Clinical Study Report

Evaluation of a Novel Biomechanical Intra-Oral Lozenge, Clearpop, for the Treatment of Acute Otitis Media

Study Sponsor: Try This First, Inc.
Investigators: Lu Pham, MD of Sutter Gould Medical Foundation, and John Calcagno, MD of Legacy Mount Hood Medical Center

The study was conducted in strict accordance with Good Clinical Practices (GCP). All patients and parents provided Informed Consent prior to enrollment and the study protocol was overseen and approved by the Western Institutional Review Board (WIRB), Puyallup, WA.

Study Objective
To determine the potential for the efficacious use of Clearpop®, a biomechanical, lollipop-like consumable intra-oral device, as a viable treatment option for acute otitis media (AOM) in children 2-12 years old.

Summary
A novel biomechanical approach has been developed to augment the body's natural ability to clear fluid blockage and minimize pain associated with AOM without the use of antibiotics or medication. A prospective, IRB controlled study was initiated to determine if use of this device would eliminate associated pain, and/or sustainably resolve fluid clogged within the Eustachian tube.

26 patients diagnosed with AOM completed detailed questionnaires pre- and post-consumption of the device in-clinic. Of these, 88.5% (23 patients) reported immediate pain relief compared to their pre-treatment pain level. At 48 hour follow-up, 78.3% (18 of 23) reported sustained relief and did not need to fill their prescription for antibiotics.

Conclusion
The use of a biomechanically designed, intra-oral lozenge may present an effective treatment option for the resolution of pain and fluid built up caused by AOM.

Background

The need for over-the-counter remedies for acute otitis media (AOM) is urgent. As recently as 2000, over 80% of doctor visits for otitis media resulted in a prescription for antibiotics. Since 2004, both medical guidelines and public sentiment have moved away from the use of oral antibiotics and toward "watchful waiting." This course of action has resulted in a drop in the prescription of antibiotics, but leaves the medical community almost empty-handed when offering safer treatment options. Watchful waiting means that parents must wait while their child experiences severe discomfort and pain due to a blocked Eustachian tube. Under watchful waiting guidelines, patients are offered only analgesics (Tylenol or Ibuprofen) and possible over the counter earache pills and drops which have no verified efficacy. Both doctors and parents, therefore, are extremely eager to find alternative treatments.

The Clearpop device represents a reasonable treatment alternative that a parent can confidently give to their child during the watchful waiting period, when the child is suffering from the pain and discomfort of AOM. Since watchful waiting is frequently employed, the use of the Clearpop will not compromise the patient by delaying use of antibiotics, and it can be given in conjunction with OTC pain relievers, if needed.

A prospective clinical trial was conducted to confirm that the Clearpop device can provide a safe, effective and appealing method for opening up the inflamed Eustachian tube in pediatric patients with AOM, by manually clearing pressure and thereby alleviating pain immediately.

Clearpop® Device Description

Clearpop, is similar to a lollipop in structure and ingredients with added proprietary features designed to appeal to children and their parents. It is distinguished from the common lollipop through its unique shape and design that conforms to the oral cavity of a child (see Figure 1) and ingredients which promote salivation. The Clearpop is made from a formula of natural sugars and flavorings. It will be registered as a Class I medical device with the FDA, which is a simple, self-registration process.

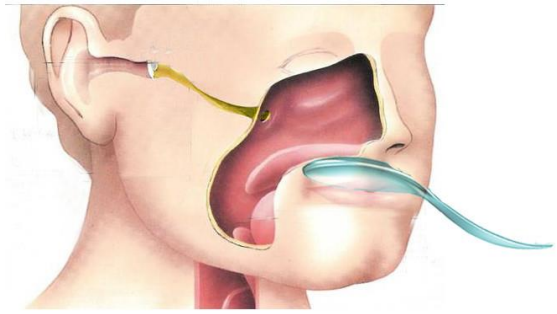

Figure 1

The Clearpop works through four mechanical actions to clear the Eustachian tube. First, the saliva produced from the Clearpop lubricates the Eustachian tube. Second, the child's sucking action of the Clearpop creates suction pressure on the Eustachian tube, pulling accumulated fluids and phlegm into the throat. Third, the movement of the jaw in the action of sucking on the Clearpop acts to open the Eustachian tube much the way that yawning clears the ears with changes in pressure while flying. Finally, by having the child's infected ear upright, gravity will assist in clearing accumulated fluids and phlegm from the Eustachian tube.

Study Overview

Two clinical sites were selected to enroll approximately 25 subjects. The sites chosen (Lu Pham, MD, Modesto, California and John Calcagno, MD, Gresham, OR) are busy, pediatric clinical practices that routinely see and treat a high volume of children presenting with AOM. The study was open to male and female pediatric patients, ages 3-12, who presented to the study investigator's office with ear pain which was subsequently diagnosed as AOM. This group of patients was selected because of the high incidence of acute otitis media occurring in their age group. Patients were excluded if they presented with other medical conditions that might require antibiotics, such as strep throat, tonsillitis or were taking medications that might confound results. Patients with cleft palate or high arch were also excluded.

