The Art of Stent Laser Processing

Abstract

Precision laser processing of medical stents is a current manufacturing method utilized around the world. In this presentation stent material, cutting techniques, finishing techniques, and inspection techniques are looked into. Tools considered include lasers, optics, positioning systems, and CNC programs. With proper care taken, precision laser processing does result in the production of medical components suitable for implant in the human vascular system.

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given at MedTec China 2009
September 9, 2009

Understanding the laser processing of medical stents starts with an understanding of the use of the stent. In the early 1990s the stent was developed by the cardiovascular surgeon as a solution to prop open traumatized vessels. Basically, all stents need to have a few specific characteristics; 1) flexible in order to travel through the vascular system for delivery, 2) compliant for deployment and in order to provide support for various vessel anatomies, 3) compatible in order to be implanted and as much as possible, invisible to the body.

Today, doctors and engineers are designing stents for innumerable applications. These applications revert from the original coronary vascular to the peripheral vascular. Other applications span birth control to kidney stone pain control. Still more applications include esophageal and gastro intestinal uses. Each application requires unique design and functional criteria. This presentation will not focus on design for the above reasons. Also, specific designs result in legal NDAs for initial project secrecy. Instead we will focus on pre-requisites, tools, and technique for successful manufacturing of most any stent requirement from metal tube.

Material

Acceptable material is a pre-requisite for achieving the goal of an artful stent. Material selection is chosen because of the various characteristics required for the application. We do not claim to be a materials expert so this discussion has been left for others. Material quality is critical, however. Variation is the death of a great stent design. Material Outside Diameter (OD) control is required for positional accuracy effecting strut variation. Specification of +/- 0.0125 millimeter are normal and +/-0.0075 millimeter are exceptional. The tighter the better but as always, there is a price to pay. Wall thickness consistency is the other regular problem. Requirements of +/-0.025 millimeter are common but problematic. Recent requirements are normally +/-0.0125 millimeter or tighter and are helpful. Consistency on these specifications over the production lot is critical and consistency from lot to lot is necessary.

Three of the “un-seeable” material characteristics that affect the stent effectiveness are inclusions, cold work, and chemistry. Chemistry is certified by the ingot vendor and is normally consistent. With nitinol, the amount of cold work from the last anneal during drawing is important. This state of the material does not affect laser cutting but does affect the stent characteristic for final shape transition. Almost any inclusions will always create scrap stents that can not be found until final visual inspection after significant added value has already occurred. Prior to delivery of the tube for stent production, the premier tube vendors are screening for inclusions on every tube shipped. However, defects in the ID are generally undetected until processing has occurred.

Tools

Lasers are a key tool to the manufacture of medical stents from metal tube. However, the laser is only one part in a complex system for successful precision tubular component manufacturing. Also to be considered are the laser delivery and optics, the precision material positioning system and the CNC program concepts. All of these components working together are required to produce functional reproducible medical stents. Manufacturers of stents do not consider talking about these details to be advantageous. Generally manufacturers prefer to focus on improving what they are personally doing to improve the system precision and accuracy. Any advantage that can be offered to a customer will be beneficial to the manufacturer and the customer alike.

Lasers provide the energy to melt the tube material, cutting out the stent pattern. Some lasers use enough energy per pulse that ablation, not melting, is the primary method of metal removal. The different laser manufacturers will argue one capability versus the other. How the laser energy is generated is not as important as a few laser characteristics. For our discussion I would like to focus on beam quality, kerf size, pulse width, and pulse frequency.

Beam quality or mode is a key. Often a Gaussian or bell curve mode is preferred. At times the Gaussian mode can result in more Heating Affected Zone (HAZ) because the edges of the laser energy are not hot enough to melt metal but still add heat to the tube. Some lasers utilize more top-hat modes with sharp edges for “biting” into the edge of the metal. These can offer advantages in the cutting operations like piercing and slag. The key to laser beam quality is delivery of the most repeatable packet of energy into the smallest physical space.

Also a consideration is optics for beam delivery and for the cutting head. Some laser energy is produced in a fiber and delivered via fiber to the cutting head. Matching the cutting head optics with the fiber output is a key in these systems. YAG lasers tend to use reflective optics instead of fiber delivery. The key for these systems is to build in enough beam position adjustment to have the flexibility to point the beam where needed while keeping the mode excellent. Optics protection and cleanliness are always important to laser beam quality. Good protection and cleanliness are invisible to the operator. Poor lens protection and cleanliness make for poorly cut parts.

Once the laser melts the tube metal, a compressed gas running coaxially with the laser can eject the liquid metal to create an opening though the wall of the tube. Traversing the tube under the laser with a drive system creates a slice or kerf in the tube wall. Kerf size or beam width is a key characteristic that is utilized by stent designers. Designers utilize tube surface with care so the smaller the beam the more features can be planned for the component. A result of better use of the tube surface means smaller tube selection by the designer. Smaller tubes in turn mean smaller delivery catheters for the stent design. As stent tubing gets thicker the beam size does need to grow a bit for better removal of slag and removal of the cutouts.

Pulse width and frequency are very much a function of the various laser system capabilities. Some lasers have the ability to produce pulse widths in the micro second lengths and some can produce pulse widths in the femtosecond lengths. The lasers capable of micro second pulses deliver power faster which does affect HAZ on the stent geometry while the femtosecond pulse lasers positively result in no HAZ but normally sacrifice cut speed. Pulse frequency is how fast the laser system puts out each pulse of energy on the tube. Frequency is very much laser dependant but typical values are 100 Hz to 10,000 Hz dependent on the system. The new femtosecond lasers can pulse near 500,000 Hz. The combination of pulse width and frequency bring the average power to the tube for the laser cutting result. The speed, therefore economics, of the laser cutting process is quite dependant on these factors.

