技资料

# Clinical Implant Materials

Advances in Biomaterials, 9

# Clinical Implant Materials

**Proceedings of the Eighth European Conference on Biomaterials, Heidelberg, F.R.G., September 7–9, 1989**

edited by

**G. Heimke**
*Department of Bioengineering, Clemson University, Clemson, SC, U.S.A.*

**U. Soltész**
*Fraunhofer-Institut für Werkstoffmechanik, Freiburg, F.R.G.*

and

**A.J.C. Lee**
*Department of Engineering Science, University of Exeter, Exeter, England.*

**ELSEVIER**
**Amsterdam — Oxford — New York — Tokyo 1990**

ELSEVIER SCIENCE PUBLISHERS B.V.
Sara Burgerhartstraat 25
P.O. Box 211, 1000 AE Amsterdam, The Netherlands

*Distributors for the United States and Canada:*

ELSEVIER SCIENCE PUBLISHING COMPANY INC.
655, Avenue of the Americas
New York, NY 10010, U.S.A.

Library of Congress Cataloging-in-Publication Data

European Conference on Biomaterials (8th : 1989 : Heidelberg, Germany)
Clinical implant materials : proceedings of the Eighth European Conference on Biomaterials, Heidelberg, F.R.G., September 7-9, 1989 / edited by G. Heimke, U. Soltész, and A.J.C. Lee.
p. cm. -- (Advances in biomaterials ; 9)
Includes bibliographical references.
Includes indexes.
ISBN 0-444-88226-X
1. Implants, Artificial--Materials--Congresses. 2. Biomedical materials--Congresses. I. Heimke, B. II. Soltész, U., 1940- . III. Lee, A. J. C., 1938- . IV. Title. V. Series. VI. Series: Advances in biomaterials ; v. 9.
[DNLM: 1. Biocompatible Materials--therapeutic use--congresses. 2. Implants, Artificial--congresses. 3. Prosthesis--congresses. WB AD23 v. 9 / QT 34 E883 1989c]
RD132.E87 1989
617'.9178--dc20
DNLM/DLC
for Library of Congress 90-3708
CIP

ISBN 0-444-88226-X



This book is printed on acid-free paper

Printed in The Netherlands

Advances in Biomaterials, 9

# Clinical Implant Materials


EUROPEAN SOCIETY FOR BIOMATERIALS

## ADVANCES IN BIOMATERIALS

Previous volumes (1-4) published by Wiley, New York.

| | |
|---|---|
| Volume 5. | Biomaterials and Biomechanics 1983 (edited by P. Ducheyne, G. Van der Perre and A.E. Aubert) |
| Volume 6. | Biological and Biomechanical Performance of Biomaterials (edited by P. Christel, A. Meunier and A.J.C. Lee) |
| Volume 7. | Biomaterials and Clinical Applications (edited by A. Pizzoferrato, P.G. Marchetti, A. Ravaglioli and A.J.C. Lee) |
| Volume 8. | Implant Materials in Biofunction (edited by C. de Putter, G.L. de Lange, K. de Groot and A.J.C. Lee) |
| Volume 9. | Clinical Implant Materials (edited by G. Heimke, U. Soltész and A.J.C. Lee) |

## SERIES FOREWORD

The series on "Advances in Biomaterials" was born after the first meeting of the European Society for Biomaterials, which was held in Strasbourg in 1977. This ninth volume contains the Proceedings of the 8th European Conference on Biomaterials, which was held in Heidelberg in September 1989, co-sponsored by the European Society for Biomaterials.

This book is aimed at clinicians, engineers, chemists, biologists and students who are involved, at any level, in the research, development, evaluation or use of medical devices made of biomaterials.

The purpose of this Series is to spread as quickly as possible the scientific information during the European Conferences on Biomaterials. The short period of time that elapses between the conference and the publication of the refereed proceedings makes their scientific content valuable, even if some works presented here may be considered as preliminary. Accordingly, we believe that the up-to-date papers contained in these proceedings should be part of the information available on the personal and library shelves of any individual or laboratory working in the area of biomaterials.

