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The Use of a Medical Device Surrogate for Cooperative Product Development Learning of Engineering Design

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Jeffrey T La Belle is currently an Assistant Professor in the School of Biological Health and Systems Engineering and the Biodesign Institute at Arizona State University. He holds adjunct status in the School of Energy and Matter Transport (Mechanical Engineering) as well as the College of Medicine at Mayo Clinic. He has a Ph.D. and Masters in Biomedical Engineering from ASU and a MS and BS in Electrical Engineering from Western New England University in Springfield Massachusetts. In the La Belle Group, we are currently developing electrochemical sensors for noninvasive glucose sensing, the novelty of our design is to obtain tear fluid for tear to blood glucose correlation in a noninvasive means to increase patient compliance. The next leap in technology for diabetes care is a multiplexed sensor that will add more depth of information for a self-monitoring blood glucose devices, here five accepted markers for DM care and management, including glucose, HbA1c, among others are simultaneously monitored on a single strip sensor. This technology we are developing could also allow for continuous and single use stress/trauma sensing technologies. Other applications of the sensing technologies include small molecule, DNA, protein, and whole cell detection to address changing climate in point-of-care technologies and medicine. On the activation side of our research, we are fabricating nitinol staggered muscle arrays that mimic skeletal muscle and we have recently demonstrated over 30% compression in our SMA's similar to muscle bundles. Our approach to design is simple, following FDA guidelines and suggestions from the start, look at what the user needs and/or wants and apply a unique solution. We have a well-diversified group to tackle the challenges in health care today, staff and students come from biomedical engineering, electrical engineering, mechanical engineering, chemical engineering, computer science engineering, as well as biology and chemistry programs at ASU. BME at ASU teaches a 8 semester wide medical device design tract that initiates the students in design, regulations, standards, IP and other aspects from day 1. Dr. La Belle has develop and courses and taught at the freshman, junior, senior and graduate level on these topics.

Mr. Aldin Malkoc, Arizona State University

Aldin Malkoc, MS is a student in the School of Biological and Health Systems Engineering at Arizona State University. Aldin is enrolled in the 4+1 program to receive his Masters of Science in Biomedical Engineering from Arizona State University in 2017 and will pursue a doctoral degree in Biomedical Engineering from Arizona State University in 2017. The primary focus in his master's thesis will pertain to the study of a point-of-care insulin sensor in biosensor development. Currently, Aldin is a graduate teaching assistant at the Fulton Schools of Engineering and wishes to develop effective engineering education strategies.

Ms. Mackenzie Honikel, Arizona State University, Biological and Health Systems Engineering

Mackenzie Honikel, a current PhD student in the School of Biological and Health Systems Engineering at Arizona State University. Mackenzie graduated from SUNY Binghamton in May 2016 with a Bachelor's degree in biomedical engineering, concentrating in biomedical devices and biomaterials. Her background is in point-of-care diagnostic sensors, and she aims to continue this work during her time at Arizona State University. Her dissertation focuses on the development towards implantable cardiovascular sensors for continuous patient monitoring and reduced embolism formation at the site of implantation.

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While many core engineering classes prepare students' technical ability, there are few classes that strictly enforce development of key concepts. The work presented is a project-based learning experience that teaches and enforces three key concepts: (1) innovation, (2) prototyping strategies, and (3) design processes crucial for engineering design. While it is important for students to learn the presented key concepts, it is imperative to ensure that upon completion of the course, each student is at an equal proficiency. The focus of this study is on translatability between professors and times a course is offered. Such that, no matter when and by whom the course is instructed, the students will effectively learn and show improvements in innovation, prototyping, and design. Our research poses the question: how will a project-based learning experience translate between different professors and times a course is offered when trying to enhance and develop concepts of innovation, prototyping, and design?

A hands-on, project-based cooperative learning lab was designed where students are placed into teams to design and develop a final prototype. The course uses the development of a board game as a surrogate for a medical device to enhance students' skills in innovation, prototyping, and design. The use of the board game allows students to focus on the process versus the development of a final specific device. Additionally, the board game *requires* consideration in all aspects of medical device design: innovation, prototyping, standards consideration, regulatory pathway, intellectual property, and design of an experiment.

The course has three main components that enforce and teach innovation, prototyping, and design. The students begin by taking a survey for self-assessment evaluation, a pre and post design challenge for instructor assessment, and expert validation of a final project prototype. From the study, the design challenges and student surveys showed significant differences between pre and post scores. This was evident in all three key concepts. Some of the key findings were, the spring 2014 semester, 76% showed improvement in innovation, fall 2015 Wednesday section showing a 73% increase in the innovation category for the student survey, and spring 2014 showing a 143% score increase in the design category of the design challenge. However, at this time, there are no reported statistical differences in validator scores for the final product prototype.

The study here hopes to address two concepts. The first being teaching and retention of concepts that are important in design, specifically senior year design. Second, it offers promise into the transferability of content and learning between professors, semesters, and time a class is offered. While this study was performed on a junior year course, a project-based learning experience is perfect for the freshmen year experience, to ensure that students are taught these skills early on in their academic careers. In addition, the methodology used in this course is applicable to any grade level. While implemented junior year, this form of teaching could greatly benefit FYE.

