Techniques for Investigation of Surgical Cutting Instruments

Eamon Price  
Institute of Technology, Sligo, Ireland

Ger Reilly  
Dublin Institute of Technology, ger.reilly@dit.ie

Brendan McCormack  
Institute of Technology, Sligo, Ireland

Andrew Macey  
Sligo General Hospital, Sligo, Ireland

Follow this and additional works at: http://arrow.dit.ie/engschmanconn

Part of the Biomedical Devices and Instrumentation Commons, and the Vision Science Commons

Recommended Citation
Copyright© 2005
by
ASM International®
All rights reserved

No part of this book may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the written permission of the copyright owner.

First printing, May 2005

Great care is taken in the compilation and production of this Volume, but it should be made clear that NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE GIVEN IN CONNECTION WITH THIS PUBLICATION. Although this information is believed to be accurate by ASM, ASM cannot guarantee that favorable results will be obtained from the use of this publication alone. This publication is intended for use by persons having technical skill, at their sole discretion and risk. Since the conditions of product or material use are outside of ASM's control, ASM assumes no liability or obligation in connection with any use of this information. No claim of any kind, whether as to products or information in this publication, and whether or not based on negligence, shall be greater in amount than the purchase price of this product or publication in respect of which damages are claimed. THE REMEDY HEREBY PROVIDED SHALL BE THE EXCLUSIVE AND SOLE REMEDY OF BUYER, AND IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES WHETHER OR NOT CAUSED BY OR RESULTING FROM THE NEGLIGENCE OF SUCH PARTY. As with any material, evaluation of the material under end-use conditions prior to specification is essential. Therefore, specific testing under actual conditions is recommended.

Nothing contained in this book shall be construed as a grant of any right of manufacture, sale, use, or reproduction, in connection with any method, process, apparatus, product, composition, or system, whether or not covered by letters patent, copyright, or trademark, and nothing contained in this book shall be construed as a defense against any alleged infringement of letters patent, copyright, or trademark, or as a defense against liability for such infringement.

Comments, criticisms, and suggestions are invited, and should be forwarded to ASM International.

ISBN: 0-87170-824-8
SAN: 204-7586
CONTENTS

Keynote

Medical Device Failures – Can We Learn from Our Mistakes? ................................................. 3
L.E. Eiselstein, B. James, Exponent Failure Analysis Associates, Menlo Park, California

Nitinol Fatigue

Bending Fatigue Characteristics of Nitinol ................................................................................... 14

High Strain Accelerated Fatigue Failure Testing of NiTi Implantable Devices......................... 20
B. Shuman, C. Finger, Spiration Inc., Redmond, Washington
K. Perry, Echobio, LLC, Bainbridge Island, Washington

Cyclic Properties of Superelastic Nitinol Tubing.......................................................................... 25
X.Y. Gong, A.R. Pelton, T. Duerig, Nitinol Devices & Components, Fremont, California
A. Hall, California Polytechnic State University, San Luis Obispo, California

Thermal Processing of Polycrystalline NiTi Shape Memory Alloys............................................ 31
C. Frick, K. Gall, A. Ortego, J. Tyber, University of Colorado, Boulder, Colorado
H.J. Maier, A. El. M. Maksound, University of Paderborn, Paderborn, Germany
Y. Liu, University of Western Australia, Chawly, Australia

Hydrogen Effects on Nitinol Fatigue............................................................................................ .. 37
J. Sheriff, A. R. Pelton, Nitinol Devices & Components, Fremont, California
L.A. Pruitt, University of California, Berkeley, California

Failure Analysis of NiTi Wires Used in Medical Applications .................................................... 43
B. James, J. Foulds, L. Eiselstein, Exponent Failure Analysis Associates, Menlo Park, California

Laser Technologies for Manufacturing Medical Devices

Corrosion of Laser Marks on Instruments.................................................................................... 51
R. Peterson, J. Dickinson, Smith & Nephew, Inc., Memphis, Tennessee

Effects of Oxygen Contamination in the Argon Shielding Gas in Laser Welding of
Commercially Pure Titanium Thin Sheet...................................................................................... 57
Y. Zhou, X. Li, University of Waterloo, Waterloo, Ontario, Canada
J. Xie, St. Jude Medical Center, Sylmar, California

Laser Drilling for Medical Device Manufacturing ....................................................................... 63
T.L. VanderWert, Prima North America, Champlin, Minnesota
Surface Engineering

