AC 2010-1700: EXPLORATION, DEVELOPMENT, AND IMPLEMENTATION OF THE CLEMSON UNIVERSITY RETRIEVAL OF EXPLANTS PROGRAM IN ORTHOPAEDICS (CU-REPO)

Michele Wabler, Clemson University

Estefania Alvarez, Clemson University

John DesJardins, Clemson University

© American Society for Engineering Education, 2010

Exploration, Development, and Implementation of the Clemson University Retrieval of Explants Program in Orthopaedics (CU-REPO)

Abstract

Total joint replacement has become one of the most successful surgical procedures of the past forty years in the treatment of arthritis, limb deformities, and chronic joint pain, relieving discomfort and joint stiffness for millions of people. It is estimated that the number of primary total hip arthroplasties (THAs) will increase 175% by the year 2030, and primary total knee arthroplasties (TKAs) will see a 675% increase in the same time frame[1]. While most total joint replacements are permanent, complications during a prosthetic's lifetime can arise that lead to revision, or in severe cases, complete removal of the implant. Explantation and characterization of such devices can lend valuable information about implant in vivo functional performance, long-term structural and material properties, and implant failure modes. The field of implant retrieval analysis can also be seen as a prime educational platform in which to engage and educate the undergraduate student in topics of medical devices, biomaterials, and clinical anatomy. This paper details the development, application, and assessment of a mentored undergraduate teaching and research program known as Creative Inquiry at Clemson University that is focused on the development of a statewide implant retrieval program for educational and research purposes.

Introduction

The mission of the Department of Bioengineering at Clemson University is to provide an outstanding education for engineers in bioengineering and developing future leaders. With this mission in mind, three goals were identified: 1) to provide students with the education needed for a rewarding career, 2) to provide an intellectually rigorous undergraduate education that emphasizes fundamental engineering and life sciences and 3) to train a workforce to sustain a growing bioengineering industry in the United States and participate in the economic development of the State of South Carolina. To assist in accomplishing these goals, the Department of Bioengineering participates in a university-wide program known as Creative Inquiry[3]. This program, unique to Clemson University, was developed to allow small teams of students to study problems stemming from curiosity, a professor's challenge, or simply the needs of the world around them. With more than 250 projects currently active, programs are available to every undergraduate student at all levels, and new projects are welcomed and encouraged. A faculty advisor, who leads the group and encourages student success, monitors the Creative Inquiry undergraduate teams. This interactive environment engages students, faculty, and community in discovery, enriching the lives of each constituency, and provoking higher-order thinking, reflection on learning, and connection experiences to traditional engineering coursework as well as the successful publication of abstracts, posters, and papers based on Creative Inquiry research[2-6].

The Clemson University Retrieval of Explants Program in Orthopaedics (CU-REPO) is one such Creative Inquiry group that was developed by Dr. John D. DesJardins in the Department of Bioengineering. Now entering its third semester, the program investigates explanted (or retrieved) medical implant devices, specifically total joint replacements, which commonly include total knee and total hip joint replacement components. While 8-10% of Americans (roughly 20-25 million people) currently have these types of implants, rare complications can lead to device failure ultimately resulting in revision surgery and removal of the implants. Unfortunately, very few retrieved implant databases exist to study implant performance and failure modes. Therefore, CU-REPO, through the means of a Creative Inquiry team, sought to establish a retrieved implant database whereby undergraduate students could interact in a hands-on manner with retrieved implants from patients of local hospitals, evaluate implant performance and failure, and present their data and educational experiences both locally and nationally through classroom and conference venues.

The Creative Inquiry program is based on the concept of 'discovery based learning,' thus it hopes to promote the development of skills that will be used in future courses and ultimately, the students' future careers. This type of learning uses the fundamentals of materials science and engineering to promote active student engagement in the medical device field and its clinical application. Therefore, this program is intended to promote discovery guided by mentoring[7].