The first volume of Advances in Biomaterials was published in 1980. The continuity of the series, published by Elsevier since 1984, is a witness of the growing worldwide activity in the field of biomaterials science that we hope to see continue.

February 1990

P.S. CHRISTEL

## PREFACE

This volume continues the Series "Advances in Biomaterials" which was inaugurated by the late Dr. George Winter, the first President of the European Society for Biomaterials, more than a decade ago with the purpose of creating a source of reference on the state of the art, progress, and history of the science of biomaterials and its various branches. For the same reason, the European Society for Biomaterials has continued to publish the proceedings of its conferences and symposia. Publication of these papers is indicative of the importance of the meetings, which are on a level that warrants the preservation of their contents as documentation on which future work can be based.

The sciences of biomaterials and biomechanics are branches of medicine and can be regarded as prototypes of interdisciplinary fields. They are bridges for the application of knowledge from almost all areas of the basic and engineering sciences to the problems of health care. This bridging function is readily demonstrated in the grouping of the contents of this volume: the more fundamental and engineering-oriented contributions (Parts I and IV) can be regarded collectively as one of the pillars of this bridge, the papers devoted to clinical aspects and experiences (Part III) as the other. Both of them comprise almost equal numbers of papers. Since the results of most recent studies indicate that considerable work lies ahead of us before the essential interface reactions can be understood, all papers particularly devoted to surface effects have been grouped in an intermediate section (Part II).

The editors wish to thank all authors for their cooperation, in particular those whose mother tongue is not English. We also acknowledge with thanks the assistance and advice of the members of the Board of Reviewers. The efforts of all concerned contributed to the solution of the partially contradictory requirements of speed of publication, maintenance of scientific standards and the esthetics of language. Only in those instances in which the English was very poor, or when misunderstandings could have arisen, has the English been corrected by the Editors. All papers have been peer reviewed before publication; about 20% of those submitted for publication were not accepted.

The Chairmen of the Organizing Committee take this opportunity to thank all who contributed to the success of the Conference, in particular the Fraunhofer-Team in Freiburg, Prof. H. Cotta, Dr. K. Rohe, and Herr H. Hietzker, Heidelberg, and Dr. F. Vizethum, Mannheim, for their able help and professional assistance.

G. HEIMKE
U. SOLTÉSZ
A.J.C. LEE

(Editors)

## LIST OF REVIEWERS

Bensmann, G., Essen, F.R.G.

Bonfield, W., London, U.K.

Breme, J., Erlangen, F.R.G.

Buchhorn, G., Göttingen, F.R.G.

Büsing, C.M., Ingolstadt, F.R.G.

Christel, P., Paris, France

Claes, L., Ulm, F.R.G.

Cohn, B., Jerusalem, Israel

de Groot, K., Leiden, The Netherlands

de Hoedt, B., Tübingen, F.R.G.

de Lange, G.L., Amsterdam, The Netherlands

de Putter, C., Amsterdam, The Netherlands

Dörre, E., Plochingen, F.R.G.

Doyle, C., London, U.K.

Ducheyene, P., Philadelphia, PA, U.S.A.

Ege, W., Wehrheim, F.R.G.

Eitenmüller, J., Brauweiler, F.R.G.

Feijen, J., Enschede, The Netherlands

Griss, P., Marburg, F.R.G.

Gross, U., Berlin, F.R.G.

Höland, W., Jena, G.D.R.

Huiskes, R., Nijmegen, The Netherlands

Jani, L., Mannheim, F.R.G.

Josefowicz, M., Villetaneuse, France

Katz, J.L., Cleveland, OH, U.S.A.

Kölbel, R., Hamburg, F.R.G.

Krempien, B., Heidelberg, F.R.G.

Lee, A.J.C., Exeter, U.K.

Meunier, A., Paris, France

Migliaresi, C., Exeter, U.K.

Oonishi, H., Osaka, Japan

Osborne, J.F., Bonn, F.R.G.

Patka, P., Amsterdam, The Netherlands

Planck, H., Denkendorf, F.R.G.

Plitz, W., Munich, F.R.G.

