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HYDROGEL CONTACT LENSES

TO ENZYME OR NOT TO ENZYME - THAT IS THE QUESTION

ABSTRACT: The purpose of this literature review is to determine whether or not an enzyme cleaner is necessary as an adjunct to daily cleaning and disinfection. This determination will be made by articles using objective findings e.g. microscopy, subjective findings i.e. patient comfort, or both methods.

KEY WORDS: ENZYMES, SURFACTANTS, NONIONIC, ANIONIC, AMPHOTERIC, POLYMERIC BEADS, SOFT CONTACT LENSES.

Deposits on hydrogel lenses have been linked with many adverse or unwanted conditions, including: Discomfort, giant papillary conjunctivitis, increased bacterial harboring, decreased visual acuity and red eyes.

Enzymatic cleaning has long been touted as an effective method to remove deposits; but is it necessary for every hydrogel wearer, or are today's surfactant cleaners able to effectively eliminate these deposits, at least for some wearers? The overall consensus is that effective deposit removal is largely related to the quantity of deposits each individual contact lens wearer secretes and therefore places on their lenses. Deposit removal does not appear to be related as much to a difference in contact lens material as it is to the type and composition of the surfactant and/or enzymatic cleaner.

CHRONOLOGICAL OVERVIEW:

1978 The March 1978 issue of the Journal of the American Optometric Association contains an article entitled "Soft Lens Cleaners: Their Effectiveness in Removing Deposits." The emphasis of this article was to compare the efficacy of surfactants, oxidizing agents, and enzyme cleaners in removing deposits from hydrogel lenses.

Hathaway and Lowther state that all polymers involved in hydrogel manufacturing have chemical sites which are potentially available for binding charged particles. They showed that all organic protein fractions normally found in

tears have the potential to form deposits. Each "cleaner" takes a different avenue in its attempt to remove these deposits.

The overall purpose of a surfactant is to lower the surface tension of the oil-water, or oil-solid interface. ^Oxidizing agents act by oxidizing the tertiary structure of the accumulated deposits.

Enzyme digestion systems act by hydrolizing the peptide linkages of the denatured protein on the lens surface.

The surfactant cleaners used in this study, ^Pliagel and Softmate, are intended to be used in a prophylactic manner, and as such are not suitable to remove built-up deposits.

The oxidizing agent Ren-^O-Gel performed well in removing built up deposits, but has been known to alter the lens matrix of HEMA type lenses. This alteration actually increases deposit formation. In addition, this system is designed for office use, and is therefore inconvenient for the patient.

The enzyme cleaner from the Allergan Company was also very effective in removing built up deposits, and did not alter the lens matrix.

This article concludes that the enzyme cleaner is the most efficacious method to remove protein at this time, and that both Pliagel and Softmate surfactant cleaners are ineffective in removing built up protein, and that their prophylactic effect has yet to be proven.

Contact Lens Forum published "Surfactant Cleaners vs. The

Enzyme Cleaner" in January 1980. Gold and Orenstein found the enzyme cleaners which contain papain reduce the size of the protein molecules which are adherent to the lens surface. They go on to say that these molecules must be removed mechanically, by a rubbing action. If these molecules aren't removed, they form a film of small tear protein molecules plus papain vegetable protein which remains on the lens. This allows increased binding of preservatives such as chlorhexidine, by as much as 100 times, vs. a clean lens.

Surfactant cleaners can remove unbound chlorhexidine, but papain binds it to the lens, rendering surfactants ineffectual in this regard.

The article concludes that each cleaner has a specific function and cannot be interchanged or omitted, therefore enzyming is necessary.

Contact Lens Forum published "Opti-Clean For Hydrophilic Lenses" in November 1982. Fontana, Meier, and Becherer state that ^Opti-Clean was developed as a unique daily cleaner that is effective against all surface deposits on hard and soft contact lenses, and that supplemental enzymatic cleaning is unnecessary. The mechanism of action is through a suspension of high molecular weight polymeric beads, and a surfactant. This combination shears deposits from the contact lens without damaging ~~the~~ its surface.

All lenses were disinfected thermally, so as to not enhance Opti-^Clean's cleaning ability chemically.

Lens surfaces were examined via slit lamp exam, and every

lens was reported as clean after six months. ^Patients reported very comfortable lens wear, good acuities, and all preferred the convenience of the ^Opti-Clean vs. the traditional daily cleaner plus enzyme approach.

CLAO published "The Safety and Effectiveness of ^Polyclens - An All ^Purpose Cleaner For Hydrophilic Soft Contact Lens" in January 1983. Polyclens is a surfactant cleaner containing polymeric beads preserved with thimerosal and disodium edetate. It was used in conjunction with chemical disinfection. Subjects did not use an enzyme cleaner during the six month study, and none required it.

Stein and Harrison concluded that patient comfort, visual acuity, and deposit removal were all excellent, and the need for weekly enzyme cleaners was eliminated. These findings were confirmed subjectively by the study participants, and objectively by slit lamp examination.

