

Using Real-Time Feedback During Cataract Surgery To Improve Refractive Outcomes

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Wavefront aberrometry has become a common method of determining refractive error in conjunction with corneal refractive surgery (e.g., LASIK). The technology has now been adapted for use in cataract surgery, providing surgeons with a tool that allows them to measure refractive error during surgery. WaveTec Vision (Aliso Viejo, CA) began commercializing ORange,[®] their intraoperative wavefront system, in early 2009. The company asked SM2 Strategic to conduct interviews with a group of surgeons who have the most experience with the technology.

The five surgeons collectively have treated over 800 eyes using this intraoperative wavefront system, which is based on Talbot Moiré interferometry. The purpose of this paper is to better understand the way this technology has impacted how surgeons approach their cases, especially with respect to the treatment of cylinder. Consequently, surgeons described how this tool is being used to bring immediate improvement over previous visual outcome results and how this impacts patient satisfaction. Equally important, analysis of the impact on both time (surgical time per case) and money (incremental surgical fee per cases) is shown to give surgeons evaluating the technology for their ASC or hospital a sense of how it can be implemented. Finally, qualitative comments by those interviewed are included to give surgeons a sense of how this technology fits in to the rapidly evolving field of cataract surgery.

Background

For the past decade, the use of wavefront aberrometry for laser vision correction has steadily increased. First employed as a diagnostic tool to allow comparison with manifest refraction, it has emerged as the dominant method of refraction in LASIK, with wavefront data being used to program or “drive” the laser in the majority of cases performed in the United States, according to data reported by Market Scope. Results for customized approaches to LASIK have improved over conventional approaches that utilized manifest refraction. Thus, it makes sense to consider whether or not a similar application of wavefront technology could be utilized to improve

outcomes for cataract surgery. Significant innovation that is taking place in lens technology as well as lens placement creates a need to improve other aspects of the surgical process, including how refractive error is measured and handled.

ORange constitutes the first-ever ability to conveniently perform wavefront-guided refractions on patients during cataract surgery itself. The device is mounted directly to the surgeon’s operating microscope and measurements are taken in the same co-axial line of sight used to visualize the eye and perform surgery. The device is connected to a separate workstation that is used to display refractive results for the surgeon. The software analyzes the data to give surgeons real-time information regarding sphere, cylinder and axis, enabling them to make decisions regarding the need to reduce residual and/or induced astigmatism while still performing the procedure. The software provides real-time wavefront-guided refraction readings following limbal relaxing incisions that allow physicians to

further optimize the LRI’s and reduce remaining astigmatism. When using Toric IOLs, the software similarly provides data to confirm axis placement or to rotate the IOL to optimize results.

Interviews were conducted with five of the leading users (see Table 1), all of whom are also adept cataract and LASIK surgeons. Early stud-

ies performed by these surgeons and their colleagues showed that using ORange for cases where the patient presented with astigmatism did indeed lead to a reduction in post-operative cylinder when compared to not using the intraoperative wavefront device. This was due to the ability to perform LRI (planned and unplanned), take additional readings, and then perform another LRI if necessary. In these studies, surgeons reported mean reduction in cylinder of 0.5 diopters that could be attributed to the surgical intervention allowed by ORange. With more experience, surgeons are finding that the real value of the technol-

Table 1: Surgeons Interviewed for ORange

SURGEON/LOCATION	TOTAL CASES TO DATE
Eric Donnenfeld, MD Garden City, NY	125
Stephen Lane, MD Minneapolis, MN	66
Mark Packer, MD Eugene, OR	77
Dan Tran, MD Newport Beach, CA	228
Robert Weinstock, MD Largo, FL	314

ogy resides in the “outliers” that are prevented by using ORange. “Outliers are very expensive,” noted Dr. Mark Packer. “There’s a huge cost not reflected in the expense of doing a LASIK enhancement; it’s the cost of a patient in tears who returns after surgery and says ‘I can’t see well’ and tells people they had surgery with me and look what happened.” The ability of a technology to prevent this scenario — and positively impact patient referrals — is of significant interest.

