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Research Article

Evaluation of the Bimatoprost Sustained Release Implant (DURYSTA®) After Posterior Chamber Implantation

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Abstract

Background: The Bimatoprost intracamerial implant (DURYSTA®) is currently only approved as a single-use device due to concerns of progressive loss of corneal endothelial cells following repeated intracameral administration. Currently depot systems such as DURYSTA® are placed in the anterior chamber, however the anterior chamber's open environment allows for unrestricted movement of implants that results in corneal endothelial cell loss. Delivery of the implant to the posterior chamber may offer a means of providing similar or elevated levels of drug to the primary target, the ciliary body, while also isolating the implant from the cornea. This in turn may provide a means of safe serial administration.

Materials and Methods: To assess migration after intracameral and posterior chamber DURYSTA® administration, a comprehensive analysis using a variety of imaging including optical coherence tomography, robotic ultrasound and slit lamp biomicroscopy video recordings were performed. Six patients (n=10 eyes) received a single DURYSTA® implant in the posterior chamber of one or both eyes. Intraocular Pressure (IOP) was measured after washout of all glaucoma medication at baseline, 1 week, 1 month and 3 months post-implantation. Paired t-tests, Cohen's d and Hedge's g compared each follow-up IOP to baseline. Finally, relative IOP lowering after posterior chamber administration was compared against reported IOP lowering in the ARTEMIS trials.

Results: For posterior chamber implant imaging, only robotic ultrasound was satisfactory for DURYSTA® visualization. Robotic ultrasound confirmed that in ten pseudophakic eyes, the implant was held well positioned, sandwiched between the iris and pseudophakic lens complex. Mean baseline Average IOP was 24.9 ± 6.66 mmHg. Average IOP was recorded 16.4 ± 5.1 mmHg at 1 week, 13.1 ± 4.1 mmHg at 1 month and 15.2 ± 4.2 mmHg at 3 months. Paired t-tests revealed statistically significant reductions at all time points with confirmation of meaningful IOP lowering despite small sample size by Cohen's d and Hedge's g. IOP lowering by DURYSTA®, was found to be non-inferior with posterior chamber administration as compared to intracameral administration data from the ARTEMIS trials.

Conclusion: Posterior chamber administration of DURYSTA® provided IOP lowering comparable to intracameral administration with no noted adverse events. ArcScan robotic ultrasound imaging confirmed stable implant positioning sandwiched between the iris and pseudophakic lens complex. This approach of delivery of implants to the posterior chamber merits further investigation as a novel implant location for ocular drug-delivery platforms to maintain efficacy while potentially reducing adverse events and opening up the possibility of serial administration.

Keywords: DURYSTA®; Bimatoprost Implant; Ciliary Sulcus; Ocular Drug Delivery; Intraocular Pressure; Safety; Anterior-Segment OCT; Ultrasound Biomicroscopy

Introduction

Topical drop-based therapy for glaucoma has numerous limitations including worsening ocular surface disease and poor patient compliance. Depot ocular therapeutics placed intracamerally could circumvent these issues. For depot therapeutics to replace topical glaucoma therapy, a means of serial administration is requisite. Although a promising option, the sustained-release intracamerally administered biodegradable Bimatoprost releasing implant, DURYSTA® (Abbvie, Chicago, IL), is only FDA approved for a single administration [1-8]. Serial administration has been linked to Adverse Events (AEs) such as Corneal Endothelial Cell Loss (CECL) and corneal edema, highlighting the need for alternative delivery locations [1,6]. One alternative, implantation of DURYSTA® in the posterior chamber, specifically the ciliary sulcus space, may be a viable solution to bypass the limitations associated with repeated intracameral use. The posterior chamber holds promise for depot drug delivery systems as it may isolate the implant from striking the cornea and in the case of DURYSTA®, localizes the implant closer to its main point of action, the ciliary body. To better understand ideal techniques and implants for posterior chamber administration, precise imaging of the posterior chamber is essential. The direct visual approach traditionally favored by ophthalmologists, while beneficial, has limitations. In particular, both slit lamp biomicroscopy and Optical Coherence Tomography (OCT) preclude imaging of structures immediately behind the iris (Fig. 1). Imaging structures in the posterior chamber obscured by the iris necessitates alternative methods like ultrasound [9-15]. Employing robotic ultrasound technology, such as the ArcScan Insight 100, has enabled imaging of detailed structures of the entire lens complex in phakic and pseudophakic eyes like [9,10,12,14,15].