The National Science Foundation (NSF) reported in 1994 that there was a need for the engineering curriculum to include 'integrative laboratory experiences that promote inquiry, relevance, and hands-on experience.' They suggested that lecture be replaced by more interactive learning experiences, to increase the ability of students to participate in laboratories, internships, and research opportunities. The same Advisory Committee noted that a high percentage of undergraduates are not prepared for the workforce due to lack of skills and motivation to continue learning[8]. To overcome this, programs such as the Creative Inquiry program at Clemson University have the ability to give students the tools and the freedom to pursue questions in their area of interest: in this case orthopaedics and biomaterials. This interactive learning experience is highly valued by students supporting their thirst for knowledge. Similarly, in this type of program, concepts and techniques learned from previous classes such as Biomaterials, Biomechanics, Orthopaedic Engineering, Anatomy, Physiology, and other courses that are the foundation of their curriculum are utilized. Therefore, the Creative Inquiry program is hypothesized to be a learning platform that not only strengthens previously learned concepts, but also gives students a direct heuristic approach to stimulate topic specific learning.

Total joint replacements are prostheses used to replace arthritic or damaged joints, and are commonly used to correct severe cases of osteoarthritis, rheumatoid arthritis, deformities, and chronic joint pain[1]. Replacements are typically composed of a metallic component (cobalt-chromium-molybdenum, titanium, or stainless steel) or a ceramic component (alumina or zirconia) and a plastic component (typically ultra-high molecular weight polyethylene)[9]. Total joint replacements are meant to be permanent, either until the lifetime of the implant is exhausted or revision surgery resulting from infection, aseptic loosening, dislocation, nerve injury, or other failure occurs. In the case of failure, explantation of these devices can lend valuable information on in-vivo functional performance, long term structural, mechanical, and material properties, as well as failure modes[1]. In 2000, the National Institute of Health (NIH) assembled a fourteen member panel representing a variety of fields to discuss the need for additional retrieval databases[10]. Topics included: expectations of the lifetime of costs, risks, and benefits of medical implants, barriers associated with developing a retrieval program, necessary information to improve performance and device design, the educational role of a retrieval database, and the research and support necessary to continue to make advances in implantable devices. The panel determined that implant retrieval and analysis is of critical importance to improving care of patients in need of implants, and there is an existing need to reduce legal and economic obstacles limiting implant retrieval and analysis, as well as the need for better communication with patients. Overall, the quality of future devices relies on basic research into the causes of implant revision and failure, and a focused educational program for patients[10]. It was with this in mind that CU-REPO was founded, to satisfy the previously stated need for more retrieval programs, and to improve the quality and performance of future devices while providing hands-on education as a means for undergraduate students to pursue their interest in orthopaedics and biomaterials.

With the founding of the CU-REPO undergraduate program in the Spring of 2009, Dr. DesJardins identified a series of questions (based on the NIH consensus statement of 2000[10]) as a means to direct this Creative Inquiry team:

Table 1. Questions used as directives for the team

• What are the patient, health care provider, and societal expectations of the lifetime costs, risks, and benefits of medical implants?
• What are the legal, ethical, religious, cultural, public policy, and economic barriers to implant retrieval and reporting, and how can they be overcome?
• What information is necessary to evaluate and improve implant and material performance and device design?
• What can the role of information data systems be in educating the public, medical community, and policymakers about medical implants and retrieval?
• What future research and institutional support is necessary to insure continuing advances in implantable devices?

This paper will discuss the specifics of the CU-REPO Creative Inquiry course including class setup, goals of the program, semester activities, and team goals. The results, including the development of a standard operating procedure, oral and written presentations, and research project proposals will be presented. It will conclude with the results of a post-semester assessment to evaluate student learning outcomes outlined in ABET criteria.

Methods

Class Setup

The Creative Inquiry program in the Clemson University Bioengineering Department is designed around a technical elective course structure in which students receive up to two credit hours per semester for up to three semesters. During each semester, teams of up to nine students are selected by the faculty leader, and each team works on a new or ongoing inquiry activity, for which the students receive a letter grade for their efforts. Students enrolled in the CU-REPO program met as a group approximately two hours every week for class discussion and student presentations. Students were encouraged to spend a minimum of six hours in the laboratory each week. The basic educational goals of the program include:

Table 2. Educational goals of the program

- Learning to work with a team
- Developing the ability to utilize print and internet resources
- Developing laboratory skills which include data recording and keeping a lab notebook
- Building hypotheses and framing research questions
- Designing experiments to assess creative inquiry activities
- Compiling and evaluating research data
- Communicating results in oral and written form

