Making Biomaterial Development Real to Students

Elizabeth Friis, Mechanical Engineering

To better prepare students for careers in industry, a mechanical engineering professor changes the way she teaches students about practical considerations of biomaterials in biomedical product development.

OVERVIEW

Background:

Two bases for introducing biomaterials

Two ideas form the basis for my teaching work with Mechanical Engineering (ME) 765, the introductory biomaterials course. First, biomaterials education for mechanical engineering students should be addressed from a design–based approach as opposed to a materials science approach. Second, biomaterials education needs to include a practical aspect of development issues with medical products.

In this poster, I present and discuss techniques for teaching students in the ME 765 course about practical considerations of biomaterials in biomedical product development in order to better prepare students for careers in industry. Many of the basic concepts I use developed out of concepts presented at the 2003 Society For Biomaterials workshop entitled “Pathways to Successful Careers: Improving the Interface Between Industry and Academia Through Education,” April 30, 2003.

Implementation:

New assignments for increasing student understanding

Through the use of open-ended homework questions and three new projects, students have the opportunity to become involved in practical issues of biomaterials. Teams of three were formed to give all students a forum for discussing homework problems. Open-ended problems included case scenarios for decision-making based on biomaterials technology.

In one new project, the Journal Club, students learned to critique biomaterials research and technology through oral review of articles from academic biomaterials journals. In another project, Reverse Engineering of a Medical Device, I gave student teams a biomedical product that they had to “reverse engineer” in order to determine its function, regulatory status and biomaterials design considerations. In the final project, student teams consulted with me to select a biomaterials topic and then proposed a new material development or product using that biomaterial. Instead of writing a traditional term paper, student teams wrote a Phase I NIH SBIR Proposal with a technical review and proposed experiment to address the research development of their new concept.

Observation:

Students grow progressively throughout the semester

At the beginning of the semester, most students had difficulty even attempting to answer the open-ended questions. Early solutions were often extremely vague and lacked depth. As the semester progressed, teams were better able to recognize and organize the thought-processes required for this type of analysis. Student comments on final course evaluations indicated enthusiasm for the open-ended comments and a desire for more courses using this approach. I also noted that homework quality on both the traditional and open-ended problems improved tremendously throughout the semester.

Journal Club was a favorite classroom activity of students. Nearly all the students read and answered questions about the articles in advance. They engaged in active debate during the in-class discussions. In semester evaluations, they commented on the usefulness of this exercise for preparation for the final project. Students also self-reported strong positive results from the biomedical product reverse engineering methods. During group presentations and the following discussions, students actively engaged in understanding the issues and comparing analyses between different product types without prompting from me.

Many students found it difficult to define a topic for the final project, so I assisted each group as they narrowed down specific subjects. On the written mock Phase I SBIR proposals, the intellectual property, regulatory and technical analysis was satisfactory, but cost and resource analysis was grossly underestimated, despite intermediate review. Students self-reported that while this experience was more difficult than a standard term paper, they also felt it was more beneficial and interesting.

<u>Reflections:</u>
From my viewpoint, this mode of student evaluation required slightly more work than a traditional approach, but it was more rewarding and easier to implement. Final course instructor evaluations increased significantly compared to previous years. These methods, based on the Society for Biomaterials workshop suggestions, have shown how valuable it is to use group work and an interactive project with a medical device.

Because of its success, I plan to expand the hands-on, interactive class work in other graduate courses. I also will adapt the Society For Biomaterials panel recommendation that students become involved in a course on design and development of a biomedical device. I am currently developing a new graduate course titled "Biomedical Product Development" that will build on the ideas established in the Biomaterials course. The project development in this new course will rely on partnerships with regional industries and our technology transfer office, as well as student collaborations with each other.

