Surgical Tools for use in Challenging Conditions

Design Issues Paper
Michigan State University
ECE 480 - Team 1
Spring 2015

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Introduction

The project goal for Design Team 1 was to create a surgical tool that would be completely suffused in antimicrobials for the duration of a medical surgery. This would be accomplished by a series of microchannels running through the tool itself and a pump to deliver the drug to the surface of the tool. Aimed towards countries with developing economies, the tool upon completion could revolutionize medical cleanliness in otherwise unhygienic environments. Desired specifications for this project include a minimum of a 6 hour battery life, a phone app that utilizes a wireless connection to the system, and a compact unit for easy mobility of the surgeon.

While designing this tool, various design issues had to be taken into account, three of them being meeting medical standards, product safety and project lifecycle management. Since the project aims at creating a medical device crucial to patient’s health, the majority of the issues addressed are focused around creating a safe and reliable product that still has a cost effective appeal. The issues listed above will be analyzed with respect to the creation of the surgical tool and potential improvements or modifications to remedy such issues will be discussed as well.

Medical Standards

Following standards will help ensure safe conduct and the ability to implement the tool in all surgical conditions. Though aimed for countries with developing economies, adhering to regulations will allow the tool to be used in any surgical environment if needed. Designing to follow these standards will overall improve the effectiveness of the tool and allow for in surgery testing.

One very important standard that the team had to adhere to is the medical standard of surgical material. Surgical tools must be made with strong material so no parts of it break off in the body during surgery. The material also must be resistant to corrosion and be fairly unreactive to most chemicals used during patient operations. This ensures that, as mentioned before, the tool will not break off during the surgery and become lodge within the patient’s body and that the tool will not chemically react with any medicine or drugs introduced to patient. Currently the medical standard for most surgical sites is to have stainless steel instruments. Stainless steel does not readily corrode, rust or stain with water as ordinary steel does. There are different grades and surface finishes of stainless steel to suit the environment the alloy must endure. Stainless steel is
used where both the properties of steel and corrosion resistance are required. Some other materials that could be used is tungsten carbide, aluminum, titanium and some durable plastics.

This had to be taken into consideration early on because the team had aspirations to do a live testing run with the college of Veterinary Medical Sciences where the tool would be attempted to use in surgery. To create the microchannels the surgical tool had to be 3D printed. So the team would have to find a machine on campus to 3D print the tool in stainless steel or outsource it to manufacturer.

Another medical standard that had to be taken into consideration is the process of sterilization. Before use in surgery, every tool must be sterilized so it can come into contact with the patient. Most tools get sterilized by the auto-clave process. An autoclave is a pressure chamber used to sterilize equipment and supplies by subjecting them to high pressure saturated steam at 121 °C (249°F) for around 15–20 minutes depending on the size of the load and the contents. Therefore the tool must be able to withstand the autoclave process and not be damaged during sterilization.

**Product Liability/safety**

The medical community has certain regulations for product safety for a surgical tool. The most important requires that the tool is able to be sterilized before the use in a surgical environment. This will reduce the chances to get a SSI (surgical site infection). To complete the task of sterilization, the tool must be able to go through high temperature methods such as steam sterilization, or low temperature methods that include hydrogen peroxide gas plasma, peracetic acid immersion, ozone. The design tool will be made out of 3D printed material and would end up not being able to go through the high temperature methods of sterilization. This requires the design tool to be cleaned with the lower temperature methods. The SAL (sterilization assurance level) needs to be as low as 10^-6. This would mean that there is a one in a million chance that an microbial lived on the tool after sterilization.

The next safety requirement on our tool is that the design tool is compatible to be used on patients. The human system is sensitive and certain materials are not able to be used in contact with it. This would require the tool be made out of the most popular surgical tool materials that include stainless steel, titanium, or tungsten carbonite. Because these materials are not able to 3D
printed, it would have to be shipped out to a medical tool manufacturing company to build it. Otherwise, it can be soaked in a compatible material to form a layer over the 3D printed plastic.

The last safety requirement on the design tool is that the antimicrobial that are being pumped through to the surface of the tool be diluted to the 0.5 percent solution that is advised. The antimicrobial that is used can cause damage on the body at higher percent dosage. This requires the directions to be precise on the amount of antimicrobial put into the IV bag that we advise doctors to use.

**Project Lifecycle Management Processes**

The first step in the project lifecycle management process would be to obtain a patent in order to protect the group’s intellectual rights from the U. S patent office. Once this has been accomplished, the standards that this product will have to comply with are the standards that are used to size different tools. These standards to be followed, according to the World Health Organization are known as the ISO 15223 [2] which include any standards related to the development or advancement for medical instrumentation and cover tools as simple as tool depressors.

Design delivery time is crucial and it depends on the number of tools that need to be designed. Currently, Team 1 only has a forceps design but there is ample room to modify and create an entire line of robust microchannel tools that can be built at the preference of the customer. In order to complete a forceps design, the approximate design delivery time to the production team would consist of 12 hours with a design completed with the Solidworks program.

