

How Disruptive Solutions Could Improve the Prevailing Healthcare Paradigm. A Novel Perspective the Treatment of Mental Health Conditions Using the Strannik Mathematical Model

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Abstract

There are few technologies which offer the potential to disrupt the prevailing biomedical paradigm. The author discusses the existence of the first technology to be based upon a precise and sophisticated simulation of how the brain regulates the autonomic nervous system and associated structures which has the potential to significantly disrupt the prevailing biomedical paradigm through the emergent neurological paradigm i.e. by understanding how the brain works and how this can be applied with diagnostic and/or therapeutic effect.

Known commonly by the trade name 'Strannik' the associated package of Strannik software programmes have been shown in initial research, in 15-20 clinical studies conducted over the period 1997-2017, that Strannik Virtual Scanning (SVS) is able to determine the onset and progression of the complete spectrum of pathologies 2%-23% more accurately than the current plethora of medical tests; screen pathological onset from the presymptomatic level; define each pathology in terms of its genotype and phenotype; determine ca. 5-15 pathologies in each of 30+ organs, provide results in ca. 10 minutes - 15 minutes; more safely/non-invasively than contemporary methods of diagnosing and treating disease; achieve therapeutic outcomes with the neuromodulation technique Strannik Light Therapy (SLT) which initial studies indicate is 75%-96% therapeutic effectiveness i.e. which appear to exceed that which is possible using biomedicine; and to do as at considerably lower cost by comparison with biomedical tests and treatments.

The author discusses the limitations of biomedicine and how such a neurological approach, in the form of the Strannik technology, could be applied to address such limitations and provide an alternative and cost-effective approach to the provision of healthcare, in particular (but not exclusively), regarding the management of lifestyle-related mental health conditions.

Keywords: *Strannik, Strannik virtual scanning; Strannik light therapy; Genotype; Phenotype; Autonomic nervous system; Physiological systems; Cognitive; Digital; Mathematical model*

Received Date: October 01, 2019; **Accepted Date:** October 28, 2019; **Published Date:** November 04, 2019

Citation: Graham Wilfred Ewing, How Disruptive Solutions How Disruptive Solutions Could Improve the Prevailing Healthcare Paradigm. A Novel Perspective the Treatment of Mental Health Conditions Using the Strannik Mathematical Model. J Clin Cases Rep 3(3): 89-114.

Abbreviations: NHS: National Health Service; MRI: Magnetic Resonance Imaging; MS: Multiple Sclerosis; SVS: Strannik Virtual Scanning; SLT: Strannik Light Therapy

Introduction

In recent years the healthcare market has witnessed the emergence of a plethora of medical technologies which have the capacity to alter healthcare however there is invariably a great deal of hype surrounding the scope of such new medical technologies. This article reviews many of the technological issues which could influence the future provision of healthcare.

Many consider that digital, software, artificial intelligence, cognitive and information-based technologies have immense potential to disrupt the provision of healthcare [1,2] however much of the research in the healthcare market is devoted to improving the efficiency of existing technologies - effectively offering 'more of the same' but at lower cost - rather than making significant improvements which advance the biomedical paradigm. The technologies which claim to be 'digital' are more precisely 'digitally-enhanced' i.e. the only aspect of these many technologies which is digital is the transmission of data by digital means *e.g.* by smart phone. The technologies which use 'artificial intelligence' are not based upon a fundamentally more advanced understanding of how the body functions but instead how algorithms could be used to improve and/or simplify the interpretation of scans generated by X-rays, MRI, Ultrasound scans etc.; i.e. the line extension of existing products. The development of miniaturized scanning technologies [3] will reduce their cost and aid more flexible working in the secondary care environment but will do little to reduce the immense complexity and cost of healthcare services.

The new generation of telemedicine and chatbot APPs mimic the GP's consultation and are unable to diagnose the health of patients with complex multisystemic and multipathological indications i.e. the ca 20%-25% of patients who take up ca 70% of healthcare resources. Indeed if biomedicine is unable to do so, so why does the APP developer, developing technologies which mimic the GP's consultation, think that their APP can do so?

"Looking after the 15.4 million people in England with at least one long-term condition already takes up 70% of the NHS's £110bn budget – £77bn – as well as £10.9bn of the £15.5bn spent on social care in England". Comments attributed to Dr. Martin McShane, National Clinical Director, Long-term Conditions, NHS England [4].

We are led to believe that the latest generation of wearable technologies add to our ability to monitor our health yet they are often purchased by 'the worried well' who have little or no need for such technologies [5]. Moreover, the accuracy of such techniques is often relatively poor [6]. It comforts the patient to have a monitor which tracks their health throughout the day. Whilst there are undoubtedly case studies which are used to justify their more widespread application their main value for most people appears to be as a placebo or distraction from the more onerous task of managing their stress, diet and lifestyle. The benefits and/or value of such technologies is often minimal. They merely add an additional layer of complexity and cost to the healthcare process.

Healthcare evolved from experiential origins. It is only by the knowledge gained from experimentation that medical research recognized the need to adopt an evidence-based approach and hence eliminate the various techniques, products and/or services which were ineffective or in some cases made the patient less well.

The organization of medical research around specific areas e.g. nephrology, mental health, neurology; or syndromes *e.g.* sleep, depression, mental health, diabetes, migraine; fails to take into account the complex nature of these conditions and the whole and/or complete nature of the body's function [7] in which pathological onset in the visceral organs influences brain function and how changes of brain function influence the stable and coherent function of the autonomic nervous system and physiological systems, resulting in pathological onset in the visceral organs and in the most destabilized and dysfunctional of these systems. For example: (i) if we eat and drink to excess and develop diabetes the problem of diabetes cannot be resolved by medication, only by reducing excessive consumption and/or hyper indulgent behaviors; and (ii) if we experience stress, perhaps a bereavement, which creates pathological onset in the heart, digestive tract, and causes aches and pains the symptoms will continue until the person is able to deal with their stress. Giving medication may enable the person to reduce the severity of the symptoms but does little to deal with the fundamental cause.

Moreover as there is not a recognized or accepted understanding of how the body functions and/or is regulated then we must consider the distinct possibility that further revelations are possible.

Despite the use of vaccines, the various medical tests and drugs, the need for healthcare and the associated costs of this paradigm continues to increase yet most of us remain relatively healthy, in particular those who live maintain their weight at relatively normal BMI and who exercise regularly.

- Drugs depend upon the autonomic nervous system for their effect i.e. upon the phenotype. They are foreign substances. If used at too low a level they are ineffective, if used at too high a level they are toxic, and if used at an appropriate level - they interfere with pathological processes and hence reduce or eliminate the symptoms which are commonly associated with the particular condition being treated; however drugs depend upon the autonomic nervous system for their effect - which is regulated by the brain.
- Vaccines- which influence genotype - prevent a future viral infection but increase susceptibility to other infections and/or medical conditions. Indeed it is upon such an observation that Jenner recognized how to vaccinate against smallpox [8].
- Considered by many to be 'a social lubricant' Ethyl Alcohol, the active constituent in alcoholic beverages, is a grade 1 poison and carcinogen [9,10].

Every way which we alter the body's biochemistry through the senses (stress) or through the viscera (by the food which we consume, water and/or what we drink, the quality of air which we breathe, viruses, drugs and vaccines) influences the body's function and overall stability.

If such medications effected a cure the burden of healthcare would be in decline however this is clearly not the case. Every year the demand for healthcare and the associated cost of providing healthcare continues to increase. The patient consults their GP and is often prescribed medication which requires that they adhere to the drug schedule, perhaps taking a pill or combination of pills, several times each day; however in many cases the drug becomes increasingly ineffective because the brain compensates for the effect of this foreign substance and/or its metabolites and thereafter an alternative drug is sought; until the patient presents with symptoms of ever greater complexity and severity which require ever greater levels of medication, testing, surgical intervention and cost. It becomes increasingly evident that the prevailing biomedical paradigm has significant shortcomings and/or limitations e.g. it is the third-leading cause of death [11], and is failing to live up to

expectations [12,13]. The total cost of outstanding legal claims for compensation in the UK, if pursued to a successful conclusion, is £65bn i.e. ca. 50%, of the UK's National Health Service budget, which is sufficient to bankrupt the organization. In the US >17.9% of GDP is spent on healthcare. The provision of healthcare by governments is at a level which is increasingly unsustainable.

In general biomedicine treats the symptoms or consequences of autonomic dysfunction. A preventative approach based upon an understanding of the causal mechanism(s) is required. It is only by understanding the psychosomatic/somatic mechanisms which regulate the body's function, that the complexity and cost of healthcare can be reduced. Accordingly there is a need for a better understanding of the mechanism by which the brain is organized and how it regulates the body's function e.g. how it maintains and/or optimizes the body's key functional parameters e.g. blood pressure, blood glucose, temperature, the supply of oxygen to the brain, pH, etc. If such mechanism could be understood this could be applied with therapeutic effect.

To this end the European Commission implemented at a cost of £1.2bn a research project (the Human Brain Project [14]) to enable leading neurologists to develop an understanding of (i) what the brain does and how it does it; (ii) how this could be applied e.g. to develop a new generation of cognition-based diagnostic technology which could determine the pathological correlates of complex medical conditions such as Alzheimer's disease; and (iii) how a unified, multi-level understanding, of how the human brain integrates the flow of pathological data from the viscera, could be applied with therapeutic effect.

The EC's Human Brain Project has been followed by the US government's Brain Initiative and more recently the Institute for Human-Centered Artificial Intelligence (HAI) which are largely intended to achieve the same objective. This has been augmented by the Cluster Exploratory, a National Science Foundation initiative, a program that funds research designed to run on a large-scale distributed computing platform developed by Google and IBM in conjunction with six pilot universities. Early CLUE projects will include simulations of how the brain regulates the nervous system and other biological research that 'lies somewhere between wetware and software' i.e. the development of a mathematical model. In Russia, despite the development of Grakov's Strannik technology [15-17], the Russian government has established a similar project known as CoBrain; and in Switzerland the Blue Brain project is a spin-off of the Human Brain Project. Such research seeks to integrate OMICS data (genomics, transcriptomics, metabolomics, etc.) with brain function e.g. the work of respected geneticists Michael Snyder [18], J. Craig Venter, etc.