DURYSTA® contact with the corneal endothelium can result in Corneal Endothelial Cell Loss (CECL) [6-8]. If it was not for clinically meaningful CECL, DURYSTA® would be approved by the FDA for serial administration [6-8]. Implants placed in the anterior chamber constantly strike and roll across the corneal endothelium and iris (Video 1). This is suggested by the observation of implants accumulating clusters of pigment on their surface (Fig. 2) and becoming rounded out over time (Fig. 2). In certain instances, albeit frustratingly unpredictable, even when angle architecture is taken into account, DURYSTA® will become well seated in the inferior angle. In this instance mobility is limited and the implant retains an overall cylindrical shape that slowly swells post administration (Fig. 2) and eventually degrades. When this occurs, motion of the implant and thus CECL is limited. While many eye care professionals are proficient in traditional ocular ultrasound techniques, fewer are acquainted with the nuances of robotic ultrasound [9-15]. The ArcScan Insight 100 distinguishes itself by employing iris registration, facilitating the serial overlay of images in a manner similar to CT or MRI scans [14,15]. This capability allows for unprecedented precision in measuring individual corneal layer thickness, the anterior chamber depth as well as precise imaging of the posterior chamber and lens complex. Leveraging this technology enables the serial measurement of sulcus-to-sulcus, angle-to-angle and the inner diameter of the ciliary muscle with an accuracy of up to 120 microns [14,15]. Such precise measurements are invaluable for evaluating local tissue changes in relation DURYSTA® and similar medications, as well as implant location within the eye.

The ArcScan Insight 100, utilizing its contact-free 50MHz ultrasound probe and a water bath, achieves the highest possible resolution scan of the entire anterior segment. This automated immersion technique, mitigates the variability caused by tear film instability and variability in probe position in relationship to ocular anatomy [14,15]. Robotic ultrasound helps eliminate the inherent black box for ocular structures immediately behind the iris by integration iris registration, thus enabling serial changes in the posterior chamber or implants occupying this otherwise not directly visualized. This approach is critical for future efforts aimed at determination of the optimal size, material and placement of posterior chamber implants. In the case of this study, it helps evaluate the potential to sandwich DURYSTA® between the iris and pseudophakic lens complex, thereby enabling it to be predictably held in a single position that is fortuitously closer to its primary target of area of action, the ciliary body and also isolated from the corneal endothelium, the main source of AEs precluding serial administration.

Materials and Methods

Patients

Inclusion criteria for the study were pseudophakic patients diagnosed with Open Angle Glaucoma (OAG) or Ocular Hypertension (OHT), already scheduled to receive a DURYSTA® Bimatoprost implant in at least one eye. Exclusion criteria included a history of the following ocular surgeries in the eye due to receive a Bimatoprost intracameral implant: Ahmed Glaucoma Valve, Baerveldt shunt, Ex-Press glaucoma shunt implantation, Molteno shunt, Trabeculectomy, Vitrectomy, retinal surgery or CyPass Micro-Stent. Prior to participation, all patients were provided with a comprehensive explanation of the study's aims and procedures and written informed consent was obtained from each participant.

Implantation Procedure

A DURYSTA® Bimatoprost implant was inserted in the anterior chamber or posterior chamber by a single surgeon (BB) at the slit lamp after standard preimplantation sterilization, including 10% betadine applied periocular and to the lashes. Next, after administration of a topical proparacaine eye drop, 5% betadine was applied to the ocular surface and then an eyelid speculum was inserted, followed by a topical drop of moxifloxacin.

With the patient at the slit lamp, the DURYSTA® administration needle was inserted at the limbus at approximately the 10 O'clock position in the right eye and 2 O'clock position in the left eye (Fig. 3). The needle was advanced across the anterior chamber with care to avoid corneal or iris contact. Crossing the pupillary center in a non-dilated eye, the needle tip was advanced to the posterior chamber approximately 3 mm past the inferior pupillary margin (Fig. 3). The implant was then injected and the needle carefully withdrawn with care to ensure the implant remained lodged between iris and intraocular lens complex, as can be seen by comparing robotic ultrasound image pre-delivery (Fig. 3) versus a robotic ultrasound image of the implant post DURYSTA® delivery (Fig. 3). DURYSTA® is highly and readily visualized after posterior chamber delivery as a barrel shaped structure immediately behind the iris (Fig 3).

In any instance in which the implant was noted to be visible at the pupillary margin, it was gently pushed back into its initial delivery position with advancement of the delivery needle. The needle was then removed and the injection site was observed to be self-sealing. A final drop of moxifloxacin and proparacaine was administered and the speculum was removed. All procedures were conducted at a single institution (California LASIK & Eye Sacramento, CA) by a single surgeon (BB).

