MEDICAL APPLICATIONS OF TiNi-BASED SHAPE MEMORY ALLOYS IN RUSSIA
ПРИМЕНЕНИЕ В МЕДИЦИНЕ СПЛАВОВ С ПАМЯТЬЮ ФОРМЫ
НА ОСНОВЕ TiNi В РОССИИ

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Abstract: This review examines conditions which determine mechanical and chemical biocompatibility of implants. Development and use of implants, devices and instruments for different areas of medicine are discussed. Various examples of their practical application are presented.

KEYWORDS: SHAPE MEMORY ALLOYS, SUPERELASTICITY, THERMOMECHANICAL TREATMENT, IMPLANTS, RECOVERY STRAIN, TWO-WAY SHAPE MEMORY EFFECT, BIOCOMPATIBILITY

In contrast to conventional metallic materials, mechanical behavior of TiNi-based shape memory alloys (SMA) with high chemical biocompatibility and low level of elastic modulus is close to the behavior of biological tissues of the human body – bones, ligaments, muscle fibers (Fig. 1). [1-4]. This peculiarity of the hysteretic behavior of living tissues was noted by V.E. Gunther and called the “Delay Law”: “There is a hysteresis relation between the magnitude of stress and strain of tissues under conditions of loading and unloading, which is expressed in a pseudoelastic behavior and return of a strain (more than 2%) in an initial condition ”[1,5].

Basic requirements for the mechanical biocompatibility of an implant lay in the fact that its critical stresses in deformation condition must be lower than the corresponding tissue stresses, and the recovery strain value on the contrary, must be higher than that of the tissue. If the recovery strain resource of implant is less than that of tissue, the implant will be deformed plastically, that should deteriorate its functional properties. Scientists, engineers and physicians of the Scientific Research Institute of Medical Materials and Shape Memory Implants ((SRIMM) with Siberian Medical University (Tomsk), have developed industrial manufacturing of biocompatible superelastic (SE) materials and implants of a new generation. Serial production of materials, semi-finished products and implants was adjusted for various medical fields [1,5,7]. The main manufactured SM materials can be divided into four classes. The first class includes bulk and wire-piece implants of TiNi (Mo, Fe) - based alloys which play the role of temporarily operating devices. E.g., fasteners of bone fragments of the facial skeleton, bones, spine and other bones; dynamic posture correctors, dilators of hollow organs tissues, intestinal anastomosis clips, etc. (Fig. 2).
and elements are stents for vessels and other hollow organs; porous permeable and mesh implants for replacement of defects of hard and soft tissues of the body, restoring function of organs (Figs. 3, 4); tissue implants with a thick or mesh of 40-60 mm have for treatment of trophic ulcers in varicose veins, hernias of the abdominal cavity, etc. [1].

The third class of materials is a new generation tools which can change the shape in their working parts (grippers, basket traps, proofreaders, dilators, compression-distraction apparatus) and retain a cutting capacity (scalpels and chisels, dental spatulas) (Figure 5).

![Figure 3. Fabric and mesh implants [1]](image)

![Figure 4. A set of porous-permeable TiNi implants for the Spine [1]](image)

Krioapplikators from porous TiNi occupy a special place among instruments and are effectively applied in the treatment of pancreas lesions, removing away of various types of benign tumors (Figure 6) [1,6,7]. The fourth class may include long-term development of incubators carrier of cellular structures of transplanted organs. These materials and implants allow solve the problem of recovering the functions of internal organs (liver, pancreas, bone marrow, etc.) at new level.

![Figure 5. Surgical instruments of TiNi and its alloys with variable geometry of the test section [1]](image)

Medical application of new class SME and SE alloys based on solid and porous TiNi as implants and instruments has begun in the late 70s of the last century [1,4,8-10].

![Figure 6. A set of porous-permeable applicators and tools for cryosurgery [1,6]](image)

The development and expansion of SMA medical applications can be seen in Russia over the past 30 years which has been intensified in recent years due to the development of high technology material production and processing (laser cutting and welding). The second peak of activity on the accounts of inventions was observed in 2005-2007 that seems to be due to the rapid development of high technologies of metal treatment. (Fig. 7) [2,9,10].

According to S.A. Muslov et.al.[2], the world leaders in developing and manufacturing of the products from Ti-Ni SMA are companies that are listed in Fig. 7, where SRIMM takes 4th place. However, in a diversity of articles in a clinical practice SRIMM takes the 1-st place.
Widespread implementation into clinical practice became possible as a result of long-term hard work and enthusiasm of Russian scientists and of creation of scientific and industrial complexes including education - Siberian Physical-Technical Institute (SPTI) and Tomsk State University, research Scientific Research Institute of Medical Materials and Shape Memory Implants (SRI MM) and production – Medical Engineering Center of Shape Memory Alloys (MEC). For example, SRIMM was organized in Tomsk in 1995. Since 2003, there is a specialization "Medical Physics" in the SPTI.

Another example - BMCI-system is a result of joint activity of technical specialists (specialists in materials science, designers, technologists) of Engineering-Medical Center (EMC "MATI-Medtech") of "MATI"-Russian State Technological University named after Tsionlovskiy) and surgeons of leading medical centers of Russia (Moscow). There is a Department of "Materials and technologies in traumatology and orthopedics" and special direction of higher education named "Biomedical engineering of materials." TiNi implants for traumatology, orthopedics and neurosurgery are fabricated at enterprises "KIMPF", "SMET" and imported to Europe (Italy, Germany, Spain, etc.), Asia (South Korea, Thailand) and to clinics in Russia and CIS countries (Belarus, Ukraine, Kazakhstan). The average annual supply of implants is about 25000 psc. More than 20 cities of Russia and CIS countries have medical centers which use shape memory devices and implants (Figure 9) [15].

In addition to implants based on the superelasticity effect which are used for traumatology, spine surgery and dentistry, removable implants (clips, vascular stents) deserve attention. They use two effects : one-way and two-way SMEs. In National University of Science and Technology “MISIS” (Moscow), together with "GLOBETEK Pty Ltd." (Melbourne, Australia) the original medical devices have been developed and are under commercialization: a superelastic trap for the removal of stones, stapler with superelastic staples for coronary artery bypass surgery, removable clips based on one-way and two-way SMEs for clamping blood vessels, etc.

Removing of the clips or stents in the case of unsuccessful placing is realized due to the TWSME induced by special thermomechanical treatment. When cooled the gap between the clip branches becomes equal to about 1-2 mm, and the "crown" of stent acquires the form of easy removing (Figure 10). [12-14].

One can predict the further expansion of spectrum of TiNi alloys application towards creation of composite materials based on nickel-titanium SMA (both bulk and porous) with a lower specific weight and relatively high shape memory and superelastisity functional properties [1,5].
References