Wilford Hall Ambulatory Surgical Center

CONSENT TO PARTICIPATE IN RESEARCH
Title: Clinical Outcomes of Contralateral Wavelight Plus-LASIK vs. Wavefront-Optimized LASIK
Principal Investigator: Maj Paramjit K. Bhullar, MD

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study.

The purpose of this study is to find out whether the wavelight plus Sightmap method or the wavefront-optimized method for calculating LASIK customization treatment gives better vision, better quality of vision, and fewer symptoms afterward. The wavelight plus Sightmap approach is newer and uses a very detailed 3D-style map of the front of the eye to find tiny surface irregularities. The laser treatment is then customized to smooth out those small imperfections while correcting your eyesight. The wavefront-optimized method is the standard LASIK approach used today. It relies mainly on your glasses prescription and aims to reshape the cornea while keeping its natural form and reducing issues like glare or halos. Both types of LASIK planning calculations are FDA-approved and are routinely used in this clinic. However, because this study randomly assigns which eye receives which method, both treatments are considered research procedures for the purposes of the study. You will be in the study for about three months and will have six clinic visits: a Pre-Op Qualification Exam, the surgery visit, and follow-up visits on 1 day, 1 week, 1 month, and 3 months after surgery. During the study, one eye will receive LASIK using the wavelight plus Sightmap calculation, and the other will receive LASIK using the wavefront-optimized calculation. You will also be asked to complete a short questionnaire about your vision during your initial Pre-Op Qualification Exam and again for 1 week, 1 month, and 3 months after surgery. This questionnaire will take approximately ten (10) minutes to complete in person during these visits.

Approximately 49 participants will be recruited for the study. The possible benefits to you as a research participant in this research study is to decrease your dependence on glasses or contact

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

lenses. While the goal is to reduce your dependence on glasses or contact lenses, if you still have a significant amount of nearsightedness or astigmatism after surgery, an additional touch-up procedure may be considered based on standard medical guidelines. However, you may not receive any direct personal benefit from being in this study, other than knowing that you helped researchers learn more about which LASIK planning method, wavelight plus Sightmap or wavefront-optimized, may give better vision.

As with any eye surgery, you may experience normal temporary discomfort or irritation. You will review and sign a separate surgical consent form that explains the risks and possible side effects of the LASIK procedure, and your surgeon will go over these with you and answer any questions before surgery. You will not be paid for your participation in this study.

If you decide not to take part, here are your alternatives: 1) if you are an active-duty service members you can still receive other approved vision-correction options, such as glasses, contact lenses, PRK (Photorefractive Keratectomy), or SMILE (Small Incision Lenticule Extraction), but these would not be part of this study; 2) if you are non-active-duty individuals, you are not eligible for DoD-funded refractive surgery. You can choose to seek LASIK or other refractive surgery procedure from a civilian surgeon at your own expense.

Your decision will not affect your future care at Wilford Hall Ambulatory Surgical Center (WHASC). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You have been selected to participate in this study because you are considering refractive surgery to reduce your dependance on glasses and/or contact lenses. The purpose of this study is to find out whether the wavelight plus Sightmap method or the wavefront-optimized method for calculating LASIK customization treatment gives better vision, better quality of vision, and fewer symptoms afterward. Both types of LASIK planning calculations are FDA-approved and are routinely used in this clinic. However, because this study randomly assigns which eye receives which method, both treatments are considered research procedures for the purposes of the study. The duration of your participation per out-patient visit is between 30 and 60 min.

There will be about 49 people taking part in the study at the WHASC JWRSC over a period of 12 months.

During the study, you will have about six (6) out-patient visits with members of the research team. You may need to return to WHASC JWRSC for the initial Pre-Op Qualification Exam refractive surgery day, and post-op day-1, week-1 (±3 days), month-1 (±7 days), and month-3 (±14 days).

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

This study is comparing the vision and quality of vision after LASIK customized treatment using wavelight plus Sightmap or wavefront-optimized planning calculation. LASIK customized treatment using wavelight plus Sightmap and wavefront-optimized have not been comparatively well-studied side by side.

