Laser Cutting of Slotted Tube Coronary Stents – State-of-the-Art and Future Developments

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Summary

The cutting process of a slotted tube coronary stent is presented. It is discussed that the applicability of conventional micro-machining techniques by means of industrial laser sources are restricted to a few metals only. For future stents made of bulk materials being more biocompatible than today's most commonly used 316L steel as well as biodegradable stents, special micro-machining processes will be required. A novel laser cutting process based on ultrashort-pulse (femtosecond) lasers will be introduced and its potential for the production of future stent generations will be demonstrated.

Key Words

Coronary stents, biodegradable stent, laser cutting, Nd:YAG laser, femtosecond laser

Introduction

Looking at a stent — an apparently simple medical implant —, one can hardly imagine the amount of research and the complexity of the manufacturing processes necessary to provide the physician and especially the patient with an effective and reliable intravascular device. It is the aim of this article to illustrate the design and cutting process of a balloon-expandable slotted tube steel stent as well as to discuss present manufacturing limitations.

Taking into account the present knowledge of stenting therapy an ideal coronary stent can be defined as summarized in Table 1.

Presently available stents represent a compromise on the properties of an ideal stent. The by far most implanted type of coronary stents are slotted tube designs made of steel (316L) [2]. The reasons why steel is the favorite stent material today are:

- nearly ideal mechanical properties,
- availability of a fast laser-based machining process,
- well established subsequent treatments of the stent preform exist for steel,
- comparatively cheap material.

The major disadvantages of steel, however, are:

- low biocompatibility,
- poor x-ray visibility.

In the following, the production steps for a slotted tube steel stent are described, using the Tenax® (BIOTRONIK, Germany) coronary stent by as an example. Moreover, the limitations of the presently applied laser-cutting process and potential future developments will be discussed.

Laser Cutting of a Slotted Tube Stent

Design

By means of computer-aided design (CAD) software, first a preliminary "start" design is generated. Based on detailed finite-element method (FEM) calculations, this design is subsequently optimized with respect to the dilatation behavior, the supporting properties, and the flexibility of the stent. The material properties, such as elasticity, ductility, and material strength, are considered in calculating the behavior of certain geometrical structures under defined acting forces. Such

General Properties

- small outer diameter
- thin struts
- high flexibility
- high expandability
- low elastic recoil after expansion
- low longitudinal contraction after expansion
- sufficient radial stability
- sufficient x-ray visibility

Mechanical Support

- high plastic formability for a large expansion
- high modulus of elasticity (Young's modulus) to minimize the recoil

Surface Properties

- low thrombogenicity
- high biocompatibility
- non-corroding
- growability of endothelial cells

Table 1. Definition of the "ideal" stent [1].

an optimized design is shown in Figure 1. Typically, strut sizes and material thickness of coronary stents are in the range of 50 - 100 µm. The diameter of a (non-expanded) stent is 1 - 2 mm. Using a CAD/CAM (computer-aided manufacturing) software, the CAD file containing the geometrical structure of the stent is translated into a computerized numerical control (CNC) code, which is then interpreted by a high-precision motion system of a laser-based stent cutter and converted into respective translations and rotations.

Laser Cutting

Today lasers are well established and a very flexible tool for producing various micro-structures [3]. Beside marking, drilling, and welding applications, cutting is the most frequently applied laser machining process. Due to its comparatively short fundamental wavelength (1064 nm), the neodymium: yttrium-aluminum-garnet (Nd:YAG) solid-state laser is the laser of choice for micro-structuring applications. A focus diameter — and thus the minimal diameter of the produced cuts — of about 20 - 30 µm can be easily realized. A free-running industrial Nd:YAG laser typically produces pulses with durations in the microsecond and millisecond range. The average laser output power is between 1 to 100 W, depending on the specific application and material parameters.

The principle setup of a laser-based stent cutter is schematically shown in Figure 2. The (fixed) laser beam is focused onto a metal tube, which is mounted on a translation/rotation system. The system moves the tube with respect to the laser beam in order to cut the desired structure into the steel tube. Typically, the positioning precision of the motion system is in the range of 1 - 2 µm.

