Tomas Bata University in Zlín
Faculty of Technology

Doctoral Thesis

The development of composite orthopedic devices

Vývoj kompozitních ortopedických pomůcek

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Ultimately, man should not ask what the meaning of his life is, but rather must recognize that it is he who is asked.

In a word, each man is questioned by life; and he can only answer to life by answering for his own life; to life he can only respond by being responsible.

— Viktor E. Frankl, *Man's Search for Meaning*

This thesis is dedicated to my mother, who left this world only a few months before the completion of the dissertation thesis.

Preface

The thesis itself is a result of the synergic effect of several workplaces. Primarily based in the work performed at the Department of Production Engineering, Faculty of Technology, Tomas Bata University in Zlin where I have had an opportunity to do my research in doctoral studies. Many engineering and analytical parts of the thesis were performed in SOLVETECH ENGINEERING s.r.o. in Zlin. During this multidisciplinary thesis, the research was conducted also in the United Kingdom in Manchester at the University of Salford at the School of Health Sciences in the biomedical engineering group.

During the work linking medicine and engineering science, there was a good opportunity to investigate new design based on structural analysis and composite materials with fibers and matrix. Recently, the application of composite and the utilization of structural analysis brings attention. This work deal with the analytical structural analysis that is further verified by the experimental study of an application of the composite material in external fixator that is an orthopedic device serving for the long bone fracture healing process.

In the study, the theoretical background is introduced together with the analytical and experimental results, which are later statistically analyzed and from the thesis, the conclusions of composite material application together with innovated design are drawn.

Filip Tomanec
Zlín, June 2019

Abstrakt

Předložená disertační práce se zabývá tematikou externích fixátorů pro léčbu zlomenin velkých kostí dolních končetin, kde mezi největší nedostatky z pohledu současného stavu techniky patří vysoká hmotnost, neprostupnost rentgenového záření při operaci a složitost seřízení. V průběhu zpracování této disertační práce byla zpracována rešerže zadaného tématu z pohledu bimechanického, materiálového a konstrukčního řešení. Dále byly stanoveny jednotlivé cíle směřující k vyřešení jednotlivých nedostatků, navržen externí fixator využívající kompozitní materiál, vytvořen unifikovaný test, sloužící pro možnost komplexní a předem stanovené metody posuzovaní fixátoru s následnou aplikací kombinace analytického a experimentálního přístupu využívající metodu konečných prvků a zátěžové zkoušky fixátoru a jeho dílů pomocí cyklického a postupného zatěžování. Zjištěné výsledky unifikovaného testu ukazují, že výsledná konstrukce z pohledu zátěžných stavů je vyhovující a vhodná pro použití fixátoru v processu atestace výrobku. Dále výsledky ukazují, že jednotlivé problémy plynoucí z práce chirurga jsou minimilazovány a posledním důležitým výsledkem je odzkoušení navrženého unifikovaného testu, který lze použít a dále ověřit i pro jiné fixátory.

Abstract

This dissertation thesis deals with the topic of external fixators for the healing process of long bone fractures of lower extremity. Nowadays, the most important disadvantages in term of state of the art are high weight, X-ray impermeability during the surgery and too difficult adjustability of external fixator. During the thesis preparation, the research of this topic has been proceeded from the biomechanical, material and engineering point of view. Further, the individual goals have been established directionaly to solve different disadvantages, designed osteosynthesis external fixator using composite material, the unified test has been created. This test serves as a complex and established method of the new fixator design evaluation with the analytical and experimental method application, using deformation analysis, external fixator and composite samples loading during the cyclic tests and gradual loading by the pressure. Results of the unified test indicate, that the new fixator design from the perspective of stress tests of unified method is convenient for the attestation process of this orthopaedic product. These results also confirm that the problems defined from the surgeon perspective are minimalized. The last important finding is an application of this new unified testing method, that can be used even for another fixator development in the future.

Acknowledgements

The thesis has been done during the busy and adventurous four years, while combining the doctoral studies and the establishing of the mechanical engineering company SOLVETECH ENGINEERING s.r.o. In these years, I have been lucky to work with the people who encouraged me in the research, gave the opportunity to work on different projects or connected me with the other important people in the field of medicine, mechanical and biomedical engineering. This is the part of thesis, where I would like to express my gratitude to them.

First, to my supervisor doc. Ing. Soňa Rusnáková, Ph.D., who gave me the opportunity to work at the project at the boarder of mechanical engineering and medicine. Also, for so many chances during my studies as a visiting conference abroad, connecting with other scientists from this field of research.

Further to Professor David Howard from the University of Salford, Manchester for an excellent opportunity to work in the multicultural biomedical engineering research group at the Brian Blatchford building, for his kind invitation and very good support during the project preparation in the field of biomedical engineering after my stay in Manchester. Together with him I would like to acknowledge Professor Laurence Kenney and Dr John Head from the University of Salford, who shared with me all the necessary knowledge in the project we have been working on.

Another gratitude points to Ing. Martina Kalová, for co-work and friendship we have developed on the way as well as the co-operation with Ing. Milan Žaludek, Ph.D.

To the university To the University hospital in Ostrava, for the opportunity to work on the projects connected with the medicine and orthopaedic field.

It is a pleasure to acknowledge also my colleagues from the Tomas Bata University in Zlin, mainly Ing. Václav Janoštík, Ing. Lenka Hýlová, Ing. Milena Kubišová, Ph.D., and last, but not least Ing. Lukáš Maňas.

At the end I would like to thank to my wonderful wife for her love, big support, she has always given. For her confidence during the difficult parts of research and business. She has always been my role model of a good person.

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1. INTRODUCTION

An application of innovative materials, as composite is, has always been a meaningful improvement [1-3]. One of the clinical products used in the orthopedic field is an external fixator. This device has been developed many decades ago and it is still widely used in traumatology applications for the long bone fractures stabilization and healing process [4-6].

One of the significant fixator characteristics is the rigidity and the ability to transfer the load applied to the patient's extremity and thus enabling the movement and loading during the healing process, that further increases the potential of successful treatment [7, 8].

Another important, but not attained aspect is the low weight of fixator, simple assembly and ability to work under the X–ray during the surgery. Whereas, these characteristics are not successfully achieved nowadays, they are the most important reasonings of this thesis and the problem that will be further addressed in this thesis. In term of improving the state of art of fixators, the application of an advanced material could bring significant improvements to the fixator's characteristics. One of these materials can be a combination of carbon fibers with epoxy matrix. The synergetic effect of this material could bring both, reduced weight of the product and improved X–ray penetration during the surgery while maintaining similar overal stiffness of the whole fixator. Moreover, the components created by carbon fiber composite allows the creation of magnetic resonance imaging and computed tomography [9, 10]. Another reasoning of the dissertation lies in the application of deformation analysis, while it has not been used in the external fixator examination enough [6].

Based on these findings and cooperation with the Faculty Hospital in Ostrava, an appropriate and innovative external fixator was designed. Both, with the composite material application and design simplification in order to get a satisfactory assembly. This 3D model was subjected to the analytical verification using structural analysis and later redesigned due to the surgeon's requirements. The final model has been later examined by structural analysis too.

These individual innovations and findings from the analytical part of the research are necessary to verify by the experimental section. However, before the fixator manufacturing the individual composite samples providing the possibility to analyze a suitable ring profile have been manufactured and tested through three-point bending method. After the selection of appropriate profile, the test prototype of the fixator has been manufactured. Because of the reduction of the final price of the research, the prototype has been manufactured from a glass – fiber composite. Fixator has been later subjected by the cyclic testing and stiffness verification, simulating the use by the patient during the healing process. After several testing periods, the final data has been recorded, verified with the analytical model and on the basis of these results.

Due to the inconsistences in assessment of the final design of external fixator, the unified testing method has been created and applied during both. Firstly, the analytical part of the fixator testing period and also during the experimental part of the thesis. Individual results, behavior and knowledges gained during this process can be found in this dissertation thesis.

The highest degree of importance of this thesis lies at several points that reacts to deficiencies or niches of the external fixator design. These points include:

- Design of the unified test for overal fixator verification (this is engaged by the analytical and experimental part of the thesis too) and its application on real case (on real manufactured fixator).

- Improvement of the state of the art of Ilizarov external fixator with material and design optimization.

- Application of deformation analysis and design optimization with this verification method.

- Application of cyclic testing, simulating fixator use during the process of healing.

- Design of new shape of external fixators rings.

2. EXTERNAL FIXATION

External fixation as a bone or joint treating method or procedure of correcting deformities and bone length has been developed during the first half of the 19th century, while its further spreading continued mostly in the beginning of 20th century. During the period of further development and improvements of technique and instruments, the orthopaedic surgeon G. A. Ilizarov came with the tool for the healing of complicated fractures. This device is named by the author - Ilizarov external fixator [6]. In these years of industrial revolution and the medicine development, number of technical devices has been developed. In this thesis, the principal findings of Ilizarov external fixation method are overviewed. For more detailed specification of external fixation or in other words external osteosynthesis can be referred to [6] and for other types of fixation in [11, 12].

2.1 External fixator overview

The external fixation method is predominantly named by the G. A. Ilizarov for the discovery he made in the half of 20th century. This discovery basically states that if the tissue is subjected by gradual strain, then it reacts by the growth and regeneration of bone, skin, etc. Thus, the method can be used for the bone deformity correction, bone lengthening, large bone fractures healing process and related operations [6, 13, 14].

In Figure 2.1 main types of external fixation can be seen seen (1 – connecting rod, 2 – connecting elements, 3 – fractured tibia bone, 4 – bone inserts including Kirschner rods or half pins, 5 – ring of external fixator). Apart from these types of fixators, there are also sectorial, semi-circular and hybrid types of osteosynthesis. Furthermore, this section deals with the circular external osteosynthesis.

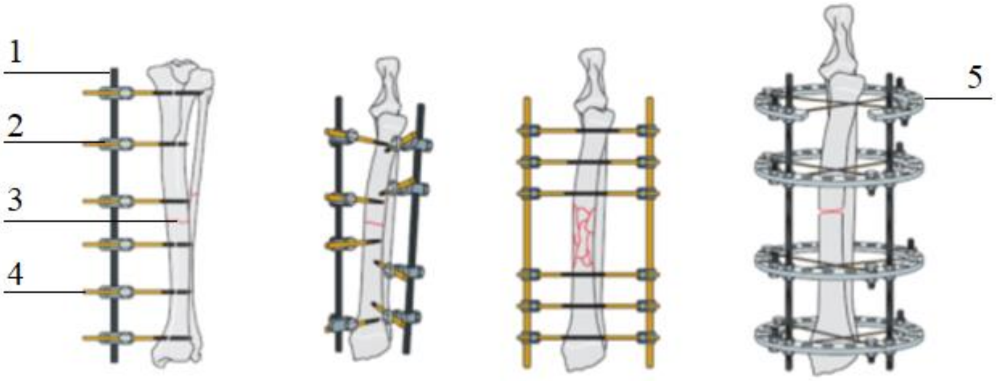


Fig. 2.1: Uniplanar, biplanar, uniplanar both – side and multiplanar - circular Ilizarov external fixator [6].

After the discovery of the regeneration effect of human tissue Ilizarov came with an external fixator (applied mostly for fractured tibia bone - 1) using Kirschner wires, which assembly can be seen in Figure 2.2. This fixator is composed of the Kirschner wires (6), supporting rings (3), connecting rods (5), connecting components of Kirchner wires (4) and connecting components of rods (2) [15].

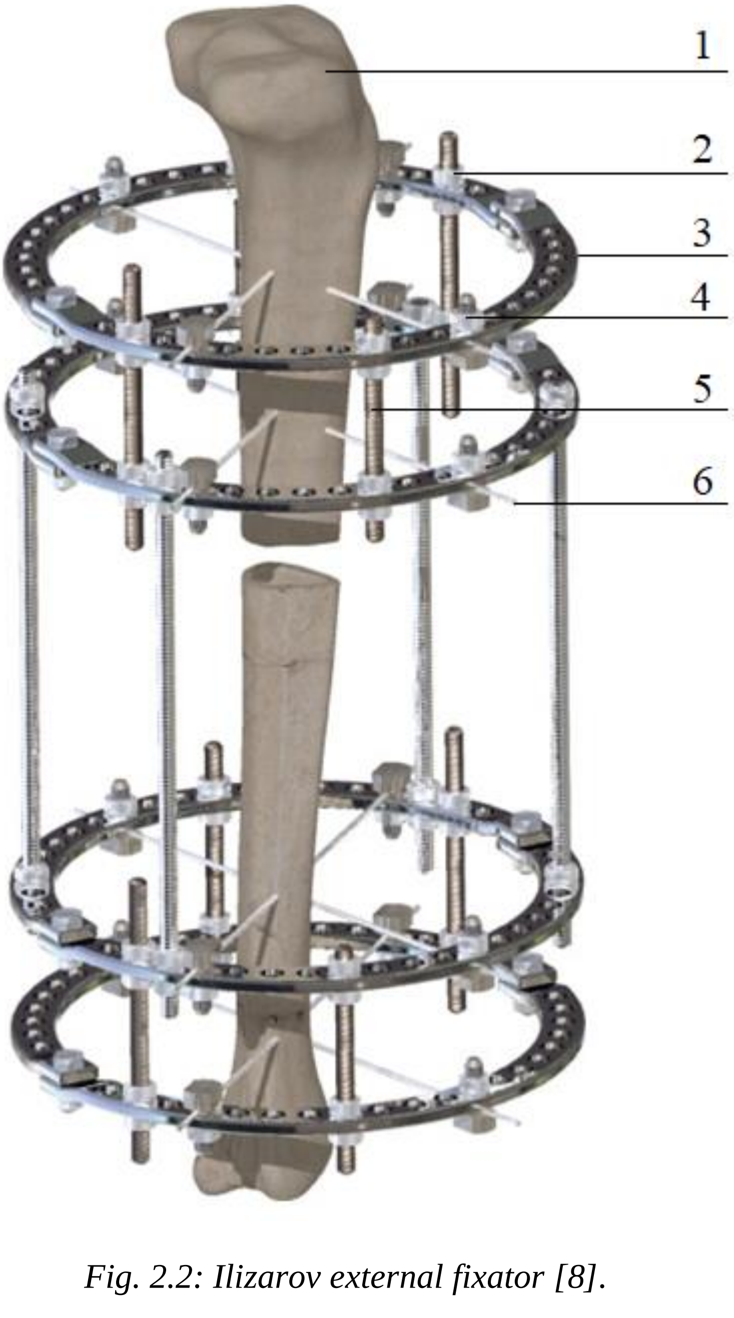


Fig. 2.2: Ilizarov external fixator [8].

As can be seen in [6, 17, 21], the material of external fixator is usually stainless steel, titanium alloy and some of the other types of metal as aluminum alloy. Further research shows implementation of polymer materials as carbon fiber, glass fiber reinforced materials [18], even three-dimensional printed fixators [19]. The Ilizarov external fixators made of composite materials as in [20] are designed and manufactured, but still little used in practice, because not many analytical and experimental examination has been done with this material so far [6] and at the same time for the higher price these materials provide. The higher price leads to the higher cost of the surgery and if the final effect of the surgery is not distinctly better, than the innovation as this material is not solution for larger number of patients [116]. Further, the materials that could be involved in Ilizarov fixator design will be described, their mathematical reasoning delivered and related to this type of fixator.

2.2 Biomechanical principles

Considering the need to assess the quality of fixators´ requirements for adequate output of the research and innovation process, there are several views on the issue of fixators. From the connection of external fixators with human tissue, to control of bone fragment position and overal stiffness. Individual principles are discussed below [6, 23].

2.2.1 External fixator inter-relationship with a human tissue

One of the basic and the most important aspect of the fixator and the tissue inter-connection is the knowledge how the human body reacts to the wires and rods inserted into the bone.

During the decades of application and research several problems have been determined, including:

- Risks of bone burns
- Bone resorption in bone – wire contact
- Inflammatory complications
- High drilling speed.

In response to these potential problems, several types of Kirschner wires has been developed (as can be seen in Figure 2.3 and 2.4). From the coated half-pins, three-facet (trocar) end of wire, through the flat (lancet) wire to the wire with drill ending, that is the most recently used type. There are also another types of bone inserts including the half-pins with the partial or full thread.

Another problem in the bone-wire or bone-pin interface could be biological tolerance. The Kirschner rods with the smaller diameter from 0,8 to 2,2 mm are usually made of surgical steel or titanium alloy and this issue is not so intense. In case of half-pins, the effect of biological acceptance is more significant. Thus, the individual thread could be covered by biologically compatible covering including biologically inert and active coating (Figure 2.3).

Fig. 2.3: Coated half - pins [6].

These improvements can further solve the problem of the pin – tissue compatibility even in case of osteoporosis in an advanced stage. Among these materials belongs hydroxyapatite covering, metal-ceramic serving as inert layer or biologically active calcium phosphate layer.

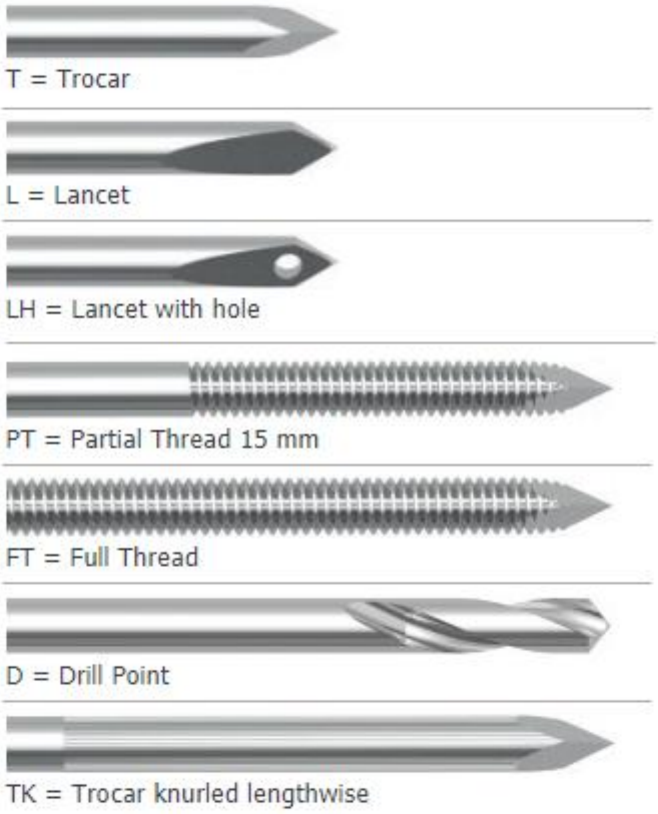


Fig. 2.4: Types of available Kirschner rods and half – pins endings for the method of osteosynthesis fixation [24].

One of the other complications that has been identified during the fixator application is development of the soft-tissue inflammation. The problem is formed because of well-known effect – relative movement between the soft tissue (skin, muscles, etc.) and the bone. During the last 50 years, several methods reducing the inflammation effect have been developed, including:

- Application of half – pins or Kirshner rods in the locality, where the minimal relative movement between the bone and soft tissue occurs. As mentioned in [25, 26, 27], the relative movement between the soft tissue and underlying bone during the body movement is up to 20 mm or even more. Thus, the localization of these large movements localities is necessary.

- Creation of the tissue – reserve for the possibility of joint movements. This reserve could be created by the concrete and specific movements occurring before the individual wire or pin application (in Figure 2.5).

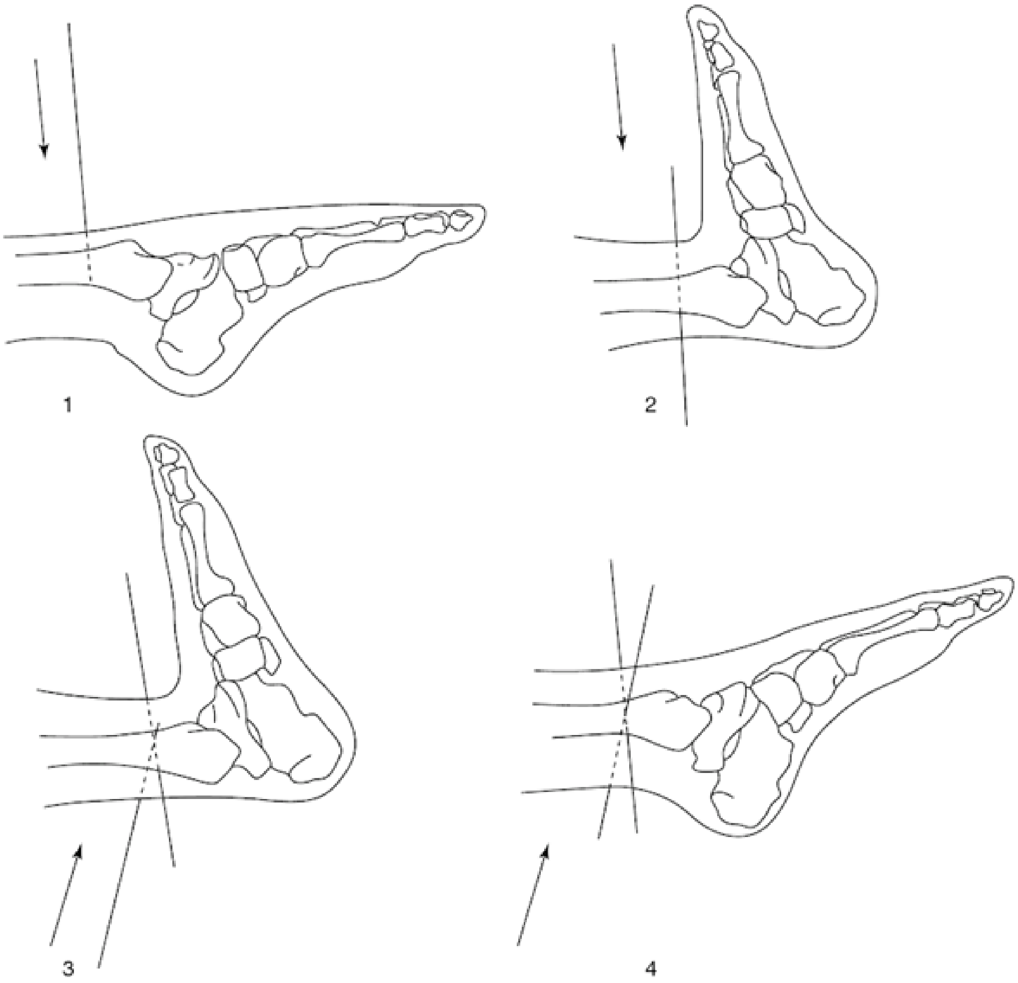


Fig. 2.5: Individual steps in the method for pin – induced joint stiffness prevention [6]

As can be seen in Figure, during the process of Kirschner rods application, every penetration through the soft tissue is followed by the bend in the joint and thus the sufficient soft-tissue reserve for future movements is created [6].

The knowledge of relationship between human tissue and the individual components can further improve the result of the external fixators´ research in other parts of the dissertation.

2.2.2 Clinical application of external fixators

Preoperative preparation

It is the first step in the clinical application of the osteosynthesis fixator including the general clinical examination and the analysis of local state of the surgical part. Series of tests are realised and the most important examination from the perspective of this research are described further.

In the locality of the fracture, the swelling pressure of the tissue is measured, blood flow asymmetry and another important characteristic for the surgery. One of the important points is also centres, where the infection can occur, but the most important part is the X-ray examination. That is usually provided by the frontal and lateral view as in Figure 2.6.

Fig. 2.6: Fractured tibia and fibula X-ray [28]

Transosseous elements – correct position

Another important aspect for the design of an external fixator is also knowledge of correct position for pins and Kirschner rods. It prevents injury of the major blood vessels, nerves and creates safe zones for transosseous element insertion. The points of appropriate locations are known in general and can be used by surgeons and in case of deformities, atypical extremities, etc., techniques as angiography, magnetic resonance imaging or computer-tomography has to be used. These outputs are important in term of appropriate external fixator design.

These positions can further improve design and function of an osteosynthesis fixator. There are 96 positions by the MUDEF and some of these positions are mentioned in the following Figures 2.7, 2.8.

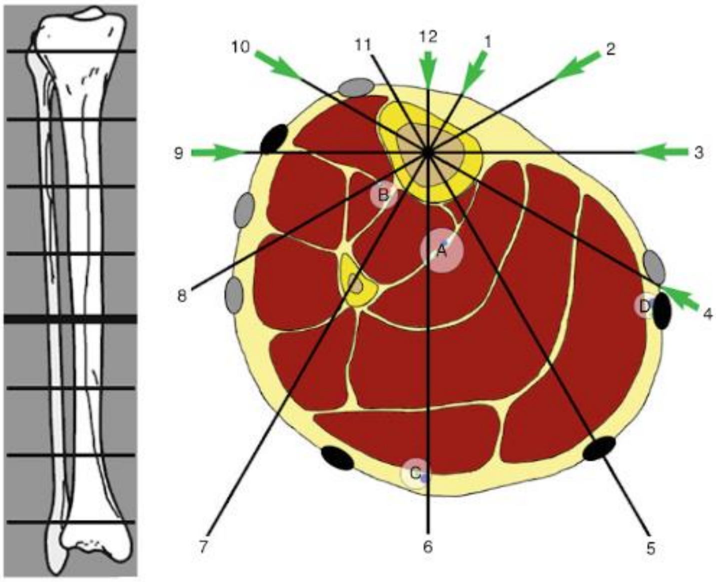


Fig. 2.7: Transosseous elements (Kirschner rods) recommended for tibia bone [6]

Another part is the position of half-pins in the bone [6]. This information further gives very important knowledge to the biomedical engineers, since the individual position of pins and rods changes between individual vertical sections.

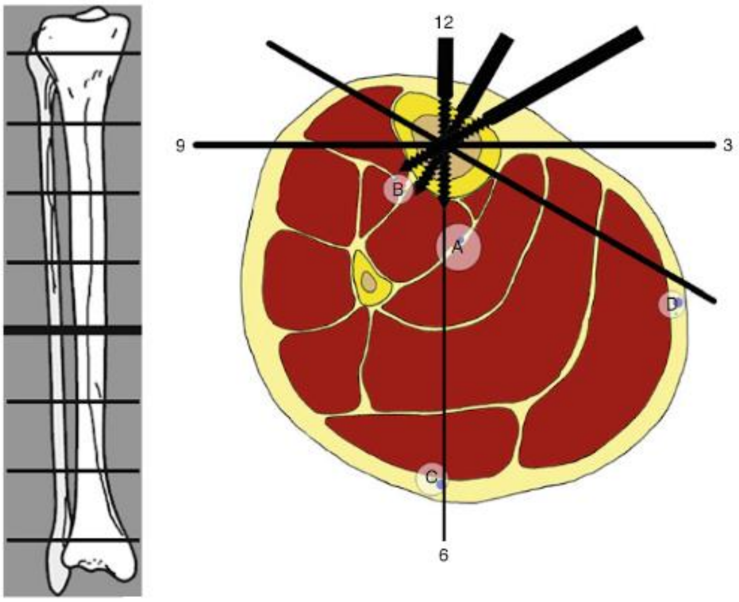


Fig. 2.8: Transosseous elements (Kirschner rods and half-pins) for tibia bone [6]

2.2.3 Fractures of the tibia and fibula

When the individual terms of an external fixation from the biomechanical view are discussed, there is also necessity to bring some knowledge from the medical sight of the problem. The knowledge about the shape and state of the fracture. Every fracture is an individual case and there is some typical occurrence of bone damage with a low quantity of bone fragments as shown in figure 2.9.

Fig. 2.9: Preoperative X-ray showing distal tibial and proximal fibular fracture [30]

And there are also some more difficult fractures in term of following surgery, where the number of bone fragments is larger, and the size of individual piece is changing as can be seen in figure 2.10.

Fig. 2.10: Preoperative X-ray showing tibial and fibular fracture [31]

2.2.4 Clinical requirements for the construction

Previous chapters from the external osteosynthesis, through the biomechanical principles to clinical application and individual fractures gives strong information base for the future construction. Nevertheless, also official requirements for the construction of fixators can be found in this chapter.

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.

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 relatively to the external supports that remain stationery.

The first method can be seen in figure 2.11 for the elimination of fragment displacement and in figure 2.12 for angular displacement.

Fig. 2.11: The correction of transverse displacement [6]

Fig. 2.12: The correction of angular deformation [6]

The second method has been further developed in recent years. That is the combination of the typical external fixation method with the computer – passive navigation inclusion. That gives a considerable opportunity to improve the bone - fracture healing process and navigate individual bone fragments through the calculated trajectory. The basic procedure can be seen in Figure 2.13.

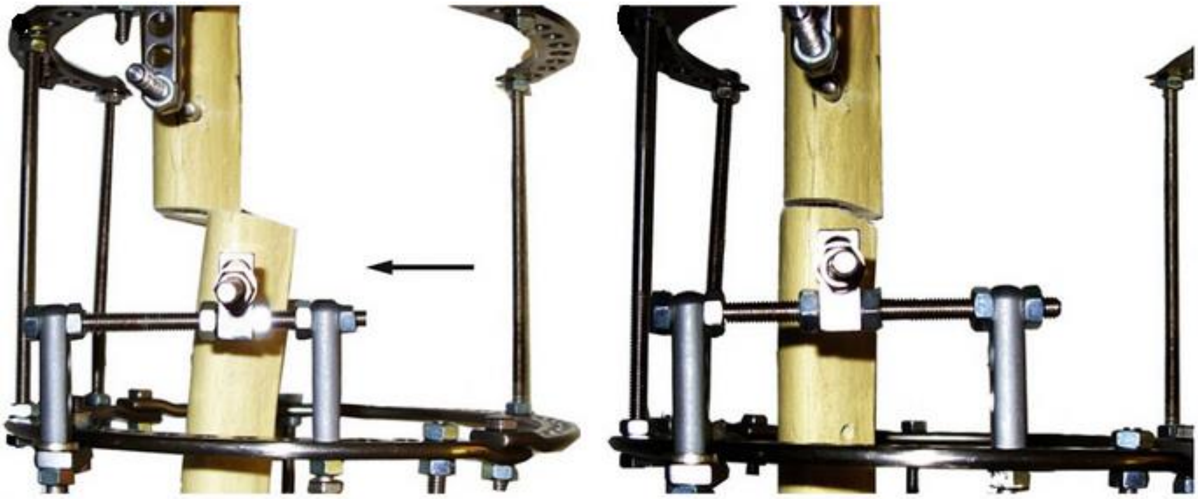


Fig. 2.13: Bone – fragment movement [6]

This method discussed before can be even further improved by the implementation of software into the one product, creating an innovative solution for the passive navigation. One of these fixators are mentioned in figure 2.14.