At the end of this research study the clinical results, including research-related results concerning about you will not be shared with you since all data will be de-identified and cannot be linked directly to you.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

You completed the WHASC Refractive Surgery Application Form as part of the screening process to determine that you meet the initial criteria to participate in this study. The preliminary review of your application indicated that you may qualify for this LASIK refractive surgery. To determine that you are fully qualify for this study you must complete the "Pre-Op Qualification Exam".

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

Before you can take part in this study, you will have a comprehensive eye exam to see if you are eligible to have LASIK refractive surgery. This is called the "Pre-Op Qualification Exam" and will take approximately 2 hours. To plan wavelight plus Sightmap LASIK, the eye undergoes several detailed imaging tests. The most important is a special corneal topography scan, which creates a high-resolution, color-coded map of the front surface of the eye, similar to a 3D terrain map. This test measures even tiny bumps or irregularities on the cornea. Additional measurements of the eye's curvature, thickness, and prescription are also taken. All of this detailed information is combined to create the Sightmap, which helps customize the laser treatment for that specific eye. For wavefront-optimized LASIK, the testing is simpler. The main measurements include your standard vision prescription, the shape and curvature of the cornea, and the thickness of the cornea. These tests are done with devices commonly used in routine LASIK evaluations. Unlike the Sightmap method, wavefront-optimized LASIK does not use a detailed "irregularity map"; instead, it applies a treatment designed to correct vision while keeping the cornea's natural shape as uniform as possible.

You will also complete the Patient Reported Outcomes with LASIK-Symptoms and Satisfaction (PROWL-SS) questionnaire as part of the Pre-Op Qualification Exam. The PROWL-SS assess vision quality. This initial questionnaire will be used as baseline measures to compare the questionnaire results gathered post-operatively at 1 week, 1 month, and 3 months.

When it is determined that you are eligible for the study during your Pre-Op Qualification Exam visit, you will be scheduled for surgery at a later day.

You will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will then have a chance of being assigned to one of the two refractive surgery treatment groups. Group 1 will have LASIK using wavelight plus Sightmap customized

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

treatment on the right eye and LASIK with wavefront-optimized treatment on the left eye. Group 2 will have LASIK with wavefront-optimized treatment on the right eye and LASIK using wavelight plus Sightmap customized treatment on the left eye.

If you are capable of becoming pregnant, a pregnancy test will also be done within 24 hours of your surgery.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

You may experience some normal eye discomfort or irritation associated with your LASIK refractive surgery. You will be required to review and sign a separate surgical consent form that will discuss the risks, and any discomfort associated with the LASIK refractive surgery procedure you will undergo. Your surgeon will also discuss these risks with you and answer any questions you may have prior to your surgery.

As with any eye surgery, LASIK has some risks. These may include a decrease in the sharpness of your best possible vision, over- or under-correction of your nearsightedness or astigmatism, trouble seeing while driving at night, headaches or eyestrain if your eyes heal differently, dry eyes, increased eye pressure, glare, halos, starbursts, hazy or blurred vision, distortion, double or "ghost" images, vision that changes throughout the day, trouble focusing, reduced depth perception, temporary light sensitivity, scratchy or gritty sensations, and general eye soreness.

Some complications are very rare (less than 1% of cases). These include cataracts, eye infections, inflammation inside the eye, double vision, droopy eyelids, or inflammation of the cornea. In up to 2% of cases, a corneal scar that affects vision may form, but this usually improves with treatment.

Very rare risks include retinal detachment, separation of the gel inside the eye (posterior vitreous detachment), or problems with the blood vessels inside the eye.

The two LASIK planning methods being studied (wavelight plus Sightmap and wavefront-optimized) are not expected to create any new risks or cause differences in vision that you would notice. Both methods are considered safe, and there are no known complications specifically linked to either calculation method. Any risk you may experience comes from the LASIK procedure itself, not from the way the treatment is calculated.

