Yu.O. Bezsmertnyi
V.I. Shevchuk
H.V. Bezsmertna
L.G. Koval
Y. Jiang

PROSPECTS FOR BIODEGRADABLE IMPLANTS IN TRAUMATOLOGY AND ORTHOPEDICS

Scientific Research Institute of Invalid Rehabilitation on the base
of Vinnitsa Pirogov National Medical University
Vinnysia National Technical University

Abstract
We have analyzed literature sources describing the main stages of development and application of biodegradable implants in traumatology and orthopedics. The new modern generation of implants represents a combination of the traditional properties of biodegradable fixators with new technologies in the field of mechanical activity. In spite of their drawbacks, biodegradable implants are a worthy competitor to metal implants in many areas of bone surgery, surpassing them in some positions.

Keywords: biodegradable implant, osteosynthesis, traumatology and orthopedics.

The study of materials used in the manufacture of fixators represents an important trend in the development of traumatology and orthopaedics [1]. Metal fixators are the gold standard in fracture treatment. However, the use of metals as implant materials, despite their relative bioinertness and lack of toxicity, has a number of significant drawbacks [2, 3]. After fracture healing, in most cases a second surgery to remove the implant is necessary, which is associated with various risks such as: infection, technical difficulties in removing metal fixators, implant migration, and associated costs from the healthcare system. Metal implants cause artefacts during MRI scans [4]. Given these characteristics, the trauma and orthopedic community is striving for a standard of osteosynthesis that does not require a staged treatment to remove a fixator that has served its purpose. One such solution is the development and introduction of biodegradable implants.

The concept of biodegradable implants emerged through the formation and development of suture materials that resorb in the body [5]. Based on the 1954 report of Higgins N.A. on the production of polyglycolic acid (PGA) by glycolic acid condensation [6], Schmitt E. E., Polistina R. A. in 1967 created a synthetic polyglycolic acid suture material [7], which led to the first synthetic biodegradable suture material. In 1966, Kulkarni R. K. et al. published a report on the biocompatibility of polylactic acid (PLA) in animals. In 1969, Schmitt E. E., Polistina R. A. described the experimental use of biodegradable devices such as pins, plates, intramedullary pins on animals for fixation of osteotomies of hind legs of rabbits [7]. They were the first authors to propose the use of glycolic acid polymer fixators in bone surgery (8). The glycolic acid polymer implants degraded rather quickly, within a few months, whereas the degradation process of lactic acid polymers was excessively long, lasting several years. In addition to PGA and PLA many other polymeric materials were known (e.g. PDS, polydioxane, PHBA, poly-beta-hydroxybutyrate), but of all available polymers only lactic acid polymer and glycolic acid polymer fulfilled the requirements for osteosynthesis. In the early stages of research, the authors did not pay due attention to such a characteristic of fixators as strength, which was mediocre and estimated at 40-70 MPa, which made their use in large bone fractures impossible [9]. A comprehensive approach greatly contributed to the development of the "self-reinforced technology, in which the transformed part of the polymer is a directed chain structure within the fixator in the form of microfibrils, macrofibrils, fibres or extended crystalline chains" [10]. The fixators made by this technology had high strength values. For example, the flexural strength values for lactic acid polymers and glycolic acid polymers with self-reinforcing technology were estimated at

300 MPa and 410 MPa, respectively [10]. By the first half of the 1980s, the fixatives were characterised by a high initial strength of the degradable material with self-reinforcing technology and the ability to retain the required strength level for several weeks under hydrolysis conditions.

The first clinical use of biodegradable implants was performed in 1984 by Professor Rokkanen P. (Helsinki). The successful result was the starting point for further experiments and studies. Confidence in the use of biodegradable fixators instead of metal fixators increased not only by eliminating the need for repeated surgery to remove the fixators, but also by the fact that during resorption of the implant, the load is gradually transferred to the fracture area, thereby forming the best conditions for biomechanical bone remodelling.

