

revolution in surgical closure

Minneapolis plastic surgeon **Joe Gyskiewicz MD** describes a device that makes surgical incisions easier to close and makes the scars look better. This surgical stapling device, which puts dissolvable staples under the skin, blossomed after a long invention process.

INVENTION

Invention is one percent inspiration and 99 percent perspiration – Thomas A Edison.

Surgery is not new. In fact, it's not even a recent development in human history. Egyptian mummies show evidence of successful, healed surgeries. Even skeletons or mummies of prehistoric tribal peoples show healed, deliberate repair of broken bones. The Inca actually did fairly sophisticated surgeries, and mummies from Aztec Mexico reveal completely healed surgical scars.

From those early efforts in which there appear to have been stitches of some sort placed in the wounds, medicine evolved sterile closure along with sterile technique in the late 1800s. Anesthesia appeared about the same time. Procedures were considerably less terrifying and painful for the patient, and easier for

the surgeon who didn't have to contend with a squirming, screaming patient while placing sutures.

As other surgical techniques developed, new kinds of suture materials were invented. Silk threads that could introduce infective agents were replaced with nylon and then synthetic materials, each step increasing the safety and strength of the closure material.

Finally absorbable stitch materials were developed so the internal closures would eventually be absorbed by the body after healing had occurred. The problem, which seemed to defy solution, was all the materials were still placed by a needle being pulled through the skin, doing damage as it went.

Furthermore, placing stitches is time-consuming, precise work, adding anesthesia time for the patient and operating time for the surgeon. It's like having to do the dishes right after preparing a gourmet meal. Although placing stitches is pretty boring and hard on the surgeon's hands, the process requires careful attention to detail and great precision.

Tissue glue was developed and worked for some surface wounds but was more efficient for smaller wounds than surgical incisions. Metal skin staplers were certainly a leap forward. With strong, quick single placement, the metal staple helped control postoperative infection, save time and seal skin incisions tightly, but the staples still had to be removed. Metal staple removal takes time and means the patient has to return to the office for another visit.

Any foreign object in the body, including metal staples, can become a magnet for infection. Metal staples may cause a 'railroad track' scar like you see in a Frankenstein movie. This scarring does not appear as cosmetic as a precisely-sewn plastic surgery closure. There was another step forward that needed to be made.

The process of invention

Successful inventions solve problems. If there's no problem you don't generally think to yourself, 'Hm m m m m. Someone should invent something that makes this easier.'

Inventions don't necessarily have to be devices. Remember, inventions solve problems, so a creation might as easily be a new approach to a daily-life problem, either at home or in the office. The best invention ideas emerge from experience and the more experience you have doing something, the more able you are to see where improvements could be made.

Inventors pay attention to more than just their own piece of the puzzle; they try to notice everything that happens in their work process. They think in creative ways, using logical steps; identifying problems; figuring out what causes the problems; envisioning solutions and planning how to put the solution into action. Sometimes the improvement will come from a new device. And the chances of coming up with great ideas are pretty good: we don't yet know 98 percent of all the available knowledge in the universe!

My brainstorm

The invention process was employed when thinking about the problems of staples and stitches. The problem was already identified and one could easily list what caused the problems:

- Sewing is tedious
- Stitches take a long time to place
- The closure materials may make the patient more vulnerable to infection
- Metal staples are faster than sewing but they also have to be removed
- Removal of metal staples requires a return visit to the doctor by the patient
- Some stitches have to be removed
- The patient suffers discomfort when stitches or staples are removed and the skin may become irritated where they were placed
- Scarring can be a problem with the use of both stitches and staples
- Sometimes the scarring is made worse by the extra holes made by the stitches or staples.

Next comes the solutions mode. One of the most important things to remember in inventing is the inventor will probably come up with hundreds of ideas, not just one perfect one. Often the final solution is a synthesis of many ideas. Inventors write down everything that comes into their mind, even if the idea seems absurd, because it's possible the seed of a great solution will come from a ridiculous idea.

