QuickStitch

Proposal Narrative
Therapeutic Device
May 31st, 2012

Primary Contact: Sohail Zahid (973) 960-6401
**Executive Summary**

Our project is a mechanical suturing instrument to aid surgeons in fascia closure. Fascia is a collagenous layer underneath the skin that wraps around the internal organs to keep them from pressing against the skin layer. After abdominal surgeries, the fascia layer has to be closed carefully to avoid postoperative complications such as herniation and evisceration. Improper fascia closure causes these complications by compromising closure integrity and increasing the risk for infections. Surgeons may also accidentally nick the bowels with the exposed needle, causing injury to the intestines that will also need additional surgeries.

Our fascia closure device, *QuickStitch*, is an inexpensive, disposable suturing tool that places sutures at regular intervals and protects the internal organs from bowel injury. It is armed with a suturing guide that helps guide placement at 1 centimeter from the incision site and 1 centimeter from adjacent sutures, as indicated in the Jonsson-Israelsson rule. To place a stitch with this device, a surgeon places the fascia layer in between the two jaws of the device and closes the handles. This device also protects the needle from accidentally puncturing the internal organs and replaces the malleable, which is a thin metal “cutting board” currently used as an *ad hoc* means of protecting vital organs. Currently, this malleable constitutes much of the inefficiency of closure as it must be readjusted for every stitch, does not adequately protect the patient, and can even cause trauma. *QuickStitch* replaces the current, imprecise, means of suturing with a method that is simpler, safer, and quicker.

**Clinical Problem**

Approximately four to five million open abdominal surgeries are performed every year in the United States [1]. In every operation, the surgeon needs to cut through the skin, fat, and muscle to access the internal bowels. At the end of the surgery, these layers must be properly closed together to maintain a successful surgery. Techniques for abdominal wall closure have remained the same throughout the last century; surgeons manually stitch fascia – the underlying collagenous tissue layer that shields the organs – with a semicircular needle, suture, and needle driver with roughly estimated suture placements.

However, current abdominal wall closure is dangerous and cumbersome. To ensure the integrity of the closure, surgeons must distribute sutures with even tension across the fascial muscle layer [2]. Surgical texts dictate that these sutures be placed one centimeter from the incision and one centimeter from adjacent stitches with appropriate force [3]. Improper closure can lead to a host of postoperative patient complications including dehiscence, infection, ischemia, evisceration, and herniation. Out of all these complications, herniation is the most significant, occurring in 9-15% of all surgeries [4-6], and contributes $2.5 billion dollars annually in rehospitalization, reoperation, and medical malpractice costs to the healthcare industry [7-8]. Therefore, there is a need for a medical device that improves abdominal wall closure to prevent the onset of post-operative patient complications. With approximately 4-5 million open abdominal surgeries annually, increasing to approximately 8 million surgeries per year in 2020 due to an increasing aging population, there is a great opportunity to deploy our product in the market [4].

![Figure 1](image1.png) By the Jonsson-Israelsson rule, sutures should be placed 1 cm from each other and 1 cm from the incision site to prevent postoperative patient complications.

![Figure 2](image2.png) Two problems that might result from improper fascia closure are herniation (left) and ischemia (right). If sutures are placed too far apart, internal bowels protrude through the opening, leading to hernia. If sutures are placed too tightly, blood flow to the region becomes occluded, so the corresponding tissue necroses, leading to ischemia.
Technological Solution
We are a team of biomedical engineers at Johns Hopkins University that has developed QuickStitch—an inexpensive, disposable suturing tool that improves the safety, efficiency, and consistency of the fascia closure process. QuickStitch minimizes needlestick injury by protecting the needle, maintains the integrity of the fascia layer by placing sutures at regular intervals, and reduces the complexity of the procedure. Ultimately, QuickStitch lowers the complication risks for patients, improves the procedure efficiency for surgeons, and reduces readmission and malpractice cases for hospitals.

