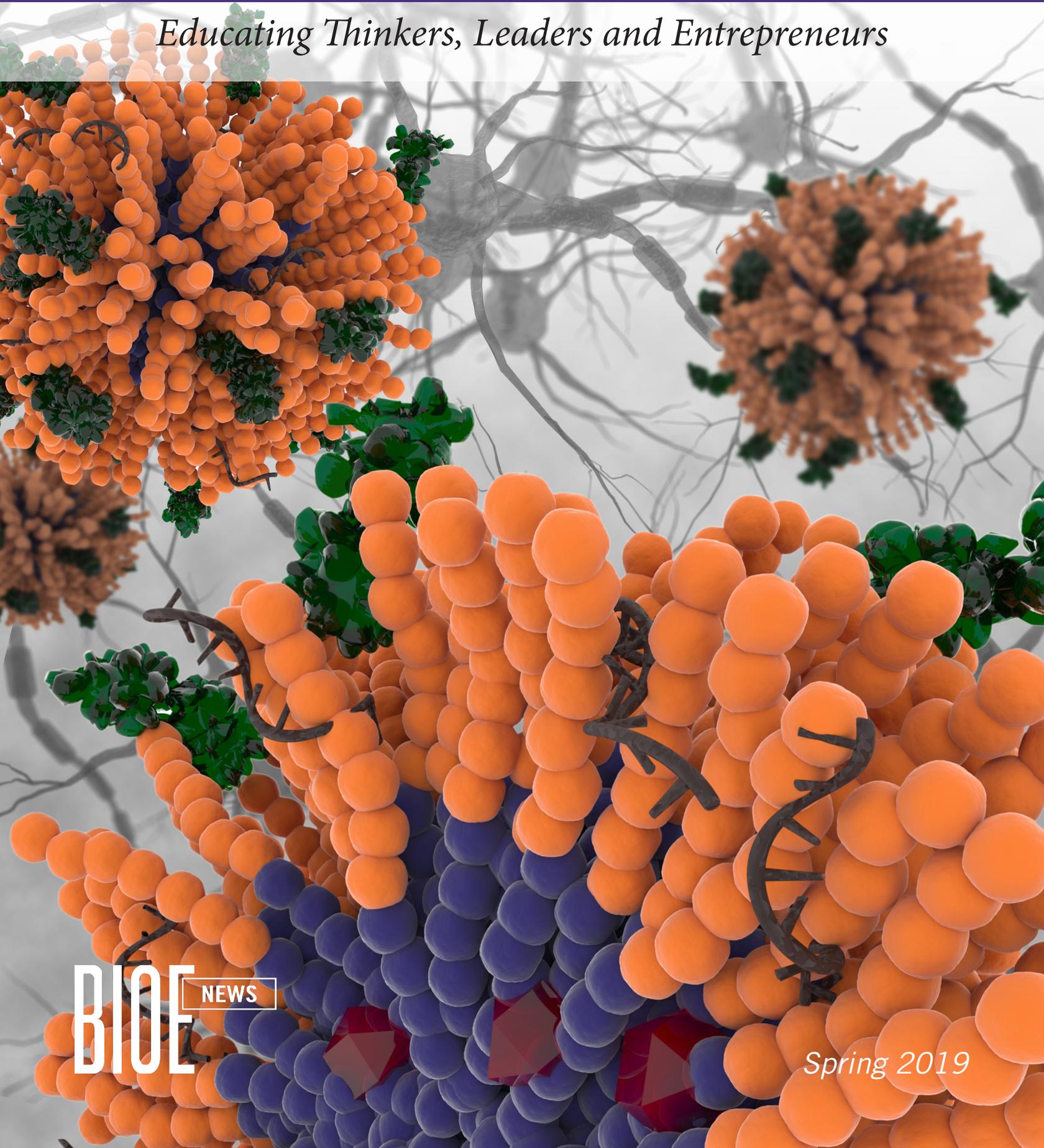


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BIOE NEWS

Spring 2019



CLEMSON BIOENGINEERING SOCIETY



CBS is Clemson's graduate student chapter for the Society for Biomaterials and the Biomedical Engineering Society.

A student-run organization providing access to professional and personal development opportunities, CBS offers outreach, social events, mentorship and professional development.



Contact cbs@g.clemson.edu

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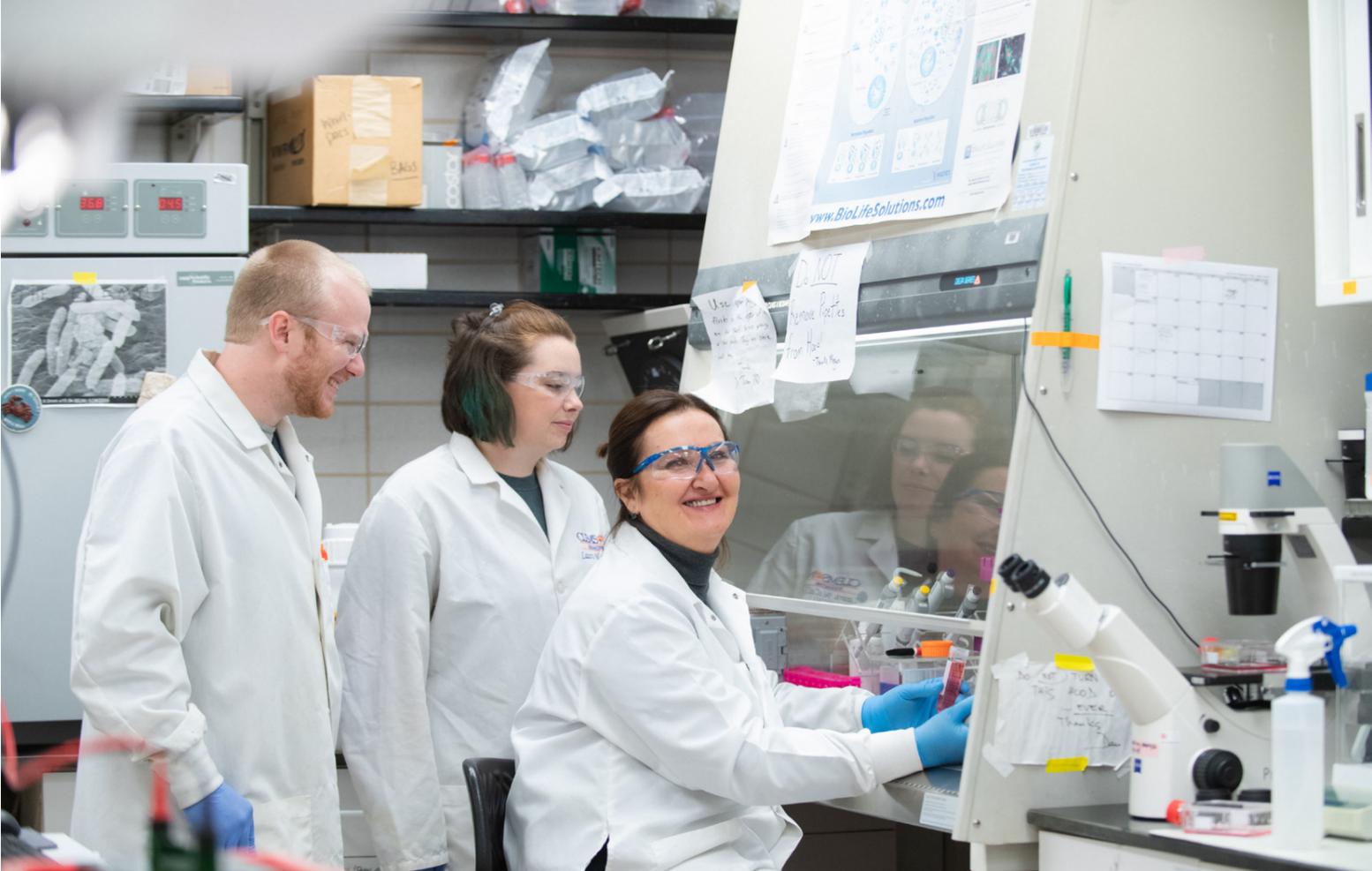
Cover illustration — *New Treatment For Spinal Cord Injuries Could Help Patients Walk Again*, pg 5



Martine LaBerge, *Chair, Department of Bioengineering*

Jenny Bourne, *Editor*

Olga Reukova, *Cover illustration and magazine design*



Agneta Simionescu, right, works with bioreactors in her lab with students Laura McCallum and Spencer Marsh.

In tissue engineering, if you are able to mimic blood vessels, then you can do drug testing on them. You don't necessarily have to do those tests on animals, which would not respond the same as human cells anyway. This is the advantage of using tissue-engineering-based models.

Diabetes Targeted in New Bioengineering Research at Clemson University

Paul Alongi

Clemson University bioengineers are launching a new research project to better understand cardiovascular disease in patients with diabetes, an affliction that affects about 13 percent of South Carolina adults and cost \$4.3 billion last year alone. What the bioengineers learn could help lay the groundwork for future studies aimed at finding new treatments.

The Clemson research will be led by Agneta Simionescu, an associate professor in the bioengineering department. She announced Monday that the National Institutes of Health is providing \$1.38 million R01 grant for her research. The impact could be huge, particularly in South Carolina, where 13 percent of adults reported that a health professional told them they have diabetes, according to a report last year by the United Health Foundation. That was sixth highest in the nation.

Simionescu's project sharpens the focus on atherosclerosis, a condition that accelerates in diabetics. The condition occurs when plaques made of cholesterol, cell debris, calcium, and other substances build up on blood vessel walls, threatening blood flow. Plaque narrows arteries and has the potential to rupture and cause blockages, which could result in heart attack and stroke.

Simionescu and her team are concentrating on the role of fibroblasts in atherosclerosis. When blood vessels are damaged, fibroblasts are deployed to make repairs by synthesizing collagen. But in diabetics, fibroblasts produce too much collagen. The vascular tissue becomes "fibrotic" and calcifies, researchers said. "The whole blood vessel becomes stiffer, and that's the hallmark of diabetes," Simionescu said.

The Simionescu team is drawing from its experience in tissue engineering to learn more. They will use three-dimensional models to study how fibroblasts communicate with two types of cells in blood vessel walls, endothelial cells and smooth muscle cells, both factors in atherosclerosis.

"Fibroblasts would not know what to do unless they get a signal from an endothelial cell or a smooth muscle cell," Simionescu said. "They need to interact with each other. That's what is hard to determine."

When researchers create their models, they will start with pig arteries that have been thoroughly stripped of their cells. What's left are elastin-and-collagen scaffolds that maintain the tubular structure of blood vessels.

Researchers will inject human endothelial cells into a scaffold. Within a few hours, the endothelial cells will naturally spread throughout the scaffold. Then researchers will then inject fibroblasts. Bioreactors will be used to simulate vascular biomechanics and diabetic conditions. "We will be able to tell at the end of the experiment if endothelial cells send a signal to fibroblasts," Simionescu said.

Researchers will also try the same experiment in different scaffolds but use smooth-muscle cells instead of endothelial cells. The models "could provide powerful toolboxes for diabetes basic research and drug screening systems," Simionescu said.

