Aerospace Medicine Implications of Advanced Medical Technologies

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Examples of New Medical Technologies
The Weak Link is the Human Being
Practical Implications for Flight Crews
Flight crews are directly responsible for the safety of flight operations, and the main challenge for aerospace medicine practitioners is to ensure the medical fitness and performance readiness of generally “normal” individuals who work in “abnormal” aerospace environments.
Clinical Aerospace Medicine & Medical Certification/Clearance Issues
Clinical aerospace medicine issues impacting health monitoring, prevention, screening, diagnosis, treatment and rehabilitation

Most medical personnel around the world are not likely to be very familiar with these advanced medical technologies

Aerospace medical certification/licensing issues (fitness for flight) - Advanced medical technologies have an impact on the medical clearance of airline/spaceline crews and their flight careers

Flight crews are a highly mobile population who can travel to other countries where advanced medical technologies may be readily available to patients while in the US are not approved by the FDA
Human-Machine-Environment Interactions
The traditional approach to understand the complex interactions between humans, machines and environment is evolving fast with the implementation of advanced medical technologies that can blur the differences between purely human and purely machine, and where the human body even has the potential to be modified to tolerate different types of environments.
Aerospace Human Factors Considerations Relevant to the Operational Performance of Flight Crews
Some advanced medical technologies are intended to restore normal functions to individuals, but they also have the potential to increase human performance capabilities beyond the range of what is considered normal, or even provide new capabilities that humans do not or cannot possess naturally.
Other Considerations
- Global availability, acceptance, medical provider expertise and technical support
- Regulatory approval and standardization
- Ethical, moral, legal, economic, political issues
- Security issues
According to FBI’s Cyber Division, health care systems and medical devices are at increased risk of cyber attacks.

Medical devices could be breached and attackers could gain access to more important health systems.
Genomics
Many companies analyze and report different genetic variants to health conditions, traits, and ancestry.
XY Leap Reseller Enquiries

Precision Medicine International Limited is an Aotearoa (New Zealand) based company that was founded in 2012 to provide precision medical genomic testing and analysis services to hospitals and clinics in the Middle East and the Asia Pacific region.

PMIL’s proprietary software, XY Leap is an internationally registered medical device (GMDN code 61777) that analyses and visualizes human genome data from results obtained through molecular genetic testing (e.g., whole genome, targeted genome, or exome analyses).

The XY Leap Precision Medicine Analytics Platform guides medical therapies and lifestyle interventions to prevent and treat injuries and diseases including obesity, diabetes, depression, cancer and cardiovascular disease. PMIL’s proprietary PGx platform, XY Analytics, incorporate US FDA-recommended clinical genomics into medical decision-making (i.e., the genotype-phenotype relationships in PGx-guided individualized drug therapy).

XY Leap’s point of difference is that the platform is designed by practising physicians that integrate the technology at specific steps in the clinical care pathway to maximise the patient’s outcomes.

Privacy and Security

Data confidentiality is paramount. Your personalised XY Leap™ online account provides secure and easy access to your information.

Contact us
Email: email@xyleap.com
Web: www.xyleap.com

Take the leap!
XY Leap™ is a non-diagnostic medical calculator for physicians to make more informed decisions about the healthcare of their patients. Like our Facebook page and stay up to date with advances in personalizing your healthcare to your DNA.
We have developed the most comprehensive, non-invasive tests available in the world. Using the latest bio-technology, our safe and speedy procedure uses a sample of your hair which we test to get accurate results for you.

We only need one sample of your hair and using our extensive systems, we will email the results to you within just 10 working days. Your test results will include all items which have shown an intolerance of 85% and over. After performing thousands of tests, we have found 85% to be the point at which symptoms begin to develop from an intolerance.

Our innovative one-step test enables us to produce a comprehensive report, divided into five areas:

- Introduction to your results explaining exactly what you need to do
- The items that appear on your results
- Where the items are found (i.e. where a particular tree originates, or what product contains the chemical)
- The nutrients your body is lacking (optional)
- Guidance on your individual results.

