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COMPARISON OF THE STRESS RELAXATION OF BIODEGRADABLE SURGICAL THREADS MADE OF Mg AND Zn ALLOYS AND SOME COMMERCIAL SYNTHETIC MATERIALS

The mechanical properties of the commercial synthetic surgical threads (i.e., monofilament *Monosyn*^{R} and polyfilament *Polysorb*^{TM}) and threads made of pure zinc and selected magnesium alloys were compared. Tensile and relaxation tests of fine fibers/wires without and with a surgical knot were performed on a Zwick 250 tensile machine and on the specially constructed tensile machine dedicated for ultra-thin samples. An about 50% decrease in the maximum tensile load was registered for both synthetic and Mg-based threads due to the presence of a surgical knot while only an about 10% decrease was documented for the zinc threads.

Keywords: Ax30, Zn, surgical threads, relaxation, mechanical properties

1. Introduction

Both, synthetic polymers (such as nylon, polyester, polypropylene) and stainless steel are the dominant materials used for surgical sutures (SSs) produced from the beginning of World War II. The possibility of the bio-degradable polymers application for this purpose began to be tested in the 1960s and now such materials are widely used in the medical practice [1] (e.g. *Atramat*^{R}, *Monosyn*^{R}, *Safil*^{R}, *Polysorb*^{TM}, etc.). However, incomplete dissolution of the bio-degradable polymers SSs in the human body after a surgical treatment was repeatedly observed. What is more, some mechanical properties of polymers do not fully meet the requirements for SSs [2]. For example, the ultimate tensile stress and biomechanical stability (i.e., the observed creep of the seam) of polymers are not sufficient for some surgical applications [3]. In such cases, metal wire SSs are preferred. Unfortunately, the stainless steel used for classical SSs is not a bio-degradable material. So, some bio- degradable metallic materials such as alloys based on magnesium [4] and/or zinc [5] are extensively studied for SSs applications. A detailed review of these materials can be found in the Ref. [2]. It should be noted that some elements used to hardening of the alloy can be harmful or even poisonous to the human body. That is why magnesium and/or zinc alloys with the body-friendly elements such as calcium constitute very perspective potential materials for the SSs. The main aim of the project under which the current paper was made is to look for new materials for resorbable surgical threads. Technology of fine Mg-Ca alloy wires with the tensile strength approaching 350 MPa was proposed [6]. Suture materials used in medicine should be characterized by low stress relaxation and a small decrease in strength characteristics due the presence of a surgical knot. However, the strength of the threads without knots are often published, especially for metallic SSs, although such data have little practical significance. The current paper provides the relaxation tests results obtained for the SSs with and without the same type of the surgical knot. Comparison of the tensile stress relaxation characteristics determined for some typical, commercial synthetic SSs and those made of alloys based on zinc and magnesium is the purpose of this work.

2. Experimental, materials and procedures

2.1. Materials characterization

Two bio-degradable metallic SSs (i.e., commercial purity *Zn* and the alloy 96.2 wt.% Mg-3.0 wt. % Al – 0.8 wt. % Ca labeled as *A30*) as well as two synthetic bio-degradable commercial SSs (i.e., *Polysorb*^{TM} *3-0* and *Monosyn*^{R} *2-0*) were selected for the present study. The Tyco Healthcare Group LP, Norwalk, CT, USA is the *Polysorb* trademark owner. This suture is braided of fibers usually made of polyglicolic acid (93%) and polyactic acid (7%) and are coated by glycolide, caprolactone and Calcium Stearoyl Lactylate [7]. According to the producer, the knot pull maximum force (i.e., max. tensile load related to the tensile strength) of Polysorbis suture size 0 (diameter 0.35 mm, collagen diameter 0.4 mm, American wire gauge 26-27) is equal to 6.04 N [8]. *Monosyn*^{R} *2-0* was developed by B-Braun Melsungen AG, Germany for the suturing of soft tissues. This suture is made of glyconate (glycolide (72%), trimethylene carbonate (14%) and

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e-caprolactone (14%)). According to the producer, the knot pull maximum force of *Monosyn* ^{R} is equal to 4.42 N [9, 10].