"In tissue engineering, if you are able to mimic blood vessels, then you can do drug testing on them," she said. "You don't necessarily have to do those tests on animals, which would not respond the same as human cells anyway. This is the advantage of using tissue-engineering-based models."

In South Carolina, 577,000 people have diabetes, and another 1.32 million have prediabetes, according to the American Diabetes Association. Nationally, more than 100 million Americans have diabetes or prediabetes, according to the Centers for Disease Control and Prevention.

Medical expenses for people with diabetes are about 2.3 times higher than people without diabetes, the American Diabetes Association reported. Total direct medical expenses for diagnosed diabetes in South Carolina were estimated at \$4.3 billion in 2017, according to the association.

Martine LaBerge, chair of the Department of Bioengineering, said Simionescu's work was made possible by a grant through the National Institutes of Health's R01 program. "Dr. Simionescu's grant is a testament to the level of scholarship and the innovative ideas she brings to bioengineering and health research at Clemson," LaBerge said. "I congratulate her on this prestigious accomplishment."

Simionescu said her project takes diabetes research beyond previous studies that focused on two-dimensional monolayers of cells. The monolayer studies were limited because cells in the human body grow in three dimensions instead of two, meaning several factors including cell communication could not be studied.

Anand Gramopadhye, dean of the College of Engineering, Computing and Applied Sciences, said Simionescu's grant helps raise the research profile of the college. "She is pushing the boundaries of health innovation to have a real impact on diabetes, one of the greatest health care challenges of our time," he said. "I congratulate her on this well-deserved honor."

NEW TREATMENT FOR SPINAL CORD INJURIES COULD HELP PATIENTS WALK AGAIN

Paul Alongi



A new treatment for spinal cord injuries that Clemson University researchers are developing in Greenville could help patients regain movement and their sense of touch. Jeoung Soo Lee, an associate professor of bioengineering, is receiving a \$1.5-million R01 grant from the National Institutes of Health to fund the research. She is using nanoparticles many times smaller than the width of a human hair to deliver drugs directly to the site of the injury to help it heal.

Spinal cord injuries can be caused by trauma or disease and usually result in permanent loss of motor and sensory function below the injury. As many as 358,000 people in the United States are living with spinal cord injuries, and about 17,700 new cases occur each year, according to the National Spinal Cord Injury Statistical Center.

Lee said patients who have suffered from spinal cord injuries have inspired her research, particularly their courage and optimism. “I believe the nanotherapeutics we are developing can provide

No treatment for spinal cord injury patients has been approved by the FDA: The number and complexity of factors contributing to spinal cord injury make recovery extremely difficult.

a platform for drug therapies that can mitigate injury damage and lay the groundwork for regeneration, Lee said. “I want to see patients achieve functional recovery and improve quality of life. That is my research goal and my personal hope.”

Lee said her results so far have been promising. Rats that received the treatment regained the ability to move their hind legs, she said. The funding comes from the National Institutes of Health R01 program and lasts four years. Lee’s goal is to have the treatment ready to test on larger animals, such as pigs or sheep, by the end of the grant period.

The treatment could be ready for human clinical trials in about 10 years, Lee said. Once ready for market, the nanoparticles would be injected into the patient, either through an IV or directly into the lumbar region of the back, Lee said. The nanoparticles would deliver the drug rolipram and small-interfering RNA to the site of the injury to promote healing. The protein L1 would help the nanoparticles target key neurons. The approach would capitalize on recent studies showing the value of therapies that employ two or more treatments simultaneously.

Martine LaBerge, chair of the Department of Bioengineering, said Lee is well positioned for success. “Dr. Lee brings an innovative approach and a high level of scholarship to her research,” LaBerge said. “R01 awards are among the top grants for research in health innovation, and Dr. Lee is highly deserving.”

The nanoparticles are key to the treatment Lee is developing. They are made of a polymer that was created in her lab and is called PgP, which is short for poly (lactide-co-glycolide)-graft-polyethylenimine. The nanoparticles are about 130-160 nanometers, visible only with a high-powered electron microscope, Lee said. Their hydrophobic core and hydrophilic shell allow the nanoparticles to carry both rolipram and small-interfering RNA to the injury, she said.

Lee is developing the nanoparticles for spinal cord injuries, but they also hold the possibility for treating other ailments, including Alzheimer’s disease, Huntington’s disease, traumatic brain injury and stroke, she said. The technology has been patented, Lee said.

Lee and her team are conducting their research at the Clemson University Biomedical Engineering Innovation Campus, or CUBEInC, at Greenville Health System’s Patewood Campus. Collaborators include Ken Webb, associate chair of undergraduate affairs in Clemson’s Department of Bioengineering, and Michael Lynn, a neurosurgeon at Greenville Health System.

Lee also expressed gratitude to the South Carolina Spinal Cord Injury Research Foundation and the SC BioCRAFT COBRE Center that helped support the initial development of her materials and technology.

Anand Gramopadhye, dean of the College of Engineering, Computing and Applied Sciences, congratulated Lee on the grant. “The amount of the award and the prestige that comes with the R01 program underscores the creativity and knowledge that Dr. Lee brings to the project,” he said. “The grant is richly deserved.”

Our multifunctional nanotherapeutics target several challenges, and with rehabilitation and other approaches, may contribute to new therapies that could lead to improvements in functional recovery and patient quality of life.

DR. WILL RICHARDSON: AN R01 TO PREDICT AND PREVENT CARDIAC FIBROSIS

Paul Alongi

The millions of patients who suffer from a condition that contributes to heart failure could receive personalized risk assessments and treatments with the help of new research led by Dr. Will Richardson of Clemson University. Richardson, an assistant professor of bioengineering, is receiving an R01 grant of \$1.9 million from the National Institutes of Health for five years of research focused on cardiac fibrosis. The condition occurs when material builds up in heart walls, hampering its ability to pump blood.

When cardiac fibrosis progresses to heart failure, it can prove deadly. As many as 60 percent of patients die within five years of developing heart failure, which afflicts 6.5 million Americans, Richardson said. No drugs have been approved to treat cardiac fibrosis specifically, and doctors are often left with trial-and-error experimentation when treating patients who have it, he said.

Our team has taken what scientists already know about how molecules interact in the body and turned that information into mathematical equations.

Dr. Will Richardson

For Richardson, the solution could start with math. His team has taken what scientists already know about how molecules interact in the body, and turned that information into mathematical equations. Richardson envisions a day when measurements from a patient's blood or tissue sample would be plugged into those equations.

"We want to have this computational tool where the clinician can come and say 'this is your risk, and we've simulated these 10 or 100 or 1,000 different drug combinations and regimens,'" he said. "We're never going to do trial and error for those many combinations, but a computer model can crank all those options overnight. "The next day the cardiologist would say, 'This is the optimized drug regimen or therapy for your particular levels.'" The research is in its early stages, and it would take more than a decade of experimentation for any new tool to hit the market, Richardson said.

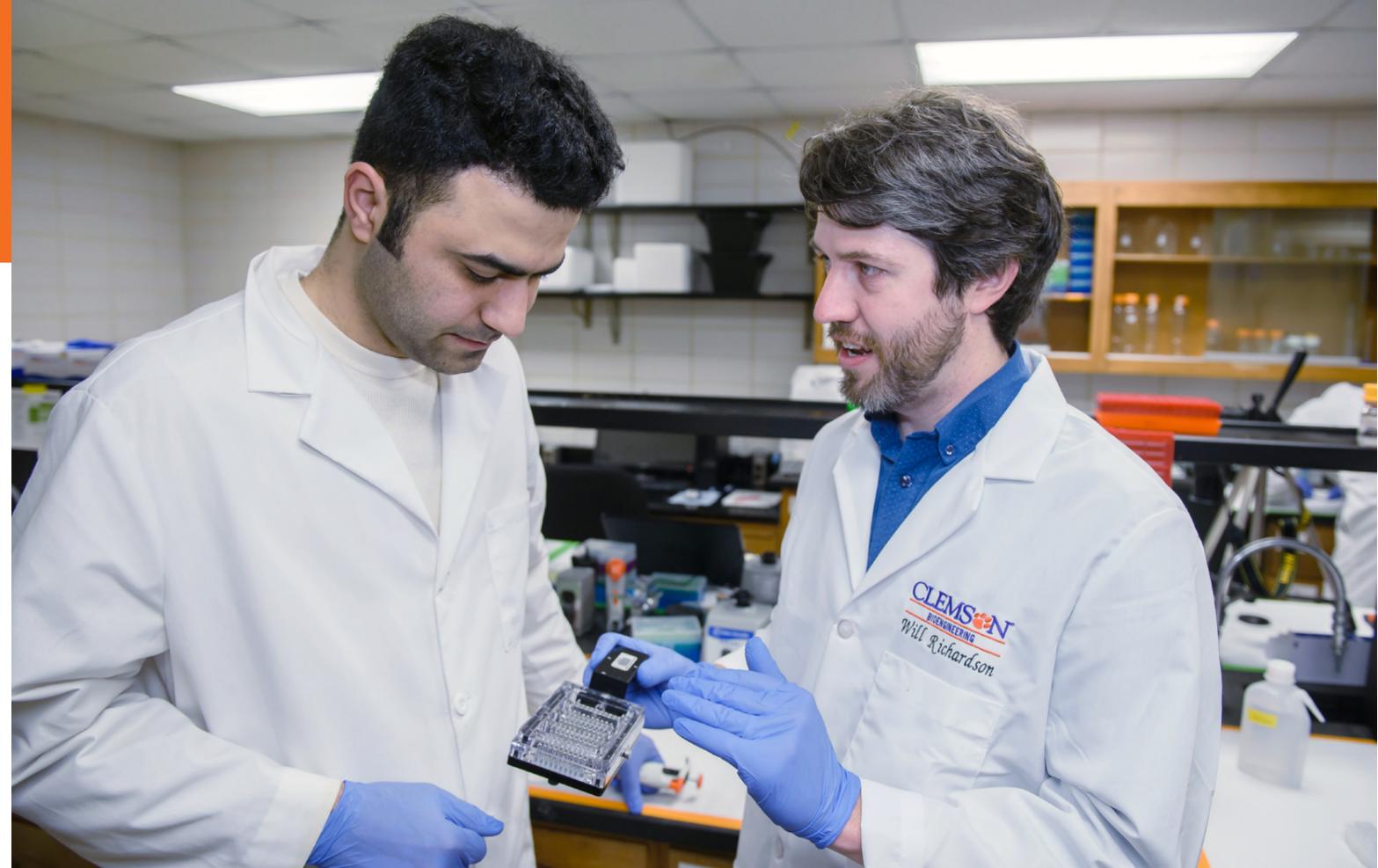
The central question that Richardson plans to address in his project is whether the mathematical model he has in place behaves as predicted and, if not, what ought to be changed. He plans to test the model with data gathered from heart failure patients at the Medical University of South Carolina. "We can test what the model predicts because we already know in those patients whether or not they got better or worse, or what their prognosis was," Richardson said. "We can test that against the model predictions to say, 'Is our model making good predictions or bad predictions?' And if it's making bad predictions, what part of the model is responsible for those bad decisions so we can come back and tweak that part of the model and improve it?"

