RING FIXATORS IN TRAUMATOLOGY
(AN ENGINEERING POINT OF VIEW)

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ABSTRACT
This article focuses on ring (Ilizarov) external fixators in traumatology and orthopedics. External fixators are used in the treatment of complicated fractures, bone shortening and lengthening, corrections of angular deformities, and similar applications. An engineering/biomechanical point of view represents an essential perspective when taking account of the recommendations of medical specialists, designing materials for fixator components, developing surface treatment methods, optimizing design concepts, and conducting experimental verification. The article presents practical experience and results gained during cooperation between medical specialists and engineers (an overview of applicable materials, design, laboratory experiments, Finite Element Modeling).

KEY WORDS
External fixator, ring fixator, biomechanics, traumatology, orthopedics, materials, design, experiments, Finite Element Method

1. Introduction

External fixators (see Fig. 1 and [1], [2] and [3]), used in traumatological and orthopedic applications for purposes of osteosynthesis, are prefabricated structures designed for limb bone fixation in humans and animals. The components of an external fixator are fixation screws, fixation wires, fixation rods, and linking elements (clamps). External fixators can be used to stabilize long bones during the treatment of open fractures, infected pseudoarthrosis and aseptic pseudoarthrosis. They can be used in situations when internal osteosynthesis is not an option, as well as in specific situations such as the correction of angular deformities, bone lengthening and shortening, or bone tissue replacement in cases of defective fracture healing.

![Figure 1 Application of an Ilizarov (ring) fixator](image1.png)

Materials are a key factor in ensuring the full functionality of a fixator; see [4] and [5]. This article therefore focuses on the properties and suitability of materials used in the manufacture of fixators.

The article also presents specific applications developed as part of cooperation between producers and hospitals; see [5], [6], [7] and [8].

The advantage of external fixators is that they can be removed simply and non-surgically after the completion of treatment (i.e. the bones are fixed to the frame by small wires or screws only until healing occurs); this is not possible with internal fixators (nails, plates, etc.); [1], [2] and [3].

![Figure 2 Types of fixators (current development)](image2.png)
Basic types of internal and external fixators are presented in Fig. 2. However, this article is focused on external fixators.

2. Requirements of materials used in the production of fixators

Long-term exposure of materials to living tissue leads to significant corrosion. In external fixators, the components exposed to body tissue are the Kirschner wires or the Schanz screws, which anchor the fixator in the bone, fix the bone fragments in place and provide stability for osteosynthesis (by transferring force effects). The material used for these components therefore has to be highly resistant to corrosion. Corrosion is primarily influenced by the variability of the chemical environment, which causes local electrochemical corrosion. Another cause of negative impacts on the material is damage to the implant surface and the disruption of passive film integrity. Another important influence on corrosion is the difference in oxygen concentrations caused by poor vascularization of tissue – i.e. oxygenation occurring in the vicinity of oxygen-rich granulation tissue. This phenomenon creates suitable conditions for electrochemical corrosion. Another factor encouraging corrosion is the presence of imperfections in the implant surface. The surface is never perfectly smooth; there may be metal contact in the protruding sections of the surface, and relatively large pressures may be concentrated in a small surface area. Abrasion and corrosion may also occur under stress; see [4].

The corrosion-resistant steels used nowadays to produce implants are primarily high-alloy austenitic steels with high Cr, Ni and Mo content and low carbon content. This chemical composition gives good resistance against most types of corrosion, including intercrystalline and point corrosion. However, it is not resistant to fretting corrosion.

Other frequently used materials are alloys of non-ferrous metals, especially cobalt. Cobalt, like iron, is allotropic – its crystal lattice changes in different temperature conditions, and thus its properties also change. Cobalt alloys used for fixators have higher compressive strength and greater corrosion resistance in active and passive states than Cr-Ni-Mo steels, and they are usually better compatible with tissues.

Titanium and its alloys have excellent properties and inertness. They give a high degree of corrosion resistance – both when exposed to air and in the chemically aggressive environment of the human body. They also retain their positive properties at low and high temperatures. For more information see [13].

Another suitable solution is the application of ceramic materials to implant surfaces. The most commonly used type are \( \text{Al}_2\text{O}_3 \) ceramics, i.e. cemented pure aluminum oxide. This is one of the most stable oxides, and its use brings considerable advantages in terms of corrosion resistance in comparison with metallic materials. Corrosion resistance is closely related to biocompatibility; this type of ceramic is a good example of a biocompatible material.