The metallic SSs have been chosen based on data from Refs [6,13-15]. The zinc wire was extruded and drown to the diameter of 1.6 mm. The wire made of the alloy *A30* with the diameter equal to 0.162 mm was produced from an extruded rod with a diameter of 1 mm. The applied technology comprised two stages – the drawing process in a heated up die and the cold drawing process [9]. The hot drawing allowed us to increase the technological plasticity of the material. However, due to the process instability resulted in a high risk of wire damage, hot drawing usually cannot be used to obtain a wire with a diameter smaller than 0.1 mm. According to the above, the second stage of the process, i.e. the cold drawing with the restoration of ductility between passes was applied to produce the wire with a final diameter equal to 0.162 mm and the grain size of 10-20 μm (Fig. 1a). Details of the process can be found elsewhere [13-15]. The *A30* SS made from one wire and braided with two or four wires with diameters d = 0.162 mm and d = 0.3 mm were used in the present study (labeled respectively as *A30/1*d*, *A30/2*d* and *A30/4*d*). Fig. 1 shows the stress-strain curves of used metallic materials obtained in tensile tests of wires. The curves were obtained on a Zwick machine using an extensometer to measure the strain. As follows from the obtained data, the alloy Ax30 is significantly more strength than Zn. On the other hand, Zn is significantly more ductile.

SEM images (obtained on a Hitachi S-3500N microscope) of both synthetic SSs (Figs. 2 and 3) show that *Polysorb*^{TM} *3-0* is a polyfilamentary thread with a diameter of 0.2-0.3 mm, braided with fibers with a diameter of 10 μm (Fig. 2). The disadvantage

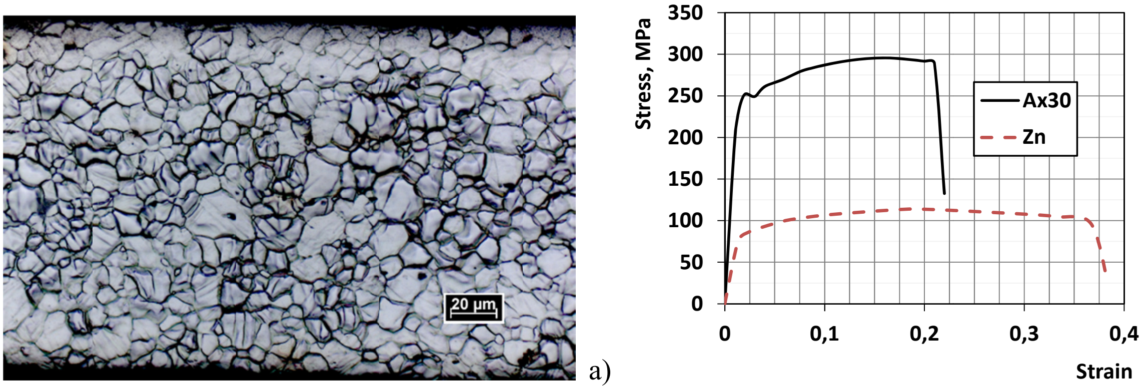


Fig. 1. Microstructure in longitudinal section of threads with diameters 0.162 mm from Ax30 alloy (a) and stress-strain curves for Ax30 alloy and Zn (b)

