

Combining Placido and OCT Imaging Technologies: Bringing Diagnostic Power to Corneal Analysis

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The ability of ophthalmic clinicians to evaluate the cornea has improved dramatically over the past quarter century. From the era of manual keratometry, new methods of imaging and analyzing corneal structure have emerged and have moved corneal care from an analog to a digital world.

In the past 10 years, an explosion of technology has emerged that at times can overwhelm the eye care practitioner. SM2 Strategic was asked by Carl Zeiss Meditec (Dublin, CA) to help eye doctors understand the path of development that has taken place and the tools that are now available to help with corneal analysis in everyday clinical practice. Three leading corneal specialists as well as a pioneer in corneal imaging were interviewed: Amin Ashrafzadeh, MD (Modesto, CA), Robert Cionni, MD (Salt Lake City, UT), Roger Steinert, MD (Irvine, CA) and Stephen Klyce, PhD (Port Washington, NY). These doctors provided their perspective on the technological milestones that have led to the current state-of-the-art in corneal imaging.

This report summarizes those interviews and intends to provide ophthalmologists with an appreciation of how rapidly the field has changed, while offering guidance in terms of decision-making with respect to future investment in corneal diagnostics.

Technology Development

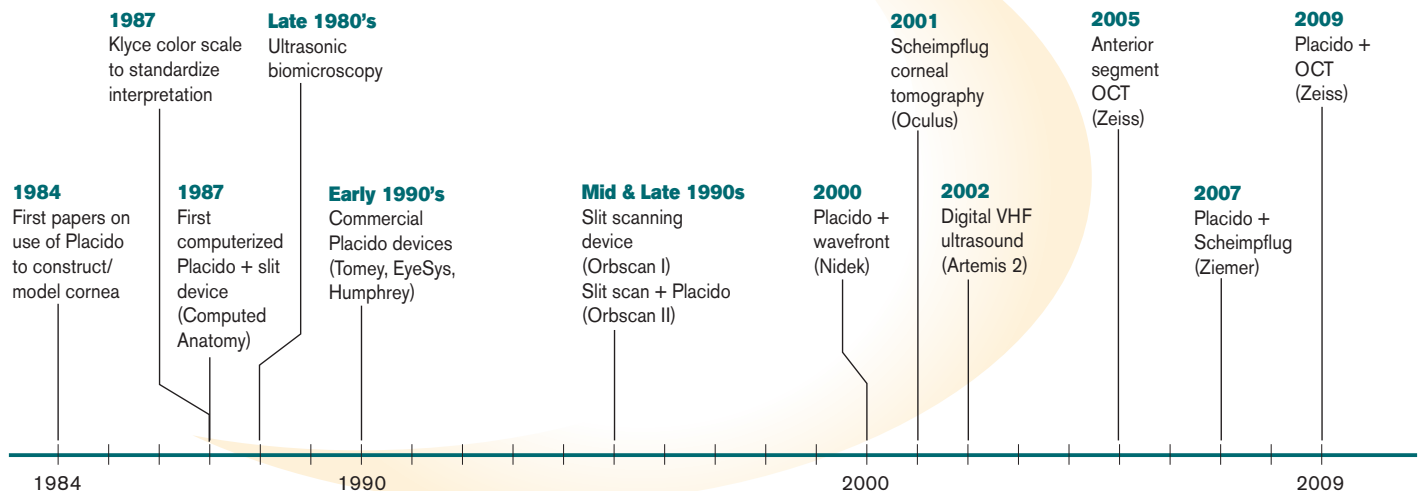
The past quarter century has provided stellar innovation in the realm of imaging and diagnosis of the cornea (see Figure 1). For most of the 20th century, clinicians had three basic tools available: the slit lamp, providing

a direct and magnified view of the cornea; keratometry, measuring the change in curvature in the central 3 mm of the cornea; and contact pachymetry, showing corneal thickness at each point of appplanation. By the mid 1980s, published papers by Rowsey, et al showed how Placido rings could be used to construct the cornea, and in 1987 Stephen Klyce, PhD (along with Leo Maguire, MD) introduced the color-coded contour map and scale to standardize interpretation, which evolved and became an ANSI Standard. The following year saw the introduction of the first computerized corneal topographer (Computed Anatomy). The modern age of corneal imaging was officially underway.

