Université Catholique de Louvain
Institut de Recherche Expérimentale et Clinique
Neuromusculoskeletal Laboratory

Locally-developed external fixators and their impact on the stability of long bone diaphyseal fractures after osteosynthesis

Kouamé Jean-Eric KOUASSI

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Supervisor: Professor Olivier Cornu
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Jury

Chair:

Professor Frederic LECOUVET

Université Catholique de Louvain, Belgium

Supervisor:

Professor Olivier CORNU

Université Catholique de Louvain, Belgium

Committee:

Doctor Olivier CARTIAUX (co-supervisor)

(Department of Health Engineering, ECAM Brussels Engineering School, Haute Ecole "ICHEC-ECAM-ISFSC", Brussels)

Professor Pierre-Louis DOCQUIER

Université Catholique de Louvain, Belgium

Professor Catherine BEHETS

Université Catholique de Louvain, Belgium

Professor Laurent FABECK

Université Libre de Bruxelles

Professor Thierry BEGUE

Université de Paris- Saclay

Professor Christine DETREMBLEUR

Université Catholique de Louvain, Belgium

Dedicace

A mes enfants , Eliakim, Nissim et Meni ;

A mon épouse Diane Prisca ;

"The high technology of surgery, like that of the Kalashnikov rifle, is only as effective or as devastating as the individual who controls it".

Rowley,1996

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List of abbreviations

ASTM: American Society for Testing and Materials

C3G: Ceftriaxone third generation

CHU: University hospital Center

DCs: Developing countries

EF: External fixation

HA: Hydroxyapatite

H3-DR: Hoffmann® 3 (H3) fixator with a double rod

H3-SR: Hoffmann® 3 (H3) fixator with a single rod

H3: Hoffmann external fixator 3

IV: Intravenous

IM: Intramedullary nailing

LCEF: Low-cost external fixator

LDEF: Locally developed external fixator

LEFS: Lower extremity functional scale

ML: Mediolateral

MCS: Mental component summary

MSCs: Mesenchymal stem cells

OTF: Open tibia fracture

OTDF: Open tibial diaphyseal fractures

POP: Plaster of Paris

PCS: Physical component summary

PTI: Pin-track infection

SD: Standard deviation

SF-12: 12-item short form furvey

TSF: Taylor spatial frame

UUEF: Unilateral uniplanar external fixator

UBEF: Unilateral biplanar external fixator

Summary

Open tibia fractures (OTF) can cause significant morbidity. These injuries justify early antibiotic therapy, adequate debridement, stable osteosynthesis, and early coverage of the fracture. The mostly poor infrastructural conditions concerning the provision of health services in developing countries (DCs) likely render adequate treatment of problematic fractures practically impossible. The hygienic conditions required for surgical treatment involving techniques of internal osteosynthesis may be insufficient; for cost reasons, the necessary devices including image intensifier and implants may be lacking in places where such treatment could indeed be offered. Thus, casting with plaster of Paris (POP) is still the commonly used restraint method due to its availability and low-cost. However, this method may cause many complications. In this context, the external fixator (EF) is still the implant of choice, which is also suitable for precarious areas. The EF has proven its usefulness in the treatment of open fractures. This alternative could be employed to circumvent the difficulties of implementing a classic osteosynthesis. There are many sophisticated external fixators on the market, but they are too expensive, which limits their usefulness in our country. This doctoral thesis investigated the locally-developed external fixator (LDEF) manufactured from available and easily accessible materials for treating shaft fractures of long bones, including the tibia. The first part of this thesis investigated the treatment of open fractures in DCs in sub-Saharan Africa. A prospective clinical study on the management of OTF in a reference health facility in Ivory Coast was carried out, as was a systematic review of literature concerning the treatment of OTF.

This was meant to establish an inventory concerning the treatment of open tibia fractures. The second part of this thesis investigated the design and biomechanical aspects of different LDEFs. Design of the LDEF was made from materials locally available in developing country like the Ivory Coast. These fixators are suitable for simple and comminuted pattern fractures. A static biomechanical study revealed a rigidity that was comparable to reference external fixator. After applying 1 million loading cycles, the overall stiffness characteristics of the frame remained unchanged. Based on these test results, the LDEF could be re-used, but certain fixator components had to be inspected and eventually replaced, especially pins. The third part of this thesis sought to evaluate the LDEF effectiveness as definitive treatment for open tibia fractures. A prospective clinical study was conducted, revealing a consolidation rate exceeding 70%, with an 80% functional recovery in LDEF-treated patients.

Keywords: biomechanical tests, developing countries, diaphyseal fracture, external fixator, locally-developed, long bones, open fractures, tibia.

General introduction

Context

An open fracture is a condition where a break in the skin enables direct communication of the fracture site or fracture hematoma with elements that are external to the usual skin protection [1]. The annual incidence of open fractures of long bones has been estimated at 11.5 per 100 000 persons, with 40% occurring in the lower limb, commonly concerning the tibial diaphysis [2]. Open tibia fractures are the most common open long bone fractures, with an annual incidence of 3.4 per 100 000[3]. These fractures most commonly occur in young adult males [3, 4],[5]. The most common causes of open tibia fracture are road traffic accidents [6, 7]. The lack of muscular covering over the anteromedial tibial aspect and poor blood supply predispose open tibial fractures to developing certain complications [6]. Various classification systems have been proposed for open fractures in an effort to grade the extent of the initial injury and to offer useful prognostic clues to help in deciding the optimal management[2]. Gustilo and Anderson classification which describes three groups of increasing severity based on the size of the open wound, the degree of its contamination and the extent of soft tissue injury was used in this thesis [8]. It is the most widely used[2]. These fractures present with a 10-20 fold increased risk of developing infection than open fractures within any other anatomical areas, and a nonunion rate as high as 28% has been reported in the literature [6]. Administration of intravenous (IV) antibiotics, meticulous wound debridement, operative stabilization of the skeletal injury, and

early soft tissue coverage of the open wound are all part of the therapeutic protocol [6]. Despite the relevance of appropriate open tibia fracture treatment, the fixation methods have evolved over the past years but remain controversial [9]. A recent study in developed countries showed that more than 88% of surgeons use an intramedullary nail for open Type I and II tibial shaft fractures. Interestingly, this number decreases to 68% for Type IIIA, and to 48% for Type IIIB fractures. The choice for the latter scenario is external fixation [10]. External fixation (EF) has been popular so far due to its relative ease of application and limited effect on the tibial blood supply, but these advantages have been outweighed by the high incidence of pin-track infections, difficulties relating to soft-tissue management, and potential malunion[11]. Sequential treatment of severe, open tibial shaft fractures with intramedullary nailing (IM) following external fixation proves to be an effective modality [12]. Better results of sequential treatment with external fixation followed by IM nailing compared to treatment with IM nailing isolated from open tibial shaft fractures have been reported [12]. IM nail fixation remains the mainstay of treatment for most open tibial shaft fractures in the developed countries[10]. However, in developing countries (DCs), where the patients present late to the hospitals and adequate facilities (in terms of manpower, theatre facilities, implants) are not always available, the situation is different [13]. Despite the advances made in technological innovations concerning the management of open fractures compared to conventional management modalities, numerous challenges remain, especially in DCs [14]. To introduce our topic, we briefly review the

burden of open tibia fractures in DCs and provide a brief historical summary of external fixators and their stability.

The burden of open tibia fractures and trauma realities in developing countries

The global burden of injury is huge and still growing, particularly in DCs [15]. Access to quality trauma care is critical for reducing mortality and disability from injury [16, 17]. Road traffic accidents, which cause most trauma injuries, are a condition of emerging prosperity [18]. In Ivory Coast and other countries in Sub-Saharan Africa, the burden of open fractures has a long historical background, while this burden is currently escalating due to legalization of motorcycles as a means of public transport [14, 19]. Rural people migrate to the cities to find jobs. They travel back and forth from their homes to these jobs. When a family is able to save money, the first purchase is often a motorbike, which becomes the family vehicle. New roads are being built at a much slower rate than the increase in the number of vehicles. The rules of the motorbike govern the road,[20], given that motorcyclists do not respect any road safety rules. The realities of trauma care in DCs are often very harsh. No pre-hospital trauma care nor even a simple pick-up service ambulance is usually available, while most patients are brought to hospital by "good Samaritans", family members, the police, or firefighters. By that time, the most severely injured have already passed away. Transport is both difficult and expensive in DCs [21].

Cost is one of the most essential factors when deciding on treatment choices. Other factors, such as experience and surgical expertise, available equipment *(e.g.,* image intensifier), infrastructure, and theatre asepsis are also crucial [22]. Thus, fractures are often firstly treated by traditional bone-setters and healers, whereas the methods used are not adapted to managing open fractures [23]. Lower-level district hospitals that initially treat most injured patients are not equipped to handle either the increased number of injuries nor their associated severity, which are often elated to road traffic accidents. Patients with more severe injuries are usually referred to larger hospitals. In DCs as ours, health insurance coverage is very low and even for those patients that detain health insurance, trauma is mostly not covered. Patients and relatives have to pay care out of their own pockets. Our center operates according to pay-before-service procedures. Patients must additionally purchase their medication and implants prior to surgery. The associated costs render these devices inaccessible for many. Outcomes are particularly poor for open fractures, which must be treated in a timely manner [20]. In this case scenario, casting or fracture stabilization using a cast (plaster of Paris [POP]) is still the most prevalent therapeutic approach for open tibia fractures in DCs, given that external fixation is not readily available [18] **(Fig. 1).** A window made on the cast often weakens its structure, which is further aggravated by wet dressing fluids and wound discharges. Prolonged cast application causes joint stiffness and quadriceps wasting with limited functional outcome.

Re-displacement of the fracture fragments is another setback observed when using casts, which may lead to mal-union and non-union in most cases [18]. Casts are associated with high rates of mal-union, ranging from 30% to 96% of cases [6, 18], and non-union in about 28% of cases [6]. These are major cast-associated problems [24]. In such contexts, the external fixator (EF) represents an attractive therapeutic choice **(Fig. 2)**, as this device is well adapted to precarious areas. EFs entered the therapeutic arsenal of professional armies on the battlefield, either as a provisional (in a damage control strategy) or definitive treatment option [25]. Using EFs is both easy and within the capacity of many doctors, without requiring special facilities or theatres [26]. There are numerous sophisticated models currently available on the market, but these are rather expensive. Numerous enterprising surgeons have, therefore, attempted to invent cheaper designs [27]. Without any doubt, these fixators likely achieve the same outcome results than those that are more expensive, provided they are properly applied.

Fig. 1 Plaster of Paris (POP) used to treat a bilateral tibial diaphyseal fracture

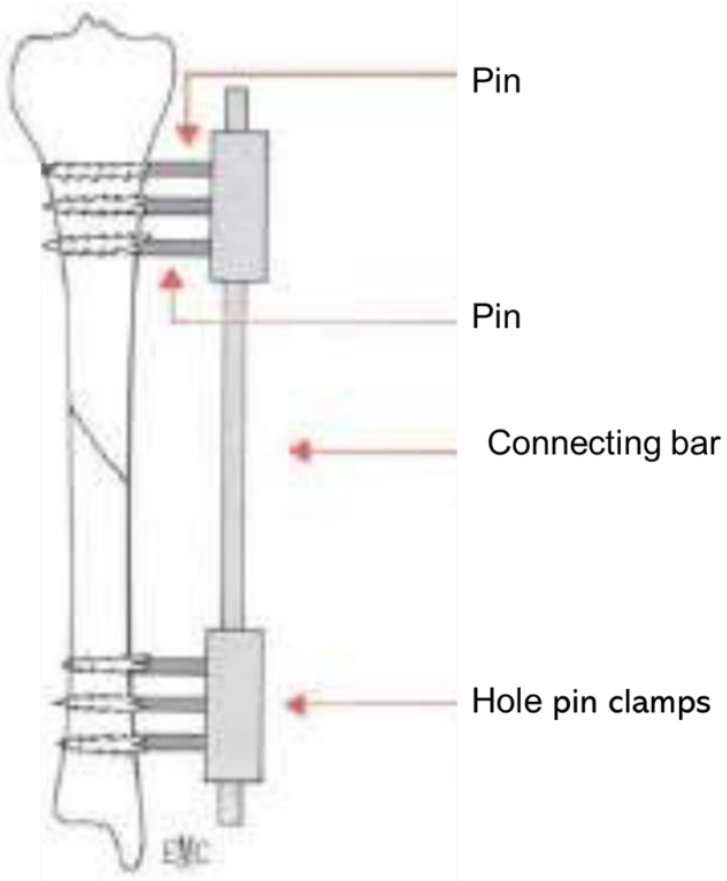

Fig. 2 External fixator with its components. Adapted from Lortat-Jacob et al. (1999)[28]

External fixation

An EF is a device used in bone and joint surgery, which allows for stabilizing bone fragments using pins that pass through skeletal parts[29]. This therapeutic method with the external fixator is referred to as an external fixation. This device stabilizes and maintains broken bone fragments in the desired position. Using the fixator can achieve the following with respect to bone fragments: neutralization, compression, dynamization, distraction, angulation, rotation, osteotaxis, ligamentotaxis, elastic fixation, and biocompression [29]. EF of tibial shaft fractures is not an entirely new concept, given that a rudimentary external device to control bone fragments in open fracture cases was previously described by Hippocrates almost 2400 years ago [30]. The EF history can be divided in two parts, with the precursors on the one hand, and the modern era on the other **(Fig. 3).**

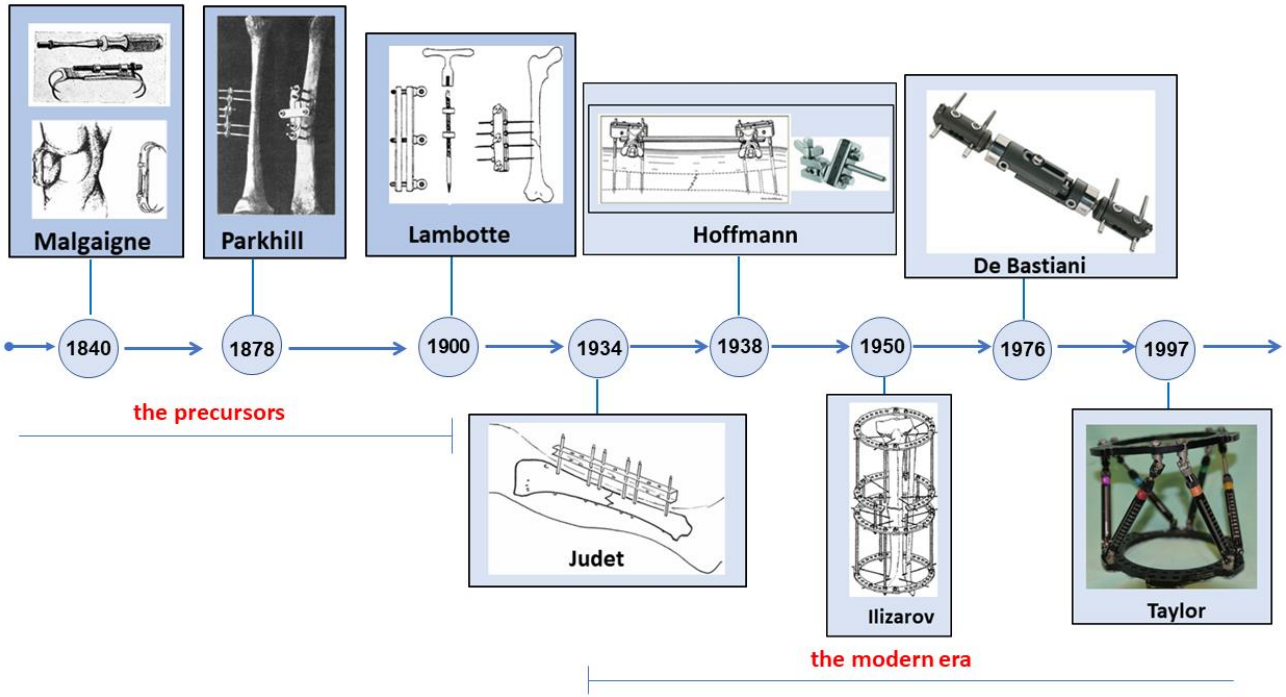

Fig. 3 External fixation history timeline

1. The precursors

Their initial aim was to stabilize the fractures without addressing the focus. This was primarily meant to avoid septic problems, but it was also due to the lack of imaging techniques. The EF history of fractures begins in the middle of the nineteenth century with Malgaigne [31], who was the first pioneer to devise and apply a practical method of external skeletal fixation. This method used for treating displaced transverse fractures of the patella consisted of two double hooks, which were inserted through the skin and engaged into the upper and lower borders of the patella. The hooks were then connected using a screw, which drew the fragments into apposition and maintained them in position during the healing period (**Fig. 4a**). In 1840, Jean-Francois Malgaigne (French) was employed other forms of external fixation. A screw that was fixed to a splint with a belt was screwed through the skin into the bone in order to keep the fracture fragments in place. When additional screws were necessary, they were joined together using a wire [31]. Von Heine employed ivory pins in 1878 [31]. With Albin Lambotte (Belgium) and Parkill (USA), the first biomechanical reflections were introduced concerning rigidity and modularity (1900). Both Parkhill and Lambotte observed that into bone inserted metal pins were extremely well tolerated by the body. They developed the clamp support and tie bar systems. Fixation was thus mono-cortical [31, 32] **(Figs. 4 b, c).**

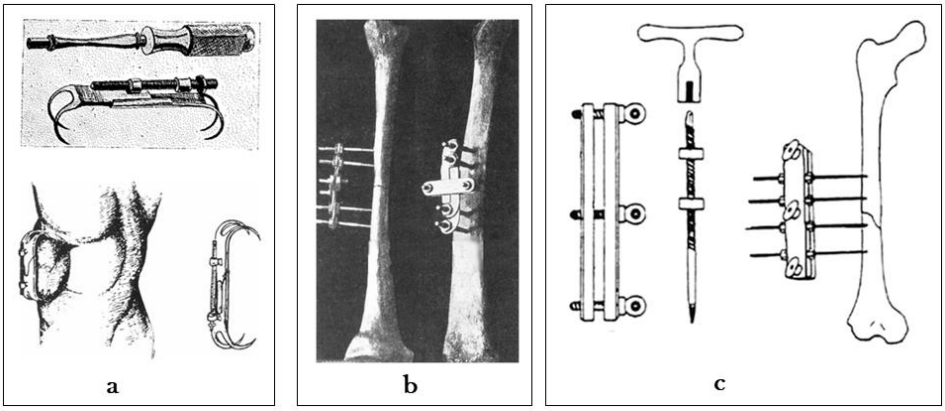

Fig. 4 a Malgaigne's external fixation of the patella. **b** Parkhill's external skeletal fixation device applied to a tibial fracture. **c** Lambotte's external skeletal fixation device applied to a femoral fracture. Adapted from Hernigou et al. (2017) [31]

2. The modern era

This period was initiated by Henri Judet who described the use of bicortical screws and demonstrated their superiority in terms of stability (1934). This principle could be applied either after securing fracture reduction or following initial transfixation by using the pins and plate in order to lead the fragments together (**Fig. 5**).

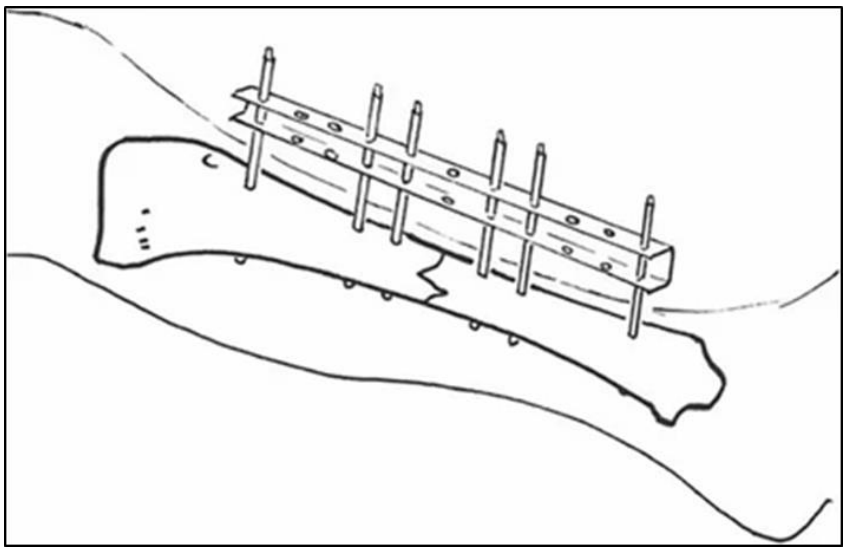

Fig. 5 Henri Judet's external fixation. Adapted from Hernigou et al. (2017) [31]

From then on, the design of external fasteners evolved in parallel with the progress made in biomechanics leading to system improvement, based on advanced knowledge concerning materials [31, 32]. We should here mention several essential authors, including Raoul Hoffman and his fixator for reducing and restraining fractures. In 1938, this expert coined the term osteotaxis [31, 32]. He developed the original Hoffmann external fixator that was devised as a system for treating broken bones without necessarily opening the fracture site in order to reposition the bone ends. This system has evolved into a more flexible, modular concept [33].

Hoffmann original: Building on the work of others, Hoffmann clearly understood that major improvements were required to render the external fixator more relevant for clinical purposes. He developed a technique that was based on closed reduction with guided percutaneous pin placement. Hoffmann's technique exemplified the first application of minimally invasive orthopedic surgery [34], which turned out to be simple but ingenious. This expert located long bone fracture fragments by "tangentially probing" and "cross probing" **(Fig.6a),** using percutaneous needles—techniques that also localized drill "guide" placement (**Fig. 6a**). The surgeon made at least three drill-holes through the far cortex, while partially-threaded pins were inserted [34]. Hoffmann designed strong clamps, he called "grips," which were made of two rectangular steel plates held together with bolts.

These bolts compressed the plates around the larger half-pins fixated into the bone. Attached to each clamp was a "ball-and-socket" joint. At this point, with one clamp secured on either side of the fracture site, the fracture was reduced using "direct external manipulation." A rigid steel bar, 8mm in diameter, was then placed through the ball-and-socket joint on either clamp, which was fastened by wing screws, thereby uniting the clamps [34]. Most important, however, was Hoffmann's observation: "*This bar can just as well be put into position before the reduction process. Its presence in no way hinders the action of reduction"* [italics added]. The ball-and-socket joints could swivel, thereby permitting the rigid bar and, indeed, the entire frame to move in continuity **(Fig. 6b)**. This, in essence, was Hoffmann's unique contribution to EF. The original components were fabricated in stainless steel with a grooved Bakelite surface enabling them to hold the pins[33] **(Fig. 6c)**. This device enabled the surgeon to complete fracture reduction, independently in three spatial planes. Additionally, secondary correction was rendered possible until optimal reduction was achieved, since only the ball-and-socket joint had to be slightly loosened, with the frame adjusted and the joint retightened.

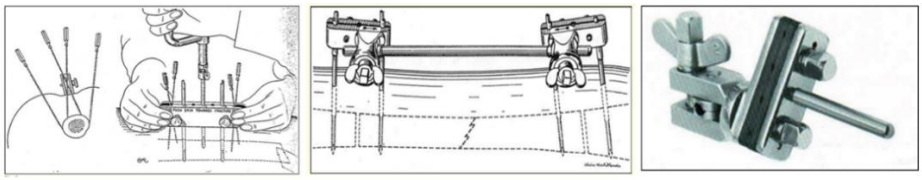

Fig. 6 a Cross-section demonstrating cross-probing and tangential probing and a drill guide with cross-probed percutaneous needles and three pins inserted into a fracture fragment (tangential needles not shown). **b** External bar connecting two ball-and socket joints. **c** The Ball Joint Rod in stainless steel with Bakelite pin holders was the workhorse of the original Hoffmann. Adapted from Seligson et al. (2015) [33] and Schwechter et al. (2007) [34]

Hoffmann® II is a second-generation modular EF system, offering advanced technology and application ease, while retaining the values of the original Hoffmann® External Fixation System. Major improvements in materials and function render Hoffmann® II the preferred modular EF system. New clamp designs enable true independent pin placements, with a unique snap-fit mechanism, thereby eliminating the need to pre-assemble components [33]. Due to the snap-fit design, components may be added to the frame at any time as necessary, without dismantling the frame and risking losing the reduction. In addition to a new clamp design, enhanced materials have been employed to fashion the clamps and connecting rods. Clamps are made of aluminum alloy, which significantly reduces overall frame weight, without compromising stability. Connecting rods are available in stainless steel, carbon, and aluminum, allowing for various elasticity types **(Fig. 7).**

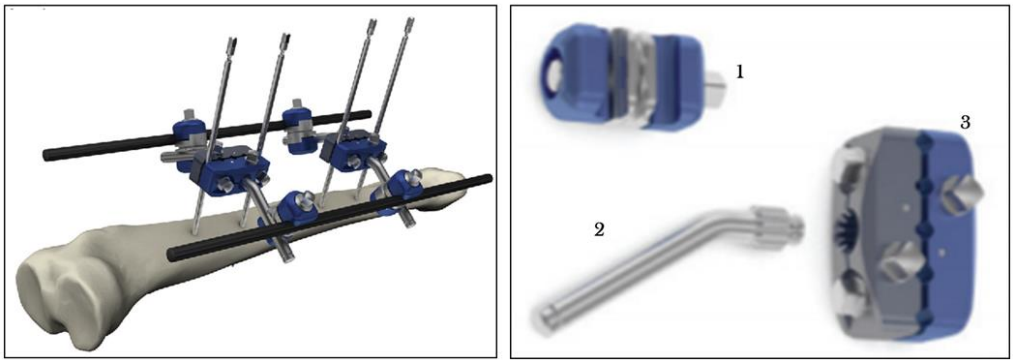

Fig. 7 Tibia shaft external fixator using a double-bar construct with the Hoffmann®II external fixator. 1. Rod-to-Rod Coupling. 2. 30° Angled Post. 3. 5-Hole pin clamp. Adapted from Eben et al. (2011)[35].

Hoffmann® III to meet the requirements of active trauma practice, modifications were made in the materials for the connecting rods to render them magnetic resonance imaging (MRI)-compatible. The Hoffmann®III was designed in Selzach as a frame with interchangeable bars, a minimum of connectors, and simple instrumentation for field use. Hoffmann®III system has been shown to be successful, particularly as a 'damage control' frame for patients suffering from significant polytrauma [33]. The connecting rods are MRI -conditional, which is an essential new requirement, as patients with severe injuries are currently more likely to survive compared with before, therefore requiring repeat advanced imaging [33] **(Fig. 7)**.

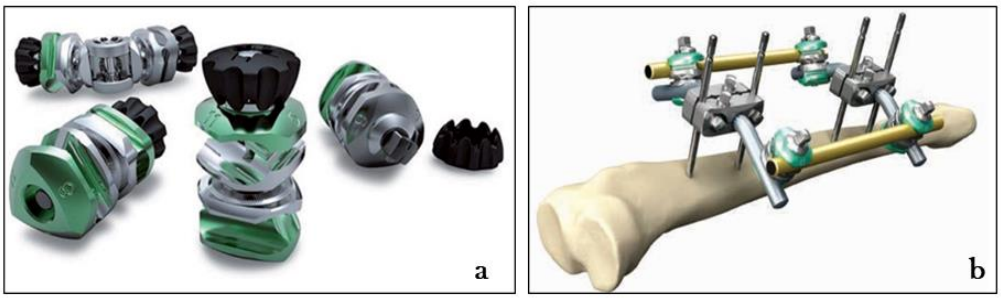

Fig. 8 a The Hoffmann®III: interchangeable connectors accept 5, 8, and 11mm bars and 4, 5 or 6mm pins. The connectors can be either added or removed without disassembling the frame. **b** Tibia shaft external fixator using a double-bar construct with the Hoffmann®III external fixator. Adapted from Seligson et al. (2015) [33] and Seligson et al. (2011) [36]

In the 1950s, Gavriil Ilizarov from the Kurgan region in the Soviet Union devised and developed a new method for treating fractures, deformities, and other bone defects. A metal frame that encircles the limb **(Fig. 9)** was attached to the underlying bone by crossing pins inserted through the bone and limb. The external rings were linked to each other by threaded rods and hinges, which allowed for the bone fragments' position to be moved without opening the fracture site. The fragments could thus be fixed in a rigid position until complete healing [37].

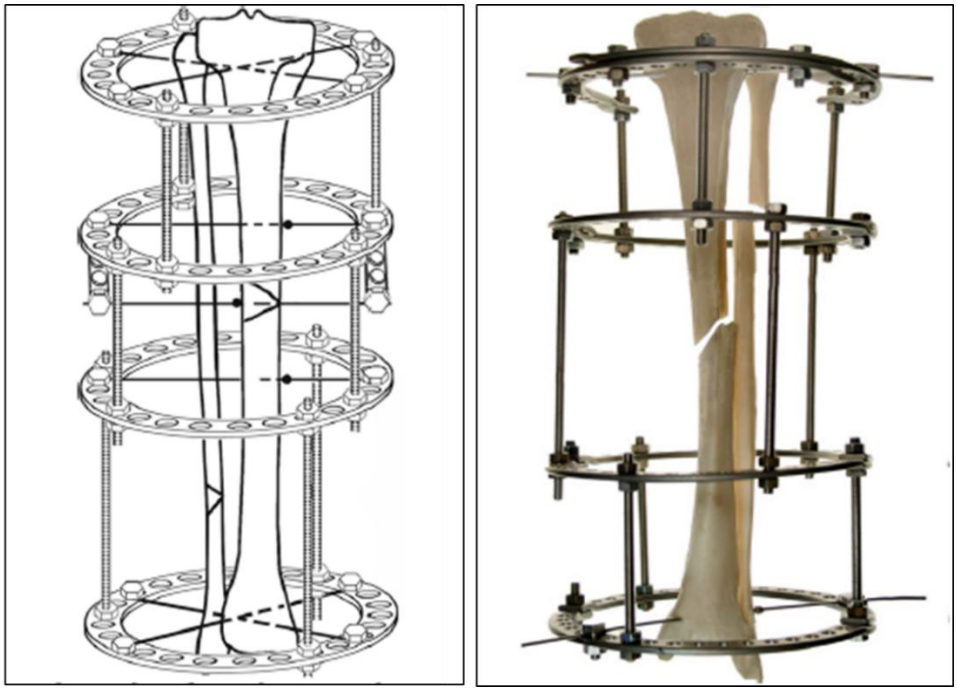

Fig. 9 Ilizarov's external fixation. Adapted from Solomin et al. (2013)[38]

The unilateral external fixator Orthofix, created by De Bastiani in 1976 [31], consists of two clamps that are connected to the central telescopic frame through spherical joints. In each clamp, four pins can be placed in one plane and at the same distance [39]. The clamp mobility is provided by spherical joints that movable in all three planes, which allows for adjusting the anatomical segment, using a secure clamp block, in the required position **(Fig. 10a).** The central part of the fixator is a telescopic frame, which enables compression, distraction, and bio-compression among the fracture fragments. Using this fixator in comminuted, multiple fragment fractures provides excellent stability of bone fragments and neutralization of weightbearing forces. Stability of the unilateral Orthofix frame is achieved by a distraction compressive mechanism within the telescopic frame. These frames can be applied for bone repair as well as for treating leg length discrepancies, bone defects, and post-traumatic shortening [39, 40]. De Bastiani additionally developed a rail external fixator, the Orthofix Limb Reconstruction System (LRS) external fixator **(Figs. 10 b,c),** for the following three main indications: bone loss with shortening; bone loss without shortening; deformity, with and without shortening, and extreme shortening [41],[42].

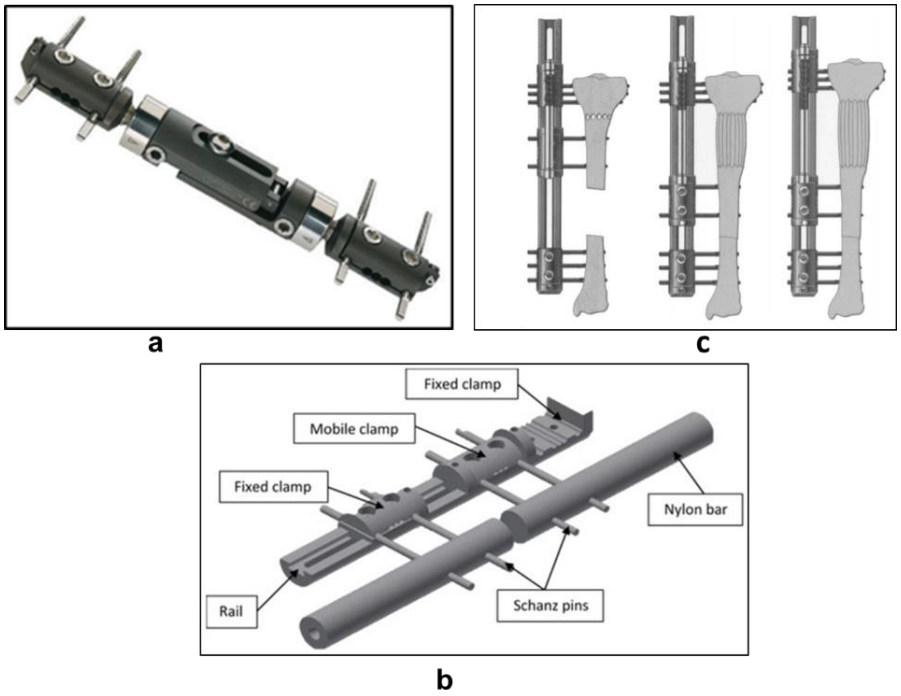

Fig. 10 a De Bastiani's external fixation (Orthofix). **b** Orthofix limb reconstruction system (LRS) external fixator. **c** Operative technique using LRS. Adapted from Martins Amaro et al. (2020) [42] and Saleh et al. (2000)[43]

In 1997, Charles Taylor (USA) presented his external fixator, the TSF (Taylor Spacial Frame), which is a circular fixator for three-dimensional angular correction and computer-assisted limb lengthening **(Fig. 11).** The Taylor spatial frame (TSF) is a hexapod external fixator that enables correcting six-axis deformities. The mathematical base of all hexapod systems is projective geometry, which describes complex repositioning of an object in space [44].

Fig. 11 Standard Taylor spatial frame (TSF) construction. Adapted from Keshet et al. (2017)[44].

3. Locally developed external fixator

Developing countries very often utilize external fixation techniques due to a consistently high rate of trauma accidents that result in the need of bone fracture stabilization [45]. Current commercially available external fixation devices are complex and expensive, affecting management of injuries in less developed countries[46]. In developed countries, with more organized healthcare systems, health insurance usually covers the cost of the external fixator. However, this is not the case in developing countries. Africa and South East Asia, which comprise of low and middle-income countries, account for over 50% of the world's traumatic injuries. Ultimately, there is a large disparity between regions that are affected by trauma and the resources that are available to treat such trauma [45]. There is a need for a low-cost, simple, readily available, safe and effective external fixation device that can be properly utilized by healthcare workers in developing countries in order to treat the huge number of patients with soft tissue injuries and long bone fractures. Locally developed external fixation devices that use readily available parts have been constructed by surgeons to meet this need **(Fig. 12)**. In 1986, Weston designed a simple external fixative from local materials for treatment of open fracture in Africa [47]. In 1988, Noor designed a simple and cheaper external fixator for the treatment of diaphyseal fractures of the tibia. His fixator was made of galvanized iron[27]. The wooden external fixator designed by Doømres, in 1992 for various indications (open fracture, infection on fracture...)[48]. Goh in 1997, designed a low-cost cylindrical tube fixator made up of iron, plastic, stainless steel[49].

Pulate in 2001, designed a locally manufactured ring fixator. An adaptation of the Ilizarov ring fixator [50]. Najeb in 2008 reported a series of 31 patients treated with a locally designed external fixator [51]. In 2013, Musa improvised an external fixator from 2 metal (iron) plates for the treatment of open long bone fractures [52]. There is no doubt that these fixators can achieve the same results as those that are more expensive, when used properly. Each development of a new locally developed fixator attempted to offer a local solution, based on available materials, local skills and the experience of surgical teams, to the same problem: the stabilization of fractures. The majority of them have unfortunately not been subject to prior mechanical evaluation or have reported limited clinical experiences. These points did not allow their generalization in other countries with a similar medical context.

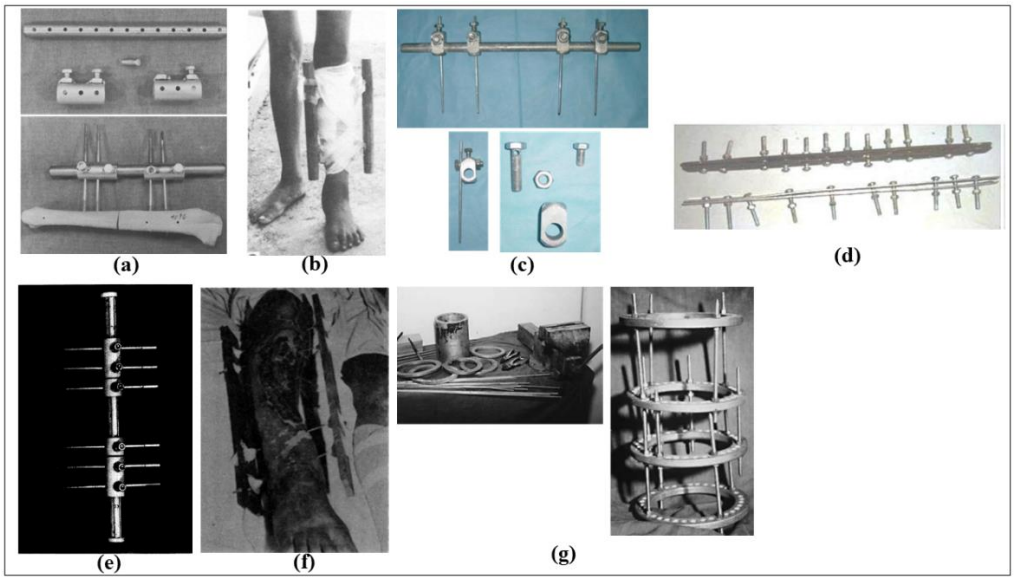

Fig. 12 Locally developed external fixation devices. Noor(a), Doømres(b), Najeb(c), Musa (d) (Goh(e), Weston (f) Pulate (g).

Bone healing with external fixation

The effectiveness of an implant in providing stability and the biological environment at the fracture surface determine the mechanism of fracture repair [53]. Bone union may occur by either direct healing (osteonal reconstruction) or indirect healing (intermediate callus formation) [53, 54].

Direct fracture healing

Direct healing does not commonly occur in the natural process of fracture healing, since it requires a correct anatomical reduction of the fracture ends, without any gap formation, and a stable fixation [54]. This kind of healing is often the primary goal sought in the context after open reduction and internal fixation surgery [54]. When these requirements are met, direct bone healing likely occurs via direct remodeling of lamellar bone, Haversian canals, and blood vessels [54]. During this process, little or no periosteal response is noted (no callus formation)[55].

Indirect fracture healing

Indirect fracture healing is the most commonly encountered form, and it consists of both endochondral and intramembranous bone healing [56]. Such healing does not require anatomical reduction or rigidly stable conditions. On the contrary, healing is enhanced by micro-motion and weight-bearing [54]. However, excessive motion or load is known to delay healing or even facilitate non-union[54]. Indirect bone healing typically occurs in non-operative fracture treatment and certain operative treatments during which some motion occurs at the fracture site, including intramedullary nailing, external fixation, or bridging plate according to a MIPO technique (minimal approach with internal

plate osteosynthesis), which is also called the internal "external fixator" with locked screws [54].

A more comprehensive description of indirect fracture healing comprises different stages. Healing starts at the time of the injury with the formation of fracture hematoma, followed by the inflammatory stage, which concludes with the formation of granulation tissue. It is followed by the formation of the soft callus, that eventually undergoes calcification and remodeling [57] **(Figs. 13a, b).**

- **Inflammation stage** (1-7days)

Immediately following the trauma, a hematoma is formed, which consists of both peripheral and intramedullary blood cells, in addition to bone marrow cells. Inflammation is initiated through the release of pro-inflammatory cytokines by the hematoma and damaged tissues [54]. This reaction causes the hematoma to coagulate in between and around the fracture ends, as well as within the medulla, thereby forming a template for callus formation [58]. Inflammatory cells are brought and contribute to remove necrotic tissues. Inflammation also leads to mesenchymal cell recruitment.

- **Angio-mesenchymal stage (**2-6weeks)

After one week, a fibrin-rich granulation tissue is progressively formed at the fracture site. It is a loose aggregate of mesenchymal, endothelial, and immune cells scattered inside an extracellular matrix [57]. Mesenchymal stem cells also proliferate in the periosteum and adjacent none marrow[57]. The fibrin deposits are removed by macrophages and fibrinolytic enzymes. The significant mitogenic activity at the area is supported by the formation of new blood vessels[57].

