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Advances in osteosynthesis - a basic overview of modern fixation materials

Postępy w osteosyntezie – podstawowy przegląd nowoczesnych materiałów zespalajacych

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Abstract. The dynamic development of trauma-orthopedic surgery and accompanying material technology has led in recent years to the need for close cooperation between researchers in these fields. In a short time, thanks to the cooperation of engineers and doctors, the general approach to the method of bone anastomosis has changed significantly. The need to optimize the effects of treatment, i.e. to quickly recovery, reduce the number of postoperative complications, reduce the number of reoperations, and reduce the costs of procedures and treatment used has resulted in the development of many new technologies that have set trends in modern traumatology. The widespread use of LCP (Locking compression plate) and locking screws, the development of polymers and biopolymers with a modified chemical structure, a significant improvement in the biocompatibility and cytocompatibility of the materials used, and the implementation of products with significant micro-roughness that improve osseointegration are the well-known and commonly used effects of this cooperation of the development to day.

Materials science related to orthopedics is an extremely complex and multi-threaded field. Its continuous development requires a periodic summary of the results and development directions provided, which allows faster evaluation and interpretation by researchers.

The purpose of the following work is to summarize the latest research on materials and methods used in osteosynthesis in a legible way for potential recipients of this information from various fields.

Abstrakt. Dynamiczny rozwój chirurgii urazowo-ortopedycznej i towarzyszącej jej technologii materiałowej doprowadził w ostatnich latach do potrzeby ścisłej współpracy pomiędzy badaczami tych dziedzin. W krótkim czasie dzięki współpracy inżynierów i lekarzy istotnym zmianom uległo ogólne podejście do sposobu zespoleń kości. Potrzeba optymalizacji efektów leczenia tj. szybkiego przywrócenia chorych do sprawności, ograniczenia liczby powikłań pooperacyjnych, zmniejszenia ilości reoperacji i redukcja kosztów stosowanych procedur i leczenia wpłyneła na rozwój wielu nowych technologii, które wyznaczyły trendy w nowoczesnej traumatologii. Powszechne użycie płyt LCP (Locking compression plate) i wkrętów blokowanych, rozwój polimerów i biopolimerów o zmodyfikowanej strukturze chemicznej, znaczna poprawa biokompatybilności i cytokompatybilności stosowanych materiałów oraz wdrożenie do użycia produktów o istotnej mikrochropowatości poprawiających osteointegrację to dobrze znane i powszechnie stosowane efekty wspomnianej współpracy już dzisiaj.

Inżynieria materiałowa związana z ortopedią jest dziedziną niezwykle skomplikowaną i wielowątkową. Ciągły jej rozwój wymaga okresowego podsumowania dostarczanych wyników i kierunków rozwoju co umożliwia ich szybszą ocenę i interpretację przez badaczy. Celem poniższej pracy jest podsumowanie najnowszych badań dotyczących materiałów i metod używanych w osteosyntezie w sposób czytelny dla potencjalnych odbiorców tych informacji z różnych dziedzin.

Key words: materials in orthopedics, osteointegration, polymers, biopolymers, bioabsorbable materials.

Słowa kluczowe: materiały w ortopedii, osteointegracja, polimery, biopolimery, materiały bio-wchłanialne.

1. INTRODUCTION

Over the past few years, there have been significant changes in views regarding fracture treatment. Early guidelines indicated the need to achieve absolute stability, that is, to exclude all movement, between the fracture fragments ¹. In an era of imperfect implants and materials, absolute stability was thought to be essential to ensure adequate fixation strength with early implementation of motion and exercise. The effects of the plates used at that time included osteoporosis and remodeling of the Haversian canals in the area of the fragments, which often led to delayed union or pseudarthritic joints. Initially, it was thought that these changes were related to the high stability of the fragments, thus also protecting them from overloading. However, later studies have shown that these changes are due to ischemia of the fractures by the fixation material ^{2,3}.

