

# Refractive Surgery Part 1: Long-term Outcomes

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## Abstract

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While LASIK and PRK have been used for two decades, there have been few long-term studies on refractive surgery. This study examined the long-term outcomes of LASIK and PRK and analyzed the risks, benefits, and technological breakthroughs of these procedures. Rates and causes of patient satisfaction are discussed in detail. Alternative techniques such as small-incision lenticule extraction (SMILE) and surgical options for presbyopia are also explored.

### KEY WORDS:

PRK, LASIK, SMILE, KAMRA, ectasia

### INTRODUCTION

Since radial keratotomy (RK) was replaced in the 1990s by excimer procedures (due to associated complications and lack of predictability)<sup>1,2</sup>, laser refractive surgery has been viewed as a long-term solution to reduce dependence on contacts and glasses.<sup>3</sup> The FDA approved the first excimer laser in 1995.<sup>4,5</sup> Meanwhile, laser eye surgery has been performed on over 16 million patients worldwide.<sup>6,7</sup>

Today, photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) are the most widely used refractive procedures in the world.<sup>3,8</sup>

Both procedures alter corneal curvature by removing tissue with an excimer laser, thus changing refractive power.<sup>8,9</sup> LASIK is the more common procedure of the two,<sup>10-12</sup> partially because of its increased comfort immediately after surgery.<sup>8</sup> With this, LASIK has gained popularity for correcting myopia, hyperopia and astigmatism.<sup>13,14</sup> Treatments for presbyopia involving LASIK are also available.<sup>15,16</sup>

While LASIK and PRK have been used for over two decades, there are relatively few long-term studies for direct comparison.<sup>17</sup>

LASIK is amongst the most common eye surgeries in the world,<sup>18</sup> and millions of patients undergo the procedure each year.<sup>19</sup> Approximately one million patients undergo LASIK annually in the US alone.<sup>10,20</sup> It has been demonstrated to feature safety, efficacy, fast recovery and minimal patient discomfort.<sup>11,12,19</sup> As a result, laser eye surgery has allowed patients to enter professions that were previously out of reach because of refractive errors.<sup>10</sup> Even astronauts have reported satisfaction and stability with laser vision correction, such as PRK.<sup>7,21</sup>

However, LASIK has been associated with complications such as dryness, night vision disturbances<sup>22</sup> and corneal ectasia.<sup>13,22</sup> While there is some evidence of modest myopic regression,<sup>11</sup> the risk of serious visual loss associated with LASIK and PRK is low.<sup>23,24</sup>

### REFRACTIVE ERROR

Refractive error affects approximately half the US population.<sup>25</sup> Other studies suggest that this prevalence may be as high as 60%.<sup>11</sup> Myopia affects 1.6 billion people worldwide,<sup>3</sup> and one-third of the world's population (2.5 bil-

lion) is expected to be affected by 2020.<sup>3</sup> In the West, about one in four people are myopic, and in regions of Asia, this prevalence can be as high as 70 to 90%.<sup>3</sup>

Hereditary and environmental factors play a role in the development of myopia.<sup>3,24,26</sup> Many years of formal education (and prolonged near work) have been associated with higher rates of myopia, and several genes linked to myopia have been identified.<sup>26</sup> A study of ethnic Chinese in Taiwan and another of army recruits in Israel have demonstrated that the prevalence of myopia increases over time.<sup>26</sup>

Although the excimer laser for hyperopia was approved in 1998, it requires peripheral annular ablation around the optical center zone, which causes steepening of the central cornea relative to the periphery.<sup>26</sup>

Hyperopic correction with LASIK has improved over time, but remains less stable than correction for myopia or astigmatism.<sup>6,27</sup>