- **Soft callus stage**

Although indirect fracture healing consists of both intramembranous and endochondral ossification, the formation of a cartilaginous callus that later undergoes endochondral ossification appears key to this process[54, 59]. Soft cartilaginous callus results from mesenchymal stem cells differentiation into chondrocytes and extends throughout the fracture gap, so connecting the ends of the bone. It can be seen as an attempt of the body to improve the stability at the fracture site before its secondary endochondral ossification. In this cartilage, the cellular density is significantly higher to that of healthy articular cartilage but its organization is different[57].

- **Hard callus stage** (3-4 months).

To progress in the bone regeneration to progress, the primary soft cartilaginous callus needs to be resorbed and replaced by a hard bony callus[54]. In some ways, this stage repeats the physiological long bone development and growth through endochondral ossification, which involves chondrocyte proliferation, hypertrophy and mineralization followed by bone apposition [54]. In the meantime, periosteal stem cells differentiate into osteoblasts which form woven bone at some distance from the fracture site. This woven bone is progressively deposited towards the periphery of the cartilaginous callus, further stiffening the healing tissue. This continues until there is no more interfragmentary movement, the callus becomes more solid and mechanically rigid [54, 57].

- **Remodeling stage** (Process taking months to years)

Although the hard callus is a rigid structure providing biomechanical stability, it does not fully restore the morphology and biomechanical properties of normal bone. In order to achieve this, the callus fracture undergoes a secondary resorptive phase, which remodels the hard callus into a mature lamellar bone structure with a central medullary cavity. This remodeling may take years to be completed and achieve a fully regenerated bone structure [59] [54].

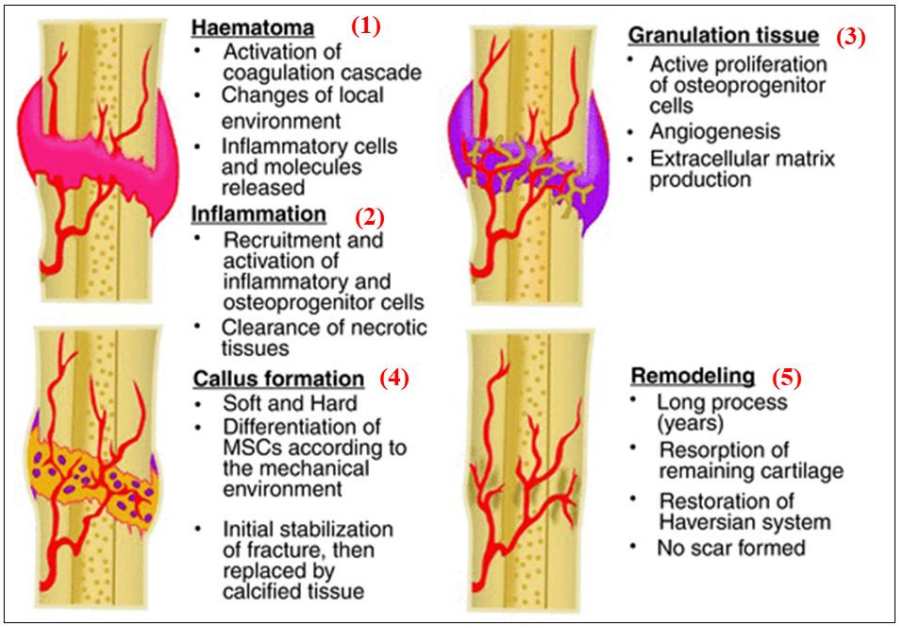

Fig. 13a the stages of secondary bone healing. Adapted from Pountos et al (2018)[57].

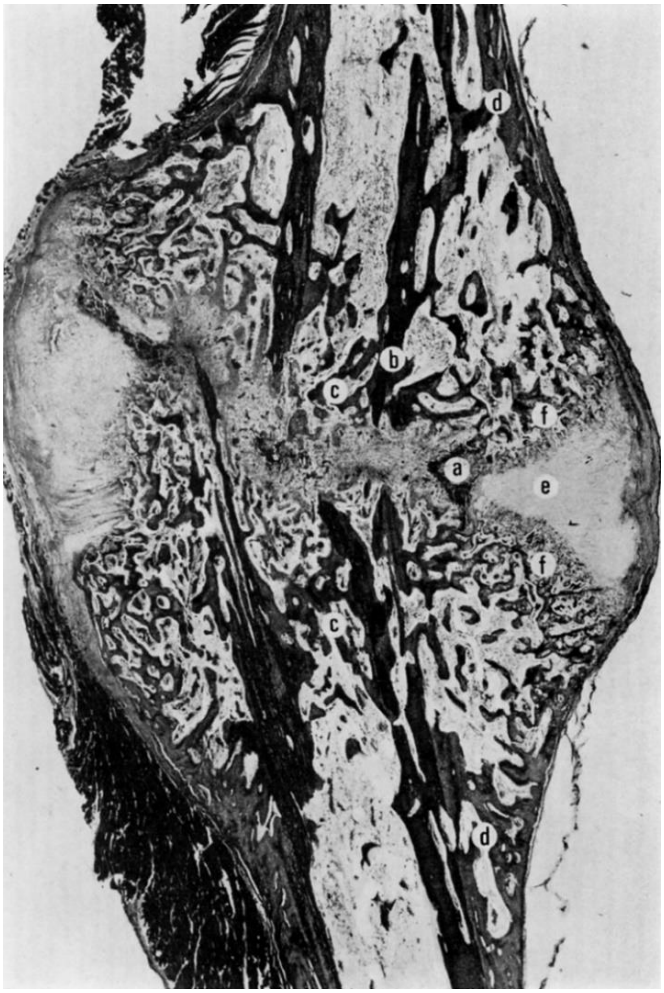

Figure 13b Histological section through a rabbit rib showing the stages of bone healing. Piece taken 21 days after an experimental fracture, decalcified and stained with trichrome (X20). Haematoma(a), Fractured bone(b), Intramedullary osteogenesis(c), Subperiosteal bone(d), Cartilage(e) Endochondral bone(f). Adapted from Coutelier L [60].

.

Biomechanics of external fixator

The different EFs in clinical use today can be categorized into unilateral or circular systems [61]. Unilateral frames are distinguished from circular frames in that they are positioned on one side of the limb [62]. Unilateral frames enable the limb to remain functional, avoid complications, and provide bony stability [62]. While circular fixators have gained popularity with limb lengthening procedures, they are especially effective in enabling the patient to weight bear and maintain some joint motion during the treatment period. These fixators are more difficult to apply, and they use smaller and a higher number of gauge pins so as to distribute the weight [62]. This thesis is a focus on unilateral systems for the tibia. The term biomechanics in orthopedics and traumatology of the locomotor system implies the study of physical properties of bones, muscles, cartilage, fasciitis, tendons, and joints, under both physiological and pathological conditions [29]. The most commonly used term in biomechanical testing is the rigidity (or stiffness). The rigidity of an external fixator construct is commonly considered when external fixators are employed for treating an acute fracture and facilitating post-traumatic reconstruction [29, 63]. The term biomechanical rigidity usually implies the externally stabilized fracture's resistance to the effect of three different forces **(Fig.14)**:

- Axial: compression and distraction;
- Bending: anteroposterior and lateromedial;
- Torsion [29].

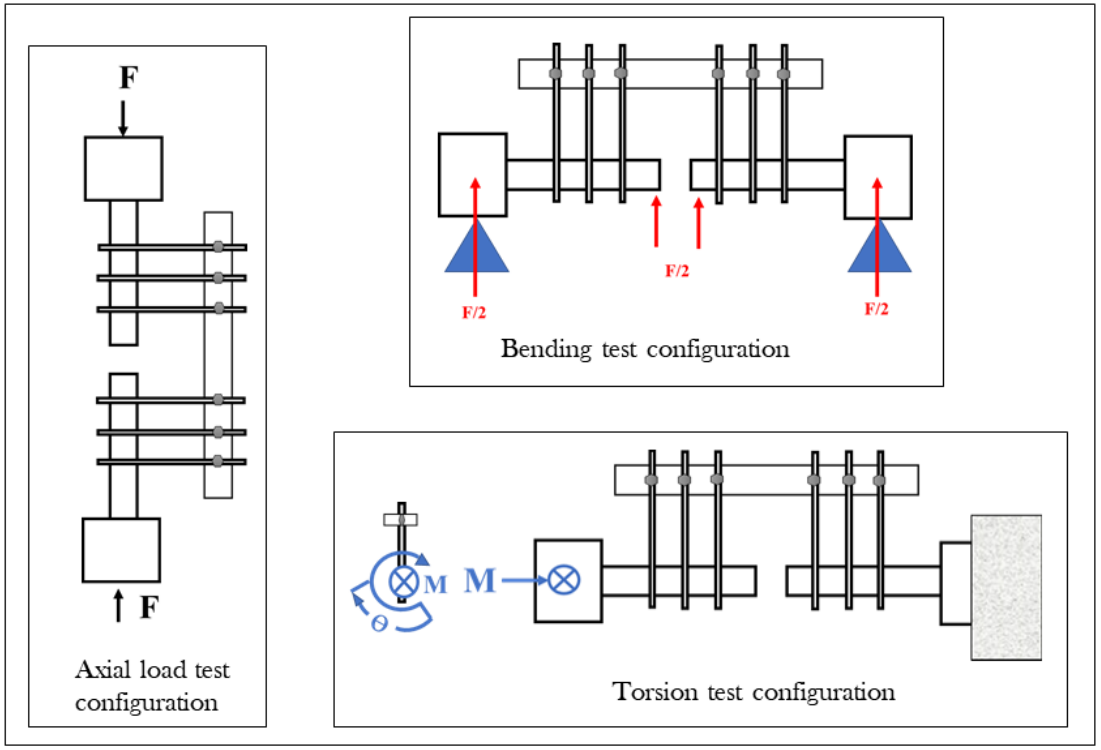

Fig. 14 Schematic representations of different biomechanical test on external fixator. F compression force, F/2 bending force, M moment

Structural rigidity (stiffness) of a fracture fixation device is determined using the load deformation curve. The linear portion of the Force/Deformation curve is used to define the rigidity of the construct[64] **(Fig. 15)**

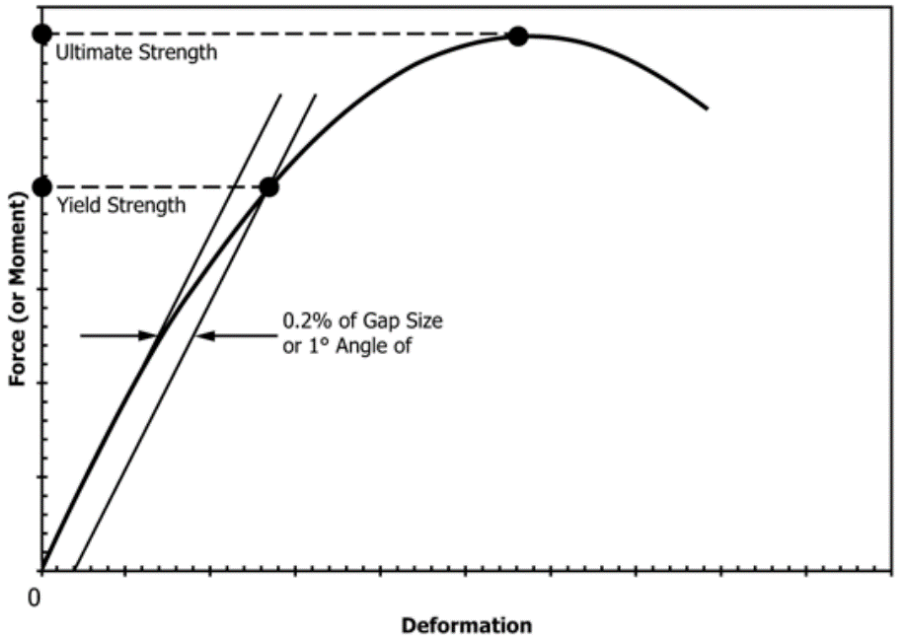

Fig. 15 Fixator-Bone construct response Curve[64].

The key biomechanical factor in determining the performance of an EF construct is the bone-segment rigidity following fixation, given that this rigidity determines gap opening of the fracture site when subjected to physiological loads like walking [61]. The factors that govern the rigidity include:

(1) bone-pin interface and pin diameter;

(2) number of pins and materials of which the pins are made;

(3) pin separation within a group and distance of pin group to fracture site;

(4) distance between the bone and longitudinal bars;

(5) pin and frame material and number of connecting bars [53, 59, 61].

Figure 16 illustrates factors governing rigidity and the evolution of the rigidity **(Fig. 16).**

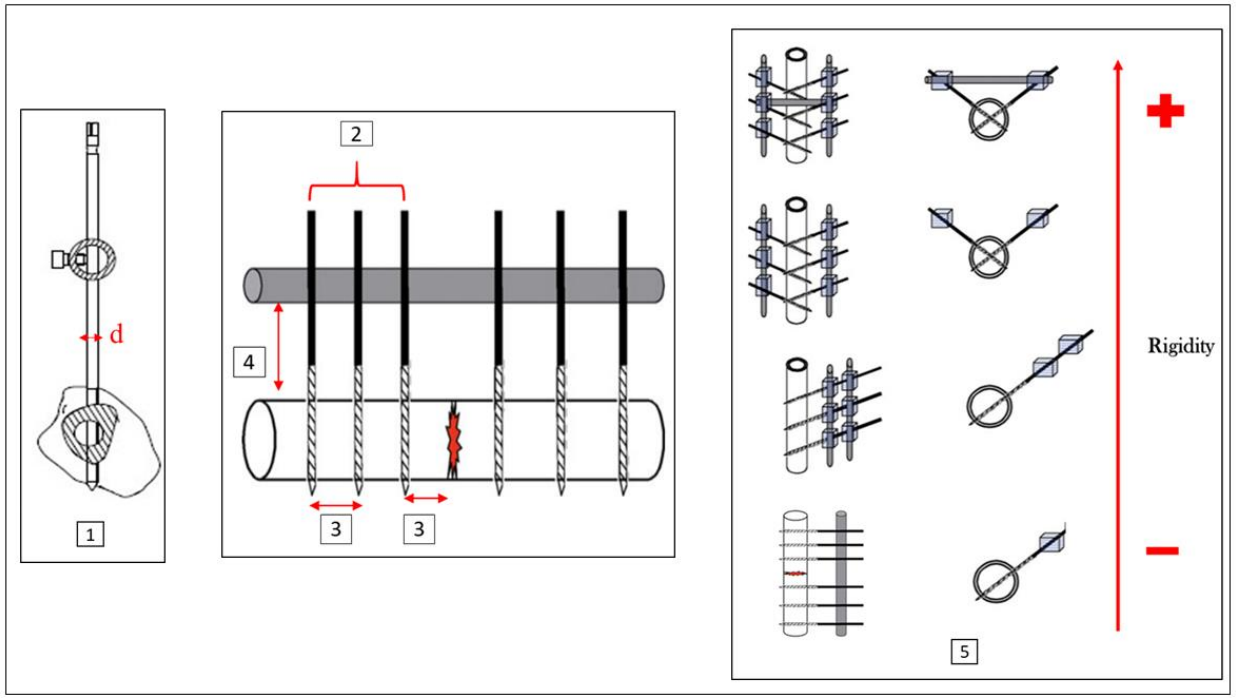

Fig. 16 Rigidity is governed by the following factors: (1) Bone-pin interface and pin diameter (d); (2) Number of pins; (3) Pin separation within a group and distance of pin group to fracture site (4) Distance between the bone and longitudinal bars; (3) Spread of pins in each main bone fragment; (5) Construction design. Adapted from Gunepin et al. (2012) [65].

Means to promote fixator rigidity are listed in **Table 2** [30]. The improved rigidity reduces the bone-pin interface, and this stresses and helps preserve longevity of stable fixation [61].

Table 2: Methods for increasing fixator rigidity

(1) Increasing pin diameter
(2) Increasing the number of pins per bone segment
(3) Decreasing the distance between the pins that are closest to the fracture site
(4) Increasing the pin group separation ('near--near'/'far--far' concept)
(5) Adding a second longitudinal bar to the same pins
(6) Decreasing the side bar separation from the bone
(7) Applying pins in different planes, as well as applying the frame in the plane coinciding with the plane of the major bending moments of the construct increases its stiffness

- **Bone-pin interface and pin diameter**

This is the crux of stability, *i.e.,* starting with a good hold and keeping a good hold of bone. Two essential parameters that influence interface stresses and bone hold are pin diameter and interference[61]. Larger diameter pins display a higher resistance to bending forces. The EF pins, which transmit the forces applied to the bone fragments, remain the critical element of the system. Each pin is subjected to stresses in traction, torsion and bending, the latter being considered as the most important. If we assume that the pins are perfectly fixed to the bone and vise, it can be likened to a deformable beam [66]. Figure 16 shows the mechanical data of the bending stress **(Fig. 17).**

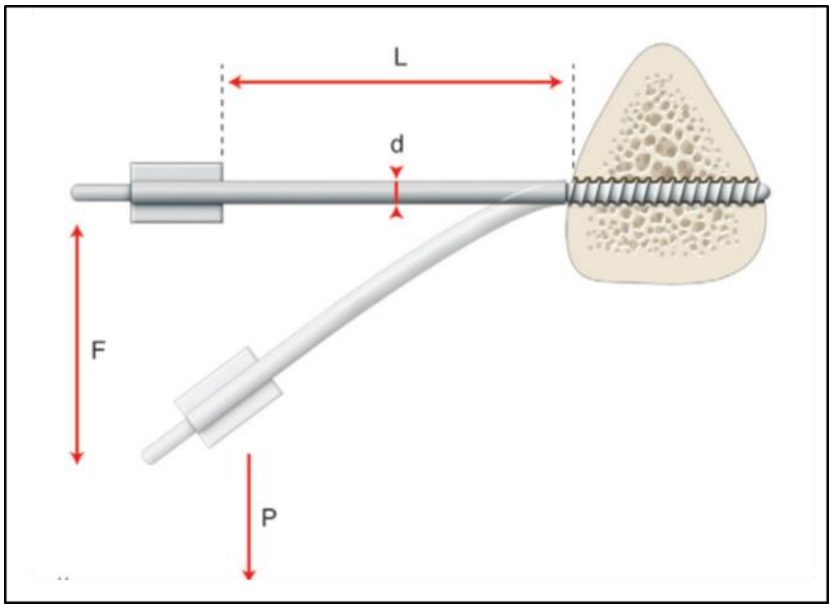

Fig. 17 Mechanical behavior of pin bending (F). P: load to which the pin is subjected; L: distance between the anchoring point in the bone and the pin holder; **d**: diameter of the pin. Adapted from Schuind et al. (2012) [66]

Rigidity is proportional to Young's modulus of elasticity and moment of inertia, and inversely proportional (to the power of three) to the length of the deformable portion of the pins [66]. While it is theoretically possible to modify the rigidity by changing the material of the pins (Young's modulus), in practice, the available pins are most often made of stainless steel. Two parameters are fundamental [28], including the moment of inertia I that depends (to the power of four) on the pin diameter: $I = 0.05 \times d^4$, and the cube of the length L of the deformable portion of the pin (L^3). Mechanical behaviour of pins bending (F) is governed by the equation.

$$F = 1/3 \frac{P \times L^3}{E \times I}$$

F: Mechanical behaviour of pins bending

P: load to which the pin is subjected

E: Young's modulus

I: moment of inertia: $I = 0.05 \times d^4$ (d: diameter of the pin)

L^3: distance between the anchoring point in the bone and the pin holder.

The most stable configuration is therefore obtained when using the largest possible diameter pins, and when the length of the deformable portion of the pins is the shortest possible, meaning when the vices are the nearest possible to the bone[66]. The limit to increasing pin size is set by the diameter of the bone into which the pin is inserted. A hole exceeding 20% of the bone diameter is likely to reduce torsional strength by 34%, and if the hole size is greater than 50%, the reduction amounts to 62% [67] [68]. In practice, it is advisable to keep pin sizes to within a third of the bone diameter in order to reduce the fracture risk upon pin removal. Hence, general guidelines for pin diameters have evolved, with both 5- and 6-mm diameter pins playing a role in tibia and femur fractures[61]. While numerous factors impact the stability of external fixators, the pin-bone interface has been demonstrated to be key in determining both long-term strength and survivability of the EF construct [69].

Interference is a measure of the grip that the pin exerts on the bone **(Fig. 18).** Traditionally, this parameter is at its maximum at the time of pin insertion, and it may decrease gradually as the fixator is loaded.

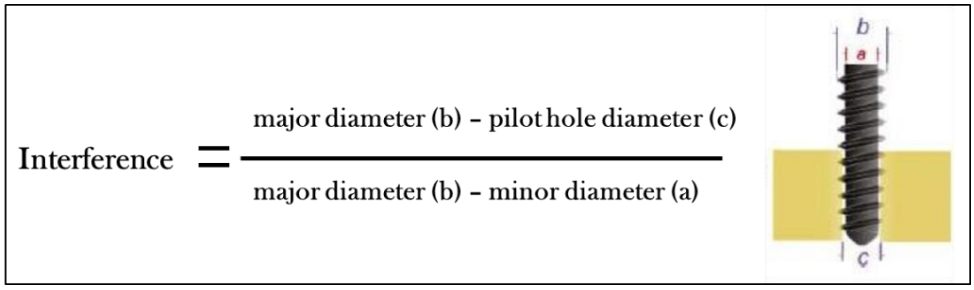

Fig. 18 Measuring pins-bone interference. Adapted from Giotakis et al. (2007). [61]

Therefore, maximizing interference at the beginning meant to promote bone hold for a longer duration [61, 70, 71]. This interface depends on bone quality, pin design, and insertion technique. While bone quality in not under the control of the surgeon, the insertion technique and pin selection are modifiable variables that affect both the stability and longevity of an EF frame [69, 72]. The insertion technique is influenced by pin design, with the two most common pin types being self-drilling and self-tapping ones [69]. The pin insertion technique is essential to improve the initial pin torque resistance in order to minimize or even avoid pin loosening [70]. Bicortical pin fixation with self-drilling pins increases the pin to bone interface strength, which may result in reduced pin loosening and improved clinical outcomes [69].

One technology that has shown great promise in comparative animal study and can prove its usefulness in clinical practice is hydroxyapatite coating of the threaded portion of the pin. With this method, bone hold increases with time. Indeed, an animal study comparing two classes of wires including hydroxyapatite coated and uncoated wires found that, average insertion torque, average initial extraction torque, bone pin contact, one between the threads and radiographic pin tract rarefaction were significantly improved in the hydroxyapatite coated pins compared with the uncoated pins. Hydroxyapatite coating was effective for improving the bone-to-pin interface[73].

A clinical study that deals with the effects of using either hydroxyapatite (HA)-coated or uncoated external fixation pins in leg-lengthening procedures on 23 patients of short stature, shows that the use of hydroxyapatite coating pins appears to be an effective method of reducing the incidence of pin loosening in external fixation with a long implantation time and for mechanically highly stressed procedures such as leg lengthening for short stature [74].

In clinical application, benefit of HA coating remains scanty [75]. The use of HA-coated pins compared with standard stainless-steel pins in external fixation for unstable wrist fractures yields only a trend towards a superior clinical outcome [75].

- Number of pins

  An increase in rigidity is provided by increasing the number of pins from two to three in any one segment, the segment being any substantial part created by the fracture; therefore, a simple transverse fracture has two segments. The added benefit from increasing pin number from three to four is minimal; therefore, three pins per segment are advised [76]. The material the fixator components are manufactured of also exerts an impact on the frame construct rigidity. As stainless steel has a higher Young's modulus than titanium, it ensures that stainless steel pins exhibit a greater stiffness than those manufactured of titanium. However, these factors alone do not determine the rigidity of the system [30].

- Spread of pins in each main bone fragment.

  Concerning pin spread, the 'near and far' rule provides guidance; pins should be spread along a segment of bone in such a manner that the segment is spanned [61, 76]. The distance between the pins should not be greater than 4cm [77]. The proximity of any pin to the fracture itself should be cautioned, given that the pin may be within the fracture hematoma. This may carry the risk of a pin site infection spreading to other parts of the fracture site. A rule of thumb is that one should stay at least 2cm from the nearest fracture line. In practical terms, when applying this rule, one must take into account soft tissue

damage, in addition to considering future plastic surgery, which may at times limit the options of pin placement [61].

- **Distance between the bone and longitudinal bars**

The distance of the connecting bars from the bone is determined by the soft tissue depth in between. Close proximity is permitted on the tibia's anteromedial surface and femur's surface. Bringing the connecting bar closer to the bone improves stability; in general, it should be kept as close as possible with enough room so as to facilitate pin site care, meaning 40-50mm from the bone surface if feasible [78] **(Fig. 19).** Connecting bars act as a bridge between the pin sites to hold the external fixator's stability [59]. Connecting bars are available in different diameters and of various materials. Whilst stainless steel has previously been popular, bars are currently made of aluminum alloy or carbon fiber composite [61]. These materials provide strength, in addition to the benefit of reduced weight[61]; these carbon fiber rods were developed to provide radiolucent sidebars for EF and facilitate radiological follow-up of fractures [79] . A study revealed that the carbon fiber rods are 15% stiffer than the stainless-steel tubes [79].

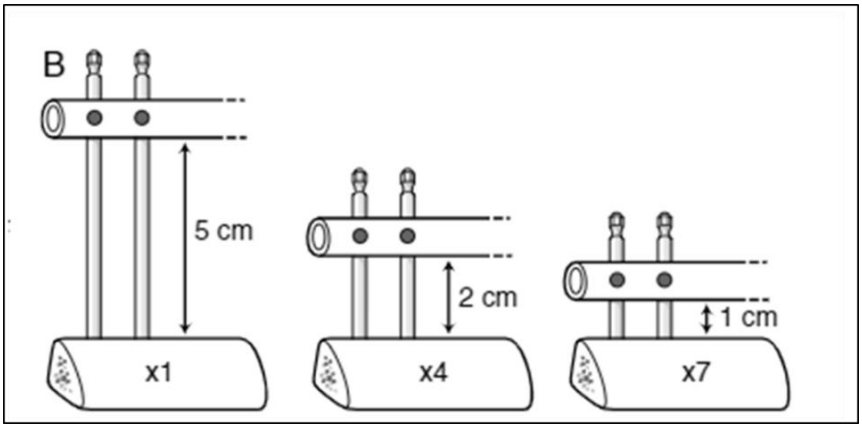

Fig. 19 Influence of distance bone-fixator on the stability of the assembly (a to c): **a.** Stability: x 1. **b.** Stability: x 4. **c.** Stability: x 7. Adapted from Meyrueis et al. (2004)[80]

- **Construction design**

Fixator configurations are subdivided according to whether they are unilateral/bilateral and uniplanar/multiplanar. The multiplanar frames (*i.e.,* placed on both sides of the bone) are stiffer; they can thus be cumbersome to apply, while they are associated with a higher potential for pin infection compared with uniplanar frames. Similarly, uniplanar frames are less obstructive for soft-tissue access, but they are four to seven times weaker under stress exerted in the plane that is orthogonal to the pins [81]. Although anatomic safe zones may be a limiting factor, the pins and bars should be aligned with the bending plane of the bone [81].

External fixation application

During placement of external fixators, several basic principles need to be followed. The surgeon must know the anatomy of the corresponding body part, including the neurovascular structures at risk. We display the anatomy corresponding to the tibia with safe corridors for pin insertion **(Fig. 20)** [82].The shape and size of the soft-tissue corridor through which the pins can be safely inserted is primarily determined by the location of the main vessels, nerves, and musculotendinous units[82]. The tibia is much better suited for the application of an external fixator, because the principal bone lies eccentrically, while the pins can be inserted through a subcutaneous bony corridor [82, 83]. Sequential cross sections of the leg **(Fig. 20)** show that in the proximal third of the tibia, pin placement is safe within an 220°arc, which extends from the posteromedial border of the tibial plateau to the proximal tibiofibular joint [82]. Excluded is a small rectangular area overlying the patellar tendon. This safe anteromedial corridor decreases to 140° just below the tibial tubercle, and to 120° at the ankle joint. Therefore, pins are inserted in the safest manner possible distally to the tibial tubercle. The pins tie down the muscles of the anterior compartment. In certain locations, neurovascular structures are threatened by pin-induced injury; hence, their use should be minimized, and their insertion must be done judiciously [82].

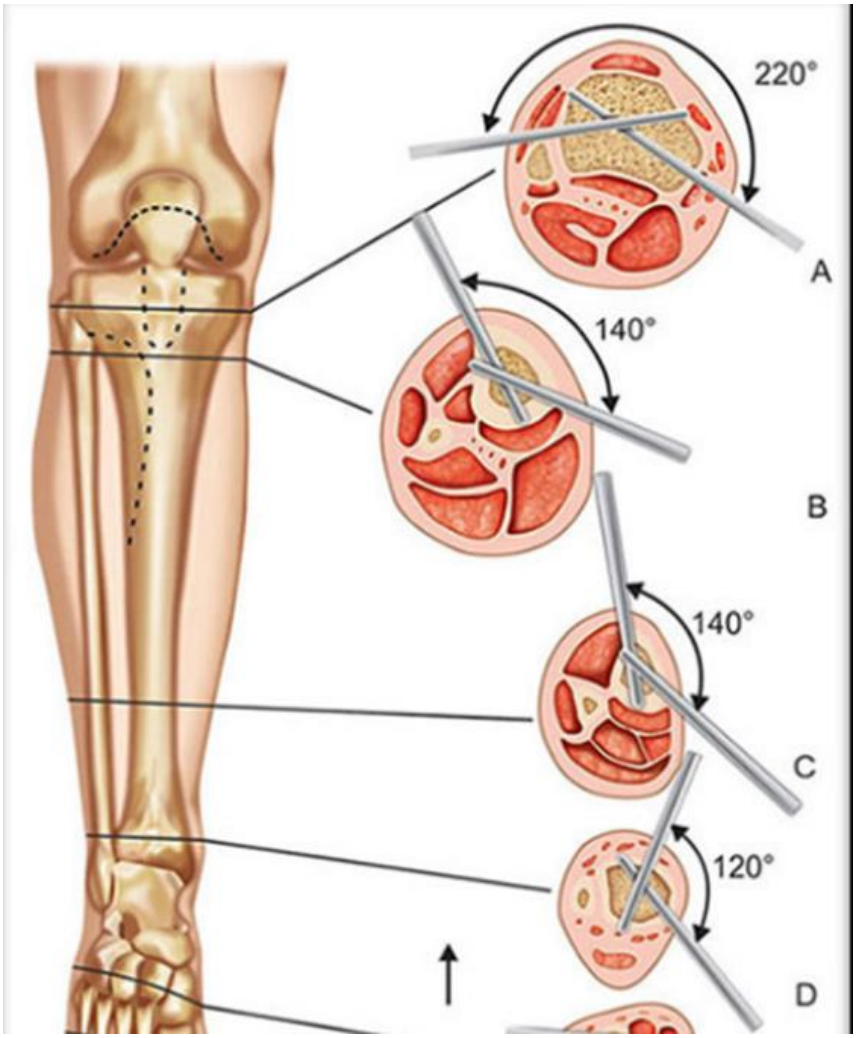

Fig. 20 'Safe corridors' for pin insertion: (A) proximal to tibial tubercle, safe arc 220; (B) just below tibial tubercle, safe arc 140°; (C) distal third tibia, safe arc 140°.The anterior tibial vessels and deep peroneal nerve are vulnerable at the lateral tibial cortex; (D) above the ankle, safe arc 120°. Adapted from Checketts et al. (2003) [30].

Aims of this thesis

The main objective has been to develop an external fixator (LDEF) using available and easily accessible materials for the management of open long bone diaphyseal fractures, concerning particularly the tibia. The LDEF must exhibit biomechanical properties (rigidity, fatigue) comparable to the external fixator reference construct (Hoffmann III) used for the biomechanical tests. The thesis is subdivided into three parts that illustrate the research process from fixator design to clinical study. **Part I** investigates the treatment of open leg fractures in sub-Saharan Africa. This is based on a prospective clinical study that was conducted prior to developing a locally-developed external fixator. **Chapter 1** describes the management of open tibia diaphyseal fractures in our hospital structure (Ivory Coast) and determines the factors that influence postoperative complications. Based on a systematic literature review concerning the treatment of open tibia fractures in developing countries in sub-Saharan Africa, **Chapter 2** identifies management strategies for open tibia fractures that have been and are being used and assesses the results obtained.

Part II focuses on the LDEF design from available and easily accessible materials, with biomechanical properties comparable to previously validated external fixators. **Chapter 1** studies LDEF design suitable for simple and complex fractures patterns. **Chapter 2,** based on a static biomechanical study, investigates the rigidity of these different LDEF constructs in three fracture patterns in comparison with a reference fixator in a saw bone model. **Chapter 3** studies the stability and possibilities of reusing LDEF through fatigue testing. **In Part III, LDEF** effectiveness as definitive treatment for open tibia fractures is evaluated in a prospective clinical study.

Research hypothesis

For this doctoral thesis we have outlined some research hypotheses, namely:

We hypothesize that the rigidity and fatigue parameters of FEDL will be comparable to Hoffmann III external fixators during biomechanical testing. We also hypothesize that post-operative complication rates (infection, bone) will be reduced in patients treated with FEDL for open diaphyseal tibial fractures in an Ivory Coast university hospital setting. Finally, we postulate that the rate of consolidation and the rate of functional outcome will be improved postoperatively in patients treated with FEDL for open diaphyseal tibial fractures in an Ivory Coast university hospital setting.

Chapter I : State of art in the treatment of open tibia fracture in developing countries

1.1 Article 1

La prise en charge des fractures ouvertes de jambe dans une structure hospitalière en Côte d'Ivoire pose-t-elle problème et pourquoi ?

Kouamé Jean-Eric Kouassi, Julie Manon, Loic Fonkoue, Michel Kodo, Christine Detrembleur, Olivier Cornu,

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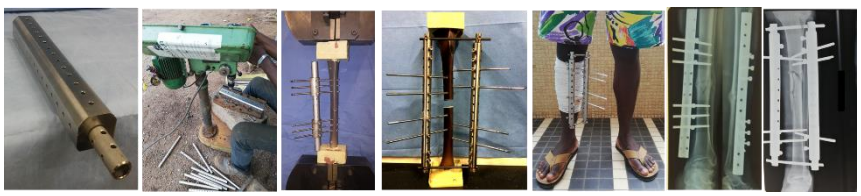

1.1.1 Abstract

Introduction: The care of patients with an open leg fracture in Ivory Coast does not meet the standards of developed countries due to socio-economic conditions, accessibility and organization of care. The objective of this study was to assess the rate of infectious or mechanical complications, depending in particular on the time to treatment and the method of treatment. Our hypothesis was that the complication rate is related to the delay in treatment.

Material and Methods: This prospective study was conducted between January 2018 and May 2018. The parameters studied were factors related to the patient, the fracture and the treatment conditions. They were correlated with complication rates by multivariate analysis.

Results: The series consisted of 30 Gustilo 1 and 2 fractures and 13 Gustilo 3 fractures. The mean operating time was 26.6 ± 8.1 h. Stabilization of the fractures was obtained by cruro-foot plaster, by external fixator and by unlocked nailing in 27,10 and 6 cases respectively. The complications were 17 malunion, 8 osteomyelitis, 3 septic non-union and 1 amputation. Uncomplicated union was observed in 15 cases and an acceptable functional result in 16 cases. Immobilization in a cast was significantly associated with a risk of complications ($p < 0.001$) while the time to treatment was not.

Conclusion: The management of open fractures in a precarious environment is associated with a high rate of complications and an unsatisfactory functional result. Immobilization with a cast is correlated with complications. The availability of external fixators would certainly contribute to a reduction in complications.

Keywords: Open leg fractures, Developing countries, Fixation, Surgical time Precarious situation

1.1.1 Abstract

Introduction : La prise en charge des patients victimes d'une fracture ouverte de jambe en Côte d'Ivoire ne rencontre pas les standards des pays développés en raison des conditions socio-économiques, de l'accessibilité et de l'organisation des soins. L'objectif de cette étude était d'évaluer le taux de complications infectieuses ou mécaniques et ce en fonction en particulier du délai de prise en charge et de la méthode de traitement. Notre hypothèse était que le taux de complications est lié au délai de prise en charge.

Matériel et Méthodes : Cette étude prospective a été menée entre janvier 2018 et mai 2018. Les paramètres étudiés étaient les facteurs liés au patient, à la fracture et aux conditions du traitement. Ils ont été corrélés aux taux de complications par analyse multivariée.

Résultats : La série comptait 30 fractures Gustilo 1 et 2 et 13 fractures Gustilo 3. Le délai opératoire moyen était de 26,6 ± 8,1 h. La stabilisation des fractures a été obtenue par plâtre cruro-pédieux, par fixateur externe et par enclouage non verrouillé dans respectivement 27,10 et 6 cas. Les complications ont été 17 cals vicieux, 8 ostéomyélites, 3 pseudarthroses septiques et 1 amputation. Une consolidation sans complication a été observée dans 15 cas et un résultat fonctionnel acceptable dans 16 cas. Une immobilisation plâtrée était significativement associée à un risque de complications ($p < 0,001$) alors que le délai de prise en charge ne l'était pas.

Conclusion : La prise en charge des fractures ouvertes en milieu précaire est associée à un taux élevé de complications et un résultat fonctionnel insatisfaisant. L'immobilisation par plâtre est corrélée aux complications. La disponibilité de fixateurs externes contribuerait certainement à une diminution des complications.

Mots-clés : Fractures ouvertes de jambe, Pays en développement, Fixation, Délai opératoire Situation précaire

1.1.2 Introduction

Les fractures ouvertes de jambe peuvent générer une morbidité importante[84]. Lorsqu'elles surviennent dans le cadre de traumatisme à haute énergie, elles se caractérisent par des lésions complexes des os et des tissus mous[85, 86] . L'infection représente la complication majeure [86, 87]. Le traitement requiert le respect de certains principes de base unanimement reconnus que sont l'antibioprophylaxie précoce, le parage adéquat, la fixation osseuse stable, et la couverture précoce du foyer de fracture [86, 88]. Dans les pays en voie de développement, comme la Côte d'Ivoire, ces conditions sont rarement réunies et causes potentielles d'échec du traitement. Le retard de la chirurgie, lié aux conditions socio-économiques des patients, à l'absence d'un système de transfert efficace des blessés vers les structures hospitalières[89] et aux plateaux techniques limités en sont la première source [24, 86, 90]. Les centres hospitaliers universitaires, centres de références, ne sont pas épargnés[86, 89]. Le but de notre travail était de préciser le taux de complications (infections osseuses, défaut de consolidation et cal vicieux) et les résultats fonctionnels après fracture ouverte de jambe et d'évaluer si le délai de prise en charge thérapeutique et le mode de prise en charge influaient sur les résultats. L'hypothèse était que le taux de complications postopératoires était corrélé au délai de prise en charge.

1.1.3 Matériel et Méthodes

Critères d'inclusion

Les données ont été recueillies prospectivement entre janvier 2018 et mai 2018 dans le service de Traumatologie-Orthopédie du CHU Bouaké en Côte d'Ivoire. Les critères d'inclusion étaient les fractures ouvertes diaphysaires de jambe, chez des patients âgés d'au moins 15 ans et admis endéans les 24 h du traumatisme. Ont été exclus les patients qui avaient une fracture ouverte négligée ou opérée dans une autre structure sanitaire ou avec un trait de fracture articulaire. Deux patients ont abandonné le traitement et ont été exclus de l'analyse.

Traitement

Une antibiothérapie par voie parentérale était instaurée dès l'admission du patient, associant une Céphalosporine (C3G) 2 g par jour et les dérivés Imidazolés (métronidazoles) 1,5 g par jour pendant 5 jours, puis un relais oral par Ciprofloxacine 750 mg deux fois par jour pour quinze jours. L'antibiogramme permettait d'ajuster si nécessaire l'antibiothérapie. La sérothérapie antitétanique était systématique. Le traitement chirurgical était réalisé au bloc opératoire sous anesthésie. Il comprenait un lavage de la plaie avec du sérum salé isotonique, un parage et une contention de la fracture. Le choix de la technique de stabilisation était dicté par les conditions économiques du patient et sa capacité de financer le traitement. Les coûts pour une immobilisation plâtrée, la location d'un fixateur externe ou un enclouage étaient respectivement de 30,49, 152,45 et 106,71 euros.

La couverture précoce du foyer de fracture était réalisée par suture pour les types I, II et par lambeau (fascio-cutané,musculaire) pour les types III. Le plâtre cruro-pédieux était fenêtré pour faciliter les pansements. Il était relayé par une botte plâtrée dès l'apparition de cal. Le fixateur externe (Orthofix, Angoulême-France ou FESSA, France) en monoplan, était également relayé par une botte plâtrée de marche dès l'apparition d'un cal.

