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Development process and manufacturing of modern medical implants with LENS technology

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ABSTRACT

Purpose: Research and development of modern medical implants is complex and demanding process focused on fulfilling requirements regarding materials, machining technologies and functionality. Typical example of modern medical implant is elbow nail for fixation of Caput radii fractures. It could be manufactured with classical machining technologies and with advanced Rapid Prototyping technologies such as highly targeted metal deposition technology LENS (Laser Engineered Net Shaping).

Design/methodology/approach: Development of modern medical implants is a multi-stage design and manufacturing process primarily based on computer aided design (CAD), computer simulations, machinability of certificated biomaterials, in-vitro biofunctionality and in-vivo tests.

Findings: LENS technology enables rapid and agile manufacturing, improved design flexibility, repair and re-manufacture. Material built with LENS technology has equal or even better mechanical and material properties. In medical application LENS technology enables development and rapid prototyping of special surgical instruments, trauma and orthopaedic high-performance implants which are hollow and thin walled.

Research limitations/implications: To confirm assumption regarding better material and mechanical properties of products made with LENS technology additional static, dynamic (the High-Cycle-Fatigue test) and material (porosity and microstructure) tests will be carried out in the near future.

Practical implications: Three different designs of bone fixation nail prototype made of titanium alloy had been manufactured with conventional machining techniques where some disadvantages due to the technology had been identified. To solve those problems LENS technology had been applied. As fourth design hollow thin walled fixation bone nail prototype made of titanium alloy powder (grain size 45μm) had been manufactured and tested.

Originality/value: Paper presents case study where LENS technology is being applied to manufacture modern medical implants. Particular focus of the paper is on material quality and quality benefits obtained in current and future medical application.

Keywords: LENS technology; Rapid prototyping; Modern medical implants; Titanium alloy; Elbow bone fixation nail

1. Introduction

Modern medical implants are products which have to satisfy strict requirements regarding materials, machining technologies and their functionality. They could be used in almost every organ of the human body. Ideally they should have biomechanical properties comparable to those of autogenous tissues without any adverse effects. The principal requirements of all medical implants are corrosion resistance, biocompatibility, bioadhesion, biofunctionality, machinability and availability. To fulfil these requirements most of the tests are directed into the study extracts from the material, offering screens for genotoxicity, carcinogenicity, reproductive toxicity, cytotoxicity, irritation, sensitivity and sterilization agent residues, [9]. Modern medical implants are regulated and classified in order to ensure safety and effectiveness to the patient. One of the most favourable biomaterial used for biomedical applications is titanium alloy Ti6Al4V due to its combination of the most desirable characteristics including immunity to corrosion, biocompatibility, shear strength, density and osteointegration. The excellent chemical and corrosion resistance of titanium is to a large extent due to the chemical stability of its solid oxide surface layer to a depth of 10 nm, [8]. Under *in-vivo* conditions the titanium oxide (TiO_2) is the only stable reaction product whose surface acts as catalyst for a number of chemical reactions.

Research and development of modern medical implants is complex multi-stage design and manufacturing process primarily based on *in-vitro* and *in-vivo* tests.

In-vitro tests are test performed in the ideal (laboratory) environment. They include biomechanical (usually strain and elongation measurements of the soft tissues), biofunctional (human or pig cadaver tests), metallurgic (corrosion resistance tests), biocompatibility, bioadhesion (histological, chemical, ect.) and machinability tests.

In-vivo tests are test performed in the real environment where we test developed implant prototype performances. Usually is such developed prototype inserted into the voluntary patients with their preceding permission or in case of deficiency of appropriate human candidates into animals which have similar tissue structure as humans (pigs).

To perform described testing protocol including usage of human cadaver parts and inserting the developed implant prototypes into the patients the permission of the Medical Chamber, Commission for Ethical Matters has to be gained. At such process all ethical issues had to be considered including data protection issues where the names of the patients for *in-vivo* tests are not published and remain confidential. Same is with human cadaver parts where only the age and the sex of the parts are determined and considered.

