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Progress in development of external fixation devices for bone fractures healing

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Modern, highly technicized both professional and everyday life as well as active recreation lead to an increase of traumas. To the most common traumas belong bone fractures. Long-lasting healing process of traumas effects, particularly osteoarticular traumas, requires exclusion of patient from professional and social life. Hence the need of search for new method and modification of already existing ones for fracture healing. External stabilization belongs to such methods. In this paper we present a review of external fixators and related equipment. Clinical aspects and technical requirements as well as possible future trends of external stabilizations are discussed. Biomechanical and biological aspects of bone fracture union are also briefly investigated.

Key words: *external fixators, solutions, biomechanics, fracture healing*

1. Introduction

On January 13, 2000 in Geneva the World Health Organization (WHO) and the Secretary General of UNO declared the decade 2000-2010 as the "Decade of Bones and Joints". This evidently shows how seriously the problem of traumas touches the societies of the XXI-th century. There are many reasons leading to accidents and traumas; for instance, excessive velocity, aging of the population of post-industrial countries. One of the most frequent cases of traumas are fractures. Among many methods of fracture healing one can distinguish the methods of external stabilization. The traditional method of plaster cast has many drawbacks. To replace it, the method of external stabilization has been invented and developed, see Sec. 2. This system can be used to the stabilization of fragments of a fractured bone, osteosynthesis, during transport of patient and to improve muscular-skeletal deformations.

Proper union of fractured bone depends on suitable positioning and fixation of fragments of fractured bone. Unfortunately, plaster cast often fails to fulfil those requirements. In the case of plaster cast, the fixation involves soft tissues. Though patient is obliged not to load the damaged limb, yet often a shift of fragments of fractured bone occurs. Often observed muscle atrophy is an additional drawback of the plaster cast. Moreover, this type of fixation is not applicable to open fractures. Once the dressing is taken off, usually a long-standing rehabilitation is necessary. Unfortunately, in many cases the limb does not attain its previous efficiency. The drawbacks mentioned of the plaster cast have been known for a long time, and thus the search for more efficient methods of fracture healing has been initiated.

Fracture healing is undoubtedly one of the oldest method in the history of medicine [2]. However, still existing methods are improved and new methods are devised. Particularly, this pertains to currently most frequently used method of external fixation, see Fig. 1.

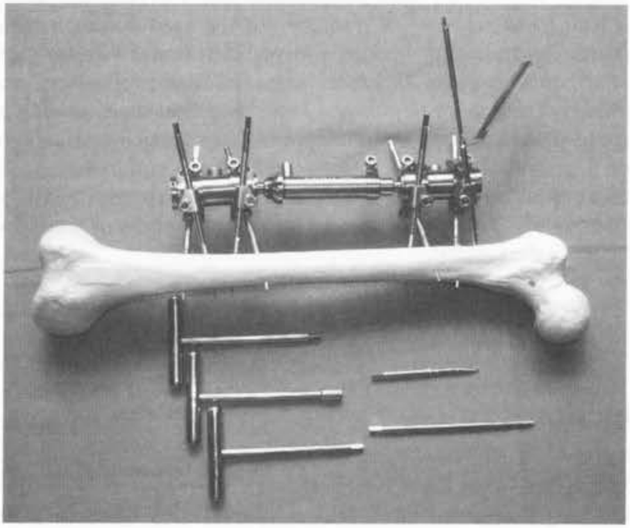


FIGURE 1. Illustrative example of the external fixator of new generation Dynastab Mechatronika 2000 jointly with the instrumentation.

External fixator is a device enabling a union of fragments of fractured bone, without interference into fractured zone or focus of inflammation. The principle of external stabilization is simple: loads are to be transmitted by an external system and not, or only partially, by fractured bone (fracture site).

Modern external fixators are devices with common characteristics assuring [5]:

- stability of fragments of fractured bone,
- possibility of compression (extension) between those fragments,
- equipment in bone grafts introduced at a distance from fractured site (bone gap, site of inflammation process).

External osteosynthesis based on usage of orthopaedic external fixators constitutes a modern method of fracture healing of bones. The forerunner of this method was Malgaine [2]. The origin of this method dates back to the middle of the XIX-th century.

Basic advantages of the method cover:

- possibility of immobilization of fragments of fractured bone outside the fracture site and outside the focus of virtual infection,
- easy nursing of coexisting wounds,
- easy assembly of majority of fixators,
- possibility of early mobility of joints in fractured bone,
- possibility of avoidance of grafting of internal metal connector (eg. AO plate).

Potential disadvantage of this healing method, possibility of pin tract infection is rather rare in clinical practice. Spatial configuration of bone screws and carrying frame are depicted in Fig. 2.

Until now many unilateral external fixation devices used in clinical practice have been proposed. One of the oldest is the Stuhler-Heise fixator. It is a frame-type fixator. Somewhat similar is the fixator Martin Dyna-fix. Significantly more modern is the fixator Shearer. The fixator Isodyn has good repositioning properties. The same pertains to the modular system of external fixators Heidelberg. In the case of the Isodyn fixator thick implants are used, with a possibility of applying up to four of them to each fracture side. The load bearing beam is such that one can regulate the spacing of clamps during shift of rods in the slideways. Such a system enables one to perform a displacement along the long axis with simultaneous protection against rotation of connected parts of the load carrying beam. In order to ensure better correction of fragments of fractured bone the clamps are connected with the beam by means of ball-and-socket joint.

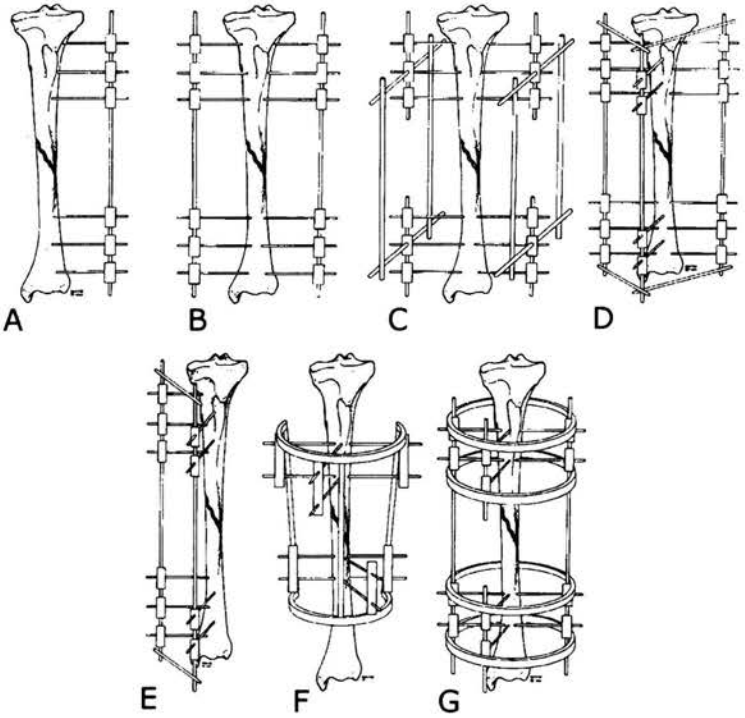


FIGURE 2. The basic frame configurations and pin arrangements in external fixation; (A) unilateral half-pin device, (B) bilateral full-pin device, (C) quadrilateral full-pin device, (D) triangular full-pin device, (E) triangular half-pin device, (F) semicircular full-pin and half-pin device, (G) circular full-pin and half-pin device. The full pins in configuration F and G can be replaced by K-wire under high tension.

Undoubtedly the Polish external fixation device Orthofix introduced a new quality in respect of design of unilateral fixators. This fixator provides an example of implementation of the idea of axial dynamization, suggested by Bastini [2]. Recognized foreign fixators are the Roger-Anders and Ex-Fix-Re fixation devices [2].

Another design enabling anatomic setting of fragments of fractured bone provides the fixator Shearer [2]. In this design the clamps of grafts are applied separately to each screw. They can be shifted along the beam. Additionally a ball-and-socket joint provides a possibility of movement during the positioning of fragments of fractured bone.

In Poland the fixation devices Zespol [10] are commonly used (Fig. 3(a)) as well as its successor Polfix, see Fig. 3(b) These are simple plate fixators and can be implanted as internal (subcutaneous) or external.

