

Wavefront-Guided Custom Cataract™ Surgery A New Value Proposition for Cataract Surgeons

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In the spring of 2009, WaveTec Vision (Aliso Viejo, CA) began commercializing a new device for cataract surgeons based on a simple premise: providing refractive information during the procedure would help improve clinical results achieved following the procedure. The company's ORange® intra-operative wavefront system is now being used by approximately 90 surgeons at 43 sites in the United States, and WaveTec has devoted much of its resources to improving the algorithms used to measure refraction and provide data that allows the surgeon to intervene and adjust refractive error during the primary procedure.

SM2 Strategic was asked to survey nine of its users and report on their usage of the device, current opinions, and predictions towards future adoption by cataract surgeons.

These nine users' (see Figure 1) collective experience exceeds 6,000 cases with ORange and represents approximately 38% of the clinical experience to date, making this group of surgeons a good proxy for how the device is being used in clinical practice.

This report aims to quantify this collective experience in order to better understand the economics of the ORange system and assist other surgeons

in their decision-making process regarding implementing the technology in their own practices. The survey covered four different aspects of the cost associated with using ORange: 1) changes in surgical fees to cover the cost of the device; 2) the cost/benefit ratio of time to perform ORange during cataract surgery versus time spent managing unsatisfied patients; 3) impact on enhancement rates and associated savings (in both time and money) by not having to perform them; 4) impact of additional patients from improved conversion and doctor referral.

Overall Clinical Impressions

ORange's goal is to improve upon the results already achieved in the most commonly performed surgical procedure in the US. Given the already high level of safety and efficacy that has been achieved in cataract surgery, many doctors have questioned the device's role: "I was skeptical it would bring value to me or my patients," admitted Fayetteville, NC surgeon Michael Woodcock. "I have never been so wrong. The added accuracy and predictability has caused my personal confidence to soar." His sentiment reflects one year and 1,300 cases experience, and he offers the device to all cataract patients and closely tracks outcomes to demonstrate its benefit.

The other eight surgeons in this survey have two or

more years experience and have seen ORange improve significantly in terms of accuracy and impact on refractive outcomes. They trust it more, especially with the latest version 2.5 software release (August 2010), which improved the user interface, capture rate, and surgical guidance. That software release has led these early users to deem ORange a commercially viable product. According

Figure 1: Surgeon Experience and Impact on Enhancement Rate

Surgeon	# ORange Procedures (as of 3/1/11)	Enhancement Rate	
		Prior to ORange	With ORange
Kerry Assil, MD	1,042	20% ----->	3%
Eric Donnenfeld, MD*	478	35% ----->	8.5%
Stephen Lane, MD	278	10% ----->	5%
Mark Packer, MD	217	16% ----->	3%
Kerry Solomon, MD	165	N/A ----->	N/A
Dan Tran, MD*	556	17% ----->	6%
Robert Weinstock, MD	798	10% ----->	6%
William Wiley, MD	1278	15% ----->	3%
Michael Woodcock, MD	1630	10% ----->	2.5%
TOTAL:	6,442	-	-
AVERAGES:	716	17% ----->	5%

* applies only to patients with prior refractive surgery.

to Stephen Lane, MD, "My confidence level is now to the point where I know ORange gives me better data on irregular corneas than what I can get with with IOLMaster or Lenstar." All surgeons except one are using it to titrate astigmatism, and all surgeons believe it a "must" for performing cataract surgery on someone who has had prior refractive surgery. Kerry Solomon, MD had tried ORange a year ago and initially did not find it valuable in changing his decision-making. He has collaborated with the company to improve software and now reports that "recent data on post-refractive cases is quite good." As a result, he is confident in charging patients because of significant value it brings to those

cataract patients with prior LASIK or PRK. Aphakic aberrometry “gives us a new opportunity,” exclaimed Eric Donnenfeld, MD. Some use it on nearly all their cataract cases, while others use it predominantly on their premium IOL cases. (Note: In late 2010, the company changed its plan from a per-use fee to a monthly subscription, enabling surgeons to pay one fixed fee each month and use the device on as many patients as they choose).

Southern California surgeon Dan Tran first used ORange simply to cross-check his own spreadsheet-driven calculations for cataract patients with prior refractive surgery. Over time he has found himself increasingly relying on ORange’s AnalyzOR software, which enables him to select the best IOL intra-operatively. “ORange has helped me refine the surgical planning process and saves me a lot of time,” remarked Dr. Tran, who uses ORange on all prior refractive cataract cases.