QuickStitch Design
QuickStitch is a plier-like device that uses spring loaded clamps in its two jaws to drive and transfer a needle with attached suture through the fascia layer. The rationale for this design is to implement a tool that is simple in design and intuitive to use. This limits the number of failure points, reduces costs in manufacturing, makes assembly more efficient, and lowers the learning curve in operating this device. The device uses a double-sided, slightly curved, tapered needle that can penetrate tissue in either direction, with suture attached to the middle. To help surgeons guide suture placement, a circular guide with a 1 centimeter radius sits at the tip of the device. When placing stitches, the surgeon aligns the circumference of the guide from the previous suture and from the incision site. This helps dictate suture placement at 1 centimeter from the incision and 1 centimeter from adjacent sutures (Jonsson-Israelsson rule). The needle is fully-contained in this process, eliminating the need for a malleable, or a metal “cutting board” placed on top of the internal organs as an ad hoc means of protecting the organs. With intuitive functionality and equipped design, surgeons can reduce closure time by at least 20%.

Figure 3. Exploded (left) and assembled (right) view of current prototype in CAD.

Figure 4. Exploded (left) and assembled (right) view of current prototype made with ABS plastic from SLS rapid prototyping at Johns Hopkins.
We have completed 15 prototypes, each iteratively improved, which have successfully gone through various stages of bench and animal testing. Simulation of usage is seen at http://tiny.cc/8uyydw, and latest animal testing is seen at http://tinyurl.com/6m27nll. We have shown that maintaining even suture placement with our device can better maintain closure strength (Figure 5). We have also shown that QuickStitch can imitate the Israelsson rule much more closely than a Johns Hopkins surgeon’s estimates (Figure 6). In our latest animal test, QuickStitch was able to successfully close the fascial layer of a pig (Figure 7).

![Figure 5. Strength testing of surgeon estimated suture placement (left) against QuickStitch estimated placement (right). QuickStitch enabled a stronger closure.](image1)

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<th>Average distance between stitches (mm)</th>
<th>Surgeon</th>
<th>QuickStitch</th>
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<td>4.78</td>
<td>9.26</td>
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![Figure 6. Numerical results of QuickStitch-aided suture placement and surgeon estimated placement. QuickStitch better mimics the Jonsson Israelsson-rule.](image2)

![Figure 7. Open incision of pig before using QuickStitch (left) and properly closed fascia layer after using QuickStitch (right).](image3)
Patent Search

A USPTO and Google Patent Search (keywords “fascia closure” and “fascia suturing”, after 1994) yielded approximately 60-80 patents. The most relevant are listed below:

5254126 - Endoscopic suture punch
4373530 - Surgical stitching instrument
5282800 - Surgical instrument
5665096 - Needle driving apparatus and methods of suturing tissue
5938668 - Surgical suturing apparatus
6071289 - Surgical device for suturing tissue
6086601 - Instrument and method for suturing anatomical tissue and tying suture material
3946740 - Suturing device
5540705 - Suturing instrument with thread management
7998149 - Suturing device, system, and method
6923819 - Apparatus and method for surgical suturing with thread management

We have found that QuickStitch does not infringe upon any of the major claims in these patents. We have filed a provisional patent through Johns Hopkins Technology Transfer with the assistance of Louisa Ryan, Eugene Yelden, Tina Tudor, and Elaine Spector to facilitate any possible litigation scenarios. It is important to consider Suturtek’s 360° Fascia Closure Device, similar technologies in arthroscopic surgery, and undeveloped surgical devices in laparoscopic surgery to determine adequate intellectual property protection. These other devices, while appropriate for bowels and joints, are insufficient for the much tougher, denser fascia. Through research and discussions with our Tech Transfer lawyers, we determined that our technology is unique (ie. spring-based clamping mechanism) and have filed claims that do not infringe on any existing patents, but still restrict entry of other technologies into this space. For additional patent information, please contact Louisa Ryan, our patent lawyer, at lryan17@jhmi.edu.

Regulatory Pathway

QuickStitch is currently undergoing animal testing, and we plan to proceed through the FDA 510(k) regulatory pathway before market entry, which usually takes from two to three years. This pathway requires medical device manufacturers to notify the FDA about their intention to release a device 90 days prior its entry into the market. We anticipate QuickStitch to be classified as Class II with substantial equivalence to Suturtek’s 360° Fascia Closure Device, which received clearance within one month of submission in 2008 [9]. Unlike Premarket-Approval (PMA) devices, our device would go through a substantially easier and cheaper pathway. We already have 10 surgeons at Johns Hopkins interested in using this device, and we will use this network to expand to additional interested surgeons.

