Contact lens Hygiene: **Importance and tools**

Professor Mark Willcox

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Professor Mark Willcox is a medical microbiologist who is particularly interested in studying the microbial colonization and the pathogenesis of the adverse events associated with contact lens wear. Here we introduce his background and motivation, with a highlight on his current research interest and activity.

To begin, what is your academic and research background and how did your career in scientific research start?

I obtained my undergraduate degree in Applied Biological Science from the University of the West of England (formerly Bristol Polytechnic). During my undergraduate studies, I had the great opportunity to work in industry for one year, and I was lucky enough to be placed at a Veterinary Investigation Centre in Reading, UK. This placement sealed my interest in microbiology – specifically medical microbiology and its role in disease diagnosis, monitoring and treatment. After obtaining my degree in 1983, I moved to the University of Manchester to start my PhD studies with Dr. David Drucker, studying the bacteria causing dental caries. This prompted my interest in microbial colonisation of surfaces. In 1988, I was lucky enough to be offered a Research Fellowship at the Institute of Dental Research in Sydney, Australia. There, I continued my research on oral microbiology for five years before moving to the School of Optometry and Vision Science, UNSW to study microbial colonisation of contact lenses. I have been in this field ever since, as well as broadening my research into fields of ocular biochemistry and immunology, and clinical trials.

What has been your primary motivation as a scientist, and why did you choose medical microbiology as a domain?

My primary motivation is discovery and the application of discoveries for the benefit of people. I am particularly interested in aspects of applied or translational science. My research has examined, for example, methods for combating microbial adhesion to dentures, contact lenses, cochlear implants and other materials used in or on the human body. Also, I am interested in the development of microbial resistance to antibiotics and disinfectants, and the emergence of microbial diseases. Medical microbiology allows me to investigate all of these issues, and has allowed me to develop new ways of combating diseases. I am a strong advocate of interdisciplinary research. For example, my research path has involved interactions with dentists, optometrists, ophthalmologists, epidemiologists, immunologists, biochemists, chemists, and material scientists. I have been fortunate also to collaborate with industry. One aspect of this has been the development of new contact lens materials, and I am currently working with Professor Naresh Kumar at UNSW in Australia and the LV Prasad Eye Institute in Hyderabad India to test new antimicrobial surfaces on contact lenses in clinical trials.

What are the potential health hazards that might result from poor contact lens hygiene?

Contact lenses are a very effective form of vision correction. They give better all-round vision than glasses. However, since they come in contact with a very delicate organ, they need to be properly cleaned and disinfected. After use, contact lenses should be kept in special storage cases filled with disinfecting solution to eliminate microorganisms. Failure of the disinfection process can lead to the growth of microbes in the storage cases and on the lens surface. These microbes can infiltrate the eye leading to corneal inflammation and in severe cases ulceration. Despite the advents made in the development of contact lens disinfecting solutions, eye infections continue to occur among contact lens users, indicating that an efficient, easy-to-use disinfection system is still lacking.

You are currently performing a clinical trial on a new contact lens disinfecting solution. What is the nature of the new disinfectant, and what are the goals of the clinical trial?

The product currently under test is called Cleadew, a disinfectant based on povidone iodine, developed by a Japanese company, Ophtecs. Povidone iodine has an excellent spectrum and intensity of antimicrobial activity, and is known as a powerful wound and skin disinfectant, however, it is currently being used for the first time as a contact lens disinfection system. The current trial aims to test the efficacy of Cleadew to eliminate microbial colonization of contact lens and their storage cases, as well as its effect on the safety and comfort of the eye when used on a daily basis.

Following the completion of the clinical trial, are you planning to extend your research on contact lens care further? What might be the scope of your next step?

I have established collaboration with Professor Fiona Stapleton from the School of Optometry and Vision Science UNSW, through which we will jointly perform a clinical trial to test the efficacy of silver-containing contact lens cases in eliminating microbial contamination. The trial is based on the known antimicrobial activity of silver, as well as our previous findings for storage cases made of a particular type of silver, which showed to prevent microbial colonisation.

