SurFACTS in Biomaterials

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Surface Modification and Biological Response of Novel Biomaterials for Medical Devices

Advancements in biomaterials are contributing to the well-being and longevity of patients

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Global Market

The global market for biomaterials is estimated to reach $88.4 billion at a compound annual rate of 15 percent by 2017. The biomaterial applications market can be broadly segmented into orthopedic, cardiovascular, neurological, dental, tissue engineering, wound healing, plastic surgery, ophthalmological and other applications such as gastrointestinal, urinary, bariatric surgery and drug delivery systems as depicted in figure 1. In 2012, the cardiovascular biomaterial segment contributed 34.5 percent to the global biomaterial market, followed by the orthopedic segment with an 8 percent annual growth rate from $6 billion in 2007 to $13 billion by 2017. The highest growth in the biomaterials market has been that of biodegradable polymers, which is increasing by 22.1 percent since 2012 due to tremendous ongoing research and their use in a wide range of applications.[1]

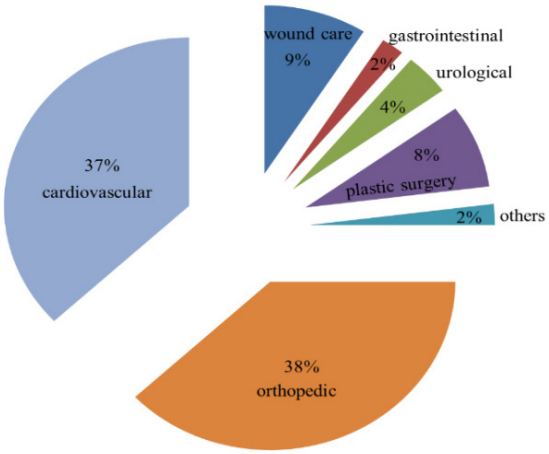

Figure 1. World market of biomaterials [2]

North America is the largest biomaterial market and is expected to grow due to an increase in the aging population. Similarly, the Asian market is expected to grow at a rate of 21.5 percent due to rising awareness of biomaterial products as a result of conferences and collaborations.[1] To date, there are approximately 135 million Americans over 45, the age at which the incidence of heart diseases is documented to increase. Many will require stents (small metal-mesh sleeves implanted in unclogged arteries by angioplasty). There has also been a major increase in the demand for prosthetics within the U.S. as well as world-wide. Thirty years ago, the average age for a hip replacement patient was 78 years, while today the average age is 59 years. In 2000, the total number of primary total joint replacement (TJR) and revision TJR procedures was 400,000 and 152,000 respectively. However, by 2020 primary and revision TJRs are projected to

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Call for Members

Dear colleague,

Thank you for your support of the Surfaces in Biomaterials Foundation. The Foundation appreciates members that are dedicated to exploring creative solutions to technical challenges by fostering education and multidisciplinary cooperation among industrial, academic, clinical and regulatory communities.

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- Input to shape the discussion and program for the national Biointerface conference
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- A subscription to the Foundation newsletter, SurFACTS in Biomaterials, which features articles relevant to the surface science and medical device industries and cutting edge technology
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If you have any questions or requests for further information, please do not hesitate to contact the Foundation. Thank you. We look forward to seeing you in Scottsdale for Biointerface.

Sincerely,

Joe Chinn, Josh Simon
Surfaces in Biomaterials Foundation Membership Committee

25th Annual BioInterface Workshop & Symposium

September 21 – 23 | Fairmont Scottsdale Princess | Scottsdale, Arizona – USA

Keynote Speaker: Dr. Stuart Williams

Surface modification of biomaterials has resulted in new generations of medical devices with improved function. These modifications were originally relatively simple changes in surface chemistries and have evolved to include chemistries that directly alter the tissue response following device implantation. Cell-based biomaterial modifications continue to evolve and now include the technology known as 3D Bioprinting. This evolution in surface modification technology will be explored with the goal of creating a new generation of "Bioficial" devices and organs.

Workshop: Hemocompatibility Technologies, Models, and Testing

Co-Chair: Chander Chawla, DSM Biomedical Inc.
Co-Chair: Bill Theilacker, Medtronic, Inc.

Session 1: CRM – Surface Characterization

Chair: Jill Mendelson, Medtronic CardioVascular
Invited Speaker: Luke Hanley, University of Illinois at Chicago

Session 2: Chemical and Physical Strategies to Regulate Biological Adhesion

Co-Chair: Chelsea Magin, Sharklet Technologies, Inc.
Co-Chair: Ethan Mann, Sharklet Technologies, Inc.
Invited Speaker: Joanna Aizenberg Harvard University

Session 3: Ophthalmic Drug Delivery

Chair: Sarah van de Graaf, DSM Biomedical Inc.
Invited Speaker: Thierry Nivaggioli, Genentech

Session 5: Integration for Tissue Repair and Regeneration

Chair: Anthony Ratcliffe, Synthasome
Invited Speaker: Tony Mikos, Rice University

Session 6: 3D Printing in Medical Applications

Chair: Chander Chawla, DSM Biomedical Inc.
Invited Speaker: Roger Narayan, NC State

Session 7: Neuroendovascular

Chair: Ramanathan Kadirvel, Mayo Clinic
Invited Speaker: David Kallmes, Mayo Clinic

Session 8: Drug Coated Balloons

Chair: Joe McGonigle, SurModics, Inc
Invited Speaker: Michael Joner, CVPath

Register today!

SIBF BioInterface Excellence in Surface Science Award

Dr. Gail Naughton founded Histogen, Inc. in 2007, and currently serves as CEO and Chairman of the Board for the company. She has spent more than 30 years extensively researching the tissue engineering process, holds more than 100 U.S. and foreign patents, and has been extensively published in the field.

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DSM

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increase to 1.1 billion and 400,000 respectively.[3]

Biomaterials

Recent advances in biomaterials have enabled medical practitioners to replace diseased body parts or to assist in the healing process. While the former application requires biomaterial implants to permanently remain in the body, the latter application only requires that the implant remain in the body temporarily or provide therapeutic treatments. In situations where a permanent implant is used for a temporary application, additional surgeries are required to remove these implants once the healing process is complete. This removal process increases medical costs and risk of patient morbidity. Several first generation biomaterials such as stainless steel, commercially pure titanium and its alloys, cobalt chromium, etc., were primarily focused on acceptable physical properties. However, more recently emphasis has been placed on controlling cell proliferation, inflammatory reactions and thrombosis for materials used for cardiovascular therapy; and reducing stress shielding while enhancing osseintegration for orthopedic applications.