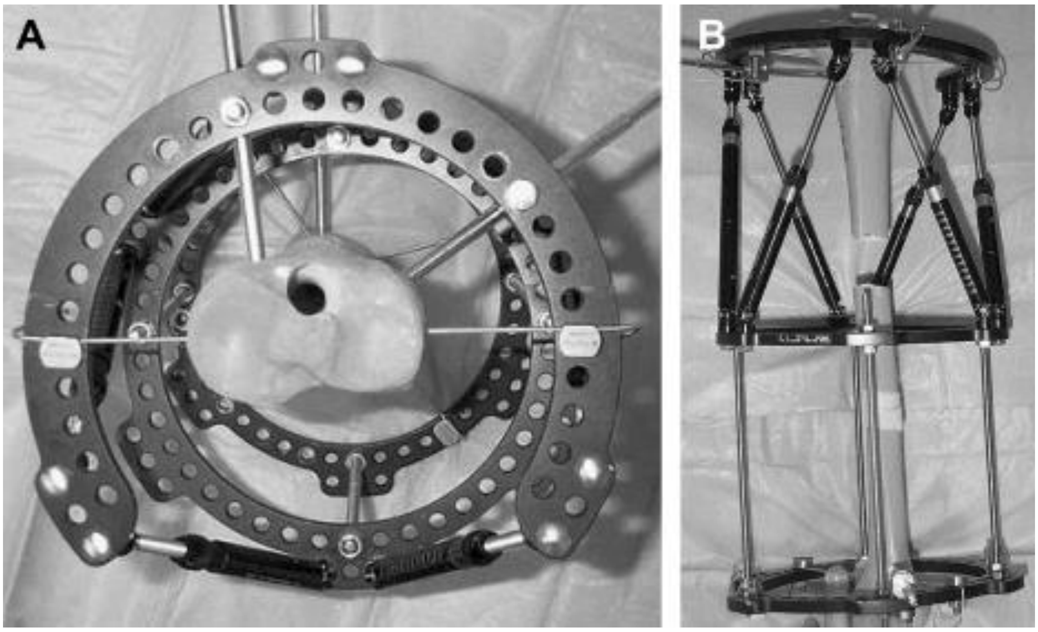


Fig. 2.14: Ortho-fix –passively navigated fixator [32]

3. EXTERNAL FIXATOR CONSTRUCTION

In a history of osteosynthesis fixation, many external fixators have been proposed [6, 33, 34, 35]. Some of them will be further described and individual characteristics will be introduced.

There can be found some fundamental statements, summarizing findings from the field of external fixation design. These findings are:

3.1 Fixator rigidity

It simply applied, the more rigid material of osteosynthesis fixator is, tougher overal fixator is. In this regard, the materials such as stainless steels, titanium alloys, chromium-cobalt-molybdenum alloys can be used as well as the composite materials that are recently under the development. One of them is also mentioned in Figure 3.1.

Fig. 3.1: Composite Ilizarov fixator [37]

3.1.1 Rigidity of transosseous elements

In conjunction with the previous statement, the overal toughness of the transosseous elements is directly proportional to the number of elements used in the construction. One of the important facts is also that the number of transosseous elements is limited due to the arteries, pin-induced joint stiffness and in direct connection with the position of pins and wires mentioned beforehand.

Based on the analytical modeling of the beam (in Figure 3.2: a - representing Kirschner rod) and the half beam (in Figure 3.2: b - representing half - pin).

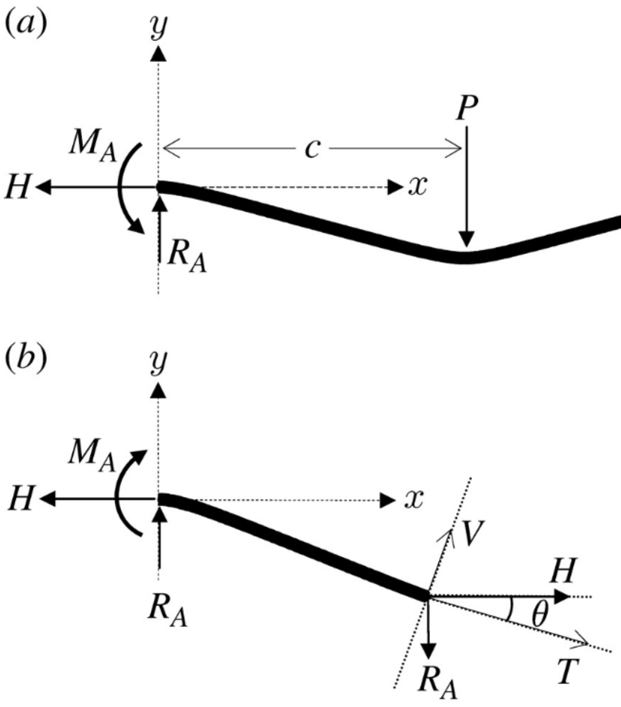


Fig. 3.2: The beams deformed under the load from axial tension [38]

Where for the bending moment, there is an equation (including classical beam theory) [38]:

$$M(x) = EI\frac{\mathrm{d}^2y}{\mathrm{d}x^2} = R_A x + M_A + P\langle x - c\rangle^1 + Hy, \tag{3.1}$$

3.1.2 Wire tensioning

The rigidity is also connected with the wire tensioning during the surgery. That means, the strain of the wires is 1000 N ±100 N. This could be further controlled during the healing process for improvement of the quality of the treatment. Individual wire can be further undergone by the stress analysis as in Fig. 3.3.

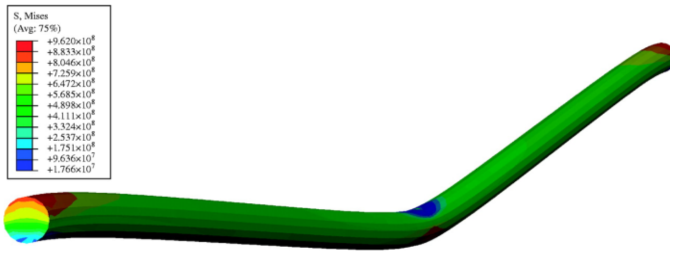


Fig. 3.3: Kirschner rod under the finite – element method stress analysis [38]

3.1.3 Selection of transosseous elements

There are several types of transosseous elements, containing Kirschner rods with diameter 0,5 – 2,2 mm or pins with diameter altering from 2 – 6 mm. It is necessary to find an optimal ratio between the transosseous element diameter and tissue injury emerging from the rod or pin application. If the rod diameter is lower, then also the overal fixation stiffness is lower. On the other side the tissue injury in this case is not so significant. This problem of tissue injury can be solved also with the Kirschner rods with stopping element as in Figure 3.4. With this improvement the rod diameter is lower, but the overal rigidity is higher.

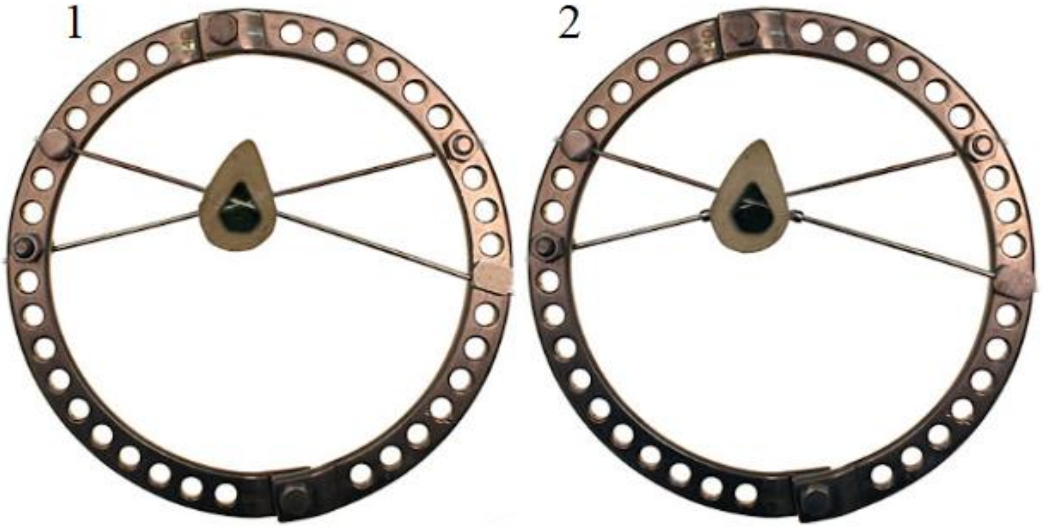


Fig. 3.4: Kirschner rods application (1 – normal Kirschner rod, 2 – Kirschner rod with stopper) [6]

3.1.4 Torque principle

Another characteristic of external fixators is based on a torque principal and it simply means that the larger distance between individual component is, bigger rigidity of whole external fixator in connection with the human limb is. That can be seen in Figure 3.4 and 3.5. The same principle can be later applied in case of pin distance.

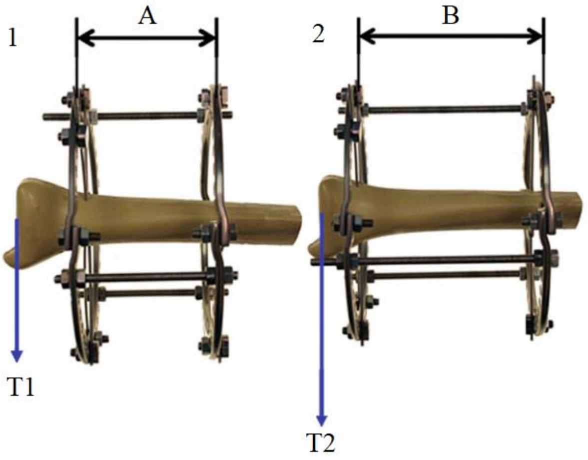


Fig. 3.5: Fixator assembly comparison – different ring distance (1 – smaller distance A – smaller rigidity T1, 2 – larger distance B – larger rigidity T2) [6]

3.1.5 External diameter

For the rigidity, the smaller circle diameter is, the higher their stiffness. Thus, the external fixators are manufactured in several dimensional types to achieving the highest possible stiffness for an individual patient. Thus, recommended gap between the external ring and the human skin fluctuating from 15 mm to 50 mm. As an example of the accurate diameter and too large diameter is mentioned in Figure 3.7.

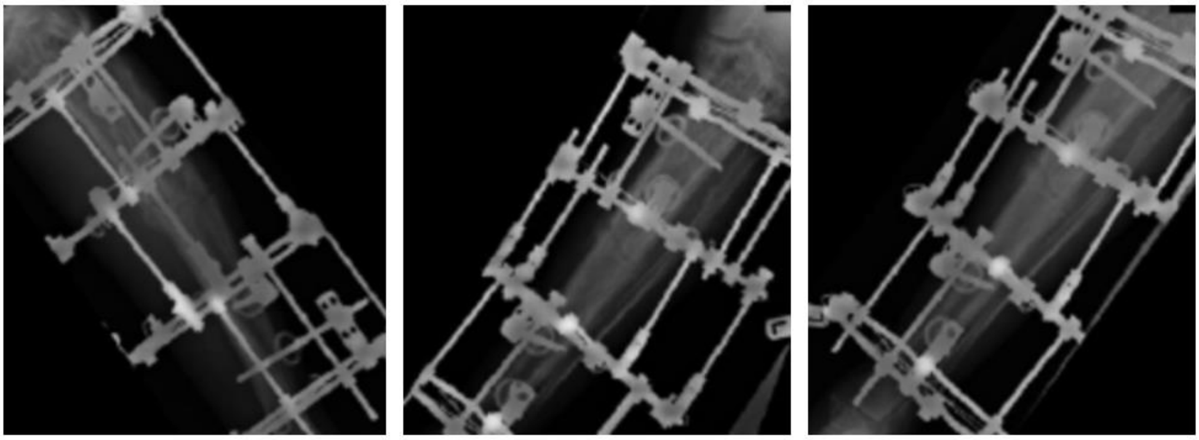


Fig. 3.6: X – ray of fixator assembly with human limb [36]

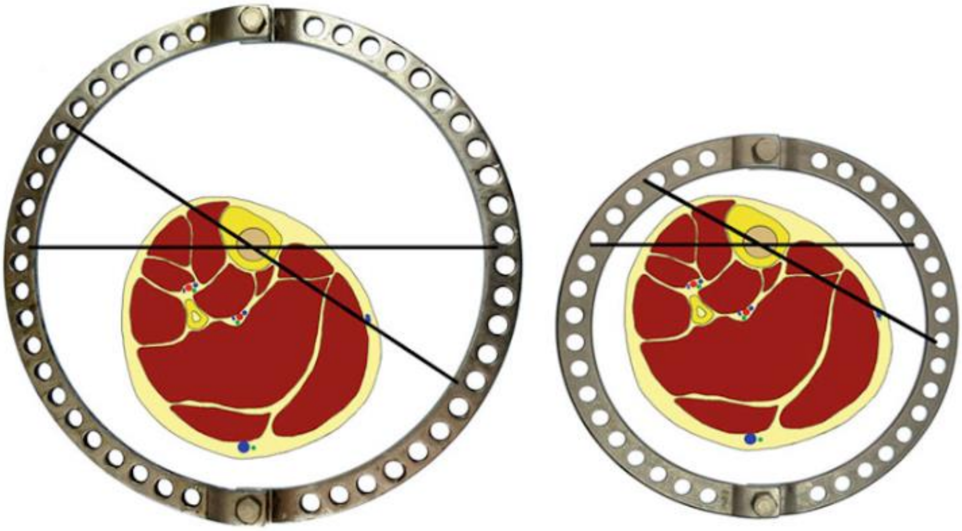


Fig. 3.7: An example of a large diameter of external ring (left) and accurate diameter of the ring (right) [36]

3.1.6 Increasing fixator rigidity

From the mechanical point of view the overal stiffness of fixator can be modified through different wires layout. The neutral wire crossing is 60°. This can be further improved with adding wires into the system as mentioned earlier and with the half pins application. If there is a necessity to increase the fixator rigidity even further, then additional half-pins in different angles can be inserted. This assembly can be seen in figure 3.8.

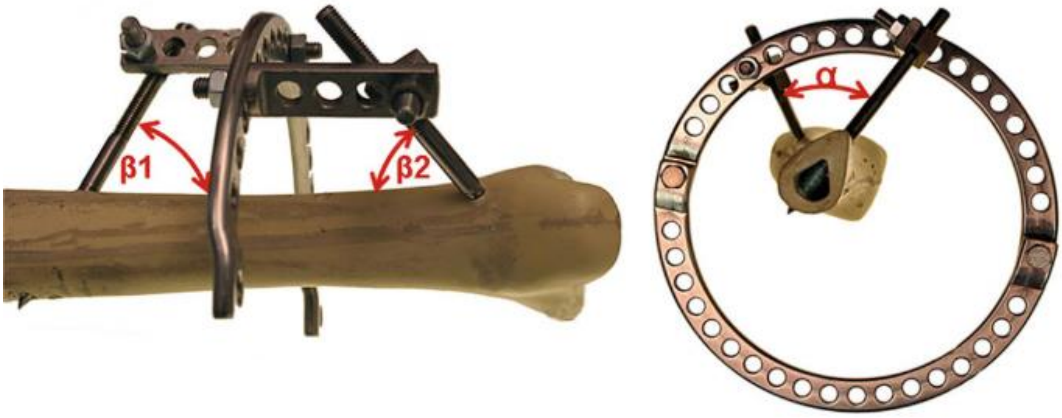


Fig. 3.8: Fixator assembly with the focus on increased rigidity [6]

3.2 Connecting rods

As mentioned in [6, 36, 37] the minimum number of connecting rods in the assembly of the fixator is three. The additional rods usually serve for the reduced fixing components as for instance three-quarter ring is. The overal number of connecting rods is derived from the individual type of fracture. There is also the difference in materials of connecting rods. Material as stainless steel, aluminum, titanium alloy or composite material can be chosen (see Fig. 3.9). Historically, mostly connecting rods with threads can be found.

Fig. 3.9: Fixator assembly with the focus on increased rigidity [6]

3.3 Tool set for an external fixator assembly

Another significant research in the field of osteosynthesis fixation has been done in the area of tools providing external fixator assembly folding. For instance, in [6, 40, 41]. These tools contain tensioners, pliers, spanners and other components as can be seen in pictures below.

Fig. 3.10: Tools for an Ilizarov fixator assembly [42]

3.3.1 Wire tensioning

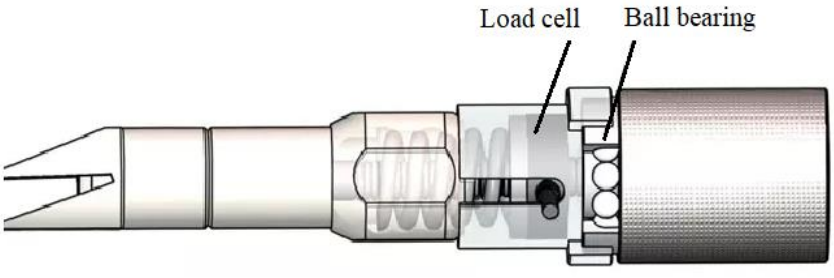


Fig. 3.11: Wire tensioner [42]

In a term of external fixation design and innovation, even these tools are an important device and source of knowledge for the Ilizarov fixator construction. These devices relate to the fixator for a short, but very significant period during the application to the patient's limb. For instance, the wire tensioner is connected to the rings and wires. Thus, providing an appropriate wire tension setting. That is further an important move to gain an appropriate assembly stiffness between the bone and fixator. As mentioned in [41] the optimum pre-tension for stable fixation is 0,98 – 1,27 kN, while bolt – tightening torques is prescribed 10 – 20 Nm. An argument for this tensioning can be seen in Figure 3.12a, where the highest stress at the bone – wire connecting surface reaches up to 1,2 GPa. Thus, an appropriate wire tensioning is required.

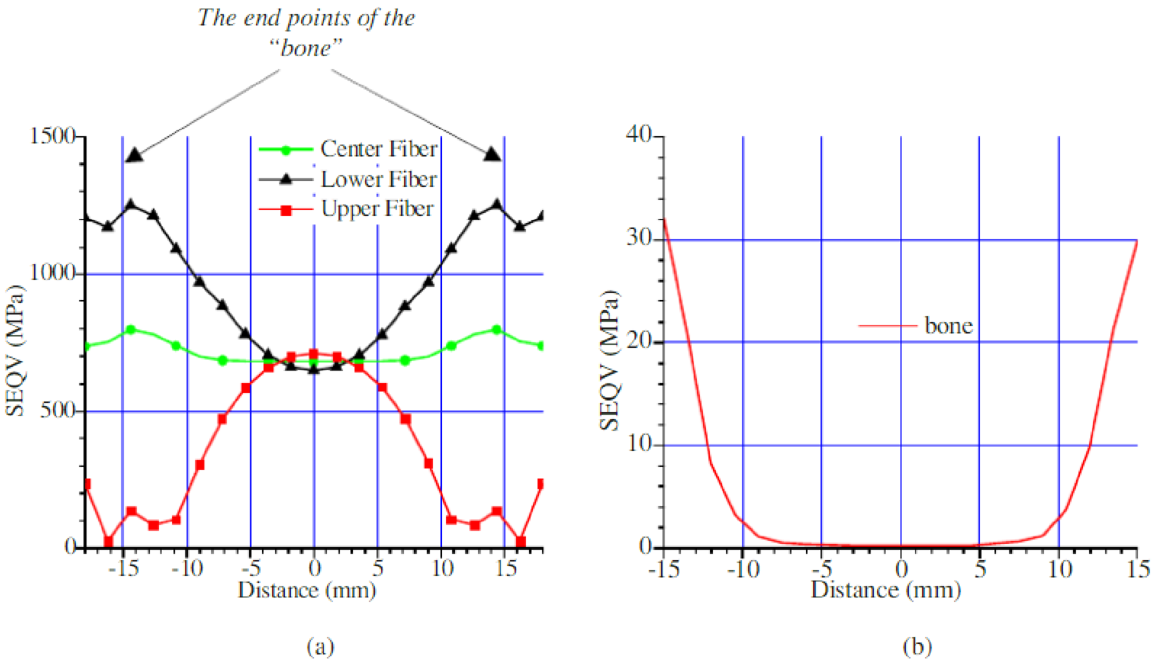


Fig. 3.12: Variation of von Misses stress along the wire (a) and along the bone-wire contact surface [41]

This finding is further examined with the result in Figure 3.12b where the equivalent stress at the surface of contact between the bone and the wire is plotted. As can be seen the highest stress appears at the interface of the outer bone surface and wire.

3.4 Ilizarov construction types

During the last decades of Ilizarov external fixator applications, research and improvements, amount of new design has been developed. From the first Ilizarov devices (one of the in Figure 3.13) made of stainless steel with simple and robust design and thus also high weight, through the optimized design with lower ring thickness containing holes for rod attachment and weight reduction as shown in Figure 3.14 [6, 44, 45].

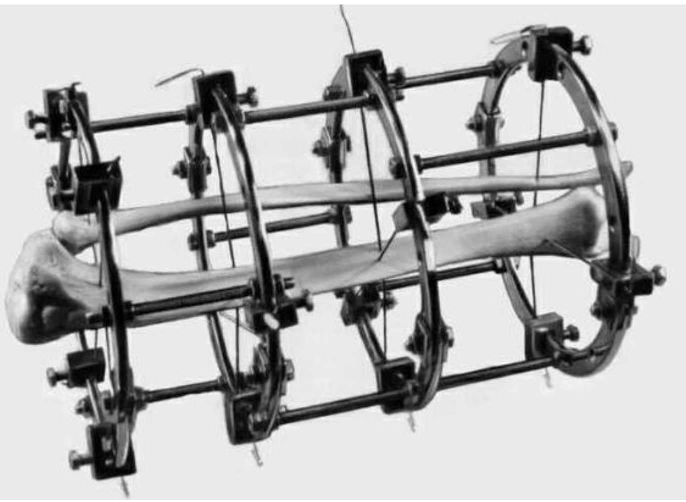


Fig. 3.13: One of the first Ilizarov apparatus [44]

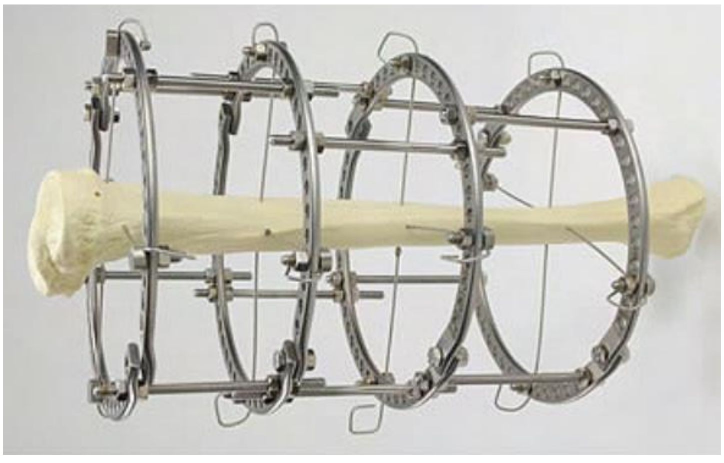


Fig. 3.14: Improved metal Ilizarov apparatus [45]

Another progression with material innovation as an implementation of aluminum and titanium alloy and in recent years also an application of composite materials. These innovations are mentioned in Figures 3.15 [46, 47].

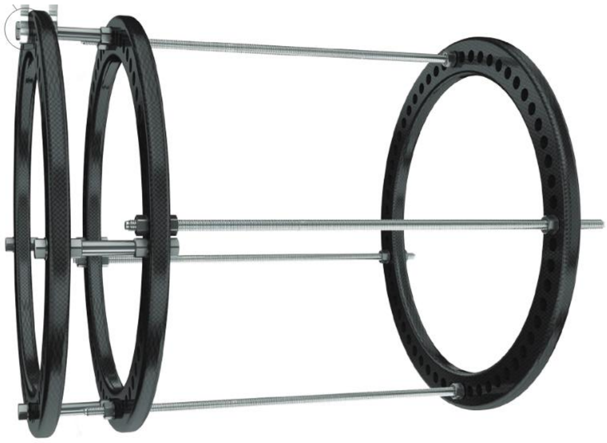


Fig. 3.15: Improved metal Ilizarov apparatus [46]

The next step in the fixator development is also the device construction improvements. From this perspective there has been large development mostly in recent years, from the attempt to apply three-dimensional printing of plastic parts [48] to the innovation of connecting rods in order to gain required degree of freedom for the individual ring, wire or internal pin. Some of these improvements are shown in Figure 3.16 [49, 50, 51].

Fig. 3.16: Improvement of Ilizarov apparatus through design changes [49, 50]

Another progression in the field of osteosynthesis fixation is Ortho-SUV Frame (OSF). This innovation is derived from the orthopaedic hexapods shown in Figure 3.17 below [52].

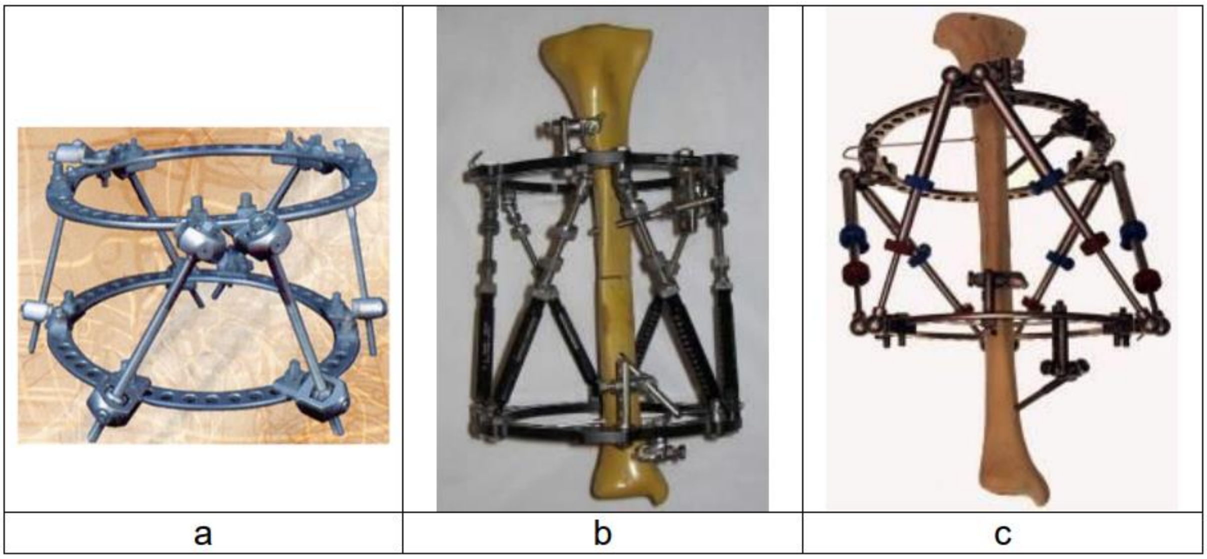


Fig. 3.17: Orthopaedic hexapods: a – device from Ilizarov research centre, b – Taylor Spatial Frame, c – Ilizarov Hexapod System [52]

This is a significant innovation of connecting rods with the main effect on the ability to set an appropriate position of individual parts. This frame can be further connected with the software for an ideal navigation serving for the passive navigation and other orthopaedic functions developed mainly during the recent years. Nowadays these methods are implemented into the clinician practice of progressive hospitals and generally improve the results of healing process with the Ilizarov device [6, 52, 53].

Fig. 3.18: Orthopaedic hexapod: Ortho-SUV Frame [52]

Finally, from the view of design overal state of the art of osteosynthesis fixation has been described from the first construction that the G. A. Ilizarov brought in 1951 to the most innovative, computer-aided models with passive software navigation for overal effectivity of the healing process.

The future direction of the Ilizarov fixator design development will be directed to the orthopaedic hexapod's application by physicians [54], application of composite materials together with the deformation analysis [6] and investigation of the problem of pin-site infection. To solve these problems different the method of oxidizing using iodine is performed [54].

As can be seen above many directions in term of future development are initiated and the future improvement of these methods is in cooperation and connection of these different methods together. That also means firstly analysing the problem by individual specialist, bringing new ideas and innovations and later synthesis of the individual findings for the future application in one fixator design together.

3.5 Other types of external fixators

While the method of osteosynthesis fixation is broad and widely used area these days, there are several types of external fixator constructions:

3.5.1 Unilateral external fixators

These types of device serve as a provisional or definitive method of tibia bone treatment. The fixator – bone stiffness is based on the number of transosseous elements and the distance between the connecting rod and bone [117].

Fig. 3.19: Unilateral external fixator [118]

3.5.2 Bilateral external fixator

This construction compared to the unilateral type brings a linkage between frames in perpendicular planes and improve the stability and strength of the fixation system. Bilateral type also decreases bending at fracture [120, 121].

Fig. 3.20: Bilateral external fixator [119]

3.5.3 Multiplanar external fixator

One of another fixation techniques using multiplanar external fixator. This solution has advantages in improved frame stability, variable construction and as possibility of the bone reconstruction (in case the bone is largely destructed) [54].

