

PRACTICAL ASPECTS OF OBTAINING DEFORMED BLANKS FOR THE PRODUCTION OF BIODEGRADABLE IMPLANTS OF INCREASED QUALITY

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ABSTRACT

This work investigates the possibility of improving the structure and properties of a cast magnesium alloy in the Mg-Nd-Zr-Ag system due to its plastic deformation. The optimal ones have been selected as modes of plastic deformation of cast blanks for the manufacture of high-quality implants. It has been shown that plastic deformation of the MC10 alloy makes it possible to significantly refine its structure by 10 times and increase the level of its mechanical properties by 3 or 5 times. Bacteriological studies of MC10 alloy blanks have shown its high antimicrobial properties, which makes it a promising material for the manufacture of implants.

***Keywords:** magnesium alloy, structure, mechanical properties, plastic deformation, implant, bacteriological studies, biodegradation, antimicrobial properties.*

INTRODUCTION

Treatment of bone fractures is a pressing medical problem with important social significance. The quality and speed of healing of a bone fracture depend on the site of traumatic injury, the stability of fixation, the condition of the body and other factors [1]. The stability of fracture fixation to a significant extent determines the positive result - fusion of fragments. Osteosynthesis is a method of surgical treatment of fractures that combines various techniques and concepts. For many years, stainless steel, cobalt and titanium alloys have been the main materials for the manufacture of implants [2, 3]. The use of these alloys in medicine has several problems: metal allergies, aseptic inflammation and metalloid. A limitation of biomaterial is the toxic ion release or metal particles due to corrosion or wear, which lead to an inflammatory process, resulting in decreased bio-compatibility and bone destruction [4 - 7].

In addition, the elastic module of these alloys does not coincide with those of bone tissue. As a result, the

formation of newly bone formed tissue decreases and negative remodeling increases leads to a violation of the stability of the implant [8, 9]. The use of fasteners made of bio-inert metals for osteosynthesis necessitates repeated surgical intervention, aimed at removing the implant. Mostly often and no less traumatic than osteosynthesis itself, it happened. This entails an increase in the overall length of hospital treatment and temporary disability of patients. In this regard, the search for materials that could dissolve in the implantation area with synchronous replacement with bone tissue, which will not require the removal of fixing devices, is constantly ongoing.

One of such materials is magnesium-based alloys. Magnesium and its bio-resorption products are characterized by high biocompatibility, which makes its use for the manufacture of implants very attractive [10 - 12]. However, the main limitation in the magnesium implementation and its casting alloys are insufficient mechanical properties. In this regard, the development of new technologies to produce implants from bio-soluble

magnesium-based alloys with improved mechanical properties is a promising direction in the development of biomaterials science and medicine [13 - 15].

Currently, there are various cast magnesium-based alloys for the manufacture of implants with satisfactory levels of properties [16, 17]. During osteosynthesis, their use for the manufacture of various fixing screws requires preparatory operations. Using a drill and a guide, a canal is formed in the bone. Using a thread tap screw-cut in the formed channel. Reliable fixation of bone tissue fragments is impossible due to the damage of the implant. Therefore, an urgent task is to improve the mechanical properties of forming a channel and cutting threads, which complicates the surgical procedure and lengthens the operation time. One of the methods for increasing the mechanical properties of an alloy is its plastic deformation, which significantly improves the structure. Therefore, this study aims to develop rational modes of plastic deformation of work pieces made of soluble alloy MC10 of the Mg-Nd-Zr-Ag system used for the manufacture of implants during osteosynthesis.

EXPERIMENTAL

The MC10 alloy was smelted in an IPM-500 type crucible induction furnace with a nominal capacity of 0.5 tons, power of 140kW, and productivity of 230 kg h⁻¹. It was also smelted in a gas-holding furnace with a nominal capacity of 150 kg. Primary magnesium pigs, zinc pigs, Mg-Nd alloy, Mg-Zr alloy, and technical silver 99.99 were used as the charge. Preheated charge materials were loaded into the IPM-500 crucible furnace and, after melting, poured into removable crucibles at temperatures from 650°C to 730°C. Removable crucibles were installed in holding furnaces, in which the alloy was adjusted to its chemical composition and refined with VI-2 flux at temperatures from 740°C to 760°C. After this, technical silver was introduced into the melt as a modifier; the melt was heated and held. Cast samples were poured at a temperature of 730°C for subsequent deformation 540°C with exposure for 10 h, air cooling, and aging at 205°C for 12 h with air cooling.

The chemical composition of magnesium alloys was monitored using optical emission spectrometers "SPECTROMAXx" and "SPECTROMAXxF", photoelectric spectrometers MFS-8, and TFS-36, "SPECTRO XEPOS". The macro- and microstructure

of the alloy under study were studied using light microscopy (Neophot 32, OLYMPUS IX 70) at various magnifications. Sections for microstructure analysis were etched with a reagent consisting of 1 % nitric acid, 20 % acetic acid, 19 % distilled water, and 60 % ethylene glycol. The mechanical properties of samples made of magnesium alloys were determined using an INSTRON 8801 tensile testing machine.

