

# Synthetic Bioabsorbable Polymers for Implants



C. Mauli Agrawal, Jack E. Parr,  
and Steve T. Lin, editors



**STP 1396**

**STP 1396**

# ***Synthetic Bioabsorbable Polymers for Implants***

*C. Mauli Agrawal, Jack E. Parr, and Steve T. Lin, editors*

ASTM Stock Number: STP1396



ASTM  
100 Barr Harbor Drive  
PO Box C700  
West Conshohocken, PA 19428-2959

Printed in the U. S. A.

## Library of Congress Cataloging-in-Publication Data

Synthetic bioabsorbable polymers for implants

C. Mauli Agrawal, Jack E. Parr, and Steve T. Lin, editors.

p. cm.—(STP; 1396)

ASTM Stock Number: STP1396.

Includes bibliographical references.

ISBN 0-8031-2870-3

1. Polymers in medicine—Congresses. 2. Biomedical engineering—Congresses. 3. Biomedical materials—Congresses. I. Agrawal, C. Mauli (Chandra Mauli) II. Parr, Jack E. III. Lin, Steve T., 1947- IV. ASTM special technical publication; 1396.

R857.P6 S954 2000

610'.28—dc21

00-040612

Copyright © 2000 AMERICAN SOCIETY FOR TESTING AND MATERIALS, West Conshohocken, PA. All rights reserved. This material may not be reproduced or copied, in whole or in part, in any printed, mechanical, electronic, film, or other distribution and storage media, without the written consent of the publisher.

### Photocopy Rights

**Authorization to photocopy items for internal, personal, or educational classroom use, or the internal, personal, or educational classroom use of specific clients, is granted by the American Society for Testing and Materials (ASTM) provided that the appropriate fee is paid to the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923; Tel: 978-750-8400; on-line: <http://www.copyright.com/>.**

### Peer Review Policy

Each paper published in this volume was evaluated by two peer reviewers and at least one editor. The authors addressed all of the reviewers' comments to the satisfaction of both the technical editor(s) and the ASTM Committee on Publications.

To make technical information available as quickly as possible, the peer-reviewed papers in this publication were prepared "camera-ready" as submitted by the authors.

The quality of the papers in this publication reflects not only the obvious efforts of the authors and the technical editor(s), but also the work of the peer reviewers. In keeping with long-standing publication practices, ASTM maintains the anonymity of the peer reviewers. The ASTM Committee on Publications acknowledges with appreciation their dedication and contribution to time and effort on behalf of ASTM.

## Foreword

This publication, *Synthetic Bioabsorbable Polymers for Implants*, contains papers presented at the symposium of the same name held in Kansas City, Missouri, on 16–17 November 1999. The symposium was sponsored by ASTM Committee F4 on Medical and Surgical Materials and Devices. The symposium co-chairmen were C. Mauli Agrawal, The University of Texas Health Science Center, Jack E. Parr, Wright Medical Technology, Inc., and Steve T. Lin, Exactech, Inc.

