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Investigating the shelf life of disposable soft contact lenses

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Abstract

Numerous studies have been done to scrutinize the sterility and/or efficacy of contact lens solutions[1-3], contact lens storage cases[4-6] and soft contact lenses (SCLs)[7-10]. To the best of our knowledge, a paucity of research regarding the sterility or efficacy of expired SCLs that are in sealed packages exists. One may question the need to investigate this facet of contact lens research. Many blogs and Q&A websites, such as the Optiboard website[11], feature contact lens practitioners or contact lens patients who are curious about the repercussions of using expired SCLs. The purpose of this pilot study is not to offer all the answers regarding expired contact lenses, but rather to initiate curiosity about the quality and utility of expired SCLs. This study endeavors to investigate the sterility of sealed SCLs that are past their expiry date. Fifty-four SCLs were tested for the presence of fungal (27 samples) and bacterial (27 samples) contamination. These samples included both expired and unexpired SCLs that were either blister packed or vial packed. A small percentage of the lenses tested positive for contamination.

Introduction

Previously, SCLs were packaged in vials (glass bottles sealed with a silicone stopper and a foil safety cap[12]). Currently, SCLs are predominantly packaged in blister packs which are lighter, cheaper and more convenient than vial packaging[12]. Each blister pack contains one soft contact lens completely submerged in sterile buffered saline solution which keeps the lens hydrated. The majority of saline solutions are manufactured with a neutral pH of between 7.0-7.4 which is similar to the pH of human tears[13] and therefore do not cause discomfort when the saline soaked lens is placed on the eye. The saline solution used in the blister pack is usually buffered to prevent the pH of the saline from declining to acidic levels[13]. Blister packs are heat sealed and made impermeable to bacteria[12] therefore, theoretically, sterility of these contact lenses should only be compromised once the seal is broken. Manufacturers advise on consumer websites and on instruction leaflets (found in the SCL boxes) not to wear contact lenses that are past their expiry date but with no reason attached to this recommendation. Therefore consumers continue to question the significance of the repercussions of using these ex-

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pired lenses. The aim of this study is to investigate the sterility of expired SCLs thereby initiating further investigations into the quality and utility of these expired lenses.

Materials and methods

Selection of lenses

Sealed contact lens containers were randomly selected from the disposable SCL stock at the optometry clinic at the University of Johannesburg. There were 54 samples in total which consisted of vial and blister packed contact lenses. Twenty seven lenses were tested for bacterial contamination and 27 lenses were tested for fungal contamination. Details of the samples are given in tables 1-5. The unexpired lenses that were cultured served as the control.

Microbial investigation

Tryptone soy agar (BIOLAB) was used as a general purpose culture medium. According to the manufacturer, this medium is suitable for the growth of a variety of both aerobic and anaerobic organisms. For the purpose of this research 7.6 g of the powder was mixed with 200 ml of distilled water and was boiled until the solute dissolved. The mixture was then placed into the autoclave at 121˚C for fifteen minutes. Thereafter the medium was poured into sterile petri dishes and was left to set for 24 hours.

The fungi specific medium was prepared with 3 g Agar-Agar (Merck) and 2 g of malt extract bacteriological medium (BIOLAB). Both these powders were mixed with 200 ml of distilled water and the medium was prepared in the same manner as the tryptone soy agar.

The culturing of the lenses was conducted in a laminar flow cupboard containing a built-in ultraviolet (UV) germicidal lamp. Nonionizing radiation by UV light is a common and efficient method of sterilizing surfaces. The UV light disrupts the microorganism's DNA thereby killing the microorganism or inhibiting its growth[14], however, UV radiation does not penetrate solid coverings efficiently therefore the rays must be in direct contact with the microorganism for the radiation to be effective[15]. The surfaces of all materials and equipment used, including the work surface, petri dishes, contact lens packages, scalpel, bunsen burner and tweezers, were exposed to 30 minutes of UV radiation. The contact lens and saline solution within the blister pack was not affected by the radiation due to the poor transmission of UV rays through solid materials as mentioned above[15] and this was confirmed by a microbiologist[16]. Prior to UV exposure, all contact lens packaging was wiped clean with alcohol as well.