Research was carried out to obtain deformed workpieces from MC10 alloy (0.78 % Zr; 2.21 % Nd; 0.3 % Zn; 0.1 % Ag; Mg rest) Ø 8 mm, as well as wire Ø 1 mm and Ø 0.63 mm, necessary for the subsequent production of various structures as biosoluble implants. The resulting cast samples from MC10 alloy were machined onto blanks Ø 13 mm for subsequent deformation

The microstructure of the initial workpieces consisted of grains of solid solution, eutectic (α + (MgZn)₁₂Nd) and individual intermetallic compounds of complex composition (Fig. 1a).

Strengthening phases in the original cast billets that did not undergo heat treatment were released in the form of a network along the grain boundaries, and after heat treatment in the form of spherical precipitates inside the grain (Fig. 1b). After heat treatment, the mechanical properties of samples from the MC10 alloy, cast in a sand-clay mold were: $\sigma_B = 235...244$ MPa and $\delta = 3.6...4.2$ %. Further improvement of the mechanical properties of the alloy was carried out due to its plastic deformation.

The influence of cold plastic deformation modes of the MC10 alloy for the manufacture of Ø 8 mm blanks from cast machined Ø 13 mm specimens was investigated. Deformation was carried out on a hydraulic press model D 3434 A with a force of 2.5 MN at room temperature with different rates of plastic deformation.

It has been established that at a rate of cold plastic deformation exceeding 5 mm s⁻¹, the workpiece is destroyed in the longitudinal direction into several fragments (Fig. 2a). The fracture at the site of destruction is light, and shiny, with a smoothed and partially crumpled relief, of a static nature (Fig. 2b). The fracture microstructure of this sample consisted of solid solution grains, eutectic (α + (MgZn)₁₂Nd), and strengthening phases (Fig. 2c, d).

Metallographic studies of samples from the MC10 alloy, deformed at a crosshead movement speed of

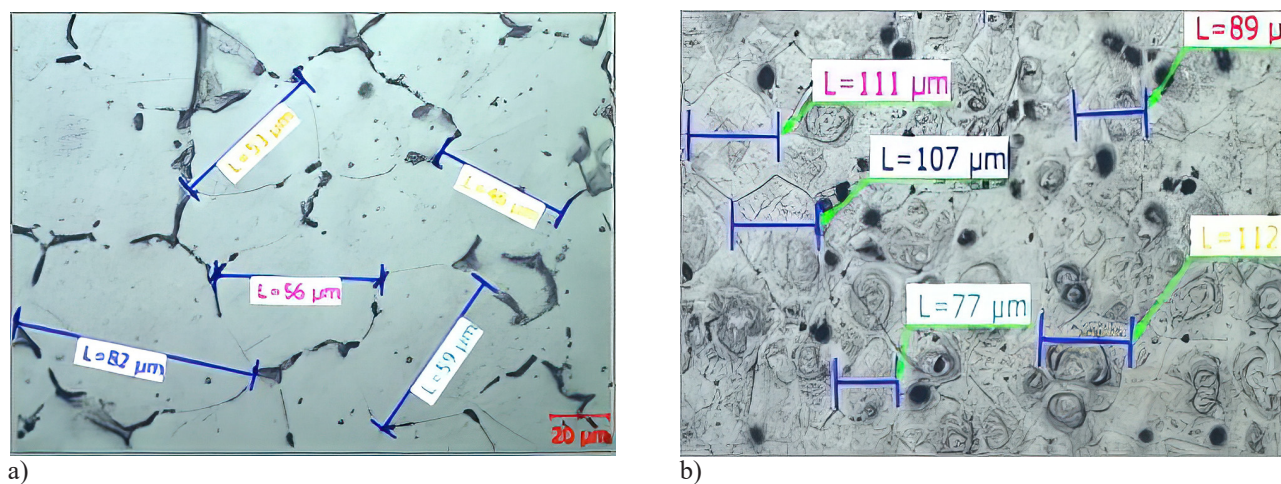


Fig. 1. Microstructure of cast MC10 alloy before (a) and after (b) heat treatment.