Rahn, B.A., Davos, Switzerland

Ravaglioli, A., Faenza, Italy

Rehm, K.E., Köln, F.R.G.

Rohe, K., Heidelberg, F.R.G.

Schneider, E., Bern, Switzerland

Semlitsch, M.F., Wintertur, Switzerland

Streicher, R.M., Wintertur, Switzerland

van Blitterswijk, C.A., Leiden, The Netherlands

van Mullem, P., Nijmegen, The Netherlands

Wagner, W., Mainz, F.R.G.

Williams, D.F., Liverpool, U.K.

# CONTENTS

**Series Foreword** ..... v
**Preface** ..... vii
**List of Reviewers** ..... viii

**Part I: Materials**

*I.1 Soft tissue and bone*

I.1.1 Effect of glutaraldehyde concentration on collagen cross-linking and absorption
B.K. Milthorpe, K. Schindhelm and S. Roe ..... 1

I.1.2 Fracture behaviour of compact bone
M. Dabestani and W. Bonfield ..... 7

*I.2 Metals*

I.2.1 Degradation of metallic biomaterials and the immune system: *in vitro* effects of iron, nickel and cobalt on the expression of human lymphocyte antigens
G.S. Carvalho, I. Bravo, M. DeSousa and M. Barbosa ..... 13

I.2.2 Cytocompatibility study of cobalt-chromium alloys using human cell cultures
M.-F. Harmand, A. Naji, R. Jeandot and D. Ducassou ..... 19

I.2.3 Leukocytes, $LTB_4$, and interleukin-1 content in titanium and PTFE hollow chambers implanted in the rat abdominal wall
A.S. Eriksson and P. Thomsen ..... 25

I.2.4 Heterogeneity of antigenic and proadhesive activity of fibronectin adsorbed on various metallic or polymeric surfaces
P. Vaudaux, X. Clivaz, R. Emch, P. Descouts and D. Lew ..... 31

I.2.5 Fretting and accelerated fretting corrosion of titatium *in vitro* and *in vivo*
S.A. Brown, R.W. Margevicius and K. Merritt ..... 37

I.2.6 Electrochemical behaviour of AISI 316 L stainless steel in a physiological solution containing lactic acid
R.A. Silva, M.A. Barbosa, A.M. Costa, M. da Cunha Belo and I. Sutherland ..... 43

I.2.7 *In vitro* and *in vivo* behaviour of a NiTi shape memory alloy
A. Cigada, G. De Santis, A.M. Gatti, G. Rondelli, B. Vincentini and D. Zaffe ..... 51

I.2.8 Biological reactions of Fe-Cr-Al alloy with an $Al_2O_3$ layer on the surface three years after implantation
H. Oonishi, E. Tsuji, T. Mizukoshi, S. Kushitani and M. Aono ..... 57

I.2.9 Production and mechanical properties of porous sintered specimens of the implant alloy TiAl5Fe2.5
J. Breme, V. Wadewitz and B. Fürbacher ..... 63

I.2.10 XPS study of retrieved titanium and Ti alloy implants
J.M. Gold, M. Schmidt and S.G. Steinemann ..... 69

I.2.11 The release of titanium into human bone from a titatium implant coated with plasma-sprayed titatium
J.F. Osborn, P. Willich and N. Meenen ..... 75

I.2.12 The effect of different insertion locales on the healing-in of pure titatium implants
L. Sennerby, R. Olsson, P. Thomsen and L.E. Ericson ..... 81

I.2.13 Removal torques of screw-shaped titanium and Ti 6Al 4V implants in rabbit bone
C.B. Johansson, T. Albrektsson and P. Thomsen ..... 87

*I.3 Polymers*

I.3.1 Fundamental study of cell migration and adhesion towards different biomaterials with organotypic culture method. Observation of two cell components implicated in these events: actin and integrin
J.L. Duval, M. Letort and M.F. Sigot-Luizard ..... 93

I.3.2 Bone-bonding polymer (Polyactive™)
D. Bakker, J.J. Grote, C.M.F. Vrouenraets, S.C. Hesseling, J.R. de Wijn and C.A. van Blitterswijk ..... 99