Between these types of osteosynthesis fixation techniques belongs the circular system of fixation, Ilizarov fixators and the hybrid types of fixators mentioned above. Thus, the dividing of external fixator types is completed. In Figure 3.21, the multiplanar type of the fixator can be seen. This type uses just the connecting rods, clamping components and transosseous elements in variable positions and rotations and thus creates a multiplanar external fixator.

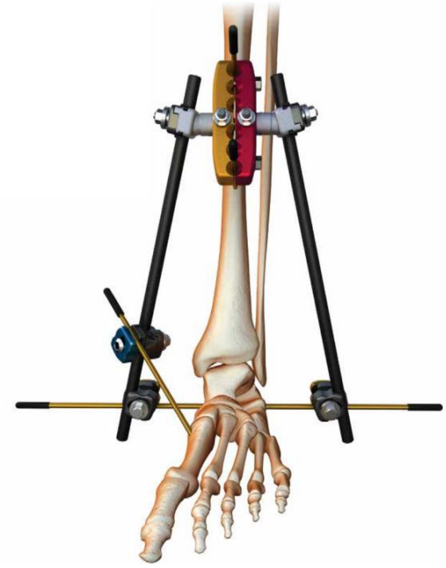


Fig. 3.21: Multiplanar external fixator [122]

4. COMPOSITE MATERIALS

The composite is a material composed of two different materials of divergent properties, which thanks to the synergic effect creates new material with the necessary properties [56, 70].

This material brings several benefits in comparison with the conventional materials [57]. These composite materials, due to its possibility to shaping, appropriate strength/toughness to density ratio are advantageously used in the aviation and automotive industry and in the area of biomedical engineering [58, 59]. One of another significant advantage of this material is further high stiffness/strength to weight ratio of the final product or device.

After the closer look to the micro-mechanics of composite materials, the individual components of micromechanical structures can be evaluated macroscopically with the equivalent composite parameters' definition. These equivalents relations are:

$$(\sigma) = \frac{1}{\mathrm{V}} \int (\sigma)\, dV \tag{4.1}$$

$$(\varepsilon) = \frac{1}{\mathrm{V}} \int (\varepsilon)\, dV \tag{4.2}$$

Based on these equivalents and with the use of Eshelby principle equality of equivalent parameters and heterogeneous structure, effective elastic properties of the composite can be defined as:

$$\frac{1}{2} \int_{(V)} (\sigma)(\varepsilon)\, dV = \frac{1}{2} (\sigma)(\varepsilon) \tag{4.3}$$

Thanks to this, the deformation energy of certain elements can be determined as a summary of the matrix energy and the summary of the energy arising from the matrix and reinforcement interaction

$$U = U^0 + U_f \tag{4.4}$$

When assessing the composite material with the long – fiber reinforcement, the composite element can be removed. Then after loading the element in the axis of reinforcement, the structural tension of the matrix and fiber arises and with the Hook law application the equation originates:

$$c_1 E_1 \varepsilon_{L1} + c_2 E_2 \varepsilon_{L2} = \sigma_L \tag{4.5}$$

During the loading and with the hypothesis of a rigid bond between the fibers and matrix within the scope of the Hook law, the relationship can be defined as:

$$\varepsilon_{L1} = \varepsilon_L \tag{4.6}$$

With this, the equivalent modulus of elasticity can be defined as:

$$E_L = c_1 E_1 + c_2 E_2 \tag{4.7}$$

And the effective ratio of Poisson constant can be determined:

$$\nu_L = \frac{-\varepsilon_T}{\varepsilon_L} = c_1 \nu_1 + c_2 \nu_2 \tag{4.8}$$

Then finally:

$$\frac{\nu_T}{E_T} = \frac{c_1 \nu_1 + c_2 \nu_2}{E_L} = \frac{\nu_L}{E_L} \tag{4.9}$$

Substituting individual constant, the formula for the efficient module can be defined as:

$$\frac{1}{E_T} \approxeq \frac{c_1}{E_1} + \frac{c_2}{E_2} \tag{4.10}$$

And through these equations and their derivation the superposition of different materials connection (in form of a matrix and the long-fiber reinforcement) is intended [60, 61].

Using the method of deduction for practical use, for example in the field of external fixation is possible to achieve required modulus of elasticity (that means for the composite material an effective modulus of elasticity), the metal material is substituted by the composite material with such a material composition of different components that achieve sufficient strength and toughness and also providing the overal weight reduction due to the optimized matrix and reinforcement volume ratio [60, 62]. And this can be achieved just with the application of synergic effect (shown in Figure 4.1).

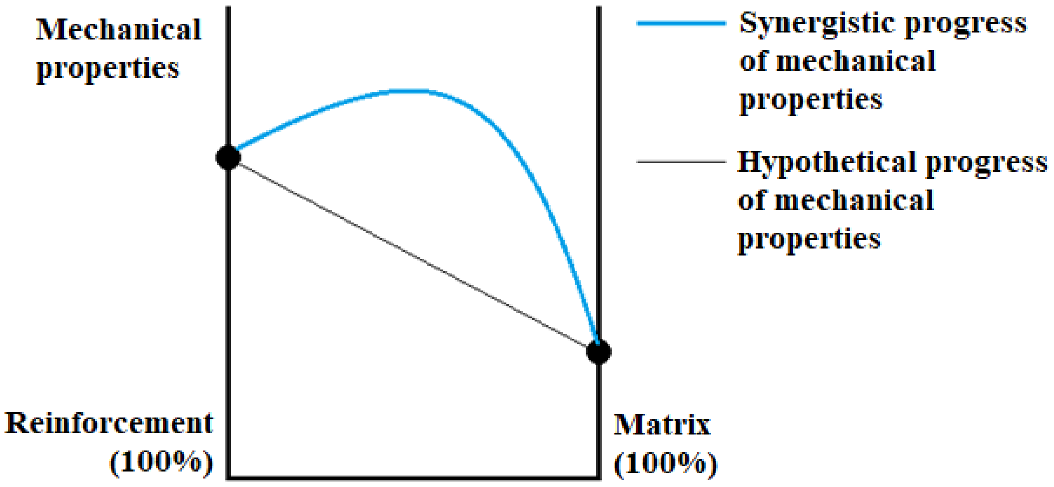


Fig. 4.1: Synergistic effect of composite material (ie. The interaction of composite)

4.1 Reinforcement

The most important segment of the composite structure is reinforcement. It may occur as a particulate filler, nanotubes, short fibers, as plates of sandwich composition or as commonly used in the form of long fibers [60, 63, 64].

Another distribution of fiber structure is based on the material selection. The material as celluloses, glass, Kevlar or carbon fibers can be used. And even the ceramic fibers can be used nowadays [60, 62, 65].

One of the most important characteristics of the composite material is the elasticity which can be expressed by the formula:

$$\frac{\mathrm{M}}{I} = \frac{\mathrm{E}}{\mathrm{R}} \tag{4.11}$$

And from this formula the equation for elasticity can be derived as:

$$\frac{1}{MR} = \frac{64}{E\pi d^2} \tag{4.12}$$

Another important characteristic of composite materials is the possibility to manufacture the product with variable flexibility or thickness [60].

Equally, important fact is the fiber – stretching, and orientation occurring during the production of long fibers. The stretching length is different for an individual material and improves the effectivity of material utilization in a product. Based on these findings, the effective composite module from a macroscopic view can be optimized [72].

The main types of fibers used in industrial practice are (individual materials compared also at Figure 4.2):

- Organic fibers – aramid, Kevlar, etc.
- Boron fibers – very fragile material
- Glass fibers – very good strength, Young modulus, higher density
- Carbon fibers – excellent strength/toughness to density ratio.

The very last two of these fiber-materials are potentially adequate materials for the use in medical applications, where is the demand for high stiffness, reliability and low weight of the final product [60].

Carbon fibers are generally materials with a very good density (2,3 g/cm^3). Material bond strength is defined by Young modulus and thanks to their high strength, the material with the high Young modulus emerging and thus also strength/rigidity versus composite overal density or product weight. Therefore, this material is widely used for applications in the automotive and aerospace industry.

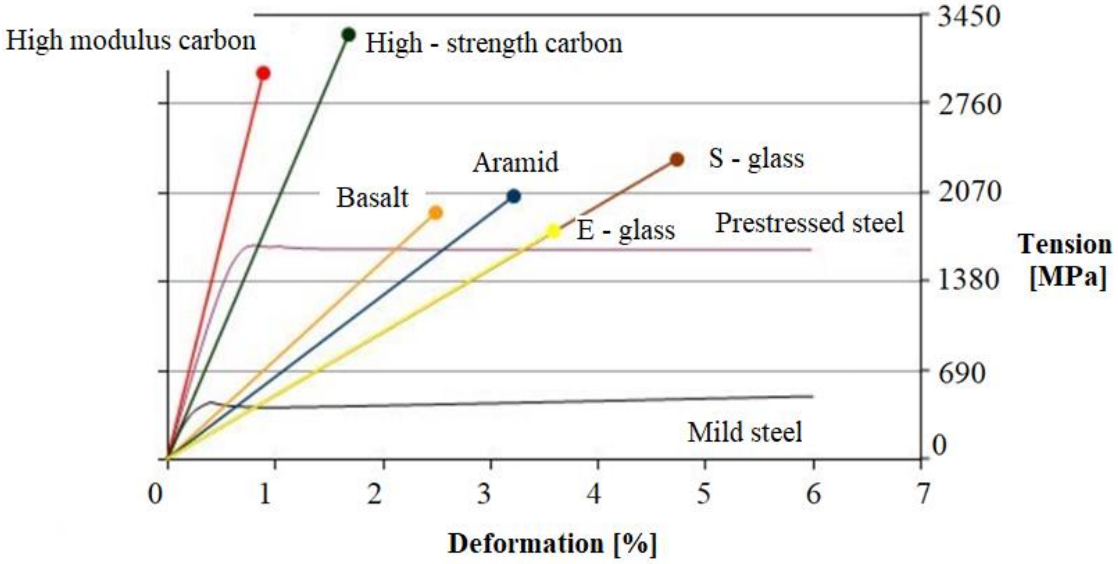


Fig. 4.2: Tension progression of different materials and reinforcements

Another widely used reinforcement material is glass fiber. With its lower density these fibers report high strength, thereby it is a suitable material for demanding applications in industry. Conversely, Young modulus does not reach significant values and from this point of view, it is rather material of average characteristics and thus the importance of the glass fibers in highly demanding application such as the aviation industry is decreased. An inalienable advantage is the lower price with which these materials suit for less sophisticated products or as a material for prototype testing [67, 71].

4.2 Composite matrix

Mostly the material of the matrix are the polymers. It is a material with complicated structure with the advantage of the low price of the manufacturing process, simplicity of processing and chemical resistance. One of the disadvantages is lower structural strength in comparison with other construction materials as for instance metal materials are.

One of the most important parameters for polymer characterization is the molecular weight. Generally, the higher molecular weight (MW) is the higher overal strength is. But also, higher molecular weight leads to the decreasing of the tension value for material failure [60]. There is an equation for molecular weight:

$$MW = DP * (MW)_u \tag{4.13}$$

The basic polymer distribution is between the thermosets, thermoplastics, and elastomers. And some of the thermosets are suitable material serving as a bond for carbon and glass fibers. The most applied matrix is polyester and epoxy matrix. More detailed sorting can be seen in Table 1.

Table 1: Types of polymer matrix [123]

Polymer matrix composites	
Thermoset matrix	**Thermoplastic matrix**
polyesters	some types of polyesters
vinylesters	polyetherimide
epoxies	polyphenylene sulfide
polyamides	polyether-etherketone
bismaleimides	liquid crystal polymers

4.2.1 Epoxy matrix

It is the most common type of composite matrix, that excels with higher moisture resistance, sufficient elasticity, low shrinkage after manufacturing and high friction among the fibers and matrix. That further ensures appropriate toughness of the final product and prevents separation of matrix and reinforcement. One of the disadvantages of this type of matrix is also a higher price.

4.2.2 Polyester matrix

This is the widely used binder with the very important advantage that is a low price in comparison with the epoxy matrix. Polyester matrix is characterized by the double C=C chemical bond. One of its disadvantages is the higher coefficient of shrinkage after curing, alternating from 4% to 8% [68].

4.3 Application of composite materials in product development

Generally, one of the most important advantages in comparison with conventional materials is the ability to manufacture the product using material prepared exactly for the specific application. Another undisputable advantage is also a possibility to manufacture a part with different characteristics in different sections of this product. This can be achieved by the different composition of the individual layer, by the orientation, etc. This can be called custom-made material applications. For an appropriate fiber laying the deformation analysis of composite material can be investigated. Just even after this optimization, due to the difficult composite material microstructure, the overal design must be validated by the method of static testing [62, 73].

Among other advantages of the composite material application belongs:

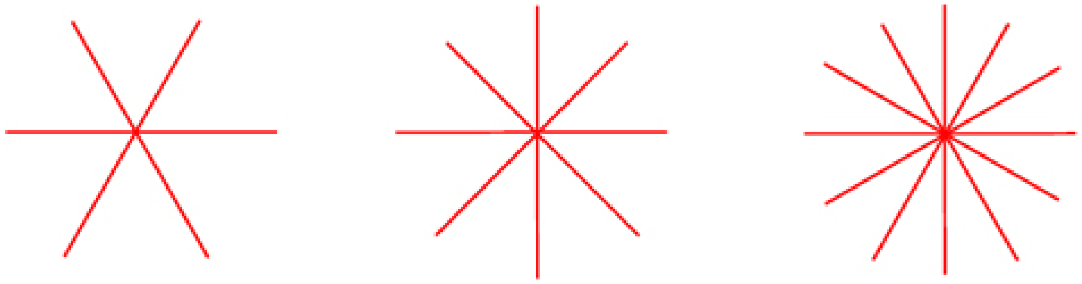
Flexibility – there is a possibility to set variable flexibility in different directions of the product by the various material composition.

Simplicity – thanks to the possibility to draft the shaped product the final number of parts can be reduced, and thus overal simplicity is achieved.

High product lifetime – composite material reports lower fatigue and material aging during the use in comparison with the commonly used materials [69].

4.4 Structural analysis of quasi-isotropic material

In a large number of investigations as in [151–157] can be found that quasi-isotropic material for its symetric lay-up (for instance in Figure 4.3) can be successfully replaced by the isotropic and in this state of the replacement can be also examined by the structural analysis using finite element method.



$N = 3\ (\Delta\theta = 60^\circ)$ $N = 4\ (\Delta\theta = 45^\circ)$ $N = 6\ (\Delta\theta = 30^\circ)$

Fig. 4.3: Fibre orientations in a typical quasi-isotropic laminate [158]

Thus, this type of material structure can, due to the multirateral fixator loading serve as an optimal layout for the load transfer during the fixator use.

4.5 Composite materials for external fixators

As mentioned in [74], an application of composite material into the osteosynthesis fixator design improves overal weight of this system and the radiographic evaluation too. The most significant fibers for fixators are aramid and carbon fibers.

Further as can be seen in [75], the composite material is also an improvement for computed tomography (CT) and magnetic resonance imaging (MRI). These days even composite fixators using short fibers can be seen on the market.

The design, application, and investigation of composite material for external fixators are tested by the structural analysis firstly. The overal design is further improved or redesigned according to the results from the deformation analysis and after the final evaluation, this composite part is manufactured. While the structural analysis is an advanced method for product testing and development, it can create large mistakes if the input data are not correct or the results are not evaluated by the static testing. This real testing further serves as a final verification of the composite fixator design [76].

Some of the current composite fixators used in medical practice can be seen in Figure 4.4 and Figure 4.5.

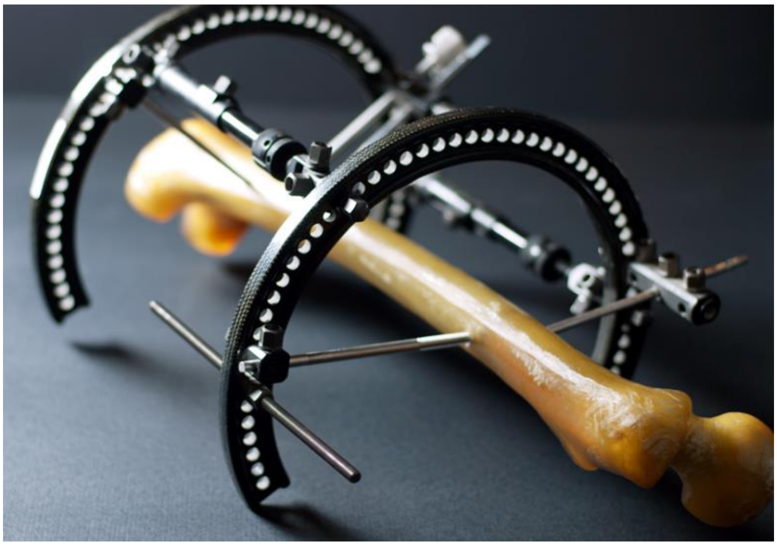


Fig. 4.4: Assembly of a composite external fixator with polymer bone [84].

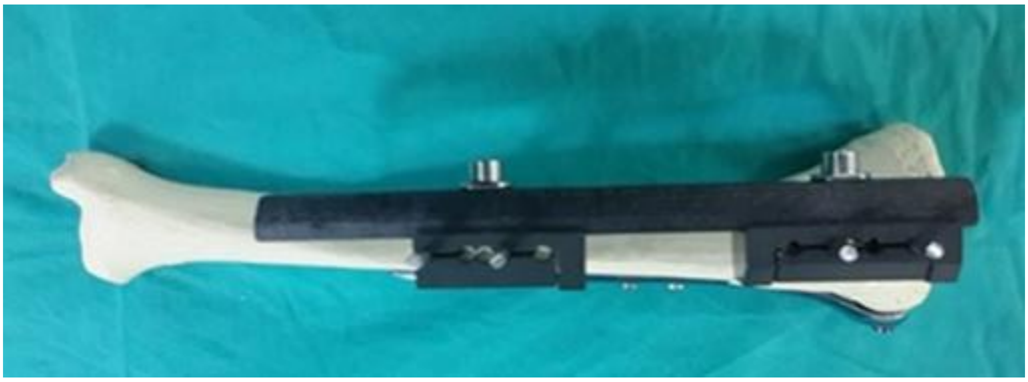


Fig. 4.5: Composite external fixator with polymer tibial bone [85].

4.6 Moulds and curing tools for composite parts production

Whereas the composite material brings large variability in final product shape and production, it also provides a variability in technologies how the product can be manufactured. In this part of the thesis, individual technologies will be briefly introduced, after that also materials suitable for mould will be mentioned and finally the mould for serial production is described [129].

4.6.1 Mould manufacturing technologies

Composite winding

It is a continuous process, most occasionally used for the hollow products. The manufacturing process contains winding of reinforcement to the mould that is rotating during the production. This method also determines possible shape of the final product. Thus, the shape can be circular, conical etc. Before the roving is wound up, the resin is applied to the fiber. After this, the final shape is cured, and the product is removed from the mould. The advantage of this method lies in the very good optimization of the reinforcement angle and its amount applied during the preparation. Another benefit is also high productivity and on the other side there is a disadvantage of higher purchase price of the production line [109, 110, 111]. The winding line can be further seen in Figure 4.6, where 1 – direct roving, 2 – fiber guide, 3 – tensioning system, 4 – carriage and platform, 5 – resin impregnation, 6 – rotating mould.

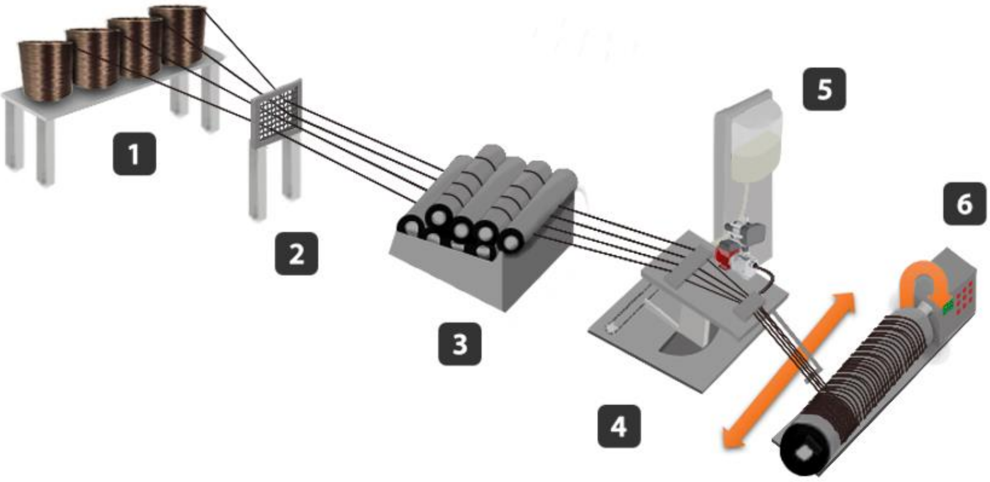


Fig. 4.6: Winding line [123]

Manual lamination

This type of lamination belongs to the first and simple procedures, successfully used nowadays for small series or one-piece production. Thus, it a viable move for boats, wind power plants or car shell prototype production. The manufacturing process contains these steps:

- Mould preparation (separator and gelcoat application)
- Fiber laying
- Process of fiber impregnation
- Curing.

Between the advantages of this method belongs good quality of one side of the surface, simplicity of production, unlimited size and shape of final product. On the other this method has many disadvantages as possibility of bubbles formation, the final product is strongly influenced by the skills of manufacturer and could have negative effect on product reliability mainly in the field of biomechanical engineering [130, 131].

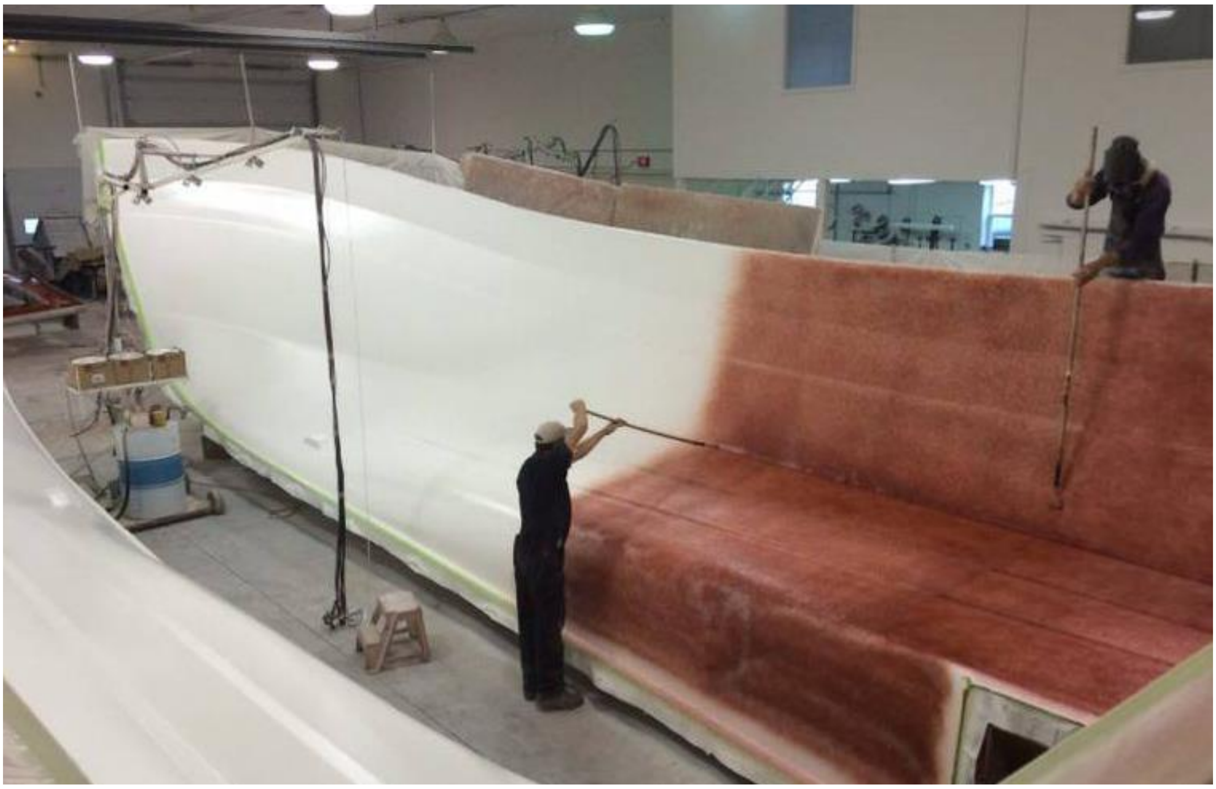


Fig. 4.7: Manual lamination of boat [124]

Resin transfer moulding (RTM)

It is one of the most reliable method of composite products manufacturing and thus serving as a manufacturing technology for higher number of products (usually from several hundreds to several thousands of parts). As the title suggest this method is contained of the process, when the resin is transferred to the closed mould, where the reinforcement is already prepared and after this period, the process of curing is accelerated by the catalyst and heat. This process is also depicted in Figure 4.8 below.

The result of this manufacturing technology is the final product with very good surface finish on both sides of the part, uniform distribution of reinforcement in the composite part. And thus, this method is widely used in automotive and electrotechnical industry [130, 131, 132].

Further when this method has been established and used in the practice other modifications of this method has appeared as Light RTM, Vacuum assisted RTM or High-speed RTM for individual cases of the production.

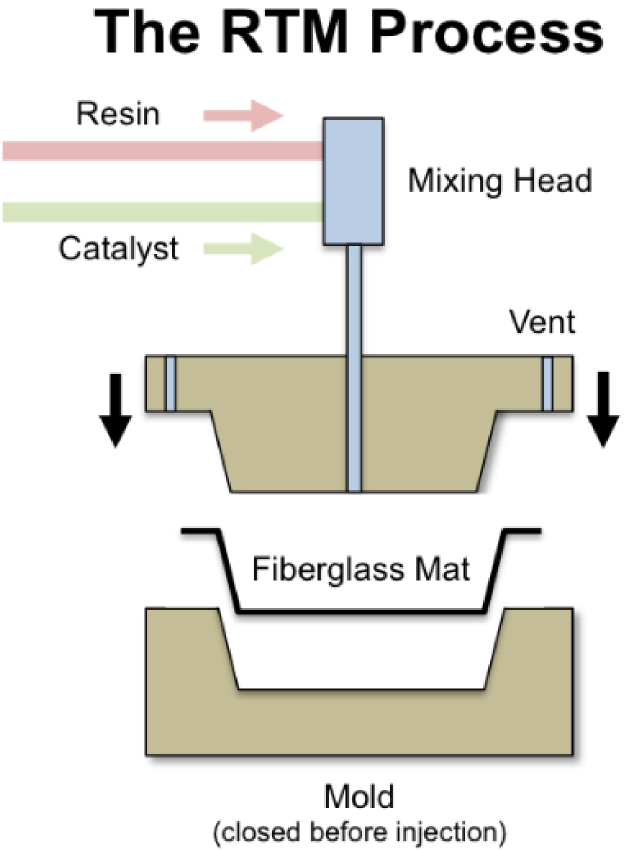


Fig. 4.8: Resin transfer moulding process [135]

Sheet moulding compound (SMC)

One of the last technologies for composite production described in this thesis is SMC method serving for prepreg preparation. It is a technology containing around 15 steps where the final product of this process is semi-finished product serving for the finalization and curing at the mould with the concrete shape and dimension. This prepreg is stored in form of roles at low temperatures to avoid further curing and chemical crosslinking before the moulding period [136, 137]

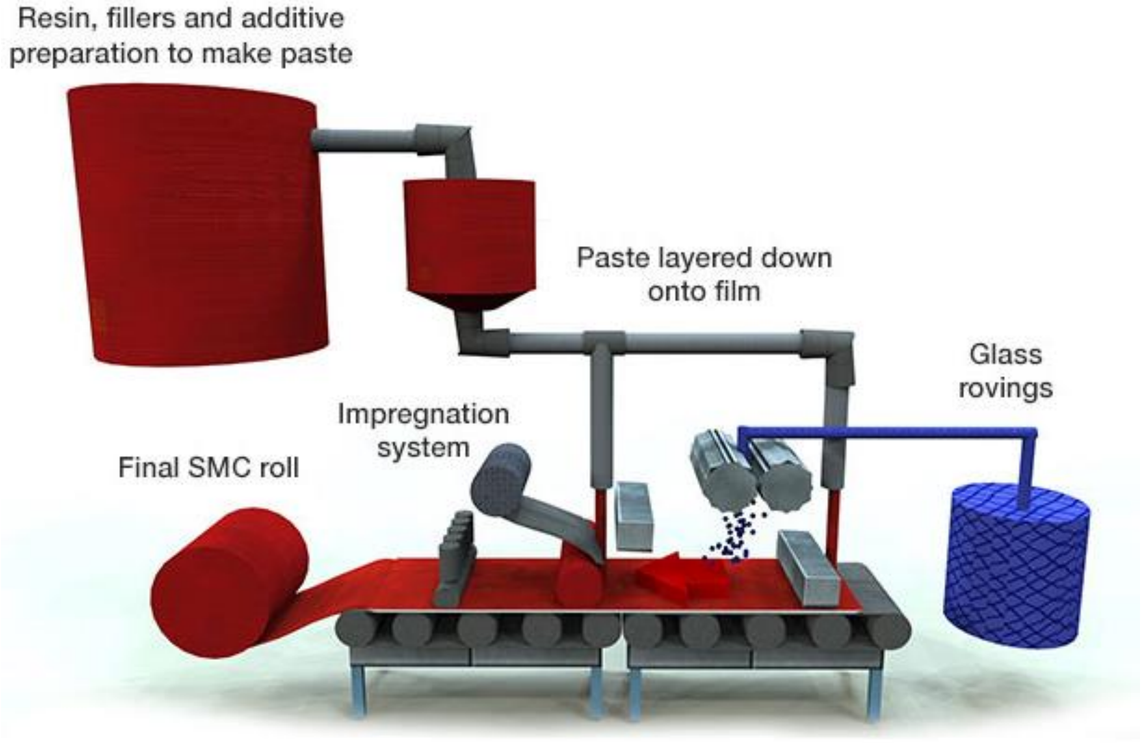


Fig. 4.9: Sheet moulding compound [138]

4.6.2 Materials of moulds for composite products

The final choice of mould material is directly dependent on several conditions [128]:

- Final price of the product
- Length of the production
- Desired quality and surface finish
- Time for mould production
- Part complexity and related manufacturing complexity
- Material compatibility
- Composite material application

Based on these conditions these various materials of mould can be used:

Table 2: Types of mould materials [124, 125, 126, 127]

Materials of composite moulds with characteristics				
Mould material	**Price**	**Density (kg*m^{-3})**	**Advantages**	**Disadvantages**
Steel	550 Euro/ton	7800	Availability, resistance	Not suitable for complicated shapes, higher manufacturing cost
Solid wood	450-1000 Euro/m^3	550-690	Availability, price, temperature resistance	The effect of moisture to the dimensional stability
PUR blocs	3200 Euro/m^3	580-700	Dimensional stability, weight, surface homogenity	Higher price
PUR paste	3200 Euro/m^3	750-1300	Dimensional stability, weight, surface homogenity	Higher price, complicated production
Epoxy blocs	10 000 Euro/m^3	730-1300	Dimensional stability, weight, surface homogenity	Higher price
Aluminum	2060 Euro/ton	2700	Availability, resistance, better manufacturing in comparison with steel	Higher price

After this evaluation, the mould material should be used also in accordance with the knowledge of mechanical engineer and manufacturing company that is producing this mould for the final composite product.