The introduction of biopolymers into practice has also revealed their negative properties. The commonly used glycolic acid polymer in vivo loses half of its strength within two weeks [10], and loses mass after 6-12 months. This high degree of degradation produces large amounts of implant degradation products, which in 3-60% [11] of clinical cases resulted in reactions to the foreign body. The solution to this problem was the use of a copolymer with optimal strength and controlled degradation time, achieved by the amount of lactic acid and glycolic acid in the copolymer composition in the ratio 85/15 respectively.

The new modern generation of implants is a combination of the traditional properties of biodegradable fixators with new technologies in the field of mechanical activity [1-3]. The mechanical (immediate) stage is provided by the special grooved surface of the implant. When implanted in hard bone, the grooved surface of the pin is compressed beneath the wall of the drilled canal, while in soft bone, the implant maintains the surface pattern with projections extending into the bone. The specific shape of the pin surface promotes the creation of channels in the bone tissue around the implant, which will subsequently provide conditions for increased vascularisation of the fracture zone, thereby stimulating osteogenesis. The hydrolytic (delayed) stage is caused by changes in the size of the implant under hydrolytic conditions. In screws, the effect of autocompression occurs due to changes in size caused by hydrolytic conditions. The screw diameter increases by 1-2% and the length decreases by 1-2% compared to the initial size, resulting in a reduced risk of unstable fractures and maintaining constant compression.

In spite of these disadvantages biodegradable implants are a worthy competitor to metal implants in many areas of bone surgery. In the current stage of development, scientists are conducting research to improve biocompatibility and eliminate tissue reactions to the presence of the implant. The use of biodegradable materials in combination with biotechnology to improve bone healing is also an issue for the future.

REFERENCES

1. Koutserimpas C, Alpantaki K, Chatzinikolaidou M, et al. The effectiveness of biodegradable instrumentation in the treatment of spinal fractures // Injury. 2018 Dec;49(12):2111-2120. DOI: 10.1016/j.injury.2018.11.008.
2. Kiani F, Wen C, Li Y. Prospects and strategies for magnesium alloys as biodegradable implants from crystalline to bulk metallic glasses and composites-A review // Acta Biomater. 2020 Feb;103:1-23. DOI: 10.1016/j.actbio.2019.12.023.
3. Sharma B, Sharma S , Jain P. Leveraging advances in chemistry to design biodegradable polymeric implants using chitosan and other biomaterials // Int J Biol Macromol. 2021 Feb 1;169:414-427. DOI: 10.1016/j.ijbiomac.2020.12.112
4. Eglin D, Alini M. Degradable polymeric materials for osteosynthesis: tutorial // Eur Cell ater. 2008 Dec 19;16:80-91. doi: 10.22203/ecm.v016a09.
5. Gilding D K, Reed A M. Biodegradable polymers for use in surgery-polyglycolic/poly(actic acid) homo- and copolymers: 1 // Polymer 20, Issue 12, December 1979; 20 (12): 1459-64. https://doi.org/10.1016/0032-3861(79)90009-0
6. Higgins N.A. Condensation polymers of hydroxyacetic acid :patent USA 2676945, 1954.
7. Schmitt E E, Polistina R A. Polyglycolic acid prosthetic devices : patent USA 3463158, 1969.
8. Raiha J E. Biodegradable implants as intramedullary nails. A survey of recent studies and an introduction to their use // Clin Mater. 1992;10(1-2):35-9. doi: 10.1016/0267-6605(92)90082-5.
9. Daniels A U, Chang M K, Andriano K P. Mechanical properties of biodegradable polymers and composites proposed for internal fixation of bone // J Appl Biomater. Spring 1990;1(1):57-78. doi: 10.1002/jab.770010109.