This process was employed to look for ways to avoid all that sewing at the end of some surgeries. Several solutions were evaluated: one used a magnetic device to guide a needle under the skin; another was an automated sewing machine and even a laser-guided system for wound closure. Each of them was a good idea but had fatal flaws. When Thomas Edison experienced a thousand failed experiments, he commented he had discovered a thousand things that didn't work!

From idea to prototype to studies and trials to production

There was a need and an opportunity in the market place. The big manufacturers had already tried to invent a 'subcuticular stapler'. Failure to hit a home run left a bad taste in their mouths, so they didn't seem interested.

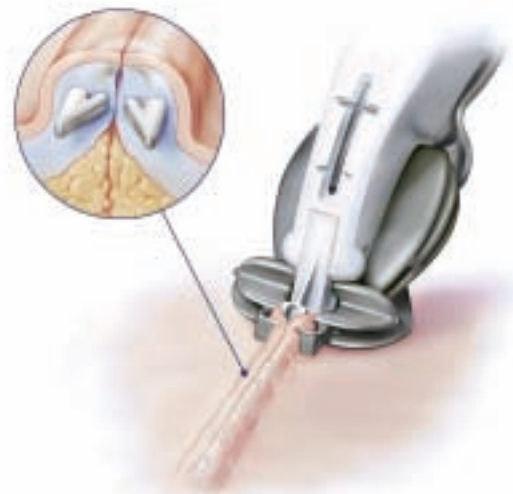
Instead a smaller company, Incisive Surgical Inc of Plymouth, Minnesota, with Jim Peterson, Vice President of Advanced Development at Incisive, led the charge from idea to invention, working long hours with engineers and designers to create the physical form of the stapler.

Eventually Incisive Surgical was able to contract for a number of tests and trials to be done, all of which were successful. The company manufactured a small number of the staplers for initial patient trials. When the tests were successful, Incisive began manufacturing and

feature



InSorb Subcuticular Stapler



Placing absorbable staples under the skin

marketing the InSorb 20 Subcuticular Skin Stapler and Absorbable Staple.

The InSorb 20 Subcuticular Skin Stapler and Absorbable Staple

The key innovation in the InSorb 20 stapler originates from its method of tissue capture. The staples are placed from the inside or 'subcuticular'. Consequently there are no surface sutures or staples to irritate the skin, yet the incision is tightly closed. The closure is fast, the staples are under the skin and dissolve, and the incision

looks like a plastic surgery closure.

The staples themselves are completely absorbable and made of a polylactide-polyglycolide co-polymer 'plastic', which has been previously used in absorbable sutures. The staple is placed horizontally into the subcuticular tissue at approximately 8-10mm intervals. The cleats of the staple hold the tissue firmly in place with no surface invasions and the staples do not have to be removed since they are absorbed by the body.

In studies the InSorb 20 stapler got great reviews from the surgeons using it for its ease and 'intuitive' style requiring almost no learning curve. I was delighted with that news. One benchmark for a successful invention is people will use it and not become frustrated because often a device may actually create more problems than it solves.

Patients in the studies preferred the InSorb 20 staples over the use of metal staples for two reasons: the InSorb 20 staples don't have to be removed – a painful process – and they don't leave extra marks alongside the incision.

Now this stapler system is being used in operating rooms around the nation. It is single use and preloaded with 20 staples, enough to close about a seven-inch incision. The InSorb 20 Subcuticular Skin Stapler recently won a national 2005 Medical Design of Excellence Award for product innovation, design and achievement.

Jim Peterson also came up with another invention to be used with the stapler: special tweezers. These forceps allow the InSorb 20 Subcuticular Skin Stapler to be used by only one person rather than two operators necessary for metal skin staplers, further increasing the speed and efficiency of wound closure.

Incisive is optimistic about the world-wide potential for the InSorb 20 Subcuticular Skin Stapler system and forceps to provide quick, sterile, comfortable incision closure, helping surgeons and patients alike.

That's the complete circle of an invention: identifying the problem, finding causes, creating the ideal solution and sharing the solution with others. **cbm**



Staple on finger to show actual size



Close-up of the InSorb Absorbable Staple



InSorb Skin Closure Forceps allows only one person to close the incision in tandem with the InSorb Subcuticular Stapler