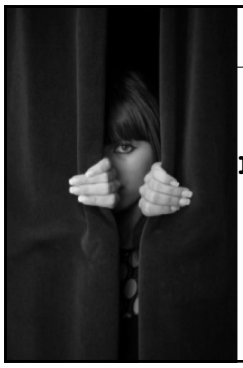

Believe It or Not! Amazing Eye Tech, Astounding Therapies, & Pioneering Procedures– Part 2

COPE# 51848-PS

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Disclosures

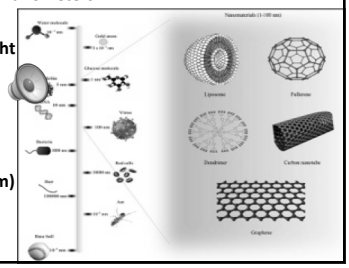
- No financial interest in any product or company discussed
- Some speaking &/or past research with Alcon, Allergan, Bausch & Lomb/Valeant, Pfizer, & Inspire
- Mention of these products in no way implies endorsement by the presenter
- (mention of these products in no way implies expertise on behalf of the presenter either!)

Believe It or Not – Part 2...

- Nanotechnology
- State of the Profession Report
- Wearable Technologies (Frames / Lenses / Contacts / Others)
- Alternative Refracting Technologies
- Implantable Refraction-Correcting Technologies
  - Corneal Inlays / IOLs / Others
- Presbyopia Management Options (Surgical / Non-surgical)
- Lesion Removal & Aesthetic Therapies
- Miscellaneous Therapeutic Advances

Nanotechnology

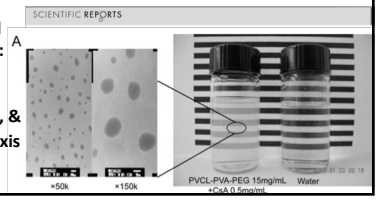
- **Head of a Straight Pin = 1,000,000 nanometers**
- **1 nm = 1 billionth of one meter**
- **1 nm = smaller than λ of visible light**
- **Human Hair = 80,000 nm**
- **Diameter of 1 RBC = >1000 nm**
- **1 nm = smaller than a living cell!**
- **Refers to engineering/mfg @ molecular scale (1 nm -100 nm)**



Nanomedicine (Biotechnology & Materials)

- **Ophthalmic Applications...**

- **Cequa (Sun Pharma)**
  - **Nanomicellar 0.09% cyclosporine**
    - **Micelle: lipid molecule that arranges into spherical form in aqueous soln. with hydrophilic & hydrophobic regions; greatly enhances penetration thru tissue**
  - **Rapid onset & well-tolerated**
  - **Phase III Trials Successful for: Dry Eye, Bleph., Scleritis, Oc. Rosacea, Atopic & Vernal Keratoconjunctivitis, & K xplant rejection prophylaxis**
  - ***FDA-approved Aug. 2018***



Topical Cataract Prevention & Treatment?!?!

Drops to prevent/treat Cataracts?!?!

- Nanoparticles infused with Lutein
- Rodent studies show reduction in cataract size within 1 wk of tx

Topical Cataract Prevention & Treatment?!?!

Drops to prevent Cataracts?!?!

- Unspecified...
  - "Nonsurgical Cataract Treatment"
  - Janssen Pharmaceutical Companies of Johnson & Johnson
    - In conjunction with UMASS
  - Protein aggregation interceptor

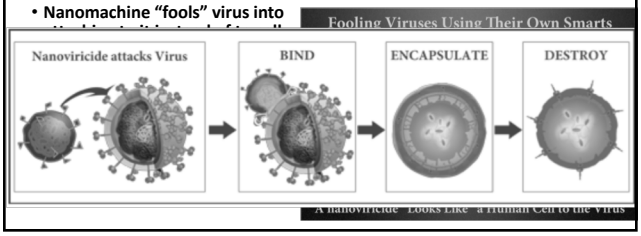
Nanomedicine

- **Molecular Machine Systems/Medical *Nanorobots***
  - Instant pathogen recognition for diagnosis & extermination
  - Chromosome replacement & individual cell surgery

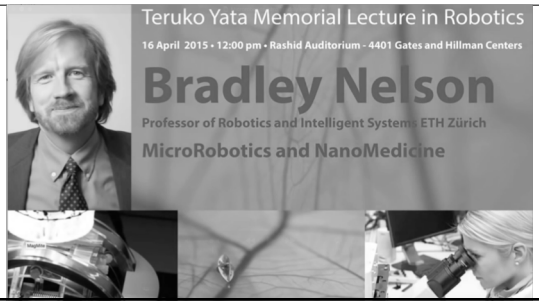
Nanomedicine (Biotechnology & Materials)

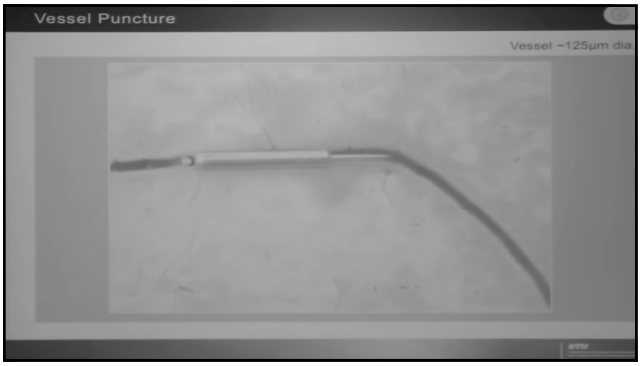
Ophthalmic Applications

- **Nanoviricides Inc.**
  - **Nanomachine "fools" virus into**

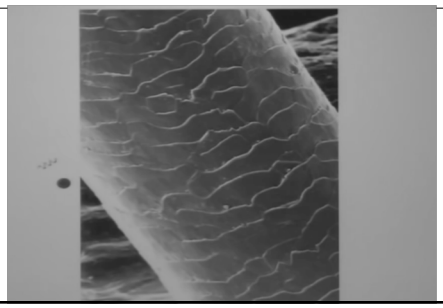


Microrobotics/Nanorobotics

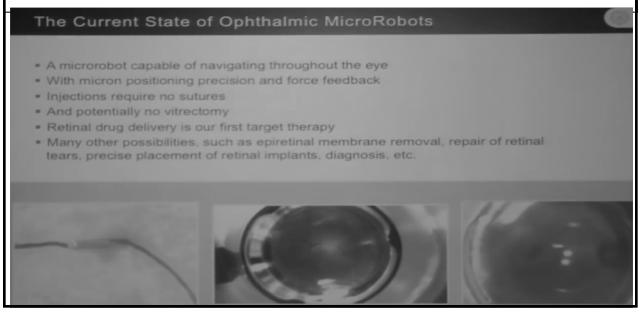




Nanorobotics



Micro/Nanorobotics



Evolving Trends in Eye Care

State of the Profession

VISION INDUSTRY OVERVIEW

January 2015

Harris Williams & Co.
middle market

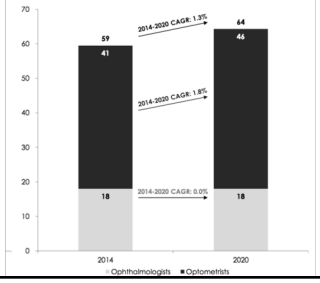
What's Trending in the Profession & in Optical?

