DOI: 10.21062/mft.2022.020 http://www.journalmt.com

Stent Wear Analysis for Percutaneous Coronary Interventions

Daniela Koštialiková (0000-0003-4981-7698), Mariana Janeková (0000-0002-9380-2760), Andrej Dubec, Petra Kováčiková (0000-0003-3450-3290)
Faculty of Industrial Technology in Puchov, Alexander Dubcek University of Trencín, I. Krasku 491/30, 020 01 Puchov, Slovakia. E-mail: daniela.kostialikova@tnuni.sk, mariana.janekova@tnuni.sk, andrej.dubec@tnuni.sk, petra.kovacikova@tnuni.sk

The given paper deals with the issue of materials used in the treatment of heart attacks. In more detail it focuses on individual types of stents and their specific properties. The article describes selected groups of biocompatible metal-based materials. Our attention is mainly paid to magnesium alloys. The introduction explains the concept of biocompa-tibility and the distribution of materials according to their biological tolerance. In the experiment, we performed an ana-lysis of the chemical composition of individual metal stents and focused on examining their wear resistance. Since it is too difficult to imitate human body environment, we opted for corrosion test for the experiment. Stents were exposed to the given concentration of the solution and temperature. The time period during which the stents were in solution was also important. In the final part, we focused on the microscopic evaluation of the surface.

Keywords: Biocompatibility, Stent, Corrosion, Magnesium alloys

1 Introduction

When the implant is inserted into a human body, artificial prosthesis materials significantly affect the response of periimplant tissues. The appropriate material properties are required for successful implant acceptance, but it has to be taken into account that the different materials elicit the different tissue responses [1].

The alloys of Nitinol, cobalt-chromium and magnesium belong among the most common materials used in biomedi-cal practice [2]. In particular, the magnesium alloys can be currently included into the promising materials for implants in living organisms. The reasons of this fast involve the low density, which is close to human bone density, biodegradability, biocompatibility and low toxicity [3,4]. The density of magnesium alloys as well as their strength is close to bone strength [5]. Nowadays, these materials are in the experimental stage to be used as materials for bone reconstruction and replace-ment of metal cardiovascular stents [6,7,8,9]. The high corrosion rate, associated with the generation of large amounts of hydro-gen gas, represents the problem of magnesium alloys for medical application [10]. The hydrogen, which occurs in the men-tioned way, forms subcutaneous bubbles during in-vivo tests. Before designing the suitable construction systems for practice with controlled and acceptable corrosion, it is necessary to assess the corrosion behaviour of alloys. This work deals with the commonly produced MgZnCu alloy.

Interacting with the body environment, the stent surfaces may be coated to increase smoothness or hydrophilicity to prevent leachate from the penetrating into the body. With the increasing anatomical and morphological complexity of destination areas, the requirements for technical and performance characteristics of stents have been increased signifi-cantly. The main deteriorative conditions that avoid the stent placement (implementation) are the vascular contraction, tight lesions, diffuse diseases as well as the high degree of calcification. These individual factors can be combined, result-ing in the increasing of the overall complexity of the cases [11,12,13,14].

2 Experiment

The aim of the work was to analyse the nature of wear of metal stents, which are used in percutaneous coronary in-terventions. The stents, made of Mg alloy and used in medical practice, were the main object of the research. These metal stents are intended for direct application into the human body. They are manufactured by a foreign company, where they are subjected to the highest quality standards.

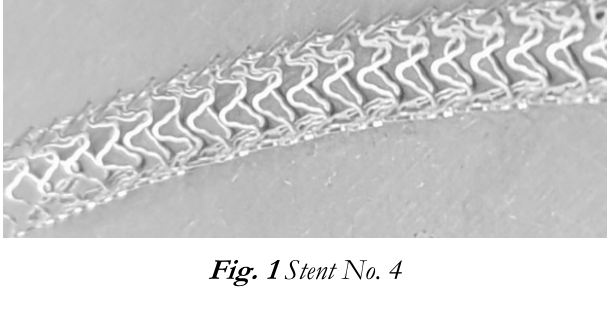


Fig. 1 *Stent No. 4*

The investigation analysis consists of:

- The evaluation of the chemical composition of materials by the EDS method,
- The calculation of weight loss of samples after the exposure to the physiological solutions of different concentration, depending on the time effect,
- The microscopic evaluation of the surface of the samples.

