AC 2009-1020: DESIGN AND PROTOTYPE OF AN INJECTION LOCATION INDICATOR: A SENIOR CAPSTONE PROJECT AND MULTIPARTY PARTNERSHIP

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Design and Prototype of an Injection Location Indicator: A Senior Capstone Project and Multi-Party Partnership

ABSTRACT

This paper presents a senior capstone project that was designed to explore the feasibility of using tissue flow impedance to indicate needle location to aid orthopedic injection. Four senior general engineering students designed and developed an instrument to prove this concept for the project client. Over the period of one year, the students experienced the entire process of a real-world engineering project, where they met the client to learn about the problem and discuss his needs; translated these needs into technical requirements; identified, evaluated and selected potential solutions; and implemented and tested the system. The prototype system consisted of a syringe equipped with a force sensor, a displacement sensor, an amplification circuit, and a laptop computer with a LabVIEW program. The LabVIEW program accomplishes data acquisition, converts force and displacement signals to pressure and flow rate, and calculates the tissue flow impedance. After the system was built, two categories of flow impedance data, when the need tip is located in the joints and the tendon, were collected from pig feet. Experimental results demonstrated that tissue flow impedance serves as a good indicator for needle tip locations. The project was financially supported by the university Office of Technology Transfer. This paper describes the technical aspects of the project and discusses the students' experience, outcome assessment, and the multi-party partnership.

I. INTRODUCTION AND BACKGROUND

Three years after the General Engineering program was established at East Carolina University, the department had their first group of seniors. Given the "general" nature of the program, a broad variety of senior projects was made available to the students, from manufacturing process monitoring, building electricity conservation, to bus schedule efficiency examination, electrical system integration, and medical instrument design. While the capstone project ideas were first initiated by the faculty coordinator and external clients, the students had the opportunity to select their preferred project topic. Four students were assigned to a project that was designed to develop a system that can help to train medical students with orthopedic injection. The training system should be able to indicate whether the needle is at the proper location (joint cavity).

The project required students to go through the entire design process over a period of two semesters. The student formulated the client's needs into attackable engineering problems, designed instrument circuits, developed data acquisition software with LabVIEW, and tested the integrated prototype system. Although the students experienced frustrations, they were excited about the opportunity to be able to work on this real-world project partnered with their client, Dr. Bartlett (an experienced orthopedist in town), and the Office of Technology Transfer at East Carolina University. The overall outcome of the project was good.

This paper first describes the technical aspects of the project (problem statement, material and methods, experiment results), presents project assessment, then discusses the successes and lessons learnt from this capstone experience, and reveals the importance of the partnership among the engineering department and the other two parties involved.

II. PROJECT DESCRIPTION

Overview of the Project:

When administrating orthopedic injections, good injection techniques often afford the highest rate of success.[1] Among these techniques, proper needle tip locations play a critical role. Experienced orthopedists usually are able to ensure the needle tip in the desired joint cavity by intuitively pointing the syringe in an appropriate way and occasionally pressing the syringe plunger to test the difficulty of injection. However, pointing the needle tip to the right place does not come easy for medical students, residents, physician assistants, and beginning physicians, although most of them have good understanding of surface anatomy, tissue planes, and musculoskeletal compartments. This is because of the fact that, once the needle is pricked into the skin, they have to lean on their tactile sense, or their feeling, to make the judgment of whether the needle tip is in the right location.[2] No instrument that displays the level of injection difficulty exists. Realizing this issue, Dr. Bartlett, a local orthopedic surgeon, who teaches future orthopedists proper joint injection techniques, filed a provisional patent through East Carolina University's Office of Technology Transfer. The patent incorporates technology to aid physicians in determining proper needle locations. The patent entails measuring pressure and flow to estimate the tissue resistance against fluid flow which verifies the location of the needle.

Trying to realize this idea for later possible marketing purposes, the Office of Technology Transfer connected the inventor and the engineering faculty to explore the possibility of using undergraduate engineering students to develop a prototype system. Thus, this idea became a senior capstone project. The students were asked to learn about the application and use their engineering knowledge to design electrical and mechanical parts and assembly them into a working device that can demonstrate the concept of indicating needle location (whether or not in joint cavity) by measuring flow impedance of the tissue.