Munroe et al. have developed biodegradable metal matrix composites (MMCs) or alloys and coatings for the manufacture of stents that will obviate the need for repeated surgical procedures.[4, 5, 6, 7] Biodegradable magnesium alloys are ideal candidates as they contain elements that are essential in human metabolic and healing processes. The biocompatibility and corrosion rate of magnesium-zinc-calcium (MZC) and other MMCs containing gadolinium (Gd) and hydroxy-apatite (HA) were dependent on basic surface characteristics, such as elemental concentration, nature and thickness of the oxide/polymer layer, surface morphology, surface charge and wettability that are modified by surface treatments and polymer coating.[4] Furthermore, the application of a biodegradable polymer coating reduces the initial degradation rate of MZC.

A new generation of titanium alloys [Ti-Mo-Zr-Fe (TMZF) and Ti-Mo-Nb-Fe (TMNF)] with high strength-to-weight ratio have been investigated. In the case of orthopedic implant materials, density and elastic modulus are critical properties to be considered. The implant material should have an elastic modulus similar to that of human bone, which continuously undergoes remodeling due to changes in mechanical load that could lead to stress shielding. Resultantly, the implant bears most of the load causing the bone to experience a reduced load, which leads to reduced bone density and other complications. Depending on the desired application of a medical device, a variety of factors must be considered. For example, if the intended use of the device is blood-contacting such as catheter, grafts and stents, then blood compatibility or hemocompatibility of the biomaterial is crucial, whereas for prosthetic applications, osseointegration is the key factor. One technique that has been found to be useful for enhancing osseointegration by modifying surface texture and morphology is anodization (ANO). The effect of the anodization of TMZF and TMNF on cell viability has been investigated and briefly discussed.

Surface Modifications

In order to achieve improved biological response between bioimplants and human physiological fluids, researchers have focused on surface characteristics such as wettability, roughness, morphology, texture, charge and chemical composition which influence cellular activity. Over the past decade, surface modification techniques such as surface oxidation, polymer coating and surface functionalization have been developed to impart distinctive surface features that control cellular activities or generate bio-active surfaces for therapeutic remedies. The aforementioned surface characteristics in relation to cell viability and platelet adhesion are discussed elsewhere[8, 9, 10] by a multidisciplinary team of researchers from the Advanced Materials Laboratory at Florida International University.

Various surface modification techniques have been applied to improve corrosion resistance such as electropolishing, magnetoelectropolishing, anodization and polymer coating of which the latter two are the focus of this article. Anodization is an electrolytic passivation process by which oxide layer thickness, composition and color can be controlled by the temperature, solution chemistry, time and applied voltage. Polymer coating is also a viable option to control corrosion rates, particularly for highly reactive biosorbable magnesium alloys as it restricts diffusion-controlled redox reactions. Degradable materials are of value

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in short term applications, such as in sutures, supportive meshes, drug delivery, orthopedic, osteosynthesis, vascular graft, stents, etc. where they can minimize the number of invasive procedures. Such materials should exhibit good mechanical properties and homogeneous degradation with non-toxic degradation products.

Results

Alloyed and surface treated Mg alloys exhibited modified surface morphology similar to that of human bone as shown in figure 2a. Figure 2b compares the corrosion rates of mechanically polished (MP) and anodized biodegradable Mg alloys. Although anodization resulted in lower corrosion rates, MZC was considered most appropriate for cardiovascular applications due to superior biocompatibility and mechanical properties.[4] Anodization resulted in the formation of a distinct oxide layer of thickness 5-10 µm (figure 2c) as compared with that produced on MP MZC (~20-50 nm) under ambient conditions.

The effect of roughness on water

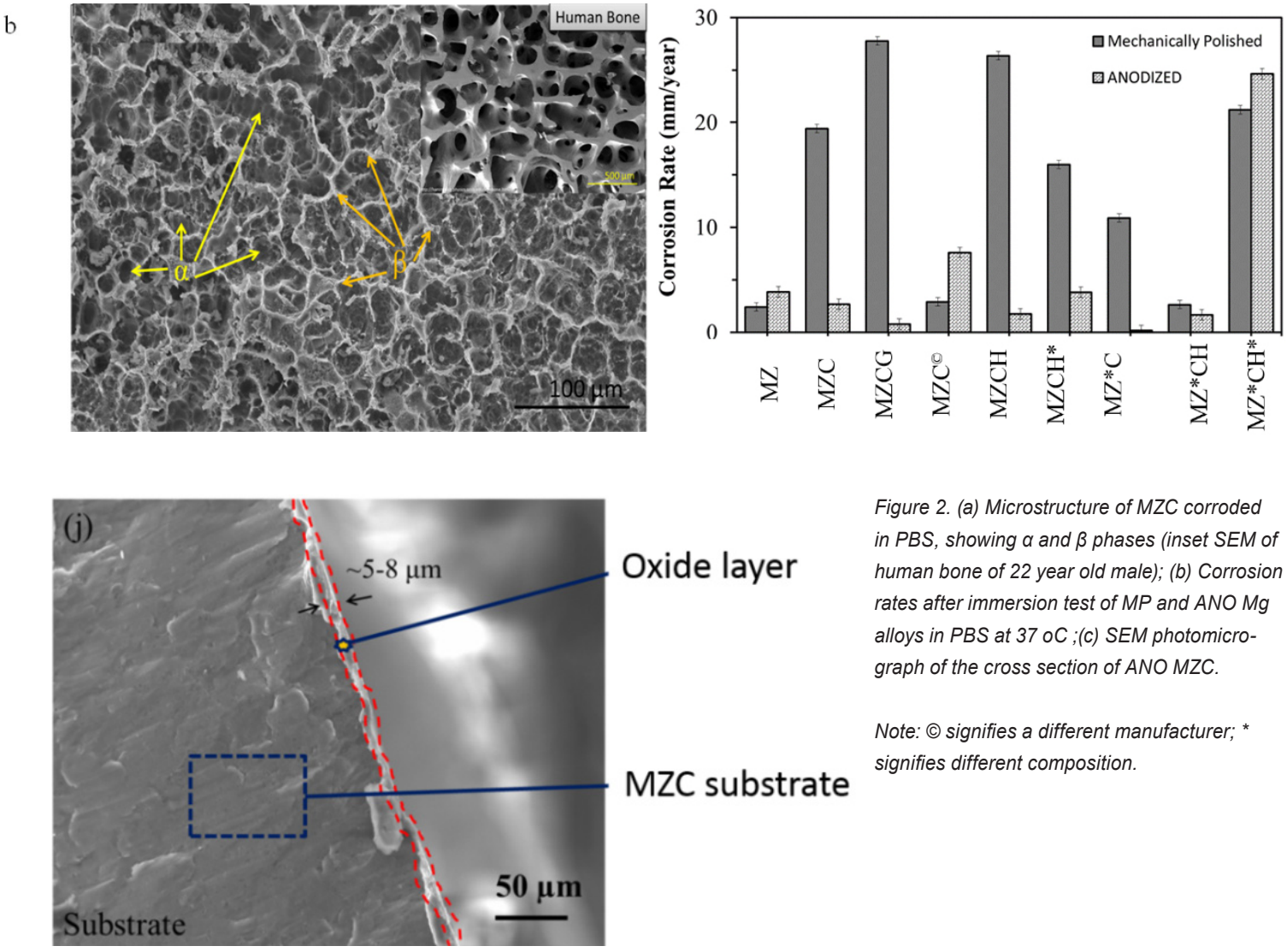

Figure 2. (a) Microstructure of MZC corroded in PBS, showing α and β phases (inset SEM of human bone of 22 year old male); (b) Corrosion rates after immersion test of MP and ANO Mg alloys in PBS at 37 oC ;(c) SEM photomicrograph of the cross section of ANO MZC.