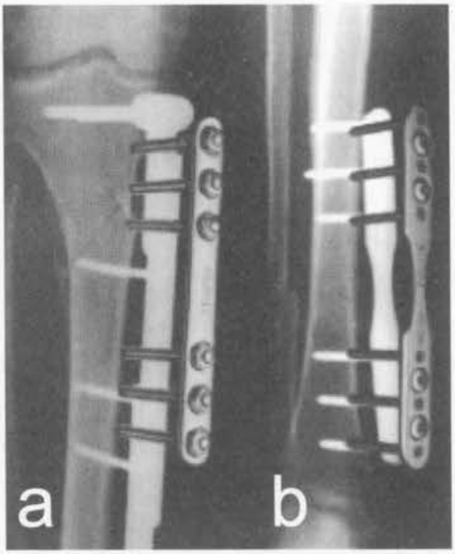


FIGURE 3. Fixation devices: (a) Zespol, (b) Polfix.

The Polish family of fixation devices Dynastab Mechatronika 2000 (see Fig. 1.) belongs to technologically advanced stabilizators (the first author took part in the design process and modifications of the constructed fixation devices). In Poland to external osteosynthesis contributed Gruca and Daab who stressed its role on the basis of clinical experience. In the papers by Czyrny, Konzal, Ramotowski and Granowski, Górecki, and Deszczyński, Karpiński and Jasińska-Choromańska selected external fixation devices were presented. The contributions by these authors are discussed in [5].

Ramotowski and Gramotowski [5] describe the fixators Zespol and Polfix (see Fig. 3) as well as achieved clinical data. Górecki [5] presented the concept and preliminary clinical data pertaining to external fixation devices made of polymer materials. Next, the papers by Deszczyński *et al.* [6] deal with a new type of external fixation devices Dynastab-DK and Dynastab Mechatronika 2000 (see Fig. 1). For related problems pertaining to external stabilization the reader is referred to the book by Będziński [1].

Some problems related to clinical application of external fixation devices and their stiffness and strength were discussed in the papers by Chehade *et al.*, cf. [2]. These aspects will be discussed in Section 4 of our paper. For similar problems related to Ilizarow fixator the reader is referred to [1] and the paper by Będziński in the present volume.

It seems that in majority of available papers related to the system unilateral fixation device-bone only the modeling of the first was considered.

Besides simple models (external fixation device as a beam), finite element method were used to the analysis of the strain and stresses in fixators [5]. Complex models of the system external fixation device-bone seem not to exist in the available literature. We mean here a model of such a system where an element like dynamization chamber would be taken into account. A more elaborated model should also include soft tissues. For available results the reader is referred to Filipiak [4], Krzesiński and Kulig [9], and the references therein. We observe that in [19] reader will find many information on the development of the Polish orthopaedics, including external fixators and osteosynthesis.

The aim of this paper is mainly threefold. In Section 2 the historical development of external fixation devices is presented. Section 3 deals with various aspects of synostosis, including modelling. In Section 4 mechanical aspects of external fixation are briefly discussed.

2. Historical outline of external fixation

2.1. Introduction

Bone fractures are disturbances leading to rupture of continuity of bone tissue. Usually such discontinuities are caused by impact loads, though in the case of severe osteoporosis bone fractures can happen under physiological loads; for instance, fractures of femoral head of elderly people may happen in this way. First historical account on bone fracture healing dates back to the time when Hippocrates lived (circa 460-377 pne). However, possibilities of healing at that time were limited because it was difficult to avoid abscess complications.

Since long time it is known that to ensure union of fractured bone immobilization of limb is necessary. Primarily, in order to immobilize limb wooden shale, splints, wax, clay and bandages impregnated with starch or wheat flour mixed with white of hen egg were used. A turning-point is linked with the introduction of plaster dressing.

The technique of immobilization with plaster dressing European medicine adopted after Arabian and Turkish physicians. British physician Guthrie [2] was probably the first who employed this method in Europe. However, wider application of the method is due to the Russian field surgeon Pirogor [2], who used it during the Crim War in 1854.

Modern dressing, used up to nowadays, employing cotton bandage with deposited plaster, was introduced by the Flemish physician Mathijsen in 1852 [2].

Parallel to methods of immobilization of fractured bone with fixed dressing, methods employing various splints have been used. It seems that the first who used such a method was the British military surgeon Pare [2]. He used it during Napoleonic wars. British surgeon Thomas [2] introduced a universal metal splint, which significantly diminished the number of amputations.

In 1853 Malgaine [2] devised a device employed by him to fractured patella. Principles of aseptics, formulated by Lamer [2] in 1894, enabled to develop operative procedures. Von Heine [2] is believed to be the first surgeon who already in 1878 employed an external fixation device after operative repositioning of fractured bone. In 1897 Parkhill [2] described the method of stabilization of fragments of fractured bone by using two pins inserted into proximal fragment and two into distal fragment connected by means of rectilinear clamp. In the paper published in 1902, the Italian surgeon Codivilla [2] proved superiority of distraction of fragments of fractured bone by applying traction by means of pin inserted through the bone (direct traction) over the indirect traction involving soft tissues. This procedure originated skeletal traction technique. The method has been widely used due to Steinman [2] and Kirschner [2], who in 1907 and 1909 respectively, introduced metal nails. Brown [2] invented splint with a stand, used till now. At the early stage, numerous efforts of operative fracture healing were mostly not successful.

Initially the methods of immobilization of fragments of fractured bone by using external fixation devices fixed to the bone by means of metal nails and screws, introduced in 1912 by Lamboldt [2] (Fig. .) and in 1917 by Humphrey, yielded mediocre effects because of numerous abscess complications. In 1919 Crille [2] introduced external fixator to stabilization of fractures of femoral bone caused by injuries experienced during war. However, his method did not become popular. Since 1927 papers were published on the application of Abotte's device to the distraction of shank, cf. [2]. Codivilla and Putti [2] devised a system called osteoton consisting of telescopic pipe with screw and spring enabling constant traction of fragments in a fixator fixed to the femoral bone by means of pins fixed to circumferential segments of bone. In this way the femoral bone was elongated by 7-12 cm.

The most difficult problem, which arised, was the lack of stiffness of the system used. In 1923 Bier [2] described 7 cases of femoral bone distraction by using osteotomy with initial close proximity of fragments for 3-5 days. Afterwards skeletal traction followed with loading up to 30 kG. In this way elongation up to 7 cm was achieved. In the same year Block [2] described a system enabling a controlled distraction of fragments. The system was modified in 1930 by Klapp [2] and presented a semicircular frame quite similar to the one described in 1953 by Wittmoser [2] and by Ilizarov in 1969 [2]. In 1939 Abott [2] introduced two pins in each fragment, thus obtaining higher stiffness of the system. Similarly Anderson's [2] device was successfully applied to elongation of femoral bone, though it was primarily devised for elongation of shank bones. In the thirties of the last century many new systems of extremities elongation were proposed both in the USA and in Europe. Riedel [2] in 1930 used an external fixation device to stabilization of fragments after osteotomy of femoral bone. In 1931 Conn [2] modified the fixator known at that time and presented 15 successful cases amongst 20 patients. In the same year Bosworth [2] described his distraction device whilst Pitkin and Blackfield [2] were the first who used bilateral fixation device. The last authors devised such a device by joining nails, conducted right through an extremity, by means of two clasps.

During 1930-50, application of external fixation devices was limited because of difficulties of obtaining stable union and common suppuration around tap screws, though successful applications were also reported. The Swiss surgeon Hoffman [2] published a series of papers in the period of 1938-54 where he presented successful results obtained by using his own method of external stabilization. This enabled not only stabilization of fracture but also osteotaxia. Hoffman was the first who proposed to use nails (screws) with the diameter of 3 mm in external fixation devices. The specific feature of these nails (screws) was that they were in contact with two layers of cortical bone. In 1943, Stader and Heine [2] proposed a stabilization device of fractures of diaphyses of children. That device was mainly used as an adjunctive element combined with plaster dressing. The same method was widely used during the Second World War by surgeons of US Naval Forces. The results were not always good, mainly because of required technical skill. This had an influence on external stabilization for over 20 years. In 1978 Meyrues [2] described a similar device designed for the French Army.

Despite satisfactory results presented by Scandinavian surgeons using external stabilization, the method of stable osteosynthesis elaborated in the 50^{th} of the last century by Müller [2], decisively influenced on the development of external fixation devices. External fixators of that time can be divided into two groups, cf. Vidal [2]. The first group covers those requiring positioning of fragments of fractured bone before putting on a fixator (e.g. Lambotte's fixator). The second group is based on the Anderson and Hoffman method [2] enabling one positioning and correction of position of fragments of fractured bone after putting on the fixators.

