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Modes of multipurpose disinfection: What are the costs?

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Abstract

Modes of multipurpose disinfection: What are the costs?

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MODES OF MULTIPURPOSE DISINFECTION

WHAT ARE THE COSTS?

By

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CHRIS JOHNSON

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A thesis submitted to the faculty of the College of Optometry
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for the degree of
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May 2002

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BIOGRAPHY PAGE

Bruce Bean is a candidate for an O.D. degree at Pacific University College of Optometry in May 2004. He graduated from the University of Utah with a Bachelor of Science degree in Medical Laboratory Science specializing in Cytotechnology in 1996. After graduation he plans to practice Optometry in Utah with an emphasis in primary care.

Chris Johnson is a candidate for an O.D. degree at Pacific University College of Optometry in May 2003. He graduated from Brigham Young University with a Bachelor of Science degree in Zoology in 1998. He spent one semester at BYU Idaho and another at Southern Illinois University. After graduation he plans to practice Optometry in Colorado with an emphasis in primary care and contact lenses.

Nathan Kohler is a candidate for an O.D. degree at Pacific University College of Optometry in May 2003. He graduated from Idaho State University with a Bachelor of Science degree in Biology in 1998. After graduation he plans to practice Optometry in Idaho with an emphasis in primary care.

Modes of Multipurpose Disinfection-What are the costs?

Introduction

Historically, proper soft contact lens care and disinfection has required three separate steps by the patient; cleaning, rinsing, and disinfection. Recently, a growing number of lens care products have received FDA approval for use as a "No-Rub" disinfection regimen.

To properly instruct our patients on the use of these products, we must have a clear understanding of the new nomenclature that surrounds the no-rub care systems. Theoretically, there are three possible forms of multipurpose solution disinfection: 1, the rub and rinse technique, 2, the no-rub technique, and 3, the immersion technique.

Rub & Rinse Disinfection

The rub and rinse technique refers to the traditional form of disinfection in which the lens is removed from the eye and a digital, in-the-palm rub, is performed with a multipurpose solution. A rinse cycle and storage in the multipurpose solution follow this step.

No-Rub Disinfection

The term no-rub has always been somewhat misleading in that many

Practitioners and patients have misinterpreted no-rub to mean "out of the eye and directly
into the solution". Use of the product in this manner is a significant deviation from the
way the product was approved and labeled by the FDA.

In reality, the term no-rub actually means that the traditional in-the-palm-cleaning regimen has been replaced by a rinsing cycle. Therefore, with no-rub, the lens is removed from the eye and the disinfection process begins with a thorough rinsing cycle, the length of which varies from one manufacturer to the next. For example, with the OptiFree Express "No Rub" indication, the traditional rub and rinse step has been replaced by a 20-second rinse cycle per lens, per day.

Immersion Disinfection

Today, immersion is only a theoretical mode of disinfection in which the product would be capable of lens disinfection by simple immersion into the solution. In other words the contact lens would be removed from the eye and placed directly into the disinfection solution without any rubbing or rinsing maneuvers by the patient. Currently, <u>no</u> contact lens care regimen is approved for use as an immersion disinfection regimen. This mode of disinfection is often inappropriately referred to as stand alone disinfection. However, "stand alone" is a term used by the FDA to describe a specific test. This test is used as part of the process required in order to obtain a no-rub indication.

An important consideration in all forms of contact lens disinfection is the ultimate cost to the patient. Therefore, we performed a series of laboratory tests in an attempt to estimate the costs for the three modes of multipurpose disinfection; rub and rinse disinfection, no-rub disinfection, and immersion disinfection.

Methods

Tests on the rub and rinse mode of disinfection were performed with the Alcon OptiFree Express solution. The no-rub and immersion forms of disinfection were performed with the Alcon OptiFree Express "No-Rub" solution. Two third-year optometry students performed the tests in a laboratory at Pacific University College of Optometry, Forest Grove, Oregon. Each student performed one half of the trials.

Rub & Rinse Disinfection

In order to estimate the volume of solution required to complete a daily cycle of rub and rinse disinfection, we followed the manufacturers suggested disinfection regimen (as described in the product package insert). This was accomplished by weighing a tarred bottle of solution after the rubbing and rinsing procedures. This was repeated 20 times and then an average value recorded, To verify that 1g=1ml, 50 ml of solution was weighed and a value of 50.4g was obtained, confirming this ratio.

One side of the lens was rinsed thoroughly with the multi-purpose disinfecting solution. This volume was multiplied by two in order to accurately represent the rinsing of both sides thoroughly as described in the package insert.

The time to thoroughly rinse the lens was approximated by calculating the time/volume ratio of five-second rinse cycles (as outlined in the no rub procedure). The volume of solution used when rinsing thoroughly was then multiplied by this ratio. An example is outlined below.