Each saline drenched contact lens was removed from its packaging with sterile tweezers and then placed on the medium without patting the lens dry. Two slits were made with the scalpel to facilitate flattening the lens onto the medium. Disinfection of the scalpel and tweezers was achieved by dipping the instruments in alcohol and flaming them over a bunsen burner after each lens was handled. Each petri dish accommodated two samples from each type of blister packed contact lens and one sample from the vial packed contact lens. Twenty-seven samples were placed on the tryptone soy agar and Twenty-seven samples were placed on the fungi specific medium. Once all samples were prepared, the petri dishes with the tryptone soy agar were placed in an incubator at 37˚C because most microorganisms are mesophiles that thrive at this temperature[14]. The petri dishes containing fungi specific medium were placed in an incubator at 25 ˚C which is the optimum growth temperature for fungi[17].

The samples were incubated for a period of 26 days. Due to restricted resources, identification and colony counts of the bacterial and fungal species were unattainable. However, Gram staining was possible and was therefore carried out on the bacterial samples collected.

Table 1: Details of Johnson and Johnson blister pack contact lenses

Expiry date	Type of lens	Contents of package	Number of lenses tested for contamination
2009-04 (unexpired)	ACUVUE oasys	Senofilcon A	4
2006-04 (approximately two years past expiry date)	ACUVUE 2	42% Etafilcon A 58% water Buffered saline solution	4
2003-08 (approximately five years past expiry date)	ACUVUE 2	42% Etafilcon A 58% water Buffered saline solution	4

Table 2: Details of Bausch and Lomb blister pack contact lenses

Expiry date	Type of lens	Contents of package	Number of lenses tested for contamination
2009-04 (unexpired)	SofLens	Hilafilcon B 59% water Saline solution	4
2007-04 (approximately one year past expiry date)	SofLens	Hilafilcon B 59% water Saline solution	4
2003-08 (approximately five years past expiry date)	SofLens	42% Etafilcon A 58% water Buffered saline solution	4

Table 3: Details of Ciba Vision blister pack contact lenses

Expiry date	Type of lens	Contents of package	Number of lenses tested for contamination
2009-03 (unexpired)	Focus monthly	45% Vifilcon A 55% water Buffered saline solution	4
2007-05 (approximately one year past expiry date)	Focus monthly	45% Vifilcon A 55% water Buffered saline solution	4
2003-01 (approximately five years past expiry date)	Focus monthly	45% Vifilcon A 55% water Buffered saline solution	4

Table 4: Details of Hydron (Cooper Vision) blister pack contact lenses

Expiry date	Type of lens	Contents of package	Number of lenses tested for contamination
2009-03 (unexpired)	Actifresh 400	27% Lidoifilcon A 73% water Buffered 0.9% saline solution	4
2007-01 (approximately one year past expiry date)	Actifresh 400	27% Lidoifilcon A 73% water Buffered 0.9% saline solution	4
2003-03 (approximately five years past expiry date)	Actifresh 400	45% Vifilcon A 55% water Buffered saline solution	4

Table 5: Details of vial packed contact lenses

Expiry date	Type of lens	Contents of package	Number of lenses tested for contamination
2002-09 (approximately six years past expiry date)	Ciba Vision (Illusions)	62.5% Tefilcon 37.5% water Buffered saline solution	2
2004-02 (approximately four years past expiry date)	Hydron (Omniflex toric)	30% MMA/VP 70% water Preservative free saline solution	2
2005-06 (approximately three years past expiry date)	Bausch and Lomb (Optima Toric)	55% Hefilcon B 45% water Buffered saline solution	2

Results

After four days of incubation the petri dishes were observed for signs of contamination. Of the 54 lenses tested, only four lenses exhibited bacterial growth (figure 1) whilst none of the lenses exhibited fungal growth

