KATHLEEN A. LAMKIN-KENNARD, AMY L. LERNER and MICHAEL R. KING

Department of Biomedical Engineering, University of Rochester, 601 Elmwood Avenue, Box 639, Rochester, NY 14642, USA. E-mail: mike_king@urmc.rochester.edu

> Incorporation of ethics into undergraduate biomedical engineering education requires a unique blend of engineering and biomedical ethics. We developed and integrated an ethics segment into Biomedical Computation, a required undergraduate course with strong emphasis on statistical methods. The objective of the ethics segment was to introduce basic engineering and medical ethics principles using case studies, then to provide an engineering context in which students could use these principles to construct ethical arguments and make ethical judgments. In follow-up surveys, students responded well to the case study approach, suggesting that ethics can readily be incorporated into core engineering curricula.

Keywords: biomedical engineering; ethics; statistics; Matlab

INTRODUCTION

INCORPORATION OF ETHICS into biomedical engineering curricula has received much attention in recent years. In order to attain engineering program accreditation in the United States, the Accreditation Board for Engineering and Technology (ABET) requires programs to demonstrate that their graduates 'have an understanding of professional and ethical responsibility' [1]. Furthermore, the American Society of Engineering Education proposes that 'new engineering graduates need substantial training in recognizing and solving ethical problems' [2]. In 2004, the Biomedical Engineering Society adopted a voluntary code of ethics that states that 'Biomedical engineers entrusted with the responsibilities of training others shall . . . honor the responsibility not only to train biomedical engineering students in proper professional conduct in performing research and publishing results, but also to model such conduct before them' [3]. Despite an ongoing acknowledgement that ethics should be included in biomedical engineering curricula [4], the methods that engineering programs can use to incorporate ethics into their curricula are not defined and are left to the discretion of individual instructors and departments.

The inclusion of ethics in an intensive engineering curriculum is often challenging. Many different approaches have been tried by various institutions, ranging from simply distributing ethical codes to entire special courses devoted solely to ethics [5]. Addition of a separate ethics course imposes many requirements on a department. Not only does this represent an additional degree requirement for students, but it requires the allocation and training of an engineering faculty member to teach the course or requires the addition of other faculty with training in ethics [6]. Incorporating ethics as an extra topic into existing engineering courses is also difficult due to time limitations. Instructors are often pressed to fit core course material into the time span of a single semester. The addition of ethics as an extra topic reduces the amount of core material that an instructor may cover [7]. To overcome these difficulties, the Department of Biomedical Engineering at the University of Rochester has adopted a strategy to continually introduce ethics to its students during their core degree requirements throughout the duration of their undergraduate program.

Teaching and learning ethics on a daily basis has been suggested as an important component of biomedical engineering education [4]. At the University of Rochester, students are initially exposed to basic ethical principles during a seminar course in their first year. Further exposure occurs during the next three years throughout their core technical courses. Students are then required to apply ethical principles as part of their senior design experience. Key benefits of this strategy are to repeatedly expose the students to ethics, to help them understand how to assimilate ethics into their engineering careers, and to reduce the amount of time individual instructors devote solely to the teaching of ethics. Part of the strategy in including ethics throughout the undergraduate program at the University of Rochester involves collaboration between faculty members. Collaboration exists between Biomedical Engineering faculty in determining the ethics content students are exposed to at various points in their academic careers and this is intended to ensure quality and continuity in the teaching of ethical principles and practice.

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In this paper, we present our method of incorporating biomedical engineering ethics into one core undergraduate course. In the fall of 2004, we undertook an endeavor to develop and integrate an ethics segment into Biomedical Computation, a highly technical, required undergraduate course with a strong focus on statistical methods. The objective of the ethics segment was to provide students with information about basic engineering and medical ethics principles and to provide a context in which they could use these principles, in conjunction with statistical data, to begin to understand how to construct ethical arguments and make ethical judgments. One desired outcome of the ethics unit was that students would be introduced to ethical principles prior to the commencement of their senior design projects and would have begun to form the skills necessary to evaluate ethical issues associated with their senior design experience. To date, the ethics unit has been presented in two consecutive years, with modifications made to the content based on student input from the first year.

The teaching method used to present the ethics material was a case study approach with both lecture and discussion formats [8]. The case study approach was used to link ethical principles with statistical methods, a primary technical component of the course. Following the segment, a questionnaire about the appropriateness and value of the case studies and overall perceived benefit of the ethics component was given to students as a means of assessment.

