CERAMICS IN CLINICAL APPLICATIONS

P. VINCENZINI

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CERAMICS IN CLINICAL APPLICATIONS

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Edited by

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PREFACE

This volume contains most of the papers presented at the BioTeC "Ceramics in Clinical Applications" organized as a Satelite Symposium of the 6th CIMTEC-World Congress on High Tech Ceramics. The Symposium was held in Milan (Italy) on June 26-28, 1986 and was organized in cooperation with the Society for Biomaterials (U.S.A.) and the Japan Society for Biomaterials.

Numerous aspects of the progress achieved in recent years both in terms of materials processing and surgical implants, and applications in the orthopaedic and maxillofacial sectors dealt with during the Symposium involved materials, either massive or in the form of deposits, essentially based on alumina, aluminates, phosphates, apatites, glasses and glass-ceramics, carbons, graphite and composite materials. One session at the Symposium was dedicated to ceramics in medical devices.

Of considerable interest were the numerous case histories regarding experiments on animals and clinical applications on humans validating the now acquired technological maturity of ceramics for important biomedical applications as well as the various prospects opening up for further progress in reconstructive surgery and prosthetic devices.

Critical revision of the texts has resulted for some of the contributions in a completely new presentation; for others only partial rewriting was necessary. In addition, in order to reduce to a minimum the time necessary for publication and thus avoid any loss of interest in the written Proceedings deriving from the fact that sectors such as bioceramics and biomedical technologires are in general subject to an intense and rapid evolution, it was decided that minor imperfections in form and in grammar would be accepted as long as the content was technically valid and understandable.

Taking into account the variety of the clinical applications presented and the multidisciplinary nature of the subject, this volume should be of considerable interest for specialists in the science and processing of bioceramics and materials in general and for surgeons involved in the applications of bioceramics and specialists in instrumental diagnosis.

The Editor, who also acted as Chairman of the 6th CIMTEC, would like to express his sincere appreciation to all the associations involved in the organization of the BioTeC and in particular to Prof. S.H. Hulbert and Prof. H. Kawara, who represented the Society for Biomaterials (U.S.A.) and the Japan

Society for Biomaterials, respectively. In addition, special thanks are due to Prof. G. Heimke, co-Chairman and coordinator of the Symposium, the executive staff of Techna S.r.l., who materially organized the Symposium, and to all others who directly or indirectly contributed to the administrative aspects of the symposium.

P. VINCENZINI
President of the World Congress
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CONTENTS

Characterization

SECTION B: DENTAL AND MAXILLOFACIAL APPLICATIONS

Clinical experience

In vivo experiments

SECTION C: ORTHOPEDICS APPLICATIONS

Clinical experience

In vivo experiments

SECTION D: CERAMICS IN MEDICAL DEVICES

INTRODUCTORY LECTURE

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CERAMICS IN CLINICAL APPLICATIONS, PAST, PRESENT AND FUTURE

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ABSTRACT

The paper presents a brief historical review of the use of ceramics in clinical applications. The paper outlines the present status of the use of bio-inert, surface-active and resorbable bioceramics. The paper also discusses the use of biocomposites using bioceramics and/or biocarbons in medical applications.

INTRODUCTION

The National Institutes of Health (USA) Consensus Development Conference on the Clinical Applications of Biomaterials developed the following definition:

> "A **BIOMATERIAL** is any substance, other than a drug, or combination of substances, synthetic or natural in origin, which can be used for any period of time, as a whole or as a part of a system which treats, augments, or replaces any tissue, organ or function of the body."

A **BIOCERAMIC** is defined as a ceramic used as a biomaterial. A **BIOCARBON** is a material consisting entirely, or substantially, of one of the forms of carbon that is used as a biomaterial.

Bioceramics and Biocarbons are classified into three sub-groups based upon their chemical reactivity in the physiological environment. (See Figure #1 and Table #1). A fourth subclassification would be composites consisting of Bioceramics and/or Biocarbons used in combination with other material systems such as metals or polymers.

TABLE I - BIOCERAMIC CLASSIFICATIONS

A. **Nearly Inert Bioceramics**
   Al_2O_3 - High Alumina Ceramics
   LTI Carbon - Low Temperature Isotropic Carbon
   ULTI Carbon - Ultralow Temperature Isotropic Carbon
   Vitreous Carbon - Glassy Carbon

B. **Surface-Active Bioceramics**
   Hydroxylapatite (HA) Ceramics
   Surface-Active Glasses
   Surface-Active Glass Ceramics

C. **Resorbable Bioceramics**
   Calcium Sulphate
   Trisodium Phosphate
   Calcium and Phosphate Salts

D. **Composites**
   Bioceramic Coatings on Metal
   Carbon Coatings on Metals and Polymers - ULTI Carbon
   Hydroxylapatite - Autogenous Bone
   Surface-Active Glass Ceramics - PMMA
   Surface-Active Glass - Metal Fibers
   Polylactic Acid (PLA) - Carbon Fibers
   Polylactic Acid (PLA) - Hydroxylapatite (HA)
   Polylactic Acid (PLA) - Calcium/Phosphorous-Base Glass Fibers