*Note: © signifies a different manufacturer; * signifies different composition.*

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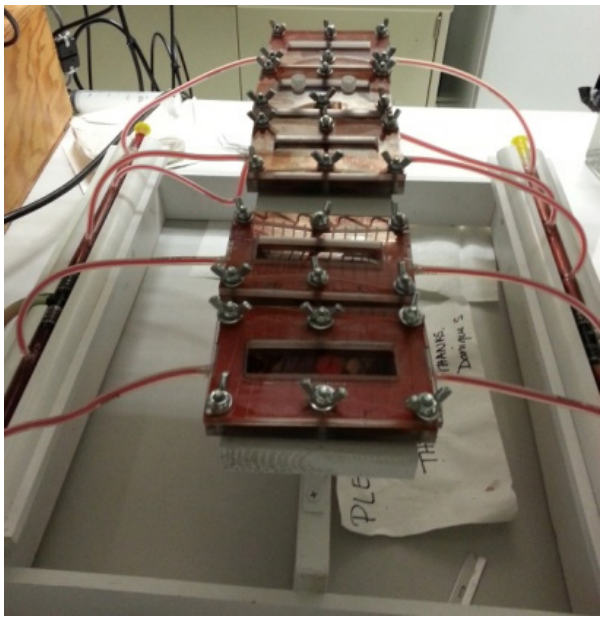
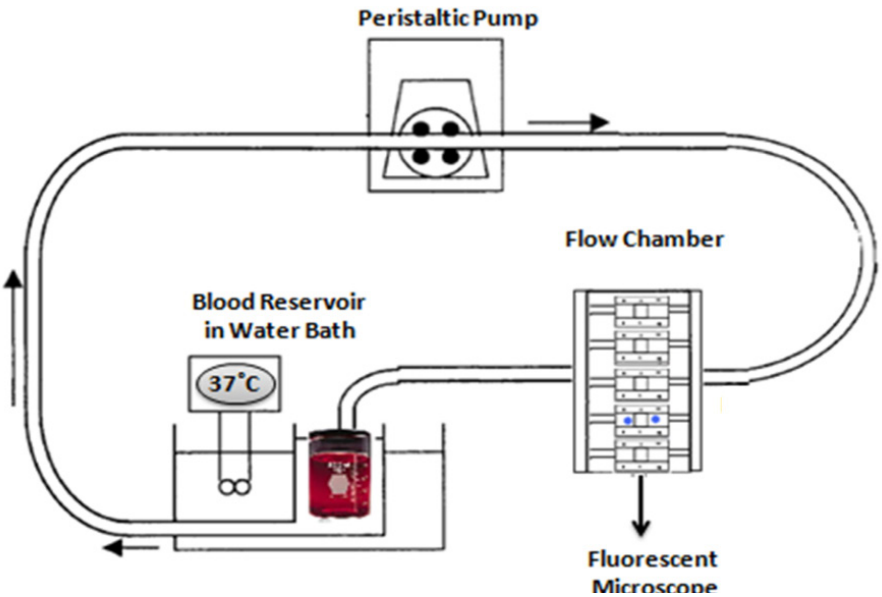
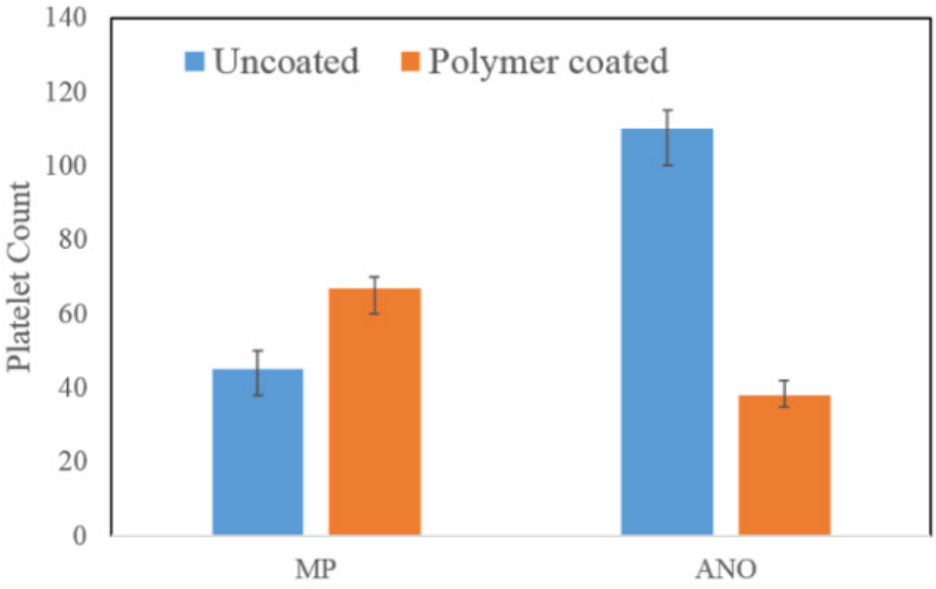
contact angle (CA) and corrosion rates (CR) of MZC was also investigated. An increase in contact angle (hydrophobicity) was observed with a decrease in surface roughness. The surface of MZC was hydrophilic at an average roughness of 0.3 µm and hydrophobic at a roughness greater than 0.5 µm (manuscript under preparation).
A custom-built, multi-specimen, laminar flow chamber was used to investigate the adhesion of blood components on implant materials. Figure 3a shows five flow chambers connected in a parallel circuit designed to the main inlet and outlet flow paths; figure 3b illustrates a schematic of the closed-loop system used for platelet adhesion studies. The flow loop consisted of a peristaltic pump to circulate the blood, silicon tubes to connect the flow chambers, a blood reservoir and a water bath to maintain the temperature of whole blood at 37 □C. The velocity of blood flow was maintained at 113 cm/s, which is within the dynamic range of velocities measured in the veins of the upper limbs of humans.