For metals the laser-cutting process can be performed by melting, by oxygen reaction, and by sublimation [4]. The latter can only be applied if the laser peak power reaches a certain value (e.g., with short-pulse lasers, see below). The advantage of sublimation cutting is that melting and heat-affected zones can be minimized or even avoided. The disadvantage is, however, that the cutting speed is relatively low due to the high evaporation enthalpy of metals. This is the major reason why present industrial laser cutters are predominantly based on melting and oxygen cutting processes. The oxygen cutting has the advantage that high machining speeds can be realized and the disad-

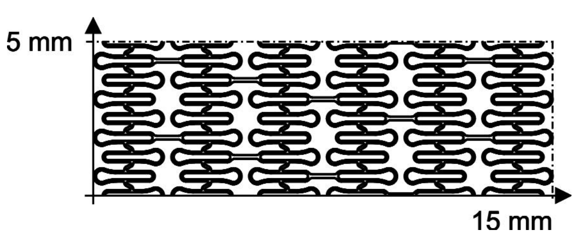


Figure 1. Optimized stent design (BIOTRONIK, Tenax 15).

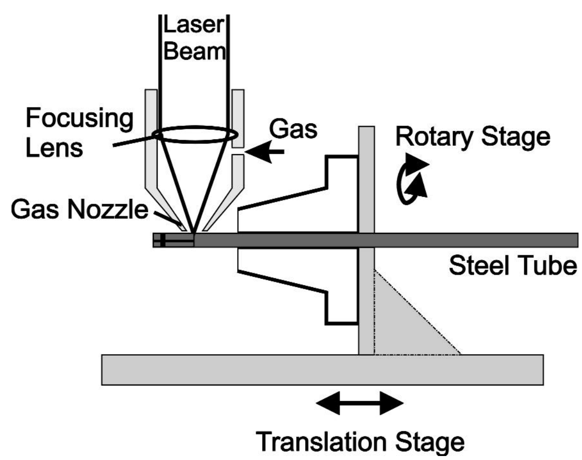


Figure 2. Schematically drawn setup of a laser-based stent cutter.

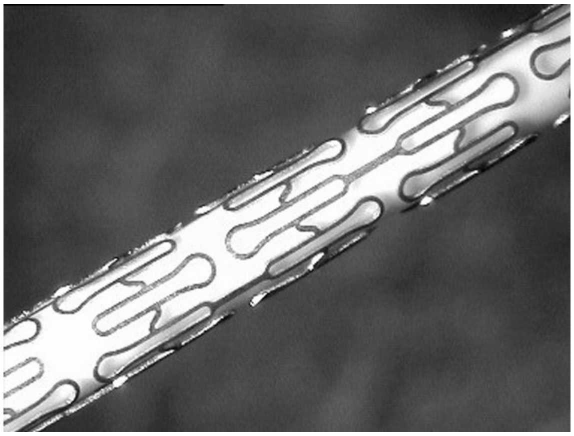


Figure 3. TENAX preform after laser cutting and pickle treatment using an ultrasonic cleaning equipment.

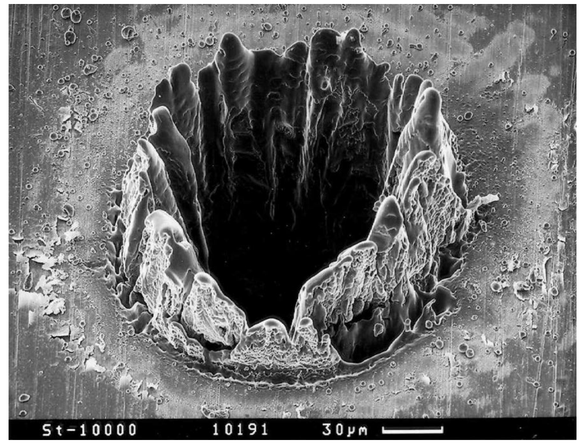


Figure 4. A drilling produced in steel using "long" laser pulses with a duration of 3.3 ns. This scanning-electron microscope (SEM) picture demonstrates the limitations of the conventional laser machining technique. Due to the presence of the liquid phase, a strong burr formation takes place and solidified droplets stick on the surface. Moreover, the heat-affected zone around the hole is clearly visible.

vantage that oxidation occurs at the produced cuts. Both processes lead to strong burr formation and depositions on the material surface. The burr and the depositions must be removed in further production steps, such as special pickle processes, in order to obtain a stent preform quality as shown in Figure 3.

