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ORIGINAL RESEARCH

Early Real-World Patient and Staff Experience with an Intracanalicular Dexamethasone Insert

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Purpose: To evaluate both the early experience of real-world patients treated with dexamethasone ophthalmic insert (0.4 mg; DEXTENZA®), hereafter referred to as DEX, after cataract surgery as well as staff/practice integration of DEX relative to eyedrops.

Patients and Methods: This was a cross-sectional survey study of 23 cataract practices in the United States. Respondents were patients and practice staff who had experience with DEX following cataract surgery. Both patients and practice staff completed an online survey. Descriptive statistics summarized the survey responses to portray the experience of the respondents.

Results: Surveys were completed by 62 patients and 19 practice staff. Almost all patients (93%) were satisfied or extremely satisfied with DEX. Patients highly preferred DEX (93%) to topical steroid drops (7%) based on past experiences with topical steroid drops. Most practice staff (95%) were satisfied or highly satisfied with DEX, reporting a 45% reduction in time spent educating patients on postoperative drop use and a 46% decrease in time spent addressing calls from pharmacies regarding postoperative medications.

Conclusion: Incorporating the DEX insert into clinical practice in cataract surgery practices can improve patient adherence, while potentially providing significant savings to practices in terms of time spent educating patients and responding to patient and pharmacy call-backs.

Keywords: intracanalicular dexamethasone insert, phacoemulsification, hands-free therapy, ocular pain, ocular inflammation, sustained-release drug delivery

Introduction

An estimated 3.7 million cataract surgeries are performed in the United States every year.[1] Phacoemulsification is considered to be a highly successful surgery in most eyes, although outcomes are dependent on factors, such as surgeon skill, technical advances in surgical systems and intraocular lenses, and perioperative medical therapy to control postoperative inflammation and infection.[2] Among Medicare beneficiaries, 55% of patients undergoing cataract surgery are prescribed 3 perioperative topical medications—a corticosteroid, a nonsteroidal anti-inflammatory drug (NSAID), and an antibiotic—and another 30% are prescribed at least 2 of these 3 drug classes. Given the complexity of the regimen—variable dosing intervals and a steroid taper over time—it is perhaps not surprising that adherence is poor, with only half of patients reporting administering 50% or more of their prescribed drops.[3] The need for additional topical eye drops to treat ocular comorbidities such as glaucoma further complicates adherence for these patients. A study by Wu and colleagues reported that glaucoma was the most prevalent ocular comorbidity in the US Medicare and Veterans Health Administration Populations with a cataract diagnosis (Medicare: 233,066 [19.3%]; VHA: 401,371 [20.9%]).[4] Another study by Gomes and colleagues demonstrated that only approximately one-quarter of all patients with glaucoma were

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able to properly self-administer topical eye drops.[5] Further, patients may not be experienced with eye drop instillation, with up to 91% of patients making one or more errors dosing their eyedrops, including 10–76% who miss the eye entirely.[5–8] Stone and coworkers found 27%-35% of patients dispensed at least 5 eye drops before one successfully got into the eye, and 17%-25% of patients could not place a drop into their eye despite many attempts, with many of these patients unaware that they were unsuccessful.[9] Self-administration of topical eye drops will likely magnify the issue with incorrect instillation in patients with comorbid conditions. A study by Lindstrom and colleagues highlighted the difficulties associated with self-administration of standard topical drops after cataract surgery. With regard to time spent by physician offices in educating patients about proper administration of drops and responding to calls after cataract surgery, the authors mention that majority of the calls to the physician offices were from patients or pharmacies regarding substitutions for prescribed post-cataract surgery eye drops and that approximately 3000 staff hours were spent annually by physician offices in responding to patient or pharmacy questions.[10] Hence, there is a burden placed on clinical staff (Surgical Coordinator, Office Manager, Lead Ophthalmic Technician, and Research Director) with a significant investment of time in training patients with regards to eyedrop administration, following up to ensure compliance, and addressing complications from improper technique.