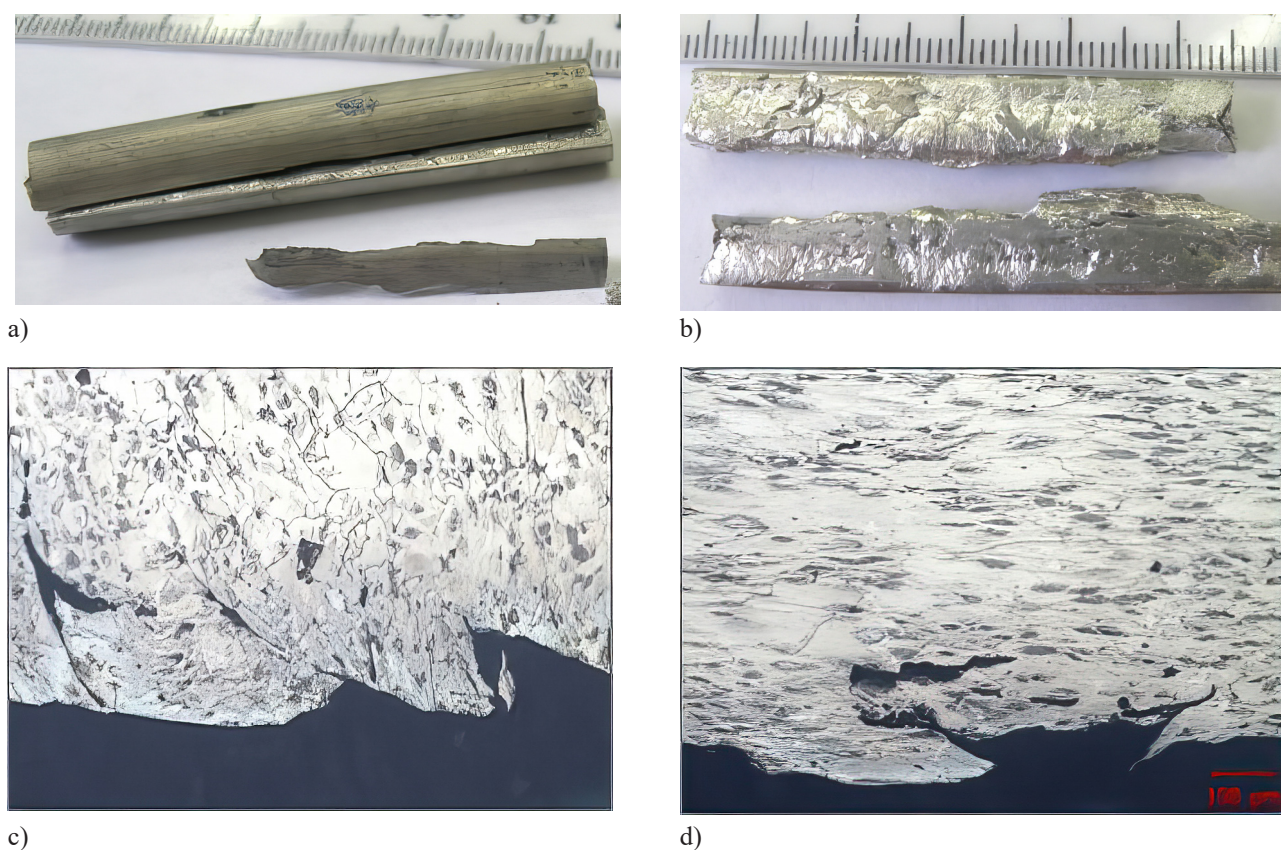


Fig. 2. Fractured sample of MC10 and its microstructure alloy after cold plastic deformation ($V > 5 \text{ mm s}^{-1}$): (a) - fractured work-piece, (b) - macro-fracture of the alloy, (c) - cross section, x 100, (d) - longitudinal section, x 100.

5 mm s^{-1} , showed that there are no defects in the metal structure (Fig. 3). The quality of the metal fully meets the requirements of regulatory and technical documentation. At the same time, its mechanical properties were: $\sigma_B = 300 \text{ MPa}$ and $\delta = 9.5 \%$, which significantly exceeds the figures for cast metal.

Thus, it has been established that to ensure deformation of the cast billet $\varnothing 13 \text{ mm}$ per rod $\varnothing 8 \text{ mm}$, it is necessary to maintain the optimal deformation rate on a hydraulic press model D 3434 A with a force of 2.5 MN at room temperature at a level of 5 mm s^{-1} , which ensures the production of defect-free metal with

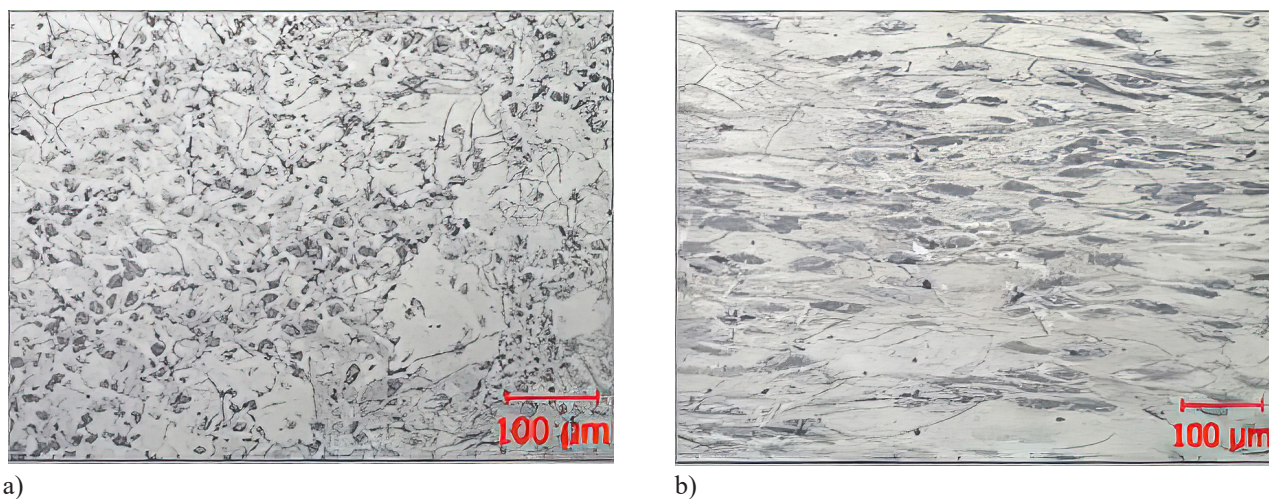


Fig. 3. Microstructure of MC alloy samples with optimal strain rate ($V = 5 \text{ mm s}^{-1}$), $\times 100$: (a) - cross section, (b) - longitudinal section.