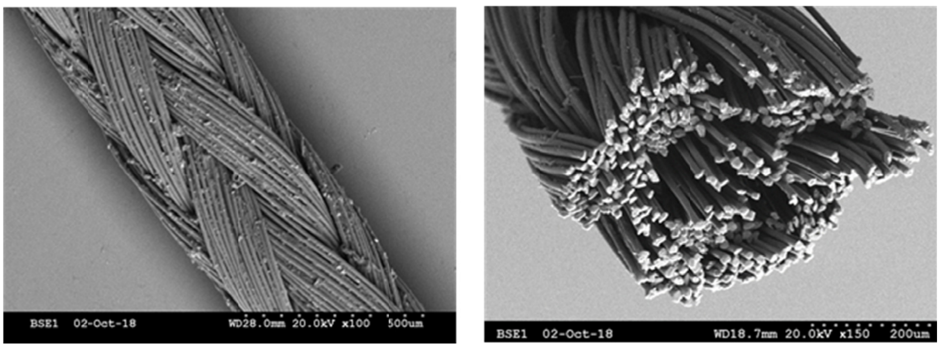


Fig. 2. *Polysorb*^{TM} *3-0*. SEM image

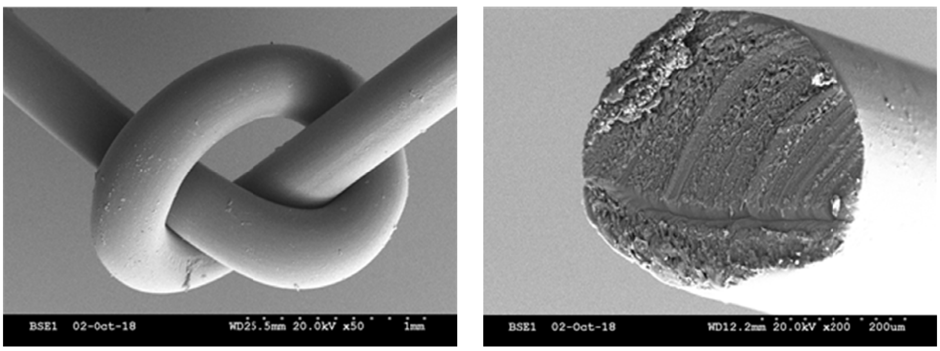


Fig. 3. *Monosyn*^{R} *2-0*. SEM image

of such filaments is the ability to transfer impurities from the volume between the fibers into the wound that may cause infections. Figures 2a and 2b show adhering particles of impurities. The advantages of such a thread is the ability to create a high-quality knot, high strength and the convenience of work. On the other hand, *Monosyn^R 2-0* is a synthetic, monofilament suture with diameter *ca.* 0.3 mm (Fig. 3). This suture is characterized by smoother surfaces which reduces the probability of infection, however, it is more difficult to tie a knot on it though the manufacturer advertises it as the easy knot-tying product [10].

The typical type of a surgical knot was applied in the present study (Fig. 4). Only for the *Monosyn^R 2-0* a double knot was applied as it is practiced.

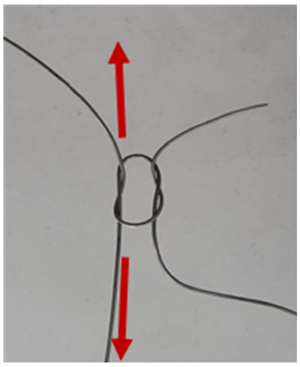


Fig. 4. Typical surgical knot used in the present study, direction of application of force is marked by arrows

2.2 Tensile test of treads

The tensile test was used for mechanical properties determination. A Zwick 250 tensile machine with a special devise for testing treads (Fig. 5a) as well as the specially constructed tensile machine (Fig. 5b) dedicated for ultra-thin samples (maximum load 50 N), were used.

Tensile test was done in the following way. First, the material relaxation tests was carried out. Then mechanical tests up to the rupture was done without removing the material from the testing device. Tensile tests (displacement rate of 0.33 mm/s) up to the rupture and the stress relaxation tests were performed for SSs with and without knots. For the relaxation test the SS was charged by a force corresponding to the force of the wound suturing, i.e. the force from the range 20-40 N and the decrease in the force value was registered within 30 min.