The Market Need for Innovative Solutions

The healthcare market has evolved from its humble ethical origins into a chain of profit centers from the point when the patient requires healthcare and enters the healthcare system until the point when the patient expires and ultimately leaves the healthcare system. It is a business sector which makes enormous profits for the many, many companies which supply products and services to the healthcare sector. Indeed the regulated nature of this business makes it difficult to enter but, when approved, offers the prospect of making significant profits in a market with relatively few, if any, direct competitors.

In addition the cost of healthcare has an adverse effect upon the ability of a government to manage its priorities. Every £/\$ which is spent on healthcare - ca.17.9% of GDP in the US and ca. 9% in the major EC markets (e.g. £45bn of the UK's National Health Service £110bn annual budget is spent on salaries [19]) - and detracts from the monies which can be spent by government, companies or the public upon their many other priorities i.e. profit, disposable income, etc. Consequently major industrialists are now examining ways of improving and/or reducing the cost of healthcare for their employees and/or

reducing the amounts spent by their companies on healthcare. Every £/\$/Euro saved has the potential to reduce the amounts required to fund healthcare, reduce the amounts spent by companies on healthcare and thereby improve company profitability, and reduce the taxes which are levied on the public. This is recognized as governments throughout the world redouble their efforts to improve the efficiency and effectiveness of healthcare e.g. by payments on results, stimulating innovation, ensuring that the medications and therapies provide a cost benefit, etc.

Originally the role of the GP was designed to diagnose and treat disease however the requirement for more comprehensive and detailed diagnoses has evolved into the current paradigm in which there is a multi-tiered approach involving primary care, secondary care, histopathological testing, and tertiary care. It is largely for this reason that there are many histopathology laboratories yet most medical tests have an accuracy which ranges between 25%-99%, many tests (estimated ca. 80%) yield a negative test result, and with the exception of antibiotics most drugs are on average abt. 50% effective [20] i.e. ca. 50% of the disease process is not being considered in the prevailing medical paradigm re the management of lifestyle-related medical conditions, and the effectiveness of drugs declines over a period. The solutions which are offered, of yet more tests and yet more drugs deal only with the consequences of dysfunction and not the fundamental cause. They fail to resolve the problem and lead to yet more side-effects of ever greater complexity and cost.

The influence of nutrition and drugs upon the body's function is considered - genomics dominates everything - but the dominant influence of 'stress' upon our physiology is largely ignored, perhaps because it is considered to be too complex to be addressed by the contemporary biomedical paradigm i.e. it does not confirm to the prevailing biomedical paradigm which involves the supply of drugs - to treat the consequences of stress - yet, almost paradoxically, most drugs act upon the phenotype.

The patient's health details are held by their doctor and/or healthcare provider(s) unless the patient specifically requests access to their health details. The primary care practice, those which offer non-mainstream healthcare services, manufacturers and suppliers of medical devices manufacturers and suppliers of drugs (as raw materials and/or drug formulations), major healthcare providers which have primary care and secondary care units, tertiary care providers/care homes, providers of electronic health record software, and an enormous range of suppliers of the materials are required to sustain the operation of these enormously complex organizations, structures and systems.

A disruptive solution would conceivably 'put the patient at the center of the healthcare ecosystem' and reduce the need for such organizations. In the UK, it was the conclusion of Sir Robert Francis QC in the NHS Mid-Staffordshire Healthcare Trust [21] enquiry conducted in the period 2010-2015 that a solution would conceivably 'put the patient at the center of the healthcare ecosystem' was necessary - placing the patient's health at the primary end-point - and should be a legal requirement for all providing healthcare. Such a solution could reasonably be expected to increase the privacy and security of patient health reports; improve the effectiveness, accuracy and security of electronic health records; reduce fraudulent claims based upon misdiagnosis; significantly reduce costs; hold doctors accountable for their actions; etc.

In addition, the healthcare market is haunted by future forecasts which have enormous implications for the future provision of healthcare i.e. the steadily increasing cost of managing the health of patients with (i) diabetes and diabetic comorbidities which now consumes more and more of healthcare budgets as patients require ever more complex and expensive interventions (ii) cardiac testing to support patients with diabetic comorbidities and smoking-related cardiac issues (iii) regressive autism

which now influences the health of 1 in 59 children [22] and which will steadily require increasing levels of medical support throughout their lives (iv) antibiotic-resistant bacterial infections (v) legal claims for misdiagnosis, misprescribing of drugs, adverse drug events, etc. (vi) pollution of the waterways with drugs, etc.

The Benefits and Obstacles to Newer and Better Healthcare Technologies

The introduction of a cost-effective screening technology could be expected to meet many of the key aims and objectives for cost-savings which have been identified by the NHS (including those outlined above) e.g.

- Reduce the flow of patients into the healthcare system i.e. a preventative care system [23,24].

"I think it's unarguable that prevention is better than cure, and if you wait until the patient presents with signs or symptoms of kidney disease, liver disease, heart disease, very often most of the damage is done and can't actually be recovered. So if it were possible to take steps while still in health to prevent or delay the onset of disease that seems to make very good sense." Sir Robert Lechler [23].

- Reduce or eliminate the need for repeat medical consultations.
- Reduce the immense cost and complexity of training the GP.
- Reduce and/or eliminate GP errors.
- Avoid erroneous drug prescribing; or for drugs to treat the side-effects of other drugs.
- Reduce the flow of patients from primary care to secondary care and hence the high level of expenditure in secondary care.

"The NHS in its current form is not well set up to look after patients who are medically complicated, especially if they have several long-term conditions, such as arthritis, heart failure and the early signs of dementia while the total number of people with long-term conditions is expected to stay at around 15 million, the number with three or more conditions is expected to rise from 1.9 million to 2.9 million by 2018". Comments attributed to Dr. Martin McShane, National Clinical Director, Long-term Conditions, and NHS England [4].

- Reduce the vast numbers of medical tests which yield a negative test result.
- Reduce the need for highly expensive scans and tests. An inexpensive screening modality would reduce the number of tests which yield a negative.
- Reduce expenditure on equipment and increase the cash which is available to support biomedical treatments and recovery.
- Enable everyone to have a clear understanding of their health and to assume control and responsibility for their health and how this is likely to be manifest in future.
- Change the focus of medicine re lifestyle issues; from treating the symptoms of disease and morbidity to that of treating the fundamental cause of disease and morbidity.
- Provide the patient with a written report of their health which they could use to seek out alternative therapeutic options which are not available in their local health services.
- Reduce the overall cost of healthcare, especially so in the financially challenged markets e.g. which are affected by financial constraints or where the per capita income is low.

Research by health economists [25] has found that the average cost of a healthy patient costs the UK's NHS ca £290 pa, those with one long-term condition an estimated £783 pa, those with two long-term conditions £1,521, those with three long-term £2,559 pa, those who need frequent treatment and monitoring with five such conditions £5,512 pa, and those with six £8,083 pa. Note 1: clearly the costs vary according to the nature of the comorbidities.

- Reduce the 3-5% of road journeys (fuel costs and pollution) which are involved in attending medical consultations, transporting samples, etc.
- Improve the accuracy and sophistication of electronic health records
- Reducing the amounts of clinical waste (rubber gloves, syringes, fluid and tissue samples, face masks)

The introduction of a cost-effective therapeutic modality could be expected to meet many of the key aims and objectives for cost-savings which have been identified by the NHS (including those outlined above) e.g.

- Improving therapeutic outcomes - conceivably up to a theoretical ceiling of 90-95%.
- Reduce the need for drugs;
- Enable the patient to be screened and treated in their homes or offices and reduce the need for treatment in primary and secondary care;
- Slow the progression of patients into tertiary care i.e. enabling them to live for longer in their home.

The healthcare system is staffed by those who are trained in clinical medicine. Accordingly, their ability to rationalize such an alternative or modified paradigm is based upon e.g. their ability to understand such a concept, their willingness to embrace such technologies, the fear of stepping out of line and associated repercussions, political considerations, how such technologies would interfere with other research priorities and initiatives e.g. genetic research and electronic health records, influence from established suppliers, etc. There is an innate bias against change and especially so against radical and disruptive healthcare solutions.

Nevertheless such a technology presents an opportunity to improve the management of current health data/management e.g.

- Reduce or eliminate claims e.g. for misdiagnosis and/or misprescribing of drugs - est. >£3BN pa in the UK [26];
- Reduce or eliminate fraudulent claims e.g. for whiplash injuries sustained in road accidents [27];
- In the US fraudulent claims from the Medicaid program [28] is >USD14bn pa (4% of Medicaid spend) whilst Medicaid fraud [29,30] is estimated at 15-22% of total spend;
- Reduce claims arising from adverse outcomes as a result of drugs [11].
- Diagnose the many medical conditions which are poorly diagnosed or where there is an unmet clinical need.
- Modern medicine is the 3rd largest cause of death [11].

The Limitations of Biomedicine

The quality of the data

All aspects of the body's function are, without exception, biological - however biology does not, and cannot, explain how the body maintains the complex executive and/or intensely regulated functions of blood pressure, blood glucose, sleep, pH, body temperature, the supply of oxygen to the brain, etc. There is an issue of 'regulation' - the distinction between biological hardware and software - which researchers have yet to explain or to accept.

Medical research is faced with the apparently paradoxical situation that there are physiological systems - which it does not understand and, as a result, chooses to disregard (despite it forming the basis of the medical examination conducted by the GP) - and that there are genes which it considers to be the panacea for all ills yet we know that our exposure to environmental factors and lifestyle, our phenotype, is far more significant than our genotype - and drugs act upon the phenotype. A recent study, published in PLoS Genetics, indicated that only a small minority (est. 5%-10%) of diabetes has genetic origins [31].