Introduction

Various engineering programs have multiple professors that can and do teach the same course. It becomes the student's responsibility to adapt and obtain useful learning methods to ensure they can understand difficult concepts, perform well on exams, and follow classroom instructions[1]. However, the responsibility of school department is to ensure that no matter the time the course was taken or which professor students have, the majority will learn the same amount of material. Furthermore, it is important that students show academic growth to ensure success in their major[2,3]. Currently, there has been various research that assesses students' growth and how well they perform longitudinally[4]. However, the missing component is that there is little research that assesses transferability of classes between semesters, instructors (if different instructors teach the same course for different sets of students), and class time and day (morning vs. afternoon). Although it is possible to look at the distribution of final grades or grade point averages, they have shown to not be the best evaluator of student performance[5,6,7]. In order to test student performance and growth before they begin the course as well as after they have completed the course, this study uses three different measures.

The considered key concepts, of innovation, prototyping, and design, are considered significant to the development of future engineers[8,4,9]. While all of the key concepts can be achieved and learned implicitly as students progress through their engineering core classes[10], it is beneficial if innovation, prototyping skills, and the design process are explicitly taught to students [11,12,13]. Studies have shown that this can be achieved through the use of project work and guided small group work[8]; the teaching method used in this course. However, the missing component is determining if instructor or day and time the class is offered has an effect on students proficiency in those areas.

This study considered three pre and post metrics to assess students learning and improvement. The interactive design challenge assessed student's ability to develop and design a device that can detect small concentrations of infectious agents. The student survey determined students' perception of proficiency. Lastly, students' performance on a final prototype presentation is assessed and scored by experts in the field. All three of these tests were assessed with innovation, prototyping, and design in mind. Additionally, it would be important to note that the core of the course is developed using the entrepreneurial mindset[14]. This form of problem-based learning has worked with students in prior courses and fits the model of using a prototype-based surrogate to teach engineering design[8].

The objective of the study was to identify if student improvement in innovation, prototyping skills, and design and the design process is affected by different instructors and during different time and day of the week. Identifying if classes that are critical to student learning and performance are transferable will help instructors and possibly departments determine the best methods to ensure all students are beginning and ending with the same level of competence.

Materials and Methods

The study presented here is of a biomedical engineering course that uses a medical device surrogate, the development of a gamma prototype of a zombie-themed board game, to teach important aspects of medical device design. See Appendix 1 Figure 8 for a direct comparison of specifications between board game design and medical device design.

Survey Design

The survey was administered anonymously at the beginning of the semester and at the end of the semester. The survey assessed student's perception of mastery in the three categories. The survey was presented with a Likert scale of ranging from 1 to 5. 1 being strongly disagree and 5 being strongly agree. Furthermore, survey responses were grouped into one of the three categories "Innovation", "Prototyping Skills", and "Design and The Design Process."

Survey Administration

The survey was given using Blackboard and students took the survey during class time the first and last week of school. The spring 2014 semester offered the course from 9:00 am to 11:50 am every Friday for 16 weeks. The second semester had two separate sets of data with a Friday session that was identical to spring 2014 and a Wednesday session offered in the afternoon from 12:00 pm to 2:50 pm. It should be noted that only the spring 2014 sample population had a varying distribution of grade levels, which ranged from freshmen level (n=3) to sophomore level (n=10) to junior level (n=24); however, all students can be ranked equivalent to juniors due to having the required pre-requisites for the course.

Design Challenge

The design challenge consisted of a single page handout that tested students' competency in innovation, prototyping skills, and design and the design process. The problem topic asked students to develop a diagnostic method to detect an infectious agent. The design challenge was given the first week and the 16^{th} week of the semester. Students were given 15 minutes to complete the challenge. The challenge was scored with a double blind standard. The evaluators did not know if they were grading pre or post design challenges and the average of the score were recorded for analysis. Furthermore, the design challenge was grouped into one of the three categories of innovation, prototyping skills, and design and the design process. The design challenge was scored on a 5-point scale, see table 1 for specific grading criteria.

Table 1: Sub-categories for assessment of "Innovation", "Prototyping Skills", and "Design and The Design Process".

Innovation	**Prototyping Skills**	**Design and Design Process**
1 pt: Exactly the same, or very similar to a well-known product used in the medical field	1 pt: There is no diagram/alpha/chart, but it is somewhat explained	1 pt: At least two components are considered. Components such as specifications on design, explanation about the manufacturing process, explanation of verification and validation process, explanation of design parts and process needs, comparability or considered of state-of-the-art method
2pts: Exactly the same, or very similar to a product extensively researched	2pts: There is some kind of diagram/alpha/chart, but is it not labeled or explained	2pts: Two-four components are considered. Components such as specifications on design, explanation about the manufacturing process, explanation of verification and validation process, explanation of design parts and process needs, comparability or considered of state-of-the-art method
3pts: Similar to something that already exists, but has smaller differences	3pts: There is some kind of diagram/alpha/chart, but is it not labeled or explained that well	3pts: At least two-four components are considered with detailed explanations. Components such as specifications on design, explanation about the manufacturing process, explanation of verification and validation process, explanation of design parts and process needs, comparability or considered of state-of-the-art method
4pts: Might resemble something that already exists, but has major differences	4pts: There is a diagram/alpha/chart, and it is labeled/explained, but there is not information about how it will be created (in terms of alpha/beta/gamma)	4pts: Three components are considered with detailed explanations. Components such as specifications on design, explanation about the manufacturing process, explanation of verification and validation process, explanation of design parts and process needs, comparability or considered of state-of-the-art method
5pts: A completely new idea-patentable	5pts: There is a diagram/alpha/chart, it is	5pts: Four or more components are considered

	labeled/explained, and there is information about how it will be created (in terms of alpha/beta/gamma)	with detailed explanations. Components such as specifications on design, explanation about the manufacturing process, explanation of verification and validation process, explanation of design parts and process needs, comparability or considered of state-of-the-art method

Final Prototype

Students were asked to develop, in 16 weeks, a board game. They were instructed about various design parameters, standards, and agencies that govern toys and items used in board games. This is very similar to what they would be expected to consider once taking their senior design. The students at the end of the semester were asked to present their final prototype to experts (business game owners, manufacturers, designers, teaching assistants, and instructors). The experts were asked to listen to a 5-minute elevator pitch of the student's prototype and assess the student on 10 different 5-point scale metrics. The metrics were grouped into the categories of innovation, prototyping skills, and design and the design process.

