

Self-Disarming Suture Needle

Biomedical Engineering Capstone Design 400,
University of Wisconsin-Madison

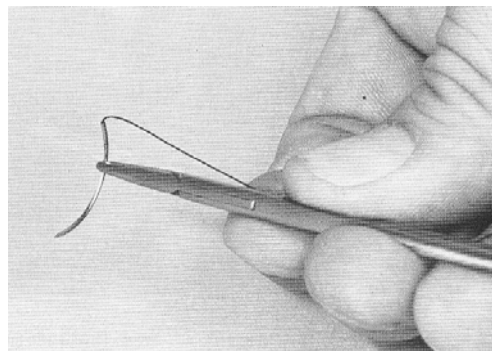
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Abstract

Accidental sticks from suture needles are an unpublicized but common problem for anyone involved in suturing. Designing a suture needle that has activated and deactivated states could significantly decrease transmission of diseases, such as Hepatitis C or HIV-1, as a result of accidental sticks with a contaminated needle. A safe suture needle does not exist in the market today. The JABE 200, a hollow sheath with two cutaways that expose a fluid filled balloon connected to a sharp metal tip, is only armed when the needle holder clamps down on the balloon, forcing the metal tip to protrude from the sheath. When the holder is unclamped, this “safer” suture needle would be unable to puncture the user’s skin because the sharp metal tip is retracted into the sheath. Future work includes making smaller scale prototypes and testing the mechanism on various types of tissues.

Problem Statement

In order to prevent accidental needle “sticks” from a suturing device to a surgeon or staff member, a disarming or retracting sterilized suture needle must be developed that allows a reversible action when passing into and through the underlying subcutaneous tissue, dermis, epidermis, or other organ tissues in the body. The device must encompass all features of sharpness, stiffness, maneuverability, and size/shape variance as a conventional needle with the added safety of needle retraction. The goal is to permanently eliminate the risk of needle puncture and infection to the operator during procedures.

Background Information

Given our lack of prior knowledge, the broad nature, and the time constraints of the project, the research was divided into four main components: the properties and composition of skin, suturing technique, the process of needle fabrication, and the demand for a safer suture. Further information on these topics is contained in Appendices 1-5.

Properties and Composition of Skin

The skin is mainly composed of the epidermis, the basement membrane and the dermis layers (Figure A1.1). The epidermis, or outermost layer, consists mostly of keratin and functions to prevent water loss from the body, and penetration by mechanical, chemical, or enzymatic

agents into the body. The next layer of skin, the basement membrane, is composed of a specialized form of collagen. Collagen is a triple helical polypeptide that forms three-dimensional waves in the skin, and especially in the dermis, or deepest layer of skin. Although skin samples vary in strength depending on location within the body and direction in which the sample was cut, the multidirectional bundles of collagen increase the shear strength of all samples of skin. With the exception of young developing tissues in the early stages of wound healing, the skin's cellular components add little to its strength. Skin's tensile strength is primarily due to collagen, and its strength increases with age (Table A1.1). The chemical properties, specifically the degree of cross-linkage between collagen fibers, contribute greatly to strength. A higher amount of cross-links leads to greater strength.

These properties of skin are important with regards to suturing. The collagen fibers can be pushed aside by a small tapered needle, but needles larger than a few millimeters will rupture them during penetration. A needle with a cutting edge that is at a right angle to the plane of the skin's surface is the most effective type of penetrating attack. Although it can be lifted into folds, the natural tension of skin limits the suturer's ability to stretch skin to compensate for tissue loss, leading to potential problems in closing the wound.

Suturing Technique

Due to the wide variety of open wounds, a large assortment of suturing materials, as well as various needle sizes, shapes, and cutting profiles, are available on the market (Appendix 2). The best needles are sharp, rigid, corrosion resistant, able to easily penetrate tissue, and are able to maintain sterility. A cutting needle would typically be used on the skin, while a tapered point needle would be used on softer tissue. Despite the variety of supplies on the market, the general procedure for closing a wound is the same. After choosing the correct suture material and needle, the operator uses a needle holder to grasp the needle about $\frac{1}{4}$ to $\frac{1}{2}$ of the needle length away from the swage, or eye of the needle. Forceps should always be used to grasp the needle to prevent accidental needle sticks. The resulting suture should allow touching wound edges that are slightly raised from the surface of the skin to allow for the natural flattening of a scar. For simple superficial wounds, a normal interrupted suture stitch is sufficient, but deeper wounds may require stitches with more support, such as mattress stitches. Deeper wounds have a tissue edge separation force than superficial wounds; the deeper penetration gathers more of the tissue and the "double stitch" of the mattress stitch provides more holding force. After passing through the

skin, the needle is grasped with a needle holder or with the fingers while the physician ties the knots to secure the wound (Appendix 2).

Process of Needle Fabrication

The need for sterility, corrosion resistance, and stiffness in a suture needle have traditionally led to the use of surgical grade stainless steel (Appendix 3) as the preferred material. Its properties allow it to be stiff and sharp in small diameters while still resisting bending. However, specialized equipment is necessary to precisely manipulate steel into the small sized needles. The size, shape, tip profile, and desired use of the needle can vary a great deal (Appendix 4). These differences determine the specific manufacturing steps that are necessary, but most needles require the following steps: extruding a wire of the desired diameter, cutting the wire to the appropriate lengths, grinding off the end to achieve the chosen tip profile, drilling and clamping a hollow cavity to hold the suture material, and forming the head according to the needle's specialization.

Demand for a Safer Suture: Needlestick Accidents

No suture needles with disarming characteristics are on the market today, although some patents exist for devices that could solve the problem. The features and merits of these concepts must be analyzed to determine why they are **not** being marketed. Other devices on the market may help with accidental sticks, such as blunted needles from Ethicon and the Auto Suture Company, or cut- or puncture-resistant gloves and glove liners from the Genibel Glove Company, ViaGARD Medical Products, Whizard Protective Wear, or the Zimmer Patient Care division (List of Safety-Engineered Sharp Devices, 2001). Due to the present high numbers of accidental needle sticks, however, these existing products must have some drawbacks that prevent their widespread use. Safer medical products have had significant coverage in news magazines in recent years. One example of this is an article from the San Francisco Chronicle concerning the prevalence of needle sticks in medical school students (Carlsen, 1999). Previous articles in the Chronicle “found that tens of thousands of the workers have contracted HIV, hepatitis and other blood-borne infections from the injuries over the past decade, even though safety [syringe] needles have been available since the late 1980s. Safety needles, the articles found, are rarely provided by employers.”

Although most press coverage concerns “pricks” from injection and syringe needles, suture needles, too, are the cause of many accidental needle sticks. The International Health Care

Worker Safety Center reported that in 1995-1997, suture needles accounted for about 30% of sharp object injuries to physicians, the highest percentage of any device, and 5% of sharps injuries of RN/LPNs, which was a lower percentage than various types of syringes (Appendices 6.1-4). Suture needle injuries occur most often in the operating room, 78%, and occur 6% of the time in the emergency department. Even though most patients are known to their surgeon, 96% of the injury causing needles were contaminated and therefore had the potential to transmit unknown as well as known diseases. Most suturing injuries occur during use or between steps (81% total), and the most common site of injury is the front, or palm-side, of the left hand (Appendix 7.1). Suture injuries account for 37% of sharps injuries in the operating room, and 25% of sharps injuries in the emergency room. The patient history is often less complete in the emergency room, so accidentally pricked ER suturers are at a greater risk for contracting an unknown disease. If a surgeon knows what diseases his patient is carrying, he or she may feel less anxiety about potential disease transmission (Appendices 6.5-6).

For any given needle stick, the risk of disease transmission is low, but an accidental prick can cause considerable anxiety and incur significant costs for the performance of multiple tests for a suspected disease over months or years; designing a better suture needle or system could be beneficial from both human factors and economic standpoints (Haughton, 2001). Also, as state and local governments realize the potentially detrimental effects of accidental needle sticks, they have been creating legislation to spur on and govern the use of safer products (Carlsen, 2001). Most of this has been limited to injection needles thus far, but the laws could be extended to safer suture products. In addition, with diseases such as HIV and Hepatitis that are transmitted by bodily fluids becoming more common, it is likely that the safety legislation may come soon. If safer suture needles become available for market purchase, now may very well be the point in time that hospitals and clinics are willing to invest more money in a product that would protect their workers' health and peace of mind (Appendix 7).

Design Definition and Specifications

In response to the suture needle stick problem, a list of product requirements and other design features were developed with Dr. Victor Haughton's help and Dr. Sidney Sontag's counsel. A detailed product design specification was the basis for generating potential solutions, and drove the brainstorming and idea-generating process (Appendix 5). Emphasis was placed on three main goals. First, the ultimate goal of the project was to design a safer needle. "Safer" meant that the new needle would ensure that the resting state of the needle had an inactivated sharp tip to deter needle sticks and minimize tissue damage. The tip must consist of

biocompatible, sterile, tough materials. Secondly, the needle should meet the quality standards of current suture needles. The final design must still close wounds securely, accommodate surgeons' individual suturing styles and techniques, penetrate tissues easily, preserve the size and weight of current suture needles, and preferably not require any additional tools or equipment. Finally, ease of manufacturing was continually considered when evaluating design concepts. The individual needle components should not require much manual assembly and should retain tight tolerances so that the variation between needles and the cost of production are minimized.

Design Alternatives and Evaluation

Many different approaches can be pursued when improving the safety of a suture needle. New suture brainstorm ideas ranged greatly in complexity and the types of engineering backgrounds required for their production. "Suture Super Glue" required an immense chemical knowledge, while designing a "Surgical Sewing Machine" would be an involved mechanical design project. In the end, two main solution categories evolved from the variety of feasible brainstorming concepts proposed: 1) devices that a surgeon would wear on his or her hand, or place near the wound to deter accidental needle sticks and 2) safety needles, with a mechanism for disarming the sharp portion of the needle.