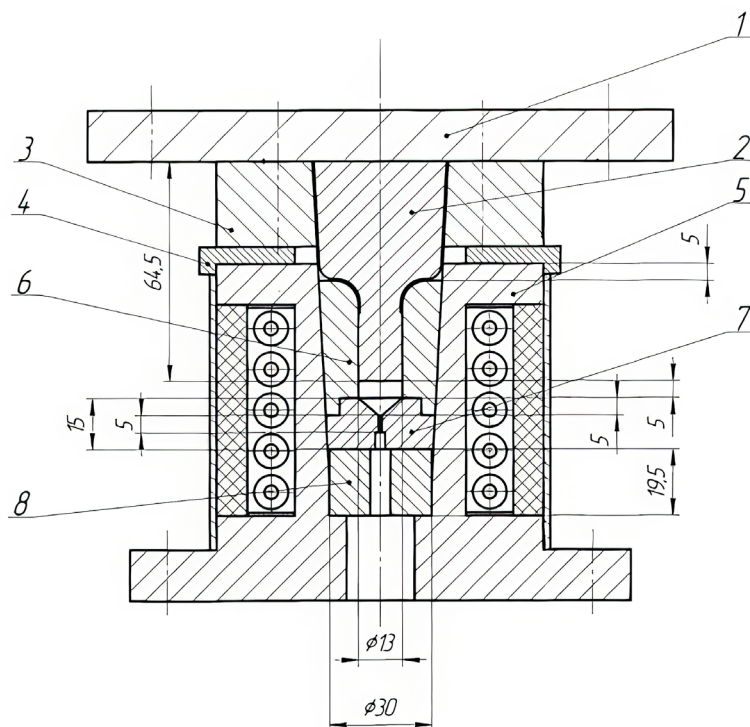


Fig. 4. Stamp for isotherm wire extrusion $\varnothing 1 \text{ mm}$: 1 - top plate, 2 - punch, 3 - punch holder, 4 - thrust ring, 5 - body, 6 - matrix, 7 - die, 8 - ring.

an increased set of mechanical properties.

Additionally, we studied the technology of plastic deformation of cast billets $\varnothing 13 \text{ mm}$ per wire $\varnothing 1 \text{ mm}$ and $\varnothing 0.63 \text{ mm}$. Wire $\varnothing 1 \text{ mm}$ was obtained by extruding the original blank $\varnothing 13 \text{ mm}$ in a multi-site matrix (Fig. 4). Before extrusion, the original workpiece was subjected to homogenized annealing at a temperature of 420°C

for 10 h to improve ductility. Extrusion was carried out using a hydraulic press model D 3434 A with a force of 2.5 MN.

In order to obtain wire of proper quality, the influence of deformation speed (press cross-beam movement) was studied, the optimal heating temperature of the initial workpiece and equipment was established,

and an effective lubricant was prescribed. A deformation (extrusion) rate of 5 mm s^{-1} led to the destruction of the wire and its tears (Fig. 5).

Microstructural analysis of sections of defective wires showed that the cracks are wide open and located at right angles to the surface. The absence of any defects of casting origin in the zones of wire destruction indicates the influence of the extrusion speed on their formation. By reducing the extrusion speed by more than 6 times (0.8 mm s^{-1}), it was possible to achieve a laminar flow in the process of obtaining wires and eliminating breaks and cracks (Fig. 6).

Extrusion of the wire was carried out by heating the lubricated initial workpiece in an electric furnace $\varnothing 13 \text{ mm}$ at a temperature of 420°C . The tool (punch, matrix, die) was heated to the same temperature by a specially built-in heater, which corresponds to the extrusion process occurring under isothermal conditions. The nominal bar extrusion force $\varnothing 1 \text{ mm}$ was 330 kN with a specific load of 2500 MN m^{-2} . To reduce the coefficient of friction and deformation force, the manufacturability of using various lubricants was additionally studied: Fenella Fluid F3606G, Fenella Oil3601G (SHELL), Molikote (Dow CORNING), PS-2 pencil with boron nitride and boron nitride powder. It has been established that the most technologically advanced is the use of boron nitride powder, which has good lubricating properties and ease of application.

Thus, extruding the wire $\varnothing 1 \text{ mm}$ with cross section $S = 0.785 \text{ mm}^2$ from the original workpiece $\varnothing 13 \text{ mm}$ with the specified deformation rate is optimal and limiting for carrying out the process of intense deformation by direct extrusion.

To determine the optimal strength and plastic characteristics of the structure and properties of the

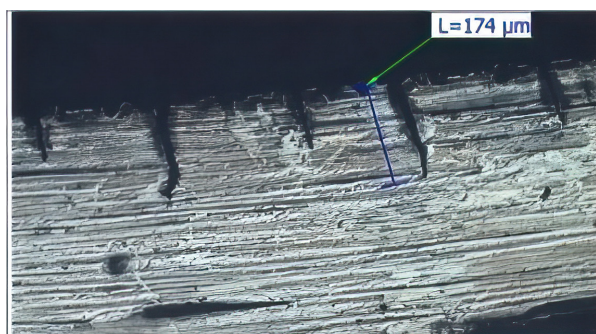


Fig. 5. Wire defects at high extrusion speed.

extruded, wire $\varnothing 1 \text{ mm}$ was examined after various heat treatment conditions.

