

Laser Micromachining for Manufacturing of Medical Implants

David L. Wall

Over the last four to five decades, the use of medical implants for therapeutic applications has exploded. Fueled not only by a better understanding of human physiology, but also by the development of minimally invasive procedures and advances in biocompatible materials, these devices challenged conventional manufacturing methods. Accordingly, the advent of laser micromachining technology has enabled many of these advances.

Laser micromachining is generally defined as machining where component and/or feature dimensions are in the range of 1.0 μm to 1.0 mm. Laser sources span the range from the infrared to the ultraviolet, with infrared lasers (e.g., Nd:YAG and CO₂ lasers) interacting via thermal processes and ultraviolet lasers (e.g., excimer lasers and frequency tripled and quadrupled diode pumped solid state lasers) interacting via photochemical ablation processes. For the smallest micromachined features and highest quality, ultraviolet lasers are generally preferred, particularly for polymer devices. Newer generations of ultrafast lasers, with laser pulse lengths in the picosecond to femtosecond range, are also starting to find application in implant micromachining applications.

A successful micromachining application requires combining three technical capabilities:

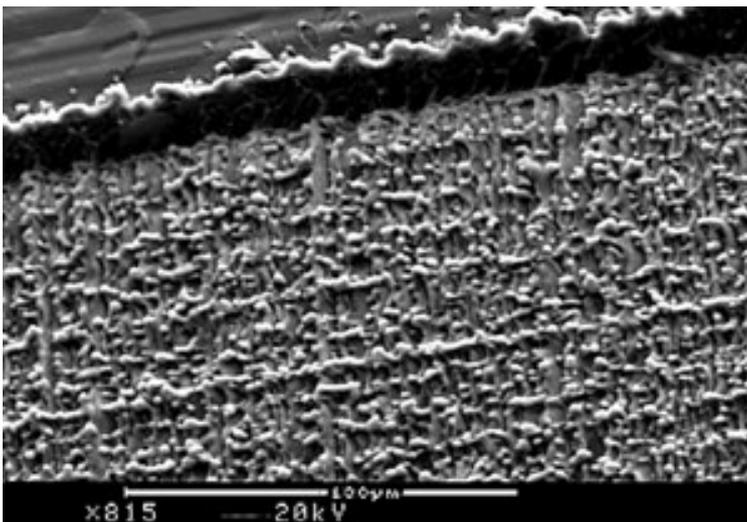


Figure 1: Laser textured titanium alloy surface. Micro to nano scale morphology can be achieved in a clean, non-contact process.

- A detailed understanding of the material properties and photon-material interactions in order to select the proper laser source and operating parameters
- Delivering laser energy to the work piece in a required fashion through efficient optical beam delivery designs and techniques
- Presenting the work piece to the laser beam in a required fashion to accurately and precisely control its motion during processing through the use of multi-axis tooling and automated machine vision alignment methods.

For optical beam delivery requirements for laser micromachining, the system design utilized depends upon the type of laser. For lasers with low order mode, Gaussian beams [e.g., diode pumped solid state lasers (DPSS)], the preferred method is direct write, focal point machining. In this method, the focused laser spot follows the defined cutting path, typically directed using high speed galvanometer optics.

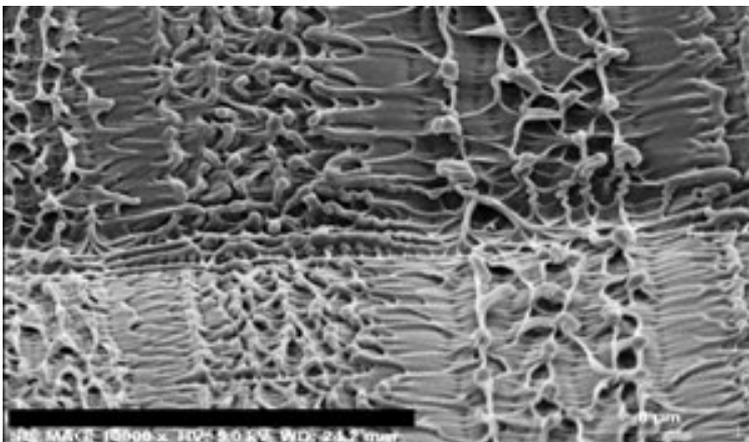


Figure 2: Laser textured polymer surface. Micro to nano scale morphology can be produced in a wide range of polymers.

