

Diabetic Retinopathy detection at the point of care with the ZEISS VELARA Teleretinal Screening System

Introduction

As healthcare systems and payors increasingly focus on quality measures and access to care, there is a need to bring services closer to patients, thereby improving the patient experience and combating rising healthcare costs. One way that this is being achieved is by expanding the reach of the doctor to non-traditional care settings. This method requires new technologies and creative business models.

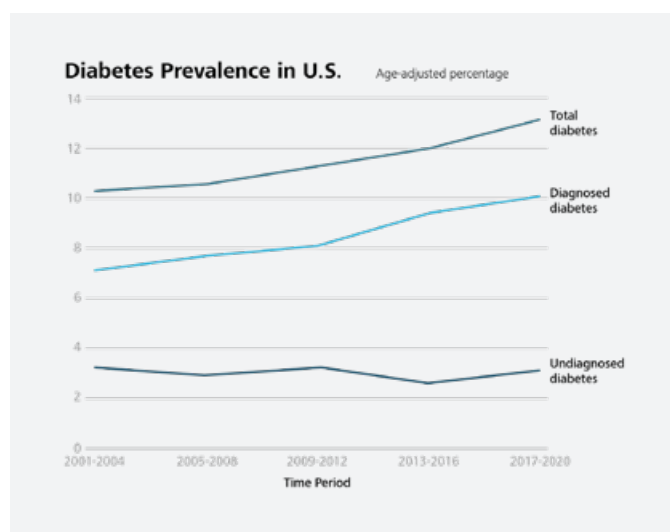


Figure 1. Total, Diagnosed and Undiagnosed Diabetes Prevalence in the United States. Data source: 2001–March 2020 National Health and Nutrition Examination Survey.²

Understanding the problem

In recent years, there are currently more than 37 million people in the United States with diabetes, which represents over 11% of the entire US population^{1,2}. Further, the prevalence of diabetes in the US continues to rise (Figure 1) and reports estimate that by the year 2050, the number of Americans with diabetes will range from 1-in-5 to 1-in-3.³

Unfortunately, less than half of insured diabetic patients get annual eye exams to screen for indications of diabetic retinopathy.⁴ Diabetic Retinopathy is the number one cause of blindness among working age adults in America⁵, and 60,000 individuals in the U.S. go blind annually from this disease.³ Excess social costs associated with blindness are substantial. The direct and indirect costs of blindness per individual have been estimated at \$4,944 and \$54,614, respectively.⁵ Fortunately, the repercussions of advanced diabetic retinopathy can be prevented with early diagnosis and treatment.^{6,7}

Outlining past challenges

Despite the significant benefits of diabetic retinal examinations, adherence with annual recommendations remains poor.⁴ These low compliance rates have caused many healthcare systems to be penalized due to poor Healthcare Effectiveness Data and Information Set (HEDIS) quality scores, low performing Healthcare Organization (HCO) ratings, loss of quality bonuses, low risk adjusted factor (RAF) rates and poor negotiations of value-based contracts. As retinal exams have not routinely been available at the point of care, primary care providers have had to rely on the patient to schedule and attend an appointment with an optometrist or ophthalmologist, and for those results to be forwarded back to the referring physician for documentation into the EMR. This has created an incredible demand for primary caregivers to be given improved control in meeting these important metrics.

Implementing a diabetic teleretinal imaging program allows primary care providers to take pictures of a patient's retinas during their regularly scheduled primary care appointment. Those photos are forwarded to an optometrist or ophthalmologist who reviews the images and returns a diagnosis and follow up plan to the referring provider. Numerous point-of-care based teleretinal solutions have been developed in the past which have provided many lessons learned regarding ease of use, payor uptake, and impact.

Most standard retinal cameras have been designed for use by skilled imagers and for patients with fully dilated pupils, limiting their use to optometry and ophthalmology clinics. Handheld cameras have been a popular option for screening due to their portability and small footprint. However, they can be difficult to use for non-ophthalmic personnel, potentially reducing an image's gradeability, thereby trading increased portability for reduced image quality.⁸

Another common issue has been a lack of end-to-end data connectivity; if data doesn't flow seamlessly from one provider to another the results may not get documented appropriately. Some previous solutions for diabetic retinal screening have been fragmented, which have resulted in poor adoption and acceptance.⁹

Other systems have adopted the use of artificial intelligence (AI) to provide quick referral feedback of retinal photos without the review of an eye care professional. Although AI will likely play a role in future retinopathy detection, the current challenge with these systems is that their diagnostic ability has been limited to diabetic retinopathy alone, leaving patients with other pathology such as glaucoma and macular degeneration undiagnosed.

