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FINITE ELEMENT ANALYSIS IN THE STUDY AND OPTIMIZATION OF EXTERNAL FIXATORS

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Abstract: *This paper reviews recent approaches using finite element analysis for designing and optimizing orthopedic external fixators for stabilizing and healing bone fractures. Key aspects include design methods, numerical simulations, experimental and clinical validations. Furthermore, the mechanical properties of the human bone are investigated. Studies have explored various external fixator designs and configurations, by employing stress analysis to understand the mechanical behavior of the external fixator-bone construct, and optimizing the design and placement of frames, rods, and pins. The primary goals are to reduce the fixator's mass while maintaining necessary external fixator-bone stiffness for stability and healing, as well as to evaluate different configurations, and to provide data on optimal external fixator removal timing. Focusing mainly on external fixators for tibial fractures, the paper also includes insights from femur fracture studies. Hybrid external fixators are less frequently studied compared to linear or Ilizarov fixators. A notable aspect is the variability in external fixator configurations, tailored to patient anatomy and fracture type. Developing a comprehensive bone model is crucial, incorporating both cortical and cancellous bone types, as well as cortical thickness, which respond differently to stress due to varying material properties such as the Young's modulus and Poisson's ratio. Additionally, stages of callus formation, essential to bone healing, correspond to changes in the stiffness of the fixator-bone system, load transfer capacity of the external fixator, and interfragmentary strain values.*

Key words: *external fixator, finite element analysis, bone, mechanical properties, orthopedics, design, simulation, stiffness.*

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1. INTRODUCTION

The treatment and management of bone fractures by means of external fixators (EFs), especially for weight-bearing bones like tibia, presents significant challenges [1–2]. These include ensuring correct bone healing under dynamic load conditions, requiring precise placement of the fixator's pins and rods to preserve blood supply and minimize infection risk. Moreover, ongoing adjustments are necessary, while the bulkiness of EFs can compromise patient comfort and mobility, impacting quality of life and treatment compliance. Consequently, the design and fixation of orthopedic EFs are influenced by both engineering and medical considerations, including the anatomical variability of patients, the specifics of their fractures, and their age and health status, which are critical factors in selecting a specific type of fixation device. Furthermore, the stiffness of the device must be carefully adjusted to maintain bone stability while allowing inter-fragmentary movement between fragments to promote callus formation [3–4].

EFs include several main components, such as fixation pins, Schanz screws and Kirschner wires, which penetrate the skin and bone to secure the device, rods and frames connected to each other to provide stabilization and alignment; clamps and couplers which attach the rings and rods to the pins and wires and allow precise adjustment of the latter to align and stabilize the bone fragments [5] (Fig. 1).

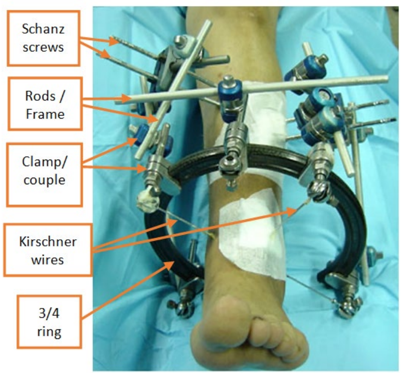

Fig. 1. Hybrid External fixator.

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Depending on the type of EF, other components such as joints and distractors can also be included in the assembly [2, 5]. EFs are commonly made of steel, and can be of unilateral design (linear EFs), circular (such as Ilizarov fixators or Taylor Spatial frame) or hybrid [6]. Hybrid EFs combine elements of circular and linear fixators, consisting of a full or partial ring, and one or more bars/rods, which are connected to the bone and to the rings at different angles. These hybrid EFs offer more adjustment possibilities, but also require greater expertise for proper mounting and adjustment [6]. Consequently, the use of engineering simulations to evaluate the impact of different EF configurations on EF-bone construct stiffness is important [7].

Optimizing the design and exploring new materials are especially significant, given the limitations of the existing EFs

These limitations include cost, particularly relevant in low-income countries [8], and the MRI incompatibility of metallic frames, compared to non-ferromagnetic and MRI-safe alternatives approved by the FDA [9].

In this context, this paper focuses on examining the literature related to the use of finite element-based investigations for the design and stiffness analysis of EF-bone interface of gathering information on several topics including human bone properties, loads and constraints, callus properties, mechanical testing, or FE model validation. This data collection aims to support the development of a robust FE model, which in turn targets the exploration of alternative carbon-based materials and composites, which can be 3D printed, thus enhancing the accessibility of these devices at reduced costs [10].

The bone of interest in this study is the tibia, and there are several important reasons for this selection. The tibia is prone to complex multiplanar fractures that require realignment and stabilization. Additionally, due to its subcutaneous location, the tibia is susceptible to soft tissue complications during treatment. Moreover, with the aid of EFs, tibial fractures benefit from early weight-bearing protocols that promote bone healing and prevent muscle atrophy [11]. However, femur-related studies are also addressed for additional insights.

2. MATERIAL AND METHOD

The research questions (RQs) to answer for fulfilling the main objectives of this review are the following:

1. What is the most common type of external fixator studied using finite element analysis (FEA) for tibia fractures?
2. What are the most common types of fractures treated with hybrid fixators, and what configurations are used?
3. What are the mechanical properties of human bone considered in FE-based studies on the behavior or design of EFs?
4. What are the key challenges and limitations associated with the application of FEA in studying EFs for tibial fractures?
5. How the validation of numerical simulations is carried out?
6. What are the key design parameters and optimization criteria for developing next-generation EFs that minimize weight while maximizing mechanical stability and patient comfort?
7. What is the impact of pins diameter, position and number over the stiffness of an EF for lower limbs fracture stabilization?

To address these RQs, the following scientific databases were searched: Clarivate Web of Knowledge, Scopus, and PubMed. The keywords used in the search included “external fixators”, “tibia”, and “finite element”, while a second search only in PubMed and Clarivate was focused specifically on bone and callus properties, which are essential for building the FE model used in simulations. The initial search produced 135 records in Clarivate alone, of which 93 were categorized under biomedical engineering, orthopedics, and surgery, in this order. Adding the term "tibia" narrowed the list of papers to 38. Twenty-five more records were added to the list from the second search. After duplicates removal, title and abstract filtering, 22 documents were kept for full read and qualitative analysis. The rejection criteria were related to non-human studies and fracture fixation by plates. The information in these papers was extracted by the following categories: material, contact definitions, fractured bone, fracture type, loads and post-processing, which are to be related to FE modeling. The results of the studies focused on bone and callus mechanical properties were discussed in the qualitative review.

