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ioRinse RTU: An Effective Pre-treatment Rinse

Gordon's Clinical Observations: Recent research has reported significant quantities of SARS-CoV-2 virus in the oral cavity and saliva. Over the past months you have seen many mouthrinse promotions claiming various levels of deactivation of this virus. Unfortunately, the claims are based solely on clean laboratory tests that ignore the challenges presented by oral cavity secretions which can neutralize many antiseptics. *The information below reports on the performance of a patented iodine antiseptic in controlled testing in the presence of fresh human whole saliva that validates virus inactivation under more realistic conditions.*

Figure 1. ioRinse RTU *(Ready-To-Use)* is a 100 ppm molecular iodine rinse available in two flavors: Mint-Apple *(left)* and Cinnamon Burst *(right)*.

TRAC RESEARCH

Mouth rinsing is a widely accepted practice for antiseptic, therapeutic, and cosmetic purposes. Now in the midst of COVID-19, mouth rinsing to inactivate the causative virus within the oral cavity is paramount in the minds of both dental clinicians and the general public. Many mouthrinse products have been suggested based on intuition, empirical evidence, or lab tests that make no attempt to replicate the complex oral environment challenges. In the oral cavity, many components in saliva interfere with a formulation's kill potential *(very high numbers of a wide variety of microbes, complex proteins, debris from soft tissues and food, etc.)*.

More realistic testing and transparency in marketing of antimicrobials of all types are critical because the product claims are often the only information clinicians have easy access to, and ultimately their choices are based on these claims. In healthcare environments, these choices directly affect the health, safety, and quality of life of many people *(clinicians and patients)* who are all trusting the dentist for protection from cross-contamination. The report below provides unbiased pertinent information on controlled testing at an independent laboratory *(BioScience Laboratories in Bozeman, MT; advised by TRAC Research)* that included the clinical challenge of fresh human whole saliva collected and pooled from 10 non-Covid-19 infected adult humans.

1. How does the performance of ioRinse RTU compare to other products suggested for Covid-19 pre-treatment rinsing?

Major Active Ingredient	60-Second Log_{10} Reduction ■ NO SALIVA PRESENT	60-Second Log_{10} Reduction ■ SALIVA PRESENT
0.01% (*100 ppm*) molecular iodine	**5.75✱**	**5.25✱**
3.8% "foaming" hydrogen peroxide	≥3.35❖	*Not Tested*❖
0.2% povidone iodine	3.0❊	*Not Tested*❊
0.12% chlorhexidine gluconate	1.0❊	*Not Tested*❊
1.5% hydrogen peroxide	<1.0❊	*Not Tested*❊

■ ***"Log_{10} reduction" is a mathematical term showing the relative number of live microbes eliminated. In this case, the larger the number, the better the antiseptic kill.***

✱ *BioScience Laboratories, Bozeman, MT*

❖ *Biochem Laboratory, Round Rock, TX*

❊ *Utah State University, Institute for Antiviral Research, Logan, UT*

Clinical Interpretation of Information in the above Chart:

- **Initially, povidone iodine and hydrogen peroxide were both suggested as pre-treatment oral rinses for SARS-CoV-2 management, and both are now in popular use by clinicians. However, neither have confirmed virus inactivation in the presence of fresh human oral fluids. As listed above, continuing research is showing other formulations to be preferable for SARS-CoV-2 oral reduction.**
- **In the iodine category, molecular iodine 0.01% *(100 ppm ioRinse RTU)* showed almost twice the virus reduction as 0.2% povidone iodine, with or without the fresh human whole saliva challenge.**
- **In the hydrogen peroxide category, 3.8% "foaming" hydrogen peroxide showed higher virus reduction than 1.5% hydrogen peroxide.**
- **Chlorhexidine gluconate formulations currently on the U.S. market have shown low *antiviral* activity, but have been useful against oral and skin bacteria.**