BACKGROUND

Course background:
The field of biomaterials is diverse. The governing factors of why a material can or cannot be used in the body are complex and depend on much more than just the materials science related issues. In this introductory course, we explore all aspects of biomaterials including but not limited to:

- Mechanical design issues
- Materials science related issues

- Biological issues
- Device / application specific issues
- Manufacturing and sterilization issues
- Marketing issues
- Regulatory issues

ME 765: Biomaterials is an introductory exploration of the use of materials in the body, with some background in the science of the materials that are used as appropriate to the applications being discussed. KU offers it each fall semester. Students enrolled in this graduate–level course are typically from both ME and Chemical Engineering. Prerequisite for the course is a fundamental materials science class. Though not required, a course in organic chemistry is beneficial. Mechanical engineers in this course approach the field of biomaterials from the design point of view. The students examine basic properties of biomaterials and explore the specific issues with each material system based on its uses in specific biomedical devices.

The goal of ME 765 is to give students a sufficient background and understanding of the field of biomaterials such that by the end of the course, students will be able to:

- Explain to a high school student what biomaterials are and how and why they are used in different sites in the body.
- Choose an appropriate biomaterial for a given implant design.
- Define biocompatibility of a biomaterial for a given implant design and use.
- Decide what is the best test protocol to use in characterizing a biomaterial.
- Determine what FDA classification a given device design would be assigned, why that assignment would be given, and what steps might be taken to avoid a PMA route.
- Apply the biomaterials principles discussed in the design of medical devices.
- Critically review biomaterials research studies and new technology.

Learning activities I'll be tracking:

- Enhanced student ability to critique the applications and potential of new biomaterials technology.
- Improvement in student ability to critique biomaterials journal article content.
- Increased interest by biomedical device industries in KU students for employment.
- Positive feedback from other instructors on the students' implementation of the proposed techniques that develop from the course.

Project Notes

Course Syllabus (see PDF)

Project background:
I began examining these new teaching ideas after co-chairing a workshop panel at the annual meeting of the Society for Biomaterials in April 2003. The panelists represented the FDA, a large engineering biomedical device company, a large biological emphasis

company, a start–up company, an ethics expert, and a successful industry transfer program in academia. Each speaker gave his or her perception of the basic skills that a new hire needs to have in order to succeed in the biomaterials industry. A discussion followed their comments. This workshop project helped me identify ways to enhance the Biomaterials course, as well as ways to improve the biomaterials curriculum, both to the benefit of the KU students who study this subject.

Proposed goals:

1. How can the biomaterials student better learn about the interplay of new technology, mechanics, regulatory issues, biology, and business considerations that often govern whether or not new biomaterials are successful in industry?

2. How can we in academia better train biomaterials students for the transition to the biomedical device industry?

Workshop conclusions 1-4:

1. It is assumed by people in industry that students are properly trained in the traditional technical areas. Most often, skills that make the difference in a student's success in industry are more nontraditional. This was true for both the large corporation setting and the start-up company setting.

2. The ability to evaluate technology and its application to a product is essential in industry. It is difficult to teach this skill through traditional mechanisms. The workshop panel recommended that special projects (similar to what is now used in this course) be implemented in biomaterials education courses.

3. The social and work ethic aspects of new hires in the workplace are extremely important. Even technical employees must be able to work with others in a team and look around to see what must be done to make the project work.

4. All new hires must have a basic understanding of regulatory issues. The workshop panel advocated providing students with an opportunity for internship or Co-Op with either a biomedical device company or the FDA.

Students' previous knowledge:

Basic materials science knowledge is assumed for ME 765, and thus it does not cover advanced materials science topics. The types of courses that would cover these topics are:

- Physical Metallurgy
- Mechanical Metallurgy
- Introduction to Ceramics as Materials
- Introduction to Polymer Science
- Advanced Materials Science I / II

IMPLEMENTATION

Students were assigned a limited number of nontraditional style homework sets and two exams. Other components included the Journal Club and two special projects.