Additionally, scientometric visualization tools were used to classify records from the initial search. Documents were sourced from the Clarivate database and exported to CiteSpace II [12] to visualize clusters of keywords and citation bursts within the timeframe of 1994–2023. This data is useful for understanding the landscape of the use of FEA for the EFs study.

3. RESULTS AND DISCUSSIONS

3.1. Scientometric outcomes

The citations chart in Fig. 2 illustrates the twenty-five most influential keywords and their bursts over the set time range. As expected, 'mechanical testing' topped the list, reflecting its direct relevance to the FEA terms used for database searches. The terms 'rigidity' and 'stiffness' also made the top 10, underscoring their significance in the design of external fixators. Conversely, keywords such as 'micro-movements' and 'fracture stiffness measurements' were less frequent, with studies on these topics emerging more recently. Interestingly, 'femur' was a commonly encountered keyword, while studies related to 'tibia' via FE modeling were not as prevalent. This discrepancy suggests a new area for detailed research and development, which will be explored in further work, thereby justifying the inclusion of 'tibia' as a relevant term for this systematic review.

Figure 3 presents the clusters identified as gathering different focuses within the field, such as “bone engineering”, “stability”, “axial stiffness” and “Sarafix system” (which is a linear fixator, commonly used in practice). Other EF studied by means of FE modeling is the Ilizarov fixator (Fig.4), only a couple of studies considering hybrid fixator as it will be shown in the next subsection.

Keywords	Year	Strength	Begin	End
mechanical testing	2007	1.33	2007	2013
rigidity	2000	1.09	2000	2005
wires	2005	1.03	2005	2010
ligaments	2014	1.48	2014	2018
dogs	2000	1.2	2000	2004
skeletal fixation	2000	1.2	2000	2004
bone	2020	1.51	2020	2023
femur	2017	1.3	2017	2020
stiffness	2004	1.21	2010	2013
foot	2005	1.18	2014	2017
bone engineering	2010	1.17	2010	2013
bone fracture healing	2010	1.17	2010	2013
plate	2017	2.58	2019	2021
finite element	2014	1.98	2017	2019
Lacroix D, 2002, J BIOMECH, V35, P1163, DOI 10.1016/S0021-9290(02)00086-6, DOI	2002	1.68	2004	2006
Chen G, 2015, MED ENG PHYS, V37, P650, DOI 10.1016/j.medengphy.2015.04.006, DOI	2015	1.44	2018	2020
internal fixation	2019	1.39	2019	2021
fractures	2005	1.05	2016	2018
tension	2017	0.96	2017	2019
model	2005	1.2	2005	2006
finite element method	2014	1.09	2014	2015
long bone fracture	2020	1.08	2020	2021
micromovement	2020	1.08	2020	2021
fracture stiffness measurement	2018	1.04	2018	2019
bone plate	2017	0.96	2017	2018

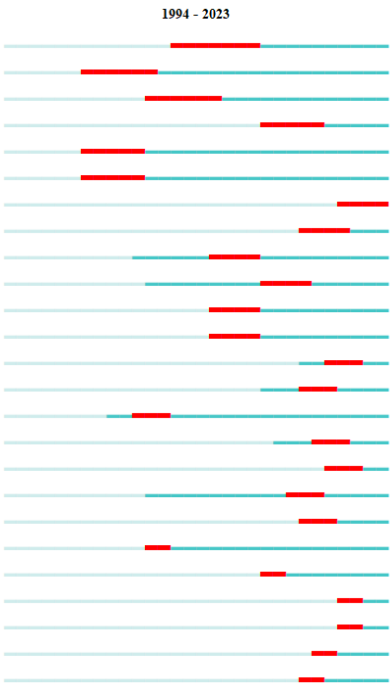

Fig. 2. Top 25 keywords for FEA studies for EFs, and their bursts.

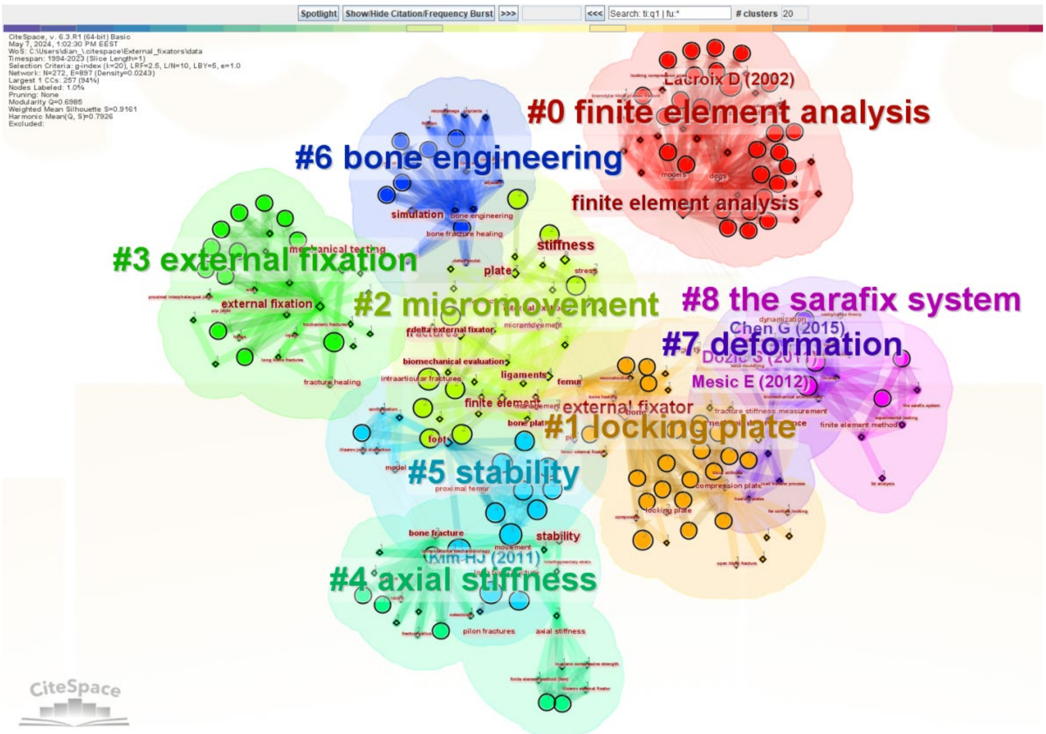

Fig. 3. CiteSpace II visualization of title clusters in the field of FEA for EFs.

Figure 4 provides a comprehensive visualization of this field landscape which proves the interdisciplinary of the topic, its connection with bone healing, EF configurations and designs, pin-bone interface, inter-fragmentary strain, etc.

