IOLMaster 500 and Integration of the Holladay 2 Formula for IOL Calculations

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The IOLMaster,® first launched as a novel approach to obtaining biometric data, has evolved over the past decade to become the predominant device and standard routine as part of a surgeon's IOL calculations prior to cataract surgery. Previous surveys by SM2 Strategic have documented its value as a tool in modern cataract surgery as well as the ongoing improvement of the platform in terms of both speed and ability to accurately read through dense cataracts.[1,2] Carl Zeiss Meditec (Dublin, CA) recently launched a new innovation that brings the Holladay 2 formula directly into the IOLMaster device, an upgradable feature that is designed to further improve outcomes with added convenience to the surgeon and increased workflow. SM2 Strategic was asked to provide a historical perspective on the evolution of IOL formulas, which was accomplished through a review of the literature and an interview with Jack Holladay, MD, well-known as a surgical innovator, optics expert, and developer of today's leading Holladay 2 formula.

History of IOL Formulas

The theoretical basis for today's advanced IOL power calculations were first developed over 100 years ago, and for decades surgeons worked with an assumed anterior chamber depth (ACD) of 4.5 mm. The original first-generation formulas of the early 1980s, such as Binkhorst 2, are best described as "single variable" formulas that used biometric measurement of axial length in its calculations.[3] In 1988, the Holladay 1 formula added keratometry to offer the first "two variable" formula, which helped improve accuracy in short and long eyes. Over time, more robust diagnostic measurement of ocular structures has allowed for more refined formulas to be developed. "The only difference between today and older formulas," remarked Dr. Holladay, "is how we predict the effective lens position (ELP)."

Indeed, the third-generation formulas such as Holladay 1, Hoffer Q, and SRK-T each had their strengths and weaknesses and became segmented for use with the specific eye type (short, medium or long) of which each was best-suited. These formulas assumed that anterior segment size was directly related to axial length. This assumption resulted in "surprise" outcomes, especially in short eyes.

Figure 1: Relative Importance of Variables Affecting IOL Calculation
(From Worldwide Study of 34,000 Eyes)

1. Axial Length	*100*
2. Average K	*76*
3. Horizontal WTW	*24*
4. Refraction	*18*
5. Anterior Chamber Depth	*8*
6. Lense Thickness	*7*
7. Age	*1*

Source: Jack Holladay, M.D.

The Role of ELP

The Haigis formula (circa 1991) uses ACD and axial length as two variables to predict the effective lens position. One limitation of the Haigis formula was that it required a large data set of several hundred cases from a surgeon in order to be "optimized," and further optimization required the use of an excel spreadsheet. (Note: in 2010, Carl Zeiss' release of the IOLMaster 500 included optimization of the Haigis formula within the device, reducing the number of cases to 50 that a surgeon needed to input in order to effectively use the formula).

In 1993, Dr. Holladay led a worldwide study involving 34 cataract surgeons to determine which of seven variables were relevant as predictors of effective lens position. In addition to axial length (now measured optically) and K readings, data were collected on horizontal white-to-white (WTW), refraction, ACD, lens thickness, and patient age at time of surgery. Because of the 2% incidence in the population of short eyes, a large data set of from 34,000 eyes was collected and analyzed to determine relative significance of each variable, as shown in Figure 1. "We were surprised to learn that horizontal white-to-white measurements emerged as the next most important variable relate to ELP after axial length and Ks," remarked Dr. Holladay. "We also proved that there is almost no correlation between axial length and size of the anterior segment in 80-90% of eyes."