In addition, current AI detection algorithms are strictly binary; resulting in a refer or do not refer treatment plan only. Professional grading allows for an eye care provider to create a customized treatment plan for each individual patient. Some AI solutions have also demonstrated a high false positive rate, which may place an unnecessary burden on patients and eye care providers.¹⁰

Creating a solution

ZEISS VELARA is a complete end to end solution for implementing diabetic retinal screening at the point of care. It was designed to connect diabetic patients, primary care providers, eye care providers, solo and group practices, health systems, and payers. For patients, ZEISS VELARA offers a convenient diagnostic tool that allows physicians to prevent blindness by detecting retinal pathology quickly. For primary care providers, VELARA is a complement to their workflow and allows them to offer an expanded service. Eye care providers benefit from a streamlined process that allows them to detect disease early and maximize their time in the office treating those patients that are in most need of care. Practices, Groups and Health Systems benefit from their ability to meet and exceed quality and performance metrics, and Payers benefit from improved compliance with retinal examination guidelines.

The first component of the system is the VELARA 200 retinal camera (Figure 2). With automated alignment, focus and image capture, the VELARA 200 camera can be easily operated by any clinic staff with only minimal training. The camera is controlled by a mobile tablet that enables the operator to be comfortably positioned anywhere in the room and allows for adequate social distancing when needed. In addition, the tablet provides clear instructions to the imager to ensure streamlined operation. The camera captures a crystal clear 45° image of the fundus of each eye through an undilated pupil.

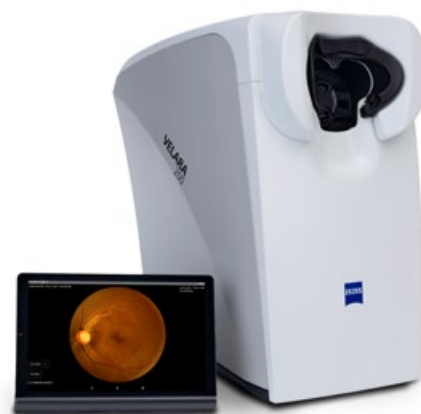


Figure 2. ZEISS VELARA 200 and tablet

The next component of the ZEISS VELARA Teleretinal Screening System is the seamless integration software and cloud-based grading application. After the images are captured, they are automatically uploaded and stored. Images are available for review by readers within seconds in the grading application. A proprietary image enhancement algorithm is used which enhances vasculature and minimizes the impact of artifacts (Figure 3).

The total solution resulted in 94% of collected images being gradable according to a study performed by an independent third-party partner.

The grading application uses simple clickable options to document the presence or absence of diabetic retinopathy and its severity, as well as macular edema. A separate field allows the documentation of any other ocular pathology found during review (Figure 4).

When asked about why the ZEISS VELARA solution was chosen for his clinics:

“It had to be meaningful, but easy to use too. We are not eye specialists. The MAs and LVNs and nurses had to be comfortable using the device. Patients had to be comfortable using the device in a setting that got them in and out without delaying their care. The last key piece was finding specialists that were able to get behind the quality of the exam. For us, it checked all three of those boxes.”

– Pierre Bergougan, CEO, Marque Medical



Figure 3. Unenhanced picture on left and enhanced picture on right

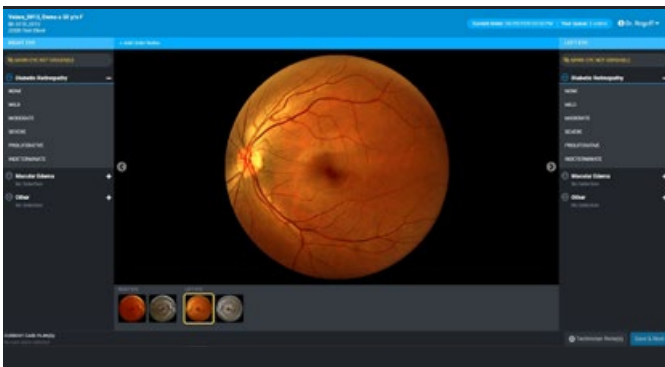


Figure 4. ZEISS VELARA Grading Application

Each diagnosis can be assigned a preferred treatment plan, and once graded, a PDF with images, diagnosis and recommended treatment plan is automatically uploaded into the electronic medical record (EMR) (Figure 5). ZEISS partners with the customer's IT team to streamline, customize, and integrate the VELARA system into their workflow and EMR system. ZEISS leads the process by providing project management resources for an efficient implementation. The system also has FORUM connectivity which maximizes workflow for disease management and long-term care.