After FDA clearance, we will establish QuickStitch to be the standard of care at Johns Hopkins Hospital and Johns Hopkins Bayview Center. We will have the majority of the pieces manufactured by independent contractors such as QuickParts, ProtoMold, Marshall Manufacturing, and Vector Medical. We will rely on soft-tooled injection molding at first, as soft-tooled molds can be modified and changed as we receive more customer feedback. Eventually, hard-tooled molds will be used, and this will further lower our costs of manufacturing. The products will be sterilized and packaged by companies such as Sterigenics to prepare the device for sale. We will then target sale to both academic medical centers and community hospitals throughout the country. When we are successful in the first stage of development and marketing, it will then reach out to group purchasing organizations such as Amerinet to reach a wider customer base nationwide.

Estimated Manufacturing Costs

We have already manufactured several prototypes using SLS rapid prototyping. We have limited the number of device components to 10 and created snap-on fit parts to limit the number of failure points and simplify manufacturing. Altogether, this device costs around $50 to make. This cost is expected to rise as we use medical grade materials that meet FDA and USP Class VI requirements. However, by transitioning to mass-manufactured plastic injection molding,
We can significantly reduce production costs to approximately $30 per device as noted by medical device consultants [10]. We plan on contracting manufacturers to perform injection molding to manufacturer QuickStitch. We estimate the needle to cost 5 dollars [11], plastic components to cost 24 dollars [10], and wires/springs to cost 1 dollar, amounting to 30 dollars per device. Quality assurance, sterilization, and packaging will be maintained by GMP certified manufacturing facilities such as Sterigenics, which will increase per unit costs by 10 dollars.

**Market Analysis**

**Market Overview**

While QuickStitch can be used in any surgery that requires a medium to large incision, we anticipate that the majority of applications will be concentrated in gastrointestinal surgery. The gastrointestinal device and equipment market was estimated to be worth $14.6 billion dollars in 2011, increasing at a rate of 4.5% per year [12-13]. Despite a large number of products in this area, the market is still considered immature with enormous opportunity for technological advancements. Kalorama Information predicts that companies offering niche technologies, like QuickStitch, will “thrive in this market” [12].

**Market Segmentation**

Within the gastrointestinal device and equipment market, we will target sales to surgeons in academic medical centers and community hospitals. Academic medical centers (AMCs) like Johns Hopkins Hospital constitute the minority of hospitals, but are key hubs of innovation. It is important to establish innovative products as the new standard of care at these centers in order for other hospitals to also adopt. Community hospitals represent the majority of all United States registered hospitals, and are further classified into governmental, not-for-profit, and investor-owned divisions. There are currently 4,985 community hospitals in the United States with 2,904 as not-for-profit, 1,013 as investor-owned, and 1,068 as governmental owned [14]. We anticipate accruing 80 percent of sales from community hospitals and 20 percent from AMCs.

**Reimbursement**

As the Center for Medicare and Medicaid Services (CMS) has recently withdrawn reimbursement payments for hospital-borne illnesses, expenses for post-operative complications will now come directly out of surgeon salaries, providing further incentive to use QuickStitch. While there is no specific CMS reimbursement code for a suturing tool, the costly complications from improper abdominal wall closure emphasizes the need for QuickStitch. The CMS code for complication repair surgery is either 43256 or 44376, depending on the incision area and costs from $369.03 to $402.16 [15]. This is especially important as studies now suggest that up to 25% of patients undergo post-operative infection after surgery [16]. More common is the risk of incisional hernia, which occurs 6-12 months after the initial surgery. The codes for hernia repair include 49495, 49650, and 49568, and the corresponding costs are $1281.59, $1853.68, and $1198.46 [15]. All of these costs are much more than the $100 price tag to QuickStitch.

**Overview of Competitors**

The main competition to QuickStitch is the status quo, which relies on a needle and needle driver. There are still companies, however, that attempted to penetrate this market. Our device is the only product that is able to close the abdominal wall layer, provide full needle protection to eliminate bowel injury, ensure consistent suture placement for fascial integrity, and provide tension feedback, all at an inexpensive price (Figure 8). There are only two other products that target the deep fascia layer, ABRA and Suturtek. ABRA is limited to a small subset of patients with severe complications while Suturtek is too expensive (~$3000 per device) and limited to be used in every day operation. QuickStitch is the only device that can perform high performance fascia closure at an inexpensive price (Figure 9).
Figure 8. This is the overview of our competitive advantage over competing products.