What does genotype mean? It means that the complex chemical and structural arrangement of the genes acts together to express a protein or complex spectrum of proteins [32]. It is not actually the genes which are important, although they are not unimportant; it is the rate of expression of proteins which is most significant. Consider that over 20 genes [33] are implicated in the expression of pre-pro-insulin! It is what the genes do that is significant - how they function in a collaborative manner to express a particular protein - not what they are! By the time we are 75 years we express only about 10% of the insulin which we expressed when we were in our prime but we do not drop dead. It is only when our demand for insulin exceeds the supply and/or reactivity of insulin that there is a problem. This illustrates the presence of a mechanism which continuously regulates and adjusts how the body functions - but this is not new to doctors, sports physiologists, neurologists, psychologists, etc.

Secondly, are the proteins coiled and reactive or uncoiled and unreactive? What are the factors which influence protein coiling?

Thirdly, how well does the expressed protein react with its substrate? Problems of protein reactivity are often denoted by the term 'protein resistance' e.g. as 'insulin resistance'. This is more commonly known as the 'phenotype' [34].

These three fundamental processes are chemical processes - proteins are characterized by a COOH group and an NH₂ group - therefore they are influenced by acidity and hence by the prevailing levels of minerals which perform an essential function, catalyzing biochemical processes. They are also characterized by the rate of emission, energetics and intensity of biophotons which influence color perception - because proteins absorb and emit biophotons [35] during the course of their reaction with enzymes and/or other substrates. The organic and inorganic chemistries coexist with mutual effect however, in general, biologists tend to ignore the immense significance of other inconvenient and complicating parameters e.g. acidity and light.

If there are (i) changes of molecular biology there must be (ii) changes of cell biology, (iii) changes of organ function, and (iv) changes of system function and/or dysfunction. Accordingly a precise mathematical model of the autonomic nervous system must diagnose at these different levels of physiological significance - at the level of the physiological system, the organs in each system, the cells in each organ, and at the molecular level (as genotype and phenotype). Moreover if there is such a precise, structural relationship this can be mathematically modelled: see Strannik operating manual, case studies and test reports [36].

Biomedicine seeks to define the nature and levels of metabolites which can be used to characterize a particular medical condition yet, as outlined, the health of a patient is far more complex than can be characterized by a single pathological process or metabolite. The body's biomedical indices vary throughout the day. Moreover, most medical conditions are multi-systemic, multipathological, polygenomic [37] and each pathology comprises its genotype and its phenotype (see below example reports).

It is for this reason that most medical tests are rarely precisely accurate e.g. the HbA1c test used to diagnose diabetes is 40% irreproducible after 1 month [38]; MRI scans used to screen patients with cardiac problems are considered to be 72%-90% accurate (10%-28% inaccurate) [39]; Mammography is considered to be only 50% accurate [40]; etc. The failings of medicine are widely recognized however the lack of a viable option which is able to significantly improve how the patient is screened and treated has not hitherto been available - so the system grinds on - without proof points or killer applications which can compete with the biomedical status-quo upon which healthcare is based.

What is the mechanism which regulates the stable and coherent function of the autonomic nervous system - the balance between the sympathetic and parasympathetic - and the organ networks? This has been referred to by various researchers as brain-wave coherence or brainwave entrainment, bioresonance, biofeedback, neuromodulation, neurofeedback, neurostimulation etc. Many such techniques have been developed in this USD10-20bn market.

Biofeedback techniques have been around for almost 100 years. It is the level of understanding of such phenomena which remains beyond such researchers.

Brain Function, EEGs, Neural Networks, Autonomic Nervous System and Physiological Systems

The EEG states are significant because we require typically 8 hours of sleep each day and we sleep for the majority of this period in the delta state; without sleep the quality of our lives declines significantly; the EEG states reflect different levels of neurological function.

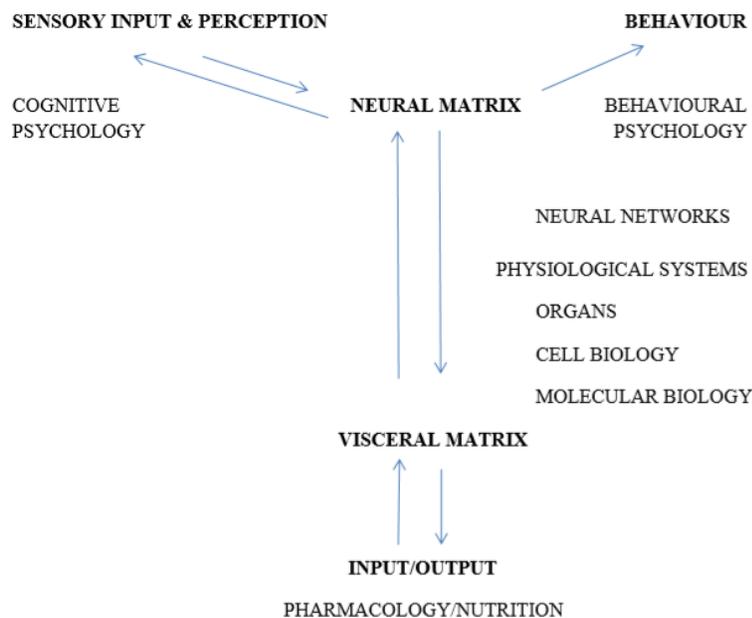


Figure 1: The structural nature of the autonomic nervous system.

Different stimuli act by stimulating the function of the different EEG states e.g. EFT (emotional freedom technique), CBT (cognitive behavioral therapy), reiki, hypnosis, meditation, music, biofeedback techniques, sleep, neuromodulation techniques (SLT), etc.

The body is a biological entity but its biology is not ‘regulating’ the body’s function. It is this dysregulation or imbalance which is responsible for what we experience as pathologies and morbidities. The brain uses the EEG frequencies to regulate the body’s function. It functions as a neuromodulator yet biological changes are responsible for the autonomic dysfunction which influences systemic stability and which alters the perceived stability of the EEG frequencies (Figure 1). This is apparent if we consider the EEG-based mechanisms which sustain the body’s function and existence. The body is a biological entity which fuels a biophysical entity - the brain.

An understanding of this mechanism would enable the provision of healthcare to treat the fundamental causal mechanisms as well as the symptomatic presentation of the person’s unique medical conditions.

Some companies now seem to have grasped the idea that such understanding could be applied by virtual reality and some are working on ‘digital pathology’, however at this time it is uncertain whether such research is based upon a fundamental scientific observation or, like so many before are just based upon an experiential understanding of the phenomena and/or principles.

The brain uses frequency to regulate the coherent function of the autonomic nervous system and physiological systems [41]. It explains why the wrong frequencies can cause photosensitive events e.g. by stimulating reductions in blood flow and/or the flow of oxygen to the brain e.g. in migraine or epilepsy. Molecular and cellular pathologies are the consequence of this process however biological input (nutrition, air, water, drugs) influences brain function i.e. the neural and visceral data matrices operate dynamically. Stress (the stress response or phenotype) influences this dynamic and is manifest as a spectrum of pathologies e.g. influencing heart function, breathing, kidney function, pancreatic function, sleep, etc.

The outcome of this process is changes of how we behave - of memory(s), speed of movement, and smoothness of movement; how we organize our lives and our priorities throughout the day, weeks and months ahead; and our effectiveness i.e. our ability to start and complete the many tasks which we require to complete each day.

What Strannik Offers

The Strannik technology [15] is based upon the principle of ‘personal biomathematical modelling’ i.e. a mathematical model of the autonomic nervous system. It is a simulation technique, typical of virtual reality, first developed in the late 1990’s. It uses a more advanced methodology and level of understanding than is currently used by any current medical technology including genetic screening and is effectively a finished solution to the aims and objectives identified in the Human Brain Project.

In principle ‘it is an open and generally permission less system which can be accessed remotely by the patient or doctor - a form of peer-to-peer system - that no government can shut down’ i.e. it exhibits the hallmarks of a technology which has the potential to disrupt the prevailing healthcare paradigm. In practice it can be offered via a PC or an online system but is nevertheless required to comply with the prevailing regulatory regulations in most markets.

Strannik comprises a suite of software programmes including (but not limited to) the Strannik test, the screening modality, Strannik Virtual Scanning and the neuromodulation modality, Strannik Light Therapy.

Strannik technology offers a number of significant benefits by comparison with contemporary methods of diagnosing and treating disease e.g.

- SVS is able to determine the onset and progression of pathologies earlier (from the presymptomatic level), better (both genotype and phenotype are defined for each pathology), more comprehensively (circa 5-15 pathologies are determined in each of 30+ organs), faster (results in circa 10 minutes - 15 minutes), and more safely (non-invasive technique) than contemporary methods of testing and diagnosing disease. As outlined SVS screens the health of the patient at the level of the physiological system i.e. identifying the degree of stability of the various physiological systems (Figure 2 and Figure 3) and in particular the most destabilized physiological systems upon which the course of SLT is based; the most dysfunctional organs; and at the cellular and molecular level(s) (Figure 4).
- SVS is offered at a price which is an order of magnitude lower than that of current diagnostic techniques - because it is a software-based technique which does not therefore involve the design, assembly and testing of a 'device'. It would for example be able to screen the health of ca 75%-90% of the entire UK population (est. 50M patients) at an estimated cost of £3bn.
- SLT is offered at a similar price to the SVS test which is considered to be an order of magnitude lower than that of current therapeutic options (digital therapeutics) - because it too is software which is designed to deliver data - and does not involve the design, assembly and testing of a 'device'.