Although many unique ideas were proposed, some were quickly eliminated when it came time to evaluate all the proposed concepts because they were not feasible. Since many commercial manufacturers have been unable to produce a suture adhesive suitable for large wounds, it was not likely that four students lacking chemistry degrees would be able to develop "Suture Super Glue." In the same way, more experience would be needed to develop a new type of metal with special bending properties similar to those currently used in stents or a form of a self-tying memory metal suture. A "Hinged Needle Cap" idea was also discarded because no feasible working mechanism could be resolved for it.

A decision matrix (Appendix 6) was used to evaluate the remaining ideas and select just a couple that seemed most promising. Criteria categories for the matrix were determined from the PDS requirements (Appendix 5), and then ranked, or ordered, based on significance. The Stapler/Surgical Sewing Machine, Finger Protection, Wound Guard, Snap-off Tips, Concentric Tip Needle, Electromagnetic Wound Guard, Mechanical Needle Pass, and Limiting Sheath Needle designs were weighed against an idea proposed by the client Dr. Haughton, for each PDS criteria category. Dr. Haughton's idea, dubbed the Trigger Activated Needle, was selected as the

datum because Dr. Sidney Sontag had already patented a very similar version of the idea, making it the current standard, and the most feasible, design idea (US005180385A and US005236443A). From the ideas included in the matrix, four main ideas were selected. These ideas were the:

- Finger Protection
- Limiting Sheath Needle
- Concentric Tip Needle
- Trigger Activated Needle

Finger Protection

The finger protection concept could be developed in several different ways. Thin, metal plates could be incorporated into the fingertips of the gloves worn by surgeons. This would be a simple idea that would not require the surgeons to adjust much from their usual suturing styles or methods. If a metal that was thin, yet impenetrable and lightweight, was added to a pair of rubber gloves, the surgeon might still have some sort of tactile sensation when wearing them. Or, for surgeons who like to use their hands and fingers to hold wounds together and stitch them into place, a two-finger thimble made of metal or hard plastic could be fashioned.

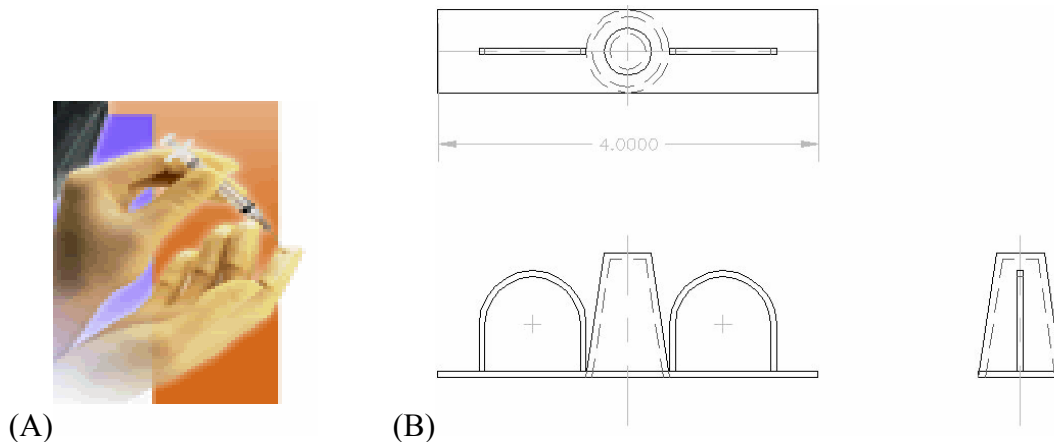


Figure 1: (A) Metal plates incorporated into the fingertips of a lightweight pair of gloves. (B) A two-finger thimble.

An elastic, mesh fabric could be used across the back of the thimble to allow more flexibility and movement for the surgeons fingers. A hard plastic web could also exist between the two finger pieces, so that a protruding needle would stop at the web instead of contacting a

surgeon's fingers that were applying pressure on the wound. The thimble would be shaped to accommodate this normal finger position.

Design Strengths

- Provides protection as the needle exits the tissue
- Allows operator to place fingers anywhere on wound

Design Weaknesses

- Decreased finger dexterity for operator
- Could encourage user to feel overconfident, and not pay attention to where the fingers are placed

Limiting sheath

The limiting sheath design resulted from the idea that a safe needle needed to pierce the patient's skin, but not that of the operator. In order to accomplish this ideal, two options of limiting the motion of the needle were proposed. The first option consists of a sharp inner needle very similar to a typical suture needle and a movable sheath that surrounds the inner needle. As the exposed tip of the inner needle pierces the patient's skin, the sheath starts to slide back along the body of the needle. The sliding occurs until the needle has passed through a predetermined distance of skin, at which point an automatic mechanism would lock the sheath in place, preventing further passage of the needle (Figure 2). After the operator removed his or her bracing fingers on the far side of the wound and disengaged the locking mechanism, the sheath would either follow the needle through the skin or be removed from the free end of the surgical gut. If the latter mechanism were used, a rapid "sheath reloader" would probably be necessary. Another option would be for the sheath to function more as a guard, and be attached to, but not surrounding, the sharp needle. As force was applied to the needle, the sheath would butt up against the skin and slides along its surface. The sheath would lock at a 90-degree angle once the needle had entered skin up to the prescribed distance. In the same manner as the first option, the operator would be required to disengage the mechanism in order for the sheath to follow the sharp needle through the skin. In this way, the device would help make the user more aware of needle placement and give them more time to get their fingers out of the way whenever a needle was poked through.

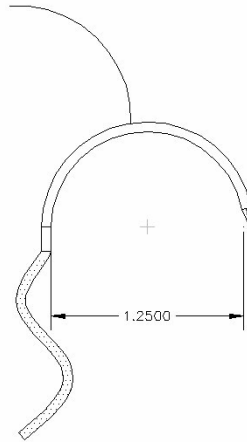


Figure 2: The Limiting Sheath design.

Design Strengths

- Increases operator awareness, because the sheath must be manually removed during each step

Design Weaknesses

- Sheath removal requires extra step, making process more tedious
- Small hinge would be required, which may be expensive to manufacture
- May not function as intended to close tissues of varying thickness

Concentric tip

This design reverses the conventional cutting suture needle. The device consists of a blunted, dull center needle that is encased in a stainless steel, hollow sheath. The end of the sheath, located near the needlepoint, is sharp around its circumference, with the ability to penetrate tissues (Figure 3). Within the hollow sheath, the blunt needle is pushed forward by a small spring that pushes the tip outside the sharp, stainless steel casing when no force is applied to the needle. The needle is fastened to the corresponding suture material at the swage end.

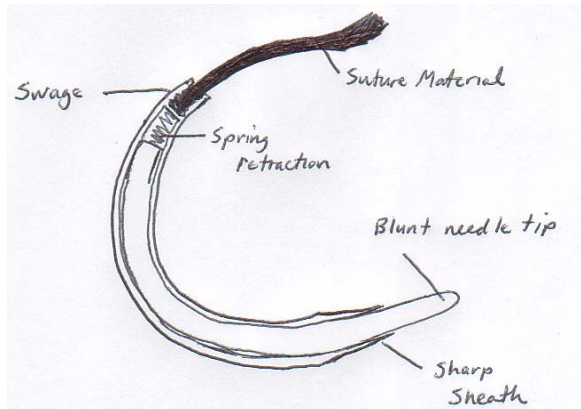


Figure 3: Full side view of concentric sheath tip design. The inner blunt needle tip is mounted on a spring fastened inside a hollow sheath near the swage. The outer sheath is sharp enough to penetrate the skin with little damage to the tissue. When force is applied to the blunt needle tip, the blunt needle retracts exposing the sharp concentric sheath.

The operation of the concentric sheath tip design is based on a “force-only” operation, in that the needle is sharp only when force is applied to push the blunt tip into the metal sheath. When the needle is applied to the tissue, the force of the skin pushes the blunt needle into the metal casing, exposing the sharp metal concentric sheath tip (Figure 4). This concentric tip pierces the skin, until it is pushed through the wound and the opposing force of the tissue diminishes. At this point, the needle retracts back outside the concentric tip to the original position. This position protects the user from accidental needle sticks by eliminating a sharp tip that can poke the operator when no force is applied. The inner needle is flush to the inside edge of the concentric tip, protecting the sharp outer edge.

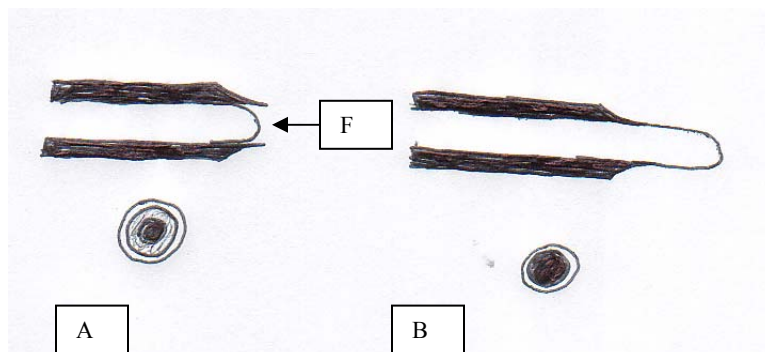


Figure 4: Close-up side views of concentric sheath tip operation. (A) When a force is applied to the blunt tip, the needle moves to the “armed” position, as the inner tip retracts within the metal sheath, exposing the sharp concentric tip. The tissue can be penetrated at this time. (B) When no force is applied to the needle, the blunt tip springs back into place, protecting the outside sharp edge.

Design Strengths

- Needle tip automatically armed

- Prevents scratching injuries

Design Weaknesses

- Automatic arming may trigger unintentionally if bumped by hand in finger

Trigger Activated Needle

As mentioned previously, the Trigger Activated needle was first proposed by the client, Dr. Haughton. It also consisted of a sharp, metal needle enclosed by a dull or rounded sheath covering. A bend, or hump, in the inner needle metal, accessible at the swage end of the needle, could be grasped by a clamp surgeons commonly use to hold and maneuver sutures. This would deform the bent section and make the inner needle longer so that it protruded past the protective sheath.