Impact on Surgical Approach

Patient Selection

Surgeons report that ORange is used with four types of cataract patients:

1. Corneal astigmatism that requires correction
2. Refractive cataract cases involving either toric or presbyopia-correcting IOLs
3. Prior corneal refractive surgery (e.g., LASIK or RK)
4. High myopia

Additionally, Dr. Dan Tran indicated that he will use ORange to help “referee” any discrepancies in his pre-op numbers or calculations. While the overall mix of cases varies among these surgeons, they are all performing “premium” cataract surgery that comprises the refractive IOLs as well as conventional monofocal IOLs. The need for astigmatic correction typically occurs in about one of every three cases, some of which is not recognized during pre-op examination, according to these surgeons.

Surgical Intervention

The availability of intraoperative wavefront refractions has created a new paradigm for the cataract surgeon. Prior to ORange, the desire for a LASIK-like outcome was dependent on the excimer laser to fine-tune results in accordance with patient expectations, a process that typically occurs several weeks to months following the primary procedure. As an alternative to laser, LRI has also been used as an enhancement tool. But the results, according to Dr. Robert Weinstock, were “hit or miss” and didn’t account for wound-induced cylinder. “We employed a ‘wait and see’ philosophy for the first few weeks and then performed either LRI or excimer.” This variability in LRI outcomes limited its use and kept surgeons from aggressively treating pre-existing or residual astigmatism.

What’s changed is the ability to fine-tune the LRI during the primary cataract procedure; real-time refractive data is being used to affect a real-time change in the refractive outcome. “This seems like a ‘nice to have’ until

you use it; then it becomes a ‘must have,’” noted Dr. Eric Donnenfeld. The immediate feedback has made LRI viable once again as a treatment modality. “I didn’t do LRIs prior to ORange; it’s now part of my standard toolkit,” noted Dr. Stephen Lane, who now uses it routinely in patients with astigmatism who are having conventional monofocal implants.

Impact on Enhancements

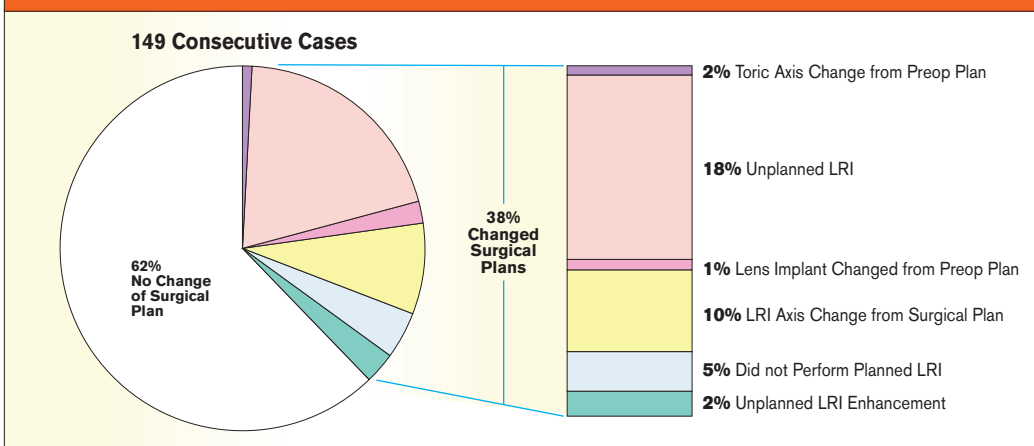
A direct by-product of increased intraoperative intervention is the corresponding reduction in the need for post-operative enhancement. Across the board, the surgeons reported a significant decrease in the number of patients needing enhancement in the 1 to 3 month post-operative period. Within this group, two surgeons published studies with relevant data: Dr. Packer performed a retrospective study to determine the impact of wavefront-guided LRIs at time of surgery on the rate of future post-operative laser enhancement. In the first group of patients (n=37 eyes) that were not measured with ORange, 6/37 (16%) went on to have LASIK enhancement. In a second group of patients (n=30 eyes) with similar pre- and post-operative characteristics that were measured with ORange, only one (3%) of the eyes went on to have LASIK enhancement, as 8/30 (27%) eyes received LRI during the primary procedure based on ORange findings. Dr. Packer contends that the results achieved in the study demonstrate the potential for cataract surgeons to reduce the burden on their patients and themselves by eliminating the need for additional procedures.

