INNOVATION OF ILIZAROV STABILIZATION DEVICE WITH THE DESIGN CHANGES

FILIP TOMANEC[1, 3], SONA RUSNAKOVA[1], MARTINA KALOVA[2,3].

[1]Tomas Bata University in Zlín, Faculty of Technology, Department of Production Engineering, Zlín, Czech Republic.
[2]Faculty of Metallurgy and Materials Engineering, VSB – Technical University of Ostrava, Ostrava, Czech Republic
[3]Center of Advanced Innovation Technologies - VSB-Technical University of Ostrava, Ostrava, Czech Republic

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e-mail: solvetech@solvetech.cz

An application of the osteosynthesis fixator as a surgical method for the large bone treatment has been deeply described during the last 70 years [Solomin 2012]. Even the design using composite material is available at the market. Nevertheless, the interconnection of the main requirements including lightweight, adequate stiffness and adjustability around the tibia bone is the next step in external fixator improvement. Thus, the overall aim of this study is the innovation of this device with the subsequent analytical verification using finite element method. Due to these requirements, innovative external fixator has been developed and further optimized with structural analysis and surgeons´ requirements as well. The final improved design of osteosynthesis device with the analytical confirmation using finite element method has been manufactured and this state of the art further serve for experimental verification.

KEYWORDS

External fixator, glass-fiber composite, tibia, Ilizarov, Kirschner.

1 INTRODUCTION TO ILIZAROV EXTERNAL FIXATOR

An external fixation method is predominantly named by the G. A. Ilizarov for the discovery he made in the middle of 20th century. This discovery basically states, if the tissue is subjected by gradual strain, then it reacts by the growth and regeneration of bone, skin and other human tissues [Solomin 2012, Ilizarov 1988, Ilizarov 1991]. An orthopedic device - Ilizarov external fixator can be applied for the long-fractured healing process of the tibia bone, fibula bone, and also other bones of leg or arm. However, this study is focused on the tibia bone. Important advantages of this stabilizing device are the possibility of fibular vasculization and quick opportunity of the weight loading after the surgery, that further improves the process of the therapy. In most cases, commercially available external fixators using carbon fiber composite rings offer the possibility to attach the fasteners to solid composite rings or rings with circular holes. On the other side, the requirement of orthopedist is both. Firstly to adjust individual Kirschner rod or half-pin at any angle around the foot. And at the same time, the requirement to move the connecting rod at any angle, while other parts are already fixed. Another important aspect for the design of an external fixator is also knowledge of correct position for pins and Kirschner rods. That prevents injury of the major blood vessels, nerves and creates safe zones for transosseous element insertion as can be seen in Fig. 1. Thus the necessity to use innovative solutions as CAD and FEM is an important move to ensure that these conditions can be achieved in the future research [Solomin 2012, Kytyr 2016, Jevremovic 2012, Kursun 2016].

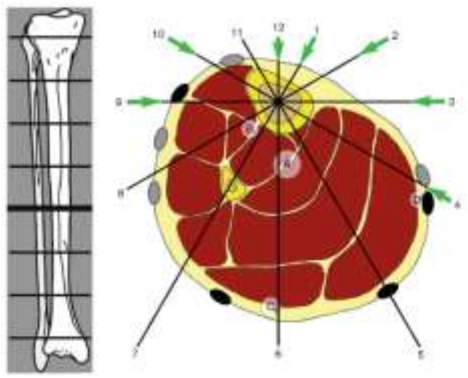

Figure 1. Transosseous elements (Kirschner rods) recommended for tibia bone [6]

Another important, but not attained aspect of this device is the low weight of fixator, simple assembly and ability to work under the X-ray during the surgery. Therefore, the application of an advanced material as the composite material could bring significant improvements to the fixator's characteristics [Fu 2007, Evans 1998].