Statistical Analysis

In order to assess the statistical difference of the *pre and post-survey* responses a Kruskal-Wallis and Mann-Whitney tests for non-parametric data was used (nSpring2014=37, nFall2015Wednesday=48, nFall2015Friday=34). The Bonferroni correction was applied to post-tests when considering multiple semester comparisons. The results shown are all on a 5-point scale.

A one-way ANOVA was performed on independent *pre and post design challenge* scores with an additional Tukey's T-test analysis to determine significance in individual categories.

The *final gamma prototype* scores were assessed with the Kruskal-Wallis test for non-parametric data (nSpring2014=37, nFall2015Wednesday=48, nFall2015Friday=34).

Lastly, Excel was used to determine descriptive statistics, compile data, and generate graphs. Statistical Package for the Social Sciences (SPSS) was used for all analysis

Results

Statistical Evaluation of Semester Difference of the Design Challenge

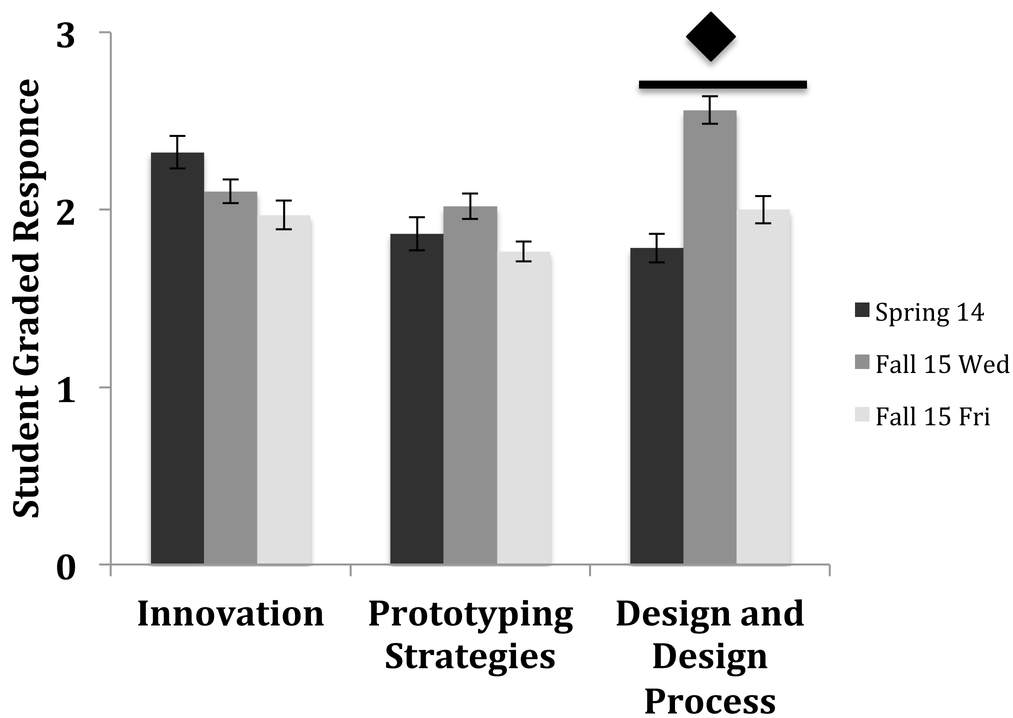

Figure 1. Statistical Analysis of Mean Initial (Pre) Design Challenge Scores Between Semesters: One-Way ANOVA analysis of the three data sets, two semesters, showed different statistical differences. There was no statistical ($p>0.05$, $n=119$, Error shown is Standard Error) significance in the innovation category when assessing the student's initial scores. There was no statistical ($p>0.05$, $n=119$, Error shown is Standard Error) significance in the Prototyping Strategies category when assessing the student's initial scores. There was statistical ($p<0.05$, $n=119$, Error shown is Standard Error) significance in the Design and Design process category when assessing the student's initial scores.

Figure 1 determines statistical differences among average initial scores in the design challenge. This information would help the instructor assess if the students are at the same baseline level when beginning the course. Semester differences were considered for design challenges initially given in the beginning of the semester. The pre-results helped determine if there were similar baseline values across the categories of innovation, prototyping strategies, and design and design process. In summary, according to the results of a one-way ANOVA, there were no statistical differences in the innovation column. There was a slightly marginal higher grade value of 2.3 in the innovation column when compared to the fall

2015 Wednesday value of 2.1 and fall 2015 Friday value of 1.97. Additionally, the same is evident in the prototyping strategies category. There was no statistical significance, however, there were slightly higher scores across semesters and times. The fall 2015 Wednesday value of 2.02 was higher than the spring 2014 value of 1.86 and fall 2015 Friday value of 1.76. Lastly, design and design process did observe statistical differences. The fall 2014 Wednesday value of 2.56 was statistically higher for the design and design process column did have statistical differences when compared to spring 2014 1.78 and fall 2015 Friday 1.76.