Average volume of a five-second rinse = 5.84ml

- 5.84ml divided by 5 seconds = 1.17ml/sec
- This was the average flow rate of the four separate bottle tips used.
- The average volume of solution required to rinse both sides of the contact lens thoroughly for the rub and rinse technique was 4.42ml
- Dividing 4.42ml by 1.17ml/sec = 3.78 seconds of rinsing

Overall, this means that the time required to thoroughly rinse both sides of a contact lens was 3.78 seconds. Additionally, the volume of solution used to cover the contact lenses in the storage case was measured.

No Rub Disinfection

With the **OptiFree** Express "No-Rub" indication, the patient is required to perform the following maneuvers on a daily basis;

- "thoroughly rinse <u>each side</u> of the contact lens for 5 seconds with OptiFree Express".
- "fill your Alcon Lens Case with enough fresh OptiFree Express to cover the lenses".
- "store the lenses for at least 6 hours".
- "before wear, rinse <u>each side</u> of the lens for 5 seconds to remove any debris from the lens."

We performed 56 five-second trials to determine the amount of solution used for rinsing two contact lenses for a period of one week. Each five-second trial was performed using a stopwatch with a five-second timer. Four different bottles of OptiFree Express No-Rub solution were used to eliminate variability in flow rate. Moderate pressure was applied to the bottle to ensure appropriate rinsing of the contact lens. The

amount of pressure applied was enough to cause a stream vs. a simple drip. The stream was delivered directly into a 10ml graduated cylinder with 0.20 increments. No contact lenses were used to prevent inaccurate solution collection due to splashing.

The lens storage case was filled until the contact lens was just covered by solution. Ten trials were performed to obtain an approximate value. Additionally, the final 16 of the 56 five-second trials were also weighed before and after each rinse to obtain the weight of the volume of each five second rinse. This confirmed the graduated cylinder volume measurements.

Immersion Disinfection

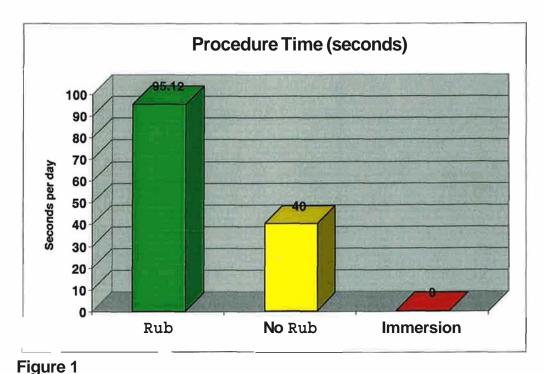
With the *theoretical* immersion technique only one step would be required for disinfection. The contact lenses would be removed from the eyes and placed directly into the disinfection solution. The volume of solution used with this technique was estimated by performing ten trials in which the contact lens was just covered by solution. These volumes were then measured in the 10ml graduated cylinder.

Results

Time Required for Lens Care

According to the package insert, the OptiFree Express rub and rinse regimen requires that each side of the contact lens be rubbed for approximately 20 seconds. This is followed by a thorough rinse, which we determined to take 3.78 seconds per contact lens. The insert also requires another rinse of the lenses before wearing. Therefore, the average time required in order to perform the rub and rinse regimen on two contact lenses

is 95.12 seconds per day. The OptiFree No-Rub system requires a total of 40 seconds per day for the rinsing of two contact lenses. The time saved using the No-Rub regimen is approximately 55.12 seconds per day. The immersion system would require only the time it takes to put the contact lenses into the case, a procedure that is required of all three techniques. See Figure 1 below.



Volume of Solution Required for Lens Care

Following the package insert directions, the amount of solution required for disinfection with the OptiFree Express rub and rinse regimen is 17.68ml for rinsing and 2.79ml per day for lens storage. This equals 20.47ml of solution per day, or 7,471.55ml of solution per year. In more practical terms, this works out to be 21.05 12 OZ bottles of solution per year.

Proper use of the OptiFree Express No-Rub regimen results in a total of eight five-second rinsing cycles per day for a pair of contact lenses. Each rinse cycle requires

5.84ml of solution or 46.72ml per day. Adding 2.79ml of solution per day to fill the lens storage case, the No-Rub regimen requires 49.51ml of solution per day or 18,071.15ml per year. That works out to be 50.90 bottles of solution per year. Therefore the difference between the rub and rinse and No-Rub regimens could be as much as 36.31 bottles of solution per year.

The immersion regimen would only require that the contact lens storage case be filled with 2.79 ml of solution per day. This equals 1,018.35ml a year or 2.87 bottles of solution per year. See Figure 2 below.

