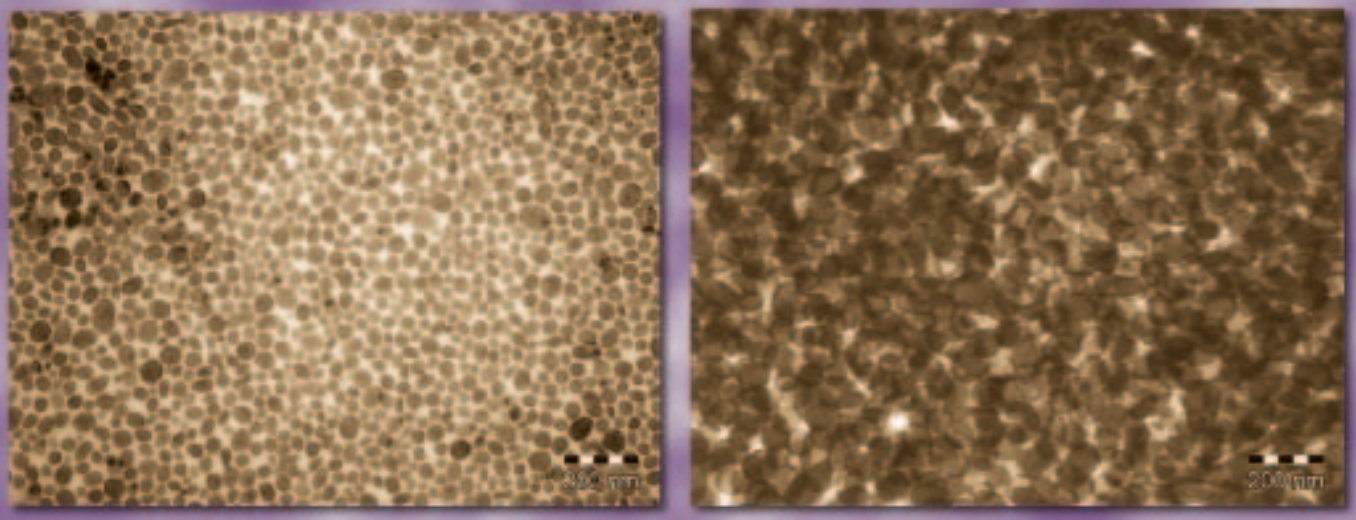
Five Tips for a Beautiful Experiment

BIOMATERIALS FORUM

Third Quarter 2008 • Volume 30, Issue 3



Polymerization Shrinkage and Microleakage of Dental Composites Evaluated using X-Ray Microcomputed Tomography

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BIOMATERIALS FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 30, Issue 3

Special Interest Group Reporters

BIOMATERIALS FORUM
SOCIETY FOR BIOMATERIALS
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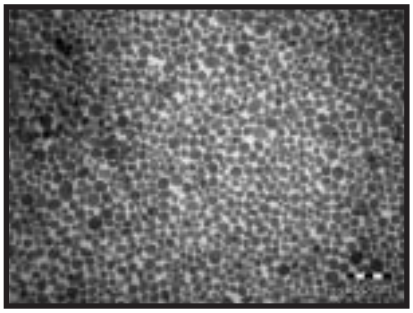
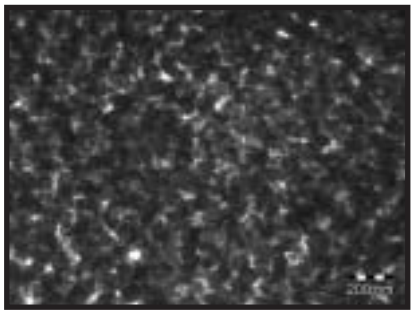
Features



Cover image 1: Transmission electron microscopy (TEM) image of a new dendritic polystyrene-polyisobutylene-polystyrene (SIBS)-type biomaterial with 9 wt% polystyrene content.



Cover image 2: TEM image of a new dendritic SIBS-type biomaterial with 30 wt% polystyrene content.

Photos courtesy of Dr. Judit E. Puskas,
Professor of Polymer Science, The University of Akron

Departments

The Torch

Biomaterials Community

Industry News

Letter to the Editor

The Torch
By Karen J.L. Burg

This issue includes a special tribute to Thomas Salthouse, one of the founding fathers of biomaterials and a former president of the Society For Biomaterials. Mr. Salthouse's histocompatibility work is widely regarded as foundational to the field of biomaterials. I remember as a graduate student, not being able to afford a copy of Dr. von Recum's *Handbook of Biomaterials Evaluation*, stealthily sneaking in to use the faculty photocopier to extract copies of the chapter by Salthouse. I used the same chapter this past week to provide an "evidence by those skilled in the art" argument to the U.S. Patent and Trademark Office. Note that the picture on page 8 of this issue shows Thomas Salthouse with the Handbook.

Compiling this special tribute made me think of how easy it is for us to take for granted, or even forget, these cornerstone nuggets of information. I attended a conference in the mid 1990s, where one of the speakers presented an overview of porosity and effect on tissue ingrowth with respect to tissue engineering, without a single reference to the vast wealth of literature from the 70s and 80s that demonstrated, among other things, the importance of surface texture and porosity to tissue ingrowth. I remember feeling surprised and somewhat disappointed that the audience had been deprived of the opportunity to learn about the historical context of cell-material *in vitro* tissue engineering concepts and deprived of the opportunity to capitalize on lessons already learned. Most of all, I felt that, in some sense, we were wasting time by reinventing a wheel.

