Acta Mechanica Slovaca **30 (1): 6 - 14,** March **2026**
https://doi.org/10.21496/ams.2025.028

Acta Mechanica Slovaca
ISSN 1335-2393
www.actamechanica.sk

Proposal of Bioresorbable Implant´s Osteosynthesis Optimization for Syndesmosis Injury

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Abstract: This narrative review focuses on biodegradable magnesium-based materials, emphasizing their biocompatibility, mechanical properties, and clinical potential for orthopedic applications. The aim of the study is to assess the suitability of magnesium alloys — particularly the ZX00 alloy (Mg–0.45Zn–0.45Ca)—for the stabilization of the tibiofibular syndesmosis (syndesmosis tibiofibularis). The work summarizes recent advances in material science, alloy optimization, surface modification, and additive manufacturing techniques that enhance the corrosion resistance and mechanical integrity of magnesium implants. It compares the biomechanical performance of magnesium alloys with conventional osteosynthetic materials such as stainless steel and titanium, highlighting their bone-like elasticity and controlled bioresorption after fracture healing. Based on preclinical and early clinical data, biodegradable magnesium implants show promising outcomes in syndesmosis fixation and may reduce the need for secondary hardware removal. Although these factors could potentially lower overall treatment costs, further clinical and economic studies are required to substantiate this benefit.

Keywords: syndesmosis; bioresorbable; osteosynthesis, additive manufacturing

1. Introduction

With longer life expectancy and increasingly active lifestyles, fractures and musculoskeletal injuries are rising. Among these, injuries to the distal tibiofibular syndesmosis represent approximately 10–20% of ankle fractures and occur most frequently in young adults and athletes. Syndesmosis injuries often result from external rotation or hyperdorsiflexion trauma and, if not properly treated, can lead to chronic instability, pain, and post-traumatic arthrosis.

In clinical practice, fixation of the syndesmosis is most commonly performed using either rigid screw fixation or dynamic suture-button stabilization. Rigid metallic screws (usually stainless steel or titanium) ensure high mechanical stability but restrict physiological micromotions between the tibia and fibula, often necessitating secondary removal. Dynamic suture-button systems allow limited motion closer to the natural biomechanics of the syndesmosis and may reduce the need for implant removal, though they are costlier and carry risks of overcompression or malreduction.

Recent research trends have focused on biodegradable magnesium-based materials as a promising alternative. These materials combine sufficient mechanical strength with gradual bioresorption, eliminating the need for hardware removal while maintaining physiological motion during healing. Magnesium's elastic modulus is close to that of bone, reducing stress shielding, and its degradation products can promote osteogenesis.

The objective of the present review is to assess the potential of bioresorbable magnesium alloys —particularly ZX00 (Mg–0.45Zn–0.45Ca) — for syndesmosis stabi-

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lization. The study aims to propose an optimization framework linking implant degradation time, required load-bearing capacity, and syndesmosis biomechanics to guide the design of next-generation bioresorbable fixation systems.

Furthermore, understanding implant–bone interaction requires consideration of osseointegration mechanisms, which can be described by two main types of models: phenomenological models, focusing on empirical relationships between bone ingrowth and implant surface properties, and mechanobiological models, which simulate cellular and tissue-level responses to mechanical stimuli. These approaches provide valuable tools for predicting long-term integration of biodegradable implants within the evolving bone environment [1].

2. Materials and Methods

From a materials science perspective, biomaterials are divided into four main groups: polymers, ceramics, metals and composites. Polymeric biomaterials are widely used in tissue engineering because they allow for the variable fabrication of implants with complex geometries and their surface properties can be easily modified. The chemical and mechanical properties of polymers can be adjusted to some extent during the sterilization process. Despite these advantages, they exhibit limited mechanical strength, which limits their use in load-bearing implants. In addition, some additives, such as plasticizers, stabilizers and antioxidants, can be released into body fluids and damage the surrounding tissue.

Ceramic materials, such as calcium phosphates, are most often used as implant surface layers. The main advantages of these materials are non-toxicity, good biocompatibility and the ability to promote bone tissue growth. However, their use is limited by their mechanical properties and high susceptibility to corrosion in acidic environments, making them unsuitable for applications in areas with higher loads [2,3].

