The development of composite orthopedic devices

Ing. Filip Tomanec, Ph.D.

Doctoral Thesis Summary

Tomas Bata University in Zlín

Tomas Bata University in Zlín
Faculty of Technology

Dissertation thesis summary

The development of composite orthopedic devices

Vývoj kompozitních ortopedických pomůcek

Author: **Ing. Filip Tomanec, Ph.D.**

Degree programme: P3909 Process Engineering

Degree course: 3909V013 Tools and Processes

Supervisor: doc. Ing. Soňa Rusnáková, Ph.D.

External examiners: doc. Ing. Petr Jonšta, Ph.D.
doc. Ing. Daniel Kytýř, Ph.D.
prof. Ing. Ildikó Maňková, CSc.

Zlín, September 2019

Published by **Tomas Bata University in Zlín** in the Edition **Doctoral Thesis Summary.**
The publication was issued in the year 2019

Key words: *composite material, external fixator, orthopedic device, deformation analysis, static testing*

Key words in Czech: *kompozitní material, externí fixátor, ortopedické pomůcky, analýza deformace, statické testování*

Full text of the doctoral thesis is available in the Library of TBU in Zlín.

ISBN 978-80-7454-857-4

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*

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 orthopedic 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.

CONTENT

1. INTRODUCTION

An application of innovative materials, as a composite is, in orthopedic devices has always been a meaningful improvement [1-6].

One of the significant fixator characteristics is the ability to transfer the load applied to the patient's extremity and thus enabling a 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 that is the one problem that will be addressed in this thesis [9, 10]. Another importance of this theses lies in the application of deformation analysis together with the experimental testing [6].

Based on these findings and cooperation with the Faculty Hospital in Ostrava, an appropriate and innovative external fixator has been designed, subjected by the analytical verification using structural analysis and later redesigned due to the surgeon's requirements.

The highest degree of importance of this thesis lies at several points:

- Design of the unified test for the fixator verification
- Improvement of the state of the art of Ilizarov external fixator
- Application of deformation analysis and design optimization
- Application of experimental testing
- Design of new shape of external fixators rings.

2. 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

    - Overall 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.

3. THEORETICAL FRAMEWORK

3.1 EXTERNAL FIXATION

External fixation as a bone or joint treating method or procedure of correcting deformities and bone length has been developed by the orthopedic surgeon G. A. Ilizarov. 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. [6, 11, 12, 13, 14].

3.1.1 External fixator overview

After the discovery of the regeneration effect of human tissue Ilizarov came with an external fixator (applied mostly to the tibia bone - 1) using Kirschner wires, which assembly can be seen in Figure 3.1. 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].

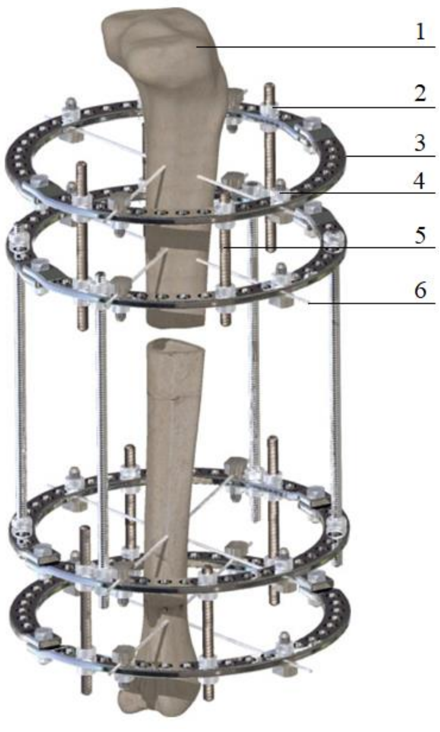

Fig. 3.1: Ilizarov external fixator [8].

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 the implementation of polymer materials as carbon fiber, glass fiber reinforced materials [18], even three-dimensional printed fixators [19].

3.1.2 Biomechanical principles

From the biomechanical perspective, there are several issues of external fixators that must be included as:

External fixator inter-relationship with a human tissue

Considering the knowledge of how the human body reacts to the inserted elements (wires and rods) and from those problems as bone burns, inflammations, etc. arising.

Clinical requirements for the construction

That further means a clear control of bone fragment position in order to set an appropriate position of individual bone pieces.

External fixator rigidity

It simply applied, the more rigid material of osteosynthesis fixator is, the tougher overall fixator is. Thus, mostly 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 [6, 33, 34, 35]. One of the important points is also the rigidity of transosseous elements, wire tensioning and torque principal. The overall rigidity is also highly influenced by the ring diameter, when the smaller diameter is, the higher overall rigidity is.

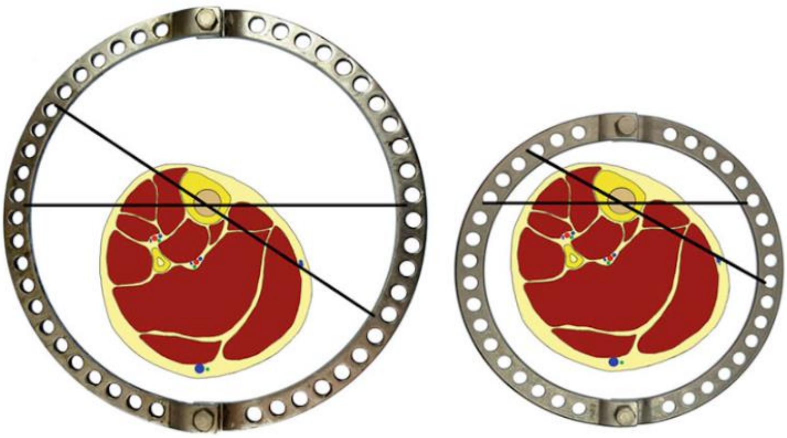

Fig. 3.2: An example of a large diameter of the external ring (left) and an accurate diameter of the ring (right) [36]

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 and fields together. future application in one fixator design together [6, 54].

3.2 COMPOSITE MATERIAL

The composite material brings benefits in comparison with the conventional materials as the superposition of different materials connection is and further gives an opportunity to achieve the same strength and toughness while the overall weight is decreased. This can be seen in the following equations [38 - 44, 51].

$$\frac{\nu_T}{E_T} = \frac{c_1\nu_1 + c_2\nu_2}{E_L} = \frac{\nu_L}{E_L} \tag{3.1}$$

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

$$\frac{1}{E_T} \approx \frac{c_1}{E_1} + \frac{c_2}{E_2} \tag{3.2}$$

The graphical interpretation can be seen in Figure 3.3 below.

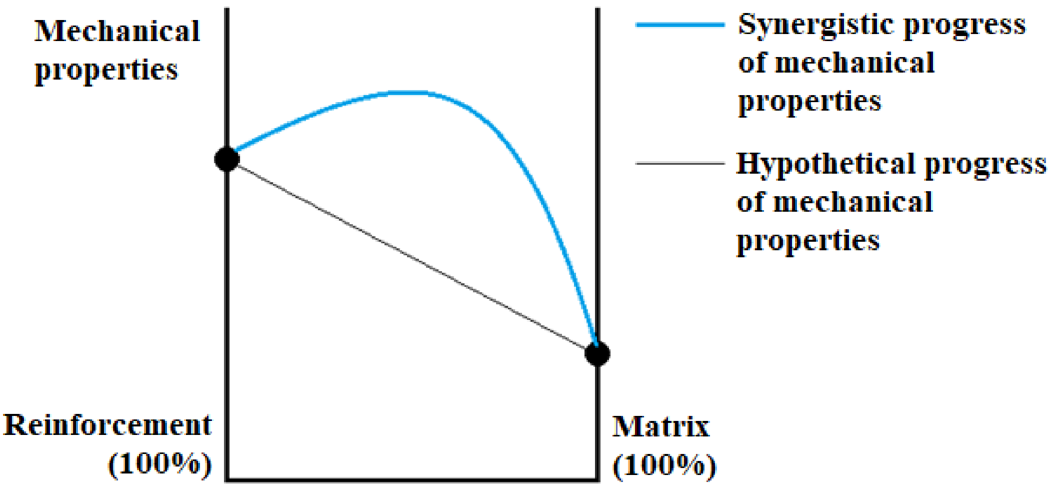

Fig. 3.3: Synergistic effect of composite material (ie. The interaction of composite)

Main components of composite structure are the reinforcement and matrix. The reinforcement can occur in different types of shape and dimensions and the comparison of individual reinforcements with the conventional materials can be seen in Figure 3.4 [42, 45, 46, 47, 48, 52, 72]. Between the matrix, the most important materials are epoxy and polyester matrix [49, 32]. One of the most important composite material characteristics are flexibility, simplicity and high product lifetime [44, 50, 54].

