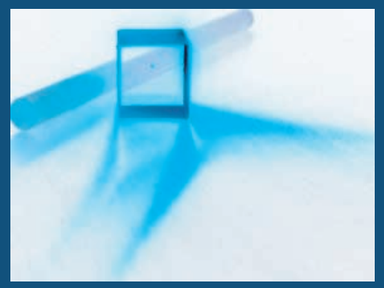

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QUALITY OF LIFE AND DISRUPTIVE TECHNOLOGIES: A VALIDATION OF THE NEI QOL-42 INSTRUMENT FOR THE CUSTOM SURGERY

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INTRODUCTION

The health care industry is replete with powerful industry forces that resist simpler alternatives to expensive treatment modalities because those innovations threaten their revenue streams. Termed 'disruptive innovations', many of these new technologies may threaten entrenched interests at the same time they benefit doctors, hospitals and patients and provide the opportunity to inject market forces into a highly regulated market. This study, focused on the laser vision correction market within the ophthalmology industry, uses a newly validated National Eye Institute Quality of Life instrument to adopt a patient-focus when evaluating new treatments for complex vision disorders. New Innovations may offer higher quality and better outcomes for patients undergoing eye surgery.

In ophthalmology, the link betweeen quality of life and quality of vision has become increasingly important. Visual scientists have developed numerous ways of measuring and predicting refractive power of a patient's eye, before and after treatment, however monitoring the quality of vision and the subjective perception of visual quality is growing in importance as part of an overall evaluation of 'efficacy' of new treatments. Companies such as Staar Surgical and others have used visual quality of life measures to accompany quantitative clinical trial data to prove new Phakic IOLs are not only safe, but effective qualitatively and quantitatively. How patients feel they see, their confidence in their vision will be as important as improvements in refractive power to regulators, surgeons, patients and other stakeholders.

Health care industry is in an expense crisis. The introduction of disruptive technologies is suggested to ease the pressure and cure the health care system. 'Disruptive' technologies offer lower 'maintenance costs, higher quality and greater convenience; They create an entirely new market through the introduction of a new kind or product or service which are technological breakthroughs.

Photography: 35mm camera → Digital camera

The introduction of these technologies have changed the degree of problems and allowed improved vision particularly in the refractive and cataract surgery ophthalmic fields.

DISRUPTIVE INNOVATIONS: CATARACT SURGERY

Cataract surgery with intraocular lens (IOL) implantation (hard to soft foldable lens) has become the most common and most successful of all operations in medicine. Sir Harold Ridley's first cataract extraction with implantation of an IOL marked the beginning of a major disruptive change in the practice of ophthalmology

Aphakic correction → **ECCE/IOL** → **Phacoemulsification/ Hard PMMA IOLs** → **Phaco/Foldable IOL**

Aphakic correction	ECCE/IOL	Phacoemulsification/ Hard PMMA IOLs	Phaco/Foldable IOL
+ve: Vision corrected -ve: Impractical thick spectacles, optical distorsion	+ve: Vision corrected, no spectacles necessary -ve: Large limbal incision, induced astigmatism	+ve: Vision corrected, no spectacles necessary -ve: Medium size limbal incision, still some induced astigmatism, requires sutures	+ve: Vision corrected, no spectacles necessary, small limbal incision, no sutures, no induced astigmatism

DISRUPTIVE INNOVATIONS: REFRACTIVE SURGERY

Excimer lasers to treat refractive errors replaced radial keratotomy for the treatment of myopia and astigmatism

SPECTACLES & CONTACT LENSES → **RADIAL KERATOTOMY** → **REFRACTIVE LASER SYSTEMS**

The idea of using an IOL without removing the patient's cyrstalline lens to treat patient refractive errors is a paradigm shift and disruptive technology. Previously intraocular surgery, actually entering the eye to treat refractive error, was considered too invasive. Staar surgical can treat myopia as low as -3D with their Phakic IOL.