I refer to this incident by way of example; it is interesting to look at the cyclical, often hysteretic, nature of research. Buzzwords and funding often drive us to rewrap established concepts in new terminology (think about "nanotechnology," "regenerative medicine," or "systems biology" – if we look at biomaterials research in retrospect, can't we re-categorize much of it as one of the three?). Often I feel that we neglect to re-introduce ourselves to the earlier literature in the field, thinking that we've outgrown the concepts, or in other cases, because some of the earlier literature is not electronically available. I challenge each of you to revisit the early Salthouse contributions, or those early contributions most relevant to your own aspect of biomaterials, and to reflect on how these concepts built the foundation for, and relate to, today's field.

Best wishes from Clemson,

Karen J.L. Burg
Hunter Endowed Chair & Professor of Bioengineering
Interim Vice Provost for Research & Innovation
Clemson University

From the President

The Torch
By Jeffrey A. Hubbell

From Excellence to Still More!

The Society For Biomaterials has transitioned from the past year into the present in very good condition, for which we thank the previous president, Martine LaBerge, and her team, and the past presidents and teams from the recent few years. The financial situation of the Society is strong and the intellectual vigor of our programming is excellent. One hallmark of Martine's leadership was responsiveness to the wishes of the membership, as it were, the demands of the customer. This is a hallmark we shall vigorously adopt. By both formal and informal methods, we hear the following:

- The Society has established excellent, cutting-edge research in areas such as tissue engineering and bioactive materials, yet we must not lose track of our roots as the intellectual hub behind the here-and-now medical device community and associated industry. Excellent programming in state-of-the-art biomaterials-related biology must continue, but this must not, and need not, be done at the expense of fundamental and applied materials science in metals, ceramics, and polymers. It is possible for our programming to be excellent in both domains.
- The Society pioneered development of the field of biointerface science, laying the foundations for both gene- and protein-chip bioanalytics, as well as understanding and modulating the behavior of biomolecules at surfaces. In spite of this fundamental work, we have perhaps missed recent opportunities for aggressive programming in continued development of the basic science, as well as driving the technologies to application in diagnostic devices and bioanalytical instrumentation. We must strengthen our programming in these exciting domains and resume our earlier leadership role.

The membership of the Society is remarkably broad in training and background, coming from bioengineering, surgery, materials science, and biology, for example. We are united in our interests in the interface between the materials system and the biological system, whether in the body, in the cell culture model, or in the bioanalytical instrument. Our programming, both at our meetings, in the tutorials at the meetings, and in our journals, must reflect this diversity and demonstrate the highest quality and innovation in those diverse aspects of our field. We are in a strong position to reach from excellence to even greater excellence!

Jeffrey A. Hubbell

Staff Update From Headquarters

By Dan Lemyre, Executive Director

Annual Business Meeting Summary

I am pleased to report that quorum was achieved at the Society For Biomaterials' 2008 Annual Business Meeting on May 29, 2008, at the World Biomaterials Congress in Amsterdam. Those present approved the proposed bylaws amendments by an overwhelming margin (more than 93% in all cases) and elected new members to the Awards, Ceremonies, and Nominations Committee, and the Membership Committee. In addition, the results of the 2008 Elections were announced: Lynne Jones from Johns Hopkins University was elected President-Elect, and Julia Babensee from the Georgia Institute of Technology was elected Member-At-Large. Alan Litsky reported that the Society finished 2007 with a net income of $131,660. Martine LaBerge reported that the Society would be launching a new Web site in the near future, and that the Branding Task Force had completed its objective with a new logo and tag line having been approved by Council:

Society For Biomaterials

Giving life to a world of materials

Committee Reporting

Each of the Society's committees is listed below, with the committee members who have been either elected or appointed, and the goals that each committee would like to accomplish during their one-year term.

Awards, Ceremonies, and Nominations Committee
Members include Michael Sefton, University of Toronto (Chair); Kristi Anseth, University of Colorado; Joel Bumgardner, University of Memphis; Andres Garcia, Georgia Institute of Technology; David Mooney, Harvard University and Narendra Vyavahare, Clemson University (Ex-Officio). The goals of the 2008-2009 committee are to solicit and evaluate nominees for the Society's awards and officers, to present Council with recommended candidates for 2009 Awards, and to present a slate of officers to the membership for election in 2009. In addition, this year's committee will supervise the revision of the Awards and Officers nominations Web sites.

Bylaws Committee
Members include Joel Bumgardner, University of Memphis (Chair); Barbara Blum, Wright Medical; Christopher Damien, Dentsply International; Shah Jahan, University of Memphis; and Jack Ricci, New York University. The goals of the 2007-2008 committee are to consider and report on questions and problems arising with respect to the bylaws of the corporation and to make recommendations for revisions to the Council.

Devices and Materials Committee
Members include Jeremy Gilbert, Syracuse University (Chair); Julie Hasenwinkel, Syracuse University; Mike Helmus, Advance Nanotech; Ebru Oral, Massachusetts General Hospital; and Nadim Hallab, Rush University Medical Center. The goals of the 2008-2009 committee are to collaborate with ASM on a new Research Materials database module and identify other areas of collaboration; to establish stronger links with partner societies in the area of regulatory matters (ASTM F-4 committee); and to develop a strategic plan to connect more strongly with medical device companies that undertake biomaterials research.

