Photorefractive keratectomy (PRK) is an elective optical procedure that reduces low to high myopia, low to moderate hyperopia, and astigmatism, according to the International Society for Refractive Surgery. During the procedure, a thin layer of cells covering the cornea, known as the epithelium, is removed so an excimer laser can sculpt the cornea and improve vision for the patient. A bandage contact lens is usually put over the eye after the procedure to speed the healing process, which typically takes three to four days. During this time, the patient may experience blurred vision as the epithelium regrows and heals.

A similar procedure known as LASIK has outperformed PRK in recent years because it provides less discomfort, faster recovery, and the ability to enhance the outcome in as few as three months after the initial surgery. However, PRK may be recommended for patients who have thin corneas since LASIK procedures create a flap in the cornea. Over the years ophthalmologists have reformed these procedures to include advanced surface ablation in which the cornea is cooled before or after surgery to reduce discomfort.

A recent study conducted by the American Academy of Ophthalmology suggests there may be a revival in PRK popularity. In 2010, 800,000 refractive surgeries were performed. PRK procedures can also be used to treat epithelial dystrophy and issues with the cornea. They can also remove scars on the cornea or strengthen the cornea through corneal collagen cross-linking. A study published the American Journal of Ophthalmology shows this cross-linking approach can also treat patients with keratoconus.

The American Board of Ophthalmology (ABO) offers primary certification in ophthalmology for initial candidates, as well as maintenance of certification (MOC) for continuing education. The American Osteopathic Boards of Ophthalmology and Otolaryngology-Head and Neck Surgery (AOBOO-HNS) offers certification for candidates who have graduated from a college of osteopathic medicine, are accredited by the American Osteopathic Association (AOA), have completed a one-year specialty track internship, and have completed a three-year residency program in ophthalmology.

For more information, please see Clinical Privilege White Paper, Ophthalmology—Practice area 148.
Involved specialties

Ophthalmologists

Positions of specialty boards

American Board of Ophthalmology

The ABO is the nation’s oldest medical specialty certifying board, recognized by the American Board of Medical Specialties (ABMS). The ABO requirements for certification are as follows:

➤ Graduate from an allopathic or osteopathic medical school.
➤ Complete a one-year postgraduate internship in an Accreditation Council for Graduate Medical Education (ACGME)–accredited program in which the candidate is primarily responsible for patient care in the fields of internal medicine, neurology, pediatrics, surgery, family practice, or emergency medicine.
➤ Complete a three- or four-year residency in an ACGME-accredited program.

After successfully completing all of the requirements, candidates are eligible to apply for the written qualifying examination, followed by an oral examination that requires candidates to “care for” a patient in six separate examinations. The panel of examiners presents a range of scenarios and then judges the candidate according to cognitive knowledge and patient care.

ABO also has MOC requirements. Board-certified ophthalmologists must meet the following requirements for MOC:

➤ Hold a valid, unrestricted license in the state in which they practice.
➤ Acquire an average of 30 Category 1 CME credits per year from an ACGME-approved organization throughout the 10-year MOC cycle. This includes 3 credit hours in ethics, and 80% of all credits must be in ophthalmology.
➤ Complete two Periodic Ophthalmic Review Tests (PORT), an online, self-review assessment. One PORT must be in core ophthalmic knowledge and one must be in a practice emphasis area of the diplomate’s choice.
➤ Pass the Demonstration of Ophthalmic Cognitive Knowledge (DOCK) examination, a proctored 150-question computerized exam in core ophthalmic knowledge and practice emphasis areas.
➤ Complete the Practice Performance Assessment through the Office Record Review. Diplomates select three modules, each of which review clinical patient records for five patients. This ensures quality of practice for self-assessment.

AOBOO-HNS

AOBOO-HNS is accredited by the AOA as a specialty board for certification in ophthalmology, the primary certification for eye laser surgeries such as PRK.
To obtain certification in ophthalmology, candidates must meet the following requirements:
➤ Graduate from an AOA-accredited college of osteopathic medicine
➤ Maintain an unrestricted state license in the state of practice
➤ Be in good standing with the AOA
➤ Complete a one-year specialty track internship (general surgery is acceptable)
➤ Complete a minimum of three years of AOA-approved residency training in ophthalmology
➤ Complete written and oral examinations

“It shall be the policy of this Board to require the Credentials Committee to carefully scrutinize the scope of specialty practice represented in each candidate’s report,” AOB00-HNS states in its requirements for certification. “Unless the candidate presents evidence that the scope of his/her specialty practice is sufficiently varied and of a major character, the Credentials Committee shall not recommend the candidate for certification.”