There is growing interest in a paradigm shift to dropless cataract surgery in an effort to simplify the perioperative experience, optimize visual outcomes, and improve the overall patient experience.[2,10–12] Sustained-release delivery of perioperative medications is a component of this approach and can help reduce or eliminate the need for postoperative eye drops after cataract surgery.[2] The dexamethasone intracanalicular insert (Dextenza [DEX], Ocular Therapeutix) is a preservative-free hydrogel-based insert that provides a sustained and continuously self-tapering dose of dexamethasone for up to 30 days and fully resorbs after the steroid is completely released.[10] The insert is approximately 0.55 mm in width and 3.0 mm in length (Figure 1). DEX can be administered by optometrists and ophthalmologists, and can be inserted in the outpatient setting.[13–15] The timing of DEX administration is flexible with administration being feasible preoperatively, during surgery, or postoperatively without compromising efficacy or safety.[13,15]

DEX has been approved by the US Food and Drug Administration for the treatment of ocular inflammation and pain following ophthalmic surgery and also for the treatment of ocular itching associated with allergic conjunctivitis[16] on the basis of results from multiple Phase 3 clinical trials.[17–19] Real-world studies have further demonstrated the role of DEX in the management of postoperative cataract surgery,[13,14] ocular surface disease,[20] refractive surgery,[21,22] minimally invasive glaucoma surgery,[23] and posterior segment surgery.[24]

We administered quantitative survey in this study to assess patient and health care provider attitudes toward DEX and its impact on clinical practice. Our analysis of physicians' experiences with DEX has been previously reported.[25] In this report, we characterize the DEX experience from the perspective of patients and practice staff.

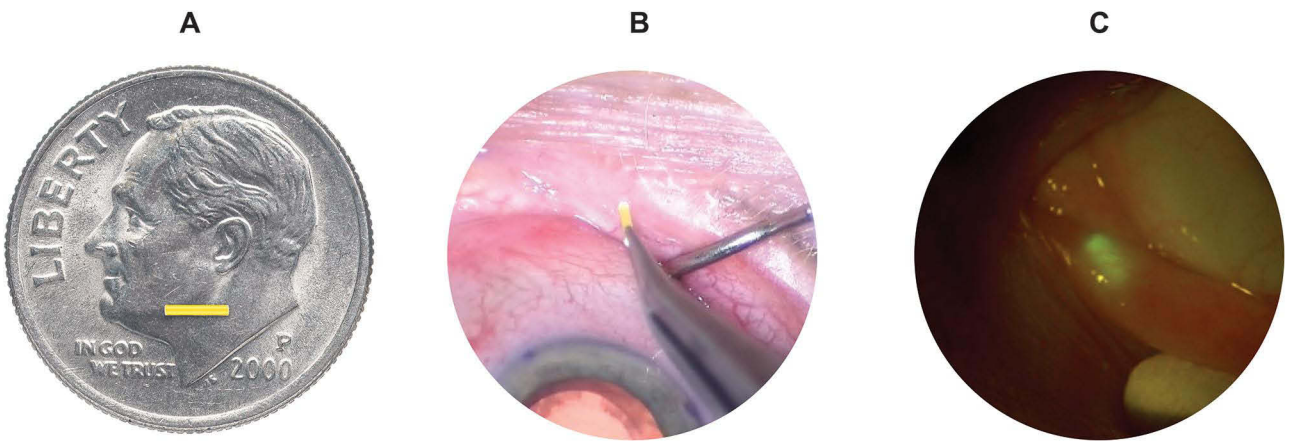

Figure 1 Dexamethasone intracanalicular insert depicted in yellow (coin for scale) (**A**). Placement of the dexamethasone intracanalicular insert in the canaliculus of the eye (**B**). The dexamethasone intracanalicular insert can be visualized by a blue light source (for example, slit lamp or hand-held blue light) with a yellow filter (**C**).

Methods

This was a cross-sectional survey study that evaluated real-world clinical experience with DEX by administering a quantitative survey. Practices were selected based on geographic region, presence of ≥2 surgical ophthalmologists, and cataract surgery volume. Once the site elected to participate in the study, surgeons performed approximately 10 cataract surgeries using DEX as the post-operative steroid. Patients aged 18 or older who either received DEX or standard of care eye drop therapy (3 drop regimen: 4 weeks of steroids, 4 weeks of NSAIDS, and 1 week of antibiotic drops) following cataract surgery were included in this study. Practice staff who had experience with DEX during cataract surgery and all patients who received DEX for cataract surgery received an online survey. Practice staff included ophthalmic technicians, office managers, surgical coordinators, and research directors from sites including ambulatory surgical clinical settings and outpatient clinical settings. Predominant functions of staff representatives included scheduling surgery with hospital/ambulatory surgical center, patient counseling, scheduling surgery with patient, answering post-operative patient question and verifying insurance coverage. Patients and practice staff were subsequently recruited from the final sample of physicians' practices agreeing to participate.

