



Complete Summary

GUIDELINE TITLE

HealOzone for the treatment of tooth decay (occlusal pit and fissure caries and root caries).

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). HealOzone for the treatment of tooth decay (occlusal pit and fissure caries and root caries). London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Jul. 21 p. (Technology appraisal; no. 92).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Dental caries (occlusal pit and fissure caries and root caries)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Dentistry

INTENDED USERS

Dentists

GUIDELINE OBJECTIVE(S)

To assess the effectiveness and cost-effectiveness of HealOzone for the treatment of tooth decay (occlusal pit and fissure caries and root caries)

TARGET POPULATION

Adults and children with dental caries (occlusal pit and fissure caries and root caries)

INTERVENTIONS AND PRACTICES CONSIDERED

HealOzone (ozone gas application) for treatment of tooth decay

Note: HealOzone is not recommended except in well-designed randomised clinical trials.

MAJOR OUTCOMES CONSIDERED

- Progression of caries
- Reversal of caries
- Adverse events
- Quality of life
- Cost effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Aberdeen Health Technology Assessment Group (see the "Companion Documents" field).

Search Strategy

Initial database searches were undertaken to identify relevant systematic reviews and other evidence-based reports. Several Web sites were also consulted to

obtain background information. Full details of the main sources consulted are listed in Appendix 1 of the systematic review companion document.

Electronic Databases Searched

- Medline/Embase/Medline Extra multifile search:
 - Medline: 1966-May Week 1 2004
 - Embase: 1980-Week 20 2004
 - Medline: Extra 17th May 2004
- Science Citation Index: 1981-16th May 2004
- Biosis: 1985-12th May 2004
- Amed: 1985-May 2004
- Cochrane Controlled Trials Register (CCTR): Cochrane Library, Issue 2 2004
- National Research Register (NRR): Issue 2, 2004
- Current Controlled Trials (CCT): 18th May 2004
- Clinical Trials: 18th May 2004
- SCI Proceedings: 1991-May 15th 2004
- Conference Papers Index: 1982-May 2002
- ZETOC Conferences: 1993-May 2004
- IADR Meetings abstracts: 2002-2004

Electronic searches were conducted to identify published and unpublished studies on the clinical and cost-effectiveness of ozone therapy for dental caries. The electronic databases searched are detailed above. Full details of the search strategies are documented in Appendix 1 of the systematic review companion document. It was anticipated that there was a small body of research available; therefore a sensitive search strategy for clinical effectiveness studies was undertaken to retrieve all information, which might be useful on ozone therapy for dental caries. Additional searches were carried out for economic data and these are detailed in Chapter 4 of the systematic review companion document. In addition, selected conferences proceedings that were not available electronically were handsearched. These were International Association for Dental Research (IADR) conference proceedings for 1999-2001 and the annual European Organization for Caries Research (ORCA) Congresses 2000-2003. Research abstracts, published on industry and users Web sites (KaVo Dental Ltd., CurOzone USA Inc., HealOzone, and DentalOzone; see Appendix 1 of the systematic review companion document for full details), were also identified. Reference lists of included studies were also checked for additional study reports.

Inclusion and Exclusion Criteria

All citations identified by the search strategy were assessed for relevance by two reviewers. Copies of the full-text, published papers of those considered to be relevant were then obtained. It was decided that studies reported in languages other than English would be identified but not included in the review. For clinical effectiveness assessment, included studies were randomised controlled trials (RCTs) of ozone treatment (HealOzone) versus at least one comparator (nil, placebo, or active treatment). Data from studies other than randomised trials were collected but not included in the review. The outcome measures were required to be measures of clinical effectiveness (e.g., reversal/progression of caries). Only in-vivo studies involving human subjects were deemed to be suitable for inclusion whilst studies reporting in-vitro results were excluded. Studies were

also excluded if their follow-up was less than six months or did not report clinically relevant outcome measures.

Data Extraction Strategy

A data abstraction form was designed (see Appendix 2 of the systematic review companion document) to collect details from each individual study. This included the type of study design, number of participants and their characteristics, intervention characteristics, caries information including location and severity of lesion, and patient outcomes such as reversal of caries, progression of caries, and any reported adverse events. In particular, the outcomes sought for the included studies were as follows:

- a. Non-cavitated caries
 - Reversal of caries
 - Progression of caries
 - Utilisation of dental services (e.g., visits to dental care units; duration of dental treatment)
 - Adverse events
 - Patient centred measures (e.g., patient satisfaction and preference, relief of pain/discomfort)
 - Quality of life
- b. Cavitated caries
 - Time to restorative interventions
 - Need for further restorative interventions and length of time between restorations
 - Symptoms of pulpal pathology

Inclusion criteria were assessed independently by two reviewers. Any disagreements were resolved by consensus or referred to a third reviewer. Reviewers were not blinded to the names of study authors, institutions, or publications.