BIOMEDICAL ENGINEERING CURRICULUM AT THE UNIVERSITY OF ROCHESTER

The University of Rochester is a private research university located in Rochester, NY. A formal undergraduate degree program in Biomedical Engineering was first offered in 1997. The undergraduate curriculum features a series of core BME courses that aim to provide students with a breadth of knowledge and skills in the field of biomedical engineering. The courses that form the 'core' of the program are: Introduction to Biomedical Engineering, Fundamentals of Biomechanics, Matlab for Biomechanics, Circuits for Scientists and Engineers, Biomedical Computation, Biomedical Signals & Measurements, Quantitative Physiology, BME Design Seminar, and Senior Design. The quality and ability of these courses to meet the educational objectives of the department are under continual review through Semiannual Curriculum Reviews, monthly meetings of the Undergraduate Curriculum Committee and ABET Committee, and an annual meeting with an External Advisory Board comprised of leaders from industry and academia.

Biomedical Computation is typically taken by students during the fall semester of their third year

and focuses on the application of computational methods to model biological systems, using the MATLAB programming language, with emphasis on transport phenomena. The objectives of the course are to: (1) learn the fundamentals of numerical computing and statistics in engineering, (2) gain exposure to problems in biomedical transport phenomena, and (3) develop proficiency in writing efficient MATLAB programs. Numerical topics are covered in lectures and homework assignments through applications to a wide range of biomedical topics, such as extracorporeal devices, drug delivery, or medical studies and clinical trials. The numerical topics covered in the course include: introduction to numerical computation, statistics and probability, linear model regression, nonlinear root finding, nonlinear model regression, numerical quadrature, integration of ODEs, hypothesis testing and tests of significance. These topics are all highly analytical and are not typically associated with the teaching of ethics. However, opportunities emerge to present applied numerical methods as they relate to specific ethical situations when presented in the context of biomedical engineering topics. These unique opportunities form the basis for our approach to incorporating ethics into an otherwise highly technical course.

TEACHING METHODS

The two primary teaching methods used to introduce ethics into Biomedical Computation were a standard lecture format and a case study approach. A standard lecture format was used to introduce basic principles of medical and engineering ethics and case studies were presented as examples of applied practice. These methods were incorporated into a lecture unit that sought to integrate numerical methods learned by the students with newly presented ethical principles. The general outline of the material can be seen in Fig. 1.

Case study approach

The utilization of case studies is a well-established teaching method in fields such as business and medicine [8–10]. However, it is only over the past 10-15 years that the use of case studies has gained acceptance in science and engineering disciplines. The use of case studies offers several benefits. A key benefit of teaching in the context of case studies is that they can be used to reinforce technical capabilities while enabling students to develop higher-order skills of learning, such as analytical and decision-making skills [11]. Furthermore, the use of case studies encourages students to critically appraise issues, to understand the process of science and its limitations, and to pose more critical questions [12]. When addressing a complex subject such as biomedical engineering ethics, case studies provide an excellent method of teaching students to critically appraise situations in which

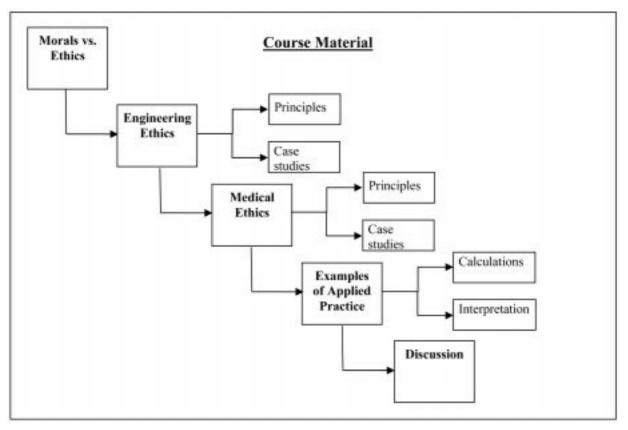


Fig. 1. Outline of ethics course material.

ethical issues in their field arise. Case studies can also provide students with opportunities to apply the technical skills they are gaining as tools to methodologically evaluate an ethical situation and to support their own ethical viewpoints. For these reasons, we chose to use a case study approach to introduce biomedical engineering ethics into the Biomedical Computation course.