A quantitative survey was conducted with participating patients 30 days after their procedure (ie 30 days after using DEX). Thirty days after using DEX, surgical staff were surveyed on the impact of using the insert on practice logistics. The analysis focused on data collected from patients and practice staff. The study was undertaken in accordance with the tenets established in the Declaration of Helsinki, and all surveys, informed consent, and patient-facing recruiting materials were approved by the Adavrra Institutional Review Board. Survey administrators obtained consent through an electronic informed consent from all study participants before they received the survey. Personally identifiable information was not shared as part of the survey. The patients were compensated to acknowledge the time and burdens of research participation and the compensation was appropriately estimated to avoid undue influence on study participation or results obtained from the study. Respondents did not have access to results from other respondents. All respondents received a minimal patient stipend for their participation, and the DEX used by practices were part of a sampling program. The practice staff were not involved in developing the questions for the survey; both design of survey questions and data collection were performed by Clinical SCORE, a third-party vendor.

A total of 92 patients consented to survey participation. Of these, 75 patients received DEX for cataract surgery. The final sample included in the study population was as follows: the first 19 clinical staff representatives (14 surgical coordinators, 1 office manager, and 4 other clinical staff) and 62 patients who received DEX for cataract surgery between April 2019 and June 2019 (after FDA approval of DEX but prior to commercial availability) who agreed and consented to participate.

At the discretion of the physician, some patients who received DEX were prescribed ≥1 topical medication for self-administration during the postoperative period (DEXTENZA plus 2 drop regimen; these patients received one less topical medication compared to those that received the standard of care). Patients completed a quantitative survey 30 days after they received DEX for cataract surgery. This survey consisted of screening questions to determine eligibility and additional questions developed to assess overall satisfaction and experience with DEX compared with standard eyedrop medications. The practice staff received a survey following completion of treatment ie 30 days after patients received DEX for cataract surgery (DEX delivers a tapered dose of dexamethasone for up to 30 days). The survey questions evaluated the impact of DEX on patient education and callback time. Survey questions used a 7-point Likert scale, value specification, multiple choice, or ranking format. Respondents completed surveys in approximately 15 to 25 minutes.

The planned analysis included only descriptive statistics that summarized the responses on each item, and no power calculations were completed.

Results

Participants

A total of 62 patients and 19 practice staff from 23 nodal sites completed the study surveys. Patient demographic data are given in Table 1. The mean age of patients was 67.8 years, and 32 (51.6%) were between 66 and 75 years old. The majority of the patients were female, were retired, and had Medicare. Twenty-six subjects (42%) who received DEX had

Table 1 Patient Demographics

Characteristics, n (%)	N=62
Age (years)	
51–55	3 (5%)
56–60	8 (13%)
61–65	9 (15%)
66–70	17 (27%)
71–75	15 (24%)
>75	9 (15%)
No answer	1 (2%)
Gender	
Female	37 (60%)
Male	25 (40%)
Comorbidities	
Glaucoma or history of elevated IOP	6 (10%)
Uveitis	0 (0%)
Dry eye	20 (32%)
Floppy iris syndrome	0 (0%)
Parkinson disease or motor impairment	2 (3%)
Psychiatric Disorder	1 (2%)
No Comorbidities	36 (58%)
Employment status	
Working or student	16 (26%)
Not working (not retired)	0 (0%)
Retired	40 (65%)
On disability	3 (5%)
Prefer not to answer	3 (5%)
Insurance Type	
Medicaid	3 (5%)
Private insurance	16 (26%)
Medicare	41 (66%)

Abbreviation: IOP, intraocular pressure.

a pre-existing comorbidity including: glaucoma, OHT, dry eye, Parkinson Disease or other motor impairment, or psychiatric disorder. Overall, 20 patients (32.3%) reported dry eye disease and 6 patients (9.7%) reported glaucoma or a history of elevated intraocular pressure. In terms of perioperative medication exposure, the standard of care for post-cataract therapy in the majority of practices was a 4-week tapered regimen for steroids (78%), 4 weeks of NSAIDs (68%), and 1 week of antibiotic drops (68%).