Research and development process is generally divided into 6 main stages. First stage is definition of the problem based upon needs and objectives of the working environment. At this point standardization of resembling fractures is reasonable. In the following second stage preliminary ideas for implant are given and preliminary design is created on the basis of computer tomography (CT) or magnetic resonance imaging **(**MRI) scans which are used to process the medical image with high resolution and precision in the reconstructed contours (3D model). In the third stage of the process is this model the basis for numerical analysis (Finite Element Analysis-FEM), further prototype improvements and manufacturing of the prototype on a CNC machine according to the program which has been elaborated. Performance and functionality of the developed prototype are verified in the fourth stage with different mechanical, chemical, histological and cadaver tests (*in-vitro* tests). In case of positive expected results prototype is tested on patients (*in-vivo* tests) in the next, fifth stage. Finally sixth stage of development is clinical use of developed implant. Parallel to the medical implant prototype development an attendance instruments is developed and tested. It should be simple and effective.

Some medical implants are produced modularly, using different materials and processing technologies. For example, the femoral stem as part of the hip endoprosthesis is produced in a combination of casting, forging and milling. The final machining operation is performed on CNC machine using CAD-CAM principle.

Generally processes of biocompatible materials machining involve conventional machining operations (turning, milling, drilling), forming operations (cold and hot forming, hydroforming, forging) and alternative machining operations (laser cutting, water-jet cutting, direct metal laser sintering, targeted metal deposition technology). Machining technologies of titanium alloy represent a great challenge, due to its relatively high tensile strength, low ductile yield, 50 % lower modulus of elasticity (104 GPa) and approximately 80 % lower thermal conductivity than that of steel, [4]. The lower modulus of elasticity may cause greater ‘spring back’ and deflection effect of the workpiece. Therefore, more rigid setups and greater clearances for tools are required. In the tool contact zones high pressures and temperatures occur (the tool-workpiece interface). The amount of heat removed by laminar chips is only approximately 25 % the rest is removed via the tool. Due to this phenomenon titanium alloys can be machined at comparatively low cutting speeds. At higher temperatures caused by friction the titanium becomes more chemically reactive and there is a tendency for titanium to »weld« to tool bits during machining operations. Over-heating of the surface can result in interstitial pickup of oxygen and nitrogen, which will produce a hard and brittle alpha case. Carbides with high WC-Co content (K-grades) and high-speed steels with high cobalt content are suitable for use as cutting materials in titanium machining operations, [4]. Cutting parameters of titanium alloys should have cutting depths as large as possible (ap up to 2 mm), cutting speeds Vc in the range from 12 to 80 m/min and approximately 50 % lower values when high-speed steel (HSS) tools are used. The heat generated in the cutting zone should be removed via large volumes of cooling lubricant. Chlorinated cutting fluids are not recommended because titanium can be susceptible to stress corrosion failures in the presence of chlorine. Any type of hot working or forging operation should be carried out below 925°C due to high level of titanium reactivity at high temperature, [4].

2. LENS Technology

Good alternative to conventional processing technologies specially for manufacturing modern medical implants made of titanium alloy and other metallic biomaterials is Rapid Prototyping (RP) which is the name for a group of technologies where the 3D physical model is built directly from the CAD file without the intermediary action. The RP technologies are divided into two groups which are technologies adding the material during the prototype building and technologies removing the material during the prototype manufacture, [3].

Laser technology is today widely used in manufacturing of modern medical implants. It can be used for cutting, selective hardening of implant surfaces, precision cutting, welding and drilling. The manufacturing accuracy is within the range of 10 µm. The CO_2, Nd:YAG or diode lasers are available. The introduction of the 5 KW ray beam and linear drives in the laser cutting devices results in the increase of efficiency and accuracy of machining.

For the production, development and prototyping of special surgical instruments, trauma and orthopaedic high-performance hollow and thin walled implants a highly targeted metal deposition technology called Laser Engineered Net Shaping Technology (LENS) is used. This laser fabrication technique was developed at Sandia National Laboratories and subsequently commercialized by the Optomec Design Company of Albuquerque, New Mexico, USA.

2.1. Principle of LENS technology

LENS is layer manufacturing technology which produces a very fine weld bead, exposing the component to far less heat than conventional methods due to smaller and more controlled heat affected zone which does not damage the underlying part. Once a geometry and material or material combination has been identified LENS can rapidly produce a 3-dimensional prototype with good mechanical properties, [1]. It enables the designer full functional and structural analysis. The tool-less process is driven directly from CAD data so a prototype of a new design or design iteration can be produced in few hours providing significant time compression advantages.

