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RESEARCH AND TECHNOLOGY ORGANISATION

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RTO TECHNICAL REPORT **TR-HFM-191**

Refractive Surgery: New Techniques and Usability for Military Personnel

(La chirurgie réfractive : Nouvelles techniques et leur application pour le personnel militaire)

Final Report of Task Group HFM-191.

Published November 2012

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The Research and Technology Organisation (RTO) of NATO

RTO is the single focus in NATO for Defence Research and Technology activities. Its mission is to conduct and promote co-operative research and information exchange. The objective is to support the development and effective use of national defence research and technology and to meet the military needs of the Alliance, to maintain a technological lead, and to provide advice to NATO and national decision makers. The RTO performs its mission with the support of an extensive network of national experts. It also ensures effective co-ordination with other NATO bodies involved in R&T activities.

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The total spectrum of R&T activities is covered by the following 7 bodies:

- AVT Applied Vehicle Technology Panel
- HFM Human Factors and Medicine Panel
- IST Information Systems Technology Panel
- NMSG NATO Modelling and Simulation Group
- SAS System Analysis and Studies Panel
- SCI Systems Concepts and Integration Panel
- SET Sensors and Electronics Technology Panel

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RTO builds upon earlier co-operation in defence research and technology as set-up under the Advisory Group for Aerospace Research and Development (AGARD) and the Defence Research Group (DRG). AGARD and the DRG share common roots in that they were both established at the initiative of Dr Theodore von Kármán, a leading aerospace scientist, who early on recognised the importance of scientific support for the Allied Armed Forces. RTO is capitalising on these common roots in order to provide the Alliance and the NATO nations with a strong scientific and technological basis that will guarantee a solid base for the future.

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List of Acronyms

Epi-LASIK	Epithelial laser-assisted *in situ* keratomileusis
LASEK	Laser epithelial keratomileusis (also known as Laser sub-epithelial keratectomy)
LASIK	Laser-assisted *in situ* keratomileusis
PRK	Photorefractive keratectomy

Nomenclature

- **Accommodation**: Ability of the eye to change focal point distances from far to near due to physiologic increases in curvature and thickness of the lens within the eye.
- **Accommodative IOL**: An artificial lens that permits a small amount of change of focus.
- **Chromophore lens**: Lens with light filtering capacity.
- **Corneal epithelium**: The outer layer of the cornea, consisting of about 6 layers of cells attached to a basement membrane.
- **Corneal ectasia**: Progressive pathologic corneal thinning and bulging; causes uncorrectable poor vision.
- **Corneal haze**: clouding of the outer surface of the cornea following surface ablation refractive surgery procedures; caused by under-controlled post surgery inflammatory response.
- **Corneal stroma**: The middle and thickest layer of the cornea, typically around 500 µm in the center, giving the cornea its strength. It consists of highly organized lamellae of parallel collagen fibrils.
- **Excimer laser**: Computer controlled ultraviolet laser that shapes tissue by photoablative DE compensation of molecular bonds. It is used for both surface ablation and LASIK.
- **Femtosecond laser**: Ultrashort infrared wavelength laser that incises tissue by vaporisation. Its use in refractive surgery is to create the LASIK flap.
- **Intraocular surgery**: Placing an artificial lens inside the eye to correct the refractive error. This can be done by extracting the natural lens (CLE), or by leaving the natural lens intact (phakic IOL, also known as ICL) depending on the size of the refractive error.
- **Keratomileusis**: Corneal shaping.
- **Keratoplasty**: Surgical replacement of a portion of the cornea with a piece of cornea of the same size and shape. Also called corneal graft.
- **Keratectomy**: Excision of a portion of the cornea.
- **LASIK**: A partial thickness corneal flap (typically 90 to 160 µm) is created and lifted prior to stromal tissue ablation with the excimer laser. The flap is then placed back over the ablated cornea.
- **Monovision**: One eye corrected for maximal distance acuity and one eye corrected for near vision.
- **Multi-focal IOL**: An artificial lens which permits an extended range of vision by virtue of having more than 1 point of focus.
- **Radial keratotomy**: An early refractive surgical technique in which deep radial incisions were made with a diamond blade into the cornea to flatten its curvature.
- **Surface ablation**: In techniques such as PRK and LASEK, a layer of cells called the corneal epithelium, approximately 50 µm thick, is first removed. The excimer laser is then used to reshape the anterior surface of the cornea.