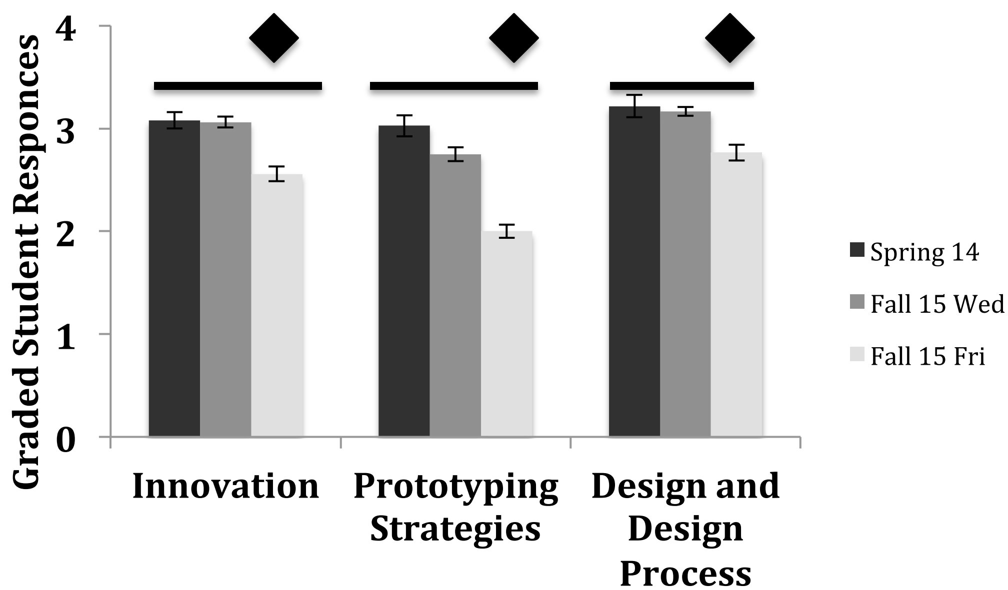

Figure 2. Statistical Analysis of Mean Final (Post) Design Challenge Scores Between Semesters: One-Way ANOVA analysis of the three data sets, two semesters, showed different statistical differences. There was statistically ($p<0.05$, n=119, Error shown is Standard Error) significance in the innovation category when assessing the student's final scores. There was statistically ($p<0.05$, n=119, Error is shown is Standard Error) significance in the Prototyping Strategies category when assessing the student's final scores. There was statistically ($p<0.05$, n=119, Error is shown is Standard Error) significance in the Prototyping Strategies category when assessing the student's final scores.

Figure 2 determines average final design challenge scores and if any are statistically different. The post data results help the instructors determine if the students learned the same level of material across semesters. Determining if there was a similar ending baseline value across the categories of innovation, prototyping strategies, and design and design process is valuable and important when assessing if students are leaving the course on equal levels. In summary, according to the results of a one-way ANOVA, there were statistical differences in all three columns. In the innovation column, the fall 2015 Friday section was a statistically lower difference from the other groups with an average score of 2.55

compared to a 3.06 (fall 2015 Wednesday) and 3.08 (spring 2014) response. The prototyping strategies column showed a similar trend with only the fall 2015 Friday section showing a statistically lower difference from the other groups when comparing a post score of 2.00 to 2.75 (fall 2015 Wednesday) and 3.02 (spring 2014) score. Lastly, the same trend was evident in the fall 2015 Friday section being a statistically lower difference from the other groups with a response score of 2.76 compared to 3.11 (fall 2015 Wednesday) and 3.21 (spring 2014) response.