Bending tests of the wire immediately after deformation showed that different sections along the length of the profile have different bending angles. There were sections of wire that bent before cracking or breaking by more than 120°C and fragments that were destroyed at an angle of less than 30°C . The macrostructure of the wire with a large bending angle without destruction, tested under a binocular microscope, was light, finely crystalline, without defects of casting and deformation origin (Fig. 7a). In the kinks of the wire with a small angle of bending before destruction, dark areas were found (Fig. 7b). Micro analysis of these wire fractures showed that the dark areas are casting defects in the form of non-metallic inclusions and micro pores.

The influence of various heat treatment modes on the mechanical properties of wire $\varnothing 1 \text{ mm}$ was studied (Table 1). The experiments were carried out after annealing in the temperature range from 300°C to 380°C and after quenching from 530°C with cooling in water and air. For comparison, samples without heat treatment were tested.

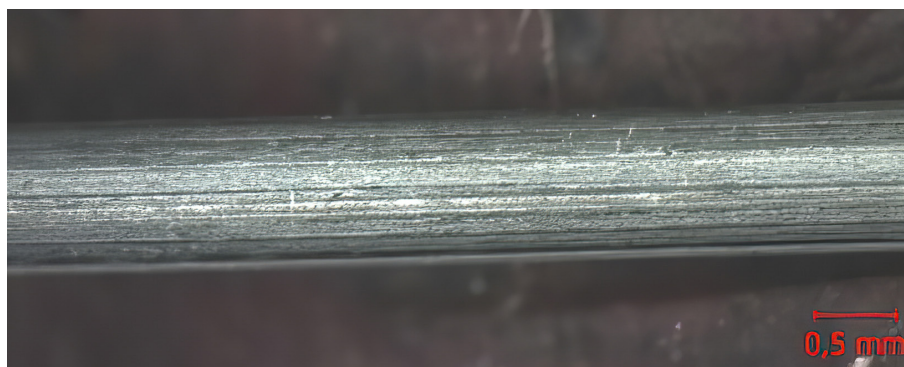
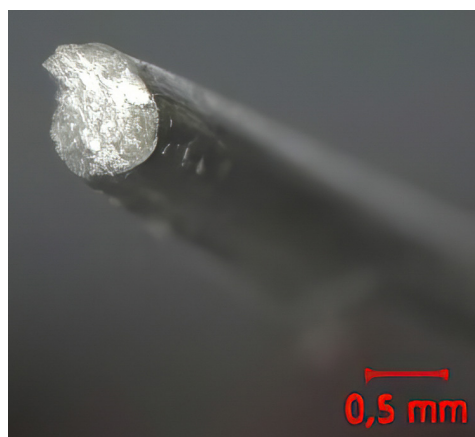


Fig. 6. The condition of the surface of the wire extruded at a reduced deformation rate.



a)



b)

Fig. 7. Wire breaks with large (a) and small (b) bending angles.



Fig. 8. Wire winding test Ø 1 mm from MC10 alloy.

It was found that various types of heat treatment contributed to some deterioration in the ductility of the alloy. At the same time, the strength properties were practically at the same level.

Assessment of the quality of the resulting wire Ø 1 mm without heat treatment was carried out by winding it onto a mandrel Ø 1 mm. The results of the experiment showed the possibility of twisting the wire onto 15 and up to 17 turns (at a norm of 5). A visual inspection of the resulting workpiece showed the presence of small cracks in the wire that did not lead to its destruction (Fig. 8). However, to use it as an implant, it is necessary to obtain a solid, defect-free metal.

Table 1. Mechanical properties of wire Ø1 mm of MS10 alloy after various heat treatment conditions.

Heat treatment		Tensile strength, σ_B , MN m ⁻²	Relative extension, δ , %
No heat treatment		240...273	14.0...20.0
Annealing temperature for 2 h °C	300°C	246...285	6.0...8.0
	350°C	233...273	6.5...17.7
	380°C	233...260	14.8...20.9
Quenching at a temperature of 530°C	Cooling into water	198...203	17.8...19
	Air cooling	208...215	14.7...15.0

For high-quality wire without breaks, studies were carried out to obtain wire with a diameter of less than 0.6 mm by drawing. Before drawing the wire Ø 1 mm was subjected to hardening at a temperature of 530°C with cooling in water. Then the hardened wire was cold drawn in 9 passes without intermediate heat treatments between transitions and was deformed to Ø 0.63 mm.

