

Laser vision correction (lasik) in the United States

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Abstract

Laser Vision Correction (LVC) is an elective, self-pay and safe surgical procedure to correct myopia and hyperopia. Since FDA approval 25 years ago, there have been a progression of technological improvements leading to better outcomes and LVC is now one of the safest surgical procedures. A potential pool of 50 million patients, 6000 trained ophthalmic surgeons regularly treat in over 1000 centers. Treatments remain low from an earlier peak of 1.4 million to less than 800,000 over last 10 years. The factors preventing patients undergoing surgery have not changed and include the cost and fear of laser surgery. The latter is overcome by word of mouth referrals and positive social media messaging. Patients can be "in and out" in less than two hours with a rapid recovery, minimal postoperative restrictions and have 20/20 vision within 24 hours. Laser vision correction and especially LASIK, remains the treatment of choice for myopic and hyperopic patients wanting to remove their dependency on glasses and contact lenses.

Keywords

Covid-19 • Excimer • Contacts

Introduction

In the twenty-five years since the US Food and Drug Administration (FDA) approval for laser vision correction (LVC) to treat myopia and hyperopia with astigmatism there has been a progression of technological improvements from unilateral Photorefractive Keratectomy (PRK), to bilateral Laser-assisted in situ keratomileusis (LASIK) with wavefront or topographical guided treatments.¹⁻¹⁰ The flap initially created by a mechanical microkeratome now uses a femtosecond laser.

We estimate over the last twenty-five years only 20-25 million eyes were treated with less than 800,000 eyes being treated each year for the last ten years. The penetration of potential patients for treatment remains low at 0.2% per annum. Word of mouth referrals and social media reviews have diminished the fear factor, but cost remains an issue. The laser vision correction and particularly LASIK remains the treatment of choice for myopic and hyperopic patients wanting to remove their dependency on glasses and contact lenses.

Literature Review

It is estimated that 75% of adult Americans or over 230 million people have some vision problem requiring correction. Eyeglasses are worn by 50% of the population and up to 14% or 46 million

individuals, wear contact lenses. Some individuals wear contacts for social occasions and glasses at work. Myopia (Nearsightedness) is the most common refractive disorder occurring in 28% of the USA population and an additional 15% are hyperopic with or without presbyopia. The cause of myopia is unknown, but incidence varies with age, gender, geography, race, genetic lines, education, early reading, time spent outdoors and computer activities. Myopia is found more frequently in younger white females with graduate education and higher socio-economic status. Up to 80% of Chinese children are myopic and references are made to an "epidemic" occurring. The 45 million (14%) myopic patients who wear contact lenses tend toward soft and disposable lenses. Myopia accounts for over 80% of LVC procedures. The second category for LVC is hyperopia (Farsightedness) which is found cumulatively in 15% of an older adult population. Nearly all patients undergoing LVC have astigmatism which is corrected simultaneously. The vision correction market generated in professional service fees of over \$5 billion in 2016 and by 2019 it increased to \$6.3 billion mainly provided by independent eye care providers. Sale of contact lens is approximately \$4 Billion; eyeglass frames \$6 Billion and prescription lenses have sales of \$9 Billion per annum in USA. The revenue from cataract surgery, which is the most common surgical procedure, is estimated at \$11 Billion with 3.7 million procedures performed in 2020 by 9,000 ophthalmic surgeons in USA. This is in contrast to less than 800,000 laser refractive procedures being performed by approximately 3000

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ophthalmic surgeons with estimated revenue of \$1.5 Billion in 2020.

Other ophthalmic surgical procedures include use of retinal photocoagulation, vasectomies and glaucoma treatments with lasers, filters, and shunts. The population of suitable candidates for LVC in years 2020-2021 is 150 million myopic and 50 million hyperopic patients.

If consideration is taken relating to age, severity of refraction, FDA approvals and affordability, of the 200 million potential candidates we estimate that the number decreases by 75% to 50 million as being the potential patient pool. This pool annually grows faster than patients being treated due to annual birth rates. The two main factors causing patients to delay or not to have LVC over the last 25 years remains fear and cost or affordability. More recently professional misinformation from optometrists and adverse media articles have also caused patients to hesitate to have LVC. In 1995 following much anticipation and excitement, the Excimer laser was approved for refractive surgery by the FDA. Initially the Summit Technology Inc, Apex excimer laser was approved on March 18th, 1995 and on 29th September 1995 the VISX excimer system manufactured by AMO LLC was approved.²⁰ The expectations by ophthalmologists, optometrists, the financial community, and laser manufacturing companies in the 1990's was that there were 'millions of patients' waiting to be treated with high expectation of a pent-up demand. Within three years of FDA approval over 65 Companies were registered in the USA to provide the LVC procedure in newly established free-standing centers in the USA.

