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Requirements for the Development of Cardiovascular Stents and Features of Increasing Their Bioactivity

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Annotation: Cardiovascular disease today is one of the leading causes of death. The heart is a muscular organ that constantly pumps blood. Over time, the blood vessels thicken and form the inner shell. This inner coating causes great inconvenience in performing the function of blood vessels. As a result, coronary heart disease occurs. In addition to preventing these types of diseases, they can currently be eliminated only by surgically installing a stent in the vessels of the heart. Below is information on the requirements for the development of stents and their properties that increase biological activity.

Keywords: Cardiovascular stents, tantalum, nitinol, biocompatibility, cobalt-chromium, metal alloys.

Cardiovascular disease today is one of the leading causes of death. The heart is a muscular organ that constantly pumps blood. Over time, the blood vessels thicken and form the inner shell. This inner coating causes great inconvenience in performing the function of blood vessels. As a result, coronary heart disease occurs. In addition to preventing these types of diseases, they can currently be eliminated only by installing a stent in the vessels of the heart surgically.

The body enriches the cell with oxygen and nutrients. This blood is delivered to the heart muscle through a network of coronary arteries. The arteries are small, but they are important blood vessels that support the functioning of the heart muscle.

Young withtime on the inner lining of the coronary arteries appear fat deposits, such as cholesterol. These fat deposits are caused by eating foods rich in animal fats and cholesterol, smoking, low physical activity, stress, hypertension, metabolic disorders, heredity, etc.

The appearance of excessive layers in the artery leads to its unevenness and a decrease in the elasticity of the vessel. Over time, they thicken and narrow blood vessels, preventing blood flow to the arteries and heart muscle. This arrangement of cholesterol changes the shape of the coronary arteries and affects the work of the heart in different ways.

However, any narrowing and even more so a complete blockage of the coronary arteries reduces the blood supply to the heart. Heart cells use oxygen and are therefore very sensitive to the level of oxygen in the blood. The accumulation of cholesterol slows down the delivery of oxygen and reduces the productive function of the heart muscle. As a result, the nutrition of the heart is disturbed, especially during physical exertion. It causes mild or moderate pain in the back of the chest, which can radiate to the hands or lower jaw, and the blood vessels can become blocked. In such cases, it can only be eliminated by installing a stent in the vessels of the heart surgically.

For the development of stents, many studies of the properties of materials and tests were carried out.

Stents must be rigid to resist the compressive force of the arterial wall, flexible to bend the vessel and at the same time adaptable to the tissue of the blood vessels.

Stents have the following requirements:

1. Tissue fluids should not be physically softened.
2. Must be chemically inert
3. It should not cause inflammation or rejection, that is, it should be biocompatible
4. Must not have carcinogenic properties
5. Must not cause allergies or sensitization
6. Must have mechanical strength
7. The plant must be suitable for production

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8. Must be suitable for sterilization

Stents can be made of stainless steel, tantalum, cobalt and nickel-titanium, titanium and magnesium alloys.

The first stent was placed in human coronary vessels in France by Jacques Puel and Ulrich Siegwart in 1986. After that, the production of stents was launched. In 1994, Express stents manufactured by Cordis/Johnson & Johnson from Palmaz-Schatz, a competitor to the Boston Scientific Corporation, became widely available.

Currently, 316L stainless steel materials are used in the manufacture of many stents. Because the composition depends on the anti-corrosion properties of steel, its strength, weldability. The composition of stainless steel 316L is as follows:

62.4%Fe; < 0.03% C; 16...18.5% Sg; 10...14 %Ni; 2...3% Mo; < 2% марганца; <0.045% P; < 0.03% C.

A steel stent that contains iron, carbon, chromium, nickel, magnetite, phosphorus, should be thin and thin along with its strength and elasticity. In the frames of stents made of this material, the fiber thickness reaches 5-10 μm. Table 1 shows the physical and chemical properties of stainless steel.

However, because stainless steels are made up of high concentrations of heavy, multivalent metals such as chromium, nickel, molybdenum, and manganese as a biological poison, they cause serious damage to the body's immune and enzyme systems and disrupt the blood clotting system.

To prevent this effect ofnon-rusting steel, stents are well needed to provide mechanical properties, well process stent coatings.

Table 1 Resource requirements by component

Physical and mechanical properties of stainless steels of various grades

Grow No gan steel	Density g/cm3	Elastic GPa module	Mustah MPa deficit limit	Liquid contact restriction d0,2 MPa	Liquid contact restriction Mpa	Chozi be %	Vertical area of Elas % of
Fe-18Cr-14Ni-2.5Mo ASTM "316ЛВМ" F138	7,95	193	670	340	330	48	0,17
Fe-21Cr-10Ni-2.5Mo ASTM F1586	7,90	195	740	430	310	35	0,22
Fe-22Cr-13Ni-5Mn ASTM F1314	7,88	193	827	448	379	45	0,23
Никель Fe-23Mn-21Cr-1Mo-1N You will	7,63	190	931	607	324	49	0,32

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Many companies offer different covers for this. "Jomed" - heparin impregnation, "BioDimond" - diamond-like carbon coating, "In Flow Dynamics" and "Medinol" - gold coating, "Biocompatible" - phosphocholin coating, "Biotronic" - silicon carbide coating, "Sorin Biomedica" - Coating "Carbofilm". In the laboratory of "Tiers Coating Ltd" (GREAT Britain), inorganic coatings were applied to the stents, which are currently used in practical medicine (amorphous carbon, diamond-like carbon - DLC, ceramic coating based on titanium and zirconium).

