3D PRINTING | ADDITIVE MANUFACTURING | PRODUCT DEVELOPMENT

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WHAT HAS 3D PRINTING GOT TO DO WITH DAIRY COWS?

LET SOMOS EXPLAIN

Sutrue

A lot of interest surrounding 3D printing in medicine recently has focussed on the use of implantable 3D printed parts such as hip joints, cranial implants or even jawbones. More often than not however, 3D printing is being used in medicine away from the body – or at least for applications that don't require permanent implantation.

Surgical tools and guides — such as those pioneered by the biomedical division of Belgium-based Materialise — have been making surgery quicker, safer and less invasive for many years. When Alex Berry, a product designer, looked at the medical industry, after watching a Professor Robert Winston documentary on robotic surgery, it was the all-important interface between internal and external — the skin — that inspired his designs.

Suturing, more commonly known as stitching or stitches, has likely been in use since around 3,000 BC in ancient Egypt, with the oldest known examples found in a mummified body dating from 1,100 BC. Initially needles were fashioned from bone and simple metals, with the suturing thread of natural origin. Animal hair, silk and catgut were used for millennia without much in the way of advancement.

Major technological advances only appeared after the industrial revolution when a number of man-made absorbent, non-absorbent and dissolvable suturing threads were invented. Needles improved with stainless and surgical steels as well as chemical sharpening. Another advance includes swaged sutures, whereby the traditional eyed needle is replaced by a needle and thread joined at the manufacturing stage. These so called atraumatic sutures reduce drag and improve hygiene practices.

Same old scene

Despite these advances little has changed in the basic theory and practice of suturing since ancient times. Hand suturing is still the most frequently employed method and remains fraught with dangers and difficulties. Needlestick injuries — where a used needle pierces both the protective clothing and skin of a medical practitioner — are a major cause of potential pathogen spread. Following the on-going Ebola outbreak in West Africa, such injuries have once again been brought into the public's attention. Two medical professionals were recently evacuated from the outbreak area to quarantine in London, having both suffered needle stick injuries in unrelated cases.

Beyond these high-profile, if relatively isolated cases, it is believed that up to two million healthcare workers globally suffer needle-stick injuries annually through the use of hypodermic and suturing needles of which 15% (240,000) are directly incurred during suturing. Although not all needle-stick injuries go on to cause further medical issues such as infection or spread of disease, each incident is extremely worrying for the affected individual and costly for them and their employer.

The Sutrue concept aims to address some of the issues surrounding this most ubiquitous of medical procedures.

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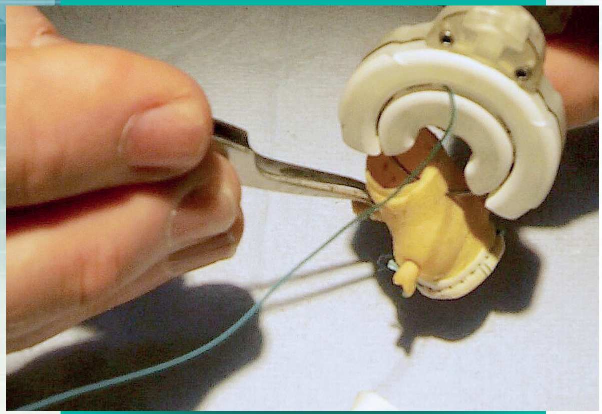
Large head with blunt taper needle suturing transplant heart valve



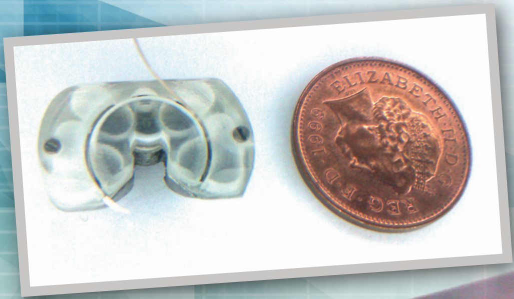
How the Sutrue devices work.
The Sutrue device removes the manual process of passing a needle through tissue by passing a standard swaged needle (which are usually semi-circular or rounded) through a series of rollers, across an open gap, and back into the device. Other devices have been explored using specialised needles, though the cost of logistics made them largely irrelevant.

The combination of rollers and spring plate pass the needle around with more force than is required to achieve the same result by hand. The head of the device then forms its own 'sharps bin', reducing the chance of post-use needlestick injuries in the waste stream.