Over the senior year, the students went through a typical engineering design cycle and delivered a demo system to their client. The design and development process is briefly introduced next.

Understand the Problem

After they accepted the project, the student went to Dr. Bartlett's laboratory twice to learn about the application. Before the first field visit, the students prepared a long list of questions, expecting to obtain answers for all of these questions after the trip. They came back with some understanding of orthopedic injection, but did not find satisfactory answers to all the questions. A second trip was then arranged and the students were able to find answers for those questions.

- What are the body locations that often require orthopedic injections?
- What is the range of force applied to the plunger?
- How deep does the needle usually go into the tissue?

- What is the insert angle?
- How many seconds/minutes does a typical injection last?
- What is the volume of a typical injection?
- What is the viscosity of the fluid, if known at all?
- What are the diameter and length of the needle?
- What are the diameter and length of the syringe?
- How does an orthopedist currently determine whether or not the needle is at the proper location?

With the hypothesis that the joint cavity and other tissues demonstrate significantly different resistive behaviors against fluid, the injection problem was transferred into an instrumentation problem: the students needed to **design an instrument that can somehow measure the difficultness of injection and aid the injection process**. This design should meet the following constraints:

- The developed instrument needs to fit the size of a typical syringe used in orthopedic injection.
- The developed instrument should perform the best (accuracy, linearity, etc) when the syringe is operated within a normal flow condition.
- The developed instrument cannot be too heavy to be mounted on a syringe.
- The way the device is mounted should not interfere with normal injection.
- The instrument needs to be cost effective, which means
    - either the installation is easy and the it is reusable;
    - or the cost is minimal and it can be disposal after each use.

Technical Alternatives

Understanding the client needs, the students brainstormed possible solutions. They started with a bold solution: as illustrated in Figure 1, a force sensor is utilized to measure the amount of force applied to the syringe during the course of an injection; the needle pricks through the various layers of tissue (skin, fat, muscle, and joint cavity). Assuming that the resistances against the movement of the needle is determined by the properties of the needle and the tissue in which the needle is located, for a typical joint, a resistance profile similar to Figure 2 can be obtained. This resistance profile can then be used to guide future injection training. To implement this idea, the instrument would need to constinuously measure the force that the user applies on the syringe while inserting it in the patient's body. A user feedback interface would display the created force curve.

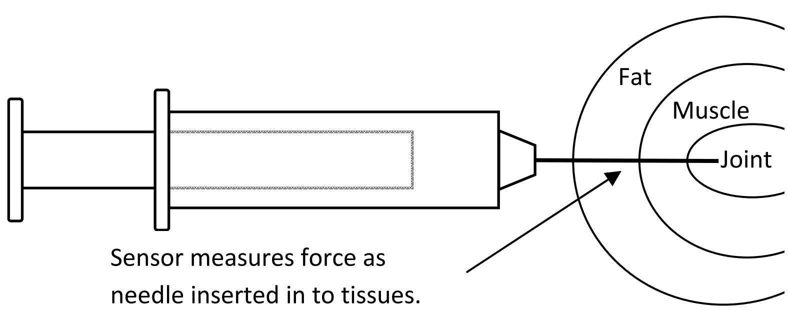


Figure 1. Sensor installation for the first alternative.

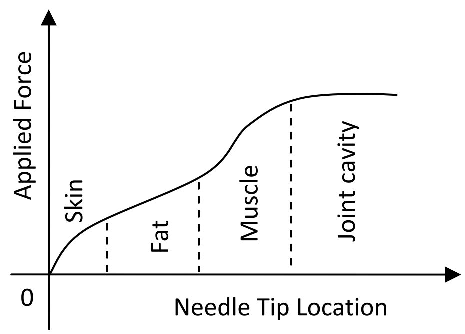


Figure 2. A possible profile of applied force during an injection: the force increases at different rates as the needle tip goes through different layers of tissue.