Contact Lens disinfecting Solutions for Proper Hygiene

Professor Mark Willcox is currently performing a clinical trial to test a unique contact lens disinfecting solution. Here we discuss the importance of maintaining good contact lens hygiene and adverse consequences of lens contamination, before detailing the properties of the new disinfecting solution and the goals of the clinical trial.

CONTACT LENS HYGIENE: WHAT CAN GO WRONG?

Soft contact lenses were first released around the world in the 1970s and silicone hydrogel lenses were released in the early 2000s. Nowadays, more than 150 million people around the globe are using contact lenses, either for medical or cosmetic purposes. Daily wear of contact lenses requires the regular use of a storage case, which contains an antimicrobial solution to disinfect the lenses overnight. Storage cases play an essential role in contact lens hygiene. However, without proper maintenance, the case may become contaminated with microorganisms during handling. Microbial contamination of contact lens cases can compromise contact lens wear and lead to serious adverse events. Furthermore, scientists have isolated identical strains of bacteria from corneal ulcers and contact lens storage cases, suggesting the case being a reservoir for the microorganisms responsible for the ulcer. Several studies have shown that lens case contamination is common, ranging from 30 to 80 percent. Despite good compliance, lens case contamination can still occur. Further compounding the problem is the formation of what is called 'microbial biofilms', which are aggregates of microbes held together within a self-produced matrix. These biofilms render microbes more resistant to the effects of disinfectants. Therefore, Professor Willcox's advises contact lens users to follow the hygiene instructions of the lens and disinfecting solution's manufacturers. This ideally includes the total replacement of the disinfectant solution usually each month and air-drying the storage case after each use. He also recommends the frequent replacement of the storage case, advisably when a new disinfecting solution is purchased.

Failure to maintain the hygiene of contact lenses or contact lens storage cases may result in contact lens–related complications, mainly due to the infiltration of the cornea by microorganisms. This causes inflammation of the cornea (scientifically known as keratitis), which is a potentially sight-threatening condition. A recent epidemiology study estimates at least 50 percent less risk of developing corneal keratitis if case hygiene is appropriately maintained.

LENS CARE SOLUTIONS TO IMPROVE HYGIENE

Contact lens disinfecting and cleaning systems are essential elements in contact lens care. Most soft contact lens users use multipurpose disinfecting solutions for antimicrobial protection. The most widely used contact lens disinfecting and cleaning solutions contain a variety of disinfectants and various cleaning agents including surfactants. The usage rate of multipurpose disinfecting solutions has gradually increased to account for 90 percent of disinfection types in the United Kingdom and Australia. However, over the past 20 years, epidemiological studies of contact lens wear showed an almost constant rate of microbial keratitis associated with lens wear, even with the release of new disinfecting solutions and new lens types. Surprisingly, the initial estimates, published in 1989, for the rates of microbial keratitis during daily wear are almost identical to those published in 1999 and 2008.

A UNIQUE DISINFECTING SOLUTION UNDER CLINICAL INVESTIGATION

Professor Willcox and researchers at the School of Optometry and Vision Science, UNSW are currently testing a new contact lens disinfecting solution called Cleadew. The solution is developed and manufactured by Ophtecs Corporation (Kobe, Japan), which is also the sponsor of the clinical study. Cleadew is based on 'povidone iodine', a fast-acting disinfectant with a wide antibacterial spectrum. To many of us, povidone iodine is well-known as a topical antiseptic in minor skin cuts, grazes and abrasions in order to prevent infections.

