THE COLLABORATIVE COMMUNITY ON OPHTHALMIC IMAGING

FORMATION MISSION AND INITIAL EFFORTS

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Disclosures for the Presenter Mark Blumenkranz

- BVI
- Combangio Corporation
- Iveric
- Jellisee
- Kedalion Therapeutics
- Lagunita Biosciences
- One Medical
- Optrx
- PEEL Therapeutics
- Verana Health

Ophthalmic Image Capture is Nearly 100 Years Old (1925) But Innovation Was Modest at Best for the First 50 Years Until the Advent of Microprocessors and Lasers in the Late 1970's

RETINAL CAMERAS AND YEARS LAUNCHED:

1925 | 1955 | 2005

Price at launch: $768 → Inflation Adjusted Price: $10,400

Price at launch: $3,000 → Inflation Adjusted Price: $26,635

Price at launch: $40,002 → Inflation Adjusted Price: $48,734

SOURCE: www.zeiss.com

It Finally Exploded Beginning in the Mid 1990's With Powerful Table-Top Devices Enabled by Advances in Digital Capture and Display, Powerful Microcomputers, Widefield and Adaptive Optics and Laser Scanning Fueling OCT Development

Time Domain OCT

Spectral Domain OCT

Swept Source OCT

Combined Retinal Angio + OCT

OCTA

Ultra-Widefield Fundus Imaging

ROP Imaging

Adaptive Optics (AO) Imaging

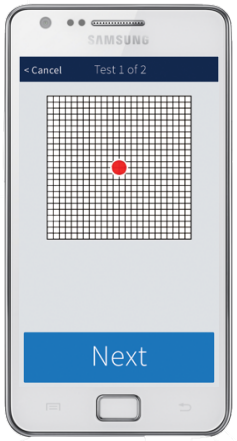
Intraoperative OCT

Virtual Surgical Displays

SOURCES: www.alcon.com, www.claritymsi.com, www.optos.com, www.heidelbergengineering.com

The Invention of Powerful Miniaturized Smart Phones from Apple, Samsung and Google Capable of Capturing Medical Grade Images and Related Out-of-Office Monitoring Created Opportunities for Care Outside the Traditional Office Setting

DIGISIGHT TECHNOLOGIES



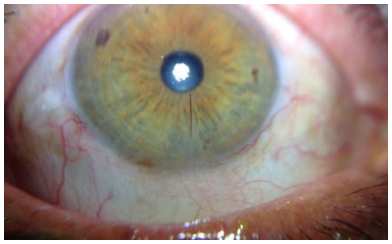
D-EYE

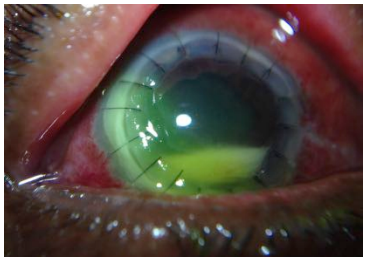
VITAL ART AND SCIENCE

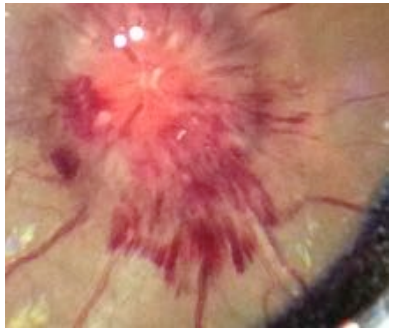
WELCH ALLYN

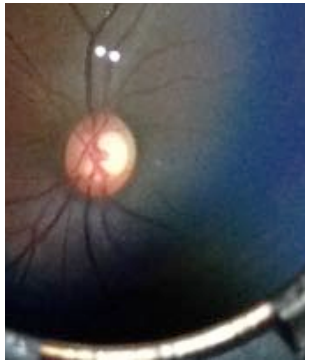
PEEK

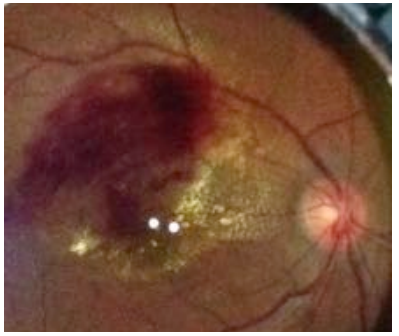
The Use of Portable Devices Has Had a Major Impact in Improving Screening and Advanced Care to Under-Served Populations Around the World