Data from a scanning electron microscope showed that the stents had corroded in organisms (rabbits). Stents with an amorphous carbon coating caused the most corrosion.

Cobalt alloys are used in the manufacture of cardiovascular stents. Cobalt alloys have high elasticity and are close in strength to stainless steel. Among the cobalt alloys, the most characteristic brand is 605 L. A comparative analysis of cobalt-chrome 605L stainless steel with 316L showed the following results.

Table 2 Resource requirements by component

316 L stainless steel grade and 605 L comparison results of cobalt-chromium alloys

Material	316 L	605 L
Stress at 30% deformation	655	1089
Return after 30% deformation	0,34	0,45
DSlope due to deformation (in MPa% deformation)	9,63	15.35
Elongation %	43	46

The cobalt advantages of alloys led to a decrease in fiber thickness and overall stent size, stability and visibility in X-rays . But cobalt-chrome stents manufactured by ArthosPico did not have the desired effect on the small diameter of the artery.

Another material for stents is tantalum. Tantalum has better visibility in X-rays than stainless steel. In addition, there is a resistant oxide film on the surface of the metal. This film slightly slowed down its corrosion and development, causing its rust. But modern varieties of tantalum did not meet the technical requirements for stent materials. Later it was processed, and its consistency was changed. When examining the mechanical properties, two features were revealed: firstly, a strong deformation for hardening into a twisted state, and secondly, the dependence of very strong plastic properties on vacuum annealing conditions. For example, 980...990 MPa will change the strength by 3%. It is extended by 26...30% under the influence of tensile strength of 530 and 290 MPa. Therefore, high pressure force and high temperature were required for production.

Nitinol is also used in the production of stents. Nitinol is an alloy consisting of 55% nickel and 45% titanium and has a satisfactory biocompatibility in vivo. The corrosion resistance is the same as that of stainless steel. Nitinol is mainly used because of its important distinguishing feature – shape memory. Nickel and titanium alloys with shape memory effect and superelastic properties were discovered in the navy in the early 60s. TiNi got its name nitinol due to its chemical formula and the abbreviation of the name. Later, this name was replaced by a chemical one - nickelide.

At low temperatures, the product can deform into the desired shape, and at high temperatures it retains its shape. The widespread use of this alloy leads to an increase in the cost of nickelide production, since the production of semi-finished products requires multi-stage technology.

In 1986, in France, Jacques Puel and Ulrich Siegwart was the first to install a nitinol stent in the coronary artery. Later it was used in European and American countries. The nitinol stent is highly flexible, adapts to the shape of the blood vessel and corresponds to the physiological curves of the artery.

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Table 3 Resource requirements by component
Physical and mechanical properties of nitinol

Nitinol	Density g/cm3	Elastic GPa module	MPa deficit limit	Liquid contact restriction d0,2 MPa	Liquid contact restriction Mpa	Chozi be %	Vertical area of Elas % of
Marten St	6,45	40	1200	200...300	900...1000	25	1,9
Cold treatment (40%)	6,45	40	1450	-	-	12	4...6
High elasticity	6,45	90	1400	-	-	14	6...8

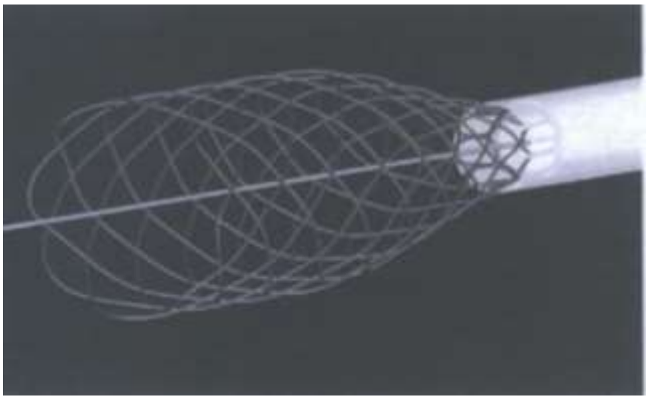
Figure 1. Arterial delivery stent made of nitinol thin fiber with transport system

The main task of arterial stents is to eliminate stenosis, restore the original lumen of the artery and, in addition, remove thrombotic layers. Stop the growth process. These stents are widely used both symptomatically and therapeutically. Stents can be installed at the site of narrowing of the artery using a special catheter. The device is equipped with a special filter and opens automatically. Damaged tissues and particles settle in this filter and prevent them from entering the blood vessels of the brain. Opening the stent from the inside pushes the narrowed walls of the artery and continuously supports them. This improves internal blood flow, improves blood supply to the brain.

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