Limitations of the Conventional Laser-Cutting Process

As already mentioned, the stent cutting by means of conventional (Nd:YAG) laser sources, producing pulses with durations in the range of nanoseconds (10^{-9} s) to milliseconds (10^{-3} s), has some limitations. First of all, the thermal load in the material due to heat conduction is relatively high, which results in large heat affected zones and the production of melting. The melting again leads to a significant burr formation at the cutting edges and to a deposition of solidified droplets, sticking on the tube surface.

As an example, Figure 4 shows a hole in steel produced with a laser delivering "long" pulses (3.3 ns duration). The burr formation due to the presence of the liquid phase during drilling (or cutting) and the droplets on the surface can clearly be seen. In stent production, both must be removed by applying several subsequent treatments. Due to the thermal load during laser cutting, the minimum producible strut size is limited. Therefore a significant reduction of the present stent sizes (e.g., for applications in smaller vessels) is not possible. Moreover, a variety of potential materials exist for the bulk of the stent that cannot be structured by this conventional technique. Thus, the demand for an alternative, less invasive laser machining technique is strong. Such a technique will be described in the following.

Future Developments

The laser market is rapidly changing. Some innovations are lasting, and others produce novel types of lasers for various (industrial) applications. In the field of ultrashort-pulse solid-state lasers, an enormous breakthrough was achieved about 15 years ago with the invention of a special amplification technique for laser pulses with durations in picosecond (10^{-12} s) and subpicosecond ranges [5]. This amplification technique (chirped pulse amplification, CPA) enables the generation of ultrashort laser pulses with high energies and peak powers as required for micro-machining applications.

To illustrate the system applied for the investigations described below, Figure 5 shows a schematic drawing of the CPA technique. Basically, the generation of high-power ultrashort laser pulses can be divided into four steps. Low-energy pulses are produced in a laser oscillator. The energy of these pulses is several orders of magnitudes below the ablation threshold of any material. Amplification by at least a factor of 1000 is necessary. Due to the extremely high intensities, how-

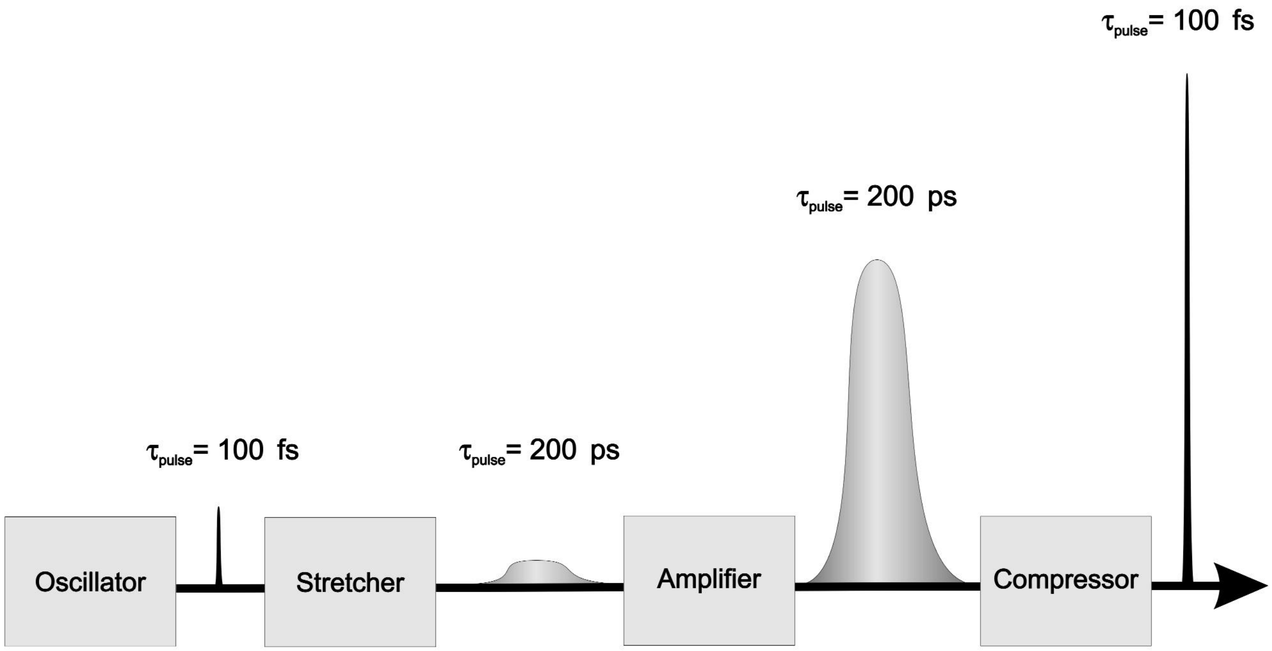


Figure 5. Schematic drawing to illustrate the principle of the Chirped Pulse Amplification (CPA) technique for ultrashort laser pulses. The given pulse durations are typical values for presently applied femtosecond laser systems.