Education and Professional Development Committee
Members include Julie Trudel, Medtronic (Chair); Angela Au, Nutramax Laboratories; Ken Messier, Genzyme; Gene Park, Medtronic; Shane Woods, Synthes; and Margaret Philips, University of Texas (National Student Chapter President). The goals of the 2008-2009 committee are to develop programmatic content for the 2008 webinar series; assist the student chapter with program development for the 2009 Annual Meeting; to reestablish as many student chapters as possible; to reexamine the Student Chapter Bylaws; to explore other opportunities for student programming. In addition, the committee will continue to evaluate endorsement requests from other organizations and will explore other opportunities for program activity.

Finance Committee
Members include Antonios Mikos, Rice University (Chair); Aaron Goldstein, Virginia Polytechnic Institute; Lynne Jones, Johns Hopkins University; Johnna Temenoff, Georgia Institute of Technology and Emory University; and Alan Litsky, Ohio State University (Ex-Officio). The goals of the 2008-2009 Finance Committee include the implementation and oversight of the Board-approved investment and reserve policies.

Liaison Committee
Members include Molly Shoichet, University of Toronto (Chair); Kevin Healy, University of California-Berkeley; Kristi Anseth, University of Colorado; and Bill Wagner, University of Pittsburgh. Goals of the 2008-2009 committee include interacting with the 2012 WBC Organizing Committee on programmatic and organizational matters, and identifying opportunities for collaboration with the ORS, MRS, BMES and other organizations.

continued on page 4

continued from page 3

Long Range Planning Committee
Members include Lynne Jones, Johns Hopkins University (Chair); and Julia Babensee, Georgia Institute of Technology. The remaining committee members have yet to be named, but will be representative of the Society's membership segments in industry, government, and academia (faculty and students). The 2008-2009 committee will work to identify strategies to expand membership in all areas, and increase the involvement of clinicians. The committee will also conduct membership surveys to evaluate possible improvements to the Annual Meeting program planning process.

Meetings Committee
Members include Jeffrey Hubbell, Ecole Polytechnique Fédérale de Lausanne (Chair); Karen Burg, Clemson University; Alan Litsky, Ohio State University; and Julia Babensee, Georgia Institute of Technology. The goals of the 2008-2009 committee are to analyze 2007 annual meeting survey data; to evaluate venues for future meetings and social events; to assess the funding and sponsorship revenue of our annual meetings; to provide recommendations for increasing these sources of revenue to better offset meeting attendee registration costs.

Membership Committee
Members include Nicholas Ziats, Case Western Reserve University (Chair); Luis Avila, Genzyme; Alireza Khademhosseini, Harvard-MIT; Helen Lu, Columbia University; and Laura Suggs, University of Texas at Austin. The goals of the 2008-2009 committee are to create a member recruitment and retention plan; to evaluate inclusion of associate membership in meeting registration; to remove barriers to membership by redefining the eligibility criteria, and to continue promotion of SFB membership.

Presidents Advisory Committee
Comprised of all past presidents of the Society and is chaired by the Immediate Past President, Martine LaBerge. The goals of the 2008-2009 President's Advisory Committee are to provide support to the President and Council in the review of the Society's publications, to determine how well the SFB and the intellectual field are currently served by them and suggest changes if any; to complete an archival monograph describing the history of the Society; to address mechanisms to assure the financial support of scholarships and education activities of the Society.

Program Committee
Members include Andres Garcia, Georgia Institute of Technology (Chair); Karen Burg, Clemson University; Elliot Chaikof, Emory University; Jeffrey Hubbell, Ecole Polytechnique Fédérale de Lausanne; Erika Johnston, Genzyme; Lynne Jones, Johns Hopkins University; Martine LaBerge, Clemson University; Kinam Park, Purdue University; Christopher Siedlecki, Pennsylvania State University; and Tim Topoleski, University of Maryland Baltimore County. The goals of the 2008 committee are to develop and promote the Fall 2008 meeting on translational research, explore new presentation methods and education techniques, and foster engagement and collaboration with and between the Society's Special Interest Groups.

Publications Committee
Members include Ashutosh Chilkoti, Duke University; Syed Hossainy, Abbott Vascular; Peter Jarrett, Genzyme; and the editors of the Society's publications: James Anderson, Case Western Reserve University (JBMR-A); Harold Alexander, Orthogen (JBMR-B); Karen Burg, Clemson University (Biomaterials Forum); and Thomas Webster, Brown University (Web site). The goals of the 2007-2008 committee include identifying an editor for the forthcoming book series; exploring the possibility of peer review on the ASM International database; redeveloping the SFB Web site; and continuing to review all Society publications.
If you are interested in knowing more about a particular issue, policy or committee activity, or if you have any suggestions for improved membership services, please contact me directly at the SFB headquarters office:

Sincerely,

Dan Lemyre, CAE
Executive Director

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George Johnson's Five Tips for a Beautiful Experiment

By Guigen Zhang, Education Editor

On the flight back to Atlanta from Amsterdam after the 8th World Biomaterials Congress, I picked up a copy of the *Financial Times*. While almost all the articles in the Life and Arts section were interesting to read, a small piece on George Johnson's "Ten Most Beautiful Experiments" particularly caught my attention. This piece summarized Johnson's book in a short list of five tips, which I now pass on to you.