The microstructure of the wire under study immediately after deformation on transverse and longitudinal sections consisted of a solid solution, eutectic ($\alpha + (\text{MgZn})_{12}\text{Nd}$), and the strengthening phase (Fig. 9a-b). After annealing at a temperature of 350°C, the microstructure consisted of recrystallized

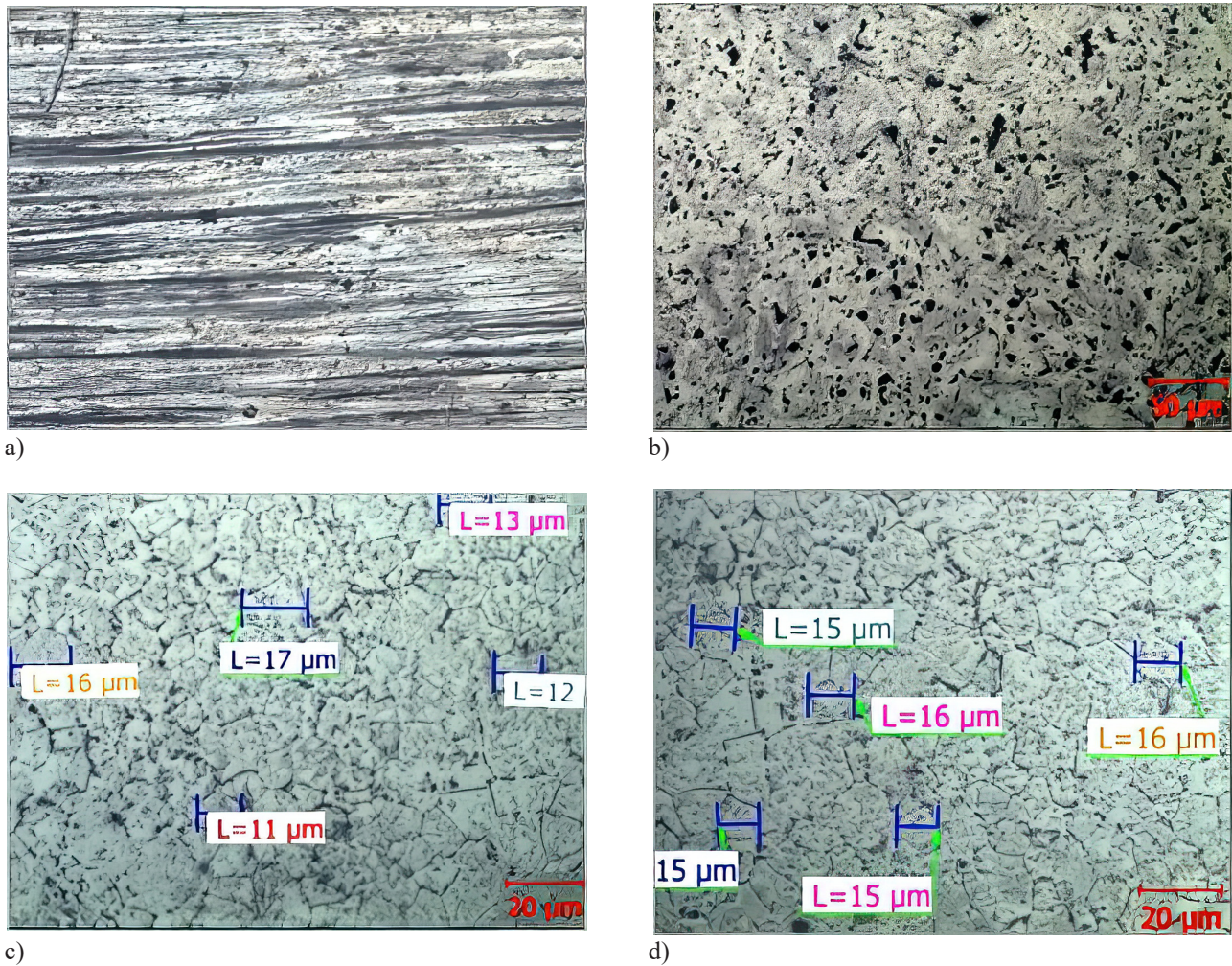


Fig. 9. Micro-structure of deformed wire from MC10 alloy without heat treatment (a, b) and after annealing (c, d): a, c -in the longitudinal direction, b, d -in the transverse direction, x 200.

grains of the solid solution and dispersed precipitation of strengthening phases of complex composition (Fig. 9c-d).

After drawing, the actual average diameter of the wire grain decreased by almost 10 times compared to the original workpiece and amounted to 0.010 mm. At the same time, annealing at a temperature of 350°C contributed to its slight increase up to 0.014 or 0.015, which is due to the occurrence of the recrystallization process.

The mechanical properties of the resulting wire after the drawing operation were determined on an INSTRON testing machine with a reduced traverse speed. Wire Tension Curves of Ø 0.63 mm are shown in Fig.10. At the same time, the load fluctuation is caused by the high sensitivity of the traverse of the tensile testing machine,

associated with the low loading speed.

Results of mechanical tests of metal wire Ø 0.63 mm from original wire Ø 1 mm after drawing without heat treatment showed a significant increase in its mechanical properties (Table 2). At the same time, the tensile strength increased to 320 MPa, and the relative elongation to 25 %, which significantly exceeded the original values. Additional annealing at a temperature of 350°C significantly worsens these characteristics, reducing the strength of the product by ~ 1.5 times and ductility by more than 2 times.

To identify the possible negative impact of the deformed MC10 alloy and its bio-degradation products on a living organism, it is necessary to additionally conduct medical tests, among which bacteriological studies occupy a very important place.