Statistical Semester Evaluation of Post-Pre Design Challenge Response Scores

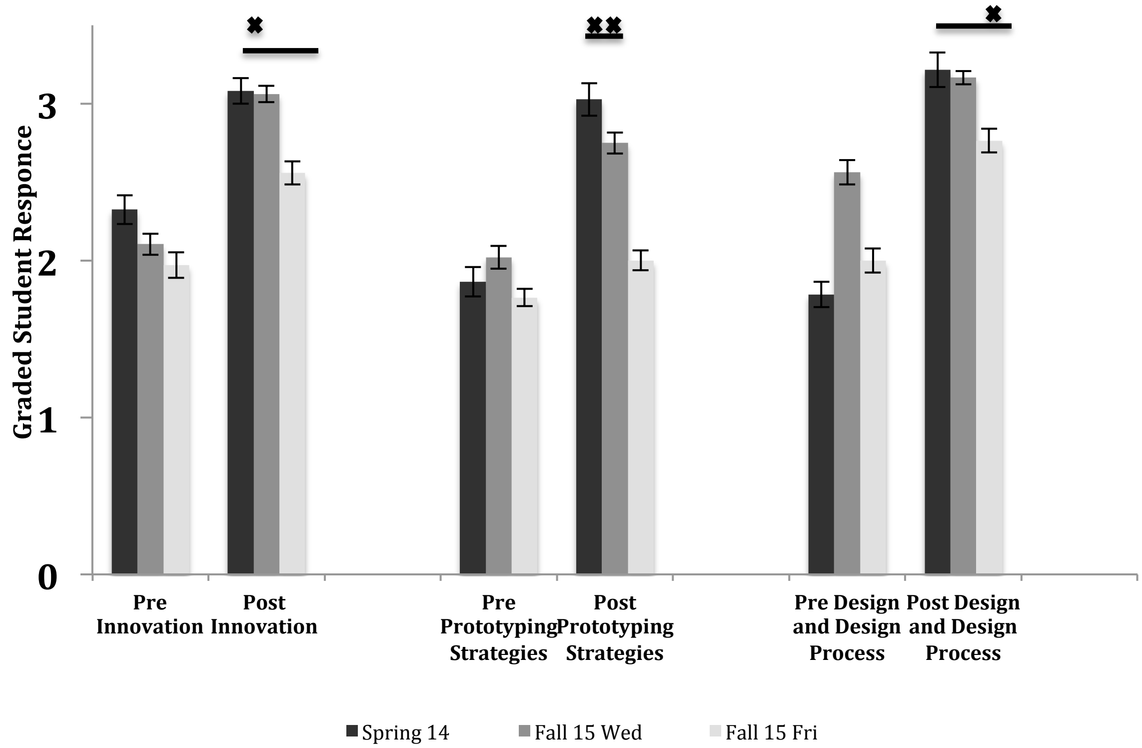

Figure 3. Statistical Analysis of Mean Post-Pre Design Challenge Scores Across Semesters: Kruskal-Wallis analysis of the three data sets, two semesters, showed different statistical differences. There was statistical (^{x} $p<0.05$, n=119, Error shown is Standard Error) significance between the post and pre scores in the innovation category across all three semesters. There was statistical (^{xx} $p<0.05$, n=119, Error is shown is Standard Error) significance between post and pre scores in the prototyping strategies category; however, only in spring 2014 and fall Wednesday 2015 semester. There was statistical (^{x} $p<0.05$, n=119, Error shown is Standard Error) significance between the post and pre in the design and design process category across all three semesters.

Figure 3 determines student improvement in the design challenge from the beginning of the semester to the end of the semester. Additionally, the assessment looks to see if the final response score of one semester is statistically different from its paired semester and other two semesters. The Innovation and design and design process category analysis of post-pre data showed statistical difference between any individual post category to any of the three pre-categories. The prototyping strategies did not show a similar trend. The post-pre analysis of fall of 2015 Friday section was not statistically significant for any of the three pre-semester responses.

Statistical Evaluation of Semester Differences of the Student Survey Responses

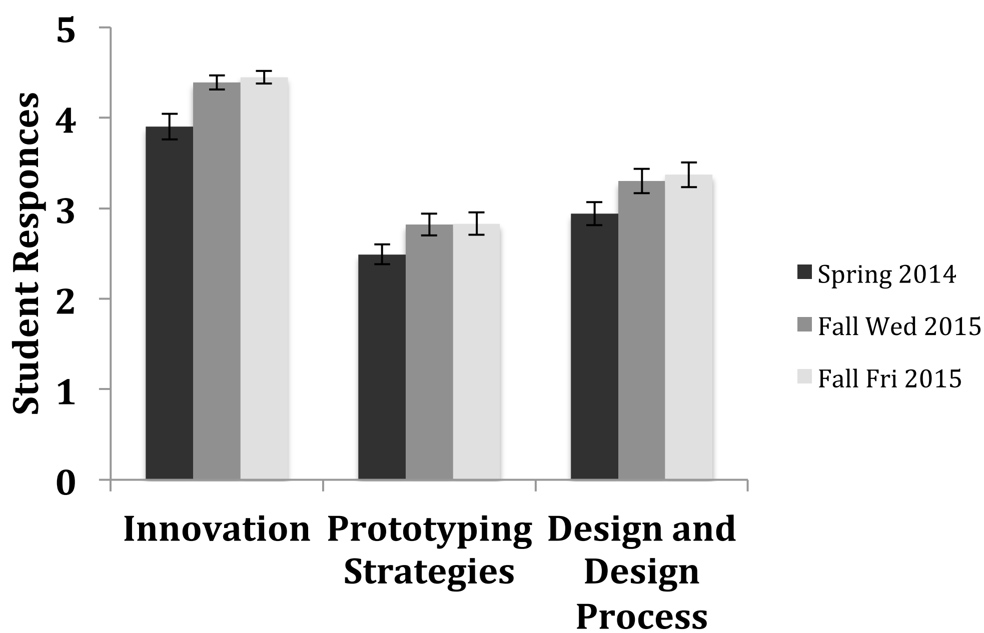

Figure 4. Statistical Analysis of Mean Initial (Pre) Student Survey Responses Between Semesters: Kruskal-Wallis analysis of the three data sets, two semesters, showed no different statistical differences with $p>0.05$, $n=119$. Additionally, error shown is Standard Error.

Figure 4 determines the initial pre-semester survey was given to students in order to determine the proficiency students themselves thought they in innovation, prototyping, and design and design process. The results show no statistical significance in any of the three categories; this includes across semesters or between the same semester at two different days and times. However, there were slightly marginal differences in all three categories. Innovation showed that students responses in spring 2014 were higher, with a response of 3.9, when compared to fall 2015 Wednesday response of 4.39 and fall 2014 Friday response of 4.45. Furthermore, in the prototyping strategies spring 2014 had a response of 2.49 compared to fall 2015 Wednesday response of 2.82 and fall 2015 Friday response of 2.83. Lastly, in the design and design process category, spring 2014 had a response 2.94 compared to fall 2015 Wednesday response of 3.3 and fall 2015 Friday response of 3.37.