Preface

In surface ablation techniques such as PRK, Epi-LASIK and LASEK, a layer of cells called the corneal epithelium is first removed. Excimer laser is then used to reshape the anterior surface of the cornea. In LASIK, a partial thickness corneal flap is created and lifted prior to the anterior surface ablation with the excimer laser. The flap is placed back over the ablated cornea. Intraocular surgery may also entail placing a lens inside the eye to correct the refractive error.

Over the last 20 years, unprecedented changes have occurred in the domain of eye surgery. Specifically, the way that refractive errors are treated has undergone a revolution with the advent of lasers that can reshape the cornea. The technology has undergone a series of step changes so that it is now recognised as being one of the safest elective procedures available. Hundreds of thousands of military personnel have undertaken to have corneal refractive surgery in recent years with extremely high levels of satisfaction. However, soldiers and commanders alike have a limited understanding of the different procedures available, the risks to the eye and the impact on occupational vision standards. Moreover, the importance of a fully informed pre-operative assessment and a comprehensive postoperative care are sometimes underestimated. This technical report seeks to clarify the issues surrounding military refractive surgery.

Foreword

The excimer laser represented a paradigm shift in refractive surgery when it was introduced in the late 1980s. This unique ultraviolet laser was able to sculpt the cornea with a microscopic precision not previously seen and without causing underlying tissue damage. Under computer control, the laser could remove a small lenticule of tissue matched precisely to correct a refractive error. This technique was collectively termed Laser Vision Correction (LVC) and refers to all refractive uses of the excimer laser, such as Photorefractive Keratectomy (PRK) and Laser In-Situ Keratomileusis (LASIK). LVC was a significant improvement over previous refractive techniques, such as Radial Keratotomy (RK). RK was quickly rejected for use in operational forces for numerous reasons that were related to the deep corneal incisions intrinsic to the procedure, such as diurnal fluctuation in vision. With the seeming advantages of the excimer laser, military ophthalmologists and researchers began evaluating defence force implications of laser vision correction almost 20 years ago. Through hundreds of studies, a high level of safety and effectiveness of LVC in operational environments became apparent. A careful review of the risks and benefits of LVC by senior officials led to the US DoD Warfighter Refractive Surgery Program in 1999 and the creation of dozens of military treatment centers around the world.

Today well over 100,000 service personnel have undergone LVC to reduce or eliminate their need for optical correction. Military services have enjoyed tremendous success primarily because LVC can increase the combat effectiveness of a fighting force. Examples are numerous. Glasses are not compatible with many of today's specialized weapon systems which require headgear, such as night vision goggles, helmet mounted targeting sights and chemical/biologic protective headgear. None of them perform at optimal levels in conjunction with glasses. Problems include restricted peripheral vision, fogging, incompatibility with swimming/diving, discomfort during prolonged wear, displacement during positive acceleration (+Gz), and reduced clarity in inclement weather. While contact lenses have generally been well received, they can have significant operational problems also. Intolerance to soft contact lenses limits their usefulness, particularly in hot, dusty, or dry environments. Soft lenses are incompatible with chemical/biological headgear. Routine lens hygiene is impractical or impossible during field operations causing personnel to abandon them or extend their wear pattern and risk added complications. Replacement lenses can be difficult to obtain while deployed.

Besides the significant advantages of improving combat effectiveness, we have observed numerous other advantages of performing LVC in the military, some of these are listed below:

1) Improved combat readiness. The requirement to maintain optical appliances (spectacles and gas-mask inserts) is an essential component of readiness for combat. By reducing or eliminating the need for optical correction, LVC has had a direct and positive impact on the readiness status of combat forces.

2) Increasing the applicant pool. Highly qualified candidates, who were previously excluded because of refractive limits, are now allowed to apply and serve in a variety of occupations. As an example, over 10% of students entering Naval flight training previously underwent LVC. Their selection for flight training was based on their potential to become effective combat pilots when judged against their peers.