Attendance accounted for 20% of the final grade, and was mandatory for all classes. Group efforts, including reports and presentations accounted for 10% of student final grades. Finally, individual efforts accounted for approximately 70% of final grades. Individual efforts differed by semester and were discussed within a contract-grading framework. These efforts could include active class participation, lab reports, lab notebooks, interaction with doctors, travel to hospital and surgical facilities, development of new implant assessment tools and analysis procedures, and writing a final research project proposal at the conclusion of the semester that focused on the use of retrieved implants to answer a larger biomaterials or orthopaedic question. Potential failure analysis methods include optical microscopy and non-contact surface profilometry. For the Fall 2009 semester (which is the focus of this paper) the students participated in:

Table 3. Outline of semester activities

- Safety, laboratory, IRB and IBC training
- Rigorous literature research on past and present implant retrieval programs, implant manufacturers, implant materials, and implant designs
- Development of implant retrieval program literature and surveys
- Solicitation and procurement of implant retrievals
- Design and development of implant retrieval analysis techniques
- Design and development of implant retrieval catalog, storage and archival methods
- Research and analysis of systematic commonalities in implant retrieval variables
- Student participation in abstracts, publications, and attendance at local biomedical conferences and seminars

At the start of the semester, previous program activities were reviewed for interested students. Implant and retrieval literature was reviewed, including the National Institute of Health Consensus Development Program on the challenges and opportunities of Improving Medical Implant Performance through Retrieval Information and the ASTM F-561-05a Retrieval Standards[11]. At the start of the semester, all students underwent International Review Board (IRB) and Institutional Biosafety Committee (IBC) safety training, which included biomedical and biohazard safety training and patient and data confidentiality training. The retrieved implants are stored in formalin and thus will become fixed after a period of time. Using conservative estimates, specimens will become sterile at a rate of 2mm/day; this rate is for solid objects and as bone is dense, this is an appropriate estimate for it. Students also exercise appropriate safety protocol when working with the implants by wearing nitrile gloves, lab coats, and safety glasses. Upon completion of the safety training, students then worked on activities that strengthened the CU-REPO mission statement and program goals. CU-REPO seeks to explore, develop, establish, promote, and grow a viable Implant Retrieval Program at Clemson University. These program goals included:

Table 4. Goals of the CU-REPO program established by the team

• Increasing patient and physician knowledge
• Creating patient and surgeon incentive to donate implants
• Creating awareness of CU-REPO
• Developing a Standard Operating Procedure (SOP) for storing and characterizing implants
• Providing a working repository for failed implants
• Constructing a solid, working database that will allow for better understanding of implant material and design
• Solidifying collaboration with local hospitals
• Expanding to a state-wide implant retrieval program

Results

The first offering of the CU-REPO Creative Inquiry course in the Spring of 2009 attracted eight students. Of those students, six were female and two were male. One student was of junior standing, and seven students were of sophomore standing. All freshman enter into Clemson University's College of Engineering and Science as 'General Engineering' majors, and thus are not officially in the Bioengineering Department until sophomore year; this accounts for the lack of freshman in the CU-REPO program. The first semester of the program was spent building the idea of a retrieval program into reality. Protocols were developed, relationships with surgeons established, safety training conducted, equipment and supplies ordered, and retrieval procedures determined. The graded portions of this work included a final report that detailed the use of specific techniques and equipment for use in implant retrieval analysis, the development and presentation of a retrieval analysis program poster, the design of a program brochure and logo, and the research and collection of information pertaining to other retrieval programs nationally. Overall, six A's and two B's were given during this semester, with no feedback from students or comprehensive educational assessment of the semester's activities undertaken.

During the summer of 2009, one undergraduate student was recruited to a 20 hour per week research position to further develop the CU-REPO activities as part of the orthopaedic research activities within the Department of Bioengineering. During this time, the first retrieved implants began to be collected from a local hospital. As a result of the successful development of the Creative Inquiry program as a source for undergraduate research experience in the orthopaedics field, the student submitted an abstract and presented an invited poster at the Southeast Biomedical Engineering Career Conference held in Washington, D.C. in October of 2009. The presentation of this type of program was found to be unique among the participating universities and it was well received[12].

In the Fall of 2009, nine students participated in the program, four of which participated in the previous semester's activities, and five of whom were recruited for their interest in the Creative Inquiry topic. Of those nine students, eight were female and one was male. Eight students were of junior standing and one student was of senior standing, with one graduate student serving as an additional group mentor in the Department of Bioengineering. The second semester of activities included building on the previous Spring and Summer development. With proper protocols in place, the new group of students was able to begin work on the actual processing and analysis of retrieved implants. Each student was assigned a pet implant (a retrieved implant that had a peculiar failure mode) for which a series of cleaning, processing, and analysis steps were established.