After a quick assessment of the difficulty of the initial idea, the students soon learnt that it is unrealistic to implement the idea: the variation of an individual's tissue thickness at different body locations makes it almost impossible to obtain a standard reference profile; the force profile for the same body location may vary over time due to one's weight change; a slight insertion angle deviation from that when the standard profile was obtained will introduce substantially different profile. Subsequently, the students decided to go for a different direction: to follow the regular operation of an orthopedist. That is, periodically check the injection difficultness to determine if the cavity is reached. An instrument, as illustrated in Figure 3, is to be designed to measure flow rate and force applied to the plunger then to obtain the flow difficultness. This approach does not use a reference profile to guide the injection. Instead, measured flow and force signals will be used to calculate the tissue flow impedance, which will be compared to experimentally determined thresholds to indicate whether the right spot has been reached.

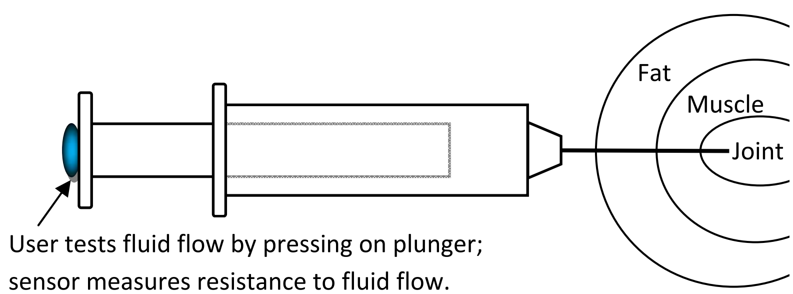


Figure 3. Sensor installation for the second alternative.

Believing the second alternative achievable, the students started extensive search for sensors that can be used in the project. While a large range of sensors were examined for possible usage, the students tried to screen out those that do not meet the design constraints, primarily from the cost and dimension perspectives. At the same time, two other issues are considered: the installation of the sensors and the dynamic ranges of the force and displacement sensors.

- As the dimension and shape of the sensors determine installation methods, two different possible installation mechanisms were explored. The first installation method is show in Figure 4, where a device that connects the needle and the syringe will house the sensors; Figure 5 demonstrates the second installation approach. After having these ideas, more search proved that no flow and pressure sensors would be small enough to be mounted in the housing device in the first idea.

The second installation method was then adopted and sensors were then accordingly identified after the measurement ranges were determined (see Figure 5).

– Preliminary experiments were designed to gather information about the required range of the sensors. The flow rate of the injection is estimated by dividing the typical injection volume by the typical injection time. The force, on the other hand, required experiments to obtain a reasonalby narrow measurement range.

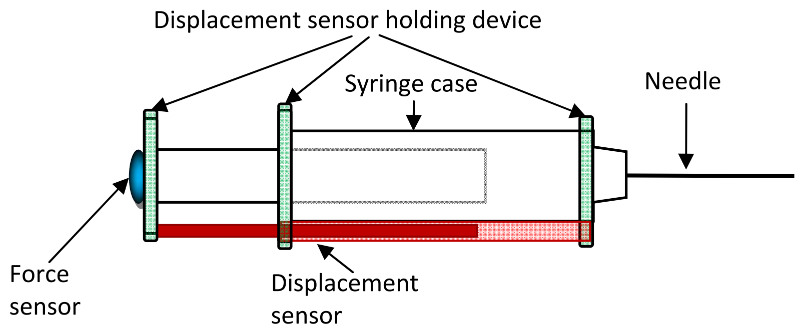


Figure 4. Possible sensor mounting method II.

Sensor Calibration

After a throughout search, a displacement sensor MicroStrain [3] and a force from Tekscan [4] were selected for a prototype system. Although the sensor documents specify the dynamic ranges and other parameters that may be used as references, the force sensor and displacement sensor were first calibrated. The calibration curves shown in Figures 5 and 6 were then fitted into linear equations. Coefficients obtained were used in the LabVIEW VI to convert corresponding voltage signal into force and displacement quantities that were further used for flow impedance calculation and display.

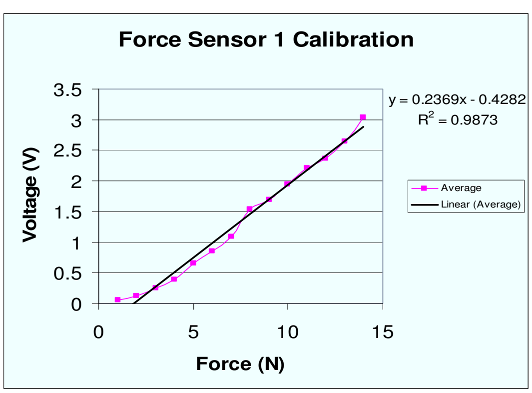


Figure 6. Force sensor calibration curve.