The best laser will mean little if a poor positioning and holding systems are utilized to move the stent tube during cutting. Motion system positioning accuracies of better than 1 micron are normal for this type of hardware. Linear drives and concentric motor encoders are helpful. However, because many systems utilize wet processing, protecting and maintenance of the drives is a significant consideration. Tube holding hardware usually consists of a collet system and a bushing type system for location. Proper clamping force on the collet during the laser cutting cycle will not damage the tube OD and also not allow slipping of the tube during the cutting operation. Bushing fit to the tube OD is crucial for minimizing stent measurement variation. Tube OD variation within a single tube length is a problem. Careful fitting the tube to the bushing is necessary.

Cutting Techniques

Once the laser / drive system is in place and the tube is fit well into the system the CNC program is the next focus. Programming a stent is not a trivial activity. Critical areas for stent fatigue must be considered for proper positioning of the start / stop points. Breaking the laser cut pattern into sections to minimize cutting far from the locating bushing interface is important for precision. Programming so the laser cut pattern is not pulled into the bushing surface is important. Utilizing laser beam lead-ins where possible will minimize over heating the stent strut edge is important. Consideration of the scrap material removal and potentially cutting these pieces smaller needs to be thought through.

While the stent pattern is being cut by the laser, maintaining a positive drive connection to the tube stock is a must. Design of the CNC program to incorporate tube drive contact points and precision removal of these contact points as the last step of the stent cutoff is critical. Many cosmetic defects can appear because of this last cut activity. Also, stent crowns are usually one of the most stressed parts of the stent design during use. The location of the stent crowns make them the most convenient drive points for the stent cutting processing. Therefore, they do make the best drive points but any material defect during the cutoff will result in scrapping the stent.

Another discussion about laser cutting technique will need to include material removal method. At times oxygen laser assisted cutting using the additional heat of the exothermic reaction will remove material faster and leave a cleaner cut stent before secondary processing. This is standard for the coronary stainless or cobalt chrome stent processing. Oxygen assist can also be used for the nitinol stent laser processing and does provide a crisp laser cut strut wall with only a small amount, if any, of brittle burr in the stent ID. Many stent manufacturers prefer this method to inert gas assisted laser processing.

Inert gas assisted laser processing usually requires argon, helium, or a compressed gas mixture during the actual stent processing. The removal method simply becomes the laser supplying the heat for metal melting and the compressed gas adding momentum to the molten metal to eject the material from the laser cut. Consequences of this method include additional material splatter on the OD of the tube/stent at each laser start point and long stringy burrs attached to the bottom on the laser cut edge in the ID of the newly cut stent. Challenges include burr removal and splatter removal before moving forward with other processing. Advantages include less laser heat affected zone on the stent surfaces resulting in less material removal during secondary stent processing and less opportunities for brittle oxides to result in cracks in the stent surfaces. Both advantages are important design considerations.

Finishing Techniques

Many finishing techniques are available for medical stent processing. Typically the stainless or cobalt chrome coronary stents are annealed, pickled, electro-polished and passivated. Cleaning may also be required before they enter a clean room for loading on the delivery balloon. Stent surfaces are usually bright and shiny with no surface defects. Stent struts can be rectangular to square with rounded corners or some requirements are for the rectangular cross-section to be rounded into a wire-like form.

Many of the nickel titanium stents require extensive post laser processing. This secondary processing is very design dependent. Standard processing steps will be honing, shape-setting, micro-blasting, etching and electro-polishing.

Key to the surface finish quality of the finished stent is the electro-polish electrode contact practice with the individual stent design. Often a rotating clip or rotating stent designs are utilized to minimize heat marks or contact marks. However, care must be taken in the system design to assure electrode contact with the stent at all times while the electro-polishing is performed. Stent surface quality is really a result of a well thought out electro-polishing system.

Inspection is no trivial matter

First, each stent when removed from the laser needs to have the scrap material gently removed from between the struts. Care must be taken to not damage the delicate structures. Once this scrap removal is accomplished all stents are visually inspected over 100% of the surface using sufficient magnification. Statistically significant data is collected on the stent production lot before any post laser processing is accomplished in order to assure success of the planned processing. If the critical dimensions result in nominal specifications and ranges then the stents are moved to secondary processing.

Once the stent forming and finishing process is complete, final inspections begin. Proper statistics must be obtained for all critical dimensions on the stent. Strut widths, crown widths, and wall thickness in multiple locations are usually looked over. Overall stent lengths and diameters are documented. 100% visual inspection of all surfaces is performed under magnification in an effort to remove any surface defect. Once all the data is gathered and reviewed, a summary report is generated for the customer's incoming inspection paperwork.

Inspection of variable data is a challenge for small precision stent features. Few inspection systems have the precision to accurately determine feature size and the productivity to make collecting many data points practical. The tool maker's microscope certainly has the precision for inspecting these small features. However, the microscope sacrifices productivity or speed for accuracy. A few computerized video inspection systems achieve both speed and accuracy for collecting the stent characteristics data. Even some of these expensive computerized inspections systems are not always capable of repeatability within accepted percentages of the tighter toleranced stent specifications.

Conclusion

If care is taken, the equipment and processes will normally result in production of quality medical stents utilizing precision laser processing capabilities and secondary finishing techniques. Careful customization is required with these processes to meet each customer's specific requirement. Early collaboration with a precision contract manufacturer will result in vital input during the design stages of the stent development.