2. What is the formulation of ioRinse RTU, and how is it different from other iodine-based oral antiseptics?

IoRinse is a patented formulation that contains 100 ppm molecular iodine, water, potassium iodate, citric acid, zinc gluconate, flavoring, and sodium saccharin. The unique feature of this patented, pale amber colored, non-staining formulation is the **100 ppm molecular iodine *(free iodine)*,** which increases its biocidal activity and decreases its toxicity. *(For example, 10% Betadine, a well-known healthcare antiseptic, contains about 30,000 ppm total iodine, but only about 3 ppm of that is **molecular iodine, which is the only biocidal iodine component.** Most of the Betadine formulation contains iodine derivatives bound to a large molecule called polyvinylpyrrolidone (popular designation "PVP-I"), all of which causes the formulation to have lower biocidal activity, and the iodine staining and irritation familiar to clinicians. The same is true of all iodine formulations known as iodophors and povidone iodine.)*

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ioRinse RTU: An Effective Pre-treatment Rinse *(Continued from page 1)*

3. Is testing in the presence of fresh human whole saliva important?

YES. Secretions in the upper respiratory tract can: 1) neutralize antiseptics and 2) cover, coat, and protect the virus from exposure ***(see Figure 2)***. In the oral cavity, saliva can act these same ways. Product claims for antiseptic kill based solely on clean laboratory tests fail to provide clinicians with essential ***realistic*** information. IoRinse RTU 100 ppm molecular iodine formulation was not substantially affected by presence of fresh human whole saliva *(see chart above).*

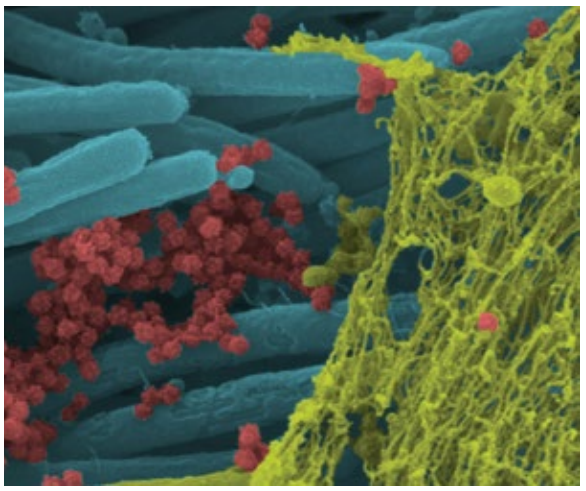

Figure 2: Color-rendered scanning electron microscope image of the SARS-CoV-2 virus *(red)* among the cilia in the upper respiratory tract *(blue)* in an infection showing the mucous coverage *(yellow)* that can interfere with the kill potential of antiseptic rinses. *(Camille Ehre, PhD, cehre@med.unc.edu)*

4. Should I buy the ioRinse RTU *(Ready-To-Use)* or ioRinse Concentrate for my office and patients to use *for rinsing*?

For *rinsing*, ioRinse RTU should be used. The ioRinse Concentrate is not flavored and is formulated for use in *irrigators* at the 50 ppm concentration. As packaged, ioRinse RTU is already at the correct dilution and dispensed in compatible packaging. Although diluting the 500 ppm ioRinse Concentrate to 100 ppm for rinsing reduces the per ounce cost, mistakes are often made with on-the-spot dilutions and, most important, the composition of bottles and caps chosen for storage after dilution are critical to avoid iodine vapor leakage with associated staining and loss of activity.

5. How should ioRinse RTU be used clinically?

***Two* 30-second *consecutive* rinses.**

A. Once the patient is seated in the operatory, hand the patient ***two*** 4 oz disposable cups *(one in each hand)*—one empty and one containing 2 oz of ioRinse RTU *(a 1 oz dispensing cup comes with each bottle of ioRinse RTU)*.
B. Ask the patient to swish half the liquid in cup #1 for 30 seconds *(clinician should time the swishing)*.
C. Expectorate into the empty cup #2.
D. Swish the remaining liquid 30 seconds and expectorate into either cup.
E. Clinician pour the expectorate down the operatory sink drain, ***and* water flush**.