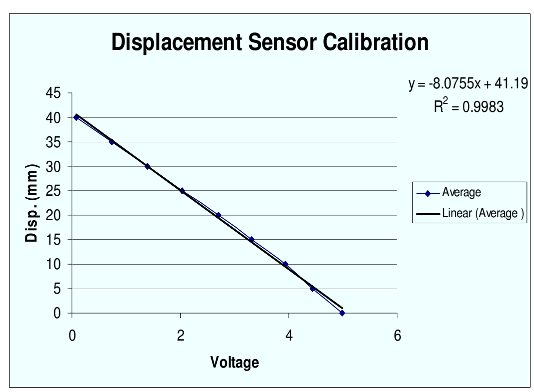


Figure 6. Displacement sensor calibration curve.

Sensor Installation:

Mounting devices (see Figure 8) were designed with *SolidWorks*® to attach the two pieces (one sliding piece and one fixed) of the linear displacement sensor to the plunger and the syringe case, respectively. An “L”-shaped bracket holds the sliding bar of the displacement sensor and attaches it to the plunger (Figure 8 (b)); a sheath device holds the fixed part of the displacement sensor to the syringe case (Figure 8 (a)). The force sensor is glued to the upper surface of the L-shaped device (see Figure 8 (c)).

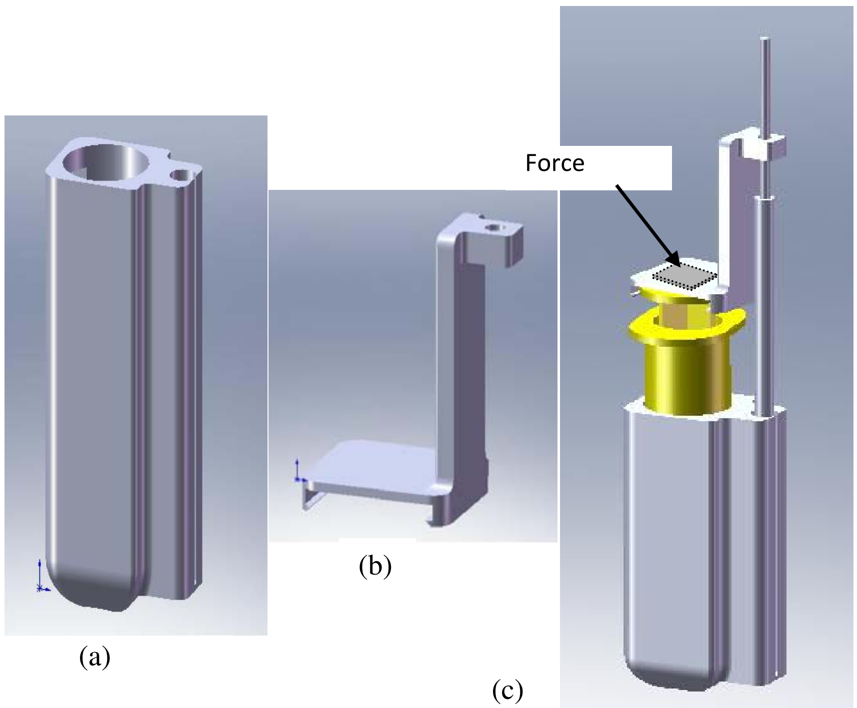


Figure 7. Sensor mounting device: (a) Syringe case sheath, (b) Plunge attachment, and (c) Syringe with displacement sensor and force sensor mounted.

Data Acquisition Software:

The students developed a LabVIEW VI [4] to for the training device. The VI accoplishes the following functions:

- Periodically acquires force and displacement signals during an injection;
- Filters noises from the collected data;
- Calculates the flow impedance with the processed force and displacement data;
- Compares the flow impedance result with pre-defined thresholds to determine whether the needle tip is in place;
- Indicates the status of the needle tip (Ready for injection or Not ready for injection).