In a study focused specifically on 48 post-LASIK patients that subsequently required cataract surgery, Dr. Tran discovered that the ORange refractive readings provided significantly greater predictability of final refraction vs. intended than a historical control group as reported by Warren Hill, MD et al. In essence, the corneal distortion created by prior refractive surgery made data from ORange more reliable than that obtained from other available diagnostics (Pentacam, IOL Master, Manifest Refraction). Additionally, Dr. Tran concluded that the need for enhancement based on study data dropped from 23% of eyes to 6%, a nearly four-fold decrease.

Impact on Patient Satisfaction

The ability of ORange to increase overall patient satisfaction is also evident among the surgeons who were interviewed. “I am better able to nail the result and reduce the need for the patient to come back for more surgery,” exclaimed Dr. Donnenfeld. “These two go hand-in-hand in creating happier patients.” The value

Figure 1: Impact of ORange on Surgical Enhancement Plans



proposition for the patient is clear to Dr. Weinstock: “We are seeing many more 20/40 or better patients on Day One post-op, which means more smiling faces and excitement.” Added Dr. Tran, “ORange allows me to create immediate patient satisfaction that I wasn’t getting before. I now have patients who are happier in their first 3 months, many of whom will never need that enhancement.” All of the surgeons voiced the ability to enhance the “wow” response by patients as moving in the direction of LASIK outcomes. “Historically, patients had to wait weeks and months to see well after cataract surgery,” said Dr. Donnenfeld. “ORange increases the chances that we can make the Day One post-op experience much better. This is a critical moment that I believe is when patients are most excited and most likely to tell their friends about what happened.” He added, “I never want to hear a patient say on day one, ‘I thought I’d see better than this.’” While direct measurement of patient satisfaction is difficult to obtain, Dr. Lane’s metric is put this way: “fewer patients are coming back wanting me to do more. That’s really good.”

Consecutive Case Study

Early results from a study to assess the impact of this technology on all cataract cases is showing the potential of ORange to improve overall outcomes by changing the way surgeons approach their cases. ORange was used to measure eyes on 156 consecutive cataract cases performed by Dr. Weinstock that included monofocal, toric and presbyopia-correcting IOLs. Successful images were obtained on 96% of cases or 149 eyes. Of those, 56 eyes (56/149 = 38%) had their surgical plan changed as a result of the ORange readings. The majority of these (26/149 = 18%) underwent LRI not previously planned but indicated by the intraoperative readings. The inverse was also true, as 8 eyes (8/149 = 5%) originally scheduled

for LRI had them cancelled based on intraoperative readings. The balance of surgical changes made are shown in Figure 1. The impact on surgical protocols are mirrored by the impact on Dr. Weinstock himself, who was initially resistant to the study concept but then became excited after seeing what transpired: “This is a great feeling of accomplishment that sends me into the next operating room on a

more positive note because I know I’m going to get better results than I did previously.”

Impact on Surgical Time

One important factor is the impact on total time to perform a cataract procedure. Once the learning curve for the technology has been achieved, surgeons are estimating it takes an extra 2-3 minutes per case to incorporate ORange. A Company-initiated time and motion study (See Figure 2) confirmed the surgeons’ subjective impressions about the additional time required. A single measurement took 21 seconds on average to perform. When additional measurements as well as surgical intervention (i.e., for LRI) was factored in, the total impact was to add 2-4 minutes of surgical time per case. This time can be further sub-divided into that required to measure the eye (average of 45 seconds, taking into account multiple measurements), with the balance of the time devoted to the surgeon thinking and then acting upon the data at hand. “This technology causes me to think on my feet more quickly,” exclaimed Dr. Weinstock.

Figure 2: Impact on Surgical Time

Surgeons	Donnenfeld, Lane, Packer, Tran, Weinstock
# Of Cataract Cases Measured	45
Average Time Per Cataract Procedure	12 minutes (range: 6 to 25 minutes)
# Of ORange Measurements in Procedure	# Cases
One Reading:	18
Two Readings:	13
Three Readings:	8
Four Readings:	4
TOTAL	45
Average Time for Each ORange Measurement	21 seconds
Average Time for All ORange Measurements	45 seconds
ORange as a % of Total Surgical Time	7%
Typical Increase in Surgical Time – Including Intervention	2-4 minutes