Harris-Williams Consultants Report 2015

- Vision represents a ~**$36 billion** industry annually
  - Services = ~$15 billion
  - Sale of corrective eye glasses & lenses = ~$21 billion
  - Refractive surgery forecast to continue to grow
- Steady growth forecasted of **~2% per year for foreseeable future**

EYE CARE PROFESSIONALS BREAKDOWN[3]

 # in '000s



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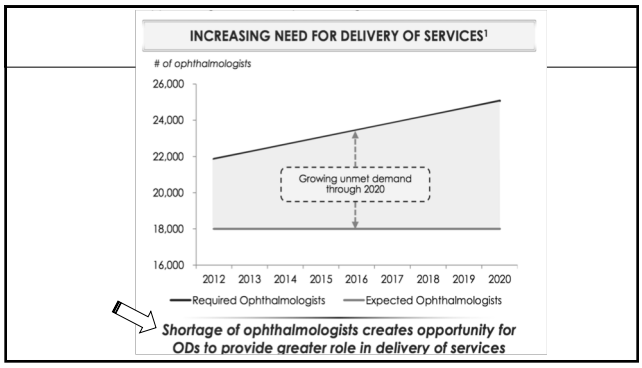
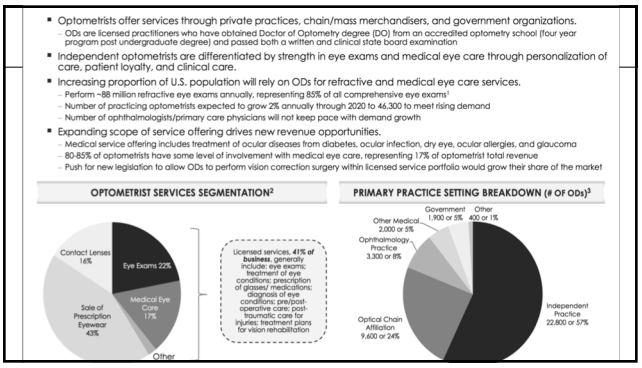
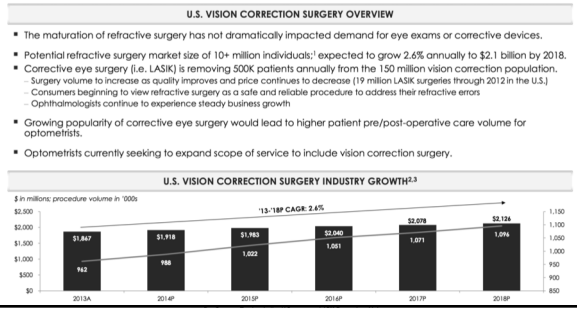




- Increasing proportion of U.S. population will rely on ODs for refractive and medical eye care services.
  - Perform ~88 million refractive eye exams annually, representing 85% of all comprehensive eye exams[1]
  - Number of practicing optometrists expected to grow 2% annually through 2020 to 46,300 to meet rising demand
  - Number of ophthalmologists/primary care physicians will not keep pace with demand growth
- Expanding scope of service offering drives new revenue opportunities.
  - Medical service offering includes treatment of ocular diseases from diabetes, ocular infection, dry eye, ocular allergies, and glaucoma
  - 80-85% of optometrists have some level of involvement with medical eye care, representing 17% of optometrist total revenue
  - Push for new legislation to allow ODs to perform vision correction surgery within licensed service portfolio would grow their share of the market

Vision correction surgery will continue to serve as only a mild demand deterrent for traditional vision care services as some potential patients are removed from the population.



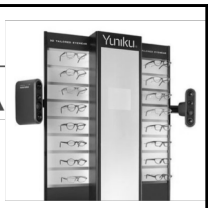
Wearable Technologies

Frames
Lenses
Contacts
Others

- Roger-Bacon

Yuniku. 3D TAILORED EYEWEAR

HOYA



- Similar product (currently avail. Europe)
- Assesses patient's visual needs *& facial features*
- Advanced software calculates ideal lens position in relation to the eyes, then designs frame based on those unique parameters
- 3D printing allows further customization of the frame according to patient's visual, comfort & aesthetic needs

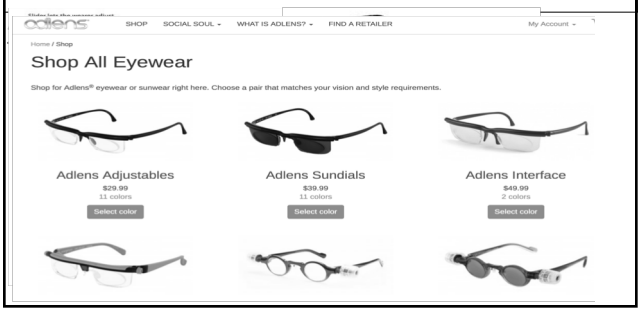
Other Custom Eyewear Solutions

- **Specsy**
  - Uses an iPad-based facial scanner & an augmented reality app to create custom 3-D printed eyewear (zyl, concrete, titanium)
- **3DNA Eyewear**
  - Custom fit frames (physically & aesthetically)
  - Frames are handcrafted using acetate, cork, exotic woods, carbon fiber, stone, buffalo horn, etc.

Spectacle Lenses

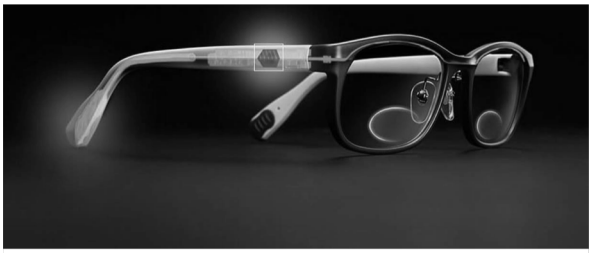
Digital free-from/Photochromics/Blue Light

- **Transitions** - **Signature VII** features new dye formulation & molecular technology & allows lenses to be more responsive to UV radiation
- **Shamir** – **InTouch** enhances visual comfort @15"-27" & add appears 25% sooner so still comfortable D/I/N with 20% wider viewing
- **Essilor** - **Varilux X** seeks to eliminate PAL distortion
- **Hoya** - **Recharge EX3** by Hoya Vision Care is a next-generation AR & filters high-energy visible (HEV/"blue") light
- **Zeiss Digital Lens** – for single vision patients, provides small add while looking @ devices; also 3 new **Precision Progressive** lenses; also **DuraVision BlueProtect** coating



Adjustable Focus Glasses: Adlens Focuss Kinetic

Electronically Adaptive Glasses: TouchFocus



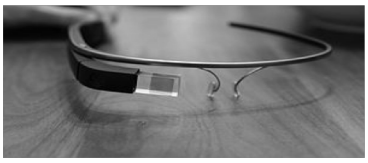
TouchFocus are electronically adaptive eyeglasses that switch to reading glasses at the touch of a button (Credit: TouchFocus)

Electronically Adaptive Glasses: TouchFocus

TouchFocus: will launch with 20 frame options (Credit: TouchFocus)

How will technology change the way we correct refractive disorders & interact with the world?

- Google Glass
- Mad Glass
- Senth IN1
- Sound Glasses
- iGlass?
- others



Other "Smart" Specs...

- **Carl Zeiss SmartOptics**

Other "Smart" Specs...

- ***Amblyz*** **(XPAND)- digital LCD amblyopia "patch" glasses**
  - **Programmable**
  - **"Good" eye lens alternates clear to opaque x 30 secs**
  - **Study of 33 kids, age 3-8 yrs with moderate amblyopia (20/40-20/100): 4 hrs of *Amlbyz* = 2 hrs patching**

Other "Smart" Specs...

- **CTRL Eyewear**

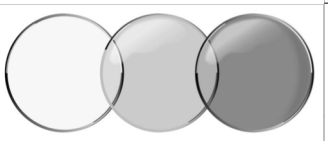
Shetters

Contact Lenses

- Material innovation
- Surface technologies
- Multifocal designs
- Scleral lenses

News > Medscape Medical News > FDA Approvals

FDA OKs First Transitional Contacts That Darken in Sunlight



Megan Brooks

DISCLOSURES | April 10, 2018

The first contact lenses that have an additive that automatically darkens the lenses when exposed to bright light have been cleared by the US Food and Drug Administration (FDA).

The Acuvue Oasys Contact Lenses With Transitions Light Intelligent Technology (Johnson & Johnson Vision Care, Inc) are soft contact lenses indicated for daily use to correct myopia or hyperopia. They can also be used by people with certain degrees of astigmatism

Google?