Quality Assessment Strategy

Two reviewers assessed the methodological quality of all included studies and any disagreements were resolved by discussion. The quality assessment of randomised controlled trials was formally assessed using a published checklist modified by the reviewers for the purpose of this review. The checklist consists of 12 questions, which focus on the following methodological aspects: method of randomisation, unit of randomisation, concealment of allocation, comparability of groups at baseline, blinding procedures, number of withdrawals/dropouts, and completeness of assessment at follow-up.

For each question a 'Yes', 'No' or 'Unclear' answer is required. The quality assessment checklist is presented in Appendix 3 of the systematic review companion document.

NUMBER OF SOURCE DOCUMENTS

Five full-text reports and five studies published as abstracts met the inclusion criteria for studies of clinical effectiveness of ozone treatment.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and

the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost Effectiveness

- No published economic evaluations were identified on HealOzone treatment of dental caries. The manufacturer submitted an economic model. The Assessment Group developed a second model, but argued that, given the current state of the clinical effectiveness evidence, economic analysis is premature and the model should therefore be taken as illustrative only. The Assessment Group's model is therefore not described further here.
- The submission from the manufacturer of the device assessed the cost effectiveness of adding HealOzone to conventional treatment that did not include preventive treatment. Effectiveness data for the addition of HealOzone treatment were based on average reversal rates of dental caries reported in the randomized controlled trials (RCTs) for non-cavitated (93.3%) and cavitated pit and fissure caries (79%), and for root caries (84.5%). The effectiveness of conventional treatment was based on the average annual progression rate of dental caries reported in clinical studies that were excluded from the Assessment Group's systematic review. The additional cost

of HealOzone treatment per filling avoided was 9.58 pounds sterling in non-cavitated pit and fissure caries, 11.63 pounds sterling in cavitated pit and fissure caries and 5.18 pounds sterling in root caries.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

HealOzone is not recommended for the treatment of tooth decay (occlusal pit and fissure caries and root caries), except in well-designed randomised controlled trials.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of HealOzone in the treatment of dental caries

POTENTIAL HARMS

None stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

HealOzone is not currently available on the National Health Service (NHS), so there are no implementation or audit considerations.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). HealOzone for the treatment of tooth decay (occlusal pit and fissure caries and root caries). London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Jul. 21 p. (Technology appraisal; no. 92).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jul

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Appraisal Committee Members: Dr Darren Ashcroft, Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Dr Peter Barry, Consultant in Paediatric Intensive Care, Leicester Royal Infirmary; Mr Brian Buckley, Vice Chairman, InContact; Dr Mark Chakravarty, Head of Government Affairs and NHS Policy, Procter & Gamble Pharmaceuticals (UK) Ltd; Mr Richard Devereaux-Phillips, Public Affairs and Reimbursement Manager, Medtronic Ltd; Professor Jack Dowie, Health Economist, London School of Hygiene; Professor Gary A Ford, Professor of Pharmacology of Old Age and Consultant Physician, Newcastle upon Tyne Hospitals NHS Trust; Dr Fergus Gleeson, Consultant Radiologist, The Churchill Hospital, Oxford; Miss Linda Hands, Clinical Reader in Surgery, University of Oxford; Professor Peter Jones, Professor of Statistics and Dean, Faculty of Natural Sciences, Keele University; Professor Robert Kerwin, Professor of Psychiatry and Clinical Pharmacology, Institute of Psychiatry, London; Ms Rachel Lewis, Staff Nurse (Nephrology), Hull Royal Infirmary; Professor Jonathan Michaels, Professor of Vascular Surgery, University of Sheffield; Dr Ruairidh Milne, Senior Lecturer in Public Health, National Coordinating Centre for Health Technology Assessment, University of Southampton; Dr Neil Milner, General Practitioner, Sheffield; Dr Rubin Minhas, General Practitioner with a Special Interest in Coronary Heart Disease, Primary Care CHD Lead, Medway PCT and Swale PCT; Mr Miles Scott, Chief Executive, Harrogate Health Care NHS Trust; Professor Mark Sculpher, Professor of Health Economics, Centre for Health Economics, University of York; Dr Ken Stein, Senior Clinical Lecturer in Public Health, Peninsula Medical School, Exeter; Professor Andrew Stevens (*Chair*) Professor of Public Health, University of Birmingham

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- HealOzone for the treatment of tooth decay (occlusal pit and fissure caries and root caries). Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Jul. 2 p. (Technology appraisal; no. 92). Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).
- Systematic review of the effectiveness and cost-effectiveness of 'HealOzone' for the treatment of occlusal pit/fissure caries and root caries. Assessment report. Aberdeen (UK): Aberdeen Health Technology Assessment Group; 2004 Nov 22. 122 p. Available in Portable Document Format (PDF) from the [National Institute for Clinical Excellence \(NICE\) Web site](#).

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0895. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- HealOzone for tooth decay. Understanding NICE guidance – information for people with tooth decay, their families and carers, and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2005 Jul. 6 p.

Electronic copies: Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0896. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information

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NGC STATUS

This summary was completed by ECRI on December 1, 2005.

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