Years of research resulted in a shift in priorities from mechanical to biological. Thus, the term "biologic internal stabilization" was coined, which has several basic assumptions - minimal implant contact with the bone, "bridging" the fracture, using fewer locking screws than traditional fixation ⁴. These fixations minimize blood supply disruption to the bone fragments caused by the implanted materials and allow, and sometimes require, movement between the injured surfaces of the fragments. Another benefit of biologic stabilization is that there is no need to perform perfect fracture repositioning (especially for multifracture fractures), and indirect repositioning techniques ^{5,6}. In this way, surgical trauma to the surrounding soft tissues, which considerably influence the course of bone fixation and bone remodeling, is significantly reduced. This procedure is consistent with the main goal of osteosynthesis, i.e., to restore adequate function to the injured area, even at the expense of lack of anatomical repositioning ^{4,7}.

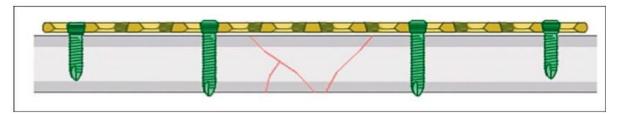


Figure 1 Bridging fixation using LCP plate and locking screws⁸.

It's hard to argue with the fact that most orthopedic implants are constructed of metal - mainly stainless steel, titanium or chromium and cobalt alloys 9,10 . Unfortunately, this material has many disadvantages, such as corrosivity, ferromagneticity, induction of electrochemical reactions, induction of local osteoporosis, and the possibility of delayed union. The disadvantages of metallic fixation resulted in a shift towards biomaterials, which are better accepted by the human body. The multitude of available polymers makes it possible to choose the one with the most suitable characteristics, strength and composition and to give it practically any form and shape 10 .

Unfortunately, polymer-based fixation materials are not free from disadvantages. Their mechanical properties do not allow them to be used in bones carrying significant loads ¹¹. Furthermore, there are studies indicating distant reactions of the body to foreign bodies, which is probably related to the acidic degradation processes of polymers ^{12,13}.

When talking about plate fixation anastomoses, one must not forget the important element that is the fixation screws. There are many factors that can influence the outcome of the fixation - the choice of the appropriate screw (cortical or cancellous), the quality of the bone, the single or bicortical locking, or the length of the screw and its thread ^{14,15}. Another noteworthy feature of screws is their ability to osteointegrate, which is particularly important in osteoporotic bones. Low bone mineral density favors weaker screw anchorage in the bone and facilitates destabilization ¹⁶. It seems that the approach to achieve rapid and stable osteointegration is to develop an appropriate surface structure for the screws.

Methods already in use today include, for example, machining, sandblasting, and etching with acids or alkalis - as studies have shown, the micro-roughness achieved by these methods allows better osteointegration than with smooth surfaces ¹⁶.

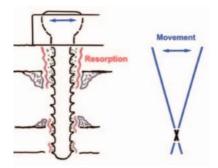


Figure 2: With non-locking screws, implant micromotion often led to fixation loosening by resorption of bone tissue near the screws ⁴.

2. THE PURPOSE OF THE STUDY

Materials engineering related to orthopedics is an extremely complex and multi-threaded field. Its continuous development requires periodic summarization of provided results and directions of development which enables their quicker evaluation and interpretation by researchers. The aim of this review paper is to summarize the latest research on the materials and methods used in osteosynthesis using plates and screws. The material is also an introduction to further research in specific areas.

3. REVIEW METHODS

Publications available in the most popular databases such as Medline (PubMed) and Google Scholar were analyzed using specific keywords such as "modern fixation materials", "osteosynthesis", "osteointegration", "biopolymers", and "bioabsorbable materials". Recent literature (published after 2010) was taken into account and compared to older publications, contrasting advances in the field described.

4. STATE OF THE ART DESCRIPTION

4.1 PLATE FIXATION

The Open Reduction and Internal Fixation (ORIF) technique remains one of the primary surgical techniques in orthopedics. Locking Compression Plates (LCPs) are now commonly used which, due to their design, limit the side effects of previously used fixations, especially ischemia of the fragments, local osteoporosis and destabilization of the fixation⁸.

The LCP owes its effectiveness to the special shape and type of holes for the screws. The holes can be used to insert conventional or locking screws. The latter have a specially shaped thread that allows the insertion of the screws, so that the stability of the whole structure is achieved not by strong pressure of the plate on the bone, but by creating a stable scaffold consisting of the plate itself and the screws.

This means that the instrumentation works on the principle of a locked internal stabilizer. Due to its design, this structure binds the fragments with a force about four times greater than traditional anastomoses. Furthermore, angle-stabilized locking screws are also available, where the hole in the plate is threaded at an angle other than 90 degrees to the surface of the plate, which further enhances the stability of the fixation ¹⁷.