Imaging

Following implantation, the Maestro II OCT and camera (Topcon, Tokyo Japan), as well as the Insight 100 (ArcScan, Golden CO USA) and biomicroscopy recording on a BQ 900 (Haag Streit, Bern Switzerland) with a modified GoPro Hero5 (GoPro, San Mateo CA) for slit lamp recording was performed. This enabled localization of the DURYSTA® intracameral implant as well monitoring of AEs including changes in corneal thickness. Both anterior segment OCT and Arcscan Insight 100 robotic ultrasound corneal imaging were utilized to assess change in corneal thickeness and implant migration in the anterior chamber. Although anterior segment OCT and robotic ultrasound provided a means of evaluating corneal changes post DURYSTA® administration, only robotic ultrasound provided a means of implant visualization in the posterior chamber.

IOP and Adverse Event Monitoring

Initial IOP was measured for each eye following a five week washout of period of all IOP-lowering medications. Using the iCare iC200 (iCare, Raleigh NC), IOP was measured at baseline, 1 week, 1 month and 3 months post DURYSTA® administration. At all time points of IOP measurement, the above imaging modalities were utilized to assess implant localization within the eye and any associated anatomic changes including change in corneal thickness. Using slit lamp biomicroscopy, anterior segment adverse events such as iritis, anterior chamber cell, iris adhesions, anterior chamber flare, keratitis, uveitis, anterior chamber inflammation, iridocyclitis and keratic precipitates were evaluated.

Statistical Analysis

For statistical analysis, paired t-tests were employed to determine whether the mean of the within-eye differences in IOP reduction was significantly different from zero. This approach is appropriate at it accounts for inter-eye variability and correlation between measurements. We also computed the Cohen's d (effect size for paired samples) and the 95% Confidence Intervals (CIs) for the mean IOP reductions at each time point. As Cohen's d is known to slightly overestimate the true effect in small sample size, we used Hedges' correction to bring the IOP lowering effect closer to an unbiased value.

Results

Patients

The study included 10 pseudophakic eyes from 6 patients diagnosed with OHT or OAG that were already scheduled to receive DURYSTA® Bimatoprost implants. Four of the patients had bilateral DURYSTA® administration. Participants were age 66-88, icluding 3 males and 3 females. 8 of the participants were Caucasian, one was Native American and one was Black (Table 1). One of the patients, representing two of the eyes in the study, had OHT and all remaining eyes had POAG.

Implantation Procedure

DURYSTA® administration was performed at a single institution (California LASIK and Eye, Sacramento CA) by a single surgeon (BB). In this single site study, each patient received a DURYSTA® implant in the posterior chamber after five week washout of IOP-reducing medication. ArcScan Insight 100, slit lamp biomicroscopy and anterior segment OCT confirmed no evidence of corneal thickness change over the entire study period. Administration of the implant as described in methods resulted in no serious adverse events and imaging confirmed stable implant positioning without migration.

Imaging

Of the 10 pseudophakic eyes receiving posterior chamber DURYSTA®, robotic ultrasound provided robust visualzation of the implant and confirmed unchanged implant location at week 1 and at 1 and 3 months. ArcScan Robotic Ultrasound imaging, Computerized Ultrasound Imaging, Anterior Segment OCT, corneal topography and slit lamp video capabilities revealed no gross anatomic or cellular changes after posterior chamber administration. This was in contrast to anterior chamber administration of DURYSTA® that often resulted in uncontrolled motion of the implant within the anterior segment (Video 1). This motion in turn created a rounded and speckled appearance to the implant visible on slit lamp biomicroscopy (Fig. 2), robotic ultrasound (Fig. 2) and OCT (Fig. 2). In cetain instances, the implant would migrate to the inferior sulcus and become well seated with minimal motion. This resulted in implants that were grossly cylindrical and largely free of any spotting from the iris (Fig. 2).

The ArcScan Insight 100 facilitated comprehensive imaging of the entire posterior chamber, including the potential for zonular imaging, (Fig. 1) thereby providing a more detailed view than UBM and enhancing diagnostic and treatment accuracy in ophthalmology. A combination of Computerized Ultrasound Imaging, Posterior chamber OCT, corneal topography and slit lamp video recording was employed to elucidate the findings from Insight 100 Ultrasound imaging in the posterior chamber (Fig. 3). The overarching aim was to monitor sulcus administration, implant migration and associated tissue changes, leveraging validated intraocular chamber findings and multimodal imaging to understand the effects and positioning of the DURYSTA® implant with ArcScan Insight 100 imaging of the sulcus, as well as its efficacy and toxicity based on location.

IOP and Adverse Event Monitoring

There were no serious adverse events or clinically meaningful CEC loss. Participants were then taken off glaucoma medications to determine their baseline Intraocular Pressure (IOP) after a 5 week wash out period. IOP measurements were taken at 1 week, 1 month and 3 months post-implantation. Mean baseline IOP was 24.9 ± 6.7 mmHg. IOP dropped to 16.4 ± 5.2 mmHg at 1 week, 13.1 ± 4.1 mmHg after 1 month and 15.2 ± 4.2 mmHg after 3 months ($p \leq 0.05$ at every time point). This data represents an 8.5 mmHg IOP reduction or 34% reduction at 1 week, 11.8 mmHg or 47% reduction at 1 month and 9.7 mmHg or 39% IOP reduction at month 3.