3.2. Numerical investigations on EFs

Table 1 presents the synthetic data extracted from the analyzed papers. As mentioned, the reviewed papers focused only on lower limb fractures, but not exclusively on hybrid fixators, as this subject was not commonly addressed. Unilateral EFs are the most investigated type, followed by Ilizarov and then hybrid (RQ1). In this sense, it is worth mentioning that several studies were found that compare the mechanical behavior of different fixators for femur, tibia bones fractures [13–14] or subtalar dislocation [15] or pilon fractures [16] by means of FEA.

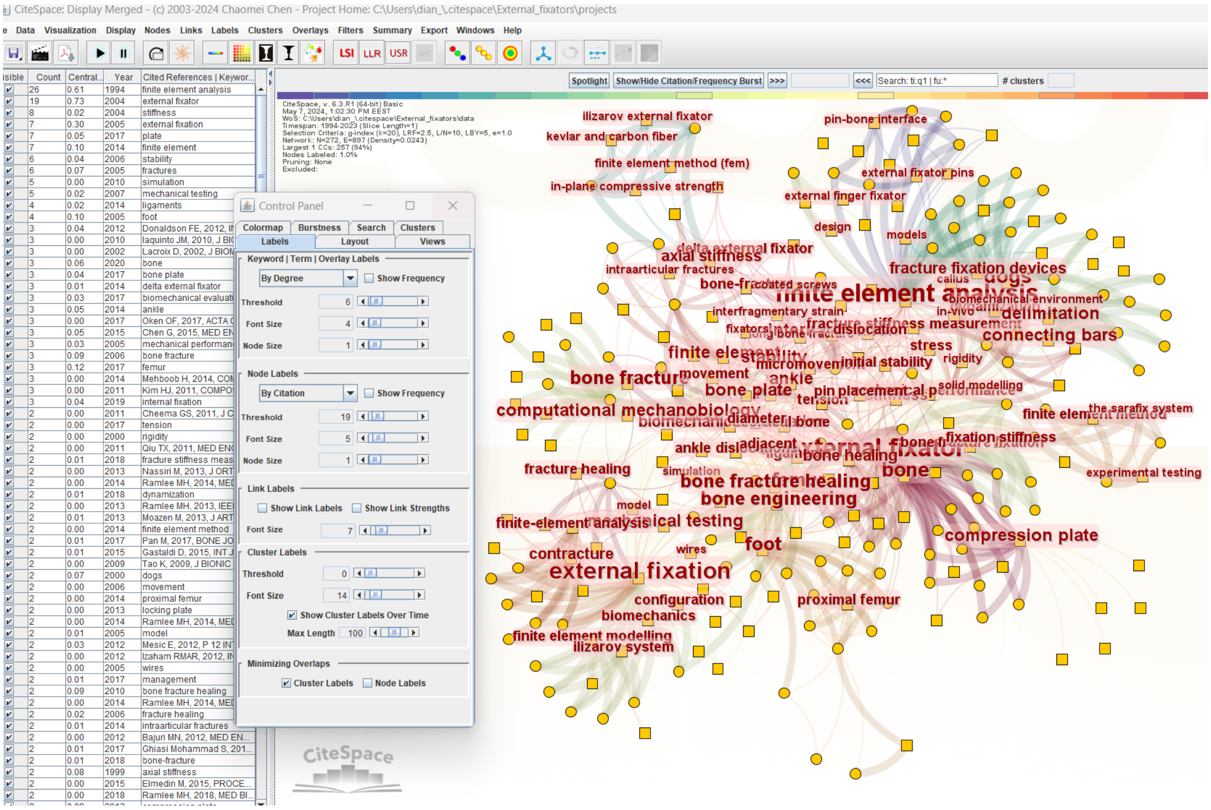

Fig. 4. CiteSpace II visualization of title clusters and hotspots in the field of FEA for EFs.

Aziz et al. [13] investigated the fixation stability provided by Ilizarov, unilateral and hybrid EFs on an oblique simulated femur fracture, the bone model being made based on computed tomography scans. Cancellous and cortical bone properties were set, Young's moduli of 150 MPa and 16.5 GPa, respectively. The femur loads were applied at its proximal end, the value simulating the stance phase. The results showed that the unilateral fixator provides more stability, followed by Ilizarov frame.

Wahab et al. [14] focused their research on the third distal tibial fracture and compared two EFs common configurations (single-cross and no-cross) with a new configuration (double cross). The Young moduli values were set at 16 GPa (cortical bone) and 1100 MPa (cancellous bone), while Poisson's ratio were set at 0.3, respectively 0.26. One can notice the difference in Young moduli between different studies. For each configuration, the stress distribution in bending, axial and torsion were determined, as well as the corresponding displacements. Results showed that double-cross configuration performs better in terms of stability in comparison to the other two. Ramlee et al. papers from 2014 [15–16] addressed analyses of unilateral, Mitkovic and Delta fixators, commonly used in practice. The results showed that Delta configuration provides better stability.

As mentioned in Introduction, the stability provided by the EFs is of critical importance. However, intermittent stress and inter-fragmentary micro-motions are necessary for callus formation. For instance, in Aziz et al. [13] 0.48 mm displacement between bone fragments were computed for the unilateral EF design which also was considered the most rigid of all three analyzed. This complicates finding the correct stiffness, hence the importance of using FE simulations for analyzing different EFs configurations, pins and rods positions etc. In this sense, using FEA, Sternick et al. showed the pins importance in ensuring the fixator stability [17]. Their diameter, position, distance to the fracture gap or number which are influencing the stiffness of the construct. More recently, Ramlee et al. [18] analyzed several pin diameters ranging from 4.5 mm to 6.5 mm of a unilateral EF for a tibial fracture. Displacements and peak stresses were computed and compared, the EF with four pins of 5.5 mm diameter demonstrating to be the optimal one. In [26] was evaluated the stability of a unilateral EF for 1-3 pins. If the cortical thickness is reduced for 5 mm to 1 mm, the number of pins should be up to 3 to ensure a proper stiffness for EF-bone construct. Hadeed et al. [2] noted that the diameter of the pins has a relevant effect on EF stability, but at the same time, a larger diameter can increase the stress and risk of fracture. Also, number of pins and pins' positioning closer to the fracture site also improve the fixation stiffness. These studies provide an answer to RQ7.

In [19] are compared two Mitkovic external fixators from titanium alloy and stainless steel. The bone was modeled on CT-derived images. Results indicated that stainless steel models exhibit lower von Mises stress (127 MPa) and higher stability with less displacement at the fibula (3.3 mm) compared to titanium alloy models (369 MPa stress and 7.4 mm displacement). Elmedin et al. conducted both numerical and experimental investigations to assess the stiffness of a Sarafix external fixator under various loading conditions, including 4-point bending (500 N), axial compression (600 N), and torsion (15 Nm) [20].