1. Make do with the tools at hand

To investigate the mysteries of motion, Galileo timed a metal ball rolling down an inclined wooden plane. Easy enough, except that there were no clocks back then. Instead, by singing to himself, Galileo could mark the ball's position on each upbeat. In the end he found that the distance the ball traveled increased according to the square of the time elapsed—an early clue that nature is mathematical.

2. Follow your obsessions

Isaac Newton was so desperate to find the secrets of light and vision that he inserted a blunt needle between his eye and his eye socket and wiggled it around, marveling at the hallucinations it created. He also stared at the sun as long as he could bear it, just to see what would happen. More productively, Newton held a prism to a hole in his window and found that white light is made from funneling together the colors of the spectrum. Everything, from rainbows to the iridescence of insect wings, suddenly made more sense.

3. Don't trust your elders

Common wisdom once held that things burned because they held a tangible something called phlogiston. Lavoisier showed that the agent of combustion was really oxygen. But he went on to propose his own canard: that heat was a fluid called caloric. It was left for another rebel, James Joule, to spin a paddle inside a can of water and show that the liquid got hotter. Heat was a form of motion.

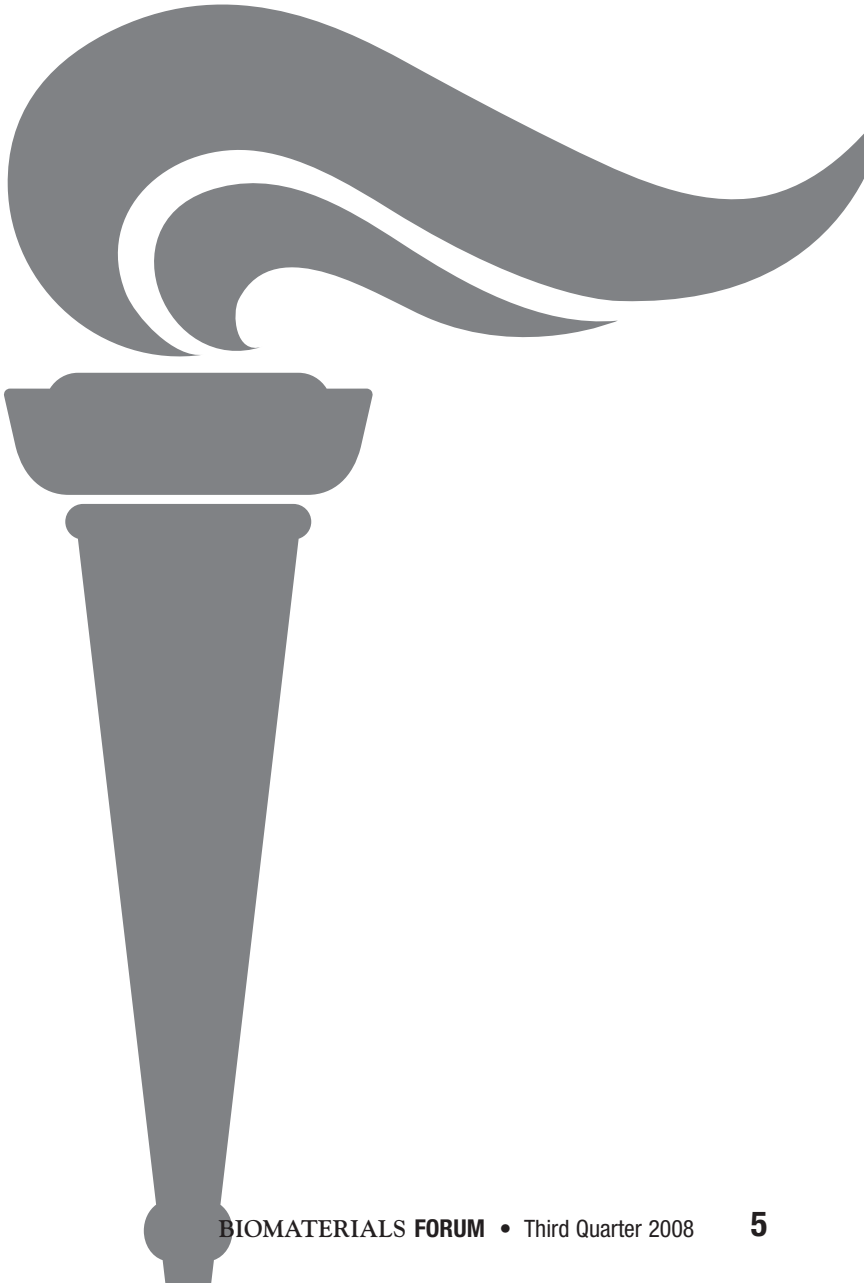
4. Don't rest on your laurels

As a young man, Michael Faraday found that a moving magnet generated electricity and that a moving electric charge generated magnetism—a connection that ensured his legacy. By middle age, he longed for more. With an Argand oil lamp and an electromagnet, he demonstrated that magnetism can twist a light beam. Three phenomena—electricity, magnetism, and light—had been tied into a single knot. Reality's order began to show through the confusion.

5. There are also beautiful failures

Albert Michelson set out to observe the movement of the earth against the ether, the invisible backdrop of space and time. When his experiments failed, he tried to explain away the results. But the truth ultimately prevailed. What he had so beautifully proved, to his own consternation, was that there is no ether—one of the most stunning results of modern science and the basis of Einstein's theory of special relativity.

