Conference paper

The Directions of Creation of Unique Technologies in Medicine on the Basis of New Generation of Biocompatible Materials and Shape Memory Implants

*Corresponding author:
V.E. Gunther, email:
gunther47@mail.ru

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V.E. Gunther[1, 2]*

[1]Tomsk State University, Tomsk, Russia

[2]Research Institute of Medical Materials and Implants with Shape Memory, Tomsk, Russia

Abstract

The article describes the main directions of creation of unique technologies in medicine on the basis of new generation of biocompatible materials and implants with shape memory effect (SME). Physical and biological fundamentals and principles of creating a new class of biocompatible superelasticTiNi-based materials were drafted. Manufacturing technique of TiNi-based materials with using the induction melting technique, self-extending high-temperature synthesis and powder metallurgy with a certain complex of properties for various fields of medicine have been developed.

1 Introduction

Years of work by Russian scientists in the field of development of materials and SME implants was expressed in the creation of new generation of medical devices and technologies for a wide range of medical purposes:such as stomatology, traumatology, surgery, otolaryngology, urology, ophthalmology, oncology and other fields of medicine. Different types of clamps for osteosynthesis of the facial skeleton and extremities bones, implants of vertebral bodies and pelvis fragments, device to create interintestinal and gastro-intestinal anastomoses, stents and implants for cardiovascular surgery, material for the replacement tissue defects, supporting frames of the trachea, bronchus and esophagus, dental implants, orthodontic system, dental casting alloys, keratoprostheses, surgical suture material, and other superelastic SME constructions were developed

2 Experimental

One of the main directions of research is associated with the development of physical and biological fundamentals and principles of creating a new class of biocompatible superelastic SME materials. The most important results on this direction are fundamental conformities of hysteresis behavior of tissues and opening of the law of delay of biological tissue [1]. Experimental studies first have established that the behavior of biological tissues under conditions of external stress is characterized by a delay reaction of tissues (Fig. 1, Fig. 2).

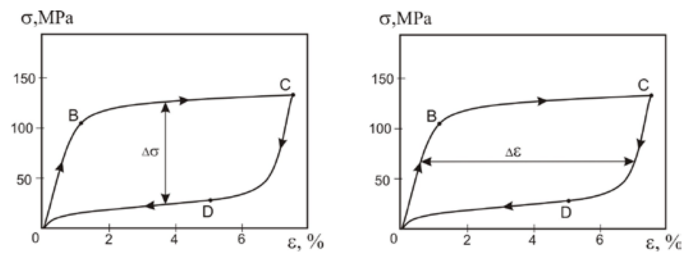

Fig. 1. Deformation dependence of tissues behavior in conditions of loading and unloading

Hysteresis behavior of changing functions of system state is a basis of the delay law (σ, ε, T, S, where σ - stress, ε - strain, T- temperature, S - entropy of the system).

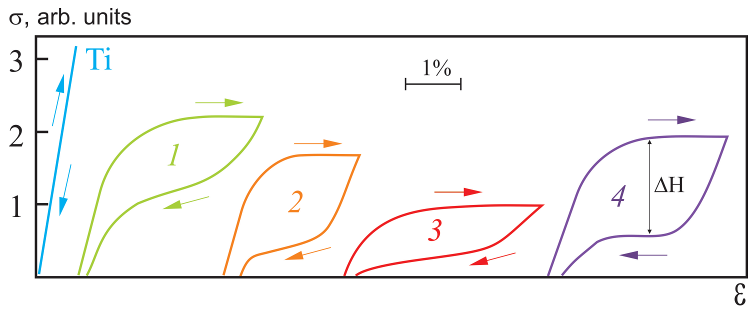

Fig. 2. The elastic hysteresis behavior of tissues (1 – hair, 2 – bone, 3 – collagen) and TiNi-based alloy (4 –TiNi alloy) in conditions the changing the functions of system state (stress and strain) σ(ε)

There is a hysteresis relation between magnitude of stress and strain of tissues in conditions of loading and unloading, which is manifested by return of strain and recovery of tissue shapes at a lower stress. The appearance of a hysteresis is connected with irreversible dispersion of energy in tissues and it is a measure of intrinsic losses. The magnitude of the greatest strain of changing shape is a measure of elasticity of tissues, which is able to return to its initial state at unloading.