Pulsed Laser Deposition of Diamondlike Carbon-Hydroxyapatite Composites ........................................... 69
R J. Narayan, B.F. Ball, Georgia Institute of Technology, Atlanta, Georgia

Metallographic Preparation of Orthopedic Medical Devices ................................................................. 73
D. Medlin, Zimmer, Inc., Warsaw, Indiana

Structural Properties of PVD Coatings on Implants and their Influence on Stimulation
Performance in Pacing Applications ............................................................................................. 79
H. Specht, F. Krüger, H. J. Wachter, O. Keitel, M. Frericks,
W. C. Heraeus GmbH & Co. KG, Hanau, Germany

Characterization and Comparison of Coated Bone Drill Bits ............................................................. 83
L. Eschbach, W. Hirsiger, G. Biguin, B. Gasser, Dr. Robert Mathys Foundation, Bettlach,
Switzerland

The Challenge of Plasma Processing - Its Diversity ........................................................................... 89
M. Larner, S. Kaplan, 4th State, Inc., Belmont, California

Mechanical Properties of Calcium Phosphate Invert Glass-Ceramic Coated
Ti-29Nb-13Ta-4.6Zr for Biomedical Applications ............................................................................. 95
M. Niinomi, T. Akahori, T. Yamaguchi, Toyohashi University of Technology, Toyohashi, Japan
T. Kasuga, Nagoya Institute of Technology, Nagoya, Japan
A. Suzuki, Daido Steel Co., Ltd., Nagoya, Japan
H. Fukui, Aichi-Gakuin University, Nagoya, Japan

Modifying the Mechanical Properties of Porous Equiatomic Nickel-Titanium to
Better Mimic Bone ......................................................................................................................... 101
A.P. Jardine, G. Baure, Shape Change Technologies LLC, Thousand Oaks, California

Nitinol Properties and Manufacture

Device Specific NiTi TTT Diagram: Lessons Learned ............................................................................ 106
B. Shuman, C. Finger, Spiration, Inc., Redmond, Washington
K. Perry, Echobio, LLC, Bainbridge Island, Washington

Development and Testing of Manufacturable Thin Film TiNi for Medical Devices ......................... 109
A.P. Jardine, G. Baure, A. N. Le, Shape Change Technologies LLC, Thousand Oaks, California
G.P. Carman, University of California, Los Angeles, California

Clausius-Clapeyron Equations in Different Types of Nickel Titanium Shape
Memory Alloy ................................................................................................................................. 113
S. Zhang, M. Denton, S. Fariabi, Edwards LifeSciences, Irvine, California

An Investigation of the Effect of Drawing Temperature on Nitinol Processing .................................. 117
G.F. Archer, Johnson Matthey, San Jose, California

Improved Fracture Healing with use of Shape Memory Alloys ........................................................... 121
J. Tyber, J. Toelle, C. Frick, A. Ortega, D. Steinke, E. Hardy, K. Gall, University of Colorado,
Numerical Modeling

Phase Transformations in Nitinol and Challenges for Numerical Modeling ....... 127
K.E. Perry, Echobbio, LLC, Bainbridge Island, Washington
P.E. Labossiere, University of Washington, Seattle, Washington

Optimization of a Combined Nitinol/Polymer Device Using FEA ...................... 131
E. Konstantino, T. Feld, AngioScore, Inc., Alameda, California
S. Keidar, Tel Aviv, Israel
G. Gershony, John Muir Medical Center, Walnut Creek, California

A Numerical and Experimental Investigation into the Forces Generated when Cutting Biomaterials ............................................. 136
C.T. McCarthy, E. O'Dwyer, M. Hussey, M.D. Gilchrist, University College, Dublin, Ireland
N.P. O'Dowd, Imperial College, London, United Kingdom

Process Simulation Applications in the Medical Industry .................................. 142
D. Lambert, J. Walters, Scientific Forming Technologies Corporation, Columbus, Ohio

Nano and Microfabricated Structures

Functionally Gradient Diamondlike Carbon Nanocomposites for Medical Applications .... 149
R.J. Narayan, D. Scholvin, Georgia Institute of Technology, Atlanta, Georgia

Material Design for Neural Applications Using Carbon Nanofibers ..................... 155
J.L. McKenzie, R. Shi, T.J. Webster, Purdue University, West Lafayette, Indiana