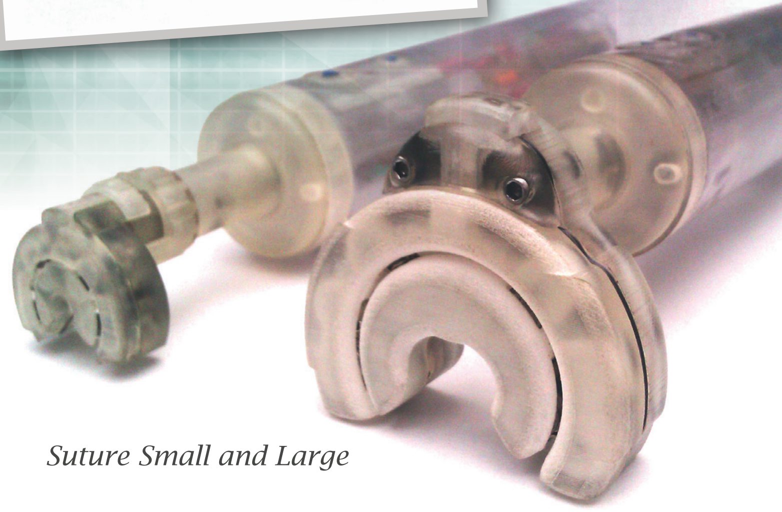
The team aims to make an endoscopic version of the device that can be inserted into the body to perform suturing applications in key-hole surgery.

In many ways, Sutrue epitomises a modern start up company; focussed on solving a problem for the greater good; supported by crowd funding; deploying the most modern tools to help in its endeavours. Not so many years ago a project like Sutrue would have taken years to develop, if indeed it could have been done at all. The use of 3D printing for rapid prototyping changed all that, allowing one-offs with complex geometries to be created (relatively) quickly and cost-effectively. Migration of 3D printing to the desktop represents development of the same order of magnitude.

The design journey included a number of iterations and some major changes



Head of the endoscopic version of the device



Suture Small and Large

Outsourced vs in-house

Sutrue's Alex Berry explained: "In the early days of the company we used to outsource our prototyping to traditional bureau with a turnaround time of about two weeks. You send a part file, then wait a couple of days for a quote then wait a couple of days to agree the quote and get the part made, then wait a couple more days at the end for shipping. So 10 days can easily be swallowed up with the supply of a prototype."

Long lead times for prototypes had knock-on effects elsewhere in the development process too. "When it takes so long to get a part made it's natural to then over-design everything to ensure you get the most value from the process as possible", explained Berry. "If the part is ultimately not fit for purpose you've lost all the design time plus the lead time for the physical prototype — which is deflating. Half of the time you also realise that your design could do with a change because of something you've discovered when working in the 10 days you're waiting for the prototype back… so the parts you do get back are immediately redundant."

Using the Form 1 and later Form 1+ the team behind Sutrue have been able to quickly iterate new design features in house, getting real parts in hand overnight.

The company's solution, which was to bring a majority of their prototyping in-house, would have been inconceivable a few years ago, especially with the demanding accuracy and finish requirements of the Sutrue devices. Salvation came in the form of another crowd-funded hardware startup, Formlabs. Using the Form 1 and later Form 1+ the team behind Sutrue have been able to quickly iterate new design features in house, getting real parts in hand overnight.

"With a printer on the desk next to you, the trend is to under design — to change the smallest attribute of a part, print it, try it and move on," continued Berry. "The design time is reduced, the speed of getting that part in your hand is hugely reduced and the cost comes down dramatically.

"I managed four prints in a day when running iterations of designs for our endoscopic suturing head, which easily have been two months worth of work if each iteration was outsourced."

Owing to the immediate success of the desktop stereolithography format, Formlabs faced delays in dispatching the first shipments of Form 1 printers. "In the time we were waiting for our machine to arrive we spent more on outsourced parts than we did on the machine," said Berry. "The sooner you start using a machine and spending 20p on a part instead of £20 the return on investment is very, very fast."

The Sutrue device prototypes feature an outer casing is clear resin, a laser cut spring plate (which is the key to the function of the device), commercial off-the-shelf internal gears and shafts surgical steel shafts, which Berry explained are actually eyebrow piercings — the shafts have a ball at one end and are already made from surgical. The rollers that grip the needles also use '3D printing' in the form of selective laser melted parts made on Renishaw and Realizer machines.

"We have been able to combine off-the-shelf parts with selective laser melting, stereolithography and laser cut parts at relatively low cost and within months, not years. Without technologies like laser cutting and 3D printing this would have taken an incredible amount of time and money to develop," Berry said.

Limited options

Interestingly, the company had not considered in-house prototyping until the Form 1 was released, feeling that the layer height would not allow the level of accuracy required. Berry explained: "The 25µm layers were of immediate interest to us when we saw the Form 1 — FDM just couldn't get close the surface finish of the SLA process, especially for the endoscopic device which has to pass down a 12 mm tube. The way the support structures joined the part, which itself has recently been greatly improved, also meant the finishing of small complex parts was much less onerous."