After the Second World War when deep insight into the physiology of wound healing was achieved an interest in external fixation devices increased. Wagner's fixator [2] was modified thus allowing for new applications. Unilateral and uniframe external fixation devices proved their advantage over other systems, both in the traumatology and orthopaedics. It was easier to provide more comfort to patients and enable better nursing care during postoperative period. The unilateral system proved really to be revolutionary in the development of external fixation devices, since it was shown that the unilateral system is versatile and sufficiently stiff allowing for applications to limbs elongation without hindering everyday activities. Wagner [2] presented his fixator in 1971 and elaborated a method of limb elongation, including open osteotomy with distraction of fragments of fractured bone. Next he proposed to insert grafts of cancellous bone between these fragments and stabilization by using a plate. In the years 1966-74, Anderson [2] published his results on healing of shank fracture by using pins in plaster dressing. In 1967-70, Vidal and his co-workers [2], basing on Hoffman's fixator, proposed their own method of stabilization. However, a real development of this healing method started at the end of 70th of the last century after publication by Ilizarov of his papers [2] in the Western literature. Simultaneously, the interest in dynamic stabilization increased, due to unilateral fixator Orthofix deviced by DeBastiani.

An alternative external stabilization device was devised by Swiss surgeons [2], which ensures stabile osteosynthesis (SO). The family of SO external fixators covers five devices which differ in size, shape and application. Two of them, most frequently used, are uni- and bilateral frame systems, which can be used both in one- and two-plane configurations. Before appearance in the Western literature of papers by Ilizarov, Lao-Zbikowski [2] proposed in 1980 and 1986 the mechanism of bio-compression, i.e. of axial compression of fragments of fractured bone, in the gap between fragments. This mechanism accelerates synostosis. The method of Lao-Zbikowski extends the system "Lazyr", being the fixator based on the principles of Hoffman and Vidal, equipped with telescopic connector. The last enables physiologic contact of fragments of fractured bone by means of ball connector (Bio-roll). Ilizarov have successfully applied his method of healing long bone deformations since early fiftieth of the last century. The method has been used both to congenital and acquired bone deformations as well as to bone elongation. In essence, the method combines application of traction with a possibility early mobilization of limb.

2.2. An overview of fixation devices

Hippocrates, 2400 years ago, seems to be the first who described an own external fixation device applicable to healing crus fractures, cf. Fig. 4. The crus fixation was very simple. After manual equalization of fracture, two cuffs were mounted on the crus; one over the bonelets whilst the second below the knee. Then the cuffs were spaced by rods. The strength of the

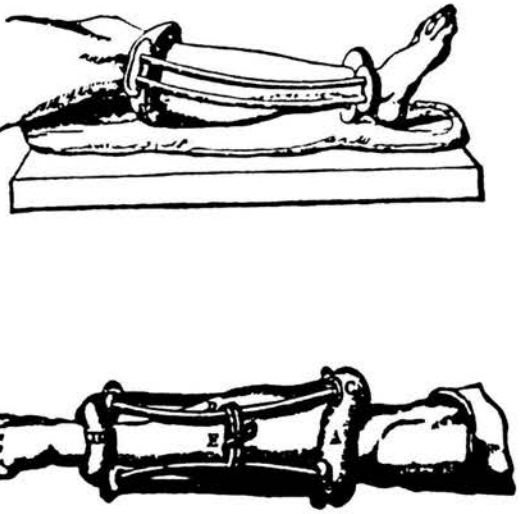


FIGURE 4. Hippocrates fixation device, after [2, 5].

device depended on the number of rods used (the more the better). These rods restrained new displacement of fragments of fractured bone.

2.2.1. External fixation devices. Considering the way the postulate of functional healing is realized, thus using dynamization, external fixation devices can be divided into 2 groups:

- passive, not using any additional system of displacement control,
- active, with such a system.

In the passive fixation devices the displacement realizing the postulate of functional healing are not controlled within the range of deflections of bone screws and rigid frame. In the active devices these displacement are controlled by means of axial dynamization system.

Let us pass to the presentation of historically, most important devices.

(a) Passive fixation devices

The first reports on an attempt of union of fragments of fractures bone in metal osteosynthesis date back to 1766 and pertain to the union of fractures by means of rod loop made of silver or gold. Such a procedure was performed by Lapoyed and Sierre [2, 5], the French surgeons from Toulouse.

The father of external osteosynthesis in Malgaine [2, 5], who in 1847 devised a pressure appliance to the union of fragments of fractured patella, cf. Fig. 5. The appliance consists of clamp with controllable length and with

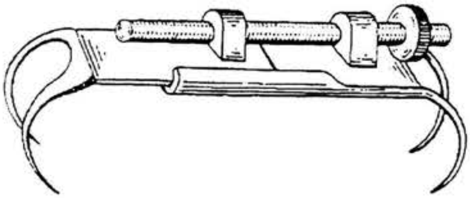


FIGURE 5. Malgaine's external fixation device, after [2, 5].

hooks at the ends driven percutaneously into the fragments of fractured bone. Two double metal hooks were connected by means of screw mechanism enabling axial pressure of fragments of fractured bones.

In 1886, Hansmann [2, 5], described the first plate osteosynthesis. The plate and screws were made of steel coated with nickel, cf. Fig. 6.

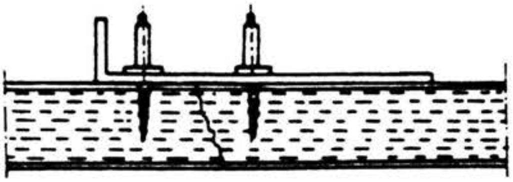


FIGURE 6. Hansmann's plate used for adaptive union of fragments of fractured bone, after [2, 5].

As one can see, the plate lies on the bone and one of its ends is bent at a 90° angle, and the screws stick out of skin. This enabled one to remove such a fixation device without repeated exposure of bone. Hansmann's method did not become popular because of inflammatory reaction of tissues caused by electrolytic action of metals (the plate was made of zinc whilst the screws of brass).

In 1894, Lane [2, 5] modified the plate, which now was made of hardened steel, giving it a special profile, cf. Fig. 7.

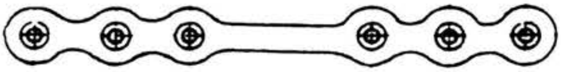


FIGURE 7. Lane's plate for adaptive union, after [2, 5].

Union was entirely internal. This surgeon initialised modern operative aseptics, the so-called Lane's techniques, which precluded touching of tissues and tips of operative tools with hands.

In 1907 Lambotte [2, 5] from Belgium presented a clasp external union, see Fig. 8. Its essence consisted in insertion of thick screwed arrow-heads into bone and connecting them by means of holders to one metal pipe.

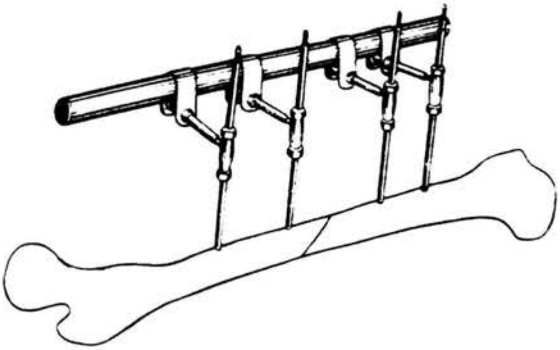


FIGURE 8. Lambotte's appliance for external union, after [2, 5].

Having in mind the level of biomechanics of that time, the fixation devices presented above were quite advanced. The disadvantages, known to their inventors, can be summarized as follows:

- it was not possible to perform a correction of fragments of fractured bone or their compression,
- applied screws and arrow-heads were inserted to only one layer of cortex, thus a sufficient stabilization of union was not possible,
- commonly used materials like carbon steel, silver or gold were not suitable for such devices.

In 1912 Sherman [2, 5] was the first who used plate made of vanadium steel. Such a material was sufficiently biocompatible. The profile of the plate was such that stress concentrations were avoided, see Fig. 9.

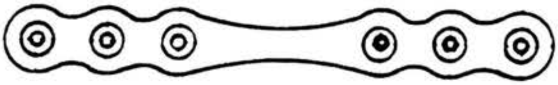


FIGURE 9. Shermann's plate, after [2, 5].