Therefore this article deal with a proposal to innovate an existing metal external fixator (Ilizarov circular fixator) using composite materials, improve the functionality in term of improving the possibility to manipulate with transosseous elements around the bone. The design of the innovated fixator has been created in CATIA V5-6 software. The changes can be found in the material selection and also in the design area of the component construction (rings, clamps, connecting rods) of an external fixator. The most used - metal surgical steel fixators are too heavy both for the patients and surgeons.

The aim of this article is thus principally functional innovation, weight reduction compared with the original fixator and the verification of mechanical properties and maximal deformation under the load. If these requirements are provided, then the external fixator can be subjected by the prescribed tests for the attestation of this orthopedic device. The lightweight and yet rigid, solid construction is comfortable for both patients and surgeons who manipulate with the construction of fixator. The Ilizarov device that can be seen in Fig. 2 is a set of several mechanical devices including rings, threaded rods, nuts, bolts, and hinges [Migliaresi 2016, Park 2007, Mehboob 2014].

Figure 2. Surgery with Ilizarov external fixator [Zhang 2016]

1.1 *Clinical requirements for the construction*

If the fracture occurs, and as a treatment method, an osteosynthesis fixation is selected, then it is necessary to control the bone fragment position and control the bone fragment rigidity as well. These methods are described further.

1.2 *Control of bone fragment position*

The aim of this approach is the ability to control individual fragments in six degrees of freedom gradually. This could be done either by the movement of external supports with transosseous elements or by the movement of these elements relative to the external supports that remain stationary.

The first method can be seen in Fig. 3 for the elimination of fragment displacement and in Fig. 4 for angular displacement.

Figure 3. The correction of transverse displacement [Solomin 2012]

Figure 4. The correction of angular deformation [Solomin 2012]

The second method has been further developed in recent years. This method employs the combination of the typical external osteosynthesis with the computer – passive navigation inclusion. This further gives a considerable opportunity to improve the bone - fracture healing process and opportunity to navigate individual bone fragments throw the calculated trajectory. The basic procedure can be seen in Fig. 5 [Solomin 2012].

Figure 5. Bone – fragment movement [Solomin 2012]

2 PROCESS OF INNOVATION

In this research, the external fixator of the tibia leg was designed in software CATIA V5-6. In CATIA, individual components of external fixator were created and assembled together with the model of a human limb. As can be seen in Fig. 6 this product is composed of supporting rings, connecting rods, internal stabilizing rods, clamping components of connecting rods and clampings of internal rods. The material of supporting rings and connecting rods is an epoxy matrix with carbon fibers. Internal stabilizing rods that are in contact with the tibia and human tissue are made of surgical steel but the rods can be manufactured of titanium alloy used for the chirurgy as well. Clamping components of stabilizing rods and screws are made of stainless steel and the material of connecting rod clamping is aluminum.

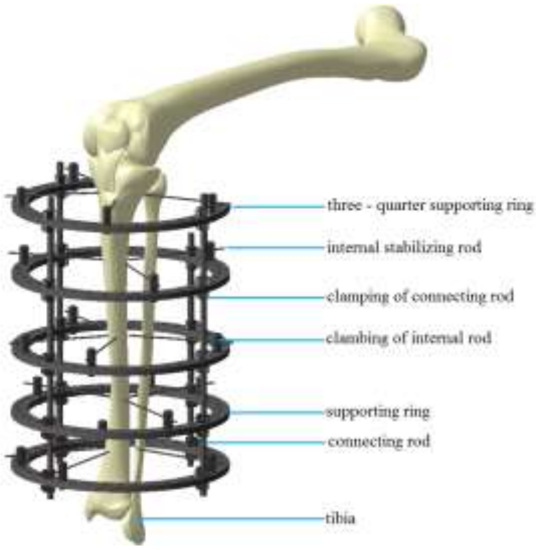

Figure 6. External fixator of the tibia

The materials of the individual parts are chosen with the emphasis on functionality and minimization of product weight. Further, the function of an individual component of osteosynthesis fixator is described.