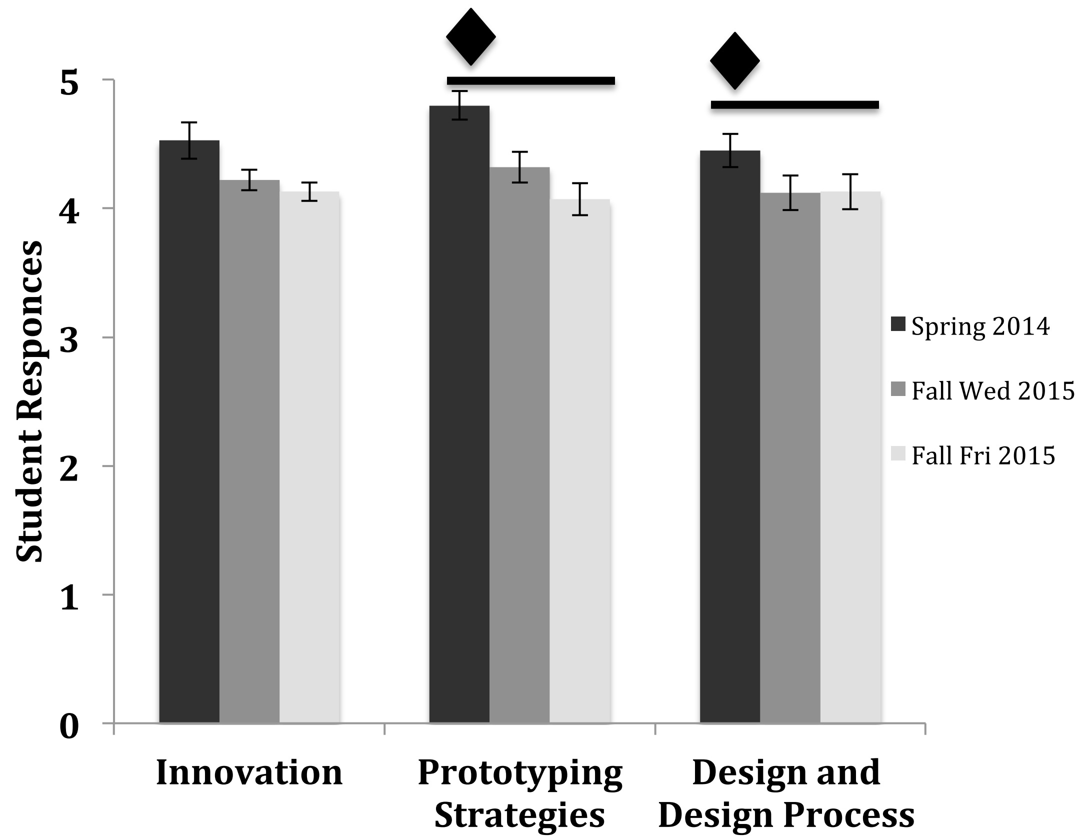

Figure 5. Statistical Analysis of Mean Final (Post) Student Survey Responses Between Semesters:. Kruskal-Wallis analysis of the three data sets, two semesters, showed selected statistical differences. There was no statistical ($p>0.05$, n=119, Error shown is Standard Error) significance in the innovation category when assessing the student's survey response. There was statistical ($p<0.05$, n=119, Error shown is Standard Error) significance in the Prototyping Strategies category when assessing the student's survey response. There was statistical ($p<0.05$, n=119, Error shown is Standard Error) significance in the Prototyping Strategies category when assessing the student's initial.

Figure 5 determines the final post assessment that considered the proficiency students thought they achieved in the three categories. The semester differences for the student survey post responses did show selected statistical differences. The innovation category was not statistically significant across the semesters however marginal differences were noticed among spring 2014 response of 4.53 compared to fall 2015 Wednesday response of 4.22 and fall 2014 Friday response of 4.13.

The prototyping strategies category spring 2014 response of 4.80 was statistically higher then both fall 2015 Wednesday response of 4.32 and fall 2015 Friday response of 4.07. Lastly, the design and design process showed a statistically higher response in spring 2014 of 4.45 when compared to fall 2015 Wednesday response of 4.12 and fall 2015 Friday response of 4.13. Additionally, it should be acknowledged that there were no differences between the fall semester classes in any of the three categories.

Statistical Semester Evaluation of Post-Pre Student Survey Responses

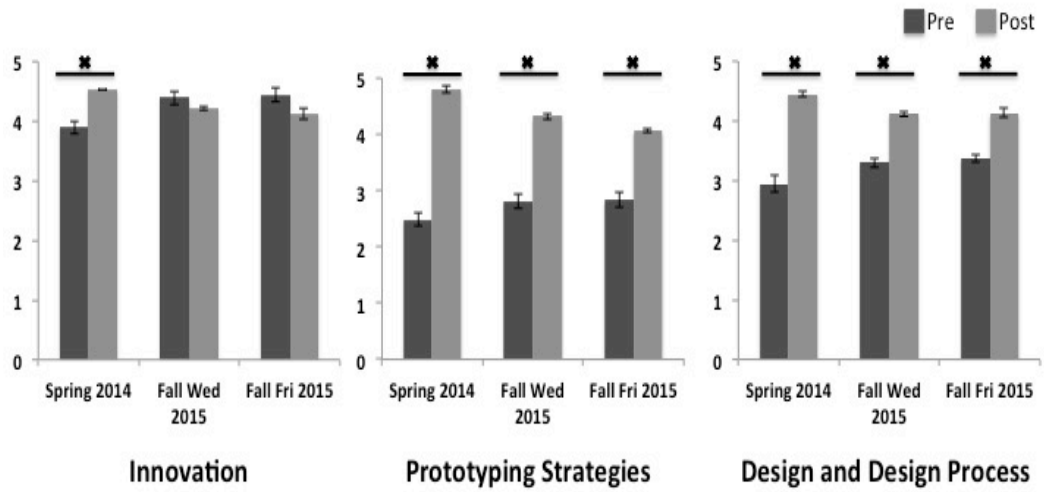

Figure 6. Statistical Analysis of Mean Post-Pre Student Survey Responses Across Semesters: Mann-Whitney analysis of the three data sets, two semesters, showed different statistical differences. There was statistical (^{x} $p<0.05$, n=119, Error shown is Standard Error) significance between the post and pre responses in the innovation category for only the spring 2014 semester. There was statistical (^{x} $p<0.05$, n=119, Error shown is Standard Error) significance between post and pre responses in the prototyping strategies and design and design process category.