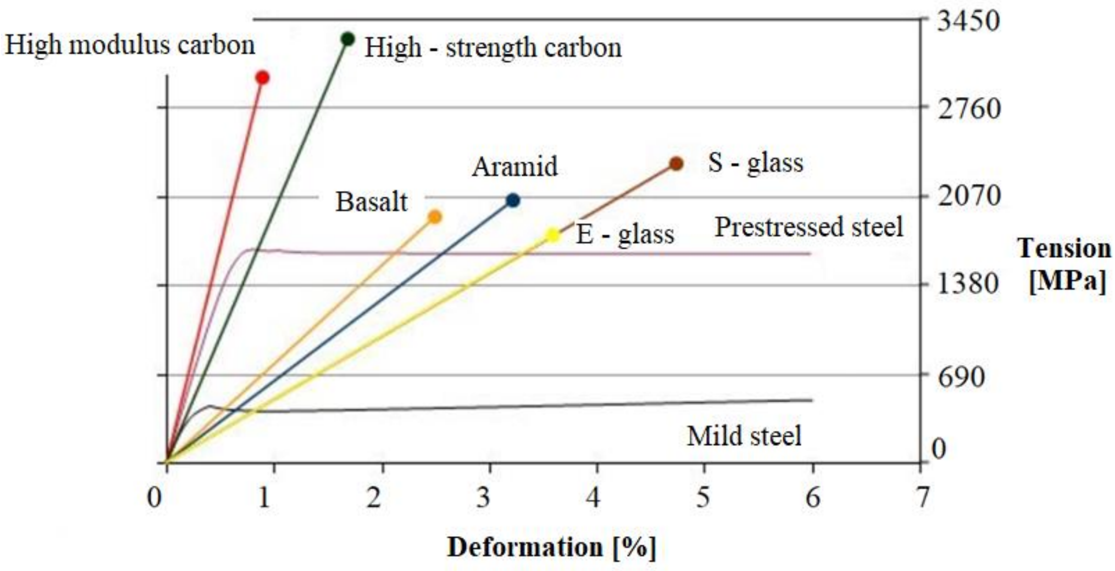

Fig. 3.4: Tension progression of different materials and reinforcements

The composite materials can be further manufactured in different material lay-up, where for the external fixator products are one of the most suitable materials quasi-isotropic composites that can be during the FEM verification analyzed as isotropic materials [22-]. An example of these types of structures can be also seen in Figure 3.5.

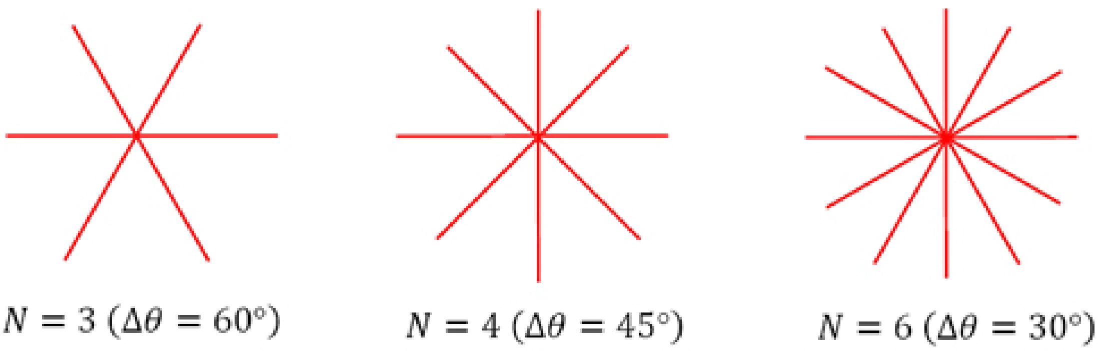

Fig. 3.5: Fibre orientations in a typical quasi-isotropic laminate [20-28]

3.3 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. Although this method is not a real situation, it brings an understanding of products physical behavior and predicts the performance of the final design. This analysis is also a good opportunity to the problems, where the weight minimalization is an important point, such in the external fixators design [64, 65].

3.3.1 Structural analysis of external fixators

Because of the fact, that the high stress arising between the bone-fixator connection, this is the most often compared detail of osteosynthesis fixator [6, 58, 59, 61, 62], some studies goes even further to the bone evaluation, while other studies compare the technical details of fixator construction [55, 60, 63].

Nevertheless, just a few investigations compared both, the analytical solution of the design and later an experimental evaluation of the real product. This FEM of fixator can be seen in Figure 3.6.

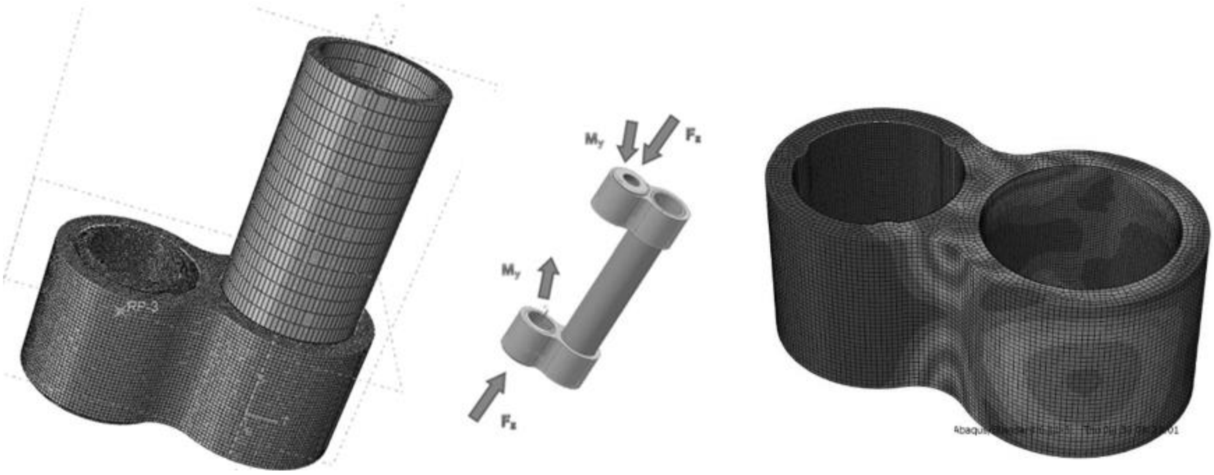

Fig. 3.6: Unilateral fixator structural analysis [76].

3.4 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. The results describe a real state of the art of manufactured external fixator [56]. As described in the previous chapter, the fixator analyzed by the FEM structural analysis is further manufactured and subjected by mechanical loading as can be seen in Figure 3.7.

In the case of the situation below, the overall system after the loading exhibits permanent deformation as can be seen in Figure 3.7. From this point, it is further possible to exactly define problematic parts of fixator design and improve the device in the future.

Fig. 3.7: The testing system for external fixator loading

Dominant characteristic during the measuring process is the rigidity or in other words an examination of osteosynthesis element to respond to displacement under the load. 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.

4. APPLIED SCIENTIFIC METHODS

Individual methods have been applied in the theoretical part firstly and after these scientific methods have been used also in the experimental part.

4.1 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.

4.2 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 overall 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.

5. EXPERIMENTAL SECTION

This part of the theses deals with the Ilizarov external fixator development together with the analytical and experimental evaluation, that has been done under the unified test designed under this dissertation thesis.

5.1 UNIFIED TEST DESIGN

Whereas the fact that there are a lot of studies investigated nowadays, also different methods of testing have been performed [59, 60, 66, 67, 72, 73, 74]. And thus there is a necessity to summarize these methods, select the more important from them and compose them to the unified testing method that will serve for this dissertation and also for further investigations of external fixators. This test is further composed of several points:

5.1.1 Deformation analysis

Based on these investigations [55, 57, 68, 69, 70, 71, 75] the important points are:

- Displacement analysis of the fixator
- External fixator deformation under the intended load

5.1.2 Identification of an appropriate ring profile

This part of the investigation is further divided:

- Loading of samples with variable dimensions
- Evaluation of results and design with good weight/rigidity ratio

5.1.3 Stress test of fixator with cyclical loading

Serving as a simulation of the real application of the external fixator in practice. This part of test is assembled from these parts:

- Pressure loading
- Cyclic testing simulating 4 weeks of walking
- Pressure loading after 4 weeks of simulation
- Cyclic testing simulating another 5 weeks of walking with the device
- Pressure loading after 9 weeks of simulation

Based on these points the overall test has been connected into the unified fixator testing method in the following Table 1.

Table 1. 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 modeling
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 a 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.

5.2 DEVELOPMENT OF EXTERNAL FIXATOR

One of the major objectives of this research is the improvement of the current state of the Ilizarov external fixator. The most problematic parts of this device are:

- Weight – creates a problém during surgery, manipulation
- Surgery – there is a problem with x-ray penetration during the surgery
- Appearance – creates a problém with social status
- Incompatibility – creating high difficulty of adjustment.

5.2.1 Development of external fixator – concept 1

The first aim of this section has been designed and model completion of Ilizarov external fixator. 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. The result of the first concept design can be seen in Figure 5.1.

