# In-Office Compounding of Cyclopentolate Ointment

# A Contamination Trial

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## Introduction

The purpose of this experiment was to determine if an in-office preparation of cyclopentolate ointment will remain contaminate free over a set period of time. It is already widely accepted that drops sting and often disrupt the exam and patient cooperation, especially in kids. Alternative delivery mechanisms such as spray bottles have previously been suggested and investigated, (Kim, Bartlett). Ointments have been reported to cause less irritation and require less of the drug for the same ocular effect (Cable). Ointments have the same systemic absorption as drops; therefore the side effects of the drug used will be the same (Fiscella, Scruggs). In-office preparations of ointment could be prepared at a reduced cost compared to commercially available or custom ointment preparations from a pharmacy.

This experiment investigates the feasibility of emulsifying a mixture of cyclopentolate solution with bland ophthalmic ointment creating a cyclopentolate ointment. The results of our experiment showed that the process of in-office preparation of cyclopentolate ointment does not appear to introduce microorganisms into the ointment during the eight week study period. Indicating a potential shelf life of at least eight weeks for this ointment.

In-office preparation of a cyclopentolate ointment from cyclopentolate solution and bland ointment is postulated to be effective, convenient, inexpensive and, as we have shown, will not pose additional risk of bacterial infection compared to commercially available cyclopentolate solution or bland ointment. This ointment mixture may be a good alternative for those practitioners looking for a better way to instill cyclopentolate.

## Method

In general, the procedure for this experiment involved combining a solution form of cyclopentolate into an ointment, then plating it for growth. To prepare the ointment, we placed 1mL of 1.0% cyclopentolate solution with 1mL of sterile ophthalmic ointment (83% White Petrolatum, 15% Mineral Oil, and 2% Lanolin) into one 5cc syringe. The syringe was then attached to another syringe with a luer lock adaptor. To mix, we simply pushed the solution and ointment back and forth between the syringes until an even consistency was achieved (see figure 1). Two ointment mixtures were prepared using this method. The ointment was stored in capped syringes at room temperature on a shelf that is exposed to normal room air circulation.

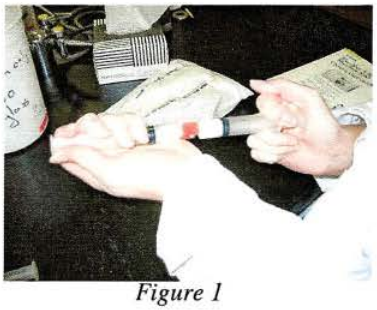

*Figure 1*

Two methods of transferring the ointment onto the plates were used: a simple technique and a sterile technique. The simple technique was to transfer the ointment from the first preparation, labeled "finger," to the agar plate using a finger washed with antibacterial soap (see figure 2). The sterile technique was to transfer the ointment from the other preparation, labeled "cotton," to the plate using a sterile cotton swab. The simple technique was used in order to simulate a more

*Figure 2*

realistic method of dispensing ointment. The sterile method was used as a control to determine if growth that might occur was from the ointment itself or from the normal flora of the skin.

Under the recommendation of a professor of microbiology at Ferris State University, we used two types of agar plates (Deregnier). Sheep's blood agar plates were used because they grow the most commonly found organisms, and Chocolate agar plates were used because they grow the more fastidious organisms, including pseudomonas.

Both the "cotton" ointment preparation, and "finger" ointment preparation were plated onto a Sheep's blood plate and a Chocolate plate. A total of four plates were used every week. For the "finger" ointment preparation, we dispensed a ¼ inch ribbon onto the tip of a finger, cleansed with an antibacterial soap, then dabbed the ointment onto the agar (see figure 3). The ointment was spread across the plate using a sterile loop and standard plating technique (see figure 4).

*Figure 3*

*Figure 4*

The ointment from the "cotton" preparation was dispensed from the syringe onto the sterile cotton swab, and then dabbed onto the plate. The ointment was spread onto the plate using the same technique as described above.

After the ointment was plated, it was placed into a candle jar to maintain the correct balance between oxygen and carbon dioxide levels (see figure 5). The candle jar containing the plates was put into an incubator maintaining a temperature of 35 degrees Celsius (see figure 6).

*Figure 5*

*Figure 6*

The plates were checked for growth at 24 and 48 hours, and again at one week. The ointments were plated once per week over an eight-week period.

This experiment called for three controls in order to have a reliable outcome. Each batch of agar plates had to be tested to make sure they were uncontaminated, and capable of growing organisms. First, one blank plate from each batch was incubated to insure sterility. Second, another plate from each batch was smeared with known organisms to determine its efficacy. Third, the finger used in the experiment was plated to determine the normal flora.

Standard methods of organism identification, including gram stain (see figure 7), were utilized to identify the cultured organisms.