Four stents, stent 1, 2, 3, 4 (samples with designation of No. 1, 2, 3, 4) of the different sizes were used for the experiment.

2.1 The evaluation of the chemical composition of materials by the EDS method

Tab. 17 *Chemical composition of sample No.4 (Mg) from the EDS analysis*

Sample No.4 (Mg)	Elements (wt. %)			
	Mg	O	Cu	Zn
	51.6	48.0	0.3	0.1

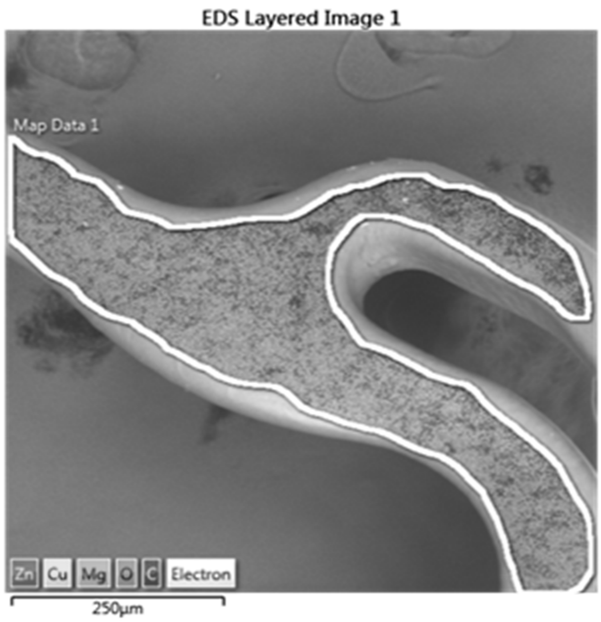


Fig. 2 *Image of the EDS analysis*

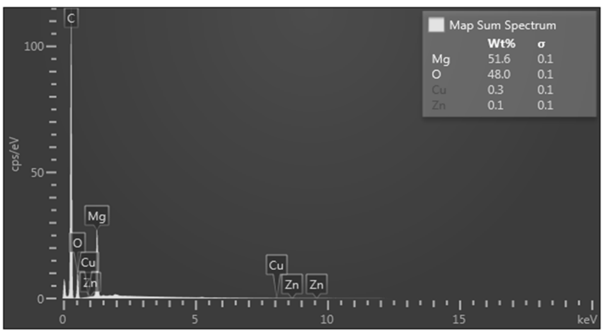


Fig. 3 *Chemical spectrum of elements for sample No. 4*

Chemical analysis of the sample No. 4 (stent 4) Fig. 4 is shown in Tab 1., Fig. 5, 6. It is the MgZnCu alloy, which is characterized by specific mechanical properties, such as: the high strength, hardness, wear resistance and superplasticity. However, the magnesium alloy is limited by its poor corrosion resistance. Magnesium corrosion commonly occurs in the most aqueous solutions. Due to the low thermodynamic stability, the magnesium-based materials react easily with aqueous solutions and release hydrogen gas.

2.2 Calculation of the weight differences for the samples after exposure to the saline solution as a function of time effect

In the second part of the experiment, we have focused on the determination of the environment effect on the material, while the given predetermined environment is comparable to the environment of the human body. Under the common conditions, the most fluids in the human body contain a 0.9% solution of NaCl and other solutions of trace ions with various amino acids and soluble proteins, which have pH values in the range from 7.2 to 7.4 at the temperature of 37 °C and a pressure of 1 atm. As a result of injury or surgery, inflammatory processes of the cells may occur and the pH of the body fluid may drop to 3 or 4 and therefore, we have chosen more aggressive solutions for the experiment.