Product testability can be performed in a lab environment by separating it into two different test modes. The objective of one test would be to test the technical functionality of the tool’s systems such as its compressor and power systems along with its internal pressure related to the re-suffusion of the tool.

As the microchannel field becomes more popular, new techniques will re-emerge and as a result, the line of tools has the potential to rearrange the system of microchannels in order to increase the efficiency of the system. This could provide the potential to upgrade the tool and remain competitive in the market when competitors arise. Furthermore other improvements that could be made could be in the power system by installing more efficient batteries. Additionally,
solar chargers could be a great addition to the current system in order to expand the use if using the device in extremely remote areas.

Production

The power consumption must be limited to an amount that will allow the tool to do its required tasks, pump liquid in this case, and not run out of battery power in the time allocated to the surgery. Team 1 has decided on a 6 hour time minimum for the product. This will give enough time for almost all surgeries and have additional power for any complications that may extend the surgery time. The power consuming components in the design are the pump motor, the bluetooth module and the pressure sensor. All of these components require small amounts of power and will not be run constantly so the the requirements will be met.

The materials needed to produce the product are a key constraint in its design. The high level of regulations in the medical field limits the choice of materials that can be used to make the tool itself. Tools used in surgery are made with surgical stainless steel which is not an exact material, but a group of alloys that are appropriate for surgery. This material is important because many of the sanitization methods involve extreme temperatures both high and low. The material will be purchased in bulk to reduce the costs but this is an issue that cannot be avoided as the tool must use an appropriate material.

The production time and cost will depend on the the number of items produced. If there is a large demand for our product, the production methods will be designed to produce a large amount of our design at a high rate. This will cost additional money but is important because the more items sold the less of an impact the initial cost will have. If there is not a large demand, the production time will be slowed slightly but the initial costs associated with production will be lower. Since this is a specialized product, there should not be an extremely large demand and the production time will be adequate being a week or less, which is the estimated time it will take to make a bulk amount of the tool. Since the design is focused on simplicity the costs to produce
will be small as majority of the costs will come from obtaining the components from other manufacturers.

The quality control for this device will be regulated under FDA standards for this class 2 medical instrument.

The considerations that need to be analyzed for this product in terms of environmental issues include the disposal of the battery in a safe manner. It can be suggested in the packaging that the battery should be taken to a recycling center. As far as the rest of the components, the rest will be provided by 3rd party suppliers which will take care of the scrap and toxic by-products on their end away from any liability from the surgical tool.

Distribution of this device will be determined by a third party medical supply company. The transportation and other logistics costs will be determined under contract. The transportation time will depend on the couriers of other countries but a tracking system to track location and sales will be implemented.

Customer training in this case will be via an instruction manual that will come with the compression system. manual will include guidelines that will outline the set-up procedures as well as instructions on how to connect the device via bluetooth to the phone or tablet that will carry out operation of the compressor. The manual will also include a section for troubleshooting the app as well as the system. Cleaning recommendations as well as use for optimal operation. Additional training videos can be provided in a website.

In order for maintenance to prevent the group from losing much profit, the team established that the tool and the system will have a one year warranty in which a repair center will repair or replace the product at no cost. Should there be anything wrong within any other time frame, the customer has the opportunity to order parts to repair the device only paying for the part or can send in for servicing paying for parts and labor.

The end of the life will be based on the products ability to maintain sanitized and that itself will depend on two important factors, the battery life, and how long the compressor can last. This product is intended to be used in very remote areas therefore the lifetime of the device is to be seen as a great investment. The lifetime of this product will be that will be based on the charge cycles of the battery which will range at a conservative value of 500 charges.
The tool with the microchannels can be reused and the tubing should be replaced at the discretion of the operating doctor or customer. Battery disposal would be the main concern and it will be advice to the customer to consider recycling the batteries.

**Conclusion**

When considering the design issues and constraints present when creating tools and machines used in the medical field, it is easy to see that the design process is heavily controlled. The obvious main constraint are the medical standards which are extremely important in the field. With the health and safety of the patients being the ultimate priority, not using the medical standards that are required creates an unnecessary risk to the health of the patients. In addition to this, the product lifecycle must also be considered as mentioned. Since many third world areas do not have access to the resources that are available in well developed countries there is a higher focus on developing a product that will last a long time. Where the military may not reuse a tool at all to prevent any infections from developing by using a dirty tool, the other side of the spectrum is true for underdeveloped areas. A tool must be reused and be able to maintain its function and remain sanitized despite being used many times.

When these issues are taken into account it is easy to see how the medical field requires a greater focus on the standards, product lifecycle, and safety. Everything from materials used to the methods of sanitizing must be considered. Functionality is still the main goal but without following the standards and remaining conscious of the many safety constraints a tool, especially one used in surgery, will not be acceptable for use regardless of application.

**References**

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