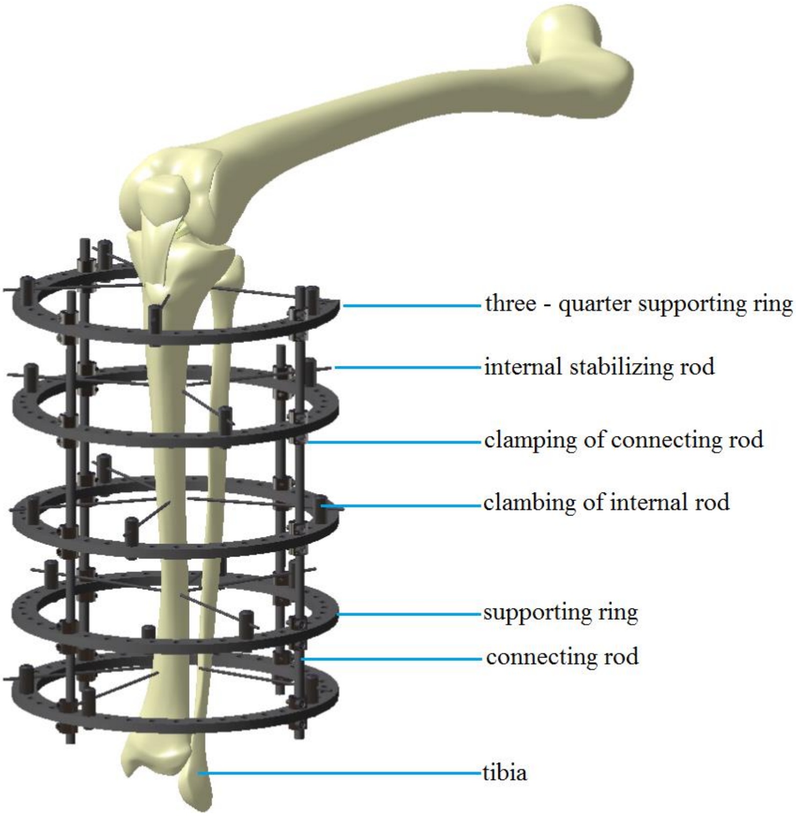

Fig. 5.1: External fixator design – concept 1

During the fixator design individual parts as the clamping system, rings have been created and later evaluated. Firstly, the structural analysis applying the MUDEF testing method has been created (shown in Figure 5.2) and later this osteosynthesis fixator has been evaluated by the surgeon. This can be seen in Table 2.

Fig. 5.2: External fixator loading during all the deformation tests

Table 2. 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

As can be seen in Table 2, several problems have been extracted and thus, the another improvement of the 1st version is necessary. This can be seen in another section dealing with the development of the second version.

5.2.2 Development of external fixator – concept 2

In the second version, mostly the problem with lower rigidity and insufficient angular setting has been solved. The result can be seen in the following Figure

Fig. 5.3: External fixator design – concept 2

After this improvement the fixator design, the device 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. Finally, also the evaluation together with the surgeon has been done and the results can be seen in the Table 3.

Table 3. 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

5.2.1 Development of external fixator – concept 3

Based on the concept 3 another design improvement have been done and the resulting construction can be seen in Figure 5.4.

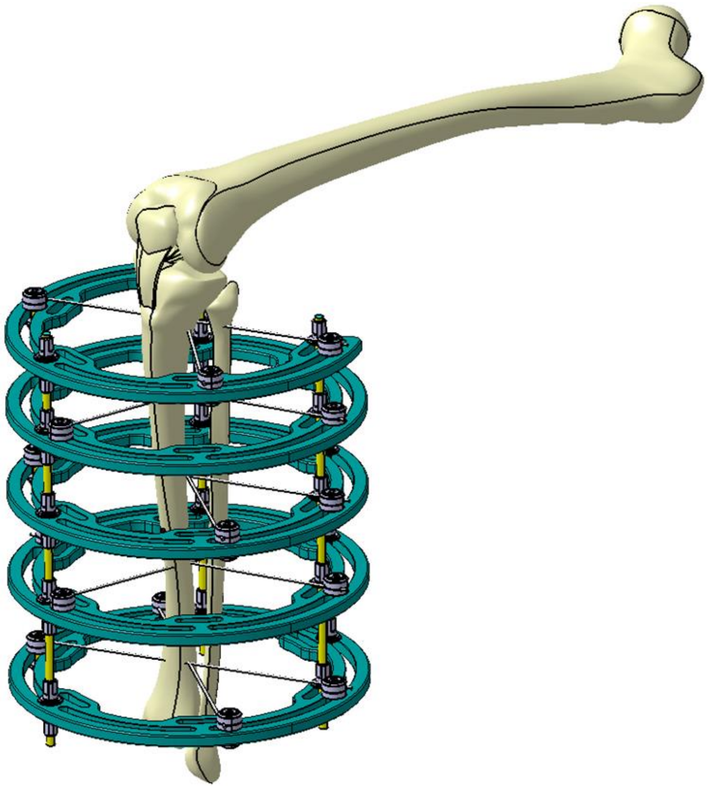

Fig. 5.4: External fixator design – concept 3

During the design innovation, the most significant changes have been done in external fixator rings profile and the final designed has been examined by the deformation analysis of the whole fixator. Based o the summary in Table 4, his 3rd concept is a final design that will be manufactured and tested experimentally.

Table 4. 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	

Main fixator dimensions can be further seen in Figure 5.5.

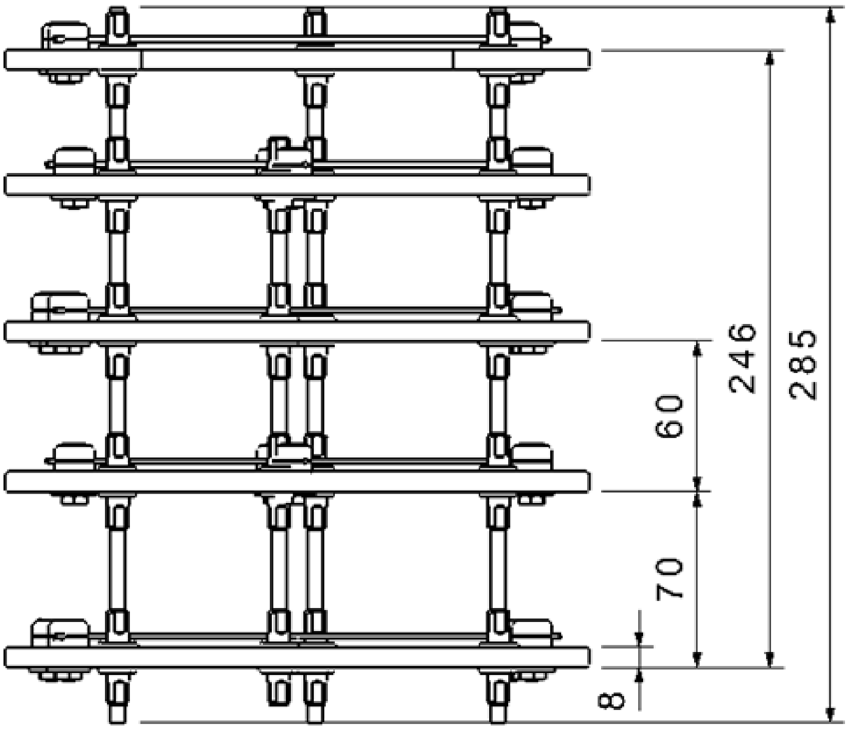

Fig. 5.5: The main dimensions of the 3rd concept of fixator – front view

5.3 EVALUATION OF FIXATOR RING LOADING CAPACITY

For the sufficient profile selection, in another part, the composite samples have been prepared and manufactured (Figure 5.6 and 5.7) and loaded by the three-point bending. The samples have prepared for the 2nd and 3rd version of fixator design as can be seen in the following Figures.

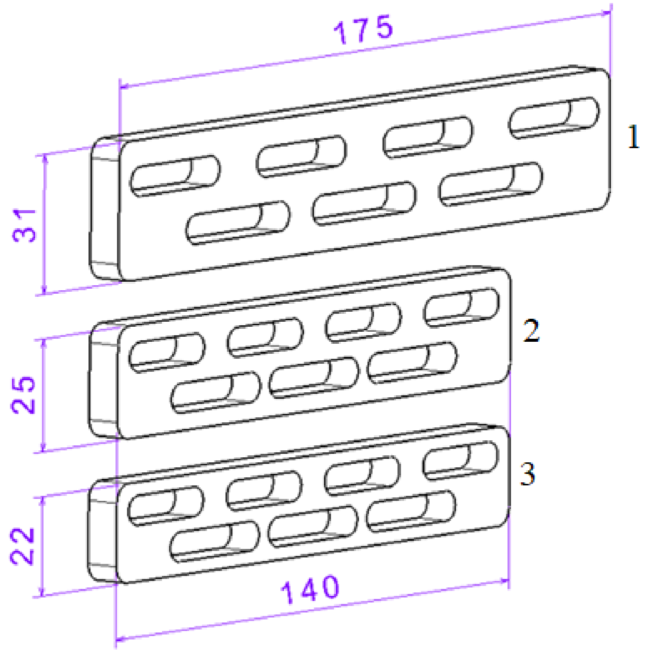

Fig. 5.6: Samples of composite fixator ring with different dimensions-concept 2

After this, the individual sample has been loaded and the results of this investigation can be seen in Table 5.

Table 5. 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

In another loading, the process of sample testing, three-point bending method has been selected again. 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). 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.

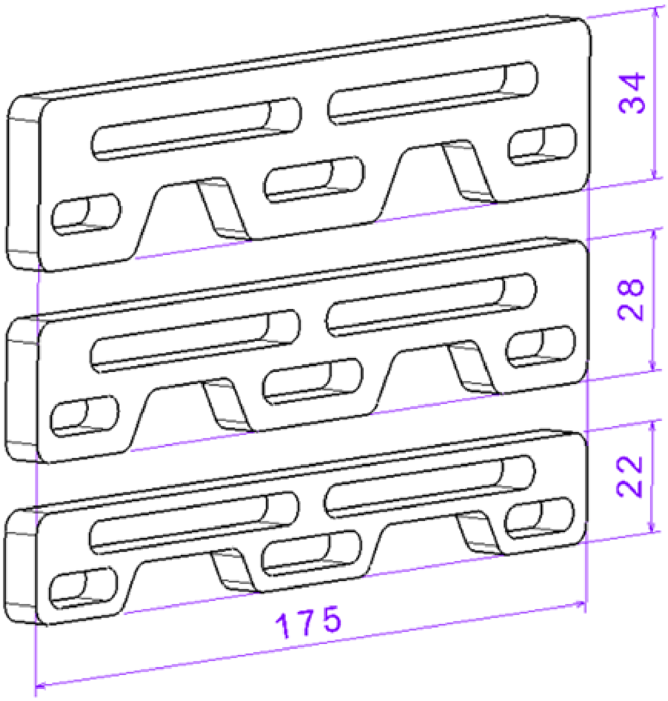

Fig. 5.7: Samples of composite fixator ring with different dimensions-concept 3

Based on the results 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.