2.1 *Supporting ring*

This part of the assembly is the essential part of external fixator (shown in Fig. 6). Its main function is the attachment of other components together, increasing the stiffness of the assembly.

This part should also ensure the possibility to rotate with connected components all around the fractured leg. An external diameter of this part is 200 mm and thickness is 6 mm for the medium size of the assembly. Usually, there are 4 pieces of a complete ring in fixator assembly and one piece of three - quarter ring. This opening serves as a space for the tight part of the human limb. Rings contains holes that serve for connecting rods, clamping of internal rods and as weight reduction.

As mentioned in [Solomin 2012], nowadays external fixators using composite materials are under the development and their clinical application is not widespread broadly. The verification with the structural analysis is further evolving in the field of external osteosynthesis. This can be seen in other parts of the article, where individual versions of fixator are subjected by the structural analysis.

2.2 Connecting rod and clamping

These components are used as the connection of individual rings. There are two lengths of connecting rod - 220 mm and 285 mm. Connection with supporting ring is through clamping system using friction force (shown in Fig. 7).

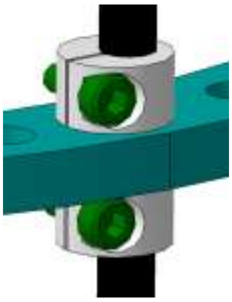

Figure 7. Clamping of connecting rod

The connecting rods are based on pultrusion technology, which is suitable for the production of various profiles. Different laminate lay-ups are possible with reinforcements of mats, fabrics and multiaxial. The finished profiles are cut to length by a saw at the end of the line [Elmedin 2015].

2.3 Internal rod and clamping

Internal rod in Fig. 8 is a component in connection with tibial bone. The hole is drilled into the bone with this rod. There are many types of rods based on the different design of ending [Solomin 2012]. Another step is a connection with the relevant supporting ring and fastening with screws. Internal rods are then equally distributed around the perimeter of the foot. This distribution is dependent on the individual patient and part of the human body.

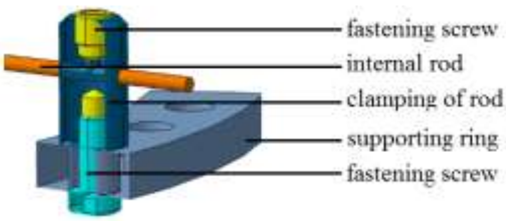

Figure 8. Internal rod with clamping

Complete assembly connected together has diameter Ø200 mm and height 285 mm. Internal rods are equally distributed around the perimeter of the foot.

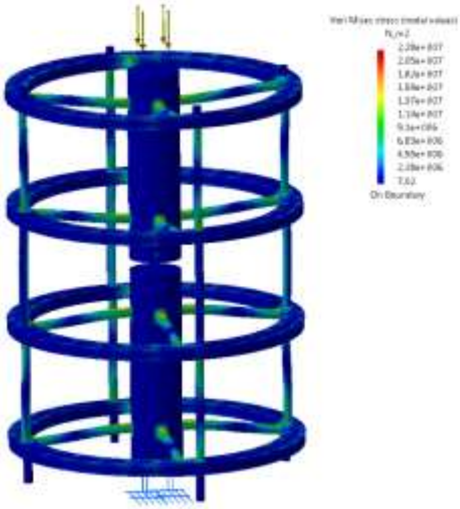

Figure 9. Version 1 – structural analysis

2.4 Optimization of composite rings

In order to further improve both, the surgeons work as well as the patients healing process, the rings of an external fixator have been developed. As in many composite fixators, there is a problem with reduced ability to move the individual rod in any angle around the bone and also a problem with the low rigidity according to the structural analysis (see Fig. 9). This ability to set an appropriate angle is usually resolved by adding another part into the assembly. This solution increases the overall weight of the fixator again. Thus, the holes for connecting rods have been replaced by the grooves. There can be seen that grooves are created in two lines. This design choice is important in order to ensure optimum stiffness at the same time with the required possibility of moving around the bone. And because of this improvement, the possibility to effectively utilize all the scope of the composite ring is increased. These changes can be seen in Fig. 10. Also, the rigidity of the whole fixator has been increased as can be seen in Fig. 11.