Table 1

Synthetic information extracted from reviewed studies on FE modeling for EF

Study	External Fixator type	Material Definition	Bone and fracture	Contact definitions	Loads	Post-processing	Methods and limitations
[13]	Three EF: unilateral, hybrid and Ilizarov	Homogeneous and linear isotropic stainless steel EF with E = 190GPa and v = 0.3.	Cortical and cancellous Femoral bone with oblique fracture	Partially bonded between the fixator and bone	Axial loads applied on the proximal end of the femur (stance phase 320 Nx, −170 Ny, − 2850 Nz)	IFM movement, Von Mises Stress and Maximum principal strain	The distance between bone and rod of the 3 models and the number of anchors used for EF may influence the results
[14]	Three axial linear EF: single-cross no-cross and delta double-cross construct	Homogeneous and linear isotropic Titanium EF with E = 110GPa and v = 0.3	Cortical and cancellous tibia bone with oblique fracture along 33º fracture angle	0.3 friction coefficient between EF/bone interface	Axial, bending loads 1500 N, 500 N at proximal and distal tibia and torsion loads 15 N at proximal tibia	Maximum principal strain	The oblique fracture modelled with no gaps between the fracture components
[15]	Two EF: Mitkovic and Delta EF		Cortical and cancellous ankle and foot bones: tibia, fibula, talus, calcaneus bone with ligaments ankle dislocation	0.4 friction coefficient between EF/bone interface and 0.3 between bones.	Two axial loads: 70 N and 350 N applied axially to the tibia bone to represent the swing and stance phases	Von Mises Stress and relative micro-movement	Ligaments links removed to model the dislocation. No high mechanical cyclic loading
[16]	Three EFs: Delta, Mitkovic and unilateral		Cortical and cancellous ankle and foot bones: tibia, fibula, talus, calcaneus bone with type III pilon fracture	0.3 friction coefficient between EF/bone interface and between bone fragments			Use of linear links to model the ligaments and 8 fragments for the pilon fractures
[17]	Axial Cromus dynamic external fixator	Homogeneous and linear isotropic Aluminum + stainless steel EF with E=190/69GPa and v=0.29/0.33	Femoral bone substitute with 20mm gap	Not specified (seems to be Bonded)	Axial force of 200 N, equivalent to the maximum force supported by device during the patient's recovery phase	Resultant displacements and von Mises	The stiffness of the EF may vary with the callus formation during healing process
[20]	Sarafix unilateral biplanar EF	orthotropic wooden bone with isotropic EF from stainless steels to composite materials	Tibia with an open fracture with fracture gap of 50 mm	Join elements of the spider type	axial compression 0 to 600 N 4 point bending force of 500 N Torsion torque Mu=15Nm	Stiffness comparing the load vs displacement values	Comparability of properties between wood and specific human bones are debatable
[22]	Hip stem and plate	Homogeneous and linear isotropic Titanium plate with E=96GPa and v=0.36.	Intact, injured, repaired, and healed femur with a transverse 5 mm gap	Bonded contact with no slipping	Axial load of 1500 N and 3000 N	Strains Axial stiffnesses VonMises Stress	The fixator is an implant and not an external fixator
[23]	Axial linear fixators - unilateral	Homogeneous and linear isotropic EF with E = from 20 to 200 GPa and v = 0.29/0.33.	Cortical tibia bone, marrow with 3 mm gap filled by callus granulation tissue	Tie constraint between bone and pins to replicate clamps	Axial load of 187.5N (25% of the body weight a of 75 kg male)	Comparison of axial stiffness of the bone-fixator and the unit from in-vitro study	The shape of a tibia simplified as a smooth circular shaft
[24]	Unilateral EF systems	orthotropic elasticity bone properties with stainless steels and titanium EF E = 180/105 GPa and v = 0.3	Periosteal–endosteal variation of tibial bone properties with one-half of the tibial midshaft fracture	Contact with zero friction	A vertical load of 700 N (partial weight bearing for an average man during a one-legged stance)	maximum and a minimum principal elastic strain	Strain-based plasticity. With focus on loosening at the pin–bone interface

A distal tibia from wood was used in the tests. The same type of EF was studied by Pevan et al. [21] for a tibia model with 50 mm gap between fragments. A linear dependence between the loads and the stress values on the fixator's rod was identified. In other studies, the axial compression was set at 1500 N for femur [22], and Kolasangiani et al. considered it at 25% of the patient's weight [23], while Lin et al. [25] applied a 1000 N axial load to the tibial plateau.

Comparative clinical studies when using Ilizarov EF vs. hybrid EF was conducted for 45 children with tibial shaft fractures in a retrospective study [26]. The outcomes showed no statistical significant differences, while hybrid fixators are cheaper and simpler to use than Ilizarov frame.

Literature data shows that hybrid EFs are more used for pilon complex fractures (RQ2).

As shown in Table 1, the contacts between bone and pins are mainly modeled with 0.3 to 0.4 friction coefficient [14 and 15], or even with no friction [24] allowing the pins to slide. This is an important boundary condition in order to evaluate the pin–bone interface loosening which can lead to pin-tract infections or even loss of fixation. However, in some other cases [22 and 23] the contact is considered as bounded, the focus being on evaluating the global fixator–bone system stiffness for different healing stages. Regarding the fracture modeling, there are two main methods used, modeling a fracture line with contact between the broken bones or fragments [13 and 16] or considering an open fracture with gap ranging from 3mm up to 50 mm [20 and 22]. In some cases [23], the gap is considered filled by callus with different tissue properties in function of the different healing stages (RQ4).

3.2.1. Bone and callus mechanical properties. To generate simulations that accurately mimic real-world scenarios and to understand the behavior of the EF-bone construct, as well as to analyze various mounting configurations and designs, it is crucial to have data on the mechanical properties of bone and callus. However, this is challenging as such properties vary with each patient, while the type of fracture and fracture gap are also specific for each medical case. Therefore, in several studies [15–16 and 18–19], bone models generated from CT scans are utilized to accurately determine various bone characteristics, such as cortical bone thickness, which has been shown to significantly influence stress in a unilateral EF. Al-Tojary et al. showed that reducing the cortical thickness from 5 mm to 1 mm increases the inter-fragmentary strain by approximately 30.3% [27].