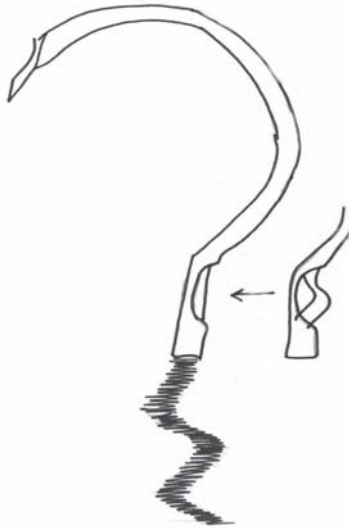


Figure 5: When the needle is not clamped at the swage end, the sharp needle edge is safely enclosed in a protective sheath. Clamping the needle pushes it out past the protective sheath end.

After conducting a patent search, it was discovered that a design very similar to this one already existed. In 1993, US patent numbers US005180385A and US005236443A were issued to Dr. Sidney Sontag. The mechanism used to trigger the needle matched the mechanism proposed by Dr. Sontag, but the metal hump was located in the center of the needle, rather than at the swage end.

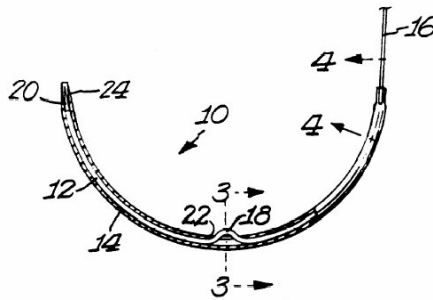


Figure 6: Dr. Sontag’s patented design (www.delphion.com/details?pn=us05180385).

Potential Problems and Project Difficulties

Several potential difficulties have already been identified for this project. A number of the best design concepts are very similar to some devices that have already been patented. Additionally, there is a potential for complications to arise during prototype building and testing. However, now that these problems have been identified and are anticipated, arrangements can be made to prevent or counteract them.

During a routine patent search, several patents were found that are similar to some of the design ideas that were developed. The owner of one of the patents, Dr. Sidney Sontag, was contacted. He seemed very excited to be working with a group of students on this project. He stated that he tried to sell the patent to Ethicon, but refused because he believed they wanted to buy his patent so as to prevent possible competition rather than produce the product (Sontag, 2001). This shows that two problems may arise: 1) the best, safe design concepts may already have been patented and proposed to manufacturers, and 2) some of the leading manufacturers may reject the idea of a safer suture needle because they believe current products are “good enough.”

The fact that so many patents existed was surprising. A search of similar products had been performed before the patent search, and very few products had been found. This raises the question as to why these devices are not being produced. Statistics (Appendix 7) seem to indicate there is a market for a safer suture needle. Another reason for the lack of production for some of the devices could be the feasibility of manufacturing them. This is another factor that needs to be taken into consideration as the final design is further developed.

Another problem encountered throughout the semester was a delay in receiving critical information. A series of unfortunate events led to great difficulty in setting up meeting times

with the client and other contacts. Brainstorming a list of possible solutions to the problem was not easy without an initial client meeting to direct the creative energy. Understanding Dr. Sontag's existing patent and the process by which he developed it was difficult until a teleconference was conducted. This information was very useful in directing prototyping efforts and in understanding how his concept could be produced. Some of his manufacturing methods could apply to the designs discussed in this paper. Contact with suture needle supply and micro-machining companies was also delayed, further delaying crucial steps in the design process.

One of the next steps in the process is to produce prototypes that are closer in size to existing suture needles. Specialized equipment is required to manufacture a small, intricate needle out of surgical grade stainless steel (Fronczak, 2001). Depending on the availability of such equipment and the level of expertise required, it is more feasible for students to manufacture a larger prototype. However, a larger sized prototype could not be tested as one that is truly identical to the proposed solution and could actually be used. A true-sized needle would allow surgeons or veterinarians, who were willing to help with this project, to test the needle on an animal or some type of material. They could then provide expert advice on the needle's ease of use, tissue penetrating ability, balance, weight, and other issues that might not have been considered.

Narrowing down the list of potential designs and trying to choose the best design was a time consuming and frustrating process as the first round of brainstorming did not produce a clear frontrunner for development for this course. Each alternative proved to have benefits in a crucial specification where the others failed. Deciding which design would be the best solution proved to be surprisingly long lasting challenge. Additional frustrations resulted from the similarity of our independently proposed ideas to those described in various patents. Ideally, the design picked for further development would be an unpatented idea so that greater freedom could be used in altering and creating a progression of related designs.

Quandaries will arise throughout the design of any product. The best defense against them is to anticipate as many as possible. Even the most thorough of preparations will not foresee all potential problems. Even so, having identified several likely difficulties will help insure that the design of a safer suture can go more smoothly.

Final Design: Mechanism and Explanation

After completing one iteration of the design process—brainstorming, design evaluation, development of top designs, and prototyping—the prototypes were examined to try to determine how each of them could be better demonstrated or manufactured. While discussing the limiting

sheath design, and how the limiting mechanism could be activated and inactivated, using an air filled bubble or balloon to prevent the needle from passing any further was proposed. It would be activated by clamping down with the needle holder, just as in the trigger-activated design. The next logical step was to just transfer the bubble idea to the force transferring mechanism in the trigger-activated model. If an air filled balloon burst while in use, it would be harmful to the healing tissue within the wound. Saline was therefore considered as the substance within the balloon because it is already used during suturing procedures and would have no adverse effects if the balloon were to burst. As an added bonus, using an incompressible fluid instead of air is a much more efficient way of transferring the force of the clamped needle holders to the needle tip to cause protrusion.

As shown in Figures 7 and 8 show, the assembly of the JABE is very similar to that of the trigger activated design. It consists of a hollow, metal sheath with bilateral cutaways that expose an inner fluid filled “balloon”. One end of the balloon is unattached, and the other is attached to the blunt end of the needle tip. The needle tip freely slides within the sheath as the balloon distends and re-collapses.

When the surgeon or needle operator uses the needle holder to clamp the exposed balloons, the fluid within the balloon is forced into the body of the sheath. Because it is virtually incompressible, the fluid has no other option than to force the tip out of the sheath. As long as the needle holder is clamped down, the tip protrudes from the sheath in the activated position and the user can suture as usual. Once the tip has just pierced the opposite side of the tissue, the user unlocks the needle holder, the balloon can re-expand to fill the cutaways, the pressure is lessened within the sheath, and the tip retracts into the sheath to the disarmed position.

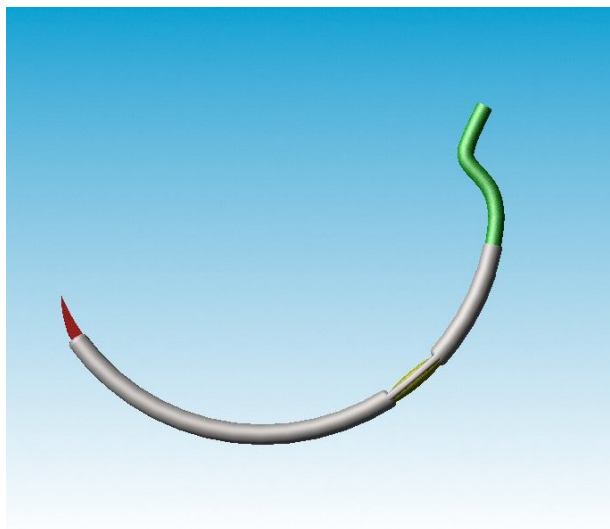


Figure 7: Profile view of the JABE device

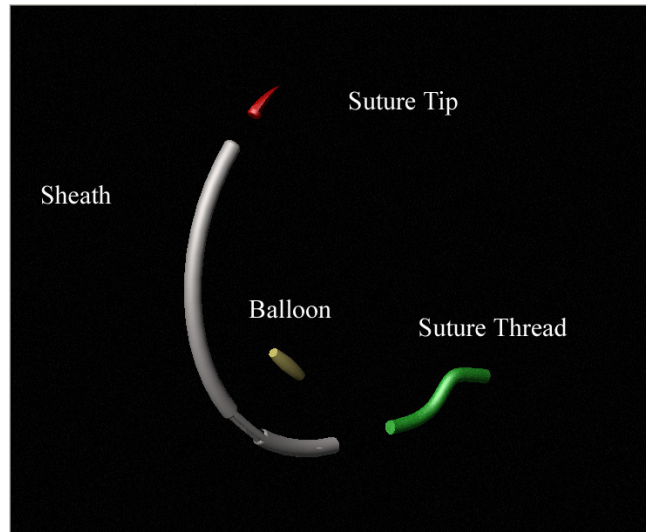


Figure 8: Exploded view of the JABE design, with all the main components listed.

Advantages and Disadvantages

Advantages

Several critical advantages of the *JABE* 200 design make it a safe and easy to use solution in a variety of medical applications. The fact that the “default” position of the needle is in the disarmed state makes the needle safe until consciously activated by the user. The needle is easy to use, as no extra steps are required to arm the needle. The operator must only grasp the trigger of the needle with the needle holders as if grasping a normal needle, approximately one third to one fourth the distance from the swage end. This is an important feature, as most medical staff will not accept even a completely safe needle if it requires extra steps that may complicate or lengthen a procedure. Furthermore, use of the needle requires no additional equipment and is ready to use immediately. Overall, the basic concept of the trigger-activating device was independently conceived by two different medical professionals, who agree that the best solution to a safe and easy-to-use needle is one that is activated by grasping a trigger with a needle holder.

Disadvantages

The fact that the design of the needle does not protect the operator from needle sticks when immediately exiting the tissue is a main disadvantage to the *JABE* 200 design, as the needle holder is still clamped firmly on the trigger, allowing the needle to remain in the active position.

As long as the needle holder serves as the activating tool that sets off the “trigger”, this will continue to be a problem. Overall manufacture of the needle may be difficult as the small balloon size and volume changes associated with the encased fluid may prove to be highly complicated to produce on a small scale. Associated with the complication of manufacturing, the needle will most likely be increased in cost significantly. The question remains as to whether an increase in cost will affect the desire to buy the safe needle, even when the risk of needle puncture is greatly reduced. Finally, selecting one cutaway location that accommodates every user in several different suturing applications will prove to be a challenge to overcome in the near future.