### **LASIK AND PRK PROTOCOL**

Over a million surgical procedures to improve vision are performed in the US annually, and LASIK is the treatment of choice.<sup>22</sup> LASIK is a surgical procedure that involves the creation of a thin flap with a microkeratome followed by excimer laser ablation of the stroma.<sup>28</sup> Adults with stable refraction are qualified candidates.<sup>11</sup> The patient should be screened for both ocular and systemic diseases that would affect the surgical outcome or recovery. Patients with rheumatologic disease are generally excluded from LASIK.<sup>29</sup> Of note, glaucoma (a neurodegenerative condition of the optic nerve<sup>30</sup>) is not a contraindication to refractive procedure.<sup>11</sup> Contraindications are conditions that affect healing and abnormal corneal anatomy, such as keratoconus, thin cornea or ocular dryness.<sup>11,31</sup> Prior to surgery, soft contact lenses should not be worn for one week and hard lenses (RGP) should not be worn for three weeks because of their greater potential for corneal warpage and refractive instability.<sup>26</sup> Moreover, the patient must not be either pregnant or breastfeeding.<sup>19</sup> A post-operative corneal bed residual thickness of >250µm should be available.<sup>19</sup> Counseling patients on realistic expectations is key.<sup>11</sup> Presbyopes must be advised that, if corrected simply for distance, they will require reading glasses following surgery.<sup>11,16</sup> Patients undergo post-operative evaluations at one day, one week, one month and three months.<sup>19</sup>

Following epithelial debridement, PRK employs an excimer laser to ablate the cornea (Bowman's layer and anterior stroma) without the creation of a flap.<sup>32</sup> The cornea usually heals within 48 to 72 hours.<sup>32</sup>

LASIK results, though comparable to those of PRK, have the advantages of quicker recovery, less discomfort and diminished risk of corneal haze, particularly in higher myopes.<sup>4,33</sup> LASIK also has a decreased need for more prolonged steroid use than PRK.<sup>33</sup>

### **LASIK RESULTS (LONG-TERM OUTCOME OF REFRACTIVE PROCEDURES)**

While LASIK is the most frequent laser refractive procedure currently performed worldwide, long-term LASIK follow-up studies have only recently begun to emerge.<sup>12</sup> However, longer-term studies of PRK have shown the safety and stability of the procedure for up to 12 years.<sup>12</sup> Ten-year data show that LASIK is safe and effective.<sup>11</sup> Thus, the clinical efficacy of LASIK for low to moderate myopia is becoming well established.<sup>28</sup>

Almost every patient who undergoes LASIK achieves visual acuity (VA) of at least 20/40.<sup>6,11</sup> An FDA review of LASIK device studies revealed that 97% of patients achieved uncorrected visual acuity of 20/40 post-surgically and 62% achieve 20/20.<sup>26</sup> LASIK success is based in part on its ease and comfort, outstanding visual outcome and low complication rate (with only remote chances of complications leading to permanent vision loss).<sup>10</sup>

High myopia is less likely to be totally corrected than moderate and low levels.<sup>26</sup> LASIK is not generally recommended for myopia greater than -12D because of the deterioration in the quality of vision and lack of refractive stability.<sup>13</sup> With high myopes, image quality post-surgery is reduced (partially based on a flatter cornea creating more spherical aberration).<sup>34</sup> The FDA maximum for LASIK is -14D.<sup>13</sup> However, high levels of functional improvement, improved quality of life and consistently enhanced levels of satisfaction were reported by patients after LASIK surgery for high myopia.<sup>13</sup>

There was a low rate of loss of best-corrected visual acuity (BCVA) post-surgically in FDA trials from 1993 to 2002, with 0 to 4.5% of eyes losing more than two lines of acuity,<sup>19</sup> and the mean percentage of losing two lines or more equating to 0.6%.<sup>19</sup> Long-term studies have shown that the effects of LASIK treatment stabilize at the three-month mark.<sup>19</sup> Therefore, the conditions at three months may provide a fair estimation of the final outcome.<sup>19</sup>

## WORLD STUDIES

A 10-year study from Singapore found that 92.6% of patients achieved VA greater than or equal to 20/40.<sup>19</sup> Patients who had surgery towards the end of the study realized even better results, consistent with FDA studies indicating a roughly 98% achievement of greater than or equal to 20/40, and 72.8% of patients achieved VA greater than or equal to 20/20.<sup>19</sup> High myopes were the least successful, with only 79.2% achieving greater than or equal to 20/40.<sup>19</sup> Myopes over -10.00D had the worst results in terms of refractive predictability, safety and efficacy.<sup>19</sup> A small amount of regression per year was noted over 10 years.<sup>19</sup> Overall, the study provided clear evidence that LASIK outcomes remain very satisfactory.<sup>19</sup>