ever, a direct amplification of pulses with picosecond or femtosecond (10^{-15} s) durations would destroy optical amplifier components. The ingenious solution to this problem was reducing the peak power by stretching the pulses temporally [5] according to:

$$P_{peak} = E_{pulse}/t_{pulse}$$

The peak power of a laser pulse (P_{peak}) is reduced by the same amount as the pulse duration (τ_{pulse}) is increased for a constant pulse energy (E_{pulse}). This temporal stretching, however, must be reversible to ensure that the amplified pulses can be recompressed to their original duration after amplification. Figure 5 illustrates the four steps:

1. the pulse generation in the oscillator
2. the pulse stretching by means of a dispersive delay line due to different optical path lengths for the spectral wavelengths of the pulse (i.e., the longer the wavelength, the shorter the optical path)
3. the amplification of the stretched pulse
4. its subsequent recompression in the compressor, which is a similar dispersive delay line as the stretcher but with the reversed effect (longer path lengths for longer wavelengths).

If the stretcher and the compressor are perfectly adjusted with respect to each other, the original pulse duration can be restored.

With the CPA technique reliable and relatively compact solid-state laser systems that produce pulses in the range of 100 fs (1 fs = 10^{-15} s) are available. A special laser machining technique, based on this type of laser, is presently being investigated to evaluate its potential for stent machining. This novel technique offers the opportunity to structure nearly all materials (e.g., metals, ceramics, glass, polymers, organic tissue, etc.) with minimum or no thermal damage [6-9], as demonstrated in Figure 6 for steel. Thus, different materials could be processed for stent bulk, which otherwise could not be structured with conventional (laser) techniques.

Other examples of simple tantalum and titanium geometrical test structures are shown in Figure 7. Except a simple ultrasonic treatment in alcohol, no aftertreatments were applied. The produced cuts are very smooth and completely burr-free, and the outer tube surface is free of deposition. This technique enables metal stents to be produced with very smooth struts and as thin as desired for a variety of applications.

The potential of the femtosecond laser machining technique is even more pronounced in the case of extremely sensitive and delicate materials. For a variety of indications, temporary stents are required that de-

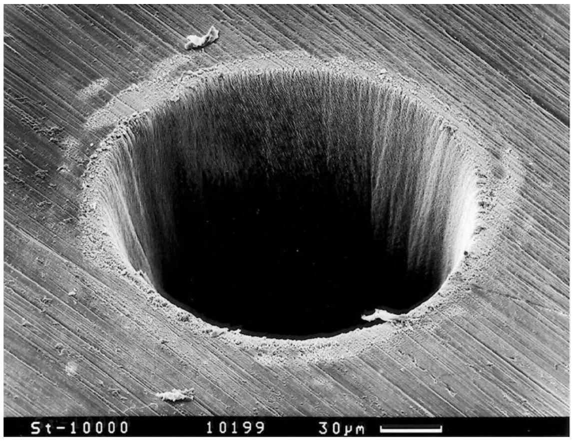
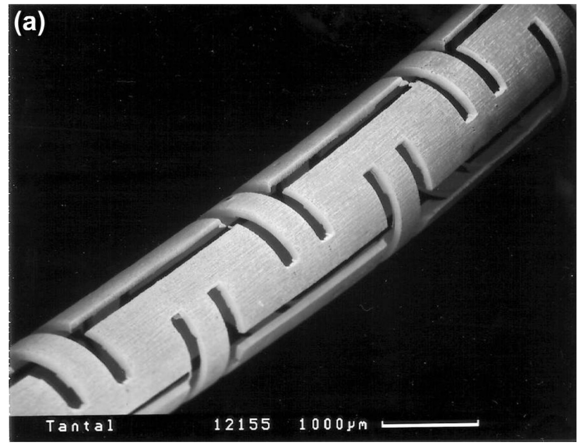