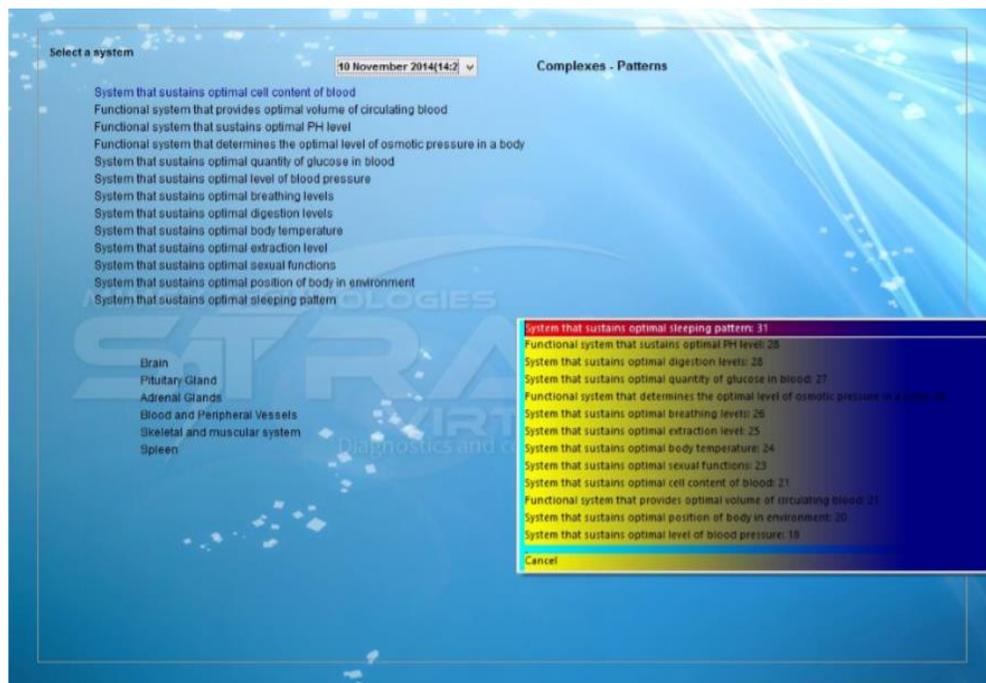


Figure 2: Example report/most destabilized physiological systems.

It meets the requirements stated by Sir Robert Lechler [23] for a technology which can be used predictively to establish and treat the range of pathologies which will emerge in future if the patient continues with their current lifestyle i.e. does not alter their unhealthy lifestyle. It will reduce the need for repeat consultations in primary care, for medical tests, for expensive screening technologies, for surgical procedures in secondary care, and conceivably reduce demand for organ transplants. It

will improve the accuracy of drug prescribing, reduce waiting lists for medical treatment, etc. An extensive bibliography of case studies and peer reviewed medical papers illustrate that it has the potential to contribute to a better understanding of many morbidities, improve therapeutic outcomes, improve quality of life indices, and significantly reduce the cost of healthcare.

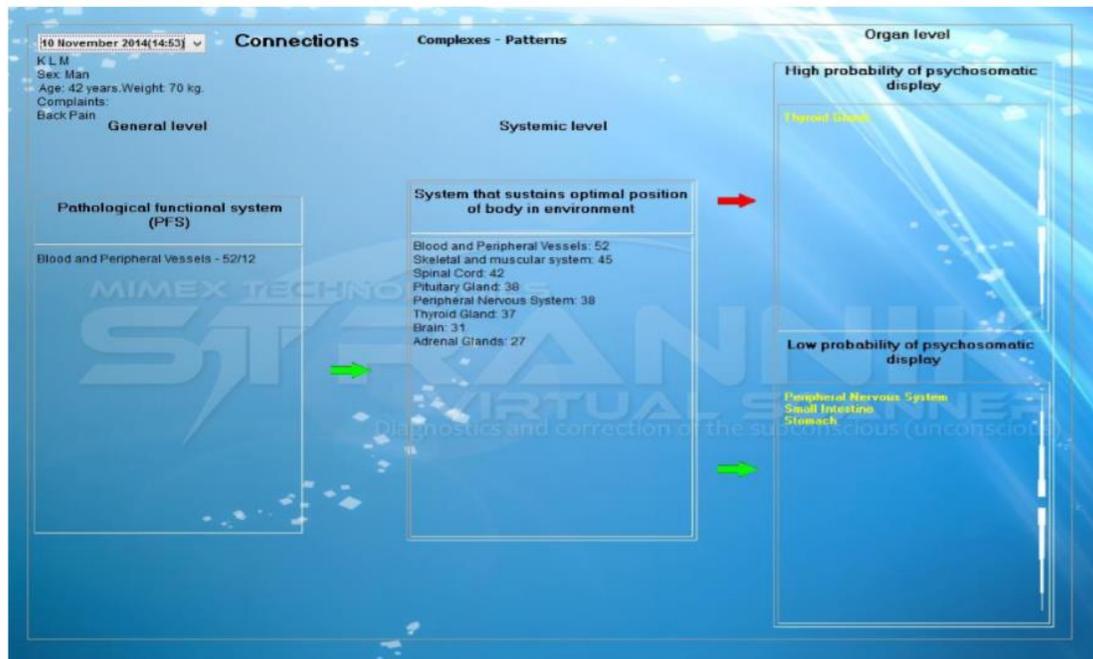


Figure 3: Example report/most destabilized physiological system and organs.

Evidence

Initial indications are that SVS is able to determine the onset of pathologies in a level of detail which is unprecedented in modern medicine. The technology has been evaluated by 15-20 groups of medical researchers (reports available upon request). The test results in these various studies [42] indicated that SVS is 2%-23% more accurate than the range of diagnostic technologies against which it was compared and which were in use in the various clinical units. A report compiled at the behest of the Russian parliament THE DUMA by Vysochin et al. at the University of St Petersburg indicated that SVS was circa 21.4% more accurate, across a range of ca 30 pathologies, than the current range of medical techniques [43-50] which were available in medical clinics, thereby justifying the claim that it could determine the onset of pathologies from the presymptomatic level; and that as a therapy it was 93.2% effective [15,43].

Two recent studies, like all before, equivalent to how the technology would be used in a GP's consultation, reported how SVS was able to identify all known medical conditions in the patient cohort [45,46] i.e. 100+% accuracy in 85% of the patients (study groups: 20-58 patients). Of the remaining patients (15% of the study group) the patients did not disclose their health profile OR were unable to complete the test to MMHL's satisfaction i.e. the results were effectively 100+% accurate in the 100% who complied with the study protocol. This data has now been incorporated into a meta-analysis of published and hitherto unpublished data [42].

An extensive range of case studies document how this technology has been used to diagnose [15,43-52] and treat [15,41,53-55] a wide range of medical conditions. Testimonials support claims that the technology has performed at a level which is more advanced than that of contemporary biomedicine and at a level which clearly illustrates patient satisfaction with the test results and therapeutic outcomes. An extensive range of articles which have been published in peer-reviewed medical journals (ca 75), conference presentations, book chapters, and books illustrates the scientific rationale for the technology.

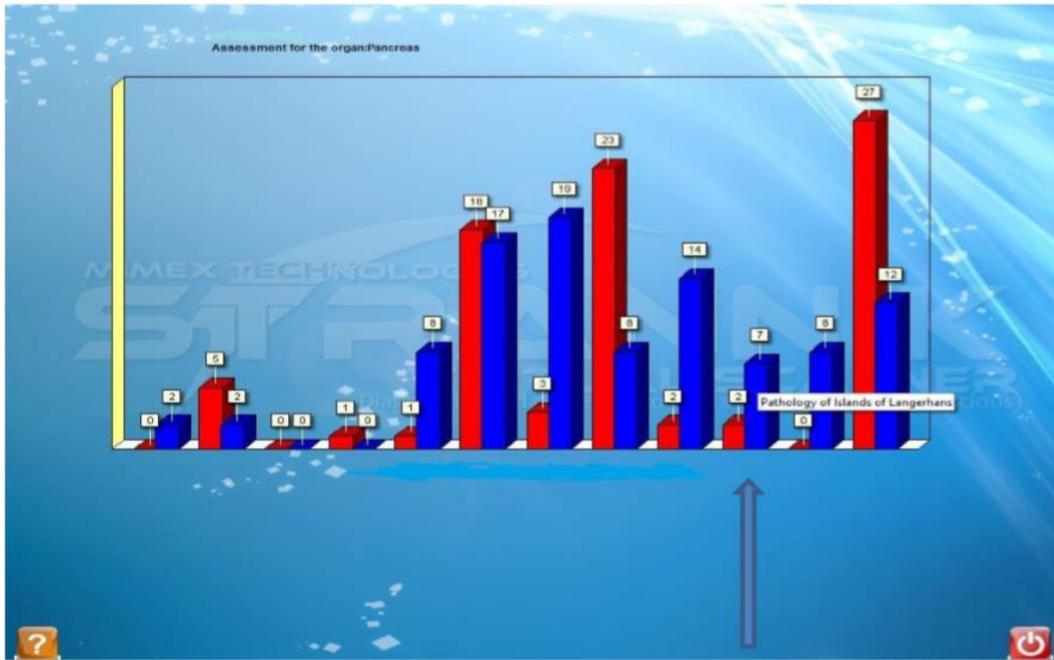
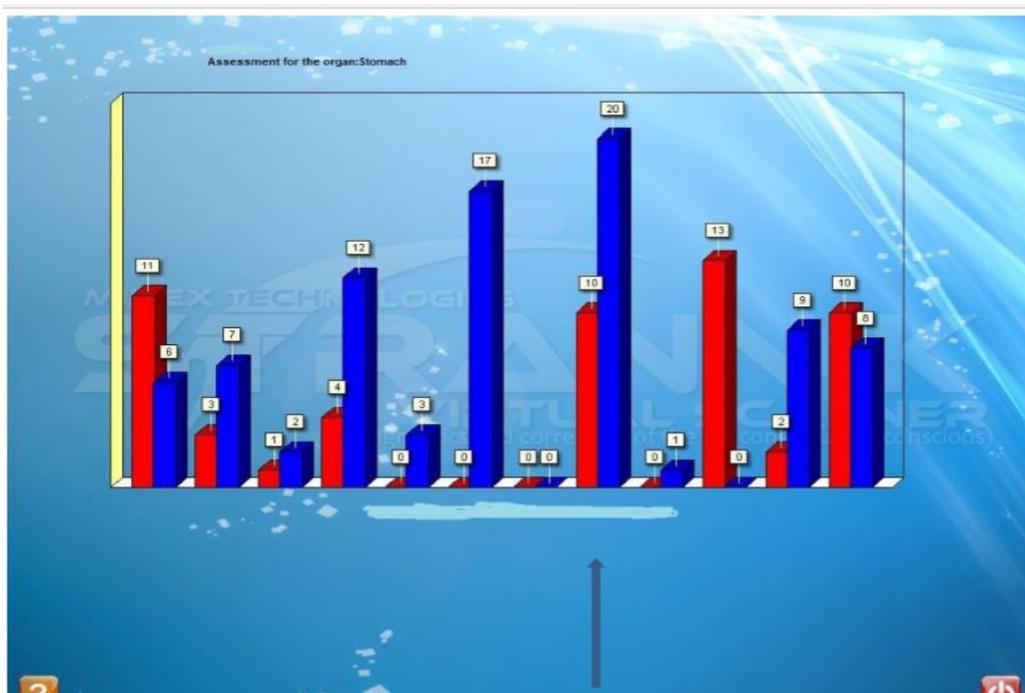


Figure 4: Example organ report/pancreas.