An investigation from Turkey of LASIK patients with very high myopia documented the 10-year follow-up outcomes of the procedure.<sup>13</sup> Although LASIK offers reliable results with a high degree of myopia (-14.00D and higher), significant regression develops over the long term.<sup>13</sup> Slow myopic regression has been shown to occur for 10 to 14 years after surgery.<sup>13</sup>

A 10-year LASIK follow-up study from Ireland showed that better results were achieved in mild to moderate myopia patients than in those with high myopia.<sup>35</sup> That study provided evidence that LASIK is a safe procedure with high patient-satisfaction and long-term stability in low to moderate myopes, while high myopes had a greater likelihood of regression.<sup>35</sup>

In a Romanian investigation, both PRK and LASIK were shown to be safe, effective and predictable in terms of correcting moderate to high myopic astigmatism.<sup>36</sup>

An Australian study found that the refraction of myopes who had undergone either PRK or LASIK continued to be stable for six and even up to nine years. Stability was similar for all myopes and both PRK and LASIK patients.<sup>3</sup> Low to moderate myopes had better post-operative uncorrected-distance visual acuity (UDVA) than the high myope group.<sup>3</sup> The mean myopic regression in this study was similar to those in other studies: 0.5D over five years and 0.58D over 12 years.<sup>3</sup>

In another study of highly myopic (-8.00D to -14.25D) LASIK patients in Germany, none of the participants lost more than two lines of BCVA and only 3% lost one line.<sup>37</sup> Half the patients gained a line of BCVA and only one complained of night vision problems.<sup>37</sup> Interestingly, it was found that LASIK elicited outcomes similar to those with phakic intraocular lenses (IOLs) without the potentially serious complications associated with intraocular surgery.<sup>37</sup>

In a Scottish study that followed 2530 patients for five years after LASIK surgery, 94.9% did not wear glasses with 90.6% having 20/20 binocular UDVA and 91% said they were satisfied with their vision.<sup>38</sup>

While PRK and LASIK were once regarded as problematic in hyperopes, recent advances have made the procedure more safe and effective in such patients (up to +4.00D).<sup>27</sup> A 16-year study of hyperopic LASIK patients in England revealed no sight-threatening complications.<sup>27</sup> However, the efficacy of the procedure was markedly lower compared to the results in myopes.<sup>27</sup> Interestingly, this may have been due to latent hyperopia becoming manifest with age as accommodation declined, rather than an inherent flaw of the surgical procedure.<sup>27</sup> Nevertheless, 89% of patients said they were happy to have undergone the LASIK procedure.<sup>27</sup>

## MILITARY STUDIES

Glasses can be expensive and inconvenient in military operations.<sup>4,39</sup> They can fog up, become scratched, get lost and so on.<sup>4</sup> They can also make it difficult to operate sophisticated optical devices.<sup>4</sup>

In a recent investigation of Japanese ground forces, a majority of soldiers wearing either glasses or contacts (66.9% of spectacle wearers and 63.5% of soldiers wearing contact lenses) reported problems during military exercises.<sup>39</sup> Only 24 of the 519 soldiers in the study (under 5%) had undergone a refractive procedure.<sup>39</sup>

Refractive surgery under the age of 21 has not been generally advised because of the expected progression of myopia<sup>5</sup> and increased risk of corneal ectasia (under age 25).<sup>40</sup> In Israel, where conscription is universal and admission to elite combat units is considered prestigious, a considerable amount of youngsters aged 17 to 20 undergo the procedure.<sup>5</sup> An eight-year Israeli study examined the effects of laser surgery on young soldiers serving in combat units. The extreme climatic conditions of military service and dark or low-contrast light conditions did not negatively affect soldiers who had undergone laser surgery.<sup>5</sup> Furthermore, dry eye and night