10. Rokkanen P, Bostman O, Hirvensalo E, et al. Bioabsorbable fixation in traumatology and Orthopaedics // Biomaterials 2000 Dec;21(24):2607-13. doi: 10.1016/s0142-9612(00)00128-9..
11. Ambrose C G, Clanton T O. Bioabsorbable implants: review of clinical experience in orthopedic surgery // Ann Biomed Eng. 2004 Jan;32(1):171-7. doi: 10.1023/b:abme.0000007802.59936.fc.
12. Wójcik, W., Pavlov, S., Kalimoldayev, M. (2019). Information Technology in Medical Diagnostics II. London: Taylor & Francis Group, CRC Press, Balkema book. – 336 Pages, https://doi.org/10.1201/9780429057618.
13. Pavlov S. V. Information Technology in Medical Diagnostics //Waldemar Wójcik, Andrzej Smolarz, July 11, 2017 by CRC Press - 210 Pages
14. Olexander N. Romanyuk; Sergii V. Pavlov, et al. Method of anti-aliasing with the use of the new pixel model, *Proc. SPIE* 9816, Optical Fibers and Their Applications 2015, 981617 (December 18, 2015); doi:10.1117/12.2229013; Index SNIP – 0,37.
15. http://dx.doi.org/10.1117/12.2229013
16. S. O. Romanyuk; S. V. Pavlov; O. V. Melnyk. New method to control color intensity for antialiasing. Control and Communications (SIBCON), 2015 International Siberian Conference. - 21-23 May 2015. - DOI: 10.1109/SIBCON.2015.7147194.

Authosr:
Bezsmertnyi Yurii Oleksiyovich
Doctor of Medical Sciences, Deputy Director for Research, Scientific Research Institute of Invalid Rehabilitation on the base of Vinnitsa Pirogov National Medical University, Vinnitsa, bezsmertnyiyurii@gmail.com
Shevchuk Viktor Ivanovich
Doctor of Medical Sciences, Director of Scientific Research Institute of Invalid Rehabilitation on the base of Vinnitsa Pirogov National Medical University, Vinnitsa,reab@ukr.net
Bezsmertna Halyna Viktorivna
PhD Candidate of Medical Sciences, Head of the Department of Rehabilitation of Persons with Disabilities, Scientific Research Institute of Invalid Rehabilitation on the base of Vinnitsa Pirogov National Medical University, Vinnitsa, bezsmertnahalyna@gmail.com
Koval Leonad Grigorovich
PhD, Head of Biomedical Engineering, Vinnytsia National Technical University, koval.l@vntu.edu.ua
Jiang Yankai
Postgraduate, Scientific Research Institute of Invalid Rehabilitation on the base of Vinnitsa Pirogov National Medical University, Vinnitsa,20126002.qq.com

ПЕРСПЕКТИВИ ВИКОРИСТАННЯ БІОДЕГРАДУЄМИХ ІМПЛАНТІВ В ТРАВМАТОЛОГІЇ ТА ОРТОПЕДІЇ

Анотація
Проаналізовано літературні джерела, які описують основні етапи розвитку та застосування біодеградіруемих імплантів в травматології та ортопедії. Нове сучасне покоління імплантів є поєднанням традиційних властивостей біодеграіруемих фіксаторів з новими технологіями в області механічної активності. Незважаючи на наявні недоліки, біодеградіруеми імпланти в багатьох областях кісткової хірургії складають гідну конкуренцію металевим імплантам, перевершуючи їх по деяких позиціях.

Ключові слова: біодеградуємі імпланти, остеосинтез, травматологія та ортопедія.

Безсмертний Юрій Олексійович
Доктор медичних наук, заступник директора з наукової роботи, Науково-дослідний інститут реабілітації осіб з інвалідністю (ннлк) Вінницького національного медичного університету ім. М.І. Пирогова, м. Вінниця, bezsmertnyiyurii@gmail.com

Шевчук Віктор Іванович
Доктор медичних наук, професор, директор Науково-дослідного інституту реабілітації осіб з інвалідністю (ннлк) Вінницького національного медичного університету ім. М.І. Пирогова, м. Вінниця, reab @ ukr.net
Безсмертна Галина Вікторівна
Кандидат медичних наук, завідувач відділу реабілітації інвалідів Науково-дослідного інституту реабілітації осіб з інвалідністю (ннлк) Вінницького національного медичного університету ім. М.І. Пирогова, м. Вінниця, bezsmertnahalyna @ gmail.com
Коваль Леонід Григорович,
Кандидат технічних наук, доцент, завідувач кафедри біомедичної інженерії, ВНТУ, koval.l@vntu.edu.ua
Джіанг Янкай
Аспірант, Науково-дослідний інститут реабілітації осіб з інвалідністю (ннлк) Вінницького національного медичного університету ім. М.І. Пирогова, м. Вінниця, 20126002.qq.com