Patient Perception of an Eyedrop Regimen Combined with DEX

More than 38% of patients reported that it was difficult to take all eyedrops exactly when they were supposed to be applied, and more than 40% of patients reported that it was difficult to apply all eye drops exactly into their eye every time (Figure 2). Most patients (77.4%) understood that compliance with post-surgical eyedrops affects their surgical outcomes (score of 5, 6, or 7 on a 7-point Likert scale). Most patients (79.0%) responded that they missed 1–2 drops in the first week after surgery. Most patients (88.7%) reported that they missed 1–3 drops on average per week during weeks 2–4 (Figure 3).

Patient Satisfaction

Overall, 91.9% of patients were satisfied to extremely satisfied (score of 5, 6, or 7 on a 7-point Likert scale; mean score of 6.5) with having used DEX for cataract surgery. No patients reported any level of dissatisfaction (score of 1, 2, or 3 on

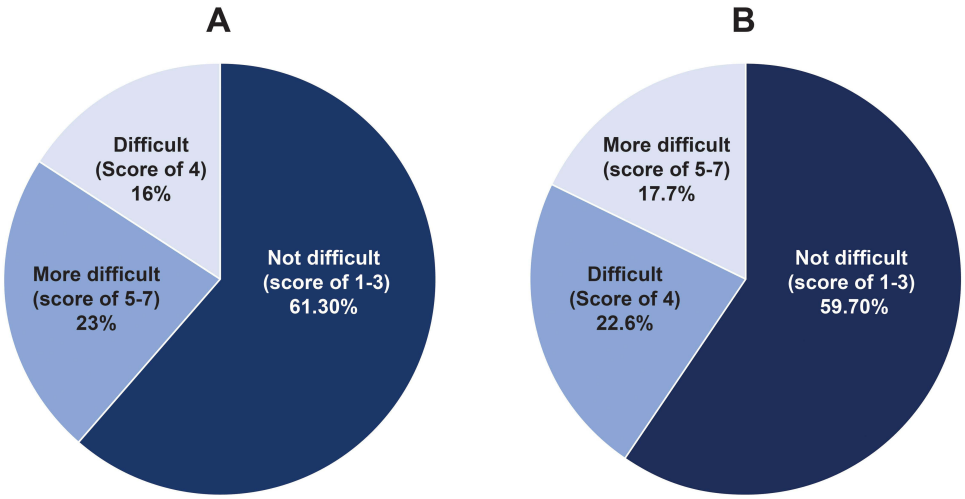

Figure 2 Proportion of patients reporting (**A**) prescribed schedule and (**B**) proper instillation of eyedrops combined with DEX after cataract surgery. More than 38% of patients reported that it was difficult to take all eyedrops exactly when they were supposed to be applied (**A**), and more than 40% of patients reported that it was difficult to apply all eye drops exactly into their eye every time (**B**).

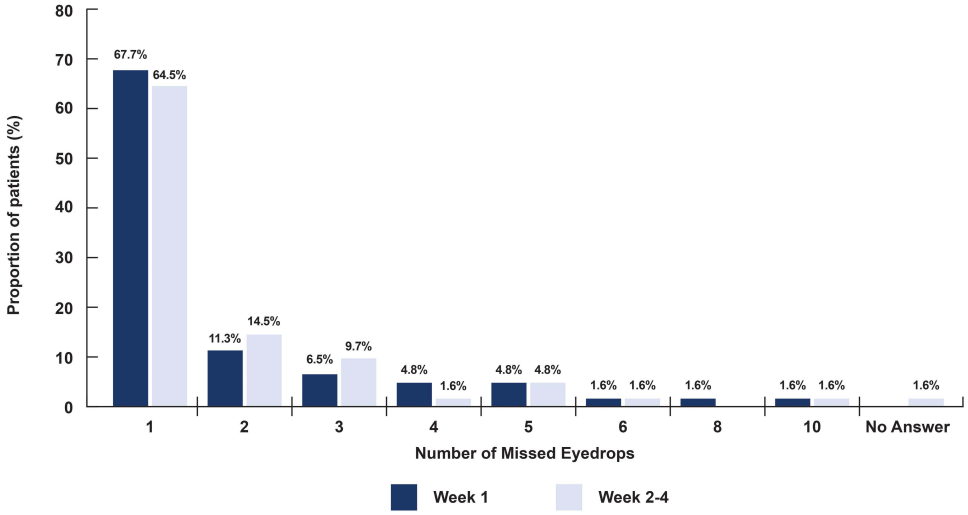

Figure 3 Proportion of patients who reported missing instillation of prescribed eyedrops combined with DEX after cataract surgery. Patients reported missing at least 1 eyedrop instillation of prescribed eyedrops after surgery.