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vision problems did not seem to negatively impact these soldiers' performance.<sup>5</sup> In fact, the dropout rate of soldiers who had undergone refractive surgery was 13.1%, while that in soldiers who wore glasses or contacts was 29.2%.<sup>5</sup> Most soldiers who had undergone surgery said their ability to contribute to their unit's missions was enhanced. Improvements were also reported in the soldiers' overall readiness, weapons-sighting, ability to perform night operations and capacity to use personal nuclear, chemical and biological equipment.<sup>5</sup> LASIK surgery presented no obstacle to serving in combat units.<sup>5</sup>

Approximately one million active US Army personnel require corrective lenses.<sup>4</sup> Over 16,000 US soldiers have undergone refractive surgery with demonstrably excellent results.<sup>4</sup> Reports of complications, such as dry eye and night vision problems, are both infrequent and apparently inconsequential to military operations or battle readiness.<sup>4</sup> The US Army now supports this surgery under the Warfighter Refractive Eye Surgery Program (WRESP).<sup>4</sup> The goal is to boost battlefield effectiveness while providing safety and survivability.<sup>4</sup> Post-operatively, no complications were described at an incidence greater than 1%.<sup>4</sup> Of 175 soldiers returning from overseas missions, 93.1% felt that their ability to contribute to the mission was bolstered by refractive surgery, and 93.7% rated their overall individual readiness as either better or much better than before the procedure.<sup>4</sup> Interestingly, the soldiers' ability to perform night operations and use night vision equipment was perceived to be improved by 85.7% of soldiers and unchanged by 9.7%.<sup>4</sup> The incidence of night vision problems was highest immediately after either PRK or LASIK, though was gradually abated; at the three-month post-operative mark, night vision complaints returned to pre-operative baselines.<sup>4</sup>

Military studies have shown improved night vision using the latest LASIK technology,<sup>41</sup> and all branches of the American military accept LASIK as a way to enhance performance. It is now approved for Navy and Air Force pilots and has most recently been approved by NASA.<sup>10</sup> One dissenting Chinese study concluded that LASIK was not safe for military personnel. The study suggested a correlation between LASIK surgery and eye injuries in military service.<sup>42</sup> Yet, in a study of American military naval aviators who had undergone femtosecond-assisted wavefront-guided LASIK, 95.9% stated they believed that LASIK had aided their professional performance and 99.6% would suggest the same treatment to others.<sup>43</sup> Ultimately, the surgery was a successful and low-risk option for naval aviators, and enabled a quick return to flight status.<sup>43</sup>

As might be anticipated, refractive surgery always carries a risk of complications, and patients should be properly counseled.<sup>44</sup> One recent case report outlined the permanent grounding of a military pilot owing to complications associated with steroid treatment following PRK-precipitated non-arteritic anterior ischemic optic neuropathy (NA-AION).<sup>44</sup> Although such instances are extremely rare, the risk cannot be completely eliminated and at-risk patients cannot be easily identified prior to surgery.<sup>44</sup>

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### SATISFACTION WITH LASIK

LASIK is one of the world's most common elective procedures and features a very high level of satisfaction.<sup>3,8,10</sup>

While surgeons are concerned with post-operative BCVA, patients are primarily concerned with how the BCVA translates to improved quality of life.<sup>10</sup> Previous studies have shown improved self-esteem and self-image as well as decreased embarrassment in social situations.<sup>10</sup> Refractive surgery patients scored higher in terms of quality of life than those wearing glasses or contact lenses.<sup>10,25</sup> The quality of life was similar to that in emmetropic patients, indicating that the enhanced quality of life was due to this surgery.<sup>10</sup>

Residual refractive errors and the need for enhancements have decreased over the last few years with improvements in eye tracking along with smoother and customized ablation.<sup>6,10,45</sup> While patient satisfaction can vary based on expectations and surgical results, most are content with their outcomes.<sup>26</sup> Well-informed patients, who understand the limitations of surgical intervention and potential side effects as well as eventual emergence of presbyopia, tend to be more satisfied.<sup>26</sup> Interestingly, subjective visual function and patient satisfaction do not always correlate with objective measurements.<sup>26</sup> In many cases, unhappy patients had good uncorrected vision.<sup>26</sup>