Metallic implants are most used for the treatment of fractures and bone defects. The most used include stainless steel, cobalt and titanium alloys, which are suitable for implants with long-term application. Their high strength and toughness ensure resistance to implants damage during application. Metallic implants can be manufactured using various technologies, such as casting, machining or powder metallurgy, which allows them to be tailored to patient requirements [4].

Despite their excellent mechanical properties, the biocompatibility of metallic implants is affected by corrosion and wear. When the metal degrades, harmful ions can be released, which can cause inflammation, cell damage or other undesirable reactions in the tissue. For example, chromium ions from Co-Cr alloys, as well as niobium, vanadium and nickel from titanium alloys, can cause negative biological reactions in the body when safe concentrations are exceeded [4]. To reduce these risks, composite biomaterials have been developed that combine the advantages of ceramics, polymers and metals. They aim to improve the mechanical strength, biocompatibility and biological activity of implants, while eliminating their disadvantages. For example, polymer-ceramic composites provide better bioactivity and higher strength, while metal-ceramic composites offer higher resistance to wear and corrosion [5]. Although good mechanical properties are crucial for implants, especially for orthopedic applications, the excessive stiffness of traditional metal implants can be detrimental to bone and tissue healing because it can lead to a stress shielding effect. This phenomenon occurs when the bone around the implant is not subjected to sufficient mechanical load due to the high stiffness of the implant. The stress shielding effect can result in bone loss near the implant, leading to loosening [6].

Similar load-dependent remodeling mechanisms have been described in other anatomical contexts. Tomaszewska applied the Huiskes mechanobiological model to analyse bone adaptation in the mandible after tooth extraction and demonstrated that local remodeling intensity is directly correlated with changes in mechanical loading. This example illustrates the same principle relevant to the syndesmosis region, where altered stress distribution around rigid implants may suppress natural bone remodeling and contribute to local osteopenia. Incorporating materials with an elastic modulus closer to bone, such as magnesium alloys, can therefore mitigate stress shielding by promoting more physiological load transfer [1].

The selection of a suitable biomaterial for bone implants depends on mechanical strength, biocompatibility, corrosion resistance, and the ability to promote bone growth. Metal implants are the most mechanically durable, ceramic implants support bone regeneration, and polymers allow flexible manufacturing and surface treatment. New biomaterials, such as biodegradable materials, are constantly being developed to help reduce patient reoperations, thereby minimizing complications and increasing patient success.

2.1. Properties of magnesium alloys

Magnesium (Mg) is an essential mineral in the body, acting as a cofactor in over 300 enzyme systems that regulate various biochemical processes, including protein synthesis, muscle and nerve function, blood glucose control, and blood pressure regulation. Magnesium is essential for energy production, oxidative phosphorylation, and glycolysis. It plays an important role in the development of bone structure and is involved in the synthesis of DNA, RNA, and the antioxidant glutathione. In addition, magnesium ions (Mg^{2+}) are known to promote tissue healing. Excess Mg^{2+} ions do not cause cellular toxicity. Mg is crucial for the active transport of calcium and potassium ions across cell membranes, which is essential for nerve transmission, muscle contraction, and maintenance of normal heart rhythm. The adult body contains approximately 25 g of magnesium, with 50–60% stored in bones and most of the remainder in soft tissues [7].

2.1.1. Mechanical properties

Magnesium alloys have gained a place in research as a new biodegradable material due to their unique degradation properties and excellent biocompatibility. Magnesium and its alloys are considered ideal candidates for orthopedic implants because they have a similar elastic modulus (41–45 GPa) to human bone and at the same time exhibit good biocompatibility [8]. From Table 1 the density, elastic modulus and yield strength of magnesium alloys are closest to those of human bone. As a result, magnesium alloys can significantly reduce the negative phenomena associated with the stress shielding effect in orthopedic and cardiovascular implants. The mechanical properties of these alloys are particularly important for implants that withstand high mechanical loads.

2.1.2. Physical and chemical properties

The low density of magnesium alloys (approximately 1.74–2.0 g/cm^3) makes them a lightweight material suitable for orthopedic implants, where weight minimization is key.