Conclusion

In the next semester, more calculations need to be done on the volume displacement and the strength of the proposed materials. More research also must be completed on possible materials for the balloon part of the device. Transferring the macro scale prototypes and concept to the meso scale necessary for these needles could be challenging. Achieving the proper wall thickness for the sheath and the balloon are critical to the success of this idea, but manufacturing and assembling these components could present some difficulties. Research and further prototyping on a smaller scale will hopefully address some of these concerns.

Assuming that a suture needle sized prototype can be manufactured, the next steps would be testing the mechanism on fabric or pieces of meat, and then obtaining approval to test versions of the device on animal and then human tissue. Since this project will be entered in the Schoof’s competition early next semester, a patent application process will also have to be started soon. Technically, the idea has already been disclosed to the public via our website, so an application must be filed in the United States before next December. WARF and the administrators of the Schoof’s prize may be able to assist on the patent process.

Although much work must be done before the JABE is brought to market, it has the potential to garner a large share of the market. Suture needles account for more sharps injuries to physicians than any other sharps device. Injuries from any kind of contaminated sharps have the potential to transmit disease, but no modified, safer suture needles have been brought to market up to this point. One aspect of the JABE that may prevent its widespread use is its anticipated augmented price compared to existing needles. It has additional safety features, and may require a more complicated manufacturing process that will drive up costs on early models at least until technological progression in the manufacturing process can be made.

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Appendix 1: Properties and Composition of Skin

Research on the properties of skin was conducted in order to gain insight on its nature and properties, especially in wounded skin. Skin is a non-homogeneous tissue with two main layers, the outer epidermis and the inner dermis (Figure A1.1). The epidermis is formed by the continuous growth and division of its basal layer. It consists mostly of keratin, the result of the flattening of dead cells in the plane of the surface. In human skin, these dead cells are arranged in a rather regular pattern. Epidermis has little effect on the mechanical strength of skin—cells can be stripped off one layer at a time by simply applying Scotch tape to the surface. It is flexible but relatively inextensible. The main function of epidermis is to prevent diffusion of water out of the body. The epidermis is also relatively resistant to attack from many chemicals and enzymes, so that it provides an environmental barrier. (Elden, 1971)

The basement membrane is a distinct layer found at the junction of the epidermis and dermis. It contains a specialized form of collagen. The dermis is not homogenous in structure—the most superficial layer has a greater density of blood vessels than deeper layers. This is presumably related to the nutrition of the epidermis and thermoregulation of the organism. The total thickness of skin varies noticeably in different parts of the body. The dermis is mostly made of collagen, which accounts for 70-80% of the dry weight and up to 30% of the wet weight of skin. Collagen is a protein formed by three polypeptides formed into a triple helix (Figure A1.2). In skin, collagen is arranged into three-dimensional waves. In mammals, the majority of the dermis consists of bundles of collagen fibrils running in many directions—in the plane of the surface as well as between planes at different depths. This arrangement increases skin's shear strength. The distribution of fiber direction is asymmetrical throughout the body, therefore skin samples are stronger in some directions than others. This variation in strength can be observed by examining samples whose only variance is the direction from which they were cut. (Elden, 1971)

Skin also contains elastin. As its name implies, elastin is an elastic protein. In humans, elastin is found in higher concentrations at the most superficial and the deepest layers of the dermis. Skin, and the elastin contained within it, is naturally under tension, thus most skin samples contract after being removed from the body. (Elden, 1971)

Cellular components of the skin are not a significant source of strength. This is due to the weak bonding between them, as well as their relatively low proportion in the skin (approximately 10-20% of tissue volume). In general, cellular effects of strength are ignored. The exception is in certain tissues, such as young developing tissues and tissues in the early stages of wound healing, which contain significantly smaller portions of extracellular material than normal skin. In these

cases, cellular effects are more pronounced. The most significant of these is the contraction of wounds, which is believed to be caused by cells. (Elden, 1971)

Human skin is potentially larger in area than the body it covers. As a result, it can be lifted into folds. However, human skin is a relatively tight fit in comparison to other mammals. This limits the possibilities for drawing skin over a wound in order to compensate for tissue loss. Skin is naturally under tension, which has been quantified by measuring the pull required to bring together the edges of a fresh wound, about 2 g/length of the wound (mm). The blanching tension is the tension needed to stop blood flow, and is about 75 g/length of the wound (mm) in human skin. (Elden, 1971)

Collagen is the most abundant structural material in skin and accounts for the ultimate tensile strength of skin. Chemical cross-links between the polypeptides of a single collagen molecule and between different collagen molecules are important in determining the mechanical strength of skin. Fewer cross-linkages result in reduced strength. Tensile strength in humans tends to increase with age (Table A1.1). The behavior of skin under tension is complex, due to the presence of both viscous and elastic elements. A characteristic load-extension curve is shown in figure A1.3. It has 3 phases denoted at around 100g and 1000g. The first phase corresponds to the straightening and orientation of the collagen fibers in the sample. The second phase corresponds to the stretching of the aligned and orientated collagen fibers. The third phase is attributed to yielding, where the sample stretches more readily due to the breakdown of individual fibers. (Elden, 1971)

The use of a suture needle represents a penetrating attack. The success of a penetrating attack depends strongly on the angle of incidence. The optimum angle for this type of attack is at a right angle to the plane of the surface. If the attacking object is circular in cross-section and tapered at the point, as in a tapered suture needle, penetration involves pushing the collagen fibers apart. However, if the penetrating object is larger than the distance between the fibers (in human skin, a few mm), the object will rupture the fibers. If a penetrating object has a cutting edge, such as is found on many suture needles, the penetrating attack is more effective. (Elden, 1971)

| <u>Age</u> | Tensile strength of skin (kg/mm ²) |
|------------------|---|
| infants-3 months | 0.25-0.3 |
| 3 months-3 years | 0.53-1.4 |
| 15-50 years | 1.61 |
| 50-80 years | 2.05 |

Table A1.1. Tensile strength of skin with age. The average tensile strength of human skin increases with age (Elden, 1971) .

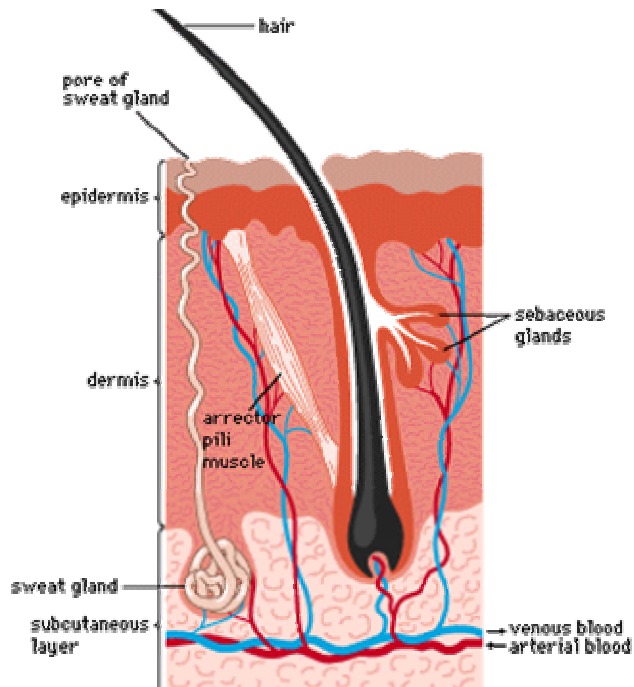


Figure A1.1. Structure of the skin. The skin consists of two layers—the superficial epidermis and the deeper dermis (Corrin, 2001).

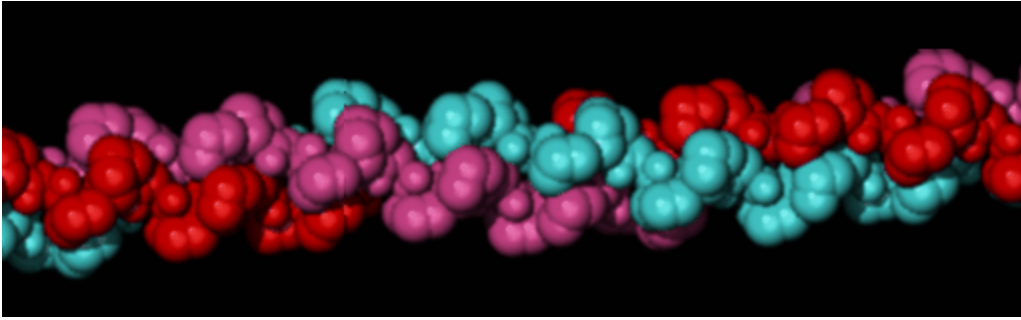


Figure A1.2. Structure of collagen. Collagen, the primary structural material of skin, is a protein consisting of three polypeptide strands arranged in a triple helix (Walshaw, 2001).

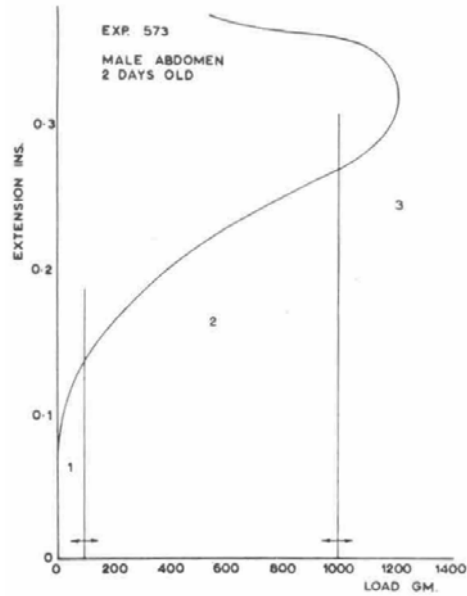


Figure A1.3. Load-extension curve of human skin. The load-extension curve of human skin is shown above. Region 1 corresponds to the alignment and orientation of the collagen fibers. Region 2 is the stretching of the aligned and orientated fibers. Region 3 is additional stretching of the sample due to the yielding of individual collagen fibers (Elden, 1971).