Pediatric and Neonatal Eye Exams
in Europe & Africa

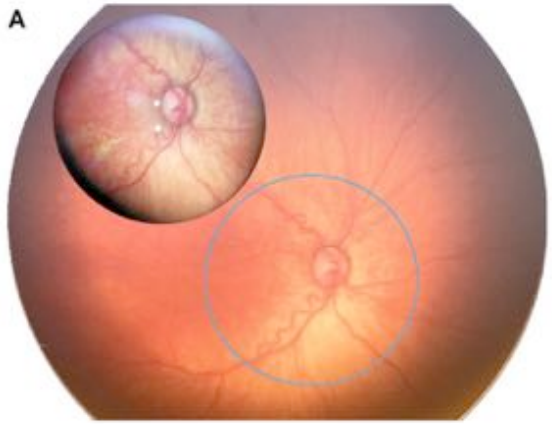
OPEN

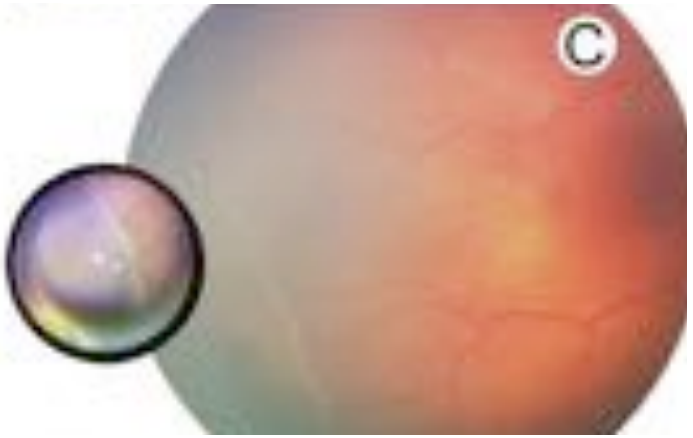
Non-contact smartphone-based fundus imaging compared to conventional fundus imaging: a low-cost alternative for retinopathy of prematurity screening and documentation

SCIENTIFIC REPORTS
nature research

Maximilian W. M. Wintergerst[1], Michael Petrak[1], Jeany Q. Li[1], Petra P. Larsen[1], Moritz Berger[2], Frank G. Holz[1], Robert P. Finger[1] & Tim U. Krohne[1*]

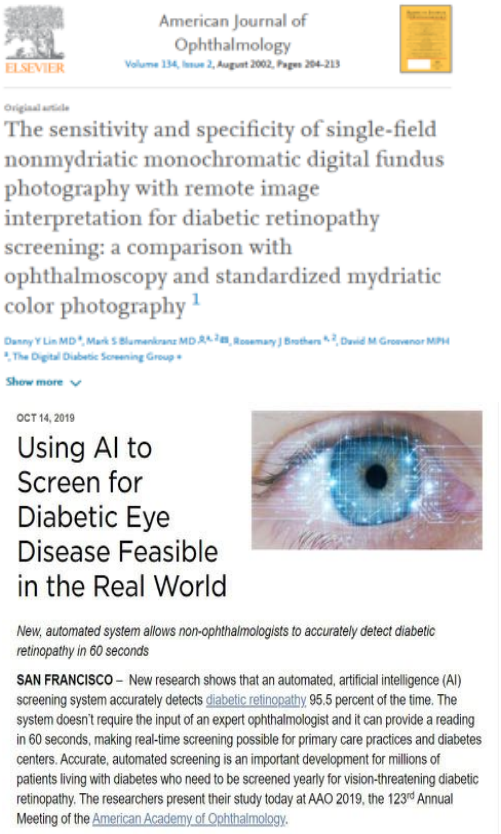
SCIENTIFIC REPORTS | (2019) 9:19711 | https://doi.org/10.1038/s41598-019-56155-x





Paxos being used in Africa for pediatric examinations

Advances in Machine Leaning Have Resulted in the Development of AI Enabled Autonomous Algorithmic Interpretation of Ophthalmic Images that Rival Expert Human Graders and Recently Been Approved for Human Use by the FDA in Ophthalmology