Overall, the improving reliability of the device is translating into greater reliance upon it by surgeons and increasing usage in the OR. One-third of WaveTec Vision’s accounts have already added a second unit in an additional operating suite, further testament to its increasing utilization with time and experience.

Impact on Fees

When ORange was first launched two years ago, some initial users were reluctant to increase their fees, a natural result of not knowing how the technology would improve outcomes. As a result of their increasing confidence in ORange technology, all surgeons have increased their fees for cataract surgery: 7 of 9 increased their premium IOL fees by several hundred dollars to include ORange, and most have a separate fee when only ORange is indicated that ranges from \$100 to \$700 (e.g., the patient presents with astigmatism and not having a presbyopic or toric IOL). This range reflects differing philosophies about when to use ORange. Lower fees are associated with surgeons who use ORange on most to all of their cases. These surgeons will even use ORange on non-paying patients, choosing not to inform the patient yet using the tool to improve outcomes. Higher fees are associated with surgeons who tend

**Figure 2: Unhappy vs. Happy Patients
The Real Cost to a Practice**

Post-op	Happy	Time Spent	Unhappy	Time Spent
1 Day	seeing 20/25 “hugs and kisses”	5	seeing 20/60 “not seeing clear, still foggy” - must reassure patient	10
1 Week	“Wow! I love it” ready to schedule fellow eye	5	“still don’t see great” - must reassure again and do refraction; not ready to schedule fellow eye	15
1 Month	final visit - very happy	5	heavy atmosphere in room; repeat reassurance and refraction; hold on 2nd eye until 3 month visit	15
3 Month	Not necessary	-	Schedule 2nd eye along with touch up for 1st eye; have no idea how many lost referrals; must also inform co-managing OD	10
4 Month	Not necessary	-	Feels like uphill battle	10
Total Minutes		15		60
			Additional Minutes	45

Source: Dan Tran, MD

to limit use of ORange to premium IOL cases. They have increased their premium IOL fees and also have a separate intra-operative refractive assessment fee for use of ORange along with performing an LRI.

Kerry Assil, MD was the first surgeon to use the ORange system and it has become a key tool in his surgical approach with patients, which has been to expand the definition of premium to include any patient that wants to be independent

from glasses. “Delivering on the promise of ‘seeing without glasses’ is an all or nothing proposition...ORange has lived up to its promise with astigmatism.” Dr. Assil’s use of ORange is part of a protocol that has led to 80% of his cataract patients seeking some form of premium package when choosing surgery. In his case and others, ORange provides the feedback loop needed to improve outcomes as a means of building the premium segment of the practice. That is, the return-on-investment is viewed “globally” to the overall practice through increased revenue from premium procedures rather than applied “locally” to the device itself.

Impact on Time

Using ORange adds 15 seconds per image capture, and most users take 2-3 images. Taking into account prep time to ensure good tear film and IOP, overall impact on the case is between 1-2 minutes. All surgeons believe it is worth the extra time during surgery, as the extra time in surgery pales in comparison to the extra time spent with an unhappy patient (See Figure 2). Michael Woodcock’s view on the extra time sums up what surgeons who use ORange express: “I look at it from the patient’s perspective, who always wants their surgeon to be careful and get it right. ORange helps me get it right, and that is totally worth the extra bit of time each case takes.”

Impact on Enhancements

As shown in Figure 1, post-cataract enhancements have been reduced significantly for all surgeons. Pre-ORange levels ranged from 10% to 35%. Using ORange, that range is now below 10% for all surgeons, ranging from 2.5% to 8.5%. These results confirm the findings of a controlled comparative study on more than 100 eyes by Mark Packer,

MD, which showed a marked reduction in the need for LASIK enhancements post-operatively by titrating residual cylinder intra-operatively based on ORange measurements. “The outliers go away once you have ORange,” noted Dr. Packer. The cost of enhancements does not readily boil down to a single number and is more relevant when analyzed by several key components:

Time/Cost spent in clinic: Surgeons face a potential enhancement when trying to turn an unhappy patient into a happy one. Before looking at that direct cost, it is valuable to assess the impact on the post-op visit regimen, as outlined in Figure 2. Dr. Tran’s experiences shows increases in duration of visits (15 minutes vs. 5 minutes) and frequency (1 to 2 additional visits) are the norm, adding approximately 40 minutes of doctor time in terms of reassuring and refracting unhappy post-op patients. Dr. Packer’s clinic generates \$1,200 per hour per room. That 40 minutes of time translates into \$800 opportunity cost – revenue that cannot be generated because the capacity is being used to compensate for “not getting it right the first time.” To this, one can add the cost of performing additional diagnostic tests as required to ameliorate patient concerns.

