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Research Article

Mechanical Properties of External Polymer-Carbon Stabilizers for Bone Fixation -

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ABSTRACT

Time and quality of bone fracture healing depends on numerous factors, including the possibility of iso-elastic fixation whose rigidness diminishes in the course of treatment. Such a fixation has two crucial advantages. It allows axial micromovements at the fracture site, which stimulates the formation of bone callus. Moreover, it also prevents torsion and angle movements that hinder the healing process. The paper focuses on mechanical fatigue examinations and biological tests conducted on the external carbon stabilizer of a highly innovative structure. Two types of carbon composite stabilizers were tested - Carboelastofix1 and Carboelastofix2 - that may both serve as an alternative to presently used metal stabilizers, mostly steel ones, and other plate osteosynthesis systems. The examined external stabilizers comprised composite plates fixed to the damaged bone by means of metal screws. The composite carbon-epoxide resin material complies with the requirements for bone stabilizers. The fatigue tests prove that the material's rigidness facilitates micromovements within the safe range, thus supporting the bone consolidation process. Additionally, the level of stiffness may be controlled by adding or removing successive composite plates. Such a flexibility of the system promotes the possibility to retain relative iso-elasticity of the stabilizer-bone fixation during the healing process. In the conducted fatigue tests Carboelastofix2 endowed with spatial structure revealed less elasticity, which makes it applicable for neutralization and bridge plating. In comparison to the metal stabilizers, carbon composite ones display one more strength - namely their radiolucent quality, which means the bone healing process may be closely monitored by x-ray examinations. They are also aesthetically pleasing and characterised by low mass. The mechanical examinations of both types of systems and the clinical trials carried out at the Chair and Clinic of Motor Organ Orthopaedics and Traumatology in Warsaw; prove the efficiency of Carboelastofix stabilizers applied for bone fracture treatment.

Keywords: Biomaterials; Bone stabilizers; Carbon composites; Orthopaedics

INTRODUCTION

Widespread research on innovative material and construction solutions for external bone stabilizers has been conducted to diminish disadvantages of plate osteosynthesis. Common drawbacks of this procedure are: wide separation of a fractured bone from the skeleton system, inadequate blood supply, growing risk of infection, rigid characteristics of the fixation leading to poor biological potential for healing and problematic treatment of open fractures [1].

The first external stabilizers were made of steel, accommodating all the deficiencies of plate ostheosynthesis method [2-5]. The main downside was stiffness of the structure which failed to stimulate the activity of cells by means of a proper stress pattern between the bone and the plate, undoubtedly prolonging the treatment. As metals are x-ray impermeable, the possibility to monitor the progress in bone consolidation was seriously impeded too. Yet the most important weakness was the rigidness of fixation with no possibility to alter flexibility consistently with the healing process. Once the stabilizer was set, it could not be modified to shorten the time of bone reconstruction [6-8]. The major shortcoming of all external systems currently lies within their inability to seamlessly adjust the stiffness analogous to human muscles. In the particular case of carbon fibre orthoses aprox. 10% reduction in patient heart rate and oxygen consumption was reported, following weight savings of around 29% compared to stainless steel equivalents [9]. Furthermore, due to the low density of carbon fibre reinforced plastic, an improvement in agility, gait and walking speed can be noticed [10].

The type and energy of the injury are crucial to successful treatment of bone fractures. The injuries with high-energy axial loading result in burst fractures which are much more challenging to stabilize and treat successfully. The mechanisms of rotating and compression axial loading may be complex as well – the more severe compression, the bigger damage to the bone. Among other factors, the fracture characteristics depend on its precise location and forces acting during the trauma. The proper bone fracture treatment is related to iso-elastic fixation, whose rigidness diminishes consistently with the healing process, allowing slight axial movements and eliminating the torsion and angle ones at the fracture site. Only such a combination will stimulate the efficient and relatively fast formation of bone callus [8,9-16]. In the case of external stabilizers the elasticity of fixation may be achieved by increasing the distance between the bone and plate and the gaps between holes in the plate or lowering the number of applied screws. The elasticity of fixation is also dependent on the material of the device [8]. The necessity to manufacture a new generation of stabilizers has drawn attention to radiolucent carbon-based composite materials endowed with controlled elasticity. Their plasticity may be matched with the bone, and in the case of multi-plate systems the stiffness of fixation may be modified by removing successive plates [17-20].