In 1932 Judet [2, 5] presented a clamp fixation device, using bone screws inserted into both cortex layers. In this manner more stable osteosynthesis is assured. After some modifications performed in 1940 [2, 5], this appliance has still been in use.

Next in 1934 Anderson [2, 5] proposed a fixation device enabling to perform correction of positioning of fragments of fractured bone without intervening into fracture zone. Anderson's device consists of two clamps connected by ball bearing with sliders acting on a suitable foundation. Screwed rods traversed both cortex layers and were fixed to metal clamping ring plaster banding. Correction of deflections in frontal and saggittal planes was not possible. However, Anderson's device enables to perform correction of reposition of rotations.

In 1938 Hoffmann [2, 5] devised an instrumentarium being an external fixation device. It could be a clamp, frame or frame-clamp system, cf. Fig. 10.

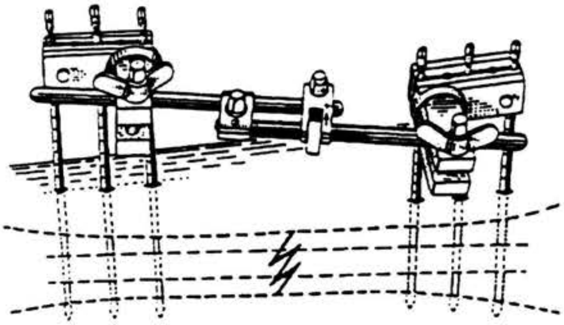


FIGURE 10. Hoffmann's external fixation device, after [2, 5].

Screwed arrow-heads traversed both cortex layers. These arrow-heads were isolated from electric conductivity by placing them in adequate clamps. The clamps were equipped with elastic holders. Shifting of holders was performed by using a screw. Hoffmann's device was commonly used to healing of multi-fragments bone fractures, pseudoarthrosis and growth disturbances.

In 1951 Ilizarov [2, 5] presented his until now well-known concept of external fixation device, cf. Fig. 11.

Ilizarov device enables to perform both compression and distraction of fragments of fractured bone as well three-plane correction of positioning. To decrease the dimension of implant, screws are replaced by modified Kirschner's wires. The wires are inserted in two crossing planes and stretched by using torque spanner, and next fixed to a hoop with special holders and screws. Maximal crossing of the wires ensures good stabilization of fragments.

In 1982 Czyrny [2, 5], proposed a compression-distraction device called CZ-2 being a modification of his previous appliance, cf. Fig. 12. This device is used to healing of gunshot fractures. Two-plane stabilization is performed by using Kirschner wires and Steinmann nails. It is also used to fracture healing of shafts of humeral and tibia bones.

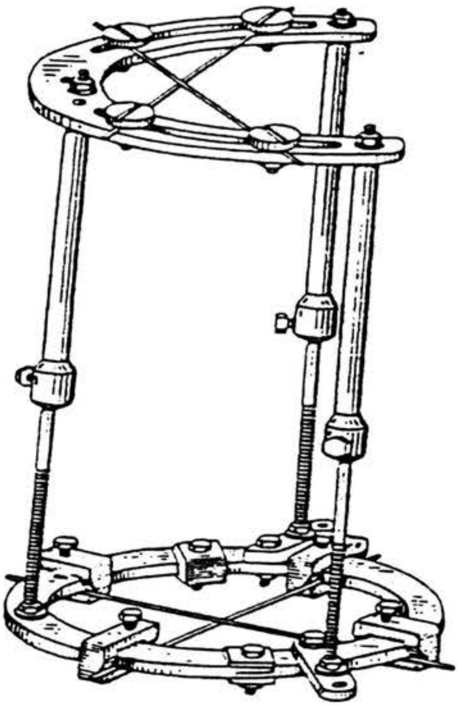


FIGURE 11. Ilizarov distraction device, after [2, 5].

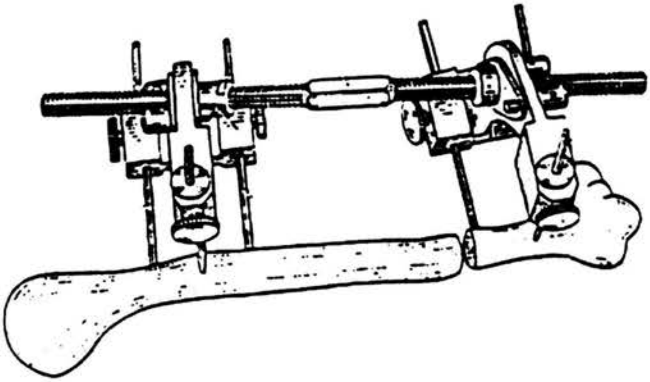


FIGURE 12. Czyrny's compression-distraction device CZ-2, after [2, 5].

In practice, other fixation devices are also used. For example, in [5] the device presented in Fig. 13 has been described. The device consists of fine-tooth plane joints (connecting elements), compression-distraction screw and Schanz arrow-head.

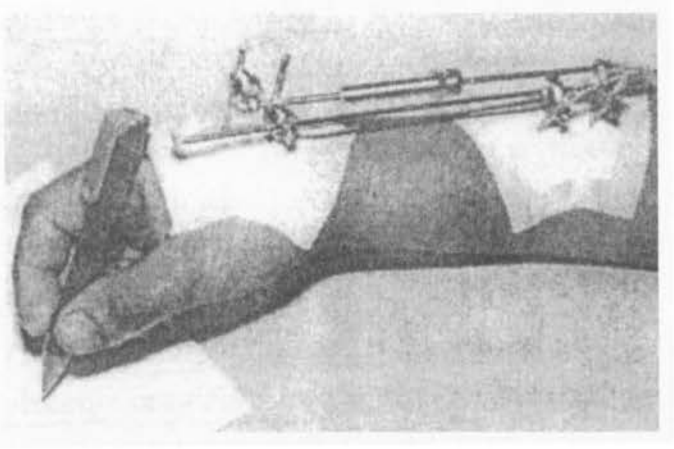
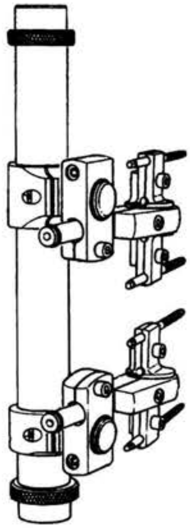


FIGURE 13. External fixation device presented in [5].

In military medicine the fixation device presented in Fig. 14 is also used.



The advantages of this device are:

- simple structure,
- possibility of replacing e.g. the frame by accessible counterpart (wood),
- repeatability of fastening elements.

Consequently the device is adequate for use in camp hospitals.

FIGURE 14. External fixation device US 005630815A.

(b) Active fixation devices

Osteogenic processes depend on many factors. Mechanical factors influencing this process are: adequate bone positioning, loading and unloading of fracture zone, micro-movements in that zone, periarticular motions. It is known that micro-movements in fractured zone are advantageous for osteogenic process due to simulation of callus growth [4, 5]. However, if micromotions are too intensive, pseudoarthrosis can be initiated.

Modern approach to fracture healing by using external fixation devices requires that the postulate of active treatment be satisfied. More precisely, normal motions in articular joints should be ensured, and micro-movements made possible, i.e. their direction and amplitude have to be controlled.

De Bastiani [2] devised a unilateral external fixation device "Orthofix" (Polish Patent No.171925B1), see also [5]. The first devices of this type were inactive. Now these devices are more versatile and enable stabilization of various bone fractures. Recent generation of these fixation devices are made of light biocompatible materials with large stiffness. Active treatment is also possible (Polish Patent No.17047B1).

The first Polish external fixation device, called "Maczek" allowing for axial dynamization (mechano-biological process of dynamic-axial stabilization), was introduced in clinical practice in 1989 by Ręcki and Borawski [5].

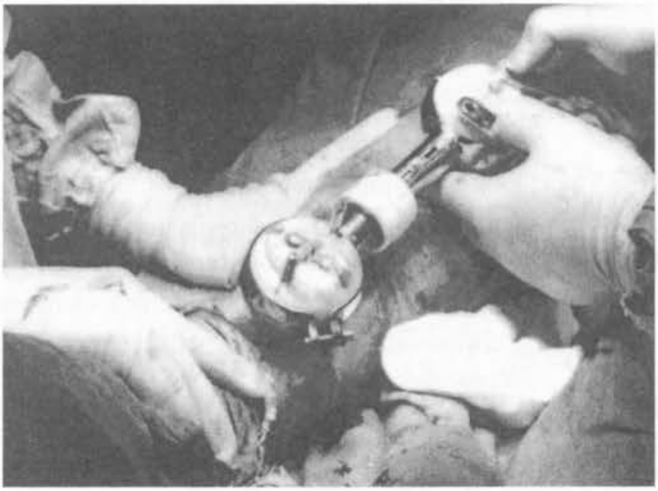


FIGURE 15. External fixation device "Maczek" during assembly, after [5].