Méthode d'évaluation

Étaient évalués : les paramètres du patient (sexe, âge), les paramètres de la fracture (étiologie, siège et type de trait de fracture, comminution, lésions associées), les paramètres du traitement (délai de prise en charge chirurgicale à partir du traumatisme, moyens de contentions, durée d'hospitalisation). La classification du trait de fracture et celle de l'ouverture cutanée selon les critères de Gustilo [91] étaient réalisées après le débridement et la réduction. Le résultat fonctionnel, la consolidation, le délai de consolidation et les complications (défaut de consolidation, cal vicieux, infection) étaient enregistrés. Les résultats fonctionnels étaient évalués par le rétablissement d'une marche normale, l'absence de boiterie, la flexion et l'extension du genou, la flexion dorsale et la flexion plantaire de la cheville [92]. La raideur articulaire du genou et/ou de la cheville était évaluée par le déficit de mobilité en flexion ou en extension pour le genou, en flexion dorsale ou en flexion plantaire pour la cheville en comparaison avec le côté sain à l'aide d'un goniomètre[91, 92] (Tableau 1). La consolidation osseuse était évaluée cliniquement par l'absence de douleur, de mobilité anormale à la mobilisation du site fracturaire, par la palpation d'une formation fusiforme correspondant au cal osseux de consolidation, l'appui indolore et l'absence de boiterie.

Radiologiquement l'existence d'un cal osseux continu entre les segments proximal et distal avec disparition du trait de fracture sur au moins trois corticales signait la consolidation [92]. La pseudarthrose correspondait aux fractures n'ayant pas consolidé plus de six mois après le traumatisme et nécessitant une reprise chirurgicale[92]. Le cal vicieux défini comme une déformation osseuse susceptible d'entraîner des conséquences fonctionnelles, était évalué cliniquement et radiologiquement. Les limites de tolérance étaient fixées à des valeurs inférieures : de 10◦pour un varus et les troubles sagittaux, 15◦pour le valgus, 10◦de rotation interne, 15◦de rotation externe et 2 cm de raccourcissement [92, 93]. L'infection postopératoire précoce dans le premier mois et tardive après le premier mois était évaluée selon les critères suivants dont au moins un était requis : plaie avec signes d'infection (douleur, tuméfaction, rougeur, augmentation de la température locale) ; présence d'un écoulement purulent au niveau de la plaie ; culture microbiologique positive du liquide ou du tissu superficiel prélevé au niveau de la plaie[86, 92]. Lorsqu'un germe était isolé, cette donnée était documentée par le chirurgien. Pour l'analyse des données, nous avons regroupé les Gustilo I et II, ainsi le seuil se situait au moment où la fermeture cutanée de première intention n'était plus possible. Le traitement chirurgical regroupait l'ostéosynthèse externe et interne.

Tableau 1 : Méthode d'évaluation des patients

	Très bon	Bon	Moyen	Mauvais
	Marche normale	Marche normale	Douleur à la marche	Douleur fréquente Mobilité réduite
Items	Flexion genou>120°	Flexion genou ≥ 90°	Flexion genou 60°-90°	Flexion genou <60°
	Extension complète du genou	Extension à 10°	Déficit d'extension genou de plus 10°	Déficit d'extension de plus 15°
	Flexion dorsale cheville à 30°	Flexion dorsale cheville à 20°	Flexion dorsale cheville à 15°	Flexion dorsale cheville à 5°
	Flexion plantaire cheville à 50°	Flexion plantaire cheville à 30°	Flexion plantaire cheville à 20°	Flexion plantaire cheville à 10°
Résultat fonctionnel	**Satisfaisant**		**Insatisfaisant**	

Analyse statistique

Les données ont fait l'objet de statistiques descriptives. Une analyse multivariée et une analyse univariée ont été réalisées à l'aide du logiciel SPSS version 25,0 (SPSS Inc., Chicago, Ill., États-Unis). Un lien entre les variables, soit le délai de prise en charge, les paramètres propres au patient, à la fracture et au traitement et les complications, a été recherché avec un seuil de signification de 0,05.

1.1.4 Résultats

La série

La série Quarante-trois patients ont été admis endéans les 24h00 de leur fracture ouverte de jambe. L'âge moyen était de 33,3 ± 14,1 ans (15–64 ans). Les patients dont l'âge était ≥ 30 ans prédominaient (51,2 %). Il s'agissait d'hommes dans 38 cas (88,3 %). Le principal mécanisme lésionnel était l'accident de la voie publique dans 40 cas (93,1 %). Un patient présentait un polytraumatisme et 13 étaient poly-fracturés. Cinq fractures Gustilo 1, 25 Gustilo 2 et 13 fractures Gustilo 3 ont été observées. La fracture était comminutive dans 30 cas (69,8 %). Le délai moyen de prise en charge chirurgicale était de26,6 ± 8,1 h (11–43 h). Vingt-deux patients (51,2 %) étaient pris en charge pour le parage dans les 24 h de survenue de la fracture et 22 patients (48,8 %) après 24 h. Le plâtre cruro-pédieux était le moyen de contention le plus utilisé (27 cas ; 62,8 %), suivi du fixateur externe (10 cas) et de l'enclouage non verrouillé (6 cas) (Tableau 2). La durée moyenne d'hospitalisation était 12,28 ± 12,0 jours (extrêmes de 3 et 60 jours).

Tableau 2 : Méthodes de contention en fonction du degré d'ouverture.

Items	I	II	IIIa
Plâtre cruro-pédieux	2	13	9
Fixateur externe	2	8	1
Clou non verrouillé	2	4	
Total	5	25	10

Résultats cliniques

Une infection a touché 22 cas (51,2 %), dont 11 ont été guéris et 11 ont évolué vers une ostéomyélite chronique. Une amputation a été réalisée chez un patient présentant une fracture type IIIC après échec de la revascularisation. La consolidation sans complications n'a été observée que dans 15 cas (34,49 %). Le délai moyen de consolidation était de 171,7 $\pm$ 21,6 jours. Le résultat fonctionnel : était très bon dans 7 cas (16,3 %), bon dans 9 cas (20,9 %) moyen dans 19 cas (44,2 %) et mauvais 8 cas (18,6 %). Le résultat global était satisfaisant dans 16 cas (37,2 %) et insatisfaisant dans 27 cas (62,8 %). Le taux de complications post-opératoire était de 65,1 % (28 patients), associant le cal vicieux dans17 cas (39,5 %) et l'infection dans 11 cas sous la forme d'une ostéite chronique dans 8 cas (18,6 %) et d'une pseudarthrose septique dans3 cas (7 %).

Facteurs pronostiques

L'analyse multivariée a montré une corrélation entre les complications postopératoires et les moyens de contentions ($p < 0,020$). L'utilisation du plâtre comme moyen de contention augmentait significativement le risque de complications postopératoires par rapport à une ostéosynthèse (Odds ratio à 12,65, un risque relatif à2,72 et $p < 0,001$) (Tableau 3). L'analyse univariée a montré que les fractures de Gustilo grade III étaient associées à un risque accru de complications postopératoires ($p < 0,017$) (Tableau 3). Il n'y avait pas d'association statistique entre le taux de complications post-opératoires et le délai de prise en charge ou les autres facteurs observés (Tableau 4). Il n'y avait pas de lien significatif entre les moyens de contentions des fractures et le pronostic fonctionnel.

Tableau 3 : Paramètres favorisant la survenue d'une complication

Variable	Complications (%)	Sans complications (%)	Total	Valeur *p*
Critère de Gustilo				**0.017**
I et II	**16 (53,3)**	**14 (46,7)**	30	
III	**12 (92,3)**	**1(7,7)**	13	
Traitement réalisé				**0.001**
Traitement par plâtre	**23 (85,2)**	**4 (14,8)**	27	
Traitement chirurgical	*5* **(33,3)**	**11(73,4)**	16	

Tableau 4 : Paramètres non significatifs

Type de fractures	Complications (%)	Sans complications (%)	Total	Valeur *P*
N (%)	28 (65,11)	15 (34,89)	43	
Sexe				**0,643**
Homme	24 (63,2)	14 (36,8)	38	
Femme	4 (80)	1 (20)	5	
Age				**0,911**
< 30 ans	14 (63,6)	8 (36,4)	22	
≥ 30ans	14 (66,7)	7 (33,3)	21	
Type de fracture				**0,742**
Comminutive	20 (66,7)	10 (33,3)	30	
Simple	8 (61,5)	5 (38,5)	13	
Siège de la fracture				**0,957**
Epiphyse	11(68,8)	5 (31,3)	16	
Diaphyse	17(62,9)	10 (37,1)	27	
Délai de prise en charge				**0,243**
>24heures	16 (76,2)	5 (23,8)	21	
≤ 24 heures	12 (54,5)	10 (45,5)	22	
Durée d'hospitalisation				**0,760**
<10 jours	14 (60,9)	9 (39,1)	23	
≥10 jours	14 (70)	6 (30)	20	

1.1.5 Discussion

Cette étude montre une fréquence élevée des fractures ouvertes de jambe dans la population jeune, associée à une prise en charge tardive. Cette prise en charge tardive n'était pas corrélée au taux de complications postopératoire. Notre hypothèse n'est pas confirmée. Le plâtre cruro-pédieux était le moyen de contention le plus utilisé. Il augmentait significativement le risque de complication postopératoire. Les résultats observés dans notre série, sur la fréquence des fractures ouvertes de la jambe dans la population jeune masculine des pays en voie de développement, avec un risque de contamination septique lié au mécanisme lésionnel et à l'environnement tropical, est confirmé par plusieurs auteurs[86, 94]. Le retard dans la prise en charge des patients dans notre série est rapporté dans la littérature[92]. Plusieurs facteurs expliquent ce retard : le mode d'admission des blessés assuré essentiellement par un transport non médicalisé[95]. En Côte d'ivoire, le SAMU (service médicale d'aide d'urgence) est la structure de choix qui est rarement sollicitée car ses prestations sont payantes et ne sont pas à la portée de tous[89]. La majorité des patients n'ont aucune couverture sociale et proviennent de zones éloignées du centre hospitalier. Les implants sont souvent indisponibles et le bloc opératoire est également utilisé pour des urgences chirurgicales abdominales et d'autres spécialités chirurgicales[23] L'instauration de l'antibiothérapie était immédiate, dès l'admission des patients aux urgences comme préconisé dans la littérature[86, 88]. Les antibiotiques réduisent l'incidence des infections précoces dans les fractures ouvertes des membres[96]. Dans notre étude, le délai de prise en charge chirurgicale n'avait aucun effet significatif sur la survenue de complications postopératoires mais notre cohorte disposait globalement d'une prise en charge tardive par rapport

aux recommandations internationales d'un débridement le plus précoce possible pour réduire l'inoculum bactérien[97]. Dans la série de Twagirayezu et al.[90], il existe une corrélation entre le délai préopératoire et le risque de complications. Kitoto et al. [92] mettent en évidence une augmentation significative des complications opératoires chez les patients opérés après plus de 48 h. Actuellement la règle de six heures est controversée [98]. Dans la littérature actuelle, il n'existe pas de corrélation claire entre le délai préopératoire et la survenue des complications infectieuses[99]. Cependant, il ne faut pas cautionner le retard dans le traitement des fractures ouvertes carle risque infectieux est toujours présent et multifactoriel surtout après 24 h, quel que soit le degré d'ouverture et indépendamment du délai du parage[100]. C'est la qualité du débridement initial qui conditionne l'avenir. L'immobilisation plâtrée prédominait, ce qui reflète une pratique largement établie dans nos conditions[18, 90, 101]. Le plâtre est préféré en raison des difficultés financières des patients et face à une faible disponibilité des moyens de synthèse[24, 101]. Si le plâtre est moins couteaux et aisément disponible dans notre centre de santé, il rend difficile la réalisation des pansements[24] et retient les sérosités. Peut-être parce qu'ils sont fenêtrés pour permettre des soins locaux, la contention est-elle fragilisée et rend compte de déplacements secondaires[24]. L'instabilité est également susceptible de favoriser les complications infectieuses ce qui pourrait rendre compte de notre taux de complication accru avec ce type de contention. Au regard de nos résultats, et en présence de certains facteurs tel que le coût élevé des implants et très souvent le manque de conditions d'hygiènes sanitaires requises pour le traitement chirurgical des fractures ouvertes par ostéosynthèse interne[26, 102], le fixateur externe se présente comme un implant de choix dans nos conditions de travail. Son usage malheureusement limité s'explique par le coût

élevé du fixateur disponible dans le commerce[102]. Le développement local d'un fixateur externe à coût réduit [102], accessible et disponible pour tous, pourrait contribuer à améliorer la prise en charge des blessés. Malgré sa conception prospective, cette étude a des limites. Elle n'est pas comparative, ni randomisée. L'attitude thérapeutique n'était pas standardisée car la méthode de contention était adaptée à chaque profil de patient. En conclusion, dans notre centre de santé ivoirien, la fracture ouverte de jambe touche une population jeune et est grevée d'un taux élevé de complications, avec des conséquences économiques graves pour les familles. Le transport rapide des victimes d'accidents vers l'hôpital, une plus grande accessibilité au bloc opératoire et une disponibilité accrue de fixateurs externes à moindre coût contribuera plus que probablement à une diminution des complications postopératoires. Le développement d'un système de couverture sociale pour les soins urgents lèverait le frein que représente le coût de soins élémentaires pour une grande partie de la population ivoirienne.

1.2. Article 2

Treatment of open tibia fractures in Sub-Saharan African countries : a systematic review

Kouamé Jean-Eric Kouassi, Julie Manon, Loic Fonkoué,
Christine Detrembleur, Olivier Cornu

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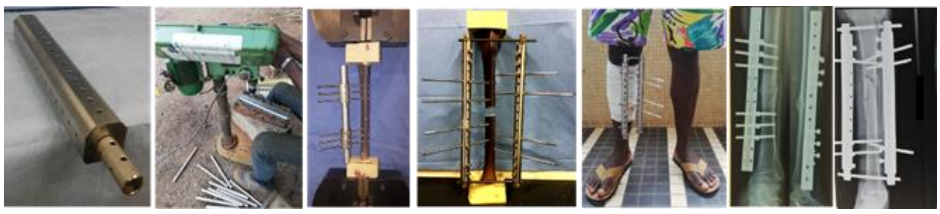


1.1.1 Abstract

Introduction Open tibia fracture (OTF) treatment is well documented in developed countries. Yet, this fracture pattern remains challenging because it is associated with an increased risk of infection and delayed union, particularly in case of Gustilo III B and C open fractures. Since access to healthcare is limited in Sub-Saharan African countries, this paper explores the results of OTF management in this setting.

Materials and methods A systematic review of the literature was conducted using current databases such as MEDLINE, Cochrane, EMBASE, PubMed, ScienceDirect, Scopus, and Google Scholar in order to identify prospective studies with cohorts of patients treated for OTF. Studies were included based on predefined inclusion and exclusion criteria. The quality of studies was analyzed by the Coleman Methodology Score (CMS).

Results. Eight papers met the inclusion criteria and had an average CMS of 70 (range 54–73). The most common treatment was non-operative management of the fracture with cast immobilization (67%). Gustilo Type II and III fractures were associated with a higher risk of complications. The infection rate was 30%. Malunion, chronic osteomyelitis and nonunion were observed in 14.5%, 12.3%, and 7% of the cases, respectively. More complications were observed with non-operative treatment (cast immobilization) than with surgical fixation.

Conclusions. Although the surgical environment does not allow for internal fixation, poor results of non-operative management of open fractures should lead to the introduction of trainings on the proper use of external fixators. It is also advisable to support the development of locally produced external devices

that utilize local source materials, which would make external fixation available at a reasonable cost.

Keywords : Africa, Cast immobilization , Developing countries, Open fracture, Tibia.

1.1.2 Introduction

Open tibia fracture (OTF) treatment is well documented in developed countries and the management principles of open fractures are well established[103]. Yet, this fracture pattern remains challenging, as it is associated with an increased risk of infection and delayed union, particularly in case of Gustilo III B and C open fractures[104-106]. Since poor urban populations in Sub-Saharan African countries have limited access to healthcare[23], the difficulties of treatment are multifactorial. Patients experience delays in surgical management that are related to their socioeconomic conditions and the absence of an efficient system to transfer the wounded to hospitals. Limited technical plateaus, lacking fixation hardware, and insufficient training in soft-tissue reconstruction techniques are also frequently reported[23, 26, 107, 108]. We therefore wish to examine the results of OTF management in this setting by performing a literature review. The aims of this systematic review were 1) to assess the published literature on OTF in Sub-Saharan African countries, 2) to identify management strategies that have been applied, and 3) to evaluate the complication rate of these fracture stabilization methods. Poorer results were expected as compared to those observed in developed countries.

1.1.3 Methods

The systematic review protocol complied with the guidelines provided by the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement[109]. Literature search Keywords were identified using the PICO method in relation to the population (open tibial fracture OR developing countries OR Africa), the intervention (external fixators OR nails

OR plaster of Paris), and outcomes (union OR malunion, OR, nonunion OR infection). The search was performed on articles dated between 2000 and October 2019, using several electronic databases: PubMed, Google Scholar, ScienceDirect, EMBASE, Scopus, the Cochrane Library, and additional African Journals. All references were exported from the databases to Endnote.

Study selection

We selected available studies that were conducted in Sub-Saharan African countries. Articles meeting the following criteria were included: the reported language was English or French, the study was prospective, the study investigated populations of at least 20 patients, demographic data was included and the well-described treatment regimen was available, the Gustilo-Anderson classification was used[91], methods of fracture stabilization were identified, union and complications were described. Articles were excluded if they did not meet the above inclusion criteria, if they related to a neglected OTF, or if the study was retrospective or a case report. Two researchers (KE, CD) independently screened the titles and abstracts of the retrieved studies to assess eligibility, after duplicates were removed. Articles that met the inclusion criteria were selected for a full-text lecture, and corresponding authors were contacted when the full text was not available. Articles that met the inclusion criteria were also included for qualitative synthesis. Disagreements were resolved through consensus.

Quality assessment

Two authors independently scored the quality of the studies using the Coleman Methodology Score (CMS)[110, 111], which was adapted (Table 1) to evaluate studies reporting on OTF. The CMS is a method of analyzing the quality of studies being reviewed by assessing the methodology using 10 criteria, giving a total score between 0 and 100. A score approaching 100 indicates that the study has a robust design and largely avoids chance, various biases, or confounding factors. A score >85 is considered excellent, 70–84 is good, 50–69 is moderate, and <50 is poor. The CMS's subsections are based on the subsections of the Consolidated Standards of Reporting Trials (CONSORT) statement (for randomized, controlled trials) [112].

Data extraction and synthesis

Two authors (KE, CD) extracted data using a pre-pilot standardized form (Table 2), which included the first author's last name, publication year, CMS number, demographic data, diagnosis (fracture pattern), the Gustilo grade of the open fracture, interventions, and any complications (infection, malunion, nonunion). Statistical analysis was performed using SigmaPlot version 13. We calculated the median and quartile [25-75] of the outcomes. The risk of developing a complication was also determined according to the stabilization method and the Gustilo type of open fracture.

Table 1 : Criteria used to compute the Coleman Methodology Score for studies reporting the outcomes of open tibial fractures.

S.no.	**Part A: only one score to be given for each of the seven sections**		Score
1	Study size—number of TARs	<20	0
		20-49	4
		50-99	7
		>99	10
2	Mean follow-up	<1 year	0
		1-2 years	4
		2-5 years	7
		>5 years	10
3	Number of different fracture stabilization techniques used	Not stated, unclear, or <90% of subjects receiving same technique	0
		More than one techniques, but >90% of subjects receiving one technique	7
		One technique used	10
4	Type of study	Retrospective cohort study	0
		Prospective cohort study	10
		Randomised control trial	15
5	Description of indications/diagnosis (e.g. fracture grade)	No	0
		Yes	5
6	Descriptions of surgical technique	Inadequate (not stated, unclear)	0
		Fair (technique only stated)	3
		Adequate (technique stated, details of surgical procedure given)	5
7	Postoperative management described	No	0
		Yes	10
	Part B: scores may be given for each option in each of the 3 sections if applicable		
1	Outcome criteria	Outcome measures clearly defined	2
		Timing of outcome assessment clearly stated	2
		Use of outcome criteria that has reported reliability	3
		General health measure included	3
2	Procedure of assessing outcomes	Subjects recruited	5
		Investigator independent of surgeon	4
		Written assessment	3
		Completion of assessment by patients themselves with minimal investigator assistance	3
3	Description of subject selection process	Selection criteria reported and unbiased	5
		Recruitment rate reported	
		<90%	0
		>90%	5

Table 2 Summary of patient characteristics - demographics, protocol, treatment outcome

Author Year [ref] Score (CMS)	**Patients: n Men/women (%) mean age±SD major cause (RTA) (%)**	**Location (%) Pr Mi Di Eph**	**Fracture pattern (%) Co Tra Ob Seg Spi**	**Time from injury to presentation**	**Mean time from injury to operation**	**Gustilo (%) I II III**	**Methods of fracture stabilization (%) EF IN CI P AMP**	**Outcome (%) IF NU MU OS**	**Union (%) Mean time to union**
Enweluzo et al. 2015[18] 76/100	n=197 73.6/26.4 36.9 ±18.9 RTA=78.2	NA	Co=11.2 Tra=32 Ob=47.2 Seg=5.6 Spi=4.1	NA	NA	I=26.4 II=49.2 III=24.4	EF=10.2 IN=13.2 CI=71.7 P=4 AMP=2	IF=22.3 NU=3 MU=6.6 Death=0.5	65.5
Kouassi et al. 2019[113] 54/100	n=43 88.3/11.7 33.3±14.1	Mi=62.8 Ep=37.2	Co=69.7 Tra=30.3	NA	>24h=48.8 ≤24h=51.2 Mean=27h	I=11.7 II=58.1 III=30.2	EF=23.2 IN=14 CI=62.8 AMP=2.3	IF=51.2 NU=7 MU=39.5 OS=18.6	34.49 25 weeks

	RTA=93.1								
Abang et al. 2018[114] 69/100	n= 40 75/25 33.5 ± 12.8 RTA:95	Pr=10 Mi=32.5 Di=57.5	Co=52.5 Tra=5 Ob=25 Seg=12.5 Spi=5	NA	NA	II=15 III=85	EF=100	IF=82.5	32.5
Touré et al. 2018 [86] 73/100	n=58 91.3/8.7 32 RTA=93.1	Pr=13.8 Mi=63.8 Di=22.4	Ob=19.1 Tra=66.1 Spi=7.4		≤24h=81 >24h=19 Mean=10h	I=24 II=55 III=21	EF=52 IN=31.4 CI=11 P=5.6	IF=35 NU=8.6 MU=27.8	91 16weeks
Handy et al. 2017 [115] 72/100	n=69 78/ 22 37.48 RTA=74	NA	NA	NA	Mean=72h	I=26 II=61 III=13	IN =100	IF=8.7 OS=4.3	87 20weeks
Tolgou et al. 2017 [116] 54/100	n=47 85/15 34.6 RTA=87.7	NA	NA	≤24h=89.3 >24h=10.7	≤24h=76.6 >24h=23.4	I=11 II=36 III=53	EF=68.1 IN=2.1 CI=29.8	IF=25 MU=16.7 OS=8.3 Death=8.3	74.47

Ifesanya et al. 2010[117] 52/100	n=98 70/ 30 33.3±14.8 RTA=83	Pr=9.2 Mi=76.5 Di=9.2	Ob=32.7 Tra=27.6 Spi=13.3	NA	NA	I=8.4 II=18 III=73.6	EF=15.7 IN=1.4 CI=71.4 P=5.7 AMP=5.7	IF=11.4 NU=4.3 MU=11 OS=13	52.3 26.2 weeks
Ikem IC et al. 2006 [24] 73/100	n=89 64/36 32.7±17.1 RTA=60.7	Pr=18 Mi=32.6 Di=49.4	Co=40.4 Tra=25.8 Ob=24.7 Seg=3.4 Spi=5.6	NA	Mean=6h	I=24.7 II=36	EF=22.5 CI=77.5	IF=48.3 NU=7.8 MU=12.3 OS=12.3	31.5 17 weeks

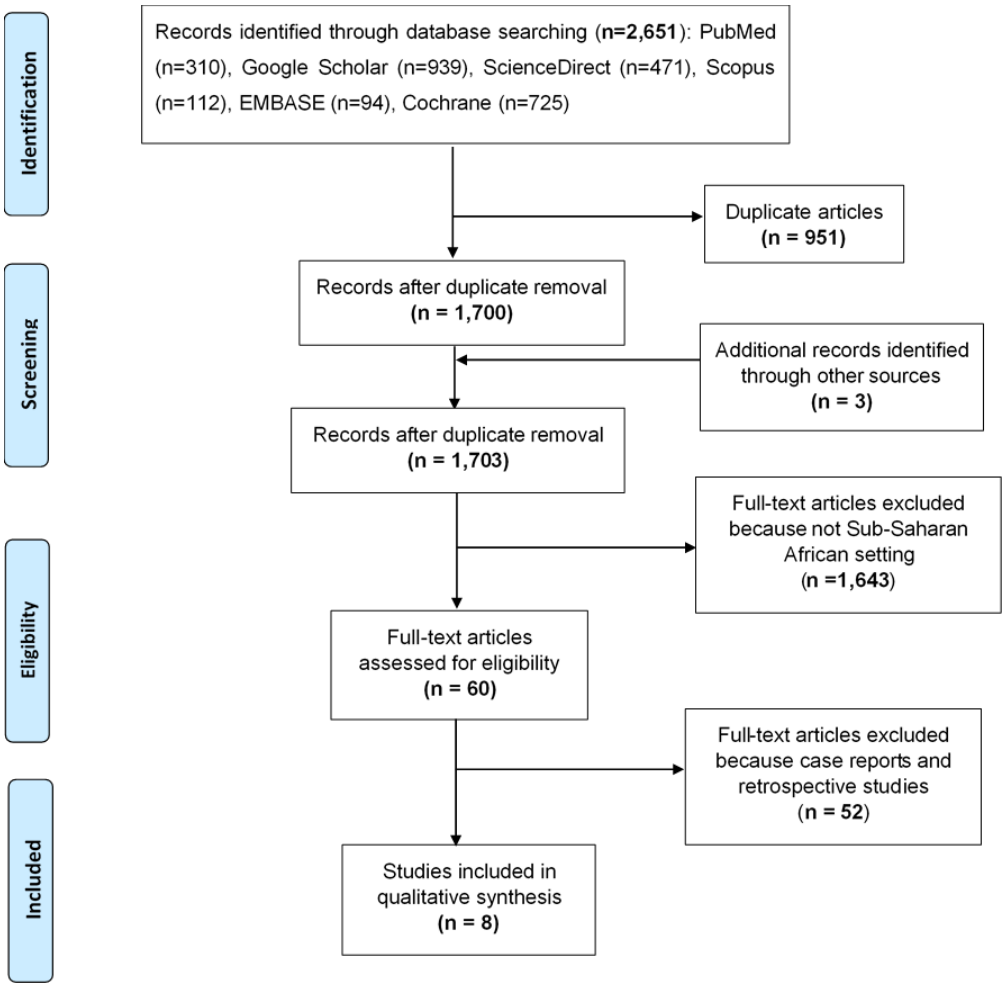
Pr=proximal; MI=middle; Di=distal; Ep=epiphyse; Co=comminuted; Tra=transversal; Ob=oblique; Seg=segmental; Spi=spiral; EF=external fixator; IN=intramedullary nails; P=plate; AMP=amputation; IF=infection; NU=nonunion; MU=malunion; OS=osteomyelitis; NA=not applicable, CI=cast immobilization

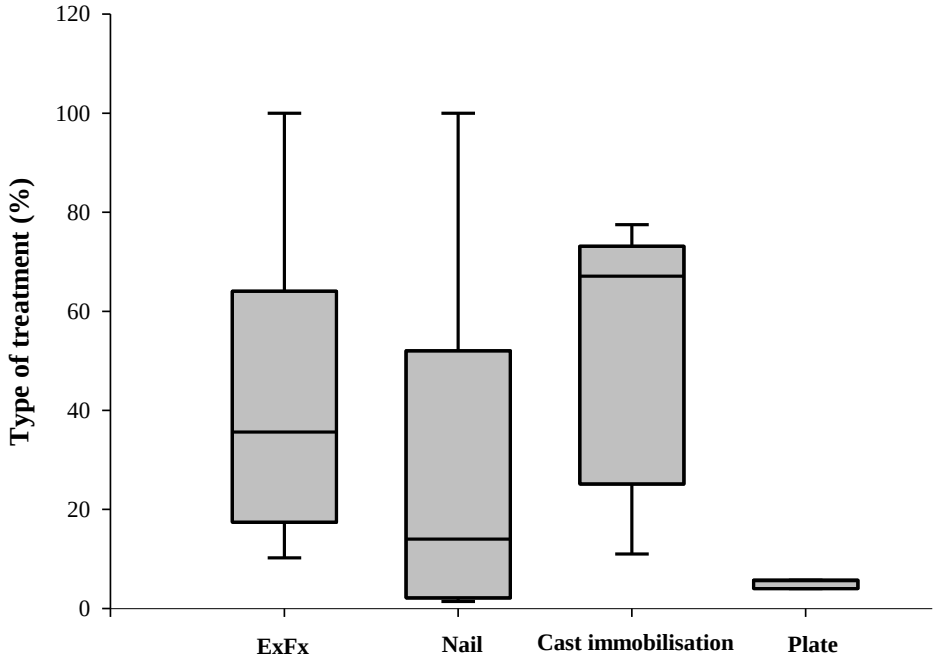
1.1.4 Results

The electronic search yielded 2,651 articles, but only eight met the inclusion criteria and were considered eligible for the study (Fig. 1). The average CMS was 70.5 (range 54–73), which is indicative of good methodological quality [110]. The eight studies [18, 24, 86, 113-117] reported on 641 patients who were treated for an OTF. Their mean age was 34 years (range 33–36), with 77% males. The mechanism of injury was road traffic accident (RTA) in 85.3% [18, 24, 86, 113-117]. Fractures were predominantly in the middle third (62.8%), followed by the distal third (36%)[24, 86, 113, 114, 117]. The comminuted fracture pattern was the most frequent (46.4%), followed by transverse (28.9%) and oblique fractures (25%)[18, 24, 86, 113, 114, 117]. Gustilo II and III fractures accounted for 42.6% and 30.2% of cases, respectively. Regarding the time from injury to operation, 76.6% of patients were operated on within 24 hours[86, 113, 116] Open wound management was described in all studies, but numerical data was only available in four studies[24, 86, 116, 117]. Skin grafting was used in 44.07%, primary closure in 21.3%, and flap coverage in only 8.5%. Secondary healing was expected in 10.8%. Several techniques were used for fracture stabilization in seven studies [18, 24, 86, 113, 116, 117], while one reported only external fixators (ExFx) [114] and another exclusively

intramedullary nailing [115]. Cast immobilization (CI) was solely used for fracture fixation in 67.1% of cases **(Fig. 2)**. Primary amputation was performed in 7.7% of patients[18, 117] and secondary amputation was performed in 2.3% of patients[113]. Fracture healing was reported after a mean delay of 20.6±4.4 weeks. The union rate was 58.9% [18, 24, 86, 113-117]. Figure 3 summarizes the pooled data regarding complication rates **(Fig. 3)**. Infections were frequent (30%), and non-operative treatment/CI was associated with an increased complication rate when compared to surgical fixation **(Fig. 4)**.

Fig. 1 Flowchart of studies inclusion





ExFx : external fixator

Fig. 2 Box plot of Methods fracture stabilisation distribution

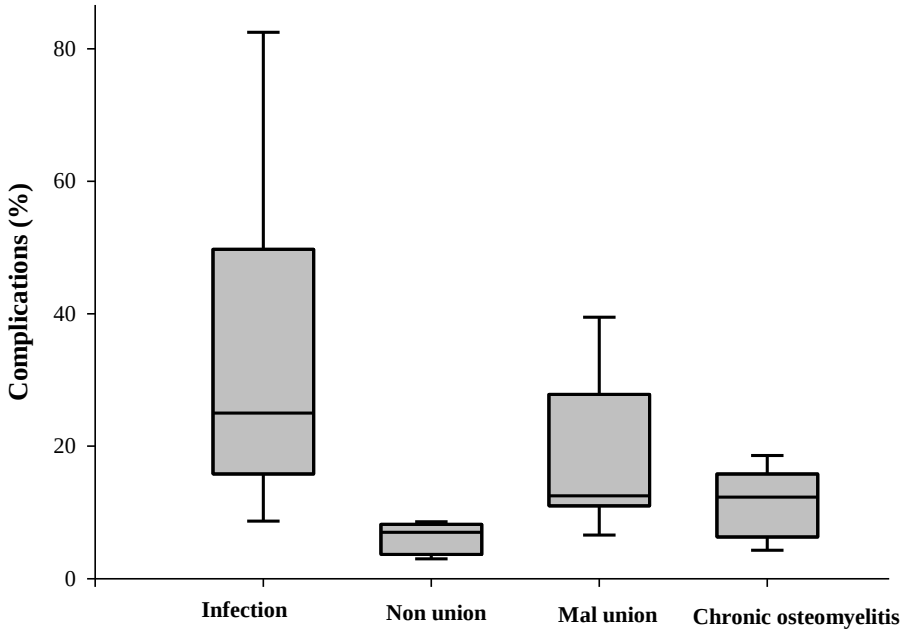


Fig. 3 Box plot of complications rate distribution

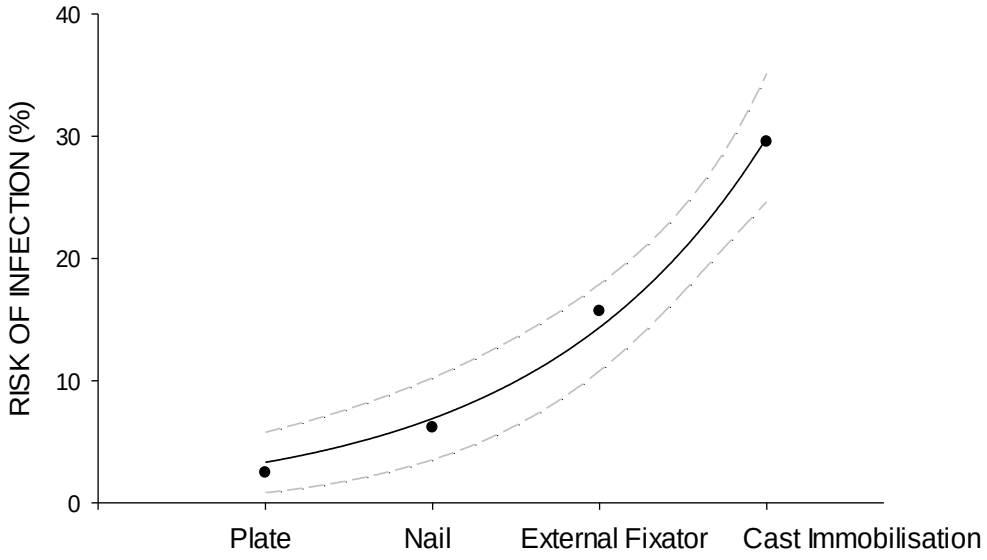


Fig. 4 The trend curve for complications / restraint methods

1.1.5 Discussion

OTF management is a significant cause for concern in developing countries[118]. OTFs are usually associated with a high complication rate[119], particularly infection, malunion, and nonunion[120] . With regards to the complications observed, the average incidence of infections was 30%. This overall infection rate is higher than the rates reported in some studies[121-123], but similar to others [119, 124-126]. The high proportion of Gustilo III fractures in this series may explain the poorer results, although a systematic review of open Gustilo III B and C fractures reported lower infection rates[106]. Better results might be expected in middle-income[121] or developed countries[127]. Delayed treatment has been proposed as a potential cause of infection. However, Reuss and Cole reported that delayed operative management of up to 48 hours did not adversely affect infection rates [128]. The timing for soft-tissue coverage is also controversial, as some advocate early flap coverage[129] and others advocate delayed wound closure[130]. It has been observed that flap coverage within 72 hours reduced infection rates[105], and, for Gustilo III B fractures, soft-tissue coverage within (versus after) one week resulted in lower rates of infection (8% versus 59%)[131]. It is not possible to confirm that the choice of secondary soft-tissue healing in our review negatively influenced the result. The average incidence of nonunion was lower than the rates reported in some studies [124, 127]. With regards to malunion, the average incidence was higher than the rates reported in the existing literature [132]. The predominant use of CI in place of modern surgical fixation in our series could explain these outcomes. However, the results are not fully comparable, due to differences in the methods used for fracture stabilization. Early stabilization is of paramount importance and, ideally, should be

performed at the time of the initial debridement. This restores limb alignment, eliminates gross movement at the fracture site, limits further soft-tissue damage, and decreases the risk of further bacterial spread [133]. The types of fixation currently available are ExFx, plates and screws, reamed and unreamed locking nails, and CI [2, 134, 135]. However, specific problems are inherent to each treatment method, which means every method is less than ideal[120]. Methods of fracture stabilization varied between studies. The CI was the most used because it is cheap, readily available and non-invasive[24, 90]. Access to the wound unfortunately remains difficult for inspection and dressing. Windows made on the CI often weaken it and compromise adequate maintenance of fracture reduction [24]. Prolonged CI application caused joint stiffness, quadricep wasting, and secondary fracture displacement [24, 135]. The potential advantages of ExFx include minimal soft-tissue stripping, as well as easy and quick application in emergency situations[136]. The disadvantages, however, include track problems with the pins, reduction loss, and the potential for fracture from the pin track site[9, 120]. The potential advantages of intramedullary nailing include improved cosmesis, early mobilization, and stable reduction[24]. Its disadvantages include the potential for deep infection (osteomyelitis) and the spread of infection through the medullary canal [137]. Postoperative infection rates are a major indicator of the viability of a particular surgical modality. In this series, the rates of infections and postoperative complications were higher with the use of plaster as a method of immobilizing fractures. This outcome was similar to that found in other studies[113, 116]. We believe that, in Sub-Saharan African countries, economic constraints favor CI as a method of treatment for these fractures. CI is cheaper than ExFx or an intramedullary nail and removes any need for special instrumentation or intraoperative image intensifiers. We believe that local development of a low-

cost ExFx [9] could provide an alternative to CI and ExFx devices that are available in developing country markets, since ExFx continues to be an acceptable modality of management in developing countries, where patients arrive late to hospitals and where local medical facilities are poorly available[24]. ExFx is technically less demanding and requires no specialized equipment [24, 118]. Although initial union rates may be lower with external fixation compared to intramedullary nailing, these fractures ultimately unite, even if the union time is prolonged [138]. Finally, applying an ExFx to the initial injury may also decrease the ultimate rate of infections and osteomyelitis, which is considerably more debilitating and morbid than the trauma of repeat surgery that is secondary to a nonunion.

Limitations and futures perspectives

Some differences can be noted in the eight studies selected, which makes it difficult to compare and generalize results. First, the inclusion criteria were not the same. Second, the therapeutic attitude was not standardized because the methods of restraint were varied. Finally, details of antibiotic administration were not well described in most of the studies. However, this study does present a prospective collection of surgical data and, where possible, reveals how this data compares favorably to other studies in the literature. Despite the limitations of our study, we recommend the local development of a new, low-cost ExFx. We also recommend promoting trainings on the proper use of techniques for early and adequate soft-tissue coverage by orthopedic surgeons. Additionally, we propose employing a score that measures quality of life with good psychometric properties, such as SF-36[139] or the lower extremity functional scale (LEFS) [140].

Conclusion

This review reveals that OTFs mainly concern young male subjects. The main cause is RTAs involving motorcycles. Fractures were essentially comminuted, and CI was mostly used as the method for fracture stabilization. The treatment of OTFs in this setting was associated with a high rate of complications, particularly when the fracture was managed non-operatively with CI. New low-cost ExFx implant designs and adequate soft-tissue cover (muscle flaps) could help improve treatment of OTFs in developing African countries.