**Intolerance Test**
Our most popular test. Your hair sample is tested against 600 different food and non-food items. Items scoring 85%+ are flagged as a potential source of intolerances.

**Nutritional Test**
Now includes a free nutritional guide. Our test identifies key nutrients potentially missing from your diet. We can currently identify up to 80 nutrients.

**Metal Toxicity Test**
A hair sample is tested against 24 unique metals. Metals can be ingested or absorbed by the body and are typically overseen as potential catalysts.
The GeneSight® Test

Precision medicine. Personal wellness.

Stop wondering which medication is right for you and start on your road to recovery. Treating mental health disorders can often be a long, frustrating process as you and your doctor spend months trying multiple medications for depression and other conditions at different doses to find the medication that works for you. During this time you could end up missing work, paying for multiple doctor visits, or losing hope that you'll ever find a medication that can help you. There's a better way.

The GeneSight® test analyzes your DNA and helps your doctor get a better understanding of what medication might work best based on your genetic makeup. Using the GeneSight test report, your doctor can personalize your treatment plan, finding the right medication faster and avoiding medicines that may cause side effects.
Pharmacogenomics

Analyses how genetic makeup affects an individual's response to drugs

Determines the influence of genetic variation on drug response in patients

Provides a tool to optimize drug therapy, with respect to the patients' genotype, to ensure maximum efficacy with minimal adverse effects
The Max Planck Institute of Psychiatry in Munich has discovered 79 biomarkers that can help doctors predict risk of suicide in patients on antidepressants.
The Eyedox Genetic Test for Color Vision is the first genetic test for color vision deficiency at the molecular level.
Gene Therapy
12 patients participated in a clinical trial through which they received an experimental gene therapy for Leber Congenital Amaurosis.

At six months after re-administration, the results were so promising that the University of Pennsylvania research team injected the gene into the untreated eyes of the remaining participants.

Injecting a healthy REP65 gene into young patients could prevent cell death and permanent vision loss.
Genetic-engineering tools have allowed scientists to provide light-sensing functions on neurons that aren't normally able to detect light.

Genes from algae and other microorganisms encode light-sensitive proteins.

It might possible to restore color vision by inserting genes for proteins sensitive to different wavelengths of light.
A new study from MIT reveals a gene that is critical to the process of memory extinction (when older memories are replaced with new experiences).

Enhancing the activity of this gene, known as Tet1, might benefit people with post-traumatic stress disorder (PTSD) by making it easier to replace fearful memories with more positive associations.
Increasing Length of Telomers

Scientists at the Stanford University School of Medicine have developed a new procedure that uses modified messenger RNA to increase the length of human telomeres, that are associated with aging and disease.
Human Longevity Inc. is a genomics and cell therapy-based diagnostic and therapeutic company focused on extending the healthy, high performance human life span.

HLI is developing cell-based therapeutics to address age-related decline in endogenous stem cell function.
The American Society of Gene Therapy and the FDA's Center for Biologics Evaluation and Research recommended studies of chronic toxicity, mutagenesis and genotoxicity of gene therapy vectors based on the class of vector, any known toxicities of the vector, the transgene product, the delivery system, the clinical indication, and the patient population for which the product is intended.
The National Gene Vector Biorepository offers an informational toxicology database as a resource to gene therapy investigators.

Studies within the database have been submitted to the US FDA in support of gene therapy clinical trials.
Postmortem Analysis Issues

Should the results of pre-mortem genetic screening be used to expand the scope of autopsies to look for evidence of certain pathologies?

Non-FDA approved gene therapies are readily available in other countries.

What forensic methods can be used to look for postmortem evidence of gene therapies?