The four contaminated lenses were all blister packed samples and included Bausch and Lomb (expiry date 2009), Ciba Vision (expiry date 2009), Johnson and Johnson (expiry date 2003) and Hydron (expiry date 2003). Surprisingly, two of the four contaminated lenses were unexpired lenses. Therefore the source of contamination was dubious and new samples from these four batches were cultured. After two days of incubating the four new samples, only the Hydron contact lens (expiry date 2003) displayed bacterial growth. At this point (day six of incubation), the initial 50 uncontaminated samples still did

not display any signs of contamination, neither fungal nor bacterial. 26 days later, Hydron (expiry date 2003) was still the only sample that displayed bacterial contamination whilst the majority of the samples remained sterile (figure 2).

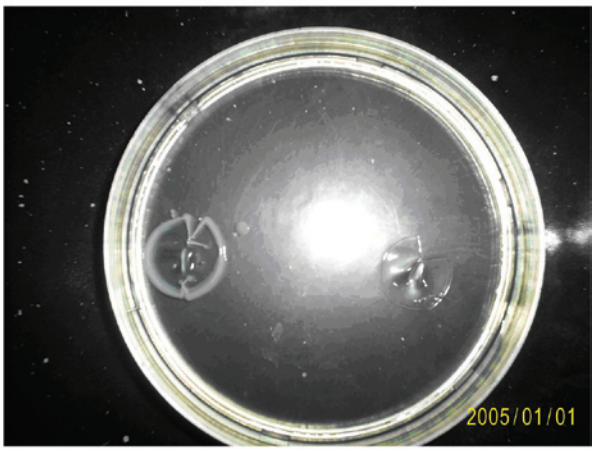

Figure 1: Bacterial growth around one sample (on the left) of a blister packed Hydron contact lens (expiry date 2003). Notice that the sample on the right remains uncontaminated. (Please ignore the date due to incorrect camera settings.)

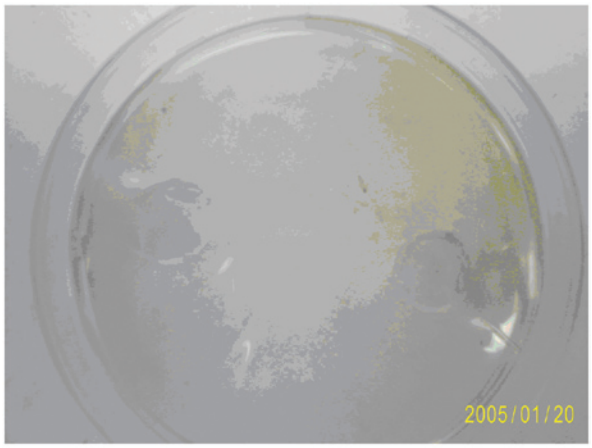

Figure 2: After 26 days of incubation the majority of samples, such as the Baucsh and Lomb (expiry date 2003) blister packed contact lens, showed no signs of bacterial contamination. (Please ignore the date due to incorrect camera settings.)

Furthermore, two other Hydron samples (expiry date 2009 and 2003) displayed fungal contamination. The 2003 sample displayed fungal contamination on and around the lens (figure 3) whilst the fungal contamination present in the petri dish of the 2009 sample was not on, but adjacent to the lens (figure 4). Once again, the source of the contamination is debatable due to the fungal growth lying adjacent to the lens.

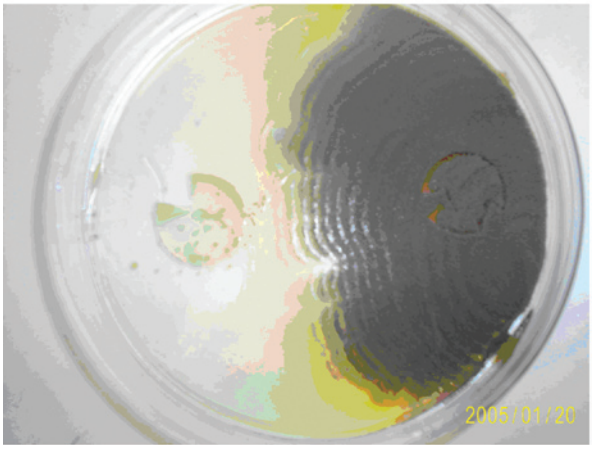

Figure 3: Fungal growth over a Hydron (expiry date 2003) blister packed contact lens after twenty six days of incubation. (Please ignore the date due to incorrect camera settings.)