Appendix 2: Suturing Techniques and Principles

The use of proper suturing materials, instrument handling techniques, and stitching methods that depend on the type of wound closure are the key aspects to a successful suturing procedure with minimal harm to both the patient and the physician.

Suturing Materials for Wound Closure

For simple laceration sutures, a single layer of fine, monofilament suturing material is strong enough to be sufficient to close the wound securely. Usually a 5.0-6.0 Nylon suture material is used in these types of procedures. Each of these numbers (ie: 5-0, 6-0, etc) is called a U.S.P. suture size designation number and they refer to the diameter in (mm) of the suture material. The baseline, average size suture's designation is 0, and more zeros indicating smaller diameters (Ethicon). The USP size 5-0 designates 00000. As suture diameter increases above "0", numbers are assigned to the suture material. The each of the numbers, however, has no direct correlation to the diameter (Figure A2.0).

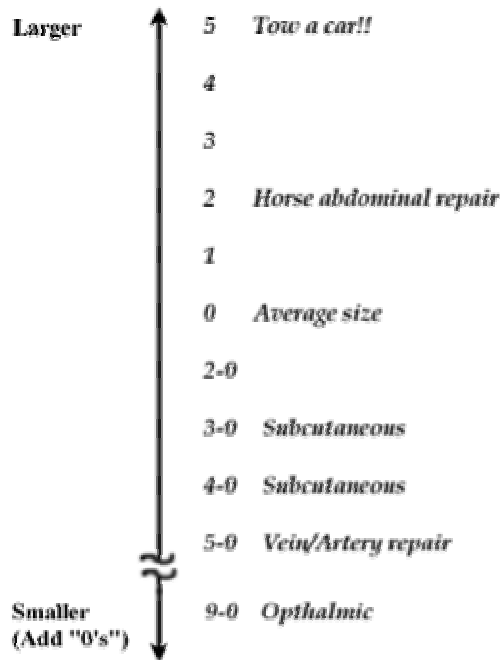


Figure A2.0: Range of suture sizes and strengths (University of Pennsylvania).

In a fast-growing child, or young adult, a faster-absorbing suture is needed to secure the wound, requiring a stronger “cat gut” suture material. If a wound is large or deep enough that sutures must be removed at some later point, non-absorbable suturing material is used. Absorbable suturing material is often used for smaller wounds that heal quickly. Synthetic suturing material is utilized when the deep part of a wound is closed. For the purpose of familiarity of materials, it is best to use the same suture material whenever possible to allow for a greater proficiency of technique (Suturing, 1990).

Instruments of Suturing and Handling Techniques

Selecting the proper suturing material is certainly not the only important aspect of a good technique. There are several other tools involved in suturing that must be considered and properly handled to obtain a successful result. A proper suturing needle is vital to the procedure as is a needle holder, irrigation device, and scissors (Suturing, 1990).

Choosing a needle holder that the physician is comfortable with is important in proficiency of technique and minimizing accidental needle sticks. The best holder to use is one that has carbide tip jaws (Figure A2.1) that are serrated for better grasp. The operator must maintain his/her fingers within the grasping ring throughout the procedure, and the jaws of the needle holder must only be opened and closed when the suturing stitch is completed to avoid slipping and puncture (Trott, 1997).

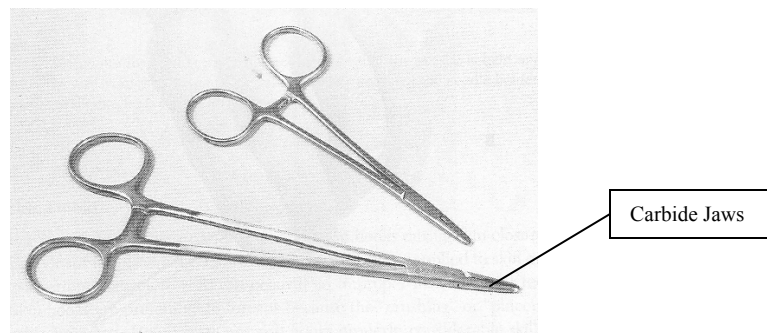


Figure A2.1: Two sizes of needle holders. Fingers should remain in the finger holes at all times during the suture procedure and the holder remains locked until the suture has penetrated both sides of the wound. Carbide jaws are located at the tip to avoid slipping of the needle while being held in the tip (Trott, 1997).

The needle itself should be grasped by the needle holders about $\frac{1}{4}$ to $\frac{1}{2}$ the distance from the swage (eye of the needle, that holds the suture material) to the tip (Figure A2.2). This position allows for the greatest stability of the needle with a tip long enough to pull the needle deeply into the wound. Needle holder tips should meet equally before jaws come together to assure security of the needle at all times. Often, too tight a grasp on the needle will cause it to

bend or break. Using the opposite hand to stabilize the needle holder is a good way to avoid needle punctures to the physician. Prior to the application of the needle to the wound, forceps are suggested to manipulate the laceration edge. Another way to avoid accidental needle sticks is to use the forceps to grasp the needle anytime that it is resting or not in use (Plastic, 1991).

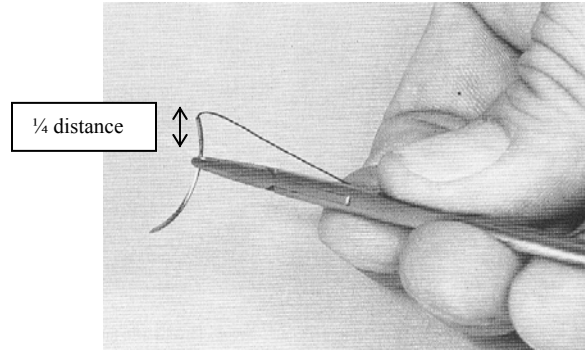


Figure A2.2: The appropriate needle holding technique for surgical suturing. The needle should be grasped $\frac{1}{4}$ of the way from the tip of the swage of the needle to the tip. Using the opposite hand to stabilize the body of the needle holder prevents accidental movements of the needle that cause injury to the user (Trott, 1997).

Surgical Suture Needles

Choosing and applying the correct needle in an application is paramount to avoiding injury to the patient and operator and results in a quicker, more efficient wound closure. Fine needles are the best type to use in order to avoid damage to underlying tissues and undesirable cosmetic scars. Some of the qualities of a good suturing needle include that it:

- Causes minimal trauma to the tissue (sharp)
- Is able to penetrate tissues easily
- Resists bending (rigid)
- Resists breaking (flexible)
- Maintains sterility at all times by not accumulating fluids or material
- Resists corrosion

The typical needle is composed of three main parts: the swage, or wide needle eye that attaches the absorbable or not absorbable suture material; the curved or straight needle body or length, that is the largest part of the needle; and a needlepoint or tip that is the thinnest section of the needle and can vary in shape (Figure A2.3) (Suturing, 1990).

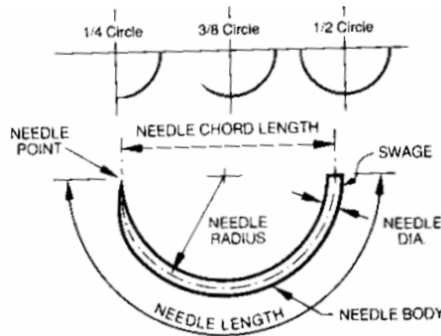


Figure A2.3: Surgical suture needle design. The thick swage attaches to the suture material being used; the needle length runs from the swage to the needlepoint ending in many various shapes. Needles can be straight or curved to $\frac{1}{4}$, $\frac{3}{8}$, and $\frac{1}{2}$ a circle in length (Wound, 1985).

There exist almost as many different types of needlepoints as there are procedures that require suturing. Some of the various needlepoints that are available are shown in Figure A2.4. In general, however, curved suturing needles have two basic configurations: tapered and cutting. Conventional cutting needles are commonly used on tougher tissues, such as the dermis and epidermis. They can also be used in suturing muscle tissue, tendons and ligaments (Suturing, 1990). Tapered precision-point needles are used in easily penetrating applications, such as peritoneum, GI tract organs, plastic surgery and cosmetic surgery (Figure A2.5).

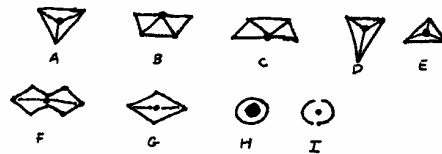


Figure A2.4: Surgical suture needlepoint varieties. (A) hand-honed cutting; (B) lancet; (C) inverted lancet; (D) reverse cutting; (E) conventional cutting; (F) spatula; (G) diamond point; (H) blunted; (I) tapered.

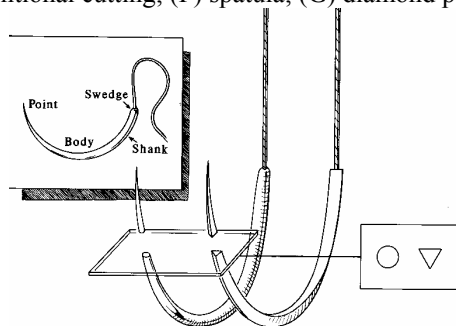


Figure A2.5: Tapered and cutting suture needles. Cross-sections of both common needle types are shown at right. A tapered needlepoint comes to a fine circular point ideal for easily penetrating tissues. A triangular conventional cutting needle is best for tougher tissues that can be “cut” while the needle penetrates the wound edge (Trott, 1997).

Suturing Techniques and Wound-Edge Eversion

The ideal wound stitch result leaves a minimal, inconspicuous scar that is very slightly raised. In order to achieve this, the physician must understand the best method of securing the wound by learning techniques of wound-edge eversion. Scars normally contract as time progresses, thus a minimally raised wound edge (Figure A2.6B) will eventually flatten over time leading to a better cosmetic appearance. In order to do this, the physician must pull the wound edges together during the closure so that they touch but do not overlap or become too tight. For a skin wound which is several centimeters long and passes a couple of centimeters into the dermis, the primary insertion of the needle should be approximately 2-3 cm away from the wound edge at a 90-degree angle to the skin surface (Figure A2.6A). Wounds that are not secured in this fashion (Figure A2.6C) often develop noticeable “pits” that become easily seen as surrounding light casts shadows on the scar (Trott, 1997).

