HYBENX® Products Bibliography

Endodontics

R. PACE, L. DINASSO, A. NIZZARDO, L. TAURO, G. PAGAVINO, AND V. GIULLANI;
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THE EFFECTS OF A NEW DECONTAMINANT SOLUTION ON ROOT CANAL
BLEEDING DURING ENDODONTIC TREATMENT: A RANDOMIZED CONTROLLED
STUDY

Alberto Antonelli, Luca Giovannini, Ilaria Baccani, Valentina Guiliani, Ricardo Pace and
Gian Maria Rosssolini. University of Florence and Careggi University Hospital

In Vitro Antimicrobial Activity of the Decontaminant HybenX® Compared to
Chlorhexidine and Sodium Hypochlorite against Common Bacterial and
Yeast Pathogens

Riccardo Pace, Luca Di Nasso, Lucia Tauro, Andrea Nizzardo, Gabriella Pagavino
Valentina Giuliani, Department of Clinical and Experimental Medicine, University of
Florence, Florence, Italy

Analysis of dentinal erosion and removing smear layer of different irrigation
protocols: an in vitro study

Riccardo Pace 1, Fabio Morecchiato 2, Luca Giovannini 2, Luca Di Nasso 1,2,
Valentina Giuliani 1,2, Debora Franceschi 1,2, Gabriella Pagavino 2, Gian Maria
Rossolini 2,3 and Alberto Antonelli 2,3,*

In Vitro Alteration by Dentine and Protein of the Antimicrobial Activity of Two
Endodontic Irrigants: HybenX® and Sodium Hypochlorite

Antimicrobial activity of sulfonated phenolics components in the root canal

Rohrer, MD, HS Prasad, and E Savord.
A Histological Assessment of a HYBENX® Oral Tissue Decontaminant in Vital
97. 2016.

The authors demonstrate that vital pulp exposures, treated with HYBENX® Oral Tissue
Decontaminant, demonstrated significant improvements in new dentin formation and
tooth vitality when compared to the conventional standard of care.

General Dentistry

Ioannidis, AB, B Stawarczyk, B Sener, T Attin, and PR Schmidlin.
Influence of dentin and enamel pretreatment with acidic sulfur compounds on

Authors concluded that HYBENX® Oral Tissue Decontaminant did not have a
deleterious etching effect on enamel or dentin. Enamel still requires conventional etching
procedures for bonding resins. Bonding to dentin was enhanced by pre-exposure to the
HYBENX® Solution.

Argüello, Claudia.
A better way to remove the disease-causing Periodontal and Peri-implant Oral
Biofilm. Dental Tribune 3(9): 10-13. 2014. (Translated from the
Author summarizes the history, etiology, and health ramifications of oral biofilm. She explains the HYBENX® Oral Tissue Decontaminant technology and recommends that the product be used adjunctively by the dental clinician to treat periodontal disease and peri-implantitis.

Nardi, GM, S Sabatini, F Scarano, and M Petruzzi. 
**Effectiveness of a new chemical agent for topical use in the treatment of a patient with aphthous major ulcers.** Poster Presentation at the National Congress of the Faculty of Dentistry, University of Rome, April 18-20. 2013. (*Translated from the original Italian text*).

Authors concluded that immediately after treatment with HYBENX® Oral Tissue Decontaminant, patients were symptom free and experienced complete healing of the ulcer surface.

**Periodontology**


Authors describe a simple adjunctive topical method for removing biofilm from tissue surfaces at the molecular level using HYBENX® Oral Tissue Decontaminant solution. Bacterial DNA pyrosequencing and inflammatory mediator immunoassays were used as surrogates for assessing cleaning efficacy.

Isola, G, G Matarrese, RC Williams, VI Siciliano, A Alibrandi, G Cordasco, and L Ramaglia. 

Authors conclude that SRP plus the desiccant (HYBENX® Oral Tissue Decontaminant) resulted in a greater reduction in clinical, microbial and inflammatory mediators compared to SRP alone and demonstrated a significant approach to control the levels of certain periodontal pathogens and inflammatory mediators in patients with CP.

**Independent Review of the above Isola Paper:** Brignardello-Petersen, R. *A Desiccant Agent as an Adjuvant to Scaling and Root Planing Improves Clinical Parameters in Patients with Chronic Periodontitis and Good Prognosis up to 1 Year after Treatment.* JADA June 17, 2017.

Author agreed with the validity of the controls used in the above RCT and indicated that the product showed merit up to the one-year follow up data point.

Lauritano, D, G Ambra, and F Carinci. 

Authors evaluated periodontal pockets in 11 patients using bacterial DNA analysis before and after HYBENX treatment. They observed a statistically significant reduction in red complex microorganisms at 15 days post treatment. They conclude that 1) HYBENX is an effective adjunct to eradicate bacterial loading in the pockets of patients affected by periodontitis and 2) HYBENX is an efficacious medical device for use in the management of moderate to severe chronic periodontitis.
Nardi, GM, S Sabatini, and FR Grassi. Effectiveness of a chemical decontaminant (HYBEN® Oral Tissue Decontaminant) in the reduction of bleeding at hypersensitivity and in improving patient comfort. Poster Presentation at the National Congress of the Faculty of Dentistry, University of Rome, April 18-20, 2013. (Translated from the original Italian text).
Authors concluded that bleeding on probing and dentinal hypersensitivity were improved in the treated cohort. Periodontal probing depth and plaque indices were also improved but did not reach statistical significance under the conditions evaluated. Patients preferred the treatment protocol versus the control (no decontamination treatment).

