Use of Engineering Standards in Teaching Statistical Design of Experiments in Biomedical Engineering

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Introduction

Engineering standards are used to teach applications of statistical principles and design of experiments in a new Biomedical Engineering (BME) course. This course, Design of Experiments (BME 346), was developed in response to input from industrial constituents for the new undergraduate BME degree program (begun during the 2000-01 academic year). Constituents wanted BME graduates to receive training in statistics for design of engineering experiments and interpretation of data. A key element of this course is an experimental design project based on applying statistical methods to an existing engineering standard. This project provides students with a real-world example of how to apply statistical principles to practical engineering problems and experiments. Student assignments for this project demonstrate 8 out of 11 outcomes required by ABET 2000 criteria.

Design of Experiments Course

The Design of Experiments course teaches basic statistics skills and introduces the principles of experimental design. This is a required course in the junior year of the BME curriculum and is the only statistics course that BME undergraduate students generally take. It is a prerequisite to the BME laboratory course required during the senior year, so that students are prepared to do statistical analysis of data from lab experiments. The BME laboratory course is then a corequisite for the senior design course sequence, which requires some experimentation. Some BME graduates later take additional statistics courses in their M.S. degree program.

Most BME undergraduate students have little or no prior training in statistics, so this course introduces the subject in depth. Topics include probability, graphing of raw data, discrete and random variables, probability distributions (Binomial, Geometric, Poisson, Normal, Student's t, Chi-Square, and F), joint probability distributions, statistical inference and hypothesis tests for one or two samples, and design of single-factor experiments (i.e. analysis of variance, ANOVA). When time allows, linear regression is also covered. These topics provide students with a foundation in statistics and data analysis that prepares them for the experimental design project and for future experimental work in the BME laboratory course and in their future careers.

The purpose of the experimental design project is to teach practical application of the statistical skills (taught through lectures, homework, and exams) to design of experiments and to interpretation of data for reaching valid conclusions. The experimental design project forces students to address an open-ended problem, learn related background information, define a statistical hypothesis statement, design an experiment to test this hypothesis, simulate a typical dataset, draw a conclusion from their dataset, and defend this conclusion. Students also develop skills in teamwork, technical presentations and writing, graphing, and use of statistical software

Table 1. Engineering standards used in experimental design projects.

TOPIC	STANDARD	TITLE / DESCRIPTION
Research	ASTM F732	Standard Test Method for Wear Testing of Polymeric Materials for Use in Total Joint Prostheses[1]
Research	ASTM F1877	Standard Practice for Characterization of Particles[1]
Research	ASTM F1906	Standard Practice for Evaluation of Immune Responses in Biocompatibility testing Using ELISA Tests, Lymphocyte, Proliferation, & Cell Migration[1]
Applied Development	ASTM F756	Standard Practice for Assessment of Hemolytic Properties of Materials[1]
Applied Development	ASTM F1635	Standard Test Method for In Vitro Degradation Testing of Poly (L-lactic Acid) Resin & Fabricated Form for Surgical Implants[1]
Applied Development	ASTM F1714	Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices[1]
Applied Development	ASTM F1717	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model[1]
Manufacturing/ Quality Control	ASTM F543	Standard Specification and Test Methods for Metallic Medical Bone Screws[1]
Manufacturing/ Quality Control	ASTM F1223	Standard Test Method for Determination of Total Knee Replacement Constraint[1]
Manufacturing/ Quality Control	ASTM F1446	Standard Test Methods for Equipment and Procedures Used in Evaluating the Performance Characteristics of Protective Headgear[2]
Manufacturing/ Quality Control	ASTM F1447	Standard Specification for Protective Headgear Used in Bicycling[2]
Clinical	ASTM F451	Standard Specification for Acrylic Bone Cement[1]
Clinical	ASTM F561	Standard Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues[1]
Clinical	ASTM F703	Standard Specification for Implantable Breast Prostheses[1]

programs. These skills prepare students for their BME laboratory and senior design project courses.

Experimental Design Projects

The experimental design project consists of a series of assignments. First, teams are formed as 3-5 students, and each team selects an ASTM[a] standard (usually a test method) that is related to Biomedical Engineering. Students prefer to choose from a short list of standards, rather than to review all available standards. Table 1 lists the ASTM standards that have been used in the experimental design projects. Standards are chosen to relate to topics including research, applied development, manufacturing/quality control, and clinical applications, and teams are named accordingly.