Intraocular surgery to treat refractive surgery once considered too invasive → **Phakic IOL foldable lens e.g. STAAR Surgical ICL (Implantable Collamer Lens)**

REFRACTIVE LASER SYSTEMS

Laser systems have evolved to meet the needs of the patients, laser surgery centers and ophthalmologists. A major disruptive change may be from the excimer laser to the solid state technology . The solid state systems eliminate the use of toxic gases for laser light generation, prove to be more economical, easier to maintain, and environmentally friendly.

EXCIMER (193NM) LASER	SOLID STATE (213NM) LASER
- Bulky gas tubes - Use of toxic gas for 193nm generation - Large consumption of energy - 193nm highly absorbed by BSS	- Diode-pumped Nd:YAG laser - Solid state crystals for 213nm generation - No gas cylinders - Energy efficient; no high voltage requirements - Stable and uniform beam energy - 213nm wavelength: high transmissilitily though water; Performance may be less susceptible to changes in humidity and corneal hydration.

CUSTOMIZED REFRACTIVE SURGERY

The treatment 'window' of refractive cases has become wider with the introduction of customized refractive surgery. The ability to treat hard, complex refractive cases is possible with new disruptive technology incorporated into the laser system. An efficient and precise customized approach requires technical features such as, a small laser spot size coupled with a fast pulse rate, fast scanning ability and homogenous beam are some of the essential requirements to perform precise corneal sculpturing with reduced treatment time, thus minimizing thermal heating and drying of the corneal surface. Custom surgery is a disruptive change and may allow greater treatment range of refractive disorders and better post-operative outcomes which in turn may increase patient quality of life. Standard cases may be treated with better accuracy and reliability and furthermore, the surgeon may begin to tackle difficult vision disorders such as irregular astigmatism.

IDEAL TECHNOLOGICAL REQUIREMENTS

- Solid state technology
- Gaussian, flying spot beam
- Small beam diameter coupled with fast pulse rate
- Efficient Fast Eye & Gaze tracking
- Integration of patient topography and wavefront data

QUALITY OF LIFE INSTRUMENT TO DETERMINE EFFECTIVENESS OF NEW TECHNOLOGIES

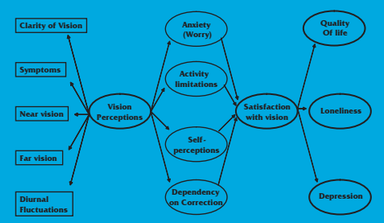
Quality of life assessment helps to demonstrate the real-life impact of a disruptive innovation on the treated patient. Customized surgery with the new CustomVis solid state laser system can treat complex refractive cases which were once considered 'non-treatable'. For these patients, an increase in 'quality of life' (QOL) is predicted as vision improvement is coupled with many lifestyle/emotional changes for the better. Vision perceptions can contribute to anxiety, activity limitations, self perceptions and dependency on correction. These factors can determine the satisfaction with vision that in turn will impact on QOL.
Assessment of QOL will include dimensions such as loneliness and depression, and it is expected that newer and disruptive innovations will have a more beneficial impact on patient QOL. Participants will be screened as surgical candidates using a subjective vision quality of life instrument; combined with quantitative assessments (BSCVA) to screen patients for surgery

- **Patients will undergo refractive surgery with the CustomVis Pulzar Laser (Solid state; 213nm)**
- **Patient's quality of life will be screened post-operatively at 6 months (typically when their vision is stabilized) to assess any signifcant changes.**

Instrument: (NEI QOL-42 Patient Questionnaire)

- **Developed by the National Eye Institute in the US, validated by Hayes & Spritzer, 2002 and approved by the US FDA and American National Standards Institute**
- **42 Questions for prospective patients around their subjective evaluation of their vision quality, and ability to perform tasks requiring visual acutiy**

VISION AND QUALITY OF LIFE



HYPOTHESIS:

Patient quality of life will be improved following custom corneal surgery with the CustomVis Pulzar Z1 solid state laser system