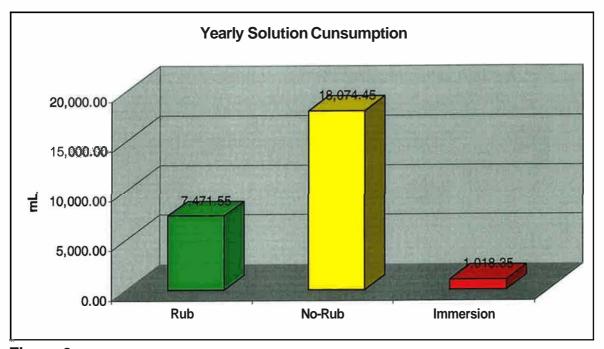


Figure 2

Cost of Solution

The retail cost of one 12 FL OZ bottle of OptiFree Express or **OptiFree** Express No-Rub Solution in the Portland Oregon area is approximately \$7.00. Therefore, the theoretical cost of the various modes of multipurpose disinfection would be as follows:

- Rub and Rinse Disinfection, (\$7.00 X 21.05 bottles) \$147.35 per year or 40 cents per day.
- No-Rub Disinfection, (\$7.00 X 50.91 bottles) \$356.37 per year or 98 cents per day.
- Immersion Disinfection, (\$7.00 X 2.87 bottles) \$20.09 per year or
 6 cents per day.

Discussion

It is a FDA requirement that solution manufacturers submit their labeling for review and approval prior to release of the product. This ensures that the proper instructions and warning are provided to the practitioner and patient. Therefore, it is wise for all **eyecare** providers to familiarize themselves with the appropriate techniques for lens cleaning and disinfection as agreed upon by the solution manufacturer and the FDA. This information is clearly outlined in the product's package insert, which should serve as our guide in providing the patient with the proper techniques for lens care and disinfection.

It is important to remember that correct instruction to the patient is ultimately the responsibility of the **eyecare** professional dispensing the solution. If an individual patient elects to deviate from our instructions, it is often beyond the scope of our control. However, whether a rub and rinse or no-rub regimen is used, we cannot stress enough the importance of the initial patient instruction. Additionally, it is always beneficial to reinforce the proper cleaning and disinfection techniques at each follow-up visit. This reinforcement is best accomplished through repetition and clarity of our terminology.

There is always a concern that patients may misinterpret the No-Rub labeling or advertisements like "rubbing is history" to mean that their lenses can be removed and placed directly into the disinfecting solution. As discussed earlier, this is not at all how the product was tested by the company or approved by the FDA. Additionally, some company representatives have done a questionable job of instructing eyecare professionals on the proper use of, their no-rub products. Without proper patient education the practitioner could be placed into a precarious medical/legal situation should the patient develop a contact lens related complication while improperly using their care products.

We should also remember that most lens care products approved with a no-rub indication are also approved for use as a traditional rub and rinse regimen. The effectiveness of the rub and rinse technique is clearly illustrated in Figure 3 below.

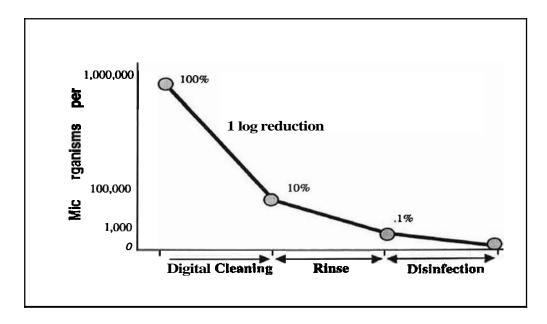


Figure 3 Used by permission of Ciba Vision

When a contact lens is covered with 1,000,000 units of microorganisms approximately 90% of the organisms are removed with the in-the-palm-cleaning

maneuver. An additional 9% are removed with a simple rinsing of the lens. This leaves only 1% of the microorganisms present on the lens to be eradicated by the disinfection solution.'

Ultimately, the issue of non-compliance is something each and every **eyecare** professional must address. Recent Neilsen Household Panel data indicates that 50% of patients never rub their lenses. Additionally, the average contact lens patient uses only three 12 OZ bottles of multipurpose solution a year, These data clearly indicate that neither the rub nor the no-rub techniques are being adequately practiced in the "real world" and that immersion disinfection is an unfortunate reality.

Therefore, a more important question to consider may be; which products will perform the best in the face of non-compliance? And to that end, lens care product engineers have developed products that clearly work in the "real world". This is born out everyday in the fact that we see very few cases of microbial keratitis in our non-compliant contact lens patients.

The decision to use rub or no-rub regimens is clearly out of the hands of each eye care professional. However, whichever regimen is chosen, it is ultimately the responsibility of the practitioner to instruct the patient on the proper use of the product.

The few minutes this takes to accomplish should always be considered "time well spent".

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