Funding for the research comes through the National Institutes of Health's R01 program. Martine LaBerge, chair of Clemson's Department of Bioengineering, said the program is nationally competitive. "Dr. Richardson is highly deserving of this grant," she said. "He has assembled an excellent, multidisciplinary team and brings to the project his expertise in cell stretching and computational modeling. He is well positioned for success." Richardson is principal investigator on the grant. Co-investigators from Clemson are Zhi Gao, Joseph Bible and Taufiqar Khan. Co-investigators from MUSC are Michael Zile, Amy Bradshaw and Catalin Baicu.

Anand Gramopadhye, dean of the College of Engineering, Computing and Applied Sciences, said Richardson and his team are in a position to advance health innovation, one of six innovation clusters identified in the ClemsonForward plan. "I congratulate Dr. Richardson on his grant," Gramopadhye said. "The amount of the award and the fact that it comes from the R01 program is a testament to its importance and the high value that his peers see in it."

Cardiac fibrosis occurs when material builds up in heart walls, hampering the ability to pump blood.

Dr. Will Richardson



Will Richardson, right, speaks with Ph.D. student Amirreza Yeganegi

The amount of the award and the fact that it comes from the R01 program is a testament to its importance and the high value that his peers see in it.

CECAS Dean Anand Gramopadhye

Dr. Richardson has assembled an excellent, multidisciplinary team and brings to the project his expertise in cell stretching and computational modeling. He is well positioned for success.

Dr. Martine LaBerge, BIOE chair

NAREN VYAVAHARE'S NIH R01: RESEARCH TO REVERSE VASCULAR CALCIFICATION

Paul Alongi

New hope is brewing that Clemson University researchers could develop the first treatment to reverse the effects of a cardiovascular condition that affects millions of patients and can lead to complications ranging from hypertension to death. Naren Vyavahare, the Hunter Endowed Chair of Bioengineering, is receiving \$2.2 million from the National Institutes of Health to further research into his team's potentially heart-saving treatment.

His approach could be the first to reverse vascular calcification, a condition that occurs when mineral deposits build up on blood vessel walls and stiffen them. The condition is most prevalent in aging patients and those with chronic kidney disease and type 2 diabetes, Vyavahare said. "The impact of an effective treatment would be tremendous," Vyavahare said. "This is a problem that's at least 5,000 years old and still not solved. There are no drugs or therapies that reverse it. Ours would be the first."

Vyavahare and his team are creating nanoparticles that are made of the protein albumin and are many times smaller than

the width of a human hair. The nanoparticles would deliver two medicines to calcified blood vessels, targeting damaged elastin. Elastin is the body's version of elastic material, making it possible for arteries to push blood forward.

One medicine, disodium ethylenediamine tetraacetic acid (EDTA), would remove the mineral deposits that cause blood vessels to become calcified. Another medicine, pentagolloyl glucose (PGG), would return elasticity to the blood vessels. What makes the nanoparticles especially innovative is that they are designed to target elastin that has degraded and calcified, while sparing healthy arteries. A relatively small amount of EDTA would be needed to treat vascular calcification. Without the nanoparticles, systemic injections of EDTA require high dosages that result in unwanted side effects, such as hypocalcemia, renal toxicity and bone loss.

The research is funded through the National Institutes of Health R01 program. Researchers at the University of South Carolina — John Eberth, Mohamad Azhar and Susan Lessner — are collaborating on the project. Vyavahare said the technology could be ready for clinical human trials by the end of the four-year grant period. A company he has formed, Elastin Therapeutics, has licensed the patented the technology from Clemson, he said.

Martine LaBerge, chair of the Department of Bioengineering, said that Vyavahare is highly deserving of the grant. "This is the latest of many high-profile grants that Dr. Vyavahare has received," she said. "His hard work and unique approach continue to advance health innovation at Clemson and beyond."

The vascular calcification targeted in Vyavahare's study differs from atherosclerosis. Atherosclerosis is associated with calcification of a site in the vessel wall known as the intima. Vyavahare's research focuses on a different site in the vessel wall called the media. Calcification of the media can happen independently of atherosclerosis.

Unfortunately, there is no FDA-approved treatment available that reverses calcification in these millions of patients. Thus, finding treatments that reverse calcification and improve elasticity of arteries is an urgent healthcare challenge.

Vyavahare's research could be a game-changer for some patients. Medial calcification has been linked to elevated systolic blood pressure and pulse pressure. It also contributes to isolated systolic hypertension. Patients with chronic kidney disease are more likely to die from cardiovascular complications than kidney failure. In patients with type 2 diabetes, medial calcification was associated with a four-fold increased risk for lower extremity amputation and two-fold enhanced cardiovascular mortality.

"Unfortunately, there is no FDA-approved treatment available that reverses calcification in these millions of patients," Vyavahare said. "Thus, finding treatments that reverse calcification and improve elasticity of arteries is an urgent healthcare challenge."

Anand Gramopadhye, dean of the College of Engineering, Computing and Applied Sciences, congratulated Vyavahare on the grant. "Dr. Vyavahare's research is aimed at one of the greatest challenges of the 21st century — engineering better medicines," he said. "With his latest grant and impeccable credentials, he is well positioned to develop new medicines with the potential to ease suffering and save lives."



The R01 is one of several high-profile grants Dr. Vyavahare has received.



Bioengineering Research and Clinical Summer Immersion at Charleston: BEACH

Directed by Drs. Tong Ye and Ann Foley and hosted by the Clemson-MUSC Bioengineering Program, BEACH is a chance for undergraduates to prove themselves to themselves while developing research skills and shadowing clinicians at MUSC. A summer program, BEACH attracts junior and senior engineering students who want to go on to graduate or professional schools, strengthen their resume by building skills during a research-clinical experience or take advantage of the program to complete an honors thesis in one summer.

Students join host labs immediately at the start of the program and spend at least 15 hours/week in research labs and clinics. Research projects typically focus on, but are not limited to, orthopedics, biomaterials, bioimaging, and stem cell-based tissue engineering. On Friday mornings, all participants meet for seminars and discussions with Clemson or MUSC faculty, postdoctoral scientists and PhD and medical students. BEACH presently hosts 6-8 students each session, giving each student ample time to interact with graduate students, undergraduates, principal investigators and clinicians.

Through days of lab time, clinical shadowing, seminar and discussion, students gain the skills and experience that graduate schools demand while learning what healthcare delivery really requires today. Nationally ranked in 5 adult specialties and 6 pediatric specialties and rated high performing in 6 adult specialties and 8 procedures and conditions, MUSC, a general medical and surgical facility, is a teaching hospital with a 700-bed medical center. It includes a nationally recognized children's hospital, the NCI-designated Hollings Cancer Center, a Level I trauma center, Institute of Psychiatry, more than 100 outreach locations across the state, and South Carolina's only transplant center.

At first, I was a little nervous going into the program as I wasn't very sure what to expect and was worried that I would be underqualified for the work. To my surprise after reading relevant material supplied to me by my PI, I was quickly ready to get to work...I feel very confident that I will be a competent student researcher for any other labs that I work in for the rest of my undergraduate degree and potential graduate degree.

Marshall Wilson, rising junior BEACH 2018

...Not only did I get the opportunity to conduct research, but I also got to see the role of bioengineers in a hospital setting firsthand. Both the research project and shadowing sessions were wonderful learning experiences. I left the program with a newfound understanding of research, and a solidified plan for my future post-graduation.

Amelia Godolphin, rising junior BEACH 2018

According to Dr. Ye, some of the skills students can expect to learn are basic biomedical research methods, such as hypothesis-driven research design; data recording and maintenance of a lab notebook; communicating results orally and in writing; recording shadowing; reflecting on the shadowing experience as a source of ideas for applications.

For additional information, students may contact Dr. Ken Webb (kwebb@clemson.edu), Dr. Tong Ye (ye7@clemson.edu) or Dr. Ann Foley (acfoley@clemson.edu); <https://cecas.clemson.edu/nfil/beach> Editor



Sara Littlejohn, Elizabeth Lee and Hunter Black

THE THING I ENJOY THE MOST ABOUT THE MENG PROGRAM IS ITS STRUCTURE:

GRACE WHITE

Initially, I chose the Master of Engineering program as a way to delay graduation by another year. To put it simply, I was not ready for the real world. Before I decided to fully commit, I met with Dr. Jeremy Mercuri, the creator of the program, in the spring of my junior year. He explained that the MEng program is very beneficial for someone who knows they want to go into industry, but are not sure what area. As he was telling me this, I caught myself thinking "there's other areas besides research and development?" Immediately, I realized I had a lot to gain from just one additional year.

The summer before the MEng program, I had the opportunity to intern with Corbion, a biomaterials company just outside Atlanta. Again, I was a R&D intern. However, this time things were a little different. I was at a relatively small company location, with fewer than 30 employees there. Yes, I worked mostly with the R&D team, but in such a small facility, it was hard to ignore the other areas. I was constantly seeing what project managers, technicians, quality control engineers and specialists, and regulatory affairs specialists do daily. This made me even more excited for what was to come in the MEng program.

It is hard to fail when everyone is on your team and rooting for your success academically, professionally and in terms of personal growth.

Little did I know, Corbion had more in store for me than just the summer internship. We were able to work out a way for me to continue working part time in Atlanta on Mondays and Tuesdays while still earning my master's degree in Clemson the rest of the week. I knew this was going to be a challenging year, to say the least. However, I also knew it was going to be an invaluable one. Working while completing my degree has allowed me to see how the things we learn in class are directly applied in industry. It has also taught me how to balance and prioritize my tasks.



The coolest part is, I am not the only one given this kind of opportunity. The MEng program not only pushes you to explore different professional areas, but helps you find an internship to broaden your scope of what a biomedical engineering career could hold for you. This is one of the many ways this program can benefit you.

The thing I enjoy the most about the MEng Program is its structure: There are tasks for you to complete, and then you are able to present your progress and findings to your professors, mentors, and even peers. Now, do not get me wrong, there are still lectures, homework, and a few exams that do require studying, but there are groups of people you can lean on for help and professors who are more like bosses in that they are there to support you along the way. It is hard to fail when everyone is on your team and rooting for your success academically, professionally and in terms of personal growth.

I also want to highlight that almost all of the professors involved in the core classes of the MEng program have worked or are currently working in industry. I think this gives the program an upper hand compared to programs taught by professors strictly involved in academia. Our professors know firsthand what it is like to be in our shoes applying for jobs, but they also know what it's like to be hiring on the company's side. Having seen both sides, our professors are able to help us prepare for the real world in ways that many other programs cannot offer.

I have also enjoyed the experiences this program has had to offer. My most memorable experience was over Fall Break, when we took a trip to Memphis, TN, where many orthopedic medical device companies are located. We toured and networked with two large companies, Medtronic and Wright Medical, and simultaneously, we all got to know our classmates better. I enjoyed this experience because not only did it expand, yet again, my view of biomedical engineering, but it allowed me to hear first hand from people in industry what they were looking for in potential employees. I found that most of it was in alignment with skills I had gained from the MEng program.