Since that first device, innovation in both imaging and interpretation has been spurred by clinical need and the rise of refractive surgery. In the 1990s, corneal topography proliferated and gave refractive surgeons the ability to measure the eye's surface out to 10 mm (ie, beyond the optical zone) both before and after laser vision correction. Devices from Tomey, EyeSys, and Humphrey (acquired from ORC) proved most popular with clinicians. By the late 1990s, surgeons realized that they needed a better way to screen for corneal thinning and determine which prospective LASIK patients were most at risk for ectasia and/or keratoconus.

Product developers focused on new approaches to imaging. Orbtec's Orbscan device used a scanning

Figure 1: 25 Years of Corneal Analysis Development Timeline



slit-beam to image the back surface of the cornea, giving clinicians posterior measurements and the ability to calculate elevation from the front to the back of the cornea. It was limited to 4 diopters of elevation change and required higher-skilled technicians to prevent patient eye movement and get reliable readings. In 2000, Nidek's OPD Scan combined Placido + wavefront measurement in a single device. The use of ultrasound (e.g., ultrasonic biomicroscopy) gave high quality images of corneal structure, but had fallen out of favor with clinicians due to the required contact via a probe or water bath. In contrast to Placido-based topographers, Oculus' Pentacam tomographer used slits to generate cross-sections of the cornea and reconstruct them into a singular image. There were now two different technologies popular for clinical diagnosis, each deriving its final answer from different approaches: the Pentacam, using Scheimpflug imaging, measured elevation directly and then calculated corneal curvature, while Placido measured corneal curvature directly.

Surgeons were drawn to the Pentacam's ease-of-use with patients and the interpretive software developed by Jack Holladay, MD; as a result, the Pentacam sold briskly to refractive surgeons in the early 2000s. By 2005, Carl Zeiss had developed an anterior segment OCT device to complement their rapidly-adopted posterior segment version for use in retina and glaucoma. The Visante OCT provided extremely crisp images of corneal structures, allowing both increased width of coverage (out to 16 mm) as well as depth of coverage (up to 6 mm). This advanced technology took multiple "Optical A-scan" images of the cornea and then re-constructed these slices into a "Optical B-scan" image, putting directly into the clinic images never before available (except in part from histology slides). The new "map" of the eye included a different pachymetric approach that automated pachymetry measurement with exponentially greater data points (2,048). This eliminated the potential inaccuracy from

measuring corneal thickness manually at a handful of well-spaced locations in the central cornea.

While this device could be used in tandem with a corneal topographer to provide greater information, it initially lacked the interpretative power afforded by the Holladay report. By 2007, corneal analysis software for the ATLAS 9000 (known as Pathfinder II) gave clinicians an anterior topographic screening module to help identify abnormal corneal conditions. And by 2009, Zeiss linked both the ATLAS and Visante together, calling the merged technologies Visante Omni. Each device now accessed the other's data, first to ensure proper biometric registration of the eye, then to conduct precise analysis of corneal structure and changes over time. Interpretation was greatly enhanced when Visante Omni

incorporated the traditional Holladay report plus several new color-scale maps to help diagnose, specifically early corneal pathology such as suspect keratoconus.

Clinical Significance

Many diagnostic innovations sought to improve upon Placido measurements and render them obsolete, yet hindsight reveals a different outcome. "We have come full circle," noted Roger Steinert, MD. "We now realize Placido-based technolo-

gies as the most reliable way to analyze anterior corneal topography." Cornea specialist Amin Ashrafzadeh, MD has been using corneal topography to plan and analyze surgical outcomes since 2001 and believes the Placido disk "remains one of the most essential instruments for imaging the corneal surface." He lamented, however, that "up until several years ago, you still had a lot of work to do in figuring out why you had an odd-looking cornea."