I.3.3 Testing of some polyurethanes for calcification and biodegradation: an *in vitro* study
B. Glasmacher-Seiler, B. Erens, M. Doersch, H. Reul, G. Rau, G. Wick and H. Pietsch ..... 105

I.3.4 Adhesion of *Escherichia coli* onto a series of poly(methacrylates) differing in hydrophobicity and charge
G. Harkes, J. Dankert and J. Feijen ..... 111

I.3.5 Modification of polymers for the prevention of foreign body infections
B. Jansen, J. Schierholz, S. Schareina, F. Schumacher-Perdreua, G. Peters and G. Pulverer ..... 117

I.3.6 The thermoductility of chopped carbon fiber reinforced PEEK
S.A. Brown, J.J. Mason, K.A. Jockisch, R.S. Hastings and S. Moet ..... 123

I.3.7 Hydrophilic thermoplastic polyetherurethanes: effects of soft segment content and molecular weight on physical properties
M. Karakelle, R.A. Taller and D.D. Solomon ..... 129

I.3.8 Relevance of dietary polyunsaturated fatty acids (PUFA) to prevent platelet aggregation of highly thrombogenic vascular prostheses
G. Galletti, G. Ussia, F. Farruggia and C. Baccarini ..... 135

I.3.9 2-Hydroxyethylmethacrylate modified bone cement
C. Migliaresi and P. Capuana ..... 141

I.3.10 The strength of the interface developed between biomaterials and bone
K.E. Tanner, C. Doyle and W. Bonfield ..... 149

I.3.11 Mechanical behaviour of rubber modified bone cement
M.M. Vila, A. Raya and J.A. Planell ..... 155

*I.4 Degradable polymers*

I.4.0 Requirements on resorbable implant materials
L. Claes ..... 161

I.4.1 A new cell-seeded artificial skin for the treatment of deep dermal wounds
G.J. Beumer, D. Bakker, C.A. van Blitterswijk and M. Ponec ..... 169

I.4.2 Mechanical stability, biodegradability, fatigue behaviour, and creep behaviour of polylactide and polylactide copolymers. An investigation on block polymerized and injection molded material
J. Eitenmüller, K.L. Gerlach, A. Pommer, H. Offergeld and G. Muhr ..... 175

I.4.3 *In vivo* and *in vitro* study of a biodegradable fracture fixation device of high molecular polyglycolic polydioxanone composite
I.C. Heyligers, P. Patka, C.P.A.T. Klein, W. den Hollander and K. de Groot ..... 183

I.4.4 Physical characteristics of 'PHB'. A degradable polymer
J.C. Knowles and G.W. Hastings ..... 191

I.4.5 Hyaluronic acid esters, a new class of semisynthetic biopolymers: chemical and physico-chemical propterties
A. Rastrelli, M. Beccaro, F. Biviano, G. Calderini and A. Pastorello ..... 199

I.4.6 The effect of the molecular weight of polylactic acid on *in vitro* biocompatibility
A. van Sliedregt, C.A. van Blitterswijk, S.C. Hesseling, J.J. Grote and K. de Groot ..... 207

I.4.7 Morphologic aspects of different cell types during *in vitro* biocompatibility testing of PLA: a preliminary study
A. van Sliedregt, C.A. van Blitterswijk, S.C. Hesseling, J.J. Grote and K. de Groot ..... 213

*I.5 Ceramics*

I.5.1 Trace element accumulation after macrophage/material interactions
H.K. Koerten, C.A. van Blitterswijk, D. Bakker, S.C. Hesseling, R.A.J. Dalmeijer and J.J. Grote ..... 219

I.5.2 Marrow cell induced osteogenesis and chondrogenesis in porous calcium phosphate ceramics
H. Ohgushi, M. Okumura and S. Tamai ..... 225

I.5.3 Adhesion strength and adhesion area of cultured cells on bioceramics
T. Ushida, T. Tateishi and N. Moriya ..... 231

I.5.4 Characteristics on the hydroxyapatite ceramics (APS-9) biocompatibility under sustained load bearing
H. Yano and S. Takagi ..... 237