American Journal of Ophthalmology
Volume 134, Issue 2, August 2002, Pages 204-213

Original article

The sensitivity and specificity of single-field nonmydriatic monochromatic digital fundus photography with remote image interpretation for diabetic retinopathy screening: a comparison with ophthalmoscopy and standardized mydriatic color photography [1]

Danny Y Lin MD [a], Mark S Blumenkranz MD [a, 2], Rosemary J Brothers [a, 2], David M Grosvenor MPH [a], The Digital Diabetic Screening Group +

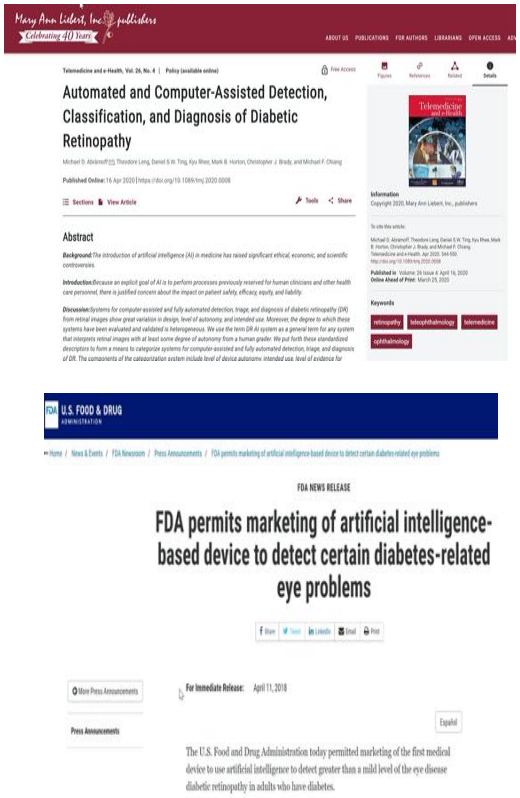
Show more

OCT 14, 2019

Using AI to Screen for Diabetic Eye Disease Feasible in the Real World

New, automated system allows non-ophthalmologists to accurately detect diabetic retinopathy in 60 seconds

SAN FRANCISCO – New research shows that an automated, artificial intelligence (AI) screening system accurately detects diabetic retinopathy 95.5 percent of the time. The system doesn't require the input of an expert ophthalmologist and it can provide a reading in 60 seconds, making real-time screening possible for primary care practices and diabetes centers. Accurate, automated screening is an important development for millions of patients living with diabetes who need to be screened yearly for vision-threatening diabetic retinopathy. The researchers present their study today at AAO 2019, the 123rd Annual Meeting of the American Academy of Ophthalmology.



Mary Ann Liebert, Inc. publishers
Celebrating 40 Years

Automated and Computer-Assisted Detection, Classification, and Diagnosis of Diabetic Retinopathy

Abstract

U.S. FOOD & DRUG ADMINISTRATION

FDA NEWS RELEASE

FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems

For Immediate Release: April 11, 2018

The U.S. Food and Drug Administration today permitted marketing of the first medical device to use artificial intelligence to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes.

FDA's CDRH Identified a Need for Well-Defined Methods to Inform Safety & Effectiveness of Rapidly Evolving Digital Health Technologies

Collaborative Communities: Addressing Health Care Challenges Together

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In the medical device ecosystem, collaborative communities bring together stakeholders to achieve common outcomes, solve shared challenges, and leverage collective opportunities. CDRH believes collaborative communities can contribute to improvements in areas affecting patients and health care in the United States. Accordingly, participation in collaborative communities is one of CDRH's strategic priorities for 2018-2020.

CDRH encourages interested stakeholders to learn more about collaborative communities and review the toolkit, which provides a collection of helpful ideas to foster strong collaborative communities that are well-prepared to take on health care challenges.

What Is a Collaborative Community?

A collaborative community is a continuing forum in which private- and public-sector members, which can include the FDA, work together on medical device challenges to achieve common objectives and outcomes. They are convened by interested stakeholders and may exist indefinitely, produce deliverables as needed, and tackle challenges with broad impacts. Collaborative communities may develop for a number of reasons, including when:

- Challenges are ill-defined or there is no consensus on the definition of the challenges
- Challenges and outcomes are complex
- Partners are interrelated
- Incremental or unilateral efforts to address the challenge have been ineffective
- Partners seek to optimize efforts, including preventing duplication of efforts
- Better outcomes could be achieved with integrating different perspectives, experiences, resources, and expertise.

