



Machine Solutions Inc.

Automating Stent Crimping

How segmental compression crimping has optimised stent production.

Expanding applications

As the world's population grows older and obesity and diabetes continue to present growing medical problems, advances in minimally invasive procedures to treat coronary and peripheral vascular disease are certain. A stent is made from biocompatible metals and acts as a scaffold within the vessel to restore its natural diameter. To deploy a stent it must first be attached to the balloon portion of an angioplasty catheter for insertion into the body, a process known as crimping. The balloon is inflated and the stent is deployed and embedded into the vessel wall. The balloon is then deflated and removed leaving the expanded stent in place. More than 400,000 percutaneous coronary interventions (PCI) procedures using stents are performed each year. With the introduction of smaller, more flexible and highly specialised stents more patients will be candidates for PCI.

The first stents on the market were bare-metal stents that were used in multiple locations throughout the body with moderate success (Table I). These early stent products were crimped onto

the balloon catheter manually by the doctor or with a split die tool just before insertion into the patient. Over time, doctors found that when crimping at the bedside, contamination was an issue that led to unexpected complications for the patient. There were also major issues with stent retention, crimp repeatability and stent profiles. These included dislodgement of the stent prior to its deployment location and stent profiles being too large to reach the small coronary vessels because of variances between doctors' crimping methods.

The stent market today

There are more than 100 different types of bare-metal stents currently used in PCI. Advances in materials and processes are leading to stents that are more diversified, specialised and capable of achieving increased success rates in smaller, more tortuous areas. New materials such as cobalt chrome and shape memory alloys are replacing stainless steel, and methods of stent manufacturing are broadening to include processes such as electrochemical and laser cutting. Instead of having one stent that works in many arteries, companies are now making

Table I: First stent procedures.

Date	Company	Product	Application
1990	Johnson and Johnson Interventional Systems	PALMAZ stent (a bare metal stent)	Bile duct obstructions
1991	Johnson and Johnson Interventional Systems	PALMAZ stent	Iliac artery
1994	Guidant	Bare metal stent products	Coronary arteries
1994	Medtronic Vascular	Wiktor stent	Coronary arteries
1994	SCIMED Life Systems	Ultraflex	Oesophageal stent

stents for each unique vessel configuration with the stent structure being designed specifically for the needs of each type of vasculature including tortuosity, lumen diameter and vessel strength. In addition to stent designs and material specialisation, manufacturers are also looking for the best way to process their stents to realise an advantage over their competitors and reduce their costs. Stent products that can demonstrate higher retention forces (the force it takes to dislodge a stent from its deployment balloon) or a more uniform expansion within the stenosis or blockage are going to have market and clinical advantages. In addition, the stent with the smallest profile and greatest flexibility will have more success in coronary vessels than its competitors.

Factory crimping

To improve these stent parameters and avoid contamination, manufacturers have moved to mechanically crimping the stents in the factory, just prior to

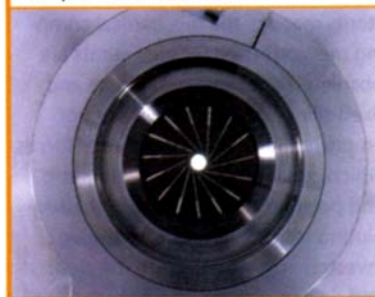
packaging and sterilisation. Many different methods are used for factory crimping such as segmental compression, flat plate, fixed-die clamshell and bladder technology. Automated mechanical crimping techniques have minimised the risk of contamination. The mechanical systems in the factory are able to apply greater and more uniform forces to the stent than the doctors can by hand. This means they are able to achieve a smaller profile, improve retention, repeatability and ensure that all segments of the stent are evenly compressed, which enables uniform expansion. As the stent market becomes more competitive, companies will strive to maintain their profit margins by looking for the crimping technique that can consistently give them the results they need with high volumes and high yields.

Segmental compression

Segmental compression has become the industry standard for automated mechanical crimping of balloon-

expandable and selfexpanding vascular stents that are bare, polymer coated or drug eluting. The technique, invented by Tom Molsenbocker (US patent 6629350 and others pending), employs multiple segments that come together to apply an even, radial compression around the entire stent with minimal shear while maintaining the stent's surface integrity. Figure 1 shows a segmental-compression mechanism. This type of crimping has been found to →

Figure 1: Close-up of a segmental-compression mechanism.



→ optimise stent profiles, increase stent retention, protect the edges of the stent, improve yields and decrease cycle times by eliminating operator variances and providing semiautomation. These advantages are achieved through the use of an even, uniform compression, increased radial force and the use of options such as thermal energy.

The future

The stent market is continually advancing and manufacturers' crimping methods and processes must be able to accommodate these changes. With the recent introduction of drug-eluting stents many of the mechanical crimping methods used for bare stents are obsolete. For example, flat plate and fixed-die clamshell designs are not employed because of high shear forces, which could easily damage the drug and polymer coatings. Also with drug-eluting stents, manufacturers have invested more money into the stent and delivery system and cannot afford

to lose product during the final crimping process. Segmental compression technology offers the greatest benefits and least risk for crimping drug-eluting stents. At the factory, the process can be monitored and controlled, and yields can be maximised by applying a consistent and uniform radial compression that is repeatable over time.

Medical advances will continue on from drug-eluting stents. Bioresorbable stents, gene-eluting stents and stents integrated with tissue such as heart valves are at various stages of research and development around the world. In some cases it may not be possible to sterilise these products in their crimped state, which will result in the need for highly repeatable crimping at the bedside. For example, clinical studies are underway on stents that are designed so that just prior to insertion doctors can crimp and load percutaneous heart valves into their delivery sheaths. The bovine valve product needs to be stored at its full size in an

aqueous solution to ensure the integrity of the delicate valve, which cannot be sterilised with the delivery system. Whatever the future holds, manufacturers need to ensure that they are getting all the possible benefits out of their crimping process. [mch](#)

Melissa Lachowitz, MS BME

is Project Engineer at Machine Solutions Inc., 2901 West Shamrell Blvd Suite 101, Flagstaff, Arizona 86001, USA, tel. +1 928 556 3109 e-mail: info@machinesolutions.org www.machinesolutions.org