The main objective of this work was to design, perform and describe the mechanical properties of the external Carboelastofix stabilizer during the long-term fatigue loading. Mechanical tests were correlated with the results of biological and clinical examinations, which provided efficient assessment of the fixation.

MATERIALS AND METHODS

The subject of examinations was the external stabilizer Carboelastofix used to treat tibial fractures. It was developed by physicians from the Chair and Clinic of Motor Organ Orthopaedics and Traumatology in Warsaw and a team of engineers from the Faculty of Materials Science and Ceramics AGH Krakow. The stabilizer was made of intermediate-modulus carbon fibers (160 g/m^2, Havel Composite, Cieszyn Czech Republic) formed as the 2D fabric and embedded in the matrix of epoxide resin (Epidian 601, Z1 hardener Ciech, Nowa Sarzyna, POLAND). Two geometric systems of Carboelastofix stabilizer were examined in this work. Each of them was constructed of two plates of the same type. The key point of Carboelastofix functional treatment is the possibility to change the stiffness of fixation by removing plates during the healing process. Figure 1 presents two types of Carboelastofix1, i.e., tent-shaped plates, and Carboelastofix2 – spatial plates which were tested as one-plate systems (Carboelastofix11, Carboelastofix21), two-plate systems (Carboelastofix12, Carboelastofix22) and three type of cross-sections of composite samples. Samples 1D (unidirectional) and 2D (made of fabric) had sixteen the same layers prepregs while 2D-1D-2D samples consisted of eight external (Four lower and upper layers) and eight internal (1D) layers. Initial clinical assessment revealed the necessity to optimize the stabilizer. Expanding the spacing of fixators improved treating oblique and spiral fractures and diminished rotating movements at the fracture site. Therefore both types of stabilizers were taken into account for further mechanical examinations and clinical trials.

The first stage of investigation was the mechanical characteristics of the assembled stabilizers fixed to a wooden bar. Wood was selected as the best possible imitation of bone as both materials are characterised by similar structure properties and comparable Young's modulus values. The elastic modulus of bone equals 10-40 GPa [22], while the one of wood is approximately 10 GPa [23,24].

Human tissues withstand changing loads constantly. Even though a changing load may be lesser than the resistance of the structure, nevertheless it may still cause damage. Weakening of the material is related to fatigue [20] that is why the combined system of the stabilizer on a wooden bar was subjected to cyclic fatigue loadings. The tests included bending, stretching and torsion. The force applied by the cyclic head equalled 10 N, the number of cycles was 1 000 000, the speed - 5 cycles per second.

The fatigue tests of stabilizers were conducted on the two-plate and one-plate systems. The introductory two-plate system was stiffer, while the system with one plate simulated the final phase of bone healing. Figure 3 presents images of the performed fatigue examinations.

The fatigue tests of three-point bending, torsion and tension were performed on the model with both one and two plates mounted (Figure 2). During the examinations a stereoscope camera was used to record the impact of the applied loading on the type and size of the micromovements at the fracture site to check if they fall within the range of safe displacement of the bones, namely 1 mm [25,26].

Clinical trials run at the Chair and Clinic of Motor Organ Orthopaedics and Traumatology in Warsaw investigated the two geometric types of Carboelastofix stabilizer. The first system was a fixator with tent-shaped plates – Carboelastofix1 which was applied to treat tibial fractures. The analysis of bone consolidation took into account 12 fractures and was performed on the basis of radiological examinations, bone density testing and calculating the surface area