Chapter II : Design and biomechanical study of locally-developed external fixator (LDEF)

2.1. Design of locally-developed external fixators

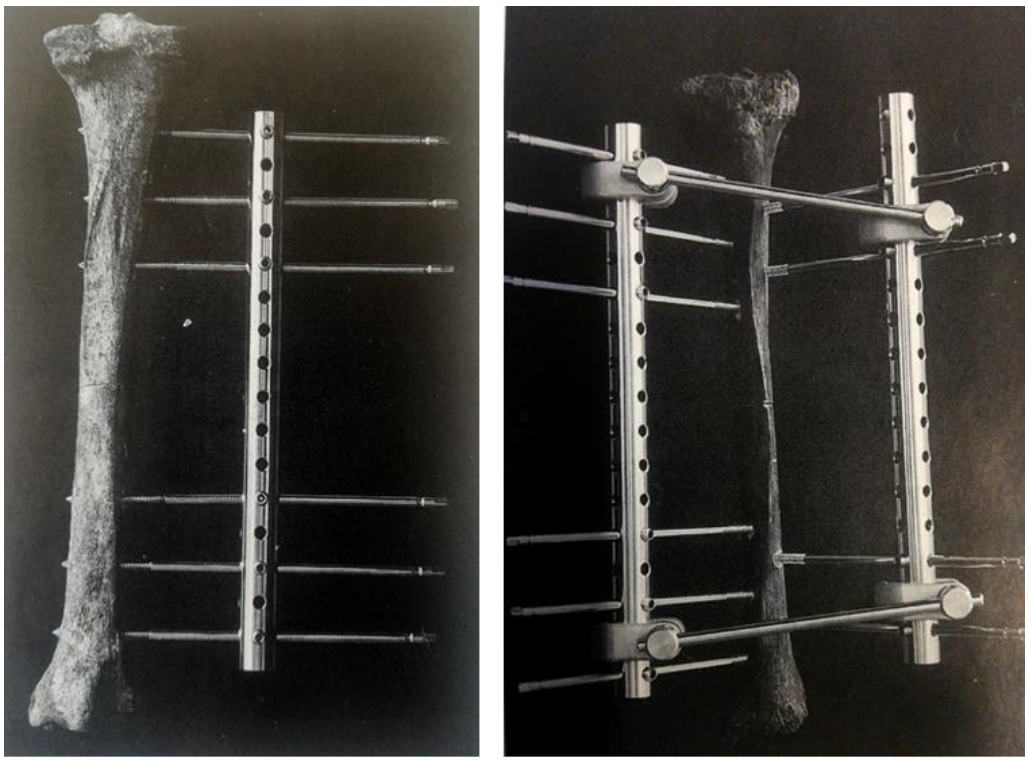
The design of our device was carried out in three stages, including inventory of materials locally available for design, followed by computer-aided design, and, finally, machining of external fixators.

2.1.1 Inventory of locally available materials

The external fixator must be economically and technically affordable with the means available to DCs in general and Ivory Coast in particular. It was, therefore, necessary for us to conduct a preliminary study on the equipment locally available and associated costs. This enabled us to ensure the availability of the materials required for our external fixator and to get a general idea on the pricing of LCEF. Wood was avoided, as its properties also depend on ambient temperature and humidity; moreover, given that wood is not a homogeneous material, its mechanical properties differ greatly from specimen to specimen [49]. We eventually opted for 304L stainless steel, as it is widely available with lower cost compared to 316L stainless steel medical grade. In addition, stainless steel can be sterilized, and it is thus re-usable.

2.1.2 Computer-aided design of LDEF

Computer-aided design (CAD), which is also known as computer-aided design and drafting (CADD), refers to using computer technology for the design process and design documentation[141]. CAD has been applied for designing the guide, in addition to different external fixator types (uniplanar and biplanar). The new fixator design consisted of a unilateral uniplanar external fixator (UUEF 1, UUEF 2) for simple pattern fractures and unilateral biplanar external fixator (UBEF 1, UBEF 2) for complex pattern fractures. UUEF 1, UBEF 1 are based on the Meyrueis's fixator[142] **(Fig. 1)** , which is a stainless steel cylinder tube available in several sizes. The tubes are drilled in two perpendicular planes with 5.2mm diameter threaded holes, spaced 15mm apart. It has several complementary materials allowing the realization of several types of mounts on the bone. It is available for each bone segment (upper and lower limb). Whereas UUEF2 is based on the Noor's fixator [27] **(Fig. 2)**, which is a 14mm diameter galvanised iron tube, 30cm long. Holes of 6mm diameter spaced 2.5mm apart are drilled in the tube, allowing the pins to pass through. This fixture requires some welding in places. It is a unilateral fixator, suitable for diaphyseal fractures of long bones (tibia, femur). The design drawings of the FEDL are in the appendix of the thesis.



a b

Fig.1 Meyrueis's fixator. **a** monoplanar, **b** biplanar.

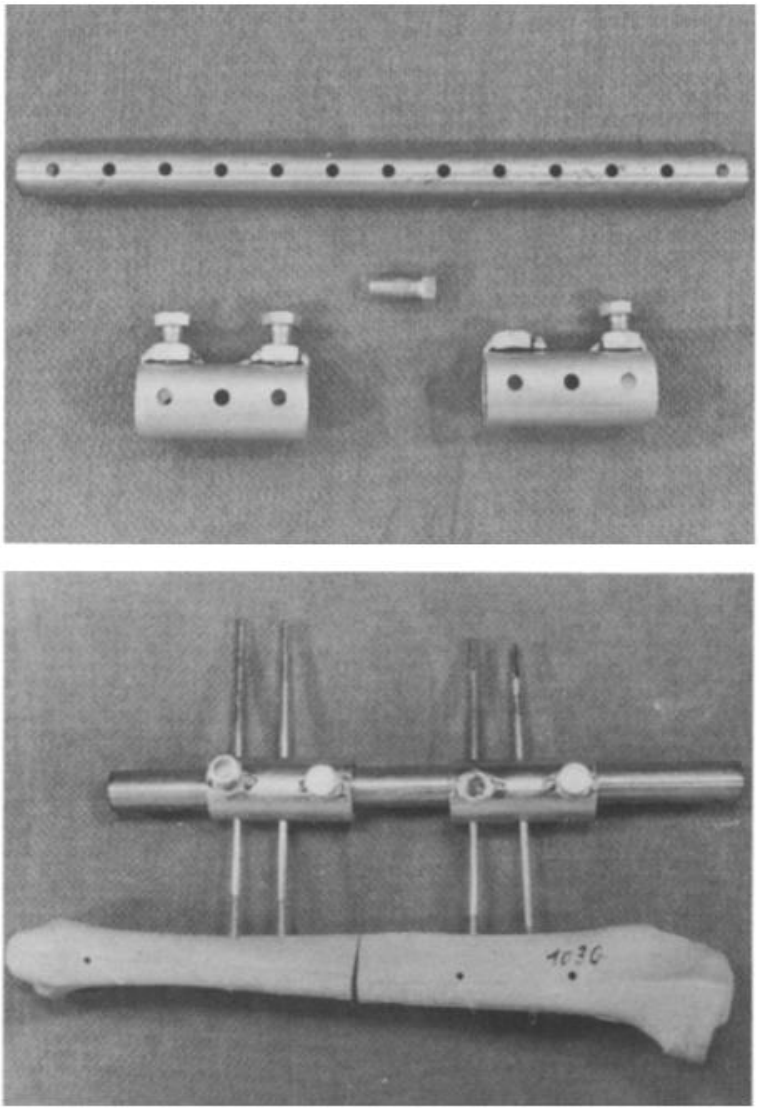


Fig. 2 Noor's fixator

❖ Unilateral uniplanar external fixator (UUEF 1)

The unilateral EF displays parallel pins in one plane with a two-point fixing of pins. The characteristics of the main bar of UUEF1 are shown in **Table 1.** Figure 3 illustrates the computer-aided design of UUEF 1 **(Fig. 3)**.

Table 1: Characteristics of main bar of UUEF 1

Characteristics	Dimension	Justification
Outer diameter (Øout)(mm)	20	available materials
Thickness (T)(mm)	2	
Length (L)(mm)	300	to cover the entire tibial shaft
Distance between holes for pins (D)(mm)	20	easy to machine
Diameter of threaded holes for metric set screws 5	M5	available
Distance between threaded holes (D)(mm)	20	easy to machine

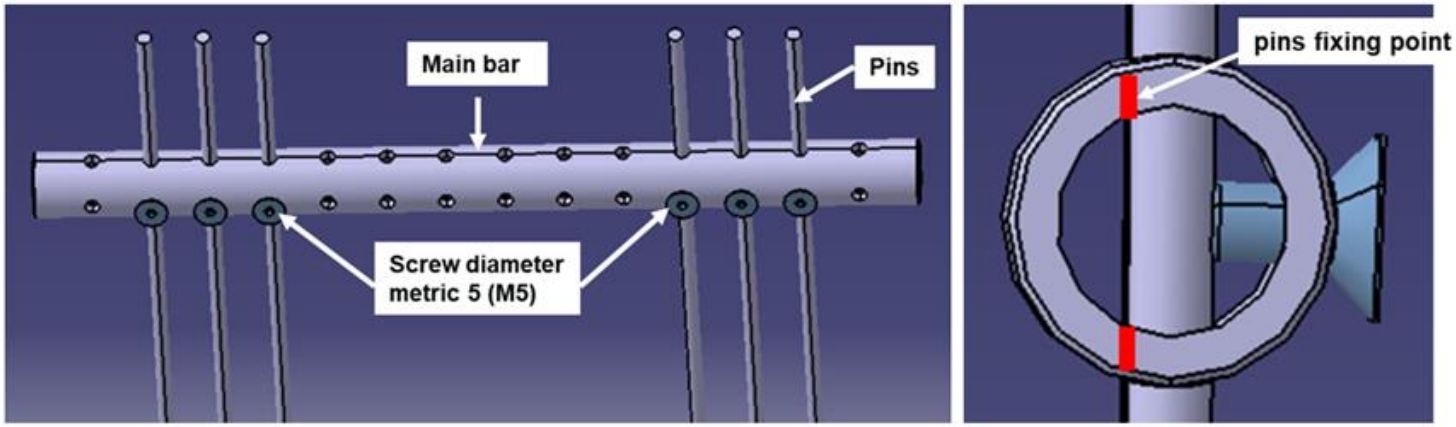


Fig. 3 Illustrates the computer-aided design of UUEF 1

❖ Unilateral uniplanar external fixator (UUEF 2)

The UUFE 2 is characterized by a four-point fixing. The characteristics of the bars of UUEF2 are listed in **Table 2.** Figure 4 illustrates the computer aided design of UUEF 2 **(Fig. 4)**.

Table 1: Characteristics of the bars of UUEF 2

Characteristics	Dimension	Justification
Main bar		
Outer diameter (Øout)(mm)	20	available materials
Thickness (T)(mm)	2	
Length (L)(mm)	300	to cover the entire tibial shaft
Distance between holes for pins (D)(mm)	20	easy to machine
Diameter of threaded holes for metric set screws 5	M5	available
Distance between threaded holes (D)(mm)	20	easy to machine
Outer ring		
Outer diameter (Øout)(mm)	30	available materials
Thickness (T)	3	
Ring length (L)(mm)	60	
Distance between holes for Schanz plugs (D)(mm)	20	easy to machine
Three threaded holes for set screws	M5	

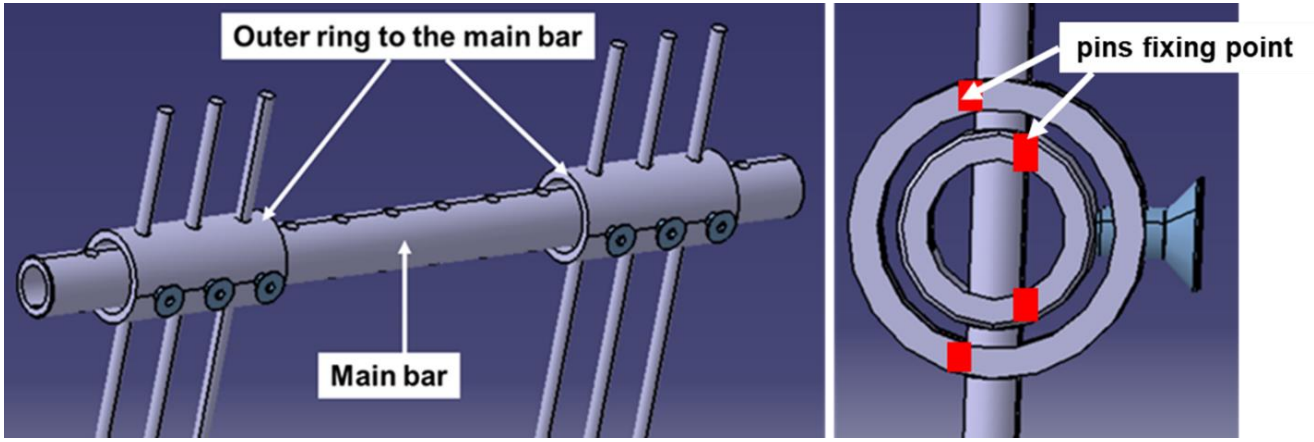


Fig. 4 Illustrates the computer aided design of UUEF 2

❖ Unilateral biplanar external fixator 1 (UBEF 1)

UBEF1 is composed of two full bars, of 6mm in diameter and 70mm in length, which ensure the connection between UUEF1 models through four hollow tubes,13mm in diameter and 40mm in length, which are attached to the four extremities of UUEF 1 hollow tube **(Fig. 5).** UBEF 1 displays less freedom between the intermediate bar and soft parts. This is particularly suitable for open fractures with less soft tissue trauma.

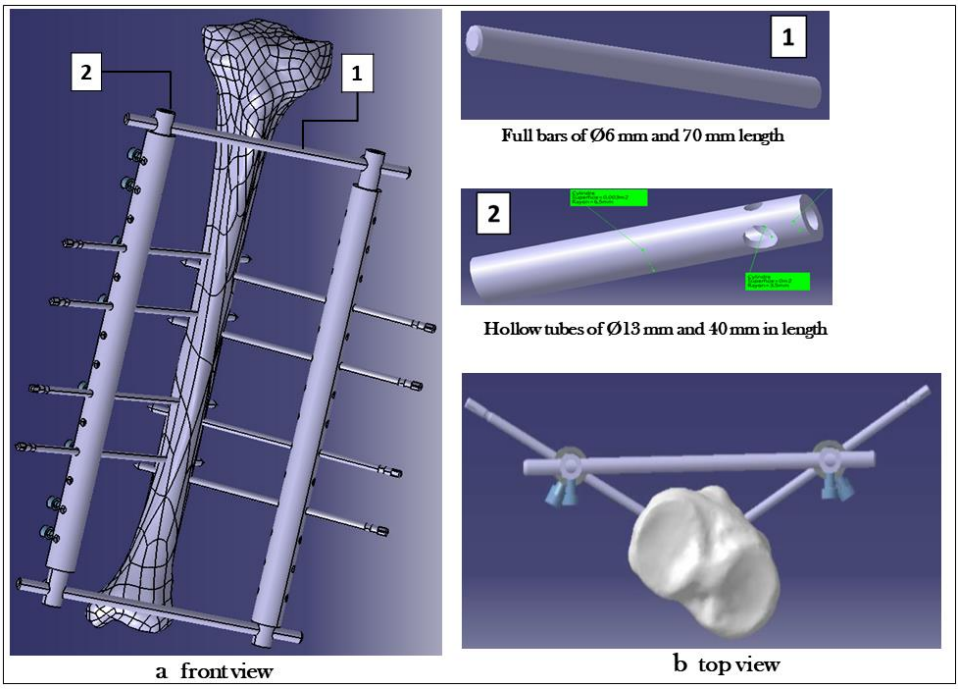


Fig. 5 Illustrate the computer aided design of UBEF 1

❖ Unilateral biplanar external fixator 2 (UBEF 2)

UBEF 2 is similar to UBEF 1 with two intermediate hollow tubes, Ø13 mm in diameter and 30mm in length, which enables a triangular assembly **(Fig. 6).** The UBEF 2 presents a higher degree of freedom due to an additional articulation. This system is suitable for fractures with significant soft tissue lesions.

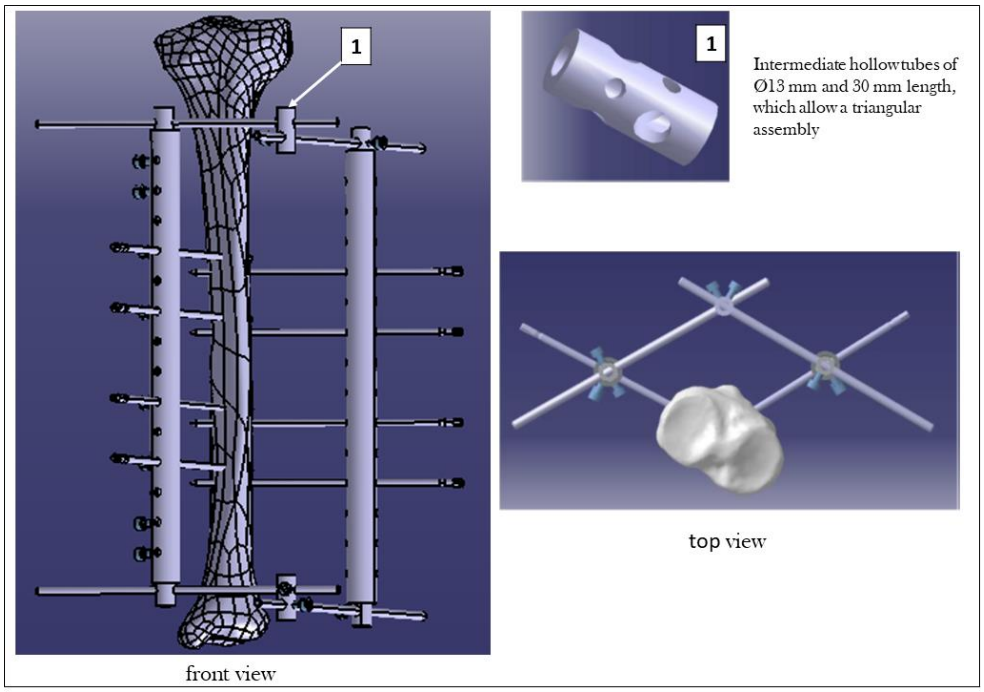


Fig. 6 Illustrate the computer aided design of UBEF 2

❖ The guide

A stainless-steel guide with appropriate characteristics has been designed to perform precision holes in the main LDEF tube.

The guide is fairly straightforward. The 20.5mm diameter (Ø) bore is designed to accommodate an Ø 20mm hollow steel bar, which constitutes the main bar of LDEF. Through Ø 5.2mm holes have been drilled through the guide in order to serve as a guide sleeve for the drill that will pierce the main bar of LDEF. These holes will not be reamed. These holes accept Ø 5mm pins.

On the side, tangent to that of the guide barrels, Ø4.2 mm holes were drilled perpendicular to the Ø5.2 mm holes. These holes also serve as a guide barrel for the Ø4.2mm drill bit. These holes are designed to make threads using manual taps. It is not necessary to perform exit holes for this utility, as the thread of LDEF main bar is only on one side. Thus, unlike the Ø5.2mm holes, these Ø4.2mm holes will not be on each side of the main bar of LDEF.

When the main LDEF bar is inserted into the guide, it will need be blocked so as to prevent it from rotating or translating along its main axis. Therefore, set screws are placed on the unused side of the guide. Three Ø5mm threaded holes, with a distance of 150mm between the holes, were created. One condition of the guide is to guarantee tightening in a vice. We use set screws that are embedded in the guide. Figure 7 illustrates the computer aided design of guide **(Fig. 7)**. The design drawings of the guide are in the appendix of the thesis.

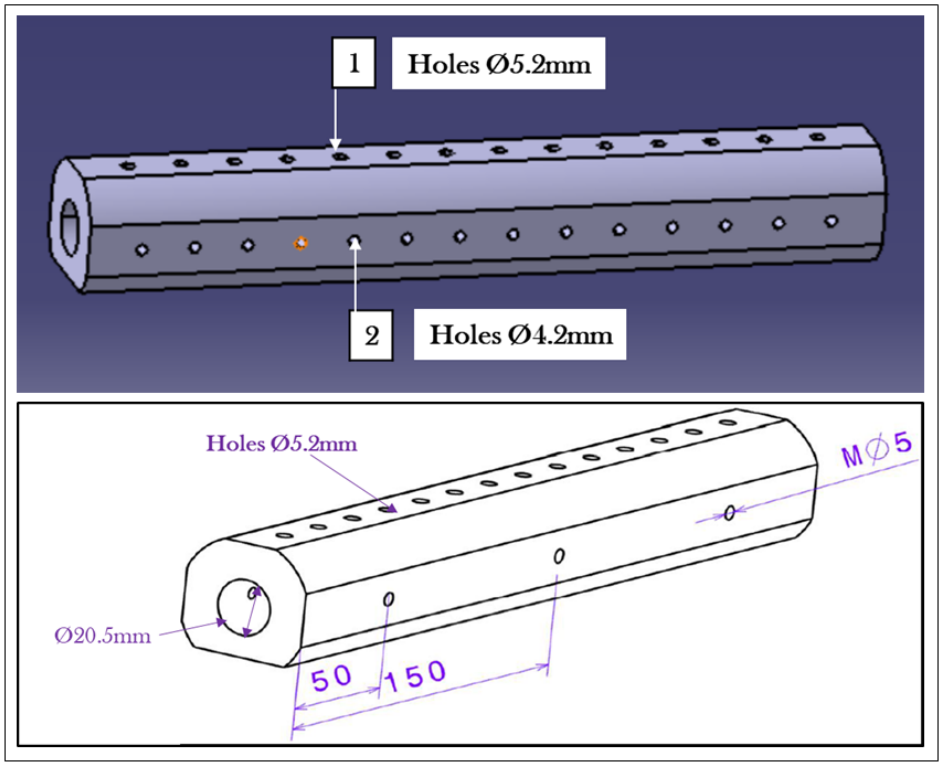


Fig. 7 Illustrates the computer aided design of guide.

2.1.3 Instruments for machining the LDEF

The necessary equipment for designing the LDEF is available, namely:

- The hollow stainless-steel bars 304L (diameter variables)
- Drill bits of variable diameter and size
- Electric drills
- Taps (multiples diameter avaible)
- Solid steel bars of variable diameter
- Manual hacksaws
- 5 metric set screws (M5)

2.1.4 Machining the guide and the LDEF

From the guide, we machined the main bar of the FEDL and proceeded to assemble the different external fixator models **(Figs. 7-11).**

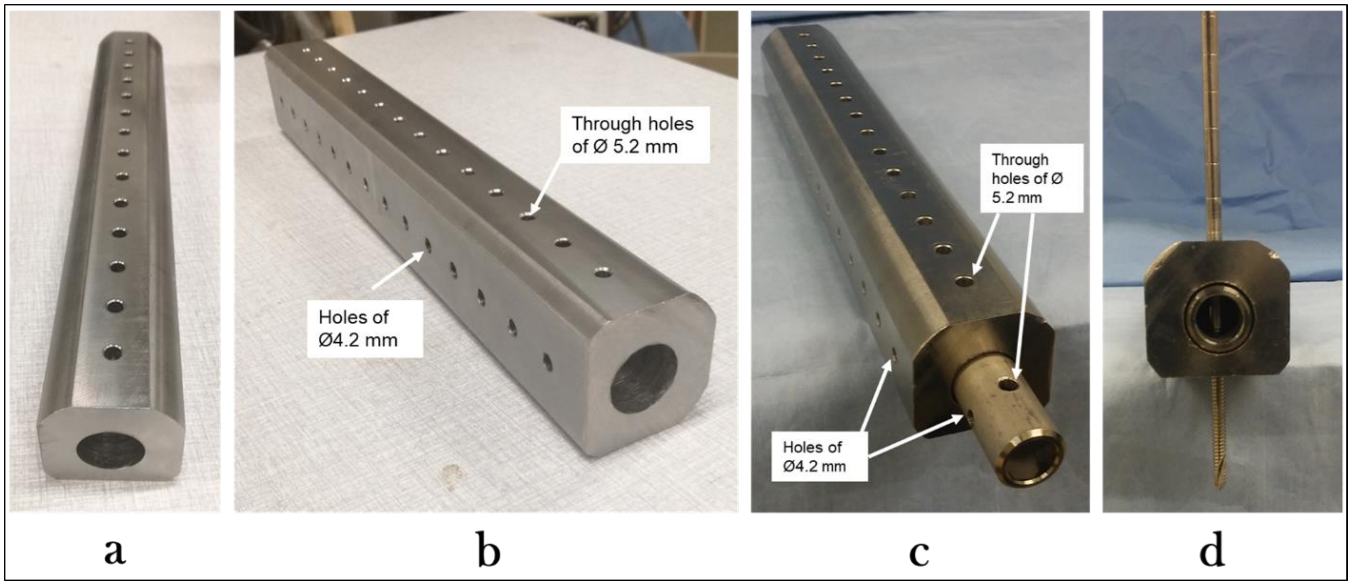


Fig. 7 Guide illustration : **a, b** different parts of the guide, **c** the tube to be inserted into the guide; **d** shows the hole pass through the guide and steel tube.

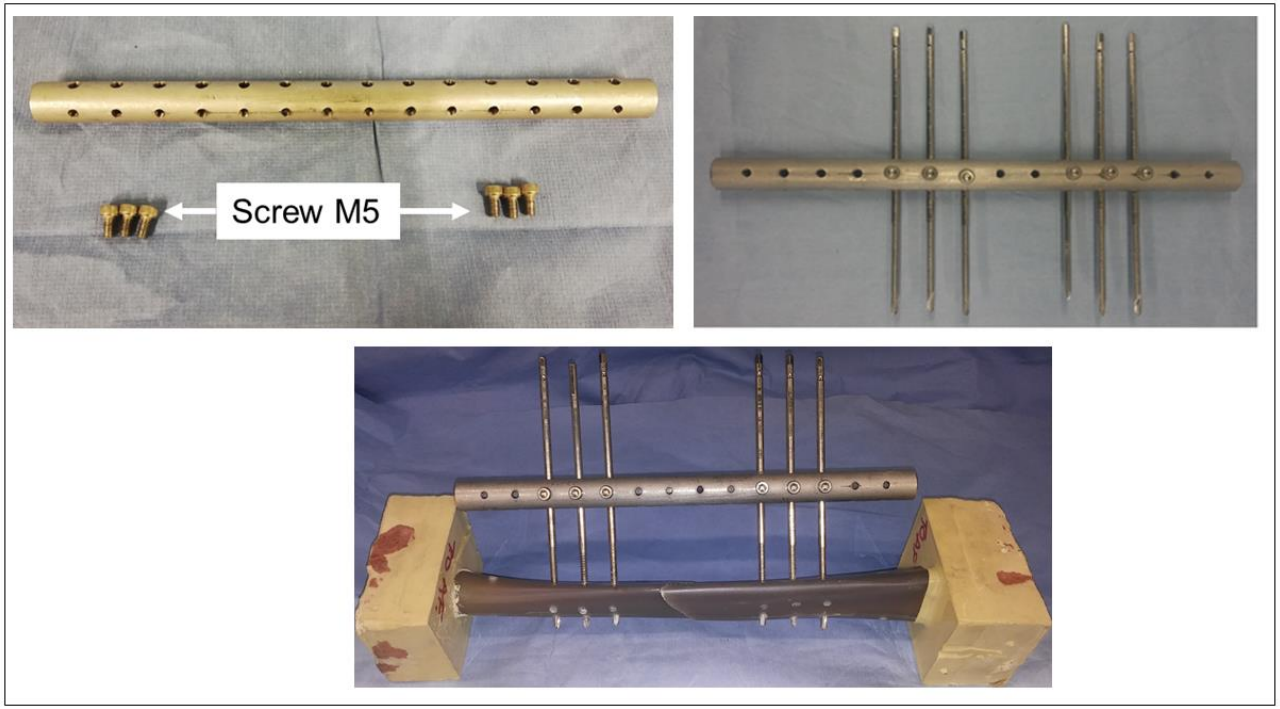


Fig. 8 Illustration of UUEF 1 design

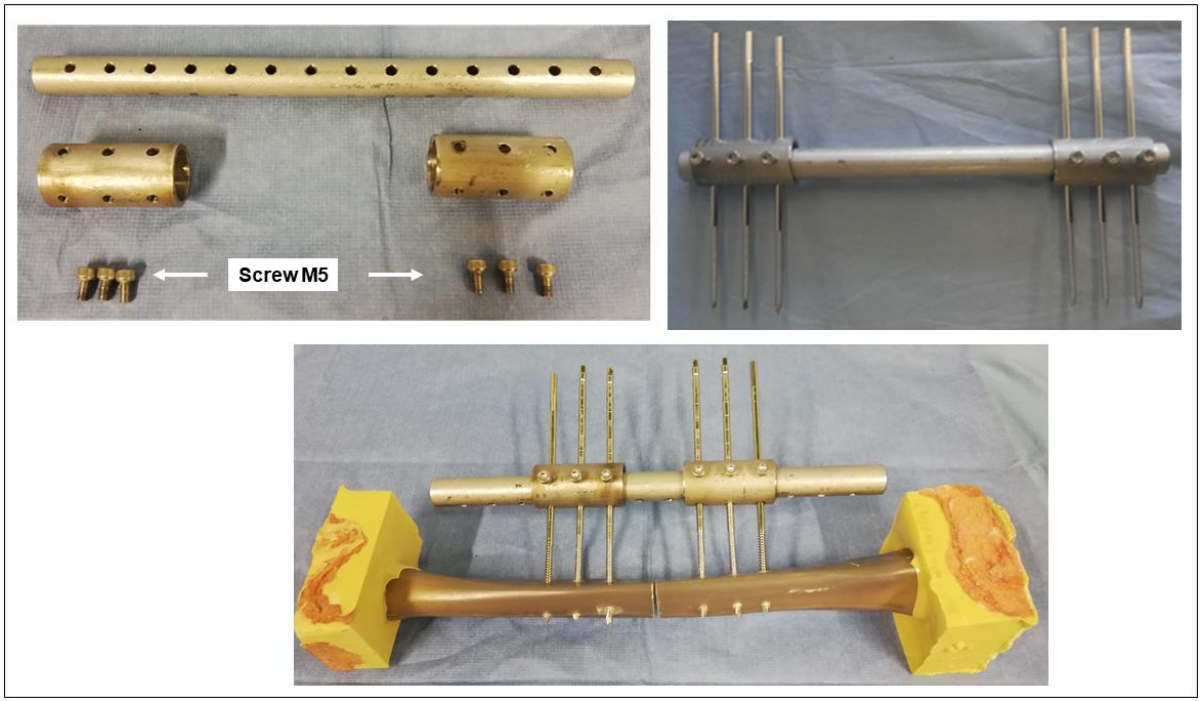


Fig. 9 Illustration of UUEF 2 design

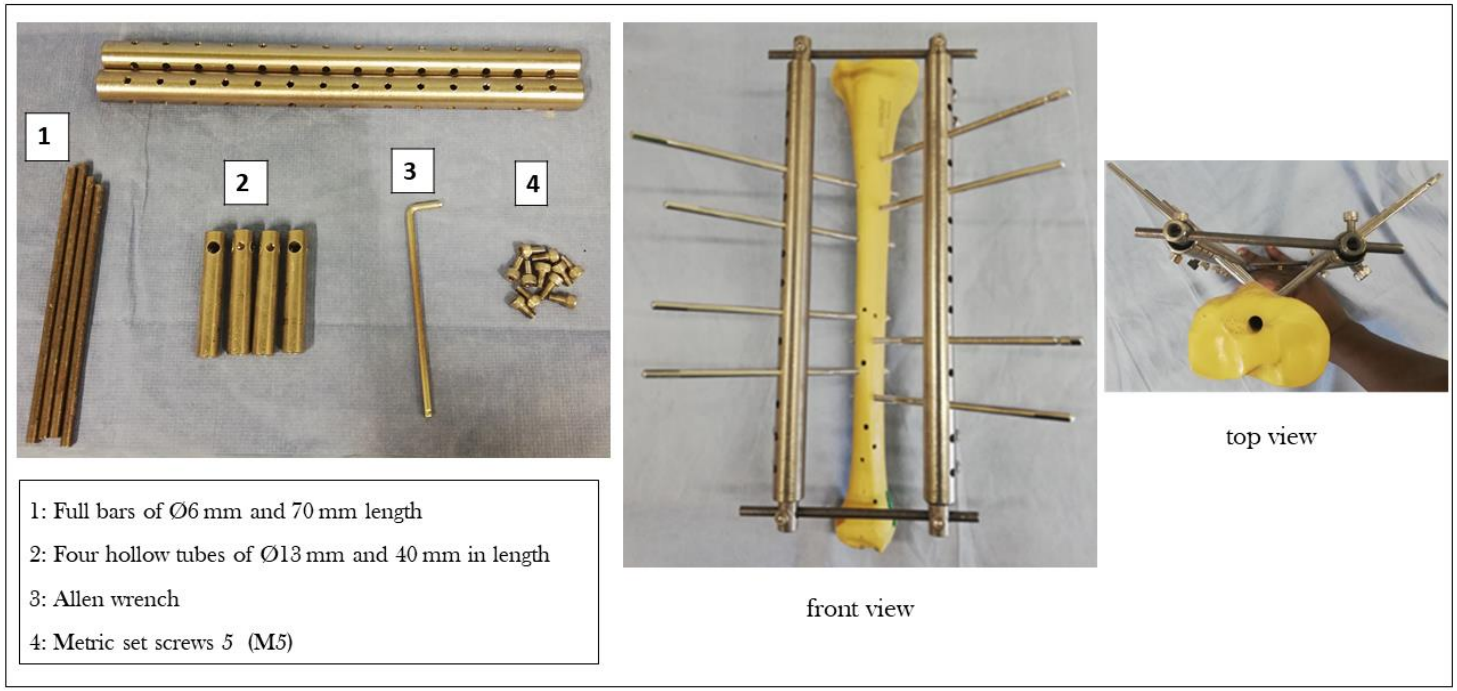


Fig. 10 Illustration of UBEF 1 design

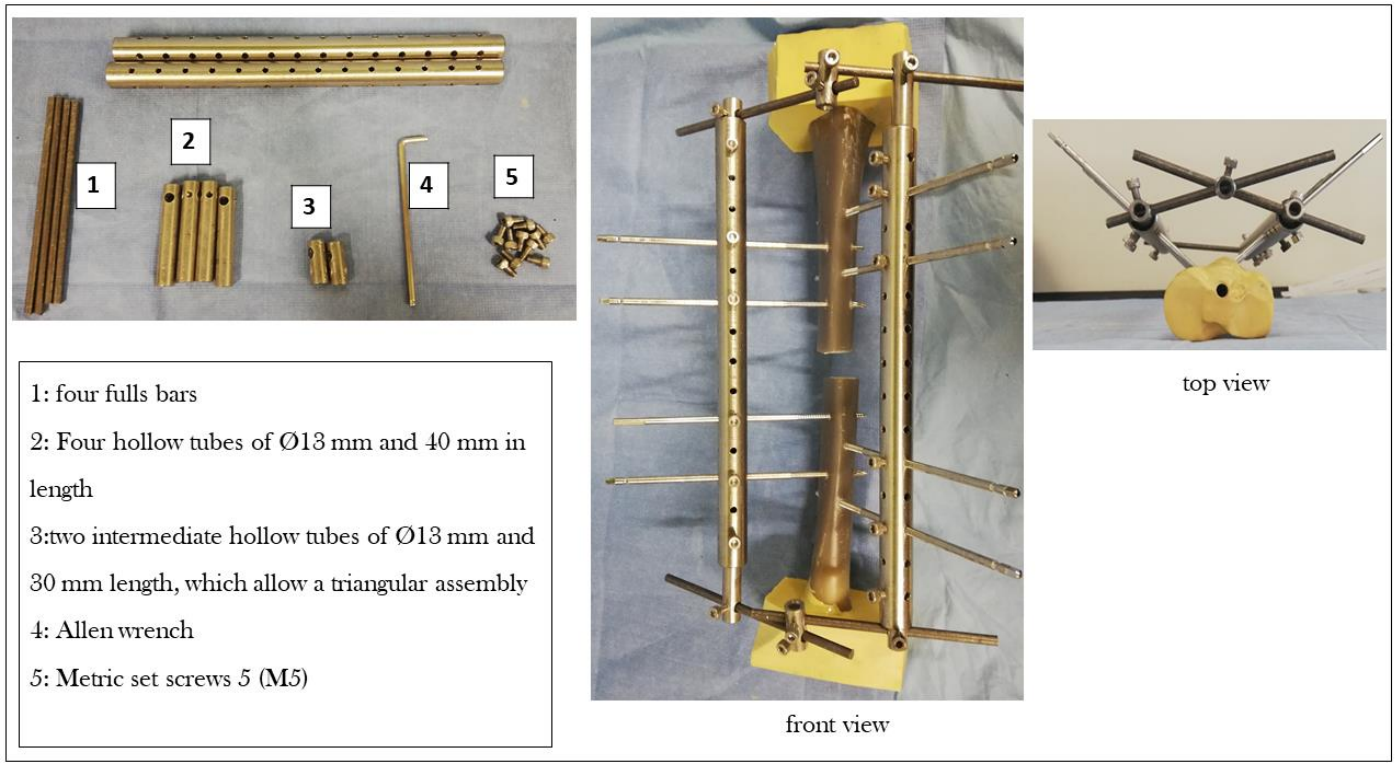


Fig. 11 Illustration of UBEF 2 design

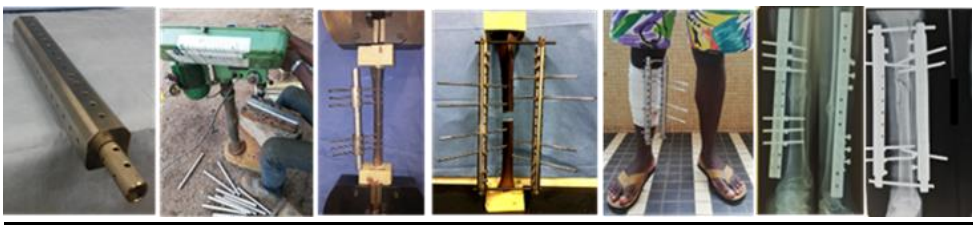
2.2 Article 3

Biomechanical study of a low-cost external fixator for diaphyseal fractures of long bones

Kouamé Jean-Eric Kouassi, Olivier Cartiaux, Loic Fonkoué, Christine Detrembleur, Olivier Cornu

Published in

Journal of Orthopaedic Surgery and Research (2020)15:247



1.1.1 Abstract :

Background: External fixation improves open fracture management in emerging countries. However, sophisticated models are often expensive and unavailable. We assessed the biomechanical properties of a low-cost external fixation system in comparison with the Hoffmann® 3 system, as a reference.

Methods: Transversal, oblique, and comminuted fractures were created in the diaphysis of tibia sawbones. Six external fixators were tested in three modes of loading—axial compression, medio-lateral (ML) bending, and torsion—in order to determine construction stiffness. The fixator construct implies two uniplanar (UUEF1, UUEF2) depending the pin-rods fixation system and two biplanar (UBEF1, UBEF2) designs based on different bar to bar connections. The designed low-cost fixators were compared to a Hoffmann® 3 fixator single rod (H3-SR) and double rod (H3-DR). Twenty-seven constructs were stabilized with UUEF1, UUEF2, and H3-SR (nine constructs each). Nine constructs were stabilized with UBEF1, UBEF2, and H3-DR (three constructs each).

Results: UUEF2 was significantly stiffer than H3-SR ($p < 0.001$) in axial compression for oblique fractures and UUEF1was significantly stiffer than H3-SR ($p = 0.009$) in ML bending for transversal fractures. Both UUEFs were significantly stiffer than H3-SR in axial compression and torsion ($p < 0.05$), and inferior to H3-SR in ML bending, for comminuted fractures. In the same fracture pattern, UBEFs were significantly stiffer than H3-DR ($p = 0.001$) in axial compression and torsion, while only UBEF1 was significantly stiffer than H3-DR in ML bending ($p = 0.013$).

Conclusions: The results demonstrated that the stiffness of the UUEF and UBEF device compares to the reference fixator and may be helpful in maintaining fracture reduction. Fatigue testing and clinical assessment must be conducted to ensure that the objective of bone healing is achievable with such low-cost devices.

Keywords: Biomechanical testing, External fixators, Low-cost, Stiffness

1.1.2 Background

Increasing urbanization and the use of motorcycles in developing countries expose people to high-energy trauma[143]. This is a source of many open lesions of the limbs, particularly in the tibial segment [144]. The generally poor infrastructure and hygiene conditions make it almost impossible to properly treat open fractures using internal osteosynthesis techniques[26]. Thus, the use of external devices provides an opportunity to improve the quality of treatment. There are numerous sophisticated models available on the market, but these are expensive. Many enterprising surgeons have therefore attempted to devise cheaper designs[27]. There is no doubt that these fixators can achieve the same results as those that are more expensive, when used properly [27, 145]. The high costs of commercially available devices present a dilemma to the healthcare industry in poorer countries where there may be patients in need who are unable to afford optimum medical care. One way around this is to reduce the cost of manufacturing a typical fixator so that it is more affordable. This could be brought about by varying the choice of material to make the fixator, the overall product finish, and overall complexity of the design[49]. With all these considerations in mind, the new low-cost external fixators, 304 L stainless steel external fixator (biplanar and unilateral) was specifically designed for the treatment of simple and comminuted patterns. These new designs are intended to provide a biomechanically reliable yet less expensive alternative to currently available devices. The materials used and the tools required are available in almost all developing countries. The construct's stiffness is its decisive factor, as this ensures correct bone alignment under a mechanical load. When used for fracture management, the stiffness should be sufficient to overcome the forces a patient is subjected to during mobilization to prevent

fracture displacement and to avoid nonunion [146]. It is also needed to foster sound callus formation[147]. The aim of this study was to determine the biomechanical characteristics of a low-cost external fixator in comparison with a validated reference fixator.

