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TECHNOLOGIES

Technology Presentation

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A 2009 OSEO-Certified Innovative Enterprise

from Italy, centuries of inspiration and innovation create custom vision

iVis Milestones

- **1993** - iVis Technologies began its extensive R&D program into the customisation of refractive surgery. The company started developing its CIPTA software.
- **1999** - The CIPTA customisation software is launched on the market. To date, over 1 million procedures were performed worldwide with CIPTA.
- **2007** - The complete **iVIS Suite was introduced in the ophthalmic community** in the second semester.
- **2009** - In December, iVIS was certified "**Entreprise Innovante**" (**Highly Innovative Company**) by **OSEO**, the agency formed by the Ministry for Economy, Finance and Industry, and Ministry for Higher Education and Research of France.
- **2010** – to date the iVis Suite is a highly successful product installed in Italy, Switzerland, Austria, Spain, Norway, Slovenia, Australia and Canada.



Corporate Headquarters of iVIS Technologies and LIGI Tecnologie Medicali, S.p.A.



The iVIS Suite Difference

- **Therapeutic and Refractive Corneal Surgery** - the only system able to deliver a variety of Therapeutic & Refractive Corneal Surgery treatments to expand the offering of a centre
- **Customisation** - 100% of treatments with the iVis Suite are customised
- **iVIS Suite : depth and breadth of applications**

REFRACTIVE SURGERY

- **cTEN** : a customized trans-epithelial, no-touch, surgery **exclusive to iVIS**;
- **MOD** : a reversible treatment for Presbyopia **exclusive to iVIS**;
- PRK;
- LASIK;

THERAPEUTIC SURGERY EXCLUSIVE TO iVIS

- **CLAT** : a customized deep lamellar keratoplasty;
- Customized Treatments to regularize eyes with impaired vision;
- Customized Epikeratophakia for high refractive disorders;
- **CCR** : a customized procedure combined with Collagen Cross Linking (CCL) to improve vision for keratoconus patients;
- Customized deep sclerectomy for glaucoma;
- Customized sclero-corneal regularization for pterygium excision

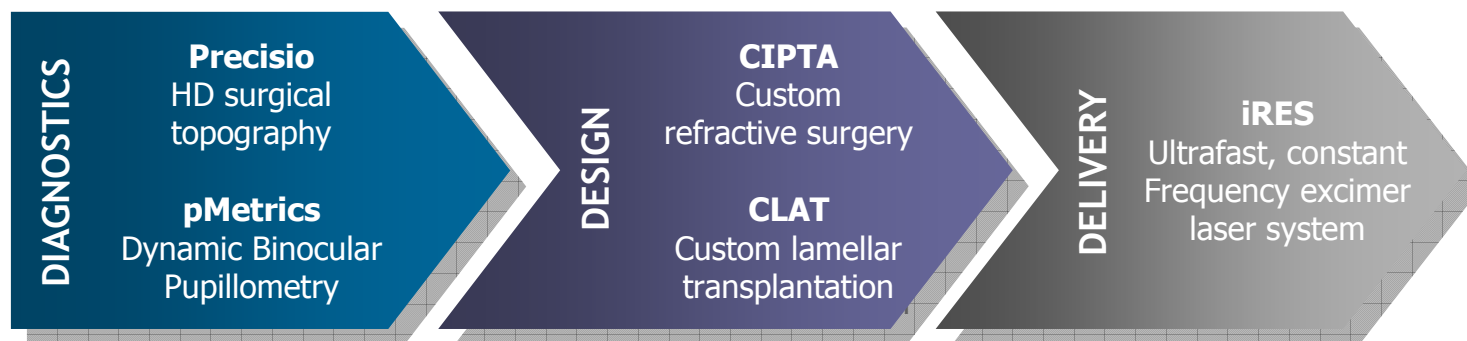
- **CIPTA by iVis Vs. Wavefront** – all treatments are driven by the morphology of the cornea, refractive error and pupil dynamic the quality of vision is improved via the regularisation of the corneal shape, thus removing the limitation of Wavefront or Placidus rings ablations
- **C-TEN** – cTEN is the proprietary superficial treatment for refractive surgery. cTEN is a no-touch procedure. The epithelium is removed by the laser, thus avoiding possible surgeon-induced complications. A safer alternative to Lasik with superior results
- **A Combination of the fastest Frequency and the Smallest Spot** – with a frequency of 1.000Hz and a spot size of 0.6mm, iRes offers the fastest treatments with unmatched precision, accuracy and smoothness of ablation
- **The ability to treat whichever order vision disorders** – the Suite allows to treat patients that previously classified as untreatable, as well as treating eyes damaged by previous laser surgery



iVIS Suite description

- **iVIS Suite : A real custom platform**

- Surgical diagnostic products,
- Surgical design applications,
- Surgical delivery system.