Positions of societies, academies, colleges, and associations

AOA
The AOA lists basic educational standards for three-year residency training in ophthalmology. Under “specialty content” the AOA lists specific requirements along with broad surgical and medical education on the management of ophthalmologic diseases. Residents are required to receive clinical training in a number of areas, including refractive surgery as well as laser therapeutics.

Residents must also perform and assist with a “sufficient number of operative procedures,” according to the AOA. Furthermore, “each resident must have major technical and patient care responsibilities in the surgery (including laser surgery)” for a number of medical conditions, including the cornea. Documentation of surgical experiences (including the number of cases the resident has served as the primary surgeon or the assistant surgeon) must be provided to the American Osteopathic Colleges of Ophthalmology and Otolaryngology-Head and Neck Surgery.

The AOA notes that not all residents are expected to have operative experience in all surgical specialty procedures, but they “must be sufficient in number and variety to provide education to the entire scope of the specialty.”

Although the AOA provides no concrete number for specific procedures, for a residency program in ophthalmology to be considered for approval there should be a minimum of 75 major ophthalmologic surgical cases per year for each resident in training.
ACGME
The ACGME offers ophthalmology program requirements for residencies. In addition to providing standards for basic medical care for patients with ophthalmologic diseases, the ACGME offers minimum operative procedures to satisfy standards of a skilled ophthalmic surgeon. Residents must perform at least six keratorefractive surgeries and three corneal surgeries. These minimums are expected for 2012 graduates.

AOS
The American Ophthalmological Society (AOS) published a Medical Student Curriculum in 2003, which lists PRK and LASIK as two types of refractive surgery approved by the FDA to improve vision with the use of laser surgery. AOS lists the following competencies for refractive surgery:
➤ Understand refractive errors and their relations to eye length, corneal curvature, and lens status
➤ Basic knowledge of refractive surgical theory and practice
➤ Understand risks and benefits of commonly discussed and performed refractive procedures

ASCRS
The American Society of Cataracts and Refractive Surgery (ASCRS) is a members-only society that publishes practice guidelines for refractive surgery. At this time it doesn’t have any guidelines or position papers available to the public on the issue of PRK.

The Cornea Society
The Cornea Society is an “international society to promote knowledge, research, and understanding in cornea external disease and refractive surgery,” according to its mission statement. The society has published Program Requirements for Fellowship Education in Cornea, External Disease, and Refractive Surgery, which outlines specific educational requirements for ophthalmology fellows specializing in refractive surgery.

According to the guidelines, fellows should see and be responsible for approximately 2,000 patients during their fellowship, although not all of them need to be refractive surgery patients. For fellows specializing in refractive surgery, the fundamentals of the surgery and its complications should be included, along with a special emphasis on forms of keratorefractive surgery such as incisional, excisional, keratoplasty, and alloplastic inserts.

Fellows should also be supervised in specific procedures, including 20 endothelial replacement cornea transplants, and assist in another 50 endothelial replacement corneal transplant cases. "In programs offering training in refractive
surgery, they will perform at least 8 laser refractive procedures (e.g. LASIK, PRK, LASEK) and assist and/or observe in at least 50 other cases,” the guidelines read.

Finally, the program director must give a written final evaluation for each fellow, including an individual performance review, as well as verification that the fellow has demonstrated competence to practice independently.

In 2003, The Cornea Society also released a position statement opposing the creation of certificates of added qualification (CAQ) in ophthalmology, noting that subspecialty certification would have a detrimental effect on the profession. The society lists the following as potential negatives to subspecialization:

- ACGME-accredited fellows would fall under the same regulations as residents. The Cornea Society argues that there is no funding for these positions and could impact the number of available resident positions.
- The Cornea Society would relinquish control of the content of its fellowship programs.
- All fellowships would be required to affiliate with residency programs, which would represent a major and possibly detrimental change for some highly respected fellowships.
- Fellows’ salaries are augmented by assistant fees and other billing. Under ACGME guidelines this would not be allowed.
- ACGME guidelines do not support or allow for fellow research.
- ABO/ABMS/ACGME fellowship certification verifies the quality of the fellowship, but this can be achieved through other methods without putting undue burden on the sponsoring practices.
- The Cornea Society has concerns about the impact of CAQ certification on the ability of the comprehensive ophthalmologist to perform general ophthalmic plastic surgery. The addition of a specific CAQ in oculofacial plastic surgery, for example, would make it more difficult for a comprehensive ophthalmologist to obtain or maintain privileges for general oculoplastic surgery.