a 7-point Likert scale). Patients highly preferred receiving DEX to instilling 4 additional topical drops per day (91.9% vs 6.5%, with 1.6% providing no answer). Overall, 95.2% of patients were likely (score of 5, 6, or 7 on a 7-point Likert scale) to recommend that a family member receive DEX for their post-cataract surgery therapy, while none were unlikely (Figure 4). Approximately, 83.9% of patients were extremely likely to recommend DEX to a family member (score of 7 on a 7-point Likert scale).

Practice Perception of Eyedrops

Practice staff ranked 6 common problems with eyedrops encountered in patients after cataract surgery in order of frequency (with 1 being the biggest problem and 6 being the smallest problem). "Inability to correctly instill the eyedrops" (mean score of 1.5) was perceived to be the biggest problem, followed by "medication cost" (mean score of 1.6) and "confusion about instructions" (mean score of 1.9). Practice staff ranked "overwhelmed by how many drops are needed" as a mean of 2.2, "noncompliance (not thinking the drops are necessary)" as a mean score of 2.8, and "difficulty in remembering to take all doses" as a mean of 3.0. Overall, 36.8% of respondents perceived no difference

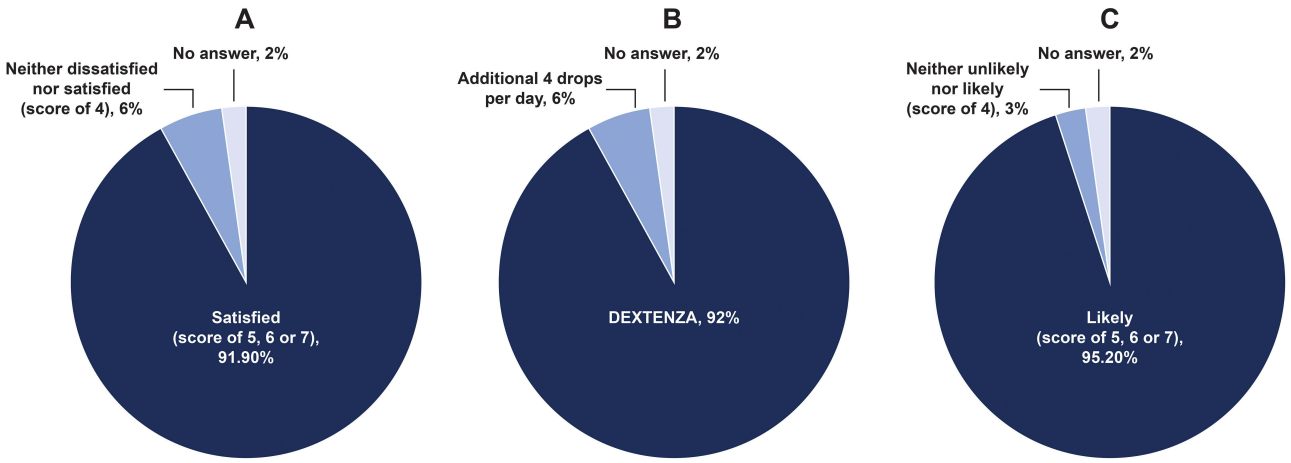

Figure 4 (**A**) Satisfaction, (**B**), preference, and (**C**) likelihood of recommending DEX to family members of patients at 30 days from DEX placement. (**A**) and (**C**) were scored on a 7-point Likert scale and (**B**) was a multiple-choice question. Patients were generally satisfied with having DEXTENZA during cataract surgery (**A**), would prefer DEXTENZA over 4 additional eye drops per day (**B**), and were likely to recommend DEXTENZA to a family member for post-cataract surgery pain control (**C**).