- **A process to achieve customised Therapeutic and Refractive Corneal Surgery that is carried out in three phases:**

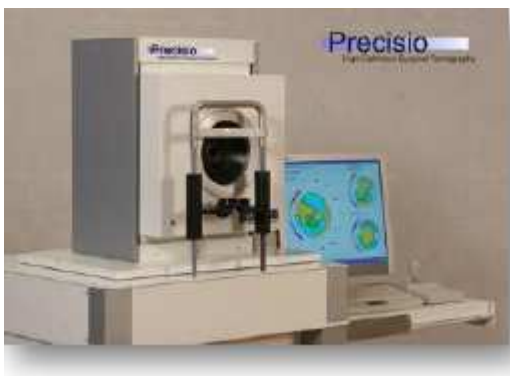
	OBJECTIVES	COMPONENT OF THE iVIS SOLUTION
Phase 1	Patient's data acquisition	Preciso™ (corneal tomographer) pMetrics™ (a pupillometer)
Phase 2	Surgical Planning	CIPTA® (Corneal Interactive Programmed Topographic Ablation) CLAT® (Corneal Lamellar Ablation for Transplantation)
Phase 3	Laser Treatment	iRES™ (Excimer Laser)



iVIS Suite description : 1. Patient's data acquisition

Diagnostic Instrument

Function



Precision™ HD Tomographer

Provides information about the corneal morphology of the patient.

Designed to detect the real shape of the corneal surface using 3-D elevation data rather than using interpreted shape from curvature data.

By matching the desired ablation outcome with the delivered ablation, Precision is able to offer a closed-loop verification of the exceptional surgical results delivered by iVis



pMetrics™ Dynamic Pupillometer

Measures pupil dimensions from scotopic to photopic.

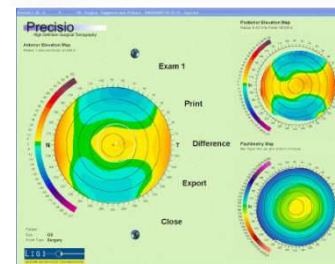
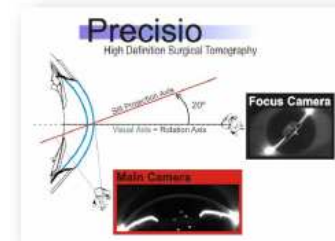
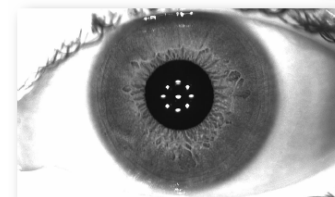
Definition of the optimized ablation area in which the Ideal Profile is delivered, utilizing the pupil's dynamic responses to specific visual environments, lighting conditions, lifestyle weighting, and pMetrics proprietary statistical analysis system



iVIS Suite description : 1. Patient's data acquisition

Precisio™ HD

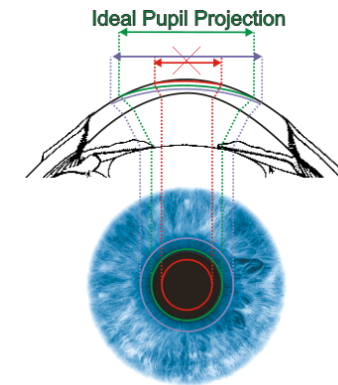
- **Precisio™** examination includes a “signature” of the ocular features. The signature is used for positive identification of the patient's eye at the laser before surgery commences.
- **Precisio™ HD** utilizes a high definition Scheimpflug camera system to acquire 50 cross sections of the cornea in only one second, and over 39,000 data points are collected with repeatability for each surface on the anterior cornea better than 3 microns.
- When all data are acquired, the surgeon has access to series of maps, and export of those data can be made via communications protocol to iVIS Suite for integration into the surgical plan.
- **Precisio™** offers, over competing machines, the following advantages:
 - repeatable and consistent readings of the same eye;
 - analysis of the anterior and posterior corneal shapes and anterior chamber depth;
 - three dimensional analysis of corneal thickness (pachymetry);
 - detects corneal vessels to provide additional references to guide eye –tracking and intra-operative registration to the patient's shape data;
 - tandem camera detection system;
 - fully automatic data acquisition;
 - high definition measurement: 39 000 points analysed per surface.



