Submicron

Today's technological advancements usually fall into one or more of three categories: more features, faster, and/or smaller. Medical devices are not immune to rapid technological change and, in fact, are pushing the envelope, as it has become extremely important to improve time to market, throughput, and tolerances. An interesting example is the manufacture of stents, where manufacturing tolerances have actually reached the submicron level. In addition, because these devices will be inserted into human arteries, they must be free of grooves and burrs and also must be completely hygienic.

• *Ken Hetrick* •

To review typical manufacturing requirements of stents:

- They are usually manufactured from stainless steel, nitinol, or a cobalt-based alloy.
- The design is usually a mesh structure or a coil; see Figure 1.
- The materials can be as thin as 25 µm.
- Typical diameters are from 2 to 5 mm.
- Complex geometries require accuracies and cutting tolerances of +/- 2.5 µm.

Just to put some of these numbers into perspective, the diameter of a human hair is approximately 100 µm, so the entire wall thickness of the material in a stent is 25% the thickness of a human hair. By reviewing these numbers, it is easy to understand the difficulties of ensuring quality manufacturing. But what is the best method of production to meet these tight tolerances?

Figure 1. A typical stent.

Laser processing

Due to its unique capabilities, laser processing has become the predominant method of cutting, ablating, and welding materials for stent manufacturing. Compared to other cutting methods, laser processing produces very smooth

accuracy in stent manufacturing

edges that substantially reduce the finishing process. Another laser processing benefit is the ability to make intricate design cuts with extreme precision and accuracy. These factors allow the system to be more cost-effective as well as to improve throughput.
The ideal laser-machining center will produce the highest quality, be highly repeatable, and will optimize the entire process. When designing the laser-machining center there are several factors to consider: the laser, motion equipment, the controller, and the base structure.

Laser

Factors to consider when selecting the laser include: laser power, bandwidth, wavelength, operating frequency, spot size, pulse duration, and beam quality. The choice of laser, which is usually YAG or fiber, will depend on the type of material being cut, the wall thickness of the tube, and the type and cutting detail that is required.

Mechanical equipment

In general, a stent-cutting machine requires a rotary and a linear axis. In its simplest form, this can be accomplished by bolting individual components together. It is then necessary to add some material handling capability. However, due to the inherent errors in the individual components themselves and the bolting of the axes together, and the addition of a material handling system, it is not possible to assemble a truly optimized system.

Improved design

With the push for tighter tolerances and higher throughput, an optimal design that integrates the rotary and linear axes, as well as the collet (material handling) mechanism, provides a better solution. An example of an optimized, integrated system (VascuLathe® series) was developed and patented by Aerotech; see Figure 2. The rotary axis has been designed to integrate directly onto the linear axis so that it is in-line with the linear motor and bearings. This design improves overall system stiffness and increases the resonant frequency. The rotary axis also has an integral pneumatic-activated collet mechanism, effectively reducing system complexity and minimizing the total system moving mass. The system also has an optional wet-cutting configuration for applications that utilize fluid to minimize the heat-affected zone, backwall damage, and to assist in the evacuation of waste material.

The cumulative effect of the VascuLathe's optimized design results in throughput improvements from 200% to 500% when compared to traditional component-level manufacturing approaches, while still maintaining submicron tolerances on tight part geometries. When comparing the VascuLathe to component-based systems, the following error was reduced from roughly 3.25 microns to 0.75 microns.

Controller

In addition to selecting the proper mechanical stages, it is equally important to choose an appropriate multi-axis motion controller. An example of a feature-rich multi-axis controller that is very good for medical device

Figure 2. Aerotech's VascuLathe integrated, optimized stent-manufacturing platform.

manufacturing, Aerotech presents Automation 3200, a software-based controller that offers up to 32 axes of synchronous motion. Key A3200 features used in medical stent manufacturing include contoured motion, PSO laser triggering, circumferential units, and multi-block look-ahead.

One feature that is extremely useful is the ability to program in circumferential units. By specifying the diameter of the cylindrical part, a program can be written as if it were in XY space. The program then translates the XY coordinates onto the cylindrical part and cuts accordingly.