Figures 5 (a): Stomach: ulcerative condition.

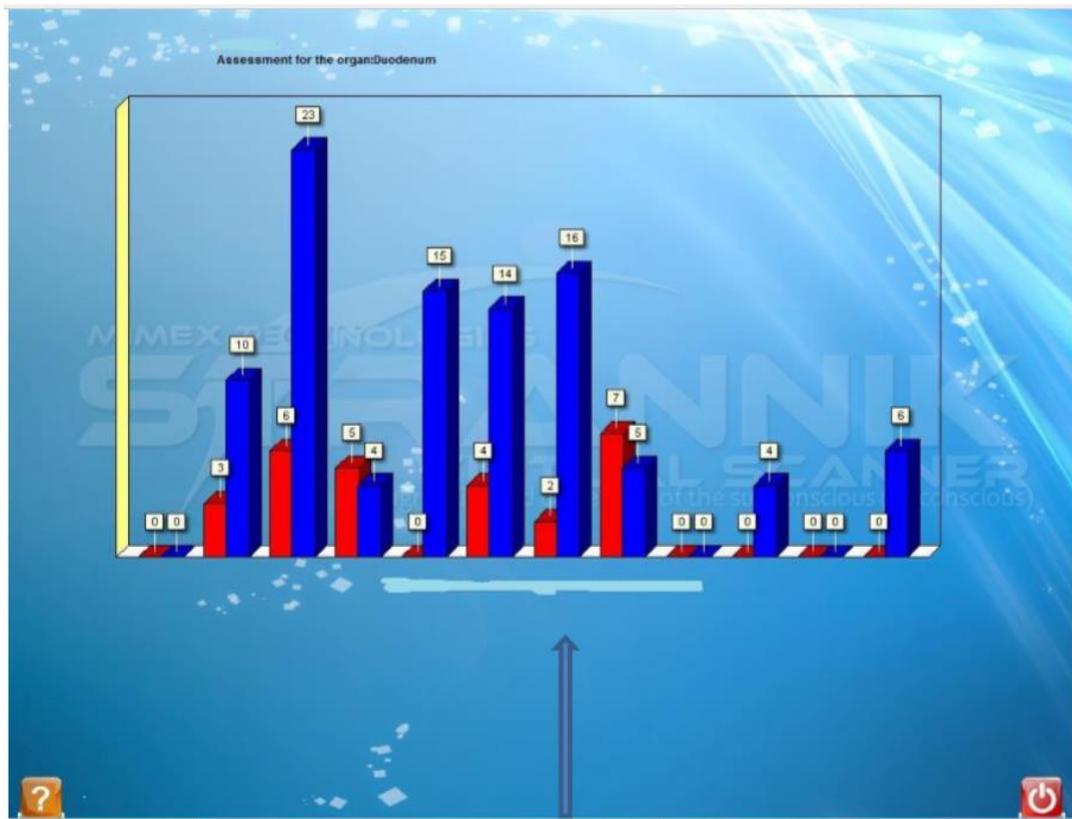


Figure 5 (b): Duodenum: ulcerative condition.

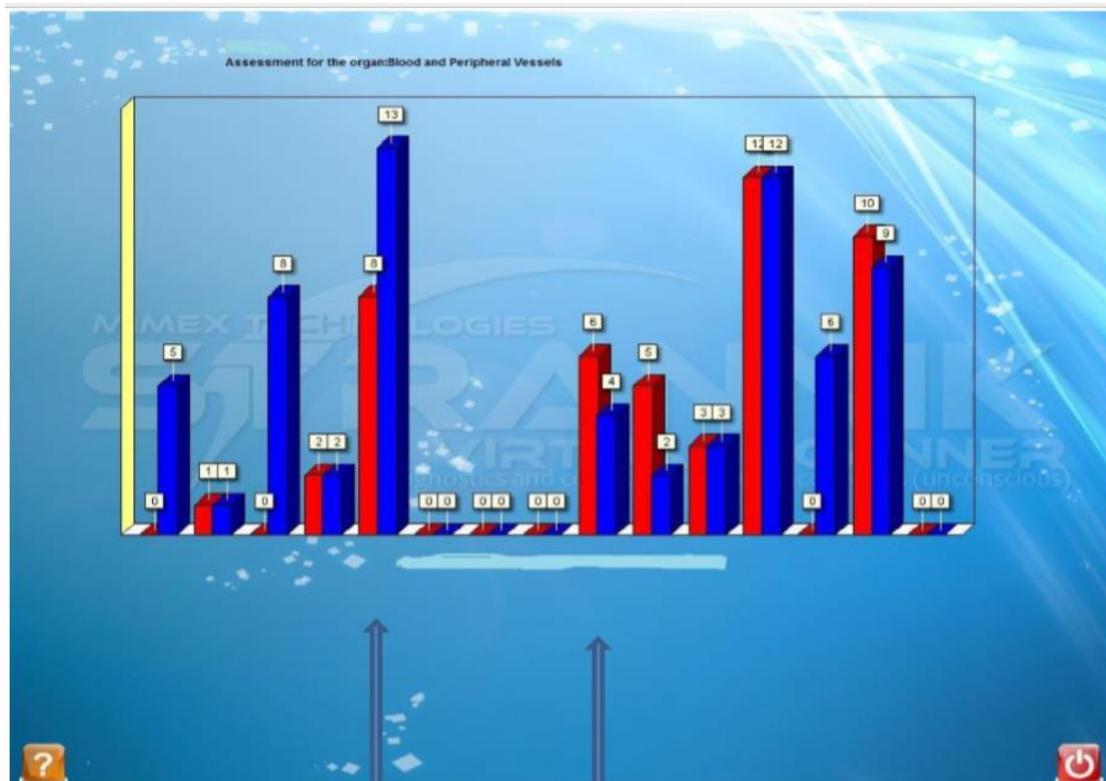


Figure 5 (c): Blood & peripheral blood vessels: Haemorrhagic diathesis, phlebitis.

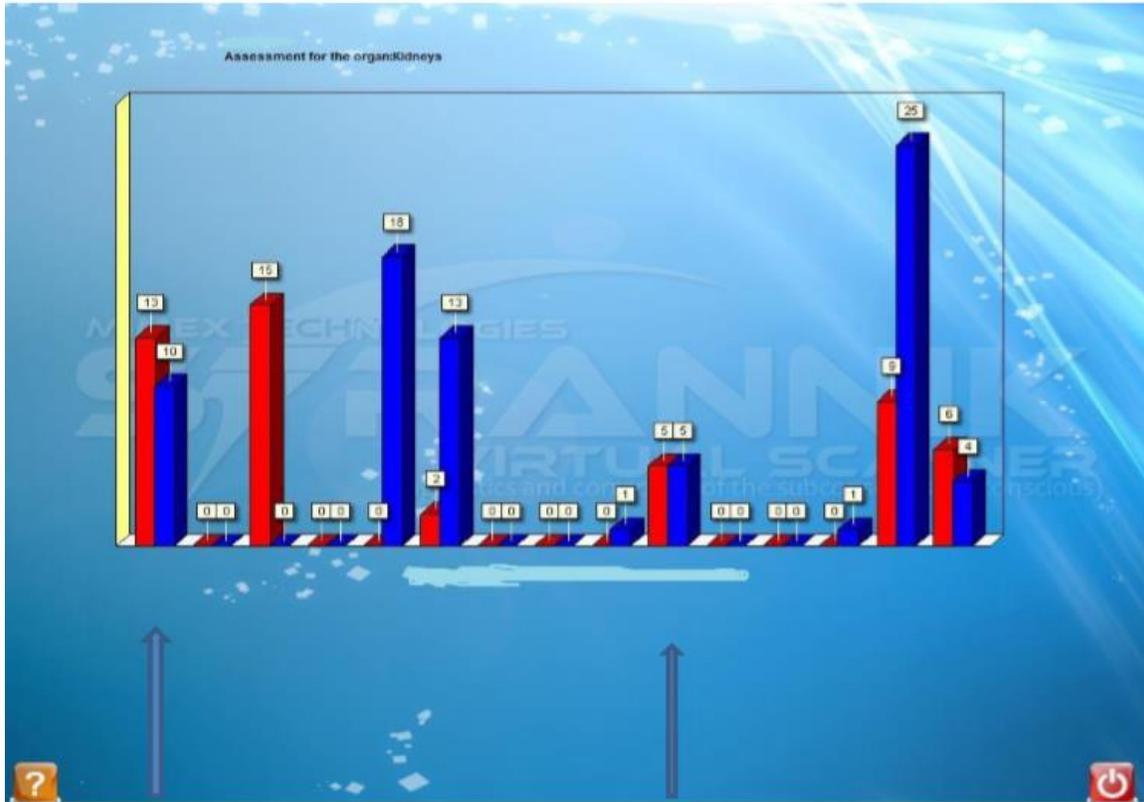


Figure 5 (d): Kidneys: Glomerulonephritis & renal insufficiency.