An ideal orthopedic implant should gradually lose its strength during tissue regeneration to allow bone growth. Magnesium, due to its biodegradability, perfectly meets this requirement. Upon contact with an aqueous environment, magnesium undergoes cathodic degradation (1) and (2), releasing large amounts of hydrogen (H_2) and forming magnesium hydroxide Mg $(OH)_2$ (3) and (4). Research shows that Mg $(OH)_2$ can deposit on the implant surface, forming a protective layer that slows down magnesium corrosion. However, under physiological conditions, the presence of chloride ions (Cl^-) is a problem, as it causes the conversion of Mg $(OH)_2$ to $MgCl_2$ (4). Since $MgCl_2$ is highly soluble, it accelerates magnesium corrosion and causes a local increase in pH, which can affect the surrounding biological balance [9,10].

$$Mg(s) \rightarrow Mg^{2+} + 2e^- \tag{1}$$

$$2H2O + 2e^- \rightarrow H2 + 2OH^- \tag{2}$$

$$2H2O + O2 + 4e^- \rightarrow 4OH^- \tag{3}$$

$$Mg^{2+} + 2OH^- \rightarrow Mg(OH)2(s) \tag{4}$$

$$Mg(OH)2 + Cl^- \rightarrow MgCl2 + 2OH^- \tag{5}$$

2.2. Strategies to improve corrosion resistance and mechanical properties

The main problem with Mg implants is their rapid degradation in a complex physiological environment. Biodegradable magnesium alloys disintegrate within four to six weeks, which is significantly shorter than the eight to twelve weeks required for natural bone regeneration [11]. According to research, the degradation rate of Mg alloys under laboratory conditions (in vitro) is usually one to four times higher than under real conditions in the body (in vivo), probably due to the lower concentration of chloride ions in the body. They are susceptible to microgalvanic corrosion due to their high elec-

Table 1: Comparison of mechanical properties of metallic materials with human bone [6].

Characteristics	Human bone	Magnesium alloys	Titanium alloys	Cobalt-chrome alloys	Stainless steel
Density (g/cm^3)	1,8-2,1	1,74-2,0	4,4-4,5	8,3-9,2	7,9-8,1
Elasticity modulus (GPa)	3-20	41-45	110-117	230	189-205
Yield strength (MPa)	130-180	85-190	758-1117	450-1000	170-310

tronegativity value (-2.37 V). In addition, with increasing corrosion potential, the corrosion rate and hydrogen release increase sharply. This can lead to serious complications such as blockage of blood vessels or tissue death due to the accumulation of hydrogen gas. Corrosion resistance studied in laboratory conditions does not consider the influence of proteins and enzymes that are present in the body under real physiological conditions and can positively or negatively influence magnesium corrosion – this topic is still under discussion. Another explanation for the differences between in vitro and in vivo degradation is the constantly changing physiological conditions in the human body [12-14]. During the gradual degradation of the Mg implant, the strength of the healing bone increases at the same time. The mechanical integrity of the implant is designed to be maintained throughout the healing process, with the implant only fully disintegrating after complete bone healing. This ensures continuous support during regeneration [15]. To improve the mechanical properties and corrosion resistance of magnesium, various alloying elements are added to its structure. However, some of them, such as aluminium and rare earth elements, can impair the biocompatibility of the material in certain alloy formulations. Due to the toxicity of some alloying elements, a conflict arises between optimizing the material properties and minimizing the biological risk. Pure magnesium has low mechanical strength and ductility, which makes it unsuitable for load-bearing applications. Although alloying magnesium with elements such as aluminium, zinc, and rare earth elements improves its mechanical properties, it is difficult to optimize strength, ductility, and degradation rate simultaneously [16-18]. Mg alloys (Table 2) micro alloyed with Zn, Zn–Ca, Sr, and Mn–Ca–Zn show safer biodegradation in the range of 0.2 to 0.5 mm/year due to the formation of protective oxide layers. These layers serve as an effective barrier against corrosive ions present in the physiological environment [19-22]. This process remains a challenge due to the non-uniform distribution of alloying elements and the low solubility of magnesium. These factors lead to the formation of heterogeneous and coarse secondary phases that accelerate the degradation of Mg alloys by creating sites for micro galvanic corrosion [23].