In 1996 Deszczyński and Karpiński introduced a compression-distraction device "Dynastab DK", presented in Fig. 16. This device allows for active treatment of fracture healing. Variable contact forces between fragments of fractured bone can also be generated. Despite of some disadvantages this fixation device constituted an important step forward in our understanding and controlling the osteosynthesis.

A modified device was proposed in 2000 [5] and called "Dynastab Mechatronika 2000", see Fig. 17.

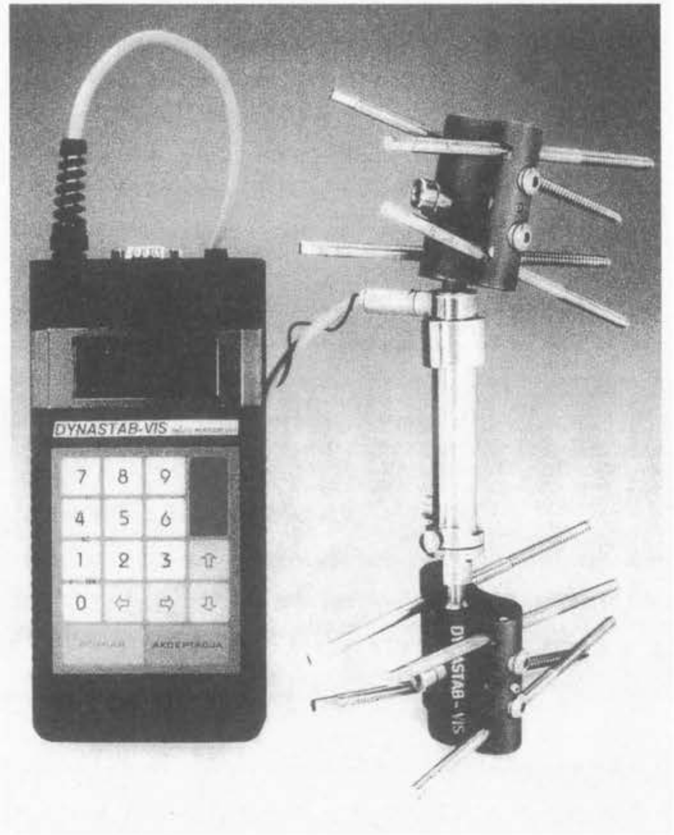


FIGURE 16. Fixation device "Dynastab DK", after [5,6].

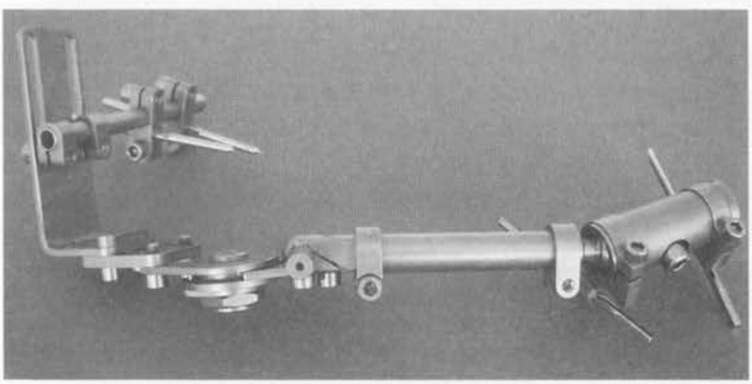


FIGURE 17. External fixation device "Dynastab Mechatronika 2000", after [5].

The first author contributed to elaboration of new series of external fixation devices "Dynastab Mechatronika 2000" applicable to fractures of lower and upper limbs [5, 6]. The new devices have been used in clinical practice in Poland and Germany. In essence, the dynamization consists then of early controlled loading of limb thus advantageously influencing the behaviour of bone moving elements.

Figure 18 presents fixation devices for healing periarticular fractures. From the last figure we conclude that the devices "Dynastab Mechatronika 2000" can be adjusted to specific joints allowing for easy positioning of fragments of fractured bone periarticular region.

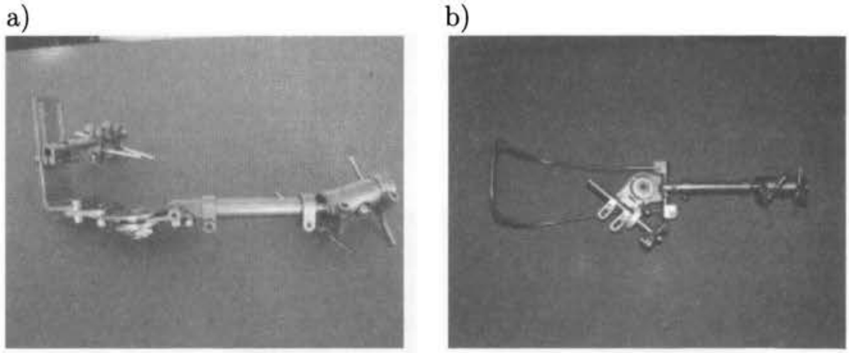


FIGURE 18. External fixation device for healing periarticular fractures: a) elbow joint, b) ankle joint, after [5].

2.2.2. Internal fixation devices. Below we present some of the Polish internal fixation devices. The first one is presented in Fig. 19 and was proposed by engineers and clinicians (Granowski, Ramotowski, Kaminski and Pilawski) in 1982. It is called "Zespol" and consists of plate, bone screws and special nuts connecting the screws with plate. This device allows for distraction and compression of fragments of fractured bone, yet is not satisfactory from the viewpoint of elasticity and strength.

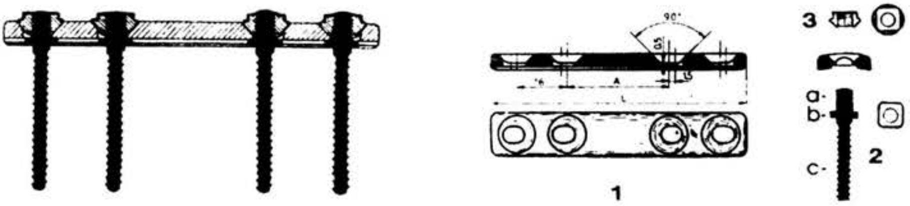


FIGURE 19. Plate fixation device "Zespol", after [10].

An improved device was devised by Ramotowski and Granowski and called "Polfix", see Fig. 20. "Polfix" is a clamp fixation device for internal and external use. It can also be used to limb distractions. Its disadvantage is increased contact stresses leading to bone resorption (osteoporosis). The system itself was too stiff. To remove these disadvantages the plate was moved away from bone and screws were elongated. Then the device becomes an external fixator because union of fragments of fractured bone is possible without direct surgical intervention in fractured zone.

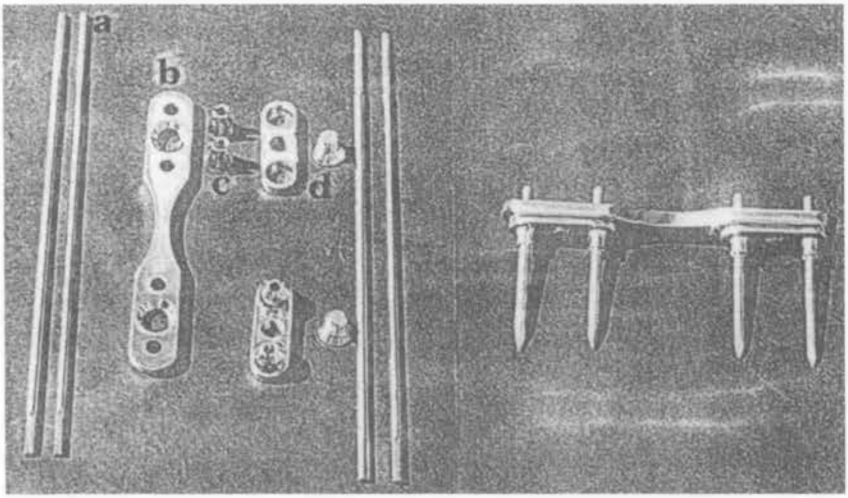


FIGURE 20. Fixation device "Polfix", after [5].