4.6.3 Mould design for series production of composite parts

For the necessity of composite parts series productions and the combination of high surface and product requirement a suitable choice is a metal mould. This method is usually used for parts with good quality surface as for instance parts for automotive industry or medicine are. Due to the requirement of high surface quality of the mould, usually the aluminium material is selected (good polishing ang machineability). The process of mould development can be divided into the two parts. Firstly, the mechanical engineering part, where the final 3D model and 2D drawings are created. After this, the second part of the process containing manufacturing by CNC machine is selected. One of the examples of this mould can be seen in Figure 4.10.

These moulds are mostly used for smaller composite parts and the products with difficult shape must be equipped with tempering system [139].

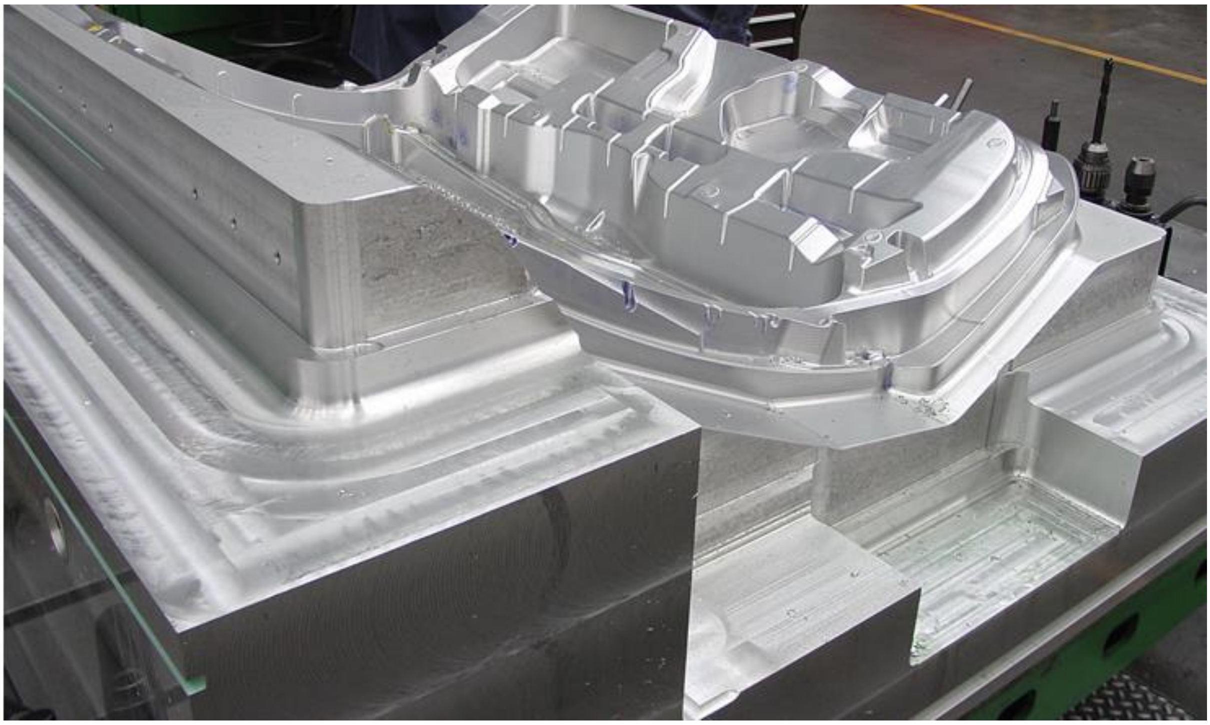


Fig. 4.10: Aluminum mould [140]

5. DEFORMATION ANALYSIS OF EXTERNAL FIXATORS

As indicated in [6], the application of the deformation analysis is just growing in the field of external fixation and in the whole biomedical engineering field as well. In this part, some of the current principles are introduced.

5.1 Introduction to deformation analysis

Generally, deformation analysis and finite element analysis serve as an analytical solution of stress in the industrial products. As a mathematical method of modeling, it is a simplified state, of the real situation. And as a simplified state it creates some inaccuracy and thus must be verified with the real situation or testing.

Although it is not a real situation it brings an understanding of products physical behavior and predicts the performance of the final design. Thus, even before the production this analysis can indicate problematic parts of the design, which can be further improved by several iterations of design and analysis. This analysis is also a good opportunity to the problems, where the weight minimalization is an important point, such in the external fixators design.

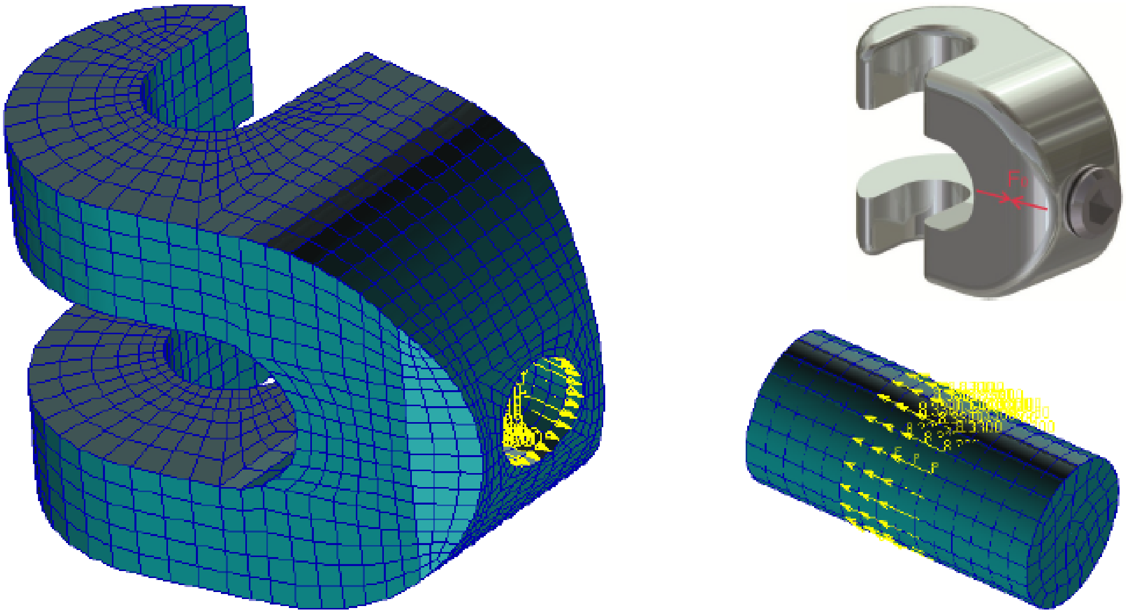


Fig. 5.1: Measured parts with mesh and deformation [92].

This mathematical modeling method further uses mathematical and physical equations and calculates the product conditions in every element of the mesh created in the compared part. Then after the pre-processing, solution and postprocessing procedure the deformation, stress and other measured values are calculated and depicted in these mesh points as can be seen in Figure 5.1 [93, 94, 61].

5.2 Structural analysis of external fixators

One of the most usually compared details of osteosynthesis fixator is an interface of the bone (with drilled hole) and Kirschner rod. One of these examples can be seen in Figure 5.2. The bone itself is replaced by the tube in order to simplify the overal analytical solution.

The bone-fixator interface and the connection of Kirschner rods to the bone have been a large problem in the 20th century due to the reduced hole quality in the bone during the healing process.

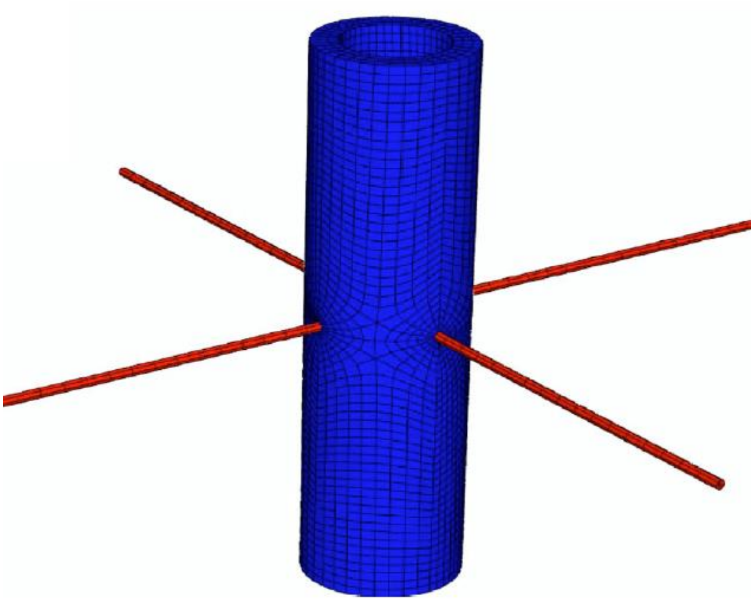


Fig. 5.2: Finite element method analysis of bone – rod interface [8].

The reason for such a common investigation of this detail is high stress arising in this part of bone-fixator assembly [6, 86, 87, 89, 90]. Some of the studies go even further to the bone structural analysis. These studies further comparing individual load conditions and the bone – fixator connection. These results can be seen in Figure 5.3 below. This information gives broad knowledge of how the bone can react to the fixator loading and which problems can occur at the bone –

fixator interface. Firstly, the integral bone is examined and then the fractured bone and its structural analysis are depicted.

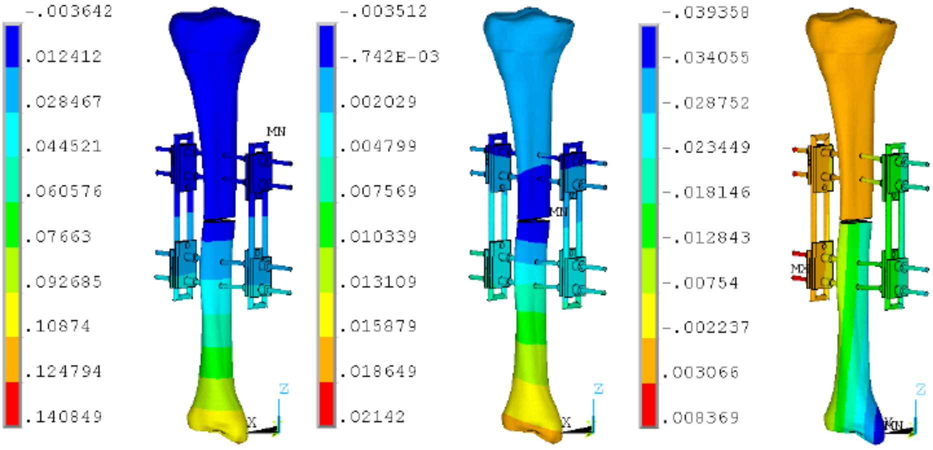


Fig. 5.3: Detailed structural analysis of bone – fixator interface [87].

Other investigation goes rather deeply into the external fixator technical details as in [88, 92]. These studies are mostly technical investigations without experimental confirmation and serve as a good example of in-depth deformation and stress analysis investigation.

Some of the results including ring analysis, investigation of connecting components, the interface of connecting parts with rings, or even whole fixator are displayed in Figure 5.4.

The most sophisticated studies go beyond mentioned investigations and combine both. The analytical method of finite element mathematical method combined with the verification by the experimental method of static testing. One of the examples can be seen in [76], where the unilateral fixator UNI-FIX by the ProSpon company serving as a device for tibia fracture healing process. This product has been investigated by the structural analysis firstly (Figure 5.5) and then static testing has been applied (as shown in capture 6) on the model.

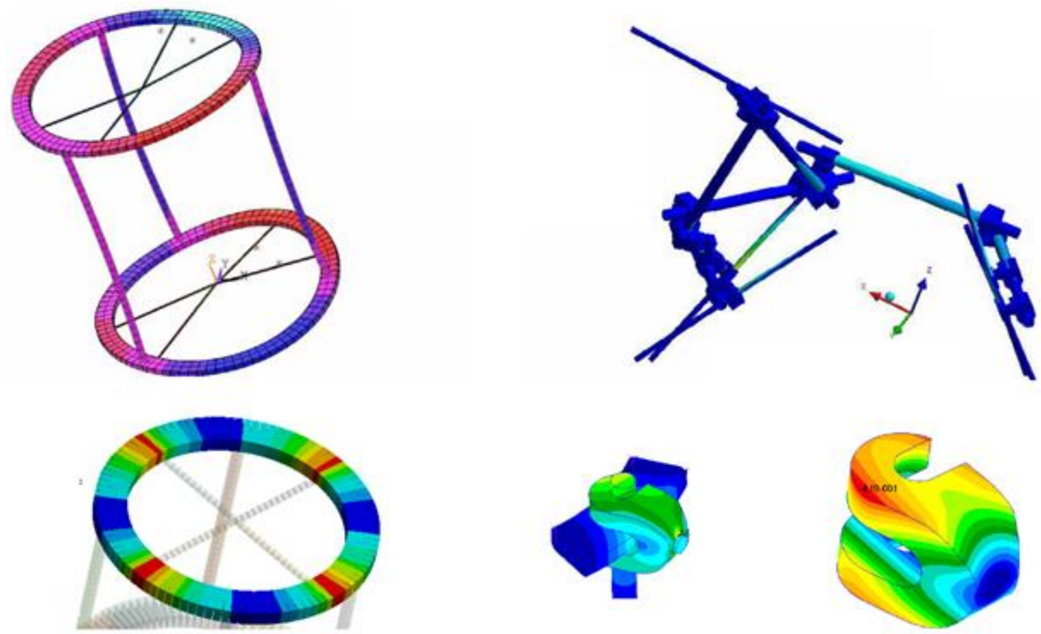


Fig. 5.4: Detailed structural analysis of the technical parts of fixator [88, 92].

The results have been later compared and from this interconnection of analytical method and experimental evaluation of the proposal, the final evaluation has been created. However, although this is quite a robust investigation of the whole fixator, any further established method for fixator analytical and experimental evaluation of individual fixator is not established up to now.

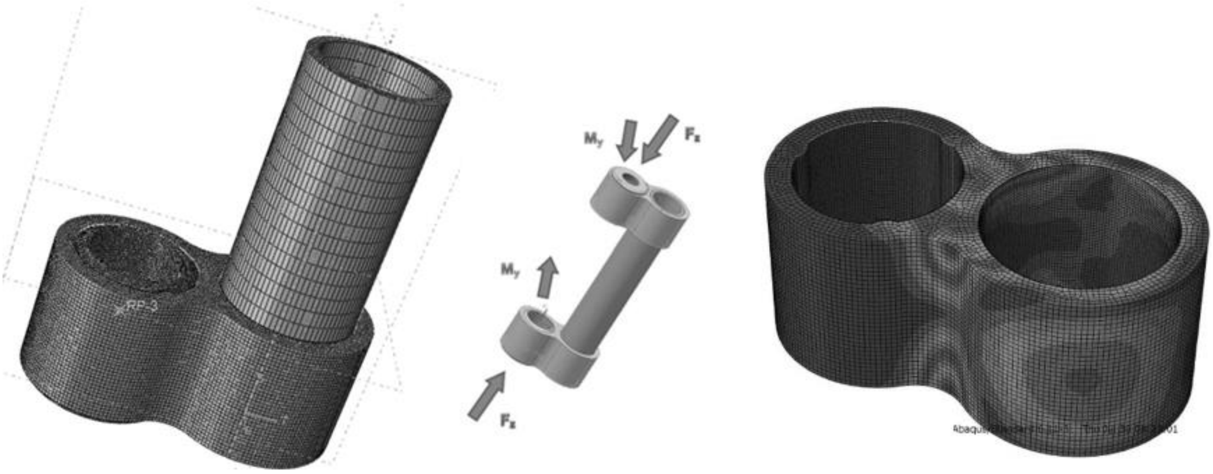


Fig. 5.5: Unilateral fixator structural analysis [76].

6. METHODS OF EXTERNAL FIXATOR TESTING

Basically, the experimental method of static loading serves as an evaluation and confirmation of the previous structural analysis model of external fixators. This describes the final state of the innovative external fixator and at the same time also results from the simplified finite element method of fixator loading [77].

As described in previous research, the connection of osteosynthesis fixator with the fractured bone is simulated with the 2-piece rod made of aluminum polymer or wooden rod (see Figure 6.1). The fixator is attached to this rod. And the rod is attached at the testing system as can be seen in Figure 6.2.

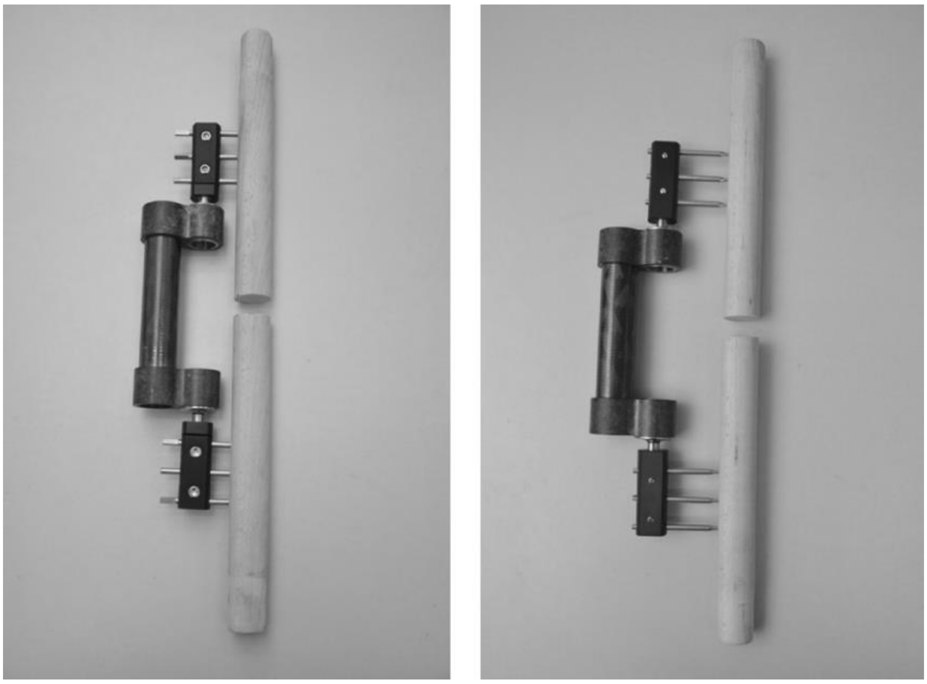


Fig. 6.1: Assemblies of external fixator prepared for testing

The overal loading is derived from the average patient weight and applied to the system of fixator at the testing machine. This loading force defers between the individual fixators and for individual type, the overal testing method is created.

Another type of fixator loading during the healing process is also cyclic loading. This is an important weight loading decreasing the overal fixator lifetime. Thus, it is an important fact for static testing of the overal fixator, and it is necessary to include also this loading into the overal testing method [76]. Individual methods differ with the number of cycles moving from 10 000 to

100 000. The result of the static testing is later derived from the final state of the fixator, that means if the individual parts are destroyed or not or if the large deformations occur during the testing period.

Fig. 6.2: The testing system for external fixator loading

In the case of the situation above, the overal system after the loading exhibits permanent deformation as can be seen in Figure 6.3. From this point, it is further possible to exactly define problematic parts of fixator design and improve the device in the future.

Another step is also verification of these results with the deformation analysis model and its further improvement and correlation with the static testing improves both. The knowledge of deformation analysis and also the final design of external fixator is directly proportional to the quality and sophistication of the analysis method.

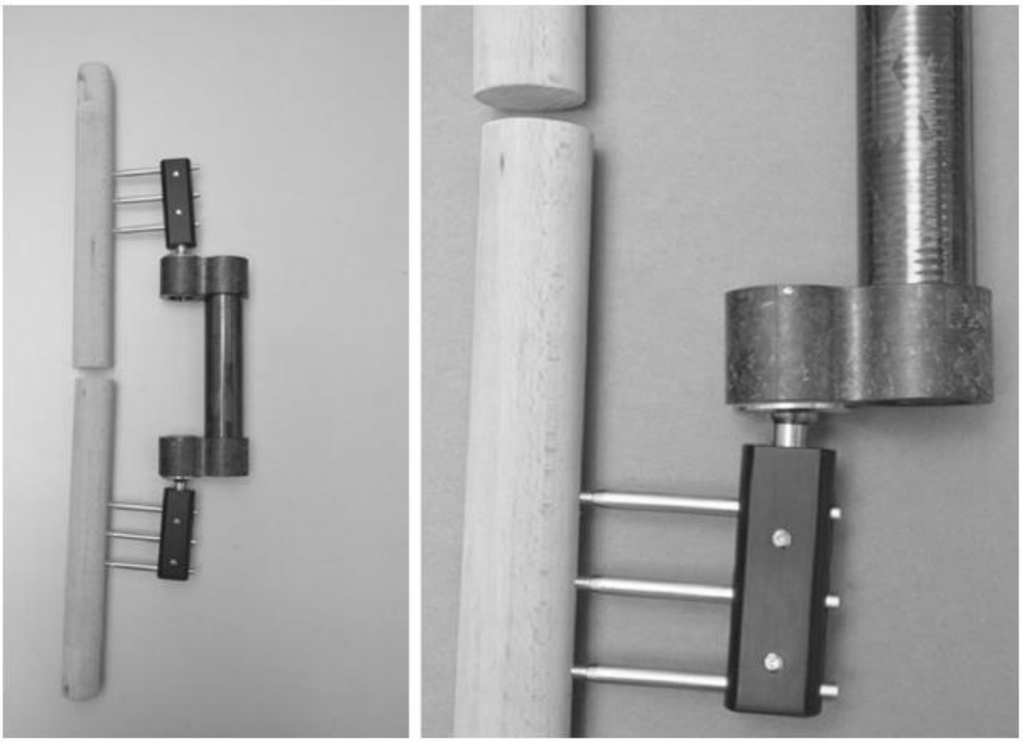


Fig. 6.3: Assembly after loading with permanent deformation

As mentioned in [78] no standard method of external fixator investigation has been established so far. There is just some smaller test trying to establish a smaller method for external osteosynthesis device testing, but any further established testing method has not occurred before. One of the common approaches during the fixator testing is the application of cyclical tests together with the stress test. These test has been evolving from the 1970 s and later were supplemented by the deformation analysis of structural analysis. These two types of strength verification of fixator are mostly used nowadays [79].

Dominant characteristic during the measuring process is the rigidity or in other words an examination of osteosynthesis element to response to displacement under the load. Another important characteristic is also compliance, that is dependent on the linear displacement during exposure to isolated load. Described properties serve as compared attributes of individual fixator during the experimental verification of the osteosynthesis device.

The experiment is usually repeated 1–3 times and combined also with the cyclical tests, simulating fixator used during the healing process by the patient. From that also the most important test can be derived. The first one is tested by axial load and the second one also tested by the cyclical loading. Eventually, for further examination, the fixator can be tested to rotational rigidity, transverse rigidity etc.

If the fixator is loaded without pins included, the applied force is from 5 to 200 N. If the fixator is loaded, it is important to track the stress curve introducing a dependence of applied load to the resulting deformation. If this dependence is linear and the deformation is adequate, then the overal rigidity is sufficient.

In order to get the exact results, the rigidity coefficient is determined as K. This coefficient further states, that in case of the longitudinal loading (see Figure 6.4), the deformation of 1 mm should occur after application of 53 N. This should be measured after the initial loading in order to skip the phase of inaccurate measurement [6, 81, 82, 83].

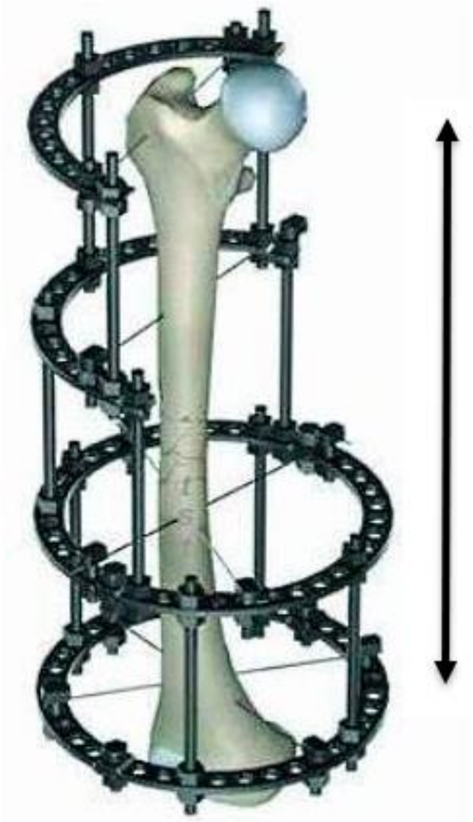


Fig. 6.4: Longitudinal direction [80].

If this measuring method is processed, then the final results bring further information and potential confirmation of the fixator design. This measuring is also the first step of the long-term verification process for fixator acceptance to the medical practice. It serves as an index of how the overal assembly could behave and if it brings further improvement to the current state of the fixator technology equipment.

7. OBJECTIVES OF THE THESIS

The doctoral thesis is devoted to the innovation of external osteosynthesis fixator. Together with the fixator another necessary step will be developed on the way and all the main objectives of this dissertation thesis are the following:

- Firstly an analysis of the state of the art of this orthopedic device and materials suitable for this application.
- Development of unified test serving as an evaluation method for the innovation of orthopedic techniques.
- Design of an innovative fixator based on knowledge gained from the theoretical part of the thesis together with the innovation using deformation analysis
- Application of the unified test on the new fixator design
    - Composite sample manufacturing and stress testing
    - Fixator analytical testing by the deformation analysis
    - Manufacturing of composite rings
    - Overal fixator manufacturing and assembling
    - Fixator pressure test with subsequent cyclical loading and another testing
- An evaluation of the test results and also the evaluation of complete test design.
- Examination of the fixator innovation and application of composite material into the fixator design.

8. APPLIED SCIENTIFIC METHODS

Individual methods have been applied in the theoretical part firstly and after these scientific methods has been used also in the experimental part. All of these steps are described below.

8.1 Theoretical part of dissertation thesis

This part contains:

- Through the analysis and synthesis of the information found in this part, the composite superposition is derived. From this the future application with the weight loss is predicted.

- Application of descriptive approach, where the findings from the exploratory part are quantified. That in this thesis means the relationship:
    - Between materials and rings dimensions for composite components.
    - Grooves size.
    - Different types of fixator construction.

8.2 Experimental part of dissertation thesis

In this part following methods are applied:

- For the deformation analysis preparation application of characteristic abstraction (definition of the loading and attachment of the fixator).

- After the deformation analysis, the knowledge gained from these analyses is connected together through synthesis and from that the overal fixator behavior is described.

- From the analytical solution, after the synthesis, the general solution is drawn (through induction). And these hypotheses are further verified with experimental testing.

As can be seen, these methods use both. Firstly, the analytical solution with following experimental verification of the fixator design and verification of deformation analysis.

In the first part of the experimental solution, even the external ring dimensions (made of composite material) are examined by the three–point bending that further serve as a valuable evaluation of these parts of fixator design.

9. UNIFIED TEST DESIGN

While the standardized testing method of external fixator has already been established and well used in the practice, the overall method of structural analysis and experimental evaluation has not been introduced before [6].

The methods used nowadays serve as final examinations of the external fixator and they have an advantage of the entirety of the fixator evaluation. On the other side, they have also several disadvantages as a high price of the whole test, high demands on technological equipment and also high time demands lasting several months to years. Thus, they are not an ideal method for primary external fixator evaluations which occur during the initial phase of the fixator development and during the research or even during the projects ongoing just for 2 or 3 years.

On the other hand, there is no other holistic method of fixator what creates inconsistent and nearly incomparable results. With regard to this fact, there is a necessity to design the test using structural analysis and experimental evaluation together serving for the initial parts of the project or study due to the need of the unification of this method.