The user interface, shown in Figure 8, allows a user to start/stop the instrument and displays necessary information about the injection process. It numerically displays the instant force, diplacement, and flow impedance. It shows the changing trend of the flow impedance over time. The two LEDs indicate the status of whether the needle tip is placed at the proper location: green for YES and red for NO. A physician, in addition to the tactile sense technique they usually exercise, can then determine the properness of needle location by checking the indicators.

Figure 8. LabVIEW interface of the developed prototype.

Experimental Results

After the sensors were set up, the students conducted experiments to collect data. Pig feet were used as the injection object (see Figure 9, sensors not shown). Two types of tissues were tried in the experiments: tendon and joint. Directed by Dr. Bartlett, the students were first trained to inject without the sensors mounted so that they could tell the differences (in terms of applied force) between injections to the two tissues. They then collected experimental data with sensors mounted to the syringe. Figure 10 (a) and (b) shows the force and displacement data for the joint and tendon, respectively. In Figure 10(a), the syringe plunge move 16 mm smoothly with a stable force of less than 4 N; while in Figure 10(b) a more than doubled force can barely move the plunge a distance a half of the previous case. It is apparent from these plots that the pig foot joint demonstrates far less impedance than the tendon does against fluid injection.

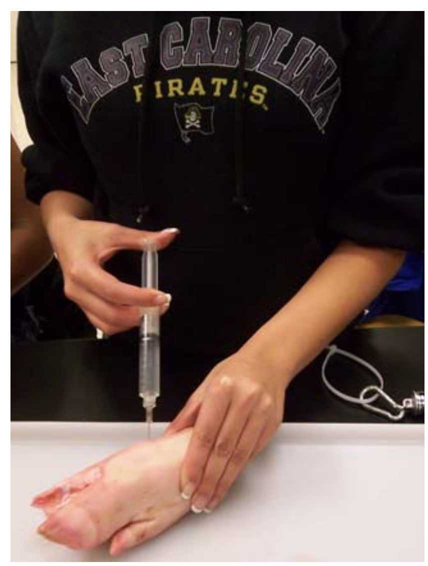
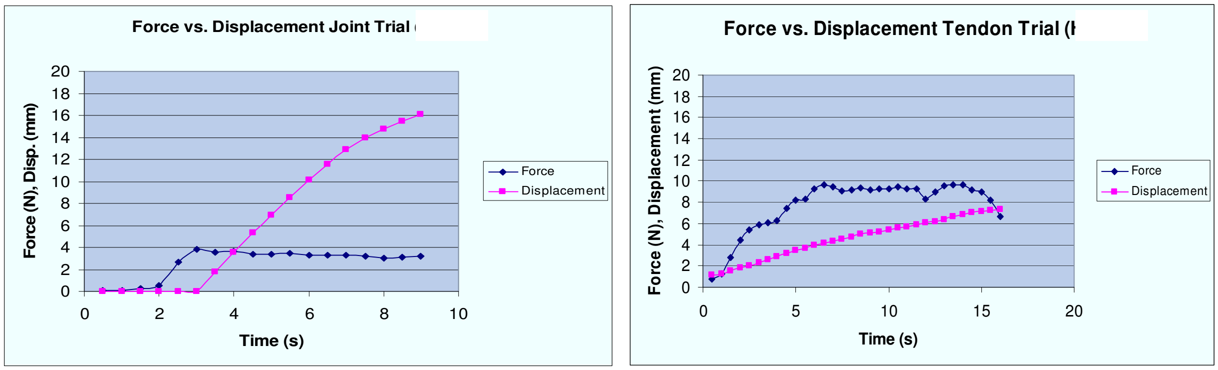


Figure 9. A student injects water into a pig foot.



(a) (b)

Figure 8. Experimental data collected with force and displacement sensor in different tissues: (a) Joint cavity and (b) Tendon.

Being able to prove the concept of indicating needle tip location was what's required by the client so that they can show potential manufactures with data about the feasibility of the invention. Although no large-scale evaluation was conducted for the didactic effectiveness of the developed system due to the time limit, one of the medical doctoral students who rotated to Dr. Bartlett's program was involved the tests. This student felt that the visual feedback, if such devices are commercially available, would be very helpful for their training.

