

**FOURTH EUROPEAN CONSENSUS CONFERENCE ON  
HYPERBARIC MEDICINE  
HYPERBARIC OXYGEN IN THE MANAGEMENT OF FOOT  
LESIONS IN DIABETIC PATIENTS**

A two day meeting among European diabetes and hyperbaric health professionals

**Friday/Saturday, 4/5 December 1998**

Forte Posthouse Hotel, Bloomsbury, London, United Kingdom

*A meeting with the support of the British Hyperbaric Association  
Recognized for Continuing Medical Education*

***A review of fundamental questions in the use of hyperbaric oxygen therapy  
in the management of foot lesions in diabetic patients  
leading to a consensus for international publication***

### **Conference Aims**

The conference will discuss five fundamental questions in the use of hyperbaric oxygen therapy in the management of foot lesions in diabetic patients:

1. What is the rationale for hyperbaric oxygen in the treatment of foot lesions in the diabetic patient?
2. Which diabetic patients may benefit from hyperbaric oxygen for the treatment of foot lesions?
3. What is the place of hyperbaric oxygen in the multidisciplinary team approach to these lesions?
4. How can the efficacy of hyperbaric oxygen for these lesions be evaluated?
5. Is hyperbaric oxygen cost effective in the treatment of these lesions?

The Conference will reach a consensus on these questions and produce a report for international publication.

### **Speakers**

Dirk Bakker (Netherlands)  
Bruno Martini (France)  
Jörg Schmutz (Switzerland)  
Jan Apelqvist (Sweden)  
N.C. Shaper (Netherlands)  
Mike Edmonds (United Kingdom)  
Alethea Foster (United Kingdom)  
T.K. Hunt (United States of America)  
Jordi Desola (Spain)  
Remi Neviere (France)  
Alessandro Marroni (Italy)  
R. Rychlik (Germany)  
Pierre Fontaine (France).

## Scientific Committee

Daniel Mathieu (France)  
Giorgio Oriani (Italy)  
Martin R. Hamilton-Farrell (United Kingdom)

## Literature Reviewers

Bruno Martini (France)  
Jörg Schmutz (Switzerland)

## Jury Members

Chairman: Professor AJM Boulton, MD, FRCP. University of Manchester (United Kingdom).  
G rard Cathelinou (France)  
Ernst Chantelau (Germany)  
Ideho Takayashi (Japan)  
Alberto de Leiva (Spain)  
Francesco Malerba (Italy)  
John Ross (United Kingdom)  
Stephen Thom (United States of America)

## Organizing Committee

Martin R. Hamilton-Farrell  
Stephen Brearley  
David Levy  
Catherine Condon

## The Questions

- 1.- What is the rationale for hyperbaric oxygen in the treatment of foot lesions in diabetic patients?
- 2.- Which diabetic patients may benefit from hyperbaric oxygen for the treatment of foot lesions?
- 3.- What is the place of hyperbaric oxygen in the multidisciplinary team approach to these lesions?
- 4.- How can the efficacy of hyperbaric oxygen for these lesions be evaluated?
- 5.- Is hyperbaric oxygen cost effective in the treatment of these lesions?

## PROGRAMME

### Friday, December 4, 1998

*Welcome* - Professor Francis Wattel, President, European Committee for Hyperbaric Medicine.

*Welcome* - Dr. Andrew Colvin, Chairman, British Hyperbaric Association.

*Formal Opening of the Conference* - Professor Sir Dillwyn Williams MA MD FRCPath FRCP, President, British Medical Association.

*Opening Remarks* - Professor Allen Hutchinson FRCGP FFPHM, University of Sheffield School of Health and Related Research, Adviser on Diabetes to the UK Departments of Health.

### Session 1

(Chairmen: Professor Francis Wattel and Professor Allen Hutchinson)

- Incidence and cost of foot lesions in diabetic patients - Jan Appelqvist (Sweden).
- Pathophysiology and evaluation of foot lesions in diabetic patients - Nikolaas Schaper (Netherlands)
- Treatment of foot lesions in diabetic patients: medical aspects - Mike Edmonds (United Kingdom)

### Session 2

(Chairmen: Dr. M.R.Hamilton-Farrell and Dr. Andrew Colvin)

- Treatment of foot lesions in diabetic patients: wound management - Alethea Foster (United Kingdom).
- Treatment of foot lesions in diabetic patients: surgical aspects - Carlo Caravaggi (Italy).
- Hyperbaric oxygen and infection in diabetic foot lesions - Jordi Desola (Spain).

### Session 3

(Chairmen: Dr. Folke Lind and Dr. David Levy)

- Oxygen and wound healing - Thomas Hunt (United States of America).
- Clinical trials evaluating hyperbaric oxygen in the treatment of foot lesions in diabetic patients - Dirk Bakker (Netherlands).
- Patient selection for hyperbaric oxygen treatment, and treatment evaluation - Rémi Nevičre (France).