Auto-focal SCL?

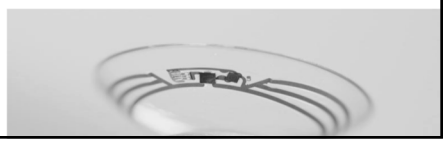
c|net Search CNET Reviews News

Google finds partner to produce 'smart' contact lenses for diabetics

An agreement between the Google[x] resesearch lab and pharmaceutical giant Novartis will license the technology for actual medical use for people with diabetes and other conditions.

by Lance Whitney @lancewhit / July 15, 2014 6:12 AM PDT

13 / 2.8K / 360 / 212 / more +



Contact Lenses

Non-pharmacologic myopia progression control?

...Myopia regression?

- Defocus Incorporated Soft Contact (DISC)
- MiSight (Cooper) – in Asia currently
- Center-distance multifocals (e.g. NaturalVue, etc.) ....

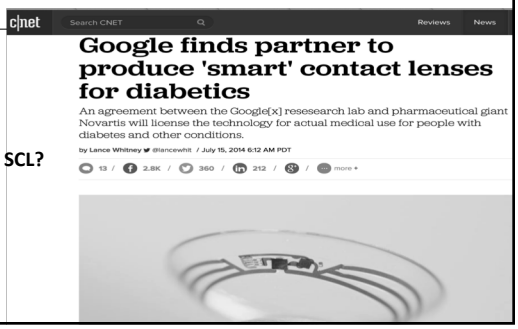
Spectacle Lenses

- Myosmart (Hoya)
  - Peripheral Defocus Spectacle Lenses
  - Launch in Asia 2018, Worldwide 2019/2020?
- Polytechnic
  - Hong Kong
- MyoVision (Zeiss)
  - Asia, Australia, Canada

NovioSense Announces Positive Clinical Trial Results of Tear Glucose Measurement Technology

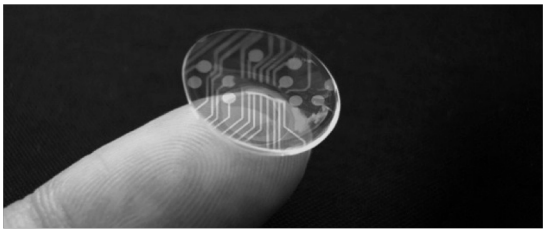
Google?

Auto-focal SCL?



Hyper-CL (EyeYon Medical)

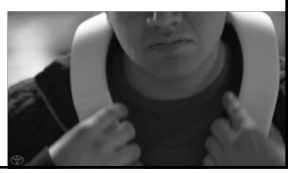
Night Vision Contacts



Vivid Vision

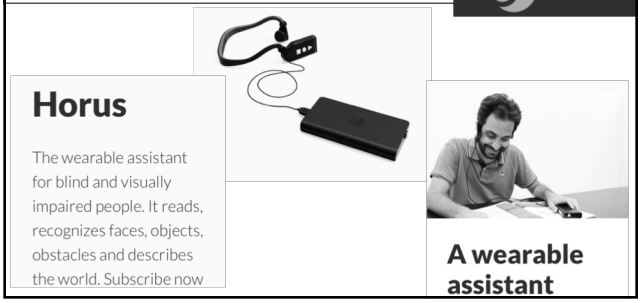
Project Blaid (Toyota)

- Wearable device that scans the environment
- Uses cameras & recognition software
- Will integrate:
  - Mapping
  - Object ID (doors, Exit signs, stairs, escalator, restroom signs, etc.)
  - Facial recognition technologies
- Users can request location of certain things & feedback audibly or by vibration



OrCam (MyEye)

Horus



Relúmino

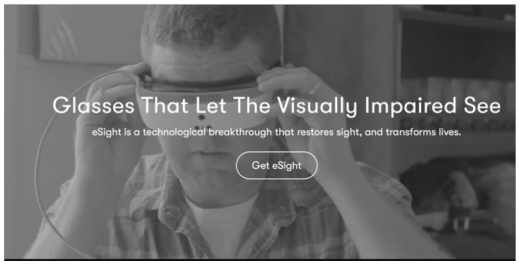
Smart visual aid for the people with low vision

- **Samsung**
- Latin "return back to the light"
- Uses image processing
- Modes:
  - Regular (enhances outlines)
  - Color Invert
  - Partial Vision
    - Scotoma Relocator
    - Tunnel Vision
  - Display Color Filter

Orama by I.C.I. (I.C. Inside)

- Combines A.I., High Def. Camera, Computer Vision, & Advanced Image Processing to enhance vision by shifting/projecting enhanced image onto healthy retina

eSight



eSight

BrainPort Vision Pro (BrainPort Technologies)

- Translates digital info from wearable vid
  electrical stimulation patterns on sur
  shape, size, location, & motion of obj
- Is adjunctive to other aids (e.g. white ca

Alternative Refracting Technologies

Digital Vision Optimizer (DigitalVision Systems)

- Virtual refracting platform to dx vision disorders & procure customized, digital, free-form lenses/glasses
- Patients interactively choose & optimize design of their corrective lenses under natural, real-world viewing conditions
- Provides "better vision and viewing comfort than conventional eyewear procured using *error-prone phoropter measurements*"
- Vision testing & fitting info xmitted to lab
- Partners: Essilor, Zeiss, Hoya, Transitions, Ga. Tech, others

Digital Vision Optimizer (DigitalVision Systems)

Technology

In the DVO, images of testing targets or real-world scenes are created by high resolution digital displays. These images then pass through the DVO's wavefront generators, which are located in a tower assembly above the patient's head. In contrast to the fixed power lenses in the phoropter lens-dial, the DVO incorporates computer-controlled, continuously-variable power lenses (CVPLs) that can be adjusted to one-hundredth of a diopter (0.00D), thereby providing twenty-five times the resolution of conventional phoropters. A wavefront-resolved refractometer in the wavefront generator measures higher order aberrations of the patient's visual system.

Images are projected from the wavefront generator to the DVO's concave viewport mirror where they are reflected to the patient's eyes. This architecture causes the corrective optics of the CVPLs to be relayed to the patient's spectacle plane, permitting a "phantom lens" or "virtual refraction" to be performed under natural viewing conditions free from obstructing instruments or head restraints. To the patient, it appears as if "phantom lenses" or "invisible spectacles" are placed before their eyes, creating a novel and unique experience. For near vision testing, the mirror is directed downward, deflecting the beams into a near-viewing accessory that provides the appropriate divergence for realistic near viewing.

Two stereo cameras above the viewport mirror provide input to an eye and head tracking system that maintains alignment of the optical system during the DVO exam and increases measurement accuracy by adjusting the power of the CVPLs as a function of eye position. The DVO permits patients to experience natural viewing conditions and normal patient movements throughout all portions of the exam and eliminates the need to look through the small viewing apertures of the phoropter.

Implantable Refraction-Correcting Technologies

New & Emerging Ocular Technology

Cataract Surgery & IOLs

(4 million cataract surgery procedures in 2015;
forecast ~40M Americans will have cataracts by 2032!)

42% of Cataract Surgeries Referred by an O.D.