These Companies ranged from solo physician practices purchasing or leasing the equipment, to facilities offering open access similar to ambulatory surgery centers. Capital was raised both privately and publicly with estimated projections of billions of dollars in revenue annually. Unfortunately, the projections never reached these optimistic projections. There were multiple reasons for these estimations being so wrong including patients fear of lasers being used on their eyes, to the cost of the procedure which was up to \$3,000 per eye. Furthermore, many ophthalmologists were reluctant to operate on a "normal" cornea with refractive errors. The lack of referrals from optometrists wanting to maintain their patients for annual eye examinations and continuing to sell glasses and contact lenses also played a part. The FDA approvals progressed through multiple stages from Photorefractive Keratectomy (PRK) on a single eye with minimal astigmatism correction, to bilateral PRK and finally the less painful procedure of bilateral laser-assisted in situ keratomileusis (LASIK) for myopia and hyperopia including treating various forms of astigmatism.¹⁻¹³ A total of 72 FDA labeling approvals have occurred for the laser manufacturers AMO, Carl Zeiss, VISX, LaserSight, Nidek, and Bausch and Lomb since 1995.

Improvements in flap creation occurred as well with replacement of the mechanical microkeratome and its inherent flap risks to use of femtosecond laser for a 'bladeless' or laser/laser refractive surgery. ¹¹⁻¹³ LASEK or Laser Assisted Sub-Epithelial Keratectomy has similar disadvantages as PRK but probably less pain and more rapid healing but has obtained minimal penetration. Epi-LASIK is also infrequently performed. Newer developments have led to wave front-guided and wave front-optimized treatments that have minimized induction of higher order aberrations after refractive surgery. Topography guided ablations have provided the ability to treat

irregular corneal topographic patterns and some studies have shown they may achieve even better uncorrected vision with normal topographic patterns.²⁸ Other procedures began developing such as Small Incision Lenticule Extraction (SMILE) and phakic intraocular procedures with lens implanted either in front or behind the iris (IOLS).

Ophthalmologists

There are over 19,000 licensed and practicing ophthalmologists both Medical Doctors (MD) and Doctors of Osteopathy (DO) in the USA. Over the last 25 years at least 6,000 or a third have undergone some form of LVC training either in residency, fellowship or post-graduate courses organized by the manufactures and professional societies. By 2020 nearly 4,000 ophthalmologists were reported being refractive surgeons giving a ratio of one surgeon per 90,000 population.¹⁴

Further findings show that 700 ophthalmologists perform nearly 80% of the LVC procedures. The majority perform approximately 2,000 to 2,500 procedures per annum with only approximately 100 to 200 surgeons focusing their practice exclusively on LVC. During the financial crises, many ophthalmologists stopped performing LVC and began focusing on building a cataract or general ophthalmology practice. As with all surgical procedures, there is a learning curve and results would indicate more experienced surgeons focusing exclusively on high volume LVC practices obtain best outcomes with the least number of unhappy patients and less potential or actual litigation.

These include approximately 65% being Surgeon-owned facilities, Corporate owned in 25% and less than 10% are hospital or military LVC treating centers. Currently there are no publicly traded companies performing LVC. From the initial Corporate companies started in the 1990's only several remain including LCA-Vision, Inc. The latter investors in 2020 acquired the Laser Vision Institute and TLC Vision centers from the Vision Group Holdings (VGH) bankruptcy, NuVision is predominately in California and the mobile laser company Sight Path offers a mobile "roll on, roll off" service for both LVC and cataracts. The J and J Visx and Alcon Wavelight account for over 90% of the installed base of over 1200 excimer lasers in the USA.¹⁴ Other companies manufacturing LVC lasers include Bausch & Lomb, Nidek, Carl Zeiss, Schwind, LaserSight and Summit Autonomous Laser, bought by Alcon which was subsequently withdrawn from the market.