2.3 Experiment procedure

Before immersion into the solution, we had weighed each sample thoroughly with an analytical scale. The individual stents were immersed in a solution with a concentration of 4% NaCl. The temperature of the solution was chosen to be similar to that of the human body during the inflammatory process (40 °C). We have ensured a constant temperature throughout the whole experiment, using the temperature-adjustable dryer. Each sample was individually immersed into the solution. We have predetermined the time effect for each sample differently: two, four, six and eight weeks. Tab. 2 shows the differences in weight before the beginning of the experiment and after the end of the experiment.

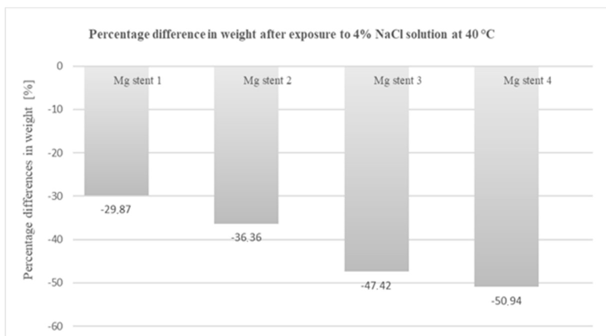


Fig. 7 *Graphical representation of the percentage differences in weight of samples*

Tab. 18 *Weight differences of samples when exposed to 4% NaCl solution*

Stents	Propor-tion [mm]	Time effect	Tempera-ture [°C]	Initial weight [g]	Final weight [g]	Difference in weight [g]	Percentage difference in weight [%]
Mg stent 1	3.5 x 15	2 weeks	40	0.0077	0.0054	-0.0023	-29.87
Mg stent 2	3.0 x 25	4 weeks	40	0.0110	0.0070	-0.004	-36.36
Mg stent 3	3.0 x 15	6 weeks	40	0.0097	0.0051	-0.0046	-47.42
Mg stent 4	3.5 x 20	8 weeks	40	0.0106	0.0052	-0.0054	-50.94

Based on the results of the immersion test, we have found that Mg stent samples lost weight even after 2 weeks of exposure to 4% NaCl solution and the percentage weight loss was up to 29.87% (see Tab. 2, Fig. 4, 5). Weight loss was not increased in dependence on the time effect in relation to solution.