As already mentioned, currently implanted plates are mainly constructed of stainless steel and titanium or chromium-cobalt alloys ¹¹. A particular disadvantage of these materials is that the stiffness is much higher than that of the cortical layer of human bone (110-220 GPa and about 20 GPa, respectively). As a result, most of the load is transferred through the anastomotic material and not through the bone, which limits the formation of ossification and calcification and promotes osteoporosis ^{18,19} and refractures ²⁰. This phenomenon is commonly known as the "stress shielding" effect and has prompted the search for other materials with greater flexibility as well as biodegradability ¹¹.

As early as in the 1980s, researchers turned to plastics to replace metals in the production of fixatons. Biopolymers are one of the basic materials used for osteosynthesis. Their particular advantage is not only biodegradability but also the possibility to control its rate ^{21,22} by modifying their structure and production techniques ²³. However, a disadvantage of polymer anastomoses is their low strength and relatively poor stabilization of bone fragments, which is why they are not suitable for fixations s of bones that carry heavy loads ²⁴. Researchers also point to the possibility of induction of inflammatory responses during the process of acid degradation of the polymer ^{25,26}. The alternative to polymers was to be bioceramics ^{27,28}, which are characterized by high biocompatibility and high corrosion resistance. Unfortunately, the low fracture resistance, significant brittleness and high stiffness of ceramics have significantly limited their applications ²⁴.

Some researchers have attempted to modify the chemical structure of polymers and ceramics in an attempt to obtain materials with more favorable characteristics suitable for wider applications. Hasan et al. decided to test the possibility of chemical modification of materials made of polylactic acid reinforced with phosphate glass fibers. They found that of the eight compounds tested, three bind covalently to the phosphate glass, resulting in an increase in shear strength and hydrophobic properties. The authors expect that chemical modifications of the tested composite may positively influence its biological properties and applicability in clinical practice. A certain difficulty may lie in the fact that the obtained materials still need to be tested for cytocompatibility and possible toxicity of the material itself and its degradation products ²⁹.

Another direction for the development of polymer plates is to use already known and recognized biocompatible materials, but to apply new processing methods to obtain better strength parameters. Such a challenge was taken up, among others, by Zheng-Ming Huang et al. who dealt with the structural processing of PEEK (Poly-ether-ether-ketone) polymer. They used the mixed yarn method with the micro-braiding technique.

As a result of their research, they built plates with stiffness and bending moment similar to stainless steel plates used clinically. Unfortunately, this study has its limitations, as the plate built did not have holes for fixing screws, which is known to weaken the mechanical properties of the whole implant, so the topic needs further research ⁹.

Researchers' attention was drawn some time ago to fixations made of degraded magnesium (Mg) alloys, characterized by a unique combination of strength and biodegradability ³⁰. Early experiments with magnesium alloys proved unpromising - too rapid degradation and hydrogen accumulation were observed ³¹, however, current metallurgical knowledge allows the development of alloys that do not exhibit these defects.

The first animal studies using anastomoses made of magnesium alloys have already been performed. Chaya et al. performed tests on 12 rabbits and obtained 24 surgical sites on the elbow bones of the animals. At each surgical site, an osteotomy was performed and then the fragments were anastomosed using a plate and four screws constructed of Mg alloy. In their study, the researchers report that all fixations were well tolerated by the animals. An initial sign of material degradation was the formation of subcutaneous gas pockets (not observed in all animals). In two cases, it was necessary to empty the pockets with a needle and syringe. Importantly, on the basis of X-rays and microCT and histopathological studies, the researchers found that degradation of the fixation did not affect fracture union ³⁰.