Nevertheless, no materials can offer absolute corrosion resistance; for this reason, patients occasionally display allergic reactions or develop infections at the point of contact between the Kirschner wires or Schanz screws and the tissue.

In order to increase the antibacterial potency of external fixators, a kaolinite/nanoTiO2 composite was laboratory prepared and its antibacterial activity tested with respect to daylight irradiation time. Scanning electron microscopy was used as a method for characterization of the morphology and elemental composition of the studied samples. A standard microdilution test was used to determine the antibacterial activity using four human pathogenic bacterial strains (Staphylococcus aureus, Escherichia coli, Enterococcus faecalis, and Pseudomonas aeruginosa). The antibacterial assays found all the samples to have antibacterial potency. For more information see [5].

When selecting suitable materials for the construction of an implant, an important role is played by the need for biocompatibility – i.e. the biological tolerance of the osteosynthetic material. Living organisms respond to fixators as foreign bodies; after implantation, the organism attempts to isolate or eliminate the foreign body. If the material does not cause irritation (both physiologically and chemically), the organism accepts it, encapsulates it and tolerates it on a long-term basis.

Of all implant materials, ceramics have the highest biocompatibility. Their behavior in the human body is mainly bioinert or even bioactive. Among bioactive materials implanted into bone tissue we can distinguish osteoinductive materials (whose presence and effects cause the growth of bone tissue cells) and osteoconductive materials (whose composition and structure support the growth of adjacent bone cells).

The biological response of an organism to the presence of an implant is not caused only by the chemical composition of the material. Corrosion resistance is not the only factor determining material biocompatibility. With respect to their biocompatibility, metals can be categorized into toxic, those causing sequestration, and inert.

Inert materials include titanium alloys, platinum, pure titanium and ceramics. Materials causing sequestration include stainless steels and cobalt-chrome alloys. However, even inert materials can occasionally be associated with complications during the treatment process.

From a biochemical perspective, an important consideration for the transfer of forces from the implant to the bone issue is the fact that the materials belonging to the second category eventually (within several weeks after implantation) become surrounded by a thin interlayer of soft tissue. If interstitial granulation tissue is formed, the force transfer is entirely eliminated, causing the implant to become loosened.
In view of the above, the physical-chemical and structural properties of the implant surface are of central importance. In addition to the selection of a suitable material, it is also necessary to take into account the correct surface structure (texture) and suitable coating options (plasma spray coating, ion nitriding, bioactive ceramic spray coating, bacteriocidal or antivirotic surfaces, etc.).

Nevertheless, despite current technological developments and the quality of medical care, there is still no ideally suitable material for this purpose; advanced biomaterials are still the subject of ongoing research.

In terms of mechanical properties, the material used for the implant must be stronger than bone and have a similar flexibility to bone – both in the long and short term.

Mechanical requirements can be summarized as follows:
- sufficient static and dynamic strength,
- contact surfaces with very low friction and not subject to excessive wear,
- modulus of elasticity similar to that of human bone,
- ability to absorb energy and dampen impacts,
- structural simplicity for purposes of implantation and re-implantation,
- hardness,
- temperature stability,
- notch toughness.

With regard to the above-mentioned mechanical requirements, metals are the most suitable material for components subjected to high loading (tensile, compressive, bending, torsion). Every material, when subjected to long-term variable loading at levels below its strength, develops latent faults which may eventually lead to fatigue fracture. A characteristic feature of fatigue fracture is that it is not accompanied by permanent material deformation. The fatigue fracture factor can be eliminated by the selection of suitable materials, structural designs and surface treatments.

Corrosion-resistant steels have very good mechanical properties in terms of yield strength, tensile strength and notch toughness. Reduction of grain size gives high strength values. A problematic factor in these materials is the high nickel content, which in occasional cases may lead to allergies. An example of basic mechanical properties is given in Table 1.

![Table 1](image)

Cobalt alloys are stronger, especially in terms of compressive strength. Mechanical properties depend primarily on the homogeneous dispersal of carbides in the structure. Materials made from these alloys are difficult to machine. An example of basic mechanical properties is given in Table 2.