For lasers with high order mode, non-Gaussian beams (e.g., excimer lasers), the preferred method is mask projection imaging. In this method, the laser illuminates a mask defining the ablation pattern to be used. The resulting pattern is then imaged onto the work piece. Multiple techniques have been developed to perform mask projection imaging on both planar 2D surfaces and 3D shapes.

Examples of Laser Micromachining of Implants

Orthopedics

Most people are familiar with orthopedic implants, such as artificial knees and hips. These are typically fabricated from metal alloys. There are many other implant components that are used in orthopedic applications, such as pedicle screws and fusion cages. Although most components are still fabricated from titanium alloys, many new devices are now fabricated from biocompatible polymers, such as PEEK.

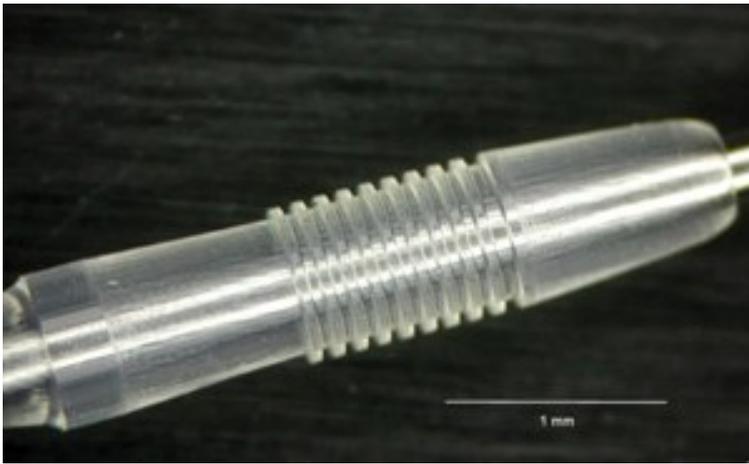


Figure 3: Polymer implant produced using 3D laser micromachining techniques. Lasers allow microfabrication beyond the capabilities of CNC machining.

In all cases, the long term stability of the implant is very dependent upon how well the components integrate with the bony structures. Beyond mechanical designs (to allow for locking geometries), micro-scale surface texturing has been shown to be effective in improving osseointegration. While conventional machining methods are appropriate for manufacture of the implant itself, laser micromachining is ideally suited for surface modification with dimensionalities of tens to hundreds of micrometers down to the nanometer range. Micro-grooves, dimple patterns, moguls, sinusoidal patterns, and similar 3D surfaces can all be produced using laser micromachining methods. Figure 1 illustrates laser texturing of a titanium alloy surface and Figure 2 illustrates laser texturing of a polymer surface. Lasers have other advantages over conventional cutting tools; for example, lasers are not subject to tool wear and do not require cutting fluids or coolants.