Table 2 presents mechanical properties of bones as considered in the analyzed papers, thus answering RQ3. Most papers consider bone as isotropic [28]. Also, one can notice differences in mechanical properties not only between different bone types (e.g., tibia vs. femur) but also between studies of the same bone type. Therefore, additional biology-focused studies were reviewed to gather data on the Young's modulus, shear modulus, and Poisson's ratio for the tibia. In [29], ultrasonic investigations were conducted on cadaver tibiae to determine the elastic properties in three zones of the bone (cuts at 30%, 50%, and 70% of bone length from the tibial plateau). The average values measured in three directions (anteroposterior, mediolateral and along the bone's axis) were as follows:

- Cancellous bone: Young's modulus: $E1$ = 202 MPa, $E2$ = 232 MPa, $E3$ = 769 MPa;
- Cortical bone: Young's modulus: $E1$ = 11.7 GPa, $E2$ = 12.2 GPa, $E3$ = 20.7 MPa; Poisson's ratio: $\nu_1 = 0.32$; $\nu_2 = 0.33$; $\nu_3 = 0.4$.

The healing process of a fractured bone involves the formation of callus (phases: inflammatory, reparative, remodeling [30] in around 3–12 weeks for an adult), whose mechanical properties dynamically change over time, adding additional challenges to creating FE models. Only a few papers have taken this aspect into account by setting different properties of the callus for different healing stages. Table 3 summarizes this data.

It should also be noted Li et al. paper in which a FE model, based on Castigliano's theory for Young modulus calculation, is proposed for investigating the influence of the healing process over the compression, torsional and bending stiffness of a unilateral EF-bone construct [31]. The purpose is to assess, using FEA-based methods, the appropriate timing for EF removal, which is important medical information.

In Ghiasi et al. [32], a computational model was developed for exploring the effects of various initial healing conditions on bone fracture recovery. Using FEA, the research simulates stress dynamics and mesenchymal stem cell diffusion in fractured bones. The results suggest that the initial mechanical stability and biological environment significantly influence the healing process. This study is another prove of the developing FE models as particular, patient-specific conditions as well as fixation rigidity influence the callus stiffness which is at its turn influences EF-bone stiffness.

3.2.2. Validation of FE-based modeling of EFs. Due to ethical considerations, validation of FE models for different EF configurations is conducted using testing equipment [33] or animal models (rats [34], rabbits [35]).The following data provide answers to RQ5.

The following types of tests are reported in the analyzed literature for the construct EF-bone: axial compression and torsion with the proximal tibia fixed in the testing equipment and the load applied at the distal end, as well as bending (cantilever, 3-point and 4-point bending) according to ASTM F1541–17, "Standard Specification and Test Methods for External Skeletal Fixation Devices" [36].

Additionally, EF components can also be the focus of numerical analysis and validation through mechanical tests. Depending on the component being evaluated, scenarios include bending, torsion, and compression. For example, rings are tested in compression [36], while pins and rods are assessed for bending and torsion [36]. More details are available in the comprehensive review by Fernando et al. [37].

An interesting type of mechanical test, not commonly used when evaluating the mechanical behavior of EFs despite its realistic scenario, accounts for callus formation and its variable stiffness over time. This approach, not addressed in [37], is presented in [38–39].

Table 2

Bone mechanical properties in analyzed literature

Study	Young modulus cortical bone (GPa)	Young modulus cancellous bone (MPa)	Poisson coefficient	Bone
[29]	16.5	150	0.3 cortical	femur
[28]	8.69 GPa (longitudinal) 4.19 GPa (transverse) 3.76 GPa (radial)	-	0.3	femur
[41]	2.2	-	0.35	generic
[42]	7.3 MPa	1100	0.3 cortical 0.26 cancellous	calcaneus
[43]	17	700	0.3 cortical 0.2 cancellous	tibia
[15-16, 18-19]	7.3	1100	0.3 cortical 0.26 cancellous	tibia, fibula, talus and calcaneus
[44]	17	7000	0.3 cortical 0.2 cancellous	generic
[23]	2-6	-	0.325 cortical	tibia
[14]	16	1100	0.3 cortical 0.26 cancellous	tibia
[45]	8.5 (radial) 7 (transverse) 18.4 (longitudinal)	1100	0.3 cortical 0.26 cancellous	tibia

Table 3

Callus mechanical properties

Tissue type	Young's modulus (MPa)	Poisson's ratio
Cartilage [46] Cortical Mature Immature	10 17000 6000 1000	0.167 0.3 0.3 0.3
Fibrous Tissue [47] Cartilage Immature bone Intermediate bone Mature bone	0.2 – 5 5 – 500 500 – 1000 1000 – 2000 2000 – 6000	0.167 0.167 0.3 0.3 0.3
0 week [45] 4 weeks 8 weeks	0 0.19 28	0 0.3 0.3
0.5 week [31]	0.0004 E_B	0.26
2 week [31]	0.0009 E_B	0.26
6 week [31]	0.0378 E_B	0.26
9 week [31]	0.1901 E_B	0.26
12 week [31]	0.6000 E_B	0.26
15 week [31]	0.6001 E_B	0.26

Note: E_B=1 6.5 GPa [31]

Burny et al. modeled the callus gap using springs with stiffness ranging from 10–405 N/mm for a Hoffmann II EF [38].The same type of EF was also studied by Ong et al., the callus formation being mimicked by filling the 3 mm fracture gap with epoxy which cured in time and this simulated the healing and union process [39]. The method was extended by using modelling clay to add the mass of soft tissue around the bone.

In their experimental tests, Di Puccio et al. used three materials with different stiffness (universal silicon, HDPE glue, Araldite) to simulate callus development stages [40]. As for the other studies, the purpose is to evidence by experimental means the ability of the testing stand which includes EF and bone to detect the changes in EF-bone system stiffness determined by callus rigidity modification during healing process.

3.2.3. 3D printing in EF design and manufacturing. Its ability to produce customized, cost-effective, and mechanically robust components has the potential to revolutionize the field of orthopedic treatment, providing better outcomes for patients with complex fractures and deformities. This level of customization is particularly beneficial for complex fractures or deformities where standard EF designs may not provide optimal stabilization. By using patient-specific imaging data, such as CT scans, 3D models of the affected bone and surrounding structures can be generated. These models serve as the basis for designing EFs that fit precisely, improving both the stability and comfort for the patient. Materials commonly used in 3D printing for EF components include polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), and Nylon with short carbon fiber (Onyx) [48–50]. These materials are selected for their mechanical properties, biocompatibility, and ease of processing. PLA and ABS are popular due to their widespread availability and cost-effectiveness, while Onyx offers enhanced strength and durability, making it suitable for load-bearing applications (RQ6).