3. Results and discussion

3.1. Results of tensile test of treads

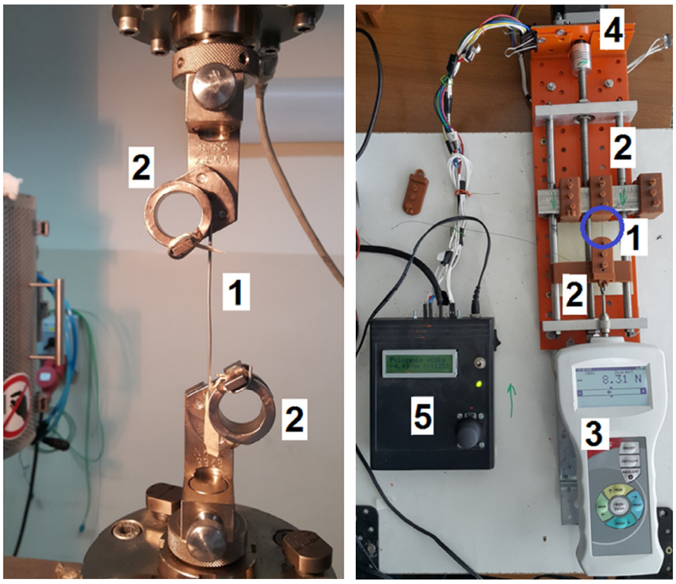
Average results obtained from at least three tests are collected in Tab. 1. Typical tensile curves are shown in Fig. 6. The data from Tab. 1 show that the tensile strength of the synthetic SSs (i.e., *Polysorb^{TM} 3-0* and *Monosyn^R 2-0*) is much higher than that of the metallic ones (respectively values from ranges of 670-780 MPa and 119-266 MPa). Moreover, the breaking force values and the tensile strength of the synthetic SSs collected in Tab. 1 are much greater than literature values (e.g. [2]). It can also be seen that a significant reduction in strength due to the knot occurrence is characteristic for almost all tested materials. Thus, due to the knot, the breaking load drops by almost half. The exception here is zinc for which this decrease is only *ca.* 7%. Data from Tab. 1 also show that the braid braking force nearly proportionally increases with the number of braided fibers as it was expected.

TABLE 1

The tensile test results

Material	*d*, mm	P_{max}, N	P_{knot}, N	P_{knot}/P_{max}	R_m, MPa
Polysorb^{TM} 3-0	0.2-0.3	48.0	22.5	0.47	670
Monosyn^R 2-0	0.3-0.35	74.5	45.3	0.61	780
Zn	1.6	212	198	0.93	119
*Ax30/1*0.162*	0.162	5.49	2.8	0.51	266
*Ax30/2*0.162*	2x0.162	11.0	6.59	0.60	266
*Ax30/4*0.162*	4x0.162	20.0	10.3	0.52	242
*Ax30/1*0.3*	0.3	19.67	-	-	278
*Ax30/2*0.3*	2x0.3	35.6	16	0.45	252

where: *d* – initial diameter of the thread, P_{max} and P_{knot} – maximum tensile load for the tread without and with the knot, respectively and R_m is the material tensile strength (thread without a knot).



(a) (b)

Fig. 5. Treads testing equipment: (a) for the Zwick machine, 1 – sample, 2-grip; (b) homemade machine, 1 – sample, 2 – rods, 3 – force sensor, 4 – electric motor, 5 – power block

3.2. The stress relaxation tests

Usually, manufacturers report a relative change in the SSs strength over working time (measured by days) [7-10]. Therefore, the current paper also provides changes in the relative