Statistical Analysis

All three reductions in IOP compared to baseline were statistically significant, with p-value less than 0.001. When applying Cohen's d and Hedges' g, robust IOP lowering was still found. All comparisons demonstrated statistically significant reductions in IOP from baseline, powered by large effect sizes (Cohen's d> 1.4). The 95% CI did not include zero and indicate substantial reduction - for example, at 1 month, IOP reduction is likely between 6.6 and 17.1 mmHg. Effect sizes and confidence intervals both underscore the treatments robust and clinically meaningful impact on lowering IOP at all the time points. Even when accounting for Hedges' g the data still demonstrated very large effect sizes even when correction for small-sample bias. All Hedges' g values were >0.8 which is considered large effect sizes. Taken together, even in the setting of small sample bias, the posterior chamber DURYSTA® administration provided robust and substantial reductions in IOP (Table 2).

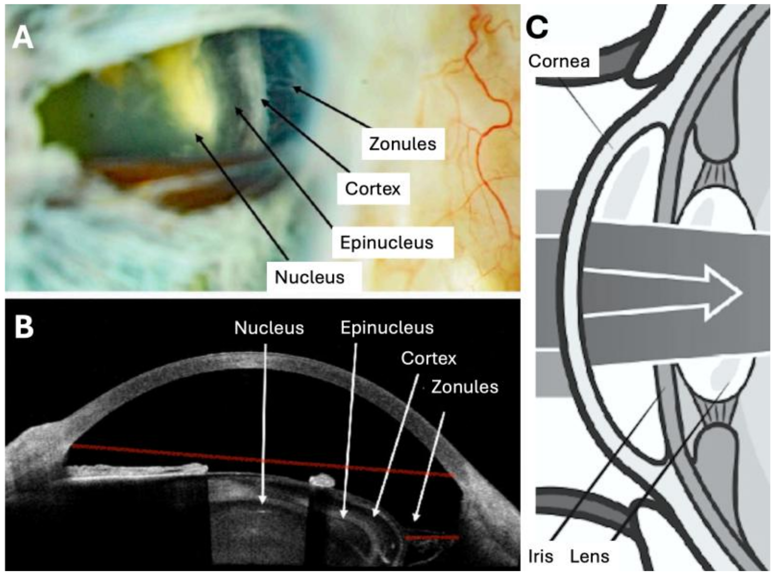

Figure 1: The problem of posterior chamber visualization. Except under limited circumstances, OCT is incapable of imaging structures immediately behind the iris. A) Anterior segment photo of a patient with a limited iris defect that provides visualization of lens complex structures anterior to the iris including the zonules, lens cortex, epinucleus and nucleus. B) Anterior segment OCT reveals visualization of these posterior chamber structures in the area of iris defect (left) but absence of visualization of these structures in the quadrants of the eye free of iris defect.