The Cornea Society believes it could put its efforts to better use by strengthening the departmental presence in hospitals, and that fellowship oversight can be achieved through alternate channels other than CAQ certification.

**ASLMS**

The American Society for Laser Medicine and Surgery (ASLMS) has published *Standards of Training for Physicians for the use of Lasers in Medicine and Surgery*. The position paper states that hospitals are responsible for establishing privileging requirements regarding the use of lasers. However, ASLMS recommends that all physicians requesting privileges for the use of lasers must first meet initial hospital standards, such as board certification, board eligibility, specialty training, ethical character, and good standing. Furthermore, physicians “should have interventional privileges in the specialty before requesting laser privileges,” according to ASLMS.
ASLMS also recommends that the physician be familiar with recent literature and have completed a training program “devoted to the principles of lasers, their instrumentation and physiological effects and safety requirements.” This program should include a minimum of eight to 10 hours of hands-on sessions with lasers. An additional 40% of the program should focus on practical sessions, with additional time built in if needed to complete basic course requirements. Physicians may need additional training on different wavelengths or applications, in which case 50% of the time should be devoted to hands-on training.

As an alternative to a training program, physicians may also obtain privileges after completing a residency program that includes significant training and practice with multiple wavelengths. ASLMS urges residents to obtain this training during residency, particularly if they anticipate applying for laser privileges.

ASLMS also recommends that physicians spend time in a clinical setting with a preceptor or a clinical expert. In terms of the number of cases that should be observed, ASLMS recommends “several brief visits or a more prolonged period suffices provided that a variety of cases is observed.”

In another position paper, Procedural Skills for Using Lasers in General Surgery, ASLMS outlines credentialing and privileging criteria for physicians who are performing procedures involving lasers. ASLMS recommends the following guidelines for credentialing physicians:

➤ Physicians will be reviewed annually for safe and effective use of lasers
➤ Newly credentialed physicians must be observed in the operating room using the laser
➤ At each biannual renewal period, the physician should have performed at least five procedures to be re-credentialed
➤ Those who have not completed five procedures may reapply after providing documentation of laser usage from another institution or attend a specialty-specific hands-on laser training program

Those applying for laser privileges must meet the following requirements:

➤ Be certified by a specialty board such as surgery, plastic surgery, orthopedics, otolaryngology, ophthalmology, urology, dermatology, plastic surgery, cardiovascular surgery, or neurosurgery
➤ Be trained to use lasers in a recognized residency program or CME course
➤ Those applying for privileges for lasers with an operating microscope must also be proficient in the use of optical equipment
➤ Know the safety hazards associated with laser use
➤ Initial use will be provisional until a qualified member of the medical staff grants approval

Residents using lasers may not perform procedures until they have received in-depth training and been supervised by an attending physician.
Positions of subject matter experts

*Alan Sugar, MD,*

*Ann Arbor, MI*

Basic requirements for privileging ophthalmologists for PRK begin with a three-year residency in ophthalmology, followed by a fellowship that specializes in cornea or refractive surgery, according to *Alan Sugar, MD,* a professor of ophthalmology and visual sciences, and associate chair of ophthalmology and visual sciences at the Kellogg Eye Center at the University of Michigan in Ann Arbor.

“If they have not taken a fellowship, they need to have taken some sort of course specifically for refractive surgery,” Sugar says.

Residents and fellows at the University of Michigan undergo didactic training and are required to observe at least five cases before being allowed to participate in mentored cases with a faculty member who regularly performs that procedure.

“When we have hired our former fellows, we have considered their training with [laser] use adequate, and they just have to do the online stuff with the laser company,” Sugar says.

In addition, ophthalmologists should be trained and certified by the manufacturer of the laser they are using through a formal course. Course curriculums vary depending on the manufacturer, but most trainees will observe cases and perform didactic training in addition to some online training.