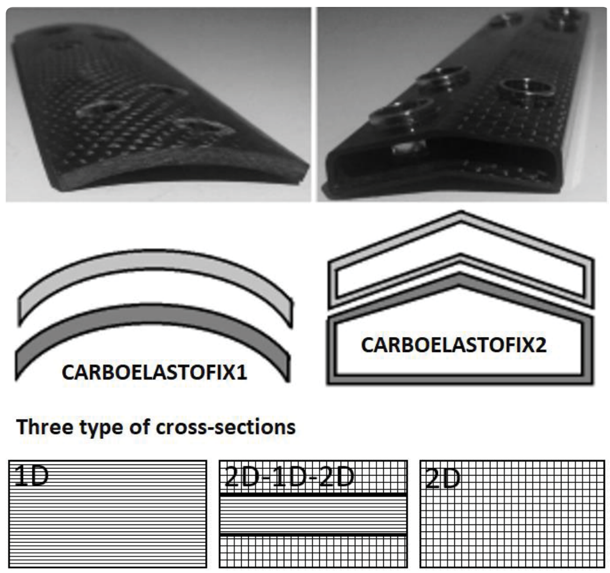

Figure 1: Types of Carboelastofix plates and the shapes of stabilizers.

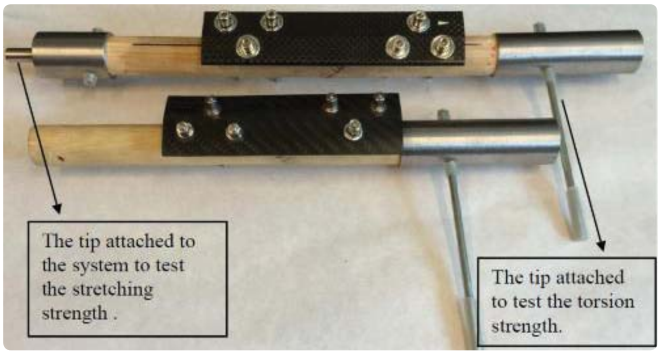

Figure 2: Types of Carboelastofix systems assembled for fatigue tests.

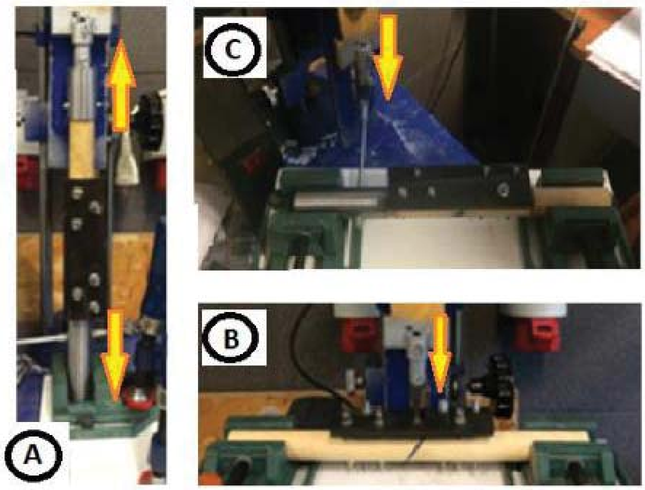

Figure 3: Fatigue tests: a) stretching, b) bending, c) torsion

of novel bone callus. The obtained results were compared to 12 randomly selected patients whose tibial fractures were treated with a metal stabilizer called "Zespol". The digital analysis of conventional x-ray technology was conducted to assess the changes in bone callus density. The gradual decrease in optical density (OD) proved the progress in fracture healing. In the case of all 12 patients the bone consolidation was achieved. Carboelastofix2 with one or two plates was used to treat 18 fractures. Clinical trials and radiological evaluation was performed to investigate the bone consolidation of this group of patients as well.

RESULTS

The first stage of this work was to select a proper material for load-carrying plates of the external stabilizer. In such cases biomimetics was the main criterion in the choice of the material whose elasticity should be comparable to the properties of bone [27]. Three types of plates characterized by different orientation of fibers and different combination of layers were manufactured. The method of prepeg pressing was applied to obtain 3 kinds of composites: 1D, 2D and 2D-1D-2D. In the latter one the core was built of parallel carbon fibers and the outer layers made of carbon fabric (Figure 1). The results of the three-bending test proved the 2D composite to be the most comparable to the bone characteristics. Its Young's modulus was close to the one of bone (approx. 20 GPa) and the bend strength about three times bigger [28].

The fatigue examination of the model Carboelastofix systems consisted in cyclic loading in three kinds of tests-bending, torsion and tension forces. The objective was to assess the impact of cyclic loading on the size of micromovements at the fracture site. In every test the time of cyclic loading lasted 24 h and the machine performed 1 000 000 cycles. The results of the tests are presented in figure 5,6.