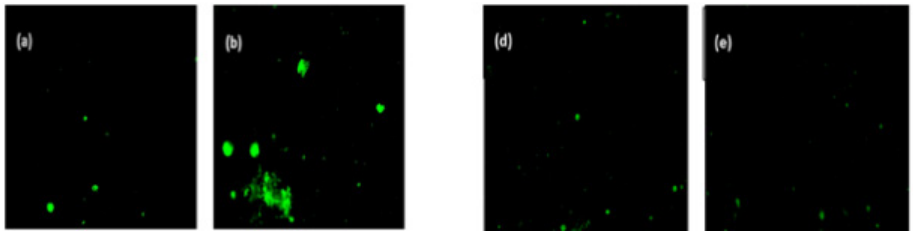


Figure 3: a) Flow chambers connected in parallel circuit to the main inlet and outlet paths
b) Schematic of closed loop system for platelet adhesion studies
c) Platelets adhered to uncoated and polymer coated MP and ANO MZC
d) a &b correspond to platelets adhered on the surface of uncoated MP and ANO MZC; c & d correspond to platelets adhered on the surface of polymer coated MP and ANO MZC

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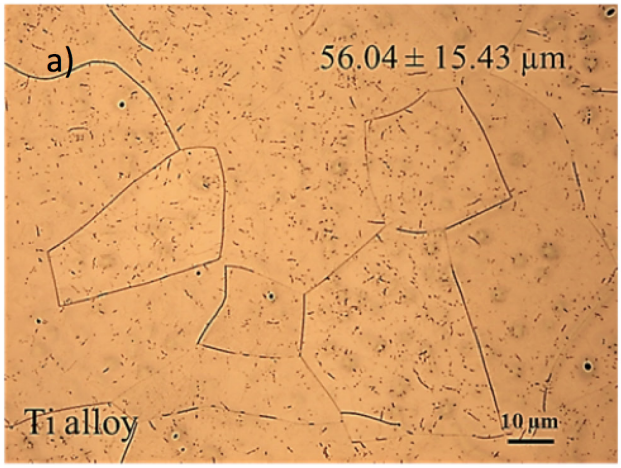
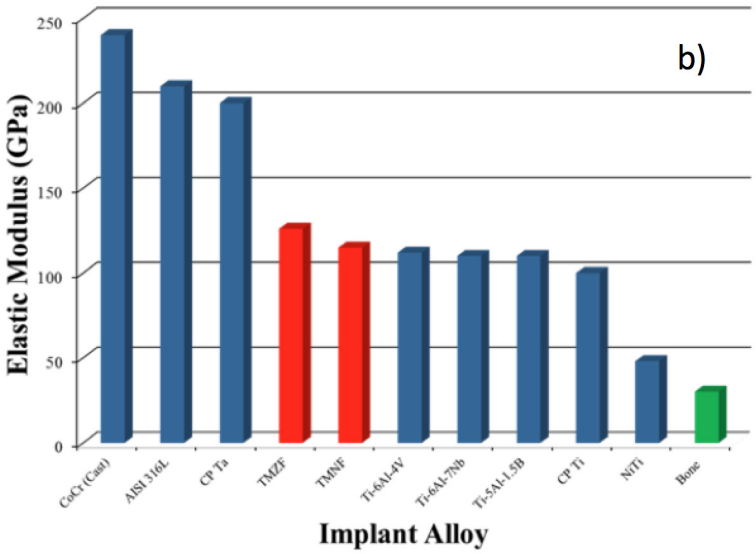
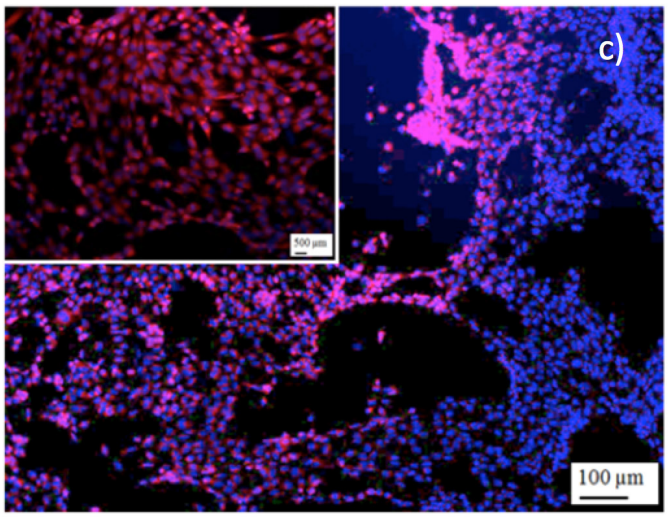
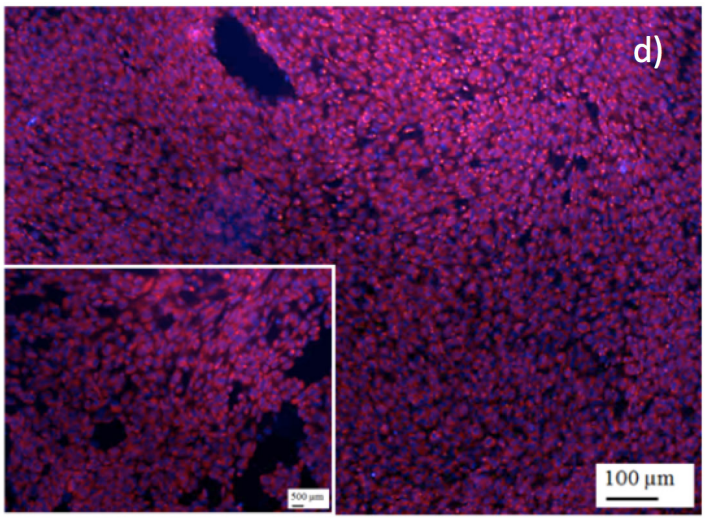


Optical micrograph of Ti alloy





Osteoblast cell growth on Ti alloy



Osteoblast cell growth on Anodized Ti alloy

Figure 4: a) Optical microscopy image revealing the grain size of TMZF
b) Elastic Modulus of TMZF and TMNF (red) and those of first generation and current implant materials
c) Osteoblast cell growth on mechanically polished TMNF (inset at a higher magnification)
d) Osteoblast cell growth on anodized TMNF (inset at a higher magnification)

The adhesion of porcine platelets on polymer coated and ANO MZC was significantly less than that on MP MZC. Figure 3d shows fluorescent microscopy images of platelets on uncoated and polymer coated MP MZC and ANO MZC. The platelets were globular in shape which indicated that they were in the resting stage with no activation. Additionally, anodization of MZC provided superior adhesion between the ANO surface and the polymer coating as compared with the MP surface.

