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On the quality and performance issues at laser manufacturing of medical implants

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Annotation: *The present work is dedicated to the design and manufacturing of stents by means of Laser Milling. The key issue is the improvement of the usability of stents with the following approaches: to increase width and to decrease thickness of stent walls in order to lower the pressure on the walls of blood vessels; - to deposit metal coatings on stent walls to increase corrosion resistance of stents and to increase the area of "useful" surface of stents by forming extra grooves ("pockets") that could be used for drugs application on stent walls making stent active surface in terms of drug delivery.*
Technological processes of stent manufacturing were verified experimentally. We used medical needle (wall thickness – 200 microns, inner diameter – 0,8 mm). As a result, 2 mm long stents with wall thickness ranging from 80 microns to 200 microns were manufactured. These stents were implanted into the body of laboratory rat and were inflated to ensure normal blood flow.
Inner protection screen was used (copper rod that was placed inside the tube workpiece and noticed that there was a transfer of screen material (Ti and Cu) on the inner walls of stent.
Keywords: *laser milling*; *laser micromachining*

The application of industrial laser systems with short and ultrashort pulses in laser material processing solved numerous problems in technological processes (presence of heat-affected zone, thermal and mechanical deformations of the workpiece, limitations in the materials selection etc). Although, some problems related to micro processing remained unsolved and still require further investigations [1].

For instance, laser processing is the most popular process at manufacturing of metal medical implants (stents). These cylindrical, thin-walled and mesh-like structures are capable of changing their diameter and withstand certain loads when implanted into the blood vessels. It is worth to mention that the width of a single string is 80 – 100 micron and its thickness is 100 – 200 microns.

There are two major drawbacks that limit the usability of stents:
- blood vessel damage during the stent inflation;
- stent absorption by the walls of blood vessel.

Nowadays, they are solved by covering stent's walls with a thin layer of drugs (one or two microns) with preliminary electro-chemical polishing (the thickness of the removed material is 1 to 10 microns). In some cases, the uneven step between stent's strings is applied or the specific-purpose Ni-based materials are used. But these techniques do not solve main problems:
- relatively small effective area of stent surface;
- high pressure on the walls of blood vessels;
- and limited volume of drugs that cover stent.

The best solution to these problems is to increase the effective area of stent walls (thus it is possible to reduce walls pressure and increase the drug-containing areas of the stent) and to generate gradient layers on stent walls with materials that are bio-neutral and clearly visible in X-rays [2-4].

It was established in this research that apart from the direct laser cutting of stents (that has the smallest travel path of working units) it is possible to apply the technology of laser milling. In this case, the processing time increases significantly but it could be neglected by taking into account numerous benefits that this technology brings:
- control over the thickness of the separate string;

- generation of a microrelief on the stent walls that will be capable to hold greater volume of drugs and will increase the effective area of stent walls (Fig.1).

Fig. 1. Technological schemes of stent's manufacturing, where: a) direct laser cutting; b) direct laser cutting with additional beam scanning; c) laser milling with beam scanning; d) laser milling with mutual movement off laser beam and workpiece

Experiment planning technique was used for the investigation of the outcome and performance of each technological process. Stainless steel 316L tubes with the diameter ranging from 1.8 to 4 mm were used in experiments. It was established that the following factors significantly influence the productivity and quality of laser processing: workpiece travel speed, focal distance of the optical system, laser beam pulse frequency, defocusing of laser beam, protective gas pressure.

In all cases the height of microrelief was no greater than 3 microns and the depth of heat-affected zone was in the range from 3 to 8 microns. Further final polishing evens the stent surface.

It was established that there is no need to minimize the thickness of the cut kerf at stents manufacturing by means of laser cutting. Cut-out fragments stuck and damage the "processed" parts of the stent (Fig.2).

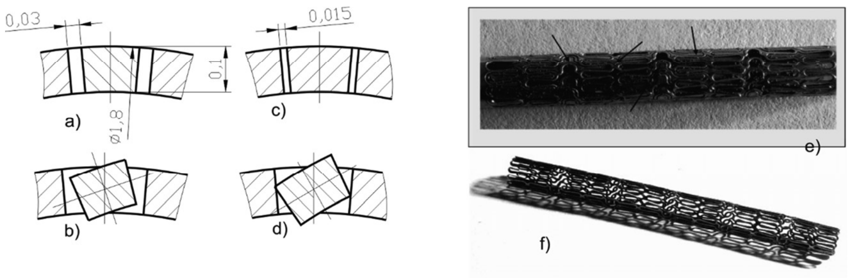

Fig. 2. Schemes of direct laser cutting of stents, where: a) kerf width – 30 microns; b) cut-out fragment leaves processing zone (kerf – 30 microns); a) kerf width – 15 microns; b) cut-out fragment is blocked in the processing zone (kerf – 15 microns); e) manufactured stent with stuck parts (kerf width – 15 microns); f) – ready-to-use manufactured stent (kerf width – 30 microns)

Stents manufactured by direct laser cutting perform well in blood vessels but tend to be covered by blood vessel tissues in a relatively short time and can hold little volume of drugs. All these drawbacks could be eliminated with help of laser milling technique [5-6].

It is possible to remove material layer by layer with step up to 5 microns and create "complex" microrelief with "pockets" that are 10 microns deep, could have a diameter ranging from 5 to 15 microns and can hold significantly greater volume of drugs that prevent the stent’s absorption. Moreover, it is possible to minimize the thickness of stent’s strings and to maximize the width of stent’s strings keeping the stent’s flexibility unchanged. All these measures prevent stent from the absorption by the blood vessel tissues (Fig.3).