Figure 9. QuickStitch is one of the three devices that can close fascia. The other devices are either for special cases or too expensive to use for everyday operations.

Works Cited

10. Dennis Smith. Vice President of Engineering. Seguro Surgical. Personal Interview
15 May 2012

The National Institute of Biomedical Imaging and Bioengineering
9000 Rockville Pike
Bethesda, MD 20892

Re: QuickStitch – Debut Challenge Entry

To Whom It May Concern:

As the director of the undergraduate design team program in biomedical engineering at Johns Hopkins University, I confirm that QuickStitch is a prototype that was designed by the undergraduate team of students listed below as part of my Design Team courses during the 2011-2012 academic year. Although the team was mentored by a clinical sponsor, external judges, my colleagues as well as myself, the students themselves originated the novel ideas associated with the now patent-pending application.

Sohail Zahid – Junior
Daniel Peng – Junior
Ang Tu – Junior
Stephen Van Kooten – Junior
Leslie Myint – Junior
Anvesh Annadanam – Freshmen
Luis Herrera – Freshmen
Haley Huang – Freshmen

Sincerely,

Robert H. Allen, PhD, PE
Associate Research Professor
Biomedical Engineering
Associate Research Professor
Gynecology & Obstetrics
Undergraduate Director
Center for Bioengineering Innovation and Design
May 25, 2012

The National Institute of Biomedical Imaging and Bioengineering
9000 Rockville Pike
Bethesda, MD 20892

RE: Support for National Institute of Biomedical Imaging and Bioengineering (NIBIB) DEBUT Challenge
for “QuickStitch” – Surgical Suturing Device to Improve Fascia Closure

To Whom It May Concern:
The “QuickStitch” project is one of the top projects in our undergraduate program this year. Out of all the undergraduate teams, they have been the most accomplished. In addition to winning a $44,500 from business plan competitions, they have been invited to present at several engineering showcases such as the International ASME iShow. This project has been equal to if not better than projects in our graduate program and has shown the most progress.

The team has done considerable work in designing for commercial viability. They have completed several design iterations to focus their idea on its most practical form, and the team has a provisional patent. The team’s design contains novel elements and has already generated IP and commercial interest.

The team has worked closely with surgeons at the Johns Hopkins hospital to observe the problems in fascia closure first hand through many hours in the operating room. As a result, the team has designed a comprehensive device to account for aspects such as surgeon ergonomics and manufacturing scalability. Furthermore, the students validated their design through multiple animal trials. Currently they are collecting publishable data for the device.

This device and team have a high potential for success in fascial closure and have already showed positive advances in animal testing as well as approval from a multitude of surgeons. I wholeheartedly endorse this project and recommend that you fund their idea for the NIBIB Debut Challenge.

Sincerely yours,

Youseph Yazdi, PhD, MBA
Executive Director
**NIBIB DEBUT Challenge Certification Form**

**Instructions:**
Each and every member of a Student Team participating in the NIBIB DEBUT Challenge must read this Certification Form and complete it by providing the date and his/her printed name and signature where indicated below.

A Student Team can include only one Certification Form with its entry, which will be submitted by one member of the Student Team appointed to do so by that Student Team (e.g., the “captain” or “submitting participant” of that Student Team).

Entries that fail to include a completed Certification Form will be disqualified from the Challenge.

**FOR FURTHER INFORMATION CONTACT:** Dr. Zeynep Erim at (301) 451-4797 or Zeynep.Erim@nih.gov.


I hereby agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this prize challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

I hereby agree to indemnify the Federal Government against third party claims for damages arising from or related to challenge activities.

I hereby grant NIBIB an irrevocable, paid-up, royalty-free, nonexclusive worldwide license to post, link to, share, and display publicly the entry on the Web, newsletters or pamphlets, and other information products.

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<th>Student Team Member Name</th>
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<td></td>
<td>Saural Zahid</td>
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