I.5.5 Structured implants as bone substitutes
P.M. Marquis, S.F. Tarrant, O.G. Titley, S.J. Dipple, Y.P. Bovell, J.E. Davies and L. Lindstrom ..... 243

I.5.6 Prostaglandin concentrations in femoral rat bone following implantation of hydroxyapatite ceramics and alumina
J.F. Osborn and J.M. Wittenberg ..... 249

I.5.7 Macroporous calcium phosphate ceramics for long bone surgery in human and dogs — clinical and histological studies
N. Passuti, G. Daculsi, S. Martin, M. Basle and S. Roher ..... 255

*I.6 Glasses and carbon*

I.6.1 Corrosion of bioactive glass under various *in vitro* conditions
Ö.H. Andersson and K.H. Karlsson ..... 259

I.6.2 Reactions between Bioverit glass ceramics and hard tissue
W. Hölland, W. Vogel, E. Beleites, T. Schubert, K. Naumann, J. Vogel and P. Wange ..... 265

*I.7 Coatings*

I.7.1 Alumina and silicium carbide coatings for passivation of alloys
M.-F. Harmand, A. Naji, J.-P. Davidas, R. Jeandot and D. Ducassou ..... 271

I.7.2 Solubility of hydroxylapatite, tricalciumphosphate and tetracalciumphosphate coatings on titatium *in vitro*
C.P.A.T. Klein, J.M.A. de Blieck-Hogervorst, J.G.C. Wolke and K. de Groot ..... 277

I.7.3 Bone tissue response to porous hydroxyapatite and wire meshs of stainless steel with and without coatings of hydroxyapatite and titaniumnitrite
J. Orth, J. Kautzmann and P. Griss ..... 283

I.7.4 HA and non HA coated carbon composite femoral stems in the canine model
G.L. Maistrelli, D. Garbuz, V. Fornasier and A. Binnington ..... 289

**Part II: Surface effects**

II.1 New aspects of biocompatibility: motion at the interface
A.F. von Recum ..... 297

II.2 Implant surface roughness and mode of load transmission influence periimplant bone structure
U. Gross, Ch. Müller-Mai, Th. Fritz, Ch. Voigt, W. Knarse and H.J. Schmitz ..... 303

II.3 The influence of various titanium surfaces on the interface shear strength between implants and bone
H.-J. Wilke, L. Claes and S. Steinemann ..... 309
II.4 Use of excimer laser as possible and valuable tools for surface processing of bioceramic materials
H.J. Koort ..... 315
II.5 Bacterial adherence to functionalized surfaces
K. Merritt, C.N. Sukenik and N. Balachander ..... 321
II.6 The characteristics of protein adsorption onto metallic biomaterials
R.L. Williams, S.J. Higgins, A. Hamnett and D.F. Williams ..... 327
II.7 A new method for ultrastructural studies of the intact interface between undecalcified bone and titanium implants
L.E. Ericson, L. Sennerby, G. Bokhede, L. Emanuelsson and P. Thomsen ..... 333
II.8 An ultra-structural study of the interface between hydroxyapatite/polymer composite and bone
C. Doyle, Z.B. Luklinska, K.E. Tanner and W. Bonfield ..... 339

**Part III: Clinical applications**

*III.1 Orthopaedics*
*III.1.1 General*
III.1.1.1. An SEM study of crystals in articular cartilage taken from arthritic joints
A. Hayes, I.G. Turner and K.A. Powell ..... 345
III.1.1.2 Development of an artificial cartilage: evaluation of biocompatibility
T. Noguchi, M. Oka, P. Kumar, Y. Kotoura, S.H. Hyon, Y. Ikada and T. Yamamuro ..... 351
III.1.1.3 Failure of diaphyseal implants in endoprosthetic replacement of bone tumors
G.O. Hofmann, W. Stöger, Th. Weber and G. Lob ..... 355
III.1.1.4 Best weightbearing time after implantation as inferred from interface observation
H. Oonishi, E. Tsuji, H. Ishimaru and J. Delecrin ..... 361
III.1.1.5 Clinical application of Tekmilon fiber (ultra high molecular weight polyethylene) in spinal surgery
Y. Ueda, S. Nishiyama, H. Yokota, H. Iwasaki and S. Tamai ..... 367