Table 6. 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

The last version that can be suitable as an external ring profile is the 6th version of the composite sample. The result for this type of construction reports the 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 unreliable value, where the large deformations occur even during the early stages of the loading process.

Fig. 5.8: Loading of the specimen by the three-point bending in the first direction

5.4 DEFORMATION ANALYSIS

The second part of the unified test design mentioned before is the deformation analysis that evaluates the deformation of fixator under the load. Firstly, the analysis setting can be seen in Figure 5.9.

Fig. 5.9: Deformation analysis setting

The test has been done under the MUDEF test, that describes that the deformation of 2 mm should be done by the force higher than 53N. As can be seen in the following Figure this condition has been successfully compared. Another investigations are described in detail in the full version of the thesis.

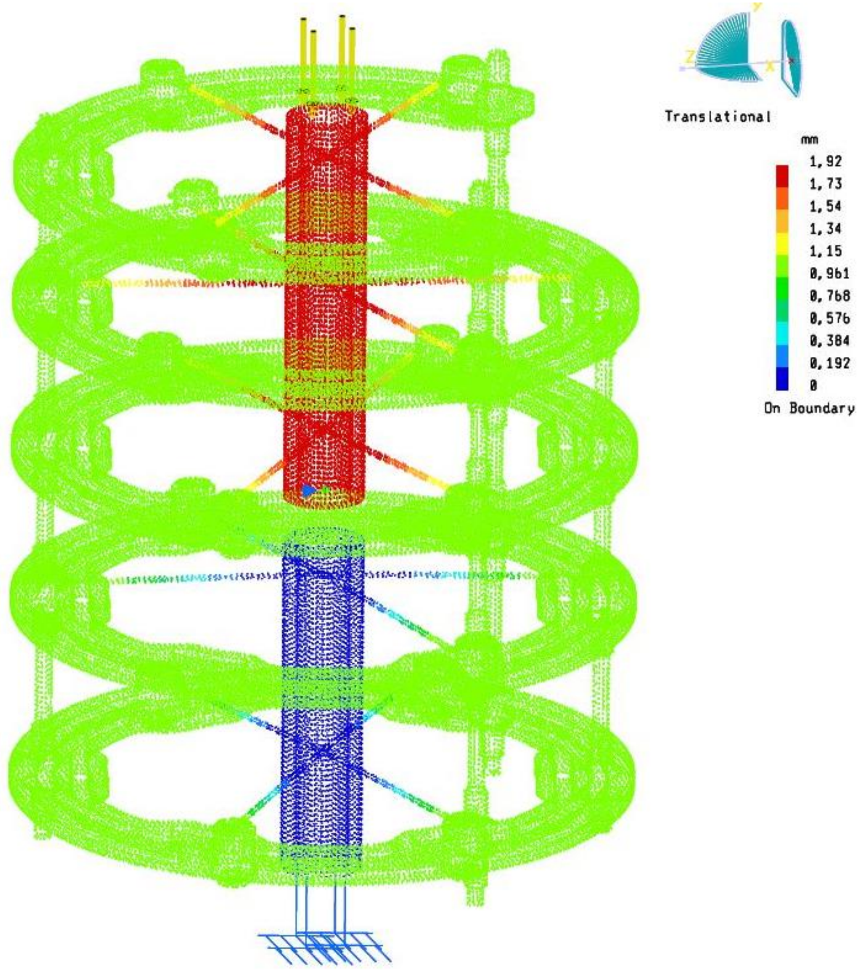

Fig. 5.10: Results of deformation analysis

5.5 EXTERNAL FIXATOR MANUFACTURING

In another step, the external fixator has been manufactured combining the glass fibers together with the DT 806 matrix. The material lay-up can be further seen in Figure 5.11, containing 13 layers in quasi-isotropic distribution.

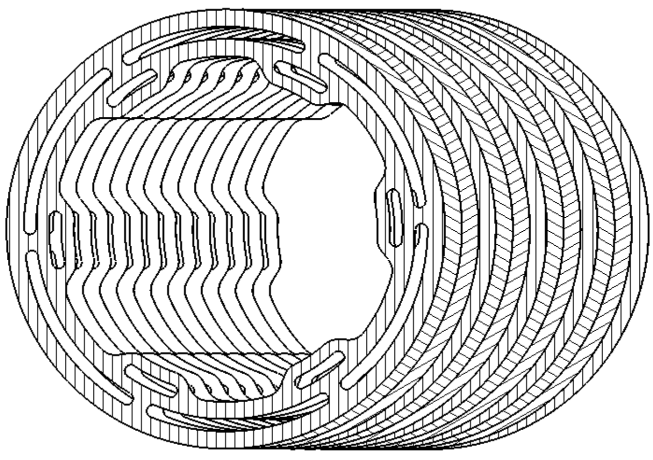

Fig. 5.11: External fixator ring - lay up of the composite structure

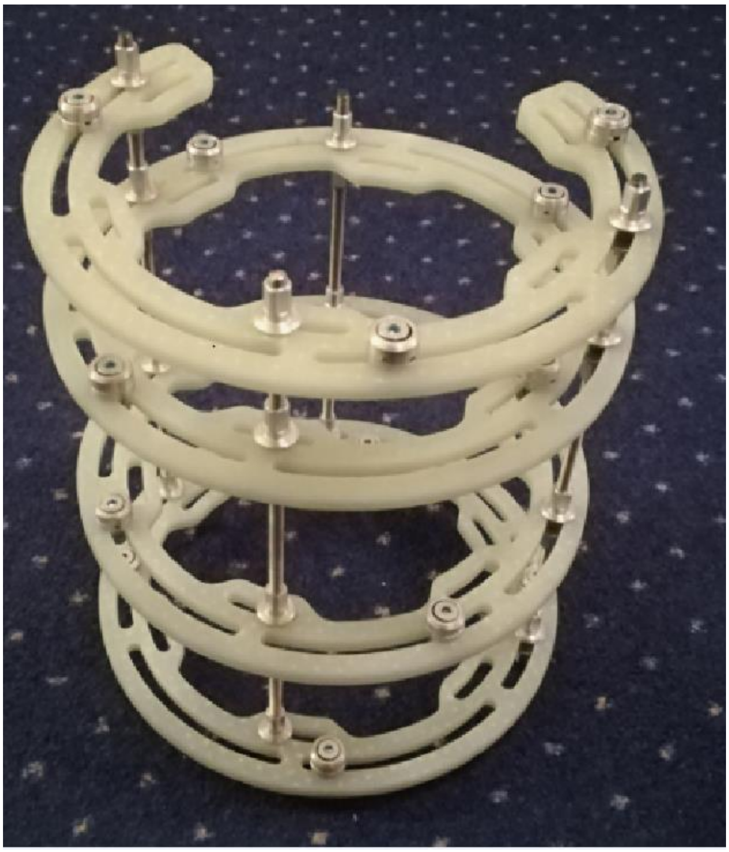

Fig. 5.12: Assembled external fixator with composite rings

5.6 STRESS TEST OF COMPLETE FIXATOR

In order to cover the simulation of the healing process of the patient, there is a necessity to design the test following 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 5.13).

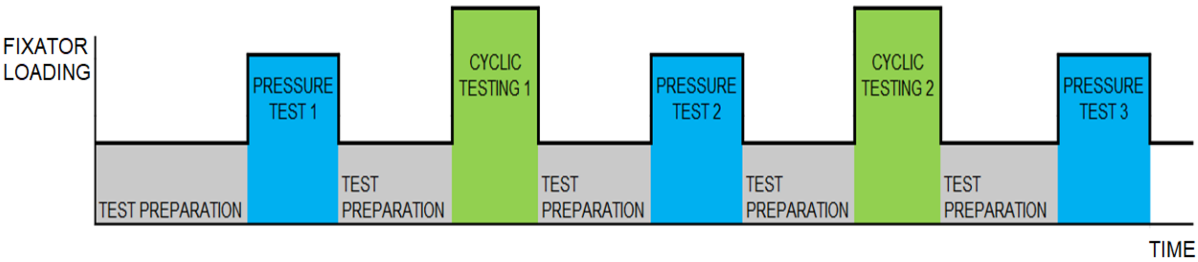

Fig. 5.13: Test design

5.6.1 Development of cyclic testing machine

For the necessities of this theses, the cyclical testing machine (Figure 5.14, 5.15) has 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 under the supervision of the author of this dissertation.