1.1.3 Methods

Bone and fracture model

Transverse, oblique, and comminuted fractures **(Fig. 1)** were created in large-sized, left tibia, synthetic composite bones (model #3402, Sawbones; Pacific Research Laboratories Inc., Vashon, Washington) using a handle saw [148, 149]. The transverse, oblique, and comminuted fractures were set by a unilateral uniplanar external fixator. The biplanar external fixator was only tested in the setting of a comminuted fracture. Twenty-seven constructs were stabilized with uniplanar external fixator (nine constructs each). Nine constructs were stabilized with biplanar external fixator (three constructs each).

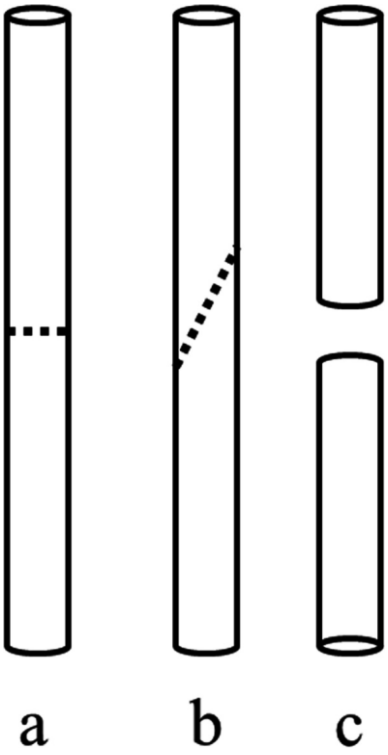


Fig. 1 Different types of fractures. **a** Transversal fracture. **b** Oblique fracture. **c** Comminuted fracture

Investigated fixators

The Hoffmann® 3 (H3) fixator (Stryker Trauma AG, Selzach, Switzerland), with a single rod (H3-SR) of 11mm diameter **(Fig. 2f)** and a double rod (H3-DR) of 11mm diameter [136]**(Fig. 2e),** was used as a reference and compared to the low-cost designed external fixators. The new fixator design consisted of a unilateral uniplanar external fixator (UUEF1, UUEF2) **(Figs. 2a and b)** and unilateral biplanar external fixator (UBEF1, UBEF2) **(Figs. 2c and d)**.

UUEF1 is based on Meyrueis's fixator **(Figs. 2a and 3)**[142] and UUEF2 is based on Noor's fixator **(Figs. 2b and 3)** [27].

UUEF1 is made of a 304-L stainless steel cylindrical tube. The standard tube has a gauge of 20 mm, a thickness of 3 mm, and a length of 300 mm. The tube is drilled into a perpendicular plane, with holes passing 5.2 mm in diameter, spaced 20mm apart. The holes accept all types of pins that have a diameter ≤ 5mm **(Fig. 2a)**. Threaded holes are perpendicular to those of the pins, which also accept hexagonal and flat-bottom screws that secure the tube/pins. For UUEF2, the fixation between the pins and the tube connection is ensured by two cylindrical external rings made of stainless steel, with an external diameter of 30 mm, a thickness of 3 mm, and a length of 60 mm. They are composed of three through-holes of 5.2mm diameter, spaced 20mm apart for the pins. Five-millimeter diameter thread screws (M5) secure the tube/pins.

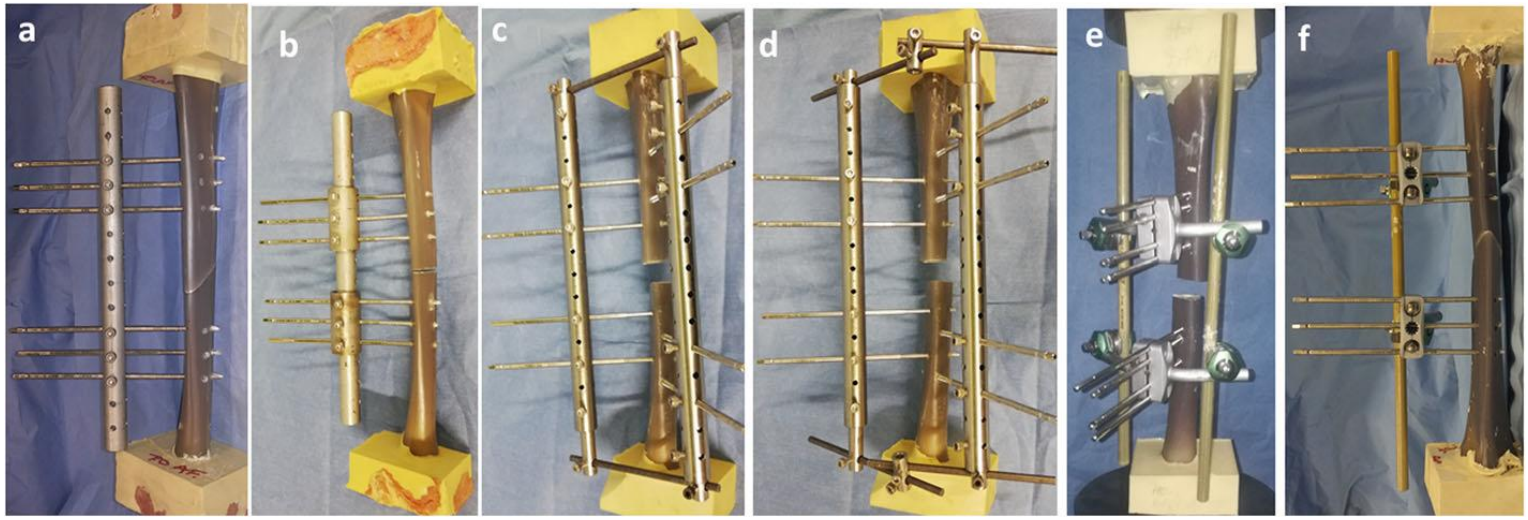


Fig. 2 The new fixator design. a UUEF1. b UUEF2. c UBEF1. d UBEF2. e H3-DR. f. H3-SR

UBEF1 is composed of two full bars of 6mm diameter and 70mm length, which ensure the connection between the UUEF1 models through four hollow tubes of 13mm diameter and 40mm in length that are attached to the four extremities of the hollow tube of UUEF1 (Figs. 2c and 4). UBEF2 is the same as UBEF1, with two intermediate hollow tubes of 13mm diameter and 30 mm length, which allow a triangular assembly (Figs. 2d and 4).

Positioning

Six external fixation frames were tested. Pins of 5 mm in diameter and 180mm in length, with a 50-mm threaded portion, were used for all tests[49, 147]. Three pins were fixed in each bony fragment for UUEF and H3-SR **(Fig. 3),** while four pins were used for UBEF and H3-DR. The distance between the bone and rod was 50mm [136], and the distance between the closest pin from the fracture site was 30 mm. Parameters that were kept constant between the different types of fixators were as follows: (1) diameter of pins, (2) number of pins used in each bony fragment, and (3) distance between bone and longitudinal rod (bone-rod distance) **(Figs. 3 and 4).**

Loading modes and test

For mechanical testing, the distal and proximal ends of the sawbones were embedded in molds. All specimens were positioned vertically with a central wood at the bottom of the molds so that the medullary axis fits into the wood. The axis of alignment was controlled with the longitudinal axis of the diaphysis. The molds were filled with polyurethane. The mechanical tests and load conditions were based on the American Society for Testing and Materials (ASTM) standard methods [64].

The stiffness of each fixator was measured in three loading modes: axial compression, mediolateral (ML) bending, and torsion **(Fig. *5*).** The axial compression and ML bending tests were performed using a tension compression machine (Zwick Roell, type BZ2 MM480xx.EC01, Germany, featuring a maximum 200 kN load cell). Stiffness was computed from the slope of the load-strain curve (N/mm). Each experiment was repeated five times for the three loading modes, after which the averages were computed. For axial compression, each assembly was placed into the machine vertically. Then, a maximum load of 700 N was applied for UUEF and H3-SR, which corresponds to the weight of a 70-kg adult person[150], and a maximum load of 2100 N was applied for UBEF and H3-DR, which corresponds to three times the weight of a 70-kg adult person walking with two crutches. In a pilot study, the static load to failure was determined to be in excess of 2100N. Hence, an axial load of up to 2100N was chosen. In the bending test, the maximum load was such that a maximum deflection of 7mm for UUEF and 10mm for UBEF was produced at the fracture site, with a speed of 3 mm min^{-1}. For the torque tests, the proximal part of the bone was clamped, and several static torques were applied to the distal part. The maximal torque allowed was 6 Nm. A test indicator dial allowed measurement of the angular deflection at each torque. Torsional stiffness was determined as the average slope of the torque-rotation curve and was expressed in Nm $degree^{-1}$

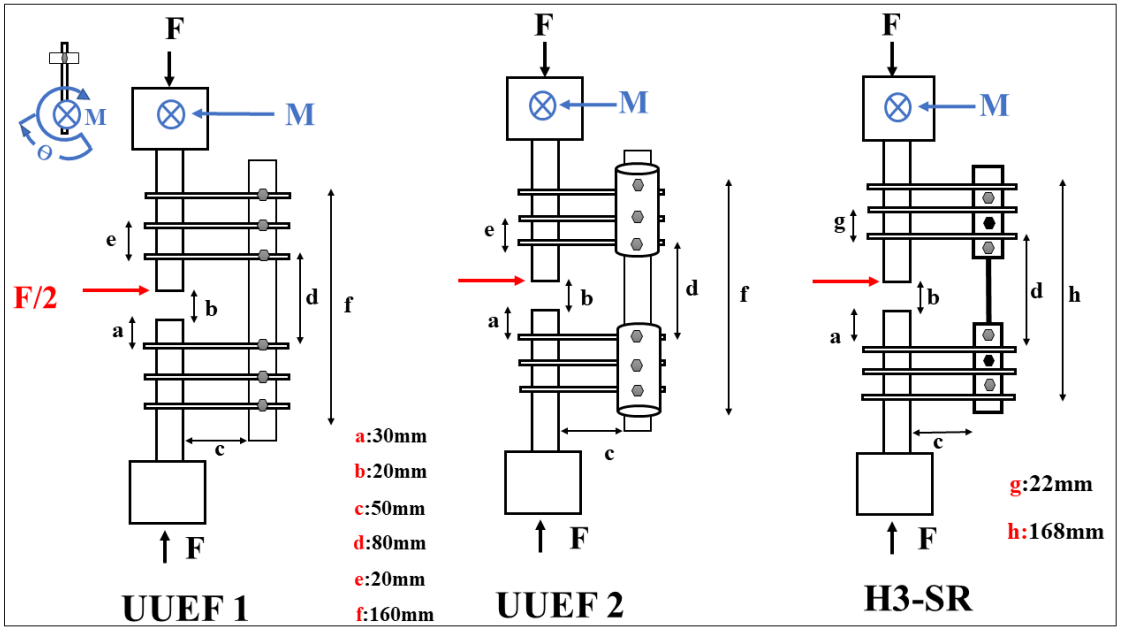


Fig. 3 Schematic representations of the external fixator design according to Annex 7 of ASTM F1541-17: F compression force, F/2bending force, M moment

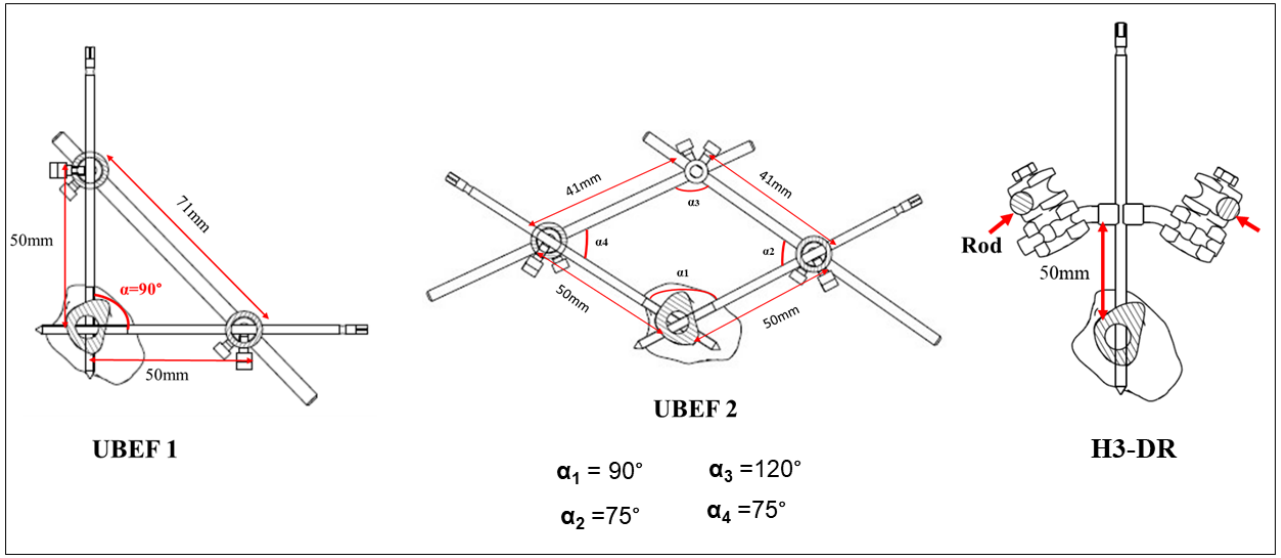


Fig. 4 Schematic representation of unilateral biplanar external fixation

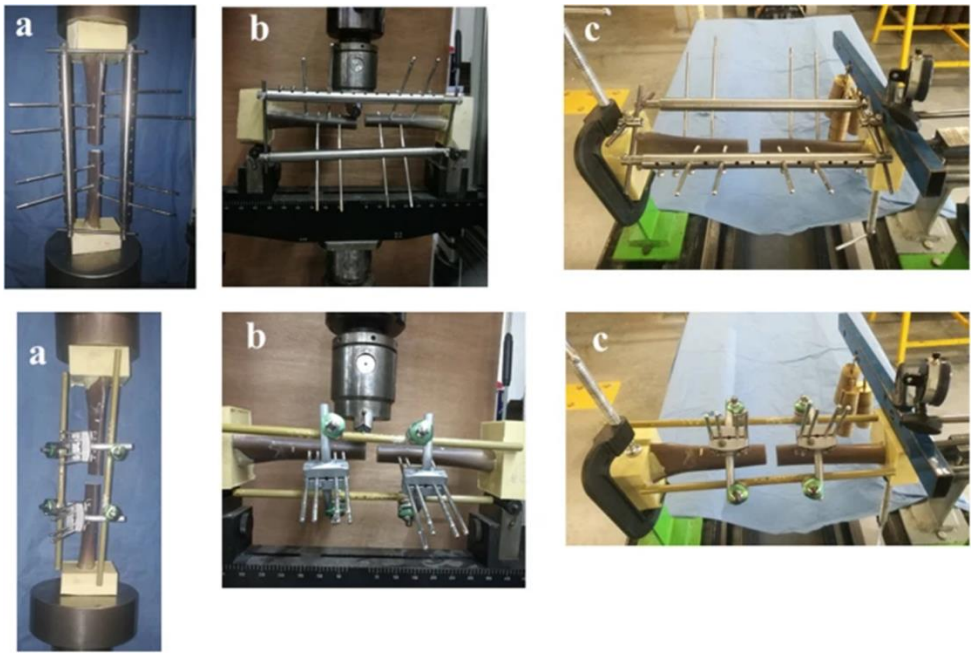


Fig. 5 Assembly characteristics and test setup. a Compression test. b Mediolateral bending test. c Torsional test

Statistics

Statistical analysis was performed using SigmaPlot version 13. We performed a one-way analysis of variance to compare the parametric data (mean ± standard deviation [SD]) of the three fixators' differences in axial stiffness, ML bending, and torsional stiffness. A Kruskal-Wallis. one-way analysis of variance on ranks was used to compare the nonparametric data (median [quartiles]). Post hoc testing was performed using the Tukey test. A level of significance of $p < 0.05$ was used as the threshold for statistical significance.

1.1.4 Results

Both UUEF models compared favorably to the H3-SR in oblique and transverse fracture patterns **(Table 1)**. UUEF stiffness was equivalent or superior to that of H3-SR. With regard to comminuted fractures, there was a significant difference between the three fixators ($p<0.05$) in the three loading modes. A post hoc Tukey test revealed that both UUEFs were stiffer than H3-SR in axial compression and torsion. However, H3-SR was stiffer than both UUEFs in ML bending. Stiffness in axial compression and torsion for both UBEFs was higher than that for H3-DR **(Table 2)**. UBEF1 was stiffer than H3-DR in ML bending ($p=0.013$). There was a significant difference between the three fixators ($p<0.05$) in the three loading modes. A post hoc Tukey test revealed that the UBEF was stiffer than H3-DR ($p=0.001$) in axial compression and torsion. UBEF1 was stiffer than H3-DR in ML bending ($p=0.013$).

Table 1 : ANOVA results (mean±SD) or median [1st-3rd quartiles] of stiffness after oblique, transversal and comminuted fractures

Type of configuration	UUEF1	UUEF2	H3-SR	*P value*	UUEF1 vs. UUEF2	UUEF1 vs. H3-SR	UUEF2 vs H3-SR
					P value	*P value*	*P value*
Oblique fracture							
Axial stiffness N mm^{-1}	78.3± 5.1	119.7±16.8	67.2±8.1	<0.001	<0.001	0.3	<0.001
ML bending stiffness N mm^{-1}	6.2[5.9-6.3]	8.5[7.8-9.2]	7.4[7.4-7.5]	0.004	0.02	0.3	0.3
Torsional stiffness Nm $degree^{-1}$	1.6[1.4-2.0]	1.5[1.4-2.0]	0.9[0.8-1.3]	0.05	0.8	0.06	0.17

Transversal fracture							
Axial stiffness N mm^{-1}	1260.1±63.0	1240.1±139.8	1326.2±141.4	0.516	-	-	-
ML bending stiffness N mm^{-1}	7.9±0.4	6.0±0.4	5.5±0.9	0.009	0.027	0.009	0.6
Torsional stiffness Nm $degree^{-1}$	1.8±0.3	1.8±0.2	1.4±0.3	0.21	-	-	-
Comminuted fracture							
Axial stiffness N mm^{-1}	48.9±3.4	71.8±2.2	35.0±2.1	<0.001	<0.001	<0.001	<0.001
ML bending stiffness N mm^{-1}	4.4±0.0	4.7±0.3	6.5±0.1	<0.001	0.2	<0.001	<0.001
Torsional stiffness Nm $degree^{-1}$	1.8±0.4	1.6±0.2	0.8±0.1	0.016	0.7	0.017	0.042

Table 2 : ANOVA results (mean±SD) of stiffness after comminuted fracture

Type of configuration	UBEF1	UBEF2	H3-DR	*P value*	UBEF1 vs UBEF2 *P value*	UBEF1 vs H3-DR *P value*	UBEF2 vs H3-DR *P value*
Axial stiffness N mm^{-1}	234.7±11.7	228.2±10.2	98.8±4.0	<0.001	0.53	<0.001	<0.001
ML bending stiffness N mm^{-1}	62.2±17.1	48.3±15.7	15.2±1.2	0.013	0.4	0.012	0.054
Torsional stiffness Nm $degree^{-1}$	1.5±0.16	1.6±0.04	1.0 ± 0.01	<0.001	0.8	0.001	<0.001

1.1.5 Discussion

Our study was designed to assess the biomechanical properties of UUEF and UBEF frames in a simple and comminuted tibia shaft fracture model. The results indicate that the mechanical behavior of both UUEF and UBEF compared favorably to the reference fixator. UBEF1 stiffness was superior for the comminuted fracture pattern in ML bending. The treatment of long bone fractures with low-cost external fixators has been reported several times in the literature[27, 49, 102, 151]. Nevertheless, few have been looking into the mechanical properties of their device, prior to clinical use. Goh et al. [49] have previously analyzed the different biomechanical aspects of the simple and low-cost external fixators (AG) compared to the commercially available AO external fixators. The results showed that no significant differences were found in the stiffness of AG and AO fixators under all loading modes. Their mechanical properties appear superior to our uniplanar design but do not significantly differ from our biplanar design. An external fixation device is also characterized by its simplicity and versatility of application, its ability to minimize soft-tissue damage, its stability at the bonescrew interface[61], its rigidity [152], and its costeffectiveness[27]. Our frame designs do not need welding as the AG fixator needs. The biplanar frame design offers also more versatility and stability than the AG with pins' insertion in two planes[61]. However, assessing the overall effective performance of a low-cost external fixator must consider more than just stiffness[49]. In addition to these fundamental requirements [6, 8], the external fixator must be inexpensive[27]. These constructs should also be compatible with patient care and allow the recovery of the softtissue envelope[153]. Ideal external fixation systems should be rigid enough to promote fracture healing without secondary loss of

reduction, when used as a definitive treatment[147, 154]. Although the Hoffmann® 3 fixator provides excellent versatility [147] and good biomechanical properties [136], its high cost limits its use in developing countries [155]. The development of the callus plays an important rôle in total fixation system rigidity. Callus with minimal elastic characteristics causes some important variations in the load transmission pattern at the bone-callus external fixator structure. A highly rigid external fixator would avoid some micromovements at early consolidation stages but would not prevent load transmission through the callus when this callus appears [156, 157]. However, excessive interfragmentary movement, due to insufficient stiffness of external fixators, can result in deficient callus formation, eventually leading to delayed union or even nonunion with ultimate implant failure[150]. Our external fixators have demonstrated sufficient stiffness. Nevertheless, the correct assessment of callus formation and bone healing has still to be done in an animal fracture model or along a prospective clinical study. However, this study has limitations. The absence of a soft-tissue envelope, including muscle compartments and the bony pin interface, can influence biomechanical behavior after limb reduction. The influence of the distance between the bone and the rod, as well as the distance between the closest pin and the fracture site, has not been evaluated. These parameters were made constant to primarily evaluate the different construct configurations and their stiffness properties. For this study, synthetic bone was used instead of cadaver tibias to eliminate variations in geometry.

Synthetic bones are considered to have similar structural and mechanical properties as natural bones and thus are close to ideal replicas for standardization in biomechanical analyses [158]. The testing procedure closely followed the ASTM standard methods [64] . This ensured reproducibility and complied with the standard biomechanical testing of external fixators. The force that we applied was around 1% of the maximal force of the 200 kN load cell. The Zwick Roell load cell was tested and calibrated according to ISO 7500-1 standard. For the order of force magnitude we applied, the maximum error for the force was less than 1%. The displacement accuracy was about 2 μm. Although an increase in stiffness could be provided by increasing the number of pins in any one segment from two to three, the added benefit of increasing the number of pins from three to four is minimal [159] Shahid et al.[146] reported that using two bars increases the axial compressive stiffness of the fixator by a factor of two. In our model, we observed an increase by three in the comminuted fracture pattern. Comparison with a reference fixator as the Hoffman 3 was preferred instead of a comparison to another locally developed external fixator or to the Ilizarov design. The objective was to offer similar mechanical properties as what is standardly used in developed countries. Comparison with an Ilizarov system is not appropriate from a mechanical perspective and the use of such device is more complex to handle, partially due to the soft-tissue transfixation, and needs more devices. UBEF is a system that does not transfixate the anterolateral compartment of the leg, which can achieve very good rigidity [160]. It is a good external fixator system for the treatment of comminuted leg fractures. We postulate that UUEF and UBEF could solve many problems, as they are inexpensive, easy to use, and suitable for both simple and complex fractures. External fixators have been selected as osteosynthesis devices for the treatment of open tibial fractures and certain

closed tibial fractures with severe injury to soft tissue[150]. External fixation devices provide a promising and satisfactory alternative for better soft tissue care and for preserving periosteal perfusion to the regions of fracture[149], and they can be implemented both in the provisional and definitive treatment of tibial fractures[148]. All parts of this device, except the pins, can be manufactured in a poor country at a very low cost. They are very cost-effective, except for the Schanz screws. A first economical assessment in Ivory Coast estimates the costs of the frame (without pins) to be the third (9 euros) of a cast immobilization (26 euros) for a tibia fracture. In less economically developed countries where there is poor healthcare, and many patients are unable to afford optimum medical treatment, such a trade-off may be valuable as a cheaper external fixator that provides simple basic fixation is better than no treatment at all [49]. The frame cost could be also reduced if it was validated to be reusable. Nevertheless, our study does not include fatigue testing and therefore we cannot insure the fatigue properties of our constructs nor its reusability. Indeed, the plastic deformation exhibited by steel at high loads could alter the biomechanics of the fracture site and potentially affect the healing process[161]. Complementary mechanical testing or clinical studies should address this matter. Medical devices are subject to specific regulations in many (most) countries. The fact that materials and device can be sourced locally and produced does not mean that it will be used without proper clinical assessment and certification in many countries. The frame should also be cleaned, decontaminated, and steam sterilized before use. Some more costs might therefore be expected.

Conclusions

The low-cost external fixators showed good stiffness properties. They appear suitable for the treatment of both simple and comminuted fractures. They could constitute an alternative to the reference external fixators that are currently sold in the market. However, a fatigue mechanical study and a clinical study are needed to determine their reusability and their ability to promote the bone healing of a fracture.

2.3. Article 4

Fatigue property study of locally-developed external fixators for diaphyseal fractures of long bones

Kouamé Jean-Eric Kouassi, Catherine Doneux, Quentin Mestrez, Alex Bertholet, Loïc Fonkoue, Christine Detrembleur, and Olivier Cornu

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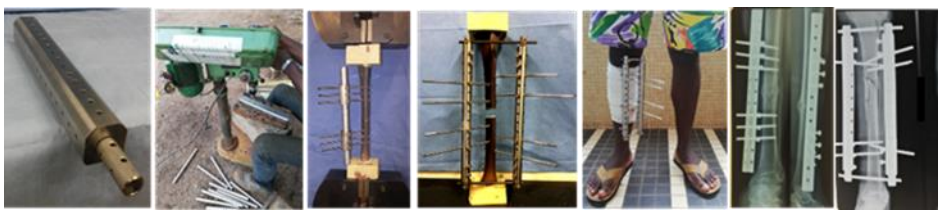


1.1.1 Abstract

Background: Fatigue failures of external fixators occur because of the loosening or wear of components under long-term cyclic loading, which can lead to variable interfragmentary displacement and impairment of fracture stability.

Methods: Two composite models of tibial bone with a diaphyseal space of 20mm were studied. They were stabilized using a locally developed external fixator (LDEF). A cyclic load in axial compression (1050N) at a 5Hz frequency was applied to the devices. The test was carried out until either failure (rupture of the implant) or end of 300.000 cycles. A four points bending test was further performed with an equivalent load to obtain a deformation equivalent to the maximum measured during the static loading. The objective was to replace the test on a real configuration with an equivalent test, which would enable us to test the fixator in fatigue with a load that was almost equivalent to the real load, but without pins. The models were further assessed for mechanical integrity and ability to obtain bone healing in a clinical series of 40 patients with an open tibia fracture.

Results: A breakage of the fixator pins was observed around 90.000 cycles in axial compression. The external fixator frame successfully completed the 300.000 cycles and 1.000.000cycles, without any implant rupture or deformation that was equivalent to clinical complications with the four points bending test. No pins breakage neither fixator disruption was reported in the clinical assay. Union was obtained in 90% of the cases after 8.5 months.

Conclusion: This study showed that the pins used in external fixator systems exhibit a relatively short fatigue life under high load conditions. The absence of pin breakage in the clinical setting might be explain by a lower load after

fracture reduction and a more progressive transfer of the load to the bone callus. It can be concluded that LDEF displays good stability and can be reused. However, some fixation components need to be inspected and replaced, especially concerning the pins.

Keywords: biomechanical testing, external fixators, fatigue, Euler-Bernoulli

1.1.2 Introduction

External fixators (EF) are currently used for temporary or definite osteosynthesis of open tibial fractures and closed tibial fractures with severe soft tissue injuries [152]. They offer mechanical stability, enhance a biological stimulus for fracture healing, and preserve limb function and blood supply with minimal operative traumas [149, 152].The geometric design of these devices has crucial effects on their mechanical performance, which, in turn, has a high impact on the efficient or deficient repair of a fracture. This impact is mainly characterized by two mechanical properties including stiffness and stability [162, 163]. EF must be strong enough to withstand high tibia loads, which cause either failure through deformation (plastic failure) or slip (slip failure); in addition, they must be durable enough to withstand repetitive loads that cause fatigue (fatigue failure), through loosening or wear, which affects fracture stability [164]. Recently, new external fixators have been locally-developed with good frame rigidity [165]. However, sufficient fatigue performance has not yet been achieved so as to guarantee its stability in clinical applications and when reusing the device.

The current study using a biomechanical model was designed to investigate the fatigue behavior of the locally-developed external fixators (LDEF) frame under bending conditions or combined bending-compression loading. A clinical assay was further conducted.

1.1.3 Methods

Large-sized left tibia synthetic composite bone models #3402 were employed in this biomechanical study [166]. A standardized midshaft osteotomy by means of an oscillating saw was performed on a tibia bone so as to create a 20mm fracture gap [136], which was measured with a vernier caliper, with the aim to simulate a comminuted tibial shaft fracture and ensure no contact between both ends of the fracture [150]. Each construct was potted proximally and distally in a pair of loading fixtures, using polymethylmethacrylate [150]. The tibia synthetic composite bone model was stabilized by means of a locally-developed external fixator (LDEF) [165](**Fig. 1a**).The fixator design consisted of a unilateral biplanar external fixator with the frame made of a 304L stainless steel cylindrical tube. The standard tube displays a gauge of 20mm, thickness of 3mm, and length of 300mm. The tube was drilled into a perpendicular plane, with holes passing 5.2mm in diameter and spaced 20mm apart. These holes accept all types of pins that exhibit a diameter ≤5mm. Threaded holes are perpendicular to those of the pins, which similalry accept hexagonal and flat-bottom screws that secure the tube/pins. To constitute a biplanar model, two full bars, 6mm in diameter, ensure the connection between both main cylindrical tubes through four hollow tubes, 13mm in diameter and 40mm in length, which are attached to the four extremities of the main tubes. Five-millimeter diameter thread screws (M5) secure the tube/tube and bar/tube fixations.

For each bone substitute, four Ø 5.0 mm stainless steel apex pins were inserted into each bone segment, the segment being any substantial part created by the fracture. Therefore, a simple transverse fracture has two segments.The distance between connecting bar from bone was 40mm [61, 136], while the distance between the closest pin was 20mm from the fracture site **(Fig. 1b).**The hereafter described configurations were assembled keeping a 20mm simulated fracture gap that allowed for an interfragmentary movement when under stress. All the screws where tightened with a moment of 4 Newton (N) using a calibrated torque wrench. Subsequently, the bone-implant constructs were mounted in an hydraulic testing machine (DARTEC 15kN). The tests were conducted in load control mode using a sinusoidal load profile with a minimum compressive load of 50 N and peak compressive load of 1050 N, corresponding to 1.5x body weight of a 70Kg person walking with crutches [167] , at a frequency of 5Hz [168]. Load was applied until either failure occurred, as defined by an implant breakage or 1.5 cm shortening, or the cycle periods of 300.000 cycles were completed, which corresponds to a simulated clinical loading time of approximately 4 months. During the tests, we observed a breakage of the fixator pins around 90.000 cycles, which occurred for two tests **(Figs. 1c,d).** These results enabled us to conclude that the pins were the weak links of the external fixator for fatigue loading. We decided to perform the tests on the external fixator's frame without the pins.

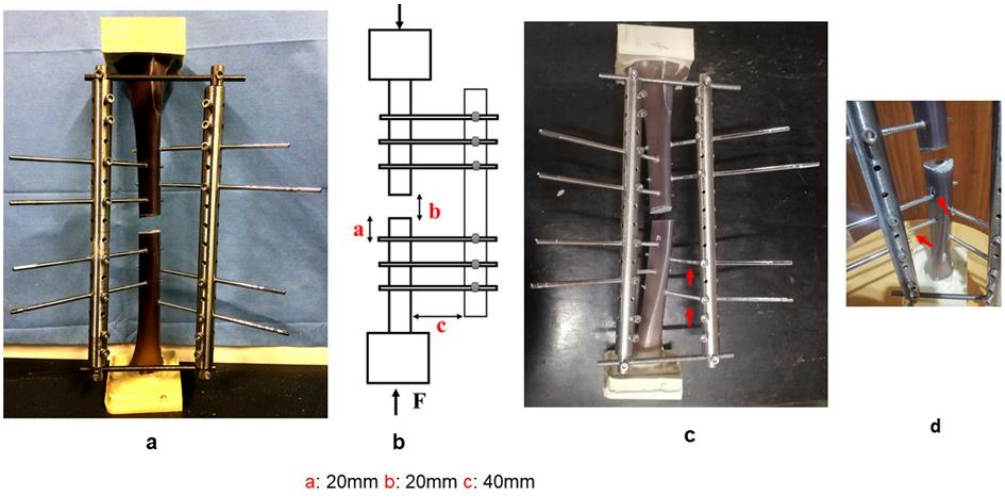


Fig. 1 **a** Locally-developed external fixator. **b** The position parameters of the external fixator. **c** and **d** Failure of the external fixator with breakage of two pins and bending of two other pins.

1. An alternative approach to test the frame of the external fixator without pins

This alternative is aimed to replace the test on a real configuration using an equivalent test that would enable the fastener to be tested for fatigue, with a load that is almost equivalent to the real load, yet without pins. This procedure is applied in four stages:

Step 1: Identify the deformations in the fixator bars using a real configuration test (fixator-sawbone) under the load of 1050N. For this step, the following equipment was used:

- amplifier data acquisition system (DAQ), Hottinger Baldwin Messtechnik (HBM) spider 8 (600Hz/DC);

- computer with software for acquisition, monitoring, and processing of measurement results;

- four strain gauges (Vishay CEA-06-125UN-350) fixed on the two main bars of external fixator.

- test machine Zwick/Roell 250 kN

The strain gauges were placed on the opposite sides of the main bars of external fixator at the same locations. Thereafter, the strain gauges were connected through two separate channels with the (DAQ) system and computer. In this way, the maximum and minimum principal strains on the measuring points were measured independently. This measurement method was applied because the main bars were subjected to a compound strain due to bending and compression, which consisted of axial tension strain and axial compressive strain **(Fig. 2)**. The device (fixator-sawbone) was positioned vertically in a test machine. A static axial compressive load of 1050N was applied to the proximal end of the device (fixator-sawbone), with the distal end being fixed. We observed a deformation of approximately 308 microstrain in compression and approximately 263 microstrain in tension **(Fig. 3)**.

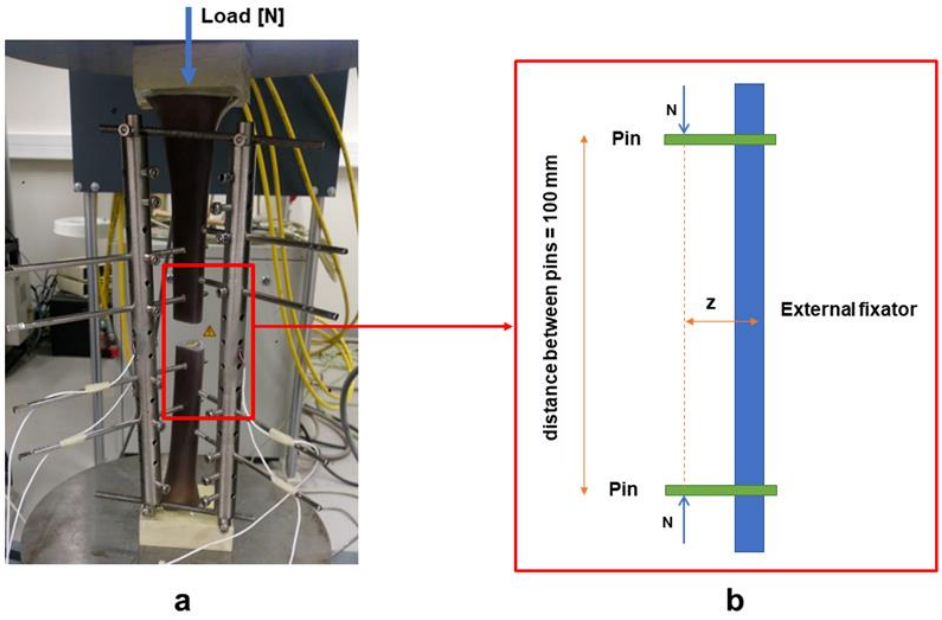


Fig. 2 **a** External fixator with 4 strain gauges in the static test machine. **b** Simplified model of the external fixator

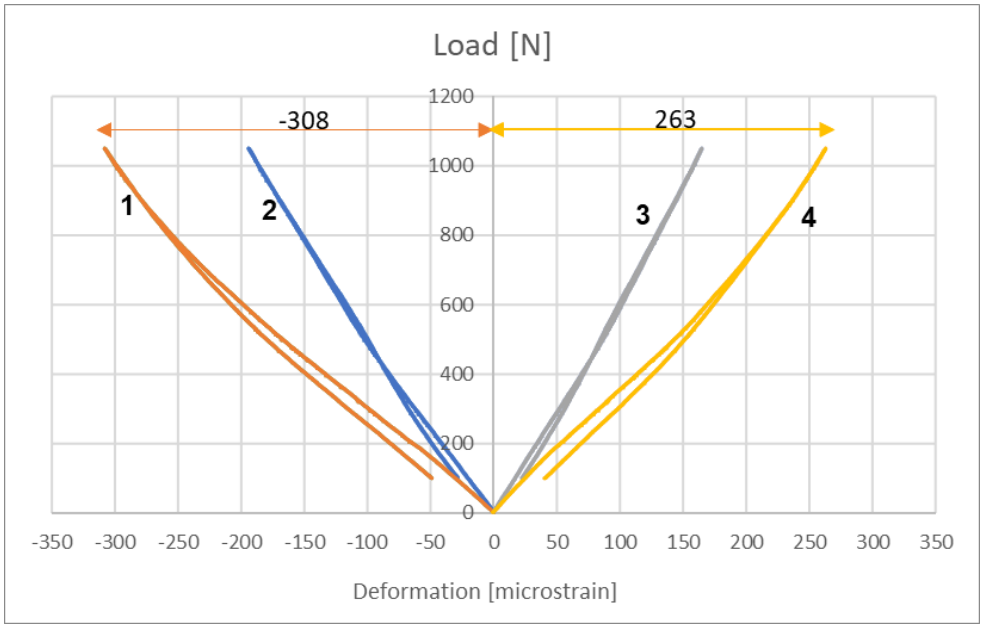
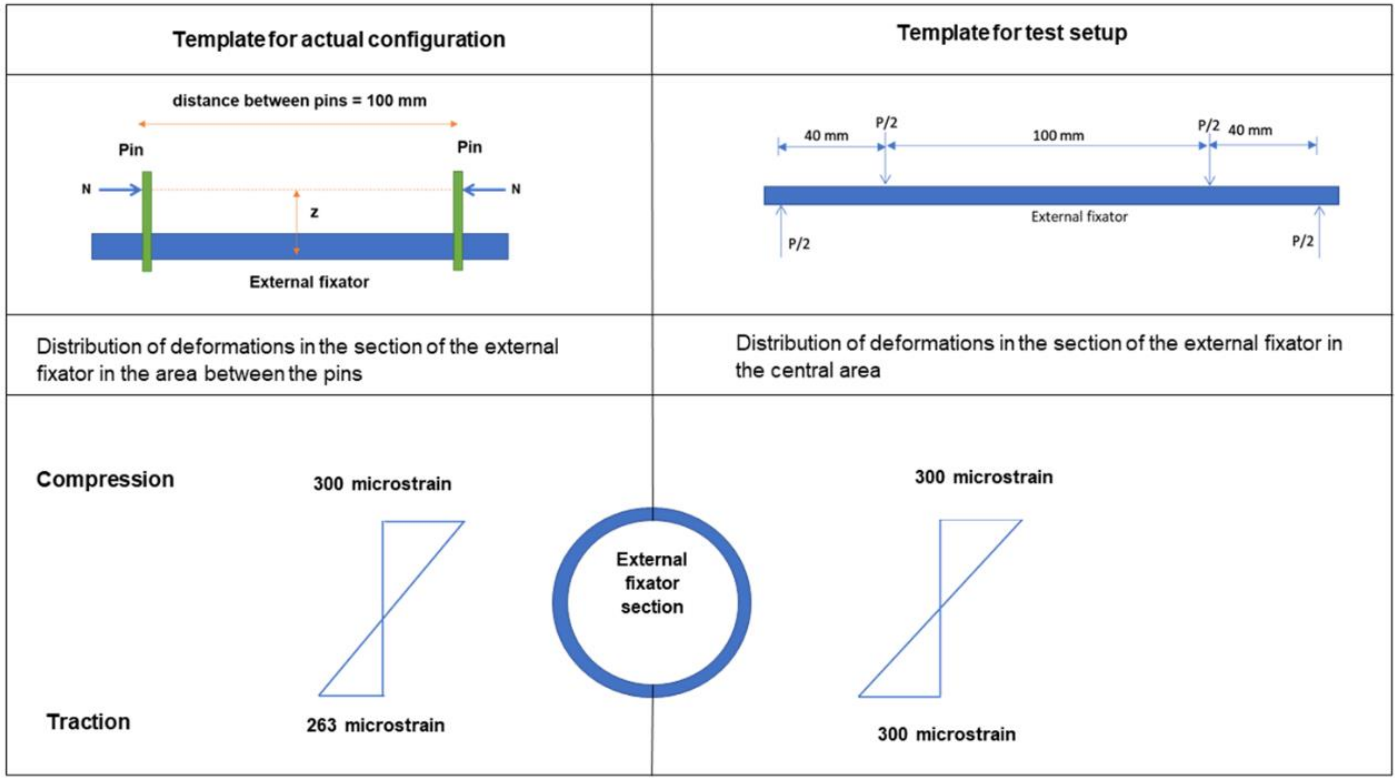


Fig. 3 Deformation measurements as a function of the applied force. **1** Compression deformation in the most stressed fixator. **2** Compression deformation in the less stressed fixator. **3** Tensile strain in the less stressed fixator. **4** Tensile deformation in the most stressed fixator.