[a] American Society for Testing and Materials.

Table 2. Criteria for Evaluation of Oral Proposals

• Purpose of the project is clearly stated.
• Project is related to team's topic.
• Selected standard is appropriate to topic.
• Background information justifies the project.
• Team understands technical aspects of this proposed project, and is able to explain them clearly.
• Justification is provided to support the work. Why is this important enough to be approved?
• Problem is stated clearly, in technical terms.
• Problem is stated clearly, in statistical terms.
• Experimental plan is well defined.
• Dependent & independent variables are identified, with methods specified to control or measure them.
• Results will provide a comparison between a test group or method and a control, so that a difference can be shown statistically.
• Problem statement is closely related to the defined variables, so that the conclusion can readily be drawn from the experimental results.
• Team is knowledgeable about the equipment needed to complete this project.
• An estimate of manpower costs was provided.
• An estimate of schedule was provided.

Oral and Written Proposals
Each team must read their standard, review related literature, and then prepare short oral (5-10 minutes) and written (1-3 page) proposals to justify work on their experimental design. These proposals include the purpose of the experiment, background information and justification, problem statement, and preliminary experimental plans with estimates of labor, costs, and schedule. Each student evaluates the other teams' oral proposals based on specific criteria (see Table 2).

Reference Summaries
Next, teams must find and read references related to their experiments and write summaries of each one. References may include refereed technical journals, books, or proceedings of technical meetings, but not websites. Each team's references must include at least one book on statistical methods or applications plus one book or proceedings and five journal articles related to the experiment. Each student must contribute three summaries for his team. Emphasis is placed on references reporting data similar to what would be obtained from each proposed experiment. This background information is later used to simulate a dataset representative of what would be obtained from the designed experiment.

Draft Experimental Plan
Each team then expands its written proposal to develop a first draft of the detailed experimental plan, which is later revised in the final written report. Sections of this draft include Background Information, Purpose of the Experiment, Technical Problem Statement, Statistical Problem Statement, and Detailed Experimental Plan. The technical problem statement defines the

population being studied, independent variables or factors being controlled, dependent variables being measured, and critical values or limits on dependent variables. The statistical problem statement defines the null and alternate hypotheses, the statistical distributions, graphical methods for displaying and analyzing data, and statistical test methods used to reach defensible conclusions. Experimental details include specification of control groups as well as sample groups, identification of factors being tested, the number of levels of each factor, the number of replicates tested for each set of experimental conditions, and the equipment to be used. Student teams usually meet with the instructor at least once during this assignment to discuss the details of their plan and to receive feedback on their progress.

Final Oral and Written Reports
Finally, each team develops a simulated dataset based on its experimental plan. This data is graphed and analyzed using the techniques defined in the technical and statistical problem statements. Conclusions are reached based on the statistical null and alternate hypotheses. Results are reported in both written and oral reports submitted near the end of the semester. The written report (5-10 pages) is similar to an industrial technical report, with sections including Introduction, Technical Problem Statement, Statistical Problem Statement, Experimental Methods and Materials, Results, Statistical Analysis, Discussion, and Conclusions. The oral presentations (10-12 minutes) are suitable for presentation of research results at a technical conference, with emphasis on the Results, Statistical Analysis, Discussion and Conclusions. Criteria for evaluating the final oral presentations are given to students in advance and are listed in Table 3.

<u>Outcomes Demonstrated by Students</u>
Students in this course demonstrate the following ABET 2000 outcomes[3] through their work on the experimental design project.

An ability to apply knowledge of mathematics, science, and engineering
Mathematics knowledge is demonstrated through the application of statistics to the design of experiments and to the interpretation and analysis of data. Science and engineering knowledge is demonstrated through the experimental plan, including the materials and test methods and interpretation of results to reach conclusions.

An ability to design and conduct experiments, as well as to analyze and interpret data
The emphasis of the experimental design project is to design an experiment and to analyze and interpret a dataset based on the experimental design. The design should address the minimum sample size based on the level of statistical significance being tested. Data analysis and interpretation develop skills in the use of spreadsheets (Excel©) and statistical software programs (SPSS©) to graph and analyze datasets. Students are taught to conduct experiments in the BME laboratory (BME 430), which is taken after the Design of Experiments course is completed.