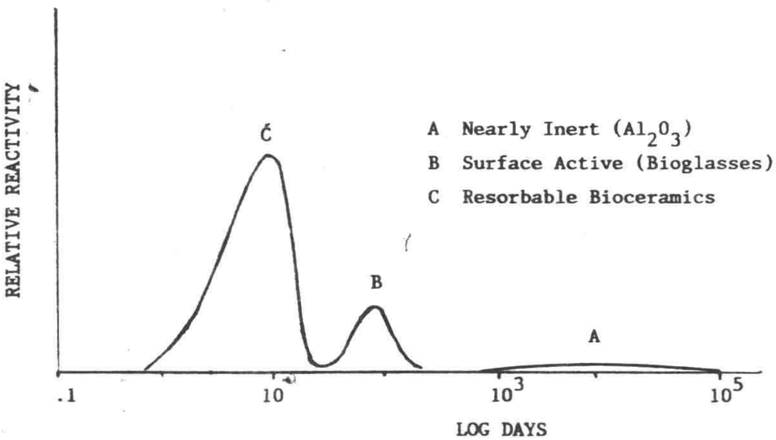

Figure 1: Relative Reactivity Spectrum of Bioceramic Materials

All materials elicit a response from living tissues. Four types of responses are possible. (1) The material is toxic and the surrounding tissue dies. This material, obviously, should not be used as a Biomaterial. (2) The material is non-toxic and biological inactive and a fibrous tissue capsule of varying thickness forms around the material, or in the case of a bone implant, the optical microscope may show direct apposition of bone to the material. In case of ceramics this could be classified as a Nearly Inert Bioceramic. (3) A third possibility, is the material is non-toxic and biological active and an interfacial bond forms between the material and tissue. Such a material would be referred to as a Surface-Active Biomaterial. (4) A fourth possibility would be that the material is non-toxic and dissolves with the surrounding tissue replacing the dissolved material. Such material would be classified as a Resorbable Biomaterial.

The potential of ceramics as biomaterials relies upon their compatibility with the physiological environment. The compatibility of bioceramics is the result of the fact that they can be composed of ions commonly found in the physiological environment (calcium, potassium, magnesium, sodium, etc.) and of other ions also showing .ery limited toxicity to body tissue (aluminum and titanium).

Inert bioceramics (oxides or carbon compositions) undergo little or no chemical change during long-term exposure to the physiological environment. Even in those cases where these bioceramics may undergo some long-term chemical or mechanical degradation, the concentration of degradation product in adjacent tissue is easily controlled by the body's natural regulatory mechanisms. Tissue response to inert bioceramics involves the formation of a very thin, several micrometers or less, fibrous membrane surrounding the implant material. Inert bioceramics may be attached to the physiological system through mechanical interlocking, resulting from tissue ingrowth into undulating surfaces. The main application to date of alumina bioceramics is in the area of articulating surfaces of orthopedic prostheses and in dental implants. The main application of LTI Carbon is in the area of cardiovascular devices.

The composition of surface-active bioceramics is designed such that the surface undergoes selected chemical reactions with the physiological environment, resulting in a chemical bond between tissue and the implant et al, reported on the use of a alumina ceramic total knee prosthesis. In 1982, the FDA approved, in the U.S., a non-cemented ceramic cup and ball hip prosthesis of the Mittelmeier design The system has been extensively studied. The wear rate is approximately 10 times lower than than which occurs with a ball and cup hip prosthesis consisting of ultra high molecular weight polyethylene in conjunction with a metal component.[3,4,5] (See Figures 2 and 3). Alumina ceramic-ultra high molecular weight polyethylene implant systems may have even lower frictional forces than ceramic-to-ceramic bearing surfaces.[17]

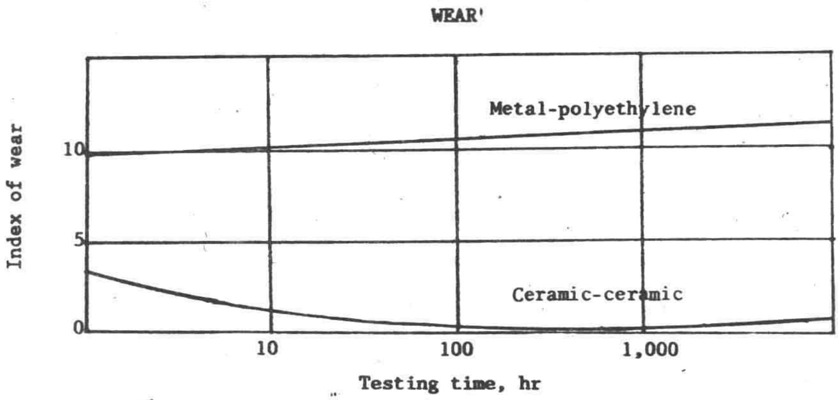

Figure 2: Long-term wear behavior of metal-polyethylene and ceramic-ceramic articulation.[5]

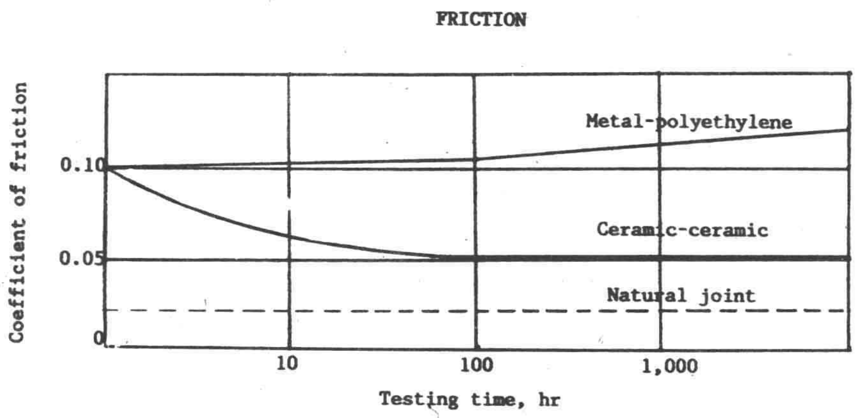

Figure 3: Frictional characteristics of metal-polyethylene, ceramic-ceramic and natural joint systems.[5]