Step 2: Fig. 4 proposes an almost equivalent model of solicitation of the fixer. The model considers a pure bending configuration with an increase of the tension deformation, which is on the safe side.



Step 3: calculate the load necessary to induce an equivalent deformation measured in real configuration. For this step we used the Euler-Bernoulli beam bending theory. If we suppose that the fixator is without hole, the Euler-Bernoulli theory allows us to calculate that to obtain a deformation equivalent to the maximum measured during the static loading of 308 microstrain, it is necessary to apply a load of about 1500 N in 4-point bending with a central span L = 100 mm and a total length between supports of 180 mm **(Fig. 5).**

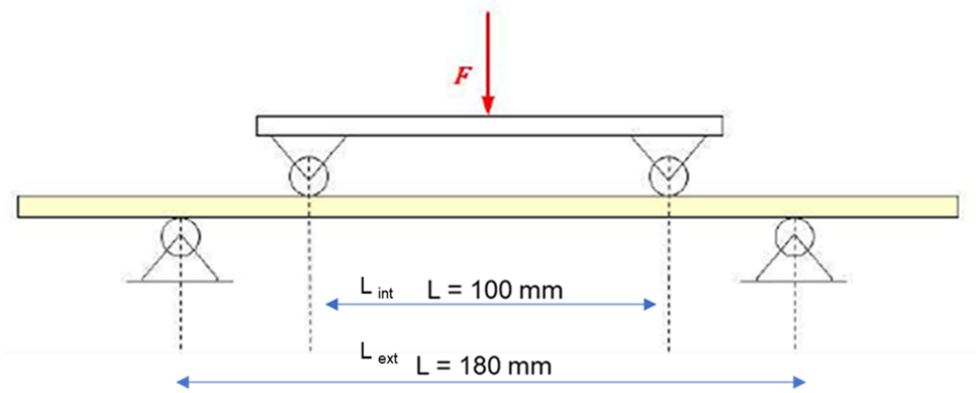


Fig. 5 Four point bending test setup.

The relationship between the applied load F and the maximal deformation ε_{max} in a tube can be written as follow :

$$\varepsilon_{max} = \frac{Fa}{2\,E\,W_{EL}}$$ F= total applied force [N] ; a=(L_{ext}-L_{int})/2=40 [mm]

L_{ext}=span between the internal support [mm]

L_{int}=span between the internal support [mm]

E=modulus of elasticity of the material =210 GPa

W_{EL} = Elastic section modulus = $\frac{\pi\,(d_{ext}^4 - d_{int}^4)}{32\,d_{ext}}$ = 463.70[mm^3]

d_{ext}= external diameter of the fixator =20 [mm]

d_{int}= internal diameter of the fixator = 16 [mm]

Step 4: validate the calculated load before the fatigue tests.

One bar still equipped with 2 strain gages was placed horizontally in the setup in the testing machine and a 4-point bending load was applied gradually. It follows that to obtain a deformation equivalent to the real configuration (approximately 300 microstrain) a load of 1800N is finally required (**Fig. 6**). **Table 1** show of the loads necessary for a deformation almost equivalent to the real configuration.

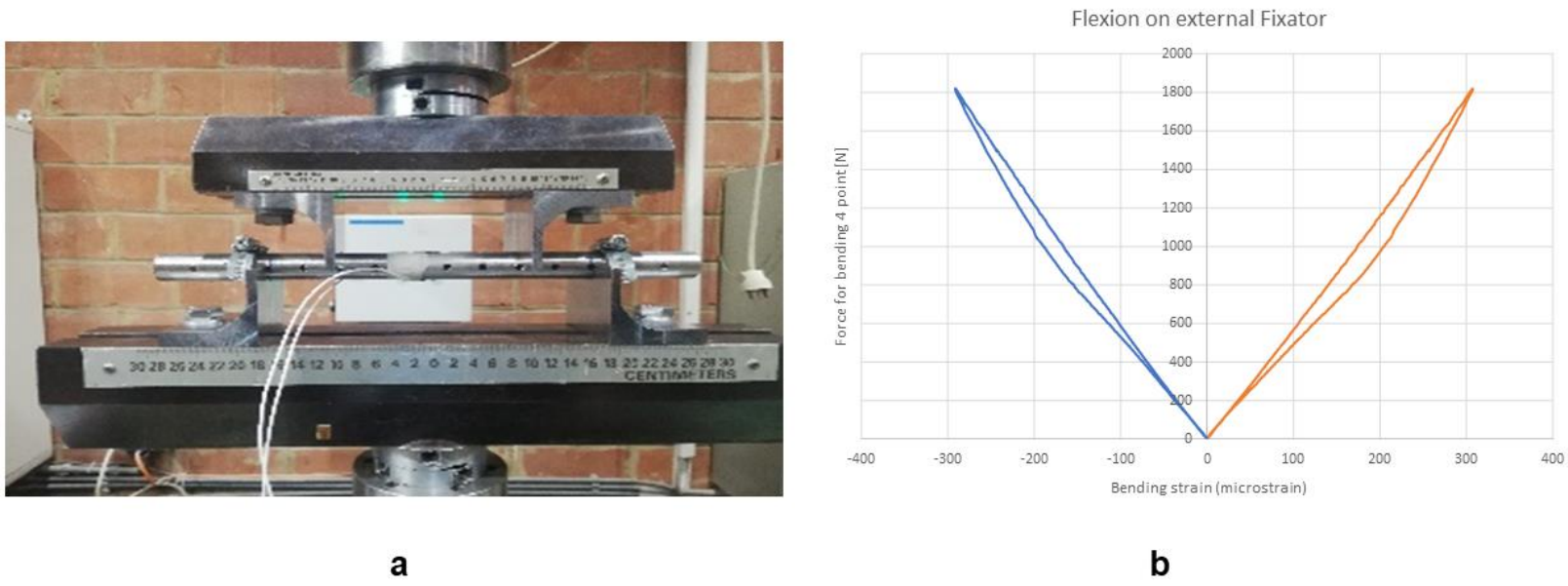


Fig. 6 a Four point bending test setup. **b** Figure showing the load necessary to obtain the deformations equivalent to the real configuration

Table 1: Summary of test parameters

Test parameters	Actual configuration	Bending theory of beams	Equivalent configuration
Load (N)	1050	1500	1800
Deformation observed			
Compression (microstrain)	-300	-300	-300
Traction (microstrain)	263	300	300

2. Four-points bending fatigue testing of external fixator devices

A four points bending test was performed on four 300mm long, Ø 20mm, 304L stainless steel cylindrical tube. In order to investigate the fatigue properties of LDEF, the main bars were placed horizontally in the hydraulic testing machine (DARTEC 15 kN). The test utilizes a two-part fixture (top and bottom) capable of applying a uniform bending moment to the central portion of an LDEF **(Fig. 6a).** The distance between the lower supports was set to 180 mm, while the upper supports were separated by 100 mm. The bending force applied was constantly increased up to 1800 N, at a frequency of 5Hz. Three tests at 300.000 cycles and one test at 1.000.000 cycles were carried out. The bending stiffness as a function of the number of cycles of the tubes was determined. If the fatigue test passes without rupture, this validates the external fixator in fatigue.

2.1 Clinical assay

40 Patients admitted for open tibia fracture were included in a prospective study with approval of the local ethical committee. to assess the LDEF in its ability to achieve fracture union. Written consent was obtained from all patients before participation in the study. This study protocol was registered in Pan African Clinical Trial Registry under N°PACTR202009854874448. Breakage of pins and loosening of the frame were registered. Union rate and delay to achieve union were also observed.

1.1.4 Results

The results show frame of external fixator has successfully conclude the 300.000 cycles and 1.000.000 cycles without any implant breakage or deformity equivalent to clinical complications **(Fig. 7)**. No pin breakage or frame loosening was reported in the clinical setting. Union was obtained in 36 cases (90%) after an average delay of 8.5 months (±1.7 (range: 5-11).

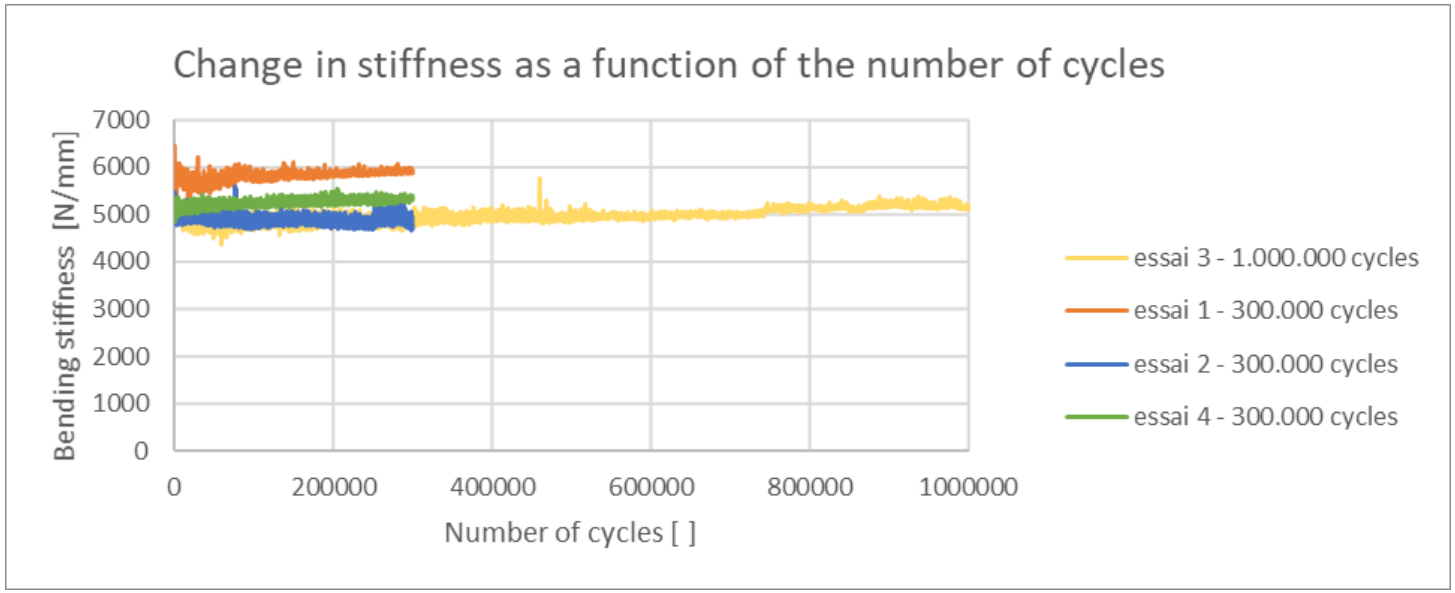


Fig. 7 Graphs showing measured stiffness for main bars of the locally-developed external fixator, which were successfully tested to 300.000 cycles and 1000.000 cycles without failure.

1.1.5 Discussion

This study was designed to assess the biomechanical properties of locally-developed external fixator in a comminuted tibia shaft fracture model. The testing configuration used in the current study exposed the fixator frame to a severe loading condition by axial compression. The test results showed the pins to break after 50.000 cycles a load of 1050N. The load used corresponds to 1.5 x body weight of a 70-kg adult person walking with two crutches [167]. A composite tibia was chosen over a cadaveric model due to the more standardized features under different loading stresses [168]. The comminuted fracture model was selected for this study as severe tibial fractures present a clinical challenge and demonstrate a high rate of complications [168]. Our results indicate that locally-developed external fixators statically are able to maintain fracture stability over twelve months (One million cycles) of normal clinical use in a comminuted tibial defect model. However, during clinical use, the pins of the external fixators should be regularly examined for possible failure. This model reflects a "worst case scenario", since under normal clinical conditions bone formation would typically occur enabling the bone to increasingly bear more load with time [168]. This test design does not account for the potentially important biomechanical influence of the continuously changing stiffness due to the kinetics of fracture healing and therefore a clinical assay was needed. In the clinical series, throughout the treatment period, no implant failure or pin-rupture were observed. Indeed, full weight bearing was lately allowed when bone union signs were observed on X-rays. Therefore, the LDEF and the pins were exposed to lower stresses than what was applied in the mechanical study. Union rate obtained with the LDEF compares favourably with others studies reporting union in complex open fractures[152,

153, 169-172]. The average delay to union (8.5 months) was similar to that reported similar to that reported by Giannoudis et al[2]. The quite long time to union observed in the clinical study can be explained by LDEF's rigidity. Indeed, a rigid fixation does not enable inter-fragmentary motion and tends to limit callus formation, resulting in more direct and slower bone healing. In this test design, the implants bore the full load throughout the duration of the test. Neither the LDEF frame failed in simulated weight-bearing conditions over four months and twelve months. This validates the ability of the locally-external fixators to maintain the stability of the fracture site during clinical use. Each patient and each fracture are different; therefore, fixators may have various degrees of load transmission. Duration of fixation, levels of weightbearing, and the patient's weight and level of activity all must be considered in judging fixation frame reusability [173].

Conclusion

This study has shown that the pins used in external fixation systems have relatively short fatigue lives under high loading conditions. When bony apposition at the fracture site is not anticipated under certain clinical applications, care must be taken to avoid high load transmission through the fixation pins. For practical and safety reasons, the locally-developed external fixators may be considered for reuse based on the current study results, provided that critical components such as the pins are replaced.

Chapter III : Clinical study with locally-developed external fixators

3.1. Article 5

Locally-developed external fixators as definitive treatment of open tibial diaphyseal fractures: a clinical prospective study conducted in Ivory Coast

Kouamé Jean-Eric Kouassi, Jean Régis Akobé, Adélaide Aya Kouassi, Loïc Fonkoue, Christine Detrembleur, Michel Kodo, and Olivier Cornu

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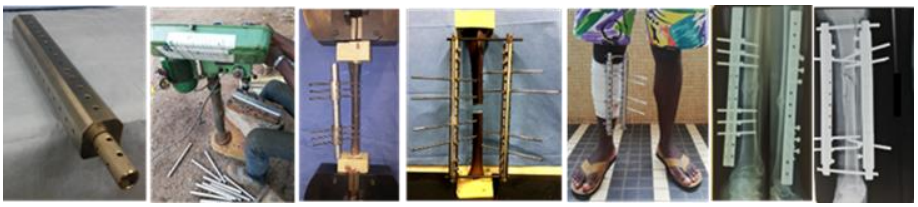

1.1.1 Abstract

Background: This study sought to evaluate the effectiveness of locally-developed external fixators (LDEF) as definitive treatment for open tibia diaphyseal fractures (OTDF) in Ivory Coast.

Methods: Gustilo I, II and IIIA OTDFs of patients admitted within 24 hours of injury were prospectively included and treated with a locally-developed external fixator. The rates of union, mal-union, septic complications, as well as the functional results were assessed, in addition to the LDEF construct's integrity. Predictive factors of failure or poor results were assessed.

Results: Overall, 40 OTDF patients were admitted within 24 hours of injury. Gustilo I, II and IIIA fractures were observed in three, 13, and 24 patients, respectively. Uneventful fracture healing was obtained in 29 cases, with an average union time of 8.47 months. Mal-union and non-union were registered in three and four cases, respectively. Pin-track infection (PTI) was observed in 13 cases, and deep infection in seven. Infection resolved in all patients except four, who developed chronic osteomyelitis. None of the non-unions were associated with an infection. The overall functional result was satisfactory in 32 patients. PTI was the only predictive factor for chronic infection. Biplanar frames, when compared to monoplanar constructs, were associated with a significantly improved functional outcome.

Conclusion: LDEF improved significantly the OTDF management, as it provided better stability and superior fracture healing rates at the rates obtained

in the same environment. PTI remains an essential problem but with, hopefully, limited negative consequences.

Trial registration: This study protocol was registered in Pan African Clinical Trial Registry under N°PACTR202009854874448. (www.pactr.org)

Keywords: definitive treatment, external fixator, development, emerging country, open diaphyseal tibia fracture

1.1.2 Introduction

Among open long bone fractures, open tibia fractures are the most common [3].They are a frequent cause of hospital admissions following road traffic injuries, and they are associated with increased mortality and morbidity [174]. This setting is all the more alarming in developing countries, such as Ivory coast, where the traffic safety norms are often ignored, along with poor traffic management [143]. Despite advances made in fracture treatment, including routine prophylactic antibiotics, prompt debridement, and early soft-tissue coverage, these injuries are sources of infection and non-union [175]. While appropriate open tibial fracture treatment appears crucial, the optimum method of definitive skeletal stabilization is still unclear [176]. In developed countries, primary debridement and intramedullary nailing are progressively becoming the preferred treatment of these fractures [177]. However, the situation differs in developing countries like Ivory Coast, where patients present late at hospitals and because adequate (intramedullary nailing and external fixators) are not always available [178]. In our hospital, as in most centers in less developed regions, open tibial fractures have been traditionally managed by casting with Plaster of Paris (POP) [113]

The high failure rate that was associated with this management protocol made us look into a locally-developed external fixator as an alternative to the commercially available external fixators and POP. External fixation provides fracture stabilization with minimal soft-tissue disturbance [177]. In austere environments, however, a greater infection risk [177, 179] and concerns regarding sterility [180] have led numerous surgeons to minimally employ internal implants so as to limit wound infection risk. Moreover, the implants for external fixation can be reused readily, thus rendering them more available

and affordable in low- and middle-income countries [181]. Although numerous sophisticated models are available on the market, they prove to be rather expensive [27]. The development of a locally-developed external fixator (LDEF) sought to build an inexpensive external fixator, whose biomechanical properties are comparable to those of a validated reference fixator [165]. The final objective was that patients who could not afford conventional expensive fixators would nevertheless be treated appropriately. This study describes the outcomes of a group of patients with open tibia diaphyseal fractures treated using this LDEF. This study sought to evaluate the LDEF effectiveness as definitive treatment for open tibia fractures, with the underlying hypothesis that the fracture healing rate and functional outcome would be improved with LDEF, as well.

1.1.3 Methods

Study design

This prospective study was carried out at University Teaching Hospital Bouake, Ivory Coast. The study was conducted from June 2019 to October 2020. The local ethics committee approved the study protocol, and written consent was obtained from all patients before participation in the study.

Patients

Consecutive patients presenting with open tibia diaphyseal fracture at consultation were eligible for the study. The inclusion criteria were patients older than 18 years with Gustilo-Anderson [91] Type I, II, IIIA open tibia diaphyseal fractures admitted to the hospital within 24 hours of injury. The exclusion criteria were open tibial fractures with intra-articular extension, Type IIIB fractures and Type IIIC according to Gustilo-Anderson, those who underwent initial debridement before arrival in our hospital, and those with neglected open tibial fractures. All the patients excluded from participation were treated appropriately. A total of 40 consecutive patients fulfilled the inclusion criteria and were entered into the study.

Management

An intravenous antibiotic therapy was established upon patient admission, combining ceftriaxone 2g per day, metronidazole 1.5g per day, and gentamycin 160mg per days for 5 days. Tetanus prophylaxis was systematically administered to all patients. Under spinal anesthesia, patients were operated on in the supine position. Thorough irrigation and debridement were performed in order to eliminate all contaminants, as well as highly contaminated or necrotic soft tissue. Fractures were stabilized using a locally-developed external fixator (LDEF) **(Fig. 1)**.

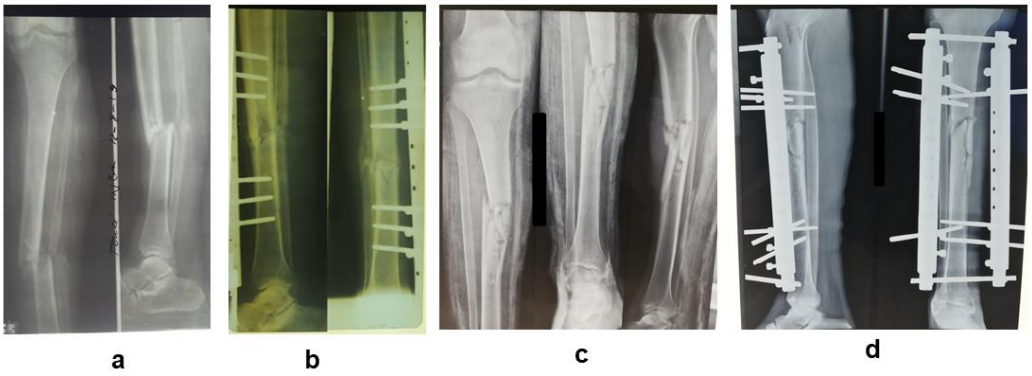

Fig. 1 Diaphyseal tibia fractures treated with LDEF. **a** Transversal tibia fracture. **b** Treatment using monoplanar external fixator. **c** Comminuted tibia fracture. **d** Treatment using biplanar external fixator

The fixator design consisted of a unilateral uniplanar external fixator or biplanar external fixator [165] **(Fig. 2)**, with the frame made of a 304L stainless steel cylindrical tube. The standard tube was provided with a 20mm gauge, 3mm, and 300mm length. The tube was drilled into a perpendicular plane, with holes passing 5.2mm in diameter, spaced 20mm apart. The holes accept all types of pins that have a diameter ≤5mm. Threaded holes are perpendicular to those of the pins, which also accept hexagonal and flat-bottom screws that secure the tube/pins. To constitute a biplanar model, two full bars, 6mm in diameter, ensure the connection between both main cylindrical tubes through four hollow tubes, 13mm in diameter and 40mm in length, which are attached to the four extremities of the main tubes. Five-millimeter diameter thread screws (M5) secure the tube/tube and bar/tube fixations. Early coverage of the fracture site was achieved by means of suturing for Gustilo Types I and II fractures and sometimes by thin skin grafting for Gustilo Type IIIA.

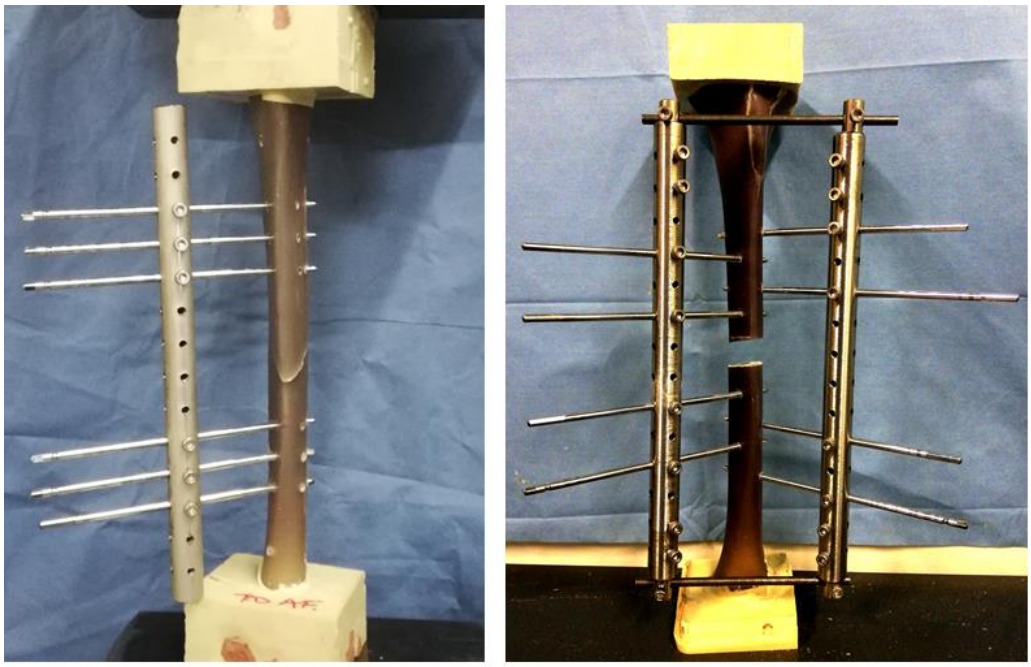

Fig. 2 Illustrations with a saw bone of monoplanar (**a**) and biplanar fixations (**b**) of oblique single (**a**) and comminuted/bone defect fractures (**b**)

Postoperative management

The patients were invited to perform early knee and ankle joint movements and muscular exercises, as well. Patient were instructed to clean the device regularly with water. One month following the initial operation, follow-up radiographs (X-rays) were obtained in order to evaluate the fracture union progress. The LDEF condition was additionally assessed. Subsequently, gradual weight-bearing was permitted. Patients then returned for both clinical and radiological assessments every 2 months until the fracture was united.

During this period, full weight bearing was permitted if an adequate bridging callus was visible on radiographs. Union of the fracture was defined clinically when the patient was able of fully weight bearing without any pain at the fracture site; fracture union was defined radiographically when the callus bridged at least three cortexes [182]. Mal-union was defined as a valgus or varus, both with an angulation of more than 5 degrees, anterior or posterior angulation of more than 10 degrees, or mal-rotational of 10 degrees or shortening of 1 cm or more comparison with the controlateral leg [9, 183]. Non-union was defined as a lack of fracture callus progression on two consecutive radiographs taken at least 3 months apart starting at 6 months post-operative or as a fracture requiring a surgical revision [184]. Infection was subdivided into superficial or pin-track infection, deep tissue infection, and chronic osteomyelitis. A pin-track infection (PTI) was defined as inflammation around the pin-track. PTIs were treated by cleaning each pin-site with a sterile pad application soaked in Dakin cooper, along with new daily dressing. Oral antibiotics (amoxicillin-clavulanic acid 1gr x 3 per day) were prescribed for 5 to 10 days. If the infection persisted, a culture of the site was carried out, and the antibiotic was adapted according to antibiogram results. X-rays were performed to assess if pin loosening had occurred. Loose pins would immediately be removed and not be replaced. A deep infection was defined as an infection involving deeper tissues, such as muscular fascia and bone [9], which require surgical debridement and appropriate antibiotics. Osteomyelitis was defined as the occurrence of more than two of the following signs/symptoms (>38°C temperature, localized swelling, localized heat, localized tenderness, and drainage at site), in addition to positive bone cultures or X-ray evidence of infection or infection recurrence following a primary apparently healed infection episode [185]. The external fixation system was removed, as an outpatient procedure, when fracture union was complete.

Upon clinical examination, knee and ankle range of movement were examined by an independent examiner using a goniometer, in comparison to the contralateral healthy side [178, 186]. The functional outcome measures were assessed at the last visit, including pain, knee and ankle motion ranges, and ability to return to normal walking, according to the Kitoko et al criteria [80] **(Table 1).**

Table 1: Kitoko RA et al. criteria for functional assessment following treatment of open tibia fracture

	Very Good	Good	Fair	Poor
Criterion	Normal walking	Normal walking	Pain when walking	Frequent pain and reduced mobility
	Knee flexion >120°	Knee flexion ≥90°	Knee flexion 60°-90°	Knee flexion <60°
	Full knee extension	Extension to 10°	Knee extension deficit of more than 10°	Knee extension deficit of over 15°
	Ankle dorsiflexion at 30°	Ankle dorsiflexion at 20°	Ankle dorsiflexion at 15°	Ankle dorsiflexion at 5°
	Ankle plantar flexion at 50°	Ankle plantar flexion at 30°	Ankle plantar flexion at 20°	Ankle plantar flexion at 10°
Overall functional result	Satisfactory		Unsatisfactory	

Primary outcome

The primary outcome was the union rate of open tibia fracture.

Secondary outcomes

Secondary outcomes included:

(1) infection type and rate, and late complication rates (non-union, mal-union, and osteomyelitis);

(2) functional outcomes as measured using the validated Lower Extremity Functional Scale (LEFS) [187, 188]. Total scores range from 0 to 80, with function defined as follows: extreme difficulty or unable to perform activity (0-19 points), quite a bit of difficulty (20-39 points), moderate difficulty (40-59 points), a little bit of difficulty (60-79 points), and no difficulty (80 points)[189]; (3) the health status was measured using the 12-Item Short Form Survey (SF-12).

[190]. The SF-12 is a reliable generic health status instrument that has been validated for use in trauma patients. This scoring system consists of a Physical Component Summary (PCS-12) score and Mental Component Summary (MCS-12) score. Scores ≥50 represent no disability; 40-49 mild disability; 30-39 moderate disability; below 30 severe disability [191]. All questionnaires were completed by the patients during their visit.

Assessment parameters

We collected and assessed data on demographics, risk factors (smoking, alcohol); mechanism of injury, admission delay in hospital, pattern and location of fracture, Gustilo fracture classification after debridement, in addition to associated injury. The hospital stay duration was analyzed. The fracture healing, duration of external fixation, time to fusion, and complications (infection, PTI, mal-union, and non-union) as well as functional results were analyzed.

Statistical analysis

Under our conditions, the union rate was 35% with the standard of care, without LDEF [178]. This study aimed to reach a union rate of 70%. Assuming a significance level of 5% and power of 80%, a minimum of 37 patients would be needed. A total of 40 patients were enrolled in this study. Statistical analyses were performed using Sigma plot 13.0 software. Descriptive statistics were performed for quantitative variables (mean, standard deviation, minimum, maximum) and qualitative variables (frequency). A multiple logistic regression model was employed to determine the risk factors of infection (infection state=1) and bone complications (bone complications state=1). Independent variables were age (years), gender, fracture line, location of fracture, Gustilo grading, treatment delay, external fixator type, and pin-track infections. A Fisher's exact test was performed to test the null hypothesis of no association between functional outcome and frame type (monoplanar versus biplanar). A p-value <0.05 was considered statistically significant.

1.1.4 Results

Overall, 40 patients were admitted with OTDF within 24 hours of injury. The mean age of the patients was 32.77±12.55 years (range: 18-77). Patients aged ≥ 30 years were predominant (n=22; 55%). The injury cause was a road traffic accident in 38 (95%) cases. The fracture type according to Gustilo classification was Type IIIA in 24 (60%). The mean treatment delay was 26.35±13.49 hours (range: 10-72). The patient characteristics are showed in **table 2**. The mean follow-up was 11.23 months [range 9-12 months].

The union rate was 29 (72.5%) with an average union time of 8.47±1.66 (range: 5-11) months **(Fig. 3)**. Deep infection and pin-track infections rates were 17.5% (seven cases) and 32.5% (13 cases), respectively. Pin-track infections were successfully treated with oral antibiotics and pin-site care without any pin-loosening registered. Complications were observed in 11 cases (27.5%), including aseptic non-union in four (10%), mal-union in three (7.5%), and osteomyelitis in the remaining four (10%, two considered PTI-related). Throughout the treatment period, no implant failure, pin-breakage, pin-loosening were observed. Extraction was performed locally without anesthesia. No refracture was observed during the follow- up period.

Table 2: Characteristics of patients

Variable	n(%)
Age (years)	
Mean±SD (range)	32.77±12.55 (18-77)
Gender	
Male	29 (72.5%)
Female	11 (27.5%)
Mechanism of injury	
Road trafic accident	38 (95%)
Other	2(5%
Fracture line	
Comminution	36 (90%)
Simple	4 (10%)
Gustilo-Anderson grading	
I	3 (7.5%)
II	13 (32.5%)
IIIA	24 (60%)
Location in the diaphysis	
Proximal-third	8 (20%)
Middle-third	26 (65%)
Distal-third	6 (15%)
Treatment delay	
≤24 hours	26 (65%)
>24 hours	14(35%)
Type external fixator	
Monoplanar	12 (30%)
Biplanar	28 (70%)
Average hospital stay duration (days)	8.98±2.97
Rate of union	29 (72.5%)

SD: standard deviation

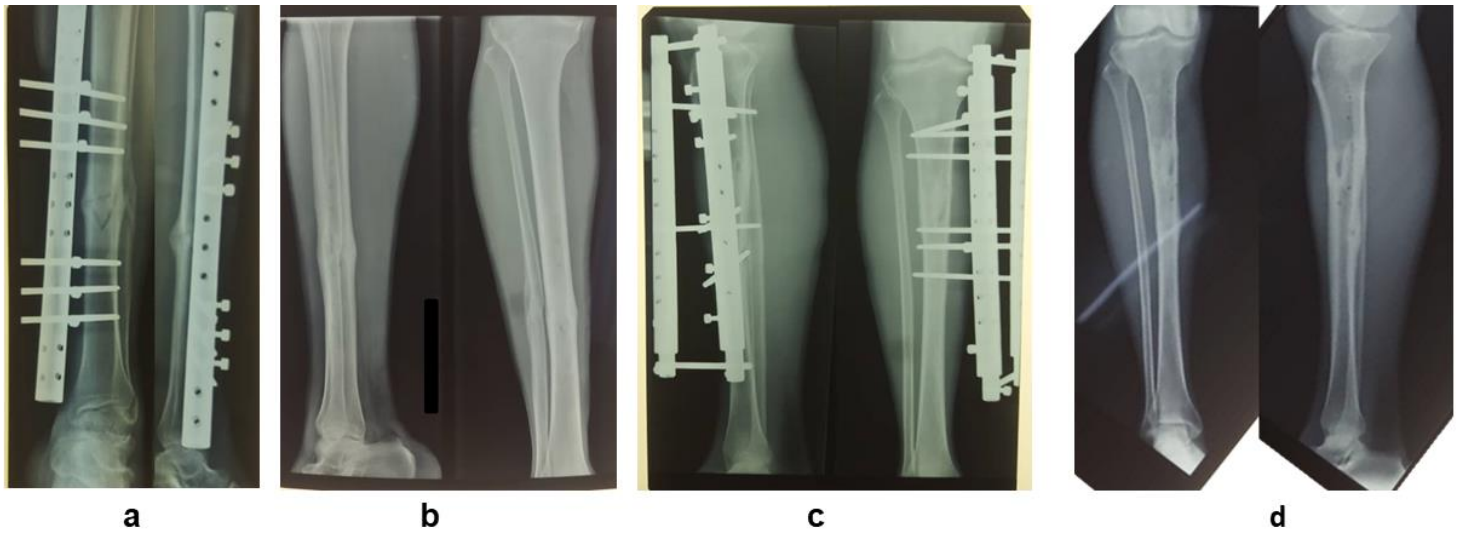

Fig. 3 Radiographs at 6 months after the initial operation **(a,c)** and at final follow-up after LDEF removal **(b,d)**

The functional outcomes were very good in 17 patients, good in 15, fair in six, and poor in the remaining two. The overall result was satisfactory in 32 cases and unsatisfactory in eight **(Fig. 4)**.

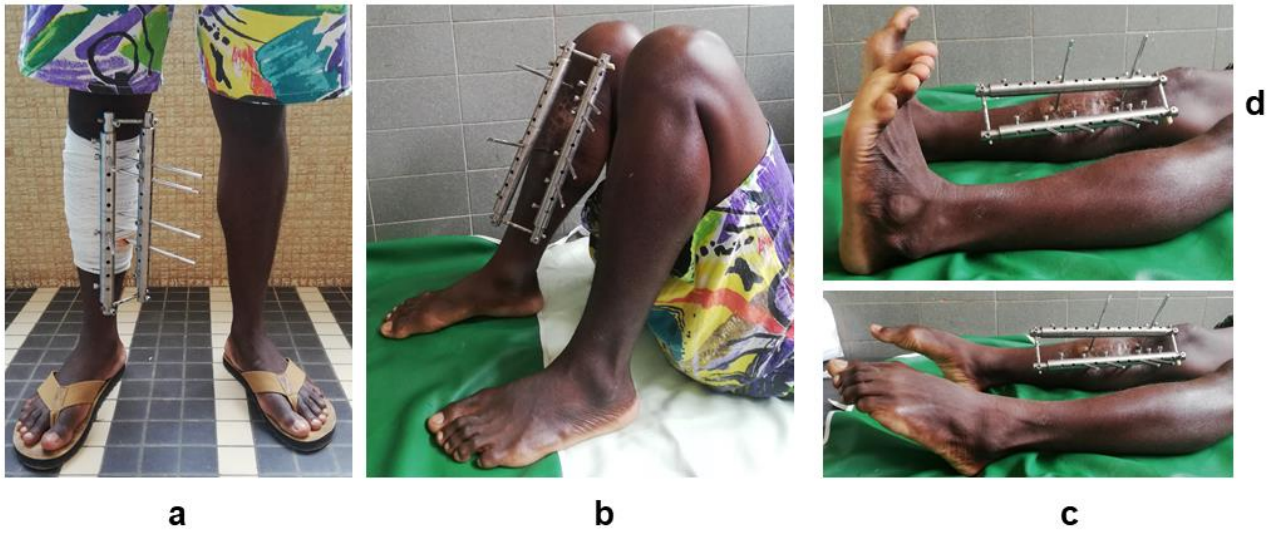

Fig. 4 Clinical images with LDEF biplanar showing functional outcome. **a** Clinical appearance. **b** Knee flexion of the patient with LDEF. **c** Ankle plantar flexion. **d** Ankle dorsiflexion

The mean SF-12 physical and mental scores were 42.54 and 46.45, respectively, meaning mild disability. The mean ELFS scale was 61.53±10.50, meaning a little bit of difficulty **(Table 3).** Patients with pin-track infections were found to be more than three times as likely to sustain deep infection and chronic osteomyelitis (odd ratio [OR]=24.332, p=0.017) **(Table 4).** No significant factor was identified to influence fracture healing related complications. However, patients with Gustilo Type IIIA fractures [OR=5.9] and those treated with a monoplanar external fixator [OR=6.9] were found to be more at risk to develop fracture healing problems **(Table 5).** Fisher's exact test analysis revealed an association between improved functional outcome and biplanar LDEF, in comparison with monoplanar constructs (p=0.039).

Table 3: Functional outcomes

Variable	n (%)
Very good	17 (42.5%)
Good	15 (37.5%)
Fair	6(15%)
Poor	2(5%)
SF-12 score	
MCS-12 (mean±SD)	46.45±8.5
PCS-12 (mean±SD)	42.54±7.3
ELFS (mean±SD)	61.53±10.50

MCS: mental component summary; PCS: physical component summary

ELFS: lower extremity functional scale; SD: standard deviation

Table 4: Results of multiple logistic regression to identify risk factors of infection

Independent variables	Coefficient ± SE	Odds ratio [LCI-UCI]	P value
Age (years)	-0.0432±0.0544	0.958 [0.861-1.065]	0.427
Admission delay (hours)	-0.105±0.0922	0.900[0.752-1.079]	0.255
Location of fracture	-0.129±1.242	0.879[0.0770-10.032]	0.917
Gustilo grading	1.563±1.259	4.774[0.405-56.281]	0.214
Treatment delay	0.0463±0.0385	1.047[0.971-1.130]	0.230
External fixator	1.728±1.344	5.629[0.404-78.416]	0.199
Pin track infection	**3.192±1.334**	**24.332[1.780-332.563]**	**0.017**

Significant Independent variable is bold; SE: standard error

LCI: 5% lower confidence interval; UCI: 95% upper confidence interval

Table 5: Results of multiple logistic regression to identify risk factors of bones complications

Independent variables	Coefficient ±SE	Odds ratio [LCI-UCI]	P value
Age (years)	-0.0198±0.0370	0.980 [0.912-1.054]	0.592
Gustilo grading I-II versus III	**1.775±1.037**	**5.902 [0.773-45.078]**	**0.087**
Treatment delay	-0.0213±0.0342	0.979 [0.915-1.047]	0.534
External fixator monoplanar versus biplanar	**1.942±1.034**	**6.971 [0.919-52.906]**	**0.060**
Pin-track infection	1.343±0.987	3.832 [0.554-26.501]	0.173
Deep infection	-0.0831±1.121	0.920 [0.102-8.277]	0.941

SE: standard error; LCI: 5% lower confidence interval; UCI: 95% upper confidence interval

1.1.5 Discussion

This Ivory Coast clinical trial employed LDEF as definitive stabilization approach for open tibia diaphyseal fractures, which resulted in a union rate exceeding 70%, without any fixator failure and good functional outcomes.