*Figure 7*

## Results

Through our experimentation of the control group, we determined that each batch of plates was capable of growing organisms and was uncontaminated. The growth from the finger was identified as normal flora consisting of three different colonies of gram-positive coagulase negative staphylococci, and one gram-negative bacillus.

The weekly results of the plated ointment are as follows:

**"Finger" Sheep's Blood Agar** **NG= No Growth, G= Growth**

| | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 8 | Week 8 sterile |
|---|---|---|---|---|---|---|---|---|---|
| 24 hours | G | -- | G | -- | G | G | NG | G | NG |
| 48 hours | G | -- | G | -- | G | G | NG | G | NG |
| 1 week | -- | -- | -- | -- | G | G | NG | -- | NG |

**"Finger" Chocolate Agar**

| | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 8 | Week 8 Sterile |
|---|---|---|---|---|---|---|---|---|---|
| 24 hours | NG | -- | G | -- | G | G | NG | G | NG |
| 48 hours | G | -- | G | -- | G | G | NG | G | NG |
| 1 week | -- | -- | -- | -- | G | G | NG | -- | NG |

**"Cotton" Sheep's Blood Agar**

| | Week 1 | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 7 sterile | Week 8 |
|---|---|---|---|---|---|---|---|---|---|
| 24 hours | NG | -- | NG | -- | NG | NG | G | NG | NG |
| 48 hours | NG | -- | NG | -- | NG | G | G | NG | NG |
| 1 week | -- | -- | -- | -- | NG | G | G | NG | -- |

**"Cotton" Chocolate Agar**

| | Week | Week 2 | Week 3 | Week 4 | Week 5 | Week 6 | Week 7 | Week 7 | Week 8 |
|---|---|---|---|---|---|---|---|---|---|

| | 1 | | | | | | | sterile | |
|---|---|---|---|---|---|---|---|---|---|
| 24 hours | NG | -- | NG | -- | NG | NG | NG | NG | NG |
| 48 hours | NG | -- | NG | -- | NG | G | G | NG | NG |
| 1 week | -- | -- | -- | -- | NG | G | G | NG | -- |

*No plates were smeared on week 2 & 4.*

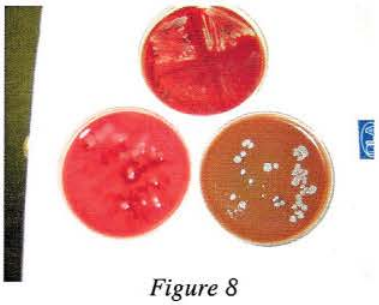

*Figure 8*

Growth was found on the "finger" ointment plates every week except week 7 (see figure 8). The growth on the "finger" plates was determined to be consistent with the normal flora from the finger. The growth on the "cotton" plates during weeks six and seven was determined to be due to the nonsterility of the cotton swabs being used during those weeks. The swabs used during those two weeks were from a "sterile" multipack of swabs, rather than the individually wrapped swabs previously used. This was determined by repeating the Week 7 inoculation by directly dispensing the ointment from the "cotton" syringe onto a third set of agar plates. The ointment dispensed directly from that preparation had no growth. Therefore the organisms were not from the ointment, but from the swabs. On week eight, the individually wrapped sterile cotton swabs were used, and no growth was found.

In Week 8 the syringe that had been used for the "finger" technique and exposed to potential contamination from direct contact with a washed finger was also plated using the sterile technique and showed no growth at 24 and 48 hours, nor at 1 week. Also, ointment that had been prepared one year previously for another experiment was plated using the sterile method and showed no growth at 24 and 48 hours, nor at 1 week.

**Conclusion**

In conclusion, neither the "finger" nor the "cotton" prepared ointments were contaminated during the eight-week period. Even the ointment that had been stored for a year remained contaminant free. However, when using the finger technique to apply ointment to the plates the normal flora of the hand, even though washed with antibacterial soap, frequently showed positive cultures.

**Discussion**

The process of in-office preparation of cyclopentolate ointment does not appear to introduce microorganisms into the ointment. Our results indicate a shelf life of at least two months for this ointment. This ointment mixture may be a good alternative to eye drops for those practitioners looking for a better way to instill cyclopentolate into patient's eyes.

Using the clinically accepted "Simple" technique of applying ointment to the cul-de-sac with a cleansed fingertip may introduce microorganisms to the eye. However, this appears to be no worse than the simple touching of the eye with a washed finger for the insertion or removal of contact lenses or the removal of common foreign bodies such as eye lashes. The decreased risk of contamination and inoculation of the eye when using sterile techniques, such as using a cotton swab or instilling the ointment directly from the

tube, must be weighed against the potential for ocular trauma from the swab or container tip.

In-office preparation of a cyclopentolate ointment from cyclopentolate solution and bland ointment is postulated to be effective, convenient, inexpensive and, as we have shown, shows no greater risk for bacterial contamination. Future studies will be needed to establish best protocols and effectiveness.

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