TMZF and TMNF exhibited elastic moduli of 124 and 115 GPa respectively (figure 4b), which was half of the moduli of first generation orthopedic implant materials. The grain size of both alloys were comparable, i.e. 56.04 ± 15.43 µm for TMZF and 54.81 ± 15.48 µm for TMNF. A good growth of osteoblast cells was observed on both TMZF and TMNF as shown in figure 4c. However, their anodized surfaces exhibited prolific cell growth as shown in figure 4d.

Concluding remarks

This article emphasizes the significance of two surface treatments, anodization and polymer coating on the biocompatibility, corrosion resistance and hemocompatibility of novel biodegradable and titanium based prosthetic materials. It is envisaged that the findings of this research will introduce a new class of biodegradable Mg based MMCs and titanium alloys for emerging cardiovascular and orthopedic applications. The expanding possibilities of introducing the aforementioned biomaterials would necessitate better understanding of the complex cellular

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interactions associated with the surfaces of implants. Nevertheless, further research is required to determine the primary material specifications for the manufacture of medical devices. Additionally, in-vivo studies and clinical trials are also essential.

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Member News

The **University of Washington** will again hold its annual biomaterials course. The 20th UWEB21 Biomaterials Intensive Short Course will be held August 10-12 at the University of Washington campus. The meeting is coordinated by Dr. Buddy Ratner and will provide an introduction to biomaterials, medical devices and biocompatibility presented by experts. It is a great opportunity to get up to speed in the field, and review trends, controversies and key clinical issues. More information can be found at: http://www.uweb.engr.washington.edu/shortcourse.

Aspen Research announced the creation of a new product development team in an effort to expand its proprietary materials while continuing to collaborate with clients and partners. The move includes hires of several key new employees as well as a rebranding effort with new logos and messaging. The company will continue to focus on providing services to clients while also bringing forward new compounds to the market.

Boston Scientific received FDA approval in March for its WATCHMAN™ device for left atrial appendage closure device as an alternative to warfarin for prevention of stroke in patients with atrial fibrillation. Years of clinical studies have shown good evidence that the device can reduce risks for ischemic stroke and is a valuable alternative for patients that can't receive anti-coagulant therapy. Boston Scientific also announced an agreement to acquire the American Medical Systems urology business including men's health and prostrate health from Endo International for up to $1.65 billion. The move is expected to compliment Boston Scientific's existing urology product portfolio. Boston also announced an agreement with C.R. Bard to distribute the Lutonix® drug coated balloon in the United States.

Medtronic received FDA approval for the Pipeline™ Flex embolization device for treatment of neurovascular aneurysm. The Flex offers an improved delivery system compared to the previous generation of the device. The company also began the U.S. product launch of the IN.PACT Admiral drug-coated balloon for treatment of peripheral arterial disease in the upper leg. Importantly, CMS has approved a transitional pass-through payment for the device based on clinical and economic outcomes. Medtronic also announced several acquisitions including: Diabeter, a diabetes care provider, Sophono, a maker of minimally invasive hearing implants, and Advanced Uro-Solutions, a developer of neurostimulation products for treatment of bladder control issues. Medtronic revealed that it will develop an innovative device for endovascular repair of thoracoabdominal aortic aneurysms under license from Sanford Health.

W.L. Gore announced the achievement of several clinical milestones. The company completed enrollment in the EXCLUDER® iliac branch clinical study of a complete system for managing iliac artery aneurysms. Gore also completed enrollment in the REDUCE study to evaluate safety and effectiveness

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of two products for septal occlusion of PFO defects in patients at risk for stroke. Finally, the company reached a milestone of 2,500 patients in its global registry of endovascular aortic treatment (GREAT). This registry includes patients treated with various Gore endoprosthesis products and has a goal of 5,000 patients being tracked over 10 years.

Corline Biomedical announced an initial public offering on the Nasdaq First North in Stockholm to raise money for development of therapeutic candidates for diabetes type 1 and kidney transplantation. Bausch + Lomb released an enhanced version of their BLIS™ Reusable Injector System for enVista® IOLs. The newly enhancements will allow greater control and safe delivery of lenses through small incisions. The system consists of a titanium handpiece and disposable cartridge for lens loading and smooth delivery. The enVista® IOL is a hydrophobic acrylic lens that has been shown to reduce glistenings or fluid-filled microvacuoles from forming within the lens.

AST Products Inc. received 510K clearance from the FDA for its lioli™ IOL Delivery System. The lioli™ IOL Delivery System is a device designed for insertion of an intraocular lens through an incision. The insertion system consists of a single-use injector cartridge coated with LubriMATRIX™ coating to provide ease of insertion.

ExThera Medical presented results on using its Seraph® Microbind® Affinity Blood Filter to remove cytomegalovirus (CMV) from blood at the 2015 Critical Care Congress. It is believed that the ability of the device to remove CMV will be helpful in treating patients with sepsis who are vulnerable to CMV viremia. Reactivation of CMV in sepsis can cause serious complications including fungal infections and increased mortality.

POST-GRANT REVIEW

A Cheaper Way to Litigate?

This column previously reported the changes in the U.S. patent law resulting from the America Invents Act (AIA). These changes include a new first-to-file inventorship priority race as well as several new procedures for challenging a patent's validity via quasi-judicial proceedings of the Patent Trial and Appeals Board (PTAB) at the U.S. Patent Office.

New, AIA post grant review (PGR), *inter partes* review (IPR) and transitional program for covered business methods (TPCBM) proceedings are essentially ways of litigating the validity of a patent within the PTAB. While the covered business method procedure is not reviewed here, its requirements and cost are similar to those of the IPR. Post-grant review, in contrast to IPR, does not include the participation of an adversarial third party and is conducted as a proceeding solely between the patent holder and the PTAB. However, PGR does provide a method to put before the PTAB prior art that was not originally considered by the examiner.

IPR, by providing a venue for the post-grant adjudication of a patent within the patent office, has provided an alternative method of challenging patent validity external to the federal court system. For a potential infringer or challenger of a patent's validity, IPR provides an attractive alternative to federal court.

The table below summarizes the differences and similarities between PGR and IPR and patent challenge in U.S. District Court.