Figure 10. Improved concept – version 2

After this optimization, several disadvantages have been found. Concerning higher weight of the rings and thus higher weight of all the fixator and also worse appearance due to the increased rings diameter and overall robustness. Even, after the discussion with an orthopedist, the problem with the movement of individual components all around the fixator has been found. More specifically if any rod or connecting component should be moved about several degrees, then, the component has to be too frequently moved from one groove to another, that is not an adequate improvement in term of fixator functional simplicity.

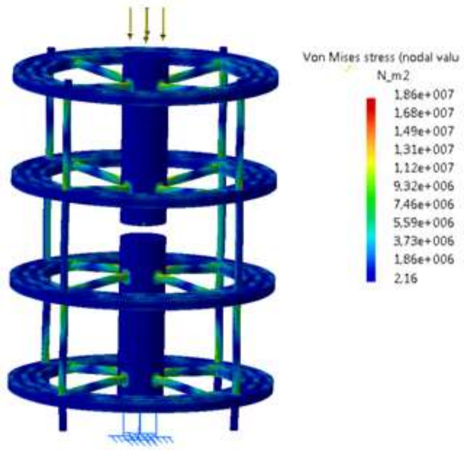

Figure 11. Version 2 – structural analysis

From the perspective of the described disadvantages, another improvement is necessary and thus the 3rd version has been developed (see Fig. 12). The groves have been replaced by the combination of longer grooves (thereby achieving the opportunity to move the components and rods in larger angle without moving from one groove to another so frequently) and shorter grooves serving as an interchange between individual grooves. This improvement also brought an opportunity to reduce the material and thus overall weight of the external fixator. The last part of the process has been optimization of ring diameters and shape of this final ring. The resultant structural analysis is in Fig. 13. In all the structural analysis in this article, there a force of 1300 N has been applied in the longitudinal direction of the bone.

Figure 12. Improved final fixator – version 3

For the needs of more detailed technical description, also main dimensions of fixator and the proportions of rings are displayed in Fig. 14, 15, 16. In orthopedy, three – types of fixators based on dimension are applied. This research deals with a one dimension type. Other variants can be manufactured after the process of attestation.

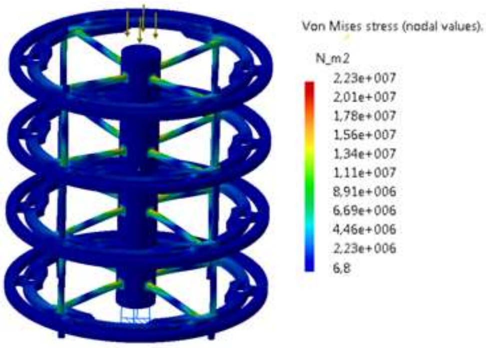

Figure 13. Version 2 – structural analysis

Figure 14. Version 3 – main dimensions of fixator – bottom view

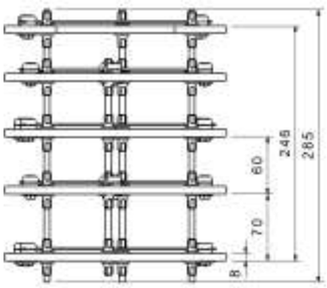

Figure 15. Version 3 – main dimensions of fixator – front view

Figure 16. Version 3 – the main dimensions of the composite ring

2.5 Manufacturing of fixator prototype

The process of fixator optimization is completed and another step of innovative product development is prototype manufacturing. This prototype (see Fig. 17) will be further tested by the method of static testing. For the price reduction of prototype production, the glass – fiber composite has been selected. It is generally known that this material in comparison with carbon fiber composite is significantly cheaper.