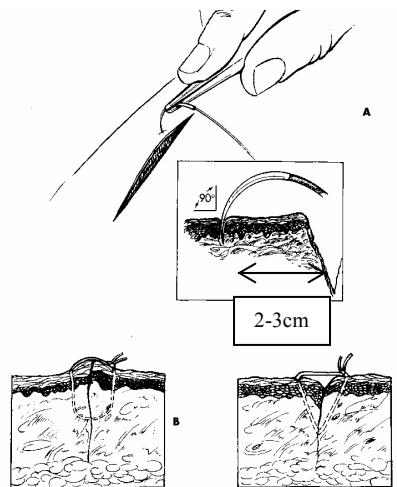


Figure A2.6: (A) The needle is inserted at a 90-degree angle with respect to the skin surface at a “bite” size of 2-3 cm away from the wound edge. This allows for the most even, least tissue-damaging scar. (B) The correct wound-edge “bottle-shaped” stitch. The slight elevation will flatten with time. (C) The improper “pitted” final result (Trott, 1997).

Before a wound is stitched, it first must be cleaned using irrigation devices and saline solution, and devitalized tissue (debridement) must be removed. In some cases, dermabrasion must be used to remove foreign objects that may cause infection of the wound. In the case of a wound of minor complexity, excess flaps of skin should be removed, if not too large, to make a more simplified wound (Suturing, 1990).

Two common suturing techniques are demonstrated below in Figures A2.7-9. In the case of a simple, moderately superficial wound, a normal interrupted suture stitch is sufficient for proper closure. In the case of a relatively deep, difficult to secure wound, a vertical mattress

suture stitch will add extra structural support to the wound when interrupted sutures will not bring divided subcutaneous tissues together.

The interrupted suture stitch, illustrated in Figures A2.7 and A2.8, is the most common suture stitch used in the emergency and operating room for a variety of procedures. It begins as physician grasps the needle with the needle holder and passes the suture needle through one flap of the wound, approximately 2-3 cm from the edge. Without damaging underlying tissue, the needle is passed underneath the skin flap to the flap on the opposite side of the wound *in the direction away from the surgeon*. Once the suture needle has penetrated the opposite side, it is grasped by the needle holder and the suture is pulled in a semi-taught manner as described above.

With the hand opposite the one holding the needle holder, the long end of the suture material is wrapped three times around the tip of the needle holder and the hands are reversed as the first knot is made. It is important to note that this first knot requires the physician to tie in a fashion so that the needle is moving *away* from the surgeon. A second knot is made as the long end of the suture material is wrapped around the needle holder two times and then pulled tightly as the hands are once again reversed. The knot is completed with a third reverse of the hands as the wrap is once again performed, creating a flat surgeon's knot. Both ends of the suture material are then trimmed approximately 1.5 cm on each side, and the process is repeated (Trott, 1997).

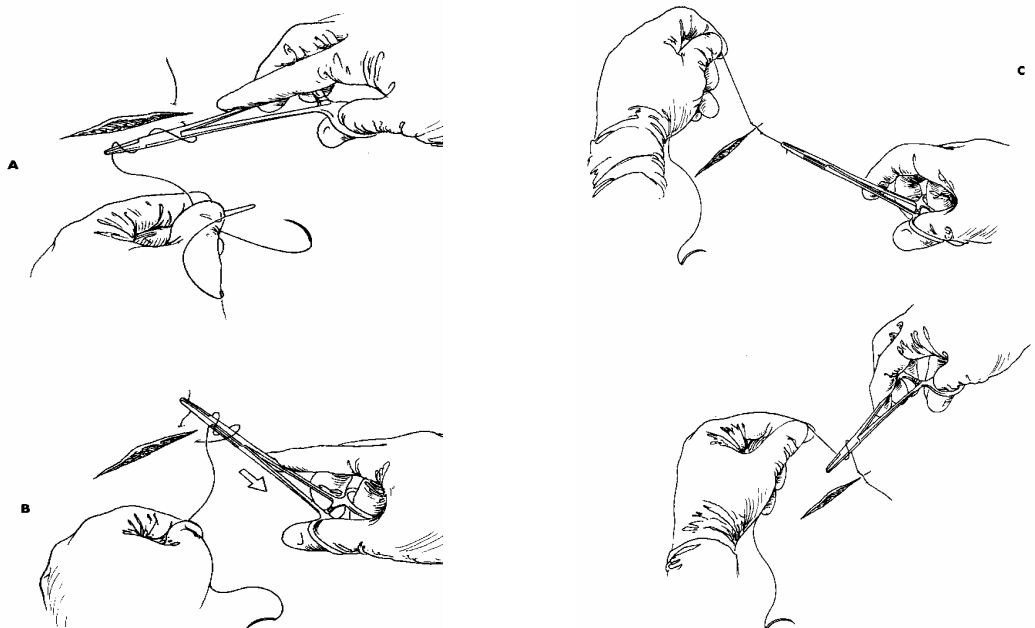


Figure A2.7: The interrupted suture stitch. (A) After the needle penetrates both sides of the wound, the loose end is wrapped around the needle holders. (B) While holding both ends the holders are pulled toward the surgeon and the loose needle is pulled away from the surgeon (C) creating the first knot. (D) A second, securing knot is begun directly over the first knot (Trott, 1997).

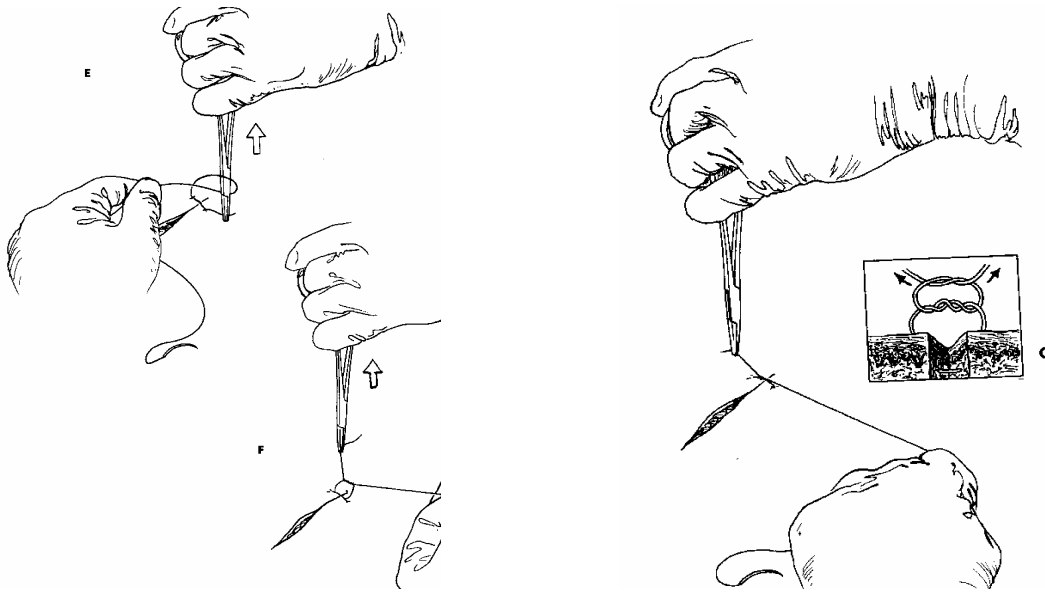


Figure A2.8: Final tying of the interrupted suture stitch. (E) A third and final knot is wrapped once around the needle holder and pulled up towards the surgeon (F) to secure, creating the flat surgeon's knot. (G) A diagram of the knot in the first two stages before fastening tightly. Hands are always reversed between each wrapping of the knot (Trott, 1997).

For deeper, hard to stitch wounds, using the vertical mattress suture will give the wound a greater stability during healing stages. The needle first penetrates deeply underneath the wound split, supplying a base for support of the stitch. The needle is then passed up through the opposite skin flap at a distance approximately 4-5 cm from the wound edge. The needle is then re-inserted on the same side of the wound, approximately 2 cm, and passed through to the other side directly over the first stitch located below in the subcutaneous tissue or epidermis. The stitch is then tied in a manner similar to that of the interrupted suture stitch (Trott, 1997).

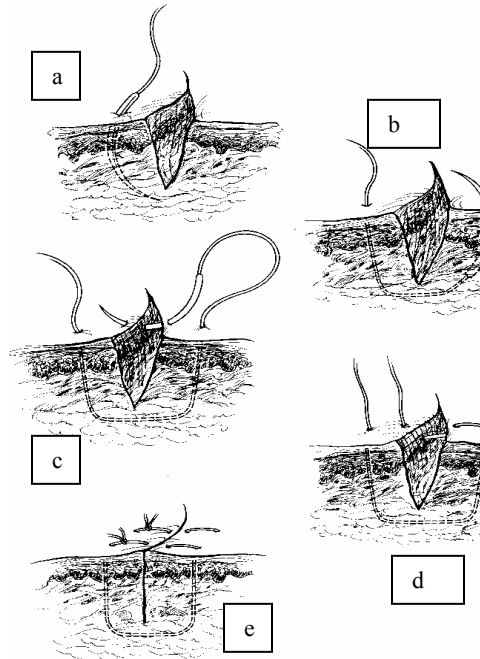


Figure A2.9: The vertical mattress suture. (a) The needle penetrates the first skin flap deeply, aiming underneath the wound. (b) The needle penetrates the opposite side flap 4-5 cm from the edge. (c) Re-insertion of the needle occurs 2 cm from the edge on the same side. (d) The needle is passed through again, and pulled tightly. (e) Tying of the suture using the flat surgeon’s knot (Trott, 1997).