The process of manufacturing a prototype of modern medical implant is based on 3D CAD model which is converted into the STL file (Fig. 1). The metallic powder of selected material is delivered by nozzle to the spot where it is melted via Nd: YAG or Fiber Laser and built in certain shape, [7].

The process of building product with LENS technology has following characteristics. A high power laser is used to melt metal powder supplied coaxially to the focus of the laser beam through a deposition head. The laser beam typically travels through the center of the head and is focused to a small spot by one or more lenses. The X-Y table is moved in raster fashion to fabricate each layer of the object. Typically the head is moved up vertically as each layer is completed. The laser beam may be delivered to the work by any convenient means. Metal powders are delivered and distributed around the circumference of the head either by gravity or by using an inert pressurized carrier gas (inert gas like argon, helium or nitrogen). Multiple powder compositions can be fed simultaneously or sequentially to produce alloying at the focal zone or provide choice of material relative to location within a desired part even in cases where it is not required for feeding an inert shroud gas is typically used to shield the melt pool from atmospheric oxygen for better control of properties and to promote layer to layer adhesion by providing better surface wetting. The building area is usually contained within a chamber both to isolate the process from the ambient surroundings and to shield the operators from possible exposure to fine powders and the laser beam. The laser power used varies greatly from a few hundred watts to 20 KW or more depending on the particular material feed-rate and other parameters. Objects fabricated are near net shape but generally will require finish machining. They are fully-dense with good grain structure and have properties similar to or even better than the intrinsic materials, [5].

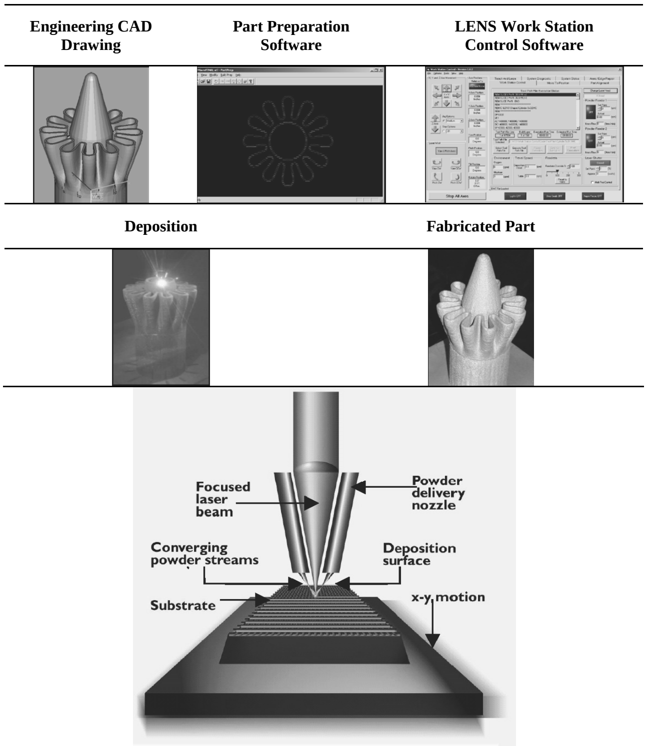

Fig. 1. Process steps and schematic diagram of the LENS technology

This process exhibits enormous potential to revolutionize the way in which metal parts, such as complex prototypes, tooling, and small-lot production parts, are produced. The result is a complex, fully dense, near-net-shape part. LENS has many potential applications, including rapid prototyping, rapid tooling, and dissimilar metal joining. Samples have been successfully manufactured from a variety of materials including steels, stainless steels (SS), nickel-based alloys, refractory metals, tool steel alloys, titanium and intermetallic compounds. Fabrications of bi-material joints as well as functionally graded materials through the use of LENS have also been successfully processed. Laser source has the benefit of concentrating much energy in the spot, but the drawback is its high cost, [6].

LENS is a technology that is gaining in importance and is in early stages of commercialization. Its strength lies in the ability to fabricate fully-dense metal parts with good metallurgical properties at reasonable speeds. A lot of research is still being done in USA laboratories. There are only three installations of LENS machines in Europe: UK, France and Slovenia.

2.2. LENS technology in medicine

The orthopedic and trauma segment are particularly promising for the LENS technology. Joint replacement is a major component of this markets where as a result of injury, degeneration or genetic defect, surgical implantation of spinal, hip, knee and other joint replacement components is needed.