I have no doubt that this program will make a significant difference in my future career. It has introduced and connected me to some incredible people and has shown me some of the

Our professors know firsthand what it is like to be in our shoes applying for jobs, but they also know what it's like to be hiring on the company's side.

most memorable experiences. Without this program, I do not think I would be where I am today, and I look forward to where it will take me in the months leading up to graduation.

IN HIS MEDICAL-SCHOOL GAP YEAR, PRESTON WALKER TAKES ON THE M.ENG.

Why you chose Master of Engineering?

My answer to this question is different from most who choose to get a Master of Engineering (M.Eng.). Prior to enrolling and throughout Clemson University's Master of Biomedical Engineering program, I have pursued the medical school route. I applied during the latest application cycle with hopes to matriculate in the beginning of fall 2019. As senior year came to an end, I began to look for jobs as well as Master of Science (MS) programs to fill my gap year. MS programs, while strengthening my application, would not necessarily separate me from other candidates, and I unfortunately found that bioengineering companies did not want to train someone who would potentially leave in a year. After regrouping and assessing my options, I decided to pursue this M.Eng. program for three reasons: uniqueness, time, and location.

I knew that having a M.Eng. would make me a more distinguished and exciting medical school candidate. This was continually reinforced during interviews for medical school this fall. A question that was commonly asked was "What are you doing now?" Replying with "Getting my Master's in Engineering," always intrigued



Another aspect I personally enjoyed was touring medical device companies. The M.Eng. program includes multiple medical device company visits with accommodations included.

the interviewer. This response easily fed into descriptions of projects, internships, and research experiences available during the program. Enrollment in this program helped to separate my application from other candidates', and subsequently led to my acceptance into medical school.

Time and location of the program also solidified my decision. Clemson's M.Eng. program covers only a fall and spring semester, making it the perfect fit for a gap year. Additionally, I was able to participate in the first program ever offered at the Medical University of South Carolina (MUSC), right in the heart of Charleston, SC. The partnership with MUSC opened doors to incredible opportunities including shadowing physicians in the clinic, sitting in on surgeries, partaking in clinical research and networking with doctors of all disciplines. Aside from the added scholastic and career benefits, the beaches, food, and small city atmosphere are great perks for anyone looking to join this program.

What is the program like?

With a two-semester time-frame, the M.Eng. program is accelerated; it covers a wide range of topics including FDA regulatory pathways; device design; manufacturing; verification and validation testing; commercialization of medical devices; and many more. Things move quickly and require hard work to keep up. You work within a team to develop a biomedical device from concept through all stages of the design process, ending with a mock FDA submission. Throughout, you collaborate alongside clinicians, industry partners, and program mentors. Weekly presentations and interviews are a norm and strengthen your presentation and interpersonal skills.

Although a number of classes are mandatory, you get the opportunity to explore your own interests through bioengineering electives covering clinical trials, regenerative medicine, and structural mechanics, to name a few. An unmatched perk of this program is the encouragement and assistance from faculty to find students internships providing research/job experience. Course credit and monetary compensation, depending on the opportunity, are awarded those who choose to intern during the semester. The faculty also work very hard to prepare you for your next career step (be it industry, Ph.D., med school... etc.), providing interview advice, reviewing resumes, and giving general career advice.

What do you enjoy about the program?

One aspect that I really appreciated was the amount of time I spent working with people. I spent a considerable amount of time working alongside my team members as well as fellow Ph.D. students, meeting with clinicians, and collaborating with industry partners. These interactions, something I believe are uncommon among postgraduate engineering programs, help to develop the good interpersonal/soft skills that engineers require to excel. Another uncommon aspect was the support from faculty and students alike that my team received to move our design project forward. During verification of our device, we struggled with limited experience and knowledge of computational modeling. The guidance given by Ph.D. students in other labs and our mentors allowed us to succeed, and more importantly gain novel experience.

Having detailed knowledge of FDA regulations and the current approval and reimbursement processes of medical devices will help me be better connected to patient care in and after medical school.

Another aspect I personally enjoyed was touring medical device companies. The M.Eng. program includes multiple medical device company visits with accommodations included. On these visits we toured manufacturing, sterilization, and device testing facilities. These tours also included discussions with recent hires about industry practices, company cultures, and hiring procedures of small-to-large medical device companies. These and other panel-like discussions with members of the medical company provided personal insight into recruitment and job placement post graduation. The ability to tour facilities was a prominent experience, and it gave me an in-depth perspective of what working at a medical device company would be like.

How do you think this program will make a difference in your future?

Having detailed knowledge of FDA regulations and the current approval and reimbursement processes of medical devices will help me be better connected to patient care in and after medical school. This knowledge will help my understanding of how policy changes will affect patients' access to and ability to afford certain medical drugs, treatments, and/or devices. These intricacies will help me to better protect the patient's best interest. The knowledge will also allow me to be a better patient advocate for policy changes that ensure the safety and efficacy of medical devices/drugs.

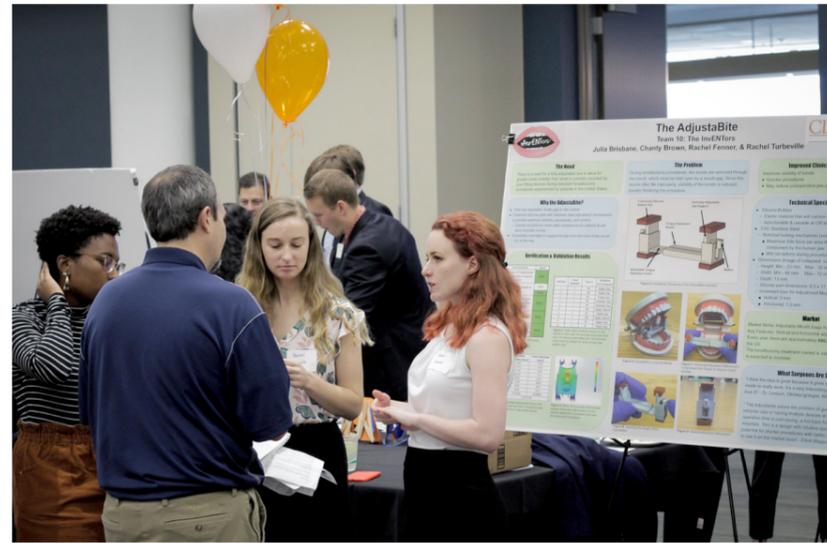
2019 Design Team Winners

With dozens of bioengineering design teams showcasing novel biomedical device prototypes, the Clemson Bioengineering Senior Design Expo continues to be one of the yearly highlights of the biotech community calendar. The 2019 event was held May 2 in the Greenville Convention Center, where more than 30 teams presented design innovations developed in partnership with local healthcare partners. More than 250 visitors from the community, industry, healthcare and academia attended.

Dr. John DesJardins is director of Clemson Bioengineering's senior design program and was faculty leader of the first, second and third place winners and the audience favorite. He stated, "These novel devices have been developed in response to real clinical needs that were voiced by our clinical partners.

Every device at the symposium was evaluated by a judging panel and the technology transfer offices of the partner institutions. The devices were considered for patents, further development, and eventual approval for use on the market."

Winning ideas will undergo another year of development in Clemson's Master's of Biomedical Engineering program or the South Carolina Regional Authority's new Medical Device Alliance Program. According to DesJardins, "We have the talent, technologies and mentors to make these medical devices a reality, and we are excited to see what 2020 will bring."



The MENG Winner

Team 1: Pivotal Orthopaedics – Total knee replacement design with rotatable polyethylene insert and medial pivot point

Students: Steven Gannon, Austin Hensley, Alisha Mah, Sarah McKain, Corey Umstead, Preston Walker

Faculty Mentor: Jeremy Mercuri

The Senior Design Winners

1st Place Sublime Surgical Solutions with Polyguided biopsy/localization for lumpectomy

TA: Timmy Samec

Faculty Mentors: Naren Vyavahare, Jiro Nagatomi, Bob Latour

Graduate Student Mentors: Matthew Burt, Scott Slaney

Clinical Collaborator: Dr. Andrea Abbott

2nd Place OrthoJAMZ with Ortho/Trauma Bone Cerclage Tunneling Device

Students: Xavier Peralta, Madeline Blankenship, Amanda Chernick, Zackary Richardson

Students: Chelsea M Rose, Eva A Caruso, Maren Leigh Downing, McKenzie Fletcher, Yvette C. Ramirez

TA: Nathan Carrington

Faculty Mentors: Drs. Tyler Harvey and Jeremy Mercuri

Graduate Student Mentors: Cody Dunton, Adam Baker, Lucas Tatem, Kyle Walker

Clinical Collaborator: Dr. Douglas Powell



3rd Place Cathaways Rotatable Cardiac catheter cord

Students: Ellen Christine Colborn, Helen Nguyen, Callie Diane Stuart, Rashed K Abdel-Tawab, Henry W.Randall

TA: Nathan Carrington

Faculty Mentors: Drs. Tyler Harvey and Jeremy Mercuri

Graduate Student Mentors: Cody Dunton, Adam Baker, Lucas Tatem, Kyle Walker

Clinical Collaborators: Berry Lovering, Dr. Alvin Kpaeyeh

Audience Favorite

AMEDD Pediatric OR Patient Warming Device

Students: Delayne Gallagher Di Gangi, Emily Logan Shook, David Michael Stanley, Meredith G. Hatchett, Adam J. Samuta

TA: Rithwik Jallepi

Faculty Mentors: Drs. Tyler Harvey and Cindy Smith

Graduate Student Mentors: Davis Ferriell, Samuel Coeyman

Clinical Collaborators: Nanette Stafford, Dr. Grace Williams, Dr. Mark Hooten

We have the talent, technologies and mentors to make these medical devices a reality, and we are excited to see what 2020 will bring.

John DesJardins



ALUMNI AWARD FOR OUTSTANDING ACHIEVEMENTS IN RESEARCH

Awards from Clemson University Research Foundation



Dr. Hai Yao receives Alumni Award for Outstanding Achievements in Research

Clemson's 2018-19 winner of the Alumni Award for Outstanding Achievements In Research is the Ernest R. Norville Endowed Chair and Professor of Bioengineering and Professor of Oral Health Sciences at the Medical University of South Carolina, Dr. Hai Yao.

Dr. Yao is working to advance the biomechanical function, degeneration and regeneration of skeletal systems, specifically

the temporomandibular joint (TMJ). Dr. Yao's group established the first multiscale TMJ model integrating joint imaging and kinematics, tissue mechanics, cell metabolism, and genetics to determine the path of normal TMJ remodeling or degeneration. He serves on the committee for a consensus study on TMJ disorders at the National Academy of Medicine.