Figure 17. External fixator prototype – version 3

Prepreg for glass – fiber composite rings have been purchased from the DELTATECH company. This material exhibits low to high viscosity range. These types of prepregs offer a very good combination of cure reactivity, versatile processing, and availability in fabric and unidirectional fiber formats. These materials allow processing by oven vacuum bag, autoclave, and press molding. Considering that these parts are manufactured by the method of press molding, the cycle of curing cycles 12-20 minutes at 135°C has been selected. The matrix of this prototype is DT 806 and its properties can be seen in Tab. 1.

Material - matrix DT 806	
Maximum glass transition temperature	135 °C
Processing temperature	65 - 140 °C
Density of pure resin	1,21 g/cm^3
Matrix tensile modulus	817 MPa
Matrix tensile strength	835 MPa

Table 1. Properties of prototype matrix – DT 806

In order to achieve high surface, dimension and structure composition ratio, a method of prepreg composition molding (PCM) has been selected.

The lamination process is selected due to the preferable case than the wet-laying method. Typical wet layered laminates have a substantial content of a residual resin occurring during the process. This cause increases fragility and reduces mechanical properties of the laminate. Preliminary lamination increases the possibility to achieve appropriate resin content, and the process increases the consistency of the manufactured parts significantly [Miller 2017].

An individual ring has been made of 13 prepreg layers together. Layers were placed in a two-piece closed aluminum mold and subsequently pressed in a heated press. Aluminum mold (see in Fig. 18) was made from aluminum alloy EN AW 5083 [AlMg4.5Mn0.7]. The design and production of this form is already the subject of another paper.

Figure 18. Aluminum mold for composite rings

Prepreg pressing conditions are listed below:

1. Attention to confirm the prepreg plies to the geometry of the released mold when laminating, especially in corners of small radius of curvature.
2. A non-perforated release film must be used, layed carefully over the laminate and mold, then sealed at the mold edges with tape.
3. Breather (non-woven polyester). Inspection that the breather covers the entire part and reaches all the vacuum valves.
4. Pressing. Use an appropriate quantity of temperature and pressure. Control the state of the parts after the pressing process.

Individual connecting components were manufactured by the method of machining and the Kirschner rods from surgical steel were purchased. This prototype will be later tested by the cyclical testing simulating the use of the fixator by the patient. After the period of time representing one week of application, the changes of stiffness will be measured.

3 RESULTS

The results of material, construction, and design changes can be seen in Tab. 2, 3 and 4. The maximum stress under the applied load on the fixator fluctuated between the versions. As can be seen, the 2nd version exhibits the lowest von Mises stress and thus it is the most robust design. Despite this fact, the design exhibits also worse ability to use one groove for the accurate internal adjustment.

VERSION COMPARISON	
VERSION OF FIXATOR	MAXIMUM VON MISSES STRESS
Version 1	28 MPa
Version 2	18,6 MPa
Version 3	22,3 MPa
Tensile Strength	125 MPa
Poissons´s Ratio	0,51
Young´s Modulus	28 GPa
Density	1,95 g*cm^{3}

Table 2. Comparison of maximum von Mises stress among the versions

The weight of fixator (see Tab. 3) has been reduced by 63% in contrast with the standard fixator and also the fixator reduced the volume of metal components in construction. The main parts of fixator will be manufactured from a composite material with carbon fibers. Furthermore, there can be seen the optimization of the clamping system in the experimental part. This innovation mainly reflecting the handling of surgery and the quality of the fixation system. During the design process, the complexity of the parts has also been reduced. These changes simplified the appearance and production of components. The weight has been measured in CATIA and the material density was set at 1,95 g/cm^3. The solver computation gives directly the result and post-processing performs an element to node smoothing.