I hope you will find these tips relevant in your world of scientific exploration and useful in devising your breakthrough, yet beautiful, experiments.



Joy Dunkers, Government News Contributing Editor
By Andras Vladar and Vincent Hackley

Polymerization Shrinkage and Microleakage of Dental Composites Evaluated Using X-ray Microcomputed Tomography

By Jirun Sun and Sheng Lin-Gibson*
NIST Polymers Division, Gaithersburg, MD 20899-8543

Photopolymerizable dimethacrylate composites are increasingly used as dental restoratives; however, volumetric contraction upon polymerization continues to be a major drawback. The curing of these materials proceeds through conversion of double bonds to single bonds, resulting in covalently bonded monomers and volumetric contraction. The percentage of shrinkage depends on the chemical structure, relative molecular mass, filler content, and degree of conversion of the resin. Polymerization shrinkage generates stress at the tooth/restorative interface and may lead to microleakage (gap between tooth and composite), recurrent caries (tooth decay), and premature failures of the restorations. The magnitude of stress and extent of microleakage depend on the restoration size and bonding geometry, with the latter often characterized by the C-factor (ratio of bonded surface to free surface). With a strong emphasis on moving toward clinically relevant studies, methods for measuring polymerization shrinkage under controlled geometries are highly desirable but still lacking.

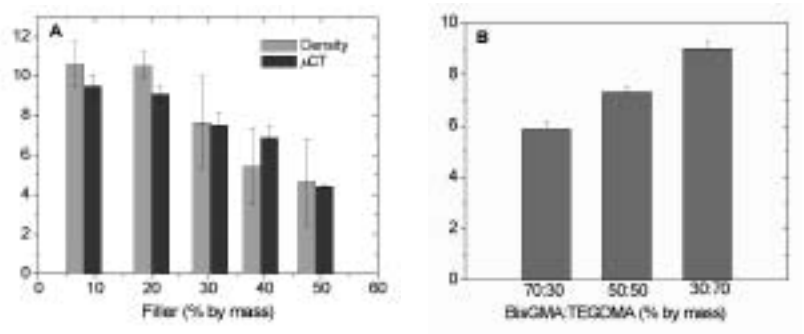


Figure 1 *A) Polymerization shrinkage of composites with different filler contents. B) Polymerization shrinkage determined by μCT of composites with constant 30 percent filler and different TEGDMA to BisGMA ratios. Error bars represent one standard deviation (n = 5) and are the estimates of standard uncertainty.*

Three-dimensional (3D) volume and position of objects can be measured with high spatial resolution using X-ray microcomputed tomography (μCT). The μCT has been widely accepted in biomedical research for examining bone and tooth structures, and for visualizing structural features in tissue engineering scaffolds, among other applications. The ability to accurately measure polymerization shrinkage, coupled with marginal adaptation in clinically relevant settings, would be ideal. However, a systematic investigation of μCT's ability to accurately determine the volume of restoratives or tooth structures and associated microleakage has not been undertaken.

Accurate and precise volume measurements for the composite before and after photopolymerization are necessary in order to calculate the correct shrinkage value. Accurate image analyses require sufficient contrast between the object (composite) and background. In addition, the selection of appropriate segmentation values that convert data from grayscale to binary images is critical in the image analysis procedure. Once the threshold value is set, stacks of 2D images can be compiled to reconstruct the 3D object, from which the composite volume can be determined.

To assess the feasibility of μCT as a viable technique for routine characterization of polymerization shrinkage, the volumes of composite samples before and after photopolymerization were examined. Composites with varying filler content and co-monomer composition were prepared for this purpose. The resin was a binary mixture of commonly used dental monomers (2,2-Bis(4-(2-hydroxy-3-methacryloxypropoxy)phenyl)propane (BisGMA) and triethyleneglycol dimethacrylate (TEGDMA)). The filler phase was comprised of a mixture of barium boroaluminosilicate glass (BBS) and fumed amorphous silica (OX50). The shrinkage was expected to change systematically, and these values were compared with results obtained by other means.

To validate the accuracy of the volumes determined by μCT, results obtained via μCT were compared with those calculated from the mass and density of the cured composites. The volumes obtained by these two independent measurements were consistent with each other, deviating by less than 2.5 percent. These results indicate that μCT can be used to accurately evaluate the volume of composites.

The above results implied that the shrinkage values could be obtained with good accuracy. In the following, we examined the use of μCT for determining polymerization shrinkage. The shrinkage was calculated based on the change of volume of composites before and after curing. Polymerization shrinkage results measured by μCT and density calculations for the series of samples with varying filler content are illustrated in Figure 1A. Since the filler does not compress, the polymerization shrinkage is expected to increase as the filler content

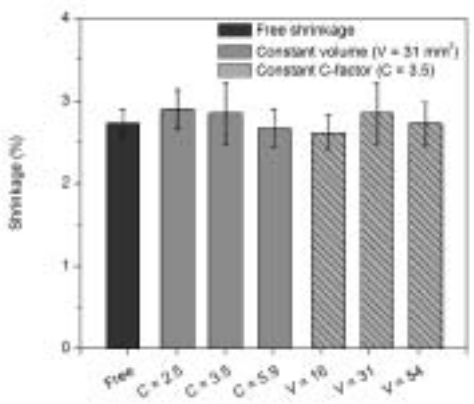


Figure 2 *Polymerization shrinkage determined for unconstrained sample geometries (free) and constrained sample geometries, varying either the C-factor or total sample volume. Error bars represent one standard deviation (n = 3) and are the estimates of standard uncertainty.*