Healthy Aims - Development of Implantable Microsystems Medical Devices ............. 161
S.B. Dunkerton, TWI Ltd/Medical Devices Faraday Partnership, Cambridge, United Kingdom
D. Hodgins, ETB Ltd., Cedicote, United Kingdom

Mechanical and Physical Properties of Medical Devices

Fluid Composition Influences Wear Testing of Artificial Knee Implants ............ 169
T. Schwenke, M.A. Wimmer, Rush University Medical Center, Chicago, Illinois
C. Kaddick, EndoLab GmbH, Rosenheim, Germany

The Development of Wear Resistant Titanium-Ceramic Composites for Orthopaedic Implant Devices .......................................................... 174

Characterization of Biomedical Wire for Optimum Performance in Suture Needle Manufacture and Use ......................................................... 180
D. Bradley, S. Chaney, S. Fischer, Fort Wayne Metals Research Products Corporation, Fort Wayne, Indiana

The Effect of Bundle Type on Cerclage Cable Fatigue Life .................................. 185
Effects of Surface Modification of Ti on Cement Bond Strengths .............................................. 187
P. Agarwal, Y. Oshida, Indiana University School of Dentistry, Indianapolis, Indiana
M. Ito, Matsumoto Dental University, Shiojiri, Nagano, Japan

Stainless Steel, Titanium and Cobalt-Base Alloy Developments

Development of Beta Titanium Alloys with Low Young's Modulus ............................................. 193
S. Hanada, T. Ozaki, H. Matsumoto, S. Watanabe, T. Miyazaki, M. Hasegawa, Tohoku University,
Sendai, Japan

Sandvik Bioline 1RK91 – an Advanced Material for Medical Device Manufacture ................. 199
S. Cowen, N. Haworth, Sandvik Bioline, Sheffield, United Kingdom
J. O. Nilsson, Sandvik Materials Technology, Sandviken, Sweden

Optimization of Melt Chemistry and Properties of Drawn Filled Tube (DFT®) Composite
Materials of 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy (UNS R30035)
Medical Grade Wire with Silver Core .............................................................................. 205
L. Kay, D. Bradley, Fort Wayne Metals Research Products Corporation, Fort Wayne, Indiana

Powder Injection Molding of Titanium Components ................................................................. 211
K.L. Simmons, E. A. Nyberg, K. S. Weil, Pacific Northwest National Laboratory,
Richland, Washington
M. Miller, University of Alabama, Birmingham, Alabama

Desirable Biocompatible and Physical Characteristics of Selected Stainless Steel Alloys and
Specialty Wire Materials for Use in the Design and Manufacture of Implants and
Medical Devices.................................................................................................................. 217
G. Kurisky, R. D’Ambrisi, Maryland Specialty Wire, Cockeysville, Maryland

Precision of Fit of the Procera® One-Piece Machined Titanium Implant Framework .......... 221
R.F. Wang, B.R. Lang, M.E. Razzoog, The University of Michigan, Ann Arbor, Michigan

In-Situ Formation of Ti Alloys Via Powder Injection Molding ................................................... 225
K.L. Simmons, E.A. Nyberg, K. S. Weil, Pacific Northwest National Laboratory,
Richland, Washington
M. Miller, University of Alabama, Birmingham, Alabama

A Study on Low Modulus Titanium Alloys for Biomedical Applications............................. 229
S.E. Kim, H. W. Jeong, Y.T. Hyun, Y.T. Lee, Korea Institute of Machinery and Materials,
Changwon, South Korea
Y.H. Park, J.H. Lee, Dong A University, Busan, South Korea

Imaging

Quantitative Assessment of Radiofrequency Attenuation Associated With NiTi Stents
in Magnetic Resonance Imaging ...................................................................................... 235
E. Walsh, A. Holton, University of Alabama, Birmingham, Alabama
R. Venugopalan, Codman and Shurtleff, A J&J Company, Raynham, Massachusetts

Tantalum Coated Carbon-Carbon Composite Material for Surgical Implants ................. 241
S. Eriksen, E. Christensen, B. Gillesberg, L. N. Langmaack, Danfoss Tantalum Technologies,
Lyngby, Denmark
H. Li, M. Lind, C. Bünger, Aarhus University Hospital, Aarhus, Denmark

Radiopaque Marking of Devices for X-Ray Imaging .............................................................. 247
R. Dickenson, Noble-Met, Ltd., Salem, Virginia