An important feature of fixations made of Mg alloys is the ability to affect the rate of degradation, and therefore the generation of gas ^{32,33,34}. In experiments conducted by Ullmann et al. the effect of structure, or more precisely grain size, on the in vivo degradation of a magnesium alloy designated LAE442 was investigated. A total of 42 implants were used in the study, subjected to different post-processing to obtain different grain sizes of the material. Each of the test animals had 2 implants placed and left for 6 months with weekly X-ray checks and evaluation of implant appearance, bone changes, and gas formation. Regular microcytes were also part of the study. Findings from the study indicated that implants characterized by a larger grain size had slower degradation and better tolerance than implants with a finer grain size. The researchers also emphasized keeping the surface of the implanted material intact to maintain its beneficial properties ³⁵.

| | Classical fixations | Biopolymers | Bioceramic materials | Magnesium Alloys |
|--------------------------|---|---|---|--|
| Stiffness | High, causing "stress shielding" effect | Low | High | Medium |
| Strength | High | Low | Significant brittleness and high stiffness reduce the strength of the fixation | High |
| Stabilization quality | High | Reduced stability of the fixation, no load bearing bone fixation possible | Severe brittleness and high stiffness create a high risk of destabilizing the fixation | High |
| Biocompatibility | Materials used for production may cause allergies, possible corrosion with multiple implants made of different alloys | Depends on material used | High | Depends on the Mg alloy used |
| Biodegradability | None | Present, possible rate control depending on polymer composition. Possible inflammatory reactions during acid degradation of the polymer | None | Rate dependent on Mg alloy used and its structure. Too rapid degradation may lead to intratissue gas bubbles. |
| Comments | Limited number of metal alloys available | Necessary studies on possible toxicity of degradation products | None | Necessary to keep the implant surface intact to maintain its beneficial properties |

Table 1. Comparison of properties of materials used in the manufacture of plate fixations

4.2 BONE SCREWS

As mentioned, the LCP plate system is designed to use both conventional and locking screws. The surgeon can choose between cancellous, cortical, self-drilling and self-threading screws. In addition, the physician can insert them in unicortical or bicortical fashion. Such a wide choice forces one to think carefully about the expected results. In osteoporotic bone, bicortical locking screws have been shown to be more effective and less likely to loosen. This is due to the increased "working length" of the screw, which is proportional to the torque strength. Bicortical screw insertion also has its drawbacks - care must be taken to ensure that the fragment protruding from the other side of the bone does not interfere with neurovascular structures ¹⁷.

When using conventional screws, fracture stability is achieved by pressing the plate against the bone with a force of approximately 2000-3000N ³⁶. This is different with locking screws, which allow the space between the plate and bone to be maintained, thus protecting the bone vascular tissue. However, as demonstrated by Ahmad et al, the stability of LCP fixation decreases as the distance between the plate and the bone increases, so it is important to select screws of appropriate length ³⁷.

Screws are an important component of the plate anastomosis - their loosening affects the stability and function of the entire fixation, so many studies have been conducted to determine which choice is most beneficial to the patient.

Pollard et al in their study decided to compare screws that differed in thickness and threading. Their choices were 3.5mm full-threaded bicortical screws and 4.0mm cancellous screws with partial threading. They used fresh-frozen cadaveric preparations on which they performed a transverse osteotomy of the medial ankle to mimic a Muller classification type B fracture. The researchers then fixed the bone fragments with test screws according to the guidelines of the AO (German: *Arbeitsgemeinschaft fur Osteosynthesfragen*). After the osteosynthesis, the resistance of the screws to pull-out was tested, where it was found that the fixation obtained with bicortical screws was stronger ¹⁴.

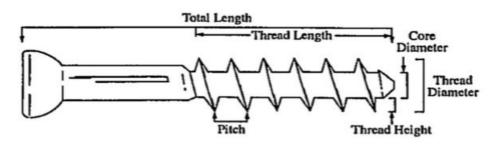


Figure 3: Schematic diagram of the screws used in osteosynthesis ¹⁴.

Interesting results were also obtained by Wang et al. comparing the stability of anastomoses using cancellous and cortical screws in the metaphyseal bone. They used 4.0 mm screws and tested their pull-out strength in standard and osteoporotic bone models. The difference in pull-out strength was found to increase in favor of cancellous screws with decreasing bone density. It was noted that with cancellous screws, a significantly greater force is required to destabilize the fixation itself. The authors of this paper concluded that cancellous screws are a much more advantageous option in the case of metaphyseal bone. Not only do these screws provide significantly more stability in the fixation, but they also allow for more compression of the bone fragments ¹⁵.