6. How long does ioRinse RTU reduce the oral SARS-CoV-2 virus count?

An after-rinse "safe period" cannot be *clinically* determined or guaranteed. Many unpredictable variables, such as virus load, replication rate, thoroughness of rinsing, etc., contribute to clearance time. Rinsing does not ***sterilize*** the oral cavity *(kill **all** microbes present)*, it simply lowers organism numbers. One virologist compared oral rinsing to use of windshield wipers during a rainstorm—it helps, but not for long! Clinically, this means for restorative procedures, immediately after rinsing, apply a dam to **isolate the treatment site from saliva**, and paint the treatment site with the rinse to disinfect it before beginning excavation. For soft tissue procedures, use re-rinsing, plus careful close proximity of the high velocity suction tip *(HVE tip 1–2 mm from operating instrument)* throughout the procedure. *For added safety, have all patients re-rinse before leaving the operatory.* **Rinsing is not a stand-alone procedure, but is one step in the "multi-layered" infection control process that includes use of full-coverage PPE, surface disinfectant, air purification, screening of all who enter the office, etc.**

7. Are there contra-indications to use of ioRinse RTU?

YES. The manufacturer states not for use by persons with known sensitivity to iodine or any of the other ingredients listed on the label, children younger than six years of age, and anyone whose physician declines use due to underlying medical conditions.

8. Where can ioRinse RTU be purchased, and what is its retail list price?

ioTech International website *(www.iotechinternational.com)* or **phone** *(561-509-0205 Ext. 5)*

Cost to professionals: $135.60/Case *(twelve 1-liter bottles)*
(Also available through many dental suppliers.)

TRAC RESEARCH CONCLUSIONS: Although rinsing with an antiseptic does not ***assure*** safety, it is one of several logical steps to lower microbe concentrations in preparation for dental treatments. Currently, ioRinse RTU is one of the only commercially available antiseptic rinses that has performed well in controlled testing using the SARS-CoV-2 Wuhan strain virus in the presence of fresh human whole saliva pooled from 10 healthy adults. **All types of products used to control clinical cross-contamination need this same type of independent testing under rigorous *clinical* conditions to validate efficacy before use with patients.**

What is CR?

WHY CR?

CR was founded in 1976 by clinicians who believed practitioners could confirm efficacy and clinical usefulness of new products and avoid both the experimentation on patients and failures in the closet. With this purpose in mind, CR was organized as a unique volunteer purpose of testing all types of dental products and disseminating results to colleagues throughout the world.

WHO FUNDS CR?

Research funds come from subscriptions to the Gordon J. Christensen Clinicians Report®. Revenue from CR's "Dentistry Update®" courses support payroll for non-clinical staff. All Clinical Evaluators volunteer their time and expertise. CR is a non-profit, educational research institute. It is not owned in whole or in part by any individual, family, or group of investors. This system, free of outside funding, was designed to keep CR's research objective and candid.

HOW DOES CR FUNCTION?

Each year, CR tests in excess of 750 different product brands, performing about 20,000 field evaluations. CR tests all types of dental products, including materials, devices, and equipment, plus techniques. Worldwide, products are purchased from distributors, secured from companies, and sent to CR by clinicians, inventors, and patients. There is no charge to companies for product evaluations. Testing combines the efforts of 450 clinicians in 19 countries who volunteer their time and expertise, and 40 on-site scientists, engineers, and support staff. Products are subjected to at least two levels of CR's unique three-tiered evaluation process that consists of:

1. Clinical field trials where new products are incorporated into routine use in a variety of dental practices and compared by clinicians to products and methods they use routinely.
2. Controlled clinical tests where new products are used and compared under rigorously controlled conditions, and patients are paid for their time as study participants.
3. Laboratory tests where physical and chemical properties of new products are compared to standard products.

Clinical Success is the Final Test

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CRA Foundation® changed its name to CR Foundation® in 2008.

This team is testing resin curing lights to determine their ability to cure a variety of resin-based composites.

Every month several new projects are completed.

THE PROBLEM WITH NEW DENTAL PRODUCTS.

New dental products have always presented a challenge to clinicians because, with little more than promotional information to guide them, they must judge between those that are new and better, and those that are just new. Because of the industry's keen competition and rush to be first on the market, clinicians and their patients often become test data for new products.

Every clinician has, at one time or another, become a victim of this system. All own new products that did not meet expectations, but are stored in hope of some unknown future use, or thrown away at a considerable loss. To help clinicians make educated product purchases, CR tests new dental products and reports the results to the profession.