*III.1.2 Hip replacements*
III.1.2.1 Wear resistant properties of various prosthetic joint materials
P. Kumar, M. Oka, K. Ikeuchi, T. Yamamuro, H. Okumura and Y. Kotoura ..... 373
III.1.2.2 SEM observation on the clinically used gamma-irradiated reinforced HDP socket in total hip replacement
H. Oonishi and E. Stuji ..... 379
III.1.2.3 Ion implantation on metal and polymer components for joint prostheses
A. Pichat, L.-M. Rabbe, J. Rieu, C. Chabrol, R. Leveque, G. Bousquet and A. Rambert ..... 385
III.1.2.4 Five-year functionality study of carbon fibre reinforced acetabular implants in dogs
B. Boenisch, R. Ascherl, A. Liebendörfer, K. Geissdörfer, M.-L. Schmeller, S. Kerschbaumer, M.A. Scherer, W. Erhardt, W. Scheer and G. Blümel ..... 391
III.1.2.5 Structural analysis of cemented hip joint replacements. Results from autopsy femora
W. Koeller and E.-J. Henssge ..... 397
III.1.2.6 Morphological changes in femoral heads following double-cup arthroplasty
L. Claes, S. Faiss, H. Gerngross and H.-J. Wilke ..... 403

*III.1.3 Knee replacements*

III.1.3.1 Cementless surface replacement of the knee with different materials
L. Claes, H.-J. Wilke, L. Dürselen and H. Kiefer ..... 409

III.1.3.2 A quantitative topographic evaluation of bone ingrowth in tibial components removed from human patients
H. Kienapfel, D.R. Sumner, J.J. Jacobs, T.M. Turner, R.M. Urban and J.O. Galante ..... 415

III.1.3.3 Cold-flow of tibial component polyethylene after knee arthroplasty
L. Ryd, A. Lindstrand, A. Stenström and G. Selvik ..... 421

III.1.3.4 Isoelastic knee prosthesis using laminated composite materials
N. Inoue, Y. Hirasawa, F. Yamashita, Y. Watanabe, T. Hirai, T. Katayama and Y. Kida ..... 425

III.1.3.5 Application of porous calciumphosphates in depressed tibial plateau fractures
P. Brändle and A.F. Leutenegger ..... 431

III.1.3.6 Internal fixation of patella osteotomies with biodegrabable implants — preliminary results of an experimental trial
H.-U. Zieren, W. Holzmüller, J. Rosenberger, H.J. Helling and K.E. Rehm ..... 435

*III.1.4 Ligaments and tendon*

III.1.4.1 Mechanical properties of artificial ligaments
L. Dürselen and L. Claes ..... 439

III.1.4.2 Para-aramid fiber for artificial ligaments
M. Dauner, H. Planck, I. Syré and K.K. Dittel ..... 445

III.1.4.3 Loss of strength and shortening of the patellar tendon after using the central one third for reconstruction of the anterior cruciate ligament
W. Holzmüller, K.E. Rehm, S.M. Perren and B. Rahn ..... 451

III.1.4.4 Late repair of the calcaneal tendon with polypropylene mesh — a new method of operation
J. Ozaki, J. Fujiki, K. Sugimoto, S. Tamai and M. Okumura ..... 455

III.1.4.5 Anterior cruciate ligament reconstruction using bone-ligament-bone allografts: an *in vitro* study
S.C. Roe, B.K. Milthorpe and K. Schindhelm ..... 461

III.1.4.6 Teflon felt cuff plasty for global or massive tears of the rotator cuff of the shoulder
J. Ozaki, Y. Nakagawa, G. Sakurai, S. Tamai and M. Okumura ..... 467

*III.2 Vascular materials*

III.2.1 Novel segmented polyurethane amides for biomedical applications
D. Cohn, S. Bilenkis, A. Penhasi and S. Yitzchaik ..... 473