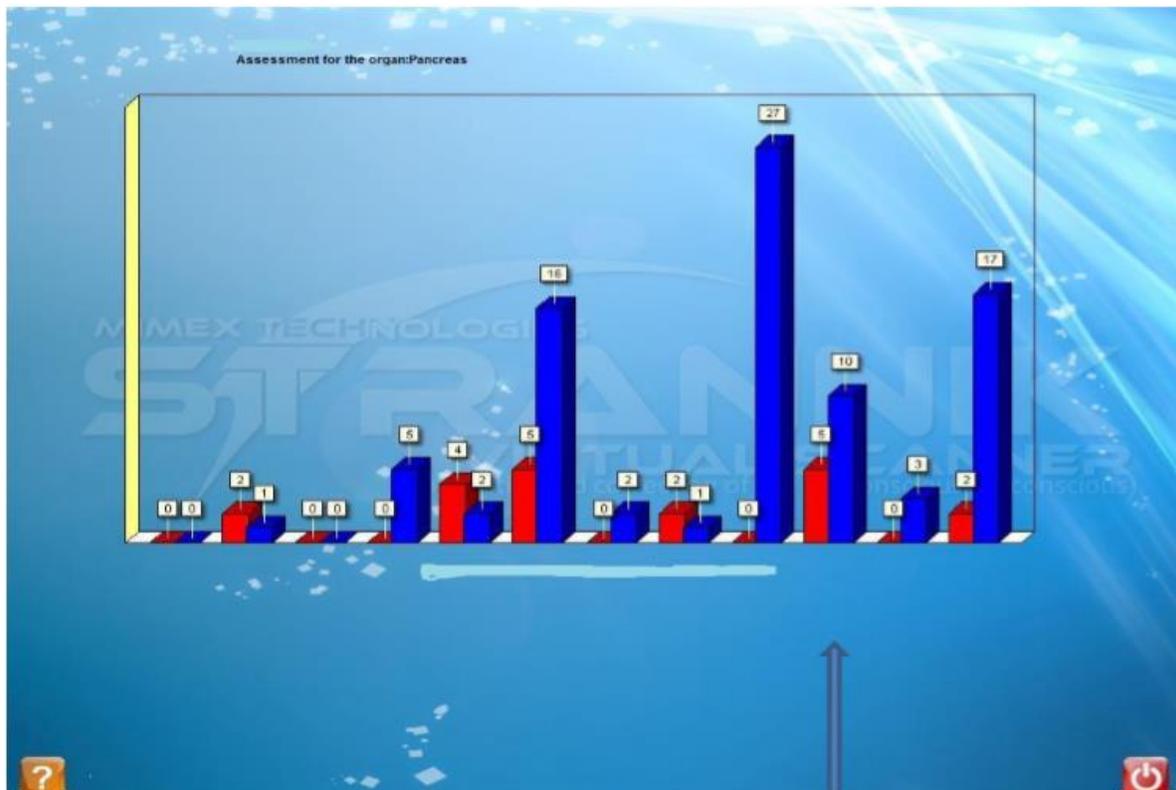


Figure 5 (e): Pancreas: Pathology of the islets of Langerhans.

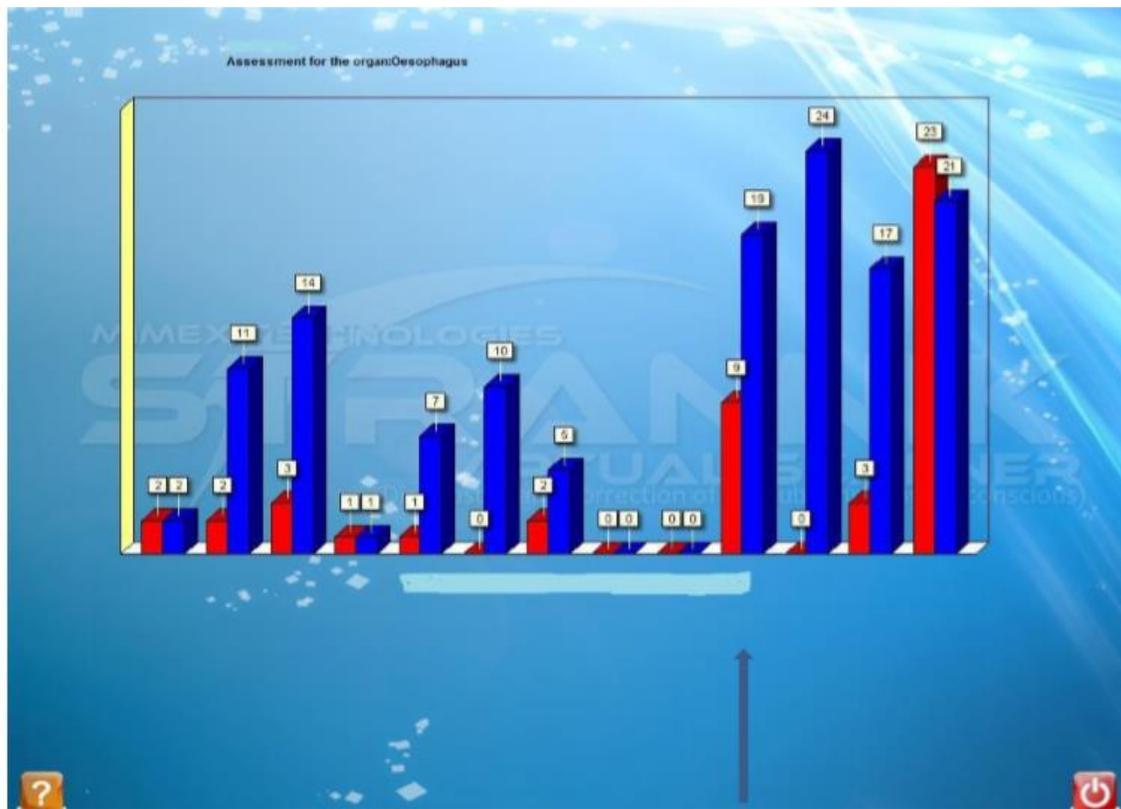


Figure 5 (f): Oesophagus: Neuroses of the oesophagus.

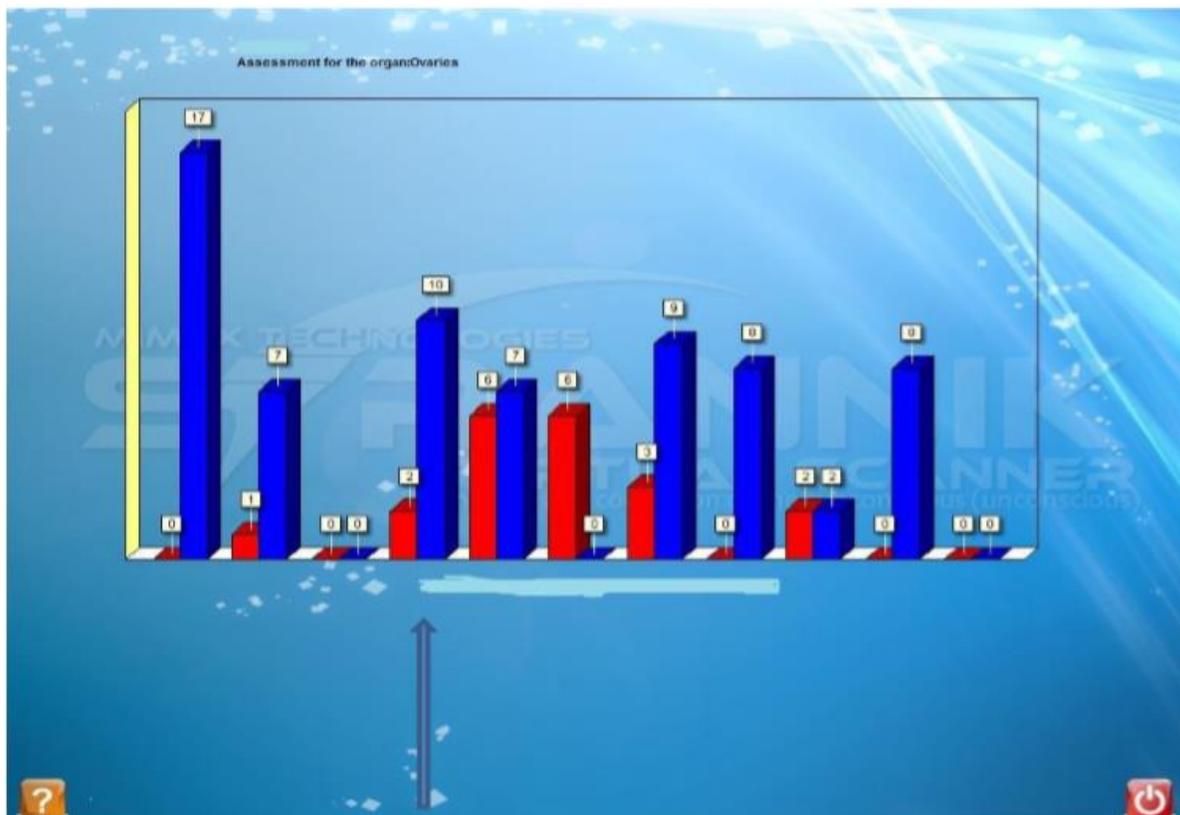


Figure 5 (g): Ovaries: Ovarian cyst.