Contact Lens Forum published "Evaluating Sof/Pro-Clean" in July 1983. Sof/Pro-Clean is a surfactant cleaner consisting of three different non-ionic detergents. Lloyd found Sof/Pro-Clean sudsed and rinsed well, and eliminated the need for weekly enzymatic cleaning. The product was well tolerated by most of the subjects, but there was some injection in a few subjects during the first six weeks of the study, which fell off rapidly during the second six weeks. This was the only adverse effect. All subjects reported improved comfort, clearer vision, and cleaner lenses while using Sof/Pro-Clean.

CLAO published "Removal of Soft Contact Lens Deposits With Surfactant - Polymeric Bead Cleaner" in July 1984. The study compared the efficacy of a polymeric bead surfactant cleaner to a different surfactant cleaner used in conjunction with a papain enzyme cleaner via scanning electron microscopy.

Deposits were divided into four sub types: 1. small granular 2. large granular 3. cell-like and 4. trabecular deposits. Most lenses exhibited all four types of deposits. There was no difference in amount or type of deposit which was attributed to the type of cleaner. The difference was that some subjects were helped more by one regimen and some were helped more by the other.

This study was purely objective in nature. All results were based on electron microscopy, and patient comfort was not considered.

Fowler and Allansmith's conclusion is "as there is no universal contact lens wearer, there is no universal contact lens cleaner."

International Contact Lens Clinic published "Breaking The Protein Bonds: The Use of Particles in Daily Cleaners" in November 1984. The article was primarily a debate between opposed factions regarding the risks/benefits of surfactant cleaners with polymeric beads.

CON: Abrasive cleaners may - 1. wear away the surface of silicone lenses, or a surface treated lens 2. scratch the lens surface and therefore increase deposits 3. cause eye irritation if not properly rinsed 4. be ineffectual if not

shaken well.

^Opponents also went onto say that a surfactant cleaner with an effective formulation doesn't need abrasive particles.

PRO: Manufacturers of surfactant cleaners with abrasive particles maintain that complaints against their products are not able to be proven scientifically, and that these cleaners offer an acceptable alternative to weekly enzyme cleaning. They further contend, that the polymeric beads are softer than plastic lenses, and that they have no sharp edges to harm lens surfaces. Claims of possible eye irritation due to improper rinsing were dispelled in two ways: 1. The milky white color of ^Opti-Clean makes it impossible to miss when traces exist on a lens. 2. A patient in a study at Alcon inserted a lens covered with ^Opti-Clean by mistake, and suffered no ill effects. Also, exaggerated studies with rabbits proved its safety.

^Opti-Clean uses the combined action of a surfactant to loosen deposits via reduced surface tension, followed by shearing of protein complexes by the polymeric beads.

The February 1988 issue of ACTA Ophthalmologica contained the article "Hydrogel Contact Lens Cleaning With or Without Multi-Enzymes." The article reported on a study comparing two types of soft contact lens cleaning methods. One method used Pliagel surfactant cleaner, and a hydrogen peroxide disinfection system. The second method was identical, but also added a multi-enzyme system - Polyzym. Polyzym contains

protease, lipase, and amylase, making it capable of removing protein, lipid, and mucin deposits. All subjects were daily soft lens wearers.

Nilsson and Lindh found that after six months the lenses treated with enzymes were more comfortable, had less deposits, and had a significantly longer tear break up time. They concluded that enzymatic removal of lens deposits was helpful in successful soft lens wear.

The March 1988 issue of Contact Lens Forum contains the article "Cleaning Soft Contact Lenses Without Enzymes." This article profiles a new type of weekly protein remover that does not use enzymes; but instead uses three types of surfactants - nonionic, nonionic with some anionic character, and amphoteric.

The premise of this new approach is that enzymes act slowly and can invade the lens matrix, whereas surfactants act quickly, and work on the lens surface. The theory is that by not invading the lens matrix, and rinsing easily, the non-enzymatic weekly cleaner will be less irritating to the eye. Edwards also states that the surfactants in Softmate Protein Remover surround, loosen, and emulsify deposits into easy to remove softened masses. These are then removed by mechanical (rubbing) action, or a device such as Barnes-Hind Hydra-Mat II.

The article offers no conclusive proof as to this products efficacy, other than a before and after photo of a soft contact lens.

International Eyecare published "Miraflow: A New Soft Lens Cleaner" in 1986. This article is an overview of Miraflow and its unique properties. Miraflow contains two detergents - Poloxamer 407 and Miranol. Poloxamer is nonionic, while Miranol is amphoteric. Isopropyl alcohol is also present, which acts as a solvent accounting for the products ability to remove lipids. It also acts as a preservative. While this article states that Miraflow is a safe and effective cleaner, it presented no evidence to confirm this.

