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Drop Foot, Bilirubin, and Harvesting:
ID Curricular Development for Medical Device Design

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Medical devices influence patient outcomes on a daily basis. New innovations enable new therapies and have improved the quality of life for individual patients and society. The medical device industry has the opportunity to change the practice of medicine and overall quality of life. This is increasingly important as society ages and life expectancy increases. This “graying of America” will have distinct requirements and opportunities for the medical device industry. Currently in the US, the industry is predicted to grow significantly and has an annual value of $140 billion dollars. With this growth comes the opportunity to do great design for the betterment of others worldwide.

Design plays an important role within the medical device industry from the design of the procedure, the device itself to the communicating the intricacies required to perform the clinical procedure. Industrial design is and has been accepted as an integral part of the development team. Our contributions can be seen in products ranging from safety syringes surgical devices, diagnostic equipment and MRI/CT imaging technology suites. All of these products have specific clinical duties developed for a particular use. For years, function has dominated the focus of medical devices while form has often been an afterthought. As clinical applications become more complex and the marketplace more competitive, form has become both an enabling and differentiating element within the medical device industry. Clinical outcomes cause new users to consider new tools and methods; however, long-term adoption relies upon the user’s belief that they can readily perform the procedure.

In designing these devices the development team is required to practice good product design as well as fully appreciate the scientific basis for the product as a whole and the underlying technology. Preparing students for a role in this industry includes lessons beyond traditional ID skills and includes the following: appropriate behavior in clinical settings, the importance of protecting oneself during exploratory labs, e.g. Hepatitis B vaccination and blood-borne pathogen training, anatomy, physiology, surgical and animal lab training, the importance of developing relationship with key clinicians and satellite centers, sterile packaging and techniques, as well as practicing FDA design control to meet the rigors of a highly regulated industry. Design control is an organized approach to development that assures the product meets its design and user objectives, that it is technically sound, and can be manufactured safely and effectively.

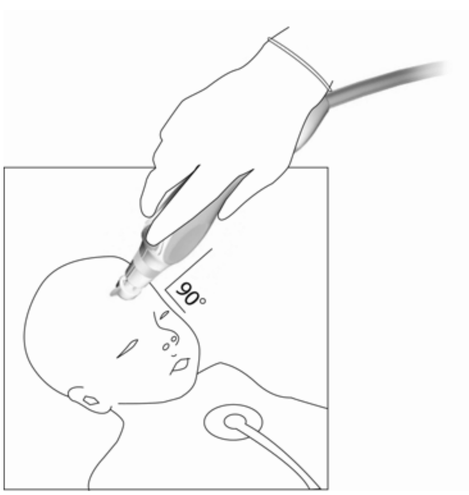
This paper describes the additional curricular requirements of preparing industrial design students to be effective in this industry. Case studies are presented that highlight the use of multidisciplinary teams, industry partnerships and the integration of the pedagogical goals. Students participate in a variety of development projects ranging from surgical tools to emergency medicine. The following projects, bilirubin diagnostic device for neonatal use, an orthotic for use with patients suffering from drop foot (a condition prevalent in stroke victims) and a minimally invasive saphenous vein harvest tool designed for use Third World countries, are highlighted as a representation of the applied learning as a result of our process. For background below is a brief description of each project: The bilirubin device noninvasively measures bilirubin and hemoglobin for infants. Bilirubin is the root cause of jaundice and the standard of care today is a needle stick or a subjective pressure test. The Orthotic project strives to bridge the gap between custom orthotics and “off the shelf” models that do not meet all of the users needs. Saphenous vein harvest is used for cardiac bypass surgery. Third World countries that are currently able to complete surgery do not have the tools and skills to complete this procedure minimally invasively. This device is geared towards ease of use and considerable cost constraints.

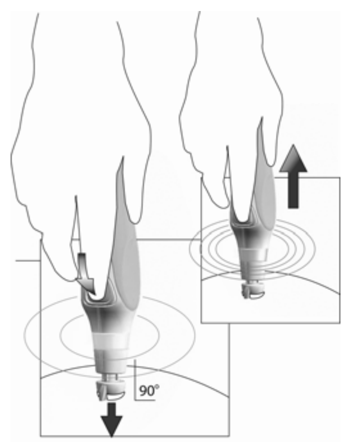
Fundamentals of Medical Device Development

All organizations within the medical device industry vary with regard to specific development process but each of the steps listed below remain common and are fundamental to medical device development. For most devices the process starts by defining the device's clinical objective in terms of end-effecter function or tissue interaction, then working toward a method of controlling it.