The team developed a Standard Operating Procedure (SOP) for retrieving, cleaning, and cataloging implants, and outfitted the CU-REPO laboratory. Refer to Table 5 for the SOP.

Table 5. Standard Operating Procedure for retrieving, cleaning, and cataloging implants

Logging Receipt of Implant and History Check	• Assigning an implant identification number • Noting any missing demographic data (age of implantation, removal co-morbidities, weight, and height among other information) • Designating an Implant Records Folder
Formalin Fixation	• Placing the implant in 10% neutrally buffered formalin for a minimum of two weeks
Implant Initial Cleaning	• Removing soft tissue from the implant with distilled water and soft brushes
Implant Final Cleaning	• Following the ASTM standard for Implant Cleaning in the ultrasonicator[13]
Photographic Documentation	• Documenting the implants in detail from multiple views
Final Inspection	• Properly storing and documenting all information associated with the implant

Students developed and executed this standard operating procedure for every retrieved implant. New implants arrived weekly from the growing number of participating hospitals, and by the end of the semester, the students had successfully processed 26 individual implant components.

In addition to the weekly processing of implants, each student was assigned a pet implant for which they were to complete a formal "grand rounds" presentation that highlighted the specific background, characteristics, and collected data on an implant of their choice. These presentations were used as a group tool to further discuss topics relating to biomaterials, implant design, implant failure mechanisms, and surgical techniques.

In the final weeks of the semester, students were given an opportunity to conduct a literature review and produce a five page research project proposal based on their interest in a particular material, implant design, or failure mode associated with the implants they encountered during the semester. Proposals detailed a literature review, objective and specific aims of the proposed research, materials and methods, timeline, resources, and references. Submitted student proposals are listed in Table 6.

Table 6. Student research proposals

• Comparison of Oxinium vs. Standard Cobalt-Chromium Femoral Component Scratching in Total Knee replacements for the Genesis II Design
• Comparative Microscopic Analysis of Surface Scratching of Retrieved Femoral Components in the NexGen Posterior Stabilized Design
• Surface Damage Analysis of UHMWPE in Retrieved Inserts: A Comparison of Polyethylene Composition (Highly Cross Linked vs. Standard) and Implantation Times
• Surface Damage Analysis of Retrieved UHMWPE Posterior Stabilized Tibial Posts in Oxinium vs. Cobalt-Chromium Genesis II Posterior-Stabilized Knee Designs
• Analysis of UHMWPE and Metal Scratching Resulting from 3rd Body Wear
• Analysis of Oxinium vs. Cobalt-Chromium Genesis II UHMWPE Retrieval Surface Damage Scoring
• Research Proposal on Obesity, BMI and Damage to Knee Replacements
• The Effect of Knee Ligament Laxity on Uni-condylar Knee Joint Kinematics

The Fall 2009 semester concluded with four of the nine students returning for the CU-REPO program in the Spring of 2010, all of whom intend to actively pursue the goals of the CU-REPO project and further explore the research proposals submitted for consideration. Two to three students will be recruited to maintain sufficient levels of student participation.

Course Assessment

At the end of the Fall 2009 semester, all students in the group were given an anonymous survey to assess learning outcomes for the CU-REPO program. The goal of this survey was to determine the students' perception of learning outcomes of the course, and to assess students' perception of perceived educational and professional value of their participation in the course activities. Five of the nine students responded to the optional survey. Considering the Creative Inquiry program is designed to have a smaller student to mentor ratio to encourage a direct and more hands-on interaction, the return of five completed surveys reflects positive feedback and acceptance of the planned activities and accomplished objectives for the group. A list of the survey questions along with the resulting average (+/-1 Standard Deviation) from the survey is listed below. Students were asked to rank their answers to pre-determined questions on a scale of one to five, with one corresponding to 'none' and five corresponding to 'very much'.