What forensic methods can be used to look for postmortem evidence of genotoxicity?
"On second thought, let's go with gene therapy."
Microbiomics

THE HUMAN BODY'S INVISIBLE INHABITANTS

1. Hair
2. Nose
3. Blood
4. Mouth
5. Stomach
6. Intestines
7. Skin
The Importance of the MICROBIOME by the Numbers

- **90%**: Up to 90% of all disease can be traced in some way back to the gut and health of the microbiome.
- **10–100 trillion**: Number of symbiotic microbial cells harbored by each person, primarily bacteria in the gut, that make up the human microbiota.
- **>10,000**: Number of different microbe species researchers have identified living in the human body.
- **100 to 1**: The genes in our microbiome outnumber the genes in our genome by about 100 to 1.
- **3.3 million**: Number of non-redundant genes in the human gut microbiome.
- **22,000**: Approximate number of genes in the human gene catalog.
- **99.9%**: Percentage individual humans are identical to one another in terms of host genome.
- **80%–90%**: Percentage individual humans are different from one another in terms of the microbiome.

How The Gut Affects The Entire Body

- **Brain**: Anxiety, Depression, Alzheimer’s, Parkinson’s
- **Mouth**: Candida Overgrowth, Gum Disease
- **Thyroid**: Weight Fluctuation, Hashimoto’s, Hypothyroidism, Graves
- **Immune System**: Weakened Immune System, Frequent Colds, Autoimmune Disease, Food Sensitivities
- **Digestion**: Constipation, Diarrhea, Gas, IBS, IBD, Acid Reflux
- **Other**: Migraines, Insomnia, Fatigue or Low Energy
- **Skin**: Acne, Eczema, Rosacea, Psoriasis
The microbiome plays an important role in regulating many physiological and pathological processes in the human body.

NASA is currently sponsoring the “Study of the Impact of Long-Term Space Travel on the Astronaut’s Microbiome. The goal of this study is to determine how the composition of the human microbiome is altered during long-term space exploration and to evaluate its potential impact on space crew health.
Stem Cells & Regenerative Medicine

Pluripotent Stem Cells

- In vivo fertilized egg
- 8 cell embryo
- Cultured undifferentiated stem cells

- Blastocyst
- Neural cells
- Cardiac muscle
- Blood cells
Medical conditions and diseases where regenerative medicine is being investigated include:

- Cancer
- Diabetes
- Rheumatoid arthritis
- Parkinson's disease
- Blood cell formation
- Alzheimer's disease
- Deafness
- Osteoarthritis
- Stroke and traumatic brain injury
- Infertility
- Learning disability due to congenital disorder
- Spinal cord injury
- Heart infarction
- Anti-cancer treatments
- Baldness
- Replace missing teeth
- Blindness and vision impairment
- Damaged corneas
- Amyotrophic lateral sclerosis
- Crohn's disease
- Wound healing
- Osteoporosis
- Muscle atrophy
- Radiation injury
Types of cells, tissues, and/or organs researchers have grown:

- Auditory hair cells
- Bone
- Bladder
- Blood vessels
- Brain
- Cornea
- Ear lobe
- Esophagus
- Hair follicles
- Heart muscle
- Intestines
- Kidneys
- Larynx

- Liver
- Lung
- Muscle
- Myelin-producing cells
- Neurons
- Pancreas
- Retinal cells
- Teeth
- Skin
- Spleen
- Stomach
- Trachea
I've been trialling that new stem cell rub on hair restorer. The good news is, it works....
Artificial Tissues & Organs
Funded by the US DOE and lead by Lawrence Livermore National Labs the **Argus I and II Epiretinal Prosthesis** have had success with implants in more than 30 blind patients with degenerative eye diseases like macular degeneration and retinitis pigmentosa.

Approved by the FDA in February 2013 it has a 200+ pixels resolution to see areas of high contrast, such as curbs and crosswalks.
Artificial retina device, consisting of a glasses-mounted camera and a microchip surgically implanted on the retina (credit: Dr. Wentai Liu)

The FDA approval currently applies to individuals who have lost sight as a result of severe to profound Retinitis Pigmentosa.