A lot of studies deal with the external fixator evaluation using structural analysis as for instance in [87, 88]. These studies give a broader understanding of fixator behavior under the load, opportunity to improve the overall design and also investigate the deformation occuring under the load during the analytical solution [102]. Nevertheless, it is just a model analytical solution of the given issue and with the reference to [103] it is not an examination of the real situation, but rather a description of the simplified model and as such must be further verified by the experimental confirmation.

An experimental assessment of external fixator is another focus of research as for instance in [6, 95, 96]. This evaluation method gives an understanding of real osteosynthesis fixator and such serve as robust verification of the final design. As documented in the aforementioned references, the test is most often based on the pressure load applied on material testing machines or on the medical testing device as can be seen in [104]. Although this experimental verification is the only possible verification of the real situation, it does not give much possibilities to further improvement and optimization of fixator design for these reasons:

- A higher cost of the process before and during the testing period (fixator design, manufacturing, testing)

- The length of the preparation and the testing itself
- The test results in term of gained knowledge about the fixator behavior are not detailed enough.

Hence, there is an importance of linking both. Firstly, the analytical examination using deformation analysis with subsequent optimization of fixator design and the after the overall manufacturing process experimental testing. Nevertheless, also these types of scientific examinations have been done in the past and they can be seen for example in [76, 97, 98]. These studies examine the mechanical behavior with deformation analysis firstly and then use the experimental checking. Another important fact mentioned in [78] is that most of the experimental studies examine the mechanical properties of the fixator just in the state after the manufacturing process, but does not further evaluate or simulate fixator during the healing process, that means after the cyclic loading of the whole assembly during the patients´ walking with fixator. That is also another condition that will be included in this unified testing method. Last, but not least, there are some another possibilities how to improve the process of development and examination, mainly while the rings are made of the composite structure and will be described as the second part of overall testing process.

9.1 Deformation analysis

Based on the examinations in [76, 79, 97, 98, 100, 101, 105] the most important points of the test has been extracted. These are mentioned below.

9.1.1 External fixator deformation under the intended load

This type of analysis is the complete fixator analysis, consisting of:

- **Mesh preparation** – the accuracy of deformation analysis can be achieved just by an appropriate element mesh size [106].

- **Material selection** – in order to get the right results, also the material with individual characteristics must be applied appropriately.

- **Anchor conditions** – in term of Ilizarov external fixator this practically means a simulation of pad and foot connection.

- **Selection of appropriate loading** – these stress conditions must simulate the real conditions of the healing process and that means the application of the weight loading in accordance with the stress exerted by the leg.

- **Computing** part, where the deformation and maximal deformation is calculated in individual points of the mesh.

- **Analysis of the results** in accordance with the expectations.

9.1.2 Displacement analysis of the fixator (bone displacement)

Another important result coming from the analysis is also displacement of the fixator and the bone in the individual point of the mesh. Due to the fact, that the maximal bone deformation during the fixator use should not exceed 2–3 mm, the maximal deformation of the bone is evaluated too.

9.2 Identification of an appropriate ring profile

The first part of this unified test should contain a method of rings evaluation in term of good weight/rigidity ratio. Therefore, the first part of stress testing is performed with the manufactured samples representing the final state of the fixator rings after the structural analysis optimization.

9.2.1 Loading of samples with variable dimensions

Firstly, the samples with different thicknesses and dimensions are manufactured, later they are loaded by the 3 – point bending method up to the point of total integrity failure. Based on the results, an ideal sample of weight/rigidity ratio is selected and also the process of destruction is observed. This information can further bring more information about the fixator understanding if the fracture occurs during the 3rd part of the unified testing method, that is the stress test of overall fixator.

9.2.2 Evaluation of results and design with good weight/rigidity ratio selection

In this point, the results of the sample stress test are evaluated and the selected sample serves as a model of final ring design. These results have to be also compared with the visible state of samples and the process of component fracture.

9.3 Stress tests with cyclical loading

One of the most important segments of this test is stress test combining the pressure test of fixator and the cyclic testing simulating walking during the healing process. This stress test generally serves as a simulation of the real application of the external fixator. To achieve this, the overall state of the fixator has to be observed during the periodical fixator use by the patient. That further means, that the fixator stress test has to be supplemented by the cyclical test simulating walking too. All these individual parts of the process are time-aligned below as they will be progressively implemented.

9.3.1 Pressure loading

To determine the actual conditions of the fixator, the construction has to be submitted by the pressure testing firstly. This gives a deeper understanding of product beahavior and it is also the result from which changes in the state of the art after the cyclic testing can be observed. During this period, the fixator is repeatedly loaded.

9.3.2 Cyclic testing simulating 4 weeks of walking

The fixator as an orthopedic device for long bone fracture healing process are usually applied for several weeks and most often up to 9 weeks. Therefore, cyclic testing is set to this period. This period is further divided into 2 parts (4 weeks and 5 weeks period), enabling insight into the fixator behavior during the healing process.

9.3.3 Pressure loading after 4 weeks of simulation

After the first period of cyclic testing, the fixator is moved again to a testing machine, where the pressure test is performed again and the results are preliminarily compared with the previous results.

9.3.4 Cyclic testing simulating another 5 weeks of walking

The fixator is assembled again back to the cyclic testing machine and the remaining five weeks of walking are performed.

9.3.5 Pressure loading after 9 weeks of simulation

The last part of this unified test is also one of the most important tests. It is the final exam, that creates and also closes the overall view of external osteosynthesis product evaluation process.

9.4 Design of unified testing method

When the list of individual tests and analysis is completed, it is appropriate to summarize them into the resulting table. This test is named as Unified Fixator Testing Method (UFTD). As mentioned above, also this test is divided into the three sections containing all these test and evaluations.

Table 3. Unified testing method of Ilizarov external device

UNIFIED FIXATOR TESTING METHOD	
Test / analysis description	Conditions, type of test, etc.
A. Evaluation of fixator rings loading capacity	
1. Loading of samples with variable dimensions	3 point bending
2. Evaluation of results and design with good weight/rigidity ratio selection.	Evaluation
(Application of this profile in the fixator design)	3D modelling
B. Analytical evaluation of deformation	
1. Displacement analysis of the fixator (bone displacement)	(maximum bone displacement = 2mm)
2. Evaluation of the possibility of permanent rings deformation	Analysis of displacement and stress peaks
C. Stress test of real fixator	
1. Pressure loading	Universal blasting machine.
2. Cyclic testing simulating 4 weeks of walking	Single - purpose testing machine
3. Pressure loading after 4 weeks simulation	Universal blasting machine.
4. Cyclic testing simulating another 5 weeks of walking	Single - purpose testing machine
5. Pressure loading after 9 weeks simulation	Universal blasting machine.

The test mentioned above has also some phases between, as the manufacturing process, external fixator design and optimization steps during the project completion are. Thus it is creating the process of fixator development even more sophisticated. Since these additional steps cannot be defined in advance, they will be described in detail in the next chapters of this dissertation thesis. When using this test to verify another external fixator, these phases that are not part of this table can be changed according to the individual case. And that is the reason why these phases are not added to the unified testing method.

10. DEVELOPMENT OF EXTERNAL FIXATOR

One of the major objectives of this research is the improvement of the current state of the Ilizarov external fixator. That further means the application of knowledge acquired during the theoretical part of the dissertation thesis including:

- An application of transosseous elements.
- The use of structural requirements for this aid resulting from the biomechanical view of the anatomical foot model.
- The inclusion of basic requirements for the fixators design.
- Furthermore, also inundation of the latest findings of the use and assessment of orthopedic devices such as osteosynthesis fixator.

Nevertheless, the described steps are one possible view of how the overall fixator design and construction could be further developed. Another part of the possible improvement of this device can be described by these current deficiencies mentioned in the table below:

Table 4. Problematic issues of Ilizarov external osteosynthesis device

Priority	**Problem**	**Reason**	**Suggested solution**
1	Weight	Difficult surgery, manipulation	Design changes, material changes
2	Surgery	X-ray penetration	Material changes
3	Appearance	Fear of social status	Material changes, design improvements
4	Incompatibility	Too difficult adjustment	Design changes with deformation analysis

Based on these findings, the fixator design is created. Whereas one of the significant problems of fixator is higher weight and X-ray penetration, then it is appropriate due to the findings in theoretical part dealing with composite materials, use this material mainly in large and heavy parts of the external fixator as the rings are.

Another solution for the design improvement is also design changes, that could do them both. In the first place decrease the overall fixator´s weight and also improve the manipulation with this device for the surgeon during his surgery or during the healing process, where the additional setting is necessary.

As mentioned in the section dealing with the deformation analysis, if the result of the design part should be insufficient quality, then the optimizitation using this analytical method has to be included into the process of external fixator design preparation. It further means design improvements based on the deformation analysis application.

Through described changes, the solution of the individual problem can be achieved. One of the important, but not so often mentioned problem is the fear o social status during the healing process [108, 109, 110]. This problem is mostly increasing in the developing countries and in many cases leads to the refrain of treatment with external osteosynthesis device. Whereas this inacceptance leads to the extremity amputation after several weeks or months later, even an appearance is an important element in the process of Ilizarov external fixator innovation. Regarding the above mentioned, appearance optimization is the last part of external fixator design innovation.

10.1 Development of external fixator – concept 1

The first aim of this section has been designed and model completion of Ilizarov external fixator. The construction is based on the knowledge from the theoretical literature research in the first part of this theses. This further means the design of external fixator with medium size (fixators differ in size mainly by the ring´s diameter) and the design from these types of parts:

- Rings of external fixator (varying from 4 to 5 pieces, where the 5th ring is three-quarters.
- Kirschner rods made of surgical steel
- Connecting components (clamping of connecting rod and clamping of the internal rod)
- Connecting rod.

During the first version of a design, was an effort to apply suggested solutions of problems with fixator. That means, the composite material has been used for the rings and connecting rods, individual connecting components were designed with an emphasis on simplicity of function and minimalistic design. Individual rings have been created with the aim of overall weight reduction too. The result of the first concept design can be seen in Figure 10.1. The description of individual components can be seen in the next figures.

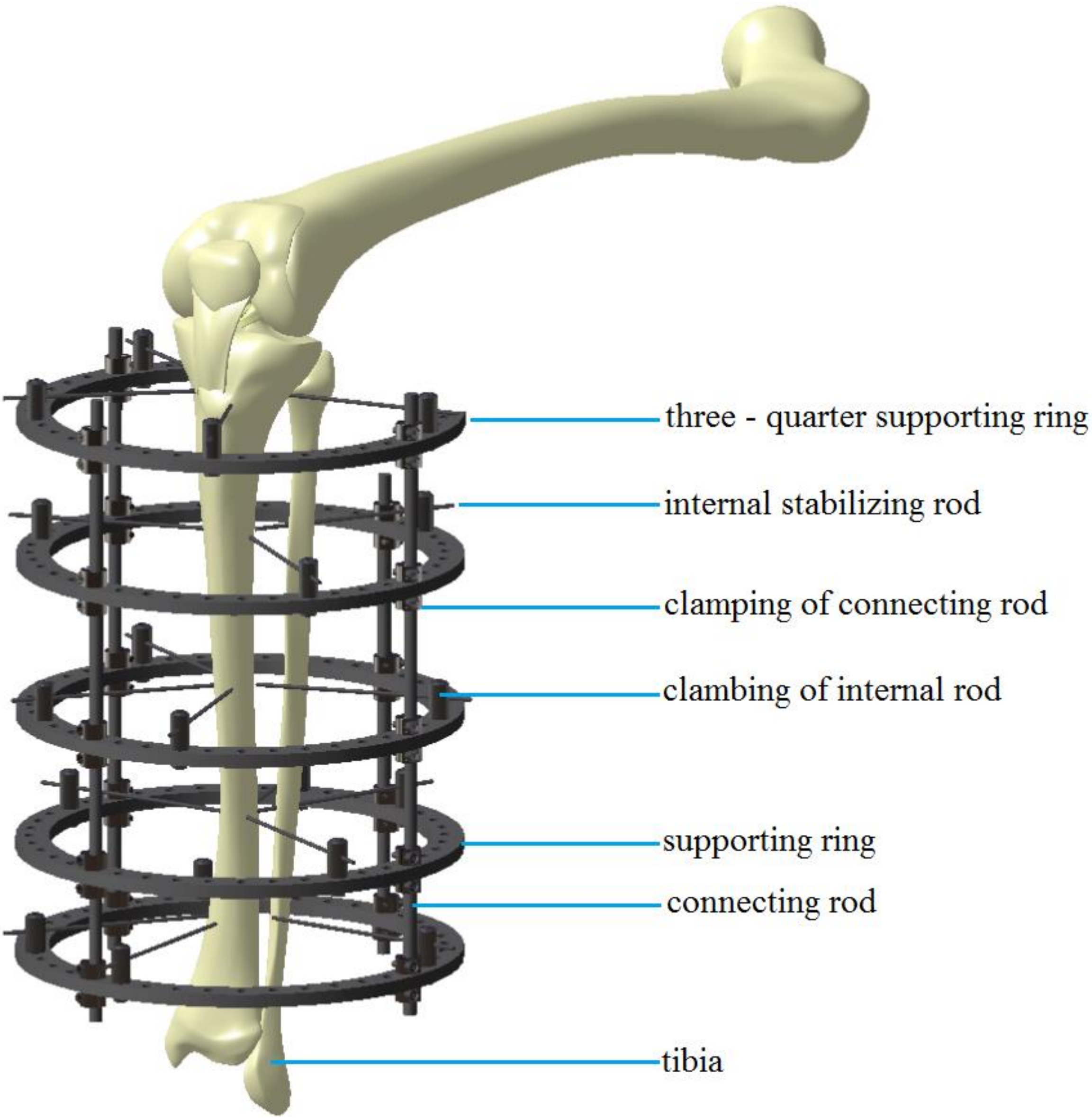


Fig. 10.1: External fixator design – concept 1

10.1.1 Supporting rings

These parts are one of the most important and connect all the parts together. It has great importance in terms of stiffness and also the weight of a complete product. Thus there was a potential to decrease the weight of this part and the thickness was selected with regard to achieving the lighter design. Also, the composite material has been selected and the holes for connecting components and rods are used.

10.1.2 Internal rods and clamping system

Due to the requirements for lighter product and X – ray penetration, the composite as a material of connecting rods has been selected. Due to this material application, also the design of connecting component has been improved and can be seen in Figure 10.2. The clamping system operates on the principle of friction force between the connecting rod and the connecting component.

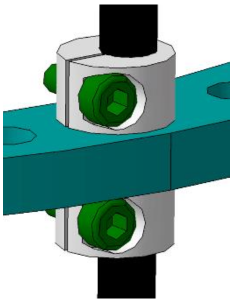


Fig. 10.2: Clamping of connecting rod – concept 1

10.1.3 Internal rod with the clamping system

Another improved part of external fixator is the clamping system of the external fixator. The solution to this system has been changed and can be seen in Figure 10.3.

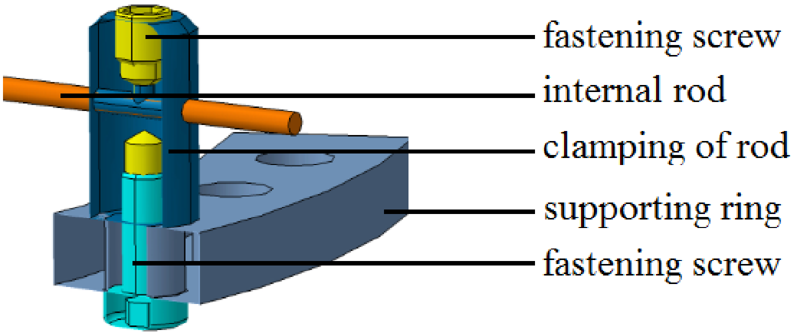


Fig. 10.3: Clamping of internal Kirschner rod – concept 1

Finally, the complete assembly has diameter Ø200 mm and height 285 mm, that can be further adjusted according to the patient´s fractured limb.

10.1.4 Evaluation of concept 1

At the point, where the concept 1 was completed, a preliminary assessment of the construction has been done using the deformation analysis. At this point, it is still a development part of the fixator innovation that precedes the fixator testing method created under this dissertation. The analysis simulates a model of the real situation, where the patient is loading the fixator by touching the floor with the foot. This connection with the floor is in analysis replaced by the fixed bond at the bottom of the fixator as seen in Figure 10.4.

Another necessary condition is also weight application, where the force applied to the fixator (shown in Figure 10.4) substitutes the loading from the patient body.

This force has been set to 53 N in accordance to the MUDEF testing method. Another variable is also material, whereas the most suitable material for this device, the carbon-fiber composite has been selected. After the loading process, the deformation of 3,46 mm has been measured, what is based on the testing method mentioned before insufficient value.

Fig. 10.4: External fixator loading during all the deformation tests

The material properties of carbon fiber components are mentioned in Table 10.1.

Table 5. Material properties of carbon – fiber components

MATERIAL OF RINGS AND CONNECTING RODS	
Poissons´s Ratio	0,51
Density	1,95 g*cm^3
Tensile Strength	125 MPa

After the design of the 1st version of fixator and analytical verification of the final model, the product has been evaluated by the physician. From both of the evaluations, the advantages of this new design can be expressed as well as the disadvantages. These advantages further serve as an appropriate direction, which should be kept also for another version, while the disadvantages are the possibilities that can be improved further. From the engineering perspective there is an obvious necessity of rigidity improvement, whereas, from the physician perspective, there is a lack of fixator adjustability as mentioned in this table. Individual improvements are mentioned in the development of concept 2.

Table 6. Concept 1 – evaluation

EVALUATION		
CHANGES	**ADVANTAGES**	**DISADVANTAGES**
Composite material of rings and rods	Very low weight	Insufficient angular setting
Rings with internal holes	Simplified design	Low rigidity
Minimization of connecting parts	Improved appearance	Lack of adjustability ring spacing

10.2 Development of external fixator – concept 2

As mentioned in the previous section, the external fixator design reports possibilities for further improvement. The major disadvantages of the first version of fixator have been applied in another version of the fixator.

Firstly, the problem with the insufficient angular setting (due to the holes in rings, that does not require to adjust the desired angle around the leg) have been further improved by replacement of circular holes to grooves. That can further improve the adjustability because of the fact, that all the grooves together gives the possibility to set a relative angle around the leg.

Another problem of fixator design has been in term of the low rigidity of this orthopedic device. Due to the fact, that (as mentioned before) the rings of external osteosynthesis device has the most significant influence to the stiffness of this system, there was a necessity to increase the rigidity of the ring.

This improvement had been implemented together with the angular adjustment improvement, where the individual grooves, have been distributed in two diameters of the ring as can be seen in Figure 10.5.

Fig. 10.5: External fixator design – concept 2

After this improvement the fixator design, the device has been has been subjected by the loading conditions as in the previous deformation analysis of concept 1. The result of this deformation describes, that the deformation of the fixator under the load of 53 N does not exceed the limit of 2 mm deformation and the maximum value is 0,426 mm.

As can be seen from this analytical solution, the overall deformation in comparison with the previous version decreased significantly and that further serve as a good example of further improvement of rigidity.

After this analysis, the second version of fixator design has been subjected by the surgeon evaluation and the results of both, the deformation analysis and surgeon evaluation are depicted in the Table 10.3 below.

As is in the table described, this second version of fixator still reports two options for further improvement. The first one (higher weight is associated with the effort to increase the stiffness of the fixator). The second disadvantage is a deteriorative appearance of the fixator which can further affect the acceptance of this orthopedic device by the patient. Due to the fact, that the number of grooves in the ring is quite high, it brings another possible opportunity for improvement.

Table 7. Concept 2 – evaluation

EVALUATION (in comparison with version 1)		
CHANGES	**ADVANTAGES**	**DISADVANTAGES**
Rings diameter changes	Improved robustness	Higher weight (870 g)
Addition of ring – grooves	Improved angular setting	Worse appearance

10.3 Development of external fixator – concept 3

In the next step, the fixator design has been optimized. All of the advantages found and created during the previous solutions have been left and the remaining discrepancies were revised.

The result of the optimization can be seen in Figure 10.6, where the 3rd version of the fixator concept is depicted. As is evident, the quantity of the grooves in the rings decreased. Instead, they were substituted by the longer grooves which are supplemented by shorter grooves bridging the space between these longer grooves.

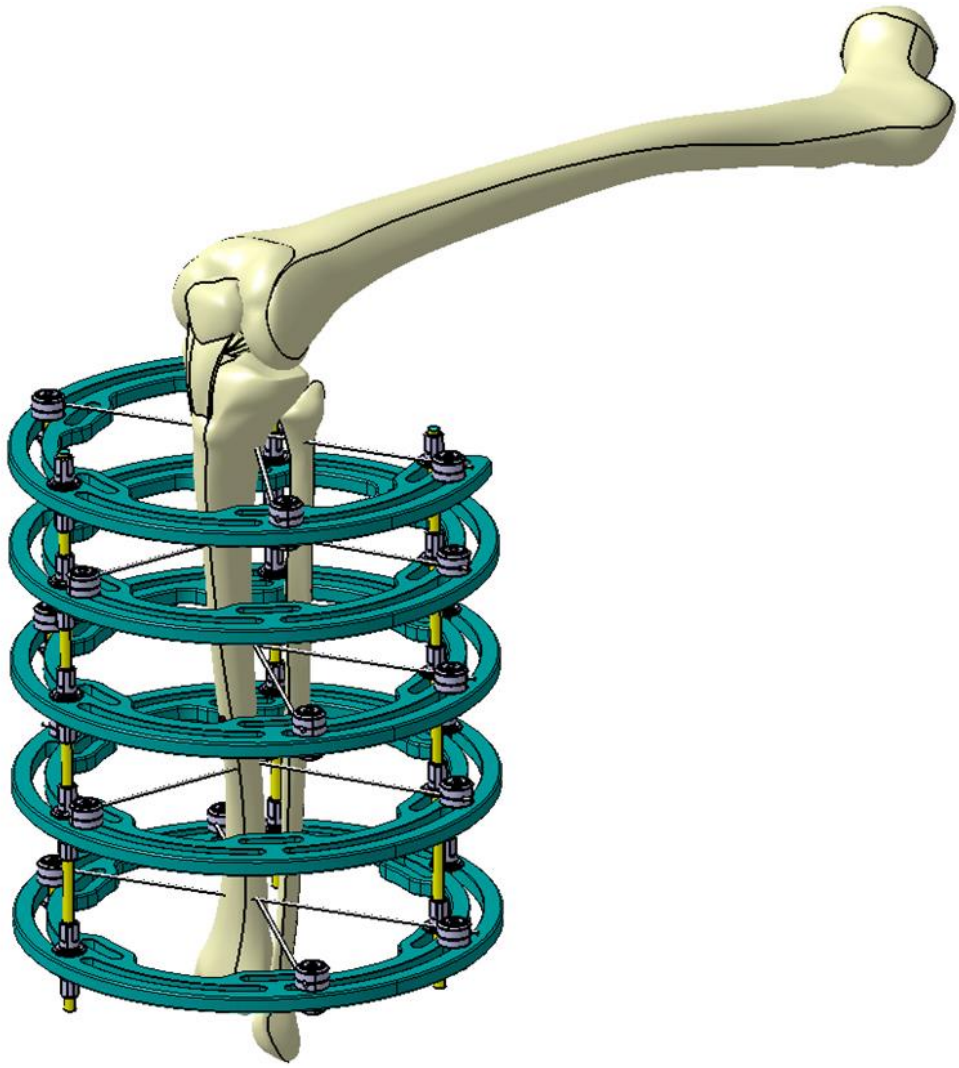


Fig. 10.6: External fixator design – concept 3

Because of fact, that the number of grooves decreased, there was an opportunity to further decrease also the mass of the rings and thus decrease the weight of the fixator. After the deformation analysis, also the final design in term of appearance has been improved. As mentioned in the evaluation of the first concept of external fixator there was lack adjustability of rings setting and thus the composite connecting rods of external fixator has been replaced by the threaded rod and also connecting components of this rod has been re-designed.

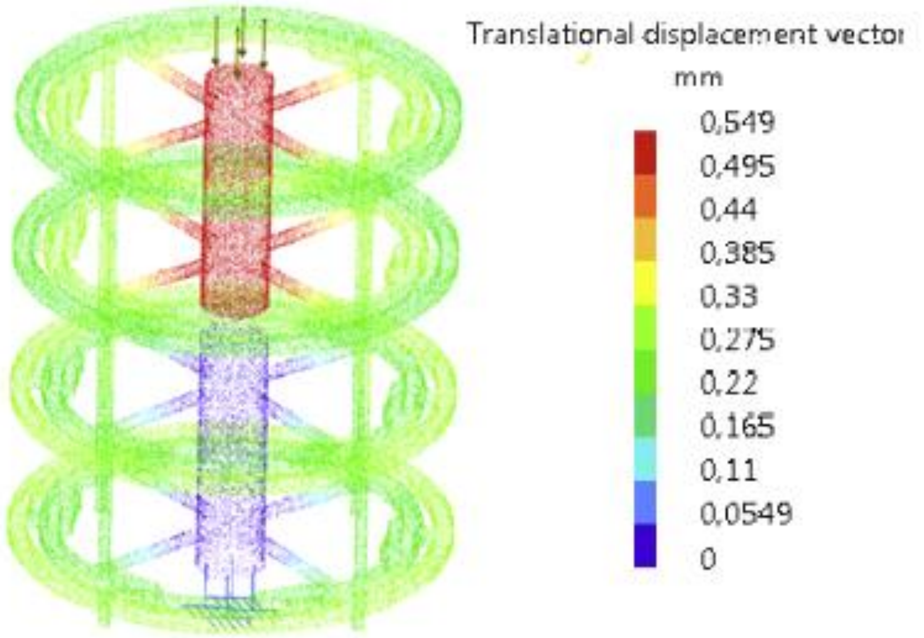


Fig. 10.7: Structural analysis of fixator – concept 3

After the finalization of the external fixator design, this device has been subjected by the deformation analysis and the result of this analytical method can be seen in Figure 10.7. As mentioned in the previous sections dealing with composite material, if the composite structure lay up is designed as a quasi-isotropic layer, than also the composite parts can be investigated as an isotropic structures. These fact has been included during the structural analysis evaluation.

Table 8. Concept 3 – evaluation

EVALUATION (in comparison with version 2)		
CHANGES	**ADVANTAGES**	**DISADVANTAGES**
Appearance vs. grooves optimization with deformation analysis	The lower weight of rings	Due to steel rods higher weight
Connecting components design changes	Simplified and stronger connecting parts	
Steel connecting rods	Improved Appearance	

The 3rd version of the fixator has been as well as the previous versions evaluated together with the surgeon, and the results are listed in table 8. One of the disadvantages appearing after the fixator optimization is the higher weight of connecting rods. Due to the fact, that the adjustability with a connecting rod is necessary, then it will not be further changed.

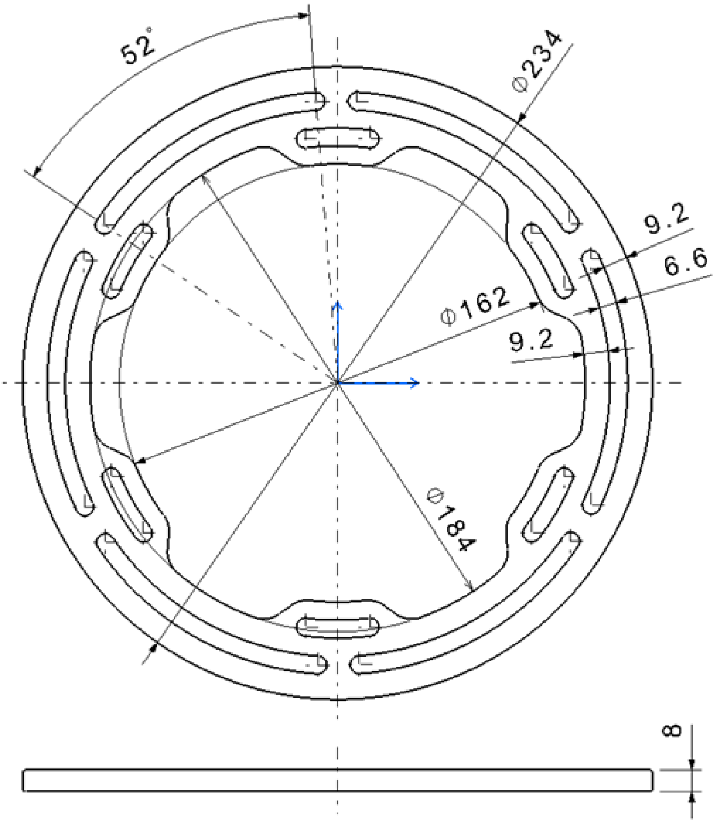


Fig. 10.8: Composite ring of external fixator – version 3

For better final shape and dimensions recognition individual composite ring is shown in Figure 10.8 (with dimensions) and Figure 10.9.

Fig. 10.9: Three-quarter composite ring of external fixator – version 3

As mentioned before, the composite connecting rods have been replaced by the steel rods with thread and thus also connecting components of these rods has been modified. This can be seen in Figure 10.10.

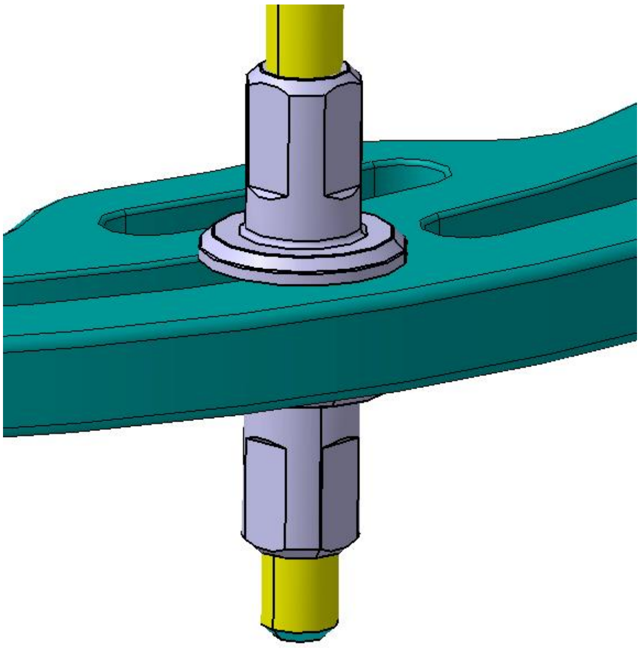


Fig. 10.10: Modified clamping components of connecting rod

One of the other details that have been upgraded is also clamping components of Kirschner rods. Because of fact, that the overall external fixator rigidity is connected with the stiffness of individual part, these clampings were improved in term of higher rigidity and stability under the load coming from the loaded bone and Kirschner rods. These improvements are shown in Figure 10.11.