- Open-ended homework: Most traditional engineering homework problems have one solution. Perhaps different pathways can be used to achieve that solution, but still there is often just one correct final answer. However, there is no one correct solution in design, just some answers that are better than others based on the defined design parameters. Since this biomaterials course was approached from a design / use / material perspective, open-ended problems provided a natural method to solicit discussion of the issues surrounding use of specific biomaterials in specific applications. I introduced open-ended problems in the homework sets gradually; i.e., a simple, more straightforward problem statement was presented in the first homework set and more complicated case scenarios were given in later sets. I believe the gradual build-up of skills in approaching open-ended problems was beneficial to the teams as they developed their interactions, plus it was not too intimidating to the students who had never been exposed to such questions. The open-ended homework format also helped prepare the student teams for the final project.
- Journal Club: In the Journal Club, groups of three to four students each read and evaluated an up-to-date journal article on a field of biomaterials appropriate for the current section of study, which was assigned by the professor. The group members then critiqued this article in terms of its merit for both science and potential applications. The groups shared their analyses with the entire class through an oral presentation.
- First project: Reverse engineering of a medical device: In the first project, students were each given a medical device similar to what a hospital would receive and use. Each student was asked to "reverse engineer" the device; i.e., to determine why the device was packaged, labeled, designed, etc., in that particular manner. The student examined the biomaterials compatibility, device function, cost, FDA guidelines, and marketing elements, followed by an analysis presentation in both written and oral formats.
- Second project: Phase I NIH SBIR proposal: The second project began when I taught students how to search the medical literature to find articles on their specific subject of interest. Each student then found at least five peer-reviewed journal articles with a common connection to that subject. They could also use one book as a reference. The next step was to write a literature review of the subject matter only as it related to the articles used. The review had to include critiques of the science and potential application of the work. This material led into the creation of a NIH Phase I SBIR Proposal. The students delivered their work via the submission of a term paper and a presentation of the concepts to the entire class.

Project Notes

1. Medical device evaluation project (see medDevEvalProj.pdf)
2. Project proposal guidelines (see projectProposalGuide.pdf)
3. Reverse engineering guidelines (see reverseEnginGuide.pdf)

4. Stress and strain assignment #4 (see homeworkAssign4.pdf)
5. Implants and more assignment #5 (see homeworkAssign5.pdf)
6. Exam revisited assignment #6 (see homeworkAssign6.pdf)

STUDENT PERFORMANCE

Open-ended homework problems:
At the beginning of the semester, most students had difficulty even attempting to answer the open-ended questions. There were, however, a few students who grasped the “big picture” concept immediately, though even their answers initially lacked depth. As the semester progressed, more students could recognize and organize the thought-processes required for this type of analysis, and depth of analysis for all students increased.

Students noted that there was often enthusiastic discussion and debate among team members during private homework team meetings. Even though teams were self-selected, peer evaluations and comments at the end of the semester indicated that there were three teams out of five in which at least one member of the team did not contribute sufficiently. This potential downfall of teamwork did not appear to have a significant negative impact on student attitude in the classroom setting.

Journal Club:
The Journal Club was a fun classroom activity for both students and me. Three Journal Club sessions were held in the semester, typically after an exam or a major project deadline. The journal topics I picked were based on lecture themes students expressed interest in. All the articles were chosen from the *Journal of Biomedical Materials Research* (*JBMR*), the premier journal in the field of biomaterials. It was somewhat challenging for me to find recent articles that were narrow enough to be completely understood by students at this level. Interestingly, several of the newer graduate students and undergraduate students did not know what a peer-reviewed journal article was. A handout questionnaire about the article had to be done in advance of class in order for the student to receive full credit. It was intended to prompt students about what they should look for in any journal article.

The application of “real life” work in the classroom seemed to be a welcome break for students. Nearly all students read the article in advance and answered questions about it. We had active debate during the in-class discussions of the article. In the course evaluations, students commented on the usefulness of this exercise for preparation for the final project.