III. ASSESSMENT

As the first comprehensive, practical project that requires working with a real client and providing real deliverable, this capstone project experience offered a great opportunity for the students to learn and practice knowledge and skills that they had never been able to experience. The capstone project also naturally served as a vehicle to assess a number of ATBET outcomes. The outcomes and the instruments used to measure them are summarized in Table I.

For most of these outcomes, the faculty advisor assessed against a set of criteria by reviewing the project report the student submitted at the end of the second semester. An assessment committee of six members, formed by individuals from the faculty and industry advisory board, evaluated primarily the students' presentation and other communication skills.

IV. RESULTS

Throughout the two semesters of the project, the students experienced both enthusiasm and frustration, but mostly engaged to the different stages of the project. They were able to go through the whole design process, work in multiple engineering areas, and interact with each other to achieve the common goals. Specifically, the students

- Worked collectively to understand the application and identify engineering constraints and explored solutions;
- Selected sensors;
- Used engineering graphics tools to design mounting devices;

– Used electric circuit knowledge to design amplification circuits;
– Used instrumentation knowledge to program software to acquire and process data.

Table I. ABET Outcome Assessment and Used Instruments. *(FA: Faculty Advisor; AC: Assessment Committee)*

Program Outcome	Assessment Method	Specific items assessed
(a) Graduates of the Engineering Program will demonstrate an ability to apply knowledge of mathematics, science, and engineering.	Project report by FA	Apply skills to design: engineering graphics, electrical circuits, software programming
(c) Graduates of the Engineering Program will demonstrate an ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability.	Project report by FA	Learn and understand client needs, engineering problem statement/constraints, identify design alternatives, develop criteria and make decisions, etc.
(d) Graduates of the Engineering Program will demonstrate an ability to function on multi-disciplinary teams.	Project report by FA	Interact between team members, clients, and collaborators (medical professionals)
(e) Graduates of the Engineering Program will demonstrate an ability to identify, formulate, and solve engineering problems.	Project report by FA	Understand client needs and translate them into engineering problems, and solve these problems
(g) Graduates of the Engineering Program will demonstrate an ability to communicate effectively.	Presentation, poster, and project report by FA and AC	Professional writing Oral presentation skills Question answering
(k) Graduates of the Engineering Program will demonstrate an ability to use the techniques, skills, and modern engineering tools necessary for engineering practice.	Project report by FA	Use *SolidWorks*® to design sensor mounting device and design data acquisition software with *LabVIEW*

After the project, the students expressed their excitement and sense of success and achievement, despite all the frustration and hard work. They were happy to see the connection between what they learnt in their college and a practical application, especially the two female students who were interesting in pursuing future career in the medical field. One of the students, in response to a post-project survey, attached a statement: "My experience working on the injection trainer project was wonderful. I enjoyed every part of the project starting with the problem solving, going through the design and finishing with the presentations. It was a great experience to work on a provisional patent and creating something nobody has ever created before. This project gave me great experience in prototypical product design, and I would be glad to work on it or any project like it again."

The student learning outcome assessment results are summarized in Figure 11, where for all the assess outcomes; the project team obtained a mean of > 4. Both groups of evaluators, within the department and from the industry, believed that the students satisfied all the program outcomes. In particular, due to the students' experience on solving such a specific engineering problem, their ability to formulate and solve engineering problem was ranked the highest, compared to other outcomes.