Procedures (LASIK)

We estimate a total of 20 to 25 million laser vision correction procedures or 10 to 15 million patients were treated in the past 25 years. LASIK will be the procedure of choice for many years to come and accounts for 80 to 85% of the procedures, PRK for 10-15% with the newer procedures such as SMILE, corneal inlay and other intraocular and phakic procedures are less than 5%. From 1995 LVC procedures increased to 1.4 million procedures by 2000 where it maintained this level for several years and then declined related mainly to the economy which it has closely tracked. In the last 10 years procedural volume has been relatively flat ranging from 600,000 to 800,000 treatments per annum.

Nearly 45% (340,000) of procedures are performed by independent surgeons in their own offices or in free-standing surgery centers. Corporate companies with less centers perform a similar 45% (345,000) procedures in their facilities. The military including and other hospital-based institutions account for under 10% (60,000) of the procedures.³⁸ Covid-19 and the elective surgical “shutdown” including LVC caused a dramatic fall off in procedures in the 1st and 2nd quarters of 2020 but there has been a rebound at the end of 2nd quarter, strong in 3rd quarter and in the 4th quarter in certain geographical areas declined due to “lockdowns” and increased fear of Covid-19 patients were reluctant to have elective surgery. This indicates that procedural volume for 2020 year will be less than 2019.

Pricing

LVC is an elective surgical procedure and is rarely covered by insurance and for the majority of patients it is a self-pay or private pay procedure. Federal Savings Account (FSA) and Medical Savings Accounts (MSA) can be used for payment. The recommended fees and final charge to a patient varies tremendously by geographical market, physician experience, name recognition, the refractive prescription, type of excimer laser used such as traditional, custom wavefront or wavefront guided, if punctal plugs were inserted and if the flap is created by mechanical blade or using a laser method.

Prices advertised to the consumer varies on various websites and the price ultimately paid by the patient, the Average Selling Price (ASP), maybe higher or lower depending on the various factors listed above.

Some facilities charge a fixed fee to include the preoperative examination, surgical procedure including drugs and disposables and postoperative visits which can vary from one to three visits or can be part of a “lifetime” plan. Enhancements which have declined over the years, may also be performed without cost for several years. Discounts are often offered to entice patients to schedule visits for preoperative evaluation and for subsequent treatment. The MarketScope 2020 reports an average price of \$2,632.00 per eye in USA. The cumulative revenue for ophthalmologists performing LVC is less than 5% compared to nearly 30% from cataract surgery due to the larger number of annual cataract procedures. Surgeons either stop performing LVC altogether and change to other procedures eg. cataracts if income decreases or perform both LVC and cataract surgeries, or exclusively perform LVC. The LVC surgery is performed either in their own private practice office or by providing services to Corporate practices on a part-time or full-time basis.

The variables influencing profitability are the average selling price, the number of treatments performed, costs associated and efficiencies in patient conversion. As surgeons become more established the word of mouth referral increases and the marketing costs can begin to decline. The LVC Centers have great surgical capacity advantages. Fixed costs can stay the same with changes in volume and only the variable cost increases or decreases proportionately with volume changes. Experiences and skilled surgeons performing LVC for over 20 years are reporting cumulative treatment volumes of 50,000 to 125,000. The surgical procedure is relatively fast, and patients can be “in and out” following an LVC treatment in less than two hours. Experienced surgeons treat up to four patients with bilateral LASIK in an hour and if staff is efficient,

the centers can perform 60 to 80 treatments in a day. Certain surgeons, require a 30- Minute period for each surgery and will not perform more than 10 to 20 treatments in a day depending on surgical experience and use of either the quicker microkeratome or slightly slower laser for creation of the flap. LVC is an elective self-pay procedure with increased expectations from the patient regarding outcomes. Minimal requirements for LVC is freedom from glasses and contacts but more realistically is the desire for the equivalent or better vision often referred as 20/Happy. Patients expect a “red carpet or five star” professional experience and near perfect vision outcomes without pain or complications and a rapid recovery. Multiple studies report outcomes from the initial FDA studies to large randomized and meta-analysis studies that show 99.5% of patients achieve 20/40 vision and 90 to 95% achieve 20/20 or better vision. The earlier complications of ghosting, halos, glare, and difficulty with night vision do not occur. In 40% of contact lens wearers, dry eyes is reported which improves with LVC and intensive eye drop regime. Ectasia is now treatable and preventable with corneal cross-linking and strict preoperative screening for subclinical keratoconus with topography and tomography and Neuropathic pain post-treatment is very rare. Postoperative instructions for LASIK have become more simplified with patients returning to most activities within hours of surgery and by using a “common sense” approach.