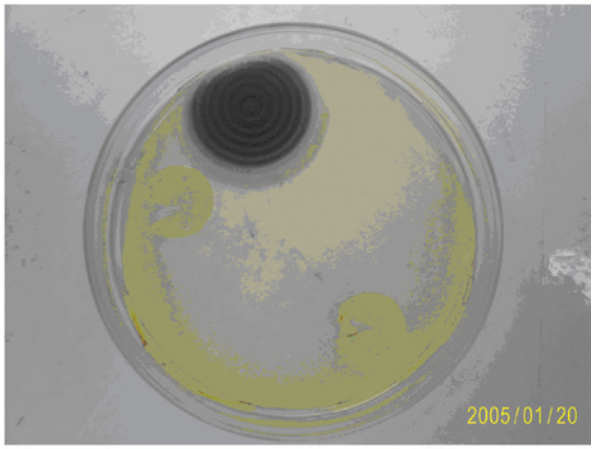

Figure 4: Fungal growth adjacent to a Hydron (expiry date 2009) blister packed contact lens after twenty six days of incubation. (Please ignore the date due to incorrect camera settings.)

Bacterial samples collected from the Hydron (expiry date 2003) and the Bausch and Lomb (expiry date 2009) contaminated lenses were Gram stained. The bacterial cells appeared to form clusters, were round in shape and the cells stained purple. Therefore both samples were identified as cluster forming Gram positive cocci[14].

Discussion

Expiry dates on some products are often questioned, and sometimes ignored, by consumers simply because it seems like a ploy by the manufacturers to make more money. Having stumbled upon thousands of rands worth of expired SCL in our public clinic,

we too began questioning the purpose of the expiry date on contact lenses hence the motivation for this research. Questions such as "are the expired lenses still sterile", "are the parameters of the lens unaltered", "is the saline still neutral", were followed by the more pertinent question "could the expired lenses be disinfected, soaked in fresh saline and dispensed to patients for free". If this were possible, money would be saved and perhaps there would be less plastic pollution to deal with as well. We enquired on Johnson and Johnson, Bausch and Lomb and Ciba Vision websites about the purpose of the expiry date. Johnson and Johnson and Bausch and Lomb provided us with some insight. Responses from both Johnson and Johnson and Bausch and Lomb were in consensus. According to these manufacturers, the saline in which the lens is stored contains preservatives and the sterility of the preservative cannot be guaranteed beyond the stated expiry date. However, as mentioned above, if the package is sealed, sterility is only compromised when the seal is broken[12] therefore their response to our question remains unconvincing. According to an American patent[18] the shelf life of the blister packed contact lenses is attributed to the loss of solution through the sealed packaging which may alter the concentration of the saline. If this is the most pertinent reason for the expiry date then perhaps that could be remedied by soaking the lens in fresh saline prior to use. The results of our research showed that only 14.8% (2/ 27) of samples tested positive for bacterial contamination (half of which were unexpired samples) and 3.7% (1/ 27) of samples tested positive for fungal contamination. This pilot study was done on a small scale to merely gain a little insight into the sterility of expired SCLs. The source of contamination of the minority of lenses that did exhibit bacterial and fungal growth was dubious due to perplexing factors, namely, bacterial growth on unexpired SCLs and fungal growth on the medium adjacent to the sample but not on the sample. This evidence by no means warrants the use of expired SCLs but does raise the question of the quality and utility of expired SCLs. Further research is required to comprehensively investigate expired SCLs thereby perhaps extending the shelf life of disposable soft contact lenses.

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