One notable application of 3D printing in EF manufacturing is the production of rings and clamps. Traditional metal rings, such as those used in Ilizarov fixators, can be replaced with 3D-printed versions that are lighter and easier to produce. Research has shown that these 3D-printed components can match the mechanical performance of their metal counterparts. For example, Landaeta et al. [10] developed a 3D-printed clamp made from Onyx material which strength was comparable to commercially available clamps. In addition to mechanical benefits, 3D printing offers economic advantages. The production of EFs using traditional methods can be costly and time-consuming, particularly for custom designs. 3D printing reduces material waste and minimizes the need for extensive machining and assembly processes. This cost-effectiveness makes it an attractive option for healthcare providers and patients, especially in resource-limited settings.

3.2.4. Ring design considerations. EF rings, including full, half, three-quarters, two-thirds or five-eighths configurations (arches), contribute to the stabilization of the EF-bone construct and are designed to allow the connection of other fixation hardware [51]. Therefore, they include open holes or elongated holes, as well as form features (Fig. 5) that ensure the connection of the other components, and their position adjustments, enabling dynamic adjustments as the healing process progresses. The rings can have a uniform rectangular section (Fig. 5,*a*) or an I-shaped section (Figs. 1 and 5,*b*) for improved rigidity. Additionally, rings' design might include blocks for connection with other components. The connection between the ring and the bone is made through wires or pins, which pass through the soft tissue and bone, and are fastened securely and tensioned on opposite sides of the ring. This provides the multiplanar adjustability required for precisely aligning and fixation of the bone fragments.

The circular design of the rings allows the radial distribution of the mechanical loads, while for the foot, the fixation external rings can have a U-shaped configuration [51]. For enhancing the construct stiffness, the dimension of the rings should be selected so that to come close to the patient's lower extremity. Full size rings are often applied to the tibia, and in case of postoperative swelling, two half rings are connected with bolts to avoid this complication [51]. Five-eighths or two-thirds rings are typically used in the proximal tibia to allow the knee flexion [6].

Rings are usually made of stainless steel or carbon fiber composites, materials selected based on mechanical strength, biocompatibility and sterilization resistance.

In the analyzed papers, full rings and arches are studied by means of FEA, their design including uniform thick section and open holes.

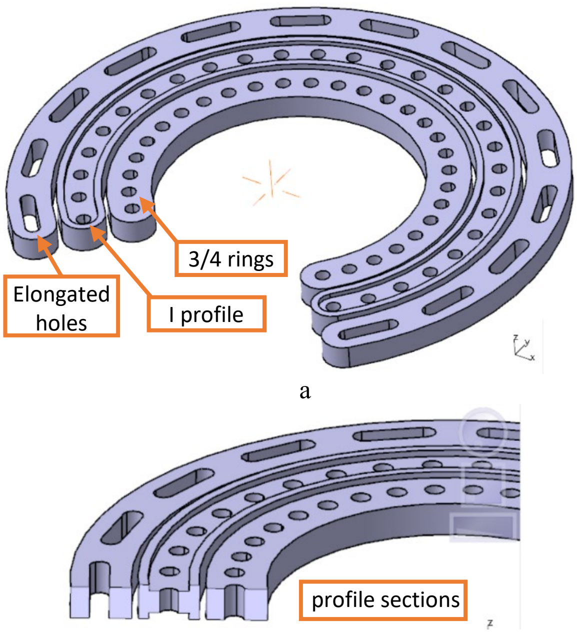

Fig. 5. EFs' rings and partial rings design: *a* – rings with uniform rectangular section; *b* – rings with I-shaped section.

3.2.5. Mechanical testing of EFs based on ASTM F1541-2015. Standards like ASTM F1541-2015 [36] specify methods for testing the mechanical properties of external fixators, including load-bearing capacity, stiffness, and stability under axial load and bending moment, based on ASTM E4-21 for EF connectors, rings, and joints.

For rings or ring segments, in-plane compressive forces are applied quasistatically at 180 ° load points until failure. The resulting load-displacement plot determines in-plane compressive strength and stiffness. Compressive stiffness (N/mm) is derived from the maximum slope of the initial load-displacement curve. Yield strength (N) is determined using the secant-offset method with a 0.2% permanent deflection. Maximum compressive strength (N) is the highest load reached or the load at a 10% deflection.

External skeletal fixator pins are tested in static four-point bending and torsion. The pin-rod joint is tested quasistatically within 30 seconds. Single-cycle testing involves preconditioning cycles until stiffness changes by less than 5%, typically around five cycles within the elastic range. Load/deformation curves and stiffness values are recorded. For multi-cycle testing, curves are recorded for at least the first five cycles, noting cycles needed for stiffness changes of less than 1%. Hysteresis severity, indicated by areas under load/deformation curves, is reported and determined by graphical or numerical integration.

3.2.6. Holographic Interferometry Testing. Holographic Interferometry Testing represents an optical technique used to evaluate the structural integrity and mechanical behavior of EFs. This non-destructive testing method is based on the principles of holography and interferometry to measure minute deformations and vibrations of the fixator under various loads. A laser beam is split into two paths, one illuminating the object (fixator) and the other is employed as a reference. The scattered light from the object and the reference beam are combined to form an interference pattern (hologram) on a photographic plate or a digital sensor [52].

3.2.7. 6D Compliance. 6D Compliance refers to the assessment of the EFs ability to resist displacements and rotations along six degrees of freedom (three translational and three rotational). The compliance in each of these directions is measured to ensure the EF ability to immobilize the fractured bone segments, promoting proper healing. This evaluation often involves applying controlled forces and moments to the fixator and measuring the resulting displacements and rotations [53].

4. CONCLUSIONS

The EF-bone construct is tailored specifically to the bone requiring stabilization, considering patient's anatomical characteristics, type of fracture, fractured boned and other existing pathologies. These medical factors influence the selection of the EF type, the number and diameter of pins, the number of wires and their tension, and the number of rods and rings as well as their positioning and orientation. Additionally, acquiring data on callus formation is important for understanding the progress of healing and estimating the time for EF removal. It becomes thus clear not only that there is a need for a custom approach when configuring EF for a certain patient, but also that the use of FEA to simulate the structural behavior of EF components, of fracture site and of EF-bone interface can provide important benefits for improving EF design and comparatively assessing diverse configurations and materials.

FEA allows for the detailed analysis of mechanical stresses and strains within the EF system and the bone, enabling the identification of potential weaknesses or failure points. By simulating various scenarios, FEA can guide the optimization of EF constructs to enhance their stability and effectiveness. This advanced computational method can also facilitate the comparison of different materials, helping to select the most suitable ones for specific clinical situations. Furthermore, integrating FEA into the design process can:

- Reduce the risk of complications by predicting how different EF configurations will influence the bone stability, stiffness and healing.
- Contribute to the development of new EF designs by providing information on the mechanical performance before clinical use.
- Improve patient outcomes by enabling individualized treatment plans.