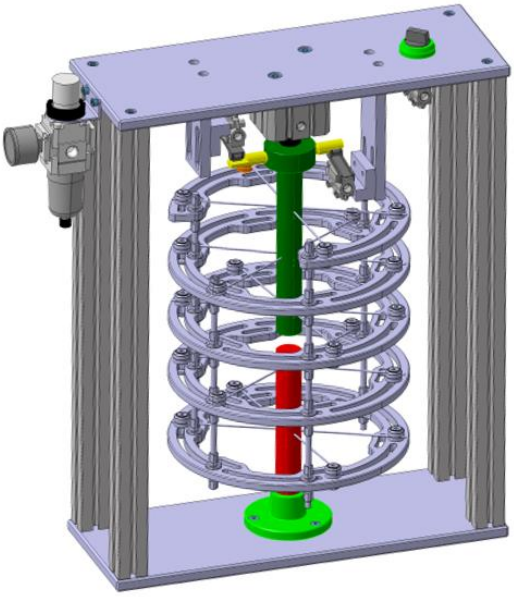

Fig. 5.14: Cyclic testing machine designed by Matěj Homola assembled with an external fixator

Fig. 5.15: Cyclic testing machine manufactured by Matěj Homola connected with the manufactured external fixator

This machine has been further applied for the cyclic testing mentioned in the test above. And another testing machine has been used for the stress test evaluation with a universal testing machine from the company Zwick-Roell. This facility is shown in Figure 5.16. During the process of fixator testing, this equipment has been used for the pressure test of the overall fixator.

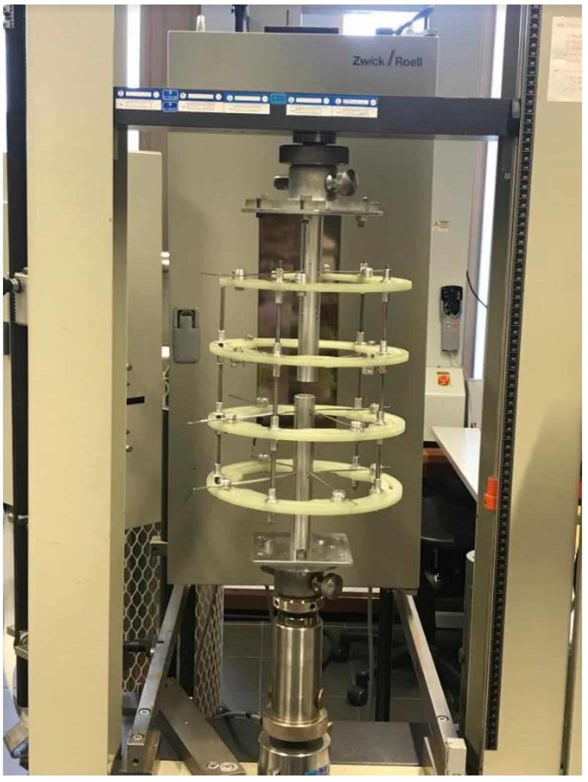

Fig. 5.16: Universal blasting machine with an external fixator

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.

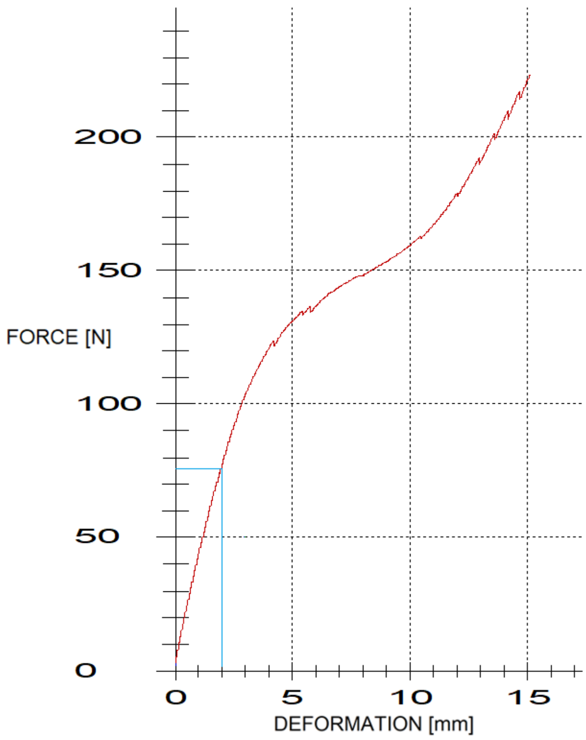

Fig. 5.17: Fixator deformation under the load

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 [37, 76, 29, 30], the 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 [76, 31]. This process of simulation is based on the standard CSN EN 62366-1 (364861) and the fixator loading during the healing process.

In the graph below 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.

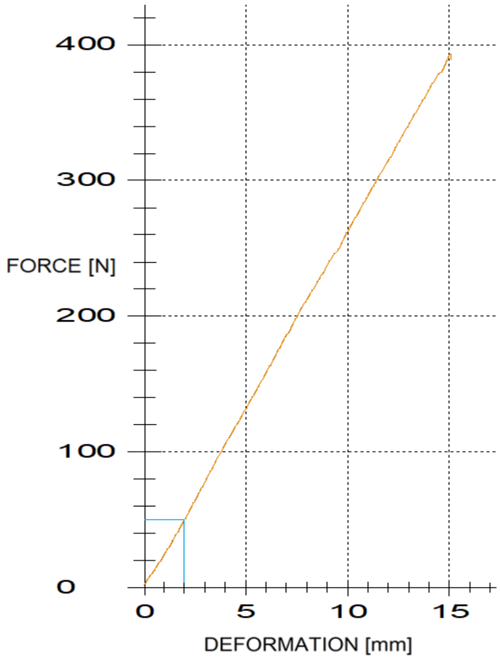

Fig. 5.18: Fixator deformation under the load after the first period of cyclic testing

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.

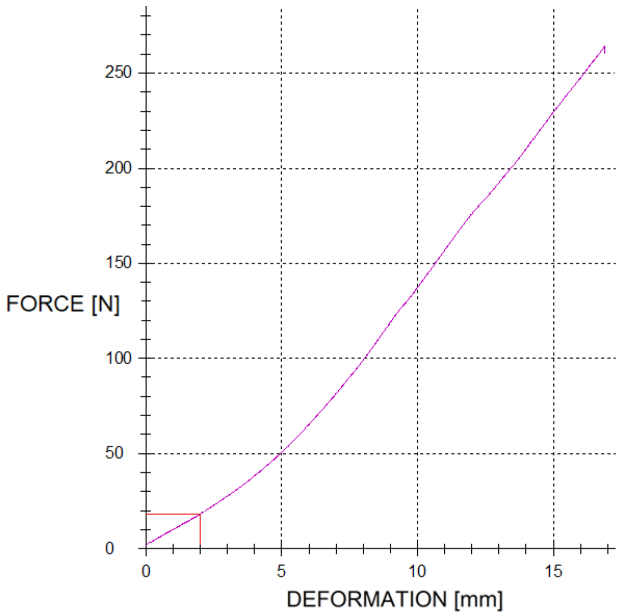

Fig. 5.19: Fixator deformation under the load after the second period of cyclic testing

6. 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 of 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.

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.

REFERENCES

[1] KYTÝR, Daniel, Tomáš DOKTOR, Ondrej JIROUŠEK, Tomáš FÍLA, Petr KOUDELKA and Petr ZLÁMAL. Deformation behavior of a natural-shaped bone scaffold. Materiali in tehnologije [online]. 2016, 50(3), 301-305 [cit. 2019-01-18]. DOI: 10.17222/mit.2014.190. ISSN 15802949. Available from: http://mit.imt.si/Revija/izvodi/mit163/kytyr.pdf

[2] JEVREMOVIC, D. P., T. M. PUSKAR, I. BUDAK, D. VUKELIC, V. KOJIC, D. EGGBEER and R. J. WILLIAMS. A RE/RM approach to the design and manufacture of removable partial dentures with a biocompatibility analysis of the F75 Co-Cr SLM alloy. Materiali in Tehnologije. 46(2), 123-129. UDK 577.1:616.314-76/-77.

[3] KURŞUN, Ali and Arsin TOPAL. Investigation of hole effects on the critical buckling load of laminated composite plates. Materiali in tehnologije[online]. 2016, 50(1), 23-27 [cit. 2019-01-18]. DOI: 10.17222/mit.2014.164. ISSN 15802949. Available from: http://mit.imt.si/Revija/izvodi/mit161/kursun.pdf

[4] FRYDRÝŠEK, Karel, Jiří KOHUT, Vojtěch BAJTEK, Milan ŠÍR and Leopold PLEVA. Ring Fixators in Traumatology (An Engineering Point of View). In: Modeling, Simulation and Identification / 841: Intelligent Systems and Control [online]. Calgary, AB, Canada: ACTAPRESS, 2016, 2016, s. - [cit. 2019-01-18]. DOI: 10.2316/P.2016.840-035. ISBN 978-0-88986-983-7. Available from: http://www.actapress.com/PaperInfo.aspx?paperId=456253

[5] SELIGSON, David, Cyril MAUFFREY and Craig ROBERTS, ed. External Fixation in Orthopedic Traumatology [online]. London: Springer London, 2012 [cit. 2019-01-18]. ISBN 978-1-4471-2199-2.

[6] SOLOMIN, Leonid, ed. The Basic Principles of External Skeletal Fixation Using the Ilizarov and Other Devices [online]. Milano: Springer Milan, 2012 [cit. 2019-01-18]. ISBN 978-88-470-2618-6.

[7] DUNGL, Pavel. Ortopedie. 2., přeprac. a dopl. vyd. Praha: Grada, 2014. ISBN 978-80-247-4357-8.

[8] ZAMANI, A. R. and S. O. OYADIJI. Theoretical and Finite Element Modeling of Fine Kirschner Wires in Ilizarov External Fixator. Journal of Medical Devices [online]. 2010, 4(3) [cit. 2019-01-18]. DOI: 10.1115/1.4001815. ISSN 19326181.Available from: http://MedicalDevices.asmedigitalcollection.asme.org/article.aspx?articleid=1451591

[9] FU, Tao, Jun-Liang ZHAO and Ke-Wei XU. The designable elastic modulus of 3-D fabric reinforced biocomposites. Materials Letters. Xi'an, China, 2007, 61(2), 330-333. DOI: 10.1016/j.matlet.2006.04.057. ISSN 0167-577X.