Appendix 3: Process of Needle Fabrication

Traditionally, suture needles have been made out of a surgical grade stainless steel (Kao, 2001), which is a mixture of iron (60-65%), chromium (17-19%), and nickel (12-14%), alloyed with minor amounts of nitrogen, manganese, molybdenum, phosphorous, silicon, and sulfur (Ratner, et al, 1996, p. 41). Surgical grade stainless steel—316L—has proved very useful in medical applications because it resists corrosion, which enhances its biocompatibility with surrounding tissues. Being a ductile material, it can also endure the stresses, such as autoclaving, required for sterilization and maintains its sterility after the process. A small grain size gives the material strength properties that allow a thin, sharpened, wire-like piece to penetrate tissue without flexing.

Manufacturing a needle out of stainless steel requires specialized equipment because of the small size and high degree of precision required (Fronczak, 2001.) The processes used to form a needle differ with the variety of needle that is produced. However, there are four main manufacturing steps (NVC Communication Company, 2001) that all needles commonly share.

First, the metal wire is extruded to the specific diameter required for the needle type. Next, this wire is cut to the length of two needles placed back to back. The ends of this piece of wire are formed and sharpened gradually by repeated grinding between two stone wheels (Figure A3.1). Tempering processes may be used to treat the metal and different surface and polishing treatments may be applied. Head formation practices vary depending upon the specialization of the needle. The head is usually shaped using a press or punch. If a hole is necessary so that the needle may be threaded, the excess material is removed with a round grinder. With suture needles, a hole is drilled into the end of the material, the suture material is inserted, and the swage is clamped to hold it in place. Repeated grinding is used a final time to ensure a sharp, penetrating tip on the needle.

| ASTM Designation | Condition | Young's Modulus (GPa) | Yield Strength (MPa) | Tensile Strength (MPa) |
|-------------------------|------------------|------------------------------|-----------------------------|-------------------------------|
| F745 | Annealed | 190 | 221 | 483 |
| F55, F56, F138*, F139* | Annealed | 190 | 331 | 586 |
| | 30% Cold worked | 190 | 792 | 930 |
| | Cold forged | 190 | 1213 | 1351 |

Table 3.1: Properties of Stainless Steel. F138, F139 are also known as 316L Stainless steel and are the forms most commonly used in medical applications (Ratner, 1996).

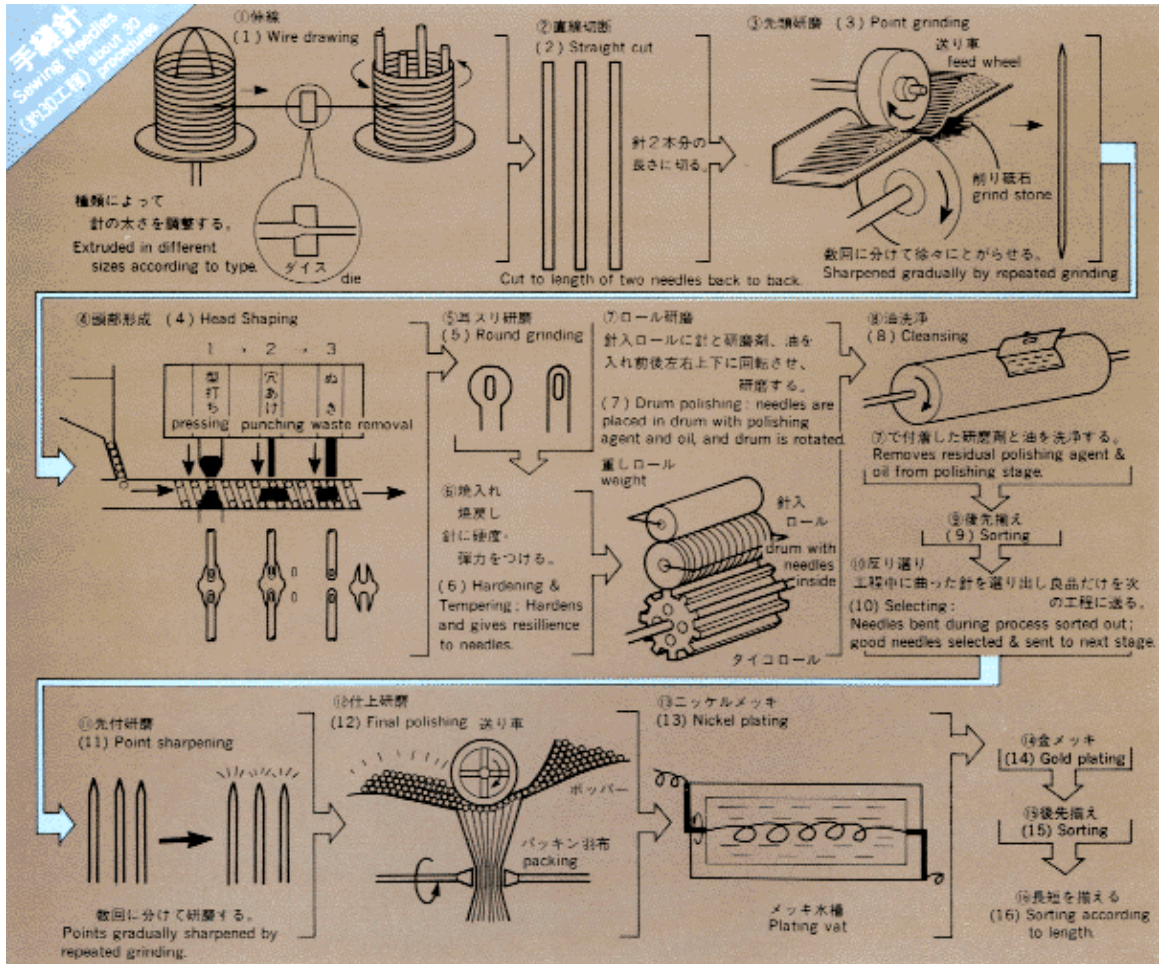
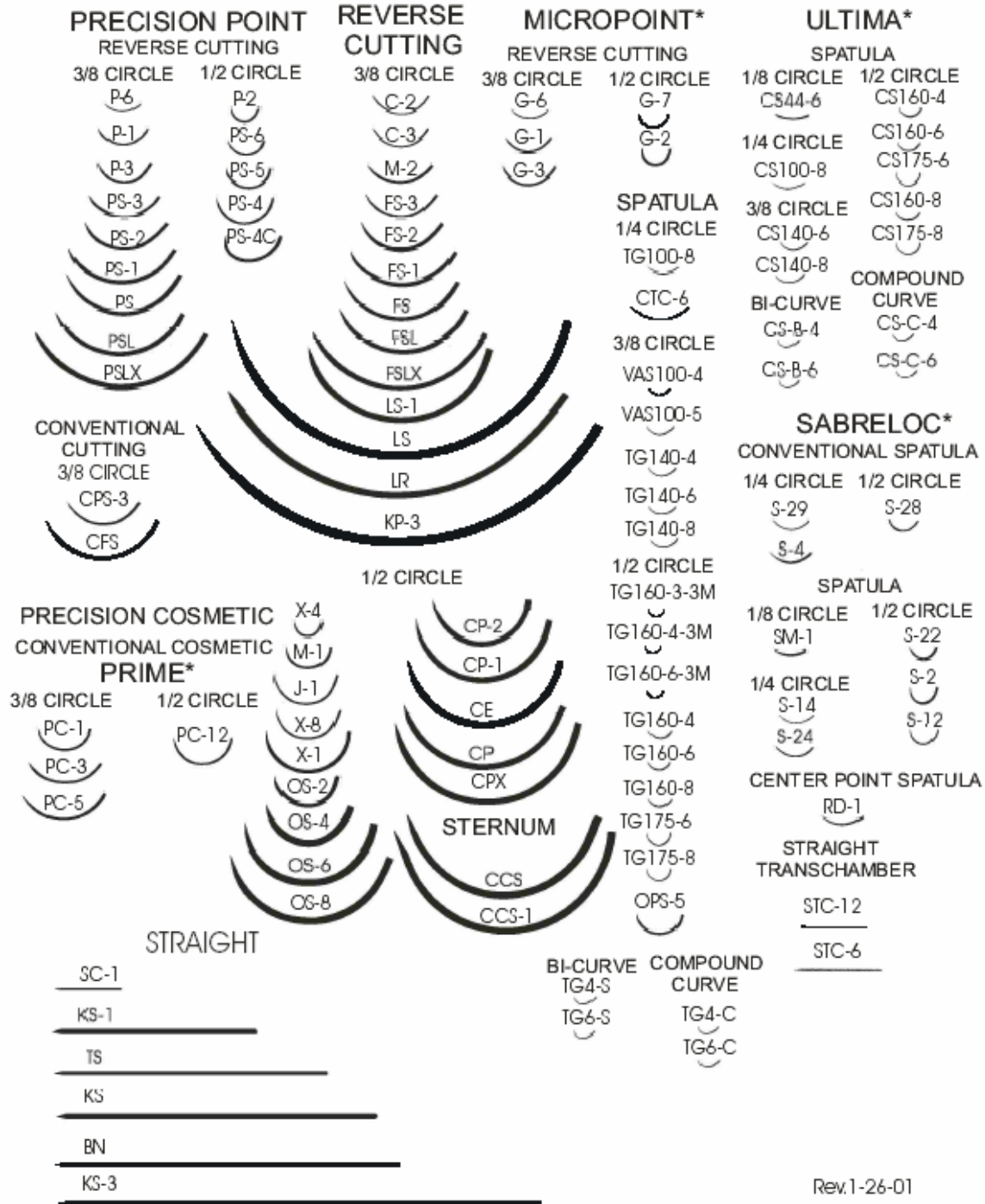


Figure A3.1: Illustrated Process for Manufacturing Sewing Needles (NVC Communications Co., 2001).