Despite the industry's maturity, innovation continues to accelerate with advancements in manufacturing and biological technologies to address strength, weight, and biocompatibility as the key drivers of device performance. At present, most manufacturing is carried out using traditional methods like machining or casting. In comparison, LENS can be used to cost-competitively manufacture standard or even custom implants with a range of functional enhancements that improve wear characteristics and ultimate quality of life for the patient (Fig. 2.). The dimensions of performance where LENS can offer significant benefits include:

- Reducing implant wear at key points;
- Fostering implant integration with native tissue;
- Avoiding toxicity, autoimmune response and bacterial formations;
- Avoiding structural failure and adverse mechanical properties;
- Maintaining long term fixation of the implant;
- Facilitating diagnosis of implant problems without surgery.

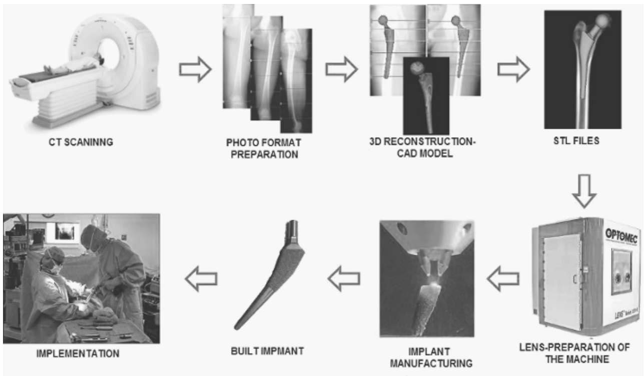

Fig. 2. Manufacturing process using LENS technology principle in medicine

Medical implants have to be extremely flexible to fit in a specific patient because of that a lot of applications are "custom-made". It is also important that the weight of these implants is as small as possible offering to the patient comfortable life and functioning. This is the reason why thin–walled parts are more welcomed and it is extremely hard (if not impossible) to produce thin-walled implants with conventional machining technologies. Such products also have better mechanical and material properties. This offers possibility to build smaller sized products (implants) which would withstand the same loading of the environment as existent products, [2].

2.3. Advantages of LENS technology

The main advantages of LENS technology are:

- fabrication of complex products, novel shapes, hollow structures and material gradients that are not otherwise feasible,
- efficient approach that reduces production costs and speed time-to-market for high-value components,
- excellent material properties, almost no porosity, possibility to combine different materials, significantly reduced material waste,
- low heat input – low distortion and heat-affected-zone. Since mechanical properties are dependent upon the microstructure of the material, which in turn is a function of the thermal history of solidification, an understanding of the thermal behaviour of the fabricated part during the LENS process is of special interest. Unlike other laser processing techniques, LENS uses low power lasers which produce a very small heat-affected zone,
- direct manufacturing from CAD to part, computer supported process with closed loop for precision deposition control.

3. Example of modern medical implant-bone fixation nail

Last part of the paper represents an example of modern medical implant prototype which has been developed at the Laboratory of Cutting (LABOD), Faculty of Mechanical Engineering, University of Ljubljana and Department of Traumatology, University Medical Centre in Ljubljana.

Elbow joint is an area of the human body where a high potential for development of new medical trauma implants exists. One of the most challenging problems is how to fixate fractures of the radius head (Caput radii) bone. As the most promising concept the Intramedullary nail (IM) had been chosen. It uses a principle of the bone fixation nail which is left in the patient permanently. The fixation of the fractures of Caput radii is made with classical medical screws which are screwed into the head of the nail. The nail has two stabilizing screw holes in the lower part which prevents slip of the nail after being implemented into the radius bone.

The nail prototypes were manufactured with conventional machining technologies (turning, drilling and grinding) and LENS technology. Material used for machining of IM nail prototypes was titanium alloy Ti6Al4V (Titanium,6% Aluminium, 4% Vanadium) in forged and annealed bars for conventional machining technologies and in powder form (45 µm grain size) for LENS technology.