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Study Procedures

Patients were examined for AOM and treated on the same day. They were administered one or two Clearpop devices under close supervision of the investigator. The child was given the Clearpop sucker and instructed to suck on it until it dissolved, the average time was approximately 20 minutes. If a patient still felt discomfort after use of the device, in most cases, they were offered a second Clearpop. A detailed questionnaire was administered to the patient before and after treatment in order to document their medical history, and the specifics of their AOM and discomfort before using the Clearpop and to compare to their pain ratings after usage of the Clearpop.

The instructions for administering the Clearpop in the study were very simple and consisted of laying the child down with infected ear facing up, placing the flat side of the Clearpop on the tongue, instructing the child to suck hard on the Clearpop until it dissolved and instructing them to not bite down or chew on the Clearpop.

After usage of the Clearpop, the physician determined clearing of the Eustachian tube by visually examining the ear and asking the patient to report on their pain level compared to before using the sucker, using a pain measurement scale specifically designed for children. Their reported pain level was compared to their pre-treatment pain level. Patients were then able to leave the office and a follow-up phone call was made to each patient/parent to determine the pain level approximately 48 hours after administration of Clearpop. If the pain and symptoms persisted on the day of treatment or was noted in the follow up call, a prescription for antibiotics was given.

Study Results

A total of 28 patients were enrolled in the clinical trial at two sites. Of these 28 patients, 18 were enrolled by Dr. Pham (Modesto, CA) and 10 were enrolled by Dr. Calcagno (Gresham, OR).

Patient age ranged from 4-12 years, with the average age of the patient being 8 years. Two-thirds of the patients were female and one-third male. Prior to receiving the Clearpop device, parents indicated how long their child had been in pain, which ranged from two hours to four days of pain.

Of the 28 patients using the device, only two were non cooperative with the instructions given by their doctor. One patient stopped using the sucker after only a few minutes of use and the second patient did not follow instructions to suck slowly or not bite it, and the pop was gone in a very short period of time.

Of the 26 patients who successfully completed the process of using the device, 23 of these patients (88.5%) reported immediate relief compared to their pre-treatment pain measurement level (*see Figure 2*). All of these patients noted a significant improvement and the majority of them noted their pain severity rating equal to "0", which according to the pain measurement scale, is that they pointed to the smiley face, e.g. "no hurt". Three (3) patients did not report any change in pain relief after use of one pop. In all cases, only one pop was used. Use of a second pop may have resulted in some relief. None of the 3 reported an increase in pain after use of the pop, and they went on to receive antibiotics. One of these patients reported a double ear infection prior to use of the pop.

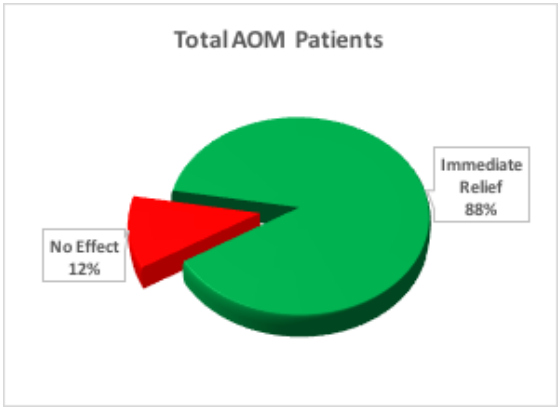

Figure 2

All subjects were contacted within 48 hours of their office visit to see how they were doing. Of these patients, 18 of the 23 (78.3%) reported sustained relief from the use of the Clearpop and did not need to fill their prescription for antibiotics (*see Figure 3*). Nearly all subjects achieved their result with the use of one Clearpop. Of the 26 subjects completing in the trial, 5 of the subjects used two pops, and all were deemed a success.

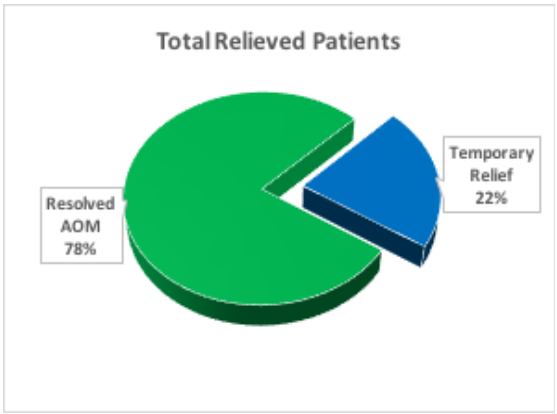

Figure 4

Of the 5 patients who did not report sustained relief 48 hours later, all 5 reported significant pain reduction at the time of using the Clearpop, so even though the Clearpop did not clear their ear completely, they were in much less pain after leaving the office, than when they arrived.

Patients were surveyed as to how they liked the taste of the Clearpop. 100% of the patients reported they liked it, with most patients exuberantly saying it "tastes great"!

Caregivers were asked at the 48 hour phone call if they believe the Clearpop was successful in alleviating ear pain in their child and whether they would use it again if available to them. The results of this survey mirrored the excellent results of the patient reports of pain improvement, with 88% of caregivers responding "yes".

In summary, results of the Clearpop prospective trial were excellent, with nearly 90% of patients reporting immediate relief from the pain of their diagnosed AOM and nearly 80% of the patients indicating that the relief was sustained and did not require a prescription for antibiotics. All patients enjoyed the lemony taste of the pop. This study confirms that Clearpop represents a very safe, effective and well-received treatment for AOM for both the parent and the child.