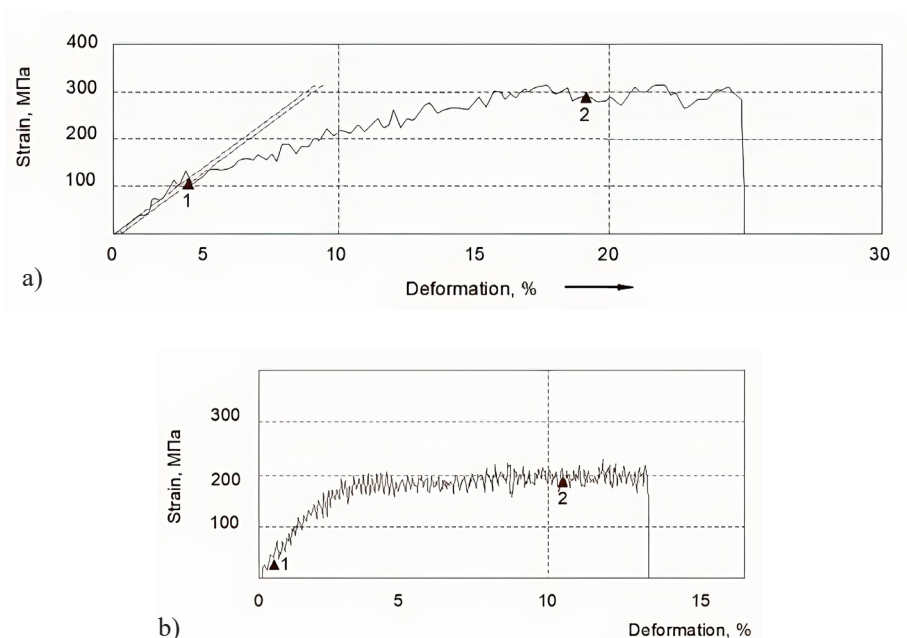


Fig. 10. Wire stretch diagram Ø 0.63 mm: (a) directly after drawing, (b) after heat treatment.

Table 2. Mechanical properties of wire Ø0.63 mm from MS10 alloy after drawing.

Type of heat treatment	Tensile strength, σ_B MN m ⁻²	Relative extension, δ %
Without heat treatment	321...322	25...26
Annealing at 350°C in flow 2 h °C	181...221	5.3...13.0

Bacteriological testing of alloys used in medical applications is critical in ensuring patient safety and the effectiveness of medical procedures. These studies evaluate the antimicrobial properties of alloys, their ability to inhibit the growth and development of bacteria, as well as their interaction with microorganisms present in the environment. The need to conduct bacteriological studies of alloys used in the manufacture of implants is due to several factors:

1. Preventing infections. Medical instruments, implants and other medical devices made from alloys may be introduced into the patient's body during operations or procedures. If the alloys have insufficient antimicrobial activity, this can lead to the development of infections around medical devices, causing serious problems for the patient.

2. Control of microbial growth. Conducting bacteriological studies allows us to assess what types of bacteria can develop near medical products and

equipment made from alloys. This helps develop materials with optimal antimicrobial activity to prevent the growth and spread of dangerous bacteria.

3. Improving the service life of materials. Bacteriological studies help determine how resistant alloys are to corrosion, especially in the presence of microbes. Corrosion can damage and destroy medical devices, reducing their service life and increasing the risk of patient infection.

4. Compliance with standards and regulations. Medical alloys must meet strict standards and regulations to be approved for medical use. Bacteriological studies can document the safety and effectiveness of alloys, which simplifies the process of certification and registration of these materials.

5. Development of new materials. Bacteriological research allows researchers and engineers to develop new medical alloys with improved properties. This may include enhancing antimicrobial activity, reducing

corrosion, or improving other mechanical and physical properties of materials.

Conducting bacteriological testing on medical alloys is an important part of the materials development and quality control process, ensuring the safety and effectiveness of medical procedures and improving patient care.

The bactericidal activity of a magnesium alloy used to produce blanks for bio-soluble implants was studied. The study of the bactericidal activity of magnesium alloy was carried out based on the Zaporozhye State Medical and Pharmaceutical University. Clinical strains belonging to different groups of microorganisms were selected for research:

- family representatives *Enterobacteriales* (gram-negative rods): 15 strains *Klebsiella pneumoniae*, 3 strains *Escherichia coli*, 4 *-Enterobacter agglomerans*, 2 *-Enterobacter sakazakii*;

- cultures of non-fermenting gram-negative microorganisms (gram-negative rods): 15 isolates *Acinetobacter baumannii* and 15 *Pseudomonas aeruginosa*;

- family strains *Staphylococcaceae*: 6 isolates *Staphylococcus aureus*, 1 *Staphylococcus haemolyticus*, 1 strain *Staphylococcus epidermidis* (gram-positive cocci);

- culture *Enterococcus faecalis* belonging to the family *Enterococcaceae* (gram-positive cocci).

All studied strains of microorganisms had typical cultural and biochemical characteristics and were characterized by multiple resistance to antibiotics. The study of the sensitivity of microorganisms to antibacterial drugs was carried out in accordance with the requirements of the European Committee on Antimicrobial Susceptibility Testing (EUCAST, 8.0, The European Committee on Antimicrobial Susceptibility Testing. Routine and extended internal quality control as recommended by EUCAST. Version 8.0, 2018. <http://www.eucast.org>). The studies were carried out using the disc diffusion method using antibiotic discs manufactured by Himedia Laboratories Pvt. Limited (India).