Authors concluded that HYBEN® Oral Tissue Decontaminant, as an adjunct during remediation of periodontal disease, greatly facilitated ease of cleaning and patient comfort.

36 patients with 393 periodontal defects were treated with full-mouth ultrasonic debridement either with, or without HYBEN® Solution as an adjunctive therapy. At 3 months followup, the HYBEN cohort was significantly improved over control. In particular, BOP in deep pockets (PPD> 7 mm) was reduced from 89 to 41% versus 90 to 63% in the control group (p = 0.0168). Authors concluded that HYBEN® Oral Tissue Decontaminant is a valuable aid to the initial treatment of chronic periodontitis.

In this randomized, split-mouth, single-blind prospective clinical study, the authors observed significant improvements in clinical outcomes at three months post-treatment in patients treated with adjunctive HYBEN® Oral Tissue Decontaminant therapy when compared to patients treated only by ultrasonic debridement. In particular, a significant reduction in the levels of anaerobic microflora and gingival inflammation was noted.

Pilot clinical trial evaluation of patients in England, Scotland, and Italy using HYBEN® Oral Tissue Decontaminant as an adjuvant in scaling and root planning. Author concluded that this treatment reduced pocket depth in 10 of 13 patients with non-responding pockets greater than 5mm at the six-week follow-up analysis.

Authors conclude that the biofilm decontamination approach using HYBENX® Oral Tissue Decontaminant seems to be a very promising technique for the treatment of acute periodontal abscesses without using systemic or local antibiotics.


Authors demonstrate the removal of biofilm from extracted teeth using HYBENX® Oral Tissue Decontaminant.

Peri-implantitis

Authors concluded that the use of HYBENX® Oral Tissue Decontaminant “can serve as a beneficial form of treatment against peri-implantitis and subsequent infected implant defects not only due to its efficacy in halting bacterial growth, but as well as its non-invasive capabilities during application”.


Authors compared the effectiveness of the use of HYBENX® Oral Tissue Decontaminant ("HOTD") vs. Chlorhexidine ("CHX") in reducing peri-implant mucositis inflammation. They concluded that HOTD was superior in reducing PPD but that CHX was superior in reducing the level of anaerobes.


The authors noted after two-year follow up that the use of HYBENX® Oral Tissue Decontaminant and air powder abrasives, followed by bone defect grafting, represents a viable option in the treatment of peri-implantitis.


Authors conclude that the use of HYBENX significantly reduced: 1) the need for invasive surgery, 2) bacterial load, 3) patient discomfort, 4) healing time, and, 5) the need for antibiotics, yielding a clear clinical improvement in both mucositis and severe peri-implantitis.


Authors conclude that the biofilm decontamination approach, using HYBENX® Oral Tissue Decontaminant, is a very promising technique for the treatment of acute periodontal abscess and peri-implantitis without the use of systemic or local antibiotics.
Authors conclude that the biofilm decontamination approach using HYBENX® Oral Tissue Decontaminant seems to be a very promising technique for the treatment of peri-implantitis in a short-term evaluation without using systemic or local antibiotics.

Author concludes that successful hygienic intervention in mucositis associated with peri-implantitis requires the use of an adjunctive debridement material such as HYBENX® Oral Tissue Decontaminant in combination with standard manual or mechanical debridement procedures.

Author indicates that the most critical step in the successful surgical restoration of severe peri-implantitis is effective decontamination of the implant surfaces with a material such as HYBENX® Oral Tissue Decontaminant to completely remove biofilm.

Oral Aphthous Ulcers


Authors conclude that Oralmedic® Barrier Solution was safe and effective for the treatment of severe recurrent oral ulcers using weekly topical applications for four weeks.

Treatment of oral ulcers with HYBENX® Solution safely, effectively, and more quickly, reduced the painful symptoms of RAS when compared to the leading alternative treatment.

Veterinary Periodontology

Klima, Larry J Et al. Use of HYBENX® Oral Tissue Decontaminant as a topical treatment in gingivoplasty in a boxer dog: a case study. (Unpublished internal report, EPIEN Medical Inc.).
Authors found HYBENX® Solution dramatically reduced bleeding during surgery and enhanced patient management.

Other Unpublished Data:

Authors observed complete obliteration of mature biofilm after a two-minute exposure confirmed by live/dead staining confocal and electron microscopy.

Huber, BJ, DVM, Diplomate, American Board of Veterinary Practioners. American Hospital of Rowlett & Diagnostic Center, Rowlett, TX. Testimonial, Internal Report, EPIEN Medical Inc. 2013.
We are routinely obtaining better outcomes using HYBENX® Products in dental cleaning procedures for improved pain management and hemostasis and removal of inflamed mucosal tissue in stomatitis patients.

We are routinely using HYBENX® Solution for treatment of periodontal pockets, furcational defects, stomatitis and mucositis lesions, gingivoplasty, and general patient case management.

We are routinely using HYBENX® Solution for cleaning, root canal cleansing, severe periodontitis, and in feline aggressive stomatitis.

HYBENX® Test Solutions exhibited strong antimicrobial activity in this preliminary pigskin infection model assessment.

HYBENX® Solution demonstrated antifungal activity in a human skin model system (Apligraf®).

US Customer NOTICE: HYBENX® Product is cleared in the US on a 510(k) HYBENX® Root Canal Cleanser for use on the interior surfaces of the tooth root canal. As such, it is deemed safe and effective on internal nerve, bone, and dentinal structures. The EU has approved the product more broadly as a Class I Medical Device for unrestricted oral cleansing applications. EPIEN Medical does not promote the product for those broader applications in the US. However, the authors above deem HYBENX to be safe for use on all oral surfaces per the published applications.

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