The current study outcomes have shown LDEF to provide a safe and effective treatment modality for treating open tibial diaphyseal fractures, resulting in significant improvements as compared to our previous series without LDEF (Table 6) [178]. In addition, the union rate compares favorably with the outcomes reported by other authors [2, 152, 153, 170, 186, 192, 193]. This positive outcome may be accounted for by the external fixators' inherent stability, operative technique used, adherence to basic surgical principles, and efforts to achieve anatomical reduction including axial and side-to-side compression. As for the quality of fracture reduction, uniplanar devices with a rigid side-bar are usually more difficult to adjust, and the surgeon must thus take care to ensure a satisfactory reduction before the external fixator is applied. Moreover, functional results proved to be superior when a biplanar frame was used.

Table 6: Comparison of open tibia fracture management without and with locally-developed external fixators in our hospital

		Without locally- developed external fixators	With locally- developed external fixators	P value
Patients (n)		43	40	
Age (years) mean±SD		33.3±14.1	32.8±12.6	0.927
Group of Age (n)				0.733
	≥ 30 years old	21	22	
	<30 years old	22	18	
Gender (n)				0.120
	Male	38	29	
	Female	5	11	
Mechanism (n)				0.934
	RTA	40	38	
	Other	3	2	
Gustilo (n)				0.129
	I and II	30	16	
	III	13	24	
Type of fracture (n)				0.044

	Comminuted fracture	30	36	
	Simple fracture	13	4	
Site of fracture				0.985
	Middle third	27	26	
	Prox/distal third	16	14	
Treatment delay (n)				0.292
	>24hours	21	14	
	≤ 24hours	22	26	
Union delay (months)		5.73±0.84	8.47±1.64	0.001
Union rate (n)				0.001
	Without complications	15	29	
	Bony complications	28	11	
Infection (n)				0.504
	Superficial	11	13	
	Deep	11	7	
Complications (n)				0.004
	Mal-union	17	3	
	Non-union	0	4	
	Osteomyelitis	8	4	
	Septic non- union	3	0	
Functional outcomes (n)				<0.001
	Satisfactory	16	32	
	Unsatisfactory	27	8	

SD: standard deviation; RTA: road traffic accident

A good initial reduction is essential when a fixator is applied, given that it is often difficult to achieve a secondary reduction in the case that the primary reduction proves unsuccessful. Moreover, the frame must be maintained long enough to prevent a secondary loss of fracture reduction [169]. The time to achieve union with external fixators varies in different studies [2, 152, 186]. In our study, the mean union (8.47 months) was similar to that reported by Giannoudis et al. [2]. However, shorter times have been published in the literature, as well [169, 192]. The long time to union observed in our study can be explained by LDEF's rigidity. Indeed, a rigid fixation does not enable inter-fragmentary motion and, thus, tends to suppress callus formation, resulting in more direct bone healing [152], yet prolonged healing times [194]. The major drawbacks of external fixators are the inadequate primary reduction and insufficient mechanical stability leading to alignment loss, delayed union or non-union [152, 194], need for re-operation, as well as to pin-tract infections [152]. In our study, the 10% incidence of non-union observed aligned with the 8% non-union incidence noted by Beltsios et al.[152, 169]. Nonetheless, these incidence rates were lower than those published by other authors in the literature, who reported non-union rates of 13%, 14.7%, 18.7%, and 28.3%, respectively [153, 170, 171, 195]. While this non-union rate observed in our study can be explained by the biology and biomechanics of segmental fractures, it is not to be accounted for by disadvantages of the external fixation method. Comminuted fractures, associated with significant periosteal- and soft tissue-injury, often result in non-union [192]. A segmental fracture of a long bone indirectly implies that enormous energy has been absorbed by this injury type, and that the two-level fracture pattern impairs or disrupts the intramedullary blood supply to the middle fragment. In the event of a severe soft tissue trauma,

the periosteal blood supply to the middle fragment may also be compromised, thereby leading to a higher probability of delayed union or non-union [170].

In the current study, the mal-union rate amounted to 7.5%, whereas in two tibia fracture cases, there was a >1.5cm shortening that did not result in significant disability. While only a few authors reported similar rates [152, 153, 169, 193, 196], most of the others revealed higher rates, such as 26%, 20%, 25%, 17% , and 31%; respectively [2, 171, 195, 197, 198]. These differences could be explained by the great efforts that the authors made to achieve an anatomic reduction, in addition to the extreme stability offered by the LDEF.

PTI is a known complication following fracture treatment with external fixators whose literature-reported incidence rates range from 32 to 80%, with an average 4% of cases developing chronic osteomyelitis [2, 169, 171, 199]. We have herein reported a 32.5% PTI rate, along with osteomyelitis noted in two cases (5%). Using the pin-site care protocol and discharge instructions comprising detailed guidance, patients suffering from pin-track infections received timely and successful oral antibiotic treatment [9].

The literature reveals differences in deep infection rates when external fixation is applied for definitive fracture treatment [123]. In our study, the deep infection rate amounted to 17.5%. This figure perfectly aligns with the 18.1% rate observed by Alhammoud [123]. In the article Giannoudis, which reviewed 536 open tibia fractures, an average 16.2% deep infection rate was reported, which turns out to be slightly lower than our result, though roughly comparable [2]. This result could be explained by a higher rate of PTI, as suggested by the multiple logistic regression analysis in which only PTI remained predictive of postoperative infection (p=0.017). The important delay in fracture

management was not associated with an increased complication rate. Literature does not support a clear correlation between preoperative time and onset of infectious complications [200]. However, the delay in managing open fractures should not be condoned because the risk of infection that is always present is indeed multifactorial, especially after 24 hours, regardless of the degree of opening and the time taken for debridement [100]. The quality of the initial debridement is paramount, as it most likely conditions the future.

The final results were assessed according to Kitoto et al [201] criteria. In our study, the functional outcomes were satisfactory and even superior to those reported by other authors [178, 201]. The mean SF-12 physical and mental scores of 42 and 46, respectively, were deemed low as compared with the normal population, thereby reflecting these injuries' severity [191]. The LEFS questionnaire analysis revealed that the lower extremity's overall function was in 'a little bit of difficulty' category. The study patients were mostly young, motivated, and cooperative, which may account for the quality of LEFS scores that are somewhat equivalent to those recorded in the general population. Biplanar LDEF frames offered a better functional result, which is probably related to the more stable construct, with quicker and easier loadbearing for the patient.

We believe that in developing countries like Ivory Coast, with heavy economic constraints, a locally-developed external fixation should be an acceptable therapeutic modality. This frame is particularly useful in hospitals devoid of local medical facilities where patients tend to arrive late. External fixation is technically less demanding, and no specialized equipment is necessary [26, 195]. External fixation is a simple technique if used selectively and provided that the basic principles are adhered to [202]. The correct application of the

external fixator on the initial lesions likely contributes to reduce the infection rates, improve the fracture consolidation, and facilitate the limb's functional recovery. The present study's limitations are as follows: (1) small sample size; (2) no comparison with other fixation methods; (3) no randomization of study participants.

Conclusion

The use locally-developed external fixators as definitive treatments for open tibial diaphyseal fractures has improved bone union and functional recovery in most cases. This approach also improved postoperative results such as: malunion, osteomyelitis. Thus, LDEF may an effective option in the treatment of open fracture of the tibia in developing countries, where the means of osteosynthesis are lacking.

Chapter IV: General discussion

This study describes the locally-developed external fixator (LDEF) for managing open tibial fractures (OTF). For each part of the thesis, a synthesis is provided here below.

Problem of treating open tibia fractures in developing country like Ivory Coast

The basic objectives of open fracture management are to prevent infection, reconstruct soft tissue defects, and achieve bony union. With the availability of antibiotics, pulse lavage, several improved fracture stabilization procedures, and superior proficiency in plastic surgery, the outcome of these injuries has improved in recent years [203]. The conditions of managing open fractures and classic complications observed in DCs are no longer observed in the developed countries, which is indeed a reminder of the huge gap between the African and European healthcare systems [23]. Access to modern medicine is still limited in Sub-Saharan Africa. In rural areas, this is mostly due to the lack of local medical facilities, while travelling conditions are difficult owing to poor roads and limited transportation means [23]. Access to healthcare is a real problem for the poor urban population, as these people may face difficulty paying hospital costs [23]. Only the main hospitals in the capital have an orthopedic surgeon.

Thus, fractures are often first treated by traditional bone-setters and healers whose methods are not at all suited for managing open fractures [23, 204, 205]. Another crucial challenge in open fracture management in our center is the time delay between patient presentation and initial debridement, which may range from 10 hours to 72 hours. Currently, the six-hour rule is controversial [206]. In the current literature, no clear correlation was observed between preoperative delay and occurrence of infectious complications [207, 208]. However, the delay in open fracture treatment should certainly not be endorsed, as there is always a risk of infections. This risk is multifactorial and appears to be especially high after 24 hours, whatever the opening degree and regardless of the time required for debridement. The debridement is believed to be the most crucial factor for reducing the prevalence of infection following an open fracture [207, 209]. The major cause of this delay is often the patients' inability to pay for treatment. Health insurance coverage being non-existent, and even for those patients that have health insurance, implants are mostly not covered. Patients and relatives must pay from their own pockets, and as our country is a poor nation with over 80% of the population leaving below the poverty line, it is often an uphill task to get patients to pay. However, despite delays in presentation, satisfactory outcomes can be obtained by applying the established surgical principles of thorough debridement, soft tissue management, and fracture stabilization [209]. The most common difficulties for local orthopedic surgeons are insufficient fixation hardware, as well as insufficient training in soft tissue reconstruction techniques [23].

The lack of postoperative physical therapy is another issue that is determinant for functional outcome. Self-performed physical therapy exercises are poorly followed. Knee stiffness was nearly systematic following diaphyseal tibia fractures. The lack of access to functional rehabilitation is especially severe in DCs where there are very few physical therapy centers, while patients additionally must pay for their use [23].

Treatment of open tibia fractures in an Ivory Coast university hospital setting: need for a locally-developed external fixator (LDEF)

Open tibia fractures are severe injuries requiring adequate debridement, appropriate fracture fixation, and early coverage. While this "orthoplastic" approach constitutes a standard in high-level trauma centers of developed countries, it is challenging for conventional orthopedic teams alone, particularly in low-resource settings [118], like ours. In a country like Ivory Coast, defined by the United Nations as a "least developed country", this problem can be exacerbated by delayed patient care, which can be related to several factors, particularly including delayed patient presentation and treatment cost. In our hospital, open tibia fractures are still a common injury, with a high risk of complications, including wound infection and bone healing problems. These latter issues are particularly the case when primarily casting with plaster of Paris (POP) for fracture immobilization [113]. Indeed, due to its cost, accessibility and limited implant availability, casting is regularly applied in African countries [23]. Concerning closed injuries, yet not open injuries, where instability can favor infection, and wound care is rendered difficult due to casting, correcting alignment defects and maintaining stable reduction are not optimal [23]. Given this context, EF remains the method of choice for fracture treatment [210]. EF is a simple technique provided that it is used selectively, and the basic principles are being followed [22].

When strictly adhering to the basic EF principles, we discovered that it was possible to largely annul the need for expensive branded frames, as well as to a certain extent, the use of costlier and more demanding implants [22]. The high costs of the commercially available devices are a dilemma for orthopedic and trauma surgeons when they are confronted with patients in need who are unable to afford optimum medical care. One way to circumvent this issue is to reduce the cost by manufacturing themselves a typical fixator that is more affordable. This could be rendered possible by varying the material chosen for manufacturing the fixator, overall product finish, and overall design[49]. Locally-developed EFs (LDEFs) enabled us to tackle this problem. The new EF design is based on numerous essential considerations, including biomechanical evaluation, cost, and effectiveness [49]. Biomechanical considerations in designing EFs involve several factors that include pin and frame characterization, structural and material properties, and osteogenic effects[49]. Whereas the construct stiffness remains the decisive factor, these other factors are instrumental in correcting bony alignment under mechanical load. When used for definitive fracture management, sufficient stiffness is needed as well in order to foster sound callus formation and avoid non-union [147]. Another essential biomechanical consideration is the loading pattern during healing[211]. Regarding long-bone healing of the leg as illustration, contraction of dorsiflexors and plantar flexors create anterior-posterior bending moments, in addition to medial-lateral ones, all around the fixation and fracture complex.

Furthermore, partial or full weight bearing results in both axial compressive and torsional effects. Likewise, loading patterns during gait are an essential consideration with respect to the fixator design, given that the higher loads or shifting loads that occur during walking create greater moments around any fixator device used for the lower limbs [49]. This precious information has been incorporated into the biomechanical testing protocol of new LDEFs. The results have revealed a comparable rigidity and stability. Besides biomechanical considerations, the relationship between economical and clinical considerations must also be taken into account when designing EFs. In DCs, cost is a most critical factor to be considered when making treatment decisions [22]. Therefore, reducing the manufacturing cost of an external fixator could be rendered possible by varying the material selected for varying the fixator, in addition to altering overall product finish and design complexity [49]. The materials ande tools required for our LDEF design are easily available in DCs. The overall cost in manufacturing the new LDEF without the pins is in the range of 28.78 - 29.5 euros for biplanar (UBEF 1,2) and in that of 9.79-11.76 euros for monoplanar types (UUEF1,2). The national minimum wage in Ivory Coast being from 91.5euros, we postulate that LDEF is clearly accessible to all social strata. Regarding financial terms, we strongly believe the LDEF cost is to be considered as a fair overall compensation for the recurrent visits, cast changes, and multiple radiographs conducted in the conservative group. The clinical study that was carried out during this thesis, which describes the clinical aspects of EFs for open tibial fractures (OTF), demonstrated an improvement in fracture healing, as well as functional results.

Whereas EF is not well tolerated and carries specific complications including pin tract infection, mal-union, and non-union, our results clearly show that it is a reliable and effective approach for managing open tibial fractures in austere environments [118],[144]. It has the added advantage that patients can be discharged early. This has been particularly helpful at our hospital, where bed shortage is a recurring problem. Another EF advantage is that a second operation for removing the device is not required, with additional implications for cost effectiveness and patients' morbidity. In our country with poor healthcare many patients unable to afford optimum medical treatment, such a trade-off proves to be valuable as a cheaper EF that provides simple basic fixation appears to be superior to either no treatment at all or using POP. We postulate that use LDEF offers a chance of substantially improving the quality of surgical fracture treatment.

Overall comparison between external fixators design

LDEF were designed based on the Meyrueis's fixator[142] and the Noor fixator [27]. However, the LDEF differs from the Noor model in several ways. The bar used in the LDEF design was made of stainless steel and has a certain resistance to corrosion, which is not the case with the Noor design which was made of galvanised iron. The design of the Noor fixator requires welding in certain places, which is a disadvantage compared to the LDEF, which does not need welding. The welding would result in additional costs, and a defect in the quality of the welding could compromise the effectiveness of the external fixator. Although the Noor fixator has been clinically tested [151], the lack of a biomechanical study is another drawback compared to the biomechanically validated LDEF. It should be noted that LDEF allows a biplane mount, thus adapted to different fracture patterns (simple and complex). This is not the case with the Noor fixator, which is designed as a monoplane. The LDEF is similar to the Meyrueis's fixator in several respects, notably the design and the materials used. However, the biplane design of the LDEF does not require the machining of specific parts such as collars, as is the case with the Meyrueis fixator. This results in additional costs for the Meyrueis fixator. On the other hand, the Meyrueis fixator offers several mounting possibilities. It is suitable for both diaphyseal and metaphyseal fractures. This is not the case with our LDEF. It has several complementary materials allowing the realization of several types of configurations on the bone, as well as dynamization.

These advantages of the Meyrueis fixator should be considered in improving further our LDEF in the future. LDEF has been validated biomechanically (static and fatigue test) and clinically, differs from those Doømres, Najeb and Musa external fixators [47, 48, 52] which have been clinically tested. It should also be noted that the materials used (wood and iron) in the design of the external fixators degrade rapidly with time, unlike the material used in the design of the LDEF. This limits the possibilities of reusing these different locally developed external fixators. In contrast, the Goh's external fixator[49] showed comparable good biomechanical stiffness. However, it has not been clinically tested. We postulate that LDEF remains an effective option in the treatment of long bone diaphyseal fractures (tibia, femur) in resource-limited countries.

Dynamization of LDEF

We noted a long time was required for consolidation due to the rigidity of our fixator. Dynamization of external fixators will certainly reduce the time for fracture union. The dynamization of osteosynthesis is a frequently used method to accelerate fracture healing[212]. The term dynamisation is used for procedures that allow a modification of biomechanical stabilisation by manipulating the rigidity and mobility of the osteosynthesis[212]. The most common type of dynamisation is the release of axial movements during intramedullary nail and external fixator osteosynthesis. The two bone fragments can move towards each other (telescopic movement) and put pressure on the fracture surfaces[212]. For the dynamization of the LDEF, we will machine a 60mm threaded rod which will be used to connect the external fixators as shown in the Figure 1 **(Fig. 1)**. Note that right- and left-hand threads will be machined on the ends of the fixator bars. Nuts are also available on the ends of the fixator bars to hold the dynamisation. After machining the parts, we will carry out a pilot study on 20 patients who will be treated with this dynamic external fixator. The objective will be to evaluate the delay to consolidation of the fractures.

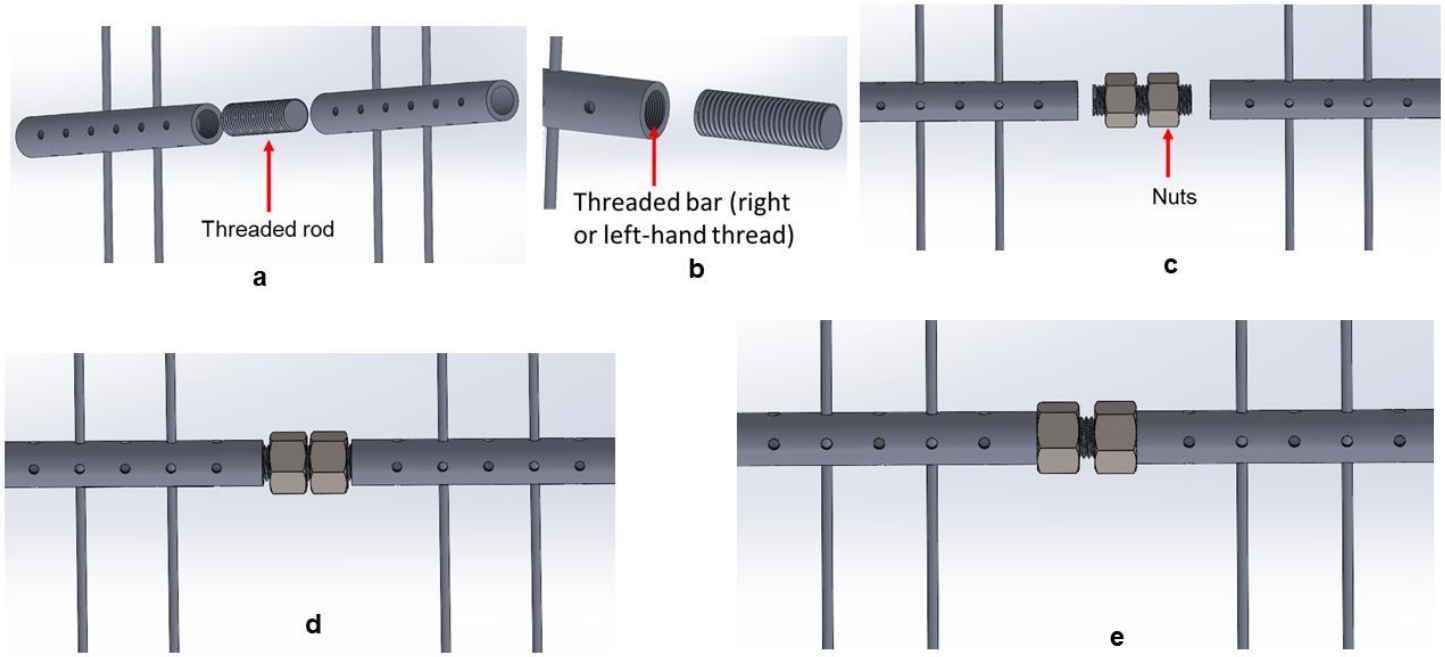

Fig. 1 Illustration of the dynamization of LDEF

Finite element analysis of LDEF

Many experimental procedures have been employed to study the characteristics of locally-developed external fixator (LDEF) [165]. These experimental procedures are important in establishing basic characteristics of external fixation devices[147, 164, 213, 214]. However, they can have some shortcomings, they are time consuming and costly. Indeed, any minor change in the LDEF device requires to rebuild the elements concerned by this change and equipping the LDEF with measuring instruments before performing the test again [215].

In order to avoid the problems associated with experimental tests, some researchers have carried out numerical simulations of the medical devices behavior[216]. In addition, numerical simulations allow to observe and quantify phenomena that experimental tests are unable to do, such as stress concentration phenomenon [216].

Numerical simulations of the LDEF device/tibia with a total loss of substance have therefor been considered. Preliminary studies were performed using Abaqus finite element software. Several tests were simulated: axial compression test, bending test and torsion test. These tests were similar to those performed during the experimental campaign tests. Concerning the compression test, we studied two cases of screw-pin contact:

- a perfect screw-pin contact (without sliding) **(Fig. 2)**
- a screw-pin contact with friction **(Fig. 3)**

This analysis showed that the distribution of stresses and their intensity depended strongly on the tightening pressure applied to the screws, as displayed in figure 2 and figure 3.

Indeed, any sliding of the pin (which would bring the pin closer to a rigid body movement) would lead to a reduction of stresses intensity on it.

Generally, for the case of a screw-pin contact with friction (which best corresponds to the case of operation of the device in real conditions), the analysis of the results of the various numerically simulated tests showed that the threshold of the limit stresses in the bone and steel materials constituting the device was never reached. We can therefore conclude that this medical device fulfills its functions.

As a perspective for this numerical study, we propose the following points:

1- Evaluate the clamping force that would both immobilize the bone and guarantee a stress intensity that respects the admissible stresses of the used materials.

2-introduce the constitutive laws of materials in a non-linear regime: The plastic behavior for metals and damage one for the bone.

3-study the LDEF-bone device under fatigue tests.

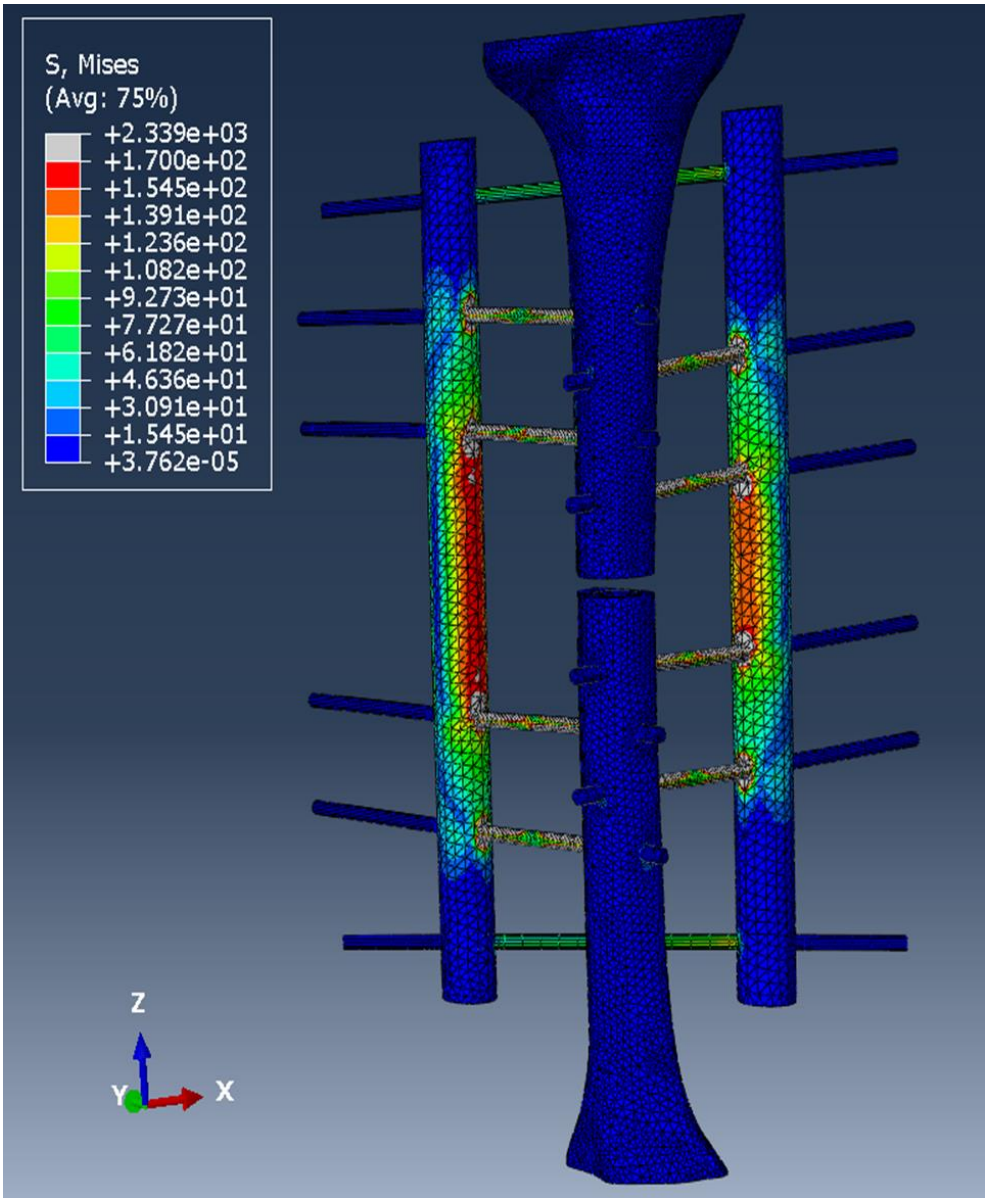

Fig. 2 perfect screw-pin contact

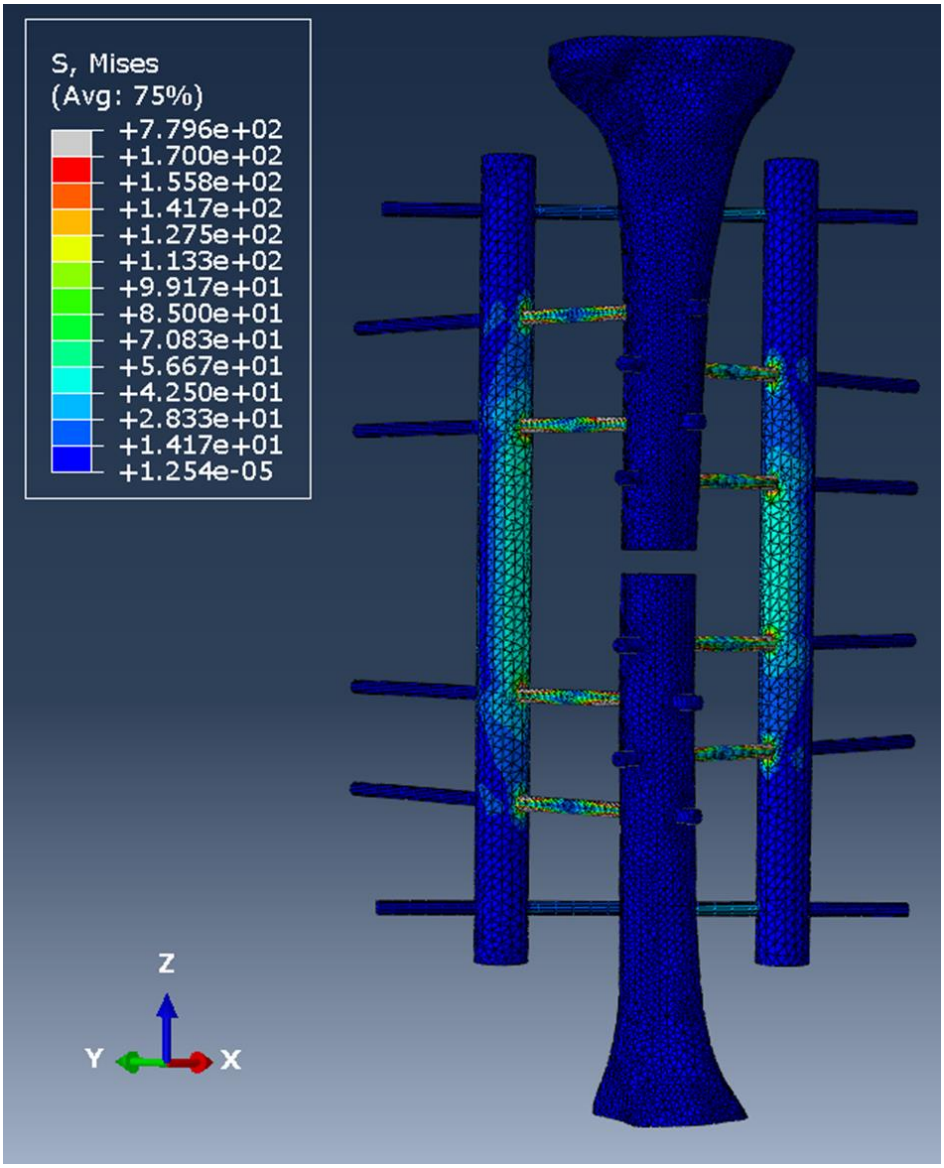

Fig. 3 screw-pin contact with friction

Classification of open fractures

All open fractures are by definition contaminated and must be treated as such. The treatment methods differ depending on the fracture type [10]. For open fractures, the Gustilo and Anderson classification is the most widely used [8]. These authors classified open injuries into three categories based on wound size, contamination level, and osseous damage as follows: (I) wound ≤1cm, minimal contamination or muscle damage; (II) wound 1–10cm, moderate soft-tissue injury (without extensive soft-tissue damage, flaps, or avulsions); (IIIa) wound usually >10cm, high energy, extensive soft-tissue damage, contaminated, adequate tissue for flap coverage, and farm injuries; (IIIb) extensive periosteal stripping, wound requires soft-tissue coverage (rotational or free flap); (IIIc) vascular injury requiring vascular repair, regardless of degree of soft-tissue injury [217]. The incidence of wound infection correlates directly with the fracture grade: Type I (0%–2%); Type II (2%–7%); Type IIIA (7%); Type IIIB (10%–50%); Type IIIC (25%–50%)[217],[218]. As with all classification systems, reliability of the classification and agreement among observers is an issue. A study evaluating the responses of orthopedic surgeons who were asked to classify open tibia fractures based on a videotaped case presentation reported an average agreement among observers of 60% [219]. We must remember that the true injury extent and severity cannot be accurately assessed in the emergency department. As a result, a Type IIIA open fracture with a small-sized wound may be misclassified as either Type I or II open fracture and treated as such. The degree of contamination and soft tissue crushing are essential factors for classifying an open fracture that may be mistakenly overlooked within a small-sized wound. Therefore, fracture classification should be performed in the operating room, immediately following wound

exploration and debridement. In addition, the classification system does not consider the extent of soft-tissue injury; therefore, the evaluation of long-term tissue viability is likely to be restricted [3]. This classification displays some value as a prognostic indicator and appears to be a useful guide as for treatment. Other classification systems may, however, be superior in classifying open fractures and the severity of associated soft-tissue injuries [3]. The Orthopedic Trauma Association (OTA) open fracture classification system, which was proposed by Agel et al., considers five categories when assessing injury severity, as follows: skin injury; arterial injury; muscle injury; contamination; bone loss [220]. This systematic approach focused on the injury's pathological anatomy is believed to be applicable to open bone fractures in both adult and pediatric cases [220]. The inter-observer reliability of the new system demonstrated favorable results in comparison with the Gustilo-Anderson system [221] and good predictive abilities in guiding treatment [222]. Compared to the Gustilo-Anderson classification, the OTA was superior in predicting treatment outcome and limb amputation requirement [223]. In daily practice, however, the OTA has not been widely accepted due to its scoring system's complex nature [223]. While this system appears to be an improvement over the standard AO classification of fractures and soft-tissue injury, more time is needed to better assess its efficacy in real-life applications [3]. Regardless of classification methods used, the overall treatment considerations should be guided by the individual clinical picture and established standards.

Use of antibiotics in open tibia fractures

Antibiotic administration in open fracture management should be automatic with early timing being paramount, ideally within 1 hour or perhaps even 3 hours of injury [10, 217]. Preoperative antibiotic prophylaxis was performed systematically upon admission of patients to our hospital. The risk of infection has been shown to decrease six-fold with this practice[10]. With the propensity for gram-positive infections in Type I and II fractures, a first-generation cephalosporin is generally recommended. Several authors have advocated adding gram-negative coverage, as well [10, 224]. Type III fractures often display contamination with gram-negative organisms, and in the case of soil-contaminated wounds (*i.e.,* farm injuries), additional coverage for anaerobic bacteria should be added [10]. The administered antibiotics consisted of tri-antibiotic therapy, combining third-generation cephalosporins, imidazol drugs, and aminoglycosides, for the Gustilo type II and III. For Gustilo type I, administered antibiotic consisted of mono-antibiotic therapy made up of third-generation cephalosporin. Several reasons justify this choice. In our setting, the open tibia fractures were contaminated with soil. Following patient admission, the surgical treatment was essentially carried out following 24 hours post- trauma. One reason for this was that the patient or its close relatives had first to gather the means for purchasing the drugs necessary for the surgery, except for the external fixator that was provided free of charge. Concerning open fracture treatment in the hospital setting, the surgeon must also be wary of nosocomial infections, including *Staphylococcus aureus* and aerobic gram-negative bacilli like *Pseudomonas aeruginosa* [10].

Specific antibiotic coverage for these organisms can be indicated. Quinolones have been proposed as an oral alternative to intravenous antibiotics, based on their broad-spectrum antimicrobial coverage, bactericidal properties, oral administration, and good tolerance. A randomized prospective study revealed that ciprofloxacin as a single agent in Type I and II open fractures resulted in a similar infection rate (6%) compared with cefamandole and gentamicin combination therapy [225]. However, in Type III open fractures, ciprofloxacin was associated with a higher infection rate of 31% compared with 7.7% in the combination therapy group [225]. Quinolones that are excellent agents against gram-negative pathogens are considered an alternative when aminoglycosides are unavailable. The duration of antibiotic therapy for open fracture management has been suggested to range between 1 and 3 days for Type I and II , and be of 5 days for Type III [226],[227]. We typically maintain antibiotic coverage until 5 days. No antibiotic can replace proper surgical management [228], and whereas microbial and pharmacological races will continue because of growing bacterial resistance, bacteria are unlikely to develop resistance to surgical steel [206]. A definitive statement of the "best" antibiotic regimen in open fractures will never be possible, given the dynamic and evolving nature of the problem. It is, therefore, critical that the orthopedic surgeon stay mindful of the historical context of each study when reviewing the literature; he must also be aware of the changing resistance patterns and available antimicrobials in the geographical area of his practice so as to target prophylaxis appropriately [206].

Techniques for skeletal stabilization in open tibia fractures

Early stabilization of open fractures provides many benefits to the injured patient. It protects the soft tissues around the injury zone by preventing further damage from mobile fracture fragments [10]. It also restores length, alignment, and rotation, which are all vital principles of fracture fixation [10]. This restoration of length also helps decrease the infection rates in open fractures [133]. Lastly, early fixation enables improved access to soft tissues surrounding the injury and facilitates the patient's early return to normal function [10]. The surgeon must decide among several fixation constructs, including external fixation, intramedullary nails, and plates. Open reduction and internal fixation of open tibial shaft fractures with plates and screws has fallen out of favor because of concerns regarding potential damage to periosteal blood supply and high complications rates, especially infection and exposed hardware [229]. Bach and Hansen reported severe osteomyelitis in 19% and hardware failure in 12% of Gustilo Type II and III open tibia fractures managed using plate osteosynthesis [230]. In a larger series involving 97 open tibial fractures, Clifford et al reported a significantly higher infection rate in Type III open fractures (44.4%) compared with Type I and II open fractures (5.4% and 7.8%, respectively) [231]. Although newer plating techniques, particularly minimally-invasive plate osteosynthesis (MIPO), seem promising towing to limited iatrogenic soft-tissue damage, no study has yet evaluated these newer techniques in the treatment of open tibial shaft fractures [229].

Although plate fixation has only a limited role in the definitive management of open tibial shaft fractures, plate stabilization has proven useful in a temporary setting. Provisional stabilization of open tibial shaft fractures with a 3.5mm limited-contact dynamic compression plate placed, which is through the traumatic wound and secured with unicortical screws, is instrumental in maintaining reduction during insertion of an intramedullary (IM) nail [232]. The plate is removed after the IM nail is locked. IM nailing is a safe, effective method of stabilization for open tibial shaft fractures. This technique offers a biomechanically superior fixation that maintains length, alignment, and rotation through static interlocking. In addition, this method enables early weight bearing and adjacent joint motion [229]. A review of the literature on the treatment of open tibia fractures found a union rate of 95% for un-reamed nailing (53% Gustilo Type III fractures) and 97% for reamed nailing (43% Gustilo Type III fractures)[229]. The choice of whether to use reamed or un-reamed interlocking nails continues to provoke debate [175]. Reaming has been suggested to enable insertion of larger diameter nails and increase stability [3]. Nevertheless, this may be achieved at the cost of damaging endosteal blood supply and diminishing cortical wall thickness [137, 233]. Un-reamed nailing shows comparable outcomes than reamed nails in terms of infection rates [229, 233], risk of nonunion, and rates of re-operation [234]. These conclusions were confirmed by a Cochrane database review, demonstrating insignificant differences in complication rates between reamed and un-reamed nailing [235]. In recent years, primary IM nailing has gained wide acceptance in open tibial fractures in developed countries [177].

However, even in expert hands, IM nailing is associated with infection issues (especially in Type IIIB fractures) and delayed union [236]. Although several reports originating from the developed world have shown IM nailing to be associated with good results, it appears difficult to extend these data to DCs, where patients consult rather late, and adequate facilities are not always available[177]. In austere environments, there is a greater risk of infection, while concerns regarding sterility lead many surgeons to minimize the use of internal implants in order to limit the risk of wound infection [176]. Our region has witnessed a surge in open tibial fractures due to the increased number of motorbikes on the roads. Our hospital, as the major orthopedic center in the interior of country, has been receiving the bulk of these patients. Our poor results with conventional casts and the unavailability of image intensifiers in the emergency operation theatre, coupled with the huge patient burden on the hospital, has prompted us to use the external fixation as a treatment option for open diaphyseal tibial fractures. The safe choice of skeletal stabilization for open long bone fractures in developing or resource-poor countries remains external fixation. This is especially true when the injuries are of high-energy variety, along with heavy contamination compounded by late presentation [237]. External fixation offered two advantages over internal fixation. First, this choice enabled rapid fracture stabilization. Second, the lack of hardware implantation at the open injury site limited further soft-tissue damage [229]. A meta-analysis reported a union rate of 94% at a mean of 37 weeks, as well as an overall infection rate of 16.2% with EF [2]. Chronic osteomyelitis reportedly developed in 4.2% of fractures[2]. Despite acceptable union rates, high complications rates have plagued most reported series, which are most commonly the result of pin loosening and pin tract infection [2, 229].

Timing of wound closure

Options for wound closure in managing open fractures include primary skin closure, split-thickness skin-grafting, and using either free or local muscle flaps [10]. Traditionally, immediate closure is defined as wound closure at the initial surgical intervention. Early closure is within the 24–72 hour window, and delayed or late closure extends beyond 3 days [10]. Our recommendation advocates primary closure of Type I, Type II, and a few selected Type IIIA fractures. The most critical factors in our decision-making process is the adequacy of the initial debridement and degree of wound contamination. Delong et al. have observed that patients who underwent immediate closure exhibited shorter hospital stays, decreased health care costs, and, most importantly, equivocal infection and fracture union rates compared with those who underwent delayed closure [238]. Primary closure is safe in the context of adequate debridement [239]. An additional argument favoring early closure is the finding that only 18% of infections following open fractures arise from the same organisms than isolated perioperatively, suggesting that most infections are acquired in hospital and thus more likely to affect wounds that are left open [225]. In modern reconstructive units within well-provisioned healthcare facilities, soft tissue reconstruction is individually tailored to the wound, available and reliable flap sources, associated injuries, and specific rehabilitation goals for each patient [240]. In low-resource settings or austere environment, however, the choices for soft tissue coverage methods are restricted.