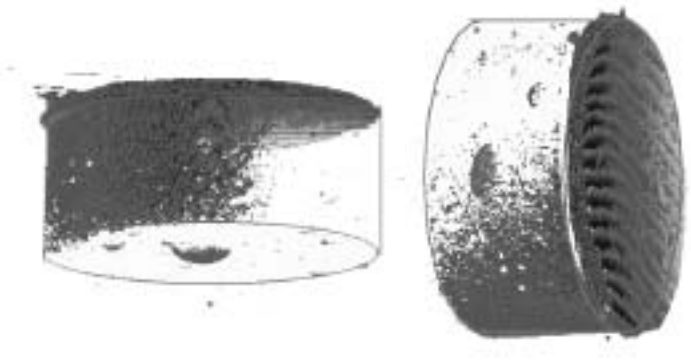


Figure 3 *3D projection images (from two different viewing angles) of microleakage predicted using μCT, comparing images of uncured and cured composites. The colored areas indicate areas of potential microleakage.*

decreases. Results from the two measurements were consistent with each other and with the expected trend. Analyses using analysis of variance (ANOVA) showed no significant statistical difference between results obtained from μCT and density changes. The second series of composites were used to test the ability of μCT to characterize polymerization shrinkage of materials with varying chemical composition. Results from μCT were in accordance with the expected trend, with compositions with higher TEGDMA concentration exhibiting higher polymerization shrinkage (Figure 1B).

The effects of C-factor and sample volume on composite shrinkage were also examined. As mentioned previously, cavity design, which is characterized by C-factor, and volume affect clinical performance. The current study separates the two parameters and examines the effect of each parameter independently by using model poly(methyl methacrylate) cavities. The C-factors and volumes were adjusted by controlling the cylindrical cavity height and diameter. For a given material, polymerization shrinkage values were comparable in experiments that held the cavity design at a constant volume with different C-factors and at a constant C-factor with different volumes (Figure 2). The results indicate that the shrinkage of this composite in a constrained holder is not affected by C-factor or sample volume. It can be concluded that the observed differences in interfacial stress and subsequent microleakage are attributed to the constrained sample geometry.

Further evaluation of images obtained before and after polymerization provides a mechanism for locating microleakage. The samples were fixed to minimize movement during experimental scans. Fiduciary markers (glass beads) were embedded at several locations within the sample chamber, and were used to correct for position changes between experimental scans if necessary. The μCT produced stacks of x-y image slices that were combined to generate 3D images. The position and volume of composites, before and after photopolymerization, were compared slice-by-slice, precisely to each voxel, using ImageJ calculation software. The 3D images of composites after curing were subtracted from those obtained prior to curing, resulting in a 3D representation of the change in volume. 3D projection images of one composite at two different viewing angles are illustrated in Figure 3. The colored regions indicate the positions at which the polymerized composite contracted from the unpolymerized composite. It is clear that significant shrinkage occurred at the top free surface. Moreover, position shifts were also detected along the composite-cavity interface, indicative of microleakage. In general, microleakage is non-uniform, as depicted in Figure 3.

The present study demonstrates that μCT can be used to effectively characterize the volume of polymeric dental composites before and after polymerization, thus allowing the determination of polymerization shrinkage. The applicability of this method was validated on multiple experimental and commercial materials (not shown). The ability to characterize polymerization shrinkage using μCT overcomes typical measurement issues associated with shrinkage measurements. Here, we have also shown a way to evaluate microleakage and its spatial distribution by precisely controlling the sample position, and calculating the volume changes at defined locations. The polymerization shrinkages values for constrained geometries were statistically identical with those measured in an unconstrained geometry. For all samples evaluated, the microleakage was non-uniform, highlighting the value of this comprehensive evaluation method.

Financial support was provided through an NIDCR/NIST Interagency Agreement Y1-DE-7005-01. The authors thank Drs. Marcus T. Cicerone, Joseph M. Antonucci, and Nancy J. Lin for their helpful discussions. The dental resins were kindly donated by Esstech Inc. Certain equipment, instruments, or materials are identified in this paper in order to adequately specify the experimental details. Such identification does not imply recommendation by the National Institute of Standards and Technology nor does it imply the materials are necessarily the best available for the purpose.

For more information on this topic, contact slgibson@nist.gov (NIST Polymers Division) and see "X-ray microcomputed tomography for measuring polymerization shrinkage of polymeric dental composites" Dental Materials, 24: 228-234, 2008.

In Remembrance

Thomas Newton Salthouse, 92, of Bethesda, Md., died April 17, 2008. Born March 8, 1916, in Fleetwood, England, he was educated at Merchant Venturer's College, Bristol University, England.

From 1942 to 1947 he served as clinical biochemist at a major English hospital, then served as Chief Technologist at the University College of East Africa Medical School until 1956. He became radiation biologist for Atomic Energy of Canada until 1959, then emigrated to the United States where he served as Research Scientist at E. I. DuPont, then E. R. Squibb, and finally Ethicon in Somerville, N.J., the research division of Johnson & Johnson. At Ethicon, he rose to the rank of Distinguished Scientist, retiring in 1981. He later served as Visiting Professor of Bioengineering at Clemson University from 1982 to 1988.