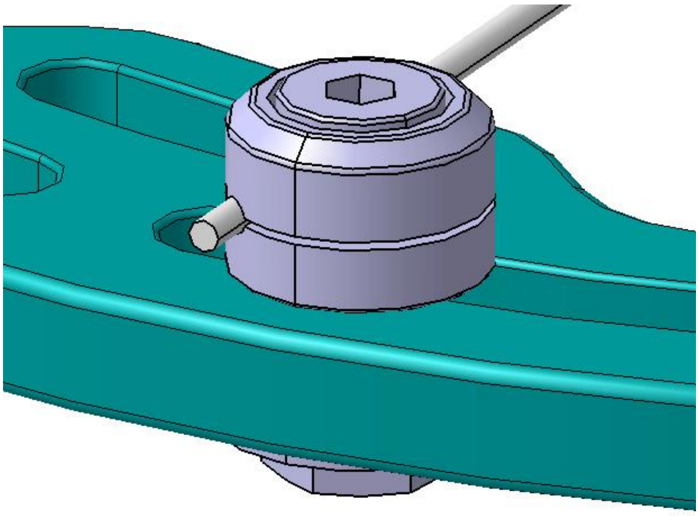


Fig. 10.11: Modified clamping components of Kirschner rod

In Figure 10.12 below, the clamping of the Kirschner rod can be seen in section view.

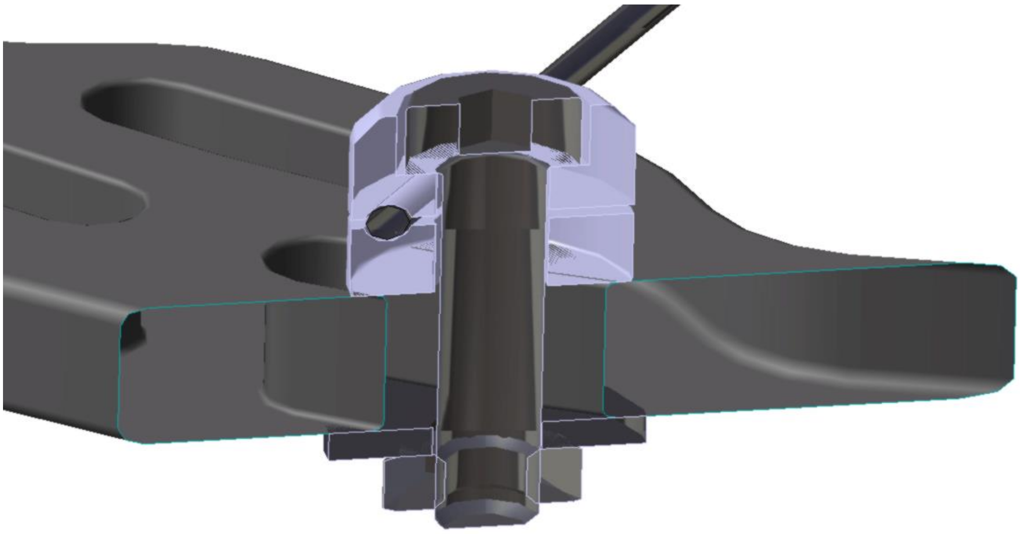


Fig. 10.12: Modified clamping components of Kirschner rod – section view

The dimensions of complete fixator in front view can be seen in Figure 10.13 and gives sufficient idea about the overall fixator size.

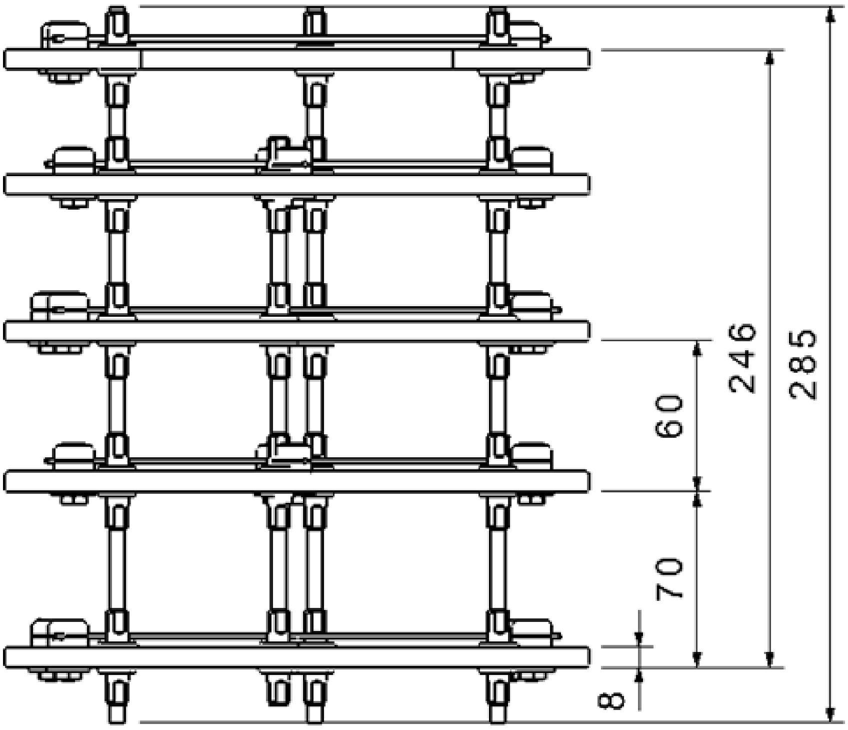


Fig. 10.13: The main dimensions of the 3rd concept of fixator – front view

11. EVALUATION OF FIXATOR RING LOADING CAPACITY

As more discussed in the section with unified test design, before the process of manufacturing, one of the suitable moves is the evaluation of fixator ring loading capacity through the sample stress testing, that is further described below.

11.1 Process of samples preparation

This assessment gives further knowledge of how the final shape with its dimensions reacts to the loading. Based on this, individual samples with an adequate dimension and thickness has been from the ring design excluded. Further, even the second version of the fixator ring was evaluated and the samples were prepared and manufactured with different thicknesses as can be seen in Figure 11.1 and Figure 11.2 (Samples A-F).

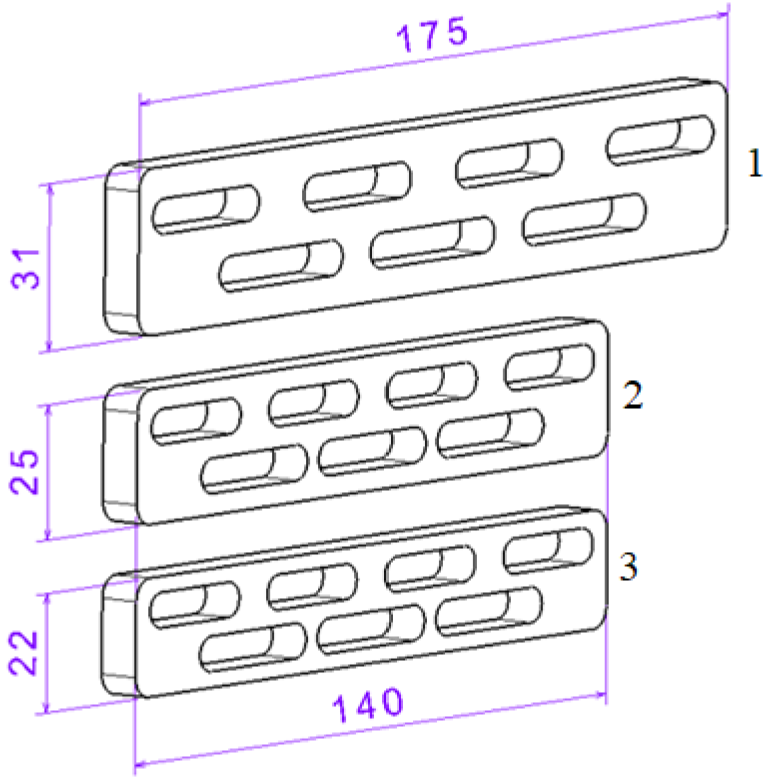


Fig. 11.1: Samples of composite fixator ring with different dimensions-concept 2

Table 9. Results of samples testing (1, 2, 3)

	1		**2**		**3**	
	E [MPa]	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**
X_A	36281	4408	30056	3836	28753	3216
s	954	106	1206	125	1359	137
v	2,6	2,4	4,0	3,3	4,7	4,3

There are three-dimensional models of individual concept, where the medial sample represents the dimension evaluated with deformation analysis, then the bottom model is a sample with reduced dimensions and the upper is a most solid part, where individual dimensions have been magnified. The same applies for concept 2 and concept 3 samples.

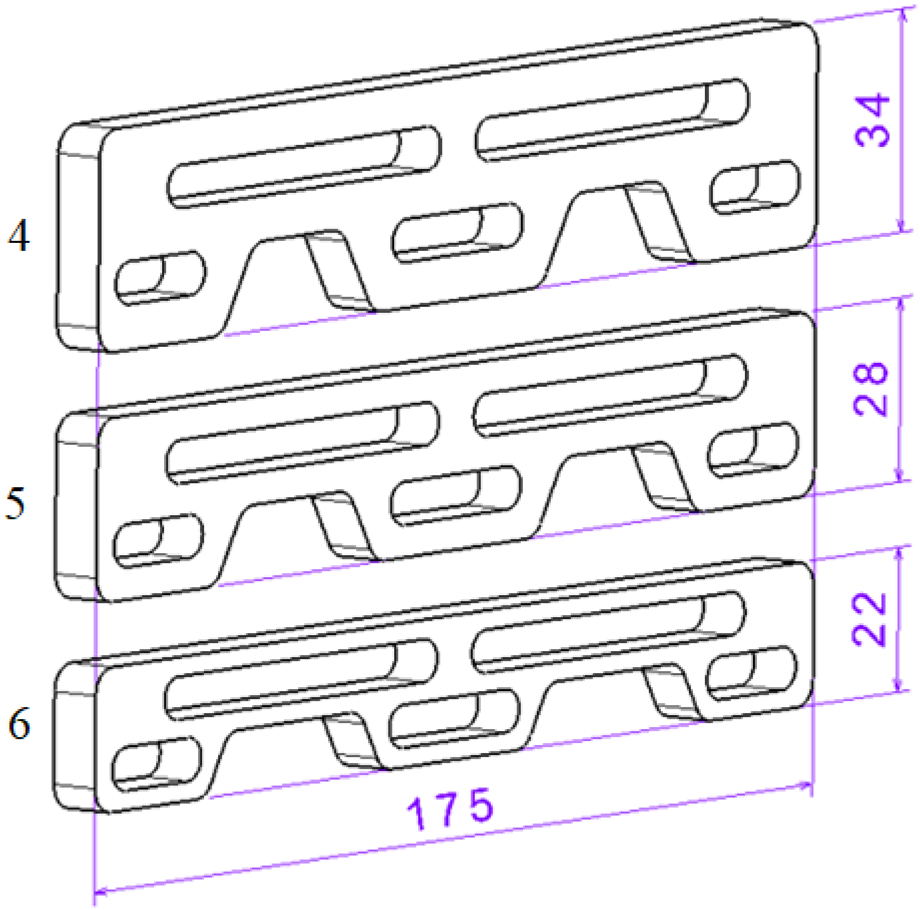


Fig. 11.2: Samples of composite fixator ring with different dimensions-concept 3

Table 10. Results of samples testing (4, 5, 6)

	4		**5**		**6**	
	E [MPa]	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**
X_A	34291	4268	30085	4056	21000	1500
s	1174	142	1327	133	1498	245
v	3,4	3,3	4,4	3,3	7,1	16,3

In the Figure 11.5, an illustration of these samples after the manufacturing process is depicted. As can be seen, the material of the sample is made of the glass fiber composite. There was a necessity to decrease the price of the innovation process and thus in the carbon fiber composite has been substituted by this material. This decision leads to other advantages, as the possibility of larger quantity manufacturing, overall lower price and the consequent possibility of more quantity of fixators.

Fig. 11.3: Water-jet cutting machine [140]

An individual component has been manufactured by the layers laying in different angles of reinforcement in an individual layer. This layers have been further pressed under the heat and the process of lamination has been completed. From this laminated sheet, the individual samples were cut out by the method of water jet cutting as can be seen in Figure 11.3 and 11.4. This method has been selected due to the the several advantages that this method brings into the manufacturing process. The most important benefits of this technology are [140, 141]:

- Ability to manufacture heat-sensitive materials as composite structures.
- This technology does not bring heat influence and material burnings.
- Burr-free cutting method.
- There is no microthline production.
- Random shape of the cut.

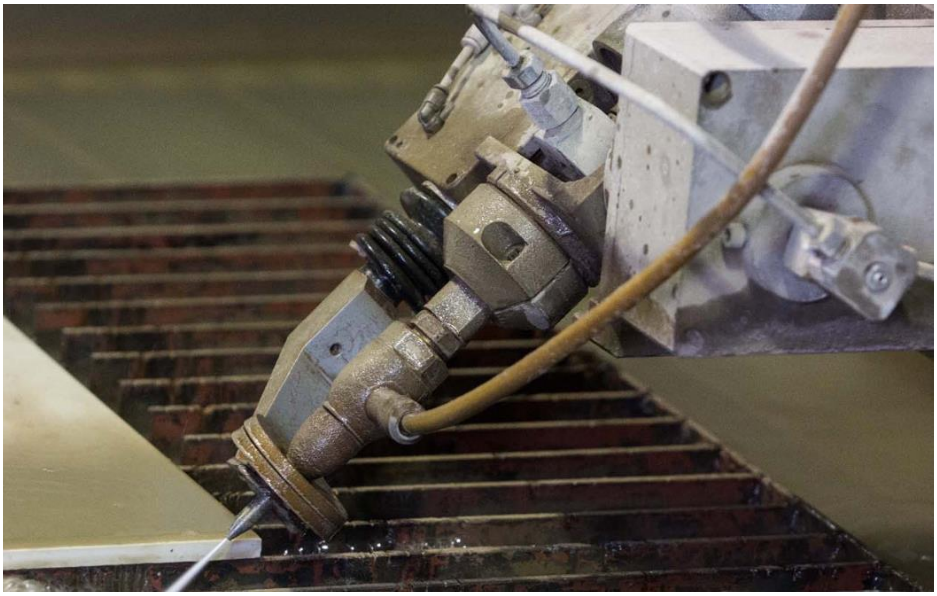


Fig. 11.4: Water-jet cutting machine in detail [140]

In the next Table 11, individual technical parameters of the water-jet cutting machine are depicted:

Table 11. Technical parameters of water-jet cutting machine [140]

Machine technical parameters	
Maximal pressure	400 MPa
Maximal flow rate	4,5 l / min
Input power	50 kW
Repeatable positioning portability	± 0,03mm
Cutting head movement accuracy	± 0,05mm
Working speed	0–16000 mm / min
Cutting width	0.1–0.3 mm
Cutting accuracy	up to 0.1 mm
Maximal working surface	3,500 x 2,000 mm

The result of this step can be seen in the picture below. Because of the possibility to apply the stress test even to the complete ring, also this ring has been after the sample testing manufactured. The complete process of testing will be described further. Every type of sample is manufacured in quantity of 10 pieces for individual testing method. These results can be further seen in Table 9 and Table 10.

Fig. 11.5: An example of manufactured samples-concept 3, concept 2

In term of material side, the composite this material has been purchased from the DELTATECH company and exhibits low to high viscosity range. These types of composite prepregs offer a very good combination of cure reactivity, versatile processing, and availability in fabric and unidirectional fiber formats. They further allow processing by oven vacuum bag, autoclave, and press molding. Considering that these parts are manufactured by the method of press vulcanization, the cycle of curing cycles 12-20 minutes at 135 °C has been selected. The matrix of this prototype is DT 806 [111] and its properties can be seen in Table 12.

Table 12. Properties of prototype matrix – DT 806 [111]

Material DT 806	
Maximum glass transition temperature Tg	**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

The thickness of the individual sample is 8 mm. The width of smaller samples is 140 mm and 175 mm of larger samples. The height of individual sample is directly proportional to the dimensions of these parts and differ from 22 mm to 34 mm. The thickness between grooves increases from 3 mm to 7 mm for the most solid samples.

11.2 Loading of samples with variable dimensions

In a process of sample testing, three-point bending method has been selected. This testing was undergone at the ZWICK 1456 device and evaluated by the Test Expert II equipment. The testing method is based on standard CSN EN ISO 178 (640607). Composite parts have been loaded in two different directions as mentioned in Figure 11.6 and 11.7. All the testing was carried out at the room temperature. Evaluated variables are the bending strength and the elasticity modulus of the individual specimen. Every part has been subjected by loading up to the component failure.

Fig. 11.6: Loading of the specimen by the three-point bending in the first direction

The results of the testing will be described further in the section of the statistical analysis of this measurement.

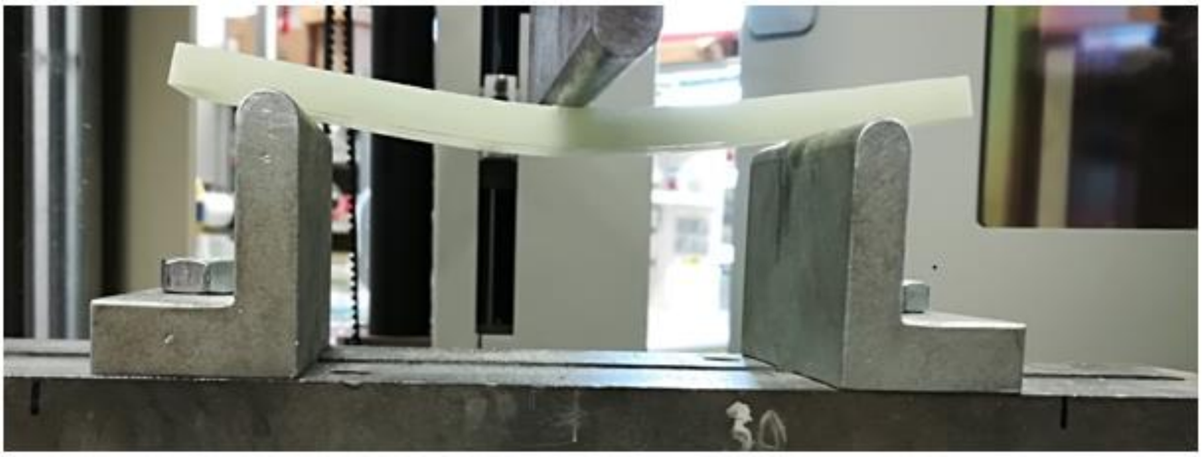


Fig. 11.7: Loading of the specimen by the three-point bending in the second direction

For the comprehensive understanding of the composite rings reaction to loading, one ring based on the results of statistical analysis manufactured and loaded by the pressure (as can be seen in Figure 11.8). This further means selection of sample with sufficient distribution of grooves and appropriate rigidity of the sample with dimensions and thickness that will be applied to the final external fixator.

Fig. 11.8: Loading of the specimen by the pressure

11.3 Evaluation and selection of the design with an appropriate weight/rigidity ratio

One of the most important knowledge from the sample testing is suitability of the individual sample dimensions to the final external fixator ring design.

For this requirement the sample with the suitable weight / rigidity ratio can be selected.

Table 13. Results of sample testing – version 2

	1		**2**		**3**	
	E [MPa]	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**
X_A	36281	4408	30056	3836	28753	3216
s	954	106	1206	125	1359	137
v	2,6	2,4	4,0	3,3	4,7	4,3

Table 14. Results of sample testing – version 3

	4		**5**		**6**	
	E [MPa]	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**	**E [MPa]**	**F_{MAX} [N]**
X_A	34291	4268	30085	4056	21000	1500
s	1174	142	1327	133	1498	245
v	3,4	3,3	4,4	3,3	7,1	16,3

Firstly, as can be seen in the previous section of dissertation thesis, the sample 1, 2, 3 represents the second version of fixator design (Table 13), that is not the most suitable version of fixator design as described before and thus, serve as a suitable option if the 3rd version of sample is not suitable from the rigidity perspective. Nevertheless as shown in Table 14., the sample stiffness is sufficient and thus the dimensions and the shape of the final external fixator rings can be selected from the sample 4, 5, 6.

While the rigidity of the ring is a significant factor for the overal fixator stiffness, the 4th and the 5th version of the sample from the results has been extracted and with the reference to the effort to the weight and dimension minimization, the 5th version as the final version of the fixator ring design has been determined. The results of the 5th version are also similar to the 4th version, that is however version increasing the fixator weight.

Based on the results in the Table 14. the arithmetic mean of the maximum force for sample 5 is merely about 5 % smaller than the arithmetic mean of force for the 4th version. In comparison to this minor decrease of maximal force, the weight of the ring is for the 5th version about 25 % lower than the weight of the 4th version. Individual deformation curves measured for the 5th version are depicted in the Figure 11.9 below.

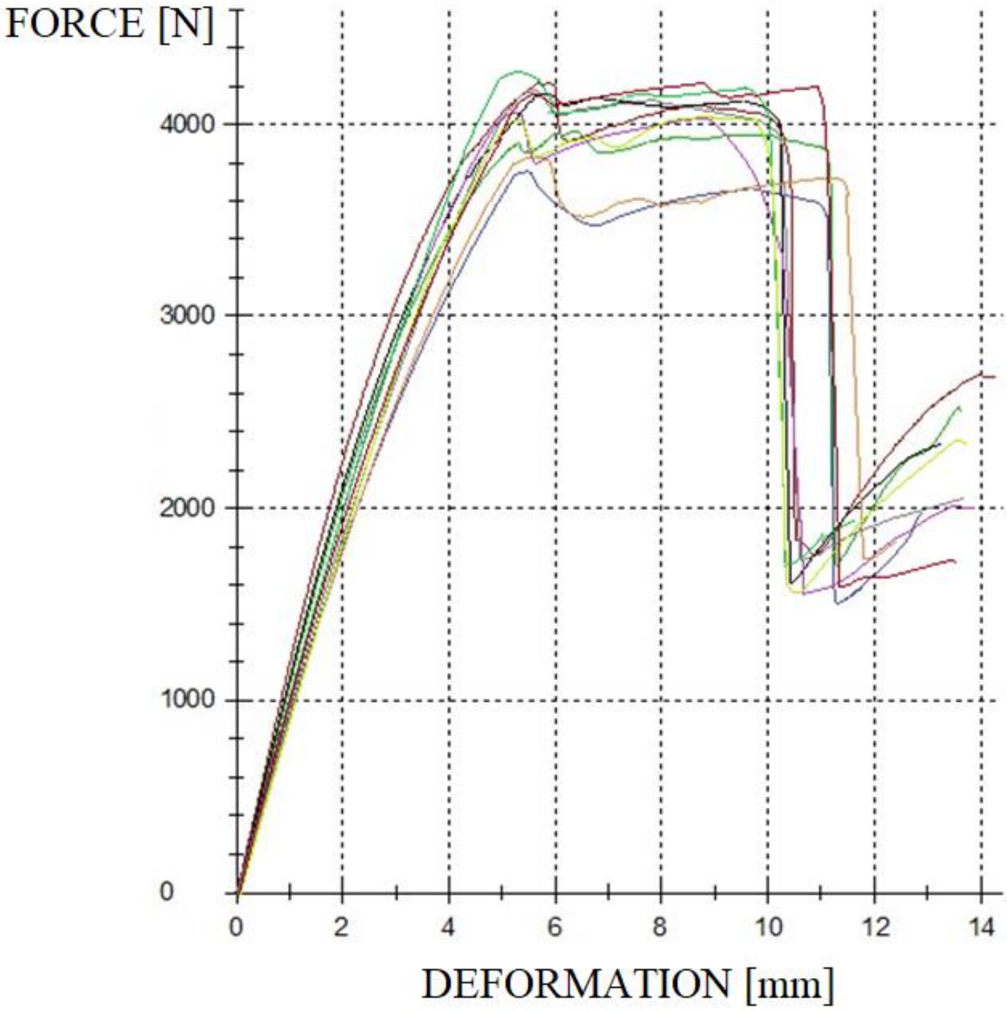


Fig. 11.9: Deformation curves of the 5th sample

The last version that can be suitable as an external ring profile is the 6th version of composite sample. The result for this type of construction reports significantly smaller amount of maximal force depicted during the three – point bend testing the 4th version. Even if the final weight of the 6th version dropped to the 48 % compared with the sample 4, the rigidity decreased to the unrealiable value, where the large deformations occur even during the early stages of the loading process as can be seen in the Figure 11.10.

Fig. 11.10: Composite sample – version 6 during the process of three - point bending

11.4 Loading of external fixator composite ring

Apart from the testing of individual samples, even the ring with profile selected in the previous section has been loaded. This ring strapped in the testing machine can be seen in Figure 11.8, while the fractured ring after the process of stress testing can be seen in Figure 11.11.

Fig. 11.11: Fixator ring with fracture after the loading process

As can be seen in this examination, the largest deformations and fractures occur in the area of the longer groove in the inner diameter. In this part, the ring collapses. The progress of deformation under the load can be observed also in Figure 11.12 below.

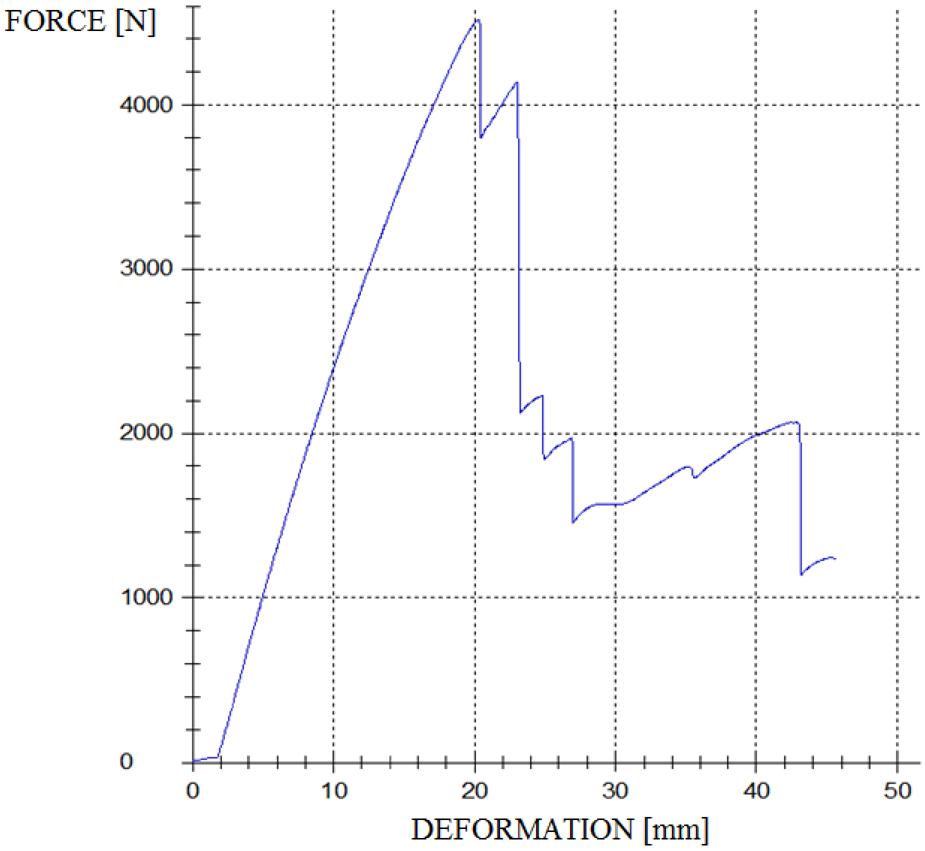


Fig. 11.12: The fixator ring deformation occurring under the load

In this graph, fixator ring behavior under the loading can be seen. There is an evident character when the loading force reaches the value around 4550 N. In this point the loading force is significantly declining to the value around 1500 N. In comparison with real part (Figure 11.8) in this point, ring fracture occurs. Further, there can be seen another growth of the loading force, that is in comparison with a fractured part region, where the inner diameter of the ring is already collapsed and another force is transferred to the external diameter. At this point, the testing process is terminated, whereas another loading and from that resulting deformation is not necessary for further knowledge of ring behavior.

On the other hand, this test also provides information, where the possibility of further improvement of fixator ring in term of the part stiffness can be obtained. That could be an important knowledge especially when the problem of larger deformations or ring fractures during the fixator use occur.

12. DEFORMATION ANALYSIS

The second part of the unified test design mentioned before is the deformation analysis which submits fixator design by more detailed analytical evaluation of the external osteosynthesis device. The process is described in this prepared test and will be discussed in detail in the upcoming section.

12.1 Preparation of deformation analysis

One of the prior parts of the deformation analysis is test of complete fixator as can be seen in Figure 12.1. The analysis had a similar course as analysis mentioned before (that also means that as has been mentioned before, the material of compisite part is quasi-isotropic and thus can be evaluated as an isotropic structure during the deformation analysis), just the individual dimensions and shape of external rings has been adjusted with respect to the selected final profile of composite ring (version 5). Fixing constrains in the lower part of the fixator simulates contact of the foot with the ground, while loading force in the upper part of the fixator simulates strain coming from the human body. In comparison with analytical evaluations mentioned before, the main goal of this test is the simulation of the static testing of the whole fixator. This testing is derived from the testing methods mentioned in [6], where the testing forces increasing from 5N with further growth of 5N (what means growth from 5N to 10N, 15N, 20N, etc.).