Challenge Method	PGR	IPR	U.S. District Court
Timing to File Petition	Within 9 months of grant	Later of nine months after grant or the date of the termination of the PGR	Any time after grant
Grounds for Asserting Invalidity	Any ground related to patent invalidity under 35 U.S.C. § 282 (except best mode)	A ground related to patent invalidity under 35 U.S.C. §§ 102 and 103 and on the basis of patents or printed publications	Any
Threshold for Institution	"More likely than not" OR important novel/unsettled legal question	"Reasonable likelihood that petitioner would prevail"	None
Real Parties in Interest	Must be identified	Must be identified	Must be identified
Estoppel	Grounds raised or reasonably could have been raised	Grounds raised or reasonably could have been raised	N/A
Conducted By	PTAB	PTAB	Federal Court
Discovery	Directly related to factual assertions advanced by either party in the proceeding	Deposition of witnesses submitting affidavits or declarations and what is otherwise necessary in the interest of justice	Full
Time for Decision	12-18 months	12-18 months	2-5 yrs
Appeal	Both parties can appeal to Federal Circuit	Both parties can appeal to Federal Circuit	Both parties can appeal to Federal Circuit
Standard of Review	Preponderance of evidence	Preponderance of evidence	Clear and convincing evidence
Presumption of validity	None	None	Presumption
Claim construction	Broadest reasonable interpretation	Broadest Reasonable interpretation	In light of specification
Cost	$25,000[1]	$150K[2]	$2-5M

[1]USPTO fees $12,000
[2] USPTO fees$23,000

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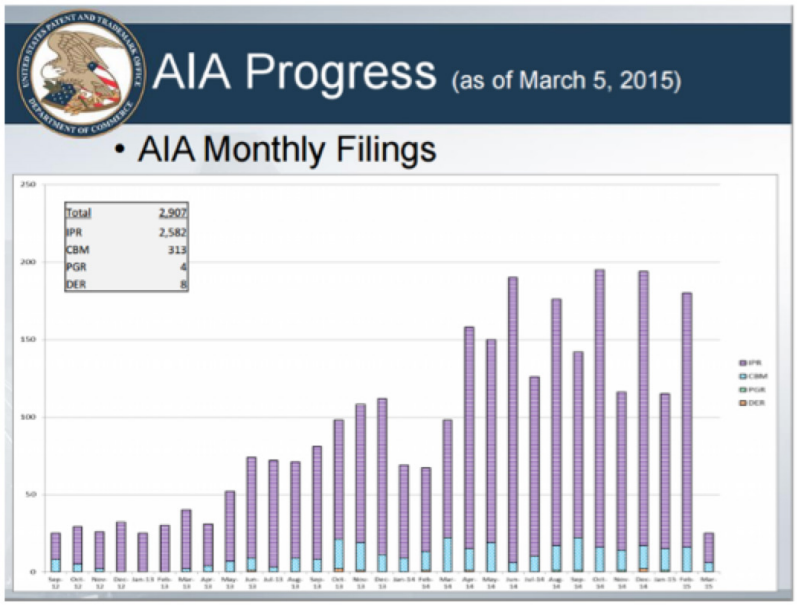

Fig.1

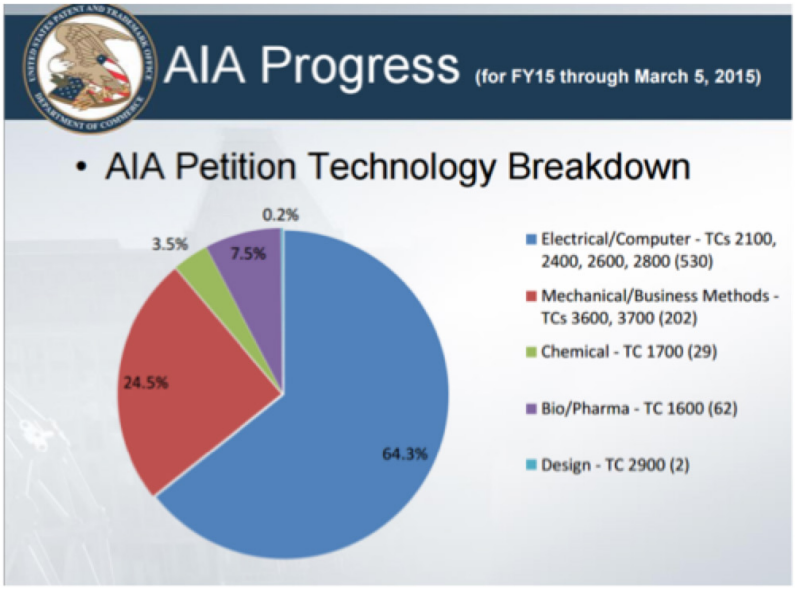

Fig.2

• AIA Petition Dispositions

		Trials Instituted	Joinders	Percent Instituted	Denials	Total No. of Decisions on Institution
IPR	FY13	167	10+	87%	26	203
	FY14	557	15+	75%	193	765
	FY15	355	84+	74%	152	591
CBM	FY13	14	0	82%	3	17
	FY14	91	1+	75%	30	122
	FY15	31	-	67%	15	46
DER	FY14	0	0	0%	3	3

Fig.3

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SurFACTS in Biomaterials is the official publication of the foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

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IPR Final Decisions					
# of Final IPR Decisions	Claims Challenged	Claims on Which IPR Proceedings Instituted	Claims Cancelled	Claims Upheld	Proceedings Allowing Amendment
78	1,242	1,107	876	231	1[5]
		89%	79%	20%	

Fig.4

As Fig. 1 shows, the number of IPRs has increased to almost 200 per month in 2014. Fig. 2 shows that the great majority of these cases are in the fields of the electrical/computer arts and mechanical arts. For those in the chemical and bio/pharma field, the statistics are a bit better as only 2.5 % and 7.5% respectively of those the IPRs instituted are in those fields. However, Fig. 3 shows that of all the IPRs filed in 2015, 74% were instituted while Fig. 4 shows that of all the IPRs instituted, 79% resulted in at least one claim cancelled. This is an important distinction as it should be understood that all the challenged claims may not be found invalid and consequently, a portion of claims in a proceeding may survive as enforceable claims (effectively providing the surviving claims with a bullet-proof finish for other would be infringers). Therefore, statistically speaking a challenger has a very high likelihood in succeeding in invalidating one claim of a potentially threatening patent.

As the chart shows, of all IPR petitions filed, 89% of those proceedings were instituted and in 79% of those cases, at least one claim was cancelled. In all, while the total cost of filing and prosecuting and IPR can be in the area of $150,000-$350,000 this amount is small compared to the $2M to $5M cost of two to three years of district court litigation.

The take-home from the above review of post-grant challenge of patents through use of the new *Inter Partes* Review is that it provides a relatively quick, relatively inexpensive and relatively easy way to challenge patents within the framework of the USPTO bureaucracy that offers a good chance of invalidating a competitors patent that it may otherwise be forced to defend itself against in District Court.

Wear Comfort Evaluation of Disposable Contact Lens

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Introduction

Wearing contact lenses has become trendy for people whether it is for cosmetic, corrective, or therapeutic reasons. Most of the disposable contact lenses are made of extremely soft hydrogels with a significant amount of water content. In addition to many designed functionalities of the contact lenses, wearing comfort is a key factor to be well controlled by the contact lens designer. Two aspects of the wear comfort are the friction between eyelid and the contact lens and the lens wettability. In this paper, evaluations of the two aspects of wear comfort will be introduced.