FACULTY NEWS

Dr. John DesJardins Receives Burtner Award

Dr. DesJardins, Hambright Leadership Professor of Bioengineering, received the Frank A. Burtner Award for Excellence in Advising. He was recognized for dedicating his career to the mentorship and support of students through collaborative research and design projects, Creative Inquiry, study abroad, and international student research and outreach programs. DesJardins's support and counsel have directly affected more than 1000 Clemson students.

The Clemson University Research Foundation (CURF) awarded Technology Maturation Fund grants in January to support the last critical step in technology development. Four of the winners are bioengineers: Drs. Kevin Champaigne, Jiro Nagatomi, Dan Simionescu and Alexey Vertegel.



CURF awarded Dr. Kevin Champaigne a matching grant to support an ongoing Phase 1 STTR from the National Institute of Mental Health. In this research, Greenwood Genetic Center and Circa Bioscience are partnering to develop a screening test for autism spectrum disorder.



CURF awarded Dr. Alexey Vertegel a grant to further develop a polymeric coating that can cling to metal implants. The technology can significantly reduce the burden of orthopedic implant pin site infections through the utilization of highly adhesive antimicrobial drug-eluting polymeric coatings.



Dr. Dan Simionescu was awarded a grant by CURF to continue development of vascular grafts that are resistant to diabetes. Numerous surgeons use small diameter synthetic grafts during bypass surgery to salvage failing limbs or hearts in diabetic patients; however, many such grafts fail dramatically in these patients. This targeted approach solves the unmet need for off-the-shelf graft solutions that are resistant to complications associated with diabetes.



Dr. Jiro Nagatomi was awarded a grant by CURF to refine a product that could replace internal sutures in laparoscopic and robotic surgeries, which would shorten surgeries and reduce complications. The hemostatic tissue adhesive technology, which has garnered early attention from industry, will undergo additional pilot studies in cardiovascular and gastrointestinal applications in collaboration with surgeons at Greenville Health System.

CLASS OF '39 AWARD GOES TO LEADING AUTHORITY IN ENGINEERING EDUCATION

Paul Alongi



A professor who is regarded as one of the world's leading authorities in engineering education and whose influence has extended from a Greenville arts festival to workshops as far away as Indonesia is winning this year's Class of '39 Award for Excellence. Lisa Benson has developed several programs that have become integral to the Clemson University community, while carving out a reputation as an outstanding teacher and researcher.

Lisa is in her second year of a five-year term as editor of the Journal of Engineering Education, the flagship research journal

of the American Society of Engineering Education. As editor, Benson plays a key role in deciding what research is published in the journal, the top in her profession.

Each year, the Class of '39 Award goes to one distinguished faculty member whose outstanding contributions over a five-year period have been judged by his or her peers to represent the highest achievement of service to the university, the student body and the larger community. As the 2018 winner, Benson's name will be engraved in stone at Carillon Gardens next to 29 past winners, who represent a variety of disciplines going back to 1989.

"I understand how special it is to be a member of the Class of '39," she said. "I actually got to meet some of them many years ago when I gave tours of the Clemson carillon, and they came up to the bell tower to ring 'their' bells. They were an amazing group of people. Winning this award is a high honor. I'd like to thank all those who supported and nominated me. This is a team effort."

Cindy Lee, chair of the Department of Engineering and Science Education, said the award is well deserved. "Lisa is a passionate educator and researcher who is making the world a better place for students, faculty members and colleagues here in Clemson, across the nation and around the world," Lee said. "She has voluntarily taken on several large projects because she sees them as ways to promote STEM, her students and colleagues."

Benson was the first faculty member hired when the department was founded in 2006 and has since developed several programs to help students, graduate teaching assistants and fellow researchers. Science As Art is among the most far-reaching and publicly visible of her programs. Students and faculty members create visual art with scientific themes, often including images pulled directly from research projects. The works are a major part of Clemson University's STEAM Exhibit at Artisphere in downtown Greenville each May.

Benson also co-founded a workshop series that helped students apply for the Graduate Research Fellowship, a prestigious honor from the National Science Foundation that helps pay for graduate school. The workshop helped boost the number of Clemson students who received the fellowship, including seven in 2016 and eight in 2017.

Benson has also been called an outstanding teacher who brings innovative, student-focused practices to the classroom. She has taught junior-level bioengineering classes and graduate-level classes aimed at preparing students to become faculty members in the sciences, engineering and mathematics. Graduate students often describe Benson as inspiring. She provides guidance and asks challenging but appreciated questions during thesis and dissertation defenses, students said.

Lisa Benson of Clemson University, a leading authority in engineering education, has established a reputation as an outstanding teacher and researcher.

Winning this award is a high honor. I'd like to thank all those who supported and nominated me. This is a team effort.

Several of Benson's students have gone on to use the work they did with her as the basis for grants they secured after graduating and becoming faculty members.

According to colleagues, Benson's research in engineering education is internationally recognized from Europe to Asia, where she has led workshops for aspiring education researchers.

Benson has played an integral role in multiple National Science Foundation grants that are aimed at supporting students and creating new innovations in Clemson's academic culture. One is the university-wide ADVANCE grant, which aims to reduce gender inequality and improve opportunities for all early- and mid-career faculty members at Clemson. Two grants are based in Glenn Department of Civil Engineering – the Revolutionizing Engineering Departments grant and the Graduate Assistance in Areas of National Need grant.

Another was "Tigers Teach," a collaboration with the College of Education on a Robert Noyce Scholarship Initiative. It provided financial support to students who plan to be STEM educators. Much of the work grew out of her CAREER award from the National Science Foundation. The award focused on the relationships between student motivation and learning in engineering. Benson is responsible for \$1.4 million in external funding over the past five years to support her research. The number climbs to \$6 million when counting her collaborative efforts to support research at Clemson as a whole.

The Class of '39 Award is the latest in a string of honors for Benson. She and her students have won four best paper awards in the past five years, and Benson received the Collaboration Award in 2015 from the College of Engineering, Computing and Applied Sciences. Anand Gramopadhye, dean of the college, said that Benson is eminently qualified for the Class of '39 Award. "Dr. Benson has devoted countless hours to serving her students and colleagues," Gramopadhye said. "She is an inspirational leader, outstanding teacher and innovative researcher. The honor is well deserved."

A LEGACY OF LEADERSHIP



I.V. Hall with wife, Susan, and daughter Abigail at the induction ceremony

Mr. Harry Thomas Hall I.V. (also known as I.V. Hall) was inducted into the Thomas Green Clemson Academy, the highest honor bestowed by the college. Below is an excerpt from Dr. Martine LaBerge's letter of nomination. Editor

Through his dedication, engagement, and service to Clemson University and its student body at-large, the Clemson University Research Foundation, the College and the Department of Bioengineering, I.V. exemplifies Academy membership. I.V. earned the Master in Bioengineering degree in May 1995 following a Bachelor of Science in Ceramic Engineering degree in 1992 from Clemson University. He received a Healthcare MBA degree from Pennsylvania State University in 2000 and graduated from Harvard Business School Advanced Management Program in 2009.

During his career, I.V. has assumed key leadership positions in the medical device industry. He currently serves as Worldwide

President for Trauma, Craniomaxillofacial and Animal Health platforms at DePuy Synthes, a J&J Company, where he is responsible for strategy to strengthen offerings globally. He leads teams responsible for accelerating innovation, growth and business performance. He previously served as Worldwide President of the DePuy Synthes Trauma Division.

In the orthopaedic medical device industry, I.V. is recognized as the ultimate leader, bridging and building relationships with divisions and customers and leading acquisitions. He helped re-engineer the franchise and platform leadership organization at DePuy Synthes to deliver consistent and balanced results for early innovation investigations, portfolio optimization, and new product development.

In 1997, I.V. joined Synthes, predecessor of DePuy Synthes, after working in the cardiovascular device industry developing products for Kensey Nash Corporation. Under his leadership,

DePuy Synthes maintained its status as number one market leader worldwide for trauma with revenue exceeding \$2.5B annually. Synthes was acquired by J&J in 2011 for more than \$23B. Synthes and Depuy, another J&J acquisition focused on the total joint replacement market, were subsequently merged to become a J&J Company. I.V. helped navigate the transition of Synthes, a privately owned company, and led its employees to a successful venture.

While I.V. was at Synthes, its owner, Dr. Hansjörg Wyss, referred to him as their best overall employee among 8,200 employees worldwide. When Clemson University proposed a partnership to Synthes for the support of the SmartState Endowed Chair in Regenerative Medicine, Dr. Wyss loudly and happily responded that he "will listen because I.V. graduated from Clemson and Synthes knows that Clemson's students are the best engineers." Literally, I.V. made it possible for Clemson to secure the match to support the \$4M Endowed Chair named, "The Hansjörg Wyss Endowed Chair in Regenerative Medicine." Through I.V.'s leadership, a \$1.6M unrestricted gift for research was made by Wyss Foundation to Clemson.

I.V. has continued to promote the talent of faculty and students at Clemson and helped advance the Clemson-MUSC O.P.E.R.A.T.E.© (Orthopaedic Program Engaging Research And Translational Education) program as a platform for innovation. As a member of the Department of Bioengineering External Advisory Board for 10 years and its past-chair for three years, I.V. has helped develop the Biomedical Engineering Capstone

Design program (considered a national model for BME design by Coulter College and VentureWell) and the Master of Engineering in Biomedical Engineering program. He conducts numerous mock interviews with students before their formal job interviews for employment in the medical device industry.

To Clemson University, I.V. has greatly contributed time, energy and leadership as an elected member of the Clemson University Research Foundation Board and is presently in his second term. He has chaired the groups of Board Structure and Nominations and Donor Development in addition to co-chairing the HR Committee. He also serves on the CECAS Dean's Advisory Council. I.V.'s gifts of time, leadership and financials (Harry T. Hall Endowment) have been transformative and clearly help position Clemson as the ultimate institution for learning, innovating and leading at our three campuses, CU-MUSC Bioengineering Program, CUBEInC, and main campus.

I.V. has significantly contributed to our College and Clemson University at large. A role model for other alumni, faculty, staff and students, I.V. serves as the ultimate ambassador for Clemson's reputation. Every faculty member and student who has had the pleasure of working with I.V. has felt transformed and empowered to lead by example. I.V. Hall has brought distinction to Clemson University through conspicuous success in his career, but his major impact is yet to come: His legacy of leadership will continue to impact students from generation to generation.



Promotions:

The following faculty were promoted with tenure:

Dr. Delphine Dean was promoted to full professor and retains the Gregg-Graniteville Professorship.

Dr. John DesJardins was promoted to full professor and retains the Robert B. and Susan B. Hambricht Leadership Professorship.

Dr. Jeremy Mercuri was promoted to associate professor.

Dr. Tong Ye was promoted to associate professor.

Alumni Spotlight: *Chelsea Ex-Lubeskie*

After graduating in 2013 with my MS in bioengineering, I moved back to Charleston, SC, to take on an entrepreneurial endeavor with my former classmate and business partner, Riley Csernica. We formed Tarian Orthotics, LLC, in August 2013 to commercialize a shoulder brace we invented as a part of Senior Design. During the first year of Tarian, I began working part-time at MUSC's technology transfer office, MUSC Foundation for Research Development. When we made the hard decision to shut the company down nearly three years later, I was offered a full-time position at MUSC FRD and began as a Marketing Analyst. In this role, I worked to market technologies managed by MUSC FRD toward licensing them to companies for commercialization.