[10] EVANS, S.L. and P.J. GREGSON. Composite technology in load-bearing orthopedic implants. Biomaterials [online]. 1998, 19(15), 1329-1342 [cit. 2019-01-18]. DOI: 10.1016/S0142-9612(97)00217-2. ISSN 01429612. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0142961297002172

[11] COOPER, Paul, Vasilios POLYZOIS and Thomas ZGONIS. External Fixators of the Foot and Ankle [online]. LWW [cit. 2019-01-18]. ISBN 978-1451171822.

[12] ILIZAROV, Gavriil A. Transosseous Osteosynthesis [online]. Berlin, Heidelberg: Springer Berlin Heidelberg, 1992 [cit. 2019-01-18]. ISBN 978-3-642-84390-7.

[13] ILIZAROV, Gavriil. The principles of the Ilizarov method. Bulletin of the Hospital for Joint Diseases Orthopedic Institute, 1988, 48, 1-11.

[14] ILIZAROV, G. A. and Yu. M. IR'YANOV. Osteogenesis under conditions of tensile stress. Bulletin of Experimental Biology and Medicine [online]. 1991, 111(2), 235-238 [cit. 2019-01-18]. DOI: 10.1007/BF00842692. ISSN 0007-4888. Available from: http://link.springer.com/10.1007/BF00842692

[15] PARVIZI, Javad. High Yield Orthopedics [online]. Elsevier Health Sciences, 2010 [cit. 2019-01-18]. ISBN 9781437736298.

[16] SLUTSKY, David J. Principles and practice of wrist surgery. Philadelphia, PA: Saunders Elsevier, c2010. ISBN 9781416056461.

[17] CHONDROS, T.G., D.D. DELIGIANNI, K.F. MILIDONIS, I.T. CHONDROU and G.A. MARGARONIS. Wire tensioning with integrated load-cell in the Ilizarov orthopedic external fixation system. Mechanism and Machine Theory [online]. 2014, 79, 109-123 [cit. 2019-01-18]. DOI: 10.1016/j.mechmachtheory.2014.04.003. ISSN 0094114X. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0094114X14001104

[18] SPIER, R. An External Fixation Device Made of Polymer Materials. UHTHOFF, Hans K. and Elvira STAHL, ed. Current Concepts of External Fixation of Fractures [online]. Berlin, Heidelberg: Springer Berlin Heidelberg, 1982, 1982, s. 125-130 [cit. 2019-01-18]. DOI: 10.1007/978-3-642-68448-7_16. ISBN 978-3-642-68450-0. Available from: http://www.springerlink.com/index/10.1007/978-3-642-68448-7_16

[19] QIAO, Feng, Dichen LI, Zhongmin JIN, Yongchang GAO, Tao ZHOU, Jinlong HE and Li CHENG. Application of 3D printed customized external fixator in fracture reduction. Injury [online]. 2015, 46(6), 1150-1155 [cit. 2019-01-18]. DOI: 10.1016/j.injury.2015.01.020. ISSN 00201383. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0020138315000248

[20] Laminate Theory: Laminate Constitutive Relations. The National Programme on Technology Enhanced Learning (NPTEL) [online]. India [cit. 2019-06-06]. Available from: https://nptel.ac.in/courses/101104010/lecture17/17_7.htm

[21] GESSMANN, Jan, Birger JETTKANT, Thomas Armin SCHILDHAUER and Dominik SEYBOLD. Mechanical stress on tensioned wires at direct and indirect loading: A biomechanical study on the Ilizarov external fixator. Injury [online]. 2011, 42(10), 1107-1111 [cit. 2019-01-18]. DOI: 10.1016/j.injury.2011.02.001. ISSN 00201383. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0020138311000659

[22] ARAO, Yoshihiko, Jun KOYANAGI, Shin UTSUNOMIYA, Shin-ichi TAKEDA a Hiroyuki KAWADA. Analysis of time-dependent deformation of a CFRP mirror under hot and humid conditions. Mechanics of Time-Dependent Materials [online]. 2009, 13(2), 183-197 [cit. 2019-06-06]. DOI: 10.1007/s11043-009-9081-1. ISSN 1385-2000. Available from: http://link.springer.com/10.1007/s11043-009-9081-1

[23] WEAVER, P M. Designing composite structures: Lay-up selection. Proceedings of the Institution of Mechanical Engineers, Part G: Journal of Aerospace Engineering [online]. 2005, 216(2), 105-116 [cit. 2019-06-06]. DOI: 10.1243/095441002760179807. ISSN 0954-4100. Available from: http://journals.sagepub.com/doi/10.1243/095441002760179807

[24] STAAB, George. Laminar Composites [online]. Boston, MA: Elsevier, 2015 [cit. 2019-06-06]. DOI: 10.1016/C2014-0-02568-3. ISBN 9780128024003.

[25] STAAB, George H. Laminar Composites [online]. Boston: Elsevier, 1999 [cit. 2019-06-06]. DOI: 10.1016/B978-0-7506-7124-8.X5000-0. ISBN 9780750671248.

[26] WANG, Bo, Kento MAEKAWA, Nobuhide UDA, Kousei ONO a Hiroto NAGAI. Compressive failure analysis of quasi-isotropic composite laminates fabricated with quasi-unidirectional woven fabric. Journal of Composite Materials [online]. 2015, 50(2), 231-241 [cit. 2019-06-06]. DOI: 10.1177/0021998315573286. ISSN 0021-9983. Available from: http://journals.sagepub.com/doi/10.1177/0021998315573286

[27] SACHDEVA, Chirag, Jitish MIGLANI a Srikant PADHEE. Stress Development Analysis within Composite Laminate for Different Layup Orientations [online]. In: . 2016-02-01, s. - [cit. 2019-06-06]. DOI: 10.4271/2016-28-0183. Available from: https://www.sae.org/content/2016-28-0183/

[28] KELLY, A. a Carl H. ZWEBEN. Comprehensive composite materials. New York: Elsevier, 2000. ISBN 978-0-08-042993-9.

[29] HOW TO: START TO TAKE STEPS IN AN EXTERNAL FIXATOR. Life with a noob [online]. 2013 [cit. 2019-02-06]. Available from: https://lifewithanoob.wordpress.com/2013/10/24/how-to-start-to-take-steps-in-an-external-fixator/

[30] SENGODAN, VetrivelChezian a MugundhanMoongilpatti SENGODAN. Early Weight-bearing Using Percutaneous External Fixator for Calcaneal Fracture. Journal of Surgical Technique and Case Report[online]. 2012, 4(2) [cit. 2019-02-06]. DOI: 10.4103/2006-8808.110263. ISSN 2006-8808. Available from: http://www.jstcr.org/text.asp?2012/4/2/98/110263

[31] SEIDE, K, N WEINRICH, M.E WENZL, D WOLTER a C JÜRGENS. Three-dimensional load measurements in an external fixator. Journal of Biomechanics [online]. 2004, 37(9), 1361-1369 [cit. 2019-02-06]. DOI: 10.1016/j.jbiomech.2003.12.025. ISSN 00219290. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0021929003004883.

[32] GIBBONS, John. Polymer Matrix Composites. Advanced materials by design [online]. Washington: U.S. Congress, 1988, s. 73-93 [cit. 2019-02-25]. Available from: https://www.princeton.edu/~ota/disk2/1988/8801/880106.PDF

[33] MATSUBARA, Hidenori and Hiroyuki TSUCHIYA. Treatment of bone tumor using external fixator. Journal of Orthopedic Science [online]. 2019, 24(1), 1-8 [cit. 2019-01-18]. DOI: 10.1016/j.jos.2018.06.022. ISSN 09492658. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0949265818302276

[34] EL-MOWAFI, Hani, Ahmed EL-HAWARY and Yasser KANDIL. The management of tibial pilon fractures with the Ilizarov fixator: The role of ankle arthroscopy. The Foot [online]. 2015, 25(4), 238-243 [cit. 2019-01-18]. DOI: 10.1016/j.foot.2015.08.004. ISSN 09582592. Available from: https://linkinghub.elsevier.com/retrieve/pii/S095825921500070X

[35] LEITE, Alessandro Marcondes, Helder Mattos MENEZES, Igor e Castro AQUINO, Jefferson Soares MARTINS and Frederico Barra de MORAES. Tibiocalcaneal arthrodesis using an Ilizarov fixator. Revista Brasileira de Ortopedia (English Edition) [online]. 2013, 48(1), 57-61 [cit. 2019-01-18]. DOI: 10.1016/j.rboe.2013.04.005. ISSN 22554971. Available from: https://linkinghub.elsevier.com/retrieve/pii/S225549711300013X

[36] BOZOVIC, Aleksandar, Rade GRBIC, Dragisa MILOVIC, Zlatan ELEK, Dusan PETROVIC, Ljubomir JAKSIC and Goran RADOJEVIC. Treatment of tibial shaft fractures with Mitkovic type external fixation: Analysis of 100 patients. Srpski arhiv za celokupno lekarstvo [online]. 2017, 145(11-12), 605-610 [cit. 2019-01-18]. DOI: 10.2298/SARH161206137B. ISSN 0370-8179. Available from: http://www.doiserbia.nb.rs/Article.aspx?ID=0370-81791700137B

[37] FRAGOMEN, Austin T. and S. Robert ROZBRUCH. The Mechanics of External Fixation. HSS Journal [online]. 2007, 3(1), 13-29 [cit. 2019-01-18]. DOI: 10.1007/s11420-006-9025-0. ISSN 1556-3316. Available from: http://link.springer.com/10.1007/s11420-006-9025-0

[38] ABOUDI, Jacob, S. M. ARNOLD and Brett A. BEDNARCYK. Micromechanics of composite materials: a generalized multiscale analysis approach. Amsterdam: Elsevier, 2013. ISBN 978-0-12-397035-0.