The implant allows some individuals to locate objects, detect movement, improve orientation and mobility skills and discern shapes such as large letters.
<table>
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| Argus II[^10] Second Sight (Sylmar, Calif.)          | • glasses-mounted camera with inductive power and data transfer to external electronics unit strapped around the eye  
• 60-electrode array implanted into the epiretinal space  
• currently the only FDA (2013) and CE (2011)-approved retinal prosthesis |
| IMI Gmbh Learning Prosthesis[^3,5] Intelligent Medical Implants (Bonn, Germany) | • uses a learning recorder to analyze and account for natural retinal processing  
• 40-electrode array implanted in the epiretinal space  
• completed safety and charge threshold trials for temporary implantation in humans  
• acquired by Pilum (now “Pilum Iris”); undergoing trials for a 150-electrode device |
| Epi-FET3 Intracocular Prosthesis[^2,22] Aachen University (Aachen, Germany) | • uses an artificial lens implanted in the anterior chamber of the eye (lens capsule); responds to extracoroidal movements  
• 25-electrode array implanted in the epiretinal space  
• completed clinical trials in six patients implanted over 28 days |
| Artificial Silicon Retina[^24] Opbionics (Chicago)    | • uses light-powered photodiodes without an external power source or other electronics  
• 5,000 microelectrode-tipped photodiodes implanted in the subretinal space  
• completed multicenter clinical trial but was unable to provide adequate stimulation current for vision restoration |
| Alpha-IMS[^25] University of Tuebingen (Tuebingen, Germany) | • uses a microphotodiode array with an external power amplifier  
• 1,500 photodiodes and microelectrodes implanted in the subretinal space  
• currently conducting a long-term multicenter clinical trial started in 2013  
• CE-approved; has attained the highest resolved visual acuity to date (20/54) |
| Boston Retinal Implant[^1,27] Boston Retinal Implant Project (Boston) | • glasses-mounted camera with inductive power and data transfer to external electronics unit strapped around the eye  
• 100-electrode array implanted in the subretinal space  
• currently undergoing preclinical trials in nonhuman primates; recently completed trials in Yucatan minipigs |
| Photovoltaic Retinal Prosthesis[^29,30] Stanford University (Stanford, Calif.) | • uses photovoltaic cells and an infrared headset to wirelessly stimulate the retina  
• 143 hexagonal pixel cells (three photodiodes each) implanted in the subretinal space  
• acquired by Pilum (“Pilum Prima”); currently conducting preclinical testing in mice |
| Liquid Crystal Polymer Prosthesis[^1] Seoul National University (Seoul, Korea) | • uses liquid-crystal polymer to provide a lightweight and durable alternative to traditional electrode substrate and casing materials  
• 16-electrode array implanted in the subretinal space  
• currently undergoing preclinical trials in rabbits |
| Bionic Vision Australia[^2] University of Melbourne | • developing a suprachoroidal and an epiretinal “Wide View” stimulator  
• 33-electrode array implanted in the suprachoroidal space (pilot studies in three patients)  
• 99-electrode array implanted in the epiretinal space (early development) |
| NIDEK Visual Prosthesis[^3,24] NIDEK (Gamagori, Japan) | • uses 32 electrodes instead of traditional contact microelectrodes  
• 49-electrode array implanted in the suprachoroidal space  
• completed pilot studies of two patients implanted over four weeks in 2011 |
Other retinal prostheses projects are under way in the United States and worldwide, including Germany, Japan, Ireland, Australia, Korea, China, and Belgium.
The vOICe Learning Edition translates video images from a regular PC camera into sounds.

Some blind people wear it daily with a wearable setup to see/hear their environment as they go around, while other blind people (blind from birth) use it to experience for the very first time what vision is like.
Hearing is seeing is believing
By converting images into a series of sounds, the vOICe system can restore "vision" to the blind.

The vOICe device uses a webcam, mounted on a pair of sunglasses, which captures the scene in front of the user.

This image is sent to a computer that converts the picture into a series of sounds (a "soundscape") that are played into the user's ears.

The user's brain initially tries to decode this information in the auditory cortex.

Around the time that the visual cortex becomes active, the users become more adept at understanding the soundscape and recognizing objects.

After 10-15 hours of training, however, regions of the visual cortex begin to "light up". This shows a very rapid redirecting of pathways in the brain.