Next, I worked as a Licensing Manager, managing a pipeline of medical device, mobile device, and software technologies. In my current position as Business Development Manager, I work with MUSC startup companies, primarily in helping obtain small business funding through NIH grants, including SBIR and STTR. I have stayed involved in Charleston's and South Carolina's entrepreneurial ecosystem: Tarian Orthotics participated in the very first Harbor Accelerator program run by Harbor Entrepreneur Center here in Charleston, and entrepreneurship is near and dear to my heart. I currently serve on SCBIO's Industry and Innovation Council, which works to keep talented graduates in SC and to expand the life sciences industry. I work closely with the South Carolina Research Authority to help provide resources for our MUSC startup companies. Most recently, I participated in Leadership Charleston, a program offered through the Charleston Metro Chamber of Commerce; we dove into the most challenging obstacles our region is facing and got further engaged with the community

Early on at MUSC FRD, I realized that many of our physicians, while they had great ideas, didn't have engineers on campus to help them prototype their concepts. Having seen a product get to market that was based on the collaboration among a physician, athletic trainer, and a team of Clemson bioengineering students, I knew the value of these types of collaboration. I reached out to Dr. John DesJardins to see if we could have some Senior Design teams work with MUSC physicians, and I'm happy to say that we've now been collaborating for two years.

In high school, I had no intention of going to Clemson. My mother went to Clemson and graduated in electrical engineering, and I wanted to pave my own way. I initially thought I would go to a smaller school like Furman or Wofford, play volleyball, and do prepharmacy. During my senior year in high school, I toured colleges across the state and got to spend time with students at each visit. I ended up shadowing a female chemical engineering student during my Clemson visit, and I began to fall in love with the campus. During my day with her, I got a call from my dad that I had received a large envelope from Clemson, and he asked if I wanted him to open it. The minute he told me I had been accepted by the College of Engineering, I knew I was going to attend Clemson in Fall 2007. As many Clemson alumni can understand, I fell in love with everything about Clemson during my time there. I played on the club volleyball team, was a member of Gamma Phi Beta sorority, served as VP of the Clemson Undergraduate Bioengineering Society for one year and always tried to immerse myself in activities all across campus.

The Department of Bioengineering and its faculty and staff members had a huge impact on my time at Clemson. Dr. LaBerge is an incredible leader, mentor, and inspiration. She took the time to truly invest in the students and listen to us when we had problems or ideas. I also worked closely with Dr. DesJardins,

During my time at Clemson, and during the years I co-operated my startup, there were so many people who helped and mentored me. I have always wanted to give back to the students and department in any way that I can.

my study abroad and Senior Design professor, and Dr. Lisa Benson, my Master's thesis advisor. Drs. LaBerge, DesJardins, and Benson all were extremely influential during my time at Clemson. They were all highly supportive of my exploration of a variety of career options, and I felt as if they all genuinely cared about me as a student and person. I am fortunate to still work with Dr. DesJardins and Dr. Delphine Dean on a variety of projects with collaborations between MUSC and Clemson.

I also wouldn't have been likely to have made it through graduate school without Ms. Maria Torres. She was my mom away from home and a huge cheerleader for me. The department always felt like a warm and inviting place, where I knew I had mentors and teachers who truly cared. During my time at Clemson, and during the years we operated our startup, there were so many people

who helped and mentored me. I have always wanted to give back to the students and department in any way that I can. One of my favorite quotations is, "Alone we can go fast, but together we can go far," and I fully believe that that quote applies to the life sciences ecosystem here in the state. I have tried to give back as much as I can, primarily by spending my time talking to students, mentoring budding innovators and entrepreneurs, and serving as an advisor to a Master's of Engineering team in Charleston.

As I continue my career, I continue to enjoy working with innovators. I want always to be involved in healthcare innovation, whether at a university or big company or by starting multiple small companies. As long as I am working in a position where I am able to impact patient outcomes and quality of life, I know I will be fulfilled. I would love to ultimately work on a state or national level to continue to help improve the innovation and entrepreneurial ecosystem in South Carolina and the southeast.

Ms. Ex-Lubeskie is one of this year's three Outstanding Young Alumni. They, along with three newly inducted members of the Thomas Green Clemson Academy of Engineers and Scientists, gathered in Memorial Stadium on the night of April 25 for the annual showcase gala of the College of Engineering, Computing and Applied Sciences. Editor



Chelsea Ex-Lubeskie lights up the score board!

South Carolina Medical Device Alliance to Invent, Advance and Bring Products to Market



South Carolina Research Authority has been awarded approximately \$750,000 in federal grant funding by the U.S. Economic Development Administration as part of the 2018 Regional Innovation Strategies Competition. The grant will fund the creation of the South Carolina Medical Device Alliance to invent and develop products and bring them to market. The alliance is a multi-stakeholder partnership including Clemson University (CU), Medical University of South Carolina (MUSC), and industry leaders; it will form a regional innovation cluster to increase the economic impact of this sector through job creation and startup formation and to attract international businesses to South Carolina.

The S. C. Medical Device Alliance brings together life science expertise throughout the state to support commercialization of innovative, early-stage medical technologies from our research institutions. *Chris Gesswein*

The MDA will move technologies to market by designing solutions, determining initial commercial feasibility, de-risking innovations with multidisciplinary teams, and launching startups that have been rigorously evaluated by seasoned industry experts. Chris Gesswein, Executive Director of the Clemson University Research Foundation, said this about the alliance, “The S. C. Medical Device Alliance brings together life science expertise throughout the state to support commercialization of innovative, early-stage medical technologies from our research institutions. By embedding industry knowledge and expertise early in the development phase, the Alliance will ensure that the technologies it supports address the validated market needs critical to successful commercialization.”

SCRA's capabilities in managing collaborations and its state-wide focus on fueling the innovation economy, provide the MDA's foundation. Through CU's Bioengineering and MBAe programs, MUSC's clinical capabilities, and SCRA's industry advisors, the state has substantial expertise and intellectual assets in the field that, once coordinated by the MDA, will lead to tremendous opportunity for economic impact. Leveraging South Carolina's existing expertise, infrastructure, and funding, the MDA will facilitate and accelerate commercialization of medical technologies; build entrepreneurial capabilities among students, faculty and clinicians; and foster startup formation in the sector.

Key personnel are Dr. John DesJardins, Hambricht Leadership associate professor in bioengineering at CU; Christine Dixon Thiesing, MBA, Director of Academic Programs at SCRA and co-

founder of CuRE Innovations; Michael J. Yost, Ph.D., Professor of Surgery and Vice Chairman of Surgery for Research at MUSC.

In Phase I, engineering students and clinical innovators will design preliminary solutions and identify commercially viable projects. CU and MUSC have a unique existing partnership in a senior design program that engages clinical innovators with engineering students to identify, develop, and solve critical clinical problems and move those solutions to become commercial products. Prior to public disclosure, the first phase of the MDA will bring industry insight to the initial stages of medical device development. Beginning with the 2018-2019 program, CU's existing Industry Advisory Board will identify the top commercially-viable senior design program projects. The top projects will then be disclosed to their respective technology transfer offices, where preliminary technology evaluations will be performed to determine patentability and commercial opportunity.



We are excited to have the medical devices invented in our senior design program serve as a pipeline in the development and commercialization of innovative biomedical devices. *Dr. John DesJardins*

The early industrial advisory board (IAB) input and preliminary technology transfer office (TTO) evaluation will better enable the TTOs at CU and MUSC to justify investing in patent filings prior to public disclosure, protecting the ability to file for patent protection world-wide. The TTOs and SCRA will identify the top faculty innovations from across the state to feed into Phase II. According to Dr. John DesJardins, Hambricht Leadership Associate Professor, Department of Bioengineering, Clemson University, “Our clinical and industry partnerships in design are essential to this educational process, and we are excited to have the medical devices invented in our senior design program serve as a pipeline in the development and commercialization of innovative biomedical devices.”

Phase II will see development of product profiles and determination of initial feasibility. SCRA will lead the effort to develop product profiles for the top technologies from Phase I. The profiles will include a regulatory assessment, comprehensive market and competitive analysis, production assessment/cost of goods analysis, patent landscape, and reimbursement assessment. The product profiles will be provided to the medical device commercialization advisory panel (MDCAP) as the background information necessary to determine the next steps of development for each project. The MDCAP also will evaluate each project based on an established, multifaceted rubric for the potential commercial value and make recommendations regarding which projects should advance to Phase III.

In Phase III, multidisciplinary teams will attempt to decrease device risks. CU will hire a Professor of Practice with extensive industry experience in medical device development who will curate and lead



multidisciplinary teams consisting of masters-level bioengineering students, business students, and law students, along with clinical subject matter experts. The teams will de-risk the medical devices to address the needs identified by the IAB and MDCAP. This phase will include funding fellowships in entrepreneurship for bioengineering graduate students. The student teams will conduct market research by convening focus groups in coordination with clinicians at MUSC and other clinical partner institutions. After one year, the students will present their findings to the MDCAP for re-evaluation and determination of the next steps.

Phase IV's focus will be to implement translation/maturation. The MDCAP, in conjunction with the PoP, will determine which of four paths a project will take in this phase:

- 1) Optimally, projects will be adequately de-risked to serve as the basis of a startup company and attract follow-on funding. Funding from the i6 will be deployed to hire an EIR to provide a strong foundation for the startup and increase the potential for successful translation into the marketplace;
- 2) Some projects may require additional de-risking. In such cases, the project will revert to Phase III for an additional year of development;
- 3) Some projects will be best suited to an out-licensing model by the relevant TTO upon completion of Phase III;
- 4) A portion of projects will have encountered an insurmountable issue, resulting in termination.

At the end of the Performance Period, South Carolina will have a sustainable mechanism to produce entrepreneurial jobs in the medical device field and expand the entrepreneurial capacity of the state. This will serve as an outlet for previously unmet clinical needs to have a significant and enduring economic impact for the state.

Dr. Dan Simionescu Co-organizes Dempsey Research Conference

Paul Alongi

A

bout 150 engineers, medical doctors, students and health professionals gathered in Greenville on Feb. 22 for the Harriet and Jerry Dempsey Research Conference. Attendance has doubled since the annual conference started bringing together Clemson University and Prisma Health-Upstate three years ago. The conference is part of a broader effort to conduct more high-profile medical research in South Carolina, a move that could mean better and lower-cost care for the state's patients.

The third annual conference is the latest effort to expand the collaboration between Clemson University and Prisma Health-Upstate, formerly known as Greenville Health System. The two institutions have several joint projects in the works, including a \$10-million Center for Biomedical Research Excellence that was announced in October and also includes the Medical University of South Carolina.

The Clemson University and Prisma Health-Upstate partnership is led by Windsor Westbrook Sherrill, associate vice president for health research at Clemson. She works with JoVanna King, also of Clemson, and the Clemson University School of Health Research, to identify sources of philanthropic support for health research.