For more information: Fostering Collaborative Communities to Improve Patient Healthcare (FDA Voices, December 4, 2018)

Members of a Collaborative Community

Collaborative communities typically include diverse, relevant organizations and individuals impacted by a specific topic. For example, patients and care-partners, academics, health care professionals, payers, federal and state agencies, international regulatory bodies, and industry may be engaged as part of a collaborative community.

Key Constituency Groups Involved in and Impacted by Ophthalmic Imaging Were Already Involved in Cooperative Research and Educational Initiatives to Accelerate Innovation in This Field and Elected to Come Together to Organize a Collaborative Community on Ophthalmic Imaging Imaging (CCOI) with FDA Participation

Accelerating Innovation in Ophthalmic Digital Health

New Frontiers for Medical Devices

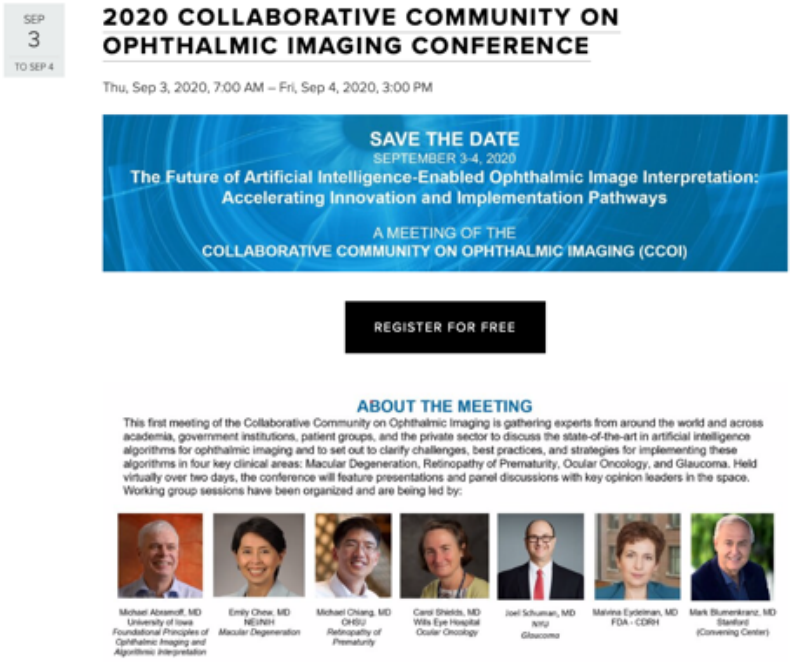
Evaluating New Ophthalmic Digital Devices for Safety and Effectiveness in the Context of Rapid Technological Development

US Food and Drug Administration Regulatory Programs for Innovative Technologies

Collaborative Community on Ophthalmic Imaging Members Mission Statement and Recent Events

OUR MISSION

The Collaborative Community on Ophthalmic Imaging has set out to clarify challenges, best practices, strategies and standards while advancing innovation in the ophthalmic imaging space. The stakeholders involved are seeking to develop solutions to refine the diagnosis, management and treatment of patients with eye diseases, along with other medical conditions.



- Current Members of CCOI

Critical Issues in AI Enabled Algorithmic Image Interpretation That Will Benefit From the Work of the CCOI

- What are the Performance Objectives
  - What are Acceptable Sensitivity and Specificity
  - Are They the Same for Screening, Change Analysis and Prognostication
  - Physician Decision Support or Autonomous Operation
  - Do They Vary Depending on Use Case and Location
  - How Do We Regulate AI Software Capable of Learning and Changing Autonomously Over Time
- What are the Standards for Oversight of Software Developed by Physicians or Healthcare Systems But Not Sold Commercially
- What is the Reimbursement Model
- What is the Liability Exposure
- What are the Ethical Considerations Involved in AI
  - Do Patients Need to Give Informed Consent
  - Do They Receive the Results Directly or Do Their Physicians Convey it to Them