1. Understanding of Anatomy and Physiology

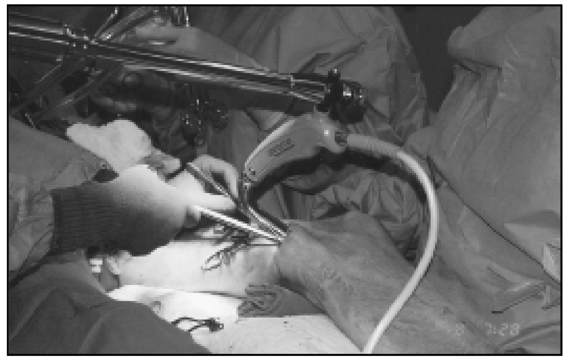
Specifically, researching the anatomy or disease state in which the device will interact. By analyzing the biomechanics of the tissue type, appreciating thickness, viscosity, and response to stimulation, the design team can avoid many pitfalls and make better decisions. Since students have little experience in handling tissue, attaining samples from a butcher or conducting an exploratory animal or cadaver lab can prove invaluable. For example, the bilirubin design team conducted research on Kernicterus, a neurological disorder caused by elevated bilirubin levels in neonates (i.e., neonatal jaundice). It can result in neurological complications such as brain damage, cerebral palsy, auditory problems and vision abnormalities. The quantification of bilirubin levels in the form of serum bilirubin in neonates typically involves a blood draw via the heel stick method. Non-invasive optical techniques have been sought by the team to minimize the blood consumption, trauma, and infection risks associated with the heel stick. The new device, the BiliPen, measures bilirubin levels by using optical reflectance spectroscopy. A computer connected to the BiliPen then uses a simple algorithm to quantify both skin bound and serum bilirubin that can be correlated to the bilirubin values obtained with the heel stick method. The image below depicts the device interacting pressing on the baby's forehead. The first measurement is taken while LEDs glow yellow then the user presses, blanching all of the hemoglobin (red blood cells) out till the device LED turns orange.





2. Importance of Hands-on Medical Device Training

Typically, designers learn through experimentation and observation. Allowing a designer to perform the intended task (in a controlled, simulated setting) aids in realizing the overall clinical goal, allows for the exploration of the specific tissue type, and provides a great team building experience. Following is a design team from performing surgery in an animal lab (image on the left). Here students learn how to interact with the tissue to discover it is highly viscous and somewhat elastic, wear protective clothing not your presentation best, and are encouraged to complete blood borne pathogen training, and get a hepatitis B vaccine. The image on the right is an observational image taken during a surgical site visit by the saphenous vein harvest team.



4. Appropriate Behavior in Clinical Settings

Virtually all device designers concerned with the user will at sometime observe clinicians during their practice in the OR or another clinical setting. It is essential that designers realize the flow of the people and devices in order to deliver care. While it is easy to be a fly on the wall, there are some tips that are useful for a better experience. Such as

- eat before you go so that you do not require care from the medical staff by fainting or getting ill,
- do not participate in any way during the procedure, it isn't your place,
- the sterile field is directly above the patient, table height, and above all instrument tables (that means the airspace as well),
- photography should always be preapproved then approved once more upon arrival to the point of care,
- do not chew gum or eat,
- Vick's Vaporub on the inside of your mask hides those bad smells.

These are just a few and many are experienced throughout the design process. Being comfortable around this environment is not for everyone and learning this early can be helpful when making career decisions.

5. Benefits of Reading and Interpreting Scientific Journal Articles

This provides the knowledge of current trends in science and advanced discovery. They are more reliable than web sites and provide the background in further detail. Throughout our design training we attempt to use research to inform and justify our approaches, but in many cases we lack the rigor of statistical analysis. In addition, most design schools and designers (author included) shy away from math in general. That said, the ability to decipher technical briefs, abstracts, and journal articles will allow designers to better integrate with and appreciate the perspectives of engineering and clinical design teams.