3.1. Examples of different nail prototype design concepts and their comparison

Conventionally three different design concepts of the bone fixation nail had been machined: classical nail with complex attendance instruments, (Fig. 3), nail with sieve-like head, (Fig. 4) and nail with groove head and attendance instruments, (Fig. 5). With LENS technology a hollow and thin walled fixation nail was produced, (Fig. 6). Fixation of the fragments of the Caput radii at LENS prototype is done with drilling screw holes during surgical operation to the head of the nail coincidentally in the best possible way to gain primary stabilization of the fracture. This is possible because of the thin walls of the nail (1 mm) and specially developed drilling tools (diamond coated). The LENS nail prototype was not post processed due to better anchoring into the bone walls (better surface-tissue interaction).

Fig. 3. Classical nail form with complex attendance instruments

Fig. 4. Nail with sieve-like head and fixation screw

LENS IM nail prototypes had been manufactured in the TIC-LENS d.o.o. company on the Optomec LENS 850R, 5-axes standard machine, using argon atmosphere. Average Fiber Laser power during manufacturing of the IM nails was 470W.

All four concepts of prototypes had been tested for osteosynthesis as subpart of biofunctionality tests on cadaver parts. Parallel the generally assessment for every developed prototype was given, assessing needed time for production, complexity of implementation into the cadaver part and weight of the nail:

- Classical nail with complex attendance instruments has failed osteosynthesis tests because there were not enough screw holes in the nail head to fix all coincidental fractures rigidly. The machining times are too long, prototype is too heavy, attendance instruments are complex and unpractical to be used effectively during operational procedure.
- Nail with sieve-like head has passed osteosynthesis tests, implementation is simple also the fixation of the screws. Disadvantage is in long machining times and precise drilling operations (detailed FEM analysis had to be done to determine the optimal wall thickness between the screw holes).
- Nail prototype with groove head and attendance instruments also passed osteosynthesis tests. Implementation is simple, attendance instruments offer good access to screw the fractures into the head of nail from different angels. Disadvantage is in slipping the screws out of the desired direction during their placement into the groove and long machining times.
- LENS prototype has passed osteosynthesis tests and no special problems occurred during implementation into the cadaver parts. It also gave the best general results in comparison to other developed prototypes. The thin wall design enables free burr hole placement and angular stability. Rigid fixation of multiple comminuted fragments can be achieved allowing early mobilization. Operation procedure is simple, insertion hole is small and only small amount of X-ray is needed to confirm primary stabilization of the nail in the bone.

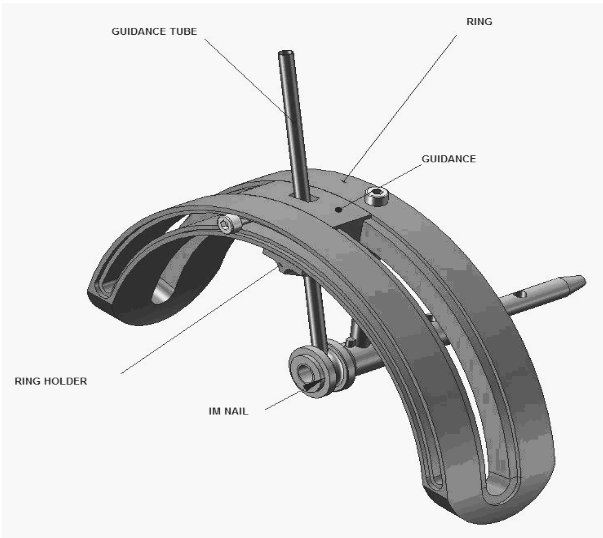

Fig. 5. Nail with groove head and attendance instruments

a) b)

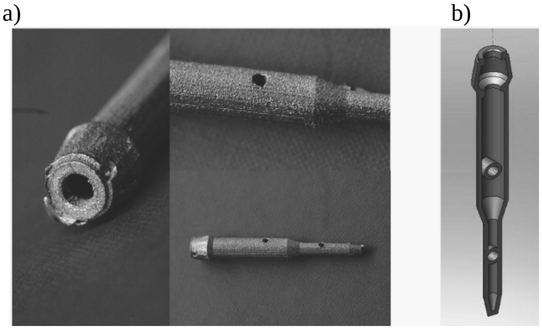

Fig. 6. a) Hollow and thin walled (1 mm) LENS prototype, b) CAD model of LENS prototype

3.2. Comparison of material properties

Some basic tests were made to compare material and mechanical properties between forged and annealed Ti6Al4V testing probes and LENS testing probes, (Fig. 7).