Appendix 4: Needle Sales Types

ETHICON NEEDLE SALES TYPES

CUTTING EDGE

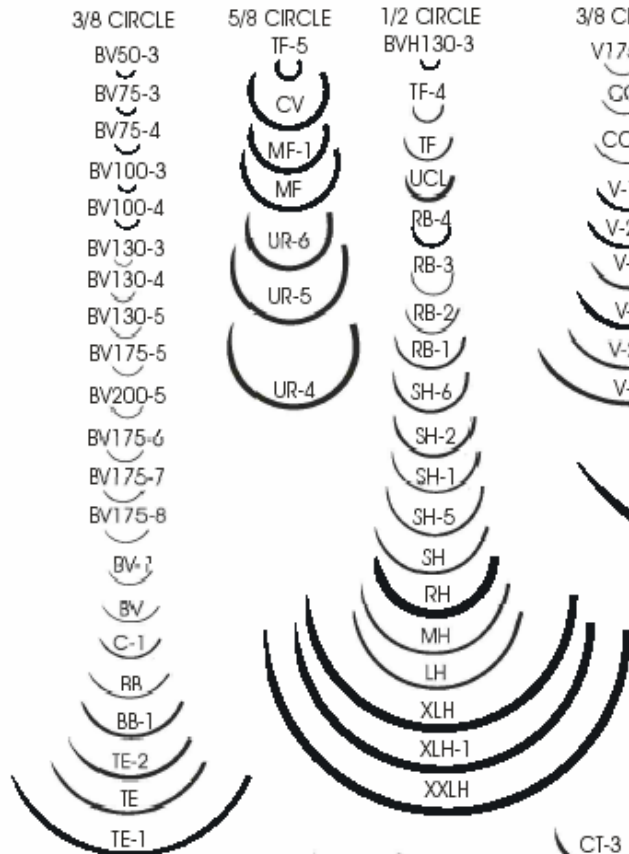


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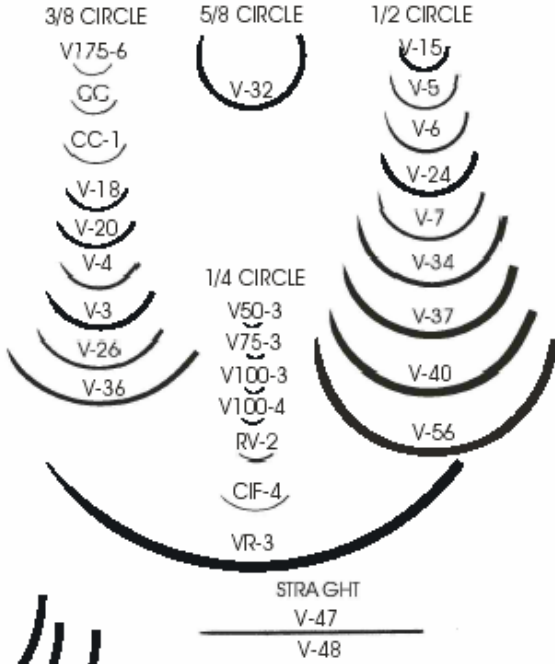
*Trademark

ETHICON NEEDLE SALES TYPES

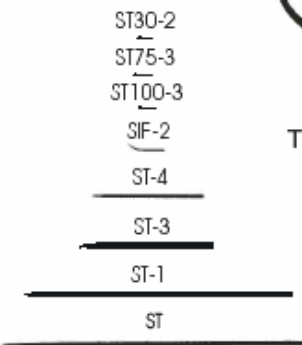
TAPER POINT



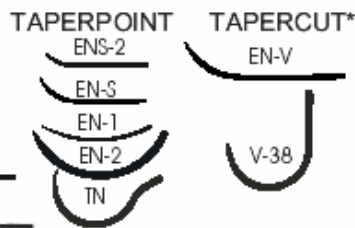
TAPERCUT*



STRAIGHT



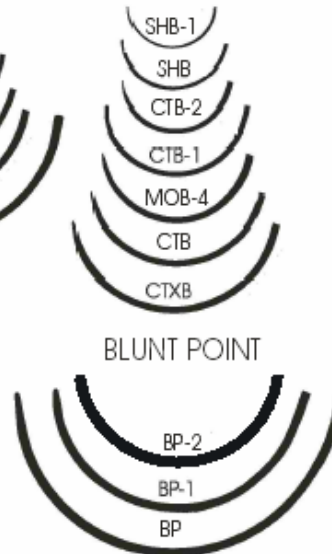
ENDOSCOPY



BLUNT POINT

1/2 CIRCLE
ETHIGUARD*

1/4 CIRCLE
BIF-4



Rev. 1-26-01

*Trademark

Appendix 5: Product Design Specifications

Client: Victor Haughton

Team Members: Briar Duffy, Angela Heppner, Elizabeth Nee, Jeffrey Phillips

December 12, 2001

1. Physical and Operational Characteristics

a. Performance requirements: The suture needle should be able to perform and accomplish any type of surgical task that current dermal suture needles can, in addition to including a pressure controlled arming mechanism that will push the sharp needle tip out of the hollow needle sheath. This mechanism allows the injury-causing tip to be normally inactivated, helping to prevent accidental needle sticks. Ideally, other needle sizes and shapes will be accommodated in future work.

b. Safety: A key safety feature will be the normally disarmed needle tip, which should be sharp and rigid enough to penetrate tissues with minimal trauma to the cells. The end of the needle tip must retract at least 0.5 mm into the sheath to ensure that needle sticks will be prevented. Users will likely need proper training in order to use the new needle safely and most effectively.

c. Accuracy and Reliability: Current suture needles rarely fail. Therefore, this design should meet or exceed current reliability. Despite the new arming feature, the needle tip must still remain rigid enough to resist buckling.

d. Life in Service: Due to the nature of the product, the needle would only be used for one procedure or operation and then safely discarded.

e. Shelf Life: These needles would be stored in a hospital cabinet under controlled environmental conditions. However, an expiration date will be necessary because the balloon and fluid materials may degrade with time. Special packaging will be required to ensure sterility.

f. Operating Environment: The needle itself will be exposed to damaged body tissues and bodily fluids. It must be made of a material, such as 316L surgical steel, that will not cause any undesirable reactions with the tissues. Extreme care must also be given to the design because the operating environment in which a surgeon would use the needle is often stressful and hectic. Therefore, it is essential that the needle and arming mechanism be simple to use, so that surgeons can easily adapt to using the new needle design, and do not have to waste precious time preparing the needle. The new safety feature allows the needle tip to be normally disarmed so that users will not injure themselves, even if they forget that they have a needle in their hand.

g. Ergonomics: The newly designed needle will be best received if it can perform the same types of stitches and be manipulated in the same manner as current needles. Although the current design affords the user flexibility as to how the device is held, more investigation is needed to determine if a user will need to apply a greater than average force to the needle when piercing tissue.

h. Size: For the scope of this course, a standard 3/8-circle needle with a diameter of approximately 32 mm (1.25 in.) will be the focus for prototype design. Ideally, other needle sizes and shapes will be accommodated in future work.

i. Weight: The weight will depend on the size of the needle. The disarming mechanism should not add any excessive weight to the needle that would interfere with its ease of use.

j. Materials: The needle will most likely be made from a non-allergenic metal that is rigid enough to resist buckling, flexible enough to resist breaking, able to preserve sterility, able to maintain a

sharp edge, and resist corrosion. The balloon arming mechanism may be produced from a medical grade plastic or rubber material that possesses the same biocompatible properties as the metal.

k. Aesthetics, Appearance, and Finish: Function will be more important than appearance, but the needle tip will likely be produced in a highly visible color to help attract attention to it, when it is armed. The balloon will also be brightly colored so that a user can easily determine where he or she should grasp it with the needle holders. The finish should be smooth to minimize additional tissue trauma.

2. Production Characteristics

a. Quantity: Eventually, these needles will be mass-produced, so the design ideally should consist of parts that can be easily produced with little intricate or manual labor. Additionally, the parts must be highly reproducible, with tight tolerances, so that little variance exists from needle to needle.

b. Target Product Cost: The redesigned needle will probably cost slightly more than current needles, because of its improved safety features. Even if the redesigned needle were to be more expensive than conventional needles, the additional features may make it desirable in certain niche markets.

3. Miscellaneous

a. Standards and Specifications: FDA approval will be required.

b. Customer: The redesigned needle must not interfere with a surgeon's preferred suturing technique.

Decision Matrix

| | Datum | A | B | C | D | E | F | G | H |
|---|-------|-----|-------|---|---|---|------|---|---|
| PDS Criteria | | | | | | | | | |
| (11) Deters needle sticks | ✓ | + | + | + | ✓ | ✓ | + | + | + |
| (10) Performs desired task (like a suture needle) | ✓ | - | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| (9) Biocompatible with surrounding tissues | ✓ | - | ✓ | ✓ | - | - | ✓/ - | ✓ | ✓ |
| (8) Reliable (complete 10-12 sutures without failure) | ✓ | ✓ | ✓ | ✓ | - | ✓ | ✓ | - | ✓ |
| (7) Ease of use | ✓ | - | ✓ | - | - | + | - | - | - |
| (5.5) Feasibility & manufacturability | ✓ | ✓ | + | + | ✓ | ✓ | - | ✓ | ✓ |
| (5.5) Cost (assuming all are disposable) | ✓ | - | ✓ | ✓ | - | ✓ | - | - | ✓ |
| (3.5) Minimizes repetitive motion | ✓ | - | ✓ | ✓ | ✓ | ✓ | ✓ | - | ✓ |
| (3.5) Range of stitching styles | ✓ | - | ✓ | ✓ | ✓ | ✓ | ✓ | - | ✓ |
| (2) No additional training required for operator | ✓ | +/- | + / ✓ | ✓ | - | ✓ | - | - | ✓ |
| | | | | | | | | | |
| Final Evaluation Ranking... | | | 1 | 2 | | 3 | | | 3 |

| |
|---|
| Positive (better than datum)= + Neutral (same as datum)= ✓ Negative (worse than datum)= - |
|---|

| Column | Design Concept |
|--------|----------------------------------|
| Datum | Trigger Activated Needle |
| A | Stapler/ Surgical Sewing Machine |
| B | Finger Protection |
| C | Wound Guard |
| D | Snap-off Tips |
| E | Concentric Tip Needle |
| F | Electromagnetic Wound Guard |
| G | Mechanical Needle Pass |
| H | Limiting Sheath Needle |