An ability to identify, formulate, and solve engineering problems
Students identify and formulate their problem statement in both technical and statistical terms as part of their oral and written proposals, at the beginning of their experimental design project. The problem statement continues to be refined and developed through the experimental design

Table 3. Criteria for Evaluation of Final Oral Presentations

• Team understands technical aspects of this project, and is able to explain them clearly.
• Problem is stated clearly, in technical terms.
• Populations being tested (including control groups) are clearly defined and appropriately selected.
• Independent variables, dependent variables, and calculated parameters are clearly defined as to their relationships to the experimental design.
• Problem is stated clearly, in statistical terms (i.e. null vs. alternate hypothesis), so that a distinct conclusion can be reached from the experimental results.
• The statistical test method for reaching a conclusion is well defined, including the distribution being used, selection of a 1-sided or a 2-sided test, and the α level.
• Assumptions required for the statistical test method are recognized and verified.
• Experimental methods & materials are well defined.
• Methods to calculate parameters are specified.
• Team is knowledgeable about the equipment and test methods required to complete this project.
• Experimental results are displayed in graphs or tables that are easy to interpret.
• Statistical analysis of the results is explained clearly.
• The results are interpreted correctly to reach a conclusion, which is stated clearly.
• The significance of the conclusion is related to the broader purpose of the experiment, in terms of its long-term impact.
• Overall, the oral presentation is effective in teaching how statistics can be applied to analyze different types of experimental data.

phase leading to the final report. Analysis and interpretation of the resulting dataset then contributes to the solution of the problem.

An understanding of professional and ethical responsibility

Professional responsibility includes the use of engineering standards, and ASTM standards are used as the basis for the experimental designs. Students are introduced to engineering standards in this course and continue using them in the senior BME design course sequence taken the following year.

An ability to communicate effectively

Students demonstrate their technical communications skills through multiple oral presentations and written reports required for the experimental design project. The final written report includes graphing and interpretation of data, which develops students' skills in use of spreadsheets (Excel©) and statistical software (SPSS©) as well as report writing (MS Word©). Oral presentations are made in-class using PowerPoint© software and a laptop computer connected to a Smartboard for projection. These activities prepare students for requirements in the BME laboratory and the senior BME design course sequence taken the following academic year.

A recognition of the need for, and an ability to engage in life-long learning
Students must review the technical literature related to their experiment and prepare written abstracts of related references. This assignment familiarizes them with technical literature related to BME, teaches them to use the campus library and associated electronic resources, and shows them that they must be able to learn new information quickly to work as a biomedical engineer. Some of these skills were taught in a prerequisite course, Introduction to Biomedical Engineering, and they continue to be used extensively in the senior BME design course sequence the following academic year.

A knowledge of contemporary issues
The ASTM standards (used as the basis for experimental designs) are chosen to relate to current topics of interest in BME. Students will expand their knowledge of contemporary issues through work on their experimental design and also through listening to oral presentations by other teams in the class working on other experimental designs.

An ability to use the techniques, skills, and modern engineering tools necessary for engineering practice
Statistical analysis is a skill necessary for engineers working in the medical field, and is demonstrated extensively through the experimental design project. Students develop skills in use of computers and software tools including spreadsheets (Excel©), statistical analysis (SPSS©), word processing (MS Word©), presentations (PowerPoint©), and technical drawing (Visio©). Although students do not conduct experiments in this project, they do learn about engineering tools and test equipment through reading the ASTM standards and related references. The experimental plan includes specification of test methods and controlled variables, demonstrating knowledge of modern engineering tools and techniques.

Conclusions

Experimental design projects were effective in teaching important statistical analysis and design of experiments skills to biomedical engineering students. Students' understanding of statistical principles and methods was challenged by these projects, which required higher-level thinking skills than solving well-defined problems from the textbook. Using ASTM standards as the basis of experimental plans taught students about current engineering technologies, even when equipment was not available to run the experiments. The experimental design projects contributed to 8 out of 11 student outcomes required by the ABET 2000 criteria.[3]

Bibliography

[1] *Annual Book of ASTM Standards*, Vol. 13.01, American Society for Testing and Materials, West Conshohocken, PA.

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[3] ENGINEERING ACCREDITATION COMMISSION, *2002-2003 Criteria for Accrediting Engineering Programs*, Accreditation Board for Engineering and Technology, Inc., Baltimore, MD, 2002.