3D Imaging and Visualization of Engineering Materials via Medical and Industrial X-Ray
Computed Tomography ....................................................................................................... 253
J. M. Wells, JMW Associates, Mashpee, Massachusetts

Three-Dimensional Atomic Structure and Compostitonal Analysis of Medical Devices
with the Local Electrode Atom Probe .................................................................................. 259
Imago Scientific Instruments Corporation, Madison, Wisconsin

A Femoral Canal Sizing Device for Hip Implants.................................................................. 263
T. Norman, R. Chasnov, A. Gianettino, A. Julian, M. Michonski, J. Proctor, T. Thompson,
S. San Gregory, Cedarville University, Cedarville, Ohio
J. D. Blaha, University of Michigan, Ann Arbor, Michigan

Managing Post Production Change ...................................................................................... 267
C. Roy, J. Fessler, S. Medhekar, Exponent, Inc., Irvine, California

Cardiovascular Device Applications

Comparing and Optimizing Co-Cr Tubing Properties for Stent Applications....................... 274
P. Poncin, C. Millet, J. Chevy, Minitubes, Grenoble, France
J. L. Proft, Metallurgical Solutions, Foster City, California

Corrosion of the Nitinol Wire of Endovascular Prostheses: Does Nickel Ion Release Impair
the Devices Performance? ................................................................................................. 279
R. Guidoin, Y. Douville, G. Dionne, Laval University, Quebec City, Quebec, Canada
M. King, North Carolina State University, Raleigh, North Carolina
A. P. Legrand, ESPCI, Paris, France
P. Doppelt, CECM-CNRS, Vitry sur Seine, France

Analysis of Nitinol Stents after Long Term in-Vivo Exposure ................................................ 285
S. Walak, Boston Scientific Corporation, Watertown, Massachusetts

A Biomimetic Stent Coating to Reduce Thrombosis and Inflammation................................. 290
J. A. Neff, W. A. Takeguchi, T. Kupumbati, Allvivo, Inc., Lake Forest, California
J. Andersson, B. Nilsson, University Hospital, Uppsala, Sweden
F. Bexborn, K. Nilsson Ekdahl, University of Kalmar, Kalmar, Sweden

Development of Iridium Oxide as a Cardiovascular Stent Coating ........................................ 296
B. O'Brien, Boston Scientific Corporation, Galway, Ireland
C. Chandrasekaran, Boston Scientific Corporation, Redmond, Washington

Determination of Constricting Forces Required for an Adjustable Systemic to Pulmonary
Artery Shunt ....................................................................................................................... 302
N.V. Thuramalla, P. Rachakonda W. I. Douglas, C.F. Knapp, J.K. Knapp,
University of Kentucky, Lexington, Kentucky
Regulatory and Biocompatibility Issues for Medical Device Manufacturers

U.S. FDA Perspective on the Regulations of Cyanoacrylate Polymer Tissue Adhesives in Clinical Applications ........................................................... 309
G. J. Mattamal, U. S. Food and Drug Administration, Rockville, Maryland

Advanced Manufacturing Technologies

Processing of Biocompatible Materials via Metal and Ceramic Injection Molding .......... 318
J.L. Johnson, D.F. Heaney, The Pennsylvania State University, University Park, Pennsylvania

Advanced Electrochemical Finishing Techniques for Medical Device Applications .......... 324
A. Bonifas, E.J. Taylor, J. Sun, Faraday Technology, Inc., Clayton, Ohio

CAD-CAM-Technology for Medical Components ....................................................... 330
W. Saxler, J. Strohmann, T. Simmich, Alfred H. Schuette GmbH, Cologne, Germany

Non-Metallic Biomaterials

Mechanical Characterization of a Novel Biodegradable Composite for Use in Osteosynthesis Applications ......................................................... 336
S.D. Ramsay, L. Yang, R.M. Pilliar, J. P. Santerre, University of Toronto, Toronto, Ontario, Canada

Advances in Surgical Instrument Technologies

Techniques for Investigation of Surgical Cutting Instruments ........................................ 342
E. Price, G.A. Reilly, B.A.O. McCormack, Institute of Technology, Sligo, Ireland
A.C. Macey, Sligo General Hospital, Sligo, Ireland