As a result of the studies, it was established that the MC10 alloy has a bactericidal effect against various types of bacteria. This is due to its chemical composition, which ensures its bio-resorption in the human body after performing its function. The biodegradation of such an

alloy is accompanied by the formation of magnesium oxides and a change in the pH of the environment towards the alkaline side, which causes a bactericidal effect.

Thus, during the process of biodegradation of the studied magnesium alloy, the pH of the environment changed from 7.2 to 9.3. Despite the ability of staphylococci and enterococcus to survive under conditions of elevated pH, the bio-degradation products of this alloy showed high bactericidal activity against these antibiotic-resistant microorganisms. Even though some strains were characterized by the ability to survive for a long time under the conditions of the extract, its bacteriostatic properties did not allow bacteria to multiply. Unfavorable living conditions led to the death of bacteria.

Thus, a technology has been developed to produce deformed blanks from cast MC10 alloy with a high complex of mechanical properties and bactericidal properties for the manufacture of implants for various purposes.

RESULTS AND DISCUSSION

It is known that cast metal has chemicals (inter crystalline, intra-granular) and structural heterogeneity (different grain sizes, micro porosity), which determines the insufficient level of mechanical properties of the products from which they are made. It is possible to improve the structure and increase the physical and mechanical properties of the alloy due to its plastic deformation, provided that the deformation modes of the workpieces are correctly selected.

The conducted studies showed the possibility of obtaining high-quality blanks for the manufacture of implants using deformation methods from cast magnesium alloy MC10.

An analysis of the literature data on the study of the influence of various technological regimes on the structure formation and properties of magnesium-based alloys showed that all experiments were associated mainly with well-known widespread magnesium-based alloys [18, 19]. Other studies on the deformation of cast workpieces are devoted to the rational choice of temperature conditions during the deformation of standard magnesium alloys [20, 21]. Studies on the influence of temperature and deformation processing

conditions for the MC10 alloy intended for the manufacture of implants have not been carried out.

A study on the influence of cold plastic deformation modes of the MC10 alloy for the manufacture of work-pieces Ø 8 mm from cast machined samples Ø 13 mm showed that at a rate of cold plastic deformation exceeding 5 mm s^{-1} , their destruction occurred. The initiation and propagation of cracks could be facilitated by lamellar inter metallic compounds, which are stress concentrated, which is consistent with studies done by other authors [22]. It has been established that for deformation of a cast billet 13 mm per rod 8 mm, it is necessary to maintain the optimal deformation rate with a force of 2.5 MN at room temperature at the level of 5 mm s^{-1} . This ensures the production of defect-free metal with an increased set of mechanical properties.

A study of the process of plastic deformation of a cast work-piece in a multi-site matrix in order to obtain wire for the manufacture of implant structures showed that at a temperature of 420°C under isotherm conditions and an extrusion speed of 0.8 mm s^{-1} ensures a laminar flow of the process and the production of wire without breaks or cracks. However, when assessing the quality of the wire by winding it onto a mandrel, small cracks were identified that did not lead to its destruction. The reasons for the formation of which could be a crushed inter metallic phase located along the boundaries of deformed metal grains, which is consistent with other researchers [23, 24]. To eliminate these defects, additional wire drawing was carried out to a diameter of 0.63 mm, which made it possible to obtain defect-free metal. At the same time, the grain size of the MC10 alloy decreased by ~ 10 times, its strength increased by $\sim 30 \%$, and its ductility increased by ~ 6 times.

CONCLUSIONS

- The prospects for using the biodegradable magnesium-based alloy MC10 for osteosynthesis have been shown, and the need to significantly improve its mechanical properties to expand the scope of its application has been substantiated.

- Technological parameters were studied and optimal technological modes of cold plastic deformation of a cast alloy of the Mg-Nd-Zr-Ag system were selected for the manufacture of high-quality implants. It has been established that cold plastic deformation of cast billets

of the alloy under study can significantly improve the macro- and microstructure of the metal, reducing the size of its structural components and the size of the initial grain up to 10 times, increasing the strength of the alloy up to 30 % and increasing its ductility by 2.5 times.

- Technological modes of hot isostatic pressing have been developed to obtain defect-free wire Ø 1 mm from biodegradable magnesium alloy MC10 in a multi-site matrix. It has been shown that additional wire drawing on Ø 0.63 mm provides additional refinement of the metal microstructure, increasing its strength to 320 MPa and relative elongation to 25 %.

- The bactericidal properties of magnesium alloy MC10 were studied. It has been established that the alloy has high bactericidal activity due to the formation of metal biodegradation products because of an electrochemical reaction and a shift in the pH of the environment towards the alkaline side - from 7.4 to 9.6.

Judging all these inclusions, we can make the conclusion that the biodegradable magnesium-based alloy MC10 for osteosynthesis is used to significantly substantiated. The developed technological modes for the production of biodegradable wire from an experimental alloy make it possible to produce high-quality implants with the characteristics required of modern materials. We are recommended this material to use in every operations.

Authors' contributions: *Authors' contributions: V.G.: Conceptualization, Methodology, Writing - Original Draft preparation; V.S.: Visualization, Investigation, Writing - Original Draft Preparation; S.B.: Design of the research, Project administration; E.K.: Editing of the manuscript.*

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