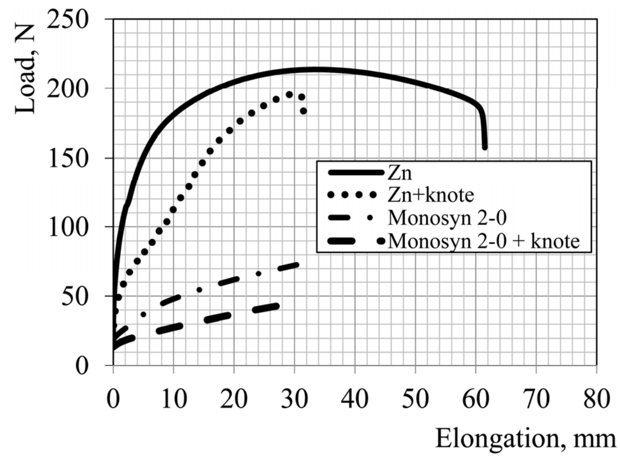


Fig. 6. Typical tensile curves for selected materials

tensile force during relaxation time (but measured in seconds), Figs 7 and 8. These figures show that for all tested samples, a large decrease in this force occurs during the first 500 seconds of relaxation, then, this change clearly decreases. Moreover, it can be seen, that for tested threads, except for those made of zinc, the presence of a knot shifts the relaxation curves towards the lower forces. To be more accurate, the current paper also provides changes in the force relaxation rate over time (Figs 9 and 10). It is clearly visible that for all tested materials a large drop in the rate of force reduction occurs during the first few seconds of relaxation. A particularly high rate of relaxation was shown by zinc, i.e., initially about 16 N/s, and below 0.6 N/s after first 7 s of relaxation. For zinc, a high rate of relaxation is a typical behavior [11]. However for the SSs made of zinc, the noticeable influence of the knot on the relaxation rate was not observed (Fig. 10). Significantly lower initial force relaxation rate is demonstrated by threads made of *Ax30*. It is slightly dependent on the force from which the relaxation started and the maximal relaxation rate (equal to initial rate of relaxation) was close to 5.5 N/s (Fig. 10). A significant reduction in the force relaxation rate due to the presence of the knot was observed for these SSs. This result surprised us, so it will be verified more precisely in the future.

A low force relaxation rate is typical for synthetic threads tested in research reported in the current paper. For *Polysorb*^{TM} *3-0* the maximal relaxation rate was below 3 N/s and below 1 N/s for SSs with and without the knot, respectively, (Fig. 9). The corresponding values were even lower for *Monosyn*^{R} *2-0* (i.e., below 1.5 N/s and below 0.75 N/s for SSs with and without the knot, respectively, Fig. 9). It should be noted however, that in the case of threads *Monosyn*^{R} *2-0*, it was necessary to tie a double knot.

4. Conclusions

1. The synthetic surgical sutures investigated in the current paper proved to have a significantly higher tensile strength than magnesium or zinc-based ones. This conclusion is contradictory to popular opinions.
2. Tensile strength of the surgical thread decreases approximately by half due the presence of a surgical knot. Threads made of zinc are an exception because this reduction is only 7%.

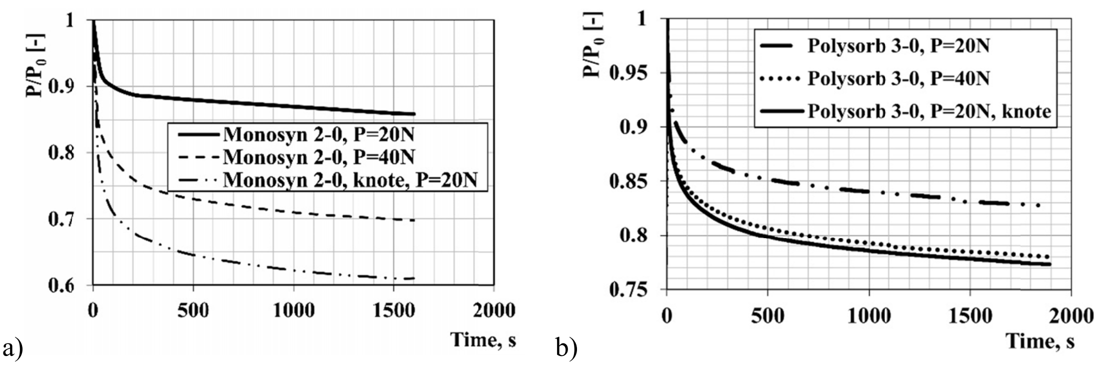


Fig. 7. Relaxation curves, synthetic threads, (a) *Monosyn*^{R} *2-0*, (b) *Polysorb*^{TM} *3-0*