DISCUSSION: The advent of hydrogel lenses has been both a boon and a scourge to the contact lens industry. Soft contact lenses have increased the total number of contact lens wearers, and therefore have generated increased dollars due to first time lens sales, more frequent replacement than hard lenses, and increased solution sales. They have also generated new problems for the wearer, and practitioner, such as GPC, red eyes, discomfort, decreased visual acuity, and increased bacterial harboring. Many of these adverse affects are attributable to lens deposits, especially protein deposits.

The aim of practitioners and contact lens solution companies alike is to effectively eliminate deposits as conveniently as possible, in an attempt to increase patient compliance. Compliance is both the nemesis and watchword for practitioners and patient - anything to increase

compliance is key.

Enzymes have been widely accepted as an effective protein remover, but because of inconvenience, some patients decline to use enzymes, or use them infrequently. Add to this the problem created when a soft lens wearer is a heavy protein secreter, and the stage is set for contact lens related problems. Additionally, some patients experience sensitivity to either the enzymes or to products which the enzyme binds to the lens. This was more true with papain, and chlorhexidine than with the newer enzymes such as pancreatin, or subtilisin, and newer preservatives such as Dymed and ^Polyquad.

Since compliance is the key, cleaning ease must be a priority. This is the reason solution companies have attempted to produce cleaners which eliminate the need for enzymes. The most successful cleaners appear to be those with polymeric beads that actually shear protein molecules from the lenses. Evidence largely supports the efficacy of these abrasive style surfactants in protein removal. Two of the three studies reviewed that directly addressed this type of cleaner were strongly in favor of its use sans enzyme. Their conclusion was based on patient comfort as well as slit lamp examination. The third study took the position that some patients need an enzyme in conjunction with some type of surfactant cleaner, while some patient's needs could be met with an abrasive style cleaner without enzymatic cleaners. In other words, it works for some and not for

others.

Another approach that has shown promise is the use of a combination of different nonionic detergents within the same cleaner, such as Sof Pro-Clean. This study utilized patient comfort and slit lamp examination to determine the cleaner's efficacy. The makers of this product feel it is superior to an abrasive type cleaner, as the abrasive particles may damage the lens matrix. This claim has been refuted by the polymeric bead type cleaner's company as follows: There are no sharp edges on the beads, and the beads are softer than the contact lens material. Sof/Pro Clean appears to be a successful alternative to enzymatic cleaning, although there was some initial incidence of injection noted by patients.

Soft Mate protein remover is another non-enzymatic method for protein removal, containing three types of surfactant with different qualities: Nonionic, nonionic with some anionic qualities, and amphoteric. This cleaner is supposed to work more quickly than enzymes without invading the lens matrix as enzymes sometimes do. It relies on it's variable surfactant nature to emulsify and loosen deposits, thus readying them for removal either by rubbing or by a Hydra-Mat system. Although the article is convincing, it offers no substantiation, other than a single before and after photo of a soft contact lens.

Another promising surfactant cleaner which may eliminate enzymes is Miraflow, which contains a nonionic, and amphoteric detergent. It also contains isopropyl alcohol,

which acts as both a preservative, and an effective lipid remover. No conclusive proof is offered for or against this product, but it has met with excellent patient reponse, and offers the advantage of containing a solvent, which enhances its ability to remove lipids. This allows a cleaner, whether surfactant or enzyme, ready access to debris and protein which may have been trapped beneath a lipid layer.

CONCLUSION: It is difficult to draw hard and fast rules for soft contact lens cleaning - especially in the area of protein removal. There are many variables to consider: 1. individual patient differences, such as sensitivity to solutions, amount of protein secreted, work and home environment, and many other factors. 2. type of soft contact lens 3. type of surfactant and 4. disinfection method.

The best approach currently appears to be a regimen utilizing a polymeric bead type cleaner initially, with regular follow up visits to determine its efficacy by slit lamp examination and assessment of patient comfort. This cleaner should be successful for many patients without enzymes, but will not be for all. In the event it fails, an enzyme cleaner may be added.

Miraflow may be used in place of or as an adjunct to a polymeric bead type cleaner. Not only is its ability to remove lipids desirable, but it ~~is~~ effectively removes hair spray from a soft contact lens surface. It appears to be an

effective cleaner, but more research needs to be done so as to determine its efficacy if it is used without enzymatic cleaning.

Soft-Mate Protein Remover suggests yet another alternative, if it can be proven to be effective by slit lamp examination and patient comfort. Its advantages would be in its speed of action, and in decreased patient handling. However, to keep things in perspective, one must remember that this reduction in patient handling occurs only once a week, and can be somewhat discounted. Soft-Mate Protein Remover does offer the advantage of being premixed, and the Hydra Mat II may appeal to a gadget loving public.

Until Soft-Mate Protein Remover and Miraflow have been researched further, it appears that a polymeric bead type cleaner is the most suitable candidate to eliminate enzymatic cleaning. It must be remembered that this will not work for everyone. Fowler and Allansmith may have put it best when they said "As there is no universal contact lens wearer, there is no universal contact lens cleaner.

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