6. Using Computational Tissue Modeling as Means of Predicting Clinical Success

In many ways, the success of a design is dependent on its relationship between look, feel, and function. Currently, the process employed to optimize this relationship is more art than science. While the FDA provides a multitude of standards, the design process itself is fluid, variable, and obtuse. The problem that exists is that the process is driven by the individual knowledge (which is also fluid, variable, and obtuse). Employing computational models of tissue-device and user-device interaction provides transparency of the process and brings consistency across device designs.

Here is a quote from an ID student concerning the computational processes of engineering:

> "I learned about the way that engineers think and do things. To actually see the work that they do and just how organized they are was quite shocking. It was also shocking to see how much

engineering they don't do, if that can make sense. I really thought that things were more calculated out and less guesswork was involved. But I learned that in order to calculate, there must be so many circumstances set up with so many 'knowns' in order to determine the 'unknowns'."

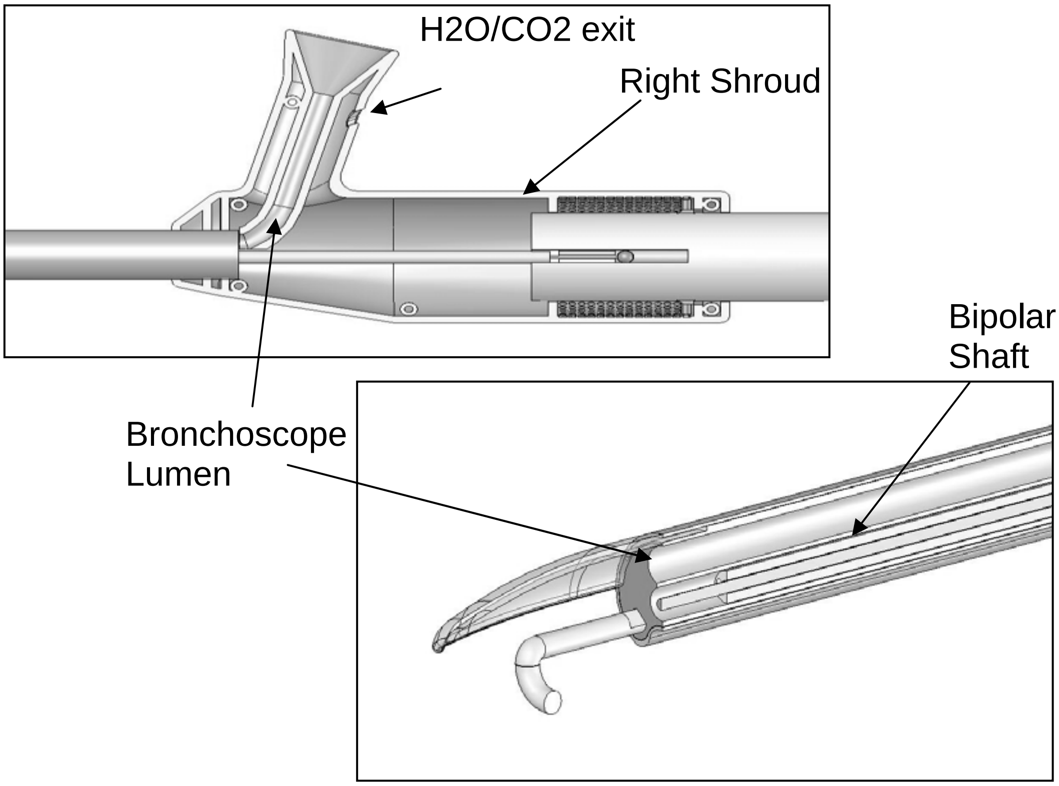
7. Using Biological Inspirations to Address and Solve Clinical Problems

Many designers use biomimicry as inspiration for form development. This is also true of scientist. For example, many biomaterial researchers are seeking the compound of spider webs as the basis for biological glue. For students this means taping into the bodies own natural responses to aid in healing.

8. Seeking Appropriate Materials and Technology for the Device and Medical Application

Small design decisions can have huge impact. For example, if a device is to interact with a biologic agent, it can't be assumed that a typical polypropylene injection molded part will work; surface texture can cause unintended tissue growth or complete part rejection by the body.