Figure 6. SEM photo of a drilling produced with nearly the same parameters as shown in Figure 4, except the fact that the laser pulse duration was reduced to 200 fs and the pulse energy could be decreased by nearly one order of magnitude in this case.

grade after a defined time. One possibility to produce such a degrading stent is the use of a biocompatible polymer blend, such as poly-(hydroxybutyrate) (PHB) [10] and poly-(L-lactide) (PLLA) [11]. Both polymers are optically transparent and very heat-sensitive materials. At present, no suitable machining process exists for cutting and structuring these polymer blends with the precision required for stent production. The femtosecond laser machining process enables a minimum invasive machining of the polymer substrate with negligible thermal load and no melting at the cutting edges, as demonstrated by the test cuts in a PHB tube (Figure 8). The non-thermal nature of this ablation process is important for polymer stent production to ensure that the material properties (with respect to solubility and elasticity) are maintained, even in the vicinity of the cuts. Presently, polymer stents with different designs are under investigation with regard to their mechanical and degrading behaviors.

Beside polymers, further potential stent materials with a high degree of biocompatibility and biofunctionality are, for example, Nitinol (nickel titanium alloys) [12] and niobium zirconium [13]. Also these materials require a special machining process and are presently under investigation.

In combination with the possibility to produce fine and precise structures, it is expected that the discussed investigations will lead to the realization of novel types of improved and optimized stents in the near future,



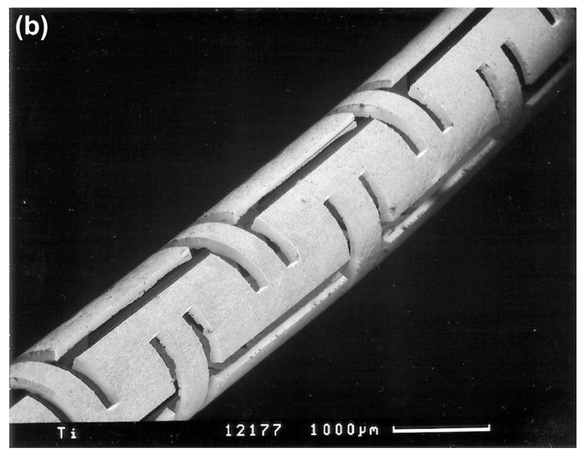


Figure 7. Test structures for stents produced in tantalum (a) and titanium (b).

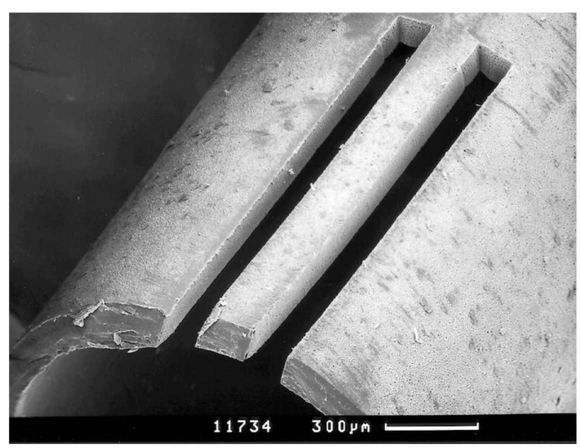


Figure 8. Test cuts produced in a PHB tube, showing that a micro-machining of this very delicate and heat-sensitive material is possible with minimum thermal load and without the creation of melting.

fulfilling all requirements defined in Table 1.

Conclusion

The production steps — from the design development to the laser cutting process — for a slotted steel tube stent have been discussed using the Tenax® as an example. It has been shown that a high micro-machining quality can be obtained for steel with conventional laser-based stent cutters. This is mainly because the use of steel enables effective subsequent treatments to remove the unavoidable melting and deposition. However, this machining process is limited to very few tube materials if a high cutting quality with a precision in the micrometer range is required.

For materials other than steel and especially for polymers, alternative laser machining processes have to be applied and developed. One promising possibility is the use of lasers producing ultrashort pulses with a duration in the femtosecond regime. With these kind of lasers, a treatment of nearly all kinds of material with minimum mechanical and thermal damage has become possible. This novel machining technique is presently under investigation, and its potential for the generation of special and new types of stents will be evaluated.

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