Sherrill and other Clemson research leaders have built a robust research-and-teaching enterprise that brings together Clemson University faculty and Prisma Health clinicians for multidisciplinary research aimed at making the world a better place through the transformation of health care. The Clemson-Prisma Health partnership has grown to include several new professorships, a \$2.66-million grant for diabetes prevention, the \$10-million Center for Biomedical Research Excellence and the \$31.5-million Clemson University Nursing Building.

Spence Taylor, president of Prisma Health-Upstate, said the conference will help strengthen the bonds between Clemson University and Prisma Health even further. "Working together, we can make great strides in advancing patient-centered care, quality improvement and service innovation," he said. "Our combined efforts can help us go further than we could working in isolation."

"What we're doing here is building a bridge, bringing the USC School of Medicine-Greenville GHS to Clemson University's campus and our campus to the medical school," Clemson bioengineer Dan Simionescu said. "We're trying to shorten that 30-mile interval." The idea behind bridging the two institutions—that Clemson can bring the engineering expertise and that the health system's clinicians can help ensure the research—remains grounded in what happens in real-world health care settings.

A key pillar of the bridge is Jerry Dempsey, who received his mechanical engineering degree from Clemson in 1954 and is the former chairman of what was then known as the Greenville Health System board of trustees.

The conference is named for Dempsey and his late wife, Harriet. An endowment he provided to Clemson in 2015 created professorships for the conference's two organizers, Simionescu and Kevin Taaffe, who both conduct research with Prisma Health-Upstate.

"This conference brings together two of South Carolina's most influential institutions, Clemson University and Prisma Health," Dempsey said. "I am glad to support it and look forward to a vigorous and fruitful discussion that ultimately leads to improved health care for all." Simionescu is the Harriet and Jerry Dempsey Professor of Bioengineering, and Taaffe is the Harriet and Jerry Dempsey Professor of Industrial Engineering.

The conference agenda included:

- Tom Borg of the Medical University of South Carolina; Extracellular Matrix in Heart development regeneration;
- Arash Kheradvar of the University of California, Irvine; Mitochondrial Transplantation for Cardiac Diseases;
- Brian Denton of the University of Michigan; Data Analytics for Optimal Detection of Metastatic Prostate Cancer;
- Raj Ratwani of MedStar Health; Understanding Physician Stress, Workflow, and Task Interruptions.

Most participants were faculty members, students and administrators from Clemson and Prisma Health-Upstate. Those in town for the Society of Academic Emergency Medicine Southeastern Regional Conference were also invited. Martine



Drs. Kevin Taaffe, Jerry Dempsey and Dan Simionescu

LaBerge, chair of the Department of Bioengineering, said the conference gives students, faculty and administrators a chance to network with peers and learn fresh perspectives.

"This conference, now in its third year, provides unique opportunities to explore new ground for collaboration," she said. "Drs. Simionescu and Taaffe did an excellent job of setting the stage for an engaging discussion."

Scott Mason, acting chair of the Department of Industrial Engineering, said the wide range of speakers on the agenda helped attract a diverse cadre of researchers and health care professionals.

"Drs. Taaffe and Simionescu are both highly accomplished and well-connected authorities in their fields," Mason said. "They tapped their extensive networks to bring some of the nation's top researchers to the conference."

Anand Gramopadhye, dean of the College of Engineering, Computing and Applied Sciences, thanked Dempsey for his support. "His generosity and vision are helping bring together Clemson University and Prisma Health-Upstate Greenville Health System to improve health care outcomes for all," Gramopadhye said. "The work we do together will help shape the future for generations to come. Jerry Dempsey is leaving a lasting legacy."

What we're doing here is building this bridge, bringing the USC School of Medicine-Greenville GHS medical school to Clemson University's campus and our campus to the medical school.

Dr. Dan Simionescu

Professor of Practice Dave Shalaby

In 2010, Dave Shalaby took on the role of president of Poly-Med, Inc. after having served on the board of directors for eight years. Under Dave's leadership, the company has grown into a vertically integrated design, development, and custom manufacturer of bioresorbable medical device and pharmaceutical products. Before stepping into his role at Poly-Med, Inc., Dave was founder and president of InSource Consulting in 1997, providing strategic consulting services to financial service companies to improve process and business efficiencies through the use of process analysis methodologies.

During his tenure, Dave personally led major merger and acquisition operational integrations for several Fortune 100 insurance companies and has overseen countless key strategic efforts in support of the InSource clients.

He grew InSource Consulting into a multimillion dollar specialty management consulting firm aimed at providing strategic support services to large companies within the healthcare, financial service, and federal government sectors. InSource Consulting was acquired by Virtusa, Inc. (NASDAQ:VRTU) in 2009. At that time, he joined their leadership team as Senior Vice President responsible for their Insurance practice.

This unique mix of strategic and business acumen has led to significant growth at Poly-Med, Inc. Several key initiatives encouraging the team to achieve elegant solutions are advancing the company to the next level, while staying true to the legacy of Dave's father, Dr. Shalaby W. Shalaby.

Education

David holds a B.S. in Aeronautical Technology from Purdue University (1992) and an MBA from Loyola University of Chicago (1994).



Success in business is achieved by seeing and taking a path others fail to deem relevant.

OUR NEWEST LECTURER, DR. TYLER HARVEY

My first exposure to Clemson Bioengineering came during an eight-week summer research program the summer before my senior year of high school. I quickly developed a passion for this field and returned to Clemson as a freshman. This department has become my home in the eight years since. During my graduate work, I had the honor of being a TA and design mentor. Quickly, I discovered that our students are among the best and brightest at what they do and getting to help them along their journey as engineers is incredibly impactful. I am truly grateful to get to stay at Clemson and give back to my bioengineering family as a lecturer beginning this fall.

One of the most exciting aspects of my role will be the opportunity to interact with students at every single level of the curriculum, starting with freshmen in Biology for Bioengineers, sophomores and juniors in the professional development seminar sequence, and ending with co-teaching their senior design experience. This exposure will give me the unique experience of getting to know our students extremely well and getting to watch them grow and develop into engineers. As a student, my faculty mentors were a critical influence on where I am today, so I hope that this exposure to our students will give me a platform to serve as an advisor and mentor in the same way. Having lived through the undergraduate curriculum as a student, I believe I have the ability to relate to students on a very personal level and truly be an advocate for them. I also think this makes me an asset to the department as we look to evaluate and evolve our curricula moving forward.

Additionally, I have a strong appreciation for the effect that STEM outreach has had on my own life and hope to develop and expand our outreach efforts as a department. My current and past relationships with the South Carolina Governor's School for Science and Mathematics have given me the opportunity to create and deliver STEM education experiences to middle and high school students all over South Carolina. I hope my new role will give me an even broader platform to work with our amazing faculty, students, and staff towards advancing STEM education in our state. I want to open up a path to engineering careers for all students, but especially those from groups underrepresented in our discipline.



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Dr. Tyler Harvey won our department's Outstanding Graduate Teaching Assistant Award this spring. The award is given to an outstanding graduate teaching assistant who has been recognized by bioengineering faculty and undergraduate students as a superior teaching assistant during the school year. Editor



BMES Time Capsule

To commemorate the 50th anniversary of BMES, the Biomedical Engineering Society partnered with Clemson University's Department of Bioengineering to create a time capsule to preserve biomedical innovation as it exists today. Employing a 2'x2'x2' stainless steel box custom-made by Clemson's College of Engineering, Computing and Applied Sciences' Machining and Technical Services, the department collected artifacts donated by a number of medical device companies and by BMES.

Using Clemson's laser printers, students engraved stainless steel tiles in recognition of industry, university, foundation and individual sponsors. Students then secured the tiles to the capsule's sides. Proceeds from tile sponsorship will be used by BMES to support student activities.

When the capsule was complete and ready for shipment, Clemson hosted BMES representative Jenn Novesky, who participated in a ceremony during which each artifact was displayed, wrapped, and placed into the capsule. The capsule will rest in in Washington, D.C., until it is opened in 50 years.

Faculty leads on the project Drs. Martine LaBerge and John DesJardins officially handed over the capsule to the BMES Executive Management team. The closing and sealing ceremony may be viewed on the College of Engineering, Computing and Applied Sciences YouTube page.

(Please, check the QR code for the video)



NAVAL VETERAN FINDS HER CALLING WITH CLEMSON UNIVERSITY'S BIOENGINEERS

Paul Alongi

The beginning of the end of Melissa McCullough's naval career started on a late-night run to pick up sailors who had been off base. As bowman, it was her job to throw the line off the small boat so that it could be tied to the dock. The boat crashed into the dock, sending McCullough flying. She landed on her back, blowing out three vertebrae. The injury was painful and it eventually dashed her hopes of becoming an officer.

But if it hadn't happened, she may never have found the purpose she has at Clemson University. McCullough is pursuing her Ph.D. in bioengineering under the guidance of Delphine Dean while teaching and working full-time as the bioinstrumentation lab manager.

Now McCullough's academic work and service to her country are earning her some recognition that colleagues said is well deserved. She is among 60 U.S. service members, veterans and military spouses who have been named to the 11th class of Tillman Scholars. The scholarship comes from the Pat Tillman Foundation, named for the former Arizona Cardinal who left his lucrative football career to join the U.S. Army and was killed by friendly fire in Afghanistan. Honorees are sharing in more than \$1.2 million in scholarship funding this year.

The journey from enlisted sailor to aspiring professor was one that McCullough never dreamed she would take. "This teaching thing — it really has turned into something I was meant to do," McCullough said. "Unless everything in my life had happened the way it did, there's no way I would have gotten here."

Dean, the Gregg-Graniteville Professor of Bioengineering, said it's fun to work with McCullough, who brings a wealth of experience and a unique perspective to their work. She is well qualified for the scholarship, which recognizes recipients' service, leadership and potential, Dean said. "She has these big goals, both in her current projects and for her long-term career," Dean said. "She wants to help people. Her long-term goal is to train and educate up-and-coming engineers."

For McCullough, the road to Clemson started in Virginia. After high school, she enrolled at Tidewater Community College and worked at Dollar Tree. McCullough enlisted in the Navy after receiving a call from a recruiter, following in the footsteps of her father, a naval

electrician's mate. She liked the discipline and structure of the Navy and wanted to become an officer.

"I went for the hardest training I could: the electronics technician rating," McCullough said. She trained to fix satellite communications systems, and that's what she did at her first duty station. But after the 9/11 terror attacks, McCullough was transferred to Italy, where she found the scope of her work expanded. "I fixed everything from sewage tank sensors to closed-caption television," McCullough said. "I fixed cars, I fixed everything; forklifts, anything. And that really taught me I could apply the knowledge I have."

She said she was stationed on Sardinia when she was hurt in the boat's collision with the dock. "It was a super painful injury," McCullough said. "All my muscles just freaked out. I thought I couldn't walk at first, but once it calmed down and everything started healing, my motions came back." At the time, McCullough was a junior enlisted sailor who lived alone off base. Senior enlisted sailors made room for her in the barracks and assigned a rotating crew to take care of her while she healed.