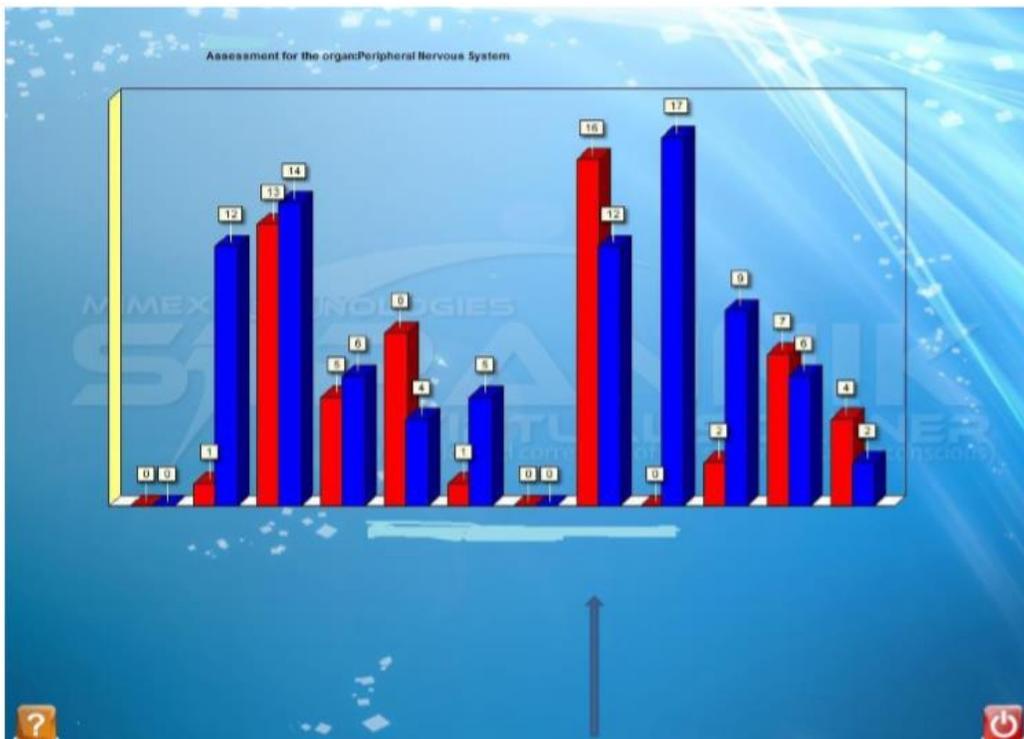


Figure 5 (h): Peripheral nervous system: Polyneuropathy.

Various 'Strannik' observations have subsequently been confirmed by medical researcher's e.g.

- (i) That depression often accompanies the onset of cardiac pathologies, and that epilepsy and migraine have common genetic origins.
- (ii) The diagnostic conclusions arising from SVS tests are consistent with the results of other researchers.
- (iii) SVS has determined the onset of various medical conditions before they could be confirmed by other diagnostic tests i.e. before they were subsequently confirmed by conventional tests e.g. the early-onset of pancreatic cancer in a lady who subsequently died, 1-2 years later, of pancreatic cancer.
- (iv) Conclusions made by Russian medical researchers indicate that the SVS technology is 2%-23% more sensitive than contemporary diagnostic techniques and that the SLT (Light Therapy) is typically 75%-96% effective. This is at the level which we could reasonably expect if, indeed, the technique is able to determine the onset of conditions from their pre-symptomatic origins and that, as claimed, it is based upon a precise understanding of the mathematical relationship between color perception and pathological onset.
- (v) The technique has been demonstrated on various occasions since 2003, to doctors and clinicians, and provides the expected results, despite being used in non-ideal circumstances i.e. outwith the conditions specified in the operating manual.
- (vi) On several occasions the results of the technique were challenged by medical doctors and/or by medical testing. SVS was proven to be correct and the medical diagnosis by the GP to be incorrect. On one occasion the patient obtained a compensatory payment for the GP's misdiagnosis of an ulcerative condition.
- (vii) The spectrum of pathologies identified by SVS re complex conditions such as migraine, Raynaud's phenomenon etc; are consistent with known etiology.

- (viii) The observations made by SVS are theoretically sound i.e. that it fills the criteria for a 'mathematical model of the autonomic nervous system and physiological systems' and explains 'the hitherto unresolved relationship between cognition and cellular & molecular biology' in particular between genotype and phenotype.
- (ix) SVS has been able to track the onset and progression of a 'migraine' signal from its presymptomatic origins until eventually the patient suffered from a migraine.
- (x) Delineate between a benign or malignant tumour.
- (xi) Determine the onset of conditions where there is not yet a satisfactory medical test e.g. Alzheimer's disease, pancreatic cancer, liver cirrhosis, whiplash injury, etc.
- (xii) SVS successfully predicted the occurrence of stroke - the test patient experienced a transient ischemic attack several months after his SVS consultation.

Example Patient Results (Table 1 and Table 2).

Date	5/12/05	22/06/06	07/07/06	04/07/08	01/02/18	05/04/18	19/04/18	15/04/19
free T4 (pmol/L)		16.8	16.2				15.2	
TSH (miu/L)	1.1	0.7	1	0.81	0.96	1.2	1	
FSH (iu/L)		6.2	2.4			11.6		
LH (iu/L)		5.4	6.8			4.9		
Oestradiol (pmol/L)							255	108
Prolactin (mu/L)		141	469					
Progesterone (nmol/L)			32					
Tri-iodothyronine(pmol/L)							4.7	
Testosterone (nmol/L)		2.1	1.8			1		1.1
Serum Cortisol level (nmol/L)								283

Table 1: The following tests were conducted by the patient's GP over the course of the last 10-15 years.

Cortisol	A normal response to Dexamethasone is suppression of Cortisol to less than 50 nmol/L. Synacthen tests: normal response is cortisol above 420 nmol/L on 30-minute sample. Consider pituitary failure if low baseline cortisol, e.g. if below 170 nmol/L in morning.
Free T4	10 - 20 pmol/L
TSH	0.45 - 4.1 (miu/L)
FSH	Increasing with age peaking at ca 40 iu/L
LH	Women in the follicular phase of the menstrual cycle: 1.9 IU/L - 12.5 IU/L. Women at the peak of the menstrual cycle: 8.7 IU/L - 76.3 IU/L. Women in the luteal phase of the menstrual cycle: 0.5 IU/L - 16.9 IU/L. Pregnant women: <1.5 IU/L
Oestradiol	Follicular: 72 pmol/L - 529 pmol/L; Ovulatory: 235 pmol/L - 1309 pmol/L; Luteal: 205 pmol/L - 786pmol/L; Post-menopause: <118 pmol/L
Prolactin	Normal levels are less than 500 mIU/L for women
Progesterone	Female (pre-ovulation): <3.18 nanomoles per liter (nmol/L). Female (mid-cycle): 15.90 nmol/L - 63.60 nmol/L
Tri-iodothyronine	3.5 pmol/L - 7.8 pmol/L
Testosterone	1.12 nmol/L - 1.79 nmol/L

Table 2: Biomarker Test Limits.

Patient SVS Results

The patient’s history includes her predisposition to digestive ulcers for which she takes an H2-antagonist; aches and pains in her back for which she has attended an osteopath; throat infections for which she has had her tonsils removed; poor sleep/inadequate sleep, and a cyst on one of her breasts.

She is 52-year-old, currently significantly overweight (ca 78kgs), has a BMI of >30, is extremely inactive and unfit, and is currently prone to bouts of extreme fatigue. Her diet often includes excessive amounts chocolate (she is a confessed chocaholic) and pasta. Her family has a history of overweight and susceptibility to phlebitis/thrombophlebitis, and hemorrhagic diathesis.

Her SVS test results are summarized as follows: Figure 5 (a) - Figure 5 (h).

- (a) Stomach: Ulcerative condition
- (b) Duodenum: Ulcerative condition
- (c) Blood & peripheral blood vessels: Haemorrhagic diathesis, phlebitis
- (d) Kidneys: Glomerulonephritis & renal insufficiency
- (e) Pancreas: Pathology of the islets of Langerhans
- (f) Oesophagus: Neuroses of the oesophagus
- (g) Ovaries: Ovarian cyst
- (h) Peripheral nervous system: Polyneuropathy

Discussion and Comparison of Test Outcomes in the Test Patient

Patient Symptoms: in the period 2005-2008: in good health, regular weight (ca 65kgs), regular sleeping patterns, physically fit; in the period 2018-2019: lethargic, continually fatigued, weight 78 kgs (ca 10 kgs overweight), BMI at threshold of obese, poor sleeping patterns, lack of regular exercise.

Conclusions based upon Biomarker Test Results

Testosterone low, Oestradiol low, all endocrine hormones within normal levels, 51/52 years patient considered to be perimenopausal although still with regular periods.

Strannik Virtual Scanning results (Figure 5(a) - Figure 5(h))

Most destabilized physiological systems: Regulation of osmotic pressure, pH and sleep (Table 3).

Oesophagus	Neuroses of the Oesophagus	19/9
Stomach	Ulcerative condition	20/10
Duodenum	Ulcerative condition	16/2
Pancreas	Pathology of Islets of Langerhans	10/5
Kidneys	Glomerulonephritis	10/13
Blood and Peripheral Blood Vessels	Haemorrhagic Diathesis	13/8
Peripheral Nervous System	Polyneuropathy	12/16
Other lesser pathologies include		
Gall Bladder	Growth of New Cells	17/9
Womb	Functional Changes	13/6

Ovaries	Ovarian Cyst	10/2
Adrenal Gland	Adrenal Insufficiency	8/4
Spinal Cord	Osteochondrosis	6/5
Kidneys	Renal Insufficiency	5/5
Blood & Peripheral Blood Vessels	Phlebitis/Thrombophlebitis	4/6
Womb	Endometritis	7/1

Table 3: Of the 5-15 pathologies reported in each of the 30 main organs the following indications were reported to be above the symptomatic threshold (7-10 units).

Conclusion

The results were completely consistent with the patients known health, their health history, current symptoms and weight. The test correctly identified all known medical conditions and others at the presymptomatic/symptomatic threshold. The test identified the presence of cellular changes in the endocrine glands although none were identified by the test to be pathologically significant. It also identified some inflammatory conditions in the womb and appendages (salpingitis, adnexitis, endometritis) perhaps associated with the patient’s perimenopausal state.

Limitations

SVS is a screening modality. It is arguably a diagnostic technology, a screening modality or a predictive statistical technique. Its primary intended purpose is to assist the patient or GP to make a precise assessment of the patient’s health. To do so the GP may wish to submit tissue or fluid samples in order to corroborate the SVS test results.