2.3. Fixation devices for animals

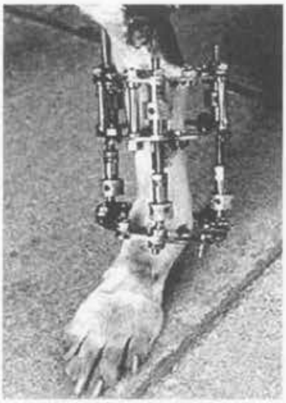
External fixators have also been used in veterinary medicine. Application of suitably constructed fixation devices in veterinary surgery increases. External stabilization is particularly important for animals like horses. Recall that natural position for horses is the standing position.

Primarily in the case of animals, union of fragments of fractured bone was achieved by using screws, next plates (internal and external) have been employed, etc.

Figures 21 and 22 present several types of animal fixation devices.

A new design, acrylic pin external fixator system (APEF) is presented in Fig. 23. The specific future of this system is that it has acrylic grafts. The system is based on replacing mechanical clamps by acrylic columns. The latter can change their shape. The system APEF is advisable in the case

(a) Ring external fixation devices



Ring fixation devices play an important role in veterinary medicine. Such devices are used for healing of deformations appearing at an early phase of leg growth. In the case of humans such devices have been used both for upper and lower limbs. Unfortunately, veterinary patients are more demanding since the structure of their forlegs and hind legs significantly differ.

FIGURE 21. Ring fixation device.

(b) Dynamic distractor

Distraction is also performed in the case of animals. For veterinary patients bilateral external fixators are much more comfortable then ring devices.

FIGURE 22. Bilateral external fixation device.

(c) Acrilic pin external fixator

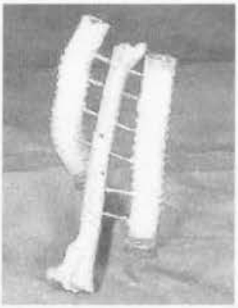


FIGURE 23. Acrylic pin fixator system, after [5].

of majorities of fractures where the bone dimension is comparable with the column of the fixator. Tests showed that the acrylic columns can ensure even greater strength than traditional devices. The system may be viewed as an alternative to classical mechanical systems with dynamization chamber. The system is simple and not expensive. Its main drawback is a lack of control of forces acting on load bearing structure and vibration reduction. The fixator is adequate for fracture healing in the case of small animals, like for instance dogs.

2.4. Bone union

In this section we intend to concisely present selected problems related to bone fracture healing. Process of proper reconstruction of bone depends on choice of fracture healing (internal and external fixation, distraction, plaster dressing).

2.4.1. Basic biological aspects of the process of fracture healing. There are three distinct phases of fracture healing: (1) inflammation, (2) reparation, (3) remodeling. The first phase, inflammation, occurs following the bone fracture. At that time, a hematoma or blood clots occur at the fracture site. This hematoma provides two important factors important to fracture healing. First, the hematoma provides a small amount of mechanical stability to the fracture site. Second, and perhaps more important, the hematoma brings osteoblast, and chondrocyte precursors to the fracture site in large numbers that can begin to differentiate into osteoblasts and chondrocytes to begin producing matrix. In addition, macrophages and osteoclasts come into site to remove damaged and necrotic site. Also, since bone fracture usually involves disruption of the periosteum surrounding the bone , more precursor cell from the periosteum will be introduced into the fracture site. Then will begin the process of making a fracture callus through the general process of osteogenesis, laying down bone on soft tissue. Both types of osteogenesis, intramembraneous and endochondral ossification may be occurring at the fracture site. The resulting proliferation of woven bone tissue will produce a fracture callus, bridging the fracture gap.

The second step in the biology of fracture healing is the reparation phase. In this phase, the process of osteogenesis continue and a fracture callus bridges the fracture site. An example of histology of callus from the pathology site is given in Fig. 24.

The bone again can be produced through intramembraneous ossification, endochondrol ossification or both. It is at this stage of fracture healing that external mechanical stimuli can have the greatest effect on fracture healing.

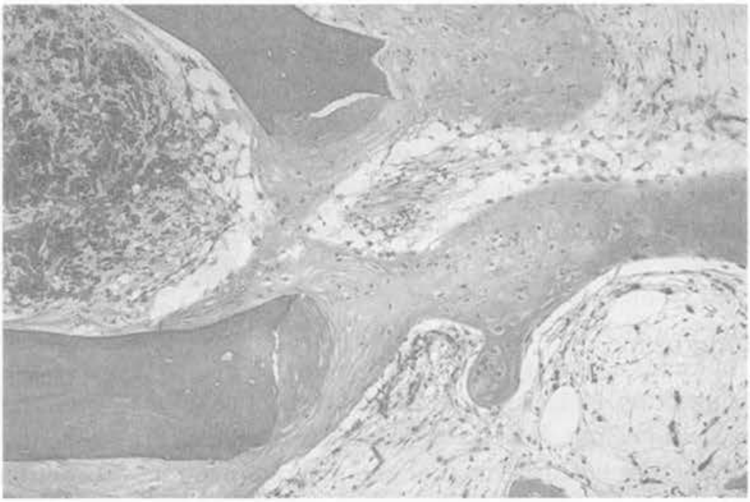


FIGURE 24. An example of histology of callus from the pathology site, after [18].

This is because mechanical stability is crucial at this stage of fracture healing. Although it is not necessary to completely immobilize the fracture, and there is some debate about the need for small motion at the fracture site, it is definitely clear that too much motion will lead to a non-union. A non-union is the healing of a fracture site with soft tissue instead of bone. The desire to prevent non-unions is the reason that different types of fracture fixation devices are used in clinical practice.

The healed bony callus is formed of woven bone and primary bone. At this point, it consist of a large bony bridge connecting the two bones. The base material of the callus typically will have lower strength and stiffness than mature lamellar bone. It is the large mass of bone in the callus that gives the construct the strength. To reduce the callus mass while maintaining mechanical integrity the callus must be remodeled to produce lamellar bone. During the remodeling period, the large fracture callus is reduced to become the size of the bone at the fracture site. The woven/primary bone is replaced with secondary lamellar bone. This process may take months or even up to a year or more in adults.

To summarize, the steps of fracture healing are as follows:

Phase 1

(i) Blending and fracture hematoma forms,
(ii) inflammation,
(iii) next 2–3 days, granulation tissue formation,
(iv) osteogenic cells invade tissue and lay down osteoid.

Phase 2

(v) At 3 weeks a soft callus forms consisting of osteoid and cartilage,
(vi) hard tissue callus forms in 6–12 weeks,
(vii) clinical union of bone ends occurs in 12–16 weeks.

Phase 3

(viii) Remodelling: the woven/primary bone is replaced with secondary lamellar bone.

3. Biomechanical aspects of healing fractures

An excellent paper by Chao and Aro [3] provides an overview of fracture mechanics of long bones and the healing mechanisms of diaphyseal fractures under stable and unstable mechanical conditions. Special emphasis is placed on the comparison of fracture fixation and bone-healing characteristics related to the use of rigid compression plates, intramedullary nails, and external fixators, cf. also Filipiak [4], Krzesiński and Kulig [9].

Prendergast and Meulen [13] discussed experiments designed to understand long bone fracture healing. These authors reviewed also different theories aiming at the description of the influence of mechanics of bone regeneration. The mechanics of bone regeneration involves understanding how the osteogenic pathway is regulated by mechanical forces within the tissue.

Prendergast and Meulen [13] reviewed the following models:

(a) Pauwels' theory. This author recognized that physical factors cause stress and deformation of the mesenchymal cells, and that these stimuli could determine the cell differentiation pathway.

(b) Interfragmentary strain theory. When a fractured bone is loaded, the fracture segments displace relative to each other. The strain produced in the fracture gap was named the "interfragmentary strain", cf. the relevant references cited in [14]. If the width of the fracture gap is given by L and the change in the fracture gap after loading is given by ΔL, then the strain in the longitudinal direction is:

$$\text{interfragmentary strain (IFS)} = \frac{\Delta L}{L}$$

Perrent's (cf. [13,14]) Interfragmentary Strain Theory proposes that the fracture gap can be filled only with a tissue capable of sustaining the IFS *without rupture*.