The obtained results revealed that torsion load had the biggest impact on the fracture. In all the run tests the higher values of the fissure expansion were obtained for the Carboelastofix2 system as compared to Carboelastofix1. For both types of stabilizers the slightest influence was noted for cyclic bending load. Still it might be concluded that Carboelastofix2 is more susceptible to cyclic loadings.

The stiffness values of the one-plate and two-plate systems were compared for both stabilizers. The size of bone displacement was measured to assess the size of fissure, which is a crucial factor in the bone consolidation process. The obtained results confirmed that in this aspect the most efficient stabilizer was *Carboelastofix1* made of 2D carbon fiber-epoxide resin composite. The fissure of fracture expanded to 0.6 mm under applied tensile loads. Both Carboelastofix1 and Carboelastofix2 stabilizers proved to be more effective in two-plate systems with the results fewer than 1 mm in all kinds of fatigue tests. It means that in the introductory stage of treatment both systems meet the requirements concerning micromovements that facilitate the bone consolidation. The difference between them lies in the fact that Carboelastofix1 is more vulnerable to tensile load and behaves best under bending loading.

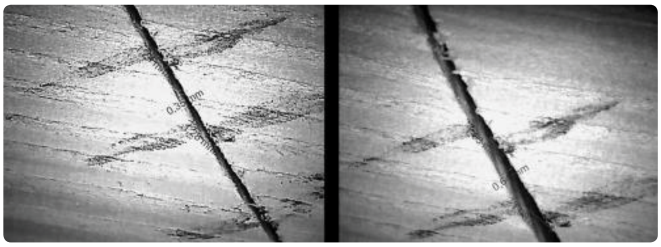

Figure 4: The fracture site before and after the torsion test.

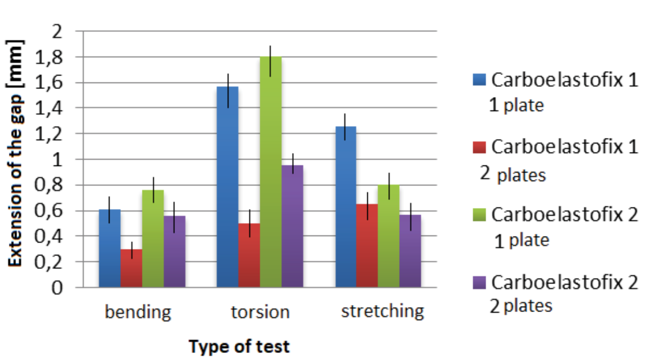

Figure 5: The expansion of fissure in particular types of fatigue tests.

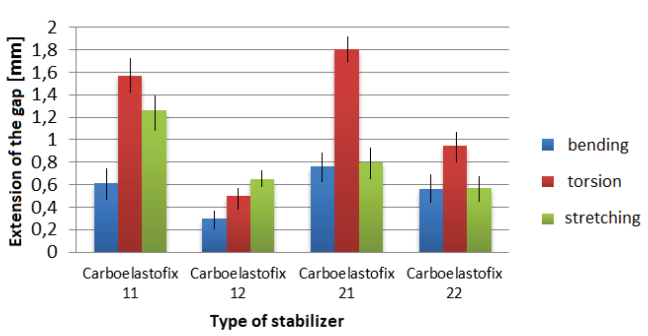

Figure 6: The expansion of fissure for particular types of stabilizers.

The healing bone has to withstand all kinds of loadings during the process of consolidation, especially bending and tensile load. In the case of torsional load which does not act in the axis of the fractured bone, the concentration of loads is observed on the bone itself and the stabilizer. The elements which have to resist the highest loads are the screws fixing the stabilizer to the bone. The torsional loads are suppressed efficiently by the two-plate systems of all the tested stabilizers.