iVIS Suite description : 1. Patient's data acquisition

pMetrics™

- **pMetrics™** permits to define the area of the anterior surface of the cornea to be re-shaped with the laser system.
- **pMetrics™**' main functionality is to determine the Ideal Pupil™ size of the patient. The ideal size of the pupil, more precisely defined as the "ideal projection of the pupil on the anterior corneal surface", must be measured to define the portion of the anterior corneal surface in which to allocate the ideal shape.
- **pMetrics™** assesses patient specific pupil dimensions and reactivity relative to the patient's unique life style requirements. The dynamic pupil dimensions are measured by two independent cameras with a telecentric objective to detect left and right eye information. Infrared video images are stepped through defined visual environments that simulate common situations ranging from scotopic to photopic luminosity settings.
- **pMetrics™** offers the following **patented** advantages over competitors:
 - analysis with both concentrated and diffused light;
 - analysis with six calibrated lighting environments with dynamic assessment of the pupil;
 - weighting of the dynamic analysis to six pre-set lifestyles, permitting to define the Ideal Pupil.





iVIS Suite description : 2. Surgical Planning

- Surgery is custom designed for each patient with a synthesis of true elevation, pupillometry, and refractive data using either one of the two iVIS software programs:
 - **CIPTA** (Corneal Interactive Programmed Topographic Ablation) executing customised therapeutic procedures of the anterior segment and refractive procedures (when the cornea is stable), such as our unique cTEN;
 - and **CLAT** (Corneal Lamellar Ablation for Transplantation) executing surgical procedure of the posterior segment such as our lamellar ablation for transplantation.
- The iVIS Suite further expands the surgeon's capabilities with **glaucoma** and **pterygium** surgical procedures and MOD, a reversible treatment for presbyopia

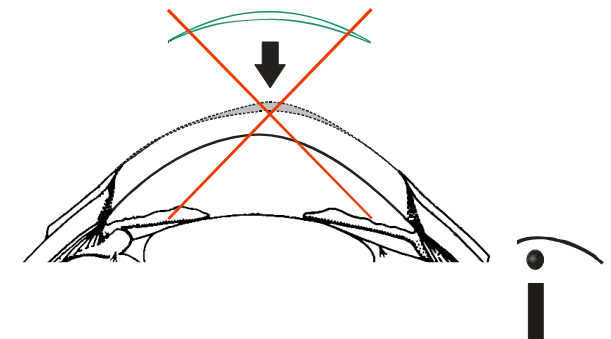
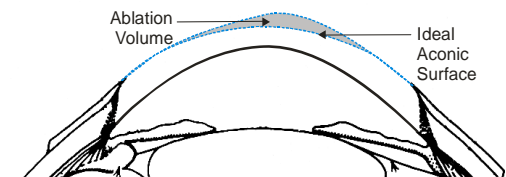


iVIS Suite description : 2. Surgical Planning - CIPTA

- **CIPTA™** is a **patented** software launched in 1999, and designed to deliver truly customised refractive surgery. As of today, over 1,000,000 LVC and TCS have been performed using CIPTA™.
- **CIPTA™** uses a complex series of 3-D modelling to automatically define and optimise the ablation volume.
- **CIPTA™** can be used with all surgical procedures:
 - c-TEN™ (Customised Trans-epithelial No-touch PRK). cTEN™ is a surgical procedure **exclusive to iVIS** in which the minimum removal of epithelial area is carried out by the laser itself, rather than being removed manually.
 - Living Lamellar Lens™ (Trans-Epithelial Epikeratophakia), a patented surgical procedure exclusive to iVIS. This procedure is applied for refractive surgical procedure primarily for the correction of high myopia and hyperopia.
 - MOD, a reversible treatment for presbyopia.
 - And customised traditional PRK, LASIK and LASEK procedures.

- **CIPTA™ : Main Principle**

- The volume of the ablation is described by the intersection of the anterior surface of the cornea and the ideal aconic corneal surface by defining the refractive error.
- The ablation takes into account the patient's real anterior corneal surface and not based upon "lens" calculation.
- The ablation strategy minimizes tissue consumption by intersecting the projection of the Ideal Pupil™ refractive area and the corneal surface.