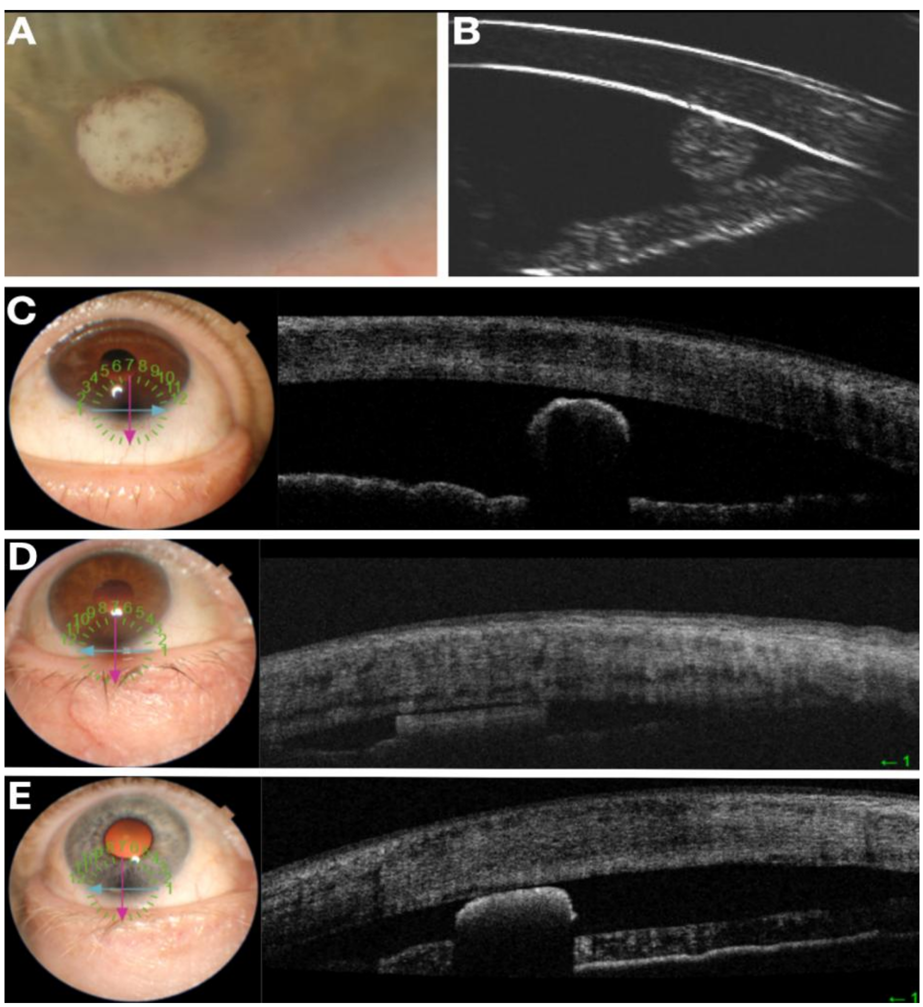

Figure 2: Imaging of DURYSTA® after intracameral administration depending on implant mobility. A) DURYSTA® implant mobile in the anterior chamber demonstrating rounded and spotted appearance. B) ArcScan robotic ultrasound image of

DURYSTA® in the anterior chamber demonstrating rounded structure indicative of mobile implant. C) Anterior segment OCT imaging of mobile DURYSTA® intracameral implant demonstrating rounded appearance. D) Anterior Segment OCT of well seated intracameral DURYSTA® implant immediately after administration. E) OCT of well seated DURYSTA® implant one month post implantation, note swelling of implant as compared to immediate delivery but retention of cylindrical shape.