SVS indicates the extent of a medical condition, bacterial or viral infection on the body. It does not, in general, make an indication of a viral or bacterial infection e.g. influenza. It does however identify hepatitis, pleurisy, pneumonia, nephritis, and herpes. It is not suitable for use in A&E and maternity i.e. by those who are pregnant or who are cognitively unable to complete the test in particular those who are too young (typically below 7 years) or too old. It is not yet determined whether the test performs satisfactorily in a patient who has had an organ removed.

SLT is a neuromodulation-type technique. Its intended purpose is to enable the patient to improve their health. It treats ‘autonomic dysfunction’ i.e. it acts upon the neural mechanism by which the brain regulates the autonomic nervous system and physiological system, and does not act upon any specific medical conditions. Whilst SLT has been used with some successes to treat severely epileptic patients (see Case Studies) it is also recognized that extreme care should be taken when using SLT to treat such patients [36].

Case Studies

SLT has been used to screen and treat the health of over 1M patients since it was first evaluated [43] and approved for use by the Russian Health Authorities in 1999. It has been used to treat a broad spectrum of over 30 categories of medical conditions, often achieving results which exceed that which has been possible using biomedicine/drugs.

We list the following example case reports arising from the use of SLT to treat a range of mainly neurological indications (the full list of case reports is available at www.montaguehealthcare.co.uk) in order to illustrate the scope of this technology:

- Male, late 40's, severely depressed following the loss of his employment several years previously. His friends described how he would often remain drunk and in his bed for several days. His condition was one of depression and of near alcoholism. After 1-2 modules of Strannik therapy this man is now once again taking an active and positive approach to life.
- Female, ca 35-year-old, suffering facial neuralgia or Trigeminal Neuralgia. In the first week of a course of SLT she has advised that she is delighted with the progress which drastically reduced her pain.
- Female, 56 -year-old, after effects of a head trauma. She suffered from migraines and of taking anti-epilepsy medications and was depressed by the effect that her condition was having upon the quality of her life and upon the lives of her immediate family. After 2 modules of SLT she was happy and healthy and no longer required medications.
- Female, 82-year-old, with migraines for many years contacted us following discussions with her GP daughter. During the third module of therapy her migraine attacks ceased. She reported reduced rate of occurrence and severity of migraines, improved vitality and mobility. Her weight reduced by 5 kg during the course of SLT. In addition she was scheduled for a knee replacement operation however she no longer suffered from pains in her knee and postponed the operation. Note: the occurrence of her migraine attacks was found to be associated with the stress of being required to prepare monthly accounts for her church.
- Male, 54-year-old, disseminated sclerosis (MS), 1st group of disablement; general weakness, shaky walk, moved only with the help of others, irritable, disturbed sleep, poor appetite, weight deficit, depression. After the first course of SLT he began walking unassisted, gained weight (2kg in 1 month), had good appetite and normal sleep. After the second course of SLT he began doing simple work at home [43].
- Patient, 60-year-old. neuritis of facial nerve/trigeminal neuralgia: skin desensitization of the right side of the face, speech infringement, and headaches. After the fourth session of SLT speech improved, and at the end of treatment course it was fully restored, headaches disappeared [43].
- Female, 60-year-old, 2-3 years without sleep following removal of a brain tumour. Her condition was emotionally unstable/tearful outbursts. Within 2 weeks of receiving her first course of SLT she settled into regular sleep, (she enquired whether it was reasonable to sleep for 12-14 hours), health and demeanor were greatly improved and sleep patterns normalized [41].
- Male, 62-year-old, extreme hypertension due to work stress; at his latest routine medical examination had been declared unfit to continue and immediately retired from work. After a course of SLT his blood pressure declined to a more normal 130/90 [34].
- Female, 50-year-old, myocardium cardiosclerosis with arrhythmia. The SVS diagnosis including a previously unidentified calcium deficit was confirmed by available diagnostic tests. After a course of SLT and the microelements supplement the patient's heart rhythm disorders fully disappeared [43].
- Male, 14-year-old had been epileptic since 8-year-old Clinical investigation identified the part of the brain responsible for epilepsy. He was sedated using medication every morning and evening. SVS diagnosed epilepsy. He commenced a course of SLT however at the first session an intense seizure occurred, ambulance called to the patient's home. Treatment continued with no further seizures/fits. After two months, during investigations, the part of the brain responsible for the epilepsy was found to be functioning normally. After a year the antiseizures medication was terminated, no headaches, no further seizures, leading an active normal life [43].

- Female, 28-year-old, endometriosis/bleeding in the womb continuously for 8 months; hospitalized several times in gynecology dept. for scrape of uterus plus hormonal treatment without any positive results. Husband posed the question about divorce. Intense anemia, erythrocytes 2.8M SLT module for ovaries plus womb and appendages, two sessions daily: after several sessions blood discharges started to thicken and stopped after the fourth session. Finished complete treatment, three months later her menstrual cycle stabilized/normalized [43].

Discussion

This paper reviews the immense scope of technologies, in particular the Strannik technology, which have been developed and/or which are planned, with the express purpose of disrupting healthcare.

The author's extensive bibliography illustrates how such a technology was developed, the scientific basis for the technology, the precedents for a technology of this type, case studies which illustrate the scope of the technology, and proof-of-concept clinical studies (perhaps more aptly 'in-market surveillance studies'), which illustrate how well the technology performs in the clinical context; and the shortcomings of the current biomedical approach to medicine e.g. that biomedicine is considered by some to be as little as 8% scientifically proven [56], that it treats the symptoms of disease rather than the fundamental causal mechanisms, and hence that national health services could be 'overwhelmed' by people with long-term medical conditions [57].

Mohanlall R when discussing the SVS test results described it as 'a great screening tool'. He particularly focused upon the SVS technology, developed by Igor Gennadyevich Grakov in a programme of research which commenced at the University of Novosibirsk in the early 1980's, the launch of the first version of Virtual Scanner (Strannik) in 1997, and which culminated in the launch of the current version in the period 2003-2006.

Such a technology, based upon an understanding the significance of bioluminescence emitted in the blood (the company BioAstral [58,59] secured a grant of ca £2M from the UK's Technology Strategy Board (the precursor of InnovateUK) to develop a screening technology based upon this phenomena), exceeds by far what many have considered possible.

Idealism has to give way to a pragmatic assessment of what is possible and indeed what is likely if the Strannik technology were more widely accepted as a diagnostic and/or therapeutic modality. The ideal application of Strannik is at the beginning of the healthcare process, screening patients and being used to reduce the effect of stress upon the patient's health. If used in this role we could reasonably expect that the flow of patients into healthcare would stabilize and thereafter steadily decline. On the other hand many patients - the ca 20%-25% of patients who use up ca 70% of healthcare resources, are at the stage when the most pragmatic approach is by drugs and/or surgery i.e. they require a combination of approaches to combat their steadily deteriorating quality of life. They have spent a lifetime devoted to their self-indulgent lifestyles and practices e.g. smoking, which have led to their current state. If their health was to improve it would only allow them to go back to what they know. So given this knowledge it is recognized that it may take a lifetime to convert healthcare from the current allostatic approach (treating the symptoms using drugs which is the 3rd largest cause of mortality [60] to a homeostatic approach (i.e. treating the causes [61,62]).

The initial assessment of what is possible is based upon the existing evidence-base which indicates the possibility to dramatically reduce the complexity and associated cost of identifying the health of the patient with SVS and then treating

them with SLT. As a screening modality SVS has the potential to reduce the flow of patients into the healthcare system – the patient can do their test and identify what is the matter with their health. This puts them in the position to make further research via the internet and to recognize whether they need to have a consultation with their GP. If the patient attends their GP it puts the GP in the position where he can reduce the number of tests required to assess the health of the patient and reduce the number of referrals to secondary care. It is estimated that SVS could for example screen the health of 50M of the UK's 65M+ population for ca £3bn pa and significantly reduce the cost of managing a wide range of medical conditions.

Initial research [40] has illustrated that SVS performs at a level which is 2%-23% more accurate than the entire range of diagnostic tests which are used to determine the patient's health. This illustrates how the amount of medical testing could be significantly reduced - an estimated >80% of medical tests yield a negative test result and are used by the GP as part of their forensic investigations to rule out specific indications – and improved; and because SVS is an inexpensive screening modality it would be used to determine whether other expensive screening techniques should be used (e.g. an estimated 20% of MRI cardiac tests yield a negative test result).

Initial research [40] has illustrated that SLT performs at a level which is 75%-96% effective. The case studies reported in this paper illustrate how SLT can be used to treat a range of mental health conditions. As most drugs (with the exception of antibiotics) are ca 50% effective [19] this presents the opportunity to improve therapeutic outcomes - not just re mental health conditions but across the full medical spectrum - and significantly reduce the costs from biomedicine (the patient paid >£1000 for the tests conducted in 2018 which were reported in 6.1) in particular re the management of lifestyle-related pathologies, perhaps significantly so.

Strannik can be accessed by any patient by PC or via the internet. It works as a decentralized network of nodes - linked to the central Strannik software - which access the system enabling the patient to provide information to the test, to generate the test data which is processed into the patient's health report which is then available for the patient or doctor to use to assess what is the matter and/or to treat the patient; or in conjunction with current diagnostic and therapeutic approaches.

Such a technology can be used by the patient, anonymously if necessary and independent of corporate or government control if required. There is no need for the patient's test results to be held on a centralized database unless the patient agrees. The patient's health data can be encrypted to preserve the patient's request for privacy.

Conflicts of Interest

The company Mimex Montague Healthcare, its CEO and author of this paper is privately funded without the involvement of any outside parties. Mimex Montague Healthcare is a company which is devoted to the commercialization of the Strannik technology.

Acknowledgement

The author recognizes the contribution of the many researchers who through their research have made this article possible, in particular Dr Igor Gennadyevich Grakov, developer of the Strannik technology; and encouragement by Dr. Syed Hasan Parvez, and others.

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