Table 7. Creative Inquiry Learning Outcomes Assessment for the Orthopaedic Implant Retrieval Program

#	**Student Assessment Questions**		**(1-5) Avg.**	**StDev +/-1**
1	My participation in the Creative Inquiry Orthopaedic Implant Retrieval Program increased my basic academic knowledge of	a. Biomaterials:	**4.4**	**0.55**
		b. Materials Science:	**3.6**	**0.89**
		c. Laboratory Methods:	**4.4**	**0.55**

		d. Functional Anatomy:	**3.6**	**0.55**	
		e. Wear of Materials:	**4.8**	**0.45**	
		f. Joint Biomechanics:	**4.2**	**0.84**	
		g. Orthopaedic Pathology:	**3.8**	**0.84**	
2	My participation in the Creative Inquiry Orthopaedic Implant Retrieval Program has given me a better appreciation and understanding of real-world biomaterials applications		**4.2**	**0.84**	
3	My interaction with Total Joint Replacement Implants in this Creative Inquiry program has given me a greater appreciation for the biomaterials content that I learned in other courses thus far. If yes, which courses?	**Written Answers** **BIOE 210**: Introductory Bioengineering Course **BIOE 302**: Junior Level Biomaterials **BIOE 320**: Junior Level Biomechanics **BIOSC 315**: Junior Level Functional Human Anatomy **BIOSC 461**: Senior Level Cell Biology	**4.5**	**1.0**	
4	Do you think that this Creative Inquiry program will give you more appreciation for the biomaterials content in your junior/senior/graduate level courses (Orthopaedic Pathology, Biomechanics, Histology, Biomaterials, Bioengineering Design)?		**4.0**	**1.0**	
5	Has your interaction with total joint replacement implants in this Creative Inquiry course given you more confidence to speak to other people about orthopaedic implant biomaterials?		**4.6**	**0.89**	
6	If applicable, has your interaction with Clinicians and Doctors as part of the Creative Inquiry course helped you decide on your future professional or academic goals?		**3.5**	**1.0**	
7	Has your interaction with total joint replacement implants in this Creative Inquiry course given you more confidence to give oral presentations on orthopaedic implant biomaterials?		**3.4**	**1.14**	
8	My participation in this Creative Inquiry program has allowed me to better understand the field of Orthopaedics and Biomaterials		**4.6**	**0.55**	
9	Has your work in this Creative Inquiry course given you more confidence to explore research questions related to orthopaedic implant biomaterials?		**4.0**	**0.71**	
10	As a result of this Creative Inquiry course, I am more likely to pursue future opportunities (classes, research, med school focus, career) that focus on orthopaedic implants and orthopaedic biomaterials		**3.8**	**0.84**	
11	Do you think your participation in this Creative Inquiry experience has better prepared you for your future courses in Bioengineering? If yes, which courses?	**Written Answers**	**Yes**	**No**	
		BIOE 370: Junior Level Bioinstrumentation **BIOE 320: Junior Level Biomechanics** **BIOE 402: Senior Design**	**5**	**0**	
12	Do you think that you will apply any of the skills, knowledge or activities towards future academic or professional activities? (research, term papers, presentations, resume)? If yes, which activities?	**Written Answers**	**Yes**	**No**	
		Resume, Career, Presentations, Research	**4**	**1**	
13	This course has allowed me to better understand what professional and/or academic focus I would like to pursue		**3.8**	**1.3**	
14	Has your participation in this Creative Inquiry fulfilled your expectations?		**3.8**	**1.3**	
15	As a result of this Creative Inquiry course, I feel more confident handling and touching implants and orthopaedic biomaterials?		**4.8**	**0.45**	
16	As a result of this Creative Inquiry course, I understand less, the same, or more about the following topics related to Orthopaedics, Implants, and Biomaterials	Results (%)	**Less**	**Same**	**More**
		a. Sterilization	0	60	40
		b. Polymers in Implants	*0*	*40*	*60*
		c. Metals in Implants	*0*	*0*	*100*
		d. Current Concepts in orthopaedics	*0*	*0*	*100*
		e. Handling of Biohazardous Materials	*0*	*40*	*60*
		f. Knee and Hip Anatomy	*0*	*40*	*60*
		g. Differences in Implant design	*0*	*20*	*80*
		h. Cleaning Protocols in Bioengineering	*0*	*0*	*100*
		i. The Institutional Review Board (IRB) Process	*20*	*60*	*20*
		j. Standard Operating Procedure Development	*0*	*20*	*80*
		k. Legal and Ethical Issues in Bioengineering	*0*	*60*	*40*
		l. Medical/Surgical Procedures in Orthopaedics	*0*	*60*	*40*
		m. Research Proposal Writing	*0*	*40*	*60*
		n. Total Joint Simulation/Wear Testing	*0*	*80*	*20*
		o. Reasons for Implant Failure and Revision	*0*	*0*	*100*
17	In your own words, please describe if you think this course has made you a better bioengineer, and if so, how.				
	Student 1: I think this CI has enabled me to grow as a bioengineer because if has been an opportunity to see a real application for research as well as the doctor-research interface. I have also learned how the dynamics of a research group can function, how each individual member brings a different aspect to the group and it can be difficult to get everyone on the same page. Also I have learned a great deal about protocols, generating SOP's, how to order materials, etc. ***Student 2: I have learned a lot, not just about implants, but also about medical technology – how there is so much yet to be figured out and how to continue solving problems and asking questions today.*** ***Student 3: Yes, The research proposal helped sum up everything I learned while in this course, which related to how implants were***				