Figure 6 determines an assessment of student post-pre survey responses. It can be noticed that in all but one category students believed their proficiency in the three categories increased over the course of the semester. This trend was evident in prototyping strategies and design and design process, however, it was only true in spring 2014 for the innovation category. Fall 2015 Wednesday and Friday class showed a decrease, however, this was not statistically significant.

Statistical Semester Evaluation of Final Gamma Prototype

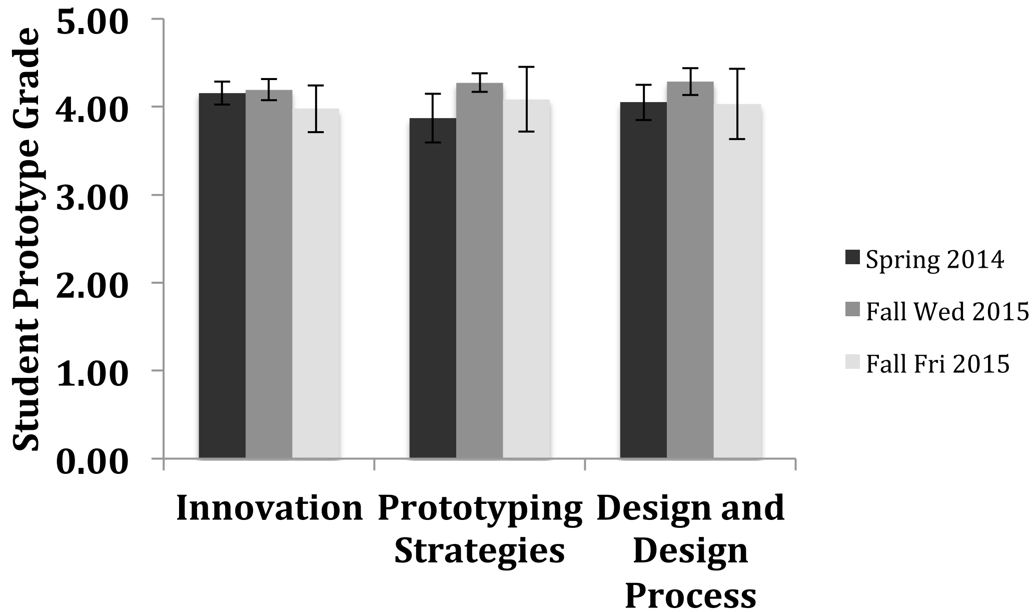

Figure 7. Statistical Analysis of Gamma Prototype Scores Across Semesters: Kruskal-Wallis analysis of the three data sets, two semesters, per category showed there was no statistical ($p>0.05$, $n=119$, Error shown is Standard Error) difference between score results in Innovation, Prototyping Strategies, and Design and Design Process.

Lastly, the final assessment for this course involved the development of a final board game prototype. The average prototype score given to each team and grouped into the three categories was statistically assessed. There were no statistical differences among innovation, prototyping strategies, and design and design process. There were small differences in the response such as innovation showed spring 2014 had a score of 4.15, while, fall 2015 Wednesday had the lowest score of 3.98. In the prototyping strategies category spring 2014 had the lowest score of 3.87 when compared to fall 2015 Wednesday score of 4.27 and fall 2015 Friday score of 4.08. Lastly, the design and design process category generally showed similar values with spring 2014 score of 4.05, fall 2015 Wednesday score of 4.29, and fall 2015 Friday score of 4.03.

<u>Discussion and Conclusion</u>

This novel study systematically examined three different metrics and three categories of study across two semesters. The results from this data offer support to the theory of transferability between professors and when courses are offered. Considering students level of proficiency in innovation, prototyping, and design across the three metrics offers support to the hypothesis. It should be noted that there were marginal differences in the post survey results and design challenge scores, however; significant growth was evident across the three classes. The literature states that students who engage in learning material earlier in their schooling and interacting with engineering faculty will learn and retain that material more efficently[15,16]. Project-based courses are not only effective at enforcing and teaching various key concepts[13], but have also demonstrated that students internalize and comprehend the concepts being taught.

The results from the pre-design challenge scores regarding innovation and prototyping strategies showed no differences in student performance. Additionally, no differences were seen when comparing both semesters and class times. However, design and the design process did show statistical differences. The fall 2015 Wednesday section showed a higher response then the previous semester by 2% and 30% when compared to the fall 2015 Friday section. Considering the student's anecdotal reviews, it seems many students in these sections had prior experience with the design process, either from their prior course work or prior education. However, on average students showed relatively similar baseline scores. Additionally, when students are exposed to new concepts/material, in project-based learning experiences, retention of that material is high[8]. Considering this, we anticipate that students will learn and retain the selected key concepts and apply in future classes, ones such as senior year design.

Post-design challenge semester data showed that students scored statistically lower in the fall 2015 Friday section in all three categories. This could be attributed to the time and day the course is offered. Gussett showed a unique and applicable trend between students enrolled in a Monday, Wednesday, and Friday morning class and afternoon class. Students were more frequently absent and performed lower on exams and homework assignments in the morning class when compared to the afternoon class[17]. This trend could explain why the fall 2015 Friday class was statistically lower in the design challenge when compared to the same class offered on Wednesday afternoon. However, when looking at participation in the design challenge there was 100% participation for all three semesters in both the pre and post design challenge. Additionally, statistical significance was evident in the post-pre assessment. Innovation showed 25% increase, prototyping 20%, and design 30% during the fall 2015 Friday section. Future work may involve giving a similar survey in the middle of the course to consider the active progression of students throughout the course of the semester.