Another feature that is essential for cutting small circles or arcs on a cylindrical part is contoured motion. This refers to motion in which multiple axes are required to work in conjunction with each other. The A3200 is not only capable of providing contoured motion, but also utilizes an advanced feature called 'multi-block look-ahead' to optimize cutting velocity as a function of part geometry; see Figure 3. While executing a program, the multi-block look-ahead function is constantly reviewing lines of code that execute later in the program. Accelerations induced by arcs and circles in the part are calculated by the look-ahead function and compared to a threshold acceleration value defined by the user. If the acceleration in an arc is above the allowable threshold, the controller will slow the cutting speed before the part feature is processed to ensure that the acceleration limit is not exceeded. Once the feature has been processed the programmed cutting velocity resumes. By adjusting the acceleration limit in the program, it is possible to directly control the part accuracy and system throughput. Reducing the acceleration limit results in lower position errors and longer processing times. Higher acceleration settings result in increased position error and increased system throughput.

Another key feature is the A3200's ability to trigger and control the laser based on position. PSO (Position Synchronized Output) uses a combination of hardware and software to allow laser triggering to be based on the actual position of the axes. When used in combination with multi-block look-ahead the PSO function will ensure consistent laser beam spot overlap as the cutting velocity changes, resulting in improved edge quality and reduced heat-affected zone.

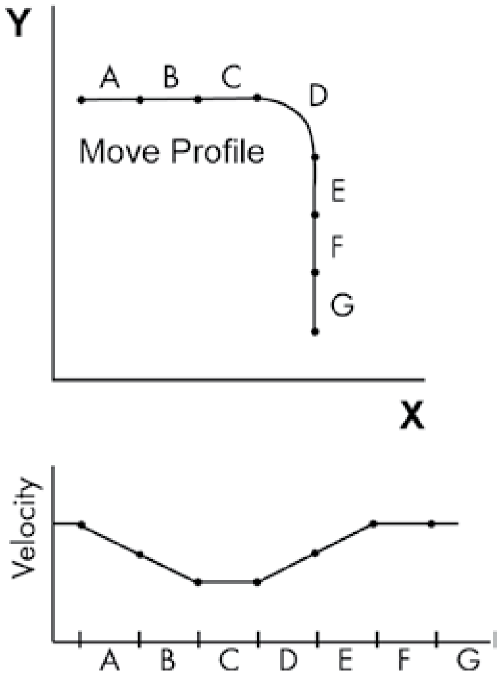

Figure 3. Contoured motion is facilitated by the multi-block look-ahead feature, which allows the controller to anticipate sharp corners and small radius arcs and automatically accelerate and decelerate as needed.

Base structure

The base structure includes the machine base, system base plate, and the support for the laser optics. If the system is not optimized for stability, significant errors can occur that will affect the quality of the parts produced. Errors are introduced into the process from high system dynamics transferring energy into the system and thus affecting the system stability and position tracking error during the process. As the axes move, reactive forces are generated within the system. In order to minimize the effects of system dynamics, a stable base structure design is recommended, which may include components such as a granite base plate, elastomeric isolation, and a steel machine base.

The other area of concern is the error that can be created in the differential motion between the part and the laser head. This error is not observable within the control system and thus cannot be corrected through the control loop. The best method for reducing this error is to optimize the stiffness of the structure holding the laser and optics. One recommended method is to provide a solid granite bridge structure to mount the optics and to minimize the length of the unsupported laser head. This design not only provides the necessary support to compensate for the moving axes, but also can support the optics, resulting in improved part quality.

Productivity

To increase productivity, a version was designed that allows simultaneous laser machining for two stents. The precision built into the axes and the ‘electronic gearing’ between the two rotary axes enables two identical stents to be produced. This is particularly advantageous for polymer stents, which require ablating rather than cutting (which is done on metals). The ablation process takes more time than cutting and the time saved to produce two stents makes a considerable difference in production throughput. The cost of adding the second rotary axis turns out to be well worthwhile for polymer stent manufacture.

Author’s note

Ken Hetrick is a senior applications engineer with Aerotech, a key supplier of high-precision, high-throughput motion systems used in manufacturing production, quality control and R&D. Aerotech is headquartered in Pittsburgh (PA, USA), operates sales and service facilities in the UK, Germany, and Japan, and has an office in China. This article is based on an earlier publication in U.S. magazine Today’s Medical Developments.

Figure 4. The VascuLathe DS version, which allows simultaneous laser machining for two stents.

Information

www.aerotech.com