Night vision problems, like glare and haloes, have been a source of patient dissatisfaction.<sup>9,10,22,46</sup> The LASIK World Literature Review, which evaluated outcomes from 1988 to 2008, found that an average of 95.4% of patients were satisfied with the procedure.<sup>10,47</sup> With over 16 million procedures completed to date, LASIK can be considered one of the most successful and satisfying elective procedures.<sup>10</sup>

Myopic and hyperopic patients are equally satisfied,<sup>10</sup> Patients in the US and across the world are equally satisfied.<sup>10</sup>

An individual's personality traits have an impact on their quality of life. Optimism and subjective well-being are related to mood, coping and faster rates of physical recovery.<sup>48</sup> Clearly, factors other than visual performance have an important role in patient satisfaction with refractive surgery.<sup>48</sup>

Satisfaction with LASIK is mainly related to the improvement in visual function, patient's pre-operative expectations, physiological characteristics and UCVA achieved.<sup>48</sup> Studies have shown that there is a disparity between high levels of satisfaction and the presence of visual disturbances.<sup>48</sup> Although a seven-year retrospective study from Finland showed that myopic regression was common, the patient satisfaction rate was 100%.<sup>12</sup> These same patients declared they would have the procedure performed again.<sup>12</sup>

Patients with existing psychiatric conditions, such as OCD (obsessive compulsive disorder), schizophrenia and bipolar disorder, and whose conditions are being treated, are stable and are known to the surgeon achieved excellent results, were satisfied with the procedures and had no specific complications.<sup>18</sup> Various studies have shown an increase of up to 30% in quality-of-life scores after LASIK in the general population.<sup>22</sup>

Younger non-presbyopic patients tend to report higher satisfaction rates with LASIK than patients over 40.<sup>25</sup> However, all patients expressed high satisfaction rates regardless of age.<sup>25</sup>

An increased sense of subjective well-being, adaptability and self-efficacy was clear after LASIK. Patients described a more optimistic attitude to life and increased quality of life after surgery.<sup>48</sup>

Many patients have doubts regarding refractive surgery and are concerned about post-operative complications.<sup>47</sup> One of the reasons contributing to this is the fact that, while many doctors advocate LASIK, most still wear glasses. Moreover, the majority of doctors are over 40 and are therefore less likely to undergo LASIK, potentially requiring a presbyopic correction, as well.<sup>47</sup>

A study from South Korea looked at the satisfaction rates of physicians who had undergone LASIK versus a control group composed of other healthcare workers.<sup>47</sup> There was no statistically significant difference in the objective clinical outcomes or subjective satisfaction rates between the physician and control groups.<sup>47</sup> Further, there were no differences in these rates between surgeon and physician subgroups. The study appears to indicate that LASIK is even suitable for patients who perform intensive near-vision tasks.<sup>47</sup> Another investigation confirmed that physicians who had undergone laser vision correction had very high satisfaction rates (95.3%).<sup>49</sup> Only 1.6% of doctors in the study stated that their ability to perform procedures had diminished as a consequence of refractive surgery.<sup>49</sup>

Perhaps even more telling, a survey of ophthalmologists who perform refractive surgery found that they were four-fold more likely to undergo the procedure themselves than the general population.<sup>7</sup> Surgeons who perform laser vision correction were also extremely likely to recommend it to immediate family (90.2% to 98.6%) and over 90% of those surgeons claimed they were better off having undergone the procedure themselves.<sup>7</sup>

Finally, an analysis of all peer-reviewed articles related to LASIK published between 2008 and 2015 did not find even one article featuring a negative impression of the procedure.<sup>6</sup> Neither was there any indication of financial interest influencing the results (the FDA PROWL study was conducted without physician or industry oversight and is consistent with other studies).<sup>6</sup> ●

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