Litigation is the worst outcome of LVC. Fortunately, LVC is one of the safest surgical procedures and many practices incorporate proactive methods to prevent litigation. A 20/unhappy patient is a dissatisfied customer even if the uncorrected vision is 20/20 or even 20/15.⁵⁸ The issue of needing reading glasses for presbyopia remains an issue for patients due to the advertising message of ‘freedom from glasses and contacts.’ Similarly, monovision or blended vision for older patients requires education and pretreatment trials with only 50% of patients being candidates for surgery. An assessment of post-refractive symptoms was carried out by the FDA in collaboration with the National Eye Institute (NEI). A questionnaire was developed for patients following LASIK at the US Naval Medical Center in San Diego with 262 participants and completed in 2014 was called PROWL-1 an acronym for the Patient Reported Outcomes with Lasik) and an additional study in 312 civilian postoperative patients was called PROWL-2.

In each of the PROWL studies, less than 1% of patients experienced difficulty performing their usual activities following LASIK surgery due to any one symptom and more than 95% were satisfied with their vision.⁵⁹⁻⁶³ As so few patients experienced debilitating symptoms, the FDA decided with its limited resources not to conduct a larger clinical study to estimate prevalence of complications more accurately or find useful predictors in post-LASIK patients. Patients besides assessing the risk versus benefits of LVC, should also include expected cost savings. The indirect and direct expenditure is equal to 8 to 10 years of purchasing glasses, contact lenses, solutions and eye care visits. Consideration of time to insert lenses and benefits of “lens free” occupations for firefighters, police, healthcare workers, safety for mothers and athletic benefits for swimmers, runners, and bikers.

Covid-19 Pandemic and Telemedicine

With forced closures for elective LVC centers due to Covid-19 pandemic from late March 2020 to slow reopening in early June 2020, the practice of LVC changed. Teleophthalmology consultation

during center closure went from minimal to nearly 80% with potential patients scheduling surgery without an examination.

Patients appeared knowledgeable of their vision prescriptions and had minimal questions besides asking about potential dates for surgery, recovery time and if any experience of pain. Factors motivating patients were glasses fogging up with wearing masks, known as 'glass fog', increased risk of wearing contact lenses due to facial hygiene with less touching and patients physical facial appearance on internet communication such as Zoom and Microsoft Teams. Following reopening of surgery centers in areas no longer under lockdown, there has been an increase in LVC and other procedures including facial aesthetic surgeries. Plotting the back log of LVC surgery post-covid using the Monte Carlo stimulation applied to elective cataract surgery study, we estimate an optimistic additional 300,000 LASIK surgeries in years 2021 to 2022.16. LVC can be performed safely with Covid-19 precautions including requesting all patients to wear masks, restrict distances in waiting rooms, asking family and friends to wait in cars outside, extensive cleaning procedure rooms between each patient and using transparent physical barriers where appropriate. Despite all these new procedures, treatment efficiencies are being maintained after the initial learning curve. Pre-operative and postoperative visits are by telemedicine if possible, with minimal physical contact between LVC staff and patients.

Conclusion

Laser Vision Correction (LVC) has now reached its 25th anniversary since FDA approval in the USA. We estimate 20 to 25 million eyes have been treated giving a very low 0.2% penetration of treatments per annum for the refractive conditions of myopia, hyperopia with astigmatism. The compounded annual growth rate for LVC is under 2% which is too low for a procedure which is safe, cost effective and reliable. Word of mouth from satisfied patients, co-management, internet patient reviews and consumer marketing are the main drivers for LVC treatments.

Cost and fear are still the major factors delaying treatments. Fear has become less with the Covid-19 epidemic due to masks fogging up glasses. Surgical outcome results have improved dramatically over the 25 years especially in high volume facilities where processes have become standardized and best practices instituted reducing errors by staff and ophthalmologist. Treated patients will not need to wear their glasses or contact lenses for their financially and professionally productive years until they become presbyopia with advancing years.

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