	inserted/removed, wear, pitting, creep, biocompatibility of materials, SOP's, and implant cleaning procedures. I am sure to use this later in my career. ***Student 4: Before this course, I had limited knowledge of the field of orthopaedics and very little interaction with implants. This course has opened up many opportunities for me – challenging me to develop stronger presentation skills, the chance to be in the operating room during surgeries, and allowing me to apply my classroom knowledge of bioengineering to a real-life situation.*** ***Student 5: I think this course has made me a better bioengineer because after completing the semester, I am more curious and open to exploring new avenues and trying new things in the field.***
18	Would you recommend this Creative Inquiry Program to a friend? Why or why not?
	Student 1: I think this CI is a great opportunity if you are interested in biomechanics and orthopaedics and would gladly recommend this program. However, I would make them aware that the program, as it is currently, requires a lot of grunt work such as cleaning implants, etc that may not live up to the expectations of the students. ***Student 2: Yes, if you like studying biomechanics, joints, how the body functions, and/or medical devices, then you would like this class.*** ***Student 3: Yes, because it is a great opportunity for Bioe's to learn about how to develop research topics and pursue researching them, along with developing papers + presentations about them.*** ***Student 4: I would absolutely recommend this CI program to a friend. It has fostered in me a love of orthopaedics, so much that I intend to follow a career path in the field.*** ***Student 5: Probably not at this stage of the program. Right now it seems that the program is still in the developmental stage and is not ready to take in new participants. Even this past semester, with only 9 students in the program, along with the legal/ethical issues, the number of implants available and the amount of other tasks was so minute that some students' participation was overlooked.***

In addition to questions that were specific to the content of the course offering, students were asked to assess the course learning objectives with respect to the National ABET Standards. This was done so that the instructor could better determine possible ABET objectives to align the course for future semesters, as well as a method to have students reflect on ABET doctrine. Based on the thirteen ABET accreditation student learning criteria, students were asked to evaluate to what extent their participation in the CU-REPO program increased their abilities, understanding, knowledge, and/or recognition of standardized measures of engineering course assessment. Through this course, students ranked the following outcomes:

Table 8. ABET Student Learning criteria survey for the Orthopaedic Implant Retrieval Program

#	**ABET Student Learning Criteria Survey**	**Average (1-5)**	**StDev +/- 1**
1	An ability to apply knowledge of mathematics, science, and engineering to bioengineering problems	**3.4**	**1.52**
2	An ability to design and conduct experiments, as well as to analyze and interpret data	**3.4**	**1.52**
3	An ability to design a system, component, or process to meet desired needs	**2.6**	**1.14**
4	An ability to function on multi-disciplinary teams	**3.0**	**1.87**
5	An ability to identify, formulate, and solve engineering problems	**3.2**	**1.3**
6	An understanding of professional and ethical responsibility	**4.0**	**0.71**
7	An ability to communicate effectively orally and in writing	**3.4**	**1.52**
8	The broad education necessary to understand the impact of engineering solutions in a global and societal context	**4.0**	**1.22**
9	A recognition of the need for, and an ability to engage in life-long learning (a desire to learn new things every day, and seek out opportunities to learn)	**4.0**	**1.22**
10	A knowledge of contemporary issues	**3.4**	**0.89**
11	An ability to use the techniques, skills, and modern engineering and computing tools necessary for engineering practice	**3.2**	**1.64**
12	Understanding of biology and physiology, and the capability to apply advanced mathematics (including differential equations and statistics), science, and engineering to solve the problems at the interface of engineering and biology	**3.0**	**1.58**
13	Ability to be able to make measurements on and interpret data from living systems, addressing the problems associated with the interaction between living and non-living materials and systems	**3.0**	**1.41**