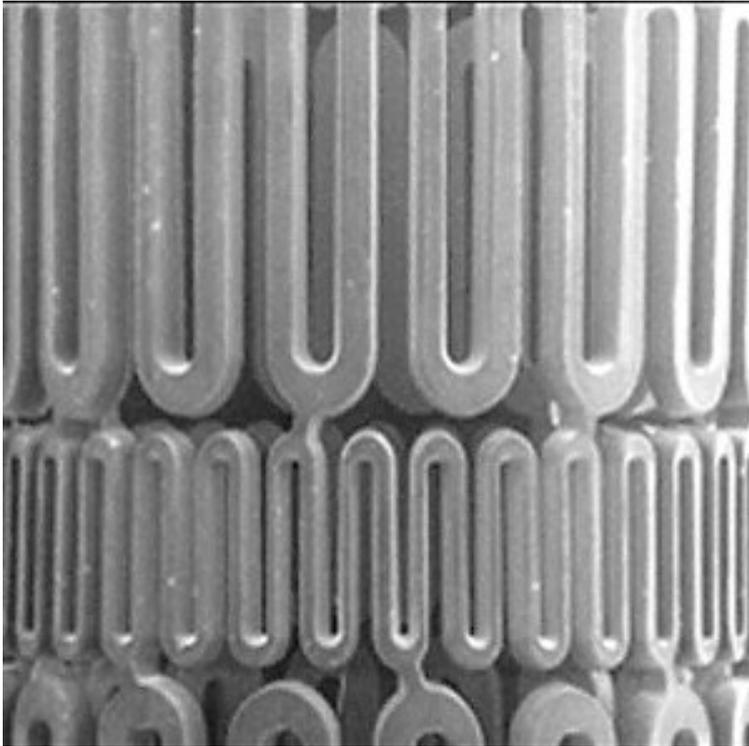


Figure 4: Bioabsorbable stent machined using UV laser micromachining technology. Use of UV photons is key to avoiding alteration of polymer properties from thermal effects.

Another orthopedic application is the use of balloon kyphoplasty for treatment of vertebral compression fractures. For such applications, nine-axis laser drilling technology can be used to drill precise patterns of holes in the balloon to control flow and distribution of bone cement into the fractured bone.

Ophthalmology

Ophthalmological implants are used for the treatment of a variety of conditions, such as glaucoma, uveitis, and cataracts. For such applications, there is a need to miniaturize implant components as much as possible—a perfect match for laser micromachining technology. For example, precision milling and hole drilling are used for glaucoma drainage shunts, drug delivery implants, and intra-ocular lenses. Figure 3 illustrates a polymer component fabricated using laser micromachining similar to a lathing process.

Interventional Cardiology

Stents are one of the most prominent type of implants used for the treatment of cardiovascular disease. Today's stents, both bare metal and drug eluting, are produced using only laser machining technology. The next generation of stents currently under development are fabricated from bioabsorbable polymers (polylactides, polyglycolides, and others), which offer certain advantages. Specifically, these materials are advantageous since the respective drug used can, in some cases, be incorporated directly into the stent material, eliminating a

separate coating step. In addition, these materials naturally break down and are absorbed by the body after their work is completed and the lesion is healed, leaving the artery propped open.

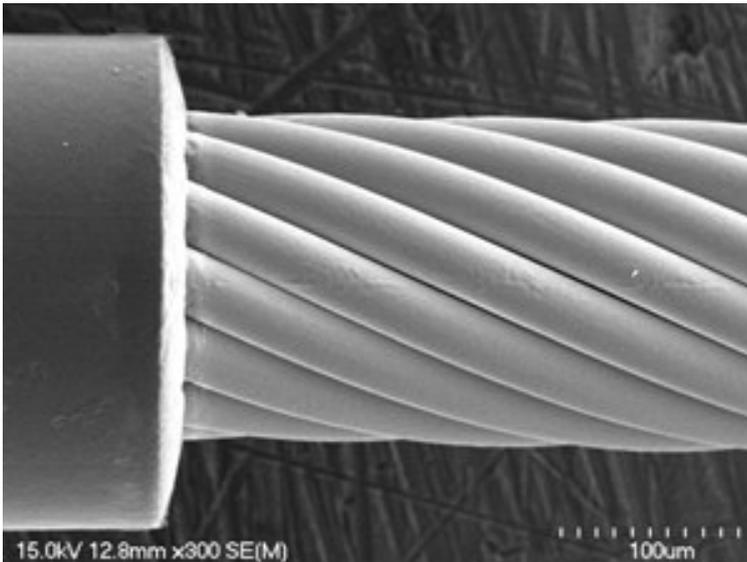


Figure 5: Laser stripped implant lead. Insulation can be cleanly and precisely removed without damage to fine wire filars.