LECTURE OVERVIEW

The lecture material began with an introduction to the concepts of morals and ethics. Students were introduced to the concept of ethics as a study of morality and presented the concepts of individual morality versus professional ethics. 'Individual morality' was defined as a set of internally held values that often guide personal beliefs and actions [13]. In contrast, professional ethics were presented as a shared understanding of proper conduct guidelines among a group of people associated by means of their profession. The objective was to help students understand that the guidelines of proper conduct act as a structure by which professionals can act given a set of external conditions and serve as guidelines as to how fellow professionals can reasonably be expected to act in the same or similar conditions [4, 13]. Following the introduction to morals versus ethics, basic principles of engineering ethics were presented, followed by a discussion of historical case studies

in which these principles could be applied. The same format, with a discussion of principles followed by case studies, was used to present basic principles of medical ethics.

Once the fundamental principles of engineering ethics and medical ethics were presented, more complex case studies were introduced to serve as examples of applied practice. During the first year, two case studies were presented. The first example was a computational exercise with ethical implications involving statistical calculations. The second example was based on a reading, assigned prior to class, that illustrated ethical issues associated with the interpretation of statistical data. Following each case study, questions were posed to the students to facilitate discussion regarding some of the ethical issues associated with the case studies. During the second year, a third case study was added to provide a recent example of applied ethics. The addition of a third example was motivated by student input from the ethics segment the previous year.

LECTURE CONTENT

Biomedical engineering ethics

Biomedical Engineering is a multidisciplinary field that uniquely requires students to have an understanding of engineering, science, technology, and medicine [3]. However, as described by Monzon [4], the inter- and multi-disciplinary

nature of the field makes it difficult to identify the set of moral principles that should govern biomedical engineers. Students are required to have technical knowledge in both engineering and medicine; thus, for our presentation of biomedical engineering ethics, we first introduced students to principles associated with both engineering ethics and medical ethics. Engineering ethics was discussed within the context of various engineering codes, such as the code presented by the National Society for Professional Engineers (NSPE) or the BMES code of ethics, which generally state that engineers have many professional responsibilities and must address ethical dimensions of engineering problems, designs, and interactions [13]. Furthermore, common ideals between the codes of ethics, regardless of the engineering discipline, address primary duties of an engineer including duty toward society, fiduciary responsibility toward an employer or client, and safeguarding the reputation and status of the engineering profession [3, 13]. These principles were presented in lecture format and example case studies given that dealt with the often conflicting responsibilities of an engineer.

One case study involved the Therac-25 Radiation Therapy machine which killed or injured several people between 1985 and 1987 by administering massive doses of x-rays. Post hoc analysis of the injuries and fatalities suggested that several factors contributed to the device's failures [14–16]. Some reasons that were suggested for the failures were that all error messages were the same and could be overridden, safety features to prevent accidental overdoses were removed between design revisions, and the software development was performed by only one person [14]. As problems began to emerge, poor management decisions were made despite evidence of safety problems [16]. This case study was used to illustrate how an engineer's responsibilities to society can often conflict with an engineer's responsibility to his or her employer and that an ensuing conflict can ultimately damage the reputation of the engineering profession.

A second example focused on the design of patient controlled analgesia (PCA) pumps. In 2003, Vincente *et al.* [17] published a study that focused on whether or not poorly designed user interfaces on PCA pumps may have contributed to patient deaths. Several individuals and groups felt that the interface design contributed to patient deaths; however, the FDA ultimately concluded that the risks from these types of devices were relatively low and no design modifications were made. Discussion points from this paper were presented to the students to illustrate conflicting ethical issues in medical device design including risk vs. benefit analyses, duties to society, and responsibilities to an employer.

Following the discussion of engineering ethics, students were introduced to the four well-established principles of medical ethics: beneficence, nonmaleficence, justice, and respect for autonomy [18]. The case study chosen to illustrate several of these principles involved the Jarvik-7 Artificial Heart, a device that helped prolong a terminally ill patient's life for several months but created a condition that was also described as 'burdensome' [19]. The device was implanted in three other patients, but all patients died within a relatively short period of time and implementation of the device was terminated. In presenting this case to the students, the question of beneficence was proposed. Students were asked to consider whether the risks of the device outweighed the benefits and what criteria actually constituted a successful outcome; i.e. was the patient's quality of life actually better with the device? Other issues that were presented involved conflict of interest by the doctors developing and implanting the device. Students were asked to consider whether the concept of nonmaleficence could be compromised if the developers knew the patients were suffering, but were gaining financial or other benefits for successfully implanting the device and extending the patient's life.