Surface treatment is a key strategy to improve the properties of Mg alloys. It can be divided into five main categories: mechanical, chemical, thermal, biological and electrical methods. The most used techniques include shot peening, sol-gel coatings and electrodeposition, which allow the material surface to be tailored for specific biomedical applications. Among the various approaches, surface treatment represents a simpler and more effective alternative to control the degradation rate of Mg alloys [26]. Although previous studies have shown that surface treatments improve the mechanical properties of biodegradable Mg alloys, there is strong evidence that these treatments do not provide sufficient corrosion protection under real-world conditions. In addition, residual stress generated during thermal or mechanical processing can negatively affect the corrosion resistance and mechanical properties of Mg alloys [24].

2.3. Mg alloy production processes

The manufacturing process directly influences the microstructure and subsequent properties, including degradation rate, mechanical properties and bioactivity. The following chapter describes several processes used to manufacture Mg bone implants. These processes can be divided into traditional techniques such as casting and powder metallurgy and state-of-the-art approaches such as laser additive manufacturing [27].

2.3.1. Casting

The casting process involves heating the metal elements above their melting point (usually in the range of 700 to 800 °C depending on the alloy composition), pouring the liquid phase into the designed mould, and solidifying the ingots of the desired shape. A protective atmosphere, most often ar-

Table 2: In vivo and In vitro degradation of selected Mg alloys. [20,21,24,25]

Alloy	Degrading environment	Degradation rate (mm/year)	In vitro solution
Mg-Ca	Body fluids	0,5	Hank solution
Mg-Zn	Subcutaneous tissue	0,7	PBS
Mg-Sr	Blood circulation	0,3	Hank solution/ simulated body fluids
Mg-Ca-Zn	Bone	0,5	simulated body fluids

gon, is usually provided during casting [27]. Due to the high chemical reactivity of molten magnesium, the casting process must be carried out with strict safety precautions. Magnesium has a relatively low ignition temperature and can ignite spontaneously in the presence of oxygen or moisture. Therefore, maintaining a stable protective atmosphere, typically argon or other inert gas mixtures, is essential to prevent oxidation and combustion during melting and pouring.

Various elements are added to the Mg matrix to tailor the desired properties of the alloy. Cu and Ag are added to provide antibacterial properties. Sr is added to improve osteogenic properties [28-30]. It should be noted that Mg bone implants must have specific shapes to fulfil their biomedical function. Bone fixation devices typically require flat plates, nails, and screws. Bone substitutes, on the other hand, require a porous structure. Casting is not suitable for the direct production of these shapes with a porous structure but is suitable to produce a base material for subsequent forming techniques that can produce parts with the desired shape or structure [31].

2.3.2. Powder metallurgy method

The powder metallurgy method consists of pressing metal powder into the desired shape under high pressure, followed by high-temperature sintering in a protective atmosphere furnace. During sintering, complex physicochemical processes such as diffusion, recrystallization, fusion welding and dissolution occur, leading to the achievement of high material density [27].

Magnesium (Mg)-based composite materials can be efficiently prepared by powder metallurgy. The sintering process is a key factor affecting the resulting density and integrity of components manufactured by powder metallurgy. However, excessive sintering time is undesirable, as it promotes the growth of a coarse-grained microstructure, which leads to the degradation of the mechanical properties of the material [27].

The production of porous structures by the powder metallurgy method is possible with the use of pore-forming agents. Seyedraoufi et al. synthesized a porous Mg-Zn-based material by this method. A powder mixture of magnesium, zinc and a pore-forming agent was pressed under a pressure of 100 MPa into a compact semi-finished product, which was subsequently sintered at 250 °C for 4 hours. Subsequent firing of the pore-forming agent at 580 °C for 2 hours created a porous structure in the magnesium matrix. However, it should be emphasized that it is difficult to achieve a homogeneous and interconnected porous network with this method. Moreover, residues of pore-forming agents may remain trapped in the magnesium matrix even after sintering. These contaminants can negatively influence the corrosion behaviour and biocompatibility of the material by introducing local inhomogeneities or releasing undesirable reaction products into the surrounding tissue [32].

One variation of powder metallurgy is the metal injection moulding (MIM) technology, which allows the economical production of implants with complex geometries while maintaining a high degree of shape accuracy. Wolff et al. applied this method to the synthesis of a Mg-Ca alloy and analysed its mechanical properties. The resulting material reached almost full density, with mechanical properties including a tensile strength of 141 MPa, a yield strength of 73 MPa, an elongation at break of 7%, and a Young's modulus of 38 GPa [33].