![Table 2](image)

Titanium and its alloys display worse properties than ferrous alloys, but they have lower density (in comparison with pure Fe = 7800 kg/m$^3$, pure Ti = 4500 kg/m$^3$), and thus lower mass. They also have high temperature stability. An important factor in the final properties of titanium (or its alloy Ti6Al4V) is its purity, i.e. the lowest possible content of impurities, especially O, N and H. For this reason the metallurgical production process takes place in a vacuum; this increases the cost of production. An example of basic mechanical properties is given in Table 3.

![Table 3](image)

Ceramic materials are produced from powders subjected to high-temperature hardening. This causes cementing to occur, thus increasing strength. The most commonly used type of ceramic is Al$_2$O$_3$. In terms of mechanical properties, it is hard and brittle. However, it has been shown to have very good surface fatigue properties under impact loading. Selected mechanical properties of Al$_2$O$_3$ ceramics are shown in Table 4. Ceramic materials are most frequently used in the production of total endoprostheses or as materials for surface spray-coating. However, ceramic materials do not play an important role in the production of external fixators.

![Table 4](image)

Plastics (macromolecular substances) consist of macromolecular chains, i.e. long molecules with the same basic structure. Important plastics for orthopedic and traumatological applications are polyethylene and (for external fixation) carbon fiber. It is essential that the plastic should not have carcinogenic effects. An important...
advantage of plastics is their X-ray transparency (see Figure 3); if a surgeon’s X-ray view of a fracture is obscured by a metallic part of a fixator in an anatomically correct configuration, the X-ray must be repeated, leading to longer operating times and unnecessary exposure of both patient and surgeon to radiation.

3. Experiment (static and dynamic measurement)

Calculations using the Finite Element Method have been used as accompaniments to experimental measurements of stiffness and strength; see [6] and [7]. The experiment was conducted using an INOVA ZUZ 100 stand (VŠB-Technical University of Ostrava). The purpose of the experiment was to verify the strength, stiffness and reliability of a ring external fixator. The measurement method involved the application and type of the external fixator (see Figure 2) to a polyamide rod divided into sections, simulating a fractured human bone; see Figure 4. This model was checked by medical specialists (Ostrava University Hospital) and subjected to experimentation.

First, static measurement was conducted. A force sensor was inserted between the two sections of the polyamid rod; it was used to measure the force that the external fixator is capable of transferring; see Figure 4. The value of the force thus measured was then compared with the resulting value of the machine’s loading force.

Dynamic measurement was conducted a total of three times for 10000 repeated cycles. The loading frequency was set at 0.15 Hz; each cycle thus has a duration of 6.7 s. The result of the measurement determined the dependency of displacement on force over time; see Figure 5. The failure of the clamps was checked during the course of the measurement by measuring the distances between the rings of the external fixator. These distances remained unchanged throughout the entire experiment. The structural design of this ring external fixator can therefore be considered reliable; the fixator is suitable for application to patients.

4. Finite Element Modeling

In order to gain a more complete picture of the behavior of the external fixator under operational loading conditions, a Finite Element analysis was carried out for all parts of the fixator (Figure 6, [6] and [7]). Ansys Workbench 14.5 software was used for this purpose, see [8] to [12].
The rings and rods of the external fixator are made from a carbon fiber composite. Two materials were considered for the clamps: first the model incorporated clamps made of Ti6Al4V, and then this material was replaced by PEEK (polyether ether ketone) resin. Basic data on the clamp materials is given in Table 5, where $E$ is the modulus of elasticity and $\mu$ is the Poisson number.

<table>
<thead>
<tr>
<th>Material</th>
<th>$E$ (MPa)</th>
<th>$\mu$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon fiber</td>
<td>159112</td>
<td>0.35</td>
</tr>
<tr>
<td>Titanium alloy</td>
<td>113800</td>
<td>0.34</td>
</tr>
<tr>
<td>PEEK</td>
<td>14000</td>
<td>0.4</td>
</tr>
</tbody>
</table>

An important factor in the numerical simulation is the correct analysis of the boundary conditions.

The Kirschner wires held by the clamps are replaced by tensile forces. It is not necessary to take into consideration the direct effect of the clamps. For each of the four rings, two Kirschner wires are considered, which are replaced by four forces $F_K = 980.72$ N in each ring (i.e. a total of 16 forces, whose values are experimentally determined). In order for the model to simulate reality more closely, the forces are introduced at the locations where the real Kirschner wires are attached, i.e. 3 mm above each of the rings. Due to this, each force $F_K$ causes an additional bending moment in the ring. The forces $F_K$ are located above the holes in the ring (i.e. the extreme scenario, in which the force acts on the weakest point in the section, influenced by the notch effect of the hole); see Figure 7.