(c) Deformation/pressure models.

(d) Models including fluid flow.

Prendergast *et al.* [12] proposed the following continuum model describing a distribution of cells:

$$\frac{dn^i}{dt} = D^i \nabla^2 n^i + P^i(S) n^i - K^i(S) n^i, \tag{3.1}$$

Here D^i is a diffusion coefficient for cell i, $P^i(S)$ is a proliferation rate and $K^i(S)$ is an apoptosis (death) rate for cell i as a function of the stimulus S. If φ_j denotes the volume fraction of the tissue j then

$$\sum_{i=1}^{n_i} \varphi_j = 1, \tag{3.2}$$

where n_j denotes the number of tissue types.

To model fracture repair, Eq. (3.1) is simplified to

$$\frac{dn}{dt} = D \nabla^2 n. \tag{3.3}$$

Thus proliferation and apoptosis were neglected. It was assumed that the only cell that differentiated was the stem cell. We recall that stem cells are defined, in general, as resting cells (not actively proliferating) that are presenting small numbers in normal tissues, cf. Muschler and Midur [11]. They share two important features: the capacity for asymmetric cell division and self renewal. In these processes, a stem cell is activated by some signal (stimulus) or event to leave its normal resting state and to divide.

Richards *et al.* [14] used the fundamental concepts of viscoelasticity to develop a mathematical model to predict tension accumulation within the gap tissue during distraction osteogenesis (DO). Richards *et al.* [14] employed a bilateral New Zealand white rabbit model of DO to address the following two hypotheses:

- Fixator stiffening leads to significant decreases in strain magnitudes within the distraction gap tissue, and these decreases in strain magnitude affect both the volume and architecture of newly formed bone.

A detailed study of biomechanical modelling of bone fracture healing will be presented in [20]. A simple model of simulation and prediction of bone union processes was proposed by the first author [5]. Let us present this model.

4. Concept of simulation and prediction of the bone union processes

One of the important problems in orthopedic clinical practice is the problem of evaluating of the bone union process. The methods which have been applied till hitherto, are based on evaluation of X-ray shadows and manual examinations by an orthopaedist. These methods are commonly applied, however they have many disadvantages. The basic ones are relatively low precision of the evaluation and significant contribution of a subjective factor, connected with experience and practice of physician. Problems concerning a new method of evaluation, monitoring and prediction of the bone union process are the subject of analyses in this section In fact, the method is based on data, which can be obtained from the measuring circuit of series of the DYNASTAB-DK external fixators. It is oriented toward applications in clinical practice. Its essence consists in measuring interactions between the bone fragments in the case of various loading of the fractured limb [5]. The measurement is performed by a microprocessor measuring circuit, equipped with semiconductor strain gauges. Analysis of the measurement data is performed with application of neural networks [6] having a multilayer structure. At the same time information flow in a feed-forward network was assumed.

A reverse error propagation algorithm was used for training the neural network. The network trained in this way can be used for simulation and prediction of the bone union process and for aiding the decision process of the physician. A significant problem in computer studies is to make this evaluation objective and to assign to it a certain measure, which characterises the advancement of the bone union process in a quantitative way. In essence, the bone union measure consists in measuring the total load acting in the broken limb and then measuring the load transmitted by the fixator bearing frame - F_1 and the bone being united - F_2. Knowing the above values, the measure of the bone union can be defined as follows:

$$M = \frac{F_1}{F} = \frac{F_1}{F_1 + F_2}. \tag{4.1}$$

We note that this measure is a function of time. Its time-course determines the so-called bone union curve. This idea consists in monitoring the bone union curve and elaborating methods, which on this basis will make it possible to determine the so-called standard bone union curve and to diagnose the healing process (deviations form the standard curve). Analysis of the standard curve in various cases will make it possible to study an influence of various factors on the bone union processes (therefore it is a significant research tool).

One more significant aspect of the problem must be discussed. Loading the fixator-bone system with an axial force is presented in Fig. 25. However, it should be noted that mechanical properties of the bone being united can be non-linear (in the neighborhood of the fracture). Therefore measures of the bone union can prove to be different in the case of various values of a

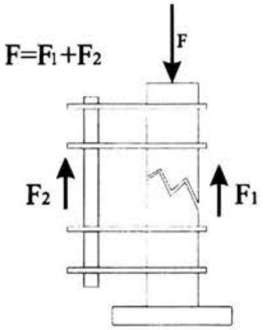


FIGURE 25. Illustration of the concept of the measure of the bone union.

given load and in the case of various kinds of loads (forces acting in various directions and moments of force). So, it seems to be reasonable to introduce an n-element vector of the bone union measure and a vector of standard curves instead of a single measure:

$$M_i = \frac{F_{2i}}{F_i} = \frac{F_{2i}}{F_{1i} + F_{2i}}, \quad i = 1, \ldots, n. \tag{4.2}$$

A positive result of healing cause a situation, when all the measures of the bone union equal zero, i.e. the whole load is transmitted by the limb.

It becomes a significant problem to choose a method of analysing the bone union curves, obtained by means of the measuring circuit of the DYNASTAB-DK fixators (in the paper description of this system is not included). It is a complicated microprocessor system being based on semiconductor strain gauges. One of the interesting tasks can be here the prediction of the bone union curve obtained on the basis of the data obtained in measurements performed at early stage of healing, in order to carry out e.g. corrections, if needed, or analysis of potential dangers. On the other hand, multiplicity of various cases (age of patients, kind of fracture, other diseases, intensity of rehabilitation exercises, drugs taken, etc.) cause difficulties in selection of computer simulation techniques. One has finally decided to apply techniques based on artificial intelligence, and more precisely, artificial non-linear and multilayer neural networks. It was assumed that separate neural structure would be determined for each kind of fracture and additionally for various sex and kind of addictions (smokers, non-smokers) of patient.

Each structure built on the basis of feed-forward type of neural network [8, 17] will have indeed a character of a recurrent neural network because of introduction of a feedback. Architecture of a neural predictor for prediction of the bone union curve is shown in Fig. 26.

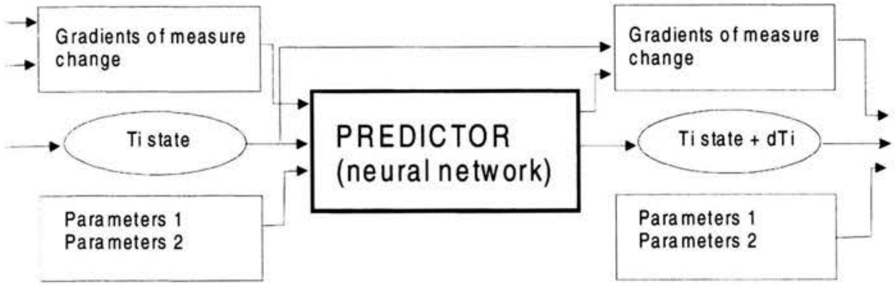


FIGURE 26. Architecture of the system for prediction of bone union curves.

The present stage of healing (Ti STAGE) is determined by seven measures of the bone union being determined in the case of various loads, according to the measures (4.2) (these measures are obtained from the measuring circuit of the Dynastab–DK fixators or taken from the previous step of calculations in the process of computer simulation). Additionally, input quantities for the neural predictor are gradients of variations of the above measures. The parameters designated by number 1 in Fig. 26 determine the values of chosen: level of Ca and P in blood serum, basic phosphates, intensity of rehabilitation exercises (measured with application of the fixator measuring circuit), run of time from the moment of installing the fixator. The parameters designated by number 2 determine the age of a patient, bone density, time of prediction dTi, operative technique applied (for instance, fixation with a preliminary pressure). A structure of three-layer non-linear neural network [8, 17] was applied for the analysis. Results of clinical examinations and algorithm of reverse error propagation were applied as a method of training. The network finally took a form of the mentioned above three-layer neural network including 617 neurones (the first layer includes 40 neurones realising transformation by means of hyperbolic tangent function, the second layer includes 570 neurones realising transformation by means of logistic function, the third layer includes 7 neurones – because that is the number of the system outputs connected with 7 measures of the bone union – realising also transformation by means of logistic function). The algorithm of reverse error propagation with a modified moment [17], mentioned before, was applied for training the neural network.

In spite of satisfactory results (they are discussed in the next section) significant numerical problems occurred consisting in very long times of network training (what limited in a significant way the number of the neurones used). The training process was convergent well enough, i.e. the program reached the desired accuracy of training characterised by the error of 0.01.