Discussion

The results of the ABET assessment indicated that almost all the educational goals of the course had been accomplished, although none of these basic educational goals received the highest reviews. Interestingly, the highest scores obtained values that extended beyond the course topic and materials, and included engaging the students in an understanding of professional and ethical responsibility, the broad education necessary to understand the impact of engineering solutions in a global and societal context, and the recognition of the need for an ability to engage in life-long learning. These high level processes are usually reserved for upper level classes and are specifically targeted through significant effort by the instructor. The ability to engage the student in these measures simply through the hands-on exposure, interaction with real-life medical devices, and the general discussion of use, failure and engineering design is a significant finding. Overall, most ABET measures received average scores above 3.0, indicating perhaps a dilution of the course's specific objectives on the part of the instructor, but perhaps also a general thinking on the part of the students of how the learned material could be applied to many other outcome measures. Students demonstrated their knowledge of mathematics, science, and engineering in part through the use of proper laboratory techniques, becoming comfortable handling and cleaning the retrieved implants, and applying their knowledge of mechanical properties in their analysis of failure modes. Students demonstrated their ability to design and conduct experiments through the development of standard operating procedures, their final literature reviews, and their research project proposals. Analyzing past designs of total hip and total knee replacements allowed students not only to criticize past total joint designs, but also suggest design improvements that could possibly increase the lifetime of future implant generations. Four of the nine students who participated in the Fall 2009 CU-REPO class have aspired to continue the project detailed in their proposals through individual research for the Spring 2010 semester. Their research and oral presentations were the manifestation of increased ability to analyze and interpret data obtained while working with their pet implants. This included analyzing patient demographics and hypothesizing implant failure modes.

Students had the opportunity to interact with orthopaedic surgeons who performed the implant retrievals and other professionals in the medical field. Group discussion on the ethical concerns (and the topics discussed by the NIH panel) was performed several times during the semester, and helped students gain an understanding of professional and ethical responsibility. Student ability to communicate effectively both orally and in writing was monitored throughout the course of the semester. Group discussion followed weekly "grand rounds" presentations on each student's pet implant. Growth in this area was evident through the final research project proposals submitted at the conclusion of the semester. Knowledge of knee and hip anatomy was crucial to understanding the interaction of total joint replacements with the body. Students demonstrated this understanding through their presentations and group discussion.

Four out of five survey participants stated that they would recommend the program to a friend, and indeed, continuing students in the Spring 2010 semester have recommended the program and succeeded in recruiting two new participants simply through word of mouth. The survey did highlight a primary concern with "grunt work" that was required by the students, in which lab hours were spent actually performing the cleaning and analysis of the implants. This was contradicted, however, with another student that would not recommend the program because there was not enough to do. Overall, however, 100% of students stated that the program made them better engineers, with some mentioning specifically that it enabled them more opportunities to “see a real application for research as well as the doctor-research interface,” “develop stronger presentation skills,” “apply my classroom knowledge of bioengineering to a real-life situations,” “learn how the dynamics of a research group can function” problem solve, and ask questions about medical technology. Evidence of life-long learning was also mentioned, with students stating that they would use the skills that they learned “later in my career,” that the course had “opened up many opportunities for me,” and they were now “more curious and open to exploring new avenues and trying new things in the field.”

All of these quotes are supported by the numerical data collected. The added value of the course from the perspective of applied learning and application of learned skills to future courses, materials, and research interests is invaluable, and has been seen to provide a strong focus for the students in orthopaedics that would not have otherwise been realized until later in their undergraduate or graduate development.

Conclusion

Considering the growing percentage of total joint replacement and subsequent revisions performed worldwide, there is a need to establish a retrieval program that not only collects implants, but can also be a source for investigation into their performance, failure modes as a function of implantation time, and demographic factors that can contribute to revision. There are currently very few retrieval implant databases across the country. At Clemson University, after three semesters, the CU-REPO program through the means of a Creative Inquiry team, sought to establish a statewide retrieved implant database whereby undergraduate students could interact in a hands-on manner with retrieved implants from patients of local hospitals, evaluate implant performance and failure, and present their data and educational experiences both locally and nationally through classroom and conference venues. This program has become a prime educational platform that involves the undergraduate student in a more hands-on discovery learning approach, combining not only courses they have taken previously, but most importantly incorporating the current problems and issues faced by the total joint replacement prosthesis, thus allowing the student to evaluate and consider typical failure modes and suggest possible design alterations. The solid foundation of this program allows it to become a source not only for undergraduate research experience, but also opens up the possibility of direct collaboration with surgeons and residents interested in using the implant collection to pursue a wide range of research questions. The ability to combine a hands-on approach with the solid academic curriculum makes this Creative Inquiry program a successful undergraduate experience that will solidify their academic understanding of bioengineering as a whole and provide students with tools and skills that will be useful for their future engineering career.