Friction Measurements

Friction is a measure of a surface's resistance to relative motion. When two surfaces are rubbing against each other, friction acts as the force to prevent the two surfaces from moving in a given direction. Continued relative motion leads to material loss or wear of the surface and its friction counterpart. Over time, a surface will degrade, due to friction and wear, to a point that renders the surface unusable for its designed application. Altering the surface chemistry can change the friction properties to better suit the application needs and help to prolong the material's useful life.

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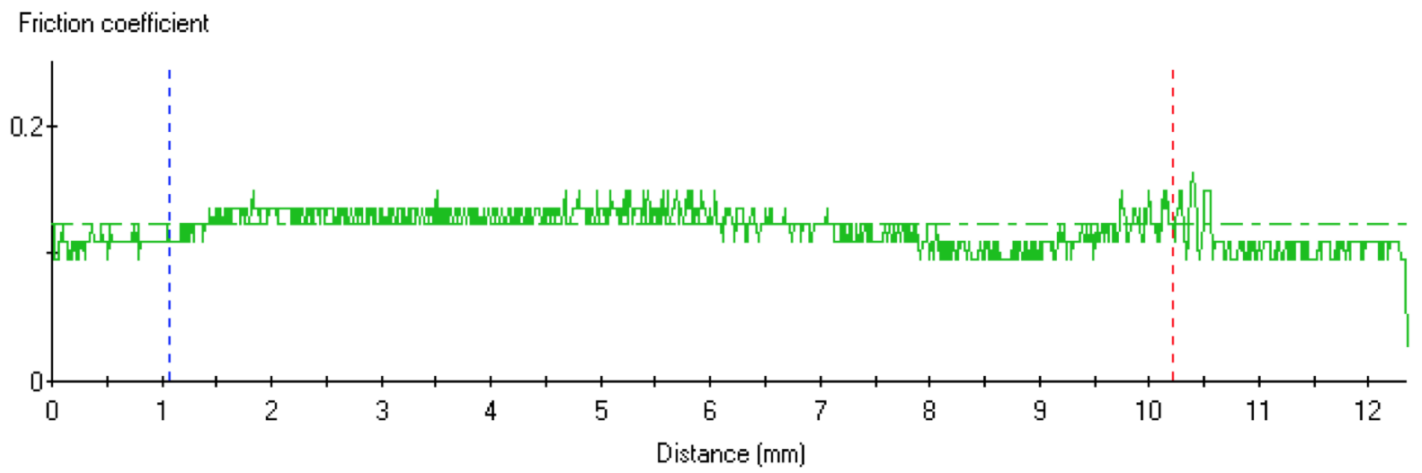

Figure 1. Friction coefficient as a function of sliding distance for the 1-Day Acuvue TruEye contact lens against glass slide in saline contact lens solution.

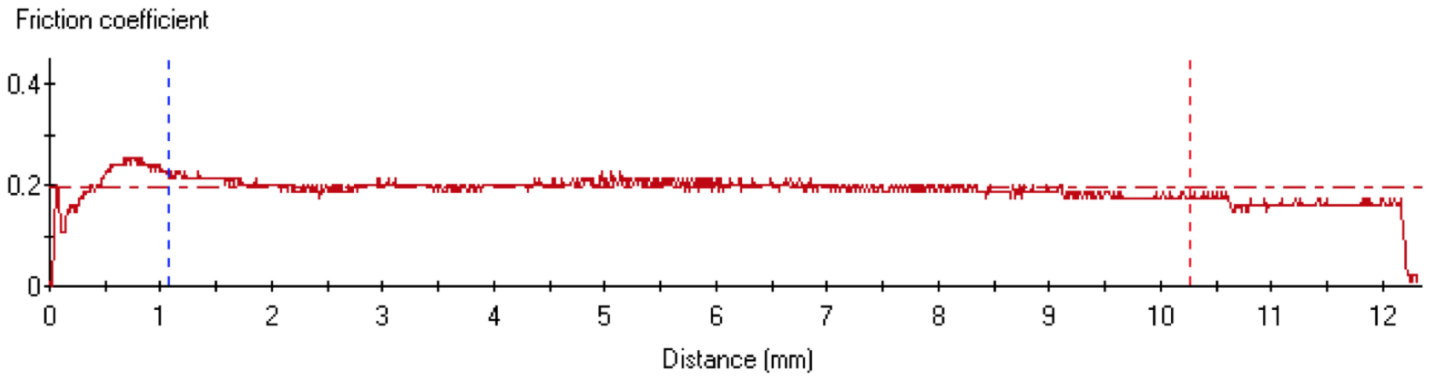

Figure 2. Friction coefficient as a function of sliding distance for the Acuvue Oaysis with Hydraclear Plus contact lens against glass slide in saline contact lens solution.

The TS-501 Triboster, manufactured by Kyowa Interface Science Co., Ltd., is capable of measuring both the static and kinetic friction coefficients of a material surface in a single pass or multiple passes under dry or lubricated conditions with temperature control from room temperature to 180ºC. The high sensitivity friction transducer and low loads employed by the TS-501 allow for softer materials like polymers, fabrics, and thin films to be tested with ease and accuracy. The velocity of the stage is automatically controlled by user input values from 0.02 mm/s to 100 mm/s.

Table 1 Static and Kinetic Friction Coefficients of Contact Lens

Friction Coefficient	1-Day Acuvue TruEye	Acuvue Oaysis with Hydraclear Plus
μ_s	0.123	0.255
μ_k	0.123	0.195

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As shown in Figures 1 and 2, and Table 1, two different kinds of commercially available disposable contact lenses from Johnson & Johnson Vision Care, Inc. were tested for friction using the TS-501. The first kind of contact lens tested was 1-Day Acuvue TruEye disposable contact lens and the second kind was Acuvue Oaysis Hydraclear Plus disposable contact lens. Both kinds of contact lenses were tested under the same conditions and parameters sliding against glass slide in saline contact lens solution. From the results, it is obvious that the static and kinetic friction coefficients for the two kinds of contact lenses are different. The different friction coefficients would result in different wearing comfort for people.

Wetting Evaluation

Wettability is a characteristic of a material that quantifies the spreading of a liquid on the material's surface. The desired wettability will depend on the application of the material. In some cases, high wettability is desirable while low wettability is desirable for others. In the case of contact lenses, a high degree of wettability allows water to easily spread over the surface and pass through miniscule pores to the eye. One method to measure surface wettability is through contact angle analysis.

In standard contact angle tests, a sample of the material of interest is placed on a dry stage for analysis. For most applications, this process works well as it is similar to the native environment for the material. For contact lenses and other wetted materials, the normal process for performing contact angle tests is quite difficult. Since testing contact lenses in a dry state does not make much sense, a different technique is required. The DM-701 Contact Angle Meter, also manufactured by Kyowa Interface Science Co., Ltd., has the capability to measure materials in a liquid environment. In instances where the test liquid has a lower density than the surrounding liquid, an inverted tip is used to place droplets on the bottom of a raised stage.