Further loading on external fixators is caused by the patients themselves, i.e. by their mass. The highest loading occurs at the moment when the patient stands on just one leg, i.e. the leg to which the fixator is fitted; see Figure 8. The external fixator is assumed to be fitted to the patient’s tibia. The extreme loading of the fixator will thus be caused by the weight force from the masses above the fixator.

For a person with a total mass of $m = 120$ kg, the foot represents approx. 1.2% of total body mass. The calculation therefore uses $p = 98.8\%$ out of the total mass $m$. The total loading force (see Figure 8) is calculated as follows:

$$F_Z = m \times p / 100 \times k_{DYN} \times g =
= 120 \times 98.8 / 100 \times 1.4 \times 9.81 = 1628.3 \text{ N},$$

where $k_{DYN} = 1.4$ is the coefficient taking into account the slight dynamic loading (as treatment also includes physical movement) and $g = 9.81 \text{ m/s}^2$ is gravitational acceleration.

It is assumed that the fractured bone has sustained extreme damage, and in the worst case it fails to transfer any loading from the patient’s mass in the area of the complicated fracture. Force $F_Z$ is transferred to the fixator via the Kirschner wires, and it is then divided into 16 equal forces acting in the individual clamps (i.e. each clamp is subjected to force $F_Z/16 = 101.76$ N; see Figure 9).
upon a total of 16 forces and 16 equal reactions from the tightening of the screws; i.e. there is one pair of forces for each clamp. The direct effect of the screw is thus not taken into account (it can be replaced by forces $F_0$).

Figure 10 Force and reaction caused by the screw in the clamp (boundary conditions)

For a correct calculation, it is necessary for the fixator to be held in place. In accordance with a person in a standing posture, a boundary condition replacing the elastic foundation (Winkler’s elastic support, see [8]) was applied to the lower surfaces of the 4 fixator rods; see Figure 11. The stiffness of the elastic support was estimated as $10 \text{ N/mm}^3$. In this case, the elastic support is a suitable approximation of the anchoring of the fixator in the limb.

Figure 11 Elastic support (boundary conditions)

The second spatial boundary is introduced in the directions of the remaining two axes, perpendicular to each other. The boundary condition for the individual directions is located at the opposite ends of the adjacent rods, in order for the limitation of displacement to be distributed as evenly as possible throughout the entire fixator (i.e. at 4 points); see Figure 12.

Figure 12 Limitation of displacement along axes x and y (boundary conditions)

5. Selected results

The aim of the FE analysis and experiments was to gain a realistic picture of the mechanical behavior of an external fixator under loading. The parameters under investigation are the maximum reduced stress according to HMH (von Mises) theory $\sigma_{\text{max,HMH}}$ and maximum displacement $\Delta_{\text{max}}$. The first of these two parameters is the more important; it must not exceed the material yield strength $R_e$. The resulting values of $\sigma_{\text{max,HMH}}$ and $\Delta_{\text{max}}$ are determined for each of the components of the fixator and then for the fixator as a whole. In the next step, the resulting values are recorded in a table, which also expresses the safety factor with respect to yield strength $R_e$. Results were gained for the two types of material under investigation.

Figure 13 Complete fixator – Maximum reduced stress /MPa/ (clamps made of Ti6Al4V)

Total reduced stress $\sigma_{\text{max,HMH}}$ and total displacement $\Delta_{\text{max}}$ for an external fixator with titanium alloy clamps are depicted in Figure 13 and Figure 14. The maximum reduced stress is illustrated in the alternating values of the lower and higher reduced stress along the circumference of the ring, caused by the effect of force due to the tightening of the Kirschner wires. Figure 14 shows the asymmetrical displacement of the external fixator caused by the asymmetrical boundary conditions of the spatial anchoring of the fixator.
A clearer picture of the course of the reduced stresses \( \sigma_{\text{HMH}} \) /MPa/ and the displacements \( \Delta \) /mm/ of fixators using PEEK clamps is shown by Figure 15 and Figure 16. These figures show that the change of the clamp material from titanium alloy to PEEK brings about a reduction in the total maximum reduced stress \( \sigma_{\text{maxHMH}} \). A further important change is the transfer of the value \( \sigma_{\text{maxHMH}} \) from the clamps to the rings. The maximum reduced stress \( \sigma_{\text{maxHMH}} \) is now located in the areas acted upon by forces from the Kirschner wires.