Examples of applied practice

More complex case studies were presented as examples of applied practice to reinforce the concepts of the basic ethical principles. As suggested by Herreid [12], deciding which facts, viewpoints, and principles to present in a case is an important step in developing case studies. The goal in presenting applied case studies was to give students an opportunity to apply the skills in statistics they had learned in Biomedical Computation to critically appraise a business decision and to critically appraise articles appearing in the literature. The first example of applied practice was chosen to mimic a situation that might occur in a corporate environment, while the second and third might arise in either an academic or industrial environment.

The first applied case study was adapted from an example found on the website http://onlineethics.org, the Online Ethics Center for Engineering and Science at Case Western Reserve University [20]. The premise for this case was that the students are engineers at a company that has developed an implantable patient monitoring device. The device is implemented on a single chip and the user may download health data by telephone to the hospital. Any mode of failure is extremely hazardous to patients, most of whom are over 50 years of age. Field data show six failures in 1.77 million parthours. If the point-estimate of the failure rate is calculated and a constant failure rate is assumed, the Mean Time to Fail is calculated as 2.95×10^5 hours. The marketing department wishes to use this calculation to claim that if the device runs continuously for one year (8760 hours) the device will operate without failures for 34 years [20].

Sample calculations were performed to show what fraction of the devices would fail after one

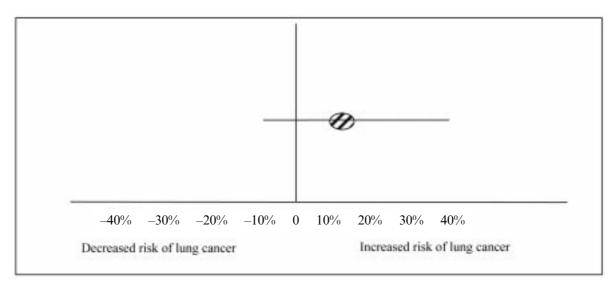


Fig. 2. Confidence interval for risk of passive smoking, from Ref. 19.

year for a given number of implanted devices. The students were then asked to calculate, if failure of Chip X results in patient death one out of three times, what is the probability of death due to Chip X failure of one or more patients after two years? The assumptions were that the entire patient population had the device installed at the same time, and that no other patient fatalities occur in the two-year interval [20]. Based on these calculations, the students were then posed the question of whether the chip is suited for its intended application and what ethical issues should be considered. Ethical principles presented earlier in the lecture were highlighted during this discussion where appropriate. The primary goal of this example was to apply statistical principles to make a business decision with ethical implications and to help students understand the complexities of issues that may arise.

The second applied example was based on an article that appeared in 1998 in a British newspaper. The newspaper reported that 'Passive smoking doesn't cause cancer-official' [21]. The newspaper story was based on a study of 650 cases with 1542 controls in which the relative risk of a non-smoker contracting lung cancer as a result of second-hand smoke was evaluated. The relative risk was compared for individuals exposed to second-hand smoke as a result of a spouse that smoked or as a result of workplace exposure. The study presented a central estimate and confidence intervals as shown in Fig. 2 [22]. The correct interpretation of the study result is that, once the confidence interval has crossed the zero percent risk line, the data below the line implies that one can no longer be 95% confident of the results. However, the newspaper article concluded that there was no risk of passive smoking causing cancer.

Using this example, the students were asked to consider ethical issues associated with misinterpretation of data and the subsequent misinformation provided to the general public. Methods in which the study could have been improved, such as reducing bias, were also discussed. Students were also asked to consider the relative magnitude of the risk associated with second-hand smoke and, if similar risks were associated with a cancer drug, how this would relate to the principle of beneficence and whether relative benefits outweigh risks. Additionally, students were asked to evaluate how public perception can also influence the interpretation of data and what ethical issues may arise when this occurs. The primary goal of this case study was to not only teach students to use analytical skills to critically evaluate potentially life threatening substances, but also to think about how identical data may be interpreted and decisions made differently when applied to different situations.

In the second year, a third case study was presented that focused on study results presented in the Journal of the American Medical Association in 2004. Study results suggested that antibiotic use increased a patient's risk for breast cancer [23]. The study presented data detailing antibiotic use in patients with breast cancer based on health insurance records denoting antibiotic use. Data for patients that had used antibiotics was obtained for 20 years while data for those that had not used antibiotics was obtained for 10 years. Based on these data, the authors concluded there was a link between breast cancer and antibiotic use. In examining this case study, the students were asked to evaluate the overall study design, potential biases, and the possibilities of an incomplete data set. The ethical issues of presenting potentially misleading results to the general public were discussed as well as the broader implications that can occur when such results are misinterpreted and presented by mass media.