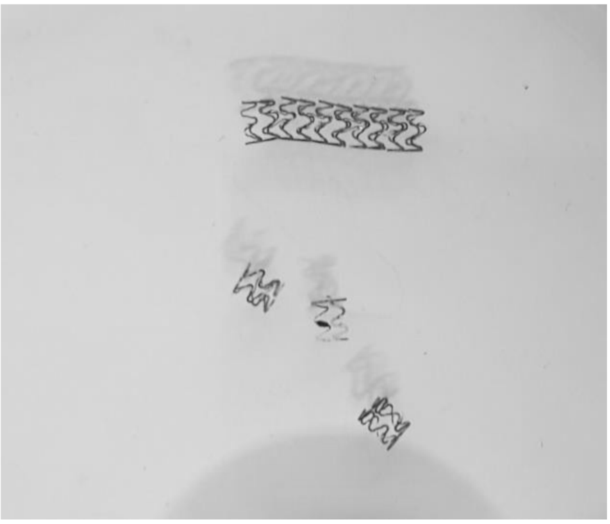


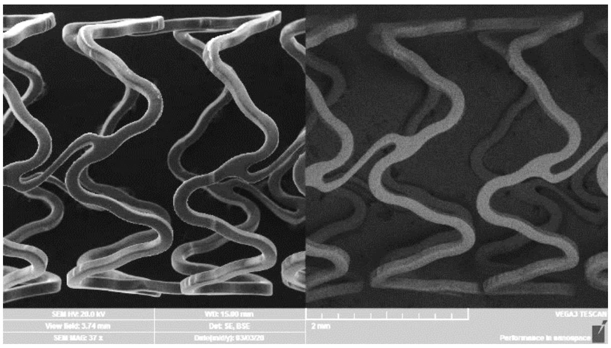
Fig. 8 *Stent after 2 weeks*

2.4 The microscopic evaluation of the surface of the samples

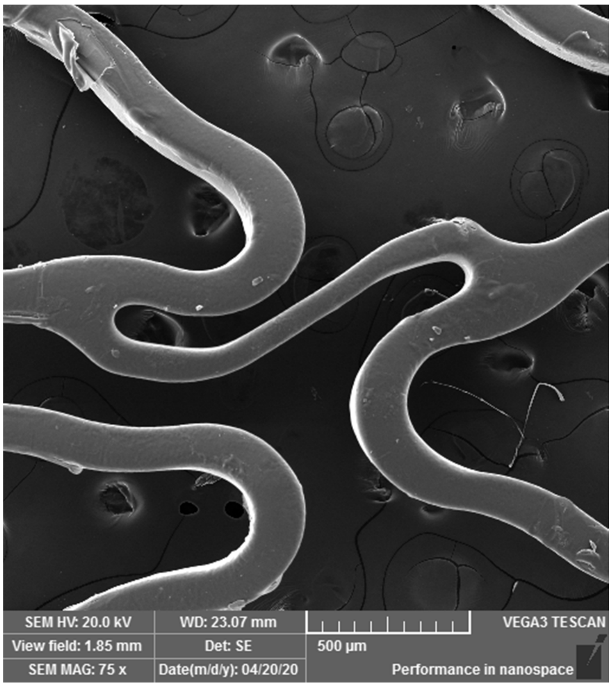
One of the investigated stents was selected for microscopic evaluation, while the effect of time on this stent was pre-determined for eight weeks. The sample (stent) was then subjected to microscopic examination, using VEGA 3 Tescan scanning thermo-emission electron microscope. Before the microscopic examination, the sample No. 4 (stent 4) was pre-cisely cleaned in an ultrasonic cleaner.

Sample No. 4 (stent 4) was observed at 37× 75× and 350× magnifications before the immersion test (Fig. 6). In the given figure (Fig. 6), there is the damaged surface of the stent observed. The damage was probably caused by the han-dling of the sample during its preparation for observation by electron microscope.

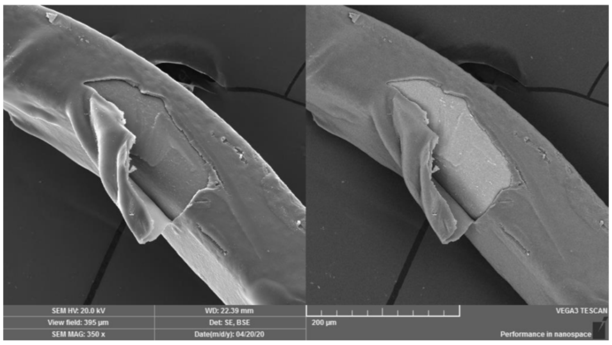
The stent after the immersion test can be seen in the Fig. 7. The material loses its mechanical integrity gradually as well as it dissolves, and it corresponds to the characteristic behaviour of resorbable stents. The disintegration of its struts was uncontrollable because it could not be endothelialized.