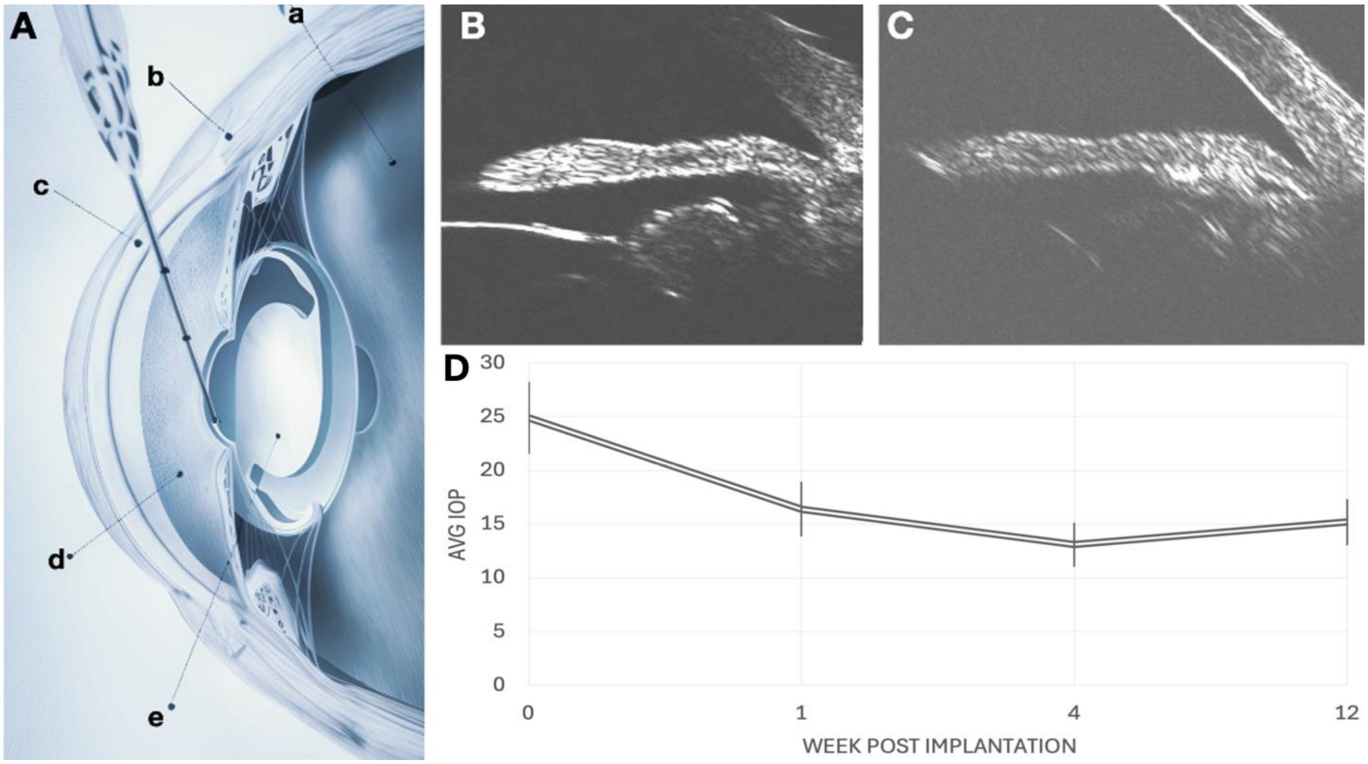

Figure 3: Delivery of DURYSTA® to the posterior chamber. A) Diagram of implant delivery approach with labeling of relevant anatomy a. vitreous b. ciliary body c. cornea d. anterior chamber e. intraocular lens. B) ArcScan robotic ultrasound image of the posterior chamber prior to DURYSTA® administration revealing a continuous space between iris and lens complex. C) Repeat ArcScan robotic ultrasound image revealing the echogenic cylindrical structure of the DURYSTA® implant immediately posterior to the iris. D) Comparative average of patient IOP measured from 10 pseudophakic eyes: pre-implantation baseline following washout (week 0), 1 week post implantation, 4 weeks post implantation and 12 weeks post implantation. Average IOP measured was 24.9 ± 6.7 mmHg at baseline, 16.4 ± 5.1 mmHg after 1 week, 13.1 ± 4.1 mmHg after 1 month and 15.2 ± 4.2 mmHg after 3 months.

Age	Sex	Ethnicity	Eye Color	Eyes
85	M	Caucasian	Blue	x2
88	F	Caucasian	Brown	x2
80	M	Caucasian	Blue	x1
66	F	Caucasian	Blue	x2
72	M	Native American	Brown	x2
75	F	Black	Brown	x1

Table 1: Demographics of study participants including age, sex, ethnicity, eye color and number of eyes in the study.

Comparison	Mean Difference (mmHg)	SD (mmHg)	t (df = 9)	p-Value	Cohen's d	Hedges' g	95 % CI (mmHg)
Baseline vs 1 Week	8.5	5.90	~4.56	< 0.001	1.44	1.33	4.3 to 12.7
Baseline vs 1 Month	11.8	7.35	~5.08	< 0.001	1.61	1.48	6.6 to 17.1
Baseline vs 3 Months	9.7	6.03	~5.08	< 0.001	1.61	1.48	5.4 to 14.0

Table 2: Relative change in IOP measured from 10 pseudophakic eyes: pre-implantation baseline following washout (week 0) compared to 1 week post implantation, 4 weeks post implantation and 12 weeks post implantation. All three reductions in IOP had t-distribution with 9 degrees of freedom between 4.56 and 5.08. Compared to baseline IOP lowering was statistically significant, with p-values less than 0.001. When applying Cohen's d and Hedges' g, robust IOP lowering was still found. Cohen's d> 1.4 and Hedges' g values were >0.8 which is considered large effect sizes.

Discussion

The primary impediment to widespread use of DURYSTA® is the potential for CECL, thereby limiting its Food and Drug Administration (FDA) approval to single intracameral administration. This preliminary study provides a means of potentially eliminating CECL by delivering the implant to the posterior chamber. This in turn may enable widespread serial use of DURYSTA® and other polymeric implants. It is critical to stress the preliminary conclusions of this study and how alone they do not prove superior safety profile of posterior chamber DURYSTA® administration over intracameral nor do they prove equivalent or superior efficacy. Notably endothelial cell count was not directly assessed so it is impossible to rule out the possibility that posterior chamber administration resulted in reduced endothelial cell loss as compared to intracameral administration. In regards to IOP lowering efficacy, although the study suggests non-inferiority, it in no way proves it as the study is just too underpowered to draw any definitive conclusions.

Compared to intracameral benchmarks, posterior chamber administration provided favorable results. The pivotal Artemis trial on which FDA approval is based upon demonstrated mean baseline of 24.5 mmHg with typical IOP reduction of ~5-8 mmHg (~20-33%) over the 12-week primary efficacy period.6 ARTEMIS 2 (phase 3) demonstrated mean reductions 6.2-7.4 mmHg through week 12; diurnal mean IOPs at weeks 2/6/12 around 16.5-17.2 mmHg (after a single administration, before week-16 redose) [6]. Taken together, this implies at 1 week, posterior chamber administration of DURYSTA® provided IOP lowering (16.4 mmHg; -34%) in the same absolute range as ARTEMIS diurnal means (~16.5-16.6 mmHg), but slightly larger due to slightly higher baseline IOP. At 1 month, posterior chamber administration IOP lowering (13.1 mmHg; -47%) was higher than typical intracameral trial averages over the same early window (usually ~6-8 mmHg, ~25-33%). At 3 months, posterior chamber DURYSTA® administration demonstrated greater IOP lowering (15.2 mmHg; -39%) than the ARTEMIS averages (again ~5-8 mmHg).