Fig. 12.1: Deformation analysis setting

In term of mesh quality, the table below shows that the mesh setting and quality is sufficient. Main material parameters applied during this evaluation are Young modulus (22 000 MPa), Poisson ratio (0,35) and Shear modulus (4400 MPa).

Table 15. Element quality

Criterion	**Good**	**Poor**	**Bad**	**Worst**	**Average**
Stretch	713952 (99,92%)	570 (0,08%)	0 (0,00%)	0,131	0,627
Aspect Ratio	659056 (92,24%)	55180 (7,72%)	286 (0,04%)	10,541	1,900

Based on the setting mentioned before, the deformation analysis has been computed and the results seen in Figure 12.2 and 12.3.

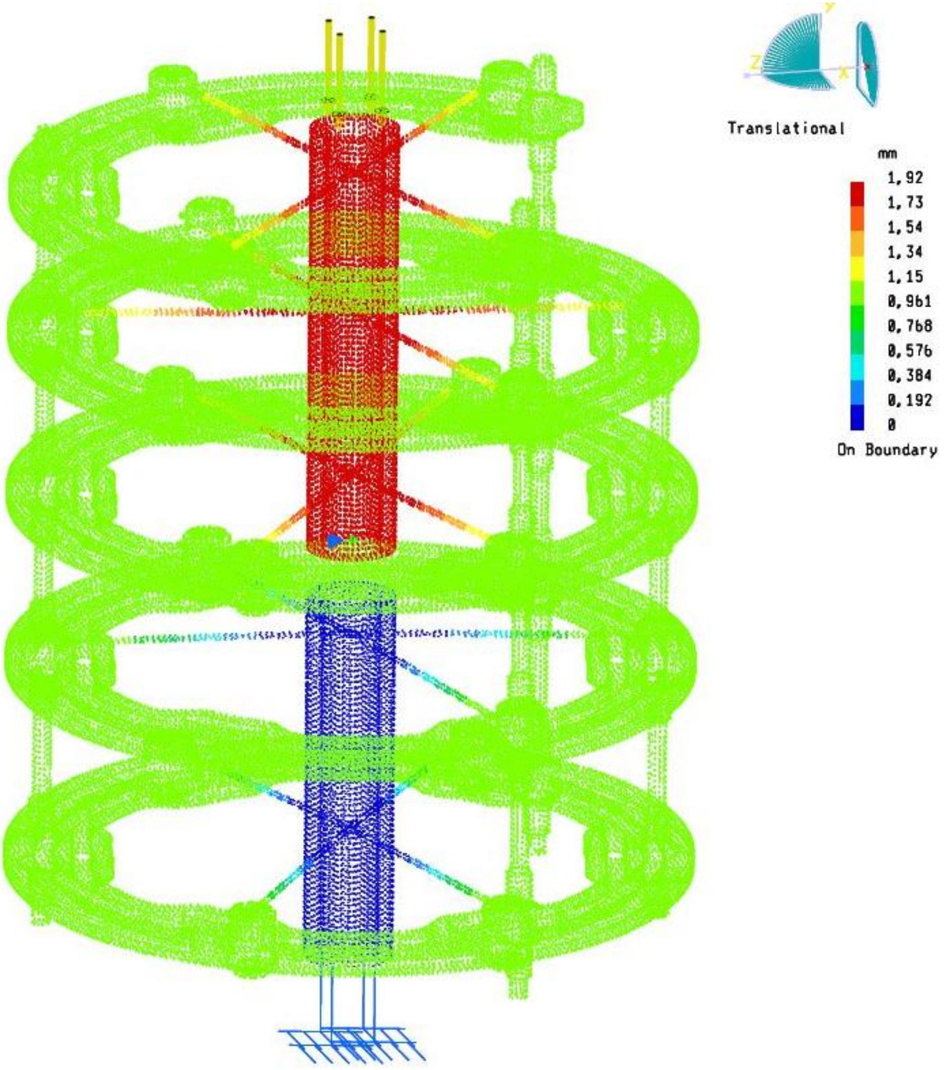


Fig. 12.2: Results of deformation analysis

The test continued up to the force 53 N, where the final deformation reached value slightly below 2 mm (that is also the maximal deformation defined by the surgeon).

12.2 Displacement analysis of the fixator (bone replacement)

Next part of deformation analysis in this unified test is related to the deformation under the load. This result has already been slightly described in the previous part concerning test preparation. Further knowledge gained from this part is also the area, where the largest deformation occurs. As can be seen in Figure 12.3 the area of the largest deformation under the load originates in the upper part of the fixator that simulates the upper piece of fractured bone.

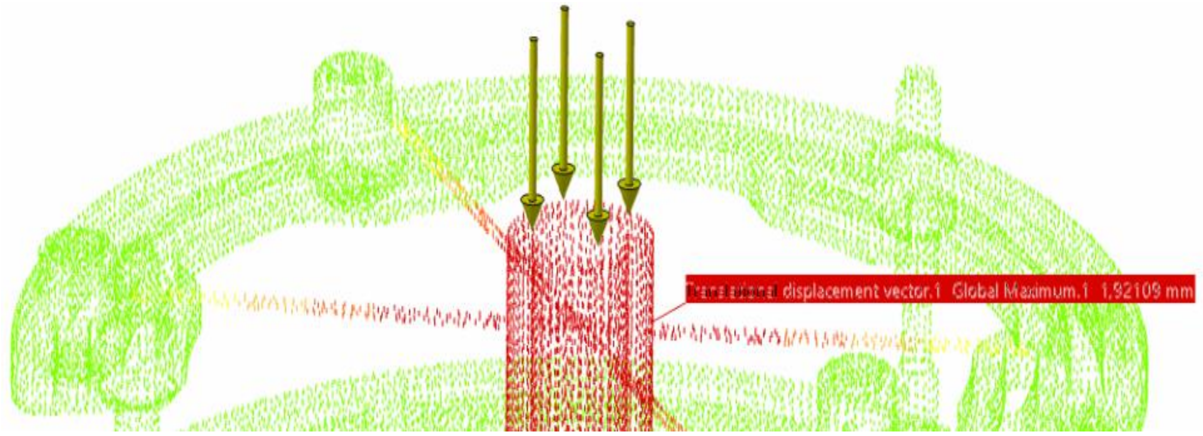


Fig. 12.3: Results of deformation analysis – are of largest fixator deformation under the load

In the Figure 12.2 is shown that the smallest deformation occurs in place of the lower piece of the fractured bone. This also further means that if the bone fragments are not too complicated in distribution in the fractured leg, then 2 rings of an external fixator with its Kirschner rods are a sufficient attachment in the lower part of the leg. Whereas, the three rings (containing also three-quarter ring are necessary for the upper part of this osteosynthesis device.

As can be seen in Fiure 12.2, the average deformation of composite rings is around 1 mm and the deformation of the Kirschner rod is dependent on the part of the broken bone in which is connected.

12.3 Evaluation of the possibility of permanent rings deformation

The final examination of the 2nd part of the unified test is th evaluation of rings deformities evolving due to the load application. As seen in Figures with the deformation above, this possibility of permanent ring deformation is secondary (deformation of rings culminates around 1 mm) and thus further examination in these part is not necessary.

One of the potential problems on account of this deformity could bet the impossibility of individual connecting rods movement in deformed grooves, but at a value around 1 mm it is not an actual issue.

12.4 External fixator manufacturing

Whereas the initial two parts of the unified test has been successfully finished, an appropriate profile of external fixator has been selected, then further test continuation is the external fixator manufacturing.

Before the manufacturing process will be summarized, the composite material lay-up is introduced in the following Figure 12.4, where the 13 layers with different fiber direction is depicted.

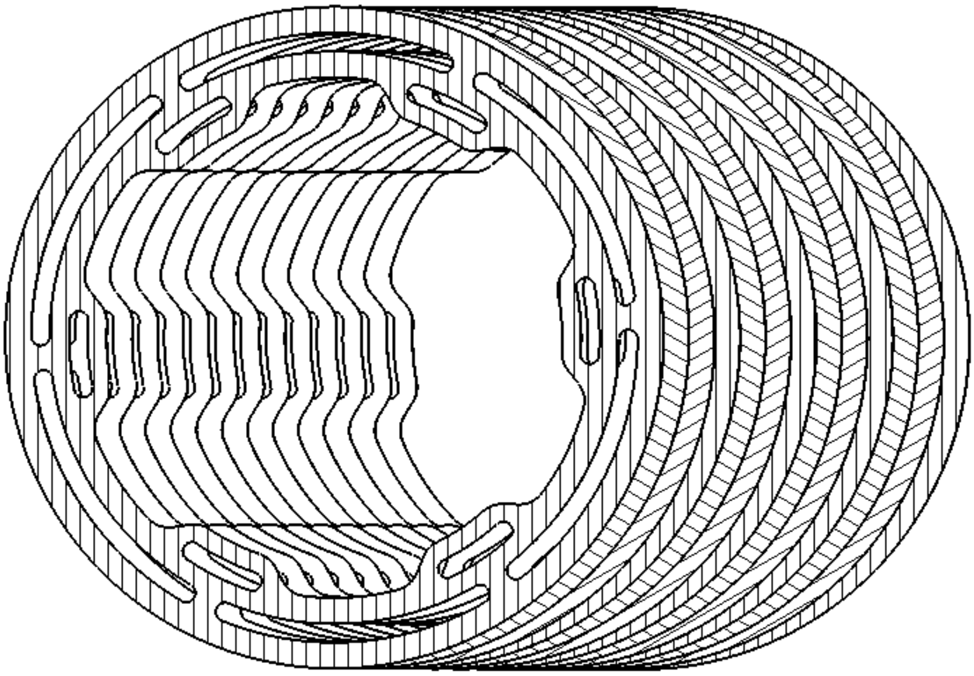


Fig. 12.4: External fixator ring - lay up of composite structure

From the material point of view, the external fixator rings made of glass fiber composite (the material properties are mentioned in Table 10. 2) have been manufactured. That means the manufacturing of 4 pieces of the full ring and the production of one piece of the three-quarter composite ring.

For the better understanding of material layout also the material cut has been implemented. As can be seen in Figure 12.5, individual layers alternates in the individual layer as mentioned in Figure 12.4 and thus the analytical evaluation with the replacement of quasi-isotropic material to isotropic is an important move.

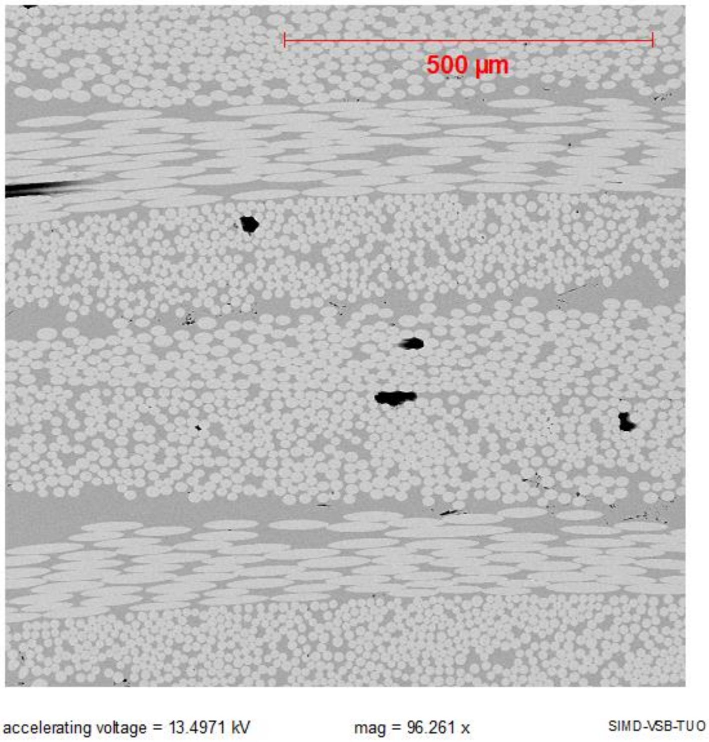


Fig. 12.5: Composite material structure after the cross – section cut

In the Figure 12.6 also the material preparation for this section cut can be seen.

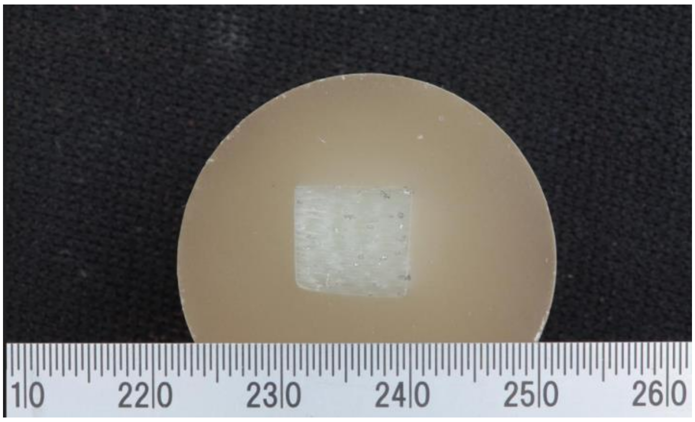


Fig. 12.6: Composite part preparation

In the next step, the connecting components have been manufactured together with the connecting rods and the Kirchner rods made of surgical steel have been purchased. The last part of this process was the assembly of complete osteosynthesis fixator that is depicted in Figure 12.7. And also the assembly with th polymer bone as can be seen in Figure 12.8 below.

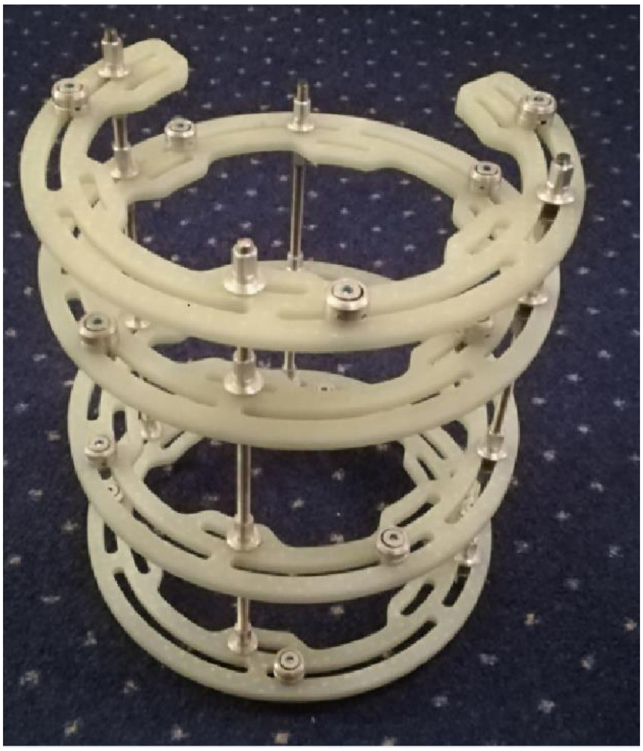


Fig. 12.7: Assembled external fixator with composite rings

Fig. 12.8: Assembled external fixator together with the polymer tibia bone

13. STRESS TEST OF COMPLETE FIXATOR

This evaluation is the last part of unified test that closes all the testing period.

13.1 Test preparation

In order to cover the simulation of the healing process of the patient, there is a neccessity to design the test folowing the loading of external fixator during the healing process. This period contains surgery, the healing time, when the fixator is not loaded by the patient, but the healing process occurs during the rest and the final part of the treatment that contains walking with this external fixation device and from the mechanical or biomechanical perspective is the most important part of the healing procedure.

Considering the above mentioned, specific test based on the surgeons experience has been designed (Figure 13.1). It contains several weeks of walking period that is boardered on both sides by the pressure testing investigating the state of this orthopedic device before and after the cyclic loading. One of the test is included into the cyclic period with regard to get better understanding of how the fixator reacts to the loading.

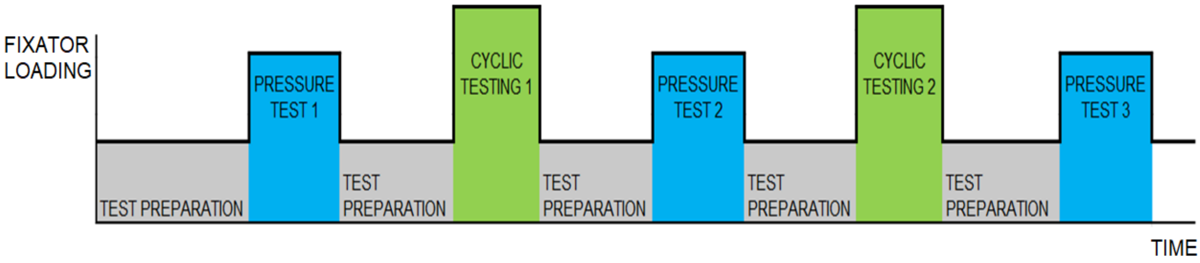


Fig. 13.1: Test design

13.2 Development of cyclic testing machine

Before this process of testing could be created, there is a necessity to develop the cyclical testing machine directly for this application. Since the design and manufacturing of this machine have been done during the period of doctoral studies at the Department of Production Engineering at the Tomas Bata University, this design was processed within the master thesis of the full-time student Matěj Homola. He has been creating his master thesis under the supervisor who is the author of this dissertation theses. Thus, the static testing machine will not be described in a detail (because of the fact that is further described in the student´s master thesis) and will be just depicted in Figure 13.2 below.

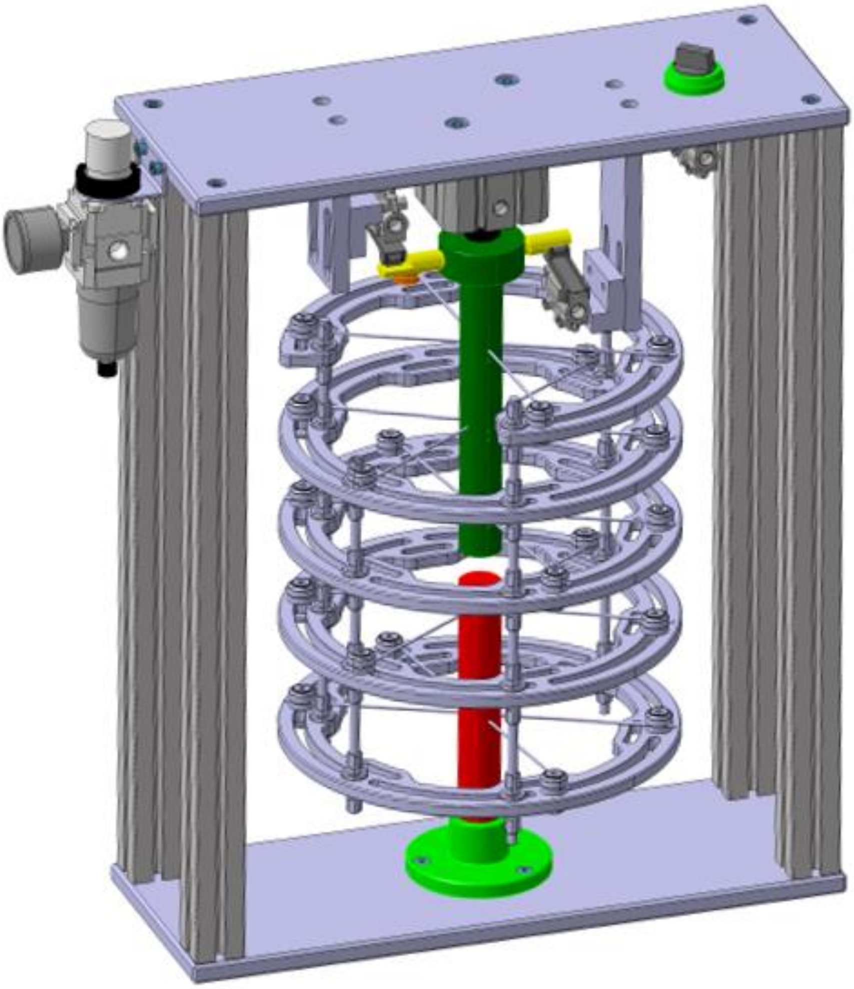


Fig. 13.2: Cyclic testing machine designed by Matěj Homola assembled with an external fixator

As can be seen in the assembly, this machines is composed of frame, pneumatic components creating the necessary cyclical loading and controlling systém serving for an appropriate speed and pressure setting. In this assembly also the fixator clamping rods and fixator can be seen.

After the manufacturing process of this testing machine that has been done under the master thesis of Matěj Homola, it was tested together with a real external fixator (Figure 13.6).

Another testing machine used for the stress test evaluation is a universal testing machine from the company Zwick-Roell. This facility is shown in Figure 13.3 during the static testing of composite samples. During the process of fixator testing, this equipment has been used for the pressure test of overall fixator.

Fig. 13.3: Universal blasting machine

13.3 Pressure loading

One of the first parts of the closing part of the overall testing of this new fixator design is a pressure test. The objective of this test is the verification of the fixator in term of deformation under the load. The fixator has been mounted on the universal blasting machine, the testing set up has been created. That further means adjustment of test speed (1 mm = 2 minutes), maximal deformation (15 mm). And the pressure loading test has been activated. The assembly of fixator with the machine is pictured in Figure 13.4.

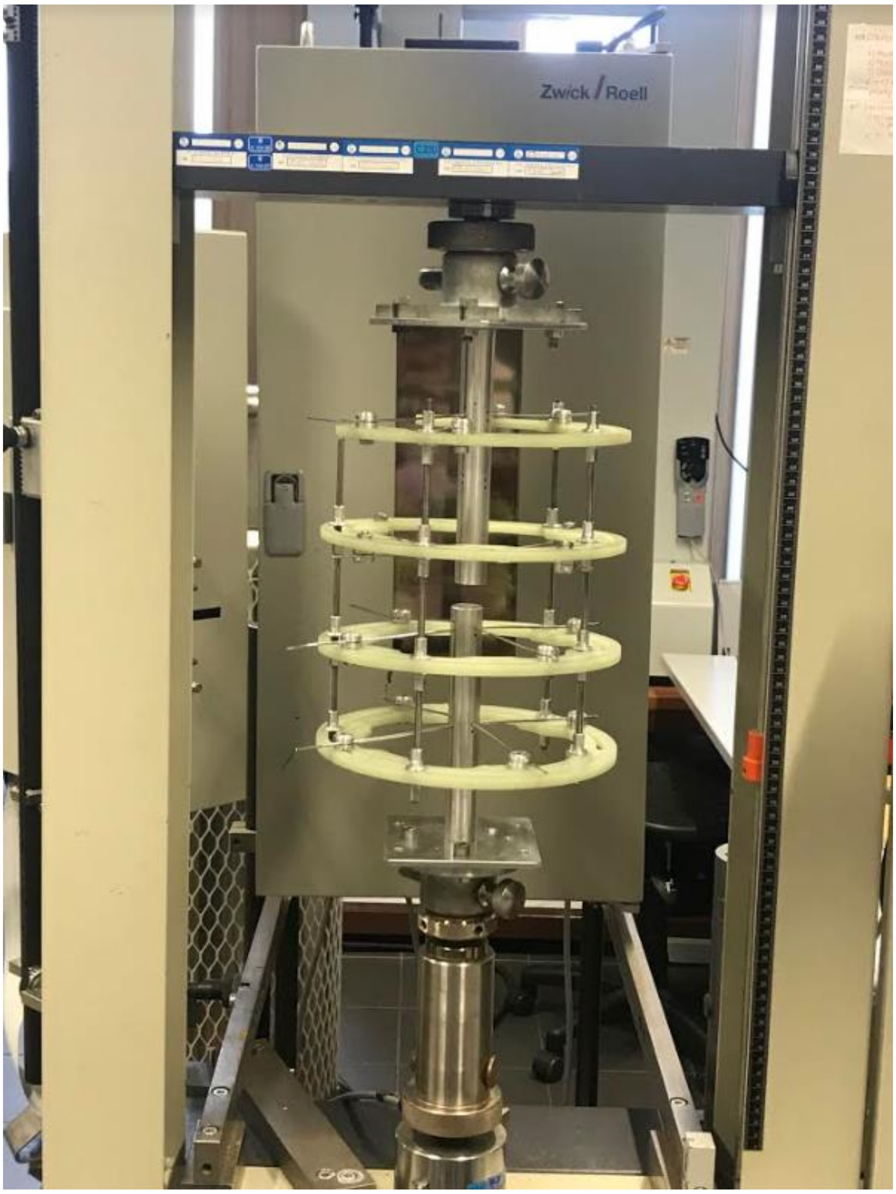


Fig. 13.4: Universal blasting machine with an external fixator

The result of this test is shown in Figure 13.5 where the initial deformation is depicted. In term of external osteosynthesis rigidity, the most important location of the measurement is from zero to two millimeters (which is indicated in the graph in blue color). In this range, an approximately linear curve can be seen and more importantly the strain required for this deformation (2 mm) reaches the value about 77 MPa.

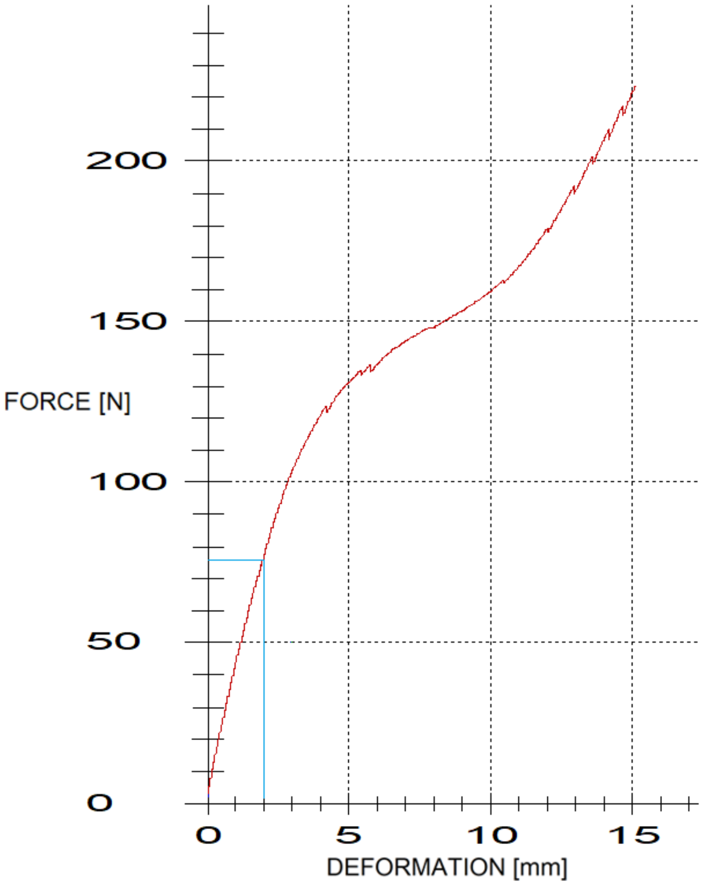


Fig. 13.5: Fixator deformation under the load

13.4 Cyclic testing simulating 4 weeks of walking

In the point, where the initial pressure measurement is finished and compared with the analytical method of fixator evaluation, another part of stress testing can be applied. That exactly means a simulation of walking with the fixator for another four weeks. In this time, while the walking is a necessary part of the healing process [54, 112, 113, 114], average patient does approximately 2000 steps in one day that is 1000 steps for each leg what means cyclical loading 1000 moves in 1 day. For four weeks it is 28000 steps. While the cyclic testing machine (mentioned in Figure 13.5 is able to perform 4 cycles in 1 second, then the accelerated test took place over 2 hours. During this type of testing, the new fixator has been loaded 28000 times and the stress during individual loading raised to the value of 300 N, that is the weight of the average loading of fixator by the patient [112, 115]. This process of simulation is based on the standard CSN EN 62366-1 (364861) and the fixator loading during the healing process.

At the moment when the test was finished, the fixator has been subjected by the observation if any part is deformed, destructed or even missing as it could affect testing significantly. None of these errors has been confirmed and thus the osteosynthesis fixator was removed back to pressure testing at Zwick-Roell testing device.

Fig. 13.6: Cyclic testing machine manufactured by Matěj Homola connected with the manufactured external fixator

13.5 Pressure loading after 4 weeks of walking simulation

During the second examination of the fixator by pressure loading the graph showing the dependence of the deformation on the load has been recorded and can be seen in Figure 13. 6.