That burden changed, according to both Steinert and Ashrafzadeh, when surgeons gained the ability to correlate topography with corneal thinning. Both had attempted to use Scheimpflug – which had become commonplace for routine refractive cases – to help with this more sophisticated analysis, but found that they

Figure 2: Corneal Imaging Technologies and Applications

	GALILEI	ORBSCAN	PENTACAM	VISANTE OMNI
TECHNOLOGY:	Placido + Scheimpflug	Placido + Slit Scanning	Scheimpflug	Placido + OCT
Anterior & Posterior Topography	●	●	●	●
Narrow angle evaluation	●	●	●	●
Clear Corneal Wound Evaluation	●	●	●	●
Cataract Evaluation and IOL Placement Analysis	●	●	●	●
Evaluation of Pars Plana	●	●	●	●
Corneal Transplant Planning & Follow-up	●	●	●	●
Iris Tumors	●	●	●	●
Imaging Through Opaque/White Corneas	●	●	●	●
Phakic IOL Planning	●	●	●	●
	● Full Capability	● Limited Capability	● No Capability	

“The real value of Visante Omni is its ability to evaluate numerous data... all in one place”

Robert Cionni, MD

checked the Placido images and found they were accurate; this triggered the realization that we needed to go back to Placido based topography.” While the ability to use a single device was indeed convenient, Dr. Ashrafzadeh found that the Pentacam software would “fill in” missing data points improperly on slightly irregular surfaces. “I liked the way that Scheimpflug image looked, but even looks can be deceiving.” Both remarked that the presence of artifacts in Scheimpflug images of suspicious corneas has been a troublesome aspect of that technology.

This issue appears to have been solved through the linking of Placido and OCT, and the applications extend beyond the cornea. Robert Cionni, MD has found that the Omni allows him greater ability to evaluate aberrations relevant only to the cornea. “I get better astigmatic analysis with Atlas and my toric IOLs are now more predictable,” according to Dr. Cionni.

Evaluation of glaucoma patients has been greatly enhanced by Omni. “Pupil size and the resultant angle opening are not influenced by Visante’s non-visible light, providing an exquisitely accurate measure of physiologic angle opening,” stated Dr. Ashrafzadeh.

Efficiency in the Clinic

Some clinicians view it a disadvantage to have to use two devices rather than one as part of their corneal screening. Dr. Ashrafzadeh finds it actually works to his advantage. “I can counsel the patient while I’m doing their Omni readings.” He described how this interaction allows him to educate the patient and discuss candidacy for refractive surgery, while also giving the patient “significant confidence in seeing the whole process in action. Omni takes away a lot of the mystery by allowing me to describe what I’m doing and what the images are telling me...in real time.”

Dr. Cionni added, “I am able to show a patient how removing their astigmatism will improve their quality of vision as well.”

“If you use Visante for other applications such as evaluating the angle, then you actually gain efficiency

were too often led down the wrong path in reaching the correct diagnosis. “Anterior topography from the Pentacam was pointing to a completely different area for astigmatism, and treating this made cylinder worse not better,” said Dr. Steinert. “I went back and

in reaching diagnosis,” remarked Dr. Steinert. Figure 2 shows the different capabilities of four popular corneal imaging devices. An earlier survey by SM2 Strategic of 32 of the first users of Visante showed significantly greater usage than anticipated once they had the device in their practice and had become familiar with its capabilities.

Interpretation Becomes Critical

The sheer volume of data on the cornea now available to clinicians places a premium on software analytics that can reliably distill the images and data points so they make sense in diagnosis. “The amount of information can be overwhelming,” according to Dr. Ashrafzadeh. “The Holladay report helps tremendously but still has deficiencies that cause me to evaluate the ring image overlaid atop the report.” The real value of Visante Omni, remarked Dr. Cionni, is its ability to evaluate numerous data such as topography, corneal aberrations, ICL positioning, pachymetry, ectasia analysis, angle measurements... all in one place. Indeed, clinicians should view Visante Omni as a workstation with multiple capabilities rather than a niche device.

Early Detection Capabilities

Each surgeon interviewed agreed that the Pentacam itself is sufficient for the refractive surgeon who is mainly concerned about corneal elevation. If you are dealing only with normal corneas, they say, then the Pentacam is fine. The dividing line is drawn around earlier detection of corneal abnormalities. Dr. Ash did a comparison study of 60 eyes, measuring them both on the Pentacam and the Visante Omni. His findings were that on corneas with no prior surgery and no opacities, there was good agreement between the devices. But in patients with prior refractive surgery, significant differences emerge. In this study, Visante showed much greater consistency in posterior surface findings compared to the variability in readings from the Pentacam, which also tended to under-detect post-LASIK ectasia. The findings on the Visante Omni correlated much more closely to what he was seeing clinically.