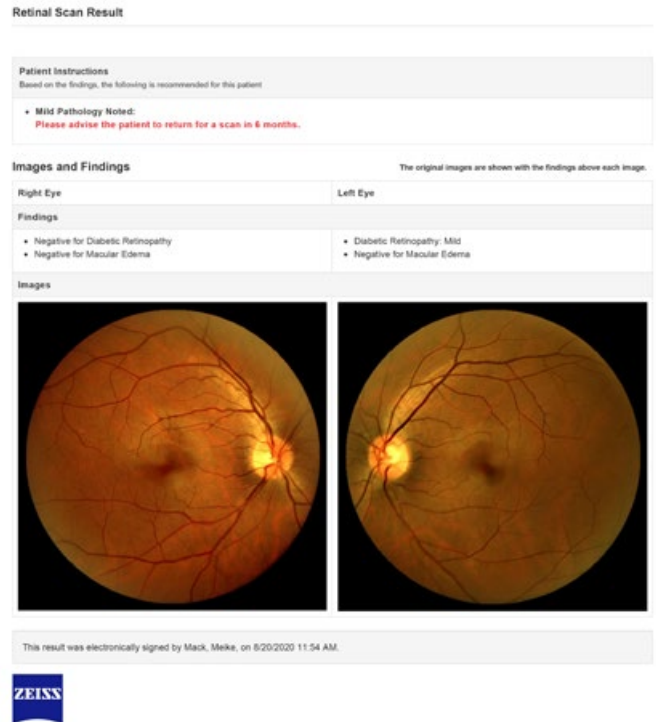


Figure 5. Sample patient EMR Report

Defining the benefits

There are many benefits to implementing a diabetic retinal screening solution at the point of care. A system that is designed for use by primary care providers, health systems, payers and multi-specialty group practices that can be operated easily by clinical staff with minimal training will help close the gap in diabetic eye care and minimize preventable blindness. This will in turn result in improved primary care quality measures, optimized practice workflow and an enhanced patient experience. Centers for Medicare & Medicaid Services (CMS) worked with the National Committee for Quality Assurance (NCQA) to

When asked how the ZEISS VELARA system adds value:

“When they come in and you’re seeing them for a sinus infection and you notice on their history that they are diabetic, you ask them ‘Hey, have you had your vision checked in the last year?’ and they haven’t, now you say ‘Well that’s something we can help you with’ instead of just saying ‘Oh, well you should get that checked.’”

– Nathan Kiskila, MD
Urgent Care General Practitioner
President Founder & Co-Owner
Marque Medical

develop a Healthcare Effectiveness Data and Information Set (HEDIS). These HEDIS measures relate to significant public health issues and can be used to identify opportunities for improvement, monitor the success of quality improvement initiatives, track improvement, and compare care. One of these measures of effectiveness for comprehensive diabetes care evaluates the percentage of diabetic adults who had a timely retinal eye exam to screen for diabetic retinal disease. Medicare Star ratings reward beneficiaries for enrolling in a plan that scores well according to CMS criteria. These ratings also consider the percentage of diabetic adults who have had a timely retinal eye exam.

Medicare Risk Adjusted Factors (RAF) utilizes a statistical process which considers the underlying health status and health spending of the enrollees in an insurance plan when looking at their health care outcomes or health care costs.

“I think, at the end of the day, it’s about population health. Driving better value for patients in more meaningful ways.”

– Elsan Sadri, MD, FACS
CEO & Founder
Visionary Eye Institute

The ZEISS VELARA Teleretinal Screening System also provides the user with a dashboard which includes all necessary metrics for reviewing utilization, performance, and rates of pathology. This dashboard includes screening counts by day, month, or all time, number of screenings with detected retinopathy and number of eyesight saves, a metric which finds moderate or worse retinopathy or other eye conditions which are considered sight threatening and require more urgent referral. In addition, the dashboard includes metrics on average turnaround time by reader and image quality with readability ratings. In a pilot study, the ZEISS VELARA Teleretinal Screening System had a readability rating greater than 95%. 9% of screened patients had diabetic retinopathy, 30% of patients were found to have some other ocular pathology, and 18% of patients had eyesight saves.



Figure 6. ZEISS VELARA Dashboard Metrics

Conclusion

The most notable benefit to the ZEISS VELARA Teleretinal Screening System is the improvement in the health and wellbeing of individual patients who will have sight threatening disease diagnosed at an earlier stage, which will allow timely intervention and treatment. The risk for severe vision loss due to diabetic eye disease can be reduced by 95% with early detection, timely treatment of retinopathy and appropriate follow up care.⁷ The implementation of a comprehensive diabetic retinal screening solution serves to connect diabetic patients, primary care providers, eye care providers, health care systems and payers together to provide quality care in a convenient and timely manner.

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