He was the author of numerous scientific papers in professional journals and of text chapters in major medical and materials books, including the Handbook of Biomaterials Evaluation. Among his many honors, in 1942 he became an Associate and later a Fellow of the Institute of Biomedical Sciences in Bacteriology & Chemical Pathology; in 1956 he was elected Fellow of the Royal Photographic Society for his medical photography, and in 1973 received the Diplomate of the Royal Microscopical Society for his medical microscopy. He was elected a Fellow of the New York Academy of Sciences, and was presented the Phillip Hoffman Award and the Clemson Award for outstanding contributions to biomaterials. He served as a member of the Histochemical Society, the Society for Cell Biology, and the Society of Toxicology. He also served as secretary-treasurer of the Society For Biomaterials from 1976-78 and as president from 1980-81. He sat on the editorial boards of professional journals, and was an invited speaker and presenter at numerous international conferences throughout North America and Europe.

His career in biomedical research spanned nearly 50 years. His ground-breaking work differentiating phospholipids in brain tissues served as the basis for later advances in treating some brain diseases. His major scientific achievements include research on cellular mechanisms in tissue response to surgical implantation of various devices (sutures, implants, reconstruction, etc.).

He was deeply devoted to his family, and will be profoundly missed by all who were privileged to be part of his life.

Remembrances of "Good Old Days and Thomas N. Salthouse"

By Dr. Jack Lemons,
Professor of Dentistry,
University of Alabama at Birmingham

We were truly multidisciplinary as we gathered annually and at other sites during the pre- Clemson, Clemson University, and Society For Biomaterials meetings. All interacted within social and lecture/discussion sessions and all were part of a steep learning curve. Synthetic and other substances as ceramic, polymeric, metallic, combination, and composite structures were considered in terms of the compatibility of exchanges as we attempted to understand biocompatibility. Groups of interest/focus evolved with leadership from both the physical and biological sciences. Some, like Tom Salthouse, demonstrated in-depth understanding and leadership that enhanced our interest in learning from him, his associates, and their investigators. As one example, the overall information, presentation, and publication on the roles of the physical size of polymeric biomaterials (suture-like), and cell/tissue–biomaterial interactions at micrometer dimensions captured significant interest and respect. These contributions constituted one area that forged many of the important aspects of the evolving discipline of biomaterials science and applications.

Importantly, Tom Salthouse was a true professional and a gentleman as an investigator, leader, and highly respected friend. We, the members of the world community of biomaterials, owe a debt of gratitude to Mr. Salthouse and remembrances of him and his abilities will continue as an example of what we collectively should represent.

Tom Salthouse Memoriam

By Dr. Shalaby W. Shalaby,
President and R&D Director, Poly-Med, Inc.

I met Tom in the early 1970s shortly after joining Ethicon Inc. at the onset of feverish pioneering research on absorbable polymers and their use, particularly for sutures. Before long, I began to work with Tom and recognized him as a model scientist, true gentleman, disciplined researcher, and exceptional teacher with a charming British accent, quiet sense of humor, and practical, American optimistic vision for the future. In the budding area of biomaterials, as a truly interdisciplinary field, Tom's pioneering work and convincing views in the histopathology of absorbable polymers have been applauded for more than the past three decades by many scientists, engineers, and clinicians who have cited his work in most relevant publications. All of his contemporaries and the younger generation of biomaterials scientists and engineers will sorely miss him, and he will be fondly remembered as a legend in the field.

BioInk

Steve T. Lin, Industrial News Contributing Editor
From Press Releases

Advanced Medical Optics Inc. (Santa Ana, Calif.), specializing in ophthalmic surgical devices and eye care products, announced U.S. FDA clearance for the iFS™ Advanced Femtosecond Laser. Capable of creating a corneal flap during the LASIK procedure in less than 10 seconds, the iFS Advanced Femtosecond Laser's inverted bevel-in side cut angle is designed to provide a virtually effortless flap lift, increase post-operative flap adhesion, and enhance the biomechanical stability of the post-LASIK cornea. With full customization capabilities, it also produces an elliptical flap to enhance surgical options and includes IntraLase-Enabled Keratoplasty (IEK).

CSMG Technologies (Corpus Christi, Texas), a technology management company, announced it has received approval of its fourth U.S. patent. The approval is for a key divisional application for Bonding of Soft Biological Tissues by Passing High Frequency Electric Current Therethrough for CSMG Technologies subsidiary Live Tissue Connects (LTC) platform tissue bonding/welding technology. LTC's surgical tissue bonding/welding device is a patented platform technology that bonds and reconnects human soft tissue through fusion, in contrast with conventional wound closing devices such as sutures, staples, sealant, or glues.

Edwards Lifesciences Corp. (Irvine, Calif.) announced that the first U.S. patients have received an Edwards heart valve implant in order to address a congenital condition in which the valve between the right ventricle and the pulmonary artery is nonfunctional. The approach involves taking the Sapien valve, which is compressed onto a balloon to the approximate diameter of a pencil, and threading it through the patient's circulatory system from a vessel in the leg to the patient's pulmonary valve. The trial, which received conditional approval from the U.S. FDA in late 2007, will include 30 patients at three hospitals. The data will ultimately be used to support its FDA application to commercialize the product in the United States.