a) Image of stent at 37× magnification

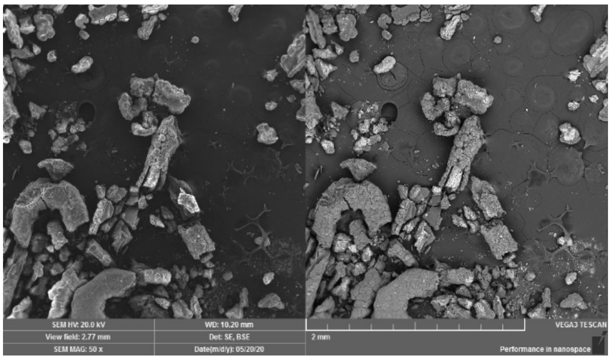


b) Image of stent at 75× magnification

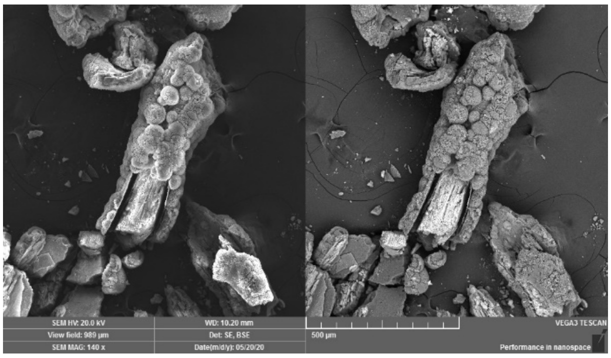


c) Image of stent at 350× magnification – damage of the surface

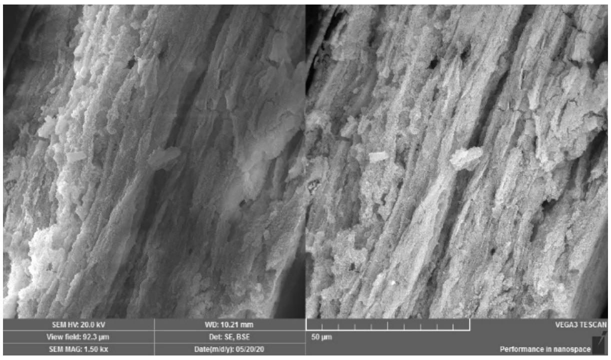
Fig. 9 *Sample No. 4 (stent 4) before the immersion test*



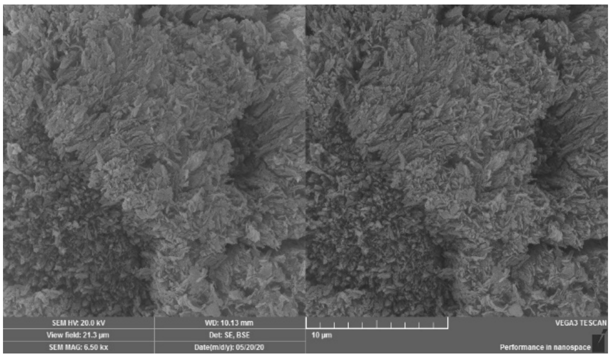
a) Image of sample No.4 (stent 1) at 50× magnification



b) Image of sample No.4 (stent 4) at 140× magnification



c) Image of sample No.4 (stent 4) at 1.5k× magnification



d) Image of sample No.4 (stent 4) at 6.5k×magnification

Fig. 10 *Image of sample No. 4 (stent 4) after the immersion*

3 Conclusion

The given investigation work was focused on the process of coronary stent wear in the predetermined environment, which was prepared to simulate the environment of the human body. The main aim of the work was to determine the chemical composition of samples and resistance to the environment under the influence of various factors. The electron microscopy was used for determination of the changes in the individual samples. For the mentioned analysis, we used coronary stents, which were provided by a foreign company. An analysis of the chemical composition was performed for the individual samples in order to determine the exact chemical composition of the individual stents. The samples were then exposed to saline solution with the strictly predetermined concentration and temperature. The time interval for the solution effect was different.

The bioresorbable magnesium stent gradually loses its mechanical integrity and dissolves and it is characteristic fea-ture of a given type of material. Therefore, the corrosion of the magnesium implant has to be controlled and it has to be carried out at a suitable speed. The speed is not allowed to be high because if it is too high, the implant can be decom-posed before it fulfils its function. On the other side, the given speed is not allowed to be low because if it is too low, the growth of the tissue can delayed or reduced. The optimal rate of implant decomposition approximately corresponds to the growth rate of new tissue (equilibrium). The rate of degradation of magnesium alloys represents the problem for further developments and research in the field of magnesium alloys.

Acknowledgment

This publication was created in the frame of the projects:

•Advancement and support of R&D for "Centre for diagnostics and quality testing of materials" in the domains of the RIS3 SK specialization, ITMS2014+:313011W442, based on the Operational Programme Integrated Infrastructure and funded from the European Regional Development Fund.