The student survey pre-results showed that there were no differences in how students perceived their knowledge of innovation, prototyping strategies, design, and the design process. There were little differences in these three areas before students took the class. Implying, collectively there was a similar baseline value regardless of semester or class time. Looking at the post data there were statistical differences between the spring and fall semester. The spring semester students scored higher in the prototyping strategies and design and design process. Klegeris has shown that student perception of growth in project-based learning courses was statistical high. Additionally, the spring semester course could have potentially skewed the results due to students evaluating themselves higher for completing a more difficult course then they are accustomed to participating in[18]. Additionally, Fisher states that students do not develop negative attitudes when they have large amounts of work or difficult work[19]. Based on the anecdotal reviews in the survey students valued themselves higher post semester due to having the persistence and positive attitude to complete high-level work the first time the course was offered. However, looking at the fall semester courses with only junior students there was no difference in the post survey of their perception of post self-perceived growth. This project-based learning course use of a gamma prototype surrogate shows having a positive impact in the teaching of key concepts regardless of instructor or time. Furthermore, students learning of innovative skills, prototyping, and design could improve their ability to tackle future difficult concepts. Application of such a course in either freshmen year or prior to their senior design could greatly benefit students.

Further analysis would need to be conducted to look for differences in student design challenges compared to student surveys. It would be unique to see how assessment of individual student graded responses on the design challenge is compared to student perception of himself or herself as performing using the student survey. Additionally, it might be possible that confounding occurred due to students taking the same challenge. Although, the design challenge is a conceptual based assessment and like many concept assessments the same pre-post questions are asked and scored[20]. However, future studies are considering random pre-post design challenge questions for students.

Considering the validators evaluation of the students' prototypes at the end of the semester showed that there were no differences between semesters or class times. Furthermore, the purpose behind using a zombie theme is that students are better able to construct new ideas when the ideas are relatable to existing knowledge[21]. Enhancing innovation, prototyping strategies, design and the design process through the use of prototyping is an effective measure[13,16,12,11]. This same measure could be applied to freshmen level courses and potentially enhance the freshmen biomedical engineering experience.

In summary, the teaching of project-based course through a hands-on, practice-based learning method showed enhancements in innovation, prototyping, and design. More specifically, our work demonstrates through the assessment of design challenges, student surveys, and presentation of final projects to external validators students’ proficiency in key concepts is not affected by different instructors and offered class times. Through engineering a board game students’ improvement in innovation, prototyping, and design is strongly supported. This unique pedagogy is an effective measure for teaching and learning that can at any grade level truly help students prepare for their senior design.

Appendix 1

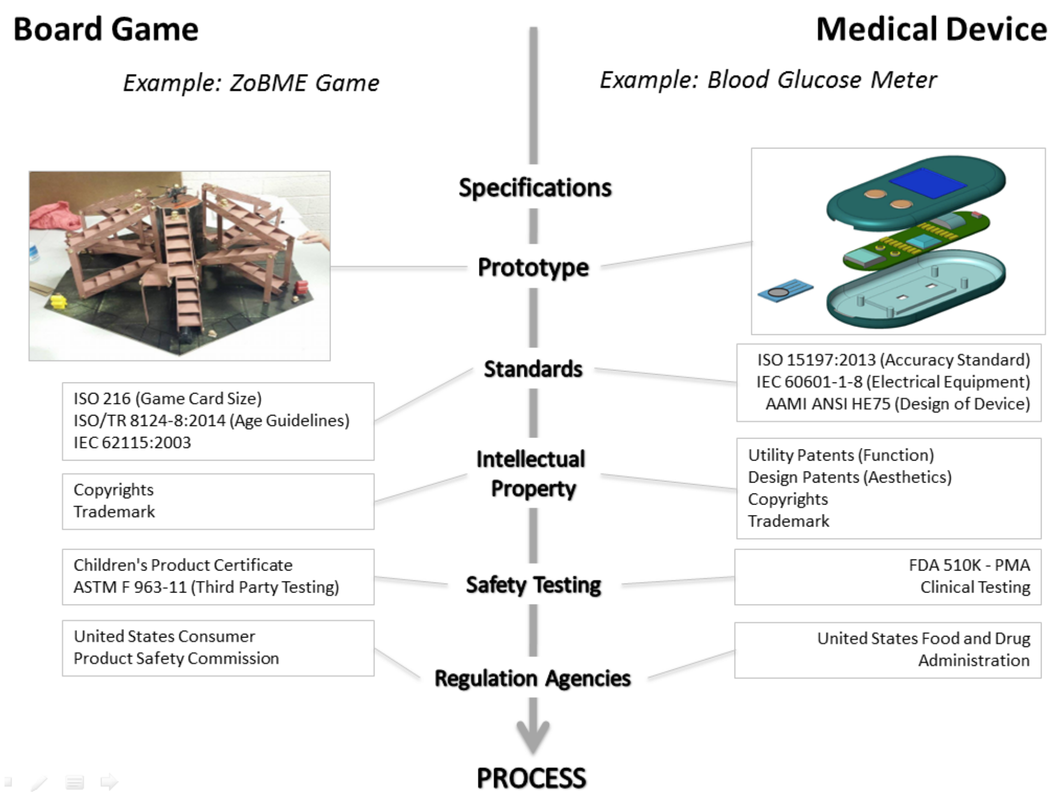

Figure 8: A comparison of a board game and medical device. The left column uses an example of the process a board game has to address before getting to market. The right column shows the process a medical device ,specifically a blood glucose meter, needs to consider before market.

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