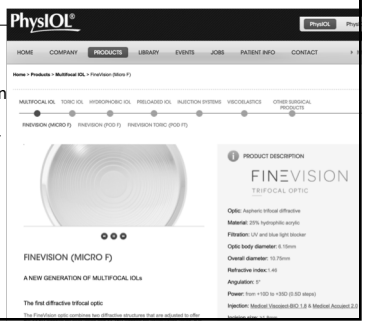
Verion Image-Guided Cataract Surgery Suite (Alcon)

"Trifocal" IOLs

- AT LISA tri 839 (Zeiss)
  - CE Mark
  - 6 mm optic (trifocal design in central 4.34 mm, bifocal design for remainder)
  - Intermediate Add= +1.76; Near Add= +3.33
  - Spherical & Toric options

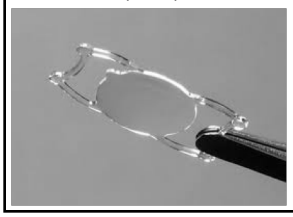
"Trifocal" IOLs

- Finevision IOL (PhysIOL)
  - CE Mark
  - Dual diffractive structure design on anterior surface (= 3 foci)
  - Intermediate Add= +1.75; Near Add= +3.50

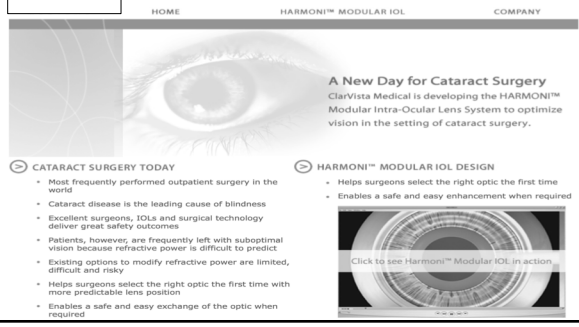


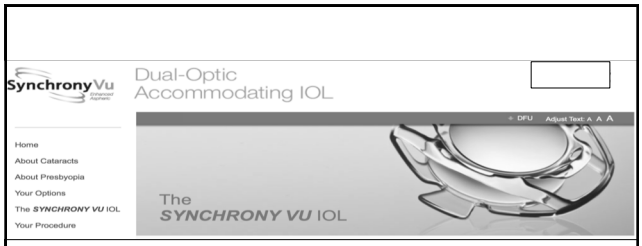
Lenstec Tetraflex

- CE Mark received
- "Accommodative" IOL
- More stable post-op refraction than Crystalens?

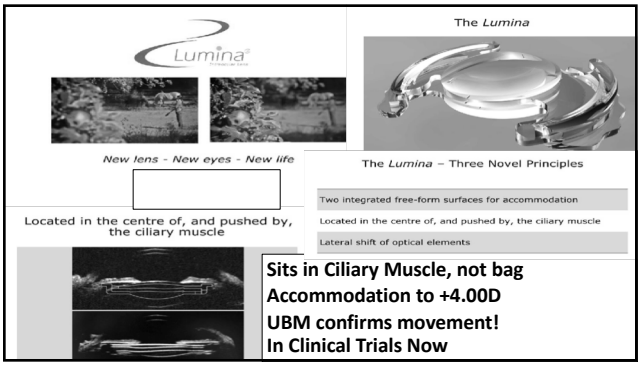


CE Mark Oct. 2015; In Clinical Trials





Approved in Europe with "good" results x 1200 patients; stalled FDA approval over "accommodating IOL" after Abbott acquired for $400M, has sunset it in US



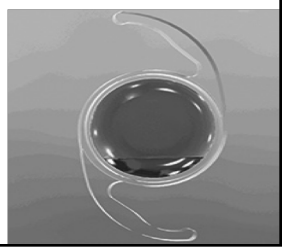
Sits in Ciliary Muscle, not bag
Accommodation to +4.00D
UBM confirms movement!
In Clinical Trials Now

LiquiLens IOL (Vision Solution Technologies)

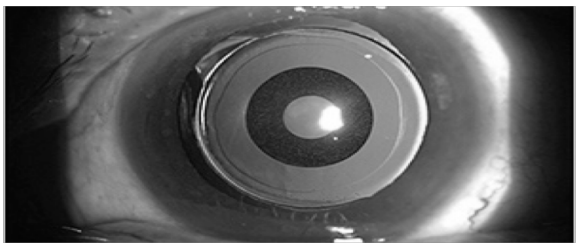
Contains 2 immiscible fluids & relies on agravity-dependent juxtaposition in downward gaze to add power in visual axis

Alan Glazier, O.D.

In Clinical Trials



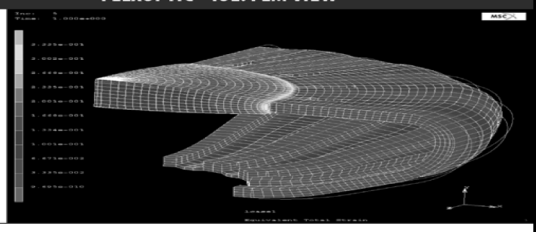
IC-8 (AcuFocus)



CE Mark in Europe; US clinical trials

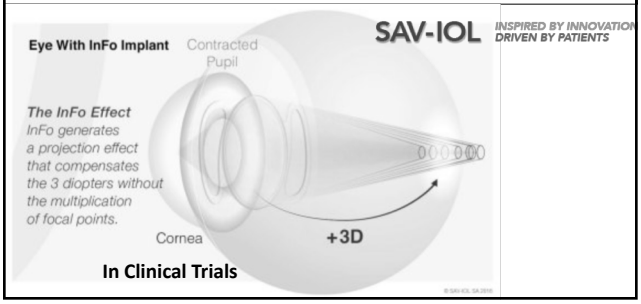
FLEXOPTIC™ IOL: FEM VIEW

Quarter Section View of FlexOptic IOL from Finite Element Model



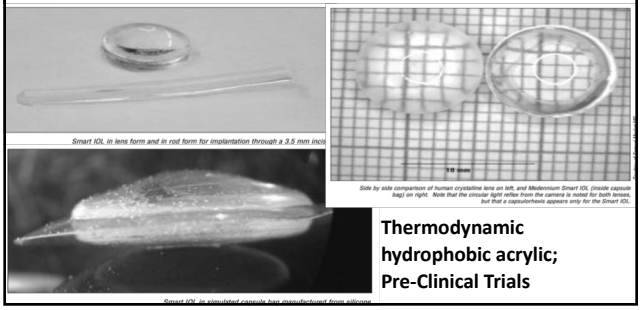
In Clinical Trials

InFo Instant Focus (Swiss Advanced Vision)



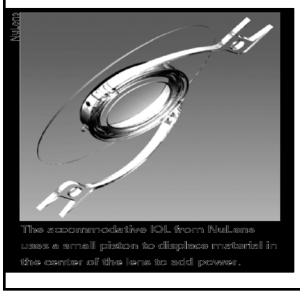
In Clinical Trials

SmartIOL (Medennium)



Thermodynamic hydrophobic acrylic; Pre-Clinical Trials

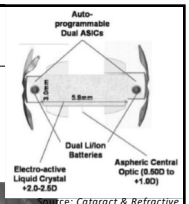
NuLens IOL (Dynacurve)



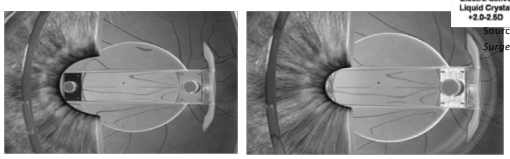
2-pc Accommodating IOL
Out of the bag
Sulcus-based
5.00D Accommodation
In Clinical Trials

Sapphire Autofocal IOL (Elenza)

- Has own power cell & embedded computer chip
- Rechargeable & fully programmable (can adjust power as visual needs change)
- Possibly ~2019?



Source: *Cataract & Refractive Surgery Today*



Far vision-mydriasis Near vision-miosis

Source: Eyemaginations/ELENZA

Vista IOL (Vista Ocular)

Electro-optical "smart lens" design

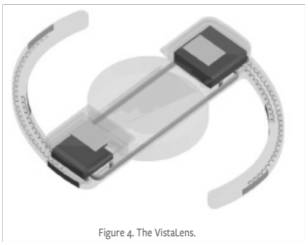
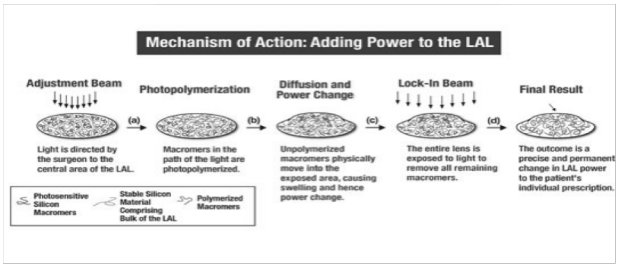


Figure 4. The VistaLens.