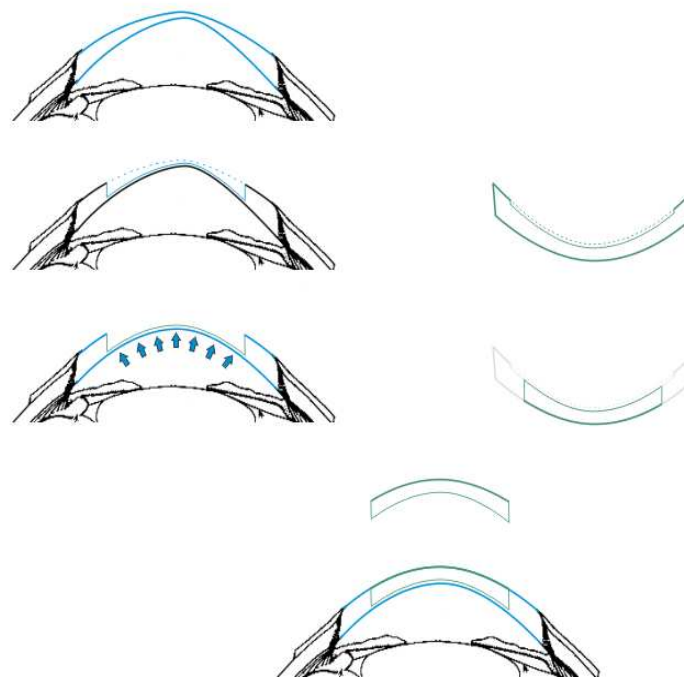


iVIS Suite description : 2. Surgical Planning - CLAT

- **CLAT™ : A procedure exclusive to iVIS**
- **Advantages of CLAT™:**
 - a unique preparation of the receiving "bed" (corneal area shaped by the laser which receives the laser-shaped donor implant) with the elimination of any irregularities in the cornea.
 - The customisation of the "bed" allows **CLAT™** to minimise the risk of rejection of the lamellar transplant by preserving biologically critical layers of the cornea (posterior stroma and endothelium) as opposed to present standard penetrating transplantation techniques.

- **CLAT™ : Main Principle**

- The volume of the ablation is generated by the intersection of the corneal pachymetry and the ideal corneal bed.



iVIS Suite description : 3. Laser Treatment

- **iRES™ : flagship product of iVIS**
 - 1,000 Hz, high resolution excimer laser system, the fastest on the market
 - 0.6 mm of spot size, also industry-leading
 - Delivers both custom therapeutic and custom refractive surgery.
- **iRES™** features comprehensive automation characteristics to accurately reproduce the planned surgery, minimizing many common tasks better managed by automated control and machine vision.



- **iRES™** laser offers an industry leading, precision surgical ablation delivery system: iFIDELITY™. Critical to custom vision surgery, iFIDELITY synthesizes six discrete elements to assure the accurate spatial delivery of the three-dimensional ablation profile to the cornea.





iVIS Suite description : 3. Laser Treatment

- **iRES™ : a real technologic advance over available competing lasers:**
 - a pulse rate of 1,000 Hz (the highest in the industry) to deliver “micrometric” customized procedures; this patent permits to minimise surgery time;
 - a beam spot size equal to 0.6 mm (the smallest on the market) to deliver high resolution customised treatments to accurately treat corneal irregularities;
 - Innovative constant surgical frequency of spot delivery per mm² of cornea (Constant frequency per surface area (CF/A™)); capitalizing on the high speed delivery, iVIS has pioneered a technique to deliver constant frequency per area of delivery (CF/A); this patent allows to normalize delivery density and to eliminate the need to incorporate various algorithms compensating for plumb, water accumulation, and drying dependencies; this feature creates an extremely homogeneous ablation;
 - Fully automated calibration;
 - Ablation rate verification with a close loop circle that eliminates surgeon and technician bias, and interpretative variability
 - The surgery is totally automated thus eliminating the risk of surgeon induced complications



iVIS fully meet demands from surgeons & patients

- iVIS believes that the excimer hardware and software technology available so far has not delivered fully customised LVC due to some technological limitations.

CUSTOMISATION

Custom ablation profiles generated by CIPTA and CLAT on the basis of Preciso and pMetrics provide accurate and repeatable data for:

- Improved quality of vision,
- Minimisation of LVC complications such as haze and halos,
- Minimisation of the surgical volume and depth thus lowering surgical risk and invasiveness.

iRES™

Precision, accuracy and ablation smoothness

- Smallest beam spot on the market,
- Highest pulse rate allows fastest trans-epithelial surgery despite the smallest beam spot,
- The constant frequency ablation per mm² eliminates results variability attributable to corneal plume,
- No need for aspiration or fan.

The Suite, the solution to these limitations

CIPTA®

Provides surgeon intuitive, clinically significant, surgical planning, 100% customized, to develop refractive and therapeutic ablations with the ability to treat virtually all vision disorders inclusive of most previously classified as untreatable.

CLAT®

Ability to expand the surgeon's scope to a new set of TCS laser procedures treating corneal customised lamellar transplantations, innovative treatment for keratoconus and transplant for leucoma, as well as rehabilitating patients with quality of vision problems that are congenital, surgically induced, or as a result of trauma

c-TEN™

Ability to perform the innovative c-TEN™ (Customised Trans-epithelial No-touch PRK) yielding minimized, post-surgical recovery compared to traditional PRK (pain, slow recovery time), but with the low invasiveness of PRK compared to LASIK. This procedure is exclusive to iVIS

Scientific References

- A comprehensive selection of scientific publication relating to the iVis Suite can be found on our website:

www.ivistechnologies.com/publications.html