4.1. Clinical and computer results

In the case of a fracture of femoral bone the following kinds of loads for the determination of seven measures of the bone union were assumed:

1. M_1 contraction of thigh muscle in a supine position,
2. M_2 active raising up of a limb by an angle of 30 degrees,
3. M_3 limb raised up passively, muscles relaxed,
4. M_4 contraction of muscles in a vertical position of the limb,
5. M_5 when laid on the sound side, limb abducted by an angle of 20 degrees,
6. M_6 load on an electronic weigher with a force of 100 N in a vertical position,
7. M_7 load on an electronic weigher with a force of 200 N in a vertical position for prediction of evolution of measures of bone union on the basis of data achieved in measurements carried out at early stage of healing. Example results of a computer simulation are presented in Figs. 28 and 29. They are compared to the real course of the values.

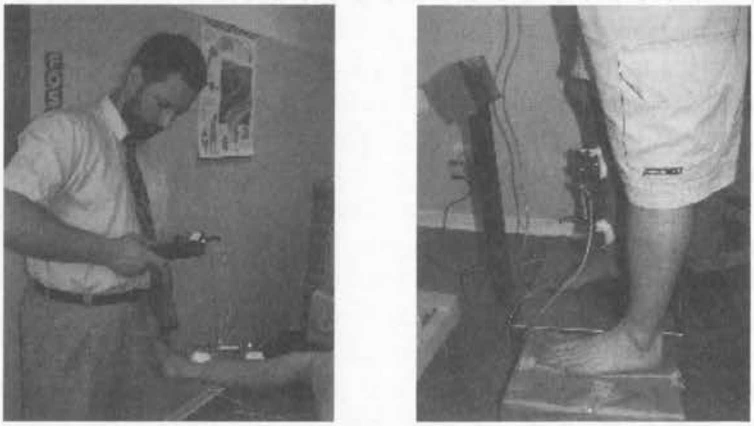


FIGURE 27. A patient in the course of healing a fracture of the tibia.

The first results achieved on the basis of a statistic test of 50 patients turned to be very promising. In Figs. 28 and 29 one can observe the appropriate choice of the bone union measure (in the progress of healing process curves reach the zero value) as well as consistence of the real values of bone union measures with the values achieved by prediction at early stage of healing process.

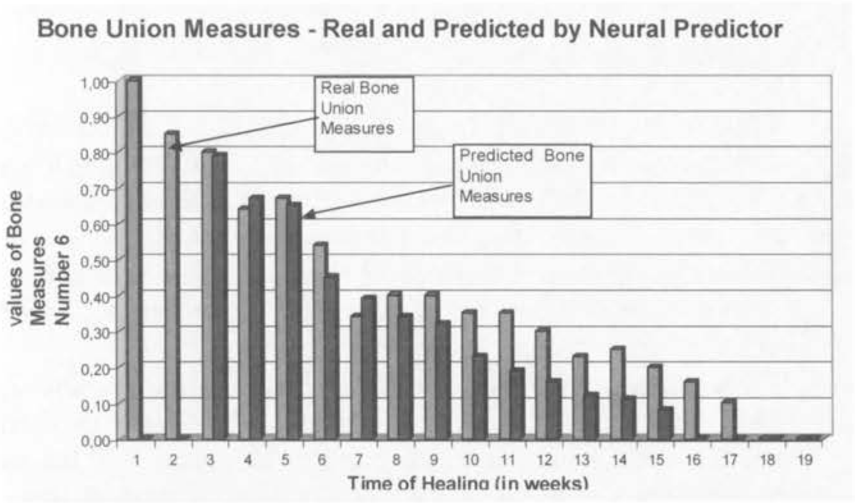


FIGURE 28. Example of prediction of bone union with application of the neural network.

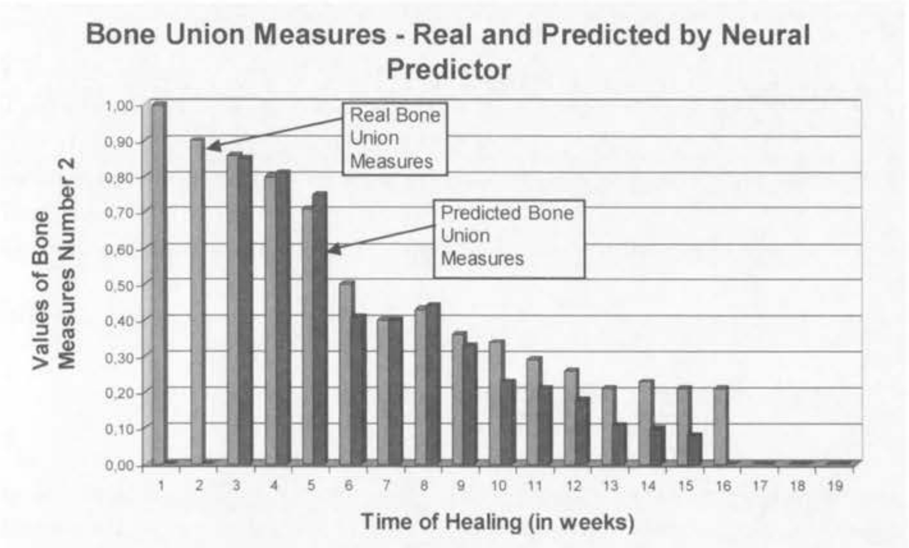


FIGURE 29. Example of prediction of bone union with application of the neural network.

5. Dynamisation process in devices aiding healing process of fractured bone

5.1. Types of dynamisation

An external fixator that includes the dynamisation chamber enables to influence the profile of whole system. The system consists of bone fragments, screws and the frame of the external fixator including the dynamisation element. We distinguish two kinds of dynamisation process:

passive – the suppressing coefficient of the dynamisation chamber has a constant value. The settings of the dynamic chamber can be different but only a physician can change it;

active – the suppressing coefficient of the dynamisation chamber can be changed during the work time of the fixator. The value of the coefficient depends on the phase of the fracture healing process and the value of the load that the fractured bone is carrying at the present time.

There are some commercial products that use the dynamisation phenomenon. One of the first was the Dynastab DK and after modifications Dynastab Mechatronika 2000 as well as the whole family of fixators based on a similar concept.

These devices use the passive dynamisation chamber. There is a project that allows us to make one step further and equip the fixators with active dynamisation devices, thus we may call these devices stabilizers [5, 6].

Active dynamisation creates new possibilities but requires also a new attitude to the healing process. A properly working device should give us a lot of additional information about the bone condition and this data should be quickly analysed. The result of this process should be immediately used to update the schedule of the healing process and be stored in a "healing process history file". This stored data could be used in the future for the analysis of system failure.

5.2. A fixator with new active elements

Modern trends in design of construction are drawing attention of engineers to the comfort of use, safety and variety of applications. Modern fixator should be small and give a possibility to unhampered movement of limbs. It should be comfortable and give a feeling of safety. The proposal of new frame of fixator with adjustable parameters of carried load, rigidity and size of movement of bone pieces based on the fixator Dynastab Mechatronika 2000 with passive dynamic chamber is presented in Fig. 30, cf. [7].

A, B – elements to be joined to the bone mountable parts

1. force element (hydraulic), chamber with active medium (ability of volume change)
2. force element (mechanical), chamber with changeable initial force value, to control the value of the carried load (by pieces of fractured bone)
3. the drive with gearbox - to create the profile the chamber with the spring

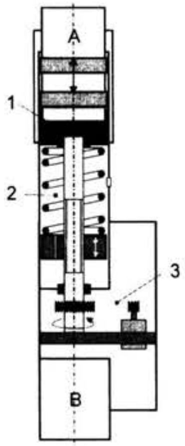


FIGURE 30. The frame with the dynamic chamber.

The hydraulic element has to assure for the fracture the optimal wave characteristics. The profile of the load is very important for the healing process. This part of dynamic chamber gives a possibility of the initial modification of load characteristics. As we know, by the change of the medium density we can influence on the frequency profile of dynamisation chamber. The spring and the linear drive with moving nut provide a possibility to change to initial value of tension. In this way we can control the size of movement of the broken bone pieces and establish the value of load that the bone can carry in the present phase of the healing process. The motor and the gearbox give the power to move the nut. The microdrive should be specialised to the application. The response of the drive has to be fast and the device has to be reliable because this part is responsible for success of the concept of active dynamisation.

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