3) Improved vision. In many individuals, LVC improves vision better than could be achieved before surgery with glasses or contact lenses. This can further enhance combat effectiveness.

4) Enhanced quality of life. This is a near universal observation in patients who have undergone successful refractive surgery. Improving the quality of life of a fighting force is not just a noble goal; it can also significantly improve morale and retention.

There have been significant technologic advances in LVC since the Warfighter Refractive Surgery Program was established over 10 years ago. This includes the femtosecond laser for the LASIK flap creation, aberrometry devices to measure all ocular aberrations and wavefront guided procedures which can correct these aberrations. Military researchers have been at the forefront of evaluating these technologies and incorporating successful innovations into clinical practice. Continued research in this regard is vital to ensure that service personnel are offered the best and most appropriate procedures in the future.

We have entered a new era with the introduction of LVC in military forces with its demonstrated ability to reduce the need for optical appliances while maintaining a high level of safety and accuracy. It adds significant and profound value to modern military medicine by not just returning injured personnel to health, but to help them perform their jobs better.

Steve Schallhorn, MD, USN, CAPT (retired)

Terms of Reference

I. ORIGIN

A. Background

Management of refractive errors in military personnel is an important operational issue. New surgical techniques continue to emerge that may provide benefit in managing and correcting refractive errors as well as enabling the expansion of the military applicant pool. A published report of the current surgical techniques available as well as a thorough discussion of the risks and related performance benefits of these procedures on military members is warranted. In Photorefractive Keratectomy (PRK) and its variant surface ablation techniques, the corneal epithelium is first removed and the excimer laser then used to reshape the anterior surface of the cornea. In LASIK, a partial thickness corneal flap is created and lifted prior to the anterior surface ablation with the excimer laser. The flap is placed back over the treated cornea following the ablation. PRK, LASIK and other technologies and techniques are increasingly being performed by some NATO military services on its members and is commonly performed in the civilian community. For some military services, both PRK and LASIK are allowed, some allow only PRK, and some do not allow either. Other refractive surgery procedures should be carefully evaluated for the safety and efficacy in the military environment.

B. Justification (Relevance for NATO)

Management of refractive errors in military personnel is an important operational issue. New surgical techniques continue to emerge that may provide benefit in managing and correcting refractive errors as well as enabling the expansion of the military applicant pool.

II. OBJECTIVES

1) Publish a technical report that reviews the clinical risks and benefits regarding PRK, LASIK, and other available refractive surgery procedures and the usability of each in military personnel without diminishing operational effectiveness; update report annually as applicable.

2) Publish a technical report that reviews available refractive surgery outcome and quality of vision assessment methodologies and the usability of each in military personnel; update report annually as applicable.

3) Publish a summary report of the current refractive surgery policy of each NATO member nation participating in this Technology Working Group (Watch Group); update report annually as applicable.

III. RESOURCES

A. Membership

Chairman: To Be Determined.

Lead Nation: United States.

Nations Willing/Invited to Participate: Belgium, Canada, France, Germany, Italy, Netherlands, Norway, Spain, Turkey, United Kingdom, United States.

B. National and/or NATO Resources Needed

Meeting facility.

Audiovisual and administrative support.

C. RTA Resources Needed

Consultant funding travel expenses for some countries.

IV. SECURITY CLASSIFICATION LEVEL

The security level will be Unclassified/Unlimited.

V. PARTICIPATION BY PARTNER NATIONS

All partners (PfP, MD and preferred Contact Countries) invited.

PfP Nations: All PfP invited.

MD Nations: All MD invited.

ICI Nations: None.

Contact Nations: Australia, Japan, New Zealand.

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Keratomileusis
Keratoplasty
Laser-assisted in situ keratomileusis
Laser epithelial keratomileusis
Monovision
Multi-focal intraocular lens
Photorefractive keratectomy
Radial keratotomy
Surface ablation

14. Abstract

The practice of military refractive surgery is recent and continues to evolve. This technology enables war fighting men and women to achieve optimal visual performance in preparation for battle. The various alliance member states have differing attitudes and policies towards refractive surgery for military personnel. All are encouraged to understand the differences between available techniques, appreciate each one's benefits while remaining aware of their limitations.

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