New Ultrafast Lasers Expand the State of the Art for Stent Manufacturing

Rajesh Patel, Spectra Physics, and Victor Matylitsky, High Q Laser

Over the past fifty years, vascular intervention technologies have migrated from traditional surgical techniques to less-invasive approaches, and the trend is accelerating. Motivated by compelling evidence of improved clinical outcomes and more rapid healing, as well as the promise of reduced healthcare costs, innovations in such procedures and devices are penetrating the surgical suite. As always, knowledge gained along the way and fresh ideas are fueling the trends for refinement of such interventions, pointing the way to smaller more complex capable medical devices.

As medical device sizes shrink, their designs increasingly push the limits of feature complexity and material properties. Advances in fabrication technologies must keep pace with the demands of cost-effectively manufacturing these increasingly micro-scale, sophisticated devices. The flexibility, superior machining results and lower operating costs achievable with lasers continue to offer pathways to meeting the challenges. And innovations in laser technology itself hold great promise for keeping laser micromachining solidly in place as a technology of choice for advanced high-volume medical device manufacturing.

Laser Cutting of Stents

Since their introduction in 1986, stents have transformed the treatment of coronary heart disease and other arterial occlusions. Laser fusion cutting was employed in stent fabrication almost from the start, with great success. Early-generation stents were made from stainless steel tubes of 2.5 - 4.0 mm diameter. Part geometries and features were relatively simple and feature tolerances could be ± 25µm or more.[1] Laser cutting, implemented with nanosecond-duration pulsed infrared lasers, easily met the accuracy requirements for machining at this level. Cut quality, however, has been a somewhat different story.

Thermal interactions of the nanosecond laser pulses with the metal generally result in non-optimal surface finish on metal parts. In addition, heat deposition in the material results in heat affected zone (HAZ) bordering the cut edges. These effects have meant development and refinement of several post-processing steps. Cleaning, deburring, etching, and final polishing are routinely employed to bring the stent's surface properties to the level and consistency required of implantable devices.

Stents on the Move: Design and Usage Trends

The success of stent-based intervention in unblocking larger coronary arteries has motivated the expansion of their application. Smaller or more-complex coronary vessels as well as thinner peripheral and neurovascular vessels thus have become targets for vascular interventions. Stent makers have thus been motivated to work with thinner-walled and smaller-diameter tubes with smaller, more complex features.

Materials have changed, too. From stainless steel, the first migration was to shape memory alloys, specifically nickel-titanium (nitinol). This material's ability to self-expand without the use of a balloon expander was key factor enabling application in longer sections of larger coronary arteries. However, smaller devices placed in more torturous or mobile arterial terrain places heavy stresses on stent, increasing chances of its failure. This motivated a second material migration, this time to high-strength superalloys such as cobalt-chromium.

Manufacturing Processes Keeping Pace

These usage trends, and the design changes driven by them, have important ramifications for manufacturing methods. In the simplest terms, finer features with necessarily tighter tolerances are more challenging to produce with high repeatability and yield. Also, HAZ starts to become a limiting factor: for the smaller stents it is difficult or impossible to remove it by post processing. And then there's the increased effect of laser-induced heat loading on dimensional stability or consistency.

Post processing techniques need to be refined, too, to avoid damaging the more fragile features of the micro-stents and impacting manufacturing yield. In some cases, post processing isn't even an option.

If You Can't Stand the Heat…

The old adage has it that you exit the kitchen. Fortunately for the stent industry, a laser solution is at hand that avoids the heat input of traditional fusion cutting while meeting the precision and speed challenges mentioned above. At pulse duration of tens of nanoseconds, conventional pulsed lasers remove material through heat.

Enter so-called ultrashort pulse (USP) lasers. Here, pulse durations are reduced to hundreds of femtoseconds (fs), some 100,000 times shorter than that of conventional nanosecond (ns) lasers, and some very different physics occurs when pulses hit the target material. The laser energy enters the material and departs almost instantaneously before it can be transferred within the material as heat.

The result is often called “cold” or “athermal” laser ablation. Its salient characteristic is the remarkably clean micro-scale machined features it produces, generally free of burrs, melting, re-cast and HAZ.

USP lasers have been around for several decades. Until recently, though, they were cumbersome, complex, and expensive. More importantly, they were low powered and not robust or stable enough to sustain the demands of the production floor. Also, the higher capital and operating costs of these lasers as compared to ns lasers, their use was rarely economically viable. If these barriers were to be removed, however, significant value could be realized for stent manufacturing, in that the post-processing steps could be greatly simplified, reduced in number, or even eliminated.