Revisiting the ethics material

Pharmacokinetic analysis and pharmacodynamics are two topics covered as part of the

Table 1. Comparison of the relative risk of contracting lung cancer from second-hand smoke through exposure to a spouse or exposure in a workplace environment, from Ref. 18

	Central	Lower	Upper
	Estimate	Limit	Limit
Spouse	1.16	0.93	1.44
Workplace	1.17	0.94	1.45

curriculum for Biomedical Computation. During the second year, the ethics material was revisited in conjunction with pharmacodynamics material presented to the students. In class, students were presented with numerical aspects of calculating mechanisms of drug action. As a homework assignment, the students were given material to read that detailed the use of statistics for parameter estimation in relating plasma concentration and associated effects. To reintroduce ethical concepts, a discussion of the relevance of statistical data to clinical trials was given and a series of questions posed regarding ethical issues associated with clinical trials. A key objective of this assignment was to provide a context in which the students could continue to apply the ethical concepts introduced previously in the course.

STUDENT ASSESSMENT

Student assessment is an important tool used by many universities to promote quality and improve course content. To evaluate student opinion of the ethics segment, a brief questionnaire was given to the Biomedical Computation students. Students were asked to respond to a list of statements on the following scale: (1) Strongly agree, (2) Agree, (3) Disagree, (4) Strongly disagree, or (5) No opinion. Here we provide a list of statements given to the students:

- 1. The ethics material presented during Biomedical Computation was informative.
- 2. The ethics material presented will be useful in my future career.
- 3. Ethics should be incorporated into engineering coursework.
- 4. I found the specific case studies presented useful in illustrating ethics principles.
- 5. I liked the ideas of case studies, but would recommend different ones in the future.
- 6. I would recommend incorporating ethics into more aspects of Biomedical Computation in the future (i.e. another lecture, homework problems with an 'ethical' component, etc.).
- 7. Additional comments or suggestions:

The aims of the questionnaire were to determine whether the students perceived any value in being presented with ethical principles, to evaluate the case study approach, and to seek recommendations for future lectures.

In the first year, the study was given via e-mail

and only a portion of the students that attended the lecture responded. However, in the first year, the general trend was that students responded positively to the ethics material. Of the respondents, 40% strongly agreed and 60% agreed that the material was informative; 60% strongly agreed and 40% agreed that ethics should be incorporated into engineering coursework; similarly, 60% felt that the information would be useful in their future careers. Disagreement did exist over whether ethics should be incorporated into more aspects of Biomedical Computation in the future.

In the second year, the questionnaires were given out in the next lecture and 30 students completed the survey, thus a more complete set of study results was obtained. Fig. 3 shows the distribution of student responses to the survey questions. Results from Question 5 are not presented due to the ambiguity of the question and a disproportionately large number of students that responded with no opinion. For Questions 1 and 2, the majority of students agreed that the material presented was informative and will be useful in their future careers. The students also responded well to the idea of ethics as well as the case study approach, as seen from the responses to Questions 3 and 4. Some specific comments obtained from the students were: 'It should be included. All Med School prospects usually take ethics, while engineers who will be in the field as well never receive ethics', 'more presentations like (this) to bring in interesting ethical topics', and 'maybe a project where we examine a case study on our own would be helpful'. However, in responding to Question 6, the students were divided over how much ethics should be incorporated into Biomedical Computation. This disagreement was consistent with findings from the previous year. Further evidence of the disagreement as to how much ethics should be incorporated was obtained from student comments. Some specific comments were: 'Ethics should be addressed but may not have to be in 221 [Biomedical Computation]', 'Another lecture might be nice, but computation is a weird place to put ethics', and 'the background was informative, but I don't want to learn any more about it at this time'. These comments and suggestions will again be incorporated in the future, with a particular focus on how much ethics should be included as well as the format for inclusion.