In addition understanding the rapid prototyping process and the tolerances inherent to a particular technology is particularly useful. For example, the saphenous vein harvest team designed their prototype to have a multichannel tube extending the length of their device (approximately 11 inches). This multichannel tube needs to have several other devices, including a flexible bronchoscope (camera) going through these channels. The design team set off with best intentions to have the part SLA'd. They retrieved it from the shop to discover that it wasn't straight, nor was it close to being straight. After a late night with a few files and some sandpaper, the team was able to rectify the process limitations. Below is an image of the device followed by details of the internal mechanism.



9. Going beyond Published Research and Developing Applicable Testing Procedures, Including IRB Approvals

Applicable test methods refer to the design control requirement of Verification; which states that a design must meet the intended design requirements and has been assessed accordingly. This means that if you say your device is white, you must have a test to verify that it in fact is white. Developing test methods in some instances is as creative as designing the product itself.

IRB (internal review board) protocol development is almost unheard of for design research, but our time is coming. This review is required for any testing involving human subjects and especially when the information gained is to be published in any form. The process requires the students to complete online training, write a research protocol, and file appropriate paperwork. This process is not exactly timely and can take up to several months to complete. In addition there must be a faculty member, usually a physician or researcher respected in the area of interest who is the primary investigator. It is difficult to get approval when you have yet to earn a bachelors degree. Below is an image of the orthotic system developed for the treatment of drop foot. This system was approved by IRB and tested on 3 patients. The students wrote the protocol, built the prototypes and completed the tests.

10. Identifying Thought Leaders and Key Partnerships

Most students have never done surgery on humans (frogs maybe). That said, developing key relationships with many different specialties enable the design team to ask those “less-informed” questions that are otherwise sought out to the best of their ability. There is a culture of medicine that should be respected. For example, many physicians will allow faculty to call them by their first names but this is forbidden for students. Students should also not call them directly on the personal phone line at the end of the day. Grumpy physicians make grumpy partners and since the team relies on their partnership for clinical access, we are somewhat at their mercy and should foster a positive exchange continuously.

In addition, medical devices are sold through the current thought leaders and their respective research. There is great pride within the medical community with regards to clinical prowess (alongside an occasional ego). Since the science of medicine is still somewhat of an art form, personal beliefs and location play a role in decision making to purchase. This, in turn emphasizes the need for students to gain an appreciation for key partnerships.

11. Multidisciplinary Approaches to Problem Solving

Design education and the practice of design thinking employs the skills necessary to problem solve through the exploration of form, among other methods. This problem solving through form and geometry is necessary when designing tools that interact with tissue, especially in cases where the device use requires intricate interaction through complex anatomy. However engineering sometimes takes a different approach and these two valid approaches must be mitigated by the team. Here is another quote by an ID student on the drop foot orthotic design team:

> *“Most of all I learned how to better communicate between the many roles in the product design cycle. At the start of the quarter there was a big gap between the information the engineers were learning and the designs that the industrial designers were posting up on the wall. We had to have a sit down conversation to discuss this gap. This opened the door of information communication. Throughout the quarter there were many times when we had a difference of opinion between the two majors and even within the majors and had to really communicate our points and weigh them out. Sometimes these discussions lasted a few hours and were very draining, but in the end we came out with better design solutions, making it worth it.”*

Conclusion

Design allows for the translation of complexity into easy-to-use, innovative products. By informing ourselves about the specifics of medical conditions e.g., disease, tissue characteristics, and utilizing our experience in multimodal communication and innovation strategies, industrial designers can play a pivotal role in driving patient-centered advances in the field of medical device design. Preparing students for this industry is challenging and rewarding for both faculty and the students.

The student quote below speaks to this well-rounded experience:

> "I learned that I like working on the medical devices. I had never really given thought to working in the medical industry; I have always thought of it as bland. But working on this project and seeing what some of the other groups were working on made me realize how much problem solving is involved in medical device design. I have always enjoyed solving problems and it was fulfilling to be able to solve problems that have the opportunity to really impact someone's life."

By extending ID curriculum to include the fundamentals of medical device design, students are better prepared to determine their interest in the medical device field. Sure, not all are interested, but those who participate fully are prepared and motivated to take on these complex problems.

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