The results show that two-plate systems are more rigid than one-plate ones for both types of Carboelastofix. Only the optimised Carboelastofix2 – due to its spatial structure – is endowed with a higher level of stiffness even with one plate. The one-plate systems displayed various results dependant on the type of applied load. As expected, the most disadvantageous load was torsion – the fissure expansion for Caroleastofix1 equalled 1.57 mm and for Carobelastofix2 – 1.80 mm. The conclusion is clear – it is highly recommended to avoid twisting action in the course of fracture treatment. Carboelastofix2 (the tent stabilizer) retained safe parameters of the fissure expansion in the other two fatigue tests. In the case of Carboelastofix1 tensile test the fissure expansion was slightly more than 1 mm after one million of cycles. The data obtained in the fatigue tests suggests that both carbon composite stabilizers are highly applicable as fixating devices supporting consolidation of a fractured bone. In the course of the examinations it was proved that the most undesirable kind of loading was torsion because of its idiosyncrasy and directions of the acting torque. The weakest element of the whole system is definitely the screws. The highest concentration of loads occurs in the place where the bone and stabilizer are put together with the screws. It is also the point where the biggest displacement and damage was noted after 1 million cycles of fatigue tests, especially where the screw was driven into the bone. All the observations lead to the conclusion that Carboelastofix1 and Carboelastofix2 are applicable for modern treatment of fractures and bone defects. They are well fit to replace conventional metal stabilizers which are uncomfortable and heavy.

CLINICAL TRIALS

The main objective of the clinical trials run on Carboelastofix2 was to assess the Iso-elasticity of fixation, which is the gradual decrease in stiffness to match it with the course of bone consolidation. The dynamization of fixation was achieved due to removal of plates during the treatment. The poorer plasticity of Carboelastofix2 revealed in the static examinations made it possible to broaden clinical indications and apply this stabilizer as neutralization and bridge plate in the cases of spiral and comminuted fractures respectively. The Carboelastofix2 stabilizer was used to treat the fractures of 18 patients. In all the cases the bone consolidation was achieved. The x-ray images of fixing the fractures by means of various stabilizers are presented in figure 7.

The clinical trials performed on both Carboelastofix1 and Carboelastofix2 confirmed the efficiency of these systems in treating tibial fractures. The elasticity of fixation lead to higher bone density and bigger area of bone callus getting formed. Unlike metals, composite materials are radiolucent, which means better monitoring of the process through x-ray examinations. Both Carboelastofix systems facilitated the dynamics of bone consolidation by modification of the stiffness, i.e. gradual removal of the plates. When comparing the both system, Carboelastofix2 proved to be endowed with more fluent change of rigidness. Additionally, in this system particular types of screws were used. The cone head screws blocked in cone-shaped nests guaranteed angular stability of fixation, preventing random and thus unpredictable movements in the stabilizer.

The next stage of examinations was comparison of the bone callus getting formed in the cases of both Carboelastofix1 and metal stabilizers. The area of the callus was significantly larger in the case of fractures treated with the composite fixator than with the metal one (Figure 8).

The further stage of clinical trials was ultrasonometer experiment to compare the rapidity of ultrasound wave propagation through the fresh callus in both a fractured bone and a regular healthy tibia. The propagation in the case of healthy bone was 27-34 μs. The fractured bone revealed a wider range of data as the transmission time shortened in the course of healing. Right after the trauma it was 51 μs and towards the end of the fracture treatment it was only 23 μs. The shorter propagation time after completion of healing is related to the higher rigidity of hard bone callus.

The main objective of the clinical trials conducted on the Carboelstofix2 system was to maintain Iso-elasticity of fixation, which means reducing the stiffness of stabilizer keeping up with the

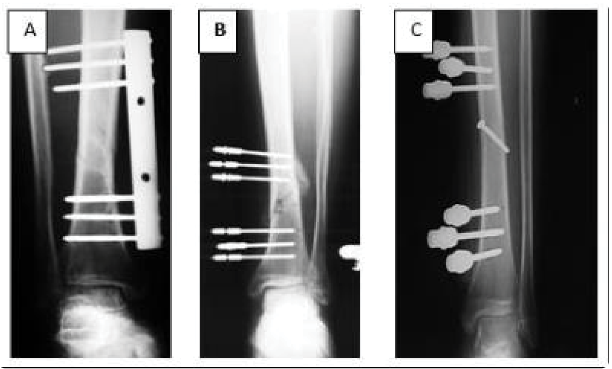

Figure 7: A-Bone healing process with no bone callus visible – 12 weeks after the application of metal stabilizer B-Bone healing process with rich bone callus – 12 weeks after the application of Carboelastofix1 C-Neutralization fixation by means of Carboelastofix2 with 100 mm sparing and the screw (post-operational image).