Cost of performing the enhancement: Direct expenses associated with performing enhancements depend on the technology employed: LRI costs \$60 - \$150, while the laser costs \$600 - \$1050 for using a more sophisticated tool and hoped-for precision in eliminating residual refractive error. Surgeons performing even a handful of enhancements each month are spending thousands of dollars per year to fix a primary procedure’s outcome.

Loss of Referrals: All surgeons who use ORange are aware of the negative impact on referrals from a patient that is unhappy, even if the situation resolves itself 3-4 months post-op. Figure 2 contrasts the tone of post-op visits between a happy and an unhappy patient. Drs. Tran, Donnenfeld and Packer all described that “queasy feeling” as a surgeon when you know a patient is living the first 3 months with sub-optimal vision; ORange helps eliminate that feeling. William Wiley, MD summarizes the financial impact as follows: “It’s hard to put a value on the happy patient but I can tell you the cost of the unhappy patient.”

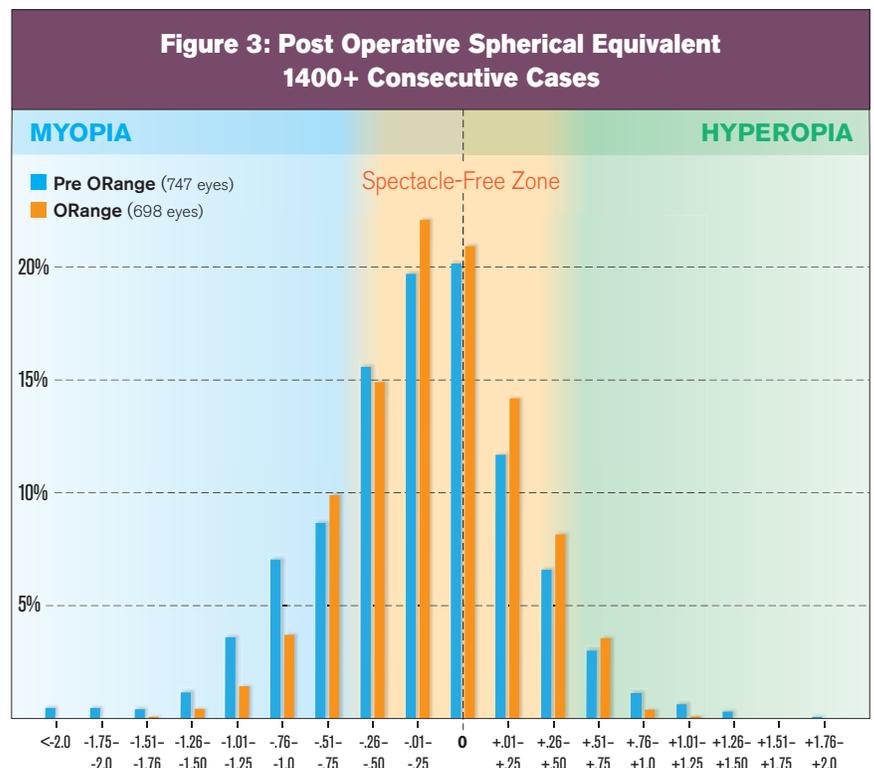
Impact on Additional Procedures and Patients

The third area to measure economic impact is in growth of procedures due to a combination of increased conversion rates (to premium, self-pay procedures) and additional new patients.

Staff Confidence: While many surgeons in this survey have not measured conversion rates in a way that can isolate the impact of ORange, all of the surgeons universally agree that ORange has fostered greater belief and confidence in their ability to deliver expected outcomes for premium (self-paying) patients, and that this increased confidence is apparent when they and staff are counseling patients.

Patient Conversion and Satisfaction: Two surgeons, however, have closely tracked the impact of ORange on conversion rate. As previously reported, Robert Weinstock, MD saw conversion rates nearly double for toric implants (going from 46% to 87% of eligible patients) and increase for presbyopic implants from 41% pre-ORange to 52% with Orange.