Spark Plasma Sintering (SPS) is an advanced powder metallurgy technique that is used to fabricate degradable Mg-based composites. This technique utilizes the self-heating effect of the powder, allowing for high heating rates and minimizing sintering time, effectively reducing grain growth. Dutta et al. successfully prepared a bioactive glass-reinforced Mg composite using SPS, achieving a homogeneous distribution of glass particles in the matrix. The results of the study indicated that the fabricated Mg composite with high elastic modulus is a promising material for applications in bone fracture fixation [34].

2.3.3. Additive manufacturing

Laser additive manufacturing has proven to be particularly suitable for the fabrication of complex porous structures and personalized implants that meet specific patient needs. In recent years, several studies have been published on the use of this technology for the fabrication of magnesium scaffolds. Li et al. fabricated porous magnesium scaffolds with a diamond-shaped cellular structure. The resulting scaffolds provided adequate mechanical support, especially in terms of Young's modulus, and showed satisfactory degradation properties with approximately 20% volume loss after 4 weeks of degradation in simulated body fluid [35]. Kopp et al.

fabricated WE43 alloy scaffolds with different pore sizes using this method. Scaffolds with smaller pores showed lower hydrogen release and less reduction in mechanical properties over time. Compared with other methods for the fabrication of porous structures, laser additive manufacturing allows for precise control of porosity. Combined with CAD and computed tomography, implants can be easily tailored to individual patient needs or specific defect sites [36]. Despite its many advantages, laser additive manufacturing of magnesium implants is less developed compared to biometals such as titanium and iron alloys. The main obstacle is the physical and chemical properties of magnesium. Its low melting point (650 °C) is close to its boiling point (1091 °C), which complicates laser processing. Another challenge is the high volatility of magnesium during laser processing due to its low boiling point, low surface tension, and low density. In addition, magnesium oxidizes easily, so it is essential to provide a protective atmosphere with a very low oxygen content (below 0.1 ppm) for laser additive manufacturing of magnesium and its alloys [37].

2.4. Magnesium alloys and ankle fracture fixation

Bioresorbable magnesium-based alloys are alternative and innovative materials used for ankle fracture fixation. Grün et al. proposed an alloy containing the essential nutritional elements Mg-0.45 wt% Ca-0.45 wt% Zn (designated ZX00). The alloy demonstrated favorable biomechanical properties, biocompatibility, bioresorbability, and osteoconductivity in animal experiments [38]. In a "laboratory to clinical practice" approach, Holweg et al. conducted a pilot clinical study using ZX00 screws for fixation of medial malleolus fractures, not for syndesmosis stabilization. The results after 12 weeks showed successful fracture healing without adverse events in all 20 patients [39]. Although the study focused on the medial malleolus, the positive clinical outcomes provide valuable insight into the mechanical and biological performance of ZX00 screws under conditions comparable to syndesmosis fixation.

Similarly, Herber et al. evaluated the clinical, functional, and radiographic outcomes of ZX00 compression screws in medial malleolus fracture fixation over 6- and 12-month follow-ups [40]. No complications such as infections, allergic reactions, or screw failures were reported, and the gradual resorption of the screw heads confirmed the material's bioresorbability. While these results do not directly concern syndesmosis injuries, the comparable mechanical environment of the ankle region supports the potential applicability of ZX00 magnesium screws in syndesmosis stabilization.

3. Results and Discussion

Stainless steel and titanium alloys are standard materials used in syndesmosis surgery. Stainless steel (AISI 316L) is most often used in traumatology due to its high strength and good affordability. On the other hand, the fixation is rigid and may inhibit the natural dynamics of the syndesmosis. Titanium alloys (Ti-6Al-4V ELI – implant quality according to ASTM F136) have a lower density than steel, better biocompatibility and a lower elastic modulus., but it is still a rigid fixation. Biodegradable magnesium alloy (e.g. ZX00 – Mg-0.45Zn-0.45Ca) screws represent a promising alternative without the need for removal. They are relatively new, less common yet, but with growing interest. For example, Mg vs. titanium in malleolar fixation shows similar therapeutic and radiological results. The main advantage is that Mg screws are gradually absorbed and usually do not need to be removed. Material mechanical properties are listed in Table 3.

