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Mechanical Bioeffects from Diagnostic Ultrasound: AIUM Consensus Statements

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Ultrasound; Bioeffects; Safety; Cavitation; Mechanical Index; Contrast agents

Introduction

Diagnostic ultrasonography has provided an incredible wealth of knowledge in medicine. Few would be willing to deny the impact this modality has had on patient care, particularly for women and children. With millions of ultrasound examinations performed each year, ultrasonography remains one of the fastest growing imaging modalities. This growth is due to its low cost, real-time image display, and, to no lesser extent, its apparent lack of bioeffects.

Regulation of Ultrasound Output: A Historical Perspective

The regulatory process that controls acoustic output from ultrasound medical devices has been dictated largely by the Food and Drug Administration (FDA), empowered by an act of the United States Congress. At present, the FDA regulates the maximum output of ultrasound devices to a predicate level through a marketing approval process requiring that devices be equivalent in efficacy and output to those produced prior to 1976. This historic regulation of ultrasound has provided a safety margin for ultrasound, while allowing clinically useful performance. The mechanism has restricted ultrasound exposure to levels that apparently produce few, if any, obvious bioeffects based on the epidemiological evidence, although there is recent evidence indicating the potential for bioeffects in animal studies.

In recent years, there have been significant changes that make the development of an acceptable standard on ultrasound safety both complicated and imperative. The development of sophisticated diagnostic ultrasound to allow discrimination of fine detail and improve diagnostic sensitivity has been accompanied by substantial increases in acoustic output. The FDA now provides an option for manufacturers to obtain market approval for medical ultrasound devices that can increase the intensity at the fetus by almost a factor of eight over previously allowable levels, provided that an output display is incorporated into the equipment design.

Based on these changes in acoustic output regulation and recent evidence of potential biological effects of ultrasound at clinical output levels, the American Institute of Ultrasound in Medicine

For inquiries related to this issue of the *Journal of Ultrasound in Medicine*, which focuses on MECHANICAL BIOEFFECTS FROM DIAGNOSTIC ULTRASOUND: AIUM CONSENSUS STATEMENTS, please contact J. Brian Fowlkes, PhD, University of Michigan Health System, Department of Radiology, Kresge III, R3315, Ann Arbor, Michigan 48109-0553, Phone: 734-763-5882, Fax: 734-764-8541, E-mail: fowlkes@umich.edu; OR

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(AIUM) sponsored a conference to assess the scientific evidence associated with the *mechanical effects* of ultrasound, such as cavitation. The conference document being published here was developed to provide the medical ultrasound community with an overview of the scientific information, summary statements, and recommendations concerning the safety of diagnostic ultrasonography with respect to mechanical effects. AIUM has a record of providing this service to the ultrasound community to ensure the safe and effective use of ultrasound in medical practice.

Increasing Role for the Operator

The change in the regulation of acoustic output from medical ultrasound systems greatly increases the role that the physician or sonographer will play in limiting the potential for ultrasound bioeffects. Because the maximum output limit was rather arbitrarily dictated by the FDA and because it might be diagnostically advantageous to increase this limit (i.e., patients with large amounts of subcutaneous fat are difficult to scan), ultrasound devices are now being allowed to increase their output given sufficient feedback to the operator of the output level and its potential for biological effects. Therefore, the responsibility of an informed decision concerning the possible adverse effects of ultrasound in comparison to desired diagnostic information will probably become more important over the next few years. As currently envisioned, information would be provided to the operator concerning the relative potential for bioeffects and would allow the increase of acoustic output beyond a level that might induce a biological response.

AIUM Mechanical Bioeffects Conference Organization

The AIUM Mechanical Bioeffects Conference was held in Aspen, Colorado, August 9–12, 1998. The function of the conference was to provide an opportunity to combine the expertise of a number of individuals knowledgeable in the field of ultrasound bioeffects with those experienced in clinical practice. These persons examined the scientific evidence concerning the mechanical biological effects from ultrasound and its relationship to diagnostic ultrasound as it is currently used.

Composition of the Organizing Committee

An eight-person organizing committee, co-chaired by Drs. J. Brian Fowlkes and Christy K. Holland, developed a detailed conference agenda and identified the appropriate participants. Academic researchers with expertise in biological effects from diagnostic ultrasound, scientists with corporate interests in technical standards, and a representative from the Food and Drug Administration all added to the breadth of this organizing committee.

- J. Brian Fowlkes, PhD, Department of Radiology, University of Michigan, Ann Arbor, Michigan
- Christy K. Holland, PhD, Department of Radiology, University of Cincinnati, Cincinnati, Ohio
- Andrew A. Brayman, PhD, Department of Obstetrics and Gynecology, University of Rochester, Rochester, New York
- Charles C. Church, PhD, Acusphere, Inc., Cambridge, Massachusetts
- Wesley Nyborg, PhD, Department of Physics (Emeritus), University of Vermont, Burlington, Vermont

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- William D. O'Brien, Jr., PhD, Bioacoustics Research Laboratory, Department of Electrical and Computer Engineering, University of Illinois, Champaign-Urbana, Illinois
- Tariq A. Siddiqi, MD, Department of Obstetrics and Gynecology, University of Cincinnati, Cincinnati, Ohio
- Mel E. Stratmeyer, PhD, Health Sciences Branch, Food and Drug Administration, Rockville, Maryland
- Kai E. Thomenius, PhD, General Electric CRD, Schenectady, New York
- James F. Zachary, DVM, PhD, Department of Veterinary Pathobiology, University of Illinois, Champaign-Urbana, Illinois

The attendees, listed by working group below, included bioengineers, biophysicists, chemists, engineers, life scientists, pathologists, physicists, physicians, and sonographers who either have special knowledge of mechanical ultrasound bioeffects or have important perspectives. Each individual made significant contributions to the individual sections that follow. In addition, all the participants were invited to review every section and provide editorial comments.