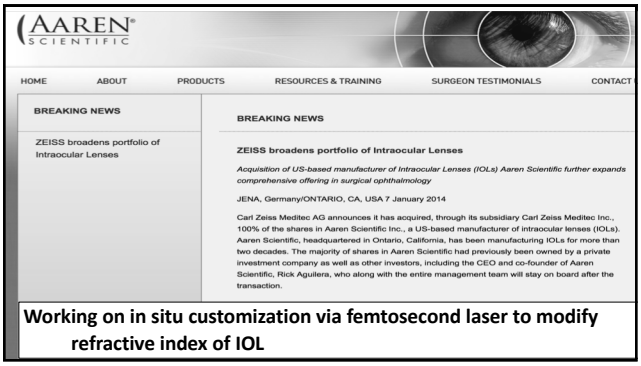
Source: *Cataract & Refractive Surgery Today*

Light Adjustable Lens (RxSIGHT)



Light Adjustable Lens (RxSIGHT)

- Post-op: Light directed to central area of IOL
- Macromers in IOL are photopolymerized
- Result = power change
- Lock-in beam used to prevent changes
- Phase III Clinical Trials Complete
  - 17 sites, 600 pts...@ 1 yr post-op: 93% of eyes 20/20 UCVA
- FDA application pending



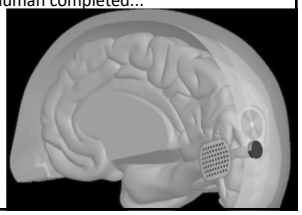
Working on in situ customization via femtosecond laser to modify refractive index of IOL

Refractive Index Shaping (RIS)

- In situ customization
- Via femtosecond laser
- Modifies index of refraction of IOL

Orion I: Visual Cortical Prosthesis (Second Sight)

- Wireless, Mulitchannel Neurostimulation System (***Visual Cortex Stimulator***)
  - Miniature, spec-mounted video camera converts image into electrical pulses then wirelessly xmitted to electrode array in patient's visual cortex
- Jan. 2018 1st implantation/activation in human completed...
  - UCLA – successful proof of concept
  - 30 yr old blind patient
  - Could perceive & localize light
  - No adverse effects
- Initial FDA application pending



Presbyopia Management Options

>1 Billion Presbyopes Worldwide

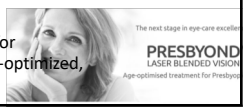
Presbyopia Reversal: Laser Ablation of Cornea

PresbyLASIK

- Multifocal LASIK = advanced laser vision correction to change corneal shape & create diff. power zones for seeing varying distance
- Just completed U.S. clinical trials (in other countries x several yrs)
- Promising results?

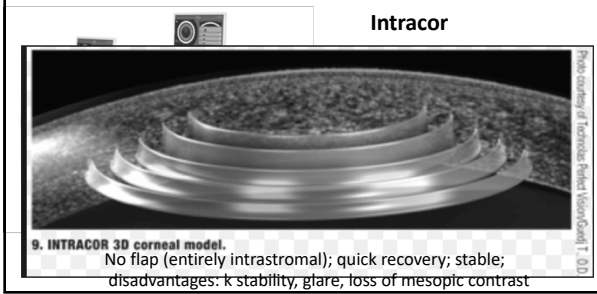
Presbyond

- Modified monovision correction (dominant eye for distance, non-dominant eye with wavefront-optimized, slightly myopic ablation)



Presbyopia Reversal: Laser Ablation of Cornea

Intracor



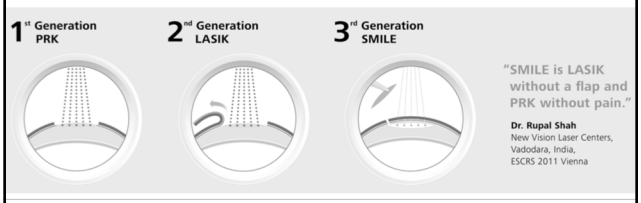
No flap (entirely intrastromal); quick recovery; stable; disadvantages: k stability, glare, loss of mesopic contrast

Presbyopia (& Myopia) Reversal: Laser "Keratectomy"

ReLEx SMILE: Uses Zeiss Visumax Femtosecond Laser

- **FDA-approved September 2016**
- **>500K Procedures Worldwide since 2011**
- **Monovision or Distance Only Correction**
- **Create thin disc-shaped lenticule within cornea which is then removed thru a small, surface LASER incision**

Presbyopia (& Myopia) Reversal: SMall Incision Lenticule Extraction



Presbyopia Reversal: Corneal Inlays

- In general, inserted on Non-Dominant eye
- Mechanisms:
  - Small Aperture Optics (KAMRA)
  - Change Corneal Curvature (Raindrop)
  - Change Index of Refraction (Flexivue Microlens, Icolens)
- Techniques:
  - Lamellar (under LASIK flap)
  - Pocket

Presbyopia Reversal: Corneal Inlays

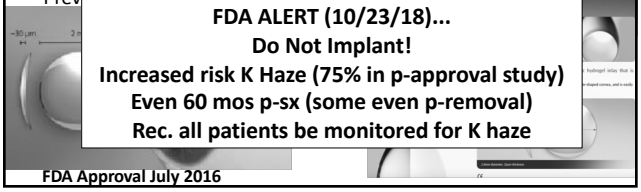
>1000 now done; Near VA stable 3 & 5 years post-op

Microscope view of an implanted KAMRA™ inlay for presbyopia, AcuFocus Inc. (Irvine, CA). Courtesy of D. Allamby, MD; Focus Clinics, London (UK)

Presbyopia Reversal: Corneal Inlays

Raindr
- Micr
- Prev

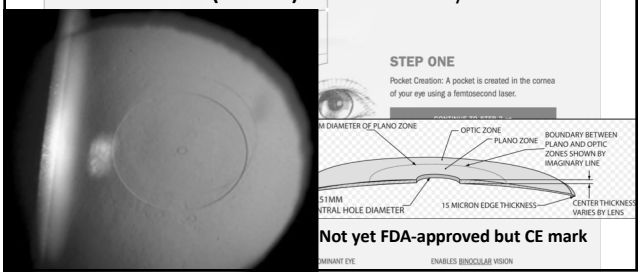
Ceased Operations Feb. 2018...
then Optics Medical bought
FDA ALERT (10/23/18)...
Do Not Implant!
Increased risk K Haze (75% in p-approval study)
Even 60 mos p-sx (some even p-removal)
Rec. all patients be monitored for K haze



FDA Approval July 2016

Presbyopia Reversal: Corneal Inlays

Flexivue Microlens (Presbia) = refractive inlay

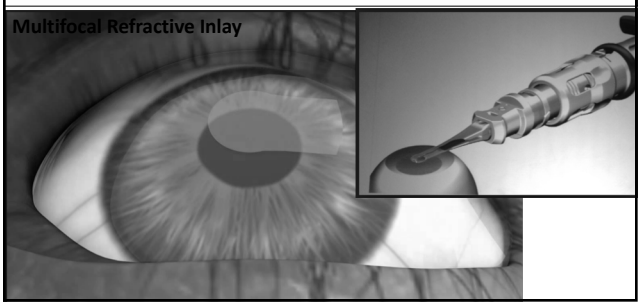


Not yet FDA-approved but CE mark

Presbyopia Reversal: Corneal Inlays

ICOLENS

Multifocal Refractive Inlay



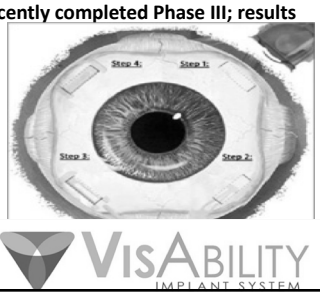
Presbyopia Reversal: Laser Ablation of Lens

Lensar Laser Lens Softening

- Uses Femtosecond Laser to soften lens nucleus
- Trials underway with encouraging initial results?