For each part of the fixator the table shows the materials used, their yield strength, and the yield strength safety factor. In terms of safety, the best results were found for the fixator rods (for both types of material); the rods have the lowest values of maximum reduced stress and the best safety factor.

Using titanium alloy clamps, the worst safety performance was given by the rings; although they did not show the highest reduced stress \( \sigma_{\text{maxHMH}} \), their safety factor was the lowest due to the lower yield strength of the carbon fiber material (safety factor = 1.7).

Using PEEK clamps, the highest reduced stress \( \sigma_{\text{maxHMH}} \) was transferred to the rings of the fixator, reducing the safety factor from 1.7 (titanium alloy clamps) to 1.6. The same safety factor (1.6) was also found for the clamps; the change of material to PEEK led to a reduction in the maximum reduced stress, but PEEK has a much lower yield strength.

The overall safety factor of the complete fixator is equal to the lowest safety factor of any of its parts. The safety factor of the complete fixator is thus 1.7 for the model with the titanium alloy clamps and 1.5 for the model with PEEK clamps. Both these values are sufficient, and both variants of the fixator can thus be recommended for application to patients.

### 6. Conclusion

Complicated fractures represent an important therapeutic problem in traumatology and orthopedics.

According to the results and applications presented in this paper (i.e. some examples of ring external fixators for the treatment of human and animal bones), the experimental and Finite Element verifications of these fixators are sufficient.

### Table 6 Overview of selected results

<table>
<thead>
<tr>
<th>variant 1</th>
<th>( \sigma_{\text{HMHmax}} /\text{MPa} / )</th>
<th>( \Delta_{\text{max}} /\text{mm} / )</th>
<th>Material</th>
<th>( \text{Re} /\text{MPa} / )</th>
<th>Safety factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>clamps</td>
<td>154.38</td>
<td>1.55</td>
<td>Ti6Al4V</td>
<td>880</td>
<td>5.7</td>
</tr>
<tr>
<td>rods</td>
<td>62.07</td>
<td>1.53</td>
<td>Carbon fiber</td>
<td>200</td>
<td>3.2</td>
</tr>
<tr>
<td>rings</td>
<td>117.53</td>
<td>1.58</td>
<td>Carbon fiber</td>
<td>200</td>
<td>1.7</td>
</tr>
<tr>
<td>Fixator - complete</td>
<td>154.38</td>
<td>1.58</td>
<td></td>
<td>200</td>
<td>1.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>variant 2</th>
<th>( \sigma_{\text{HMHmax}} /\text{MPa} / )</th>
<th>( \Delta_{\text{max}} /\text{mm} / )</th>
<th>Material</th>
<th>( \text{Re} /\text{MPa} / )</th>
<th>Safety factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>clamps</td>
<td>110.42</td>
<td>1.75</td>
<td>PEEK</td>
<td>172</td>
<td>1.6</td>
</tr>
<tr>
<td>rods</td>
<td>69.04</td>
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<td>Carbon fiber</td>
<td>200</td>
<td>2.9</td>
</tr>
<tr>
<td>rings</td>
<td>128.78</td>
<td>1.62</td>
<td>Carbon fiber</td>
<td>200</td>
<td>1.6</td>
</tr>
<tr>
<td>Fixator - complete</td>
<td>128.78</td>
<td>1.75</td>
<td></td>
<td>200</td>
<td>1.6</td>
</tr>
</tbody>
</table>
Therefore, these fixators are reliable and safe and can be used for treatment of patients in traumatological or orthopedic centers. Clinical trials of new external fixators (i.e. clinical testing) are now performed in the Ostrava University Hospital, Trauma Center (Ostrava, Czech Republic).

The one interesting novelty of ring fixator is using the PEEK material, which is partially invisible in X-ray snapshots. Due to the PEEK material, the weight of the whole fixator system is lower too.

This paper has reported an important engineering/biomechanical viewpoint on new ways of designing external fixators, based on the results of previous work by the authors and other researchers. The new designs and materials of fixators will satisfy the ambitious demands of modern science. The results clearly reveal improvements in the design of fixators.

The VŠB-Technical University of Ostrava and the Ostrava University Hospital are cooperating with the Czech company MEDIN a.s. on the design of external fixators.

Acknowledgements

This work was supported by the Czech projects FR-TI3/818, Eupro II LE 13011 and SP2016/145.

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