Impact on Fee Schedule

The commercial success of a medical device rests on its ability to “pay for itself” as part of the overall procedure cost and process. On top of the capital expenditure for the system, use of ORange entails a separate expenditure that ranges from \$60 to \$150 per case, based on monthly utilization. All the surgeons interviewed have a tier fee schedule for cataract surgery that incorporates the use of ORange as a refractive component that can be billed separately to patients. As shown in Figure 3, Surgeons typically employ a three-tier system, with astigmatic correction via LRI at the first level (fees of \$500 to \$1,250 per eye), astigmatic correction via toric IOL correction at the second level (\$1,200 to \$1,600 per eye), and presbyopia correction at the third level (fees of \$2,000 to \$3,250 per eye). All surgeons increased fees several hundred dollars or more to cover ORange. Dr. Packer increased his historical fee to perform LRI by \$225 to incorporate ORange, while Dr. Lane’s fee includes a \$300 refund to the patient if LRI is not required. Dr. Weinstock uses a two-tier system that collapses ORange plus any required astigmatic correction (LRI or Toric IOL) into a single fee.

Impact on Patient Counseling and Conversion

Each of the surgeons has employed a script that allows them and their surgical counselors to describe the benefits of ORange to prospective cataract patients. Common themes include the use of a new tool that can measure the eye and guide the surgery, allowing the surgeon to give the patient better vision after surgery without glasses. Drs. Tran, Donnenfeld and Packer all indicate nearly 100% acceptance in those monofocal cases where astigmatism needs to be corrected. For patients with prior refractive surgery, Dr. Tran is even more emphatic: “I tell patients that I must use this tool to give them the best result and that it has a separate fee. If they don’t want it, I simply won’t do their surgery.” Surgeons’ counselors indicate that describing ORange helps ease anxiety when counseling patients. Dr. Weinstock continues to refine his description into even more patient-friendly understanding: “We tell patients that the doctor is ‘shooting a light into the eye to make sure the power is correct and if any adjustment is needed.” In a year over year comparison of conversion rates to one of the two refractive packages offered by Dr. Weinstock, the practice found that when ORange is offered as part of these packages, conversion increased from 46% to 87% for a refractive package that included astigmatism correction. For the presbyopic-correcting

Figure 3: Fee Schedules With ORange

	Average	Range	Fee Increase for ORange
ORange + LRI	\$845	\$500 - \$1,250	\$225 - \$300
ORange + Toric IOL	\$1,440	\$1,200 - \$1,600	\$225 - \$500
ORange + PC IOL	\$2,504	\$2,000 - \$3,250	\$0 - \$250 (\$0 = included in overall fee)

package, conversion increased from 41% to 52% (Note: all patients who were clinically qualified were offered one of these two refractive packages). While other surgeons have yet to specifically measure ORange’s impact on conversion, they all agree that ORange has increased the confidence among patients that they are in the right place with the surgeon using the right tools to optimize results.

Summary and Discussion

The success of LASIK as a vision correction procedure has placed similar pressure on cataract surgery to produce refractive-type results. The utility of ORange is proving itself among these skilled surgeons, who vary in practice style and patient volume. It is clear from the surgeon interviews that having real-time refractive data during surgery increases their confidence to act immediately to improve visual outcomes while simultaneously reducing the need for future enhancements. While all results get incrementally better, it is the prevention of an outlier or refractive surprise that may generate the greatest benefit to the surgeon. Experienced surgeons know that the cost of a less-than-desired outcome is far higher than the additional chair time and laser expense. The real cost is in the loss of referrals from a dissatisfied patient. Figure 4 shows the economic justification for use of the technology as a means to improve a patient’s refractive outcome from cataract surgery.

In addition to the benefits derived from the current system, we look forward to assessing the value of the soon to be released aphakic power calculation in helping physicians optimize refractive outcomes.

Figure 4: Managing Refractive Outcomes

	LASIK, Without ORange	LRI, With ORange
When Performed	Separate Procedure, 30-90 days Post-Op	Simultaneously, During Cataract Procedure
Cost to Perform	\$600 - \$1,000 per eye	\$60 - \$150 per eye
Ability to Charge a Patient Fee	No, especially when included in fee for PC IOL	Yes, especially when performed in conjunction with monofocal IOL
Patient Fee Amount	None	\$845 per eye (average)
Applicable Patient Population	10-20% of PC IOL cases that require enhancement	33% of monofocal IOL cases that present with at least 1 Diopter of Cylinder
Improvement in Patient Satisfaction	30-90 Days post-op	Day One post-op