To measure the contact angle of an O2 Optix contact lens manufactured by CIBA Vision in saline solution, the lens was placed in a special holder with a steel ball to keep the material rigid enough for measurement. Since the measurement surface is not flat, a curvature correction routine was applied to compensate for the shape of the lens. In this case, the radius of curvature of the contact lens was measured to be 4987 µm. With the contact lens in place, an air bubble was generated underneath the contact lens and brought into contact with the surface. By using air as the testing fluid, the contact angle of saline on the specimen surface was determined for the contact lens by subtracting the measured contact angle of the air bubble from 180°. The extension and contraction methods were used to create stable air bubbles for measurement. This method also gave the added benefit of determining the advancing and receding contact angles for the contact lens. By knowing the advancing and receding angles, we know the maximum and minimum contact angle supported by the material; the difference between the two is also known as the contact angle hysteresis.

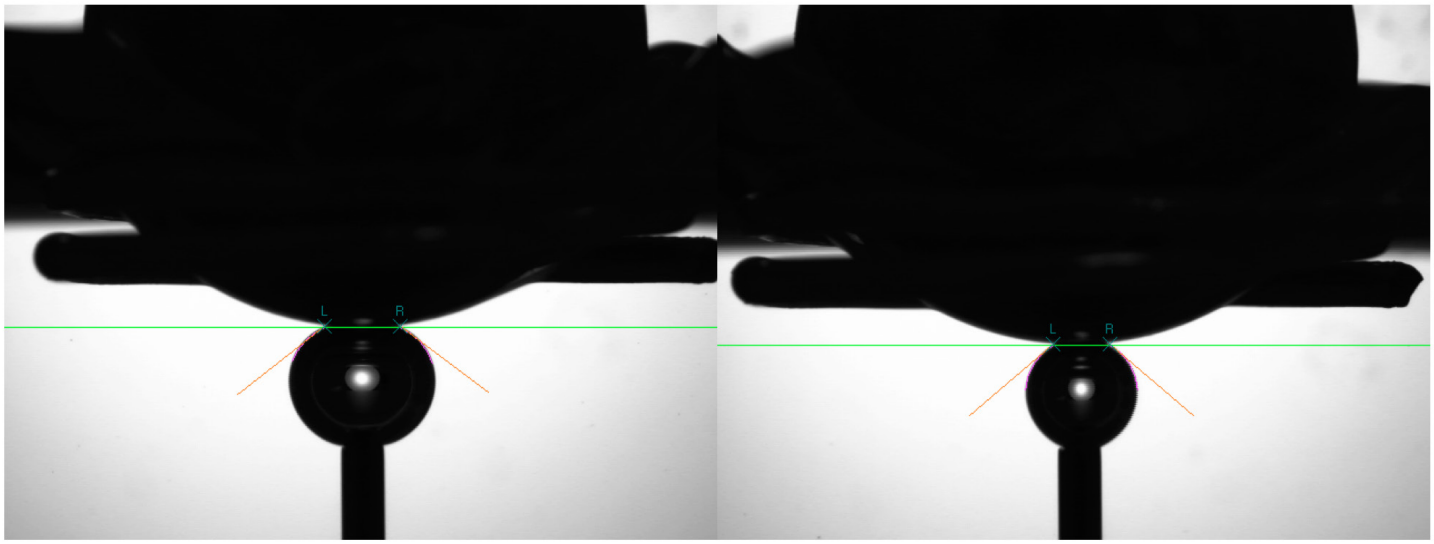

Figure 3. Captured images of an air bubble used for contact angle analysis in saline contact lens solution for O2 Optix contact lens manufactured by CIBA Vision.

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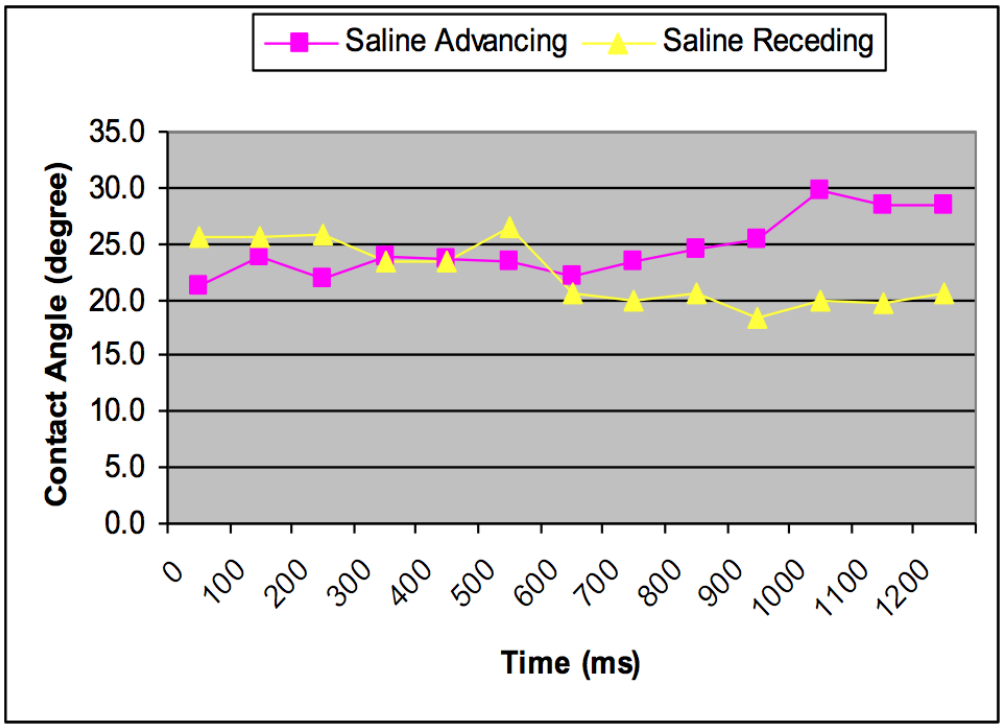

Figure 4. Plot of the advancing and receding contact angle results over time for O2 Optix contact lens manufactured by CIBA Vision.

As seen from the plot in Figure 4, the advancing angle (from the air bubble contraction test) was approximately 28° and the receding angle (from the air bubble extension test) was approximately 20°. These results have indicated that the contact lens surface is hydrophilic in nature with relative small contact angle hysteresis. These wetting characteristics will have influence on wearing comfort.

Concluding Remarks

The wearing comfort of disposable contact lenses is an important factor for manufacturers to consider and quantify. The surface friction and contact angle are two parameters that can be readily measured and related to the wearing comfort of the contact lens user. With measured data for surface friction and wettability of the contact lens, the wear comfort of disposable contact lenses may be optimized and improved.

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