An ability of alive tissues to respond with delay on any effects including mechanical, is manifested by the fact that at tissues deformation to a certain level they resist to the applied load. And when removing a stress the tissues resist to removal of a load, remaining in a stressed state. The hysteresis magnitude of tissues is their individual characteristic.

The mean of the established delay law of biological tissues manifestes in that the elastic hysteresis behavior of alive tissues presents certain criterions and medical-technical requirements to a choice of materials for implantation into an organism of alive system. An optimal material and implant have to be similar to the behavior of alive tissue, namely, to have a certain hysteresis on the diagram loading-unloading, to show a corresponding level of reversible strain, to possess a high extent of shape recovery and to be characterized by a considerable resistance of fatigue. Traditional medical materials: titanium, tantalum, stainless steel, cobalt-chromium-molybdenum alloys do not correspond to these requirements (Fig. 3), and therefore they can not be used for long-term functioning in the body as an implant material.

During 30 year period of active work of Russian scientists a new class of TiNiMoFe-based materials a have been developed, which satisfy to conditions of hysteretic behavior of tissues.

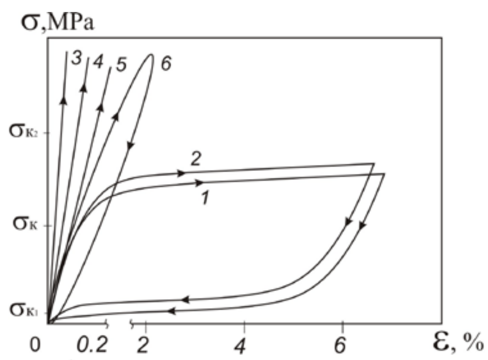

Fig. 3. Deformation dependence $\sigma(\varepsilon)$ in conditions of loading and unloading of the biological tissues and various artificial materials (qualitative dependence) 1 – biological tissue (bone, collagen, cartilage, etc.), 2 – TH-10 alloy, 3 – stainless steel, 4 – tantalum, 5 – titanium, 6 – polymers

Manufacturing technique of TiNi-based materials with using the induction melting technique, self-extending high-temperature synthesis and powder metallurgy with a certain complex of properties for various fields of medicine have been developed (Fig. 4).

Fig. 4. Semi-finished of TiNi-based solid alloy of TN-10 brand

This class of materials is characterized by an optimal combination of unit wiight, strength, ductility, durability, cyclic and corrosion resistance, high fatigue resistance. In view of the fact as body tissues possess utmost characteristics such as porosity, permeability, wettability, so unique designs of porous and permeable materials for long functioning in an organism have been made. The implants made of such materials (Fig. 5) allow qualitatively anew to solve the problem of creating artificial organs, endoprostheses and tissue systems.

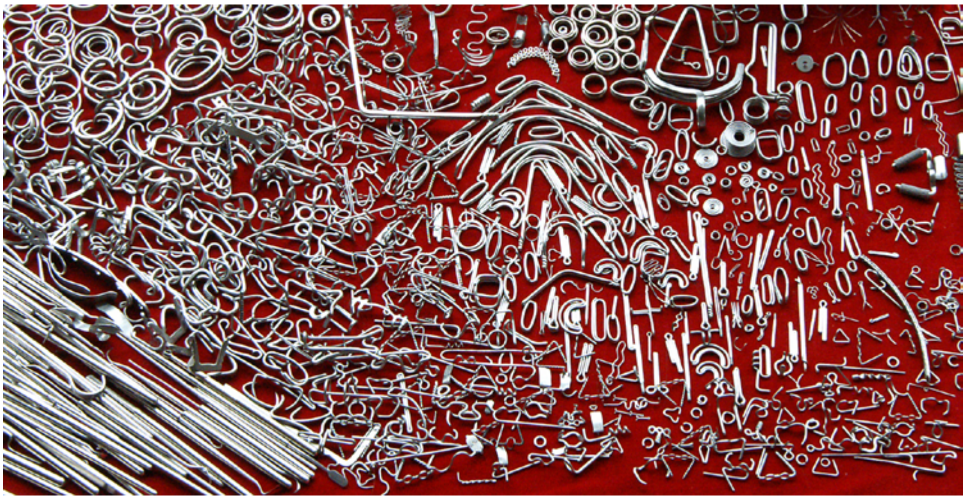

Fig. 5. Clamps and others individual design of SME implants for various fields of medicine