These results indicate that the stability of the fixation is influenced by many factors that depend on the implant - in this case, the screw. Not only the diameter of the screw is important, but also the method and spacing of the threads, the location (single- or bicortical) and the material from which the implant is constructed. The challenge of determining how individual screw properties affect their behavior in the living body was taken up by Rouhi et al. using a two-dimensional finite element model (FEM). In their study, they examined the effects of four screw characteristics - number of threads, screw pitch, dimensions and flexural modulus. Their results may be of great importance in designing the next generation of implants. First, they found that increasing the number of threads results in more continuous load transfer. This is especially important for the first thread, which carries the most load in the plate retaining screw. If too much load is applied here, the screw breaks and destabilizes the fixation - increasing the number of threads relieves the load on the first thread, making the entire anastomosis stronger. The next two results confirm that the stability of the screw is due to its contact surface with the bone, so decreasing the thread pitch and increasing the external dimensions of the screw result in greater stability. The findings on the last parameter may be an incentive to look for new building materials for screws.

As shown in other works, the flexural modulus of bone is relatively low (it is 1-20 GPa), especially when compared to metals used for fixation. As demonstrated in the present work, increasing the screw's flexural modulus from 110 GPa (titanium) to 210 GPa (stainless steel) resulted in much higher stress concentrations, which weakened the bone and caused destabilization of the implant ³⁷.

Along with research into the shape of implants, work is also underway on other implant characteristics, such as the building material and surface structure.

Titanium is one of the most popular building materials for orthopedic implants, but work on improving its structure continues. In their study, Lin et al decided to test implants made of titanium sandblasted with coarse grains and acid-etched (a material called SLAffinity-Ti) on an animal model and compare them to screws with a plasma-sprayed titanium surface. The goal was to verify whether the new material would provide better osteointegration and therefore increase the strength of the fixation. Both imaging (micro-CT), mechanical and histological studies confirmed better integration of the SLAffinity material into the bone and improved the fixation strength, resulting in promotion of early bone union and improved bone union outcomes after screw implantation ¹⁶.

In addition to improving anastomoses made from known metals, new biodegradable materials are being developed all the time. Suryavanshi et al. decided to modify a popular compound such as polycaprolactone (PCL) by enriching it with various amounts of MgO nanoparticles and silk fibers. The mixture containing 10% of MgO and 20% of silk showed the best mechanical properties. The screws made from this material had twice the pull-out strength of implants made from the PCL alone. Moreover, no toxic effects were observed, so the new implant could be used in orthopedic procedures that require bone to soft tissue connections, such as anterior cruciate ligament (ACL) reconstruction ³⁸. As mentioned earlier, implants based on magnesium compounds are very promising due to their favorable mechanical properties (similar to bone tissue) and due to their biodegradability. Song et al. decided to compare the results achieved in ACL reconstruction with screws made of pure magnesium and polylactide in a cadaveric study. The results indicated that magnesium screws yielded similar anastomotic strength to those of polylactide screws. The benefit of using magnesium was known to others to promote bone healing and remodeling by the aforementioned element ³⁹.

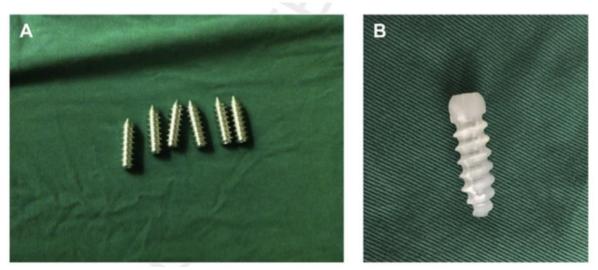


Figure 4: Screws constructed of magnesium (A) used by Song et al. and a commercially available polylactate screw manufactured by Smith&Nephew³⁹.

5. CONCLUSION

The fixations using plates and screws remain one of the basic techniques used in orthopedics. Currently, the most commonly used type of plate is the LCP (Locking compression plate), which is characterized by minimizing the disruption of blood supply to the bone. Research on orthopedic plates focuses not only on modifying their shapes but also on developing new materials for plate construction. Some studies focus on finding a material with similar mechanical properties to bone and protection against the "stress shielding", others focus on creating anastomoses with optimal biological properties and biodegradability. Similar trends can also be seen in orthopedic screw research. First, researchers are focusing on developing the right screw shape to provide the strongest possible fixation without the possibility of loosening. Second, much research is focused on developing new materials that can replace the polymers already in use today.

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