

Safe, Simple Cost-Effective Mechanism to Clean Dental Unit Waterlines

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INTRODUCTION

Levels of bacteria detected in untreated dental unit waterlines (DUWLs) are typically μ 1,000,000 colony forming units per milliliter (CFU/mL).¹⁻³ Given that the acceptable standard for drinking water is [500 CFU/mL, DUWL water is generally considered unfit for human consumption. In 1995, the American Dental Association (ADA) established a year 2000 DUWL water quality goal of "no more than 200 CFU/mL of aerobic mesophilic heterotrophic bacteria at any point in time in the unfiltered output of the dental unit."⁴⁻⁵

Daily treatment with Dentacide[®], an iodine-based DUWL chemical treatment, has been clinically shown to satisfy the ADA's goal of [200 CFU/mL by controlling DUWL biofilms.⁶⁻⁷ In addition, this product improves DUWL water quality without damaging dental unit water-circulating components.⁸ In this study, the iodine-based treatment was evaluated for biocompatibility and efficacy in a reduced frequency treatment protocol to determine the feasibility of a more cost-effective maintenance protocol.

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SAFE

BIOCOMPATIBILITY TESTING

METHODS: Testing was performed by an independent laboratory, Northview Biosciences. All tests were performed according to federal guidelines for evaluating the biocompatibility of medical devices. Testing included assays for acute oral toxicity in rats, primary eye and dermal irritation in rabbits and dermal sensitization in guinea pigs. Extracts of polyurethane and silicon tubing exposed to the iodine-based chemical treatment were evaluated for cytotoxicity against mammalian cells *in vitro*.

TEST PERFORMED	RESULT
Acute Oral Toxicity*	not toxic at 5,000 mg/kg
Primary Eye Irritation*	no positive irritation
Primary Dermal Irritation*	non-irritating
Cytotoxicity ^{1,2}	not cytotoxic
Cytotoxicity ¹ of treated polyurethane and silicon, DUWL tubing at 3, 6 & 12 mo	Polyurethane - not cytotoxic Silicon - not cytotoxic
Dermal Sensitization ³	not a contact sensitizer

* per 16 CFR Part 1500.42, Consumer Product Safety Commission (CPSC), and Federal Hazardous Substances Act (FHSA) guidelines.
¹ U.S. Pharmacopeia 23 standardized test and compliant with International Standards Organization (ISO) Standard 10993-5.
² ASTM Standard F895-84.
³ ASTM Standard F720-81 (reapproved 1992) and compliant with International Standards Organization (ISO) Standard 10993-5.

SIMPLE



Use with an independent water reservoir

At the end of the day...

- A. Remove remaining water
- B. Add treatment to the water reservoir
- C. Introduce the treatment into the waterlines and leave in overnight
- D. Leave the water reservoir empty and store dry overnight

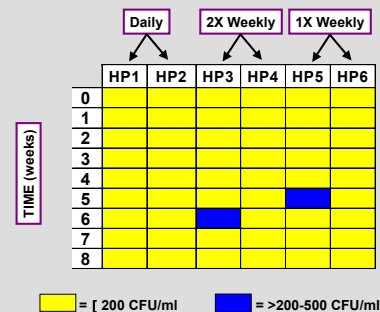
At the beginning of the day...

- A. Fill the water reservoir with fresh water and flush lines

COST-EFFECTIVE

REDUCED TREATMENT PROTOCOL

METHODS: A reduced-frequency treatment, or maintenance protocol, was performed on university clinic dental units (>20 years old). Previously, all units had been treated daily with the iodine-based chemical agent to remove biofilm. Next, the units were either treated daily (control), twice weekly, or weekly for 8 weeks. Water samples (~5 mL) were collected weekly from the high-speed handpiece (HP) tubing of each unit and plated in triplicate on R2A agar containing 0.1% sodium thiosulfate. After incubation at 25 ± 2 °C for 7 days, total CFU/mL was determined. Data is expressed below as [200 CFU/mL (yellow) or >200 to <500 CFU/mL (blue).



SUMMARY & CONCLUSIONS

Previous studies demonstrate that the iodine-based chemical treatment used in this study reduces DUWL contamination to a level consistent with the ADA's year 2000 goal by controlling DUWL biofilms.

The current study demonstrates that this DUWL treatment is non-toxic, non-irritating and non-sensitizing, and thus safe for patients and practitioners, should they ever be exposed.

The success of this reduced-frequency treatment protocol demonstrates that once biofilm has been removed from the DUWL, the product can be used less frequently to maintain low bacterial counts. Less frequent use saves product, time, and therefore, money.

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