The University of Michigan also has a general laser use committee that builds policies for the use of any laser for any kind of surgery. While the committee does not provide a specific number of surgeries that need to be performed each year, physicians need to verify that they have performed an adequate amount of cases each year to maintain their skill with the laser. It is then up to the medical staff to determine whether they have indeed met those criteria. If not, the physician must have the first three cases proctored, Sugar says.

Because LASIK surgery is so similar to PRK, most ophthalmologists are certified for both procedures. The LASIK procedure requires the surgeon to make a flap on the cornea using a different type of laser, but an excimer laser is used in both procedures to sculpt the cornea.

“They are not so much interchangeable as they are complementary,” Sugar says. “You could do PRK without knowing how to make a flap, although most people who do refractive surgery don’t limit themselves to that particularly niche.”
Jay Grochmal, MD, PA
Baltimore

In recent years, PRK procedures have increased in popularity, says Jay Grochmal, MD, PA, a vision correction and LASIK surgeon at Grochmal Eye Center in Baltimore. Grochmal cites a recent study by the American Academy of Ophthalmology that estimates 800,000 refractive surgical procedures were performed in 2010. The reason for the sudden increase is because there is much more emphasis on the thickness of the cornea when it comes to LASIK versus PRK, he says.

“You want at least 300 microns of untouched cornea [for LASIK procedures] to prevent future complications,” he says. “Two hundred and fifty is the clinical standard, but I tend to err on the conservative side.”

Additionally, more patients are coming in for vision surgery five years after their last LASIK surgery because their cornea is already compromised, and ophthalmologists are recommending PRK for corrections and improvements.

To perform PRK procedures, most doctors should have a corneal fellowship that involves hands-on training and live observed cases, Grochmal says. In some cases, a residency may be enough to satisfy requirements, as long as the residents have been adequately trained. Although this was a viable alternative in the past, many residencies aren’t providing enough hands-on training, so a fellowship is preferred after residency.

“I got very comprehensive training in my residency,” says Grochmal, who did not complete a corneal fellowship. “I did a lot of cornea transplants, but nowadays residents are coming through and they aren’t doing nearly as much surgery in their residency as I did, so I think it would be preferable to have residencies in corneal and external disease.”

Finally, all ophthalmologists who perform PRK are required to be trained and certified by the laser manufacturer, which usually includes a few days of didactic training and then a specified number of observed cases. Each facility has different requirements, but most require at least 10 proctored cases before the physician is able to practice on his or her own.

Physicians should also perform between 10 and 25 surgeries per year in order to retain their privileges, Grochmal says, although that will also depend on the individual policies of each facility as well as the number of patients choosing PRK surgery.

“You really need to use your skills to maintain them and be comfortable in doing the procedure,” he says.
Positions of accreditation bodies

CMS

CMS has no formal position concerning the delineation of privileges for PRK. However, the CMS Conditions of Participation (CoP) define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:
➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.
The Joint Commission

The Joint Commission has no formal position concerning the delineation of privileges for PRK. However, in its Comprehensive Accreditation Manual for Hospitals, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

➤ Developing and approving a procedures list
➤ Processing the application
➤ Evaluating applicant-specific information
➤ Submitting recommendations to the governing body for applicant-specific delineated privileges
➤ Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
➤ Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

➤ The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
➤ Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
➤ Consistent application of criteria
➤ A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
➤ Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested

Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism

A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)

A process to determine whether there is sufficient clinical performance information to make a decision related to privileges

A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws

Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.
**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for PRK. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for PRK. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.
Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements

➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status

➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding PRK.

**Minimum threshold criteria for requesting privileges in PRK**

**Basic education:** MD or DO

**Minimal formal training:** Successful completion of an ACGME- or AOA-accredited residency program in ophthalmology, followed by a fellowship or experience in refractive or corneal surgery. In addition, successful completion of an FDA-approved postgraduate PRK course is required.

**Required current experience:** Demonstrated current competence and evidence of the performance of at least 10 PRK procedures in the past 12 months or completion of training in the past 12 months.

**References**

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference
may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

**Reappointment**

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism, as well as demonstrated current competence and evidence of the performance of at least 20 PRK procedures in the past 24 months based on results of ongoing professional practice evaluation and outcomes. In addition, continuing education related to PRK should be required.

**For more information**

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Photorefractive keratectomy

Procedure 71

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