Factors that affect treatment decisions include the surgeon's expertise and available resources (*e.g.,* surgical equipment, antibiotics, laboratory analysis facilities and number of available beds)[241-243]. For these reasons, the simplest solution for coverage is always preferred [241-243]. Transposition or rotational, fascio-cutaneous flaps and muscle flaps are the two types that are mostly used, regardless of injury location or cause [242]. Since these flaps do not require pedicle dissection, this procedure could be readily performed by surgeons with no specialized training in plastic surgery [242]. Free flaps were never chosen because of absent training and expertise in free tissue transfers. Furthermore, free flaps require lengthy operative times, which likely jeopardizes the operating room activity in our center, as we do not have several operating theaters. The flap is an essential initial treatment for fighting against infection, especially when only poor technical and medicinal resources are available [244]. This simple and reliable technique has numerous indications in war surgery and low-resource settings [241]. In fact, two main flaps should be considered by the orthopedic surgeon for leg coverage in precarious conditions, including the muscular or myo-cutaneous gastrocnemius flap and sural flap. These flaps are able to cover most defects on the leg. Amputation should be discussed when the treatment appears too long, which renders its management at field hospitals difficult [244].

Problem of pin tract infection

Pin tract infection (PTI) and pin loosening are the major complications associated witg EF of fractures. The infections likely decreases the stability of pin-bone interface. Conversely, instability of the fixator-pin-bone construct can lead to pin loosening and infections [245]. There is no universally accepted protocol for the optimal care of pin sites [245]. The appropriate time to commence pin track care varies greatly in the literature, with published times ranging from 24 hours to 10 days [245-249]. The frequency of pin track cleaning also differs, with authors suggesting once daily [249, 250], twice daily [247, 251], weekly [249], or only when required[252]. Various cleaning solutions are advocated in the literature, including soap and water, sterile water, normal saline, peroxide, polyvinylpyrrolidone iodine, isopropyl alcohol and chlorhexidine [245]. In our study, PTIs were treated by cleaning each pin-site with a sterile pad application soaked in Dakin cooper, along with new daily dressing. Oral antibiotics (amoxicillin-clavulanic acid 1gr x 3 per day) were prescribed for 5 to 10 days. If the infection persisted, a culture of the site was carried out, and the antibiotic was adapted according to antibiogram results. X-rays were performed to assess if pin loosening had occurred. Loose pins would immediately be removed and not be replaced. Pin tract infection is an almost inevitable complication with EF use, which remains a clinically challenging problem. Standardized pin site protocols that encompass an understanding of external fixator biomechanics and meticulous surgical technique during pin insertion, along with postoperative pin site care and removal could indeed limit the incidence of major infections and treatment failures.

Based on the results revealed in this thesis, we recommend as a preventive approach for pin tract infection that pins are inserted after pre-drilling with sharp drills using sleeves to protect soft tissues. The care around the pins is performed three times a week by cleaning each pin site with a sterile pad soaked in a solution of povidone iodine (Betadine dermal). Upon healing of the operative wound, daily showering is encouraged with the device when patients remove the dressings, enabling water to rinse the frame, while using an antibacterial liquid soap. The leg and frame are dried using a clean towel. However, when a patient suffers from a pin tract infection, we recommend daily use of dilute sodium hypochlorite (Dakin's) soaked on a sterile pad as a dressing solution around the wires, as well as the use of oral antibiotics like amoxicillin-clavulanic acid 1gr three times per day on 5 to 10 days. In addition, the patient is encouraged to reduce his activities, while weight bearing associated with elevation of the limb (in case of swelling) is recommended. As many questions remain as to how effectively reduce the risk of pin site infections in patients treated with pins, the surgeons and nursing staff should adopt a uniform pin care protocol that works for their patients and can be taught to everyone involved in patient's care. Using a consistent protocol likely helps ensure that the patient is not receiving different information from different members of the healthcare team. This is indeed a common problem that can lead to confusion and loss of confidence. Providing patients with a handout describing the pin site care protocol is an effective way that allows for communicating to home nursing and family members that are involved in the pin site care.

Conclusion

Overall, this thesis probably lays the foundations for discussion and thoughts about the resource allocation and the cost-effectiveness of managing open tibial fractures in our country. It highlights the difficulties of managing open tibia fractures in our hospital. The LDEF made from available materials, which is easily accessible as well as biomechanically and clinically validated, has significantly improved the treatment of open tibia fractures in our health center. This thesis has demonstrated the usefulness LDEF as definitive fixation option for a wide variety of open diaphyseal tibial fractures, in a cost-effective manner, in our hospital. At the end of this thesis, we issue the following recommendations **(Fig. 1)** for managing open leg fractures in resource-limited settings:

- Start antibiotic prophylaxis as soon as the patient is admitted to the emergency department. Choose antibiotics targeting Gram-positive, Gram-negative, and anaerobic germs. We recommend a tri-antibiotic therapy combining a cephalosporin, an aminoglycoside, and an imidazole over 5 days for Gustilo II and III. For Gustilo type I, we recommend mono-antibiotic therapy made up of cephalosporin.
- Take a photography of the wound, then cover it with a sterile bandage.
- Tetanus prophylaxis must be carried out according to the patient's vaccination status, involving immunotherapy (250 IU of specific human immunoglobulins) and vaccination to be carried out for patients who have never been vaccinated.
- Debridement should be performed as soon as possible of the admission.
- Fractures should be restrained using an EF.

- Immediate coverage should be favored using simple techniques (suture, fasciocutaneous flaps, or muscular) for Type I, II and IIIa, IIIb fractures.
- For Type IIIc fractures, do not rule out primary amputation as a treatment option.
- A sterile compress dressing soaked in povidone-iodine (Betadine yellow) should be applied to the surgical wound and to the wounds around the plugs every two days.
- The patient should be invited to regularly clean the external fixator components.
- Pin tract infections should be identified and treated, preferably with a daily Dakin dressing.
- All loose pins must be removed, with the assembly to be modified as necessary.

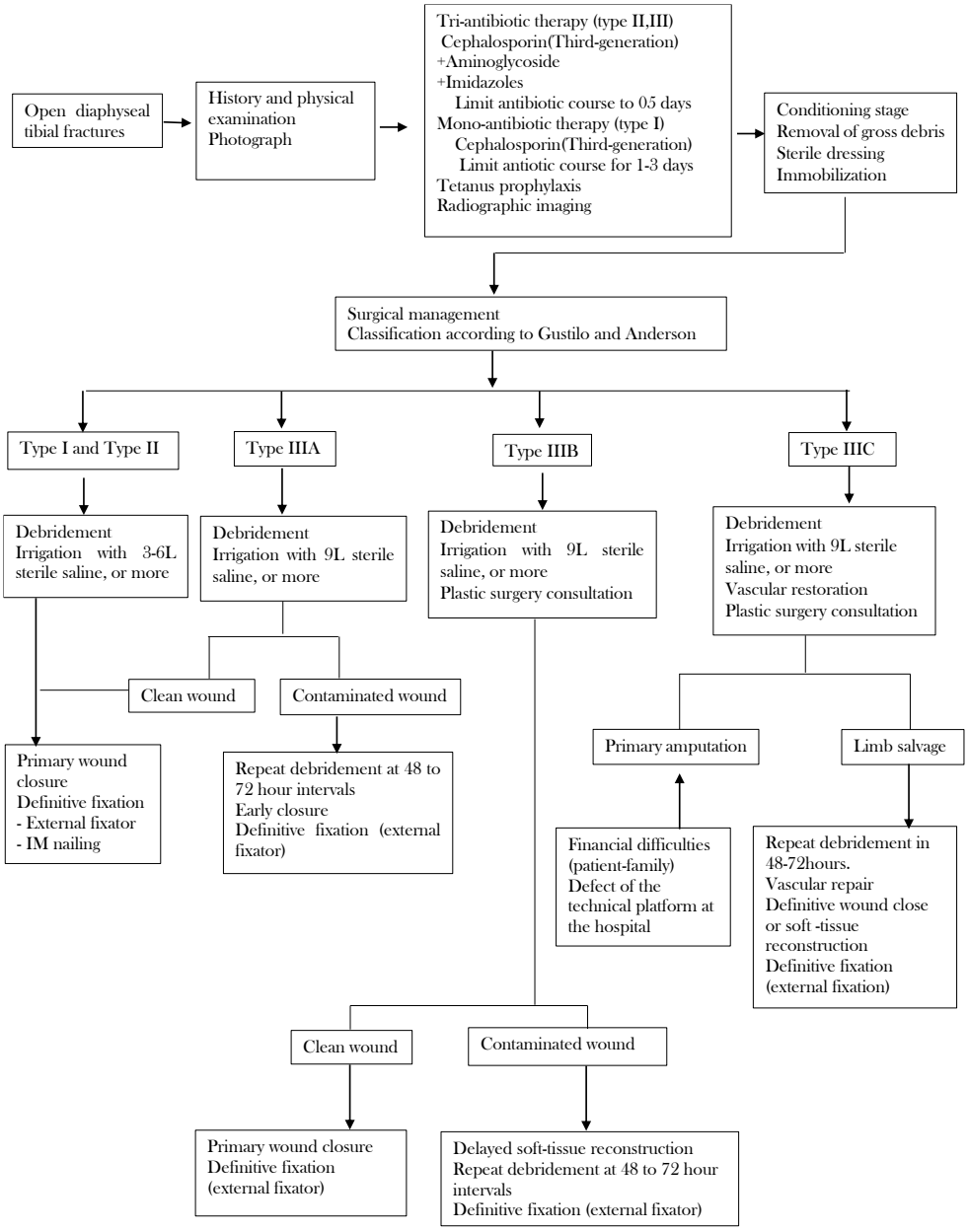

Fig. 1 Treatment algorithm for open diaphyseal tibial fractures in a limited resource environment.

Perspectives

Furthermore, additional research is required to fully evaluate and quantify the socioeconomic impact of open tibia fractures in Ivory Coast. This will help highlight disease burden and also inevitably lead to increased investment into primary prevention strategies and treatment options. This opens up prospects for other explorative studies. The observation that distances are long, with ambulances rarely available, is unlikely to change in the foreseeable future. For the time being, it appears more feasible to exploit any reserves available for shortening the period between sustaining an open fracture and its operative treatment by optimizing the management of these injuries inside the hospital. This approach requires formally paving the way for open fractures from casualty to operating theatre, while raising the awareness of all medical personnel concerning the emergency degree of these cases and by providing rules for their management that enable paramedics, nurses, and doctors to perform the right intervention without unnecessary waiting for academic-decision-making. It appears crucial here to overcome the widespread opinion that orthopedic emergencies are not as urgent as those pertaining to general surgery. This option is so common because general surgery has been undertaken for much longer at these hospitals than has operative fracture treatment. In most DCs, only very few hospitals at tertiary care level are likely to dispose of orthopedic or trauma surgeons. Hospitals in remote regions, however, must rely on general surgeons and other doctors to provide damage-controlling, primary operative treatment for open fractures including POP immobilization. We must succeed in training orthopedic surgeons so that they

are able to perform the initial debridement of open fracture wounds and apply an external fixator as an emergency procedure that should be available day and night. We also need to train them in orthoplastic techniques in order to ensure coverage of open lesions.

One of the most problems during the application of LDEF is the difficulty in visualizing the fracture line when realization control X-rays in front and side view, because it is covered by the frame. To overcome this inconvenience, it is necessary to perform supplementary oblique views that can be difficult to interpret. The design of the external fixator with radiolucent bars could be a solution to this problem. This also opens up prospects for other explorative studies. Another perspective is the modelling of the dynamic external fixator by the finite element method. In this way we could perform a theoretical analysis and finite element simulation of dynamic external fixator -bone system rigidity on healing progression.

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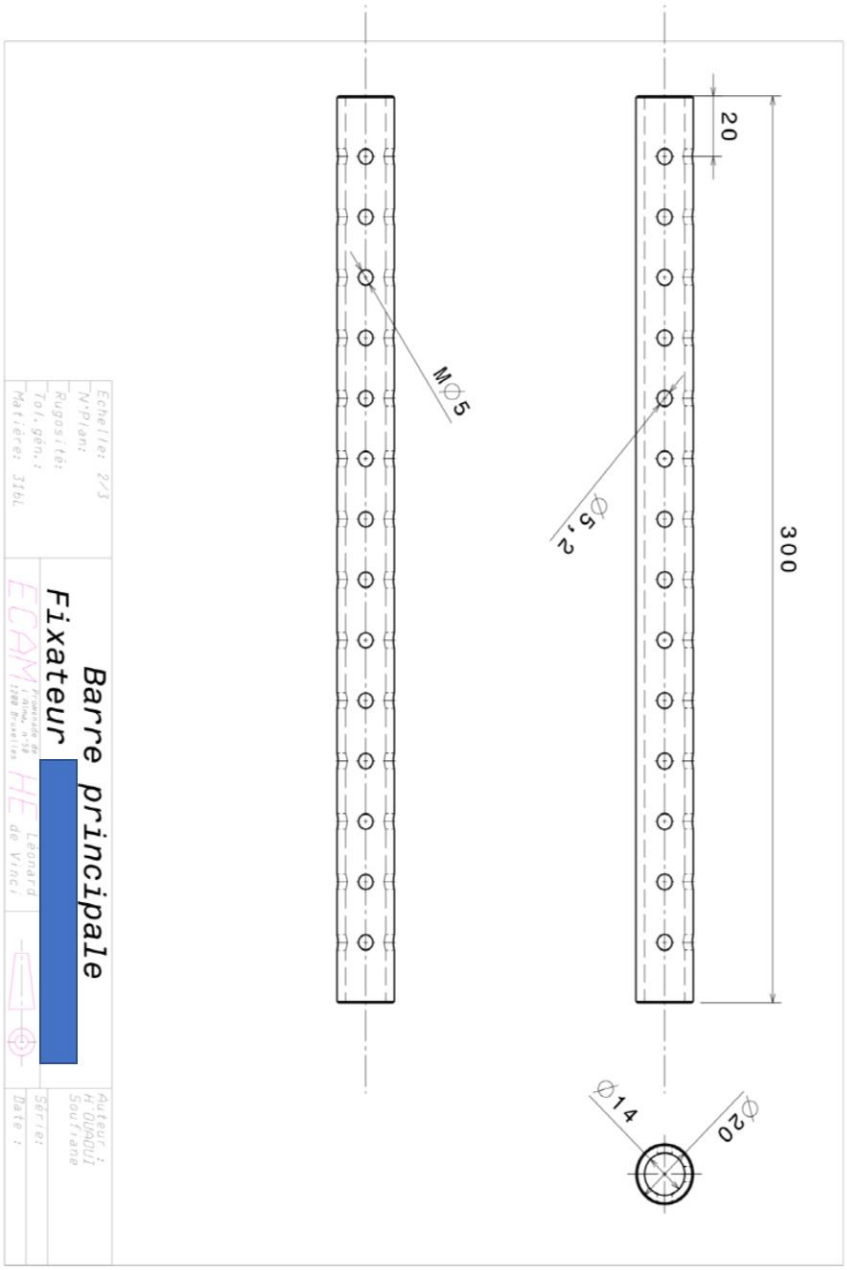
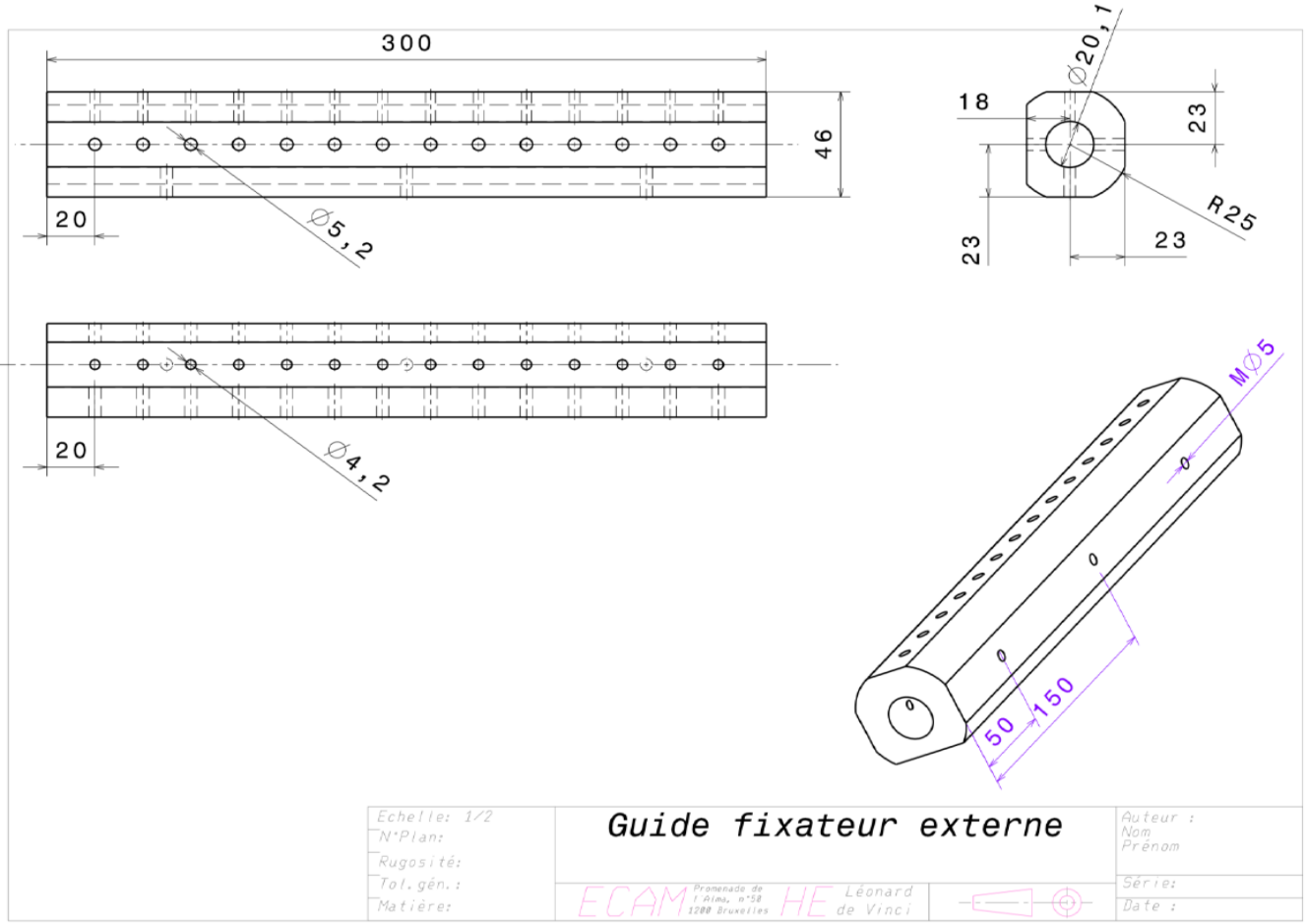
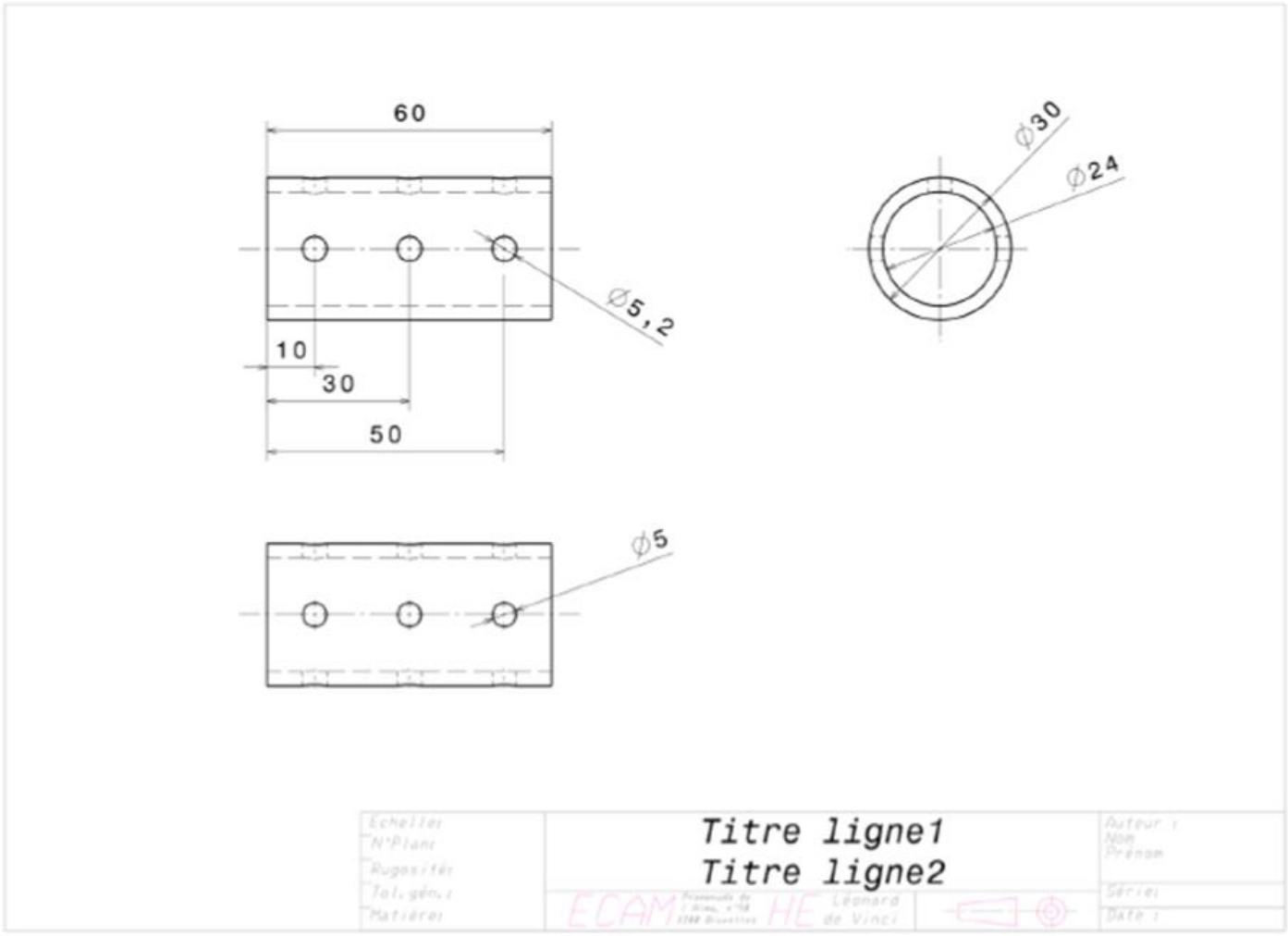
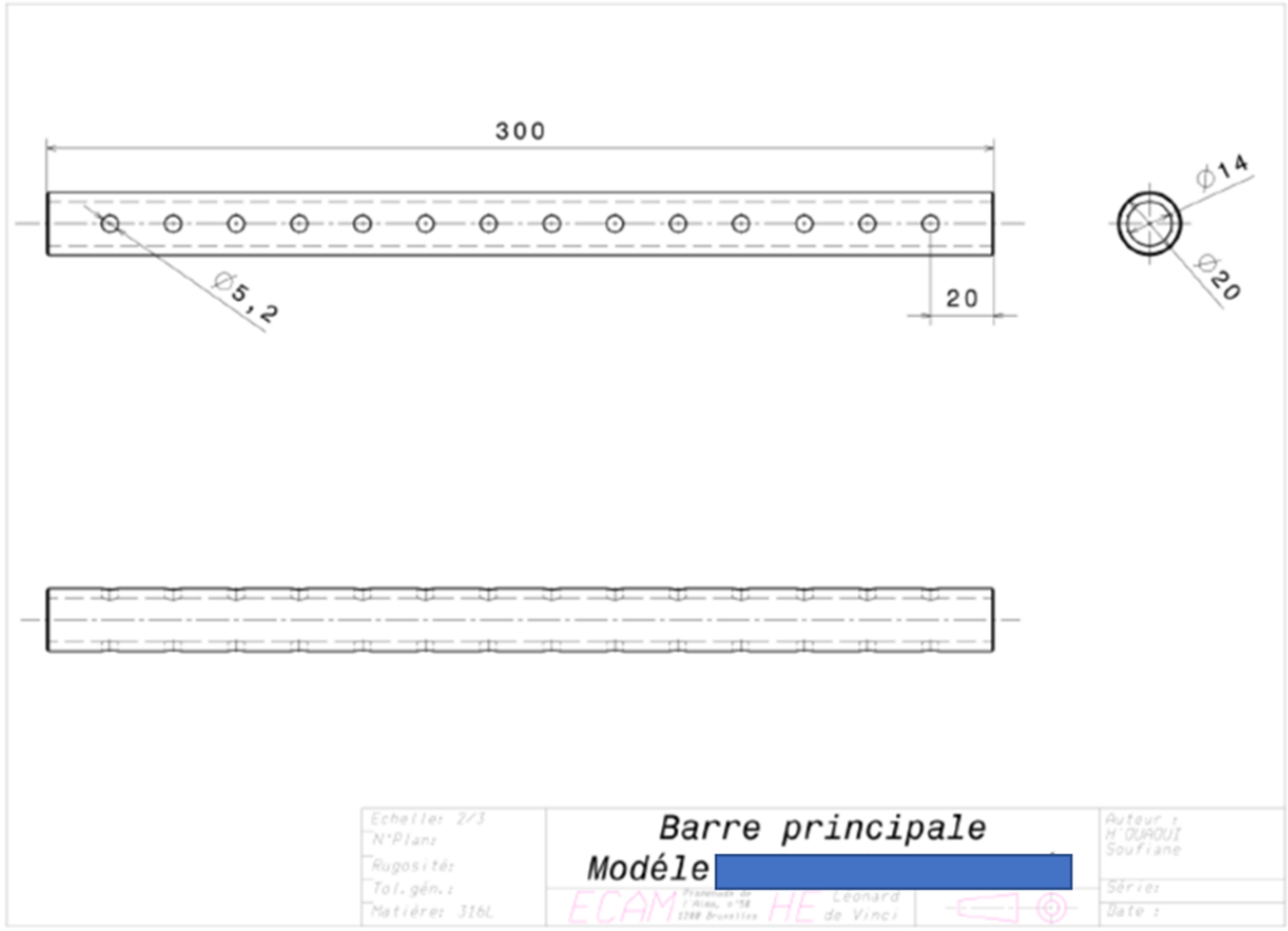
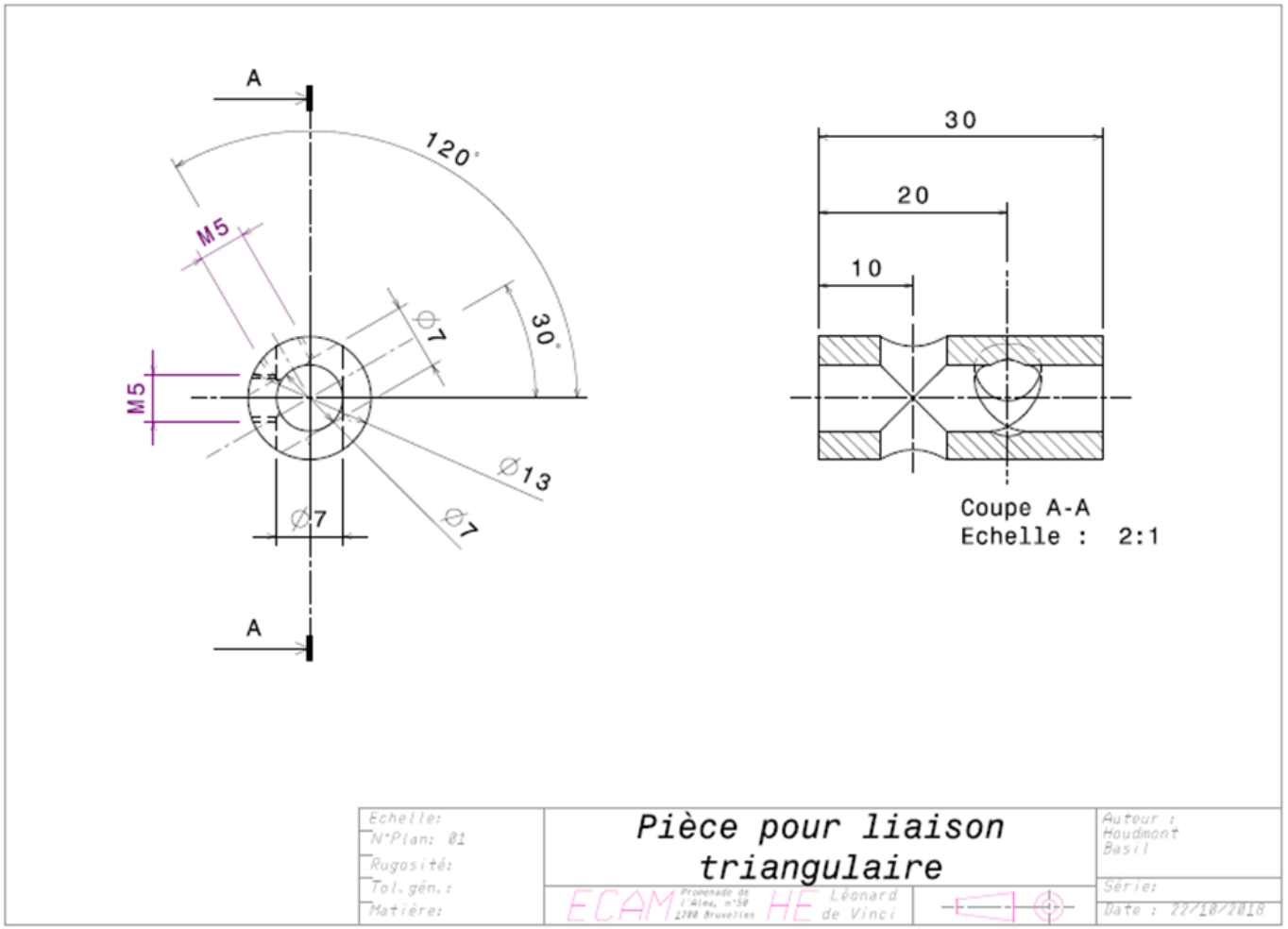
Appendix

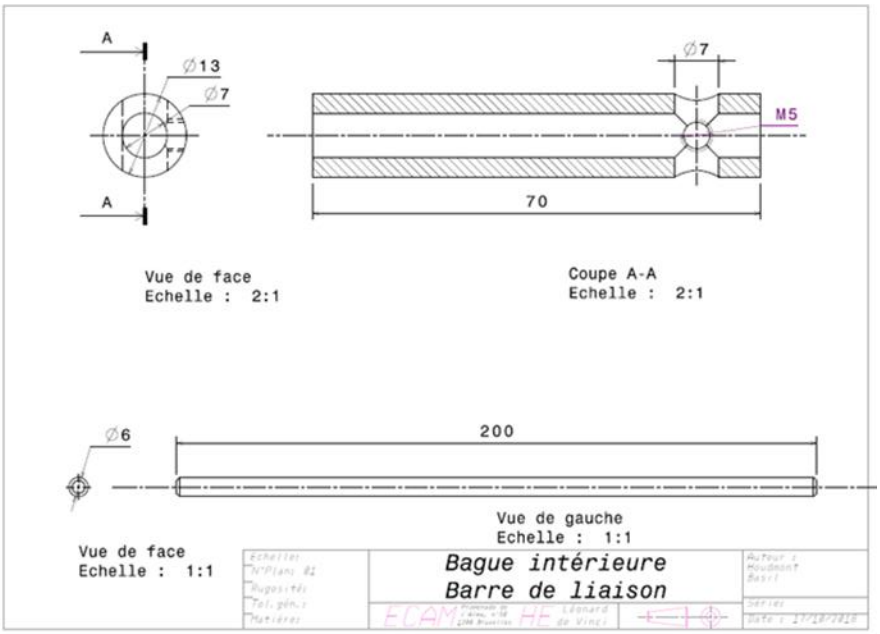

Barre principale
Fixateur
Echelle: 2/3
N°Plan:
Rugosité:
Tol.gén.:
Matière: 316L
Auteur: H'DHAOUI Soufiane
Série:
Date :
ECAM
Léonard de Vinci
20
300
M∅5
∅5,2
∅14
∅20

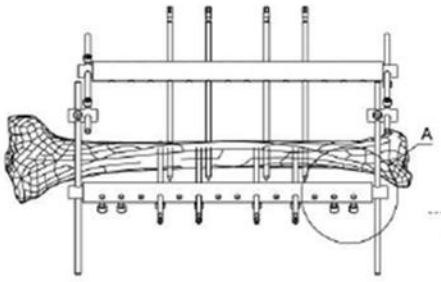

300
46
20
Ø5,2
20
Ø4,2
Ø20,1
18
23
R25
23
23
M Ø5
50
150
Echelle: 1/2
N°Plan:
Rugosité:
Tol. gén.:
Matière:
Guide fixateur externe
ECAM Promenade de l'Alma, n°58 1200 Bruxelles HE Léonard de Vinci
Auteur :
Nom
Prénom
Série:
Date :

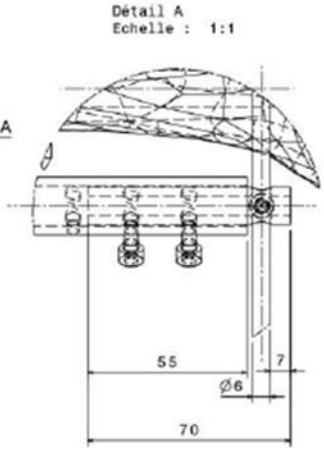

60
10
30
50
Ø5,2
Ø5
Ø30
Ø24
Echelle:
N°Plan:
Rugosité:
Tol. gén.:
Matière:
Titre ligne1
Titre ligne2
ECAM
Léonard de Vinci
Auteur :
Nom
Prénom
Série:
Date :


300
Ø5,2
20
Ø14
Ø20
Barre principale
Modéle
Echelle: 2/3
N°Plan:
Rugosité:
Tol.gén.:
Matière: 316L
Auteur :
H'OUAQUI
Soufiane
Série:
Date :
ECAM HE Leonard de Vinci


A
120°
M5
M5
Ø7
30°
Ø13
Ø7
Ø7
A
30
20
10
Coupe A-A
Echelle : 2:1
Echelle:
N°Plan: 01
Rugosité:
Tol.gén.:
Matière:
Pièce pour liaison triangulaire
ECAM
Promenade de l'Alma, n°50 1200 Bruxelles
HE
Léonard de Vinci
Auteur :
Houdmont
Basil
Série:
Date : 22/10/2018


A
∅13
∅7
A
∅7
M5
70
Vue de face
Echelle : 2:1
Coupe A-A
Echelle : 2:1
∅6
200
Vue de gauche
Echelle : 1:1
Vue de face
Echelle : 1:1
Bague intérieure
Barre de liaison
ECAM
HE Léonard de Vinci


A
Vue de face
Echelle : 1:3


Détail A
Echelle : 1:1
55
7
∅6
70

QUESTIONNAIRE DE LA QUALITÉ DE VIE (forme abrégée) SF-12

1. Dans l'ensemble, pensez-vous que votre santé est :

☐ 1 Excellente ☐ 2 Très bonne ☐ 3 Bonne ☐ 4 Médiocre ☐ 5 Mauvaise

2. En raison de votre état de santé actuel, êtes-vous limité pour :

• des efforts physiques modérés (déplacer une table, passer l'aspirateur, jouer aux boules)?

☐ 1 Oui, beaucoup limité ☐ 2 Oui, un peu limité ☐ 3 Non, pas du tout limité

• monter plusieurs étages par l'escalier ?

☐ 1 Oui, beaucoup limité ☐ 2 Oui, un peu limité ☐ 3 Non, pas du tout limité

3. Au cours de ces 4 dernières semaines, et en raison de votre état physique :

• avez-vous accompli moins de choses que vous auriez souhaité ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

• avez-vous été limité pour faire certaines choses ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

4. Au cours de ces 4 dernières semaines, et en raison de votre état émotionnel (comme vous sentir triste, nerveux ou déprimé) :

• avez-vous accompli moins de choses que vous auriez souhaité ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

• avez-vous eu des difficultés à faire ce que vous aviez à faire avec autant de soin et d'attention que d'habitude ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

5. Au cours de ces 4 dernières semaines, dans quelle mesure vos douleurs physiques vous ont -elles limité dans votre travail ou vos activités domestiques ?

☐ 1 Pas du tout ☐ 2 Un petit peu ☐ 3 Moyennement ☐ 4 Beaucoup ☐ 5 Enormément

6. Les questions qui suivent portent sur comment vous vous êtes senti au cours de ces 4 dernières semaines. Pour chaque question, indiquez la réponse qui vous semble la plus appropriée.

• y a t-il eu des moments où vous vous êtes senti calme et détendu ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais • y a t-il eu des moments où vous vous êtes senti débordant d'énergie ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais • y a t-il eu des moments où vous vous êtes senti triste et abattu ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

7. Au cours de ces 4 dernières semaines, y a t-il eu des moments où votre état de santé physique ou émotionnel vous a gêné dans votre vie sociale et vos relations avec les autres, votre famille, vos amis, vos connaissances ?

☐ 1 Toujours ☐ 2 La plupart du temps ☐ 3 Souvent ☐ 4 Parfois ☐ 5 Jamais

Lower Extremity Functional Scale (LEFS) en Français (EFMI) : Echelle fonctionnelle des membres inferieurs

	ACTIVITÉS	*Extrêmement difficile ou incapable de réaliser l'activité*	*Beaucoup de difficulté*	*Difficulté modérée*	*Un peu de difficulté*	*Aucune difficulté*
a.	Faire vos activités habituelles au travail, à la maison ou à l'école.	0	1	2	3	4
b.	Participer à vos passe-temps, vos loisirs ou vos activités sportives habituelles.	0	1	2	3	4
c.	Entrer ou sortir de la baignoire.	0	1	2	3	4
d.	Marcher d'une pièce à l'autre à la maison.	0	1	2	3	4
e.	Mettre vos souliers ou vos bas.	0	1	2	3	4
f.	Vous accroupir.	0	1	2	3	4
g.	Soulever un objet du plancher, par exemple un sac d'épicerie.	0	1	2	3	4
h.	Effectuer des activités légères autour de la maison, par exemple laver le comptoir.	0	1	2	3	4
i.	Effectuer des activités lourdes autour de la maison, par exemple passer l'aspirateur.	0	1	2	3	4
j.	Entrer ou sortir de la voiture.	0	1	2	3	4
k.	Marcher une distance de deux coins de rue.	0	1	2	3	4
l.	Marcher une distance d'un mille (1.6 km).	0	1	2	3	4
m.	Monter ou descendre 10 marches (environ un étage).	0	1	2	3	4
n.	Vous tenir debout pendant 1 heure.	0	1	2	3	4
o.	Rester assis pendant 1 heure.	0	1	2	3	4
p.	Courir sur un terrain plat.	0	1	2	3	4
q.	Courir sur un terrain inégal.	0	1	2	3	4
r.	Changer brusquement de direction lors d'une course rapide.	0	1	2	3	4
s.	Sautiller.	0	1	2	3	4
t.	Vous retourner dans le lit.	0	1	2	3	4
Total de chaque colonne :						

Score :_____/80

Authorization from the hospital's ethics committee to carry out the clinical study

MINISTERE DE LA SANTE ET DE L'HYGIENE PUBLIQUE

CENTRE HOSPITALIER ET UNIVERSITAIRE DE BOUAKE

DIRECTION GENERALE

DIRECTION MEDICALE ET SCIENTIFIQUE

Réf. N° 033 - - -

REPUBLIQUE DE COTE D'IVOIRE

Bouaké, le 18/02/2019

Au
Dr. KOUASSI Kouamé Jean Eric
(Assistant Chef Clinique Service Orthopédie -Traumatologie)

Objet : réponse à votre demande d'autorisation de traitement chirurgical des fractures ouvertes de jambe par un fixateur externe localement développé

Monsieur,

Nous accusons réception de votre courrier en date du **18/02/2019** demandant notre accord pour mener une étude préliminaire sur 80 patients qui seront recruté aux Urgences Chirurgicales.

Nous venons par la présente vous donner notre accord pour cette étude.

Nous vous prions de recevoir, Monsieur, nos salutations distinguées.

Le Directeur Médical et Scientifique

Ampliations :
UA.....1
DAF.....1
CHRONO.....1