Presbyopia Reversal: Scleral Procedures

- **Scleral *Spacing* Procedure; recently completed Phase III; results improved x time**



VISABILITY IMPLANT SYSTEM

Presbyopia Reversal: Scleral Procedures

LaserAce (AceVision)

- Scleral modification procedures
  - Research: Sclera moves during accommodation, decreasing with age
- 9 YAG laser micro-incisions in 4 oblique scleral quadrants
- Optical axis unaffected (i.e. no change distance VA) with continuous range of focus, far/intermediate/near
  - Disadvantage: 360° periotomy & manipulation of conjunctiva
- Early data:
  - In 64 eyes of 32 patients, aged 42-69 yrs:
    81% J2 or better sc @ near, 85% J3 sc @ intermediate
    Overall: 78% were spectacle-independent @ near & 98% @ intermediate
    No complications

Presbyopia Reversal: Pharmacologic

The Benozzi Method

- 1% *Pilocarpine*
  Parasympathetic stimulation generates ciliary muscle contraction & increased lens thickness = increased depth of focus (better NVA, poorer DVA)
- + 0.1% *Diclofenac*
  Reduces intensity of pupillary & ciliary muscle contractions for good vision @ all distances
- 100 emmetrope study: DVA remained 20/20 with enhanced accommodation/improved NVA x 5 yrs (only 4% pref. specs)

Presbyopia Reversal: Pharmacologic

Liquid Vision **(Presbyopia Therapies)**

- Topical BID dosing & Reversible
- Short-term treatment for presbyopia
- Miosis *without accommodative spasm*
- Clinical Trial Presbyopes in Mexico (avg age 51): Avg NVA = 20/22
- Phase II trials

Presbyopia Reversal: Pharmacologic

Investigational Compound CSF-1 (Orasis Pharmaceuticals)

- Funded by OMD venture capitalists
- Is a patented combo product to restore crystalline lens elasticity
- Now in Phase II Studies
  - Prelim. clinical study data have reportedly demonstrated strong efficacy & safety profiles

Presbyopia Reversal: Pharmacologic

Other formulations in study, including:

- Presbeyedrops
  - 2 parasympathomimetics + 1 NSAID
- PresbyPlus
  - 2 Parasympathomimetics + 1 Parasympatholytic

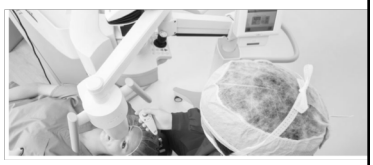
Presbyopia Reversal: Pharmacologic

EVO6/Dioptin? **(Encore Vision)**

- Proposed mech. action for Presbyopia = intracellular redox (lens proteins x-link = harden)
- Topical drop to "break" cross links & restore accommodation
- BID dosing x 30 days = ~ 2.0 D Accommodative Recovery
- Met Primary Safety & Efficacy Outcomes for Phase I-II
  - 75 patients b/t 45-55 yrs old with 20/20 BCDVA & worse than 20/40 DCNVA
  - Dosed BID
  - 1st Improvement @ Day 15, continuing thru the 90-Day Study Period

Corneal Collage Crosslinking (CXL)

- **FDA-Approved April 18, 2016**



Used in conjunction with Orthokeratology? Hyperopic LASIK?

Corneal Collage Crosslinking (CXL): Treatment of Myopia?

- Clin Ophthalmol. 2014; 8: 697–702.
- Published online 2014 Apr 7. doi: 10.2147/OPTH.S59934
- PMCID: PMC3984063
- **Novel myopic refractive correction with transepithelial very high-fluence collagen cross-linking applied in a customized pattern: early clinical results of a feasibility study -** Anastasios John Kanellopoulos
- 4 cases; treated transepithelially in a myopic pattern, total = 12 J/cm2
- Avg = 2.3 D myopic correction achieved wk 1, with slight regression to 1.44 D @ 1 mo post-op (stable to 6 mo post-op)
- Mean keratometry Δ = 44.90 D to 43.46 D, no signif Δ endothelial cell counts or k clarity; mild Δ epi thickness distribution (mean = 8 µm)

Columbia Engineers Invent a Non-Invasive Technique to Correct Vision

- May 25, 2018
- Columbia Engineering researcher Sinisa Vukelic has developed a new, non-invasive approach to permanently correct vision
- Preclinical models show excellent efficacy
- Uses a femtosecond oscillator (pulses of very low energy at high repetition rate) for selective, localized alteration of the biochemical & biomechanical properties of corneal tissue (i.e. XL)
- Can be done irrespective of corneal thickness, dry eyes, etc.
- Moving to clinical trials late 2018

Evolving Trends in Eye Care

Alternative Technologies & Delivery Models

Changes in Health Care Delivery?

- **AI/Machine Learning**
- **Telemedicine/Tele-optometry/Apps**
- **Scope Needs/Physician Extenders**

Google's

DeepMind

- Google's Artificial Intelligence Computer Program
  - Taught itself how to play 49 different video games with only raw pixel input
- Plans to use >1M anonymized eye scans to "teach computers how to diagnose eye disease"

IBM Watson

- IBM Researchers in Australia have trained Watson to detect abnormalities (e.g. AMD, diabetic retinopathy, & glaucoma) in retinal photographs
  - Able to measure C/D & determine signs of glaucoma with up to 95% accuracy

IDx

- Uses Artificial Intelligence algorithms to automate the diagnosis of Glaucoma, AMD, DR

FDA OKs AI Device to Detect Diabetic Retinopathy in Primary Care

Telemedicine/Teleoptometry/App-Based Screeners

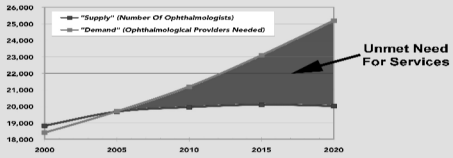
- **Telemedicine/Teleoptometry**
  - MD Live
  - Teladoc
  - Digital Optometrics
  - Etc.
- **App-based vision screeners/Online CL & Glasses**
  - Opternative
  - Simple Contacts
  - 20/20 Now
  - Pupil
  - Etc.

Evolving Trends in Eye Care

Scope of Practice Needs

Patient Needs Must Be Addressed

Demand for ophthalmologic services increases by 28% from 2005 to 2020

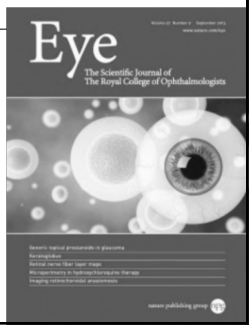


While the supply of Ophthalmologists remains flat...

* Us Department of Health and Human Services Publication - *Physician Supply Projections to 2020.*

Physician Extenders/Replacers

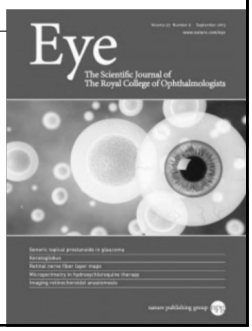
- ...for Intravitreal injections?



Disposable Intravitreal Injection Speculum

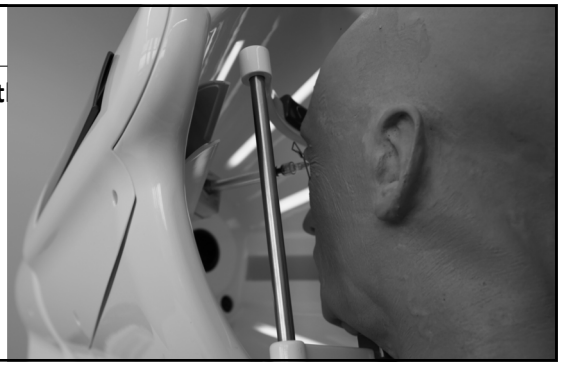
Physician Extenders/Replacers?