# Contents

## Overview

<b>Mechanical Evaluation of 70:30 Poly (L/DL-Lactide) Bone Screws After <i>In Vitro</i> Degradation</b> —J. A. DISEGI, J. W. DWYER, AND R. E. FAIRER	1
<b>Evaluation of Adhesive and Absorption Properties for Absorbable Tissue Adhesives</b> —J. M. ALLAN, J. A. FLAIE, J. D. KLINE, R. L. DOOLEY, AND S. W. SHALABY	8
<b>Bacterial Polyesters for Biomedical Applications: <i>In vitro</i> and <i>in vivo</i> Assessments of Sterilization, Degradation Rate and Biocompatibility of Poly (<math>\beta</math>-hydroxyoctanoate) (PHO)</b> —Y. MAROIS, Z. ZHANG, M. VERT, X. DENG, R. W. LENZ, AND R. GUIDOIN	12
<b>Novel Biodegradable Polyurethanes for Medical Applications</b> —K. GORNA AND S. GOGOLEWSKI	39
<b>Effects of Thermal History and Physical Aging on Thermal Properties of Poly-L-Lactide</b> —M. DENG, J. M. ALLAN, J. T. CORBETT, AND S. W. SHALABY	58
<b>Resorption Profile and Biological Response of Calcium Phosphate filled PLLA and PHB7V</b> —N. L. JONES, J. J. COOPER, R. D. WATERS, AND D. F. WILLIAMS	69
<b>The Clinical Evaluation of a Bioresorbable Minipin</b> —D. W. HUTMACHER, A. KIRSCH, K. L. ACKERMANN, H. LIEDTKE, AND M. B. HÜRZELER	83
<b>The Use of the Vibrating Particle Technique to Fabricate Highly Porous And Permeable Biodegradable Scaffolds</b> —C. M. AGRAWAL, J. S. MCKINNEY, D. HUANG, AND K. A. ATHANASIOU	99
<b>Modulation of Pore Topography of Tissue Engineering Constructs</b> —K. J. L. BURG, C. E. AUSTIN, AND J. P. SWIGGETT	115
<b><i>In Vitro</i> Compression Testing of Fiber-Reinforced, Bioabsorbable, Porous Implants</b> —M. A. SLIVKA, N. C. LEATHERBURY, K. KIESWETTER, AND G. G. NIEDERAUER	124
<b>Clinical Evaluation of a Bioresorbable Membrane for Hard Tissue Regeneration</b> —D. W. HUTMACHER, A. KIRSCH, K. L. ACKERMANN, AND M. B. HÜRZELER	136
<b>Design and Fabrication of a 3D Scaffold for Tissue Engineering Bone</b> —D. W. HUTMACHER, S. H. TEOH, I. ZEIN, K. W. NG, J. T. SCHANTZ, AND J. C. LEAHY	152

# Overview

---

Over the past decade, the use of synthetic bioabsorbable polymers in the field of medicine has grown steadily, and it is not uncommon today to find bioabsorbable devices commercially available for use as implants. The popularity of bioabsorbable polymers in medicine stems from the fact that implants fabricated from these materials are absorbed by the body over time. Moreover, the rate of absorption can be designed to meet the needs of the application. This is a significant advantage because nonabsorbable implants often have to be removed surgically after tissue healing has occurred. Also, most synthetic bioabsorbable polymers can easily be injection molded or extruded into a variety of shapes, which facilitates manufacturing and reduces cost.

As the awareness and the concomitant use of bioabsorbable devices increases, there is a need to address issues of novel and new applications, test and characterization techniques for raw materials and devices, efficacy, and long-term effects. The purpose of this symposium was to explore these issues, teach the latest developments in applications and test techniques, and promote the standardization of minimum requirements and test methodologies.

The papers included in this volume covered a variety of topics such as basic polymer properties and characterization, testing techniques, and tissue engineering. At the present time one of the most popular strategies used in tissue engineering is the implantation of a porous biodegradable scaffold at the defect site in the tissue. This scaffold may carry cells or other biomolecular signals to enable tissue regeneration. Synthetic biodegradable polymers are often used for the scaffolds, and thus, play an important role in tissue engineering. Also discussed were various aspects of biodegradable scaffolds. Lastly, bioabsorbable polymers are receiving attention as replacements for metallic fracture fixation devices and systems.

This STP provides an overview of the use of synthetic bioabsorbable polymers in the medical field at the present time. We predict that in the future such materials will play a very significant role as implants.

We would like to thank the ASTM staff (Dorothy Fitzpatrick, Teresa Cendrowska, and Annette Adams) for working so diligently on this project.

*C. Mauli Agrawal*  
The University of Texas Health Science Center  
San Antonio, Texas  
Symposium Chairman and Editor

*Jack Parr*  
Wright Medical Technology, Inc.  
Arlington, Tennessee  
Symposium Chairman and Editor

*Steve Lin*  
Exactech  
Gainesville, Florida  
Symposium Chairman and Editor

ISBN 0-8031-2870-3