References

1. R.M. Garcia, M.J. Kraay, P.A. Conroy-Smith, and V.M. Goldberg, “Management of the Deficient Patella in Revision Total Knee Arthroplasty,” *Clinical Orthopaedics and Related Research*, **466** [11] 2790-2797 (2008).

2. P. Dawson, I. Han, M. Cox, C. Black, and L. Simmons, "Residence Time and Food Contact Time Effects on Transfer of Salmonella Typhimurium from Tile, Wood and Carpet: Testing the Five-Second Rule," *Journal of Applied Microbiology,* **102** [4] 945-53 (2007).
3. J. Epstein, "Small Group Learning for 14,000 Undergrads" (2007) Inside Higher ED. Accessed on: August 1, 2007. Available at <http://www.insidehighered.com/news/2007/08/01/clemson>
4. B.I. Lee, S. Kaewgun, W. Kim, W. Choi, J.S. Lee, and E. Kim, "Visible Light Photocatalytic Properties of Polymorphic Brookite Titania," *Journal of Renewable and Sustainable Energy,* **1** [2] 023101 (2009).
5. J.R. Wagner, "Embedding Creative Inquiry in the Undergraduate Geology," p. 218 in Vol. 38 *2006 Geological Society of America Annual Meeting (22-25 October 2006).* Philadelphia,PA, 2007.
6. J.R. Wagner, R.D. Bixler, E.R. Carraway, S.M. Moysey, L.R. Murdoch, M.A. Schlautman, and R.D. Warner, "The Creative Inquiry Approach to Early Undergraduate Research Experiences at Clemson University," p. 246 in Vol. 39, *2007 Geological Society of America Annual Meeting (28-31 October 2007).* Denver, CO, 2007.
7. R.B. Foulds, M and B. Mantilla, "Integrated Biomedical Engineering Education Using Studio-Based Learning " *IEEE ENGINEERING IN MEDICINE AND BIOLOGY MAGAZINE* **22** [4] 92-100 (2003).
8. NSF Division of Undergraduate Education Directorate for Education and Human Resources. *NSF Restructuring Engineering Education: A Focus on Change*. Report on NSF Workshop for Engineering Education. 1995.
9. Ph. Hernigou, G. Mathieu, A. Poignard, O. Manicom, P. Filippini, and A. Demoura, "Oxinium, a New Alternative Femoral Bearing Surface Option for Hip Replacement," *European Journal of Orthopaedic Surgery & Traumatology*, **17** [3] 243-246 (2006).
10. N.I. Health, "Improve Medical Performance through Retrieval Information: Challenges and Opportunities " (2000) NIH Technology Assessment Conference Summary. <http://consensus.nih.gov/2000/2000MedicalImplantsta019html.htm>
11. "Standard Guide for Retrieval and Analysis of Medical Devices and Associated Tissues and Fluids," ASTM Designation F 561-05 A. American Society for Testing and Materials, Philadelphia, PA.
12. M.E. Wabler, C.J. Wright-Walker, E. Alvarez, and J.D. DesJardins, Exploration, Development, and Implementation of the Clemson University Retrieval of Explants Program in Orthopaedics (REPO), South East Biomedical Engineering Career Conference, Washington, DC, Oct.30,2009, 2009.
13. "Standard Guide for Wear Assesment of Prosthetic Knee Designs in Simulator Devices," ASTM Designation F 1715. American Society for Testing and Materials, Philadelphia, PA.

Acknowledgements

The authors wish to thank Clemson University for providing funding to Creative Inquiry, without which, a program such as this would not have been possible. We are also very grateful to the donating patients, physicians, and their corresponding universities and hospitals for their generous implant contributions to the program. The authors would also like to acknowledge Cassandra Wright-Walker for her help in the IRB and IBC approval process, as well as the CU-REPO students (Spring 2009, Fall 2009) for their extensive research and implant processing, through which they have laid the foundation for a successful program that will aid in the improvement of artificial joints for many years to come.