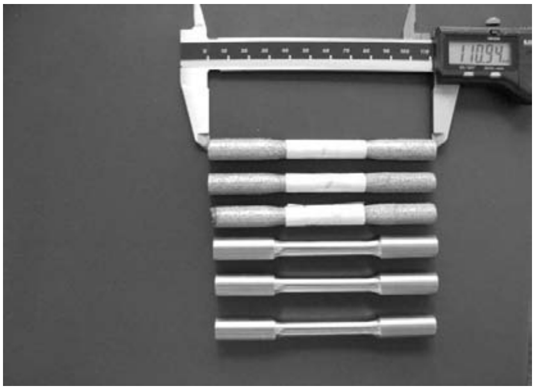

Fig. 7. Testing probes made of wrought titanium and with LENS technology

The determination of the force–displacement relation and the ultimate force to failure and elongation to break was performed by a constant rate of specimen extension (CRE) standard on the universal testing machine type Zwick Z050. The accuracy of the testing machine was 0.5 N for force measurements and 0.04 mm for measurement of displacement. The maximum payload of the machine was 10 kN and the maximum displacement was 0.8 m.

One end of the specimen was held in a virtually stationary clamp, and the other end was gripped in a clamp that was driven at a constant rate. The chosen constant rate of displacement of the moving clamp was 1 mm/s. The specimen was loaded with uniaxial tension and extended until rupture.

Table 1.
Comparison between the tensile properties of both types of testing

	LENS Ti6Al4V	Ti-forged and annealed Ti6Al4V
E Modulus, [N/mm^2]	118669.00	103696.00
Rp 0.1, [N/mm^2]	949.34	937.99
Rp 0.2, [N/mm^2]	964.20	954.00
Rp x 1%, [N/mm^2]	988.80	947.80
Rm, [N/mm^2]	1056.09	1017.82
ε-Fmax, [N%]	3.61	3.68
RB, [N/mm^2]	1047.41	739.46
ε-at break, [%]	12.09	12.23

The LENS technology offers equivalent tensile properties to forged material what is also visible in Table 1 where a comparison between the tensile properties of both types of testing probes is given. This indicates that the parts will meet performance criteria in the target industries. EADS study of fatigue properties shows that LENS manufactured Ti6Al4V is equivalent to the highest quality forged material: >162 million cycles at 587 MPa, [2]

Hardness in HV was also measured through the cross section of testing tubes (Fig. 8). LENS Ti tubes have approximately 100 HV higher hardness what could be interpreted as better material properties.

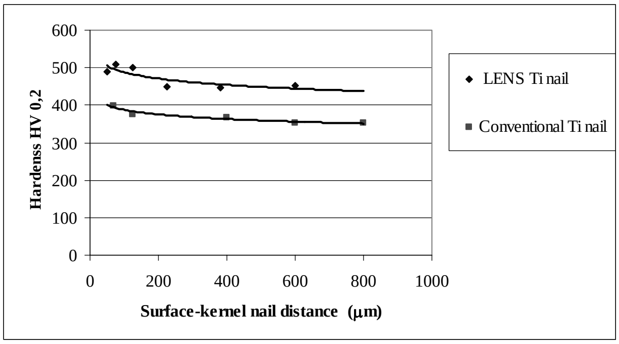

Fig. 8. Hardness of LENS and conventional IM Ti nail trough cross section

To confirm assumption regarding better material and mechanical properties of products made with LENS technology the High-Cycle-Fatigue tests will be carried out at the Faculty of Mechanical Engineering, University of Ljubljana.

4. Conclusions

The additive manufacturing technology (LENS) offers the potential to rapidly manufacture of high performance products and effectively repair a wide range of these components.

IM nail as an example of modern medical implant produced with LENS technology has more advantages for practical usage than conventional titanium IM nail. It is lighter due to hollow structure, easier to insert (very good osteosynthesis), the operation procedure is less complicated and no complex attendance instruments are needed. The surface of the LENS IM nail could stay rough and consequently improves its primary stabilization in the bone. As we have expected LENS technology provided two huge advantages – manufacturing of complex shapes that are hardly produced with conventional technologies and above that also same or even better material characteristics as classical used materials of the same alloy. We expect that LENS technology will have a significant place in the medical industry.

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