Although efforts are made to protect subjects' research study records, there is always a small risk for breach of confidentiality in which someone could get access to your personal information in your medical records or other information researchers have stored about you. The researchers will take every precaution to protect your health information by using and disclosing it only as permitted by your consent and HIPAA Authorization and as directed by state and Federal law.

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

The possible benefits to you as a research participant in this research study is to receive laser surgical correction of distance vision to decrease dependence on glasses or contact lenses. However, there is no guarantee that you will benefit from being in this research. In addition, you may receive the satisfaction of knowing that you participated in a study that may expand our knowledge regarding which LASIK customization treatment, wavelight plus Sightmap or wavefront-optimized, results in better vision.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for treating your nearsightedness. Alternative treatments and/or procedures that may be available to you include: glasses, contact lenses, or other refractive surgery procedure such as PRK (Photorefractive Keratectomy) or SMILE (Small Incision Lenticule Extraction). You should talk with your eye doctor about these options. Active-duty service members will still be offered the above-mentioned refractive treatment, but these would not be part of this study. Non-active-duty individuals are not eligible for DoD-funded refractive surgery. You can choose to seek LASIK or other refractive surgery procedures from a civilian surgeon at your own expense.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation (payment) for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Maj Paramjit K. Bhullar, MD
Refractive Surgeon
WHASC, Joint Warfighter Refractive Surgery Center
3746 Klinker St.
JBSA-Lackland, TX 78236
Phone: 919-798-5423

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Ophthalmology Department, WHASC. As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

12. SOURCE OF FUNDING:

This study is partially funded by a grant from Alcon Vision, LLC, Fort Worth, TX and the 59 MDW Science & Technology/Clinical Investigation and Research Support, Lackland AFB, TX

13. LOCATION OF THE RESEARCH:

WHASC, Joint Warfighter Refractive Surgery Center, JBSA-Lackland, TX

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by research staff members associate with this study from the Joint Warfighter Refractive Surgery Center, the San Antonio Institutional Review Board (SA IRB) (a committee responsible for protecting research participants), and the Defense Health Agency Office of Research Protections as part of their duties, as needed. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: coded data stored on a password-protected document, only accessible on CAC-enabled unclassified government-issued computers with firewalls (i.e., protection or barrier within a computer to protect the information from being viewed by unauthorized people). As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, a description of this clinical trial will be available on http://www.ClinicalTrials.gov

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Those listed below will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law:

- The members of the research team
- 59 MDW Human Research Protection Office
- San Antonio Institutional Review Board

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

16. USE OF INFORMATION AND SPECIMENS

The information collected as part of this research will not be used or distributed for future research studies.

17. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

18. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled. Any identifiable information gathered concerning you will be destroyed.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

19. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must contact the principal investigator, Maj Paramjit K. Bhullar, using the contact information in the ICD section #21 below. If you decide to no longer participate in this research study, the researcher will use the de-identified research data that was part of this research study. Any identifiable information gathered concerning you will be destroyed.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

20. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the ICD section #21 below.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active-duty military, dependent of active-duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

21. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Maj Paramjit K. Bhullar
Phone: Cell 919-798-5423
Mailing Address: WHASC, Joint Warfighter Refractive Surgery Center, 3746 Klinker St., JBSA-Lackland, TX 78236

Research Coordinator: Dr. José E. Capó-Aponte
Phone: Office 210-292-2554; Off duty 845-216-0600
Mailing Address: WHASC, Joint Warfighter Refractive Surgery Center, 3746 Klinker St., JBSA-Lackland, TX 78236

59th Medical Wing Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC at Phone: 210-292-2977

San Antonio Institutional Review Board (SA IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the SA IRB Office at: 210 916-2598 or 210-916-2000. Mailing Address: San Antonio IRB Office, Brooke Army Medical Center ATTN: MCHE-ZQ, Department of Quality and Safety 3551 Roger Brooke Drive Fort Sam Houston, Texas 78234-4504

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

San Antonio IRB
IRB NUMBER: C.2026.011
IRB APPROVAL DATE: 12/03/2025