A Durable and Lubricious Polymer Composite Coating for Medical Devices ................. 348
J.G. Nawrocki, R. E. Maurer, Ethicon, Inc., a J&J Company, Somerville, New Jersey

A Model of the Failure Process of Skin During Cutting ............................................... 354
C. Doran, Waterford Institute of Technology, Waterford, Ireland
B. McCormack, Institute of Technology, Sligo, Ireland
A. Macey, Sligo General Hospital, Sligo, Ireland

Corrosion

Interpretation of Corrosion Test Results and Prediction of Clinical Performance of Medical Devices ................................................................. 362
M. Marek, Georgia Institute of Technology, Atlanta, Georgia

Passivation Stability of Titanium ............................................................................... 368
Y. Oshida, Indiana University School of Dentistry, Indianapolis, Indiana
F. Farzin-Nia, ORMCO Corporation, Glendora, California
M. Ito, Matsumoto Dental University, Shiojiri, Nagano, Japan
W. Panyayong, Prince of Songkla University, Songkhla, Thailand

Effect of Grain Size on the Electrochemical Properties of Oxide Films on Titanium and
its Alloys For Orthopedic and Spinal Applications ................................................................. 373
I. Trausch, N. Istephanous, Medtronic Inc., Minneapolis, Minnesota
H. Rack, J.I. Qazi, Clemson University, Clemson, South Carolina

Effect of Radical Transfer Reaction by Free Oxygen on the Corrosion of Ti-Nb Implant Alloys ................................................................................................................................. 379
D. Zander, B. Heisterkamp, University of Dortmund, Dortmund, Germany

Effect of Temperature and pH on Corrosion Resistance of Nitinol ............................................... 385
A.R. Pelton, C. Trepanier, Nitinol Devices & Components, Fremont, California

Galvanic Corrosion of Cobalt-Base and Titanium-Base Implant Material Couples .................. 391
L. Zardiackas, M. Roach, University of Mississippi Medical Center, Jackson, Mississippi
J. Disegi, Synthes, West Chester, Pennsylvania

Acidic Fretting Tests of Oxidized Zr-2.5Nb, CoCr and SS Femoral Heads .............................. 396
V. Pawar, B. Jones, J. Sprague, A. Salehi, G. Hunter, Smith & Nephew, Inc., Inc., Memphis,
Tennessee

Electrolytic HA/ZrO$_2$ Double Layers Coating on Co-Cr-Mo Alloy for Orthopaedic Applications ................................................................................................................................. 402
S.K. Yen, C.M. Lin, G.S. Lin, S.H. Chen, National Chunghsing University, Taichung, Taiwan
Preface


In 2002 ASM International organized a Materials for Medical Devices (MMD) Task Force that evaluated the need and feasibility of sponsoring a conference on the topic area of biomaterials. After a year of analysis, organizing, and numerous teleconferences, the first *Materials and Processes for Medical Devices Conference* was held in Anaheim, California, on September 8–10, 2003. The number of technical presentations, exhibitors, and attendees at this conference exceeded the initial estimates and this gave the MMD Task Force an indication of the high level of interest in this technical subject matter. The MPMD Organizing Committee quickly responded by organizing a second conference described in these proceedings. Once again, the number of exhibitors and attendees exceeded the expectations, indicating the intense interest of this topic.

The overwhelming success of these two MPMD conferences is attributed to the organizing committee’s balance of medical device technology, new materials, new processes, testing issues, regulatory issues, and specific device application concerns. These topical areas are likely to be of interest to material scientists, metallurgical engineers, medical device design engineers, regulatory professionals, government agencies, and medical practitioners involved with the vascular, dental, and orthopedic business segments. By bringing professionals from these diverse backgrounds together in a common forum, the opportunity to transfer new material and process technologies is one of the beneficial outcomes of this conference.

Many volunteers from the medical devices industry, suppliers, regulatory agencies, and academia participated by organizing and contributing to the development of this outstanding program. We sincerely thank them for their dedication and commitment. We also thank the staff of ASM International for their assistance in executing the vision and plan of the 2004 MPMD Organizing Committee, as well as the co-sponsors of this event: ASTM F04 Committee, Society for Biomaterials, AAOS, SMST, CRS, and Biomat.net.

Mike Helmus
Co-Chair, MPMD Organizing Committee
Boston Scientific Corporation
Natick, MA

Dana Medlin
Co-Chair, MPMD Organizing Committee
Zimmer, Inc.
Warsaw, IN