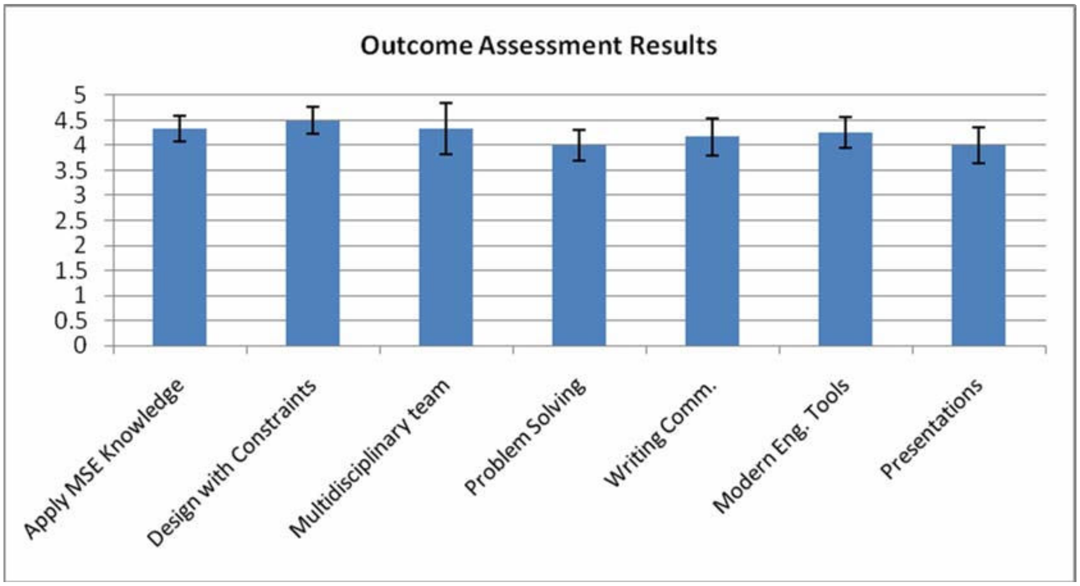


Figure 9. Learning outcome assessment results.

The clients (Dr. Bartlett and East Carolina University Office of Technology Transfer) were very pleased with the successful proof of the concept that flow impedance can be utilized as an indicator for the location status of the needle tip. To better explain the project idea when approaching potential manufactures, a marketing film was made. The client, the engineering department, and the Office of Technology collaborated once again to make this film. Two students working in neighbor cities were called back to campus for interviews that can be included in the marketing material.

V. DISCUSSION

This capstone project encourages thoughts in many ways: we learnt things about the newly-built engineering curriculum, the engineering students; the collaboration between academician and industry; invention and proof of concepts, etc.

This was the first group of seniors out of a new engineering department. As this first capstone experience served a very good opportunity to assess the student ability, it functioned the same to the entire engineering curriculum. From the assessment effort, several concerns were identified:

- While the students were able to collect information about orthopedic injection surgery, how to convert these basic facts into actions presented the most difficult task. In other words, the students underwent the biggest difficulty in formulating the real-world task into an attachable engineering problem. More comprehensive, open-end design projects are expected to be integrated into the curriculum.

- Presenting the project, especially writing the project report, posed the biggest pain for the students. Although much detailed writing guidelines were provided, the students struggled with translating items in the writing guidelines into their specific project. Writing experience that forces student understanding of engineering design process needs to be added to future curriculum.

The partnership among the engineering department, the Office of Technology Transfer, and the client is important. As mentioned, the client has the idea of using instrument to assist orthopedic injection, filed the patent, and looked for people to develop a prototype prove the concept so that he can make the next step to turn ideas into products. East Carolina University Office of Technology Transfer, wanting to see the success of the idea, bridged the engineering faculty-student team and the client, and provided funds for purchase of supplies and material. Over the two semesters, the client and the Office of Technology Transfer were closely involved in the different parts of the project: the client helped the student understand to problem, trained students the injection operation, and tested the developed prototype. Both the client and the office of Technology Transfer helped review the student project report, attended their oral/poster presentations, and provided feedback. The direct involvement of the outside individuals motivated the students to work and behavior more professionally.

The collaboration among the new engineering department, the East Carolina University Office of Technology Transfer, and the East Orthopedist was not incidental. Over the years, numerous innovative ideas come out of individuals working a rich spectrum of service and research groups in the healthcare sector. The lack of expertise to turn these ideas into reality has long called for existence of an engineering program at East Carolina University. During the last couple of years, the state of AAA started an initiative on medical devices, much similar to the pharmaceutical effort the state legislatives initiated in the 1980s. This initiative aims to facilitating exchange between healthcare industry and academia to promote innovative research. Within East Carolina University's engineering program, the first group of claimed Biomedical engineering students will come out in Fall 2009. With these growths, more collaborative projects like the injection project are expected in the coming years. The collaboration model will be readily applied to future projects.

VI. SUMMARY

This paper presents a senior capstone project that a group of four general engineering students designing an instrument to assist orthopedic injection. The paper describes the technical details of the project and points out the partnership among the three parties. The partnership was critical for the success of the project and will serve as a collaboration model for future projects.

References:

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