The results from this study led to the release of Holladay 2 formula and an easy-to-use program that allowed for data entry of the new variables and instant calculation of ELP and the appropriate IOL power selection. It also led to a new paradigm of evaluating eyes by both their axial length (short, normal, long) and their anterior segment size (small, normal, large). In essence,

there are now nine eye types – not just three – that could be used to classify a given patient's eye,[4] as shown in Figure 2. The WTW measurements demonstrated that normal axial length eyes (21-26 mm) had an equal distribution of eyes being of either large (2%) or small (2%) anterior segment size. In short axial length eyes (<21 mm), 80% would be considered normal and 20% would be considered small in terms of anterior segment size. In eyes of long axial length (>27 mm), "ELP is much less a factor than obtaining an accurate axial length measurement in the first place, because the IOL power is so low," commented Dr. Holladay. Following this study, 17 independent, peer-reviewed studies have been published showing improved accuracy with the Holladay 2 formula.

Figure 2: Categorization of 34,000 Eyes Axial Length vs. Interior Segment Size

Anterior Segment Size	Short	Normal	Long
Large	*Megalocornea + Axial Hyperopia (0%)*	*Megalocornea (2%)*	*Large Eye Buphthalmos Megalocornea + Axial Myopia (10%)*
Normal	*Axial Hyperopia (80%)*	*Normal (96%)*	*Axial Myopia (90%)*
Small	*Small Eye Nanophthalmia (20%)*	*Microcornea (2%)*	*Microcornea + Axial Opia (0%)*

Source: Jack Holladay, M.D. — Axial Length

Impact on Modern Cataract Surgery

"For the first time we understood clearly why cataract surgeons were struggling to gain 'refractive-like' outcomes on a more consistent basis," added Dr. Holladay. "This study showed that the more you know about the anatomy, the better you can predict the outcome. But, you must automate your measurements to get the benefits of the precision of the formula."

Holladay 2 has emerged as the "state of the art" IOL calculation formula and today is the leading formula used by US surgeons.[5] With over 11,000 IOLMaster devices are in use worldwide, Carl Zeiss has now made it a priority to increase access to this formula by integrating it directly into the IOLMaster itself. Until now, using Holladay 2 required transfer to an external computer as well as purchase of a separate software package.

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Through an exclusive agreement with Dr. Holladay, IOLMaster users can now upgrade their IOLMaster and do calculations within the device, eliminating the need to transfer data to an external computer and the need to purchase a separate software package. While other systems still require data transfer to a PC in order to gain access to the Holladay 2 formula, Dr. Holladay confirmed that "the IOLMaster 500 is the only instrument on the market that has the Holladay 2 formula inside the unit."

Summary

Improvements in technology have allowed accuracy of cataract surgery to double every 5-10 years.[6] The IOLMaster device and the Holladay 2 formula are key contributors to this trend. Current surveys suggest that 8 of 10 surgeons use the IOLMaster platform, yet only 3 of 10 surgeons use the Holladay 2 formula. The fact that Zeiss has now "married" them into the same box will only help increase access to the Holladay 2 formula. "I'm gratified that a much larger population of surgeons and their patients will benefit from the improved accuracy of IOL power calculations by having direct access to the Holladay 2 formula," remarked Dr. Holladay.

As more and more surgeons face increasing demand on their time and skills due to an aging population (that also often has higher expectations on their cataract outcomes than in the past), the convenience offered by this upgrade will have a positive impact on clinic workflow and overall reputation of the ophthalmic surgical practice.

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1 Mahdavi, S. *The IOLMaster and its Role in Modern Cataract Surgery*, November 2011, available at www.sm2strategic.com.

2 Mahdavi, S. *IOLMaster 500: Improving Upon the Gold Standard in Biometry for Cataract Surgery*, November 2010, available at www.sm2strategic.com.

3 Tyson, F. *Choosing the Proper Formula for Accurate IOL Calculations*. Ophthalmology Times, August 2006.

4 Holladay JT, Gills JP, Leidlein J, Cherchio M. *Achieving Emmetropia in Extremely Short Eyes with Two Piggyback Posterior Chamber Intraocular Lenses*. Ophthalmology. 1996; 103: 1118-23.

5 2011 *Leaming Survey of ASCRS Members*, available at www.analeyz.com.

6 Hill, W. *Highly Accurate IOL Calculatons*. Cataract & Refractive Surgery Today, March 2005.67-70.