Implants, as well as tissues, are characterized by the hysteresis behavior and react with delay on a change of stress and strain, have a specified distribution of pore sizes and appropriate level of permeability and wettability. Physical and biological studies of the behavior of a new class of superelastic SME materials have revealed fundamental laws of interaction of materials and implants with body tissues. Detailed analysis of corrosion resistance, pharmacodynamic and antimicrobial properties, features of disinfection and sterilization, as well as toxicology and carcinogenicity has defined appropriate new class of materials with a high level of medical and technical requirements and specifications. The first time it was shown that implantation of the porous-permeable elastic material on TiNi-based (Fig. 6) creates conditions of a harmonious interaction between tissue and implant.

Fig. 6. The porous-permeable individual SME implants for various fields of medicine

The porous-permeable individual implants are able to function for a long time in body, not rejecting. Implants provide stable cell regeneration and create a reliable fixation with body tissues through of a cells formation and tissue growth in the implant. For example, reaction of bone tissues on the implant consists in forming a nature bone tissues with structure similar to the bone matrix. Origin and growth of bone tissue in the porous structure of an implant occur simultaneously in many pores in the form of individual nuclei (domains), which then grow and unite in single tissue system, filling the implant pores and connecting their channels. Total bone formation inside the pores of the implant occurs primarily to 3 months. A structural picture of the tissue in the pores virtually doesn't change with time.

New materials have predetermined a creation of unique medical technologies of treatment with using a new generation of biocompatible implants that can be similar to the tissues properties.

In spinal surgery, new technologies are presented by methods of treatment of the wedge compression fractures of vertebral bodies of posterior and anterior internal fixation by superelasticity SME implants and techniques of spine support with using a wide range of porous-permeable implants if you could not use donor bone tissue. Methods of spinal deformity correction by SME devices and methods of combined treatment of spinal injuries using the porous and monolithic SME implants were first carried out and described. The methods of a program dynamic deformation of spine correction in an outpatient setting are highly effective. The elastic «softly» operating work items of correctors with a «memory» allow to exclude surgical methods of treatment of spine in children in many cases. Superelastic SME implants open up new possibilities in the treatment of bone cancer. The techniques of plastic replacement of bone tissues defects were developed. Herewith the problems of preserving the function of support ability of spinal tissue were solved. An important result in a development of new treatments of bone tissues is the possibility of osteosynthesis on an implant matrix from porous-permeable TiNi-based material in inflammation conditions. It is an undoubted contribution to the development of methods of surgical treatment of chronic osteomyelitis.

The big cycle of researches has been carried out for section of traumatology and orthopedics. The surgical treatments of the shoulder girdle, articular fractures, fractures of tubular and thighs bones by means of SME-implants were developed. The sparing treatments of damage metatarsal bones and hand bones using mini implants were created. Today there is no such traumatology section, which not has improved traditional osteosynthesis treatments or new effective technology of treatment of damaged bone tissue. More than 200 various implants designs for traumatology were drafted.

Section of new technologies in dentistry is presented by studies, primarily, in maxillofacial surgery. A wide range of designs includes new unique methods of osteosynthesis by SME clamps: at injuries and diseases of facial skull, fractures of mandible and maxilla, and zygomatic bone, osteosynthesis after osteotomy of jaws and at removal of malignant tumors of oral cavity, pharynx and fractures, complicated by osteomyelitis. One of the major results in the development of new biocompatible materials and implants with hysteretic behavior are methods of endoprosthesis of facial bones (Fig. 7, Fig. 8). Endoprosthesis of mandible and maxilla, orbit and temporomandibular joint by means of compositions porous-permeable, monolithic and fabric mesh implants, corresponding to the bone defect shapes puts dentistry on a new level.