The resorption characteristics of these stents are dictated by the polymer's properties. As such, conventional laser processes (for fabrication of metal stents) cannot be used due to adverse thermal effects on these polymer properties. UV lasers operating at wavelengths below 300 nm (266 nm DPSS lasers and 248 nm and 193 nm excimer lasers) are the preferred lasers for this application, with 193 nm excimer being the laser of choice for many of these polymers based on optimum laser-material interaction properties. Newer generation ultrafast lasers are also finding utility in this field on the basis of minimal thermal input to the material (the pulse length is too short to allow heat to start to diffuse into the material). Figure 4 is an example of a laser micromachined bioabsorbable stent.

Another new development in this area is the use of transcatheter aortic valve implantation. This is a minimally invasive technique for heart valve replacement as an alternative to major open heart surgery. An adjunct to this technique is the use of embolic protection filters to reduce risk of stroke from emboli being produced during placement of the valve. Laser micro-hole drilling of polymer films for embolic protection filters is a long standing laser application with UV excimer laser micromachining being the manufacturing method of choice.

Neurovascular Disease and Neuromodulation

Laser micromachining is also an important technology for the manufacture of devices for treatment of aneurisms for prevention of hemorrhagic stroke. One type of device consists of tiny platinum coils that are inserted into the aneurism (endovascular coiling) to prevent blood flow into the aneurism. Lasers can be used

for highly precise cutting of these small coils, free of burr and slag. In some designs, lasers can also be used to selectively remove polymer coatings from coil assemblies or delivery components. Figure 5 illustrates laser stripping of polymer insulation from an implant lead.

Another application in neurology is implantable electrode arrays for chronic pain management. Spinal cord stimulators are a good example of this technology. Electrode arrays are typically fabricated from multi-lumen polymer catheters with a series of skives to allow placement of metal electrodes. UV laser technology is well suited for precisely cutting these skives without damaging the inner lumen walls. Figure 6 illustrates an example of a skived multi-lumen catheter.

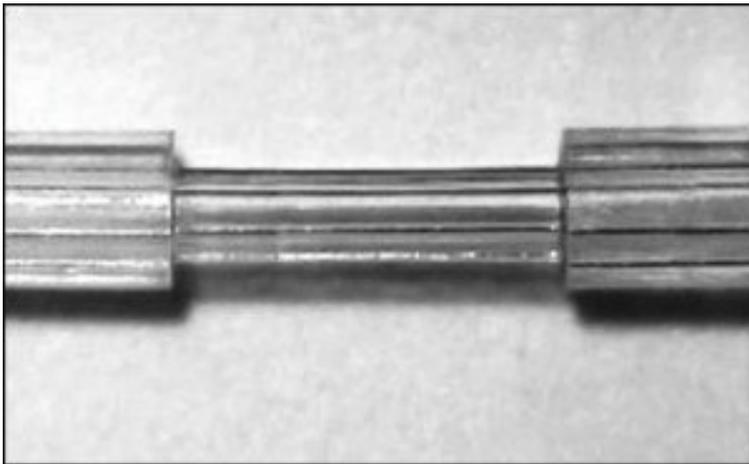


Figure 6: Multi-lumen catheter skived for lead/electrode placement. Laser micromachining provides control necessary to avoid damage to adjacent lumen walls.

Conclusion

The increased use of medical implants in widely ranging therapies has been enabled by advances in biocompatible materials, device miniaturization for minimally invasive procedures, and the development of new manufacturing technologies. Laser micromachining has been in the forefront of these advances due to the micro-scale accuracy and precision it affords and the wide range of materials that can be machined in a highly controlled and cost effective manner. Laser micromachining technology continues to advance to keep pace with the demands of the implant development arena.

David L. Wall is the director of technical sales support at Resonetics LLC [1]. He is responsible for coordinating technical communications between customers and Resonetics' Applications Engineering and R&D groups, and for project management of new contract manufacturing opportunities. Wall can be reached at 603-521-6227 or davewall@resonetics.com [2].

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[1] <http://www.resonetics.com/>

[2] <mailto:davewall@resonetics.com>