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The materials selection for desktop 3D printers is improving all the time, with one in particular of interest to Berry. The castable resin for the Form 1+ could open up new opportunities in the medical device industry where final parts in surgical steel are sought after.

"We have some of the flexible and castable resins from Formlabs and from a medical device point of view the castable is very interesting. Ultimately you want to be looking to surgical steel for the final parts so the ability to cast metals from a print, while retaining the same sort of cost benefits as direct production of prototype is very interesting. If the finish of the parts in castable resin is the same as the clear or white polymer parts at the moment the finish of the cast parts would be better than the finish of an SLM metal part," explained Berry.

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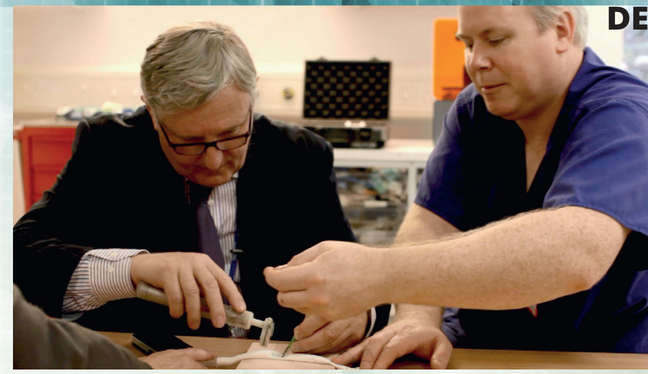

Professor Pepper and Richard Trimett

The company is now looking to produce some parts for its endoscopic device through using this method. When scaled up the polymer is strong enough to withstand the forces needed to drive the needle, but at 1:1 scale some pieces will simply shear and will have to be replaced by metal. "We have another device that we can't talk about too much at the moment that would be used in so-called 'beating heart' operations for which a number of the parts will need to be cast — we're experimenting with that at the moment too," said Berry.

Fuelling collaboration

While the Sutrue device is interesting as a standalone project it is the collaboration between medical professionals and product designers and engineers that signals the biggest potential benefit of this type of workflow. An average development time for a medical device can easily reach ten years, but by employing 3D printing and other modern technologies Berry and his team are hoping to turn around the new beating-heart device in just six months.

Mr Richard Trimlett, a cardiac Surgeon at the Royal Brompton hospital in London, who has been involved in trialling the device, has aided the development of the Sutrue project. Trimlett foresees a future where a surgeon can walk in to see designers and engineers and discuss new product ideas based on the challenges they face in surgery. Berry picked up on this concept: "A lot of surgeons are mechanically minded — many of them work on cars as hobbies — but they maybe don't have the time or design skills to create products themselves. With modern CAD and 3D printing they can start to co-create with trained engineers and solve some really interesting problems. The ability to iterate in a short time scale means that medical professionals can easily stay involved in the process."

Currently the barriers to trying out an idea to see if it's something worth pursuing are too high. By using what they have learned on the Sutrue project the team hopes to be able to collaborate with other medical professionals to develop niche but potentially life-saving products.

Desktop 3D printing in real life

It's clear then that in the right situation having a 3D printer on the desk of the designers and engineers can revolutionise workflows and help develop better products, more quickly. Certainly the use cases are expanding daily, but it's still not something to be approached lightly as Berry explained: "When you first take the 3D printer out of the box, it's brand new and clean and it prints something. There's the worry that new users will experience that and think that the machine is invincible and not take into consideration that it's a complex optical device. It takes maintenance, it's not a toaster!

"You have to keep it in a clean environment, be aware of the temperature variance which can impact the viscosity of the resin and cause parts to fail. Likewise the mirrors and build trays need to be spotlessly clean or you will get failed print after failed print. Impirtantly on the Form 1+, the build trays are consumables too, they don't last indefinitely but they also don't decay in a way that lets you see you have 20 hours of printing left, for example. So if you start getting failed prints try swapping the resin tank for a fresh one and you may find your problem.

"I dripped resin onto the main mirror, didn't realise and once the laser hit it solidified and that was the end of the mirror. Relatively easily done but certainly something to watch for."

As for finishing the parts, Berry bought in a simple but effective piece of kit — a UV light box used for curing finger nail gels in salons: "It's the right size for the parts that come off the Form 1+ and is mirrored inside so that light reaches pretty much every facet of the part. Once the soaking in isopropyl alcohol is complete we stick the parts in the UV box for maybe 30 mins and they come out about as finished as they'll get."

The full Sutrue device, including battery within the main body, in front of the team's Form 1

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