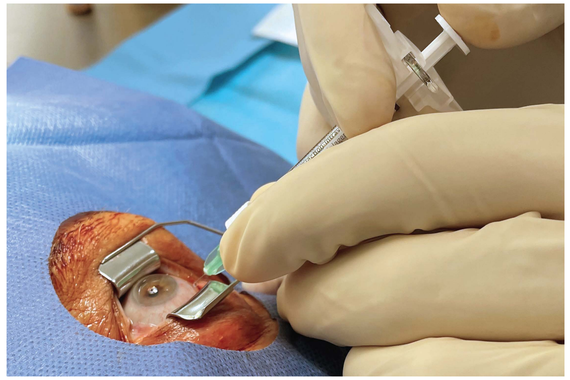


Introduction

In the current standard practice of intravitreal injections, the accuracy, precision and reproducibility of the delivered volume depend on the size of the syringe and the physician's experience[1]. Despite industry efforts to provide a means of repeatably accurate injection dose volume, precise dosing of intravitreal injectables remains an unmet need.

This work is focused on evaluation of a device to aid in precise, repeatable dosing of intravitreal injections (IVIs) and is based on the results of two earlier phases of in-depth market analysis and systematic user-centric research.[2, 3] During the user-centric research, retina specialists with extensive experience in IVIs selected their preferred injection-aiding device from a number of concepts. A prototype of this selected device was then used in a hands-on laboratory-based study to further investigate the dose volume accuracy for three target dose volumes of 20, 50 and 80 microliters (µl).

Purpose

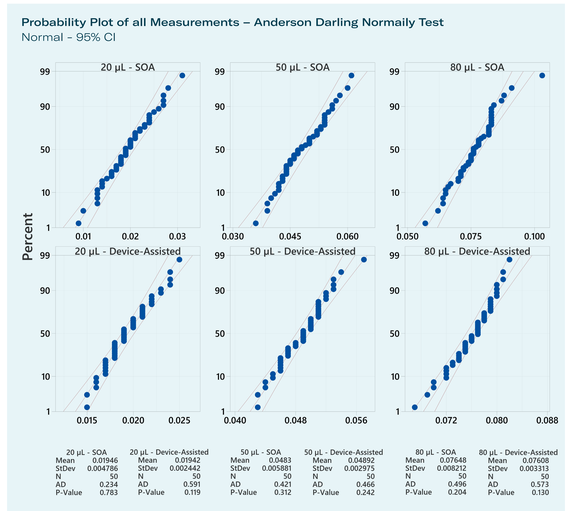
The purpose of this research was to evaluate the accuracy of injection dose volumes delivered by the prototype of the previously selected injection-aiding device concept. Moreover, a comparative analysis was conducted to compare the accuracy of injection dose volumes delivered by the device concept with those delivered by a conventional PFS using state-of-the-art techniques employed in current practice (dose marking on the syringe).

Materials and Methods

Laboratory testing was performed to study accuracy and repeatability of injections of a fixed dose (D1= 20 µl, D2 = 50 µl and D3 = 80 µl) followed by statistical analysis of the results of injection with the device compared to the current state-of-the-art. Furthermore, descriptive statistics was performed to study differences between the injection volumes of the injection-aiding device compared to the current state-of-the-art using prefilled syringes. A total of (n=5) users performed injections of the three target dose volumes of 20, 50 and 80 µl using both methods (n=10 injections per person and target dose volume) resulting in a total 50 datapoints per target injection volume.

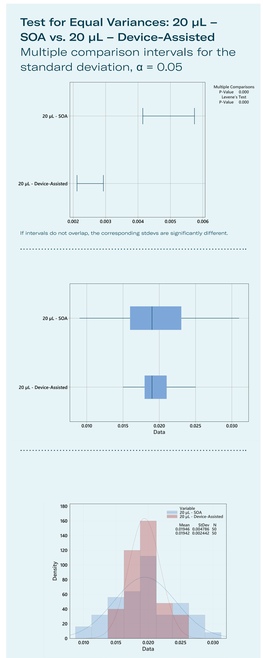
Results

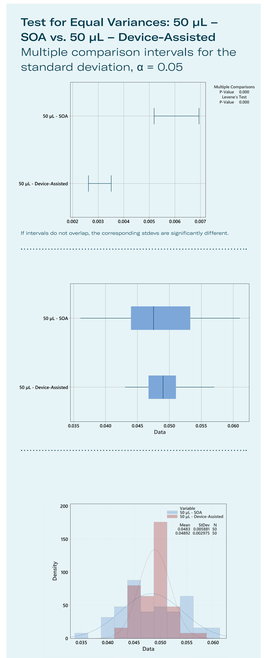
Injection volumes measured while using an injection-aiding device, demonstrated less dispersion around the target 20, 50 and 80 µL doses compared to those performed free-hand ie with a prefilled syringe. Initially all data (n=100) was tested for normality within each group to assure suitability of the further statistical testing, Injection volumes were calculated based on the weight of fluid dispensed from the syringe. Data collected by all test operators was pooled to form a large sample of data for each target injection dose volume (n=50 per injection volume of 20 , 50 and 80 µL). Finally, analysis of variance was performed between device and state-of-the-art groups. For all three target injection volumes, a significant difference of the variances were observed between device-assisted and state-of-the-art injection volumes. (95% Bonferroni Confidence Intervals for Standard Deviations, Individual confidence level = 97.5%, p<0.000 for all three data set comparisons)

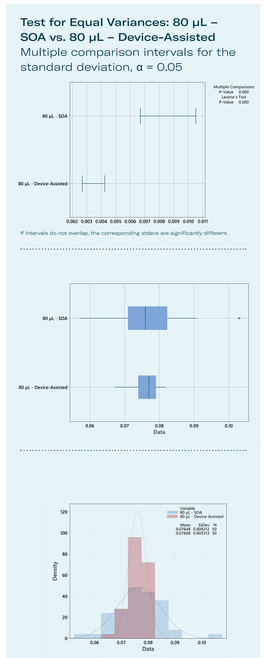


Conclusions

This study demonstrated that, despite the advancements in drug therapeutics and the practice of intravitreal injections, there remain unmet needs that may be addressed by an injection-aiding device which can facilitate injection through improved handling and accuracy of the injection volume. Compared to the current IVI procedure, an accurate device has the potential to increase repeatability of the injected dose volume and hence enhance safety for patients. Additionally, it may lead to a shorter procedure times, and reduce cost for medical staff and for expensive operating rooms.







Acknowledgments

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