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While iodine is poorly soluble in water, Ophtecs has developed a unique water soluble preparation suitable for disinfection of contact lens. Cleadew is provided in a package containing small tablets and a dissolving solution. These tablets are composed of a rapidly acting outer layer of povidone iodine and a late-acting inner layer containing an iodine neutralizing agent and a proteolytic enzyme (breaks down protein particles). The contact lenses to be disinfected are placed into the storage case, and then the provided solution is added to the case along with one of the iodine tablets. As the tablet is placed in the solution, the outer layer dissolves quickly, releasing the iodine, which disinfects both the contact lenses and the storage case. Over time, the inner layer eventually dissolves to neutralize the iodine and to release the proteolytic enzyme which helps to remove lens deposits. This system allows the contact lens to be disinfected within 5 minutes, which is significantly faster than other solutions. However, the manufacturers recommend keeping the lenses in the case for four hours, allowing sufficient time for the action of the cleaning enzyme.

The main goal of the current clinical trial on Cleadew is to evaluate the status of microbial contamination in lens storage cases during daily wear. Professor Willcox and his fellows are investigating the level of microbes in cases using traditional microbial culture techniques as well as non-culture techniques which can detect microbial DNA in the storage cases. Additionally, the eyes of the participants are being examined for comfort and absence of irritation during the use of the disinfectant. Professor Willcox and his colleagues have shown in previous clinical trials that contact lens cases can be contaminated by a variety of microbes, and that some disinfecting solutions allow Gram-negative bacteria to grow in storage cases. ‘Certain types of disinfecting solution result in around 50 percent of the examined cases being colonized by Gram-negative bacteria’, said Professor Willcox. Furthermore, users of the disinfecting solutions that allowed the growth of Gram-negative bacteria experienced a higher incidence of keratitis. The current clinical trial is important to validate the efficacy and safety of Cleadew for use as contact lens disinfectant.

Prior to market release, and in addition to success in clinical trials, all contact lens disinfecting solutions need to comply with governmental regulatory requirements of efficacy and safety. The International Organization for Standardization (ISO) 14729 ‘stand alone’ disinfection test is often recommended to demonstrate efficacy. The test requires qualifying contact lens disinfecting solutions to show a specific spectrum and intensity of antimicrobial activity at the manufacturer’s recommended disinfection time. Cleadew has successfully passed these tests, as well as other tests that demonstrated excellent efficacy against Gram-negative bacteria known to resist other disinfecting solutions. With regard to safety, Cleadew has been proven safe in multiple tests examining the toxicity of its solution to mammalian cells in the laboratory. This is in addition to limited trials on volunteers to assess potential irritation to the eye during use. The findings of these regulatory tests were presented at many international conferences such as the ‘British Contact Lens Association Annual Meeting’, recently held in 2015. Interestingly, Cleadew has recently acquired the CE mark, which authorizes its commercialization in the European markets.

THE NEXT STEP IN CONTACT LENS HYGIENE RESEARCH

Professor Willcox is planning to continue research and clinical trials on contact lens disinfecting solutions. He is currently collaborating with Professor Fiona Stapleton from the School of Optometry and Vision Science, UNSW in studying some further aspects of microbial contamination of contact lens cases and the efficacy of silver-containing contact lens storage cases. Silver has a good antimicrobial activity and can kill many different types of microbes. ‘We have previously shown that one particular type of silver lens case had significantly less microbes in the case than normal control cases’, said Professor Willcox. This work will be mainly done by a dedicated doctoral researcher, Ananya Datta, who is planning to test the feasibility of other silver-containing storage cases to minimize lens microbial colonisation and the associated adverse effects in a clinical trial.

Researcher Profile

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Professor Willcox is interested in contact lens research, specifically studying the microbial causes of adverse events during contact lens wear. He has established several animal and cell-based models for studying contact lens adverse events and biomaterial infections. He developed new techniques that allow researchers, for the first time, to assess the contribution of particular proteins or lipids to the production of adverse responses during lens wear. He also investigated the use of tears as the source of biomarkers for diabetes, breast and prostate cancer. His research has led to the publication of 12 patents and over 350 peer reviewed papers.

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