First project: Reverse engineering of a medical device:
Some of the students were very engaged by this project, while others did only a cursory evaluation as evidenced by presentation enthusiasm and the extent and depth of the evaluations presented. Students self-reported strong positive results from the biomedical product “reverse engineering” methods. During group presentations and resulting discussions, students actively engaged in understanding the issues and comparing analyses between different product types without prompting from me. The purpose of this project was to prepare students for the thought processes and criteria

needed to evaluate and develop a biomaterial in a product application as required in the second project. It was not clear if the reverse-engineering project was successful in this development, but it was an educational enjoyed by all.

Second project: Phase I NIH SBIR proposal:
Many students found defining a topic difficult for the final project, so I assisted each group as they narrowed down specific subjects. Areas of interests and choices of topics varied greatly among groups. On the written mock Phase I NIH SBIR Proposals, the intellectual property, regulatory, and technical analysis was marginal to satisfactory, but cost and resource analysis for all teams was grossly underestimated, despite intermediate review and suggestions. From my experience as a reviewer for NIH SBIR proposals, the student teams made many of the mistakes that I also see typically made by novice grant applicants. I hope that this experience will help the students improve their ability with grant proposals in their future careers.

Students self-reported that while this experience was more difficult than a standard term paper, they also felt it was more beneficial and interesting. Grading of the proposal was actually easier and more interesting for me than doing term papers. Project presentations made by the teams were, for the most part, excellent, as they took great pride in sharing their ideas. During presentations, other students asked many questions. These questions were of much higher quality and substantially greater in number when I compare them to questions over term paper presentations that students had asked in previous years.

Peer-evaluation of the presentations and content was accomplished by asking students to pretend that they were venture capitalists who were deciding how to divide $1,000,000 among the five projects. They had to justify the spending through written comments. Student teams received anonymous feedback regarding their funding plan. It was interesting to see how students self-evaluated and spent money. They appeared to realize the shortcomings of their own work after completing their presentations and hearing peer questions. In my opinion, students received and considered this feedback better than they do the written comments I typically provide.

Project Notes

1. Student work on assignment 4 (see studentHW4.pdf)
2. Student work on assignment 5 (see studentHW5.pdf)
3. Student #1 work on assignment 6 (see student1HW6.pdf)
4. Student #2 work on assignment 6 (see student2HW6.pdf)
5. Student #3 work on assignment 6 (see student3HW6.pdf)
6. Student #4 work on assignment 6 (see student4HW6.pdf)
7. Group # 1 combined report (see group1Report.pdf)
8. Group #1 final project (see groupFinalProject1.pdf)
9. Group #2 final project (see groupFinalProject2.pdf)

REFLECTION

Impact on student learning:
In my opinion, the students learned much more from this nontraditional course format than from more traditional formats in previous semesters. Initially, students were slightly resistant to the open-ended problem format. They complained in lecture about not seeing "an answer" at the end, rather than realizing that the goal was the development of their thought processes involved in analyzing a problem. Later in the semester, students seemed to overcome this initial resistance and embraced these types of questions.

At the end of the semester, student interest and enthusiasm was definitely much higher than in previous semesters. Only one team out of six (the only team with two members) required instructor intervention and counseling. Based on discussion with those two students, I believe their lower performance happened because of limited discussion and support as opposed to less work put in by fewer team members. One problem for several teams was that they put off the bulk of the final project work until the last two weeks before it was due, despite intermediate deadlines for locating papers and a one-paragraph statement of the project purpose. Several student groups changed their initial topic after the intermediate statement because they had not developed the concept to a high enough level. Resolution of this problem is required to improve student success.

Next steps:
As I continue to refine the course, I will use this same format but will change my lecture and interactions approach with student groups. In order to have more inter-group discussion, I will hold ten-minute periods at the beginning of the lecture period one time per week for all student groups together to discuss problems encountered in the projects. In this way, students will learn from each other and will (hopefully) keep the project on task in a more timely fashion.

An additional way that I plan to keep students on track and emphasize the importance of timely progress on a project will be through log / date books. I will require students to keep a record of major steps in the development of their projects. I'll review and grade this book weekly; this score will be included in the final project grade. When I meet weekly with the student teams, I'll make sure they have shown a sufficient quantity of work with quality analysis.