[39] MARKOVIČOVÁ, Lenka and Viera ZATKALÍKOVÁ. Composite Materials Based on pa Reinforced Glass Fibers. Materials Today: Proceedings[online]. 2016, 3(4), 1056-1059 [cit. 2019-01-18]. DOI: 10.1016/j.matpr.2016.03.047. ISSN 22147853. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2214785316002522

[40] KAMALIEVA, Rumiya N. and Ramaz V. CHARKVIANI. Creation of Ultra-light Spacecraft Constructions Made of Composite Materials. Procedia Engineering [online]. 2017, 185, 190-197 [cit. 2019-01-18]. DOI: 10.1016/j.proeng.2017.03.337. ISSN 18777058. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1877705817314911

[41] CHAKRAVARTHY, Y. Kalyan, P. VIGNESHWAR, P.V. KEDARNATH, Y. Sai HARISH and A. SRINATH. Optimum Material Selection to Prosthetic Leg through Intelligent Interface of RSM and FEA. Materials Today: Proceedings [online]. 2017, 4(2), 1998-2007 [cit. 2019-01-18]. DOI: 10.1016/j.matpr.2017.02.046. ISSN 22147853. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2214785317302420

[42] ŠUBA, Oldřich. Dimenzování a navrhování výrobků z polymerů. Vyd. 3. Zlín: Univerzita Tomáše Bati ve Zlíně, 2010. ISBN 978-80-7318-948-8.

[43] Introduction to finite element analysis: Basic principles. Open Learn [online]. [cit. 2019-01-18]. Available from: https://www.open.edu/openlearn/science-maths-technology/introduction-finite-element-analysis/content-section-1.5

[44] ST-PIERRE, Luc, Ned J. MARTORELL and Silvestre T. PINHO. Stress redistribution around clusters of broken fibers in a composite. Composite Structures [online]. 2017, 168, 226-233 [cit. 2019-01-18]. DOI: 10.1016/j.compstruct.2017.01.084. ISSN 02638223. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0263822316328811

[45] BATISTA, A.C.M.C., S.R.L. TINÔ, R.S. FONTES, S.H.S. NÓBREGA and E.M.F. AQUINO. Anisotropy and holes in epoxy composite reinforced by carbon/glass and carbon/aramid hybrid fabrics: Experimental and analytical results. Composites Part B: Engineering [online]. 2017, 125, 9-18 [cit. 2019-01-18]. DOI: 10.1016/j.compositesb.2017.05.066. ISSN 13598368. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1359836816331754

[46] EL MOUMEN, A., M. TARFAOUI, K. LAFDI and H. BENYAHIA. Dynamic properties of carbon nanotubes reinforced carbon fibers/epoxy textile composites under low velocity impact. Composites Part B: Engineering [online]. 2017, 125, 1-8 [cit. 2019-01-18]. DOI: 10.1016/j.compositesb.2017.05.065. ISSN 13598368. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1359836817306042

[47] ZHANG, Qiang, Zhiling LUO, Qilin GUO and Gaohui WU. Preparation and thermal properties of short carbon fibers/erythritol phase change materials. Energy Conversion and Management [online]. 2017, 136, 220-228 [cit. 2019-01-18]. DOI: 10.1016/j.enconman.2017.01.023. ISSN 01968904. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0196890417300237

[48] CHUNG, Deborah D. L. Composite materials: science and applications. 2nd ed. New York: Springer, c2010. ISBN 9781848828308.

[49] HALARY, Jean-Louis, Françoise LAUPRÊTRE and L. MONNERIE. Polymer materials: macroscopic properties and molecular interpretations. Hoboken, N.J.: Wiley, c2011. ISBN 978-0470616192.

[50] ZWEBEN, Carl and Peter BEAUMONT, ed. Comprehensive Composite Materials II. 2nd Edition. United Kingdom: Elsevier, 2018. ISBN 978-0-08-100534-7.

[51] Composite materials handbook. Warrendale, Pa.: SAE International on behalf of CMH-17, a division of Wichita State University, 2013. ISBN 9780768078114.

[52] DONG, Chensong, Mehdi KALANTARI and Ian J. DAVIES. Robustness for unidirectional carbon/glass fiber reinforced hybrid epoxy composites under flexural loading. Composite Structures [online]. 2015, 128, 354-362 [cit. 2019-01-18]. DOI: 10.1016/j.compstruct.2015.03.059. ISSN 02638223. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0263822315002421

[72] MAPLES, Henry A., Steven WAKEFIELD, Paul ROBINSON and Alexander BISMARCK. High performance carbon fiber reinforced epoxy composites with controllable stiffness. Composites Science and Technology [online]. 2014, 105, 134-143 [cit. 2019-01-18]. DOI: 10.1016/j.compscitech.2014.09.008. ISSN 02663538. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0266353814003418

[54] MITYUSHEV, Vladimir and Wojciech NAWALANIEC. Basic sums and their random dynamic changes in description of microstructure of 2D composites. Computational Materials Science [online]. 2015, 97, 64-74 [cit. 2019-01-18]. DOI: 10.1016/j.commatsci.2014.09.020. ISSN 09270256. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0927025614006314

[55] PADOVEC, Zdeněk, Pavel RŮŽIČKA, Radek SEDLÁČEK and Milan RŮŽIČKA. Design, analysis and testing of an external fracture fixation device manufactured from composite materials. Applied and Computational Mechanics [online]. 2017, 11(2) [cit. 2019-01-18]. DOI: 10.24132/acm.2017.398. ISSN 1802680X. Available from: https://www.kme.zcu.cz/acm/acm/article/view/398/428

[56] EASTERBY-SMITH, Mark. Management research. 2nd ed. London: SAGE Publications, 2002. ISBN 978-0761972853.

[57] STERNICK, Marcelo Back, Darlan DALLACOSTA, Daniela Águida BENTO and Marcelo Lemos DO REIS. RELATIONSHIP BETWEEN RIGIDITY OF EXTERNAL FIXATOR AND NUMBER OF PINS: COMPUTER ANALYSIS USING FINITE ELEMENTS. Revista Brasileira de Ortopedia (English Edition) [online]. 2012, 47(5), 646-650 [cit. 2019-01-18]. DOI: 10.1016/S2255-4971(15)30017-3. ISSN 22554971. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2255497115300173

[58] ZAMANI, Ahmad R and S Olutunde OYADIJI. Clamping of fine Kirschner wires in external fixators. Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine [online]. 2016, 230(11), 1036-1042 [cit. 2019-01-28]. DOI: 10.1177/0954411916671155. ISSN 0954-4119. Available from: http://journals.sagepub.com/doi/10.1177/0954411916671155

[59] MRÁZEK, Michal. Biomechanická studie fixátorů aplikovaných na tibii[online]. Vysoké učení technické v Brně. Fakulta strojního inženýrství, 2013 [cit. 2019-01-18]. Available from: http://hdl.handle.net/11012/24785. Disertační práce. Vysoké učení technické v Brně. Fakulta strojního inženýrství. Ústav mechaniky těles, mechatroniky a biomechaniky. Supervisor: Zdeněk Florian.

[60] PEROUTKA, Michal. FEM Analysis of selected type joint of Ilizarov external fixator. [online]. Ostrava, 2013 [cit. 2019-01-18]. Master thesis. VSB-TUO. Supervisor: Rojíček, Jaroslav.

[61] GIORDANO, Vincenzo, Alexandre Leme GODOY-SANTOS, William Dias BELANGERO, Robinson Esteves Santos PIRES, Pedro José LABRONICI and Hilton Augusto KOCH. Finite element analysis of the equivalent stress distribution in Schanz screws during the use of a femoral fracture distractor. Revista Brasileira de Ortopedia (English Edition) [online]. 2017, 52(4), 396-401 [cit. 2019-01-18]. DOI: 10.1016/j.rboe.2017.07.003. ISSN 22554971. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2255497117300939

[62] WIEDING, Jan, Robert SOUFFRANT, Andreas FRITSCHE, Wolfram MITTELMEIER, Rainer BADER and Boris RUBINSKY. Finite Element Analysis of Osteosynthesis Screw Fixation in the Bone Stock: An Appropriate Method for Automatic Screw Modeling. PLoS ONE [online]. 2012, 7(3) [cit. 2019-01-18]. DOI: 10.1371/journal.pone.0033776. ISSN 1932-6203. Available from: https://dx.plos.org/10.1371/journal.pone.0033776

[63] FRYDRÝŠEK, Karel, Jaroslav JOŘENEK, Oldřich UČEŇ, Tomáš KUB'N, Luboš ŽILKA and Leopold PLEVA. Design of External Fixators used in Traumatology and Orthopedics – Treatment of Fractures of Pelvis and its Acetabulum. Procedia Engineering [online]. 2012, 48, 164-173 [cit. 2019-01-18]. DOI: 10.1016/j.proeng.2012.09.501. ISSN 18777058. Available from: https://linkinghub.elsevier.com/retrieve/pii/S187770581204564X