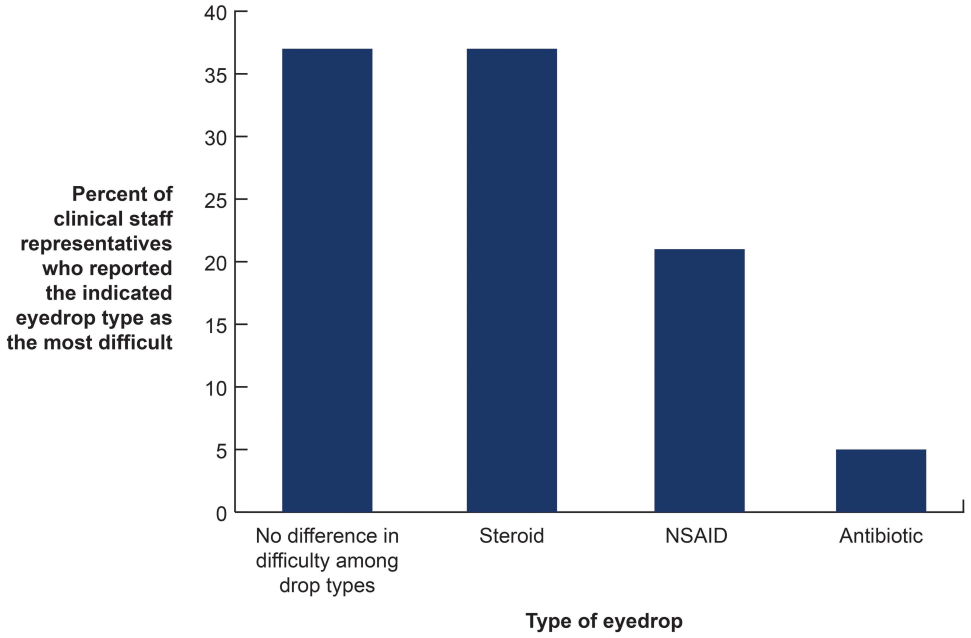

Figure 5 Proportion of practice staff representatives who reported patients having difficulty with a type of ocular medication. Patients more frequently had difficulty with steroid medications compared to NSAIDs or antibiotics. NSAID, non-steroidal anti-inflammatory.

among the difficulties associated with different types of eyedrops, while 36.8% of practice staff felt that steroids caused patients the most difficulty in the traditional peri-operative eye care regimen, whereas 21.1% felt that NSAIDs caused the most difficulty and 5.3% felt that antibiotics caused the most difficulty (Figure 5).

Practice Burden of Patient Education

Staff reported that practices spent an average of 24.5 minutes on patient education and 9.5 minutes handling patient call-backs (per patient) with the standard-of-care eyedrops following cataract surgery. When DEX was used for patients following cataract surgery (ie, the use of one less medication), staff reported an average of 11.1 minutes saved on patient education (45% reduction) and 4.4 minutes saved (46% reduction) on patient call backs per week, resulting in an average time savings of 15.5 minutes per patient. (Figure 6). Given the mean of ~160 cataract surgeries per week at participating

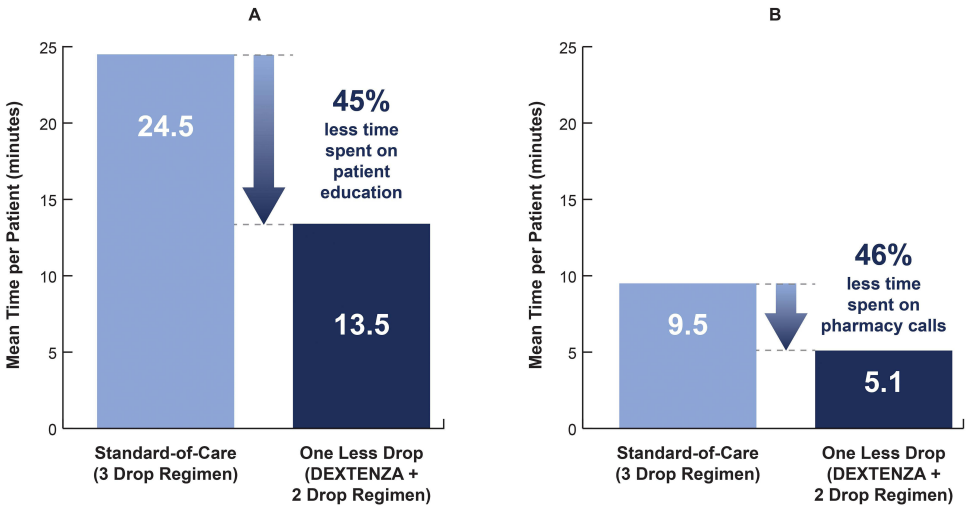

Figure 6 Practice staff time spent on patient education and pharmacy callbacks reduced with DEXTENZA. (**A**) Practice staff spent 45% less time on patient education and (**B**) 46% less time on pharmacy calls with DEXTENZA compared to the standard of care 3-drop regimen.

practices, the use of DEX was estimated to save approximately 40 hours per week—the equivalent of a full-time employee—in each practice.