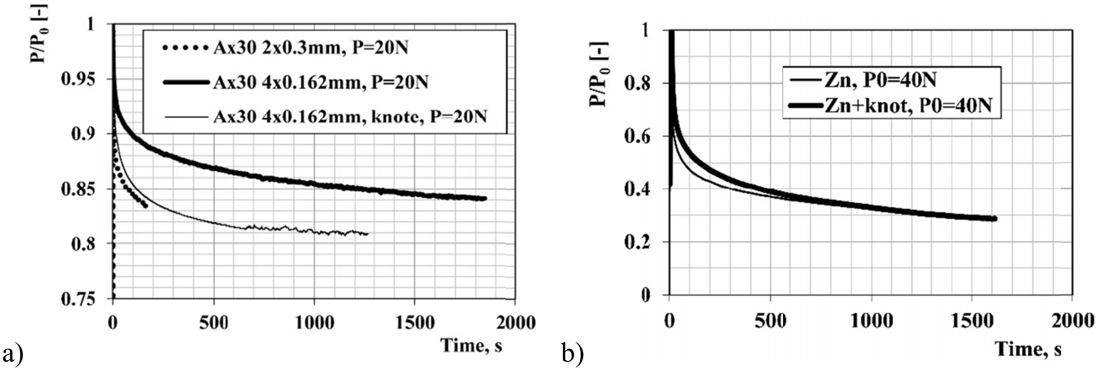


Fig. 8. Relaxation curves, metallic threads, (a) *Ax30*, (b) *Zn*

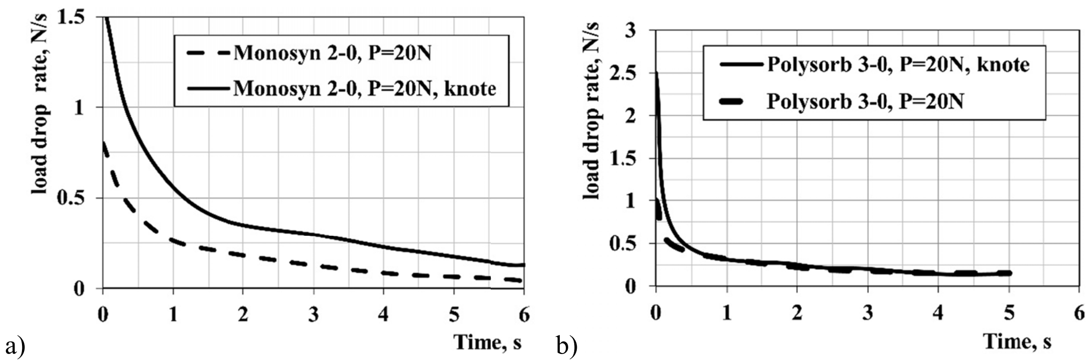


Fig. 9. The force relaxation rate *vs*. time, synthetic threads, (a) *Monosyn*^{R} *2-0*, (b) *Polysorb*^{TM} *3-0*

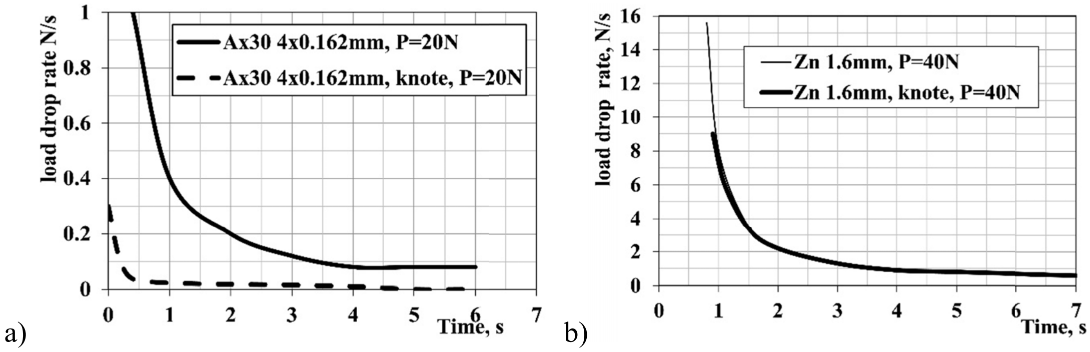


Fig. 10. The force relaxation rate *vs*. time, metallic threads, (a) *Ax30*, (b) *Zn*

3. For all tested threads, a highest rates of the force relaxation occur in the first few seconds. It may be important to choose the technique for tying a strong surgical knots.
4. The maximal rate of the force relaxation is significantly higher for surgical threads made of zinc than for the *Ax30* ones.
5. The presence of a knot does not affect the force relaxation rate of the surgical thread made of zinc.

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