VERSION COMPARISON	
VERSION OF FIXATOR	WEIGHT
Version 1	690g
Version 2	870g
Version 3	910g

Table 3. Comparison of weight among the versions

Finally, also the displacement of each fixator under the stress has been measured and as can be seen in Tab. 4, the second and the third version reports significantly lower displacement than the first version. That is an important fact for the surgeon.

VERSION COMPARISON	
VERSION OF FIXATOR	DISPLACEMENT UNDER THE LOAD
Version 1	1,2 mm
Version 2	0,34 mm
Version 3	0,55 mm

Table 4. Comparison of relative displacement under the load among the individual versions

Values indicated in this table are detected in the same structural analysis that creates also the results for overall fixator displacement under the load. This deformation display can be seen in Fig. 19.

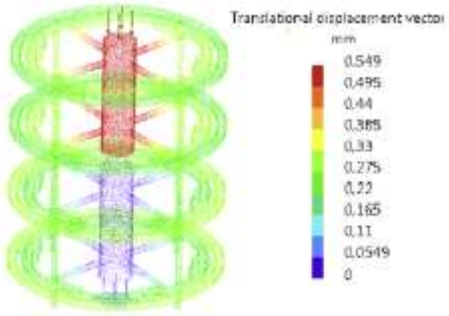

Figure 19. Deformation display o version 3

4 DISCUSSION

As can be seen in the results section, the weight of fixator decreased significantly and thus became more variable for the needs of patients and surgeons. The number of composite components increased and therefore the possibility of surgery under the X-ray is improved too. One of the important points of this construction is the application of composite as a material of connecting rods. In comparison with other publications [Elmedin 2015, Jennison 2014] and commercially available products, this innovation goes beyond the state of the art mostly by the development and application of grooves into the design that improvemes the fixator function during the surgery and during the treatment, where individual setting is necessary. That brings the opportunity for the surgeon to simply move internal and also connecting rods around the fractured bones. During this movement in the period after the surgery, individual component is guided by the groove in a constant distance from the bone. This further improves the accuracy of the surgeon´s service.

Another advantage of composite material selection is also the improvement of the product appearance. The disadvantages of this solution are the higher price of composite parts production, the necessity of mold production, the need for testing in medical practice and the requirement of stress tests. The proposal was dealt comprehensively as overall design and appearance improvement and as can be seen in experimental and result section, this aim was successfully implemented into the final design of external fixator.

5 CONCLUSION

In this study, the material, design and construction changes of fixator were created and evaluated with the structural analysis. The research shows that the weight was significantly reduced and thus the main aim of the research was achieved. Also, another innovation in replacement of holes to grooves can be seen. This is the most important innovation of the external fixator solution that gives an opportunity to manipulate with rods and components at a 360° angle around the bone. This solution also further improves appearance and handling and brings innovation throw material and design solutions. An appearance is a very important attribute for patients, that could be a very important fact in the future parts of the project when the device will be applied with patients. After the model optimization with the structural analysis, the first prototype was manufactured. For the price reduction of the development process, the prototype has been manufactured from the glass – fiber composite. This design will be further subjected by stress analysis and after that, the carbon fiber fixator will be manufactured.

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CONTACTS:

Ing. Filip Tomanec
Tomas Bata University in Zlin, Faculty of Technology, Department of Production Engineering,
Vavrečkova 275, Zlín, 760 01, Czech Republic.
e-mail: solvetech@solvetech.cz, www.solvetech.cz

doc. Ing. Sona Rusnakova, Ph.D.
Tomas Bata University in Zlín, Faculty of Technology, Department of Production Engineering,
Vavrečkova 275, Zlín, 760 01, Czech Republic.
e-mail: rusnakova@utb.cz, http://www.utb.cz/ft

Ing. Martina Kalova
VŠB-Technical University in Ostrava, Faculty of Metallurgy and Materials Engineering,
17.listopadu 15/2172, Ostrava, 708 33, Czech Republic
e-mail: kaloma13@seznam.cz