The vOICe software scans across the image from left to right, converting each pixel into a beep, with the frequency representing its vertical position. The volume of each beep represents the brightness of the pixel.
Heart

VAD Size Comparison

Older Technology → New Technology

Heartmate: 170mm x 55mm, 1150g
Novacor: 145mm x 60mm, 1000g
DuraHeart: 73mm x 48mm, 540g
Levator: 440g
Ventricast: 298g
Heart Mate II: 81mm x 43mm, 281g
InCor: 120mm x 30mm, 200g
HVAD: 145g
HeartAssist5: 92g
University of Pittsburgh researchers reported the design and testing of the new Paracorporeal Ambulatory Assist Lung (PAAL), a prototype of a device that may lead to a wearable lung for patients waiting for or recovering from a lung transplant.
Ford partnered with Medtronic and others to develop a complete In-Car Health-Management System.

The system compromises of a Bluetooth-enabled continuous glucose monitor that connects to Ford’s Sync hands-free control system.

WellDoc’s disease management platform where patients can document asthma attacks, glucose levels, and allergic reactions, all without letting go of the steering wheel, and access to data from SDI Health’s Allergy Alert app that can provides local allergy related information.
The convergence of medical developments in genomics, regenerative medicine, bioengineering of artificial materials and nanomedicine are creating unique opportunities to produce new types of tissues and organs that combine artificial and natural components for better physiological integration in the human body.
Scientists at the University of Essex are developing an artificial blood substitute that would be able to be stored at room temperatures for up to two years, which would allow it to be distributed worldwide without the need for refrigeration and make it immediately accessible at the site of natural disasters.

As a claimed universal blood replacement it could be administered to anyone, regardless of blood type.
Georgia Tech and Chapman University researchers have developed platelet-like particles (PLPs) that are able to move toward sites where clotting is occurring and contracting the clots much like natural platelets do.
Postmortem Analysis Issues

Are current postmortem analysis protocols appropriate to look for evidence of bioengineered tissues and organs?

Are current forensic methods appropriate to look for postmortem evidence of biomaterial toxicity?

Should available digital data recorded by some bioengineered organs be used for post-mortem forensic purposes?

Forensic protocols are needed to identify pre-mortem malfunctioning of bioengineered organs following a fatal aviation accident where only fragmented body remains are found.
BIOMATERIAL TOXICITY

Biological Effect

- Sensitization
- Genotoxicity
- Subchronic toxicity
- Cytotoxicity
- Implantation
- Irritation
- Hemocompatibility
- Systemic toxicity
Neurotechnology
Repetitive Transcranial Magnetic Stimulation (rTMS) is being tested as a treatment tool for migraines, strokes, Parkinson's disease, schizophrenia, dystonia, tinnitus, depression and auditory hallucinations.
Transcranial Alternating and Direct Current Stimulation is being used to treat patients with insomnia, depression, anxiety, chronic pain, schizophrenia, dementia, Parkinson’s disease and cerebral stroke.
Researchers at **HRL Laboratories**, a Malibu, CA firm, have shown that their novel transcranial direct current stimulation system successfully helped novice pilots improve their flying skills.

Expert pilots well versed in tasks that were to be taught to the fresh aviators had their brain activity recorded during flying exercises.
A working prototype of a low-cost EEG (less than $30) device funded by the US Defense Advanced Research Projects Agency (DARPA) is the first step in the agency’s effort to jumpstart a do-it-yourself revolution in neuroscience.
Scientists at the Institute for Flight System Dynamics at Technische Universität München (TUM) and Technische Universität Berlin (TU Berlin) are involved in the EU-funded Brainflight project.

The goal of project BRAINFLIGHT is to investigate what are the best approaches and parameters that allow fast learning to control an aircraft using brain signals, while allowing pilots to multitask.
Brain Computer Interfaces for Prosthetic Control
Third Eye Diagnostics out of Bethlehem, PA has been developing a promising device called Cerepress that measures central retinal venous pressure (CRVP) and how fast blood is flowing through the ophthalmic artery, which together correlate well with intracranial pressure.
Nanomedicine
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Examples of Nanomedicine Applications

- Cancer Diagnosis & Treatment
- Chemotherapy
- Vaccine Delivery
- Antibiotic Delivery
- Tissue Healing
- Microorganism Detection
- Parasite Detection
A new sensor developed at Stony Brook University may become a clinically useful tool for detecting disease biomarkers in breath.