This study highlights the potential damage created by mobile intracameral implants. Although not directly evaluated in our study, it lends support to intracameral implants than can be anchored in the anterior chamber. One such depot solution that is also PGA eluting is the iDose TR (Travoprost intracameral implant, Glaukos, Aliso Viejo CA). Unlike the non-anchored DURYSTA® implant, iDose much like its predecessor from the same company iStent, anchors in the trabecular meshwork. This device is non-biodegradable and thus although serial administration may be possible, it requires recovery of the spent depot therapeutic.

One of the large advantages of iDose over DURYSTA® is lack of implant motion. The approach advanced in this study, namely posterior chamber administration of DURYSTA®, not only mitigated implant motion, but also prevented implant contact with the cornea. It also left the precious real estate of the trabecular meshwork untouched. As DURYSTA® degrades, it is held in position in the shifting potential space between the pseudophakic lens complex and the iris. In our pilot study, we observed some degree of focal elevation in the iris at the location of the DURYSTA® implant, a finding that aligns with expectations given the iris's limited structural robustness. Interestingly, this characteristic of the iris its capacity to adjust to implants of varying sizes and to morphological changes during implant degradation suggests that the posterior chamber could be particularly suited for depot therapeutics that swell and degrade. Without a concurrent change in the potential space between the iris and lens complex as the implant degrades, the implant could cease to be well anchored and could migrate. This is critical as non-published studies from AbbVie have shown vitreous administration of DURYSTA® does not lead to appreciable IOP lowering. Notably, this is not the first report of depot therapeutics to the posterior chamber. In a proof-of-concept study, Dr. Nathan Radcliffe delivered DURYSTA® to the posterior chamber with a goal of reducing Corneal Endothelial Cell (CEC) loss [2]. In his study, albeit it limited by lack of washout of glaucoma medication and use of robotic ultrasound imaging, he similarly reported IOP lowering with absence of AEs. Taking the Radcliffe study and this study together, we still don't have sample size sufficient to rule out more long-term AEs. For example, it is possible that if DURYSTA® is too large for the space available in the posterior chamber this could result in iris chaffing. Although neither study reported damage to the iris, manifesting as chafing, pigment loss and inflammation, neither study involved serial DURYSTA® administration or sample sizes sufficient to detect what may be a relatively rare but clinically meaningful occurrence. Moreover, neither study employed the most sensitive means of detecting CECL, specular microscopy.

This study provides further promise of serial posterior DURYSTA® administration. Moreover, it provides for the first time a means of serial imaging of DURYSTA® following posterior chamber administration with use of robotic ultrasound. This effectively illuminates the black box that was the posterior chamber enabling questions such as the impact of size of the posterior chamber or implant migration on UGH or other AES. The authors initiated this study recognizing that the future of ophthalmic treatment, particularly for glaucoma, lies in the advancement and repeated application of depot intraocular therapy.

The authors envision a future in which depot glaucoma ocular therapeutics are administered in the clinic much like anti- Vascular Endothelial Growth Factor (VEGF) therapeutics. Notably in both this study and the Radcliffe study, DURYSTA® was administered with patient in an upright position at the slit lamp. In many ways, this is an ideal approach for posterior chamber administration as it circumvents the cost associated with OR administration and enables the use of gravity to encourage DURYSTA® to remain in the posterior chamber and not migrate posteriorly into the vitreous as would be more likely be the case with a patient laying supine on an operating table.

Polymeric-based implants, such as DURYSTA®, adapt to the confines of their placement area, much like how collagen punctal plugs expand to occupy the available space. This adaptability could offer a means to achieve optimal fit and functionality within the unique anatomical spaces of the posterior chamber of different patients. This in turn may open the possibility of serial administration of DURYSTA® and may further inform development of posterior chamber specific implants. Undoubtedly, visualization is critical to all of these efforts and thus this study lays an important groundwork for the use of robotic ultrasound for simultaneous anatomic and implant imaging in the posterior chamber.

This study has numerous limitations. Principally the small sample size is underpowered to identify rare adverse events. Moreover, although AS-OCT and Arcscan imaging of the cornea demonstrated no evidence of corneal edema, corneal endothelial count was not directly measured. Another clear limitation is absence of testing of the hypothesis that serial DURYSTA® administration to the posterior chamber is free of adverse events. As this is the principal rationale for posterior chamber delivery, this is an obvious next step to assess this approach. Finally, as all implants were delivered by a single surgeon, it does not robustly address the repeatability of such an approach by all surgeons to enable delivery of the implant to the posterior chamber without migration into vitreous or anteriorly to an intracameral position.