•KEGA 011TnUAD-4/2021 Implementation of progressive methods of analysis and synthesis of mechanical systems in the educational process.

References

[1] LI, N., ZHENG, Y. (2013). Novel Magnesium Alloys Developed for Biomedical Application: A Review. J. Mater. Sci. Technol. Vol. 29, Issue (6), p. 489-502. doi: 10.1016/j.jmst.2013.02.005

[2] MAO, L., SHEN, L., CHEN, J. et al. (2017). A promising biodegradable magnesium alloy suitable for clinical vascular stent application. Sci Rep. Vol. 7, 46343, doi.org/10.1038/srep46343

[3] CHEN, YJ., XU, ZG., SMITH, C., SANKAR, J. (2014). Recent advances on the development

of magnesium alloys for biodegradable implants. *Acta Biomater*, Volume 10 (11), p.4561–4573. doi.org/10.1016/j.actbi o.2014.07.005

[4] VOJTĚCH, D., KUBÁSEK, J., VODĚROVÁ, M. (2012). Structural, mechanical and in vitro corrosion characterization of as-cast magnesium-based alloys for temporary biodegradable medical implants. In: *Manufacturing Technology*, 2012, 12(2):285-292

[5] YUNAN, Y., et. al. (2015). Effectiveness of Biodegradable Magnesium Alloy Stents in Coronary Artery and Femoral Artery. *Journal of Interventional Cardiology*. Volume 28, Issue 4, p. 358–364

[6] JONER, M. et al. (2018). Preclinical Evaluation of Degradation Kinetics and Alemental Mapping of First-And Second-Generation Bioresorbable Magnesium Scaffolds. EuroIntervention.12, 14(9), p. 1040–1048

[7] SEZER, N., EVIS, Z., KAYHAN, S. M., TAHMASEBIFAR, A., KOÇ, M. (2018). Review of magnesium-based biomaterials and their applications. In: *Journal of Magnesium and Alloys*, Vol. 6, No. 1, pp. 23-43

[8] ALJIHMANI, L. et al. (2019). Magnesium-Based Bioresorbable Stent Materials: Review of Reviews. *Journal of Bio – and Tribo-Corrosion*. Volume 5, Issue 1, doi: org/10.1007/s40735-019-0216-x

[9] KAMRANI, S., FLECK, C. (2019). Biodegradable magnesium alloys as temporary orthopaedic implants: a review. *Biometals*. Volume 32, p. 185–193

[10] GU, X.N., ZHENG, Y. (2010). A review on magnesium alloys as biodegradable materials. Front Mater Sci China, Volume 4, (2), p.111–115, doi.org/10.1007/S11706-010-0024-1

[11] COY, A.E., VIEJO, F., SKELDON. P., THOMPSON, G.E. (2010). Susceptibility of rare-earthmagnesium alloys to micro-galvanic corrosion. *Corrosion Science*. 52(12), p. 3896–3906. doi: 10.1016/J.CORSCI.2010.08.006

[12] DVORSKÝ, D., KUBÁSEK, J., VOJTĚCH, D., VOŇAVKOVÁ, I., VESELÝ, M., ČAVOJSKÝ, M. (2017). Structure and mechanical characterization of Mg-Nd-Zn alloys prepared by different processes, IOP Conference Series: *Materials Science and Engineering*, 2017

[13] ROUDNICKA, M., BAYER, F., MICHALCOVA, A., KUBASEK, J., ALZUBI, E.G.H., VOJTĚCH, D. (2020). Biomedical titanium alloy prepared by additive manufacturing: Effect of processing on tribology, *Manufacturing Technology*, 20(6), p. 809-816. doi: 10.21062/mft.2020.112

[14] PODANY, J., STARY, V., TOMICEK, J. (2021) 3D surface roughness characteristics for biological applications, Manufacturing Technology, 21(6), p. 836-841. doi: 10.21062/mft.2021.096