The current paper reviewed the work in the FEA for orthopedic EFs in order to identify the commonly used approaches, the modalities used for analysis depending on type of fixator. Additionally, data related to bone properties and callus properties were gathered for use in numerical modeling. The main findings revealed both differences and commonalities among the analyzed papers regarding the EF-bone contact definition and validation methods. The analysis showed the current limitations in this field as follows: callus stiffness variability with time was considered only in a couple of studies, tibia fracture are less commonly addressed than femur fractures, unilateral EF are more frequently studied than hybrid and circular fixators.

REFERENCES

[1] Bible, J.E.; Mir, H.R. External Fixation: Principles and Applications. J. Am. Acad. Orthop. Surg. 2015, 23, 683–690

[2] Hadeed, A., Werntz, R. L., & Varacallo, M. (2019b). External Fixation Principles and Overview. StatPearls. https://europepmc.org/article/MED/31613474

[3] Gómez-Benito, M. J., García-Aznar, J., Kuiper, J. H., & Doblaré, M. (2005). A 3D computational simulation of fracture callus formation: influence of the stiffness of the external fixator. Journal of Biomechanical Engineering, 128(3), 290–299.

[4] Wu, J., Shyr, H., Chao, E. Y., & Kelly, P. J. (1984). Comparison of osteotomy healing under external fixation devices with different stiffness characteristics. Journal of Bone and Joint Surgery. Vol. 66(8), 1258–1264.

[5] Seligson, D., Mauffrey, C., & Roberts, C. S. (2012b). External fixation in orthopedic traumatology. In Springer eBooks. https://doi.org/10.1007/978-1-4471-2197-8.

[6] Fragomen, A. T., & Rozbruch, S. R. (2006). The mechanics of external fixation. HSS Journal, 3(1), 13–29.

[7] Alqahtani, M.S.; Al-Tamimi, A.A.; Hassan, M.H.; Liu, F.; Bartolo, P. Optimization of a Patient-Specific External Fixation Device for Lower Limb Injuries. Polymers 2021, 13, 2661.

[8] Saeidi, M., Barnes, S. C., Berthaume, M. A., Holthof, S. R., Milandri, G. S., Bull, A. M. J., & Jeffers, J. R. (2022). Low-cost locally manufacturable unilateral imperial external fixator for low- and middle-income countries. Frontiers in Medical Technology, 4.

[9] Morandi, M., Simoncini, A., Hays, C., Garrett, J. V., Barton, R. S., Chen, A., & Solitro, G. F. (2020). Optimal configuration for stability and magnetic resonance imaging quality in temporary external fixation of tibial plateau fractures. Orthopaedics & Traumatology: Surgery & Research, 106(7), 1405–1412.

[10] Landaeta FJ, Shiozawa JN, Erdman A, Piazza C. Low cost 3D printed clamps for external fixator for developing countries: a biomechanical study. 3D Print Med. 2020;6(1):31. doi: 10.1186/s41205-020-00084-3.

[11] Joslin CC, Eastaugh-Waring SJ, Hardy JR, Cunningham JL. Weight bearing after tibial fracture as a guide to healing. Clin Biomech (Bristol, Avon). 2008 Mar; 23(3):329–33.

[12] Chen, C. (2006) CiteSpace II: Detecting and visualizing emerging trends and transient patterns in scientific literature. Journal of the American Society for Information Science and Technology, 57(3), 359–377.

[13] Aziz, A. U. A., Wahab, A. H. A., Rahim, R. a. A., Kadir, M. R. A., & Ramlee, M. H. (2020b). A finite element study: Finding the best configuration between unilateral, hybrid, and ilizarov in terms of biomechanical point of view. Injury, 51(11), 2474–2478.

[14] Wahab, A. H. A., Wui, N. B., Kadir, M. R. A., & Ramlee, M. H. (2020c). Biomechanical evaluation of three different configurations of external fixators for treating distal third tibia fracture: Finite element analysis in axial, bending and torsion load. Computers in Biology and Medicine, 127, 104062.

[15] Ramlee, M. H., Kadir, M. R. A., Murali, M. R., & Kamarul, T. (2014a). Biomechanical evaluation of two commonly used external fixators in the treatment of open subtalar dislocation—A finite element analysis. Medical Engineering & Physics, 36(10), 1358–1366.

[16] Ramlee, M. H., Kadir, M. R. A., Murali, M. R., & Kamarul, T. (2014b). Finite element analysis of three commonly used external fixation devices for treating Type III pilon fractures. Medical Engineering & Physics, 36(10), 1322–1330.

[17] Sternick, M. B., Dallacosta, D., Bento, D. Á., & Reis, M. L. D. (2012). Relationship between rigidity of external fixator and number of pins: computer analysis using finite elements. Revista Brasileira De Ortopedia, 47(5), 646–650.

[18] Ramlee MH, Sulong MA, Garcia-Nieto E, Penaranda DA, Felip AR, Kadir MRA. Biomechanical features of six design of the delta external fixator for treating Pilon fracture: a finite element study. Med Biol Eng Comput. 2018 Oct; 56(10):1925-1938.

[19] Ramlee, M. H., Wahab, A., Wahab, A. A., Latip, H. F. M., Daud, S. A., & Kadir, M. R. A. (2017). The effect of stress distribution and displacement of open subtalar dislocation in using titanium alloy and stainless steel mitkovic external fixator – a finite element analysis. Malaysian Journal of Fundamental and Applied Sciences, 13(4–2), 477–482.

[20] Elmedin, M., Vahid, A., Nedim, P., & Nedžad, R. (2015). Finite element analysis and experimental testing of stiffness of the Sarafix external fixator. Procedia Engineering, 100, 1598–1607.

[21] Pervan, N.; Mešić, E.; Muminović, A.J.; Muratović, E.; Delić, M. Analysis of Biomechanical Characteristics of External Fixators with Steel and Composite Frames during Anterior–Posterior Bending. Appl. Sci. 2023, 13, 8621.

[22] Ebrahimi H, Rabinovich M, Vuleta V, Zalcman D, Shah S, Dubov A, Roy K, Siddiqui FS,H, Schemitsch E, Bougherara H, Zdero R. Biomechanical properties of an intact, injured, repaired, and healed femur: an experimental and computational study. J Mech Behav Biomed Mater 2012;16:121–35.

[23] Kolasangiani R, Mohandes Y, Tahani M. Bone fracture healing under external f ixator: investigating impacts of several design parameters using Taguchi and ANOVA. Biocybernetics and Biomed Eng 2020;40:1525–34.

[24] Donaldson FE, Pankaj P, Simpson AHRW.(2012) Bone properties affect loosening of half pin external fixators at the pin–bone interface, Injury , 43:1764–70

[25] Lin, W., Lin, K. C., Chen, C. H., Li, B. H., Li, J. Y., Chen, W. C., Tsai, C., & Huang, S. (2015). A simple external fixation technique for treating bicondylar tibial plateau fracture: a finite element study. In IFMBE proceedings (pp. 330–332).