Based on the mechanical and biological characteristics summarized in Table 3, the ZX00 alloy appears to be a promising material for use in ankle and potentially syndesmosis fixation. Its elastic modulus is closer to that of cortical bone than that of stainless steel or titanium alloys, which could reduce the stress-shielding effect and allow for more physiological load transfer between the tibia and fibula. The alloy contains only biogenic elements—magnesium, zinc, and calcium—thereby minimizing risks of long-term toxicity or allergic reaction. During biodegradation, calcium- and phosphorus-rich apatite-like surface layer forms, promoting osteoconduction and gradual replacement of the implant by bone tissue without chronic inflammatory response. Clinical and preclinical studies [41] have demonstrated favourable degradation behaviour and sufficient mechanical stability during the early healing phase, supporting the potential of ZX00 as a bioresorbable fixation material in the ankle region. Nevertheless, the current evidence remains limited, and the performance of ZX00 in syndesmosis stabilization should be validated in direct comparative studies with conventional titanium screws and modern suture-button systems to confirm its long-

Table 3: Comparison of mechanical properties of selected materials.

Material	Elasticity modulus E [GPa]	Yield strength $Rp_{0.2}$ [MPa]	Tensile strength Rm [MPa]	Elongation [%]	Density [g/cm^3]	Advantages	Disadvantages	Clinical implications for syndesmosis stabilization
Stainless steel (AISI 316L)	190–210	170–300	500–1000	≥ 40	~7,9	High strength, long clinical history, low cost, fatigue resistance	High stiffness → stress shielding, rigid fixation, Ni allergy, requires removal	Provides rigid stabilization but limits physiological micromotion of the syndesmosis and typically requires a second surgery for removal.
Titanium alloy (Ti-6Al-4V ELI)	100–115	795–900	860–960	10–14	~4,43	Lower modulus, high strength, biocompatible, corrosion-resistant	Rigid fixation, higher cost, difficult removal	Allows slightly better load distribution than steel but still restricts natural tibiofibular movement; removal is often necessary.
Magnesium alloy ZX00 (Mg-0,45Zn-0,45Ca)	40–45	110–160	220–280	8–12	~1,74	Bone-like modulus, osteoconductive, biodegradable, eliminates removal	Possible gas formation, variable degradation rate, limited long-term data	May enable semi-dynamic fixation closer to physiological motion and avoid implant removal; long-term clinical validation is still required.

term biomechanical and functional equivalence. Until such data is available, ZX00 can be regarded as a potentially suitable alternative rather than a definitively superior material.

4. Conclusions

Complications of surgical treatment of ankle fractures remain a common and clinically significant problem in contemporary traumatology. Their management is influenced by many factors, including fracture morphology, soft-tissue condition, patient comorbidities, and surgeon experience. Appropriate preoperative planning and the selection of an optimal osteosynthetic material are the first steps toward achieving a favourable therapeutic outcome.

The growing diversity of available fixation materials and systems highlights the importance of individualized material selection, choosing an implant whose mechanical behaviour, degradation profile, and biocompatibility correspond to the patient's specific anatomical and biological conditions. Bioresorbable magnesium alloys such as ZX00 offer attractive theoretical advantages, including bone-like elasticity and gradual resorption, but their clinical role in syndesmosis stabilization is still being defined.

At present, no fixation method has demonstrated proven superiority in the treatment of syndesmosis injuries. Consequently, there is a clear need for well-designed head-to-head comparative studies evaluating biodegradable magnesium alloys (e.g., ZX00) against established materials such as titanium and stainless-steel (AISI 316L) screws and dynamic suture-button systems. Such investigations will be crucial for determining the optimal balance between mechanical stability, biological integration, and clinical outcomes.

Continued research integrating materials science, biomechanics, and clinical evaluation will enable the development of next-generation fixation systems that minimize complications, reduce the need for reoperation, and better support functional recovery after ankle and syndesmosis injuries.

Acknowledgments

This research was supported by the Slovak Research and Development Agency under the contract No. APVV-22-0340. This research was supported by project KEGA 054TUKE-4/2025 Use of CAx systems in prosthetic and orthotic practice.

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