The change in patient conversion to premium IOLs for Michael Woodcock has come as a natural by product of a methodical study of the impact of ORange on post-op spherical equivalent. He has compared outcomes achieved on 700 eyes operated on just prior to adopting ORange with the first set of 700 eyes operated on using ORange. As shown in the distribution of outcomes across these eyes (see Figure 3), a higher percentage of eyes are within +/- 0.25 diopters of plano, the heart of the emetropic spectacle free zone. His pre-ORange results would be classified as excellent, as 74% of his eyes are within one-half diopter of plano. The data show that ORange has improved Dr. Woodcock’s accuracy even further; in this first series of nearly 700 eyes, over 80% of eyes were within a half-diopter of plano (Dr. Woodcock believes the next 700 cases will



show even better outcomes). He believes the improved accuracy has a direct impact on conversion rates to premium IOLs, which have moved from 30% to 39% since incorporating ORange. He credits ORange with increasing the belief among himself and his staff in their ability to deliver on the promise of helping patients live spectacle-free.

OD Referral Patterns: Six of nine surgeons report that ORange has positively and significantly impacted optometric referrals, as optometrists appreciate the ability to return patients from cataract surgery whose refractions are “spot on like never before,” remarked Dr. Woodcock. Several surgeons noted they have gained additional ODs referring patients because of the presence of ORange itself and the improvement of outcomes noted when the patient returns to the optometrist for follow-up.

The potential of enhancing relationships with referring doctors can be illustrated through this account from Dr. Wiley: One of Dr. Wiley’s happy patients happened to be the father of a non-referring optometrist who chose Dr. Wiley because of ORange. That patient encounter has led the OD to shift his referrals to Dr. Wiley, resulting in a significant number of added surgical patients for the practice each month, half of whom choose premium IOLs. While this may be a special situation, it illustrates the potential appeal of such a device to optometrists in the community.

Summary and Discussion

Every new technology struggles to gain adoption with customers, and WaveTec Vision’s ORange is no exception. It has taken several years and multiple iterations of software to come to a point where customers now believe that the technology used to measure refraction intra-operatively is robust and commercially viable.

Surgeons in this survey are seeing an overall economic justification based on increased fees, time savings in clinic, and improved stature with staff, patients and referring doctors. The required investment threshold to obtain ORange has been lowered to make this technology accessible to a much wider group of surgeons. With costs that are now fixed at just under \$50,000 per year* to use the technology, it becomes viable for most cataract surgeons. As more surgeons evaluate the technology and ask themselves whether it is worth the cost, it is essential to keep in mind the future direction of cataract surgery and, more importantly, the emerging patient. In 2011, the first of 78 million Baby Boomers turned 65. This generation has shown a willingness to pay for improved lifestyle in material goods, higher levels of service, vacation experiences, and elective healthcare. “Seeing better as one gets older” is certainly no exception to this, and tools that help the surgeon fulfill this expectation will resonate with both surgeon and patient.

How ORange is shifting the Value Proposition for Cataract Surgeons

ORange has changed the way surgeons are discussing cataract surgical options with patients. Here is a sampling of how the value proposition that a surgeon can offer his patients is changing, thanks to ORange:

What Patients Want

“ORange allows us to make the right decision in the moment. So we now ask, ‘do you want your astigmatism eliminated?’ rather than ‘do you want us to do an LRI?’; We now understand that what they want is to not wear glasses, not have a specific service.”

-Mark Packer, MD

LRI Included at No Extra Fee

“For prior refractive patients, my fee to use ORange varies based on whether or not I did their original LASIK surgery. If they need an enhancement (LRI or laser) post ORange, I include it as part of the ORange fee, which gives them a feeling of greater value.”

-Eric Donnenfeld, MD

Getting it Right the First Time

“My use of LASIK to enhance cataract surgery has dropped from 20% to under 5% (which I will still do to make patients happy). This tells me that 95% + of my premium patients are happy coming out of the gate... and are excited about telling their friends.”

-Kerry Assil, MD

Offered to All Patients

“I offer and recommend ORange to all cataract and IOL patients. I have the outcomes to demonstrate the benefit of using ORange in all of these patients, even high myopia. As a philosophy, I always strive to do my best. How can I rationalize only offering my best work to “premium” patients? Everyone values their vision and their eyes.”

-Michael Woodcock, MD

Spending Time Now vs. Later

“ORange has cut my enhancement rate in half to 5%. The slight increase in time that the test takes to perform is more than worth it to get the right IOL power. These extra seconds spent during surgery certainly outweigh the hours I might have to spend with an unhappy patient.”

-Stephen Lane, MD

*Over 36 months, the device costs are \$36,000 per year fixed use cost plus \$13,333 per year in amortization and service, for a total of \$49,333 per year. This amount decreases slightly after year 3.