Conclusion

Given the documented efficacy of the DURYSTA® implant and the chronic nature of glaucoma, an alternative to intracameral delivery is needed. This study suggests the possibility of posterior chamber administration overcoming some of these but is far from conclusive. Before any conclusions could be drawn, large studies that carefully evaluate IOP and corneal endothelial loss with specular microscopy would be required in the setting of serial administration. The current contraindications for DURYSTA® are ocular or periocular infections, corneal endothelial cell dystrophy, prior corneal transplantation, absent or ruptured posterior capsule and hypersensitivity. The administration of DURYSTA® behind the iris may enable use of

DURYSTA® in individuals who have had corneal transplant or have corneal endothelial dystrophy as the implant will not directly contact the cornea. Even in individuals with healthy corneas, if every intracameral injection leads to corneal cell loss, inherently, only a limited number of DURYSTA® implants can be employed. If instead the posterior chamber is utilized, this may enable serial administration for the life of the patient. In the Artemis I and II trial, corneal Treatment-Emergent Adverse Events (TEAEs) were most reported with serial administration every 3 months for a total of 3 administrations. Although occurrence or worsening of Corneal Endothelial Cell Loss (CECL) was not reported after the first and second administrations, 3.8% (6/156) of patients after the third administration (through the end of the week 52 visit window) and 5.8% (9/155) of patients during the extended safety follow-up through month 2. CECL was reported in 0.6% (1/176) of patients after the first administration, 4.2% (7/165) of patients after the second administration, 11.6% (17/147) of patients after the third administration and 14.6% (21/144) of patients during the extended safety follow-up through month. In addition to CECL, serial DURYSTA® administration increased the incidence of corneal edema and corneal touch as well as inflammatory TEAEs such as anterior chamber cell and iritis. Phase I/II evaluation noted that 5-10% of patients showed indications of corneal endothelial cell loss by endothelial cell counts as measured by specular microscopy.

By isolating the DURYSTA ® implant away from the corneal endothelium, posterior chamber administration makes immense sense. Albeit in a small sample size, this pilot study demonstrates that against the published intracameral benchmarks, posterior-chamber delivery shows larger absolute and percentage IOP reductions at 1 and 3 months (-11.8 and -9.7 mmHg; -47% and -39%) than the ~5-8 mmHg (≈20-33%) typically reported in the pivotal trials over the first 12 weeks. That said, because this data is limited by sample size, posterior-chamber efficacy evidence must be interpreted cautiously until large scale well controlled trials are conducted. These must involve serial administration much like the intracameral studies to evaluate if other adverse events may develop with posterior chamber administration. Due to localization, concern for chaffing of iris or damage to delicate zonules must be carefully studied. The robustness of robotic ultrasound for imaging the entire anterior segment will enable future studies to not only evaluate for corneal changes similar to OCT but also any changes to the lens complex including shifting effective lens position that would result from zonular trauma.

This study highlights the potential of DURYSTA® posterior chamber administration and the necessity of robotic ultrasound for monitoring. The Insight 100 employs iris registration and a robotically controlled 50MHz ultrasound probe to enable systematic imaging of relative anatomy as well as implant after posterior chamber DURYSTA® administration. The potential expansion of the posterior chamber as a site for depot drug delivery, signals a promising future for treating a wide range of ocular conditions with enhanced precision and safety. Overcoming the traditional hesitancy towards posterior chamber intervention will require a collective shift in perception, recognizing the safety and efficacy of these approaches, especially with the support of advanced imaging techniques like the ArcScan Insight 100. The future of ophthalmology lies in harnessing these innovations to expand the clinical armamentarium, offering novel treatment options that promise improved patient outcomes and a broader scope of therapeutic applications.

Conflict of Interest

BB is a consultant for ArcScan Inc. and Abbvie, KL and BS are former employs of ArcScan Inc., SR and RH have no conflicts to report.

Funding Statement

This research was conducted under an investigator-initiated trial with AbbVie.

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Data Availability Statement

Data from this study is freely available upon request.

Ethical Statement

Ethical review and approval were waived for this study, as single administration of DURYSTA® to the posterior chamber was considered off-label use.

Informed Consent Statement

Ethical review and approval were waived for this study, as single administration of DURYSTA® to the posterior chamber was considered off-label use.

Authors' Contributions

The authors contributed to the study: conceptualization, BB, BS.; Methodology, BB, BS; Formal Analysis, BB, SR, KL, BS; Data Curation, BB, SR, KL, BS; Writing - Original Draft Preparation, BB, RH; Writing - BB, RH.

Supplementary Materials

Video 1- Movement of intracameral implant. Note motion of implant in anterior chamber resulting in rounded and brown-speckled appearance from uptake of iris pigment.

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