Definitions and Description of Mechanical Mechanisms (Section 2)

- Charles C. Church, PhD, Acusphere, Inc., Cambridge, Massachusetts
- Wesley L. Nyborg, PhD, University of Vermont (Emeritus), Burlington, Vermont
- Peter D. Edmonds, PhD, Stanford Research Institute (Emeritus), Menlo Park, California
- Frederick W. Kremkau, PhD, Wake Forest University, Winston-Salem, North Carolina

Selected Biological Properties of Tissues: Potential Determinants of Susceptibility to Ultrasound-Induced Bioeffects (Section 3)

- James F. Zachary, DVM, PhD, University of Illinois, Champaign-Urbana, Illinois
- Leon A. Frizzell, PhD, University of Illinois, Champaign-Urbana, Illinois
- John G. Abbott, PhD, Advanced Technology Laboratories, Bothell, Washington
- Floyd Dunn, PhD, University of Illinois (Emeritus), Champaign-Urbana, Illinois
- Narendra T. Sanghvi, MSEE, Focus Surgery, Inc., Indianapolis, Indiana

Bioeffects in Tissues with Gas Bodies (Section 4)

- Christy K. Holland, PhD, University of Cincinnati, Cincinnati, Ohio
- William D. O'Brien, Jr., PhD, University of Illinois, Champaign-Urbana, Illinois
- Lawrence A. Crum, PhD, University of Washington, Seattle, Washington
- Peter L. Ferrer, MD, University of Miami, Miami, Florida
- Alice Tarantal, PhD, University of California, Davis, California

Nonthermal Bioeffects in the Absence of Well-Defined Gas Bodies (Section 5)

- J. Brian Fowlkes, PhD, University of Michigan, Ann Arbor, Michigan
- Edwin L. Carstensen, PhD, University of Rochester (Emeritus), Rochester, New York

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- James F. Greenleaf, PhD, Mayo Clinic, Rochester, Minnesota
- Douglas L. Miller, PhD, Batelle NW, Pullman, Washington

Mechanical Bioeffects in the Presence of Gas-Carrier Contrast Agents (Section 6)

- Andrew Brayman, PhD, University of Rochester, Rochester, New York
- Junru Wu, PhD, University of Vermont, Burlington, Vermont
- Diane Dalecki, PhD, University of Rochester, Rochester, New York
- James Wible, PhD, Mallinckrodt, Inc., St. Louis, Missouri

The Mechanical Index and Other Exposure Parameters (Section 7)

- Kai E. Thomenius, PhD, General Electric CRD, Schenectady, New York
- Marvin C. Ziskin, MD, Temple University, Philadelphia, Pennsylvania
- Paul L. Carson, PhD, University of Michigan, Ann Arbor, Michigan
- Gerald R. Harris, PhD, Food and Drug Administration/CDRH, Rockville, Maryland
- Tariq A. Siddiqi, MD, University of Cincinnati, Cincinnati, Ohio
- Mel E. Stratmeyer, PhD, Food and Drug Administration, Rockville, Maryland
- Jacques S. Abramowicz, MD, Strong Memorial Hospital, Rochester, New York
- Lori L. Barr, MD, Children's Hospital Medical Center, Cincinnati, Ohio
- Andrea Skelly, MPH, RDMS, RDCS, University of Washington, Seattle, Washington
- Kenneth J. W. Taylor, MD, PhD, Yale University, New Haven, Connecticut

During the conference, presentations were made in each of the subjects and then all conference attendees openly discussed the conclusions and recommendations found in Section 1. Conclusions are drawn from scientific material presented in the review of ultrasound bioeffects data in each section of the conference document. Recommendations are statements about how the medical ultrasound community should respond to these conclusions. The purpose of the conference was to finalize recommendations and conclusions and to determine, by consensus vote, which of the summary statements would be forwarded to the AIUM Bioeffects Committee. If consensus were reached, the conclusion or recommendation was forwarded to the AIUM Board of Governors for final approval as Official AIUM Statements and appear in Section 1 of this document.

In addition to the conference participants, there were some specific contributors to the writing process that should be recognized. These are

- Jacques S. Abramowicz, MD ("Mechanical Bioeffects in the Presence of Gas-Carrier Ultrasound Contrast Agents"), University of Rochester, Rochester, New York
- Phillip J. Bendick, PhD ("Nonthermal Bioeffects in the Absence of Well-Defined Gas Bodies"), William Beaumont Hospital, Royal Oak, Michigan
- Peter P. Chang, PhD ("Mechanical Bioeffects in the Presence of Gas-Carrier Ultrasound Contrast Agents"), Pennsylvania State University, University Park, Pennsylvania

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- Richard S. Meltzer, MD (“Mechanical Bioeffects in the Presence of Gas-Carrier Ultrasound Contrast Agents”), University of Rochester, Rochester, New York
- Thomas R. Porter, MD (“Mechanical Bioeffects in the Presence of Gas-Carrier Ultrasound Contrast Agents”), University of Nebraska Medical Center, Omaha, Nebraska
- Kirk K. Shung, PhD (“Mechanical Bioeffects in the Presence of Gas-Carrier Ultrasound Contrast Agents”), Pennsylvania State University, University Park, Pennsylvania

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