[26] Hui, T., Wang, J., Yu, Y., Dong, H., & Lin, W. (2024). External Fixator versus Ilizarov External Fixator for Pediatric tibial shaft fractures: A Retrospective Comparative study. Injury, 11376.

[27] Al-Tojary, G. A., Mohandes, Y., & Tahani, M. (2022). A finite element study of a fractured tibia treated with a unilateral external fixator: The effects of the number of pins and cortical thickness. Injury, 53(6), 1815–1823.

[28] Bazyar, P.; Baumgart, A.; Altenbach, H.; Usbeck, A. An Overview of Selected Material Properties in Finite Element Modeling of the Human Femur. Biomechanics 2023, 3, 124-135.

[29] Rho, J. (1996). An ultrasonic method for measuring the elastic properties of human tibial cortical and cancellous bone. Ultrasonics, 34(8), 777–783.

[30] ElHawary H, Baradaran A, Abi-Rafeh J, Vorstenbosch J, Xu L, Efanov JI. Bone Healing and Inflammation: Principles of Fracture and Repair. Semin Plast Surg. 2021 Aug;35(3):198-203.

[31] Li J, Zhao X, Hu X, Tao C, Ji R. A theoretical analysis and finite element simulation of fixator-bone system stiffness on healing progression. J Appl Biomater Funct Mater. 2018 Jul;16(3):115-125.

[32] Ghiasi MS, Chen JE, Rodriguez EK, Vaziri A, Nazarian A. Computational modeling of human bone fracture healing affected by different conditions of initial healing stage. BMC Musculoskelet Disord. 2019 Nov 25;20(1):562.

[33] Aziz, A. U. A., Ammarullah, M. I., Wui, N. B., Gan, H., Kadir, M. R. A., & Ramlee, M. H. (2024). Unilateral external fixator and its biomechanical effects in treating different types of femoral fracture: A finite element study with experimental validated model. Heliyon, e26660.

[34] Qi W, Feng X, Zhang T, Wu H, Fang C, Leung F. Development and validation of a modularized external fixator for generating standardized fracture healing micromotions in rats. Bone Joint Res. 2021;10(11):714-722.

[35] Karunratanakul K, Kerckhofs G, Lammens J, Vanlauwe J, Schrooten J, Van Oosterwyck H. Validation of a finite element model of a unilateral external fixator in a rabbit tibia defect model. Med Eng Phys. 2013 Jul;35(7):1037-43.

[36] ASTM F1541–17, Standard Specification and Test Methods for External Skeletal Fixation Devices

[37] Fernando, P., Abeygunawardane, G. A., Wijesinghe, P., Dharmaratne, P., & Silva, P. (2021b). An engineering review of external fixators. Medical Engineering & Physics, 98, 91–103.

[38] Burny, F., Burny, W., Donkerwolcke, M., & Behrens, M. (2012). Effect of callus development on the deformation of external fixation frames. International Orthopaedics, 36(12), 2577–2580.

[39] Ong, W., Chiu, W. K., Russ, M., & Chiu, Z. K. (2016). Integrating sensing elements on external fixators for healing assessment of fractured femur. Structural Control & Health Monitoring/Structural Control and Health Monitoring, 23(12), 1388–1404.

[40] Di Puccio, F., Mattei, L., Longo, A., & Marchetti, S. (2017b). Fracture Healing Assessment Based on Impact Testing: In Vitro Simulation and Monitoring of the Healing Process of a Tibial Fracture with External Fixator. International Journal of Applied Mechanics, 09(07), 1750098.

[41] Zamani, A., & Oyadiji, S. O. (2010). Theoretical and finite element modeling of fine Kirschner wires in Ilizarov external fixator. Journal of Medical Devices, 4(3).

[42] Pan M, Chai L, Xue F, Ding L, Tang G, Lv B. Comparisons of external fixator combined with limited internal fixation and open reduction and internal fixation for Sanders type 2 calcaneal fractures: Finite element analysis and clinical outcome. Bone Joint Res. 2017 Jul;6(7):433-438.

[43] Paulino, M. F., Roseiro, L., Balacó, I., Neto, M. A., & Amaro, A. M. (2022). Evaluation of Bone Consolidation in External Fixation with an Electromechanical System. Applied Sciences, 12(5), 2328.

[44] Roseiro, L., Neto, M. A., Amaro, A. M., Leal, R. P., & Samarra, M. C. (2014b). External fixator configurations in tibia fractures: 1D optimization and 3D analysis comparison. Computer Methods and Programs in Biomedicine, 113(1), 360–370.

[45] Kim, H.-J., Kim, S.-H., & Chang, S.-H. (2011). Bio-mechanical analysis of a fractured tibia with composite bone plates according to the diaphyseal oblique fracture angle. Composites Part B: Engineering, 42(4), 666–674.

[46] Byrne, D., Lacroix, D., & Prendergast, P. J. (2011). Simulation of fracture healing in the tibia: Mechanoregulation of cell activity using a lattice modeling approach. Journal of Orthopaedic Research, 29(10), 1496–1503.

[47] Mehboob A., Mehboob H., Kim J., Chang S. H., and Tarlochan F., Influence of initial biomechanical environment provided by fibrous composite intramedullary nails on bone fracture healing, Compos. Struct., vol. 175, pp. 123–134, Sep. 2017.

[48] O'Connor, H.A., Adams, L.W., MacFadden, L.N. et al. 3D Printed Orthopaedic External Fixation Devices: A Systematic Review. 3D Print Med 9, 15 (2023).

[49] Corona, P. S., Vicente, M., Tetsworth, K., & Glatt, V. (2018). Preliminary results using patient-specific 3d printed models to improve preoperative planning for correction of post-traumatic tibial deformities with circular frames. Injury, 49, S51–S59

[50] Qiao F, Li D, Jin Z, Gao Y, Zhou T, He J, et al. Application of 3D printed customized external fixator in fracture reduction. Injury. 2015;46(6):1150–5.

[51] `https://musculoskeletalkey.com/circular-external-fixation-components-and-design-considerations/#F5-4` (accessed September 2nd)

[52] Jacquot, P., Rastogi, P. K., & Pflug, L. (1984). Mechanical testing of the external fixator by holographic interferometry. orthopedics, 7(3), 513-523.[53] Meleddu, A., Barrault, S., & Zysset, P. K. (2007). A rigorous method for evaluation of the 6D compliance of external fixators. Biomechanics and modeling in mechanobiology, 6, 253-264.