Practice Satisfaction

Most practice staff (94.7%) were satisfied (score of 5, 6, or 7 on a 7-point Likert scale; mean score of 6.2) and 5.3% were neither dissatisfied nor satisfied (score of 4 on a 7-point Likert scale) with using DEX as a new means of providing 30 days of steroid treatment for cataract patients (Figure 7). No practice staff reported any dissatisfaction (score of 1, 2, or 3 on a 7-point Likert scale) with DEX. Among practice staff who were satisfied with DEX (score of 5, 6, or 7 on a 7-point Likert scale, n = 19), the top reasons for satisfaction included improved patient compliance due to fewer drops (94.7%), more convenient recovery for patient (78.9%), ability to use DEX in a variety of cataract patients (68.4%), and reduction of patient call-back time (57.9%) (Table 2).

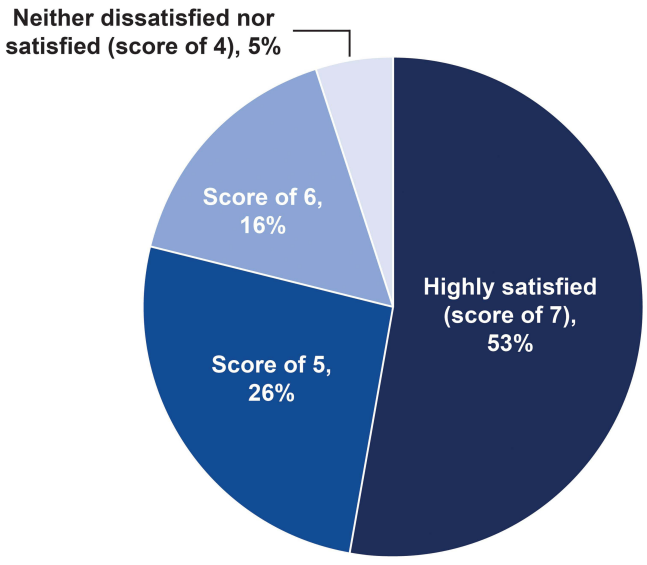

Figure 7 Satisfaction of practice staff representatives with using DEXTENZA as a new means of providing 30 days of steroid treatment for patients undergoing cataract surgery. Scores are based on 7-point Likert scale with 1 being highly dissatisfied, 4 being neither dissatisfied nor satisfied, and 7 being highly satisfied. Approximately 95% of practice staff representatives were satisfied to highly satisfied.

Table 2 Satisfaction of Practice Staff Representatives (N = 19) with DEXTENZA

Characteristics	Neither Dissatisfied nor Satisfied (Rating=4) n (%)	Satisfied (Rating=5) n (%)	Very Satisfied (Rating=6) n (%)	Extremely Satisfied (Rating=7) n (%)
DEXTENZA provides adequate pain control post-surgery	4 (21)	0 (0)	1 (33)	3 (30)
Intracanalicular inserts are a preferred way to achieve sustained drug delivery	4 (21)	1 (17)	0 (0)	3 (30)
DEXTENZA reduces inflammation	8 (42)	2 (33)	1 (33)	5 (50)
DEXTENZA improves patient compliance (fewer drops)	18 (95)	6 (100)	2 (67)	10 (100)
DEXTENZA may make recovery more convenient for the patient	15 (79)	5 (83)	1 (33)	9 (90)
DEXTENZA can be used in a variety of cataract patients	13 (68)	2 (33)	1 (33)	10 (100)
DEXTENZA can be used in various ocular surgeries	4 (21)	1 (17)	1 (33)	2 (20)
DEXTENZA is FDA approved providing evidence of good safety and tolerability	8 (42)	2 (33)	1 (33)	5 (50)
DEXTENZA reduces patient callback time	11 (58)	3(50)	0 (0)	8 (80)

Abbreviation: FDA, Food and Drug Administration.