- Nurses provided 3,355 hospital-based intravitreal injections
- No complaints from patients
- Only 0.3% adverse events (all minor: subconj. heme & k abrasion)
- Conclusion: Appropriately trained non-medical staff can improve efficiency & access



Ophthorobotics

Opht



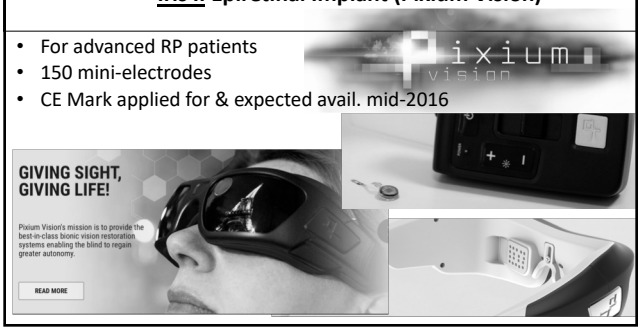
New & Emerging Ocular Technology

Implantable Technology

Implantable Telescope: CentraSight

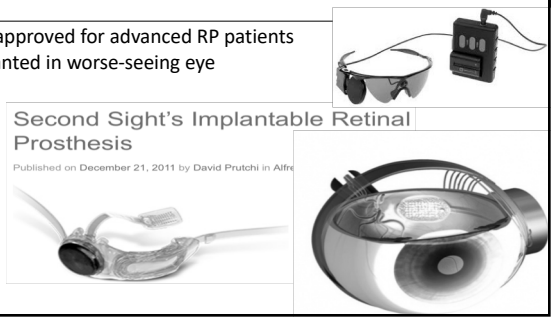
Iris II Epiretinal Implant (Pixium Vision)

- For advanced RP patients
- 150 mini-electrodes
- CE Mark applied for & expected avail. mid-2016

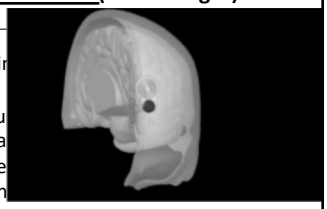


Argus II Retinal Prosthesis System (Second Sight)

- FDA-approved for advanced RP patients
- Implanted in worse-seeing eye



Orion I: Visual Cortical Prosthesis (Second Sight)



- Wireless, Mulitchannel Neurostim
  Stimulator)
  - Miniature video camera (mou
    into electrical pulses tha
    array on surface of patie
- First implantation & activation in
  - UCLA – successful proof of concept
  - 30 yr old blind patient
  - Could perceive & localize light with no adverse effects
- Initial FDA application

Eyemate (Implandata Ophthalmic Products)

- Formerly PRO-IOP
- Implantable Microsensor (in capsular bag, in front of IOL)
- Capable of Measuring Absolute IOP continuously or on-demand
- Sends data via GSM/modem to Patient/Doctor with ALERT if IOP high

Eyemate (Implandata Ophthalmic Products)

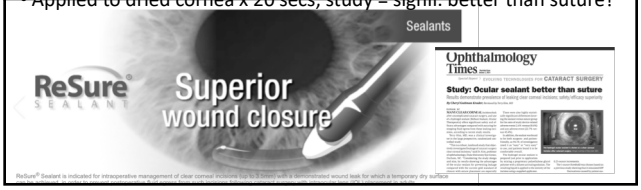
New Ophthalmic Meds

MKO Conscious Sedation (Imprimis)

- Novel proprietary formulation (midazolam-ketamine-ondansetron)
- Sedation + anesthesia/analgesia
- Can be used in place of IV sedation for cat sx in 85% of patients
- Specifically for ophthalmic use (as well as other procedures)
- Available as of 2016
- Sublingual

ReSure (Ocular Therapeutix)

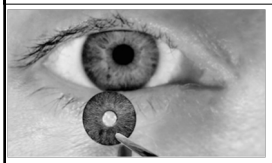
- Hydrogel corneal wound sealant with blue visualization aid
- Indication for Cataract Surgery Incision Closure (& others?)
- Applied to dried cornea x 20 secs; study = signif. better than suture?



New & Emerging Ocular Technology

Other Miscellaneous Therapeutic Advances

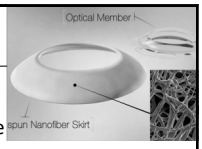
CustomFlex Artificial Iris FDA-Approved



Clinical Trial:

- 389 adult & pediatric pts with aniridia or other iris defects undergoing bilateral cataract sx
- >70% of pts reported signif. decreases in photophobia & glare, as well as an improvement in health-related quality of life
- 94% of patients were satisfied with appearance

CorNeat Kpro (CorNeat Vision)



- Patent-pending, 2-piece synthetic cornea
- Utilizes "advanced cell technology" to integrate artificial optics within resident ocular tissue
- Stimulates cellular growth via nanoscale chemical engineering
- Steps: Conjunctival periotomy, Corneal trephination, Insertion of synthetic cornea, Repositioning of conj & suturing
- Successful in animal trials to-date

Second Skin

Fugo Plasma Blade

- First portable, electrosurgical nanomedical incising device employing plasma for ablation (yields nanotechnological arrangement of molecular lattice)
- Numerous ophthalmic applications:
  - Glaucoma Surgery (transciliary filtration)
  - Cataract Surgery (anterior capsulotomy)
  - Peripheral Iridotomy
  - Lesion Removal

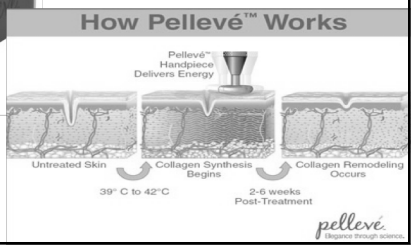
Approved in U.S.

Ellman Radiofrequency Unit

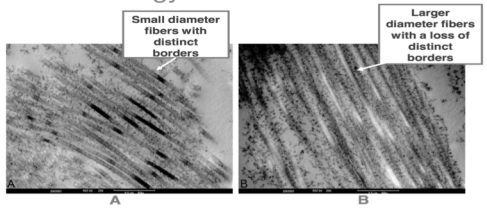
Approved in U.S.

Uses radio waves to deliver electrical current to tissue for excising/incising with hemostasis

Pelleve'...now TempSure (Hologic)



Pellevé Histology



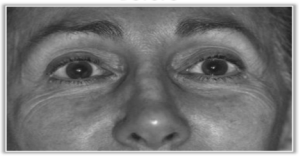
TEM (25,000x) shows scattered diffuse changes in collagen fibril architecture with shift from smaller diameter collagen fibers in the untreated samples **(A)** to larger diameter and loss of distinct borders fibers in the treated samples **(B)** compared with normal fibrils

Javate, R, Cruz, R. Khan, J., Trakos, N., Gordon, R. Nonablative 4-MHz Dual Radiofrequency Wand Rejuvenation Treatment for Periorbital Rhytides and Midface Laxity, *Ophthal Plastic Reconstr uctive Surg, Vol. 0, No. 0, 2011*