It's an experience that has stuck with her. "Nobody told them how to do it — they just did it," McCullough said. "They didn't have to do it as well as they did, certainly. And I think like that. That's how my leadership is — you take care of folks." She was honorably discharged and enrolled at Old Dominion University, where she received her Bachelor of Science in electrical engineering technology.

I've really found what I'm supposed to be doing, and that is incredibly cool.

After graduation, McCullough began working for engineering contractors who did work with the U.S. Department of Defense and State Department. For about five years, she traveled the world, designing security systems, deterrents, radars and people monitors. Her work took her from Baghdad and Kabul to Benghazi and Sudan. The work was lucrative, high risk, high speed and high intensity, McCullough said.

"I was doing mission after mission," she said. "I did full deployments. I would get the flak jacket and helmet. I would deploy out with the military folks." It took a toll on her health. McCullough ended up with stress sickness, which came with ulcers and high blood pressure, she said. It was time to dial things down. By this time, she had settled in Charleston. She took classes at Trident Technical College, and then headed to Columbia, where she continued her studies at Midlands Technical College.

When it was time to go back to work, she found a job listing at Clemson. She remembers applying for the job and a transfer as a student on the same afternoon, and she got both. "I thought I would stay here a year or two and get some more schooling and fill up my bank account again and then off I'd go," McCullough said. "I thought I'd go back to contract engineering overseas."

But she found something at Clemson: a calling. McCullough started teaching, and Dean let her try new things. A Creative Inquiry course that centers on a bionic arm took off, earning great reviews from students and faculty members. "I was able to run teams and show kids how to fix things and make things," McCullough said. "When I came up with ideas to solve problems, they did them — and they worked!"

Quan Le, a rising senior who works as McCullough's research assistant, said that she has become a mentor who has taught him a lot. Among the most important lessons: "It doesn't matter where you come from or who you are," Le said. "You can get there if you have a goal in mind." McCullough said her success boosted her confidence and helped convince her to push hard on graduate school.

Now McCullough wants to be a tenure-track professor. She is developing a urinalysis device aimed at early detection of chronic kidney disease and estimates she has a year or two left before getting her Ph.D. Her story, she said, could not have happened any other way. "I've really found what I'm supposed to be doing, and that is incredibly cool," McCullough said. "I get really giddy when I think about it. I don't know how to express it without a big grin on my face."

Martine LaBerge, chair of the department of bioengineering, congratulated McCullough on her scholarship. "Melissa has brought her unique experience and talents to bear on the challenges students, faculty and staff face in the department of bioengineering," LaBerge said. "As a Tillman Scholar, she is well positioned to maximize and deepen her impact."



Melissa McCullough, right, works with rising senior Quan Lee on a urinalysis device she is developing as part of her Ph.D. studies.

National and Regional Awards

Spring 2018-Spring 2019

Matthew Coombs

National Institutes of Health K99 Pathway to Independence

Robert Coyle

National Institutes of Health F31 predoctoral fellowship

Ian DeMass, Kaleb Guion, Bennett Hardymon, Andrew Moore, Casey Young

National Institutes of Health-Venturewell Venture Prize

Colin Fair, Mina Gad, Alex Giron, Nick Matel, Tusharbhay Patel

National Institutes of Health-Venturewell 2nd place

Lauren Alford, Sheena Amin, Nicholas Baxter, Bryce Kunkle, John McGreevey, Julia Spieker

National Institutes of Health-Venturewell Honorable Mention

Alex Ormerod, Bradley Scammon, Lucas Tatem

National Institutes of Health-Venturewell Honorable Mention

Josh Walters

Graduate Assistantship from the South Carolina Space Grant Consortium

Julia Brisbane

National Academy Engineering Grand Challenge Scholar

Irene Cheng

National Security Education Program Boren Award

Aniqa Chowdhury

National Science Foundation Graduate Research Fellowship

Timothy Samec

Honorable Mention, National Science Foundation Graduate Research Fellowship

OrthO-X Lab members Ryan Borem, Josh Walters, Allison Madeline

Society for Biomaterials Honorable Mention

Alex Ormerod, Bradley Scammon, Lucas Tatem

2nd Place, Biomedical Engineering Society, 2018 Undergraduate Design Competition

Sarah Johnson, Noah Wright

ACC Academic Consortium Fellowship in Creativity and Innovation, 2018

Lucy Lu

Star Award, Society for Biomaterials, Atlanta, GA, 2018

Kyle Snethen

Force & Motion Young Scientist Award, Orthopaedic Research Society, 2018

Carson Brewer, Ian DeMass, Ryan Gilbert, Kaleb Guion, Nathan Guion

A VentureWell E-Team Award, 2018

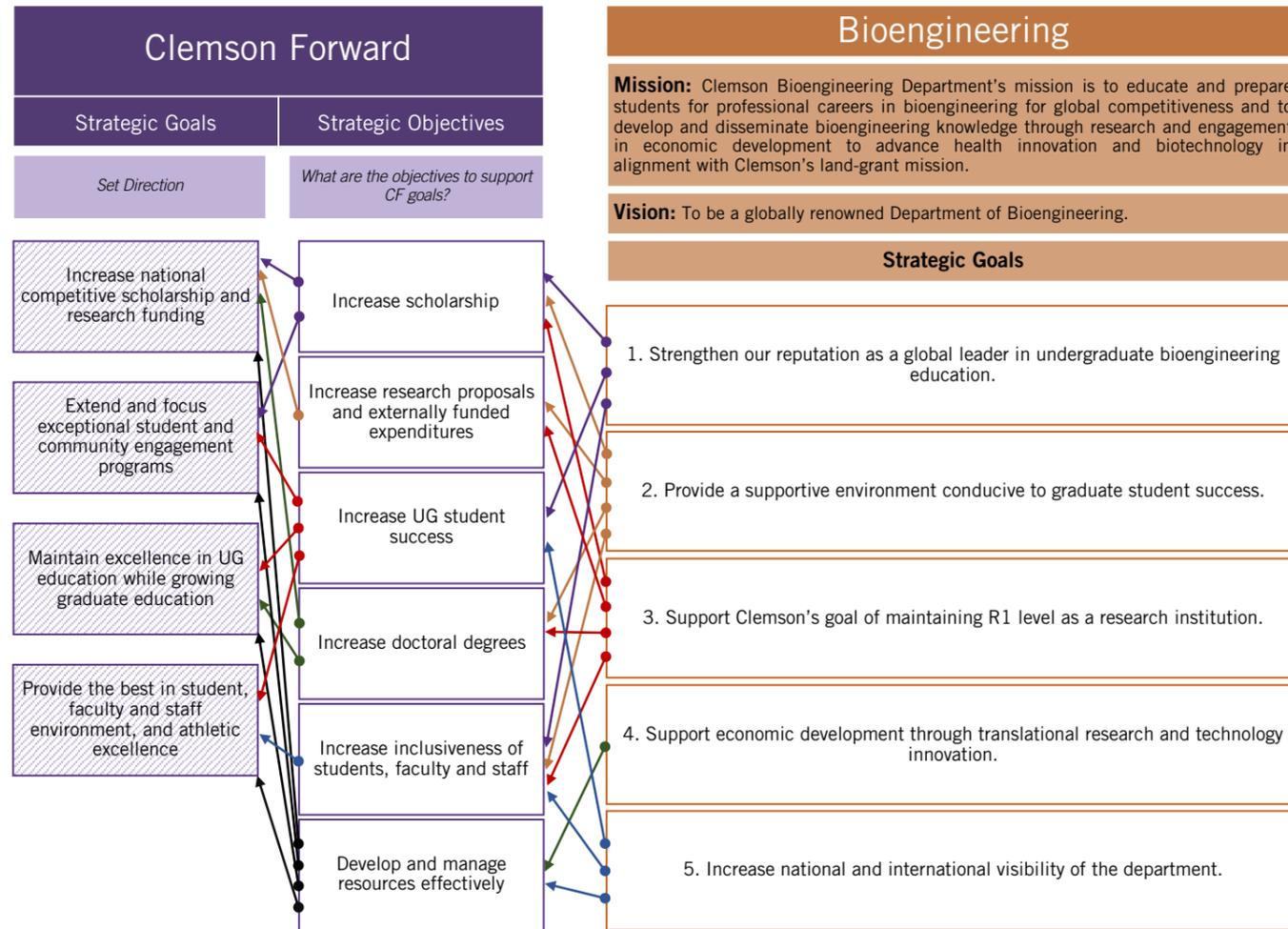
CONGRATULATIONS TO THE CLASS OF 2019



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Congratulations to the most recent alumni including BS, MS, M.Eng and PhD

Strategic Planning



In 2018-2019, the department developed a new strategic plan aligned with the university's Clemson Forward Strategic Initiatives. The department's faculty and staff and student and external advisory boards endorsed a revised mission and associated vision. That Mission is to educate and prepare students for professional careers in bioengineering for global competitiveness and to develop and disseminate bioengineering knowledge through research and engagement in economic development to advance health innovation and biotechnology in alignment with Clemson's land-grant mission. Our vision is to be a globally renowned department. Clemson Bioengineering contributes to Clemson University's overall mission and its Clemson Forward strategic initiatives by working toward meeting five strategic goals aligned with meeting the vision stated above:

1. Strengthen our reputation as a global leader in undergraduate bioengineering education.
2. Provide a supportive environment conducive to graduate student success.
3. Support Clemson's goal of maintaining R1 level as a research institution.
4. Support economic development through translational research and technology innovation.
5. Increase national and international visibility of the department.

Clemson Forward is built on four strategic priorities: Research, Engagement,

Academic Core and Living Environment (REAL). REAL focuses on the future and the 21st-century challenges facing South Carolina, the nation and the world. The plan: To ensure that Clemson fulfills its core mission as a land-grant university and consistently ranks among the nation's top 20 public universities and Carnegie tier-one research institutions. Clemson Bioengineering is dedicated to provide outstanding education through translational research using an interdisciplinary approach by providing high quality undergraduate and graduate educational programs that prepare students to apply science and engineering principles to solve problems in biology and medicine; generate and disseminate knowledge in bioengineering to benefit humankind; and apply that knowledge towards improvement of healthcare and for scientific and technological development of South Carolina and the nation. Over the past decades, Clemson Bioengineering has impacted the field globally by educating a premier workforce and documenting advances in biomaterials science and engineering, regenerative medicine, bioinstrumentation, molecular modeling, wound healing, drug delivery, biomanufacturing, biofabrication and biomechanics. We look forward to implement our new strategic plan and better serve our constituents.



BMES BIOMEDICAL ENGINEERING SOCIETY

ANNUAL MEETING
October 16-19, 2019

Philadelphia Convention Center
Visit us at booth 608

DROP-IN RECEPTION

OCTOBER 17, 2019
from 8:00pm to 11:00pm

Salon K - Philadelphia Marriott Downtown

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Guest Entrance at
1200 Filbert St, Philadelphia, PA 19107



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