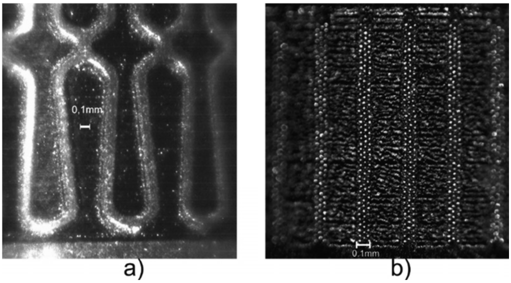

Fig. 3. Intermediate stages of stent’s manufacturing by means of laser milling technique, where: a) stent’s pattern generation with layer by layer milling; b) simultaneous “pocket” generation on stent’s strings at laser milling

If a protective screen is used (metal rod installed within the tube workpiece its surface vaporizes under the influence of focused laser beam and deposits on the inner walls of the workpiece from plasma plume (Fig.4).

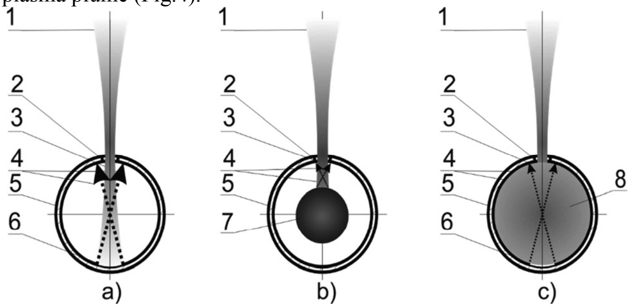

Fig. 4. Technological schemes of stent’s manufacturing by means of focused laser beam without the protective screen (a), with metal rod used as a protective screen (b) and with cooling liquid used as a protective screen (c), where: 1 – laser beam, 2 – laser beam processing zone, 3 – laser beam that passes through the processing zone, 4 – reflected laser beam, 5 – workpiece, 6 – heat affected zone, 7 – metal rod, 8 – cooling liquid.

Two different protective screens were used – copper and titanium rods with the diameter of 1 mm. Deposition of these materials on the surface of the workpiece was detected (Fig.5).

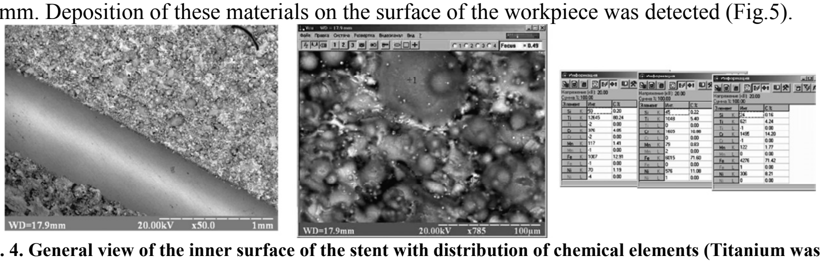

Fig. 4. General view of the inner surface of the stent with distribution of chemical elements (Titanium was used as a protective screen.

It means that if noble and bio-neutral materials are used as a protective screen it is possible to cover the inner walls of the stent with a thin layers that would prolong stent's lifetime. The penetration depth of the deposited layer is up to 10 microns. What is more, when the tantalum is used as a protective screen, it is possible to create a coating that would be non-transparent for the X-rays thus making the stent's location traceable.

Therefore, the micromachining of stents could be done both by direct laser cutting and laser milling. The latter one opens new prospects for the development of unique stent designs. The use of noble materials as protective screens at laser processing brings new opportunities for the formation of coatings with pre-defined properties.

Питання якості та працездатності при лазерному виробництві медичних імплантів

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Анотація: *Поява промислових лазерних систем, які генерують лазерні імпульси з надкороткою протяжністю у часі (піко та фемпто лазери) дозволила зняти багато проблем, які властиві лазерній мікрообробці (вести обробку практично будь-яких матеріалів без зон термічного впливу та деформацій оброблених виробів). Проте існують певні проблеми, вирішення яких потребують подальших ретельних досліджень.*

Розглянемо деякі з них на прикладі медичних ендопротезів, які виготовленні з металевих матеріалів. Як відомо, стент - це «сітко» подібна металева циліндрична конструкція, яка здатна змінювати свій діаметр і при цьому витримувати певні навантаження. Варто зазначити, що ширина окремої нитки складає 80-100мкм, товщина 100-200мкм а отже застосування лазерів для їх виготовлення є майже стандартною процедурою.

Було встановлено, що після вставлення стента відбувається його «поглинання» артерією а також можливе пошкодження артерії стентом під час його розкриття . Для вирішення даних проблем в даний час на поверхню ендопротеза наноситься шар лікарських засобів (товщина декілька мкм), причому попередньо поверхня стента ретельно обробляється за допомогою електрохімічного полірування (знімаємий припуск - 1-10мкм) до дзеркального блиску. Крім того, створюються стенти з нерівномірним кроком ниток, змінюються матеріали (особливо ті, які містять Ni). Проте, дані методи не дозволяють вирішити головну проблему стентування – малу «площу» ниток і відповідно зменшити їх тиск на стінки судини та малу кількість лікарських засобів, яку містить поверхня ендопротеза.

В літературі повністю відсутні дані про взаємодію системи лазерний промінь – заготовка – допоміжні системи при обробці тонкостінних циліндрчних конструкцій. Вирішенню вказаних проблем і присвячена дана робота.

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