Upper Eyelids

Periorbital

Before



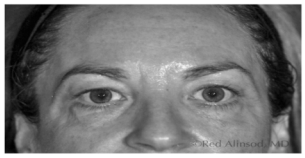
After

Sixty days post third treatment
Courtesy of Red Alinsod, MD

CYNOSURE

Pellevé Eyes & Forehead

Before



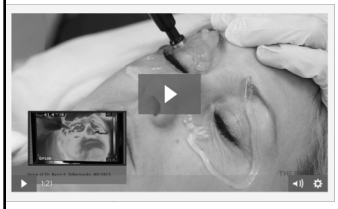
30 Days After 4th Pellevé Treatment

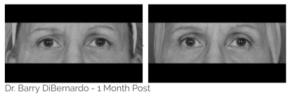
Courtesy of Red Alinsod, MD

THERMI

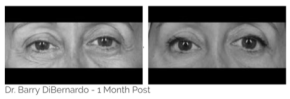
an almirall company

THERMISMOOTH FACE RESULTS





Dr. Barry DiBernardo - 1 Month Post

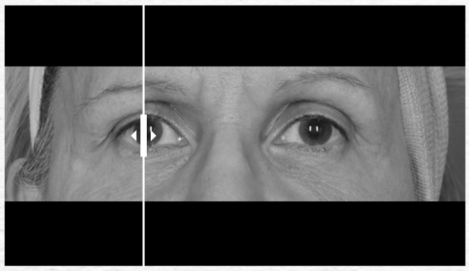


Dr. Barry DiBernardo - 1 Month Post

ThermiSm

THERMISMOOTH FACE RESULTS

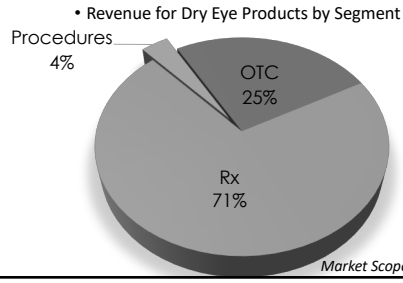
Drag the arrow to the left to see the after image and to the right to see the before image.



Dr. Barry DiBernardo - 1 Month Post

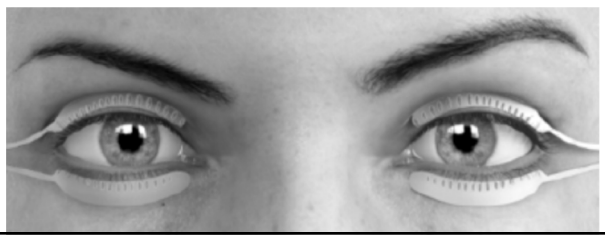
Procedures Currently ~4% of all US Dry Eye Revenue

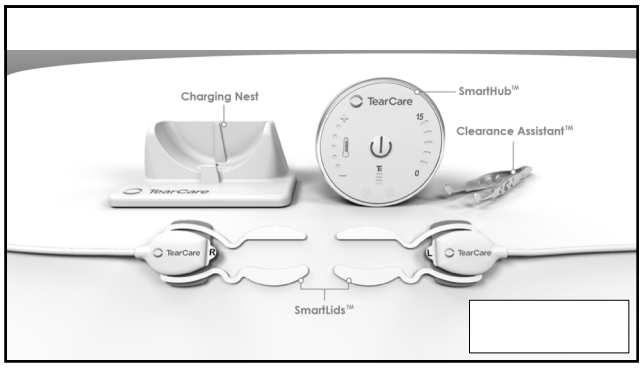
• Revenue for Dry Eye Products by Segment

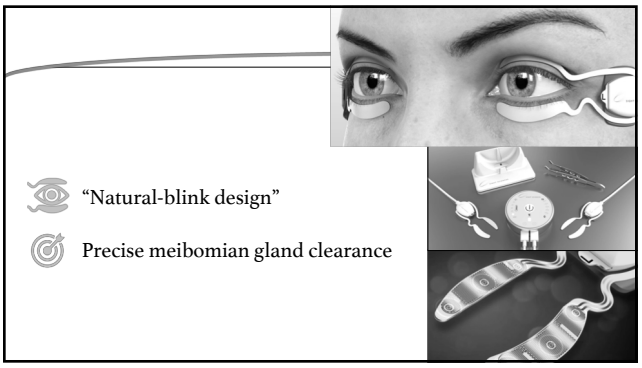


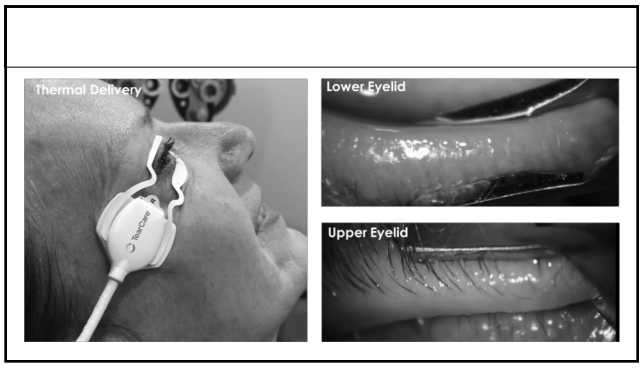
Market Scope 2017, Dry Eye Products Report

TearCare™ System



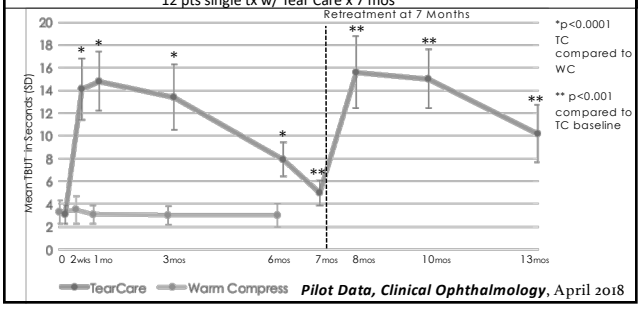






Tear Breakup Time

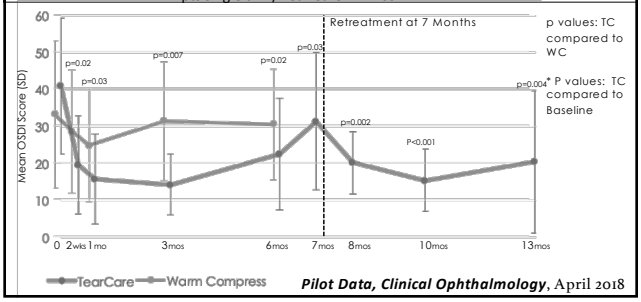
Single cntr, prospective, randomized, controlled trial; 12 pts warm comp x 5 min qd; 12 pts single tx w/ Tear Care x 7 mos



Pilot Data, Clinical Ophthalmology, April 2018

OSDI Score

Single cntr, prospective, randomized, controlled trial; 12 pts warm comp x 5 min qd; 12 pts single tx w/ Tear Care x 7 mos



Pilot Data, Clinical Ophthalmology, April 2018

iLux (Alcon)

- **For Meibomian Gland Dysfunction/DED**
- **Portable, in-office treatment**
- **Applies light-based heat via disposable silicone pads to view, unblock, & express meibomian glands**
- **FDA-approved Dec. '17**

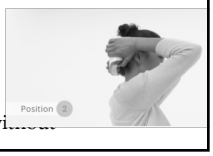
FDA Approves Device to Treat Migraines With Auras

Nearly 38% of migraine patients who used the Cerena Transcranial Magnetic Stimulator (TMS) were headache-free two hours after using the device; after 24 hours, nearly 34% of the Cerena TMS users were pain-free.

The US Food and Drug Administration (FDA) approved Cerena Transcranial Magnetic Stimulator (TMS), the first device to relieve pain caused by migraine headaches that are preceded by an aura—a visual, sensory or motor disturbance immediately preceding the onset of a migraine attack.

Treatment Devices for Migraine with Aura

- FDA-approved initial version = Cerena (eNeura)
- New model = sTMS mini (eNeura)
- Requires rx from provider
- Utilizes single pulse, transcranial magnetic stimulator
- FDA Study:
  - 201 Patients
  - Mostly Moderate-to-Strong Migraines
  - Aura >=30% of time
  - Results:
  - 38% pain-free 2 hours after using vs. 17% without
  - At 24 hrs, 34% pain free vs. 10% of controls



Changes in Optometric Education?

"People tell me, 'You're such an optimist.'

Am I an optimist? An optimist says the glass is half full.

A pessimist says the glass is half empty.

A survivalist is practical.

He says, 'Call it what you want, but just fill the glass.'

I believe in filling the glass."

- Louis Zamperini

(subject of bestselling book & major motion picture *Unbroken*)

THANK YOU!

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