Discussion

This survey study demonstrated that patients perceive drops to be a troublesome aspect of post-operative care and are satisfied to extremely satisfied with DEX following cataract surgery to reduce the medication burden. Practice staff were satisfied with the impact of DEX on their practices, reporting an average reduction of almost 50% in time spent educating patients on postoperative medication use.

The patient experience reported in this study—with 92% preferring DEX over topical steroid therapy—is similar to that seen in prior studies. In a qualitative companion study to the phase 3 cataract surgery trials, 92% of patients reported that they were very satisfied with DEX, 100% found insert comfortable (84% were unaware of it), and 96% found it convenient or very convenient compared to eye drops.[26] In a real-world evaluation of patient experiences with DEX administration in one eye compared with topical therapy in the other eye following cataract surgery, 96% of patients (N = 56) expressed a strong preference for the eye treated with DEX, with comparable outcomes in pain and inflammation management.[27] High percentages of preference (53%–90%) for DEX over drops were noted following other ophthalmic procedures and disorders, including photorefractive keratectomy, refractive lens exchange, small incision lenticule extraction, and meibomian gland dysfunction.[13,20,27,28]

Adherence associated with DEX use was an important attribute identified by both patients and practice staff. Regimen complexity is an established contributor to nonadherence.[28] The use of DEX eliminated 4 drops per day in the early postoperative period and eliminated the need to follow a complex tapering schedule over a 4-week period. Even with the reduction by one medication and 4 drops per day, 80% of patients still missed 1–2 drops (mean 1.9) during the first postoperative week. Practice staff expressed concern regarding patient adherence to the complex postoperative regimen, and the topical steroid—and the need to taper its frequency over time—was felt to pose the greatest challenge to adherence. As for difficulty administering drops, only 18% of patients in our study reported no trouble instilling the drops, which is consistent with other studies reporting that up to 91% of patients report difficulty with self-administration of topical eye drop therapies.[5,8,9,29,30] These findings indicate that in the real-world setting, DEX may provide more consistent dosing over topical steroids, which may improve control of inflammation, and may reduce the risk of vision-limiting adverse events such as cystoid macular edema, which is the most common cause of decreased vision after cataract surgery.[23]

Perhaps the greatest impact of DEX use on clinical practice was a nearly 50% reduction in time spent educating patients on how to use their postoperative drops. Patient education on drop use decreased by 45% when DEX was used, and the time spent addressing pharmacy calls regarding medication use decreased 46% when DEX was used. This equates to 15.5 minutes per patient, and in a busy cataract practice performing 150 or more cataract cases per week, this time commitment (~40 hours per week) equates to that of a full-time employee. This finding was consistent with a study

by Lindstrom and colleagues that found that the majority of the calls to the physician offices were from patients or pharmacies regarding substitutions for prescribed post-cataract surgery eye drops and that approximately 3000 staff hours were spent annually by physician offices with high cataract surgery volume in responding to patient or pharmacy questions.[10] Thus, there are potentially meaningful cost savings available to practices using DEX in most or all of their cataract surgeries.

Data collected outside conventional randomized clinical trials provide insights into adapting a hands-free and sustained release steroid therapy into routine clinical practice from a patient and practice staff's perspective. Our analysis of the surveys in the study was intended to be descriptive, and the small sample of patients and practice staff representatives may not project the opinions of a larger population of patients and practice staff representatives. The number of survey questions was limited and does not include all aspects of medication therapy or of the postoperative period. Some patients did not answer or responded with "unknown", which limited the findings of this study. Given that patients did not use corticosteroid drops in their postoperative period, patients could only assume whether they would prefer DEX over traditional therapy. Patients and practice staff representatives completed the survey retrospectively; thus, as with all surveys, the results are limited by the respondent's abilities to accurately recall and report data.

Our study has a few limitations. First, the study lacked a control group and the authors relied on the patients' past experiences with topical eye drop use. We limited this study to a select number of sites (ophthalmology practices) who had agreed to participate in the study. Secondly, the site selections for the study were not random. Hence the surveyed clinical staff at the ophthalmology practices do not represent the entire population of clinical staff in the United States. Lastly, the survey responses of patients may have been limited by their ability to accurately recall and report data.

Conclusion

DEX is a physician administered and sustained release therapy designed to provide a tapering dose that may improve adherence and offers a potentially significant cost savings to practices due to time saved on patient education regarding postoperative medication use.

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Disclosure

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