III.2.2 Mechanical properties of a polyester-collagen vascular prosthesis
C.C. Berndt, D. Collinson and G. Roberts ..... 481

III.2.3 Heparinized cuprophan
G.H.M. Engbers, T. van Mechelen, B.M.T. Croonen, L. Robertson, J.M. Courtney and J. Feijen ..... 487

III.2.4 Realisation of bioartificial vascular substitutes: morphological study of an original collagenic coating
M.Y. Jablonski, Th. Darnis, L. Bordenave, R. Bareille, F. Rouais and Ch. Baquey ..... 493

III.2.5 New arterial prostheses by filament winding
D. Cohn, G. Marom and B. Gershon ..... 501

III.2.6 Angiogenesis and neovascularization in different prosthetic vascular grafts: the significance of graft porosity
M.D. Menger, P. Walter, F. Hammersen and K. Messmer ..... 511

III.2.7 Character and biological behaviour of biocompatible dextran-ironoxide magnetic fluid
M. Hasegawa, S. Maruno, M. Tobita and N. Fujitsuka ..... 517

III.2.8 Fresh and glutaraldehyde preserved frame mounted homograft and porcine bioprosthetic heart valves: leaflet geometry, dynamics and function
M. Butterfield, J. Fisher, G.A. Davies, J.M. Kearney, F. Sureta and D.A. Watson ..... 523

*III.3 ENT-surgery and related fields*

III.3.1 Reconstructive measures in the middle ear and mastoid using a biocompatible cement — a preliminary clinical experience
G. Geyer and J. Helms ..... 529

III.3.2 Biological and functional analysis of hydroxyapatite as clinically applied in otology
C.A. van Blitterswijk, S.C. Hesseling, K. de Groot, H.K. Koerten and J.J. Grote ..... 537

III.3.3 Secondary correction of traumatogenic enophthalmos. An indication for hydroxylapatite blocks
A. Hemprich and J. Hidding ..... 543

III.3.4 Reconstruction of the orbital floor and the skull base with preformed dense hydroxyapatitie ceramic (Osprovit)
J.F. Osborn and K.D. Böker ..... 549

*III.4 Dentistry, oral and maxillofacial surgery*

III.4.1 Histology and microradiography of tissues surrounding dental implants
G.L. de Lange and C. de Putter ..... 555

III.4.2 *In vitro* cytocompatibility assessment of biomaterials towards gingival tissue by organ culture method: fundamental characterization of the epthelial nature of the cultured cell layer
M. Letort, A. Akoum and M.F. Sigot ..... 561

III.4.3 Application of porous hydroxyapatite ceramic in tuberculoplasty of the temporomandibular joint
J.F. Osborn ..... 567

III.4.4 Treatment of zygomatic fractures with biodegradable poly(L-lactide) plates and screws
K.L. Gerlach ..... 573

III.4.5 Biodegradation of three bioactive glasses for the repair of bone defects in dentistry
A.M. Gatti, D. Zaffe, G.P. Poli, A. Ravaglioli and A. Krajewski ..... 579

III.4.6 Shear bond strength of glass-ionomer cements
C. Nucci, C. Prati and M. Chiara Montanari ..... 585

III.4.7 Early and post-24 hour shear bond strength of dentin bonding systems and composite resins
C. Prati, C. Nucci and G. Montanari ..... 591

III.4.8 Shear bond strength of new conventional bonding systems after dentin pretreatments
C. Prati, C. Nucci and F. Fava ..... 597

III.4.9 Factors affecting the lifetime of dental veneers
P.M. Marquis ..... 603

*III.5 Percutaneous devices*

III.5.1 The ability of deep connective tissue to inhibit epithelialisation of percutaneous implant devices
T.G. Heaney, P.J. Doherty and D.F. Williams ..... 609

III.5.2 Fibroblast and epithelial cell reaction to surface treated implant materials
J.A. Jansen, J.P.C.M. van der Waerden and K. de Groot ..... 615