[64] Introduction to Finite Element Analysis (FEA) or Finite Element Method (FEM) [online]. [cit. 2019-01-18]. Available from: https://www.engr.uvic.ca/~mech410/lectures/FEA_Theory.pdf

[65] Introduction to the Finite Element Method for Structural Analysis. OÑATE, Eugenio. Structural Analysis with the Finite Element Method[online]. Dordrecht: Springer Netherlands, 2009, 2009, s. 1-42 [cit. 2019-01-18]. Lecture Notes on Numerical Methods in Engineering and Sciences. DOI: 10.1007/978-1-4020-8733-2_1. ISBN 978-1-4020-8732-5. Available from: http://link.springer.com/10.1007/978-1-4020-8733-2_1

[66] TIZIANI, Simon, Georg OSTERHOFF, Stephen J. FERGUSON, et al. Biomechanical Comparison of Different External Fixation Configurations for Posttraumatic Pelvic Ring Instability. Advances in Orthopedic Surgery [online]. 2014, 2014, 1-5 [cit. 2019-01-25]. DOI: 10.1155/2014/360165. ISSN 2356-6825. Available from: https://www.hindawi.com/archive/2014/360165/

[67] PAVIC, Arsen, Janos KODVANJ, Srecko SABALIC, Fabijan CUKELJ and Bore BAKOTA. Novel external fixation fracture method with circular locking mechanism compared with the application of dynamic axial external fixator on experimental tibial model ensures better stability in bending and favourable performance in dynamic loads. Injury[online]. 2013, 44, S52-S55 [cit. 2019-01-25]. DOI: 10.1016/S0020-1383(13)70199-2. ISSN 00201383. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0020138313701992.

[68] MESIC, Elmedin, Adil MUMINOVIC and N. REPČIĆ. Mechanical stability analysis of the external fixation system sarafix: 24 May 2012. DS 70: Proceedings of DESIGN, the 12th International Design Conference. [online]. 2012, (Dubrovnik, Croatia), 1029-1038 [cit. 2019-01-25]. Available from: https://www.designsociety.org/publication/32071/MECHANICAL+STABILITY+ANALYSIS+OF+THE+EXTERNAL+FIXATION+SYSTEM+SARAFIX

[69] ELMEDIN, Mešić, Avdić VAHID, Pervan NEDIM and Repčić NEDŽAD. Finite Element Analysis and Experimental Testing of Stiffness of the Sarafix External Fixator. Procedia Engineering [online]. 2015, 100, 1598-1607 [cit. 2019-01-25]. DOI: 10.1016/j.proeng.2015.01.533. ISSN 18777058. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1877705815005603

[70] ROSEIRO, Luis M., M. Augusta NETO, Ana AMARO, Rogerio P. LEAL and Miguel C. SAMARRA. External fixator configurations in tibia fractures: 1D optimization and 3D analysis comparison. Computer Methods and Programs in Biomedicine [online]. 2014, 113(1), 360-370 [cit. 2019-01-25]. DOI: 10.1016/j.cmpb.2013.09.018. ISSN 01692607. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0169260713003258.

[71] ALI, Shady, Matteo GIACHINO, Andrea BONANI, Alessandro APRATO, S. RIYAHI-ALAM, Aly KHATTAB, Cristina BIGNARDI and Alessandro MASSE. Pelvic ring fractures: External fixation comparative numerical structural analysis. In: 2014 Cairo International Biomedical Engineering Conference (CIBEC) [online]. IEEE, 2014, 2014, s. 10-14 [cit. 2019-01-25]. DOI: 10.1109/CIBEC.2014.7020934. ISBN 978-1-4799-4412-5. Available from: http://ieeexplore.ieee.org/document/7020934/

[72] Finite Element Analysis: What is von Mises Stress? Simwiki [online]. [cit. 2019-01-25]. Available from: https://www.simscale.com/docs/content/simwiki/fea/what-is-von-mises-stress.html

[73] GILL, John, Phil JOHNSON and Murray CLARK. Research methods for managers. 4th ed. Los Angeles: SAGE, 2010. ISBN 9781847870940.

[74] COHEN, Debbi. Medical Device Testing: Internal Fixation vs. External Fixation. ADMET: Material testing system manufacturer [online]. 2012 [cit. 2019-01-25]. Available from: https://www.admet.com/medical-device-testing-internal-fixation-vs-external-fixation/

[75] MENG, L., Y. ZHANG and Y. LU. Three-dimensional finite element analysis of mini-external fixation and Kirschner wire internal fixation in Bennett

fracture treatment. Orthopedics & Traumatology: Surgery & Research [online]. 2013, 99(1), 21-29 [cit. 2019-01-25]. DOI: 10.1016/j.otsr.2012.07.015. ISSN 18770568. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1877056812002794.

[76] This surgery involves the application of an external fixator placed into one of the lower limbs of your body. The MHE Reresearch Foundation [online]. [cit. 2019-02-06]. Available from: http://mheresearchfoundation.org/files/mherf_fixator_care.pdf

LIST OF FIGURES

LIST OF TABLES

LIST OF SYMBOLS, ACRONYMS AND ABBREVIATIONS

∫	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 [$kg \cdot mol^{-1}$]
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

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

Publications registered in the SCOPUS database:

TOMANEC, Filip, Sona RUSNAKOVA and Martina KALOVA. INNOVATION OF ILIZAROV STABILIZATION DEVICE WITH THE DESIGN CHANGES. MM Science Journal [online]. 2019, 2019(01), 2732-2738 [cit. 2019-03-14]. DOI: 10.17973/MMSJ.2019_03_2018005. ISSN 18031269. Available from: http://www.mmscience.eu/2018005

TOMANEC, Filip, Soňa RUSNÁKOVÁ and Milan ŽALUDEK. Optimization of the Material of External Fixator with FEM Simulation. Materials Science Forum [online]. 2018, 919, 275-281 [cit. 2019-03-14]. DOI: 10.4028/www.scientific.net/MSF.919.275. ISSN 1662-9752. Available from: https://www.scientific.net/MSF.919.275

TOMANEC, Filip, Soňa RUSNÁKOVÁ and Milan ŽALUDEK. Improvements of prosthetic limb design: Cooling and pressure reduction in a socket. Manufacturing Technology. 2018. 17. 978-981. Available from: https://www.researchgate.net/publication/322114562_Improvements_of_prosthetic_limb_design_Cooling_and_pressure_reduction_in_a_socket

KALOVA, Martina, Sona RUSNAKOVA, Zdenek JONSTA, **Filip TOMANEC** and Jiri KOHUT. MOLD DESIGN FOR RINGS OF EXTERNAL FIXATOR. MM Science Journal [online]. 2019, 2019(01), 2739-2746 [cit. 2019-03-14]. DOI: 10.17973/MMSJ.2019_03_2018002. ISSN 18031269. Available from: http://www.mmscience.eu/2018002

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.

- HRADIL, Dominik. The design of end effector and selection of the optimal industrial robot for parts manipulation in the automotive industry. Zlin, 2019. Bachelor thesis. Tomas Bata University in Zlin. Supervisor Filip Tomanec.

PROFESSIONAL STRUCTURED CURRICULUM VITAE

Name, surname, title: Ing. Filip Tomanec, Ph.D.

Phone/email: +420 731 461 789 / solvetech@solvetech.cz

EDUCATION:

2015–2019: **Doctoral** studies – completely combined form of study – Department of Production Engineering, Faculty of Technology, Tomas Bata University in Zlin.

2010–2012: **Master´s** degree – Faculty of Technology, Tomas Bata University in Zlin. Specialization: Technological Equipment Construction.

2007–2010 **Bachelor´s** degree – Faculty of Technology, Tomas Bata University in Zlin. Specialization: Process Engineering.

PRACTICAL EXPERIENCES:

06/2015 – so far: SOLVETECH ENGINEERING s.r.o.

Managing director of mechanical engineering office (**robotic lines**, transportation industry, self-purpouse machines, moulds).

09/2018 – so far: VSB-TECHNICAL UNIVERSITY OF OSTRAVA

Researcher in the field of biomedical engineering.

08/2012–05/2015: AV ENGINEERING, a.s.

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

01/2011–07/2012: Modular Construction company

Technical designer of steel structures, CAD implementer.

06/2008–**12/2010: H. P. - SERVIS, s.r.o**.

Technical designer, CNC machine operator, machinist.

FOREIGN RESEARCH AND EDUCATION PROJECTS:

06-07/**2018** – **University of Salford, Manchester** (UK) – a two-month internship at the biomechanical engineering laboratory focusing on the research and development of prosthetic upper limbs for children.

09/**2015 - Austria – Villach** – Leadership seminar focusing on the management and development of people´s potential.

03/**2015 -Spain – Cádiz** – Seminar focused on company management and marketing strategies.

09/**2014 - Spain – Donostia** – Seminar about local bussinesses.

LANGUAGE SKILLS:

- Czech - mother tongue
- English - C1 – very advanced
- German - B1 – intermediate
- Russian - A2 – learner
- Japanese - A1 – beginner

Further: driving licence B, member of MENSA Czech Republic.

The development of composite orthopedic devices

Vývoj kompozitních ortopedických pomůcek

Doctoral Thesis Summary

Published by: Tomas Bata University in Zlín,

nám. T. G. Masaryka 5555, 760 01 Zlín.

Edition: published electronically

Typesetting by Filip Tomanec

This publication has not undergone any proofreading or editorial review.

Publication year: 2019

First Edition

ISBN 978-80-7454-857-4