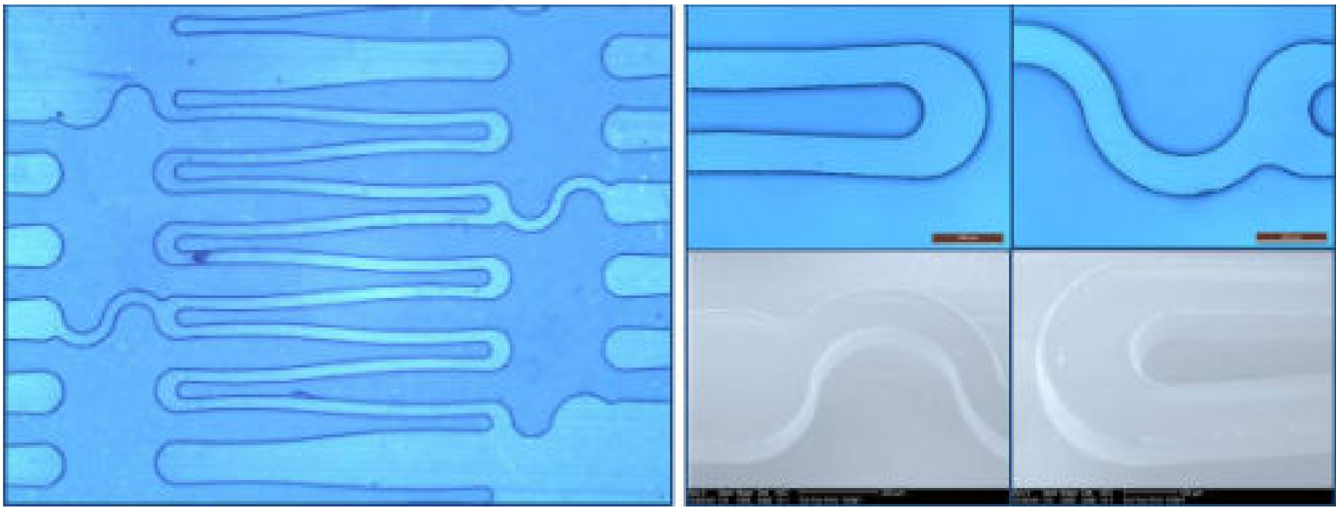
Yet until recently the goal of a reliable industrial femtosecond laser suitable for the high-volume 24x7 manufacturing environment has remained elusive.

Figure 1 shows Spectra Physics’ new Spirit laser industrial femtosecond (fs) laser. Compact and engineered to be rugged and reliable enough for the shop floor, Spirit delivers eight watts of power in the form of high-energy fs pulses at high pulse repetition frequencies (PRFs). The PRF is an important factor governing how quickly the beam may be moved over the workpiece during machining operations, which dictates processing speed.

Figure 2 shows a micro-stent machined by the Spirit laser. Key characteristics include tight machining tolerances, absence of HAZ, no heat-induced distortion of the delicate lattice structure, and very clean cut edges.

The Road Ahead

No discussion of high-performance stent technology would be complete without mention of bioresorbable stent materials, which may represent the future of the stent market. This third-generation devices machined from polymers that, after serving their purpose of propping open occluded vessels, dissolve in the human body.



A challenge from manufacturing perspective, is that polylactic acid (PLLA) and polyglycolic acid (PLGA), the low-melting-point materials used today in some of the bioresorbable stents, cannot tolerate the heat effects of conventional ns-laser machining. Here, athermal ablation carried out by fs lasers such as Spirit is not just a means of reducing costs. Rather, these lasers fundamentally enable the bioresorbable technology by providing a viable manufacturing solution. Figure 3 shows some recent results achieved with the Spirit laser in PLLA.

So where leads the road ahead for stents and the broader medical device industry? Current device trends will continue, driving the need to machine smaller parts with tinier features and tighter tolerances. Post processing will become more problematic as devices become more delicate, imparting larger yield losses. Doing away with post processing will become increasingly attractive, particularly as bioresorbable materials enter the scene. And laser micromachining will continue to support these trends as athermal ablation processes, delivered by the new generation of fs lasers, overcome the barriers encountered by ns-laser machining. New lasers such as Spectra Physics' Spirit laser will finally deliver on the long-held promise of USP laser technology: precise athermal micromachining that is robust, reliable and fast for industrial manufacturing environments.

References
[1] Michaels, B. Advanced machining processes are key to manufacturing tomorrow's stents. MPMN 2011; 27(7).