Life Science Intelligence (Huntington Beach, Calif.) predicted, in their *2008 U.S. Markets for Spinal Disc Repair and Replacement Technologies* report, that the U.S. market for artificial disc replacement will grow from $55 million in 2007 to $440 million by 2013. The report states that artificial disc replacement technologies were expected to rapidly penetrate the market for spinal fusion patients due to their potential to preserve motion, limit further degeneration, and avoid the need for fusion. However, since the approval of DePuy Spine's Charité for lumbar disc replacement in October 2004, growth has been restrained by reimbursement challenges, limited long-term data, and the need to use an anterior approach for lumbar disc replacement. According to the report, a number of products should be approved by 2013 and growth in lumbar and cervical disc replacements will increase due to positive developments in reimbursement, favorable clinical results, and the use of alternatives to the anterior approach. Emerging markets such as annulus repair and nucleus repair/replacement could begin to limit the growth of artificial discs toward the end of the forecast period.

Thoratec Corp. (Pleasanton, Calif.) announced it has received FDA approval of a PMA application, allowing the use of HeartMate II LVAS (Left Ventricular Assist System) as a bridge-to-transplantation (BTT) in patients suffering from advanced-stage heart failure. The HeartMate II is a mechanical circulatory support device intended for a broad range of advanced-stage heart failure patients. An axial flow device, the HeartMate II can pump up to 10 liters of blood per minute, the full output of a healthy heart, and is designed to provide long-term cardiac support. The device is implanted alongside a patient's native heart and takes over the pumping ability of the weakened heart's left ventricle.

According to the **U.S. Food and Drug Administration**, the recent contaminated heparin scandal has drawn attention to U.S. FDA policies on foreign facilities and imported products. Congress is considering legislation that would hold FDA to certain facility inspection requirements and call for country-of-origin labels on devices. The FDA Globalization Act of 2008 would affect the food, drug, cosmetics, and device industries. Provisions of the FDA Globalization Act of 2008 Draft Related to Devices include:

- Annual registration with the FDA of device facilities operating in the United States or exporting products to the United States. A registration fee would cover the FDA inspection cost.
- FDA inspection of foreign and domestic facilities every two years.
- Device labeling that indicates the country of manufacture.
- Unique identification numbers for device facilities and importers, which would identify parties involved in a crisis sooner.
- A dedicated foreign inspection staff to monitor foreign facilities.
- Closing or consolidation of FDA field labs or district offices prohibited.

U.S. Solicitor General Paul D. Clement filed an amicus brief with the Supreme Court, supporting drugmaker **Wyeth's** (Madison, N.J.) argument that FDA approval preempts the right of a consumer to sue a manufacturer in state court if a drug or device later causes injury. The solicitor general determines the cases in which Supreme Court review will be sought by the federal government and the positions it will take before the court, conducts oral arguments, and determines whether the government will participate as an amicus curiae or intervene in cases in any appellate court. The high court is set to hear the case in October of Wyeth v. Diana Levine, a Vermont woman who alleged she lost her arm from adverse events tied to Wyeth's nausea and motion sickness drug Phenergan (promethazine). Consumer advocates have argued that a ruling in favor of Wyeth would shield drugmakers from the responsibility of ensuring their products are safe and would weaken manufacturers' economic incentive to take corrective actions.

Discover the Difference

Bose® Technologies make for Tissue Engineering

Multi-specimen ElectroForce® BioDynamic® Test Instrument

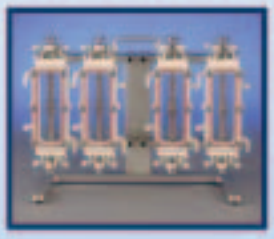
ElectroForce® test instruments, by incorporating proprietary Bose® motor technologies and WinTest® controls, offer exceptional fidelity, precision and versatility for biomaterials and tissue engineering applications. Bose multi-specimen BioDynamic™ test instruments provide a new standard of performance for characterization and stimulation of multiple biological specimens within a cell culture media environment.

Bose BioDynamic compact frames are suitable for use in a cell culture incubator, and all components in contact with samples and fluid are sterilizable. Individual specimen chambers can be harvested during an experiment so that time studies can be performed. Additionally, chambers can be rotated through the frame for intermittent mechanical loading and characterization.

Integrated Loading and Measurement

- Combinations of pulsatile flow and tension/compression loading can be used for biomaterials, orthopaedic constructs and tubular specimens such as blood vessels, bladder and trachea tissues.
- A load cell and pressure transducer are provided for each specimen for mechanical properties characterization. An optional laser micrometer is available for measuring the outer diameter of a tubular specimen to create pressure-diameter curves.

Convenient Specimen Handling



- Chambers can be mounted horizontally or vertically in the stand provided to allow easy assembly in a sterile flow hood or on a bench-top.
- Horizontally mounted chambers can be partially filled with fluid to facilitate specimen mounting.
- The chamber stand can also be used for the incubation of static control samples that are not subject to mechanical loading.

Flow Loop Flexibility

- Complete flow loops are provided with all BioDynamic configurations, and each loop includes the pump, reservoir bottle, tubing, fittings and autoclavable filter for gas exchange at the reservoir bottle.
- Independent flow loops for each specimen eliminate random fluid flow splitting so that fluid flow profiles are similar between specimens.
- A single reservoir bottle may be used when fluid is shared among all samples, or four independent bottles can be utilized if different cells, scaffolds or cell culture media are used in each chamber.

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