*III.6 Internal medicine*

III.6.1 Neoesophageal epithelization on an artificial esophagus with collagen layer structure
O. Ike, Y. Shimizu, T. Okada, T. Natsume, S. Watanabe, Y. Ikada and S. Hitomi ..... 621

III.6.2 Clinical studies of adriamycin-containing poly(L-lactic acid) microspheres administered into the pleural cavity of patients with pleuritis carcinomatosa
O. Ike, S. Hitomi, R. Wada, S. Watanabe, S.-H. Hyon, Y. Ikada and Y. Shimizu ..... 627

III.6.3 Membranes for a biohybrid pancreas
M. Renardy, H. Planck, J. Trauter, P. Zschocke, U. Siebers, T. Zekorn and K. Federlin ..... 633

**Part IV: Biomechanics**

IV.1 *In vivo* hip joint force measurements in one patient
G. Bergmann, A. Rohlmann and F. Graichen ..... 639

IV.2 An experimental and finite element analysis of the influence of the stem-cement interface in total hip replacements
A.W. Miles, S.E. Clift, S. Wainwright and N. Wood ..... 645

IV.3 Visualization methods in biomechanics
T. Tateishi, K. Hyodo, K. Homma and M. Yamada ..... 651

IV.4 Might biomechanical effects influence biocompatibility tests in bone?
U. Soltész, D. Siegele and E. Baudendistel ..... 657

IV.5 Biomechanical properties of lumbar spinal ligaments
L.-P. Nolte, M.M. Panjabi and T.R. Oxland ..... 663

**Author Index** ..... 669

**Subject Index** ..... 673

*Clinical Implant Materials*, edited by G. Heimke, U. Soltész and A.J.C. Lee,
*Advances in Biomaterials, Volume 9*,
Elsevier Science Publishers B.V., Amsterdam, 1990 — Printed in The Netherlands



# EFFECT OF GLUTARALDEHYDE CONCENTRATION ON COLLAGEN CROSS-LINKING AND ABSORPTION

B.K. Milthorpe, K. Schindhelm and S. Roe
Centre for Biomedical Engineering, University of New South Wales, Kensington, NSW 2033 (Australia)

## SUMMARY

Collagenous xenograft materials for implantation generally have been treated with glutaraldehyde at concentrations exceeding 0.5% w/v in order to make the material resistant to degradation and to improve the immunogenic properties of the material. These concentrations produce a material with poor anastomoses to host tissue.

In this study the effect of glutaraldehyde concentration, in the range 0 to 2.0% w/v, on the thermal denaturation temperature ($T_d$) and host resorption was examined. The thermal denaturation studies showed a rapid rise in $T_d$ with glutaraldehyde concentration from 0 to 0.075% w/v and effective saturation from there on.

Explants of tendons which had been implanted for 12 weeks in rabbit paravertebral muscle elicited a corresponding decrease in invasion with increasing $T_d$. Untreated tendon gave a more inflammatory response with deep penetration of host cells, whereas 0.1% and 2.0% w/v GA-treated samples demonstrated a narrow band of encapsulation.

## INTRODUCTION

Collagenous tissues for implantation generally are treated with glutaraldehyde in saturating concentrations (0.5% w/v or greater). These tissues have been shown to be highly resistant to degradation and to elicit minimal immunogenic response. Although highly successful for porcine heart valves, this treatment has not been successful for the treatment of orthopaedic xenograft tissues, e.g. tendon and ligament (refs. 1,2), the prostheses failing to form adequate junctions with tendon or bone. Shikata (ref. 3) used lower concentrations for tendon prostheses in a rabbit model and concluded that 0.05% w/v was optimal.

The failure of glutaraldehyde (GA) treatment to produce satisfactory tendon and ligament grafts may be due to the lack of host tissue ingrowth at the anastomoses (ref. 1). Allowing increased host cell penetration by reducing the degree of crosslinking by GA may improve this property, although the graft may also be subject to more rapid resorption by the host.

This study was designed to examine the effect of low concentrations of GA on the crosslinking and resistance to cellular invasion of kangaroo tail tendon (KTT). Thermal denaturation temperature ($T_d$) was chosen as the relative measure of crosslinking (ref. 4)