### Session 4

(Chairmen: Dr. Daniel Mathieu and Mr. Stephen Brearley)

- Cost effectiveness of hyperbaric oxygen in the treatment of foot lesions in diabetic patients - Alessandro Marroni (Italy) & R.Rychlik (Germany).
- Experience of a multidisciplinary unit - Pierre Fontaine (France).
- General discussion.

**Saturday, December 5, 1998**

### Workshops

#### **Examination of the diabetic foot.**

The Diabetic Foot Clinic Team, King's College Hospital, London.

*Sponsored by RDG Medical, United Kingdom.*

#### **Foot pressure and gait evaluation.**

*Presented and sponsored by Musgrave Systems Ltd., United Kingdom.*

#### **Footwear for diabetic patients.**

The G.C. Hanson Diabetic Centre, Whipps Cross Hospital, London.

*Sponsored by Jane Saunders & Manning, United Kingdom.*

#### **Hyperbaric Oxygen Treatment.**

The Hyperbaric Unit, Whipps Cross Hospital, London. *Sponsored by Sechrist Industries Inc., United States of America & Radiometer Ltd., United Kingdom.*

#### **Bioengineered Human Dermal Replacement.**

The Diabetic Foot Clinic Team, King's College Hospital, London.

*Sponsored by Smith & Nephew Healthcare Ltd., United Kingdom.*

**The Conference is supported by:**

Undersea and Hyperbaric Medical Society  
European Underwater and Baromedical Society  
International Congress in Hyperbaric Medicine  
Société de Physiologie et de Médecine Subaquatiques et Hyperbares de Langue Française (France)  
Société Nationale Française de Médecine Interne (France)  
Association de Langue Française pour l'Etude du Diabète et des Maladies Métaboliques "ALFEDIAM" (France)  
Société Suisse de Médecine Sub-Aquatique et Hyperbare (Switzerland)  
Societa Italiana di Medicina Subacquea e Iperbarica (Italy)  
Societa di Anestesia Analgesia Rianimazione e Terapia Intensiva (Italy)  
British Medical Association (United Kingdom)  
University of Manchester Department of Medicine (United Kingdom)  
University of Sheffield School of Health and Related Research (United Kingdom)  
Kings Healthcare NHS Trust (United Kingdom)  
National Hyperbaric Centre, Aberdeen (United Kingdom)  
Japanese Society for Hyperbaric Medicine (Japan)  
Gesellschaft für Tauch und Überdruckmedizin (Germany)  
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Academic Medical Center, Amsterdam (Netherlands)  
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Diving Diseases Research Centre (United Kingdom)  
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## RECOMMENDATIONS OF THE JURY\*

### QUESTION 1- What is the rationale for HBO in the treatment of diabetic foot lesions?

The three conditions adversely affecting the outcome and length of treatment are:

- persistent soft tissue infection
- critical limb ischaemia
- osteomyelitis

The Jury was aware of the lack of studies in animal models and humans specifically addressing the above points in diabetes. However, there was evidence of the efficacy of HBO in animal and human studies in radiotherapy-induced hypoxia. There was evidence from animal studies in non-diabetic models of the efficacy of HBO in osteomyelitis and soft tissue infections; however, evidence from diabetic models remained to be presented. (Level 1 evidence).

### QUESTION 2- Which diabetic patients may benefit from HBO for the treatment of foot lesions?

Patients with diabetic foot problems warrant treatment by foot care teams with careful evaluation of metabolic, neuropathic and vascular factors. Potential candidates for HBO may include those with Wagner grade 3 to 5 lesions treated unsuccessfully by standard methods when amputation seemed a possibility. There was some evidence from a number of trials, each of which suffered from methodological problems, to support the use of HBO in ischaemic limb-threatening problems in diabetic patients. (Level 2 evidence).

A result of the meeting was the recognition of the urgent need for a collaborative international trial for the application of HBO in diabetic foot lesions. Pre-treatment evaluation should include an assessment of the probability of its success which might include:

- TcPO<sub>2</sub> and O<sub>2</sub> challenge at pressure.
- Assessment of peripheral circulation by invasive and non-invasive methods.

### QUESTION 3- What is the place of HBO in the multidisciplinary approach to these lesions?

There was evidence from a number of specialist diabetic foot centres that the multidisciplinary team approach reduced the incidence of recurrent ulcerations and amputations. (Level 3 evidence).

If HBO was to be used in the diabetic foot, it should always be in the multidisciplinary team setting.

### QUESTION 4- How can the efficacy of HBO for these lesions be evaluated?

A priori definitions of primary and secondary end-points in clinical trials of HBO were essential. These may include limb salvage, length of hospitalization, rates of healing and cost efficacy. Assessment of quality of life and foot function should always be included in such studies. Careful monitoring of potential adverse effects, including diabetic retinopathy should occur.

### QUESTION 5- Is HBO cost-effective in the treatment of these lesions?

Data suggested that the cost of HBO was equivalent to other new treatments in the diabetic foot, and may be cost effective. The proposed randomized controlled trial in diabetic foot lesions must include cost-effectiveness analysis.