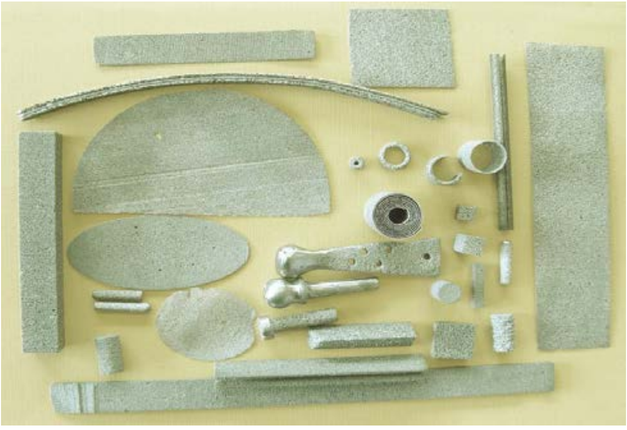

Fig. 7. Set of implants for midface

Fig. 8. An individual combination endoprosthesis of mandible

The created implants function as replaced bone tissues throughout later life. The important sections of dentistry, in which scientists have made a significant contribution, are orthopedics and dental implantology. Developments of new methods of dental prosthetics with using superelastic SME implants are presented. The structure of implants is able to adapt to a tissue system and carry significant functional loads. Now the devised methods of prosthetics allow to expand indications for dental implantation. Designed cast alloy with elastic properties has a fundamental importance of dentistry. Prostheses made from such alloy are characterized by a low unit weight, high elasticity and compliance to medico-technical and aesthetic requirements of application. Section of orthodontics in dentistry is presented by a new class of superelastic orthodontic devices and new methods of orthodontic treatment based on their use. The devices act on dentition system on a given program according to individual characteristics of patients.

Preventive dentistry is represented by development of methods for frame filling at defects of dental hard tissues using SME materials, and self-locking developments superelastic tires. Nowadays dentistswidely learn a high affectivity of a use of new technologies.

New medical technologies in surgery with using superelastic (SE) implants are represented by numerous works in the thoraco-abdominal and gastrointestinal surgery, gastroenterology and coloproctology, in surgery of parenchymal organs, trachea and bronchi, in reconstructive vascular and cell surgery. Methods of a compression gastrointestinal and interintestinal anastomosis with using elastic SME implants were initially developed. A technique of formation terminal colic and thin-colic valve anastomoses is effective. The new principles of surgical treatment of trachea and bronchi using knitted mesh (Fig. 9), porous-permeable elastic material and implants were designed

Fig. 9. Knitted materials of thin threads (40-60 microns) are similar to behavior of body tissues

Stomach resection method is presented on a qualitatively new level: SME implant with the hysteretic behavior instead of traditional hand-stitch to form gastrojejunostomy is used. New techniques can significantly reduce a complications rate. A wide range of developments of new operational treatment technologies is presented in works of otolaryngologists. A line of unique new designs is submited in urology and gynecology. Methods of treatment of urethral strictures and precancerous cervical disease were drafted using woven and knitted SME implants. The methods for the treatment of severe retinal detachments using elastic SME threads and method of cryosurgical treatment of focal lesions of pathological adnexa eye and modus of eyeball stump formation were developed in ophthalmology. New self-locking permeable keratoprostheses were developed. Section of new cryosurgical technologies is represented by new generation of high-capacity porous-permeable cryoapplicators. Cryotherapy treatment methods of hemangiomas, scars, benign neoplasm of different tissues, esophagus, liver and cervix were designed.

The developments of treatment of internal diseases by cell therapy techniques relate to results have a high scientific practical role. Isothermal cell culture carriers incubators were created in world firstly. Based on them the unique methods and technical resources of treatment of complex diseases such as diabetes, liver disease, pancreas and bone marrow were developed. Many methods of surgical treatment are based on the use of a new class of developed tools combining such properties as durability, flexibility and elasticity of the cutting working part of a tool, the ability to change a shape in accordance with the surgeon requirements at the highest level.

A scientific novelty of developments of Russian scientists is to establish a common regularity in behavior of biological systems in nature including the body tissues, phenomenon of hysteresis behavior of biological tissues and creation of unique technologies of treatment with use of a new generation of biocompatible SME materials and implants, which are similar to behavior to body tissues.

3 Summary

The created materials and implants qualitatively correspond to new level of medical and technical requirements: they are able to function in the body for a long time, flexibly respond to changing forms of organ tissues, and not break down after repeated exposure. Such materials and implants have allowed to create a new generation of medical devices and new high-technology medical surgical treatments for a wide range of applications in various medicine fields.

4 Acknowledgments

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