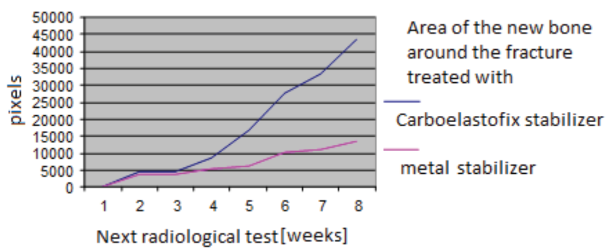

Figure 8: The growth of the bone callus area in the course of treatment with Carboelastofix1 and metal stabilizer related to the healing time (successive x-ray examinations).

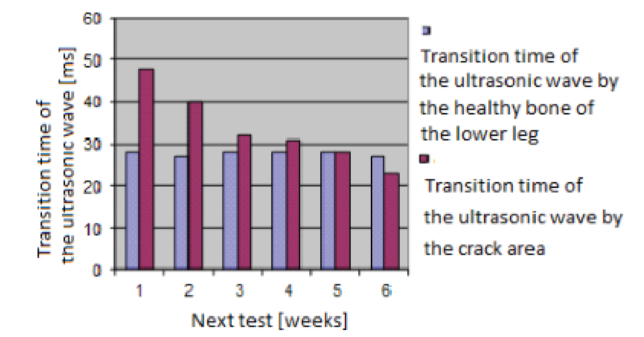

Figure 9: The ultrasound wave propagation alterations in the course of treatment.

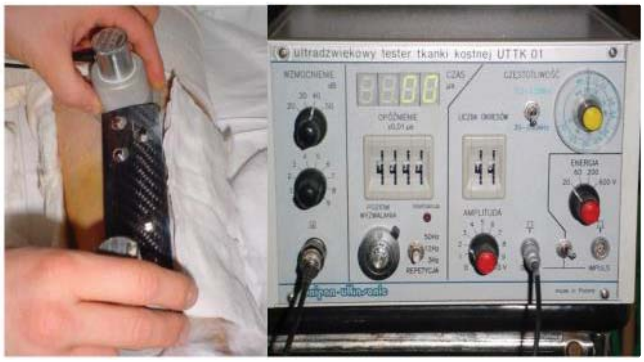

Figure 10: Ultrasonometer tests to assess the propagation of ultrasound wave through the fresh bone callus.

pace of bone consolidation process. The dynamization of fixation was achieved by removing successive plates of the stabilizer during the treatment. In the trials the two-plate system was replaced by the three-plate stabilizer to provide more fluent change of flexibility.

The clinical supervision performed of the progressing bone healing was performed every four weeks. It was complemented by expert judgement based on x-ray imaging and quantitative evaluation through ultrasonometer observations. The clinical trials of the fracture treatment using Carboelastofix2 stabilizer were performed on 18 patients, all of which succeeded in bone consolidation.

The observations were performed from the surgery to complete bone consolidation and the mean period of observation lasted 23 weeks (the shortest – 17 weeks, the longest – 23 weeks). There was no difference noted in the pace of bone consolidation achieved by means of Carboelastofix, as compared to the control group treated with the metal stabilizer.

CONCLUSIONS

1. The composite material of carbon fiber and epoxide resin meet the requirements for bone stabilizers and the fatigue tests confirm that its stiffness allows micromovements at the fracture site within the safe range.
2. The post-operational examinations of the carbon plate stabilizer CARBOELASTOFIX applied to treat tibial fractures confirm its clinical utility.
3. Due to its unique mechanical properties and radiolucency, CARBOELASTOFIX is more efficient than the presently used metal plate stabilizers, lacking their deficiencies.

4. The dynamization of fixation is advantageous to the formation of fresh bone callus, yet it does not remarkably affect the pace of healing.
5. The elasticity of fixation improves the bone density and widens the area of fresh callus.
6. Both systems of CARBOELASTOFIX stabilizer facilitate the dynamization of bone consolidation, However, the Carboelastofix2 reveals more fluent elasticity alterations in its plasticity.

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