The nanoprobe based technology is currently able to detect acetone, but should be modifiable to spot other compounds.
Nanoposts to Trap Metastatic Cells

Massachusetts General Hospital Cancer Center developed the Circulating Tumor Cell (CTC) microchip, which is about the size of a business card and holds 80,000 microscopic posts coated with an antibody that attracts and traps tumor cells circulating in the blood.
Nanotubes for Dental Implant Healing
Tokio University researchers have developed a nanosheet material that clings to irregular skin and keeps out infectious bacteria.
Nanosponges for Bloodstream Toxin Removal
Nanoparticles to Diagnose Ebola, Dengue and Fellow Fever
Research into the toxicological impact and possible hazard of nanoparticles to human health is still in its infancy.

Techniques in nanomedicine make it possible to deliver therapeutic agents into targeted specific cells, cellular compartments, tissues, and organs by using nanoparticulate carriers.

Intravenous and subcutaneous injections of nanoparticulate carriers deliver exogenous nanoparticles directly into the human body without passing through the normal absorption process.
Postmortem Analysis Issues

Non-FDA approved drug delivery nano devices are being used in other countries

FDA approved drug delivery nano devices are being used in the US in clinical trials

What forensic methods can be used to look for postmortem evidence of medical nano devices?

What forensic methods can be used to look for postmortem evidence of toxicity of medical nano devices?
"If you increase the magnification another million times you can see the safety regulations."
Body-Worn Medical Sensors & Body Networks
Fitness Monitoring Systems

Sensoria Smart Socks

Primo 3

iRiver Earbuds

Vivofit

Angel Sensor

Fit Core

Shine

Airo

Earbuds

Primo 3
Fitness Monitoring Systems

- FitBit Ultra, FitBit Flex and FitBit Pro
- Fitbit Charge HR and Fitbit Surge
- Larklife
- Echo Fit
- Jawbone UP™
Fitness + Oxymetry Monitoring Systems

Withings

Withings Activité

FreeWavz

Oxitone

Basis
Applications include:

- Zooming in on distant objects
- Get useful facts to pop up in the field of view
- Create virtual cross-hairs
- Holographic driving panels surfing the Web
- Visual aids for vision-impaired people
- Immersive video games
DARPA funded Innovega’s iOptik contact lenses are intended to enhance normal vision by allowing to view virtual and augmented reality images without the use of any bulky device.
Smart Contact Lenses to Monitor Intraocular Pressure

The Sensimed Triggerfish is a smart contact lens capable of continuous measurement of intra-ocular pressure throughout the day and is currently in clinical trials.
Google developed a wireless chip and miniaturized glucose sensor, embedding them between two layers of soft contact lens material. This formed a prototype of a smart contact lens capable of generating one reading of glucose levels per second.
Massachusetts Eye and Ear Institute developed new drug dispensing contact lenses containing encapsulated latanoprost-polymer films that achieve concentrations in the aqueous humor, comparable with daily eye drops.
Electronic Skin Patches
Researchers at University of California, San Diego have demonstrated in a proof-of-concept study a glucose sensing skin patch.

The device samples interstitial fluid within the skin that contains glucose, among other analytes.

The patch is entirely printed and remains flexible while stuck to the skin.
The Lloydspharmacy and Proteus Biomedical Digital Health medicine platform is a medication management and adherence system that includes sensor-enabled pills, a peel-and-stick biometric sensor patch worn on the body, and companion smartphone apps.

The patch records when a pill is ingested and also tracks other things like sleep patterns and physical activity levels.
The **Hexoskin System** is a new sensor-fitted T-shirt and companion device that analyzes physical activity, heart rate and variability, respiratory rate and volume, and sleep, then sends the data to an online account via a smartphone.
Posture Sensors

LUMOback 3

Valedo

UpRight

LUMO knows when you SLOUCH
LUMO knows when you SIT STRAIGHT

Posture Sensors

iPosture

Lumbia