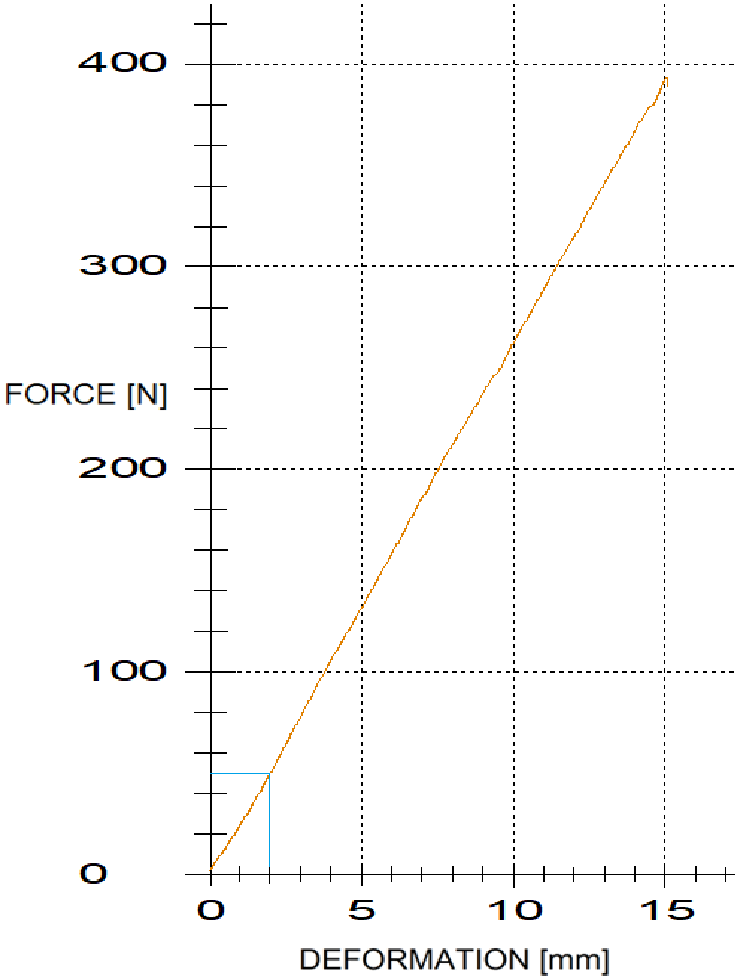


Fig. 13.7: Fixator deformation under the load after the first period of cyclic testing

In the graph above and in comparison with the pressure testing that can be seen in Figure 13.5, the overall decrease of loading necessary for deformation is noticeable. After 4 weeks of testing, this force forming a deformation of 2 mm decreased from 77 N to 53 N. That is the result still convenient for external fixator application.

13.6 Cyclic testing simulating another 5 weeks of walking

In the next step of cyclic testing, an examination proceeded for longer time simulating another 5 weeks of walking with this orthopedic device. The fixator has been mounted on the cyclic testing device and at the moment this examination has been completed, the condition of the fixator has been evaluated again.

After completion of this inspection, none of the errors of measurement, deformation or destruction of fixator as well as the cyclic testing machine has been found. Thus the final pressure testing can be done.

13.7 Pressure loading after 9 weeks of walking simulation

The last pressure test closing all of the unified testings of external fixator has been conducted under the same condition as the tests before. In the graph in Figure 13.6 the deformation of 2 mm occurring already under the force of 38 N what is an insufficiently high force in this deformation range. On the other hand, this deformation occurs after 9 weeks of walking simulation which is typically not the condition in which the fixators are tested. More detailed analysis of this result will be described later.

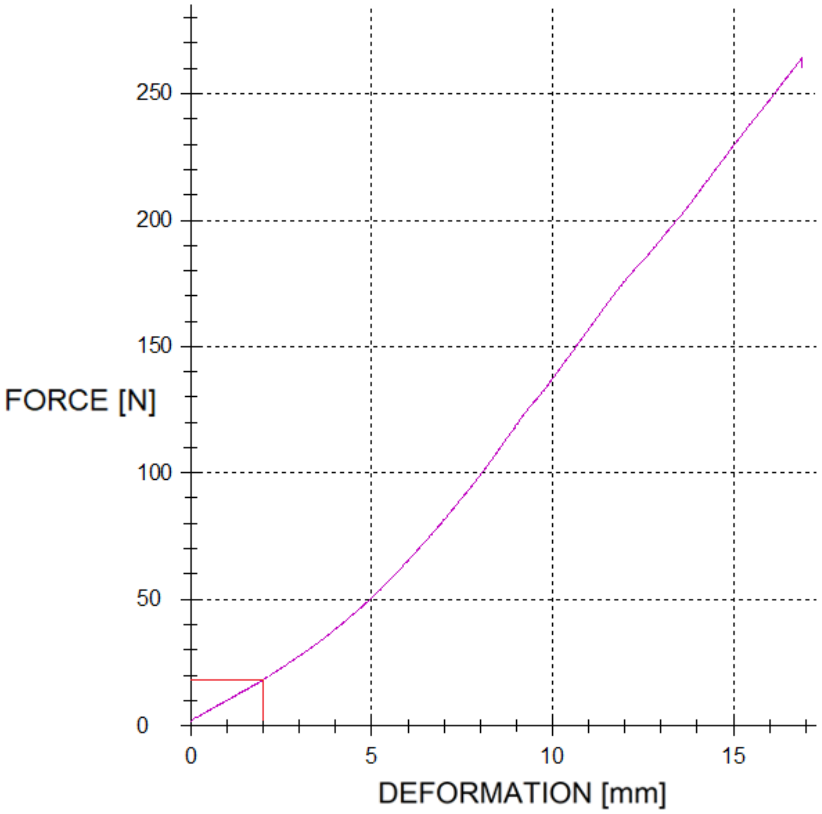


Fig. 13.8: Fixator deformation under the load after the second period of cyclic testing

Looking in the Table 9.1 this examination has been the last part of the unified test. After this, the testing period is closed and the individual results will be compared with the desired status from the test or theoretical part.

14. EVALUATION OF THE UNIFIED TEST COMPLETION

One of the last parts of the complete thesis is the evaluation of overall unified fixator testing method and also an evaluation of the complete fixator design.

At the first point, the test can be evaluated. During the test creation, these key points have been realized:

- Before the test itself, an innovative external fixator has been designed and improved using deformation analysis, surgeon recommendations, and individual evaluations.

- Samples of different shapes and dimensions have been manufactured and the most appropriate sample has been selected and used as a model example for the further shape of external rings.

- The whole external fixator structure has been examined by the deformation analysis and from that, the characteristics of fixator have been evaluated.

- After these sections that confirmed and improved the osteosynthesis fixator design, individual components have been manufactured and the fixator was assembled together.

- In the part of the stress test of the real fixator, the pressure test has been combined together with the cyclical testing simulating walking of the patient during the healing process (for this examination, the testing machine for cyclical testing has been designed and manufactured by another student mentioned before).

During the fixator examination by the unified testing method, the most important results have been observed. These include:

- Selection of the suitable external ring profile.
- Displacement analysis of the fixator.
- Pressure test in the course of cyclical loading.

These results mentioned above are primary results of external fixator examination, that must be achieved for successful design completion. Further, from other results, the 85 % of them must be correct if the fixator design should be identified as suitable design and innovation with the recommendation for further examination by the long-term test that was further described in the theoretical part of this thesis.

14.1 Evaluation of new external osteosynthesis fixator design

With the closer look to the section with results of individual tests and deformation analysis, it is evident, that the three major and most important results mentioned above are met. There can also be seen that also of the analysis in the first and second section are successful.

During the third part of the test, containing deformation testing most of the parts went well, just in the last part, where the pressure test after 9 weeks of walking is performer, the resulting stress required for the deformation of external fixator in the range of 1 millimeter declined under the permissible limit of 53 N.

When evaluating the entire design and test of the fixator, just one of all parts of this test has not been met. For a total number of twelve tests, that means that aproximately 91 % of the results are achieved and in comparison with the desired 85 % of successful results this new design of external fixator can be labeled as the prototype suitable for further more sophisticated and more expensive testing for the final attestation of this product.

For the possibility of further testing of this orthopedic device, the innovative design of external fixator has been also assigned into the patent proceedings, where this new designed will be officially protected.

14.2 Evaluation of composite material application

Based on the results mentioned in the previous section, the application and innovation of external fixator through the composite material has been a useful move toward new fixator design. Thus, the application of these composite ring is a recommended move to the overall fixator improvement in the future.

Table 16. Unified test of the innovative fixator with the results.

UNIFIED FIXATOR TESTING METHOD	
Test / analysis description	✓
A. Evaluation of fixator rings loading capacity	
1. Loading of samples with variable dimensions	✓
2. Evaluation of results and design with good weight/rigidity ratio selection.	✓
(Application of this profile in the fixator design)	✓
B. Analytical evaluation of deformation	
1. Displacement analysis of the fixator (bone displacement)	✓
2. Evaluation of the possibility of permanent rings deformation	✓
C. Stress test of real fixator	
1. Pressure loading	✓
2. Cyclic testing simulating 4 weeks of walking	✓
3. Pressure loading after 4 weeks simulation	✓
4. Cyclic testing simulating another 5 weeks of walking	✓
5. Pressure loading after 9 weeks simulation	✗

15. CONTRIBUTION OF THESIS

One of the last parts of this theses is final valorization of the overall design, manufacturing, testing, improvement and innovation of the fixator design.

During the proceeding of this thesis, broad knowledge about the external fixator development and connection with the human body has been introduced and together with that also the design of external fixator has been created. One of the important parts of this thesis is also composite material application and evaluation and thus, also the material superposition and application has been introduced.

In another part of the development, this design has been evaluated and optimized by the deformation analysis and the results in the form of new fixator design that is a significant part of this thesis as well as a contribution to the state of the art of actual external fixators.

Further, the unified test has been established and applied to this new fixator design. This test is based on the previous research and was created for the necessity to fix and unification of the testing method. Unless even the fixator design will not be used in another examination this test can serve as a model example how to create a testing process for new fixator design. This can also improve the fixator innovation widely, whereas such a complex unified method has not been created and tested so far (meant for the cases of research and innovation of external fixators in the initial phase of the research).

During the examination process, individual samples have been tested with the method of three – point bending that gives deeper knowledge about the behavior of the composite parts with grooves.

At the deformation analysis part and the experimental part, where the external fixator is examined both, by the analytical and the experimental solution the contribution of this theses can be found in the application of these methods for this type of product. Another contribution is in the application of cyclical loading, simulating the real state of the fixator during the healing process, that is not a typical examination of the overall design. This can further improve and refine the testing process completely and improve the fixator state of the art before the official attestation of this orthopedic device.

In the end, this thesis brings also further knowledge about fixator from the material and biomechanical perspective and can serve as a source of knowledge for the experts in the area of biomechanical engineering.

16. FUTURE RESEARCH RECOMMENDATION

As can be seen in the experimental part of this thesis, the unified test has been created as a method for evaluation of external fixators. This method has also been tested at this dissertation thesis with a satisfactory result.

Nevertheless, this testing method should be applied many times in the future for robust verification. Through these repeated verifications the testing method could be even improved in the future and thus serve as a reliable procedure for external fixator examination.

Another clear possibility of improvement lies in an innovative fixator design, where is the possibility of future improvement and optimization.

Firstly, the material of external fixator rings can be manufactured as carbon fiber with the epoxy matrix, then the connecting rods from the hexapod system can be used and also the static testing together with the different types of connecting components can be applied. The composite material combining epoxy matrix can bring exceptional mechanical and thermal properties [142]. This material is characterized by the optimal weight to strength ration and also as very high level of rigidity and durability. Thus, this material is suitable for aerospace, automotive, marine [143, 144] and also biomechanical constructions.

In the connection with the future research recommendation, also the testing period can be improved through the application of the wire tensioning device, that is not easily available. This improvement can further refine the overall testing process.

At the end, when the fixator will be accepted as a final design for the expensive attestation process, the result gained through this test can improve the knowledge about the fixator behavior as well as a final state of this device in the future.

As a last part also the comparison with the current technologies has been done. The individual fixator parts can be manufactured also by the additive technology of the 3D printing using matrix with carbon fibres. The price of this technology compared to the ordinary solution is just slightly more expensive and does not exceed 1000 euros for the whole fixator.

As mentioned in the another research [145, 146, 147, 148, 149, 150] the future research opportunities lies mostly in different fields cooperations as in these research for instance application of super-computer for analytical solution is.

SUMMARY

The main objective of this thesis has been the development and innovation of an external fixator with an application of composite material. During the process of critical research in the first part and also problem analysis with the surgeon, another objectives of the thesis have been introduced. These improvements are X-ray penetration through the fixator, lighter construction, and easier manipulation.

While the theoretical background for the research has been detected, even another problem of external fixator design and development has been found. This issue is connected with the process of fixator testing and evaluation. As can be seen in the research that has been done so far (mentioned in the previous sections), all the research differ significantly. In many of them, just the analytical approach is applied, while in others the experimental evaluation can be detected, but the remaining analytical solution is missing. Finally, just in a small percentage of the publication both (analytical and experimental) solution can be found. Even in these complete fixator evaluations, the process of how the results were obtained or the methods of testing differed between individual examination significantly.

Thus, another goal of this thesis containing the design of the unified testing method for an analytical and experimental solution has been established. This test is divided into three main sections. The first section relates to an appropriate ring profile examination through the experimental testing of composite samples. Another part of the test applies this recommended dimensions and shape of the rings into the design and examine overall fixator by the deformation analysis, where the emerging deformations under the load are analyzed. Based on these findings all the fixator components are manufactured and assembled together. During the third part of unified test, the condition emerging during the healing process is simulated and the state of the fixator is evaluated with a pressure test. More details can be seen in the experimental part of this thesis. One of the preparation parts for this test is fixator design, where the requirements for design and surgeon requirements have been implemented.

Whereas the unified test limits have been established and the results of this evaluation lie in the positive section of these limits, the test assesses fixator as a suitable design of an external fixator for another evaluation and attestation process. On the other hand, also the test conditions have been adjusted accurately and thus also this unified test can be recommended for further application during the fixator evaluation.

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LIST OF SYMBOLS, ACRONYMS AND ABBREVIATIONS

$\int$	Integral
σ	Stress [MPa]
ε	Deformation [-]
π	Mathematical constant [-]
ν	Kinematic viscosity [-]
V	Volume [m^3]
c	Elastic material coefficient
CATIA	Computer Aided Three-dimensional Interactive Application
C=C	Carbon-carbon bond
cm	Centimetre
CT	computed tomography
°C	Celsius degree
d	Derivation
DT	DeltaTech
E	Tensile modulus [MPa]
FEA	Finite element analysis
FEM	Finite element method
g	Gram
H	Horizontal tension
HIV	human immunodeficiency virus
I	Moment of inertia [kg*m^2]
kg	Kilogram
ksi	Pressure unit in inch systém
M	Bending moment [N*m]
mm	Millimeter
MPa	Megapascal
MRI	magnetic resonance imaging
MUDEF	Method of Unified Designation of External Fixation
MW	Molecular weight [kg·mol^{-1}]
N	Newton
OSF	Ortho SUV Frame
R	Reaction (force)
SEQ	sequence
TBU	Tomas Bata University
U	Deformation energy [J]
UNI-FIX	Unilateral fixator
V	Vertical tension
V5	version 5

APPENDICES

Matrix TDS – Technical Data Sheet
Issue 1: September 2014

www.delta-tech.it

DT806 Resins

Versatile Low
Viscosity Epoxy Matrices

Introduction

The **DT806** group of resins are in the low to medium viscosity range. **DT806** prepregs are suitable for processing by oven vacuum bag curing, autoclave bag curing or press moulding.

DT806 prepregs offer a versatile curing range from 65°C to 140°C. They can be offered with AX003 epoxy film adhesive, which has similar curing characteristics.

The main resin is **DT806R**, which is a low viscosity system suitable for solvented (fabric) and hot melt (UD) prepregs.

In addition, there is **DT806W** which offers higher tack, mainly for solvent impregnated fabric prepregs.

It is anticipated **DT806** prepregs will find uses in industrial, marine and sport goods applications.

Key Features

The **DT806** group of thermosetting epoxy resins offer a good combination of cure reactivity, versatile processing and availability in fabric and unidirectional fibre formats.

Main features are:

- Maximum DMA Tg of 135°C
- Processing by oven vacuum bag, autoclave curing and press moulding
- Flexible cure characteristics between 65°C and 140°C
- 21 days outlife at 21°C
- Low tack DT806R, Medium tack DT806W

DT806 Group of Resins

The following are the resins offered within this group:

Resin	Description	Application
DT806R	Low viscosity, unpigmented resin	Fabric (solvent) and UD (hot-melt) prepregs
DT806W	Higher tack version of DT806R	Usually for fabric (solvent) prepregs.

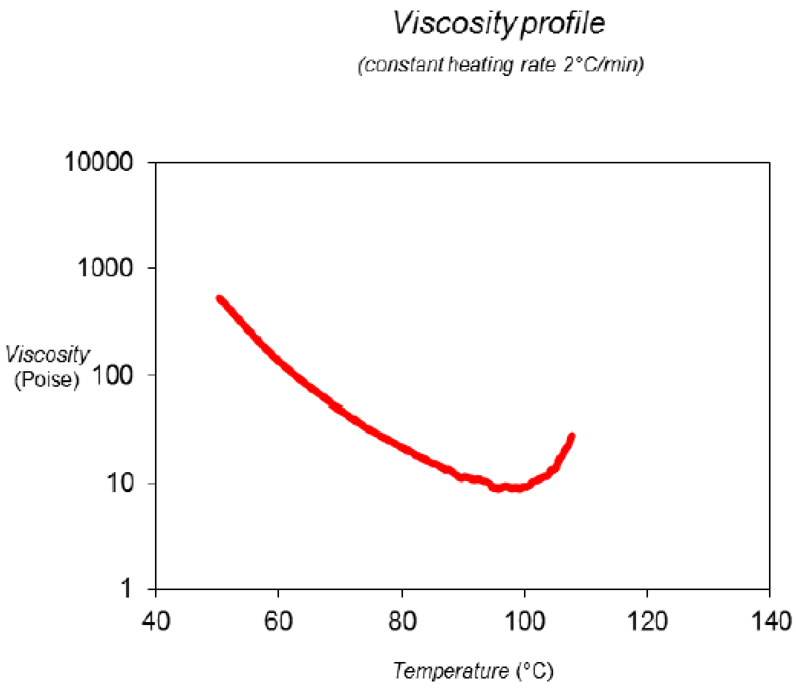
DT806 Resin Matrix Properties

Chemical nature	Epoxy Thermosetting Resins
Curing Temperature range	65 to 140°C
Density of cured neat resin	1.21 g/cm³ (DT806R)
Dynamic viscosity	Low, < 300 Poise @ 60°C, frequency 10 rad/sec, for DT806R and DT806W.
Gel Times (ASTM D 3532), For all DT806 resins.	50 to 60 minutes @ 80°C 15 to 19 minutes @ 100°C 4 to 6 minutes @ 120°C 2 to 3 minutes @ 130°C

The following charts show the rheological behaviour of **DT806R and DT806W**

Firstly, a dynamic viscosity profile for these two resins.

Followed by Figure 1 giving isothermal viscosity profiles for **DT806R**.



DT806R & DT806W

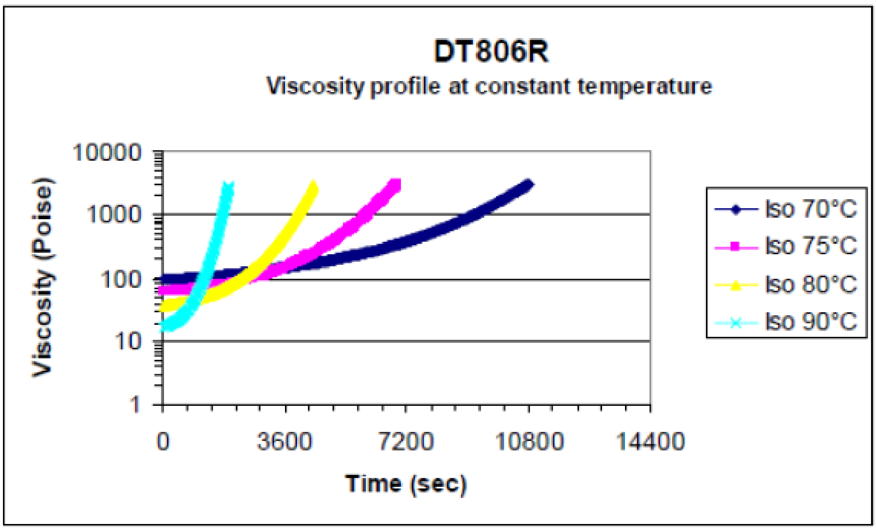


Figure 1: Isothermal Viscosity profiles for DT806R at four temperatures.

Thermal Performance of DT806R Laminates

All resins in the DT806 group have very similar thermal performance and have the same recommended cure cycles. The following table indicates the typical glass transition temperature (Tg) developed by **DT806R** laminates.

Cure Cycle	Tg (°C)
16 Hrs @ 65°C	70 to 80
5 Hrs @ 80°C	90 to 100
1.5 Hrs @ 100°C	110 to 120
1 Hr @ 120°C	120 to 130

Note: The Tangent Modulus Intercept Tg values have been measured by DMA, according ASTM D7028.

Mechanical Properties of Carbon Fabric Reinforced Laminates

Table 1 and **Table 2** below shows some indicative averaged mechanical characteristics of **DT806R** carbon fibre laminates. These are with a 200 gsm (g/m^2) high strength carbon twill fabric and a 150 gsm (g/m^2) high strength carbon fibre unidirectional prepreg.

Table 1

GG200T(Tenax HTA-3k)-DT806R-42 Fabric Laminate

Mechanical Tests	Test Method	RT
Tensile Strength (0°) (MPa)	ASTM D 3039	817
Tensile Modulus (0°) (GPa)	ASTM D 3039	56.6
Tensile Strength (90°) (MPa)	ASTM D 3039	835
Tensile Modulus (90°) (GPa)	ASTM D 3039	55.9
Compression Strength (0°) (MPa)	ASTM D 6641	710
Compression Modulus (0°) (GPa)	ASTM D 6641	54.2
Compression Strength (90°) (MPa)	ASTM D 6641	701
Compression Modulus (90°) (GPa)	ASTM D 6641	53.6
In-Plane Shear Strength (MPa)	EN 6031	128.2
In-Plane Shear Modulus (GPa)	EN 6031	3.50
ILSS (MPa)	EN 2563	79.2

Table 2

Tenax STS 24k-150-DT806R-36 UD Laminate

Mechanical Tests	Test Method	RT
Tensile Strength (0°) (MPa)	ASTM D 3039	2330
Tensile Modulus (0°) (GPa)	ASTM D 3039	124.0
Tensile Strength (90°) (MPa)	ASTM D 3039	45.0
Tensile Modulus (90°) (GPa)	ASTM D 3039	8.23
Compression Strength (0°) (MPa)	ASTM D 6641	1130
Compression Modulus (0°) (GPa)	ASTM D 6641	109.0
Compression Strength (90°) (MPa)	ASTM D 6641	154
Compression Modulus (90°) (GPa)	ASTM D 6641	8.7
In-Plane Shear Strength (MPa)	EN 6031	125.4
In-Plane Shear Modulus (GPa)	EN 6031	3.90
ILSS (MPa)	EN 2563	90.4

Recommended Cure Cycles for DT806 products

The versatility of **DT806** products allows processing by oven vacuum bag, autoclave and press moulding. The recommended cure cycles cover curing up to 120°C for the conventional bagging routes. With shorter cure cycles of 120°C and beyond allocated to press moulding.

Oven Vacuum Bag and Autoclave Curing Cycles

The following are recommended cycles up to 120°C:

Cycle 1:	16 Hours @ 65°C
Cycle 2:	10 Hours @ 70°C
Cycle 3:	5 Hours @ 80°C.
Cycle 4:	3 Hours @ 90°C.
Cycle 5:	1.5 Hours @ 100°C.
Cycle 6:	1.0 Hours @ 110°C.
Cycle 7:	1.0 Hour @ 120°C.

All these cure cycles use an initial heating ramp-rate of 1 to 3°C/min from room temperature to the cure temperature. A vacuum should be applied to the bagged component during cure. For autoclave bag curing, the applied cure pressure needs to be between 3.0 and 6.0 bar.

If using oven vacuum bag curing, an intermediate dwell of 15 to 30 minutes at 65°C can be helpful in producing a low voidage component.

Faster Curing Cycles for Press Moulding

The high reactivity of **DT806** products allows for short cure cycles if press moulding is chosen as the processing option. It is assumed a pre-prepared **DT806** prepreg preform will be placed on a hot press tool set at the cure temperature. The following are a starting point for suggested cure cycles.

Cycle P1: 15 to 25 minutes @ 125°C

Cycle P2: 12 to 20 minutes @ 130°C

Cycle P3: 10 to 15 minutes @ 135°C.

Cycle P4: 6 to 10 minutes @ 140°C.

Note: These press moulding cure times are approximate, and may need to be adjusted taking account of specific conditions for each prepreg, part and press tool.

The following graph provides data on the gel times for **DT806R** at these higher temperatures:

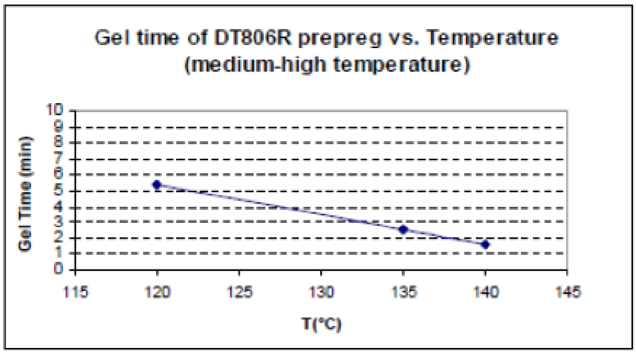


Figure 2: Gel Times for DT806R.

Post-Cure Options for Low and Reduced Temperature Cures

If maximum Tg is required then postcuring can be applied, with an initial cure of 100°C or less. This covers **Cycles 1 to 4** inclusive.

The free-standing postcure cycle is:

- Heat the part at 2°C/ minute ramp rate to the initial cure temperature (either 65°C, 70°C, 80°C, 90°C or 100°C).
- Slow the ramp rate.
- Heat the part at 0.3°C/min (20°C/Hour) to 120°C (*Important).
- Dwell at 120°C for 1 Hour.
- Cool the part at 2°C/min.

Note: *The reduced ramp-rate is essential for even development of Tg in the part and avoiding part distortion.

Processing Guidelines

Important notice: Prepregs rolls must be stored in a freezer at -18°C when not being used. Thaw the prepreg to room temperature before removing the roll from the protective bag of polyethylene. This may typically take six (6) hours. This will prevent the uncured prepreg product from absorbing moisture from the air, as this can affect the quality of the final part. After using the roll of prepreg it is recommended to seal the roll in the protective bag before replacing it in the freezer.

Prepreg Lay Up and Laminating

1. Prepreg: Pay particular attention to conform the prepreg plies to the geometry of the released mould when laminating, especially in corners of small radius of curvature.
2. A non-perforated release film must be used. Lay carefully over the laminate and mould, then seal at the mould edges with tape. This will prevent any leakage of resin from the part and coming into direct contact with the vacuum bag during the cure process.
3. Breather (non-woven polyester). Make sure the breather covers the entire part and reaches all the vacuum valves. A heavyweight breather is recommended.

4. Vacuum bag. Use a generous quantity of high temperature bagging film to cover the part. Make sure the bag can fill all corners of the part with excess film, and there is no bridging of the film which could cause a bag burst in the autoclave.
5. Make sure the vacuum in the bag is to a high level, typically 980 mbar. Check the vacuum tightness of the bag before curing, by removing the vacuum pump for at least 5 minutes. The loss of vacuum pressure should not be greater than 50 mbar.

For further information, please contact Delta-Tech's Technical Service Department.

Exothermic Reaction

DT806 are reactive resin formulations which can undergo excessive exothermic heating during the initial curing process if the correct curing procedures are not followed. Care must be taken to use the heating rates and dwell temperatures in the recommended cure cycles. The risk of exotherm increases with laminate thickness and increasing cure temperature.

If oven vacuum bag or autoclave curing laminates are greater than 5 mm in thickness, please contact our technical department for confirmation of the correct cure cycle.

With press moulding, metal tooling provides a good means of dispersing the heat generated by the resin reacting. The higher temperatures do however increase the risk, so curing beyond 140°C is not advised unless care is taken.

Available Products/Prepregs

DT806 resins can be impregnated with a wide range of fibre reinforcements, such as woven and unidirectional tapes of high strength and high modulus carbon fibre, woven E-glass, S-glass and multi-axials, with a range of fibre weights per square metre.

Prepreg Storage

Out Life: 21 days @ 21°C
Shelf Life: 12 months @ -18°C

Handling Precaution

When handling uncured resins and fibrous materials precaution should be considered. It is recommended to use clean protective gloves in order to protect the operators and avoid contamination of the components.

LIST OF PUBLICATIONS BY THE AUTHOR, PROJECTS AND THESIS SUPERVISION:

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Publications in the review process:

JABRAN, **F. TOMANEC**, HEAD, J., HOWARD, D. Peter. Editorial: Trent International Prosthetics Symposium Special Issue. Assessment of Adjustable Electrode Housing Device for Transradial Myoelectric Prostheses.

TOMANEC, Filip, Soňa RUSNÁKOVÁ Jiří KOHUT and Martina KALOVÁ. Composite external fixators: Design with subsequent FEM analysis optimization. Manufacturing Technology. 2019.

Project participation:

- Innovative therapeutic methods of locomotive apparatus in trauma surgery, registration number: CZ.02.1.01/0.0/0.0/17_049/0008441.
- IGA/FT/2017/002 - The research of polymer composite materials and tools for their simulations and processing.
- IGA/FT/2018/004 Research, simulation and evaluation of polymer and composite materials and tools for their processing.
- IGA/FT/2019/006 Research, simulation and evaluation of polymer and composite materials and tools for their processing.

Thesis supervision:

- HOMOLA, Matěj. The design and manufacturing of a testing machine for external fixators applied in medicine. Zlin, 2019. Master thesis. Tomas Bata University in Zlin. Supervisor Filip Tomanec.
- MAHDAL, Daniel. The design and optimization of the manufacturing processs of the end effector of robotic workplace within the welding line. Zlin, 2019. Master thesis. Tomas Bata University in Zlin. Supervisor Filip Tomanec.
- GAVENDA, Martin. The design of end effector for robotic workplaces with application in the automotive industry. Zlin, 2018. Bachelor thesis. Tomas Bata University in Zlin. Supervisor Filip Tomanec.
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Managing director of mechanical engineering office (**robotic lines**, transportation industry, self-purpouse machines).

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Project manager and designer **of rail vehicles** (tramvaje **SKODA TRANSPORTATION** trams, renovation of locomotives CZ LOKO).

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The development of composite orthopedic devices

Vývoj kompozitních ortopedických pomůcek

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