FUTURE RECOMMENDATIONS

Based on our experiences and student assessment, one recommendation for other institutions interested in attempting a similar approach would be to focus more on group discussions early on. Given that students are not typically used to participating in group discussions in technical courses such as Biomedical Computation, it was a challenge to draw students into participating in the applied case study discussions. By facilitating

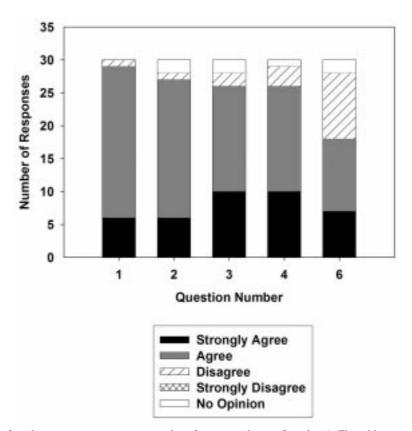


Fig. 3. Distributions of student responses to survey questions from second year. Question 1: The ethics material presented during Biomedical Computation was informative. Question 2: The ethics material presented will be useful in my future career. Question 3: Ethics should be incorporated into engineering coursework. Question 4: I found the specific case studies presented useful in illustrating ethics principles. Question 6: I would recommend incorporating ethics into more aspects of Biomedical Computation in the future (i.e. another lecture, homework problems with an 'ethical' component, etc.). Note that there are no questions to which students responded 'Strongly Disagree'.

several group discussions, perhaps students would be more comfortable with the idea of group discussions later on during the ethics unit. Breaking the students into smaller groups could also serve as another method for facilitating group discussions. One student comment suggested this method and proposed they would like 'to get students into groups to discuss solutions'. An additional recommendation would be to focus less on principles and more on specific examples. Basic ethical principles could be provided to the students as a reading assignment or in other courses, allowing more time for case study discussions in either small or large group formats. A final recommendation would be to intersperse the ethics material throughout the course rather than focusing as heavily on the material in a single unit. One lecture could be devoted to the discussion of principles and case studies, then examples presented to the students as appropriate throughout the duration of the course. As previously described, we tested this approach later in the course during the second year. Students were given a homework assignment on pharmacokinetics and pharmacodynamics that involved numerical calculations but also prompted them to think about ethical issues associated with drug design.

CONCLUSION

Overall, given the generally positive response from students about the ethics segment, we conclude that our initial endeavor to incorporate ethics into a highly technical undergraduate course was successful. One of our preliminary goals was to determine whether ethics could readily be incorporated into a highly technical course such as Biomedical Computation. Based on student responses, we believe that this effort was indeed successful in teaching ethics in the context of statistics and plan to incorporate many of the student suggestions into the course in future years. Furthermore, we intend to follow up with the students after their senior design sequence to determine if the inclusion of ethics in Biomedical Computation was beneficial to their senior design experience.

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Kathleen A. Lamkin-Kennard is a former Post-Doctoral Researcher of the University of Rochester in the Department of Biomedical Engineering, and is currently as Assistant Professor of Mechanical Engineering at the Rochester Institute of Technology. She received a B.Sc. degree from Worcester Polytechnic Institute in Physics and an M.Sc. degree in Biomedical Engineering from Drexel University. Following several years in industry, she received a Ph.D. in Biomedical Engineering from Drexel University. Dr. Lamkin-Kennard was supported by an NIH Kirchstein National Research Service Award. Her research interests involve microcirculatory phenomena, biofluid mechanics, and computational modeling of integrated physiological systems.

Amy L. Lerner is an Associate Professor of Biomedical and Mechanical Engineering at the University of Rochester. She received B.Sc. degrees in Textile Science and Apparel Design from Cornell University and in Mechanical Engineering from the University of Delaware. She later received M.S. and Ph.D. degrees from the University of Michigan, where she was also a Fischer post-doctoral fellow in Pediatric Orthopaedic Biomechanics. Her research interests involve osteoarthritis and biomechanics of the knee joint. Dr. Lerner is currently the director of the University of Rochester Senior Design Program, a customer-driven introduction to the design of medical and bio-research devices.

Michael King is an Associate Professor of Biomedical Engineering and Chemical Engineering at the University of Rochester. He received degrees from the University of Rochester and University of Notre Dame in chemical engineering. King is a Whitaker Investigator, a James D. Watson Investigator of New York State, and is a recipient of the NSF CAREER Award. His research interests include biofluid mechanics and cell adhesion. King is coauthor of two books published by Elsevier in 2005: (1) *Principles of Cellular Engineering: Understanding the Biomolecular Interface*, and (2) *Heat Transfer and Fluid Flow in Minichannels and Microchannels*.