

Statement in response to NICE review

Biberach August 2005

The National Institute for Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. On 1 April 2005 NICE joined with the Health Development Agency to become the new National Institute for Health and Clinical Excellence (still known as NICE).

In February 2003, NICE first approached KaVo to provide an official Submission to them with respect to the possible use of the KaVo HealOzone Device, within the UK NHS. After reviewing this document they also reviewed the various completed studies. NICE has now issued a report relative to the treatment of tooth decay through the application of ozone, as delivered by the KaVo HealOzone Medical Device, based upon the data available at that time.

The report states that within the confines of the costs to the UK National Health Service, "HealOzone is not recommended for the treatment of tooth decay (occlusal pit and fissure caries and root caries), except in well-thought out, randomised controlled trials".

In accordance with this statement from NICE, the independent scientific advisory board for HealOzone recommends that KaVo should continue to proceed with the HealOzone project, so that existing and future studies may be completed and in addition, patients within the Private Sector may continue to receive the obvious clinical benefits that HealOzone treatment affords.

The scientific advisory board also sees tremendous potential and opportunity for HealOzone treatment to become both a preferred, alternative therapy and an adjunct to existing therapies.

Below, a list of clinical studies is shown, which at the time of our official Submission to NICE back in August 2004, were completed but not yet published.

Below, a list of current clinical studies is shown. These studies will be submitted to peer reviewed dental journals for publication, as and when completed.

To date, CurOzone USA Inc. and KaVo Dental GmbH have sold in excess of 2,000 HealOzone devices, which are in daily use in dentists' offices through out Europe, Australia, Canada and New Zealand. They are being successfully used on a regular basis for the treatment of root, pit and fissure caries.

KaVo and CurOzone have received only positive comment from the clinicians who have been using this device in General Dental Practice for up to four years, spontaneously reporting on the positive effect of ozone treatment on caries. An appendix of testimonials from satisfied UK dentists is attached hereto.

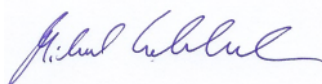
Furthermore the University of Florence incorporates HealOzone in their post-graduate educational programme, as it is considered to be a less invasive and valuable emergent technology.

Both CurOzone and KaVo Dental GmbH support the objectives of NICE and will ensure that all appropriate clinical studies are passed to them as soon as they are published. This should allow NICE to undertake an urgent review and update their original findings.

With best regards



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Executive Vice President
Curozone USA Inc.



Michael Eidenschink
Business Unit Manager High Tech
KaVo Dental GmbH



Melanie Raiber
Productmgmnt. HealOzone
KaVo Dental GmbH

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Topic	Start	End	Faculty	Principal Investigator	Publication
The impact of ozone treatment on enamel physical propriety	Jun 03	Sep 04	University of Bern Switzerland	Prof. Lussi	Submitted, American Journal of Dentistry
Effect of ozone on non-cavitated fissure carious lesions in permanent molars <i>a controlled prospective clinical study</i>	Mar 03	Feb 04	University of Munich Germany	Prof. Hickel	Accepted, American Journal of Dentistry
Influence of ozone treatment on marginal adaptation of fissure sealing	Aug 03	Jul 04	University of Regensburg Germany	Prof. Schmalz	Poster published, at CED in Istanbul, Aug 2004
Treating Caries in anxious children with Ozone	Aug 03	Sep 04	University of Bern Switzerland	Prof. Lussi	Presented, American Journal of Dentistry
Root canal disinfection	May 03	Mar 04	University of Marburg Germany	PD Dr. Stoll	Presented, Intern. Endodontic Journal
The impact of ozone treatment on enamel physical properties	Mar 03	Feb 04	University of Munich Germany	Dr. K. C. Huth	Accepted, in press, American Journal of Dentistry
Effect of ozone on enamel and dentine on bond strength	Sep 03	Sep 04	University of Zürich Switzerland	Dr. P. Schmidlin	Journal of adhesive Dentistry, VOL 7, Nr. 1
Use of ozone gas in Endodontics In-vitro-study	Nov 04	May 05	University of Berlin Germany	Prof. Kielbassa	Accepted for lecture DGZMK Berlin, Oct 2005
Antibacterial activity of the HealOzone device and its comparison with dentin bonding systems In-vtro-study	Jan 05	July 05	University of Freiburg Germany	Dr. P. Hahn	Submitted in International Dental Journal
Ability of Ozone to inactivate cariogenic bacteria in multi species artificial biofilms	Nov 04	June 05	University of Tokyo Japan	Dr. Matin	Presented in Japan oral biofilm meeting June 2005 Submitted congress of preventive dentistry, Liverpool Sept. 05

Below, a list of current clinical studies is shown. These studies will be submitted to peer reviewed dental journals for publication, as and when completed.

Topic	Start	End	Faculty	Principal Investigator
Root canal disinfection with Ozone in compared to NaOCl	Dec 04	Nov 05	University of Witten Germany	Dr. L. Steier
Children, hypersensitive tooth necks, dentin surface caries: Ozone effectivity	Jul 04	Aug 05	University of Homburg Germany	Prof. Hannig
Basic science studies for clinical use of DIAGNOdent and HealOzone on patients diagnosed with molar incisor hypomineralisation	Dec 04	Sept 05	University of Göteborg Sweden	Dr. T. Nilsson
Cavity disinfection and Root Canal disinfection <i>in vitro / in vivo study</i>	Jul 04	Aug 05	University of Jena Germany	Prof. Glockmann & Prof. Kneist
Root canal disinfection with ozone compared to calcium hydroxide <i>Double blind in vivo study, randomized</i>	Mar 04	Nov 06	University of Berlin Germany	Prof. Kielbassa
The ozone concentration in approximal areas	Mar 05	Dec 05	University of Zürich Switzerland	Dr. Schmidlin
Fissure sealant > Efficacy Prophylactic effectivity (3 year study) hypersensitive root necks, endodontics, periodontology	Jan 03	Nov 06	DH school Zürich Switzerland	Prof. Saxer
Evaluation of the safety and efficacy of the use of ozone for the management of fissure caries <i>Multi-center study</i>	Mar 05	Dec 07	University of Indianapolis USA	Dr. D. T. Zero
Oral Health Preventive programme for patients with fixed orthodontics <i>Double blind study, randomized</i>	Jul 04	Dec 08	University of Copenhagen and Bogotá Denmark/ Columbia	Prof. Ekstrand & Dr. S. Martignon & Dr. M. I. Lemos

List of over 130 relevant scientific, ozone-related publications

<http://www.dentalozone.co.uk/research15.html>

Università degli Studi di Firenze

International Post-Graduate Course in Ozone and Innovative Dentistry

<http://www.med.unifi.it/segreteria/didattica/perfezionamento/2004-2005/ozono/brochure.pdf>

HealOzone Testimonials

<http://www.kavo.com/healozone/testimonials.asp>

Biological Therapies in Dentistry – Vol.1, Supplem.1, June/July 2005

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http://www.kavo.com/En/downloads/healozone/biological_therapies_in_dentistry.pdf