“At present, Visante Omni is the only technology that I can truly rely upon for subtle changes.”

Roger Steinert, MD

This type of study illustrates the sentiment of Dr. Steinert regarding a surgeon’s ability to trust the device you are using: “You need confidence in your device if you are doing refractive surgery to pick up the subtle things like Form Fruste

“You must use Placido for early detection of Keratoconus”

Stephen Klyce, PhD

suited to screening the cornea, as it is 20x less sensitive than Placido to changes in the amount of corneal curvature. “The use of posterior corneal data has not been shown convincingly to be useful for early detection. Anterior surface Placido is the standard; you must use Placido for early detection of Keratoconus.”

Reimbursement

Lastly, changes in reimbursement effective January 2011 puts into effect a new code for Anterior Segment OCT (92132, a Category 1 CPT code). Prior to this, doctors were treated unevenly. Some were able to bill and get reimbursed, while others’ claims were denied. The presence of a new code – specifically for anterior segment OCT – will help achieve a consistency that is better overall when one considers patient care standards on a national basis. Although it is tempting to bemoan the fact that the code now pays bilaterally (i.e., \$36.35 national average reimbursement for both eyes), the previous SM2 survey showed users billing an average of 18 uses per month out of 47 uses overall (including refractive evaluation). With a specific billing code in place to guide clinicians, one would expect the reimbursable usage to increase significantly. A pro-forma analysis is

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Stephen Klyce, PhD, widely regarded as a pioneer in corneal imaging and analysis, believes that Scheimpflug is not well

shown in Figure 3. As patient loads increase with the aging population, this justification becomes even more attractive and helps the ophthalmic practice harness the power of these two innovative technologies.

Summary and Discussion

Ophthalmic diagnosis and treatment paradigms have evolved significantly in the past two decades. Better diagnostics for the cornea have improved surgeons’ abilities to the point that most recognize they can perform refractive surgery on patients who were not considered candidates ten years ago...and vice-versa. The negative publicity surrounding LASIK in the past several years can be attributed in part to the lack of understanding of the cornea in the initial period following US commercialization. What surgeons needed – and now have – is a clinical “safety net” as a result of technological innovation.

The power in diagnosis afforded by Visante Omni and its marriage of Placido and OCT technology raises the bar for all ophthalmic surgeons in several respects. First, increased understanding of the risks presented by abnormal corneas – and how to best mitigate those risks – puts a premium on being able to detect it earlier in its development. Second, an aging population will bring an increasing prevalence of all eye diseases, including those in the anterior segment (e.g., glaucoma). Taken together, these two issues put additional pressure on clinicians to get the right diagnosis in an efficient manner. And just as the lines between refractive and cataract surgery are blurring, technology such as Visante Omni is making it possible for all ophthalmic clinicians to more accurately diagnose disease.

Figure 3: Return On Investment

	VISANTE	VISANTE omni	KEY ASSUMPTIONS
Cost			
Cost Per Month	\$708 – \$1,018	\$982 – \$1,382	Monthly lease cost includes device and service for 5 years. Range reflects value of trade-in, and new/refurbished unit.
Reimbursed Procedures			
OCT (CPT code 92132)	\$647	\$647	18 reimbursed procedures per month (from prior SM2 survey of Visante users); national average reimbursement of \$36.35 bilateral
Corneal Topography (CPT code 92025)	-	\$700	20 submitted claims per month (25% of 80 eyes per month) \$35 average reimbursement
Non-Reimbursed Procedures			
OCT	\$1,044	\$1,044	29 per month (from prior SM2 survey of Visante users); \$36 per eye component of elective fee, built-in to refractive fee for LASIK and/or Premium IOL's
Total Return per Month	\$1,691	\$2,391	
Return on Investment Ratio	1.7x – 2.4x	1.7x – 2.4x	